

**Submitter :** Ms. Kim Patrick  
**Organization :** DaVita Dialysis  
**Category :** Dietitian/Nutritionist

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Dede Erickson

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please approve thsi initiative

**Submitter :**

**Date:** 10/24/2006

**Organization :**

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mr. Richard Turner

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

Vascular access is one of the greatest sources of complications and cost for dialysis patients. This is because we use more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arteriovenous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205, and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mr. Jerry Chambers

**Date:** 10/24/2006

**Organization :** None

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I think every caution should be taken without extreme cost to the patient.

**Submitter :** Sonja Thompson-Pollock

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Other Technician

**Issue Areas/Comments**

**ASC Office-Based Procedures**

ASC Office-Based Procedures

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

**ASC Office-Based Procedures**

ASC Office-Based Procedures

Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.

**Submitter :** Ms.  
**Organization :** Ms.  
**Category :** Nurse

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I believe out patient procedures for fistula creations would be advantageous for pt. and insurances alike, the cost has to be significantly less. Less stress on pt. and hospital loads in outpt surgery. waits would be shorter. My only concern is that qualified surgeons for the procedure be used. and that all pt. have previous mapping of veins to ensure a successful creation of a natural fistula.

**Submitter :** Mrs. Rosa Jaramillo  
**Organization :** DaVita Healthcare Lab.  
**Category :** Laboratory Industry

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

**GENERAL**

GENERAL

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.



**Submitter :** Mr. Barnett Schwartz  
**Organization :** Mr. Barnett Schwartz  
**Category :** Individual

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

\* Please Support ESRD Patients like myself. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

\*

Please Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.

**Submitter :** Ms. Dorothy Noder

**Date:** 10/24/2006

**Organization :** DVA Laboratory Services (DaVita)

**Category :** Laboratory Industry

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category : Individual**

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Dr. Steve Cooksey

**Date:** 10/24/2006

**Organization :** Renal Endocrine Associates

**Category :** Physician

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Dorothy Noder

**Date:** 10/24/2006

**Organization :** DVA Laboratory Services (DaVita)

**Category :** Laboratory Industry

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

The single most significant barrier to patients is their ability to get into the surgical facility for placement of an A-V access. Allowing them to use an ASC will greatly enhance our ability to provide quality care for them and thereby extend their lives.

**Submitter :** Mrs. Bettie Carney

**Date:** 10/24/2006

**Organization :** Mrs. Bettie Carney

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

The fistula surgery would be better if performed in a hospital rather than a surgical care center that does not have some juice or food if needed. I would not want it done in a surgical care center after watching TV coverage stating they usually don't have Dr. Anthiest's putting you under, just unqualified nurses doing it. Some places didn't even life support equipment. Just because you don't have medical insurance shouldn't mean you get poor care.

**Submitter :****Date: 10/24/2006****Organization :****Category : Other Health Care Professional****Issue Areas/Comments****ASC Payable Procedures****ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list. Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting. Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL****GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae. The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.



**Submitter :** Dr. Steve Cooksey  
**Organization :** Renal Endocrine Associates  
**Category :** Physician

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures

**Submitter :** Mrs. Jenny Maher  
**Organization :** Frederick Davita Healthcare  
**Category :** Nurse

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I think that the Ambulatory Surgical center is a great idea and limits the amount of hospitalizations related to access placements and access issues for our dialysis patient population.

**Submitter :**

**Date: 10/24/2006**

**Organization :** frederick davita

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

ambulatory surgicAL CENTERS ARE GREAT ESPECIALLY FOR OUR DIALYSIS PT.IT DECREASES THE NUMBER OF HOSPITALIZATIONS.

**Submitter :** Dr. Jack Kronfield

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Physician

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Any policy aimed at increasing the number and effectiveness of fistulae in ESRD patients must accomplish three things:

1. Ways must be sought to overcome the reluctance of PCPs to refer patients with renal insufficiency to nephrologists EARLY in the course of their disease.
2. Nephrologists must convince patients who appear to be heading to ESRD to have fistulae created long before they are at end stage.
3. Only qualified and certified vascular access surgeons must be allowed to create fistulae.

**Submitter :** Mrs. Sherry Hallowell

**Date:** 10/24/2006

**Organization :** DaVita Dialysis

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.

**Submitter :** Mrs. Tracey Milligan

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

As a health care professional, I work with ESRD patients daily. It is extremely important that they be able to get their vascular access taken care of quickly, safely, and with minimum expense. I believe that ambulatory surgery centers are able to provide this care. I believe that angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings. Thanks for your consideration.

**Submitter :** Ms. Summer Scott

**Date:** 10/24/2006

**Organization :** Davita

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

GENERAL

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mr. Carl Palmer

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Nurse

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

**ASC Payable Procedures**

ASC Payable Procedures

Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.



**Submitter :** Miss. Shirley Miller

**Date:** 10/24/2006

**Organization :** DaVita Dialysis

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

Support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings

**Submitter :** Mr. joe gerko

**Date:** 10/24/2006

**Organization :** Mr. joe gerko

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

i want more money fro kideny patients for dr and med bills plus money for house hold bills and to get gas for cars...

**Submitter :** DENNIS TRELEASE

**Date:** 10/24/2006

**Organization :** DENNIS TRELEASE

**Category :** Ambulatory Surgical Center

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

As a care provider for my mother in-law it is important that you consider the inclusion of CPT codes 35475,35476,36205 and 37206 to the list of already approved ambulatory surgical center (ASC) procedures. Having these codes provide in an out patient setting allows for significant cost savings, superior patient outcomes and outstanding patient satisfaction. My mother in-law refuses to return to the hospital for these procedures. According to her the hospital wastes her time and treats her like "dirt". The treatment for ESRD vascular access should be treated by nephrologists for their patients and the patients should be treated outside of the hospital setting. These people (in hospital ORs) do not hold ESRD patients in very high regard and it is evident by the manner that they treat them.

**GENERAL**

**GENERAL**

I have witnessed such a marked improvement in my mother in-laws care as a result of the stand alone vascular access center, here in Atlanta. She is treated like a human being and the care is administered to her by her own nephrologists who totally understand her ESRD needs. I beg you to review the Kidney International, Vol. 66 (2004), pp 1622-1632 article, "Effectiveness and safety of dialysis vascular access procedures performed by interventional nephrologists". It is a better place to treat ESRD patients who need this care!

CMS-1506-P2-168-Attach-1.PDF

CMS-1506-P2-168-Attach-2.PDF

DIALYSIS – TRANSPLANTATION

## Effectiveness and safety of dialysis vascular access procedures performed by interventional nephrologists

GERALD A. BEATHARD, TERRY LITCHFIELD, AND PHYSICIAN OPERATORS FORUM OF RMS LIFELINE, INC.

RMS Lifeline, Austin, Texas; and RMS Lifeline, Vernon Hills, Illinois

**Effectiveness and safety of dialysis vascular access procedures performed by interventional nephrologists.**

**Background.** The purpose of this report was to analyze the results obtained from a group of interventional nephrologists working in multiple centers performing basic procedures that are used routinely in the management of vascular access problems, with an effort toward establishing standards for evaluating success, complication rates, and acceptable times for procedure duration and fluoroscopy.

**Methods.** Data on six basic procedures were analyzed—angioplasty of arteriovenous fistulas (AVF-PTA), angioplasty of synthetic grafts (graft-PTA), thrombectomy of arteriovenous fistulas (AVF declot), thrombectomy of synthetic grafts (graft declot), placement of tunneled dialysis catheters (TDC placement), and tunneled dialysis catheter exchange (TDC exchange). These data were examined both as a group and by individual physician operator.

**Results.** A total of 14,067 cases were performed under the six categories of procedure that were the subject of this report; 13,503 cases (96.18%) were successful. The overall complication rate for the combined group of procedures was 3.54%, with 3.26% falling within the minor category and 0.28% within the major. The number of cases performed in each individual category with success rates for each were as follows: TDC placement—1765 cases, 98.24% successful; TDC exchange—2262 cases, 98.36% successful; AVF-PTA—1561 cases, 96.58% successful; graft-PTA—3560 cases, 98.06% successful; AVF declot—228 cases, 78.10% successful; graft declot—4671 cases, 93.08% successful.

**Conclusion.** This study demonstrates that appropriately trained interventional nephrologists can perform these basic procedures in both a safe and effective manner.

In the United States, hemodialysis vascular access represents an enormous problem. Its management is a procedure-intensive endeavor. Increasingly, these procedures are being performed by interventional nephrologists who have shown that, with appropriate training, they can perform a major portion of the procedures that are necessary for access management.

Simply stated, an interventional nephrologist is a nephrologist that performs interventional procedures essential to the management of patients with renal disease. Classically, the nephrologist has performed kidney biopsies and inserted temporary dialysis catheters. In recent years, a few in this specialty have started inserting peritoneal dialysis catheters. The newest development has been in the area of interventional procedures necessary for dialysis vascular access maintenance. These procedures include tunneled catheter placement and exchange, along with angioplasty and thrombolysis procedures on synthetic grafts and native fistulas. This type of activity, management of the hemodialysis vascular access, represents the primary focus of the interventional nephrologist's activity.

Interventional nephrology is becoming an active subspecialty of nephrology. Although the trend has begun to change with the recent development of academic training programs, the subspecialty originated, developed, and continues to grow primarily within the private practice setting. In the absence of academic involvement, there has not been a comprehensive publication of clinical results.

The purpose of this study was to present a large body of data derived from a diverse group of interventional nephrologists performing basic procedures that are used routinely in the management of hemodialysis patients with vascular access problems. Although diverse, these physician operators are performing these procedures using standardized techniques.

**Key words:** interventional nephrology, dialysis vascular access, angioplasty, thrombectomy, tunneled hemodialysis catheter.

Received for publication March 3, 2004  
and in revised form April 15, 2004  
Accepted for publication April 28, 2004

© 2004 by the International Society of Nephrology

**METHODS****Design of study**

The data utilized for this study were derived from 11 freestanding outpatient interventional facilities located in different regions of the United States [Atlanta, GA; Baltimore, MD; Birmingham, AL; Cincinnati, OH;

Detroit, MI (two); Houston, TX; Riverside, CA; San Diego, CA; Tyler, TX; and Wichita, KS]. A total of 29 interventional nephrologists were involved in performing the procedures from which the data were gathered, although not all operators participated for the full period of the study. All of these interventionalists, except for four, were trained in the RMS Lifeline training program, which is accredited by the American Society of Diagnostic and Interventional Nephrology. In some instances, the period of an individual physician operator's participation in this study included their training period. All except one are associated with private practice nephrology groups. The patient populations served by these interventional facilities range from 475 to 2200.

The data used for this study were collected prospectively over a period of one year (the calendar year 2003) as part of a fully electronic centralized medical record system. Monthly verification of the electronic record was performed against each individual procedure room log for quality assurance purposes. Individual patient data were then randomly selected for verification against the medical record, and the physician procedure note by using a random number generator. Patient follow-up data were collected by review of patient records at individual dialysis facilities.

Data on six basic procedures were analyzed for this study—angioplasty of arteriovenous fistulas [AVF-percutaneous transluminal angioplasty (PTA), angioplasty of synthetic grafts (graft-PTA), thrombectomy of arteriovenous fistulas (AVF declot), thrombectomy of synthetic grafts (graft declot), placement of tunneled dialysis catheters (TDC placement), and tunneled dialysis catheter exchange (TDC exchange)]. The data collected consisted of the total number of each procedure performed, the success rate, the aborted procedure rate, the procedure failure rate, the complication rate along with the types of complications observed, the procedure time, and the fluoroscopy time. These data were examined both as a group and by individual physician operator.

### Description of procedures performed

**Tunneled catheter (TDC) placement.** All TDCs were placed using both ultrasound and fluoroscopic guidance. Preferred sites for placement in their order of preference were right internal jugular vein, left internal jugular vein, and femoral vein. The TDC placement procedure was classified as successful if the catheter could achieve blood flow sufficient to perform a single hemodialysis treatment without significantly changing the dialysis prescription. Sufficient blood flow was defined as 300 mL/min or greater [1]. Blood flow was verified with the dialysis facility on all catheters.

**Tunneled catheter (TDC) exchange.** The indications for TDC exchange were catheter dysfunction (thrombo-

sis) and catheter-related infection. Catheters were exchanged over a guidewire with fluoroscopic guidance. Where indicated, a new tunnel and exit site was created, but in most instances, the TDC was exchanged utilizing the preexisting site. Angiography was performed routinely at the time of catheter exchange to detect the presence of a fibrin sheath. If a sheath was detected it was ablated prior to the placement of the new catheter. The same criteria were used to judge success as for primary catheter placement [1].

**Angioplasty (PTA).** Both the AVF-PTA and the graft-PTA were performed using a similar technique. Only lesions found to be 50% stenotic or greater were treated. The access was cannulated at a point determined by the expected location of the anticipated stenotic lesion based upon physical examination of the access. After cannulation, an initial angiogram was performed to identify the pathology. A guidewire was then introduced. The size of the angioplasty balloon was selected so as to provide 20% to 30% overdilatation of the vein. Dilatation was generally affected using pressure generated by hand with a 10 mL syringe for routine situations and a 3 mL syringe for more resistant lesions. The degree of stenosis and the degree of residual were both determined by estimation by the operator using the adjacent normal vessel or graft, and not by actual measurement. The percentage stenosis of the original lesion and the percentage of the residual were both recorded. Inflow evaluation was performed where medically indicated, along with angioplasty of any significant lesions identified at the arterial anastomosis or within the adjacent artery. A residual stenosis of 30% or less as prescribed by National Kidney Foundation-Kidney/Dialysis Outcome Quality Initiative (NKF-K/DOQI) Guideline 19 [2] was used as the definition of success for all angioplasty procedures.

**Thrombectomy (declot).** Endovascular thrombectomy was performed by mechanical means. Although the technique varied slightly from one facility to another, the technique used in all instances could best be categorized as thromboaspiration. This is a combined procedure involving angiography to evaluate the anatomy and localize stenotic lesions, balloon-assisted thrombectomy with thrombus aspiration through a sheath, and angioplasty to treat any associated venous stenosis. Mechanical devices and thrombolytic enzymes were not routinely used. In the case of fistulas, treatment varied somewhat depending on thrombus size and included balloon-assisted mechanical thrombectomy, and pharmacomechanical thrombolysis using tPA (Cathflo™ Activase®, Genentech, South San Francisco, CA, USA). Inflow evaluation was routinely performed in all thrombectomy cases, along with angioplasty of any significant lesions identified at the arterial anastomosis or the adjacent artery. The percentage stenosis of all associated lesions and the percentage of any residual left following angioplasty were recorded.

The thrombectomy procedure was considered successful if unobstructed flow through the access could be sufficiently established and was persistent enough to allow for one subsequent normal dialysis [3].

An arteriogram was done routinely during the course of the thrombectomy procedure to evaluate the arterial anastomosis, juxta-anastomotic access, and the adjacent artery. In general, however, an arterial embolus was looked for only in cases with ischemic symptoms suggesting its presence.

#### Medical management during procedure

In most cases, patients were sedated with either midazolam (Versed) or a combination of midazolam and fentanyl (Sublimaze) during these procedures. Blood pressure, pulse, EKG, and oxygen saturation were monitored continuously during the conduct of all procedures by a trained nurse, who was also responsible for recording all complications.

#### Definitions

*Procedure outcomes.* The outcome for each procedure performed was recorded as successful, failed, or aborted. The definitions of success for each of the six procedures were as defined above. A failed procedure was one that was completed but did not meet the stated criteria for success. An aborted procedure was one that was attempted but could not be completed and was abandoned. In actuality, all procedures are either successful or unsuccessful, and this determination should be based upon intent to treat; however, there is a subtle difference between aborted and failed that is of value in the evaluation of an operator's performance for quality improvement (CQI) purposes. For this reason, these definitions were used here. Both terms, failed and aborted, should be regarded as unsuccessful procedures.

*Complications.* The complications observed in this study were classified according to the reporting standards of the Society for Interventional Radiology [4]. According to this standard, all complications, including pulmonary and cardiac events that occur within 30 days following the procedure, are considered procedure related. Minor complications are those that require either no therapy or only nominal therapy, and which are resolved without any adverse consequence. Major complications are defined as those that require an increase in the level of care, or result in hospitalization, permanent adverse sequelae, or death.

In addition, each type of complication was individually tabulated for each procedure. In doing this, the classification of hematomas previously described [5] was used in tabulating that type of complication in PTA and thrombectomy cases. Each of these represents a degree of vein rupture heralded by the extravasation of contrast, blood, or both, resulting in the appearance of a

hematoma. In summary, this classification is as follows: grade 1 hematoma—stable and does not affect flow, grade 2 hematoma—stable and either slows or stops flow, grade 3 hematoma—represents a complete rupture of the vessel, resulting in a hematoma that is not stable but continues to expand. This generally results in a loss of the access. Grades 1 and 2 are considered minor complications, and a grade 3 hematoma is defined as a major complication. These designations are independent of determinations of success of the procedure, although they can obviously affect it. For example, if a grade 2 hematoma stops flow, but can be successfully treated to restore flow, the success of the procedure will be unchanged. However, if it cannot be treated successfully, it will result in a failure of the associated procedure.

Delayed bleeding was defined as a bleeding episode that required medical management after initial hemostasis had been obtained. A reaction to medication was, in most instances, an adverse reaction to radiocontrast. If the oxygen saturation dropped to less than 90% at any point during the procedure, it was recorded as a complication.

*Timed components of procedures.* The procedure time was defined as the time that lapsed between the initial administration of local anesthesia and either the completion of any suturing that was required in the case of catheter insertion procedures or the completion of any process used to obtain hemostasis in the case of peripheral access related procedures. It did not include site preparation time or hemostasis time, the latter being the time required to actually obtain hemostasis. With peripheral access (graft and AVF) related procedures, hemostasis was obtained either by the placement of a suture at the cannulation sites or the application of an adhesive, collagen-coated, compression dressing (Tip-Stop, Cobe, Gambro Hospital Co., Lakewood, CA, USA) along with digital pressure. The end of the timing of procedure time was signaled by the completion of the suture or the application of the dressing.

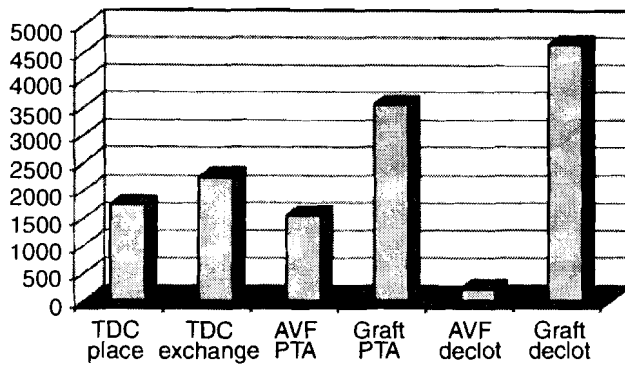
The cumulative time that fluoroscopy was activated during the procedure was totaled and recorded by the machine itself. This recorded time was transferred into the medical record at the end of each procedure and designated as the fluoroscopy time for that procedure.

Once the mean procedure and fluoroscopy times were determined for individual operators for each category of procedure, a median for these mean times was identified to serve as an index of efficiency for individual operators within the group.

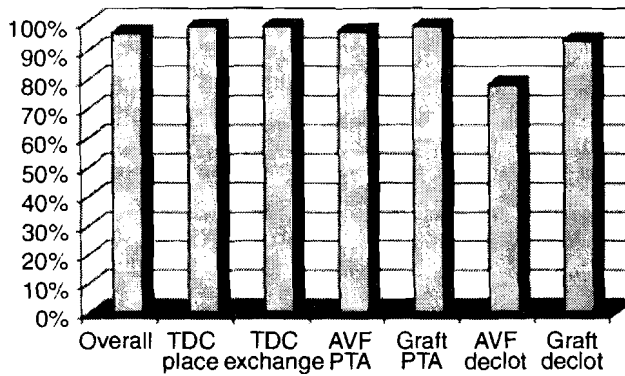
## RESULTS

### Combined series

A total of 14,067 cases were performed under the six categories of procedure that were the subject of this



**Fig. 1. Number of cases in each category.** TDC place, tunneled dialysis catheter placement; TDC exchange, tunneled dialysis catheter exchange; AVF-PTA, arteriovenous fistula angioplasty; Graft-PTA, graft angioplasty; AVF declot, arteriovenous fistula thrombectomy; Graft declot, graft thrombectomy; overall, combined group.



**Fig. 2. Success rate for each category.** TDC place, tunneled dialysis catheter placement; TDC exchange, tunneled dialysis catheter exchange; AVF-PTA, arteriovenous fistula angioplasty; Graft-PTA, graft angioplasty; AVF declot, arteriovenous fistula thrombectomy; Graft declot, graft thrombectomy; overall, combined group.

report (Fig. 1). Using the adopted definitions, 13,503 cases (96.18%) were successful (Fig. 2). The procedure failed in 414 cases, or 2.94%, and was aborted in 150 cases, or 1.06% (Table 1). The overall complication rate for the combined group of procedures was 3.54% (Fig. 3), with 3.26% falling within the minor category and 0.28% within the major (Table 1). The mean procedure time for the combined series was  $39.5 \pm 25.6$  minutes. The fluoroscopy time mean was  $5.9 \pm 5.7$  minutes (Table 2).

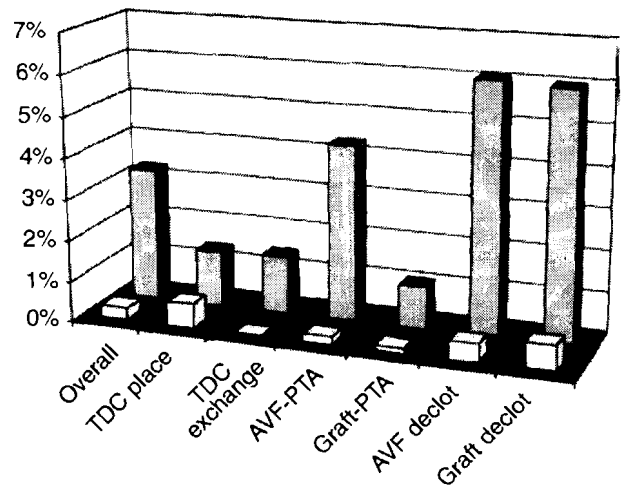
**Placement of tunneled dialysis catheters (TDC placement)**

This procedure was performed in 1765 (12.54%) of the cases in this series (Table 1). This was successful according to the stated definition in 1734 (98.24%) of the cases. The procedure was classified as failed in 19 (1.08%) of the patients, and was aborted in 12 (0.68%). The number of catheters placed by an individual operator ranged from 3 to 183. The median number of cases performed

**Table 1. Summary of procedures performed**

Procedure <sup>a</sup>	Number	Success	Failed	Aborted	Complication	
					Minor	Major
TDC placement	1765	98.24%	1.08%	0.68%	1.36%	0.06%
TDC exchange	2262	98.36%	1.11%	0.53%	1.37%	0.04%
AVF-PTA	1561	96.58%	2.63%	0.83%	4.29%	0.19%
Graft-PTA	3560	98.06%	1.52%	0.42%	1.04%	0.11%
AVF declot	228	78.10%	16.67%	5.26%	6.07%	0.44%
Graft declot	4671	93.08%	5.07%	1.84%	5.99%	0.62%
Combined	14,067	96.18%	2.94%	1.06%	3.26%	0.28%

<sup>a</sup>TDC placement, tunneled dialysis catheter placement; TDC exchange, tunneled dialysis catheter exchange; AVF-PTA, arteriovenous fistula angioplasty; graft-PTA, graft angioplasty; AVF declot, arteriovenous fistula thrombectomy; graft declot, graft thrombectomy; PTA, percutaneous transluminal angioplasty.



**Fig. 3. Complication rate for each category.** Columns in rear, minor complications; columns in front, major complications. TDC place, tunneled dialysis catheter placement; TDC exchange, tunneled dialysis catheter exchange; AVF-PTA, arteriovenous fistula angioplasty; Graft-PTA, graft angioplasty; AVF declot, arteriovenous fistula thrombectomy; Graft declot, graft thrombectomy; overall, combined group.

in this category was 60. The individual operator success rate ranged from 71.4% (14 cases performed) to 100% (3 to 159 cases performed). The operator with the greatest number of cases (183) had a success rate of 99.4%.

There were 25 (1.42%) adverse events; 24 (1.36%) of these met the definition of a minor complication, and 1 (0.06%) fell within the major category. Of the minor complications, 23 (1.30%) were delayed bleeding requiring medical management, and one was a reaction to medication. The single major complication was a pneumothorax. This was managed by the interventional nephrologist.

The mean procedure time (Table 2) for all TDC placements was  $33.2 \pm 18.6$  minutes. The median time was 28 minutes, with a range of 10 to 100 minutes. The median for individual operator mean procedure times was  $34.9 \pm 19$  minutes (88 cases performed), with a range of  $22.9 \pm 12.4$  (169 cases performed) to  $67 \pm 16.5$  minutes

**Table 2.** Timed components of procedures

Procedure <sup>a</sup>	Procedure time			Fluoroscopy time		
	Mean	Median	Range	Mean	Median	Range
TDC placement	33.2 ± 18.6	28	10–100	2.8 ± 3.0	1.9	0.1–27.9
TDC exchange	31.6 ± 20.1	26	3–90	2.9 ± 3.3	2.0	0.1–35.2
AVF-PTA	38.8 ± 23.9	33	3–185	6 ± 4.8	4.6	0.3–34.8
Graft-PTA	24.4 ± 15.5	20	3–179	4 ± 3	3.2	0.2–31.8
AVF declot	88.8 ± 41.8	84	15–120	14.6 ± 10	12.2	0.4–56.4
Graft declot	51.8 ± 27.6	45	12–220	8.8 ± 6.4	6.9	0.2–48.5
Combined	39.5 ± 25.6	33	3–220	5.9 ± 5.7	4.2	0.1–56.4

<sup>a</sup>TDC placement, tunneled dialysis catheter placement; TDC exchange, tunneled dialysis catheter exchange; AVF-PTA, arteriovenous fistula angioplasty; graft-PTA, graft angioplasty; AVF declot, arteriovenous fistula thrombectomy; graft declot, graft thrombectomy; PTA, percutaneous transluminal angiography.

(4 cases performed). The mean fluoroscopy time was  $2.8 \pm 3$  minutes, with a median of 1.9 minutes and a range of 0.1 to 27.9 minutes. The median for individual operator mean fluoroscopy times was  $3.1 \pm 2.6$  minutes (88 cases performed), with a range of  $0.9 \pm 1.2$  (98 cases performed) to  $11 \pm 9.9$  minutes (4 cases performed).

#### Tunneled dialysis catheter exchange (TDC exchange)

There were 2262 (16.08%) cases of TDC exchange in this series (Table 1). The procedure was successful in 2225 cases (98.36%). Only 25 (1.11%) of the cases failed, and 12 (0.53%) were aborted. The number of catheter exchanges performed by an individual operator ranged from 7 to 169. The median number of cases performed in this category was 89. The individual operator success rate ranged from 85.7% (5 cases performed) to 100% (11 to 169 cases performed). The operator who had the greatest number of cases (169) had a success rate of 100%.

Complications were recorded in 32 (1.41%) instances, all of which were of the minor variety. Delayed bleeding was the problem in 29 (1.28%) of the cases, an oxygen saturation less than 90% was observed during the procedure in two cases, and a reaction to medication was seen in one instance.

The mean procedure time (Table 2) for all TDC exchanges was  $31.6 \pm 20.1$  minutes. The median time was 26 minutes, with a range of 3 to 90 minutes. The median for individual operator mean procedure times was  $28.5 \pm 19.1$  minutes (110 cases performed), with a range of  $13.4 \pm 6.6$  (50 cases performed) to  $81.2 \pm 32.5$  minutes (14 cases performed). The mean fluoroscopy time was  $2.9 \pm 3.3$  minutes, with a median of 2.0 minutes and a range of 0.1 to 35.2 minutes. The median for individual operator mean fluoroscopy times was  $2.5 \pm 2.1$  minutes (42 cases performed), with a range of  $0.9 \pm 0.7$  (130 cases performed) to  $6.9 \pm 6.1$  minutes (7 cases performed).

#### Angioplasty of arteriovenous fistulas (AVF-PTA)

This procedure was performed 1561 times in this series (Table 1). This represented 11.1% of the total. The results obtained were classified as successful in 96.58% of the cases, or in 1527 patients. The procedure failed in

2.63% or 41 cases, and was aborted in 0.83%, or 13 cases. The number of AVF-PTAs performed by an individual operator ranged from 1 to 121. The median number of cases performed in this category was 55. The individual operator success rate ranged from 0% (1 case performed) to 100% (6 to 97 cases performed). The operator who had the greatest number of cases (121) had a success rate of 94.2%.

The percentage of stenosis present in association with fistulas was judged to be  $74.1\% \pm 14.1\%$ . Following angioplasty it had been reduced to  $12.9\% \pm 6.6\%$ . A total of 70 complications were encountered, representing an incidence of 4.48%. Of these, 4.29% were minor complications. A grade 1 hematoma was seen in 53 (3.35%), a grade 2 hematoma in 6 (0.4%), an episode of oxygen saturation less than 90% in 2, delayed bleeding in 3, and a reaction to medication in 3 cases. Major complications were seen in 3 patients, or 0.19% of the total, all of which were grade 3 hematomas.

The mean procedure time (Table 2) for all AVF-PTAs was  $38.8 \pm 23.9$  minutes. The median time was 33 minutes, with a range of 3 to 185 minutes. The median for individual operator mean procedure times was  $34.2 \pm 22.3$  minutes (92 cases performed), with a range of  $17 \pm 10.6$  (62 cases performed) to  $59.2 \pm 24.4$  minutes (59 cases performed). The mean fluoroscopy time was  $6 \pm 4.8$  minutes, with a median of 4.6 minutes and a range of 0.3 to 34.8 minutes. The median for individual operator mean fluoroscopy times was  $5.5 \pm 2.9$  minutes (42 cases performed), with a range of  $2.2 \pm 0.9$  (121 cases performed) to  $10.5 \pm 7.1$  minutes (103 cases performed).

#### Angioplasty of synthetic grafts (graft-PTA)

A graft-PTA was performed in 3560 cases, or 25.31% of the total (Table 1). Success was obtained with this procedure in 98.06%, or 3491 patients. Only 54 (1.52%) cases failed, and 15 (0.42%) were aborted. The number of graft-PTAs performed by an individual operator ranged from 25 to 278. The median number of cases performed in this category was 110. The individual operator success rate ranged from 91.8% (49 cases performed) to 100% (25 to



59 cases performed). The operator who had the greatest number of cases (278) had a success rate of 98.6%.

The percentage of stenosis present in association with grafts was  $73.7\% \pm 14.7\%$ . This was reduced to a residual of  $17.2\% \pm 9.1\%$ . There were 41 complications in this group, or 1.15%, 37 (1.04%) of which were minor, and 4 (0.11%) that were classified as major complications. Of the minor complications, 27 (0.76%) were grade 1 hematomas, and 4 (0.11%) were grade 2. Oxygen saturation less than 90% occurred during the procedure in 3 cases, and an additional 3 cases experienced a reaction to medication. The major complications consisted of 2 patients who experienced a grade 3 hematoma and 2 patients who died within the 30-day period following the procedure.

The mean procedure time (Table 2) for all graft-PTAs was  $24.4 \pm 15.5$  minutes. The median time was 20 minutes, with a range of 3 to 179 minutes. The median for individual operator mean procedure times was  $23.6 \pm 8.6$  minutes (138 cases performed), with a range of  $16 \pm 6.3$  (140 cases performed) to  $38 \pm 23.5$  minutes (49 cases performed). The mean fluoroscopy time was  $4 \pm 3$  minutes, with a median of 3.2 minutes and a range of 0.2 to 31.8 minutes. The median for individual operator mean fluoroscopy times was  $4 \pm 1.7$  minutes (138 cases performed), with a range of  $2.0 \pm 1.8$  (60 cases performed) to 6.5  $\pm$  4.5 minutes (27 cases performed).

#### **Thrombectomy of arteriovenous fistulas (AVF declot)**

An AVF declot was performed in 228 cases in this series (Table 1). This represented 1.62% of the total procedures. Of these cases, 178 (78.10%) were successful and 38 (16.67%) failed. Twelve cases (5.26%) were aborted. The number of AVF declots performed by an individual operator ranged from 1 to 30. The median number of cases performed in this category was 8. The individual operator success rate ranged from 0% (1 case performed) to 100% (1 to 9 cases performed). The operator who had the greatest number of cases (30 cases) had a success rate of 83.3%.

The complication rate was 7.89%, with complications being recorded in 18 cases. These were classified as minor in 17 cases (7.45%), and major in only 1 (0.44%) patient. The minor complications consisted of a grade 1 hematoma in 13 cases (5.7%), and a grade 2 hematoma in 2 cases (0.88%). Oxygen saturation below 90% occurred once, and delayed bleeding was reported in one case. The single major complication was a grade 3 hematoma.

The mean procedure time (Table 2) for all AVF declots was  $88.8 \pm 41.8$  minutes. The median time was 84 minutes, with a range of 15 to 120 minutes. Because of the small numbers of cases performed by some operators, times for individual operators were analyzed only for those with eight or more cases. For these operators, the me-

dian for individual operator mean procedure times was  $85.3 \pm 35.9$  minutes, with a range of  $59.8 \pm 29.4$  to  $117.8 \pm 32.2$  minutes. The mean fluoroscopy time was  $14.6 \pm 10$  minutes, with a median of 12.2 minutes and a range of 0.4 to 56.4 minutes. For individual operators with eight or more cases, the median for individual operator mean fluoroscopy times was  $13.6 \pm 10.3$  minutes, with a range of  $7.1 \pm 3.4$  to  $24.8 \pm 10.6$  minutes.

#### **Thrombectomy of synthetic grafts (graft declot)**

A graft declot was performed in 33.21% of the cases in this series, or 4671 times (Table 1). A 93.08% success rate was observed, which represented 4348 cases. Failure was reported in 237 cases (5.07%), and the procedure was aborted in 86 instances (1.84%). The number of graft declots performed by an individual operator ranged from 28 to 325. The median number of cases performed in this category was 148. The individual operator success rate ranged from 78.4% (133 cases performed) to 98.1% (137 cases performed). The operator who had the greatest number of cases (325) had a success rate of 95.8%.

Complications occurred in 299 cases (6.4%). Of these, 270 (5.99%) were minor and 29 (0.62%) were major. The minor complications consisted of 202 (3.32%) grade 1 hematomas and 39 (0.83%) grade 2 hematomas. The oxygen saturation dropped below 90% during the procedure in 10 cases (0.21%). Nine patients had delayed bleeding as a complication, eight cases had an adverse reaction to medication, and there were two cases of infection of the graft that occurred during the 30 days following the procedure. The 29 major complications consisted of 19 instances (0.41%) of grade 3 hematoma, 18 cases (0.38%) of peripheral artery embolism, and two patients who died during the 30 days following the procedure on their graft, one at 10 and one at 17 days.

The mean procedure time (Table 2) for all graft declots was  $51.8 \pm 27.6$  minutes. The median time was 45 minutes, with a range of 12 to 220 minutes. The median for individual operator mean procedure times was  $53.8 \pm 5.6$  minutes (212 cases performed), with a range of  $36 \pm 17.2$  (325 cases performed) to  $81.2 \pm 32.5$  minutes (36 cases performed). The mean fluoroscopy time was  $8.8 \pm 6.4$  minutes, with a median of 6.9 minutes and a range of 0.2 to 48.5 minutes. The median for individual operator mean fluoroscopy times was  $9.3 \pm 5.1$  minutes (137 cases performed), with a range of  $3.3 \pm 1.6$  (278 cases performed) to  $17.5 \pm 6.2$  minutes (28 cases performed).

## **DISCUSSION**

It is of interest to note that the distribution of cases between angioplasty, thrombectomy, and catheter-related procedures was about equal. This is a typical distribution of cases for outpatient, freestanding facilities of the type

represented in the study. The numerical difference between fistula-related and graft-related cases is partially reflective of the access profile present in the populations being served and partially due to the fact that fistulas have fewer problems than grafts. The difference between the ratios of angioplasties to thrombectomies for fistulas versus grafts is due to the fact that the thrombosis rate for fistulas is much lower than that for grafts.

The NKF-K/DOQI guidelines define tunneled dialysis catheter success as an ability to deliver at least 300 mL/min blood flow during the first attempted dialysis [3]. Guideline 34 states that the primary failure rate for placement should not exceed 5% [6]. In this study the combined failure rate for 1765 primary catheter placements was 1.76% (failed in 1.08% and aborted in 0.68%). For the 2262 catheters placed as part of a catheter exchange the combined failure rate was 1.64% (1.11% failed and 0.53% were aborted). This gave a combined success rate for all 4027 catheters of 98.32% (Table 1). Although there are small series of tunneled catheter placements [7] that have reported 100% primary success rate, this level of success is certainly superior to that prescribed by NKF-K/DOQI.

A variety of complications can occur at the time of tunneled catheter placement. The major determinant for these problems is the experience of the operator [8] and whether or not ultrasound guidance is used for cannulation [9]. Even in the hands of an experienced surgeon in the operating room, blind insertion can result in complication rates as high as 5.9% [10, 11]. These complications [12] include pneumothorax (0% to 1.8%), hemothorax (0% to 0.6%), hemomediastinum (0% to 1.2%), recurrent laryngeal nerve palsy (0% to 1.6%), and bleeding that required exploration and/or transfusion (0% to 4.7%). In a report of 237 catheters [13] designed to demonstrate that an interventional radiologist could be as successful as a surgeon, a complication rate of 4.22% was reported. Of these, 2.5% were due to six cases of pneumothorax and two cases of air embolism. The conclusion of this report was in favor of the radiologists.

Most of the complications of catheter placement are related to the cannulation of the vein, and these adverse events can generally be avoided by using real-time ultrasound guidance [9]. The use of ultrasound is strongly recommended by NKF-K/DOQI guideline 5 [14]. However, since the technology is readily available and the complication rate without it is so significant, it should be considered mandatory. All of the catheters placed in this series were done with both ultrasound and fluoroscopic guidance.

The 1.42% complication rate observed with primary tunneled catheter placement seems to be quite acceptable, especially in view of the fact that only one major complication was seen (0.06%). The most frequently ob-

served problem was related to oozing at the cannulation and exit sites. This incidence was significantly less than the 2% threshold recommended by NKF-K/DOQI guideline 34 [6]. All of the 29 complications observed with catheter exchange were of the minor variety, which is what one would expect to see with a procedure of this type.

In this series, 36.4% of the procedures performed involved the prospective treatment of venous stenosis. Approximately one third (1561) of these were patients with arteriovenous fistulas (Table 1). In these patients, the technical success rate was 96.58%. There are only a few small studies available that present data derived strictly from fistulas. These have reported a success rate ranging from 89.5% to 97% [15–19]. The largest of these involved a series of 100 cases [19]. This report had a 97% success rate, with a complication incidence of 6.6%. The AVF angioplasties in the current series had a success rate comparable to this study, but a complication rate (4.48%) that surpasses it. Turmel-Rodrigues [20] has reported an 8% incidence of vein rupture with radial-cephalic fistulas and 15% with upper arm fistulas. This rather high complication rate represents a considerable difference from what was observed in the current larger series. The majority of the complications observed in the fistula cases in the current report were minor, with hematoma formation being the most common occurrence. Only three major complications occurred, and these were all related to grade 3 hematomas.

Not all cases of venous stenosis associated with a dialysis access graft can be successfully treated by angioplasty. Failure, when it occurs, may be related to the presence of a lesion that cannot be crossed with a guidewire, or it may be related to a lesion that has a post-treatment residual that exceeds the accepted definition for success [1]. The success rates that have been reported in the literature for this procedure are in the range of 82% to 98% [21–26]. The success of the cases reported here is equal to the top end of that spectrum, with a success rate of 98.06% (Table 1). The major complication associated with angioplasty of hemodialysis grafts is vein rupture [5, 30]. The incidence of this complication has been reported to be in the range of 1.7% to 3.8% [23, 27–30]. The 0.93% combined rate (all grades) noted in this series is certainly better than what has been previously reported. As with AVF-PTA, the majority of the complications associated with graft-PTA were of the minor variety, and the bulk of these were related to grade 1 and grade 2 hematomas. The two deaths that are listed as complications were not temporally associated with the procedures, they only occurred within the 30-day period required by the definition.

The thrombosis rate for an AVF is reported to be approximately one sixth that for synthetic grafts [31]. Nevertheless, with increasing numbers of fistulas in use within a practice, clotted fistulas will present to the

interventional facility. In the past, the prevailing dogma suggested that a clotted AVF could not be successfully treated [32]. The fallacy of this opinion has been demonstrated by this and previous studies [33–39]. However, when a fistula thromboses, the nature of the problem is somewhat different than a clotted graft. The thrombectomy procedure for a graft can be standardized to a great degree. This is not the case with a fistula; it has to be individualized. The degree of stenosis is generally much more severe, its location is variable, and the presence of collaterals may make the anatomy very difficult to unravel radiographically. Additionally, cannulation may be a challenge. These difficulties are reflected by the longer procedure and fluoroscopy times recorded with these cases (Fig. 2). The thrombus volume in a thrombosed fistula is quite variable, ranging from minimal to large [34]. In most cases, it is minimal, with much of the fistula remaining patent because of the development of collaterals. For all of these reasons, the exact technique required may vary considerably, and there is a steep learning curve when it comes to performing thrombectomies on arteriovenous fistulas [33]. This was manifest by considerable variability in results between individual physician operators in performing this procedure. With very small numbers of cases, a single failure results in a major percentage shift.

With only 228 cases of fistula thrombectomy and half of the 29 operators performing eight or fewer cases, it has been difficult to gain significant experience in this procedure. Nevertheless, the success rate obtained of 78% is comparable to that which has been reported in the literature, which ranges from 73% to 100% [33–39]. In one series of 73 upper extremity fistulas [35], the incidence of major complications was 9.5%. These included a pulmonary embolus, a bleeding episode that required transfusion, and five instances (6.5%) of vein rupture that required stent placement. This latter complication would be comparable to our grade 3 hematoma. Compared to this report, the complication rate observed in this series with a minor complication rate of 7.45% and a single major complication (0.44%) looks very good. The major complication was a grade 3 hematoma. Most of the minor complications (5.7%) were grade 1 hematomas with no significant clinical sequela.

An inescapable relationship exists between the use of a polytetrafluoroethylene (PTFE) graft as a dialysis access and thrombosis. Endovascular thrombectomy has become a common approach for its management. There are a variety of techniques that have been used for this purpose, including balloon-assisted thrombectomy, pulse-spray pharmacomechanical thrombolysis, and a variety of different thrombectomy devices. Although some differences in success have been reported, no clear advantage of one technique over another has ever been documented. Reported success rates for endovas-

cular thrombectomy have ranged from 62% to 95% [40–56].

Most series of endovascular thrombectomy that have been reported have been relatively small; very few have exceeded 100 cases. Considerable variability exists in these patients. There is variability in location of the graft, age of the graft, degree of stenosis, location of stenosis, and number of prior procedures that may have been performed. For these reasons a small series must raise questions concerning significance. The largest series (1176 cases) that has been reported had a success rate of 95% [46]. The 93% success rate documented in this series of 4671 cases compares well with reports in the literature and significantly exceeds the minimum success rate of 85% prescribed by NKF-K/DOQI Guideline 21 [57].

The combined minor and major complication rate associated with this category of procedure (multiple techniques) has been reported to be as high as 10% to 16% [58, 59]. The 6.4% incidence noted in this series is well below this range. The most complete presentation of the complications associated with endovascular thrombectomy from a single institution available is a report based upon a retrospective review of 935 cases [60]. In this paper, an overall complication rate of 3.3% was observed. Major complications made up 2% of these, and 1.3% were minor. While the overall incidence of procedure-related adverse events is better than that seen in this current series with 6.4% complications, the incidence of major complications (0.66%) is considerably lower. The most common complication reported in association with the endovascular thrombectomy procedure is vein rupture, resulting in what we have referred to as a grade 1, and, to a lesser degree, a grade 2 hematoma [46, 60]. This was also the case here with 5.15% of the observed complications falling within this category. The major unique procedure-related complication requiring interventional therapy is the occurrence of a peripheral artery embolus [5]. The incidence of this problem has been reported to be as high as 6% in some studies [53]; however, the frequency with which arterial emboli are reported is strongly influenced by the diligence with which they are sought. In most series the reported incidence actually reflects the incidence of symptomatic occurrence. In the current series an arterial embolus was diagnosed in 0.38% of the cases; the percentage of these that were symptomatic was not recorded. Table 3 compares the complications that have been reported in the literature [40–57] with those seen in this study.

The timed components of the procedures (Table 2) are of importance. The duration of the procedure time relates to two factors: the skill of the operator and the difficulty of the case. In most instances, the operators with the longest mean procedure times were the ones with the least number of cases. However, even those operators with the greatest experience had an occasional long

**Table 3.** Comparison of complication rates reported in literature [40–57] for graft thrombectomy compared to current series

Complication	Literature	Current series
Venous rupture/hematoma	1.2–7%	5.57% 4.32%–Gr 1 0.83%–Gr 2 0.41%–Gr 3
Arterial emboli	1.2–6.7%	0.38%
O <sub>2</sub> sat <90%	Not reported	0.21%
Acute respiratory arrest	1.6–2.3%	None
Minor bleeding	2.8–11.1%	0.19%
Major bleeding	0.7–1.7%	None
Medication reaction	0.7–1.4%	0.17%
Sepsis/infection	1.2–2.0%	0.04%
Death	0–1.5%	0.04%

case. It is important that an operator be able to perform these cases in a timely manner for several reasons. First, the patients are sedated using a short-acting sedative, and if the case is too long, repetitive administration of sedative is required. This adds to the patient's discomfort and can increase the complications related to the drugs being used. Second, many of the patients require dialysis. Getting the procedure completed and the patient to the dialysis clinic is a high priority. Third, interventional facilities of the type involved in this study support dialysis patient populations of such size that six to eight cases per day are usual, and occasionally, as many as 12 to 13 cases may present requiring treatment.

The mean time for all of the procedures combined was 39.5 minutes (Table 3). Half of the procedures were completed in 33 minutes (median time) or less. Accounting for patient and procedure room preparation, this generally allows for one patient to be cared for each hour. The thrombectomy procedures required the most time, especially when a fistula was involved. These procedures are definitively more involved and more difficult to accomplish.

The fluoroscopy times are also quite important as an index of radiation safety both for the patient and for personnel. It is important that these times be kept as short as can be reasonably achieved. A mean time of 5.9 minutes was recorded for the total group of procedures, with half being accomplished in 4.2 minutes (median time) or less.

Most of the hemodialysis vascular access procedure series that have been reported do not list either procedure or fluoroscopy times so comparison is difficult. However, there are a number of reports of endovascular thrombectomy series on grafts in which procedure times are listed. These relate to thrombectomies done by a variety of percutaneous techniques. The procedure times given in these various reports range from 33 minutes up to 3.5 hours [43, 46, 61–64]. The mean time of 51.8 minutes for the 4671 graft thrombectomies reported here falls within the lower portion of this range. It should be noted that half of the procedures were performed in 45 minutes (median time) or less.

## CONCLUSION

Considerable concern has been expressed relative to training requirements for physicians performing interventional procedures on hemodialysis vascular access [65–67]. While this is understandable, the effectiveness and safety with which these procedures are performed is ultimately what is important, and it is this that should be given major consideration. Intuitively, one would conclude that there is a learning curve for procedures of the type described here, but it is of interest that in only one instance did the operator with the greatest experience as far as case numbers are concerned have the best result of the series. When the overall results obtained in the cases represented in this series, performed by a diverse group of interventional nephrologists, are compared with that which have been reported in the medical literature derived primarily from interventional radiologists, it is clear that interventional nephrologists can perform these procedures both effectively and safely. An overall success rate of 94.86% for 14,067 procedures with a major complication rate of only 0.28%, a procedure time of 39.5 minutes, and a fluoroscopy time of 5.9 minutes is unsurpassed.

## ACKNOWLEDGMENTS

The authors would like to thank Rick Cotar, RT, for his technical support and expertise in this study and its development as well as Lance Rozvar for his assistance in the reports and generation of required data.

Reprint requests to Gerald A. Beathard, M.D., Ph.D., 2800 Waymaker Way, #68, Austin, TX 78746.  
E-mail: Gerald@beathard.com

## REFERENCES

1. NATIONAL KIDNEY FOUNDATION: NKF-K/DOQI clinical practice guidelines for vascular access guideline 23: Treatment of tunneled cuffed catheter dysfunction. *Am J Kidney Dis* 37(Suppl 1): S166–167, 2001
2. NATIONAL KIDNEY FOUNDATION: NKF-K/DOQI clinical practice guidelines for vascular access guideline 19: Treatment of stenosis without thrombosis in dialysis AV grafts and primary AV fistulae. *Am J Kidney Dis* 37(Suppl 1):S163–164, 2001
3. NATIONAL KIDNEY FOUNDATION: NKF-K/DOQI clinical practice guidelines for vascular access guideline 21: Treatment of thrombosis and associated stenosis in dialysis AV grafts. *Am J Kidney Dis* 37(Suppl 1):S164–165, 2001
4. SACKS D, McCLENNY TE, CARDELLA JF, LEWIS CA: Society of interventional radiology clinical practice guidelines: Introduction. *J Vasc Interv Radiol* 14:s199–s202, 2003
5. BEATHARD GA: Management of complications of endovascular dialysis access procedures. *Semin Dial* 16:309–313, 2003
6. NATIONAL KIDNEY FOUNDATION: NKF-K/DOQI clinical practice guidelines for vascular access guideline 34: Primary access failure rate—tunneled cuffed catheters. *Am J Kidney Dis* 37 (Suppl 1):S166–167, 2001
7. GALLIENI M, CONZ PA, RIZZIOLI E, et al: Placement, performance and complications of the Ash Split Cath hemodialysis catheter. *Int J Artif Organs* 25:1137–1143, 2000
8. SZNAJDER JI, ZVEIBIL FR, BITTERMAN H, et al: Central vein catheterization: Failure and complication rates by three percutaneous approaches. *Arch Intern Med* 146:259–261, 1986
9. TREROTOLA SO, JOHNSON MS, HARRIS VJ, et al: Outcome of tunneled hemodialysis catheters placed via the right internal jugular vein by

- interventional radiologists. *Radiology* 203:489-495, 1997
10. BOUR ES, WEAVER AS, YANG HC, GIFFORD RRM: Experience with the double lumen silastic catheter for hemoaccess. *Surg Gynecol Obstet* 171:33-39, 1990
  11. McDOWELL DE, MOSS AH, VASILAKIS C, et al: Percutaneously placed dual lumen silicone catheters for long-term hemodialysis. *Am Surg* 59:569-573, 1993
  12. SCHWAB SJ, BEATHARD GA: The hemodialysis catheter conundrum: hate living with them: Can't live without them. *Kidney Int* 56:1-17, 1999
  13. LUND GB, TREROTOLA SO, SCHEEL PF, JR., et al: Outcome of tunneled hemodialysis catheters placed by radiologists. *Radiology* 198:467-472, 1996
  14. NATIONAL KIDNEY FOUNDATION: NKF-K/DOQI clinical practice guidelines for vascular access guideline 5: Type and location of tunneled catheter placement. *Am J Kidney Dis* 37(Suppl 1):S145-146, 2001
  15. SUGIMOTO K, HIGASHINO T, KUWATA Y, et al: Percutaneous transluminal angioplasty of malfunctioning Brescia-Cimino arteriovenous fistula: analysis of factors adversely affecting long-term patency. *Eur Radiol* 13:1615-1619, 2003
  16. CASTELLAN L, MIOTTO D, SAVASTANO S, et al: The percutaneous transluminal angioplasty of Brescia-Cimino arteriovenous fistulae. An evaluation of the results. *Radiol Med (Torino)* 87:134-140, 1994
  17. LAY JP, ASHLEIGH RJ, TRANCONI L, et al: Result of angioplasty of brescia-cimino haemodialysis fistulae: Medium-term follow-up. *Clin Radiol* 53:608-611, 1998
  18. BOHNDORF K, GUNTHER RW, VORWERK D, et al: Technical aspects and results of percutaneous transluminal angioplasty in Brescia-Cimino dialysis fistulas. *Cardiovasc Intervent Radiol* 13:323-326, 1990
  19. LONGWITZ D, PHAM TH, HECKEMANN RG, HECKING E: Angioplasty in the stenosed hemodialysis shunt: Experiences with 100 patients and 166 interventions. *Rofo Fortschr Geb Rontgenstr Neuen Bildgeb Verfahren* 169:68-76, 1998
  20. TURMEL-RODRIGUES L: Diagnosis and endovascular treatment for autologous fistula-related stenosis, in *A Multidisciplinary Approach for Hemodialysis Access*, edited by Gray R, Sands J, New York, Lippincott Williams & Wilkins, 2002, pp 170-183
  21. GLANZ S, GORDON DH, BUTT KHM, et al: The role of percutaneous angioplasty in the management of chronic hemodialysis fistulas. *Ann Surg* 206:777-781, 1987
  22. HUNTER DW, SO SK: Dialysis access: Radiographic evaluation and management. *Radiol Clin North Am* 25:249-260, 1987
  23. BEATHARD GA: Percutaneous transvenous angioplasty in the treatment of vascular access stenosis. *Kidney Int* 42:1390-1397, 1992
  24. KANTERMAN RY, VESELY TM, PILGRAM TK, et al: Dialysis access grafts: Anatomic location of venous stenosis and results of angioplasty. *Radiology* 195:135-139, 1995
  25. BEATHARD GA: Percutaneous angioplasty for the treatment of venous stenosis: A nephrologist's view. *Semin Dial* 8:166-170, 1995
  26. SAFA AA, VALJI K, ROBERTS AC, et al: Detection and treatment of dysfunctional hemodialysis access grafts: Effect of a surveillance program on graft patency and the incidence of thrombosis. *Radiology* 199:653-657, 1996
  27. RUNDBACK JH, LEONARDO RF, POPLAUSKY MR, ROZENBLIT G: Venous rupture complicating hemodialysis access angioplasty: Percutaneous treatment and outcomes in seven patients. *AJR* 171:1081-1084, 1998
  28. RAYNAUD AC, ANGEL CY, SAPOVAL MR, et al: Treatment of hemodialysis access rupture during PTA with Wallstent implantation. *J Vasc Interv Radiol* 9:437-442, 1998
  29. TURMEL-RODRIGUES L, PENGLOAN J, BAUDIN S, et al: Treatment of stenosis and thrombosis in haemodialysis fistulas and grafts by interventional radiology. *Nephrol Dial Transplant* 15:2029-2036, 2000
  30. PAPPAS JN, VESELY TM: Vascular rupture during angioplasty of hemodialysis graft related stenoses. *J Vasc Access* 3:120-126, 2002
  31. BEATHARD GA: Complications of vascular access, in *Complications of Dialysis—Recognition and Management*, edited by Lameire N, Mehta R, New York, Marcel Dekker, Inc., 2000, pp 1-27
  32. WHITE GH: Planning and patient assessment for vascular access surgery, in *Vascular Access—Principles and Practice*, edited by Wilson SE, St. Louis, Mosby Year Book, Inc., 1996, pp 6-11
  33. RAJAN DK, CLARK TW, SIMONS ME, et al: Procedural success and patency after percutaneous treatment of thrombosed autogenous arteriovenous dialysis fistulas. *J Vasc Interv Radiol* 13:1211-1218, 2002
  34. SCHON D, MISHLER R: Salvage of occluded autologous arteriovenous fistulae. *Am J Kidney Dis* 36:804-810, 2000
  35. HAAGE P, VORWERK D, WILDBERGER JE, et al: Percutaneous treatment of thrombosed primary arteriovenous hemodialysis access fistulae. *Kidney Int* 57:1169-1175, 2000
  36. TURMEL-RODRIGUES L, PENGLOAN J, RODRIGUE H, et al: Treatment of failed native arteriovenous fistulae for hemodialysis by interventional radiology. *Kidney Int* 57:1124-1140, 2000
  37. TURMEL-RODRIGUES L, RAYNAUD A, LOUAIL B, et al: Manual catheter-directed aspiration and other thrombectomy techniques for declotting native fistulas for hemodialysis. *J Vasc Interv Radiol* 12:1365-1371, 2001
  38. SCHON D, MISHLER R: Pharmacomechanical thrombolysis of natural vein fistulas: Reduced dose of TPA and long-term follow-up. *Semin Dial* 16:272-275, 2003
  39. TURMEL-RODRIGUES L: Application of percutaneous mechanical thrombectomy in autogenous fistulae. *Tech Vasc Interv Radiol* 6:42-48, 2003
  40. SCHUMAN E, QUINN S, STANDAGE B, GROSS G: Thrombolysis versus thrombectomy for occluded hemodialysis grafts. *Am J Surg* 167:473-476, 1994
  41. TREROTOLA SO, LUND GB, SCHEEL PJ, JR., et al: Thrombosed dialysis access grafts: percutaneous mechanical declotting without urokinase. *Radiology* 191:615-617, 1994
  42. BERGER MF, ARUNY JE, SKIBO LK: Recurrent thrombosis of polytetrafluoroethylene dialysis fistulas after recent surgical thrombectomy: Salvage by means of thrombolysis and angioplasty. *J Vasc Interv Radiol* 5:725-730, 1994
  43. MIDDLEBROOK MR, AMYGDALOS MA, SOULEN MC, et al: Thrombosed hemodialysis grafts: Percutaneous mechanical balloon declotting versus thrombolysis. *Radiology* 196:73-77, 1995
  44. VALJI K, BOOKSTEIN JJ, ROBERTS AC, et al: Pulse-spray pharmacomechanical thrombolysis of thrombosed hemodialysis access grafts: Long-term experience and comparison of original and current techniques. *AJR Am J Roentgenol* 164:1495-1500, 1995
  45. SCHWARTZ CI, McBRAYER CV, SLOAN JH, et al: Thrombosed dialysis grafts: Comparison of treatment with transluminal angioplasty and surgical revision. *Radiology* 194:337-341, 1995
  46. BEATHARD GA, WELCH BR, MAIDMENT HJ: Mechanical thrombolysis for the treatment of thrombosed hemodialysis access grafts. *Radiology* 200:711-716, 1996
  47. SHARAFUDDIN MJ, KADIR S, JOSHI SJ, PARR D: Percutaneous balloon-assisted aspiration thrombectomy of clotted hemodialysis access grafts. *J Vasc Interv Radiol* 7:177-183, 1996
  48. UFLACKER R, RAJAGOPALAN PR, VUJIC I, STUTLEY JE: Treatment of thrombosed dialysis access grafts: Randomized trial of surgical thrombectomy versus mechanical thrombectomy with the Amplatz device. *J Vasc Interv Radiol* 7:185-192, 1996
  49. OVERBOSCH EH, PATTYNAMA PM, AARTS HJ, et al: Occluded hemodialysis shunts: Dutch multicenter experience with the Hydrolyser catheter. *Radiology* 201:485-488, 1996
  50. TREROTOLA SO, VESELY TM, LUND GB, et al: Treatment of thrombosed hemodialysis access grafts: Arrow-Trerotola percutaneous thrombolytic device versus pulse-spray thrombolysis. Arrow-Trerotola Percutaneous Thrombolytic Device Clinical Trial. *Radiology* 206:403-414, 1998
  51. VESELY TM, WILLIAMS D, WEISS M, et al: Comparison of the angiojet rheolytic catheter to surgical thrombectomy for the treatment of thrombosed hemodialysis grafts. Peripheral AngioJet Clinical Trial. *J Vasc Interv Radiol* 10:1195-1205, 1999
  52. SOFOCLEOUS CT, COOPER SG, SCHUR I, et al: Retrospective comparison of the Amplatz thrombectomy device with modified pulse-spray pharmacomechanical thrombolysis in the treatment of thrombosed hemodialysis access grafts. *Radiology* 213:561-567, 1999
  53. LAZZARO CR, TREROTOLA SO, SHAH H, et al: Modified use of the arrow-trerotola percutaneous thrombolytic device for the treatment of thrombosed hemodialysis access grafts. *J Vasc Interv Radiol* 10:1025-1031, 1999
  54. BARTH KH, GOSNELL MR, PALESTRANT AM, et al: Hydrodynamic

- thrombectomy system versus pulse-spray thrombolysis for thrombosed hemodialysis grafts: A multicenter prospective randomized comparison. *Radiology* 217:678-684, 2000
55. FALK A, GULLER J, NOWAKOWSKI FS, et al: Reteplase in the treatment of thrombosed hemodialysis grafts. *J Vasc Interv Radiol* 12:1257-1262, 2001
  56. SMITS HF, SMITS JH, WUST AF, et al: Percutaneous thrombolysis of thrombosed haemodialysis access grafts: Comparison of three mechanical devices. *Nephrol Dial Transplant* 17:467-473, 2002
  57. NATIONAL KIDNEY FOUNDATION: NKF-K/DOQI clinical practice guidelines for vascular access guideline 21: Treatment of thrombosis and associated stenosis in dialysis AV grafts. *Am J Kidney Dis* 37(Suppl 1):S164-165, 2001
  58. ARUNY JE, LEWIS CA, CARDELLA JF, et al: Quality improvement guidelines for percutaneous management of the thrombosed or dysfunctional dialysis access. *J Vasc Interv Radiol* 14:S247-253, 2003
  59. McCUTCHEON B, WEATHERFORD D, MAXWELL G, et al: A preliminary investigation of balloon angioplasty versus surgical treatment of thrombosed dialysis access grafts. *Am Surg* 69:663-667, 2003
  60. VESELY TM: Complications related to percutaneous thrombectomy of hemodialysis grafts. *J Vasc Access* 3: 49-57, 2002
  61. GRAY RJ: Percutaneous intervention for permanent hemodialysis access: A review. *J Vasc Interv Radiol* 8:313-327, 1997
  62. TREROTOLA SO, VESELY TM, LUND GB, et al: Treatment of thrombosed hemodialysis access grafts: Arrow-Trerotola percutaneous thrombolytic device versus pulse-spray thrombolysis. Arrow-Trerotola Percutaneous Thrombolytic Device Clinical Trial. *Radiology* 206: 403-414, 1998
  63. ROCEK M, PEREGRIN JH, LASOVICKOVA J, et al: Mechanical thrombolysis of thrombosed hemodialysis native fistulas with use of the Arrow-Trerotola percutaneous thrombolytic device: Our preliminary experience. *J Vasc Interv Radiol* 11: 1153-1158, 2000
  64. VOGEL PM, BANSAL V, MARSHALL MW: Thrombosed hemodialysis grafts: Lyse and wait with tissue plasminogen activator or urokinase compared to mechanical thrombolysis with the Arrow-Trerotola Percutaneous Thrombolytic Device. *J Vasc Interv Radiol* 12: 1157-1165, 2001
  65. TREROTOLA SO, GRAY R, BRUNNER M, ALTMAN S: Interventional care of the hemodialysis patient: It's about quality. *J Vasc Interv Radiol* 12: 1253-1255, 2001
  66. LEVIN DC, BECKER GJ, DORROS G, et al: Training standards for physicians performing peripheral angioplasty and other percutaneous peripheral vascular interventions. *J Vasc Interv Radiol* 14:S359-361, 2003
  67. SACKS D, BECKER GJ, MATALON TA: Credentials for peripheral angioplasty: Comments on Society of Cardiac Angiography and Intervention revisions. *J Vasc Interv Radiol* 14:S363-367, 2003

## Aggressive treatment of early fistula failure

GERALD A. BEATHARD, PERRY ARNOLD, JERRY JACKSON, TERRY LITCHFIELD,  
and PHYSICIAN OPERATORS FORUM OF RMS LIFELINE

Physician Operators Forum of RMS Lifeline, Inc., Austin, Texas; Dialysis Access Specialists, Baltimore, Maryland; Nephrology Vascular Lab, Birmingham, Alabama

### Aggressive treatment of early fistula failure.

**Background.** Fistula failure has been classified as early and late. Early failure refers to those cases in which the arteriovenous (AV) fistula never develops to the point that it can be used or fails within the first 3 months of usage. It has been common practice to abandon these early failures; however, aggressive evaluation and treatment of early fistula failures has been shown to result in the salvage of a large percentage. The two most common causes of the failure seen at this time are juxta-anastomotic stenosis (JAS) and the presence of accessory veins. Both of these can be easily diagnosed by physical examination. This study reports the results of early fistula failure managed aggressively in an attempt at salvage.

**Methods.** These studies were conducted in six freestanding outpatient interventional facilities in different regions of the United States. Interventional nephrologists are employed at all of these facilities except one that is operated by an interventional radiologist. Each patient was first evaluated angiographically to identify the anatomy of their AV fistula and detect abnormalities that might be present. Stenotic lesions were then treated with angioplasty and accessory veins thought to be significant were obliterated. All patients were then followed to determine if the fistula was usable for dialysis.

**Results.** One hundred patients were identified that met the definition of early failure. Venous stenosis was present in 78% of these cases. In 43% of the cases, the lesion was in the JAS location. In 15%, this was the only lesion present. In 24%, it was associated with an accessory vein, in 6% with a proximal stenosis, and in 4% with both. A proximal stenosis lesion was present in the fistula in 36%. In 6%, it was associated with an accessory vein, in 6% with a JAS, and in 4% with both. The definition of arterial anastomosis stenosis was met in 38% of the cases. This was always in association with JAS. In four cases, a stenotic lesion was present in the artery above the anastomosis. An accessory vein was present in 46% of the cases. In 12% of the cases, this was the only lesion present. In 24% of the cases, this anomaly was associated with JAS, in 6% with proximal stenosis, and in 4% with both. Angioplasty was performed to treat venous stenosis in 72% of the cases with a 98% success rate. Angioplasty of the arterial anastomosis was performed in 38 cases with a 100% success rate. Accessory

vein obliteration was performed in 46% of the patients with a 100% success rate. The overall complication rate in this series was 4%. of these 3% were minor and 1% were major. It was possible to initiate dialysis using the fistula in 92% of the cases. Actuarial life-table analysis showed that 84% were functional at 3 months, 72% at 6 months, and 68% at 12 months.

**Conclusion.** If correctable pathology is detected in patients with early fistula failure, the incidence of correctable lesions is relatively high and an aggressive therapeutic approach can be expected to have a high yield.

The superiority of the native arteriovenous (AV) fistula as a vascular access for chronic hemodialysis over an AV graft is an accepted fact. In multiple studies, it has been shown to have significantly improved patency rates and lower complication and infection rates [1]. For these reasons it has been recommended that maximum efforts be exerted to increase the number of fistulae in both incident and prevalent patients [2]. Coincident with attempts to increase fistula prevalence, an increased number of fistula failures occur [1]. Fistula failure can be classified as early and late. Early failure refers to those cases in which the AV fistula never develops to the point that it can be used or fails within the first 3 months of usage. Late failure refers to those cases that fail after 3 months of successful usage [3, 4]. Although there is considerable overlap, the typical causes for failure in these two groups are somewhat different [3, 4].

The clinical manifestations of early fistula failure are failure to develop adequately to permit repetitive cannulation for dialysis and inadequate flow to support dialysis and thrombosis. These are clinical diagnoses. However, in general, they are related to anatomic problems [3-5]. Even in the case of patients diagnosed clinically as having a thrombosed fistula, an anatomic lesion is generally found to be the cause of the dysfunction. In most cases, either no thrombus or very minimal thrombus is actually present.

Although it has been common practice to abandon these early failures, aggressive evaluation and treatment of early fistula failures has been shown to result in the salvage of a large percentage [5]. This study reports a

**Key words:** hemodialysis, vascular access, arteriovenous fistula, failed vascular access

Received for publication February 25, 2003  
and in revised form May 10, 2003  
Accepted for publication May 22, 2003

© 2003 by the International Society of Nephrology

prospective observational study in which early fistula failures were aggressively evaluated and treated in a salvage attempt.

## METHODS

### Design of study

These studies were conducted in six freestanding outpatient interventional facilities in different regions of the United States (Baltimore, Maryland; Birmingham, Alabama; Tyler, Texas; Detroit, Michigan; Cincinnati, Ohio; and Riverside, California). Interventional nephrologists are employed in all of these facilities except one that is operated by an interventional radiologist (P.A.). The patient populations served by these laboratories ranged from 475 to 2200. All patients referred to one of these facilities for evaluation of early fistula failure over a 15-month period (January 1, 2001 through January 31, 2002) were entered into the study. Each patient was first evaluated angiographically to identify the anatomy of their AV fistula and to detect abnormalities that might be present. Stenotic lesions were then treated with angioplasty and accessory veins thought to be significant were obliterated. All patients were then followed up to determine if the fistula was usable for dialysis. None of these patients has been included in any previous report.

### Definitions

Early fistula failure was defined as an AV fistula that never developed to the point that it could be used or failed within the first 3 months of usage. Venous stenosis was defined as 50% or greater decrease in lumen diameter based upon a comparison with the adjacent, normal vein. These lesions were categorized into three categories based upon location: (1) juxta-anastomotic, (2) proximal, and (3) central. Juxta-anastomotic stenosis (JAS) was defined as narrowing in that portion of the fistula immediately adjacent to the arterial anastomosis (Fig. 1). Proximal venous stenosis was defined as a stenotic lesion anywhere in the vein from the juxta-anastomotic portion to the central veins. Stenosis in the central veins (subclavian, innominate, and superior vena cava) was classified as central stenosis. Stenosis of the arterial anastomosis was defined based upon the appearance of an inflated angioplasty balloon placed across the anastomosis. A 50% defect in the balloon was required to be classified as a stenotic anastomosis. A 4 mm balloon was used to evaluate radial artery anastomoses and a 6 mm balloon was used for brachial artery anastomoses. Arterial stenosis was defined as a 50% or greater decrease in lumen diameter based upon a comparison with the adjacent, normal artery occurring in the main artery feeding the fistula. For the purposes of this study, the fistula was defined as that portion of the vein up to the elbow for forearm fistulas and up to the shoulder for upper arm fistulas.

An accessory vein was defined as a branch coming off of the main venous channel that comprised the fistula (Fig. 2). These veins are normal variants of anatomy, but they can cause problems with fistula development. This is in contrast to a collateral vein, which is pathologic and develops in response to a pressure changes that result from a downstream stenosis. A decision to treat an accessory vein was based upon a subjective assessment of its significance judged by its size and flow. Augmentation of downstream fistula pulse and thrill by manual occlusion of the accessory vein was also helpful in making the decision of significance. If there was an associated venous stenosis in a downstream (proximal) location, the accessory vein was evaluated for significance after the stenosis was treated. A side branch that appears to be significant in the presence of downstream stenosis can disappear or appear insignificant after the stenotic lesion is resolved.

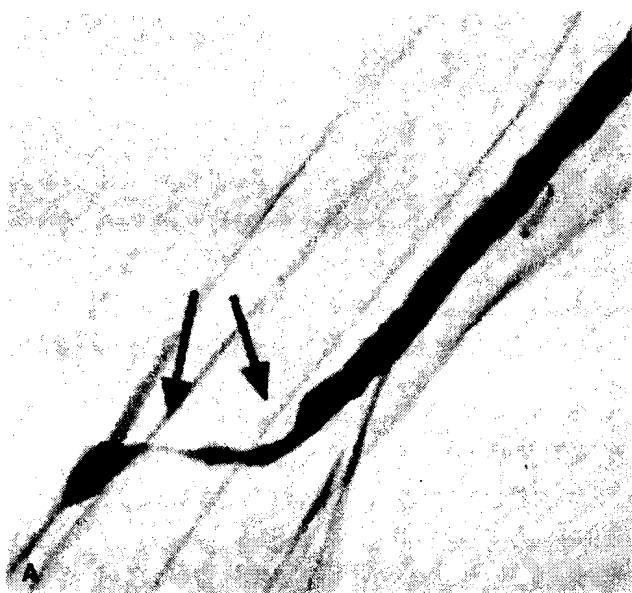
A functional fistula was defined as one that could be cannulated and could support a dialysis blood flow of at least 350 mL/min without recirculation. The duration of functional patency or primary patency was defined as that period of time that the fistula could be cannulated successfully and support a dialysis blood flow of at least 350 mL/min without recirculation and without a repeat procedure, the end point being the repeat procedure.

### Description of procedures performed

**Angiogram.** An angiogram was performed as follows. The AV fistula was first examined to determine the most probable cause of the problem and its location. Based upon this examination, a cannulation site was selected. The AV fistula was then cannulated using a Micropuncture needle (Cook, Bloomington, IN, USA). The micropuncture wire was inserted into the vein and was used to introduce a 5 F dilator. Contrast was injected through this dilator to visualize the fistula and draining veins. The entire venous drainage up through the central circulation was routinely evaluated in all cases. By occluding the fistula downstream (proximal) from the tip of the dilator, the distal vein, arterial anastomosis, and distal artery were visualized (retrograde injection). It was never necessary to use a blood pressure cuff or any other occlusion device to attain a retrograde injection. The standard angiogram procedure used in this study involved only the cannulation of the vein (fistula). It was not necessary to cannulate the artery routinely.

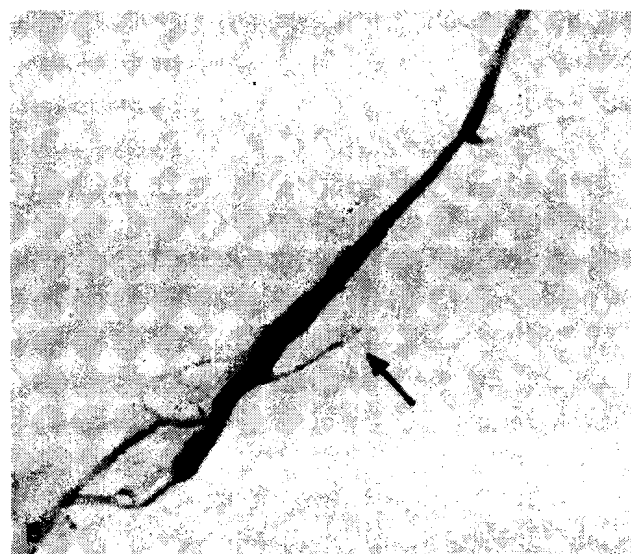
**Angioplasty [percutaneous transluminal angioplasty (PTA)].** A PTA (Fig. 1) was performed as follows. After the AV fistula was cannulated and the initial angiogram was performed, a guidewire was introduced. For lesions downstream (antegrade) from the cannulation site, the guidewire was passed through the draining veins up to the level of the central veins. If the lesion was upstream (retrograde) from the cannulation site, the guidewire was generally passed across the arterial anastomosis. The





**Fig. 1. Radial-cephalic fistula with juxta-anastomotic stenosis. (A)** The affected segment of vein. **(B)** Postangioplasty treatment.

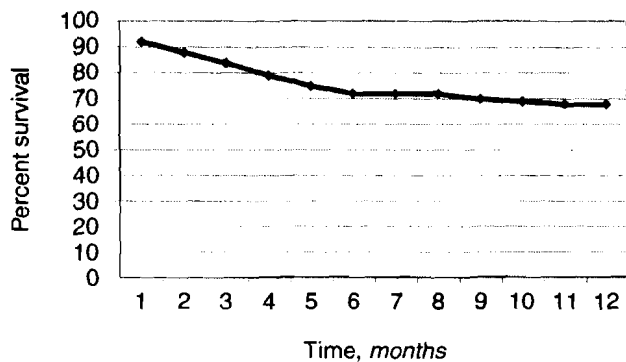
size of the angioplasty balloon was generally selected to provide 20% to 30% overdilatation of the vein. Either a  $6 \times 4$  or an  $8 \times 4$  angioplasty balloon was generally used within the fistula and the draining veins up to the level of the central veins. A  $12 \times 4$  balloon was generally used centrally. In most cases, if the balloon was to be used across the arterial anastomosis, a  $4 \times 4$  balloon was used across a radial anastomosis and a  $6 \times 4$  balloon across a brachial anastomosis, depending upon the size of the artery. Dilatation was affected using pressure generated by hand with a 10 mL syringe for routine situations and a 3 mL syringe for more resistant lesions. The result of the dilatation was judged by comparison with the adja-



**Fig. 2. Radial-cephalic fistula with large accessory vein. (A)** Initial angiogram. A is cannulation site just above anastomosis. B is cephalic vein comprising fistula, and C is accessory vein arising from lateral aspect of fistula. **(B)** Angiogram performed postcoil obliteration. Arrow indicates location of coil.

cent normal vessel on a repeat angiogram. The success of an angioplasty procedure was judged by anatomic criteria (Fig. 1). The procedure was classified as successful if there was less than a 30% residual lesion according to National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-K/DOQI) guidelines [6].

**Accessory vein obliteration.** Only those accessory veins that were thought to be of significant size with significant flow were treated. Although this determination was somewhat subjective, a size of at least one third of the diameter



**Fig. 3. Primary patency of patients with early fistula failure after therapy.** Primary patency is defined as that time period during which no procedure or intervention is required to maintain patency or function.

of the fistula was generally required (Fig. 2). If the accessory vein was associated with a downstream (antegrade) stenosis, its significance was evaluated after treatment of the stenosis. After the presence and location of the accessory vein was identified by angiography, it was obliterated either by ligation or by the insertion of a coil, depending upon the operator's preference. One of two methods was used for vein ligation. If the vein was relatively superficial and could be easily seen or felt, it was ligated percutaneously. This involved placing a 3-0 nylon suture (Ethilon) around the vein close to its junction with the main trunk of the fistula [7]. No incision was made. If it was thought that this percutaneous technique was not possible, an incision was made and the vein was ligated using a silk tie. The incision was then closed. Insertion of a coil involved selective cannulation of the accessory vein using a 5 F catheter followed by the insertion of the coil through the catheter. The size of the coil was selected based upon the size of the vein. The selection of the method of vein obliteration was based upon the operator's choice. In all instances, the success of obliteration was confirmed by an angiogram.

#### Data collection

The data were collected prospectively as part of a fully electronic medical record. The data were validated by auditing the electronic medical record, physician procedure notes, and digital fluoroscopic images. Data collected on these patients included patient age, primary disease, date fistula was created, location of fistula, if fistula become usable, date usable fistulas were first used, duration of functional patency, and details of the procedures performed. The Kaplan-Meier method was used to calculate life-table analysis data.

#### RESULTS

To be included in this study, the patient had to meet the definition of having an AV fistula that never devel-

**Table 1. Patient demographics**

Gender %	
Male	70
Female	30
Age years	61 ± 14.3
Ethnicity %	
African American	67
Comorbid conditions	4.7 (average)
Diabetes %	48.7
Age of fistulas months	4.7 (average)
Type of fistula %	
Radial-cephalic	55
Brachial-cephalic	39
Brachial-basilic	6
Location %	
Left arm	76
Right arm	24

**Table 2. Lesions identified**

Type	Number
Accessory vein	12
Accessory vein + JAS	24
Accessory vein + proximal venous stenosis	6
Accessory vein + JAS + proximal venous stenosis	4
JAS	15
Proximal venous stenosis	20
JAS + proximal venous stenosis	6
Diffusely small vein	3
Central stenosis	9
Arterial anastomosis stenosis	38
Arterial stenosis	4

JAS is juxta-anastomotic venous stenosis.

oped to the point that it could be used or failed within the first 3 months of usage. A total of 100 patients met this definition for inclusion in the study. Demographically (Table 1) the patients were characterized by being 70% male with a mean age of 61 ± 14.3 years (range, 24 to 87 years). Ethnically, 67% of the cases were African American. The average number of comorbid conditions was 4.7; diabetes was present in 48.7%.

By type, 55% of the fistulas were radial-cephalic, 39% were brachial-cephalic, and 6% were brachial-basilic transpositions (Table 1). The fistulas were located in the left arm in 76% of the cases and in the right in 24%. The average age of the fistulas at the time of treatment was 4.7 months. As shown in Table 2, a variety of lesions were identified. Venous stenosis was present in 78% of the cases. In 43% of the cases, the lesion was in the JAS location. In 15%, this was the only lesion present. In 24%, it was associated with an accessory vein, in 6% with a proximal stenosis, and in 4% with both. A proximal stenosis lesion was present in the fistula in 36%. In 6%, it was associated with an accessory vein, in 6% with a JAS, and in 4% with both. A central venous stenotic lesion was present in 9% of the cases, but never as an isolated lesion. It was always seen in association with

another lesion. In one of these cases, the central vein was totally occluded. In 3% of the cases, the vein comprising the fistula was diffusely narrow throughout its entire length. The definition of arterial anastomosis stenosis was met in 38% of the cases. This was always in association with JAS. In four cases, a stenotic lesion was present in the artery above the anastomosis. An accessory vein considered to be significant according to size and flow was present in 46% of the cases (46 patients). In 12% of the cases, this was the only lesion present. In 24% of the cases, this anomaly was associated with JAS, in 6% with proximal stenosis, and in 4% with both. In all cases in which an accessory vein was associated with JAS, the vein in question originated downstream (antegrade) from the stenosis. A single accessory vein (of significance) was present in 30 of the 46 cases, two in 14 cases and three in two cases. All early failure cases that were referred for evaluation had some type of anatomic abnormality. None had negative angiograms.

Angioplasty was performed to treat venous stenosis in 72% of the cases with a 98% success rate. The degree of venous stenosis pretreatment was  $74\% \pm 15\%$  (50% to 100%). This was reduced to  $13\% \pm 15\%$  (0% to 60%). Angioplasty was judged to be unsuccessful in two cases. Angioplasty of the arterial anastomosis was performed in 38 cases with a 100% success rate. Accessory vein obliteration was performed in all cases in which it was present and thought to be significant (46% of the patients) with a 100% success rate. In 34 cases, this was done using an intravascular coil, in 12 it was done by ligation. In eight instances, ligation was accomplished by surgical incision, in the remaining four, it was by percutaneous ligation.

The complication rate for this study was determined according to the reporting standards of the Society of Cardiovascular and Interventional Radiology [8]. According to this standard, all complications, including pulmonary and cardiac events that occur within 30 days of the procedure, are considered procedure related. Minor complications are those that require either no therapy or only nominal therapy without any consequence. Major complications are defined as those that require an increase in the level of care, or result in hospitalization, permanent adverse sequelae, or death. The overall complication rate in this series was 4%, of these 3% were minor and 1% were major. All of these adverse events were associated with angioplasty procedures. The single major complication consisted of a vein rupture with an expanding hematoma. It resulted in loss of the access. The three minor complications were all hematomas that required no treatment and had no sequelae.

It was possible to initiate dialysis in 92% of the cases. The eight failures included all three of the cases with diffusely narrowed veins, the one case with central vein occlusion, the case with a ruptured vein, and three cases

in which the fistula thrombosed prior to being used for dialysis. Actuarial life-table analysis showed that 84% were functional at 3 months, 72% at 6 months, and 68% at 12 months (Fig. 3).

## DISCUSSION

A major hurdle to achieving the goal of increasing the numbers of AV fistulas in both prevalent and incident patients is the frequency of early fistula failures. Aggressive efforts at placing fistulas can be expected to increase this frequency. Although the definitions varied, studies of 20 to 25 years ago observed early failure rates in the range of 10% to 25% [9-14]. In more recent reports, the incidence has been higher, in the range of 20% to 50% [15-29].

When listed, the most common cause for fistula failure in these series has been failure to mature adequately for use. The two most common identifiable causes for failure in these cases are JAS and the presence of accessory veins [4, 5, 30]. Frequently, these two conditions occur together [4]. Both problems can be easily diagnosed by physical examination [31, 32]. It is important to note that in an optimum patient, either of these problems might be present and not prevent fistula development. In fact, in optimum patients, the presence of an accessory vein might be beneficial, providing additional vessel for cannulation. The fact that these problems interfere with fistula development may be evidence that the patient was not an optimum candidate for such an access. Nevertheless, success is possible with aggressive management.

An aggressive approach to the evaluation of early fistula failure to detect correctable problems, with appropriate intervention, has been shown to result in a high salvage rate in these cases [5]. In that study, 71 patients with early fistula failure were evaluated. Eight had inadequate arterial inflow and were not evaluated further. The remaining 63 underwent ligation of an accessory vein, angioplasty of a stenotic lesion, or both. Venous stenosis was present in 33.3% of the cases, in 27% it was in the JAS location. Accessory veins were present in 78% of the cases; they were multiple in 44%. As a result of the salvage attempts, 82.5% of the fistulas matured adequately to support dialysis for a period of 90 days. The 1-year primary patency was 74.7%. In the current study, the incidence of JAS was higher at 45%, while that of accessory veins was considerably lower at 46%. Nevertheless, the salvage rate in both studies was comparable; 82.5% were able to support dialysis for 90 days in the previous report and 84% in the current series. The 1-year survival in the previous study exceeded that of the current series, 74.7% versus 68%. The reasons for this are not clear. It is important to note that none of the patients of the previous series were included in the current study.

The existence of accessory veins and the concept of

their contribution to the failure of a newly created AV fistula to develop have been questioned [33, 34]. It has been postulated that these side branches all develop in response to downstream (antegrade) stenosis. Further, it is alleged that simply treating the stenosis will cause the veins in question to disappear. The demonstration of cases in which this does not occur, or cases in which there is no causative stenosis, is dismissed as evidence that the offending stenotic lesion was simply missed. This argument can be easily dispelled by a study of normal anatomy. The veins that are used in the creation of fistulas have branches normally, especially the cephalic vein in the forearm. While the number and pattern of these branches is variable, they nevertheless exist in normal anatomy. When a fistula is created, they do not go away. In some patients, the accessory vein does not distract from the development of the major vein into a usable fistula. In fact, the accessory vein may develop to the point that it too is usable for dialysis access. However, under less than optimal circumstances, the accessory vein can prevent the development of the fistula. As has been shown in this study and previous reports [5, 7, 26], obliteration of these veins can result in fistula salvage. The issue is sometimes confused by the well-recognized fact that, if there is a downstream stenosis, there is a tendency for collateral veins to develop and a tendency for normal side branches to become more prominent. This process may be resolved by treating the stenosis. Unfortunately, however, resolution of the stenosis does not always result to a disappearance of the side branch. In these cases, we consider obliteration of the vein to be a useful procedure. In the current study, care was used to ensure that a downstream stenosis was not present in any instance in which an accessory vein was diagnosed and treated. It is of interest to compare the reported results obtained when accessory veins have been addressed and when they have not. The primary patency at 90 days of 84% and 1 year of 68% in the current study where these veins were addressed is obviously superior to that of a previous report of 67% and 39% [34], respectively, in which they were ignored. This later study [34] also reported an immediate complication rate of 13% with a 3% delayed major complication rate. Whether this inordinately high rate of complications could have contributed to their poor result is not clear.

The current study is unique in that all causes of dysfunction were evaluated and all were aggressively treated. This approach resulted in an excellent long-term success rate in fistulas that had previously been unusable. This success was attained with very few complications.

One must raise the question as to whether the anomalies that result in early fistula failure are avoidable. The answer to this question is suggested by a review of reports in which aggressive patient evaluation was conducted prior to fistula placement [1, 18, 26, 28, 35–38]. These

studies used venous mapping to evaluate patients prior to access placement. Mixed results have been reported. There appears to be no question that the use of vein mapping will increase the likelihood of a fistula being created as opposed to the placement of a synthetic graft, but it will not ensure against early failures. In one study [26], the number of patients that were ultimately dialyzed with a fistula doubled with the use of vein mapping, but of those that were created only 54% matured adequately to be usable for dialysis. Early fistula failure has been reported to be more common in females, even with vein mapping to guide surgical creation of the access [39]. Even with an aggressive approach to intervention for early failure, this report found a significant discrepancy between the success rate in females and males [39]. This reported difference between males and females was not apparent from our data. However, it must be noted in this study some degree of selectivity may be at play because only those patients referred for evaluation by their nephrologist were involved. In the previous study [39], all cases from a single center were included.

The ultimate success of a fistula is also dependent upon its depth. Optimally, it should be no more than 1 cm below the surface. Fistulas that are too deep cannot be palpated well and, because of the length of the dialysis needle, cannot be easily cannulated on a repetitive basis. Data obtained at the time of vein mapping can serve as a guide in selecting a target vein of an optimum depth for fistula creation. It can also indicate the need to transpose a vein to a more superficial location when no other acceptable alternative is evident.

The type of aggressive approach used in this report raises two additional questions: (1) how should fistula adequacy be determined and (2) how early should a newly created fistula be evaluated to detect problems with development? Basically, fistula adequacy requires two things, fistula maturation and blood flow. While these are somewhat separate issues, they are also closely interrelated. Maturation refers to changes that occur in the vein comprising the fistula that allow for it to be repetitively cannulated. Blood flow must be adequate to support dialysis. Flow can be measured with a reasonable degree of accuracy. It only needs to be marginally greater than the dialysis blood pump rate [40]. If the patient is to dialyze at a pump speed of 400 mL/min, a fistula blood flow of 600 to 700 mL/min should be adequate to avoid recirculation. The issue of cannulation is somewhat harder to judge. It involves subjective elements that cannot be measured. Nevertheless, vessel size is important and that can be measured.

Robbin et al [41] found that if fistula diameter was 0.4 cm or greater, the chance that it would be adequate for dialysis was 89% versus 44% if it was less than 0.4 cm. The chances that the fistula would be adequate for dialysis were 84% if the flow was 500 mL/min or greater but

only 43% if it was less than this level. Combining the two variables increased the predictive value of the measurements. A minimum fistula diameter of 0.4 cm and a minimum flow volume of 500 mL/min resulted in a 95% chance that the fistula would be adequate versus 33% if neither of the minimum criteria were met. Of considerable interest was the fact that experienced dialysis nurses had an 80% accuracy in predicting the ultimate utility of a fistula for dialysis. In this study, the ability of an experienced dialysis nurse to successfully cannulate the fistula and the ability of the access to support a minimum dialysis blood flow of 350 mL/min was used as the criteria to judge maturation.

Evaluation by physical examination at 30 days to detect problems with adequacy has been recommended on an empiric basis [5]. This was based upon the observation that an AV fistula that did not appear to be adequate at that time was generally not adequate at a later date. Actually, increased blood flow occurs very early. In one prospective study [42], average arterial blood flow preoperatively was  $30 \pm 18$  mL/min. Within 24 hours of surgery to create a fistula, the fistula blood flow was up to  $472 \pm 315$  mL/min, and by 1 week it had increased to  $861 \pm 565$  mL/min. In another study in which patients were divided into two groups based upon the internal diameter of their feeding artery [43], it was found that blood flow increased from a preoperative level of  $46 \pm 6$  mL/min up to  $184 \pm 13$  mL/min at 1 day,  $202 \pm 14$  mL/min at 1 week,  $274 \pm 17$  mL/min at 3 weeks,  $488 \pm 95$  mL/min at 8 weeks, and  $562 \pm 131$  mL/min at 12 weeks in the group with the best results. This group had a feeding artery with an internal diameter greater than 1.5 mm and a 12-week primary patency rate of 83%. Robbin et al [36] found that there was no significant difference in fistula blood flow in the second, third, or fourth month following creation and that vessel diameter changed very little.

## CONCLUSION

These studies suggest that a fistula that is going to mature adequately for dialysis does so relatively early and that evaluation after 1 month should detect those that need further study. The fact that maturation can be judged with 80% accuracy by physical examination [41] and that the major causes of failure to mature can be diagnosed by physical examination [31, 32] suggest that the protocol for accomplishing this task can be very simple. An experienced person should examine a newly created fistula at 4 weeks. If it does not appear to be developing adequately for eventual use as a dialysis access, it should be studied angiographically. If correctable pathology is detected, it should be treated by endovascular means. If endovascular therapy is not effective, referral to the vascular surgeon should be considered. The incidence of correctable lesions is relatively high and an

aggressive therapeutic approach can be expected to have a high yield.

Reprint requests to Gerald A. Beathard, M.D., Ph.D., 2800 Waymaker Way, #68 Austin, TX 78746.  
E-mail: Gerald@beathard.com

## REFERENCES

1. ALLON M, ROBBIN ML: Increasing arteriovenous fistulas in hemodialysis patients: Problems and solutions. *Kidney Int* 62:1109-1124, 2002
2. NKF-K/DOQI CLINICAL PRACTICE GUIDELINES FOR VASCULAR ACCESS: Guideline 29: Goals of Access Placement—Maximizing Primary AV Fistulae. *Am J Kidney Dis* 37(Suppl 1):S169, 2001
3. BEATHARD GA: Strategy for maximizing the use of arteriovenous fistulae. *Semin Dial* 13:291-296, 2000
4. BEATHARD GA: Angioplasty for arteriovenous grafts and fistulae. *Semin Neph* 22:202-210, 2002
5. BEATHARD GA, SETTLE SM, SHIELDS MW: Salvage of the nonfunctioning arteriovenous fistula. *Am J Kidney Dis* 33:910-916, 1999
6. NKF-K/DOQI CLINICAL PRACTICE GUIDELINES FOR VASCULAR ACCESS: Update 2000. Guideline 19: Treatment of Stenosis Without Thrombosis in Dialysis AV Grafts and Primary AV Fistulae. *Am J Kidney Dis* 37(Suppl 1):S163-S164, 2001
7. FAHAYZ R, ABREO K, ZAMAN F, et al: Salvage of poorly developed arteriovenous fistulae with percutaneous ligation of accessory veins. *Am J Kidney Dis* 39:824-827, 2002
8. ARUNY JE, LEWIS CA, CARDELLA JF, et al: Quality improvement guidelines for percutaneous management of the thrombosed or dysfunctional dialysis access. *J Vas Interv Radiol* 10:491-498, 1999
9. KINNAERT P, VEREERSTRAETEN P, TOUSSAINT C, VAN GEERTRUYDEN J: Nine years' experience with internal arteriovenous fistulas for haemodialysis: A study of some factors influencing the results. *Br J Surg* 64:242-246, 1977
10. BONALUMI U, CIVALLERI D, ROVIDA S, et al: Nine years' experience with end-to-end arteriovenous fistula at the "anatomical snuffbox" for maintenance haemodialysis. *Br J Surg* 69:486-488, 1982
11. REILLY DT, WOOD RF, BELL PR: Prospective study of dialysis fistulas: Problem patients and their treatment. *Br J Surg* 69:549-553, 1982
12. PALDER SB, KIRKMAN RL, WHITTEMORE AD, et al: Vascular access for hemodialysis. Patency rates and results of revision. *Ann Surg* 202:235-239, 1985
13. WINSETT OE, WOLMA FJ: Complications of vascular access for hemodialysis. *South Med J* 78:513-517, 1985
14. KHERLAKIAN GM, ROEDERSHEIMER LR, ARBAUGH JJ, et al: Comparison of autogenous fistula versus expanded polytetrafluoroethylene graft fistula for angioaccess in hemodialysis. *Am J Surg* 152:238-243, 1986
15. ROCCO MV, BLEYER AJ, BURKART JM: Utilization of inpatient and outpatient resources for the management of hemodialysis access complications. *Am J Kidney Dis* 28:250-256, 1996
16. WONG V, WARD R, TAYLOR J, et al: Factors associated with early failure of arteriovenous fistulae for haemodialysis access. *Eur J Vasc Endovasc Surg* 12:207-213, 1996
17. HODGES TC, FILLINGER MF, ZWOLAR RM, et al: Longitudinal comparison of dialysis access methods: risk factors for failure. *J Vasc Surg* 26:1009-1019, 1997
18. SILVA MB, JR, HOBSON RW, 2ND, PAPPAS PJ, et al: A strategy for increasing use of autogenous hemodialysis access procedures: Impact of preoperative noninvasive evaluation. *J Vasc Surg* 27:302-307, 1998
19. HAKAIM AG, NALBANDIAN M, SCOTT T: Superior maturation and patency of primary brachiocephalic and transposed basilic vein arteriovenous fistulae in patients with diabetes. *J Vasc Surg* 27:154-157, 1998
20. GOLLEGE J, SMITH CJ, EMERY J, et al: Outcome of primary radiocephalic fistula for haemodialysis. *Br J Surg* 86:211-216, 1999
21. MILLER PE, TOLWANI A, LUSCY CP, et al: Predictors of adequacy of arteriovenous fistulas in hemodialysis patients. *Kidney Int* 56:275-280, 1999

22. ASCHER E, GADE P, HINGORANI A, et al: Changes in the practice of angioaccess surgery: Impact of dialysis outcome and quality initiative recommendations. *J Vasc Surg* 31:84-92, 2000
23. REVANUR VK, JARDINE AG, HAMILTON DH, JINDAL RM: Outcome for arterio-venous fistula at the elbow for haemodialysis. *Clin Transplant* 14:318-322, 2000
24. WOLOWCZYK L, WILLIAMS AJ, DONOVAN KL, GIBBONS CP: The snuffbox arteriovenous fistula for vascular access. *Eur J Vasc Endovasc Surg* 19:70-76, 2000
25. GIBSON KD, CAPS MT, KOHLER TR, et al: Assessment of a policy to reduce placement of prosthetic hemodialysis access. *Kidney Int* 59:2335-2345, 2001
26. ALLON M, LOCKHART ME, LILLY RZ, et al: Effect of preoperative sonographic mapping on vascular access outcomes in hemodialysis patients. *Kidney Int* 60:2013-2020, 2001
27. OLIVER MJ, McCANN RL, INDRIDASON OS, et al: Comparison of transposed brachio basilic fistulas to upper arm grafts and brachiocephalic fistulas. *Kidney Int* 60:1532-1539, 2001
28. SEDLACEK M, TEODORESCU V, FALK A, et al: Hemodialysis access placement with preoperative noninvasive vascular mapping: Comparison between patients with and without diabetes. *Am J Kidney Dis* 38:560-564, 2001
29. DIXON BS, NOVAK L, FANGMAN J: Hemodialysis vascular access survival: Upper-arm native arteriovenous fistula. *Am J Kidney Dis* 39:92-101, 2002
30. ROMERO A, POLO JR, MORATO EG, et al: Salvage of angioaccess after late thrombosis of radiocephalic fistulas for hemodialysis. *Int Surg* 71:122-124, 1986
31. BEATHARD GA: Physical examination of the dialysis vascular access. *Semin Dial* 11:231-236, 1998
32. BEATHARD GA: Physical examination: The forgotten tool, in *A Multidisciplinary Approach for Hemodialysis Access*, edited by GRAY R, SANDS J, New York, Lippincott Williams & Wilkins, 2002, pp 111-118
33. TURMEL-RODRIGUES L: Diagnosis and endovascular treatment for autologous fistulae-related stenoses, in *A Multidisciplinary Approach for Hemodialysis Access*, edited by GRAY R, SANDS J, New York, Lippincott Williams & Wilkins, 2002, pp 170-183
34. TURMEL-RODRIGUES L, MOUTON A, BIRMELE B, et al: Salvage of immature fistulas for haemodialysis by interventional radiology. *Nephrol Dial Transplant* 16:2365-2371, 2001
35. RUTHERFORD RB: The value of noninvasive testing before and after hemodialysis access in the prevention and management of complications. *Semin Vasc Surg* 10:157-161, 1997
36. ROBBIN ML, GALLICHO MH, DEIERHOI MH, et al: US vascular mapping before hemodialysis access placement. *Radiology* 217:83-88, 2000
37. MENDES RR, FARBER MA, MARSTON WA, et al: Prediction of wrist arteriovenous fistula maturation with preoperative vein mapping with ultrasonography. *J Vasc Surg* 36:460-463, 2002
38. DALMAN RL, HARRIS JE, VICTOR BJ, COOGAN SM: Transition to all-autogenous hemodialysis access: The role of preoperative vein mapping. *Ann Vasc Surg* 16:624-630, 2002
39. MILLER CD, ROBBIN ML, ALLON M: Gender differences in outcomes of arteriovenous fistulas in hemodialysis patients. *Kidney Int* 63:346-352, 2003
40. SHERMAN RA, BESARAB A, SCHWAR SJ, BEATHARD GA: Recognition of failing vascular access. *Semin Dial* 10:1-4, 1997
41. ROBBIN ML, CHAMBERLAIN NE, LOCKHART ME, et al: Hemodialysis arteriovenous fistula maturity: US evaluation. *Radiology* 225:59-64, 2002
42. YERDEL MA, KESENCI M, YAZICIOGLU KM, et al: Effect of haemodynamic variables on surgically created arteriovenous fistula flow. *Nephrol Dial Transplant* 12:1684-1688, 1997
43. MALOVRH M: Non-invasive evaluation of vessels by duplex sonography prior to construction of arteriovenous fistulas for haemodialysis. *Nephrol Dial Transplant* 13:125-129, 1998

**Submitter :** Ms. Carol Gunter

**Date:** 10/24/2006

**Organization :** Davita

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Catherine Fekete  
**Organization :** Maui Medical Group  
**Category :** Dietitian/Nutritionist

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

My practice is determined by Medicare guidelines and only see patients who are Stage 3 or 4 and do not have access issues. However, if it is documented that these procedures can be done ACS's without negative outcomes this may result in less hardship for the patient.



**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

The ability to have access to these centers is absolutely vital. This would save patients from being hospitalized and being subjected to long waits for access placements. This would also save money. An access could be monitored before it fails instead of after it fails. This would save tons of money.

**Submitter :** Mr. Keith Ketover

**Date:** 10/24/2006

**Organization :** DaVita Inc.

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

GENERAL

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Ms. michele becher

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Nurse

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I feel that vascular access procedures for dialysis patients that can be performed in an out-patient setting should be paid for by CMS. This is a cost-effective way to handle the volume of procedures that our patients need.

**Submitter :** Denise Davis

**Date:** 10/24/2006

**Organization :** DaVita, Inc.

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is the life line for hemodialysis patients. If care could be provided in an out patient setting that can come to the patient quickly it would impact not only costs but also quality of life for the patient. The impact would be less travel and family/friend hurdles requiring jumping.

**Submitter :** Mrs. Linda Isham

**Date:** 10/24/2006

**Organization :** DaVita Rx

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mrs. Bobbie Duke

**Date:** 10/24/2006

**Organization :** Mrs. Bobbie Duke

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings. I am in full support of the ASC system.

**Submitter :** Mrs. Mardetta Lynch, M.S.W.

**Date:** 10/24/2006

**Organization :** Lake Elsinore Dialysis Center

**Category :** Social Worker

**Issue Areas/Comments**

**ASC Payment for Office-Based Procedures**

**ASC Payment for Office-Based Procedures**

The patient's access is their life line. Without it, they cannot receive dialysis and cannot live. I help patients arrange appointments for vascular surgery for their accesses. I often have to advocate for patients when dealing with people in the medical community or insurance industry who do not understand what an access is or why it is so important. Time delays for surgical appointments are not uncommon, leaving the patient vulnerable to the effects of inadequate dialysis and severe infections arising from the use of chest catheters. It would be ideal if I could send our patients to our local access center, run by area nephrologists and staffed by people who understand the patients' need for an effective dialysis access site immediately. The dialysis patient cannot afford to wait. Authorizing ambulatory surgical centers to place vascular accesses will save CMS the expense of many hospitalizations due to infected catheters and the effects of inadequate dialysis by allowing patients to have the access placement they need in a timely manner.

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category : Dietitian/Nutritionist**

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

October 24, 2006

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1506-P2  
P.O. Box 8011  
Baltimore, MD 21244-1850

Dear Sirs:

Please consider the following comments for CMS 1506-P2; The Hospital Outpatient Prospective Payment Systems and CY 2007 payment Rates; FY 2008 ASC Payment.

ASC Payable Procedures (exclusion Criteria):

We support CMS' practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay by the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in an ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

Thank you.

Sincerely

Ester Ibrahim  
114 East Brandon Blvd.  
Brandon, Florida 33511

**ASC Payable Procedures**

ASC Payable Procedures

General Comment:

Vascular access is one of the greatest sources of complications and cost for dialysis patients, because the USA uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistula.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedure would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.



**Submitter :** Mrs. Jan Arnold

**Date:** 10/24/2006

**Organization :** Mrs. Jan Arnold

**Category :** Nurse

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

in today's rising healthcare costs, it makes good healthcare and good business sense to provide outpatient vascular access insertions in ASC centers. These centers can provide the same resources a larger hospital can provide with less overhead. These centers provide an outpatient link in the continuum of care. They provide the same service that an outpatient center attached to a hospital could provide.

**GENERAL**

**GENERAL**

The "fistula first" program needs supported, especially early on in the developing stages of renal disease. Surgeons should be financially reimbursed for trying fistulas first, as opposed to getting reimbursed at a higher rate for grafts.

**Submitter :** Dr. Thomas J. Watts III

**Date:** 10/24/2006

**Organization :** CIR

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

CMS should abide by the procedures recommended by the Medicare Payment Advisory Commission (March, 2004). Developing technology has made it practical and safe for patients to be prepared for vascular access in an ambulatory setting as well as a hospital, and this capability should be acknowledged by Congress.

**GENERAL**

GENERAL

I strongly urge the Congress to include CPT Codes 35474, 35476, 36205, and 36206 in the effort to reduce costs and promote better treatment for ESRD patients.

**Submitter :** Mrs. Terri Rogers

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mr. Jerry Medsker

**Date:** 10/24/2006

**Organization :** davita patient

**Category :** Individual

**Issue Areas/Comments**

**ASC Inflation**

ASC Inflation

You know that dialysis patients have to go to centers for treatment. With the price of gasoline as high as it is , How do you expect the dialysis patient to afford the trips to the centers to get treatments. I dont think we should have decide to get treatments to live or to eat or pay for the gas to go to treatments,. I think the goverment should give the patient a tax break so that we can afford to having treatments

**Submitter :** Mr. Strait Gaston

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

GENERAL

Anything that would encourage fistulas would be a tremendous improvement in ESRD overall quality of life. This is probably the single most important aspect in regards to a longer life.

**Submitter :** Mrs. Michelle Ocker

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

Submitter :

Date: 10/24/2006

Organization :

Category : Nurse

Issue Areas/Comments

**ASC Payable Procedures**

**ASC Payable Procedures**

People with ESRF usually can;t afford the care required for surgery to insert shunt or the high cost of dialysis. If anything the benefits to treat this disease should be increased if any changes are made. Just a few diaysis session could wipe out ones entire savings and/or retirement fund. When one is disabled from ESRF they don't receive enough money to pay for the care that is required.

esrf

**Submitter :** Mrs. Marla Garbat  
**Organization :** Davita  
**Category :** Dietitian/Nutritionist

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

Support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

I support Support CMS' Fistula First Initiative and would encourage that Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings. this would benefit the health and well being of all dialysis patients giving them greater more timely access to the support needed for excellent dialysis care.



**Submitter :**

**Date: 10/24/2006**

**Organization :** DaVita -- BCDC

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Michelle Ocker

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mr. JAMES GATTI SR.

**Date:** 10/24/2006

**Organization :** DAVITA INC.

**Category :** Other Technician

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mrs. Audrey Hing  
**Organization :** Mrs. Audrey Hing  
**Category :** Individual

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payment for Office-Based  
Procedures**

ASC Payment for Office-Based Procedures

Please rule in favor of approval for vascular procedures performed in ambulatory sites.

**GENERAL**

GENERAL

It is important that ESRD patients have assurance that the treatments and procedures required are accessible and are covered by insurance.

**Submitter :** Mr. Thomas Myers

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I support CMS'practice of re-examining its policies as technonogy improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission in their March 2004 reprot to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and con be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely staisfied with having the ooption to secure vascular access repair and maintenance care in an outpatient setting. Further, the CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mr. Henry Lewis

**Date:** 10/24/2006

**Organization :** Mr. Henry Lewis

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Lisa Simonton  
**Organization :** Renal Endocrine Associates  
**Category :** Ambulatory Surgical Center

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

As the Executive Director of a nephrology practice I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

I have heard 1st hand the comments of patients treated for access related issues in the ASC setting. They appreciate the care the overall service and care they receive in the ASC setting.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Pamela Clarke

**Date:** 10/24/2006

**Organization :** Mrs. Pamela Clarke

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.



**Submitter :** Mr. scott eller  
**Organization :** Mr. scott eller  
**Category :** Individual

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting

**Submitter :** Melissa Miller

**Date:** 10/24/2006

**Organization :** Melissa Miller

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Just wanted to say that health care is very important to everyone no matter where you are to... as a 24 year old female who had a kidney transplant 5 months ago I know this first hand and I am lucky enough to have found a match for me even though I was waiting a four years to get one... health care should be on the top of everyone list of things to look after... people are the number one thing in this world... we should take care of them

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category : Individual**

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mrs. Melinda Wrighter  
**Organization :** National Renal Alliance, LLC.  
**Category :** Nurse

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

i am for this procedure

**Submitter :** Mrs. Stellouise Ramer  
**Organization :** DaVita Reliant Dialysis  
**Category :** Social Worker

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I support vascular access procedures being performed in Ambulatory Surgical Centers because there is scientific evidence that these procedures can be safely performed in ambulatory surgical centers and patients like the option of being able to utilize the outpatient setting for access placement. The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Richard Sha  
**Organization :** Richard Sha  
**Category :** Individual

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

GENERAL

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category : End-Stage Renal Disease Facility**

**Issue Areas/Comments**

**GENERAL**

GENERAL

October 24, 2006  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1506-P2  
P.O. Box 8011  
Baltimore, MD 21244-1850

Dear Sirs:

Please consider the following comments for CMS 1506-P2; The Hospital Outpatient Prospective Payment Systems and CY 2007 payment Rates; FY 2008 ASC Payment.

General Comments

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

ASC Payable Procedures (Exclusion Criteria)

We support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

Thank you.

Sincerely,

Bonnie Craddock  
222 Foxbriar Street  
Slidell, La 70461

**Submitter :** Ms. Linda Walker

**Date:** 10/24/2006

**Organization :** DaVita, Inc.

**Category :** Nurse

**Issue Areas/Comments**

**CY 2008 ASC Impact**

**CY 2008 ASC Impact**

I support ESRD Patients' Access to Quality Care. There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center (ASC) settings.

I support CMS' Fistula First Initiative. Angioplasty codes should be included to permit a full range of vascular access procedures to be performed in accessible, cost-effective ASC settings.



**Submitter :** Mr. Richard Bruner

**Date:** 10/24/2006

**Organization :** Davita, Inc.

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mr. Michael Hayes

**Date:** 10/24/2006

**Organization :** Sierra Rose Dialysis Center

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

ASC would reduce costs to medicare and medicaid due to fact that pt would not have to be hospitalized and could make treatment in their facility not the hospital.

**Submitter :** Mr. Victor Lentz

**Date:** 10/24/2006

**Organization :** Mr. Victor Lentz

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS'practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by their Medicare Payment Advisory Commission (MEDPAC)in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in ambulatory Surgical settings. And more importantly, patients are extremely satisfied. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current hospital setting.

Please treat End Stage Renal patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Ruth Welty  
**Organization :** McDonough Dialysis  
**Category :** Social Worker

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Office-Based Procedures**

ASC Office-Based Procedures

Vascular Access is so vital to maintaining life and health for dialysis patients. This is a growing population and to be able to do surgical procedures in an outpatient setting can only improve the quality of life of patients who spend so much time in a medical setting. I strongly support more accessible treatment sites for my dialysis patients.

**Submitter :** Mrs. Carol Baird

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** Nurse

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I have been a Nephrology nurse for 19 years and know what a trial it is for our patients to get the procedures done to have safe and long lasting access for dialysis. I would like to encourage the use of outpatient procedures for access placement and revisions in part because it is safe and also to avoid the risk of infection that hospitalization poses.

**GENERAL**

**GENERAL**

All patients need to be able to have vascular access procedures done in a quick and efficient manner. I support any efforts to make life easier for this very stressed population of patients.

**Submitter :** Mrs. Ella Dowell  
**Organization :** Mrs. Ella Dowell  
**Category :** Individual

**Date:** 10/24/2006

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Give patients their dignity. Let them chose what facility is right for them.

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category :** Nurse

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures

I support CMS' practice of re-examining its policies as technology improves and practice patterns change. Please support patient choice! There is a clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center settings, and patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. The inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting. Please treat ESRD patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :**

**Date: 10/24/2006**

**Organization :**

**Category : Nurse**

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205, and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for ESRD patients through more thoughtful reimbursement and regulation of vascular access procedures.



**Submitter :** susan vogel  
**Organization :** s valley regional dialysis center  
**Category :** End-Stage Renal Disease Facility

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

ASC Payable Procedures  
vascular access

**ASC Payable Procedures**

ASC Payable Procedures

allowing fistulas to be placed in surgery centers will allow for timely repair and return to the dialysis center and keep costs out of the hospital, thereby lowering total costs to the medicare esrd program

**Submitter :** Miss. Erin Vlack

**Date:** 10/24/2006

**Organization :** Care for family members with PKD

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

I personally feel this is a good idea to increase access. HOWEVER, I think overall it is a bad idea, because of the problems that can occur. I have personal experience with the staffing at one of these sorts of centers being less experienced and putting in a port incorrectly, causing infection and multiple visits.

**Submitter :** Dr. frrederick weiss

**Date:** 10/24/2006

**Organization :** Dr. frrederick weiss

**Category :** Physician

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

ptients who are able to access surgical centers as opposed to hospitals love this ability. They spend less time making appointments, less time in waiting for the procedure and less time in getting the procedure accomplished.

For patients who already need to spend three times a week getting their dialysis treatments, to have their access declotting procedures done at an outpatient center is fabulous. Many times, the procedure can be scheluded for the same day as the dialysis and the patient can be dialyzed after that procedure.

For my patients who are working, that is a vast improvement over trying to get them set up for a hospital procedure. This never happens on the same day. It means a loss of a working day.

For patients who need procedures done after a weekend, the ability to get them done and the patient dialyzed as an outpatient the same day is also time and cost effective. Many of these patients have fluid and electrolyte problems. To wait and get their procedure done in hospital, many times means that the patient will end up being admitted for an acute dialytic procedure to treat congestive heart failure and or hyperkalemis.

I heartily endorse the outpatient payment process for fistula and catheter placement and revision.

**Submitter :** Mr. william strickland

**Date:** 10/24/2006

**Organization :** Mr. william strickland

**Category :** Individual

**Issue Areas/Comments**

**GENERAL**

GENERAL

I support ESRD patients to Quality care and I support CMS Fistula First Initiative

**Submitter :** julie edwards

**Date:** 10/24/2006

**Organization :** DaVita Memorial Dialysis

**Category :** Nurse

**Issue Areas/Comments**

**GENERAL**

**GENERAL**

Please allow payment to ambulatory surgical centers for dialysis vascular procedures. This would be a great benefit to the patients and save unnecessary hospital admissions.

**Submitter :** Mrs. Lisa Mcallister

**Date:** 10/24/2006

**Organization :** Mrs. Lisa Mcallister

**Category :** Nurse

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS' practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission in their March 2004 report to congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS' Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat ESRD patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mr. Adrian Amedia

**Date:** 10/24/2006

**Organization :** DaVita

**Category :** End-Stage Renal Disease Facility

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**Submitter :** Mrs. Barbara Dean  
**Organization :** Mrs. Barbara Dean  
**Category :** Individual

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.



**Submitter :** Mrs. Christine Amedia

**Date:** 10/24/2006

**Organization :** Mrs. Christine Amedia

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Mrs. Marilyn Amedia

**Date:** 10/24/2006

**Organization :** Mrs. Marilyn Amedia

**Category :** Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

**Submitter :** Dr. Chester Amedia  
**Organization :** Care Level Management  
**Category :** Physician

**Date:** 10/24/2006

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.

Submitter : Mr. Walter Baker

Date: 10/24/2006

Organization : Mr. Walter Baker

Category : Individual

**Issue Areas/Comments**

**ASC Payable Procedures**

**ASC Payable Procedures**

I support CMS practice of re-examining its policies as technology improves and practice patterns change, especially when supported by recommendations made by the Medicare Payment Advisory Commission (MedPAC) in their March 2004 report to Congress. The report concludes that clinical safety standards and the need for an overnight stay be the only criteria for excluding a procedure from the approved list.

Please support patient choice! There is clear scientific evidence that vascular access procedures are safe and can be performed in Ambulatory Surgical Center setting, and more importantly, patients are extremely satisfied with having the option to secure vascular access repair and maintenance care in an outpatient setting. Further, the inclusion of angioplasty codes in the ASC setting would support CMS Fistula First initiative by permitting a full range of vascular access procedures to be performed in an ASC setting, a less expensive and more accessible option than the current prevalent hospital setting.

Please treat End Stage Renal Disease patients fairly by ensuring all angioplasty codes, including CPT 35476 are allowed in the ASC setting.

**GENERAL**

**GENERAL**

Vascular access is one of the greatest sources of complications and cost for dialysis patients. Why, because America uses more surgical grafts and catheters for vascular access than the rest of the developed world, even though there is substantial evidence that they impose higher initial and maintenance costs, lead to greater clinical complications, and result in higher mortality than arterio-venous (AV) fistulae.

The inclusion of CPT codes 35475, 35476, 36205 and 37206 to the list of Medicare approved ambulatory surgical center (ASC) procedures would provide Medicare the opportunity to reduce the cost of, and promote quality outcomes for, end-stage renal disease (ESRD) patients through more thoughtful reimbursement and regulation of vascular access procedures.