



Complication risks and costs associated with Ponte osteotomies in surgical treatment of adolescent idiopathic scoliosis: insights from a national database

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Abstract

Purpose Risks of Ponte osteotomies (POs) used for posterior spinal fusion (PSF) for Adolescent Idiopathic Scoliosis (AIS) are challenging to assess because of the rarity of complications. Using a national administrative claims database, we evaluated trends, costs and complications associated with PO used in PSF for AIS patients.

Methods Using ICD-9/CPT codes, we identified patients (ages 10–18) with AIS who underwent PSF (\pm PO) between 2007 and 2015 in the IBM[®] MarketScan[®] Commercial Databases. Costs and trends of POs were evaluated. Odds of neurological complications and readmissions within 90 days and reoperations within 90 days and 2 years were assessed.

Results We identified 8881 AIS patients who had undergone PSF, of which 8193 had 90-day follow-up and 4248 had 2-year follow-up. Overall, 28.8% had PO. Annual rate of POs increased from 17.3 to 35.2% from 2007 to 2015 ($p < 0.001$). Risk-adjusted multivariable logistic regression demonstrated no relationship between POs and neurologic complications ($p = 0.543$). POs were associated with higher odds for readmission (1.52 [1.21–1.91]; $p < 0.001$) and reoperation (2.03 [1.13–3.59]; $p = 0.015$) within 90 days, but there were no differences in the odds of reoperation within 2 years ($p = 0.836$). Median hospital costs were \$15,854 (17.4%) higher for patients with POs ($p < 0.001$) and multivariable modeling demonstrated POs to be an independent predictor of increased costs ($p < 0.001$).

Conclusion Annual rate of POs increased steadily from 2007 to 2015. POs were not associated with increased odds of neurological complications but had higher costs and higher rates of readmissions and reoperations within 90 days. By 2 years, differences in reoperation rate were not significant.

Level of evidence III.

Keywords Adolescent idiopathic scoliosis · Ponte osteotomy · Scoliosis · Spinal fusion · Pediatrics · Adolescent

Introduction

Adolescent idiopathic scoliosis (AIS) is a three-dimensional spinal deformity that arises in otherwise healthy adolescents at or around puberty. It is the most common form of scoliosis, with a prevalence in the at-risk population (children ages 10–18 years) of approximately 1–3% [1]. AIS patients with severe curvatures often have severe psychosocial

limitations [2, 3] and curve progression has been linked to sequelae, such as back pain, impaired pulmonary function, and decreased quality of life [4].

Surgical intervention is typically offered when the major curve has a Cobb angle greater than 45°–55° [5]. The objectives of surgical treatment are to arrest curve progression and achieve multiplanar correction [4]. Instrumented spinal fusion is the mainstay of modern surgical treatment, with most cases being treated with a posterior approach and instrumentation. Posterior releases, such as facetectomies, are commonly used to facilitate fusion and curve correction but the indication for more extensive posterior spinal osteotomies are controversial [6].

The posterior column or Ponte osteotomy (PO) is a modification of the Smith-Peterson osteotomy and consists of a

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wide resection of the superior and inferior articular facet joints and as well as portions of the spinous process, lamina and ligamentum flavum [7, 8]. Although initially described for the treatment of kyphosis, POs have been shown to facilitate deformity correction in AIS, particularly for restoring normal kyphosis across hyperlordotic curves and with respect to coronal and axial planes [9, 10]. The exposure of the dura and the necessity of passing multiple instruments near the neural elements at the interspace where the osteotomy is performed may increase the risk of neurologic injury when compared to facetectomy alone. Furthermore, epidural bleeding is commonly encountered during PO which may also confer increased perioperative risk. Single and multi-center case series have associated the use of PO with effective deformity correction, apparently without an increase in the risk of complications [6, 11, 12]. However, due the overall low incidence of complications after posterior spinal fusion (PSF) for AIS, it is challenging for clinical studies to be adequately powered to detect rare complications. Additionally, the published case series evaluating the safety and efficacy of Ponte osteotomies are typically composed of cases from surgeons within high volume academic centers that may not accurately represent the risk profile of the average scoliosis case.

In this study, we use a large national administrative claims database to describe trends in PO usage in the United States and to compare complications and costs in AIS patients undergoing PSF with and without PO.

Materials and methods

Data source

In this retrospective longitudinal study, we analyzed 2007–2015 data from the IBM® MarketScan® Commercial Databases (MarketScan®). These databases include de-identified health insurance claims and enrollment from

more than 100 large employers, managed care organizations, hospitals, Electronic Medical Record (EMR) providers, and commercially managed Medicare and Medicaid plans. These databases collectively contain inpatient and outpatient claims of over 150 million employees, retirees, and dependents from all 50 states of the United States. Although these databases do not use sampling weights and are not necessarily nationally representative, they provide detailed and rigorously maintained claims data for a substantial portion of individuals covered by commercial insurance providers in the United States. Covered patients are also assigned a unique identification number, which enables longitudinal analysis. The databases were accessed for this study under a license agreement and are publicly available from IBM® MarketScan® Research Databases to researchers for a fee. The study does not constitute research involving “human subjects” pursuant to 45 CFR 46.102 and is therefore exempt from review by the institutional review board.

Identification of diagnoses, patients and other outcomes

The databases were searched for adolescent (ages 10–18) AIS patients who underwent PSF with and without PO using *International Classification of Disease, Ninth Revision, Clinical Modification* (ICD-9-CM) and *Current Procedural Terminology* (CPT) codes (Table 1). Patients were excluded if they had additional diagnoses that were inconsistent with AIS and/or PO. A list of ICD-9-CM and CPT codes that were excluded are set forth on Table 2.

Complications were identified using ICD-9-CM/CPT codes and defined based on the pediatric complex chronic conditions (CCC) classification system [13], with additional spine-related complications identified with the methodology described by Ratliff et al. (with modifications to exclude complications related to the cervical spine) [14]. Readmissions during the 90-day period following PSF and differences in rates of reoperations during the 90-day and 2-year

Table 1 Diagnosis and procedure codes for AIS, PSF and POs

Type	Codes
Adolescent idiopathic scoliosis	
ICD-9-CM codes	
Scoliosis [and kyphoscoliosis], idiopathic	737.30
Posterior spinal fusion	
CPT codes	
Posterior non-segmental instrumentation	22840
Posterior segmental instrumentation	22842, 22843, 22844
Arthrodesis, posterior, for spinal deformity, with or without cast	22800, 22802, 22804
Ponte osteotomy	
CPT codes	
Osteotomy procedures on the spine (vertebral column)	22210, 22212, 22214, 22216

Table 2 Diagnosis and procedure codes used to exclude patients with non-idiopathic scoliosis and identify the final cohort

Type	Codes
ICD-9-CM diagnosis codes	
Malignancies	170.2, 191.9, 192.0, 192.2
Neurofibromatosis	237.70, 237.71, 237.72, 237.79
Dwarfism	259.4
Cerebral degeneration	330.0, 330.8
Parkinson's disease	332
Extrapyramidal disease and abnormal movement disorders	333.0, 333.2, 333.4, 333.5, 333.7, 333.9
Spinocerebellar disease	334
Anterior horn cell disease	335
Other diseases of spinal cord	336.1, 336.8
Unspecified disorder of autonomic nervous system	337.9
Multiple sclerosis and other demyelinating diseases of central nervous system	340, 341
Hemiplegia and hemiparesis	342
Infantile cerebral palsy and other paralytic syndromes	343, 344
Other conditions of the brain	348.1, 348.4
Muscular dystrophies and other myopathies	359.0, 359.1, 359.2, 359.3, 359.89, 359.9
Occlusion of cerebral arteries	434.01, 434.91
Diaphragmatic hernia without mention of obstruction or gangrene	553.3
Congenital anomalies	740, 741, 742, 745.1, 745.2, 745.3, 745.6, 746, 747.1, 747.2, 747.3, 747.4, 747.81, 747.89, 756.0, 756.10, 756.13–756.19, 756.2–756.8, 758, 759.5, 759.7, 759.81, 759.82, 759.83, 759.9
Conditions originating in perinatal period	767.0, 767.4, 768.7
Persistent vegetative state	780.03
Complications peculiar to certain specified procedures	996.2, 996.63, 996.83, 996.84
Organ/tissue replacement	V42.1, V42.2, V42.6, V43.2
Cerebrospinal fluid drainage device	V45.2
Fitting/adjustment of device	V53.01, V53.02
ICD-9-CM procedure codes	
Excision/destruction of brain/meninges	01.52, 01.53
Shunt of spinal theca	03.7, 03.79, 03.97
Operations on skull, brain, and/or cerebral meninges	02.2, 02.3, 02.4, 02.93
Implantation/replacement of peripheral neurostimulator	04.92
Operations on respiratory or cardiovascular system	33.5, 33.6, 35.8, 37.5, 37.61, 37.63, 37.65–37.68
CPT codes	
Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment	22206–22208
Anterior spinal fusion	22808, 22810, 22812, 22845–22847
Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral	63090

periods following PSF were identified with ICD-9-CM and CPT codes. In addition, ICD-9-CM and CPT codes were analyzed to determine the primary reasons for reoperation during the 90-day and 2-year periods following PSF. The ICD-9-CM/CPT codes used to identify complications, reoperations and readmissions are set forth on Table 3.

Length of hospital stay (LOS) and average total hospital cost were also compared between AIS patients undergoing

PSF with (vs. without) PO. Costs were converted to 2015 United States dollars using the medical care component of the Consumer Price Index from the US Bureau of Labor Statistics. MarketScan[®] reimbursement data capture total gross payments, including deductibles and coinsurance paid by the patient. Patients with capitated or partially capitated plans were excluded since their financial information is unreported or not validated.

Table 3 Diagnosis and procedure codes for neurological complications and reoperations

Code	Description
Neurological complications	
ICD-9-CM diagnosis codes	
997.0, 997.00, 997.1	Nervous system complications
953.2–953.3	Injury to lumbar/sacral nerve root
Reoperation	
ICD-9-CM diagnosis code	
996.4	Mechanical complication (unspecified, loosening, dislocation, broken implant, fracture around implant, osteolysis, wear, other mechanical complication, other complication)
ICD-9-CM procedure codes	
78.69	Removal of internal fixation device (vertebral, pelvic, or phalangeal)
81.34–81.38	Refusion of spine
CPT codes	
22830	Exploration procedures on the spine (vertebral column)
22849	Reinsertion spinal fixation device
22850, 22852, 22855	Removal of instrumentation
63042	Re-exploration laminotomy (hemilaminectomy) with decompression of nerve roots, including partial facetectomy, foraminotomy, and/or excision of herniated intervertebral disc

Additional complications defined as in Ratliff et al. [14]

Statistical analysis

Annual rates of POs were calculated and trends were assessed with simple linear regression. Analyses of the 90-day and 2-year outcomes included only patients with continuous health plan enrollment during these time frames.

Univariate differences in complication, readmission, and reoperation rates were first assessed with chi squared and Fisher's exact tests. Subsequently, logistic regression was used to compare the odds for complications (overall and neurological), readmissions and reoperations with (vs. without) PO after risk adjustment for differences in patient and surgical factors. The risk adjustment included patient demographics (age, sex, region of the country [South/North Central/West/Northwest], rural/urban residence based on metropolitan statistical area [MSA] and year of surgery), comorbidities (according to the pediatric complex chronic conditions classification system, version 2) and number of fused spinal levels (fewer than 7 levels, 7–12 levels, and more than 12 levels). When necessary, post hoc tests were conducted using the Tukey–Kramer method. The models for 90-day complications and readmissions and 2-year reoperations included the full risk adjustment outlined above. Due to the limited power for the neurological complication and 90-day reoperation models, backwards elimination was performed in order of decreasing p value until only significant ($p < 0.05$) or trending ($p < 0.1$) terms remained in the models. Results are presented as odds ratios and 95% confidence intervals. Risk-adjusted generalized estimating equation (GEE) models for costs and LOS were conducted with the

full risk adjustment outlined above. All statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC) with a two-sided level of significance of 0.05.

Results

A total of 12,046 AIS patients aged 10–18 with PSF were identified. After excluding patients with non-idiopathic scoliosis diagnoses and those without 90-day follow-up, the final cohort consisted of 8193 patients. 4248 of these patients (47.8%) had 2-year follow-up. The average age at the time of spinal fusion was 14.3 ± 1.9 years. 6178 (75.4%) were females. Overall, 28.8% of AIS patients undergoing PSF received PO, and 7.1% had more than seven POs. The rate of PO use increased during the study period, from 17.3% in 2007 to 35.2% in 2015 ($p < 0.001$, Fig. 1). Patients who had POs were more likely to have longer fusion constructs ($p < 0.001$, Table 4). 32.2% of patients who had PSF with PO had 13+ fused spinal levels, versus 20.6% of PSF without PO. Demographics for the overall and stratified cohort are included in Table 4.

Complications

The overall 90-day complication rate following PSF was 8.6% for patients with PO and 7.3% for patients without PO ($p = 0.037$) (Table 5). After risk adjustment, POs were not related to increased rates of complications (OR [95% CI] 1.12 [0.93–1.34]; $p = 0.243$) (Fig. 2). Neurological

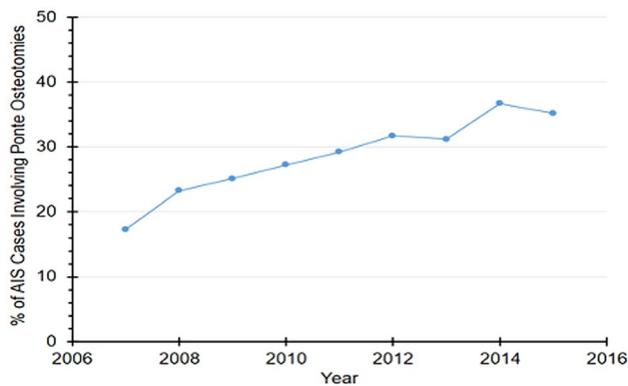


Fig. 1 Percentage of AIS patients undergoing PSF with POs, 2007–2015

complications occurred in 0.4% of patients with PO and 0.3% of patients without PO ($p=0.583$) (Table 5). The risk adjustment for the final 90-day neurological complications model included sex ($p=0.004$), year ($p=0.009$), and metabolic comorbidities from the complex comorbidity index (0.083) after variable reduction. Following this risk adjustment, there was no significant relationship between POs and neurological complications (1.27 [0.56–2.69]; $p=0.543$) (Fig. 2). The rate of neurological complications declined by year from 2007 to 2015 (0.81, [0.69, 0.95], $p<0.001$).

Pulmonary complications were more common among patients with POs ($p=0.040$). However, there were otherwise no significant differences in the incidence of specific types of complications between AIS patients undergoing PSF with and without PO (Table 6).

Readmissions/reoperations

The incidence of readmission within 90 days was 5.9% for patients undergoing PSF with PO and 3.9% for patients undergoing PSF without PO ($p<0.001$). Rates of reoperation with (vs. without) PO were 0.9% (vs. 0.5%) within 90 days ($p=0.031$) and 3.9% (vs. 4.1%) within 2 years ($p=0.767$) (Table 5). After risk adjustment, POs in AIS patients were associated with greater odds for readmissions (1.52 [1.21–1.91]; $p<0.001$). The 90-day reoperation model required variable reduction and included age ($p=0.066$), sex ($p=0.047$), year ($p<0.001$), # levels operated ($p=0.004$), and renal complications from the complex comorbidity index ($p=0.019$) in the final risk adjustment. After this risk adjustment, 90-day reoperations (2.03 [1.13–3.59]; $p=0.015$) were greater in PO vs. non-PO patients following PSF (Fig. 2). However, POs in AIS patients were not associated with greater odds of reoperations within 2 years following PSF (1.04 [0.72–1.48]; $p=0.836$) after risk adjustment (no variable reduction required) (Fig. 2). The rate of 90-day and 2-year reoperations declined with time from 2007 to

2015 (90-day OR: 0.79 [0.70–0.90], $p<0.001$; 2-year OR: 0.87 [0.81–0.94], $p<0.001$).

Sub-analyses of ICD-9-CM codes demonstrated that the primary reasons for reoperations for AIS patients with or without PO were related to deformity or instrumentation/device complications (Table 7). During the 90-day post-operative period, AIS patients with (vs. without) PO had significantly higher rates of reoperations related to instrumentation/device complications and deformity (0.76% vs. 0.38%; $p=0.036$). The rate of reoperations from infections and fluid accumulations was also higher, but did not reach statistical significance (PO: 0.17% vs No PO: 0.10%; $p=0.487$). At 2 years, rates of reoperations from instrumentation/device complications and deformity (PO: 2.79% vs. No PO: 2.03%; $p=0.190$) and infections and fluid accumulations (PO: 0.56% vs. No PO: 0.49%; $p=0.958$) were also higher in PO patients but did not reach statistical significance.

Length of stay and total costs

Average LOS was 4.8 ± 2.4 day for AIS patients undergoing PSF with PO and 4.7 ± 2.6 days for AIS patients undergoing PSF without PO ($p=0.004$) (Fig. 3). Following risk adjustment, increased numbers of POs were associated with longer LOS. Patients with seven or more POs stayed in the hospital 0.31 (95% CI: 0.10–0.53; $p=0.011$) days longer than those with no POs. Total costs for patients with PO were \$15,854 (17.4%) higher than those without PO ($p<0.001$) (Fig. 3). After risk adjustment, costs were associated with the number of POs. Patients with 1–6 POs incurred \$9765 (\$6377–\$13,153; $p<0.001$) more in costs than those without PO and patients with 7+ POs incurred \$21,767 (\$16,369–\$27,165; $p<0.001$) more in costs than those without POs (Fig. 3).

Discussion

In the current study, we observed the annual rate of PO usage increase steadily from 17.3 to 35.2% during 2007–2015 ($p<0.001$). The reasons for this observed trend are uncertain, but several possible explanations exist. The enhanced ability to de-rotate the spine afforded by pedicle screw-based constructs necessitates careful attention to the correction of apical lordosis typically seen in AIS. As recognition of the importance of the sagittal plane in AIS correction has grown, the frequency of application of POs may have grown as well as a tool to facilitate posterior column lengthening and thereby restore kyphosis. Furthermore, recent evidence has also shown that POs are useful to facilitate correction in multiple planes [11, 15, 16] even though the clinical significance of this is controversial and contested by other studies [17]. Depending on local compensation structures, there

Table 4 Demographics of AIS patients who had 90 days of continuous enrollment following PSF

Variable	PO (n = 2360)	No PO (n = 5833)	Overall (n = 8193)
Age (years)	14.4 ± 2.0	14.3 ± 1.9	14.3 ± 1.9
Sex (female)*	1653 (70.0%)	4525 (77.6%)	6178 (75.4%)
Region*			
Northeast	565 (23.9%)	1020 (17.5%)	1585 (19.3%)
North Central	381 (16.1%)	1361 (23.3%)	1742 (21.3%)
South	1020 (43.2%)	2,448 (42.0%)	3468 (42.3%)
West	337 (14.3%)	837 (14.3%)	1174 (14.3%)
Unknown	57 (2.4%)	167 (2.9%)	224 (2.7%)
Rural residence*	283 (12.0%)	979 (16.8%)	1262 (15.4%)
Levels fused*			
≤ 6	221 (9.4%)	1051 (18.0%)	1272 (15.5%)
7–12	1379 (58.4%)	3582 (61.4%)	4961 (60.6%)
13+	760 (32.2%)	1200 (20.6%)	1960 (23.9%)
Number of POs*			
0	0 (0.0%)	5833 (100.0%)	5833 (71.2%)
1–6	1782 (75.5%)	0 (0.0%)	1782 (21.8%)
7+	578 (24.5%)	0 (0.0%)	578 (7.1%)
Thoracoplasty*	52 (2.2%)	40 (0.7%)	92 (1.1%)
Comorbidities			
Obesity*	61 (2.6%)	101 (1.7%)	162 (2.0%)
Neurologic/neuromuscular	3 (0.1%)	8 (0.1%)	11 (0.1%)
Cardiovascular*	73 (3.1%)	132 (2.3%)	205 (2.5%)
Respiratory	13 (0.6%)	22 (0.4%)	35 (0.4%)
Renal/urologic	15 (0.6%)	40 (0.7%)	55 (0.7%)
Gastrointestinal	21 (0.9%)	42 (0.7%)	63 (0.8%)
Hematologic/immunologic	22 (0.9%)	54 (0.9%)	76 (0.9%)
Metabolic	52 (2.2%)	111 (1.9%)	163 (2.0%)
Other congenital/genetic defect	44 (1.9%)	146 (2.5%)	190 (2.3%)
Malignancy	9 (0.4%)	13 (0.2%)	22 (0.3%)
Premature/neonatal	3 (0.1%)	3 (0.1%)	6 (0.1%)
Technology dependence (e.g., gastrostomy, cerebrospinal fluid ventricular shunts, tracheostomy)	75 (3.2%)	173 (3.0%)	248 (3.0%)
Transplantation	5 (0.2%)	12 (0.2%)	17 (0.2%)

Descriptive statistics for age are presented as means and standard deviations. For all others, descriptive statistics are presented as n (%)

*p < 0.05 in univariate tests

Table 5 Univariate comparison with and without PO of any complication, readmission, reoperation and neurological complication within 90 days and reoperation within 2 years

	PO (n = 2360)	No PO (n = 5833)	p value
Any complication*	203 (8.6%)	423 (7.3%)	0.037
Neurological Complication	10 (0.4%)	20 (0.3%)	0.583
Readmission	140 (5.9%)	225 (3.9%)	< 0.001
Any reoperation (90 days)*	22 (0.9%)	30 (0.5%)	0.031
Any reoperation (2 years)	48 (3.9%)	125 (4.1%)	0.767

*p < 0.05

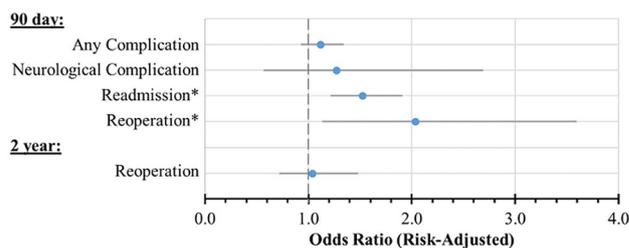


Fig. 2 Risk-adjusted odds ratio (OR) of any complication, neurological complication, readmission and reoperation within 90 days and OR of reoperation within 2 years of PSF for AIS with (vs. without) POs. (*Statistically significant, p < 0.05)

Table 6 Univariate comparison with and without PO of other complications within 90 days

	PO (n = 2360)	No PO (n = 5833)	p-value
Cerebrovascular complication	2 (0.1%)	4 (0.1%)	> 0.999
Pulmonary complication*	33 (1.4%)	52 (0.9%)	0.040
Pneumothorax	3 (0.1%)	7 (0.1%)	> 0.999
Pneumonia	22 (0.9%)	45 (0.8%)	0.464
Pulmonary embolism	2 (0.1%)	7 (0.1%)	> 0.999
Deep vein thrombosis	5 (0.2%)	14 (0.2%)	0.810
Myocardial infarction	2 (0.1%)	3 (0.1%)	0.630
Congestive heart failure	2 (0.1%)	1 (0.0%)	0.201
Dysrhythmia	21 (0.9%)	40 (0.7%)	0.331
Renal failure	1 (0.0%)	3 (0.1%)	> 0.999
Urinary tract infection	38 (1.6%)	77 (1.3%)	0.312
Infection	63 (2.7%)	120 (2.1%)	0.090
Hematoma	22 (0.9%)	39 (0.7%)	0.209
Wound dehiscence	34 (1.4%)	77 (1.3%)	0.669
Other wound complications	12 (0.5%)	22 (0.4%)	0.402
Delirium	4 (0.2%)	4 (0.2%)	0.239
Blood transfusion	2 (0.1%)	8 (0.1%)	0.734
Dural tears	10 (0.4%)	27 (0.5%)	0.811

* = p < 0.05

may be financial incentives to surgeons to perform POs to maximize reimbursement. It is not clear, however, that this

is a significant contributor to the observed trend as the coding for POs has remained constant during the study period.

Despite the increasing frequency of this procedure, there is a paucity of population-based studies evaluating postoperative outcomes in AIS patients undergoing spinal fusion with PO. The risks of POs are challenging to assess in clinical studies because of the rarity of complications after PSF for AIS. In this study, we used a large administrative claims database to evaluate the risks of POs in AIS patients undergoing PSF.

After risk adjustment for baseline differences in demographic and surgical factors, we found no association between AIS patients undergoing PSF with vs. without POs and 90-day complications (overall or neurological). These findings, using a substantially larger sample size than has previously been reported to examine complication risk with PO in AIS patients, confirm that of previous studies [11, 16]. In the largest study to date, which evaluated 2210 patients with 2-year follow-up using a multicenter prospective registry, the Harms study group found an increased but statistically insignificant rate of neurological complications among AIS patients with vs. without PO (0.37% vs 0.17%) (p = 0.45) [18]. They also demonstrated a statistically significant increase in the rate of neuromonitoring alerts in PSF cases with vs. without POs (9.3% vs 4.2%; p < 0.001) [18]. This finding raises the concern that the prior study was simply underpowered to detect a small difference in the risk of neurologic injury. The current study found no significant difference in the rate of neurologic injury with nearly twice as many patients with 2-year follow-up and nearly four times as many patients with 90-day follow up.

Despite the absence of any association between POs and 90-day complications, we did find higher odds for

Table 7 Reasons for reoperation

	PO n (90-day follow-up)=2360	No PO n (90-day follow-up)=5833	p value
Post-operative time period ≤ 90 days			
Instrumentation/device complications and deformity progression ^a	18 (0.76%)	22 (0.38%)	0.036
Infections and fluid accumulation ^b	4 (0.17%)	6 (0.10%)	0.487
Other	0 (0.00%)	2 (0.03%)	> 0.999
> 90 days to 2 years	n (2-year follow-up)=1231	n (2-year follow-up)=3049	p value
Instrumentation/device complications and deformity progression ^a	25 (2.03%)	85 (2.79%)	0.190
Infections and fluid accumulation ^b	6 (0.49%)	17 (0.56%)	0.958
Other	4 (0.32%)	11 (0.35%)	> 0.999

^aInstrumentation/device complications and deformity progression included the following ICD-9-CM codes: 996.49, 996.2, 996.40, 996.47, 996.78, V54.01, V52.8, 996.63, 996.75, 996.77, 737.30, 737.32, 737.39, 759.89, 754.2, 721.3, 722.52, 732.0, 756.19, M40.295, M41.114 and 343.9. (There was one patient whose reason for reoperation was coded for infantile cerebral palsy (343.9). Since we excluded all patients who had an infantile cerebral palsy diagnosis on or prior to the date of the PSF (see Supplemental Table 2 for a list of all exclusions), we suspect this was either a coding error or was only included at a time prior to the PSF for which data were not available on MarketScan.)

^bInfections and fluid accumulations included the following ICD-9-CM codes: 998.59, 996.67, 996.69, 998.13, 998.13, and 998.51

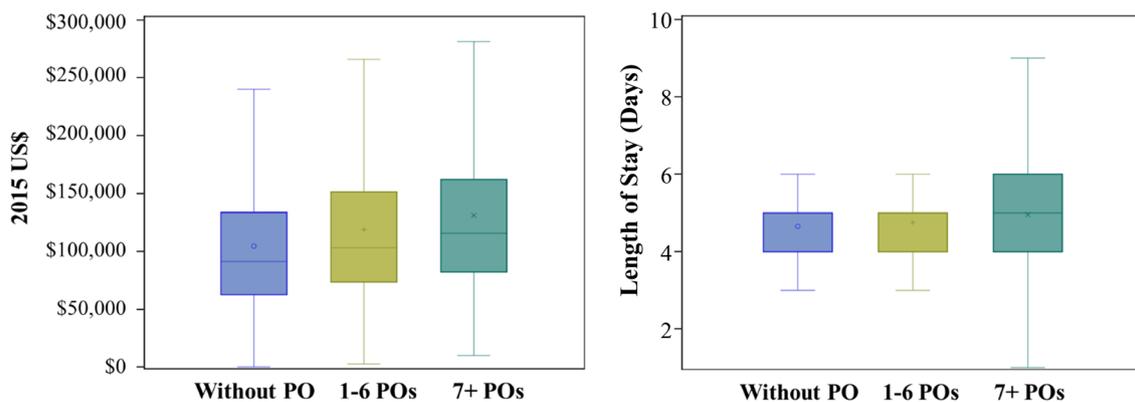


Fig. 3 Box and whisker plots showing hospital costs and length of stay (days) for AIS patients undergoing PSF without POs, with 1–6 POs and with > 7 POs. Central lines indicate median costs/length of stay. Box edges indicate interquartile ranges (IQRs) and whiskers indicate 1.5*IQR

readmissions and reoperations within 90 days for patients having POs. Bleeding or uncoded incidental durotomies are potential mechanisms through which POs could increase incidence of readmissions and/or reoperations within 90 days of surgery. While rates of early reoperations from infections and fluid accumulations were slightly higher in patients with vs. without POs, this did not reach statistical significance and warrants further study. Reoperations from instrumentation/device complications and deformity progression were significantly higher in patients with (vs. without) POs but a causal link between POs and these reasons for reoperation is not as obvious. It is possible that some of these reoperations may represent early presentations of pseudoarthrosis. POs could increase the risk of pseudoarthrosis by creating a gap in the posterior elements and destabilizing the spine. Increased incidence of reoperation from instrumentation/device complications and deformity progression may be more indicative of unmeasured patient or surgical characteristic than whether the patients had a PSF with PO. For example, patients with (vs. without) POs may have larger or more rigid curves, which are not detectable in administrative databases such as MarketScan[®]. The increased prevalence of longer fusion constructs among patients with POs seen in our baseline demographics may indicate larger or stiffer curves. Although we could control for this and other measured demographics, we acknowledge that unmeasured characteristics likely exist and may increase readmission/reoperation rates independent of POs. We found no prior studies evaluating reoperation and/or readmission risks as a function of POs. Further studies that help formulate clinical guidelines specifying when enhanced deformity correction provided by PO outweighs its short-term risks are warranted.

Interestingly, by 2 years, there was no longer a difference in the odds for reoperations in AIS patients with (vs. without) PO. The incidence of reoperations in patients with PO

grew from 0.9% within 90 days to 3.9% by 2 years, whereas the incidence of reoperations in patients without PO grew from 0.5% within 90 days to 4.1% by 2 years. In sub-analyses of ICD-9-CM codes, rates of reoperations within 2 years from both (1) instrumentation/device complications and deformity progression and (2) infections and fluid accumulations did not significantly differ in patients with vs. without PO. Overall, our findings suggest that by 2 years, whatever small difference in reoperation risk is conferred by PO is overshadowed by other causes of reoperation that seem to be unrelated to PO.

We additionally found POs to be associated with a 17.4% (\$15,854) increase in median hospital costs for patients with POs, with only a modest increase in LOS. After risk-adjustment, we found that patients with seven or more POs stayed in the hospital 0.31 (0.10–0.53; $p = 0.011$) days longer than those without POs and incurred \$21,767 (\$16,369–\$27,165; $p < 0.001$) more in costs. Multivariable modeling, which controlled for primary drivers of reimbursement, also demonstrated POs to be an independent predictor of increased costs ($p < 0.001$). Although the exact mechanism is unclear, this is likely at least partially related to direct increases in billing related to performing the osteotomies. Prior studies have also demonstrated that although decreasing LOS reduces costs, intraoperative variables in the direct control of the surgeons (such as use of POs and spine instrumentation) have a much greater impact on cost [19]. These findings indicate the substantial incremental financial burden associated with the use of POs. Prior work has demonstrated improved deformity correction associated with the usage of POs but no demonstrable difference in health-related quality of life [18]. Unfortunately, the administrative claims database approach that we used here does not allow us the ability to assess health-related quality of life. Coupled with our findings on cost, this suggests the need for further studies evaluating the cost effectiveness of the usage of POs in AIS patients.

This study has several strengths, including analysis of large-scale, nationally representative, all-payer databases over a period of 9 years with over 100 million records. Using these databases, we were able to analyze a sample size substantially larger than any prior study evaluating complication risks in AIS patients undergoing spinal fusion with and without POs. The databases also provided patient-level information across multiple years, which allowed us to analyze long-term follow-up data of individual patients. Despite these strengths, there were several limitations in the current study, many of which are inherent to research using administrative claims databases. While MarketScan® provides data for over 150 million unique individuals in the United States, the data are not necessarily nationally representative since it only includes data for individuals who possess some form of employer-based health insurance. Using ICD-9-CM/CPT codes for cohort and outcome identification is also dependent on the accuracy and completeness of administrative claims coding. Coding within an administrative claims database is optimized for billing and not prospectively designed to risk stratify or capture complications. Among other coding issues, surgical complications may be underreported due to a fear that they equate with substandard care and this may be reflected in administrative claim databases [20]. Some studies have even demonstrated that administrative claims databases accurately capture life-threatening complications but other complications may be underreported [20, 21]. Detecting neurological complications using administrative databases can be particularly challenging as minor neurological injury may not be captured. We therefore could not assess the severity of neurological complications beyond the granularity of the applicable ICD/CPT code. Despite this limitation, we suspect that clinically significant neurological complications that result in deviation in treatments, such as bracing for a foot drop, rehabilitation, or the use of other durable medical equipment should likely be captured because of the associated billing. This database approach therefore is likely to not be particularly sensitive for all neurologic injury, but it should be sensitive and specific for severe clinically significant neurologic injury. In addition, we did not have access to complete health records for individual patients and were therefore unable to analyze certain details, such as the extent of spinal deformity, operating time, blood loss and rate of neuromonitoring alerts. This is a significant limitation as some surgeons may selectively apply POs to patients with more severe deformity, thereby introducing a selection bias into our sample. This selection bias may result in more high-risk patients undergoing PO, which may weaken the conclusion that POs are the cause of increases in LOS, readmission and early reoperations but strengthens the finding of a lack of association with neurologic complications. Future research investigating aspects of this phenomenon that could not be analyzed in

this administrative claims study is warranted. Incorporating radiographic criteria, which would help control for differences in curvature or sagittal plane aberrations, may be of particular relevance in future research. Another limitation inherent to any study of POs (even those as large as the current study) is the low incidence of neurological complications. This MarketScan® cohort is the largest to date used to investigate rates of PO in AIS [11, 18]. In univariate tests, the sample size of 8193 for 90-day follow up provided over 80% power to detect a difference of 0.37% in the rate of neurological complications between the non-PO and PO groups via a chi-squared test with a two-sided level of significance of 0.05. Despite the use of variable reduction to maximize power, the confidence interval for PO from the multivariable model was somewhat wide due to the low incidence rate of neurological complications. Nonetheless, these results provide the strongest evidence to date and do not provide evidence of increased rates of neurological complications with PO in AIS.

In conclusion, we present the first population-based assessment of the risks and costs associated with PO in PSF for AIS patients. We demonstrate that, in this AIS population, PO usage has become increasingly common from 2000 to 2015 and is associated with an increasing financial impact. We found a transiently increased risk of re-admission and reoperation within 90 days that was associated with PO usage but at 2 years this relationship was no longer significant. At no time point did we find a significant association with PO usage and neurologic injury. These conclusions must be considered in the context of limitations in power and limitations inherent to using a database approach. Further research using prospective registries may be able to more clearly define the risks and benefits of POs in the future.

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Availability of data and material The data that support the findings of this study are available from IBM® MarketScan® Commercial Databases but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the corresponding author upon reasonable request and with permission of IBM® Watson Health™.

Code availability The code used for analysis will be shared upon reasonable request from the corresponding author.

Declarations

Conflict of interest The authors declare no conflicts of interest or competing interests.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent For this type of study, informed consent is not required.

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