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Prevalence and Indications for Unplanned Reoperations following Index Surgery in the Adult Symptomatic Lumbar Scoliosis NIH-Sponsored Clinical Trial

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Abstract

Study Design—Longitudinal cohort

Objective—To report on the prevalence and indications for unplanned reoperations following index surgery in the Adult Symptomatic Lumbar Scoliosis NIH-sponsored Clinical Trial

Summary of Background Data—Reoperation following adult spinal deformity surgery exposes the patient to additional surgical risk, increases the cost of care, and decreases the potential cost-effectiveness of the intervention. Accurate data regarding the prevalence and indication for reoperation will facilitate future efforts to minimize risk.

Methods—153 patients underwent adult spinal deformity surgery as part of the observational, randomized, or cross-over groups and were eligible for 2 year follow-up. Reoperations were meticulously tracked as part of the NIH-mandated Serious Adverse Event (SAE) reporting. The primary indication for reoperation was obtained from the treating surgeon's operative report.

Results—Thirty-two patients had one re-operation, two patients underwent 2 reoperations and three patients underwent 3 reoperations. A total of 45 reoperations in 37 patients. Eleven patients

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(7%) underwent reoperation within 90 days of the index surgery: 2 for superficial wound dehiscence, 3 for radiculopathy with screw removal, and 6 for acute proximal junctional failure (PJF). Four patients underwent reoperation for PJF more than 90 days from index surgery. Twenty-six patients underwent 28 reoperations for rod fracture/pseudoarthrosis.

Conclusion—In a consecutive series of adult spinal deformity surgery patients with meticulous follow-up, 24% of patients required an unplanned reoperation. The most common indication for reoperation was rod fracture/pseudoarthrosis which occurred from 9 months to 3.7 years following the index surgery and accounted for 62% (28/45) of the reoperations. The second most common indication for reoperation was PJF which occurred from 1 month to 1.6 years following index surgery and accounted for 22% (10/45) of the reoperations. As these complications will likely increase with longer follow-up, efforts to lower the rates of these complications are warranted.

Level of Evidence—II

Keywords

adult lumbar scoliosis; degenerative scoliosis; complications; revisions; proximal junctional kyphosis; pseudoarthrosis

Introduction

Although adult spinal deformity surgery has been shown to dramatically improve quality of life in well-selected patients [1–4], complication rates and unplanned reoperations continue to be a clinically significant problem [5–16]. Unplanned re-operations following adult spinal deformity surgery expose the patient to additional surgical risk, increase the cost of care, and decrease the potential cost-effectiveness of the intervention [8,9]. Efforts to avoid unplanned re-operations are warranted.

Previous large, multi-institution database studies that have examined unplanned re-operations following adult spinal deformity surgery are limited by incomplete follow-up rates, which may misrepresent the true incidence of re-operation [11–16]. Smaller, single-institution studies may be biased by local risk factors that are not generalizable [7–9].

Accurate estimates of the incidence of re-operation and the identification of risk factors will facilitate future efforts to minimize the risk of re-operation in this patient population. The purpose of the current study was to determine an accurate prevalence and timeframe for the various etiologies for unplanned re-operation following surgery in patients with adult symptomatic lumbar scoliosis. We hypothesized that prospectively-collected, NIH-trial data with meticulous follow-up will provide the best available evidence regarding unplanned reoperations.

Methods

After receiving Institutional Review Board Approval for this secondary analysis, 153 patients who underwent primary adult spinal deformity surgery as part of the observational, randomized, or cross-over groups enrolled in the National Institutes of Health-sponsored Multi-Centered Prospective Study of Quality of Life in Adult Scoliosis (R01-AR-055176;

NCT NCT00854828), and reached a minimum of two-year follow-up or had a revision surgery prior to two years after the index surgery were included in the analysis. All one hundred and fifty-three of the patients included in the current study underwent surgery while enrolled in the NIH-monitored study. The included patients from the observational group were patients that had declined to participate in randomization, but agreed to enroll in the observational arm of the NIH study in which they were allowed to choose surgery. The included randomized patients were randomized to surgery or eventually crossed-over to surgery from the non-surgical group.

Following the NIH-approved protocol, patients were enrolled by nine centers from 2010–2014. Inclusion criteria were: 40–80 years old, lumbar Cobb ≥ 30 degrees and Scoliosis Research Society-22R (SRS-22R) score ≤ 4.0 in Pain, Function or Self-Image domains or Oswestry Disability Index (ODI) ≥ 20 . Patients were excluded from the trial if they had undergone prior spinal deformity surgery or prior instrumented fusion. Reoperations were meticulously tracked as part of the NIH-mandated Serious Adverse Event reporting. The primary indication for reoperation was obtained from review of the treating surgeon's operative report.

Results

One hundred fifty-three patients met inclusion criteria. Mean age at index surgery was 59.91 ± 8.81 years with 136 females and 17 males. The majority of patients (141, 92%) had a posterior-only surgery. The mean number of surgical levels fused posteriorly was 10.64 ± 3.93 levels with transforaminal interbody fusions in 1.05 ± 1.0 levels. There were 85 (56%) Smith-Petersen osteotomies, 3 pedicle subtraction osteotomies and 2 vertebral column resections. In the 12 patients who had a combined antero-posterior approach, the mean number of surgical levels fused anteriorly was 2.20 ± 1.81 . Thirty-two patients had one re-operation, two patients had 2 reoperations and three patients had 3 reoperations. Therefore, a total of 45 unplanned reoperations in 37 (24%) of the 153 (Table 1). The multiple reoperation patients had early reoperation for malpositioned screws or early PJF followed by later reoperations for pseudoarthrosis.

Eleven patients (7%) had reoperations within 90 days of the index surgery: 2 (1.3%) for superficial wound dehiscence, 3 (1.9%) for radiculopathy with screw removal, and 6 (3.9%) for acute proximal junctional failure (PJF). Four (2.6%) patients underwent reoperation for PJF more than 90 days from index surgery. A total of 10 patients (7%) underwent reoperation for PJF. A total of 26 patients (17%) underwent 28 reoperations for rod fracture/pseudoarthrosis. As five patients had multiple surgeries, 45 unplanned surgeries occurred 37 out of the 153 patients in the study.

The most common indication for reoperation was rod fracture/pseudoarthrosis which occurred from 9 to 44 months following the index surgery and accounted for 62% (28/45) of the reoperations. By the two-year follow-up visit, 85% (22/26) of the rod fractures were identified, while 15% (4/26) were identified after the two-year follow-up visit. The second most common indication for reoperation was proximal junctional failure which occurred

from 1 to 19 months following index surgery and accounted for 22% (10/45) of the reoperations.

Discussion

In this consecutive series of 153 adult scoliosis surgery patients from the NIH-sponsored trial, the most common indication for reoperation was rod fracture/pseudoarthrosis in 26 (17%) patients from 9 to 44 months following index surgery. The second most common indication for reoperation was proximal junctional failure in 10 (7%) patients from 1 to 19 months following index surgery. As the prevalence of these complications will likely increase with longer follow-up, efforts to follow these patients over a longer time frame are warranted.

Comparison of the current study results to previous literature is somewhat limited by the heterogeneity of “adult spinal deformity” surgery. In 2009, Mok et al reported a single institution series of 89 patients that underwent at minimum of 4-level fusion for adult spinal deformity. With 91% follow-up, the cumulative re-operation rate was 26%. Infection was the most common indication for re-operation, followed by adjacent segment problems, then implant failure and pseudoarthrosis. On multivariate analysis, smoking was more common in the reoperation group [7].

Interestingly, surgical site infection requiring a return to the operating room was not reported in the current study population. Two patients (1.3%) did have early reoperation for superficial wound dehiscence. It is unclear if these two patients would have been later classified as a surgical site infection without the early reoperation. Future studies are needed to determine which factors may have contributed to the very low wound complication rate. Infection prevention protocols were not standardized among centers, nor was data collected for the current study. Possible strategies in current use may include: avoiding high-risk patients (e.g. poorly controlled diabetics or smokers), perioperative glycemic control, perioperative antibiotics, intra-operative irrigation with or without betadine, and intrawound vancomycin powder.

In 2010, Pichelmann et al reported a large, single institution series of 643 patients who underwent a minimum of 5-level fusion for adult spinal deformity. The reoperation rate was relatively low at 9%, with pseudoarthrosis reported as the most common cause. Of note, the mean age of the group was significantly lower than the current study (38 years versus 60 years) and the group was more heterogeneous by diagnosis [6]. In 2014, Sánchez-Mariscal et al reported 59 patients who underwent a minimum 4-level fusion for adult scoliosis. The reoperation rate was relatively high at 36%, with painful/prominent implants reported as the most common cause. Of note, length of follow-up was 8.5 years with 41% of the patients having greater than 10-year follow-up [7]. In 2015, Barton et al reported risk for rod fracture following posterior correction of adult spinal deformity in 75 consecutive patients. The overall incidence was 9.3%. Risk factors for rod fracture included crossing both the thoracolumbar and lumbosacral junction, sagittal rod contour > 60 degrees, rod connectors at the site of failure, and pseudoarthrosis at > 1 year follow-up [10].

Several previous reports have used patient samples from the International Spine Study Group (ISSG), which is a multi-center, prospective database of adult spinal deformity patients with a more heterogeneous inclusion criteria when compared the inclusion criteria of the current study. Additionally, variations in study design and follow-up rates have provided a range of reoperation rates from 17% to 28%. In 2013, Scheer et al reported reoperation rates from the ISSG database. The reoperation rate was 17% and the most common indications for reoperation included instrumentation complications and radiographic failure not otherwise specified [14]. In 2015, Soroceanu et al reported “radiographic and implant-related complications” (RIC) in a sample of adult spinal deformity surgery patients from the ISSG. All patients with complete 2-year follow-up were included. The incidence of RIC was 32% with 53% requiring reoperation. Rod breakage and proximal junctional kyphosis were also common indications for reoperation [15]. In 2016, Smith et al reported complication rates associated with adult spinal deformity surgery in a sample of patients from ISSG. At least one revision was required in 28% of the patients who reached the 2-year minimum follow-up [16]. Also in 2016, Passias et al reported on revision surgical procedures in a sample of adult spinal deformity patients from ISSG. The authors intentionally excluded wound complications. With two-years of follow-up, they reported a 16.5% incidence with nearly half of the revision occurring between one and two year follow-up. Implant complications including rod failure and proximal junctional kyphosis were the most common indications for revision.

Recently, a non-ISSG study was published in 2016. Puvanesarajah et al used the PearlDiver database (2005–2012) to estimate revision surgery following primary adult spinal deformity surgery (posterolateral fusion of 8 or more levels) in patients 65 years and older. The authors reported a 10.5% revision rate at one-year and 18.5% revision rate at five-year follow-up [16].

The results of the current study support the previous literature showing clinically significant reoperation rates in adult spinal deformity patients. The precise prevalence varies in the literature due to the heterogeneity of “adult spinal deformity surgery,” as well as, the heterogeneity of study design and follow-up rates. Although a multi-variate analysis to identify risk factors associated with unplanned surgery would have been ideal, the sample size in the current study is too small and the number of variables to consider too many to produce valid results. The current study suggests that efforts to decrease the incidence of proximal junctional failure and rod fracture/pseudoarthrosis appear to be the most promising areas for improvement. Future studies are needed to more clearly understand the various risk factors and prevention strategies for rod fracture/pseudoarthrosis and proximal junctional failure in the adult spinal deformity population.

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Table 1

Indications for revision and prevalence

Indication for reoperation	Time Post-op	Prevalence (n =153)
Rod Fracture/Pseudoarthrosis	9–44 months	26 (17%)
Proximal Junctional Failure	1–19 months	10 (7%)
Radiculopathy/screw removal	< 90 days	3 (2%)
Wound dehiscence/drainage	< 90 days	2 (1%)
Total	0–44 months	37 (24%)