CVPH
MEDICAL CENTER

Champlain Valley Physicians
Hospital Medical Center
75 Beekman Street
Plattsburgh, New York 12901-1493

Stephens M. Mundy, CHE
President

Telephone: 518-561-2000
www.cvph.org

May 15, 2006

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Hospital Redesignations and Reclassifications**

Dear Sir or Madam:

These comments relate to section III.H.6 of the proposed rule regarding "Proposed Wage Indices for Reclassified Hospitals and Proposed Reclassification Budget Neutrality Factor."

Champlain Valley Physicians Hospital Medical Center ("CVPH") (33-0250) is a 341-bed acute care hospital located in Plattsburgh, New York that serves the residents of six counties in Northeastern New York and Northwestern Vermont. CVPH is designated by Medicare as both a Rural Referral Center and Sole Community Hospital.

CVPH is located in Rural New York for Medicare payments purposes. However, CVPH qualifies for wage index reclassification to the Burlington-South Burlington, VT Metropolitan Statistical Area ("Burlington MSA"). However, because of the manner in which CMS determines the wage index for reclassifying hospitals, this reclassification does little to equalize payments between CVPH and the hospitals in the Burlington MSA with which it competes for labor.

There are two hospitals in the Burlington MSA, Fletcher Allen Hospital (47-0003) and Northwestern Medical Center (47-0024). Fletcher Allen, of course, is eligible for exceptional treatment pursuant to section 508 of the *Medicare Modernization Act of 2003*, and therefore it receives an extraordinary wage index of 1.1274 for fiscal year 2006. Northwestern, on the other hand, also receives a considerably higher wage index of 1.0189 for fiscal year 2006, because the Burlington MSA is subject to the "rural floor" established pursuant to Section 4410 of the *Balanced Budget Act of 1997*. For fiscal year 2006, the wage index applicable to CVPH as a hospital reclassifying into the Burlington MSA is 0.9278.

CVPH is severely disadvantaged in relation to its competitors across Lake Champlain when it comes to attracting labor. CVPH is paid considerably less from Medicare than hospitals in the Burlington MSA.

CVPH is not the only hospital with this problem. According to our analysis, 11 other hospitals around the country reclassify into MSAs in another state where the MSA is supported by the rural floor.

In order to remedy this situation, CVPH recommends that CMS provide that hospitals that reclassify into areas subject to the rural floor are likewise eligible for the rural floor, and that such hospitals receive the same wage index as those in the area to which they reclassify.

The purpose of the reclassification process is not being fulfilled for hospitals like CVPH because of the way CMS applies the rural floor only within a state. Hospitals that reclassify into an area have demonstrated that they compete with hospitals in that area. Yet, CMS is treating these reclassified hospitals differently simply based on the hospital's location on one side of a state line or the other.

Congress established the reclassification process because it recognized that MSAs were not always appropriate proxies for area labor markets, and that additional manipulation of wage index assignments would be necessary in some cases to more accurately define labor markets. Although CVPH is able to avail itself of the reclassification process, the manner in which CMS determines the wage index applicable to reclassifying hospitals does not fulfill the congressional intent of more accurately defining labor markets.

CMS has the authority to make the change proposed above. The Secretary has broad authority under section 1886(d)(3)(E) of the Act to "adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates...for area differences in hospital wage levels by a factor (established by the Secretary)...." CMS relied on this same authority when it established the imputed rural floor for "all urban states." 69 *Fed. Reg.* 48,916, 49,109 (Aug. 11, 2004). As such, CMS has the discretion to adopt a policy that would adjust wage areas in the proposed manner.

We appreciate your consideration of our situation and these comments. Please call me at 518-562-7055, if you have any questions concerning these comments.

Respectfully,

Stephens M. Mundy
President/CEO

tlr

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MEDPAC Medicare Payment Advisory Commission

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Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

April 19, 2006

3:17 PM
5/1/06

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

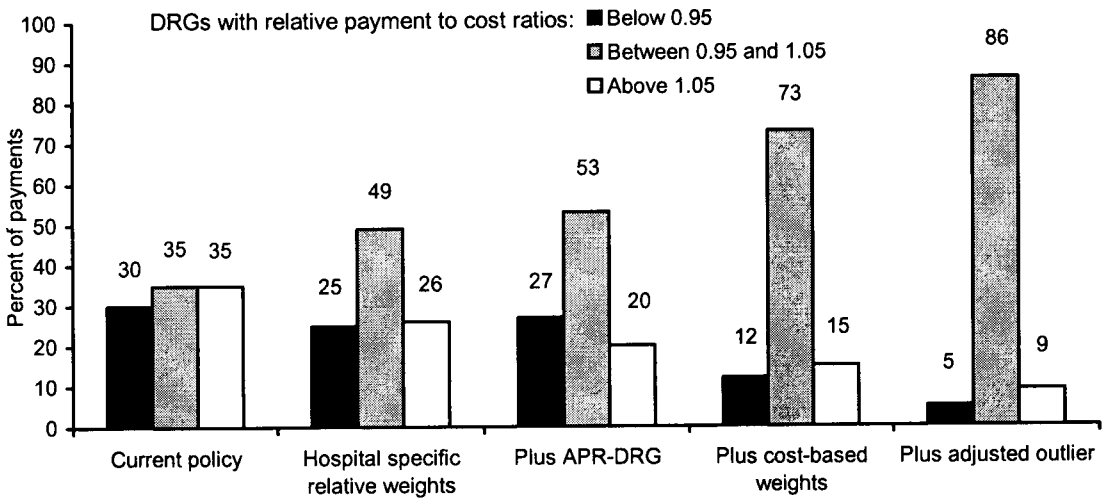
We have completed an initial review of the proposed changes in the inpatient prospective payment system. We will comment more extensively at a later date, but we wanted to provide some initial reactions. Specifically, we wanted to reiterate our strong support for improving the inpatient payment system's ability to accurately compensate providers for the type and severity of the cases they treat.

First, we are pleased that CMS has proposed three of MedPAC's four recommended changes to the inpatient PPS system. We are fully aware that undertaking these significant changes to the payment system will not be easy given CMS's workload. As you know, we recommended four changes to the prospective payment system: cost-based weights, hospital specific relative values, improved severity adjustment, and DRG specific outlier financing. Using cost-based weights and hospital specific relative values will help remove distortions caused by hospital charges that reflect a wide variance in "mark ups" from service to service. We endorse your proposal to adopt hospital specific cost-based weights in FY 2007.

We are also pleased that you have proposed an adjustment to payments for severity. As we illustrated in our 2005 specialty hospital report, the expected profitability of patients currently varies widely based on the severity of the case. For example, we found
that for hip procedures (DRG 210) the payment-to-cost ratio for the least severely ill patients (APR-DRG severity level 1) was 4 percent higher than the payment-to-cost ratio for the average Medicare patient. The payment-to-cost ratio for the most severely ill patients (APR-DRG severity level 4) was 36 percent lower than the ratio for the average Medicare patient. Clearly, current payment policies benefit hospitals that focus on less severely ill patients. However, we are concerned that you are proposing to delay the severity changes until FY 2008. It is important to correct for differences in patients' severity concurrently with the corrections for charging distortions.

In fact, we believe that all four of the proposed changes to the IPPS should happen concurrently. As is shown in Figure 1 below, by implementing all four of our payment reforms, the relative profitability of treating different types of patients would become much more uniform.

Figure 1. Improving the accuracy of payments



Note: DRG (diagnosis-related group), APR–DRG (all-patient refined diagnosis-related group).

Source: MedPAC analysis of Medicare hospital inpatient claims and cost reports from CMS, fiscal year 2000–2002

Some have characterized the increases in payments to certain hospitals and decreases to others resulting from the changed payment rates as "unintended". In fact, the redistribution of payments among hospitals is the intended, necessary consequence of correcting the current distortions in the IPPS payment rates. The hospitals that treat cases that are now relatively underpaid should receive an increase in payments while hospitals treating cases that are currently overpaid should receive a decrease in payments. Payment redistributions should not be permitted to forestall needed payment reforms; they reflect the fact that the current system is inaccurate and therefore, unfair to some hospitals.

As Table 1 shows, implementing all four of our policy recommendations in a budget-neutral manner would entail a small (1 to 2 percent) change in payments for most categories of hospitals. The one exception would be physician-owned specialty hospitals.

These hospitals have specialized in types of patients for which Medicare tends to overpay and should receive a significant reduction in their inpatient payments. Within each of the categories of full-service hospitals shown in the table, there would be both winners and losers, reflecting hospitals' unfavorable or favorable mix of patients in light of current payment distortions.

Table 1: Distributional effects of more accurate inpatient payments

Category of hospital	Percent change in payments	Percent of hospitals losing 5% or more	Percent of hospitals gaining 5% or more
Urban	-0.2%	7%	21%
Rural	0.9	6	18
Physician-owned heart hospitals	-9.6	88	0
Physician-owned Orthopedic hospitals	-8.2	77	0
Major teaching	-1.9	15	10
Other teaching	-0.4	8	15
Non-teaching	1.2	6	22

Source: MedPAC analysis of Medicare hospital inpatient claims and cost reports from CMS, fiscal year 2000–2002

It is also important to understand that examining impacts by the traditional category of hospital masks the underlying impacts. Urban hospitals as a group experience a very small reduction (-0.2 percent) in payments, but most urban hospitals would gain. Our analysis suggested that major teaching hospitals payments overall would decrease by 1.9 percent under our policy recommendations. But 10 percent of major teaching hospitals would experience a 5 percent or more increase in payments while 15 percent would face a 5 percent or more downward adjustment.

The problem of over- and under-payments and the resulting distortions in providers' financial incentives can affect both specialty hospital and community hospital behavior. Our reforms are needed to remove the opportunity for specialty hospitals to profit simply from DRG and patient selection. But, changing payments to specialized hospitals is not enough. Reforms are also needed to correct distortions in the payment systems that affect all hospitals.

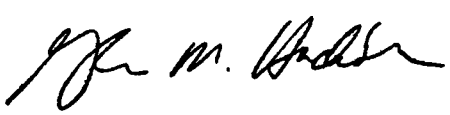
We want to again stress the importance of adopting all four of our recommended policy changes concurrently. Each of our recommendations targets a specific source of distortion in the current payment rates. Failure to adopt any of them would leave some payment distortions in place, thereby continuing to favor some kinds of patients over others. Consequently, we reiterate our previous recommendation that Congress grant the Secretary the authority to address the limitations of the current outlier financing policy. Adopting all of the policies we recommended would create the most accurate payments and prevent hospitals from facing unjustified shifts in their payments that may occur under partial adoption of the payment reforms. Concerns about giving hospitals time to adapt to the changes may be better managed by implementing all four changes in 2007 and then giving hospitals a transition period. In the absence of congressional action on outlier legislation, we urge you to move ahead immediately with the changes that can be accomplished through regulation.

We are pleased that you are considering requiring hospitals to report secondary diagnosis present at admission as part of your implementation of Section 5001(c) of the DRA. Identifying secondary diagnoses present at admission is important to ensure that hospitals do not receive additional payment for the specified preventable conditions that develop during the stay. Collecting data on all conditions present on admission for all DRGs is critical to enable Medicare to develop and apply payment adjustments based on the quality of care more broadly. This is important for accuracy of payment and as one component of paying for performance. MedPAC previously (March 2005) recommended that secondary diagnosis present at admission be collected for all Medicare admissions, and we would urge you to include such a requirement in your final rule.

Finally, we want to support your efforts in developing a plan to move forward on hospital pay for performance. As you know, we have recommended a legislative change to allow redistributing a portion of inpatient payments among hospitals that achieve a high level of quality or improve the quality of their care. We believe a sufficient number of accepted quality indicators are available to move ahead quickly on hospital pay for performance.

Thank you for considering our comments.

Sincerely,



Glenn M. Hackbarth, J.D.
Chairman

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DEPARTMENT OF EMERGENCY MEDICINE
RALEIGH BUILDING, ROOM 304
600 GRESHAM DRIVE
NORFOLK, VIRGINIA 23507-1999

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May 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, Maryland 21244-1850

Dear CMS:

I am writing to express our strong objection to the proposed rule of including didactic activities (ie, Journal Clubs, lectures, and seminars) as nonpatient care activities, and therefore not included in either a hospital's DGME or IME resident count. I am writing on behalf of the Graduate Medical Education Council (GMEC) at the Eastern Virginia Medical School (EVMS) in Norfolk, Virginia. The GMEC is comprised of all of the Program Directors (16 total) of the residency programs at EVMS, and as such we are intimately involved in, and ultimately responsible for, graduate medical education at our school.

Scholarly activity, such as lectures, Morbidity and Mortality conferences, Journal Clubs, etc. are an integral and important part of patient care activities. It is an opportunity for residents to learn how to take care of patients, learn about specific disease processes, and new treatments which affect patients, their presentation, diagnosis, and management. Conference, as opposed to self-reading, allows the free-exchange of information and ideas between the speaker (ie, faculty) and residents. Residents can ask questions on issues they do not fully understand, clarify conflicting information, and be actively assisted in understanding difficult concepts, all relating to patient care. An excellent example is Morbidity and Mortality conference, which at most training programs, is one of the most valuable conferences from a teaching perspective. In these conferences, the care of specific patients is evaluated thoroughly and objectively, with the emphasis on how to improve outcome in the future. Residents learn from the mistakes of others to directly improve their own patient care activities. It is extremely short sited of CMS to consider this as nonpatient care.

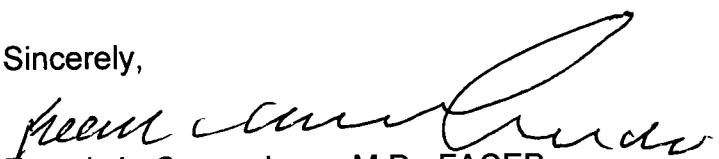
Despite the philosophical argument, we think it also extremely impractical, if not impossible, to apply the proposed rule. In nearly every resident educational conference in the hospital, resident physicians (and faculty) are on-call for various services. It is not

uncommon for a resident to be paged out of a conference, attend to patient care (ie, direct patient care), and then return to the conference. This can happen several times for multiple residents during a conference. Would you expect each resident to keep track of the times they entered and exited the conference room for purposes of DGME and IME reimbursement?

It is our understanding that there is no legislative requirement that a resident be engaged in "patient care activities" with regards to counting residents within the hospital setting for DGME payments. All resident time in the hospital complex may be counted for DGME payment, as long as the resident is in an approved residency training program. Similarly, there is no specific reference to patient care activities in the IME legislation. We ask that you comply with the legislation as written, and not reinterpret it.

Once again, didactic activities are an integral component of patient care and should be considered as such. We strongly urge you to reverse your position regarding the proposed rule. If you have any questions, we would be more than happy to discuss this important issue with you.

Sincerely,



Francis L. Counselman, M.D., FACEP
Chairman
Academic Affairs Subcommittee
Graduate Medical Education Council
Eastern Virginia Medical School

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>Please Do Not Reply This Email.
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>Public Comments on Medicare Program; Hospital Inpatient
>Prospective Payment
>Systems Implementation of the Fiscal Year 2007 Occupational
>Mix Adjustment
>to the Wage Index:========
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>Title: Medicare Program; Hospital Inpatient Prospective Payment Systems
>Implementation of the Fiscal Year 2007 Occupational Mix
>Adjustment to the
>Wage Index
>FR Document Number: 06-04608
>Legacy Document ID:
>RIN: 0938-AO12
>Publish Date: 05/17/2006 00:00:00
>Submitter Info:
>
>
>First Name: margaret
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>City: pelham
>Country: United States
>State or Province: AL
>Postal Code: 35124
>Organization Name: st vincents hospital
>
>Comment Info: ================
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>General Comment:this would be a burden for all health care
>providers and
>confuse the elderly
>
>
>

St. Luke's HOSPITAL

May 10, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: "Hospital Quality Data"

To Whom It May Concern:

I wish to comment on the proposed changes to the "Reporting of Hospital Quality Data for Annual Hospital Payment Update".

According to the proposed rules, "hospitals will be required to complete and return a written form on which they pledge to submit data on the following set of expanded quality measures (anticipated 21 clinical quality measures), starting with discharges that occur in CY 2006. Hospitals will be required to submit data on the expanded measures to the QIO Clinical Warehouse beginning with discharges that occur in the first calendar quarter of 2006 (January through March discharges). The deadline for hospitals to submit their data for first quarter 2006 is August 15, 2006." The proposed changes go on to say that "we do not anticipate significant burden on hospitals regarding the starter set of 10 quality measures or the anticipated 21 clinical quality measures because all JCAHO-accredited hospitals are currently required to adhere to these sampling requirements in acute myocardial infarction, heart failure, pneumonia, and surgical infection prevention for accreditation and core measure reporting purposes."

Our hospital currently has a process whereby we abstract data on acute myocardial infarction, heart failure and pneumonia cases shortly after discharge. We currently do not collect data on the surgical infection prevention measures, as JCAHO requires participation in only 3 of the 4 measure sets. It **would** be a burden to our organization to collect surgical infection prevention measures from the first quarter of calendar year 2006 data and submit it by the August 15, 2006 deadline. We have examined the current abstracting requirements for the surgical infection prevention measures, and while they sound simple, it involves eight pages of data collection according to our core measure vendor's abstraction tool. Our vendor has told us that it took other hospitals approximately 45 minutes to one hour per medical record to abstract the necessary data when they began data collection for surgical infection prevention. Adhering to the minimum sampling requirement, this would equate to 63-84 hours of retrospective data collection for January through March 2006 discharges alone. It would require the hiring and training of a part-time person devoted solely to collecting this measure. This additional staff was not included in the hospital's fiscal year 2007 budget.

Please reconsider revising the proposed changes with the retrospective data collection requirement for surgical infection prevention from the first quarter of 2006. Perhaps data collection could begin with July 2006 discharges to allow hospitals the time to develop a process to collect the additional measures. I would be happy to discuss this issue further if you wish to contact me.

Sincerely,

Jan Hess
Administrator
St. Luke's Hospital
232 S. Woods Mill Road
Chesterfield, MO 63017
Telephone: 314-205-6072
Email: janhess@stlukes-stl.com

Submitter : **Dr. Todd Florin** **Date: 05/12/2006**

Organization : **Mount Sinai Medical Center**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 600 bed hospital located in Miami Beach,I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation s number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital s ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were thrown out of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to charge compression. The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient s illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better u

LESLIE STERN
MD, PhD, FACS

Board-Certified:
American Board of
Neurological Surgery

- General neurosurgery
- Microneurosurgery
- Reconstructive spinal surgery
- Minimally invasive spinal surgery

LESLIE STERN MD, PHD, PC
NEUROSURGERY

May 9, 2006

CMS
Dept. of Health & Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

This is in support of the use of the "X-STOP IPD", which is of value in patients who have lumbar spinal stenosis with or without radiculopathy. This device, which is a "minimal trauma procedure", is helpful in patients who have not done well on conservative treatment for the symptoms of lumbar spinal stenosis, and who would like to avoid the major procedure of lumbar laminectomy. This is particularly true in patients who may be medically at risk for a larger procedure, such as laminectomy. Therefore, this procedure fills a gap between the patients who fail conservative treatment, and those who would require laminectomy as the next step. These patients with implantation of an X-STOP have a good response rate with relief of symptoms, over a one-to-two year period since its use began. Therefore, this procedure should be a treatment option in patients that fit into this category.

Yours sincerely,

Leslie Stern, M.D., Ph.D., F.A.C.S.

LS:eh

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HARRIS METHODIST
Continued Care Hospital
Texas Health Resources

May 18, 2006

Mark McClellan, M.D., Ph. D.
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates -- CMS–1488- P

Dear Dr. McClellan:

Hospitals-Within-Hospitals

Harris Continued Care Hospital submits these comments on proposed rules published on April 25, 2006 at 71 Fed. Reg. 23996. This rulemaking proposes revisions to the regulation governing grandfathered long-term care hospitals-within-hospitals (HwHs). Harris Continued Care Hospital was established in September 1989 and is located at 1301 Pennsylvania Avenue, 4th Floor Harris Main, Fort Worth, Texas on the campus of Harris Methodist Fort Worth. We are a grandfathered HwH under Section 4417(a) of the Balanced Budget Act of 1997. We serve a significant percentage of Medicare patients residing in Dallas/Fort Worth Metroplex. For the reasons discussed below, it is critical that

the exceptions contained in the proposed revisions to the grandfathered HwH rule be expanded to allow grandfathered HwHs to increase their square footage and number of beds to improve operations and patient care.

The Grandfathered Hospital-within-Hospital Rule

Under the current rule, to retain grandfathered status a HwH may not:

- change (increase or decrease) square footage;
- change (increase or decrease) the number of its beds; or
- change its term and conditions of operations in any way.

CMS has interpreted the above conditions to preclude a grandfathered HwH from making any changes in square footage or bed number that affect Medicare or Medicaid payments.

Proposed Revisions to Grandfathered HwH Rule

In the proposed rate year 2007 update rule for hospitals subject to the inpatient short-term acute hospital prospective payment system (IPPS), CMS has proposed limited revisions to the rule governing grandfathered HwHs:

- to allow for increases or decreases in square footage, or decreases only in the number of beds, due to relocation of the hospital (a) to permit construction or renovation necessary to comply with state, federal or local

law affecting the physical facility, or (b) because of a catastrophic event, such as a fire, flood, earthquake, or tornado;

- to allow for decreases only in the number of beds or square footage.

CMS' proposed changes to the grandfathered hospital-within-hospital rule at 42 C.F.R. §412.22(f) are inadequate.

CMS' proposed revisions to 42 C.F.R. §412.22(f) do not address the need for grandfathered HwHs to change programs to meet patient care requirements. Harris Continued Care Hospital has several needs. We have 10 rooms and are currently licensed for 15 beds. We are unable to put 2 patients in our semi-private rooms due to an increased need to isolate patients, particularly for MRSA and VRE. We need to expand our space to include all private rooms. We also need a small conference room where physicians and staff can meet with families privately. Currently, there is no such space available; when the need arises we vacate an office, but first we have to make sure all private information is secured. The nursing station and staff areas need to be expanded to meet HIPAA requirements. There is not a private area for staff and physicians to discuss/report on patients or for physician to dictate.

Because of the layout of the 75 year old building we are in, if we were to expand our rooms from 10 to 15 we would be converting space that currently belongs to Harris Methodist Fort Worth and includes 8 patient rooms. We also have a need for more managed care beds, and would like to add those three extra beds for that purpose, without increasing our Medicare beds. Those beds could be decertified for Medicare.

Harris Continued Care Hospital is scheduled to go up on the Electronic Health Record by 2008. There are space requirements for the hardware that we are also having difficulty meeting.

If Harris Continued Care Hospital is not allowed to make changes to its terms and conditions of operation, as described above, then Harris Continued Care Hospital will be unable to respond to the evolving needs of our patient population and to changes in medical practice. Harris Continued Care Hospital believes that such an application of the rule would be inconsistent with the needs and best interests of Medicare beneficiaries.

The preamble to the proposed rule states CMS' underlying reason for imposing restraints on the operations of LTCHs grandfathered by 42 C.F.R. §412.22(f) is the potential of patient shifting between co-located entities and a host hospital. The changes in patient care services and operations which Harris Continued Care Hospital needs to undertake to serve its patient population do not implicate the patient substitution of services issued which are of concern to CMS.

In view of the foregoing, Harris Continued Care Hospital urges CMS to expand its proposed revisions to the grandfathered HwH regulation to allow for increases in the number of beds or square footage where such increases are consistent with the needs and best interests of Medicare beneficiaries (e.g. to create isolation rooms, provide ancillary services or therapeutic services necessary for patient care, add or expand on-site provider-based activities related to patient care or to increase ventilator support). In addition, there

should be an exception for increases in square footage to accommodate administrative offices since such increases do not result in increased costs to the Medicare program.

In addition, please note that Harris Continued Care Hospital endorses the comments to the proposed rules as submitted by the National Association of Long Term Hospitals. Harris Continued Care Hospital thanks you for your consideration of these comments.

Sincerely,

Louise Baldwin, President
Harris Continued Care Hospital

From: Robin Bostic [mailto:Robin.Bostic@thoratec.com]
Sent: Tuesday, May 23, 2006 11:26 AM
To: Hartstein, Marc (CMS/CMM)
Subject: Comments on Left Ventricular Assist Device Procedures and Proposed Hospital Inpatient Prospective Payment System Rule - CMS-1488-P

Mr. Hartstein,

I am attaching a letter to you directly regarding Comments on Left Ventricular Assist Device Procedures and Proposed Hospital Inpatient Prospective Payment System Rule – CMS-1488-P. I apologize for sending it direct to your email, but I kept getting thrown out of the CMS comment portion which would not allow me to send a Microsoft word document. This is such an important issue I felt it was imperative that you receive this information. A hard copy will also be following. Sometimes the old mail system is the most reliable. Anyway, please review our comments and let me know if you have any questions. Thank you for your help.

<<CMS Comments to FY07 Proposed Rule v052306.DOC>>

Robin R. Bostic
Vice President of Reimbursement
Office: 603-598-0422
Cell: 617-416-6359

5/23/2006

THORATEC
CORPORATION

May 23, 2006

Centers for Medicare and Medicaid Services
Mr. Marc Hartstein
7500 Security Blvd.
Mail-Stop C4-08-06
Baltimore, MD 21244-1850

Re: Comments on Left Ventricular Assist Device Procedures and Proposed Hospital Inpatient Prospective Payment System Rule – CMS-1488-P

Dear Mr. Hartstein:

This letter serves to provide Thoratec Corporation's comments on the Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Proposed Inpatient Payment System rule for 2007 which would make a number of changes important to hospitals providing left ventricular assist devices (LVADs) to Medicare patients, including hospital-specific cost relative weights in 2007. We understand CMS is looking at refining the current DRG system to better recognize severity of illness (SOI) and has proposed utilization of a consolidated severity grouper that could be an alternative to the current DRG grouper. CMS is proposing these changes in an attempt to better recognize SOI among the Medicare population and use SOI as another factor in grouping patients into appropriate paying DRGs. CMS is proposing to adopt a consolidated severity DRG system in FY2008 (if not earlier). We seek to provide additional data on the impact of CMS proposals, and to recommend updates of this system as it pertains to patients who need left ventricular assist devices.

SUMMARY AND RECOMMENDATIONS

1. Patients who require a left ventricular assist device (LVAD) typically suffer from end stage heart failure.

2. Since FY04, CMS has properly grouped many LVAD patients, in particular those receiving an internal, implantable device into pre-MDC DRGs for patients requiring a heart transplant (DRG 103) that reflects patients with a high level of serious and severe illness, and a high degree of resources required to treat the patient. Other LVAD patients (e.g., those treated with an external implantable device) have been classified to DRG 525 for Other Heart Assist System Implant.

3. The proposed CMS consolidated severity adjusted (CSA) DRGs would improperly classify LVAD patients with patients receiving defibrillators which reflect a significantly different level of patient severity and hospital resources.

4. If CMS finalizes and implements the CSA DRGs, internal implantable LVAD procedures represented by ICD-9-CM procedure code 37.66 should be classified in new CSA DRGs 4, 5, and 6 based on similar SOI definitions.

5. This classification of LVAD procedures in CSA DRGs 4, 5, and 6 will be consistent with prior CMS classifications of LVAD procedures with heart transplant patients, and will more accurately pay hospitals for the resources needed to treat these severely sick cardiac patients.

6. Alternatively, CMS could create CSA DRGs unique to LVAD procedures.

BACKGROUND: SIGNIFICANT CLINICAL AND COST DIFFERENCES FOR IMPLANTED HEART ASSIST SYSTEM PROCEDURES REQUIRED RE-CLASSIFICATION OF ICD-9-CM PROCEDURE CODE 37.66 TO PRE-MDC DRG 103

CMS expanded coverage for LVADs in 2003 to recognize patients who needed LVADs for "destination therapy". Corresponding changes to the DRG system were subsequently made, including first a technical correction to DRG 525 in 2004. Second, CMS removed 37.62 from DRG 525 to 104/105. Non-FDA approved axial flow pumps were initially tracked to 37.62 but where then moved into 37.66 for 2004.

CMS is now in the midst of updating and possibly changing the DRG system by transitioning to hospital cost specific relative weights. The relative weights proposed under DRG 525 (for ICD-9-CM procedure code 37.65) and DRG 103 (for ICD-9-CM procedure code 37.66) seems to capture the specific cost and resources associated with VADs.

TABLE 1: DRG Assignment for ICD-9 37.65, FY2001-2005

Fiscal Year	N	Average LOS	Average Total Charges	Assigned DRG (MedPAR Source)	DRG base payment
2001	117	15 days	$171,192	DRG 525 (FY03)	$56,500
2002	142	13 days	$195,132	DRG 525 (FY04)	$73,400 [a]
2003	127	18 days	$267,053	DRG 525 (FY05)	$56,500 [b]
2004	137	14 days	$312,503	DRG 525 (FY06)	$58,900
2005	113	18 days	$352,541	DRG 525 (FY07 Pr.)	$64,000

Source is MedPAR data, but data presented excludes heart transplant. Cases with both 37.65 and 37.66 were included in the 37.66 set and excluded from the 37.65 set (to avoid being counted twice).

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a. All 37.65 cases were assigned to DRG 525 in FY2003-2004, but 37.62 was moved to DRGs 104/105 in FY2004, resulting in a significant payment difference for DRG 525 across the 2 years.

b. All 37.65 were assigned to DRG 525 in FY2004-2005, but 37.66 was moved to DRG 103 in FY2006, resulting in another payment difference in DRG 525 across these 2 years.

TABLE 2: DRG Assignment for ICD-9 37.66, FY2001-2005

Fiscal Year	N	Average LOS	Average Total Charges	Assigned DRG (MedPAR Source)	DRG base payment
2001	72	53 days	$434,000	DRG 525 (FY03)	$56,500
2002	83	45 days	$409,000	DRG 525 (FY04)	$73,400 [a]
2003	76	47 days	$561,000	DRG 103 (FY05)	$97,200
2004	158	42 days	$494,000	DRG 103 (FY06)	$95,600
2005	322	43 days	$565,000	DRG 103 (FY07 Pr.)	$104,000

Source is MedPAR data, but data presented excludes heart transplant. Cases with both 37.65 and 37.66 were included in the 37.66 set and excluded from the 37.65 set (to avoid being counted twice).

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a. All 37.65 cases were assigned to DRG 525 in FY2003-2004, but 37.62 was moved to DRGs 104/105 in FY2004, resulting in a significant payment difference for DRG 525 across the 2 years.

Issues Related to CMS' Proposal to Implement CSA-DRGs

CMS has proposed a new Consolidated Severity Adjusted (CSA) Diagnosis Related Group (DRG) system to reimburse for inpatient hospital cases. The CSA-DRG system is the first major change to the DRG system since it was originally implemented in 1983, and incorporates a severity of illness (SOI) algorithm into the DRG classification system. The SOI algorithm has been developed by 3M, which named their system the APR-DRG system. In the FY07 proposed rule, CMS modified the 3M APR-DRG systems and proposed its own CSA-DRG system.

For FY06 and FY07, the primary ICD-9-CM procedure codes describing LVAD placement and the DRGs to which these cases would be assigned are:

Table 3: FY06 and FY07 DRG Assignment for Thoratec LVAD Devices

Thoratec Product(s)	ICD-9-CM Procedure Code	Primary DRG Assigned	FY06 DRG Relative Weight*	FY06 Median Payment Across 69 DT Centers*
PVAD	**37.65** Implant of external VAD	**525** Heart Assist Systems	11.4	$83,929
IVAD, HM XVE	**37.66** Implant of internal VAD	**103** Heart Transplant and Heart Assist	18.6	$136,318

In its CSA-DRG proposal, however, the proposed grouper algorithm does not recognize a key policy change enacted by CMS which identifies ICD-9-CM procedure code 37.66 as a pre-MDC procedure and assigns it to DRG 103.

Instead, based on the 3M APR DRG grouper, cases involving either ICD-9-CM procedure code 37.66 and 37.65 that did not include a heart transplant generally would be assigned to the following CSA-DRGs:

Table 4: Proposed CSA DRG Assignment for ICD-9-CM Procedure Codes 37.65 and 37.66

CSA-DRG	Descriptor
204	CARDIOTHORACIC PROCEDURES SOI 4
207	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 1
208	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 2
209	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 3

We believe this oversight is due to the fact that the development of the APR-DRG system by 3M took place before, and was not able to account for, FY04 changes implemented by CMS whereby cases including ICD-9-CM procedure code 37.66 were assigned to a pre MDC and mapped to DRG 103.

Assigning 37.66 to pre-MDC status and re-aligning 37.66 with heart transplant CSA-DRGs would have a minimal budgetary impact while better aligning the LOS and resources associated with these patients. Simply stated, patients who need LVADs are

more appropriately classified with heart transplant (or lung transplant) patients, in terms of diagnosis, severity of illness, and hospital resources, than what has been proposed in the FY07 proposed rule, which aligns these cases with patients needing defibrillators. Based on MEDPAR 2004 data published by CMS, the number of cases, LOS, and charges for the key CSA-DRG groups for this discussion are as follows:

Table 5: CMS Analysis of Number of Cases, Average LOS, and Average Charges Across Relevant Proposed CSA DRGs

CSA-DRG	Descriptor	N	Avg LOS	Avg Charges
4	HEART &/OR LUNG TRANSPLANT SOI 1 & 2	261	12.80	$200,583
5	HEART &/OR LUNG TRANSPLANT SOI 3	242	31.60	$328,397
6	HEART &/OR LUNG TRANSPLANT SOI 4	258	44.20	$524,070
204	CARDIOTHORACIC PROCEDURES SOI 4	21,158	18.30	$182,309
207	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 1	5,543	2.20	$86,365
208	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 2	22,400	3.70	$97,810
209	CARDIAC DEFIBRILLATOR & HEART ASSIST IMPLANT SOI 3	25,923	6.60	$118,694

Our own analysis of the MEDPAR 2004 file of cases involving 37.66 that did not include a heart transplant procedure revealed that these cases would have been assigned to CSA DRG 204, 208, and 209, but are far more similar to cases assigned to CSA DRGs 4, 5, and 6.

Table 6: Thoratec Analysis of Non-Heart Transplant Cases Coded with ICD-9-CM Procedure Code 37.66 Assigned to CSA DRGs 204, 208, and 209 under the FY07 Proposed Rule

Proposed CSA-DRG Assignment for 37.66 Cases	N	Avg LOS	Avg Total Charges
204 – SOI 4	165	42.54	$534,828
208 – SOI 2	1	18.00	$330,806
209 – SOI 3	15	24.33	$328,066

Recommended Modifications to Proposed Rule

We recommend that if CMS plans to adopt the CSA DRG system:

ICD-9 37.66 cases should be assigned to pre-MDC DRGs 4, 5, and 6 instead of 204, 207, 208, and 209,

This would create a more homogeneous DRG and would be consistent with the treatment of 37.66 cases since the FY04 Final Rule.

Alternatively, CMS could create a separate set of Heart Assist Implant DRGs separate from DRGs 204, 207, 208, and 209 which include not just procedure code 37.66 but also other heart assist system related procedure codes including 37.65.

We further recommend that CMS collect cost data in 2007 and 2008 to insure CSA DRG adequately captures hospital cost and resources.

- ICD-9 37.65 implant of an external VAD
- ICD-9-37.66 implant of implantable VAD

If you should have any questions, please do not hesitate to contact me at 603-598-0422. We look forward to working with CMS to resolve this issue.

Thank you for your consideration in this matter.

Sincerely,

Robin Bostic
Vice President of Reimbursement
Thoratec Corporation

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~~CMS-2231-IFC-3~~

Submitter : Dr. Michael Bailey

Organization : Nashville Arrhythmia Consultants, PC

Category : Physician

Date: 05/13/2006

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern,

I am a physician in Nashville, TN, that practices electrophysiology, the specialty specifically trained to deal with heart rhythm disorders. I do not agree with the proposed changes in the payment rule that is referenced above. Without pretending to be aware of all the details that contribute to the plan outlined above, I know that this change will bankrupt my hospital. We spend a significant time (administrators and physicians) debating how to improve patient care and safety and at the same time budget money for the continued technological advances that have made such an impact in patient lives. I implant defibrillators in patients at high risk for sudden death. This therapy is cost effective but expensive. It is the only therapy available to patients at risk that effect significant positive change. At my institution, with cardiology carrying the rest of the hospital financially as is the case with most centers, we will not be able to continue providing this life saving therapy or many other therapies that are not cost effective for the hospital. In short, this change will cost lives. It is reckless and poorly considered and I do not support this measure. Please reconsider before going further.

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~~CMS-2231-IFC-4~~

Submitter : Dr. sankar varanasi

Organization : HUDSON VALLEY HEART CENTER

Category : Physician

Date: 05/13/2006

Issue Areas/Comments

Background

Background

PROPOSED PAYMENT CUTS FOR HOSPITALS PERFORMING HEART RHYTHM PROCEDURES

GENERAL

GENERAL

As a electrophysiologist,als o known as a heart rhythm specialist i am quiet concerned about the potential impact of proposed payment cuts to hospitals performing heart rhythn procedures.Implantable cardiac defibrillators are life saving devices used to prevent sudden cardiac arrest the nations number one killer of all people. The implementation of the proposed cuts would have a devastating impact on my hospitals ability to provide care for my patients in the community. For example the administrative costs of the recently mandated regisury requires administrative costs .This is a quality improvement service which would not be supported by the hospital due to reduction in resources.
The proposed system has inherent flaws that make the system prone to severe adverse impact on the hospitals and medicare beneficiaries.
I would like you to consider these comments seriously and consider postponing the implementation of theses changes to better analyse the impact of these changes as well as CMS to reconsider their proposals.
On behalf of my community and the patients i serve , i thank you for kind consideration of these comments.

sincerely
SANKAR N VARANASI MD FACC

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~~CMS-2231-IFC-6~~

Submitter : Dr. Arjun Sharma
Organization : Dr. Arjun Sharma
Category : Physician
Date: 05/14/2006

Issue Areas/Comments

Background

Background

Defibrillator and pacemaker reimbursement has been low in the past

GENERAL

GENERAL

The proposed reimbursement for pacemakers and defibrillators are less the purchase cost of the device alone let alone any hospital cost for work up and surgical procedure and staffing.
If CMS really wants to control costs why do you not have the government fix device and drug prices! Not likely. Instead you make it a money loosing situation for hospitals. What incentive is there for any hospital to provide good care by established guidlines if they are guarantoed to loose money by trying to provide care? How is this going to improve the health of Americans?

Provisions

Provisions

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

13

Board Certified
Orthopedic Surgeons
JAMES P. O'NEILL, D.O.
RAYMOND D. DRAGANN, D.O.
PAUL M. SIMONELLI, D.O.
THOMAS J. RENZ, D.O.
MARC P. OLIVERI, D.O.
JOSEPH W. MEHM, M.D.

Orthopedic Consultants LTD.

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Fracture Care
Work/Sport Fitness Evaluation
Arthroscopic Surgery

May 22, 2006

CMS
Dept of Health & Human Srvcs.
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: X STOP IPD

Dear Sirs:

I have had the opportunity to use the X STOP device by St. Francis Medical Technologies.

This is an excellent addition to our treatment options as far as treating low back pain and neurogenic claudicatory discomfort. I have had the opportunity to use the device myself and have had excellent results in getting people back to work quicker with a smaller, less invasive surgery.

I think in the long run, it may save Medicare money in that a lot of times these diagnoses which we are doing surgery for are spinal stenosis and also spondylolisthesis. Usually for spinal stenosis and spondylolisthesis, if conservative measures have failed, surgical option would include a lumbar laminectomy and a fusion which could include using pedicle screws, rods and interbody fusion cages and some sort of bone graft material. That is obviously a very expensive proposition. The X STOP device is much less expensive and also from the preliminary data from research the results are very comparable to a laminectomy and fusion.

I believe the X STOP is going to be and will continue to be, in my practice, a good alternative to standard laminectomy and fusion techniques. I believe it will afford the patient a quicker recovery; and it will be cheaper for the insurance systems.

Sincerely,

Marc P. Oliveri, D.O.

MPO/lr
Dictated/not read

CC: St. Francis Medical Technologies, Inc.
960 Atlantic Avenue, Suite 102
Alameda, CA 94501

14

DON SHERWOOD
10TH DISTRICT, PENNSYLVANIA

ASSISTANT MAJORITY WHIP

APPROPRIATIONS COMMITTEE

SUBCOMMITTEES:
LABOR, HEALTH AND HUMAN SERVICES AND EDUCATION

INTERIOR

FOREIGN OPERATIONS

Congress of the United States
House of Representatives
Washington, DC 20515–3810

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FAX: (202) 225–9594

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☐ 330 PINE STREET, SUITE 202
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☐ 106 ARCH STREET
SUNBURY, PA 17801
(570) 286–1723
FAX: (570) 286–1725

☐ DISTRICT WIDE TOLL FREE:
1–888–366–7210

May 16, 2006

Dr. Mark B. McClellan, Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and FY07 Rates Published in the Federal Register on April 25, 2006

Dear Dr. McClellan:

I am writing to remind you of my continued interest, as the Member of Congress representing Susquehanna Health System (SHS) in Williamsport, Pennsylvania, in securing for them a more equitable wage index. Beginning in 2002, when I started working with CMS to resolve the Medicare underpayment problem, my staff was informed that the issue would be resolved as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Section 508 one-time appeal process. Unfortunately, the regulation effectively excluded SHS hospitals from access to Section 508.

The Health System continues to try to work through the regulatory process and a meeting with CMS was held in my office in July 2005 to find a solution. To that end, the FY 2007 Inpatient Prospective Payment System Proposed Rule now presents an opportunity for CMS to fix this problem. Thus, I am submitting the following comments in support of and on behalf of The Williamsport Hospital & Medical Center relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications". I firmly believe now is the time for CMS to fix this problem.

The FY 2007 Inpatient Prospective Payment System Proposed Rule asked for comments concerning the reclassification for hospitals located in a single hospital MSA surrounded by rural counties. The proposed rule invited comment on three specific questions and this letter responds to those questions.

1. What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?

A hospital, such as The Williamsport Hospital & Medical Center, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in an area that receives a wage index reimbursement that is significantly higher than the competitors' own actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its own average hourly wage. This excess reimbursement allows these reclassified hospitals to invest in new technology and services. The disadvantage for the hospital receiving a wage index reflecting its own wages, while trying to compete with reclassified hospitals, is that it must

continually work to keep wages competitive, continue to purchase new technology and continue to provide the services needed by Medicare beneficiaries in its community.

2. Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals, which have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?

A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals with whom it competes (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these circumstances, the wage index reclassification rules interfere with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is exactly the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

In the case of The Williamsport Hospital & Medical Center, it competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. Williamsport Hospital has only been able to remain viable and continue to compete with it competitors in the level of services it provides as a result of the efficiencies Williamsport Hospital achieved through its affiliation with Susquehanna Health System in 1994. Now, with no additional costs left to cut and Williamsport Hospital's competitors continuing to receive higher wage indexes, Williamsport Hospital is at a competitive disadvantage which will adversely impact the services that Williamsport Hospital is able to provide the community. If Williamsport Hospital is not reclassified into the Harrisburg MSA, Williamsport Hospital will not be able to retain its employees and patient care and access to care will be adversely affected as Williamsport Hospital is no longer able to make up the shortfall through any additional cost reduction efforts because it has already achieved a high level of efficiency as a result of the affiliation.

In rendering decisions on requests for reclassification, the Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. Unless Williamsport Hospital is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare beneficiaries. Accordingly, CMS must level the playing field and provide Williamsport Hospital with appropriate regulatory criteria under the wage index regulations, allowing the hospital to reclassify to the same area where its competitors are have been reclassified.

3. Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?

CMS has stated that geographic reclassification is limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located"(physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. In addition, CMS has indicated that hospitals seeking reclassification to another area must demonstrate an economic connection to the area to which reclassification is requested. Accordingly, the focus is on competition as demonstrated through an economic connection, not on location per se. Williamsport Hospital has an economic connection to the Harrisburg MSA because that is where Williamsport Hospital's competitors are located and/or have been reclassified. In addition, the Harrisburg MSA represents the relevant market for purposes of (1) wage comparison in the context of employee recruitment and retention; (2) comparability of service delivery needs/capabilities with respect to patient care; and (3) the area with which Williamsport Hospital competes for staff and patients. Accordingly, CMS should permit Williamsport Hospital to reclassify to the Harrisburg MSA even thought it is further away than other, closer urban labor market areas

I hope I've brought clarity to the questions CMS has raised and again, I ask you to use the regulatory process to address the Susquehanna Health System's legitimate concerns on this isolated situation where reclassification rules do not provide a remedy.

Please feel free to contact me if you need any further information on this request.

Sincerely,

Don Sherwood
Member of Congress

DLS:tb
cc: Centers for Medicare & Medicaid Services ✓
Department of Health & Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Rural Referral Center
• Sole Community Hospital
coalition
20 YEARS Supporting Rural Health Care Since 1986
600 13th Street, NW • Washington, DC 20005
202.756.8148 phone • 202.756.8087 fax

May 24, 2006

VIA OVERNIGHT MAIL

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; 71 *Fed. Reg.* 23,996 *et seq.* (Apr. 25, 2006); CMS-1488-P

Dear Sir or Madam:

On behalf of the Rural Referral Center/Sole Community Hospital Coalition ("the Coalition"), please accept these comments regarding **SCH/MDH Changes in Qualification Status**.

Formed in 1986, the Coalition is comprised of hospitals designated as Rural Referral Renters and Sole Community Hospitals ("SCHs") under the Medicare Program. Coalition hospitals share the common goal of ensuring that federal hospital payment policies recognize the unique and important role and contributions of these hospitals.

In furtherance of this goal, the Coalition respectfully requests that the Centers for Medicare & Medicaid Services ("CMS") address several ambiguities in its proposal, and modify the proposed reporting requirements for SCHs. (Although CMS has likewise proposed comparable reporting requirements for Medicare-dependent hospitals, and many of our comments would apply for MDHs too, we are focusing our comments on SCHs, given our membership).

Congress established the SCH designation and its attendant benefits to identify and buttress hospitals that, by reason of their geographic isolation, are critical to the healthcare infrastructure of their communities and are financially vulnerable. **The Coalition agrees that hospitals that do not meet the qualification criteria should not retain SCH designation and continue to receive special financial protection.** However, the proposed reporting requirement and penalties are problematic for a number of reasons, and need to be clarified and revised to be consistent with the intended purpose of the SCH program.

First, hospitals are not always, and in fact are most often not, in the best position to monitor ongoing compliance with the SCH qualification criteria. Although a hospital qualifying by being more than 35 miles from another "like hospital" may often know when a new facility locates within a 35-mile distance, it is not always the case. Take for example the hospital that qualifies by being more than a 35-mile distance from another "like hospital," but which nonetheless has a critical access hospital ("CAH") located within 35 miles. The SCH may not always know if the CAH converts to general acute care hospital status.

The problem is more pronounced for hospitals qualifying for SCH status under the other eligibility criteria. The other qualification criteria are far more complicated and difficult for hospitals to monitor. For example, hospitals do not maintain or readily have access to data on inpatient admissions at other regional hospitals, and would have to gather this information from state hospital associations or their fiscal intermediaries to know whether they continue to qualify under 42 C.F.R. § 412.92(a)(1)(i). One Coalition hospital that is located near a state border, and that has a service area that spans two states shared with us their difficulties obtaining admissions data from two state hospital associations when they initially qualified.

Similarly, a hospital that qualifies for SCH status by omitting a nearby provider under the 8 percent threshold used to identify "like hospitals" would be unable to know if the nearby hospital eventually exceeds the threshold, and would then qualify as a "like hospital."

CMS and its fiscal intermediaries maintain hospital status, patient admissions and days data. Much of this data is generally not readily available to hospitals. As such, it is unreasonable to expect hospitals to effectively monitor this data for changes. It is far more reasonable to expect CMS and its fiscal intermediaries to periodically evaluate this data for SCH eligibility.

It is similarly unreasonable to expect hospitals to monitor and know when and for how long there were prolonged severe weather conditions that closed area roads, and thus to know whether they continue to qualify under § 412.92(a)(1)(iii) or (a)(2). It likewise would be unreasonable to expect hospitals to monitor and know whether traffic patterns or posted speed limits in a particular region have changed such that they no longer qualify under § 412.92(a)(3). Requiring hospitals to constantly monitor whether they continue to meet these requirements imposes a tremendous and unreasonable administrative burden on hospitals that have already been shown to have higher costs than other hospitals, and that have been singled-out by Congress because of their vulnerability. *See*, 70 *Fed. Reg.* 68,515, 68,556-61 (Nov. 10, 2005).

Given these concerns, CMS should continue to place the responsibility for determining and reconfirming SCH status with its fiscal intermediaries.

CMS likewise should re-evaluate the proposed timetable for canceling SCH status when a hospital self-reports. The proposed 30-day timetable is unreasonably short. Losing SCH status would be at best financially significant and at worst devastating for hospitals that have relied on this support, and planned future operations and improvements with the expectation of its continuation. Thirty days does not provide a hospital with adequate opportunity to make necessary adjustments to prepare for reduced Medicare payments. **CMS instead should**

encourage hospitals to self-report by revoking SCH status after the later of six months or the start of a hospital's next cost reporting period.

The Coalition also is concerned with the proposed retroactive penalty in cases where a hospital does not immediately notify CMS that it no longer meets the SCH qualification criteria. First, this penalty would seemingly apply regardless of whether the hospital had actual knowledge that circumstances changed. Take for example the hospital that qualifies for SCH status by being more than 45 minutes from another "like hospital." Suppose a governmental authority changes a posted speed limit on a road along the route to the nearby hospital. If this change comes to the attention of CMS, but not the hospital with SCH status, CMS would revoke the status retroactively. **CMS should penalize a hospital only where the hospital had actual knowledge of the changes that preclude it from qualifying for SCH status.**

Second, CMS needs to specify some limitation on this penalty. If the change to the posted speed limit in the hypothetical above was made 5, 10, or even 15 years prior, would CMS revoke the hospital's SCH status that far back? Although not expressly discussed in the proposed rule, the implication is that CMS could seek repayment of any payment differential resulting from SCH status. If CMS then chose to seek a repayment from a hospital for the period during which it did not qualify as an SCH, such a financial penalty could force many hospitals immediately out of business. Moreover, this practice would be inconsistent with Medicare regulations which generally limit CMS and intermediaries from reopening matters after three-years. *See,* 42 C.F.R. § 405.1885. It is unclear whether CMS intends to seek retroactive revocation and repayments beyond this typical three-year reopening time period.

These penalty provisions are unreasonably harsh, and punish hospitals regardless of any good faith efforts to comply with the SCH requirements. **The Coalition recommends that a hospital that does not self-report despite having actual knowledge of changes that preclude it from qualifying for SCH status lose its SCH status immediately, but not retroactively.** If CMS wishes to provide incentives to self-report, and penalties for failure to do so, immediate revocation of SCH status would be ample incentive and penalty. **Moreover, CMS should clarify that hospitals will not be expected to make repayments when they lose SCH status, unless fraud is present.**

CMS also should take this opportunity to reevaluate its definition of "like hospital." *See,* § 412.92(c)(2). Presently, CMS does not consider a hospital to be a "like hospital" if its total inpatient days are less than 8 percent of those of the SCH. The 8 percent threshold was arbitrarily determined, and is not based on any empirical study or evidence. *See,* 67 *Fed. Reg.* 49,982, 50,054 (Aug. 1, 2002). CMS should consider increasing this threshold to 10 percent, and also permitting aspiring SCHs to also exclude nearby hospitals based on Medicare days, as well as total days (which is consistent with § 412.92(a)(1)(i)), and discharges and beds with a comparable numerical threshold.

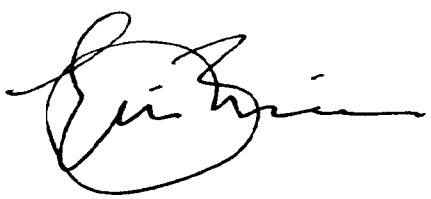
Moreover, CMS should use this opportunity to insulate SCHs from the looming threat of specialty hospitals. The 8 percent rule is inadequate given the proliferation of specialty hospitals. It is possible that some hospitals might lose SCH status because another nearby

specialty hospital exceeds the 8 percent threshold, although the two hospitals serve very different populations and functions. In addition to excluding hospitals based on a percentage of days, or some other appropriate measure, CMS also should exclude from the definition of "like hospital" a "specialty hospital" as defined by the Stark law. *See,* 42 U.S.C. § 1395nn(h)(7); 42 C.F.R. § 411.351. Also excluding "specialty hospitals" will ensure that an SCH is not penalized if a specialty hospital that does not meet the 8 percent rule is located in its service area. A cardiac specialty hospital that happens to have a significant number of beds and inpatient days, but which nonetheless primarily provides cardiovascular services, is not a "like hospital" and should not force a nearby hospital to forfeit SCH status.

Finally, CMS should take this opportunity to reconsider appropriate treatment of hospitals that fail to maintain appropriate market share necessary to retain SCH status under § 412.92(a)(1)(i). A hospital that initially qualified for SCH status under this opportunity, but which is later found to have serviced only 74 percent of the persons admitted to a hospital in its service area could lose its SCH status as a result. While bright line rules are important, some flexibility is warranted in this instance. CMS might instead require a hospital to service at least 75 percent of the hospital inpatients in its service area to initially qualify, but allow the hospital to drop as low as 65 percent before losing SCH status. Alternatively or additionally, CMS could permit hospitals to demonstrate compliance by reaching the 75 percent threshold in at least two of the most recent three years before losing SCH status. Of course, the multiple-year review is consistent with other portions of the SCH qualification regulations.

Please call me at 202.756.8148 if you have any questions about these comments.

Sincerely,



Eric Zimmerman

Ball Memorial Hospital, Inc.

May 23, 2006

VIA FEDERAL EXPRESS

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Geographic Reclassifications; Requested Reclassification for Hospitals Located in a Single Hospital MSA Surrounded by Rural Counties**

Dear Sir or Madam:

This letter responds to your request for comments under section IV.G.6 (Requested Reclassification for Hospitals Located in a Single Hospital MSA Surrounded by Rural Counties) concerning hospitals in single-hospital Metropolitan Statistical Areas ("MSAs") that are ineligible for wage index reclassification. Ball Memorial Hospital confronts a very similar circumstance to the one raised by the commenter, and concurs that CMS should address the shortcomings of the reclassification rules that prevent these hospitals from qualifying for reclassification.

Ball Memorial Hospital (provider number 15-0089) is a 410 bed community hospital serving Muncie and the surrounding areas of East Central Indiana. BMH is the only hospital in Delaware County, and therefore the only hospital in the Muncie, IN MSA (34620). Because Ball is alone in the Muncie MSA, it cannot qualify for wage index reclassification.

A. Ball Cannot Qualify for Reclassification

Ball satisfies two of the three tests required for wage index reclassification. Ball is located 10.2 miles from the Madison County line, which presently is part of the Anderson, IN MSA. As such, Ball is proximate to the Anderson County MSA. Ball also satisfies the 84 percent test to the Anderson, IN MSA. Ball's three-year average hourly wage for fiscal years 2005 through 2007 ($24.0532) is 98 percent of the AHW of hospitals in the Anderson, IN MSA ($24.4749).

However, Ball cannot satisfy the 108 percent test, because the test mathematically cannot work when there is only one hospital in the MSA. CMS has provided no mechanism for a hospital that is alone in its MSA to satisfy this wage comparison test, and to therefore qualify for reclassification. Moreover, Ball cannot qualify for reclassification as a hospital group, because the Muncie MSA is not part of the Indianapolis Combined Statistical Area ("CSA").

B. CMS Should Revise the Reclassification Regulations to Allow Hospitals in Single-Hospital MSAs to Qualify for Reclassification

For the following reasons, CMS should revise the reclassification regulations in a manner that would allow Ball and other hospitals that are in single hospital MSAs to qualify for wage index reclassification.

The purpose of the reclassification process is not being fulfilled for these hospitals because of the way CMS has set up the 108 percent test. Envision two hospitals, identical in terms of size and services offered, and located across the street from one another. However, running down the street that separates the two hospitals is a county line and MSA boundary. As such, the two hospitals are located in distinct MSAs. Like gas stations located on opposite street corners that match gas prices, these hospitals could have exactly the same AHW, because they compete with one another for hospital employees. It is undeniable that these hospitals would be in the same labor market. Yet, they could be assigned very different wage indexes because they are assigned to distinct MSAs.

Congress established the reclassification process to address exactly this type of scenario. However, if one of the hospitals is the only hospital in that MSA, it could not qualify for reclassification to the neighboring MSA. In this instance, the reclassification process would not be functioning as it should for this hospital. This scenario is essentially the situation faced by Ball.

The notion that hospitals that are alone in their MSA should not need to reclassify, because they determine their own wage index, denies the purpose of reclassification. Conceding for argument sake that a hospital in a single-hospital area is adequately compensated because it determines its own wage index, these hospitals still should be eligible for geographic reclassification. Whether or not a hospital unilaterally determines its wage index says nothing about whether that hospital competes with hospitals on the other side of an MSA boundary, whether the applicant is in the same labor market as those other hospitals, or whether the wage index assigned to that hospital is appropriate.

Additionally, it is disputable whether determining one's own wage index necessarily means the hospital is compensated adequately. Just because payments to a hospital may be determined using a hospital-specific wage index does not mean that the hospital is adequately compensated for its labor costs, or even that it is appropriately positioned to fairly compete with other

hospitals in its labor market. Because of the way CMS uses MSAs to define labor markets, huge wage index disparities and reimbursement differentials can exist among hospitals in the same labor market, if they are assigned to different MSAs.

The situation confronting Ball illustrates this point. The two hospitals closest to Ball are St. Johns Health System (15-0088) and Community Hospital (15-0113). Ball undeniably competes with both for hospital labor. Ball, St. Johns and Community all have very comparable average hourly wages: $24.0532, $24.3172 and $24.6828, respectively. Yet, St. Johns and Community receive a significantly higher wage index. Both St. Johns and Community are in the Anderson, IN, MSA, and both qualify for wage index reclassification to the Indianapolis, IN MSA. Both Saint Johns and Community will have a wage index of 0.9582 during FY 2007, while the wage index applicable to Ball will be 0.8479. The fact that Ball sets its own wage index is of little consolation in this instance, and is completely irrelevant to the question of whether Ball is able to compete fairly with the hospitals in its labor market. If Ball, St. Johns and Community compete in the same labor market for hospital employees, Ball should have the opportunity to reclassify, so that it can compete on a level playing field with those other providers.

Furthermore, the notion that hospitals that are in single-hospital areas can rectify their situation by increasing labor compensation, and thereby increasing the prevailing wage index ignores several fundamental characteristics of the functionality of the wage index in Medicare reimbursement. First, the wage index does not provide a dollar-for-dollar return to hospitals for their labor cost investments. While hospitals in single-hospital areas can unilaterally determine their wage index, they cannot affect the portion of the payment that is adjusted by the wage index. CMS does not use a hospital-specific labor share adjustment to determine the portion of the standardized amount modified by the wage index. Rather, CMS uses a national labor-share adjustment. To the extent that labor cost as a percentage of total cost is less than the applicable labor share adjustment, these hospitals could not hope to recoup their full investment, even though their wage index would increase.

Moreover, because the wage index is determined using labor cost data from three years prior, it would take Ball at least three years before it began to realize any return on its investment in hospital labor. Ball operates on a thin margin, and cannot afford to carry inflated labor costs for three years in the hope that it will get some return on that investment in the future.

Finally, a closer look at the facts and circumstances shows a pattern that demonstrates that Ball is at a disadvantage. For all practical purposes (other than Wage Index Classification), Ball is part of "metropolitan Indianapolis." Frequently, individuals who live in the Muncie MSA choose to not commute – but in fact move – to the Indianapolis MSA – sometimes after first being trained and even working in the Muncie MSA for a period of time. Ball, in fact, has to compete with hospitals in the Anderson and Indianapolis MSAs – despite the disparities in reimbursement.

CMS has previously said, "We believe that geographic reclassifications should be limited to those hospitals which are disadvantaged by their current geographic classification because they compete with the hospitals that are located in the geographic area to which they seek to be reclassified."[1] Ball is disadvantaged by its current geographic classification because it competes with hospitals that are located in nearby MSAs. Yet, Ball is barred from even applying for reclassification. Ball should be able to avail itself of the reclassification process.

C. Proposed Solutions

The commenter advocated a change to the urban county group reclassification regulations whereby a hospital in a single hospital MSA surrounded by rural counties would be able to reclassify to the closest urban area that is part of a CSA located in the same State as the hospital. This, of course, is one way to resolve the problem. While it is not entirely clear whether this solution would enable Ball to qualify for reclassification, because the Muncie MSA is not contiguous to the Indianapolis MSA, and it is not clear how CMS would define some of the terms, such as what it means to be "surrounded by rural counties," this solution likely could be refined in a manner that would benefit Ball. Nonetheless, there also are other ways CMS could revise the reclassification rules to resolve the problems confronted by Ball and other similarly situated hospitals.

1. Exempt hospitals in single-hospital areas from the 108 percent test.

CMS could resolve the problem confronted by hospitals in single-hospital areas by exempting them from the 108 percent test. The purpose underlying the 108 percent test is for the applicant to demonstrate that its wage costs are disproportionately high compared to its neighbors. Where the applicant has no neighbors in its MSA, a meaningful average area wage cannot be determined, and the 108 percent test is not an appropriate comparison. CMS exempted hospital groups from a local wage comparability test for this very reason. CMS recognized there would be no way for these hospitals to satisfy such a test. CMS can adequately evaluate whether the applicant is disadvantaged by its geographic classification by requiring it to demonstrate wage comparability with, and proximity to a neighboring area, much like it does for hospital groups.

2. Combine single-hospital areas with neighboring MSAs

CMS could partially resolve the problem for hospitals in single-hospital areas by combining the MSA in which the hospital is located with another MSA. This proposal would address CMS's concerns with single-hospital labor markets. According to CMS, single-hospital labor markets

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[1] 56 *Fed. Reg.* 25,458, 25,469 (June 4, 1991).

"create instability in the wage index from year to year for a large number of hospitals."[2] CMS further noted that single-hospital labor markets "reduce the averaging effect of the wage index, lessening some of the efficiency incentive inherent in a system based on the average hourly wages for a large number of hospitals."[3]

CMS cited these reasons as the basis for rejecting Micropolitan Areas for purposes of defining labor markets. CMS could further address concerns with single-hospital labor markets by combining these areas with neighboring MSAs to form larger labor markets with more hospitals for purposes of determining the wage index. CMS could implement this change in a variety of ways. For example, CMS could merge a single-hospital MSA only when it is adjacent to another MSA. Where the single hospital MSA is adjacent to two or more other MSAs, CMS could base the merger determination on commuting patterns, and merge the single-hospital MSA with the MSA with which it shares the highest commuting pattern interchange. In many ways, this would be similar to Lugar reclassifications made pursuant to § 1886(d)(8)(B). There are 49 MSAs with only one hospital. Not all of these MSAs are adjacent to another MSA. As such, this proposed change would affect fewer than 49 hospitals.

* * * * *

Ball is proposing two solutions that would enable the hospital to qualify for reclassification, and to receive a somewhat higher wage index. However, it is important to note that neither solution would be a complete remedy. As previously noted, Ball competes for labor most directly with the two hospitals in Madison County; Ball also competes for labor with hospitals in surrounding rural areas, including those in Grant, Blackford, Jay, Randolph and Henry counties. There are two general acute care hospitals (and several critical access hospitals) located in these surrounding counties: Henry County Memorial Hospital and Marion General Hospital. Both Henry County and Marion General qualify for wage index reclassification into the Indianapolis MSA. Consequently, the four hospitals in closest proximity to Ball – Saint Johns, Community, Henry County and Marion General – all will have a wage index of approximately 0.9582 during FY 2007.

If CMS makes one of the changes recommended above, and Ball is able to qualify for reclassification into the Anderson MSA, it still will be severely disadvantaged vis-à-vis its competitors. Of the 33 hospitals in closest proximity to the hospital, Ball is paid at the second lowest rate. Only Fayette Memorial Hospital is paid less, and it is located in Rural Indiana. Ball's wage adjusted Medicare payment amount is approximately 6 percent lower than the hospitals physically located in Indianapolis and 5.2 percent lower than the hospitals that reclassify into Indianapolis. As such, enabling Ball to qualify for reclassification would hardly

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[2] 69 *Fed. Reg.* at 28,251.
[3] *Id.*

level the playing field, as it should be. Nonetheless, such a change would be a step in the right direction, and a significant help to the hospital.

We appreciate your consideration of our situation and these comments. Please call me at 765.747.3251 or our counsel, Eric Zimmerman, at 202.756.8148, if you have any questions concerning these comments.

Sincerely,

Brent L. Batman, President

c: Senator Richard G. Lugar

Senator Evan Bayh

Congressman Mike Pence

Eric Zimmerman, Attorney at Law

17

ORLANDO REGIONAL
Medical Education
GRADUATE MEDICAL EDUCATION ADMINISTRATION

May 26, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

Orlando Regional Healthcare welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background
The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of

86 W. Underwood St., Suite 100 • Orlando, Florida 32806 • 321 841-5243
www.orlandoregional.org

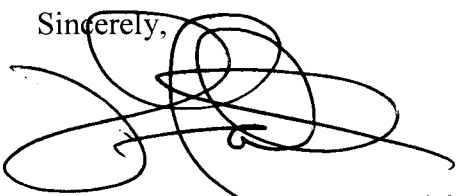
a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Our residency programs consider didactic conferences integral to patient care delivery. Conferences such as "morning report", "morbidity and mortality", etc, review active cases to solicit broad input from the entirety of the faculty as to the appropriate care for patients. Much of our "topic oriented" discussions are built around recent cases where an evidence-based approach is taught that enhances care for the next patient presenting with that condition.

Additionally, the accounting and reporting of resident activities on an hourly basis would be nearly impossible to accurately accomplish and would require tremendous resources.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,



Jay L. Falk, M.D., FACEP, FCCM
Chief Academic Medical Officer
Orlando Regional Healthcare
Clinical Professor, Medicine and Emergency Medicine
University of Florida College of Medicine
Clinical Professor, Clinical Sciences
Florida State University College of Medicine

4440 West 95th Street
Oak Lawn, Illinois 60453
Telephone 708.684.8000
www.advocatehealth.com

Advocate Christ Medical Center

May 23, 2006

Centers for Medicare and Medicaid Services
Marc Hartstein
7500 Security Blvd.
Mail-Stop C4-08-06
Baltimore, MD 21244-1850

Dear Mr. Hartstein:

This letter will serve to make comment regarding the Centers for Medicare and Medicaid Services (CMS) Hospital Inpatient Proposed Payment System 2007 rule which CMS is proposing to adopt a consolidated severity DRG system in FY2008 (if not earlier). We seek to provide additional data and to recommend updates of this system as it pertains to left ventricular assist devices.

A VAD System is designed to assist the pumping function of the natural heart's ventricles in patients with end-stage heart failure. It can be used as a destination therapy (the device is permanent) or as a bridge-to-transplant. In the bridge-to-transplant case, the device is used to extend the life of the patient until a new heart can be found.

Advocate Christ Medical Center has continued to be a leader in mechanical assist device technology and medical treatment of heart failure. The Left Ventricular Assist Device (LVAD)/Heart Failure program has been the second busiest LVAD program in the state of Illinois since January 2001 and is one of the 69 CMS LVAD Destination Therapy sites in the country. Advocate Christ Medical Center continues to be a leader in education and clinical research with a special interest in patient selection, management, and long-term outcomes.

CMS has proposed a new Consolidated Severity Adjusted (CSA) Diagnosis Related Group (DRG) system to reimburse for inpatient hospital cases which would drastically reduce payment for implanting a VAD by almost 50%. The CSA-DRG system is the first major change to the DRG system since it was originally implemented in 1983, and incorporates a severity of illness (SOI) algorithm into the DRG classification system. Unfortunately, in its CSA-DRG proposal the proposed grouper algorithm does not recognize a key policy change enacted by CMS which identifies ICD-9-CM procedure code 37.66 as a pre-MDC procedure and assigns it to DRG 103. Instead, based on the 3M APR DRG grouper, cases involving either ICD-9-CM procedure code 37.66 and 37.65 that did not include a heart transplant. If CMS plans to adopt the CSA DRG system ICD-9 37.66 cases should be assigned to DRGs 4, 5, and 6 instead of 204, 207, 208, and 209, which would be consistent with the treatment of 37.66 cases since the CMS changes in the FY04 Final Rule.

With only 69 Centers recognized by CMS as Destination Therapy (DT) LVAD Centers, this type of reduction would place a significant burden on those centers providing this level of care for a very sick patient population.

The table below reflects the impact in payment to Advocate Christ Medical Center from 2006 to 2008.

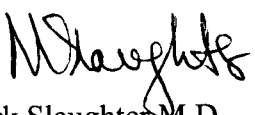
Table 1 Advocate Christ Medical Center DRG payment

DRG103	DRG 525	DRG 204		DRG 209	
FY06	FY06	FY08P	n	FY08P	n
$123,321	$75,927	$63,366	51	$37,081	140

CMS is encouraged to modify the suggested CSA DRG system to parallel the recommendations CMS made in the 2004 Inpatient Rule and is still in effect today which included grouping implanted long-term VADs into the same DRG as Heart Transplantation or create new CSA DRGs for VADs which reflect the cost and resources required to provide the level of care.

Thank you for your attention in this matter.

Sincerely,



Mark Slaughter M.D.
Surgical Director for Mechanical Assist Device Program
Advocate Christ Medical Center

EASTERN VIRGINIA MEDICAL SCHOOL
DEPARTMENT OF PHYSICAL MEDICINE AND REHABILITATION
825 FAIRFAX AVENUE
NORFOLK, VIRGINIA 23507-1912

TELEPHONE (757) 446-5915

May 12, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, M.D. 21244-1850

RE: CMS-1488-P

Dear Sir or Madam,

I am writing to you to express my concerns regarding the proposed change in reimbursement to hospitals for resident services. As I understand it, the proposed changes would exclude reimbursement for the hours a resident is attending didactic conferences. As a physician who has spent her whole career in academic medicine teaching medical students and residents, I cannot object strongly enough to this proposal. The changes proposed will severely impede the ability of residency education programs to provide teaching for residents. We all recognize that residency should be a mix of patient care activities, bedside teaching, and didactic instruction. The health of our nation depends upon a steady supply of well trained physicians. Any activity which impedes that training endangers each of us individually and all of us collectively. I urge you not to approve the proposed change and to continue to cover resident's hours in which residents are involved in formal, didactic, learning experiences. Your personal health and safety depends upon your decision.

Sincerely,

Jean E. Shelton, M.D.
Lydia Myers Professor and Chair
Residency Program Director
Eastern Virginia Medical School
Department of Physical Medicine and Rehabilitation

JES/vmp

Cc: Linda Archer, PhD

20

Debra F. Sukin
Vice President
Chief Executive Officer

ST. LUKE'S
Community
Medical Center
The Woodlands

May 19, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

My hospital is a 91-bed acute care hospital located in The Woodlands, Texas. As a community medical center, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

17200 St. Luke's Way The Woodlands, Texas 77384 www.stlukeswoodlands.com

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the past three years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Debra P. Sukin

Debra Sukin

cc. John Cornyn, U S Senator
cc. Kevin Brady, Member of U S Congress
cc. Texas Hospital Association

Cardiology Associates, P.C.
North River Medical Center
4401 Watermelon Road
Northport, AL 35476
205-391-2117

May 22, 2006

Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: CMS proposed hospital inpatient payment rule for FY07, dated 4-12-2006

Dear Sir,

The rule recommends significant changes to the DRG methodology that moves funds away for cardiology services, including proven, cost-effective therapies like implantable cardioverter defibrillators (ICDs) and drug eluting stents, and into other hospital services. CMS' proposed methodology changes are intended to address concerns about the growth in physician-owned specialty hospitals but will affect all hospital services. I am writing to you to communicate our concerns about this proposed rule.

There are some significant methodological problems with this proposed rule. First, it adopts a methodology called hospital specific relative values that is specifically known to have an adverse impact on payments to the hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduce payments for cardiology services implants such as drug eluting stents, ICDs, and pacemakers. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall cuts to cardiology. Any move to a cost based system from the current charge based system should be on requirements for improved cost reporting by the hospitals. Hospital cost reports were never intended to be used to develop accurate procedure specific payments weights.

The reduction payments in cardiology could reduce patient access to interventional procedures and we request your assistance in modifying the current proposal which the DRGs is flawed and should be rejected until the data and methodology are corrected. The most appropriate course of action for CMS would be to return to the current charge based

methodology for the coming fiscal year and work with the stakeholders to improve hospital cost reporting processes before any transition to cost based weights.

We appreciate your review of the proposed changes and are confident that you will see the need for modification of the changes before the final rules are published.

Sincerely,

Anand Pandey

Anand Pandey, MD

TENET

Hahnemann University Hospital
Graduate Medical Education
Broad & Vine Streets
Mail Stop 623
Philadelphia, PA 19102
Tel: 215-762-2618
Fax: 215-762-4488

May 25, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1580

Regarding: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

Drexel University College of Medicine/Hahnemann University Hospital graduate medical education programs (internships, residencies and fellowships) welcome this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS and Agency) proposed rule entitled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." (71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes graduate medical education (GME) time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care." We strongly disagree as our journal clubs, lectures and seminars are directly related to patient care and the role of the house staff in the quality of such care.

CMS's position is in stark contrast to the Agency's previous position of 1999, at which time Tzvi Hefter, Director of Acute Care, wrote in correspondence that **patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty."** We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities in which house staff are engaged during their internship, residency and fellowship training years.

With the possible exception of extended time for "bench research," a rare component of any of our GME programs, all other GME experiences are related to patient care activities. The learning model used in graduate medical education is delivery of quality care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved GME training program is built upon the delivery of excellent patient care and the house staff member's educational development into a competent and autonomous practitioner.

All of our programs and faculty view the educational activities as differentiating between a trade school where simple, repetitive skills are taught and an academic institution where teaching and learning, questioning, growing and developing, research and publishing, and life-long learning are encouraged. As an educator, I know that learning does not take place in isolation. Practice does not make perfect; perfect practice makes perfect. If we do not teach house staff to think, question, and probe into complex patient problem solving, where will they learn to care for the complex interactions they will face in the future. Skills cannot be taught in isolation and definitely need the complement of the classroom.

In summary, our 36 programs urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of interns, residents and fellows during their graduate medical education training.

Thank you for your consideration.

Sincerely,

Jay M. Yanoff, Ed.D.
Director of Educational Development and Support
Designated Institutional Official

23

St. Joseph Healthcare
St. Joseph Hospital
In the Spirit of Healing
Sponsored by The Felician Sisters

360 Broadway, PO Box 403
Bangor, Maine 04402-0403
ph: 207.262.1000 **fax:** 207.262.1922

May 26, 2006

CMS
P.O. Box 8011
Baltimore, MD 21244-1850

To: CMS

My name is Alicia Noyes. I am the director of cardiac services at St. Joseph Hospital in Bangor, Maine in addition to a member of the American College of Cardiac Administrators. We are a small community hospital licensed for 112 beds. We have a single room cath lab in which we perform implantations and removals of pacemakers, AICD's and bi-ventricular pacemakers.

I am writing with concern to the 2007 Inpatient rule that would cut the reimbursement for cardiovascular services. The costs of devices in the year 2003 are greatly different than they are now in 2006. The difference in cost may range from hundreds to thousands of dollars. The reimbursement for these items in our institution generally does not cover the cost of the device despite active negotiation with the device vendors. The proposed cuts may result in us not being able to provide the service in our rural community.

I would like to be on the record in opposing the proposed cuts for 2007 in the cardiovascular service area. I appreciate your time regarding this issue.

Sincerely,

Alicia Noyes

Alicia Noyes, RN, BSN, CHPN
Director of Cardiac Services
St. Joseph Hospital

/bp

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

To whom it may concern:

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 1000 bed hospital located in Houston, Texas, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation's number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital's ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were "thrown out" of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

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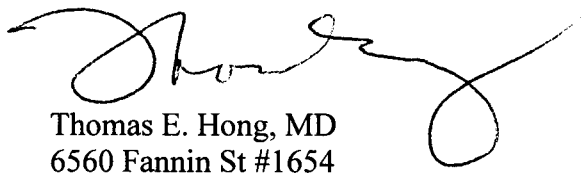
single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient's illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary to get this right.

Sincerely,



Thomas E. Hong, MD
6560 Fannin St #1654
Houston, TX 77030

Infirmary West

Infirmary Health System

May 17, 2006

Mark McClellan, M.D., Ph. D.
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates -- CMS–1488- P

Dear Dr. McClellan:

Hospitals-within-Hospitals

I am submitting comments on the proposed rules published on April 25, 2006 at 71 Fed. Reg. 23996. This rulemaking proposes revisions to the regulation governing grandfathered long-term care hospitals-within-hospitals (HwHs). The ***Mobile Infirmary Long Term Acute Care Hospital***, in Mobile, Alabama is licensed for 191 long term acute care beds and is co-located on the same campus as Infirmary West Hospital. The LTAC hospital was licensed as a long term acute care hospital in August, 1993. It is a grandfathered HwH under Section 4417(a) of the Balanced Budget Act of 1997. It is the ONLY long term acute care hospital in southern Alabama and serves all acute facilities in the medical service area therefore provides services to all Medicare patients in this region.

Under the current rule governing grandfathered HwHs, to retain grandfathered status ***the Mobile Infirmary Long Term Acute Care Hospital*** may not:

- change (increase or decrease) square footage;
- change (increase or decrease) the number of its beds; or
- change its terms and conditions of operations in any way.

Under the proposed rate year 2007 update rule for hospitals subject to the inpatient short-term acute hospital prospective payment system (IPPS), CMS has proposed limited revisions to the rule governing grandfathered HwHs:

- to allow for increases or decreases in square footage, or decreases only in the number of beds, due to relocation of the hospital (a) to permit construction or renovation necessary to comply with state, federal or local law affecting the physical facility, or (b) because of a catastrophic event, such as a fire, flood, earthquake, or tornado;
- to allow for decreases only in the number of beds or square footage.

We support your changes to allow for reduction of square footage and licensed beds as the changes in CMS rules for admission of patients to LTAC facilities have changed significantly since 1997 which has reduced the need for beds in the larger, more established facilities. But we also believe that the CMS' proposed changes to the grandfathered hospital-within-hospital rule at 42 C.F.R. §412.22(f) are inadequate.

If the proposed revisions to the rule are adopted, ***the Mobile Infirmary Long Term Acute Care Hospital*** still will be precluded from, any changes to adapt to the needs of the regional patients such as more critical care space, dialysis expansion, create private (i.e., single-bed) isolation rooms for patients with infections or communicable diseases or immuno-suppressed patients, or providing appropriate outpatient provider-based activities. Under the proposed revisions to 42 C.F.R. §412.22(f), these changes, which are designed to improve operations and patient care, still may not be made by ***the Mobile Infirmary Long Term Acute Care Hospital.*** Any of these activities will cause ***the Mobile Infirmary Long Term Acute Care Hospital*** to lose its grandfathered status and no longer qualify for Medicare participation.

We are especially concerned that CMS' current payment rule directly restricts grandfathered hospitals' ability to modify operations and services to meet changes in medical practice and related medical program needs of the patients it serves. I believe that such an application of the rule is contrary to the Congressional intent of Section 4417(a) of the BBA which was to protect these hospitals from restrictions on their operations. It is also inconsistent with the needs and best interests of Medicare beneficiaries. The proposed rule unduly and unfairly restricts the ability of grandfathered HwHs, like ***Mobile Infirmary Long Term Acute Care Hospital*** to improve the services they provide to Medicare beneficiaries.

If the proposed revisions are adopted, grandfathered HwHs still will be faced with the untenable choice of not making operational changes or clinical changes to improve operations and patient care, on the one hand, or engaging in extremely costly corporate and operational reorganizations of health systems with the destruction of long-standing, favorable employment relationships with Medical Directors and Chief Executive Officers, on the other hand.

It is critical to the continued viability of ***the Mobile Infirmary Long Term Acute Care Hospital*** and the Medicare beneficiaries it serves, that CMS adopt further revisions to the grandfathering rule to allow for changes consistent with the needs and best interests of Medicare beneficiaries, for example, pursuant to a state Certificate of Need, to create isolation rooms, to provide ancillary services or therapeutic services necessary for patient care, to add or expand off-site outpatient provider-based activities related to patient care, to add or expand on-site provider-based activities related to patient care, or to increase ventilator support. None of these changes would truly result in increased costs to the Medicare program.

I respectfully request CMS to expand the proposed revisions to the grandfathered HwH regulation to include the provisions listed above.

Sincerely,

Thomas J. Gibson
Administrator

Holmes Regional
Medical Center

Health First

1350 South Hickory Street
Melbourne, Florida 32901
Telephone 321.434.7000

www.health-first.org

May 26, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS – 1488-PPO, Box 8011
Baltimore, MD 21244-1850

RE: Comment period for Proposed Rule - HSRV Weights

Dear Sir or Madam:

The following are comments from Holmes Regional Medical Center (Holmes) regarding the proposed Rule for 2007 Fiscal Year Inpatient Hospital Services. Holmes is a 574-bed hospital located in Melbourne Florida, with the only Level II Trauma Center on the Space Coast. Holmes is also a major Medicare provider on the east central coast. This change represents over $5,000,000 negative impact to hospital resources for fiscal year 2007.

We believe the change from "Charged Based Relative Weight" system to the "Hospital Specific Relative Value" (HSRV) is a major change from the way DRG's have been weighted since the inception of the program in 1983. Since this change represents a major step in matching payments and costs, we believe a change of this magnitude should be phased in over a period of years.

Historically, each major change in prospective payment has had a phase-in period. We cite two examples of these changes in the past 20 years. First, the phase-in period for the change to DRG base from cost based in the 1980's. This took four years to complete. Second, the phase-in period for Capital Cost reimbursement was accomplished over a ten-year period. The purpose of these phase-ins was to allow hospitals to make changes in their billing and accounting systems to accommodate the new reporting requirements, and to lessen any adverse impacts to hospitals.

The calculations of the HSRV involved the use of ten cost centers based on cost report lines on worksheet C part 1. The issue at hand relates to the cost report lines. Over the years, as hospital services have changed and evolved, we have subscripted many lines on the cost report. In subscripting lines, hospitals have had to assign a HCRIS code which identifies the service. In the proposed rule there is no indication that these HCRIS codes were used to determine if cost centers were used properly in the assignment of cost to charge ratios as presented in table A of the proposed regulation. For example, we set up our Cardiac Cath Lab as subscripted cost center 58.02 with a HCRIS code of 3120. With this setup there is no assurance that the costs and charges of Cardiac Cath were included with Cardiology (which is line 53 of the cost report) and could have contributed to the major reductions in reimbursements in MDC 05.

By having a phase-in period, we as well as other hospitals, can change our cost reports to better conform to the requirements of HSRV and in the end have an accurate measure of costs. We would propose a four year phase-in period to accomplish this.

The regulation also presents APR DRG's as a possible change for 2008 or sooner. Again while this is a coding issue we believe we need additional time to enhance our coding departments in order to handle the change. Changes such as this cause data processing issues and impact Information Technology departments as well. As with the change to DRG's in the 1980's, hospital coding departments, given a phase-in period, were able to make the changes needed in the education of coders and presentation of data for inclusion on the patients' bill. These phase-in periods, as noted earlier, lessen the impacts of learning curves in the process.

We anticipate your response in subsequent documents.

Very truly yours,

Roberta B. Stoner, CPA
VP/Controller

cc: U.S. Congressman Dave S. Weldon

Cardiology
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05/19/2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
PO Box 8011
Baltimore MD 21244-1850

Dear CMS Officials:

This letter addresses the issue of decreasing DRG reimbursements for cardiology services.

I urge CMS to delay any implementation of adjustments in DRG so that the methodology of these changes can be further studied.

The magnitude of the proposed changes is such that it will dramatically alter access to cardiology services for Medicare patients across the United States.

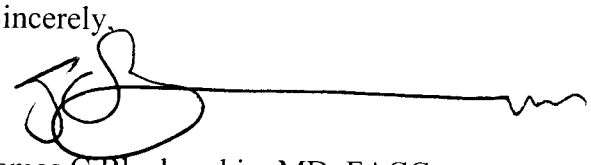
While CMS may be appropriately scrutinizing reimbursements for some services such as imaging, CMS should be aware that the DRGs it is planning to decrease are for therapies that have been proven to decrease mortality in Medicare patients.

CMS officials should clearly understand that reducing reimbursements for these DRGs will decrease the ability of hospitals to invest in the technologies and facilities that allow these new devices to be delivered.

In summary, I urge CMS to delay implementation of any changes in DRG reimbursement until the methodology can be further studied. Proceeding with the proposed changes may be catastrophic, and it may be very embarrassing

for CMS when they have to reverse their changes to allow facilities to deliver cardiac care that is proven to be lifesaving.

Sincerely,



James C Blankenship, MD, FACC
Director, Cardiac Catheterization Laboratory
Department of Cardiology

JCB/mmp; D: 05/19/2006 12:14 P; T: 05/22/2006 11:48 A; Doc #: 3544970

P.S. This letter reflects personal opinions and is not meant to reflect the opinions of the American College of Cardiology or the Americal Medical Association Relative Value Update Committee.

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MID-AMERICA CARDIOLOGY ASSOCIATES, INC.

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James J. Harbrecht, M.D.
Loren D. Berenbom, M.D.
Charles B. Porter, M.D.
Edward J. Laughlin, M.D.
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Steven D. Owens, M.D.
Thomas L. Rosamond, M.D.
James L. Vacek, M.D.
Randall E. Genton, M.D.
Dak R. Burnett, M.D.
Martin P. Emert, M.D.
Peter N. Tadros, M.D.

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Kansas University School of Medicine
Division of Cardiovascular Diseases
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David B. Wilson, M.D.

Kevin M. Mulhern, M.D.
S. Roy Hegde, M.D.
Robert L. Herman, M.D.
Steven P. Freeman, D.O.
Dennis R. Bresnahan, M.D.
Rhea C. Pimentel, M.D.
Robert C. Candipan, M.D.
Brian C. Weiford, M.D.
Marina N. Hannen, M.D.
Dana Flory, RN, MSN, FNP-C
Jill Keast, RN, MSN, ARNP-C
Jana Kistler, RN, MSN, ARNP-C
Dianna Newton, RN, MSN, ARNP-CD
Christy Russell, RN, MSN, ARNP-C

May 23, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

As a practicing heart rhythm specialist, also known as an electrophysiologist, at a 473 bed hospital located in Kansas City, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. Technologies such as implantable cardioverter defibrillators are used to prevent sudden cardiac arrest, the nation's number one cause of mortality. Cardiac ablations are used to treat debilitating and life threatening cardiac arrhythmias such as ones that lead to stroke.

The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on my hospital's ability to serve patients in my community. These proposed reductions will impact hospital staffing for these critical procedures which will ultimately be translated into reduced patient access and care. CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Without accurate and appropriate reimbursement for these critical services, hospitals will not be able to dedicate resources to important quality improvement initiatives such as this.

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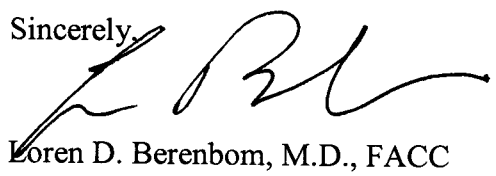

Loren D. Berenbom, M.D., FACC
Director, Electrophysiology, The University of Kansas Hospital
Governor, American College of Cardiology, Kansas

For Appointments Call:
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of Illinois

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Blue Island, IL 60406
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Mokena, IL 60448
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Palos Park Office
Peace Professional Center
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Luke Pascale, M.D. Emeritus
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Ronald Stella, M.D.

Electrophysiology:
Charles A. Kinder, M.D.
Albert Lin, M.D.
Sean P. Tierney, M.D.

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

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Sincerely,

Charles Kinder, M.D.

Director, Heart Rhythm Program

Heart Care Centers of Illinois

30

100 TOP HOSPITAL
2003

Freeman Health System
1102 WEST 32ND STREET • JOPLIN, MO 64804-3599 • 417.347.1111
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May 15, 2006

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

My hospital is a 328 bed acute care hospital located in Joplin, Missouri. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely,

Gary D. Duncan
President and CEO
Freeman Health System

cc: Senator Christopher Bond
Kara Vlasaty Smith
Senator Jim Talent
Faith Cristol
Representative Roy Blunt
Cheryl Yeager
Marc Smith, President, Missouri Hospital Association

Gregory B. Nazar, M.D., FACS,FRCS

Diplomat of the American Board of Neurological Surgery

ADULT NEUROSURGERY

JELSMA AND NAZAR ASSOCIATES

31

May 15, 2006

CMS
Dept of Health & Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear CMS,

I am currently a practicing neurosurgeon in Louisville, Kentucky, who has had the opportunity to become exposed to the X STOP Technology offered by St. Francis Medical Technologies. I have reviewed the FDA data as well as I have personally implanted the X STOP procedure on one of my patients with excellent results. The patient had dramatic relief of her bilateral leg pain related to neurogenic claudication from her spinal stenosis. The implantation avoided the patient from having a more invasive surgical procedure and she is very pleased with the results. Currently, I have 3 additional patients who would benefit from the operation. However, I am having trouble obtaining approval for the surgery. The problems of approval pertain not to their insurance but rather to the hospitals that are concerned about the cost of the new technology itself and related reimbursements. This now appears to be the major stumbling block from allowing these patients to benefit from the intervention. There also is no question in my mind that there is an important niche of patients that do benefit from this procedure and for the majority of patients this avoids the need for more aggressive surgical intervention with its associated complications. It does improve the lifestyle of these patients when they are properly selected and when the guidelines for recommended implantation are followed. I would also strongly endorse CMS to do everything possible to allow this procedure to become available for these patients.

Main Office:
410 Audubon Medical Plaza
Louisville KY 40217
Phone: (502) 636-2667
Toll Free: (877) 585-2667
Fax: (502) 636-2668

Bardstown Office:
300 West John Finch, Suite 100
Bardstown KY 40004
Phone: (502) 348-3512
Fax: (502) 348-9075

Baptist Hospital Northeast
1023 New Moody Lane, Suite 202
LaGrange KY 40031
Phone: (502) 222-3884
Fax: (502) 222-3453

Please don't hesitate to call should you have any questions or concerns (502) 636-4208.

As always,

Best personal regards,

Gregory B. Nazar, M.D., FACS, FRCS
GBN/jqa
P.S.: I am a private practice neurosurgeon and have no interest or relationship to either X STOP or St. Francis Medical Technologies. My primary purpose of this endorsement is to allow this procedure to become available to my patients.

cc: St. Francis Medical Technologies
CMS Comments
960 Atlantic Avenue
Ste 102
Alameda, CA 94501

32

FRANCIS W. GAMACHE JR., M.D., F.A.C.S.

523 EAST 72ND STREET
NEW YORK, NEW YORK 10021

OFFICE:
(212) 988-5200

May 9, 2006

CMS
Department of Health and Human Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

Dear Sirs:

I wanted to take this opportunity to pass along my appreciation to the St. Francis Medical Technologies, Incorporated for the investigation and development of the X-Stop Interspinous Process Decompression Device. This device is useful primarily in patients who have spinal lumbar spondylosis and in particular foraminal stenosis. As you recall, approximately 80% of North Americans develop back pain some time during their lives. Approximately half of these people get better with no therapy, but the other half require some kind of intervention. X-Stop is a minimally invasive device which can be surgically placed in a very brief period of time in an inpatient setting under either local or general anesthetic. It is particularly useful in senior citizens who wish to avoid more aggressive, more radical procedures which require lengthy operations frequently involving more complicated spine instrumentation. Since the development of the X device, I have received several calls each day from patients who have heard about X-Stop on the internet and who are interested in exploring less invasive procedures than spinal fusion for their lumbar stenosis.

In short, the X-Stop is a simple device which is easy to install, safe, and avoids more complicated and more expensive spinal procedures (with more expensive hardware). While the instrument is not intended for every patient with degenerative lumbar spine disease, it does fulfill the needs of a select population of spine problem patients: namely, the elderly, where "less is better than more."

As a former representative for the American Association of Neurological Surgeons & Congress of Neurological Surgeons to the FDA Committee for New Drugs & Devices, I believe this instrument deserves your attention.

If I may be of any additional help, please feel free to contact me.

Sincerely,

Francis W. Gamache, Jr., MD
Clinical Associate Professor of
Neurological Surgery

/pwp-m 303102
cc: St. Francis Medical Technologies, Inc.
960 Atlantic Avenue, Ste. 102
Alameda, CA 94501

Gillen Surgical Company
220 Maple Ct.
Haworth, NJ 07641

33

MEDICAL COLLEGE OF WISCONSIN

Department of Physical Medicine and Rehabilitation

May 26, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

The Medical College of Wisconsin, Department of Physical Medicine and Rehabilitation welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

Residency Program Activities and Patient Care
With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Teaching is not limited to the floor or in the clinic. Residents need protected lecture time to learn; to ask questions, to discuss cases, to analyze and debate; to learn from one another. Didactic time is also time spent doing hands-on learning. The fast pace environment of the clinic or inpatient unit sometimes does not allow for proper teaching opportunities. We need to be sure to give the residents as much opportunity as possible for learning. To downplay the importance of didactic time; to say it is "not related to patient care" is absurd. Health care consumers want the best care available and the only way that we can provide that is to ensure that we have didactic time to deliver the latest information in our field to our residents. This allows all participants, faculty, residents and fellows to learn the information in a consistent manner; to allow for questions and clarification. It seems that there are so many changes in how resident physicians need to perform, document and process patient information, yet the opportunities (i.e., didactics) for them to become better physicians is being considered not important. Resident physicians do a lot of giving and sacrificing to provide the best patient care. The more you take away from them; devalue the importance of resident educational experiences, the more the prestige and worth of the profession will fall.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,

Kerry Harris
Medical Education Coordinator II
Medical College of Wisconsin
Physical Medicine & Rehabilitation

The WISCONSIN HEART HOSPITAL

The Wisconsin Heart Hospital, LLC
10000 West Blue Mound Road
Wauwatosa, Wisconsin 53226
414.778.7800 Fax: 414.778.7811
www.twhh.org

May 18, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1488 – P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in response to your request for comments concerning the proposed Medicare Inpatient PPS rule for FY 2007. I understand the final rule will be published by August, with an expected implementation date of October 1, 2006.

As the President of a 60-bed specialty cardiac facility in Milwaukee, Wisconsin, I have grave concerns about this proposal. While I recognize that a major focal point of your proposal deals specifically with cardiac DRGs in an effort to address what you perceive to be inequities in Medicare reimbursement for cardiac services that may favor specialty hospitals, I want to make you aware of several facts that distinguish The Wisconsin Heart Hospital (TWHH) from other for-profit cardiac facilities.

By way of background, TWHH is the only cardiovascular specialty hospital and accredited chest pain center in the Milwaukee area. The 60-bed hospital was designed for the complexities of heart and vascular care. Our services include surgery, diagnostic imaging, emergency department, outpatient care, inpatient care and wellness and preventive medicine programs. The hospital features four cardiac/electrophysiology catheterization labs for immediate cardiac intervention and one peripheral vascular lab with easy access to operating rooms.

The ownership of TWHH is comprised of a mix of a not-for-profit community-based health care system (Wheaton Franciscan Healthcare -- 49%) and physicians and other community investors (51%). In addition, 50% of the members of the TWHH governing board are representatives of Wheaton Franciscan Healthcare. I am confident that the ownership and governing structure of TWHH is unique in the specialty hospital arena. I believe this arrangement positions TWHH as a true asset to the community and as a resource for quality cardiac care with ready access to a broad range of other health care services at our partner facilities.

In addition, TWHH operates a 24-hour, full service emergency department which is staffed by board-certified emergency department physicians. We are a key participant in the County EMS system, and have become a dependable resource for the community in terms of expanded access

to emergency care. Last year alone, our emergency department treated approximately 2,200 patients.

Our average patient length of stay for coronary artery bypass surgery is significantly lower than other hospitals, according to the STS Fall 2005 report. The median stay for our patients is 4 days; in 2005, 71.2% of our patients had a length of stay less than 6 days, as compared to other hospitals in the database with 51.7%. Our operative mortality for 2005 was 1.3% versus 2.6% for other hospitals. We would be happy to share other clinical outcomes with you, if necessary.

Finally, TWHH has adopted the same charity care policy as our not-for-profit partner. In fact, the Wheaton charity care policy was recently revised and is considered one of the most generous policies in the area. The simple fact is: TWHH accepts all patients, regardless of ability to pay and can demonstrate this commitment through the applicability of our charity care policy.

With respect to the proposed rule, our financial analysis shows that if implemented as is, TWHH will see Medicare reimbursements decline significantly. While we have not been able to successfully predict how the expansion of DRG classifications will affect our reimbursement, we do know that the case-mix adjustments will result in at least $2.3 million in Medicare reimbursement losses per year. These losses represent 18% of our overall Medicare reimbursement, which comprises approximately 62% of our total payer mix. Clearly, the losses that will result from the proposed rule will have a considerable impact to our bottom line and may affect our ability to continue to provide needed services in both cardiac and emergency care for the community.

I respectfully ask that as you consider the final implementation of this rule, you take into account the vast differences that distinguish TWHH from most other specialty cardiac hospitals. While cutting cardiac DRGs across the board will certainly have a dramatic negative impact on all specialty cardiac facilities, I would contend that not all specialty cardiac facilities are alike. The many noteworthy distinctions that make TWHH unique also address many of the typical criticisms levied at specialty hospitals. I hope that you will take these facts into serious consideration as you look toward final implementation of this rule.

If you have any questions, please feel free to contact me directly at 414 778-7801. I would be happy to provide you with any supporting materials you may require. Thank you for your consideration of this important matter.

Sincerely

Norma J. McCutcheon

Norma McCutcheon
President

35-0
(22)

ST. ELIZABETH MEDICAL CENTER
Sponsored by The Sisters of St. Francis
2209 Genesee Street • Utica, New York 13501-5999
(315) 798-8100

May 23, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Sir or Madam:

As a member of the St. Elizabeth Medical Center Medical Staff, St. Elizabeth's administration has advised me of proposed changes to the way the Medical Center will be reimbursed for surgical DRGs starting on October 1, 2006. The changes as explained by management are of great concern to me and to my practice. I believe that my patients will likely be negatively affected by the proposed changes.

St. Elizabeth is an acute care general community hospital. It depends upon the positive margins it receives on the cardiac services (which will be the hardest hit by the changes) to support the programs and services that are not as profitable or may lose money. Many of those programs are where my patients receive care in the community. If the changes are implemented, St. Elizabeth may be forced to discontinue services and as a result, I may lose patients and my patients will lose access to care close to their homes.

This is of particular concern when we are told that the proposed regulations adopt a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for high severity conditions. The change is drastic in that it changes the entire emphasis and understanding of what severity means, as it relates to treatment of patients and reimbursement for patient care. We have also been told that the new CMS methodology contains technical errors and assumptions that worsen the overall payment cuts to service lines that are critical to St. Elizabeth and the community. Finally, to force hospitals to absorb these significant changes immediately and not in a phased approach will unnecessarily strain the system in general and St. Elizabeth specifically. It is suggested that if the changes are inevitable, that they be phased in over a period of years.

Thank you for your consideration.

Very truly yours,

Print Name: JOHN J. THOMAS II MD

cc: Congressman Sherwood Boehlert
Senator Charles E. Schumer
Senator Hillary Rodham Clinton
Sister M. Johanna President and Chief Executive Officer

IOWA HEALTH
DES MOINES
Methodist • Lutheran • Blank

June 1, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

Attention: **CMS-1488 – P "Resident Time in Patient-Related Activities"**

Dear Dr. McClellan:

As the Designated Institutional Official for the Graduate Medical Education Programs at Iowa Health - Des Moines, I am appreciative of this opportunity to comment on Centers for Medicare & Medicaid Services' proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.* 71 Fed. Reg. 23996 (April 25, 2006). I strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

The position is a clean reversal of the Agency's previously stated position in 1999 when the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. I concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

With the exception of "bench research" extended time, there is no residency experience in our programs that is not related to patient care activities. The learning model we use (as is the case in all teaching hospitals) is the delivery of care to patients under the supervision of fully-trained physicians. We consider that everything a resident physician learns as parts of an approved residency training program is built upon the delivery of patient care and the development of that resident physician into a well trained and independent practitioner.

Each of our residency programs has didactic teaching conferences scheduled throughout the week, and I assure you that these conferences all ultimately focus upon the provision of quality patient care and the education of our residents. Our morbidity and mortality conferences

Each of our residency programs has didactic teaching conferences scheduled throughout the week, and I assure you that these conferences all ultimately focus upon the provision of quality patient care and the education of our residents. Our morbidity and mortality conferences likewise are attended by residents, and faculty, and all focus upon actual patient care delivery issues and improvement.

In summary, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes for DGME and IME payments. I think it is appropriate to recognize rather the integral nature of all of these activities as referenced above to the patient care experiences of residents during their residency programs.

Sincerely,

Douglas B. Dorner, M.D., FACS
Senior Vice President, Medical Education and Research
Director of Medical Education
Designated Institutional Official

37

1402 South Grand Boulevard
Room 260
St. Louis, MO 63104
Phone: 314-977-9853
Fax: 314-977-9852
www.slu.edu

SAINT LOUIS
UNIVERSITY

Office of the Associate Dean
Graduate Medical Education
and Veterans Affairs

School of Medicine
Health Sciences Center

May 30, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

RE: CMS-1488—P "Resident Time in Patient-Related Activities"

Dear Administrator McClellan:

Saint Louis University School of Medicine welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates"* 71 Fed. Reg. 23996 (April 25, 2006). We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spend in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures... and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

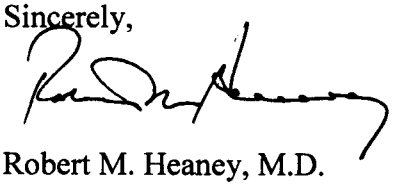
Residency Program Activities and Patient Care

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

Educational conferences are interdigitated with the process of care: patient safety, morbidity and mortality, new therapeutics, and other areas of critical importance to current patients.

To reiterate, we urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,



Robert M. Heaney, M.D.
Professor of Internal Medicine
Associate Dean for Graduate Medical Education
and Veterans Affairs
Saint Louis University School of Medicine

RMH:dd

The UNIVERSITY of VERMONT
COLLEGE OF MEDICINE
DIVISION OF NEUROSURGERY

Bruce I. Tranmer, MD
Professor and Chairman
Bruce.Tranmer@uvm.edu

Paul L. Penar, MD
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Michael A. Horgan, MD
Assistant Professor
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Assistant Professor
Patrick.Graupman@uvm.edu

May 30, 2006

Mr. Sean McKinney
Reimbursement Manager
CMS
Department of Health & Human Services
Attn: CMS-1488-P
P. O. Box 8011
Baltimore, MD 21244-1850

Dear Mr. McKinney:

This letter is in response to your letter addressed to me, May 5, 2006. You have requested information regarding the **X STOP PID**.

You have asked specific questions to include the following points which are the following:

1) Why you would like to incorporate use of the device in your practice?

This device gives older patients with lumbar spinal stenosis an alternative to lumbar spine surgery. This device can be implanted under local anesthesia and only requires a short hospital stay. The surgery is simple, quick and what I have seen of the results is effective. I will certainly incorporate the use of **X STOP PID** into my practice.

2) Anecdotal experiences you may share:

I have yet to implant an **X STOP PID** however I am in the process of scheduling several patients.

3) Why inpatient and outpatient setting options are important in your clinical decision making process for your **X STOP** patients?

This device will be implanted into the older population. These patients can have medical problems and therefore inpatient services may be necessary. In the healthier patient, outpatient setting would be appropriate.

4) A statement of support regarding **X STOP IPD** filling a niche for your patient population as a treatment option.

X STOP IPD will be a useful device for patients with lumbar spinal stenosis. We will be offering it to my patients. A full lumbar-lamenectomy with its known problems may not always be appropriate for the older patient with lumbar spinal stenosis.

I hope this answers your questions satisfactorily.

Sincerely,

Bruce I. Tranmer, M.D.
Professor and Chairman

Copy sent to: St. Francis Medical Technologies directly

The Heart Clinic
Ronald P. Koepke, MD, FACC, FACP
102 Thomas Rd, Suite 400
West Monroe, LA 71291
Phone 318-322-1161
Fax 318-322-9313

May 30, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in regard to the proposed changes to CMS hospital payment rules for FY07. I am concerned about the proposed change to a cost-based system from a charge-based system. This change is based on hospital cost reporting, a system not intended to be used to develop accurate procedure-specific payment weights. Therefore, the current proposal to modify DRGs appears to be flawed. I would suggest a return to the current charge-based methodology and working with stakeholders to improve hospital cost reporting processes before a transition to cost-based weights.

Thank you for your consideration.

Sincerely,

Ronald P. Koepke, MD

40

Chico Cardiology Associates

185 East 7th Avenue, Suite A • Chico, California 95926

Eugene V. Moffett, M.D., Inc.
(530) 343-0200

Christopher S. Massa, M.D.
(530) 343-5828

May 22, 2006

Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

To Whom It May Concern:

Through multiple sources I have just been advised again of the changes in reimbursement for the proposed hospital in–patient payment schedule for fiscal year 2007. As in years past the proposal is not based on clinical date or care of patients and is based on the hospital's specific relative values.

This system has been acknowledged as being flawed by both CMS in the past, congressional committees, etc, and again is not clinically relevant to patient care. It reduces payments for proven and effective therapies which in the long run would decrease hospital costs and improve patient care such as drug-eluding stents, ICDs, pacemakers and a variety of other cardiology procedures.

In medicine we are concerned about the cost effectiveness of procedures we perform and all the above procedures have been proven to be cost effective both in the long run for the cost of care as well as improving the clinical care of patients. I think that the specific relative system is flawed and will result in inappropriate shifting of funds from one procedure to another and will impinge on the clinical care of patients.

This is a problem that goes on year after year with the evaluation of CMS with both doctors and hospital payments and there must be some mechanism in the future to become more fair, more clinically-oriented, and a more stable system.

Sincerely,

Eugene V. Moffett, M.D., F.A.C.C.

EVM:ss
5/24/06

Joe W. Rhudy, M.D., 1939-1985
Founder

MORGANTOWN INTERNAL MEDICINE GROUP, INC.

300 Wedgewood Drive
Morgantown, West Virginia 26505-2494

(304) 599-8802
FAX (304) 599-5607

May 23, 2006

Centers for Medicare and Medicaid Services Dept.
Health and Human Services
ATTN: CMS 1488P
PO Box 8011
Baltimore, MD 21244-1850

Dear Sir or Madam:

It is my understanding that there are proposed rule changes with regards to reimbursing cardiovascular services across the board with a 10% reduction in reimbursement. You are obviously unaware of the difficulties physicians and hospitals are presently facing with regards to overhead and the expense of doing business. To face a reduction of this magnitude would be devastating with regards to our ability to remain in business. Most of us remain on the edge with regards to overhead with the present numbers. To face a reduction of this magnitude would be devastating. There would be serious detrimental consequences to the changes proposed and I respectively request that they be revisited before any change is adopted.

Sincerely,

John H. Lobban, M.D., F.A.C.C.
Cardiac Electrophysiology

/ccg

42

MUNSON MEDICAL CENTER

June 5, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P – Medicare program: Changes to the Inpatient Prospective Payment System and 2006 Rates – April 25, 2006 Federal Register

Dear Dr. McClellan:

As the Director of Cardiology Services at Munson Medical Center in Traverse City, MI, I am quite concerned Medicare beneficiaries will have limited access to life-saving and life-enhancing cardiac care due to the recently proposed inpatient rule. The full implementation of the CMS proposed Inpatient Prospective Payment System would have a devastating impact on Munson's ability to serve patients in our community. These proposed reductions will most likely impact both hospital staffing and product availability for these critical procedures, which will ultimately be translated into reduced patient access and care.

Recently, CMS and Congress have emphasized the development of quality measures and activities. For example, the recent CMS mandate for hospitals to enroll in the ICD Registry represents personnel the hospital has to dedicate for this important initiative. Also, CMS has in the recent past appropriately expanded the indications for the use of many of these life-saving and life-enhancing procedures and devices such as drug-eluting stents and implantable defibrillators (ICD's). **As an example, even considering *only the hospital's direct costs*, the proposed changes will lead to an average loss *per procedure* of $1443 for stent procedures and $4510 for ICD implants here at Munson Medical Center.** Without accurate and appropriate reimbursement, hospitals can not hope to dedicate even meager resources to important – and mandated - quality improvement measures and will be severely restricted in their ability to provide the newest advances in cardiovascular care that the public has grown to expect.

I support an accurate hospital payment system and the goal of improving payment accuracy in the DRG system. However, the implementation of these sweeping changes will replace one system with another that has inherent flaws and miscalculations. I am concerned that CMS has used old data that is not reflective of current practice and that the data used from cost reports is not accurate. Additionally, it is troubling to me that significant errors and technical decisions have been made by CMS that exacerbate the problem. It is my understanding that over 200 hospitals were "thrown out" of the data set including large numbers of academic health centers. This will distort any analysis that CMS conducts. Additionally, CMS failed to adjust for hospital volume of care. The result of this flawed approach is that a small hospital of 50 beds has as much weight in the calculation as a large tertiary care center/academic health center.

Furthermore, CMS has failed to address issues related to "charge compression." The rule fails to fix the charge compression problem that has penalized technology-intensive procedures for years. In fact, it makes the situation worse. Instead of increasing specificity to identify actual device costs, the rule lumps costs together into just 10 national cost centers to derive cost-to-charge ratios. Most devices and supplies are in a single cost center. Under this rule, distinctions between procedures - and even hospital departments - are lost.

The goal of the proposal is to improve the accuracy of the current payment system by designing a more refined system than the existing DRGs for grouping patients. CMS proposes to implement a new system based on the severity of the patient's illness in 2008 or earlier. The new CMS-DRG system does not make distinctions based on complexity, so a move in this direction is a good one. However, technologies that represent increased complexity, but not greater severity of illness, also need to be recognized. The payment methodology changes and the DRG severity changes should be implemented together, but there is no way to fairly identify and respond to their joint impact this year.

Thank you very much for your consideration of these comments. On behalf of my patients and the community in which I serve, I thank you and recommend that these changes be deferred so that all stakeholders can better understand the impacts and that CMS devotes the time necessary.

Sincerely,

Robert F. Stanton
Director of Cancer and Cardiovascular Services

43

TAMPA ORTHOPEDIC CLINIC
A PARTNERSHIP OF P.A.'s

3000 EAST FLETCHER AVENUE
SUITE 370
TAMPA, FLORIDA 33613
PHONE: (813) 977-4767

DAVID J. SCHULAK, M.D., P.A.
ORTHOPEDIC SURGERY

Fellow American Academy
of Orthopaedic Surgery
Fellow American
College of Surgery

May 1, 2006

CMS, Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sir/Madam:

I am writing you to support the X STOP IPD. I have taken the course and look forward to incorporating this device in my practice. I think it will offer significant patient benefit at a much lower risk and reduced cost than other treatments currently available. I have discussed this with several patients, but have not as yet done the procedure clinically. The patients are interested in the device and, should other treatments fail, are eager to have the procedure since it gives them a good chance of relief of neurogenic claudication from spinal stenosis. I have talked to one of the surgeons in our area who has used this device with significant success.

The outpatient setting and capacity for local anesthesia significantly minimizes operative risk associated with other types of surgical treatment for neurogenic claudication from spinal stenosis and it is an important option to have particularly when dealing with the Medicare patients, the group of patients who would most frequently have this sort of problem and be candidates for the use of this device.

Therefore, I think the X STOP IPD would fill a useful niche in my patient population. I look forward to using it in properly indicated cases and very much support Medicare payment for use of this device.

Sincerely yours,

David J. Schulak, M.D.
DJS:TRI:sf
T: 6/02/06

JUN -2 2006

BON SECOURS HEALTH SYSTEM, INC.

May 31, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 443-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

REF: CMS-1488-P and CMS-1488-P2

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

Bon Secours Health System is pleased to submit the following comments on the notice of proposed rulemaking for the Fiscal Year 2007 Hospital Inpatient Prospective Payment System (*Federal Register*, Vol. 71, No. 79) published April 25, 2006, as revised by the May 17, 2006 Centers for Medicare and Medicaid Services (CMS) notice "Medicare Program; Hospital Inpatient Prospective Payment Systems Implementation of the Fiscal Year 2007 Occupational Mix Adjustment to the Wage Index."

The proposed rule, if adopted would make the most significant changes to the hospital inpatient prospective payment system (IPPS) since its implementation. The proposal includes:

- Significant changes in the methodologies used to calculate the relative weights of the diagnostic related groups (DRGs). These changes would switch from the charge-based system used since 1983 to an estimated cost-based system to determine the payment weights for each patient category.
- Changes in the method for identifying the variation in patients' severity of illness.

These two changes, if implemented simultaneously with the court-mandated expansion of the occupational mix adjustment to apply to 100 percent of the wage index, will bring three potentially major de-stabilizing factors to bear on the financial situation of many hospitals.

Comments on the DRG Reclassifications

- It is recommended that CMS postpone until at least FY 2008 implementation of the proposed hospital specific cost-based DRG relative weight determination policy. The postponement would allow CMS to complete the analysis and pilot test the new payment methodology.
- It is further recommended that the proposed hospital specific cost-based DRG relative weight determination policy and the proposed severity adjustment policy be implemented simultaneously but no earlier than FY 2008. A simultaneous implementation would help to smooth out the major redistributive effects on hospital payments.
- Finally, it is recommended that CMS provides at least a three year transition period of the proposed policies during which hospitals are protected from major payment disruptions.

The proposed hospital specific DRG relative value weight policy change would base the DRG relative weights on the estimated cost of providing care. Such weights would be based on the national average of the hospital specific relative values for each DRG. CMS says that the purpose of the proposed change is to help reduce the bias by accounting for the differences in charge markups across cost centers. The proposed change was initially recommended by the Medicare Payment Assessment Commission (MedPAC), however, CMS did not accept MedPAC's proposed methodology. Instead, CMS asked for comments on an alternative methodology, which it proposes to fully implement October 1, 2006.

We appreciate CMS's concern with MedPAC's recommended methodology, but are concerned that the alternative methodology being proposed by CMS hasn't been thoroughly evaluated. For instance, CMS proposes to base payments on "cost" – but such "costs" are not actual costs incurred by a hospital for the treatment of a particular category of patient, but rather a rough estimation of such costs. The estimation process assumes a uniform hospital markup – but in fact, markups vary from product to product. In addition, the proposed changes would further distort the estimation of accurate costs by combining multiple costs centers on hospital cost reports into ten CMS-designated cost centers. CMS would then determine ten national average cost-to-charge ratios for each of the designated costs centers, however, such ratios would not be weighted by each hospital's Medicare charges. This would allow very small hospitals to have just as much impact on the national cost-to-charges ratios as larger hospitals.

In addition, CMS is proposing to implement by October 1, 2007 another major payment policy change to refine DRGs based on severity of illness. If CMS includes a behavioral adjustment offset in response to case-mix increases stemming from improved documentation and coding, it is recommended that such an adjustment not be applied across the board but on a case-by-case basis.

We are concerned about the potential unintended consequences and implications of such unproven payment changes on hospitals. We respectively urge CMS to postpone implementing either of these proposals pending thorough analysis. Such analysis should include running the proposed changes side-by-side with the current payment policies in order to better track and discern any unexpected patterns or impact.

Comments on Implementation of Proposed FY 2007 Occupational Mix Adjustment

To comply with the court's order, CMS is proposing to use the first three months (January 1, 2006 through March 31, 2006) of the survey data collected on the 2006 Medicare Wage Index

Occupational Mix Survey and apply that adjustment to 100 percent of the FY 2007 wage index. Hospitals are required to submit this occupational mix data no later than June 1, 2006. Thus, while CMS will use new data to apply a 100 percent occupational mix adjustment factor, such adjustments will only be as accurate as the data reported.

We understand the unusual restraints stemming from the court-mandated order as regards the application of the occupational mix adjustment to 100 percent of the wage index. However, it is strongly recommended that CMS use its discretionary authority to smooth out the impact of this change on adversely affected hospitals. Such attention could take the form of a multi-year transition or the use of corridors, as CMS has used in the past.

Comments on Value-Based Purchasing

CMS has noted the legal requirement to develop a plan to implement value-based purchasing beginning with FY 2009. CMS went on to say that the plan must consider a number of issues, including incentive methodology, and asked a number of questions.

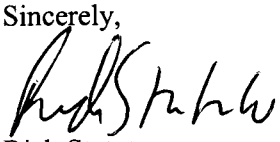
Before addressing these incentive methodology questions, we wanted to raise a more fundamental question – "What is the goal of value-based purchasing?" Is it to improve quality of care? Or is it to reduce Medicare spending? We feel the goal should be to improve the overall quality of care. And, if in the process, Medicare savings are realized, then such savings should be considered an unexpected value, but one that does not take precedence over the primary goal.

The above perspective is what guides our recommendations below to the incentive methodology questions poised by CMS:

- Reward hospital for continued improvement over time.
- A 1 to 2 percent bonus is an adequate quality incentive. However, penalties for "poor performance" are not in keeping with the quality improvement spirit.
- Examine the possibilities of improving care coordination as an incentive funding source.
- Make incentive payments on a periodic, lump sum, quarterly basis.
- Use the highlighted composite scoring methodology currently being used for the Premier Hospital Quality Incentive Demonstration.

In closing, we want to thank you for the opportunity to comment on the proposed FY 2007 IPPS rule. If enacted as proposed, this rule will have the largest impact on hospitals since the inception of the IPPS in 1983. Given these proposed changes, we again urge CMS to defer implementation of the DRG related changes for at least a year in order to better assess the potential unintended consequences.

Sincerely,



Rich Statuto
President and CEO

46-0
(31)

May 25, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital IPPS and FY 2007 Rates
Published in the Federal Register on April 25, 2006, regarding:

Geographic Reclassifications –

- Requested Reclassification for Hospitals Located in a Single Hospital MSA Surrounded by Rural Counties

Dear CMS:

The following comments are submitted in support of The Williamsport Hospital & Medical Center relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications."

I am a member of the Board of Directors of Providence Foundation, which is an affiliate of The Williamsport Hospital & Medical Center. This hospital serves our patients and community very well and very efficiently. They provide many critical services performed by health care workers that are not easy to attract and retain. The ER Department is particularly busy and important to our community, especially when our community hosts the Little League World Series every year.

We offer as many if not more services than our competitors yet they are paid more for their labor costs under the Medicare Program. This is not fair. I think the Medicare Program needs to "level the playing field" otherwise The Williamsport Hospital & Medical Center will not be able to attract and retain the healthcare workers that are so important to our patients - especially the elderly, representing 50% of our inpatients.

Please approve this rule that would allow for more equitable treatment compared to the others hospitals with which we compete.

Thank you.

Sincerely,

Mary Fish

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(15)

MOUNT SINAI
SCHOOL OF
MEDICINE

Barry Stimmel, M.D.
Dean for Graduate Medical Education

Katherine and Clifford Goldsmith
Professor of Medicine (Cardiology)

Professor of Medical Education

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May 29, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: CMS-1488-P "Resident Time in Patient-Related Activities"

Dear Administrator McClellan:

The Mount Sinai School of Medicine Graduate Medical Educational Consortium consists of thirteen hospitals and over 2,100 residents. We welcome this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates" [71 Fed. Reg. 23996 (April 25, 2006)]. We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

Background

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care."

This position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty" [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

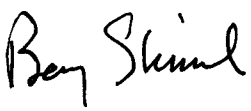
Residency Program Activities and Patient Care

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

In fact, the ACGME has specifically mandated that residents be assessed on six Core Competencies two of which—Systems-Based Practice and Practice-Based Learning and Improvement—can only be completely acquired through didactic sessions and are intimately involved with improving patient care. Indeed virtually all didactic sessions are directed toward improving the care and outcome of patients.

To reiterate, I urge CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments, and to recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,



Barry Stimmel, M.D.
Dean for Graduate Medical Education

cc: Dr. K. Davis
Dr. D. Charney
Dr. D. Muller

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Randall D. Mckinnon, PhD
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mckinnon@umdnj.edu

June 1, 2006

CMS Dept. of Health & Human Services
ATT: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: X STOP IPD

To Whom It May Concern:

I am writing in support of St. Francis Medical Technologies implant, the X STOP IPD. This is a device unique in the medical field that uses a relatively minimally invasive technique to provide relief to the thousands of patients who are suffering from the sides and symptoms of neurogenic claudication secondary to lumbar spinal stenosis. This is a relatively simple device to install with no significant interruption of the patient's normal anatomy. It does provide relief for carefully selected individuals without the need to undergo a major invasive laminectomy and decompression. The procedure for implanting the device is simple and of short duration. The patients can be discharged on a same day basis, negating the need for long hospital stays such as the normal situation for patients who require the more formal laminectomy and decompression procedures. While the patients to receive the X STOP need to be carefully selected, it does fill a very important void providing relief for these patients with a minimal of discomfort and does not interfere with any future operations which may be required.

Sincerely,

Michael G. Nosko, MD, PhD
Assoc. Professor & Chief
Division of Neurosurgery

MGN/fck

Dictated Not Read

Cc: St. Francis Medical Technologies
960 Atlantic Ave., Suite 102
Alameda, CA 94501

THE UNIVERSITY
OF KANSAS HOSPITAL
KUMED

Health System Finance
Budget, Reimbursement,
Cost Accounting & Revenue Cycle

June 2, 2006

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, Maryland 21244-1850

Re: Proposed Changes to the Hospital IP Prospective Payment Systems & FFY 2007 Rates

Dear Sir or Madam:

The University of Kansas Hospital (UKH) appreciates the opportunity to comment on CMS's proposed FFY 2007 inpatient PPS rule. We are a 473-bed teaching hospital with approximately 428 residents.

Summary of Comments

UKH supports a DRG weighting methodology based on costs, but does not believe the proposed methodology is sound. We request that CMS delay the implementation of this methodology until improvements can be made.

UKH supports the implementation of severity adjusted DRGs, but believes that the number of diagnoses and procedures used to determine severity should not be limited. Severity adjusted DRGs should be implemented at the same time as the DRG weighting methodology based on costs.

UKH believes that the Cardiology and Orthopedic DRG weights are understated due in part to improper identification of implant costs.

UKH does not support the elimination of direct graduate medical education (DGME) and indirect medical education (IME) reimbursement for resident didactic training in non hospital settings.

DRG Methodology Proposal

While we support a cost-based weighting system (hospital-specific relative value cost center or HSRVcc), we believe that CMS needs to delay implementation due to several flaws in the calculation. We understand that CMS excluded data from its calculations for a significant number of hospitals, because the data appeared aberrant. We would like to request that CMS include all hospital data in its calculations. Also, it is our understanding that each hospital's cost-to-charge ratios (CCRs) were weighted equally, regardless of case volume, to achieve the national CCRs. We ask that CMS weight each hospital's CCRs according to the hospital's case volumes. We believe that the outcome of these two changes will result in a better representation of actual costs.

Even if these changes are made, however, we still believe that the HSRVcc weighting system would result in inadequate reimbursement for academic medical centers that treat severely ill

patients. Thus, we would like to see the cost-based system implemented at the same time as the consolidated severity adjusted DRGs (CS-DRGs). Also, we ask CMS to consider lifting the CS-DRG limit of nine diagnoses and six procedures to accommodate all of the comorbidities and services that reflect the complexity of clinical care provided.

Reduction in Cardiac and Orthopedic DRG Weights

We believe that the Cardiology DRG weights for procedures with implants are understated due to improper identification of implant costs. The proposed Cardiology DRG weights will have a negative impact on our Hospital's ability to serve the patients in our community. Medicare Reimbursement is already below cost for many of these Cardiology DRGs, and the proposed rule will exacerbate this situation. The following examples list average losses based on internal cost accounting data and Medicare payments (including outlier) for discharges from 7/1/05 through 12/31/05:

- DRG 535 – Cardiac Defib Implant w/ Cardiac Cath w/ AMI/HF/Shock: $14,399 proposed reduction, $22,099 resulting loss per discharge
- DRG 551 – Permanent Cardiac Pacemaker Implant w/ Major CV Diagnosis or AICD Lead or Gnrtr : $3,233 proposed reduction, $17,696 resulting loss per discharge
- DRG 536 – Cardiac Defib Implant w/ Cardiac Cath w/o AMI/HF/Shock: $11,738 proposed reduction, $16,447 resulting loss per discharge
- DRG 515 – Cardiac Defib Implant w/o Cardiac Cath: $9,513 proposed reduction, $15,620 resulting loss per discharge
- DRG 552 – Other Permanent Cardiac Pacemaker Implant w/o Major CV Diagnosis: $2,304 proposed reduction, $3,852 resulting loss per discharge

All of the above examples involve cardiac implants. It would be beneficial if CMS could compare calculated implant cost information with costs provided by implant manufacturers in order to ensure that the above DRG weights are not understated due to low hospital markups on implants. We are already losing a significant amount of money for outpatient cardiac procedures involving implants. We realize that the understatement of implant costs is not intentional and trust that you will attempt to correct the cost data.

Another area of concern is the Spinal Fusion DRG weights. The following examples list average losses based on internal cost accounting data and Medicare payments (including outlier) for discharges from 7/1/05 through 12/31/05:

- DRG 496 – Combined Anterior/Posterior Spinal Fusion: $4,853 proposed reduction, $31,024 resulting loss per discharge
- DRG 497 – Spinal Fusion Except Cervical w CC: $2,025 proposed reduction, $13,216 resulting loss per discharge

We urge you to review the cost data for these Spinal Fusion DRGs as well. All of the above losses are significant and will negatively impact the Hospital.

Medical Education Didactic Training

In the proposed rule, a clarification was made that would prohibit teaching hospitals from including, for purposes of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments, time that residents spend in didactic activities outside of the Hospital. Is the assumption being made that time spent in didactic training at an adjoining

University building is not related to patient care? It seems odd that this distinction is being made. Also, for purposes of DGME, it would make sense to include all activities that are necessary to achieve board certification.

We ask you to consider dropping this clarification from the final rule, as it will be quite difficult for teaching hospitals with adjoining University buildings to implement.

Thank you for your consideration.

Sincerely,

Sally Enevoldson

Sally Enevoldson
Director of Reimbursement

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June 1, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: FY 2007 Medicare Inpatient Prospective Payment System – Proposed Rules

Dear Madam or Sir:

I am writing this letter to comment on the FY 2007 Medicare Inpatient Prospective Payment System – Proposed Rules. As stated in the published documents, CMS is proposing significant changes to the inpatient reimbursement system, the most sweeping changes since the DRG reimbursement methodology was implemented in 1983. Although I commend CMS for their desire to ensure that reimbursements are properly aligned with expenses, I believe the FY 2007 Proposed Regulations have some fundamental errors which need to be addressed.

As a full service, teaching healthcare system operating 5 acute care hospitals, I have some concerns related to the proposed regulations, especially in the area of cardiology services. As you are aware, the evolution of new technologies in the area of cardiology, including drug eluting stents and ICD implants, has helped reduce the number of patients requiring highly invasive open-heart procedures. Unfortunately, these new and wonderful technologies come at a price. Furthermore, with the aging of our population as well as the significant number of patients who are obese, cardiology services will continue to grow.

In analyzing the proposed regulations, it appears there is a mismatch between reimbursements and expenses. If you look at the DRG's with the largest increase in DRG weights, they appear to be those DRG's which are not dependent on new, more expensive technologies (Pneumonia, Psychoses, Septicemia). On the other hand, if you look at the DRG's with the largest decrease in the DRG weights, the majority are associated with DRG's that have an expensive supply or device associated with it. Furthermore, the cost data being utilized to develop the weights is several years old while the increase in supply expense is impacting providers today. Finally, in trying to understand how costs are derived from charges, I believe the cost to charge ratios associated with many of the cardiac procedures is artificially low since many of these expensive devices are marked up at a much different and higher rate than traditional medical supplies.

Because of the factors outlined above, I believe the larger hospitals which operate teaching programs and treat patients with a higher acuity level will be adversely impacted by the proposed Medicare inpatient rates effective October 1, 2006.

I appreciate your consideration in amending the proposed rates to more accurately match reimbursements to expenses.

Sincerely,

Andy Strausbaugh

Andy Strausbaugh
Division Director of Reimbursement
Norton Healthcare
(502) 629-8269

50

NEUROSURGERY NORTHWEST

A Member of Franciscan Medical Group

Daniel G. Nehls, MD, FACS
Diplomate American Board
of Neurological Surgery

Lee J. Bergmann, PA-C
Physician Assistant - Certified

Sandra Blair-Gale, RN, BSN, CNRN
Certified Neuroscience Registered Nurse

Laura A. Lindh
Practice Manager

May 31, 2006

CMS, Department of Health and Human Services

Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing in support of St. Francis Medical Technologies X-STOP IPD application. I have had the opportunity to implant this device in several patients and have been pleased with the outcome. This is a procedure which is much less invasive and easier for the older population who require treatment of spinal stenosis. I believe that the X-STOP represents a significant development, which may reduce the need for larger open laminectomies. I would very much like to support the X-STOP IPD filing, as this is a device that, I believe, benefits to our increasingly ageing population to a significant extent.

Daniel G. Nehls, MD, FACS

DGN:dram/band

cc: St. Francis Medical Technologies
CMS, 960 Atlantic Avenue, Suite #102
Alameda, CA 94501
By fax, #(510) 747-3007

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Tacoma, WA 98405
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Suite D
Puyallup, WA 98371
Tel 253.841.1909

www.neurosurgerynorthwest.com

RML
SPECIALTY HOSPITAL

June 1, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1485-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1488-P

Dear Dr. McClellan:

RML Specialty Hospital (RML) is pleased to have the opportunity to present comments on the Medicare Program; proposed changes to the Hospital In-Patient Prospective Payment Systems and Fiscal Year 2007 Rates.

By way of background, RML Specialty Hospital (RML) is a freestanding hospital licensed in the State of Illinois and is recognized by Medicare as a long-term acute-care hospital (LTCH). RML is a 501(c)(3) not-for-profit limited partnership, whose members are Rush University Medical Center and Loyola University Medical Center. RML's clinical focus is on ventilator weaning (respiratory), complex medical, and wound services. Because of these programs, RML has traditionally maintained a high-case mix (one of the highest in the country for LTCHs). During the last 12-months, our overall case-mix index fluctuated between 1.75 and 2.05 for Medicare patients. Patients treated at RML are referred from approximately 60 hospitals in Illinois. These patients primarily come from ICUs, critical-care units, burn units, and step-down units.

This letter will briefly review recommendations, concerns, and questions that RML has regarding the above-identified proposed rule.

1. As you are well aware, LTCHs are faced with two Medicare changes per year. The first is associated with the LTCH-PPS rate year, which begins on July 1 and the second corresponds to the change in weights, which are published as part of the hospital inpatient prospective payment system, which becomes effective October 1. I strongly suggest that CMS reconsider implementing changes to LTCHs two times per year. It is difficult to manage and plan under this situation. As an organization whose fiscal year begins on June 1, it is difficult to effectively plan for anticipated changes in the LTC PPS system and estimate the impact from changes in case weights as part of the final rule associated with the hospital inpatient PPS system. If changes could be made to the LTC PPS system once per year, it would allow organizations to more effectively plan and implement strategies to address the changes all at one time.

5601 South County Line Road • Hinsdale, Illinois 60521 • *telephone*: 630-286-4000

2. The recently finalized short-stay outlier changes to the LTC-PPS system, which will begin July 1 are concerning. Most long-term care hospitals do not maintain the DRG pricers for both LTCHs and short-stay hospitals. There will be a much higher administrative cost to manage under this system. The most difficult aspect of this payment situation is to identify whether our information systems will be able to appropriately calculate the reimbursement using two different pricer systems. Most billing systems are not set up to handle this "blended" payment methodology like the one approved in the final rule. It could become problematic to issue bills in a timely and correct fashion. I suggest that CMS convene a group from the industry to discuss this topic in more detail.

3. It is interesting to note that the changes to LTC-PPS case weights will have a much greater impact on high-case mix providers than on low-case mix providers. It appears as if the "average" impact statement made by CMS focused on the changes across all DRGs and does not use a weighted average calculation of the DRGs used primarily by LTCHs. Is it possible to make available the weighted-average calculation showing the impact? As a high acuity provider, the case weight changes cause an approximate 5% drop in RML's total case mix index.

4. The LTC DRG lengths-of-stay are decreasing. Has CMS calculated the effect the drop in the geometric lengths-of-stay will have on the average lengths-of-stay across all LTCHs? The 25-day average length-of-stay requirement is still in place for LTCHs. Therefore, if length-of-stays continue to drop, there would appear to be a high likelihood that many LTCHs will not be able to maintain their Medicare designation as a LTCH because their average lengths-of-stay will be below the 25-day requirement. Is CMS actively going to pursue those organizations that have less than 25-day lengths-of-stay? I assume that CMS is fully aware of the contradictory incentives that have been set up by the new LTC short-stay outlier system. If there is a drop in most of the 5/6 geometric mean lengths-of stay, then LTCHs <u>should</u> have an incentive to lower their lengths-of stay. However, for those facilities that have ALOS which hover around 25 days, there will be no incentive to decrease their 25-day average.

5. Quality Reporting – Even though the proposed rule does not require LTCHs to report quality statistics, I strongly encourage CMS to work with the LTCH industry to develop quality reporting as soon as possible. I believe this is an opportunity for the industry and CMS to identify appropriate quality measurement indicators and for the industry to begin collecting and publicly reporting results across providers.

6. On page 335, a review of the HCAHPS is presented. Is this system applicable to LTCHs? If not, is there an opportunity to include LTCHs in this system?

7. On page 346, the Premier Hospital Quality Incentive Demonstration Project is discussed. Can LTCHs be added to this project?

8. On page 363, there is discussion pertaining to hospital-acquired infections. I believe these concepts will need to be transferred over to LTCH providers as soon as possible. However, I suggest that input be provided from LTCHs prior to the development of a policy on this matter. The reason for this caution is that many patients come to LTCHs in very compromised clinical conditions. Patients may have acquired a nosocomial infection from the referring hospital primarily due to long lengths-of-stay. It is not uncommon for patients coming into an LTCH to have already received significant courses of antibiotics, which would place them at much higher risk for nosocomial infections, etc. If CMS is considering this type of policy for LTCHs, I strongly encourage discussions take place before the development of any specific policy.

9. On page 477, the charge-to-cost ratios (CCR) and the discussion of statewide ceilings are reviewed. Why are statewide floors not used? I understand the situation where charges could be artificially adjusted in any particular year to improve reimbursement. However, if a provider has a historical consistency of having a low RCC, then that provider should be allowed to use their statewide floor RCC.

10. Should LTCHs anticipate that CMS will utilize a system similar to the hospital specific relative value cost weights (HSRVcc) for the LTCHs? Has this (HSRVcc) system been run for the LTCH-PPS system to determine its applicability in the in LTCH environment? If hospitals are required to use this new system, then it seems plausible to assume that LTCHs will similarly be required to use the same methodology. Your thoughts on this matter would be greatly appreciated.

I appreciate the opportunity to comment on the proposed rule and CMS' willingness to request input from providers. RML is willing to work with CMS to explore these issues in more detail. We are also ready to work with CMS to develop quality measures for LTCHs as was suggested in Medpac's March 2006 report.

If we can be of assistance, please do not hesitate to call upon us. I can be reached at (630) 286-4120.

Sincerely,

James R. Prister, FACHE
President/CEO

Attachment

52

CAMC Health Education and Research Institute

ADMINISTRATION

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June 2, 2006

Mark B. McClelland, M.D., Ph.D
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: RESIDENT COUNT AND DOCUMENTATION

Dear Administrator McClellan:

As a sponsoring institution of Graduate Medical Education (GME), the Charleston Area Medical Center (Medicare provider #51-0022) located in Charleston, WV appreciates the opportunity to comment on the CMS proposed rule entitled "Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates." 71 Fed.Reg.23996 (April 25, 2006). We strongly urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and the indirect medical education (IME) payments.

BACKGROUND

The proposed rule excludes a number of activities when determining full time equivalent resident counts for all IME payments and for DGME payments when these activities occur in a non-hospital setting, such as a physician's office or an affiliated medical school. The stated rationale for the exclusion assumes that this time is not "related to patient care."

This position is in stark contrast to the Agency's past position and audit practice that interpreted the intent of the legislation to include educational activities that are relevant and important to both the education process and the patient care process. In a letter written in 1999 to Mr. Scott McBride of Vinson and Elkins, the Director of Acute Care, Mr. Tzvi Hefter, verified that HCFA interprets patient care activities to broadly include "scholarly activities, such as educational seminars, classroom lectures, research conferences, patient care related research . . . . and presentation of papers and research results to fellow residents, medical students and faculty." He further concluded that hospitals may include these activities "as part of the entire time spent by residents" in its FTE count for GME/IME payment calculations. As a result, sponsoring institutions such as our organization, have relied upon this broad definition to maintain our program requirements and to promote continuous performance improvement of patient care services. **Due to the past interpretation taken by the agency, the most recent "clarification" is paramount to a proposed new regulation that we adamantly oppose.**

RESIDENCY PROGRAM ACTIVITIES AND PATIENT CARE

The recent clarification asserts a false assumption that patient care activities conducted by residents has no relevance to academic activities of residents. In reality, graduate medical education is totally organized around the clinical patient care experience. As a large clinical teaching hospital, our entire

education mission is focused on learning and innovation around patient care. All didactic sessions, grand rounds presentations, seminars, journal clubs, mortality-morbidity conferences and other scholarly activity is focused on clinical quality and on the direct evaluation and presentation of learning cases within the overall environment. In our environment, there are no research laboratories and no bench research. All research is clinical, health services or quality improvement research. Our residents are engaged in a number of activities that are not only essential to their learning, they are essential to a quality patient care experience:

- Residents engage in morning report or other patient related meetings that create a team learning approach in which the entire time is focused on the discussion of current patients and a team evaluation of the treatment regimen that has been initiated or proposed.
- GME departments sponsor daily or weekly educational sessions in each specialty area during which current or recent patient case reports, quality team results, new medical innovations or other aspects of patient care are presented.
- Residents participate in all of the institution's quality/performance improvement councils or teams within their service areas. These groups are studying the improvement of patient care activities related to treatment effectiveness, operational efficiencies, and quality of care to patients. Residents play a vital role in these activities as they are often caring for the patients in most need, and most assuredly CMS beneficiaries. *Teaching residents to continuously evaluate their care and to improve patient care through these activities is an investment in cost-effectiveness and clinical quality for the future.*
- Residents are assigned lectures and didactic teaching to focus on identifying and treating special patient populations with the most up-to-date and cost-effective methods. They allow learners to interact with real-time experiences of faculty and co-learners about real-time patient experiences. These activities contribute significantly to actual patient care in that they prepare the resident for the next patient experience. They reduce potential for error, waste, adverse events and loss of life. *CMS should be promoting not only residents to engage in these activities but requiring the long-term practitioner to be more involved in both teaching young residents and in keeping themselves current.*
- Residents participate in conducting autopsies or attend pathology, mortality-morbidity conferences which review autopsies of patient experiences. These activities add further dimension to the training and again prepare the resident for the next patient.
- Residents are required to attend simulation training programs, which prepare them for real-time patient care experiences. Simulation learning represents the training model of the future where virtual patient care technology creates a realistic training experience further reducing potential for error and adverse events for real-time patients. *CMS should promote and encourage an investment in this technology rather than create reimbursement disincentives for institutions that may be struggling to afford it.*
- In recent years, all Residency Review Committees have emphasized research requirements. With more restrictive duty hour requirements, institutions are challenged to support research time for residents and for their supervising faculty. In our institution, research requirements are focused on the evaluation of clinical care or the evaluation of clinical delivery services. Protocols involve prospective patient study or retrospective analysis of patient services/data. They may be oriented to primary prevention objectives, quality or cost comparative analysis, decreasing length-of-stay, or other objectives; they are all related to patient care and evaluate real-time patient care experiences.

TIME AND PLACE---IT'S ALL ABOUT PATIENT CARE

Since we believe these activities to be integral to the patient care experience, there should not be a distinction of DGME and IME payments based on non-hospital locations versus hospital based locations. The distinction among provider-based versus free-standing locations or medical school practice offices and hospital clinics are founded on legal, structural or financial issues. Indeed, at our institution, hospital and non-hospital locations might simply be across the hall or on the next floor from each other. They are non-discrete from patient or resident viewpoints with no differentiation of the patient care or learning experience. CMS has made recent distinctions of payments at these sites based solely on bearing "all or substantially" all costs of the residency program which remains a subject of confusion, complexity, and controversy. The creation of further "clarifications" of this payment based on any location of didactic versus patient care time is unnecessary and onerous.

Furthermore, it is a rare resident who works a 40-hour week. The average working week in our institution ranges between 60-70 hours per week. Regardless of time assigned to didactic or scholarly activity, residents would still spend in excess of 40 hours per week in direct patient care involvement. The burdens that could be placed on residents and institution's to account hour for hour where an individual resident may be, in what activities they may be engaged or what topics they may be discussing or learning is certainly not productive by anyone's standards.

In summary, we believe that previous broad interpretations both stated and practiced in audit should not be changed and that the purported "clarification" has resulted in a new proposed rule that we think to be seriously flawed. We believe that didactic and other scholarly activity is the very component of GME that assures continuous learning and continuous quality improvement to the patient care experience. On any given hour, it may be true that residents are evaluating, consulting, discussing or learning about current/past patients instead of actually treating current patients, but it is not true that these activities are not related to patient care. They are all about patient care and more pointedly about **delivering** actual patient care for the next day, the next patient, or the next generation of patients. In fact, these activities are all about affecting and protecting a standard of quality, which CMS seems to be attempting to promote---the right care, to the right patient, at the right time.

We urge CMS to rescind its "clarification" in the proposed rule relating to the counting of all didactic time or scholarly activity time for purposes of DGME and IME payments no matter what the site location. An attempt to separate them from the patient care experience is simply an error in logic. An attempt to implement or document such a separation is at best unrealistic and burdensome, if not impossible.

Sincerely,

Sharon A. Hall

Sharon A. Hall
President, CAMC Institute
Designated Institutional Official for GME

c: Karen Fisher, AAMC
David L. Ramsey, President and CEO, Charleston Area Medical Center
Senator Robert C. Byrd
Senator John D. Rockefeller, IV
Congresswoman Shelley Moore Capito

Leesburg Regional Medical Center

LRMC

June 1, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS 1488-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on the Hospital-Specific Impacts of Proposed 2007 Hospital Inpatient PPS Rule

Leesburg Regional Medical Center ("LRMC") is a 309-bed acute care not-for-profit hospital that serves a large retirement community in Central Florida. Approximately 75% of LRMC's patients are Medicare, 5% Medicaid and 5% uncompensated care, charity or self-pay. As a not-for-profit organization, we have always been committed to providing the services needed in our community. The proposed changes to the Medicare DRG Case Weights will have a significant negative impact on our ability to serve this large retiree community. We believe that our case may be unique and would invite further review of our situation.

We have evaluated the impact of the proposed changes on our organization that will go into effect on October 1, 2006. The estimated impact from the proposed changes will result in a decrease in annual payments to LRMC of approximately $6.0 million. It is estimated that LRMC will experience a real net decrease in reimbursement of over $2 million from our fiscal year 2006 to 2007. This decrease only accounts for nine months of operations since the hospital's fiscal year begins on July 1. The analysis shows that the decrease is primarily driven by the decrease in the cardiac DRG weights. LRMC does approximately one thousand cardiac surgeries and over 3,500 cardiac caths each year. These large volumes are driven by the fact that LRMC is the only facility in Lake and Sumter counties that provides comprehensive cardiac services. The proposed changes will have a devastating impact and in my experience they appear to be the most devastating that I have seen since the implementation of DRG's.

We understand that the proposed changes reflect recommendations from the Medicare Payment Advisory Commission (MedPAC), and response to some Congressional concerns that the existing system may create incentives for certain hospitals to "cherry-pick" more profitable cases. The reforms will significantly affect payments to specialty hospitals – hospitals that typically are owned, in whole or in significant part, by physicians who serve as referral sources. LRMC is not a specialty hospital and is not owned by physicians and it is our opinion that the hospital is being unfairly impacted by proposed changes and that this impact is an unintended consequence of the proposed new regulations.

LRMC is located in Lake County which is the 21st fasting growing county in the United States and much of this growth is driven by retirees relocating to Central Florida. LRMC serves the largest retirement community in the United States in The Villages, Florida through our wholly owned The Villages Regional Hospital. LRMC is a guarantor on the recently issued $75 million in bonds to expand the facility from 60 to 198 beds to support this fast growing retiree community. The proposed DRG weight changes dramatically impact our ability to hit the financial targets committed to six months ago when the bonds were issued to finance the expansion.

I want to reemphasize that LRMC serves and is committed to serving a large Medicare population. However, this commitment is being severely challenged by the proposed changes. It is unreasonable to expect LRMC to continue to support our retiree community's growing health care needs, with even less reimbursement than in the past year. As a result of these proposed cuts, we had to revise our FY 2007 budget and, after many painful decisions, were able to project a marginal operating profit margin of only 1.6%. This margin is simply not adequate to meet the growing needs of this elderly community. Our costs for personnel, supplies, utilities, maintenance and equipment are continually increasing yet we now find that Medicare will pay us less than was paid in the prior year. To further reduce our costs we would have to reduce services to our Medicare population, and we do not believe that this is what MedPAC, Congress or CMS intended to happen.

We respectfully request that you revise the formula to take into account those hospitals which are providing essential cardiac services to large Medicare populations. Many hospitals with smaller Medicare percentages may be able to sustain these changes but for those hospitals with a large volume of cardiac Medicare patients the changes would be a severe drain on the facilities. Should you choose not to revise then formula then we request that you phase in the reductions so that the facilities have an opportunity to adjust the services that we will be able to afford to offer to the community.

Please do not hesitate to contact me if I can provide you with any additional information.

Sincerely,

Louis H. Bremer, Jr.

Louis H. Bremer, Jr., CHE
President & Chief Executive Officer

54-0
(2)

American Hospital Association

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June 8, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of the American Hospital Association's (AHA) 4,800 member hospitals, health care systems and other health care organizations, and our 35,000 individual members, we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the fiscal year (FY) 2007 inpatient prospective payment system (PPS) and occupational mix adjustment proposed rules.

The rule proposes the most significant changes in the calculation of diagnosis-related group (DRG) relative weights since 1983 by creating a version of cost-based weights using the newly developed hospital-specific relative values cost center methodology (HSRVcc). It also proposes refining the DRGs to account for patient severity, with implementation likely in FY 2008. In addition, the rule would update the payment rates, outlier threshold, hospital wage index, quality reporting requirements, and payments for rural hospitals and medical education, among other policies.

While the AHA supports many of the proposed rule's provisions, we have serious concerns about the proposed changes to the DRG weights and classifications.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. We believe the AHA and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs, which will provide an equal incentive to treat all types of patients and conditions. However, more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows

the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change.

Specifically, the AHA supports the following:

- **One-year Delay:** The AHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- **A New Classification System Only if the Need Can Be Demonstrated:** The AHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes.

- **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals.

- **Collaborative Approach to Moving Forward**: The AHA commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

We have enclosed detailed comments that further explain our concerns and recommendations on the proposed DRG weight and classification system changes, as well as our position on many other issues in the proposed rule.

The AHA appreciates the opportunity to submit these comments. If you have any questions about our remarks, please feel free to contact me or Danielle Lloyd, senior associate director for policy, at (202) 626-2340 or dlloyd@aha.org.

Sincerely,

Rick Pollack
Executive Vice President

American Hospital Association
Detailed Comments on the
FY 2007 Inpatient Prospective Payment System Proposed Rule

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PROPOSED CHANGES

DRG CHANGES

In response to payment recommendations from the Medicare Payment Advisory Commission (MedPAC) to address the proliferation of physician-owned, limited service hospitals, the Centers for Medicare & Medicaid Services (CMS) proposed the biggest changes to the calculation of diagnosis-related group (DRG) relative weights since the creation of the prospective payment system (PPS). These changes would significantly redistribute payments among the DRGs and among hospitals. Specifically, CMS proposes the use of hospital-specific relative values (HSRVs) and a modified version of cost-based weights rather than charge-based weights in fiscal year (FY) 2007. CMS also proposes an alternative patient classification system called consolidated severity adjusted DRGs (CS-DRGs), with implementation likely in FY 2008.

The hospital field supports meaningful improvements to Medicare's inpatient PPS. We believe the AHA and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs which will provide an equal incentive to treat all types of patients and conditions. We also believe the system should be simple, predictable, and stable over time. One of the fundamental values of a *prospective* payment system is the ability of providers to reasonably estimate payments in advance to inform their budgeting, marketing, staffing and other key management decisions. Another core feature of the PPS is clinically cohesive and meaningful DRGs that are somewhat intuitive for providers and coders to follow, and that reflect similar resource use within DRGs. And, ultimately, the inpatient PPS should foster innovation and best practice in care delivery. The AHA believes that these are essential characteristics of a well-functioning PPS and it is within these policy goals that we evaluate CMS' proposal.

While we are providing CMS with comments under separate cover on its interim report to Congress regarding the development of a strategic implementation plan on physician-owned, limited service hospitals as required under the *Deficit Reduction Act of 2005* (DRA), we would like to emphasize here that payment changes alone will not remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for services. We strongly urge CMS to rigorously examine the investment structures of physician-owned, limited-service hospitals and consider our comments on the interim report on the strategic plan. It is imperative that CMS continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the strategic plan developed has been fully implemented and Congress has had an opportunity to consider CMS' final report.

NEW DRG WEIGHTS: HSRVCC

CMS proposes an alternative to MedPAC's approach to HSRVs and cost-based weights that could be characterized as a short cut. CMS asserts that this combined methodology, known as the HSRV cost center methodology (HSRVcc), achieves similar results in a more administratively feasible manner. But that is not the case. Specifically, the CMS proposal involves two major steps.

1. Develop, on a charge-basis, hospital-specific relative weights for each DRG. CMS established 10 cost center categories based on broad hospital accounting definitions: routine day costs; intensive care day costs; and eight ancillary cost centers. CMS calculated DRG relative weights for each of the 10 cost centers by DRG for each hospital and then used those hospital-specific weights for calculating national DRG weights. CMS' current process aggregates charges for all hospitals at the DRG level to calculate weights. CMS believes the new approach removes the variation introduced by hospital characteristics such as teaching, disproportionate share, location and size, among others.

2. "Scale" the charge-based DRG weights to "costs" using the national cost center cost-to-charge ratios (CCRs) developed from the cost report data (as opposed to using hospital-specific CCRs at the claim level). CMS believes this approach will remove the effect of different CCRs across departments within hospitals. CMS chose this methodology because the use of national average rather than hospital-specific departmental CCRs is administratively easier.

The AHA supports the move to cost-based weights but believes CMS' proposed method is flawed. More work is needed to determine the best way to create cost-based weights. Hospitals are willing to work with CMS in a process to develop consensus around the right way to make this change. Below we discuss our detailed concerns and questions regarding the proposed HSRVcc methodology.

HSRVcc METHOD CONCERNS

The AHA believes that more time is needed to develop a sound methodological approach to create cost-based weights and to understand their potential impact.

1. **Errors:** While analyzing CMS' proposed rule, the AHA uncovered a series of data errors, inconsistencies across databases and questionable methodological choices. Further analyses commissioned by the AHA, the Association of American Medical Colleges and the Federation of American Hospitals and conducted by The Moran Company, Inc. to investigate these questions showed that small changes in method lead to large changes in DRG weights, signaling that the proposed changes are highly unstable (see attached technical appendix).

   For instance, the following, more minor, inconsistencies were identified:

   - CMS inadvertently included organ acquisition costs in the data used to set weights for DRGs. These costs should be excluded. This error has a material effect on the resulting weight calculation for transplants. For example, CMS publishes a weight of 5.5466 for DRG 302 (Kidney Transplant), but with this correction The Moran Company calculates a weight of 3.0102.

   - CMS was inconsistent in its treatment of certain categories of hospitals between their calculation of the FY 2007 HSRVcc weights and the proposed CS-DRG weights, making it hard to directly compare the results. For example, hospitals in Maryland were included in the FY 2007 MedPAR data used for the HSRVcc weight calculation and excluded from the CS-DRG calculation.

- The Moran Company used transfer-adjusted charges prior to calculating weights. It was CMS' policy to do this. However, it is unclear whether the weights published for CS-DRGs included this step.

- Data cleaning steps used were not always consistent with standard CMS practices (e.g., removal of cases with 0 charges, low volume DRGs, etc.).

- The cleaning steps applied to the cost report data were not consistent with the cleaning steps applied to the MedPAR claims data, which resulted in different hospitals being included in data sets used for the calculation of the weights and the calculation of the scalers to the weights. For example, hospitals in Maryland and hospitals without cost reports for FY 2003 were excluded from the cost report data used to calculate the scalers and included in the MedPAR file used to calculate the weights.

2. **Trimming:** CMS trimmed the cost center CCRs at 1.96 standard deviations from the geometric mean. We believe that this skews the CCRs, as the hospitals with high routine charge mark-ups are systematically removed from the calculation. This results in the exclusion of 198 hospitals' routine CCRs, accounting for over 26 percent of total routine charges. It also creates a mismatch between the CCRs used and the charges they are applied to, as the hospitals that are trimmed out of the CCRs are still included in the charges that are then reduced to costs and determine the cost shares.

3. **Weighting:** CMS also hospital-weighted rather than charge-weighted the calculation of the CCRs which in turn are used to calculate the scaling factors used to convert the charge-based relative weights to "cost." There are several issues with this approach:

   - This approach gives an equal weight to each hospital in the national cost-to-charge ratio calculation even though hospitals can range in size from fewer than 25 to more than 1,000 beds.
   - This method is inconsistent with the method of averaging used to develop the cost center-specific DRG weights to which the scaling factors are applied. For this part of the analysis, CMS calculated hospital-specific DRG relative weights, but then used a case-weighted average to develop the national value.

   - The hospital-weighted approach results in a 1 percent to 54 percent difference versus a charge-weighted approach in the resulting scaling factors used for the conversion to cost.

The above errors in the calculations over-weight CMS' routine cost shares and under-weight the ancillary cost shares, creating erroneously large swings in DRG weights. Table 1 illustrates how these methodological problems affect the factors used to scale the cost center-specific relative weights. This table shows the impact of trimming the cost center CCRs at 3.0 rather than 1.96 standard deviations from the geometric mean and charge-weighting rather than hospital-weighting the calculation of the national average CCRs that are used in developing the scalers.

Table 1

Impact of Methodological Changes on "Scalers"

Published versus Revised with Methodological Changes

Scaler	CMS Published	Methodological Changes			Percent Change vs. Published
		Trimming Only	Weighting Only	Weighting/ Trimming	
Routine days	0.2881	0.2882	0.2646	0.2490	-14%
Intensive days	0.1919	0.1933	0.1668	0.1636	-15%
Drugs	0.0877	0.0884	0.0939	0.0970	11%
Supplies	0.1150	0.1142	0.1325	0.1383	20%
Therapeutic	0.0384	0.0381	0.0390	0.0388	1%
Operating room	0.0812	0.0838	0.0861	0.0888	9%
Cardiology	0.0241	0.0246	0.0351	0.0371	54%
Laboratory	0.0670	0.0659	0.0681	0.0687	3%
Radiology	0.0427	0.0437	0.0460	0.0474	11%
Other services	0.0639	0.0600	0.0677	0.0712	12%

Source: Moran Company analysis.

These methodological problems have a large impact on the relative weight calculations at the DRG level. Table 2 shows, for key DRGs, how these methodological problems affect the DRG weights and, therefore, hospital payments.

Table 2

DRG Weights with Current Methodology vs. HSRVcc with Various Corrections

High Volume DRGs with Largest Changes in Weights Due to Corrections

DRG (v24)	DRG Title	Number of discharges	Current Charged-based Weights w/v24 Grouper	New DRG Weights: Published vs. Corrected			Change vs. Old Weights		
				CMS Published HSRVcc Weight	HSRVcc w/ Technical Corrections Only	Corrected, Weighted and Trimmed CCRs	DRG Weight Change Current Method vs. Published	DRG Weight Change Current vs. Corrected, Weighted, and Trimmed	Published vs. Corrected, Weighted, and Trimmed
430	PSYCHOSES	74,671	0.8060	1.2416	1.2416	1.1110	54.0%	37.8%	-10.5%
12	DEGENERATIVE NERVOUS SYSTEM DISORDERS	56,042	0.8983	1.0105	1.0099	0.9635	12.5%	7.3%	-4.7%
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	119,513	3.4236	3.8279	3.8366	3.8573	10.6%	8.8%	-4.5%
277	CELLULITIS AGE >17 W CC	118,691	0.8676	1.0015	1.0026	0.9578	15.4%	10.4%	-4.4%
87	PULMONARY EDEMA & RESPIRATORY FAILURE	96,506	1.2954	1.5810	1.5824	1.4899	10.6%	6.1%	-4.0%
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	224,491	0.8611	0.9538	0.9544	0.9162	10.8%	6.4%	-3.9%
294	DIABETES AGE >35	97,122	0.7769	0.8642	0.8638	0.8307	11.5%	7.2%	-3.9%
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	246,948	0.8213	0.9041	0.9042	0.8701	10.1%	5.9%	-3.8%
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	159,994	1.6539	1.7531	1.7539	1.6880	6.7%	4.6%	-3.8%
243	MEDICAL BACK PROBLEMS	100,498	0.7888	0.8680	0.8693	0.8363	10.0%	6.0%	-3.7%
554	OTHER VASCULAR PROCEDURES W CC W/O MAJOR CV DX	77,003	2.0690	1.9493	1.9560	2.0085	-5.7%	-2.9%	3.1%
110	MAJOR CARDIOVASCULAR PROCEDURES W CC	57,436	3.8616	3.6419	3.6558	3.7563	-5.7%	-2.7%	3.1%
124	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	119,991	1.4508	1.1070	1.1732	1.2380	-19.6%	-14.7%	6.1%
544	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY	444,118	1.9514	1.8941	1.9047	2.0147	-2.9%	3.2%	6.4%
551	PERMANENT CARDIAC PACEMAKER IMPL W MAJ CV DX OR AICD LEAD OR GNRTR	53,717	3.0391	2.6539	2.6491	2.8453	-13.3%	-6.4%	8.0%
552	OTHER PERMANENT CARDIAC PACEMAKER IMPLANT W/O MAJOR CV DX	81,744	2.0837	1.7670	1.7771	1.9468	-15.2%	-6.6%	10.2%
125	CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	91,648	1.1117	0.7852	0.7913	0.8717	-29.3%	-21.6%	10.9%
557	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W MAJOR CV DX	123,550	2.8755	2.1323	2.1499	2.4236	-25.8%	-15.7%	13.7%
515	CARDIAC DEFIBRILLATOR IMPLANT W/O CARDIAC CATH	59,000	5.2591	4.1471	4.1765	4.7099	-21.1%	-9.7%	15.7%
558	PERCUTANEOUS CARDIOVASCULAR PROC W DRUG-ELUTING STENT W/O MAJ CV DX	191,677	2.1920	1.4299	1.4456	1.7238	-34.8%	-21.4%	20.6%

Source: Moran Company analysis of FY 2007 proposed inpatient PPS rule. Uses FY 2005 MedPAR.
Notes: High volume DRGs defined as over 50,000 cases. Those included in the table were those with the greatest absolute change in weight moving from the CMS published DRG weight to the DRG weight calculated by trimming CCRs at 3.0 standard deviations, using weighted CCRs, and correcting for technical errors.

These changes have a material impact on hospital payment. CMS' method for weighting and trimming redistributes $1.4 billion dollars among hospitals. Charge-weighting the CCRs and trimming them at three standard deviations would reduce the shift in dollars to $900 million – a reduction of ***half a billion dollars***, or 33 percent. This highlights the need for more work to validate each methodological step to understand how it affects payment and ensure it adds to "accuracy."

4. **Failure to Calculate Costs at the Claim Level:** CMS chose to use *charges* to initially calculate the relative weights at the DRG level and then a national scaler to make the conversion to "cost-based" weights. The national scaler converts the 10 cost center charge-based weights to one national weight using the actual share of costs across departments. CMS maintains that this adjusts for differential mark-ups across hospital departments. In contrast, MedPAC estimated *costs* at the claim level to calculate relative weights. CMS provided no validation of the methodological shortcut they propose.

5. **Cost Centers:** CMS aggregates charges into 10 cost centers for each DRG, then applies a cost-center level CCR (derived from the cost reports) to charge figures (from claims data). But because hospitals often report charges on the cost reports differently than charges on the claims, the cost-center level CCRs are calculated based on a different set of charges than the charges to which the CCRs are later applied. We believe this may materially distort the DRG weights and needs to be thoughtfully considered and accounted for in any methodology. If CMS is going to move to cost-based weights, regardless of the methodology, hospitals will need time to align their mapping of cost centers into departments or cost categories for purposes of cost reporting with that of claims reporting.

6. **Validation:** As mentioned above, CMS provided no analysis to validate that the proposed changes result in better payment policy. While measuring improved payment accuracy is difficult, the large degree to which the weights fluctuate given methodological changes alone indicates the need for further analysis and study. CMS should construct a process to test the sensitivity of weights to various methodological assumptions and publicly share the result, including:

    - Compare CMS weights to MedPAC's HSRV-cost approach;
    - Compare CMS weights to an approach using standardized costs (as opposed to HSRV);
    - Compare CMS weights to weights calculated by estimating costs at the claims level using the 10 cost center approach;
    - Evaluate alternative methodologies for estimating costs (e.g., method used by New York state's Medicaid program);
    - Compare stability of weights over time; and
    - Determine whether payment policy is improved.

Assessment of "payment accuracy" conducted by The Moran Company as well as The Health Economics and Outcomes Research Institute (THEORI), a division of the Greater New York Hospital Association, finds the CMS HSRVcc approach to be not at all to marginally better than the current system. Fixing the major methodological flaws yields minimal improvement, according to THEORI. CMS' HSRVcc approach actually creates new areas of care where systematic incentives for specialization could occur. This analysis raises significant questions about CMS' approach and further analysis should be conducted before any changes to the current charge-based methodology are made. These analyses will help determine the most effective and administratively feasible approach for a shift to cost-based weights in FY 2008.

NEW PATIENT CLASSIFICATION: SEVERITY OF ILLNESS

CMS also proposes moving to an entirely new patient classification system beginning in FY 2008 *or earlier*. Currently, Medicare uses 526 DRGs to classify all Medicare patients. CMS considered use of 3M's all-patient refined DRGs (APR-DRGs) as an alternative to its current DRGs, which would increase the number of categories to 1,258. However, CMS ultimately proposed refining the APR-DRG system by consolidating APR-DRGs into fewer categories. This would result in a new DRG system with 861 consolidated severity-adjusted DRGs, or CS-DRGs.

The AHA believes that the need for and best approach to changing the patient classification system has not been concretely and objectively demonstrated. More careful analysis is needed, along with greater access to the specifics of CMS's methodology and the new GROUPER. Below we discuss our detailed concerns and questions about this proposal.

CS-DRG METHOD CONCERNS

1. **Validation:** It is unclear whether there is a need for a new patient classification system. More work is needed to assess the proposed system and others that might be considered. As with the HSRVcc proposal, CMS provided no analysis that shows that the proposed changes result in an improved hospital payment system compared to the existing DRG system or APR-DRGs.

   CMS must test the degree to which the variation in costs within cases at the DRG level is reduced under both CS-DRGs and APR-DRGs. Payment classifications that still exhibit a high degree of cost variation should be identified and potentially revised. We suggest comparing the distribution of the coefficient of variation at the DRG level for various grouping approaches.

   For instance, CMS chooses to collapse the tier-four cases within major diagnostic categories (MDCs). It is unclear whether all of the tier-four cases are clinically cohesive enough to be combined and whether consolidation adequately considers variations in resource requirements. CMS also aggressively collapses the DRGs with low Medicare volume such as obstetrics, psychiatric and substance use services without any discussion of the potential ramifications for other payment systems, such as other Medicare PPSs, Medicaid and the

private sector that often bases payment off the Medicare inpatient DRG system. CMS believes that a new patient classification system that distinguishes more-sick from less-sick patients will reduce the "cherry picking" of healthy patients, but there may be other, easier ways to accomplish this. For example, CMS embarked on a new way to differentiate patients last year based on the absence or existence of a major cardiovascular diagnosis but did not discuss the possibility of other similar, less disruptive changes to the system as an option in this year's rule.

Even more fundamentally, today's DRG system was created to distinguish the resource use required among patients. It has been modified over time to reflect changes in clinical practice and technology. The APR-DRG system is based on severity of illness, not necessarily the resource use required. The impact of a move to CS-DRGs – an APR-DRG hybrid – is unclear. But the implications of moving from a resource-based system to a severity-based payment system must be more fully explored and understood.

2. **Budget Neutrality Adjustment:** CMS suggests in the proposed rule that it would reduce payments to hospitals by instituting a budget neutrality adjustment to offset the fact that case mix may increase because of improved coding rather than actual changes in acuity. However, CMS did not propose an adjustment or even a methodology for determining an adjustment. CMS often institutes such adjustments that are based on assumptions but never checked or later corrected. We recommend that CMS hold off on such an adjustment until there is evidence that one is needed.

3. **Availability of the GROUPER:** The proprietary nature of the proposed CS-DRG GROUPER is of concern. The current DRG GROUPER logic has been in the public domain since the inception of the PPS. Without the new GROUPER logic, it is virtually impossible for AHA or anyone else to thoroughly analyze the system and comment – without access to the new GROUPER, we have no understanding of how and why patients fall into certain CS-DRGs and cannot evaluate whether it represents policy improvement. If CS-DRGs are adopted and the GROUPER remains proprietary, the AHA would be limited in our ability to educate and assist our member hospitals. Moreover, a single company's monopoly would be both more expensive and more difficult to integrate into our hospitals' existing systems. Maryland hospitals report a GROUPER price of $20,000 per hospital with the ultimate price varying based on criteria such as whether it is used on a mainframe or PC. We urge CMS to make any new classification system widely available to the public.

4. **Too Few Diagnoses and Procedures Considered:** We are concerned that CMS' GROUPER does not use all diagnoses and procedures that affect a patient's severity of illness and/or the resources utilized. The current DRG GROUPER only considers nine diagnoses and up to six procedures. Hospitals submit claims to CMS in an electronic format. The HIPAA compliant electronic transaction 837i standard allows up to 25 diagnoses and 25 procedures. Many fiscal intermediaries are ignoring or omitting the additional codes submitted by hospital providers since these additional diagnoses and procedures are not needed by the GROUPER to assign a DRG.

   Capturing all diagnoses and procedures meeting the definitions of reportable secondary diagnoses and procedures will provide a more complete picture of patient complexity. As

CMS considers methodologies for refining the patient classification system, the number of secondary diagnoses may be an important factor in determining differences in patient characteristics. This is particularly true of patients with many chronic illnesses that add to the complexity of treating them.

AHA RECOMMENDATIONS

The hospital field supports meaningful improvements to Medicare's inpatient PPS. We believe the AHA and CMS share a common goal in refining the system to create an equal opportunity for return across DRGs which will provide an equal incentive to treat all types of patients and conditions. However, more time is needed to understand the significant proposed policy changes, which redistribute from $1.4 to $1.7 billion within the inpatient system. Analysis shows the impact of the proposed changes to be highly unstable, with small changes in method leading to large changes in hospital payment. And the validity of CMS' proposals versus potential alternatives to improve the DRG weights and classification system is uncertain. Moving forward requires thoughtful change. Specifically, the AHA supports the following:

- **One-year Delay:** The AHA supports a one-year delay in the proposed DRG changes given the serious concerns with the HSRVcc and CS-DRG methodology. The AHA and the hospital field are committed to working with CMS over the next year to address these concerns.

- **Valid Cost-based Weights:** We support moving to a DRG-weighting methodology based on hospital costs rather than charges, but CMS' proposed HSRVcc method is flawed.

- **A New Classification System Only if the Need Can Be Demonstrated:** The AHA does not support a new classification system at this time, as the need for a new system is still unclear. Much more work understanding the variation within DRGs and the best classification system to address that variation is still needed before CS-DRGs or any other system should be selected or advanced.

- **Simultaneous Adoption of Any Changes to Weights and Classifications:** If the need for a new, more effective classification system is demonstrated and developed, it should be implemented simultaneously with the new weighting system to provide better predictability and smooth the volatility created by these two, generally off-setting changes. For example, of the 2,566 hospitals that would experience an increase in payment using the HSRVcc[1] methodology alone, 48 percent would experience a net loss when CS-DRGs and HSRVcc are done together. Of the 859 hospitals that have a decrease in payment under the HSRVcc methodology alone, 33.9 percent would become overall winners when CS-DRGs and HSRVcc are done together.

- **Three-year Transition:** Any changes should be implemented with a three-year transition, given the magnitude of payment redistribution across DRGs and hospitals. We recommend that CMS provide a three-year transition with a blend of the old DRG

[1] Source: Moran Company analysis of 2004 MedPAR under FY 2007 payment policies using weighted CCRs and trimming CCRs at 3.0 standard deviations.

weights and the new DRG weights. In the first year, hospitals would be paid based on an average of DRG weights: 75 percent of the old weights; 25 percent of the new weights. The second year would be 50 percent of each, and the third year would be 25 percent of the old weights and 75 percent of the new weights. Another method of transition is dampening the reduction for DRGs with significant decrease in relative weights similar to the dampening of APC weights in the outpatient PPS. Dampening could be more feasible – especially if a significant change to the classification system is made – because it does not require CMS to calculate payments using two different systems.

We further believe that a stop loss should be instituted as part of this transition. This would be similar to the approach currently used under the inpatient psychiatric PPS whereby no hospital can receive less than 70 percent of what they would otherwise have been paid under the old system. In combination with the DRG blend or dampening, this would result in less significant losses in the first year than in the last year of the transition. To avoid having to run all claims under both DRG weights, CMS could establish a payment-to-cost ratio for each hospital in FY 2006 and use that as a base against which to compare payments under the new system.

- **Collaborative Approach to Moving Forward**: The AHA commits to working with CMS to develop and evaluate alternatives for new weights and classifications.

DRG RECLASSIFICATIONS

DRGs: Pancreas Transplant. We agree with the proposed coding changes for DRG 513 (Pancreas Transplant), which removes the requirement that pancreas transplant patients also have kidney disease. This change is consistent with the newly approved National Coverage Determination (NCD) to cover pancreas transplants alone as reasonable and necessary under limited circumstances for patients with Type I diabetes.

DRGs: Dual Array Implantable Neurostimulators for Deep Brain Stimulation. We oppose CMS' recommendation to keep the implantation of dual array implantable neurostimulators for deep brain stimulation in DRG 1 (Craniotomy Age >17 with CC) and DRG 2 (Craniotomy Age >17 without CC). CMS should recognize the higher resources associated with this technology.

DRGs: Carotid Artery Stents. We oppose the proposed delay in making any changes to carotid artery stent cases. The higher costs associated with carotid stents should be recognized within the existing DRG system.

DRGs: Cardiac Resynchronization Therapy, Defibrillators (CRT-D). We agree with the proposal to add code 37.74 (Insertion or Replacement of Epicardial Lead [Electrode] into Atrium) to the DRG logic so that all types of defibrillator devices and lead combinations would be included in the following DRGs:

- DRG 515 (Cardiac Defibrillator Implant without Cardiac Catheter);
- DRG 535 (Cardiac Defibrillator Implant with Cardiac Catheter with AMI/Heart Failure/Shock); and

- DRG 536 (Cardiac Defibrillator Implant with Cardiac Catheter without AMI/Heart Failure/Shock).

This change would bring the DRGs into alignment with the change in coding advice to assign code 37.74 in conjunction with implantation of CRT-D defibrillators.

Application of Major Cardiovascular Diagnoses (MCVs) List to Defibrillator DRGs. We oppose the proposal to delay refining defibrillator DRGs based on MCVs. We believe it is appropriate for CMS to apply a clinical severity concept similar to the approach used in FY 2006 to refine cardiac DRGs to an expanded set of DRGs (e.g., defibrillator DRGs) based on the presence or absence of an MCV.

DRGs: Hip and Knee Replacements. For FY 2006, new codes were created to differentiate between new and revised hip and knee replacements. In addition, more specific codes were created to identify the joint components replaced. After publication of the FY 2006 inpatient PPS final rule, a number of commenters advised CMS that the DRG logic for DRG 471 (Bilateral or Multiple Major Joint Procedures of Lower Extremity) included knee and hip procedures that are not bilateral or do not involve multiple major joints. We agree with CMS' proposal to remove the codes from DRG 471 that do not capture bilateral and multiple joint revisions or replacements.

DRGs: Severe Sepsis. We agree that providers have found the coding of systemic inflammatory response syndrome (SIRS), sepsis and severe sepsis confusing in the last few years. The classification of these conditions has changed several times during this period. We concur that data have not been consistent and that a new DRG for severe sepsis would be inappropriate. However, we recommend that a change be made so patients with severe sepsis associated with respiratory failure requiring mechanical ventilation may be properly recognized. The ICD-9-CM classification instructions require that these patients be coded with the systemic infection as the principal diagnosis. The infection codes do not group to DRG 475 (Respiratory System Diagnosis with Ventilator Support) despite the use of resource-intensive mechanical ventilation (procedure code 96.7). This results in a significant loss of reimbursement for these patients.

Since the change in coding sequencing of these patients, the Coding Clinic Editorial Advisory Board has discussed this issue several times. In addition, several proposals have been submitted to the ICD-9-CM Coordination and Maintenance Committee to allow the sequencing of respiratory failure as the principal diagnosis. To date, no changes have been made. At this point, reverting the sequencing instructions would be confusing to coders and would once again disrupt trend data.

Instead, we recommend considering mechanical ventilation as a pre-MDC DRG on the basis of the procedure code. If this is not possible, we recommend that CMS add systemic infections (038.xx,) as acceptable principal diagnoses for DRG 475 when reported in conjunction with mechanical ventilation or tracheostomy.

DRGs: Complications/Comorbidities (CC) Categories 403-404. Effective October 1, changes have once again been made to the definition of the fifth-digits for categories 403 (Hypertensive Chronic Kidney Disease) and 404 (Hypertensive Heart and Chronic Kidney Disease). Prior to October 1, 2005, a fifth digit of "0" indicated "without chronic renal failure," while a fifth digit of "1" indicated "with chronic renal failure." While all patients in categories 403 and 404 had chronic kidney disease linked to hypertension, only those with a fifth digit of "1" had progressed to the point of kidney failure. Effective October 1, 2005, the definition of the fifth digits changed to "with or without chronic kidney disease." This was confusing since all patients in categories 403 and 404 by definition were supposed to have a chronic kidney condition. The change also blurred the distinction between the patients with more severe kidney failure and those with less kidney damage. The most recent change for this year once again changes the meaning of fifth digit "0" to identify patients "with chronic kidney disease stage I through stage IV or unspecified," while fifth digit "1" identifies patients "with chronic kidney disease stage V or end stage renal disease." As such, Table 6E of the proposed rule has identified codes 403.10, 403.90, 404.10 and 404.90 as non-CCs. The stages of chronic kidney disease are a fairly new concept introduced into the ICD-9-CM classification last year, which physicians do not routinely document in the medical record. Many physicians still document the older and more common term "chronic renal failure," which translates into "unspecified stage" in the ICD-9-CM. More importantly, physicians differ in their opinion of what constitutes renal failure – whether it starts in the middle of stage III, stage IV or stage V.

While we understand that CMS may not want to consider a code that would include patients in the early stages of hypertensive kidney disease as a CC, because of the potential inclusion of more serious chronic renal failure patients in codes 403.10, 403.90, 404.10 and 404.90, we recommend that CMS instead rely on the supplemental code from category 585 (Chronic Kidney Disease) to recognize the CC.

Implementing a Modern Clinical Classification System. We continue to agree with CMS' assessment in the May 9, 2002 hospital inpatient PPS notice of proposed rulemaking that ICD-10 is an improvement over ICD-9-CM and will provide greater specificity and detail. We believe that CMS should continue with plans to implement ICD-10. Implementing the significant DRG changes is a temporary fix, and a more refined DRG system can only be accomplished with more specific clinical classification systems, capable of painting a more complete picture of a patient's condition and the services provided to treat that condition – namely ICD-10-CM and ICD-10-PCS.

LONG-TERM CARE HOSPITAL (LTCH) DRGS

The AHA is very concerned about the proposed reweighting of the long-term care hospital (LTCH) DRGs for FY 2007. The projected payment cut resulting from the reweighting – 1.4 percent – in combination with the payment cut resulting from the recent LTCH PPS final rule for 2007 – 7.1 percent – will cause substantial volatility for LTCH providers, and ultimately restrict access for patients needing long-term acute care services. It would be extremely difficult for any provider group to withstand an 8.5 percent cut in one year. By pursuing these changes, CMS is misinterpreting MedPAC's estimate of 2006 Medicare margins for LTCHs and creating an extremely unstable regulatory environment for LTCHs. MedPAC projected a 7.8 percent Medicare margin for LTCHs in 2006 and recommended no market basket update for FY 2007.

However, this MedPAC projection does not include two major policy changes that also decrease Medicare margins for LTCHs: the projection excludes the impact of the "25% Rule" limiting payments to co-located LTCHs and the new reductions associated with the LTCH short-stay outlier policy. Therefore, CMS goes too far with this proposal to reduce Medicare payments even further.

Given these considerations, we urge the agency to forgo the proposed 1.4 percent cut and instead implement the reweighting in a budget-neutral manner.

This would appropriately redistribute allocated funds among the payment categories to reflect current costs and omit the inappropriate modification of total payments due to unrelated considerations. **It is irrational to treat the LTCH PPS differently than other Medicare payment systems by failing to reweight the LTCH PPS in a budget-neutral manner.**

At this time, CMS should focus on developing further patient and facility criteria for LTCHs to ensure that patients who are clinically suitable continue to have access to the LTCH setting. We strongly support CMS' pursuit of a scientific foundation for these expanded criteria and are eager to review the recommendations currently under development by CMS' contractor the Research Triangle Institute.

HOSPITAL QUALITY DATA

The Deficit Reduction Act of 2005 (DRA) expands quality reporting requirements for hospitals to be eligible to receive a full market basket update. The proposed rule states that to qualify for their full market basket update, hospitals would have to pledge to submit data on all 21 measures currently part of the Hospital Quality Alliance's (HQA) public reporting on www.HospitalCompare.hhs.gov for patients discharged on or after January 1. Hospitals failing to submit data for the first calendar quarter of 2006 by August 15 would receive an inpatient update equal to the market basket minus two percentage points. Hospitals that fail data validation tests for data submitted for the first three calendar quarters of 2005 would also lose the two percentage points from the market basket update.

As a partner in the HQA, the AHA and its member hospitals fully support the HQA's effort to make more information on hospital quality available to the public, and we join with CMS in wanting to make it happen quickly and accurately. However, as written, the proposed rule would require hospitals to reopen files from which data have already been abstracted, renegotiate agreements with the vendors that assist them in collecting and processing the required information, and resubmit information to the clinical data warehouse. Such retroactive alterations in the data files are difficult and costly, and open the door for the introduction of many new kinds of errors in the data. To require this reopening of the files makes no sense. **CMS should make the data collection prospective. This could be accomplished by requiring that hospitals that want a full market basket update pledge to submit the relevant data for all 21 measures for patients beginning on or after July 1.**

The DRA gave the Secretary of the Department of Health and Human Services (HHS) the authority to further expand the measures that must be reported to qualify for full market basket update in future years. **We strongly urge CMS to select measures only from those used by**

the HQA for public reporting. To choose different measures would thwart efforts to streamline quality reporting, add to the "babble" of quality measurement that currently exists in health care and dilute efforts to create a single source to share solid reliable information with the public. In addition, whenever the Secretary intends to expand the set of measures linked to payment, **CMS should consider publishing the proposal at least one full year prior to the start of the fiscal year.** This will enable hospitals and their vendors to put the needed data collection processes in place to be able to provide the requested data.

Further, we agree with CMS that it is critical that the collected data be validated. The process used to validate the HQA data was reviewed by the Government Accountability Office, which concluded that there was "a high overall baseline of accuracy," but recommended several changes to improve the validation process. CMS proposes to look at the validation results for data submitted on patients who were discharged during the first three calendar quarters of 2005. CMS has hired a contractor to randomly select five patient records per quarter. That contractor selects the patients, asks the hospital to send a copy of the medical record for the hospitalization of the patients that occurred during that period, and then reabstracts the same data that the hospital abstracted from the medical record. A comparison is made between the data the hospital submitted and the data the contractor abstracted, and if there is at least an 80 percent agreement, the hospital is said to have passed validation. In the proposed rule, the hospital would have to have at least 80 percent agreement across the 15 medical records that the contractor reabstracted. This methodology assumes that the contractor has correctly reabstracted the data and that discrepancies must mean erroneous data submission on the part of the hospital. However, that is not always the case. This validation process is still in its infancy and seems to be working to correctly validate the information submitted by many, but unfortunately not all, hospitals. Significant problems have occurred for some hospitals of which we are aware.

Some data validation problems have actually begun with the data submission process. Hospitals and their data collection vendors submit data to the Quality Improvement Organization (QIO) data warehouse in a good-faith effort to get the information submitted in the right format, with all of the right labels and coding. An "error report" is generated that is supposed to alert the hospital if it appears data were received in a way that is not consistent with the requirements. The hospital is supposed to receive this report in time to make any necessary corrections. However, the report can be hundreds of pages long with a multitude of meaningless notations. A significant problem in data transmission might have occurred, but the indications of it are buried in this voluminous report and may not be discovered until it is too late for the hospital to make a correction. In addition, the data collection vendors on whom the hospitals rely to format and submit the data correctly do not have access to these error reports, nor do they have any other mechanisms for checking to make sure that the data they sent was received correctly. This has inevitably led to errors not being caught in time. When these errors are then left in the database, the CMS contractors' reabstraction of the data does not match up with what is recorded for the hospital in the database, leading to the hospital failing validation.

Another common problem results when the contractor has asked for the medical record pertaining to a particular patient, but has not specified which admission it wanted. Since it is not uncommon for heart failure patients to be readmitted for care, the omission of the specifics on which admission was being reabstracted has inevitably led to the hospital copying and

submitting data on one admission, and the contractor trying to make that match up with the data for a different admission – and the data simply will not match up.

There also have been many reported instances in which the contractor conducting the reabstraction of the data failed to find information that was clearly in the medical record – a simple human error, but one that should not be used to penalize the hospital.

CMS was made aware of these problems with the validation process and it has begun to work to improve the process reliability so it can be used to support payment decisions. However, in the first three calendar quarters of 2005, the validation process did not have sufficient integrity to warrant hospital payments being withheld based on the validation results. At this juncture, we firmly believe that the problems with the validation process itself need to be resolved before any payment decisions are made solely on the basis of the contractor's work. **We strongly urge CMS to review, on a case-by-case basis, any incidence where a hospital's payment would be put in jeopardy as a result of the validation process. It should allow the hospital to submit information showing that it made a good-faith effort to supply the data warehouse with accurate information so that the public could be informed about the quality of its care. If the hospital has made a good-faith effort, it should receive full payment regardless of whether the data are deemed accurate enough for public display.** In addition, CMS should instruct its QIO data warehouse to accept any significant corrections so that the public can have a full and accurate picture of hospital quality.

OUTLIER PAYMENTS

The rule proposes establishing a fixed-loss cost outlier threshold equal to the inpatient PPS rate for the DRG, including indirect medical education (IME), disproportionate share hospital (DSH), and new technology payments, plus $25,530. While this is not a particularly sizable increase from the FY 2006 payment threshold of $23,600, we remain very concerned that the threshold is too high. According to our analyses, actual outlier payments for FY 2006 are estimated to be 0.47 percentage points lower than the 5.1 percent of funds withheld from hospitals to fund outlier payments. CMS spent only 3.8 percent, or $1.15 billion less than set aside in FY 2005, and only 3.5 percent, or $1.3 billion less than the funds withheld in 2004.

In the rule, CMS proposes to use a one-year average annual rate-of-change in charges per case from the last quarter of 2004, in combination with the first quarter of 2005, to the last quarter of 2005, in combination with the first quarter of 2006, to establish an average rate of increase in charges. This results in a 7.57 percent rate of change over one year, or 15.15 percent over two years.

The AHA appreciates that CMS is proposing this methodology in an effort to avoid using data from 2003 when charges may have been atypically high. **However, using the proposed charge inflation methodology will only result in an inappropriately high outlier threshold and a real payment cut to hospitals. The AHA strongly opposes using this methodology to estimate the outlier threshold.** The AHA conducted a series of analyses to identify a more appropriate methodology. Below we put forth for CMS' consideration a methodology that incorporates both *cost* inflation and *charge* inflation. We believe the use of more than one indicator will make the threshold calculation more accurate and reliable.

First, we inflated 2005 charges by 15.71 percent (the inflation factor used by CMS in the proposed rule) and then reduced the charges to costs. Instead of using the cost-to-charge ratios (CCRs) from the CMS Impact File, we used the CCRs from the March 31, 2006 HCRIS release. In addition, we accounted for the nine-month lag from the end of a cost-reporting period until the FI is able to update the CCR. We accomplished this by projecting forward from the most recent fiscal period in the March 31 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining federal FY 2007 outlier payments.

The cost inflation factor for projecting CCRs was determined from the cost reports of a cohort of 3,253 matched hospitals for periods beginning in federal FYs 2002, 2003 and 2004. All three cost reports were available for each hospital from the recent update of HCRIS. The 2002-2004 aggregate annual rate of increase in the cost per discharge for these hospitals was 5.69 percent[2]. This cost inflation factor and the CMS charge inflation factor of 7.57 percent were used to project CCRs over the time periods described above. The projected CCRs were applied to projected federal FY 2006 charges to simulate the determination of costs for FY 2007 outlier payments. **The estimated fixed-loss amount that would result in 5.1 percent outlier payments under this methodology is $24,000.**

The AHA strongly urges CMS to adopt this methodology, which is applicable regardless of what DRG changes are made or not made in FY 2007. We estimate that the fixed-loss threshold necessary to achieve 5.1 percent in FY 2006 should have been set at $21,275 as compared to the $23,600 actually utilized. We believe CMS underspent the funds set aside for outliers by an estimated $3 billion over FYs 2004, 2005 and 2006. **This is a real cut in payments to hospitals that cannot be recouped. If CMS leaves the threshold at $25,530, rather than dropping it to $24,000, we believe that CMS will again significantly underspend by over $300 million.** We urge CMS to adopt our recommended methodology to lower the outlier threshold. Attached is the full analysis, conducted by Vaida Health Data Consulting.

CORE-BASED STATISTICAL AREAS (CBSAS)

In adopting the Core-based Statistical Areas (CBSAs) in FY 2005, a small number of hospitals that were classified as urban in FY 2004 became classified as rural in FY 2005. Because moving from a Metropolitan Statistical Area (MSA) to the rural statewide average would have resulted in a significant decline in these hospitals' wage indexes, CMS implemented a three-year transition period (FYs 2005-2007). The AHA supports the continued transition for these hospitals to give them the opportunity and time to reclassify.

OCCUPATIONAL MIX ADJUSTMENT

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 requires CMS to collect data every three years on the occupational mix of employees from hospitals subject to the inpatient PPS in order to construct an occupational mix adjustment to the wage

[2] An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 2,729 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2006 HCRIS update.

index to control for the effect of hospitals' employment choices – such as greater use of registered nurses (RNs) versus licensed practical nurses or certified nurse aides – rather than geographic differences in the costs of labor.

CMS initially stated in the proposed rule that it would again limit the occupational mix adjustment to 10 percent because of concerns regarding the validity of the data and the potential financial impact on hospitals. However, as a result of the decision handed down by the U.S. Court of Appeals for the Second Circuit on April 3 in *Bellevue Hospital Center v. Leavitt*, CMS on May 12 released a proposed rule revising the occupational mix adjustment portion of the FY 2007 inpatient PPS proposed rule. Under the court ruling, CMS must collect new data on the occupational mix of hospital employees and fully adjust the area wage index (AWI) for FY 2007.

Hospitals are required to collect the hours and wages for employees from January 1 through June 30, 2006. Data initially was supposed to be collected by July 31; however, hospitals are required to submit data by June 1 for the first calendar quarter of the year and by August 31 for the second calendar quarter. Data from the first quarter will be used to adjust the FY 2007 AWI, while data for the full six months will be used to adjust the AWI for FYs 2008 and 2009.

Definitions and Covered Employees. In filling out the interim-survey, our members found that the placement of certain employees caused confusion. Examples include surgical technicians, paramedics who are employed by the hospital and usually work in the emergency department, and unit secretaries who are also known as ward clerks. CMS clarified after the proposed rule was released that these employees should be placed in the "all other" category for the interim-collection. Moving forward, CMS should re-evaluate where these employees belong. **However, such changes should not be made to the ongoing collection, as it would necessitate the resubmission of the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009.** If CMS believes that such changes are warranted, then the hospitals will need notification prior to the release of the final inpatient PPS rule in order to meet the August 31 deadline for submissions.

Cost Centers. We agree with CMS' "bright line" clarification for this collection that only nursing personnel within the cost centers listed should be included in that category for the purposes of consistency. It is significantly less work for hospitals to focus on certain cost centers, and we continue to support this methodology. **We believe that the vast majority of nursing personnel within a hospital fall within these cost centers and do not believe that CMS should include every cost center that may have a few nursing personnel included in it.**

However, CMS should consider refining the list for future collections. Every hospital has a different method for attributing costs to the cost centers, thus there are probably a few cost centers that contain a significant number of nursing personnel for certain hospitals that were not captured for this collection. Given the shortened comment period in combination with the magnitude of the other changes proposed by CMS in the inpatient PPS rule this year, we were unable to extensively research which cost centers CMS should add. We suggest that CMS accept comments on any potential changes to the cost center list before making such changes. **In addition, we believe that additional cost centers should *not* be added to the ongoing collection as it would necessitate the resubmission on the first calendar quarter's data to ensure that both quarters could be used for FYs 2008 and 2009.** If CMS believes that such

changes are necessary for the current collection, then hospitals would need notification prior to the release of the final inpatient PPS rule in order to meet the August 31 deadline for submissions.

Non-responsive Hospitals. Because data from all hospitals is needed to construct an accurate national average hourly wage, full participation is critical. There is a general sentiment that hospitals that do not participate should not benefit from the participation of others. However, given the rushed collection and general confusion around the interim-collection, we believe that, to the extent possible, **CMS should substitute data from the previous survey for hospitals that did not turn in their data for the first calendar quarter of 2006.**

However, hospitals will have plenty of notice and time to submit data for the second calendar quarter in August. Thus, moving forward CMS should consider a methodology that penalizes hospitals that do not participate. We caution CMS not to simply substitute unfavorable data for these hospitals, as it also will impact other area hospitals that conscientiously reported data. CMS could alternatively substitute the national average hourly wage for non-responsive hospitals in calculating an area's wage index, and then require hospitals that did not turn in data to use something lower than their area's wage index. This would avoid CMS having to create an extensive hospital-specific wage index table and would minimize the effects on the other hospitals in the area. **We urge CMS to construct an application of the occupational mix adjustment that encourages hospitals to report but does not unfairly penalize neighboring hospitals.**

Corrections. **The AHA urges CMS to allow hospitals to turn in both calendar quarters of data in August whether for the first time or with corrections.** Again, as this collection has been rushed, the idea is to allow hospitals to improve the data for the FYs 2008 and 2009 adjustment. For hospitals that were previously non-responsive, the submission of the first calendar quarter would remove any penalty, while those that continue to be non-responsive will continue to incur a penalty.

Comment Timeframe. While we understand that CMS is under severe time pressure due to the timing of the court's decision, we do not believe that the 30-day comment period was sufficient, as hospitals were busy during this time trying to meet the new survey deadline and answering requests for information from the FIs. In addition, we believe it would be appropriate for CMS to take comments on the calculation after the initial results of the survey are tabulated and posted. The results of the survey could be material. For instance, if the segregation of RNs who are management versus RNs who are staff does not produce a reliable result, CMS might consider consolidating the two for the purposes of the calculation. While CMS might not have time to make such changes for FY 2007, it could entertain comments on the implementation for FYs 2008 and 2009. **Thus, we urge CMS to publish the occupational mix adjustment changes as an interim-final rule in August with an associated comment period.**

HOSPITAL REDESIGNATIONS AND CLASSIFICATIONS

Section 508 Reclassifications. Section 508 of the *Medicare Modernization Act* (MMA) provided $900 million over three years for a one-time geographic reclassification opportunity, which expires March 31, 2007. Because the 508 reclassifications expire mid-year and hospitals may

not receive Section 508 funding at the same time as any other form of reclassification, CMS has proposed special provisions for accepting or denying partial-year reclassifications for FY 2007.

In FY 2006, CMS stated that individual hospitals reclassified under Section 508 would be allowed to request regular reclassification for the portion of the three-year period that the hospital is not receiving Section 508 funding, or to turn down the Section 508 reclassification for the first half of FY 2007 and receive regular individual reclassification for the full three years.

CMS also stated that Section 508 hospitals that would like to be part of a group reclassification could turn down their 508 reclassification for the first half of FY 2007 and join a group for the full three-year period. Or the hospitals could maintain Section 508 reclassification while the rest of the group gets their "home wage index" for the first half of the year. The entire group then could reclassify together for the rest of the three-year period.

In the proposed rule, CMS clarifies that "home wage index" means that hospitals could receive the wage index they otherwise would have, absent the group reclassification. For some hospitals, this might literally be the wage index for the area in which they are located. For others, this may mean an individual reclassification to another area.

Section 508 hospitals, and those involved in a group reclassification with a Section 508 hospital, would normally have been required to accept or reject reclassification within 45 days of the publication of the proposed rule; however, the complications with the occupational mix adjustment will prevent this. **We appreciate and support CMS' flexibility around the expiration of Section 508 and the reclassification deadlines given the unusual circumstances this year.**

GEOGRAPHIC RECLASSIFICATIONS

Multi-campus Hospitals. Payment is determined using the wage index value for the MSA in which a campus is located, even though the organization may have other campuses located in different labor market areas. Because multi-campus hospitals submit a single cost report that does not break down wage data by campus, an individual campus historically has been unable to seek reclassification. For FYs 2006-2008, CMS authorized individual campuses to use the average hourly wage data of the entire multi-campus hospital system to seek geographic reclassification to the labor market area in which the other campus(es) are located. CMS also stated in the FY 2006 rule that, in the future, it would continue to consider mechanisms to collect the data necessary for geographic reclassifications that are not unduly burdensome for providers. However, CMS now proposes rescinding this option, as there was only one hospital in the country that was affected by this situation and, after the change in labor market areas in FY 2005, it has subsequently joined an urban county group that is reclassified to the area in which it was previously reclassified using the multi-campus hospital rule.

The AHA opposes CMS' proposal to remove this option. While CMS may know of only one hospital at this point, there may be others, and additional hospitals may be affected after the next census collection and subsequent changes in labor market definitions. In addition, the need for this provision has not subsided as CMS suggests. This hospital will need to use either campus-

specific or hospital-wide data for its next reclassification, whether group or individual, and lack a method to do so.

CMS suggests that each campus should disaggregate and receive its own provider number. A multi-campus hospital with a single provider number provides certain health and treatment benefits to patients, such as the ability to move among campuses for various aspects of treatment. Each campus may specialize in a particular service (oncology, cardiology, etc.) and patients can move among the campuses with one medical records system, one billing system and a unified medical staff. Economies of scale reduce costs for the whole system. **Thus, we do not believe it is a realistic or appropriate option to force these campuses to apply for individual provider numbers.**

We recommend that CMS continue to allow multi-campus hospital systems to use the data from all campuses as a proxy for individual campuses to reclassify to an area where another one of the campuses is located given how few hospitals are expected to use this option. This is a reasonable request as most multi-campus hospital systems likely pay equal or similar wages at each campus. If CMS finds that the situation becomes more prevalent, it could require the manual completion of the campus-specific Schedule S-3 for those hospitals that do not have the appropriate individual campus data. However, if CMS moves to a campus-specific S-3, CMS still needs to extend the current special rule for five years until the new campus-specific data is useable for an application.

Urban Group Reclassifications. The AHA supports CMS' proposal to allow hospitals located in counties that are in the same CBSA as the county in which they seek redesignation to be considered to have met the proximity requirement. By failing to include CBSAs in the proximity criteria, CMS has excluded one group of hospitals, those located in Palm Beach County, FL, from being able to reclassify to the Fort Lauderdale-Pompano Beach-Deerfield Beach division of the Miami CBSA. **Given that CBSAs are actually more refined classifications than Combined-statistical Areas, we believe that the inclusion of CBSAs in the proximity criteria would be consistent with CMS' policy goals and protect hospitals from unintended consequences.**

Critical Access Hospitals in Lugar Counties. As a result of changes in the labor market area definitions made in response to the results of the 2000 census, counties in which a number of Critical Access Hospitals (CAHs) are located became "treated" as urban instead of rural under the inpatient PPS because of a statutory provision modifying the status of rural counties with certain commuting patterns to metropolitan areas. In its FY 2005 final rule, CMS interpreted this provision as applying to CAHs located in these counties (known as "Lugar counties" after the Senate sponsor of the provision) and allowed these facilities a grace period to seek reclassification as rural in order to retain their CAH status.

While accommodating CAHs in this manner, the agency also took the position that any CAH being reclassified would no longer be eligible for pass-through payments for the services of certified registered nurse anesthetists (CRNAs). Its reasoning was that the facility was no longer "located in a rural area (as defined for purposes of section 1886(d) of the Social Security Act)" as the pass-through statute requires, but were only reclassified as rural.

In response to comments received on the FY 2006 proposed rule, CMS announced a policy change in the final rule for FY 2006 stating that Lugar county designation would not affect a CAH's rural status because the statutory provision creating such counties only applies to hospitals paid under the inpatient PPS (CAHs are paid under a separate, cost-based system). This policy change had the effect of eliminating the need for these CAHs to seek either geographic reclassification or a waiver of the Lugar statute (which CMS has maintained it has no authority to do). **In effect, under this new reading of the law, the provision creating Lugar counties does not apply *at all* for purposes of CAH eligibility.**

Despite this policy change, CMS continues to maintain that a CAH located in a newly-designated Lugar county cannot qualify for CRNA pass-through payments. This position is at odds with the agency's view that *it is geographic reclassification that renders a CAH ineligible for such payments* – since, under CMS' revised policy, a CAH located in such a county need not seek geographic reclassification to be a CAH. Apparently, it is CMS' view that these CAHs can never qualify for CRNA pass-through payments, whether they have sought reclassification (under the old policy) or not (under the new policy). **We believe that all CAHs located in a newly-designated Lugar county should receive pass-through payments, regardless of whether they sought reclassification, and urge CMS to revise its regulations accordingly.**

WAGE INDEX BUDGET NEUTRALITY

CMS eliminates the CAH data from the wage index file it uses to compute the national average hourly wage (NAHW). For FY 2007, 1,191 CAHs representing approximately 24 percent of all inpatient PPS hospitals (as of FY 2000) – 55 percent of all rural hospitals in FY 2000 – have been eliminated from the file. Because CAHs have lower average hourly wages (AHWs) than the average PPS hospital, the elimination of this data results in an overstated NAHW. While the NAHW has been increasing, the systematic withdrawal of low-wage hospitals has artificially inflated the NAHW to some extent. This artificial increase is included in the negative budget neutrality adjustment that consequently reduces payment, resulting in the national inpatient PPS operating payments being understated by an estimated $1.52 billion over five years (2003-2007). **Thus, we believe that CMS should apply a positive budget neutrality adjustment in FY 2007 to compensate for the underpayments.** The understatement increases each year as more hospitals become CAHs and more data are eliminated from the wage index data. However, we believe that this could be a one-time adjustment as we expect very few hospitals to convert to CAH status now that the necessary provider designation is no longer an option.

LOW-VOLUME HOSPITAL PAYMENT ADJUSTMENT

Section 406 of the MMA created a payment adjustment under the inpatient PPS to account for the higher costs per case of low-volume hospitals. The law defined eligible hospitals as those located more than 25 miles from another facility with fewer than 800 total discharges annually. The rule proposes to maintain a 25 percent increase, the maximum allowable, in payments to hospitals with fewer than 200 discharges. For those hospitals that have between 200 and 800 discharges, CMS proposes to maintain its current policy, applying no payment increase. Only two hospitals will receive this adjustment in FY 2007 according to CMS estimates. **The AHA is concerned that CMS is ignoring congressional intent and denying a group of hospitals –**

those with more than 200 discharges but fewer than 800 discharges – access to this necessary payment increase.

SCH/MDH Changes in Qualification Status

The proposed rule would require an approved sole community hospital (SCH) or Medicare dependent hospital (MDH) to notify the appropriate CMS Regional Office of any change affecting its classification as such. To date, it has been the FIs responsibility to evaluate hospitals' continuing qualification for SCH or MDH status. CMS expects the hospital to now self-disclose any material changes in circumstances or potentially face a retroactive cancellation of their designation once an FI discovers its ineligibility.

This appears to be an inappropriate shift of the burden from the FIs to hospitals. For instance, hospitals are neither involved in, nor have any control over, the building of new roads or new hospitals and thus should not be accountable to report such changes. It also would be very difficult for hospitals to know when and for how long there were prolonged severe weather conditions that closed area roads, or to note changes to posted speed limits and traffic patterns. In addition, some of the qualifying criteria, such as inpatient admissions at other regional hospitals, would be hard to monitor as the hospitals do not have this sort of data on their competitors. Requiring hospitals to constantly monitor whether they continue to meet these requirements would impose a tremendous and unreasonable administrative burden on hospitals. **The AHA recommends that this function remain a responsibility of the FIs, who are in a better position to monitor these circumstances. If CMS requires hospitals to report changes in circumstances, then the specific types of situations should be noted and should only include aspects of their operation that are within their control (e.g., number of beds).**

CMS' proposal to retroactively withdraw SCH or MDH status if a hospital does not appropriately self-report a change in circumstances could be financially devastating. CMS should at minimum give consideration to whether the hospital had knowledge of the disqualifying circumstance. Hospitals should not have to repay CMS based on the difference between the inpatient PPS or outpatient PPS payment and the SCH or MDH payment when they did not know that they no longer qualified for the program. Instead CMS should develop a prospective process for withdrawing the hospitals' SCH or MDH status. We believe that a 30-day timetable for losing SCH/MDH status is unrealistic given the financial implications of such a change and the inability for a hospital to plan for this outcome. **CMS should re-evaluate the proposed timetable for canceling SCH/MDH status when a hospital is found to be disqualified or self-reports disqualification and consider revoking the hospitals' status as of the following cost-reporting period.**

SCH/MDH Volume Decrease Adjustment

An SCH or MDH may apply for special payments if it experiences a decrease of 5 percent or more in its total number of inpatient discharges that was out of its control from one cost-reporting period to another. If the hospital qualifies, it must demonstrate that it took measures to scale back its nursing force commensurately. The adjustment is intended to cover the fixed costs that the hospital is unable to reduce in the year following the volume decrease. CMS believes

that only "core staff and services" should be covered by these special payments. To date, CMS has used the AHA's HAS/Monitrend Data Book to compare the hospital's staffing to other similar hospitals in the area to determine if the hospital is staffing its routine and intensive care units appropriately. However, the Data Book has not been updated since 1993. CMS has been using the 1989 publication. Thus, CMS proposes using the occupational mix adjustment data currently being collected for wage index purposes to calculate nursing hours per inpatient day for a hospital in question and local peer hospitals.

The occupational mix adjustment was only partially implemented in its first three years, primarily due to the questionable data and results. The current collection, which is occurring again under rushed circumstances, may also result in questionable data. **We do not believe that it is wise to assume that the occupational mix adjustment data will be appropriate for this use. The AHA believes that the data within the AHA annual survey should be sufficient for CMS to determine the nursing levels per patient day.**

RURAL REFERRAL CENTERS

If a hospital wants to become a Rural Referral Center (RRC) but does not have 275 or more beds, it must meet two mandatory alternative criteria plus one of three additional criteria. The proposed rule would update the alternative criteria for RRC designation in FY 2007.

Until recently, the median case-mix index values were very stable. The chart below illustrates the volatility over the past few years in the values for two regions:

Region 7 West South Central	
FY 2005	1.1371
FY 2006	1.3532
FY 2007	1.2445
Region 6 West North Central	
FY 2005	1.0855
FY 2006	1.2252
FY 2007	1.2856

While it is not clear why this is occurring, it does suggest a possible methodological problem. **Thus, we recommend that CMS undertake additional analyses to determine the cause of the recent fluctuations.** This is particularly important given the possible disruption to case-mix patterns as a result of a new patient classification system such as the CS-DRG proposal.

CRITICAL ACCESS HOSPITALS (CAHS)

On November 14, 2005, CMS issued interpretive guidelines on the relocation of CAHs as a follow-up to the FY 2006 inpatient PPS final rule that established the "75% test" – serving 75 percent of the same population, providing 75 percent of the same services and employing 75 percent of the same staff – for necessary provider CAHs. The guidelines not only extended the 75% test to *all* CAHs, but it also altered the definitions of "mountainous terrain" and "secondary road."

We believe that these guidelines go well beyond the regulations included in the FY 2006 rule that provoked numerous critical responses from individual CAHs, associations and congressional representatives. The "mountainous terrain" and "secondary road" definitions are overly prescriptive and the 75% test does not provide reasonable flexibility based on natural variation in demographics, patient needs distribution patterns, normal employee and board attrition, and necessary changes in services to meet community needs. **Rural hospitals that move a few miles are clearly the same providers serving the same communities.**

Many CAHs are planning to rebuild in the near future to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or making other essential upgrades. Facilities expect to relocate when they rebuild for a multitude of reasons: to be closer to a highway, to connect to municipal water and sewer, because of seismic safety concerns, or other similar concerns. **Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service, yet CMS' guidelines discourage these improvements.**

CMS' guidelines will not only impose an unnecessary burden on CAHs, but will preclude many of them from securing financing for needed capital improvements. The hospitals themselves, their hospital districts and their lenders cannot risk investing in a hospital that will be unsure of its status until a year after moving. **CMS should create a preliminary approval process to give assurances to those involved in the project that the CAH relocation will be approved if it meets the assertions made in the attestation submitted to CMS.**

Again this year, almost 60 congressional representatives signed a letter to CMS showing their support for their CAHs and urging changes to these guidelines. We agree with their recommendations and reiterate our suggestion from last year that a safe harbor be established for hospitals relocating within five miles of their existing locations. These providers are not only clearly serving the same communities, but trying to improve the quality of and access to needed health care services. A safe harbor will reduce the administrative burden on not only the hospitals, but CMS and the state survey agencies as well. **We urge CMS to create a safe harbor for CAHs moving a short distance and to make significant changes to these guidelines based on the feedback from CAHs around the nation as detailed in our letter under separate cover to Thomas Hamilton, director of the survey and certification group.**

GRADUATE MEDICAL EDUCATION (GME) PAYMENTS

Exclusion of Didactic Training. The proposed rule states that resident training that occurs at non-hospital sites must be related to patient care if a hospital wishes to count that time for direct medical education (DGME) and indirect medical education (IME) payment purposes. Resident time spent in didactic activities that often occur in associated medical schools – such as educational conferences, journal clubs and seminars – would specifically be excluded. CMS noted that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS also noted that time spent in these activities could be counted for DGME purposes if they occur in a

hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

We strongly urge CMS to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare DGME and IME payments. The stated rationale for the exclusion of this time is that it not "related to patient care." This position is in stark contrast to CMS' position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty."[3]

We strongly agree with CMS' 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. In addition, it would be very difficult to separate out time spent at these activities. **We urge CMS to withdraw this change in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.**

EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA)

Definition of "Labor." **The AHA supports CMS' proposal to modify the definition of "labor" at 489.24(b) to allow a certified nurse-midwife or other qualified medical personnel operating under their scope of practice, as defined in hospital medical staff bylaws and in state law, to certify that a woman is in false labor.** This change recognizes that licensure and scope of practice should remain under the purview of state law and regulation. Further, this change provides hospitals with the staffing flexibility needed to maintain access to and the efficiency of vital obstetrical services, particularly in hospitals located in areas of the country that may find it difficult to attract and retain physicians, such as rural areas.

Hospitals without Dedicated Emergency Departments (ED). Under the proposed rule, a hospital with "specialized capability" is required to accept appropriate transfers under EMTALA regardless of whether it has a dedicated ED. **Guidance is still needed on the definition of specialized capability.** The EMTALA technical advisory group (TAG) has the ability to make recommendations for clarifying guidance, and we look forward to working with its members on this topic. In addition to questions related to the availability of on-call physicians and inpatient psychiatric resources, this proposed regulation calls into question application to inpatient rehabilitation facilities and long-term acute care hospitals.

The AHA agrees that a physician-owned, limited-service hospital should be treated as a hospital "with specialized capability or facilities" under EMTALA without regard to whether it has an ED. However, in the DRA-mandated HHS interim report to Congress on its development of a strategic plan regarding physician investment in specialty hospitals, the Secretary suggested that this interpretation of EMTALA "may result in an increase in the number of specialty hospitals accepting transfers of emergency patients on nights and weekends." (CMS

[3] September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins.

uses "specialty" to mean the hospitals covered under Congress's moratorium, i.e., physician-owned, limited-service hospitals providing primarily cardiac, surgical or orthopedic services.) **As presented in our statement to the EMTALA TAG when this question was considered, we believe it is unlikely this will result in improved access for patients to the specialty care they need.**

It is important to separate the capabilities of the practicing physicians from the capabilities of the facility in which they are practicing. While the physician expertise housed in the physician-owned, limited-service facility could be capable of meeting the needs of community hospital patients, the facility is seldom designed or operated in a manner to support this level of practice. Although physician-owned, limited-service hospitals hold themselves out as "hospitals," many of these facilities actually have a range of capabilities more similar to a hospital department or ambulatory surgical center. These hospitals often do not have emergency capabilities, as they are geared toward elective cases of minor severity. Their capabilities are typically limited to a single major diagnostic category, and they staff for minimal inpatient capacity. Many of these facilities minimize resource consumption by being almost a Monday through Friday operation. For these reasons, it generally would not be in the best interests of community hospital patients to be transferred to these facilities.

At the same time, many physician-owned, limited-service hospitals have withdrawn specialist services from the community at-large. As their physicians maintain an increasing amount of their practice at these hospitals or other sites outside the community hospital (e.g., ambulatory surgical centers), they are much less willing to accept on-call responsibility for the broader community's emergency needs. While withdrawing specialist services from on-call coverage, these same physician-owned, limited-service hospitals presume to rely on the community hospital for back-up in the event of complications requiring around-the-clock access to emergency care and inpatient admission to the community hospital. With the change in physician practice patterns and the increased number of physicians requesting only courtesy admitting privileges at community hospitals, relying only on the professional obligations attached to admitting privileges is not sufficient to assure appropriate transfer arrangements and the availability of physicians to provide emergency specialty capacity. **Every physician-owned, limited-service hospital that relies on the community's emergency services capacity should be obligated to support it.**

In addition, this policy does not address the problem of patients at physician-owned, limited service hospitals who suffer from complications appearing in a hospital ED with no warning call, no medical history, no operative report, no information on the anesthesia used and, often, no ability to reach the treating surgeon for consultation. **Physician-owned, limited-service hospitals should be required to have agreements with the community hospitals they plan to rely on in the event that they do not have the capacity to treat a particular patient.**

Specifically, the AHA recommends the following:

- **A physician-owned, limited-service hospital should be required to have a pre-existing agreement with the community hospital(s) it intends to rely on for emergency back-up services.**

- **The Secretary should establish the terms that must be addressed by an agreement, including:**

  - **Procedures for an appropriate transfer for patients not covered under EMTALA** (e.g., inpatient or outpatient whose condition develops into an emergency beyond the capability of the limited-service hospital and consequently needs to be transferred to a full-service hospital);
  - **Continuity of care** (e.g., telephone consultation with the receiving hospital and physician, sending the patient's medical records along when transferred, etc.); and
  - **Support for maintaining full-time emergency capacity at the community hospital, including on-call coverage** (e.g., physician-owned, limited-service hospital physicians serve in on-call panels at the community hospital, or the physician-owned, limited-service hospital provides financial support to the community hospital to maintain on-call coverage).

NEW TECHNOLOGY

Section 503 of the MMA provided new funding for add-on payments for new medical services and technologies and relaxed the approval criteria under the inpatient PPS. This important provision was enacted to ensure that the inpatient PPS would better account for expensive new drugs, devices and services. However, CMS continues to resist approval of new technologies and considers only a few technologies a year for add-on payments. **The AHA also is disappointed that CMS has not increased the marginal payment rate to 80 percent rather than 50 percent, consistent with the outlier payment methodology, as previously requested by the AHA.**

Moreover, we are concerned about CMS' ability to implement add-on payments for new services and technologies in the near future. Recognizing new technology in a payment system requires that a unique procedure code be created and assigned to recognize this technology. The ICD-9-CM classification system is close to exhausting codes to identify new health technology and is in critical need of upgrading.

Since the early 1990s, there have been many discussions regarding the inadequacy of ICD-9-CM diagnoses and inpatient procedure classification systems. ICD-10-CM and ICD-10-PCS (collectively referred to as ICD-10) were developed as replacement classification systems.

The National Committee on Vital and Health Statistics (NCVHS) and Congress, in committee language for the MMA, recommended that the Secretary undertake the regulatory process to upgrade ICD-9-CM to ICD-10-CM and ICD-10-PCS. Congress' call for action recognized that procedure classification codes serve to identify and support research and potential reimbursement policies for inpatient services, including new health technology, as required under the *Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000.*

To date, despite these recommendations, as well as the recommendations of several federal health care agencies and offices and health care trade and professional associations, HHS has not yet moved forward to adopt the ICD-10 classification upgrades. We believe that absent a switch

to ICD-10 soon, there will be a significant data crisis in the U.S. This coding crisis will affect the efficiency of the current coding process, adding significant operational costs. In addition, failure to recognize this looming problem will only impede the efforts to achieve President Bush's goal for an electronic health record by 2014.

At the April 2005 ICD-9-CM Coordination and Maintenance (C&M) committee meeting, there were many impassioned discussions on the need to start limiting the creation of new procedure codes in order to allow the classification system to last at least two more years. ICD-9-CM procedure code categories 00 and 17 were created to capture a diverse group of procedures and interventions affecting all body systems. The establishment of these code categories represented a deviation from the normal structure of ICD-9-CM and a stopgap measure to accommodate new technology when no other slots in the corresponding body system chapters (e.g. musculosketal system, circulatory system, etc.) were available. The plan was to use codes in chapter 00 first and then begin populating chapter 17.

Category 00 is now full, and the C&M committee is entertaining proposals for codes in category 17. At the April C&M meeting a proposal was presented that would in effect leave only 80 codes available in this category. Many of the specific body system chapters are already filled (e.g., cardiac and orthopedic procedures). In recent years, as many as 50 new procedure codes have been created in a single year. This means that it is possible for ICD-9-CM to completely run out of space in one-and-a-half years. We concur with the NCVHS recommendation to issue a proposed rule for adoption of ICD-10. We also would support an implementation period of at least two years following issuance of a final rule.

The AHA strongly recommends that the Secretary undertake the regulatory process to replace ICD-9-CM with ICD-10-CM and ICD-10-PCS expeditiously. HHS should take the necessary steps to avert this crisis and avoid being unable to create new diagnosis or procedure codes to reflect evolving medical practice and new technology. It is easier to plan for this migration than respond to a crisis that will likely result in unreasonable implementation timeframes. It is imperative that the rulemaking process start immediately.

OTHER FUTURE CONCEPTS

TRANSPARENCY OF HEALTH CARE INFORMATION

The proposed rule includes the introduction of a proposed initiative to expand the public availability of consumer information on health care quality and pricing. HHS intends to identify several regions in the United States with high health care costs where there is significant interest in reducing those costs and improving health care quality.

Significant progress has been made in making quality information more transparent. The AHA, the Federation of American Hospitals and the Association of American Medical Colleges partnered with CMS and others to form the Hospital Quality Alliance (HQA). The work of the HQA has led to the voluntary reporting and sharing with the public of 21 quality measures on the *Hospital Compare* Web site, and more measures of hospital quality and patient satisfaction are planned for the future. This effort has been tremendously successful, with nearly all inpatient

PPS hospitals voluntarily reporting quality information. **Efforts to further expand public availability of hospital quality information must continue to be pursued through the HQA.**

While progress has been made regarding quality transparency, similar information on hospital pricing is less accessible. In the proposed rule, CMS details four options for providing pricing information to health care consumers, including:

- Publishing a list of hospital charges, either for every region of the country or selected regions of the country;

- Publishing the rates that Medicare actually pays to a particular hospital for every DRG, or for selected DRGs, which could be adjusted to account for the hospital's labor market area, teaching hospital status and DSH status;

- Establishing conditions of participation for hospitals that relate to the posting of prices and/or the posting of their policies regarding discounts or other assistance for uninsured patients; and

- Posting total Medicare payments for an episode of care. Under this proposal, CMS could include the costs for an inpatient hospital stay, physician payments (including the surgeon and the anesthesiologist), and payments for post-acute care services such as those provided in an inpatient rehabilitation facility, skilled nursing facility or LTCH for a certain service (such as hip replacement).

People deserve meaningful information about the price of their hospital care. Hospitals are committed to sharing information that will help people make important decisions about their health care. Sharing pricing information, however, is more challenging because hospital care is unique. Hospital prices can vary based on patient needs and the services they use; prices reflect the added costs of hospitals' public service role – like fire houses and police stations – serving the essential health care needs of a community 24 hours a day, seven days a week; and most hospitals cannot yet provide prices that reflect important information from other key players like the price of physician care while in the hospital or how much of the bill a patient's insurance company may cover. But more can, and should, be done to share hospital pricing information with consumers.

Providing *meaningful* information to consumers about the price of their hospital care is the most significant challenge hospitals, and CMS, face in increasing transparency of hospital pricing information. Objectives for improving pricing transparency should include:

- Presenting information in a way that is easy for consumers to understand and use;

- Making information easy for consumers to access;

- Using common definitions and language to describe pricing information for consumers;

- Explaining to consumers how and why the price of their care can vary; and

- Encouraging consumers to include price information as just one of several considerations in making health care decisions.

The AHA recently released a position statement on hospital pricing transparency outlining steps to be taken to improve the pricing information available to health care consumers. The following four steps represent the AHA's roadmap for pricing transparency.

1) A federal requirement for states, working with state hospital associations, to expand existing efforts to make hospital charge information available to consumers.

- Thirty-two states already have statutes requiring hospitals to report pricing information that is made available to the public either by posting to a hospital, hospital association or government Web site, issued in a government or hospital association report, or made available to consumers upon request; five additional states voluntarily do so.

- State efforts on price transparency vary, from making individual hospitals' master list of charges available to the public (e.g., California), to making pricing information on frequent hospital services available to the public (e.g., Missouri, Florida, Nevada, North Carolina), to making information on all inpatient services available to the public (e.g., Colorado, Kentucky, Oregon, Pennsylvania, Wisconsin).

2) A federal requirement for states, working with insurers, to make available in advance of medical visits, information about an enrollee's expected out-of-pocket costs.

- This information is especially important to the majority of consumers who already have some type of health insurance coverage. Their likely interest is in knowing the amount for which they personally are financially responsible. This information is provided today to consumers by their insurance company – it is called an "explanation of benefits, or EOB – but is only given after care is provided. To help inform consumers in advance of their out-of-pocket obligations, insurers could provide an "advance EOB." This information could be shared with an insured individual by phone or electronically through an insurer's Web site. Aetna is currently piloting a project like this for physician services in Cincinnati.

3) A federal-led research effort to better understand what type of pricing information consumers want and would use in their health care decision-making.

We have learned much based on research about what kind of information consumers want about the quality of their health care. But we know less about what consumers may want to know about pricing information. Consumers need different types of price information, depending on whether and how they are insured. The following illustrates different consumer needs:

- **Traditional Insurance.** Because traditional insurance typically covers nearly all of the cost of hospital care, people with this type of coverage are likely to want information

about what their personal out-of-pocket cost would be if they receive care at one hospital versus another.

- **Health Maintenance Organization (HMO) Insurance.** People who have HMO coverage will have even more specific price information needs. They have agreed, in advance, to adhere to certain limits on their choice of physician or hospital in exchange for broad-based coverage of their health care needs. A person with HMO coverage typically faces no additional cost for care beyond their premium and applicable deductibles and copayments, but must agree to use physicians and hospitals that are participating in that HMO plan. These individuals likely have little, if any need for specific price information.

- **High-Deductible or Health Savings Account (HSA) Insurance.** People with HSAs have more interest than a typically insured person in price information. These types of plans are designed to make consumers more price-sensitive and to encourage consumers to be prudent "shoppers" for the care they need. A typical plan of this type has a deductible of $2,500. But consumers with HSA coverage are likely to be more interested in price information for physician and ambulatory care than for inpatient hospital care for several reasons:

    - Many patients admitted to the hospital were first seen on an emergency basis in the hospital emergency department. These are not price-shopping patients, but patients who found themselves in need of emergent care and either came or were brought to the nearest hospital emergency department.
    - For patients admitted to the hospital for a scheduled or elective procedure, inpatient hospital price information may be less important because most, if not all, hospital admissions result in a cost that exceeds the typical HSA deductible of $2,500, and therefore, are covered by most HSA plans.
    - People with HSA coverage may be most interested in comparing prices and shopping for care to be delivered that leads up to meeting their deductible (typically $2,500). People with this type of coverage may be most interested in prices for physician office visits and other ambulatory care for which they are likely to be responsible for paying the full cost.

- **Uninsured Individuals of Limited Means.** People without insurance who have limited means for paying for the health care services they have received need to know how much of their hospital or physician bill they may be responsible for. In the case of hospital care, the information they need must be provided directly by the hospital, after the hospital can ascertain whether a patient may qualify for state insurance programs of which they were unaware, free care provided by the hospital, or other financial assistance.

4) A hospital-led effort to create consumer-friendly pricing "language" – common terms, definitions and explanations to help consumers better understand the information provided.

More can be done to explain pricing information to consumers clearly and consistently. Hospitals will lead an effort to create common terms, definitions and explanations of complex pricing information. This will include sharing innovative and understandable ways for displaying pricing information for use by consumers.

The four points of this roadmap include an appropriate role for HHS, which should provide incentives to the states to improve transparency at the state and local level. HHS, through the Agency for Healthcare Research and Quality (AHRQ), is in the best position to complete research on what consumers want and would use in purchasing health care services.

HOSPITAL VALUE-BASED PURCHASING

The DRA required CMS to develop a plan to implement hospital value-based purchasing (pay for performance) beginning in FY 2009. The plan must consider the following issues:

- Measure development – the ongoing development, selection and modification process for measures of quality and efficiency in hospital inpatient settings;
- Data infrastructure and refinement – reporting, collecting and validating of quality data;
- Public reporting – disclosure of information on hospital performance; and
- Incentives – the structure of payment adjustments, including the determination of thresholds for quality improvements that would substantiate a payment adjustment, the size of such payments, and the sources of funding for the payments.

Hospitals remain committed to providing safe, effective, patient-centered, timely, efficient and equitable care to all patients, and the AHA is committed to working with CMS on the development of a value-based purchasing system for Medicare. It is critically important that the system be well thought out.

The HQA is not only accomplishing its goal of making standardized, easy-to-understand information available to the public, but also is reducing the measurement "babble" that had been generated by a large variety of separate organizations asking hospitals to produce quality information. These disparate data requests impede rather than support quality improvement. Conversely, the HQA has brought focus to hospitals' improvement efforts.

Significant resources already have been invested in the HQA effort and the *Hospital Compare* Web site by all of the participants. Nearly 4,200 hospitals – representing more than 99 percent of all eligible Medicare PPS hospitals and over 600 CAHs – have committed to this process, leading the way by sharing data with their communities and the public. **This is a solid foundation on which we must continue to build, and it should be the foundation for any pay-for-performance program included in legislation. To base the pay-for-performance initiative on the work of a group other than the HQA would be duplicative, wasting significant knowledge and expertise.**

Smaller hospitals will face challenges, regardless of the measures chosen for use in a pay-for-performance system. The limited number of patients in small hospitals means that their performance rates can be volatile. In designing a system that rewards excellence, this type of volatility can lead to inappropriate conclusions about the quality of care at these hospitals and affect whether they qualify for a reward under an incentive program. At the same time, omitting small hospitals from a program may suggest to some patients that they do not provide care that is comparable in quality to that of larger organizations. The implications of this volatility in their data must be carefully considered so that hospitals with small sample sizes can participate and receive appropriate recognition for the excellence they achieve.

Payment rewards should be based on evidence-based measures of adherence to quality improving "processes." By using evidence-based *process* measures (e.g., aspirin provided at arrival to patients with acute myocardial infarction; antibiotics provided one hour prior to surgery), *every* provider has the opportunity to succeed, thereby improving the overall quality of the system. Incentive approaches should incorporate rewards for both attainment of a certain threshold of performance and improvement in performance.

We are concerned about premature efforts to tie payments to issues that could change incentives, such as efficiency. We believe that, for now, pay-for-performance initiatives should focus solely on quality improvement. There is no common definition of efficiency of care for hospitals. Efficient over what period of time: the course of a hospitalization or a stated period? Also, efficient for whom: the hospital ... the patient ... the government ... other payers? Each answer would lead to the development of different measures of efficiency and very different conclusions about whether care was efficient.

In addition, measuring and rewarding performance based on a particular definition of efficiency may have considerable consequences for patients. For example, just a few years ago, HMOs developed criteria for efficient care that their physicians and other providers were told to follow. But the resulting headlines referencing denials of tests and treatments, and the accompanying public outcry, led to a fall out in traditional, staff-model HMOs.

Much more work needs to be done to define what should be encouraged in terms of efficient care before it is incorporated into payment policy.

Incentive approaches to payment should use a system of rewards to increase payments or reduce regulatory burden for successful providers. Because the Medicare inpatient PPS already pays less than the cost of care for more than one-third of hospitals, incentives involving penalties should not be used. Additionally, rewards should be sizeable enough to cover the costs of implementing process changes and allow for reinvestment in quality improvement efforts.

To be effective, incentive approaches must align hospital and physician incentives, encouraging all to work toward the same goal of improving quality and providing effective, appropriate care. This is imperative. Incentive approaches rewarding improvement can be successful only if physician and hospital performance can be successfully aligned, in terms of both performance and finances.

HEALTH INFORMATION TECHNOLOGY (IT)

The proposed rule states that it "supports the adoption of health IT as a normal cost of doing business to ensure patients receive high quality care." It also notes that the quality and efficiency benefits of health IT may provide a policy rationale for promoting the use of health IT through the Medicare program. Consequently, CMS asks for comments on:

- Its statutory authority to encourage adoption and use of IT;
- The appropriate role of IT in any value-based purchasing program; and
- The desirability of including use of certified health IT in hospital conditions of participation.

The AHA strongly believes that health IT is a very important tool for improving the safety and quality of health care, and our members are committed to adopting IT as part of their quality improvement strategies. They also view IT as a public good that requires a shared investment between the providers and purchasers of care.

Health IT is a very costly tool, requiring both upfront and ongoing spending. A 2005 AHA survey of hospitals and health systems found that the median amount hospitals invested on health IT in one year was more than $700,000, 15 percent of total capital expenses. Hospitals spent even greater amounts – a median of $1.7 million or 2 percent of all operating expenses – on operating costs. Survey respondents identified the upfront and ongoing costs of IT as the greatest barriers to further adoption. The survey also found that hospitals with negative margins and those with lower revenues use less IT.[4]

The proposed rule highlights the anticipated benefits of health IT as laid out by the RAND Corporation. However, it overlooks another of the study's major findings – that the financial benefits of IT investments accrue more to the payers and purchasers of care than the hospitals and health systems that pay for them.[5]

Simply put, our members have not seen financial returns greater than the costs of implementing clinical IT systems, particularly in the short term. They adopt clinical IT because it is the right thing to do for improving patient safety and quality of care, not because it saves them money. Thus, while IT may be a "normal cost of doing business," it systematically raises those costs. **Given that they reap many of the financial benefits of IT, the AHA believes that the payers and purchasers of care should share in the costs of IT.**

Finally, we learned through the HIPAA process that efficient health information exchange requires all parties to upgrade their systems and work from a common set of standards. As we

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[4] "Forward Momentum: Hospital Use of Information Technology." Washington, DC: AHA (2005).
[5] R. Hillestad, J. Bigelow, A. Bower, F. Girosi, R. Meili, R. Scoville, and R. Taylor. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs," *Health Affairs*, September 1, 2005; 24(5): 1103 - 1117.

moved toward implementation of health IT in hospitals, payers – including the federal government – must modify their own systems to accept electronic data.

Statutory Authority. The broad question of whether CMS has statutory authority to encourage adoption and use of health IT will depend on the specific mechanisms it selects. For example, CMS has some authority to pursue demonstration projects. However, more systematic approaches, such as value-based purchasing or payment adjustments, would require legislative action.

Value-based Purchasing. As noted elsewhere in this comment letter, the AHA believes that any value-based purchasing program should not be punitive. **With regard to IT, only programs that add funds to the inpatient PPS should be pursued because IT is costly, requiring both upfront and ongoing expenditures.** Decreasing payments to those that have not been able to afford IT further limits their ability to invest. A budget-neutral approach also ignores the reality that health IT systematically increases hospitals' costs.

The AHA also believes that value-based purchasing programs should build off the consensus measures endorsed by the broad spectrum of organizations – including CMS – that participate in the HQA. In general, the HQA favors measures that address quality outcomes, rather than the tools used to get there.

Health IT can play a role in reducing the burden of quality reporting. Presently, electronic health records (EHRs) and other clinical IT systems do not automatically generate quality measures. Most hospitals still require special calculations – including expensive manual chart abstraction and use of third-party contractors – to submit quality data. CMS could advance the quality agenda by investing in the development of algorithms for the calculation of the quality measures it wants reported from EHRs and encouraging vendors to include them in their products.

Rather than including health IT in a value-based purchasing program, **CMS could support adoption of health IT through a payment adjustment funded with new money.** For example, it could increase payments to hospitals that use health IT that improves the safety and quality of care by 1 percent. This kind of payment adjustment represents Medicare's share of the necessary investment to achieve this goal and would recognize the greater costs of a "wired" health care system. The AHA will pursue legislation authorizing such a payment adjustment. Other mechanisms, such as loan guarantees and grant funds, are needed to help hospitals finance the upfront costs of implementing health IT.

Conditions of Participation. The AHA firmly believes that **CMS should not include health IT in the Medicare conditions of participation (COP) for hospitals.** The COPs address the basic, essential infrastructure needed to ensure patient safety and must be clearly understood. Successful implementation of quality-enhancing IT requires careful planning and changes to work processes. The hospital field is still developing its understanding of how to implement these systems correctly. In addition, the commercial health IT applications available do not always meet hospitals' needs. The evidence on health IT does not yet support this level of requirement and would amount to an unfunded mandate. A recent report supported by the AHRQ found that the existing research on the quality benefits of health IT is limited to a handful of leadership institutions that generally developed their own systems. And, while promising, the

results are not yet generalizable to the average community hospital using the vendor systems currently on the market.[6]

While the AHA appreciates the efforts of the Certification Commission on Health Information Technology (CCHIT) to provide the market with better confidence in vendor product, we do not believe those efforts are sufficiently advanced to warrant inclusion in any adoption incentives CMS might pursue. CCHIT is only at the beginning stages of looking into certification of hospital inpatient products. CCHIT's work on ambulatory products is more advanced but, while it shows promise, has not yet proven itself in the marketplace.

HOSPITAL-ACQUIRED INFECTIONS

In the proposed rule, CMS has asked for ideas about how to effectively implement the DRA provision requiring the agency to identify instances in which the reliable application of science and appropriate processes of care should prevent infections, and to ensure that Medicare does not pay more for the hospital care of patients who becomes infected as a result of their care than it does for patients who are infection free.

It is difficult to identify the confluence of known science and effective care processes to prevent infections. **We believe that until a broad array of expertise is brought together to consider what conditions, procedures and circumstances should be targeted for this change, it is impossible to know how to most effectively implement the provision.** As the representative of America's hospitals and health systems, the AHA would be pleased to be part of those discussions.

We believe that the right starting point for this work is to build off CMS' substantial investment in the Surgical Care Improvement Project (SCIP). Surgical wound infections are among the most common and hazardous hospital-acquired infections. There is a readily available community of expertise among the broad group of organizations involved in SCIP, including the American College of Surgeons, the American Society of Anesthesiologists, the Association of periOperative Registered Nurses and the Centers for Disease Control and Prevention, among others. The existing SCIP partners' expertise can help identify a few surgical procedures that might be most appropriate for the change Congress envisioned. We believe these are likely to be relatively "clean" surgeries, meaning surgeries on patients whose conditions or wounds have not already put them at higher risk for infection, and patients who do not already have a variety of complicating conditions that would place them in higher paying DRGs. Additional expertise on coding and the DRG GROUPER also is needed for these discussions to help address questions of what data are helpful and readily available to determine which infections were acquired in the hospital versus the community, and which codes actually lead to enhanced payments.

In addition, there is good evidence to suggest that even when reliable science and appropriate care processes are applied in the treatment of patients, not all infections can be prevented. Therefore, we suggest that by utilizing the SCIP program as the basis for responding to the

[6] "Costs and Benefits of Health Information Technology." Agency for Healthcare Research and Quality Publication No. 06-E006 (April 2006).

congressional mandate, CMS could choose not to penalize a hospital if, despite their best efforts, an infection occurs. For example, if a hospital's performance on the SCIP surgical wound infection prevention measures show that it reliably performs the necessary infection prevention steps all or nearly all of the time, CMS might not make any change to the current payment system for that hospital.

Inpatient Prospective Payment System (IPPS) Analysis for FY2007

Technical Appendix

Date: June 6, 2006

THE MORAN COMPANY

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Inpatient Prospective Payment System (IPPS) Analysis for FY2007
Technical Appendix

Date: June 6, 2006

I. Introduction

For the Federation of American Hospitals (FAH), American Hospital Association (AHA), and Association of American Medical Colleges (AAMC), The Moran Company (TMC) analyzed alternative methodologies to those proposed by CMS in the FY 2007 Proposed Rule for the Inpatient Prospective Payment System (IPPS). This involved first replicating the proposed methodology and then applying alternative methodological choices at various points and comparing how the weights changed. The weights we calculated from our replication of the proposed rule were within 0.5% of the published weights for 90% of the DRGs and for the CS-DRG weights our calculated weights were within 3% for 90% of the CS-DRGs.

This document provides a brief overview of the data sources, methodology, and alternative methodology models. In the following section, we give a brief background to the proposed rule and the aims of this modeling project. Next we provide detail on the methodology we used in calculating weights. First we provide detail on the methods used to replicate the CMS weights. After that we describe technical corrections to how the weights were calculated that we made uniformly for our alternative models, the calculation of the current (FY2006) weights and steps vary in the different alternative models.

II. Background

In the FY 2007 Proposed Rule, CMS proposed the "first significant revision of the inpatient PPS since its implementation in 1983."[1] CMS has proposed a revision of the methodology used to calculate the weights assigned to Diagnosis Related Groups (DRG) for FY 2007 as well as a potential alternative DRG system to be used – an alternative known as "Consolidated Severity-adjusted DRGs" (CS-DRGs) for FY 2008 "or earlier".

The proposed methodology, known as Hospital Specific Relative Value with Cost Centers (HSRVcc) is a departure from the current methodology of charge-based weights. This proposed methodology attempts to account for variations in charges among hospitals through calculation of relative charges. In comparison, the current system uses Indirect Medical Education (IME), Disproportionate Share Hospital (DSH), and wage index adjustments to "standardize" hospital charges.

CMS calculated proposed FY 2007 weights using the FY 2005 MedPAR data and the CS-DRG weights using the FY 2004 data. In order to compare the results of our alternative models, we

[1] CMS, Medicare Proposes Payment and Policy Changes for Acute Care Hospital Services to Inpatients, April 12, 2006, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1833.

calculated many of the alternatives on both data sets, to eliminate differences due solely to the data year.

In our analysis of alternatives to the proposed methodology we:

- Replicated the proposed methodology and weights for FY 2007,
- Replicated the CS-DRG weights,
- Calculated weights using the "current" FY 2006 weight calculation methodology, and
- Calculated weights using combinations of alternative methodological choices.

In our analyses, we calculated weights using various combinations of methodology, DRG grouper (version 24 and CS-DRG), and data year. We performed a set of technical corrections which we explain in Section IV which we applied uniformly to all of the alternative simulations. The alternative methodology choices that we modeled were:

- Weighting the cost-to-charge ratios for hospital costs and charges,
- Trimming the cost-to-charge ratios at 3.00 standard deviations rather than 1.96, and
- Calculating costs at the claim level by multiplying charges by hospital specific and department specific cost-to-charge ratios.

See table 1 below for an overview of the models and the data and methodology and grouper used for each. Two of these models replicate the CMS weights (Base, rule replication and Base, 2004, CS-DRG). The full list of separate sets of weights modeled by TMC is as follows:

Table 1: Methodology Combinations for Calculation of Weights

Short description	Long description	Year of data used	Methodology system	DRG system
Base, rule replication	Replicate HSRVcc methodology proposed by CMS	2005	HSRVcc	Grouper 24
Base, rule replication with corrections	Replicate HSRVcc methodology proposed by CMS with technical corrections	2005	HSRVcc	Grouper 24
Base but with 2004, with corrections	Take replication logic and apply it to 2004 MedPAR data (Grouper 23) for comparison to the CS-DRG analysis that can only be run on the 2004 data. Include technical corrections.	2004	HSRVcc	Grouper 23
Base, 2004, CS-DRG	Replicate HSRVcc with 2004 MedPAR data, but using CS-DRG.	2004	HSRVcc	CS-DRG
Base, 2004, CS-DRG, with corrections	Replicate HSRVcc with 2004 MedPAR data, but using CS-DRG. Include technical corrections.	2004	HSRVcc	CS-DRG
Base, corrected CCR, weighted	Replicate HSRVcc but adjusting how the cost to charge ratio and the scaling factor is computed. We weight the CCR for volume.	2005	HSRVcc	Grouper 24

Short description	Long description	Year of data used	Methodology system	DRG system
Base, corrected CCR, weighted, and trimming.	Replicate HSRVcc but adjusting how the cost to charge ratio and the scaling factor is computed. We weight the CCR for volume, and trim CCRs at 3.00 standard deviations instead of 1.96.	2005	HSRVcc	Grouper 24
Base, corrected CCR, trimming, not weighted	Replicate HSRVcc but adjusting how the cost to charge ratio and the scaling factor is computed. We trim CCRs at 3.00 standard deviations instead of 1.96.	2005	HSRVcc	Grouper 24
HSRV, departmental level CCRs for costs	Use hospital specific, departmental specific cost to charge ratios that were calculated using 2003 data for the prior project and apply those to the charges at the claim level, then use the HSRV calculation on the costs. This does not use cost centers.	2005	HSRVcc, but departments instead of cost centers.	Grouper 24
Charge based methodology, 2005	Replicate the "current" charge based methodology including standardized charges.	2005	Relative weights -- Existing system	Grouper 24
Charge based methodology, 2004	Replicate the "current" charge based methodology applied to 2004 data, including standardized charges using the CMS grouper 23 DRGs.	2004	Relative weights -- Existing system	Grouper 23
Charge based methodology, CS-DRGs	Replicate the "current" charge based methodology applied to 2004 data, including standardized charges, but using the CS-DRG.	2004	Relative weights -- Existing system	CS-DRG
HSRV without cost centers.	Use HSRV charge based methodology alone (no cost scaler)	2005	HSRV	Grouper 24
Weighted CCRs/HSRVcc/ CS-DRG	This model takes the logic in 3a, but uses weighted CCRs.	2004	HSRVcc	CS-DRG
Weighted and Trimmed CCRs/HSRVcc/ CS-DRGs	This model takes the logic in 3a, but uses weighted and trimmed CCRs	2004	HSRVcc	CS-DRG
Trimmed only/HSRVcc/CS -DRG	This model takes the logic in 3a, but uses trimmed CCRs	2004	HSRVcc	CS-DRG
Weighted CCRs/HSRVcc	This model take the logic in 3a, but uses trimmed CCRs.	2004	HSRVcc	Grouper 23
Weighted and Trimmed CCRs/HSRVcc	This model takes the logic in 3a, but uses trimmed CCRs.	2004	HSRVcc	Grouper 23
Trimmed only/HSRVcc	This model takes the logic in 3a but uses trimmed CCRs.	2004	HSRVcc	Grouper 23

III. CMS Methodology Replication

This section discusses some of the technical details on how we replicated the CMS weights. In order to completely replicate the weight calculation a very high level of detail is needed. In just a few areas CMS did not include sufficient detail in the proposed rule. We are very grateful to CMS staff who clarified many fine points of detail.

CMS used two sources of data for calculation of weights, hospital inpatient claims and hospital cost reports. We used the same sources. They are:

- *Hospital Inpatient Claims* - Data from the FY2004 MedPAR and the FY2005 MedPAR files were used. CS-DRGs existed only on the FY2004 MedPAR data so all analyses conducted with CS-DRGs were with that data.

- *Hospital Cost Report Data* - Hospital Cost report data were from the Hospital Cost Report Information System (HCRIS), from their data release of December 31, 2005.

We describe below five steps to calculating the HSRVcc weights:

- Data cleaning,
- Calculating CCRs,
- Calculating hospital specific relative value (HSRV) weights using charges,
- Creation and application of the scalers, and
- Normalizing the weights.

A. Data cleaning

In the Proposed Rule, CMS used slightly different data cleaning approaches for their analyses that were conducted with 2004 data versus the analyses conducted with 2005 data. The data cleaning steps for the 2004 data are more comparable to the MedPAC analysis. This discussion will focus on the 2005 data cleaning since we used that in most of our models. There will be a brief section highlighting some of the differences on the 2004 analysis.

1. Cleaning of Hospital Inpatient Claims

We followed what CMS described starting at P. 184 of the display copy of the Proposed Rule. These are the steps in cleaning the data file that CMS applied to the FY 2005 data for calculation of the proposed FY 2007 weights. CMS used slightly different cleaning rules for the FY 2004 data with the CS-DRG weights. To be able to compare between the replication and alternative policy models, we used the data cleaning that CMS applied to the FY 2005 data to all of our simulation models even those using the FY 2004 data, with the exception of the one model in which we are replicating the CS-DRG weights to compare to the published weights (Base, 2004, CS-DRG).

We excluded discharges that:

- Were not from PPS hospitals – third digit of provider code was not equal to 0 or special unit characteristic code was not blank.
- Had total charges equal to 0.
- Had length of stay equal to 0.
- Had an "ungroupable" DRG assignment: DRG 470 in Grouper versions 23 or 24, CS-DRG 999. Note: This exclusion is not explicitly in the rule, but verified with CMS during a phone call.
- Were for Medicare Beneficiaries enrolled in a Medicare+Choice (Medicare Advantage) plan.
- Had total charges that differed by more than $10 from the sum of the component charges.
- Were from hospitals that were Critical Access Hospitals (CAH) or later became CAHs. The list of CAHs was downloaded from the CMS website. (http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS063084, which as of 6/2/06 has a note saying that the list will be updated in the Final Rule).
- Were for heart and heart-lung, liver and/or intestinal, or lung transplants (DRGs 103, 480, and 495) performed at hospitals not approved by Medicare for transplants.
- Were at providers not included on the provider specific file list provided by CMS. (http://www.cms.hhs.gov/AcuteInpatientPPS/FFD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=2&sortOrder=ascending&itemID=CMS061281). As a by-product of this restriction, Cancer and Indian Health Service hospitals were removed.
- Were at providers where there were no charges in at least 8 of the 10 cost centers.
- Had total charges and total charges per day greater than three (3) standard deviations from their respective geometric means.[2]

[2] We verified that CMS used the logical "and" in applying this outlier exclusion criteria. That is, if an observation meets on only one condition, total charges or charges per day are outliers, the record is retained for calculating weights.

The following are the major differences between the cleaning steps used with the 2005 and the steps CMS used with the 2004 data for the CS-DRG replication.

- In 2004, hospitals from Maryland were excluded, but they were included in 2005.
- Providers were excluded if they did not have charges in the two accommodation cost centers and at least one ancillary cost center. This is in contrast to requiring 8 cost centers in the 2005 analysis.

When preparing the data, we did the following:

- We assumed that professional fees – MedPAR Service Charge category 22 should be counted under "Other". We verified this assignment during a phone call with CMS.
- Transfer DRGs identification.
    - For Grouper 23 and 24, we followed the identification of whether or not a DRG was considered a transfer DRG as reported by CMS.
    - For CS-DRGs, we determined what could be a transfer DRG based on logic published on August 12, 2005 in the Federal Register on P. 47484. The language reads:

> "(A) The total number of discharges to post acute care in the DRG must equal or exceed the 55th percentile for all DRGs;
> (B) The proportion of short-stay discharges to post acute care to total discharges in the DRG exceeds the 55th percentile for all DRGs; and
> (C) The DRG is paired with a DRG based on the presence or absence of a comorbidity or a complication or major cardiovascular condition that meets the criteria specified under paragraph (d)(3)(ii)(A) and (d)(3)(ii)(B) of this section."

2. Cleaning of Hospital Cost Report data

For cleaning of the hospital cost report data, we followed the logic starting on P. 190 of the display copy of the Proposed Rule.

We removed hospitals if they met any of the following criteria:

- Critical access hospitals (CAHs)
- Located in Maryland
- Indian Health Service
- Cancer hospitals
- All-inclusive rate hospitals. Based on guidance from CMS during a phone call, these were identified by having a "Y" in cost report location S2_1_32.
- Was not a full year (365 days) cost report.
- Cost report did not start during Federal FY2003 (October 1, 2002 through September 30, 2003).

We discovered that the calculation of CCRs is very sensitive to which hospitals are included or excluded. Using the same list of CAHs is particularly important.

All cost reports are used whether or not the cost report is settled or merely submitted. The cleaning of the cost report data and the cleaning of the MedPAR data are independent of each other. Hospitals can be excluded from the cost report file for not having a full year cost report or an available cost report for FY 2003, but claims from these hospitals would be kept in the MedPAR claims.

B. Calculate CCRs

We created 10 cost centers based on the mapping starting on P. 186 of the display copy of the Proposed Rule. CMS used an internal file in a different format, though derived, from the file that is publicly available. When we attempted to match the scalers CMS posted on the web site, our results came closest if we did not include the sublines in the cardiology cost center. Our replication of the scalers was within 0.5% for all of the cost centers except cardiology, other services and laboratory, with cardiology being the furthest away from the CMS released number. For cardiology when we included appropriate sublines we were 7.4% lower than CMS's number. When we excluded the sublines, we were 2.1% lower than CMS's number.

We trim the individual cost center cost to charge ratio (CCR) to remove outliers. An individual cost center CCR is not used in calculations if one of the following is true:

- CCR is greater than 10.
- CCR is less than 0.01.
- CCR is more than 1.96*standard deviations different from the geometric mean.

The trimming of the CCRs is done in this order so that the geometric mean is computed after the cost center CCRs with the unreasonable values were removed from the calculations.

When trimming, we only removed the CCR for that individual cost center, the other CCRs for that provider are still present. Therefore, slightly different pools of hospitals are used for every calculation of cost center CCRs.

After the trimming, we compute the geometric mean of the CCR for every cost center. CMS computed an unweighted geometric mean.

C. Calculating hospital specific relative value (HSRV) weights using charges

In order to replicate the methodology for HSRVcc, we followed the basic logic laid out starting on P. 186 of the display copy of the Proposed Rule. This methodology is applied at the cost center level.

The basic logic of the HSRVcc is summarized as follows:

1. Calculate each hospital's average charge per discharge for all discharges for each of the 10 cost center groupings. This is calculated as the sum of the charges divided by the transfer adjusted case count.

2. Calculate the relative charge per discharge for each of the 10 cost center groupings. Divide the total charges for each individual discharge by the average charge per discharge for all that hospital's discharges (from step 1).

3. Initialize the Case Mix Index (CMI) as 1.0.

4. Calculate the CMI adjusted relative charge. Multiply the relative charge per discharge (from step 2) by CMI (from step 3).

5. Calculate the mean CMI adjusted relative charge for each DRG, for each cost center grouping. This is calculated as the sum of the CMI relative adjusted relative charge (from step 4) divided by the sum of the transfer adjusted case count (from step 4) for each DRG.

6. Calculate the mean CMI adjusted relative charge at the national level. This is calculated as the sum of the CMI adjusted relative charge (from step 4) divided by the sum of the transfer adjusted case count (from step 4) at the national level.

7. Calculate the first set of weights. Divide the mean CMI adjusted relative charge at the DRG level for each cost center grouping (step 5) by the mean CMI adjusted relative charge at the national level (step 6). This is computed for each DRG.

8. Assign these weights to all the cases for each hospital.

9. Calculate each hospital's case mix index (CMI) using these new weights (Step 8).

10. Calculate a new CMI adjusted relative charge. This is computed by multiplying the relative charges by the new computed CMI.

11. Calculate a new mean CMI adjusted relative charge at the DRG level.

12. Calculate a new mean CMI adjusted relative charge at the national level.

13. Calculate a new weight by dividing the results of step 11 by step 12.

14. Repeat back to step 8 until the maximum change in national case mix index from the current iteration compared to the previous iteration is less than 0.000001.

15. At this step, we have 10 weights (one for each cost center) for every DRG.

D. Creation and application of the scalers

16. Using the national average CCR for each cost center, multiply the total unadjusted charges for that cost center by the national average CCR for that cost center to compute a "cost" for that cost center.

17. Sum the 10 cost center costs (computed in step 16) to create a single "total cost" for the discharge.

18. For each cost center, divide the "cost for the cost center" (step 16) by the "total cost" (step 2). The result is a "scaling factor" for each cost center.

19. Apply the scaling factor for each cost center (step 18) to the cost center weights for each DRG.

20. Sum the results of step 19, to create a single weight for each DRG.

E. Normalizing the weights

21. Apply the normalization factor to the weights by multiplying the weight (step 20) by the normalization factor. We used the normalization factor published in the Proposed Rule.

22. For low-volume DRGs (DRGs with less than 10 cases), on models using Grouper 23 or 24, we replaced weights following the mapping starting on P. 192 of the display copy of the Proposed Rule. For models using CS-DRGs, we did not make any adjustments.

IV. Corrections from the CMS Methodology

There were a few "corrections" made to our model from the replication to our corrected models. These were either mistakes that had been made by CMS or inconsistencies between the treatment of 2004 data and 2005 data that we wished to be consistent in our modeling. Below we list those corrections applied to all of our alternative models.

- *Organ acquisition costs in 2005.* In our replication, we discovered that organ acquisition costs appeared to have been incorrectly included in the total charges. We verified this with CMS. CMS noted that they will make this correction in the final rule. We do not believe that they made this mistake when using the 2004 data.

- *Transfer adjustment.* When replicating the 2005 results, we used transfer adjusted weights. However, when attempting to replicate the 2004 results with CS-DRGs, our results were closest when we did not use transfer adjustments. We believe though that there should be transfer adjustment when using CS-DRGs and so in our corrections, that is done.

- *Differences between CMS's analysis using 2004 and 2005 data.* There are several differences between CMS's analysis using 2004 data and their analysis using 2005 data. The major differences are:
    - Exclusion in 2004/Inclusion in 2005 of discharges from Maryland hospitals. In the 2004 analysis, CMS excluded the Maryland hospitals but they included them in 2005. As noted above, this was intentional in order to have CS-DRG weights that used the 2004 data more comparable to MedPAC's analysis. Because we wanted consistency between our models in general in our "corrected" models, we followed 2005.
    - Cleaning of MedPAR file based on cost centers. In 2004, CMS required charges in the two accommodation cost centers as well as one ancillary cost center. In contrast, in 2005, CMS required presence of data in at least 8 cost centers. For our general "corrected" models, we followed the 2005 approach.
    - Use of transfer adjusted case counts versus non-transfer adjusted cases while computing Case Mix Index (CMI) during the iterations. CMS used transfer adjusted counts of cases to calculate the CMI used during the HSRV weight calculation iterations in the 2004 data used for CS-DRG weights. In the proposed FY 2007 weight calculation (HSRVcc DRG) using 2005 data, CMS calculated the CMI without adjusting for transfer cases. For our corrected models, we followed the logic for the FY 2007 proposed weights. (See P. 190 of the display copy of the Proposed Rule for details.)

V. Overview of Current Methodology Replication

In this section we provide a summary of how CMS calculated the DRG weights in 2006 – the "current methodology". We used these steps to calculate what the weights would have been using the 2005 and 2004 data (Charge based methodology, 2005 and Charge based methodology, 2004) to be able to compare what effect the change in the calculations had on the weights separate from the changes due to using a different dataset.

Total charges for each discharge are adjusted by the hospital's wage index, IME, DSH, and COLA factors according to the following formula:

Operating portion

(a) std_labor_operating=((total_charges*labor_share)/wage_index)

(b) standardized_operating=std_labor_operating
/(1+ime_adjustment_operating+dsh_adjustment_operating)

Capital portion

(c) std_labor_capital=((total_charges*(1-labor_share))/cola_adjustment)

(d) standardized_capital=std_labor_capital
/(1+ime_adjustment_capital+dsh_adjustment_capital)

Combined – final standardized charge

(e) standardized_charge=standardized_operating
+ standardized_capital

The weights are then calculated using these standardized charges using the following steps:

1. Calculate mean for each DRG of the standardized charges.
2. Calculate mean standardized charge of all discharges.
3. Divide the mean standardized charges for the DRG by the mean of all discharges.
4. Multiply each weight by the normalization factor. We used the normalization factor published in the Proposed Rule.

VI. Methodology Variations

For our different models, we adjusted certain aspects of the cleaning and methodology. The list here presents variations. Our models are combinations of these changes, the CMS methodology, different years of data and different DRG groupers.

Inpatient claims cleaning – organ acquisition cost correction

Applies to:	All 2005 Models except Base, rule replication
Change:	CMS incorrectly included the organ acquisition costs with 2005 data. This change removed the charges related to organ acquisition.

Inpatient claims cleaning – cost centers

Applies to:	Base, 2004, CS-DRG, with corrections
Change:	We removed providers who did not have information in at least 8 of the 10 cost centers, following how CMS analyzed the FY2005 data. This is in contrast to their analysis of 2004 data where they removed providers if the provider did not have charges in: routine days, intensive days, and at least one other cost center.

Weighted CCRs

Applies to:	Base, corrected, CCR, weighted; Weighted CCRs/HSRVcc; Weighted CCRs/CS-DRGs.
Change:	We computed a weighted national CCR as opposed to a geometric mean CCR.

Weighted and trimmed CCRs

Applies to:	Base, corrected CCR, weighted and trimmed; Weighted and trimmed CCRs/HSRVcc/CS-DRGs; Weighted and trimmed CCRs/HSRVcc.
Change:	We computed a weighted national CCR as opposed to a geometric mean CCR. In addition, we trimmed outliers that were at least 3.00*standard deviation away from geometric mean as opposed to 1.96*standard deviation away from the geometric mean.

Trimmed CCRs

Applies to:	Base corrected CCR, trimming, not weighted; Trimmed only/HSRVcc; Trimmed only/HSRVcc/CS-DRGs
Change:	We trimmed outliers that were at least 3.00*standard deviation away from geometric mean as opposed to 1.96*standard deviation away from the geometric mean.

Single cost center

Applies to:	HSRV without cost centers
Change:	This model uses a single cost center as opposed to the 10 cost centers.

Costs

Applies to:	HSRV, departmental level CCRs for costs
Change:	This model uses total costs as opposed to the 10 cost centers using charges. Total costs are calculated at the claim level by multiplying the charges for each of the 30 costs centers in MedPAR by the relevant

departmental CCR for that hospital and summing the costs across the 30 cost centers.

CMS DRGs V. 23 and HSRVcc

Applies to:	Base, but with 2004, with corrections
Change:	This model followed P. 65 of the display copy using the transfer adjusted case mix as opposed to the non-transfer adjusted case mix.

MODELING FFY 2007 OUTLIER PAYMENTS

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DATA SOURCES:

1. The MEDPAR 2005 computer file obtained from CMS. The file contains 13,715,186 records, each corresponding to a Medicare hospital discharge occurring in FFY 2005.

2. CMS FFY 2007 Impact File (Proposed Rule Version). This file produced by CMS shows the estimated level of FFY 2007 outlier payments by hospital (as percentages). It also shows the hospital-specific parameters used for calculating PPS payments, such as DSH and IME adjustment factors, cost to charge ratios (CCRs), wage indexes, etc.

3. The March 31, 2006 update of the HCRIS database. This database consists of Medicare cost reports beginning in Federal Fiscal Years (FFYs) 1996 through 2005.

REPLICATION OF THE CMS ESTIMATED 2007 OUTLIER PAYMENT LEVELS (IPPS 2007 PROPOSED RULE).

The regular and outlier FFY 2007 payments were estimated for 11,447,430 discharges in the MEDPAR database subject to IPPS. These are the same discharges used by CMS to generate the 2007 Proposed Rule Impact File[i]. Regular payments were calculated based on the proposed DRG weight, the patient discharge destination (for identifying transfers), the applicable proposed standardized amounts and the other hospital-specific parameters determining PPS payments. The latter are the wage index, the non-labor cost of living adjustment, and the DSH and IME adjustment factors. Each of these parameters has different values applicable to operating and capital payments. The parameters were obtained from the CMS Impact File.

Outlier payments were calculated inflating 2005 charges by 15.71 percent (the inflation factor used by CMS[ii]), reducing charges to costs using the cost to charge ratios from the CMS Impact File and comparing costs to the proposed FFY 2007 fixed loss amount of $25,530. The latter was adjusted as appropriate on a hospital-specific basis. It should be noted that the Impact File cost to charge ratios are mostly from fiscal periods beginning in FFY 2004. Also, no allowance was made for the anticipated continued decrease in the CCRs.

With these assumptions, the FFY 2007 operating and capital outlier payments were estimated at 5.1 and 4.81 percent of the respective total payments, net of DSH and IME amounts. These estimates are in good agreement with the CMS figures of 5.1 and 4.87 percent, respectively. The dollar amount of FFY 2007 outlier payments was estimated at $4,774B.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT USING THE MOST RECENT COST TO CHARGE RATIOS.

More recent cost to charge ratios were calculated from the latest cost reports available in the HCRIS database. Medicare inpatient operating costs were obtained from Worksheet D-1, Part II, Medicare inpatient capital costs from Worksheet D, Parts I and II and Medicare inpatient charges from Worksheet D-4. A comparison with the dates of the CCRs in the Impact File, presumably used to establish the proposed FFY 2007 fixed loss threshold, is shown in the table below.

Beginning in FFY	Number of Cost Reports Used for the Impact File CCRs	Percent of Cost Reports Used for the Impact File CCRs	Number of HCRIS Most Recent Cost Reports for Impact File Hospitals	Percent of HCRIS Most Recent Cost Reports for Impact File Hospitals
	(a)	(b)	(c)	(d)
2001	5	0.2%	3	0.1%
2002	39	1.4%	13	0.4%
2003	739	27.0%	92	2.6%
2004	1,949	71.1%	2,948	84.0%
2005	10	0.4%	453	12.9%
Unknown/Not Matching	780		13	
Total	3,522		3,522	

Table Notes: Column (a) numbers are based on matching Impact File CCRs with HCRIS CCRs for fiscal periods beginning between 2001 and 2005. If both operating and capital HCRIS CCRs were within 0.001 of their respective Impact File counterparts, the HCRIS cost report was considered to be the source for the Impact File CCRs. Percentages in columns (b) and (d) are based on the total of FFYs 2001-2005, i.e., unkown/not matching hospitals were not included.

Using the more recent HCRIS CCRs and the CMS assumptions listed above, the estimate of the fixed loss threshold is **$24,990**.

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT PROJECTING BOTH CHARGE AND COST INFLATION.

Outlier payments are calculated from costs. Costs are determined by applying a cost to charge ratio to actual charges. It follows that accurate outlier estimates require projecting **both** costs and charges. An additional complication is the inevitable lag between CCRs that can only be determined retrospectively at the end of an elapsed cost reporting period and the current charges to which they are applied. Historically, CMS has projected outlier payments by projecting only costs or only charges and ignored the time lag problem. This approach works well in periods when cost and charges move more or less in tandem. When costs and charges change at significantly different rates, relying on only one measure of inflation can result in either outlier over- or underpayments[iii]. An alternative methodology that overcomes these shortcomings is described below.

In order to account for the time lag problem, cost to charge ratios were projected from the most recent fiscal period in the March 31, 2006 HCRIS update to the fiscal period(s) expected to be used for the calculation of the CCR(s) determining FFY 2007 outlier payments. The CMS Program Memorandum A-03-058 dated July 3, 2003 instructs Fiscal Intermediaries to update the CCRs "not later than 45 days after the date of the tentative settlement or final settlement used in calculating the CCRs". Combining this deadline with the maximum of eight months between the end of the cost reporting period and tentative settlement, it is reasonable to expect CCRs to be updated no later than nine months after the end of the cost reporting periods. Assuming a nine-month lag in updating CCRs, FFY 2007 outlier payments will be based partly on 2005 and partly on 2006 ratios, depending on the fiscal period ending date (FPE). Hospitals with a January FPE will have their CCR updated to the FPE January 2006 value by October 31, 2006. Their FFY 2007 outlier payments will be based on the FPE January 2005 CCR for one month (October 2006) and on the FPE January 2006 CCR for the remaining eleven months. Similarly, FFY 2007 outlier payments for hospitals with a February FPE will be based on the 2005 CCR for two months and the 2006 CCR for ten months, and so on. Hospitals with a December FPE would have their FFY 2007 outlier payments based entirely on the FPE December 2005 CCR.

The cost inflation factor for projecting CCRs was determined from the costs reports of a cohort of 3,253 matched hospitals for periods beginning in FFYs 2002, 2003 and 2004. All three costs reports were available for each hospital from the recent update of HCRIS and covered a full twelve months. The 2002-2004 aggregate annual rate of increase in the cost per discharge for these hospitals was 5.69 percent[iv]. This cost inflation factor and the CMS charge inflation factor of 7.57 percent were used to project cost to charge ratios over the time periods described above. The projected CCRs were applied to projected FFY 2007 charges to simulate the determination of costs for FFY 2007 outlier payments. The estimated fixed loss amount that would result in 5.1 percent outlier payments in this scenario is **$24,000**. It should be noted that this model (as well as all the

ones discussed here) does not take into account the potential impact of outlier reconciliation. The model assumes FFY 2007 outlier payments based on costs determined using pre-2007 CCRs. If outlier payments were adjusted retrospectively based on FFY 2007 "true" costs determined using 2007 CCRs, final outlier payments would be lower (assuming a continuing trend of decreasing cost to charge ratios).

ESTIMATE OF THE FFY 2007 FIXED LOSS AMOUNT PROJECTINGONLY COST INFLATION.

This is the methodology CMS used for the FFYs 1994-2002. For projecting FFY 2007 outlier payments it consists of applying historical CCRs to FFY 2005 charges to determine FFY 2005 costs. These costs are projected forward to FFY 2007 using a cost inflation factor. However, the "cost inflation only" approach ignores the time lag problem. This may result in underestimating FFY 2007 costs for outlier payment determination and, therefore, underestimating the FFY 2007 fixed loss threshold. The underestimate results from using historical CCRs generally more recent than the CCRs actually available in 2004[v].

The cost inflation approach using an annual cost inflation factor of 5.69 percent and the Impact File CCRs resulted in a FFY 2007 estimated fixed loss amount of **$23,055**. If the most recent CCRs from the HCRIS database were used instead, the estimated FFY 2007 fixed loss amount was **$22,645**.

ESTIMATE OF THE FFY 2006 OUTLIER PAYMENTS

The 2007 IPPS Proposed Rule states that FFY 2006 outlier payments are now estimated at 4.71 percent of total DRG payments. Using the "charge inflation only" model and the Impact File cost to charge ratios, the outlier payment level was estimated at 4.64 percent, essentially replicating the CMS finding. Using the same model, the 2006 fixed loss amount that would result in a payment level of 5.1 percent was estimated at **$21,530**.

The FFY 2006 fixed loss amount was estimated using all the other models described above. Still using the "charge inflation only" but substituting the most recent HCRIS CCRs for the Impact File ratios, the fixed loss threshold was estimated at **$21,160**. It should be noted that the most recent CCRs used in these model were selected by taking into account their applicability to FFY 2006. For example, assuming a nine-month lag in updating CCRs, hospitals with fiscal periods ending in June 2006 had their first six months of FFY 2006 outlier payments based on the June 2004 FPE cost to charge ratio, and the last six months based on the June 2005 FPE ratio. Even if the June 2005 FPE ratio was available from the HCRIS database, the CCR used in this model was an average of the 2004 and 2005 ratios weighted by the number of months of usage in FFY 2006.

If both cost and charge inflation are taken into account, and assuming a nine-month lag in updating CCRs, the FFY 2006 fixed loss threshold amount was estimated at **$21,275**.

Using the "cost inflation only" models the fixed loss amounts were estimated at **$20,460**

and **$20,095**, based on Impact File and most recent HCRIS cost to charge ratios, respectively. Because of the problems with the "cost inflation only" model noted for the FFY 2007 estimates, i.e. not taking into account the lag in updating CCRs, it is quite likely these amounts are underestimated.

Both FFY 2006 and 2007 results and underlying assumptions are summarized in the tables on the following pages.

CALCULATION OF THE FFY 2005 FIXED LOSS AMOUNT THAT WOULD HAVE RESULTED IN OUTLIER PAYMENTS OF 5.1 PERCENT

The level of outlier payments actually made in 2005 can be determined from the 2005 MEDPAR data. The operating outlier payment, if any, is explicitly shown for each Medicare discharge. The regular DRG operating payment can be easily determined from data in the file. Specifically, the operating payment net of indirect medical and disproportionate share adjustments is the DRG PRICE less CAPITAL, DSH and IME payments. The amounts shown in capitals are all fields in the MEDPAR records. The total outlier payments made in 2005 amounted to 3.051B[vi]. This represents 3.8 percent of total Medicare IPPS payments net of indirect medical and disproportionate share adjustments. The result is significantly different from the CMS estimate of 4.1 percent. The 3.8 percent level of outlier payment translates into a shortfall of $1.1B.

The outlier amounts that should have been paid could be calculated from the MEDPAR data if the cost to charge ratios actually used were available. To my knowledge there is no public data source for them. An alternative would be to estimate the CCRs from other data sources, e.g., HCRIS. However, this would involve assumptions about the rates of cost and charge inflation. In order to avoid dependence on such assumptions the CCRs were estimated from the MEDPAR file itself. The comparison of any two outlier payments *calculated using the same CCRs* allows the determination of the CCR:

$O_1 = 0.8 \times (OPCCR \times C_1 - D_1 - AFL)$

$O_2 = 0.8 \times (OPCCR \times C_2 - D_2 - AFL)$

where O = outlier payment, C = charges, D = DRG payment, AFL = adjusted fixed loss amount and OPCCR = operating cost to charge ratio. Note that AFL is actually dependent of the cost to charge ratios, but since it cancels out of the final equation, this fact can be ignored

Subtracting the second equation from the first and solving for OPCCR:

$$OPCCR = [(O_2 - O_1) / 0.8 + (D_2 - D_1)] / (C_2 - C_1)$$

A similar calculation can be carried out for the capital cost to charge ratio. This method was used to determine the CCRs by arraying all outlier payments made to a hospital during a given quarter in increasing order of the covered charges. The calculation shown

above was performed by comparing each outlier payment in the array to the outlier payment with the highest covered charges and, again,
to the outlier payment with the lowest charges. The median of the CCRs thus obtained was considered to have been the CCR used to determine outlier payments for the quarter and hospital under consideration. If the actual CCR remained the same during the entire quarter, the method above should in principle determine it exactly. If the CCR did change during the quarter, the calculation yields an approximate "effective" CCR. (The date of discharge shown in the public version of MEDPAR is limited to the quarter of discharge). The approach outlined above can be applied only when a hospital had at least two outliers in a given quarter. For hospitals with less than two outliers in a quarter, the CCR ratios were taken from the CMS Impact File for FFY 2005 (the Final Rule version).

In order to validate the CCRs obtained as described above, they were used to calculate "simulated" 2005 outlier payments based on the fixed loss amount of $25,800 effective in FFY 2005. The total amount of "simulated" payments was $3,036B compared with the actual amount of $3,051B[vii]. The CCRs were then used to calculate the 2005 fixed loss amount that would have resulted in a 5.1 percent outlier payment level. The result was **$19,790**.

FFY 2007 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (Proposed Rule, Rate of Change from Jul-Dec 2004 to Jul-Dec 2005) (Per Year)	Cost Inflation (Per Year)	Change in Cost to Charge Ratios (Per Year)	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2007 FIXED LOSS AMOUNT ($)
Charges Projected From FFY 2005 to FFY 2007	CMS Impact File-Proposed FY 2007	7.57%	None	None	None	25,530
Charges Projected From FFY 2005 to FFY 2007	HCRIS 03/31/2006 Update	7.57%	None	None	None	24,990
Charges Projected From FFY 2005 to FFY 2007; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2007 Outlier Payments	HCRIS 03/31/2006 Update	7.57%	5.69% (From HCRIS Cost Reports 2002-2004)	-1.75%	Nine Months	24,000
Costs Projected From FFY 2005 to FFY 2007	CMS Impact File-Proposed FY 2007	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	23,055
Costs Projected From FFY 2005 to FFY 2007	HCRIS 03/31/2006 Update	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	22,645

FFY 2006 ESTIMATED FIXED LOSS AMOUNTS AND UNDERLYING ASSUMPTIONS

METHODOLOGY	Data Source for Cost to Charge Ratios	Charge Inflation (Proposed Rule, Rate of Change from Jul-Dec 2004 to Jul-Dec 2005) (Per Year)	Cost Inflation (Per Year)	Change in Cost to Charge Ratios (Per Year)	Assumed Lag Between the Fiscal Period End and Effective Date of the CCRs	ESTIMATED FFY 2006 FIXED LOSS AMOUNT ($)
Charges Projected From FFY 2005 to FFY 2006	CMS Impact File-Proposed FY 2007	7.57%	None	None	None	21,530
Charges Projected From FFY 2005 to FFY 2006	HCRIS 03/31/2006 Update	7.57%	None	None	None	21,160
Charges Projected From FFY 2005 to FFY 2006; Cost to Charge Ratios Projected to Simulate Effective CCRs for FFY 2006 Outlier Payments	HCRIS 03/31/2006 Update	7.57%	5.69% (From HCRIS Cost Reports 2002-2004)	-1.91%	Nine Months	21,275
Costs Projected From FFY 2005 to FFY 2006	CMS Impact File-Proposed FY 2007	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	20,460
Costs Projected From FFY 2005 to FFY 2006	HCRIS 03/31/2006 Update	None	5.69% (From HCRIS Cost Reports 2002-2004)	None	None	20,095

[i] These are discharges subject to IPPS and with non-zero covered days and charges. The number of these discharges is the same as the number of "Bills" for all the hospitals in the Impact File.

[ii] The two-year inflation factor in the Proposed Rule is stated to be 15.15 percent. This is not consistent with the annual inflation ratio of 7.57 percent stated in the same Proposed Rule. The annual inflation rate of 7.57 percent translates into a 15.71 percent two-year rate.

[iii] Of course, regardless of methodology, over- or under estimates of outlier payments may result from cost and/or charge inflation projections -usually based on the assumption that historical values are a reasonable indicator of future trends- that turn out to be inaccurate.

[iv] An audit adjustment was applied to costs from "as submitted" cost reports. The audit adjustment was determined by comparing 2,791 "as submitted" cost reports from the December 31, 2003 HCRIS database with the settled reports of the same hospitals in the March 31, 2006 HCRIS update.

[v] This discussion assumes charges increasing at a faster pace than costs. In that case, because FFY 2007 "costs for outlier payment determination" are obtained by applying CCRs from earlier periods to FFY 2007 charges, 2005 "costs" should be determined with similarly lagged CCRs.

[vi] The aggregated amount of outlier payments for the 11,447,430 discharges in the 2005 MEDPAR selected as described on Page 1.

[vii] The comparison was limited to cases when outlier payments were actually made. Simulated payments for all cases are slightly higher ($3,132B). This may reflect situations when outlier payments were denied for not being submitted in accordance with Medicare laws and regulations.

ORTHOPAEDIC SPECIALISTS P.C.

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Minimally Invasive Spine Surgery

Team Physicians For:

June 5, 2006

CMS
Department of Health & Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am writing this letter to show my support for the X STOP IPD device. I have had the pleasure of using this device in my practice for patients with mild to moderate spinal stenosis at one or two levels. This procedure has allowed me to provide an alternative to the traditional laminectomy procedure in those patients. Those patients have had an uneventful recovery with excellent outcomes to date.

One of the potential advantages for the X STOP device could be its use in outpatient settings. The relative ease of risk free insertion of these devices as well as the limited local tissue injury occurred during its placement would allow for this to be done in the appropriate candidate as an outpatient. As such exorbitant inpatient costs would be avoided. Clearly on some patients the ability to have them stay 23 hours as an inpatient would also be helpful.

Once again I would like to reiterate my statement of support regarding the X STOP IPD. This does fill a niche within my patient population as a treatment option. I would also like to be able to offer it as an outpatient procedure in those select individuals. Please take this into consideration.

Sincerely,

Michael Dolphin, DO
MD/mmt

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56

Englewood Orthopedic Associates, P.A.

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Anne J. Miller, M.D.
Hand and Upper Extremity Surgery

Brian A. Cole, M.D.
Adult and Pediatric Spinal Surgery

Michael F. Pizzillo, M.D.
Hand & Upper Extremity Shoulder Surgery

Peter A. Salob, M.D.
Sports Medicine and Pediatric Orthopedics

Asit K. Shah,M.D., Ph.D.
Minimally Invasive Total Joint Replacement

Marc Ross, P.A.
Physician Assistant

Julie Chita, P.T., OCS
Director, Physical Therapy

Edward Gulko, FACMPE, CHE
Administrator

May 30, 2006

CMS
Department of Health and Human Services
CMS-1488-P
PO Box 8011
Baltimore, MD 21244-1850

RE: X STOP IPD/MEDICARE APPLICATION COMMENTS

To Whom It May Concern:

As a spine surgeon, I would like to provide my comments with regard to the X STOP device manufactured by St. Francis Medical Technologies. I am writing this letter in support of preserving the financial viability of this device. It is a very helpful tool in helping the patients who may not be candidate for traditional surgery for lumbar spinal stenosis. Fortunately, I have had experience with this device and all of my experiences thus far have been overwhelmingly and positive.

To give you just an example, I had a lady recently who had severe spinal stenosis who was wheelchair bound and because of pulmonary fibrosis could not have lumbar decompressive surgery because of her lung condition. She was dependant upon an O2 nasal cannula. She presented to me as a last resort. Fortunately, I was able to provide her intervertebral distraction utilizing the X STOP device. The results were greatly dramatic. The day of the surgery, she reported reduction of her pain. She was able to get out of her wheelchair. The response was so overwhelming that I have heard from other patients who have a similar condition.

I do not think the X STOP is appropriate for all patients, however, there are some that require this type of device because of their various medical conditions. It would be a shame that I am not able to provide this for my patients. Therefore, I am in support of the utilization of X STOP IPD for filling a need in the treatment options for lumbar stenosis.

If you have any further questions, please do not hesitate to contact me.

Sincerely,

Brian A. Cole, M.D./BAC:cbs/gs

DUKE UNIVERSITY HEALTH SYSTEM
Corporate Finance

Stuart Smith
Assistant Vice President
Reimbursement & Revenue Accounting

June 6, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: **CMS-1488—P "Resident Time in Patient-Related Activities"**

Dear Administrator McClellan:

Duke University Hospital welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates"* 71 Fed. Reg. 23996, (April 25, 2006). We request the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments.

The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full-time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a non-hospital setting, such as a physician's office or affiliated medical school. The stated rationale for the exclusion of this time is that the time is not "related to patient care".

This position conflicts with the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures . . . and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins]. We concur with the Agency's 1999 position. The activities cited in the 1999 letter and cited again in the purported clarification are an integral component of the patient care activities engaged in by residents during their residency programs.

With the possible exception of extended time for "bench research," there is no residency experience that is not related to patient care activities. The learning model used in graduate medical education (GME) is delivery of care to patients under the supervision of a fully-trained physician. Everything that a resident physician learns as part of an approved residency training program is built upon the delivery of patient care and the resident physician's educational development into an autonomous practitioner.

DUMC 90536 • Durham, NC 27708 • tel: (919) 416-6826 • fax: (919) 416-4748 • email: stuart.smith@duke.edu

The following comprise the core of Duke University Hospital's argument against this proposal:

- **Didactics in residency programs are inseparable from the care of the patient.** For example, a resident team may be caring for a particular patient diagnosed with diabetes. Conferences that discuss the following promise a framework in which the resident can deliver state of the art, evidence based, yet individualized patient centered care:

    - Basic causes of diabetes
    - Types of complications patients experience
    - Options for treatment
    - Pros and cons of available medications
    - The impact of the patient's culture on how the disease will be viewed
    - Communication strategies that will maximize the likelihood that the patient will succeed in dealing with proposed lifestyle changes.

- **Providing adequate didactics is one of the requirements of having and maintaining ACGME residency education.** For many specialties, the ACGME defines in detail the number of conferences and hours of conference time that will be expected. They usually require documentation that residents have attended, and in many cases require that the faculty also attend to facilitate the discussions that are so critically important to problem solving and active learning. If one of the requirements for CMS funding is an accredited residency program, it makes little sense to exclude some of the essential components that the residency program must provide to stay accredited.

- **"Geography" is irrelevant, especially in an area of telephone and intranet communications.** Increasingly, conference space is being "displaced" from the hospital to accommodate more patients and more equipment. Administrative offices and rooms to discuss patient care may be displaced next door, across the street, etc. Space may be owned by a school of medicine or by a physician practice. However, all space is involved in the care of patients. In fact, if patients were better managed in a non-hospital setting, and residents learned more, perhaps the patients would need fewer and less lengthy hospitalizations, resulting in marked cost savings to CMS.

- **Important learning activities could be penalized.** All specialties are required to have conferences at which residents learn how to learn from patients without optimal outcomes. Some of these conferences involve error and provide an opportunity to critically examine the quality of care.

- **Most of our residents make a tremendous time investment in direct patient care that is supported by relatively few hours in didactics.** On the average, residents spend considerably over 40 hours per week (70-75 hours per week) in direct patient care activities. The majority of residents spend 4-6 hours a week in conferences. Each resident FTE works twice the average United States workweek. The resident makes a tremendous time investment in direct patient care that is supported by relatively few hours in didactics.

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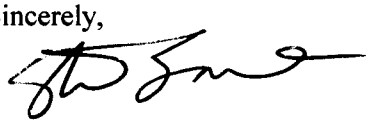
- **The practical logistics of "counting" and attempting to separate these activities is daunting.** If a resident is in a conference and is paged to attend to a patient, does this resident "clock out" and "clock in" upon returning to the conference? Adequate documentation would be difficult and an added administrative burden on hospitals. Because Duke University Hospital has expanded significantly, it is not easily discernible who owns space. For example, a conference room may be on one side of the hall and be owned by the school of medicine, and "not count", or be on the opposite side of the hall and be owned by the hospital.

To reiterate, Duke University Hospital urges CMS to rescind its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,



Stuart Smith, FHFMA
Assistant Vice President
Reimbursement and Revenue Accounting

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American Society for Bariatric Surgery
100 SW 75th Street, Suite 201
Gainesville, FL 32607

June 5, 2006

Mark B. McClellan, MD, PhD
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop: C5-11-24 Room: C5-25-25
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Proposed Changes to Hospital Prospective Payment Systems, FY 2007 (CMS-1488-P)

Dear Dr. McClellan:

The American Society for Bariatric Surgery (ASBS), which represents the foremost American surgeons to advance the art and science of bariatric surgery, is pleased to submit comments and recommendations in response to the Proposed Changes to Hospital Prospective Payment Systems, FY 2007, issued in the Federal Register by the Centers for Medicare & Medicaid Services (CMS) on April 25, 2006.

The ASBS is concerned about the proposed changes in Medicare's hospital inpatient payment system to make the payment rates better approximate the cost of services. We fully support efforts to base payments on the cost of providing services but the proposed changes do not appear to achieve that goal.

The proposal appears to have methodological flaws and to be based on weak or inaccurate data. We are particularly distressed with the recommendation to decrease the base payment for DRG 288 – O.R. Procedures for Obesity from $10,502.08 (final FY2006) to $9,201.59 (proposed FY2007); a payment change of -$1300.49 or –12.4%. We understand that the hospitals where we perform bariatric surgery are currently losing money on each bariatric surgery performed on Medicare beneficiaries. A reduction in payment of this magnitude will only further serve to restrict the access Medicare patients will have for bariatric surgery.

We hope that CMS can resolve this issue before it implements changes and we would appreciate the opportunity to review and comment on the modified proposal before it is implemented.

In summary, the ASBS urges CMS to refine its proposed methodology and collect better data on obesity surgery costs. We also recommend that CMS not proceed until it has corrected the errors and provided a full opportunity for hospitals to see the actual impacts of the changes. We thank CMS' for their consideration to this matter and hope that dramatic and unwarranted changes to hospital payments do not affect our ability to provide high quality care to Medicare beneficiaries.

Sincerely,

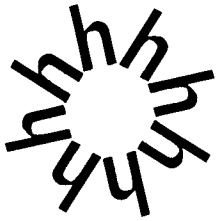
Neil Hutcher, MD
ASBS President & Bariatric Surgeon

PHONE: 352-331-4900 • FAX: 352-331-4975 • E-MAIL: INFO@ASBS.ORG

American Society for Bariatric Surgery
100 SW 75th Street, Suite 201
Gainesville, FL 32607

CC: Mark B. McClellan, MD, PhD
Administrator, Centers for Medicare and Medicaid Services
Department of Health and Human Services
HHH Building, Room 314 G
200 Independence Ave SW
Washington, DC 20201

PHONE: 352-331-4900 • FAX: 352-331-4975 • E-MAIL: INFO@ASBS.ORG



Rural Wisconsin
Health Cooperative

June 6, 2006

VIA OVERNIGHT MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Reference: CMS-1488-P; FY07 IPPS NPRM, *Federal Register* April 25, 2006.

Dear Administrator McClellan:

The Rural Wisconsin Health Cooperative (RWHC) appreciates the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment systems for fiscal year 2007, published in the April 25, 2006, *Federal Register*. We appreciate your ongoing commitment to rural health care, and RWHC looks forward to working with you in our mutual goals of improving access and quality of health care for all rural Americans.

RWHC, which began in 1979, supports and enhances rural health and quality of care. RWHC is a strong, innovative and mutually supportive network of hospitals with diversified services who combine their strengths to meet local community health needs through advocacy and high value products and services. RWHC serves as a catalyst for regional collaboration and as an aggressive, creative force on behalf of rural communities and rural health. Owned and operated by 30 rural acute, general medical-surgical hospitals, RWHC's emphasis on developing an integrated network among freestanding entities distinguishes it from alternative approaches.

The proposed rule is exceedingly complex, implementing among the most significant changes to hospital payments since the inception of the program. In summary:

- **We strongly support CMS's efforts to finally move the system from relative weights based on price to relative weights based on cost, consistent with the agency's original intent. The change is long overdue, and we oppose any delay.**

- **The CSA DRG changes are significant, burdensome, and the lack of a complete impact analysis has denied hospitals the opportunity for appropriate review and comment. It is premature to implement the CSA DRG change for FY07.**

880 Independence Lane • P.O. Box 490 • Sauk City, Wisconsin 53583 • (608) 643-2343 • FAX (608) 643-4936 • www.rwhc.com

Our detailed comments are as follows:

HSRV Weights

CMS proposes to make major changes to the calculation of DRG relative weights by using hospital-specific relative values and a modified version of costs instead of charges (HSRVcc). There has been a longstanding bias in the PPS system that skews DRG weights upwards for services performed mostly at larger urban facilities, such as teaching hospitals. Up until now, the calculation of DRG relative weights has been done by using hospital charges as a proxy for hospital costs. There may or may not be a good correlation between individual hospital charges and costs, so using charges as a basis for DRG weights is not an appropriate way to determine resource utilization based on underlying costs. RWHC supports the effort to restructure DRG weights based on cost in order to remedy this longstanding inappropriate determination of resource consumption.

Furthermore, we are all well served by remembering that the original intent of the prospective payment system was to base DRG reimbursement on costs, not charges. **We strongly support CMS's efforts to finally move the system from relative weights based on price to relative weights based on cost, consistent with the agency's original intent. The change is long overdue, and we oppose any delay.**

DRGs: Severity of Illness

RWHC has serious concerns about the proposal to use consolidated severity adjusted (CSA) DRGs. According to CMS's analysis, this proposal will lower payments to rural hospitals by 3.1 percent. When combined with the HSRVcc proposal, rural hospitals see a net cut of 0.4 percent. (Table L, *Federal Register* p. 24025.) The effect for small hospitals is even more damaging, with cuts of 5.2 percent under the CSA DRG proposal, and a net reduction of 1.3 percent from both proposals. This payment reduction will have a serious affect on rural hospitals ability to continue providing care and will restrict access to care in rural communities.

We note that there have been several analyses done outside of CMS that attempt to replicate CMS's work while correcting for various technical flaws. These analyses find the same trend for rural hospitals, but in different orders of magnitude. For example, the Moran Company's analysis addressed several technical flaws in the data, and subsequently found that rural hospitals would see a net cut of 1.2 percent under the combined HSRVcc and CSA DRG proposals. Clearly the impact analysis is highly sensitive to changes in methodology, which raises the concern that the impact of the final rule will vary widely from the proposed rule, while providing no further opportunity for comment.

Furthermore, we point out that Section 1102(b) of the Social Security Act requires a regulatory impact analysis that describes the impact on small rural hospitals, including a description and estimate of the number of small entities that will be affected, and a description of steps the agency took to minimize the economic impact. This required impact analysis is lacking for the CSA DRG proposal.

RWHC is also very concerned about the use of a proprietary system (3M Health Information Systems) to implement public policy. Under the current system, there is adequate information publicly available to replicate various aspects of the derivation of DRGs and the assignment of specific cases to a particular DRG. This degree of transparency is missing in the proposed system. There is the very real possibility of changes in public policy being brought about through changes made in a proprietary system. In addition, there is a financial burden that rural hospitals will incur if they must implement this CSA DRG system. If the new 3M Health Information Systems grouper is not in the public domain it will likely come at a high cost, given that it only available from 3M Health Information Systems or through a contract with a vendor that has a contract with 3M Health Information Systems. This cost will be borne disproportionately by rural hospitals.

Therefore, RWHC strongly advises against implementation of the CSA DRG for FY07 given the fact that (1) hospitals have not have opportunity to review and comment on a full impact analysis of the CSA DRG proposal; (2) small rural hospitals have not had the opportunity to review and comment on the 1102(b) impact analysis required by statute; (3) the data are highly sensitive to changes in methodology, which means the impact analysis provided in the NPRM will be somewhat moot if CMS changes its methodology; and (4) implementation of this proposal will impose large financial and administrative burdens on small hospitals. **The CSA DRG changes are significant, burdensome, and the lack of a complete impact analysis has denied hospitals the opportunity for appropriate review and comment. It is premature to implement the CSA DRG change for FY07.**

The RWHC appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact Richard Donkle, Director of Financial Consulting Services, at 608-643-2343 if you have any questions about these comments.

Sincerely,

Tim Size

Tim Size
Executive Director

600
(10)

ST. ELIZABETH MEDICAL CENTER
Sponsored by The Sisters of St. Francis
2209 Genesee Street • Utica, New York 13501-5999
(315) 798-8100

June 5, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
4/25/2006 Federal Register Pages 23995-24550

Dear Sir or Madam:

I am a member of the administrative team at St. Elizabeth Medical Center. St. Elizabeth is a 201 bed acute care general community hospital located in Utica, New York that is sponsored by the Sisters of St. Francis of the Neumann Communities. It is one of two hospital systems that serve the greater Utica New York area of Oneida County, New York. Over 64% of our patients are Medicare and Medicaid patients. Approximately 30% of our admissions and our revenue come to us through our cardiac surgery, angioplasty, electrophysiology and catheterization program - the program that will be hurt most by the proposed changes to the CMS regulations on DRG weights.

I request that the CMS proposed regulations that change the DRGs not be implemented as proposed and that CMS consider other alternatives to address its goals.

St. Elizabeth has a one hundred and forty year history of caring for everyone regardless of ability to pay. To this end, our Medicare and Medicaid patient volumes are, as a percentage of services provided, higher than the majority of hospitals in our region. The $3.8 million reduction in Medicare payments as proposed, coupled with the over $300,000 reductions to proposed by President Bush to Medicare, and New York State's $920,000 Medicaid reductions and trend factor freeze, have the effect of making it difficult to recruit and retain staff in a very competitive compensation environment.

Over the last few years, we have worked very hard to work more efficiently. St. Elizabeth has the highest patient severity case mix adjustment and among the lowest gross length of stay statistics of all the hospitals in the Central New York region. This is a tribute to our fine employees and the dedicated care that they provide to our patients. The reimbursement reductions that St. Elizabeth will receive if the regulations are amended as proposed will make it difficult for the Medical Center to maintain its compensation programs at competitive levels; stifle the staff development and improvement programs that are currently offered; and reduce investments in patient care services and equipment that the Medical

Center has been able to make historically. We believe that our community deserves the best possible care and access to the most effective technology that is available to treat the high demand patients that St. Elizabeth has become known to treat.

As we have reviewed the CMS amendments and how those amendments were computed, we identified a number of concerns and inequities. The most significant issue appears to St. Elizabeth in the use of the 2003 cost reporting period. Using the cost reporting period starting in January 1, 2004 would be more representative of the type of cost being incurred by St. Elizabeth for the 2007 fiscal year. For example, in 2003, before drug-eluting stents were available, the cost per stent at St. Elizabeth was $400. In 2004, when drug-eluting stents were available, the cost per stent at St. Elizabeth was $2,900. With the advent of drug-eluting stents, almost all stents implanted are drug-eluting. St. Elizabeth uses on average, 2 to 3 stents per patient which means that since January 1, 2004, the average cost per patient went from $1,200 per patient to $8,700 per patient. This is an increase in excess of 700%.

Use of this new technology has been the major reason why cardiac surgical procedures and repeat angioplasty procedures have gone down. This has increased the life expectancy of cardiac patients and minimized the invasive surgical procedures that cardiac patients have historically experienced. The cost of the angioplasty and drug-eluting stent surgical procedure costs far less than the cost of a more invasive Coronary Artery Bypass Graph procedure. Additionally, the patient recovery time is faster, increasing patient satisfaction, decreasing mortality, decreasing morbidity and extending life expectancy. In short, the procedures that will see the greatest reductions in Medicare reimbursement, are more efficient and cost effective from a pure dollars and quality of life perspective than the alternatives.

Commentators on the proposed regulations have indicated that the CMS revisions are being driven to some extent by recommendations made by MedPAC. MedPAC's recommendations were being driven by:

1. concerns that specialty hospitals are taking too much profit out of the Medicare program while other services are not being paid at adequate levels;
2. the need to move the reimbursement system away from charge based payments and toward cost based payments; and
3. the need to refine severity adjustments to the payment system.

<u>Specialty Hospitals/Limited Service Hospitals</u>

Although St. Elizabeth has a high percentage of cases that are brought about by the reductions, St. Elizabeth should not be confused as being a specialty/limited service hospital. St. Elizabeth is an acute care, general, community hospital. The margin that is realized through the efficient use of St. Elizabeth's facilities and the hard work of our employees are plowed back into the community's hospital services, some for the benefit of the Medicare population, some for the Medicaid population and the balance for the commercially insured and the uninsured populations. St. Elizabeth's status as a community hospital means that it

provides a full range of services and operates for the benefit of the entire community on a 24/7 basis.

St. Elizabeth Medical Center is an Area Trauma Center. As such it receives more complex cases and a wider variety of cases than specialty or limited use hospitals and most community hospitals. The changes to the regulations as proposed will severely limit St. Elizabeth's ability to address this population at reimbursement levels that are fair and equitable and at levels that will support this needed service in the Community. St. Elizabeth is the only Area Trauma Center between Albany, New York and Syracuse, New York, a distance of approximately 150 miles.

If CMS's intention was to address the specialty or limited service hospitals' use of margin to benefit their physician owners, address it. Do not cast the net unnecessarily wide to encircle community hospitals. We recommend that CMS include in its regulations some hold harmless provision that will provide community hospitals from the unintended consequence of the reductions that are focused more on specialty or limited service hospitals.

Movement Away from Charge Based Reimbursement

It is our understanding that the proposed regulations adopt a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. The change is drastic in that it changes the entire emphasis and understanding of what severity means, as it relates to treatment of patients and reimbursement for patient care.

We understand that there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights. When the drug-eluting stent was approved by the FDA, St. Elizabeth updated its charge master to reflect the significant increase in stent cost from $400 per uncoated stent to $2,900 per drug-eluting stent. We believe that a significant percentage of hospitals nationally did not do this. There is not a significant margin being earned by the hospitals, but rather an exaggerated margin shown on paper because charge masters were not updated to reflect changes in actual costs.

The effect of these reductions will mean that hospitals cannot afford to provide the services to those that need it, but rather will need to limit or ration the service to only the most critical patients. The availability of services will be limited due to cost, since adequate facilities will not be able to be built and maintained to supply the demand. Rationing of healthcare services has not been, to date, a goal of the Medicare program and is not consistent with the mission of St. Elizabeth.

Severity Adjustments to DRGs

Reviewing of the severity adjustments to DRGs is a good thing, but when those are reviewed, appropriate weight and consideration should be provided to severity issues. Over the last few years, St. Elizabeth Medical Center has become very efficient. Its unadjusted case mix length of stay is 5.4 days which is among the lowest in the Central New York region; its occupancy rate of 89.2% which is the highest in that same region; and its case mix is in excess of 2 which is among the highest in Central New York. These impressive statistics are a testament to the hard work that our 1900 employees provide to the sickest patients in our community. Our clinical staff is on the front line in caring for those patients with multiple morbidities and care that treats higher severity conditions. If the changes is inevitable, postponing or phasing the DRG changes to address the addition of the 300+ new DRGs would appear to be a better approach rather than doing part now and part later.

Technical Points

The changes that CMS is proposing are significant. There is significant precedent to have changes of much less significance be phased in over a 5 to 10 year time frame. This will allow current programs to properly plan and develop modifications so that when the change is ultimately implemented, appropriate community planning could have occurred. Community planning can take a number of forms from collaboration to consolidation, among many others. Allowing time for the community to plan will ensure that the medical and surgical services that are being provided are appropriate to meet the community need.

Shifting of the reductions in DRG payments of 903 hospitals to 2,619 hospitals nationally is inequitable and discriminates against those 903 hospitals who must pay for the benefit being received by the 2,619. In New York State the problem is greater in that 30 hospitals will have their reimbursements reduced while 149 hospitals will see their reimbursements increased. Both in New York State and nationally, the very large reduction in payments on a hospital by hospital basis is spread very thinly over the large number of hospitals that will see increased payments under the proposed regulation.

Summary

The payment methodology changes that CMS has proposed would have a severe financial impact on St. Elizabeth, our employees and our community – without accurate data to justify the change. In addition to requiring the potential dismantling of this infrastructure, St. Elizabeth would face the uncertainty of what other changes will be proposed by CMS that will put St. Elizabeth in further financial jeopardy. Access issues will develop as a result of this shift. Finally, use of the 2003 cost report does not ensure an accurate reflection of cost to be used on a going forward basis.

We respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity-adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments. We ask that you reconsider the changes to the regulations

and if elimination of the changes cannot occur, that CMS consider a gradual phase in of the effect of the regulations on hospitals such as St. Elizabeth – acute care general community hospitals.

Thank you for your consideration.

Very truly yours,

Sister Rose Vincent
Board of Trustees Member
Emeritus

Enclosure – 2 copies of letter
cc: Congressman Sherwood Boehlert
Senator Charles Schumer
Senator Hilary Clinton
Board of Trustees of St. Elizabeth Medical Center

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Orchard Medical Center
330 Orchard Street · Suite 210
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Arrhythmia Center of Connecticut, P.C.

MARK H. SCHOENFELD, M.D., F.A.C.C. MARK A. MARIEB, M.D., F.A.C.C.
MARK L. BLITZER, M.D., F.A.C.C.

June 6, 2006
(DOS May 29, 2006)

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

I am aware that apparently CMS will be proposing significant changes to its DRG methodology. As a cardiac electrophysiologist I understand that the area of cardiology will be targeted in this cut back in reimbursement. I am not sure of all of the details of your proposal as it is very complicated.

From a standpoint of a practicing physician I would note several issues.

Firstly, hospitals are at this point in a "crisis." I am not sure you are aware but if you have been an inpatient in any hospital recently in the United States the hospitals are dirtier, less efficient; there are less personnel to care for patients, etc. Overall, the quality of health care has declined significantly due to cutbacks. As the cost of living and the cost of basically everything is increasing you are actually decreasing things more than it appears given the fact that everything including equipment, etc. costs more.

I would note that from my standpoint we are offering more and more complex procedures. Our procedures sometimes take many hours to complete. This requires an increase in technology, room time, etc. Thus, overall, your proposal should take into account an increase and the cost of care as opposed to decrease.

I hope that you would consider what would happen to yourselves if you were sick. I do think you would want the highest quality care possible. You are definitely reducing the quality of health care by your proposed cut backs both to physicians and hospitals. Again, I would have expected yearly increases due to increasing technology and complexity of procedures and increasing costs as opposed to proposed decreases. I really hope that instead of looking at the "bottom line" you look at the quality of patient care which is really what you should be concentrating on especially as you yourself may become patients some day.

Please do not hesitate to contact me should you wish to discuss this further.

Thank you very much, again.

Sincerely,

Mark A. Marieb, M.D.

MAM/plw

Madonna
Rehabilitation Hospital

TherapyPlus
Outpatient
Services

Rehabilitation
Specialists
Physicians Group

Research Institute
Rehabilitation
Science &
Engineering

St. Jane de Chantal
Extended Care
Services

Foundation
Supporting
Madonna
Rehabilitation
Hospital

June 7, 2006

Mark McClellan, M.D., Ph. D.
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates -- CMS–1488- P

Dear Dr. McClellan:

Hospitals-Within-Hospitals

Madonna Rehabilitation Hospital (MRH) is writing to you in response to the Centers for Medicare and Medicaid Services (CMS') proposed rules published on April 25, 2006 at 71 Fed. Reg. 23996. This rulemaking proposes revisions to the regulation governing grandfathered long-term care hospitals-within-hospitals (HwHs). MRH is a not-for-profit Catholic facility located in Lincoln, Nebraska and sponsored by Diocesan Health Ministries, a division of the Catholic Dioceses of Lincoln. Madonna is considered a local, regional and national provider of comprehensive rehabilitation services. Inpatients from 29 states throughout the United States have received their rehabilitation at Madonna over the past 5 years. MRH is a grandfathered HwH under Section 4417(a) of the Balanced Budget Act of 1997. As a result, we are precluded from making any changes in square footage or bed number that affect Medicare or Medicaid payments. In order to retain grandfathered status, MRH may not:

- change (increase or decrease) square footage;
- change (increase or decrease) the number of its beds; or
- change its term and conditions of operation in any way.

For the reasons discussed below, it is critical that the exceptions contained in the proposed revisions to the grandfathered HwH rule be expanded to allow grandfathered HwHs to increase their square footage and number of beds to improve operations and patient care.

In the proposed rate year 2007 update rule for hospitals subject to the inpatient short-term acute hospital prospective payment system (IPPS), CMS has proposed limited revisions to the rule governing grandfathered HwHs:

- to allow for increases or decreases in square footage, or decreases only in the number of beds, due to relocation of the hospital (a) to permit construction or renovation necessary to comply with state, federal or local law affecting the physical facility, or (b) because of a catastrophic event, such as a fire, flood, earthquake, or tornado;
- to allow for decreases only in the number of beds or square footage.

We are grateful for these exceptions, however, we feel that CMS' proposed changes to the grandfathered hospital-within-hospital rule at 42 C.F.R. §412.22(f) are inadequate.

CMS' proposed revisions to 42 C.F.R. §412.22(f) do not address the need for grandfathered HwHs to change programs to meet patient care requirements. As a community-based rehabilitation hospital, MRH has always developed and expanded programs to meet the healthcare needs of the residents of Lincoln, the state of Nebraska and the Midwest region. Over the years, we have modified our hospital to: create additional private patient rooms to accommodate patients with communicable and infectious diseases; increase the size of rooms to accommodate patient care equipment such as ventilators, power wheelchairs and patient lifts; and, develop program specific ancillary service space for dialysis and comprehensive rehabilitation.

If MRH is not allowed to make operational changes as described above, then MRH will be unable to respond to the ever changing needs of its patient population and community, and to changes in medical practice.

The preamble to the proposed rule states CMS' underlying reason for imposing restraints on the operations of LTCHs grandfathered by 42 C.F.R. §412.22(f) is the potential of patient shifting between co-located entities and a host hospital. We can understand this concern. MRH is one of the few grandfathered HwH facilities that is co-located with an Acute Rehabilitation Hospital or Inpatient Rehabilitation Facility (IRF) and not an acute care hospital. Year-to-date for fiscal year 2005-06, we have admitted only 11 or 1.4% of our total LTCH admissions from our co-located IRF. From a historical perspective, this number averages .9% or less than 1% of our total LTCH program admissions. Based upon this data, hopefully it is clear that virtually all of our LTCH admissions came from external sources and not our co-located IRF hospital and changes in conditions of operation such as bed size and square footage would not increase patient shifting.

In view of the foregoing, MRH requests CMS expand its proposed revisions to the grandfathered HwH regulation to allow for increases in the number of beds or square footage where (1) such increases are consistent with the needs and best interests of Medicare beneficiaries, for example, to create isolation rooms, to provide ancillary services or therapeutic services necessary for patient care, to add or expand on-site provider-based activities related to patient care, or to increase ventilator support or (2) a grandfathered HwH is co-located with an IRF and not with an acute care hospital.

Please also note that Madonna Rehabilitation Hospital endorses the comments submitted by the National Association of Long Term Hospitals on this issue. Thank you for your consideration of these comments.

Sincerely,

Paul A. Dongilli, Jr., Ph.D.

Paul A. Dongilli, Jr., Ph.D., CHE
Vice President Rehabilitation Services

SPINE CENTER NORTHWEST
2211 NW Professional Dr
Corvallis, OR 97330

CMS Dept of Health & Human Srvcs.
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Dear Sirs,

I have been using the X-Stop device, manufactured by St. Francis Medical, in my practice the last several months. I decided to incorporate the uses device in my practice based upon what I felt was sound mechanics, device construction, trial performance and minimal surgical exposure.

During this time I've perform the procedure on 10 patients including 16 levels of disease. To date every one of these patients has rated the results of this procedure as excellent. I've attempted to follow the criteria for patient selection including age over 50, a sitting tolerance of 50 minutes, poor standing and walking tolerance but of at least 50 feet, six months of felt prior treatment and no osteoporosis.

This procedure has exceeded my expectations. The short term results for spinal stenosis including three these patients with a grade 1 degenerative spondylolisthesis, I believe is better than that which I see in a fairly matched group of patients who have had decompressions and fusion surgery for the same pathology. The recovery time for this procedure is amazingly short and most of the patient's report that the decades of degenerative spine pain is relieved as well.

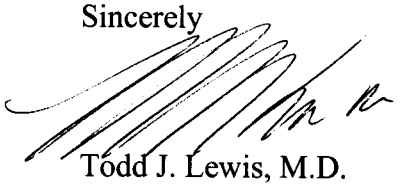
Personally, I perform this procedure as an inpatient though their stay is less than 24 hours in the hospital. I do not have an outpatient facility available in my area. Also many of these patients have called morbid factors which I preferred a monitor in a controlled environment after surgery. I do perform the surgery under general anesthesia, not local, as it provides another level of control over the operating environment.

At this time I am extremely enthusiastic about the early results I'm seeing with this device. I'm well aware that they may be some recurrent problems due to the nature of the patient's pathology, but the more extensive decompression and fusion surgeries will have the same potential difficulties over time as surgery for spinal stenosis as a time related failure rate.

At this time there are some billing difficulties for this procedure as the exposure code would frequently involves removal of some osteophytes from the facet joints to facilitate a laminar level approach, is not a code that bundles with insertion of his spine device in that it is not a fusion code. This generates an appeal for every one of these that I perform

through Medicare as the insurance. I do not have this issue with non Medicare providers in my area whom have been reimbursing for this procedure.

Sincerely



Todd J. Lewis, M.D.

ST. FRANCIS MEDICAL TECHNOLOGIES, INC

URGENT

May 30, 2006

Todd Lewis, MD
3640 Nw Samaritan Dr
Corvallis, OR 97330

Re: X STOP IPD / Medicare Application Comments

2nd REQUEST

http://www.cms.hhs.gov/AcuteInpatientPPS/downloads/cms1488p.pdf (pages 257 – 261)

Dear Dr. Lewis,

St. Francis Medical Technologies is working hard toward preserving financial viability for our X STOP prescribers and client hospitals and your Medicare patients. Toward this effort it is extremely important that you participate in the above process.

We strongly encourage you to submit comments to CMS in support of the X STOP IPD application. If approved, it would mean a significant difference to your partner hospitals.

Deadline for receipt of public comments is **Friday, June 9, 2006**. Optimally, we ask that you include the following points:

- Why you would like to incorporate use of the device in your practice.
- Anecdotal experiences you may share.
- Why inpatient and outpatient setting options are important in your clinical decision making process for your X STOP patients.
- A statement of support regarding X STOP IPD filling a niche for your patient population as a treatment option.

Comments must be submitted in ***TRIPLICATE*** to:

CMS
Dept of Health & Human Srvcs.
ATTN: **CMS-1488-P**
P.O. Box 8011
Baltimore, MD 21244-1850

960 Atlantic Avenue, Suite 102
Alameda, California 94501
510.337.2600
Fax 510.337.2698
info@sfmt.com

We would be grateful if you would share a copy of your comments with SFMT directly. Please forward to us at:

St. Francis Medical Technologies
CMS Comments
960 Atlantic Avenue, Ste. 102
Alameda, CA 94501

Or VIA FAX: (510) 747-3007

Thank you for your consideration.

Respectfully,

Mary M. Corkins, MBA, CPC
Director, Health Economics
(224) 715-1770 Cell
(510) 337-2611 Office

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(8)

GOOD SAMARITAN
Medical Center
Tenet South Florida

1309 North Flagler Drive
West Palm Beach, Florida 33401
Tel 561.655.5511

June 6, 2006

Overnight Mail Tracking No: 16479298850
(DHL)

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Proposed Changes to the Inpatient Prospective Payment Systems and FY 2007 Rates regarding "Geographic Reclassifications – Urban Group Hospital Reclassifications" (File Code CMS-1488-P)

Dear Sir or Madam:

The purpose of this letter is to comment on the FFY 2007 proposed Inpatient Prospective Payment System (IPPS) regulation regarding geographic wage index reclassifications and urban group hospital reclassifications.

Good Samaritan Medical Center is a 333 bed, for profit, acute care facility located in Palm Beach County Florida. 50.01% percent of our patient population consists of Medicare beneficiaries and adequate Medicare reimbursement is critical to our continuing ability to meet their needs.

In 2004, when the FFY 2005 proposed IPPS regulation regarding geographic wage index reclassifications and urban group hospital reclassifications was published, Palm Beach County hospitals had, for the first time, qualified for the opportunity to reclassify for wage index purposes. Palm Beach County hospitals qualified in part because the FFY 2005 proposed rule allowed Metropolitan Divisions within a CBSA to qualify for an urban group reclassification. Based on the FFY 2005 proposed regulation, we joined with all other Palm Beach County hospitals and applied for the urban group reclassification. However, the final FFY 2005 IPPS regulation revised the proposed criteria and eliminated the ability for Metropolitan Divisions within a CBSA to qualify for an urban group reclassification.

We subsequently learned, however, from CMS through the FFY 2007 IPPS proposed regulation that the intent of the urban group reclassification was, and is, "to allow hospitals located in counties that are in the same CBSA (in the case of Metropolitan Divisions) as the area to which they seek redesignation to be considered to have met the proximity requirement We agree with CMS on the point above and agree with CMS on the following two points; that "the proximity standard for group reclassifications is intended to allow all of a county's hospitals to reclassify to an adjacent area where there is sufficient economic integrations that there can be an expectation that both areas are competing in a similar labor market area," and that "we believe there is sufficient economic integration between Metropolitan Divisions within a CBSA that urban county reclassifications within a CBSA or a CSA should be permitted."

We thank CMS for recognizing the economic integration between Metropolitan Divisions within a CBSA and request that CMS, at a minimum, adopt the FFY 2007 IPPS proposed urban group reclassification eligibility criteria [Sec. 412.234(a)(3)] as proposed, without modification.

However, we do believe, based on the CMS comments quoted above from the FFY 2007 IPPS proposed regulation, that the hospitals of Palm Beach County should have been allowed to qualify for an urban group reclassification beginning in FFY 2006 had the final FFY 2005 IPPS regulations correctly recognized the economic integration between Metropolitan Divisions within a CBSA (as CMS had done in the FFY 2005 proposed regulation and now again recognizes in the FFY 2007 proposed regulation).

Therefore, we respectfully request that CMS, in the final FFY 2007 IPPS regulation, make the FY 2007 proximity criteria effective for urban group reclassifications beginning on October 1, 2006 (as opposed to October 1, 2007) IF the urban area:

- Filed an application for urban group reclassification by September 1, 2004 for reclassification beginning on October 1, 2005;
- Met all of the non–proximity urban group reclassification criteria published in the FFY 2005 final regulation;
- Had the application denied only because the urban area did not meet the flawed FFY 2005 proximity criteria;
- Would have had the application approved had the FFY 2007 proposed proximity criterion been the criterion in the FFY 2005 final regulation;
- Meets the proximity and non-proximity criteria described in the FFY 2007 IPPS proposed regulation; and
- Files an application for urban group reclassification by September 1, 2006.

Based on the aforementioned information we request that CMS incorporate the proposed revision, as written above, in the FFY 2007 final IPPS regulation. We believe the requested revision is critical to the financial stability of the hospitals located in the West Palm Beach Metropolitan Division and should take effect, for payment purposes, for all hospitals in the West Palm Beach Metropolitan Division beginning October 1, 2006 rather than delaying until October 1, 2007. If granted this revision will allow the urban group reclassification to take effect one year sooner than otherwise currently proposed, though a year later than the date which we would have otherwise qualified (October 1, 2005) had the final FFY 2005 regulation properly recognized the intent of the economic integration criteria.

We appreciate your consideration of this comment to the FFY 2007 proposed IPPS regulation.

Respectfully,

Paul Echelard
Chief Executive Officer

65

St. John's Hospital
800 E. Carpenter Street
Springfield, Illinois 62769
(217) 544-6464 • www.st-johns.org

June 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Post Office Box 8011
Baltimore, Maryland 21244-1850

RE: CMS-1488-P; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates

Commenting on: General Comments; HSRV weights

Dear Dr. McClellan:

My name is Steve Eavenson and I am the Chief Financial Officer of St. John's Hospital in Springfield, Illinois. St. John's Hospital is a 731 bed teaching facility with a 130 year history of caring for the health care needs of the Springfield community. St. John's is a member of the Hospital Sisters Health System and employs over 3,000 individuals. Recognized as one of the largest cardiac providers in the State of Illinois, St. John's also serves as a Level 1 Trauma Center as well as a Level III Neonatal Intensive Care Unit. As one of the largest acute care providers in the region, St. John's serves over 22,000 inpatients including 10,000 Medicare inpatients a year.

I appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates (CMS-1488-P). While I am supportive of many of the provisions in the proposed rule, I am very concerned about the proposed methodologies resulting in inaccurate payment amounts, particularly for the cardiovascular services we provide our patients. In particular, I am extremely concerned about the proposed DRG weight setting methodology. If the proposed weight setting methodology were adopted, St. John's Hospital would face an additional estimated loss of $8.4 million in Medicare reimbursement in Fiscal Year 2007. This reduction will, without any exaggeration, cause a huge disruption in our hospital.

Because of the inaccurate payment amounts being developed by the proposed methodologies with numerous calculation flaws, I urge CMS to allow time for further study of the proposals

until further analysis can be performed to understand the full impact to hospitals and patients, but in the meantime continue with the current charge-based system. I agree that payment rates should accurately reflect the cost of services provided. However, inaccurate payment rates could limit hospitals' capabilities to perform services and this limit patient access to some therapies. The current proposal, if implemented, could have unintended and inappropriate consequences.

Questions and issues have been raised about CMS's proposed rate setting methodology. Some of these include:

- CMS used old data to calculate the payment rates. DRG weights under the new rule are based on data that are 3 to 5 years old. This particularly impacts technology based DRGs. Medical technologies typically have a short lifecycle, meaning that many of the innovative technologies available today, such as cardiac resynchronization therapy defibrillation (CRT-D), were not widely in use at the times these data were collected.

- The use of nonstandard data leads to increased inaccuracy. The current cost reports were designed for a different purpose; CMS should put more thought into how to improve and verify the accuracy of this data prior to making it the basis of its new payment system. CMS assumed in its crosswalk of the Medicare cost report that it would develop 10 distinct cost centers from the data. They further assumed that hospitals filed cost reports utilizing the same line numbers for expanded cost centers that are close to the "parent" cost center line number. This is generally done by componentizing the hard coded line number on the cost report. For example in Cardiology, line number 53 is hard coded as "Electrocardiology" on the cost report. CMS has assumed any Cardiology related services have been numbered using either line number 53 or line number 54 in their crosswalk. This would only be true if hospitals have followed the same logic that CMS has assumed, that additional break-out Cardiology related cost centers on the cost report have been numbered using components of 53 and 54 (i.e. 53.1). The same would hold true for the other 9 cost centers. There has been nothing in the cost report instructions dating back to cost based reimbursement that states how an incremental cost center should be numbered. In fact, in the days of completing costs reports on paper, there were only blank lines at the bottom of each section that were open to be used for adding cost centers. This same sequence of reporting cost centers was most likely carried over by these same hospitals to file their electronic reports. In the case of St. John's Hospital, line 59 has traditionally been used to report Cardiac Cath Lab costs. There have been no

cost report instructions to ever do otherwise nor was the issue ever a point made upon cost report audit. Under CMS' crosswalk, these very high Cardiology costs were mapped to the "Other Services and Charges" cost center and not Cardiology where they belong. Such a mismatch by St. John's and other providers will cause the understatement of costs.

- Technical mistakes as well as questionable technical assumptions alter the estimated impact on payments. In one example, CMS excluded approximately one quarter of large hospitals' routine day charges in calculating cost-to-charge ratios, which almost doubled the cuts in some DRGs and raised the increase in equal amounts to others. Had these data been included, the large shift in payments for some DRGs would be reduced by nearly half. Another example is how CMS failed to adjust for the volume of care among hospitals, resulting in a small hospital do a relatively few number of Cardiac procedures having as much weight in Cardiology as a large volume hospital with a huge Cardiac base.

- Charge compression continues to be a major issue, particularly for costly, high value medical devices. Despite continued pleadings from industry, hospitals, Congress and others, charge compression was not addressed in the FY 2007 rule, and is in fact, made worse. Instead of individually analyzing the high cost, high value devices to better understand real costs, CMS decided to put everything together in 10 national cost centers. The problem is that there are no standards- most devices and supplies are put in a single cost center, and hospitals across the country put them in different categories, so the real costs may never be captured.

The current proposed DRG payment rates are in some cases the same or lower than the purchase price for ICDs and CRT-Ds. Proposed rates for ICD and CRT-D procedures are sometimes below the device acquisition cost, not allowing hospitals payment for operating procedures, supplies, and personnel. For example, DRG 515, where a majority of ICD implants fall, was paid at a base of $28,441 in 2006; for 2007 Medicare is proposing a sharp decrease in payment of 23%, down to $22,015- one of the biggest percentage decreases any DRG faces this year.

If this change is implemented, hospitals could find themselves with limited capabilities to offer their patients leading edge, high value lifesaving technologies. Hospitals cannot sustain themselves economically when inaccurate payments do not cover the cost of supplies, equipment, staff and medical devices. This could result in hospitals altering normal treatment patterns, restricting technology selection and limiting patient access in order to avoid extraordinary financial losses.

I urge CMS to delay implementation of the 2007 proposed rule until careful analyses are performed and the full impact to hospitals and patients is understood. Although the proposed changes are directionally correct, the sheer magnitude of the changes coupled with the many unintended flaws requires CMS to delay implementation. I further urge CMS to continue with the stable, charge based system that has been in place for the past 23 years until a better, more accurate alternative can be found. Finally, once an appropriate alternative is developed, I would ask CMS to allow a three year transition period of implementation.

I appreciate CMS's efforts to improve the inpatient payment system and agree that it is our mutual goal to improve the lives of Medicare beneficiaries. We all must work together with diligence and with dedication to address these complex issues.

Sincerely,

J. Steven Eavenson
Chief Financial Officer
St. John's Hospital
800 E. Carpenter Street
Springfield, Illinois 62769
Telephone: (217) 544-6464

cc: Honorable Richard J. Durbin
Post Office Box 790
Springfield, Illinois 62705

Honorable Barack Obama
607 East Adams Street
Springfield, Illinois 62701

Honorable John Shimkus
3130 Chatham Road
Springfield, Illinois 62704

Honorable Ray LaHood
3050 Montvale Drive
Suite D
Springfield, Illinois 62704

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(3)

Electrophysiology Associates, PA

MORRISTOWN MEMORIAL HOSPITAL • 100 MADISON AVENUE • MORRISTOWN, NEW JERSEY 07962-1956

Stephen L. Winters, MD
Jay H. Curwin, MD
Robert F. Coyne, MD

Tel: 973.971.4261
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June 5, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates

Commenting on: General Comments; HSRV Weights

Dear Dr. McClellan:

I am a cardiac electrophysiologist in New Jersey. My partners and I are the primary implanters of pacemakers and defibrillators in our hospital. Medicare patients are an important part of our practice, and the inpatient hospital payment system can affect how we are able to treat them.

I'd like to share my concerns regarding the proposed inpatient rule for FY2007. I believe that if these changes are implemented, they could have a negative effect on some hospitals, and ultimately could impact the patients we treat.

These comments will discuss:

1. That payment rates should accurately reflect the cost of services provided; inaccurate rates could limit hospitals' capabilities to perform services, and thus limit patient access to some therapies.
2. The potential impact of these payment inaccuracies on patients, particularly cardiovascular patients who are treated with high-technology solutions.

Payment rates should accurately reflect the cost of services provided. Inaccurate rates could limit hospitals' capabilities to perform services, and thus limit patient access to some therapies. The current proposal, if implemented, could have unintended and inappropriate consequences.

- **Questions have been raised about CMS's proposed rate-setting methodology.** At a high level, some of these issues include CMS's use of data that are 3–5 years old to calculate the payment rates; technical discrepancies such as counting a small hospital equal to a large hospital in calculations; throwing out a quarter of the hospitals' routine day charges in calculating cost-to-charge ratios; as well as questionable technical assumptions that can alter the estimated impact on payments. Charge compression, a major issue for high-value, high-technology devices, also continues to be a problem and is not properly addressed in the proposal.

- **The current proposed DRG payment rates are in some cases the same or lower than the purchase price for ICDs and CRT-Ds.** Proposed rates for ICD and CRT-D procedures are sometimes below the device acquisition cost, not allowing hospitals payment for operating procedures, supplies, and personnel. For example, DRG 515, where a majority of ICD implants fall, was paid at a base of $28,441 in 2006; for 2007 Medicare is proposing a sharp decrease in payment of 23%, down to $22,015—one of the biggest percentage decreases any DRG faces this year.

Poor economics mean hospitals have to make difficult decisions when it comes to using leading-edge, high-technology solutions for their patients.

- If this change is implemented, hospitals could find themselves with limited capabilities to offer their patients some advanced and technologically-driven therapies, particularly for certain cardiovascular therapies such as implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy with defibrillator (CRT-D) therapy.

- This could result in hospitals altering normal treatment patterns, restricting technology selection, and limiting patient access in order to avoid extraordinary financial losses. As a result, patients may not receive the already underused lifesaving ICD and CRT-D therapies because hospitals are not receiving payment that recognizes the full cost of the services provided.

- Hospitals cannot sustain themselves economically when inaccurate payments do not cover the cost of supplies, equipment, staff, and medical devices.

- **ICD and CRT-D therapies are the standards of care** as recognized by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) practice guidelines for many patients. It is important to set payment rates that allow for physicians to provide the right care at the right time for the right patient.

Conclusion

Sweeping decisions of this nature need thorough analysis prior to being implemented. Additionally, intended and unintended consequences need to be examined carefully prior

to making major changes that could adversely affect hospitals, physicians, and most important, patients.

To ensure continued access to high quality care for Medicare beneficiaries, appropriate payment under the prospective payment system is critical. As such, I reiterate my request that CMS allow time for further study of the proposals, but in the mean time continue with the current charge-based system.

I appreciate CMS's efforts to improve the inpatient payment system, and agree that it is our mutual goal to improve the lives of Medicare beneficiaries. We all must work together with diligence and dedication to address these complex issues.

Sincerely,

Jay H. Curwin, MD

67-0
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June 5, 2006

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Docket Number: CMS-1488-P

Dear Dr. McClellan:

I am writing as a healthcare controller of Deaconess Hospital, Inc., an acute care nonprofit hospital in southern Indiana. We provide care for a population of almost 900,000 residents of southern Indiana, western Kentucky and southern Illinois.

As a regional tertiary referral hospital we have had a longstanding tradition of being a leader in cardiovascular care and providing many firsts to the tri-state in this service. We have been named as a top 100 heart program. Our cardiovascular program brought open heart surgery to the region in the late 1970s and over the last 30 years has provided the latest in technology and procedures. We are on course to this year perform more than 550 open heart surgical procedures and more than 900 percutaneous coronary intervention (PCI) procedures. Our Electrophysiology program assesses patients for the clinical indicators that place them and risk for sudden death, and provides life saving device implants.

As a hospital, we have more than 4,000 inpatient discharges each year categorized as a cardiovascular DRG. Of our cardiovascular inpatients, 70 percent of them are Medicare beneficiaries. In partnership with our cardiologist, we offer more than 22 rural cardiovascular clinics, where our cardiologists travel to small rural hospitals bringing cardiovascular services to communities that otherwise do not have access to this specialty care.

I appreciate the considerable effort of you and your staff in the development and improvement of the inpatient prospective payment system (IPPS) and recognize that there is need to evolve the system to reflect the current landscape within the medical field. I appreciate that there are significant complex matters in gathering accurate cost data, and that that data serves at the basis of payment systems such as the proposed IPPS.

CMS Proposed Changes

As I understand the current situation, CMS is proposing to make significant changes to IPPS, in a response to what seems to be primarily based upon the MedPAC report. While the work of MedPAC was to address the "specialty hospital" situation, this resulting change in reimbursement is targeted at all hospitals, and particularly those that provide significant tertiary referral cardiovascular care. Tertiary referral hospitals see more procedure based cardiovascular patients – those financially targeted the most by the CMS changes.

There are two significant areas of concern with the proposed IPPS. First, the proposal incorporates an estimated "cost-based" system, rather than a charge-based system for determining the payment weights for each patient category in 2007. Second, the proposal seeks to change the way of identifying the variation in patients' severity of illness that would be implemented in 2008, or potentially 2007. Each change is significant and in previous years would be considered a major modification to the payment system. Changing both at one time is unprecedented.

CMS proposes to base payments on "cost". In many ways this can be looked upon as a positive change and is consistent with how private insurers handle costs associated with technology. However, the primary difference between CMS's proposed methodology and private insurers is the timing of cost data. Private insures are utilizing data in real-time and are paying actual invoice cost for technology used in the care of patients. In CMS's proposal, the "cost" for a particular category of patients is not an approximation of the actual price the hospital pays for the items and services required to treat patients, rather it is a rough approximation of costs.

To calculate the cost estimates for Fiscal Year 2007 payments, CMS proposes to utilize hospital claims data from Fiscal Year 2005 and hospital cost reports from Fiscal Year 2003. The cost reports provide the actual cost and the actual charges for all patients (non-Medicare and Medicare patients). The use of any data from Fiscal Year 2003 fails to account for current technology costs, particularly drug-eluting stents and bi-ventricular pacemakers/defibrillators. These devices today are the mainstay of any cardiovascular program across the nation and represent a clinical standard of cardiovascular care in any community. As this stands, the estimates on cost that CMS will use to put forth its rates in 2007 will necessarily be incorrect and will inadequately compensate hospitals for the care of Medicare patients.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by approximately 10 percent. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6 percent to surgical DRGs, while increasing medical DRGs by 6 percent. In addition, technology intensive DRGs will be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24–34 percent, ICD implants will be reduced 22–24 percent and pacemakers will be reduced 12–14 percent severely impacting these services.

These proposed reductions to cardiac services are severe and are not rooted in any type of realistic mechanism for assessing costs to provide treatment. While it is appropriate to pursue a better understanding of actual cost to treat cardiac patients, and such efforts must be made with the intention of producing accurate information – the end result may well be an alteration in the existing infrastructure for cardiac services reimbursement. However, the existing proposal simply cannot be implemented in its current form, as the impact for cardiac programs across the country will be grave and may potentially limit patient access to leading edge technology (because hospitals will not be able to adequately recover their acquisition costs). I do not believe that this is what CMS intends to achieve with this proposal.

Given the situation described, delaying the implementation of any changes to cardiac services reimbursement until such time as accurate and appropriate information regarding cost to treat and manage patients with cardiovascular diseases can be compiled is the only prudent approach that can be taken.

Cardiovascular disease is our nation's number one killer, and residents of Evansville, Indiana and the tri-state we serve have a higher rate than the nation of dying from this disease. These changes are very real to our hospital cardiovascular program and will significantly impact our financial ability to provide the level of services our community has become accustomed to receiving from us.

I realize that this is an extremely complex issue, that CMS is committed to ensuring adequate reimbursement for all clinical services and desires to ensure that hospitals remain able to provide access to high quality cardiovascular care involving cutting edge technologies in all settings of care. I appreciate your consideration of this matter.

Sincerely,

Cheryl A. Wathen
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BlueCross
of Northeastern Pennsylvania

An Independent Licensee of the
BlueCross and BlueShield Association
Agent for Pennsylvania BlueShield

Denise S. Cesare
President and Chief Executive Officer

June 1, 2006

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attn: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Comments to Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
Published in the Federal Register on April 25, 2006

Dear Directors Kuhn & Smith:

As Chief Executive Officer of the largest insurer in northeastern Pennsylvania, I am submitting this letter in support of the Susquehanna Health System (SHS) in Williamsport PA, to achieve parity with neighboring hospitals regarding their Medicare wage index.

SHS, through The Williamsport Hospital & Medical Center, provides key medical services to the western counties of the 13-county region serviced by Blue Cross of Northeastern Pennsylvania. As a healthcare leader in this region, many patients from around the area come to Williamsport for much needed medical services. Additionally, the Health System is instrumental in recruiting physicians to the north central region, further evidencing their role as the major health care provider for Lycoming and surrounding counties.

I, and Plan officials, have met with SHS executives many times over the past 12 years to review the Health System's service delivery, operations and finances. Since the creation of SHS in 1994, the Health System has consolidated many services and therefore operates in an efficient manner. Payments from the Medicare Program, however, are less than operating costs as a result of the low Medicare Wage Index that is being assigned to them. Since 49% of all services performed by The Williamsport Hospital and 40% of services performed by Divine Providence Hospital are provided to Medicare beneficiaries, the shortfall experienced by both hospitals is considerable – totaling almost $4 million.

To add to the concern of hospital officials, they identified for me that other major hospitals, namely Geisinger Medical Center (Danville) and Evangelical Hospital (Lewisburg), have been assigned the Harrisburg Wage Index rates, which provide higher payments for Medicare services – approximately 6% on every service provided. Both are within 35 miles of The Williamsport Hospital and Divine Providence Hospital, and both compete aggressively for clinical staff, such as registered nurses, CRNAs, critical care nurses, etc. The differential in payment rates by the Medicare Program has existed for

many years; however, this continued disparity places the SHS hospitals at a significant disadvantage in structuring a competitive compensation / benefits program.

As the largest commercial health insurer in northeastern Pennsylvania, Blue Cross would like to see government payers pay their fair share of the cost of operating hospitals in our region and believe the payment rates for The Williamsport Hospital & Medical Center are an especially egregious problem, disadvantaging the hospital. The FY 2007 Inpatient Prospective Payment System Proposed Rule now presents an opportunity to address this problem. Consequently, Blue Cross of Northeastern Pennsylvania would like to submit the following comments in support of and on behalf of The Williamsport Hospital & Medical Center relating to the section of the FY 2007 Inpatient Prospective Payment System Proposed Rule titled "Geographic Reclassifications."

The FY 2007 Inpatient Prospective Payment System Proposed Rule asked for comments concerning the reclassification for hospitals located in a single hospital MSA surrounded by rural counties. The proposed rule invited comment on three specific questions and this letter responds to those questions.

1) What is the justification for reclassifying a hospital that is receiving a wage index reflecting its own wages?

   A hospital, such as The Williamsport Hospital & Medical Center, that receives a wage index reflecting its own wages is justified in seeking reclassification when its competitors have all been reclassified to and/or are located in an area that receives a wage index reimbursement that is significantly higher than the competitors' own actual wages. The geographic reclassification rules have created an anomaly whereby a reclassified hospital may receive wage index reimbursement above its own average hourly wage. This excess reimbursement allows these reclassified hospitals to invest in new technology and services. The disadvantage for the hospital receiving a wage index reflecting its own wages, while trying to compete with reclassified hospitals, is that it must continually work to keep wages competitive, continue to purchase new technology and continue to provide the services needed by Medicare beneficiaries in its community.

2) Why should a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals, which have received one form or another of special payment status relating to their rural locations, receive special treatment under the wage index?

   A hospital should receive special treatment under the wage index when it is a single hospital in an urban county surrounded by rural counties that is within a modest distance of a number of hospitals *with whom it competes* (in terms of services provided, emergency room visits and case/mix) that have received one form or another of special payment status relating to their rural locations. Under these

circumstances, the wage index reclassification rules interfere with a competitive market to the detriment of Medicare beneficiaries. A single hospital in an urban county must offer a broad range of services to meet the needs of the Medicare beneficiaries in its large service area while competing with hospitals that offer fewer services yet receive increased reimbursement due to their ability to reclassify. This is exactly the type of situation the geographic reclassification process is designed to address but, due to its unique location, a single hospital in an urban county is unable to reclassify through the general reclassification process.

In the case of The Williamsport Hospital & Medical Center, it competes for employees with a number of hospitals, but is the only one of these hospitals that does not receive increased reimbursement. Williamsport Hospital has been able to remain viable and competitive as a result of the efficiencies achieved through the creation of Susquehanna Health System in 1994 (a joint operating agreement) – and the ensuing consolidation of services between The Williamsport Hospital & Medical Center and Divine Providence Hospital – and the premium paid by private insurers, like Blue Cross. Now, with no additional costs left to cut and Williamsport Hospital's competitors continuing to receive higher wage indexes, the Hospital is at a competitive disadvantage which will adversely impact the services that Williamsport Hospital is able to provide the community. If Williamsport Hospital is not reclassified into the Harrisburg MSA, Williamsport Hospital will not be able to retain its employees and patient care and access to care will be adversely affected as Williamsport Hospital is no longer able to make up the shortfall through any additional cost reduction efforts because it has already achieved a high level of efficiency as a result of the affiliation.

Also, as a result of inappropriate payments to providers, such as Williamsport Hospital, Blue Cross and other private payers will be required to pay, as a matter of practical necessity, higher margins to providers in order to subsidize Medicare patients – a condition that only worsens the cost of healthcare coverage for our members and employers. Given the increase in utilization patterns and health care inflation, this added burden is a cost that insurers can no longer afford to match. It is unfair that Medicare payment rates underpay for the services rendered to Medicare patients.

In rendering decisions on requests for reclassification, the Medicare Geographical Classification Review Board is required to consider information provided by a hospital applicant with respect to the effects of a hospital's geographic classification on access to inpatient hospital services of Medicare beneficiaries. Unless Williamsport Hospital is able to reclassify, there will be a negative impact on access to inpatient hospital services for Medicare beneficiaries. Accordingly, CMS must level the playing field and provide Williamsport Hospital with appropriate regulatory criteria under the wage index regulations, allowing the hospital to reclassify to the same area where its competitors are have been reclassified.

3) **Why should a hospital be allowed to reclassify to a labor market area that is further away than other, closer urban labor market areas?**

CMS has stated that geographic reclassification is limited to hospitals that are disadvantaged by their current classification because they compete with hospitals that are "located"(physically located or located by reason of being reclassified) in the geographic area to which they seek reclassification. In addition, CMS has indicated that hospitals seeking reclassification to another area must demonstrate an economic connection to the area to which reclassification is requested. Accordingly, the focus is on competition as demonstrated through an economic connection, not on location per se. Williamsport Hospital has an economic connection to the Harrisburg MSA because that is where Williamsport Hospital's competitors are located and/or have been reclassified. In addition, the Harrisburg MSA represents the relevant market for purposes of (1) wage comparison in the context of employee recruitment and retention; (2) comparability of service delivery needs/capabilities with respect to patient care; and (3) the area with which Williamsport Hospital competes for staff and patients. Accordingly, CMS should permit Williamsport Hospital to reclassify to the Harrisburg MSA even thought it is further away than other, closer urban labor market areas. Additionally, the Harrisburg market is more readily accessible to residents of Lycoming County than other, closer urban areas, such as Scranton – Wilkes-Barre. This accessibility is due to the geography between the two regions.

We hope that our position and comments will satisfactorily answer the questions published by CMS through the rule-making process. We offer these comments as a genuine attempt to address the legitimate concerns of SHS officials - supported by Blue Cross - on this isolated situation, where Medicare reclassification rules do not provide a remedy.

My office is ready to convene whatever meetings are necessary should you require further discussion regarding our position.

Sincerely,

Denise S. Cesare

Cc: Steven P. Johnson
Susquehanna Health Systems

Charleston Area Medical Center

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June 7, 2006

Centers for Medicare and Medicaid Services
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7500 Security Boulevard
Baltimore, MD 21244-1850

Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.
71 Fed.Reg.23996 (April 25, 2006).

Comment on DRG Weights:

The Charleston Area Medical Center ("CAMC"), located in Charleston, West Virginia, appreciates the opportunity to comment on the above CMS proposed rule. CAMC is the largest hospital in West Virginia and has one of the largest heart programs in the United States. CAMC is the true safety net provider for all of central and southern West Virginia. We have the only Level I Trauma Center in southern West Virginia as well as one of two Level III Neonatal Intensive Care Units. CAMC is the largest provider of healthcare to Medicare beneficiaries in the state as well as the largest provider of Medicaid and charity care.

We are very concerned with the proposed DRG weight setting methodology. If the proposed weight setting methodology were adopted, CAMC would receive $7.9 million less in Medicare reimbursement in fiscal year 2007. This reduction will, without any exaggeration, cause a huge disruption in our medical center. Because of West Virginia's demographics, CAMC is very dependent on government payors.

CAMC understands the need for and can support a true cost setting methodology as recommended by both MedPAC and various congressional committees. However, we believe that the proposed methodology is fundamentally flawed. Our comments follow.

CMS is not proposing a true cost-based methodology

CMS is proposing to use 2003 cost report data and 2005 MedPAR charge data. For cardiology, this method does not recognize the huge cost increases we have experienced since the 2003 cost reporting period. Specifically, with the introduction of drug eluting stents and the expanded criteria for the use of AICDs and other devices, we have experienced large increases in our total cost without commensurate increases in revenue.

A second issue is that hospitals have multiple ways to report supply costs. CAMC records the costs of medical devices such as stents, AICDs and other implantables in the "central supply" cost center instead of the "cardiology" cost center. The proposed CMS weight change methodology depends heavily on hospitals recording expenses consistently into the same cost centers.

The third issue is that the proposed weight setting methodology is not cost based at all, but is charge based with a cost-to-charge ratio (CCR) multiplier. This results in a huge distortion, since it ignores the fact that expensive technology is marked up at a lesser percentage than hospital wide averages. As an example, CAMC's mark up for drug eluting stents and AICDs is cost plus 20 percent. Other lesser expensive items are marked up on a sliding scale ranging from 1.2 to 7 times cost. The CMS proposed methodology assumes all items are marked up at the same percentage. This is not the case for most, if not all, hospitals.

The fourth issue is that the proposed change in the DRG weighting system is incorrectly calculated due to 260 large hospitals being excluded from the CCR calculations but included in the DRG weight calculation. In addition, the national CCRs are un-weighted. Small hospitals with very few discharges are given the same weight as large hospitals with many times the discharges.

The Medicare Cost Report is not designed to capture the true cost of individual DRGs!

Payment less than the cost of the implant

Because of methodological flaws, the proposed DRG base payment rates are in some cases lower than the purchase price for AICDs and other implantables.

As an example, CAMC was reimbursed approximately $30,020 (including DSH, IME and other adjustments) for DRG 515 last year. If the proposed rates for FY 2007 remain in effect, CAMC would be reimbursed $23,269 given the same adjustments to the base rate decline of 22 percent. Our average purchase price for AICDs is $21,000 for a single chamber, $23,500 for a dual chamber and $28,500 for a heart failure model. The heart failure model is $5,231 more than the proposed DRG reimbursement. CAMC would, of course, have substantial costs in other supplies and personnel on top of the cost of the device. This one example clearly demonstrates that the proposed DRG rate setting methodology is not only inaccurate, but also blatantly unfair.

Severity Adjustments and MedPAC's Recommendations

In his letter to Mark McClellan, M.D., Ph.D., CMS Administrator, the Chairman of MedPAC indicated that the payment to cost ratio for the most severely ill patients was 36 percent lower than the ratio for the average Medicare patient. The Chairman wrote, "Clearly, current payment policies benefit hospitals that focus on less severely ill patients." As the tertiary care safety net hospital for all of central and southern West Virginia, CAMC strongly supports the proposal to implement severity adjustment consolidated DRGs; however, we opposed delaying the severity changes until FY 2008. As stated in the Chairman's letter, "**It is important to correct for differences in patients severity concurrently with the corrections for charging distortions.** (emphasis added)"

CAMC's recommendations

1. **Fix the flaws in the DRG weight setting methodology. Several of the more significant errors have been highlighted in this letter. The flaws must be fixed and then tested before being implemented.**

2. **Implement the severity adjustments at the same time as the new weight setting methodology.**

3. **If CMS is not prepared to implement the new severity adjustments in FY 2007, then all changes should be postponed until FY 2008.**

We appreciate the opportunity to comment on the proposed changes.

Sincerely,

David L. Ramsey
President and CEO

c: Senator Robert C. Byrd
Senator John D. Rockefeller IV
Representative Shelley Moore Capito

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June 5, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
4/25/2006 Federal Register Pages 23995-24550

Dear Sir or Madam:

I am the President and Chief Executive Officer of St. Elizabeth Medical Center. St. Elizabeth is a 201 bed acute care general community hospital located in Utica, New York that is sponsored by the Sisters of St. Francis of the Neumann Communities. It is one of two hospital systems that serve the greater Utica New York area of Oneida County, New York. Over 64% of our patients are Medicare and Medicaid patients. Approximately 30% of our admissions and our revenue come to us through our cardiac surgery, angioplasty, electrophysiology and catheterization program - the program that will be hurt most by the proposed changes to the CMS regulations on DRG weights.

This letter outlines St. Elizabeth's comments to the proposed DRG changes.

Cardiac Program Impact

Cardiac disease is a major health issue in Oneida County, New York. It has been said that the highest incidence of cardiac disease in the United States is in New York State; and Oneida County (on a per capita basis) has the highest incidence of cardiac disease of any County in New York State. The conclusion to this is that (on a per capita basis) Oneida County has the highest incidence of cardiac disease of any County in the United States. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Since inpatient services in general and inpatient cardiac services specifically are a key component of what we provide, the changes that have been proposed to the DRGs for cardiac services will inequitably impact St. Elizabeth. This impact will affect not only the cardiac program, but, since we are an acute care general community hospital, it will also impact other non-cardiac services that we provide.

The proposed regulations adopt a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Of the $3,838,362 reduction that St. Elizabeth will see if the amendments are adopted as proposed, over $2 million will be attributable to two angioplasty DRGs (DRG 558 and 557) that use the new drug-eluting coated stent. Most of the balance of the $3.8 million reduction will also involve cardiac surgery and cardiac implants like defibrillators.

The most significant issue appears to St. Elizabeth in the use of the 2003 cost reporting period. Use of the 2003 information does not take into account the full annual cost of the drug-eluting stent that was introduced late in the first half of 2003 and not generally available until 2004. Using the cost reporting period starting in January 1, 2004 would be more representative of the type of cost being incurred by St. Elizabeth for the 2007 fiscal year. For example, in 2003, before drug eluting stents were available, the cost per stent at St. Elizabeth was $400. In 2004, when drug eluting stents were available, the cost per stent at St. Elizabeth was $2,900. With the advent of drug eluting stents, almost all stents implanted are drug eluting. St. Elizabeth uses on average, 2 to 3 stents per patient which means that since January 1, 2004, the average cost per patient went from $1,200 per patient to $8,700 per patient. This is an increase in excess of 700%. It is our understanding that there are some hospitals in the country that have a fiscal year other than a calendar year like St. Elizabeth. Those hospitals are even more disadvantaged than St. Elizabeth when computing the cost of the drug eluting stent's impact on their costs for 2007. They may have had no drug eluting stent costs or very little included.

Use of this new technology has been the major reason why cardiac surgical procedures and repeat angioplasty procedures have gone down. This has increased the life expectancy of cardiac patients and minimized the invasive surgical procedures that cardiac patients have historically experienced. The cost of the angioplasty and drug eluting stent surgical procedure costs far less than the cost of a more invasive Coronary Artery Bypass Graph procedure. Additionally, the patient recovery time is shorter, increasing patient satisfaction, decreasing mortality, decreasing morbidity and extending life expectancy. In short, the procedures that will see the greatest reductions in Medicare reimbursement, are more efficient and cost effective from a pure dollars and quality of life perspective than the alternatives.

It is our understanding that the proposed regulations adopt a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. The change is drastic in that it changes the entire emphasis and understanding of what severity means, as it relates to treatment of patients and reimbursement for patient care.

In discussing the effect of the proposed regulations with other hospitals, vendors and internally, we believe that within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights. When the drug-eluting stent was approved by the FDA, St. Elizabeth updated its charge master to reflect the significant increase in supply cost for the cardiac program in its use of the new and improved technology. (Note: prior to the introduction of drug eluting stents our cost per sent was $400 per stent; while the drug eluting stents cost us $2,900 per stent.) We believe that a significant percentage of hospitals nationally did not do this. As a result, when CMS compares its reimbursement levels for these procedures with the charge masters across the board for these procedures, CMS correctly notes a significant paper margin. In actuality, there is not a significant margin being earned by the hospitals, but rather an exaggerated margin shown on paper because charge masters were not updated to reflect changes in actual costs.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for angioplasty will be reduced by 34%, ICD implants will be reduced by 24% and pacemakers will be reduced by 14% severely impacting these services.

The effect of these reductions will mean that hospitals cannot afford to provide the services to those that need it, but rather will need to limit or ration the service to only the most critical patients. The availability of services will be limited due to cost, since adequate facilities will not be able to be built and maintained to supply the demand. Rationing of healthcare services has not been, to date, a goal of the Medicare program.

Community Provided Cardiac Services

St. Elizabeth Medical Center and Faxton-St. Luke's Healthcare (the other hospital system in the greater Utica, New York area) have collaborated to provide cardiac services through Mohawk Valley Heart Institute, Inc. This "hospital without walls" was formed with the encouragement of the New York State Department of Health as a way to make necessary cardiac services available to our community and avoid duplication of services. Cardiac surgery, angioplasty and cardiac catheterizations are performed at St. Elizabeth Medical Center while cardiac catheterizations and cardiac rehabilitation are performed at Faxton-St. Luke's Healthcare's campuses. As a result of this collaboration, St. Elizabeth became more focused on the surgical services that have become the target of CMS's reimbursement reductions. There is financial sharing between the two hospital systems on the collaborative services, but St. Elizabeth will be more negatively affected by the surgical DRG reductions, while our partner will be similarly benefited by the medical DRG increases. St. Elizabeth may appear like a specialty or limited service hospital because of the collaboration referred to

above, but it is not. St. Elizabeth's, an acute care general community hospital, would suffer unintended consequences as a result of these DRG reimbursement changes.

Specialty Hospitals/Limited Service Hospitals

It has been said that part of the motivation for CMS to develop the proposed regulations is so that it can hold specialty hospitals accountable for siphoning the high profit margin services away from hospitals that provide all services to all patients. This is particularly an issue in states that do not have a Certificate of Need requirement for construction and operation of hospitals. (Please note that New York State has a very extensive Certificate of Need process.) Based upon the changes to the Medicare reimbursement that is proposed by CMS at this time, it appears that the cardiac specialty hospitals are the focus of concern by CMS. The concerns are justified since physicians have been able to own and operate hospitals that their professional specialty allows them to make direct referrals to and obtain the benefit of not only the professional reimbursement for the services being provided, but also some significant share of the Part A reimbursement for that service. Additionally, since those facilities are limited in the services that they provide, they do not use the margin that they may be realizing on the Part A reimbursement to operate Emergency Rooms; service low margin surgical and medical services; or financially support care to the indigent.

Acute care general community hospitals use the margin that they make on the profitable services (specifically cardiac services) to support the mission of caring for everyone regardless of race, national origin, creed *or ability to pay*. St. Elizabeth's status as a community hospital means that it provides a full range of services and operates for the benefit of the entire community on a 24/7 basis.

St. Elizabeth Medical Center is an Area Trauma Center. As such it receives more complex cases and a wider variety of cases than specialty or limited use hospitals and most community hospitals. The changes to the regulations as proposed will severely limit St. Elizabeth's ability to address this population at reimbursement levels that are fair and equitable and at levels that will support this needed service in the Community. St. Elizabeth is the only Area Trauma Center between Albany, New York and Syracuse, New York. Trauma patients should go to the nearest Trauma facility. St. Elizabeth is the most centrally located Trauma Center for much of Central New York.

If CMS's intention was to address the specialty or limited service hospitals' use of margin to benefit their physician owners, address it. Do not cast the net unnecessarily wide to encircle community hospitals. We recommend that CMS include in its regulations some hold harmless provision that will provide community hospitals from the unintended consequence of the reductions that are focused more on specialty or limited service hospitals.

Effect of CMS's Proposed Regulations on Commercial Insurance and Medicaid

The changes to the regulations that are proposed by CMS are not the only reductions in reimbursement that St. Elizabeth is facing. President Bush has proposed legislation that will result in a reduction in Medicare reimbursement to St. Elizabeth of an additional $350,000 on

top of the reductions proposed in the CMS regulation. New York State's 2006-2007 budget, which runs through March 31, 2007, will result in a $920,000 reduction in Medicaid revenues and elimination of trend factor increases to Medicaid reimbursement. These reductions coupled with the CMS proposed revisions to the DRGs will result in a $5 million reduction in reimbursement or freezes in current reimbursement. Those types of changes to reimbursement for Medicare and Medicaid mean that the hospital, and the community that we serve, must make unnecessarily inequitable decisions. Services (inpatient and outreach) must be reduced or eliminated, or the costs shifted to other payors. It should be noted that the Medicaid reduction of $920,000 to St. Elizabeth compares to a $750,000 reduction for the other five hospitals in our Primary Market Area combined. This apparent unequal application of Medicaid reductions is a result of St. Elizabeth's position as caring for more Medicaid patients than all the other hospitals combined.

Commercial payors already contract with St. Elizabeth at rates which are, in some cases, in excess of what the true cost of providing that care might be for their patients. As an acute care general community hospital, the margin on those services are used by St. Elizabeth to cover the losses that are being experienced on its Medicare and Medicaid patients and for those services that incur a loss for St. Elizabeth. Whether the service makes a profit or a loss for St. Elizabeth is a concern for us, but our primary concern is to provide the best quality medical care to our patients as possible.

As St. Elizabeth continues to demand more from the commercial payors the premiums for that health insurance continues to rise. The rising health insurance premiums make employer provided health insurance less affordable and ensure that more employees and dependents will be dropped from those programs. The end result is that there will be more uninsured and more bad debt/charity care expenses for hospitals. This will dramatically increase the rolls of the uninsured in New York State. If St. Elizabeth reduces services because it cannot afford to provide the full range of services that it currently provides, the Medicare and Medicaid populations and the poor will be most effected negatively.

Technical Points

There are a few points that need to be specifically addressed.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, technology costs will very likely be underpaid. Underpayment of technology costs will mean that patients will not get the best that technology can provide, because hospitals cannot afford to make it available to the patients it serves. Technology expenses need to be monitored and controlled to ensure that a technology "arms race" does not occur. There are more effective ways to control the purchase of technology than to fail to support the technology through reductions in the severity adjustments.

Over the last few years, St. Elizabeth Medical Center has become very efficient. Its unadjusted case mix length of stay is 5.4 days which is among the lowest in the Central New

York region; its occupancy rate of 89.2% which is the highest in that same region; and its case mix is in excess of 2 which is among the highest in Central New York. These impressive statistics are a testament to the hard work that our 1900 employees provide to the sickest patients in our community.

The changes that CMS is proposing are significant. There is significant precedent to have changes of much less significance be phased in over a 5 to 10 year time frame. This will allow current programs to properly plan and develop modifications so that when the change is ultimately implemented, appropriate community planning could have occurred. Community planning can take a number of forms from collaboration to consolidation, among many others. Allowing time for the community to plan will ensure that the medical and surgical services that are being provided are appropriate to meet the community need.

In our review of the cost or weights that CMS has assigned to the cardiac DRGs, we note that there are some significant disagreements with the St. Elizabeth's cost accounting system. These significant errors must be reconciled before the proposed rule is implemented.

We also believe that the shifting of the reductions in DRG payments of 903 hospitals to 2,619 hospitals nationally inequitably discriminates against those 903 hospitals who must pay for the benefit being received by the 2,619. In New York State the problem is greater in that 30 hospitals will have their reimbursements reduced while 149 hospitals will see their reimbursements increased. Both in New York State and nationally, the very large reduction in payments on a hospital by hospital basis is spread very thinly over the large number of hospitals that will see increased payments under the proposed regulation.

Summary

The payment methodology changes that CMS has proposed would have a severe financial impact on St. Elizabeth – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs. The reduction in payment for cardiology services would also have a severe impact on the infrastructure that has been built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure St. Elizabeth would face the uncertainty of what other changes CMS could decide to make to overhaul the Medicare reimbursement system again and put St. Elizabeth in further financial jeopardy. Access issues will develop as a result of this shift. Finally, use of the 2003 cost report does not ensure an accurate reflection of cost to be used on a going forward basis. Use of the 2004 cost reports establishes a more reasonable base year if CMS is concerned about accurately reflecting costs to the program.

We respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments. We ask that you reconsider the changes to the regulations and if elimination of the changes cannot occur, that CMS consider a gradual phase in of the

effect of the regulations on hospitals such as St. Elizabeth – acute care general community hospitals.

Thank you for your consideration.

May God Bless You,

Sister M. Johanna
President and Chief Executive Officer
Enclosure – 2 copies of letter
cc: Congressman Sherwood Boehlert
Senator Charles Schumer
Senator Hilary Clinton
Board of Trustees of St. Elizabeth Medical Center

71-0
(41)

ST. ELIZABETH MEDICAL CENTER
Sponsored by The Sisters of St. Francis
2209 Genesee Street • Utica, New York 13501-5999
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May 24, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Re: Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates
4/25/2006 Federal Register Pages 23995-24550

Dear Sir or Madam:

I am a member of the Board of Trustees of St. Elizabeth Medical Center. St. Elizabeth is a 201 bed acute care general community hospital located in Utica, New York. It is one of two hospital systems that serve the greater Utica, New York area of Oneida County, New York. Approximately 30% of our admissions and our revenue come to us through our cardiac surgery, angioplasty and catheterization program - the program that will be hurt most by the proposed changes to the CMS regulations on DRG weights.

Management advises that the proposed changes to the Medicare DRGs will threaten the premier service that is provided by St. Elizabeth to our community, the cardiac program. Over ten years ago, after significant community support from the medical, hospital, political and business communities and the general public, the community received New York State approval for a cardiac surgery program that would include angioplasty services. Since this was a community effort, both community hospital systems in the Utica area began collaboration through Mohawk Valley Heart Institute, Inc. to provide cardiac services in a "hospital without walls" concept. 2007 reimbursement reductions proposed by CMS will negatively impact both hospital systems if implemented. It is not likely that CMS's intent is to punish our community hospitals' successful cardiac program that has had exceptional patient outcomes in the community where the majority of our patients reside and which supports many other programs offered by St. Elizabeth. CMS is encouraged to exempt community hospitals such as St. Elizabeth from the onerous impact of the DRG weight reductions. St. Elizabeth has been able to use its cardiac program to support other necessary medical programs in the community like the Area Trauma program and to serve the poor and uninsured.

Management advises that there are technical flaws in the calculation of the cost variances used to determine the proposed reimbursement levels. Most significantly is the use of the 2003 cost reporting period which does not reflect the over 700% increase in costs experienced with the introduction of drug eluting stents in the second half of 2003. Use of a more comparable cost reporting period to 2007 would mean that reimbursement reductions will likely be less onerous when comparing true costs.

We hope that the CMS reimbursement proposals set out in the draft regulations can be eliminated. If they cannot be eliminated, we request that they be at least phased in over a longer period of time so that management can implement changes to our operation to more reasonably anticipate the changes in reimbursement.

Another effect of implementation of the reduced DRG reimbursement to St. Elizabeth will be that St. Elizabeth must look to other payors to fill the void created by Medicare's reductions. This will mean that the commercial payors that we use to provide health insurance to our employees will need to increase their

premium rates to Utica area businesses to cover the increased cost. This shifts the costs of the health dollar away from Medicare and on to the businesses that employ the patients being seen by St. Elizabeth. This effect should not be minimized to the long term financial health of our community and to the State.

We respectfully request that CMS withdraw its proposed DRG payment changes for 2007, but if it is not possible to withdraw those changes, that they be phased in over an extended period of time.

Thank you for your consideration.

Very truly yours,

Mr. Nicholas Matt
Trustee

Enclosure – 2 copies of letter
cc: Congressman Sherwood Boehlert
Senator Charles Schumer
Senator Hilary Clinton
Board of Trustees of St. Elizabeth Medical Center

DRGBoT5-24.06l.doc M:PayorCMS

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NATIONAL RURAL HEALTH ASSOCIATION

VIA OVERNIGHT MAIL

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

June 7, 2006

Reference: CMS-1488-P; FY07 IPPS NPRM, *Federal Register* April 25, 2006.

Dear Administrator McClellan:

The National Rural Health Association (NRHA) appreciates the opportunity to comment on the proposed rule implementing changes to the hospital inpatient prospective payment systems for fiscal year 2007, published in the April 25, 2006 *Federal Register*. We appreciate your ongoing commitment to rural health care, and NRHA looks forward to working with you in our mutual goals of improving access and quality of health care for all rural Americans.

The NRHA is a national nonprofit membership organization with approximately 10,000 members that provides leadership on rural health issues. The Association's mission is to improve the health of rural Americans and to provide leadership on rural health issues through advocacy, communications, education and research. The NRHA membership consists of a diverse collection of individuals and organizations, all of whom share the common bond of an interest in rural health. Please find our comments are below.

The proposed rule is exceedingly complex, implementing what will be the most significant changes to hospital payments since the inception of the program. We have concerns about several significant rural policy changes proposed, and the impact these proposals will have on rural communities.

Our comments include the following:

Deficit Reduction Act Provisions Benefiting Medicare Dependent Hospitals
The proposed regulation implements provisions from the Deficit Reduction Act of 2005 that reauthorize the Medicare Dependent Hospital program, add 2002 as an allowable base year,

increase payments from 50 percent to 75 percent of the difference between PPS payments and the hospital-specific rate, and remove the 12 percent disproportionate share hospital (DSH) cap. The NRHA supports this change and appreciates CMS's timely implementation of this new payment methodology.

HSRV Weights

CMS proposes to make major changes to the calculation of DRG relative weights by using hospital-specific relative values and a modified version of costs instead of charges (HSRVcc). There has been a longstanding bias in the PPS system that skews DRG weights upwards for those services preformed mostly at higher cost facilities, such as teaching hospitals. Put simply, the current system rewards surgical DRGs with higher weights while setting inappropriately low weights for medical DRGs. NRHA supports the effort to restructure DRG weights based on cost in order to remedy these longstanding inequities. That said, several concerns and errors have been identified in CMS' proposed methodology to move to cost-based weights and CMS should address these concerns before moving to cost-based relative weights.

We are all well served by remembering that the original intent of the prospective payment system was to base DRGs on costs, not charges. We support CMS's efforts to finally move the system to one that is consistent with Congress's original intent. The change is long overdue, and welcomed.

DRGs: Severity of Illness

NRHA has serious concerns about the proposal to use consolidated severity adjusted (CSA) DRGs. According to CMS's analysis, this proposal will lower payments to rural hospitals by 3.1 percent. When combined with the HSRVcc proposal, rural hospitals see a net cut of 0.4 percent. (Table L, *Federal Register* p. 24025.) The effect for small hospitals is even more damaging, with cuts of 5.2 percent under the CSA DRG proposal, and a net cut of 1.3 percent from both proposals. This payment cut will have a serious affect on rural hospitals ability to continue providing care and will restrict access to care in rural communities.

We note that there have been several analyses done outside of CMS that attempt to replicate CMS' work while correcting for various technical flaws. These analyses find the same trend for rural hospitals, but in different orders of magnitude. For example, the Moran Company's analysis addressed several technical flaws in the data, and subsequently found that rural hospitals would see a net cut of 1.2 percent under the combined HSRVcc and CSA DRG proposals. Clearly the impact analysis is highly sensitive to changes in methodology, which raises the concern that the impact of the final rule will vary widely from the proposed rule, while providing no further opportunity for comment.

Furthermore, we point out that Section 1102(b) of the Social Security Act requires a regulatory impact analysis that describes the impact on small rural hospitals, including a description and estimate of the number of small entities that will be affected, and a description of steps the agency took to minimize the economic impact. This required impact analysis is absent for the CSA DRG proposal.

NRHA is also very concerned about the financial burden that rural hospitals will incur if they must implement this CSA DRG system. If the new 3M grouper is not in the public domain it will likely come at a high cost, given that it is only available from one vendor. Furthermore, hospitals will face an increased administrative burden because they will need to learn a new and complicated coding system. We question how smaller hospitals will be able to afford the 3M grouper and the new training and staffing that will be necessitated by these changes.

Therefore, NRHA strongly advises against implementation of the CSA DRG for FY07 given the fact that (1) hospitals have not have opportunity to review and comment on a full impact analysis of the CSA DRG proposal; (2) small rural hospitals have not had the opportunity to review and comment on the 1102(b) impact analysis required by statute; (3) the data are highly sensitive to changes in methodology, which means the impact analysis provided in the NPRM will be somewhat moot if CMS changes its methodology; and (4) implementation of this proposal will impose large financial and administrative burdens on small hospitals. **These changes are significant, burdensome, and the lack of a complete impact analysis has denied hospitals the opportunity for appropriate review and comment. It is premature to implement the CSA DRG change for FY07.**

Sole Community Hospital and
Medicare Dependent Hospital Reporting Requirements

CMS proposes to implement a mandatory reporting process whereby an SCH or MDH would report to its CMS Regional Office when the circumstances under which it was approved as an SCH or MDH have changed. The Regional Office would determine whether the change affects the SCH or MDH status and notify the hospital if its status will be canceled, with the cancellation effective 30 days after the Regional Office determination. If the hospital does not disclose the change, the Regional Office will cancel the SCH or MDH designation retroactive to the earliest discernible date on which the intermediary can determine that the hospital no longer met the qualification criteria.

While we appreciate CMS's concern that an SCH or MDH should lose its special status if the circumstances that gave rise to this status have changed, we are concerned with the burden this proposed regulatory change would place on SCHs and MDHs. SCHs, in particular, can qualify based on a variety of circumstances, including the inpatient admission patterns of area residents, weather conditions, travel times, etc. We believe that new monitoring and reporting requirements for these eligibility criteria are burdensome, an unnecessary deviation from past policy, and/or impracticable.

In particular, it is unclear from the proposed regulations whether CMS is placing some sort of requirement on an SCH to re-measure the circumstances that gave rise to its classification on an annual or other unspecified periodic basis. This is very unclear, particularly given the CMS discussion under the Collection of Information Requirements. In this section, CMS states that it estimates only one hour will be required of less than 10 SCHs to comply with this requirement. CMS either grossly underestimates the cost and time required to comply with this requirement, or CMS does not expect SCHs to monitor this data on an annual basis. Specifically, it appears

that CMS does not intend to require SCHs to remeasure the market share test of 42 CFR 412.92(b). We agree with this position and request that CMS clarify that intent.

We believe the responsibility for monitoring criteria such as a nearby critical access hospital converting to a PPS hospital is most appropriately monitored by the FI. The FIs are already clearly responsible for monitoring such matters including whether MDHs continue to meet the 60% test in two of the last three audited cost reports, and that is where this responsibility belongs.

We believe that if CMS is to shift any responsibility to SCHs and MDHs, it should only require SCHs or MDHs to monitor readily-available, objective data. In the case of a SCH, this would include the opening of a new hospital within 35 miles, or the mileage criterion on which their eligibility is based. For an MDH, this would include the addition of available beds that would exceed 100. The proposed regulations should be clarified with regard to this requirement.

At the same time, we are concerned with the dramatic financial impact that retroactive revocation of SCH or MDH status could have on a hospital. **Unless CMS has clear evidence that a hospital knew it no longer met the criteria to qualify for SCH or MDH status, there should be no retroactive recovery of Medicare funds if a hospital's special status is revoked. CMS can encourage self-reporting by requiring immediate revocation of status if the hospital does not report a change in circumstances, while revoking status at the start of the next cost reporting period, or six months from notification, whichever is later, if the hospital does self-report.**

Finally, we recommend that CMS retain its current grandfathering policy for SCHs. CMS discussed and clarified many of the rules and policies governing SCHs in the August 1, 2001, PPS Final Rule because of the legislative changes that had recently occurred. On Page 39874 CMS stated:

> "Section 6003(e)(3) of Public Law 101-239 specifically stated that any hospital classified as an SCH as of the date of enactment of Public Law 101-239 (December 19, 1989), will retain its SCH status even if the hospital did not meet the criteria established under section 6003(e)(1) of that law. These hospitals are the "grandfathered" SCH hospitals. Therefore, we have continued to allow hospitals designated as SCHs prior to December 19, 1989, to be "grandfathered" under current criteria."

We request that you modify 42 CFR 412.92(b)(4) to reflect this position on grandfathered SCHs and also clarify that any final regulation requiring self monitoring and reporting does not apply to grandfathered SCHs described in the foregoing paragraph.

Occupational Mix Adjustment

CMS recently announced that, pursuant to the lawsuit of Bellevue Hosp. Ctr v. Leavitt, the Court of Appeals for the Second Circuit ordered CMS to apply the occupational mix adjustment to 100 percent of the wage index effective for FY07. Hospitals must now provide occupational mix

data on an extremely expedited timeline, with little or no time for review, and no ability to see how the data will affect their FY07 payment rates. NRHA is concerned about the affect this change will have on rural hospital payments and recommends that CMS provide opportunities for review, comment, and adjustment to the occupational mix data (including the ability to appeal or amend inaccurate or incorrect data), as needed, to the extent allowable under the Court order.

Critical Access Hospital Relocation

NRHA would like to take this opportunity to reiterate our opposition to CMS's interpretive guidelines governing relocation of Critical Access Hospitals (CAHs). The FY06 Final IPPS regulation set forth the "75 percent rule," which required that all necessary provider CAHs that rebuild after January 1, 2006 need to demonstrate that they are serving 75 percent of the same population, retaining 75 percent of the same staff, and providing 75 percent of the same services.

The interpretive guidelines issued on November 14, 2005 went much farther than the final regulation. The guidelines set prescriptive and stringent standards that are not supported by Congressional intent and have no basis in the statute or final FY06 regulation. The additional requirements set forth in the interpretive guidelines include:

- Extending the relocation restrictions to all CAHs, not just necessary providers;
- Setting forth a more stringent 75 percent requirement that requires the CAH to: serve 75 percent of the original families with incomes at less than 100 percent of the federal poverty level; serve at least 75 percent of the original Medicaid and Medicare beneficiaries; and bill at least 75 percent of the billing codes and volume for inpatient and outpatient services;
- Setting overly prescriptive definitions of mountainous terrain and secondary roads;
- Requiring that the CAH send a letter of attestation after relocating, affirming that it remains essentially the same provider serving the same community in its new location. However, CMS will not make its determination until after the CAH has relocated, and CMS may conduct a review one year after relocation.

The interpretive guidelines are problematic for numerous reasons. First, it was clearly not the intent of Congress in the Medicare Modernization Act to prohibit a Critical Access Hospital from replacing or relocating their facility into perpetuity.

Second, relocation is oftentimes the best option for a CAH that needs to modernize its facility. Many CAHs are old, built 40 to 50 years ago, and are well past their useful service life. These facilities may no longer meet modern health care code and service requirements. The hospital's structure is often not suitable for major remodeling to correct deficiencies. Furthermore, many rural hospitals are located on a small campus in the middle of residential neighborhoods. In this instance, CAHs are landlocked with little or no room for expansion, and must rebuild where there is affordable land available or at a location where land has been donated to them. In other instances, facilities need to, or choose to, rebuild on a new site to be closer to a highway, connect to municipal water and sewer, because of seismic safety concerns, or other reasons that will improve patient safety and quality of care provided. In short, for a variety of reasons, relocation is often the most appropriate, and sometimes only, alternative. CMS's guidelines fail to take into

account these factors. Instead, the interpretive guidelines will force CAHs to allocate funds to renovate structures that no longer meet either the needs or the demands of modern health care.

Another serious concern is that CMS will not determine whether the CAH can retain its status until up to one-year after relocation. This requirement reflects a fundamental misunderstanding of the way business entities make decisions. Whether a hospital can retain its CAH status is a critical factor that must be weighed when deciding whether it is cost effective to build a new facility. Without this information, it is difficult for a hospital to assess the business case for relocating, how can it do so without knowing how it will be reimbursed under Medicare? This problem is compounded by the fact that hospitals will have trouble securing the necessary financing from loan providers without assurance that they will retain their CAH status.

For these reasons, NRHA urges CMS to reconsider the overly restrictive requirements governing CAH relocation. We propose that instead, CMS develop a 5 mile safe harbor such that CAHs can retain their status as long as they move within 5 miles of the existing facility. This alternative will greatly reduce the administrative burden for CMS, the uncertainty for CAHs, and is sufficient to assure that CAHs will continue to serve the same community.

Conclusion:

The NRHA appreciates the opportunity to submit these comments on the proposed rule. Please do not hesitate to contact Jennifer Friedman, Vice President of Government Affairs and Policy at 703-519-7910 if you have any questions about these comments.

Sincerely,

William Sexton
President

parkview
MEDICAL CENTER
400 WEST 16th ST., PUEBLO, CO 81003

Date 06/06/06

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1488-P,
P.O. Box 8011,
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

My hospital is a 350_____ bed acute care hospital located in PUEBLO,CO._____. As a major health care provider in our area, we implant medical devices and perform other cardiac procedures on a significant number of Medicare beneficiaries in the inpatient setting. Because inpatient services are a key component of what we provide, I am writing to express my concerns regarding the inpatient payment proposed rule and its recommendations to change the way Medicare pays for inpatient services.

First, it adopts a methodology called hospital-specific relative values that is specifically known to have an adverse impact on payments to hospitals that deliver cardiology services. Second, it adopts a new and untested approach to what are known as "cost-based" DRG weights that inappropriately reduces payments for cardiology procedures featuring device implants such as drug-eluting stents, ICDs, and pacemakers. In fact, these are the hardest hit of *all* procedures in the DRG system. And finally, even within the new CMS methodology, there are technical errors and assumptions that worsen the overall payment cuts to cardiology. Any move to a cost-based system from the current charge-based system should be predicated on requirements for improved cost reporting by hospitals. Hospital cost reports were never intended to be used to develop accurate procedure-specific payment weights.

The impact of the CMS proposal will reduce reimbursement to cardiac services across all hospitals by about 10%. Application of hospital specific values to the current DRG system would result in an overall average decrease of approximately 6% to surgical DRGs, while increasing medical DRGs by 6%. In addition, technology intensive DRGs will also be significantly reduced under the CMS proposals. As a result of these changes, the proposed DRGs for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24% and pacemakers will be reduced 12 to 14% severely impacting these services.

With regard to the severity adjustment proposed for next year (FY08), severity does not include the technology costs paid by hospitals for more complex cases. As a result, my technology costs could be underpaid.

The payment methodology changes that CMS has proposed would have a severe financial impact on my hospital – without accurate data to justify the change. This is particularly true for device intensive cardiology DRGs where the proposed payment level is often significantly less than my hospital's actual cost to deliver the service.

The reduction in payment for cardiology services would also have a severe impact on the infrastructure I have built up over the years to treat the number one killer in America today - heart disease. In addition to requiring the potential dismantling of this infrastructure I would now face the uncertainty of knowing that next year, or any other year, CMS could decide to under-fund whatever service area I build up next to meet patient needs. Obviously, as I'm forced to scale back or not develop service capacity due to payment swings and financial uncertainties, patient access could be negatively affected.

I respectfully request that CMS delay the proposed inpatient payment revision, with a return to the current methodology, until the methodology and underlying cost data are improved to ensure the accuracy of payments. Similarly, severity adjusted DRGs should not be implemented until the technology costs incurred by my hospital can be appropriately reflected in the DRG payments.

Thank you for your consideration.

Sincerely, Michael Del Priore
MICHAEL DEL PRIORE
DIRECTOR CARDIOPULMONARY SERVICES

Parkview Medical Center

c. SENATOR KEN SALAZAR
c. AMERICAN HOSPTAL ASSOCIATION

Cardica, Inc. • 900 Saginaw Drive, Redwood City, CA 94063
Tel (650) 364-9975 • Fax (650) 364-3134

June 6, 2006

By FedEx

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

CMS-488-P

Subject: "New Technology" Add-On payments for New Services and Technologies – C-Port® Distal Anastomosis System

Cardica, Inc. is grateful for the opportunity to submit comments to CMS regarding the "New Technology" Add-On payment for the C-Port® Distal Anastomosis System. Additionally, Cardica would like to specifically address in summary format with this letter, and in greater detail with the Attachments to this cover letter, the CMS questions regarding newness of the technology and Medicare patient benefits.

The C-Port® Distal Anastomosis System meets all CMS standards for an add-on payment for new technology:

- The C-Port® System is the first and only new technology for the automated creation of a distal coronary anastomosis. This technology was recently cleared by the FDA in November 2005.

- The C-Port® System represents an advance in technology that substantially improves treatment options for Medicare beneficiaries. The clinical data from the pivotal C-Port study demonstrates superior graft patency outcome when compared to the medical literature.

- The C-Port® System is new because no or very limited data on the costs of the technology have become available reflecting any ICD-9-CM code available for the procedure, and thus no data has been used for DRG recalibration.

- The C-Port® System meets the cost threshold, and current DRG payment levels are inadequate.

CMS in its proposed rule (Fed. Reg. April 25, 2006, pages 24071-24072) acknowledges that the C-Port® Distal Anastomosis System meets the cost threshold. Our comments below respond to specific CMS questions on newness and substantial clinical improvement in the proposed rule.

The C-Port® System is new and unique from any other technology currently available on the market. While staples and stapling devices have been available for some time, the C-Port® System is unique for the following reasons:

- **First and only technology capable of automated creation of the distal anastomosis in coronary bypass procedures.** Existing and former cardiac anastomosis devices are intended for proximal anastomoses only. They were not designed to create and could not be used for the more difficult distal anastomosis.

- **The C-Port® System is the only currently available fully automated anastomosis system indicated for cardiac use.** Other devices indicated for coronary bypass use are not automated. They require manual creation of an arteriotomy separate from placement of staples or clips.

- **C-Port® System is designed for coronary indication**. The design principles of the C-Port® System for the creation of coronary anastomoses, which include the integrated and automatic creation of an arteriotomy, are fundamentally different from those of other automated anastomosis systems indicated for gastrointestinal, peripheral vascular or urological use.

- **Additional training and education is required prior to use**. Performance of a coronary bypass procedure using the C-Port® System requires new steps and preparation that both the surgeon and OR staff must be trained to do. Additionally, proctored use of the device for initial procedures is required to ensure proper outcome.

The C-Port® System represents an advance in technology that potentially improves treatment options for Medicare beneficiaries. It is a unique and novel means of creating a mechanical, automated and interrupted bypass anastomosis that provides the following potential benefits to Medicare patients:

- **Improved procedural reliability.** Use of the automatic mechanical anastomosis system may reduce the hand-sewn surgical variability amongst surgeons. This may mitigate some of the variables that negatively influence graft patency.

- **Quality of anastomosis is independent of coronary (target) vessel size.** Graft patency in hand-sewn anastomoses is a function of target vessel diameter. The smaller the vessel the greater the difficulty in creating quality hand-sewn sutured anastomoses. C-Port® System is an automated system that creates quality anastomoses for target coronary arteries as small as 1 millimeter in diameter.

- **Facilitate beating heart (off pump) procedure.** The quality of hand-sewn anastomoses may be negatively affected by beating heart procedures despite the known benefits of avoiding artificial cardiopulmonary bypass. The potential risk of poor outcome is reduced by use of the automated C-Port® System regardless of the procedure (on or off pump) used.

- **More access for patients.** The use of the an automated device produces consistently reproducible anastomoses that are independent of surgical skill set thereby providing more consistent quality of care to the patient.

Cardica hopes that the summary above provides sufficient introduction to the information contained in our submission. The questions regarding newness of the C-Port® System technology and benefits to patient are answered in greater detail in Attachment 1. Please refer to the peer reviewed journal publication of the pivotal Cardica C-Port clinical trial in Attachment 2. Cardica has also included copies of the references cited in the detailed response as well as a video presentation of a typical coronary bypass procedure using the C-Port® Distal Anastomosis System (Attachments 3 and 4, respectively).

Because the C-Port® System potentially improves patient outcomes and procedural reliability by facilitating the creation of a reproducible and compliant, interrupted mechanical anastomosis, CMS should approve the C-Port® System for Add-On Payment New Services and Technologies status. Furthermore, due to its recent FDA clearance and limited commercialization, data regarding the use of mechanical, automated and interrupted coronary bypass devices are not reflected in the DRG weights through recalibration.

Again, Cardica would like to thank CMS for the opportunity to present additional information regarding the application for "New Technology" Add-On payment for the C-Port® Distal Anastomosis System.

Sincerely,

Bernard Hausen

Bernard Hausen M.D., Ph. D.
President & CEO
Cardica, Inc.

Attachment 1 Responses to CMS comments
Attachment 2 C-Port® Distal Anastomosis Journal Publication
Attachment 3 References
Attachment 4 Video case of C-Port distal anastomosis

ATTACHEMENT 1

RESPONSES TO CMS COMMENTS

CMS -1488 – P

Subject: "New Technology" Add-On payments for New Services and Technologies – C-Port® Distal Anastomosis System

Summary

The C-Port® Distal Anastomosis System meets all CMS standards for an add-on payment for new technology:

The C-Port® System is the first and only new technology for the automated creation of a distal coronary anastomosis. This technology was recently approved by the FDA (Nov. 2005).

The C-Port® System represents an advance in technology that substantially improves treatment options for Medicare beneficiaries. The clinical data from the pivotal C-Port study demonstrates superior graft patency outcome when compared to the medical literature.

The C-Port® System is new because no or very limited data on the costs of the technology have become available reflecting any ICD-9-CM code available for the procedure, and thus no data has been used for DRG recalibration.

The C-Port® System meets the cost threshold, and current DRG payment levels are inadequate.

CMS in its proposed rule (Fed. Reg. April 25, 2006, pages 24071-24072) acknowledges that the C-Port® Distal Anastomosis System meets the cost threshold. Our comments below focus on the question of 1) newness and 2) substantial clinical improvement. In the following we would like to respond to the specific questions CMS stated in the proposed rule.

CMS Question 1: Newness

While the device appears to meet the criteria for being considered new based on its FDA approval date, we are concerned that various forms of surgical staples and clips have been used for more than a decade in a wide range of surgical procedures. In fact, the FDA found the C-Port® System "is substantially equivalent to the predicate devices with regard to indications, device characteristics, method of use, labeling and materials."

Thus, given its similarity to other devices currently on the market, we are concerned that the C-Port® System may not qualify as new.

Cardica, Inc. Response:

1. Use of a "predicate" in a regulatory submission does NOT necessarily imply functional similarities between the applicant device and the sited predicate(s). The 510(k) process identifies predicate devices having a similar - *not necessarily identical* - use and function. A good historic example of this, is the fact that bowel staplers were cleared under the 510(k) process and used conventional suture as their "predicate". Very clearly the manual creation of a bowel anastomosis with conventional suture and a needle holder is fundamentally different from the automated creation of a bowel anastomosis using stapling technology. There can be no doubt that the surgical community did consider stapling devices for bowel anastomosis at the time of their introduction into market as "new" and even "revolutionary" despite their regulatory clearance using suture as a predicate. This very clearly demonstrates that the definition of a predicate from a regulatory point of view can be quite broad but by no means should it be interpreted literally. Finally, none of the predicate devices sited in the C-Port® submission required clinical data for approval. In contrast the FDA did require extensive clinical data with long-term endpoints before approving the C-Port® through the 510(k) process. This emphasizes the fact that for the FDA the C-Port was considered "new" and "different" mandating a more burdensome submission with more clinical data to support safety and efficacy.

   There is NO other fully-integrated anastomotic system cleared by the FDA for creation of an anastomosis between a blood vessel graft and a target coronary artery.

2. There are NO clip or staple-based automated distal coronary anastomotic devices such as the C-Port® Anastomosis System approved by the FDA. Therefore in the regulatory submission of the C-Port® System, Cardica chose a combination of predicates, each of which being relevant to certain aspects of the C-Port® function, but by themselves not sufficient as a "standalone" predicate. Cardica used the following predicates:

   A. U-Clip: The U-Clip is a Nitinol clip at the end of a stain-less steel wire and conventional needle.

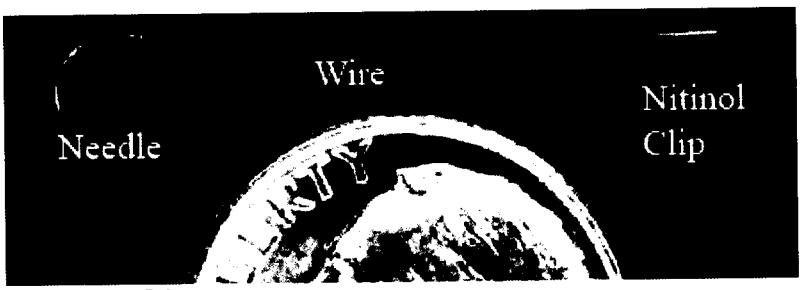

Figure: U-Clip

The surgeon uses the needle with needle holder to penetrate the vascular walls he intends to connect, then manually pulls the wire through the tissue and manually releases the clip from the wire. Once released the clip "curls-up" and thereby connects the two vascular walls. In essence, the clip replaces the suture and alleviates the need to tie a stitch, as would otherwise be necessary if the same compliant anastomotic technique was performed with interrupted sutures. The following images depict the sequence the surgeon would follow to place a U-Clip.

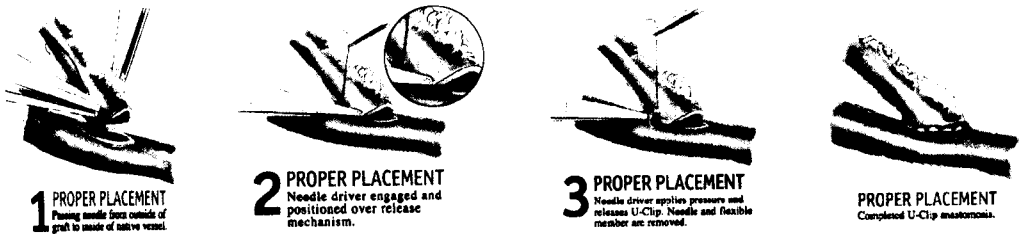

Figure: U-Clip deployment sequence

Cardica chose the U-Clip as a predicate to the C-Port® as it was an example of multiple clips being used to attach vessels. This predicate did not cover the automated portion of the anastomosis creation with the C-Port®, as with the U-Clip the placement, positioning and arteriotomy are all manually performed in a series of sequential, discrete steps. With the C-Port®, the complete anastomosis, including the arteriotomy, is performed in one integrated and automated procedure.

B. The second predicate chosen in the C-Port® submission was the AUTO-SUTURE Modified VCS Clip device, a clip applier that manually places individual titanium clips to attach blood vessels.

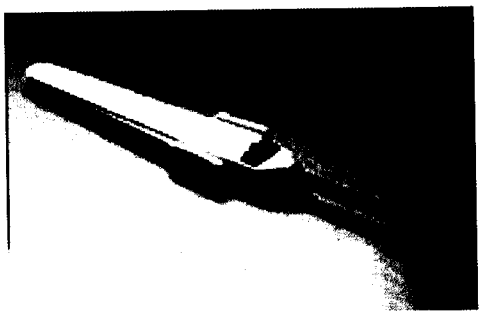

Figure: VCS Individual clip applier

Similar to the previously mentioned U-Clip, placement, positioning and arteriotomy are all manually performed in a series of sequential, discrete steps. None of the anastomosis creation is automated, and therefore, distinctly different from the C-Port® system. Similar to the U-Clip Cardica chose the VCS-Clip as a predicate to the C-Port®, as it was an example of multiple clips being used to attach vessels. In contrast to the U-Clip and the VCS clip, the C-Port®

system is fully integrated in that it creates the coronary arteriotomy and deploys the clip array for creation of the anastomosis with a single firing of the device.

C. To cover the automated aspect of staple deployment Cardica sited the Endopath/Proximate Systems (Ethicon Endo-Surgery) as predicates to the C-Port. Both the Endopath and the Proximate Systems are linear staplers that have an application throughout the alimentary tract and in thoracic surgery for transection and resection of internal tissues. These products divide (transect) tissue while minimizing bleeding from either side of the cut line. To accomplish this objective, the following sequence of operation is performed with these staplers:

- The tissue to be divided is clamped with the device.
- The staples are deployed from a cartridge, which provides one side of the tissue clamp - through the tissue - and formed against an anvil that comprises the other side of the tissue clamp. The staples are deployed in rows – usually 2 or 3 rows per side of the intended transection line to prevent bleeding.
- The clamped tissue is divided (transected) between the rows of staples. The staples seal off any vessels in the tissue thereby minimizing bleeding from either side of the cut line.

The Endopath/Proximate Systems have not been designed to create an anastomosis but rather to cut and divide tissue. In the C-Port submission they were used as predicates on how rows of staples can be deployed in an automated fashion. The purpose of the C-Port is to connect the open end of a graft vessel to the side of a coronary artery and automatically incise the top wall of the coronary to establish blood flow between the two vessels (graft and target vessel).

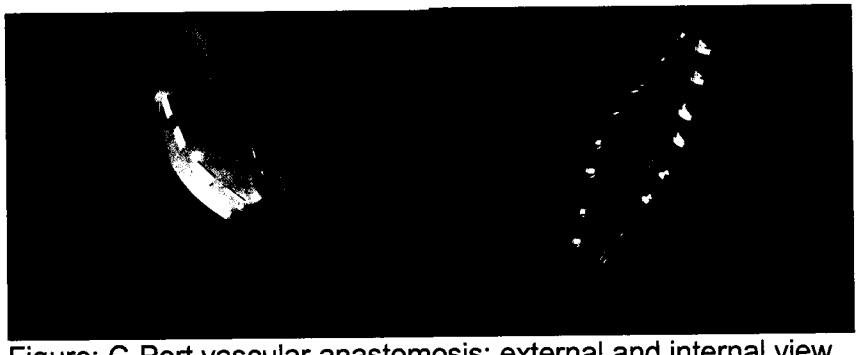

Figure: C-Port vascular anastomosis: external and internal view

This significant, fundamental difference in purpose leads to corresponding significant, fundamental differences in the mechanism of action between the C-Port® and the Endopath/Proximate Systems.

1. With the C-Port®, tissue is clamped in two distinct linear zones which straddle the graft – no other existing stapling device clamps in this fashion.

II. The C-Port® device is designed to attach the specially prepared open end of a graph vessel to the side of a coronary artery. This connection is made between a single layer of the open end of a graphed vessel and a single layer of the side wall of a coronary artery. Traditional stapling technologies have never attempted to connect the end of one vessel to the side of another.

III. Since the open end of the graph vessel is being connected to the side wall of the coronary artery with the C-Port®, cutting is only applied to the coronary vessel wall to open a path for blood flow from the graft vessel into the coronary artery.

In summary, the actual technology, indications, system features and functional differences of the C-Port® System are sufficiently different from all other devices as to meet CMS conditions as being a new technology in the predicate context.

3. C-Port® was approved November 10, 2005. As stated, the use of stapling devices in creating distal coronary anastomosis does not have clinical precedence and there are no ICD-9-CM codes for any other stapling devices. The newness of the product on the market, and the absence of any other products or procedure codes makes clear that CMS would not have had access to data on charges for the C-Port® system. Most important, in the absence of any such data, there could have been no recalibration of DRG weights. Thus, C-Port® qualifies under the newness criterion because its costs are not reflected in the DRG weights.

The average charge of C-Port deployments per patient is approximately $6,000. By contrast, a very different product -- U-clips have average unit charges in the range of $60 for total procedure charge of approximately $1,800, assuming 12 U-Clips manually placed per anastomosis, and on average 2.5 anastomosis per procedure or patient. Neither the charges of C-Port® or U-Clips could have been considered in the recalibration of the CABG DRGs.

CMS notes that surgical staples have been used in a wide range of surgical procedures. Such products, however, have not been used until very recently in cardiac surgery. Earlier surgical staplers and clip uses sited by Medicare were for intestinal anastomoses, non-intracranial use, etc. Please note that the DRGs affected by these stapling devices and clips (e.g. DRGs 110, 11, 170, 171, 315, 442, 443, 486, 154, 155, 1156, 288, 406, 407, 539 and 540), are all **non**-cardiac bypass surgery DRGs (e.g., CABG DRGs 106, 547, 548, 549 and 550).

4. Additionally, in 2004 CMS approved the Medtronic Kinetra device, which already had a Medtronic predecessor. CMS noted, the Kinetra device is not, "significantly different in terms of how it achieves its desired clinical results from its predecessor Solerta. "The stimulation mechanism by which the Kinetra system treats patients' symptoms remains substantially the same as the predecessor device. The enhancements are primarily to features such as control,

power, monitoring and reliability." The Kinetra device approval established precedence for C-Port approval.

CMS Question 2: Newness

We also note that there is currently no ICD-9-CM code used to identify how the anastomosis is performed. The surgical technique used to graft the bypass to the arterial vessel is part of the surgical procedure itself and is not separately identified in our current coding structure. Thus, if a new code is created, we would be creating a code that is a subset of the surgical procedure that identifies whether the graft was performed by hand-sewing or using a device like the C-Port System, a distinction that has been unnecessary to date for inpatient hospital payments. Furthermore, we note that such a coding distinction would only be necessary for the new technology add-on payment period if the device met all of the criteria. Once the new technology add-on payments are completed, the surgical technique used for the anastomosis would not need to be identified because the code that describes the grafting procedure would be the same whether or not this technology is used.

Cardica, Inc. Response:

CMS has an important opportunity now to clarify that there are distinct procedures involving the creation of an anastomosis, and we recommend that ICD-9-CM codes be created that differentiate:

a. anastomosis, manual,

from

b. anastomosis, automated , using single or multiple clip array deployment technology.

For example, before the development of Medtronic's Kinetra implantable neurostimulator for deep brain stimulation, treating bilateral symptoms of patients with these disorders required the implantation of two neurostimulators (in the form of a product called Soletra also manufactured by Medtronic), i.e., neurostimulator codes existed prior to the Kinetra technology. At the December 2003 ICD-9-CM meeting Medtronic requested a revision of the current neurostimulator codes. An ICD-9-CM code was approved for dual array pulse generator devices, effective October 1, 2004 for tracking IPPS purposes. The codes will not identify cases with this specific device and will only be used to distinguish single versus dual channel-pulse generator devices. The Kinetra neurostimulator generator is designed to eliminate the need for two devices by accommodating two leads. The manufacturer argued the development of the Kinetra system provides a less invasive treatment option for patients, and for simpler implantation, follow up, and programming procedures for physicians. By approving CMS recognizes the need for differentiation based on specific

technology and allowed creation of separate ICD-9 CM procedure codes for the use of dual versus single lead deployments.

Additionally, prior to Johnson and Johnson's request for a drug –eluting stent IDC-9-CM procedure code, stent procedures and stent ICD-9-CM procedure codes were well-established clinical practices. The creation of unique multiple ICD-9-CM procedure codes for drug-eluting stents resulted in CMS providing codes for a subset of the already coded stent devices and widely used stent procedures. Furthermore, Johnson & Johnson has projected that the drug-eluting stent will replace bare stents. This is an example where distinct ICD-9 CM procedure codes were allowed for virtually identical technologies which are inherent to the stent procedure.

Cardica, Inc. asks that CMS provide the C-Port® technology the same consideration as the above mentioned technologies. The procedural predicate for the C-Port® System is the manual, suture-based creation of a vascular connection. The C-Port® Distal Anastomosis System is a unique and novel means of creating a mechanical, automated, and interrupted bypass anastomosis. The differences between the manual and automated creation of a vascular anastomosis are significantly more distinct that those sited in the examples stated above.

Furthermore, independent of CMS Add-On Payment New Services and Technologies, the C-Port® Distal Anastomosis procedure should be assigned a new IC-9-CM procedure code as it is not a typical part of the bypass procedure and requires specialized training in use and appropriate patient selection, set-up time and cost. The performance of the automated mechanical anastomosis procedures comprises additional new steps and preparation in the bypass procedure. Both the physician and the OR staff must be trained and proctored to use the equipment. Additional education is required to ensure proper patient selection and outcomes. The following clarifies the differences between a hand-sewn procedure and the C-Port System procedure and their intended outcome.

CMS Question 3:

The applicant made several arguments in support of the device meeting the 'substantial clinical improvement' criterion. The manufacturer argues that the C-Port® creates a reliable and fully compliant end-to-side anastomosis between a vein graft and a coronary artery in less time than is required to create a hand-sewn distal anastomosis. The applicant also states that the C-Port® System integrates deployment of the anastomotic clips and creation of the arteriotomy, thus enabling deployment to occur without occlusion of blood flow through the target vessel. However, we note that the applicant submitted evidence suggesting that the device does not always produce reliable anastomoses; specifically, a study of 130 patients

receiving 132 devices reported 13 incomplete anastomoses in 12 patients, and the study also noted that additional manual stitches were required in the majority of the patients studied. Therefore, we are concerned that these studies suggest that the C-Port® System may not represent a substantial clinical improvement over the traditional hand-sewn technique

Cardica, Inc. Response:

Creating a vascular anatomosis during coronary artery bypass surgery currently involves creating a 5-8 mm opening in the coronary artery downstream or distal to a critical obstruction and then manually attaching a graft (vein or artery) to this opening in order to provide blood flow past the obstruction. The current technique inherent to manually creating the bypass utilizes a non-absorbable suture with a running technique and typically takes 10-20 minutes depending on the skill of the surgeon, exposure and tissue quality. While this manual hand-sewn technique is currently universally used, there remain intra-operative as well as long term failures, which the patient, surgeon and ultimately the health care system must absorb. Intra-operative anastomotic failures with the hand sewn technique occur in approximately 10% of patients and include:

1. The suturing technique does not provide adequate blood flow due to imperfections in the graft-to-target vessel interface and the anastomosis requires surgical revision. On average 3% of all hand sewn anastomosis require intraoperative revision and this is more frequent when dealing with small and/or diseased target vessels[1,2,3,4,5,6,7,8,9,10,11]. Revision of the anastomosis is also more prevalent in beating heart surgery, as the creation of an anastomosis over a 10-20 minute period is more difficult with the target vessel moving with each contraction of the heart [1,4,5,7,8].
2. The anastomosis is not hemostatic, i.e., there is bleeding from the suture line. This may be recognized and corrected immediately during the surgical procedure by placement of additional individual stitches. In 2-4% of patients undergoing heart surgery, excessive postoperative bleeding requires surgical revision with a rethoracotomy, a procedure that significantly increases the overall morbidity of cardiac surgery[12].

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[1] **Ancona et al** *European Journal of Cardio-thoracic Surgery* 2000; 287:293

[2] **Falk et al** *J Card Surg.* 1995;10:147-60

[3] **Louagie et al** *Ann Thorac Surg.* 1994;57:357-64
[4] **Mack et al** *Ann Thorac Surg.*1999;68:383-9
[5] **Taggart et al** *Ann Thorac Surg.*2003;75:870-3
[6] **Walpoth et al** *Ann Thorac Surg.* 1998;66:1097-100
[7] **Hol et al** *Ann Thorac Surg.* 2002;73:813-8
[8] **Reuthebuch et al** *Heart Surg Forum.* 2003;6(suppl 1):S19
[9] **Lin et al** *Ann Thorac Surg.* 2000;70:1350-4
[10] **Takahashi et al** *Interactive CardioVascular and Thoracic Surgery* 3 (2004) 479–483
[11] **Balacumaraswami et al** *J Thorac Cardiovasc Surg* 2004;128:238-44
[12] **Unsworth-White et al**, *Ann Thorac Surg* 1995;59:664-667

3. Acute thrombosis of the anastomosis due to poor run-off or anastomotic imperfections occurs in approximately 10% of manually sewn bypass grafts.

While intra-operative hand sewn anastomotic failures can sometimes be corrected, long term graft patency of hand-sewn anastomosis is affected by a number of additional factors:

1. The type of graft used (artery versus vein), its quality (diseased, aged) and diameter are known predictors of graft patency. Diseased grafts tend to provide less patency over time. A smaller graft diameter improves long-term patency. Arterial grafts provide longer patency than venous grafts [13]. Diffuse intimal thickening is a universal finding in vein grafts that have been in place for more than 1 month [14]. 30% of vein grafts patent at 1 year have some degree of intimal hyperplasia sufficiently gross to be demonstrable by angiography [15].
2. Target vessel selection: Graft patency is considered to be a function of graft blood flow, which in turn is a function of amount myocardium supplied by the grafted vessel. Grafts placed to larger coronary targets with good "run-off" remain patent longer [16]. Paz et al demonstrated that grafts placed to coronary targets $\leq$ 1 mm in diameter are occluded in 40% of cases within 30 days post surgery.
3. Graft endothelial trauma during manipulation and creation of the anastomosis: Preservation of the endothelial layer has been shown to be of paramount importance for long-term bypass longevity. The endothelial layer is very sensitive to trauma.
4. Graft routing: The presence of kinks along the course of the graft inside chest cavity can results in stasis of blood flow, thrombosis formation and occlusion
5. Certain patient comorbidities predispose to graft occlusion [16]
   a. Diabetes mellitus
   b. Hyperlipidemia
   c. Obesity
   d. History of congestive heart failure
6. Antiaggregant treatment with, for example Aspirin, can reduce the incidence of graft failure / occlusion [14, 17]

This extensive list demonstrates that the current hand sewn technique has its limitations, especially when used in conjunction with vein grafts, and outcomes can be less than perfect. Falk et al [22] evaluated vein graft patency using a meta-analysis of 28 published studies with more than 28,000 grafts. Based on this analysis, early (within 30 days of surgery) occlusion occurs in approximately 12%

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[13] **Cho et al** *Eur J Cardiothorac Surg.* 2006 Apr;29(4):511-6.
[14] **Griffith LS**, *J Thorac Cardiovasc Surg* 1977;73:668-79
[15] **Favaloro RG**, *J Am Coll Cardiol* 1998;31:1B-63B
[16] **Paz et al**, *Annals of Thoracic Surgery*,1993: 56, 1101-1106
[17] **FitzGibbon et al**, *J.Thorac.Cardiovasc.Surg.* 1986;91:773-8

of vein grafts and intermediate –term (6 month) occlusion occurs in 20% of all vein grafts.

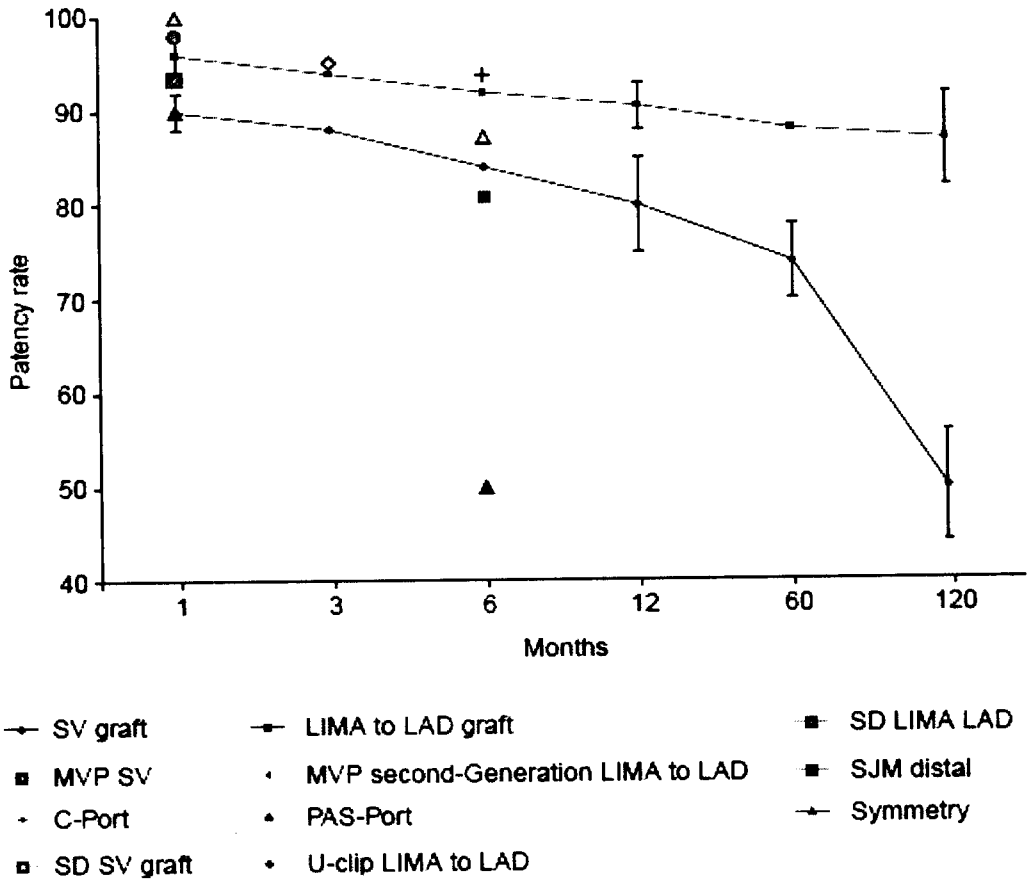

Figure 1. Standard patency rates of saphenous vein and internal thoracic artery bypass grafts as compared with patency rates from reported data for anastomotic devices.
LAD: Left anterior descending; LIMA: Left internal mammary artery; MVP: Magnetic Vascular Positioner; SJM: St Jude Medical; SV: Saphenous vein.

Falk et al [22]

The C-Port® Distal Anastomosis System is a unique and novel means of creating a mechanical, automated, and interrupted bypass anastomosis. Its use in creating a distal coronary anastomosis does not have clinical precedence and may mitigate some of the negative factors noted above which influence vein graft patency with a hand sewn anastomosis. Vein graft patency utilizing the C-Port® Distal Anastomosis Device at discharge and 6 months postoperatively was 99% and 96%, respectively[20]. Compared to hand sewn anastomotic patency rates obtained from historical controls of 88% and 80% at 30 days and six months, respectively, the C-Port® data is compelling[18, 19]. The improved graft patency rates are believed to be due to the mechanically governed reliability and repeatability of the mechanical anastomosis procedure, which is completely independent of the operator skill set. In addition, the C-Port® system produces an

interrupted and thus fully compliant anastomosis which has advantages over a running anastomosis.

Tozzi, et al and others have demonstrated in animal models the advantages of an interrupted anastomosis, where the improved compliance of the blood vessel connection maximizes the anastomotic lumen and provides a considerably higher cross-sectional area at the anastomosis compared to a continuous suture. This in turn reduces flow turbulence, shear stress and intimal hyperplasia [18]. This has been confirmed in a human study conducted by Wolf et al, where the use of a compliant anastomosis has resulted in all arterial grafts placed with this technique to remain patent 6 months after the operation [19]. Further evidence of the superiority of a compliant vascular anastomosis has been published by Shenoy and Baguneid [20,21].

Further, improved outcome in especially smaller target vessels can be expected with this technology due to the fact that the ability of the C-Port® system to create an anastomosis is independent of the target vessel size including target vessels as small as 1 mm in internal diameter. As cited previously, Paz et al had shown a significant decline in vein patency when coronaries with an internal diameter of 1 mm are used as the target vessel [17]. This is especially important given the fact that current coronary stent technology is unsuitable for use in small coronary targets, and therefore, coronary bypass surgery remains the only therapeutic option for patient with diffuse coronary artery disease, a disease state that is prevalent in the older Medicare patient population.

This automated mechanical anastomosis procedure has been shown to provide excellent patient outcome. None of the patients in the pivotal C-Port trial required a reintervention of the C-Port® anastomosis in the more than 1-year follow up. It is reasonable to expect that this system will allow patients who normally would not be surgical candidates to have additional surgical options. There are many examples of such options:

- Coronaries that are too small to predictably perform a hand–sewn anastomosis
- Renal Failure patients with often severely diseased coronary arteries have been shown to be more susceptible to morbidity associated with the use of cardiopulmonary bypass and who would benefit from being operated off-pump. An automated system such as the C-Port® system would provide consistent surgical outcome in this challenging environment.
- Redo procedures in which a sternotomy can not be performed safely due to extensive scarring in the surgical field can be potentially operated through smaller incisions with less risk to the patient.

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[18] **Tozzi et al** *European Journal of Cardio-thoracic Surgery* 2001;19:477-81
[19] **Wolf et al** *J Thorac Cardiovasc Surg* 2003;126:168-78
[20] **Shenoy et al**, *J Vasc Surg* 2003;38:229-35
[21] **Baguneid et al**, *J Vasc Surg* 2001;33:812-20
[22] **Falk et al**, *Expert Rev. Med. Devices* 2005 ;2:223-233

- Patients with poor ventricular function that poorly tolerate manipulation of the heart for the prolonged period necessary to complete a hand sewn anastomosis, would benefit from the expedited procedure using a automated mechanical anastomosis system.
- Patients that cannot tolerate an interruption to blood flow within their coronary target would benefit from the C-Port® System's ability to perform a distal anastomosis without interruption of native artery blood flow
- The C-Port® system produces a compliant distal anastomosis with its inherent benefits [20,21].

It is important to note that the 10% 'failure rate' sited in the C-Port publication (reference Attachment 2) does not represent a failure of the device but rather a failure by the surgeons deploying the C-port device to understand the device's application early in their exposure to the device. Application of the device in creating an anastomosis requires familiarity and as is typical for new technology is often associated with learning curve. Proper device deployment and operation are all important and require training and initial supervision/proctoring.

In summary, the C-Port® Distal Anastomosis System is a unique and novel means of creating a mechanical, automated, and interrupted bypass anastomosis through a 1mm incision in the target artery. Its use in creating a distal coronary anastomosis does not have clinical precedence and may mitigate some of the negative factors influencing vein graft patency with a hand-sewn anastomosis.

Also, because the C-Port® System potentially improves patient outcomes and procedural reliability by facilitating the creation of a reproducible and compliant, interrupted mechanical anastomosis, CMS should approve the C-Port® System for Add-On Payment New Services and Technologies status. Furthermore, due to its recent FDA approval and limited commercialization, data regarding the use of mechanical, automated, and interrupted coronary bypass devices are not reflected in the DRG weights through recalibration.

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Graft revision after transit time flow measurement in off-pump coronary artery bypass grafting ☆

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Abstract

Objective: To determine whether coronary graft patency can be predicted by transit time flow measurement (TTFM). **Methods**: From May 1 1997 to December 31 1998, TTFM was prospectively evaluated in 409 patients undergoing coronary artery bypass grafting (CABG) without cardiopulmonary bypass (CPB). All grafts (1145) were tested with TTFM. **Results**: Thirty-seven out of 1145 grafts (3.2%) were revised in 33 patients (7.6%). In six cases (18.1%) use of CPB was necessary during revision due to hemodynamic instability. The remaining patients underwent revision off-pump. Thirty-four grafts (91.9%) were revised for both low flow and abnormal flow curve patterns. Findings at revision included: thrombosis of the anastomosis ($n = 6$), stenosis at the toe or heel of the anastomosis ($n = 8$), coronary flap or dissection ($n = 5$), dissection of the internal mammary artery ($n = 5$), graft kinking ($n = 4$), flap at proximal anastomosis ($n = 1$), coronary stenosis distal to the graft ($n = 3$), and no findings ($n = 2$). After revision all flow values and flow patterns improved. Although three additional grafts (8.1%) were revised for low flow (<7 ml/min) despite normal flow patterns, there were no findings at revision and flow values and curves remained unchanged after revision. Postoperatively, one patient developed a stroke (3%), one had an acute myocardial infarction (MI) (3%), one had a sternal wound infection (3%), and one required prolonged ventilatory support (3%). **Conclusion**: Evaluation of TTFM is valuable in determining the status of a coronary graft after CABG. Correct interpretation of flow patterns allows for correction of abnormalities prior to chest closure.

Keywords: Transit time flow measurement; Off-coronary pulmonary bypass; Graft; Revision

1. Introduction

The increasing popularity of coronary artery bypass grafting (CABG) performed on a beating heart without cardiopulmonary bypass (CPB), has raised interests and concerns about intraoperative evaluation of graft patency. In the past, a wide variety of flow measurement techniques have been used to assess intraoperatively the quality of the anastomoses after traditional CABG performed under CPB conditions [1,2].

Transit time flow measurement (TTFM) has recently been introduced as an effective and reliable mean for intraoperative evaluation of coronary grafts. This technology allows for flow determination independently of vessel size, shape and Doppler angle used [3]. Exact interpretation of transit time flow patterns is essential to correctly use this technology in both off-CPB and traditional CABG [4,5].

The objective of this study was to assess the clinical applicability of TTFM in detecting anastomotic imperfections following myocardial revascularization in off-CPB coronary artery surgery.

2. Materials and patients

From May 1997 to December 1998, TTFMs were evaluated in 409 patients undergoing off-CPB coronary artery surgery via median sternotomy. A total of 1145 grafts were tested with TTFM.

2.1. Surgical technique

After median sternotomy and conduit harvesting, the pericardium was opened and pericardial stay sutures were placed. Exposure of the different coronary branches was obtained placing the 'single' suture in the oblique sinus of the pericardium [6]. Coronary stabilization was achieved

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with the CTS stabilizer (CTS, Cupertino, CA). Systematical proximal snaring (4-0 pledgetted suture) and intracoronary shunting of the involved coronary artery branches were used.

The distal anastomoses were performed with 7-0 prolene running suture. The proximal anastomoses were performed with 6-0 prolene running suture on a partially excluded ascending aorta.

2.2. TTFM technique

At the end of every single anastomosis, flow values and flow curves were obtained using the TTFM device (Medistim BF 2004, Medistim, Oslo, Norway).

The TTFM probe was perfectly fitted around the graft. Different probe sizes were available to avoid distortion or compression of the graft. Skeletonization of a small segment of the mammary artery was necessary to reduce the quantity of tissue interposed between the vessel and the probe. Aqueous gel was used to improve probe contact.

TTFM was evaluated both with and without proximal snaring of the native coronary artery to detect any possible imperfection localized at the toe of the anastomosis and to exclude flow competition from the native vessel. Before making any measurement, adequate deairing of the grafts was performed, adequate systemic blood pressure was maintained, traction on the pericardium was released and the stabilizer was removed from the epicardial surface to allow for the heart to return to its anatomical position. TTFM was repeated before chest closure to confirm graft patency and to detect any possible graft kinking or compression.

2.3. Curve interpretation

During our clinical experience we developed a progressive expertise in TTFM findings interpretation. To correctly address the TTFM findings, flow curves, pulsatile index (PI) and mean flow values are evaluated.

The curves should always be coupled with the EKG tracing to correctly differentiate the systolic from the diastolic flow. In a patent coronary graft, the hemodynamics are similar to those physiologically observed in the coronary circulation: blood flows mainly during diastole with minimal systolic peaks taking place during the isovolumetric ventricular contraction (QRS complex) (Fig. 1).

The PI, expressed as an absolute number, is a good indicator of the flow pattern and, consequently, of the quality of the anastomosis. This number is obtained by dividing the difference between the maximum and the minimum flow by the value of the mean flow. In our experience, the PI should be included between 1 and 5. The possibility of a technical error in the anastomosis increases for higher PI values.

The mean flow is expressed as ml/min and, being very dependent by the quality of the revascularized coronary artery, is not a good indicator of the quality of the anastomosis. Mean flow values should always be interpreted together with TTF curves and PI values.

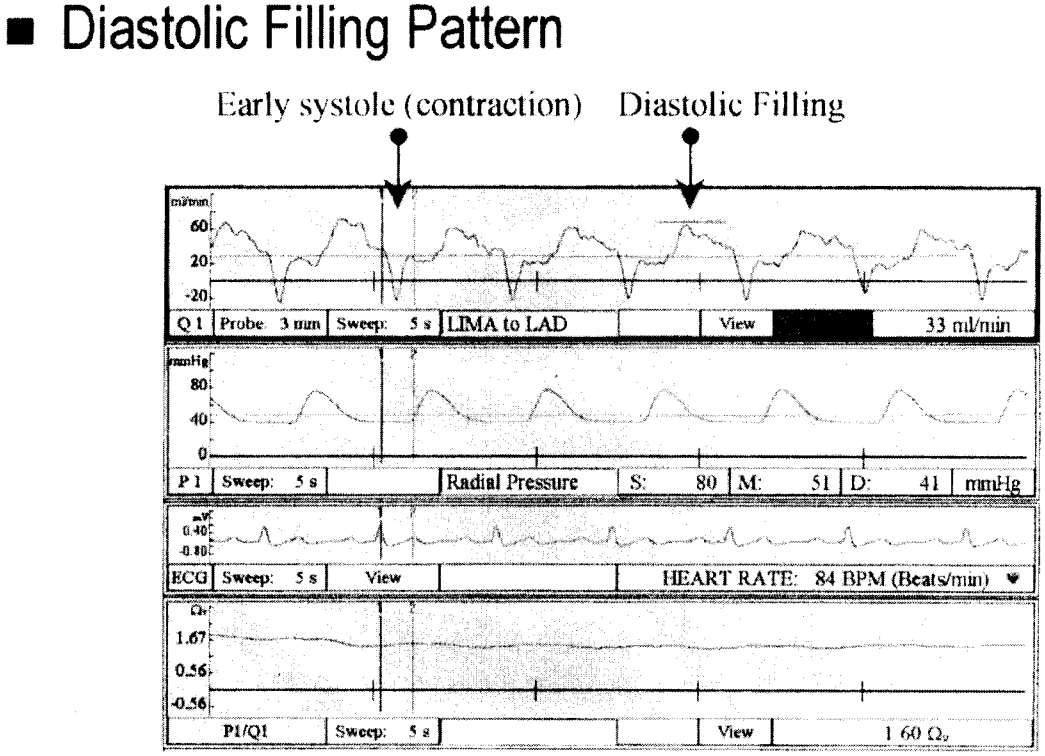

Fig. 1. TTF normal curve.

3. Results

Forty-one grafts (41/1145) were revised in 33 patients. In three patients, four flow curves and flow values were not properly stored in the TTFM device hardware and for this reason have not been included in this study.

A total of 37 grafts are included: 18 to the left anterior descending coronary (LAD) and diagonal branches, ten to the circunflex system and nine to the right coronary artery system (RCA) (Table 1).

A total of six patients (18.1%) underwent graft revision on CPB.

TTFM findings before revision are summarized in Table 1.

Curve patterns, flow and PI values remained unchanged after topical use of vasodilators (papaverine and nitrates). Twenty-nine grafts (78.37 %) were revised for abnormal (systolic) flow patterns, high PIs and low flow values. In five cases (13.51%), despite abnormal flow curves (systolic spikes) and high PIs, flow values were on average greater than 15 ml/min. Findings at revision of these 34 grafts included: thrombosis of the anastomosis (six patients), stenosis at the toe or heel of the anastomosis (eight patients), intimal flap or dissection in the native coronary artery (five patients), dissection of the internal mammary artery (five patients), graft kinking (four patients), flap at proximal anastomosis (one patient), coronary stenosis distal to the graft (three patients) and no findings (two patients). After revision, all flow patterns improved (diastolic flows) and mean flow values increased from a mean value of 3.85 ± 4.63 to 32.47 ± 28.59 ml/min with proximal snare

Table 1
TTFM findings in 37 grafts before revision[a,b]

Graft	% Coronary stenoses	Size coronary (mm)	Mean flow w/wo snare (ml/min)	PI w/wo snare	Resistance w/wo snare (Ω)	Flow pattern
SVG ⇒ RCA	*90*	*1.5*	*12/12*	*49/49*	*7.08/7.08*	*Systolic*
LIMA ⇒ LAD	100	2	5/5	6.6/6	12/12	Systolic
SVG ⇒ RCA	70	2.5	3/3	55/50	25.6/25.6	Systolic
SVG ⇒ D	85	2.0	6/12	10.8/4.2	9/7.83	Systolic
LIMA ⇒ LAD	90	2.5	0/1	7/7	60/60	Systolic
SVG ⇒ RCA	**100**	**1.5**	**5/5**	**0/3.3**	**11/11**	**Diastolic**
LIMA ⇒ LAD	85	2	0/4	4.2/3.2	80/23.24	Systolic
LIMA ⇒ LAD	*90*	*2.5*	*8/19*	*4.5/1*	*10.25/4.31*	*Systolic*
LIMA ⇒ D	90	2	12/7	3/3	6.5/11.42	Systolic
RIMA ⇒ RCA	100	2.5	0/15	48/4.3	62/3.86	Systolic
SVG ⇒ CX	50	1.5	0/1	12.7/12.6	51/51	Systolic
SVG ⇒ OM	90	2.0	0/0	45.7/45.7	83/83	Systolic
LIMA ⇒ LAD	90	1.5	1/1	34.6/34.6	87/87	Systolic
SVG ⇒ CX	90	1.5	0/0	22.1/22.1	67/67	Systolic
LIMA ⇒ LAD	**85**	**1.5**	**10/6**	**4.3/4.6**	**9.3/13.5**	**Diastolic**
SVG ⇒ RCA	80	2.0	0/14	10.4/2	73/5.7	Systolic
LIMA ⇒ LAD	90	2.0	1/4	14/4.9	69/17.5	Systolic
SVG ⇒ RCA	*95*	*2.0*	*13/13*	*8.2/8.2*	*7.3/7.3*	*Systolic*
LIMA ⇒ LAD	100	1.5	6/12	5.8/3.5	11.83/6.16	Systolic
LIMA ⇒ LAD	80	2.0	6/5	10/10	68/70	Systolic
SVG ⇒ OM	80	2.5	3/1	13.9/22	21.5/71	Systolic
SVG ⇒ OM2	90	2	0/10	225/6.5	70/7	Systolic
SVG ⇒ RCA	100	1.0	3/5	12/12	25.3/15.2	Systolic
SVG ⇒ D	90	1.5	0/0	52.8/52.8	67/67	Systolic
SVG ⇒ OM2	100	2.5	6/6	11.7/11.7	9/9	Systolic
SVG ⇒ LAD	90	1.5	0/11	58.4/2	86/8.3	Systolic
LIMA ⇒ LAD	**50**	**1.5**	**7/7**	**1.3/1.3**	**16.57/16.57**	**Diastolic**
LIMA ⇒ LAD	90	2.0	2/13	30.9/4.3	34/5.38	Systolic
SVG ⇒ LAD	60	1.5	0/0	265/265	89/89	Systolic
SVG ⇒ CX	60	1.5	1/1	67.1/67.1	57/57	Systolic
SVG ⇒ RCA	70	2.0	11/11	10/10	60/60	Systolic
SVG ⇒ OM1	*75*	*2.0*	*9/12*	*33.5/5*	*6.5/4.9*	*Systolic*
SVG ⇒ D	75	2.0	0/0	70.5/11	74/74	Systolic
SVG ⇒ RCA	95	2.5	8/4	14/14	8/16.25	Systolic
SVG ⇒ OM2	100	1.5	0/2	16/10	100/50	Systolic
SVG ⇒ OM1	*90*	*2.5*	*15/20*	*15/6.5*	*5.3/4.5*	*Systolic*
LIMA ⇒ LAD	90	2.5	0-1/0	60/60	78/78	Systolic

[a] Bold characters indicate grafts revised on the basis of low flow values despite normal flow patterns. Italic characters indicate grafts revised on the basis of abnormal flow patterns despite flow values greater than 15 ml/min on average.

[b] LIMA, left internal mammary artery; SVG, saphenous vein graft; RIMA, right mammary artery; LAD, left anterior descending; D, diagonal; RCA, right coronary artery; CX, circumflex coronary artery; OM, obtuse marginal.

($P < 0.0001$) and from 6.58 ± 6.00 to 36.29 ± 26.91 ml/min without snare ($P < 0.0001$). PI values also improved from 38.45 ± 56.56 to 3.03 ± 1.6 with snare and from 24.44 ± 46.51 to 2.80 ± 1.68 without snare ($P < 0.0001$). TTFM findings after revision are summarized in Table 2. In three additional grafts (8.1%) revision was performed on the basis of low mean flow values (7.3 ± 2.51 ml/min with snare and 6 ± 1 ml/min without snare) despite normal flow curves (diastolic) and PI values (1.86 ± 2.20 with and 3.06 ± 1.66 without snare). There were no findings at revision and curves, flow and PI values remained unchanged after revision (Tables 1 and 2).

Postoperatively one patient developed a stroke (3%), one had an acute myocardial infarction (AMI) (3%), one required reoperatioin for bleeding (3%), one had a sternal wound infection and one required prolonged ventilatory support (3%). All patients were discharged after a mean hospital stay of 8.15 days.

4. Discussion

Several techniques have been used in the past to test coronary graft flow intraoperatively: electromagnetic flowmeters, initially adopted in coronary surgery, have been recently replaced by ultrasonic technology (Doppler and TTFM). Many authors have demonstrated the superiority of TTFM over Doppler systems in direct real time detection of flow independently of vessel diameter and Doppler angle [2,3].

Increasing interest in intraoperative evaluation of graft flows has followed the advent of CABG without CPB.

Table 2
TTFM findings in 37 grafts after revision[a]

Graft	% Coronary stenoses	Size coronary (mm)	Mean flow w/wo snare (ml/min)	PI w/wo snare	Resistance w/wo snare (Ω)	Flow pattern
SVG ⇒ RCA	*90*	*1.5*	*25/25*	*3/3*	*4/4*	*Diastolic*
LIMA ⇒ LAD	100	2	41/41	1.5/1.5	1.41/1.41	Diastolic
SVG ⇒ RCA	70	2.5	10/10	8.7/8.7	10/10	Diastolic
SVG ⇒ D	85	2.0	21/21	2.5/2.5	2.85/2.85	Diastolic
LIMA ⇒ LAD	90	2.5	31/34	2.8/1.7	2/1.91	Diastolic
SVG ⇒ RCA	**100**	**1.5**	**5/5**	**2/1**	**10/10**	**Diastolic**
LIMA ⇒ LAD	85	2	11/11	1.9/1.9	7.2/7.2	Diastolic
LIMA ⇒ LAD	*90*	*2.5*	*35/35*	*1.2/1.2*	*2.28/2.28*	*Diastolic*
LIMA ⇒ D	90	2	14/31	1.8/1.3	5.8/2.5	Diastolic
RIMA ⇒ RCA	100	2.5	4/47	1/0.8	1.4/1.2	Diastolic
SVG ⇒ CX	50	1.5	22/49	3.1/2.1	2.9/1	Diastolic
SVG ⇒ OM	90	2.0	23/24	5/5	2.69/2.69	Diastolic
LIMA ⇒ LAD	90	1.5	150/150	2.3/2.3	0.53/0.53	Diastolic
SVG ⇒ CX	90	1.5	85/85	2.2/2.2	0.98/0.098	Diastolic
LIMA ⇒ LAD	**85**	**1.5**	**10/5**	**5/5**	**9/13**	**Diastolic**
SVG ⇒ RCA	80	2.0	15/22	2/1.8	4.33/2.9	Diastolic
LIMA ⇒ LAD	90	2.0	23/19	1.8/3.9	3.3/4	Diastolic
SVG ⇒ RCA	*95*	*2.0*	*19/19*	*4/4*	*4/4*	*Diastolic*
LIMA ⇒ LAD	100	1.5	28/49	5.1/3.5	2.6/1.5	Diastolic
LIMA ⇒ LAD	80	2.0	24/35	2.9/1	2.9/1.9	Diastolic
SVG ⇒ OM	80	2.5	64/64	4.1/2.9	0.9/1	Diastolic
SVG ⇒ OM2	90	2	18/14	3.6/5.4	3/6	Diastolic
SVG ⇒ RCA	100	1.0	86/63	1.8/0.7	0.8/1.18	Diastolic
SVG ⇒ D	90	1.5	6/6	4.6/4	11.16/11.16	Diastolic
SVG ⇒ OM2	100	2.5	31/32	6.2/6	1.74/1.74	Diastolic
SVG ⇒ LAD	90	1.5	9/19	1.8/1.9	7.4/3.5	Diastolic
LIMA ⇒ LAD	**50**	**1.5**	**8/6**	**3.4/2.6**	**10.3/14**	**Diastolic**
LIMA ⇒ LAD	90	2.0	22/31	3.5/2.7	3.5/2	Diastolic
SVG ⇒ LAD	60	1.5	31/31	1.6/1	1.83/1.83	Diastolic
SVG ⇒ CX	60	1.5	15/15	3.3/3.3	3.8/3.8	Diastolic
SVG ⇒ RCA	70	2.0	52/56	4/3.2	1.36/1.25	Diastolic
SVG ⇒ OM1	*75*	*2.0*	*19/19*	*3/2.9*	*3.15/3.15*	*Diastolic*
SVG ⇒ D	75	2.0	28/20	3/2.5	3/ 4.2	Diastolic
SVG ⇒ RCA	95	2.5	50/54	4.5/4	2/2	Diastolic
SVG ⇒ OM2	100	1.5	12/20	1.5/1	5/5	Diastolic
*SVG*OM2*	*90*	*2.5*	*40/50*	*2/3*	*3/2.7*	*Diastolic*
LIMA ⇒ LAD	90	2.5	40/33	2/2.3	2/2.4	Diastolic

[a] LIMA, left internal mammary artery; SVG, saphenous vein graft; RIMA, right mammary artery; LAD, left anterior descending; D, diagonal; RCA, right coronary artery; CX circumflex coronary artery; OM, obtuse marginal.

Intraoperative flow measurement together with post-operative angiographic follow-up are important methods aimed at documenting the feasibility of this operation. We began using TTFM routinely in off CPB coronary surgery since 1996. After 3 years of clinical experience we believe that this technology is effective in detecting highly stenotic coronary anastomoses.

The sensitivity of TTFM in detecting less than critical stenoses remains to be defined. Cerrito et al. [7] indicated that neural network pattern recognition analysis of graft flow characteristics, can improve detection of anastomotic errors with intra-operative TTFM. After a complex mathematical analysis of the flow curves is possible to detect stenoses causing a 50% or greater narrowing of the anastomoses. It is evident that less than critical stenoses can not be detected by TTFM due to the fact that no modifications in the hemodynamic performances of the grafts happen at this level. At the present, standard or nominal curves and flow values for different type of grafts and revascularized vessels have not been described and the variability between different subjects and within subjects is extremely large.

In an interesting survey, Spence et al. [8] tested the ability of 19 international surgeons to detect anastomotic errors by evaluating mean flow and flow waveforms. More than 70% of the surgeons accepted anastomoses with severe stenoses but, all of them, were able to detect highly stenotic anastomoses (>90% stenosis).

It is important to emphasize the fact that the ability to correctly interpret TTFM findings is slowly acquired with clinical and experimental experience.

Even if we understand there is a limit in TTFM findings interpretation, our clinical experience with more than 1000 grafts tested, has showed that early detection of stenotic grafts can be achieved by the surgeons' simulataneous evaluation of flow patterns, PI values, flow values and clinical findings (i.e. EKG tracing, hemodynamic values). Flow curves in patent grafts have a mainly diastolic pattern with a small component of negative systolic flow. The diastolic flow is the actual flow that at every diastole flows from the graft in to the coronary through the anastomosis, the systolic component is retrograde flow that cannot flow in to the anastomosis during systole and goes backwards in to the graft (Fig. 1). In the case of stenotic anastomosis the flow curve becomes spiky and mainly systolic (Fig. 2): in this situation the main flow through the graft is systolic and there is minimal perfusion of the anastomosis during diastole. Even if these rules apply generally to all vessels, we have noticed some differences whenever testing grafts anastomosed to the right coronary system. A good component of blood flow in to the right coronary takes place during systole simply due to a minor compression of the epicardial vessels during right ventricular contraction. For this reason, a larger component of systolic positive flow can be observed in patent anastomoses to the RCA.

As mentioned, we do not have nominal flow and PI values to suggest for a correct interpretation of TTFM findings and our statements are based on the simple visual assessment of

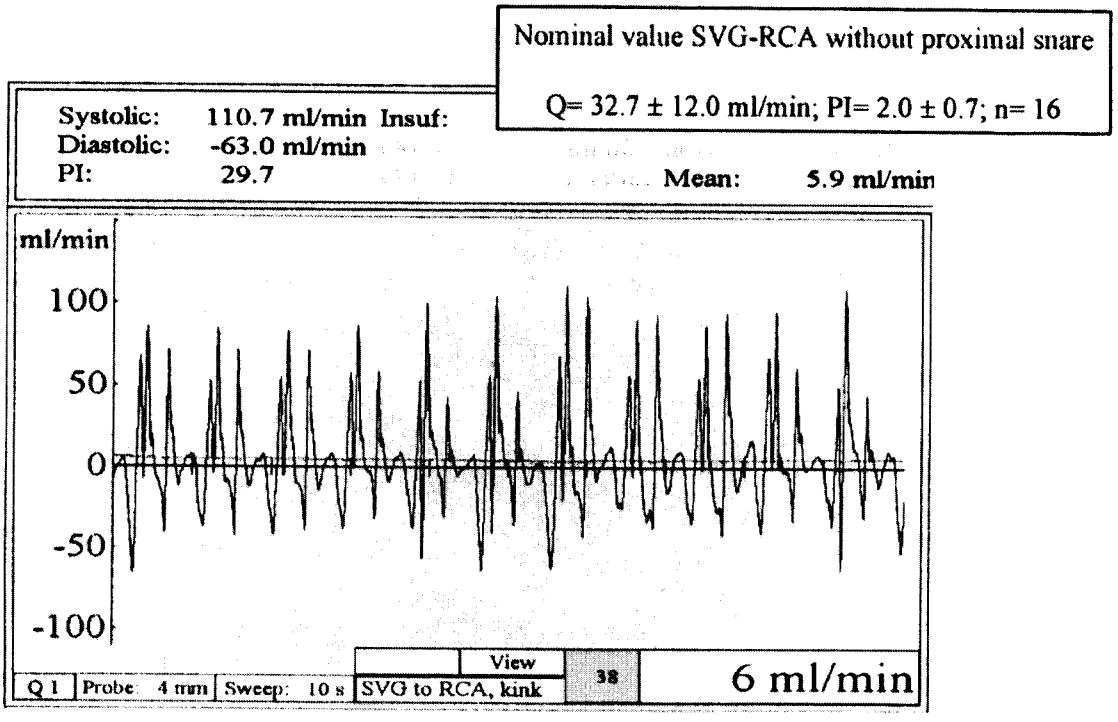

Fig. 2. TTF curve in a severly stenotic saphenous vein graft to the RCA.

flow curve morphology and clinical findings. Di Giammarco et al. [9] have analyzed the differences in TTFM patterns in different coronary grafts but, at present, no standard values have been reported.

We are convinced that flow value per se is not a good indicator of the quality of the anastomosis and can not justify graft revision: absolute flow is influenced by too many variables including type and size of the graft, and quality of the coronary artery distal territory. In our experience graft revision was erroneously performed in three cases only on the basis of low flow values despite satisfactory flow patterns and low PI values: at surgical inspection no anastomotic lesions were found and the flow values remained unchanged after revision (Tables 1 and 2). Use of vasodilating agents (i.e. papaverine and nitroglycerine) did not improve the flow values and the small caliber of the revascularized coronary arteries (<1.5 mm) was responsible for our findings.

Coronary flow reserve can help in correctly diagnose anastomotic imperfections and, as described by Walpoth et al. [10], the quality of the anastomosis can be tested by recording the modifications of flow during infusion of adenosine. We do not have experience with calculation of flow reserve but we believe that a more precise detection of anastomotic imperfections with TTFM could be achieved by testing the dynamic ability of the anastomoses to increase the blood flow whenever the oxygen requests of the myocardium are increased.

If mean flow values are not good predictors of grafts' quality, on the contrary PI values are, per se, very suggestive of the actual status of the anastomoses. As mentioned in the results, we correctly revised five grafts on the basis of abnormal flow curves and high PI values (22.04 ± 21.17 with snare and 13.94 ± 19.77 without snare) despite flow was on average higher than 15 ml/min. At surgical inspection all five anastomoses resulted to be severely stenotic and after revision flow patterns and PIs were improved (2.64 ± 1.07 with snare and 2.82 ± 1.01 without snare) (Tables 1 and 2).

To our knowledge, an absolute PI value has never been officially proposed and we empirically decided the limit of 5 on the basis of our clinical experience. Di Giammarco et al. [9] proposed a value of 2.5 as the limit PI above which an anastomosis should be revised but, again, this value seems to be derived by personal clinical experience.

Flow curves, PI and mean flow values should always be evaluated with and without occlusion of the native coronary arteries: proximal snaring of the native coronary is, in our opinion, important in order to achieve a reliable interpretation of TTFM findings. The shape of the curve should remain unchanged when snaring the coronary proximally and an increase in absolute flow should be recorded if competition from the native coronary was present with the unsnared coronary. The proximal snare will also permit to detect lesions at the level of the toe of the anastomosis: in this situation whenever the coronary is snared the absolute flow will drastically decrease documenting lack of antegrade flow through the anastomosis.

Verification of intraoperative TTFM findings can be obtained with immediate postoperative angiographic studies. Even if we do not have a systematic angiographic follow up for our revised grafts, we believe our immediate postoperative clinical results being satisfactory and somehow confirming intraoperative TTFM findings. Angiography, per se, gives a limited bidimensional view of the coronary arteries and the coronary grafts without giving any specific information about the hemodynamic parameters of the anastomoses; for this reason a comparative study between postoperative angiography and intraoperative TTFM may result difficult. In reoperative CABG for example, we found conflicting results when comparing preoperative angiography and intraoperative TTFM; in one particular case angiographic documentation of anastomotic subocclusion of an old saphenous graft, was not confirmed during surgical revision and intraoperative TTFM.

In an interesting study, Louagie et al. [11] reported that intraoperative hemodynamic assessment, via pulsed Doppler flowmeter, can have a satisfactory predictive value for midterm graft occlusion, on the contrary the same hemodynamic parameters are useless for prediction of midterm graft stenosis. Together with Dr Louagie we feel that midterm stenosis development is a dynamic process related to scar tissue formation and degeneration of the graft and, for this reason, can not be detected at the time of the procedure.

TTFM has also been compared with other techniques of postoperative graft patency verification that, differently from angiography, can give more precise informations about the hemodynamic characteristics of the grafts. In a series of 22 patients, Walpoth et al. [12] have shown a significant correlation between intraoperative TTFM and post-operative magnetic resonance findings of the internal mammary artery grafts.

In conclusion we may say that there are certainly some limits in the interpretation of TTFMs findings and there is still necessity to define the sensitivity of TTFM in detecting less then critical stenosis [7,8]. Correct interpretation of flow curves, mean flows and PI values are crucial in reducing the number of undetected technical errors and in decreasing the number of grafts erroneously revised. The mean flow value per se is not a good indicator of the quality of the anastomosis. Acceptable flow values with abnormal flow patterns and high PIs may underline highly stenotic lesions of the anastomoses (five cases in our experience). On the contrary, we observed low flow conditions with good flow curves in three anastomoses which, at revision, resulted in fully patent anastomoses. This situation may occur whenever the revascularized territory has poor run off.

TTFM is reliable in detecting technical errors after CABG without CPB. Graft revision should be promptly performed whenever flow curves, mean flows, and PI values

are abnormal. In this situation, revision of the distal anastomoses leads to improvement in flow patterns. Postoperative outcome can be improved by a meticulous use and understanding of TTFM in patients undergoing coronary artery surgery with and without CPB.

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Appendix A. Conference discussion

Dr A. Royse *(Victoria, Australia)*: You certainly have a very large series. I think you have shown us fairly well from your data that a high PI value and abnormal flow curves was correlated with a critical conduit of anastomotic stenosis, but what you haven't shown us is what is the denominator? How many of those who had a normal or slightly abnormal flow curve actually had a critical stenosis but you missed it or you didn't revise it? In other words, you are only telling us of the critical stenoses that you actually revised, not how many theoretically there were in those that you didn't revise.

My question is, have you done any other tests such, as, perhaps angiography to try and establish if there is a critical stenosis in those who you didn't revise?

Dr D'Ancona: No, we didn't make any angiographic study. I outlined in the conclusion, we really are not able to say how critical should be the stenosis to be detected by the TTFM. Dr Paul Spence's group in Louisville, Kentucky did make some experimental settings showing that TTFM is able to detect stenosis that at angiography result higher than 50%.

Dr J. Melo *(Carnaxide, Portugal)*: When we measurements low flows should we take precautions like a late angiography?

Dr D'Ancona: In our experience, if we are sure that the size of the vessel and the territory revascularized were very poor, we are not really very much concerned when we have low flows if we have good curves and good PI values, so we don't do anything, and as a matter of fact, we didn't have any clinical postoperative implication using this strategy. So I think you shouldn't be worried about any angiographical study in those patients. This is our personal opinion.

Thermal Coronary Angiography for Intraoperative Patency Control of Arterial and Saphenous Vein Coronary Artery Bypass Grafts: Results in 370 Patients

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ABSTRACT ***Background and aim of the study:*** **Early graft failure is often associated with technical failures and is therefore potentially avoidable. We used thermal coronary angiography (TCA) for intraoperative graft patency control in 370 patients undergoing routine coronary artery bypass graft surgery to determine whether consequent intraoperative bypass graft control may result in improved patency rates.** ***Methods:*** **The temperature differences generated in between the myocardium and the grafts by injecting cold cardioplegic solution into the proximal end of a vein graft or by warmer blood running through an internal thoracic artery (ITA) graft were detected using three different infrared camera systems. The resulting "heat pictures" were evaluated for anastomotic patency and to outline graft anatomy.** ***Results:*** **A total of 693 vein grafts were visualized. In 9.4% TCA failed to produce usable images. In the remaining 628 grafts, TCA revealed intraoperative patency in 98.8%. Out of 370 ITA grafts, only 14 could not be sufficiently visualized by TCA. Nineteen ITA occlusions (5.3%) were found: 5 intimal flaps; 11 suture imposed strictures; and 3 proximal ITA occlusions. All occluded grafts were subsequently revised or replaced. All sequential ITA as well as 15 right ITA grafts proved to have patent anastomoses.** ***Conclusion:*** **Using TCA an early graft dysfunction rate of 1% for vein grafts and 5.3% for ITA grafts could be demonstrated. Most occlusions were due to technical mistakes at the distal anastomosis. TCA outlines grafts and the attached coronaries by temperature differences without the need for a contrast agent. There is no interference with the surgical procedure. It is an ideal, noninvasive method to immediately document the success or failure of myocardial revascularization.** *(J Card Surg 1995;10:147-160)*

Evaluation of early function of saphenous vein (SV) grafts is usually based on probe calibration and injection of saline into the distal end of the graft. Internal thoracic artery (ITA) grafts are judged by inspection and palpation only. Intraoperative angiographic control of coronary artery bypass grafts (CABGs) is rarely performed.

Reports of early graft dysfunction and the fatal outcome of patients with early postoperative bypass failure have created the need for direct

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J CARD SURG
1995;10:147-160

intraoperative CABG control. Since early graft failures are often due to technical mistakes,[1,2] such control should prevent postoperative complications due to graft closure and help to further decrease mortality in CABG surgery.

There is a lack of intraoperative graft patency control, especially for the technically more demanding arterial grafts for which early postoperative dysfunction rates of 5% to 10%, mostly associated with technical faults, have been reported.[3] None of the techniques proposed for this purpose (high-frequency epicardial echocardiography [HFE], Doppler flow measurements, electromagnetic flow measurements) has made its way into daily routine yet.

This article updates our results with intraoperative bypass graft patency control using thermal coronary angiography (TCA) in 370 patients. Other imaging techniques for intraoperative bypass control are discussed and compared with TCA for their feasibility and efficacy.

TABLE 1
Preoperative Patient Characteristics for Patients Undergoing CABG Surgery With or Without TCA Control

	TCA Group	Control	p
Number	370	204	—
Age (years)	63.2	63.4	ns
Sex (m) (%)	81.6	82.0	ns
3 vessel disease (%)	78.1	76.5	ns
Preop. MI (%)	67.8	68.1	ns
NYHA Class IV	20.5	19.6	ns
Number of grafts per patient	2.9	2.8	ns
Reoperation (%)	5.1	4.9	ns
Use of ITA graft (%)	100	100	ns
Additional valvular lesion (%)	4.3	4.4	ns

CABG = coronary artery bypass graft; ITA = internal thoracic artery; MI = myocardial infarction; TCA = thermal coronary angiography; ns = not significant.

MATERIALS AND METHODS

Patients

During a 1-year period, TCA for graft patency control was performed in 370 patients. All patients had routine CABG surgery using at least one ITA. There were 302 (81.6%) male and 68 (18.4%) female patients, with a mean age of 63.2 years (range 36 to 85). Three vessel disease was present in 289 patients and two or one vessel disease in 81. Thirty patients (8.1%) underwent reoperation; 67.8% of the patients had experienced one or more myocardial infarctions prior to CABG surgery. Left ventricular function was reduced in 64.8% (Table 1).

All patients were operated on in moderate hypothermia using cold cardioplegia (HTK-Bretschneider solution) delivered antegradely or retrogradely. Patients received a total of 1078 grafts (2.9 per patient), including 20 sequential ITA and 15 right ITA grafts. To determine whether TCA prolonged cross-clamp time, operative data were compared to a matched control group.

Thermal coronary angiography

Thermography is based on the detection of infrared radiation and its conversion into a voltage signal by a photovoltatic detector (InSb, HgCdTe). This signal can be visualized in real time on a video display. Accordingly, TCA reflects "heat pictures" of the heart using small temperature gradients to outline coronary morphology. Silizium lenses with optimal transmission in the infrared spectrum are used to detect infrared radiation in the range of 3 to 5 μm wavelengths.

We used three different electronically cooled thermovision systems (AGA 870® [Agema Infrared Systems, Danderyd, Sweden]; AVIO TVS 8000® [Avionics, Hughes Co, Ocean City, CA, USA]; AV 750® [Inframetrics, North Billerica, MA, USA]).

The camera was focused onto the surface of the heart at a distance of 1 meter and at a perpendicular angle, when possible. Using multiple detector arrays, the maximum spatial resolution that could be achieved under these conditions was 2.2 to 3.5 mrad. Thermal resolution was between 0.2°C and 0.4°C and was limited to a depth of 2 to 3 mm. Modern thermographic systems allow for real-time imaging with 25 to 30 frames per second. The images were displayed in black and white or color on a conventional high-resolution monitor and stored on videotape. The thermal camera was operated from outside and had no contact with the sterile field.

Thermal coronary angiographies of vein grafts were obtained following completion of the distal anastomosis by injecting cold cardioplegia into the proximal end of the graft.

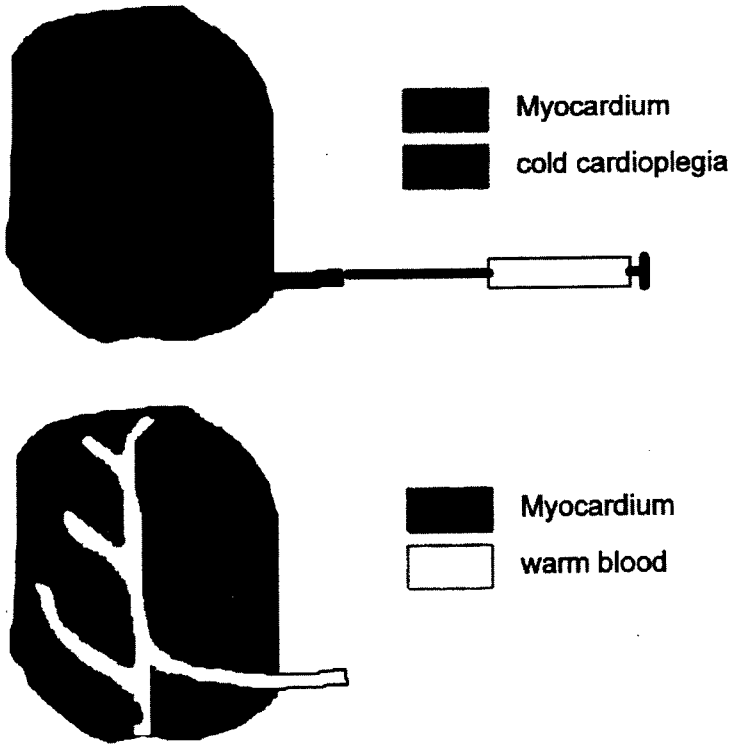

Figure 1. *Principle of thermal coronary angiography (TCA). The coronary vascular bed is outlined by a temperature gradient to the myocardium that is generated by injecting cold saline into the proximal end of a vein graft (myocardium relatively warmer [top]) or by warmer blood running through an ITA graft following release of the vascular clamp (myocardium colder [bottom]).*

ITA graft anastomoses were evaluated after release of the vascular clamp before aortic unclamping. At that time blood temperature exceeded the surface temperature of the heart by 10°C. This temperature gradient was used to outline graft and coronary anatomy (Fig. 1).

Patency of grafts, intactness of anastomoses, native coronary stenoses, and initial flow patterns were evaluated. A graft was considered to be occluded if no perfusion could be detected by TCA. In an early experimental work, Oster et al.[4] have shown that, under the assumption that the heart is a homogeneous body and neglecting energy loss by convection or radiation, the myocardial temperature in a first approximation is described by a heat exchange process. As the specific heat of the cardioplegia as well as the mass and specific heat of the myocardium remain constant, the temperature change of the myocardium, induced by the injection of cardioplegic solution or inflow of blood, is a function of the flow through the coronary arteries. Accordingly, by measuring temperature changes in the perfusion area of a bypass graft against time, bypass graft flow can be estimated. Bypass flow was judged by TCA as being optimal, reduced, or low. Epivasal spot measurements were performed as described elsewhere.[5]

Statistics

Data are presented as mean ± SD. The Chi-square and Student's *t*-test were used as indicated. A p value < 0.05 was considered significant.

RESULTS

Surgery

Mean total cross-clamp time was 68.9 ± 24.6 minutes as compared to 60.9 ± 23.2 minutes in the control group without TCA patency control ($n = 204$, $p = 0.019$). When cases were excluded in which TCA led to revision of a graft

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TABLE 2
Postoperative Outcome of Patients Who Had Intraoperative TCA Patency Control Compared to an Uncontrolled Patient Group

	TCA Group	Control	p
Aortic cross-clamp time (min)	68.9 ± 24.6	60.9 ± 23.2	0.019
Perioperative MI (%)	3.0	3.4	ns
Need for IABP assist (%)	1.6	2.4	ns
Hospital mortality	3.2	4.4	ns

There was no significant difference in aortic cross-clamp times when cases were excluded in which TCA led to revision of a graft and thereby caused a second time of cross-clamping. IABP = intra-aortic balloon pump; MI = myocardial infarction; TCA = thermal coronary angiography; ns = not significant.

and thereby caused a second time of cross-clamping, the difference was not any longer significant (66.2 ± 22.2 min vs 60.9 ± 23.2 min, $p > 0.05$). Hospital mortality was 3% in the TCA group and 4.4% in the control group (n.s.). In the TCA group 1.6% of patients needed temporary intra-aortic counterpulsation, as did 2.4% in the non-TCA group (n.s.). Perioperative myocardial infarction rate was higher in the control group (3.4%) than in the TCA group (3.0%), but this difference again was not significant (Table 2).

Thermal coronary angiography

A total of 693 vein grafts including 58 sequentials, 370 left ITA grafts including 20 sequentials, and 15 right ITA grafts have been studied by TCA. In general, visualization was best for grafts anastomosed to the left anterior descending (LAD) artery or to its side branches. For anatomical reasons, grafts to the distal portion of the right coronary artery as well as to the marginal branches of the circumflex artery were more difficult to image. In 9.4% of the studied vein grafts (65/693), TCA failed to outline graft and coronary anatomy due to various reasons. Thermal imaging was compromised by excessive epimyocardial fat tissue in 21 cases. Grafts to the posterior wall could not be sufficiently visualized in 44 cases because exposure of the area of interest was incomplete for anatomical reasons. Of the remaining 628 vein grafts, the intraoperative patency rate was 98.8% (620/628).

Figure 2 (left) shows the TCA of a vein graft to a marginal branch of the circumflex artery. Optimal antegrade filling of the attached marginal branch is documented. TCA was confirmed by direct intraoperative angiography as shown in Figure 2 (right). In Figure 3 another example of the TCA of a vein graft to the distal LAD is shown.

Vein graft occlusions at the distal anastomosis were detected by TCA in eight cases. None of the 58 sequential vein grafts was occluded primarily at the site of the anastomosis. In one sequential vein graft to a heavily calcified first and second marginal branch, TCA revealed occlusion of the first marginal 1 cm distal to the anastomosis. An additional vein graft was therefore performed and a loose plaque was found to have caused the obstruction.

Due to the lack of a standardized injection pressure while injecting saline into the distal end of the graft, no flow estimation could be made for vein grafts. Therefore, quantification of flow was by subjective criteria only. Low flow through vein grafts was seen in 12.7% (79/620) and mostly due to poor distal runoff. Almost all low-flow vein grafts were attached to arteries of 1 mm in diameter as determined by coronary probing.

In eight patients, an anticipated vein graft was not performed because TCA revealed excellent collateral perfusion by an already grafted artery.

Thermal coronary angiography failed to produce usable images in 14/370 (3.8%) of the ITA grafts due to various reasons (excessive epimyocardial fat [n = 10]; low temperature gradient [n = 2]; intramural artery [n = 2]). In 292/356 cases (82%) optimal antegrade flow could be documented. Figure 4 gives the time sequence of a TCA of an ITA graft to the LAD after clamp release. TCA reveals optimal filling patterns of both the graft and the attached coronary. All major side branches are visual-

Figure 2. *TCA of a vein graft to the marginal branch of the circumflex artery. TCA shows patent anastomosis and outlines the native vascular bed (left). Intraoperative angiography by injecting contrast agent directly into the graft confirms TCA results (right).*

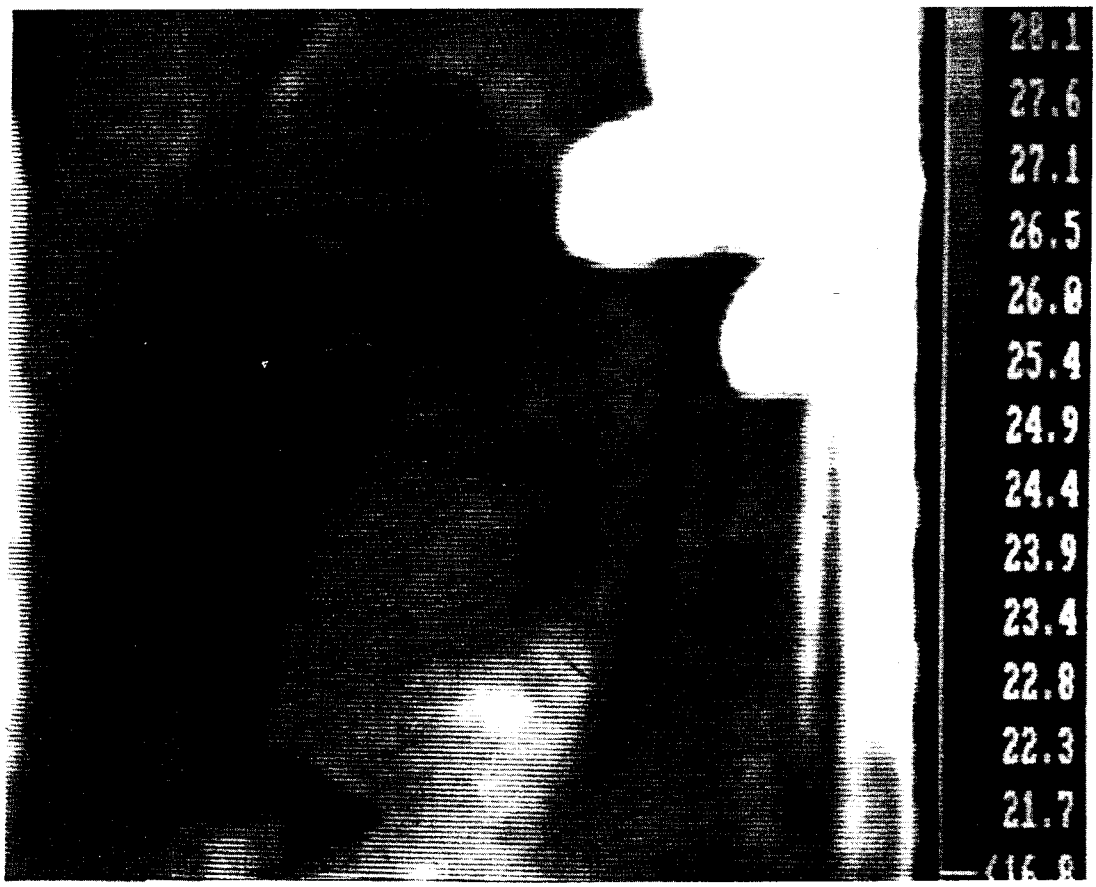

Figure 3. *TCA of a vein graft to the distal LAD. Besides a patent anastomosis, perfusion of a second diagonal branch can be seen. There is no retrograde flow due to stenosis of the LAD proximal to the anastomosis.*

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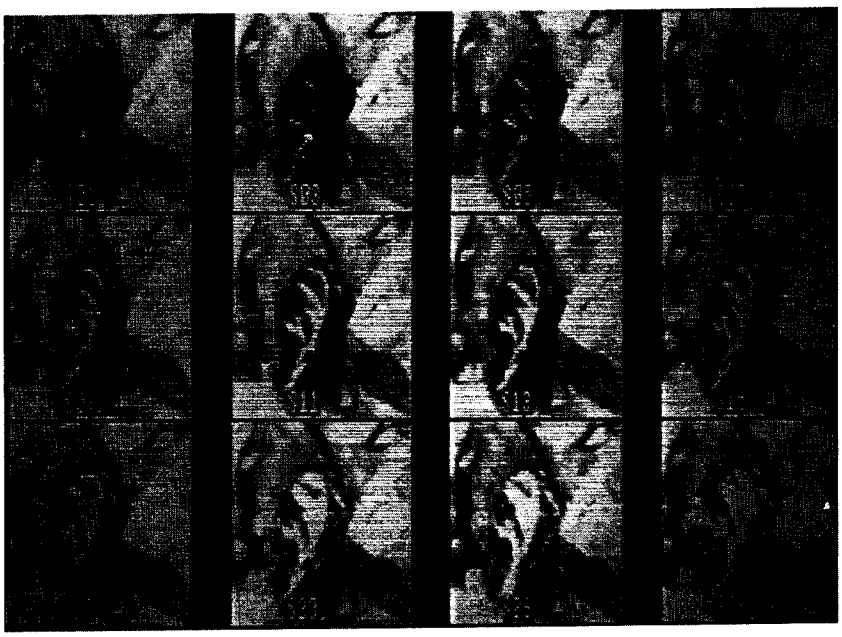

Figure 4. *TCA of an ITA graft to the LAD. The time sequence (0-30 seconds following release of the vascular clamp) shows optimal filling patterns of both the graft and the attached coronary as well as of all side branches. The time (in seconds) following the release of the vascular clamp is given at the bottom of each picture.*

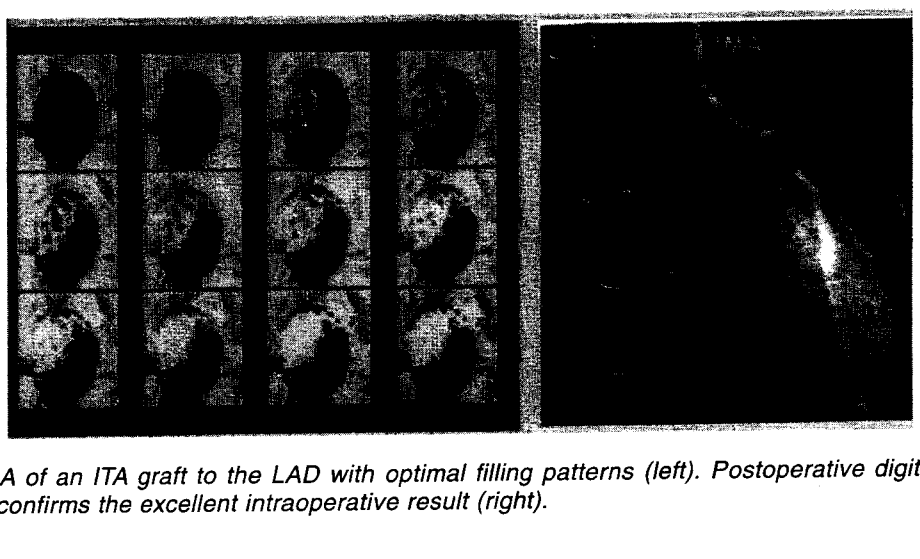

Figure 5. *TCA of an ITA graft to the LAD with optimal filling patterns (left). Postoperative digital subtraction angiography confirms the excellent intraoperative result (right).*

ized. Another example is shown in Figure 5. Again there is immediate filling of the graft as well as of the LAD and all of its side branches. This excellent result was confirmed by postoperative digital subtraction angiography. All of the 20 sequential internal mammary artery grafts were classified as having optimal flow with patent anastomoses. TCA also demonstrated patency of all right ITA grafts (n = 15). Of the ITA grafts, 45/356 (12.6%) were judged as having reduced antegrade flow. As in vein grafts, most of the low-flow ITA grafts were attached to small caliber vessels with severe peripheral disease. As such, low flow with patent anastomoses was usually due to poor runoff. However, in five cases an additional vein graft was added distal to the ITA since it was felt that ITA graft flow was inadequate. Retrograde probe passage confirmed patent anastomoses in these cases.

Figure 6. *ITA graft to the LAD. TCA shows ITA graft occlusion at the level of the tip of the anastomosis and with absent antegrade perfusion of the LAD. A first diagonal branch fills retrogradely. During revision an intimal flap was found to have caused ITA anastomotic obstruction. The graft was revised successfully.*

Internal thoracic artery graft occlusion, either at the anastomosis or proximal to it, was detected in 5.3% (19/356) of the patients. Out of the 19 occlusions, 16 were at the distal anastomosis and due to technical mistakes, as confirmed during revision. Intimal flaps (n = 5) and suture-imposed strictures (n = 11) were found to have caused ITA stenosis and dysfunction. Figure 6 gives an example of ITA graft occlusion at the distal anastomosis caused by an intimal flap that obstructed the lumen of the LAD. TCA shows no perfusion of the LAD while a first diagonal branch fills promptly, indicating retrograde anastomotic patency. The success of anastomotic revision with (n = 3) or without an additional vein patch (n = 15) or vein graft (n = 4) was documented by TCA in all cases.

Proximal ITA occlusion was present in three cases, most likely due to an intramural hematoma caused by trauma during harvesting of the ITA or induced by the vascular clamp. In one case ITA dissection was found to have caused graft failure. In the latter cases an additional vein graft was added to replace the nonfunctioning ITA graft.

Unexpected peripheral native coronary artery stenoses were detected by TCA in eight cases and followed by additional vein grafting when suitable (n = 3). Since fat tissue is a thermal isolator, a thermographically detected peripheral stenosis had to be differentiated from epimyocardial fat tissue covering part of the coronaries. Decision making was therefore guided by epivasal single spot temperature measurements. An example of such measurements is given in Figures 7 and 8. Figure 7 shows a grafted LAD with a good initial inflow pattern and normal epivasal temperature curves at various spots along the LAD. The maximum temperature of 32°C is reached at spots M1 to M3 (proximal to distal LAD) without any delay. In contrast, in Figure 8 there is a substantial delay in epivasal temperature rise behind a distal LAD stenosis, and the maximum temperature is not reached at spot M3 within 20 seconds.

CONCLUSION

Early graft patency rates

A recently published study[6] showed that in 927 patients who underwent vein graft angiography at an interval of up to 2 weeks postopera-

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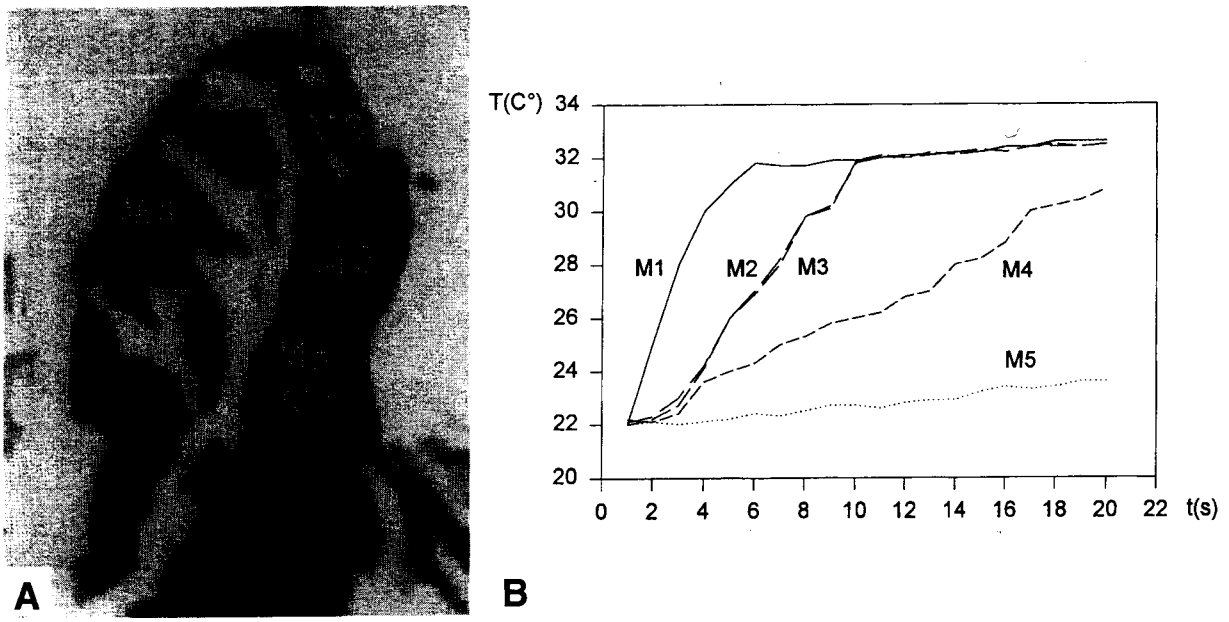

Figure 7. *Epivasal temperature spot measurements of an ITA graft to the LAD. (A) shows an ITA graft to the LAD with normal filling patterns and no distal stenosis. (B) demonstrates the epivasal temperature change along the graft. The graph shows the time course of epimyocardial temperature rise. Temperature curves are normal at all spots along the vascular bed. X axis = time in seconds; Y axis = temperature in degrees centigrade; M1 = anastomosis; M2 = mid-portion of the LAD; M3 = distal portion of the LAD; M4 = LAD perfusion area; M5 = outside LAD perfusion area.*

tively, 15.1% (337/2237) of the distal anastomoses were already occluded. The early graft occlusion rate ranged from 8.8% for vein grafts to the LAD with a good quality distal vessel to 27.6% for vein grafts to the LCX or right coronary artery with a poor distal vessel. In a postmortem study of patients who died within 30 days of CABG surgery, 24% of all saphenous vein-to-coronary anastomoses were not functioning. Most occlusions were due to various technical failures.[7] These results are in accordance with intraoperative angioscopic and echocardiographic findings of SV grafts using high-frequency echocardiography.

There is little information about early ITA graft patency because routine postoperative conventional angiography for bypass graft control is not performed. In a series of 169 consecutive postoperative angiograms, the patency rate for ITA grafts was 96%.[3] Even more alarming, 10% of all ITA grafts showed stenosis of more than 50%, associated with anastomotic defects in most cases. In another study,[8] the incidence of ITA graft stenosis and ITA graft occlusion at 8-day follow-up angiography was 15.6% and 6.4%, respectively. Recently Ramström et al.[9] found an early patency rate of 93% (43/46) for left ITA grafts. It should be emphasized that selection of patients for angiography in the studies mentioned was not based on symptoms of ischemia or clinically suspected ITA graft failure. This should be kept in mind as the usually quoted low early ITA dysfunction rate was clinically diagnosed by signs of hypoperfusion.[10] However, ITA dysfunction may often not be recognized by clinical evaluation alone. Thus, some authors[11] emphasize that evaluation of ITA graft patency should include angiography.

Strictures at the level of ITA graft anastomoses are not a rare finding.[2] Torsion of the pedicle and inadequate length of mobilization, which may lead to tension and shear wall stress, are among the technical problems that can be associated with ITA grafting. Traumatic wall disruption during mobilization as well as dissection of the graft may eventually lead to graft dysfunction. Application of a vascular clamp and electrocautery can cause endothelial injury. Most importantly, suture-imposed strictures will cause anastomotic failure.[2,12-14] Also, commonly used hydrostatic dilatation may have deleterious effects on the ITA wall.[15]

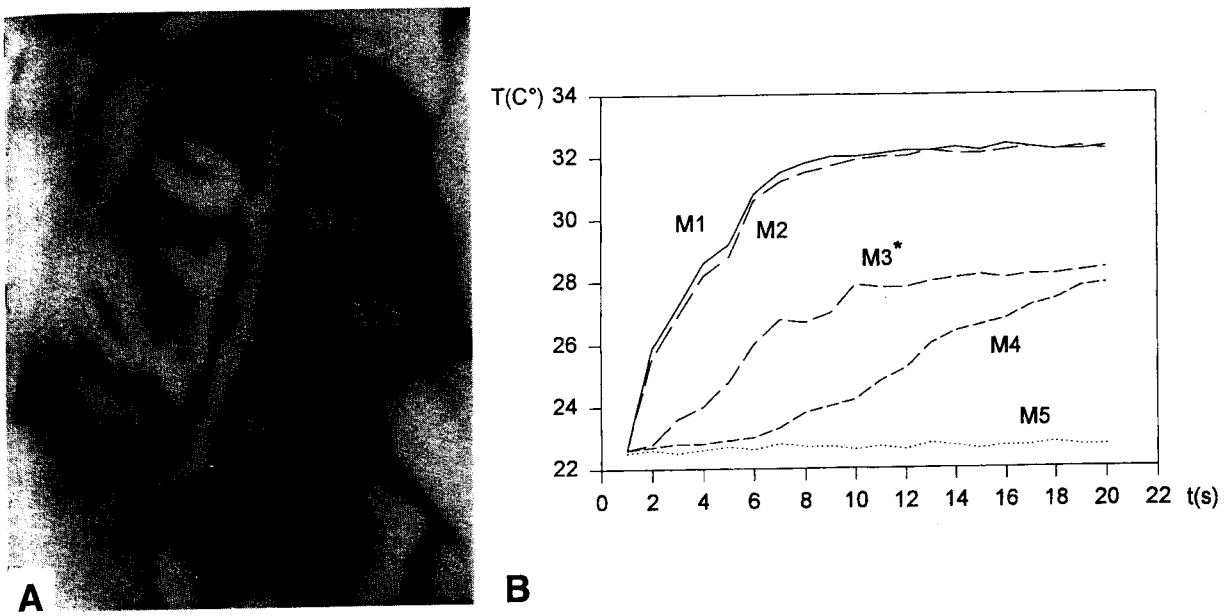

Figure 8. *Epivasal temperature spot measurements (B) show a delay of epivasal temperature rise at spot M3 (distal vascular bed) due to a peripheral LAD stenosis (A). Compare to Figure 7. M1 = anastomosis; M2 = mid-portion of the LAD; M3 = distal portion of the LAD; M4 = LAD perfusion area; M5 = outside LAD perfusion area; S = stenosis.*

The reported early failure rates of both ITA and SV grafts clearly demonstrate the need for intraoperative bypass patency control.

Methods of intraoperative bypass graft patency control

Different methods for the intraoperative evaluation of native coronaries and of coronary artery bypass grafts have been proposed.

Bypass flow has been assessed intraoperatively using *electromagnetic flow meters* (EMF).[16] These studies revealed that low graft flow was predictive of early graft occlusion in both SV and ITA grafts.[17,18] The causes for low blood flow were competition of flow with the native coronary circulation, poor distal runoff in the grafted coronary artery, small caliber of the coronary artery at the level of the anastomosis, and technical problems with the anastomosis.[19] EMF, however, does not allow for estimation of distal runoff and for the quality of the anastomoses.[20] Furthermore, accurate flow volume can be measured only if the cross-sectional area of the vessel is known. Segmental exposure of the vessel is required for circumferential probe fitting. This may cause graft injury or spasm. A wide range of sterilized probes of varying diameters needs to be available. For these reasons, EMF is not recommended for routine use of ITA graft patency control.[21]

In 1982 *high-frequency epicardial echocardiography* (HFE) was introduced for intraoperative imaging of coronary arteries. Qualitative changes in wall structure, such as diffuse wall thickening and calcification, were easily detected using HFE. The results have been validated against histopathological findings.[22,23] HFE allows for the identification of suitable sites for distal anastomoses in proximal occluded coronaries that cannot be visualized by preoperative angiography.[24] Furthermore, HFE has been used for the assessment of SV graft anastomoses. In one series,[25] 8.8% of vein grafts showed anastomotic defects that required operative revisions. In another series,[26] 4.9% of the imaged vein-to-coronary anastomoses were judged as having minor defects. In addition 1/13 imaged ITA grafts had a distal anastomotic defect, not apparent by external inspection, which was subsequently revised. However, using epicardial HFE it is not always possible to trace coronary arteries accurately due to "shadowing" of calcified arterial segments.[27]

For intraoperative *perfusion contrast echo-*

cardiography albumin-coated microbubbles are injected into SV grafts. With this technique, the effectiveness of myocardial revascularization has been indirectly assessed by the evaluation of regional myocardial perfusion.[28] Furthermore, coronary collateral flow has been evaluated using intraoperative two-dimensional contrast echocardiography.[29]

Intraoperative *Doppler* measurement of ITA graft flow like EMF measurements only provides information about flow and as a velocimeter does not allow for visualization of anastomoses.[30] However, the findings of severely reduced flows and velocities using Doppler techniques have described graft dysfunction and led to revision of anastomoses.[31] More recently, *Doppler color flow mapping* of epicardial coronary arteries has been shown to be useful for the detection of characteristic flow patterns in normal and diseased coronary arteries.[32] However, these observations are still at an experimental stage and require time-consuming procedures that lead to an undesirable delay of the operation.

With *implantable ultrasonic Doppler miniprobes*, bypass graft blood flow can be measured not only intraoperatively but also during the postoperative period, allowing for continuous assessment of bypass function.[33,34] Although this method allows for measuring acute changes in bypass flow following therapeutic interventions, it does not provide any information about the integrity of the anastomosis.

Angiography still is the gold standard for the morphological evaluation of the coronary arteries. However, there is great interobserver variability regarding the severity of stenoses in the evaluation of coronary angiograms, and in vivo coronary atherosclerosis often proves to be more widespread intraoperatively than predicted by preoperative angiography.[35-38]

Only a few centers perform intraoperative *digital subtraction angiography* (DSA) of CABGs by injecting a contrast agent into the distal end of the graft.[39,40] The technical equipment needed to obtain acceptable DSA or angiographic images, as well as the cost of such techniques, are not justified in routine CABG surgery. We have used direct intraoperative angiography of vein grafts in 20 patients (43 grafts) to confirm TCA findings. In that study,[41] only 76.7% (33/43) of the grafts could be accurately imaged by intraoperative angiography. It should be noted that even in postoperative studies under optimal conditions, which cannot be achieved in the operating room, nonselective intra-arterial DSA demonstration of distal anastomoses is possible in only 40%.[42] Intraoperative direct angiographic control of arterial grafts is not feasible at all.

For intraoperative assessment of coronary stenoses and vein graft anastomoses, *angioscopy* has been successfully applied.[43] Intraoperative angioscopic studies of SV graft anastomoses revealed intimal lesions or flaps and thrombi in 25% of the grafts studied.[44] This underscores the need for early intraoperative graft assessment. Like all catheter-based methods such as intravascular ultrasound (IVUS), angioscopy bears the potential danger of intimal injuries, and its use is again limited to the evaluation of vein grafts and native coronaries.[45]

Anastomoses, grafts, and coronaries can also be visualized under a black fluorescent light by injecting fluorescein into the distal end of a bypass graft. The application of intraoperative coronary *angiography using fluorescein* like angiography is limited to vein grafts, since there is no feasible access for the evaluation of in situ arterial grafts.[46]

Intravascular ultrasound is another promising technique that has been recently applied to the evaluation of SV graft morphology. It has potential advantages since it gives a circumferential view of the different layers of the vascular wall. SV and ITA graft flow can be assessed using intravascular Doppler spectral analysis.[47,48] Intraoperatively, this method has rarely been used for graft evaluation. Table 3 summarizes the advantages and disadvantages of the different methods used for intraoperative bypass graft control.

Thermography was introduced into cardiac surgery in 1971.[49] Since then, this technique has been mainly used to evaluate surface cooling induced by the various application modes of cardioplegia.[50,51] Different thermographic studies have shown the relationship of epimyocardial temperature changes to the amount of coronary artery blood flow.[52-56] In 1982 Shabbo and Rees,[57] and later Pantaleo et al.[58] evaluated SV graft function using thermography and

TABLE 3
Comparison of Different Techniques for Intraoperative Bypass Graft Control (y = yes/possible; n = no/impossible)

	Contact to Sterile Field	Invasive	Need for Contrast Agent	Anatomical Picture	Flow Quantification	SV Graft Evaluation	ITA Graft Evaluation
Angiography	y	y	y	y	(y)	y	(y)
Angioscopy	y	y	n	y	n	y	n
IVUS	y	y	n	y	(y)	y	n
HFE	y	n	n	y	n	y	y
Doppler	y	n	n	n	y	y	y
EMF	y	n	n	n	y	y	y
Flourescein	y	n	y	y	n	y	n
TCA	n	n	n	y	(y)	y	y

EMF = electromagnetic flow meter; HFE = high-frequency echocardiography; ITA = internal thoracic artery; IVUS = intravascular ultrasound; SV = saphenous vein; TCA = thermal coronary angiography; y = method definitely used; (y) = method provides some information but reliability has not yet been proven.

demonstrated a relationship of graft flow measured with EMFs and the velocity of induced temperature changes in the grafted myocardium. However, thermal resolution did not allow for the delineation of anatomical structures in these early studies.

In experimental studies using more advanced technology, we have shown that TCA is able to detect coronary artery stenoses in arrested hearts. These findings have been validated against intraoperative angiography.[59] In an early clinical trial, the sensitivity of intraoperative TCA for graft patency control was confirmed.[60] During these studies it became obvious that TCA is most helpful for the evaluation of ITA graft patency and is able to document anastomotic stenosis or occlusions as well as ITA occlusions.[61] In a larger study population, a 6.2% early ITA graft failure rate has been demonstrated using intraoperative TCA for graft patency control.[62]

Besides its use for evaluation of early ITA graft function, the potential of TCA to detect unexpected new stenotic lesions in distal vessels has been noted. Furthermore, it has been shown that in the absence of peripheral stenoses or wall abnormalities, the time course of the induced rise in mean epimyocardial temperature of the LAD perfusion area, calculated 20 seconds after clamp release, correlates to free ITA graft flow.[5]

Thermal coronary angiography of vein grafts required injection of cold saline or cardioplegic solution, using a standard syringe, into the proximal end of the bypass. As this procedure is routinely performed to test bypass patency, it did not interfere with the surgical procedure. Bypass flow could not be quantitatively estimated for vein grafts as it was influenced to a great extent by the force applied during injection. For this reason, thermographic flow estimations have been performed for ITA grafts only. Epivasal spot temperature measurements facilitated differentiation of stenoses from artifacts produced by fat tissue covering the coronary arteries.

In contrast to invasive methods like angioscopy or IVUS that will give a circumferential view of part of the vessel, TCA outlines the vascular bed completely. However, it does not allow for the characterization of wall abnormalities that can be obtained by IVUS, HFE, and angioscopy. Doppler and EMF studies will not display graft and coronary anatomy but will allow for quantification of bypass flow. Thermographically, only initial inflow patterns through ITA grafts can be estimated. It remains to be determined whether this early inflow pattern is predictive for long-term patency. So far we have not observed postoperative ITA failure when intraoperative patency was confirmed by TCA.

Our results in 370 patients confirm an early graft failure, due to technical mistakes, in 1.2% of the vein grafts and in 5.3% of the ITA grafts. All occluded grafts were revised or replaced without complication. The time of aortic cross-clamping did not substantially differ from that of a comparable cohort of patients. Thus, TCA itself does not prolong the surgical procedure. This study failed to demonstrate a short-term beneficial effect of TCA on postoperative recov-

ery as there was no significant difference in operative mortality and perioperative infarction rate, although both were lower in the TCA group. This may be explained by the fact that the surgical team was not the same during the two periods. Furthermore, analysis of the control group was performed retrospectively. We are currently undertaking a prospective randomized controlled clinical trial to determine whether TCA is able to lower the postoperative complication rate due to early recognition of dysfunctioning grafts and will further improve the outcome of CABG surgery. Furthermore, follow-up angiographic studies are required to evaluate whether the long-term patency rates of ITA and SV grafts will improve with consequent intraoperative TCA control.

The cost of commercially available infrared cameras may easily be saved if one or two reoperations for early graft failure are prevented each year. The first infrared camera specially designed for use in CABG surgery is now available (IVA® System, OPGAL, Karmiel, Israel) and is awaiting clinical trials.

So far we conclude that TCA is a powerful tool to intraoperatively assess early bypass graft patency for both vein and ITA grafts, without the need for a contrast agent. It can guide the decision to redo a failing graft or document a favorable result of the revascularization procedure. TCA is easy to handle, can be applied from outside the sterile surgical field, and requires only focusing of the camera by the surgeon. The TCA images resemble angiographic studies that are familiar to every surgeon. Prior teaching for interpretation of thermograms is therefore not necessary if one keeps in mind the technical limitations. There are no procedure-related complications. Results are displayed in real time and available within seconds. This is a major advantage when compared to other more time-consuming techniques (IVUS, HFE, angioscopy, angiography).

Further studies are underway to prove whether routine use of TCA may reduce the incidence of morbidity and mortality related to graft failure.

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Intraoperative Electromagnetic Flowmeter Measurements in Coronary Artery Bypass Grafts

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This study attempts to relate flow findings in internal mammary (IMA) and saphenous vein coronary artery bypass grafts to postoperative outcome. From 262 patients undergoing coronary artery bypass grafting, 601 electromagnetic flow measurements were obtained in IMA and saphenous vein grafts, and free graft flow was measured in 227 IMAs prior to grafting. Retrograde flushing of the IMA with diluted papaverine hydrochloride resulted in a marked increase in IMA free flow (124 ± 4 mL/min versus 66 ± 5 mL/min; $p < 0.001$). However, IMA free flow did not correlate with electromagnetic flow measurements after grafting to the left anterior descending coronary artery. The use of IMAs with free flows lower than 50 mL/min did not affect clinical outcome. Flow measured in saphenous vein grafts (66 ± 9 mL/min) with an electromagnetic flowmeter was significantly greater ($p < 0.001$) than that in the IMA grafted on the left anterior descending coronary artery (36 ± 3 mL/min) under comparable hemodynamic conditions. For the purpose of data analysis, patients were separated into three groups based on increasing incidence of complications: levels 0, 1, and 2. Patients with an uneventful outcome had a mean graft flow at chest closure of 51 ± 3 mL/min versus 51 ± 4 mL/min for patients in complication level 1 and 45 ± 11 mL/min for patients in complication level 2 (p = not significant). Free flow measured in a vasodilated IMA was a poor predictor of flow into a grafted IMA and did not affect clinical outcome. We were unable to validate any flow limit to use of the IMA. Clinical outcome did not depend on flow measured in bypass grafts using electromagnetic flow measurements but rather was affected primarily by the preoperative clinical situation.

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Use of the internal mammary artery (IMA) as a coronary bypass graft has been criticized on the basis of its small caliber and inability to provide sufficient flow to large regions of ischemic myocardium, particularly in emergency situations where vasospasm may be present and high volume is necessary. Therefore, various methods have been used to evaluate IMA flow capacity intraoperatively. Timed volumetric collections of the cut end of the IMA is the simplest method, and lower limits of flow have been established. It was generally recommended that IMAs with intraoperative flows of less than 50 mL/min before pharmacologic manipulation and less than 120 mL/min after injection of hydrochloride papaverine are not suitable for use as grafts [1, 2]. Electromagnetic flow probes have been widely used to assess flow in coronary artery bypass grafts during cardiac operations [3–6], and lower flows in IMA grafts compared with saphenous vein (SV) grafts were frequently noticed [3–6].

Recently, Doppler measurements in IMA and SV grafts gave velocity profiles, but flow had to be approximated, and the error was greater when flow was studied in an IMA [7]. However, these limitations will probably be overcome with the advent of pulsed Doppler flowmeters with the capacity to determine the internal diameter of the graft.

Despite the considerable progress in flowmetry, important questions, such as the minimal flow required for an IMA to maintain adequate perfusion, remain unanswered. This is because there are no data available, to our knowledge, correlating flow studies and clinical outcome. The purpose of this study was to tabulate flows from the open end of the IMA, to compare those with flows through completed IMA and SV grafts on the coronary arteries, and to try to elucidate the influence of these flow findings on the postoperative outcome.

Material and Methods

Patient Population

From October 1987 to November 1989, a total of 262 patients underwent measurement of flow in a bypass graft using an electromagnetic flowmeter, measurement of flow at the cut end of an IMA by timed blood collection, or both. The patients were not consecutive, as electronic flowmeter determinations depended on the availability of sterile probes of adequate size. A total of 734 bypass grafts were constructed (2.8 grafts per patient; range, 1 to 5 grafts), 240 IMA and 494 SV grafts. The mean age at operation was 61.6 ± 0.5 years (range, 35 to 83 years). There were 211 men and 51 women, and body surface area was 1.88 ± 0.01 m^2.

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Angina class was as determined by the system of the Canadian Cardiovascular Society. There were 2 patients in class I, 139 patients in class II, 83 patients in class III, and 38 patients in class IV. Sixty-one patients (23.3%) had unstable angina and 22 (8.4%), impending myocardial infarction. The extent of coronary artery disease at angiography was as follows: one-vessel disease, 31 patients (11.8%); two-vessel disease, 67 patients (25.6%); three-vessel disease, 157 patients (59.9%), and left main disease, 51 patients (19.5%). Total ejection fractions and regional ejection fractions were calculated from a single-plane left ventriculogram in the right anterior oblique view using a computerized tracing program. Segmental wall motion was quantified using the method of Leighton and colleagues [8]. Isotopic ventriculograms with technetium 99m–labeled human red cells as the tracer were obtained in the absence of a cineangiogram and in high-risk patients. Mean left ventricular ejection fraction as determined angiographically was 0.58 ± 0.01 and 0.53 ± 0.01 by isotopic means. Twenty-seven patients had a left ventricular ejection fraction of less than 0.40.

Anesthesia and Surgical Techniques

A peripheral line and an arterial line were placed under local anesthesia. General anesthesia was accomplished with fentanyl citrate (25 μg/kg) and pancuronium bromide (0.1 mg/kg) (Pavulon; Organon Inc, West Orange, NJ). A Swan-Ganz thermodilution catheter was introduced percutaneously through the internal jugular vein. Measurement of cardiac output was done with a cardiac output computer (Hellige GmbH, Freiburg im Breisgau, Germany). The results were stated as the mean of three consecutive recordings. The following hemodynamic variables were calculated:

$$\text{Cardiac index} = \text{cardiac output/body surface area}$$

$$\text{Left ventricular work index} = \text{cardiac index} \times (\text{mean arterial pressure} - \text{pulmonary capillary wedge pressure}) \times 0.0136$$

All operations and flow measurements were performed by the same surgical team to eliminate possible variability resulting from the use of different surgeons. Dissection of the left IMA (LIMA) was performed from its origin to the seventh rib and was facilitated by use of a Favaloro retractor. Standard cannulation of the aorta was performed. Ascending aortic venting was accomplished through a catheter having a Y connection to the cardioplegia line. The cardiopulmonary bypass (CPB) system was primed mainly with crystalloids and occasionally with banked blood to maintain a hematocrit greater than 20%. Extracorporeal circulation was performed with a Stöckert heart-lung machine (model 10-00-00; Stöckert Instrumente Gmbh, Munich, Germany) using a membrane oxygenator.

The ascending aorta was cross-clamped, and cardioplegic solution was infused into the aortic root. Our practice is to infuse 1,000 mL initially and then 300 to 500 mL after the completion of each distal anastomosis. The composition of the cardioplegic solution was as follows: 200 mg of procaine hydrochloride, 2.5 g of magnesium sulfate, 13.5 mmol of potassium chloride, and 7 mmol of sodium bicarbonate in 1 L of Hartmann's solution. The heart was further cooled topically by the liberal application of cold normal saline solution (1 to 2 L) and sterile crushed ice. Patients were cooled systemically and were kept at a temperature of 28°C until completion of the distal anastomoses. The vast majority of patients had anastomosis of the LIMA to the midportion of the left anterior descending coronary artery (LAD) and SV grafts to all other vessels. Thirteen sequential bypasses (1.8%) were performed. All distal anastomoses were done during a single period of aortic cross-clamping, and the proximal anastomoses were constructed during the period of reperfusion with the aorta side-clamped. Mean duration of CPB was 129 ± 2 minutes, and mean aortic cross-clamp time was 74 ± 1 minutes.

Flow Measurements

In the first 48 patients, diluted papaverine solution was applied externally to the entire IMA pedicle to ensure maximum dilation before any flow measurements were made. In subsequent patients, retrograde flushing of the IMA was performed as described by Mills and Bringaze [2]. An olive-tipped (1-mm) metal needle (No. 31001; DLP, Inc, Grand Rapids, MI) was introduced into the distal end of the IMA graft, and 4 mL of diluted papaverine chlorhydrate (40 mg in 40 mL of electrolyte solution [Plasmalyte; Travenol Laboratories, Inc, Deerfield, IL]) was injected. Retrograde injection into the unclamped IMA was performed gradually over a 30-second interval, with care taken to avoid hydrostatic dilation.

Free graft flow was measured by allowing the transected end of the IMA to bleed into a graduated cylinder for 30 seconds. Intraoperative bypass flow in the grafts was measured with a precalibrated electromagnetic flow probe (Statham Instruments, Inc). Recording sites were in the proximal vein graft segment and the midportion of the IMA pedicle where a segment was isolated, with care taken not to destroy the accompanying mammary veins. Consecutive measurements were performed at the following three periods: before discontinuation of CPB, at normothermia after the patient was off CPB, and before sternal closure. Probe size was 3.0 ± 0.1 mm (median size 3 mm; range, 2 to 5 mm) for measurement of IMA flow and 4.3 ± 0.1 mm (median size 4 mm; range, 2 to 8 mm) for measurement of SV graft flow. To validate the technique of flow measurement, we simultaneously measured graft flow with the electromagnetic flowmeter and by timed volumetric collection of blood when the distal graft was open in 12 patients. The validation study showed a satisfactory correlation between the two methods ($r = 0.93$; $Y = 4.02 + 0.94X$).

The resistance of the IMA before implantation and the resistance resulting from the grafted IMA and runoff coronary bed were calculated using the simplified expression of the Poiseuille-Hagen equation (Appendix 1).

Data Analysis

Patient outcome was differentiated into three categories characterized by complications of increasing severity. We took into account the extent of inotropic support needed for weaning from CPB, cardiac function as assessed by left ventricular work index measurements before and after CPB, difficulty (several attempts) in weaning from CPB, the need of intraaortic balloon counterpulsation, and hospital death from cardiac-related cause. Complication level 1 included a left ventricular work index after CPB that was inferior to that obtained before CPB, need of dopamine hydrochloride or dobutamine hydrochloride at more than 5 $\mu g \cdot kg^{-1} \cdot min^{-1}$ or epinephrine at any dosage for weaning from CPB, or difficult weaning from CPB. Complication level 2 included the need of intraaortic balloon counterpulsation or hospital death from cardiac failure. Complication level 0 was characterized by the absence of these criteria.

Data are presented as the mean ± the standard error of the mean. Data were compared by two-sample t test for paired or unpaired data, χ^2 test, or Fisher's exact test when appropriate. Two-way analysis of variance was used for comparisons between groups at specific time points. Probability values were obtained for the overall group effect, overall time effect, and group–time interaction. Correlation was assessed by the Pearson coefficient (r).

Results

Hospital mortality was 2.3% (6 patients). Intraaortic balloon counterpulsation was necessary in 14 patients (5.3%), 2 of whom had insertion of the intraaortic balloon preoperatively. Eighty-two patients were in complication level 1 and 16, in complication level 2. The patients in complication level 2 were characterized by a higher incidence of unstable angina (11/16), evolving myocardial infarction (4/16), and female sex (8/16).

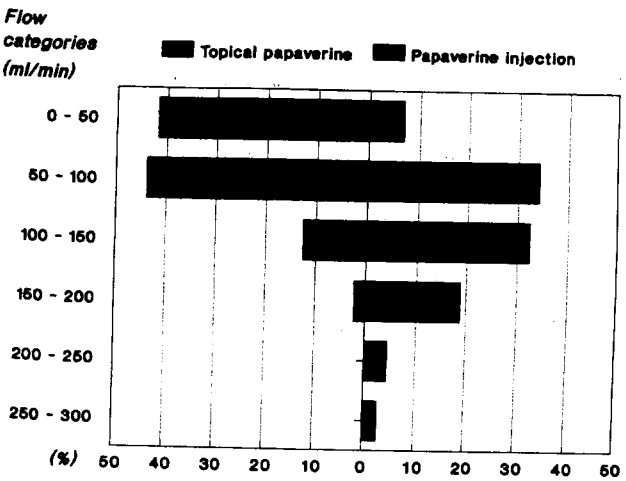

Fig 1. Internal mammary artery free flow after topical papaverine application and after maximal vasodilation with intraluminal papaverine injection. The horizontal axis represents relative frequencies in percents, and the vertical axis shows the different free flow categories.

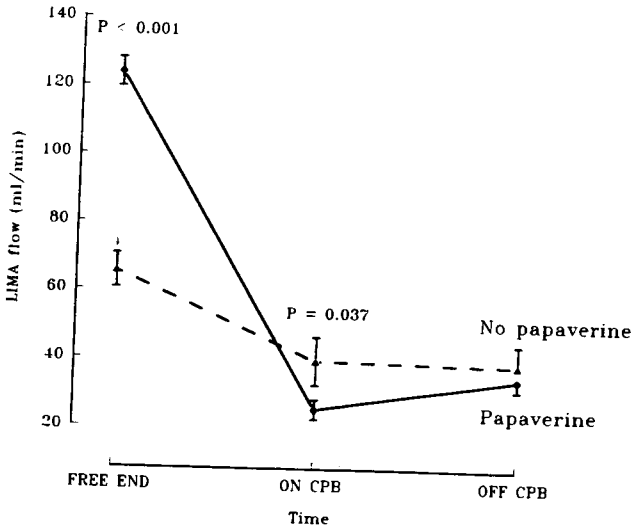

Fig 2. Left internal mammary artery (LIMA) flow measured before grafting by timed volumetric collection (FREE END) was markedly higher after papaverine injection (Papaverine) than after topical papaverine application (No papaverine). Flows measured by electromagnetic flowmeter were significantly lower in the papaverine group at the first postgrafting measurement at the end of cardiopulmonary bypass (ON CPB). There was no difference in the flows measured after weaning from CPB before chest closure (OFF CPB).

The cardiac index and left ventricular work index before CPB were 2.53 ± 0.05 $L \cdot min^{-1} \cdot m^{-2}$ and 2.88 ± 0.06 $kg \cdot min^{-1} \cdot m^{-2}$, respectively. By the end of CPB, these values reached 4.25 ± 0.09 $L \cdot min^{-1} \cdot m^{-2}$ and 4.45 ± 0.09 $kg \cdot min^{-1} \cdot m^{-2}$, respectively. The improvement in both indices was very significant ($p < 0.001$).

Free Mammary Graft Flow

Internal mammary artery free flow was markedly higher in the group having intraluminal injection of papaverine than in the group having topical application (124 ± 4 mL/min versus 66 ± 5 mL/min; $p < 0.001$) (Fig 1). However, the difference vanished with grafting (Fig 2), and flow was significantly lower in the papaverine injection group at the first measurement after grafting.

The resistance of the IMA after papaverine injection was 0.71 ± 0.03 peripheral resistance units (PRU).

There was a weak but significant correlation between free flow in the IMA after papaverine injection and mean blood pressure ($r = 0.27$; $p = 0.002$), diastolic blood pressure ($r = 0.26$; $p = 0.013$), and body surface area ($r = 0.28$; $p = 0.006$). There was no correlation with age ($p = 0.452$).

To disclose any influence of LIMA free flow capacity on clinical outcome, we compared LIMA free flow of patients in complication levels 1 and 2 with that of patients in complication level 0. Patients with the worst outcome (level 2) had a LIMA free flow of 107 ± 12 mL/min, which is comparable with a LIMA free flow of 105 ± 5 mL/min in patients having an uneventful outcome (level 0). Patients in level 1 had a LIMA free flow of 128 ± 8 mL/min, which was significantly higher than the level 0 group ($p = 0.008$). A complicated outcome was not associated with reduced IMA free flow capacity.

Table 1. Electromagnetic Flow Measurements[a]

Type of Grafts	On CPB	After CPB	Chest Closure	Results of ANOVA
IMA grafts to LAD	30 ± 4 (78)	41 ± 9 (16)	36 ± 3 (119)	Group effect: $p < 0.001$
SV grafts to LAD	67 ± 10 (20)	69 ± 15 (13)	66 ± 9 (20)	
SV grafts to Diag	62 ± 8 (10)	64 ± 34 (3)	48 ± 6 (26)	Group effect: $p = 0.017$
SV grafts to OM	60 ± 7 (37)	76 ± 10 (14)	54 ± 4 (93)	Time effect: $p = 0.029$
SV grafts to RCA	76 ± 9 (27)	111 ± 26 (10)	79 ± 7 (39)	Two-factor interaction: $p = 0.909$
SV grafts to PDA	63 ± 13 (22)	73 ± 6 (6)	58 ± 6 (48)	
Average (all grafts)	51 ± 3 (194)	70 ± 7 (62)	51 ± 2 (345)	Time effect: $p = 0.022$

[a] Data are shown in milliliters per minute. Numbers in parentheses indicate the number of measurements.

[b] ANOVA = analysis of variance; CPB = cardiopulmonary bypass; Diag = diagonal branch; IMA = internal mammary artery; LAD = left anterior descending coronary artery; OM = obtuse marginal; PDA = posterior descending artery; RCA = right coronary artery; SV = saphenous vein.

Conversely, when patients were separated into two groups based on IMA free flow (<50 mL/min and ≥50 mL/min), 23% (6/26) with IMA free flow of less than 50 mL/min and 35% (71/201) with IMA free flow equal to or greater than 50 mL/min ($p = 0.214$) were in complication levels 1 and 2.

Flow in Mammary and Venous Grafts

Electromagnetic flow measurements made immediately after mobilization of the IMA from the thoracic wall by diathermy, before distal transection and pharmacologic manipulation, resulted in flows averaging 7 ± 1 mL/min. The results of electromagnetic flow determinations obtained after grafting are shown in Table 1. After completion of the distal anastomosis and under comparable hemodynamic conditions, flow in SV grafts was significantly greater than in IMA grafts (group effect, $p < 0.001$). Further, flow in SV grafts was influenced by the runoff bed (group effect, $p = 0.017$), the highest flow being in SV grafts on the right coronary artery. Finally, the time of the measurement was of importance (time effect, $p = 0.022$), the highest flow being obtained immediately after weaning from CPB (70 ± 7 mL/min). Analysis of variance disclosed no significant group–time interaction effect.

The resistance of the IMA after grafting on the LAD was 3.85 ± 0.38 PRU.

Flow in the IMA grafted on an LAD midsegment did not correlate with IMA free flow after papaverine instillation ($p = 0.396$) but did correlate significantly with the preoperative determination of regional ejection fraction of the apical segment ($p = 0.026$; $r = 0.31$; $Y = 17.3 + 0.64X$) (Fig 3).

Blood flow patterns of the two graft types were compared (Fig 4). In both SV and IMA grafts to a single outflow artery, flow was highest during diastole and decreased to zero in early systole during maximal myocardial wall tension development. Flow patterns were characterized by a short systolic peak followed by a predominantly diastolic flow of longer duration. The sudden reduction in flow starting at early systole corresponds to isometric contraction of the left ventricle, whereas the short systolic peak corresponds to isotonic contraction of the left ventricle. Bypasses to the right coronary artery demonstrated antegrade flow throughout the pulse cycle, thereby reflecting the lower intramural systolic compressive forces of the right ventricle. Intraaortic balloon pumping was shown by intraoperative electromagnetic flow measurement to augment diastolic graft flow in the IMA (Fig 5).

Flow and Clinical Outcome

As intraoperative bypass flow studies were significantly different in IMA and SV grafts implanted on the LAD, we separated our patients into two groups based on the type of graft used on that artery (Table 2). Patients with an SV graft on the LAD were at higher risk than those with an IMA graft. The former patients were older and more frequently had unstable angina or an evolving myocardial infarction requiring emergent operation. As for intraoperative variables, the SV group was characterized by a shorter duration of aortic cross-clamping and a higher flow in the grafts on average. Nevertheless, the group also was characterized by a higher complication level and a higher death rate. Thus, the theoretical advantages of a shorter cross-clamp time and higher flow in the graft did

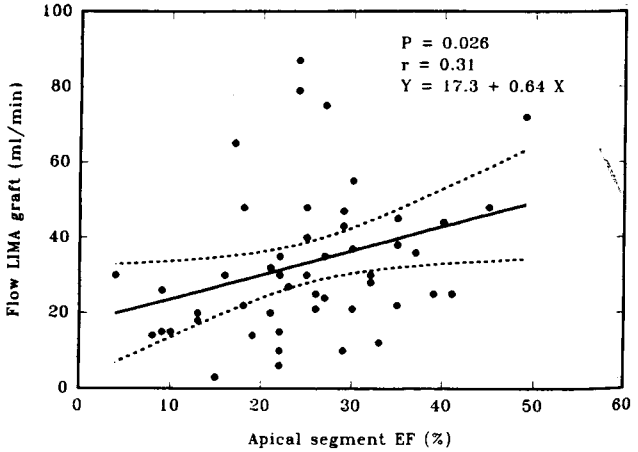

Fig 3. Flow in left internal mammary artery (LIMA) grafted on left anterior descending coronary artery measured by electromagnetic flowmeter correlated significantly with regional ejection fraction (EF) of the apical segment as determined by preoperative left ventriculogram. The broken lines on either side of the regression line are the 95% confidence limits.

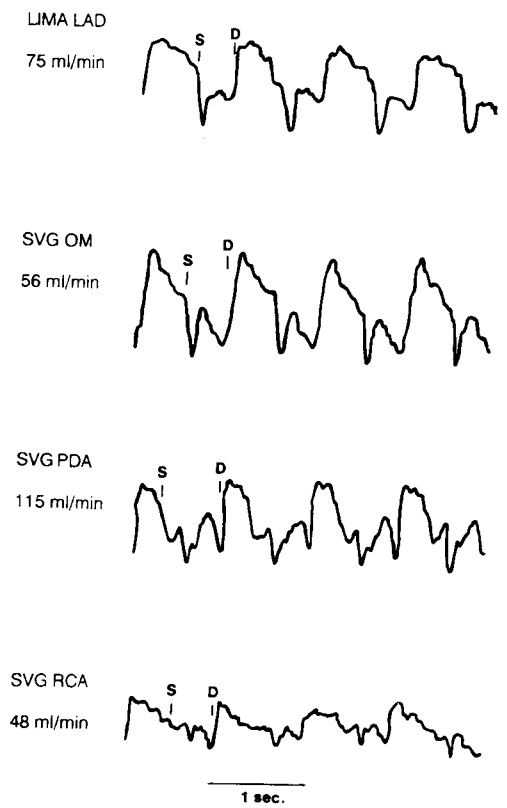

Fig 4. Examples of electromagnetic flow patterns obtained in a left internal mammary artery (LIMA) implanted on a left anterior descending coronary artery (LAD) and in saphenous vein grafts (SVG) anastomosed to obtuse marginal (OM), posterior descending (PDA), and right coronary (RCA) arteries. Numbers indicate flows measured. The onset of systole (S) and diastole (D) is marked. Flow was predominantly diastolic with peak diastolic flow greater than peak systolic flow.

not offset the influence of increased preoperative risk factors.

As a general rule, flow in the grafts as determined before sternal closure had no effect on postoperative outcome. Indeed, patients having an uneventful outcome had an average flow in the grafts of 51 ± 3 mL/min, which

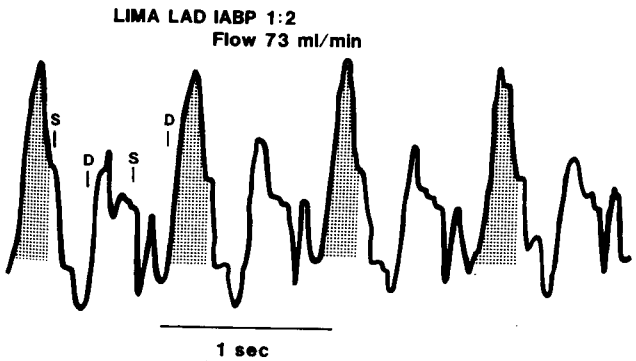

Fig 5. Electromagnetic flow pattern obtained in a left internal mammary artery (LIMA) implanted on a left anterior descending coronary artery (LAD) in the presence of alternate (1:2) intraaortic balloon counterpulsation (IABP) indicated by dotted area. *Intraaortic balloon counterpulsation was shown to augment diastolic graft flow.*

Table 2. Influence of Preoperative, Intraoperative, and Postoperative Variables on Clinical Outcome After Internal Mammary and Saphenous Vein Grafting on Left Anterior Descending Coronary Artery[a]

Variable	LIMA–LAD (n = 229)	SVG–LAD (n = 33)	*p* Value
Preoperative			
Age (y)	61 ± 1	64 ± 1	0.044
Female sex	44 (19.2)	7 (21.2)	NS
Anginal functional class III/IV	98 (42.8)	23 (69.7)	0.003
Unstable angina	40 (17.5)	21 (63.6)	<0.001
Emergent operation	29 (12.7)	20 (60.6)	<0.001
Evolving myocardial infarction	16 (7.0)	6 (18.2)	0.030
Left main disease	42 (18.3)	9 (27.3)	NS
Three-vessel disease	136 (59.4)	21 (63.6)	NS
LV ejection fraction <0.40	21 (9.2)	6 (18.2)	NS
Cardiac index ($L \cdot min^{-1} \cdot m^{-2}$)	2.52 ± 0.05	2.68 ± 0.24	NS
LV work index ($kg \cdot min^{-1} \cdot m^{-2}$)	2.86 ± 0.06	3.07 ± 0.21	NS
Operative			
Distal anastomoses	2.8 ± 0.1	2.8 ± 0.1	NS
Aortic cross-clamp time (min)	75 ± 1	67 ± 3	0.018
Pump time (min)	129 ± 3	134 ± 5	NS
Flows (mL/min)			
Grafts on LAD	36 ± 3	66 ± 9	<0.001
Grafts on diagonals	47 ± 6	61 ± 20	NS
Grafts on obtuse marginals	55 ± 4	49 ± 7	NS
Grafts on RCA	80 ± 8	73 ± 14	NS
Grafts on PDA	57 ± 7	67 ± 14	NS
Average	50 ± 2	63 ± 5	0.028
Postoperative			
Cardiac index ($L \cdot min^{-1} \cdot m^{-2}$)	4.25 ± 0.09	4.22 ± 0.29	NS
LV work index ($kg \cdot min^{-1} \cdot m^{-2}$)	4.49 ± 0.09	4.17 ± 0.21	NS
IABP	10 (4.4)	4 (12.1)	0.064
Myocardial infarction	11 (4.8)	4 (12.1)	0.090
Complication level 1	66 (28.8)	16 (48.5)	0.023
Complication level 2	11 (4.8)	5 (15.2)	0.020
Death	3 (1.3)	3 (9.1)	0.005

[a] Numbers in parentheses are percentages.

IABP = intraaortic balloon counterpulsation; LAD = left anterior descending coronary artery; LIMA = left internal mammary artery; LV = left ventricular; NS = not significant; PDA = posterior descending artery; RCA = right coronary artery; SVG = saphenous vein graft.

is similar to the flow of 51 ± 4 mL/min for patients in complication level 1 and 45 ± 11 mL/min for patients in complication level 2.

Comment

Cases of IMA hypoperfusion with catastrophic consequences are frequently reported [9–11]. Various causes

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including intimal tears [9], imbalance between IMA flow and demand [10], and spasm [11] are cited. With the expanding use of the IMA as a bilateral or sequential bypass graft in conjunction with small-diameter arterial grafts such as the gastroepiploic, epigastric, and radial arteries, the risk of myocardial hypoperfusion is increasing. On the other hand, techniques of intraoperative assessment of maximal flow potential of an arterial graft need careful evaluation, as restrictive criteria of selection could lead to the rejection of valuable grafts. Conversely, the failure to match graft flow potential and myocardial demand may create a situation of inadequate perfusion with dramatic consequences.

Measurement of IMA flow into an open beaker depends on the resistance imposed by the artery and the systemic pressure. Because the freshly dissected IMA is frequently spastic, the use of a topical or intraluminal vasodilator is mandatory. In the present series, use of the technique of intraluminal papaverine injection described by Mills and Bringaze [2] resulted in nearly double IMA free flow, thus allowing easier surgical anastomosis, as the IMA was fully dilated. Flows obtained by intraluminal injection of papaverine (124 mL/min) were superior to the flows resulting from topical application of sodium nitroprusside (108 mL/min) reported by Cooper and associates [12]. Hillier and co-workers [13] refuted the suggestion that intraluminal papaverine may damage endothelial cells of the IMA, and Jett and colleagues [14] demonstrated that among various vasodilators, papaverine produced the greatest maximal inhibition of both potassium- and norepinephrine-induced contraction of human IMA. Van Son and co-workers [15] showed that increased shear stress may have detrimental effects on the histologic characteristics of the intima and the internal elastic lamina of the IMA, but in our series any hydrostatic dilation of the IMA was carefully avoided. For these reasons, we think that IMA vasodilation by intraluminal instillation of papaverine is beneficial, providing the technical details of administration are scrupulously observed. Our data confirm that IMAs from the elderly are not more susceptible to reduction in flow because of size [16] and that the free flow rate of IMA grafts is significantly reduced in patients with a smaller body structure [17].

Although the advantages of obtaining maximal vasodilatation are obvious, the implications of flows measured under that condition are questionable. Indeed, it is generally admitted that IMAs with an intraoperative flow of less than 50 mL/min are not suitable for use as grafts [1], and it has been suggested that the IMA should be discarded unless the free flow rate after papaverine instillation is more than 120 mL/min [2]. In the present study, the mean IMA free flow rate was 66 mL/min with topical papaverine and 124 mL/min with intraluminal papaverine vasodilation. Had the aforementioned flow limits been observed, 38.8% of the IMAs from the topical papaverine group and 48.9% of the IMAs from the papaverine injection group would have been discarded or implanted as free grafts. To our knowledge, the aforementioned flow limits were not corroborated by any published clinical evidence. Further, critical variables like systemic pressure

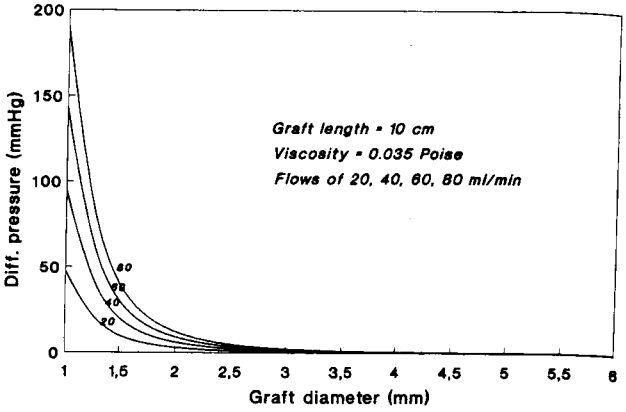

Fig 6. Relation of pressure gradient to inner diameter of a cylindrical tube 10 cm in length. Viscosity is in the low normal range for human blood. Flow rates are comparable with those that might occur in the human internal mammary artery. However, in this example, flow is considered to be steady and laminar.

and body surface area were never considered in the interpretation of the results.

Actually, free graft flow, as measured by a timed volumetric collection just before the anastomosis is done is probably a poor indicator of flow after completion of the anastomosis, as it represents flow obtained with a negligible resistance at the distal ostium and an infinite runoff. Indeed, under normal conditions, resistance offered by the IMA is low (0.71 PRU) compared with the total resistance of the vascular bed (3.85 PRU). Moreover, when the maximal flow capacities of the IMA (124 mL/min) are compared with flows measured by electromagnetic flow probes placed around the IMA (36 mL/min), it is seen that the flow capacity of the IMA is about 3.4 times the flow measured through functioning grafts. Therefore, the fact that flow measured in implanted IMA grafts was significantly influenced by variables revealing resistance of the runoff vascular bed, such as the regional ejection fraction of the apical segment, rather than IMA free flow is not surprising.

Likewise, if Poiseuille's equation is adapted to the IMA (see Appendix 1), as shown in the system of curves in Figure 6, there is little increase in pressure drop with narrowing of the arterial segment until a radius of less than 2 mm is reached. Even at this radius, flows as high as 80 mL/min would produce only a 12 mm Hg pressure drop across a segment 10 cm long. Nevertheless, increases in flow rate would be expected to produce significant pressure drops. For example, in situations of flow demand exceeding 150 mL/min, the pressure gradient would reach 22 mm Hg in the vessel (2-mm radius). Interpretation of this mathematical model confirms the clinical observations made by Jones and colleagues [10], who recommended that an IMA of questionable size (<2 mm) not be grafted on a large LAD (>2 mm) free from distal disease when the proximal stenosis is severe (>90%).

Our flow study showed uniformly lower flows in the IMA compared with the SV, results corroborated by data

in the literature. Indeed, IMA grafts tend to have immediate flows that are half that supplied by an SV to the same coronary bed. Flows measured by an electromagnetic flow probe range from 34 to 50 mL/min in IMA grafts and from 61 to 117 mL/min in SV grafts [3–6, 18]. The lower flow observed in the IMA group may be due in part to the higher resistance the IMA contributes to the vascular system than does the wider SV graft. Further, the segmental exposure of the IMA necessary for the flow measurements is likely to induce spasm.

Nevertheless, the impact of that reduced flow on clinical outcome was limited. It is obvious that a single IMA bypass graft is not supplying the entire heart and that the native coronary circulation and other bypass grafts contribute. This could also help explain why most patients with an IMA bypass graft do not experience difficulty; only when there is a great disparity will it become apparent. Likewise, using radionuclide angiography, Kawasuji and associates [19] showed that IMA grafts respond to the increased demand of exercise in the same way as SV grafts in the majority of patients and that there is a potential for inadequate flow to an undersupplied myocardial mass only in a small group of patients (6 of their 27 patients with IMA grafts to the LAD had exercise-induced wall motion abnormalities at the anteroseptal or apical segment or both).

The results of the comparison between patients with an IMA graft on the LAD versus those with an SV graft need to be interpreted cautiously. Indeed, IMA grafts were avoided in the high-risk patients, IMA sequential bypasses were not performed, and bilateral IMA bypasses were rare. Further, IMA flow potential was carefully assessed before grafting. Thus, conditions leading to IMA hypoperfusion were well controlled, and clinical outcome was affected primarily by preoperative risk factors and not by IMA flow potential.

The highest flow rates were obtained with SV grafts on the right coronary arteries. Because compressive forces exerted by the right ventricle are ordinarily far less than those of the left ventricle, perfusion of the right ventricle is not interrupted during systole. This is confirmed by phasic-flow Doppler studies [20], which showed that flow in the right coronary artery is more continuous and is less affected by systole.

The electromagnetic flowmeter has been an important tool for measuring flow in grafted IMAs and SVs. The magnetic field that is induced around the iron magnetic core of the probe by an electrical current generates a voltage difference in the conductive field. Two small electrodes positioned opposite each other sense the differential voltage generated and produce an electrical signal proportional to the velocity of flow. Thus flow volume can be measured only if the cross-sectional area of the vessel is known. Accurate measurement depends on the availability of a probe that fits snugly around the vessel, precalibration, and segmental exposure of the vessel. The electromagnetic flowmeter cannot be recommended for general use because, to obtain satisfactory circumferential electrical contact, the surgeon must fully expose the artery, and this is likely to cause injury to the graft wall or induce vasospasm. Also, a wide range of sterilized probes of varying diameter must be at hand.

The accuracy of these flow probes is now well documented, and our validation study shows that in intraoperative applications, the electromagnetic flowmeters evidenced a satisfactory correlation with absolute flow measurements. Conversely, ultrasonic flowmeters can be used readily in routine clinical applications and have been applied in our daily practice since 1989 mainly to identify technical errors. Yet, all these tools have the same general limitation in that they are essentially velocimeters, and measurement of the diameter of the vessel to calculate volume flow may lead to large errors, principally for small grafts like IMA grafts.

In conclusion, free flow measured in the vasodilated IMA was a poor predictor of flow in the grafted IMA, which was influenced chiefly by resistance of the outflow vascular bed, and clinical outcome was not affected by IMA free flow. Consequently, we were unable to validate any flow limit for using the IMA. Papaverine injection allowed better qualitative assessment of the IMA before use and facilitated the anastomosis. Flow measured in a LIMA grafted on an LAD was inferior to the flow in SV grafts supplying the same coronary bed. Nevertheless, in a series of carefully selected IMA grafts, clinical outcome did not depend on flow in the bypass grafts but rather was primarily affected by the preoperative clinical situation.

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Appendix 1.

The relation between the laminar flow in a long, narrow tube, the viscosity of the fluid, and the radius of the tube is expressed mathematically in the Poiseuille-Hagen formula:

$$Q = \Delta P \cdot (8L\eta/\pi r_i^4) \quad (1)$$

where Q = flow, ΔP = pressure gradient between points A and B in the arterial system, L = length of the artery, η = viscosity of blood (0.035 poise), and r_i = inside radius.

The following portion of the formula is often said to constitute the "fluid resistance" (R): $8L\eta/\pi r_i^4$.

Thus,

$$Q = \Delta P \cdot R \quad (2)$$

or

$$R = P1–P2/Q \quad (3)$$

where R is expressed in mm Hg · min/mL (peripheral resistance units, PRU), and P1–P2 is the pressure drop across the segment being evaluated.

For the computation of the resistance of the IMA before implantation, assuming that P1 equals mean arterial pressure (mean P) and that P2, pressure at the cut end, is negligible, equation 3 becomes: R = mean P/Q, where Q is volume flow (mL/min) measured in a graduated cylinder.

Likewise, for the computation of the total resistance offered by the grafted IMA and runoff coronary bed, assuming that the driving pressure is the pressure gradient between the proximal ostium of the IMA and the coronary sinus, which can be approximated by the right atrial pressure (PRA), equation 3 becomes: R = (mean P − PRA)/Q, where Q is volume flow (mL/min) measured simultaneously by an electromagnetic flowmeter.

Results of Graft Patency by Immediate Angiography in Minimally Invasive Coronary Artery Surgery

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Background. Although minimally invasive direct coronary artery bypass (MIDCAB) is being employed for revascularization of the left anterior descending coronary artery (LAD) with the left internal mammary artery (LIMA), little objective data exist regarding graft patency. Because the procedure is performed on a beating heart through a limited access approach, concerns have been raised regarding the ability to perform as accurate an anastomosis compared with conventional coronary artery bypass (CAB).

Methods. A prospective study of consecutive patients undergoing MIDCAB LIMA to LAD was undertaken. All procedures were performed through a limited anterior thoracotomy incision with a stabilization device. Selective angiography of the LIMA graft was performed intraoperatively or in the immediate postoperative period.

Results. One hundred and three patients underwent the MICAB procedure. Angiographic evaluation of the anastomosis was obtained in 100 patients (97%). Angiographic graft patency was 99%, with perfect graft patency (no stenosis greater than 50%) being 91%. Three grafts were revised in the operating room. One patient underwent reoperation and 3 more underwent percutaneous transluminal coronary angioplasty. There were two noncardiac mortalities (1.9%), both with patent grafts.

Conclusions. Immediate graft patency after MIDCAB is acceptable, and comparable with conventional CAB data, although meaningful comparison is difficult. The significance of early angiographic findings and the role for early angiography remain to be defined.

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Minimally invasive coronary artery bypass (MICAB) has become widely employed as an approach for revascularization of the left anterior descending coronary artery (LAD) with the left internal mammary artery (LIMA). Despite widespread acceptance, concerns have been raised regarding the ability to perform an accurate coronary anastomosis on a beating heart through a limited access incision, thus replicating the results of conventional coronary artery bypass grafting with the LIMA [1, 2].

Coronary angiography has been accepted as the "gold standard" for assessment of graft patency. We, therefore, undertook a prospective study of MICAB patency as determined by immediate angiography.

Patients and Methods

From December 1996 through December 1997, 100 of 103 consecutive patients undergoing minimally invasive LIMA to LAD procedure by a limited access approach were studied by intraoperative or immediate postoperative angiography. The patient demographics and characteristics of the study population are contained in Table 1. There were two main population cohorts. One group was young, healthy patients with single-vessel disease who usually presented with LAD re-stenosis after a previous catheter-based procedure. A second group of patients were higher risk, ie, elderly, (15 patients [15%] $\geq$ 80 years old), had previous bypass surgery, (14 [14%]), or significant comorbidities that precluded cardiopulmonary bypass. These included chronic renal insufficiency, cerebral vascular disease, or severe chronic obstructive pulmonary disease ($FEV_1 \leq 20\%$ of predicted).

Operative Procedure

The procedures were performed under general endotracheal anesthesia with a double-lumen endotracheal tube. Monitoring was performed with an arterial pressure line, Swan-Ganz catheter, and transesophageal echocardiography (TEE). External defibrillator patches were placed before operative preparation. A full-body sterile preparation to the knees was performed. A perfusionist was available for all procedures, but cardiopulmonary bypass equipment was not routinely assembled.

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Table 1. Patient Population Undergoing Minimally Invasive Coronary Artery Bypass

Variable	Number of Patients (n = 103)
Age (years)	64.94 (range 38–87)
Gender M/F	71%/29%
Previous coronary artery bypass graft	14 (13%)
Depressed left ventricular function	38 (37%)

Table 2. Minimally Invasive Coronary Artery Bypass Procedures: Operative Data

Operative Data	Number of Patients (n = 103)
Conversions	0
Operating time	139.85 ± 46.32 min
Internal mammary artery harvest time	32.63 ± 12.49 min
Anastomosis time	16.52 ± 5.00 min

Harvest of the internal mammary artery was most commonly performed under direct vision using a chest wall retractor to allow pedicle visualization. Video assistance was frequently used to facilitate dissection of the proximal portion of the internal mammary artery. The full length of the internal mammary artery (IMA) was harvested to assure adequate length and to alleviate concerns regarding side branch steal. Division of the LIMA was performed after administration of 1 mg/kg of heparin systemically. Intraluminal instillation of a vasodilator, papaverine, into the LIMA was used at the discretion of the operating surgeon to alleviate spasm from manipulation.

After the LAD was identified on the anterior surface of the heart and a satisfactory target site for anastomosis for ascertained, Silastic snares were placed proximal and distal to the target site. A mechanical stabilization device was placed to provide local immobilization of the anastamotic area. Preconditioning was not routinely employed because in our experience it was found not to be necessary. An end-to-side anastomosis with one or two running sutures was performed. The proximal Silastic snare was tightened to occlude blood flow, but the snare was not used for retraction or stabilization. The distal snare was tightened only if necessary to obtain a bloodless field after the arteriotomy was performed. Frequently, distal retrograde flow was minimal, allowing the snare to be left slack. A carbon dioxide blower was used to clear blood from the operative field and to distend the coronary artery for suture placement, obviating the need to touch the vessel wall with forceps. On completion of the anastomosis, the pericardium was divided and a "trough" created for the LIMA pedicle to lie in a straight line with positioning medial to the reexpanded lung. A small chest tube or Silastic drain was placed in the left pleural space before incision closure.

The patients were routinely extubated in the operating room if not mechanically ventilated preoperatively. Care in the intensive care unit for the first 24 hours was routine, and discharge was planned for between the second and fourth postoperative day after angiographic evaluation was complete.

Angiographic Technique

Evaluation of the LIMA conduit was performed either intraoperatively or in the immediate postoperative period (≤ 96 hours). For those evaluated intraoperatively, arterial access was gained by either the right or left femoral artery with a 6 F LIMA catheter. A portable C-arm digital imaging system (OEC Series 9600 Cardiac Mobile Digital C-Arm; OEC Medical Systems, Salt Lake City, UT) was employed, and standard right anterior oblique and left anterior oblique views were obtained. The full length of the IMA, anastomosis, and distal coronary artery were examined. Additional views were obtained if necessary for complete evaluation.

In those patients who underwent postoperative evaluation, angiography was performed in the cardiac catheterization laboratory. Access for angiography was usually through a left brachial artery approach, and a 4 F LIMA catheter was used to obtain the standard left anterior oblique and right anterior oblique views. Additional views were taken as necessary to obtain accurate assessment of the anastomosis.

Results

Between December 1996 and December 1997, a total of 103 patients underwent isolated revascularization of the LAD using the LIMA by a limited access approach on a beating heart. All patients who underwent this procedure during this time period were included in this study. Patients in this time period who underwent conventional coronary artery bypass grafting, beating heart revascularization by a median sternotomy approach, or more than one bypass through a limited access incision were not included in this study. All procedures were successfully accomplished without conversion to either cardiopulmonary bypass or median sternotomy. Operative data are contained in Table 2. Postoperative management results are contained in Table 3. Seven patients (7%) were discharged on the first postoperative day, 42 patients (41%) on the second postoperative day, and 15 (14%) on the third postoperative day. Complications (Table 4) included two operative mortalities (1.94%).

One patient was a 79-year-old man who had under-

Table 3. Minimally Invasive Coronary Artery Bypass Procedures: Postoperative Data

Postoperative Data	Number of Patients (n = 103)
Extubated in operating room	90 (87.4%)(1 reintubation)
Intensive care unit stay ≤ 24 h	85 (82.5%)
Hospital stay (days)	
Mean	4.12 ± 2.72
Median (Range)	3 (1–18)

Table 4. Complications of Minimally Invasive Coronary Artery Bypass Procedures

Complications	Number of Patients (n = 103)
Operative mortality	2 (1.94%)
Atrial fibrillation	8 (7.7%)
Respiratory insufficiency	7 (6.8%)
Pleural effusion	5 (4.8%)
Post thoracotomy pain	5 (4.8%)
Reoperation for bleeding	4 (3.9%)
Cerebral vascular accident	1 (0.9%)
Exacerbation of renal failure	1 (0.9%)

gone repair of a ruptured abdominal aortic aneurysm 4 weeks before MICAB and required reintubation three times due to recurrent ischemic pulmonary edema. He was ventilator dependent with a tracheostomy. Cardiac catheterization revealed severe left main coronary artery occlusion, and he underwent a MICAB LIMA to LAD before stenting of the left main coronary artery (hybrid procedure). The LIMA graft was demonstrated to be patent 24 hours postoperatively. He subsequently developed hospital-acquired pneumonia and died of sepsis 12 days post-MICAB procedure.

A second patient with idiopathic pulmonary fibrosis and cirrhosis developed adult respiratory distress syndrome postoperatively and succumbed to respiratory failure. He was demonstrated to have a patent graft intraoperatively.

Other complications included atrial fibrillation in 8 patients (7.7%), reoperation for bleeding in 4 patients (3.9%), pleural effusion requiring thoracentesis in 5 patients (4.8%), postoperative cerebrovascular accident in 1 patient (0.9%), exacerbation of preexisting renal failure in 1 patient (0.9%), respiration insufficiency in 7 patients (6.8%), and postthoracotomy pain in 5 patients (4.8%).

Intraoperative or immediate postoperative angiography (≤ 96 hours) was performed on 100 of 103 consecutive patients. Three patients did not receive angiography due to preexisting renal insufficiency (serum creatinine 4.0 mg/mL) or inability to gain peripheral arterial access in the operating room for IMA angiogram (2 patients). All 3 patients are alive and asymptomatic from a cardiac standpoint.

All angiograms were evaluated by the FitzGibbon grading system (Table 5) [3]. Ninety-nine of the 100 grafts evaluated by angiography were patent. One obese patient with an intramyocardial LAD underwent postoperative angiography demonstrating graft occlusion (Table 6). Ninety-one patients (91%) had patent grafts with no significant (greater than or equal to 50%) stenosis (FitzGibbon Grade A). Eight patients had grafts with a significant angiographic abnormality (FitzGibbon Grade B).

Table 5. FitzGibbon Grading System of Postoperative Angiography

Grade	Definition
A	Excellent graft with unlimited runoff
B	Stenosis reducing caliber of proximal or distal anastomosis or trunk to < 50% of grafted coronary artery
O	Occlusion

Table 6. Results of Left Internal Mammary Artery Angiography

Variable	Number of Patients (n = 103)
Angiograms	100 (97%)
Intraoperative	38
Postoperative	62
Patency	99 (99%)
Grade A	91 (91%)
Grade B	8 (8%)

Of the 38 patients who underwent intraoperative angiography, three grafts were revised in the operating room on the basis of the angiographic findings. One patient with diminished flow in the graft was demonstrated to have a 180° torsion of the IMA pedicle. Another patient with an anastomotic stenosis and diminished flow had an intramural hematoma in the distal IMA. The third patient who had the bypass placed to an intramyocardial LAD had diminished flow with no obvious obstruction. However, upon revision, flow promptly improved.

Of the 62 patients who underwent postoperative angiography, 1 patient with an intramyocardial LAD had unsuspected total occlusion. Five additional patients had a significant angiographic abnormality. One patient underwent percutaneous transluminal coronary angioplasty for stenosis of the distal IMA pedicle, and another for a stenosis in the LAD just distal to the anastomosis in 1 patient. In the 3 additional patients, it was elected to follow expectantly without revision after an ischemia study. Positron emission tomography (PET) scan was demonstrated to be normal. All 3 patients are alive and asymptomatic. Two of these patients have undergone repeat angiography at 6 months, with the previously stenotic area of the IMA graft resolving in both patients (Fig 1). One additional patient with a demonstrated patent graft immediately postoperatively has developed graft occlusion 4 months postoperatively and underwent reoperation.

Comment

Numerous issues are raised by this study, including the role of immediate angiography in the evaluation of LIMA graft patency, the significance of abnormal angiographic findings, and the comparability of these results with existing data regarding LIMA patency in conventional coronary artery bypass grafting.

Regarding the technique of intraoperative angiography, numerous issues exist. Should it be performed by the surgeon or by a cardiologist? In our institution, when performing intraoperative angiography, a cardiologist

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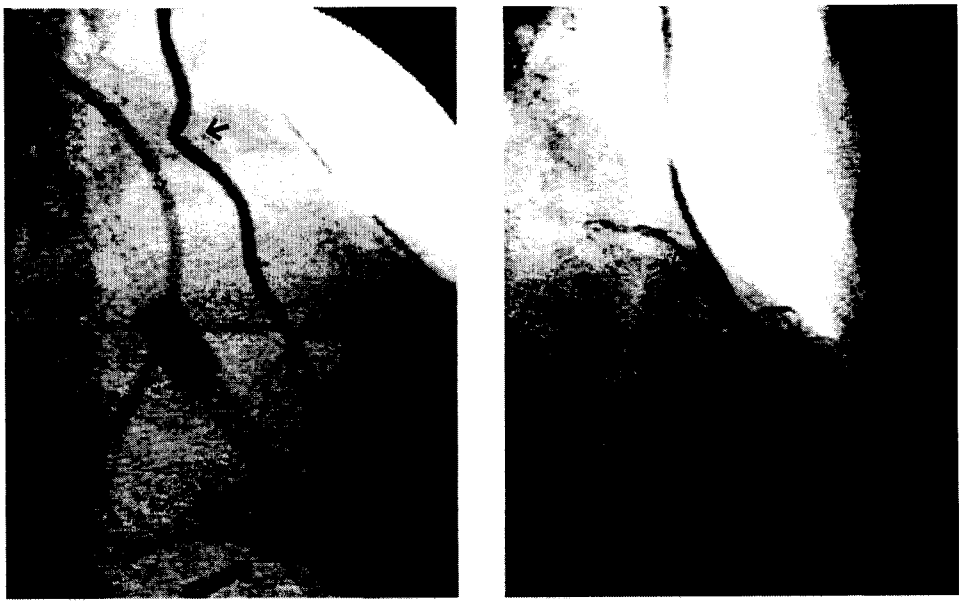

A B

Fig 1. (A) Selective LIMA angiogram 48 hours postoperatively showing stenosis and kinking (arrow) of the LIMA. (B) Repeat angiogram at 6 months demonstrates resolution of the angiographic abnormality.

was willing to be available for the procedure, but in some other institutions, when performing intraoperative angiography, the cardiac surgeons themselves have been performing the angiographic study [4]. Another issue is the additional operative time necessary to perform intraoperative angiography. In our patients who underwent intraoperative angiography, an additional 45 to 60 minutes was necessary, although other institutions report being able to perform the intraoperative angiogram in a 15- to 20-minute period.

Also, an issue is the availability of roentgenogram equipment of sufficient quality to accurately judge quality of the anastomosis. Most operating rooms have a C-arm image intensifier that can be used, but does not give state-of-the-art cardiac cath-quality images. Portable digital angiography systems are now commercially available, capable of quality imaging, but add significant capital expenditure to the heart team.

The advantage of obtaining an intraoperative angiogram is the ability to document graft patency before leaving the operating room. Conversely, there is the issue of what to do with the abnormal findings. Some angiographic stenotic lesions may be due to clot or intramural hematoma, which many investigators (A. Calafiore, V. Subramanian, personal communication) have found resolves without additional intervention. In addition, diminished flow has been documented by many other surgeons to be due to spasm, which again resolves after the immediate postoperative period. Therefore, the presence of an angiographic abnormality may lead to an unnecessary revision, which has happened in some centers.

Postoperative angiography offers the benefit of being able to document graft patency before discharge, but involves an additional procedure with the associated additional expense. Nevertheless, this short time interval may allow for some early abnormalities (eg, spasm) to resolve.

Other issues exist regarding early postoperative angiography. It is not known whether early graft patency translates to long-term graft patency. Although our follow-up period is short (mean follow-up 6 months), 1 additional patient has required reoperation for graft occlusion of a previously demonstrated patent graft.

Other diagnostic modalities exist to evaluate immediate graft patency, including intraoperative functional flow reserve measurement and Doppler transit time. However, correlation of the accuracy of these techniques with the "gold standard" of angiography has not yet been documented in a large series.

What is the significance of the results obtained in this study, and can these results of immediate intraoperative angiography be compared with existing information on IMA graft patency in conventional coronary artery bypass grafting in a meaningful manner? From 1972 through 1997, there had been at least 34 manuscripts in the literature addressing the issues of patency and/or survival advantage after conventional coronary artery bypass grafting with use of the LIMA. These studies include series from 17 different medical centers, three different multicenter studies, the Coronary Artery Surgery Study (CASS), the Veteran's Administration Cooperative Trial on Antiplatelet Therapy, and the International Multi-Center Aprotinin Graft Patency Experience (IMAGE). Also published were editorials by Loop and Spencer.

Of the other 32 papers, 8 had no information on graft patency, evaluating the efficacy of LIMA grafting by examining survival advantage compared with saphenous vein conduits. Twenty-four studies from 17 medical centers did contain information regarding angiographic demonstration of graft patency at varying intervals post-

Table 7. Results of Early Angiography (≤ 1 Month) After Conventional Coronary Artery Bypass

Author	Year	No.Studied/ Operated	Percent Studied	Interval	Graft Patency	Exclusions/Notes
Barner [5]	1976	139/307	45	20 days	95	Nonsurvivors
Geha [9]	1979	175/208	82	2 weeks	99	6 nonsurvivors (3%)
Tyras [6]	1980	527/765	69	1 month	95	Nonsurvivors (1.4%)
Grondin [7]	1984	37/40	92	1 month	97	2 nonsurvivors, 1 patient declined
Ivert [8]	1988	91/99	92	2 weeks	94	2 nonsurvivors
Gill [10]	1997	25/25	100	4–6 h	96	
Berger [11]	1997	645/768	84	10.8 days	98.8	Additional 7.8% had graft stenosis > 50%

operatively. There were 4 studies from the group at St. Louis University, 4 from the Cleveland Clinic, 2 from Milwaukee, with single reports issued by the remaining 14 centers.

Meaningful analysis of published data is difficult due to different inclusion/exclusion criteria for the different studies as well as a varying percentage of patients undergoing LIMA graft patency that were studied at postoperative intervals. Most series, because angiography was not performed in the immediate postoperative period, include only survivors in the studies. One cannot assume that the LIMA graft was patent in nonsurvivors. In a significant proportion of the studies, only a minority of the patients undergoing LIMA grafting were actually studied. Many series were retrospective analyses of the patients, frequently those who happen have undergone a postoperative angiogram for any reason at the institution. In addition, some of the series date to the initial use of LIMA grafting in 1972, and therefore include a "learning curve" perhaps yielding slightly inferior results compared with those that would be inspected in more recent series.

In an attempt to compare early angiography data of LIMA graft patency contained in this study with existing published data on results of LIMA grafting, all articles addressing this issues were reviewed. Of the 24 series containing information on angiographic graft patency after conventional coronary artery bypass surgery, the majority of the studies addressed long-term graft patency. However, seven studies did contain information regarding the results of early angiography (≤ 1 month) (Table 7) [5–11]. Barner and associates [5] published the angiographic results after LIMA grafting in 307 patients in 1976. One hundred and thirty-nine (45%) of the patients were studied angiographically in the postoperative period at a mean interval of 20 days. Graft patency was documented to be 95% in those studies. Another 2% (3 patients) had a graft stenosis greater than 50%. Nonsurvivors, the percent not stated, were not studied.

Geha and Baue in 1979 [9] performed angiography at 2 weeks after conventional coronary bypass surgery. In 175 (82%) of 208 patients grafted, graft patency on the IMA grafts studied was 99%. A total of 6 nonsurvivors (3%) were excluded from analysis.

Tyras and associates in 1980 [6] analyzed results of angiography performed at a 1-month interval after LIMA grafting in 527 of 765 patients (69%). Graft patency was 95% with nonsurvivors (1.4%) excluded.

Grondin and associates in 1984 [7] studied 37 of 40 patients (92%) at 1 month. Two patients died before they could be studied, and 1 patient declined. Graft patency was 97%.

Ivert and associates [8] studied 91 of 99 eligible patients (92%) at a mean interval of 2 weeks after conventional CAB. Graft patency was 94%. Two patients died before early angiography was possible.

Two more recent studies contain information regarding graft patency. Gill and associates [10] studied 25 consecutive patients 4 to 6 h after conventional coronary bypass graft as part of a study comparing MICAB with conventional CAB. All patients were studied and patency was 96%.

Berger and associates [11] reported on 645 patients who underwent angiography as part of the IMAGE study of aprotinin. The percent of patients who received a LIMA graft who were studied was 84%. The angiography was performed at a mean of 10.8 days postoperatively with a graft patency of 98.8%. An additional 7.8% had a graft stenosis greater than 50% (FitzGibbon grade B).

There are four published studies containing angiographic information regarding graft patency after MICAB (Table 8) [10, 12–14]. Schaff and associates [12] studied 15 of 16 patients (94%) after successful LIMA bypass of the LAD via the MICAB approach. All were patent; however, 3 were revised in the operating room due to kinking of the LIMA in 1, an anastomosis was revised in the second, and no problem was found in the third patient.

Calafiore and associates [13] reported on angiographic results in 34% of MICAB patients studied between 1 and 26 days with a 91% graft patency. Subramanian [14] studied 89% of 189 patients after MICAB at an interval of 24 to 36 hours. Graft patency was stated at 92%; however, a patent, stenotic graft was considered occluded for purposes of this study.

Gill and associates [10] in the MICAB arm of the previously mentioned study was able to study all 29 patients at an interval of 4 to 6 hours postoperatively. Twenty-eight grafts were patent (97.5%); however, 19% had a stenosis of greater than or equal to 50% (FitzGibbon grade B). These were followed, and later follow-up angiography (mean 10 months) has revealed anastomotic

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Table 8. Published Series of Left Internal Mammary Artery Graft Patency in Minimally Invasive Coronary Artery Bypass

Author	Year	No. Studied/ Operated	Angio/ Operation	Interval Post-op Study	Graft Patency	Exclusions/Notes
Schaff [12]	1996	15/16	94%	intraoperative	100%	3 revised
Calafiore [13]	1996	53/155	34%	1–26 days	91%	
Subramanian [14]	1997	169/189	89%	24–36 h	92%	stenosis = occlusion
Gill [10]	1997	29/29	100%	4–6 h	97.5%	additional 19% stenosis > 50%
Current series	1998	100/103	97%	38 intraoperative 62 48–96 h	99%	additional 8% stenosis > 50%

irregularities to have resolved in 4 patients (I.S., Gill personal communication).

Our series yielded substantially similar results to other MICAB series. Although our patency rate of 99% was acceptable, a significant stenosis of ≥ 50% in 8 additional patients caused us some concern. This led to reintervention (either repeat CAB or PTCA) in the earlier part of our series. However, due to our own experience as well as others, both published and by personal communication, we have adopted a practice of conservative management with observation only if no ischemia is demonstrated in the revascularized target vessel distribution. Gratifyingly, we have demonstrated resolution of stenotic lesions in 2 patients at 6 months on repeat angiography.

Further data to help answer whether the LIMA graft patency with MICAB is comparable with that of conventional CAB hopefully will be gained from a current, ongoing multicenter study (POEM). The POEM study (patency, outcomes, economics, MIDCAB) is enrolling 400 nonrandomized, but consecutive patients undergoing conventional CAB (200) and MICAB (200) to compare LIMA graft patency by each approach. The primary end point will be a 6-month angiographic graft patency. Results should be available in late 1999.

In conclusion, results of this study demonstrate that graft patency with LIMA grafting by the minimally invasive approach is comparable with published series with conventional bypass surgery. Although the studies are not strictly comparable due to variability in inclusion and exclusion criteria in each study, MICAB results appear to be equivalent to conventional CAB. Hopefully, the current ongoing multicenter study will be able to give a more definitive comparison.

Important remaining questions include the role of early angiography after MICAB. Should every MICAB be evaluated by early angiography? From our experience, we believe that at least early in a center's experience of MICAB, immediate angiographic evaluation is crucial to demonstrate adequacy of the procedure. Information helpful to the surgeon early in his or her MICAB experience can be gained by angiography that helps modify techniques.

A very difficult question is how to evaluate the significance of early angiographic findings. Our early management included revision of significant angiographic abnormalities; however, based on our experience, along with many anecdotal reports from other centers, that early, stenotic angiographic lesions frequently resolve, it is currently our practice to obtain a functional ischemia study on any patient with a patent graft and angiographic stenosis (FitzGibbon grade B) and follow the patient without further invention if no ischemia is demonstrable. Current ongoing studies hopefully will answer whether other less cumbersome intraoperative evaluation tools may eventually be able to supplant immediate angiography. It is our recommendation, however, if a center is relatively inexperienced in MIDCAB surgery, that intraoperative or early postoperative angiographic documentation of graft patency is indicated. It serves not only to document results but helps ensure not only surgeon self-confidence but instills confidence in the referring physicians. If any significant concern regarding the angiogram exists, however, prompt revision or angioplasty should be performed until a center gains experience in knowing which findings are safe to observe.

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DISCUSSION

DR ROBERT W. EMERY (Minneapolis, MN): Thank you, Dr Anderson, Dr Pairolero. Congratulations to Michael Mack for an excellent presentation and another piece of excellent work from him and his colleagues in Pennsylvania and Texas for this work.

This project deals with two particularly important questions in contemporary cardiovascular surgery. The first is the question of patency of the internal mammary anastomosis performed on the beating heart. These data included a series of patients with an exemplary rate of postoperative angiography whose anastomotic patency rate is no different than that recorded in commonly referenced studies in the surgical literature. In fact, the documentation rate was higher than the great majority of those studies we cite so commonly. This indicates that in the hands of surgeons trained to perform such procedures and with appropriate instrumentation, the process is secure in the short term. The long-term data remain unknown, however.

The second issue addressed is the available data on the established patency of IMA-LAD anastomosis performed on the still heart. We find less than complete information and less than desirable gold standard documentation of patency. This has and will cause us to look carefully at the results we cite and indicate to our patients. Certainly in the early years of IMA use, the patients were younger, predominantly male, and had better ventricular function, and as such were selected for success. IMA bypasses were not considered for the old, frail, or those with confounding risk factors in whom they are so commonly performed today, as shown by this study. Thus, it is not only the technical skill of the operator that determines anastomotic patency over the long and short term. Other factors including the quality of the conduit and the quality of the vessel that is bypassed need to be addressed, as they may more importantly impact long-term patency rates.

For instance, this discussion slide shows a photomicrograph of the IMA on a patient on whom I performed a MIDCAB operation. The vessel was shown to be nonfunctional. And at reoperation on this 89-year-old woman, unable to be weaned from intravenous meds, the IMA was found to have an intramural dissection extending from approximately 1 cm above the anastomosis to nearly the level of the subclavian artery, even in areas that had not been surgically traumatized. One can see the patency of the lumen in the center with its surrounding muscular wall.

Additionally, the issue of what is the appropriate appearance of the anastomosis at immediate angiography has been raised. Are irregularities of the anastomosis in the face of excellent flow important? Is functional assessment, as suggested by Dr Leon and Dr Kern, necessary as well?

Three questions come to mind, Dr Mack. Firstly, does your group plan to follow this series of patients over the long term and report to us in the future based on some form of yet-to-be-determined test of cardiac ischemia, or graft function?

Secondly, in review of the angiograms, did your group find any indications as to which might allow us to determine which abnormalities may be followed or which need revision at the time of the hospital admission?

And lastly, were the quality of the vessels used to bypass and being bypassed evaluated in any fashion?

Again, congratulations on an important piece of work.

DR BARTLEY P. GRIFFITH (Pittsburgh, PA): I would like to rise to compliment Dr Mack for continuing to show appropriate leadership in this new and at times contentious field. It is hard to improve upon what we have heard, and I salute him for working hard to justify where we are and pointing us to where we need to go. I have two questions.

The first one deals with the Doppler examination. My colleague, Marco Zenati, MD, has operated upon and followed a series of 200 patients at Pitt for whom we believe it was necessary for most to have postop angiograms to "qualify" for the procedure, but who have demonstrated superior >98% patency. We have become interested in the Doppler exam as a sensitive exam to diagnose abnormalities. The problem with the angiogram is that you know it is patent, but you do not know what to do with those other minor findings that keep troubling you. Our feeling is that the Doppler gives additional information on the "flow" and not just patency. Unless there are radical abnormalities with the Doppler wave in terms of the diastolic pulse, we are not recommending an angiogram for all patients.

Finally, do you have any information (although it was not the intent of your presentation) to indicate to us how many of the patients that underwent MIDCAB had multivessel disease and whether or not you relieved angina? You certainly had a remarkably good survival rate. Thank you.

DR MACK: Thank you, Drs Griffith and Emery, for your comments. There are a number of issues raised. First of all, we are continuing to follow all patients that have been studied, although we will not follow them with repeat angiography. However, we are participating in a multicenter study with seven other institutions, including Dr Griffith's institution in Pittsburgh, in the POEM study, which is Patency Outcomes Economics of MIDCAB. The primary end point of that study is 6-month graft patency. The reason that was chosen was it will allow us to evaluate the true patency after all these immediate postoperative abnormal angiographic findings either resolve or do not resolve, so we will probably have a more accurate idea as to what is the true graft patency.

I do not know what to make of a lot of these immediate findings. In addition, there are what the cardiologists term a "MIDCAB anastomosis." Frequently there is a haziness at the anastomosis that on repeat angiography resolves. I think it is due to either spasm, clot, or edema at the anastomosis that does resolve. So we will follow all these patients, but with short-term angiography only in our current study.

The second question of Bob's was regarding revision of the anastomosis. Do we have any guidance as to when to revise?

Preliminary Experience With a Novel Intraoperative Fluorescence Imaging Technique to Evaluate the Patency of Bypass Grafts in Total Arterial Revascularization

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Background. Early graft failure is a common cause of cardiac morbidity and mortality after coronary artery bypass grafting (CABG), and there is particular concern about graft patency in off-pump CABG. We describe our preliminary experience with a novel imaging technique (the SPY system), based on fluorescence of Indocyanine Green when exposed to near infrared light, for the intraoperative assessment of coronary graft patency.

Methods. Graft patency was assessed in patients undergoing off-pump and on-pump total arterial revascularization. The imaging technique requires injection of a 1-mL bolus of Indocyanine Green into the central venous line, followed by imaging with the SPY system.

Results. We assessed intraoperative graft patency in 213 conduits in 84 patients (mean, 2.54 grafts per patient), of which, 65 (77%) were done off-pump. It took approximately 3 minutes to image each graft. Skeletonized conduits provided better visualization than pedicled ones. Fluorescence, confirming graft patency, was observed in all but four (1.9%) conduits in 4 (5%) patients. In these latter cases, graft revision was necessitated.

Conclusions. Fluorescence imaging of coronary grafts using the SPY is a uniquely simple, safe, noninvasive, and reproducible technique for intraoperative confirmation of graft patency. In 4 patients, it necessitated revision of the initial intraoperative procedure. Quantification of graft flow would enhance the value of the system.

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Early graft failure is a major cause of cardiac morbidity and mortality after coronary artery bypass grafting (CABG). It is the most common cause of perioperative myocardial infarction, which is detectable in up to 9% of patients after CABG [1]. Concerns about quality of grafts and anastomoses are especially prevalent with off-pump coronary artery bypass grafting (OPCABG), and current studies show graft compromise in 5% to 20% of patients at discharge [2]. Postoperative angiography, used to assess graft patency before hospital discharge, has resulted in reoperation in some patients [3, 4].

Consequently, several techniques have been employed to assess intraoperative graft patency. These have included electromagnetic [5], ultrasound flow measurement [6], Doppler velocity waveform [7], epicardial echocardiographic [8], and conventional [9] and thermal coronary angiography [10] techniques. However, all have limitations and frequently provide indirect or poor resolution definition of the grafts and flow, as well as being subject to misinterpretation, as they are particularly operator dependent. Conventional coronary angiography remains the gold standard [9], but is highly invasive (requiring arterial puncture), increases operating time, and is infrequently available in the operating theater.

We describe our preliminary experience with a novel, simple, and rapid imaging technique for intraoperative assessment of coronary grafts. The technique is based on capture, by a charge-coupled device video camera, of fluorescence of Indocyanine Green (ICG) when illuminated with near infrared light using laser energy from the SPY imaging system (Novadaq Technologies Inc., Toronto, Canada).

Material and Methods

The SPY imaging system is based on fluorescence of ICG. The system has CE marking in Europe, which allows patient use in the European Community.

As ICG binds to plasma proteins it is confined to the intravascular compartment. ICG fluoresces when illuminated at 806 nm (near infrared light) using laser energy, and the fluorescence is captured by a charge-coupled device video camera at a rate of 30 images per second. The laser used by the SPY system has a total output of 2.2 W spread over an area of 7.5 × 7.5 cm on the surface of

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Table 1. The Breakdown of Coronary Targets Grafted and Conduits Used in the 84 Patients Undergoing CABG

Coronary Target	Bypass Conduit				
	RITA	LITA	RA	SV	GEA
LAD	36	38	1	2	0
OM	2	29	18	3	0
DIAG	1	5	9	2	0
PDA	2	1	31	8	1
Other	4	9	7	4	0

Sixty-five (77%) of these underwent off-pump CABG. Seventy-one (85%) underwent total arterial revascularization.

CABG = coronary artery bypass grafting; DIAG = diagonal coronary artery; GEA = gastro-epiploic artery; LAD = left anterior descending coronary artery; LITA = left internal thoracic artery; OM = obtuse marginal coronary artery; PDA = posterior descending coronary artery; RA = radial artery; RITA = right internal thoracic artery; SV = saphenous vein.

the heart, avoiding the risk of thermal myocardial damage and eliminating any risk to the operating theater staff. Indocyanine Green (ICG) has been used for many years in ophthalmic video-angiography and is a very safe compound, with a reported risk of minor adverse reactions of less than one in a thousand.

After completion of the distal coronary artery anastomosis, 1 mL of ICG dye is injected through the central venous line and flushed through with 5 mL of normal saline. Screening is started at the time of injection, and the grafts are imaged as the fluorescent dye passes through them. Images are then recorded on videotape or computer hard drive. The procedure takes 3 to 4 minutes per anastomosis.

Results

We initially performed this technique in 84 patients assessing 213 conduits (see Table 1), all performed by one surgeon (DPT) with a mean of 2.54 grafts per patient. Sixty-five cases (77%) were OPCABG, the remaining cases being on-pump CABG or CABG combined with another cardiac procedure. The primary outcome measure was the rate of graft revision influenced by the information provided by the imaging system.

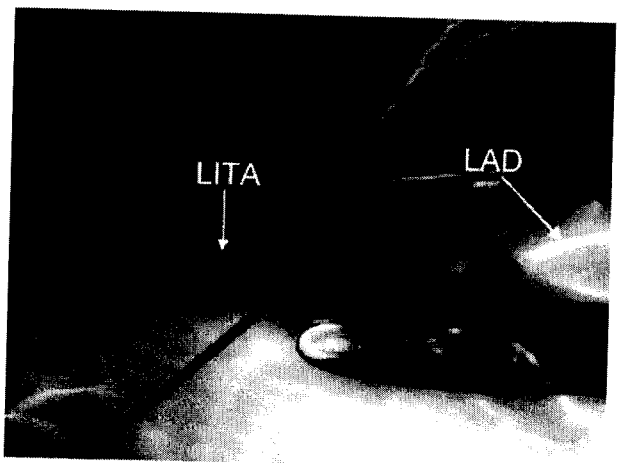
There were no mortalities and no adverse consequences associated with the use of the ICG dye.

Imaging took approximately 3 minutes per graft. Flow was visualized in all grafts confirming patency, and in the majority resulted in images of similar quality to that observed with conventional angiography (see Figs 1–4). As for conventional angiography, the still image is more difficult to interpret than the moving image. Although the anastomotic site was clearly visualized in three-quarters of cases, it was not usually possible to demonstrate precise anatomical detail. Skeletonized conduits (ie, internal thoracic arteries and radial arteries) permitted better visualization than pedicled ones.

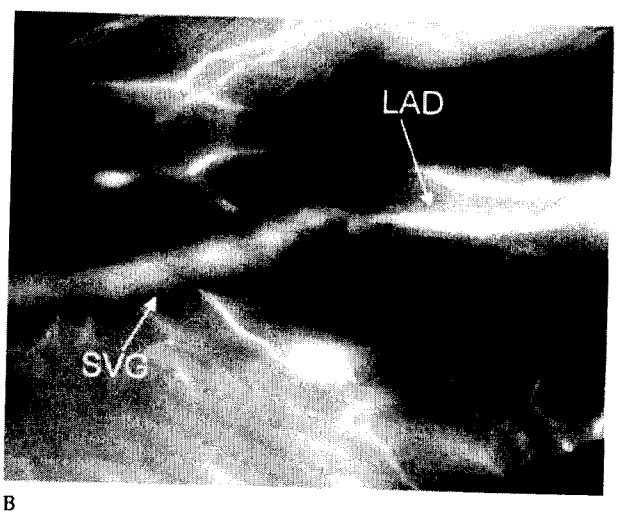
Absent or poor flow in four grafts (5% of patients in this series), as detected by fluorescence imaging, necessitated graft revision. These cases are summarized below.

A 77-year-old patient underwent OPCABG including a left internal thoracic artery (LITA) to the left anterior descending artery (LAD) and right internal thoracic artery (RITA) to the distal right coronary artery (RCA). Flow in the LITA to the LAD was poorly visualized (Fig 1A), suggesting either an anastomotic problem or the presence of disease distal to the anastomosis. Consequently, a vein graft was placed to the distal coronary artery with excellent flow (Fig 1B).

A 55-year-old patient with single-vessel disease and good left ventricular function underwent LITA to LAD on pump. Flow in the LITA to the LAD was not visualized. The graft was revised and the anastomosis reconstructed distally, with excellent flow (Fig 2).



A



B

Fig 1. (A) SPY image showing an in situ left internal thoracic artery (LITA) graft to the left anterior descending (LAD) coronary artery. The native coronary arteries are occluded proximal to the anastomotic site using a sling so that flow in the coronary arteries is purely attributed to patency of the graft. Note that no fluorescence is seen in the LITA graft. As a result of this, a saphenous vein graft is placed onto the distal LAD (see B). (B) SPY image showing saphenous vein graft onto LAD. Note fluorescence in vein graft and native coronary artery. (SVG = saphenous vein graft.)

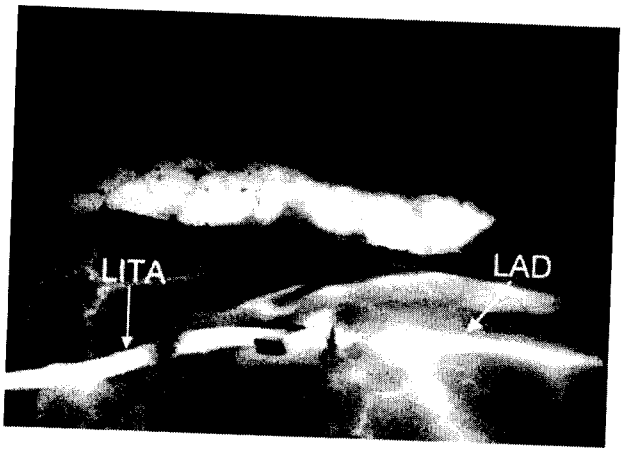


Fig 2. SPY image of in situ left internal thoracic artery (LITA) graft to left anterior descending (LAD) coronary artery, taken after revision of the anastomosis. The initial image showed no fluorescence in the LITA graft.

A 66-year-old patient with three-vessel disease underwent OPCABG, including an in situ RITA to the LAD and radial artery (RA) to the obtuse marginal coronary artery (OM). The proximal end of the RA was attached to the side of the RITA. The flow in the RITA to the LAD beyond the RITA-to-RA anastomosis was not visualized (Fig 3A). The RITA-to-RA anastomosis was reconstructed, with excellent flow (Fig 3B).

A 57-year-old patient with three-vessel disease and good left ventricular function underwent OPCABG, including an in situ RITA to the LAD and an in situ LITA to OM. The flow in the LITA to the OM was not visualized (Fig 4A). The LITA-to-OM was reconstructed distal to the initial site and adequate flow was visualized (Fig 4B).

Comment

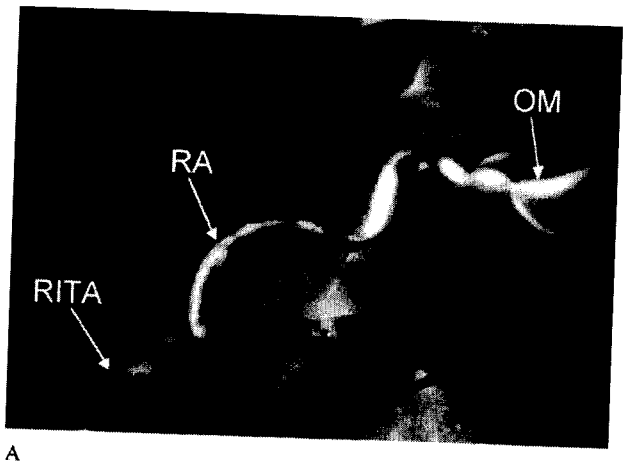
The need for an intraoperative imaging system to assess graft patency is demonstrated by the plethora of techniques currently available [5–10], all of which have limitations. Early graft failure is a cause of perioperative myocardial infarction and may necessitate reoperation for revision of the relevant bypass grafts accordingly [6]. This is particularly true in the setting of off-pump total arterial revascularization and especially for bilateral ITA grafts, which may offer survival advantages [11], but are generally considered to be technically more challenging.

To our knowledge, this is the first report describing the use of this novel technique in the intraoperative setting of coronary artery surgery. Our preliminary results demonstrate that the SPY imaging system, based on fluorescence of ICG, is a safe, simple, rapid, repeatable method for the intraoperative assessment of graft conduits.

The strengths of the technique are its simplicity and safety. It is minimally invasive in that no arterial puncture is required, and avoids the need for ionizing radiation. ICG has been very widely used in a variety of clinical situations, and adverse reactions are very uncommon, having been reported in the region of 0.004% [12]. In most situations, the graft was well visualized within 3 minutes and provided semiquantitative estimates of flow with real-time images. A major attraction is that it provides information in a fashion similar to coronary angiography, with which the surgeon is familiar and can easily interpret.

The value of the imaging system was illustrated by altering the intraoperative management of 4 patients, highlighting that graft flow compromise occurred in 5% of patients in this series and in 1.9% of all performed grafts.

There are currently limitations to the technique. First, the technique is only semiquantitative, in that it permits assessment of graft flow as "excellent," "satisfactory," or "poor," but does not provide an exact measure of graft flow. Developments are currently underway that will permit the imaging system to give quantitative flow



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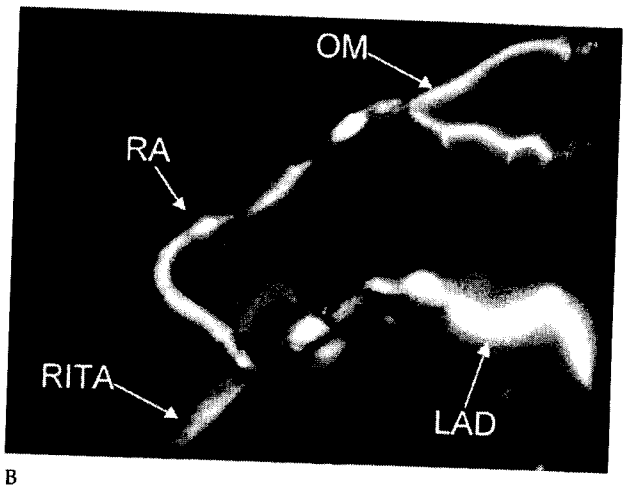
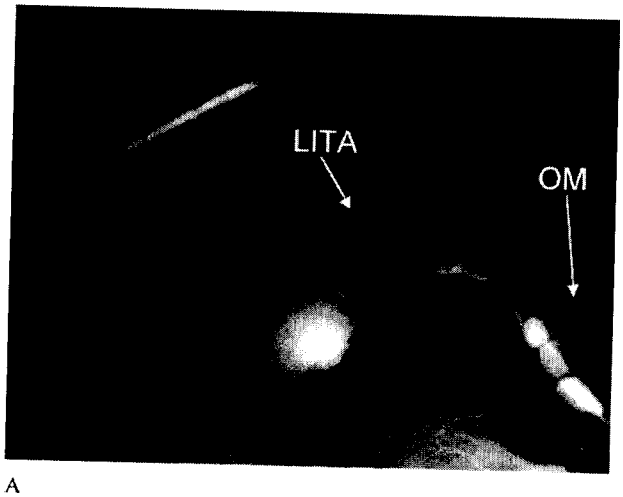


B

Fig 3. (A) SPY image showing in situ right internal thoracic artery (RITA) graft to the left anterior descending (LAD) coronary artery. A composite pedicled radial artery (RA) graft was placed from the RITA to the obtuse marginal artery. Note that no fluorescence was seen in the RITA distal to the RA anastomosis, which was taken down and reconstructed (see B). (B) SPY image taken after revision of RA-to-RITA anastomosis, seen in A. Note fluorescence now seen in distal portion of RITA graft and in LAD coronary artery. (OM = obtuse marginal coronary artery.)



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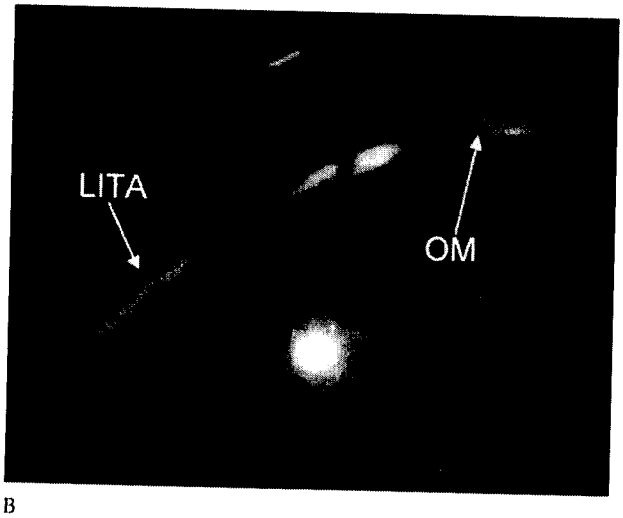

B

Fig 4. (A) SPY image showing in situ left internal thoracic artery (LITA) graft onto obtuse marginal coronary artery (OM). Note that no fluorescence was seen in LITA or native coronary, necessitating revision of the distal anastomosis (see B). (B) SPY image taken after revision of the distal anastomosis in A. Note the fluorescence in LITA and in the OM coronary artery.

measurements. Second, the technique only allows precise definition of anastomotic quality in around three-quarters of grafts. This is because depth of penetration of the laser beam is only around 1 mm, and is therefore vulnerable to varying depths of the native coronary artery (eg, when intramyocardial). For the same reason, imaging can only occur when the chest is open and pedicled conduits are less well visualized than skeletonized ones. A more powerful, pulsed laser might resolve these limitations, and would be balanced against the fact that the device intentionally uses low-power laser energy so as to avoid thermal myocardial damage.

Conclusions

The fluorescence imaging technique of coronary grafts that is described has the advantages of safety, simplicity, reproducibility, repeatability, speed of assessment, and allows immediate surgical revision if necessary. Quantification of flow would further enhance its value.

The camera and dye were provided by Novadaq Technologies, Inc (Toronto, Ontario, Canada), for investigational purposes.

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Transit-time flow measurement for detection of early graft failure during myocardial revascularization

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Transit-Time Flow Measurement for Detection of Early Graft Failure During Myocardial Revascularization

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Background. A low-flow situation in arterial and venous grafts has been associated with high rates of perioperative infarction and mortality. This study was designed to look at intraoperative graft flow and resistance in patients with coronary artery disease.

Methods. Coronary artery bypass graft flow was measured in 46 patients. Transit-time flow was used for coronary flow measurements at rest as well as after maximal vasodilation with adenosine infusion.

Results. Forty-three of the 46 patients showed normal internal mammary artery graft flow (>20 mL/min); 3 patients had no or minimal graft flow. Redoing the graft anastomosis in these 3 patients resulted in normalization of graft flow. The mean flow increased significantly after correction from 0.5 ± 0.7 mL/min to 15.7 ± 9.6 mL/min ($p < 0.02$). Conversely, vascular resistance decreased significantly from 138 ± 10 to 4.8 ± 1.8 Ohmv ($p < 0.0001$), as did the pulsatility index (from 146.9 ± 95.7 to 3.4 ± 1.8; $p < 0.001$). After correction, coronary flow reserve was 2.5 ± 1.1.

Conclusions. Measurements of intraoperative flow and resistance as well as derived variables allow assessment of early graft function and thus help prevent graft failure and reduce perioperative infarction. Transit-time volume flow might be a simple tool for quality control in coronary bypass procedures.

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Coronary flow measurement allows functional evaluation of coronary artery bypass grafts and may be predictive of the patient's immediate and late outcome after myocardial revascularization [1–4]. With the advent of minimally invasive coronary artery bypass grafting, including multivessel revascularization on the beating heart, quality control of the anastomoses becomes particularly important [5–8]. Easily accessible flow-measuring devices are prerequisites for a reliable assessment of coronary grafts, especially to detect technical failure at the anastomotic site early and to identify low-flow situations resulting from vasospasm or poor runoff [9–13]. Recently, the transit-time ultrasound principle has been introduced into cardiac surgery to measure blood volume flow. Several studies [14–16] have demonstrated the particular value of this method to determine coronary graft flow after revascularization.

In the present study, intraoperative transit-time flow recordings were used to compare the flow characteristics of 3 patients with failure of the coronary anastomosis with those of 43 control patients at baseline and after maximal vasodilation with adenosine.

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Patients and Methods

Forty-six patients underwent coronary artery bypass grafting using the left internal mammary artery (IMA). In our institution, intraoperative transit-time flow measurement is routinely performed in patients who are undergoing coronary artery bypass procedures and are at increased perioperative risk because of hemodynamic instability, severely reduced left ventricular function, or diffuse coronary artery disease. Our operative technique includes moderate hypothermic cardiopulmonary bypass (32°C) and antegrade cold blood cardioplegia. After the completion of all distal and proximal anastomoses and the weaning of the patient from cardiopulmonary bypass, coronary flow is measured in the arterial and venous grafts at baseline and after maximal vasodilation with adenosine, 23 $\mu g \cdot kg^{-1} \cdot min^{-1}$ injected into the left ventricle. This adenosine dosage was found to induce maximal vasodilation in a previous trial [17].

Flow was measured by the transit-time method with the CardioMed Trace System (CM 4008; Medi-Stim AS, Oslo, Norway) and probes of 3 and 4 mm to fit the actual vessel size [15]. Invasive arterial pressure monitoring was done through a radial artery catheter. Simultaneously, the electrocardiogram (leads V_5 and II) was recorded for the timing of systolic and diastolic flow patterns. The arterial pressure and electrocardiogram were interfaced from a Hellige monitor to the flowmeter to evaluate the vascular resistance and the diastolic filling pattern.

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Table 1. Flow, Resistance, and Derived Variables in 3 Patients With Graft Occlusion Before and After Correction[a]

Variable	Before Correction	After Correction	*p* Value
Mean graft flow (mL/min)	0.5 ± 0.7	15.7 ± 9.6	<0.02
Pulsatility index	146.9 ± 95.7	3.4 ± 1.8	<0.001
Diastolic backflow (% insufficiency)	68 ± 35	8.2 ± 9.4	<0.001
Mean arterial pressure (mm Hg)	69 ± 7	68 ± 2	NS
Vascular resistance (ΩV = mm Hg · mL^{-1} · min^{-1})	138 ± 10	4.8 ± 1.8	<0.0001
Systolic to diastolic flow ratio (%)	...[b]	61 ± 6	NS
Systolic to diastolic time ratio (%)	62 ± 7	59 ± 13	NS
Area FFTQ	1.7 ± 0.6	0.6 ± 0.2	<0.05
Diastolic filling pattern	No	Yes	...

[a] Data are shown as the mean ± the standard deviation. [b] This could not be measured because of occlusion.

FFTQ = fast Fourier transformation of flow curve; NS = not significant.

The transit-time method is based on the fact that the time required for ultrasound to pass through blood is slightly longer upstream than downstream. As the ultrasound beam is wider than the diameter of the vessel lumen, the ultrasound wave will cover every flow vector in the vessel, thus making the transit-time difference proportional to the true volume of blood flow in milliliters per minute. The following variables were calculated: mean systolic and diastolic flow in milliliters per minute; pulsatility index (Pi = [maximum flow − minimal flow]/mean flow); early diastolic backflow expressed as percent insufficiency (volume of backward flow/volume of forward flow); fast Fourier transformation of the flow curve; and systolic to diastolic flow and time ratios. In addition, heart rate and radial artery mean, systolic, and diastolic pressure were recorded. Vascular resistance was calculated using the equation R = P/Q, (where P = mean radial artery pressure, and Q = mean volume flow [Ohm volt = milliliters of mercury per milliliter per minute]). Coronary flow reserve was calculated from the maximum flow assessed during adenosine infusion divided by flow at baseline.

Results

In 43 patients, flow through the IMA graft was normal (>20 mL/min). In 3 patients, a low-flow situation (mean flow, < 0.5 ± 0.7 mL/min) was found in the left IMA to the left anterior descending coronary artery. Calculated vascular resistance was significantly elevated (138 ± 10 Ohmv or mm Hg · mL^{-1} · min^{-1}), pulsatility index was pathologically high (147 ± 96), diastolic backflow showed an insufficiency of more than 50%, and diastolic filling was absent (Table 1). The reason for the low-flow situation was distal IMA dissection in 1 patient, an obstructing intimal IMA flap in 1, and an intramural hematoma with compression of the IMA anastomosis in 1. In only 1 patient transient electrocardiographic changes and poor contractility of the anterior wall of the left ventricle were observed. In all 3 patients, the distal anastomosis was reconstructed with the patient on cardiopulmonary bypass.

A typical recording from a patient with minimal flow in the IMA graft is demonstrated in Figure 1. The low flow and the large pulsatility index (Pi = 147) with a systolic forward flow and a similar diastolic backflow (68% insufficiency) resulted in minimal antegrade flow in the IMA, which suggests graft occlusion (1 mL/min as shown in Fig 1A). There was a considerable change in the flow pattern from a more systolic to a more diastolic flow after correction and adenosine infusion.

Transit-time flow and resistance recordings were repeated after surgical reconstruction of the distal anastomosis. There was an increase in mean flow from 0.5 ± 0.7 mL/min to 15.7 ± 9.6 mL/min ($p < 0.02$). Pulsatility index, diastolic backflow, and vascular resistance reached values comparable to those of the control group (Table 2). However, the baseline IMA flow in the 3 patients remained significantly lower after surgical correction compared with the flow in the control group (15.7 ± 9.6 mL/min versus 33 ± 27 mL/min; $p < 0.02$). After maximal vasodilation with adenosine, mean flow increased to 39 ± 11 mL/min and vascular resistance decreased to 1.9 ± 0.7 Ohmv in the 3 patients, thus nearly corresponding to the changes in the control group. Therefore, the calculated coronary flow reserve was higher, though not significantly so, in these 3 patients after the anastomosis was redone than in the control group (coronary flow reserves, 2.5 versus 1.4). The systolic to diastolic flow ratio was significantly higher at rest in the 3 patients than in the control group (61% ± 6% versus 47% ± 15%; $p < 0.03$). This ratio decreased with adenosine to 26% ± 14% in the 3 patients in contrast to the controls, in whom it did not change significantly. With reference to the fast Fourier transformation of the flow curves, the nonharmonic signal with many different, high-frequency content observed in the 3 patients with graft occlusion became a harmonic repetitive signal with a limited amount of frequency content after correction (see Fig 1B) and adenosine injection (see Fig 1C).

Comment

Low coronary artery bypass flow is associated with early graft failure and high risk of perioperative myocardial infarction [18, 19]. Thus, early recognition of low graft flow will alert the surgeon and avoid early graft occlusion. The purpose of the study was to evaluate the impact of transit-time flow and resistance measurements on graft function and patency in 46 patients with coronary artery disease undergoing coronary artery bypass grafting. In 43 patients, good functional reserve was observed with a mean flow of 33 ± 27 mL/min at rest, which increased to 45 ± 18 mL/min after adenosine infusion.

In 3 patients, a low-flow situation was detected by the flow probe, and a redo procedure was immediately

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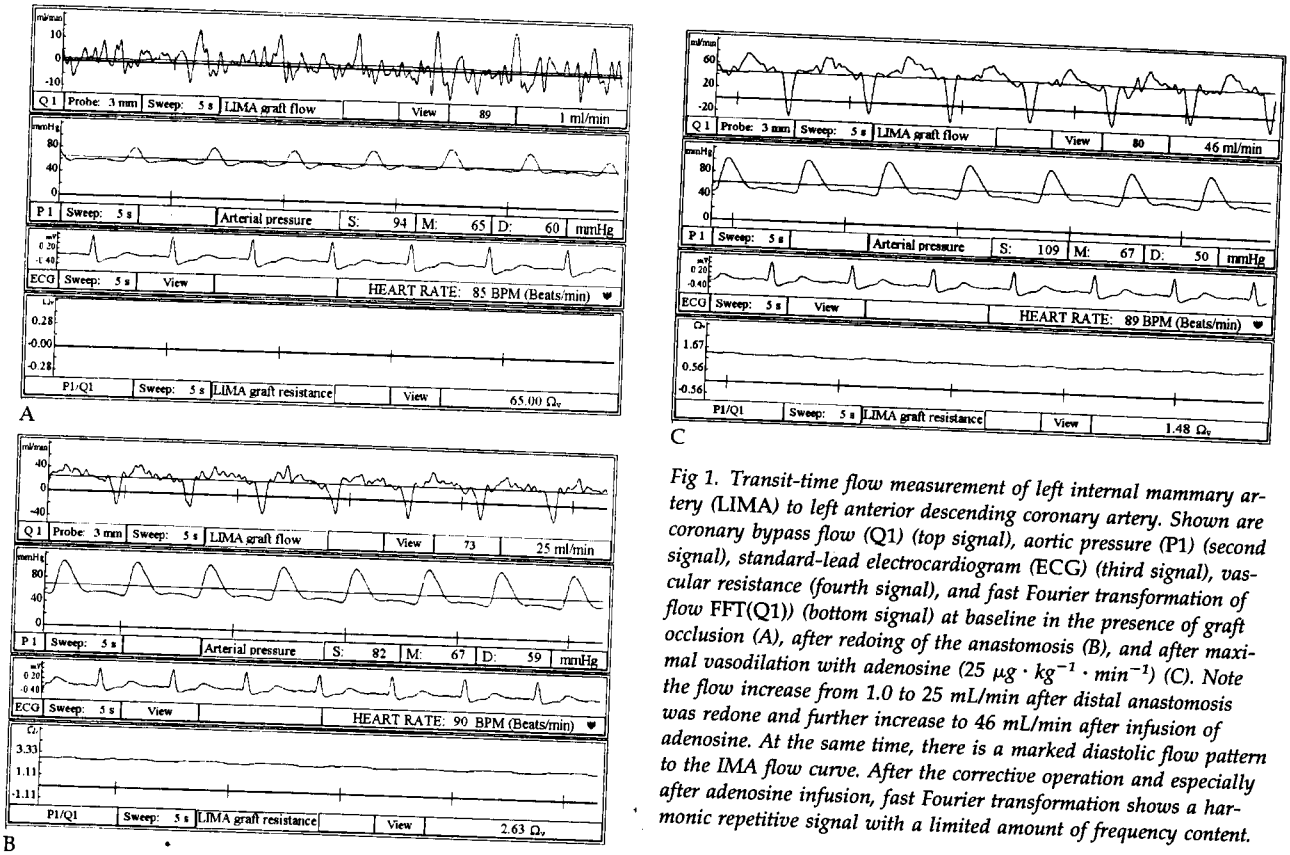

Fig 1. Transit-time flow measurement of left internal mammary artery (LIMA) to left anterior descending coronary artery. Shown are coronary bypass flow (Q1) (top signal), aortic pressure (P1) (second signal), standard-lead electrocardiogram (ECG) (third signal), vascular resistance (fourth signal), and fast Fourier transformation of flow FFT(Q1)) (bottom signal) at baseline in the presence of graft occlusion (A), after redoing of the anastomosis (B), and after maximal vasodilation with adenosine (25 $\mu g \cdot kg^{-1} \cdot min^{-1}$) (C). Note the flow increase from 1.0 to 25 mL/min after distal anastomosis was redone and further increase to 46 mL/min after infusion of adenosine. At the same time, there is a marked diastolic flow pattern to the IMA flow curve. After the corrective operation and especially after adenosine infusion, fast Fourier transformation shows a harmonic repetitive signal with a limited amount of frequency content.

performed. This intervention led to improvement in IMA graft flow, which increased significantly from 0.5 ± 0.7 mL/min to 15.7 ± 9.6 mL/min. Coronary flow reserve after adenosine infusion amounted to 2.5 ± 1.1, which is normal. After the anastomosis was redone, there was a significant decrease in vascular resistance from 138 ± 10 to 4.8 ± 1.8 (see Table 1). After adenosine, the systolic to diastolic flow ratio decreased from 61% to 26% ($p < 0.05$). These data indicate that reoperation was successful (see Table 2).

Comparison With Other Techniques

Other techniques that may help detect early graft failure include: electromagnetic or Doppler flow measurements or direct coronary angiography [5, 14, 20]. Electromagnetic flow measurement is often difficult and is sensitive

Table 2. Flow Characteristics in 3 Patients After Correction of Occlusion and in 43 Control Patients Before and After Maximal Vasodilation With Adenosine[a]

Variable	Before Adenosine		After Adenosine	
	Occlusion Group (n = 3)	Control Group (n = 43)	Occlusion Group (n = 3)	Control Group (n = 43)
Mean graft flow (mL/min)	15.7 ± 9.6	33 ± 27[b]	39 ± 11	45 ± 18[c]
Coronary flow reserve	...	...	2.5 ± 1.1	1.4 ± 0.7
Pulsatility index	3.4 ± 1.8	3.6 ± 2.2	2.5 ± 0.1	2.2 ± 0.7[c]
Diastolic backflow (% insufficiency)	8.2 ± 9.4	5.7 ± 6.6	2.1 ± 0.5	1.1 ± 1.5[c]
Mean arterial pressure (mm Hg)	68 ± 2	80 ± 9[b]	68 ± 2	78 ± 7
Vascular resistance (ΩV = mm Hg · $mL^{-1} \cdot min^{-1}$)	4.8 ± 1.8	3.9 ± 2.9	1.9 ± 0.7	2.1 ± 0.8[c]
Systolic to diastolic flow ratio (%)	61 ± 6	47 ± 15[b]	26 ± 14	43 ± 9[b]
Systolic to diastolic time ratio (%)	59 ± 13	57 ± 10	44 ± 3	57 ± 6[b]

[a] Data are shown as the mean ± the standard deviation. [b] Significance: $p < 0.05$ versus occlusion group. [c] Significance: $p < 0.05$ versus before adenosine.

to technical errors such as drift and zero adjustment. Doppler flow measurement is affected by insonation angle and indicates only velocity. Intraoperative angiography is often unsatisfactory because of poor vessel filling, low resolution, and problems related to the optimal projection. Transit-time volume flow measurement may help overcome these problems. The method is simple and reliable, provides accurate flow measurement, and is highly reproducible [14–16]. A major advantage of this technique is its use for measuring coronary bypass flow during minimally invasive coronary bypass procedures, as it may detect early graft failures in a timely fashion [7, 8].

Clinical Implications

Graft failure remains one of the most important aspects of coronary artery bypass grafting. Early intraoperative recognition is essential for immediate correction of any problem. On the basis of our experience with transit-time flow measurement, we have reached the following conclusions:

1. Transit-time volume flow measurement is simple, reliable, and easy to perform.
2. Low flow in a coronary bypass graft requires reexploration of the anastomosis unless severe spasm of the conduit or poor runoff is strongly suspected.
3. Redoing the distal anastomosis leads to significant improvement in flow and decreases vascular resistance in the presence of anastomotic failure.
4. Determination of coronary flow reserve with adenosine may help differentiate vasospasm from anastomotic graft failure.
5. Early recognition of graft failure is cost-effective and possibly prevents hemodynamic instability in the intensive care unit during the early postoperative period.

Measuring intraoperative flow may help detect bypass failure early and thus improve postoperative outcome in patients undergoing coronary artery bypass grafting. This might be of great importance in patients having minimally invasive surgical procedures.

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THE ANNALS OF THORACIC SURGERY

The importance of intraoperative angiographic findings for predicting long-term patency in coronary artery bypass operations

Per K. Hol, Erik Fosse, Runar Lundblad, Sigurd Nitter-Hauge, Paulina Due-Tønnessen, Karleif Vatne and Hans-Jørgen Smith

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The Importance of Intraoperative Angiographic Findings for Predicting Long-Term Patency in Coronary Artery Bypass Operations

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Background. The quality of anastomosis is the cornerstone in coronary artery bypass operations. Intraoperative coronary angiography confirms graft patency with the possibility to revise graft failure. The aim of this study was to describe the lesions found at "on-table" angiography, and to evaluate the significance of these immediate angiographic findings for the long-term patency.

Methods. A total of 57 grafts (42 left internal mammary artery grafts and 15 saphenous vein grafts) in 45 patients who underwent off-pump coronary artery bypass operations were included. On-table angiography was carried out with fixed angiographic equipment installed in the operating room. Follow-up angiographies were performed at 3 months and at 12 months.

Results. The most frequent finding in an on-table angiogram was spasm, which was not present at follow-up. Out of nine kinks, only one developed into a significant stenosis at follow-up. Of 44 grafts that were normal on-table, 37 (84%) were normal at the follow-up. Of 11 grafts with significant lesions on-table, eight (73%) were normal at the follow-up. Five percent of the grafts were revised because of the on-table angiography.

Conclusions. On-table angiograms can be occasionally difficult to interpret because not all findings are important for later patency. Optimal results on-table predict good long-term results with a negative predictive value of 0.84, whereas significant lesions on-table have less impact on the follow-up results because the positive predictive value was only 0.38.

(Ann Thorac Surg 2002;73:813–8)

The quality of the graft, as well as of the anastomosis, is fundamentally important for the results of coronary artery bypass operations. Although Doppler [1] and transit time flow measurements [2, 3] are exact and reproducible, the ability to detect moderate or even severe stenosis at the anastomotic site is limited [4–6]. Coronary angiography is the most commonly used tool for evaluation of the coronary arteries, both preoperatively and postoperatively. Intraoperative angiography has advantages compared with postoperative catheterization, such as instant confirmation of graft patency and the possibility for immediate revision of graft failure. Intraoperative angiography can be performed with fixed angiographic equipment when an operation is carried out in the catheterization laboratory [7], with a portable C-arm in the operating room [8] or with fixed angiographic equipment installed in the operating room [9]. Fixed installation in the operating room entails that angiography is easily available when needed and gives the opportunity of obtaining multiplanar views of grafts and anastomoses with images of high quality. Our hospital has had such a combined angiography and operating room at the Interventional Centre (Oslo, Norway) since 1996 [10].

The aim of this study was to describe the lesions found at "on-table" angiography in off-pump coronary artery bypass operations, and to compare the intraoperative angiographic findings with angiographic results after 3 and 12 months.

The regional ethical committee approved this study.

Material and Methods

A total of 57 grafts, 42 left internal mammary artery (LIMA) grafts and 15 saphenous vein grafts, were studied in 45 patients who underwent off-pump coronary artery bypass operations from August 1996 to April 1999 (Table 1). All patients were included after informed consent. There were 41 male and 4 female patients, with a mean age of 63 years (range, 38 to 79 years). In 19 patients with single vessel disease, the LIMA was anastomosed to the left anterior descending artery through a left anterior small thoracotomy operation. In 8 patients the left anterior small thoracotomy operation was combined with concomitant percutaneous transluminal coronary angioplasty or stenting of the circumflex or right coronary artery, a so-called hybrid approach. A total of 27 patients

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Table 1. Baseline Demographics in 45 Patients, With a Total of 57 Grafts[a]

Age	63 (38–79)
Male	41 (91%)
New York Heart Association class	2.8 (2–4)
Ejection fraction	72 (32–93)

[a] Data are mean and number of males, with range and percentage in parentheses.

were thus operated on through a thoracotomy. Eighteen patients were operated on through a sternotomy allowing full revascularization, but without the use of cardiopulmonary bypass.

All anastomoses were sutured with a continuous suturing technique using 7-0 Prolene (Ethicon, Livingstone, Scotland). Pericardial stay sutures were applied to displace the target coronary artery into the operating field, and stabilization devices were used to achieve local immobilization. A bloodless field was obtained using snaring sutures (CV-3 Gore-Tex; W. L. Gore & Associates, Flagstaff, AZ) or intracoronary shunts in combination with a suction-wash device. Heparin (1 mg/kg) was administrated systemically, with maintenance doses to hold activated clotting time greater than 250 during the operation. All patients were anticoagulated with acetyl acetic acid for at least 3 months.

All operations were performed in a combined catheterization and operating room, containing fixed angiographic equipment (Advantx; General Electrical Medical System, Milwaukee, WI). On-table angiography was carried out after closure of the wound while the patient was still on general anesthesia. Catheters (6 French LCB, RCB or IM curve style; Boston Scientific Scimed, Maple Grove, MN) were introduced through a right femoral artery sheath to inject nonionic contrast material (Visipaque 320 mgI/mL, Nycomed, Oslo, Norway) in all grafts.

The angiographies were performed by one member of a team consisting of two radiologists and one cardiologist, and they were evaluated visually by three independent readers. Discrepancies between the readers were settled by consensus. The lesions were defined following FitzGibbon's classification as normal (less than 50% reduction in diameter), significant (more than 50% reduction in diameter), or occluded [11]. Narrowing of the grafts or coronary arteries that were not present at the preoperative studies, which dissolved partly or completely by injection of nitroglycerin or papaverine, were defined as spasms. Kinking was defined as a sharp angle of the graft presenting a contrast defect. Lesion localization in the most distal end of the graft was called anastomosis proper; lesions in the native coronary artery at the proximal portion of the anastomosis were called heel; and lesions in the native coronary artery at the distal part of the anastomosis were called toe.

A follow-up angiography of all grafts and native coronary vessels was carried out with the same angiographic equipment by the same personnel after 3 months in 44 patients, and after 12 months in 35 patients.

Data of this study are presented as mean, range, or percentages. The sensitivity, specificity, and positive and negative predictive values of intraoperative angiography as predictor of follow-up angiography were calculated on the basis of Table 2. Significant lesions and occlusions in these analyses were grouped together as pathologic findings.

Results

All patients who had off-pump operations with intraoperative and angiographic follow-up in the specified time period were included in this study. All patients were alive at the latest follow-up. One patient, who had a single LIMA to the left anterior descending artery through a thoracotomy, had missed the 3-month follow-up, but had normal findings both intraoperatively and at the 12-month angiographic follow-up. Of the 10 patients who missed their 12-month follow-ups, 7 had excellent grafts at intraoperative angiography; one patient had a significant lesion in the LIMA graft that had disappeared at 3 months, and in 2 patients the LIMA grafts were occluded intraoperatively. Of the 7 patients with an intraoperative normal angiography who missed their 12-month follow-up, 1 patient had significant stenosis developed and 1 patient had occluded graft at 3 months; both of these patients were asymptomatic.

The angiographic findings are summarized in Table 2. Forty-four of 57 grafts (77%) were normal on-table compared with 45 of 57 (79%) at follow-up. Thirteen of 57 grafts (23%) had pathologic findings on-table (11 significant lesions and two occlusions) compared with 12 of 57 (21%) at follow-up (seven significant lesions and five occlusions). The sensitivity and specificity of intraoperative angiography were 0.42 (5 of 12) and 0.82 (37 of 45), respectively, whereas the positive and negative predictive values were 0.38 (5 of 13) and 0.84 (37 of 44), respectively.

Subgroup analyses are shown in Table 3. The most frequent finding on-table was spasm, appearing in 50% of the grafts (Fig 1). Twenty-four of the 42 LIMA grafts (57%) and 5 of the 15 vein grafts (33%) had spasms on-table. Approximately the same degree of spasms occurred in sternotomy patients as in thoracotomy patients. None of the spasms were found at 3- and 12-month follow-ups. A total of nine kinks (Fig 2) were found in 5 of 42 LIMA grafts (12%) intraoperatively. At 3 months follow-up, five of these nine kinks disappeared (three were unchanged), whereas in one a significant

Table 2. Pathological (Significant Lesions and Occlusions) and Normal Angiographic Findings Intraoperative and at Follow-up of 57 Grafts

Intraoperative Angiography	Follow-up Angiography		
	Pathologic	Normal	Total
Pathologic	5	8	13
Normal	7	37	44
Total	12	45	57

Table 3. Subgroup Analyses of Intraoperative and Follow-up Angiographic Findings

Intraoperative Finding	Graft Type	Operation	Follow-up
Spasm (n = 29)	24/42 Left internal mammary artery (57%) 5/15 Vein (33%)	13/29 Sternotomy (45%) 16/29 Thoracotomy (55%)	Dissolved ...
Kink (9 kinks in 5 grafts)	5/42 Left internal mammary artery (12%)	9/9 Thoracotomy	5/9 Disappeared 3/9 Unchanged 1/9 Significant lesion
Dissection (n = 2)	2/42 Left internal mammary artery (5%)	1/2 Sternotomy 1/2 Thoracotomy	1/2 Open 1/2 Occluded
Normal (n = 44)	30/42 Left internal mammary artery (71%) 14/15 Vein (93%)	24/44 Sternotomy (55%) 20/44 Thoracotomy (45%)	37/44 Normal (84%) 4/44 Significant (9%) 3/44 Occluded (7%)
Significant lesions (n = 11)	10/42 Left internal mammary artery (24%) 1/15 Vein (7%)	11/11 Thoracotomy	8/11 Normal (73%) 3/11 Significant (27%)
Occlusion (n = 2)	2/42 Left internal mammary artery (5%)	1/2 Sternotomy 1/2 Thoracotomy	...

lesion appeared at the site of a kink. Two of 42 LIMA grafts (5%) had a dissection at the distal part of the graft. Of these, one graft was occluded, the other was found open both at 3 and 12 months follow-up (Fig 3).

Forty-four grafts, 30 of 42 LIMA grafts (71%) and 14 of 15 vein grafts (93%), were normal on-table. Of these, 37 of 44 grafts (84%) were normal both at the 3-month and 12-month follow-up. In 4 of 44 (9%), all LIMA grafts, a significant lesion occurred at 3 months, and 3 of 44 grafts (7%), all vein grafts, were occluded at 3 months.

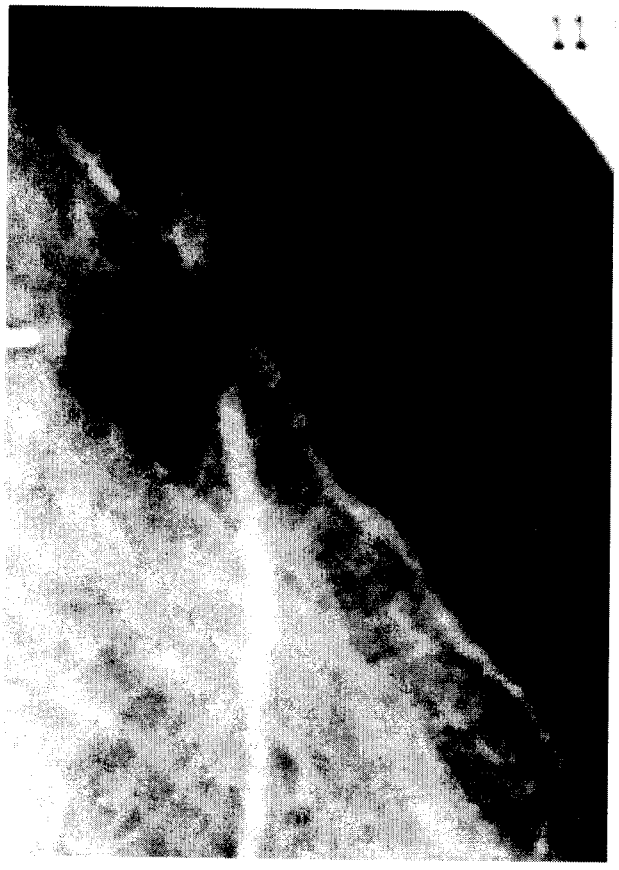

Fig 1. Most frequent finding at on-table angiography was spasm, which can be difficult to distinguish from stenosis of other causes. Spasm was not present at follow-up angiography.

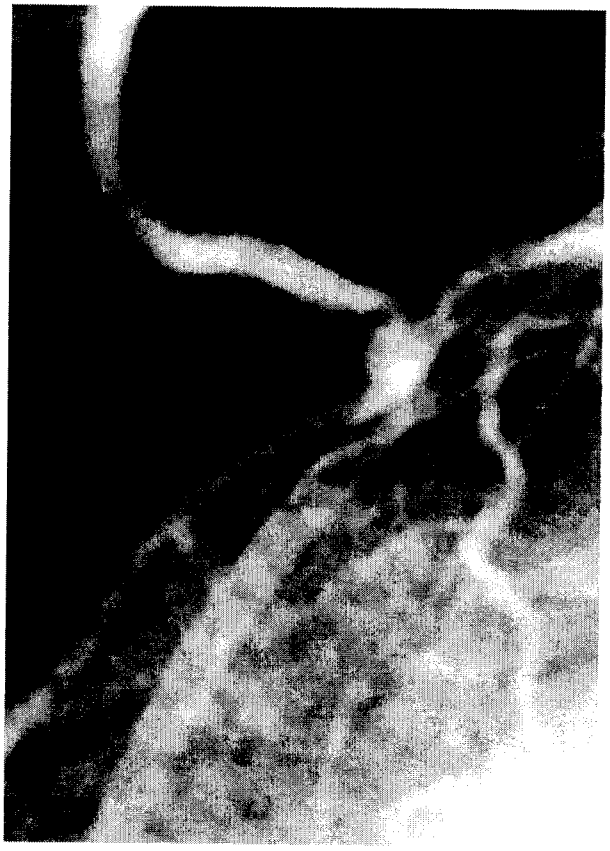

Fig 2. A kink demonstrated in the distal part of a left internal mammary artery graft at on-table angiography. A total of nine kinks were found in this study, and no revision was performed. In only one case a significant lesion was found at follow-up in a patient free of angina.

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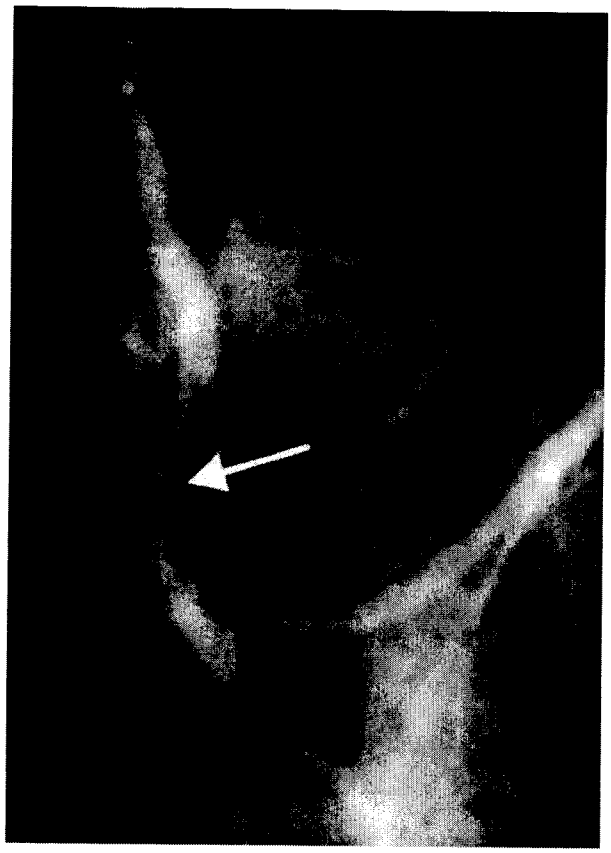

Fig 3. One of two left internal mammary artery grafts with dissection at on-table angiography was left untreated. At 12 months follow-up the dissection was still present (arrow) *and the graft fully patent.*

Ten of 42 LIMA grafts (24%) and 1 of 15 vein grafts (7%) had significant lesions on-table. Of these 11 grafts, eight were normal at 3 months follow-up, whereas three were unchanged. Six of these 11 significant lesions were localized at the anastomosis proper (Fig 4), three in the heel, one in the toe, and one in the graft itself proximal to the distal anastomosis.

Two LIMA grafts were occluded on-table, one in a redo patient with probable competitive flow from the existing vein graft where the lesion turned out to be insignificant, and the other caused by dissection distally in the LIMA that was unsuccessfully revised in a patient with a left anterior descending artery of small caliber.

Three of the 57 grafts (5%) were revised as a consequence of the on-table angiography. Two of the revisions were caused by occluded LIMA grafts. One of these had a dissection distally in the LIMA, and after revision there was still no flow into the left anterior descending artery. The left anterior descending artery was, however, of small caliber, and further attempt of revascularization was not performed. At 3 months follow-up the patient had no angina. At revision of the other occluded LIMA graft, an intimal flap was removed, and the repeated on-table angiography showed a perfect anastomosis. The third graft to be revised was a vein to the obtuse marginal with a 90% stenosis at the anastomosis proper. Strangulation at the distal anastomosis was found at revision, and a perfect graft was demonstrated at the repeat angiography.

The intraoperative angiography added about 30 minutes to the total operative time, up to 60 minutes with a few patients.

At the on-table angiography, 40 of 42 LIMA grafts (95%) and 15 of 5 vein grafts (100%) were patent, giving an overall patency rate of 96% (55 of 57). At the latest of the 3- or 12-month follow-ups, 39 of 42 LIMA grafts (93%) and 13 of 15 vein grafts (87%) were patent, giving an overall patency rate of 91% (52 of 57).

Comment

Although some reports of on-table coronary angiography exist [9, 12–15], most of them with the portable C-arm, little is known about the on-table angiographic findings and its significance for later patency.

Our study with a low positive predictive value of 0.38 demonstrated that on-table angiographic findings did not predict poor long-term patency. A normal on-table finding is more predictive of a normal finding at follow-up (negative predictive value, 0.84), although some angiographic changes arise at follow-up.

Fig 4. Significant lesions were most frequently found at the anastomosis proper. Significant lesion on-table was not a good predictor of later patency because 73% disappeared at follow-up.

Multiple factors can cause these changes in angiographic findings. Certain abnormalities in the on-table angiograms, such as spasm, vessel wall edema, thrombus formation, or wall hematoma, may resolve spontaneously, resulting in normal angiograms at the follow-up. The natural progress of the coronary disease itself and intimal hyperplasia can lead to progression of the angiographic findings or appearance of new lesions at follow-up. After operation, lesions can be also caused by sutures that are too tight, as demonstrated in the vein graft that was successfully revised.

The technique of intraoperative angiography is of importance. The accessibility of fixed angiographic equipment in the operating room, and the use of a radiologist or a cardiologist to perform the angiographic examination, provides angiograms of good quality in all patients without procedure-related complications. The disadvantage is the prolongation of the operative time by 30 to 60 minutes.

In an operation through a minithoracotomy the access is limited as compared with an operation through a sternotomy. However, no difference was found between operations performed through a sternotomy and thoracotomy with regard to the number of grafts with spasm, dissection, or intraoperative graft occlusion, and normal intraoperative findings.

Spasm, the most frequent on-table finding in our study, did not always disappear completely after injection of papaverine or nitroglycerin. The snaring sutures can cause a spasm in the coronary arteries close to the anastomosis. Widespread spasm was distinguished from disseminated atherosclerotic disease by performing repeated angiography after injection of papaverine or nitroglycerin or by comparing the on-table angiogram with the preoperative study. A localized spasm can be difficult to distinguish from a stenosis by other causes. A spasm can cause restricted flow and thus increase the possibility of graft occlusion. We did not register any relationship between on-table spasm and later occlusion. The two vein grafts that were normal on-table and occluded after 3 months had both poor run-offs in the native coronary vessel, demonstrating the importance of unrestricted flow for later patency.

Both Izzat and colleagues [13] and Mack and colleagues [15] reported graft revision to be performed in 8% after routine intraoperative angiography. In this study, intraoperative angiography led to a revision of 3 of 57 grafts (5%) and revealed lesions that probably should have been revised. Occluded grafts should always be revised. When to perform graft revision after demonstrating a significant lesion on-table remains to be clarified. Before operating we did not define criteria of when to revise significant lesions, and our material contained too few patients with abnormal grafts to elucidate which would have benefited from graft revision. Lazzara and colleagues [16] reported 2 patients with a kink proximal to the distal anastomosis that was corrected immediately as a consequence of on-table angiography. Our series, with the development of only one significant lesion in 9 patients with kinking, demonstrates that revision might be unnecessary. The one LIMA graft with a dissection on-table and with unobstructed passage of contrast material at 3 and 12 months follow-up, indicated that even dissections may be left untreated, although we would normally make a graft revision after on-table demonstration of such lesions.

Although costly and time-consuming, intraoperative angiography may have a place in surgical coronary revascularization. Transit time flow measurement is a much simpler, less costly, and time-consuming method, but it has limitations in detecting moderate or even severe stenosis at the anastomotic site [4–6]. Evidence-based practice is important when new treatment modalities are implemented, and the only way to obtain evidence is to use all available means. Therefore intraoperative angiography, together with transit time flow measurements, should be used to demonstrate the accuracy in off-pump coronary artery bypass operations. But further studies are needed to correctly interpret on-table angiographic findings and define its role for intraoperative assessment of graft patency. Meanwhile, on-table angiography has to be interpreted with care.

In conclusion, on-table coronary angiography gives valuable information of graft assessment, but can be difficult to interpret because not all findings are of importance for later patency.

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INVITED COMMENTARY

The quality of the vascular anastomosis remains a critical issue for off-pump coronary artery bypass grafting (OPCAB). This is particularly pertinent because several variations of the OPCAB technique exist and there is a learning curve associated with each. As the technical goal of CABG is to achieve a satisfactory anastomosis, this is something that has to be proven, *not* assumed, at least at the beginning of one's learning curve. Although ultrasound-based flowmeters and thermal imaging could be helpful, on-table coronary angiography is still held by many to be the gold standard in evaluating the quality of the anastomosis and provides an option for the operator to revise it if needed. Along this line of thinking, Hol and colleagues should be complimented for this timely and stimulating study.

The findings presented in this article, however, are confusing with respect to the role of routine intraoperative angiography. A quarter of the LIMA grafts studied had significant angiographic lesions on-table, and among these, the authors only chose to revise two grafts. Despite this, about half of the grafts with kinks and two-thirds with "significant lesions" became normalized on follow-up even without revision. The reasons why remain unclear. One limitation of this study is that the angiographic lesions and the revision criteria were not carefully defined. Did the authors decide before surgery that they were not going to act on the intraoperative angiographic findings? If so, could they justify the additional risk, operative time and costs? A significant number of patients with abnormal angiography remained the same or got worse radiologically on follow-up. As the authors admit, it would be difficult to argue that at least some of these patients would not have benefited from an attempted graft revision.

Another important aspect brought out in this article is the potential advantage of a hybrid procedure in enhancing clinical outcome. Although this may appear to be clumsy and unnecessary at first sight, surgeons, radiologists and cardiologists could work together in a combined operative angiography suite to achieve something that each specialist alone may not be able to do. It would be very interesting to see the long-term results of the group of patients who underwent a hybrid procedure.

This provocative article stimulates us to dissect deeper into the rationale behind intraoperative angiography, and how to interpret the results. However, the paper raises more questions than for which we currently have answers.

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The importance of intraoperative angiographic findings for predicting long-term patency in coronary artery bypass operations

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98% complete follow-up) showed all grafts to be patent (100% early patency rate). At 3 months postop. stress EKG demonstrated signs of myocardial ischemia in 1 of the 45 pts. evaluated to date.
CONCLUSION: The PAS-Port system allows for an easy attachment of veins to the implant. Proximal anastomoses can be performed safely in one single step within seconds without aortic clamping. This study demonstrates 100% early angiographic patency and absence of exercise induced myocardial ischemia at 3 month postop. in 98% of the patients.

29 EARLY BYPASS OCCLUSION WITH THE AORTIC CONNECTOR DEVICE

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OBJECTIVE: Off-pump coronary artery bypass grafting (OPCABG) has gained increasing acceptance due to the reduction of negative effects of extra-corporeal circulation. However, manipulation of diseased aorta may increase the risk for neurologic complications. The mechanical Symmetry-connector (SC) anastomosis device (St. Jude Medical) allows for performing a mechanical proximal vein-to-aorta anastomosis without side-clamping the aorta. This study reports early postop complications following usage of the SC device at our institution.
METHODS: Between 6/2001-4/2002, 77 SCs (1.3/patient) were deployed in 61 patients (51m/10f, mean age 68 ± 8.6 years) in OPCABG procedures. Graft flow was assessed using a flow probe.
RESULTS: Loading of the SC was simple. Time for anastomosis was <15s. No neurologic deficiencies were observed. 54/61 (89%) patients had an uneventful course. However 7 patients (11%) encountered device-related complications: 1 intraoperatively, 2 within 5 days and 4 within 6 months postoperatively. Angiography demonstrated occlusion of the neoostium of the vein graft in 6 patients. 3 patients were reoperated within 6 days. 1 vein graft was dilated and 2 grafts were stented.
CONCLUSIONS: Based on these observations the routine use of the SC device is not advised and it should be reserved for patients with severely calcified ascending aorta where other alternative techniques are not possible. It appears that further investigations and improvements of the connector system are necessary to evaluate the benefits of this promising technology.

30 FIRST CLINICAL EXPERIENCE WITH A 30° END-TO-SIDE CORONARY ANASTOMISIS COUPLER

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[1]Department of Cardiovascular Surgery, University Hospital, Kiel, Germany; [2]Converge Medical, Sunnyvale, CA, USA

OBJECTIVE: The purpose of this study is to evaluate the safety and efficacy of a novel coronary anastomotic Coupler (Converge Medical, Inc., Sunnyvale, CA) that facilitates a sutureless vein graft to coronary artery anastomosis.
MATERIAL AND METHODS: The Coupler will be evaluated in a multi-center, non-randomized, open study in up to 35 patients. The Coupler relies on a set of concentric mating frames that clamp vessel tissues together to enable healing. The frames are manufactured from Nitinol, a nickel titanium shape-memory alloy. The Nitinol frames attach the bypass graft to the coronary artery in a 30° end-to-side configuration. A total of 4 patients (3 male, 1 female, mean age 65 years) were admitted for coronary artery re-vascularization and included in the study.
RESULTS: Three patients were successfully treated with Coupler. One patient did not meet the intraoperative exclusion criteria, and was excluded from the study due to small and heavily calcified vessels. There was minor bleeding in one patient, which was corrected by arranging the bypass graft along the axis of the coronary vessel with fibrin glue. Average mean flow through the Couplers was 51 ml/min, compared to an average flow rate of 24.8 ml/min in conventionally sutured grafts, and 34.47 ml/min in IMA bypass grafts. Patients will be angiographically assessed at 8 weeks postoperatively.
CONCLUSION: Initial results indicate that the Converge Coupler can be used to create a safe and effective 30° vein graft to coronary artery anastomosis.

31 NOVADAQ SPY™: IMMEDIATE BYPASS FUNCTION CONTROL IN OFF-PUMP CABG

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OBJECTIVES: Off-pump coronary artery bypass grafting (OPCAB) is an emerging technique. However it is technically demanding. To assess quality of anastomoses and quality of grafts the Spy™ imaging system (Novadaq, Canada) was evaluated. Based on fluorescence properties of indocyanine green (ICG) the dye was intravenously injected and area of interest illuminated with a laser. Images were captured with CCD camera, digitally processed, immediately analyzed and finally saved on CD-ROM.
METHODS: Between April 02 and August 02 a total of 37 consecutive patients (25m/12f) with 107 grafts (45 arteries/62 veins) were included in the study. Immediate and fast run-off of dye as well as extended opacification of myocardium was supposed equivalent to good quality of anastomosis and high intravascular ICG-signal for good graft quality respectively. For cross-check flow was measured with doppler flow-probes (Medistim, Norway).
RESULTS: The system is easy to handle and no side-effects of ICG were observed. 4/107 grafts (3.73%) had to be revised (3 anastomotic constrictions, 1 graft dissection). Optical assessment correlated with measured flow. Each image required approximately 1.25-2.5mg ICG. Distinct images were equivalent to angiography without the need for X-rays and catheter insertion. Course of coronaries in redo-cases and obese patients could be detected.
CONCLUSIONS: Optical assessment of graft flow and graft quality is a very advantageous tool not only in OPCAB surgery. Immediate bypass control can lead to immediate corrections with better postoperative results. Future improvements of the system could include a quantitative flow measurement and flow curve analysis.

Evaluation of graft patency during minimally invasive coronary artery bypass grafting with Doppler flow analysis

Jeffrey C. Lin, Don L. Fisher, Michael F. Szwerc and James A. Magovern

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Evaluation of Graft Patency During Minimally Invasive Coronary Artery Bypass Grafting With Doppler Flow Analysis

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Background. An objective method for determining intraoperative graft patency is an essential part of minimally invasive direct coronary artery bypass. This study compares angiography and Doppler methods for graft analysis during minimally invasive direct coronary artery bypass and presents long-term outcome in a cohort of patients.

Methods. Between March and October 1997, 35 patients had elective minimally invasive direct coronary artery bypass procedures in which the left internal mammary artery was anastomosed to the left anterior descending coronary artery. Immediate graft patency was determined with intraoperative angiography using selective injection of the left internal mammary artery from a femoral approach and with Doppler flow analysis using a 1-mm, 20-MHz Doppler probe placed directly on the graft.

Results. There was immediate perfect patency with brisk flow in 91% of patients (32 of 35). A normal Doppler study, defined as a diastolic predominant pattern with a diastolic flow velocity of greater than 15 cm/second, was found in all patients with normal angiograms. All patients with abnormal angiograms also had abnormal Doppler flow. Thus, Doppler analysis was 100% accurate for confirming graft patency and for detecting failed grafts. All abnormal grafts were successfully revised, which allowed 100% early patency. Operative mortality was 2.8% (1 of 35) and there have been no late deaths at a follow-up of more than 2 years. One patient required angioplasty of the anastomosis (1 of 34, 2.9%), but none have required subsequent surgical intervention.

Conclusions. Objective analysis of graft flow in the operating room is necessary to achieve 100% early graft patency with minimally invasive direct coronary artery bypass operations. Doppler analysis is the preferred initial method, because it is safe, accurate, and rapid.

(Ann Thorac Surg 2000;70:1350–4)

Minimally invasive direct coronary artery bypass (MIDCAB) has been shown to be less expensive and less morbid than traditional operations [1]. However, the operation is technically demanding, and concerns about graft patency and long-term outcome have been raised [2, 3]. Doppler methods for determining flow in coronary bypass grafts have been published but are not widely used [4, 5]. In addition, these methods have not been directly compared with angiography, which is generally regarded as the standard for determining graft patency. In this report, we present our experience with concurrent intraoperative angiography and pulsed-Doppler flow measurements in 35 consecutive patients who had MIDCAB procedures in which the left internal mammary artery (LIMA) was grafted to the left anterior descending coronary artery (LAD). We also present long-term clinical follow-up of this cohort of patients at 2 years postoperatively.

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Material and Methods

Patients

Between March and October 1997, 35 consecutive patients with single-vessel disease of the LAD had MIDCAB and gave permission for intraoperative angiography. The mean age was 61 ± 10 years, ranging from 34 to 80 years of age, and most patients (25 of 35, 71%) were male. Three patients had previous coronary artery bypass grafting. Three patients in this series had MIDCAB after being refused for traditional operation because of associated conditions, such as hepatic cirrhosis (n = 1), active gastrointestinal bleeding (n = 1), and recent stroke (n = 1). Patients with multi-vessel disease who had MIDCAB as part of a staged revascularization with endoluminal techniques were not included in this study. All patients discharged from the hospital returned for an office visit 4 to 6 weeks postoperatively. Late follow-up was completed as of August 31, 1999 by office visit or telephone contact.

Operative Technique

Our technique of perioperative anesthesia management has been described previously [6]. A double-lumen endotracheal tube and a fourth interspace anterior thora-

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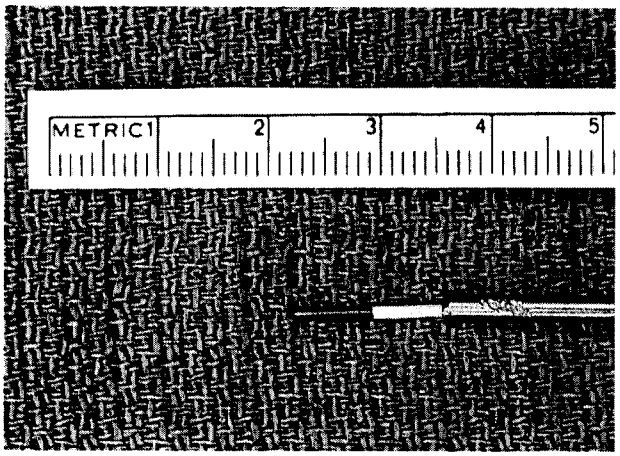

Fig 1. The 1-mm, 20-MHz Doppler probe is quite flexible and can be passed through a small metal suction tip to provide stability.

cotomy were used in each case. The LIMA pedicle was harvested under direct vision with electrocautery and clips. The minithoracotomy exposure was facilitated by using the CTS Access MP retractor (PN# CMS-151; Cardio Thoracic Systems, Inc., Cupertino, CA). The pedicle was mobilized completely, extending from the fifth rib to the subclavian junction, and heparin (10,000 U) was administered. The distal half of the LIMA pedicle was skeletonized in order to inspect the artery and to increase the functional length.

The pericardium was opened after dividing the plane between the thymic and the pericardial fat pads and then extending the pericardial incision parallel to the phrenic nerve. The LAD invariably is in this region, and cephalad extension of the pericardial incision prevents kinking of the LIMA pedicle on the edge of the pericardium [7, 8]. Pericardial stay sutures were used to displace the heart anteriorly, and mechanical stabilization was used to facilitate the anastomosis in each case (CTS Access MV Stabilizer, PN# CMS,175; CardioThoracic Systems, Inc). A carbon dioxide blower was used to displace blood from the coronary arteriotomy, but an intraluminal shunt was not used unless bleeding was persistent or hemodynamic deterioration occurred. Arterial anastomosis was done with a running 7-0 polypropylene suture.

Intraoperative Assessment of Graft Flow

Color pulsed-Doppler flow analysis was done with a 1-mm, 20-MHz micro-Doppler probe (PN# P15 EME2005; Nicolet Biomedical, Madison, WI) and recorded on the Nicolet Pioneer TCD System, software version 2.31 (Fig 1). The software-determined Doppler interrogation depth was set at 1.0 mm and volume at 0.5 mm. The tip of the flow probe was applied gently onto the mammary artery at a 45-degree incidence, and flow readings were obtained within several seconds (Fig 2). Pertinent flow pattern data included peak and mean flow, as well as systolic-diastolic flow pattern.

Intraoperative selective angiography of the LIMA was done by a cardiologist (DLF) through the femoral approach. A 6F introducer was inserted using the Seldinger technique. The 6F IMA angiography catheter (Cordis Endovascular, Miami, FL) was then threaded over a guide wire into position at the orifice of the LIMA under C-arm high resolution fluoroscopy (OEC 9600, OEC Medical Systems, Inc, Salt Lake City, UT). Hand bolus injection of 3 to 8 mL of Hypaque 76 or Omnipaque 350 was delivered, and the LIMA graft was examined in anteroposterior, mild left anterior and right anterior oblique views. The angiograms were imaged with the 9-inch field, with further image magnification if necessary. The results were documented on videotape and X-ray spot film but were not recorded on cine-film. Graft and anastomotic success was judged by flow criteria according to Fitzgibbon and associates [9] as no flow (occluded), patent with 50% stenosis with restricted run-off (compromised), or widely patent with unrestricted run-off (normal).

Results

All cases were successfully completed without the need to perform sternotomy or to use cardiopulmonary bypass. Angiograms and Doppler flow recordings were obtained in each patient, and no complications occurred as a result of the evaluation techniques. Most patients (85%) were extubated in the operating room. The mean length of stay in the hospital after surgery was 4 days. There were no strokes, no reexplorations for bleeding, and no instances of perioperative myocardial infarction, as documented by electrocardiographic changes. There was one operative death in a high-risk patient with hepatic cirrhosis, who died from multisystem organ failure. Angiography and Doppler showed a satisfactory graft, and the patient had no evidence of myocardial ischemia after surgery. The remaining 34 patients were discharged to home and all were seen as outpatients at 6 to 8 weeks postoperatively. None had recurrent angina or required cardiac catheterization in the early postopera-

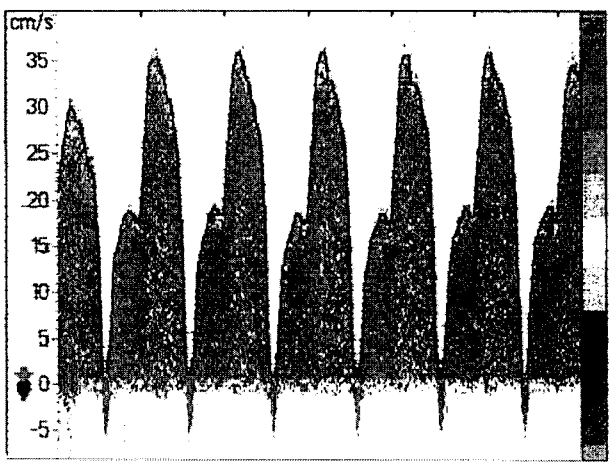

Fig 2. Normal flow velocity pattern in a left internal mammary to left anterior descending artery graft. There is pan-diastolic flow with a velocity of more than 30 cm/second, indicating a patent graft.

Table 1. Graft Flow Velocity

	Mean Diastolic Flow Velocity (cm/sec)	Mean Flow Velocity (cm/sec)
All patients (n = 35)	27.4 ± 12.1	18.8 ± 9.3
100% LAD occlusion (n = 7)	16.6 ± 4.2	9.3 ± 1.4
<100% LAD stenosis (n = 28)	31.9 ± 9.3[a]	21.7 ± 8.2[a]

[a] $p = 0.01$.

LAD = left anterior descending artery.

tive period. Three patients had minor complications, including wound seroma (n = 1), pericarditis (n = 1), and persistent incisional pain (n = 1). There were no wound infections.

Graft Flow

A normal Doppler signal, defined as a diastolic predominant, pan-diastolic tracing with a mean diastolic flow velocity greater than 15 cm/second, was found in 32 of 35 patients. The mean diastolic flow velocity was 27 cm/second, with a range of 15 to 40 cm/second (Fig 2). Patients with a chronic 100% LAD occlusion (n = 7) had a lower mean diastolic velocity than those whose vessel was not occluded (n = 28) (Table 1). Three patients had grossly abnormal flow tracings which showed a high systolic peak velocity with minimal diastolic flow or disorganized flow velocity signals (Figs 3 and 4). None of these patients had echocardiographic evidence of ischemia, hemodynamic instability, or any obvious abnormality of the graft. These same 3 patients also had abnormal grafts by angiography, consisting of one graft with complete occlusion and two with compromised flow. The other 32 patients had normal grafts by angiography. All of the grafts determined to be normal with angiography had normal Doppler signals and vice versa. Thus, each technique was 100% accurate for distinguishing between a functional and a compromised graft.

Causes of Graft Failure

The abnormal grafts were revised in the operating room. Of the three problem grafts, two resulted from an issue with the LIMA pedicle and one from anastomotic failure. All grafts were revised successfully, and repeat confirmatory angiography and Doppler analyses were done. Therefore, all patients left the operating room with a patent LIMA to LAD graft with good flow.

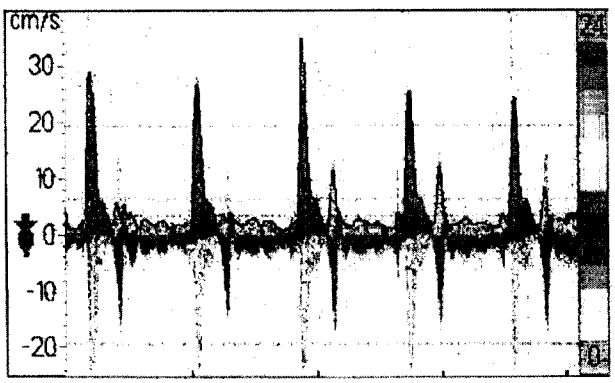

Fig 3. The tracing shows a spike with high initial systolic flow velocity but no significant diastolic flow. This indicates obstruction of the anastomosis resulting in poor diastolic flow.

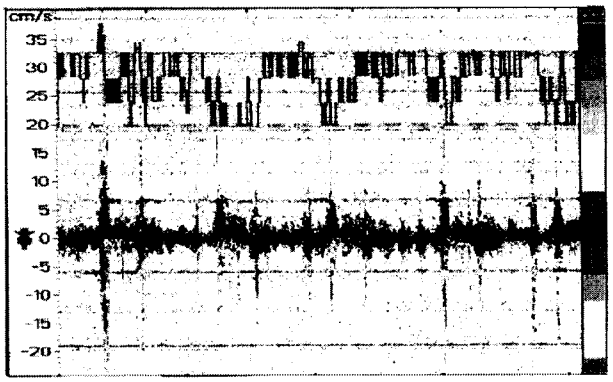

Fig 4. The tracing shows disorganized, low velocity flow indicating inadequate inflow to the mammary artery. This indicates that there is a problem with the mammary pedicle, such as a twisted pedicle, a proximal hematoma, or a dissected mammary artery.

Late Outcome

Long-term follow-up was obtained in all of the discharged patients. Angiography or stress testing were not obtained systematically, but all patients were contacted by telephone or office visit and carefully questioned about clinical status at a mean of 26 months (range, 22 to 30 months) postoperatively. There were no late deaths. One patient had recurrent angina and required angioplasty for an anastomotic stricture at 4 months postoperatively. Another patient developed a symptomatic new left main stenosis and had successful stenting of the left main coronary artery, which was done because the patient was protected by a patent LIMA to LAD graft. No patient required redo coronary artery bypass grafting. Therefore, at a mean follow-up time of over 2 years, 97% of patients (33 of 34) were free from target vessel (LAD) reintervention, and 94% (32/34) were free from any coronary reintervention. None of the 3 patients whose grafts were revised in the operating room had recurrent angina or required reintervention.

Comment

The initial experience with LAD revascularization with the LIMA on the beating heart was reported by Kolessov in 1967 [10]. However, this technique was largely forgotten after the development of coronary bypass using cardioplegic arrest, until the concept of beating heart coronary artery bypass grafting was revived by surgeons interested in reducing the morbidity associated with traditional sternotomy and cardiopulmonary bypass techniques [11, 12].

Long-term survival benefits after coronary revascularization with the internal mammary artery graft have been well documented [13]. Hence, a legitimate concern re-

garding coronary revascularization on the beating heart is the quality of the graft anastomosis. The early clinical experience with MIDCAB was complicated by cardiac motion, but this problem has been minimized by routine application of epicardial stabilizing devices [14].

Nonetheless, concern still exists that the patency of MIDCAB grafts is not equal to those done on the arrested heart, even when dedicated equipment is used. The review of the literature by Mack and associates [15] of angiographic outcomes after conventional coronary artery bypass grafting for LIMA grafts found early graft patency between 94% and 99%. A more recent report from Mack and associates [16] of early postoperative coronary angiography in 100 MIDCAB patients showed an overall patency of 97%, but this result included 6% of patients with 50% or less graft stenosis. Because of the greater technical difficulty of beating heart anastomoses, and the concern about immediate graft patency, it is essential to have a reliable, objective method to determine graft patency in the operating room. Several published reports have described intraoperative angiography, utilizing a femoral or radial artery approach [17, 18]. Angiography certainly gives a definitive answer about graft patency, but it is time-consuming, often requires cardiology assistance, and is not without risks, so we adopted pulsed Doppler flow velocity recordings as a method for confirming graft patency.

Our results demonstrate several important points. First, a normal pulsed Doppler result is equivalent to angiography in confirming a patent graft. When there is a diastolic-predominant flow pattern with a pan-diastolic flow velocity of more than 15 cm/second, all grafts were patent by angiography. Most of the grafts had a diastolic flow velocity greater than 25 cm/second, especially when the LAD was not chronically occluded. Second, a grossly abnormal flow velocity pattern was equivalent to angiography in confirming a nonfunctional graft. We have seen two types of failed grafts. In the first type there is a problem with the LIMA pedicle, which restricts inflow, leading to a pattern of very low velocity in the distal pedicle. In the other type there is an anastomotic problem resulting in satisfactory inflow but poor run-off, which results in a high systolic velocity peak with no diastolic flow. Third, failure of MIDCAB grafts is not always caused by anastomotic failure and can be caused by problems with the LIMA pedicle. And finally, grafts with satisfactory flow determined by Doppler methods have excellent long-term results. At 2 years follow-up, all surviving patients were without angina and 97% were free from reintervention on the LAD.

Our data showed a lower LIMA graft flow velocity when the native LAD was chronically occluded compared with the situation when the LAD was open but had a tight proximal stenosis (greater than 70%). The physiology of a vascular bed supplied entirely by collateral vessels is different from one supplied by a stenotic epicardial coronary artery. It is possible that the antegrade flow velocity would increase with time, but we have no data to support that hypothesis. From a practical viewpoint, a borderline low flow velocity (15 to 20 cm/second) is not a source of major concern if the LAD is chronically occluded but should arouse suspicion in a graft to a vessel with a tight stenosis. None of the grafts were done to vessels with less than 70% stenosis, so we do not have any data on the expected flow velocity in the presence of significant competitive flow.

Intraoperative Doppler techniques for graft assessment during MIDCAB have been described by others, but they have not used the system we employed. Elbeery and colleagues [19] reported on the use of continuous wave Doppler flow assessment of the LIMA graft with concurrent intraoperative angiography in 50 patients. They used a nonquantitative and subjective methodology for analysis of the Doppler flow signal (graded as: 0=no flow, 1+ = poor or questionable, and 2+ = good flow with diastolic augmentation), and demonstrated a 75% sensitivity and 93.5% specificity in correctly identifying anastomotic problems. Calafiore and colleagues utilized intraoperative pulsed-Doppler echocardiography to introduce objective documentation of the flow velocity and systolic/diastolic flow characteristics of the LIMA graft [20]. Graft flow volume determinations by transit -time flow measurement has been recommended for analyzing the patency of coronary grafts [21, 22].

These studies show that Doppler flow velocity and transit time flow measurements can distinguish between patent and functionally occluded grafts. It is not known whether these techniques can identify degrees of graft stenosis. An experimental study by Jaber and associates [22] showed that transit time flow measurement did not predict stenosis reliably unless it was more than 75%, which is not surprising because this is the level at which flow is obviously restricted. No comparable data are available for pulsed Doppler flow velocity measurements, but there is no reason to expect that the situation would be different. Calafiore and colleagues [23] used the Azoulay manuever during perioperative LIMA duplex interrogation to detect anastomotic stenosis. The Azoulay maneuver transiently augments venous return, which increases cardiac output and graft flow. Normal grafts show an increase in diastolic flow velocity whereas stenotic grafts do not. We have no experience with this technique, but it might be a helpful modification of our method.

The significance of mild to moderate degrees of anastomotic stenosis, in the absence of flow restriction, is not known. Recent studies by Mack and associates [16] and Wiklund and colleagues (Wiklund L, Brandup-Wognsen G, Bugge M, et al. Difficulties in interpretation of the coronary angiogram early after CABG on the beating heart [Abstract]. Presented at the 13th Annual Meeting of the European Association for Thoracic Surgery, Glasgow, Scotland, September 5–8, 1999:66, #88.) suggest that certain minor abnormalities noted at early angiography, such as small filling defects and anastomotic narrowing, are reversible and might resolve with time. They concluded that minor graft abnormalities found at perioperative angiography might not be clinically important, especially when graft flow is brisk. Our data support that hypothesis. At the completion of the operation, all grafts

in this study had good flow, as determined by both angiography and Doppler methods, and during the next 2 years only 1 patient had recurrent symptoms resulting from a problem with the LIMA to LAD graft.

This method for Doppler analysis uses the Nicolet Pioneer TCD system with the Nicolet 1-mm, 20-MHz probe. This system has been used extensively in neurosurgery, primarily for assessment of cerebral blood flow before and after cerebral aneurysm clipping. The device is flexible and has user-programmable variables, such as interrogation depth and volume, which permits sampling of flow velocity in the middle of the arterial lumen. In addition, systolic and diastolic flow velocity are displayed graphically in real time, which allows careful examination of diastolic flow rather than average flow velocity over the entire cardiac cycle. Doppler flow measurements are not as familiar as angiograms to surgeons, but they provide useful information and avoid the risks of contrast dye and injury to the LIMA by a catheter.

The major limitation of this study was that the angiograms were recorded in real time on a fluoroscopy monitor, and not on cine-film. Therefore, we were not able to examine the anastomotic site carefully for subtle degrees of stenosis. However, a cardiologist was present for each angiogram and made the final decision about the quality of the grafts as judged by flow characteristics. Another limitation was the relatively small size of the study. Because graft problems were uncommon we have limited data on failed or borderline-abnormal grafts.

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Evaluation of graft patency during minimally invasive coronary artery bypass grafting with Doppler flow analysis

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Institutional report - Coronary

SPY™: an innovative intra-operative imaging system to evaluate graft patency during off-pump coronary artery bypass grafting☆,☆☆

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Abstract

Off-pump coronary artery bypass grafting (CABG) has been rapidly increased, because of its less invasiveness with low complications. However, graft patency rate highly depends on the operators' capability due to technical difficulties. The SPY™ system, based on the fluorescence of indocyanine green, is an innovative device that permits validation of graft patency intra-operatively. Real time images of grafts are obtained with no need for catheterization, X-rays or iodine contrast medium. High-quality images could be obtained in all 290 grafts of 72 off-pump CABG cases (mean 4.0 grafts per patient). Four anastomoses (1.4%), including two proximal and two distal, were revised because of defects detected by SPY images. In one case, the SPY™ system revealed no blood flow in a radial sequential graft, although transit-time flow meter measurements showed a diastolic dominant pattern. SPY images provide critical information to surgeons to detect non-patent grafts, allowing them to be revised while the patient is still on the operating table. Using the SPY™ system, technical failures could be completely resolved during surgery. The use of the SPY™ system for intra-operative graft validation during off-pump CABG may become the gold standard for surgical management in the near future.

Keywords: Off-pump coronary artery bypass grafting; Intra-operative graft validation; Indocyanine green; SPY system

1. Introduction

The incidence of off-pump coronary artery bypass grafting (CABG) has increased rapidly, because of the potential for eliminating complications associated with the use of the bypass pump. However, there are still concerns about reduced graft patency rates due to technical difficulties.

If defective grafts can be detected and revised in the operating room, post-operative graft patency rate will approach 100%. The SPY™ intra-operative imaging system (Novadaq Technologies Inc., Toronto, Canada) has been developed as a means for detecting dysfunctional grafts during CABG [1,2]. The SPY™ imaging system acquires fluorescence coronary angiograms using the dye indocyanine green (ICG).

The purpose of this study was to evaluate the innovative SPY™ imaging system during off-pump CABG.

2. Materials and methods

2.1. Intra-operative imaging

Intra-operative imaging was performed using the SPY™ imaging system. This imaging system makes use of the fluorescence properties of ICG to acquire images of grafts and native coronary arteries. The device incorporates an 806 nm laser light source that illuminates an area of 7.5×7.5 cm^2 on the surface of the heart. As ICG passes through this field of illumination it fluoresces, emitting light in a broad band centered at 830 nm. This fluorescence is captured by means of a charged coupled device video camera equipped with appropriate filters to block the passage of laser (and room) light while maximizing transmission of the emitted fluorescence light. Images are captured at a rate of

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30/s and downloaded directly to the computer disc. Images of grafts are seen in real time and may also be reviewed immediately following capture. The imaging device is composed of an imaging head that contains the optical components and a mobile cart that contains the electrical controls and the computer. The imaging head is attached to the cart by means of an articulating arm that allows the cart to be positioned approximately 1 m from the operating table.

Imaging of each graft takes 2–3 min. The imaging head, enclosed in a sterile drape, is positioned about 30 cm above the heart. Selection of the appropriate field of view is achieved with the aid of a real time image on the monitor. For each image sequence a bolus of ICG (2.5 mg in 1.0 ml) is injected into the central venous line. At the same time the laser is activated by means of a command to the computer. Within 5–6 s fluorescence images of the grafts and coronaries are seen on the monitor. The fluorescence is initially seen in the coronary arteries and grafts, then in the microcirculation as a background flush and finally washing out through the coronary veins. The laser shuts off automatically after 30 s at which time another image sequence can be acquired. Images can only be acquired during the first pass of the bolus of ICG through the field of view. Once the ICG has distributed throughout the blood volume, the concentration is too low for further acquisition. Subsequent image acquisition requires injection of a further bolus of ICG for each image sequence acquired.

ICG has been widely used for over 40 years for measuring cardiac output, assessing hepatic function and for ophthalmic angiography. The drug has an excellent safety profile with a low incidence of adverse effects [3,4]. Based on the data from the developing company (Daiichi Pharmaceutical Co., Ltd Tokyo), the adverse drug reaction rate of ICG is lower (0.17%) than iohexol iodine contrast media (2.65%). (Table 1).

The ICG is excreted unchanged by the liver with a half life of 3–5 min, thus there is no potential for nephrotoxic effects for those patients with compromised renal function.

2.2. Surgical management

Seventy-two consecutive patients undergoing off-pump CABG in our institute were included in the study. Eight patients underwent minimally invasive direct coronary artery bypass (MIDCAB) via a small incision without sternal splitting. The other 64 patients underwent off-pump CABG via median sternotomy (OPCAB). The average age was 68.5 years, and 21 females were included. Twenty-one (29.2%) patients underwent emergency operation for acute coronary syndrome. Twenty (27.8%) suffered from diabetes mellitus, and six patients were receiving dialysis for chronic renal failure.

Table 1
Comparison of the incidence of adverse drug reaction rates for indocyanine green and iohexol iodine contrast media

	Contrast media (iohexol)	ICG
ADR reporting no./total no.	452/17,039	36/21,278
ADR %	2.65	0.17
Cardiovascular ADR %	0.33	0.023

ICG, indocyanine green; ADR, adverse drug reaction.

The internal thoracic artery (ITA) was dissected in a full skeletonized fashion using a harmonic scalpel. The radial artery was also completely skeletonized. Syringe infusion of diluted olprinone hydrochloride (Eisai Co., Ltd, Tokyo) into the interspaces between the radial artery and the fascia was very useful to prevent spasm, when fasciotomy was performed. The DONUT™ Heart Stabilizer (MediVas LLC, San Diego, CA, USA) invented by the author [5–7] was utilized in most patients to achieve a stable operative field on the beating heart.

Our operative strategy for isolated coronary artery disease is complete arterial revascularization for all stenosed coronary branches. The total number of distal anastomoses was 290. The average number of distal anastomoses was 1.38 in MIDCAB, and 4.36 in OPCAB. Two patients received maximal nine bypass grafts. One hundred and ninety-one conduits were utilized, including 72 ITAs, 68 RAs, 42 saphenous veins, 8 gastroepiploic arteries, and 1 inferior epigastric artery. 53.4% of conduits were used as single grafts (one distal anastomosis per graft), and 46.6% were sequential grafts (more than one distal anastomosis per graft). Target arteries included 79 (27.2%) left anterior descending (LAD), 40 (13.8%) diagonal, 13 (4.5%) intermediate, 57 (19.7%) obtuse marginal, 31 (10.7%) circumflex, 36 (12.4%) posterior descending, 15 (5.2%) posterior lateral, 12 (4.1%) major right coronary artery, and 7 (2.4%) right ventricular branch. Proximal radial or venous anastomoses were constructed onto the aorta in most cases. Chest computed tomography scan was routinely performed to rule out aortic calcification, or intra-operative direct aortic echocardiogram was performed when the pre-operative computed tomography scan had not been performed in emergent cases.

3. Results

3.1. Clinical outcomes

Off-pump CABG could be safely performed in all 72 patients, even in emergency cases. No adverse drug reactions of ICG were observed. There were no operative deaths, peri-operative myocardial infarction, additional intra-aortic balloon pumping, and cerebral infarction. No major complications occurred post-operatively.

3.2. Imaging results

Excellent quality SPY images could be obtained for all 290 distal anastomoses. Examples of the images are shown in Video 1.

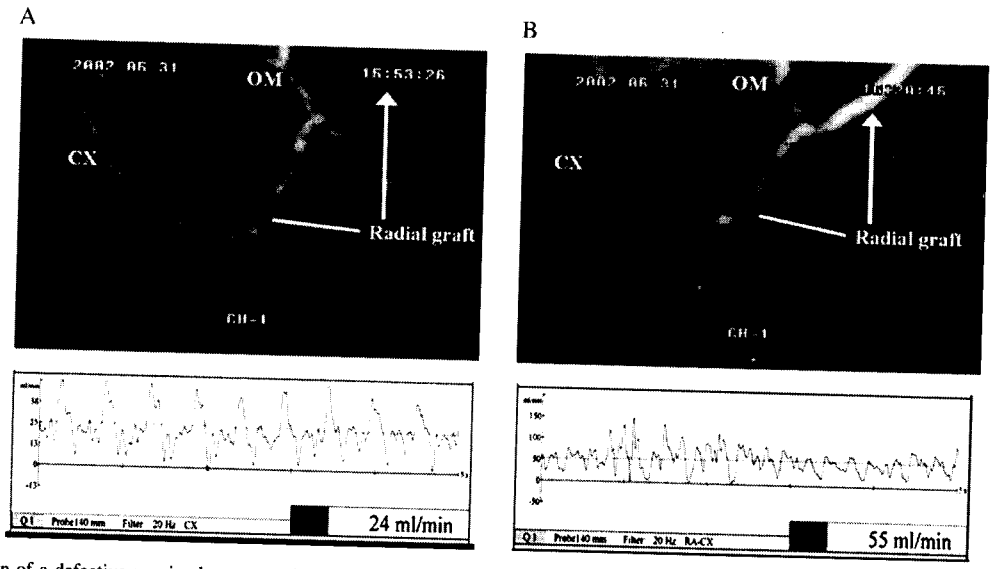

Fig. 1. Detection of a defective proximal anastomosis in a radial artery graft. A radial artery was grafted from the aorta to the obtuse marginal 1 and the circumflex. Fluorescence images were acquired as described in the legend to Video 1. (A) Fluorescence image acquired following completion of the graft. The arrow indicates the lack of fluorescence signal in the proximal segment of the graft. Note that the transit-time flow measurement indicates an adequate flow of 24 ml/min with a diastolic dominant waveform. (B) Fluorescence image of the same graft following revision of the proximal anastomosis. The arrow indicates excellent filling of the proximal segment of the graft. Note that the transit-time flow measurement has now increased to 55 ml/min. LITA, left internal thoracic artery; OM, obtuse marginal artery; CX, circumflex artery.

The skeletonized conduits provided better visualization than pedicled ones.

Four anastomoses (1.4%), including two proximal and two distal, were revised because of defects detected by SPY images. In a 66-year-old male patient, images obtained using the SPY™ system indicated no blood flow in the proximal segment of a radial artery sequentially grafted from the aorta to obtuse marginal 1 and the circumflex, although the transit-time flow meter showed a diastolic dominant pattern. After revision of the proximal anastomosis, excellent flow in all segments of the graft could be observed in the SPY images (Fig. 1). Following graft revision the transit-time flow measurement increased to 55 ml/min (from 24 ml/min observed prior to revision). In an 88-year-old female, the left ITA was anastomosed sequentially to the diagonal and the LAD. SPY images showed occlusion of the ITA graft between the diagonal and the LAD. After revision of the anastomosis to the diagonal, excellent flow to the LAD could be observed in the SPY images (Fig. 2 and Video 2).

In several cases of competitive blood flow between the graft and native coronary artery, SPY imaging could demonstrate the anastomotic patency (Fig. 3).

3.3. Comment

In this report we have described intra-operative graft validation during off-pump CABG using the SPY™ imaging system. Real time images of grafts are obtained following injection of a low dose of ICG via the central venous line. The imaging is very rapid and safe with no need for catheterization, X-rays or iodine contrast media.

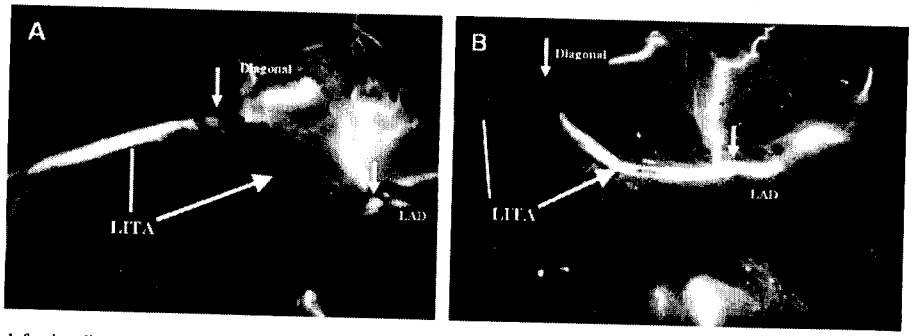

Fig. 2. Detection of a defective distal anastomosis in a left ITA graft. A left ITA was sequentially grafted to the 1st diagonal branch and to the LAD. Fluorescence images were acquired as described in the legend to Video 1. (A) Fluorescence image acquired upon completion of the graft. The arrow indicates lack of fluorescence in the segment of the graft between diagonal 1 and the LAD. (B) Fluorescence image acquired following revision of the distal anastomosis to the diagonal branch. The arrow indicates excellent filling of the distal segment of the graft. LITA, left internal thoracic artery; LAD, left anterior descending artery.

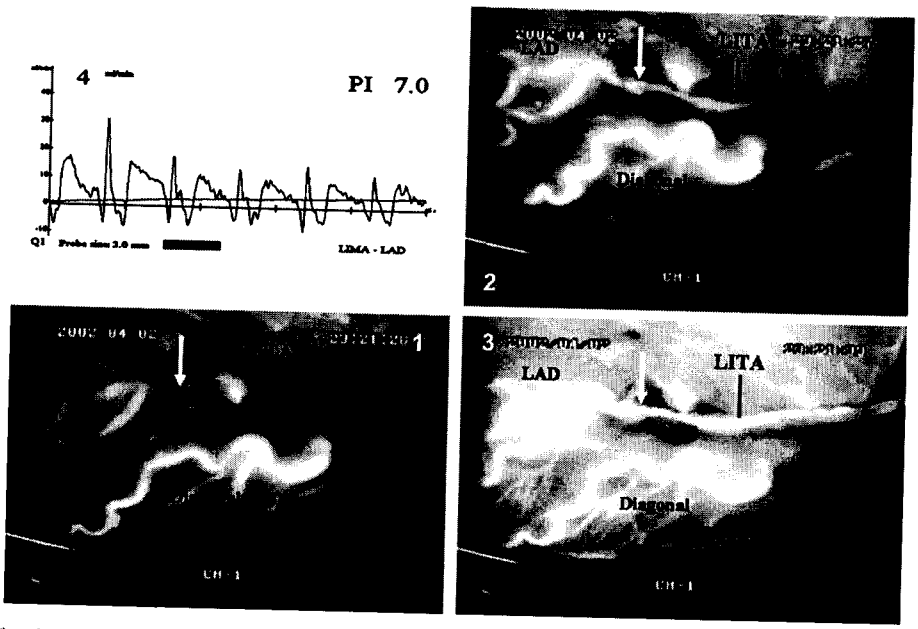

Fig. 3. Verification of graft patency in the presence of competitive native coronary flow. LITA, left internal thoracic artery; LAD, left anterior descending artery.

SPY images could show the real-time graft flow even in case of competitive graft flow.

Several techniques for intra-operative graft validation have been introduced. Transit-time flow measurement [8] is a very easy device to use, however, it cannot show the visual image of the graft. When the graft is subjected to spasm, or the stenosis of the native coronary artery is not very severe, flow measurement data may not be diagnostic (Fig. 3). Epicardial echocardiogram [9] and thermal coronary angiography [10] have been employed as non-invasive graft assessment technologies. However, they are very difficult to use for lateral or posterior wall coronary arteries and additionally provide very poor resolution. Conventional intra-operative X-ray angiography using portable digital subtraction angiographic device requires the use of iodine contrast media, and risky catheter insertion into the ostia of the grafts. The SPY™ system may overcome the problems and deficiencies of the above-mentioned alternate technologies.

For surgeons, great courage is necessary to decide whether the anastomosis must be revised or not, even in situations when they are not totally confident in the quality of the anastomosis they performed. SPY images provide critical information to surgeons to confidently detect non-patent grafts, allowing them to be revised while the patient is still on the operating table. Taggart et al. [2] reported that compromised graft flow occurred in 5% of the patients and in 1.9% of all grafts performed. We also revised the anastomoses in 1.4% of all 290 grafts in this series. This device may greatly contribute not only to the patients' life but also to the surgeons' work.

There are some limitations to this technology. First, it does not provide an exact graft flow quantity measurement. Quantitative graft flow measurement software is currently being investigated. Second, the laser light source is of relatively low power to ensure safe clinical use. However, this limits the penetration of the light through tissue to about 1 mm. Thus, clear images could not be obtained when the coronary artery has a deep intra-myocardial location. The pedicled conduits with significant amounts of overlying tissue are also less well visualized. However, we believe that full skeletonization of the arterial conduits is a very useful and important technique for complete arterial revascularization of all the coronary vascular regions. We believe that the use of the full skeletonization technique may optimize the long-term graft patency. In Europe, the cost of the procedure may be around 200–350 €. This will include use of the device, ICG and the drape.

4. Conclusions

The SPY™ system is a very useful technique for intra-operative graft validation. The device has the great advantages of non-invasiveness and safety. The ability to confidently confirm graft patency at the time of surgery encourages the surgeon to attempt challenging techniques and strategies. Off-pump CABG using SPY™ intra-operative validation may become the gold standard for surgical management in the near future.

Acknowledgements

We gratefully acknowledge the help of Dr John Docherty in the preparation and translation of the manuscript.

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Appendix A. Conference discussion

Dr B. Walpoth *(Geneva, Switzerland)*: I would like to congratulate you on your clinical study with a new promising device. I agree with you that you will have a morphologic imaging and you will know where the problem is, especially if you measure flow and you have a low-flow situation.

In occlusions, however, both techniques will confirm the occlusion, but none of the techniques will give you the exact localization. How long does this technique take to do in the operating room and how many injections can you perform and how fast is the washout of the contrast?

Dr Takahashi: Two or three minutes to take one picture. I dilute the ICG to 20 ml, and one time I used 1 ml of diluted ICG, so 20 times we can do for the one patient.

Dr Walpoth: So the washout is very rapid?

Dr Takahashi: Yes.

Dr Walpoth: You have no staining of the myocardium?

Dr Takahashi: That's right.

Dr B. Buxton *(Heidelberg, Vic., Australia)*: An excellent technique. It has potential use for us as surgeons. Did you detect spasm during your technique, particularly in the radial artery grafts, and if so, what steps did you take to eliminate the spasm? Also, could you tell spasm from a mechanical obstruction or narrowing?

Dr Takahashi: When the graft is patent?

Dr Buxton: When the graft is patent and looked narrowed such as that last demonstration, did you take any steps to eliminate the spasm, with the use of GTN or a PD-III inhibitor?

Dr Takahashi: I have never experienced graft occlusion due to spasm after I used full skeletonized arterial graft and PD-III inhibitor to prevent spasm. So I recognized that all the non-functional grafts detected by SPY system cause technical failure.

Dr Buxton: Could you see a technical failure on your imaging technique and correct it?

Dr Takahashi: Sorry, I can't understand.

Dr Dion: The question is, this tool, did it change something to your technique, did you do something differently technically to perform the anastomosis? Did this tool, this imaging, influence your surgical technique for the anastomosis?

Dr Takahashi: Yes. I always prefer to use the fully skeletonized radial arterial graft, after SPY system has been introduced in my hospital. The spasm is not a reason for the non-functional graft detected by SPY, just technical failure I think, I believe it.

Appendix B. ICVTS on-line discussion

Author: ***Dr. Hitoshi Hirose***, *Juntendo Univesity Hospital, Department of Cardiovascular Surgery, Hongo, Bukyo-ku, Tokyo*

Date: 18-May-2004

Message: The SPY system would be an excellent modality to evaluate the bypass patency in the operating room. One of the advantages of the SPY over the flow prove is the capability to detect sequential bypass. In sequential bypass, if one of the anastomosis is patent, the flow meter may give normal value and normal wave form (false positive), because the flow is dependent on one of the patent anastomoses. By using the SPY, as the figure shown by the authors illustrates, each sequential anastomosis patency can be detected individually. I believe this to be an important point of the SPY system.

Author: ***Dr. Kenji Minakata***, *The Tominaga Hospital, Division of Cardiovascular Surgery, 1-4-48 Minatomachi, Naniwa-ku, Osaka-city, 556-0017 Japan*

Date: 26-May-2004

Message: This is a very nice study which introduces a new device to evaluate the quality of graft anastomoses during off-pump CABG. As OPCAB is getting more popular, the issue of long-term graft patency raises a great interest. Clearly, it is necessary to improve the early outcome to have better long-term results. The authors demonstrate in the article that the SPY system can be used both very safely and easily as well as detect potential technical failures during OPCAB thus allowing the surgeons to revise it at the same time. Since I personally observed this device recently, it is absolutely true that the images are quite vivid and impressive with great resolution. I agree with the authors that the SPY system can be a standard tool just like a TEE in the field of modern cardiac surgery, pretty soon.

The Journal of
Thoracic and Cardiovascular Surgery

Does off-pump total arterial grafting increase the incidence of intraoperative graft failure?

Lognathen Balacumaraswami, Yasir Abu-Omar, Kyriakos Anastasiadis, Bikram Choudhary, David Pigott, Siu-Kae Yeong and David P. Taggart

J Thorac Cardiovasc Surg 2004;128:238-244

Does off-pump total arterial grafting increase the incidence of intraoperative graft failure?

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Taggart, Balacumaraswami, Pigott, Abu-Omar, and Choudhary *(left to right)*

Background: Early graft failure is a common cause of cardiac mortality and morbidity after coronary artery bypass grafting, but there is little information on its natural incidence. Furthermore, there is particular concern about graft patency in off-pump coronary artery bypass grafting and total arterial grafting.

Methods: We performed a prospective observational study to assess intraoperative graft patency in patients undergoing off-pump and on-pump coronary artery bypass grafting, who also underwent total arterial grafting. We used an intraoperative imaging system, SPY (Novadaq Technologies Inc), based on the fluorescent properties of indocyanine green dye.

Results: We assessed the intraoperative graft patency of 533 conduits in 200 patients. The mean number of grafts was 2.7 per patient. Of these patients, 155 (78%) had off-pump coronary artery bypass grafting, and 45 (22%) had on-pump coronary artery bypass grafting. Overall, 161 (80%) had total arterial grafting, with composite arterial grafting performed in 120 (60%) patients. Fluorescence, confirming graft patency, was observed in all but 8 (1.5%) conduits in 8 (4%) patients, necessitating graft revision. Six (3.9%) and 2 (4.4%) of these patients, respectively, had off-pump coronary artery bypass grafting and on-pump coronary artery bypass grafting.

Conclusion: Intraoperative fluorescence imaging demonstrated a low (1.5%) but well-defined incidence of intraoperative graft failure, which affects around 4% of patients. This emphasizes the need for routine assessment of graft patency. Intraoperative fluorescence imaging permits detection and revision of failed grafts in the operating room. We found no difference in the incidence of failed grafts when comparing on-pump and off-pump total arterial grafting.

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There is growing evidence that arterial grafts[1-3] and off-pump coronary artery bypass grafting (OPCABG)[4] improve the outcome of coronary revascularization.

However, total arterial grafting (TAG) and OPCABG are considered to be technically more demanding, and there are continuing concerns that OPCABG results in both a reduced number of grafts[5] and inferior patency rates.[6-8] Cheng and colleagues[5] reported that technical difficulties in constructing anastomoses resulted in incomplete revascularization in patients undergoing OPCABG (mean distal anastomoses, 1.9 vs 3.3; $P < .001$) when compared with those undergoing on-pump coronary artery bypass grafting

(ONCABG).[5] Sabik and colleagues[9] likewise reported a significantly lower number of grafts in patients undergoing OPCABG (2.8 vs 3.5, $P < .001$), particularly to the circumflex and right coronary territories. Gundry and associates[7] reported that 20% of patients undergoing OPCABG required either a coronary angioplasty or redo coronary artery bypass grafting (CABG) for recurrent symptoms. Most recently, in a prospective randomized trial of 104 patients allocated to ONCABG or OPCABG, Khan and colleagues[8] reported an inferior 3-month angiographic patency rate of 88% in the OPCABG group compared with 98% in the ONCABG group ($P < .01$).

Recently, we described the value of an intraoperative fluorescence imaging (IFI) system (SPY, Novadaq Technologies Inc) to confirm graft patency.[10] We have now used this system to prospectively compare graft patency in patients undergoing, predominantly, total arterial grafts in the setting of ONCABG and OPCABG.

Material and Methods

All patients undergoing CABG performed by a single surgeon (DPT) between November 2001 and June 2003 were included in the study, with the exception of a few cases when the imaging system was not available. Our general principle is to perform off-pump TAG whenever practical and feasible. In general, ONCABG is performed in patients with poor left ventricular function (ejection fraction, <25%). Likewise, there is a higher use of vein grafts rather than radial artery grafts in patients with poor left ventricular function because of the higher likelihood of need for inotropic support.

Intraoperative graft patency data were collected prospectively in patients undergoing CABG with the IFI system (SPY, Novadaq Technologies Inc) on the basis of fluorescence of indocyanine green (ICG). We have described this technique previously.[10] Briefly, ICG rapidly binds to plasma proteins when injected intravenously and fluoresces (emits light at 830 nm) when illuminated with a monochromatic laser light source at 806 nm. The fluorescence is captured on a charged couple device video camera. The low-intensity laser, with a total output of 2.7 W over an area of 7.5 × 7.5 cm at a distance of 30 cm above the heart, has an excellent safety profile for both the patient and theater staff. In particular, it does not require any eye protection. The system has CE marking in Europe, which allows patient use in the European community.

ICG has been widely used in clinical practice, particularly in ophthalmic angiography, for over 4 decades and has an excellent safety profile. The incidence of allergic reaction to ICG is approximately 1:40,000 and has been reported especially in patients allergic to iodine.[11] The risk is strongly dose dependent, being greatest with doses greater than 0.5 mg/kg body weight.

The sterile draped camera head, guided by a range detector diode, was positioned at 30 cm above the heart. After completion of the distal coronary anastomosis, 1 mL (0.03 mg/kg weight) of ICG dye was injected into the oxygenator in the ONCABG group or through the central venous line and flushed through with 10 mL of normal saline in the OPCABG group. Screening was started at the time of injection, and the grafts were imaged as the fluorescent dye passed through them. Images were then recorded on the computer hard drive. The procedure took approximately 3 minutes per anastomosis. Skeletonized conduits provided better visualization than pedicled ones. The appearance of fluorescent images as the dye passed through the bypass grafts confirmed graft patency.

Surgical Technique

All patients underwent CABG through a median sternotomy. Both internal thoracic arteries (ITAs) were harvested as skeletonized conduits. The radial artery (RA) was harvested and stored in heparinized blood containing phenoxybenzamine in the earlier patients[12] and additional verapamil in the later patients[13] before performing the anastomosis. The long saphenous vein was harvested by using a minimally invasive technique.

Although there are several variations depending on precise coronary anatomy and disease patterns, our basic primary strategy for construction of anastomoses was to place the right ITA (RITA) to the left anterior descending artery, the left ITA (LITA) to the obtuse marginal branch of the circumflex artery, and a composite RA graft from the LITA to the posterior descending branch of the right coronary artery.

The ITA conduits were used as in situ grafts to perform single or sequential distal coronary anastomoses. Some of the ITA and RA conduits were recycled and used for constructing composite Y grafts to maximize their use. In a few cases, the recycled free ITA conduits were anastomosed as Y grafts from the parent in situ ITA to achieve composite grafting. Where possible, composite multivessel grafting was performed to achieve TAG, with complete avoidance of aortic manipulation.

ONCABG

Cardiopulmonary bypass (CPB) was instituted by using ascending aortic cannulation and a 2-stage venous cannulation in the right atrium. A standard CPB circuit incorporated a roller pump (Jostra HL 20) and a hollow-fiber membrane oxygenator (Affinity NT, Medtronic). The extracorporeal circuit was primed with 1000 mL of Hartmann solution and 2500 IU of heparin. Nonpulsatile flow with a flow rate of 2.4 $L \cdot m^{-2} \cdot min^{-1}$ was maintained. Arterial filtration was not used. Cardiotomy suction was used. Acid-base balance was managed with alpha-stat control. The temperature was allowed to drift to 34°C during construction of anastomoses before rewarming. Myocardial protection was achieved with intermittent antegrade cold crystalloid cardioplegia. On completion of all distal anastomoses, the aortic crossclamp was removed, and the proximal anastomosis was performed with partial clamping.

OPCABG

Complete anticoagulation with heparin was achieved as in the CPB group. The lateral and inferior walls were exposed by means of a combination of a deep pericardial stay suture, Trendelenberg and right decubitus positions, and opening of the right side of the pericardium to the inferior vena cava. Regional myocardial immobilization was achieved with a suction stabilizer (Octopus, Medtronic Inc; Guidant, Cardiothoracic Systems Inc). The target coronary vessels were snared proximally with a silastic sling. In our earlier experience, an intracoronary shunt (Guidant Axius) was used when there were signs of electrocardiographic instability or excessive bleeding during construction of the anastomosis. Lat-

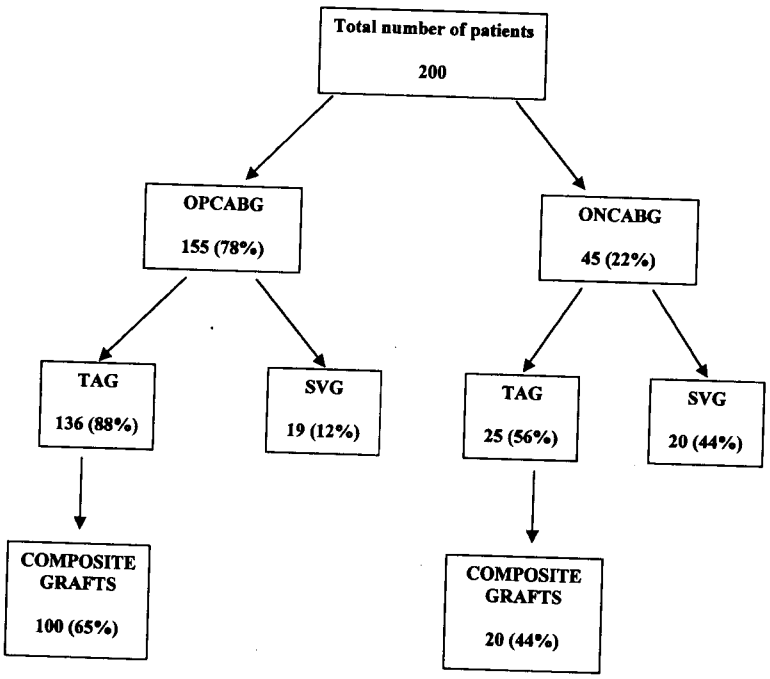

Figure 1. Flow diagram. *OPCABG*, Off-pump coronary artery bypass grafting; *ONCABG*, on-pump coronary artery bypass grafting; *TAG*, total arterial graft; *SVG*, saphenous vein graft.

terly shunts have been used routinely. A surgical blower-mister device enhanced visualization (Medtronic Clearview, Medtronic Inc).

Off-pump TAG with avoidance of aortic manipulation was achieved in 84.5% of cases. In the occasional cases in which saphenous vein grafts were performed, proximal anastomoses were made to the ascending aorta at a controlled systolic pressure of between 70 and 80 mm Hg and a side-biting vascular clamp.

Statistical Analysis

Results for categoric variables are expressed as numbers (percentages of total). Continuous variables are presented as means ± SD. The χ^2 test was used for comparison of categoric variables. The continuous variables were compared by using the Student t test.

Results

Intraoperative graft patency was assessed in 200 patients. Our previously reported preliminary experience of 84 patients is included in this study.[10] A total of 533 distal coronary anastomoses were constructed. The ONCABG group includes 3 patients with concomitant aortic valve replacement and 1 patient undergoing reoperative CABG. In the OPCABG group 5 patients underwent reoperative CABG.

The mean number of distal anastomoses was 2.7 per patient. Of these patients, 155 (78%) underwent OPCABG, and 45 (22%) underwent ONCABG (Figure 1). The mean number of distal anastomoses for the ONCABG group was 2.9 per patient compared with 2.6 per patient for the OPCABG group ($P < .05$, Table 1). However, the OPCABG group had a higher proportion of patients with single-vessel or double-vessel disease. In patients with triple-vessel disease, the mean number of grafts for the OPCABG and ONCABG groups was similar (OPCABG, 3.2 ± 0.4; ONCABG, 3.3 ± 0.5), with no difference between the 2 groups.

Overall, 161 (80%) patients had TAG, of which composite arterial grafting was performed in 120 (60%) patients. TAG was performed in 136 (88%) patients in the OPCABG group and 25 (56%) patients in the ONCABG group. A total of 100 (65%) composite grafts were performed in patients undergoing OPCABG, which was significantly more ($P = .05$) than the 20 (44%) grafts in the ONCABG group (Table 1). Excluding those with single-vessel disease, bilateral ITA conduits were used in 109 (59%) patients: 87 (62%) in the OPCABG group and 22 (51%) in the ONCABG group.

There was no significant difference in the number and location of coronary arteries bypassed or the number of ITA grafts between the 2 groups. There were significantly more saphenous vein grafts (OPCABG, 6% of grafts; ONCABG, 24% of grafts; $P < .01$) and significantly fewer RA grafts (OPCABG, 29% of grafts; ONCABG, 18% of grafts; $P < .05$) used in constructing the distal anastomoses in the ONCABG group because of a higher proportion of patients with poor left ventricular function in the ONCABG group. The overall pattern of conduit use include the LITA in 216 (40.5%) distal anastomoses, the RITA in 119 (23%) distal

TABLE 1. Mean age and anastomoses, diseased vessels, conduits used, and composite grafts in patients

Variable	OPCABG (n = 155)	ONCABG (n = 45)	*P* value
Mean age (y)	63.7 ± 10.6	63.2 ± 10.7	.71
Mean anastomoses	2.6 ± 0.8	2.9 ± 0.9	.02
Mean anastomoses in triple-vessel disease	3.2 ± 0.4	3.3 ± 0.5	.1
Single-vessel disease (%)	15 (9.7)	2 (4.4)	.26
Double-vessel disease (%)	49 (31.6)	11 (24.4)	.35
Triple-vessel disease (%)	91 (58.7)	32 (71.1)	.13
BITA (%)	87 (56)	22 (48.9)	.39
LITA (%)	150 (97)	44 (98)	.73
RITA (%)	91 (59)	25 (56)	.71
RA (%)	103 (66)	23 (51)	.06
SVG (%)	19 (12)	18 (40)	<.01
Composite grafts (%)	100 (65)	20 (44)	.05

OPCABG, Off-pump coronary artery bypass grafting; *ONCABG*, on-pump coronary artery bypass grafting; *BITA*, bilateral internal thoracic arteries; *LITA*, left internal thoracic artery; *RITA*, right internal thoracic artery; *RA*, radial artery; *SVG*, saphenous vein graft.

TABLE 2. Overall configuration of conduit use in distal anastomoses (patients, n = 200; conduits, n = 533)

Distal vessel	No. of patients*	LITA, n (%)	RITA, n (%)	RA, n (%)	RGEA, n (%)	SVG, n (%)	Total
LAD	189	88 (16.5)	100 (18.7)	4 (0.7)	-	6 (1.1)	198
DIAG	49	19 (3.5)	3 (0.6)	25 (4.7)	-	2 (0.3)	49
INT	24	11 (2)	1 (0.1)	10 (1.8)	-	2 (0.3)	24
OM	137	95 (17.7)	8 (1.5)	32 (6)	-	15 (2.8)	150†
RCA	3			1 (0.1)		2 (0.3)	3
PDA	103	1 (0.1)	7 (1.3)	67 (12.5)	2 (0.3)	27 (5)	104
LVBR	5	2 (0.3)	-	2 (0.3)	-	1 (0.1)	5
Total		216	119	141	2	55	533

LITA, Left internal thoracic artery; *RITA*, right internal thoracic artery; *RA*, radial artery; *RGEA*, right gastroepiploeic artery; *SVG*, saphenous vein graft; *LAD*, left anterior descending artery; *DIAG*, diagonal branch; *INT*, intermediate artery; *OM*, obtuse marginal branch of the circumflex artery; *RCA*, right coronary artery; *PDA*, posterior descending branch of the right coronary artery; *LVBR*, left ventricular branch of the right coronary artery.
*The total number of grafts to each distal coronary target might not add up due to the same vessel being grafted twice in a small number of patients.
†The total number of grafts to the obtuse marginal vessel includes 12 patients with grafts to 2 obtuse marginal vessels.

TABLE 3. Revised grafts

No.	Age (y)	Sex	No. of diseased vessels	CABG on-off pump	Culprit anastomosis	Revision with good flow
1	77	M	2	Off	LITA to LAD	Distal vein graft to LAD
2	55	F	1	On	LITA to LAD	Revised LITA to LAD
3	66	M	3	Off	RA from RITA as Y graft to OM	Revised RITA-RA anastomosis
4	57	M	3	Off	LITA to OM	Revised LITA to OM
5	74	M	3	On	LITA to OM	Revised LITA to OM
6	68	M	3	Off	RA from LITA as Y graft to OM	Revised LITA-RA anastomosis
7	72	M	3	Off	RA to diagonal branch	Revised RA to diagonal graft
8	68	F	2	Off	LITA to OM	Revised LITA to OM

CABG, Coronary artery bypass grafting; *LITA*, left internal thoracic artery; *LAD*, left anterior descending artery; *RA*, radial artery; *OM*, obtuse marginal branch; *RITA*, right internal thoracic artery.

anastomoses, the RA in 141 (25.5%) distal anastomoses, the gastroepiploic artery in 2 (0.4%) distal anastomoses, and the long saphenous vein in 57 (10.6%) distal anastomoses. The configuration of conduits anastomosed to various distal coronary targets is shown in Table 2. Overall, the LITA was used as a recycled conduit or in sequential grafts in 20 (10%) patients. The RITA and RA conduits were each recycled in 3 patients.

TABLE 4. Graft revision reports in the literature

Published reports	Operation	Intraoperative technology used to assess graft patency	No. of patients	No. of grafts	Graft revision (% patients)	Graft revision (% grafts)
D'Ancona and coworkers[6]	OPCABG	Transit-time flowmetry	409	1184	7.6	3.2
Falk and coworker[17]	ONCABG	Thermal angiography	370	370	-	5 (ITA)
Louagie and coworkers[22]	ONCABG	Pulsed Doppler flow analysis	352	ITA, 698 SVG		1 (SVG)
Mack and coworkers[19]	MIDCABG	Conventional angiography	103	909	2	
Taggart and coworkers[10]	OPCABG and ONCABG	Fluorescence imaging	84	103	-	3
Walpoth and coworker[15]	ONCABG	Transit-time flowmetry	46	213	5	1.9
Hol and coworkers[20]	OPCABG	Conventional angiography	45	-	6.5	-
Reuthebuch and coworker[21]	OPCABG	Fluorescence imaging and transit-time flowmetry	37	57	-	5
Lin and coworkers[16]	MIDCABG	Pulsed Doppler flow analysis	35	107	-	3.7
				35	8.5	8.5

OPCABG, Off-pump coronary artery bypass grafting; *ONCABG*, on-pump coronary artery bypass grafting; *ITA*, internal thoracic artery; *SVG*, saphenous vein graft; *MIDCABG*, minimally invasive direct coronary artery bypass grafting.

Eight (1.5%) grafts in 8 (4%) patients demonstrated no fluorescence within the conduits during image acquisition (Table 3). None of these grafts were imaged again to demonstrate flow. Hence we cannot label any of these as spasm. None of these patients demonstrated intraoperative electrocardiographic or hemodynamic changes. In 2 patients graft failure was caused by dissection in the conduit wall, in 2 patients it was caused by intimal flaps in the native coronary vessel, in 1 patient it was caused by an inadvertent stitch in the posterior wall of the coronary vessel, and in 1 patient it was caused by kinking at the heel of the anastomoses. In 2 patients there was no readily discernable cause. Two (4.4%) of these patients underwent ONCABG, and 6 (3.9%) underwent OPCABG. There was no statistical difference in the number of grafts revised between the 2 groups. The occluded grafts were revised, after which the grafts were reimaged and patency was confirmed with the IFI system.

On initial imaging, 5 (0.9%) grafts performed to the posterior descending coronary artery and 4 (0.75%) to the obtuse marginal branch of the circumflex artery did not demonstrate fluorescence, whereas the heart was "distorted" by being "upended" with a suction cap. However, on subsequent imaging, with the heart in its natural position, flow could be seen in the proximal portion of the graft, confirming graft patency. We assume that lack of flow in initial imaging was due to a transient decrease in cardiac output and systemic arterial pressure combined with compression of the graft between the lateral border of the heart and the sternal edge. In one patient the RITA-to-intermediate-artery anastomosis did not demonstrate fluorescence on initial imaging in its natural position but did demonstrate satisfactory flow, with a higher systemic arterial pressure on subsequent imaging. In this case intrinsic graft spasm might be the cause.

Discussion

Although the need for coronary angiography for quality control is universally accepted for percutaneous interventions, most CABG operations are still performed without any immediate confirmation of a satisfactory technical result. Indeed, until recently and in the absence of suitable devices for assessment of graft patency, the current natural incidence of intraoperative graft failure has been poorly documented. Although intraoperative graft failure might be asymptomatic, it can contribute to early morbidity and mortality and adversely affect long-term outcomes.[14] Consequently, there is a growing appreciation of the desirability to confirm graft patency in the operating room, particularly in the setting of new operative techniques and interventions, such as OPCABG and TAG.

Our current prospective study of 200 patients undergoing both on-pump and off-pump CABG confirms our own preliminary experience[10] and the findings of others[6] that there is a small but definite incidence of intraoperative graft failure that can be detected and corrected in the operating room. We found that 8 (1.5%) grafts in 8 (4%) patients were occluded, necessitating revision (Figures 2 and 3). It is of particular importance in these cases of graft occlusion that the surgeon was unsuspecting and that there was no hemodynamic instability or electrocardiographic evidence of myocardial ischemia in the area subtended by the grafted artery. Without formal assessment of graft patency, graft occlusion would have remained undetected.

However, in contrast to the findings of others,[5,7-9] we did not find that OPCABG either reduced the number of grafts or increased the failure rate in comparison with ONCABG. Although the overall mean number of distal coronary anastomoses was significantly higher in the ONCABG group because of a higher proportion of patients with single-vessel or double-vessel disease in the OPCABG group, there was

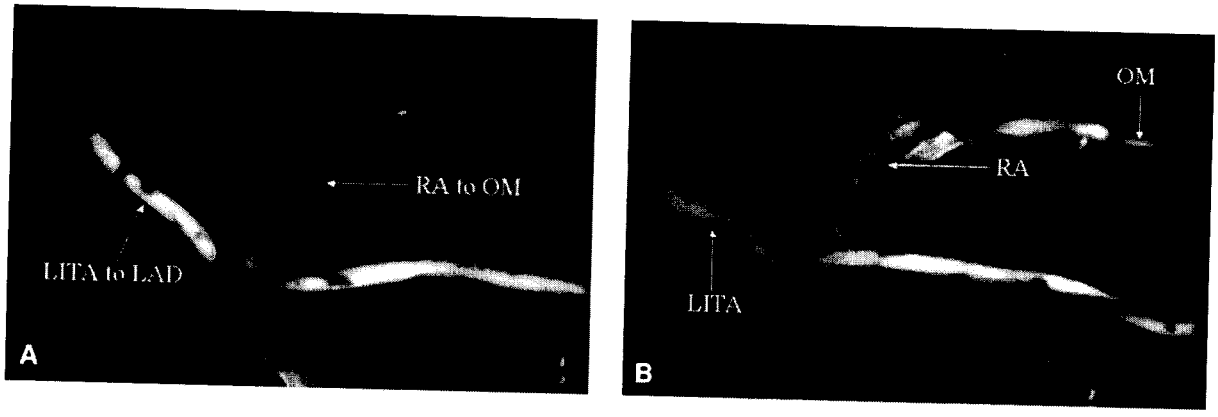

Figure 2. A, Image showing in situ left internal thoracic artery *(LITA)* graft to the left anterior descending *(LAD)* artery. A composite radial artery *(RA)* graft from the LITA is anastomosed to the obtuse marginal *(OM)* artery. Note fluorescence is not seen within the RA. B, This image was taken after revision of the LITA-to-RA anastomosis seen in panel A. Note that fluorescence is now seen in the RA and OM coronary artery.

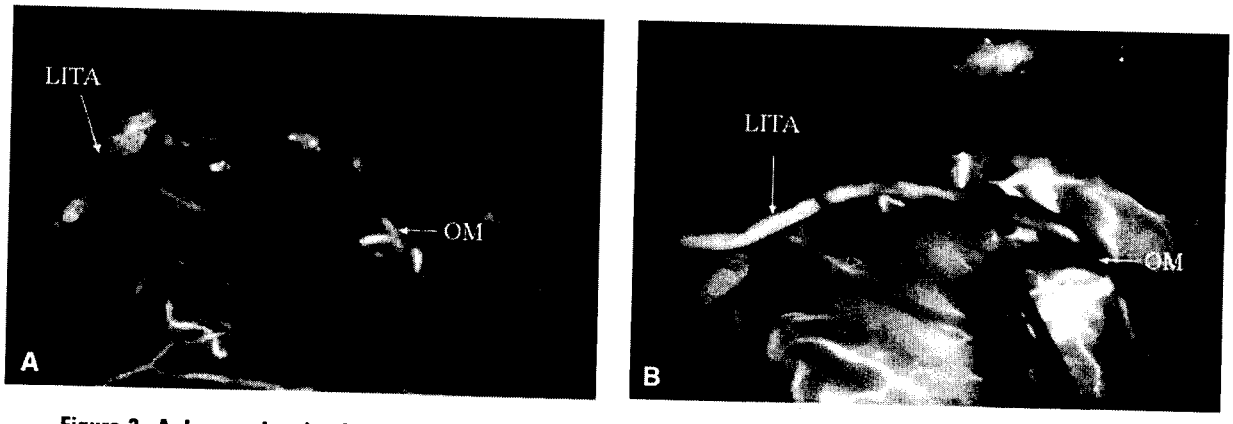

Figure 3. A, Image showing in situ anastomosis of the left internal thoracic artery *(LITA)* to the obtuse marginal *(OM)* artery. Note that no fluorescence is seen in the LITA graft but is seen in the OM artery as a result of native flow. B, Image obtained after revision of the anastomosis in panel A. Note that fluorescence is seen in both the LITA and the OM coronary artery.

no significant difference in the mean number of distal anastomoses in patients with triple-vessel disease in the 2 groups (OPCABG, 3.2 ± 0.4; ONCABG, 3.3 ± 0.5).

The plethora of techniques that have been proposed to confirm graft patency (Table 4)[15-21] emphasizes the lack of a single and universally accepted method. Conventional coronary angiography is the gold standard technique for graft assessment but is highly invasive (requiring arterial puncture), increases operating time, and is infrequently available in the operating room. Although numerous other methods on the basis of electromagnetic,[22] ultrasound,[6,15,23] Doppler flow analysis,[16] echocardiographic,[24] and thermal angiography techniques[25] have been described, all have limitations precluding their widespread use. Currently, transit-time flowmetry (TTFM) and IFI appear most promising.

TTFM uses the principle of ultrasound to measure flow in bypass grafts. A flow probe housing 2 ultrasonic transducers and an acoustic reflector is used to obtain the transit time taken for the wave of ultrasound to travel from one transducer to another. The difference between the integrated transit times is a measure of the flow volume. By using TTFM, D'Ancona and colleagues[6] reported the need to revise 37 (3.2%) of 1145 grafts in 33 (7.6%) of 409 patients undergoing OPCABG. They emphasized the reliance on correct analysis of TTFM flow patterns to correct abnormalities. Absolute mean flow values are of little value, particularly in low-flow situations, and appropriate interpretation of certain derived values, such as the pulsatility index and the diastolic flow index, are variable.

The IFI system, on the contrary, is a simple, safe, and reproducible intraoperative imaging technique that enables routine assessment of graft patency in the operating room. IFI visibly demonstrates graft patency by means of fluorescence of ICG dye as it passes through the graft. The ICG

dye transit time is dependent on various factors, including the diameter of the conduit, systemic arterial pressure, competitive native coronary flow (depends on severity of the native stenoses), and size and state of the distal coronary vascular bed. Proximal snaring of the target coronary vessel with a Silastic sling after completion of the anastomosis[6] eliminates competitive flow and results in a shorter dye transit time with superior fluorescent images.

Although several groups have reported intraoperative patency rates in CABG, to our knowledge, this is the first reported study of intraoperative imaging for graft patency assessment in both ONCABG and OPCABG, which provides evidence to support its routine use in CABG.

Limitations

This is an observational study with all grafts performed by a single surgeon and might overestimate or underestimate the true natural incidence of graft failure. The results are, however, consistent with the incidence of graft failure observed in other reports in the literature. Although the IFI system confirms intraoperative graft patency, it does not permit precise angiographic assessment of the quality of the anastomosis and hence cannot ensure long-term patency, which would require angiographic follow-up studies. The IFI system would be considerably enhanced by means of quantification of graft flow.

Conclusion

IFI demonstrated a low but well-defined incidence of intraoperative graft failure in both on-pump and off-pump operations, which underlines the need for routine assessment of graft patency. An IFI system allows verification of graft patency and immediate correction of failed grafts and should be considered for routine use in patients undergoing CABG.

The camera and the dye were provided by Novadaq Technologies Inc (Toronto, Canada) for investigational purposes.

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Does off-pump total arterial grafting increase the incidence of intraoperative graft failure?

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Resternotomy for Bleeding After Cardiac Operation: A Marker for Increased Morbidity and Mortality

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Abstract

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Over a 2-year period from January 1, 1992, to December 31, 1993, of 2,221 patients undergoing cardiac operations in our unit, 85 (3.8%) were reopened for the control of bleeding (9 patients more than once). The incidence of resternotomy in coronary cases was 2.3%, but resternotomy was more than three times as likely in valve cases (odds ratio, 3.4; 95% confidence interval, 2.1 to 5.4). Previous cardiac operation was more common among resternotomy patients than among the remainder (18% versus 9%, respectively; $p = 0.018$). An identifiable source of bleeding was found in 57 of the 85 patients (67%), but a concurrent coagulopathy was common (45 patients). Resternotomy patients, as a group, had higher preoperative risk scores (Parsonnet) than did the other patients ($p < 0.0001$), stayed longer in the intensive care unit ($p < 0.0001$), and had greater requirements for intraaortic balloon counterpulsation (14% versus 3%) and hemofiltration (9% versus 3%) ($p < 0.0001$ and $p < 0.01$, respectively). Nineteen resternotomy patients (22%) died in the hospital, a proportion significantly greater than the risk assigned to this group of patients preoperatively

(12.8%) ($p = 0.008$). In contrast, the observed mortality for the other 2,136 patients (5.5%) was significantly less (8.3%) ($p < 0.00006$). Multiple forward stepwise logistic-regression analysis confirmed resternotomy for excessive bleeding after cardiac operation to be a significant independent predictor of a prolonged stay in the intensive care unit ($p < 0.0001$), the need for intraaortic balloon counterpulsation ($p < 0.0001$), and death ($p < 0.0001$).

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Excessive bleeding after cardiac operations remains a major source of morbidity and a risk of death for patients. Such patients may require urgent resternotomy and are at greater risk from the hazards of transfusion reactions and blood-borne infections. There have been many studies examining the hemostatic damage inflicted by the cardiopulmonary bypass circuit and others considering the various strategies for blood conservation. However, there has not been a recent appraisal of the incidence of emergency resternotomy for the management of excessive bleeding after cardiac operations nor an assessment of the morbidity and mortality incurred by this group of patients.

Saint George's Hospital is a regional referral center for cardiac surgery. Over a 2-year period (January 1, 1992, to December 31, 1993), we conducted 2,221 cardiac operations, including routine coronary and valve procedures, complex aortic procedures, and cardiac transplantation. This study was performed to examine the incidence, underlying cause, and outcome of resternotomy for excessive bleeding after a cardiac operation in our unit.

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All patients who underwent cardiac operations during the 2-year period January 1, 1992, to December 31, 1993, were entered prospectively onto our computer database. For each patient, the database included a preoperative risk profile and a record of the patient's course in the cardiac intensive care unit (ICU). Using this source, we identified 85 patients who underwent emergency resternotomy for excessive bleeding. Nine patients were reopened more than once, but the data used for these patients in this study pertain only to the first resternotomy. We have calculated the resternotomy incidence for each operation type and a Parsonnet score for each patient. The Parsonnet scoring system [1] stratifies cardiac operations into levels of operative risk on the basis of various preoperative characteristics, and has been validated in British cardiac practice [2].

We recorded the interval between the patient's arrival in the cardiac ICU and return to the operating room for resternotomy, the blood loss, the nature of hemostatic factor replacement

therapy, the coagulation profiles during bleeding, and the findings at resternotomy. We also recorded the clinical outcome for each patient, including the time spent in the ICU as well as the morbidity and survival rates.

All patients undergoing cardiac operation were screened before operation for coagulation abnormalities. This included history-taking and a clinical examination combined with coagulation studies (prothrombin time, activated partial thromboplastin time, and thrombin clotting time). Further hematologic tests were performed when indicated. Patients who were bleeding excessively postoperatively were screened again to search for correctable causes of their bleeding diathesis.

Most patients undergoing elective procedures were asked to discontinue aspirin therapy at least 5 days before admission for their operation. However, many of our patients were urgent referrals who were still receiving aspirin or intravenous heparin up until the time of operation. Hemostatic factors (antifibrinolytic agents and platelets or fresh frozen plasma) were not routinely given. Exceptions included anticoagulated heart transplant recipients, patients with infective endocarditis, and anticoagulated patients undergoing redo valve operations. Patients were anticoagulated before cardiopulmonary bypass with 3 mg/kg of sodium heparin (approximately, 3 U/mL), and the pump prime contained an additional 10,000 units. During bypass, anticoagulation was adjusted to maintain the activated clotting time at greater than 400 seconds. Heparin was reversed after decannulation with protamine sulfate on a 1:1 basis or until the activated clotting time had returned to within 20 seconds of its prebypass value. During bypass, all of the blood from the pericardial and pleural cavities was returned to the bypass circuit by means of cardiotomy suction. At the end of bypass, all remaining blood in the cardiotomy reservoir was returned to the patient. Postoperative autotransfusion of shed mediastinal blood was used in approximately 30% of our patients during the study period.

Statistical analysis was performed using Fisher's exact and Mann-Whitney tests and analysis of proportions, as described by Altman [3]. Multiple forward stepwise logistic-regression analysis was used to assess the influence of resternotomy on morbidity and mortality when Parsonnet scores were taken into account.

The decision to perform resternotomy was made by the surgeon responsible, in line with our published policy [4], which is essentially that as promulgated by Kirklin and Barratt-Boyes [5], as follows:

I. Drainage of:
   - More than 500 mL during the first hour.
   - More than 400 mL during each of the first 2 hours.
   - More than 300 mL during each of the first 3 hours.
   - More than 1,000 mL in total during the first 4 hours.
   - More than 1,200 mL in total during the first 5 hours.

II. Excessive bleeding that restarts (indicating a possible surgical cause).

III. Sudden massive bleeding.

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Patient Characteristics

Eighty-five patients underwent resternotomy for excessive bleeding (3.8% of the total undergoing cardiac operations). Their sex, age, and preoperative risk stratification (Parsonnet score) are summarized in Tables 1 and 2. The sex ratio and age distribution were not significantly different from those of the remaining patients. Taken as a group, the Parsonnet scores in the resternotomy patients were significantly higher than those in the remaining patients (Mann-Whitney, $p < 0.0001$).

View this table: [in this window] [in a new window] *Table 1. . General Characteristics of Resternotomy Patients and Total Patient Population*

View this table: [in this window] [in a new window] *Table 2. . Parsonnet Score Distribution Among Resternotomy and Remaining Patients*

The types of operations performed in these 85 patients are listed in Table 3. In comparing the findings for coronary and valve operations (with or without concurrent coronary artery grafting), valve patients were noted to be more likely to undergo resternotomy for the management of bleeding ($p < 0.00006$), with an odds ratio of 3.4 (95% confidence interval, 2.1 to 5.4).

View this table: [in this window] [in a new window] *Table 3. . Distribution of Operation Types Among the Resternotomy Group and the Total Patient Population*

Fifteen patients (18%) had undergone previous cardiac procedures. This contrasts with a figure of 9% for the remaining patients ($p = 0.018$). Of the 85 resternotomy patients, 8 were anticoagulated with warfarin and another 9 with unstable angina were receiving heparin infusions up until the time of operation. Five of these latter patients had also taken aspirin the day before operation, as had another 9 who were not otherwise anticoagulated.

Cause of Bleeding

Postoperative coagulation studies were performed in 78 patients before resternotomy, and results

were abnormal in 71 (91%). Forty-five of these 71 patients had a surgically correctable cause for their bleeding, in addition to their coagulopathy.

Overall, a surgical cause of the bleeding was found in 57 of the 85 patients (67%). A surgical cause was defined as a clearly identifiable source, and these are listed in Table 4. Twenty-three patients were described as having a ``general ooze'' from the raw surfaces of the mediastinum without a surgical cause being found to explain their excessive blood loss.

View this table: *Table 4. . Findings at Resternotomy*
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The median blood loss before resternotomy, including drainage from the time of chest closure to arrival in the ICU, was 2,156 mL (interquartile range, 1,440 to 2,435 mL) and ranged between 400 and 7,910 mL. The median time to resternotomy was 6.4 hours (interquartile range, 3 to 9 hours), although there were 2 patients well outside this interquartile range: one patient collapsed after removal of his epicardial pacing wires on postoperative day 6 and the other had delayed cardiac tamponade 8 days after aortic valve replacement. The median hourly blood loss for patients with a surgical cause was 305 mL (interquartile range, 203 to 432 mL), and was 431 mL (interquartile range, 240 to 620 mL) for the nonsurgical bleeders (Mann-Whitney, $p = 0.12$).

Before being returned to the operating room, resternotomy patients received a median of 4 units of blood (interquartile range, 2 to 6 units). In addition, many patients received other hemostatic factors, as shown in Table 5.

View this table: *Table 5. . Hemostatic Factors Received by Resternotomy Patients*
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Morbidity and Mortality

The postoperative morbidity was considerable in this group of patients, and the types are summarized in Table 6. Thirty-three patients required inotropic support (balloon counterpulsation in 12 of these-14% of the resternotomy patients), and 8 patients (9%) required hemofiltration after resternotomy. In comparison, among the 2,136 nonresternotomy patients, only 66 received intraaortic balloon counterpulsation (3%) and only 71 patients (3%) required hemofiltration (Fisher's exact test, $p < 0.0001$ and $p < 0.01$, respectively). Consistent with the increased morbidity associated with resternotomy, the ICU stay was also significantly greater in patients reopened for bleeding (Mann-Whitney, $p < 0.0001$) (Table 7).

View this table: *Table 6. . Morbidity After Resternotomy for Bleeding*
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View this table: *Table 7. . Length of Stay in Intensive Care Unit*
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The mortality was also high in the resternotomy group. Nineteen patients (22%) died in the hospital, a proportion significantly greater than the death rate observed for the remaining patients ($p < 0.00006$). Not all of this excess mortality is accounted for by the higher preoperative Parsonnet risk scores in the patients who ultimately required resternotomy. The observed mortality for these patients was significantly greater than the preoperative risk of 12.8% that was allocated to this group ($p = 0.008$). In contrast, the observed mortality for the 2,136 patients who did not undergo resternotomy was significantly less than the preoperative risk (5.5% versus 8.3%; $p < 0.00006$).

Multiple forward stepwise logistic-regression analysis (taking the Parsonnet scores into account) confirmed resternotomy for excessive bleeding after cardiac operations to be a significant independent predictor of prolonged ICU stay ($p < 0.0001$), the need for intraaortic balloon counterpulsation ($p < 0.0001$), and death ($p < 0.0001$). The independent prediction of hemofiltration was of borderline significance ($p = 0.05$).

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Continuing blood loss from bypass graft side branches, anastomotic sites, and other identifiable sources is compounded by a multifactorial hemostatic defect [6]. In this series of resternotomy patients, more than half were found to have both a surgical cause for their bleeding and an abnormality in their clotting screen. Twenty-seven of these patients were either fully anticoagulated before operation or had continued receiving aspirin up to the day of operation, which has been shown to be related to an increased postoperative blood loss and increased resternotomy risk [7].

Our overall resternotomy rate of 3.8% is in keeping with that cited for other published series [8, 9], and the rate for coronary operations is relatively low. These rates demonstrate a dramatic improvement since the early days of extracorporeal bypass for cardiac procedures, when resternotomy rates in excess of 15% were reported [10].

The age and sex profiles between the resternotomy and nonresternotomy patients were

comparable, but the preoperative Parsonnet scores were significantly higher in the resternotomy group. The Parsonnet risk stratification includes operation type and redo operations in its additive model, and therefore part of this difference is accounted for by the distribution of these variables in our resternotomy set. Patients undergoing valve procedures were more than three times as likely to undergo resternotomy for bleeding than were patients undergoing coronary grafting, and 18% of the resternotomy patients had undergone redo cardiac procedures, compared with only 9% in the remainder. This emphasizes the importance of considering the case mix when comparing resternotomy rates among cardiac units.

The burden of morbidity and mortality for patients reopened for hemorrhage is considerable. More than 1 in 5 resternotomy patients in our series subsequently died and many more suffered considerable morbidity. The cost to the unit in terms of added operating room time, extra blood products, invasive interventions, and prolonged ICU stay has been large. Indeed, we have shown in this study that intraaortic balloon counterpulsation and hemofiltration were employed more commonly and that the ICU stay was significantly longer in patients reopened for bleeding.

Is resternotomy for the management of bleeding an independent risk factor for morbidity and mortality after cardiac operations? Parsonnet scores allow us to compare the preoperative risk and observed mortality rates. The observed mortality rate for our resternotomy patients was significantly greater than the risk allocated by the Parsonnet model; that for the remainder was significantly less. Logistic regression modeling, taking Parsonnet scores into account, has confirmed that, not only is resternotomy for excessive bleeding an independent risk factor for death, but also for a prolonged ICU stay and the need for intraaortic balloon counterpulsation, and possibly also for the need for postoperative hemofiltration.

In summary, we have shown that the more complicated cases are at greater risk for requiring resternotomy for bleeding, and that resternotomy is a significant independent marker for morbidity and mortality after cardiac operations. This is in keeping with the concept of a general inflammatory response to cardiopulmonary bypass, which might reasonably be expected to link extensive disruption of the hemostatic mechanisms with other end-organ damage.

Acknowledgments

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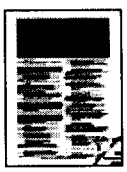

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Increased Fibrinolysis and Platelet Activation in Elderly Patients Undergoing Coronary Bypass Surgery

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Serial angiographic follow-up of grafts one year and five years after coronary artery bypass surgery

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Abstract

Objective: We studied retrospectively the patency of grafts after coronary artery bypass grafting (CABG) using serial angiographies performed one year and five years after surgery. **Methods:** One hundred and nine patients who had available coronary angiographies at both one year and five years after CABG were included. Morphologic changes of anastomotic sites and grafts were traced in the same group of patients using the FitzGibbon grading system. **Results:** The arterial graft patency rate (FitzGibbon grade A + B) was significantly higher than the saphenous vein grafts at both one year (98.0% vs 82.4%, $p < 0.001$) and five years (90.7% vs 80.2%, $p = 0.006$) after surgery, respectively. The arterial graft patency rate was superior to vein grafts in the left anterior descending coronary artery territory at both one year (97.5% vs 82.0%, $p = 0.001$) and five years (90.9% vs 78.0%, $p = 0.042$) postoperatively. Other territories showed similar patency rates between arterial and vein grafts. The vein graft patency rate at five years postoperatively was lowest in the right coronary territory when compared with other territories. When the patency pattern was compared between postoperative years 1 and 5, the proportion of FitzGibbon grade B grafts increased significantly in the vein grafts (3.1% vs 7.5%, $p = 0.002$), while that of arterial grafts remained stable (8.6% vs 7.3%, $p = 0.774$). When the graft patency at postoperative year 5 was compared between patients with recurrent angina and those without, the patients with recurrent angina showed a higher proportion of FitzGibbon grade B grafts (19.2% vs 4.8% in arterial grafts, $p = 0.023$; 20.5% vs 4.8% in vein grafts, $p = 0.003$) and lower grade A grafts (65.4% vs 86.4% in arterial grafts, $p = 0.019$; 43.6% vs 78.2% in vein grafts, $p < 0.001$), and a lower vein graft patency rate (64.1% vs 83.0%, $p = 0.014$). **Conclusions:** The arterial graft patency rate was significantly higher than that of saphenous vein grafts, especially in the left anterior descending coronary artery territory, at one year and five years postoperatively. The decreased patency rate of the vein grafts, along with insulin-dependent diabetes mellitus, were associated with angina recurrence.

Keywords: Coronary artery bypass grafting (CABG); Angiography; Ischemic heart disease

1. Introduction

Several studies have investigated the patency rates of grafts after coronary artery bypass grafting (CABG) and shown that arterial grafts have superior patency than vein grafts [1–4]. However, most of these studies were cross-sectional investigations performed at a defined point in time after CABG. The aims of this study were (1) to compare the patency of arterial and saphenous vein grafts in patients who had received coronary angiography at both one year and five years after CABG, (2) to evaluate the graft patency rates based on target territories, and (3) to elucidate the predictors for angina recurrence.

2. Patients and methods

2.1. Patients

Of the 197 patients who underwent isolated conventional CABG between January 1995 and December 1997, 109 (55.3%) patients who received both one year and five years follow-up coronary angiographies were included for evaluation of the anastomotic sites and patency of the grafts. Patients who required concomitant cardiac operations, who had early (<30 days) or late (>30 days) mortality after CABG, or who did not receive both follow-up coronary angiographies were excluded from this study. Written, informed consent was obtained from each participating patient, and Institutional Review Board approval was provided.

The patients were 78 males and 31 females with a mean age of 59 ± 9 years at the time of surgery. Preoperative coronary angiography revealed one-vessel disease in 5 patients, two-vessel disease in 19 patients, three-vessel

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Table 1
Patient preoperative characteristics and risk factors

Patient characteristics	N
Sex (male:female)	109 (78:31)
Age (years)	59 ± 9
LVEF (%)	58 ± 10
Unstable:stable	83:26
Risk factors, N (%)	
Smoking	56 (51.4)
Hypertension	54 (49.5)
Diabetes mellitus	32 (29.4)
Hyperlipidemia	27 (24.8)
Age > 70 years	9 (8.3)
LVEF < 40%	7 (6.4)
Angiographic diagnosis, N (%)	
Three-vessel disease	64 (58.7)
Two-vessel disease	19 (17.4)
One-vessel disease	5 (4.6)
LMD with or without peripheral disease	21 (19.3)

LMD: left main coronary artery disease; LVEF: left ventricle ejection fraction.

disease in 64 patients, and left main coronary artery disease with or without peripheral coronary artery disease in 21 patients. Eighty-three patients (76%) had unstable angina, 32 patients (29%) had diabetes mellitus, and 9 patients (8%) were older than 70 years (Table 1).

All the operations were performed by a single surgeon (K.-B.K.).

2.2. Operation

Conventional CABG was performed with single-stage venous cannula drainage, moderate systemic hypothermia, and antegrade or retrograde cold-blood cardioplegic solution. The patients were heparinized with an initial dose of heparin (3 mg/kg) and periodically supplemented with additional doses to maintain an activated clotting time of >480 s. At the end of the procedure, 1 mg of protamine per each milligram of heparin was given.

2.3. Postoperative follow-up

All the patients received aspirin (300 mg/day) postoperatively and follow-up examinations at three-month intervals after discharge. Follow-up coronary angiographies were performed at one year (14 ± 4 months) and five years (64 ± 9 months) after CABG. Patients received one year and five years follow-up coronary angiographies regardless of any angina symptoms, but angiographies were not performed in patients with renal dysfunction or in patients who refused the procedure. Follow-up coronary angiography included four-plane selective coronary and bypass graft angiography. One physician initially reviewed all the coronary angiograms and consensus was reached after review.

2.4. Grading of anastomoses

All of the anastomoses were reviewed and graded as described by FitzGibbon and associates [5] as follows. Grade A was defined as an excellent graft with unimpaired run-off. Grade B was defined as a graft displaying stenosis that reduced the caliber of the proximal or distal anastomosis or trunk to <50%, or a graft that was functionally impaired by new stenosis equivalent to >50% of the impairment before the operation, which was proximal or distal, as relevant to the anastomosis site. Grade O was defined as occlusion. The grade for the entire graft was determined by the lowest of the three site grades.

2.5. Statistical analysis

Statistical analysis was performed with the Statistical Analysis System software package (version 11.0; SAS Institute, Cary, NC, USA). The patency rates of the arterial and vein grafts were compared using the χ^2-test. The graft patency rate and the proportion of FitzGibbon grade B grafts between the one-year and five-year coronary angiographies were compared using the χ^2-test with McNemar examination. The freedom from graft occlusion during the follow-up period was calculated using the Kaplan–Meyer survival curve, and the factors affecting graft occlusion were analyzed using the Cox proportional hazard model. The factors affecting angina recurrence were analyzed using the simple logistic regression analysis.

All results are expressed as mean ± standard deviation; a p value < 0.05 was considered significant.

3. Results

The average number of distal anastomoses per patient was 3.5 ± 1.1. Of the 378 distal anastomoses performed, internal thoracic arteries (ITA) were used in 144 (38.1%), radial arteries were used in 7 (1.9%), and saphenous veins were used in 227 (60.1%). Bilateral ITAs were used in 21 of 109 (19.3%) patients. The sequential anastomotic technique was performed in 42 of 151 (27.8%) distal arterial grafts and in 77 of 227 (33.9%) saphenous vein grafts.

3.1. Patency of grafts at one year and five years postoperatively (Table 2)

The one-year patency rate (FitzGibbon grade A + B) was 98.0% for arterial graft (including 100%, 7/7 for radial arteries) which was superior to the one-year patency rate of 82.4% for saphenous vein grafts ($p < 0.001$). The grade A patency rate was 89.4% for arterial grafts (including 85.7%, 6/7 for radial arteries), which was also higher than the grade A patency rate of 79.3% for saphenous vein grafts ($p = 0.011$). The proportion of FitzGibbon grade B grafts was higher in the

Table 2
Graft patency rate at one year and five years postoperatively

FitzGibbon grade		Arterial graft (%)	Vein graft (%)	p
A	One-year	135/151 (89.4)	180/227 (79.3)	0.011
	Five-year	126/151 (83.4)	165/227 (72.7)	0.018
B	One-year	13/151 (8.6)	7/227 (3.1)	0.032
	Five-year	11/151 (7.3)	17/227 (7.5)	1.000
O	One-year	3/151 (2.0)	40/227 (17.6)	<0.001
	Five-year	14/151 (9.3)	45/227 (19.8)	0.006
Patency (A + B)	One-year	148/151 (98.0)	187/227 (82.4)	<0.001
	Five-year	137/151 (90.7)	182/227 (80.2)	0.006

arterial graft group than in the vein graft group (8.6% vs 3.1%, $p = 0.032$).

The five-year patency rate (FitzGibbon grade A + B) was 90.7% for arterial grafts (including 100%, 7/7 for the radial arteries), which was higher than the 80.2% rate for saphenous vein grafts ($p = 0.006$). The grade A patency rate was 83.4% for arterial grafts (including 85.7%, 6/7 for radial arteries), which was also higher than the grade A patency rate of 72.7% for saphenous vein grafts ($p = 0.018$). The proportion of grade B grafts was similar in both arterial and vein grafts at five years postoperatively (7.3% vs 7.5%, $p = 1.000$).

3.2. Graft patency rates (Table 2)

The arterial graft patency rate decreased significantly from one year to five years after surgery (98.0% to 90.7%, $p = 0.001$) while the vein graft patency rate remained stable (82.4% to 80.2%, $p = 0.063$). However, the proportion of grafts with FitzGibbon grade B increased in vein grafts (3.1% to 7.5%, $p = 0.002$) while grade B arterial grafts (8.6% to 7.3%, $p = 0.774$) remained stable between one year and five years.

3.3. Comparison of graft patency rates according to target territories (Table 3)

We defined target territories as the left anterior descending coronary artery (LAD) territory, which includes the LAD or diagonal branches; the left circumflex coronary artery (LCX) territory, which includes the ramus intermedius or obtuse marginal branches; and the right coronary artery (RCA) territory, which includes the RCA, posterior descending artery, or posterolateral branch. Most of the arterial grafts were used in the LAD or LCX territories. In the LAD territory, the patency rate of vein grafts was inferior to arterial grafts at both one year and five years (82.0% vs 97.5% at one year, $p = 0.001$; 78.0% vs 90.9% at five years, $p = 0.042$). In the LCX territory, the patency rate of vein grafts was not statistically different from that of arterial grafts (87.2% vs 100% at one year, $p = 0.122$; 87.2% vs 87.5% at five years, $p = 1.000$). In the RCA territory, the patency rate was similar between the vein and arterial grafts (77.1% vs 100% at one year, $p = 0.334$; 73.5% vs 100% at five years, $p = 0.330$), although arterial grafting was used in the RCA territory in only a small number of patients. The arterial graft patency rate was similar in all territories at one year and five years after surgery. The vein graft patency rate was also similar in all territories at one year; but it was lowest in the RCA territory at five years after surgery (73.5%, 61/83) when compared with other territories (78.0% in LAD territory, $p = 0.680$; 87.2% in LCX territory, $p = 0.023$).

3.4. Effect of grafting techniques on graft patency rate

Arterial sequential anastomoses were made in 42 (27.8%) of the 151 distal anastomoses. The patency rate of the sequential anastomoses at one year and five years was 97.6% (41/42) and 90.5% (38/42), respectively. There were no differences in patency of arterial sequential grafting compared with individual grafting (98.2%, 107/109 at one year, $p = 1.000$; and 90.8%, 99/109 at five years, $p = 1.000$). The patency rates of sequentially grafted veins were also similar to those of individual grafts (87.0%, 67/77 vs 80.0%, 120/150 at one year, $p = 0.204$; 84.4%, 65/77 vs 78.0%, 117/150 at five years, $p = 0.294$).

In 46 of 151 (30.5%) distal anastomoses using arterial grafts, proximal inflow was supplied by an arterial Y-composite graft. Composite vein grafts for proximal inflow were used in 6 of 227 distal anastomoses. The patency rates of the distal anastomoses in the composite graft groups were similar to those of non-composite graft groups at both one year and five years after surgery.

3.5. Fate of FitzGibbon grade B grafts

There were 13 FitzGibbon grade B arterial grafts at one year postoperatively. Eleven of the grafts were found to be slender and the other two showed anastomotic stenosis. Seven of 13 became occluded while six remained grade B at five years postoperatively. Six of the seven occluded arterial

Table 3
Comparisons of graft patency rates according to target lesions

Target	Time	Arterial graft (%)		Vein graft (%)	p
		ITA (%)	RA (%)		
LAD territory[a]	One-year	118/121 (97.5)		41/50 (82.0)	0.001
		117/120 (97.5)	1/1 (100)		
	Five-year	110/121 (90.9)		39/50 (78.0)	0.042
		109/120 (90.8)	1/1 (100)		
LCX territory[b]	One-year	24/24 (100)		82/94 (87.2)	0.122
		21/21 (100)	3/3 (100)		
	Five-year	21/24 (87.5)		82/94 (87.2)	1.000
		18/21 (85.7)	3/3 (100)		
RCA territory[c]	One-year	6/6 (100)		64/83 (77.1)	0.334
		3/3 (100)	3/3 (100)		
	Five-year	6/6 (100)		61/83 (73.5)*	0.330
		3/3 (100)	3/3 (100)		

LAD: left anterior descending coronary artery; LCX: left circumflex coronary artery; RCA: right coronary artery.
[a] LAD territory: left anterior descending artery and diagonal branches.
[b] LCX territory: ramus intermedius and obtuse marginal branches.
[c] RCA territory: right coronary artery, posterior descending coronary artery and posterolateral branches.
* $p = 0.023$ when compared with LCX territory.

Table 4
Graft patency at five years postoperatively in patients with recurrent angina

Graft	Grade	Angina (+), N = 20	Angina (−), N = 89	p
Arterial graft (%)	A	17/26 (65.4)	108/125 (86.4)	0.019
	B	5/26 (19.2)	6/125 (4.8)	0.023
	O	4/26 (15.4)	11/125 (8.8)	0.293
	A + B	22/26 (84.6)	114/125 (91.2)	0.293
Vein graft (%)	A	17/39 (43.6)	147/188 (78.2)	<0.001
	B	8/39 (20.5)	9/188 (4.8)	0.003
	O	14/39 (35.9)	32/188 (17.0)	0.014
	A + B	25/39 (64.1)	156/188 (83.0)	0.014

grafts (grade O) were associated with moderate stenosis (<80%) of the native vessel. Four newly occluded arterial grafts at five years postoperatively were all associated with moderate stenosis of the native vessel.

There were seven FitzGibbon grade B vein grafts at one year postoperatively. All seven demonstrated segmental narrowing in the trunk of the vein grafts. All seven remained as grade B grafts at five years postoperatively; however, two of them required percutaneous interventions because of recurrent angina. Five newly occluded vein grafts at five years postoperatively were grade A grafts at one year postoperatively.

3.6. Freedom from graft occlusion

Freedom from arterial graft occlusion at one year, three years, and five years postoperatively were 99.1%, 96.2%, and 94.8%, respectively. Freedom from SVG occlusion at one year, three years, and five years postoperatively were 90.3%, 65.6%, and 64.3%, respectively. Cox proportional hazard model failed to define any risk factors for graft occlusion in both arterial and vein grafts.

3.7. Recurrence of angina and graft patency (Table 4)

During the follow-up period, 20 patients experienced the recurrence of angina. When graft patency was compared between patients with recurrent angina and those without, the main differences were higher FitzGibbon grade B grafts (19.2% vs 4.8% in arterial grafts, $p = 0.023$; 20.5% vs 4.8% in vein grafts, $p = 0.003$) and lower grade A grafts (65.4% vs 86.4% in arterial grafts, $p = 0.019$; 43.6% vs 78.2% in vein grafts, $p < 0.001$), and a lower vein graft patency rate (64.1% vs 83.0%, $p = 0.014$). Of the 20 patients with recurrent angina, 5 underwent percutaneous interventions (two for new native lesions, two for vein graft lesions, and one for LAD with occluded ITA). One patient without recurrent angina underwent percutaneous intervention for a progressed native coronary lesion. When the predicators for angina recurrence were analyzed, multivariate analysis identified insulin-dependent diabetes mellitus as the only predictor for angina recurrence (odds ratio: 14.278, $p = 0.007$) among the patient variables.

4. Discussion

This study demonstrated four main findings. First, the patency rates were significantly higher in arterial grafts than in vein grafts at both one year and five years after CABG. Second, the benefit of using arterial grafts was most prominent in the LAD territory at one year and five years after surgery. Third, the decreased patency rate of the vein grafts, along with insulin-dependent diabetes mellitus, were associated with angina recurrence. Fourth, most of the decrease in patency of arterial grafts was associated with moderate stenosis of the native coronary artery and most of the decrease in patency of vein grafts was associated with graft disease itself.

The lower graft patency rate of the saphenous vein than with the ITA has prompted surgeons to use arterial grafts in CABG to improve the long-term outcome of myocardial revascularization. However, the saphenous vein is still being utilized frequently as a graft in CABG. In addition to immediate postoperative graft failure caused by thrombosis, the long-term patency of the saphenous vein graft can be affected by fibro-intimal hyperplasia during the first year after surgery [6] and by atherosclerosis beyond the fifth postoperative year [7,8]. In contrast to most of the previous studies investigating the patency of grafts by cross-sectional study at a specific time point, we performed coronary angiography in all of the 109 patients at both one year and five years after CABG to trace the changes of the anastomoses and grafts in the same patient population.

The ITA has demonstrated higher intermediate and late patency rates than saphenous vein grafts and has a >90% patency rate five years after CABG [2,9,10]. The present study demonstrated that both the overall (grade A + B) and grade A patency rates were significantly higher in the arterial grafts than in the saphenous vein grafts at one year and five years after surgery. However, the patency rate of arterial grafts decreased significantly between one year and five years after surgery (98.0% to 90.7%, $p = 0.001$), when analyzed using the χ^2-test with McNemar examination. We used the χ^2-test with McNemar examination, instead of the simple χ^2-test, because the present study analyzed the morphologic change of anastomotic sites in the same patients group.

One study found no difference in the adjusted risk of one-year occlusion rates between these two grafts [11]. The authors suggested that this difference in one-year occlusion rates could be attributed to a difference in the distribution of graft characteristics related to the target coronary arteries rather than to the graft material. We found that the vein graft patency rates in the LCX and RCA territories were comparable with those of arterial grafts until five years after surgery. However, the patency rates of arterial grafts were superior to vein grafts in the LAD territory at both time points (97.5% vs 82.0% at one-year, $p = 0.001$; 90.9% vs 78.0% at five-year, $p = 0.042$). Excellent arterial graft patency rates regardless of target territories in the present study correlated with previous studies [12,13]. Although previous studies [14,15] demonstrated a lower patency rate of RITA in the RCA territory, we did not observed the finding in our small number of arterial grafts in the RCA territory.

The patency of sequential vein grafting has been demonstrated to be superior to individual grafting if the most distally located anastomosis had good quality and

diameter [16]. In the present study, we failed to identify a difference between sequential and individual vein grafting at one year and five years after surgery. The excellent patency rate of arterial sequential anastomoses (97.6% at one year and 90.5% at five years) in the present study correlated with the previous reports [12,17].

Although the occlusion rate of saphenous vein grafts has been reported to be 2–2.5% per year between the first and fifth postoperative years [18], the patency of vein grafts remained stable in the present study (82.4% to 80.2%, $p = 0.063$). This study supports the idea that very little change occurs between one year and five years in the overall patency rate of saphenous vein grafts [19,20]. Instead, the proportion of FitzGibbon grade B grafts increased in vein grafts (3.1%, 7/227 to 7.5%, 17/227, $p = 0.002$) while the proportion of grade B arterial grafts (8.6%, 13/151 to 7.3%, 11/151, $p = 0.774$) remained stable during the four-year interval. Interestingly, most of the decreased patency of arterial grafts in the present study seemed to be associated with the status of the native coronary artery. Of the 11 occluded arterial grafts after one year, 10 (90.9%) were associated with moderate stenosis native disease (<80% stenosis). Only 1 of 11 occluded arterial grafts needed a percutaneous intervention in the native coronary artery because of angina recurrence. The decrease in vein graft patency was associated with disease in the graft itself, demonstrated by segmental narrowing in the vein graft trunks. Although all seven of the grade B vein grafts at one year remained as grade B, two needed percutaneous interventions because of progressive stenosis and recurrent angina at five years. The increase in the FitzGibbon grade B and grade O vein grafts and decrease in the grade A vein grafts were associated with angina recurrence in the present study. However, multivariate analysis failed to correlate the graft occlusion to angina recurrence. Only the insulin-dependent diabetes mellitus predicted the angina recurrence. Its deleterious effect on the progression of native coronary artery disease as well as grafts could be a possible explanation for this. When the predicators for angina recurrence were analyzed according to the patient variables, multivariate analysis identified insulin-dependent diabetes mellitus as the only predictor for angina recurrence (odds ratio: 14.278, $p = 0.007$).

There are limitations to the present study that must be recognized. First, the present study was not performed in a randomized manner with regard to the type of conduits and the target vessels because randomized controlled trials with regard to this type of study are often unrealistic and impractical. Second, this study had a relatively small sample size, which might be insufficient to compare the fate of grafts. Third, we might have overestimated the patency rates by selecting the patients who survived and had angiographies performed at one year and five years after surgery. Eight saphenous vein grafts (four in patients with inadequate left ITA flow, three in emergent cases, and one additional vein graft to the LAD in a patient with cardiopulmonary bypass weaning difficulty) were used to revascularize the LAD whereas nearly 100% of LAD grafts are arterial grafts in most current practice. These might serve as confounding variables. Fourth, the present study included a low risk group of patients with young age and good left ventricular function. Consequently, the conclusions of this study should be applied for those patients undergoing conventional CABG with comparable risks.

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Occlusive changes at the coronary artery–bypass graft anastomosis

Morphologic study of 95 grafts

Ninety-five bypass graft anastomoses in 52 patients dying up to 4 years after direct coronary revascularization were studied at autopsy by angiograms and serial histologic sectioning of the graft-artery anastomosis. When new coronary occlusions and narrowings occurred, they were adjacent to either the proximal or distal ends of the anastomosis and were due to compression or loss of circumference of the arterial lumen (40 per cent), thrombus formation (40 per cent), mural dissection of the coronary wall (8 per cent), or the combination of compression and thrombosis (12 per cent). Small coronary artery diameter, local atheromas, and extension of the arteriotomy into a branch vessel were significant factors predisposing to occlusive changes. The findings emphasize the importance of careful artery selection for bypass, the need to avoid local vascular disease and branch-points, and the technical difficulties encountered in the presence of local vascular lesions or small coronary arteries.

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Revascularization of the heart by direct anastomosis of either a vein graft or internal mammary artery to the coronary arteries has been successful in alleviating symptoms of angina pectoris in eighty-five to ninety per cent of patients.[2–5] Despite the symptomatic relief afforded by this procedure, approximately fifteen to thirty per cent of the bypass grafts are occluded one year after operation.[6–15] In addition, new total occlusions of the intrinsic coronary artery have been identified at postoperative catheterization in a large number of patients.[6–12] Many of these new occlusive changes were noted to begin or terminate at the bypass graft–to–coronary artery anastomosis site.[6]

The nature of these occlusive changes has not been completely defined. On the basis of postoperative catheterization findings, at least four possible mechanisms have been suggested: progression or worsening of pre-existing atherosclerotic disease, thrombosis as a result of diminished volume and velocity of blood flow within the coronary segment proximal to the graft-artery anastomosis,[16–17] turbulence within the coronary artery at the anastomotic site, or technical factors related to the construction of the anastomosis.

In the present study, postmortem radiographic and histologic examinations of the bypass graft–to–coronary artery anastomosis were undertaken to define both the nature and frequency of these occlusive changes in autopsy material. This study will show that occlusive postoperative changes occur more commonly in coronary arteries with a small internal diameter, arteries that have required endarterectomy, or those in which the graft-artery anastomosis was made across a major branch-point of the coronary artery.

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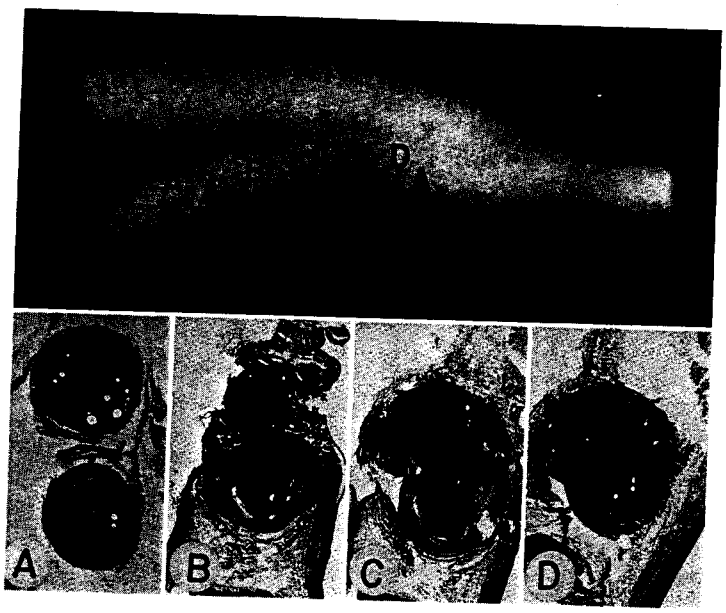


Fig. 1. Widely patent saphenous vein graft to coronary artery anastomosis. *Top,* Radiograph of tissue block containing the anastomosis. *Bottom,* Selected serial histologic transverse sections taken at the points indicated by the lettered *arrows* on the radiograph. *A,* The vein graft above and the coronary artery below. *B,* The proximal end of the anastomosis. *C* and *D,* The midportion of the anastomosis with the vein graft forming a roof over the opened artery below. The injection mass in the lumen stains dark. (Elastic stain. Original magnification ×3.)

Materials and methods

The clinical and pathological features of the 52 patients in the autopsy files of The Johns Hopkins Hospital who had received one or more coronary artery bypass grafts between 1969 and September, 1975, were reviewed. The hearts had been studied by postmortem coronary arteriograms and bypass graft injection with a barium-gelatin-pigment injection mass.[18] In all but 2 cases the hearts were fixed in formalin in a distended state prior to sectioning, and stereoscopic radiographs were prepared in at least two planes. The heart, radiographs, gross photographs, and a variety of histologic sections of the heart and the bypass grafts were available for review.

The terminal portion of each bypass graft, including the distal anastomosis and part of the intrinsic coronary artery proximal and distal to the anastomosis, were removed "en bloc." Stereoscopic radiograms of each block were prepared in two planes. The block was then given light decalcification, routinely processed, and embedded in paraffin. The block was serially sectioned transversely at 8 μ beginning at the proximal end and every fifteenth section retained. Of the retained sections, every third was stained with hematoxylin and eosin, the second series of every third section was stained with an elastic stain, and the third series with connective tissue or other stains as appropriate. Whenever a vein Y graft was present, the distal anastomosis of each limb was examined histologically in the same manner. The proximal anastomosis of the vein graft to the aorta was examined by serial histologic sections when any abnormality was noted on gross examination.

Each case was then reviewed. Patency of the bypass graft and any occlusive change in the intrinsic coronary artery at the graft-artery anastomosis were determined from the radiographs, gross examination, and review of serial histologic sections. An example of a "satisfactory" vein graft–to–coronary artery anastomosis is shown in Fig. 1. Four sections were chosen for each anastomosis: the coronary artery about 5 mm. proximal to the proximal end of the arteriotomy, from which the caliber and extent of plaque in the coronary artery could be determined *(A);* the point of maximal narrowing of the coronary lumen at the proximal end of the arteriotomy *(B);* a similar point of maximal lumen narrowing at the distal end of the arteriotomy *(D);* and a section representative of the coronary lumen approximately 5 mm. beyond the distal end of the arteriotomy *(E).* In almost every case, the maximal narrowing of the intrinsic coronary artery occurred immediately at the terminal ends of the coronary arteriotomy.

Table I. *New occlusive narrowings in 95 coronary arteries at graft–coronary artery anastomosis*

Coronary artery bypassed	No.	Narrowed 70-90%		Occluded 100%		Narrowed or occluded 70-100%	
		No.	%	No.	%	No.	%
Proximal end*							
LAD	45	5	11	7	16	12	27
RCA	28	3	11	3	11	6	21
CIRC	22	3	14	1	5	4	18
Totals	95	11	12	11	12	22	23†
Distal end*							
LAD	45	3	7	10	22	13	29
RCA	28	5	18	6	21	11	39
CIRC	22	6	27	5	23	11	50
Totals	95	14	15	21	22	35	37†

Legend: LAD, Left anterior descending artery. RCA, Right coronary artery. CIRC, Left circumflex artery.

*Proximal and distal: Location of occlusive change in coronary artery at either proximal or distal end of graft-artery anastomosis.

†Significant difference: $p < 0.05$.

Table II. *Mechanisms of occlusive coronary artery change in 95 grafts*

	Proximal		Distal		Proximal and distal	
	No.	%	No.	%	No.	%
Coronary arteries with new 70-100% occlusions	21		31		52	
Compression	8	38	13	42	21	40
Thrombosis	8	38	13	42	21	40
Dissection	2	10	2	6	4	8
Compression and thrombosis	3	14	3	10	6	12

Sections from the four locations were then projected, and outlines of the lumen, internal and external elastic lamina, and adventitia of the coronary artery were drawn on tracing paper.[19] A calibrated millimeter grid was also projected and traced. The area of the entire cross-sectional coronary artery, as well as the area of the lumen, intima plus plaque, media, and adventitia were determined from the tracing by use of a planimeter. The diameter and circumference of the lumen and the entire coronary artery were calculated from the planimetered areas. The maximum reduction in cross-sectional area of the coronary lumen at both the proximal and distal ends of the anastomosis was then calculated. The area of the coronary lumen at *B* was compared to the area at *A*, and the lumen area at *D* was compared to *E*.

Reduction by more than 70 per cent of the lumen area at *B* or *D* was considered significant. The postoperative occlusive changes were grouped as 100 per cent or total occlusion, 70 to 99 per cent occlusion, or 0 to 69 per cent occlusion. The per cent of atherosclerotic plaque present in the coronary artery at *A* and *E* was calculated by dividing the planimetered area of intima plus plaque by the planimetered area of the entire artery within the adventitia.

In a final review of the pathological information, the mechanism of new significant occlusive changes was determined. Three mechanisms—compression or loss of circumference, thrombosis, and mural dissection—will be described in the *Results* section.

Results

General. The first bypass graft procedure was done at The Johns Hopkins Hospital in December of 1969. Operations for the first and last patients in this reported autopsy series were in June, 1970, and August, 1975, respectively. The hospital mortality rate at The Johns Hopkins Hospital for all patients who received at least one bypass graft between December, 1969, and December, 1975, was 10.5 per cent (65/621). If patients who had unstable angina pectoris, a myocardial infarction within 2 weeks of operation, or those who had combined operative procedures (bypass grafting plus either prosthetic valve replacement, aneurysmectomy, or closure of ventricular septal defect) are excluded, the hospital mortality rate in patients with stable angina during this same period was 4 per cent (16/391). The hospital mortality rate of patients with stable angina during 1974 and 1975 was 1.2 per cent (2/168).

The mean age (±SEM) of the 52 patients included in this study was 55±1 years (range 35 to 68). Thirty-nine (75 per cent) were men. Of the 95 bypass grafts placed, 91 were reversed saphenous vein and four were internal mammary artery grafts. All graft–to–coronary artery anastomoses were of the end-to-side type. Eighteen patients had one bypass graft placed, 26 patients had two, 7 patients had three, and one patient had four grafts. In 6 cases, prosthetic valve replacement was performed in addition to coronary artery bypass graft surgery. Of the 52 patients, 30 died intraoperatively or within 24 hours after operation (61 grafts), 14 died from one day to one month postoperatively (21 grafts), and 8 survived more than one month and up to 48 months (13 grafts).

Frequency of occlusive changes. Examination of serial histologic sections of the bypass graft–to–coronary artery anastomosis revealed that most significant occlusive changes in the intrinsic coronary artery occurred immediately adjacent to either the proximal or distal ends of the graft-artery anastomosis (Fig.

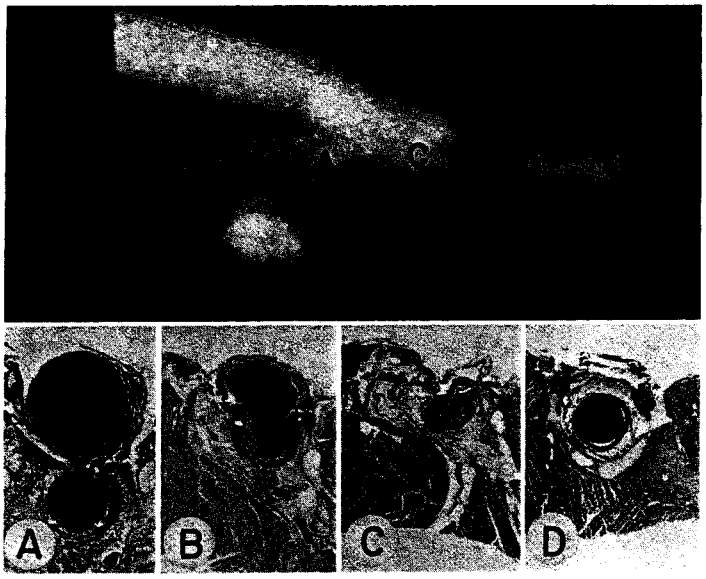


Fig. 2. Saphenous vein graft–to–coronary artery anastomosis with an occlusion at the distal end of the anastomosis caused by compression. *A*, A widely patent graft above and coronary artery below filled with injection mass. *B*, The mid-portion of the anastomosis is also patent. *C*, The distal end of the anastomosis is completely occluded. Note that an atherosclerotic plaque is present here but not in *A*, proximal to the anastomosis. *D*, The area past the point of occlusion is filled with injection mass from collateral channels and shows a normal lumen. (Elastic stain. Original magnification ×3.)

1). A new significant occlusive change was defined as a reduction of the cross-sectional area of the coronary artery lumen by 70 per cent or more. More new occlusive narrowings were found at the distal end of the anastomosis than at the proximal end ($p < 0.05$) (Table I). However, 29 per cent (10/35) of these significant changes at the distal end occurred in coronary arteries in which the anastomosis was made across a major branch-point and occlusion occurred in one of the two artery branches. (See *Anastomosis across a branch-point* section.)

Mechanisms and frequency of occlusive change in coronary arteries. Three mechanisms of occlusive change in the coronary artery at the anastomosis site were identified: (1) compression or loss of circumference; (2) thrombosis: and (3) mural dissection. These mechanisms could occur separately or in combination.

Compression or loss or circumference refers to the reduction in coronary artery lumen that occurs when part of the intrinsic coronary wall circumference is everted or compressed by suturing during construction of the graft-artery anastomosis. An example of compression or loss of circumference is shown in Fig. 2. A diagrammatic explanation of this mechanism is shown in Fig. 3. At operation, sutures are placed in both the bypass graft and coronary artery in such a manner as to evert both vessel walls and permit intima to intima contact. In the midportion of the anastomosis (point *C*), the vein graft provides ample "roof" or gusset to more than compensate for any loss of circumference that occurs as a result of everting a portion of coronary wall. At the proximal and distal ends of the arteriotomy, the vein graft does not, however, provide any roof. Any portion of the arterial wall circumference immediately at or just beyond the apex of the arteriotomy that is

Table III. *Frequency and mechanism of occlusive change depending on time of death after operation*

	Time of death after operation					
	Within 24 hr. (30 pts.)		*1-30 days (14 pts.)*		*1-48 mo. (8 pts.)*	
	No.	*%*	*No.*	*%*	*No.*	*%*
Coronary arteries bypassed	61		21		13	
New 70-100% occlusion*	31	51	9	43	8	62
Mechanism of artery narrowing						
Compression	14	45	5	56	1	13
Thrombosis	8	26	1	11	6	75
Dissection	3	10	1	11	1	13
Compression and thrombosis	2	6	2	22		–
Unknown	4	13		–		–

*Only the most severe narrowing or occlusion of each bypassed artery (at either proximal *or* distal end of anastomosis) is recorded.

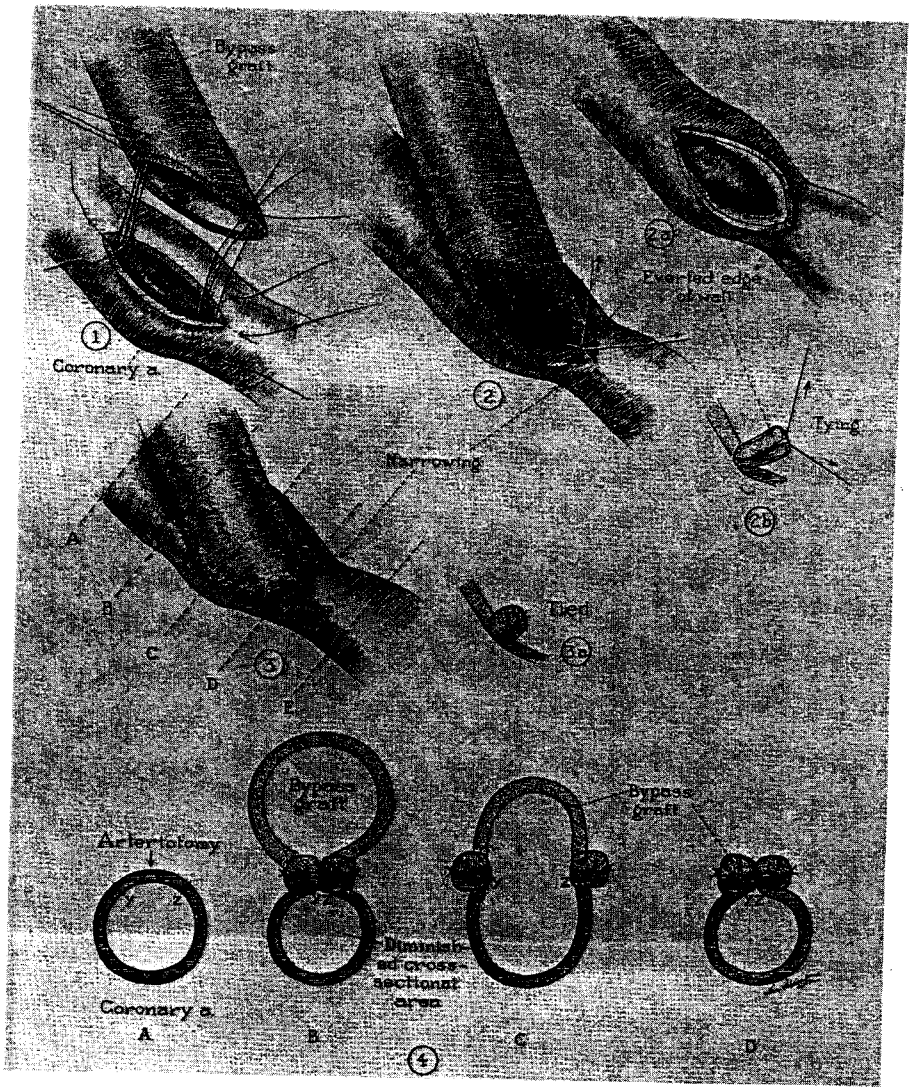


Fig. 3. Diagram showing mechanism of compression of coronary artery lumen during construction of anastomosis. *1*, Suture placement at terminal portions of arteriotomy. *2*, First suture tied with eversion of coronary artery and graft walls by suture. *2a*, Coronary artery wall everted; graft not drawn. *3*, Anastomosis complete. Narrowings present at both ends of anastomosis owing to compression or loss of circumference (*B* and *D*). *4*, Sections through *A*, *B*, *C*, and *D*. Location of arteriotomy shown *Y* and *Z* are points where suture through wall enters coronary lumen. At both ends of anastomosis, *Y* and *Z* meet. See text for explanation.

everted during construction of the anastomosis will directly reduce the coronary artery circumference and, hence, the cross-sectional area of the coronary lumen. The distance from the edge of the arteriotomy where each suture is placed through the coronary wall determines the width of artery wall that is everted. Hence, the internal circumference of the coronary artery at each end of the arteriotomy is reduced by the width of the everted segment on *both* sides of the arteriotomy.

Thrombosis at the site of graft–to–coronary artery anastomosis is shown in Fig. 4. In this example, there was no appreciable loss of arterial circumference when the anastomosis was made, yet the coronary artery at the proximal end is totally occluded and the distal artery is severely narrowed as a result of thrombus. *Mural dissection* of the coronary artery wall with a resulting significant decrease in cross-sectional area of the lumen was found in four bypassed arteries.

Twenty-two of the 95 (23 per cent) bypassed coronary arteries were narrowed by 70 per cent or more at the proximal end of the anastomosis. Twenty-one of these 22 proximal narrowings were examined histologically and the mechanisms of new occlusive changes determined (Table II). Compression was responsible for

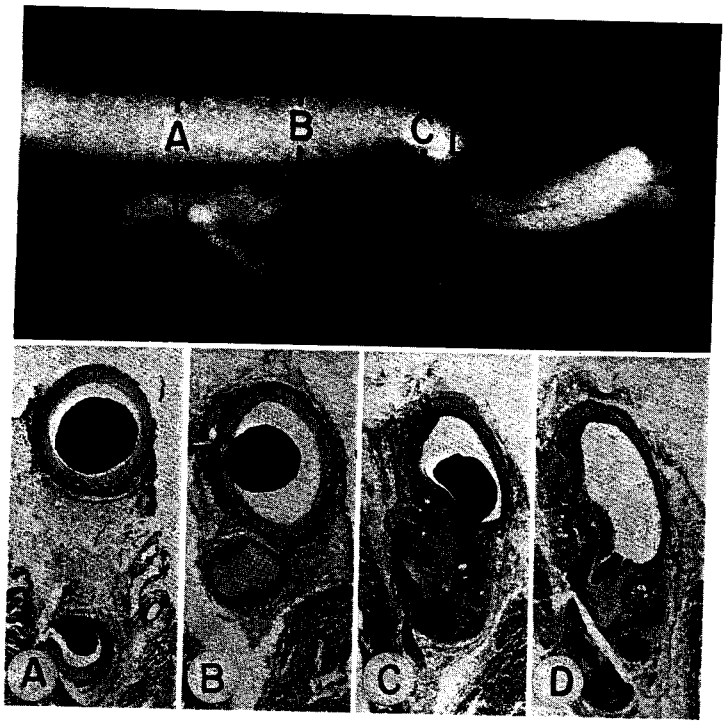


Fig. 4. Saphenous vein graft–to–coronary artery anastomosis with occlusion of proximal and obstruction of the distal end by thrombosis. *A*, Vein graft above and patent artery below. *B*, Just proximal to the arteriotomy with patent graft above and occluded artery below. *C* and *D*, Near distal end of arteriotomy showing small channel through organized thrombus. (Elastic stain. Original magnification ×4.)

Table IV. *Characteristics of coronary artery at graft-artery anastomosis site*

	No.	*Internal diameter (mm.)*	*External diameter (mm.)*	*Plaque (%)*
Anterior descending				
Proximal	40	1.6 ± 0.1	2.4 ± 0.1	31 ± 3
Distal	36	1.4 ± 0.1	2.1 ± 0.1	30 ± 3
Circumflex marginal				
Proximal	20	1.7 ± 0.2	2.5 ± 0.1	24 ± 4
Distal	15	1.8 ± 0.2	2.3 ± 0.1	19 ± 6
Right				
Proximal	20	1.6 ± 0.2	3.2 ± 0.1	53 ± 4
Distal	14	1.6 ± 0.1	2.4 ± 0.2	37 ± 5

Table V. *Internal diameter of coronary artery and new postoperative occlusive narrowings*

	Small arteries (diameters ≤ 1.2 mm.)		*Large arteries (diameters ≥ 1.3 mm.)*		
	No.	*%*	*No.*	*%*	*Difference*
Proximal					
Arteries (no.)	26		53		
New 70-100% occlusion	8	31	11	21	NS
Distal					
Arteries (no.)	20		44		
New 70-100% occlusion	12	60	10	23	$p < 0.01$
Combined proximal and distal					
Arteries (no.)	46		97		
New 70-100% occlusion	20	43	21	22	$p < 0.01$

or contributed to a significant new narrowing of the coronary artery at the proximal end of the anastomosis in 11/95 (12 per cent) instances. Thirty-five (37 per cent) of the 95 bypassed arteries were narrowed by 70 per cent or more at the distal end of the anastomosis. Ten of these 35 significant distal narrowings occurred when the anastomosis extended across a major branch-point; here one branch was significantly narrowed or totally occluded and the other branch widely patent. (See *Anastomosis across branch-point*). Thirty-one of the significant distal narrowings were examined histologically. Compression was responsible for or contributed to a new acute narrowing at the distal end of the anastomosis in 16 instances. Thrombosis was the important causative factor in an equal number of occlusive changes that occurred at either the proximal or distal ends of the anastomosis.

Table VI. *New occlusive changes in coronary arteries after bypass graft surgery*

	Patients restudied	Postop. interval (mo.)	Grafts placed	Grafts patent		Patent bypass graft				
						Coronary arteries	New (≥50%) Narrowing		New total occlusion	
				No.	%		No.	%	No.	%
Johns Hopkins[6]	71	6	120	79	66	68	8	12	20	29
Montreal Heart[7]	105	11	154	103	67	103	3	3	40	39
New York Univ.[8]	50	9	118	86	73	86	5	6	38	44
Alabama[9]	121	12	210	147	70	147	12	8	59	40
Toronto General[10]	100	20	143	108	76	108	7	6†	37	34
Univ. Oregon*[11]	100	5	88	73	83	73	–		35	48
Peter Bent Brigham[12]	67	13	115	67	58	67	6	9	35	52
	614	11.5	948	663	70	652	41/579	7	264/652	40‡

*Patency of bypass grafts and new occlusive changes in intrinsic coronary artery described only for arteries that filled antegrade on preoperative arteriogram.

†New narrowing or worsening ≥25 per cent.

‡Eighty-five per cent of new total occlusions were proximal to patent graft-artery anastomosis, and 15 per cent were distal to anastomosis.[6-8, 10-12]

The influence that time of death after operation has on the frequency and cause of these occlusive narrowings is shown in Table III. In this table, only the most severe narrowing of a bypassed artery at either the proximal or distal end of the graft-artery anastomosis is recorded. Although a similar frequency of significant occlusive changes is found in the three postoperative periods, the mechanism of occlusion differs. Compression or loss of circumference was the principal mechanism of these changes observed up to 30 days after operation. Thrombosis was the major cause of occlusions observed in patients who died more than one month after operation.

Characteristics of distal coronary artery at graft-artery anastomosis site. The features of the coronary artery that appear important in determining success or failure of the anastomosis are shown in Table IV. The internal and external diameters of the intrinsic coronary arteries that were available for histologic examination, as well as the per cent plaque present in the arterial wall, are recorded. The segment of coronary artery selected for measurement was approximately 5 mm. proximal and distal to where the graft-artery anastomosis began or ended. Excluded from this table are the measurements of coronary arteries subjected to endarterectomy and measurements at the distal end of any anastomosis where the arteriotomy was extended across a branch-point and down one branch.

On the basis of external diameter, the distal right coronary artery was the largest of the three arteries usually bypassed. Because the distal right coronary artery had the most atherosclerotic plaque of the three arteries, the largest internal diameter was in the circumflex marginal coronary artery. The anterior descending had the smallest luminal diameter.

Artery lumen size and prevalence of postoperative occlusive changes. The influence of size of the coronary artery lumen on the occurrence of either a new narrowing of ≤70 per cent or a new 100 per cent occlusion is examined in Table V. The diameter and cross-sectional area of the coronary artery lumen proximal and distal to the anastomosis were utilized to "size" the coronary segment at the proximal and distal ends of the anastomosis.

A separation into favorable and less favorable groups appeared to occur if the *internal* coronary diameter was 1.3 mm. or more ("large" artery) or 1.2 mm. or less ("small" artery). More occlusive changes were found in "smaller" arteries than in "larger" arteries (Table V). This difference was significant at the distal end of the anastomosis and when the changes at both the proximal and distal ends were combined ($p < 0.01$).

Anastomosis across a branch-point. There were 12 anastomoses in which the coronary arteriotomy was carried across a branch-point because the atherosclerotic plaque extended down one branch. This is schematically depicted in Fig. 5. The frequency of significant occlusive changes in both the arteriotomy branch and nonarteriotomy branch groups is also shown. Half of the branches in each group were narrowed by at least 70 per cent or were totally occluded. These occlusive changes began immediately distal to the branch-point. In those arteries in which histologic studies were available to determine the mechanism of these occlusions, 80 per cent of these significant occlusions were due to compression or loss of circumference and 20 per cent to thrombosis. Ten of the 12 arteries in

Occluded bypass graft			*No bypass graft*		
ronary teries	*New total occlusion*		*Coronary arteries*	*New total occlusion*	
	No.	*%*		*No.*	*%*
39	24	62	81	13	16
51	18	35	161	6	4
32	4	13	36	4	11
62	40	65	145	3	2
34	11	32	128	10	8
15	4	27	86	5	6
48	18	38	89	2	2
281	119/281	42	726	43	6

which the arteriotomy was extended across the branch-point demonstrated significant occlusive change in at least one of the two branches. An example of a branch-point occlusion is shown in Fig. 6.

In other anastomoses in which the distal end of the arteriotomy ended just proximal to a branch-point, there were no occlusive changes. The circumference and diameter of a vessel are greatest just proximal to its flow divider,[20] which may account for the better results seen in cases in which the arteriotomy ended immediately before a branch-point.

Endarterectomy. An endarterectomy was performed at the time of bypass surgery in 12 coronary arteries. In six arteries, there was a significant new occlusion (narrowed 70 to 100 per cent) at one or both ends of the anastomosis. Three of these occlusions involved an anastomosis across a branch-point and one branch was occluded. No histologic material on late results of endarterectomy was available for study. Seven of these 12 patients died at operation and the remaining patients died within 2 days of the operation.

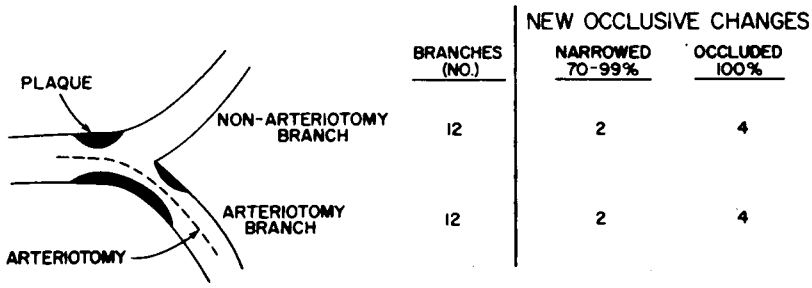
Occlusive changes in bypass grafts. Of the 95 bypass grafts placed in these 52 patients, 88 (93 per cent) were patent and seven were occluded by thrombosis at the time of autopsy examination. Five of the seven arteries to which these occluded grafts were connected demonstrated a significant narrowing in the coronary artery at one or both ends of the anastomosis. One internal mammary artery graft was occluded as a result of mural dissection in the graft wall. In this situation, there was also mural dissection of the bypassed coronary artery.

The aorta–vein graft anastomoses showed no occlusive narrowings except for one graft with a severe narrowing produced by thrombosis. There were no occlusive narrowings in the three Y grafts at the vein graft–to–vein graft anastomosis.

Discussion

Seven surgical centers, including The Johns Hopkins Hospital, have recorded complete postoperative catheterization findings in over 600 patients detailing not only bypass graft patency rates but also the frequency rates of new occlusive changes in the intrinsic coronary artery circulation.[6–12] These data are shown in Table VI. The definition of a new total occlusion used in this table is failure to visualize a segment of coronary artery at postoperative catheterization that had been opacified before the operation. Despite some variability in the criteria for the selection of patients for postoperative catheterization, there is remarkable similarity in the frequency with which these occlusive changes were found at these seven institutions. These are the only major published reports that have compared pre- and postoperative coronary arteriograms. No surgical center has looked for these occlusive changes in the intrinsic coronary circulation and not found them in comparable frequency. By other criteria, such as operative mortality rate,[4, 14, 21–23] extent of postoperative symptomatic improvement in angina,[2–4, 23, 24] and the frequency of new Q waves after operation,[25–28] the surgical results of these seven institutions are similar to results from other institutions that have not reported postoperative arteriograms of the intrinsic coronary circulation.

Occlusive changes in the intrinsic coronary circulation similar to those described at postoperative catheterization have been demonstrated in the present autopsy study. As suggested by catheterization studies,[6] the most severe narrowings in the bypassed coronary artery occur immediately adjacent to both the proximal and distal ends of the anastomosis and not within the anastomosis. The incidence of significant occlusive changes (both new narrowings *and* new total occlusions) in bypassed coronary arteries is somewhat higher in the present autopsy material than in the postoperative catheterization data from the seven surgical centers (Table VII). This may be partially due to the increased sensitivity of pathological techniques to identify significant narrowings adjacent to the graft-artery anastomosis or simply to the bias of an autopsy population. The higher graft patency rate, more frequent $\geq$50 per cent narrowings, and less frequent new total occlusions in the autopsy material may be explained by the shorter interval from operation to postmortem examination of the patients in this series as compared to the time after



	BRANCHES (NO.)	NEW OCCLUSIVE CHANGES	
		NARROWED 70-99%	OCCLUDED 100%
NON-ARTERIOTOMY BRANCH	12	2	4
ARTERIOTOMY BRANCH	12	2	4

Fig. 5. Bypass graft anastomosis across branch-point. Diagram showing arteriotomy extended down one branch because of local plaque. Twelve anastomoses across branch-point found in autopsy material. Frequency of 70 to 99 per cent and 100 per cent occlusion found in arteriotomy and nonarteriotomy branches is noted.

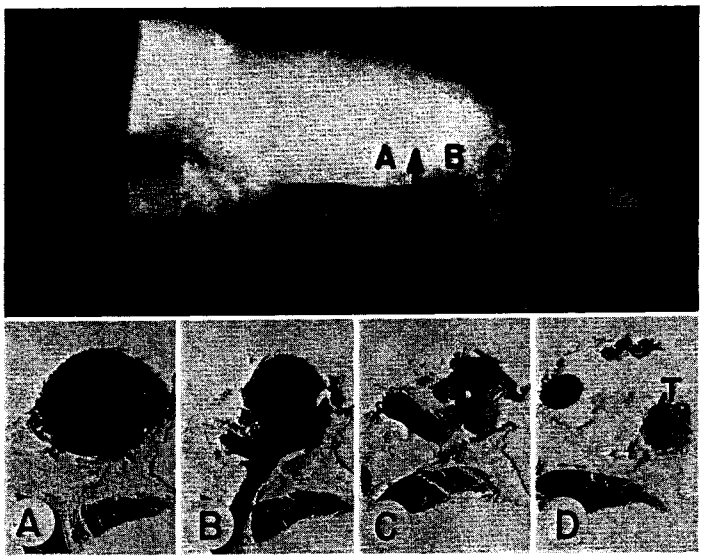


Fig. 6. Saphenous vein graft–to–coronary artery anastomosis with occlusion of the distal end caused by thrombosis. The graft has been placed into a point of branching in the coronary artery and the arteriotomy extended into the branch occluded by thrombus. *A,* Across the patent portion of the anastomosis. *B,* At the point of branching of the coronary artery with a penetrating branch below and two superficial branches. *C,* The anastomosis continuing down a branch occluded by thrombus. The other branch is filled with injection mass. *D,* At the distal most end of the graft with the thrombosed (T) branch having a suture in its upper portion. As shown in the radiogram, the thrombosed vessel is filled by collaterals beyond the point of thrombosis. (Elastic stain. Original magnification ×3.)

operation that patients underwent postoperative catheterization. If the interval after surgery in the autopsy group had been longer, it is probable that some of the severe narrowings of the intrinsic coronary artery would have progressed to total occlusion. The similar frequency of occlusive changes in the catheterization and autopsy data suggest that the postmortem findings may not be unduly biased, i.e., representing only "poor" surgical results, because all of the patients died.

Histologic examination of bypassed arteries demonstrated that these narrowings were the result of three mechanisms: compression or loss of circumference, thrombosis, and mural dissection. Compression and thrombosis, which occurred with almost equal frequency, accounted for 90 per cent of these occlusive changes. Thrombosis was considered to be responsible for 33 per cent of the occlusive changes in patients dying within 30 days of operation and 75 per cent of the changes in patients who died more than one month after operation. McEnany and his associates[29] have shown a higher graft patency rate (84 per cent) one year after surgery in patients treated with warfarin compared to the patency of a control group that received a placebo

(72 per cent). If comparable data are shown for occlusive changes in the intrinsic coronary artery, it may be that anticoagulant therapy is advisable to prevent or minimize those occlusive changes that are secondary to thrombosis.

Lumen size of the distal coronary segment and the presence of atherosclerotic plaque at this location appear to predispose to occlusive change after the operation. Compression and thrombosis were more common in those arteries with an internal diameter of 1.2 mm. or less than in arteries with a diameter of 1.3 mm. or more. These data suggest that a critical step in making the graft-coronary anastomosis relates to the width of arterial wall that is everted or used at both ends of the anastomosis. Because the bypass graft does not provide any roof or circumference at these two points, the width of arterial wall everted on both sides of the arteriotomy directly reduces the circumference of the intrinsic coronary artery. If the intrinsic coronary artery is large, reduction in circumference at either end of the anastomosis is not important. On the other hand, if the artery is small, everting a segment of arterial wall can significantly reduce the cross-sectional area of lumen.

To illustrate the potential importance of coronary artery size, the reduction in lumen area for two coronary arteries, one with an internal diameter of 2 mm. and the other 1 mm. (Table VIII), can be calculated for two different suture bites. Given the internal lumen diameter, the lumen area for each artery can be calculated. For both arteries, two typical suture bites are shown, one 0.5 mm. back from the edge of the arteriotomy and the other 1.0 mm. The circumference of the coronary artery immediately at the apex of the arteriotomy may be reduced by an amount equal to the width of everted wall on both sides of the arteriotomy. In the 2 mm. artery, the two hypothetical suture bites will reduce the cross-sectional area of the coronary lumen either by 29 per cent or 54 per cent. In the smaller 1 mm. artery, the same two suture bites will reduce the cross-sectional area by 52 per cent and 89 per cent. This situation of necessity occurs only in case of eversion of the wall.

The presence of extensive atherosclerotic plaque in the distal coronary segment also appears to predispose to occlusive changes in the intrinsic coronary artery. Plaque will diminish the internal circumference available for anastomosis and reduce the pliability of the coronary wall for suturing. If extensive, an endarterectomy may have to be done. If plaque extends down a major branch of the distal coronary artery, then it may be necessary to extend the arteriotomy and anastomosis down this branch. Previously, the surgical approach at The Johns Hopkins Hospital was to incise directly into a distal plaque in an effort to roof this lesion and permit bidirectional flow both proximally and distally in the artery. If necessary, an endarterectomy would be done, and, if plaque extended across a branch-point, the arteriotomy would be extended down one branch. Our practice now is to avoid making an anastomosis at the site of recognized plaque. If necessary, we place separate grafts on either side of this plaque.

The results of the present study emphasize that selection of patients for coronary bypass surgery should include not only consideration of their clinical status but also evaluation of the caliber of the distal coronary lumen and the extent and location of atherosclerotic plaque in this distal segment. These autopsy findings suggest that new postoperative occlusive changes in bypassed coronary arteries may be the consequence of

Table VII. *Frequency of postoperative occlusions in bypassed coronary arteries identified at catheterization and postmortem arteriography*

	Postop. catheterization		*Postmortem arteriography*		
	No.	*%*	*No.*	*%*	*Difference*
Arteries bypassed	933		95		
Patent grafts	652	70	88	93	$p < 0.001$
New 100% occlusion	383	41	29	31	NS
New 70-99% narrowing	41	4*	19	20	$p < 0.05$
New narrowing 70-100%	424	45	48	51	NS
Postop. interval (mo.)	11.5		1.3		

*New postoperative narrowing at catheterization is defined as ≥50 per cent.

Table VIII. *Decrease in cross-sectional area of intrinsic coronary artery adjacent to graft-artery anastomosis*

	Preop. dimensions	*Postop. dimensions: Width of everted wall*	
		0.5 mm.	*1.0 mm.*
Two millimeter artery			
Circumference (mm.)	6.3	5.3	4.3
Diameter (mm.)	2.0	1.7	1.4
Cross-sectional area (sq. mm.)	3.1	2.2	1.5
Area reduction (%)	–	29	54
One millimeter artery			
Circumference (mm.)	3.1	2.1	1.1
Diameter (mm.)	1.0	0.7	0.4
Cross-section area (sq. mm.)	0.8	0.4	0.1
Area reduction (%)	–	52	89

characteristics of the distal coronary segment. Smaller coronary arteries have more occlusive changes than larger arteries. The presence of atherosclerotic plaque in the distal coronary segment, especially if it involves a major branching point, is accompanied by more occlusive changes than if plaque is not present in this segment. Not only are more patients with more extensive distal plaque undergoing bypass surgery at this time, the surgical objective of complete revascularization includes bypassing into smaller secondary branches if there is a significant proximal narrowing. With currently available surgical techniques, smaller coronary arteries may have insufficient internal circumference to permit construction of the graft-artery anastomosis without creating a significant narrowing in the intrinsic coronary artery. In our opinion, the optimal magnification provided by the use of loups has permitted a greater frequency of satisfactory anastomoses in smaller coronary arteries. It is possible that greater magnification and even more meticulous suture techniques would diminish the frequency of significant occlusive changes in bypassed coronary arteries and increase the patency rates of conduits to these small coronary arteries.

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Critical Analysis of Coronary Artery Bypass Graft Surgery: A 30-Year Journey

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As there is even yet a lingering doubt in many minds with regard to some trees, whether they bear flowers and seed or not, it is the more important to show not only that they do, but for what purpose.
—Henry David Thoreau: *Faith in a Seed*

The year 1997 marked three decades of coronary artery bypass surgery. Thousands of papers have been published. I will try to summarize the principal steps taken toward myocardial revascularization, focusing the analysis on the main issue of our daily practice: how to offer our patients proper treatment based only on scientific knowledge, avoiding personal bias. Naturally, I will concentrate on controversial areas.

Brief Historical Summary

Direct myocardial revascularization is the consequence of the monumental work that Mason Sones and collaborators carried out at the Cleveland Clinic beginning in 1958, when selective coronary angiography was introduced (1). On January 5, 1962, Effler and his team (2) were able to repair a severe obstruction of the left main trunk coronary artery by the patch graft technique developed by Senning (3). The same month Sones demonstrated for the first time that Vineberg's concept was correct: by means of collateral circulation the implanted left internal mammary artery could ameliorate the myocardial perfusion deficit of the anterolateral wall of the left ventricle due to a severe obstruction of the left anterior descending branch of the left coronary artery.

I was extremely fortunate to arrive at the Cleveland Clinic in February 1962 and to become part of a team led by William Proudfit in the Department of Clinical Cardiology, Mason Sones in the Cardiovascular Laboratory, and Donald B. Effler in the Thoracic and Cardiovascular Surgery Department.

There was a unique collection of hundreds of excellent-quality cine coronary angiographies kept at the basement in Sones' Laboratory. I spent long hours at night, once duties as a fellow of the Department of Thoracic and Cardiovascular Surgery were over.

Very soon it became clear that two distinct groups of patients could be recognized: (a) those with diffuse disease, with or without collateral circulation, and (b) those with localized obstructions, mainly in the proximal coronary branches. Analysis of the left ventriculogram demonstrated correlation between the severity of the coronary disease and the state of the left ventricle. As a result the surgical approach was directed to application of the Vineberg approach (4–6), direct repair with the patch repair technique and reconstruction of the left ventricle when indicated (7).

In 1966 I was able to dissect the internal mammary artery through a midline anterior thoracotomy with the aid of a special self-retaining retractor (8). The technique allowed us to dissect both right and left internal mammary arteries, giving birth to the double Vineberg approach (9,10). Later it contributed to the utilization of the mammary artery as an arterial conduit for direct myocardial revascularization. The utilization of the midline anterior thoracotomy also allowed us to perform combined simultaneous procedures (11) particularly in patients with abnormal ventricles (ventricular aneurysmectomy or scar tissue resection) or patients with valvular diseases, introducing new concepts based mainly on the overall analysis of patients with coronary arteriosclerosis.*

As previously mentioned, direct myocardial revascularization was performed at the beginning with the patch graft technique. A longitudinal incision was made over the obstruction and the lumen was enlarged with a patch of pericardium utilizing a running suture. The results on the right coronary artery were gratifying and the operative mortality was acceptable for those days (10.5% in the first 142 patients). However, mortality was extremely high in patients with left main obstruction (eleven deaths in fourteen patients).

Initially, only localized obstructions were selected. When more experience was acquired, longer and longer patch reconstructions were performed. Very soon we realized that there was a direct relationship between the length of the repair and the rate of postoperative thrombosis. A longer repair increased

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*A critical discussion of the Vineberg indirect revascularization may be found in one of my books (12).

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Abbreviations and Acronyms

ACC	= American College of Cardiology
ACIP	= Asymptomatic Cardiac Ischemia Pilot
AHA	= American Heart Association
AMI	= acute myocardial infarction
AMRO	= Amsterdam-Rotterdam Trial Comparing Excimer Laser and PTCA
BARI	= Bypass Angioplasty Revascularization Investigation
BENESTENT	= Belgian Netherlands Stent Study
BH	= beating heart
BHAT	= Beta-Blocker Heart Attack Trial
CABG	= coronary artery bypass grafting surgery
CABRI	= Coronary Angioplasty Versus Bypass Revascularization Investigation
CARE	= Cholesterol and Recurrent Events study
CASS	= Coronary Artery Surgery Study
CAVEAT	= Coronary Angioplasty Versus Excisional Atherectomy Trial
CCAT	= Canadian Coronary Atherectomy Trial
CPB	= cardiopulmonary bypass
EAST	= Emory Angioplasty Versus Surgery Trial
ECG	= electrocardiogram
ER	= emergency room
ERBAC	= Excimer Laser, Rotablator and Balloon Angioplasty Comparison
GABI	= German Angioplasty Bypass Surgery Investigation
GISSI	= Gruppo Italiano per lo Studio della Streptochinasi nell'Infarto miocardico
GUSTO	= Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries
ISIS	= International Study of Infarct Survival
LAD	= left anterior descending coronary artery
LATE	= Late Assessment of Thrombolytic Efficacy
LBBB	= new left bundle branch block
LDL	= low density liproprotein
LIMA	= left internal mammary artery
LVSD	= left ventricular systolic dysfunction
MITI	= Myocardial Infarction Triage and Intervention
NHLBI	= National Heart, Lung, and Blood Institute
NRMI	= National Registry of Myocardial Infarction
NYHA	= New York Heart Association
OR	= odds ratio
PAMI	= Primary Angioplasty in Myocardial Infarction trial
PET	= positron emission tomography
PTCA	= percutaneous transluminal coronary angioplasty
RCA	= right coronary artery
REGRESS	= Regression Growth Evaluation Statin Study
RITA	= Randomized Intervention Treatment of Angina Trial
RWMA	= regional wall motion abnormalities
SK	= streptokinase
SPECT	= single-photon emission computed tomography
STRESS	= Stent Restenosis Study
t-PA	= tissue-type plasminogen activator
TAMI	= Thrombolysis and Angioplasty in Myocardial Infarction
TEC	= transluminal extraction catheter
TIMI	= Thrombolysis In Myocardial Infarction
VA	= Veterans Administration

the rate of postoperative failure because the surface we left in the inner layer of the coronary artery was irregular and had many crevices, inducing turbulence and precipitating thrombosis.

At the Cleveland Clinic we had gathered a broad experience with saphenous vein grafts in peripheral and renal artery reconstruction. Early in 1967 I started thinking that by using the saphenous vein we might overcome many of the problems we faced. I discussed the idea with Mason Sones and collaborators and we decided that initially we would try grafting in patients with total occlusion of the right coronary artery in whom the distal segment was perfused by collaterals originating from the left coronary artery. If for any reason the graft occluded, the patient would not be harmed.

The first operation was performed in May 1967 on a 51-year old woman. The right coronary artery was reconstructed by the interposition of a segment of saphenous vein. A few days later—Sones was very anxious to restudy her—cineangiography showed an excellent reconstruction of the right coronary artery.

In the early days of our experience we realized the limitation of the interposed technique. Consequently we started placing the proximal anastomosis of coronary artery bypass grafts (CABG) in the anterolateral wall of the aorta. We went slowly at the beginning (13), since we were very interested in the late evolution of the graft. My Latin enthusiasm was restrained by Sones many times. He would say "look if they are plugged in three months!" By the end of 1968 we knew that the veins would remain open without dilation within a year. That was one of our main concerns (14). By December the largest series in the world had been accumulated (171 patients).

Significant progress occurred in 1968:

1. We were able to combine CABG with ventricular aneurysmectomy or scar tissue resection of the left ventricle (12) following ideas originating in 1966 (11).

2. CABG with concomitant valve replacement was performed after the routine utilization of cine coronary angiography in patients with valvular disease (12).

3. Emergency revascularization in impending infarction and acute infarction (15).

4. We applied the bypass operation to the left coronary artery (12). It was gratifying to see that a single bypass connected to the proximal anterior descending coronary artery could perfuse the entire left coronary artery tree. Left main coronary obstruction had been defeated after so many years of struggle.

5. At the end of the year I performed a double bypass (right and anterior descending coronary artery) in our institution, previously performed with the interposed technique in a bifurcated right coronary artery in March 1968 (12), thus opening the doors to the multiple bypass approach.

In 1969 the promising results from continuous observation were compiled by Sheldon et al (16,17) in detail. The contributions by W. D. Johnson et al from Milwaukee (18–21), showing that bypasses could be placed in the distal segments of the coronary artery distribution, widened the scope of indica-

tions for CABG. By June 1970 (22), we had performed 1,086 CABGs in 951 patients with an overall mortality of 4.2%.

There was a transitional period during which we combined the indirect approach (Vineberg implants) with the saphenous vein graft. Daily experience showed that the number of single and double implants diminished steadily as a consequence of the increasing number of multiple bypasses (until August 1970, 196 patients underwent double, triple, or quadruple grafts with 4.1% of hospital mortality) (23).

In 1970 thanks to the superb work of George Green in New York (24) the author started using the direct mammary coronary anastomosis. I talked to Green on several occasions and he told me that over 100 hours in the laboratory would be required to learn how to use the microscope (that is the way he did his operations). It seemed that this approach would never be popularized and therefore I decided to dissect the left mammary artery and connect it to the anterior descending artery with the routine interrupted suture technique with the only help of the lenses that we used in our daily work. Then indications were extended to the diagonal and circumflex branches. After I left the Cleveland Clinic in 1971, Loop et al (25) emphasized and standardized this method and demonstrated the excellent results on long-term follow-up (26). Of note, in 1968 I performed a direct anastomosis with interrupted suture between the right coronary artery and the right internal mammary artery (27).

This brief historical summary would be incomplete without mentioning that Garrett and collaborators performed the first successful CABG in Houston on November 23, 1964 (reported in 1973) (28). The original objective of the operation was to perform an endarterectomy followed by reconstruction using a venous patch. Because of some complications they decided to solve the problem with a saphenous graft to the anterior descending branch of the left coronary artery. The implications of this case were not fully appreciated. They were convinced that the saphenous vein graft could be used as a substitute for the Vineberg approach. Several publications by Garrett, Diethrich and collaborators from 1964 to 1967 (29–34) presented in detail how the grafts could be connected to the descending aorta and implanted in a tunnel on the lateral and posterior wall of the left ventricle. They began to use CABG as a consequence of the cumulative results of the Cleveland Clinic by mid 1968 (35–36).

The reader can find a more detailed description of the history of CABG in three of my publications (37–39).

The Evolution of the Surgical Technique

Many changes have taken place in the operating room in the last thirty years. If we had recorded all the conversations during a cardiac operation in the 1970s, 1980s and 1990s, it would be realized that different languages were spoken. This is not the place to analyze all changes in detail but it is worth emphasizing that improvement in the delivery of anesthesia, excellent extracorporeal circulation system, careful monitoring of all the physiological parameters, minimal utilization of blood, recovery of blood elements by the Cell Saver equipment (mainly in reoperations), new suture materials, assisted circulatory support during and after the operation and a wide variety of medications to correct deviation of cardiovascular stability have contributed to the low operative risk even though we operate on patients with more severe coronary artery disease and concomitant medical problems such as: (a) less single- and double-vessel disease, more triple-vessel disease; (b) more patients with left ventricular deterioration; (c) patients of advanced age; (d) renal insufficiency; (e) severe hypertension; (f) diabetes; (g) unstable angina; (h) emergency and urgent operations, and increased number of reoperations (40–67). If I had to choose one contribution that has changed our lives as cardiovascular surgeons, undoubtedly it would be myocardial protection (68–70).

The introduction of percutaneous transluminal coronary angioplasty (PTCA) has played a significant role in the spectrum of the surgical population, not only because it is performed mainly in patients with single- and double-vessel disease but also because it is applied in the low risk three-vessel-disease group. On the other hand, it has increased the number of emergency CABGs. Naunheim (59,67) has shown that the clinical profile of the PTCA population in the year 1985 closely resembles the low-risk profile of the CABG patients in the year 1975.

It is futile to evaluate raw mortality data without appropriate risk stratification. As an example the overall CASS (Coronary Artery Surgery Study) operative mortality was 2.3% (44), but the predicted operative mortality rates varied from 1.4% to 5.1% in relation to the risk factors involved. Edwards and collaborators (64) analyzed the data base of The Society of Thoracic Surgeons using a modification of the Bayesian algorithm. It comprised patients operated between 1980 and 1990. They found a steady increase in the average age (58.5 vs. 64.1 years in 1990), a trend toward higher proportion of women (17% vs. 27%), an increased number of reoperations (1.9% vs. 7%), a progressive deterioration of ventricular function (average ejection fraction 0.62 in 1980 and 0.51 in 1990), and an increased number of emergency and urgent operations (4.1% vs. 18.2%). The overall operative mortality was 3.2%. Nevertheless it is important to note that between the ages of 50 and 70 the mortality was 2.6%. In patients over 70 it increased to 6%. In the first operation elective surgery carried a mortality of 2.2 vs. 5.7% among emergency patients. In reoperations the values were 5.3 and 12.6% respectively. They concluded that since the mid 1980s the CABG patient population had expanded to those with prognostically important adverse characteristics mainly older age, ventricular dysfunction, associated diseases and surgical priority. The selected Bayesian model has proved effective in this clinical context and has an extreme flexibility in accommodating temporal changes in the population (57,61). It could serve as a benchmark representing a standard care of the national experience. Individual institutions may classify their patient populations to obtain a direct risk-adjusted comparison of results.

In another publication (66) that comprises 205,778 patients

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Table 1. Predicted Mortality for Patients Undergoing CABG From 1984 to 1993*

No. of Patients	Risk Stratification	Difference Between 1984 and 1993
99,332	0% to 2.5%	−17.5%
47,191	2.5% to 5%	—
31,278	5% to 10%	+6.2%
22,218	10% to 20%	+9.1%
2,767	20% to 30%	+1.4%
2,035	30% to 50%	+1.1%

*Data from Clark et al. (66). CABG = coronary artery bypass graft surgery.

operated between 1984 and 1993, they found no significant changes since 1990 in the distribution of risk factors. Six categories of predicted operative mortality were identified from 0 to 2.5% up to 30% to 50% risk. In Table 1 the lowest-risk group (0 to 2.5%) decreases 17.5%. In the second group there was virtually no change, but there was an increase in the highest-risk group, particularly the 10% to 20% group. Nevertheless it is interesting to note that most of the patients (72%) belong to the group between 0 and 5%. Since 1990 the differences among the six categories are minimal. When the population is examined as a whole the predicted operative mortality of 2.9% is identical to the observed operative mortality. When the validated model is applied to more recent years, the predicted operative mortality is within the range of 5%. Even when statistical risk models have gained widespread acceptance, they should be interpreted with knowledge and sound surgical judgment acquired by experience (71).

The data base of The Society of Thoracic Surgeons gives an idea of the overall practice of CABG in USA but cannot be applied to each individual surgeon or institution. The mortality achieved is in accordance with the type of patient accepted in daily practice. To cite an example, if we analyze 1,000 consecutive patients operated on in our hospital from February 1995 to April 1st, 1996, where 214 patients were above 70 years of age, 412 had a previous myocardial infarction (61 were operated within 30 days), 153 had history of cardiac insufficiency, 194 were diabetic, 33 had severe renal insufficiency, 580 were hypertensive, 125 had definite lower-limb claudication, 398 had unstable angina, 101 underwent previous myocardial revascularization, 74 were operated on within three days of a PTCA, 160 were urgent operations, 47 were emergencies, 410 demonstrated severe triple-vessel disease, 184 had left main trunk obstruction, 273 had ejection fraction of 0.3 or less and 108 had ejection fraction 0.2 or less. Thus, a 4.5% mortality is amply justified.

Therefore it is not adequate to present the raw mortality data without analyzing the surgical population properly. It may lead to a general misconception. Increased mortality is not always related to "poor surgery." It seems that society and health regulation organizations are pressing for "safe" surgery. However, it is important to realize that if all of us were competing to show low operative mortality, there is no doubt that the moderate and high-risk patients will be denied the chance of undergoing operation.

In summary, review of the literature demonstrates that since 1985 the subset of patients referred for CABG has evolved into a population with a high incidence of advanced age, severe coronary artery disease, left ventricular dysfunction, and various concomitant medical problems. Urgent and emergency procedures continued to increase in frequency.

Campeau (72,73), Bourassa (74) and Grondin (75) demonstrated the deterioration of the saphenous vein in time mainly because of arteriosclerotic changes, and Loop (26) showed —after comparing 2,306 patients who received a mammary graft to the anterior descending branch of the left coronary artery, plus one or more saphenous vein grafts, with 3,625 who had only saphenous vein bypasses—that at ten years there was a clear advantage of the group with mammary artery grafts in patients with single-, double-, or triple-vessel disease even among those with moderate or severe left ventricular impairment. Many additional contributions have shown (24,76–155) that arterial bypasses with one or two mammaries are the grafts of choice. It is worth mentioning that up to 1980, only 13% of the surgeons were using mammary grafts (91). Since the mid 1980s the number has increased steadily and today most surgeons employ them.

Review of the literature has clearly demonstrated that, when internal mammary arteries are utilized:

1. the operative mortality and the rate of perioperative myocardial infarction decrease, even at reoperations;
2. the patency rate (early and late) is higher than when saphenous vein grafts are utilized;
3. the major events, mainly myocardial infarction, are less frequent;
4. they become an independent predictor of late survival in all categories of patients and should not be denied in any subgroup: older and younger patients, men or women, normal or impair ventricles, single-, double-, triple- and left-main-trunk obstruction;
5. the maximal diastolic flow velocity is higher than that in saphenous vein grafts.
6. they adjust to physiological demands and clearly enlarge overtime;
7. they improve left ventricular performance;
8. they improve exercise tolerance;
9. they resist degenerative changes.

It should be emphasized that the use of these grafts is certainly possible in elderly patients. Reports in the literature (122–124,153) and our own experience show that the mammary artery remains free of atheromatous changes in patients over 70 years of age. It also can be used in emergency revascularization operations, including patients with failed angioplasty (156–166). With appropriate technical skill, the dissection of the mammary artery will not take more than 10 minutes. It is important to realize that we do not have to perform a proximal anastomosis. As a consequence the anoxic

time will be equal to that utilized in the construction of a saphenous graft.

Due to the excellent results of the internal mammary graft, surgeons looked for other sources of arterial conduit. The right gastroepiploic artery was first utilized in myocardial revascularization by Bailey and associates for a Vineberg type operation (167). In 1987 Pym (168), Suma (169) and Attum (170) reported the early application of the gastroepiploic artery for direct myocardial revascularization. Later Mills (171) and Lytle (172) confirmed good clinical and angiographic results. Several publications promoted the utilization of this vessel (173–181). Use of the inferior epigastric artery was introduced by Puig (182) in 1990, mainly applied in grafts to the diagonal, lateral branches of the circumflex and right coronary artery. Afterward several contributions (183–190) analyzed its practical application.

Recently Buche and associates (191) presented their experience with arterial revascularization in which 167 distal anastomoses were connected to the inferior epigastric artery with excellent early patency rate. At an average of 8.5 months, 44 of the 48 inferior epigastric artery grafts were patent, but eight showed some narrowing. Schroeder and collaborators (192) reported an early patency rate of 90% (ten days from the operation) and 84% at 24 months.

In 1971 Carpentier introduced the radial artery as an alternative for coronary artery bypass. His early experience was reported in 1973 (193). Two years later he advised that its use be discontinued because of a 30% incidence of graft occlusion. Nevertheless 18 years later a patient in whom postoperative arteriography showed total obstruction was restudied and surprisingly the radial artery was fully patent with no evidence of atherosclerotic changes. Three other patients had similar cine coronary angiographic findings. It seems logical that arterial spasm was the cause of the "early obstruction" of the graft.

Consequently, in 1989, Carpentier's group (194,195) revived the use of the radial artery, adding the administration of calcium channel blockers during and after the operation. Up to January 1995, three hundred and twenty-seven patients were revascularized with the radial artery in addition to internal mammary arteries. Postoperative angiography in 141 patients between one month and one year showed a 92% patency rate. A recent long-term follow-up (mean 5.4 years) in 100 patients demonstrated a patency rate of 84.2% (personal communication with Acar).

After the French experience the radial artery is utilized in most of the cardiovascular centers. A detailed description of the technique of harvesting the radial artery can be found in a paper by Reyes and collaborators (196). The Allen test is mandatory preoperatively and after the exposure has been performed, in order to avoid any possible ischemic complications in the hand (197).

The concept of anastomosing another bypass graft to an attached internal thoracic artery was introduced by Mills (198) in 1982 to avoid placing it into a severely atherosclerotic ascending aorta. Sauvage (137) employed a similar approach to bypass all coronary arteries and Tector emphasized its advantage in 1989 (142,199).

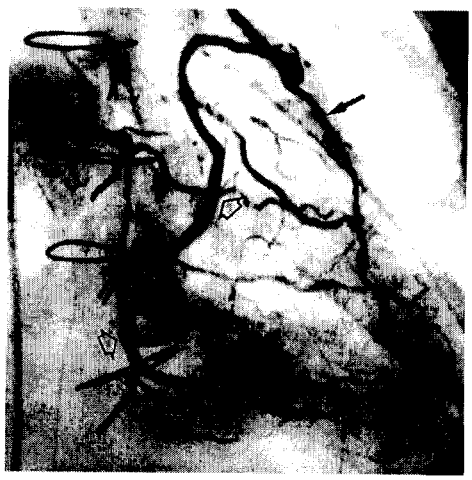

Figure 1. Solid arrow indicates left internal mammary artery anastomosed to the anterior descending branch of the left coronary artery. **Open arrows** indicate radial artery with a proximal anastomosis to the left internal mammary artery and connected afterward to the three circumflex artery branches.

Calafiore, a pioneer in utilizing composite grafting (200,201), said that "these arteries are normally third- or fourth-order branches of the aorta, so they are usually submitted to a pattern of flow that is quite different and therefore cannot tolerate the flow of the ascending aorta. When these conduits are anastomosed to the aorta the abrupt increase in pressure wave can result in wall stretching with intimal tearing and subsequent development of premature hyperplasia" (200). Certainly the rate of rise of left ventricular pressure in their natural position is different from that in the ascending aorta.

At present different options can be utilized for multiple arterial coronary revascularization. In our department of thoracic and cardiovascular surgery we follow this pattern:

1. Both internal mammary arteries in situ are used, with or without distal sequential anastomosis. Very seldom do we use more than two for each mammary artery. The right one is generally placed through the transverse sinus as suggested by Puig in 1984 (101). The author believes that it is mandatory to connect both mammary arteries to the left coronary artery distribution.

2. In order to reach distal coronary branches, the right mammary artery is anastomosed to the left mammary artery end-to-side. Rarely do we connect a mammary artery to the ascending aorta.

3. The radial artery is our next choice, anastomosing it to the left mammary artery. All the distal lateral branches of the circumflex coronary artery and even the distal distribution of the right coronary artery can be reached (Fig. 1).

4. Because of its length, the inferior epigastric artery (we use only the proximal portion), is connected to one of the mammary arteries and, distally, mainly to diagonal and lateral branches of the circumflex (Fig. 2).

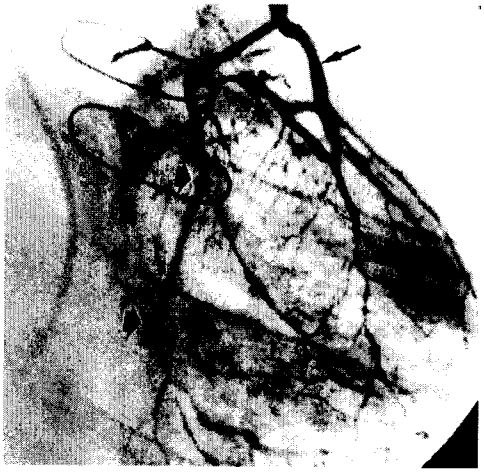

Figure 2. Long arrow indicates left internal mammary artery anastomosed to the anterior descending branch of the left coronary artery. **Short arrows** indicate epigastric artery with a proximal anastomosis to the left internal mammary artery and connected afterward to two circumflex artery branches.

5. The gastroepiploic artery is utilized, with less frequency, mainly for the distal distribution of the right coronary artery.

We try not to "hang the heart" (202) on a single internal mammary artery by connecting all the other bypasses to it, even though postoperative studies confirm that the artery enlarges significantly when multiple distal anastomoses are connected to a single internal mammary artery. Two sources of inflow are preferable. Of course saphenous vein grafts are still utilized, mainly in older patients; although they deteriorate in time, 35.7% are still open 22 years later (203).

It is worth emphasizing that the internal mammary artery remains the graft of choice and is our first option. Physiological and histological studies confirm its advantage (204–215).

The fear of increasing sternal disruption proves groundless if we dissect the artery properly, avoiding wide pedicles that must be dissected with careful utilization of the electrobistoury. Excessive burning is the most important cause of postoperative complications. Except in diabetic patients, the rate of infection—mainly mediastinitis—is not increased, even when both mammaries are utilized.

Although there is not total agreement that the utilization of both mammary arteries results in longer survival, Cosgrove and collaborators (216) clearly demonstrated that among patients under 60 years of age their utilization is preferable.

In the early days we were able to accomplish CABG on a beating heart without the pump (14,217–219) to the right coronary artery or the anterior descending branch of the left coronary artery in a small, select group of patients. Afterward, in 1975, Trapp and Ankeney reported a similar approach (220,221). Benetti (222–225) and Buffolo (226,227) operated on a significant number of patients with a low operative mortality. It is worth mentioning that the 1,274 patients operated on by Buffolo (228) represented 20.3% of the total number of patients submitted for CABG in his hospital. Most of the grafts were placed on the right coronary artery (RCA) (659 grafts) or the left anterior descending (LAD) (365 grafts). Only 130 distal anastomosis were placed on lateral or diaphragmatic branches; 7.7% underwent three bypasses. The left internal mammary artery (LIMA) was utilized in 42.9% of the grafts. They emphasized that "the technique is particularly suitable for patients with lesions in the LAD or RCA." A seven-year follow-up was presented at the seventy-seventh Annual Meeting of the AATS held in May 1997, which compared 107 patients operated on a beating heart (BH) with 122 patients operated on with cardiopulmonary bypass (CPB) during 1989. The final decision was often taken in the operating room. A total of 260 vessels were bypassed in the BH group vs. 362 in the CPB group. Almost all patients had a bypass performed to the LAD branch (88% vs. 86% BH and CPB, respectively). A high proportion of obtuse marginal (100% vs. 62%) and posterior descending vessels (46% vs. 16%) were bypassed in the CPB group. At seven years 80% of the BH group and 79% of the CPB group were alive. But 16 patients of the BH group underwent PTCA and five repeat CABG. Only five patients of the CPB group had PTCA. Even though only 34 patients were catheterized, the patency rate demonstrated a significant higher rate of patency in the CPB group (72 vs. 34%). They conclude that

> Parity between groups was achieved only by using three times as many post bypass interventions in the BH group. It would appear that beating heart bypass produces results intermediate between conventional bypass (best) and angioplasty (worst). It further suggests that limited revascularization, by either PTCA or BH bypass will produce long-term results comparable to full revascularization, if one accepts the need for additional procedures later.

It should not be forgotten that Kolessov in Russia performed a mammary coronary anastomosis without extracorporeal circulation in 1965 (229).

Personally, I believe it will be extremely difficult to perform the present technique of multiple composite arterial bypasses on a beating heart if we realize that, to obtain good results, a meticulous and delicate technique with 8–0 running sutures must be utilized. Perhaps this will be possible in the hands of a few privileged master surgeons who cannot be emulated by most of us.

Recently, a less traumatic operative technique was introduced (230–235): a single internal mammary artery graft to the anterior descending branch of the left coronary artery can be accomplished without extracorporeal circulation through a small left anterolateral thoracotomy. Calafiore et al popularized this technique and reported the world largest series (236). If we bear in mind that this is the most important branch of the coronary circulation, this new approach constitutes a significant step forward. Patients can be discharged within two or three days, significantly reducing the cost. The number of patients can be increased if we combine it with PTCA for localized obstructions of the right coronary artery or circumflex branches of the left coronary artery. In some patients a

composite graft to the diagonal branch of the left anterior descending branch can be accomplished utilizing small segments of the epigastric artery.

It is possible that thoracoscopy will play a role in dissecting arterial conduits. Automatic suture stapling devices, laser welding or gluing for construction of the anastomoses may become feasible. It is too early to make any prediction, but we should be always open to new ideas and development, understanding that judgment and criteria are necessary to evaluate them properly.

The Controversies

Initially it was extremely difficult to convince our medical colleagues that a very simple operation could ameliorate the myocardial perfusion deficit, even when several observations confirmed that the delivery of oxygen is enhanced by CABG (237–261). Probably the main reason was the failure of previous attempts of myocardial revascularization, starting with Jonnesco's ideas (262,263). In most of them the indications and results were judged only on a clinical basis and since Proudfit, Shirey and Sones' contribution (264), where they correlated the results of the clinical and electrocardiographic diagnosis with findings of cine coronary angiography in 1,000 patients, we know that in approximately 20% of the patients the clinical impression may be wrong.

After the introduction of cine coronary angiography the natural history of coronary arteriosclerosis is better understood. Several studies (265–272) have clarified the prognosis of patients with single-, double-, triple-vessel disease and left main trunk obstruction and their relation with the left ventricular status. Cine coronary angiography allows us: (a) to confirm or exclude the diagnosis of coronary arteriosclerosis; (b) to evaluate the degree and distribution of the occlusive disease; (c) to select the proper candidates for revascularization procedures, and (d) to obtain an objective evaluation of the postoperative result.

The early surgical experience of the Cleveland Clinic in 741 patients operated on from May 1967 through December 1970 was carefully evaluated by Sheldon and collaborators (273). The hospital mortality rate was 3%. Perioperative myocardial infarction occurred in 6.9% of the patients. All survivors were followed for 36 to 85 months (average 45.8). Forty-seven patients died during this period (28 due to cardiac causes). Postoperative angiographic studies showed a patency rate of 77.3% (79.5% of grafts connected to the anterior descending branch of the left coronary artery) at a mean interval of 16.2 months. New proximal occlusions occurred in 33% of the grafted arteries: 87.7% occurred in arteries that were severely stenosed 80% to 90% in the proximal segment preoperatively. The survival of the surgically treated group was compared with a medical group compiled by Webster and collaborators (272) who had cine coronary angiography from 1960 through 1965. The average annual attrition rate was 3.5%, 9.8% and 19.3% for single-, double- and triple-vessel disease in the medically treated group. The surgical group, including hospital mortality, had, respectively, 2.4%, 4.6% and 4.6% attrition annually for single-, double- and triple-vessel disease.

The medical survival curves were similar to a study undertaken by Bruschke (268), but Webster's data were chosen because they included patients who had been considered candidates for graft surgery by criteria applied in 1970, mainly severe proximal obstructions. It was clear that patients with double- and triple-vessel disease were highly benefited by surgery. In patients with single-vessel disease the difference did not have statistical value with the exception of proximal obstruction of the left anterior descending branch. The attrition rate per year of this group was 1.7% for the surgical patients and 4.8% for medical. Patients with moderate impairment of left ventricular function were also benefited. Eighty-nine percent of these patients survived three years compared to 94% of survivals among patients with normal or mild deterioration. Complete revascularization was achieved in more than half of the patients studied: 87% were asymptomatic on evaluation. On the other hand, in patients with incomplete revascularization, only 42% remained asymptomatic, and 32.8% had angina class II. The surgical group demonstrated definite improvement on exercise tolerance testing. This report summarized our early experience at the Cleveland Clinic (learning period). Several reports confirmed these preliminary data (18,35,274–286). By 1974 hospital mortality decreased to 1.4%, perioperative myocardial infarction, to 4.1%, and graft patency rate increased to 83.6% (eighty-nine percent of the patients had one or more functioning grafts). The early occlusion rate (5% to 15% at one month) (287–289) diminished steadily with the administration of aspirin and dipyridamole suggested by Chesebro et al (290,291).

Nevertheless the opinions were highly divided; on the one hand, the enthusiasts (273,283,292–317), on the other, the opponents and colleagues who had sounded a word of caution (281,318–348).

Three methods were used to compare the long-term effect of coronary bypass surgery with medical treatment up to 1977:

1. *Retrospective matched studies.* The surgery performed during the 1970s had been compared to the evolution of the patient treated medically in the 1960s. There were two problems: (a) it was difficult to match the patients because of selection bias, and (b) it was difficult to assume that the medical management used during the 1960s had remained the same during the 1970s, when medical treatment had improved. Even so, we have to recognize that already in the 1960s there was a decline of 18.4% in the death rate of ischemic heart disease. The advantage of this method was that we could select patients with the same angiographic pattern in an era when CABG was not performed.

2. *Prospective matched studies.* This method entailed creating a protocol and entering patients into the study as they were observed. Nevertheless selection bias might occur and influence the entry of patients; it did not guarantee that all the variables were equalized, mainly the number and precise location of the obstruction at the coronary level.

3. *Comparison of study groups with life tables.* It was possible

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to estimate the yearly survival rate of persons living in the United States with the life table generated in the Department of Health Education and Welfare or by tables from insurance companies and compare them to the survival curves of the study group. Some critics stated that the number of patients of the study group was small when compared with the general population and might not be a representative sample.

A critical analysis of the first ten years of CABG from two different points of view can be found in a contribution by J. Willis Hurst and collaborators (311) in which the value of the new surgical approach is emphasized, and in a special article by McIntosh and García (349), a collection of papers highly critical of CABG. As an example of one of them, Achuff and collaborators (329) questioned whether alleviation of angina was due to a patent graft or to a new myocardial infarction to the "angina-producing" segment. They reported 71 patients (7.8% operative mortality) mainly with single and double bypasses (only four triple grafts) and a 63% postoperative damage!

On March 7, 1978 in the Louis F. Bishop Lecture at the 27th Meeting of the American College of Cardiology (316) I analyzed the myths and realities of a ten-year journey. In 1977 we had clear evidence that the new blood supply: (a) improved myocardial performance; (b) relieved angina pectoris; (c) improved the quality of life; (d) prolonged life in properly selected patients with left main coronary obstruction, double- and triple-vessel disease, including patients with abnormal ventricles and lower ejection fraction; (e) diminished the incidence of sudden deaths; and (f) appeared to decrease the incidence of myocardial infarction. The percentage of perioperative myocardial damage played a significant role when the comparisons were made.

The Randomized Trials

During the first ten years of CABG the discussions between cardiologists and cardiovascular surgeons emphasized the need of randomized trials, which indeed appeared in the last part of the decade.

The first randomized trial was the Veterans Administration (VA) cooperative study. A preliminary report of a subgroup of patients with significant left main lesions (113 patients from January 1970 through December 1974) demonstrated a significantly higher survival of the surgical patients. In September 1977 (350) they released the first publication of their overall population with three-year survival. Afterward, several contributions (351–363) compared the results at different intervals up to an eighteen-year follow-up.

A total of 5,538 patients with stable angina were screened, 2,125 had coronary arteriography and 1,015 patients were randomized. Reading of the cineangiographic films was complicated. After an initial study revealed considerable interobserver and intraobserver variability in interpretation, all coronary angiographies were reread by each observer, using a standardized data sheet. Data presented in that report were based on the second-reading information. Goffredo Gensini was asked (personal communication) to review the coronary angiographies of patients included in the study. He later wrote to Marvin Murphy, stating

> I am sure you will agree that some of the early films hardly show the outline of the coronary arteries at all, thus the determination of the size, degree of stenosis and the surgical adequacy of the runoff is quite chancy at best. Under such circumstances I believe that a not insignificant number of patients were randomized to either medical or surgical therapy when they should not (or could not) have been selected for surgery in the first place. If you assume for a moment that a statistically significant number of patients had surgery when either the runoff was inadequate or the bypass was unnecessary, it would not be surprising to find no difference between medical and surgical therapy. In fact, these patients when randomized to surgery would tend to have poor results.

Patients with (a) myocardial infarction less than 6 months before operation; (b) persistent diastolic hypertension (more than 100 mm Hg) despite treatment; (c) marked cardiac enlargement; (d) previous operation for angina pectoris; (e) unstable angina or angina of increasing severity, suggesting "impending infarction"; and (f) congestive heart failure unless clinically compensated for at least three weeks, were excluded (352). Some degree of abnormal left ventricle contractility was observed in 53.5% of the surgical group and 55.3% of the medical group. Nevertheless only 15% of both groups had an ejection fraction below 0.45.

A high risk patient was defined as one with three-vessel disease and some abnormality of left ventricular function (38% of medical and surgical groups). A low-risk patient was defined by default as one not in the high-risk group or one with undetermined risk because of incomplete data (92 patients, 50 medically and 42 surgically randomized) (352). The 5.6% operative mortality was high if we consider that approximately two thirds were low-risk patients. Furthermore, 18% of them had had perioperative myocardial infarction and at one year only 69% of the grafts were open (all the grafts were occluded in 13% of the patients). At three years there was no survival difference between the two groups.

There was a surprisingly low mortality rate at two years in the medically treated group with an overall survival of 90% (88% among patients with triple-vessel disease). We did not know how many of them had proximal obstructions. In the early Cleveland Clinic series—where most of patients had indeed proximal obstructions—the survival in three-vessel disease was 66% (268,269) and 63% (272). As we will discuss later three-vessel disease is not a single entity.

In 1981 another risk stratification was done based on four non-invasive characteristics: New York Heart Association (NYHA) angina class III and IV, history of hypertension, history of myocardial infarction, and ST segment depression on routine electrocardiography. The risk function was developed by applying the Cox-Breston life table regression model. Patients were divided into low, middle and high-risk terciles. At six years surgery prolonged life in the high-risk tercile.

When the analysis was restricted to the ten hospitals with lower 30-day mortality (3.3%) even the mid-risk tercile was benefited.

It is interesting to note that patients that were excluded from the original protocol were included in the high-risk group (ST segment depression on electrocardiography, previous myocardial infarction, history of hypertension, and angina class III and IV) and were highly benefited by surgery.

At five years the surgically treated patients had significantly higher relief of angina and better exercise performance; however, at seven years a gradual loss of survival benefit occurred presumably due to increasing graft closure, and at ten years, relief of angina and exercise performance were comparable. Survival of the surgical angiographically high-risk group remained higher than that of the medical group until the eleventh year was reached. The cumulative rate of crossover for medical to surgical therapy was 25%, 40%, 57% and 62% at five, eleven, fifteen and eighteen years, respectively.

In summary, even though the VA study comprised a group of patients selected mainly on a clinical basis (poor cineangiography in a significant number of patients) with relatively high operative mortality, high incidence of perioperative myocardial infarction, and low patency rate of the bypasses performed, when the hospitals with high operative mortality were excluded, surgery improved survival in patients with left main coronary artery disease and patients in mid and high-risk terciles.

The second randomized study was published in November 1978: Unstable Angina Pectoris—National Cooperative Study with the auspices of the National Heart, Lung, and Blood Institute (NHLBI). The first two publications (364,365) clearly demonstrated that patients with different prognoses were included. Thirty-six percent of the 147 medically assigned group (49% with triple-vessel disease) were operated on at 30 months. Any final conclusions were prevented by the high crossover rate and the small number of different subsets. In 1982 Hultgren and collaborators (366) agreed: "the high incidence of crossover and the short follow-up time, limited the evaluation of comparative survival data." In 1981 they published the results among patients with left anterior descending coronary obstruction (367). The 9% mortality in the surgical group and the 23% incidence of perioperative myocardial infarction in patients with proximal anterior descending coronary artery obstruction did not allow any further conclusions.

The third randomized study came from Europe and the early results were reported in 1979 (368–372). It included only males under 65 years of age with two or three-vessel disease (including left main trunk obstruction) and a left ventricular ejection fraction of 0.5 or higher. Patients with severe angina pain that could not be controlled by medical treatment were not included. Likewise, patients with uncontrolled arterial hypertension were not admitted. The proportion of patients receiving a beta blocker at the time of randomization was 74% in the medical group and 75% in the surgical group. A comparison was made between 373 patients included in the medical group and 395 patients that underwent operation. The operative mortality was 3.6%, including eight deaths that occurred before the operation. Graft patency rate was 90% within nine months and 77% between 9 and 18 months. At five years 90 patients (24%) of the medical group had had a CABG (because of disabling angina) and were kept in the medically treated group.

At five and eight years patients with left main coronary obstruction, and three-vessel disease—mainly when a proximal obstruction ≥50% was present in the anterior descending artery—were highly benefited by surgery. For the first time we had clear evidence that, in patients with double-vessel disease, surgery improved survival if the anterior descending artery had >75% narrowing. In patients with ischemic ST segment depression of >1.5 mm during exercise test, the prognosis was significantly improved by surgery. In summary, in selected subsets of patients with left main obstruction or double and triple-vessel disease, surgery improved survival.

The conclusions of the Consensus Development Conference on Coronary Artery Bypass Surgery, organized by the National Institutes of Health were reported in 1980 (373):

> The symptom of angina pectoris is reported to be relieved in 80% to 90% of patients undergoing surgery for chronic stable angina. Bypasses have reduced the subsequent number of cardiac related events, the amount of medication required, and the frequency of hospitalization. The majority of patients have been able to increase their exercise capacity and improve their NYHA functional class after operation. The operation has been documented by improvements in functional exercise testing, angina threshold, left ventricular wall motion, left ventricular ejection fraction, during exercise and lactate extraction across the myocardium. There is the conclusion of the panel that CABG represents a major advance in the treatment of patients with coronary artery disease. Evidence has been presented to support the conclusions that an improvement in the quality of life, a decrease in myocardial ischemia, and an increase in survival have been demonstrated after CABG in selected subsets of patients.

In the early 1980s CABG experienced real advances, with a decrease of operative mortality and perioperative myocardial infarction, mainly because of cardioplegia and despite the fact that the number of high-risk patients had increased steadily. Long-term follow-up started to show that the utilization of internal mammary artery grafts improved later survival. At that time the National Heart, Lung and Blood Institute organized the Coronary Artery Surgery Study (CASS); its original protocol appeared in 1981 (374). The first data of the randomized trial were released in November 1983 (375), and as a consequence, the dispute flared up with renewed vigor.

From 15 participating clinics, eleven took part in the randomized trial. A total of 24,959 patients were included in the registry. Only 12.7% met the criteria for randomization. Finally, 780 patients (4.7%), 65 years of age or younger, were included.

As in the VA study, the accuracy of the cine coronary angiography was not uniform. The report of the Quality Control Committee (376) emphasized that

Table 2. Clinical Characteristics of Subsets for Randomization in CASS*

No. of Pts	General Description	Angina	Heart Failure	Ventricular Function	Previous MI
514	Mild angina with normal left ventricular function	Mild (CCS class I or II)	Absent	LVEF ≥ 0.50 or normal pattern in at least 4 or 5 segments (RAO ventriculography)	Yes or no (>3 wk)
106	Mild angina with left ventricular dysfunction	Mild (CCS class I or II); primary problem, angina	If present, not primary problem and not decompensated	LVEF = 0.35–0.50 or abnormal pattern in ≥2 of 5 segments (RAO ventriculography)	Yes or no (>3 wk)
160	Asymptomatic after MT	Asymptomatic	If present, not decompensated	Not a criterion for this group, but likely to be normal	Yes

*Data from reference 375. CASS = Coronary Artery Surgery Study; CCS = Canadian Cardiovascular Society; LVEF = left ventricular ejection fraction; MI = myocardial infarction; Pts = patients; RAO = right anterior oblique.

the reproducibility of interpretation of films of good or acceptable quality or completeness was better than the reproducibility of readings of arteriographies judged to be of poor quality or incomplete studies. When one angiographer reads a stenosis of 50% or more in the left main coronary artery, it is estimated that a second reader will report no lesion 18.6% of the times. The reproducibility of angiography is improved with high quality films and complete studies. There is an indication that differing clinics can reduce the variability between their readings by concerted effort to improve both the quality and the completeness of the angiographic examination.

Furthermore the anterior descending artery was considered diseased if 70% or greater stenosis was present in segments 12, 13, 14, 15 or 16 (above the first septal perforation, below the first septal perforation, mid portion, first diagonal and second diagonal). This approach may be inappropriate, because the prognosis would vary significantly in relation to the different locations (310,377–380).

Evaluation of the left ventricle was done, but although the clinical sites were encouraged to obtain a 60% to 70% left anterior oblique, only the right anterior oblique view was utilized in CASS publications (381). Therefore the entire lateral wall of the left ventricle was not considered. The wall motion score, the myocardial jeopardized index, the corrected ventricular score and the residual left ventricular score utilized in CASS protocols gave only a partial interpretation of the left ventricular status. Thus the reading of the left ventricular aneurysm was confusing (381):

In absolute terms, the agreement between the quality control centers and clinical sites with respect to reading left ventricular aneurysms was poor. When one observer indicated the presence of left ventricular aneurysm, the other observer agreed that there was an aneurysm of the same segment in 26% of cases. However, when 'nearest neighbor' differences were excluded, the agreement was much better. When one observer read the presence of a left ventricular aneurysm, the other site read either an aneurysm or dyskinesis of the same or an adjacent segment in 77% of cases.

The consideration of left ventricular aneurysm in the CASS registry became even more confusing when they reported the surgical experience accumulated (382). Of 1,131 who were enrolled in the registry, 467 underwent surgery and only 238 had ventricular resection!

The characteristics of the randomized population (the first patient was assigned in August 1975 and the last in May 1979) are described in Table 2. The clinical and angiographic characteristics (Table 3) demonstrate that the randomized patient belonged to a low-risk group (383):

1. Mild angina was present in 620 patients and no angina in 160 patients, altogether representing only 4.7% of the 16,626 patients originally screened.

2. Ejection fraction above 0.50 was present in 74% of patients. Only 160 patients had moderate impaired deterioration: 0.35 to 0.50, and the mean ejection fraction of the 780 patients measured was 0.61.

3. There was a modest extent of coronary artery disease: 67% had one or two-vessel disease and we only know that 31% showed proximal left anterior descending coronary artery obstruction (only half of the number included in the European Coronary Artery Study). No data are available in the original article relative to proximal obstruction on the right and circumflex coronary arteries. Nevertheless, if we carefully read

Table 3. Clinical and Angiographic Characteristics of 780 Patients From the CASS Randomized Trials*

Characteristic	% of Pts
CCS class I angina	65.9
CCS class II angina	13.6
No angina symptoms	20.5
LVEF >0.5	73.7
LVEF 0.35–0.5	20.5
1- or 2-vessel disease	66.9
3-vessel disease	33.1
3-vessel disease with 3 proximal obstructions	1.0
LMCA equivalent	5.2
LAD proximal lesion >70%	31.5
Proximal obstruction of Cx or RCA	Unknown
Induced ischemia	40.0

*Data from Favaloro (383). Cx = circumflex coronary artery; LAD = left anterior descending coronary artery; LMCA = left main coronary artery; RCA = right coronary artery; other abbreviations as in Table 2.

the publication from CASS related to the surgical treatment of "left main equivalent" (384) we will see that 41 patients (5.25%) had concomitant proximal left anterior and circumflex lesions in the very proximal segments in the randomized trial, and only 51 patients (3.87%) of 1,315 patients in the randomizable group, suggesting that only a minimal number of patients with proximal obstruction were included in the randomized and randomizable groups. This was further highlighted in the CASS contribution presented by Myers and collaborators at the 22nd Annual Meeting of the Society of Thoracic Surgeons (January 1986) (385): of 195 patients with triple-vessel disease and normal ventricle included in the randomized series, only 8 (two in the medically treated group and six in the surgically treated group) had three proximal stenoses. It is logical to think that the majority of patients included in the randomized trial with triple-vessel disease had very few proximal obstructions.

4. Further evidence that the trial was a low-risk group is the fact that only 40% of the patients had exercise-induced myocardial ischemia.

The operative mortality was 1.4%. Perioperative myocardial infarction occurred in 6% of the 357 surgical patients. All patients were followed for 3.8 years, 69% for five years, 40% for six years and 11% for seven years. Consequently all the data analyzed are derived by actuarial analysis.

At five years there was no difference of outcome between the medical and surgical groups. The five-year mortality in patients assigned to surgical therapy was 5.5% (1.1% per year). In patients with single-vessel disease it was 3.5% (0.7% per year); in double-vessel disease, 5% (1% per year); and 7.5% (1.5% per year), in patients with triple-vessel disease. In patients with ejection fraction less than 0.50% the five-year mortality was 8.5% (1.7% per year). In patients assigned to medical therapy the five-year mortality was 8% (1.6% per year). In patients with single-, double- and triple-vessel disease, the five-year mortality was 7% (1.4% per year); 6% (1.2% per year) and 10.5% (2.1% per year). In patients with an ejection fraction less than 0.50 the five-year mortality was 16.5% (3.3% per year).

Therefore the message (375) was that

> In patients similar to those enrolled in the CASS trial, a strategy of medical management until worsening symptoms require surgical palliation does not carry a mortality penalty. Furthermore, deferring surgery does decrease immediate health care costs and preserve both veins and mediastinum if surgery is required later. Thus, the decision to proceed with bypass surgery in these patients can be reduced to the question of whether the current level of symptoms is acceptable to the patient. These findings have important implications for both cardiologists and cardiac surgeons in their diagnostic and therapeutic efforts.

Once more as in the previous randomized trials, patients were considered to belong to the therapeutic group to which they were initially assigned (intention to treat) regardless of the subsequent therapy received (386). Accordingly, of 390 patients assigned to receive medical therapy, 23.5% (4.7% per year) had bypass surgery within five years. The crossover rates were 10%, 21% and 38%, respectively for single-, double- and triple-vessel disease. As we previously mentioned, only 69% of the patients were followed for five years, leaving the possibility that more patients might cross over by the time full five-year follow-up was completed. A total of 280 patients (74.4%) in the medically treated group followed their assigned therapy. The operative mortality in patients assigned to medical therapy but subsequently undergoing surgery was 2 in 100. More than 50% were patients with triple-vessel disease (386). I think we have to agree that by following the intention-to-treat policy, the medically treated group was highly benefited.

If we are to compare two different therapies, crossover represents failure of medical treatment. Using this approach in patients with three-vessel disease, Rahimtoola (387) included death, myocardial infarction and crossover as events in the medically assigned group and death and myocardial infarction in the surgically assigned group. The failure rate was 61% in the medically assigned group and 22% in the surgically assigned group.

Willis Hurst had clearly emphasized in an editorial (388) that the CASS report was "overshadowed" by general misinterpretation. But certainly, it impacted our colleagues. As an example, in six counties of the Rochester area (389), catheterization decreased 19% and CABG, 13%.

Another article from CASS (390) clearly demonstrated that the quality of life improved in the surgically treated group as manifest by relief of chest pain, subjective and objective improvement of the functional status (there was a remarkable fall in the percentage of treadmill-induced ischemia at 6, 18 and 60 months), and a diminished requirement for drug therapy.

The publication of the CASS data produced a significant impact in our field and even among the general population when articles appeared in the lay press. The fact that CASS comprised a low-risk group of patients was not properly understood. It was a mistake to extrapolate from its result the overall population of patients with coronary arteriosclerosis or even surgical candidates. An example was the editorial that Braunwald wrote in 1983 (391):

> I consider CASS to be an excellent clinical trial and the most up-to-date examination of the important question of the effects of CABG on survival and on the occurrence of myocardial infarction in patients with coronary-artery disease. The lack of statistical evidence in CASS that survival is improved after surgical treatment in any patients other than those with disease of the left main coronary artery. I believe that this operation should, and increasingly will be, restricted to patients in whom intensive medical therapy has failed or in whom improved survival after surgery has been unambiguously demonstrated, rather than as a panacea for coronary-artery disease.

Nevertheless, he ameliorated his previous strong statement by posing some questions concerning the effect of CABG:

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(a) Will a statistically significant benefit of the procedure emerge from a longer follow-up of patients in CASS, particularly those with three-vessel disease? (b) Can survival be improved significantly by the use of CABG in asymptomatic or mildly-symptomatic patients with specific anatomic features, such as the so-called left main equivalent disease or large fractions of viable myocardium perfused by a single, critically narrowed coronary artery? (c) Can a subgroup of patients in CASS be identified, using clinical criteria such as those in the Veterans Administration trial or a combination of clinical hemodynamic, and angiographic findings, whose survival is improved with surgical treatment?

Of the 1,315 patients that refused randomization 570 were operated on. In another publication the 745 patients that received only medical treatment were compared with the former. They reached similar results at six years (392). As a consequence they concluded "that the data from the randomizable patients thus support and extend the inference of the generally very good survival of both the medically and surgically assigned patients of the randomized trial."

However, there were significant differences between the randomized and randomizable patients, as has been emphasized by Gunnar and Loeb (393). The randomized surgical groups had 48.7%, 2.1% and 32.8% of triple-vessel disease, left main and proximal artery disease respectively. The randomizable surgical group had 62.3%, 9.1% and 46.1%. Therefore we arrive at the conclusion that patients with different prognoses have been compared. If we consider that the surgically-assigned randomizable group was at a significantly high risk, CABG improved their survival because they reached similar mortality rate at six years with the medically assigned group (low-risk population).

Recalling that the original protocol (374) indicated that refusal to accept randomization was decided by the physician in 69% of the cases, the following comments of Rahimtoola are correct: "However, when one examines the therapy administered to patients who were not randomized, a difference becomes evident. Fifty-six percent of patients with disease of the proximal LAD and 54% of patients with three-vessel disease who were not randomized underwent CABG. This contrasts with 33% of patients with two-vessel disease and 31% of patients with one-vessel disease who were not randomized and underwent CABG."

Passamani and collaborators (394) reported actuarial survival curves for the 106 patients having low ejection fractions. They conclude that "the data reported support the premise that elective surgical therapy in patients with triple-vessel disease and moderately impaired ventricular function confers a substantial survival benefit at seven years, in addition to the widely recognized relief of angina."

In 1984 CASS published the data on myocardial infarction related to the randomized trial (386). Perioperative myocardial infarction occurred in 6% of 357 surgical patients. It was 3% in patients with one-vessel disease, 6% in those with two-vessel disease and 8% in those with three-vessel disease. The six-year cumulative probability of remaining alive and free of myocardial infarction was similar in the medical and surgical groups (79% vs. 80%). Nevertheless, patients with three-vessel disease showed a probability of remaining alive and free of nonfatal myocardial infarction slightly better in surgically assigned patients (88% vs. 80% for the medically assigned group). The difference was greater for patients with an ejection fraction less than 0.50 (88% vs. 74% in surgically and medically assigned groups, respectively).

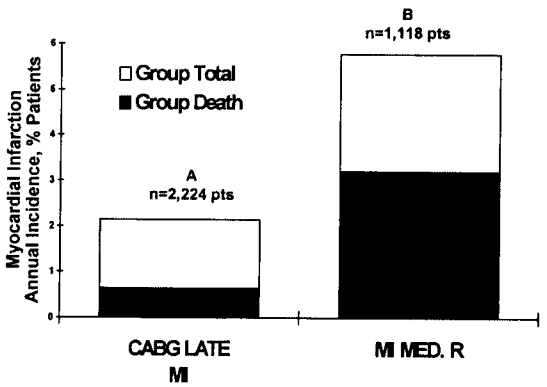

Figure 3. Annual incidence of total and fatal myocardial infarctions (MI) in surgically treated versus medically treated patients with stable angina. CABG = coronary artery bypass graft surgery; MED. R = medical regimen. Data from Mason et al. (397).

Certainly, perioperative myocardial infarction plays a significant role. I consider that the incidence was high in this particular group of low-risk patients. Another report from the CASS registry (395) showed that in 9,777 patients operated on between 1974 and 1979—2,012 were in angina class IV (20.5%), 3,934 had unstable angina (40.2%), and 4,648 had triple-vessel disease (47.5%)—the incidence of perioperative myocardial infarction decreased from 6.6% in 1974 to 4.1% by 1979. In 1987 another contribution from CASS (396) carefully documented by mathematical analysis (Cox model with 51 variables and propensity score) 413 medical patients who were analyzed and compared with 443 surgically treated patients, all with class I and II angina and triple-vessel disease, and showed that the possibility of lowering the risk of future myocardial infarction by surgery required at least two proximal severe obstructions (72% vs. 92% free of new myocardial infarction in the medically vs. surgically treated group). The possibility of benefit also varied with the status of left ventricular function and was greater in patients with mild and moderate left ventricle impairment (77% vs. 92% and 74% vs. 88%, respectively). Early surgery was the strongest independent predictor of freedom from new myocardial infarction.

In 1980 Mason and collaborators (397), after extensive evaluation of the literature that revealed eight institutions with satisfactory data in 2,224 patients, reached the following conclusion: "properly performed coronary bypass grafting is more effective than modern medical therapy in reducing both the incidence and the fatal outcome of subsequent acute myocardial infarction (AMI) in patients with stable angina" (Fig. 3).

Table 4. Predicted Survival Rate for Two Patients With Left Ventricular Ejection Fraction >50% and Three-Vessel Disease*

	Patient 1		Patient 2	
	Medical Therapy	Surgical Treatment	Medical Therapy	Surgical Treatment
1 yr	82%	94%	98%	98%
3 yr	58%	88%	95%	98%
5 yr	42%	82%	92%	97%

*Data from Califf et al. (400).

Another important contribution from the CASS registry, by Holmes and collaborators (398), compared 6,260 medically treated patients with 7,216 surgically treated patients. They demonstrated that coronary bypass surgery diminished the incidence of sudden death at a mean follow-up of 4.6 years (1.8% of surgically treated patients vs. 5.2% of medically treated patients). In triple-vessel disease the difference was even greater (2.7% vs. 14%).

This CASS contribution corroborates what we found in 1977 (316,399) in 206 surgically treated patients and 196 medically treated patients; the incidence of sudden death at 40 months was 1.4% in the surgically treated group vs. 11.2% in the medically treated group. The great majority of sudden deaths in the medically treated group occurred in patients with two and three-vessel disease. The same conclusion was reached by Vismara and collaborators the same year (309).

Limitations of the randomized trials have been analyzed by Califf et al. (400) in an editorial in 1986. After describing significant weaknesses they advise that clinicians should evaluate reports from nonrandomized studies, other scientific observations and personal experience in their own institution, in addition to the evidence from randomized trials. To cite an example (Table 4), they presented, from Duke data base, two patients with three-vessel disease and a rest ejection fraction >50%:

> Patient 1 is a 64-year-old man with frequent exertional angina, peripheral vascular disease, a previous inferior infarction, resting ST segment depression, a resting ejection fraction of 51%, and a 95% stenosis of the proximal left anterior descending artery. Patient 2 is a 51-year-old man with one episode of angina per week, no peripheral vascular disease, no previous infarction, a normal electrocardiography, a resting ejection fraction of 64%, and 75% distal left anterior descending lesion. The difference in survival with medical therapy is dramatic and the predicted benefit from surgery is quite different between the two patients.

These estimated probabilities of survival were based on statistical models developed from the entire population of patients.

In my opinion, randomized trials, particularly CASS, produced more confusion than clarification. The high crossover rate, mainly among patients with triple-vessel disease, with the intention-to-treat policy, obscured the true results; crossovers should be considered therapeutic failures if we want to compare different treatments. However, several publications, including some from the CASS Registry (44,45,398,401–410), confirm that CABG, when properly indicated, definitely improves survival in the majority of patients with severe coronary artery disease. Diminution of sudden deaths and rate of myocardial infarction were realities that could not be denied. Even though the surgical population included progressively more patients at high risk, improvement in surgical technique allowed us to perform operations with low operative mortality and morbidity, including patients of advanced age (409,411–416), and significant deterioration of the left ventricle or function (410,417–423).

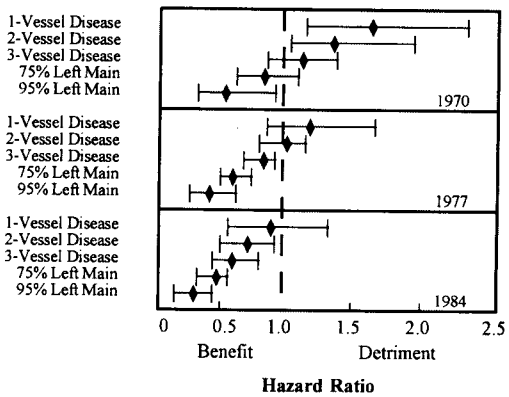

Figure 4. Comparison of medical and surgical average hazard ratios for patients treated in 1970, 1977 and 1984 according to coronary anatomy. **Diamonds** = point estimates; **horizontal bars** = 95% confidence limits of average hazard ratios. Data from Califf et al. (424).

The results in 5,809 patients receiving medical or surgical therapy analyzed by the Cox proportional hazard regression model and Kaplan-Meier survival estimation at Duke University (424) (Fig. 4) is a clear example of the evolution of the results of CABG surgical attempts. The higher the risk, the more the patients gain from surgery, even after accounting for the increased surgical mortality.

In 1994 Yusuf and collaborators (425) published an overview of 10-year results from randomized trials in patients with stable angina. Besides the three largest contributions (VA, European and CASS) they added another four that included small numbers of patients. Altogether they compared 1,324 patients assigned to CABG surgery and 1,325 patients to medical management between 1972 and 1984. A detailed protocol was developed with the aim of obtaining data on every patient. The statistical method (Kaplan-Meier calculations, odds ratio for mortality, study interaction by chi-square tests, logistic regression analysis, restricted means analysis) was focused on mortality. The patients' mean age was 50.8. No angina was found in 11.2% of the population; in the others angina was class I or II in 53.8% and class III and IV in 35%. Only 19.7% of patients were judged to have abnormal ejection fractions and 10.2% had one-vessel disease, 32.4% two-vessel disease, 50.6% three-vessel disease and 6.6% left main artery disease. The proximal anterior descending artery was affected in 59.4%. The operative mortality was 3.2%.

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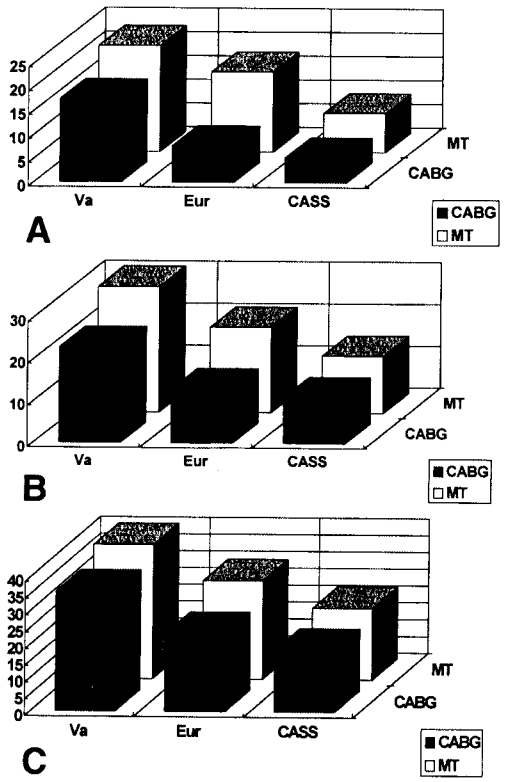

Figure 5. Mortality rate at 5 (**A**), 7 (**B**) and 10 years (**C**). **Dark bars** = coronary artery bypass graft surgery (CABG); **open bars** = medical therapy (MT). CASS = Coronary Artery Surgery Study; Eur = European study; Va = Veterans Administration Cooperative study.

If we concentrate our analysis on the three largest randomized trials (Fig. 5), we will observe that the surgical group had a better prognosis at five, seven and ten years.

There was a significant risk reduction with CABG at five years (39%), seven years (32%) and ten years (17%). For patients with left main artery disease (VA and European) the mortality reduction was 68% at five years and 33% at 10 years. Mortality was also significantly lower with CABG in patients with three-vessel disease at five years (42%) and ten years (24%). There was a nonsignificant trend toward lower mortality in patients with single- or double-vessel disease at five years, but no apparent difference at ten years. Nevertheless, all patients with proximal left anterior descending stenosis benefited from CABG. Among patients without disease of the proximal left anterior descending artery significant reduction was seen only in patients with triple-vessel disease. During follow-up the difference in mortality narrowed but remained significant. Overall 37.4% assigned to medical treatment crossed over to surgery (25% at five years, 33% at seven years and 41% at 10 years). The crossover rate was higher for patients with left main artery disease (65% at 10 years) and three-vessel disease (48%). It is worthwhile mentioning that 66.1% of the medical group were taking beta blockers. Following the VA criteria, patients at high risk obtained greater benefit than patients at low risk. There was a trend toward a greater benefit from surgery in those with an abnormal exercise test.

The conclusion of this meta-analysis was that

> The overview showed that a policy of routine early CABG surgery improves survival over a policy of initial medical therapy (with delayed surgery for advanced symptoms). The benefits are especially pronounced in patients with more extensive coronary disease or ischemia and in those who have clinical or angiographic features indicating high or moderate risk. However, in patients at low risk of death (about a third of the patients in this data set) the effect on survival was small and the data were insufficient to indicate whether lives were prolonged or shortened.

The Introduction of PTCA

On September 16, 1977, Andreas Gruentzig performed the first coronary angioplasty (426). Since then, thousands of patients have been clearly benefited by this procedure. In 1983 about 32,300 PTCAs were done in U.S.A. Three years later the number had increased to 159,643; in 1990 it increased to 300,000; and in 1995 it increased to 400,000 (884,000 worldwide) (427).

At present PTCA can be performed with low morbidity and mortality. Death occurs in ~1% or less and the rate of major complications (death, myocardial infarction and emergency coronary bypass surgery) is usually between 3% and 5% (428–442). Certainly the results improve with time and experience, as clearly demonstrated by the analysis of the NHLBI PTCA Registry (434). The angiographic outcome and in-hospital untoward event rate demonstrate that the number of patients with one or more lesions reduced by >20% and with residual stenosis <50% and no death, myocardial infarction or CABG increase from 55.5% in the first cohort (1977 to 1981) to 75.1% in the second cohort (1985 to 1986). The improvement in angioplastic intervention increased the percentage of event-free survival on late follow-up, accompanied by significantly better clinical outcome (435,443).

Initially, PTCA was applied mainly in patients with single-vessel disease. Even in 1988 and 1989, an analysis from a private insurance data base (444) showed that, at community level, 96% of procedures were performed on patients with one-vessel disease. In recent years multivessel angioplasty increased steadily, especially at leading interventional cardiology centers. It is widely accepted that PTCA should be the treatment of choice among patients with single-vessel disease even though there are not sufficient data to prove that it increases life expectancy (445–454). Relief of angina and better quality of life undoubtedly improve in the angioplastic population (449,455).

I would like to point out that we must be very cautious in matching patients with single-vessel disease for analysis of different treatments. As we will discuss later, the location of the obstruction, the size of the artery, the distal runoff and collateral circulation must be carefully observed. Single-vessel disease is not a uniform group of patients or entity. In our

series of 703 acute and subacute myocardial infarctions operated on between 1971 and 1986, 12 of 45 patients operated due to severe intractable mitral insufficiency had single-vessel disease (eight right coronary and four circumflex artery occlusion), and 18 of 56 patients operated due to ventricular septal defect also had single-vessel disease (nine right coronary, five anterior descending, and four circumflex artery occlusion). Of course, all had large vessels (dominant coronary circulation) and collaterals were absent.

As mentioned previously, with increased experience angioplasty was applied to patients with multivessel disease. Only 25% were included in the first NHLBI Registry; the percentage increased to 53% in the second registry. This was the result of important contributions that started at the Mid America Heart Institute where Hartzler and collaborators were advocating a more aggressive application of interventional cardiology (456,457).

Innumerable contributions comparing PTCA with CABG appear in the literature in the 1980s. Comparison of different populations made the interpretations difficult. For example, Finci and collaborators tried to demonstrate that patients revascularized with both internal mammary arteries obtained superior results in comparison to multivessel coronary angioplasty. The series were incompatible: triple-vessel disease was present in 20% and 61% of the PTCA and CABG populations, respectively (458). McCallister and collaborators from the Mid America Heart Institute (459) compared PTCA to CABG in patients with multivessel disease. The prevalence of triple-vessel disease was 47% and 88%, respectively, in the two groups. The disparity was even greater in the series analyzed by Akins and collaborators (460): triple-vessel disease comprised 75% of the surgical group versus 6% of the angioplasty group.

Very seldom is the location of the obstruction clearly specified. We really do not know how many of the lesions dilated were in proximal segments. If we analyze the contribution of Teirstein and collaborators (461) from the Mid America Heart Institute, left main equivalent lesion (obstruction at the proximal segment of the left anterior descending and circumflex branches of the left coronary artery) comprised only 45 patients (1.45%) of the 3,100 reported between 1981 and 1985 (461). Complete revascularization (both obstructions) was accomplished only in 64% of the patients, emergency CABG was required in 5 patients (11%) with 2 deaths (4.4%) and event-free survival at 22 ± 7 months was 89% only among patients in whom complete revascularization was performed. Of 5,000 consecutive angioplasties performed in the same hospital only 275 patients had dilation within each of the three major coronary arteries or their branches as a single procedure (462).

Analysis of the status of the left ventricle in most of the publications divided the angioplastic group by ejection fraction above and below 0.40 or 0.45. This does not appropriately analyze patients with a more severe reduction of ejection fraction.

As an example Myler and collaborators (463) classified 533 patients treated by angioplasty in the following way: 425 patients (79.7%) had an ejection fraction of at least 0.45, in 73 patients (13.7%) the ejection fraction was between 0.44 and 0.35, in 18 patients (3.4%) between 0.34 and 0.25 and in 17 patients (3.2%) below 0.25. Then we know that only 3.2% were patients with severe left ventricular deterioration. It is very difficult to compare different treatments if the left ventricular function is not classified into normal and mild, moderate and severe.

The literature available in the 1980s demonstrates that in certain anatomical locations the results of angioplasty were poor because of a low patency rate, a higher complication rate and a significant increase of reocclusion within six months:

1. Right coronary artery ostial lesion (464): with 79% primary success, 9.4% emergency CABG and 38% repeat PTCA.

2. Proximal left anterior descending (465–468): mainly because of lower primary success and the high rate of acute closure and restenosis. For instance, the decline in left anterior descending angioplasty at Emory University from 70% (1981 to 1982) to 56% (1983 to 1984) might be due to the limitation of angioplasty for proximal left anterior descending lesions (469).

3. Total occlusion (470–477): success rate is acceptable if the occlusion is less than one week in duration (74%) but it significantly decreases as time passes (between 55 and 65%). The longer the period that elapses the worse the results (even lower than 30%). In addition, restenosis rate increases significantly: between 38 and 48%.

4. Segmental stenosis: although sometimes the initial success is gratifying in stenoses greater than 10mm (89%), the incidence of emergency CABG (3%) and myocardial infarction (8%) clearly indicates that the results were not comparable to those of localized obstruction (478) and the recurrence rate increases with the length of the obstruction (479).

5. Multilesion in a single coronary branch: when more than one obstruction is present in one vessel (467,480–482) primary success is lower and the restenosis rate is higher (up to 50%). It is well known that the risk increases if the obstruction is eccentric, calcified, located at a branch point or near a tortuosity with an angle ≥45° (lesion on a bend) (483).

Undoubtedly, restenosis is the most important problem related to angioplasty, documented since the early Zurich experience by Gruentzig (484). In a study carried out at Emory University the arteriograms of 82 patients (107 lesions) were analyzed using electronic calipers (485) within 48 hours 10% of the asymptomatic successful PTCA showed restenosis but some of them improved during the healing phase. These results were confirmed by a contribution from Japan (486): at 24 hours 9% of the patients already showed clear evidence of restenosis. Rodriguez and collaborators (487) also confirmed this finding. A repeat catheterization at 24 hours demonstrated that 23% had early loss of luminal diameter. This group of patients had a significant restenosis rate at six months.

Furthermore, the utilization of early assessment by dipyridamole, thallium-201 single photon computed tomography in 40 patients (mean 1.9 days) demonstrated reversible perfusion

defects in 35%. In this group catheterization performed at a mean follow-up of 5.2 months showed 57% restenosis (488).

Most believe that in approximately 20% to 30% of successful angioplasties, restenosis may be recognized within 6 months. However, reviewing several contributions (466–468,471,472,475,477,480–482,489–504) yields the impression that the restenosis rate is higher because, although symptomatic patients are restudied more often, it has been found that between 19 and 28% of the asymptomatic patients also showed restenosis of previously successful PTCA. Therefore, absence of angina is not a reliable index of patency. As pointed out by Myler and Shaw (501) the percentage can be presented in different ways: in their series of 470 patients of multiple PTCA, 286 were followed during 6 months and only 164 had repeat catheterization, 92 of whom showed restenosis. The percentage can be calculated as follows: 92 of 164 = 56%; 92 of 286 = 32%; 92 of 470 = 20%. They believe 32% is much more realistic than 56% or 20%. Their approach to the problem is indeed open to discussion. Only repeat catheterization in consecutive patients will give us realistic numbers and the percentage in such reports varies between 32% and 40%. Furthermore, in patients with multivessel disease the recurrence rate is higher and appears to be cumulative. Patients with diabetes, smoking, shorter angina duration and prior myocardial infarction are more prone to develop restenosis. Balloon size, higher balloon inflation pressure, difficulty in crossing the stenosis, more than one dilation, higher diameter stenosis pre PTCA, higher residual stenosis post PTCA, residual transluminal pressure gradient, presence of a clot, characteristics of the distal flow and location of the obstruction increase the percentage of restenosis.

Several pharmacological approaches, including heparin, aspirin, dipyridamole, ticlopidine, nifedipine, prostacyclin and steroids, failed to decrease the rate of restenosis (505–513). At present, there are new promising approaches, mainly through molecular biology. An excellent summary may be found in a recent publication by Spencer King (514).

New devices (515) have expanded the indications for intraluminal treatment, mainly in overcoming some of the limitations of balloon angioplasty. They have been the subject of considerable debate since 1990 (516–524). The concept of atherectomy (atheroma removal) was introduced by John Simpson (525,526). It has gone through a period of major enthusiasm, followed by a reduction in its use after the result of two randomized trials, CAVEAT (527) and CCAT (528), in which no clear advantage could be seen. Nevertheless there are some kinds of lesions, not tested against other devices, where atherectomy still seems to have a role: LAD-origin lesions, ostial lesions, severely eccentric lesions and bifurcation lesions (529).

High speed rotational atherectomy developed by Hansen and Auth (530) is a procedure that has proven to be especially effective where complex lesion characteristics such as calcification, tortuosity, small caliber, ostial location and diffuse disease typically increase the risk of intervention with conventional catheters (531). Restenosis rates are comparable to balloon angioplasty in the randomized ERBAC trial (532).

The transluminal extraction catheter (TEC) or extraction atherectomy (533) is a percutaneous, over the wire, motor driven, cutting and aspiration system. The distal cutting tip has a conical configuration consisting of two stainless steel blades with adjacent windows. It is a device adapted with vacuum capability to treatment and removal of thrombi and also indicated for saphenous vein graft lesions. As a limitation it has a relatively high incidence of myocardial infarction due to distal embolization of plaque.

In two trials, the AMRO trial (534,535) and the ERBAC trial (532) the excimer laser was tested against balloon angioplasty and Rotablator; it did not show any advantage over conventional percutaneous balloon angioplasty.

The principal limitations of balloon angioplasty, coronary occlusion and restenosis, have been reduced with the utilization of stents, from 42.1% to 31.6% in the STRESS study (536) and from 32% to 22% in the BENESTENT group (537). But in stented vessels <2.6 mm in diameter, the 6-month restenosis rate was 38% compared with 22% in vessels >3.4 mm (538). In both randomized trials, the acute gain in luminal diameter was greater for stents than for balloons but at six months there was a greater late loss for stents than for balloons (0.65 vs. 0.32 in BENESTENT and 0.74 vs. 0.38 in STRESS). Long-term studies are necessary. Topol (539) pointed out that "tens of thousands of patients are receiving a prosthetic metal device in their coronary arteries without adequate long-term follow-up, and most of these patients are receiving it for indications that have not been systematically or rigorously evaluated". Nevertheless, at present, between 40% and 60% of the patients sent for angioplasty are getting one or more stents. It is important to remember that this therapy is indeed very expensive, average laboratory cost in the STRESS trial was approximately $ 3,200 more than PTCA (540).

Nowadays more than twenty designs of stents have been implanted in patients, with an added risk of complications due to the anticoagulation regime. Nevertheless, with intracoronary ultrasound guidance, Colombo showed the safety of stent deployment with high pressure balloon inflation, avoiding the oral anticoagulation with consequent reduction of the vascular complications and reduced hospital stay (541). This strategy may facilitate the expanded use of stents to provide the benefit of decreased restenosis while simultaneously reducing the cost and complications associated with stent insertion.

Lastly, recent advances in the intravascular ultrasound imaging technique have enabled visualization of the intraluminal and intramural morphology of the coronary arteries, a helpful technique in improving proper indications (542–546).

The introduction of new developments—such as the catheter, which can deliver beta radiation to prevent restenosis—seems to be promising (547,548). The search for the ideal stent continues. Areas of intense interest such as the polymer stent loaded with antithrombotic or antiproliferative agents, the exciting concepts of stents made of materials that can be degraded or absorbed and the promising new field of the

Table 5. Population Included in Five Randomized Trials

Trial and Location	Single or Multi-VD	CABG (no. of pts)	PTCA (no. of pts)	Duration of Follow-Up (yr)
CABRI				
Europe	Multi-VD	513	541	1
RITA				
UK	Single-VD (n = 456) and Multi-VD (n = 555)	501	510	4.7
EAST				
USA	Multi-VD	194	198	3
GABI				
Germany	Multi-VD	177	182	1
BARI				
USA and Canada	Multi-VD	914	915	5
Total:		2,299	2,346	

BARI = Bypass Angioplasty Revascularization Investigation; CABRI = Coronary Angioplasty Versus Bypass Revascularization Investigation; EAST = Emory Angioplasty Versus Surgery Trial; GABI = German Angioplasty Bypass Surgery Investigation; PTCA = percutaneous transluminal coronary angioplasty; RITA = Randomized Intervention Treatment of Angina Trial; VD = vessel disease; other abbreviations as in Tables 1 and 2.

radioactive stent may expand the use of stents in the hope of reducing restenosis, the Achilles' heel of PTCA.

The Randomized Trials: PTCA Versus CABG

As a consequence of the dissenting opinions about patients with multivessel disease randomized trials were required. In one of his last contributions Andreas Gruentzig (484) said, "Patients with single-vessel disease treated with angioplasty seem to have passed the test of time; however, patients with a more complex multivessel disease present more difficult problems in the follow-up period. Randomized trials now under way will help to determine the value of angioplasty in patients with multivessel disease."*

My analysis will concentrate on five trials: Coronary Angioplasty versus Bypass Revascularization Investigation (CABRI), Randomized Intervention Treatment of Angina (RITA) Trial, Emory Angioplasty versus Surgery Trial (EAST), German Angioplasty Bypass Surgery Investigation (GABI) and Bypass Angioplasty Revascularization Investigation (BARI). They comprise the largest populations recruited from 1986 to 1992. The data in Table 5 allow comparison between 2,346 patients belonging to the PTCA group and 2,299 of the CABG group (549–553).

In Table 6 the baseline characteristics of the population demonstrate that, except for the RITA trial, all of them were restricted to patients with double- and triple-vessel disease. RITA and GABI included a small number of patients with triple-vessel disease. In fact, RITA should be considered a double- and single-vessel disease trial and GABI, a double-vessel disease trial. Patients with unstable angina were accepted in BARI, RITA and GABI.

Patients were included in RITA, GABI and BARI only when surgeons and cardiologists agreed that both procedures could be applied. As we will discuss later, this approach introduces a significant bias in the selection process. Patients with severe triple-vessel disease—though not explicitly specified—were excluded from CABRI. In EAST the eligibility criteria were confusing: "the clinical criteria for exclusion were insufficient myocardium at risk to warrant surgery (318 patients)." The principal angiographic criteria for exclusion "were old (more than eight weeks' duration) chronic occlusion of bypassable vessels serving viable myocardium" and "two or more total occlusions." Triple-vessel disease with multiple lesions comprise only 27% and 26% in the PTCA and CABG group (554). Patients with left main coronary obstruction were excluded from all five trials.

Table 7 demonstrates that the in-hospital death rate of the five trials was slightly higher in CABG than in PTCA patients (1.8% vs. 1.5%, odds ratio [OR] 1.17). The combined risk of death and nonfatal myocardial infarction was also higher in CABG than in PTCA patients (7.6% vs. 4.6%, OR 1.67).

Table 6. Description of Study Populations of Five Clinical Trials

	BARI	RITA	CABRI	GABI	EAST
Men	74%	81%	78%	80%	74%
Mean age (yr)	61	57	60	59	62
Mean LVEF	57%	—	63%	56%	61%
Prior MI	54%	42%	42%	47%	41%
Angina					
CCS class 0–II	14%	41%	34%	35%	20%
CCS class III–IV	17%	59%	66%	65%	77%
Unstable	64%	55%	—	14%	—
No. of coronary arteries narrowed					
1	2%*	45%	0	0	0
2	57%*	43%	60%	82%	60%
3	41%*	12%	40%	18%	40%

*Diseased territory >50%. Data presented are percent of patients or mean age. Abbreviations as in Tables 2 and 5.

*The EAST Trial was first conceived by Andreas Gruentzig.

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Table 7. In-Hospital Results

	CABG (% of pts)	PTCA (% of pts)	Odds Ratio
Death			
RITA	3.60	3.10	1.15
CABRI	0.70	1.30	0.54
GABI	2.30	1.10	2.06
EAST	1.03	1.01	1.02
BARI	1.30	1.10	1.20
Average	1.80	1.50	1.17
Death+nonfatal MI			
RITA	8.80	9.80	0.90
CABRI	2.70	2.80	0.98
GABI	9.60	3.30	2.91
EAST	11.30	4.00	2.81
BARI	5.70	3.00	1.93
Average	7.60	4.60	1.67

Abbreviations as in Tables 1, 2 and 5.

Within one year (Table 8) death and myocardial infarction remained higher in CABG (10.4% vs. 8.7%, OR 1.20). At three years the rate was slightly higher among PTCA patients (12.8% vs. 11.3%, OR 0.89). At five years, the BARI trial also showed a slightly higher rate among PTCA patients (21.3% vs. 19.6%, OR 1.00). During the first year (Table 9) PTCA patients required additional procedures (PTCA + CABG) (43.9% vs. 4.1%, OR 0.9). This rate increased within three years (62.6% vs. 8.3%, OR 0.13) in RITA, EAST and BARI trials. The difference was slightly greater at five years for the BARI trial (63% vs. 8%, OR 0.13). In Table 10 it is clear that patients treated with CABG were significantly more likely to be angina free.

The conclusions of the five trials can be summarized as follows: in patients with multivessel disease a strategy of initial PTCA compared to a strategy of initial coronary artery bypass did not differ with respect to the occurrence of primary end point: death and myocardial infarction during hospitalization and midterm follow-up. However, a clear difference existed between the two treatment policies in terms of the requirements for additional revascularization procedures and relief of symptoms. CABG involved longer initial hospitalization and convalescence, but thereafter surgically treated patients enjoyed better relief of angina and required fewer antianginal drugs.

Are these conclusions representative of a carefully documented analysis? Let us concentrate on BARI, which comprises the largest number of patients in a single trial.

On March 23, 1995, the *American Journal of Cardiology* released a supplement that included four contributions with BARI baseline features. The first (555) included the patients screened (Fig. 6). From 12,530 "clinically eligible" patients 915 were finally randomized to PTCA and 914 to CABG. As planned by the original protocol, the final determination of eligibility involved the subjective judgment of both the angioplasty operator and the surgeon, but in most settings exclusions were made primarily by the angioplasty operator (90%) (Table

Table 8. Follow-up Results: Cardiac Death and Myocardial Infarction

	CABG (% of pts)	PTCA (% of pts)	Odds Ratio
During 1st yr			
RITA	6.20	6.70	0.93
CABRI	5.70	7.90	0.72
GABI	10.20	5.50	1.85
EAST	18.40	13.70	1.34
BARI	11.70	9.80	0.84
Average	10.40	8.70	1.20
During 1- to 3-yr follow-up			
RITA	8.90	10.10	0.88
CABRI	5.70	7.90	0.71
GABI	0.60	2.20	0.26
EAST	27.00	28.80	0.94
BARI	14.40	14.80	0.98
Average	11.30	12.80	0.89
At 5 yr			
BARI	19.60	21.30	1.00

Abbreviations as in Tables 1, 2 and 5.

Table 9. Follow-Up Results: Additional Interventions (PTCA and/or CABG)

	CABG (% of pts)	PTCA (% of pts)	Odds Ratio
During 1st yr			
RITA	4.8	40.8	0.12
CABRI	2.9	35.9	0.08
GABI	7.3	45.6	0.16
EAST	3.1	50.0	0.06
BARI	2.5	47.0	0.05
Average	4.1	43.9	0.09
At 3 yr			
RITA	6.0	68.6	0.09
EAST	13.9	63.1	0.22
BARI	5.0	56.1	0.09
Average	8.3	62.6	0.13
At 5 yr			
BARI	8.00	63.0	0.13

Abbreviations as in Tables 1, 2 and 5.

Table 10. Follow-Up Results: Prevalence of CCS Class II or Worse Angina

	CABG (% of pts)	PTCA (% of pts)	Odds Ratio
At 1 yr			
RITA	10.60	20.60	0.52
CABRI	11.00	15.60	0.70
GABI	25.20	28.40	0.89
EAST	9.00	18.50	0.49
Average	13.90	20.80	0.67
At 3 yr			
RITA	16.00	18.10	0.88
EAST	11.20	19.00	0.59
Average	13.60	18.60	0.73

Abbreviations as in Tables 1, 2 and 5.

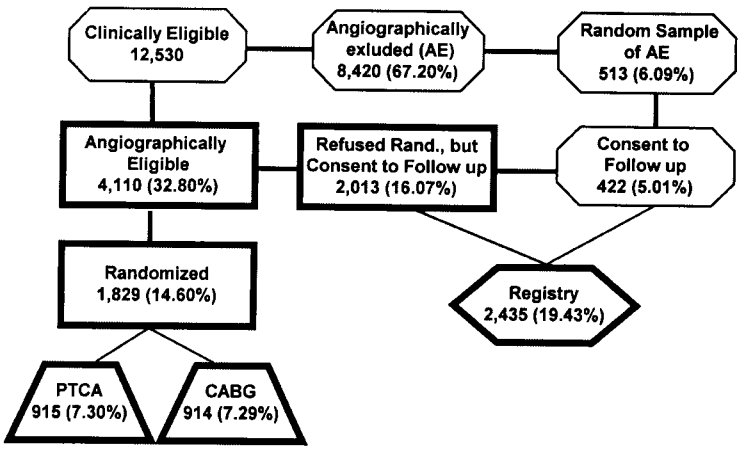

Figure 6. Number of inclusions and exclusions in Bypass Angioplasty Revascularization Investigation (BARI) recruitment. CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty; Rand. = randomization. Data from Bourassa et al. (555).

11). In 49.8% of patients excluded by the angioplasty operator, CABG was indicated. On the contrary, among patients excluded by the surgeon only in 1.4% was PTCA done or intended.

The reasons for angiographic exclusion among those judged unsuitable were: total occlusion, predominantly diffuse disease and excessive length, angulation, calcium and tortuosity, and, among those judged dangerous, were: the potential for abrupt closure leading to shock and impossibility of protection of side branches, in addition to other reasons.

They concluded: "It is clear from the angiographically excluded data that patients with the most complex coronary artery disease were treated, as a rule, with CABG. Thus, the BARI randomized and eligible but not randomized cohorts represent that portion of patients with multivessel coronary artery disease whose coronary anatomy allows the option of either procedure and who present for revascularization with less complex lesion morphology."

The second paper (556) analyzed the baseline clinical and angiographic data. The analysis of the randomized patients (Table 12) demonstrated similar characteristics. The percentage of proximal left anterior descending lesions was similar to the CASS randomized population and was half that of the European study. The analysis of Table 13 showed that

The angiographically excluded group, as expected, had more extensive coronary artery disease on angiography as was evident from more three-vessel disease, more type C lesions, more total occlusions, more proximal stenoses, lower ejection fractions, and more jeopardized myocardium than the randomized or eligible but nonrandomized groups. Further analysis of a second registry of patients ineligible for randomization due to coronary anatomy unsuitable for either PTCA or CABG demonstrated that such patients were older, had more prior myocardial infarctions, heart failure and stable angina presentation.

Regarding the angiographically excluded patients "in view of their advanced age, stable anginal pattern, severe coronary disease, and worse left ventricular function, it is not surprising that, at 3 months follow-up, many (33%) were still being managed with medical therapy, very few (5%) had undergone PTCA, and the remainder (60%) had received CABG." They conclude that: "although the BARI randomized population seems representative of the universe of patients meeting the BARI entry criteria at the participating centers, it is not representative of all patients with multivessel coronary artery disease who have clinical indications for revascularization, because many such patients do not qualify for both PTCA and CABG."

Table 11. Angiographic Exclusions and Treatment Received or Intended as of Hospital Discharge (8,420 patients)

Therapy Received or Intended	PTCA Only (n = 7,576)	CABG Only (n = 420)	PTCA and CABG (n = 424)
PTCA			
Received	83	101	17
Intended	54	96	10
CABG			
Received	1,091	1	4
Intended	2,680	5	9
Medical treatment			
Received	1,288	142	315
Intended	2,380	75	69

Data presented are number of patients. Abbreviations as in Tables 1 and 5.

Table 12. Baseline Characteristics of BARI Trial Randomized Patients

	PTCA (% of pts)	CABG (% of pts)
Proximal stenoses		
Proximal LAD stenosis ≥50%	36	37
Proximal or mid-LAD stenosis ≥50%	77	76
Any proximal stenosis ≥50%	68	68
Dominance		
Right	80	81
Left	7	6
Mixed	13	13

*Data from Rogers et al. (556). BARI = Bypass Angioplasty Revascularization Investigation; other abbreviations as in Tables 1, 2, 3 and 5.

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Table 13. BARI Trial: Angiographic Data

	Randomized	Eligible, Not Randomized	Angiographically Excluded
No. of pts enrolled	1,829	2,013	422
No. of pts with angiographic interpretation available	1,826	1,945	417
VD (50% stenosis criteria)			
Single	2%	2%	2%
Double	57%	61%	38%
Triple	41%	37%	60%
Lesions with stenosis ≥50%			
Mean	3.5	3.0	4.2
Median no./pt	3	3	4
Proximal stenoses			
Proximal LAD stenosis ≥50%	37%	35%	47%
Proximal or mid-LAD stenosis ≥50%	77%	69%	80%
Any proximal stenosis ≥50%	68%	68%	81%
Total occlusions			
Mean	0.4	0.3	1.1
Median no./pt	0	0	1
None	63%	69%	26%
1	31%	28%	41%
2	6%	3%	26%
≥3	<1%	<1%	6%
Type C lesions			
Mean	0.5	0.5	1.3
Median no./pt	0	0	1
None	60%	63%	22%
1	32%	31%	39%
2	7%	6%	28%
≥3	1%	1%	11%

Data from Rogers et al. (556). Abbreviations as in Tables 2, 3 and 5.

The third paper (557) concentrated on the procedural characteristics of patients randomized to coronary angioplasty:

> There were 6,530 coronary arterial lesions identified in the 915 patients assigned to angioplasty. Angiographically significant (≥50% diameter reduction) lesions accounted for 52.5% of all lesions. Angiographically significant lesions within the left anterior descending, left circumflex, or right coronary arteries were usually located in either the proximal (40.8%) or mid (44.8%) segments. Total occlusions accounted for 11.9% of angiographically significant lesions. The lesions most frequently attempted ranged between 50% and 79% diameter reduction. This group is followed by those in the 50–59% and 80–89% ranges. Lesions <49% and those >90% were less frequently attempted. In contrast, only 30.1% of lesions classified as 99–100% were attempted.

The way the data are presented in this contribution is potentially confusing. Table 1 from this paper is a clear example. Critical analysis demonstrated that only 47.1% of the lesions greater than 50% were successfully dilated (Table 14). It is worth mentioning that 393 lesions with 99% obstruction and 53 total occlusions were attempted with a 23.8% successful rate.

Analysis of the EAST, CABRI, RITA and GABI trials showed success rates of 54%, 60%, 61% and 79% for PTCA, respectively, for the total number of obstructions.

An important question is whether the significant rate of repeat PTCA and CABG in the angioplasty group is a consequence of restenosis or initial incomplete revascularization. Since the NHLBI early contribution (558) we know that incomplete revascularization increases the number of new interventions.

The fourth paper (559) analyzed the characteristics of patients randomized to bypass surgery. They conclude that "indeed, 60% of clinically eligible patients were judged unsuitable for PTCA but were suitable for CABG. Clearly, choosing patients with multivessel involvement based on their suitability for PTCA selects patients with less advanced coronary atherosclerosis. Approximately only 33% of patients with multivessel disease were considered potential candidates for either PTCA or CABG."

Detre and collaborators (560) in a recent survey of the centers that participated in the BARI trial and 75 other institutions, concluded that approximately 12% of all patients who required revascularization would be eligible for the BARI trial.

The subgroup of patients with treated diabetes had better survival with coronary artery bypass, as shown by the absolute difference of 16%, and led to a clinical alert release on September 21, 1995 (561).

Robert Frye, in his presentation of the BARI results (personal communication) during the annual meeting of the American Heart Association (November 1995), stated that

> BARI was designed to determine the safety of a strategy of initial PTCA in selected patients with multivessel coronary artery disease. This finding and the desire of many patients and doctors to avoid for as long as possible the sternotomy associated with coronary artery bypass prompts testing the following question: in patients needing revascularization, can PTCA, a less invasive strategy, delay or prevent the need for CABG without adverse consequences? The answer is clearly yes.

I believe that "selected patients with multivessel disease" do not represent the true picture. Instead they could have been replaced by only 33% of a selected group of patients with triple-vessel disease candidates for both PTCA and CABG.

It is worth mentioning that even when complete revascularization is performed with PTCA in patients with multivessel disease, the results are quite similar to those of the randomized trials. Vacek and collaborators (562) selected 152 patients (only 5% of the total PTCA population of the Mid America Heart Institute) where three or more dilatations in the major coronary arteries were accomplished, and compared them with 134 patients who had more than three bypass grafts (left

Table 14. Lesions Present, Intended, Attempted and Successful for Angioplasty in BARI Trial Patients*

	No Lesions in Pts Assigned to PTCA (n = 915)	No Lesions With Intended PTCA	No Lesions With Attempted PTCA	No Lesions With Successful PTCA
All lesions	6,530	2,296 (35.7%)	2,218 (33.1%)	1,681 (26.1%)
50% to 79% total	2,585	1,732 (67.8%)	1,612 (63.1%)	1,273 (49.8%)
80% to 95% total	396	286 (73.3%)	274 (70.3%)	216 (55.5%)
99% to 100% total	446†	145 (33.0%)	132 (30.1%)	104 (23.8%)
Total	3,427	2,163 (63.9%)	2,018 (59.6%)	1,594 (47.1%)

*Data elaborated from Williams et al. (557). †Total occlusion 11.9%. Abbreviations as in Tables 2 and 5.

internal mammary in 75% of the cases). The PTCA group received an average of three dilatations, the surgical group, 3.9 bypasses. At 110 weeks of follow-up the rate of deaths and myocardial infarctions were 14% vs 16% in the PTCA and CABG groups, respectively. But in the PTCA group 49%, 17%, 5% and 3% had 1, 2, 3 or 4 repeat catheterizations. Thirty percent had a second PTCA and 23% underwent CABG. In the surgical group only 10% underwent a second catheterization, 2% had a reoperation, and another 2% a PTCA. Survival at two years was similar: 91% and 90% for the PTCA and CABG groups, respectively. The CABG population had more extensive triple-vessel disease (68% vs 6% on the PTCA group) a higher percentage of left anterior descending artery obstructions and lower ejection fraction.

They concluded:

> However, our data would suggest that for important cardiac end points, CABG for multivessel disease, which routinely uses left internal mammary artery bypass grafts, is a superior intervention when compared with multivessel angioplasty. Proposed financial savings attributable to angioplasty may also be obviated by the need for a greater number of repeat studies and interventions in follow-up. Caution should be exercised in the widespread application of multivessel PTCA.

As we have seen, a significant number of patients require further revascularization procedures after the first PTCA. I have the impression that a careful examination of the cine coronary angiography of the patients from randomized trials that required surgery as a second procedure would constitute a significant contribution. Perhaps some clues could be found for improvement in the indications for PTCA.

Johnson and collaborators (563) analyzed a group of 256 patients with multivessel disease treated with angioplasty. One hundred and twenty-eight who had successful PTCA (group A) required subsequent CABG performed at a mean interval of 16.7 months (22 patients—17.2%—had CABG within 30 days of initial PTCA). Sixty-five patients (51%) had 92 additional PTCA before the operation. Of the other 128 patients (group B) none required CABG, and 24 (18.8%) had a second PTCA at a mean interval of 11 months. Patients who required emergency CABG associated with their initial PTCA and those who had unsuccessful angioplasty were excluded from both groups.

Clinical characteristics were similar, except that patients with diabetes comprised 27.3% of group A vs 14.1% in group B. The analysis of the angiographic characteristics (Table 15) clearly demonstrates that patients in group A had more obstruction with increased number of left anterior descending, circumflex and left main trunk lesions. "Nearly all of the patients in group A with four or more coronary stenoses ≥70% required their operation within one year." I think this contribution demonstrates that in most of the patients from group A, PTCA was not the proper indication.

Many years ago I pointed out (316,399) that the single-, double- and triple-vessel disease classification is not enough if we want to analyze patients with coronary artery disease properly and it is inadequate for comparison of different treatments.

Table 15. Location and Severity of Coronary Lesions in the Two Study Groups*

Lesion Severity and Location at Initial PTCA	Group A (CABG subsequent to PTCA)	Group B (no CABG subsequent to PTCA)	p Value
Total no. of lesions (any lesions)	4.1 ± 2.2	3.27 ± 1.9	0.002
Lesions ≥70%	2.7 ± 1.5	1.97 ± 1.2	0.0001
Pts with LAD ≥70%	98 (70.6%)	75 (58.6%)	0.002
Pts with Cx ≥70%	57 (44.5%)	34 (26.6%)	0.006
Pts with RCA ≥70%	65 (50.8%)	67 (52.3%)	0.900
Any LMCA stenosis	15 (11.7%)	8 (6.3%)	0.126
LMCA ≥50%	3 (2.3%)	0 (0%)	0.081

*Data from Johnson et al. (563). Data presented are mean value ± SD or number (%) of patients. Abbreviations as in Tables 1 to 3 and 5.

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Table 16. Six-Year Survival Rates (±1.96) by Number of Vessels Diseased, Number of Proximal Arterial Segments Diseased and Left Ventricular Wall Motion Score (number of patients in cell at enrollment) for the CASS Study*†

No. of Diseased Vessels/ No. of Proximal Segments Diseased	Left Ventricular Score			Total No. of Pts (n = 8,535)
	5–11	12–16	17–30	
0/0				
6-yr survival	93 ± 2%	76 ± 13%	78 ± 27%	
No. of pts	1,836	45	9	1.890
1/0				
6-yr survival	92 ± 2%	81 ± 8%	65 ± 20%	
No. of pts	1,430	219	36	1.685
1/1				
6-yr survival	90 ± 3%	76 ± 9%	55 ± 19%	
No. of pts	796	204	65	1.065
2/0				
6-yr survival	81 ± 6%	49 ± 22%	52 ± 18%	
No. of pts	652	128	37	817
2/1				
6-yr survival	86 ± 4%	67 ± 10%	54 ± 14%	
No. of pts	617	188	71	876
2/2				
6-yr survival	72 ± 9%	51 ± 14%	43 ± 20%	
No. of pts	234	102	39	375
3/0				
6-yr survival	76 ± 10%	53 ± 12%	25 ± 36%	
No. of pts	238	96	29	363
3/1				
6-yr survival	74 ± 7%	43 ± 12%	47 ± 13%	
No. of pts	371	191	71	633
3/2				
6-yr survival	66 ± 8%	47 ± 9%	24 ± 13%	
No. of pts	297	165	74	536
3/3				
6-yr survival	57 ± 13%	29 ± 14%	16 ± 14%	
No. of pts	156	93	46	295

*Data from Rinqvist et al. (566). †Zero includes patients with minimal or moderate disease; the percentages in relation to the status of the heart muscle are similar to the randomized series: 5–11 = 77.6%; 12–16 = 16.7%. Data presented are mean value ± SD, unless otherwise indicated. Abbreviations as in Table 2.

In 1977 Abedin and Dack (310), and later on Leong et al (377), Brooks et al (378), and Chaitman et al (379) demonstrated that the prognosis of patients with obstruction of the anterior descending coronary artery is related to the site of the obstruction.

In 1982 Mock and collaborators (564,565) emphasized the role of the proximal obstruction among patients with multivessel disease and in 1983 Ringqvist (566) contributed an excellent paper which indicated (Table 16) that, in addition to the number of diseased vessels, the location of the obstructions and the status of the left ventricle defined the future of patients with coronary artery disease. Survival at six years varied between 92% and 16%!

Afterward, Myers and collaborators (385,396,567) remarked that the number of obstructions is an important landmark. Fifty-one variables, including therapy, were tested by Cox model and a propensity score was utilized to compare medical and surgical treatment. As an example, at six years significantly longer survival was not found in patients with severe angina, triple-vessel disease, normal left ventricular function and one proximal obstruction (87% vs. 91% survival in the medical and surgical groups respectively). However, there was improved survival with two proximal obstructions (73% vs. 89%) and three proximal obstructions (38% vs. 90%). In patients with triple-vessel disease and mild angina (385) there was improved survival with two proximal obstructions (67% vs 89%) and three proximal obstructions (54% vs 84%).

Following Ringqvist's classification, it would be a good idea to compare the group of patients included in the five randomized trials that underwent CABG after being treated with PTCA with patients who remained in the PTCA group.

Recently, Jones and collaborators at Duke University (568) completed a previous report (569) of 9,263 patients (CABG 3,890, PTCA 2,924 and medical treatment 2,449) followed for a mean interval of 5.3 years. They classified patients into nine categories (left main trunk obstructions were excluded). Besides single-, double- and triple-vessel disease, they specified the presence of 75% and 95% obstructions and 75% and 95% proximal left anterior descending obstructions (Fig. 7). The analysis clearly demonstrated (Fig. 8 and 9) that CABG improved survival in relation to the number, severity and location of the obstruction.

I think this important contribution clearly demonstrates that the simple classification of single-, double- and triple-vessel disease is not enough.

The Future

There are two areas of potential increased application of CABG: (a) asymptomatic patients and (b) AMI.

Asymptomatic Patients

In this category we should differentiate patients who lead a normal life without any restriction of their physical capacity, from the group who limit their activities on advice of their physician. The discussion will concentrate on the first group.

The natural history of coronary arteriosclerosis shows that the incidence of prodromata among patients suffering a first myocardial infarction ranges from 15% to 65% (570–579). Pain has been reported in 27% and 45% and in only one study was its prevalence 59% (578). On the other hand, half of all deaths due to coronary arteriosclerosis are sudden (580,581) and about 50% occur in patients with no previously known ischemic heart disease (582). It is clear that pain is a late and luxurious manifestation of coronary arteriosclerosis.

Myocardial ischemia is frequently painless (583–586). Asymptomatic ischemia is the most common form of myocardial perfusion deficit (587), even in patients who experience clinical episodes of angina. It is recognized that myocardial ischemia is an important determinant of mortality and morbidity (587–598) and it is related to the extent of coronary artery disease and myocardium at risk (401,599–601).

	Prognostic Group									
Coronary anatomy	1	2	3	4	5		6		7	8	9
Number of Stenoses ≥75%	1	1	2	2	1	2	2	3	3	3	3
Number of Stenoses ≥95%	0	1	0-1	2	1	1	1	0	1	0-2	1-3
Any LAD Location	±	N	±	N	Y	Y	Y	Y	Y	Y	Y
≥75% Stenosis Proximal LAD	N	N	±	N	Y	N	Y	N	N	Y	Y
≥95% Stenosis Proximal LAD	N	N	N	N	Y	N	Y	N	N	N	Y

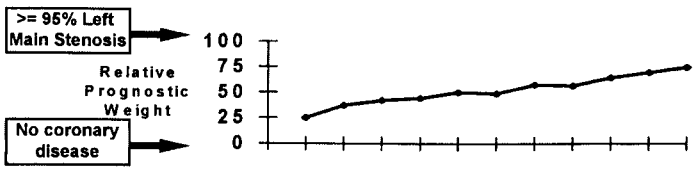


Figure 7. Coronary anatomy score for 6,034 medically treated patients undergoing coronary angiography at Duke University Medical Center between 1969 and 1984. The anatomic classification of coronary artery stenosis is related to the corresponding relative prognostic weight. LAD = left anterior descending coronary artery; N = no; Y = yes. Data from Jones et al. (568).

There are different ways in which patients with asymptomatic coronary arteriosclerosis seek medical advice:

Asymptomatic patients with previous myocardial infarction. In 1984 we analyzed the data accumulated in 344 patients studied by cine coronary angiography after only one previous myocardial infarction (399). In anterior infarction 43% had multivessel disease and 3% had left main trunk obstruction (Fig. 10, left). In posterolateral infarction (Fig. 10, right) 55% had multivessel disease, and 4% had left main trunk obstruction. We might predict that in patients with only one previous infarction most should have only one major obstruction, but this occurs only in 51.8% and 40.8% of anterolateral and posterolateral infarctions, respectively.

We should add to this group of patients those who have abnormal electrocardiograms on routine examination, especially those with evidence of a previous silent myocardial infarction. The Framingham Study (602) showed that the prognosis for patients with silent myocardial infarction manifest only electrocardiographically is similar to that for patients with a clear-cut history of previous myocardial infarction.

Patients with atherosclerotic manifestations in noncoronary vascular beds. Since 1972 in our cardiac laboratory we have studied all the patients that required visualization of a particular vascular territory by cine angiography. Coronary angiography was performed during the same time period as other investigations (603,604) even though angina was not present.

As can be seen in Table 17, 84% of the patients demonstrated different degrees of coronary atherosclerosis including 7% with left main trunk disease. If we analyze the last consecutive 124 patients (78 with peripheral vascular disease

Figure 8. Adjusted hazard ratios comparing coronary artery bypass graft surgery (CABG) and medical therapy (MT) for the nine coronary anatomy groups. LAD = left anterior descending coronary artery; N = no; Prox = proximal; Surv. = survival; VD = vessel disease; Y = yes; 95% = 95% coronary artery stenosis. Data from Jones et al. (568).

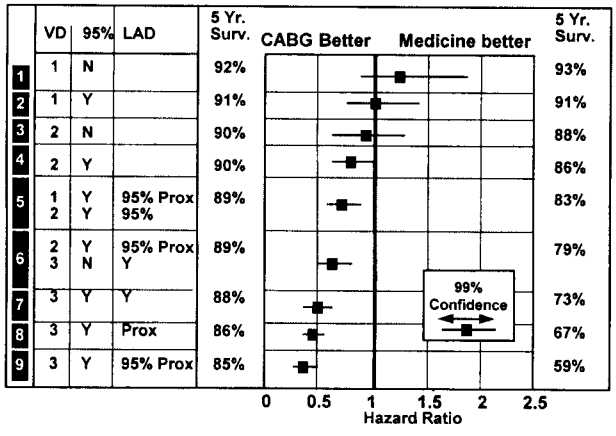
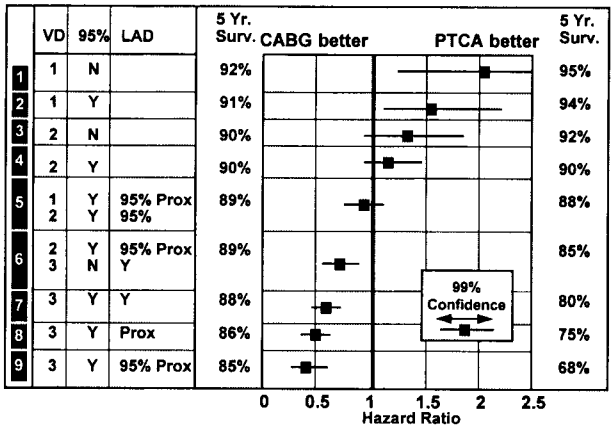


Figure 9. Adjusted hazard ratios comparing coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA) for the nine coronary anatomy groups. Other abbreviations as in Table 8. Data from Jones et al. (568).



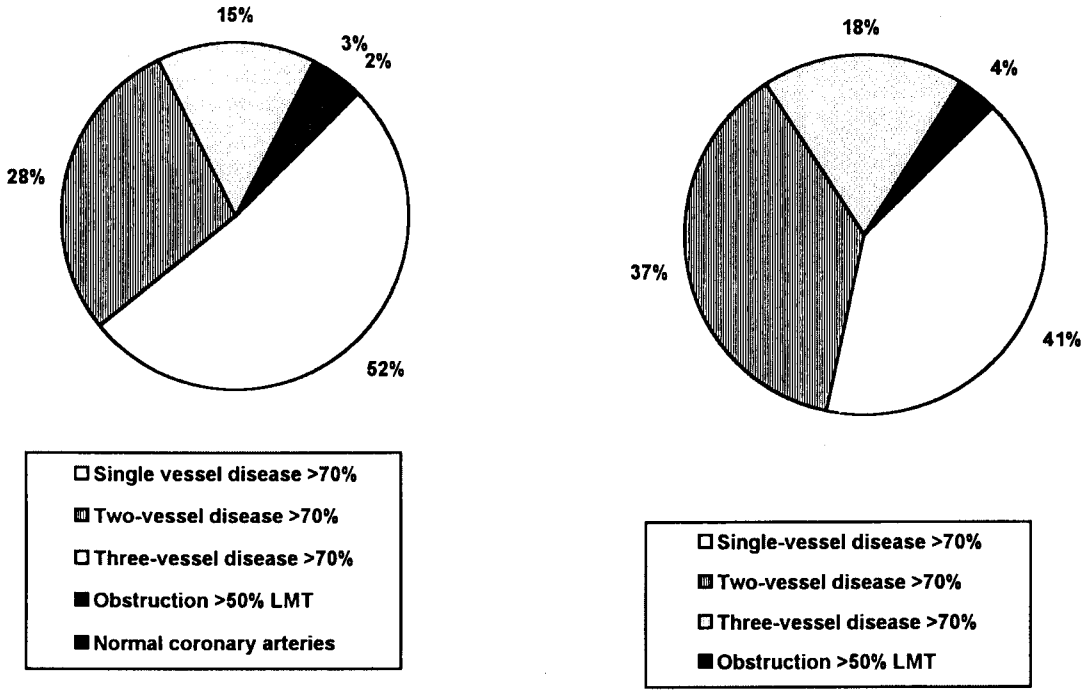


Figure 10. Asymptomatic anterior (**left**) and posterior (**right**) myocardial infarction: angiographic findings. LMT = left main trunk. Data from Favaloro (399).

and/or abdominal aorta disease, 40 with cerebrovascular insufficiency, and 6 with renal artery obstruction) in whom we studied the coronary arteries even though there was no anginal episode in their clinical history, we found that 38 patients (28.3%) had one-vessel disease, 17 patients (14.1%) had two-vessel disease, 31 patients (25.8%) had three-vessel disease, 7 patients (6%) had left main trunk obstruction, and 31 (25.8%) had normal coronary arteries.

Table 17. Coronary Cine Angiography Associated With Cine Studies of Other Vascular Territories in 500 Consecutive Patients and Angiographic Findings in Coronary Arteries*

Cine Coronary Angiography Associated With Cine Studies of Other Vascular Territories	No. (%) of Pts
Selective arteriography of limbs	220 (44%)
Selective arteriography of neck vessels	160 (32%)
Abdominal aortography (with or without selective renal arteriography)	90 (18%)
Selective arteriography of neck vessels and inferior limbs	30 (6%)
Angiographic findings in coronary vessels	
1-VD	125 (25%)
2-VD	110 (22%)
3-VD	150 (30%)
LMCA disease	35 (7%)
Normal coronary arteries	80 (16%)

*Data from Favaloro (399). Abbreviations as in Tables 1, 3 and 5.

Patients with a definite family history or the presence of other risk factors. Such high risk factors mainly include abnormal lipids, hypertension and diabetes.

Patients with associated valvular disease. First in Cleveland and since 1971 in Buenos Aires, most patients with valvular disease who were candidates for reconstruction or valvular replacement underwent routine coronary angiography during catheterization. Patients with aortic or mitral valve disease could have concomitant severe coronary atherosclerosis, even though angina was absent (605).

Patients with positive exercise tests on routine examination. Review of the literature is confusing and it is difficult to draw definite conclusions mainly because the majority of the publications are based on a small number of patients or because there is not a clear analysis of the correlation with the cine coronary angiography (337,606–626). In patients with a positive exercise test the probability of detecting coronary atherosclerosis is high. Those with ischemic-type ST depression, with or without angina tend to have more extensive coronary artery disease than those without, and the prognosis is related to the severity of the disease (600,627).

We should add to this group patients identified by ambulatory electrocardiography (Holter). Those with silent ischemia had an increased risk for adverse outcome (628–630).

It is clear that a significant number of patients will demonstrate different degrees of coronary artery disease even though they are totally asymptomatic. An important subgroup consists of those who have a history of previous myocardial infarction. Do we need to perform catheterization in every postinfarction asymptomatic patient to detect mainly multivessel coronary diseases?

There are two roads that may be followed. One is initial use of noninvasive methods from a simple ergometric test to the more complex cardiac radionuclide imaging and/or stress echocardiography. Myocardial perfusion imaging shows that the size and number of the perfusion defects are the best indicators of the extent of severely obstructive coronary disease. Thallium 201 planar scintigraphy showed an average sensitivity and specificity of 83% and 88% by visual analysis. A recent study using technetium 99 perfusion has shown similar results (631). Thallium 201 single-photon emission computed tomography (SPECT) scintigraphy demonstrated an average sensitivity and specificity of 89 and 76% respectively. SPECT imaging yields better detection of individual coronary stenoses. Positron emission tomography (PET), an expensive imaging modality, showed higher specificity than SPECT both in the diagnosis of patients and in identifying individual coronary artery stenoses. Pharmacological myocardial perfusion imaging (dipyridamole, adenosine and dobutamine) indicated high sensitivity (90% average) and acceptable specificity (70% average). The special report of the AHA/ACC Task Force (631) concludes that

> because of the low positive predictive value of non-invasive testing in asymptomatic patients, radionuclide techniques are not ordinarily recommended as a screening strategy for coronary artery disease. However a stress radionuclide test is valuable in asymptomatic patients with positive exercise electrocardiography stress test results, in that it may assist in determining the need for coronary angiography.

At present, as the cost-effectiveness of newer techniques and technologies becomes increasingly scrutinized, exercise echocardiography (with or without dobutamine or dipyridamole) (632–649) has demonstrated an overall sensitivity for the presence of severely obstructive coronary artery disease of 91%. For identification of multivessel disease the overall sensitivity and specificity are 73% and 70% respectively (640).

In summary, noninvasive evaluation is helpful and should always start with a simple exercise test, taking into account its limitations (650).

The second road is to directly perform cine coronary angiography that, with accurate reading, provides the best tool for detection of coronary stenoses and enables prediction of probable risk in individual patients.

The final decision in asymptomatic patients should be made in each individual starting with a careful analysis of the clinical record. The data accumulated by the different non-invasive tests are based on the patient population. As an example I will be more inclined to advise cine coronary angiography for a 50-year-old male with a strong family history, presence of mild hypertension and lipid abnormality and 1-mm ST-segment depression on treadmill electrocardiography than on a 70-year-old patient with a history of myocardial infarction one year before, who stopped smoking, controls his hypertension, follows a low fat diet (normal lipid values), does regular exercise including some sports, and who has 1-mm depression on treadmill testing.

Table 18. Coronary Bypass Operation in 328 Patients Without Angina Pectoris*

Pt Characteristic	No. of Pts	No. of Deaths
Asymptomatic pts after previous MI	143	1
Asymptomatic pts with vascular disease in other territories	77	1
Noncharacteristic thoracic pain	54	
Valvular disease	34	1
Positive stress test	14	
Fatigue	3	
Family history or risk factor	3	
Total	328	3

*Data from Favaloro (399). Abbreviations as in Tables 2 and 3.

The Asymptomatic Cardiac Ischemia Pilot (ACIP) study (586,651,652) was designed for comparison of three treatment strategies (angina guided, ischemia guided, and revascularization) intended to suppress asymptomatic ischemia detected by ambulatory electrocardiography or exercise treadmill tests. Of 192 patients assigned to undergo revascularization 94 had PTCA attempted, 79 had CABG performed and 19 did not have any revascularization procedure because either the patient or treating physician refused after randomization. At 12 weeks the percentage of patients with no ischemic episodes on ambulatory electrocardiogram was 70% in the CABG patients vs 46% in the PTCA group. They remained practically unchanged at one year (71% vs 52%). At the qualifying visit, exercise-treadmill-test-induced ischemia was present in 80% and 49% on CABG and PTCA patients, respectively. It diminished to 10% and 30% at 12 weeks, and at one year it was 15% and 24%. Multivessel disease was present in 86% of patients undergoing CABG and in 62% of patients undergoing PTCA. One patient in the CABG group had experienced a myocardial infarction and in the PTCA group three had had myocardial infarction; two of the patients of the PTCA group had repeat PTCA and four had CABG surgery. The silent ischemic episodes were also reduced in the medically treated group, but CABG was the most effective in reducing ischemia.

Up to 1983, as can be seen in Table 18, we had operated on 328 asymptomatic patients with three hospital deaths. We continued this policy after we established the Institute of Cardiology and Cardiovascular Surgery (ICYCC) of our Foundation. From June 1992 to December 1996, 185 patients were operated on, with three in-hospital deaths.

Recently, FitzGibbon and collaborators reported a long follow-up of 118 asymptomatic patients operated between 1971 and 1979 (68% had triple-vessel disease and 15% left main disease). With one exception all of them were younger than 45 years. At 15 years they had similar survival to that of symptomatic patients that were operated on by the same group. They concluded that there was "no reason why the same basic surgical principles of treatment, namely relief of coronary stenosis, should not be applied equally to all groups of patients" (653).

Acute Myocardial Infarction

During the early years of myocardial revascularization when the Vineberg approach was utilized, I was intrigued by the discordance between clinical and pathological findings in patients who died suddenly or within a few hours in the early postoperative period as a consequence of a large myocardial infarction. Electrocardiography had documented acute myocardial infarction as the cause of death. At autopsy (I used to perform them with my colleagues from the pathology department) it was not possible to detect the area of the infarction macroscopically and even with routine microscopy it was very difficult to define an acutely infarcted zone. "Insufficient time had elapsed for the infarction to be recognized" was the response of L. K. McCormack, in charge of the cardiovascular section of the pathology department. Electron microscopy showed afterward that most of the myocardial cells were intact. In 1968 Cox et al (654) demonstrated, by dehydrogenate staining after experimental ligation and sectioning of the anterior descending branch of the left coronary artery, that only ischemic changes (swelling of mitochondria on A bands and loss of extramitochondrial enzymatic activity with preservation of the normal myocardial architecture) were seen within six hours of coronary ligation.

Physiologic observations of the ischemic heart and its relation to oxygen consumption, as analyzed by Braunwald et al and Sonnenblick et al (655–659), convinced me that if we could increase quickly the reduced blood supply to the "infarcted area," the contractile state of the myocardium could be changed and certainly CABG was the way to do it.

The early experience that started in April 1968 was summarized in Chapter Ten of one of my books (660) and in my last contribution in Cleveland (15) before returning to my home country:

> Cardiovascular surgeons are on the doorstep of a more aggressive surgical approach among patients with acute coronary insufficiency. Although the present clinical experience is limited (eighteen operations were performed upon patients with impending infarction and eleven upon patients with AMI), certain conclusions can be made: (1) Emergency coronary cineangiography can be performed with minimal risk; (2) Patients with impending myocardial infarction can undergo operation with a low mortality rate and minimal complications. These patients are ideal candidates. The operation can prevent myocardial infarction; (3) When operations are performed within 6 hours of an AMI, most of the heart muscle can be preserved; (4) In patients with AMI and cardiogenic shock, assisted mechanical circulation is mandatory as the first step.

Several contributions appeared in this early period, indicating that the operations could be performed with low operative mortality and good clinical results (661–671).

The Spokane group (DeWood, Berg et al) (588,671–675) accumulated the largest experience: 440 transmural infarctions (84% in prior clinical class I and II) were operated on, with a 5.2% hospital mortality. In 261 patients with nontransmural infarction, the hospital mortality was 3.1%. However, transmural anterior infarction showed a 14% hospital mortality, and in all patients with triple-vessel disease it was 9%. Forty-three patients in prior class IV had a 28% hospital mortality. The mortality decreased (3.8%) in 291 patients that were placed on cardiopulmonary bypass within six hours.

At ten years (675) the total mortality was 8%, 12% and 17.4%, respectively, for patients with single-, double- and triple-vessel disease in transmural myocardial infarction. At eight years the total mortality was 4.2%, 6.3% and 8.4%, respectively, for single-, double- and triple-vessel disease in nontransmural myocardial infarction. Patients who were operated on within six hours of the acute episode had a total mortality of 8.2% vs 21% among patients with late reperfusion. The authors analyzed the early mortality with conventional medical therapy at their community (11.5%) and the mortality among survivors reported in the literature in those years (8% to 15% during the first year, 5% to 10% per year thereafter) (581,676,677). Even though they recognized their patients probably included many less likely to benefit from surgical reperfusion, they stated that only controlled randomized trials could be definitive. The Spokane experience was criticized as an unproved experimental clinical trial (678,679) mainly because the presentation of the data was incomplete, lacking the usual parameters utilized in clinical trials. DeWood et al answered this criticism (680) by presenting a complete report of 387 patients (200 on conventional therapy and 187 who underwent emergency CABG) with a hospital mortality of 11.5% vs. 5.8% on the medical and surgical groups respectively. Early reperfusion (<6 hours) resulted in a lower mortality rate (2% vs. 15.5%). Follow-up at 10 years demonstrated a mortality of 41% in the medical group vs. 27% in the surgical group. I believe they showed that early reperfusion can be accomplished in a large number of patients with low operative mortality (except in patients with three vessel disease and anterior infarction) and excellent survival in long-term follow-up. It should be emphasized that these results were accomplished in a decade of mediocre myocardial protection.

We continued our efforts in Buenos Aires. Experimental work in monkeys (681) confirmed that within six hours most of the myocardial cells could be reconstituted if blood supply was reestablished. Up to 1983, 583 patients were studied with cine coronary angiography in the acute and subacute phase of myocardial infarction without mortality, confirming once more that visualization of the coronary tree can be done as an emergency procedure, following the original contribution of Begg et al (682). Sixty-six percent of 148 uncomplicated myocardial infarctions had cine angiography within the first ten days. Most of the studies were performed among 340 patients who developed angina (50% were studied within the first 10 days); 95 patients underwent cine angiography due to acute mitral insufficiency, ventricular septal defect, intractable arrhythmia or severe heart failure. Analysis of the cine coronary angiography of patients with post-AMI angina (683) can be summarized as follows: type I, single severe obstruction of a coronary artery that produces a myocardial infarction smaller than the irrigated area; type II, obstruction similar to type I

and additional lesions in other coronary vessels; type III, total occlusion of a coronary artery that produces a small infarction because of partially adequate noncompromised collateral circulation; type IV, total occlusion of a coronary artery that produces a small infarction because of the presence of partially adequate compromised collateral circulation; type V, total or subtotal obstruction that produces a large myocardial infarction with concomitant obstruction in other coronary artery territories; and type VI, total occlusion of a coronary artery that produces an acute ventricular aneurysm with concomitant obstruction in arteries supplying other vascular territories. Collateral circulation is compromised when the artery that supplies it presents a critical obstruction. Careful analysis of the cine angiography allowed us to perform CABG in 174 patients (44.7% operated on within 10 days) with seven deaths (4.1%).

Several contributions had appeared in the literature since the mid-1970s (673,684–709). Analysis demonstrated that (a) the operations could be performed with a low mortality except on emergency indications within the first 24 hours. The risk was higher when CABG was done during the first week (~8%); (b) mortality increased with clinical status: age, Q wave myocardial infarction, anterior infarction, triple-vessel disease and low ejection fraction; (c) operation limited infarction size and enhanced muscular recovery with improvement of left ventricular function; (d) long-term follow-up showed survival rates similar to those of the population with a history of a previous remote infarction that underwent CABG; (e) operation could be life-saving in patients with cardiogenic shock even though the mortality varied between 12% and 30%. Only one series reported a mortality of 54.5% (six deaths in eleven patients) (702). Utilization of intra-aortic balloon counterpulsation improved the hemodynamic status, decreasing operative mortality. Even with present medical treatment (population from 1992 to 1993) an international registry found a 71% mortality in patients with shock (710).

Post-AMI angina constitutes an expanding subset of patients from the 1980s. Our results, already mentioned, were confirmed by Jones (711) and Levine (712). Later, several contributions (696,703,713–722) demonstrated the feasibility of CABG in this challenging group of patients, with a hospital mortality from 0% to 10.5%. Of course the series were not entirely comparable. Significant differences in age, degree of clinical instability, extent of disease and status of the left ventricle can indeed be found. Medium and long-term follow-ups were gratifying; actuarial curves demonstrated a survival of 95.3% at 18 months, and 85% at five years.

These results contrast dramatically with the reports from medical treatment. Chaturvedi et al (723) showed a mortality of 23% within three months after discharge and 37% within one year, and Schuster and Bulckley reported an overall mortality of 56% at a mean follow-up of six months (590). As we know, angina suggests the presence of viable ischemic heart muscle. In this group the incidence of a second infarction in medically treated patients within one year varies from 13% to 86% (715,724–729) with an early mortality of 29% if the second infarction is transmural (712).

In conclusion early experience demonstrated that patients with APAMI should be carefully monitored. Cine coronary angiography is indicated in the majority of them and CABG can be performed with low mortality.

The introduction of fibrinolytic agents has opened a new era in AMI. At the beginning, intracoronary streptokinase (SK) was utilized. The results of some early clinical (730–735) and randomized trials (736–739) reported a lower mortality and improved left ventricular function after coronary reperfusion. A small number of patients was included. In 1983, 250 patients were enrolled in a multicenter randomized community-based study (740,741). Reperfusion was achieved in 68% of the treated group, with an overall 30-day mortality of 7.2% vs 11.2% in the control group. At one year the reduction persisted only among patients in whom perfusion was reestablished. This early experience demonstrated that a high-grade stenosis remained in a significant number of patients. As a consequence, a complementary combined approach with early PTCA and CABG was reported (693,742–747).

It has been demonstrated through large-scale randomized trials in patients with AMI starting in 1979 (738,748–764) that when intravenous thrombolytic therapy is administered within twelve hours after onset of symptoms it reduces hospital mortality and the survival advantage persists. The late mortality was also low (765,766) particularly when comparing it with previous series antedating the use of thrombolytic therapy (767).

Nevertheless, Van de Werf (768), in a recent meta-analysis of long-term benefits of intravenous thrombolytic therapy based on more than 40,000 patients from well-controlled trials, showed that the risk of death after one month was the same in survivors of an AMI whether or not thrombolysis was given on admission. In 18,826 patients who were treated within twelve hours, 3.9% died during the following five months vs 4% (18,014 patients) of the placebo group. In patients treated within three hours the mortality rates were 3.7% vs 3.6%, respectively. After six months the death rate was also very similar with or without thrombolytic therapy. Van de Werf posed a very important question: "Why is not there any extra benefit after hospital discharge?"

Perhaps a critical analysis of the data accumulated could help us. In several trials without thrombolytic agents retrospective analysis showed that patency of the infarct-related artery appears to be important (769–771). Dalen et al (759) in the TIMI trial of 1988 demonstrated that within one year the mortality in 289 patients was 15% if the arteries were occluded at 90 minutes vs. 8% if the arteries were patent.

It has become clear that even with the best thrombolytic regime available, the percentage of early true reperfusion (TIMI flow 3) is disappointingly low (~50%) (772–776). Even though earlier reports had suggested that left ventricular function, infarction size, and morbidity may be inferior in patients with TIMI 2 flow rather than TIMI 3 flow after thrombolysis (773,774,777), recently several reports clearly

confirmed (778–782) that patients with TIMI 2 flow should be considered an inadequate result of therapy. Recurrent ischemia is significantly higher in patients with TIMI 2 flow (22.9% vs 16.9%). Reocclusion was observed more frequently (10.4% vs 2.2% between 18 and 36 hours) and hospital mortality was also higher (6.7% vs 3.8% in a pooled data of 3,960 patients). Global and regional left ventricular function are better preserved in patients with complete TIMI 3 infarcted vessel patency than in those with TIMI 2 flow. Patients with TIMI 2 flow had a lower residual luminal diameter in the culprit lesion than patients with TIMI grade 3 flow. The TIMI investigators (783) had shown that the one year mortality rate in patients with <60% diameter stenosis in the infarcted related artery was 1.6%, compared with 4.4% in patients with >60% stenosis. The European Cooperative Study Group (780) showed that at five years, patients with TIMI 2 flow had mortality rates similar to those with TIMI 0 and 1 flow. Consequently we can conclude that only TIMI 3 flow should be regarded as patency in the sense of predicting a good clinical outcome.

Recurrent ischemic events are known to increase after thrombolytic therapy (749,754,784,785). They are present within one week in from 19.2% (786) to 22.9% (781). They increase to 25.8% at two weeks (787) and 29% within six weeks (788–791). Therefore, it is not surprising that reocclusion occurs in 5% to 10% before discharge (774,792–794), and 12.2% (11.8% to 16.3%) with standard tissue-type plasminogen activator (t-PA) (795–803), 7.2% (5.2% to 9.1%) with accelerated t-PA (798,804–807), 4% (3.1% to 6.9%) with streptokinase (SK) (774,808–813) and 3.8% (1.6% to 5.1%) with anisoylated plasminogen SK activator complex (APSAC) (805,810–815) within six weeks, with a concomitant high incidence of reinfarction (751,761,762,816), particularly in patients with non-Q wave infarction (817,818).

In the GUSTO trial the incidence of reinfarction within four days was 3.4% in the subcutaneous SK group and 4% in the other 31,180 patients. The hospital mortality was significantly elevated (between 16.8 and 20% in this reinfarction group) in comparison with the overall mortality (between 6.3% and 7.4%) (819). The incidence of reinfarction increased to 6.5% within six weeks (788–790). The TIMI II investigators had shown that at three years nonfatal reinfarction is an independent predictor of death, more powerful than other important patient characteristics (820).

It is possible that more potent inhibitors of platelet action such as platelet fibrinogen receptor will increase the degree of lysis and lessen rethrombosis (821). The tools of molecular biology and genetic engineering modify plasminogen activator function and contribute to a new "third generation" of thrombolytic agents (reteplase, staphylokinase, t-PA-scu-PA chimera, bat-t-PA, TNK mutant, antibody-targeted plasminogen activators and antibody targeting of adjunctive agents) that have been recently analyzed by Bode et al (822). They believe these show promise to improve clinical outcome and perhaps a reduction of intracranial bleeding (between 0.5% and 1.5% in patients with the present treatment). However, megatrials will be required because the absolute reduction in mortality with our current thrombolytic therapy ranges between 2% and 4%.

Hirudin and hirulog, highly specific antithrombin agents, seem to be more effective than heparin in the prevention of reocclusion after t-PA (823,824) or SK (825). However, current patient numbers are small and hirudin is associated with more cerebral bleedings than heparin (824,826–828).

I think it is important to remember that patients receiving thrombolytic therapy constitute a minority extracted from consecutive patients with myocardial infarction seen in the emergency room (ER).

Cragg and collaborators analyzed 1,471 patients admitted with an AMI from April 1986 to June 1988 (829). Only 230 (16%) received thrombolytic therapy. The comparison with the other 1,144 demonstrated that they comprised a low-risk population. Mortality was fivefold higher among ineligible patients. These findings were consistent with data from GISSI I (749) and ISIS-2 (754) of 1986 and 1988 respectively. The National Registry of Myocardial Infarction (NRMI) showed that among 240,989 patients (September 1990 to December 1993), 35.1% received thrombolytic therapy (830). In 269,035 patients registered between July 1994 and December 1995, only 30.3% (81,577 patients) received thrombolytic therapy (personal communication, W. J. Rogers).

Most of the patients reported in the literature with myocardial infarction and treated with thrombolytic agents are <65 years of age, and although only 13% of the U.S. population is >65 years of age, 80% of all hospital deaths due to myocardial infarction are in this age group (831).

Even though the analysis of the cineangiography is insufficient, in some of the trials the proportion of patients with triple-vessel disease is quite low (7% to 20%) (740,766,767,780–783,796,818,832–846), if we compare these data with the populations reported in the prethrombolytic era (23% to 50%) (848,849).

What about non-Q wave myocardial infarction? Non-Q wave myocardial infarction is often associated with continued perfusion deficit to the infarcted zone because of subocclusive flow-limiting stenosis (849–851). Total coronary occlusion occurs in only 32% of these patients (849). In several trials the mortality rate in patients with ST segment depression was not influenced by thrombolytic therapy (749,764,830,852). It is well known that patients with non-Q wave infarction have a relatively low in-hospital mortality rate (853,854). However, recurrent ischemia, reinfarction and death frequently occur after discharge (855–858).

Langer et al., in the LATE study (859), randomized 644 patients with non-Q wave myocardial infarction to treatment with t-PA and 665, to placebo. The benefit conferred by the administration of t-PA was evident at 35 days (death: 5.4% vs. 9.6%; reinfarction: 1.9% vs. 5.8%). After one year, mortality was 10.6% vs. 16.2% and reinfarction 6.4% vs. 10.8%.

Braunwald and Cannon (860) found the results interesting, surprising and provocative, mainly because thrombolytic therapy provides a substantial benefit in the subgroup of patients with ST-segment depression where current treatment leaves a

lot to be desired. Langer suggested that additional prospective rigorous trials should be carried out to corroborate their results. I do believe cine coronary angiography is indicated in the early stages.

CABG in the Thrombolytic Era

CABG also plays a role in the thrombolytic era. Several publications appeared in the early and mid 1980s (742,861–873) and, even though they report small numbers of patients, on review it is evident that they comprise patients at high risk, on whom CABG was done frequently on an emergency basis, during the first 24 hours. After these preliminary attempts in 1988 Petrovich (874) published the results of 388 patients operated after being treated with intracoronary or intravenous streptokinase (SK) and compared them with 318 patients treated medically after receiving the same thrombolytic drug. The average interval from SK to CABG was 4 ± 3.2 days. In the surgical group 70.3% had shown multivessel diseases with severe residual stenosis on the culprit vessel. The in-hospital mortality was 3.6% vs 9.4% in the medical group. No data were available after discharge.

In 1991 Kereiakes et al reported the overall results from the TAMI study group (875,876), partially documented in two previous publications (877,878). Three hundred and three patients were operated on after being treated with t-PA, urokinase or both and compared them with 1,387 patients who received the same thrombolytic agents. As a group, patients having surgery were older and more often had diabetes or a prior myocardial infarction; 20% had single-vessel disease and 46%, triple-vessel disease. In the medical group, 56% had shown single-vessel disease and only 11%, triple-vessel disease. The operation was done as an emergency procedure within the first 24 hours in 36 patients (24% in cardiogenic shock). Mortality was 17% in the emergency group and 5% in the deferred group (overall hospital death was 6.6%). The medical group showed a 5.9% mortality. At three years death was similar: 7.2% in the CABG group and 6.2% on the medical group, non-fatal myocardial infarction occurred in 5.3% and 8.4% in the surgical and medical groups respectively. The degree of recovery of global and regional (infarct zone) left ventricular function in the surgical population clearly exceeded the degree of functional recovery noted following thrombolysis alone.

The results were quite similar during hospitalization but certainly they were comparing two different populations. I think it is more appropriate to state that as a consequence of CABG, a group of patients at high risk had early results similar to those at low risk (triple-vessel disease: 46% vs 11% in the medical and surgical groups, respectively). The same comments can be made with the outcome at three years. In addition 18% of the medical group required PTCA or CABG vs. 7% in the surgical group.

In 1994 Nicolau presented another important series (879): 128 patients were operated on and compared with 147 patients receiving medical treatment. All patients had received SK. Cine angiography was performed between 48 and 72 hours. Multivessel disease was present in 76.8% and 40.7% of the surgical and medical groups, respectively. Hospital mortality was 4.7% in the surgical group vs 10.9% in the medical group. All the patients who left the hospital were followed for six years. Survival was 68.4% and 86.4% in the medical and surgical groups, respectively.

In 1995 CABG after thrombolysis was analyzed in the TIMI II Phase II trial (845). The 390 patients who underwent bypass were classified into two groups: (A) 54 patients who underwent surgery within 24 hours after entry into the trial or within 24 hours of PTCA performed within 42 days of enrollment; (B) 336 patients who underwent CABG between 24 hours and 42 days after entry. Multivessel disease was present in 51% and 65.1% in groups A and B, respectively (triple-vessel disease in 11.8% and 25.2%). Only one operation was categorized as elective in group A, and 66.7%, in group B. Sixty-two percent had internal mammary artery conduits (only 18.5% in group A). Perioperative mortality was 5.6% (16.7% and 3.9%, respectively, in group A and B). Perioperative myocardial infarction was 6.2% (5.6% and 6.2% in groups A and B). Among 322 survivors there were only seven deaths during the first year (mortality rates were 2.2% and 1.9% in groups A and B). Only one patient had a documented myocardial infarction, during the second year. No patients in group A died and only six patients in group B died.

In summary: (a) intravenous thrombolytic therapy for evolving myocardial infarction is associated with a significant increase in subsequent coronary revascularization compared with patients receiving conventional therapy (759,838,880); (b) CABG is performed in patients at high risk with an acceptable operative mortality except on emergency indications within the first 24 hours. In this particular group, the majority is in poor hemodynamic condition, including patients in cardiogenic shock and in the TIMI population, 58% required intra-aortic balloon; (c) blood loss increased in CABG done in patients receiving thrombolytic agents, particularly when surgery is performed during the first 24 hours, when hemorrhagic events and reoperations are common. The cooperation of an expert in coagulation therapy is mandatory in the operating room and in the immediate postoperative recuperation.

PTCA in the Thrombolytic Era

The first PTCA for AMI was performed in 1981 at the Mid America Heart Institute (881). Thereafter they accumulated a significant experience demonstrating that angioplasty can be done as an emergency procedure with a high success rate and low morbidity and mortality (882). Costantini et al, based on previous experimental work performed at the Cedars-Sinai Medical Research Institute since 1975 (883), started PTCA in AMI in Argentina in 1982. Since 1985 several publications appeared, ten of them being compiled by Eckman et al (884) in a meta-analysis. From 2,073 patients, the success rate was 91% with a hospital mortality of 8.3%.

The utilization of PTCA after thrombolysis, although it is a

widely used technique, remained a controversial issue. Up to 1992 some trials suggested a certain benefit (835,885–888) but other trials showed no advantage (757,787,796,801,832,889–898). In 1993 three prospective randomized trials (789,790, 899) appeared simultaneously in the *New England Journal of Medicine* showing a better clinical outcome for primary angioplasty compared with standard thrombolytic therapy, particularly in the PAMI trial (789): the incidence of deaths and reinfarction was 5.1% for PTCA vs 12% for thrombolysis. The reduction was particularly marked in patients >65 years of age (8.6% vs 20%). Recurrent ischemic events were markedly reduced in the patients treated with PTCA compared with t-PA-treated (10.3% vs 28%). The independent beneficial effect of angioplasty on freedom from death or reinfarction was maintained at six-month follow-up (death occurred in 8.2% vs 17%). Certainly these publications resulted in an increased utilization of PTCA in AMI.

Recently a critical analysis was reported by Michels and Yusuf (900). They carried out an excellent quantitative overview of the randomized clinical trials, dividing them into different groups. The seven trials that compare primary PTCA vs. thrombolytic therapy demonstrated a considerable reduction in mortality with PTCA at 6 weeks (3.7% vs 6.4%, OR 0.56, 95% confidence interval, 0.33 to 0.94). When death and nonfatal myocardial infarction were combined, the reduction was similar (6.1% vs 11%). This benefit has been confirmed to a lesser degree by the GUSTO IIb Trial: within 30 days death, myocardial infarction, and stroke comprised 13.1% of the patients in the thrombolytic group vs 9.6% of the PTCA group. These clinical benefits greatly exceed those observed in the GUSTO I Trial, in which t-PA was found to be a superior regime, as has been pointed out by Grines (901). In the t-PA group 30% of the patients also had PTCA during hospital admission (in 25% of the cases the cine angiographies were done as emergencies). If we add the GUSTO IIb Trial to the seven previous studies, we find that death in the PTCA group was 4.7% vs 6.7% in the thrombolysis group, and death plus myocardial infarction was 7.8% vs 11.6% in the PTCA and thrombolysis groups, respectively. Once again the t-PA group is not a pure thrombolytic population. This is a common finding in most of the trials, mainly as a consequence of recurrent angina. In the TIMI Trial Phase II (787), among the entire group assigned to the conservative strategies, 262 patients (16.1%) had PTCA and 170 patients (10.5%) had CABG. In the PAMI Trial (789) the t-PA group required PTCA in 24.5% of the cases.

The results of the Primary Angioplasty Registry (902,903) can be also utilized for comparison because patients with usual contraindications to thrombolytic therapy were excluded to provide a population similar to previous U.S.-based thrombolytic trials. In 258 patients death, reinfarction and stroke occurred in 8% of the population.

In conclusion, the analysis of the various trials suggests: (a) primary PTCA may be more beneficial than thrombolytic therapy in AMI; (b) besides the reduction in hospital mortality, angioplasty results in a smaller infarct size and a better preserved left ventricular function, probably due to early and improved coronary flow (904,905); (c) PTCA also reduced the incidence of recurrent angina, reinfarction and reocclusion within six months (786,789,790,903–910) commonly found in thrombolytic trials. Nevertheless these remain significant: recurrent ischemia 10% to 15%, reinfarction 3% to 6% and reocclusion of the infarcted-related artery 5% to 10%, in hospital and six months results, respectively (901).

PTCA was also used as an adjunct to thrombolytic therapy. Michels and Yusuf (900) also analyzed several trials categorizing them according to four different approaches: immediate PTCA compared with no PTCA, early PTCA compared with no PTCA, delayed PTCA compared with no PTCA and immediate PTCA compared with delayed PTCA. Mortality at six weeks showed trends toward increased risk in the more aggressively-treated group (immediate and early). Nevertheless, in none of these categories were there significant differences.

Only a few trials included patients in whom PTCA was performed on occluded vessels. As an example, in the Phase II TIMI Trial, 177 patients (12.1%) were excluded from the group of invasive strategies because they showed total occlusion. As a consequence the experience with rescue PTCA is limited (812,844,911–914). Its indication remained controversial because of an imperfect success rate, the high mortality of patients with failed angioplasty which outweighed the clinical benefit, the high incidence of reocclusion and the increased incidence of bleeding complication at the access site. Therefore rescue angioplasty should be a subject of future clinical trials in AMI. I believe patients with TIMI 2 flow should be included. Nevertheless PTCA appeared to be useful in the prevention of death or severe heart failure with improvement in exercise ejection fraction in patients with anterior AMI (844).

The benefit of PTCA in anterior infarction has been recently confirmed by the PAMI investigators (915). Compared with t-PA, in-hospital mortality was reduced by angioplasty (1.4% vs 11.9%). PTCA also reduced death and reinfarction (1.4% vs 18%), recurrent ischemia (11.3% vs 28.4%) and stroke (0% vs 6%).

The overall analysis of the data on primary PTCA is promising and encourages its utilization, but it is important to remember that the trials analyzed were conducted in a few highly qualified centers and perhaps the outcome would be less impressive if the procedure were performed in hospitals with low volume operators (916,917). In the MITI Trial (AMI) (918) PTCA was performed in 801 patients in high-volume hospitals with a mortality of 4.5%. In 207 patients the procedure was done in low-volume hospitals with a mortality of 8.1%.

Even though we do not have enough data regarding long-term follow-up of patients submitted to PTCA in AMI, due to the high incidence of early restenosis that varies between 19% (919) and 51% (920) (recently Horrigan and collaborators [921] in a meta-analysis of 860 patients found an average of 43%), it is logical that acute angioplasty of the culprit lesion is

a temporary partial solution mainly among patients with multivessel disease.

Of particular interest is the application of PTCA in patients with cardiogenic shock due to AMI. As we know cardiogenic shock is the leading cause of death in patients hospitalized with AMI. The incidence (~8%) and mortality (~80%) remained unchanged (922) under the traditional medical treatment. Recently, Stone (923) reviewed 18 publications in which PTCA was applied in 626 patients with an overall mortality of 46% (it varied between 18% and 58%). Results of an international registry (710) showed a 60% mortality in the PTCA group. Patients clinically selected to undergo cardiac catheterization were significantly younger and had a lower mortality than those not selected (51% vs 85%) (710). Certainly I believe PTCA should be considered the first choice for this high-risk group of patients.

Reports of comparison of the relative benefits of primary coronary angioplasty and thrombolytic therapy are open to some criticism. Many times the data were not properly presented. As an example Every et al (918) from the MITI project analyzed the results of 1,050 patients treated with primary angioplasty and compared them with 2,095 in the thrombolytic group. There was no difference in mortality during hospitalization (5.6% vs 5.5% in the thrombolytic and PTCA groups). At three years, patients treated with thrombolytic therapy were less likely to have undergone coronary angiography (19.7% vs. 28.3%), coronary angioplasty (15.9% vs. 18.8%) and similar proportions had CABG, but there was no difference in long-term survival. The high-risk group had similar results during hospitalization (mortality 8.1% vs. 8.7% for thrombolysis and PTCA, respectively). A slightly better survival was noted at three years in the thrombolytic group (17.8% vs. 24.8%). However, they did not emphasize that 74% of the thrombolytic group underwent angiography and 32% underwent PTCA during hospitalization. Consequently this would be a clinical trial that compares primary PTCA vs. thrombolytic therapy plus primary PTCA.

It is interesting that in the same journal Lange and Hillis (924) in a "clinical debate" related to the Every article argue that thrombolytic therapy should be the initial therapy and Grines (925) favors coronary angioplasty. The former believes that the preferred treatment should be thrombolysis because it can be applied more quickly, safely and expertly, but he did not mention a word on patency, recurrent angina, reocclusion and reinfarction. Of course Grines is in the "opposite corner" emphasizing all this setback from thrombolysis, but without a word on the high rate of restenosis registered in the literature. On the contrary, "reocclusion after angioplasty may be related to factors that can be easily corrected." How difficult it is to avoid personal bias!

A summary of all the publications related to primary PTCA vs. thrombolysis in AMI has been a tremendous effort by Lieu et al (926) aimed at providing a scientific groundwork to assist physicians in deciding which intervention is indicated. It is important to remember that the numbers and percentages are averages of a certain number of patients. The clinical stratification and the catheterization data, of course, are not included. The tables will serve only as a guide for a broad orientation.

Stenting in AMI

Initial series of stent placement reported a disappointingly high recurrence of stent closure (~25%) (927,928). The incidence increased with emergency stent placement (929). It was held that one of the most important factors associated with stent thrombosis is the presence of intracoronary thrombus before or after implantation and, as we know, the acute coronary syndrome is commonly associated with intracoronary thrombus. It was also emphasized that no antithrombotic regimen was identified as being effective in prevention of thrombosis in a suboptimally deployed stent (930). As a consequence it was illogical to think that stent would have a therapeutic role in patients with AMI.

Nevertheless the contributions of Goldberg (931) and Colombo (541) and co-workers demonstrated that, by means of intravascular ultrasound and with conventional implantation techniques, stent deployment was suboptimal in up to 87% of the cases with incorrect apposition of the device to the coronary surface. They therefore suggested additional high pressure noncompliant balloon angioplasty to fully expand the stent.

Several investigators using ultrasound progressively diminished and finally stopped anticoagulation regimen and observed very low closure rates with combined aspirin-ticlopidine treatment, as a consequence of Morice et al contributions (932–934).

Mak and collaborators (935) reported preliminary data of a multicenter trial evaluating the ultrasound criteria proposed by Colombo and colleagues. From 2,630 patients with at least 3,141 stents using antiplatelet agents without warfarin, only 33 (1.3%) have developed stent thrombosis (two thirds of these patients did not have ultrasound imaging). At present, full antiplatelet therapy without ultrasound guidance but with "blind" high pressure angioplasty of >12 atmospheres, has become routine clinical practice. Recently several reports (927,928,936–943), although with small numbers of patients, have shown that stents can be applied in patients with AMI with a high success rate and significantly low rates of restenosis and reocclusion.

The multicenter PAMI Stent Pilot Study is now investigating the role of stenting as a reperfusion strategy in patients with AMI (901). Preliminary data in 125 patients showed that stents were successfully deployed in 99% with no death or reinfarction and a low rate of recurrent ischemia (2.4%). Repeat revascularization (PTCA or CABG) was needed in 0.8% of the patients. Aspirin and ticlopidine were given.

It seems that primary stenting may be safely performed in patients with AMI with good clinical results. Further experience and long-term follow-up results are needed. The introduction of more potent antiplatelet agents, such as the TE3 glycoprotein IIb/IIIa receptor antagonist may further reduce

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the incidence of complications and recurrent ischemia. Nevertheless stents cannot be applied in all the patients mainly because the arterial diameter should be >2.5 mm. In the PAMI Stent Pilot Study, 31% of the patients were considered ineligible for stent placement "if they had small vessels (diameter <2.75 mm), if >2 stents were required, if there was a huge residual thrombus, if there was a possiblity that a stent would be needed in the ostium of the left anterior descending coronary artery or left circumflex, if major side branches were in jeopardy, or if delivery or expansion of the stent might not be feasible." Coincidentally, for similar reasons, stent was not attempted in 32% of the patients reported by Saito (944).

Comments on Thrombolysis, PTCA and CABG in AMI

At present thrombolysis, PTCA and CABG may be performed in patients with AMI. As in many other issues in medicine opinions are divided. We should try to make decisions and draw up guidelines on such an important subject, bearing in mind that each year 900,000 people experience AMI and roughly 225,000 die for the same cause in the U.S. The following comments are the result of a critical analysis of the guidelines for the management of patients with acute myocardial infarction of the ACC/AHA Task Force Report (945).

A clinical examination that only takes a few minutes, gives us important information. We know that infarct-related mortality increases with age, female gender, a history of chronic angina, previous infarction, hypertension, diabetes and the presence of peripheral vascular disease (946–950). Significant tachycardia (>100 per minute), hypotension, signs of congestive heart failure, atrial and ventricular arrhythmias, persisting angina and persisting ST segment depression indicate that patients in this category are at high risk.

The classification by Killip and Kimball (951) is very useful thanks to its simplicity and easy application. The four groups are related to the extent of the left ventricular dysfunction. The TIMI, Phase II co-investigators (952) analyzed the presence of eight risk factors before thrombolytic therapy was administered: age ≥70 years, female gender, a history of diabetes mellitus or previous myocardial infarction, electrocardiographic evidence of evolving anterior infarction or atrial fibrillation, evidence on physical examination of mild pulmonary congestion, hypotension (systolic pressure <100 mm Hg), and sinus tachycardia (heart rate >100 beats/min).

Among 3,261 patients, 864 had no risk factors and the mortality rate at six weeks was only 1.5%; for those who had one risk factor mortality was 2.3% (1,384 patients); for two risk factors, 7% (689 patients), for three, 13% (231 patients) and >4, 17.2% (93 patients).

Therefore clinical examination and the presence of risk factors, easy to remember and without a numeric score, as in the Peel (953) or Norris (954) indices, can clearly categorize patients at low and high risk.

A 12-lead electrocardiogram (ECG), for primary screening, will identify three groups: (a) ST segment elevation or new left bundle branch block (LBBB). Most of these patients will evolve into Q-wave myocardial infarction; (b) isoelectric ST segments but sharp symmetrical T-inversion. A small subset will evolve into a Q-wave myocardial infarction; (c) ST segment horizontal depression usually striking in multiple leads, especially precordial leads. It generally indicates severe subendocardial infarction.

Even though between 1976 and 1987 several publications (955–966) analyzed the utilization of echocardiography in AMI, the contributions by Sabia et al (967,968) demonstrated that regional wall motion abnormalities (RWMA) (carried out with two-dimensional echocardiography in 180 patients in the ER) that occur within seconds of coronary occlusion (969,970) increase the diagnostic yield for AMI compared with conventional approach, using clinical and ECG information. Even though RWMA cannot differentiate between ischemia and necrosis, it can detect the extent of myocardium involved and it is a useful predictor of in-hospital complications. In addition RWMA provides information concerning the status of the myocardium remote from the region of acute injury and this may suggest severe stenosis in coronary arteries that supply these beds and therefore be indicative of multiple coronary artery disease.

As we know left ventricular systolic function is a potent independent predictor of survival (591,600,767,946,971–975). Analysis of left ventricular systolic dysfunction (LVSD) by echocardiography in 171 patients (968), also performed in the ER, can help us predict events occurring within 48 hours of admission (cardiac-related death, nonfatal myocardial infarction, serious arrhythmia and coronary revascularization). When LVSD was present, events occurred in 26.9% of the patients vs. 3.3% when LVSD was absent.

The introduction of myocardial contrast echocardiography (976,977) with the possibility of new contrast agents administered intravenously (978) constitutes a new technique that will take its place among investigations during the acute phase of myocardial infarction.

The laboratory plays an essential role in establishing the final diagnosis of myocardial infarction. Creatinine kinase MB is the current standard. Rapid whole blood bedside assays of cardiac specific troponin T (cTnT) and I (cTnI) are now available; increase in serum levels occurs early (979–981). The analysis of the ECG and the serum cardiac enzymes will finally categorize AMI into Q waves and non-Q waves.

Balloon flotation right heart catheter monitoring is very helpful in patients with early signs of left ventricular deterioration. Pulmonary capillary wedge pressure and cardiac output will help in evaluation. Of course, its utilization is mandatory in patients with cardiogenic shock.

Patients at high risk should be sent directly to the cardiac laboratory for emergency cine angiography and concomitant PTCA in most. After careful review, patients with severe left main coronary artery disease, left main equivalent, or three or more proximal obstructions will be sent for CABG, with or without previous PTCA of the culprit lesion. It is important to

remember that survival after AMI is determined by the infarct size and the capacity of remote, non-ischemic myocardium to support the systemic circulation by hypercontractility (982). A recent report by Jaarsma et al (983) showed a 69% mortality in patients who did not have remote hypercontractility. A previous contribution by Schuster and Bulckley (590) reported a 72% late mortality rate in patients with "ischemia at a distance." Certainly, remote myocardium may become relatively ischemic if it is supplied by severely stenotic coronary arteries and is called upon to increase contractile function. Patients in cardiogenic shock should be sent immediately to the cardiac laboratory for possible PTCA as the only chance to reduce the extremely high mortality with the present medical treatment (926).

Patients in the low-risk category with ST segment elevation or LBBB who have no contraindications should be treated with intravenous thrombolytic therapy, watching their evolution closely. The preliminary stratification can change within a few hours.

Since DeWood's fundamental contribution we know that occlusive coronary thrombosis is present in more than 90% of patients with ST segment elevation (588). Thrombolytic therapy should be initiated as soon as possible, including patients with LBBB that may obscure the electrocardiographic diagnosis. The incidence of acute thrombosis is low in patients with modest ST segment depression (849,850,984) and thrombolytic therapy has proved ineffective and even harmful (764).

Early discharge after thrombolytic therapy can be accomplished in low-risk patients with uncomplicated myocardial infarction (absence of reinfarction, ischemia, stroke, heart failure, balloon pumping, emergency cardiac catheterization and, of course, early CABG within four days), as has been demonstrated in the GUSTO Trial (846).

What should be done before discharge in the large group of low-risk patients? Following a conservative approach in patients with definite signs of reperfusion a submaximal exercise test (5 mets) is indicated in patients who can exercise. Symptom-limited exercise has been suggested (985,986). They showed an increased number of positive tests with a similar rate of complications. Hamm et al (987) reported data compiled from 151,949 after AMI in 570 institutions; 28,052 symptom-limited test vs. 96,695 low-level test showed similar overall fatality (0.03%). Patients with negative tests can be sent home under medical treatment. Between 3 and 6 weeks later an exercise test (full Bruce protocol with or without thallium 201) or exercise echocardiography should be performed. As many as 35% of patients with a negative predischarge submaximal exercise test may demonstrate evidence of myocardial ischemia on a more strenuous testing (589,988). Patients with negative tests are followed under medical treatment (mortality at one year <2%) (989–992); patients with positive tests should be sent for catheterization (mortality at one year is as high as 15%) (990).

Patients who cannot exercise may be investigated (with caution) by pharmacological thallium 201 or dipyridamole echocardiography or be sent directly to the cardiac laboratory. They represent 10% to 22% of survivors of AMI. Such patients have a high mortality rate and a high incidence of recurrent events (595,842,993–995). If the noninvasive test is negative they can be followed closely under medical treatment. If fibrinolytic treatment is contraindicated or no reperfusion is obtained, those patients should be sent to the cardiac laboratory.

This overall approach has certain limitations because, as has been recognized by Pitt (950), one of the leading authorities in nuclear cardiology, the sensitivity and specificity of myocardial imaging in a low risk population has a high percentage of false positive and false negative results. Kulick and Rahimtoola (948) pointed out that a substantial percentage of patients (about 17% to 23%) who are at risk for recurrent AMI or death will fail to be identified by noninvasive testing. Furthermore they remark that the sensitivity of exercise testing for the detection of multivessel disease in survivors of AMI has been <75%. In a critical analysis of the noninvasive predischarge test they finally summarized their comments as follows: from 100 patients, 15 would not be able to perform the test; of 85 taking the test, the results would be abnormal in 37 and in 19, inconclusive. Upon the negative testing, full Bruce protocol after discharge would show that in nine patients the results would be abnormal. They believed all those 80 patients should have cine coronary angiography. As we know, the presence of multivessel coronary artery disease and the status of the left ventricle are the best predictors of late survival. The presence of viable myocardium supplied by an obstructed coronary artery (risk segments) is associated with a high incidence of adverse cardiac events (600). Without any doubt only cine coronary angiography can give us the real picture of the coronary artery in the distribution of lesions.

In summary the low risk group of patients will be given fibrinolytic agents (Fig. 11). Patients who can exercise have submaximal exercise tests, and those who show positive results will be sent to the cardiac laboratory. Patients with single-vessel disease will be treated with PTCA, patients with multivessel disease and significant proximal obstruction will be operated on. Still, some patients will be kept on medical treatment for the same reasons already mentioned as well as other patients with severe diffuse coronary arteriosclerosis with poor distal runoff. Careful analysis of the cine angiography will determine whether PTCA or CABG are indicated during the same admission. Still another group of patients will be treated with PTCA or CABG after a positive test is done between 3 to 6 weeks after the acute event.

In patients who cannot exercise catheterization performed directly or after a pharmacological test is positive determines another group in whom PTCA or CABG is indicated. The same approach is valid for patients in whom thrombolysis is contraindicated or patients with failed thrombolytic therapy.

Of course these are guidelines for general orientation. Each patient should be analyzed properly with judgment and definite criteria in order to reach the best therapeutic decision. Clinical stratification should be the bench mark. There is enough time to evaluate patients at low risk after the fibrinolytic treatment

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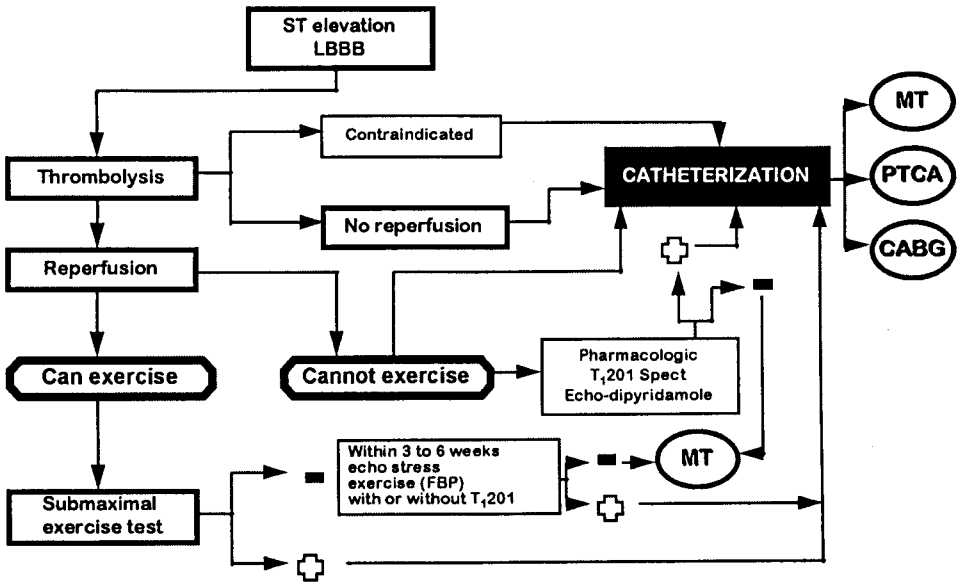

Figure 11. Guidelines for management of low-risk patients with acute myocardial infarction. Echo = echocardiography; FBP = full Bruce protocol; LBBB = left bundle branch block; Spect = single-photon emission computed tomography; T_1 201 = thallium-201; other abbreviations as in Figures 5 and 6.

is instituted. Once again we have to remember that only ~50% of the culprit arteries will be really open. PTCA and CABG will be indicated in a large number of patients.

Patients at high risk should be sent to the cardiac laboratory as quickly as possible. Most of them will be treated during the early hours with PTCA. Only a very small number are candidates for emergency CABG. Thereafter, careful analysis of the cine angiograms will determine when CABG should be performed. If recurrent angina appears during hospitalization, catheterization will be mandatory in this early stage.

Anterior infarctions merit particular attention, because they carry a higher short- and long-term mortality rate (382,996); cine angiography will be needed in most of them. The same is true for non-Q wave myocardial infarction. Although hospital mortality is low, they have a high incidence of recurrent ischemia (727,994,997,998) and a high mortality after hospital discharge (999,1000), associated with severe residual coronary narrowing. I believe cine coronary angiography should be the first choice in the evaluation of non-Q wave myocardial infarction. Nevertheless a submaximal or symptom-limited exercise test can be done in patients with non-Q wave myocardial infarction. The results are similar (985,994, 1001,1002) to those of Q wave myocardial infarction.

Young patients (<50 years of age) have a lower incidence of extensive coronary artery disease (592,972,1003,1004). Analysis of the clinical record (familiar dyslipidemia, hypertension, diabetes, smoking) will determine the necessity of cine angiography.

As we already commented, most deaths due to AMI occur in elderly patients. They have a threefold or greater late mortality than younger patients (975,1005–1008), mainly as a consequence of an increased number of multivessel lesions. There are limited data on the role of noninvasive testing, because most series have excluded older patients. Moreover, a significant percentage will be unable to complete satisfactorily an exercise test after AMI. Therefore, cine angiography should be considered for older patients who are in good clinical condition.

One important question remains unanswered: is it possible to apply the plan that I present at a community level? In 1988 it was established by zip code analysis that 63% and 83% of the U.S. population live within 30 and 60 minutes, respectively, of a cardiac laboratory (755). It is probable that the percentage has increased in recent years. Nevertheless, in 1993 it was estimated that only 18% of institutions had facilities to perform PTCA in the U.S. (10% in Europe) (924) and not all of these are prepared to perform emergency catheterization. Therefore, the preliminary answer to the question posed should be "no." However, I think it is possible to organize a strategy by geographical areas in order to obtain adequate coverage. Patients admitted to the coronary care unit at the community level may undergo a rapid clinical stratification. Patients at high risk will be immediately sent to a well-equipped hospital with a catheterization laboratory and personnel qualified for both PTCA and CABG. Time can be saved by having well-trained personnel in the coronary care mobile units, as suggested by the ACC/AHA Guidelines for patients with AMI. A preliminary analysis will determine high risk and need for transfer to a well-equipped hospital.

Patients at low risk will receive thrombolytic therapy at the community hospital. If they develop postinfarction angina, serious arrhythmia, significant left ventricular failure, or a submaximal exercise test is positive, they could be transferred to the qualified centers. The feasibility of this approach has already been demonstrated by a health maintenance organization program in the areas of Los Angeles and San Diego (707).

An analysis of the NRMI showed that early primary PTCA was performed in 5.9% of the patients and emergency CABG in 0.6%. During hospitalization, 20.5% underwent PTCA and 10.8%, CABG (personal communication, W. J. Rogers). In the

GUSTO trial (1009,1010), of 21,772 patients, 72% underwent angiography before discharge and of those 59% underwent revascularization (70% PTCA and 30% CABG). The TIMI IIIB trial (1011) presented similar results: in the conservative strategy (733 patients) 64% had catheterization within six weeks. Revascularization was performed in 49% (PTCA in 26% and CABG in 23%). These three trials can give us a general idea of the present approach among patients with AMI.

We can conclude that at present PTCA and thrombolysis are at the front line for emergency treatment in patients with AMI. CABG is indicated in a small number of patients in the first 24 hours, but later there is adequate opportunity for its application.

Final Conclusions

The early period of CABG was characterized by widespread controversies. If we summarize the first decade, it is obvious that the benefit of CABG was related to the severity and number of the obstructions of the coronary lumen and benefits increased with the number of severe coronary lesions (at the Cleveland Clinic we were always referring to proximal obstructions). It is difficult to deny that at least in left main trunk obstruction and triple-vessel disease the evidence was quite clear. With increased experience, the surgical mortality and the incidence of perioperative myocardial infarction decreased significantly, even though the surgical population started to include patients with abnormal ventricles.

Our medical colleagues were demanding randomized trials. The VA Trial and the European Study were the first to appear. The VA Trial was not properly organized and hospitals with different mortalities (some of them unacceptable) were combined. Nevertheless, clinical risk stratification was valuable, even though it served to demonstrate that patients that were excluded from the trial were the most benefited. The VA Trial confirmed the opinion that patients with left main trunk obstruction and patients with triple-vessel disease, particularly those with an abnormal left ventricle were candidates for operation. The benefit was remarkable in the high-risk group. The European Study only accepted patients with normal ventricles. For the first time patients with double-vessel disease with 75% obstruction of the proximal segment of the anterior descending artery showed improved survival with CABG.

In 1980, when the results of the Consensus Development Conference were released, it appeared that the controversies between cardiologists and cardiovascular surgeons would diminish. But in 1993 the results of the CASS randomized trial stirred up the dispute. I think the outcome of the 4.7% low-risk group of patients included in the randomized trial could not be applied to the overall population of patients with coronary disease.

Utilization of internal mammary grafts definitely improves surgical results, and it also improves long-term survival. Arterial bypasses certainly are the grafts of choice. Radial, epigastric and gastroepiploic arteries allow multiple bypasses by composite arrangements. CABG, performed in millions of patients, has contributed in part to the decline of coronary artery disease mortality (1012).

The introduction of PTCA in 1977 deepened our responsibilities. Now our patients can follow three different roads. We should know all of them in detail to select the proper treatment, avoiding any personal preference: treatment selection must be based only on scientific evidence.

In patients with single-vessel disease, PTCA is indeed the initial treatment preferred in many cases. In patients with multivessel disease the landmarks are not clear. Analysis of the five principal randomized trials (BARI, EAST, CABRI, GABI and RITA) clearly demonstrates that they compare a low-risk double- and triple-vessel disease population. Even though the data sometimes are incomplete, meticulous analysis conclusively showed (mainly in the BARI trial) that patients included in the randomized trial comprise only a small proportion of patients with multivessel disease. Certainly this is not the population that we are facing every day in the operating room.

The classification of single-, double- and triple-vessel disease is totally inadequate today. Readings of cine coronary angiograms should specify the number of proximal obstructions and the size of the coronary arteries and which vessel is dominant. Ringqvist's classification and Myers' contributions are extremely valuable in this regard. If we want to compare different therapeutic approaches it is time to realize that the classification of single-, double- and triple-vessel disease only gives us a partial and unsatisfactory overview of the coronary anatomy (383).

The problem of silent ischemia has been evaluated in the analysis of asymptomatic patients. I am sure that such cases will increase in our daily practice. Exercise tests are common during yearly routine checkups. New technology will help in the early detection of coronary arteriosclerosis. Noninvasive quantification of myocardial blood flow by PET (1013), ultrafast computed tomography (1014–1016), and ultrasound to detect early coronary plaques in carotid abdominal and peripheral circulation (1017,1018) will help us to screen asymptomatic patients with coronary atherosclerosis.

In patients with AMI, fibrinolytic therapy and PTCA are the initial choices. I emphasized the limitation of the former, even though it can be applied at the community level, only ~50% of the arteries are really open. TIMI 2 flow should be considered unfavorable at early and late results. Surprisingly, in a recent contribution from the GUSTO Trial (1019) TIMI 2 flow is reported together with TIMI 3 flow. Recurrence of angina, reinfarction and reocclusion are common during and after hospitalization.

Angioplasty requires well-organized centers with trained personnel. The mortality is related with the experience of the operator. No doubt many high-risk patients should be treated primarily by angioplasty, particularly patients in shock. The preliminary experience with stents is promising, mainly after Colombo's contribution. I presume this will be the treatment of choice, of course at a significantly high cost.

Surgery within six hours will be reserved for a small number

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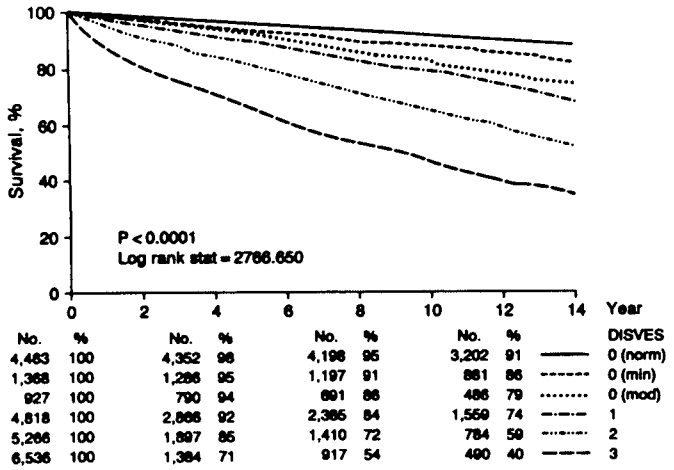


Figure 12. Survival rates for medically treated CASS trial patients by number of diseased vessels (DISVES [1, 2, 3]), with three categories for zero-vessel disease: normal (norm), minimal (min) and moderate (mod). CASS = Coronary Artery Surgery Study; stat = statistic. Data from Emond et al. (1020).

of patients at high risk including some in cardiogenic shock but CABG should be indicated in a large number during the subacute phase after fibrinolytic therapy or successful PTCA. Neither modifies the underlying coronary artery disease and the long-term outlook will be related closely to the location, severity and extent of residual disease including the TIMI 2 flow in the infarct-related artery. CABG before discharge is indicated in recurrent angina, reinfarction and reocclusion after thrombolytic therapy or PTCA. Of course, careful analysis of the cine angiography will determine in which patients this approach should be utilized. So far all these considerations are related to Q wave myocardial infarction.

To prepare this analysis of CABG, I personally reviewed hundreds of papers, and sometimes it was difficult to reach conclusions quickly. As an example Emond et al (1020) presented a long-term survival of medically treated patients in the CASS registry: 23,467 were included, although they indicated that, 10,976 eventually had CABG (9,013 within the first year). The figures from the different tables are confusing. As an example, if we analyzed Figure 12, we would realize that 1,384 is not 71% of 6,536. If that were the relationship, the real number at 0 year should be 1,949. Therefore, 4,587 would be missing (in my belief most were operated on). Consequently, this figure does not represent strictly follow-up survival of patients under medical treatment.

Zhao et al. (554) analyzed the effectiveness of revascularization in the EAST trial. It is not simple to understand clearly what they mean by index lesion, index segments and high priority index segments. Figure 1 (of that paper) is difficult to analyze. Furthermore, in Table 3 (also from that paper) the follow-up at one and three years of complete and incomplete revascularization is given for the total number of patients (CABG and PTCA together). It would have been valuable to know the figures for CABG and PTCA separately in the four categories into which patients were placed. The success rate (76%) is calculated only in relation to the 360 lesions for which PTCA was attempted. The total number of lesions is 471. Therefore only 56% of them were dilated. In comparison, from 474 lesions, CABG was "attempted" in 464 (98%) based on operative report. Certainly, instead of "attempted," the proper term is "performed."

I doubt whether the findings of some reports can be applied in daily practice. As an example, in 1994 the CASS compared 253 patients surgically treated with 47 medically treated (all had >70% left main trunk obstruction plus a severe obstruction of a significant right coronary artery) (1021) and 105 surgical with 30 medical patients with left main equivalent disease plus a severe obstruction on the right coronary artery (1022) showing that they had similar survival at 16 years. A reproduction of a cine coronary angiography typical of this kind of patients is included (Fig. 13). How many of us will advise medical treatment?

At present in order to understand most contributions, particularly clinical and randomized trials, a physician has to be a mathematician. Risk reduction and odds reduction are not enough; at least Kaplan-Meier curves, hazard ratio, Cox proportional hazard regression, stepwise procedures, log rank test, propensity score, etc. are necessary. The modified Mantel-Haenszel method seems to be the most appropriate to organize a meta-analysis. "In essence, the observed minus expected values of the treatment group for each trial are summed and then divided by the sums of the square root of the sum of the variances for each trial:

$$Z = \Sigma(O_i - E_i)/\sqrt{\Sigma V_i},$$

where O_i is the observed response in trial i; E_i is the expected response in trial i; and V_i is the variance in trial i (1023). Still, we cannot deny their contribution. However, many times they have been utilized to justify previous personal expectation.

Risk reduction represents the variation percentage between the treated group and the control group rather than their absolute difference. It can be seen in Table 19 that one can obtain the same values of risk reduction over a broad range of absolute differences (0.1% to 100%), i.e., if risk reduction is presented out of context, the clinical significance can be misinterpreted.

Figure 13. Severe obstruction (**arrows**) of the (**A**) left main and (**B**) right coronary arteries.

Risk reduction also depends on the control group value because the percentage is calculated from this value. Table 20 lists different control values with the same absolute differences, showing that risk reduction is in inverse proportion to the value of the control group. The higher the control value, the lower the value of risk reduction.

We can compare three trials where risk reduction is shown (375,1024,1025). In Table 21 no doubt 23.08% vs. 3% and 14.8% vs. 1.1% are more impressive. Utilizing t-PA we save only 1 patient in 100. Nevertheless, for the GUSTO investigators, utilizing risk reduction the difference is "highly significant." In my opinion it is highly significant if we take into account that currently t-PA treatment costs approximately $2,000 and SK $350. If risk reduction is applied to the CASS randomized trial data (Fig. 14), no doubt the first indication for CABG should be patients with single-vessel disease.

Table 19. Analysis of Risk Reduction

Control (%)	Treatment (%)	Absolute Difference (%)	Risk Reduction
0	0	0	50
2	1	1	50
20	10	10	50
50	25	25	50
200	100	100	50

Table 20. Analysis of Risk Reduction

Control (%)	Treatment (%)	Absolute Difference (%)	Risk Reduction
5	0	5	100
10	5	5	50
20	15	5	25
50	45	5	10
100	95	5	5

Randomized trials have developed such high scientific stature and acceptance that they are accorded an almost religious sanctification (1026). A critical analysis has been done by Feinstein (1027). After several considerations he concluded that

> Randomized trials are too difficult, too expensive, or too controversial for routine use in answering all the clinical questions that will arise in the future for a burgeoning diagnostic and therapeutic technology. Whether we like it or not, most of our future decisions about medical practice, health care, and scientific technology will have to be made without evidence from randomized trials. To acknowledge this reality requires no loss of reverence, allegiance, or respect for the primacy of randomized trials as a "gold standard" in scientific research.

Can the overall results of clinical and randomized trials be applied to all patients? The answer has been given by Rothwell (1028):

> Strictly speaking, the results of clinical trials cannot be applied to individuals. A single patient cannot experience a 50% reduction in death or a 20% improvement in survival. Such risks can only be calculated from analysis of groups of similar patients. However, patients included in a clinical trial are heterogeneous and may, for example, differ in the severity of illness and consequently in the absolute risk of a poor outcome.

Treatments for patients with coronary arteriosclerosis have changed so rapidly that even the most recent data from a large trial may be obsolete. As a consequence new trials have been appearing. Cheng compiled 244 in 1992 (1029), approximately 900 (1030) in 1994, and over 1,300 in 1996 (1031). And many more will come. We can mention internal mammary artery graft to the anterior descending branch of the left coronary artery performed with a minithoracotomy approach vs. PTCA of proximal lesion on the same branch, or multiple arterial composite bypass grafts vs. angioplasty with new devices. The evaluation of stents in AMI is already underway by the multicenter PAMI Stent Pilot Study.

I believe clinical and randomized trials with proper interpretation have been valuable. Nevertheless, they cannot replace clinical judgment. If relied on exclusively they may be

Table 21. Examples of Risk Reduction*

Trial	Placebo	Propanolol	SK	t-PA	MT	ST	Difference	Risk Reduction
BHAT	13%	10%					3%	23.08%
GUSTO			7.4%	6.3%			1.1%	14.86%
CASS								
1-VD					7%	3.5%	4%	50%
2-VD					6%	5%	1%	17%
3-VD					10.5%	7.5%	3%	28.57%

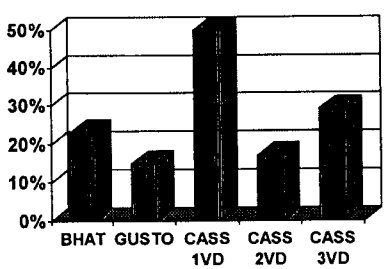
*Data from references 375, 1024 and 1025. BHAT = Beta-Blocker Heart Attack Trial; CASS = Coronary Artery Surgery Study; GUSTO = Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries; MT = medical therapy; SK = streptokinase; ST = surgical treatment; t-PA = tissue-type plasminogen activator; VD = vessel disease.

dangerous, as was pointed out by Paul Wood in 1950 (1032): "Yet there is plenty of evidence to show that we are in danger of losing our clinical heritage and pinning too much faith in figures thrown up by a machine. Medicine must suffer if this tendency is not checked."

From the beginning I have always emphasized that CABG is only a palliative treatment (1033). Undoubtedly, development in surgical or catheter-based revascularization procedures yielded significant improvements in the care of patients. Although new technologies will certainly result in further advances in the diagnosis and treatment of atherosclerotic lesions, the incidence of coronary heart disease will only be decreased by proper preventive measures. The general agreement in the medical community about the clinical benefit of comprehensive risk factor identification and management is substantiated by data from interventional studies, mainly in the field of blood lipids modification (1034–1042). Different cholesterol lowering interventions using either life style changes and hypolipidemic drugs (1034,1043) resulted in a reduction of the rate of progression or even in a modest reduction of the size and extent of coronary lesions.

It is highly probable that in regression studies (1044), the actual anatomical changes have been underestimated. In fact, plaque changes were documented using angiography, a method highly valuable to assess coronary disease extension but rather insensitive to evaluate changes in those lesions that, although small, are responsible for a large number of acute coronary events (627,1039,1045–1048) and might respond better to a lipid lowering therapy than stenotic, large and mostly fibrocalcified advanced plaques.

Figure 14. Risk reduction for three clinical trials. BHAT = Beta-Blocker Heart Attack Trial; GUSTO = Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries; other abbreviations as in Figures 5 and 8.



A recent angiographic study, the Regression Growth Evaluation Statin Study (REGRESS) added renewed support to the concept that cholesterol lowering in CHD (coronary heart disease) patients is beneficial (1049).

Recent studies have demonstrated that a reduction of LDL-cholesterol is associated in animals and humans with a distinct endothelial-dependent vasodilatory response, as opposed to the vasoconstriction that is evoked in the presence of hypercholesterolemia (1050–1054). This functional normalization might explain the relatively rapid clinical improvement observed in symptomatic coronary patients after the initiation of aggressive lipid-lowering therapy (1055), even though significant anatomical changes are not reasonably expected at this time.

Whatever the mechanism involved, either anatomical or functional, the actual benefit for the patient is to be measured in terms of clinical changes. In this respect, several early studies have demonstrated that a favorable lipid modification is associated with a reduction in cardiovascular morbidity and mortality (1035,1056). However, only recently could it be demonstrated that a lipid lowering treatment may reduce total mortality. The results from the Scandinavian Sinvastatin Survival Study (4S), have clearly shown a reduction in coronary mortality by 42% and total mortality by 30% (1057).

The enthusiastic notion that lipid-lowering therapy might benefit coronary patients even if their basal cholesterol concentration is relatively normal (a common finding in coronary subjects) was recently subjected to scientific evaluation. In the Cholesterol and Recurrent Events (CARE) study, presented at the American College of Cardiology (March 1996) (1058) 4,159 post-myocardial infarction patients with a mean total cholesterol concentration of 209 mg/dl at initial screening (inclusion criteria: total cholesterol <240 mg/dl and LDL-cholesterol 115 to 174 mg/dl) were randomized to receive pravastatin 40 mg/dl or placebo and followed during a mean five-year period. Lipid changes, although modest, were accompanied by a significant 24% reduction in coronary heart disease death and nonfatal myocardial infarction. Moreover, active treatment was associated with a 26% reduction in the incidence of CABG surgery and a 22% reduction in the incidence

of angioplasty. Interestingly, the benefit of aggressive therapy seemed to be limited to patients whose baseline LDL-cholesterol concentration was greater than 125 mg/dl, a figure that fits well with the current U.S. guidelines (1059) where drug therapy is suggested in secondary prevention if LDL-cholesterol concentration remains above 130 mg/dl after dietary therapy.

Currently only 15% to 25% of patients who had CABG or PTCA undergo intensive cholesterol lowering and risk management programs (1060). Furthermore, the lack of adequate control extends to most other risk factors, including blood pressure, body weight, cigarette consumption and glucose levels. Therefore, it seems reasonable to make efforts to evaluate more carefully the many negative factors (skepticism in patients or doctors, motivation of patients, insufficient patient health education, inadequate risk factor detection or chronic management, costs of preventive treatments, etc.) that might account for the unreasonable gap between the medical enthusiasm devoted to acute interventions and the meager efforts currently devoted to secondary prevention.

Significant advances have been made in our knowledge of the pathogenesis of coronary artery disease (1036,1061) and certainly the last battle will be gained finally in the laboratories, mainly through molecular biology.

I cannot finish this presentation, perhaps my last comprehensive one in medicine, without some ethical considerations. I have participated in innumerable international meetings in different parts of the world and many times I had the impression that the discussions were held only to defend the income of the participants. Gorlin (1062) has clearly pointed out that

> there is an inherent conflict of interest for both practitioners and hospitals in the performance of these interventional procedures. They are remunerative. Thus, we must be scrupulously conscientious in ensuring that we are not performing them to fill our hospital beds and to support our practices. Self-referral is an obvious ethical mistake.

The last contribution from the GUSTO trial (1063), utilizing the classification-and-regression-tree model, demonstrated that the guidelines for treatment of acute myocardial infarction have not been followed:

1. Facilities for performing cine angiography and angioplasty within a hospital determine the indication. As an example, if the hospital does have facilities, 81% of the patients will have the chance of undergoing catheterization; if the hospital does not have these facilities, the chance will decrease to 63%. There are other contributions that confirm these data (1009,1064,1065).

2. Catheterization was performed mainly among patients at low risk who, as we know, have a positive outcome. Patients at high risk have similar chances to undergo catheterization.

3. Exercise tests, very important to delineate prognosis, were performed in less than 30% of the patients.

What is more serious, after adjustment for the severity of illness, rural and teaching hospitals were less likely to perform angiography, whereas larger hospitals and those owned by investors were more likely to do so.

In another recent publication, Spertus and coworkers (1066) came to a similar conclusion. In an analysis of 4,823 infarct survivors, they found that, except for recurrent angina, clinical variables predictive of higher mortality were associated with a lower likelihood of angiography and angioplasty. When evaluating other factors that may influence the decision to perform catheterization, angioplasty or surgery in patients with acute myocardial infarction, Spertus remarked that fears of malpractice, types of patient employment and physician reimbursement may be important in the final approach.

Pilote and collaborators (1063) conclude that

> these findings point to a divergence between an ideal decision-making strategy and the reality of clinical practice. In many cases the convenience of having facilities available seems to outweigh the needs of the patient. Finally, practitioners appear to be selecting the patients likely to have good procedural outcomes rather than those who would derive the most benefit from a procedure. In an ideal world, clinicians would develop an overall estimate of the likely outcome given one treatment as compared with another, and would preferentially allocate resources to patients with more potential for benefit.

I think it is time to pause and think deeply about our duties and responsibilities. In 1992 when I delivered the honorary lecture at the American Association for Thoracic Surgery meeting, I presented what I believe the principal characteristics of a prospective cardiovascular surgeon should be, and the ten commandments of a master surgeon. The principal thrust was that the person of vital importance is the patient, who should enjoy privileges and our total devotion. We must demonstrate responsibility, energy, intensity and enthusiasm for the work at hand. Cardiovascular surgery demands total dedication and sacrifice. We should have the judgment and responsibility to make informed decisions and humility to ask for help when we consider it advisable, recognizing the need to learn from others. We are part of a team where academic freedom is essential. New ideas should be discussed, avoiding pressures and bias and with ethical and moral integrity.

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Predictors of Early Saphenous Vein Aortocoronary Bypass Graft Occlusion

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To identify factors determining early saphenous vein aortocoronary bypass occlusion, we analyzed the data base of the GESIC study, a trial comparing antiplatelet drug regimens that included 927 patients with 1,854 saphenous vein grafts. The univariate analysis showed female sex ($p < 0.0097$), obesity ($p < 0.001$), rest angina ($p < 0.0026$), history of congestive heart failure ($p < 0.037$), the revascularized artery ($p < 0.0001$), the quality of distal bed ($p < 0.00001$), the diameter of the grafted vessel ($p < 0.00001$), the lack of antiaggregant treatment ($p < 0.017$), and a nonsequential technique ($p < 0.0002$) as predictors of early (28 days) graft occlusion. In the multivariate analysis the last five variables were independent predictors. Using the two preoperative variables, it was possible to identify groups at different risk; the occlusion rate ranged between 8.79% (left anterior descending coronary artery and good distal vessel) and 27.58% (right coronary artery or left circumflex coronary artery and poor distal vessel). The combination of three variables (grafted vessel, artery diameter, and antiaggregant treatment) also allowed identification of different risk groups; the occlusion rate ranged between 3.5% and 63.1%. Thus, it is possible to anticipate the risk of graft occlusion in patients undergoing coronary artery bypass grafting, which may help in the selection of both patients and antithrombotic treatment.

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Coronary artery bypass grafting is the most frequently performed cardiac surgical procedure [1]. Although the internal mammary artery is considered the graft of choice, widespread use of the saphenous vein continues because of limitations in the use of the internal mammary artery, mainly the lack of sufficient arterial conduit for grafting in patients with multiple-vessel disease [2, 3]. Early vein occlusion resulting from thrombosis is a frequent complication, its incidence ranging from 8% to 18% in different series [1, 4, 5]. As occlusion of aortocoronary grafts is associated with recurrence of symptoms, prevention of graft occlusion is mandatory.

It has been clearly demonstrated, in experimental as well as in clinical studies, that endothelial damage during vein extraction and manipulation promotes platelet activation and thrombosis, causing graft occlusion [6, 7]. In this regard, several controlled studies have shown that platelet-inhibiting drugs may partially prevent early graft occlusion [8, 9]. However, other factors may also contribute to early vein occlusion, and several patient and graft characteristics, especially those promoting slow flow through the graft, have been implicated [1, 10, 11]. The precise knowledge of these mechanisms may help in selecting those patients and techniques that will assure improved graft patency.

The Spanish Group for Aortocoronary Bypass Follow-up (GESIC) recently published the results of a multicenter, randomized, placebo-controlled trial carried out to identify the efficacy in early saphenous vein graft patency of two different antiplatelet treatments [12]. The study included 927 patients with 1,854 saphenous vein grafts and represents the largest published trial comparing antiplatelet drug regimens for the prevention of early bypass occlusion. The aim of the present study was to identify the factors determining early bypass occlusion using the data bank of the GESIC study.

Materials and Methods

Study Population

The study was organized by the "Grupo Español para el seguimiento del injerto aortocoronario" (Spanish Group for Aortocoronary Bypass Follow-up [GESIC]), a working group of the Spanish Society of Cardiology (Appendix 1). The study protocol has been previously published elsewhere [12].

In brief, all patients younger than 71 years old undergoing elective aortocoronary bypass grafting with saphenous vein grafts at the six participating institutions were considered eligible for the study. The following exclusion criteria were used: previous cardiac operation, heart valve disease requiring surgical repair, documented peptic ulcer disease with previous bleeding or a recent (3 months) history of ulcer symptoms, thromboembolic episodes requiring either anticoagulant or antiplatelet treatment, allergy or intolerance to contrast material and drugs under trial, history of cerebrovascular accident, renal failure under chronic dialysis, type I diabetes mellitus, severe

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chronic obstructive pulmonary disease, any condition that increased the risk of aortocoronary vein graft angiography, and lack of informed consent.

From June 1984 through August 1988, 1,647 patients were considered eligible; 1,149 (69.8%) of these patients entered the study. The remaining 498 met at least one exclusion criterion. Of the 1,149 entering the study, 1,112 were finally randomized to receive either aspirin, aspirin plus dipyridamole, or placebo according to a randomization code prepared at the coordinating center.

Protocol

All patients received 100 mg of dipyridamole orally four times a day, 48 hours before operation, the last dose being administered the day of the operation at 6 AM. One hour after the operation, 100 mg of dipyridamole was administered through a nasogastric tube. Patients were then randomized into three groups, and the treatment was started through the nasogastric tube, 7 hours after the operation. On the day after the operation and daily thereafter, patients received, three times a day, in a double-blind fashion, either 50 mg of aspirin, 50 mg of aspirin plus 75 mg of dipyridamole, or placebo. The study protocol was approved by the ethics committee of each institution.

Surgical Procedure

Saphenous vein grafts were implanted following the usual technique at each institution. Although no attempt was made to establish a uniform surgical protocol for all institutions, the saphenous vein graft was dissected primarily under the knee so that calibers matching those of the coronary arteries to be grafted could be used; the groin portion of the vein was also used when more than two vessels required revascularization. The distal anastomoses were performed first, and then proximal grafting was performed under partial aortic cross-clamping during the rewarming period after myocardial reperfusion.

Internal mammary artery grafts were implanted concomitantly in some patients, but only saphenous vein grafts were considered for the purpose of this study. Calibrated probes were used to assess the diameter of the grafted artery. Distal anastomoses per patient averaged 2.4 and varied from 1.9 to 3.2 among hospitals, and the number of grafts per patient averaged 2.03 and ranged from 1.8 to 2.4. Heparin used during cardiopulmonary bypass was neutralized by protamine sulfate. No other anticoagulant was administered between the operation and the angiographic study.

Coronary Angiography

Preoperative angiograms were evaluated at each institution by the principal investigators. Percent stenosis and quality of distal vessels were assessed from multiple angiographic views. Postoperative angiography was performed between the 8th and the 28th day after operation (mean, 10 days). A graft was considered not patent when the occluded origin was selectively visualized or when the origin could not be visualized and the contrast material failed to flow through the graft into the grafted artery on the aortic root injection. A distal anastomosis was defined as occluded if the entire vein graft was occluded at the origin, or if the contrast agent failed to flow from the vein graft into the grafted artery. For the purpose of this study, graft patency and occlusion refer to patency and occlusion of the distal anastomosis. A randomly selected sample accounting for 10% of all preoperative and postoperative angiograms was examined independently by two qualified cardiovascular angiographers at the coordinating center. There was complete agreement among the independent reviewers and the participating institutions regarding the classification of occluded and patent grafts.

Data Management and Statistical Analysis

All data were recorded in specifically designed, computerized forms and sent to the coordinating center for review, storage, and analysis. Clear definitions were established in advance for each variable.

The statistical analysis was performed using the BMDP package available at the University of Barcelona. Comparison of groups was performed by means of the χ^2 test for the qualitative variables and the one-way analysis of variance corrected by the Bonferroni test for continuous variables. To identify independent predictors of graft occlusion, a stepwise logistic regression analysis was applied to patency data; the occlusion of distal anastomoses was considered the dependent variable. Independent variables included both graft- and patient-specific characteristics as well as a dichotomous variable that indicated whether the patient did or did not receive antiplatelet treatment.

Results

Patient Data

A total of 1,112 out of the 1,647 eligible patients were randomized. Patients included in this study were comparable with those excluded with regard to most of the analyzed variables; however, a significantly higher prevalence of peripheral vascular disease (17.6% versus 12.6%, $p < 0.005$), rest angina (31.1% versus 21.7%, $p < 0.0001$), angina during the 48 hours before operation (29.9% versus 23.6%, $p < 0.005$), and history of congestive heart failure (7.7% versus 3.2%, $p < 0.001$) was observed in the excluded patients.

Of the 1,112 patients randomized, 927 underwent postoperative vein graft angiography; 185 patients were excluded because of death (27), patient refusal (50), drug intolerance (26), complications (69), and protocol deviation (13). Mean age for the entire population was 57 years, 90% were men, 55% had a history of previous myocardial infarction, and the mean length of symptoms was 36.9 ± 43 months. Patients with three-vessel disease accounted for 73% of the entire cohort; mean left ventricular ejection fraction was 0.56 ± 0.13. A total of 1,854 grafts were implanted in the 927 patients undergoing postoperative vein graft angiography (mean, 2.0 ± 0.8 grafts per patient); the mean number of distal anastomoses per patient was 2.4 ± 1. The left anterior descending artery was the recipient artery in 37.8% of the patients, the right coro-

Table 1. Univariate Predictors of Graft Occlusion

Variable	Percent of Distal Anastomosis[a] Patent	Occluded	*p*
Female	9.0 (167)	13.5 (45)	<0.0097
Obesity	39.4 (738)	48.9 (163)	<0.001
Rest angina	20.7 (394)	13.6 (46)	<0.0026
CHF	2.9 (55)	5.2 (17)	<0.037
Good run-off	79.7 (1,445)	65.4 (214)	<0.00001
Diameter of recipient artery (mm)			
<1	5.8 (98)	21.5 (63)	
1.1–1.5	52.6 (896)	51.2 (150)	
>1.5	41.6 (708)	27.3 (80)	
Recipient artery			
LDA	39.7 (755)	26.1 (88)	
LCx	33.4 (635)	44.2 (151)	<0.0001
RCA	26.8 (510)	29.1 (98)	
Sequential grafting	29.9 (568)	19.9 (67)	<0.002
Antiplatelet treatment			
Placebo	32.4 (615)	40.1 (135)	
Antiaggregant	67.6 (1,285)	59.9 (202)	<0.017

[a] Number in parentheses is number of graft occlusions.

CHF = congestive heart failure; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery.

nary artery in 27.2%, and the left circumflex system in the remaining 35%.

Patency Data

A total of 337 of the 2,237 distal anastomoses were occluded (15.1%). Among hospitals, patency of distal anastomoses ranged between 91.5% and 74% ($p < 0.001$). At least one internal mammary artery was implanted in 285 (30.1%) of the 927 patients undergoing postoperative angiography. The proportion of patients with at least one occluded vein graft was similar in patients with and without mammary artery implants (27% and 28%, respectively).

Occluded grafts were more likely to be implanted in female patients (9.0% patent versus 13.5% occluded), obese patients (39.4% versus 48.9%), patients with rest angina (79.3% versus 86.4%), and patients with a history of congestive heart failure (2.9% versus 5.2%). Neither diabetes nor a history of peripheral vascular disease was associated with graft occlusion. As shown in Table 1, among the angiographic variables only the revascularized artery, the quality of the distal bed, and the diameter of the grafted vessel correlated with the fate of the graft. Finally, graft patency was also higher in sequential grafts and in patients receiving antiplatelet treatment.

Multivariate Predictors of Graft Occlusion

Logistic regression analysis selected five variables as independent predictors of graft patency. As shown in Table 2, the diameter of the distal vessel and the grafted artery showed the best correlation, followed by the type of graft (sequential vs nonsequential), the antiaggregant treatment, and the angiographic quality of the distal vessel. Table 3 shows the occlusion rate according to the significant variables available before operation. The occlusion rate varied between 8.8% when a left anterior descending coronary artery with good distal bed was grafted to 27.6% in patients with grafts to either the right or circumflex coronary artery and poor distal vessel.

Table 2. Multivariate Predictors of Graft Occlusion

Variable	Odds Ratio (95% CL)
Artery diameter	
1.5 mm vs ≤1 mm	0.54 (0.38–0.77)
≥2 mm vs ≤1 mm	0.23 (0.15–0.35)
Circumflex artery	2.05 (1.44–2.90)
Sequential grafting	0.55 (0.40–0.76)
Antiaggregants	0.62 (0.42–0.85)
Poor distal vessel	1.42 (1.05–1.92)

CL = confidence limits.

Table 4 displays the occlusion rate according to the grafted vessel, the artery diameter, and the administration of antiaggregant treatment. As expected, grafts to arteries with diameters of 1 mm or less showed the highest rate of occlusion; even in this high-risk group, the effect of the grafted artery and the administration of antiaggregant treatment could be appreciate, with the occlusion rate ranging from 26% among grafts to left anterior descending coronary arteries receiving antiaggregants to 63% in right coronary artery/left circumflex coronary artery grafts without treatment. On the contrary, grafts to left anterior descending coronary arteries ≥2 mm in diameter showed a high patency rate irrespective of the treatment (Fig 1).

Comment

Occlusion of aortocoronary bypass grafts compromises the surgical results and determines the recurrence of symptoms [3, 5]; therefore, identification of factors determining saphenous vein graft closure is important to improve graft patency and select appropriate candidates for operation. We found that two angiographic (preoperative) variables, the grafted artery and the quality of the distal bed, and three operative variables, the diameter of

Table 3. Percent of Graft Occlusion According to Significant Preoperative Variables

Artery	Quality of Distal Vessel[a] Good (%)	Poor (%)
LAD	8.79 (625)	17.18 (192)
LCx or RCA	15.37 (1034)	27.58 (290)

[a] Number in parentheses is number of grafts at each category.

LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery.

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Table 4. Occlusion Rate According to the Grafted Vessel, Artery Diameter, and Antiaggregant Treatment

	Grafted Artery[a]			
	LAD		RCA/LCx	
Diameter (mm)	AT (%)	No AT (%)	AT (%)	No AT (%)
≤1	25.6 (39)	43.3 (30)	40.5 (69)	63.1 (19)
1.5	7.9 (265)	15.6 (141)	17.9 (378)	17.2 (191)
≥2	5.2 (192)	3.5 (84)	10.8 (313)	7.3 (179)

[a] Number in parentheses is number of grafts in each category.

AT = antiaggregant treatment; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery.

the vessel, the type of graft, and the administration of antiaggregant treatment, correlate with the fate of the graft. These results are in keeping with previous reports in the literature, which found that graft occlusion occurs particularly under circumstances promoting slow flow [1, 10, 11]. It has been clearly demonstrated, in experimental as well as in clinical studies, that early saphenous vein graft occlusion is thrombotic in origin [7]. The initial event is the injury of the vein endothelium during harvesting of the saphenous vein for implantation, which results in platelet aggregation, thrombus formation, and eventually occlusion of the graft. Factors determining inadequate run-off facilitate thrombus formation and may contribute to graft closure [1, 7]. Thus, technical as well as artery-related factors, such as kinking or compression of the graft, a technically deficient anastomosis, small artery diameter, and poor distal vascular bed, have been implicated as causes of graft closure in the first few postoperative weeks [4].

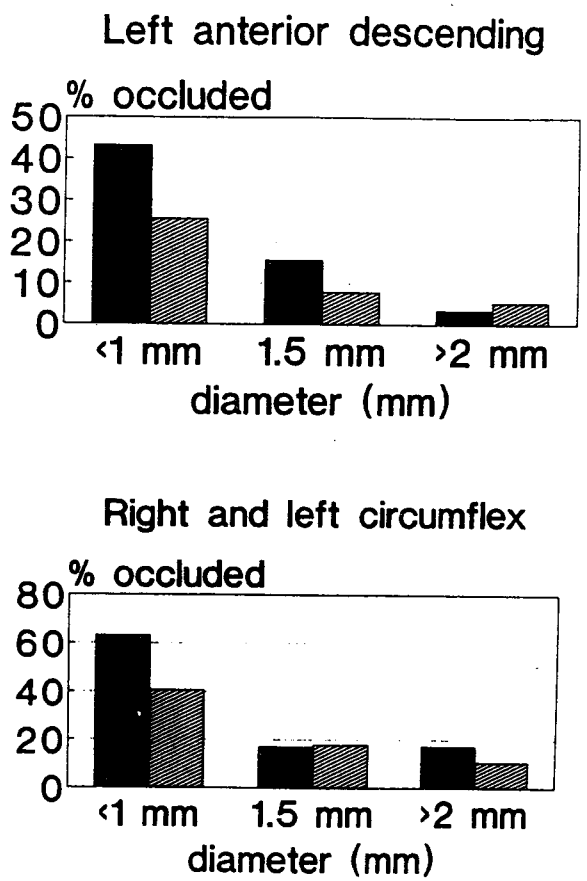

Fig 1. Probability of risk occlusion according to the diameter of the grafted vessel, the use of antiaggregant treatment, and the revascularized artery (left anterior descending in the upper panel and left circumflex/right coronary artery in the lower panel). The black columns *represent patients not receiving antiaggregant treatment.*

The diameter of the grafted artery has been unanimously identified as a predictor of graft patency. Crosby and colleagues [13] observed a stepwise increase in graft patency with increasing coronary artery diameter from 1 mm up to 2 mm; from 2 mm to 4 mm, all vessels were patent [13]. Björk and colleagues [10] observed that patency was significantly less in grafts sutured to coronary arteries with internal diameters close to 1.0 mm. Similar results have been reported by other authors [4, 11, 13–16]. Similarly, the angiographic quality of the distal vessel has also been correlated with graft outcome. Lesperance and colleagues [17] reported a 76% late patency rate in vessels with good run-off as compared with 24% among those with inadequate run-off. Mehta and colleagues [14] developed an angiographic score based on the distal coronary artery diameter, measured at the time of operation, and the quality of run-off of the grafted artery. Index scores were directly proportional to flow rates measured at the time of operation, confirming that flow through the graft relies, at least in part, on the size and quality of the grafted artery. Furthermore, in that study, graft patency correlated with the flow rate measurements.

It has been suggested that grafts performed on the left anterior descending coronary artery have a better outcome than those performed on either the right or the left circumflex coronary artery [4, 11, 14, 16]. However, some controversy still remains [18]. In the present study, multivariate analysis selected the grafted artery as the best predictor of early graft closure; irrespective of artery diameter, type of bypass, and quality of the distal vessel, graft patency was higher in grafts implanted on the left anterior descending artery. Mehta and colleagues [14] observed, when comparing the flow rates in the three major coronary trunks, that left anterior descending flows were significantly higher than flows in either the right coronary or left circumflex artery. A larger mass of myocardium supplied by this artery and a higher work load and myocardial oxygen demand per gram of cardiac muscle in this region may well explain the higher blood flow and, as a consequence, the higher patency rate in grafts implanted in the left anterior descending artery [14]. The fact that the larger portions of the saphenous vein in the circumflex and right coronary arteries are used could also account for the higher incidence of graft occlusion in these vessels. The combination of two angiographic variables, the artery to be grafted and the quality of the distal vessel, resulted in four categories of patients with early graft occlusion rates ranging from 8.8% in

grafts implanted in a left anterior descending artery with good run-off to 27.6% in those implanted in either a right coronary or left circumflex artery with poor distal bed. On the other hand, the combination of three variables, grafted artery, diameter of the vessel, and antiplatelet treatment, allowed an even better characterization of risk, with 12 groups in which graft patency ranged from 3.5% to 63%.

Characteristics and Limitations of the Study

This retrospective analysis is based on the data bank of the GESIC study comparing antiplatelet drug regimens for the prevention of early aortocoronary bypass occlusion. As the protocol called for a complete 48-hour period of preoperative treatment with dipyridamole, patients undergoing emergency operations were not included. Thus, the study population, which represents 57% of all patients undergoing coronary artery bypass grafting in six large teaching hospitals during the time frame of the study, is representative of patients submitted to elective coronary artery bypass grafting.

Independent predictors of graft patency were derived by means of multivariate analysis from more than 20 variables, not only patient characteristics but also most of the graft characteristics known to be risk factors for occlusion. Although identification of high-risk patients by means of subgroup analysis should be regarded with caution, the results of the present study deserve attention because of the large numbers on which they are based. In any case, our results confirm, on larger numbers, the suggestions of other studies in which factors determining aortocoronary saphenous vein graft patency were considered.

As no attempt was made to establish a uniform surgical protocol, differences in handling the graft among hospitals could influence the results of the present investigation [18–20]. Although saphenous vein grafts were implanted using a similar technique in all participating institutions, significant differences were found among hospitals regarding graft patency. However, when only the four institutions contributing the largest number of patients and accounting for 85% of the entire population were considered in the analysis, differences were no longer significant.

Clinical Implications

The results of the present investigation underscore the importance of adequate selection of both patients and surgical technique in determining surgical outcome. They also show that the risk of graft closure can be anticipated with the use of simple preoperative variables, namely the artery to be revascularized and the quality of the distal vessel. Measuring the artery diameter at the time of operation improves prediction and allows selection of patients at high risk of graft closure. As the rate of graft occlusion in these high-risk patients remains between and 60% despite antiplatelet treatment [8, 12], it may be worthwhile in the future to evaluate the effect of oral anticoagulants or new antithrombotic agents in this subset of patients.

Appendix 1

The participants in the Spanish Group for Aortocoronary Bypass Follow-up were as follows: Hospital Gregorio Marañón, Madrid: Manuel Gómez-Recio, MD (principal investigator); Juan Duarte, MD; Hospital Virgen del Rocío, Sevilla: Juan A. Fournier, MD (principal investigator), José A. P. Cortacero, MD, Luis Castillon, MD; Clinica Universitaria, Pamplona: Eduardo Alegría, MD (principal investigator), Ricardo Hidalgo, MD, Félix Malpartida, MD, Julio Arriola, MD, Rafael Llorens, MD, Ramón Arcas, MD, Diego Martínez Caro, MD, José Calabuig, MD; Hospital Virgen del Pino, Las Palmas: Ignacio Coello, MD (principal investigator), Alfonso Medina, MD, Eduardo Olaya, MD, Manuel Trillo, MD, Armando Bethencourt, MD, José Quintana, MD, Esperanza Pardo, MD; Hospital Clinic, Barcelona: Gloria Oller, MD (principal investigator), Mariona Cardona, MD, Amadeo Betriu, MD, José L. Pomar, MD, Mariona Matas, RN; Hospital Marqués de Valdecilla, Santander: Antonio Pajarón, MD (principal investigator), Javier Ruano, MD, Thierry Colman, MD, José L. M. Ubago, MD, Alvaro Figueroa, MD; *Coordinating Center*: University of Barcelona School of Medicine: Ginés Sanz, MD; *Executive Committee*: Ginés Sanz, MD (chairman), Antonio Pajaron, MD, Eduardo Alegría, MD, Mariona Cardona, MD, Juan A. Fournier, MD, Manuel Gómez-Recio, MD, Alfonso Medina, MD; *Angiography Review Committee*: Hospital Valle de Hebrón, Barcelona, Juan Angel, MD, Hospital de Bellvitge, Barcelona, Enrique Esplugas, MD; *Statistical Analysis*: University of Barcelona School of Medicine, Xavier Bosch, MD.

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Coronary bypass graft fate

Angiographic study of 1,179 vein grafts early, one year, and five years after operation

A total of 1,179 vein grafts were studied angiographically in 353 (45%) unselected survivors (male, mean age 45.5 years) of 786 coronary bypass operations. Studies were conducted early (0.96 months), 1 year (12.8 months), and 5 years (59.7 months) postoperatively. A previously described technique was used to grade the patency of the grafts, and a new technique was used to assess intimal irregularity, presumably caused by atherosclerosis; this new technique indicated both intimal surface distribution of disease and profile (relief or elevation). Ten percent, 17%, and 26% of grafts were occluded early, at 1 year, and at 5 years, respect[illegible] Distal anastomotic defects were the commonest cause for low grades in the patency classification. Irregularities in patent grafts increased from 9% at 1 year to 42% at 5 years, with 11% of all the 1 year lesions and 20% of all the 5 year lesions having a high profile (more than 50% graft stenosis); of the lesions categorized as showing the widest surface spread, 17% were in high relief at 1 year and 34% at 5 years. Thus, the lesions we believed to be atherosclerotic proliferated in both surface spread and elevation. All severely diseased grafts at the 1 year study had been normal in outline early; 79% at the 5 year study had been disease free at 1 year. All newly occluded grafts at the 1 year study had been normal in outline and 82% had had good patency early; 78% of newly occluded grafts at the 5 year study had been disease free at 1 year and 77% had had good patency. Normal appearance of the intima in grafts studied at 1 year had no prognostic value for 5 year findings. However, 62% of all grafts with the appearance of intimal disease at 1 year showed deterioration by 5 years, and 28% were occluded. The differences between these outcomes are highly significant ($p < 0.0005$). In conclusion, the appearance of intimal irregularity compatible with atherosclerosis in a coronary bypass graft 1 year after operation carried a poor prognosis for adverse angiographic change at 5 years. On the other hand, normally appearing intima at 1 year had no predictive valve for the 5 year study despite a generally better prognosis for nondiseas[illegible] grafts.

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Several factors, some purely technical, determine the early fate of coronary bypass grafts. However, atherosclerosis is emerging as the major determinant of long-term vein graft viability.[1-3] We[4] have previously reported an angiographic grading system for coronary bypass graft patency and have applied it to a large series of consecutive cases studied early and 1 year after operation. The follow-up time has now been extended and assessment techniques have been added to include evidence of what is considered to be graft atherosclerosis. We report a substantial series of coronary vein grafts, all of which were studied early and at approximately 1 and 5 years after operation.

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Patients and methods

We included in the study only those patients who had angiograms early (mean 0.96 months), 1 year (mean 12.8 months), and 5 years (mean 59.7 months) after

Table I. *Patency grades*

Grade	Early		One year		Five years	
	No.	*%*	*No.*	*%*	*No.*	*%*
A	989	84	909	77	810	69
B	76	6	69	6	58	5
A + B	1,061	90	978	83	868	74
O	118	10	201	17	311	26

Legend: A, B, and O graft patency gradings: A, Excellent. B, Graft narrowing to less than 50% of *grafted coronary artery*. O, Occlusion.

Table II. *Grafts graded B at various times*

Category	Early	One year	Five years
I	76	53	16
II			
LP	0	6	3
HP	0	5	2
III			
LP	0	4	11
HP	0	1	26
Total	76	69	58

Legend: B, Grafts narrowed to less than 50% of *grafted coronary artery*. LP, Low-profile irregularity narrowing *graft* by less than 50%. HP, High-profile disease narrowing *graft* by more than 50%.

coronary bypass grafting, and we observed the morphologic characteristics of 1,179 vein grafts. Our patients were predominantly military personnel and thus relatively young. Their initial evaluations and all follow-up studies were done at the Cardio-Pulmonary Unit, National Defence Medical Centre, Ottawa, Canada, and their operations were undertaken by four surgeons at the University of Ottawa Cardiac Unit (now Heart Institute) where they remained usually for only 24 to 48 hours postoperatively. To define our patient population more precisely, in groups similar to the present we[5,6] have reported 92.4% (668/723) of patients alive 6.52 years after operation and a perioperative myocardial infarction rate of 7.8% (transmural 3.2%) with a perioperative mortality of 0.6%. At the end of this study period on Nov. 10, 1984, there were available to us (that is, alive) for examination the survivors of 786 coronary bypass operations. Of these, 353 (45%) had actually been examined at the three relevant times. Three hundred forty patients, all men, were involved. Eleven had been followed up after one reoperation and a single subject after two reoperations for sufficiently long to be included more than once in the study. The ages of the patients ranged from 30 to 70 years (mean 45.5 years). All grafts were selectively opacified, for the most part via the Judkins size 4 right coronary catheter, in at least four vertical planes ranging from 60 degrees to the right of midline to 90 degrees to the left of midline, occasionally with axial views also. Catheterization was facilitated by graft markers placed on the aortic wall at operation. Occluded grafts were demonstrated to be so by opacification of stumps and sometimes by collateral evidence in selective coronary angiograms, as well; very rarely, flood angiograms of the proximal aorta were made. High-resolution radiographic equipment was used to make records on 35 mm cine film at 60 frames per second. These had been interpreted once for routine purposes, but for this study all were read again by six physicians working in pairs, each pair including at least one senior angiographer.

We used the grading system previously reported to define bypass graft patency.[4] The proximal and distal anastomoses of the graft and the trunk were assessed separately and each assigned a letter: A (excellent), B (fair), or O (occluded). The B grade indicated stenosis reducing the lumen to less than 50% of the *grafted artery. The grade for the entire graft was the lowest of the three site gradings.* To classify angiographic appearances we believe caused by atherosclerosis, we devised another simple grading system. Category I indicated that the graft outline was completely smooth without any irregularity that might be due to disease; category II indicated that less than 50% of the estimated surface area of the graft intima was irregular; category III indicated that more than 50% of the intima was involved. To define this more closely and perhaps add prognostic value, we classified the lesions into high-profile or low-profile (that is, high or low elevation or relief) types depending on whether they encroached more or less than 50% on what was considered to be the normal *graft* lumen at that point. These grading systems, which were all based on the worst aspects of four-plane views, required an essentially "eyeballing" technique; to suggest otherwise would entail extraordinary technical facilities or intellectual dishonesty. Great care was taken, however, to classify grafts as accurately as possible within the framework outlined.

Statistical analyses were done by the chi square method.

Results

Of the 1,179 bypass veins there were 3.47 grafts per patient and 3.34 per operation, there being more operations than patients. Twenty-five percent of the grafts were to the right coronary artery and its branches, 29% to the margino-circumflex system, 27% to the anterior descending coronary artery, and 19% to the diagonal

Table III. *Graft disease categories*

Category	Early	One year		Five years	
		No.	%	No.	%
I	1,061	888	91	503	58
II	0	66	7	184	21
III	0	24	2	181	21

Legend: I, Smooth graft intimal surface. II, Disease involving less than 50% of graft intimal surface. III, Disease involving more than 50% of graft intimal surface.

branches of the latter. Vein was harvested with minimal manipulation and placed in normal saline containing papaverine 60 mg/100 ml. It was not distended with solution or blood. Graft occlusion rates early and at 1 and at 5 years (Table I) were 10%, 17%, and 26%, respectively. The patent grafts were mainly graded A, with a small and little changing core of B grades. These results are similar to those we[4] published in our early and 1 year follow-up study. It is probably surgically important to note that 153 of the 203 B grades (75%) involved the distal anastomosis. 137 of 203 B grades (68%) were given for distal anastomotic defects alone, and 69 of the 76 *early* B grades (91%) were assigned for isolated anomalies of the distal anastomosis. None of the B grades was associated with what was considered an atherosclerotic lesion in the early study, but in the 1 and 5 year studies (Table II), 16 of 69 (23%) and 42 of 58 (72%), respectively, were associated with atherosclerosis in the same graft. At 5 years most of these lesions were category III and the greater number were high profile.

No graft had features suggesting atherosclerosis early after operation. In the 1 year study (Table III), 91% of the grafts appeared smooth walled; the remainder had some irregularity of outline, which was considered to involve more than 50% of the surface area (III) in less than one quarter of the grafts. At 5 years, however, the number of grafts with normal appearing intima had fallen to 58% and, of those considered to be atherosclerotic, one third were classified category III and half of these were high profile. With respect to atheroma profiles (Table IV), although the total number triples, the proportions of low-profile and high-profile irregularities remains about the same for category II grafts at 1 and at 5 years. However, in addition to the striking increase in category III grafts from 24 at 1 year to 181 at 5 years, there is a 15-fold increase in the number of high-profile irregularities. There is thus proliferation of what we believe to be atherosclerosis, in elevation or relief, at an equal pace with surface spread.

Table IV. *Graft disease elevation or profile*

	Early	One year		Five years	
		No.	%	No.	%
II					
LP	0	60	91	172	93
HP	0	6	9	12	7
III					
LP	0	20	83	120	66
HP	0	4	17	61	34

Legend: II, Disease involving less than 50% of graft intimal surface. III, Disease involving more than 50% of graft intimal surface. LP, Low-profile disease reducing *graft* lumen by less than 50%. HP, High-profile disease reducing *graft* lumen by more than 50%.

Table V. *Five-year status of grafts diseased at 1 year*

	Five years					
	II LP	*II HP*	*III LP*	*III HP*	*O*	*Total*
One year						
II LP	27		21	4	8	60
II HP			1	1	4	6
III LP			7	4	9	20
III HP					4	4
Total	27		29	9	25	90

Legend: II, Disease involving less than 50% of graft intimal surface. III, Disease involving more than 50% of graft intimal surface. LP, Low-profile disease narrowing *graft* lumen by less than 50%. HP, High-profile disease narrowing *graft* lumen by more than 50%. O, Graft occluded.

To be valid and useful, our classification of vein graft irregularities believed the result of atherosclerosis must have prognostic value. Table V shows what happened in the 5 year study to grafts considered diseased (categories II and III) at 1 year. Of the 66 category II grafts at that time, 27 remained unchanged at 5 years. The remaining 39 moved into a worse category, five becoming high-profile category III grafts and 12 of the 66 (18%) becoming occluded. Of the 24 category III grafts at 1 year, seven remained unchanged, four deteriorated to the high-profile category III, and 13 (54%) became occluded, including all four of the grafts in high-profile category III at 1 year. Thus, of the 90 grafts found diseased at 1 year (73% in category II), 62% (56/90) were in a worse disease category at 5 years and 28% (25/90) were occluded. On the other hand, of 888 grafts in category I at 1 year, 502 (56%) remained the same, 158 (18%) became category II, 143 (16%) became category III, and 85 (10%) were occluded at 5 years. The differences between the fates of category I grafts and of all diseased grafts, with respect to development or

Table VI. *Antecedents of grafts with most widespread disease*

Category	One year		Five years	
	No.	%	No.	%
I	25	100	143	79
II	0		27	15
III	0		11	6
Total	25	100	181	100

Legend: Table shows at 1 year what had been early examination antecedents and at 5 years what had been 1 year examination antecedents of category III grafts. I, Smooth graft intimal surface. II, Disease involving less than 50% of graft intimal surface. III, Disease involving more than 50% of graft intimal surface.

Table VII. *Antecedents of newly occluded grafts*

	One year		Five years	
	No.	%	No.	%
I				
A	68	82	77	70
B	15	18	9	8
II	0		12	11
III	0		12	11
Total	83	100	110	100

Legend: Table shows what had been early examination antecedents of grafts found newly occluded at 1 year and what had been 1 year examination antecedents of grafts found newly occluded at 5 years. I, Smooth graft intimal surface. II, Disease involving less than 50% of graft intimal surface. III, Disease involving more than 50% of graft intimal surface. A, Excellent graft patency. B, Graft narrowed to less than 50% of *grafted coronary artery.*

worsening of disease and also with respect to occlusion, are highly significant ($p < 0.0005$).

It is instructive to examine the antecedents (Table VI) of the category III grafts, considered the most severely diseased. At 1 year, all of these were derived from grafts having normal appearing intima in the early examination. However, at 5 years, 143 of 181 (79%) were also derived from grafts that had been considered to have a normal intimal surface at 1 year. Only 15% and 6%, respectively, had been derived from category II and category III grafts in the 1 year study. Also important are the "atherosclerosis" antecedents of grafts found newly occluded in the 1 and 5 year studies (Table VII). All grafts found newly occluded in the 1 year study had been derived from vessels considered to have normal intimal linings radiologically in the early study. However, 86 of 110 grafts (78%) found newly occluded at 5 years had also been derived from veins with a normal appearing intima at 1 year. Of the remainder, half had shown category II and half category III lesions. Table VII also shows that twice as many grafts found

Table VIII. *Grafts occluded at 5 year study*

	No.	%
Right coronary system	81/295	28
Margino-circumflex system	94/337	28
Anterior descending vessel	69/321	22
Diagonal branches of anterior descending vessel	67/226	30
Total	311/1,179	26

newly occluded at 1 year were derived from early B grafts as were grafts found occluded at 5 years and derived from 1 year B grafts. This observation suggests that an earlier surgical factor was partly responsible. Table VIII shows graft occlusions by the coronary arterial system grafted. The better patency rate of grafts to the anterior descending coronary artery compared with grafts to each of the other vessels is statistically significant ($p < 0.05$).

Obviously, mortality statistics could not have been obtained during this study. However, 15 patients (4.4%) died between their 5 year postoperative angiographic examination and the end of the study period. The mean survival time of these patients was 8.8 years after operation. At the 5 year study in these subjects, 30% of the grafts were occluded and 55% of those patent were diseased. Conversely, at the end of the 5 year study period, 325 patients were still alive. In their 5 year examinations, 26% of the grafts were occluded and 41% of those patent were diseased. These numbers are too small for statistical comparison.

Discussion

We believe it is possible and desirable to classify coronary bypass grafts angiographically in terms of quality and disorders. Use of a reproducible grading system enables those problems to be defined attendant upon the surgical origins of coronary bypass grafts and also the disease that besets them later. We[4] have previously described a grading system for patency using the letters A, B, and O. The A and O grades are easy to designate; the B grade is less so. Grafts graded B exhibit stenosis at the proximal or distal anastomosis or in the trunk, which reduces the size of the lumen of the graft to less than 50% of the *grafted artery.* We believe that the honest applicability of the B grade has been validated. We[4] demonstrated that 24% of early B grafts became occluded at 1 year and 39% remained the same, whereas only 6% of the A grafts became occluded and 4% changed to B ($p < 0.0005$).

Designating abnormalities as the result of a particular disease process is more difficult. The lack of immediate

pathologic corroboration imposes a speculative element in naming atherosclerosis as the cause of particular appearances in opacified grafts. Fibrointimal hyperplasia and thrombosis present a diagnostic challenge, as suggested by Lytle and associates.[3] Furthermore, there is a factor that may influence the appearance of our patients' grafts to an as yet unknown degree. From the beginning of our experience with coronary bypass grafting in 1971, we have routinely used medications influencing platelet behavior in our patients. This practice has involved administering two of the three commonly used drugs, aspirin, dipyridamole, and sulfinpyrazone. We have used these drugs for 15 years to attempt to prevent or retard the progress of atherosclerosis in coronary arteries and in bypass grafts, basing this therapy on theoretical considerations arising from Duguid's encrustation theory[7] of the pathogenesis of atherosclerosis. Our prescription of these drugs for all our patients has been uncontrolled and is not the subject of this paper. Their use must be kept in mind, however, since they may be important in relation to fibrous intimal proliferation, accelerated atherosclerosis,[8] and even graft patency.[9] In any event, with respect to our classification of "diseased" grafts, we believe that the weight of pathologic and angiographic evidence[1-3, 10-24] justifies ascribing an atherosclerotic cause to angiographic appearances that have been well described by Grondin and colleagues.[18] These included low- and high-profile wall irregularities with filling defects appearing like plaques, circumferential stenoses, "cauliflowers," and "spurs" or "diaphragms." Similar findings are generally ascribed to atherosclerosis when seen in coronary arteries. Finally, we believe our data confirm that atheromas not only progressively cover greater and greater areas of vessel wall but also become elevated from the intimal surface and protrude more and more into the lumen of the graft. Thus, use of profile, elevation or relief, in addition to area grading, seems justifiable.

We have demonstrated that 26% of our coronary bypass grafts were occluded at 5 years, that 42% of the patent grafts were diseased, we believe atherosclerotic, half of them extensively, and that 20% (73/365) of the diseased grafts had irregularities encroaching 50% or more upon the graft lumen. We have demonstrated progression of disease in grafts between 1 and 5 years after operation and have shown that progress from less disease to more disease and from disease to occlusion is worse than progress from no disease at 1 year to any grade of disease or to occlusion at 5 years after operation. The escalation of disease in vein grafts confirms our belief that there is nothing as atherogenic as atheroma. However, we are concerned with the inadequate prognostic value of the angiogram showing no evidence of disease at 1 year. All severely diseased (category III) grafts at the 1 year study had been disease free (category I) early, and 79% of severely diseased grafts at the 5 year study had been disease free at the 1 year examination. One cannot specifically link graft occlusion only to preceding atherosclerosis. Nevertheless, it is important that all grafts found newly occluded at the 1 year study had been disease free (category I) early and that 82% had had grade A patency. Furthermore, 78% of grafts found newly occluded at 5 years had been disease free at 1 year and 77% had had grade A patency.

To summarize, intimal irregularity, which we believe to indicate atherosclerosis, in a coronary bypass graft at the 1 year postoperative angiographic study heralded a high risk of accelerated disease or vessel occlusion by 5 years. Conversely, the 5 year prognosis of a nondiseased graft at 1 year was better. However, a normal appearing intimal surface at 1 year gave no important reassurance of the absence of serious disease at 5 years. Disease begets disease, but normal grafts do not necessarily remain normal.

Our future efforts will be directed at studying what we believe to be atherosclerosis in coronary bypass grafts at periods beyond 5 years. We will try to determine what factors may determine disease progression and what prognostic indicators might be of clinical value.

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Animal model to compare the effects of suture technique on cross-sectional compliance on end-to-side anastomoses☆

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Abstract

Objective: An animal model has been developed to compare the effects of suture technique on the luminal dimensions and compliance of end-to-side vascular anastomoses. **Methods**: Carotid and internal mammalian arteries (IMAs) were exposed in three pigs (90 kg). IMAs were sectioned distally to perform end-to-side anastomoses on carotid arteries. One anastomosis was performed with 7/0 polypropylene running suture. The other was performed with the automated suture delivery device (Perclose/Abbott Labs Inc.) that makes a 7/0 polypropylene interrupted suture. Four piezoelectric crystals were sutured on toe, heel and both lateral sides of each anastomosis to measure anastomotic axes. Anastomotic cross-sectional area (CSAA) was calculated with: $CSAA = \pi \times mM/4$ where m and M are the minor and major axes of the elliptical anastomosis. Cross-sectional anastomotic compliance (CSAC) was calculated as $CSAC = \Delta CSAA/\Delta P$ where ΔP is the mean pulse pressure and ΔCSAA is the mean CSAA during cardiac cycle. **Results**: We collected a total of 1 200 000 pressure-length data per animal. For running suture we had a mean systolic CSAA of 26.94 ± 0.4 mm^2 and a mean CSAA in diastole of 26.30 ± 0.5 mm^2 (mean ΔCSAA was 0.64 mm^2). CSAC for running suture was $4.5 \times 10^{-6} m^2/kPa$. For interrupted suture we had a mean CSAA in systole of 21.98 ± 0.2 mm^2 and a mean CSAA in diastole of 17.38 ± 0.3 mm^2 (mean ΔCSAA was 4.6 ± 0.1 mm^2). CSAC for interrupted suture was 11×10^{-6} m^2/kPa. **Conclusions**: This model, even with some limitations, can be a reliable source of information improving the outcome of vascular anastomoses. The study demonstrates that suture technique has a substantial effect on cross-sectional anastomotic compliance of end-to-side anastomoses. Interrupted suture may maximise the anastomotic lumen and provides a considerably higher CSAC than continuous suture, that reduces flow turbulence, shear stress and intimal hyperplasia. The Heartflo™ anastomosis device is a reliable instrument that facilitates performance of interrupted suture anastomoses.

Keywords: Vascular anastomosis; Arterial compliance; Piezoelectric crystals

1. Introduction

Running versus interrupted suture can be reasonably considered one of the most frequent subject of discussion since vascular surgery moved its first steps. To date, this is still an open issue despite many scientific works have been published all over the world. The suture material selected and the suture technique employed can influence the size and the distensibility of the anastomotic lumen [1]. Cross-sectional compliance in the perianastomotic zone, wall shear stress, axial stress, and their relationship with intimal hyperplasia are the most frequently considered parameters to compare the two different techniques [1,2]. If we try to resume the pros and cons of each technique we conclude that running suture is faster and somehow easier to do but it can produce a purstring effect that can impair the hemodynamic performance of the anastomosis. Multiple stitch technique avoids purstring effect but requires more time and is often characterized with bleeding from the suture line.

The development of a surgical device that allows performance of a multiple stitch coronary sutures in an easier and faster way than usual, and the possibility to calculate the cross-sectional anastomotic area during each phase of the cardiac cycle using a brand new technology based on piezoelectric crystals, led us to develop an animal model to compare the effects of suture technique on luminal dimensions and compliance of end-to-side anastomoses.

2. Methods

Instrumentation: length measurements were obtained with small piezoelectric crystals that transmit and receive

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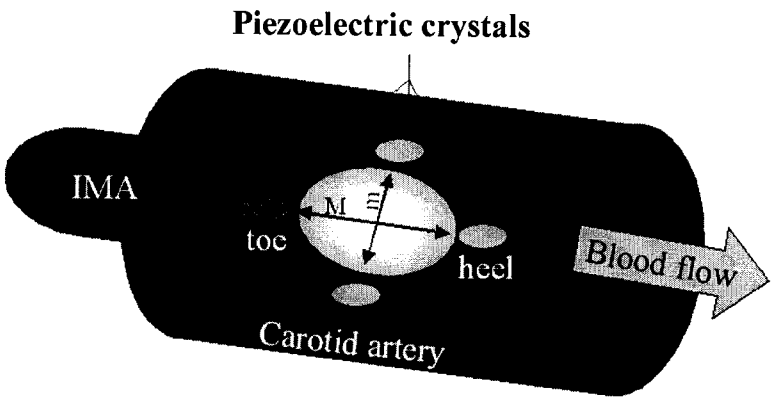

Fig. 1. Representation of end-to-side anastomosis between IMA and carotid artery. In yellow piezoelectric crystals that have been placed on toe, heel and lateral side of the anastomosis.

short ultrasonic pulses. The crystals were sutured on toe, heel and both lateral sides of each anastomosis to measure distances as shown in Fig. 1. Under electric stimulation a crystal produces a sound wave that is detected by a second crystal, inducing an electrical response. A simple calculation (Distance = Velocity × Time) yields the distance between the crystals. Sound velocity in pig's heparinized blood at 38°C is 1.04 mm/μs [3]. The system setting is as follows: sampling rate 457 Hz; transmit pulse 357 m/s; sampling time 5 s. Extensive description of the device and validation of the technique have been reported previously [4].

Arterial pressure was obtained using high fidelity pressure probe (Millar Mikro-Tip, model MPC-500) with a pressure range of −50 to 300 mmHg and a sensitivity of 5 μV/V per mmHg.

The Heartflo™ anastomosis device (Perclose/Abbott Labs, Inc.) was used to perform the end-to-side anastomosis with interrupted suture technique. It consists of a hydraulically activated delivery mechanism, and two branches, with each branch housing needles and the opposite ends of ten 7-0 polypropylene sutures. The device first simultaneously delivers ten sutures of one branch through the wall of the vessel (coronary), and then through the wall of the graft. The surgeon completes the anastomosis using conventional surgical knot tying techniques (Fig. 2).

The experiment was performed on three domestic pigs, 90 kg in weight. All animals received human care in compliance with the European Convention on Animal Care and the study has been approved by our ethics committee.

Surgical technique: pigs were given Ketamine 15 mg/kg, Azaperon 0.5 mg, Atropine 2 mg. General anaesthesia was induced and maintained with Fluotane 1.5%. EKG, $SatO_2$ and pCO_2 were continuously monitored. Pigs lay on the back with a neck extension of 160°. Both carotid arteries were exposed. The pressure probe was inserted in the left common femoral artery and pushed up to the aortic arch. After median sternotomy, both internal mammalian arteries (IMAs) were isolated and 9000 U of Heparin were injected. IMAs were sectioned distally and rotate of 180° to perform an end-to-side anastomoses on carotid arteries. The carotid arteriotomy was performed with the Heartflo™ scissors that

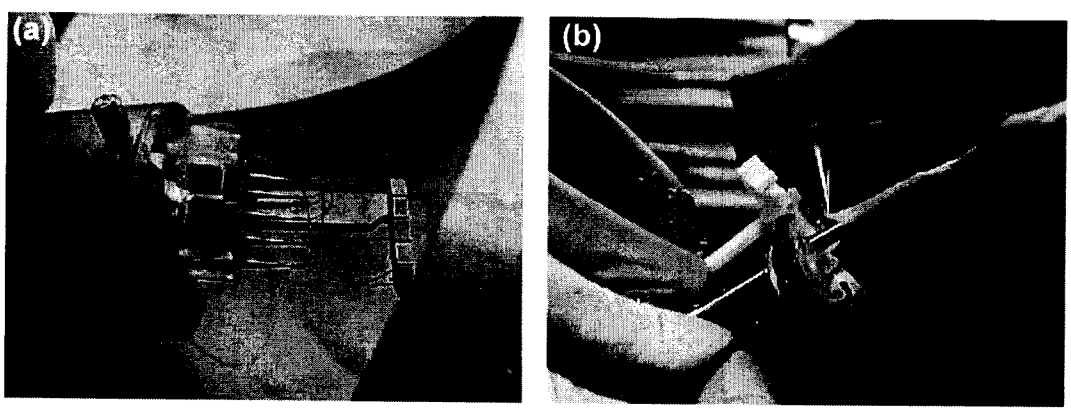

Fig. 2. The Hearthflo™ anastomosis device (Perclose/Abbott Labs, Inc.) was used to perform the end-to-side anastomosis with interrupted suture technique. It consists of a hydraulically activated delivery mechanism, and two branches, with each branch housing needles and the opposite ends of ten 7-0 polypropylene sutures. The device first simultaneously delivers ten sutures of one branch through the wall of the coronary vessel (a), and then through the wall of the graft (b). The surgeon completes the anastomosis using conventional surgical knot tying techniques.

makes the correct arteriotomy length in which the device perfectly fits. One anastomosis was performed with 7-0 polypropylene running suture. The other was performed with the Heartflo™ anastomosis device. Four piezoelectric crystals were sutured on the carotid artery at toe, heel and sides of each anastomosis to measure major and minor anastomotic axes (Fig. 1). Carotid arteries were clamped proximally to the anastomosis. Finally, pressure probe, EKG and crystals were connected to our measurement system. Artery was irrigated with NaCl 0.9% solution at 37° every 10 min to prevent desiccation and to control its temperature. During data acquisition we carefully avoided any manipulation of the animal. In animal No. 3 blood flow in both carotid arteries was assessed with a high fidelity flowmeter probe (Medi-Stim perivascular flowmeter probes, size 4 mm with flow relative accuracy of 1%, resolution of 1 ml/min, flow sample rates 333 Hz).

Data collection: both carotid arteries were clamped 2 cm proximally to the anastomoses and after 15 min of stabilisation, data collection was carried out for a period of 5 s without interruption at least four times per minute for 1 h for each animal. During every second of acquisition anastomotic diameters of both types of sutures and blood pressure were captured 457 times.

To avoid blood mass and pulse waves interference we switched the transmitter and receiver functions of the piezoelectric crystals.

Anastomotic cross-sectional area was calculated assuming that the shape of the anastomosis corresponds to a regular ellipse and distances between crystals corresponds to major and minor axes of the considered ellipse (Fig. 1). If those hypotheses are accepted Cross-Sectional anastomotic area (CSAA) can be calculated as:

$$CSAA = \pi \frac{mM}{4}$$

where m and M are the minor and major axes of the anastomosis. CSAA is expressed in mm^2. Cross-sectional anastomotic compliance (CSAC) was calculated as the ratio between variations in anastomotic cross-sectional area (ΔCSAA) and blood pressure (ΔP):

$$CSAC = \frac{\Delta CSAA}{\Delta P}$$

CSAC is expressed in m^2/kPa.

Data are presented as mean ± standard deviation (SD)

3. Results

We collected a total of 6×10^5 simultaneous data for blood pressure, and anastomotic axes for both anastomosis, per animal. For running suture we had a mean systolic CSAA of 26.94 ± 0.4 mm^2 and a mean CSAA in diastole of 26.30 ± 0.5 mm^2 (mean ΔCSAA was 0.64 ± 0.0 mm^2 that correspond to 2.4% incrementation of diastolic area during systole). CSAC for running suture was 4.5×10^{-6} m^2/kPa. For interrupted suture we had a mean CSAA in systole of 21.98 ± 0.2 mm^2 and a mean CSAA in diastole of 17.38 ± 0.3 mm^2 (mean ΔCSAA was 4.6 ± 0.1 mm^2 that correspond to 20.9% incrementation of diastolic area during systole). CSAC for interrupted suture was 11×10^{-6} m^2/kPa. Table 1 reports anastomotic CSAA values in systole and diastole for both sutures.

Mean diastolic pressure was 60 ± 13.2 mmHg; mean systolic pressure was 99 ± 12.8 mmHg; pulse pressure was between 20 and 46 mmHg (mean 32 ± 8 mmHg) and the mean heart rate was 88/min ±18.

Blood flow in carotid was 54 ± 12 ml/min for interrupted suture, and 62 ± 13 ml/min for running suture.

IMAs had a mean diameter of 3 ± 0.2 mm. Carotid arteries had a mean diameter of 5.2 ± 0.2 mm.

The mean time to perform the interrupted suture was 10 ± 2 min. The mean time to perform the continuous suture was 7 ± 1 min.

4. Discussion

This study demonstrates that suture technique has a substantial effect on CSAC of end-to-side anastomoses. Interrupted suture provides a CSAC considerably higher than continuous suture and can be reasonably considered the most 'physiologic' suture because it keeps the biomechanical properties of arterial wall as close as possible to those of native vessel [2]. This anastomotic behavior appears to result mainly from the elastic recoil of the arterial wall constituents that is better preserved with interrupted suture [5]. Therefore, the notion that difference in hemody-

Table 1
Mean cross-sectional anastomotic area[a]

	Running suture			Interrupted suture		
Animal	Diastole	Systole	%ΔCSAA	Diastole	Systole	%ΔCSAA
1	25.68 ± 0.2	26.38 ± 0.2	2.7	17.23 ± 0.1	21.71 ± 0.2	20.6
2	27.12 ± 0.3	27.67 ± 0.2	2	17.04 ± 0.2	21.89 ± 0.1	22.1
3	26.11 ± 0.3	26.79 ± 0.3	2.6	17.87 ± 0.2	22.34 ± 0.2	20
Mean ± SD	26.30 ± 0.5	26.94 ± 0.4	2.4	17.38 ± 0.3	21.98 ± 0.2	20.9

[a] Mean cross-sectional anastomotic area (CSAA) (mm^2) ± standard deviation, in systole and diastole for running and interrupted end-to-side anastomoses calculated assuming anastomosis being a regular ellipse in shape.

namic property of end-to-side anastomoses done with the two considered techniques are negligible [1], deserves reappraisal.

Furthermore, it is clear from the data provided in the study that systolic increase of cross-sectional anastomotic area (CSAA) is definitely bigger if interrupted suture is used and this behavior may theoretically improve the systolic flow through the anastomosis.

The limitations of the study resides in the fact that the model represents a situation that doesn't exist in surgical practice. It should reproduce the hemodynamic condition of end-to-side anastomosis between IMA and Left Anterior Descending coronary artery, but carotid and coronary artery have a different histological pattern. Actually, muscular layer is much more represented in carotid than in coronary arteries.

The surgical procedure may also have modified the genuine elastic properties of the vessel wall. However, careful attention was paid not to severe the adventitia in the proximity of the sutures, and in the translation of IMAs to avoid kinking and twisting.

Another limitation of the model is that we assume the anastomosis has a perfect elliptic shape and that distances we calculate with piezoelectric crystals correspond to the maximal and minimal diameters of this ellipse. Although other authors have done this assumption before [1,5] we are doing histological morphometric studies on end-to-side anastomoses performed with Heartflo™ device to verify their geometry.

The reference method for arterial diameter and cross-sectional compliance determination is the non-invasive ultrasound (NIUS 02) [6]. But, if we consider that end-to-side anastomosis doesn't lie on one cross-sectional plan we can assume that A-mode echotracking system is not a reliable method to calculate CSAC. Baumgartner proposes to measure anastomosis axes on the radiographs after anastomosis is removed, but it seems to be the less accurate method [1]. We chose sonometric technology to calculate CSAA and CSAC. Piezoelectric crystals have the highest resolution (15 μm) [4] and are easy to handle. This technique has been extensively used in vascular surgery mostly to validate Intra Vascular Ultra Sound measurements [3,4].

In Fig. 3 is plotted the correlation between pulse pressure and CSAA for interrupted and continuous sutures. The two parameters are directly correlated only if interrupted suture technique is used ($R_{interrup} = 0.94$ vs. $R_{running} = 0.56$). The CSAA increase during systole causes a reduction of vascular resistance and this can improve the blood flow through the anastomosis as hypothesised the first time in 1960 by Szilagyi [7]. However, when we measured the flow through the anastomosis we did not find any difference in systolic outflow between the two techniques and this is probably due to the sensibility of the flowmeter probe.

CSAA was slightly smaller for interrupted suture probably because we used a dedicate Pot's scissors for the arteriotomy so that the device can perfectly fit in the arteriotomy.

Better anastomotic compliance means less suture-line stresses [8,9], reduces flow disturbances and may reduce the disposition toward the development of intimal hyperplasia or thrombosis [5,10]. Computer flowdynamic simulation demonstrates that a more compliant anastomosis is associated with a less stagnation point due to flow separation (typically on heel, toe and the hood of the graft) giving rise to low wall shear stress that is associated with intimal hyperplasia [11].

Despite 51 patented ideas describing vascular anastomotic devices, and the growing need for them in minimally invasive coronary bypass procedures, no data have been published concerning their clinical evaluation. In an elegant study, Scheltes and colleagues evaluate 11 most attractive end-to-side anastomotic devices and conclude that, in a coronary anastomotic device, the concept of using an anvil for the application of micromechanical bonding elements is not attractive, because excessive wall strain is likely to occur [12]. The Heartflo™ anastomosis device does not use bonding elements. This is a surgical instrument that automates the suture delivery process during the anastomosis procedure via the simultaneous delivery of ten standard 7-0 polypropylene suture through the vessel wall. After the deployment of the device, the surgeon manually ties off the ten sutures to complete the anastomosis, similar to a hand-sewn interrupted anastomosis (Fig. 2). No significative bleeding from the suture line has been observed.

The Heartflo™ anastomosis device reduces the time to perform an interrupted end-to-side anastomosis and it should facilitate a consistent and reproducible anastomosis for minimally invasive and beating heart surgery.

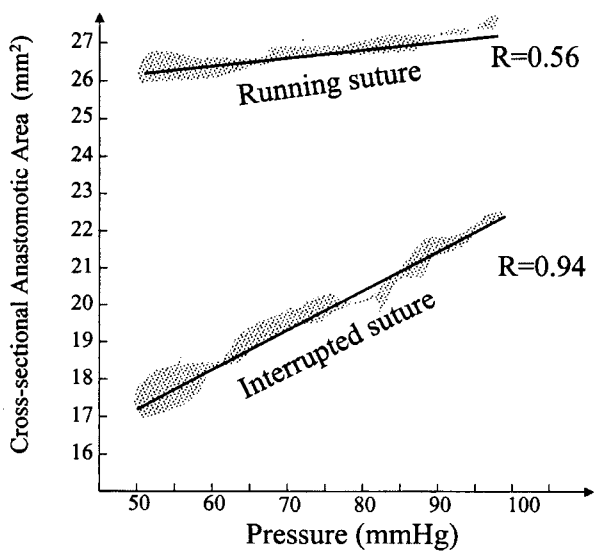

Fig. 3. The correlation between pulse pressure and cross-sectional anastomotic area (CSAA) for running and interrupted sutures are plotted. The two parameters are directly correlated only if interrupted suture technique is used ($R_{interrup} = 0.94$ vs. $R_{running} = 0.56$).

5. Conclusions

We believe this model, even with the limitations described above, can be a reliable source of information improving the outcome of coronary artery bypasses. This study demonstrates that suture technique has a substantial effect on cross-sectional anastomotic compliance of end-to-side anastomoses. Interrupted suture may maximise the anastomotic lumen and provides a considerably higher CSAC than continuous suture, that reduces flow turbulence, shear stress and intimal hyperplasia. The Heartflo™ anastomosis device is a reliable instrument that facilitates performance of interrupted suture anastomoses.

Acknowledgements

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Clinical and six-month angiographic evaluation of coronary arterial graft interrupted anastomoses by use of a self-closing clip device: A multicenter prospective clinical trial

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Dr Wolf

Objectives: To evaluate the safety and effectiveness of a self-closing surgical clip with an interrupted technique in left internal thoracic artery to left anterior descending artery bypass grafting.

Methods: Eighty-two patients were enrolled and treated (February 2000 through August 2001) in a prospective, nonrandomized, multicenter trial. Left internal thoracic artery to left anterior descending artery anastomoses were performed in 60 off-pump coronary artery bypasses (73%), 12 conventional coronary artery bypass grafting (15%), and 10 minimally invasive direct coronary artery bypass (12%) procedures. Angiograms (64 to 383 days, mean 200 days) were obtained on 63 patients (77%). Qualitative and quantitative angiographic assessment was performed by an independent core laboratory.

Results: The self-closing surgical clip was used for 82 left internal thoracic artery to left anterior descending artery interrupted anastomoses without the requirement for knot tying or primary suture management. Minimum left internal thoracic artery to left anterior descending artery anastomosis time was 3 minutes. There was one perioperative and one late death (both not heart related) and one reexploration for bleeding unrelated to the anastomotic site. FitzGibbon grades were as follows: A (n = 60, 95.2%), B (n = 3, 4.8%) including one kinked left internal thoracic artery, and O (n = 0, 0%). Quantitative analysis (n = 57) showed mean lumen diameters of left internal thoracic artery proximal to the anastomosis of 2.1 mm, at anastomosis of 2.0 mm, and in the left anterior descending artery distal to the anastomosis of 1.9 mm. The average ratio of the anastomosis to the left anterior descending artery diameter was 1.14 (0.45 to 1.93). Anastomotic stenosis as a percentage of average left internal thoracic artery to left anterior descending artery diameter was −2.3%, comparing favorably with results (23% to 24%) reported from the Patency, Outcomes, Economics, Minimally invasive direct coronary artery (POEM) bypass study.

Conclusions: The interrupted technique, facilitated by a self-closing anastomotic clip, yields favorable 6-month angiographic results when compared with other published studies.

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The frequent presumption of a long-term (> 10 years) left internal thoracic artery (LITA) to left anterior descending artery (LAD) patency rate of 96% by many heart surgeons has recently been called into question. Results of 96% patency rates at 5 and 10 years, reported by Lytle,[1] Loop,[2] and their associates at the Cleveland Clinic in 1985 and 1986, were obtained by use of a compliant, interrupted suture technique in conjunction with cardiopulmonary bypass. Extrapolation of these benchmark Cleveland Clinic results to the continuous suture

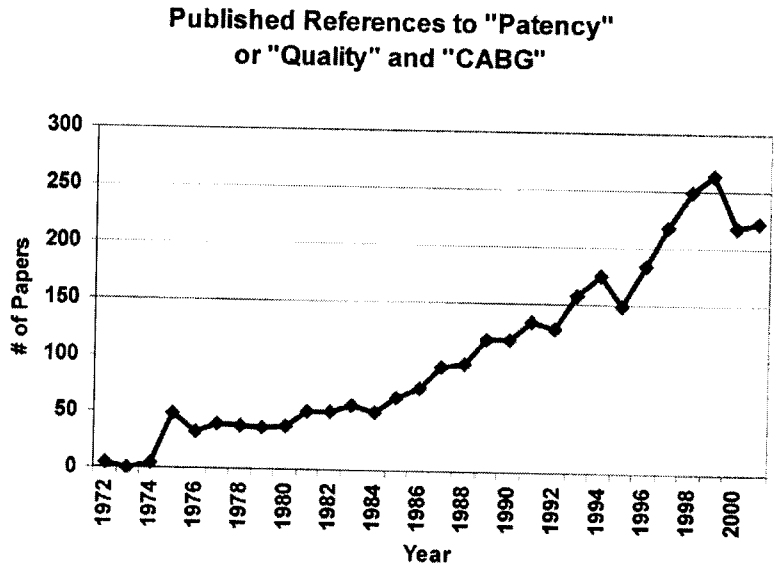

Figure 1. The number of studies that come up each year from the MEDLINE search "(patency or quality) and CABG."

technique and to current minimally invasive procedures including off-pump or beating heart surgery is not supported by other published studies[3-5] (Table 1). These studies have invariably used the more expedient continuous suture technique.[3,4] Reintervention rates for coronary artery bypasses have recently been reported to be as high as 39% within 8 years.[6]

The emergence of beating heart surgery has resulted in a widespread reassessment of anastomotic quality. This is illustrated by the significant upswing in the number of articles about coronary artery bypass grafting (CABG) published with reference to "patency" or "quality" (Figure 1) since the introduction of the off-pump technique. It is clear that the raison d'etre of heart surgery must be a high-quality anastomosis, and the fact that this must frequently be achieved on a beating heart while working through smaller incisions continues to motivate the development of improved surgical techniques and facilitating surgical technology.

One of the issues that recently has emerged again in this context is the question of continuous versus interrupted suture technique. The vascular anastomosis originally developed by Alexis Carrel, 1912 Nobel Laureate in Medicine, used a modified interrupted technique. This interrupted suture technique was initially adopted by heart surgeons as surgical revascularization became the standard of care in the late 1970s. Results published in now-seminal articles by Loop[1] and Lytle[2] and associates have been based on this interrupted approach. Subsequently, as CABG procedures became more prevalent, there occurred a shift in basic anastomotic methods away from the established interrupted technique to a more expedient, continuous suture approach in response to pressures associated with resource use and operating time. Microvascular, pediatric and neurovascular surgeons have demonstrated that there are significant advantages to using an interrupted technique.[7,8] However, until recently, issues of suture management, manpower, and resource use continued to inhibit adoption of this interrupted technique.

TABLE 1. 100+ patient ITA patency studies with ≥ 5-year angiographic follow-up

Author	Publication date	Time (years)	Reported patency
Loop	1986	10	96%
Lytle	1985	≥5	96%
Tyras	1980	5	90%
Ivert	1988	5	89%
Ivert	1988	10	87%
Okies	1984	5	81%
Fitzgibbon	1996	≥5	80%

This study was intended to formally revisit the use of the interrupted technique to improve anastomotic patency and quality by use of a now well-established self-closing clip technology. The Investigational Device Exemption– (IDE) based clinical trial was designed in consultation with the Food and Drug Administration (FDA) with the objective of demonstrating the safety and effectiveness of the Coalescent Surgical U-Clip anastomotic device (Sunnyvale, Calif) for specific cardiovascular/CABG indications.

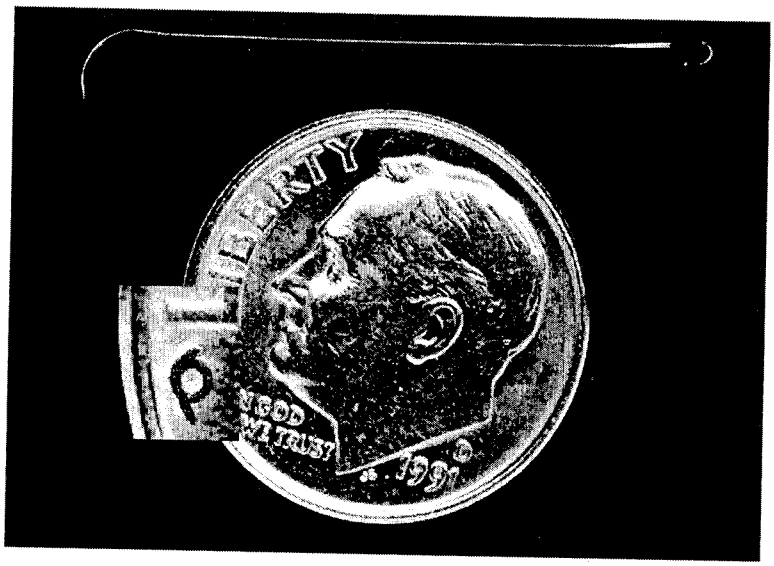

Figure 2. Photograph of the study device (Coalescent U-Clip device).

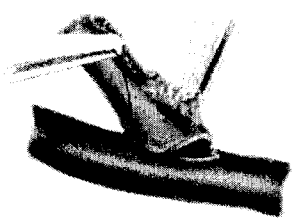

Fig 3a.

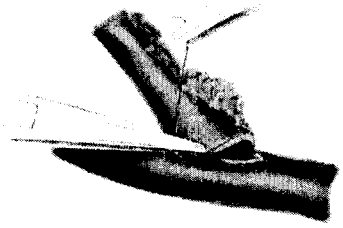

Fig 3b.

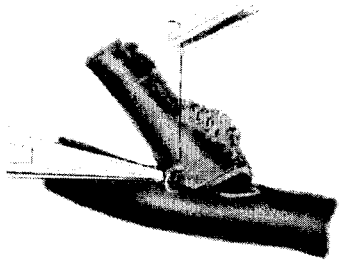

Fig. 3c.

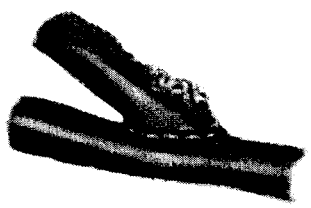

Fig 3d

Figure 3. a, Placement of U-Clip device; b, pressure applied to release; c, U-Clip closure and removal of needle and flexible member; d, finished anastomosis.

Figure 4. Completed LITA-LAD anastomosis with "cobra-head" appearance.

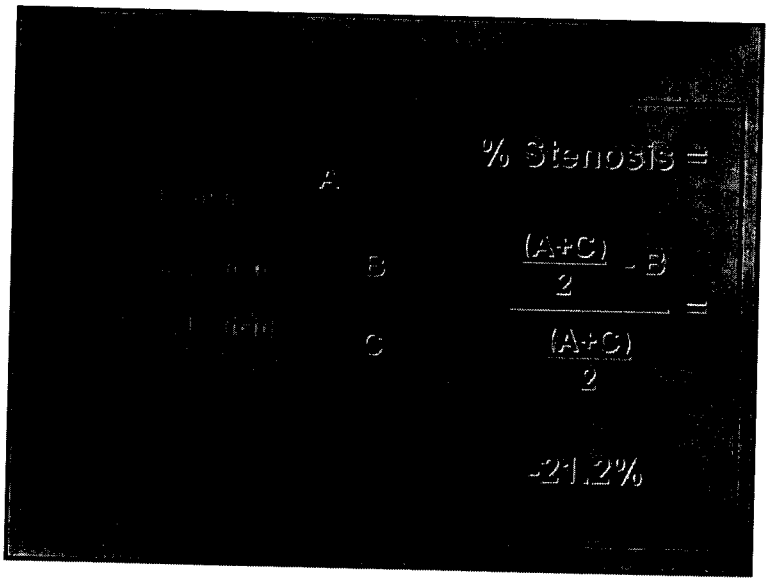

Figure 5. Anastomotic dimensions determined during QCA. A, portion of LITA graft immediately proximal to anastomosis; B, anastomosis dimension (typically defined as MLD); C, native LAD immediately distal to anastomosis site. Calculation for average percent diameter stenosis is shown.

Materials and Methods

This was a prospective, nonrandomized study designed to compare interrupted anastomotic technique facilitated by the U-Clip study device with historically published results obtained by use of continuous suture. The requirement for approximately 60, 6-month postoperative angiograms was established by use of an FDA-suggested method. Enrollment continued until it was clear that the minimum number of required 6-month angiograms would be obtained.

The U-Clip (Figure 2) comprises four basic components: a self-closing clip, a release mechanism, a flexible member, and a needle. Surgical application consists of (1) piercing the desired tissue with the needle and placement of the clip by pulling the flexible member and release mechanism through the tissue (Figure 3, *a*), and (2) closure of the clip and release of the delivery mechanism by the application of pressure (Figure 3, *b*). Once released, the needle and flexible member are removed and dis-

TABLE 2. Enrollment, demographics, and follow-up

Site	Treated	Sex		Average		Patient follow-up	
		M	F	Age	BMI	No	Angiography
DSH	31	26	5	65.4	29.2	31	19 (61%)
OSU	18	13	5	65.6	27.6	18	16 (89%)
SJH	18	18	0	64.4	29.3	18	17 (94%)
WASH	7	6	1	63.9	27.4	7	7 (100%)
UNMC	7	6	1	67.1	30.8	7	3 (43%)
KFH	1	1	0	65.0	29.1	1	1 (100%)
Total	82	70	12	65.2*	28.8†	82	63 (77%)

DSH, Desert Samaritan Hospital; *OSU,* Ohio State University; *SJH,* St Joseph's Hospital; *WASH,* Washington Hospital Center; *UNMC,* University of Nebraska Medical Center; *KFH,* King Fahad Hospital.
*$P = .95$.
†$P = .38$.

TABLE 3. Procedural summary (core lab measurements)

Site	No. beating heart	No. median sternotomy	Average diameter (mm)		
			LITA	Anastomosis	LAD
DSH	31/31	28/31	2.11	1.78	1.88
OSU	13/18	13/18	2.00	2.09	1.68
SJH	18/18	17/18	2.32	2.25	1.99
WASH	7/7	7/7	2.17	1.84	1.91
UNMC	1/7	6/7	1.80	1.93	2.13
KFH	0/1	1/1	1.40	1.32	0.96
Total	70/82	72/82	2.12*	2.00†	1.86‡

*$P = .3$.
†$P = .07$.
‡$P = .22$.

TABLE 4. Core lab results

Site	TIMI flow			Patency	Fitzgibbon grade			Average ratio anastomosis/ LAD	Average % stenosis at anastomosis
	3	2	1	%	A*	B†	0‡		
DSH	17	0	2	100	17	2	0	1.05	6.4%
OSU	15	0	1	100	16	0	0	1.28	−12.8%
SJH	17	0	0	100	17	0	0	1.17	−4.2%
WASH	6	1	0	100	7	0	0	1.00	4.9%
UNMC	3	0	0	100	2	1	0	0.91	5.0%
KFH	1	0	0	100	1	0	0	1.38	−11.9%
Total	59	1	3	100	60	3	0	1.14	−2.3%§

*<50% stenosis graft trunk or anastomosis.
†>50% stenosis.
‡Occluded.
§$P < .1$.

carded (Figure 3, *c*). Anastomoses are formed in the usual manner with a number of clips applied in a circular fashion around the anastomotic site (Figure 3, *d*). Individual placement of U-Clips results in a desired "cobra-head" appearance of the completed anastomosis (Figure 4).

Study inclusion and exclusion criteria were adopted from the joint American College of Cardiology and American Heart Association practice guidelines for coronary artery bypass graft surgery[9] and coronary artery angiography.[10] Other inclusion criteria were ages between 18 and 80 years, body mass index (BMI) of less than 35 kg/m^2, and left ventricular ejection fraction of 30% or greater. The exclusion criteria of this study are listed in the Appendix.

A total of six clinical sites and eight principal investigators participated in the study. Investigators were allowed to use either arrested heart or beating heart techniques, depending on their individual preference and the operative situation. Each investigator was given the opportunity to use the study device to complete anastomoses on a porcine heart ex vivo before the device was used clinically. This was the only training that each investigator received before beginning the study. Patients meeting all inclusion criteria and signing informed consent were enrolled into the study. The study device was used to complete a LITA-LAD interrupted anastomosis in the same basic manner as suture, with the exception of knot tying. Case report forms were completed per protocol. Patients were treated after operation in the usual and customary fashion, with no additional anticoagulation administered. All patients were followed up at approximately 2 weeks and then again at 6 months after discharge.

The core angiographic laboratory at Stanford University Medical Center, under the direction of Edwin Alderman, was used to independently evaluate all LITA-LAD anastomoses. Alderman (using standard angiographic computer software) personally completed the quantitative analysis of all of the postoperative angiograms obtained during this study. Standard measurements taken are shown in Figure 5 along with the calculation described below.

Results

Enrollment, Demographics, and Follow-up

Seventy men and 12 women with a mean age of 65.2 years (43 to 81) and a mean BMI of 28.8 kg/m^2 (19.7 to 40.6 kg/m^2) were enrolled and treated (Table 2). All patients had follow-up office visits, and a total of 63 (77%) consented to return for detailed angiographic study at an average of 200 days after operation (64 to 383 days). Two angiograms (3%) were completed before 160 days (64 and 110 days), 47 (74%) were completed between 160 and 200 days after operation, 11 (17%) were completed between 200 and 300

days, and 4 (6%) were completed at more than 300 days after operation.

Intraoperative Summary

LITA-to-LAD interrupted anastomoses were completed by use of the U-Clip in 82 total procedures; 70 (85%) were completed off-pump on the beating heart (Table 3). A total of 72 (88%) were completed by median sternotomy approach including 60 (73%) off-pump coronary artery bypass (OPCAB) procedures and 12 (15%) classic CABG (median sternotomy, on pump) procedures. The remaining 10 (12%) were completed by use of a minimally invasive direct coronary artery bypass (beating heart) (MIDCAB) or video-assisted direct coronary artery bypass procedure.

The average LITA diameter (immediately proximal to the anastomosis) and LAD (immediately distal to the anastomosis) lumen diameters (measured quantitatively at time of follow-up angiography) were 2.1 and 1.9 mm, respectively (Table 3), with 30% of LADs less than 1.5 mm. Two cases were excluded during operation per the protocol exclusion requirement of "unexpected intraoperative findings creating an unreasonable intraoperative risk, an increased probability of postoperative complications in terms of recovery or later completion of postoperative angiogram." As reported earlier,[11] one of these two patients undergoing an OPCAB procedure required an unusually long onlay patch-like anastomosis because of a severely calcified target vessel. The second patient (the first case attempted at one of the institutions) was excluded during operation because of what the surgeon reported as a "LAD and LITA wall thickness mismatch."

The average number of U-Clips used was 11.8 with a minimum of six and a maximum of 24. Mean LITA-LAD anastomosis time was 12.4 minutes (3 to 35 minutes) overall and averaged less than 10 minutes after the first 8 cases. These post initial learning curve times are entirely consistent with typical times required for completing anastomoses on beating hearts by use of a continuous suture technique. Each investigator reported the occasional requirement for the removal of one or more clips and subsequent replacement without problem or difficulty. There was one perioperative death (duodenal perforation) and one late death (respiratory failure at 11 days after operation). One reexploration was performed for bleeding found to be unrelated to any of the anastomotic sites. One perioperative myocardial infarction occurred in 1 patient. This adverse event was reported to be unrelated to the LAD target distribution. No adverse events, either during operation, before discharge, or at follow-up, were attributed to the U-Clip. There were 2 cases of arrhythmia, 1 transient ischemic attack, and 1 case of pleural effusion reported during the 6-month follow-up period. Including all treated patients, the reported 6-month major adverse cardiac events (MACE) rate was 2.4% (2/82), both unrelated to the use of the study device. There were no differences in morbidity or mortality rates or obvious clinical outcome among the 63 patients who returned for follow-up angiography and the 19 patients who refused.

TABLE 5. Analysis of FitzGibbon grade B results

Patient	FitzGibbon grade	Ratio anastomosis/ LAD	% Stenosis at anastomosis	TIMI score
UNMC1 (Patient 1 of 7)	B	0.45	40.9%	3
DSH1 (Patient 1 of 31)	B	0.83	26.1%	3
DSH12 (Patient 9 of 31)	B	0.48*	45.9%*	1

*Estimated. Competing native vessel flow impaired anastomotic measurement.

Core Laboratory Analysis

The core angiographic laboratory at Stanford used both qualitative and quantitative methods to evaluate each anastomosis. Qualitative methods included estimates of Thrombosis In Myocardial Infarction (TIMI) trial flow and general assessments of patency. More definitive, quantitative techniques included assignment of FitzGibbon score that included not only the quality of the anastomosis (greater or less than 50% stenosed) but graft quality and patency as well. Finally, the most quantitative analysis was completed by measuring the luminal diameters of the LITA distal and immediately proximal to the anastomosis, the anastomosis itself, and the luminal diameter of the native LAD immediately distal to the anastomosis. These dimensions made it possible to calculate the ratio of the anastomosis to the LAD and also the average percent diameter stenosis, as used in the Patency Outcomes Economics MIDCAB (POEM) study (see discussion below).

Angiograms were completed on a total of 63 out of 82 treated patients (76.8%). All 63 (100%) LITA-LAD anastomoses completed with the U-Clip device were found to be patent at follow-up (Table 4). The core angiographic laboratory graded 60 (95%) of the 63, 6-month postoperative angiograms as FitzGibbon grade A (< 50% stenosis of either graft trunk or anastomosis when compared with LAD) and three (5%) as FitzGibbon grade B (> 50% stenosis), including one kinked LITA graft unrelated to the anastomosis. There were no occlusions (FitzGibbon grade O) observed. Detailed quantitative analysis (n = 57) showed mean lumen diameters of the LITA proximal to the anastomosis of 2.1 mm, at the anastomosis of 2.0 mm, and in the LAD distal to the anastomosis of 1.9 mm (Table 3). The average ratio of the anastomosis to the LAD diameter was 1.14 (0.45 to 1.93). Anastomotic stenosis as a percentage of average LITA/LAD diameter was −2.3%, excluding the one FitzGibbon grade B result that could not be quantified because of competing native vessel flow and including

CSP

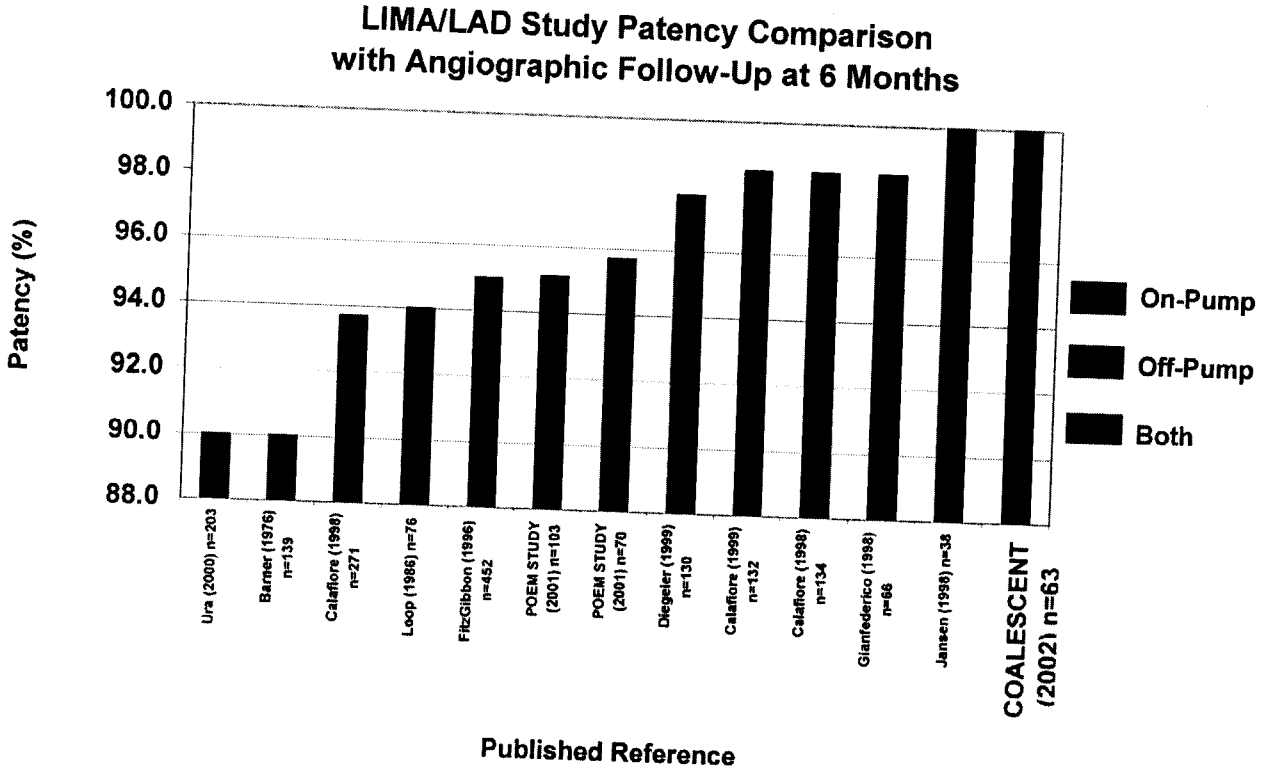

Figure 6. Patency comparison among studies with angiographic analysis at 6 months.

30 instances (48%) where the anastomosis was found to be larger than the reference vessel diameter.* Fifty-nine cases (93.7%) were graded TIMI grade 3, one (1.6%) was graded TIMI grade 2, and three (4.7%) were graded TIMI grade 1 because of poor distal bed runoff (Table 4). There was very poor correlation between these subjective TIMI flow measurements and objective quantitative analysis (Table 5). Again, this highlights the importance of quantitative angiographic analysis (QCA) for evaluating new techniques and technologies in CABG procedures.

Further analysis of the three instances of FitzGibbon grade B results (Table 5) revealed that 2 of these 3 cases represented the first cases completed by each of two surgeons. In two instances the ratio of the anastomosis to LAD was just under 50% (0.45 and 0.48). In the third case the ratio was greater than 50% (0.83); however, a kink in the LITA was measured at less than half of the LAD luminal diameter and, consequently, the result was categorized as grade B. There was no correlation with TIMI flow because two of the three grade B results showed perfect TIMI grade 3 flow.

*This percent diameter calculation was made using the identical methodology—including treatment of negative percent diameter stenosis results—used by the Cardiovascular Research Foundation (CRF) for the POEM study.

Discussion

The results from this clinical study can be compared with three different categories of published studies: (1) studies (both on and off pump) reporting simple qualitative patency only (with or without TIMI flow) between 6 and 12 months after operation (Figure 6); (2) studies reporting more quantitative FitzGibbon scores between 6 and 12 months after operation (Figure 7); and, (3) the one recent study reporting highly quantitative specific "percent diameter stenosis" values at 6 months (POEM study, Table 6).

Of the 17 CABG and 28 OPCAB studies reviewed (3368 and 2743 patients, respectively) only four were multicenter studies, 12 included angiographic follow-up at 6 months, five reported quantitative coronary angiography, three used an independent core angiographic laboratory, and only one study reported percent average diameter stenosis for both conventional CABG and OPCAB.[1-6,12-49]

Only one study (single-center, single surgeon)[31] of a total of 12 reporting angiographic patency results at 6 months showed the same 100% patency rate as was observed in the U-Clip study (Figure 6).[2,5,32-39,49] All other available studies at the same 6-month follow-up period reported occlusion rates of between 1.5% and 10%. Study sample sizes ranged from 38 to 452 patients, and the overall average patency rate for all 12 studies was

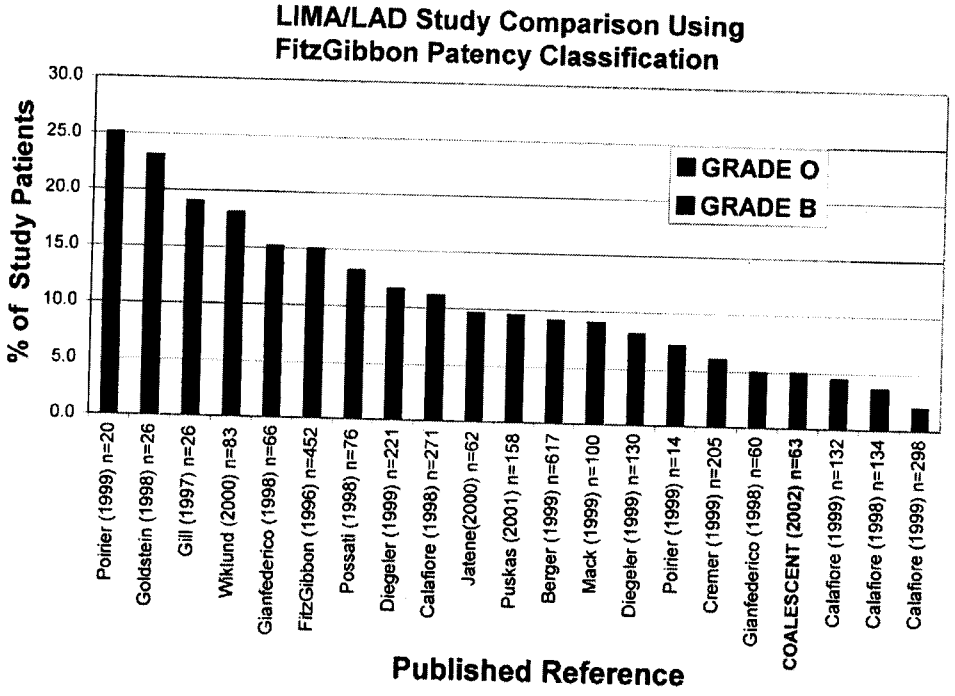

Figure 7. Studies reporting results by use of FitzGibbon patency classification scale.

the same 95% reported by FitzGibbon[5] in the largest single study.

On the more quantitative FitzGibbon scale, there were three reports[35-37] out of 20 other studies reporting Fitzgibbon scores that were marginally better than those observed in this U-Clip study (Figure 7).[5,35-48] However, these three studies reported the observation of total occlusions not experienced in the U-Clip study.

Finally, when the results are compared with the most quantitative study available, the POEM study[35] (Table 6), a significant improvement in overall patency and average percent diameter stenosis (calculations shown in Figure 5) using the U-Clip device is evident. The POEM trial represents an example of the next generation of anastomotic clinical study. It was a multicenter study of on- and off-pump CABG that used an independent core angiographic laboratory [Cardiovascular Research Foundation (CRF)] that used QCA, ensuring representative sampling of surgical skill and nonbiased review of angiographic data. CRF reported an average of 23% and 24% average percent diameter stenosis (63% 6-month angiographic follow-up) in the POEM study for CABG and MIDCAB, respectively (Table 6). This average percent diameter stenosis value (a calculation favored by CRF) compares the size of the anastomosis with the average of the LITA immediately proximal to the anastomosis and the LAD immediately distal to the anastomosis. The U-Clip study by comparison showed anastomotic stenosis as a percentage of average LITA and LAD diameter to be −2.3%. This result is significantly superior to what was reported in the POEM study ($P < .001$).

TABLE 6. Quantitative angiographic results: comparison to POEM* study

	POEM CABG (n = 70)	POEM MIDCAB (n = 103)	Coalescent (n = 63)
Reference			
LITA (mm)	2.3 ± 0.5	2.4 ± 0.5	2.1 ± 0.5
LAD (mm)	1.9 ± 0.4	1.8 ± 0.3	1.9 ± 0.5
MLD (mm)	1.8 ± 0.6	1.9 ± 0.	2.0 ± 0.5
Patency (%)	95.7	95.1	100.0
% Diameter stenosis	24 ± 24	23 ± 27	−2.3 ± 19

*Patency, Outcomes, Economics of MIDCAB, as reported by the CRF http://www.tctmd.com/expert-presentations/

Limitations of this study include a modest sample size and a nonrandomized patient population selected for conformance to prespecified inclusion and exclusion criteria. Given these limitations, however, the results appear to support the hypothesis that an interrupted technique results in a superior vascular anastomosis. This is believed to be due to two primary factors. Firstly, increased anastomotic compliance and flow rate resulting from the interrupted technique, and, secondly, the elimination of the potential for purse-string and puckering effects encountered when attempting to achieve hemostasis by use of a continuous piece of conventional suture.[47-49] An additional advantage of the

U-Clip is the availability of a fresh, sharp needle with each clip, decreasing target vessel needle injury, especially in the less than ideal target.

We believe that it is important to carefully and objectively assess achieved anastomotic quality rather than make the potentially incorrect assumption of a 96% patency rate (shown by the Cleveland Clinic when an interrupted technique is used). This is best done with objective 6- to 12-month postoperative QCA as a benchmark. This is consistent with the adoption of QCA as the standard of care by the American Heart Association[50] and the establishment of QCA as a requirement by the FDA for evaluation of any new interventional and surgical anastomotic device.

To date, more than 100,000 interrupted coronary anastomoses have been completed worldwide by use of the U-Clip device. This possible trend toward returning to the interrupted suture technique will allow further assessment of the impact on both individual graft patency and the continued viability of surgical revascularization.

In relationship to cost, any significant increase in procedure cost in this era of managed care would be of concern. After an initial learning curve, 8 to 10 clips are typically used per anastomosis for a cost of approximately $150. Suture costs per anastomosis vary widely, depending on several factors, including technique (interrupted versus continuous), suture material (silk, polypropylene, etc), needle configuration, hospital volume, and overall group purchasing organization affiliation. Silk sutures, often used for the interrupted technique, vary in price from $7 to $15 per strand, yielding a price per anastomosis ranging from $84 to $180 (assuming 12 sutures per anastomosis).[51]

Polypropylene sutures, most frequently used in a single-stranded continuous technique, vary in price from $15 to $120, yielding a similar price per anastomosis.

In 1998 average cost of CABG was reported as $44,820.[52] With this used as a benchmark, conversion of three distal anastomoses from suture to the U-Clip anastomotic device would result in an incremental procedural cost of $405 (less than 1% of overall procedural cost) at worst and would be cost neutral at best.

Conclusions

Use of the U-Clip device to facilitate an interrupted anastomosis resulted in excellent and unequaled long-term graft patency and anastomotic quality as objectively assessed by use of quantitative, 6-month postoperative angiographic analysis. These results were obtained in spite of the variables associated with a multicenter, multisurgeon, multitechnique study that included the learning curve associated with the use of a new device.

The results of this study show that the U-Clip device is capable of facilitating the use of the interrupted technique in both on- and off-pump CABG procedures and, as such, represent an important next step in the effort to continuously improve the quality of cardiovascular anastomosis.

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Discussion

Dr Erik W. Jansen *(Utrecht, Netherlands).* This is an interesting multicenter trial on an innovative coronary artery, actually a general vascular, anastomosis technique. On average, 11.8 self-closing clips were used to create the LITA-to-LAD anastomosis, requiring a mean anastomosis time of 10 minutes and a minimum of 3 minutes. Most were done on OPCAB. So this is really a smooth procedure. That is very good. There were only two conversions, no reoperations for bleeding. What was the rate of extra sutures or clips for hemostasis?

The quality of the anastomosis is well studied by use of the current standards of FitzGibbon, TIMI, and POEM in angiography in 77% of patients. The 6-month patency rate as a standard is good, 94% FitzGibbon grade A, and a favorable percent diameter stenosis. This compares with the patency in all recent off-pump trials.

There is little intravascular nitinol, thus low thrombogenicity. Did the patients receive any antithrombotic medication?

The technique looks very attractive and simple. Basically, it is a classic interrupted technique creating a wide patency, as you showed. Clear advantages are demonstrated. This is an anastomosis technique based on the surgeon's skill that is highly compliant to vessel structure and presentation, and an interrupted suturing technique that is highly compliant to local calcification and a

CSP

A multicenter study of permanent hemodialysis access patency: Beneficial effect of clipped vascular anastomotic technique

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Objective: There is an urgent and compelling need to reduce the morbidity and expense of maintaining hemodialysis vascular access patency. This large, long-term, retrospective, multicenter study, which compared access patency of autogenous arteriovenous fistulas (AVF) and synthetic bridge grafts (AVG) created with conventional sutures or nonpenetrating clips, was undertaken to resolve conflicting results from previous smaller studies.
Design: Patency data for 1385 vascular access anastomoses (clipped or sutured) was obtained from 17 hospitals and dialysis centers (Appendix). Five hundred eighteen AVF (242 clip, 276 suture) and 827 AVG (440 clip, 384 suture) were analyzed. Statistical comparisons were made with Kaplan-Meier survival analysis, log-rank test, two-sample *t* test, and X^2 test. The Cox proportional hazards model was used to confirm Kaplan-Meier analysis.
Results: Access patency (primary, secondary, overall, and intention to treat) was significantly improved in access anastomoses constructed with clips. In the intention-to-treat group, primary patency at 24 months was 0.54 for clipped AVF and 0.34 for sutured AVF, and was 0.36 for clipped AVG and 0.17 for sutured AVG. At 24 months, primary patency rate for AVF successfully used for dialysis was 0.67 for clips and 0.48 for sutures, and for AVG was 0.39 for clips and 0.19 for sutured constructs. Interventions necessary to maintain patency were significantly fewer in clipped anastomoses.
Conclusion: Replacing conventional suture with clips significantly reduces morbidity associated with maintaining permanent hemodialysis vascular access. This beneficial effect may be due to the biologic superiority of interrupted, nonpenetrating vascular anastomoses. (J Vasc Surg 2003;38:229-35.)

The population with end-stage renal disease (ESRD) is increasing at a rate of 6% per annum, and more than a billion dollars is expended annually to maintain vascular access patency and manage access-related complications.[1-5] Anastomotic neointimal hyperplasia (ANH) resulting in stenosis and eventual access occlusion remains the leading cause of access failure.[6,7] Interventions targeted at reducing ANH by changing anastomotic hemodynamics with vein cuffs, patches, and anastomotic angle, all based on conventional suturing, have failed to improve patency.[3,4] Thus, despite a need to improve access patency, reduce morbidity, and relieve a growing financial burden, there have been no significant technical improvements since inception of the procedure.[3,5]

Nonpenetrating arcuate legged clips that enable an everted, elastomeric, flanged "blood-tight" anastomosis with streamlined blood flow and improved hemodynamics have recently been introduced into clinical practice (VCS; US Surgical Corp/Tyco Inc).[8] Experimental studies and preliminary clinical reports have demonstrated the superiority of clips for end-to-side and end-to-end vascular anastomosis, with reduced ANH, improved patency, and appreciated cost savings.[9-12] Although improved long-term patency of both clipped autogenous arteriovenous fistulas (AVF) and synthetic bridge-graft fistulas (AVG) have been reported,[13,14] other single-institution studies have not confirmed patency differences.[15,16]

To resolve this important question, a long-term multicenter retrospective study was undertaken to determine whether clips have a beneficial effect on fistula patency compared with conventional sutures. This report describes the superior outcome of clipped vascular anastomoses on vascular access patency.

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Competition of interest: The VCS clip is manufactured and sold by US Surgical Corp/Tyco Inc, New York. The patent for the clip is assigned to the University of New Mexico Medical Center and licensed to US Surgical Corp. Dr Kirsch receives a royalty from US Surgical Corp in accordance with the regulations and bylaws of the University of New Mexico Medical Center. Dr Kirsch has no financial interest in the company or its competitor that makes the product (the VCS clip) described in this article.
Dr Stewart has been paid a speaking fee by US Surgical Corp/Tyco, which markets the VCS clip.

Additional material for this article may be found online at www.mosby.com/jvs.

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Table I. Patient distribution

Location	*AVG*		*AVF*	
	Suture (N = 384)	*Clip (N = 443)*	*Suture (N = 276)*	*Clip (N = 242)*
St Louis, Mo	76 (4)	104 (1)	63 (6)	60 (2)
Miami, Fla	55 (1)	44	47 (5)	57
Stockton, Calif	28 (1)	35	2	1
Tucson, Ariz	40	19	2	1
Portland, Ore	29	21	5 (1)	0
Detroit, Mich	24 (1)	27	8	5
Riverside, Calif	23 (1)	14 (1)	32	17 (1)
Baltimore, Md	24	19	15	10
Florence, SC	16	74	32 (1)	13 (1)
Opelousas, La	18	37	3	4
Hartford, Conn	9	18	5	8 (1)
Boston, Mass	1	0	0	8
Easton, Pa	7 (1)	4	19	12 (1)
Natick, Mass	4	1	32	35 (1)
Pittsburgh, Pa	9	10	2 (1)	0
Dallas, Tex	9	10 (3)	1 (1)	0
New Bedford, Mass	11	6	8	11

Thirty six of 40 excluded procedures appear in parenthesis. The other four were procedures without details on technique (Riverside, Calif, 3; Dallas, Tex, 1).
AVG, Arteriovenous graft; *AVF*, arteriovenous fistula.

Table II. Demographic data and risk factors

Variable	*AVF*				*AVG*			
	Clip (n = 199)		*Suture (n = 199)*		*Clip (n = 401)*		*Suture (n = 344)*	
	n	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Demographic data								
Age, mean ± SD	55.9 ± 16.2		57.5 ± 14.8		60.8 ± 14.9		58.9 ± 16.2	
Gender								
Male	146	73.3	126	63.3	157	39.1	149	43.3
Female	53	26.7	73	36.7	244	60.9	195	56.7
Race								
White	77	38.7	93	46.7	106	26.4	102	29.7
African American	96	48.2	86	43.2	261	65.1*	189	54.9
Other	79	39.7	18	9	30	7.5*	45	13.1
Uncertain	7	3.5	2	1.0	4	1.0	8	2.3
Renal disease								
Intrinsic	19	9.5	26	13.1	24	6.0	27	7.8
Congenital	6	3.0	8	4.0	6	1.5	3	0.9
Systemic	138	69.3	131	65.8	317	79.1	271	78.8
Uncertain	36	18.1	34	17.1	54	13.5	43	12.5
Access location								
Radiocephalic	114	57.3	96	48.2	174	43.4	148	43.0
Brachiocephalic or basilic	51	25.6	69	34.6	81	20.2	68	19.8
Thigh	9	4.5	24	12.1	23	5.7	14	4.1
Uncertain	25	12.6	10	5.0	123	30.7	114	33.1
Risk Factors								
Diabetes								
Yes	81	40.7	77	38.7	216	53.9	165	48.0
No	113	56.8	113	56.8	168	41.9	153	44.5
Uncertain	5	2.5	9	4.5	17	4.2	26	7.6
Erythropoietin therapy								
Yes	102	51.3	95	47.7	200	49.9	149	43.3
No	85	42.7	94	47.2	178	44.4	168	48.8
Uncertain	12	6	10	5.0	23	5.7	27	7.8
Albumin <3 g/L								
Yes	18	9	17	8.5	16	4	20	5.8
No	153	76.9	157	78.9	335	83.5	274	79.7
Uncertain	28	14.1	25	12.6	50	12.5	50	14.5

AVF, Arteriovenous fistula; *AVG*, arteriovenous graft.
* $P = .01$; all others nonsignificant (within access type).

Table III. Exclusions

	*AVF (n = 541)**				*AVG (n = 844)**			
	Clip		*Suture*		*Clip*		*Suture*	
	n	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Recruited	249		291		445		396	
Exclusions								
Occluded	31	12.4	46	15.8	39	8.8	43	10.8
Failed to mature or not used	12	4.8	31	10.7†	0		0	
Follow-up data incomplete‡	5	2.0	11	3.8	5	1.1	9	2.3
Date of placement unknown‡	2	0.08	4	1.4	0		0	
Remaining for Analysis	199	79.9	199	68.4	401	90.1	344	86.9

AVF, Arteriovenous fistula; *AVG*, arteriovenous graft.
*Attachment method unknown for 1 AVF and 3 AVG.
†$P < .05$.
‡Excluded from intention-to-treat analyses.

Table IV. Postoperative complications

	AVF		*AVG*	
	Clip (n = 199)	*Suture (n = 199)*	*Clip (n = 401)*	*Suture (n = 244)*
Steal	5	4	11	9
Infection	4	7	13	26*
Bleeding	0	9†	6	7
Nerve injury	0	0	1	1

AVF, Arteriovenous fistula; *AVG*, arteriovenous graft.
*$P < .05$.
†$P < .01$.

METHODS

Patency, morbidity, and demographic data were analyzed for 1385 fistulas (541 AVF, 844 AVG) placed in 1110 patients at 17 institutions by 21 different surgeons between January 1996 and June 1999 (Table I). Individual cases were tracked with examination of hospital, office, and dialysis center records to acquire duration of primary, assisted primary, secondary, and overall patency.[17] Fistulas with both arterial and venous anastomoses, or the venous anastomosis of the AVG, constructed with clips, comprised the clip cohort. Renal disease and factors that affect fistula survival, eg, diabetes, erythropoietin (EPO) therapy, and serum albumin concentration, were also documented (Table II).

Primary patency duration is defined as time from fistula placement to first intervention or occlusion. Assisted primary patency duration is time from fistula placement to first occlusion in fistulas with previous surgical or endovascular interventions. Secondary patency duration is defined as time from fistula placement to fistula abandonment because of nonfunction or occlusion, for fistulas with previous successful interventions to treat thrombosis. Overall patency duration is defined as total number of fistulas in use for dialysis at the end of the study. Patency comparisons were performed only for fistulas used successfully for dialysis (five consecutive treatments). Excluded from patency comparisons were fistulas with uncertain placement date or anastomotic technique, fistulas with incomplete follow-up data, fistulas that failed to mature, fistulas that were patent but not used, and fistulas that occluded before use. To eliminate exclusion bias, intention-to-treat analysis was also performed for all fistulas with complete data (Table III). Intention to treat was defined as all AVF or AVG procedures intended to be used for successful dialysis, in essence, all graft or fistula procedures. All cases with complete follow-up data were included in intention-to-treat patency analysis. The biostatistical group at a nonparticipating center (Center for Health Research, Loma Linda University School of Public Health) performed data collation and analysis. Data entered were verified at each participating center by the respective investigator. A different reviewer at the four centers that performed most procedures again verified accuracy of data collection.

Statistical methods. Patency of AVF and AVG (clipped versus sutured) were compared with Kaplan-Meier survival analysis and log-rank test. Demographic data and risk factors were compared with an independent two-sample t test for continuous variables and X^2 test for nominal variables. Differences resulting in $P < .05$ were considered significant. A Cox proportional hazards model was used to confirm the results of Kaplan-Meier analysis for primary patency alone, because there were too few cases for the multivariate Cox model to be appropriate for other patency data.

RESULTS

Comparative patency: AVF. Three hundred ninety-eight AVF (199 clip, 199 suture) in 382 patients (derived from 541 access procedures in 488 patients) qualified for patency analysis over the 40-month study period. One hundred forty-three AVF (50 clip, 92 suture, 1 uncertain anastomotic technique) were excluded: 77 became (14%) occluded before maturation, 43 (8%) remained patent but were not used for dialysis, and 23 (4%) lacked complete follow-up data (Table III). Demographic data, cause of renal disease, and risk factors for thrombosis were similar

Table V. Patency survival: Clip vs suture for AVF and AVG access

	Clip		*Suture*		
Patency	*n*	*Mean survival (mo)*	*n*	*Mean survival (mo)*	P*
AVF					
Primary	199	28	199	24	.0072
Primary ITT	242	23	276	18	.0003
Primary assisted	11	34	22	22	.26
Primary assisted ITT	15	25	24	20	NS
Secondary	12	24	13	29	.0673
Secondary ITT	14	24	20	20	NS
Overall	199	34	199	29	.024
Overall ITT	242	29	276	21	.0002
AVG					
Primary	401	20	344	14	.0001
Primary ITT	443	19	384	13	.0001
Primary assisted	70	22	50	20	NS
Primary assisted ITT	72	22	58	17	.067
Secondary	95	27	119	20	.0067
Secondary ITT	106	24	128	19	.0304
Overall	401	31	344	24	<.0001
Overall ITT	443	29	384	22	<.0001

AVF, Arteriovenous fistula; *AVG*, arteriovenous graft; *ITT*, intention to treat; *NS*, not significant.
*Log-rank test.

Table VI. Revisions

	AVF		*AVG*	
	Clip (n = 199)	*Suture (n = 199)*	*Clip (n = 401)*	*Suture (n = 344)*
Fistula-years	127	146	312	212
Revisions	28	54	268	367
Revisions per fistula-year	0.22*	0.37	0.86†	1.73

AVF, Arteriovenous fistula; *AVG*, arteriovenous graft.
*$P < .05$.
†$P < .001$.

for both groups (Table II). Postoperative bleeding occurred more frequently with sutures ($P < .01$) (Table IV).

Primary patency was significantly improved in the clip group ($P = .007$; Fig 1, *A*). Assisted primary patency between the groups did not reach statistical significance ($P = .26$), but the number of fistulas that required interventions was small (Table V). Secondary patency ($P = .07$) was marginally better in the suture anastomosis group (Fig 2, *A*). Overall patency of the clip AVF cohort was significantly improved ($P = .02$; Table V).

To maintain patency during the study period, 82 secondary procedures were performed in 53 AVF (28 clip, 54 suture). The number of secondary procedures per fistula ranged between one (n = 38) and five (n = 1). Clipped AVF required 0.22 procedures per fistula-year to maintain patency, compared with 0.37 procedures per fistula-year for sutured AVF ($P < .001$) (Table VI).

Of 541 AVF, 518 (276 suture, 242 clip) qualified for intention-to-treat analysis. Twenty-three AVF (7 clip, 15 suture, 1 uncertain) with incomplete data were excluded (Table III). A significantly improved primary patency rate ($P = .0003$; Fig 3, *A*) and overall patency rate ($P = .0002$; Table V was found for clip AVF. No difference was observed in secondary intention-to-treat patency, because of small numbers (Fig 4, *A*).

AVF were performed by 22 different surgeons; 6 surgeons performed 15 or more procedures. Sets of indicator variables were created to test for surgeon effect and location effect. A Cox model was created, with sex, age, surgeon, clip or suture, and location included as independent variables. This model was used to analyze primary patency data. After controlling for the above-mentioned covariates, clips continued to be significantly protective over sutures (odds ratio, 0.58; $P = .008$).

Comparative patency: AVG. Seven hundred forty-five AVG (401 clip, 344 suture) of 844 procedures qualified for patency comparisons. Ninety-nine AVG (44 clip, 52 suture, 3 uncertain) were excluded: 82 AVG (39 clip, 43 suture) became occluded or were abandoned within 2 months after placement, and follow-up data were incomplete for 14 (Table III). Demographic data, cause of renal disease, and risk factors were similar for patients in both groups, except for a difference in racial distribution (Table II). There were more African American and nonwhite patients in the clip group. Seventy-four complications were encountered, with significantly lower infections in the clipped cohort (Table IV).

Primary, secondary (Figs 1, *B*, and 3, *B*), and overall patency rates were significantly improved in the clip AVG group ($P = .0001$, $P = .007$, and $P = .001$, respectively; Table V). To maintain patency, 635 secondary procedures were performed in 293 AVG during the study. Procedures per fistula ranged between one (n = 149) and 15 (n = 1).

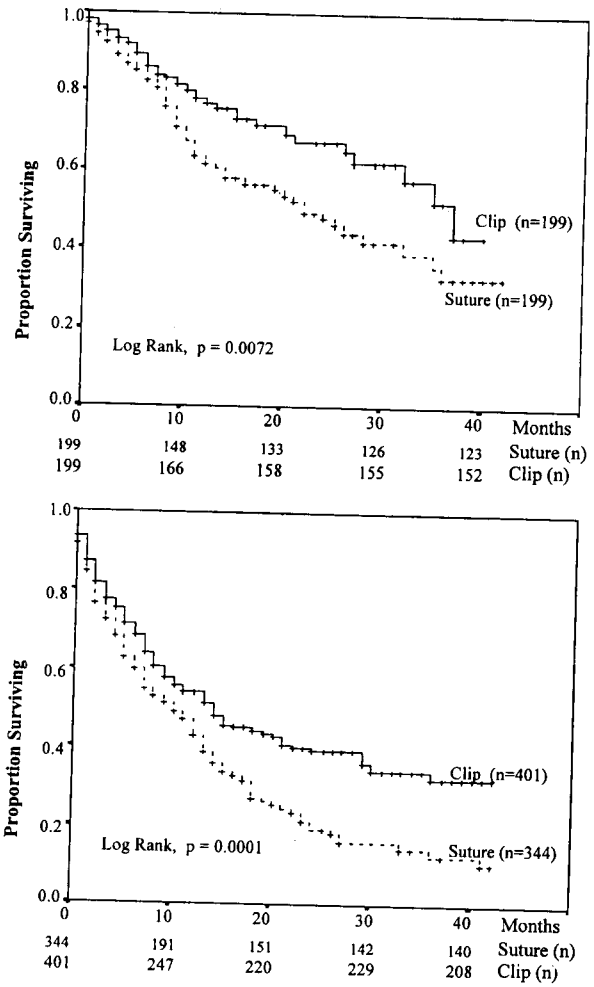

Fig 1. Kaplan-Meier analysis of primary patency for AVF (**A**) and AVG (**B**), with numbers remaining at risk.

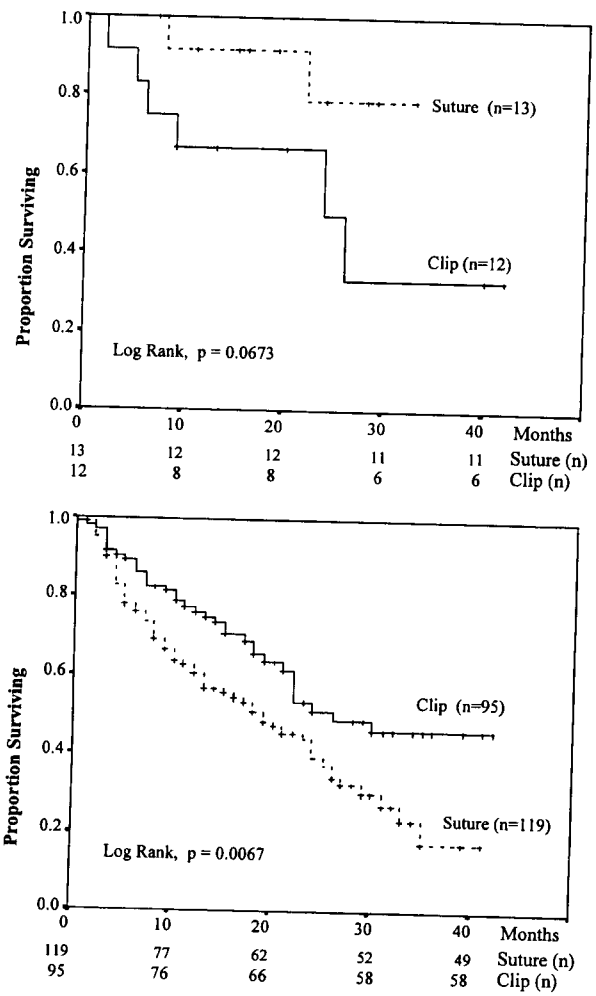

Fig 2. Kaplan-Meier analysis of secondary patency for AVF (**A**) and AVG (**B**), with numbers remaining at risk.

Sixty-eight AVG required two revisions, 38 required three revisions and 15 required four revisions. Clipped AVG required 0.86 procedures per fistula-year, compared with 1.73 for sutured constructs, to maintain patency ($P < .05$; Table VI).

Intention-to-treat analysis was performed for 827 (443 clip, 384 suture) of 844 AVG; 17 were excluded because of incomplete technical or follow-up data (Table III). Primary ($P = .0001$; Fig 3, *B*), secondary ($P = .03$; Fig 4, *B*), and overall patency ($P < .0001$; Table V) rates were significantly improved in the clip group.

Six of 21 surgeons involved in AVG construction performed more than 20 procedures each. Sets of indicator variables were created to test surgeon and location effect. A Cox model was created, with sex, age, surgeon, clip or suture, and location included as independent variables. This model, when applied to primary patency rate, showed a significant benefit for clips over sutures (odds ratio, 0.67; $P < .001$).

DISCUSSION

This 40-month, multicenter retrospective study shows significantly improved patency and reduced revision rates for clipped AVF and AVG compared with conventionally sutured constructs. These data emphasize the importance of the vascular anastomotic technique on vascular access patency. This single modification of a standard surgical procedure enables a significant reduction in morbidity, and could result in decreased financial burden on third-party payors such as Medicare. This benefit is apparent when overall patency rates of clipped and sutured AVG ($P = < .0001$) are compared. Other studies have reported 30% to 50% secondary patency rate for AVG at 2 years despite extensive salvage procedures, a patency rate that is consistent with our suture group.[4] In this study, clipped AVG had a secondary patency rate of nearly 60% at 2 years.

The uniformly improved access patency rate observed with an interrupted anastomosis performed with nonpenetrating clips confirms the positive trend reported earlier

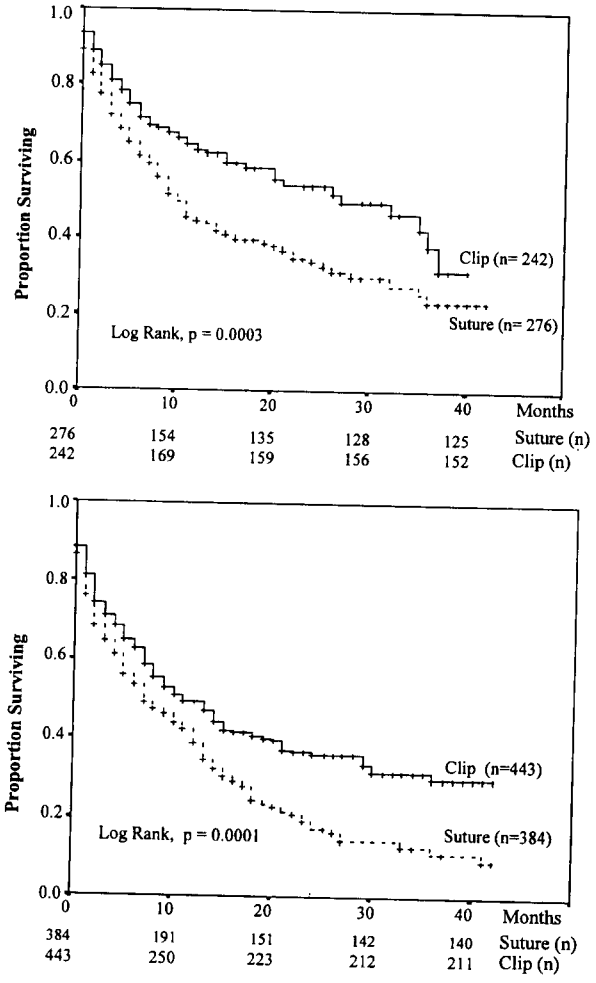

Fig 3. Kaplan-Meier analysis of primary patency for AVF **(A)** and AVG **(B)** intention-to-treat cohorts, with numbers remaining at risk.

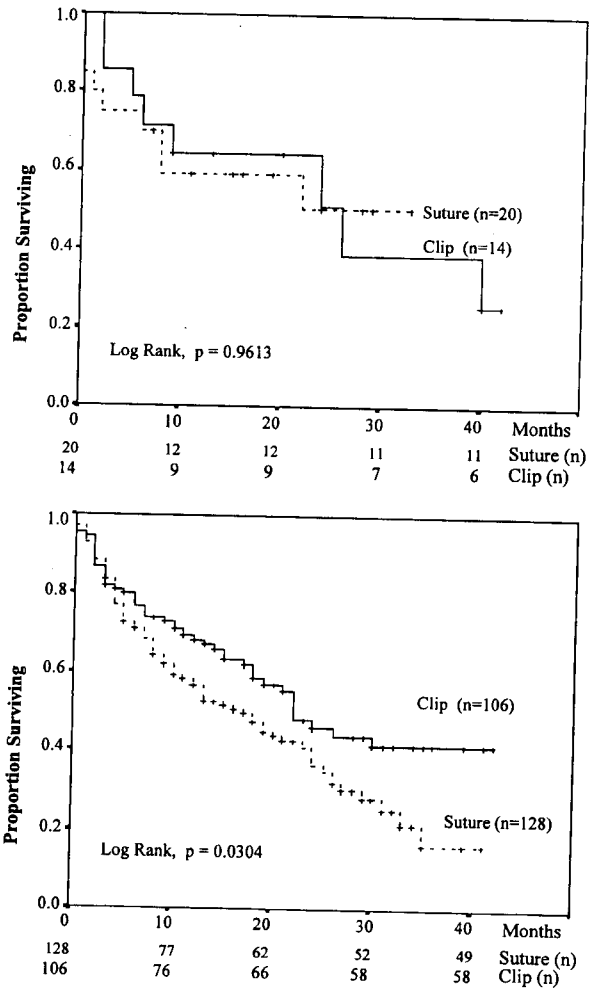

Fig 4. Kaplan-Meier analysis of secondary patency for AVF **(A)** and AVG **(B)** intention-to-treat cohorts, with numbers remaining at risk.

from smaller, single-institution studies.[14,15] A significant difference in patency outcome between clipped and sutured access was not apparent in other single-center studies with smaller numbers of cases and shorter follow-up.[15,16] Data from one of the these centers are included in this analysis.[15]

Fistula failure, though most frequently due to ANH, is multifactorial. Repeated needle sticks, tissue infiltration, hemorrhage and hematoma, dialysis-related hypotension, cytokine release, and local compression at needle stick sites contribute to loss of patency.[5] ANH, the common cause for access failure, is difficult to evaluate with direct tissue examination, because this requires biopsy of the anastomotic region. Indirect evidence for ANH is loss of access patency. It is postulated that the unique nonpenetrating quality of the vascular clip enables rapid healing, reduces compliance mismatch, and provides a "blood-tight" interrupted anastomosis.[9,18,19] Unlike sutured anastomoses, no intraluminal material is present at the clipped anastomotic line, minimizing endothelial and vessel wall trauma and inflammatory tissue response. These biologic and hemodynamic differences between clip and suture anastomoses, particularly the end-to-side construct, may account for the beneficial effects of clips.

Data acquisition and analysis for hemodialysis access outcomes is problematic with regard to accuracy and reliability, because the surgeon is only part of the multidisciplinary team that cares for patients with ESRD. Follow-up, particularly in large institutions, is often fragmented, and until recently there were no universally accepted definitions and reporting standards for data analysis.[17] To ensure accuracy and reliability of our analysis, a number of safeguards were instituted during data collection and entry. The number of procedures excluded because of inaccurate information and incomplete follow-up was small (AVF, 5.8%; AVG, 2.7%). Exclusions because of early occlusion were 14% for AVF and 9% for AVG, an incidence consistent with previously reported studies.[20,21] Fistulas (AVF, 8%; AVG, 0%) patent at data analysis but not yet used for dialysis were also excluded. The positive results in the

intention-to-treat analysis of the entire cohort of AVF and AVG provide further validation of these results.

This large retrospective study of consecutive access procedures over a 40-month period is a reasonable alternative to the ideal double-blind prospective, randomized trial. In agreement with our results, previous smaller randomized prospective studies have also demonstrated superior patency for clipped vascular access.[11,13]

Three factors can influence the validity of our results: center effects, surgeon effects, and time effects. Although two academic centers (University of Miami Medical Center and Washington University School of Medicine) contributed most cases (35%), the distribution of access procedures over the course of the study shows an equivalent number of evaluable sutured and clipped anastomoses. Thus no clustering of clipped or sutured procedures occurred at any of the 17 centers. Although dialysis methods vary among centers, the distribution of cases among academic and private dialysis units was similar. Data for this study were extracted from centers distributed throughout the United States, correcting for recognized regional diversity of access management.[22]

Results can be biased by a surgeon effect, in which degree of familiarity with technique has a role. In this study, all surgeons were more experienced with sutures than with clips; thus bias is weighted against clipped procedures. Clips were generally introduced later in the individual series as experience with the device was accrued; thus a clip learning phase was inevitable. The same surgeons performed both sutured and clipped procedures. During the study period (January 1996 to June 1999) there were no significant changes in dialysis techniques or vascular access techniques (other than the clip itself) that would be likely to substantially improve vascular access patency, thus obviating a time effect.

In conclusion, this multicenter study provides convincing evidence that use of vascular clips rather than conventional suture improves patency rate of vascular access for hemodialysis. Clip usage results in significant cost savings in management of ESRD, with reduction in surgical morbidity. These results suggest that use of the clip in other cardiovascular surgeries may have similar long-term beneficial effects.

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APPENDIX, online only

Participants in the multicenter vascular access study who contributed cases for analysis are as follows: Alan S. Coulson, MD, PhD, Dameron Heart Institute, Stockton, Calif; Normand Miller, MD, Luis A. Queral, MD, The Vascular Center, Mercy Medical Center and Union Memorial Hospital, Baltimore, Md; Bobby Nibhanupudy, MD, University of Texas Southwestern Medical Center, Dallas, Tex; Stanley Byshe, MD, Susan Forlifer, Kevin Stitely, Easton Memorial Hospital, Easton, Md; David Schaffer, MD, Boston, Mass; Scott Berman, MD, Tucson, Ariz; Francisco Escobar, MD, Henry Ford Hospital, Detroit, Mich; Satish Muluk, MD, University of Pittsburgh Medical Center, Pittsburgh, Pa; Blayne Standage, MD, Portland, Ore; Surendra Shenoy, MD, Barnes Hospital, Washington University, St Louis, Mo; Arnold Miller, MD, Metrowest Surgical Associates, Harvard Medical School, Natick, Mass; A. Frederick Schild, MD, Jackson Memorial Hospital, Miami, Fla; James D. Simpson, MD, Kaiser Permanente, Riverside, Calif; Leslie Stewart, MD, McLeod Regional Medical Center, Florence, SC; Elliott Badder, MD, Mercy Medical Center, Baltimore, Md; Roger Rosen, MD, New Bedford, Mass; Lewis Brown, MD, Hartford, Conn; Kerry T. Thibodeaux, MD, Opelousas General Hospital, Opelousas, La.

A comparison of para-anastomotic compliance profiles after vascular anastomosis: Nonpenetrating clips versus standard sutures

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Purpose: Anastomotic compliance is an important predictive factor for long-term patency of small diameter vascular reconstruction. In this experimental study we compare the compliance of continuous and interrupted sutured vascular anastomoses with those using nonpenetrating clips.

Methods: Both common carotid arteries in nine goats (average weight, 57 ± 5.7 kg) were transected, and end-to-end anastomoses were constructed with nonpenetrating clips or polypropylene sutures. The latter were applied with both interrupted and continuous techniques. Intraluminal pressure was measured with a Millar Mikro-tip transducer, and vessel wall motion was determined with duplex ultrasound equipped with an echo-locked wall-tracking system. Diametrical compliance was determined. Environmental scanning electron microscopy was performed on explanted anastomoses.

Results: There was a reduction in anastomotic compliance and associated proximal and distal para-anastomotic hypercompliant zones with the use of all techniques. However, compliance loss was significantly less in those anastomoses with clips and interrupted sutures when compared with continuous suture ($P < .001$). Furthermore, the total compliance mismatch across anastomoses with continuous sutures was significantly greater than those with clips or interrupted sutures ($P < .05$). The mean time for constructing clipped anastomoses was 5.7 ± 1.4 minutes, which was significantly less than either continuous ($P < .0001$) or interrupted sutures ($P < .0001$). Furthermore, environmental scanning electron microscopy demonstrated minimal intimal damage with good intimal apposition in the clip group.

Conclusion: Anastomoses performed with nonpenetrating clips resulted in improved para-anastomotic compliance profiles and reduced intimal damage when compared with those with polypropylene sutures. These benefits may enhance long-term graft patency by reducing the risk of anastomotic intimal hyperplasia. (J Vasc Surg 2001;33:812-20.)

Despite the use of autologous saphenous vein, grafts may ultimately fail through the development of anastomotic intimal hyperplasia (IH).[1,2] Creation of an anastomosis invariably generates a focal decrease in diameter and a drop in compliance.[3] This is determined by both surgical technique, depending on whether an interrupted or continuous anastomosis is constructed, and the rigidity of suture materials, with their high elastic modulus. Although several theories exist regarding the development of anastomotic IH, para-anastomotic compliance mismatch is thought to play an important role.[4-6] This generates para-anastomotic flow disturbances resulting in abnormal mechanical shear stresses that may ultimately lead to endothelial cell loss, thereby initiating uncontrolled cellular proliferation.[7,8] Furthermore, there is a paradoxical increase in compliance within a few millimeters on either side of the suture line in the order of 50%.[3,9,10] It has been suggested that this region, known as the para-anastomotic hypercompliant zone (PHZ), is also responsible for IH through inter alia the process of increased cyclical stretching.[7,9,11]

In standard anastomotic techniques for vascular reconstruction, the continuous monofilament suture is commonly used; less frequently, an interrupted technique is used. Both of these techniques result in the inevitable presence of foreign material at the blood graft interface and direct intimal damage exposing thrombogenic extracellular matrix to turbulent blood flow.[12,13] The first report on the use of penetrating metal clips for performing vascular anastomoses appeared more than 40 years ago.[14] Despite the significant reduction in anastomosis time, it was not widely adopted by surgeons. Since then, Kirsch et al[15] have developed a system using titanium clips that relies on compression of two surfaces, thereby avoiding intimal damage. The impetus for this development was a need to reduce the risk of graft failure consequent to intimal damage at the suture line after cerebrovascular reconstruction. In earlier studies in which this type of anastomosis was used, equivalent or superior mechanical properties were demonstrated when compared with standard sutures.[15] Furthermore, similar or even improved healing characteristics of anastomoses with nonpenetrating clips compared with standard sutures have been reported in recent studies.[16]

Although it is accepted that interrupted sutures result in better compliance profiles than continuous sutures,[4,17]

From the Department of Vascular Surgery, Manchester Royal Infirmary and Medical School,[a] and the Vascular Haemodynamic Laboratory, University Department of Surgery, Royal Free and University College Medical School, The Royal Free Hospital.[b]

Competition of interest: nil.

VCS Clips and specially designed apposition forceps were provided by Auto Suture, a division of TYCO, Norwalk, Conn.

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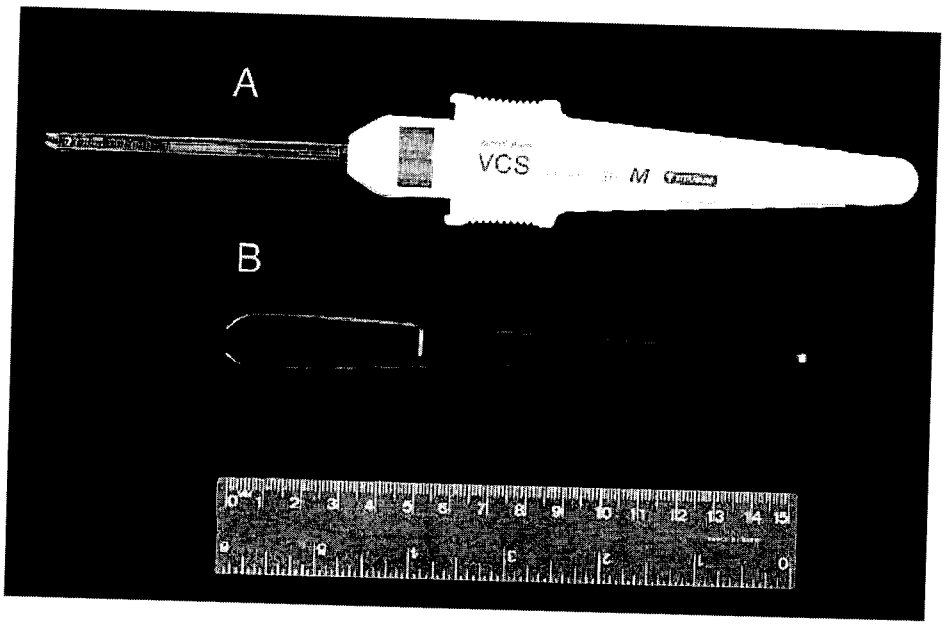

Fig 1. Medium-sized arcuate-legged clips within its applicator **(A)** and specially designed everting forceps **(B)**.

as yet, in no studies has the para-anastomotic compliance mismatch between standard sutured and clipped anastomosis in vivo been compared. Therefore, the aim of this study was to compare compliance profiles between anastomoses with nonpenetrating clips and those with standard polypropylene sutures in a large animal model.

METHODS AND MATERIALS

Animal welfare and experimental model. The study was conducted under a license granted by the Home Office in accordance with the Animals (Scientific Procedures) Act 1986. A goat carotid artery model was used to evaluate the different anastomoses. Both common carotid arteries were used to study end-to-end anastomosis of transected native vessel to ensure that the suture line between proximal and distal segments was both isodiametric and isocompliant. In this way, changes in diameter and compliance were solely a function of the anastomosis.

Animal preparation and surgical procedure. Large female Saanen goats (n = 9; average weight, 57 ± 5.7 kg) were used. The animals were premedicated with azaperone (Stresnil; Janssen Animal Health, Saunderton, Buckinghamshire, UK), 0.1 mL/kg intramuscularly. After induction of anesthesia with ketamine hydrochloride (Ketaset; Willows Francis Veterinary, UK), 5 mg/kg intravenously, the animals were intubated and mechanically ventilated. Anesthesia was maintained with halothane (May and Baker Ltd, Dagenham, UK), nitrous oxide, and oxygen through a standard anesthetic circuit. Hind limb vein was cannulated for fluid administration. The animal's temperature was maintained at 36° to 38°C with an electronic heating mat. A pulse oximeter (Ohmeda Biox 3740-pulse oximeter; Ohmeda Co, Louisville, Colo) was used for continuous monitoring of arterial oxygen saturation and heart rate. All animals were allowed to stabilize for 20 minutes before baseline measurements were recorded. Common carotid artery blood flow (CCABF) was measured throughout the procedure with a dual Transonic Medical Flowmeter system (HT207; Transonic Medical System Inc, Ithaca, NY) with a 4-mm diameter transonic flowmeter perivascular probe placed around the distal carotid artery.

After dissection of a 5-cm segment of the common carotid artery (CCA), 5000 units of heparin was given intravenously before clamps were applied on the CCA. The vessel was then transected at its midpoint, and an anastomosis was performed with continuous or interrupted 6-0 polypropylene sutures or medium-sized, 1.4-mm nonpenetrating, arcuate-legged clips (VCS, Auto Suture, A Division of United States Surgical Corporation, Norwalk, Conn). In the case of the latter, two 6-0 polypropylene stay sutures were placed to assist closure and edges everted with a specially designed nonpenetrating everting forceps (Fig 1). Eighteen anastomoses were constructed in random fashion, 6 with nonpenetrating clips, 6 with a continuous suture technique, and 6 with interrupted sutures.

On completion of the experiment, the animal was humanely killed with a lethal dose (20 mL, 200 mg/mL) of sodium pentobarbitone (Expiral; Sanofi Animal Health, UK). The vessel was explanted to examine the luminal surface of the anastomosis with digital photography and environmental scanning electron microscopy (ESEM).

Determination of the compliance of the carotid artery. The change in vessel wall diameter regarding each cardiac cycle was measured at discrete sites along the carotid artery with measurements taken in the sagittal

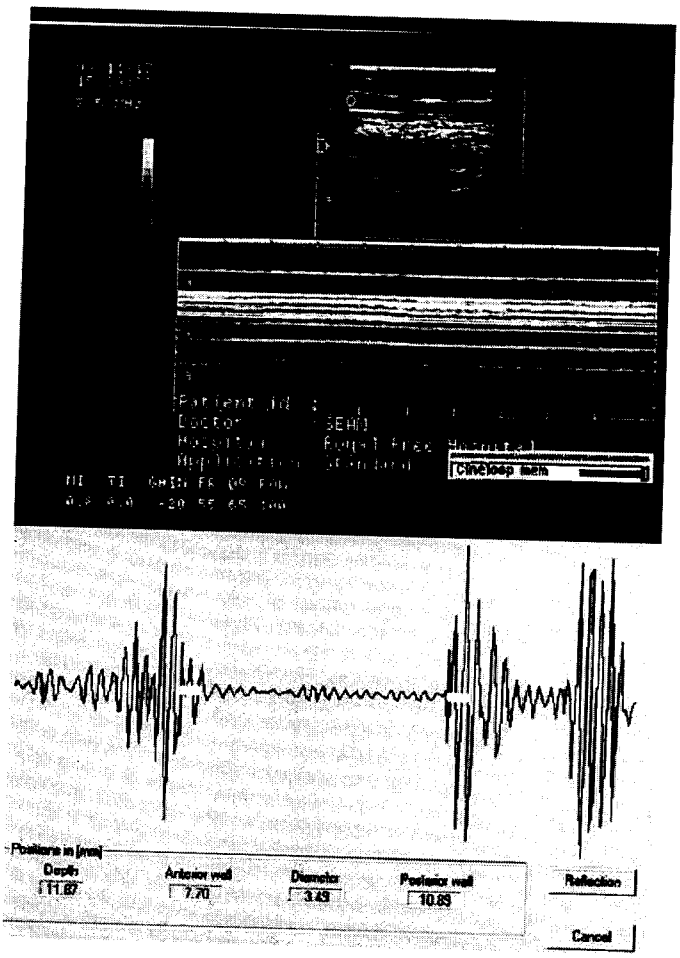

Fig 2. CCA was imaged with specially adapted duplex color Doppler ultrasound system. Vessel wall movement was followed by tracking assigned points of induced radiofrequency signal deemed to be representative of anterior and posterior arterial walls.

plane at 90 degrees to the long axis of the vessel. Segments of artery were imaged with a specially adapted, duplex color Doppler ultrasound scanning system (Pie 350; Pie Medical Systems, Maastricht, The Netherlands) with signal output to a high-resolution, echo-locked wall tracking system (Wall Track; Pie Medical Systems). This system, with a manufacturer-stated tracking accuracy of 8 μm, allowed the measurement of vessel wall movement by automatically tracking assigned points of induced radiofrequency signal deemed to be representative of the anterior and posterior arterial wall over a period of time (Fig 2). A detailed description of the system has been published.[18,19] Real-time M-mode images of the arterial wall were obtained with a 7.5-MHz linear array probe clamped above the artery and with the M-mode cursor positioned perpendicular to the long axis of the vessel; the change in induced radiofrequency signal received from the vessel walls was sampled. Data were then transferred to a personal computer for real-time display of displacement waveforms of both the anterior and posterior arterial walls, allowing automatic determination of end-diastolic and end-systolic intraluminal diameters for each cardiac cycle. Intraluminal pressure was acquired with a Millar Mikro-tip catheter (Millar Instrument, Inc, Houston, Tex), which claims an accuracy of ± 3 mm Hg at sites corresponding to the recorded luminal diameter. At each discrete site, three sets of intraluminal pressure and vessel wall movement were acquired simultaneously at sampling rates of 195 Hz for 3 seconds (Fig 3). Cross-sectional or diametrical compliance of the vessel was calculated, as previously described,[19] from the mean of three acquisitions with the following formula:

$$C = \frac{(D_s - D_d)}{(P_s - P_d)D_d} \times 10^4$$

where D and P are vessel diameter and intraluminal pressure, respectively, and the subscripts s and d refer to systole and diastole. The units for compliance are percent/millimeters of mercury × 10^2. It has been estimated that, with this system, the overall error of the com-

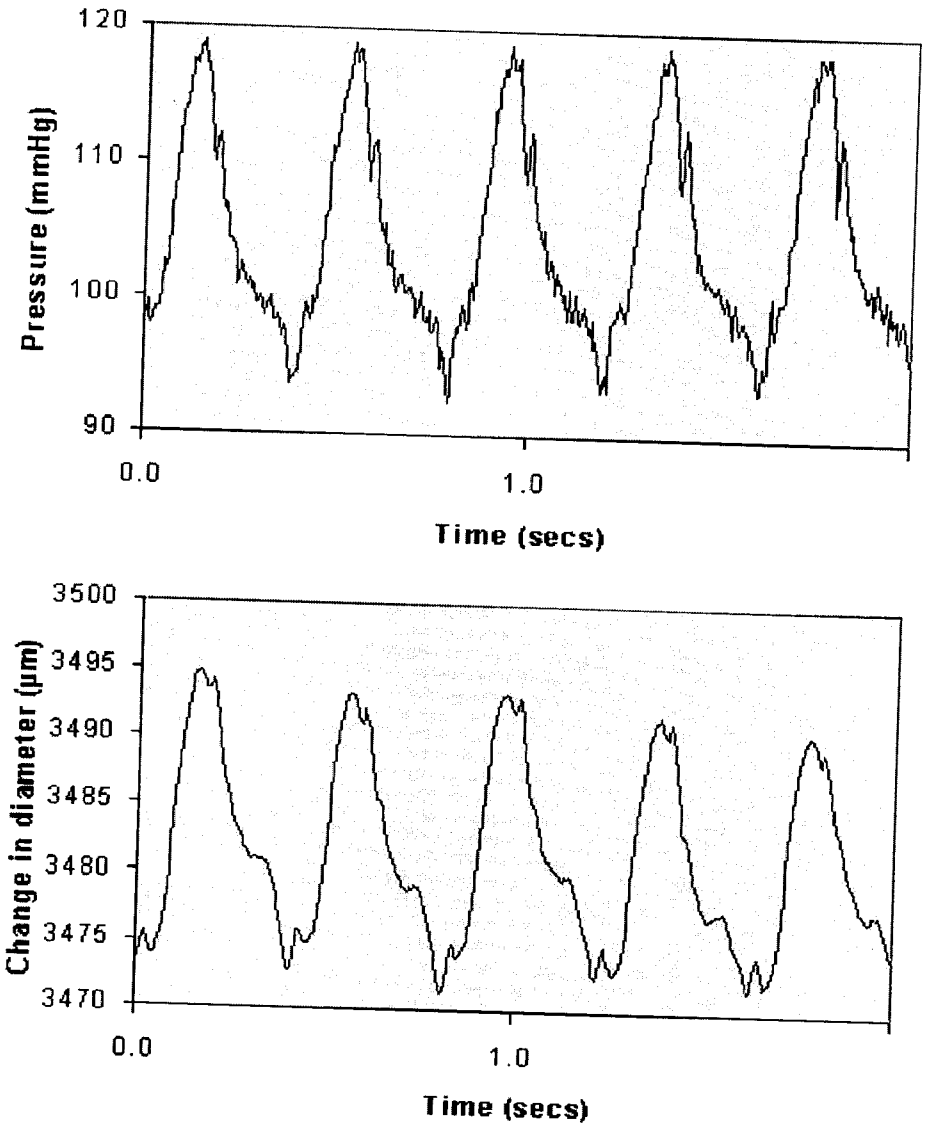

Fig 3. Changes in arterial diameter (*bottom*) and luminal pressure (*top*) were recorded simultaneously.

pliance value from error propagation through diameter and pressure readings is about ± 4%. On completion of an anastomosis, recordings of vessel wall motion and intraluminal pressure were taken after a 30-minute period of hemodynamic stabilization at the position of the intended anastomosis and 4 mm on either side before transection of CCA and repeated on completion of anastomosis with readings at the suture line and 2, 4, 6, 8, 10, 15 and 20 mm on either side. On average, measurements were completed in 20 minutes after completion of the anastomoses. An enhanced set of compliance parameters were computed for each compliance-distance profile along the CCA, as previously described (Fig 4).[3] Reference values (C_{ref}) were calculated as the average of the compliance measurements at 20 mm away from the suture line. C_{peak} represents the maximum compliance value recorded between C_{ref} and the anastomosis (C_a). Furthermore, the difference between C_{ref} and C_{peak} or C_a was represented as C_{rise} and C_{loss}, respectively. The sum of C_{rise} and C_{loss} represents the total compliance mismatch (C_{tot}). All computations were performed for both proximal and distal aspects of the anastomosis; therefore, each parameter has the superscript *P* or *D*.

ESEM. Fresh specimens of explanted artery were cut into 1-cm segments, and the luminal surface of the anastomosis was washed with deionized water before examination with an Electroscan E3 ESEM (Electroscan Corporation, Wilmington, Mass). Digital images were acquired in a wet

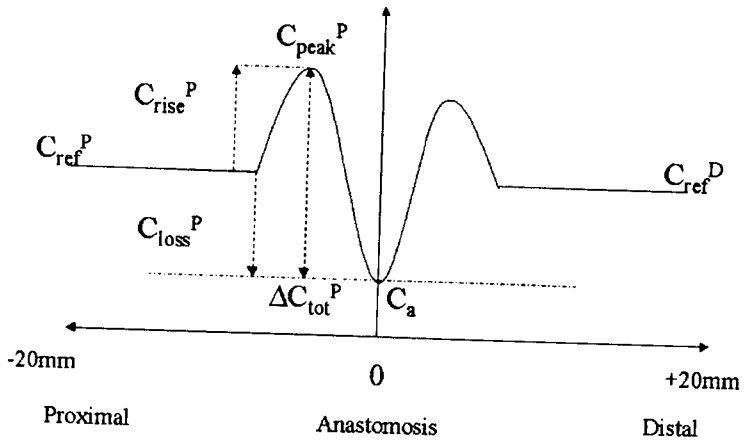

Fig 4. Typical compliance profile around anastomosis demonstrating proximal and distal PHZs. C_{ref} represents compliance of the vessel 20 mm from anastomosis (C_a). C_{peak} represents maximum compliance recorded, and the difference between C_{peak} and C_{ref} and C_a and C_{ref} is represented as C_{rise} and C_{loss}, respectively. Superscripts *P* and *D* denote proximal or distal sites.

Table I. Summary of demographic data (mean ± SD)

Technique of anastomosis	*Clips (n = 6)*	*IS (n = 6)*	*CS (n = 6)*	P *value**
Body weight (kg)	57.0 ± 5.7	55.3 ± 6.6	56.0 ± 7.4	.210
CCA mean diameter (mm)	3.80 ± 0.11	3.67 ± 0.30	3.44 ± 0.27	.674
CCA compliance (%/mm Hg × 10^2)	6.02 ± 0.42	5.91 ± 0.39	5.81 ± 0.32	.199
Time taken for anastomosis (min)	5.7 ± 1.4	14.3 ± 1.9	12.8 ± 1.9	.0021
CCABF before anastomosis (mL/min)	548 ± 59	529 ± 77	482 ± 42	.197
CCABF after anastomosis (mL/min)	492 ± 25†	498 ± 59†	404 ± 59‡	.084

*By multiple comparison analysis among clips, IS, and CS with Kruskal-Wallis one-way analysis of variance by ranks.
†$P > .6$ compared with preanastomosis CCABF with the paired *t* test.
‡$P = .020$ compared with preanastomosis CCABF with the paired *t* test.
CCA, Common carotid artery; *CCABF*, common carotid artery blood flow; *CS*, continuous suture; *IS*, interrupted suture.

chamber environment at 8°C, 5 to 10 torr with a primary beam voltage of 20 to 25 keV.

Data analysis and statistical methods. The average vessel wall movement was obtained over three cardiac cycles, and the diametrical compliance was calculated according to the luminal pressure measured at the corresponding time and site. The average of three sets of compliance data at a given site was then calculated to obtain mean values for each site along the vessel in each animal. When a comparison with C_{ref} was required, the value calculated for the proximal site was used. Intergroup differences in diametrical compliance were compared with the unpaired *t* test. Comparisons of diametrical compliance among different sites on the same vessel were assessed with the Kruskal-Wallis analysis of variance. CCABF before and after creation of an anastomosis was compared with the paired *t* test.

RESULTS

There was no significant difference in baseline demographic data such as weight, vessel diameter, CCABF, and CCA compliance among the three groups (Table I). Although there was a greater reduction in CCABF (16% ± 7%) after continuous sutured anastomoses than with either clips or interrupted sutures, this was not statistically significant with multiple comparison analysis.

At the time of explantation, all vessels were patent, as determined by the flow probe. Although hemostasis was achieved immediately on release of vessel clamps in all anastomoses with continuous sutures, an additional clip needed to be adjacent to a stay suture in one case, and an additional suture was required in a single case of the interrupted-suture group. Anastomoses were constructed with a median of 10 middle-sized clips (range, 9-12) in the clipped group, and 11 sutures (range, 10-13) were necessary with interrupted sutures. The mean time for completing clipped anastomoses was 5.7 ± 1.4 minutes, which was significantly less than either continuous (12.8 ± 1.9 minutes; $P < .0001$) or interrupted (14.3 ± 1.9 minutes, $P < .0001$) sutures. Fig 5 shows the compliance distribution as a function of distance from the anastomosis for each group, and Table II summarizes the computed data from compliance-distance profiles. In all cases, C_{ref} at proximal and distal sites of the CCA was similar. Although

Table II. Summary of compliance parameters computed from distance-compliance profile along the blood vessel from −20 to +20 mm on either side of anastomosis

Technique of anastomosis	*Clips (n = 6)*	*IS (n = 6)*	*CS (n = 6)*	P *value**
Proximal site				
C_{ref}^{P}	6.58 ± 0.72	5.75 ± 0.42	5.48 ± 0.98	.195
C_{peak}^{P}	7.28 ± 0.67	8.45 ± 1.05	11.48 ± 1.54	.013
C_a	4.83 ± 0.62	5.38 ± 0.90	2.53 ± 0.39	.021
C_{rise}^{P}	0.90 ± 0.37	2.70 ± 1.38	6.00 ± 2.26	.022
C_{loss}^{P}	1.75 ± 1.16	0.38 ± 0.61	2.95 ± 1.26	.049
C_{tot}^{P}	2.45 ± 1.01	3.08 ± 1.48	8.95 ± 1.25	.022
Distal site				
C_{ref}^{D}	6.68 ± 0.24	6.50 ± 0.61	5.08 ± 0.83	.045
C_{peak}^{D}	6.73 ± 0.50	7.98 ± 0.63	10.90 ± 4.35	.011
C_a	4.83 ± 0.62	5.38 ± 0.90	2.53 ± 0.39	.021
C_{rise}^{D}	0.05 ± 0.61	1.48 ± 0.97	5.83 ± 4.47	.013
C_{loss}^{D}	1.85 ± 0.47	1.13 ± 1.11	2.55 ± 1.04	.160
C_{tot}^{D}	1.90 ± 1.03	2.60 ± 0.29	8.38 ± 4.21	.019

The compliance is computed in units of %/mm Hg × 10^2. C_{ref} represents the compliance of the vessel 20 mm from the anastomosis (C_a). C_{peak} represents the maximum compliance recorded, and the difference between C_{peak} and C_{ref} and C_a and C_{ref} is represented as C_{rise} and C_{loss}, respectively. Superscripts *P* and *D* denote proximal or distal sites.
*By multiple comparison analysis among clips, IS, and CS with Kruskal-Wallis one-way analysis of variance by ranks.
CS, Continuous suture; *IS*, interrupted suture.

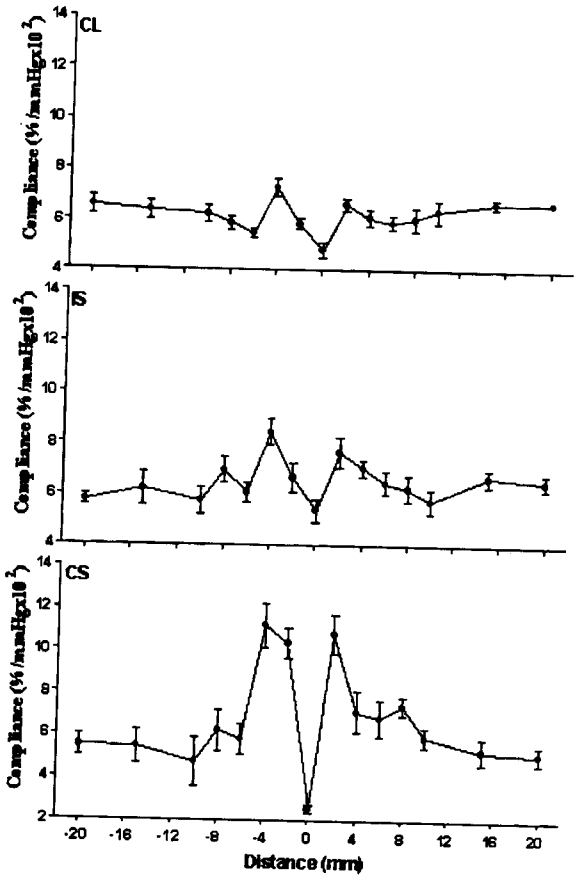

Fig 5. Comparison of para-anastomotic compliance profiles among anastomoses constructed with clips (*CL, top*), interrupted sutures (*IS, middle*), and continuous suture (*CS, bottom*).

there was a significant drop in compliance between C_{ref} and the anastomosis (C_a) in the continuous suture group (P = .018), there was no significant drop in either the clipped (P = .057) or interrupted (P = .308) suture groups, who used the paired t tests. Furthermore, there was significantly greater loss of compliance at the anastomosis (C_a) in those using a continuous suture when compared with those using clips or interrupted sutures (P < .001, unpaired t test). However, there was no significant difference between the C_a of clipped and interrupted suture groups (P = .351). Although proximal to the anastomosis there was a significant rise in compliance (C_{rise}) of 119% ± 71% (P = .013) and loss (C_{loss}) of 52% ± 17% (P = .018) in the continuous-suture group when normalized by the reference value (C_{ref}), there was only a significant C_{rise} of 42% ± 27% (P = .030) in the interrupted-suture group but no significant loss in compliance. In the case of clipped anastomoses, both C_{rise} and C_{loss} were not significantly different when normalized by C_{ref} (P = .15 and .057, respectively).

The total compliance mismatch (C_{tot}) was similar when calculated for proximal and distal sites of an anastomosis. However, the absolute value of C_{tot} in both the clip and interrupted-suture groups was similar (P = .513) but significantly less than that for continuous sutures (P < .05).

Macroscopic findings of the luminal surface of explanted anastomoses demonstrated good intimal apposition and no exposed foreign material in the clipped group. However, suture material associated with thrombus is clearly seen in the other two groups (Fig 6). Furthermore, although no fibrin, vessel wall thrombus, or intimal injury was noted in specimens from the clipped group with ESEM, these were noted around suture material and areas of intimal damage in the other two groups, particularly at the point of penetration through the intima (Fig 7).

DISCUSSION

Creation of an anastomosis affects the compliance at both the suture line and regions proximal and distal to this anastomosis.[3] Although loss of compliance at an anastomosis is of great importance, the PHZ augments any existing compliance mismatch and invariably leads to abnormal stress and strain development within the arterial wall.[5] A finite element analysis of vascular wall mechanics demonstrated an eightfold elevation in stress concentration at the suture line when compared with native vessel in an end-to-end anastomosis, despite the use of a graft with an ideal compliance match.[20] The resulting change in vessel wall elasticity greatly affects propagation of pressure pulse waves along a blood vessel and ultimately alters the blood flow velocity profile, producing areas of flow separation and turbulence.[21-23] This in turn affects wall shear stress,

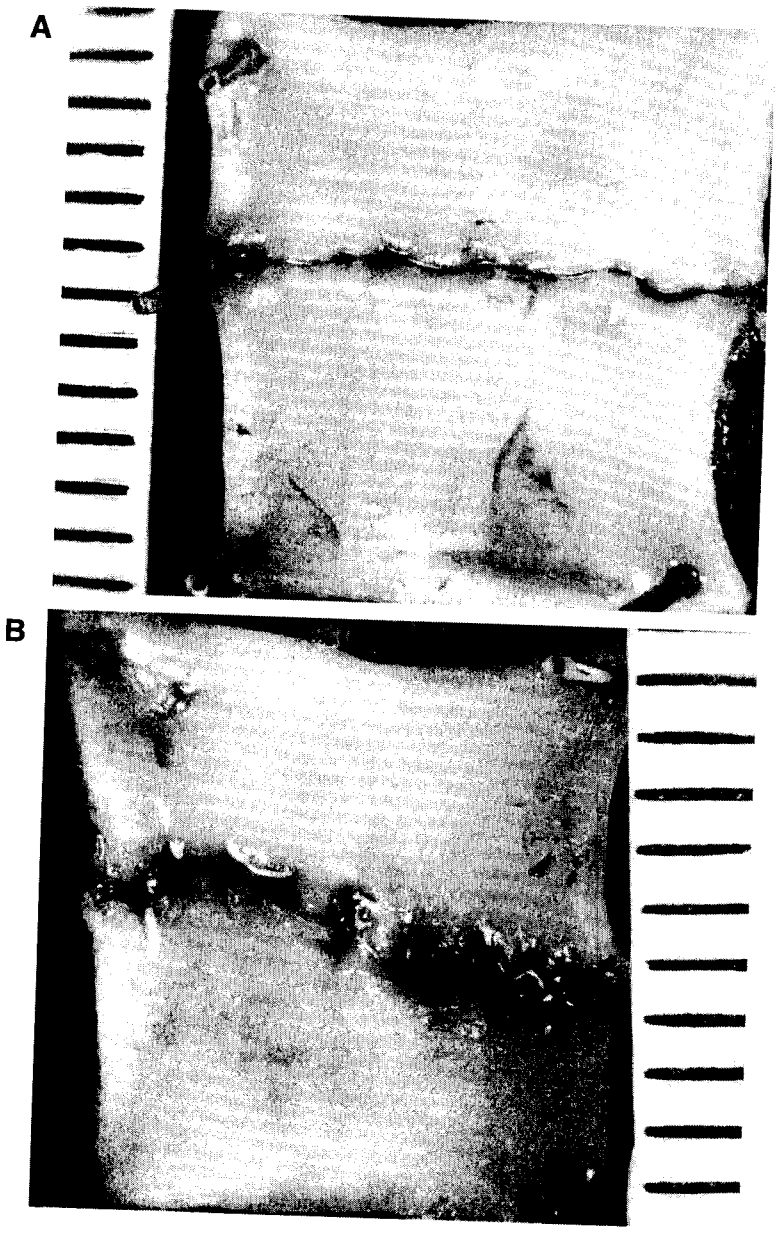

Fig 6. View of luminal surface of explanted clipped **(A)** and interrupted-sutured **(B)** anastomoses. No intimal penetration was observed when clips were used. However, fibrin and thrombus were seen around sutures.

a factor that is known to modify the biological response of an endothelial layer.[24] Furthermore, the presence of PHZs is thought to be responsible for IH development, through increased cyclical stretching of arterial wall within this region, a process known to stimulate the activity of cultured smooth muscle cells.[11,24]

In this study we have shown that all three types of anastomoses produce a compliance drop at the anastomotic line and were associated with both proximal and distal PHZs. However, there was significantly less compliance loss at the anastomosis with clips or interrupted sutures when compared with continuous sutures. Furthermore, both clipped and interrupted-sutured anastomoses resulted in better para-anastomotic compliance profiles with significantly less mismatch than those with continuous sutures. However, it was not possible to infer any significant difference between compliance profiles of interrupted-sutured and clipped groups. These results, in part, confirm earlier studies that demonstrated improved compliance profiles with interrupted sutures compared

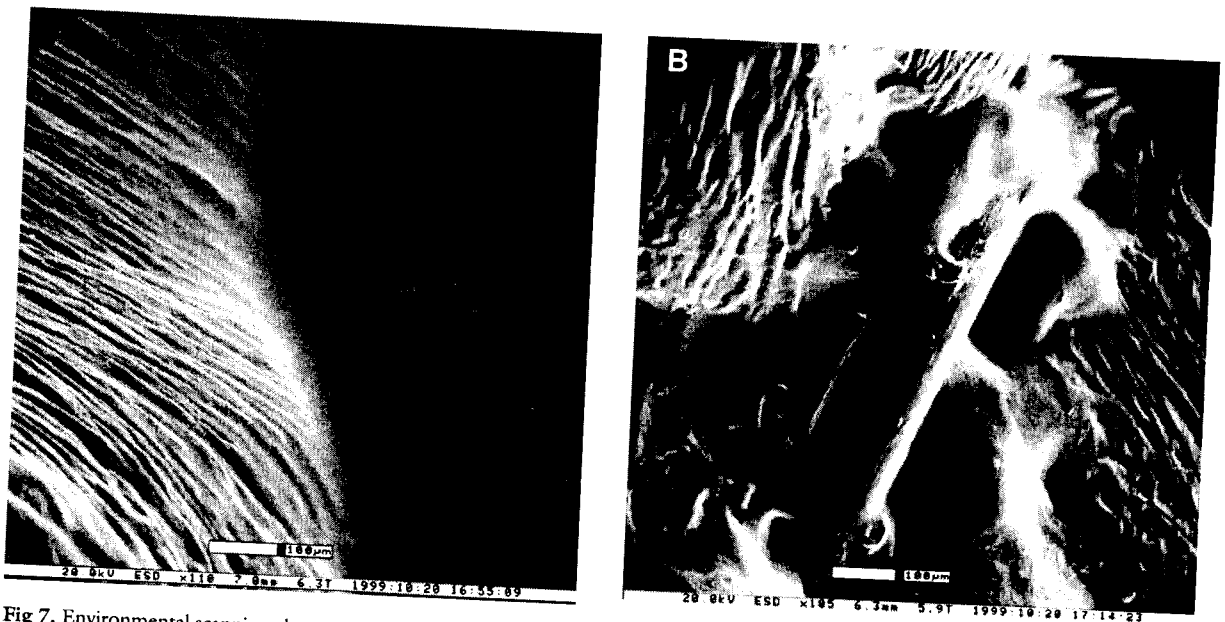

Fig 7. Environmental scanning electron micrographs (original magnification, ×100) of luminal surface of explanted clipped (**A**) and sutured (**B**) anastomoses. Good intimal apposition was noted with clips, whereas intimal damage and fibrin were seen around exposed sutures.

with continuous sutures.[4,17] Nevertheless, despite these previous reports, interrupted-sutured techniques are not widely practiced by vascular surgeons because they are time-consuming. However, our results are in agreement with other workers in this field, in that considerably less time is required to construct anastomoses with clips than with conventional polypropylene sutures.[16,25,26]

Although it is unclear whether the degree of compliance mismatch determines the extent of IH that develops, improved blood flow profiles certainly enhance endothelial cell function in vitro.[27] Anastomotic IH is a result of a failure of host tissues to heal in a regulated fashion and is multifactorial in etiology. Although earlier studies in which silver nonpenetrating clips were used demonstrated significant perivascular and suture-line fibrosis, the current titanium system has been shown to result in minimal reactive changes with virtually no inflammation in the vessel wall.[28] In this study we observed that standard sutured techniques penetrate all layers of the vessel wall causing intimal damage and leaving potentially thrombogenic material exposed to blood flow; nonpenetrating clips demonstrated minimal intimal injury and produce anastomoses with good intimal apposition for healing. There are now a few reports demonstrating that healing of anastomoses with nonpenetrating arcuate-legged clips is similar if not better than that with sutures.[16,28-30] In a study in which clip and standard suture closure of iliac arteriotomies and venotomies in a porcine model was compared, Leppaniemi et al[28] demonstrated no significant difference in intimal thickness or intima-to-media height ratios among vessels closed with clips or sutures at 3 months. More recently, a canine model study of a femoral arteriovenous fistula with an expanded polytetrafluoroethylene graft demonstrated improved flow profiles, good intimal apposition, and no perianastomotic hematoma in those access grafts constructed with nonpenetrating clips when compared with those with continuous polypropylene sutures.[25]

Although there are several reports of successful use of nonpenetrating clips in patients, including those undergoing renal access procedures, coronary anastomosis, and carotid endarterectomy,[31-33] they are not widely used for peripheral vascular reconstruction currently. Earlier reluctance to use this technology was based on concerns of intimal dissection in arteries with significant atheromatous disease and also doubts about the strength of this type of anastomosis. Greater familiarity and training in their use may encourage more surgeons to use this technique for vessels with minimal to moderate disease and, particularly, in patients undergoing local endarterectomy. Our finding of improved para-anastomotic compliance profiles and reduced intimal damage with nonpenetrating clips may enhance long-term graft patency by reducing the risk of IH. Furthermore, the results of ongoing studies addressing the issue of compliance profiles in healing anastomoses may increase our understanding of the significance of PHZs in the development of IH.

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Anastomotic devices for coronary artery bypass grafting

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With the advent of off-pump and minimally invasive coronary artery bypass grafting, efforts to facilitate construction of the graft to coronary anastomosis have increased. As a result, a number of anastomotic devices have been developed. While the ideal anastomotic device should be easy to use, produce a geometrically optimal anastomosis with minimal endothelial damage and minimal blood-exposed nonintimal surface, a number of design constraints apply. This review collects the available preclinical and clinical data for some of the devices, with special regard as to surgical outcome, patency rate and the need for additional perioperative anticoagulation treatment.

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One of the first coronary artery bypass grafting (CABG) procedures ever performed was carried out on the beating heart using an anastomotic device. In 1960, Robert Goetz used a Tantalum-Payr cannula, a metal tube, to construct an end-to-end anastomosis between the right internal thoracic artery (ITA) and the right coronary artery, demonstrating the feasibility of performing arterial grafting on the beating heart [1]. Another pioneer in the field of bypass surgery, Vassili Kolesov, not only performed the first left ITA to the left anterior descending (LAD) artery on the beating heart, but also created clip devices for vascular anastomosis in the early 1960s. Due to the widespread introduction of cardiopulmonary bypass, cardioplegic arrest and the use of vein grafts, suturing the anastomosis soon became the gold standard and the interest in anastomotic connectors was lost. While interrupted sutures may avoid purse stringing and provide more compliance at the anastomotic site for practical reasons, running sutures are commonly used in CABG. With the event of off-pump coronary artery bypass grafting (OPCAB) and minimally invasive CABG, efforts to facilitate construction of the graft to coronary anastomosis have increased. A variety of proximal and distal anastomotic connectors have subsequently been developed and evaluated in experimental and clinical trials.

Rationale for use

The rationale to use anastomotic devices instead of sutures for constructing a graft to coronary anastomosis were mainly driven by the development of minimally invasive and off-pump bypass procedures. OPCAB was initially considered more technically challenging due to uncompensated heart motion that made suturing more difficult. Given the limitations of the human operator, in terms of tracking a target in motion, it came as no surprise that in the early era of off-pump surgery, patency rates were inferior to those achievable on the arrested heart [2]. At the same time, surgeons found that exposure of the back wall of the heart caused some hemodynamic impairment and OPCAB was often performed at the cost of incomplete revascularization. It therefore seemed advantageous to limit the time of heart displacement and temporary target vessel occlusion by the use of an anastomotic device. One of the advantages of OPCAB, besides operating without cardiopulmonary bypass, was the fact that aortic clamping was no longer required except for performing the proximal vein graft anastomosis. The potential to avoid the risk of embolization and adverse neurologic outcome that has been associated with aortic clamping (total or partial) triggered the development of proximal anastomotic connectors that could be applied without aortic clamping and minimal aortic manipulation.

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Limited access procedures such as minimally invasive direct coronary artery bypass grafting (MIDCAB) or total endoscopic coronary artery bypass grafting (TECAB), also created the desire for an anastomotic device that would potentially facilitate the performance of an anastomosis under the conditions of space restrictions.

Another trigger for the development of anastomotic devices was the observation that patency rates in bypass grafting rarely approach 100% and that even the most capable surgeons will eventually encounter some anastomotic failures. Although the causes for anastomotic failures are numerous and depend largely on target vessel quality and run-off, graft material and quality, the anticoagulation regimen and a number of patient-related risk factors, technical errors occur. Ideally, an anastomotic device could provide the surgeon with a standardized anastomosis with a defined orifice area and anastomotic quality.

Requirements for an ideal anastomotic device

The requirements for an ideal anastomotic device are listed in BOX 1. Any device that is put into a coronary vessel exposes a foreign material surface to the bloodstream, causes shear stress and initiates an inflammatory response. Finally, neointimal growth will cover the implant leading to a reduction in effective orifice area. A substantial difference to percutaneously placed stent implants is the fact that an anastomotic device is usually placed in a nondiseased area of the target vessel and no dilatation is performed. Thus, as opposed to stenting, coronary injury is lower, and plaque rupture, a strong trigger for intimal hyperplasia and restenosis, does not occur. However, any nonintimal surface can trigger thrombosis and an inflammatory response. Scheltes has performed a systematic analysis of the blood-exposed nonintimal surface (BENIS) area of various anastomotic devices. The BENIS depends on anastomotic orifice size, wall thickness and the size and location of bonding components; ideally it is minimal. According to Scheltes' findings, standard sutured anastomoses contained approximately 1.3 mm^2 BENIS area. The tissue BENIS area (i.e., nonintimal tissue surface area) for anastomotic devices ranged from 0 to 6 mm^2 and total BENIS areas (i.e., sum of tissue BENIS and foreign body surface area) ranged from 0.3 to 80 mm^2. While zero BENIS anastomosis configurations are, in principal, desirable, configurations with greater than 90° arteriotomy edge eversion lead to dangerously high wall stress in the coronary arteriotomy corners [3].

Box 1. Features of an ideal anastomotic device.

Physiologic requirements
- Minimal blood-exposed nonintimal surface area
- Minimal shear stress
- Minimal vessel trauma
- Minimal inflammatory response
- Minimal risk for thrombosis
- Minimal risk for endothelial hyperplasia
- High compliance

Handling requirements
- Applicability to arterial and venous grafts
- Applicability to all target vessel diameters
- Interchangeable proximal/distal sequencing of the anastomosis
- Damage-free deployment mode
- Quick, easy and safe deployment
- Deployment at all angles and in confined spaces
- Easy recovery mode for unsuccessful deployment

Patency requirements
- Patency equal or better to standard hand-sewn anastomosis

Other
- Low cost

Not only the amount of foreign material but also the angle of a graft to coronary connection and the compliance may have an impact on the quality of the anastomosis. The more rigid the anastomosis, the greater the wall stress. An ideal anastomotic device would thus be compliant and allow a favorable angle of insertion. The requirements for pre- and postoperative anticoagulation should ideally not differ from the current standard in CABG surgery (low-dose aspirin pre- and postoperatively).

In terms of handling, the ideal distal device would be applicable to both arterial and venous grafts. Tissue manipulation during deployment must be minimal in order to avoid intimal damage. In order to allow placement in all locations and all quality vessels, the ideal device would come in various sizes in order to accommodate all luminal diameters (up to 5 mm for venous grafts and down to 1 mm for coronary arteries) and would be adaptable enough to be placed in calcified regions or areas with wall irregularities. Easy and fast deployment to limit ischemic time is key to the success of any device. It is of utmost importance that any misdeployed device can be safely recovered without collateral damage to the coronary artery. Following removal of a device, conventional suturing should still be possible at the same site. For use in limited access surgery, delivery systems should be available that allow deployment in confined spaces.

Ultimately, any anastomotic device has to have the same or better patency as a standard hand-sewn anastomosis (FIGURE 1). The reported patency rates for both arterial and venous grafts vary substantially due to a number of factors influencing all graft patency. For saphenous vein grafts the early patency largely depends on the quality of distal bed, diameter of the grafted vessel and lack of antiaggregant treatment. In the Grupo Espanol para el Suguimiento del Injerto Coronario (GESIC) study group, the early occlusion rate (<28 days) ranged from 3.5% (LAD coronary artery, good distal vessel [2 mm] and antiaggregant treatment) to 63.1% (right coronary artery or left circumflex coronary artery, poor distal vessel [1 mm] and no antiaggregant treatment) [4]. At 1 year, the overall patency rate for saphenous vein grafts ranges from 80 to 85% and at 10 years, patency is in the range of 50 to 60%. For the ITA to LAD CABG, early graft patency (≤1 month) ranges from 94 to 99%. Late graft patency (up to

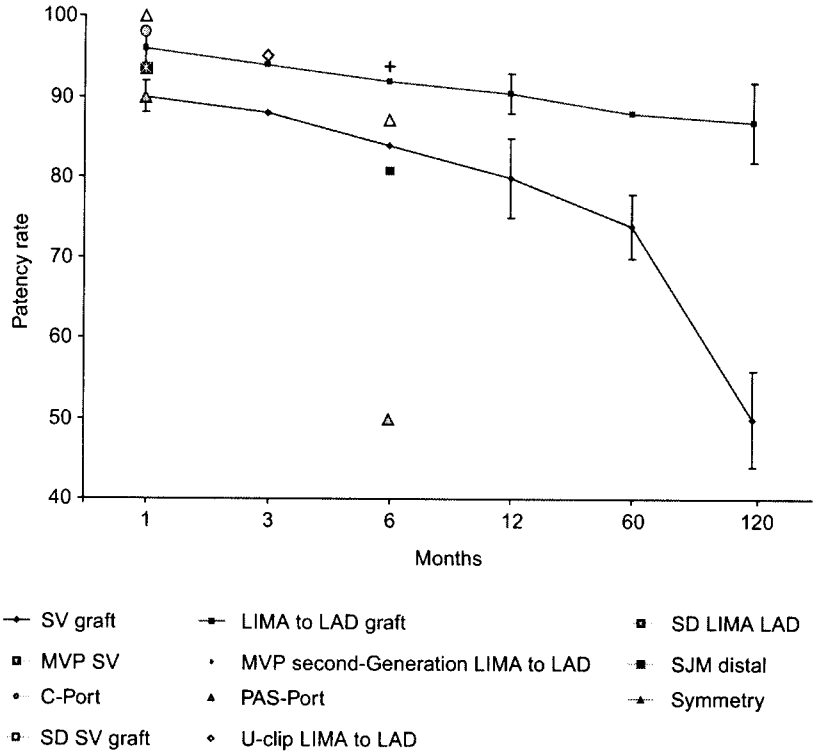

Figure 1. Standard patency rates of saphenous vein and internal thoracic artery bypass grafts as compared with patency rates from reported data for anastomotic devices.
LAD: Left anterior descending; LIMA: Left internal mammary artery; MVP: Magnetic Vascular Positioner; SJM: St Jude Medical; SV: Saphenous vein.

15 years) is in the range of 70 to 98%. Left internal mammary artery (LIMA) graft patency in MIDCAB demonstrated an early graft patency rate of 91 and 99% [5].

While early patency is clearly influenced by the quality of the anastomosis, late graft failure is usually the result of progression coronary artery disease and atherosclerotic degeneration of vein grafts. Anastomotic healing and endothelial overgrowth of foreign material is considered complete after 3 months. Angiographic follow-up at 6 months is therefore considered to accurately reflect patency rates of anastomotic devices.

Proximal anastomotic devices

The development of proximal anastomotic devices was triggered by the event of OPCAB. Since clamping of the aorta was no longer required to induce cardioplegic arrest, the next logical step was to avoid manipulation of the aorta altogether by inserting vein grafts into the ascending aorta without partial clamping, known for its potential for atherosclerotic embolization. Most proximal connector designs are based on expandable stents that connect the graft to the aorta without the need for aortic clamping.

Symmetry™

The Symmetry™ Aortic Connector System from St Jude Medical (SJM, MN, USA) uses a nitinol stent to connect the vein graft to the aorta. The saphenous vein is placed over a transfer sheet and loaded onto the delivery system, which is selected according to graft diameter. The hooks of the connector penetrate the wall of the proximal (aortic) end of the graft to prevent graft dislocation. After creating an aortal hole using a rotating blade, the actual delivery is performed. This process can be accomplished in a few seconds. Due to the design of the device, the proximal anastomosis has to be performed first and comes off the aorta in a 90° angle. Initially, this design purposefully resembles the take-off of the native coronary arteries out of the aortic root. The CE Mark, a US Food and Drug Administration (FDA) approval, was issued in May 2001 and according to the manufacturer more than 80,000 devices have been implanted worldwide. With more widespread use, some conflicting reports concerning patency results were documented in the literature. In one study, intraoperative graft patency did not differ between the connector (n = 23) and hand-sewn group (n = 23). Graft patency decreased to 50% in the Symmetry group, compared with 90% in the suture group at 3–5 months angiographic follow-up. Another 25% of the Symmetry grafts were found to have significant stenosis in the connector, resulting in what the authors felt was an unacceptably low intermediate result [6]. In another study, 1-year follow-up for major adverse cardiac events (MACEs), of 162 patients who received at least one Symmetry device, was compared with a hand-sewn control group. Patients with connectors demonstrated an accelerated number of MACEs, resulting in an increased requirement for early repeat target vessel revascularization. The MACE rate increased 180 days from the time of surgery and stabilized at approximately 300 days; this particularly affected noninsulin-dependent diabetics [7]. Carrel found a 38% (five out of 13) incidence of stenosis in the proximal vein graft segment with the connector [8]. In an additional study, 131 out of 144 proximal vein graft anastomoses were performed in 74 patients. In 11 patients that were readmitted with unstable angina after a mean of 173 ± 39 days, angiography demonstrated severe stenosis (n = 12) or occlusion (n = 6) in 20 saphenous vein bypass grafts containing 19 connectors [9]. Anecdotal reports also indicate the risk for aortic dissection, which was 1.9% in one series [10] and acute ostial thrombosis by the use of the Symmetry device [11]. The FDA also filed reports of early device disconnection.

Design changes have subsequently been initiated, with a similar deployment mode as for the SJM distal device (see below), avoiding manipulations in the vein graft during loading and avoiding the 90° take-off angle by creating a side-to-side anastomosis.

While initial results appeared promising, and despite the fact that the device may still have some good indications, SJM has declared the cessation of their anastomotic device business in the meantime.

PAS-Port

The PAS-Port System by Cardica is a one-shot device for proximal vein graft anastomosis to the aorta. It can be used for grafts of a diameter ranging from 4 to 6 mm. For loading of the graft, the vein is pulled through the stainless steel implant and then manually everted over the end with the help of a poke-through tool; the everted vein is then attached to the implant. The deployment tool is placed on the aorta and the anastomosis is completed by a rotational movement at the end of the device. As with the Symmetry device, the proximal anastomosis has to be performed and the take-off angle is also 90°. Due to its design, there is no direct contact of the device within the bloodstream, thus minimizing BENIS.

The results of a multicenter trial with the first-generation device were promising. The clinical trial included 55 patients undergoing elective CABG. Five patients were excluded due to inadequate vein size (n = 4) or consent withdrawal (n = 1). Finally, 47 out of the 55 patients enrolled had at least one anastomosis successfully completed. Five implants had to be removed (one due to accidental damage and four due to leakage). In total, 47 patients received 50 implants. Based on an intention to treat, the primary implant rate was 78%. Veins from 3.8 to 6 mm were successfully utilized (mean = 4.8 mm). There were no implant-related adverse events. Predischarge angiographic follow-up in 46 patients (49 implants evaluated; 98% complete follow-up) showed all grafts to be patent (100% early patency rate). At 3 months, postoperative stress electrocardiogram (ECG) demonstrated signs of myocardial ischemia in one out of 45 patients. At 6-months follow-up there was no mortality or implant-related severe adverse events. Patency assessment was possible for 47 implants by either angiogram (n = 42) or magnetic resonance imaging (MRI, n = 5). The overall PAS-Port graft patency at 6 months was 87.2% and thus similar to hand-sewn vein grafts. At 2 years, two patients had died of implant-unrelated causes. Of the remaining 45 patients, 42 completed the follow-up (93%) and there were no implant-related MACEs, the resting ECGs were free of new postoperative myocardial infarcts (MI). One patient showed signs of stress-induced ischemia that was not believed to be implant related [12,45].

CorLink™

The CorLink™ automated aortic anastomotic system (Cardiovations, NJ, USA) is a self-expanding nitinol extraluminal device. The graft is pulled through the inserter and then everted over the distal end of the delivery system. The everted segment of the vein is penetrated by five intimal pins that are deployed from the cartridge of the delivery system. A hole in the aorta is created by a punching instrument that is inserted through the handle of the delivery system. Thus, as opposed to the Symmetry, this device provides the arteriotomy device and the connector through the same delivery device. After the aortic punching device is withdrawn from the handle, the delivery system is advanced into the aorta and the connector is released. The connection is made by partial penetration of the aortic wall by the inner pins, while the outer pins stabilize the graft externally to the aortic adventitia. Only limited data regarding the device are available. In an initial sheep model, delivery proved to be safe and effective. However, the patency rate at autopsy was 71% and intimal thickening was found in 44.7% of the anastomoses [13]. In one clinical trial, the device was implanted in 17 sheep with no mortality or device-related morbidity. At a mean follow-up of 48 days, patency was demonstrated by angiography in six patients [14]. In another prospective and randomized study, a total of 13 CorLink anastomoses were performed in 11 patients. In two patients, additional sutures were necessary to control anastomotic leakage. In one additional patient, eversion of the vein graft was not possible. Multislice computed tomography (CT) demonstrated patency of 12 out of 13 grafts at 6 months. In the hand-sewn control group, all 15 study vessels were demonstrated to be patent [15]. In a cadaver model, the CorLink device was successfully deployed endoscopically in total endoscopic multivessel revascularization procedures using the da Vinci™ telemanipulation system [16], demonstrating the potential benefit of a proximal anastomotic connector in limited access surgery.

Distal anastomotic devices

The search for an ideal anastomotic device for performing a distal graft to coronary anastomosis has led to hundreds of different designs, employing a variety of different materials, clips, clamps, staplers, stents and tubes. In a recent review, Scheltes identified 57 truly new applications for the distal coronary anastomosis, which were categorized into 11 types according to the anastomosis configurations [3].

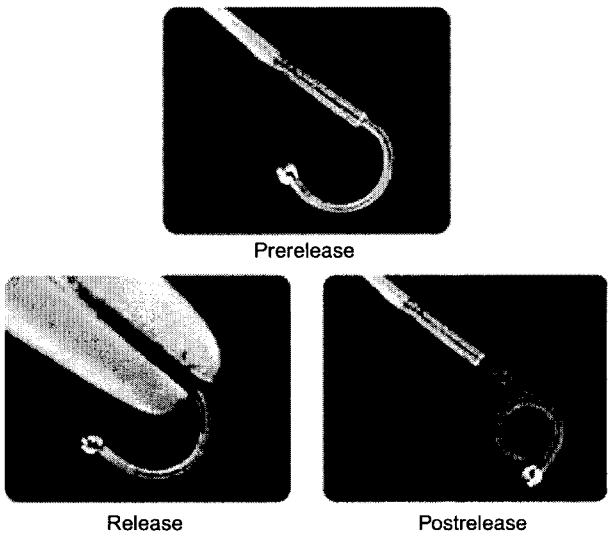

Figure 2. U-clips.

U-Clips

Interrupted suture techniques are known to provide excellent anastomotic quality. Time constraints and additional technical complexity, however, have prevented broad adaptation of the interrupted suturing technique in CABG surgery. The U-Clip™ (Coalescent Surgical, CA, USA) offers the advantage of an interrupted suture, while avoiding the additional workload of extensive knot tying. The U-clip is a self-closing nitinol clip that is attached to a suture needle. The needle is passed through the graft and coronary artery in a conventional manner. As soon as it is pulled through, the clip is released, changing its initial U-configuration to a close-loop configuration (FIGURE 2). In general, 12 to 16 clips are used to construct a coronary anastomosis. No knot tying is required. The potential benefits of an interrupted anastomosis have again been demonstrated using the clip. The interrupted anastomoses created with the Coalescent U-Clip anastomotic device demonstrated significantly better anastomotic compliance, pulsatility index, peak flow and percentage of diastolic flow. The cross-sectional area was improved, degree of luminal deformity was less and endothelial preservation improved as compared with hand-sewn anastomoses [17–19]. It remains to be seen whether these findings will affect long-term patency. Anastomotic times are less than with a hand-sewn anastomosis [20].

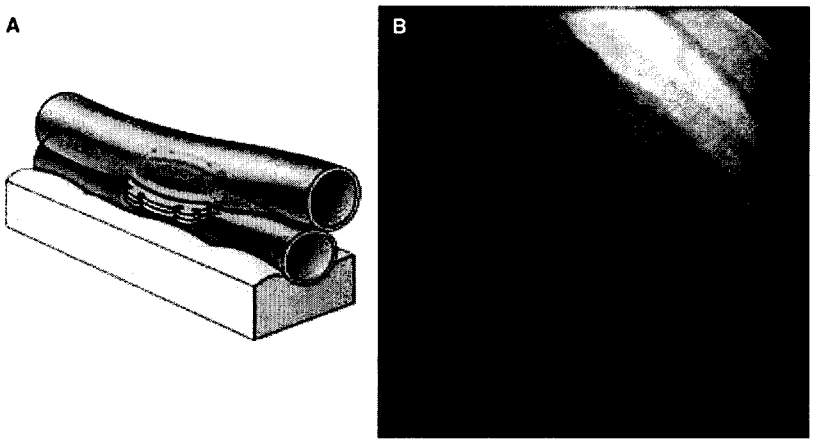

Figure 3. Magnetic vascular positioner. (A) Schematic illustration. **(B)** Typical angiogram demonstrating patent left internal thoracic artery to left anterior descending graft at 6-months follow-up.

The device has been extensively used clinically and the reported patency results are favorable. In a prospective, nonrandomized multicenter trial, left ITA to LAD artery anastomoses were performed in 60 off-pump coronary artery bypasses (73%), 12 conventional CABG (15%) and ten minimally invasive direct coronary artery bypass (12%) procedures. At a follow-up of 64 to 383 days, qualitative and quantitative angiographic assessment was available in 77% of the patients. Patency was rated Fitzgibbon grade A in 95.2% and grade B in 4.8% of the patients. Quantitative analysis (n = 57) showed a mean lumen diameter of left ITA proximal to the anastomosis of 2.1 mm, at anastomosis of 2 mm and in the LAD artery distal to the anastomosis of 1.9 mm. The average ratio of the anastomosis to the LAD artery diameter was 1.14 (0.45 to 1.93), yielding an anastomotic stenosis (calculated as a percentage of average left ITA to LAD artery diameter) of -2.3% [21]. As suturing is considered technically challenging in a closed-chest environment, the U-clips have also being used in a number of patients for TECAB [22]. More recently, U-clips have also been used for creating proximal anastomosis.

Magnetic Vascular Positioner

The first generation of the Magnetic Vascular Positioner (MVP™) System (Ventrica, Inc., CA, USA) consisted of two pairs of elliptically shaped, gold-plated magnets with an orifice area of 8.1 mm^2. One pair of implants is placed into a 5-mm longitudinal incision near the end of a ligated graft vessel to create an anastomotic port. One magnetic implant is placed within the graft lumen at the incisional site (intravascular magnetic implant). The extravascular magnetic implant is placed on the external surface of the vessel and is held in place by magnetic attraction, thus creating an elliptically shaped anastomotic port. The second pair of magnetic implants forms an identical port in the coronary artery. The two ports are then connected by magnetic attraction and form a side-to-side anastomosis (functional end-to-side) (FIGURE 3). Animal data demonstrated excellent patency at mid-term follow-up and complete anastomotic healing [23].

An initial multicenter trial included 41 patients. The MVP device was successfully implanted in 32 out of 41 cases (78%). In nine cases, the MVP device could not be placed due to inappropriate coronary diameter (n = 4) or posterior wall plaque (n = 1). In three patients, the MVP had to be removed after coupling for incomplete hemostasis. The anastomotic time ranged from 65 to 370 s. Predischarge angiograms demonstrated an overall patency rate of 93.5% versus 91.7% in hand-sewn grafts. For the ITA grafts (n = 9), early patency was 100%. Notably, there was a 9.3% rethoracotomy rate for bleeding that was attributed to the anticoagulant requirements (pre- and perioperative administration of ASS and clopidogrel) [24]. The design was changed in order to minimize the BENIS and enhance hemostasis by splitting the extravascular magnets and placing two pieces lateral to the intravascular implants. A second multicenter trial was performed using this second-generation device in ITA grafts to the LAD exclusively. The 6-month angiographic return rate of eligible patients was 88.8% (48 out of 54). The patency rate was 93.8% (45 out of 48) and repeat target vessel revascularization by percutaneous coronary intervention (PCI) was 4.2% [UNPUBLISHED DATA].

The device has been used in MIDCAB, with a mean anastomotic time of 199 s and 100% 6-month patency (n = 8) [24,25], as well as in multivessel OPCAB procedures [26]. A prototype

delivery system also allowed use of the device for experimental TECAB in a canine model. TECAB on the beating heart was performed in dogs with the da Vinci telemanipulation system. The procedure was performed off-pump endoscopically using robotic instruments to guide and place the magnetic clips. The combination of robotic technology allowing for dexterous manipulation in a closed-chest environment and a simple yet effective and time-saving technique for anastomotic coupling greatly facilitated beating heart TECAB [27].

Heartflo™

The Heartflo™ anastomotic device (Perclose/Abbott Labs, CA, USA) automates the suturing process with simultaneous delivery of ten standard polypropylene sutures that are placed through the graft and the coronary vessel wall to construct the anastomosis. All sutures have to be tied manually after deployment. One study of 60 patients has been reported. In the first 30 patients, automated anastomoses could be completed in 16 patients (53%) using 1.7 ± 1 additional stitches. Following device modification, procedural success in the next 30 patients was improved (86% deployment rate) with a mean of 1.2 ± 1 additional stitches for achieving hemostasis. Anastomotic times were prolonged compared with conventional suturing (19 ± 3 min in the first 30 patients and 15.6 ± 2 min in the second group). Angiographic data regarding patency are not available and the device is not currently available [30]. Another series demonstrated similar results with a mean anastomotic time of 17.7 ± 2 min. All anastomoses (n = 13) required additional stitches to achieve hemostasis and two were converted to a hand-sewn anastomosis. Again, no angiographic patency data were presented [31]. Due to these technical limitations and no obvious benefit, the Heartflo device is currently not in use.

SJM Distal Connector

The stainless steel clip system of SJM is mounted on a catheter that is inserted through the distal end of the graft. Once the graft is perforated and loaded onto the catheter, an incision is made in the target coronary artery and the catheter introduced through the incision. The clip is deployed by means of balloon inflation, effectively connecting the graft with the coronary by a side-to-side anastomosis. The catheter is withdrawn through the open distal end, after which the graft is clipped distal to the anastomosis (FIGURE 4). Initial animal data demonstrated promising results with 100% patency in a chronic canine model after a minimum of 30 (n = 8), 90 (n = 5) and 180 days (n = 5). In the off-pump feasibility study, total grafting time including loading and deployment was 10.5 ± 2.5 min [30,31].

In a clinical study that enrolled 45 patients, the device was deployed in 32 patients (2.5 mm size [n = 14] and 2 mm size [n = 18]), mainly in the right coronary and obtuse marginal branches. Perfect hemostasis was obtained in 28 patients. Three connectors were removed due to minor leakage at the connection site and one connector was removed because of mismanipulation after successful deployment. Intraoperative flow was assessed by transit time Doppler and averaged 71 ± 24 ml/min. There was one death (patent connector confirmed at autopsy) and one perioperative MI. There were no adverse cardiac events in the remaining patients. In total, 35 angiograms were available in 21 patients; after 3 and 6 months, 17 anastomoses were patent and four were occluded, yielding a patency rate of 81% [32-34]. Despite some advantages of the flexible catheter-based design that allowed performance of the anastomosis off-pump, without the need for temporary target vessel occlusion, the device did not receive CE Mark and is no longer available.

C-Port

The C-Port™ (Cardica, CA, USA) device integrates all of the necessary functions in one tool, to enable rapid automated distal coronary anastomosis. A compliant, angled, end-to-side anastomosis is performed by automatically placing eight individual clips and creating an arteriotomy with the push of a button (FIGURE 5). In a multicenter study, the safety and efficacy of the system were evaluated. A total of 111 C-Port devices were deployed in 107 patients. Deployments were technically successful in 100 cases (90%). Incomplete anastomosis occurred due to tissue interference (n = 5) or severe coronary artery disease (n = 6). Three devices were removed due to inadequate blood flow and were replaced with hand-sewn anastomosis with no improvement in perfusion. An individual stitch was required at the toe and heel of the anastomosis in the majority of cases. Three patients died of causes unrelated to the device. There were no device-related adverse events. The average flow through the index graft was 45 ± 27 ml/min. Graft patency at discharge was 98% (80 out of 82 analyzed grafts patent) [35]; 6-month follow-up data are pending.

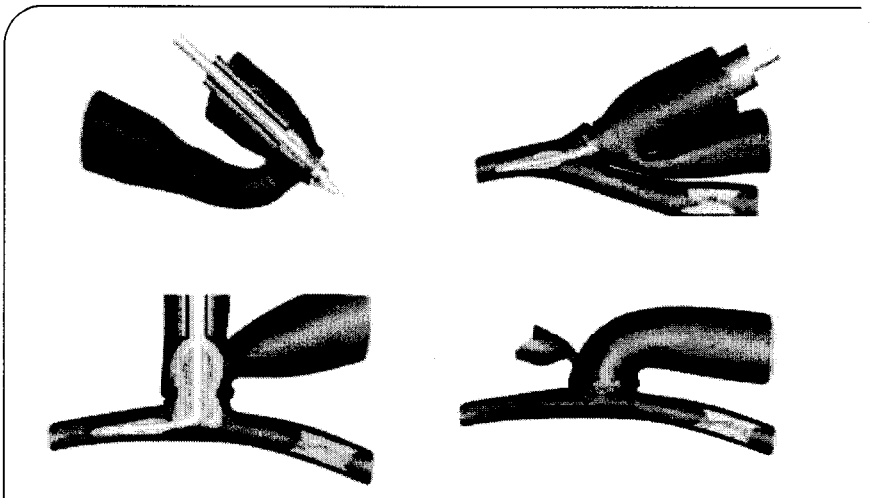

Figure 4. St Jude Medical distal anastomotic connector. Steps of deployment.

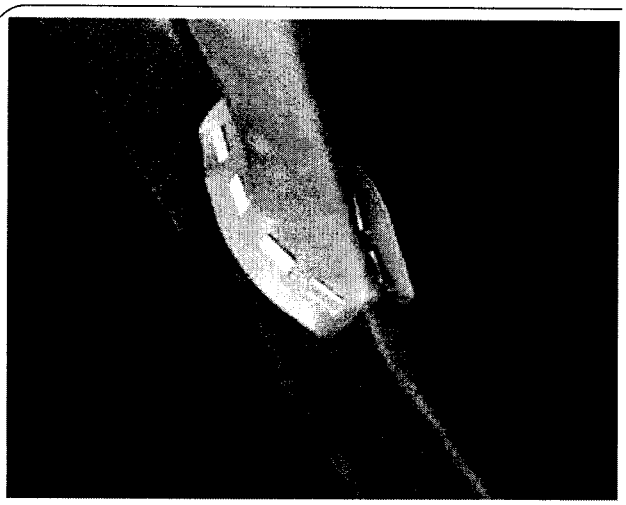

Figure 5. C-Port distal connector.

S2-Device

The S2 Anastomotic System (iiTech BV, The Netherlands) is a one-shot distal anastomotic device that uses staple-like elements to construct the anastomosis. In an animal study (ten pigs) an ITA to LAD bypass was created on the beating heart. The graft-loading and coronary ischemia time were 1.2 ± 0.3 min and 3.0 ± 0.6 min, respectively. No technical failures or anastomotic leaks requiring additional sutures were reported. At 5 weeks, post mortem angiography demonstrated 100% Fitzgibbon grade A patency. Macroscopic evaluation revealed an anastomotic orifice of 2 mm and negligible neointimal covering of the connector was found at histomorphologic evaluation [36]. Clinical data are not yet available.

Converge

The Converge device is a stent/clip-based system that constructs an atraumatic distal end-to-side vein graft to coronary anastomosis at an angle of 30° (FIGURE 6). Currently, clinical experience is limited to on-pump cases and large vessels (>2 mm). At the 2003 ISMICS meeting, data were presented on 27 patients, 17 of which had the device implanted [45]. After a follow-up of 60 days, patency was confirmed in 16 out of 17 grafts.

Discussion

OPCAB and limited access coronary bypass surgery have renewed the interest in anastomotic devices. Proximal connectors were introduced to avoid aortic clamping and thus potentially minimize the risk of neurologic injury following OPCAB. Although some devices entered clinical trials, only the Symmetry device was finally implanted in a large cohort of patients. Early reports indicated the feasibility and safety of using the device and some found a reduction in the rate of microembolism when using the device [38]; this was not confirmed by others [39]. While initially there was great enthusiasm, reports of early graft stenosis and occlusion finally led to the withdrawal of the device from the market [40–42]. All other proximal devices have been used by too few numbers to derive any scientific conclusion. Patency data are sparse and no large randomized trials have been reported. However, some lessons have been learned. Manipulation of the graft that may occur with loading may cause endothelial injury, which may be a critical event for the development of anastomotic stenosis. A 90° take-off angle requires careful planning of graft positioning to avoid kinking. Similar to stents, intraluminal exposure of metal may cause thrombus formation, raising the question of appropriate anticoagulant treatment when using anastomotic devices. Probably the best alternative in order to avoid any aortic manipulation and ensure long-term graft patency is the exclusive use of arterial grafts including both ITAs and radial artery T-grafts.

The situation for distal devices is similar. BOX 2 lists the potential advantages and disadvantages of distal devices. In terms of ease of handling, some devices such as the MVP demonstrate a clear advantage over suturing and their potential benefit in limited access surgery is evident. However, this must be weighed against the additional costs that are usually not reimbursed, at least in most European countries. Most trials that have been reported include less than 100 patients. Since no guidelines exist regarding how to define the procedural success, it is unknown for most devices how many patients were screened and how many were preoperatively or intraoperatively excluded from the various studies. Thus, the number of patients that were actually included in a clinical trial based on an intention-to-treat may be completely different from the number of patients that finally received the device. In most studies only target vessels of 2 mm or larger and with absent or minimal distal disease were chosen. It is well known that patency rates in these vessels should be superior to the average patency rate of all grafts to all territories. Without clear definitions, patency rates may not therefore be compared with historic controls of hand-sewn anastomoses. Regarding anticoagulant treatment, most devices required only

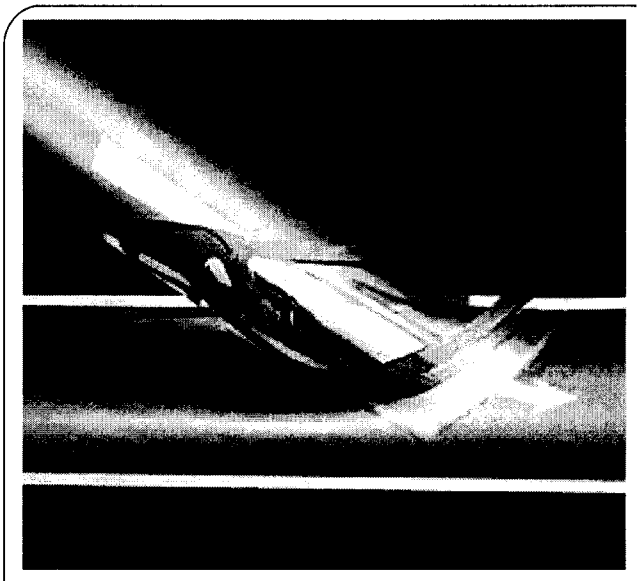

Figure 6. Converge distal connector.

Box 2. Potential advantages and disadvantages of anastomotic devices.

Potential advantages
- Time saving (decrease in ischemic time/coronary occlusion)
- Facilitate limited access surgery
- Facilitate off-pump coronary artery bypass grafting surgery
- Standardized anastomosis (predetermined orifice area)
- Avoidance of aortic clamping (for proximal devices)

Potential disadvantages
- Compliance mismatch at anastomotic site
- Fixed angle of graft
- Potential of vessel injury
- Neointimal proliferation
- Limited applicability in diseased and small vessels
- Need for extensive perioperative anticoagulation
- Costs

standard postoperative application of low-dose aspirin, which is also the standard in conventional CABG surgery. Only the MVP protocol required preoperative loading with clopidogrel and aspirin, both of which were continued postoperatively. It came as no surprise that bleeding complications were higher than with the regular protocol. Follow-up of most trials is usually limited to only 6 months or 1 year at the most (TABLE 1). Although it is believed that by 6 months the healing process in the anastomotic area is complete, long-term data are still required to allow a thorough assessment of any device put into the coronary circulation. The concept of BENIS is interesting but not commonly applied. A comparison between different devices is therefore difficult. Uncertainty exists concerning the best animal model, the number of animals and the duration of chronic models to test potential devices. Usually, devices are placed in healthy coronary arteries and the coronary is tied-off proximal to the anastomosis. Under these circumstances, with no atherosclerosis present and absence of competitive flow through the native graft, conditions for the device are optimal but far from reality. Preclinical evaluation is therefore only of limited value. Clearly, a standardized animal model is needed for comparison of results for different devices. Likewise, uniform guidelines defining intention to treat, inclusion and exclusion criteria, selection of target vessels, technical failures and follow-up periods should be developed.

The question of appropriate trial design has been addressed by the FDA in their March 2004 Circulatory System Devices Advisory Panel Meeting [44]. According to the FDA, most clinical trials lack important information. Denominator information is not usually submitted, adverse events are underreported and presentation of results is often biased. Therefore, no recommendation regarding the safety of the devices can be derived from the few published data. For future trials, the panel recommended 6 months of angiographic follow-up as a requirement to determine patency as an end point, regardless of graft type. After 6 months, not all stenoses but graft failure would be evident. For determining intermediate patency multislice CT or MRI were regarded appropriate. Some studies have used CT or MRI for assessing graft patency [43], however, angiography is still considered as the gold standard. With more advanced imaging technology and better results regarding sensitivity and specificity, multidetector CT may become an acceptable alternative to assess graft patency. This would greatly facilitate future trials, as repeat angiography has always been one of the major obstacles for inclusion. According to the panel, clinical follow-up should last for 1 year and patients should be followed thereafter. Postmarket follow-up was regarded important. The debate for randomization is still controversial. If patency data are used to power a randomized trial, these trials will probably be too large to be performed. However, since multiple factors (antiplatelet therapy, target vessel size and location and multiple other patient-related factors) influence graft patency, historic controls may be of limited value. To use patients as their own control (one hand-sewn anastomosis and one with device implant) is also problematic, as the best target will usually be used for the device. While patency is a clear end point, safety is more difficult to assess, as it is difficult to determine whether an adverse event is truly device related for a number of problems (such as aortic dissection and acute thrombosis). The cardiac surgical community should therefore provide clear guidelines regarding how to design future trials that are powerful enough to derive conclusions about patency and safety of a device and at the same time can be realistically performed.

Expert opinion

Anastomotic devices were designed to facilitate OPCAB and limited access bypass procedures. While some devices have been successfully introduced into clinical practice, the ideal design has not yet been discovered. In general, application of the device is safe and recovery procedures for misplacement are usually simple. However, some promising devices have already been taken off the market after reports of a high incidence of anastomotic occlusion or stenosis were published. Although suturing an anastomosis may be far from perfect, it is a very flexible approach that respects wall irregularities and compliance of the target vessel. It allows tailoring of a graft even in the face of graft and target vessel diameter mismatch. Future designs will probably address these requirements. From the reported results of small series, it is currently difficult to derive recommendations regarding the use of anastomotic devices and longer follow-up is required.

Five-year view

With the introduction of drug-eluting stents and the ongoing trend for more percutaneous interventions, CABG is facing new challenges. The total number of procedures is declining and the population that is referred for surgery is in an advanced age and presents with increased comorbidity; a much worse coronary

Table 1. Patency results for various anastomotic devices.

Device	n (implants)	Graft	Follow-up	Patency (%)	Ref.
Proximal devices					
Symmetry	23	SV	3–5 m (A)	50	[6]
Symmetry	43	SV	3 m (A)	81	[42]
PAS-Port	50	SV	6 m (A)	87	[*]
PAS-Port 2nd	60	SV	D c (A)	100	[12]
Cor-Link	11	SV	6 m (MSCT)	92	[15]
Distal devices					
U-clip	92	LIMA	2–13 m (A)	95.2 FG-A 4.8 FG-B	
MVP 1st	23	SV and LIMA	Dc (A)	93.5	[24]
MVP 2nd	48	LIMA	6 m (A)	93.8	[*]
SJM distal	21	SV	3–6 m (A)	81	[32–34]
C-Port	82	SV	Dc (MSCT)	98	[35]

The number of successful implants may vary from the number of patients initially included in the study. Follow-up was not completed for all studies.
* Unpublished data.
A: Angiography; Dc: Discharge; FG: Fitzgibbon classification; LIMA: Left internal thoracic artery; MSCT; Multislice computed tomography; n: Number of successful implants with patency data; SV: Saphenous vein.

status and left ventricular function. However, CABG is set to remain and in times of decreasing budgets, may be a valid alternative to multiple or repeated stent implantations provided that the long-term results remain in favor of bypass surgery. Off-pump surgery with its potential to decrease perioperative morbidity and arterial grafting, which provides better long-term patency, are appropriate answers to this challenge. Patient desire will also continue to drive the search for less invasive methods of bypass grafting. Due to technical challenges, minimal access bypass surgery such as MIDCAB or totally endoscopic approaches such as TECAB have not yet found a widespread clinical application. In this context, an easy to handle anastomotic device may play a major role to further open the minimally invasive bypass surgery market. Clearly, the costs of a device have to reflect budget restrictions and widespread use will only be possible at low costs.

Key issues

- With the event of off-pump and minimally invasive coronary artery bypass grafting, efforts to facilitate construction of the graft to coronary anastomosis have increased. As a result, a number of anastomotic devices have been developed.
- While the ideal anastomotic device should be easy to use, produce a geometrically optimal anastomosis with minimal endothelial damage and minimal blood-exposed nonintimal surface, a number of design constraints apply.
- The reported clinical results vary in terms of patency rates that are equal or better than hand-sewn controls in some studies but less satisfactory in others.
- Anastomotic times can be significantly decreased by applying anastomotic couplers.
- Some safety concerns regarding the proximal connector with the most widespread application have led to withdrawal of the device.
- The search for the ideal anastomotic device is currently ongoing.

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June 7, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

Attention: **CMS-1488—P "Resident Time in Patient Activities"**

Dear Administrator McClellan:

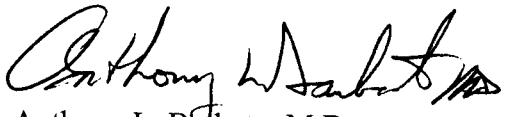
The Loyola University Medical Center welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled "*Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.*" 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the Agency to rescind the purported "clarification" in the proposed rule that excludes medical resident time spent in didactic activities in the calculation of Medicare direct graduate medical education (DGME) and indirect medical education (IME) payments. The stated rationale for the exclusion of time devoted to these activities is that they are not "related to patient care". The proposed rule cites journal clubs, classroom lectures, and seminars as examples of didactic activities that must be excluded when determining the full time equivalent resident counts for all IME payments (regardless of setting), and for DGME payments when the activities occur in a nonhospital setting, such as a physician's office or affiliated medical school.

The proposed rule position is in stark contrast to the Agency's position as recently as 1999, at which time the Director of Acute Care wrote in correspondence that patient care activities should be interpreted broadly to include "scholarly activities, such as educational seminars, classroom lectures ...and presentation of papers and research results to fellow residents, medical students, and faculty." [September 24, 1999 Letter from Tzvi Hefter, Director, Division of Acute Care to Scott McBride, Vinson & Elkins].

We support the Agency's 1999 position. The activities cited are an integral component of the patient care activities engaged in by residents during their residency programs. We urge CMS to withdraw its clarification in the proposed rule relating to the counting of didactic time for purposes of DGME and IME payments and recognize the integral nature of these activities to the patient care experiences of residents during their residency programs.

Sincerely,



Anthony L. Barbato, M.D.
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June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir:

The Metropolitan Chicago Healthcare Council (MCHC) represents 140 hospitals and health systems in metropolitan Chicago and surrounding counties and appreciates the opportunity to comment on behalf of our membership to the recently published *Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates.*

We have carefully reviewed this proposed rule. Our focus is on CMS's proposal NOT to extend the regulation at 42 C.F.R. §412.230(d)(2) (iii) beyond FY2008. This regulation provides a method for a campus of a multi-campus hospital to apply for reclassification to the metropolitan division where the other campuses are located.

Background material is located at the end of this document.

COMMENT ON THE PROPOSED TERMINATION OF REG 412.230(d)(2) (iii):

Without §412.230(d)(2) (iii) a campus of a multi-campus hospital is not permitted to apply for reclassification because it does not have campus-specific wage data. Section 412.230(d)(2)(iii) which applies only to requests submitted for reclassification effective in FY's 2006 through 2008, permits a campus of a multi-campus hospital to submit composite wage date for the entire multi-campus hospital in its application for reclassification. CMS implies that without the special rule a campus of a multi-campus hospital may still apply for reclassification in a group application. CMS states in the Proposed Rule that "for reclassification requests for FY2009 and thereafter, a campus of a multi-campus hospital would be required to obtain a separate provider number in order to provide the required wage data from the CMS hospital wage survey for the average hourly wage comparison in its Medicare Geographic Classification Review Board ("MGCRB") reclassification application.

CMS provides two reasons for proposing the discontinuation of this rule:

1) CMS believes that a campus should be required to use campus specific data
2) This rule was utilized by only one hospital, Highland Park Hospital (HPH), and this campus hospital has since been successfully reclassified with their other campus hospitals in the county in which they are located. Therefore, CMS has concluded that the special rule is no longer needed.

We disagree and respectfully point out that the need for this rule remains. HPH will need to use either campus-specific or hospital-wide data for its next reclassification whether group or individual and there will be no regulatory means to do so. The non-extension of this regulation may cause significant problems for HPH and Evanston Northwestern Healthcare (ENH) *as well as the other Lake County Illinois hospitals.* Moreover, it may cause significant problems for other multi-campus hospitals located nationwide in the future.

For these reasons, we advocate, on behalf of our membership, for CMS to reconsider its proposal and make §412.230 (d) (2) (iii) permanent. Failing that, we urge CMS to consider and release a new rule that allows a campus of a multi-campus hospital to submit hospital-specific wage data on a supplemental form to the multi-campus hospital single cost report *without obtaining a new provider number* and extending §412.230(d)(2)(iii) until FY2012. FY2012 is the earliest FY that a campus could provide the necessary campus-specific data because wage data used for geographic reclassification precedes the payment year by five years.

IMPORTANCE OF MAINTAINING §412.230 (d) (2) (iii)

1) Other multi-campus hospitals may be affected after the next census collection and subsequent changes in Office of Management and Budget (OMB) labor market definitions.

2) Highland Park Hospital will need to request geographical reclassification, whether group or individual, in FY2009

3) Group reclassification by all Lake County IL hospitals will be adversely affected if there is no means for Highland Park Hospital to report either campus-specific or hospital-wide data. Therefore, under "normal reclassification rules" the MGCRB will not have the authority to reclassify the Lake County Illinois hospitals as a group in 2010 because proper data for HPH would be lacking.

PROPOSED SINGLE PROVIDER NUMBER ALTERNATIVE

The Proposed Rule states that if a campus of a multi-campus hospital wants to apply for an individual reclassification, it "would have to obtain a separate provider number AND be treated for Medicare purposes as an independent entity in order to provide wage data for the specific campus." This would prove costly and burdensome for all parties involved:

- Patients of the Evanston Northwestern Healthcare system. Many patients require specialized care that crosses over to another ENH campus. If HPH was mandated to operate under a new provider number, patients would have to be discharged from one campus and admitted to the second. Medical records at the first campus would be closed on discharge and another medical record would have to be established at the second campus. Outpatients would have separate medical records at each campus.

- Evanston Northwestern Healthcare would bear an expensive undertaking to separate HPH campus from a wholly integrated multi-campus hospital. This unnecessary expense could have the unintended impact of raising costs, increasing barriers to clinical and financial information flow and jeopardizing patient care.

- Medicare: Changes to per diem DRG payments, outlier payments and adjustments for direct and indirect medical education for a transferred patient could increase Medicare's costs Additionally the Fiscal Intermediary (FI) would be required to audit an additional cost report, increasing their administrative burden.

ORIGIN OF §412.230(d)(2)(iii) FOR MULTI-CAMPUS HOSPITALS

We believe that this regulation is a fair and appropriate rule. CMS noted in its preamble to the FY2006 IPPS rule, a campus of a multi-campus hospital must already demonstrate a close proximity to the area in which it seeks reclassification. Due to the close proximity, it is "reasonable to speculate that the average hourly wage for an individual campus and the whole hospital are similar because the two (or more) campuses and the whole hospital are operating as a single entity under one Medicare provider number, are under common ownership and control and are clinically and financially integrated. Further, when a campus of a multi-campus hospital is in close proximity to the other campuses there likely is not a wide range of salaries for the same occupational categories within the same institution. These factors are true for HPH and demonstrate the fairness of allowing a campus of a multi-campus hospital to submit the wage data for the entire hospitals as its wage data for reclassification purposes.

CMS also noted two other reasons supporting the special rule for reclassification of a campus of a multi-campus hospital;

1) that the use of the entire hospital's wage data is "practical and administratively feasible for hospitals, CMS and the fiscal intermediaries" and
2) that use of the wage data for the entire multi-campus hospital is consistent with CMS's treatment of multi-campus hospitals for calculating area wage index values, GME, DSH and provider-based rules.

These reasons, previously recognized by CMS support the special rule and continue to support the permanency of that rule.

BACKGROUND

Highland Park Hospital, located in Lake County, Illinois, is one of three campuses operated by ENH, a not-for-profit health system. The three campuses are Highland Park Hospital, located in Lake County, Illinois and Evanston and Glenbrook Hospitals, both located in Cook County, Illinois. Highland Park Hospital merged into ENH effective January 1, 2000, at a time when all three campuses were located in the same wage index area. At the time of the merger, CMS terminated HPH's former provider number and authorized Highland Park Hospital to use the ENH provider number as of the merger date. HPH became a campus of the multi-campus ENH system. All HPH wage data is reported on the single ENH cost report.

As a result of changes made by OMB after the 2000 census and adopted by CMS effective October 1, 2004 for Medicare payment systems, Lake County, Illinois, where Highland Park Hospital is located, was sliced off and paired with more rural Kenosha County, Wisconsin to form the Lake County, Illinois-Kenosha County, Wisconsin Metropolitan Division. All of the other constituent counties that formed the former Chicago statistical area are now in the Chicago Metropolitan Division. After discussions and comments submitted to CMS on behalf of HPH, CMS recognized that the criteria for reclassification of hospitals to another wage area at the time of the adoption of the OMB changes did not address the situation of a single campus of a multi-campus hospital seeking reclassification. The reason for this is that CMS requires a multi-campus hospital to report data for the entire hospital on a single cost report. As a result, there was no wage survey data for the individual campus as was required by § 412.230 of the reclassification regulations. Without hospital specific data, the MGCRB would not reclassify HPH. Recognizing this, CMS promulgated a regulation permitting a campus of a multi-campus hospital to use the average hourly wage of the entire multi-campus hospital system as its appropriate wage data for reclassifications effective in FYs 2006-2008.

The proposed and final rules published in the Federal Register regarding the adoption of this special rule, discussed the possibility of permitting a campus of a multi-campus hospital to submit campus-specific wage data on a manual Worksheet S-3 in a reclassification request. The *final rule rejected* this proposal in favor of a single campus of a multi-campus hospital using multi-campus data.

We appreciate the opportunity to present these comments. If MCHC can be of further assistance, please do not hesitate to contact me at 312-906-6003.

Sincerely,

Daniel T. Yunker
Vice President

cc: Rick Pollack, Executive Vice President, AHA
Kevin Scanlan, president-elect, MCHC

York Hospital
A Not-for-Profit Community
Health Care Center Since 1904.

77

June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates : Hospital Redesignations and Reclassifications

Dear Sir:

York Hospital appreciates the opportunity to comment on the proposed hospital inpatient prospective payment systems for fiscal year (FY) 2007 rates. Our comments are directed to hospital redesignations and reclassifications.

General rules relating to hospital reclassifications are:

- Hospitals must be proximate to the labor market area to which they are seeking reclassification.
- Hospitals must demonstrate characteristics similar to hospitals located in that area.

Hospitals meeting these general rules are allowed to reclassify to other areas for the purpose of using the other area's wage index. We are concerned that hospitals are allowed to use only the "base" wage index of a county to which it may reclassify, with no consideration given to the effects of rural floors or out-migration adjustments. Further, the wage index of the area to which the hospital reclassifies may be affected by the reclassifying hospital's wage data if it is advantageous to the overall area.

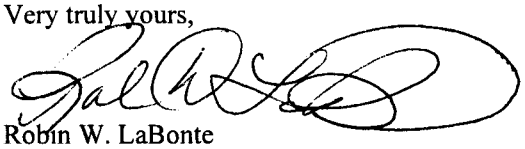
York Hospital firmly believes that the intent of the regulations at 412.230 through 412.280 is to help hospitals who are more like their neighboring hospitals than those in their "home" areas to receive appropriate reimbursement, allowing them to stay competitive with the hospitals in their peer groups, as opposed to those in their physical geographic location.

Because of this intent, York Hospital recommends that, if a hospital is successfully reclassified to another area for purposes of the wage index, it should receive the full wage index for that area. If the area is subject to the rural floor or is eligible for an out-migration adjustment, the reclassified hospital should enjoy this benefit, since it has met the requirement of demonstrating similar characteristics. Only in this manner can the intent of the regulations be fully realized.

Since a reclassifying hospital's wages may help the area to which it reclassifies, it only makes sense to allow it to benefit from the total wage index, not an arbitrary subset. We recommend that the Centers for Medicare and Medicaid Services adopt the use of the actual wage index for reclassified hospitals, including the effects, if any, of out-migration and the rural floor, in order to ensure the true intent of the regulations is realized and in order not to competitively disadvantage hospitals based solely on their geographic location.

York Hospital appreciates the opportunity to comment on this proposed rule. If you have any questions or would like to discuss our comments further, please feel free to contact me at (207) 351-2391 or rlabonte@yorkhospital.com.

Very truly yours,



Robin W. LaBonte
Chief Financial Officer

SSM HEALTH · CARE℠

June 7, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mailstop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Ladies and Gentlemen:

SSM Health Care (SSMHC) joins the American Hospital Association (AHA) and others in applauding the goals of the proposed Medicare Inpatient PPS rule change. We appreciate CMS' work to mitigate the incentive for physicians to refer more lucrative cases to facilities in which they have a financial interest. However, in the proposed rule's current form, SSMHC opposes implementation of the rule on October 1, 2006.

With 20 urban and rural hospitals in four states, SSMHC represents a microcosm of the health care industry. We are very concerned with the mathematical errors identified by the Moran Group in a study of the proposed rule with regard to new DRG weights. Given the sweeping nature of the proposed changes, we strongly believe these concerns need to be addressed and the calculations validated before the rule is imposed. Attempts to retrofit the rule with corrections after implementation will impose enormous costs to hospitals around the country, jeopardizing our ability to serve.

We also have serious concerns in the methodology for the proposed Severity-based Patient Classification System (CS-DRG). A patient needing two hips replaced, for example, is classified the same as one needing a single hip replaced. Obviously, the former is a more complicated case requiring more time, supplies and general care. Given such basic problems with the proposed CS-DRGs, we ask for full careful reconsideration of the methodology.

In summary, we ask for a minimum of a one year delay to provide for further study and refinement before implementation. The proposed rule, as written, puts further pressure on community hospitals degrading our ability to provide quality care to all who come to us.

Faithfully,

William C. Schoenhard

William C. Schoenhard, FACHE
Executive Vice President/COO

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Malcolm Baldrige National Quality Award
2002 Award Recipient

CATHOLIC HEALTH INITIATIVES

Saint Joseph HealthCare

June 8, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Sent Via Overnight Courier

RE: Provider Comments
Proposed Changes to Inpatient PPS (FFY 2007)
File Code CMS-1488-P

To Whom It May Concern:

The comments outlined in this letter are in regard to the Centers for Medicare and Medicaid Services' (CMS) proposed changes to Medicare's inpatient prospective payment system (PPS). The proposed rule was published in the April 25, 2006 Federal Register.

In accordance with the Federal Register notice, CMS is receiving these comments in advance of the June 12, 2006 deadline. Also as required by the Federal Register notice, these comments are being sent in original form, along with two copies.

Provider Background

Saint Joseph HealthCare (SJHC) is a multi-hospital system located in Lexington, Kentucky and is a member of Catholic Health Initiatives, a Denver, Colorado-based national Catholic hospital system. SJHC is composed of three hospitals in Kentucky, two in Lexington and one in Berea. The two in Lexington will be directly impacted by CMS's proposed PPS changes, Saint Joseph Hospital (SJH) and Saint Joseph East (SJE). For over 125 years, SJH has faithfully pursued its mission of reaching out to central and eastern Kentucky, areas synonymous with underserved healthcare needs.

The SJHC primary, secondary and tertiary service area comprises 57 of the 120 counties in Kentucky. The percentage of Kentuckians living in poverty is 14.9%, which is above the national average of 12.5%. Of the 57 counties that SJHC serves 49 have a percentage of the population living in poverty that exceeds the national average. The 20 poorest

Counties in the state are in our secondary or tertiary service area with a percentage of residents living in poverty that exceeds 22.5%. As a Catholic provider our services are provided to persons regardless of their ability to pay. In FY 2005 Charity Care of over 12 million dollars and a below cost subsidy to Medicaid patients of 3.4 million dollars was provided, aside form other direct service programs of care for the poor and disenfranchised. We are committed to serve those dependent upon our geographic reach regardless of ability to pay.

Proposed Regulatory Changes

Based on our understanding of the April 25, 2006 Federal Register, CMS is proposing a two-phase implementation of the changes. First, beginning October 1, 2006, diagnosis related groups (DRGs) would be re-weighted in an effort to reflect hospitals' costs instead of charges. Second, beginning October 1, 2007, the current 526 DRGs would be replaced with a severity-adjusted system of 861 separate DRG classifications, or some other system yet to be determined. The combination of these changes is intended to be fiscally budget-neutral in the aggregate.

Provider Position on the Proposal and its Impact on Provider Service

Saint Joseph HealthCare supports the direction to move Medicare to a cost-based weights system that is severity adjusted, **however the proposed method and most importantly the initiation in October of 2006 would be devastating to the ability of Saint Joseph Hospital (SJH) and Saint Joseph East (SJE) to continue to provide the service to the people of Central and Eastern Kentucky (Appalachian region) that rely upon SJHC for medical services.**

SJH is greatly concerned about the equity of Medicare payments under the proposed rule and we envision an environment where material disparities may exist between a hospital's actual resources expended for treating Medicare patients and the corresponding Medicare payments received. The first phase of the proposal alone represents a reduction of payments to SJHC of approximately 7 million dollars using data from the current fiscal year. Our projections demonstrate that if the proposed weights were overlaid in the current fiscal period the cost of care for our Medicare patients would exceed reimbursement at SJHC. The change to a cost-based weight system must recognize the impact on established not-for-profit providers that have evolved into specialty areas of clinical excellence, upon which large geographic portions of a state are dependent. In the current decade, Saint Joseph Hospital has been honored as being among "America's 50 Best Heart Hospitals" in *U.S. News & World Report*, as well as twice being recognized as a Solucient Top 100 Heart Hospital. Similarly, earlier this year Solucient named Saint Joseph East as one of the nation's 100 Top Hospitals.

The redistribution of Medicare monies as proposed is most significantly a reduction of reimbursement for surgical cardiology. Saint Joseph Hospital is the largest provider of surgical cardiology cases in the State of Kentucky. A significant portion of our inpatients are treated for cardiac conditions that require surgical intervention and are from the counties outside of the five county MSA in which Lexington is situated:

- In 2005 at SJH 21% of discharges (3,634) were MDC 5 Surgical DRGs
- In 2005 at SJE 11.4% of discharges (864) were MDC 5 Surgical DRGs

The most significant people served are from rural Central and Eastern Kentucky, who reside outside of the Lexington – Fayette County MSA and face the challenges of high levels of poverty as identified earlier:

- 66% of the cases served at SJH
- 87% of the cases served at SJE

Saint Joseph Hospital was the first institution in Central Kentucky to offer cardiac catheterization services and open-heart surgery in the 1950s long before Medicare and certainly before prospective payment was instituted as a form of managing care. The service and clinical excellence did not occur recently as the result of a market strategy, but rather developed over time in response to community need in this state.

The 3 major hospital systems in Lexington provide over 50% of the services in each of 8 of the poorest counties in Kentucky (70% or more in 5). Citizens in all but 2 of the poorest 20 counties obtain surgical cardiology services in Lexington. The state of Kentucky is dependent upon 3 institutions for 33% of surgical cardiology and two are in Lexington.

We would ask that the proposed changes in the PPS system be delayed so that unintended negative consequence to institutions like Saint Joseph Hospital and Saint Joseph East, and subsequently to the populations we serve, can be avoided.

Heart Center Institutions Exemptions:

In the event that a system wide change to the PPS is not delayed for further study we would recommend that an exception be constructed to minimize the devastating impact on heart institutes with a proven history of clinical excellence and tertiary cardiology services. To that end ideas such as the following should be considered for inclusion now or in a future proposals:

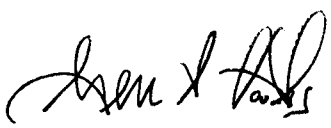
- Geographic population dependence on a few tertiary centers in a given state or region
- Out migration from medically underserved counties or counties with higher than average national poverty rates

- Evidence of Community Benefit & Access for all persons regardless of ability to pay
- Nationally recognized quality performance

We stand ready to work with those charged with evaluating system change that is committed to the CMS principles of reform and to access to specialty services for all our residents regardless of geography or ability to pay.

We further appreciate the opportunity to comment on the proposals and should you have any questions please feel free to contact our executive offices regarding this issue at 859.313.1844.

Sincerely,



Eugene A. Woods, FACHE
President and CEO
Saint Joseph HealthCare

Cc: Senator Mitchell McConnell
Senator Jim Bunning
Representative Ben Chandler

CATHOLIC HEALTH INITIATIVES

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June 12, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1488-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

Catholic Health Initiatives appreciates the opportunity to comment on the proposed rule (CMS-1488-P) that would change the Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2007 Rates. Catholic Health Initiatives is a faith-based health system that includes 70 hospitals, 43 long-term care, assisted-living and residential units, and five community health service organizations in 19 states.

The proposed rule would revise the methodologies used to calculate the relative weights of the Diagnosis Related Groups (DRGs) used to determine Medicare inpatient hospital services payment. The proposal would replace charge-based weights with a modified version of cost-based weights using hospital-specific relative values (HSRVs). The Centers for Medicare and Medicaid Services (CMS) also proposes a major revision to the DRG classification system to account for patient severity.

Adoption of the proposed DRG weight changes and proposed severity adjustments would result in the biggest change to the hospital inpatient prospective payment system (IPPS) since its inception. These changes would significantly redistribute payments among the DRGs and among hospitals.

Catholic Health Initiatives supports improving DRG payments to more accurately reflect resources used in caring for Medicare patients, but it is not clear that the proposed DRG weight changes or new patient classification system will result in a more accurate hospital payment system. Impact estimates at the DRG and hospital level are extremely sensitive to methodological variations. Implementation in FY 2007 would be premature.

We urge CMS to delay these changes, undertake more in-depth analyses of their impact, and evaluate alternative methodologies for improving the DRG system.

While the proposed rule has many provisions impacting our hospitals, we would like to comment specifically on the following issues:

HRSV Weights

Catholic Health Initiatives supports a move to cost-based weights but has several concerns about the adequacy and validity of the proposed methodology. More work is needed to determine the best way to create cost-based weights. If changes are made to DRG weights, those changes should be phased in over three years with "stop loss" protections to allow significantly impacted hospitals time to prepare for payment changes.

In particular, **CMS should further analyze and evaluate the impact of:**

- **Use of 2004 Data** – CMS uses claims data taken from the FY 2004 MedPAR file in its methodology. Clinical practice has changed in many areas, especially cardiology, over the past two years. The data used may not reflect current clinical practice. CMS may need to make specific changes to specific DRGs to reflect the change in clinical practice. For example, interventional cardiology DRGs do not reflect the cost of current clinical practice.

- **Variation in Markups** – The CMS methodology assumes a uniform hospital markup, but markups vary from product to product.

- **Distortion of Costs** – The proposed methodology would distort the accuracy of cost estimates by combining multiple cost centers on hospital cost reports into ten CMS-designated cost center. CMS would then determine ten national average cost-to-charge ratios for each of the designated costs centers but the ratios would not be weighted by each hospital's Medicare charges. This would allow very small hospitals to have just as much of an impact on the national cost-to-charge ratios as larger hospitals.

- **Access to Centers of Excellence** – The proposed changes are particularly significant for large volume hospitals and may have a negative impact on Centers of Excellence, which could impede beneficiary access to high quality services.

Catholic Health Initiatives recommends delaying until at least FY 2008 the proposed cost-based DRG weights. CMS should undertake a more thorough analysis, including parallel pilot testing, of the proposed changes to identify any unintended consequences. If DRG weight changes are implemented, they should be phased in over three years with "stop loss" protections.

DRGs: Severity of Illness

CMS has proposed a new classification system to reflect severity of illness among patients beginning in FY 2008 or earlier. CMS has proposed adoption of CMS-developed Consolidated Severity-Adjusted DRGs (CS-DRGs) rather than the widely applied All Patients Refined DRG system endorsed by MedPAC. Additional information and further analysis is needed to determine whether the CMS-proposed system, or another classification system, would result in an improved hospital payment system.

Until hospitals have a final GROUPER that can accurately assign the new CS-DRGs, it is difficult to calculate the impact. While we have surrogate methods of calculating the impact, GROUPERs used to calculate payments have changed in the past and minor changes can cause major changes in reimbursement.

We anticipate that for some hospitals the reimbursement changes resulting from new severity adjustments would adjust payments in the opposite direction from reimbursement changes resulting from new cost-based DRG weights. For other hospitals, both changes could be positive or both negative.

We are concerned about the impact of making two major payment changes in two successive years. We are also concerned about the ability of hospitals to adapt to these major changes in PPS in the short time frame proposed.

If the need for and best approach for changing the patient classification system is clearly demonstrated, CMS should simultaneously implement the DRG weight changes and new classification system to provide greater stability and predictability in hospital payments. These changes should not be implemented before FY 2008. A three-year phase-in period with "stop loss" protections should be provided to ensure that redistribution of hospital payments is not unduly disruptive to negatively impacted hospitals.

Catholic Health Initiatives recommends further analysis by CMS to determine if the proposed CS-DRGs, or an alternative patient severity classification approach, would result in more accurate payments. If the effectiveness of, and need for, a new patient classification system is demonstrated, CMS should implement the new DRG system at the same time as the DRG weight changes. A three-year phase-in with "stop loss" protections should be allowed to provide greater stability and predictability in hospital payments. A new patient classification system should not be implemented before FY 2008.

Physician-Owned, Limited Service Hospitals

The DRG changes proposed by CMS seek to address the proliferation of physician-owned, limited service hospitals in response to recommendations from the Medicare Payment Advisory Commission. However, we do not believe that payment changes alone will remove the inappropriate incentives created by physician self-referral to limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for

services. We strongly urge CMS to rigorously examine the investment structures of physician-owned, limited-service hospitals.

Catholic Health Initiatives urges CMS to continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the CMS strategic plan has been developed and Congress has had an opportunity to consider CMS' final report on physician-owned, limited service hospitals.

Hospital Quality Data

Catholic Health Initiatives supports expansion of the number of measures to be reported for the Annual Hospital Payment Update. This expansion follows the recommendation of the Institute of Medicine. However, we do have a concern with the timing of the final regulation and the requirement to begin the expanded reporting with January 1, 2006 discharges.

Hospitals are currently abstracting information for quality reporting for the January – March 2006 period with a closing date of mid-July. For those hospitals that have been collecting the "starter set" of 10 quality measures and have not begun abstracting the additional 11 measures, this retroactive requirement may pose an undue monetary and administration burden.

By the time the final rule is published, these hospitals may not have time to go back retrospectively and still meet the data submission deadlines for that period, especially if they need to have their vendor contracts amended to allow for the addition of an entire core measure set. These hospitals may also have difficulty retroactively collecting the second quarter information.

Catholic Health Initiatives recommends that CMS start the reporting period for the expanded quality measures with services provided on or after July 1, 2006.

Critical Access Hospitals

On November 14, 2005, CMS issued interpretive guidelines on the relocation of CAHs as a follow-up to the FY 2006 inpatient PPS final rule that established the "75% test" – serving 75 percent of the same population, providing 75 percent of the same services and employing 75 percent of the same staff – for necessary provider CAHs. The guidelines not only extended the 75% test to *all* CAHs, but also altered the definitions of "mountainous terrain" and "secondary road."

We believe that these guidelines go well beyond the regulations included in the FY 2006 rule that provoked numerous critical responses from individual CAHs and congressional representatives. The "mountainous terrain" and "secondary road" definitions are overly prescriptive and the 75% test does not provide reasonable flexibility based on natural variation in demographics, patient needs distribution patterns, normal employee and board attrition, and necessary changes in services to meet community needs. Rural hospitals that move a few miles are clearly the same providers serving the same communities.

Many CAHs are planning to rebuild in the near future to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or making other essential upgrades. Facilities expect to relocate when they rebuild for a multitude of reasons: to be closer to a highway, to connect to municipal water and sewer, to serve a moving population, or other similar concerns. Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service, yet CMS' guidelines discourage these improvements.

CMS' guidelines will not only impose an unnecessary burden on CAHs, but will preclude many of them from securing financing for needed capital improvements. The hospitals themselves and their lenders cannot risk investing in a hospital that will be unsure of its status until a year after moving.

Almost 60 congressional representatives signed a letter to CMS showing their support for their CAHs and urging changes to these guidelines. We agree with their recommendations and urge establishment of a safe harbor for hospitals relocating within five miles of their existing locations. These providers are not only clearly serving the same communities, but trying to improve the quality of and access to needed health care services. A safe harbor will reduce the administrative burden on not only the hospitals, but CMS and the state survey agencies as well.

Catholic Health Initiatives recommends use of a preliminary approval process by CMS to give assurances that the CAH relocation will be approved if it meets the assertions made in the attestation submitted to CMS. We urge CMS to create a safe harbor for CAHs moving a short distance. We also encourage CMS to make significant changes to the relocation guidelines based on the feedback received from CAHs around the nation.

Value-Based Purchasing

The Deficit Reduction Act of 2005 requires the Secretary to identify by October 1, 2007 at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through application of evidence-based guidelines.

For discharges occurring on or after October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission. CMS seeks input on which conditions and which evidence-based guidelines should be selected.

The proposed rule discusses hospital acquired infections as a complication that could trigger higher payments and an area for consideration. Our concern with the selection of hospital acquired infections as a condition for denying additional payment is that the codes currently used in billing data do not accurately distinguish hospital-acquired infections from community-acquired infections.

Even surgical site infections, which should intuitively be accurately identified through administrative data, have proven to be grossly in error when compared to data collected and reviewed by infection control practitioners using Centers for Disease Control and National Infection Surveillance System definitions.

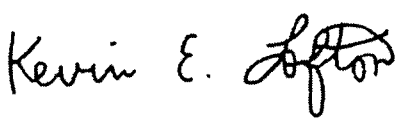
Instead of hospital acquired infections, CMS may want to consider hospital falls with injury and pressure ulcers not present on admission as two conditions that are potentially preventable through use of evidence-based practices.

In any case, we believe that administrative data should not be the sole decider. Just as there is additional data gleaned from records for the core quality measures, we believe that the adverse outcome concept can only be adequately gauged by reviewing the actual record to ensure that the event is accurately captured, and that the appropriate preventive measures were, or were not, followed. Only then would it be reasonable to base reimbursement on the occurrence.

Catholic Health Initiatives recommends that CMS select two "preventable" conditions for additional payment denial that can be most accurately identified as not present upon admission through billing data. Once identified, patient records should be reviewed to determine whether appropriate preventive measures were followed before denying additional payment for the condition.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,



Kevin E. Lofton
President and Chief Executive Officer

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June 8, 2006

Mr. Marc Hartstein
Deputy Director
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Inpatient PPS New Medical Services and Technologies
Mailstop C4-08-06
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: DRG Reassignment for the CHARITÉ™ Artificial Disc: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, CMS-1488-P

Dear Mr. Hartstein:

DePuy Spine is pleased to submit comments to the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule on the Medicare Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2007 Rates (Federal Register, April 25, 2006). DePuy Spine is an operating company of DePuy, Inc., a member of the Johnson & Johnson family of companies and a leading manufacturer of orthopedic and spine implants. We are known throughout the medical world for the development, manufacture, and marketing of innovative solutions for a wide range of spinal pathologies.

On February 13, 2006, DePuy Spine requested that the CHARITÉ Artificial Disc be reassigned from DRGs 499 and 500 to DRGs 497 and 498 for Federal Fiscal Year 2007. On April 25, 2006, the 2007 Proposed IP Rule was published (Federal Register, Volume 71, No. 79). CMS responded to this request stating that a Proposed Non-Coverage Determination (NCD) for the CHARITÉ Artificial Disc was in review. Under these circumstances, CMS did not believe that it was appropriate to reassign procedure code 84.65 from DRGs 499 and 500 to DRGs 497 and 498. On May 16, 2006, the final Decision Memo for Lumbar Artificial Disc Replacement (CAG-0029N) was published. CMS rendered a national non-coverage determination for beneficiaries over the age of sixty years old. However, for Medicare beneficiaries sixty years of age and under, there is no national coverage determination, leaving such determinations to be made on a local basis. Since coverage decisions for the Medicare disabled population will be made by local contractors, DePuy Spine is requesting that CMS, once again, evaluate the data and reassign Lumbar Artificial Discs to DRGs 497 and 498.

The final coverage decision discusses studies comparing the CHARITÉ Artificial Disc to spinal fusions for patients suffering from degenerative disc disease. For example, the coverage Decision Memo discussed in detail the IDE study of the CHARITÉ Artificial Disc, a prospective, multi-center, randomized, controlled study of two different surgical treatments for the treatment of low back pain.[1] The CHARITÉ Artificial Disc

[1] Blumenthal SL, McAfee PC, Guyer RD, et al. A Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemptions Study of Lumbar Total Disc Replacement with the CHARITÉ™ Artificial Disc Versus Lumbar Fusion Part I: Evaluation of Clinical Outcomes. *Spine* 2005;30:1565-75.

group and the control group experienced an average of 32.4 months and 26.7 months, respectively, of conservative treatment prior to the index surgery. All patients were surgical candidates for a fusion procedure. Clearly, the Lumbar (CHARITÉ) Artificial Disc is an alternative therapy to spinal fusion for patients with similar diagnoses. This is also true for the Medicare disabled population.

Because the CHARITÉ Artificial Disc is an alternative to spinal fusion and the FY 2005 MedPAR data shows that the CHARITÉ Artificial Disc is currently assigned to DRGs that are dissimilar in terms of average charges to the CHARITÉ Artificial Disc cases, DePuy Spine requests that CMS reassign the ICD-9-CM Procedure Code, 84.65, Insertion of total spinal disc prosthesis, lumbosacral to DRGs 497 and 498 for spinal fusion because of the similarity of clinical diagnosis, treatment, hospital charges and costs. With this assignment, it is further recommended that the DRG descriptors for the DRGs 497 and 498 be amended to reflect this change: " 497 - Spinal Fusion or Lumbar Artificial Disc Replacement, Except Cervical with CC and 498 – Spinal Fusion or Lumbar Artificial Disc Replacement, Except Cervical without CC".

MedPAR Data

Three analyses of charge data are shown below; one using FY 2005 MedPAR file supports this change. DePuy Spine engaged Direct Research, Inc. to analyze the 2005 MedPAR data in the Proposed Rule file. This analysis identified the CHARITÉ Artificial Disc cases (ICD-9 84.65 and 722.52) currently assigned to DRGs 499 and 500 (54 total).

ICD-9 CM		Description
Procedure Code	84.65	Insertion of total spinal disc prosthesis, lumbosacral
Diagnosis Code	722.52	Intervertebral disc disorders, degeneration of thoracic or lumbar intervertebral disc, lumbar or lumbosacral intervertebral disc

DRG	Both 84.65 and 722.52	Discharges	Mean Charge	Adjusted to Cost Based on Hospital's 2003 Cost Report
497	Total	30,521	$71,587	$24,584
498	Total	21,188	$55,489	$19,178
499	Total	34,547	$26,974	$ 9,127
499	No	34,524	$26,951	$ 9,122
499	**Yes**	**23**	**$61,750**	**$17,086**
500	Total	46,171	$17,731	$ 5,977
500	No	46,140	$17,707	$ 5,967
500	**Yes**	**31**	**$53,802**	**$19,094**

This table shows the mean charges for the CHARITÉ Artificial Disc cases are more similar to all cases in DRGs 497 and 498 than to DRGs 499 and 500. In fact, the differences between charges for the CHARITÉ Artificial Disc cases and the DRGs to which they are currently assigned are greater than the charge differences found by CMS last year when it decided to move cases involving the administration of tissue plasminogen activator (tPA) for patients with ischemic strokes (August 12, 2005 Federal Register, page 47287). Therefore, we urge CMS to follow that precedent and move these cases to a more clinically and resource appropriate DRGs.

We have also compared the costs of the CHARITÉ Artificial Disc cases to all cases in DRGs 497, 498, 499, and 500. For this analysis, we adjusted the charges on the claims by each hospital's corresponding cost center cost-to-charge ratio. This analysis is consistent with the analysis of charges. The CHARITÉ Artificial Disc cases are much more similar in cost to the fusion cases in DRGs 497 and 498.

There are similarities between the traditional fusion procedure and insertion of a total artificial spinal prosthesis. Both procedures are used to treat degenerative disc disease in a clinically similar patient population and utilize an anterior surgical approach. In addition, a total discectomy is performed before proceeding to fusion instrumentation or insertion of the artificial disc. Fusion instrumentation involves the application of fusion devices (screws, rods, plates, cages) with bone graft: BMP, autograft or allograft. CHARITÉ Artificial Disc replacement consists of implantation of two end plates in the intervertebral space followed by insertion of a core disc. Since bone graft is not required with insertion of the disc prosthesis, the incremental cost of the artificial disc can be partially offset by the averted cost of a bone graft procedure. This analysis demonstrates that the charges and costs associated with Lumbar Artificial Discs are very similar to the charges and costs in DRGs 497 and 498 while very dissimilar to DRGs 499 and 500, where they are currently assigned.

In addition to the MedPAR analysis, as part of the new technology DRG application process, DePuy Spine engaged two independent consulting firms to collect and analyze hospital claims for the CHARITÉ Artificial Disc. Both consultants confirmed that the current assignment of the CHARITÉ Artificial Disc to DRGs 499 and 500 was inappropriate from a hospital resource perspective.

	Direct Research, Inc.	Navigant Consulting	Total
Total Claims	94	214	308
Medicare	3	6	9
Percent Medicare	3.0%	2.8%	3.0%
Average Standardized Charge	$43,065	$45,791	
DRG 499 Threshold	$24,828	$24,828	
Amount in Excess of Threshold	$18,237	$20,963	

Summary

A detailed analysis of the patients undergoing anterior lumbar fusion with the BAK cage or the CHARITÉ Artificial Disc indicates a patient population with similar clinical characteristics and comparable hospital inpatient resource consumption. A detailed analysis of the proposed DRG assignments for new procedure code 84.65, Insertion of total spinal disc prosthesis, lumbosacral, clearly demonstrates that the most appropriate DRG assignment is DRG 497, 498. This assignment:

(a) assures a clinically coherent grouping
(b) groups candidates for an artificial disc with other procedures that include fusion and
(c) reflects comparable resource utilization including instrumentation, i.e. permanent implant.

One of the fundamental principles of the DRG system is to categorize together patients with similar diagnoses and resource consumption to provide adequate reimbursement to hospitals and to assure patient's have access to appropriate medical care. For all of these reasons, we urge CMS to change the DRG assignment for Lumbar Artificial Discs (84.65) for FY 2007.

Thank you for your consideration to this request.

Sincerely,

John Argiro
Director of Reimbursement

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VIA OVERNIGHT MAIL

June 8, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Blvd
Baltimore, MD 21244-1850

Attention: CMS-1488-P – PPS for Inpatient Hospital Services Proposed Rule for 2007 Fiscal Year

Dear Administrator McClellan:

OhioHealth Corporation in Columbus, Ohio, welcomes this opportunity to comment on the *"PPS for Inpatient Hospital Services Proposed Rule for 2007 Fiscal Year."* The OhioHealth Corporation includes:

- Riverside Methodist Hospital – Provider No. 36-0006
- Grant Medical Center – Provider No. 36-0017
- Doctors Hospital Columbus – Provider No. 36-152
- Marion General Hospital – Provider No. 36-0011
- Grady Memorial Hospital – Provider No. 36-02
- Hardin Memorial Hospital – Provider No. 36-1315
- Doctors Hospital Nelsonville – Provider No. 36-1305

Background

The OhioHealth Corporation has several healthcare facilities located around Ohio, including rural hospitals, critical access hospitals and community hospitals. The core of the system operations consists of three acute care hospitals located in Columbus, Ohio: Riverside Methodist Hospital, Grant Medical Center and Doctors Hospital. According to calculations utilizing 2004 Medpar data, Riverside Methodist Hospital and Grant Medical Center are expected to lose between $7.8 and $15.1 million and $1.0 and $2.8 million respectively as a result of the proposed rule changes to move to HSRVcc's and Consolidated Severity-Adjusted DRGs. This significant

reduction in reimbursement is directly related to the volume of heart services provided by Riverside Methodist and Grant Medical Center. Although Riverside provides a wide variety of medical services in addition to the heart service line, they do not provide some of the services that would negate the negative impact such as burns and transplants.

The Proposed Process Results in Significant Reimbursement Reductions

At the DRG level, the proposed rule notes that a number of DRGs would experience payment reductions, particularly DRGs involving cardiac care. For example, cardiac procedures involving stents, both drug eluting and non drug eluting, would see payment reductions. We are concerned about such drastic reductions for these and other cardiac procedures. While the payment reductions could "potentially reduce the incentives . . . for the further development of specialty hospitals" (71 Fed. Reg. at 24006), we are concerned that the reductions also would significantly affect community and teaching hospitals that do significant amounts of cardiac care. Unlike many specialty hospitals, however, these hospitals have emergency rooms, treat significant numbers of Medicaid and uninsured patients, and also accept complex cardiac cases.

Specifically, for Riverside Methodist Hospital (RMH) and Grant Medical Center (GMC), the changes to the cardiac surgical DRGs in MDC 5 are of particular concern. For example, DRG 535 is currently reimbursed $44,158.02 for RMH; however, under HSRVcc the reimbursement is proposed to be $32,646.42, an $11,511.64 reduction. These reimbursement amounts result in significant reductions that, even when considering the additional movement to Consolidated Severity-Adjusted DRGs, will not cover the direct costs of treatment. This represents one specific example of many significant reductions to DRGs (DRG 108, 109, 515, 547, 557, 558, etc.). These reductions, which are resulting in proposed payments lower than cost on an individual hospital basis, are most likely the result of inconsistent application of the cost and charge assignments to the ten cost centers in accordance with the CMS methodology. Many hospitals combine heart services into EKG cost centers; some have separate cath lab cost centers, etc. This difference in reporting may easily contribute to payments for some hospitals that are less than the cost of providing the care.

Given the significant reimbursement dollar impact of the changes proposed to be implemented on October 1 of this year, coupled with the court order requiring the occupational mix adjustment to be included 100% in the wage index calculations for the MSA's, Riverside Methodist Hospital and Grant Medical Center already are beginning to look at reducing capital spending which will place the current services at risk. This is significant for Columbus, Ohio, since OhioHealth Corporation contributed more than $118 million of charity care during the fiscal year ending June 30, 2005. Our ability to continue to provide these valued services to our community could be at risk should this proposed rule be implemented.

Conclusion

Understandably, CMS is moving to a DRG weight methodology that may be easily reconciled to cost and can withstand media and congressional scrutiny. However, hospitals such as Riverside Methodist and Grant Medical Center will be forced to review their ability to provide services and to maintain their existing charity care programs at current levels. CMS should give immediate

consideration to a methodology that utilizes each specific hospital's cost and not move these costs to a national average based on consolidation into ten cost centers. We respectfully oppose this rule as proposed and urge you to reconsider the methodologies utilized in this proposed rule.

If you have questions concerning these comments, please contact Lars Schmidt, Director of Reimbursement, at 614-544-5770.

Sincerely,

David P. Blom
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Aurora Health Care

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June 8, 2006

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05 7500 Security Blvd.
Baltimore, MD 21244-1850

Dear Dr. McClellan:

Aurora HealthCare wishes to comment on the April 25th Federal Register entitled, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates. Aurora HealthCare owns and operates the following Hospitals in the Eastern Wisconsin area:

Aurora St. Luke's Medical Center	Provider # 52-0138
Aurora Sinai /Medical Center	Provider # 52-0064
Aurora Medical Center – Washington County	Provider # 52-0038
Aurora Medical Center – Oshkosh	Provider # 52-0198
Aurora Medical Center - Manitowoc County	Provider # 52-0034
Aurora BayCare Medical Center	Provider # 52-0193
Aurora Medical Center – Kenosha	Provider # 52-0189
Aurora Medical Center – Sheboygan County	Provider # 52-0035
Aurora Lakeland Medical Center	Provider # 52-0102
Memorial Hospital of Burlington	Provider # 52-0059
West Allis Memorial Hospital	Provider # 52-0139

In particular, Aurora HealthCare would like to comment on the changing of the DRG weight calculation from a charge based to a cost based system, removal of offsite non patient care time for Indirect Medical Education reimbursement, the movement to severity adjusted DRG's, the expansion of number of quality measures to report on, and non payment for infections not present at the time of admission.

DRG Reclassification

Aurora HealthCare takes issue in the re-weighting of the Medicare inpatient DRG's based upon costs rather than billed charges. Our main issues are as follows:

- Not all hospitals have the same cost to charge ratios. In fact, in order to remain competitive, many urban facilities do not mark up expensive surgical supplies such as drug eluding stents and pacemakers, very much at all to keep managed care companies from not authorizing a potentially life saving surgery. These supplies in the CMS calculation are marked up based upon overall department markup, which may not reflect actual supply mark-up.

- Two hundred sixty very large hospitals representing twenty five percent of the total charges were excluded from the cost center cost to charge ratio calculation. However, these hospitals were not exempt from the effects of the DRG weight change, even though the data from their Hospital(s) were not included in the calculation of the DRG weights. Large hospitals offer cutting edge technology services such as Cardiology, and Neurosurgery. Excluding these hospitals from the cost to charge ratio calculation does not give an accurate national cost to charge ratio for modeling purposes.
- Hospitals do not consistently group costs in the same manner on the Medicare cost report. This will lead to cost to charge ratio inaccuracies for the calculation of the DRG payments.
- The cost to charge ratio data used in the calculation is based upon cost report information from 2003. Current technology such as drug-eluding stents, and bi-ventricular pacemakers were in its infancy in 2003, and does not accurately reflect the utilization of these services as it exists today. This leads to inaccuracies in the way these DRG's are proposed to be reimbursed by CMS compared to the actual costs the Hospital incurs for the inpatient stay.
- Cardiology related services will be hit unusually hard in this proposal. As a result of these changes the proposed DRG's for stents will be reduced 24 to 34%, ICD implants will be reduced 22 to 24%, and pacemakers reduced 12 to 14%. Drug eluding stents cost $3,000 a piece. The average number of stents per patient is 1.65. Cost for drug eluding stents per patient is $4,950. With the average reimbursement for DRG 558 being $7,200, this leaves $2,250 to cover the surgery, all of the other supplies, drugs, and the patient stay of two days. This will not even cover the direct costs much less the overhead it takes to run a hospital. The payment shortfall will have a devastating impact for Cardiology programs across the country, and will potentially cause access problems due to programs not being able to recover the cost of the leading edge technology. This is clearly not the intent of what CMS wanted to do.

With DRG's being a payment system of gains on some DRG's and losses on others, recalculation of the DRG weights based upon costs, will cause a lot more losers than gainers. This could cause hospitals not to invest in expensive life saving treatments due to lack of adequate payment, and therefore inhibit potentially life saving patient care.
Due to the drastic financial effect this has on hospitals, at a minimum this change should delayed for one year, or be phased in over a four year period of time to allow hospitals to adjust to the new payment.

DRG's: Severity of Illness

Aurora HealthCare supports CMS's concept of paying claims more accurately by having severity payment levels within each DRG. However, there needs to be a lot more work done before severity DRG's can be implemented.

- More time is needed before implementation for coding staff training.
- The Severity of illness DRG grouper needs to be released to the public so other information system vendors can perform the necessary programming for medical records and business office software systems. Having 3M maintain control of the grouper software limits access by other software vendors to begin reprogramming of the many of computer systems that needs to have the severity adjusted grouper software and are not compatible with the 3M grouper. This needs to happen well before implementation so hospitals can test their systems, and study the impact on their facilities.

- The new version of the UB-92 needs to be released, so the additional ICD-9 codes beyond nine can be accepted by claims processing system. Without this change hospital providers may not get paid accurately under the severity adjusted system.
- ICD-10 codes need to be implemented in order to obtain an accurate patient diagnosis.
- The effect the severity adjusted payment system has on outliers needs to be studied more closely to make the sure payment is accurate for the resources consumed by the patient.

CMS also needs to take the additional time to implement this so their systems operate smoothly and not create accounts receivable problems for the hospitals.

Hospital Quality Data

Aurora HealthCare supports CMS's effort to expand the number of quality measures hospitals report on in order to receive the full market basket payment increase. However, more time is needed in order for hospitals to implement the expansion. With the final notice not coming out until the beginning of August, and the quarterly data that CMS wants providers to report the expanded data is due on August 15th. That is not enough time for providers to implement the change. Many hospitals use external vendors to compile and submit the data to CMS. Vendors need adequate time to deal with the programming changes necessary to implement the revised quality measures after the regulation is final. Software testing at the hospital needs to be completed to make sure the data is complete and accurate. Aurora HealthCare proposes delaying this provision for at least six months to allow for a smooth implementation.

Value Based Purchasing

Aurora HealthCare is opposed to CMS's recommendation to not pay additional payments for infections acquired while the patient is in the hospital. Hospitals, most of the time, have no control over what the patient complications arise when they are in the hospital. Many visitors who may come to the hospital have drug resistant staph infections, and not even realize it. This can be passed along to the patient quite easily.
Hospital's infection control departments have measures in place to prevent infections as much as they can. However, they cannot possibly control all of the infections all of the time. Hospital's still need to be paid adequately for taking care of the patient, especially the complex hard to treat patient with acquired infections.

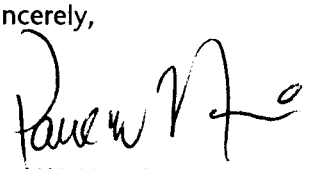
FTE Resident Count and Documentation

Aurora HealthCare remains opposed to CMS's interpretation of Public Law 105-33 requiring only patient care time spent be allowed in the FTE count calculation when the Intern or Resident is training outside of the Hospital.
Interns and residents, in order to obtain proper training must spend significant non-patient care time out of the hospital. Time spent at external seminars, reviewing clinic patient charts, researching patient symptoms for related diseases, virtual learning (practice suturing ect.) and documentation coordination with the physician in their clinic, are just of the few of very important functions the Intern or Resident spends doing activities outside of the hospital. These are very essential roles for the education of future

Physicians. Residents are bound to train for a maximum of 80 hours per week, so wherever the resident may have down time, they spend their time on these non - direct patient care functions. Without these functions, the training programs cannot exist.
CMS has made a commitment to fund Graduate Medical Education programs. Without adequate funding by CMS for these programs, many programs will not be able to survive and forced to shut down.

Aurora HealthCare would like to thank CMS for the opportunity to submit our comments on this very important proposed regulation. Should you have any questions, please feel free to call Steve Kowske at 414-647-3429.

Sincerely,



Paul W. Nannis
Vice President, Government and Community Relations

June 8, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1488–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS–1488–P
April 25, 2006, IPPS Proposed Rule
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the inpatient PPS fiscal 2007 proposed rule published in the April 25, 2006, **Federal Register**. We are a regional CPA firm serving approximately 400 hospitals nationwide. Our comments are as follows:

DRGs: Severity of Illness

CMS proposes adopting consolidated severity-adjusted DRGs in fiscal year 2008 if not earlier. This would represent a dramatic change for hospitals already dealing with other challenges, including quality reporting standards, electronic health records and various other technology challenges. Adding this change would overwhelm smaller hospitals with limited resources. We urge CMS to approach such changes cautiously and consider the impact on all hospitals. CMS should release impact files by hospital far in advance of any implementation of such a dramatic change.

CMS also solicits comments on adjusting the standardized amount to eliminate the effect of changes in coding or classification of discharges that do not reflect real changes in case-mix. We understand CMS has discretion to make such adjustments for changes that are likely to occur. However, absent strong evidence that such changes are likely, we urge CMS to avoid making negative adjustments to the standardized amount.

From a recent study of Missouri hospitals, we have demonstrated that the 80 general acute-care hospitals in the state lost an average of over $1 million each on Medicare inpatient services

during the most recent year of data available, for cost reporting periods beginning in federal fiscal 2004. The negative Medicare outpatient, skilled nursing and home health margins average an additional $1.7 million for each Missouri hospital.

Hospitals cannot continue to sustain such large negative margins serving Medicare patients without quality of care being impacted. Wherever CMS has discretion to adjust hospital payments, we urge restraint be used to avoid further damaging hospitals' financial conditions.

Hospital Redesignations and Reclassifications

CMS publishes a list of hospitals qualifying for geographic reclassification for fiscal year 2007 in Table 9A. Several Pennsylvania hospitals appear to have inadvertently been left off this list. We are aware of at least two specific providers, Provider Nos. 39-0052 and 39-0093, that received geographic reclassification including fiscal year 2007 that have been left off of Table 9A.

These two providers are incorrectly included in Table 9C as hospitals that have elected to be treated as rural hospitals under Section 1886(D)(8)(E) of the Act. Table 9C shows them redesignated from rural Pennsylvania to rural Pennsylvania, which is obviously in error. We suspect all 13 of the rural Pennsylvania hospitals shown in Table 9C are shown in error, though we are only aware of these two providers for which their geographic reclassification has been mistakenly omitted from Table 9A.

Hospital Quality Data

The Deficit Reduction Act of 2005 (DRA) requires the Secretary to begin expanding number of quality measures hospitals are required to report. CMS proposes to implement this expansion retroactively to the start of 2006, with data for the first quarter of 2006 due by August 15, 2006. While we believe reporting quality of care rendered by hospitals is a valuable and important process, retroactively implementing such changes is not appropriate. We encourage CMS to implement such changes prospectively, effective October 1, 2006.

CMS also describes the process a hospital would use to request reconsideration of a CMS decision that the hospital did not meet the quality reporting requirements. We request CMS make it very clear which hospitals it believes did not meet the requirements – releasing a list publicly so that affected hospitals will know immediately that CMS believes they are not in compliance with quality reporting requirements.

CMS requests comments on the use of electronic medical records (EMRs) that will further facilitate the reporting of clinical quality data. EMRs may hold great promise for the future. However, smaller rural hospitals do not have the resources to invest in EMR systems at this time. We encourage CMS not to mandate the use of EMRs at any point in the near future and approach any such changes cautiously due to the prohibitive costs.

Value-Based Purchasing

DRA also requires the Secretary to develop a plan to implement a value based purchasing program beginning in fiscal year 2009. In developing such a program, we encourage CMS to consider the unique characteristics of different types of hospitals, urban vs. rural, teaching vs. nonteaching, etc. Rural and other smaller hospitals should not be disadvantaged by such a program due to their lower volumes of services.

CMS notes that the 0.4% penalty for not reporting quality data has been sufficient to generate widespread compliance with the quality reporting requirements. For this reason, we do not believe significant penalties are warranted, nor should they be proposed during the initial implementation of a value based purchasing program.

CMS requests comments on its statutory authority to encourage the adoption and use of health information technology (HIT). We are very concerned that CMS approach this area slowly and cautiously. Hospital resources to invest in new HIT are extremely limited at this time, particularly with the large negative margins hospitals are experiencing treating Medicare patients.

SCH/MDH Volume Decrease Adjustment

CMS describes the process whereby intermediaries make special payments to sole community hospitals (SCHs) and Medicare dependent hospitals (MDHs) that experience decreases in inpatient volume of five percent or more. To determine if the hospitals had appropriate staffing levels, American Hospital Association (AHA) Monitrend data is used. CMS notes that the last Monitrend data book was published in 1989. We would note that individual Monitrend reports were generated through 1993 and represent more current data available to measure the appropriateness of hospital staffing levels.

CMS proposes using occupational mix survey data to replace Monitrend staffing data for volume requests in 2008 and subsequent years. Our concern with this proposal is matching the hours reported in the occupational mix survey with appropriate patient day data. In particular, the 2006

occupational mix survey is being completed in two parts, generally for nursing hours in the first quarter and second quarter of calendar year 2006. However, the survey does not request patient day information.

CMS proposes to use patient days reported on the Medicare cost report to compute paid nursing hours per patient day. CMS does not describe the process it would use to reconcile the different time periods used in the cost report (12 months) compared to the occupational mix survey (three or six months, depending on whether the two 2006 surveys would be combined). We are concerned with the accuracy of taking the numerator of the computation from a three or six month survey with the denominator from the annual Medicare cost report, presumably with one of the numbers adjusted to account for the time differences involved.

We encourage CMS to work with the AHA to see if AHA could develop appropriate survey tools in a timely manner to meet the timeframes mentioned by CMS. In the meantime, CMS should continue to allow the best available Monitrend data be used for payment requests.

SCH/MDH Changes in Qualification Status

CMS proposes to implement a mandatory reporting process whereby an SCH or MDH would report to its CMS Regional Office when the circumstances under which it was approved as an SCH or MDH have changed. The Regional Office would determine whether the change affects the SCH or MDH status and notify the hospital if its status will be canceled, with the cancellation effective 30 days after the Regional Office determination. If the hospital does not disclose the change, the Regional Office will cancel the SCH or MDH designation retroactive to the earliest discernible date on which the intermediary can determine that the hospital no longer met the qualification criteria.

While we appreciate CMS' concern that an SCH or MDH should lose its special status if the circumstances that gave rise to this status have changed, we are concerned with the burden this proposed regulatory change would place particularly on SCHs. A hospital can qualify to become an SCH based on a variety of circumstances, including the inpatient admission patterns of area residents, weather conditions, travel times, etc. We believe requiring hospitals to monitor these various conditions on an ongoing basis presents an unwarranted burden on hospitals that have already shown they are the sole source of care reasonably available to Medicare beneficiaries in their service areas.

It is unclear from the proposed regulations whether CMS is placing some sort of requirement on an SCH to remeasure the circumstances that gave rise to its classification on an annual or other unspecified periodic basis. This is very unclear, particularly given the CMS discussion under the

Collection of Information Requirements. In this section, CMS states that it estimates only one hour will be required of less than 10 SCHs to comply with this requirement. CMS either grossly underestimates the cost and time required to comply with this requirement, or CMS does not expect SCHs to monitor this data on an annual basis. Specifically, it appears that CMS does not intend to require SCHs to remeasure the market share test of 42 CFR 412.92(b). We agree with this position and request that CMS clarify that intent.

We believe the responsibility for monitoring criteria such as a nearby critical access hospital converting to a PPS hospital is most appropriately monitored by the FI. The FIs are already clearly responsible for monitoring such matters including whether MDHs continue to meet the 60% test in two of the last three audited cost reports, and that is where this responsibility belongs.

If CMS determines to shift some of this responsibility to the SCHs and MDHs, CMS should make very clear exactly what criteria the hospitals are responsible for monitoring. We believe CMS should only require SCHs or MDHs to monitor readily-available, objective data. In the case of an SCH, this would include the opening of a new hospital within 35 miles of the SCH, or the mileage criterion on which their SCH status is based. For an MDH, this would include the addition of available beds that would exceed 100. The proposed regulations should be clarified with regard to this requirement. If CMS does not change the proposed regulations, it should acknowledge the administrative burden it is placing on providers and significantly modify the Collection of Information Requirements.

At the same time, we are concerned with the dramatic financial impact that retroactive revocation of SCH or MDH status could have on a hospital. Unless CMS has clear evidence that a hospital knew it no longer met the criteria to qualify for SCH or MDH status, there should be no retroactive recovery of Medicare funds if a hospital's special status is revoked. CMS can encourage self-reporting by requiring immediate revocation of status if the hospital does not report a change in circumstances, while revoking status at the start of the next cost reporting period, or six months from notification, whichever is later, if the hospital does self-report.

CMS discussed and clarified many of the rules and policies governing SCHs in the August 1, 2001, PPS Final Rule because of the legislative changes that had recently occurred. On Page 39874 CMS stated:

> "Section 6003(e)(3) of Public Law 101-239 specifically stated that any hospital classified as an SCH as of the date of enactment of Public Law 101-239 (December 19, 1989), will retain its SCH status even if the hospital did not meet the criteria established under section 6003(e)(1) of that law. These hospitals are the "grandfathered" SCH hospitals.

> Therefore, we have continued to allow hospitals designated as SCHs prior to December 19, 1989, to be "grandfathered" under current criteria."

We request that you modify 42 CFR 412.92(b)(4) to reflect this position on grandfathered SCHs and also clarify that any final regulation requiring self monitoring and reporting does not apply to grandfathered SCHs described in the foregoing paragraph.

Payments to MDHs

The DRA made several significant changes to the statutory provisions related to MDHs. Section 5003(b) of DRA provides the option for an MDH to compute its hospital-specific payments using "the 12-month cost reporting period beginning during fiscal year 2002". A simple interpretation of this provision would be that it relates to the cost reporting period beginning on or after October 1, 2001 and before October 1, 2002.

In implementing Section 5003(b), CMS has proposed a new 42 CFR 412.79(a)(1) providing use of a cost report from "the 12-month or longer cost reporting period ending on or after October 1, 2001, and before October 1, 2002." CMS erroneously uses the word "ending" in this proposed regulation, when the word "beginning" should be used. We request that this error be corrected, stating that an MDH may use the 12-month or longer cost reporting period beginning on or after October 1, 2001, and before October 1, 2002, and correcting the related references throughout 42 CFR 412.79.

On a related matter, CMS proposes that the 2002 base period costs be updated using the methodology set forth in 42 CFR 412.73(c)(14) and (c)(15). Hospitals with fiscal years beginning on October 1 can easily have their base period costs updated using the normal PPS update factors put into effect each October 1. However, most hospitals do not have fiscal years beginning on October 1, and should have at least a partial update for the period from the start of their 2002 base period to the start of the next federal fiscal year. We would suggest an update process similar to that used in 42 CFR 412.73(c)(10), and request CMS clarify this issue.

Rural Referral Centers

Annually, CMS publishes the national and regional case mix values a hospital must have to qualify for rural referral center status. We are concerned that the regional case mix values fluctuate so dramatically from year to year. Looking at the values published in the fiscal 2004, 2005 and 2006 final rules as well as those published in the fiscal 2007 proposed rule yields the following comparisons:

	Case-Mix Index Value – Federal Register for FFY			
Region	2004	2005	2006	2007
1	1.2245	1.2157	1.2300	1.2678
2	1.2262	1.2118	1.2469	1.2701
3	1.3146	1.2365	1.3277	1.1781
4	1.2489	1.1957	1.2762	1.3156
5	1.2511	1.0901	1.2911	1.2009
6	1.1841	1.0855	1.2252	1.2856
7	1.2705	1.1371	1.3532	1.2445
8	1.3482	1.1696	1.3620	1.3024
9	1.2845	1.2698	1.3241	1.3620

While Regions 1 and 2 have relatively stable values, most of the others have dramatic changes in at least two of the years presented. We request CMS review the process used to compute these values and determine if they are being computed accurately, or determine why some of the values fluctuate so dramatically from year to year. If the values are being computed incorrectly, we request that they be corrected in the Final Rule. If the corrections cannot be made in time to incorporate them into the Final Rule, we request the corrected FFY 2007 amounts be published as quickly as possible and providers that may have been disadvantaged by any error be allowed an appropriate extension of time to seek RRC status.

There appear to be two other provisions of the RRC section of the Proposed Rule Preamble that should be addressed.

The last sentence of the "Case Mix Index" discussion states "In keeping with our policy on discharges, these CMI values are computed based on all Medicare patient discharges subject to DRG-based payment." We believe it would be in inappropriate to include discharges paid under the LTC DRG payment system. Assuming that discharges paid under the LTC DRG-based payment system are excluded, this sentence should be changed to specify "...under the Inpatient PPS DRG-based payment system."

The last paragraph of the "Discharges" discussion states:

> "We reiterate that if an osteopathic hospital is to qualify for rural referral center status for cost reporting periods beginning on or after October 1, 2006, the hospital would be required to have at least 3,000 discharges for its cost reporting period that began during FY 2003."

42 CFR 412.96(c)(2)(ii) indicates that such an applicant for RRC status "must have at least 3000 discharges during its most recently completed cost reporting period to meet the number of

discharges criterion." We believe the regulation wording is consistent with CMS's past policies and that the preamble wording should be corrected.

DSH Adjustment

Section 951 of the Medicare Modernization Act of 2003 required CMS to release certain DSH data by December 8, 2004. Due to the significance of this issue, we request CMS provide an update on its efforts to make this data available, and expedite the provision of this information.

Health Care Information Transparency Initiative

CMS describes the growth in health care costs as a situation caused partially by the fact that consumers are frequently not aware of the cost of care. CMS discusses a number of options to make more information available to consumers. We are concerned about adding another burden on hospitals to report data, such as prices. Many states and other entities are proposing similar requirements. Hospital pricing is a very confusing issue, given the need to price supplies and services individually, and uniformly among Medicare and other payers.

Prices for the entire hospital stay for two different patients with the same diagnosis can vary widely based on each patient's age and other complications that develop, as well as the tests and other services ordered by each patient's physician. The services received by a patient are determined by physicians, not by the hospitals providing the services. If CMS wants to educate consumers, and lawmakers, for that matter, it would be beneficial to explain the use of hospital charges in the Medicare cost reporting process to apportion hospital costs by department.

CMS could provide average charges to the public by hospital for selected high-volume DRGs, as well as explaining how different hospitals are paid for the same service, with regard to all of the various components that comprise a hospital's payment rate. We also agree with the comment CMS makes with regard to explaining other components of care, including physician payments and payments for post-acute services.

However, we believe all of the foregoing can be accomplished without adding another burden to hospitals to report pricing data.

Operating Payment Rates

CMS proposes an outlier fixed-loss cost threshold of $25,530, compared to only $23,600 for fiscal 2006, an increase of 8.2%. In the August 12, 2005, **Federal Register**, CMS notes that fiscal 2004 outlier payments were only 3.52% of total DRG payments. In this proposed rule, CMS notes that fiscal 2005 outlier payments were only 4.1% of total DRG payments, and CMS projects fiscal 2006 outlier payments will be only 4.71% of total DRG payments.

CMS reduces the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases, which CMS has estimated to be 5.1% for the last several years. Actual outlier payments had exceeded this 5.1% estimate in fiscal 2003 and 2004. However, as actual payments have now been less than estimated for the past three years, we request CMS avoid implementing such a significant increase in the fixed-loss cost threshold for fiscal 2007.

We appreciate this opportunity to comment on these important proposals. If you have any questions concerning our comments or require further information, please contact Tim Wolters at 417-865-8701.

BKD, LLP

BKD, LLP

Cleveland Clinic

Steven C. Glass
Chief Financial Officer

June 12, 2006

Mark B. McClellan, Ph.D., M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. McClellan:

On behalf of the Cleveland Clinic Foundation (CCF), a major teaching and tertiary hospital located in Cleveland, Ohio, we appreciate the opportunity to comment on the proposed changes in the inpatient prospective payment system (IPPS). We strongly support your efforts to improve the inpatient payment system, and we are aware of the immense challenges the Center for Medicare and Medicaid Services (CMS) has undertaken in this endeavor.

We applaud the efforts of CMS to develop a payment system for hospital inpatient services that more accurately reflects the costs of those services. CCF is a leading provider of health care and often treats the most critically ill patients. As such, we understand the complexity of trying to match resource consumption and appropriate Medicare payments to the respective DRG. However, we have two principal concerns with the proposed IPPS regulations: 1) the methodology used to determine the weights based on costs; and 2) the time frame for implementing the proposed changes to the payment system.

Concerns with the Weighting Methodology

The first concern that CCF has relates to the methodology used by CMS to determine the weights based on cost. It is our understanding that CMS adjusted the weights to be based on costs as opposed to charges because of concerns that there was bias in the weights due to hospital markup and strategic pricing adjustments of ancillary services. However, the methodology used by CMS is biased in that it assumes costs for the various services occur equally for surgical and medical days. For example, in the routine care cost center, CMS has assumed that a medical day has the same cost as a surgical day with the same length of stay for the routine cost center. This is not typically the case. While most providers do not have different charges for medical days and surgical days, the costs are different. In other contexts, CMS has officially recognized that routine costs can differ between medical and surgical days as evidenced by the Medicare transfer policy which pays double the per diem for the first day of certain transfer surgical DRGs. The proposed cost to charge ratio in the CMS model is inconsistent in that it does not recognize these surgical/medical differences. In addition, the cost to charge ratio does not recognize that a Medicare patient may consume resources for different services at a greater or lesser rate than other payers.

The Cleveland Clinic Foundation
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The cost methodology employed by CMS in the proposed rule also results in an understatement of costs relating to surgical cases that employ devices or implants. As you know, devices and implants are typically high cost items to which most providers add only a small markup to the charge for these items. If CMS applies a universal cost to charge ratio, it will significantly and unfairly understate the cost of certain implants and devices. Since the use of a cost to charge ratio is an overall average and if these devices and implants are understated, other DRG costs relative to this area will be overstated.

The data support this analysis. For example, according to CMS statistics cited in the Federal Register, specialty hospitals such as cardiac and orthopedic will generally experience reductions in reimbursement under the proposed payment system. These areas of care typically have more extensive use of devices and implants than other areas of care, so the impact of this flaw is more obvious with specialty hospitals. We understand CMS's intent to address hospitals that are "cherry-picking" the more profitable DRGs, as well as other hospitals avoiding the severely ill patients, but this should be accomplished through other regulatory means. Using this flawed weighting method unfairly penalizes major urban teaching tertiary hospitals which take care of the sickest patients in our country while providing high quality specialized care. While the use of cost to charge ratios is appropriate when attempting to determine costs within a department, it is simply the wrong method to determine costs across product lines or across DRGs because the ratio measures only averages. A service can have a low or high cost item that when using a cost to charge ratio will result in an overstatement or understatement of cost. It would be much more fair and accurate for CMS to use more cost centers to arrive at the appropriate cost to charge ratio, as opposed to compressing the vastly complex structure into 10 cost centers under the proposed system.

Moreover, the increased complexity of the proposed methodology will undoubtedly cause a decrease in productivity among provider coding personnel. This in turn will lengthen revenue cycles. It is important to recognize that coding personnel have been working with a consistent framework for the past 23 years. The CMS proposed payment system will require re-training of literally every person responsible for inpatient coding – thousands of workers across the country. Finally, the increased complexity of the proposed system will make it much more time consuming to code individual patient cases, particularly at the outset.

Timeframe for Implementation

While CMS's proposed time table for implementing the new payment system is laudable on the one hand, the problems associated with such an aggressive approach will create numerous problems for providers and ultimately the Medicare program itself. First, the time table for implementing HSRV weights does not allow providers enough time to properly prepare for the changes in terms of modifying databases and information systems as well as retraining essential billing and coding personnel. Providers need more time to plan for such major changes.

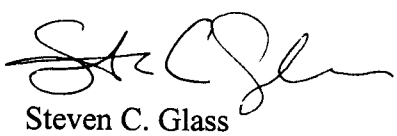
There is ample precedent to support a delay in implementing the proposed payment system.

In recent years, when CMS has implemented significant changes such as these that impact substantially on provider reimbursements, CMS has provided sufficient lead time and phase in periods to implement these changes. In the past, for example, CMS has phased in significant changes to hospital reimbursement for several different areas such as rehabilitation hospitals, psychiatry units, and capital expenditures. We feel that the proposed changes to the IPPS warrant such action.

We respectfully request that CMS implement the DRG changes and severity adjustment changes concurrently in 2008. This would give hospitals an opportunity to fully understand the changes from HSRV weights and CSA DRGs as well as plan for the impact of these changes. In addition, it would give CMS an additional year to address the concerns of the HSRV weights identified by CCF and other healthcare providers, and perhaps consider a reimbursement rule using more than 10 cost centers for tertiary care and teaching hospitals which take care of the most critically ill patients.

We appreciate the opportunity to comment on these regulations. Please do not hesitate to contact me if I can be of assistance. We would be happy to meet with you to discuss possible alternative formula calculations which better reflect costs in our business model or any other issues.

Sincerely,



Steven C. Glass
Chief Financial Officer

Ellis HOSPITAL

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June 1, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

To Whom It May Concern:

We are writing on behalf of Ellis Hospital in Schenectady, NY, to express our concern and opposition to the changes to the Medicare inpatient Diagnosis Related Groups (DRGs) and weight calculations being proposed by the Centers for Medicare and Medicaid Services (CMS). We believe this new methodology creates a bias against, and penalizes hospitals that treat clinically complex cases. Additionally, we take issue with the short implementation period that is being proposed.

While we applaud CMS's efforts to update these policies, we feel the proposed changes unfairly penalize specialty hospitals like Ellis that provide such services as cardiac surgery. Ellis Hospital will lose $1.5 million for fiscal year 2007 as a direct result of these changes. This amount of money would be financially devastating because Ellis, like not-for-profit hospitals across New York State and the nation, is in a year-to-year struggle to make ends meet. *The proposed DRG methodology penalizes our hospital by providing significantly less reimbursement for treatment of cardiac surgery patients – far less than what is required to provide care in such clinically complex cases. This stands in stark opposition to the relatively higher reimbursements that hospitals with less clinically complex cases will receive under the proposed new system.* In the end, this new DRG methodology will strip funding from specialty service hospitals like Ellis, while rewarding hospitals that do not offer specialty services like cardiac surgery.

Ellis Hospital has a 121-year tradition of serving its community, providing high quality care to anyone who walks through its doors regardless of their ability to pay. Our quality is exceptional, as we are ranked among the top 5% of hospitals nationwide for clinical excellence by HealthGrades, an independent rating agency. *Ellis Hospital is the only hospital in New York State to earn this distinction in 2005 and 2006.* Ellis' cardiac program, in particular, has achieved national recognition from HealthGrades as being top 5% in the nation, top three in New York State and the best in New York State's Capital Region for overall cardiac care. *Despite our high quality cardiac program, a case mix that reflects our ability to treat high acuity patients, and the correspondingly higher costs associated with providing care to more clinically complex cardiac cases, Ellis will lose a significant amount of reimbursement under the proposed severity-adjusted DRGs and revised weight calculations. The result of CMS' proposed changes is inadequate reimbursement for specialty hospitals like Ellis.*

Furthermore, we strongly suggest an extended and blended phase-in period for the proposed reimbursement changes. A blended transition model that gradually phases in the new methodology over a multi-year period would enable hospitals like Ellis to more readily adapt to new rates, and absorb the negative financial losses that will result if the proposed changes are implemented as currently written. The estimated impact from the change in DRG weights, in conjunction with the estimated impact of the severity-adjusted DRGs proposed for fiscal year 2008, will result in drastic swings to a facility's revenue stream and will bring volatile operating impacts to an already fragile and unstable health care environment. Historically, CMS has implemented significant changes to the Medicare program over a longer period of time. We hope that CMS will follow its past practices and extend the proposed DRG changes beyond a two-year time frame.

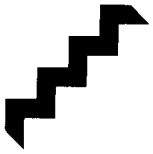
We strongly urge CMS to revise the proposed Medicare inpatient DRGs and weight calculations to ensure that changes are fair across the board, and to allow a sufficient period of time for changes to be implemented. **These proposed changes unfairly penalize specialty hospitals like Ellis Hospital that treat clinically complex cases with the highest provision of care.**

Thank you for your time and consideration.

Sincerely,

Robert E. Smanik, FACHE
President & CEO

G.E. (Jay) Hoffman, Jr., CPA
Chief Financial Officer



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June 08, 2006

Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

REF: CMS-1488-P and CMS-1488-P2

RE: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Payment Rates; Proposed Rule.

Dear Dr. McClellan:

On behalf of Catholic Healthcare Partners (CHP) and our affiliated twenty-nine acute care hospitals and fourteen Long Term Care facilities, we appreciate the opportunity to comment on the proposed rule for the 2007 Medicare Prospective Payment System (PPS) for inpatient admissions. This year's proposed rule contains pivotal policy changes that not only have the potential to significantly impact our hospitals' financial position, but also impact operations especially in Health Information Management, Quality, and Financial Analysis departments. We appreciate CMS willingness to provide clarifications to existing definitions and policies that have been problematic for hospitals regarding EMTALA related-transfers to specialty hospitals and proper tracking of Graduate Medical Education and Allied Health training. The proposed 2007 Inpatient Prospective Payment System (IPPS) rule again provides a "mixed-bag" of changes to our member hospitals which include teaching hospitals, Critical Access Hospitals, Sole Community Hospitals, Medicare-Dependent Hospitals and Long Term facilities. Specifically we want to comment regarding the following proposed changes:

1) DRG Reclassifications
2) Cost Based Weights: Outlier Threshold
3) DRGs: Hip and Knee Replacements
4) CBSAs
5) Occupational Mix Adjustment
6) Hospital Quality Data
7) EMTALA
8) Blood Clotting Factor Payment Rate

Attached you will find our specific comments and recommendations on the topics contained within the proposed rule.

Catholic Healthcare Partners appreciates the opportunity to submit comments for your consideration. If your staff has any questions about these comments, please feel free to contact me at 513-639-0129 or Cheryl Rice, CHP Corporate Director of Corporate Responsibility at 513-639-0116 clrice@health-partner.org.

Sincerely,

Matthew D. Williams
Vice President, External Relations
Catholic Healthcare Partners

Attachment
Clr

DRG Reclassifications

The proposed rule, if adopted, would result in the most significant change to the Inpatient Prospective Payment System (IPPS) since its implementation in the 1980s. Changes of this nature can not be taken lightly or rushed into without proper planning and analysis. We recognize that in order to expand care access to beneficiaries, provide equitable reimbursement for rendered services, and improve overall health care quality to Medicare beneficiaries and others, the current methodology of payment needs to be adjusted to account for changes in the healthcare delivery. Our overall concern, however, is that the proposed rule initiates so many policy changes that their "collective" impact is difficult to quantify from both a financial and operational perspective. Catholic Healthcare Partners (CHP) is willing to work toward implementing a refined DRG payment methodology, however our hospitals need sufficient time and information to understand DRG remapping, validate cost-based calculations, plan for financial changes to operations, train staff on coding policy and retool our hospital information systems in order to accurately and successfully transition to cost-based and severity-adjusted DRGs. Specifically we recommend the following considerations:

1. Delay the implementation of hospital specific relative values (HSRVs) and cost-based weights (HSRVcc) until at least FY 2008. The proposed rule offered two different methodologies for arriving at hospital specific relative values and cost-based weights. Upon review, the simplified CMS proposed methodology had the benefit of focusing costs into ten manageable cost centers for national cost-to-charge ratio development and supported an annual update process. Hospitals frequently encounter annual fluctuations in costs for drugs, supplies, and staff that are driven by market forces beyond their control. The annual update process provides some flexibility in adjusting for those unexpected costs particularly in markets prone to shortages and recalls that drive up costs. Unfortunately, the American Hospital Association notified its member hospitals that the CMS methodology had several serious calculation errors which could result in unintended financial consequences. **We recommend CMS work with the AHA to identify and address the areas of concern, and once resolved re-issue the respective cost-based calculation methodologies along with a comparative schematic of each calculation methodology and an example of how cost would be calculated under each methodology using a common set of same data. This information should be released in time for adequate analysis and comment for FY 2008.**

2. Amend the ten Cost Centers proposed under the CMS recommendation to include inpatient costs from Medicare Cost Report Worksheet C Part I Column 5 line 62 – Observation to fully capture clinical costs associated with direct patient care. In reviewing the services to be considered in cost-based DRG weighting, it appears CMS excluded line 62 – Observation costs. Although Observation services are typically considered an "outpatient" service, inpatients can legitimately spend up to 48 hours (i.e. 2 days) prior to their inpatient admission in Observation status. By excluding inpatient costs reported for line 62, CMS would be understating associated DRG costs for medically necessary nursing services. CMS has repeatedly instructed hospitals to

appropriately prepare complete Cost Reports by separating routine and ancillary by inpatient and outpatient costs. The CMS proposed cost-based methodology will finally recognize those hospitals which have been compliant in completing their Cost Reports as instructed. Worksheet C Part I Column 5 line 62 allows hospitals to distinguish between costs associated with "pure" outpatient Observation cases versus costs associated with patients who were placed in Observation prior to an inpatient admission. **As such, CMS should include the costs of care spent in Observation that ultimately results in an inpatient admission as reported in line 62 in the overall DRG cost-based weighting.**

3. Delay the implementation of the severity-adjusted DRG methodology until at least FY 2008. We understand and share CMS concern regarding charge-driven biases and "DRG complication-co morbidity creep" that has been occurring since the inception of DRGs. We also support the decision to move to DRGs that are more reflective of intensity of service and severity of illness as demonstrated by the presence of underlying complications, multiple co-morbidities and secondary diagnoses. However we are concerned that hospitals have not been given sufficient information and/or time to evaluate the impact of either proposed MedPAC APR-DRGs or CMS Consolidated DRGs. Specifically, hospitals have not been given sufficient cross-maps from the current 526 DRGs to each of the respective proposed 1258 APR-DRGs or 861 Consolidated DRGs. Without the cross-maps, a true financial impact analysis can not be completed. Many DRGs can be intuitively matched based on description, but there are a significant number of DRGs that can regroup to numerous severity-adjusted DRGs depending upon the reclassification of specific ICD-9 diagnosis and procedures codes under the severity-adjusted DRG grouper. We are also concerned that hospitals will not have sufficient time to purchase and implement a new DRG Grouper that will be required to generate the severity-adjusted DRGs on a daily basis to support hospital inpatient billing, effective October 1, 2006. According to the proposed rules, only one vendor, 3M, was identified as having access to the grouper. With over 4,000 hospitals requiring a new severity-adjusted DRG Grouper, it is not feasible or reasonable to expect that one vendor could service all the hospitals nationally in the few months between the posting of the final IPPS rule and an October 1, 2006 implementation. We are concerned that new coding requirements associated with the reporting of secondary diagnoses and hospital acquired infections will require additional coding staff training and some reprogramming of internal software and claims processing to allow for the additional codes to appear on hospital claims. **Hospitals need additional time to be able to verify that coders understand and implement crucial coding policy changes, new groupers are functioning, programming and claim processing functions are reporting necessary ICD-9 and DRG information properly to ensure financial and operational stability during the transition to severity-adjusted DRGs.**

4. Implement simultaneously, but not earlier than FY 2008, the proposed cost-based DRG relative weight determination policy and the proposed severity adjustment policy. The simultaneous implementation approach should help to smooth out the major redistributive effects on hospital payments.

5. Limit the severity-adjusted DRG methodology to a 3-digit DRG to minimize extra costs associated with reprogramming and retooling information systems to handle a 4-digit DRG. Under the MedPAC proposal, hospitals would have to reprogram existing health information, claims processing, and decision-support systems to accommodate a 4-digit

DRG. A field length change is an extremely expensive customization to most existing information systems and the fact that the DRG number is such a key data element in most software systems only compounds the problem. Essentially moving to a 4-digit DRG could result in the same level of reprogramming and operational changes as Y2K. Hospitals do not have enough time to prepare by October 1, 2006 and may not be enough time by October 1, 2007 to make all the necessary software changes. **CHP supports the decision to use the consolidated DRGs as it would avoid 4-digit DRGs. Every provider or entity that collects or evaluates DRG information would have to make programming changes if a 4-digit DRG, as proposed by MedPAC APR-DRG, is adopted. Moving to a 4-digit DRG would add undue programming costs to health care and related healthcare markets and move limited financial resources away from initiatives focused on improving quality care and access to healthcare.**

6. Consider transitioning to severity-adjusted DRGs at the same time as implementation of ICD-10 potentially in FY 2009. Although this option was not presented in the proposed rule, it could reduce the overall cost in the long term for severity-adjusted DRG changes and provide a significant improvement to the current system. As hospitals move to severity-adjusted DRGs, coding and claims processing systems will need to be revised to factor expanded code ranges, new coding algorithms and revised code fields within system software and forms. Exactly the same type of coding and software changes would have to be adjusted for the implementation of ICD-10. Migrating to new severity-adjusted DRGs and to new ICD-10 codes simultaneously would allow hospitals to update their encoders, groupers, and internal software systems once and thereby reducing overall costs associated with reprogramming, retraining, and re-installations. A simultaneous transition would also consolidate staff downtime or unproductive training time. **The end result would include an updated ICD-10 coding structure that matches to the rest of the world and an updated DRG structure that accommodates severity of illness, multiple complications and co-morbidities. We recommend that CMS give serious consideration to finalizing all these changes no later than July 1, 2007, for an October 1, 2009 implementation, to provide adequate time for transition, training, systems re-design and testing.**

Cost-Based Weights: Outlier Threshold

According to the proposed rule, cases would qualify for outlier payments in FY 2007 if costs exceed the inpatient PPS rate for the DRG, including indirect medical education, disproportionate share hospital, and new technology payments and a fixed-loss threshold of $25,530. CMS has consistently budgeted a higher outlier payment amount for each fiscal year that has exceeded amounts actually paid (i.e. versus 5.1% budgeted for both years versus 4.1% and 4.7% paid in 2005 and 2006 respectively).

We are concerned that the increase in the fixed-loss threshold amount from $23,600 to $25,530 is unwarranted and would further reduce the payment to our associated hospitals for the medically necessary care provided. Presently our hospitals receive approximately $12 million dollars in inpatient outlier payments, which is a very small portion of our overall total revenue, but is vital payment especially to our smaller facilities. **We would like to see an analysis of the proposed changes to the 2007 DRGs and rationale for the increased outlier threshold.**

In addition we recommend the following considerations for outlier payment as CMS moves forward with severity-adjusted DRGs:

1. Maintain current fixed-loss outlier threshold of $23,600 for FY 07 and at least FY08 to ensure payment stability during this transition period until the full impact and disclosure of severity-adjusted DRGs in provided. We are also concerned that the impact of severity-adjusted DRGs relative to outlier payment has not been fully analyzed and disclosed to hospitals in the proposed rule. Without more detail on how specific severity-DRGs would be adjusted to incorporate payment that normally would be paid as a separate outlier, hospitals are unable to determine if the higher severity of illness DRG payment will be sufficient to offset the need for a separate outlier payment in the future. Furthermore, the elimination of a separate outlier payment would require a legislative change which may not be accomplished by the FY07 Final Rule timeframe.

2. Continue to provide a separate outlier payment after the transition to severity-adjusted DRGs to provide a stop-gap for unusual cases that require intensive interventions. Outlier payments were designed to provide some financial protection for providers who treat "extraordinary" or intensive cases beyond the normal care protocol. Hospitals need the assurance that financial assistance will be available to serve "all" beneficiaries, not just beneficiaries that fall within the norm. Although severity-adjusted DRGs can account for some of the outlier cases, the fact remains that there will always be cases that do not fit the norm due to the individuality of patients. If outlier payments are eliminated altogether, Medicare beneficiaries could face unintended consequences like care rationing or withholding of needed services. We do not believe that Medicare desires this outcome for their beneficiaries or the public in general.

DRGs: Hip and Knee Replacements

We support CMS in the movement of ICD-9 procedure codes 00.71, 00.72, 00.73, 00.81, 00.82, 00.83, 00.84, 81.53, 81.55 from DRG 471 to DRG 545 and the corresponding correction to the Medical Code Editor (MCE) for the Bilateral Procedure Edit.

CBSAs

We continue to be deeply concerned about the manner in which the Medicare wage index negatively impacts hospitals in our communities – not just those who are part of CHP. With that said, our analysis of the FY'07 proposed rule indicates that the wage index changes will result in an overall reduction of almost half of the total Medicare inpatient update for CHP. A reduction of this magnitude creates severe hardships in our ability to carry out our mission to serve our communities with a particular emphasis on those who are poor and underserved. We believe that a reduction of this size is unwarranted and that it should be reversed in the final rule.

Perhaps most troubling from our perspective is that the manner in which Medicare wage index changes are made is inconsistent with the agency's stated public policy goals. For instance, on June 1, CMS Administrator Mark McClellan was quoted in a release by the Department of Health and Human Services as saying, "In all areas of care -- hospitals, physicians, nursing homes, health plans, and prescription drugs -- we are supporting collaborative efforts that are providing unprecedented information to help people get **the best quality care for the best**

price." (emphasis added.) The Medicare wage index ensures that the higher the cost as part of a nationwide comparison, the more a hospital in a given area receives through its wage index.

To that end, a hospital in Knoxville, Tennessee is competing with a hospital in San Francisco, California for its Medicare wage index increase. And while we are not submitting that the wage indexes in Knoxville and San Francisco should be identical, a hospital in Knoxville should not see its Medicare wage index reduced year-on-year when its wages are increasing year-on-year. The practical effect of the current wage index policy ensures that a hospital in Knoxville is penalized for increasing wages at rates that are reasonable for their market.

The use of CBSAs continues to fall short of the need for a real-time measurement of the marketplace for those individuals whose salaries determine the Medicare wage index.

The most poignant example of this reality for us is St. Vincent Mercy Medical Center (SVMMC), located in downtown Toledo, Ohio. The hospital employs a richer blend of clinicians with higher levels of education and training based on the high acuity of those individuals we serve, including a high mix if Medicare patients. Our average hourly wage continues to be more than 108 percent above that of the Toledo, Ohio CBSA. Yet, due to a change in the CBSAs in the FY'05 hospital inpatient rule, SVMMC no longer meets the 15-mile test for the Ann Arbor CBSA. At the same time, there are numerous advertisements in the Sunday issues of *The Toledo Blade* placed by health care institutions located in the Ann Arbor MSA. There are shuttles running clinicians up the Interstate from Toledo to Ann Arbor where higher wages are offered, due at least in part to the higher Medicare wage index.

It is with this background that we would offer the following policy recommendations for the final FY'07 inpatient hospital rule:

1. There should be a stop-loss for hospitals whose average hourly wage increases from one year to the next. In other words, a hospital should not receive a lower wage index while its average hourly wage is increasing.

2. A hospital that is currently re-classed into a CBSA should be allowed to maintain their re-class in subsequent three-year increments through the Medicare Geographic Classification Review Board if they continue to meet the 108 percent test regarding their CBSA and the CBSA to which they are currently re-classed. In addition, there should be a one-time, one-year grace period with the creation of such a policy for those facilities whose 3-year reclassification has just expired.

3. The use of CBSAs continues to fall short of recognizing markets for those individuals whose salaries contribute to the measurement of the Medicare wage index. The agency is not required to use CBSAs as the measure of determining the Medicare wage index and should seek an alternative that is a better reflection of the real-time marketplace.

Occupational Mix Adjustment

The acceleration of the due date for the data submission of the Occupational Mix Survey information to June 1, 2006 has caused undo hardship upon calendar year reporting facilities for which 2005 Medicare Cost Reports were due on May 31, 2006. Many facilities had planned on preparing the Occupational Mix Survey information during the month of May 2006. The announcement of the accelerated due date has not given hospitals adequate time to plan and budget for the required additional resources. The strain on resources could potentially impact the results reported by hospitals both for the submitted Cost Report as well as Occupational Mix Survey. Since the Cost Reports are the key to underlying proposed changes for 2007 IPPS proposal, hospitals should be allowed adequate time to focus on accuracy and compliance. Staff were not afforded sufficient time to review findings of either report as allowed in past years. We recognize that the change in due dates were the result of a Federal court decision beyond CMS' control, however, we wanted to voice our disappointment in a decision that benefited a few hospitals but severely inconvenienced a greater number of hospitals across the nation. **We appreciate CMS providing an alternative proposed rule to address the handling of the fully implemented Occupational Mix Survey and look forward to submitting comments. However we are concerned that the accelerated and constrained reporting period could result in the filling of inadequate reports which could impact national figures as well as individual facility rates.**

Hospital Quality Data

CHP supports CMS' drive toward achieving greater accuracy in the validation process and its requirement of hospitals to meet chart validation by combining samples proposed for federal fiscal year (FFY) 2007. The combining of 15 cases from the first, second, and third quarters into a single sample to determine whether or not the 80% reliability test is met is an improvement in current program procedures. However, CHP would be supportive of an even more statistical robust methodology. Moving beyond the proposed threshold to a higher level of hospital data validation by as many as 25 cases would foster Centralized Data Abstraction Center (CDAC) standards, increased statistical reliability, provide hospitals with needed flexibility, as well as mitigate the effect that a random error could place on a hospital from receiving its full update for FFY 2007. Moreover, CHP is supportive of the CMS proposal that hospitals would attest to the completeness and accuracy of the quarterly data submitted to the Quality Improvement Organization (QIO) clinical warehouse.

EMTALA

Currently Physicians and Non-Physician Practitioners are authorized by hospital medical staff bylaws as "qualified medical personnel" and are able to determine when a woman is in "labor" under current EMTALA regulations. However, only a Physician is able to certify that a woman is in "false labor" and may be released from the Emergency Room without further EMTALA obligations. It is ironic that specially trained Non-Physician Practitioners can deliver a baby, but under current Conditions of Participation provisions for EMTALA are not able to determine that a woman is not in labor; particularly when the current requirement permits physicians to phone in their certification of "false labor" without physically viewing the patient. **We support CMS' proposal to amend the Conditions of Participation for EMTALA which would allow Non-Physician Practitioners to certify "false labor."**

This privilege is a reasonable service to permit within State scope of practice and State law for the specially trained staff and can be easily accommodated in our affiliated hospitals medical staff bylaws.

Blood Clotting Factor Payment Rate

Over the years, CMS has made payment policy changes impacting the coverage of blood clotting factors provided to inpatient hemophiliac patients. The blood clotting factors are necessary for patient health and healing. **We support CMS in their quest for a uniform approach for drug payment. We recommend CMS continue to provide the additional Medicare Part B drug payment for blood clotting factors in the future even if severity-adjusted DRGs are implemented. This is a vitally important medical treatment for hemophiliacs.**

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Beaumont Hospitals®

June 9, 2006

Kenneth J. Matzick
President and
Chief Executive Officer

VIA DLH EXPRESS

Mark McClellan, M.D., Ph.D, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; 71 *Fed. Reg.* 23,996 *et seq.* (Apr. 25, 2006); CMS-1488-P

Dear Dr. McClellan:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services ("CMS") proposed changes to the Hospital Inpatient Prospective Payment Systems ("IPPS") and Fiscal Year 2007 Rates. 71 *Fed. Reg.* 23996, *et seq.* (Apr. 26, 2006).

William Beaumont Hospital ("Beaumont") is a two-hospital regional medical center located in metropolitan Detroit. Our Royal Oak Hospital ("Beaumont Royal Oak") (23-0130) has evolved into a 1,061-bed tertiary care, teaching, research and referral hospital and had the highest number of admissions in 2004 of any U.S. hospital according to the American Hospital Association. Our Troy Hospital ("Beaumont Troy") (23-0269) is a 254-bed community and teaching hospital that is ranked among the nation's busiest smaller community hospitals. Today, our medical staff includes more than 2,400 physicians representing more than 91 medical and surgical specialties.

Beaumont is consistently recognized as our region's healthcare provider of choice. Beaumont Royal Oak was recognized in 2005 for the 10th year in a row as "most preferred hospital" in southeastern Michigan by the National Research Corporation. Recently we have also received two prestigious National awards. *U.S. News and World Report*, in its 2005 "America's Best Hospitals" issue, recognized Beaumont Royal Oak in 11 of its medical specialty categories. Furthermore, Beaumont Royal Oak in 2004 became the only Michigan hospital granted the coveted Magnet designation for nursing. Magnet status is the highest recognition a nursing organization can achieve.

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Although Beaumont Royal Oak has the second highest number of Medicare admissions of any hospital in the country (per CMS), it has not come without a cost to our operations. In our fiscal year that ended December 31, 2005, our Medicare cost of uncompensated care (operating expenses for the Medicare program exceeding Medicare net revenues) was approximately $67 million ($49.5 million deficit at Royal Oak and $17.5 deficit at Troy). It is important to note that this loss is not due to inefficient operations, as we compare favorably to our peers in routine benchmarking studies.

If the final rule does not contain significant revisions, then it is entirely possible that our financial burden from our Medicare business will force us to eliminate an indeterminate amount of jobs. In 2006, our Royal Oak Hospital alone has already completed a reduction in force which eliminated 169 full time equivalents. Such reductions will result in fewer resources being available to patients, including Medicare beneficiaries, which in turn may ultimately affect access to critical health care services. We have significant concerns about the proposed rule because it will cause our already significant loss on Medicare operations to increase considerably.

In general, we recommend that: (1) CMS consider a one-year delay in the proposed DRG changes to ensure that, if enacted, the changes truly help create a better payment system; (2) any changes should be implemented with a three-year transition, given the extent of the payment redistribution that will arise from these changes; and (3) any comprehensive reclassification system be implemented at the same time as the new weighting system to provide for a smoother transition period.

The following are more specific comments and recommendations based on our review of the proposed rule. We have also incorporated comments provided to us by our medical leadership.

Changes to the DRG Classifications and Relative Weights

CMS is proposing the most significant changes to the calculation of the DRG relative weights since IPPS was first implemented. These changes would result in a dramatic redistribution among both DRGs and hospitals. For FY 2007, CMS proposes two major changes: use of hospital-specific relative values ("HSRVs") and a modified version of cost-based weights instead of weights based on charges.

The revised DRG weights will result in a significant redistribution of Medicare inpatient payments among hospitals. For FY 2007, in general, weights for the medical DRGs increase while those for surgical DRGs decrease significantly. At Beaumont Royal Oak we estimate that the impact of the FY 2007 proposed rule relative to the changes in the DRG weights would yield an additional annual loss of $8.2 million. We expect Beaumont Troy to experience an additional loss of $0.1 million in FY 2007.

In our review of the HSRV methodology, we have found several technical problems that we believe need to be addressed and corrected before implementation.

- There is not an accurate estimate of national average cost utilized in the current HSRV, particularly in the routine cost center (CMS line number 25 on the Medicare Cost Report). CMS has provided for only two options to group routine services -- routine and intensive care. Most hospitals today have many unique routine charge codes on their charge master to reflect the resources utilized and cost of care required to treat that particular patient. The current CMS methodology uses an average for all such routine services and therefore cannot account for the cost differences related to the various patient room types. As a result, the methodology in the proposed rule does not accurately estimate the weighted average room cost per DRG for each hospital and on a national scale.

  To illustrate, in 2006, we have roughly 10 unique room and board rates on our charge master. As expected, there are certain room types such as progressive care or step-down beds that typically have a higher charge than average medical/surgical rooms (and would still be grouped to the routine cost center under the proposed methodology). This disparity is due to the higher operating costs required for progressive care rooms for items such as high technology monitors and equipment (capital costs) and higher than average nursing time spent caring for the patient. Generally speaking, cardiac patients require this higher rate room type. The charges and cost for these patients would be understated by CMS in the FY 2007 proposed DRG system, thereby lowering the relative weight and applicable payment. Of all our service lines, we have seen by far the most dramatic underpayment in Cardiology. Until the DRG weighting methodology is changed to incorporate these issues, Medicare reimbursement will not reflect the actual costs incurred by Hospitals. Moreover, reimbursement for areas such as Cardiology clearly will be inadequate. We would be happy to work with CMS to discuss this matter further and share any relevant data.

- We understand that many large hospitals (*i.e.*, that make up over 25 percent of Medicare inpatient charges) were excluded by CMS from the cost center CCR (cost to charge ratio) calculation. However, the data for these hospitals were included in calculation of the DRG weights. We recommend that the data for these hospitals be studied further by CMS for inclusion into the IPPS.

- In our review of the methodology discussed in the proposed rule, we believe that the national CCR methodology is not weighted fairly. Specifically, large urban, teaching hospitals are weighted the same as small rural hospitals, regardless of Medicare volume. We believe that CMS should carefully consider adjusting its methodology to weigh its averages based on the charges contributed. In addition, the proposed CCR methodology tends to highlight charge compression. This impacts the most device-intensive cardiac DRGs.

- The claims data used by CMS is generally three to five years old and is now potentially too old to rely upon when considering advances in technology, such as drug-eluting stents.

- Generally speaking, we believe the hospital cost reports utilized for the FY 2007 proposed DRG system are not appropriately utilized as the basis for the new DRG weights, because the cost report was not designed for such purposes.

Due to the gravity of these matters, we strongly urge CMS to postpone implementation of the HSRV methodology to establish DRG weights until FY 2008. We support the goal of both MedPAC and CMS to align payments with costs, but we do not believe this can be accomplished under the proposed rule. We believe the following two suggestions would result in a more a more accurate DRG system.

1. CMS should consider modifying the existing cost report forms to better account for routine costs. The current CMS approach is to group all routine costs into either intensive care or routine care. Our experience shows that progressive care and other more costly room types are not being properly weighted by CMS (due to the use of high level averages across all room types) in the calculation of the DRG weights. If the routine cost line (CMS cost report line number 25) were increased to match the room and board offerings at a hospital, we believe we would have a better matching of cost and payment since this methodology would be incorporated for each applicable DRG. Although the work required to obtain this additional level of detail would create an administrative burden to hospital cost report preparers, the end result would be cost beneficial. We suggest CMS forego these proposed changes until several years worth of cost report data is available in this format. CMS would be in the best position after this data has been collected to make the transition to the HSRV DRG system. We have specific ideas for the necessary changes in the cost report forms and would be willing to share those with CMS.

2. CMS should consider creating a separate interim survey to "explode" certain routine cost report line data from the cost report to arrive at more meaningful cost per day and discharge information. This would be the same theory as step one, only a hospital would need to manually break out the routine costs on a separate report instead of being done prospectively on the cost report.

Representatives of CMS stated in the May 5, 2006 Open Door Forum that they would like hospitals to comment on the move to the new severity-adjusted DRG system. This change is scheduled to be implemented by CMS in FY 2008 or sooner and would increase the active DRGs from 526 to 861. Responding to such a dramatic change to IPPS is not feasible at this time, since we do not have readily available the tools to measure the impact. A free and standard crosswalk has not been made available by CMS, and we therefore have not had the time or opportunity to study this impact in sufficient detail.

Beaumont provides cutting edge, innovative treatments to its patients. We support CMS's goal that any severity-adjusted DRG system take into account the added costs of treatments that involve technologies that are innovative and highly complex, but that may not be performed on patients with a greater severity of illness. Otherwise, we will withhold our comments on the

consolidated severity-adjusted system until the CMS request for public comment begins when it issues the FY 2008 (or other time of implementation) proposed rule. [1]

Outlier Payments

CMS has proposed to increase the fixed-loss cost outlier threshold approximately 8.2 percent from $23,600 to $25,530. CMS earmarks 5.1 percent annually of the total IPPS payments for outlier payments. Currently, there is no "look back" provision incorporated by CMS to ensure that the amount of actual outlier payments paid by Medicare is consistent with the amount budgeted.

Recent experience indicates that CMS is not reimbursing providers up to the expected 5.1 percent payment level. Specifically, CMS estimates that it spent 4.1 percent for outliers in FY 2005 and will spend 4.7 percent in FY 2006. We believe it is unreasonable to increase the outlier threshold in light of this evidence. We believe this recent claims experience suggests that a proposed change to lower the outlier threshold is warranted at this time. We urge CMS to strongly reconsider this increase to the outlier threshold and implement a reduction to the outlier threshold that is consistent with the trending of FY 2005 and FY 2006 outlier claims experience.

IME/GME Payments

The Medicare Modernization Act of 2003 requires CMS to reduce the Indirect Medical Education ("IME") payment adjustment multiplier from 1.35 to 1.32. This legislation will increase our Medicare loss on operations annually by $1.5 million ($1.4 million loss at Royal Oak and $.1 million loss at Troy).

The proposed rule states that resident training that occurs at non-hospital sites must be related to patient care if a hospital includes time for Graduate Medical Education ("GME") and IME payment purposes. Resident time spent in didactic activities such as educational conferences, journal clubs and seminars would be specifically excluded. CMS noted that its statement in a previous letter on this topic "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME ... was inaccurate." CMS also noted that time spent in these activities could be counted for GME purposes if they occur in a hospital; however, the counting prohibition applies for IME payments regardless of where the educational activity occurs.

As a result of clarifications CMS has issued in recent years, for a provider to include in its FTE count for IME and GME purposes rotations to the nonprovider setting, the provider is required to compensate the nonprovider setting for the cost incurred in teaching and supervision activities. Moreover, CMS has stated that the provider is required to compensate the nonprovider setting

[1] We do not believe, however, that some of the changes proposed by CMS need to be delayed until a new DRG system is in place. First, we oppose the proposed delay in changing the reimbursement for carotid artery stent cases. Hospitals should be compensated under the current system for the higher costs associated with carotid stents. Second, we do not think it is necessary to delay refining defibrillator DRGs based on Major Cardiovascular Diagnoses ("MCVs"). CMS should apply a clinical severity concept similar to the approach used in FY 2006 to refine cardiac DRGs to an expanded set of DRGs based on the presence or absence of an MCV.

for cost related to the didactic time, not for the time spent in the provision of patient care, since the nonprovider setting already is compensated for the provision of patient care. The proposed rule, therefore, establishes a paradox: the very didactic time for which CMS requires the provider to compensate the nonprovider is the time that the provider cannot include in its FTE count. Accordingly, if a provider does not compensate the nonprovider setting for costs related to didactic time, the provider should have the right to claim the nondidactic time in its FTE count.

Beaumont is a member of the Association of American Medical Colleges ("AAMC") and we carefully consider the AAMC's opinion on matters relating to medical education reimbursement. The AAMC generally believes that the historical expectation is such that didactic education time is generally allowable for IME and GME payment purposes. These activities are an integral part of the residents' patient care activities during their residency periods. Moreover, it would be very difficult to separate out time spent at these activities. Based on this general expectation from the provider community, and in light of the $1.5 million statutory payment reduction discussed above, we strongly recommend that CMS not implement this exclusion of didactic education time.

Transparency Initiative

While progress has been made in quality transparency, similar information on hospital pricing is less accessible. The proposed rule discusses the CMS perspective on the difficulties in providing information for health care consumers and offers several options to consider. Proposals offered by CMS include:

- Publishing a list of hospital charges either for every region of the country or for selected regions of the country.

- Publishing the rates that Medicare actually pays to a particular hospital for every DRG, or for selected DRGs, that could be adjusted to take into account the hospital's labor market area, teaching hospital status and disproportionate share hospital status.

- Establishing a Medicare condition of participation for hospitals to post prices and/or post their policies for discounts or other assistance for uninsured patients.

- Posting total Medicare payments for an episode of care. Under this proposal, CMS could include the costs for an inpatient hospital stay, physician payments (including the surgeon and the anesthesiologist), and payments for post –acute care services such as those provided in an inpatient rehabilitation facility, SNF or LTCH for a certain service (such as hip replacement).

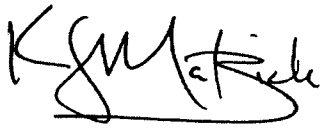
Beaumont is supportive of moving toward transparency in a proper context. We believe partial data, or data without adequate explanation, impedes progress. Reporting of hospital payments without standardization for area wage index, DSH, GME and IME payments would leave the consumer without complete information on the relative cost of care at different hospitals. CMS and Congress have sound policy reasons for these additional payments.

As CMS has already determined, hospital charges and payments for the same procedure vary widely throughout the country and within states. Publishing this information would not aid consumers, as their Medicare coinsurance is based on Medicare payments, not charges. Since payment and charges are dramatically different, we do not support this CMS proposal in this current format. Generally speaking, consumers and the general public do not understand the fundamental differences between charges and payments, and furnishing this data will only cause additional confusion to a matter that is already tenuous.

Beaumont agrees with the Michigan Hospital Association's recommendation to CMS to convene a workshop of AHA and Medicare beneficiaries to identify the core issue to be resolved by the transparency initiative. Once that is identified, the hospital industry can provide meaningful input to resolve the problem.

Thank you for your review and consideration of these comments. If you have any questions about this letter please feel free to contact our reimbursement director, Michael Klett, at (248) 423-4392 or mklett@beaumonthospitals.com.

Sincerely,



Kenneth J. Matzick
President and Chief Executive Officer
William Beaumont Hospitals

lb

Kaiser Foundation Hospitals
Walnut Center
Pasadena, California 91188

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June 9, 2006

VIA DHL OVERNIGHT MAIL

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1488–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS–1488–P, EMTALA

Thank you for the opportunity for Kaiser Foundation Hospitals ("KFH") to comment on the proposed rule regarding EMTALA, file code CMS 1488-P. KFH is a California nonprofit corporation that owns and operates 28 hospitals in three states.

KFH strongly supports the proposed rule to allow certified nurse midwives ("CNMs") and other qualified medical personnel to certify false labor. It has long been within the scope of practice of CNMs to evaluate labor and determine when a patient is in false labor, but CMS's past interpretations have required unnecessary consultation with a physician, delaying a patient's discharge from the hospital. This process has significantly impacted the throughput of Labor and Delivery departments and decreased patient satisfaction.

Although KFH supports expansion of CMS's interpretation of ETMALA from past interpretation with respect to "false labor," we also suggest that CMS clarify that "labor" is not synonymous with an "emergency medical condition" and that CMS eliminate the requirement for certification of false labor entirely, as it is not consistent with EMTALA requirements. EMTALA requires hospitals to provide a medical screening examination within the capability of the hospital to determine whether the patient has an emergency medical condition, and if the patient has an emergency medical condition, to provide stabilizing treatment within the capability of the hospital, or to provide for an appropriate transfer to another hospital with the capability to provide treatment.

"Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in

(A) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
(B) Serious impairment of bodily functions; or
(C) Serious dysfunction of any bodily organ or part.

With respect to a pregnant woman who is having contractions, "emergency medical condition" means

(A) That there is inadequate time to effect a safe transfer to another hospital before delivery; or
(B) That transfer may pose a threat to the health or safety of the woman or the unborn child.

The definition of "labor" is irrelevant to whether the hospital has provided a medical screening examination or whether a pregnant woman has an emergency medical condition. The term "labor" is not used at all in the definition of an emergency medical condition, nor is it used in 489.24(a), which requires the performance of a medical screening examination. There is nothing in this definition to suggest that "labor" by itself is an emergency medical condition that would warrant a requirement that false labor be certified. Under EMTALA, once qualified medical personnel have provided a medical screening examination and ruled out an emergency medical condition, as defined above, the hospital has met its EMTALA obligation.

A definition that provides that a pregnant woman having contractions is in true labor unless a qualified person certifies false labor begs the question, "What if the woman is in 'true labor'?" Even "true labor" has no implications for EMTALA because "true labor" is not an emergency medical condition. The purpose of certification of false labor has never been clear, but it appears that CMS is trying to use a back-door to include "labor" alone as an emergency medical condition when this was clearly not included in EMTALA. CMS should not use a definition in the regulation to impose additional obligations that do not exist in EMTALA, particularly when the additional obligation does not further the intent or purpose of EMTALA. KFH supports the EMTALA TAG recommendation to delete the second sentence of the definition of labor, and urges CMS to adopt the advisory group's recommendation.

Thank you for your consideration of Kaiser Permanente's views. If you need further information or have questions, you may contact me at 626.405.5963.

Sincerely,

Kristin Bear

Kristin Bear
Senior Counsel
Kaiser Foundation Hospitals

UNIVERSITY of VIRGINIA HEALTH SYSTEM

VICE PRESIDENT *and* CHIEF EXECUTIVE OFFICER
of the MEDICAL CENTER

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June 8, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

Attention: **CMS-1500—P**

Dear Administrator McClellan:

The University of Virginia Medical Center welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006).

We strongly urge the Agency to postpone implementing the purported move from a charge to a cost-based DRG weighting methodology by one year. The rationale for the one year postponement is to allow for further analyses and data collection which will result in the submission of the best possible data from not only The University of Virginia but all providers. To date providers have been given a 60 day period to review and comment on the proposed rule changes. Given the complexity of the regulations and the potential impact additional time is necessary to ensure proper implementation.

The University of Virginia Medical Center supports the AHA proposal of a one year postponement in the implementation and subsequent three year phase in of the move to cost-based DRG weighting methodology. The University of Virginia Medical Center will continue to work through AHA and AAMC to support CMS efforts to identify if the changes are improvements and if the methodology is optimal.

In conjunction with the requested three year phase-in above, we also support the AHA proposal to phase-in the implementation of the consolidated severity-adjusted DRGs. The implementation of the changes in a simultaneous three year phase-in period will result in reduced payment violatility.

P.O. Box 800809 • Charlottesville, VA 22908-0809
434-243-9308 • Fax: 434-243-9328

We do not oppose CMS position to transition to a cost-based DRG weighting methodology and consolidated severity-adjusted DRGs with further study and a phased-in approach.

Sincerely,

R. Edward Howell
VP and CEO,
UVa Medical Center

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Eric M. Sontz, M.D.

Richard N. Roger, M.D., Emeritus
Keenan F. Barber, M.D., Emeritus
Merle R. Bolton, M.D., Emeritus

June 9, 2006

The Honorable Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
PO Box 8011
Baltimore, MD 21244-1850

RE: CMS-1488-P; Proposed Changes to the Hospital Inpatient Payment Systems and Fiscal Year 2007 Rates

Commenting on: General Comments; HSRV Weights

Dear Dr. McClellan:

I am a busy clinical electrophysiologist practicing at Eisenhower Medical Center in Rancho Mirage, CA. Over 75% of the patients I treat enjoy Medicare coverage for the majority of their medical expenses. The inpatient hospital payment system can affect how I am able to treat them.

I'd like to share my concerns with you regarding the proposed inpatient rule for FY2007. I believe if these changes are implemented, it could have a negative effect on some hospitals, and ultimately could impact the patients that I treat.

These comments will discuss:

1. That payment rates should accurately reflect the cost of services provided; inaccurate rates could limit hospitals' capabilities to perform services, and thus limit patient access to some therapies.
2. The potential impact of these payment inaccuracies on patients, particularly cardiovascular patients when treated with high-technology solutions.

As such, I urge CMS to allow time for further study of the proposals but in the meantime continue with the current charge-based system.

Payment rates should accurately reflect the cost of services provided. Inaccurate rates could limit hospitals' capabilities to perform services, and thus limit patient access to some therapies. The current proposal, if implemented, could have unintended and inappropriate consequences.

- **Questions have been raised about CMS's proposed rate-setting methodology.** At a high level, some of these issues include CMS's use of data that are 3–5 years old to calculate the payment rates; technical mistakes such as counting a small hospital equal to a large hospital in calculations; throwing out a quarter of the hospitals' routine day charges in calculating cost-to-charge ratios; as well as questionable technical assumptions that can alter the estimated impact on payments. Charge compression, a major issue for high-value, high-technology devices, also continues to be a problem and is not properly addressed in the proposal.

- **The current proposed DRG payment rates are in some cases the same or lower than the purchase price for ICDs and CRT-Ds.** Proposed rates for ICD and
  CRT-D procedures are sometimes below the device acquisition cost, not allowing hospitals payment for operating procedures, supplies, and personnel. For example, DRG 515, where a majority of ICD implants fall, was paid at a base of $28,441 in 2006; for 2007 Medicare is proposing a sharp decrease in payment of 23%, down to $22,015—one of the biggest percentage decreases any DRG faces this year.

Poor economics mean hospitals have to make difficult decisions when it comes to using leading-edge, high-technology solutions for their patients

- If this change is implemented, hospitals could find themselves with limited capabilities to offer their patients some advanced and technologically-driven therapies, particularly for certain cardiovascular therapies such as implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy with defibrillator (CRT-D) therapy.

- **This could result in hospitals altering normal treatment patterns, restricting technology selection, and limiting patient access in order to avoid extraordinary financial losses**. As a result, patients may not receive the already underutilized lifesaving ICD and CRT-D therapies because hospitals are not receiving payment that recognizes the full cost of the services provided.

- **Hospitals cannot sustain themselves economically when inaccurate payments do not cover the cost of supplies, equipment, staff, and medical devices.**

- **ICD and CRT-D therapies are the standards of care** as recognized by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Heart Rhythm Society (HRS) practice guidelines for many patients. It is important to set payment rates that allow for physicians to provide the right care at the right time for the right patient.

Conclusion

Sweeping decisions of this nature need thorough analysis, stakeholder input, and time and consideration prior to being implemented. Additionally, intended and unintended consequences need to be carefully examined prior to making major changes to a stable environment that could adversely affect hospitals, physicians, and most importantly, patients.

To ensure continued access to high quality care for Medicare beneficiaries, appropriate payment under the prospective payment system is critical. **As such, I reiterate my request that CMS allow time for further study of the proposals but in the mean time continue with the current charge-based system.**

We appreciate CMS's efforts to improve the inpatient payment system, and agree that it is our mutual goal to improve the lives of Medicare beneficiaries. We all must work together with diligence and dedication to address these complex issues.

Sincerely,

Leon A. Feldman, MD, FACC
Co-Director, Eisenhower EP laboratory
Desert Cardiology
Rancho Mirage, California, 92270
760-275-6211
lfeldman@desertcard.com

cc: Diane Feinstein
Barbara Boxer
Mary Bono

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June 9, 2006

Mark B. McClelland, MD, PhD
Administrator
Centers for Medicare and Medicaid Services (CMS)
P.O. Box 8011
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClelland:

I am writing to you on behalf of the over 5,000 members of the American Organization of Nurse Executives (AONE) who as Registered Professional Nurses provide executive nursing leadership in America's hospitals and in the health systems field.

As a professional nursing organization directly involved with the day to day operations and delivery of patient care, we have chosen not to directly comment on **CMS-1488-P Medicare Program: Proposed Changes to the Hospital Prospective Payment Systems for Fiscal Year 2007 Rates**. Our interest in this proposal lies in the opportunity it presents to make significant changes to the hospital cost system and specifically to diagnosis–related group (DRG) relative weights. It also provides an opportunity to factor in nursing care and validate the economic relationship of nursing care costs to staffing, education, quality and patient outcomes.

The stated goal of CMS is to align future hospital payment with actual cost expenditures; however under the current system it is not possible to calculate the true cost or impact of nursing care. Under the original conceptualization of the DRG System, arguments were made to create a separate cost center for nursing; however, the final design subsumed these costs in what has evolved as room and board room costs. Since the design of the DRG system, nursing research has evolved to show the critical relationship between nursing education, the hours of professional nursing care and patient outcomes. If the overall intent of CMS is to change the current prospective payment system to reflect the cost of care and accommodate varying levels of acuity, the contributions of nursing must be directly reflected in whatever system is developed and implemented.

As a practitioner, you are aware of the tremendous changes that have occurred in our Nation's hospitals. This change is most evident in the complexity of the patient mix and the nursing skill and intensity that must be employed to effectively manage patients and save lives. In this context, we view the CMS proposal as an opportunity to begin a dialogue to examine and understand the true cost of nursing and its relationship to hospital costs. It is our hope that you will view our request as a call for action to bring a full and complete understanding to the complex world of hospital costs and provide recognition to the critical component of nursing care.

Thank you for the opportunity to comment. You may direct questions or comments concerning our remarks to me or Jo Ann Webb, senior director for federal relations and policy at (202) 626-2321 or jwebb@aha.org

Sincerely,

Kathleen D. Sanford, RN, DBA, FACHE

Kathleen D. Sanford, RN, MA, DBA, FACHE
President

Flaget Memorial Hospital

June 9, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1488-P; Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

Flaget Memorial Hospital appreciates the opportunity to comment on the proposed rule (CMS-1488-P) that would change the Hospital Inpatient Prospective Payment System (PPS) and Fiscal Year 2007 Rates. Flaget Memorial Hospital, located in Bardstown, Kentucky, is a faith-based, 52-bed acute care hospital serving eight counties in the central part of the state.

The proposed rule would revise the methodologies used to calculate the relative weights of the Diagnosis Related Groups (DRGs) used to determine Medicare inpatient hospital services payment. The proposal would replace charge-based weights with a modified version of cost-based weights using hospital-specific relative values (HSRVs). The Centers for Medicare and Medicaid Services (CMS) also proposes a major revision to the DRG classification system to account for patient severity.

Adoption of the proposed DRG weight changes and proposed severity adjustments would result in the biggest change to the hospital inpatient prospective payment system (IPPS) since its inception. These changes would significantly redistribute payments among the DRGs and among hospitals.

Based on calculations provided by the American Hospital Association, the DRG changes would negatively impact Flaget Memorial Hospital by $313,000 in the first full year of implementation.

We support improving DRG payments to more accurately reflect resources used in caring for Medicare patients, but it is not clear that the proposed DRG weight changes or new patient classification system will result in a more accurate hospital payment system. Impact estimates at the DRG and hospital level are extremely sensitive to methodological variations. Implementation in FY 2007 would be premature.

We urge CMS to delay these changes, undertake more in-depth analyses of their impact, and evaluate alternative methodologies for improving the DRG system.

While the proposed rule has many provisions impacting our hospital, we would like to comment specifically on the following issues:

HRSV Weights

We support a move to cost-based weights but have several concerns about the adequacy and validity of the proposed methodology. More work is needed to determine the best way to create cost-based weights. If changes are made to DRG weights, those changes should be phased in over three years with "stop loss" protections to allow significantly impacted hospitals time to prepare for payment changes.

In particular, **CMS should further analyze and evaluate the impact of:**

- **Use of 2004 Data** – CMS uses claims data taken from the FY 2004 MedPAR file in its methodology. Clinical practice has changed in many areas, especially cardiology, over the past two years. The data used may not reflect current clinical practice. CMS may need to make specific changes to specific DRGs to reflect the change in clinical practice. For example, interventional cardiology DRGs do not reflect the cost of current clinical practice.

- **Variation in Markups** – The CMS methodology assumes a uniform hospital markup, but markups vary from product to product.

- **Distortion of Costs** – The proposed methodology would distort the accuracy of cost estimates by combining multiple cost centers on hospital cost reports into ten CMS-designated cost center. CMS would then determine ten national average cost-to-charge ratios for each of the designated costs centers but the ratios would not be weighted by each hospital's Medicare charges. This would allow very small hospitals to have just as much of an impact on the national cost-to-charge ratios as larger hospitals.

- **Access to Centers of Excellence** – The proposed changes are particularly significant for large volume hospitals and may have a negative impact on Centers of Excellence, which could impede beneficiary access to high quality services.

We recommend delaying until at least FY 2008 the proposed cost-based DRG weights. CMS should undertake a more thorough analysis, including parallel pilot testing, of the proposed changes to identify any unintended consequences. If DRG weight changes are implemented, they should be phased in over three years with "stop loss" protections.

DRGs: Severity of Illness

CMS has proposed a new classification system to reflect severity of illness among patients beginning in FY 2008 or earlier. CMS has proposed adoption of CMS-developed Consolidated Severity-Adjusted DRGs (CS-DRGs) rather than the widely applied All Patients Refined DRG system endorsed by MedPAC. Additional information and further analysis is needed to determine whether the CMS-proposed system, or another classification system, would result in an improved hospital payment system.

Until hospitals have a final GROUPER that can accurately assign the new CS-DRGs, it is difficult to calculate the impact. While we have surrogate methods of calculating the impact, GROUPERs used to calculate payments have changed in the past and minor changes can cause major changes in reimbursement.

We are concerned about the impact of making two major payment changes in two successive years. We are also concerned about the ability of hospitals to adapt to these major changes in PPS in the short time frame proposed.

If the need for and best approach for changing the patient classification system is clearly demonstrated, CMS should simultaneously implement the DRG weight changes and new classification system to provide greater stability and predictability in hospital payments. These changes should not be implemented before FY 2008. A three-year phase-in period with "stop loss" protections should be provided to ensure that redistribution of hospital payments is not unduly disruptive to negatively impacted hospitals.

We recommend further analysis by CMS to determine if the proposed CS-DRGs, or an alternative patient severity classification approach, would result in more accurate payments. If the effectiveness of, and need for, a new patient classification system is demonstrated, CMS should implement the new DRG system at the same time as the DRG weight changes. A three-year phase-in with "stop loss" protections should be allowed to provide greater stability and predictability in hospital payments. A new patient classification system should not be implemented before FY 2008.

Physician-Owned, Limited Service Hospitals

The DRG changes proposed by CMS seek to address the proliferation of physician-owned, limited service hospitals in response to recommendations from the Medicare Payment Advisory Commission. However, we do not believe that payment changes alone will remove the inappropriate incentives created by physician self-referral to

limited-service hospitals. Physicians will still have the ability and incentive to steer financially attractive patients to facilities they own, avoid serving low-income patients, practice similar forms of selection for outpatient services and drive up utilization for services. We strongly urge CMS to rigorously examine the investment structures of physician-owned, limited-service hospitals.

We urge CMS to continue the suspension of issuing new provider numbers to physician-owned, limited-service hospitals until the CMS strategic plan has been developed and Congress has had an opportunity to consider CMS' final report on physician-owned, limited service hospitals.

Hospital Quality Data

We support expansion of the number of measures to be reported for the Annual Hospital Payment Update. This expansion follows the recommendation of the Institute of Medicine. However, we do have a concern with the timing of the final regulation and the requirement to begin the expanded reporting with January 1, 2006 discharges.

Hospitals are currently abstracting information for quality reporting for the January – March 2006 period with a closing date of mid-July. For those hospitals that have been collecting the "starter set" of 10 quality measures and have not begun abstracting the additional 11 measures, this retroactive requirement may pose an undue monetary and administration burden.

By the time the final rule is published, these hospitals may not have time to go back retrospectively and still meet the data submission deadlines for that period, especially if they need to have their vendor contracts amended to allow for the addition of an entire core measure set. These hospitals may also have difficulty retroactively collecting the second quarter information.

We recommend that CMS start the reporting period for the expanded quality measures with services provided on or after July 1, 2006.

Critical Access Hospitals

On November 14, 2005, CMS issued interpretive guidelines on the relocation of CAHs as a follow-up to the FY 2006 inpatient PPS final rule that established the "75% test" – serving 75 percent of the same population, providing 75 percent of the same services and employing 75 percent of the same staff – for necessary provider CAHs. The guidelines not only extended the 75% test to *all* CAHs, but also altered the definitions of "mountainous terrain" and "secondary road."

We believe that these guidelines go well beyond the regulations included in the FY 2006 rule that provoked numerous critical responses from individual CAHs and congressional representatives. The "mountainous terrain" and "secondary road" definitions are overly prescriptive and the 75% test does not provide reasonable flexibility based on natural

variation in demographics, patient needs distribution patterns, normal employee and board attrition, and necessary changes in services to meet community needs. Rural hospitals that move a few miles are clearly the same providers serving the same communities.

Many CAHs are planning to rebuild in the near future to improve site safety and quality of care by adding fire and smoke barriers, upgrading infrastructure to support utilities and air handling, modernizing telecommunications to support health information technology, or making other essential upgrades. Facilities expect to relocate when they rebuild for a multitude of reasons: to be closer to a highway, to connect to municipal water and sewer, to serve a moving population, or other similar concerns. Such improvements will undoubtedly result in higher quality care, better patient outcomes and more efficient service, yet CMS' guidelines discourage these improvements.

CMS' guidelines will not only impose an unnecessary burden on CAHs, but will preclude many of them from securing financing for needed capital improvements. The hospitals themselves and their lenders cannot risk investing in a hospital that will be unsure of its status until a year after moving.

Almost 60 congressional representatives signed a letter to CMS showing their support for their CAHs and urging changes to these guidelines. We agree with their recommendations and urge establishment of a safe harbor for hospitals relocating within five miles of their existing locations. These providers are not only clearly serving the same communities, but trying to improve the quality of and access to needed health care services. A safe harbor will reduce the administrative burden on not only the hospitals, but CMS and the state survey agencies as well.

We recommend use of a preliminary approval process by CMS to give assurances that the CAH relocation will be approved if it meets the assertions made in the attestation submitted to CMS. We urge CMS to create a safe harbor for CAHs moving a short distance. We also encourage CMS to make significant changes to the relocation guidelines based on the feedback received from CAHs around the nation.

Value-Based Purchasing

The Deficit Reduction Act of 2005 requires the Secretary to identify by October 1, 2007 at least two conditions that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through application of evidence-based guidelines. For discharges occurring on or after October 1, 2008, hospitals would not receive additional payment for cases in which one of the selected conditions was not present on admission. CMS seeks input on which conditions and which evidence-based guidelines should be selected.

The proposed rule discusses hospital acquired infections as a complication that could trigger higher payments and an area for consideration. Our concern with the selection of hospital acquired infections as a condition for denying additional payment is that the codes currently used in billing data do not accurately distinguish hospital-acquired infections from community-acquired infections.

Even surgical site infections, which should intuitively be accurately identified through administrative data, have proven to be grossly in error when compared to data collected and reviewed by infection control practitioners using Centers for Disease Control and National Infection Surveillance System definitions.

Instead of hospital acquired infections, CMS may want to consider hospital falls with injury and pressure ulcers not present on admission as two conditions that are potentially preventable through use of evidence-based practices.

In any case, we believe that administrative data should not be the sole decider. Just as there is additional data gleaned from records for the core quality measures, we believe that the adverse outcome concept can only be adequately gauged by reviewing the actual record to ensure that the event is accurately captured, and that the appropriate preventive measures were, or were not, followed. Only then would it be reasonable to base reimbursement on the occurrence.

We recommend that CMS select two "preventable" conditions for additional payment denial that can be most accurately identified as not present upon admission through billing data. Once identified, patient records should be reviewed to determine whether appropriate preventive measures were followed before denying additional payment for the condition.

Thank you for the opportunity to comment on this proposed rule.

Sincerely,

Bruce A. Klockars
President and Chief Executive Officer

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NEW ISLAND HOSPITAL

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Stephen H. Neff
President
Chief Executive Officer

June 9, 2006

Centers for Medicare and Medicaid Services
Dept. of Health and Human Services
ATTN: CMS-1488-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: Revised Inpatient PPS DRG Weights

To Whom It May Concern:

In response to your recent proposed changes to the Hospital Inpatient Prospective Payment System relating to the revisions to the Inpatient DRG Weights, please be advised that this Hospital supports this policy change. We believe that this proposal is a market-based response to complaints from the not-for-profit community providers that niche providers were drawing the most profitable cases from general community hospitals. We believe that by adjusting the weights and expanding and revising the DRGs, you have successfully improved the accuracy of payments so that all DRGs are equally profitable or unprofitable and have therefore removed the incentive to specialize in a particular service.

For a number of years, community general hospitals have incurred substantial losses at the expense of specialty hospitals who were overly compensated for their services. It is timely that CMS has recognized this issue and has adjusted the weights to mitigate this condition. We believe this change should be made as soon as possible and that no "phase in" is needed.

On behalf of New Island Hospital, we would like to express our thanks for addressing this issue.

Sincerely,

Stephen H. Neff
President
Chief Executive Officer

cc: Nassau Suffolk Hospital Council
HANYS
AHA
GNYHA

TGH Tampa General Hospital

June 8, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1488-P and P2
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule.

Dear Dr. McClellan:

Tampa General Hospital (TGH) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS or the Agency) proposed rule entitled *"Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems [IPPS] and Fiscal Year 2007 Rates."* 71 Fed. Reg. 23996 (April 25, 2006). Tampa General Hospital serves a 12-county region with a population in excess of 4 million, in West Central Florida. TGH serves as the primary teaching hospital for the University of South Florida (USF) College of Medicine. Since 1971, the College of Medicine has graduated nearly 1,700 physicians and prepared 2,000 doctors in specialty residency programs. Ranked among the nations top 100 research universities, USF and TGH are committed to developing advances in medicine through both clinical practice and research.

This letter focuses primarily on two areas that have important implications for teaching hospitals and the academic medical community: a) proposed changes to the diagnosis-related group (DRG) weighting and classification systems, and b) a purported "clarification" that would prohibit hospitals from counting much of the resident time spent in didactic activities when calculating indirect medical education (IME) and direct graduate medical education (DGME) payments.

In brief, we do not oppose moving from a charge to a cost-based DRG weighting methodology, but believe that a one-year postponement is necessary to allow for further analyses to address data and computation issues and to ensure that the best possible methodology ultimately is implemented. We also support refinement of the DRGs but believe that the proposed consolidated severity-adjusted DRGs (CS-DRGs) require

further examination and likely modifications before implementation. We believe that these changes should be implemented simultaneously to ensure equity and minimize payment volatility for hospitals. Finally, because they will likely result in the redistribution of over a billion dollars in Medicare payments among hospitals, a significant transition period should accompany the changes. Tampa General is estimating that the changes as proposed result in no increases for TGH in FY 2007. Reimbursement will remain stagnant in contrast to reported increases per the rule and therefore will provide us with no ability to meet inflationary increases in costs.

Concerning the DGME and IME issues, we strongly urge CMS to rescind the purported "clarification" in the proposed rule. The Agency should instead reaffirm its 1999 position defining patient care activities to include didactic activities.

In this letter, we also comment on several other important issues raised in the proposed rule, including: the outlier threshold, reporting hospital quality data, payment for new technologies, the Emergency Medical Treatment and Labor Act (EMTALA) requirements. We also include our perspectives on value-based purchasing, and the Agency's health care information transparency initiative.

PROPOSED CHANGES TO THE DRG WEIGHTING AND CLASSIFICATION METHODOLOGIES

Because it has approximately 42 million beneficiaries, the vast majority of who are over 65, the importance of the Medicare program to hospitals and the health care system generally is self-evident. Consequently, significant changes to the program, such as those proposed, have a profound effect. Moreover, one must also keep in mind that many Medicaid and private sector payers follow Medicare's payment methodology. This ripple effect reinforces the imperative that significant changes to the Medicare system, like the DRG weighting and classification changes, must be subjected to comprehensive and thorough analysis to ensure that the goals of the intended policy change are met without undue stress to the system.

Current System

Under the IPPS, Medicare pays hospitals a per case payment that varies according to which diagnosis-related group (DRG) the case is assigned and the DRG's payment "weight." Each weight is intended to represent the average hospital resources required to treat a case within a DRG compared to the average required per case resources across all DRGs. Thus, cases that require higher levels of resources, on average, will have higher weights than cases that require relatively lower levels of average resources.

Cases are assigned to one of 526 DRGs, predominantly based on the patient's principal diagnosis, up to eight additional diagnoses, and up to six procedures performed during the stay. The determination of which case types comprise a DRG is based on both clinical coherence and similar resource consumption. Hospitals do not decide to which DRG a case is assigned. Rather the assignment is done by the Medicare GROUPER

software program, based on the diagnosis and procedure code information provided by the hospital.

Currently, the DRG weights are based on Medicare allowable charges per discharge. These charges are standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals in Alaska and Hawaii, the applicable cost-of living adjustment.

An average standardized charge per DRG is then calculated by summing the standardized charges for all cases in the DRG (excluding those cases whose charges are viewed as unreasonable based on statistical tests) and dividing by the number of transfer-adjusted cases in the DRG. Each DRG's average standardized charge per case is then divided by the national average standardize charge per case to determine its relative weight.

Proposed Changes

Under the proposed rule, in FY 2007, Medicare would move to a "hospital-specific relative value cost center" (HSRVcc) DRG weighting methodology. In FY 2008 ("if not earlier" according to the proposed rule) the current 526 DRGs would be replaced by 861 "consolidated severity adjusted DRGs" (CS-DRGs). According to the proposed rule press release, these two proposals represent the "first significant revision of the Inpatient Prospective Payment System (IPPS) since its implementation in 1983."

Analyzing the Proposed Changes

Despite the obvious complexity associated with the methodology, combined with the major financial impacts associated with the resultant DRG weight changes, hospitals were given only 60 days to review and comment on the proposed rule changes. During this period, Tampa General has been able to model the end result of what the weight changes will do to reimbursement but not the underlying rationale and wisdom in such changes. Any impact of the proposed APR-DRG system is contingent on the hospital buying that grouper technology from 3M, essentially making any independent hospital level analysis of the new APR-DRG system impossible.

Overall Impact of the Proposed Changes

While the proposed rule changes are budget-neutral, if implemented, over a billion dollars in Medicare payments would be significantly redistributed among hospitals as well as among DRGs

At the DRG level, the proposed rule notes that a number of DRGs would experience payment reductions, particularly DRGs involving cardiac care. For example, cardiac procedures involving stents, both drug eluting and non-drug eluting, would see payment reductions. Tampa General is concerned about such drastic reductions for these and other cardiac procedures. While, the payment reductions could "potentially reduce the incentives . . . for the further development of specialty hospitals" (71 Fed. Reg. at 24006), we are concerned that the reductions also would significantly affect community and

teaching hospitals that do significant amounts of cardiac care. Unlike many specialty hospitals, however, Tampa General's emergency rooms treat significant numbers of Medicaid and uninsured patients, and also accept complex cardiac cases.

At the same time, we recognize and appreciate that a number of more "routine" DRGs, such as pneumonia, would see payment increases. These cases often result from emergency room admissions, which disproportionately occur in teaching and other safety net hospitals.

To the extent that changes are offered that are intended to improve the payment system, they must be carefully analyzed and assessed. Because such budget-neutral changes naturally result in payment "winners" and losers" it is critical that the underlying policy rationale for the change be sound and, if that test is met, implementation of that change be accomplished with a methodology that best achieves the policy goal. Finally, because Medicare is a critical revenue source for hospitals, to the extent the changes result in significant payment reductions, these reductions must be phased in over a reasonable period so that hospitals have time to transition to the new system without experiencing significant and relatively unexpected disruptions to operations.

1. Tampa General is NOT opposed to moving to a DRG weighting methodology based on the costs of providing care so long as it improves the accuracy of the payment system and the methodology is sound, stable, and reliable.

We support the idea of moving to cost-based weights, despite the fact that a number of major teaching hospitals would likely see payment reductions. However, a change of this magnitude cannot be entered into precipitously.

While seemingly a simple concept, developing "cost based" weights is actually a complex undertaking. Unlike other industries, the costs of providing hospital care cannot be identified directly. Consequently these costs must be "estimated" using cost-to-charge ratios (CCRs) that are reported on hospitals' Medicare cost reports and applying them to charge amounts that are reported on Medicare claims. However, even then, there are various ways of utilizing the CCRs and implementing a cost-based methodology. The methodology developed by the Medicare Payment Advisory Commission (MedPAC) is significantly different than the HSRVcc methodology. In addition there are modifications to both of these methodologies that should also be considered.

We believe more work is needed to determine the best way to develop cost-based weights. We are committed to working with CMS and other hospital organizations to identify an appropriate methodology.

2. Tampa General is in favor of refining the DRGs to better reflect patient severity and complexity, but we have serious concerns whether the proposed CS-DRGs achieve this goal. Further study, and likely changes, to CMS's proposed CS-DRGS are needed.

We appreciate CMS's recognition of the need to better account for patient severity in the IPPS (71 Fed. Reg. at 24026). It is important that the DRG classification system reflect those cases that involve the sickest and most complex Medicare patients. As common sites of care for these patients, ensuring that these cases are assigned to DRGs that adequately reflect the resources needed is a fundamental principle for major teaching hospitals.

We have concerns, however, about the proposed CS-DRGs, in part because they reflect patient severity only and do not recognize service complexity. CMS agrees with these concerns, stating "a method of recognizing technologies that represent increased complexity should be included in the system." (71 Fed. Reg. 24014). We are very interested in the proposed rule statement that CMS plans to "develop criteria for determining when it is appropriate to recognize increased complexity in the structure of the DRG system and how these criteria interact with the existing statutory provisions for new technology add-on payments." (Ibid). How CMS determines these criteria and their resultant impact on the classification system will have important implications for the IPPS.

3. **Implementation of a "cost-based" DRG weighting methodology should be postponed for one year to allow for further work.** This change should then be implemented simultaneously with an appropriate expansion of the current DRGs.

As discussed above, and below, additional analysis is needed before a significant change to the DRG weights can be implemented. Consequently, we believe that the implementation of any such changes should not occur on October 1, 2006 but rather should be postponed for one year. A one-year delay would also allow for the simultaneous implementation of the new weighting methodology with refined DRGs. Each of these changes significantly redistributes payments, often in offsetting ways. Implementing both together would minimize the volatility associated with two separate changes.

4. A significant transition period must accompany these changes.

We appreciate the proposed rule's request for comments regarding a transition period (71 Fed. Reg. 24028).

Historically, Medicare changes of significant magnitude have included some type of transition period. For example, the move to a PPS for capital was transitioned in over a 10 year period. Other changes that were accompanied by transitions include: implementation of the operating IPPS (four years), eliminating day outliers (four years), and removing the costs of teaching physicians and residents in the calculation of the wage index (four years).

While it is unclear what an appropriately devised new DRG classification and weighting system might look like, it is obvious that such a change will still involve the redistribution of hundreds of millions of dollars. Accordingly a significant transition period must accompany any final changes.

THE OUTLIER PAYMENT THRESHOLD

Under the Medicare inpatient prospective payment system, if the costs of a particular Medicare case exceed the relevant DRG operating and capital payment (including any disproportionate share (DSH), IME, or new technology add-on payments) plus an outlier threshold, the hospital will receive an outlier payment. This payment equals 80 percent of the case's costs above the threshold calculation.

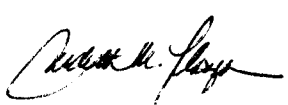
The outlier fixed-loss cost threshold is set at a level that is intended to result in outlier payments that are between five and six percent. Outlier payments are budget-neutral. Each year the Agency reduces the inpatient standardized amount by 5.1 percent and estimates a cost threshold that should result in outlier payments that equal 5.1 percent.

The proposed rule would increase the fixed-loss cost threshold for outlier payments to be equal to a case's DRG payment plus any IME and DSH payments, and any additional payments for new technologies, plus a $25,530 outlier threshold, an increase of 8.2 percent over the FFY 2006 threshold of $23,600.

CMS proposes an increase to the threshold even though the Agency estimates that outlier payments for FFY 2006 will represent only 4.71 percent of actual total DRG payments. Further, CMS estimates that outlier payments represented only 4.1 percent of total DRG payments in FFY 2005 and, according to the August 12, 2005 final rule, only 3.52 percent of total DRG payments in FFY 2004 (70 Fed. Reg. 47496). Because outlier payments were less than the 5.1 percent reduction to the standardized amount, the result is less total Medicare payments to hospitals in all three consecutive years, contrary to the intent of the outlier payment policy.

We believe the FFY 2007 cost threshold must be reduced. CMS relies only on charge inflation to determine projected increases in per case costs, which determines outlier payment outlays. Along with the American Hospital Association (AHA), and Federation of American Hospitals, we conducted an analysis that incorporates both cost and charge inflation, which we believe makes the threshold calculation more accurate and reliable. Using this methodology, the threshold should be $24,000 for FFY 2007. We urge you to review and give serious consideration to the methodology and postpone its implementation until further study can be done.

Sincerely,



Judith M Ploszek
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(7)

June 12, 2006

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P and P2
7500 Security Boulevard
Baltimore, Maryland 21244–8012

Re: CMS-1488-P and P2, Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2007 Rates; Proposed Rule

Dear Dr. McClellan:

Forest Hills Hospital welcomes the opportunity to comment on the proposed rule related to the Medicare Prospective Payment System (PPS) for inpatient admissions. Below are our comments.

DRG WEIGHTS

Summary and Recommendations

The Centers for Medicare and Medicaid Services (CMS) has proposed substantial changes to the calculation of Diagnosis Related Groups (DRGs) and weights that will result in a significant redistribution of Medicare inpatient hospital payments in both federal fiscal year (FFY) 2007 and FFY 2008.

CMS proposes to revise the calculation of DRG weights in FFY 2007. The CMS proposal relies on the Hospital-Specific Relative Value (HSRV) methodology as the basis for determining the weights. Analysis has found that weights calculated using an HSRV methodology tend to be more compressed than weights calculated using other methodologies. To avoid systematic payment errors, this effect must be taken into account when applying the HSRV methodology. There is no evidence that CMS considered this issue or evaluated the proposed weights to ensure that they do not materially over-compress DRG payments.

In addition, CMS proposes a modified version of the HSRV weights characterized as the HSRV cost center (HSRVcc) methodology. The intent was to develop an alternative HSRV calculation that avoids the calculation of costs using hospital-specific cost-to-charge ratios (CCRs) by substituting national cost center charge ratios to "scale" the weights. The Medicare Payment Advisory Commission (MedPAC) recommended a hospital-specific cost-based HSRV methodology. According to CMS, the HSRVcc methodology achieves similar results in "a more administratively feasible manner." However, CMS did

not provide evidence to validate this statement. The HSRVcc methodology is substantially different from a cost-based HSRV methodology. It represents a distinct and untested method for calculating weights that should be fully analyzed to verify that it results in equitable DRG payments.

CMS should not select the HSRVcc methodology simply because it is administratively feasible, without considering the potential tradeoff between ease of calculation and accuracy of results. Cost-based weights may be more complex to calculate; however, other payment systems such as the Outpatient PPS and the Inpatient Rehabilitation Facility PPS calculate weights using costs determined at the hospital level. CMS did not indicate that it had explored such alternatives or compared the HSRVcc weights to weights calculated using other alternatives, to assess payment equity.

Finally, analysis by industry groups indicates that the CMS calculation of the proposed HSRVcc weights contains errors and technical problems. As a result, the tables and impact statements provided by CMS in the proposed rule are based on flawed calculations that result in an inaccurate representation of the effects that the revised weights would have on hospital payments. These problems must be addressed and the proposed weights recalculated and released for public evaluation before any decision can be made regarding the proposal.

CMS has proposed implementation of consolidated severity-adjusted (CS) DRGs in FFY 2008. CS DRGs are a modified version of the all-patient refined (APR) DRGs created by 3M Health Information Systems. While there is evidence that the current Medicare DRGs could benefit from refinement, the APR DRGs and CS DRGs represent a substantial restructuring of the patient classification system that goes beyond refinement of the current DRGs. Analysis has shown that the APR DRGs and CS DRGs, which are based on differences in patient severity, do not necessarily provide an accurate reflection of differences in complexity of treatment or relative resource use.

Forest Hills Hospital Recommendations:

- **Implementation of revised weights should be postponed. This would allow time for a thorough evaluation of the HSRVcc methodology and other alternative methodologies. Weights calculated using the HSRVcc methodology, or alternative methods should be compared to weights based on costs determined using hospital-specific CCRs (such as the methodologies used for the Outpatient PPS or for the New York State Medicaid weights) to ensure the variance between profit margins by DRG is minimized.**

- **The implementation of weight revisions and the implementation of new DRGs will both cause significant payment redistributions, often with offsetting results for individual hospitals. Therefore, simultaneous implementation will be less disruptive and will avoid the payment swings that would result from separate changes.**

- **CMS should further evaluate the CS DRGs and consider alternative DRG refinements. CMS should first evaluate the current Medicare DRGs to determine the need for complete replacement of the system as opposed to focused improvement for specific problem areas.**

A patient classification system that is being used for reimbursement purposes should include resource use as a primary factor in determining the groups. A number of existing patient classification systems are based on refinements to the existing Medicare DRGs. These may provide a better reflection of resource use and complexity of treatment than the CS DRGs. In addition, systems that refine the existing DRGs would be less disruptive to existing systems and processes.

- **Any major changes to the DRG weights or patient classifications will result in significant payment redistribution between hospitals and DRGs. When weights or DRGs are implemented, a transition period should be provided with a phase-in based on a blend of the revised and the current methodology. This would allow time for refinement of the new methodology and limit the degree of payment disruptions.**

  In addition, a "stop-loss" similar to the approach currently used under the Inpatient Psychiatric PPS should be instituted as part of this transition.

- **CMS should ensure that any alternative DRG system that is selected should be publicly available and that rules governing access to software and logic for the new DRGs is no more restrictive than rules regarding access to the current DRG system.**

OUTLIER PAYMENTS

The rule proposes establishing a fixed-loss cost outlier threshold equal to the Inpatient PPS rate for the DRG, including Indirect Medical Education (IME), Disproportionate Share Hospital (DSH), and new technology payments, plus $25,530, an increase compared to the FFY 2006 payment threshold of $23,600. We are concerned that the proposed threshold is too high. Based on CMS' current estimates, actual FFY 2005 outlier payments were 4.1% of total payments and FFY 2006 outlier payments are estimated to be 4.7% of total payments. **Forest Hills Hospital urges that the methodology recommended by AHA in its comment letter be used to calculate the threshold. The estimated fixed-loss amount that would result in 5.1% outlier payments under this methodology is $24,000.**

OCCUPATIONAL MIX ADJUSTMENT

Due to a recent U.S. Court of Appeals decision in *Bellevue Hospital Center v. Leavitt*, CMS was ordered to implement a full occupational mix adjustment to the FFY 2007 wage index, based on a new data collection. To comply with the court decision, CMS set forth a strict timeline for facilities to adhere to with minimal time to review and correct for errors.

Non-compliant Providers

Forest Hills Hospital recommends that a penalty be assessed to providers that failed to meet the June 1 deadline for their January through March occupational mix submission. Forest Hills Hospital also recommends that CMS construct an application of the occupational mix adjustment that does not unfairly penalize neighboring hospitals. CMS could alternatively substitute the national average hourly wage for non-compliant hospitals in calculating an area's wage index and then require hospitals that did not turn in data to use something lower than their area's wage index. This would minimize the effects on the other hospitals in the same labor market area.

Corrections for FFY 2008 and FFY 2009

Facilities were required to submit their January through March occupational mix data to their fiscal intermediary (FI) by June 1. Subsequently, facilities are given approximately two weeks to review the data published by CMS for errors due to CMS or FI mishandlings. In its response to MedPAC, CMS planned to provide an annual process and timetable for reviewing the occupational mix data, similar to the review process for wage index. However, for FFY 2007 providers received an abbreviated review process and were unable to correct for their own errors due to strict timeframes to implement by October 1.

Forest Hills Hospital strongly recommends that CMS in subsequent years provide a review process for the occupational mix data that allows sufficient time for providers to review and correct their own errors, in addition to any CMS or FI mishandlings of the data. This will ensure that providers have ample time to submit accurate and reliable data. In addition, **Forest Hills Hospital encourages CMS to consider allowing providers an opportunity to review their January through March occupational mix data for any errors or missing data and correct the data for use in the FFY 2008 and FFY 2009 wage index calculation.**

UPDATE FACTORS

The hospital update is based on a "marketbasket" factor that is intended to reflect the average change in the price of goods and services hospitals purchase to furnish inpatient care. CMS contracts with Global Insight, Inc. for marketbasket projections and its projection for FFY 2007 is 3.4%. We believe this projection significantly under-estimates the inflation pressure that hospitals face in serving Medicare beneficiaries.

FTE RESIDENT COUNT AND DOCUMENTATION

By law, resident time spent in non-hospital settings in non-patient care activities cannot be included in a hospital's Direct Medical Education (DME) or Indirect Medical Education (IME) full-time equivalent (FTE) resident count. In contrast, in the hospital setting, resident time spent in non-patient care activities can be included in a hospital's DME resident count. However, only patient care activities may be counted for the purposes of IME.

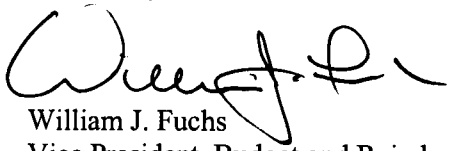
CMS is making this clarification, in response to comments based on a 1999 letter from CMS "implying that didactic time spent in non-hospital settings could be counted for direct GME and IME." According to the proposed rule, CMS states that the "statement was inaccurate."

In the case of the hospital setting, CMS is not required by law to limit IME counts to time spent in patient care. In the proposed rule, CMS states, *"we understand that, as part of an approved medical residency program, residents are often required to participate in didactic and "scholarly" activities such as educational conferences, journal clubs, and seminars."*

Forest Hills Hospital urges CMS to recognize that participation in such didactic activities is an integral part of residents patient care experience. Specifically, we request that CMS align the IME and DME resident count philosophy as it relates to the hospital setting and allow the non-patient care activities to be counted for the purposes of IME. In addition, Forest Hills Hospital believes it will be difficult for hospitals to document time spent on these activities.

Forest Hills Hospital appreciates having the opportunity to comment on the proposed rule. If you have any questions regarding our comments, please contact me at (516) 876-6000.

Yours truly,



William J. Fuchs
Vice President, Budget and Reimbursement

97

DePuy
a Johnson & Johnson company

June 8, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1427-FC
P.O. Box 8010
Baltimore, MD 21244-8018

Re: Proposed changes to orthopaedic DRGs 544 and 545 - "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates; Proposed Rule" April 25, 2006 [CMS–1488–P]

DePuy Orthopaedics, Inc., a Johnson & Johnson company, is a driver of transformational change in orthopaedic care, with a focused commitment to help surgeons achieve excellence in surgical practice. DePuy Orthopaedics is committed to the development of innovative therapies and treatments to enhance patient care.

In response to the Centers for Medicare and Medicaid Services' (CMS) proposal to a) change the current charge-based method used to develop the annual DRG weighting factors to a hospital-specific, relative-value (HSRV), cost-based system and, b) modify the DRG system to "consolidated severity adjusted DRGs," DePuy Orthopaedics respectfully submits the following comments.

Deletion of DRG 209 and Creation of DRGs 544 and 545. In the FY 2006 final rule (70 FR 47303), CMS deleted DRG 209 (Major Joint and Limb Reattachment Procedures of Lower Extremity) and created new DRGs 544 (Major Joint Replacement or Reattachment of Lower Extremity) and 545 (Revision of Hip or Knee Replacement). The establishment of two new DRGs was intended to more appropriately compensate hospitals that perform revisions of joint replacements since the revision procedures are more resource intensive than original replacement procedure. While this change represented a major modification to the reimbursement methodology for these procedures, we applaud CMS for taking the initiative to adjust the payment discrepancies that may have existed under DRG 209.

Reduction in Reimbursement for DRGs 544 and 545. We are greatly concerned by the two proposals put forth in the proposed rule which will result in a reduction in reimbursement for DRGs 544 and 545, a mere seven months after the initiation of the new DRGs. The new HSRVcc and consolidated severity adjusted DRGs would result in an overall decrease in reimbursement to hospitals for DRGs 544 and 545. The analysis contained in the rule projects a payment reduction of 13.0% for DRG 545 (Revision of Hip or Knee Replacement).[1]

[1] CMS-1488-P (Display Copy) "Table I.--Payment Impact from HSRVcc and Consolidated Severity-Adjusted DRGs by Selected High Volume DRGs." Pgs 99-100.
2. Bozic K, Katz P, Cisternas M, Ono L, Ries M, Showstack J. Hospital resource utilization for primary and revision

Payment Impact from HSRVcc and Consolidated Severity-Adjusted DRGs by Selected High Volume DRGs

CMS DRG V23.0	CMS DRG Description	Number of Cases	Percent Change in Relative Weight Due to HSRVcc	Percent Change in Discharge Weighted Average Weight Due to Consolidated Severity-Adjusted DRGs	Total Impact All Changes
544	REATTACHMENT OF LOWER EXTREMITY	407,310	-4.0%	-1.0%	-5.0%
545	REVISION OF HIP OR KNEE REPLACEMENT	41,021	-3.0%	-10.0%	-13.0%

Creation of DRG 545 was intended as stated in the FY05 IPPS final rule, (page 47305) to "replace payment issues for hospitals that perform the more difficult revisions of joint replacements." We feel it is premature to propose a payment reduction within less than a year of implementation and that claims data are insufficient to understand the true financial impact to hospitals.

Data Submission by Massachusetts General Hospital, the Mayo Clinic and the University of California at San Francisco. This group of researchers completed two studies on hospital resource utilization in total joint arthroplasty (TJA). A pilot study compared detailed resource utilization (using activity-based costing methodology) between primary and all types of revision total hip arthroplasty (THA) procedures at UCSF.[2] The second, a multi-center study involving more than 10,000 patient clinical and financial records from all three institutions, compared relative resource utilization among primary, single component and both component revision THA and total knee arthroplasty (TKA).[3]

The findings were consistent with those of previous investigators [4-6] who demonstrated significant differences in operative time, length of stay, complication rates and overall resource utilization between primary and different types of revision TJA procedures.

The April 25 2005 Federal Register contained an announcement from CMS splitting DRG 209 into two separate DRGs: DRG 544 (Primary Hip and Knee Replacement) and DRG 545 (Revision Hip and Knee Replacement). In explaining its decision, CMS cited the importance of the input from the American Academy of Orthopaedic Surgeons (AAOS) and orthopaedic surgeons, stating, "We agree with the commenters and the AAOS that the creation of a new DRG for revisions of hip and knee replacements should resolve payment issues for hospitals that perform the more difficult revisions of joint replacements."

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total hip arthroplasty. *J Bone Joint Surg Am.* 2005;87(3):570-576.

3. Bozic K, Durbhakhala S, Berry D, et al. Differences in Patient Characteristics, Procedures Characteristics, and Hospital Resource Utilization in Primary and Revision TJA. *J Arthroplasty* (Accepted for Publication, March. 2005).

4. Iorio R, Healy W, Richards J. Comparison of the hospital cost of primary and revision total hip arthroplasty after cost containment. *Orthopedics* 1999;22(2):195-199.

5. Lavernia C, Drakeford M, Tsao A, Gittelsohn A, Krackow K, Hungerford D. Revision and primary hip and knee arthroplasty. A cost analysis. *Clin Orthop* 1995 Feb;(311):136-141.

6. Barrack RL, Sawhney J, Hsu J, Cofield RH. Cost analysis of revision total hip arthroplasty. A 5-year followup study. *Clin Orthop* 1999 Dec;(369):175-178.

CMS also noted that the data they received on differences in resource utilization in primary and revision TJA were most convincing. "The commenters reported on a recently completed study comparing detailed hospital resource utilization and clinical characteristics in over 10,000 primary and revision hip and knee replacement procedures at three high-volume institutions: the Massachusetts General Hospital, the Mayo Clinic, and the University of California at San Francisco."

CMS credited the importance of input and collaboration with members of the AAOS and AAHKS in helping it understand the issues related to coding deficiencies and reimbursement discrepancies related to TJA procedures.

Consolidated Severity-Adjusted DRGs by Selected High Volume DRGs

It is documented that the creation of DRG 545 last year took into account the financial burden to hospitals for this procedure and was the result of detailed claims and cost reporting analysis. Such an immediate reduction in reimbursement would place hospitals performing revision procedures at a further financial disadvantage. In addition, we are concerned that the hospitals currently performing the complex, resource intensive revision procedures may choose to limit access to this procedure, due to the reductions in payment. Consolidating the severity-adjusted DRGs would undo this change, and assign revisions together with initial replacements. Essentially CMS is undoing the payment adjustment made in 2006 to reflect the greater resource utilization seen with revision hip and knee surgeries.

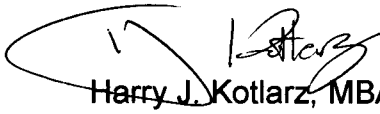
We suggest that the relative weight of DRG 545 be maintained at the FY 2006 level until a sufficient amount of claims data is available to determine the true financial impact to hospitals.

Several health care groups including the American Hospital Association and the Heart Rhythm Society (HRS) support at least a one-year delay of CMS's proposed changes to the Inpatient Prospective Payment System.

We appreciate your consideration of the above comments. Please contact the undersigned if you have any questions.

Best Regards,

DePuy Orthopaedics, Inc.
a Johnson & Johnson company



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AMERICAN ACADEMY OF NEUROLOGY

American Association of Neurological Surgeons

CONGRESS OF NEUROLOGICAL SURGEONS 1951 ERUDITIO OBSERVANTIA SOCIETAS

American Heart Association. | American Stroke Association.
Learn and Live.

June 9, 2006

Mark McClellan, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1488-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates

Dear Dr. McClellan:

The American Academy of Neurology (AAN), the American Stroke Association (ASA), a Division of the American Heart Association, the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) appreciate this opportunity to comment on the proposed hospital inpatient prospective payment rule for FY 2007.

The AAN is a professional organization of 19,000 practicing neurologists and neuroscientists dedicated to providing the best possible care to patients with neurological disorders. Neurology is the primary medical specialty directing the treatment of stroke patients, who number 750,000 per year in the U.S.

The ASA, a division of the American Heart Association, is a leading voluntary health organization focused on stroke and is dedicated to improving stroke prevention, treatment and rehabilitation through research, advocacy and development. With over 22.5 million AHA and ASA volunteers and supporters, the ASA is committed to achieving a reduction in stroke and associated risk by 25 percent by 2010.

The AANS, founded in 1931, and the CNS, founded in 1951, are the two largest scientific and educational associations for neurosurgical professionals in the world. These groups represent

approximately 5,200 neurosurgeons in the United States, Canada, Mexico, Europe and the Pacific Rim. Neurosurgery is the surgical specialty concerned with the prevention, diagnosis, treatment and rehabilitation of disorders that affect the spine, brain, nervous system, and peripheral nerves.

Statement of the Problem

Our organizations support CMS' objective of improving the accuracy and fairness of the DRG payment system. In particular, we support the development of DRGs which better reflect patient severity of illness (SOI). However, we are very concerned that the consolidated APR-DRGs proposed for use in FY 2008 or potentially earlier, would reverse recent progress in ensuring that hospitals receive fair and appropriate payment for care provided to stroke patients.

In the FY 2005 IPPS, CMS approved the creation of new DRG 559 for "Acute Ischemic Stroke with use of Thrombolytic Agent" to properly recognize the increased inpatient hospital costs associated with providing care to stroke patients who receive a reperfusion agent. Under the proposed rule, CMS is effectively reversing this change through implementation of a new DRG system which does not include a DRG for treatment with a reperfusion agent. As explained below, we believe this change would be entirely inconsistent with and would undermine the agency's goal of creating DRGs which more accurately reflect severity of illness.

Background

In 2004 and 2005 our organizations met with CMS staff to discuss clinical advances in stroke care including, in particular, the role of reperfusion agents. We advocated for, and CMS agreed to, a change in stroke DRGs to reflect the higher inpatient costs associated with administration of the reperfusion drug, tissue plasminogen activator (tPA), to stroke patients who qualify for this treatment. CMS announced the creation of DRG 559 (acute ischemic stroke with use of thrombolytic agent) in the preamble to the final FY 2006 IPPS rule. At that time, the agency stated that it agreed with the position taken by our organizations and others that there is an increased cost in caring for stroke patients receiving thrombolytic agents "including increased use of the intensive care unit, more diagnostic imaging studies, and laboratory and pharmacy resources." 70 Fed. Reg. 47287 (August 12, 2005) CMS further stated that "the data indicate that patients receiving thrombolytic therapy have increased severity; and . . reperfusion therapy is a good means to segregate these patients into a separate DRG." More specifically, CMS stated that its analysis of MedPAR data showed that "charges for cases treated with a reperfusion agent are more than $16,000 and $10,000 higher than all other cases in DRGs 14 and 15." Id. In recognition of this higher cost, CMS established a weight of 2.2473 for DRG 559 – almost double that of DRG 14 and approximately two and half times that of DRG 15.

In the proposed IPPS rule for FY 2007, published in the April 25 Federal Register, CMS proposes to change from the current DRG system to a new consolidated APR-DRG system. One of the agency's objectives, in implementing the new DRG system, is to have hospital DRG payments more accurately reflect the patient's severity of illness. Our organizations fully support this goal. In fact, that was the very reason for the creation of DRG 559. Consequently, we are very concerned that the consolidated APR-DRGs have no DRG comparable to DRG 559 which recognizes the high severity of illness associated with stroke patients who receive thrombolytic therapy.

If the consolidated APR-DRGs are implemented in their current form most stroke cases which are currently assigned to DRG 559 would be assigned to one of the three ischemic stroke DRGs in the consolidated APR-DRG system (DRGs 56-58). Those DRGs describe CVA and precerebral occlusion with infarct, SOI 1, SOI 2 and SOI 3. The weights for those DRGs are: .7865, 1.0195 and 1.5486 – all of which are weighted less than the current weight for DRG 559. Thus, even the highest level DRG for ischemic stroke does not begin to compensate hospitals for the higher costs associated with stroke patients who receive a reperfusion agent.

Further, under the proprietary 3M algorithm used to assign cases to the consolidated APR-DRGs, most stroke cases involving administration of thrombolytic agent would not be assigned to the highest SOI level stroke DRG. Our analysis, using 2004 MedPAR cases, shows that if the 2061 cases from 2004 that would have been assigned to DRG 559 (had it been in existence) were mapped instead to the consolidated APR- DRGs, 113 would be assigned to DRG 56 – the lowest SOI level; 962 to DRG 57 (SOI level 2) and only 734 to DRG 58 (SOI level 3). (The rest would be assigned to other DRGs). Overall, the weighted average DRG weight for DRG 559 cases, under the consolidated APR-DRGs, would drop by 35% to 1.4563. Even cases assigned to the highest SOI level would receive DRG payments far less than under the current DRG 559.

Moreover, the 3M algorithm does not even recognize use of thrombolytic agent (procedure code 99.10) as relevant in DRG assignment. (See attached sample 3M "APR DRG Assignment Report.) However, even if it did, the weights for the highest SOI DRG are still far below those of DRG 559.

Request

It is essential that a DRG corresponding to DRG 559 be included in any new DRG system. If CMS intends to proceed with the consolidated APR-DRGs we ask that they be revised to include a DRG comparable to DRG 559. Without this, the progress recently made in achieving equitable payment to hospitals that care for these complex patients will be lost. Appropriate payment for the administration of a thrombolytic agent to acute ischemic stroke patients is necessary in order to facilitate patients' access to this treatment. Patients who receive tPA within the first three hours after the start of symptom, are 30% more likely to have minimal or no disability in three

months as compared to those patients who go untreated. Therefore, any Medicare DRG system should include a DRG that specifically accounts for the costs associated with the administration of tPA and acknowledges that this drug can lead to improved patient outcomes and help to reduce overall Medicare spending on outpatient services.

Rationale

Stroke continues to be a significant cause of morbidity and mortality in the United States. Each year about 700,000 people have a new or recurrent stroke e and it remains a leading cause of long-term disability in the United States. [1] Between 15 to 30 percent of stroke patients are permanently disabled and 20% will require some form of institutional care three months after onset. [2]

Nearly 88% of all stroke patients have an ischemic stroke – which means that these patients have strokes caused when blood clots block the blood flow to an area of the brain. Currently, the only FDA-approved drug for treating ischemic stroke is the administration of tPA. When tPA is administered within the first three hours after the start of symptoms, the patient is at least thirty percent more likely to have minimal or no disability in three months compared with those patients who go untreated.

Evidence-based guidelines developed by our organizations on acute stroke treatment indicate that reperfusion with tPA is supported by Level 1A evidence.[3] This is the highest endorsement for an acute stroke therapy. Hospitals administering tPA in accordance with the Level 1A guideline incur substantial costs compared to cases in which tPA is not indicated or administered. These costs include increased personnel requirements to rapidly evaluate and follow acute stroke patients, intensive care unit services, increased diagnostic and other ancillary services, and the cost of the drug itself. However, use of tPA can ultimately save money because it can reduce the need for long-term care and rehabilitation services.

Conclusion

For all of the above reasons, the undersigned organizations strongly request that the consolidated APR-DRGs be modified to include a DRG that specifically describes use of thrombolytic

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[1] American Heart Association, *Heart Disease and Stroke Statistics – 2006 Update. Dallas Tex: American heart Association: 2006.* Available at http://circ.ahajournals.org/cgi/reprint/CIRCULATIONAHA.105.171600v1. Accessed on May 31, 2006.

[2] Id. at 21.

[3] Harold Adams, Robert Adams, Gregory Del Zoppo, and Larry B. Goldstein Guidelines for the Early Management of Patients With Ischemic Stroke: 2005 Guidelines Update A Scientific Statement From the Stroke Council of the American Heart Association/American Stroke Association; Stroke 36: 916-923.

therapy in treatment of ischemic stroke. If we can be of any further assistance, please do not hesitate to contact Steven R. Rush, MA, LP, Practice and Patient Safety Manager, AAN at srush@aan.com or 651-695-2803; Penelope Solis, Regulatory Relations Manager for the ASA at penelope.solis@heart.org or 202-785-7905; or Katie Orrico, Director, Washington Office of the AANS and CNS at KOrrico@neurosurgery.org or 202-628-2072.

Sincerely,

Thomas R. Swift, MD, FAAN
President, American Academy of Neurology

Ralph L. Sacco, MD, MS, FAAN
Chairman, ASA Advisory Committee

Donald O. Quest, MD, President
American Association of Neurological Surgeons

Richard G. Ellenbogen, MD, President
Congress of Neurological Surgeons

Enclosure

3M™ APR DRG Assignment Report - Output

Data Output Screen

Detailed Report Show

Printer Friendly

Summary Report

3M Health Information Systems

APR DRG Assignment Report (Summary)

APR DRG Version 23.0

Patient Code :	*Not entered*	**Sex :**	Male
Age in years :	67 (Group G)	**Status :**	1 - Home, self-care (routine)
Days Mech Vent (DMV) :	0	**DMV Option :**	6 - No DMV

APR DRG Results

APR DRG : 45 - CVA & PRECEREBRAL OCCLUSION W INFARCT
MDC : 1 - DISEASES AND DISORDERS OF THE NERVOUS SYSTEM
SOI : 1 - Minor Patient Severity of Illness
M/S : Medical
RETURN CODE : 0 - DRG assigned

CMS DRG ver 23.0 : 559 - ACUTE ISCHEMIC STROKE WITH USE OF THROMBOLYTIC AGENT
Consolidated APR DRG : 56 - CVA & PRECEREBRAL OCCLUSION W INFARCT SOI 1

Diagnosis Codes

	Diag	Description	Valid	Affect DRG	Affect SOI
(PDX)	43301	Ocl bslr art w infrct	Yes	Yes	Yes

Procedure Codes

Proc	Description	Valid	O.R.	Affect DRG	Affect SOI
9910	Inject/inf thrombo agent	Yes	-	-	-

APR DRG Assignment

APR DRG : Principal diagnosis code of CVA w/infarct

Patient PDX 43301 used for DRG and SOI assignment

Phase 1 - Results

Diag	Phase 1 - S O I						
	Step1	Step2	Step3	Step4	Step5	Step6	MSL

Phase 2 - Results

Step 7	SOI

Phase 2 - S O I	
Step 8 - Max of all SDX subclass	1
Step 9 - Maximum Severity Subclass	1

Phase 3 - Results

Phase 3 - S O I	
Step 10 - PDX/DRG modification	1
Step 11a - DRG/Age modification	1
Step 11b - PDX/DRG/Age modification	1
Step 12 - DRG/nOR Proc modification	1
Step 13 - DRG/Proc modification	1
Step 14 - DRG/multiple Proc modification	1
Step 15 - ECMO modification	1
Step 16 - PDX/DRG/nOR Proc modification	1
Step 17 - Multiple SDX modification	1
Step 18 - Final Severity of Illness	**1**

System version: **2.0**, revision: **10**, build: **2**. Embedded grouper version: **23**, build: **1.1**.

BAKER | NEWMAN | NOYES LLC

Certified Public Accountants

INTEGRITY · · · SOLUTIONS

June 9, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1488-P, Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Medicare Program: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates : SCH/MDH Volume Decrease Adjustment 71 FR 24075-24078, April 25, 2006

Dear Sir:

We have several comments relative to the proposed use of the occupational mix in determining the core staffing requirements of a sole community hospital (SCH). We first commend the Centers for Medicare and Medicaid Services (CMS) on the realization that the outdated 1988 HAS Monitrend Report is not the appropriate medium for current cost reporting period comparisons. Besides, the regulations published in the March 29, 1985 Federal Register does not even imply hospitals should be held to a peer comparison. The Regulations appear clear that hospitals should review staffing levels and reduce them to the appropriate level for their individual needs and circumstances. It is clear to us that the intent of the regulation was not to establish a fixed cap on full-time equivalents (FTEs) or even benchmark against each other but consider individual needs. Our following comments are based on that basic understanding of the Regulations.

A. Based on the aforementioned statement, we do not believe that hospitals should be strictly held to fixed hours per patient day but, rather, fiscal intermediaries should be given a range which considers a hospital's individual needs and circumstances. The straight use of the occupational mix does not consider patient acuity, quality results or staffing issues for an individual hospital. Providing a staffing range would allow for mitigating circumstances for each hospital.

B. In using the current occupational mix including RN's, LPN's and Aides, this number also includes orderlies and attendants. A hospital that hires lower paid staff should not have this group determining the number of nursing staff FTE's. It seems it would be much more appropriate to use only RN's and LPN's in the adult and pediatric (A&P) and intensive care unit (ICU) cost centers since that data is also available.

C. Also, if the occupational mix is to be used, and all data is available for all hospitals why not compare a hospital to a smaller peer sample (i.e., its own state rather than a census region or based on MSA's)? This would allow for a more accurate and appropriate comparison. As an example, should a rural hospital in Alaska be compared to an urban hospital in California, or a hospital in rural Vermont to an urban hospital of the same size in Rhode Island?

D. Because the occupational mix includes total hospital staffing, any adjustment should not be made strictly to the A&P cost center. Any adjustment that would be made should be prorated to all services, inpatient, ancillary and outpatient. A small SCH may have small inpatient utilization but have a significant number of outpatient staff, so this should not be adjusted against only the inpatient costs.

CMS, having recognized that the 1988 HAS Monitrend Report is not an appropriate indication of current staffing requirements, should recommend the fiscal intermediaries use other available documented and auditable information such as audited cost report A&P/ICU total hours divided by total days in current SCH exceptions. Because of revisions and a provider's lack of knowledge in completing the occupational mix survey, it is difficult to comment on the viability of it being meaningful to the SCH peer adjustment at this time.

Thank you for considering our comments.

Very truly yours,

Vinal C. Doody
Principal

VCD/smm

LAKE REGIONAL HEALTH SYSTEM

June 7, 2006

Certified Mail Receipt No. 7003 0500 0001 2667 1079

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1488–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS–1488–P
April 25, 2006, IPPS Proposed Rule
Submission of Comments

Dear Sir or Madam:

We appreciate this opportunity to comment on the inpatient PPS fiscal 2007 proposed rule published in the April 25, 2006, **Federal Register**. We are a 100-bed rural hospital located in Osage Beach, MO. Our comments are as follows:

Payments to MDHs

The DRA made several significant changes to the statutory provisions related to Medicare-dependent hospitals (MDHs). Section 5003(b) of DRA provides the option for an MDH to compute its hospital-specific payments using "the 12-month cost reporting period beginning during fiscal year 2002". A simple interpretation of this provision would be that it relates to the cost reporting period beginning on or after October 1, 2001 and before October 1, 2002.

In implementing Section 5003(b), CMS has proposed a new 42 CFR 412.79(a)(1) providing use of a cost report from "the 12-month or longer cost reporting period ending on or after October 1, 2001, and before October 1, 2002." CMS erroneously uses the word "ending" in this proposed regulation, when the word "beginning" should be used. We request that this error be corrected, stating that an MDH may use the 12-month or longer cost reporting period beginning on or after October 1, 2001, and before October 1, 2002, and correcting the related references throughout 42 CFR 412.79.

54 Hospital Drive, Osage Beach, Missouri 65065 573-348-8000

On a related matter, CMS proposes that the 2002 base period costs be updated using the methodology set forth in 42 CFR 412.73(c)(14) and (c)(15). Hospitals with fiscal years beginning on October 1 can easily have their base period costs updated using the normal PPS update factors put into effect each October 1. However, most hospitals do not have fiscal years beginning on October 1, and should have at least a partial update for the period from the start of their 2002 base period to the start of the next federal fiscal year. We would suggest an update process similar to that used in 42 CFR 412.73(c)(10), and request CMS clarify this issue.

We appreciate this opportunity to comment on this important proposal. If you have any questions concerning our comments or require further information, please contact me at 573-348-8388.

Sincerely,

Dan Probstfield

Dan Probstfield
Senior Vice President/Chief Financial Officer

DP/cl

cc: Michael E. Henze, CEO