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DEFORMITY

Defining a Surgical Invasiveness Threshold for Increased Risk of a Major Complication Following Adult Spinal Deformity Surgery

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Study Design. Retrospective review.

Objectives. The aim of this study was to define a surgical invasiveness threshold that predicts major complications after adult spinal deformity (ASD) surgery; use this threshold to categorize patients into quartiles by invasiveness; and determine the odds of major complications by quartile.

Summary of Background Data. Understanding the relationship between surgical invasiveness and major complications is important for estimating the likelihood of major complications after ASD surgery.

Methods. Using a multicenter database, we identified 574 ASD patients (more than 5 levels fused; mean age, 60 ± 15 years) with minimum 2-year follow-up. Invasiveness was calculated as the ASD Surgical and Radiographic (ASD-SR) score. Youden index was used to identify the invasiveness score cut-off associated with optimal sensitivity and specificity for predicting major complications. Resulting high- and low-invasiveness groups were divided in half to create quartiles. Odds of developing a major complication were analyzed for each quartile using logistic regression (alpha = 0.05).

Results. The ASD-SR cutoff score that maximally predicted major complications was 90 points. ASD-SR quartiles were 0 to 65 (Q1), 66 to 89 (Q2), 90 to 119 (Q3), and ≥120 (Q4). Risk of a major complication was 17% in Q1, 21% in Q2, 35% in Q3, and 33% in Q4 ($P < 0.001$). Comparisons of adjacent quartiles showed an increase in the odds of a major complication from Q2 to Q3 (odds ratio [OR] 1.8; 95% confidence interval [CI]: 1.0–3.0), but not from Q1 to Q2 or from Q3 to Q4. Patients with ASD-SR scores ≥90 were 1.9 times as likely to have a major complication than patients with scores <90 (OR 1.9, 95% CI 1.3–2.9). Mean ASD-SR scores above and below 90 points were 121 ± 25 and 63 ± 17, respectively.

Conclusion. The odds of major complications after ASD surgery are significantly greater when the procedure has an ASD-SR score ≥90. ASD-SR score can be used to counsel patients regarding these increased odds.

Key words: adult spinal deformity, ASD-SR, complication, invasiveness, major complication, outcome, threshold.

Level of Evidence: 3

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Surgical correction of adult spinal deformity (ASD) can greatly improve a patient's quality of life.[1–5] Although major advances have been made recently in surgical techniques for ASD surgery, complications remain a concern. Methods of classifying postoperative complications in ASD patients vary among studies, resulting in reported rates of major complications ranging from 11% to 51%.[6–10] Studies have described risk factors for complications after ASD surgery, including major blood loss, neurological complications,[11] junctional kyphosis,[12–14] and the need for revision surgery.[15,16]

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Although it is important to understand how certain factors may modify a patient's risk of complications, ASD is a heterogeneous condition with similarly heterogeneous options for surgical treatment. Thus, many surgical and radiographic factors vary among patients. Some patients may require short thoracolumbar fusions for correction of mild deformity, whereas others may need arthrodesis of many vertebrae and a three-column osteotomy to achieve adequate deformity correction. The ASD Surgical and Radiographic (ASD-SR) score was developed and validated to quantify the degree of invasiveness of ASD surgical procedures, allowing better prediction of estimated blood loss and operative time.[11] Certain variables used to calculate the ASD-SR score, such as three-column osteotomy and the number of levels fused, are associated with increased risk of complications,[17] but the ASD-SR score has not been used to assess overall risk of major complications.

The objectives of this study were to define a surgical invasiveness threshold that predicts increased odds of major complications after surgical treatment of ASD; use this threshold to categorize patients into quartiles defined by invasiveness cutoff score; and determine the odds of major complications in each invasiveness quartile. Secondarily, we sought to identify the association between this invasiveness threshold and the odds of minor complications. The ASD-SR score can be calculated easily by surgeons and accounts for many of the surgical and radiographic risk factors known to modulate complication risk in ASD patients. Thus, defining a surgical invasiveness threshold for major complications will allow for more personalized patient counseling during the perioperative period and will elucidate the ability of the ASD-SR score to accurately predict the risks associated with ASD procedures according to their invasiveness.

METHODS

This study was approved by the institutional review board at each participating institution.

Patient Selection

We retrospectively reviewed a longitudinally collected, multicenter database of patients enrolled in a study evaluating operative versus nonoperative treatment of ASD. Patients were enrolled at 11 sites and treated by 15 surgeons across the United States. The following inclusion criteria were used for patients who underwent operative treatment: age >18 years; more than 5 spinal levels fused; and diagnosis of degenerative or idiopathic scoliosis. In addition, patients had to meet at least one of the following radiographic parameters for inclusion: sagittal vertical axis (SVA) >5 cm, Cobb angle $\geq 20^{\circ}$, pelvic tilt (PT) >25°, or thoracic kyphosis >60°. Patients were excluded if they had spinal deformity secondary to malignancy, neuromuscular causes, or deformity due to infectious causes.

At the time of writing, 1281 patients had been enrolled in the study; however, some of these patients underwent surgery more recently than 2 years ago and were not yet eligible for 2-year clinical follow-up. Of the 760 patients who were eligible for 2-year follow-up based on their date of surgery, 574 (76%) had complete preoperative and 2-year clinical data and were included in our analysis.

Radiographic Evaluation

Radiographic measurements were taken using full-length standing scoliosis lateral radiographs preoperatively and at 6-week follow-up. Measurements were performed using a validated software system (Spine-View, ENSAM Paritech, Paris, France)[18,19] at a central location with a dedicated study team that was not involved in the care of enrolled patients.

HRQoL Measures

Two standardized HRQoL questionnaires, the Oswestry Disability Index (ODI) and the Scoliosis Research Society version 22-revised (SRS-22r), were used to evaluate patients preoperatively and at 2-year follow-up. Both are validated questionnaires that are widely used when studying outcomes in patients with ASD.[20,21]

ASD-SR Index

The ASD-SR index assigns point values to 13 operative and radiographic factors to quantify the degree of invasiveness of surgical ASD procedures. Point values for surgical and radiographic components of the ASD-SR index were determined by using beta coefficients from multivariate regression models to predict estimated blood loss (EBL) and operative time.[11] The surgical components of the ASD-SR index are decompression, fusion, osteotomies performed, the use of interbody spacers, iliac fixation, and revision surgery. The radiographic components of the ASD-SR index are the preoperative to postoperative changes in pelvic incidence minus lumbar lordosis (PI-LL), pelvic tilt (PT), sagittal vertical axis (SVA), and thoracic kyphosis (TK) (Table 1).

Complications

Data on complications were collected prospectively, and complications were classified as major or minor. Major complications were defined as those requiring return to the operating room, those necessitating a prolonged hospital stay, or those that were unresolved at the time of data analysis. Minor complications were defined as those requiring only minor changes to routine clinical care.

Statistical Analysis

Descriptive statistics are reported as mean ± standard deviation or number (%) unless stated otherwise. A cutoff point that optimized sensitivity and specificity of predicting major complications was determined using a receiver operating characteristic curve (Youden index).[22,23] Patients with scores above this cutoff comprised the "high invasiveness" group, and those with scores below this cutoff comprised the "low invasiveness" group. These 2 groups were divided in half to create four quartiles. Patient-reported outcomes were compared among quartiles using one-way analysis of variance. χ^2 tests were used to compare the prevalence of major, minor, and individual complications above and below the

TABLE 1. Scoring of the ASD-SR Invasiveness Index

Variable	Points
Surgical variables	
Posterior	
Decompression	1 Per vertebra
Fusion	2 Per vertebra
Instrumentation	1 Per vertebra
Osteotomies	1 Per vertebra
Three-column	14 Per osteotomy
Smith-Petersen	1 Per osteotomy
Interbody fusion	
Anterior lumbar	8 Per interbody fusion
Transforaminal/posterior lumbar	2 Per interbody fusion
Iliac fixation	2
Revision surgery	3
Radiographic variables	
PI-LL	0.5 Per 1° change
Pelvic tilt	2 Per 1° change
Sagittal vertical axis	0.2 Per 1-cm change
Thoracic kyphosis	0.5 Per 1° change

ASD-SR indicates Adult Spinal Deformity-Surgical and Radiographic; PI-LL, pelvic incidence minus lumbar lordosis.

ASD-SR cutoff score. Student *t* tests were used to compare patient-reported outcome scores between the high- and low-invasiveness groups. Odds of developing a major complication in each invasiveness quartile were analyzed using binary logistic regression, controlling for baseline ASD frailty index values[24] and radiographic deformity measures. Statistical analysis was performed using Stata software, version 15 (StataCorp, LLC, College Station, TX). Significance was considered at $P < 0.05$.

RESULTS

Patient and Treatment Characteristics

Mean (± standard deviation) patient age was 60 ± 15 years, and 78% of patients were women. Half of patients (n = 287) had undergone previous spine surgery. Patients had the following mean preoperative radiographic parameters: SVA, 6.4 ± 7.3 cm; PI-LL, 16° ± 21°; PT, 24° ± 11°; SS, 31° ± 12°; TK, 15° ± 0.88°; and LL, 23° ± 0.61° (Table 2).

Mean preoperative ODI value was 44 ± 18, and SRS-22r score was 2.8 ± 0.7. By the 2-year postoperative timepoint, the mean ODI value improved to 28 ± 20 ($P < 0.001$), and the mean SRS-22r score improved to 3.7 ± 0.8 ($P = 0.034$).

The mean number of spinal levels fused was 11 ± 4.3, and 22% of patients (n = 127) underwent three-column osteotomy (Table 2). Mean estimated blood loss (EBL) was 1651 ± 1492 mL, and mean ASD-SR score was 91 ± 36 points. A total of 422 patients (74%) were admitted to the intensive care unit postoperatively.

Nonresponder Analysis

We performed a nonresponder analysis, comparing the final analytic cohort with patients who were eligible for 2-year follow-up but did not have complete follow-up data. Compared with included patients, those lost to follow-up were slightly older (61 vs 59 years, $P < 0.010$), had greater SVA (7.5 ± 2.9 cm *vs.* 6.4 ± 7.3 cm, $P = 0.006$), and were less likely to be female (69% *vs.* 79%, $P < 0.001$). We found no significant differences between patients who were

TABLE 2. Patient, Radiographic, HRQoL, and Treatment Characteristics of 574 Adult Spinal Deformity Patients

Characteristic	Mean ± SD	N (%)
Patient factors		
Age, y	60 ± 15	
Female sex		448 (78)
Previous spine surgery		287 (50)
Preoperative radiographic measures		
Lumbar lordosis (°)	23 ± 0.61	
PI-LL (°)	16 ± 21	
Pelvic tilt (°)	24 ± 11	
Sacral slope (°)	31 ± 12	
Sagittal vertical axis, cm	6.4 ± 7.3	
Thoracic kyphosis (°)	15 ± 0.88	
Treatment factors		
Number of spinal levels fused	11 ± 4.3	
3-column osteotomy		127 (22)
Estimated blood loss, mL	1651 ± 1492	
ASD-SR invasiveness index	91 ± 36	
Intensive care unit admission		422 (74)

ASD-SR indicates Adult Spinal Deformity-Surgical and Radiographic; HRQoL, health-related quality of life; PI-LL, pelvic incidence minus lumbar lordosis; SD, standard deviation.

included versus those lost to follow-up in terms of preoperative ODI value ($P = 0.230$) or SRS-22r Total score ($P = 0.104$).

ASD-SR Cutoff Score

An overall ASD-SR cutoff score of 90 was determined (Figure 1), with 278 patients (48%) above or equal to the cutoff, and 296 patients (52%) below the cutoff. Example radiographs are shown for patients above and below the ASD-SR cutoff score (Figure 2A–H).

Patients above the cutoff had a higher rate of any complication (68%) than did patients below the cutoff (62%) ($P < 0.001$). Patients above the cutoff also had a higher rate of radiographic proximal junctional kyphosis at any point (48%) *versus* those below the cutoff (33%) ($P < 0.001$). Finally, patients above the cutoff had a higher rate of having any complication requiring reoperation (28%) than did patients below the cutoff (22%) ($P = 0.008$; Table 3).

Mean improvements in ODI value and SRS-22r Total score were not significantly different between the high- and low-invasiveness groups ($P = 0.943$, $P = 0.110$, respectively; Table 3).

Major Complications

Patients above this cutoff score had a significantly higher prevalence of having any major complication (36%) *versus* patients below the cutoff (19%) ($P < 0.001$). Patients above the cutoff also had a higher prevalence of the following specific major complications: neurologic deficit (19% *vs.* 11%, $P = 0.008$), pseudarthrosis with instrumentation failure (9.4% *vs.* 4.4%, $P = 0.018$), and excessive blood loss (8.1% *vs.* 4.0%, $P = 0.014$). We found no significant differences in the prevalence of deep vein thrombosis, pulmonary embolism, infection requiring irrigation and debridement, or pneumonia above *versus* below the cutoff (all, $P > 0.05$).

Minor Complications

Patients above the ASD-SR cutoff score did not have a significantly higher prevalence of any minor complication ($P = 0.266$). Patients above the cutoff did, however, have a higher prevalence of incidental durotomy (12%) compared with those below the cutoff (6.1%) ($P = 0.005$). We found no significant differences in the prevalence of neurological deficit, infection, pleural effusion, ileus, implant loosening, or urinary tract infection (all, $P > 0.05$).

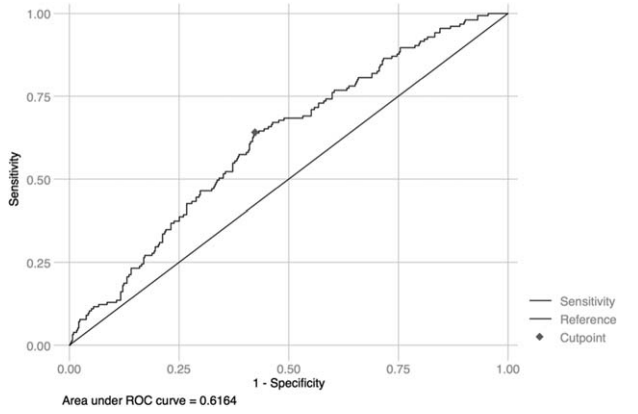

Figure 1. Receiver operating characteristic (ROC) curve showing the cutoff point that optimizes sensitivity and specificity for predicting major complications after adult spinal deformity surgery.

Comparison of Quartile Cutoffs

Patients were divided into quartiles by ASD-SR scores as follows: 0 to 65 points (Q1); 66 to 89 points (Q2); 90 to 119 points (Q3); and ≥120 points (Q4). Q1 consisted of 145 patients (24%); Q2 of 149 patients (24%); Q3 of 162 patients (26%); and Q4 of 154 patients (24%). When comparing the odds of experiencing a major complication by adjacent quartiles, we found a significant increase between Q2 and Q3 (odds ratio, 1.8; 95% confidence interval: 1.0–3.0), but no such increases from Q1 to Q2 or from Q3 to Q4 ($P < 0.05$). Similarly, patients above the ASD-SR cutoff score of 90 (Q3 or Q4) were 1.9 times as likely to have a major complication than were patients below this threshold (Q1 or Q2) (odds ratio [OR], 1.9; 95% confidence interval [CI]: 1.3–2.9) (Figure 3). We found no significant differences in the odds of having any minor complication between invasiveness groups (all $P > 0.05$).

We also analyzed the preoperative to 2-year postoperative changes in ODI value and SRS-22r Total score in relation to these quartiles. We found no significant differences in ODI values ($P = 0.683$) or SRS-22r Total scores ($P = 0.906$) between quartiles.

DISCUSSION

Patients with ASD who undergo surgical procedures with an ASD-SR score ≥90 are almost twice as likely to experience a major complication as are patients below this threshold. Patients with scores substantially higher than 90 do not have significantly greater odds of developing a major complication. Our study is the first to use the ASD-SR score as a risk-stratification tool for major complications.

The ASD-SR invasiveness index affords a simple method to assess surgical invasiveness and can be calculated early in the postoperative period (by using the degree of radiographic correction) or in the preoperative period (by using the planned radiographic correction). Although we recognize that the invasiveness of a surgical procedure is not typically a modifiable factor, in some cases, a less invasive procedure may be considered in a high-risk patient. Our results show that the greatest increase in major complication risk is at an ASD-SR score of approximately 90. When this cutoff was used to divide the patient population in half, those in the highest invasiveness quartile did not have significantly more major complications than those in the second highest quartile. We believe this indicates a "plateau" in the prevalence of major complications above an ASD-SR invasiveness score of 90; after this point, increasing surgical invasiveness is not associated with substantially increased risk of major complications. This finding suggests that, for patients at high risk of complications and for whom the planned surgical procedure has an ASD-SR score of approximately 90, it may be

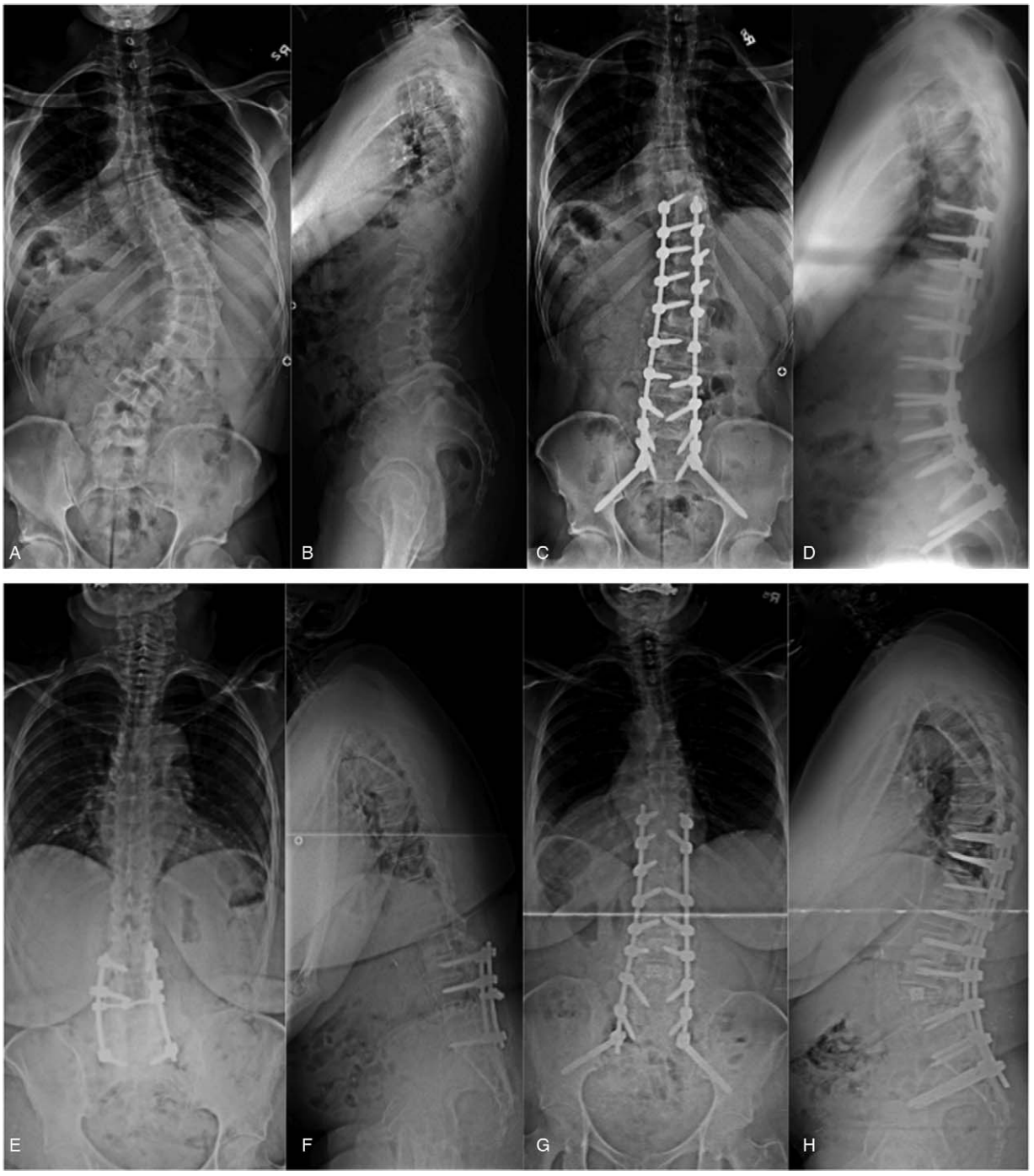

Figure 2. Radiographs of two patients who underwent adult spinal deformity procedures that were below and above the Adult Spinal Deformity Surgical and Radiographic (ASD-SR) cutoff score of 90 points, respectively. Preoperative anteroposterior (**A**) and lateral (**B**) and postoperative anteroposterior (**C**) and lateral (**D**) radiographs of a patient whose procedure had an ASD-SR score of 63. This patient underwent primary arthrodesis from T9 to the pelvis (30 points) with 6 Smith-Petersen osteotomies (6 points) and two levels of decompression (2 points), iliac fixation (2 points), and anterior lumbar interbody fusion (ALIF) (8 points). Treatment resulted in a 1.1-cm increase in sagittal vertical axis (0.2 points), a 9° decrease in thoracic kyphosis (4.5 points), a 2° decrease in pelvic incidence minus lumbar lordosis, and a 4.7° increase in pelvic tilt (9.14 points). The patient had no major postoperative complications. Preoperative anteroposterior (**E**) and lateral (**F**) and postoperative anteroposterior (**G**) and lateral (**H**) radiographs of a patient whose procedure had an ASD-SR score of 103. This patient underwent revision arthrodesis (3 points) from T10 to the pelvis (27 points), involving a 3-column osteotomy (14 points), iliac fixation (2 points), and ALIF (8 points). Treatment resulted in a 13-cm decrease in sagittal vertical axis (2.6 points), a 35° increase in thoracic kyphosis (17.5 points), a 31° decrease in pelvic incidence minus lumbar lordosis (15.5 points), and a 6.6° decrease in pelvic tilt (13.2 points). The patient had a major complication (pulmonary embolism) on postoperative day 4, which was treated appropriately and eventually resolved.

TABLE 3. Complication Rates and Patient-reported Outcomes According to Surgical Invasiveness Above or Below the ASD-SR Cutoff Score of 90 Points

Complication	N (%)			*P*
	All Patients (n = 574)	Patients Above ASD-SR Cut-off (n = 296)	Patients Below ASD-SR Cut-off (n = 278)	
Any complication	372 (65)	201 (68)	171 (62)	<0.001
Radiographic PJK at any point	234 (41)	141 (48)	93 (33)	<0.001
Complication requiring reoperation	143 (25)	83 (28)	60 (22)	0.008
Major complications				
Any major complication	155 (27)	56 (19)	99 (36)	<0.001
Neurologic deficit	27 (4.7)	33 (11)	53 (19)	0.008
Deep vein thrombosis	8 (1.3)	3 (1.0)	5 (1.8)	0.735
Pulmonary embolism	16 (2.8)	5 (1.7)	11 (4.0)	0.099
Pseudarthrosis with IF	35 (6.1)	13 (4.4)	26 (9.4)	0.018
Infection treated with I&D	14 (3.0)	10 (3.4)	4 (1.4)	0.081
Pneumonia	7 (1.2)	5 (1.7)	2 (0.72)	0.221
Excessive blood loss*	35 (6.1)	24 (8.1)	11 (4.0)	0.014
Minor complications				
Any minor complication	222 (39)	108 (36)	114 (41)	0.266
Incidental durotomy	54 (9.4)	36 (12)	18 (6.5)	0.005
Infection (deep or superficial)	17 (3.0)	8 (2.7)	9 (3.2)	0.908
Pleural effusion	28 (4.9)	16 (5.4)	12 (4.3)	0.344
Ileus	37 (6.4)	16 (5.4)	21 (7.6)	0.514
Implant loosening	11 (1.9)	5 (1.7)	6 (2.2)	0.842
Urinary tract infection	13 (2.3)	6 (2.0)	7 (2.5)	0.868
Patient-reported outcomes				
Change in ODI value†	−16 ± 18‡	−16 ± 18‡	−16 ± 18‡	0.943
Change in SRS-22r total score†	0.89 ± 0.73‡	0.85 ± 0.73‡	0.95 ± 0.75‡	0.110

ASD-SR indicates Adult Spinal Deformity Surgical and Radiographic; I&D, irrigation and debridement; IF, instrumentation failure; ODI, Oswestry Disability Index; PJK, proximal junctional kyphosis; SRS-22r, Scoliosis Research Society version 22-revised.

**Greater than 1 4standard deviation above the mean blood loss of all ASD patients.*

†Change calculated as 2-year postoperative score minus preoperative score.

‡Expressed as mean ± standard deviation.

beneficial to avoid aggressive deformity correction or additional factors that add to surgical invasiveness. However, patients for whom highly invasive surgical procedures are planned (ASD-SR score much higher than 90), may benefit less in terms of complication risk from slight reductions in surgical invasiveness.

Various strategies have been used to predict the risk of postoperative complications in ASD patients. Recently, Scheer *et al*[8] developed a model that predicted major postoperative complications in ASD patients with 87% accuracy. Similar predictive models for surgical complications in ASD patients have been developed with up to 92% accuracy.[25,26] In the model developed by Scheer *et al*,[8] the five variables most predictive of major complications were patient age, presence of leg pain, ODI value, number of decompression levels, and number of interbody fusion levels; two of these variables are accounted for in the ASD-SR invasiveness index. Given that the area under the receiver operating characteristic curve in our study showed 62% accuracy, the ASD-SR score should not serve as the sole metric for attempting to predict major postoperative complications. However, this study helps clarify the relationship between invasiveness and complications and suggests that there is an invasiveness threshold above which risk factors that have been identified in predictive models (eg, three-column osteotomy) may not contribute as much to complication risk in patients who are not already undergoing a highly invasive surgery.

The ASD-SR invasiveness score has not been well studied beyond its initial validation; however, studies of the Spine Surgical Invasiveness Index (SSII) developed by Mirza *et al*[27] serve as a useful comparison for our results. The SSII is not specific to deformity patients and thus does not account for radiographic changes. Cizik *et al*[28] showed that patients with higher SSII values are at higher risk of developing surgical site infection, and other studies reported that patients with higher SSII values are at higher risk of pulmonary complications,[29] cardiac complications,[30] and unintended durotomy.[31] The SSII has also been factored into predictive models and shown to be independently associated with a higher risk of major postoperative complications.[32] In the future, similar investigations should evaluate the

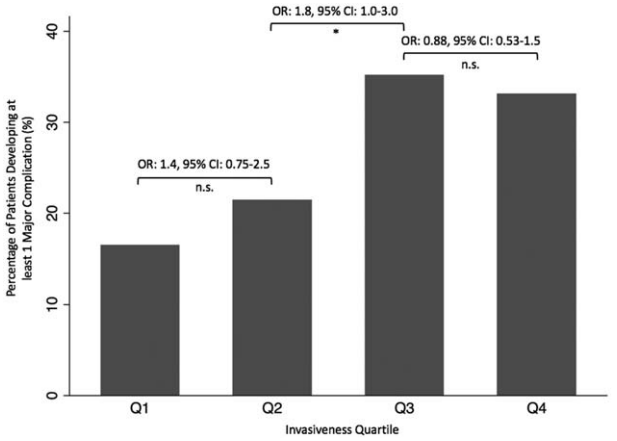

Figure 3. Odds of developing a major complication across invasiveness quartiles. Patients were divided into quartiles according to the Adult Spinal Deformity Surgical and Radiographic (ASD-SR) invasiveness score as follows: 0 to 65 points (Q1); 66 to 89 points (Q2); 90 to 119 points (Q3); and ≥120 points (Q4). When comparing the odds of experiencing a major complication across adjacent quartiles, we found a significant increase between Q2 and Q3 (odds ratio, 1.8; 95% confidence interval: 1.0–3.0), and nonsignificant changes from Q1 to Q2 and from Q3 to Q4 ($P < 0.05$). CI indicates confidence interval; OR, odds ratio; n.s., not significant. ∗Indicates significance with $P < 0.05$.

extent to which the ASD-SR is associated with specific complications in ASD patients.

Our study should be viewed within the context of several limitations. Although the data were collected prospectively, our study question was proposed and analyzed in a retrospective manner. ASD-SR scores were calculated on the basis of the surgery that was performed, precluding modification of surgical invasiveness between groups to assess a causal relationship between invasiveness and complications. The patients we assigned to the ''higher invasiveness'' groups are likely to have more severe deformity and may have additional comorbidities. However, our analysis provides clinically important information regarding high-*versus* low-invasiveness procedures and how the ASD-SR score may be used to assess their associated risks. Our study is strengthened by the large sample size, 2-year follow-up, and enrollment from a diverse group of study centers with surgeons who have various surgical preferences and degrees of experience.

CONCLUSION

ASD patients who underwent surgical procedures with ASD-SR invasiveness scores of ≥90 had greater odds of experiencing major complications, whereas their odds of minor complications (except for incidental durotomy) were not greater above this threshold. By ASD-SR score quartiles, the largest increase in complications was when ASD-SR score increased from below 90 to ≥90. These results improve the utility of the ASD-SR invasiveness index when counseling patients during the perioperative period and provide a better understanding of the complex relationship between surgical invasiveness and complication risk.

➢ Key Points

- ❑ ASD patients whose ASD-SR score is above a cutoff of 90 points are 1.9 times as likely to have a major complication than patients whose scores are below this threshold.
- ❑ ASD patients with ASD-SR scores ≥90 are not more likely to have minor complications, except for incidental durotomy.
- ❑ The ASD-SR score can be used as a tool to counsel ASD patients regarding increased odds of complications based on preoperative factors and planned radiographic correction.

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