

When Not to Operate in Spinal Deformity: Identifying Subsets of Patients with Simultaneous Clinical Deterioration, Major Complications, and Reoperation

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STRUCTURED ABSTRACT

Study Design: Retrospective review of a prospectively enrolled adult spinal deformity (ASD) database.

Objective: To investigate what patient factors elevate the risk of sub-optimal outcomes after deformity correction.

Background: Currently, it is unknown what factors predict a poor outcome after adult spinal deformity surgery, which may require increased pre-operative consideration and counseling.

Methods: Patients >18yrs undergoing surgery for ASD (scoliosis $\geq 20^\circ$, SVA ≥ 5 cm, PT $\geq 25^\circ$, or TK $\geq 60^\circ$). An unsatisfactory outcome was defined by the following categories met at 2Y: (1) clinical: deteriorating in ODI at 2Y f/u (2) complications/reop: having a reoperation and major complication were deemed high risk for poor outcomes postoperatively (HR). Multivariate analyses assessed predictive factors of HR patients in adult spinal deformity patients.

Results: 633 ASD (59.9 years, 79%F, 27.7 kg/m² CCI: 1.74) were included. Baseline severe Schwab modifier incidence (++) : 39.2% PI-LL, 28.8% SVA, 28.9% PT. 15.5% of patients deteriorated in ODI by 2 years, while 7.6% underwent a reoperation and had a major complication. This categorized 11 (1.7%) as HR. HR were more comorbid in terms of arthritis (73%) heart disease (36%) and kidney disease (18%), $p < 0.001$. Surgically, HR had greater EBL (4431ccs), underwent more osteotomies (91%), specifically Ponte (36%) and Three Column Osteotomies (55%), which occurred more at L2 (91%). HR underwent more PLIFs (45%) and had more blood transfusion units (2641ccs), all $p < 0.050$. The multivariate regression determined a combination of a baseline DRAM score in the 75th percentile, having arthritis and kidney disease, a baseline right lower extremity motor score ≤ 3 , cSVA > 65 mm, C2 slope $> 30.2^\circ$, CTPA $> 5.5^\circ$ for an R² value of 0.535 ($p < 0.001$).

Conclusions: When addressing adult spine deformities, poor outcomes tends to occur in severely comorbid patients with major baseline psychological distress scores, poor neurologic function, and concomitant cervical malalignment.

Key Points

1. In a multicenter prospectively enrolled study, we investigated what patient factors justify determining a patient ineligible for a surgical spinal deformity correction.
2. Patients deemed at high risk for postoperative complications had both deteriorating HRQL at 2 year follow up and reoperations or major complications.
3. Patients deemed high risk had greater comorbidities and higher blood loss with more severe deformity compared to operative patients.
4. When addressing adult spine deformities, poor outcomes tends to occur in severely comorbid patients with major baseline psychological distress scores, poor neurologic function, and concomitant cervical malalignment.

INTRODUCTION

Malalignment of the spinal column categorized as adult spinal deformity (ASD) results from asymmetric degeneration of the intervertebral disks and facet joints.¹ In view of the growing elderly population, this degeneration and ultimate ASD diagnosis has become a significant public health issue, with an estimated 68% of the elderly affected.²⁻⁴ Along with the growth in the aging population, we see major advances in surgical tools and techniques, leading to operative intervention as a major source of treatment for ASD patients.

Deformity corrective surgery often involves multilevel, invasive procedures in order to achieve optimal coronal and sagittal alignment.^{5,6} With such extensive procedures, risk assessments are vital to preoperative planning and informed consent. Age and elevated comorbidity status put patients at risk of poor postoperative outcomes, and such a high-risk status is becoming increasingly typical of ASD patients requiring surgical intervention.⁷⁻⁹ Additionally, studies have determined that deformity severity significantly impacts outcomes.¹⁰

Use of preoperative patient factors to predict varying postoperative outcomes in the field of spine surgery has been evolving. Given that surgeons and their patients are invested in obtaining the most positive outcomes, determining specific factors that may lead to extremely unfortunate outcomes should be explored. In some cases, these rare, poor outcomes may warrant that operative intervention should not have been considered. Specifically these poor outcome cases include those were patient present with a major medical complication, reoperation, and clinical deterioration as measured by patient-reported metrics. The aim of this study was to determine

which baseline demographic, clinical, and radiographic factors can help render a patient ineligible for deformity correction.

MATERIALS AND METHODS

Data Source and Study Design

We retrospectively analyzed a prospectively collected database developed by the International Spine Study Group (ISSG) and containing patients enrolled at thirteen participating centers from 2013-2018. The database includes patients greater than 18 years of age who meet radiographic criteria of adult spinal deformity (coronal Cobb angle $\geq 20^\circ$, sagittal vertical axis ≥ 50 mm, pelvic tilt $\geq 25^\circ$ and/or thoracic kyphosis $> 60^\circ$) with plans to undergo surgical intervention. Patients with deformity of neuromuscular etiology or those with active infections or malignancy were excluded from the database. Institutional Review Board approval was granted and informed consent was obtained from each patient. The study inclusion criteria required ASD patients with available health related quality of life (HRQL) data at baseline and 2-year postoperatively.

Data Collection and Radiographic Assessment

Standardized data collection forms tracked demographic, patient comorbidities, and surgical parameters. HRQL measures collected at baseline and follow up included the Short Form-36 (SF-36), the Oswestry Disability Index (ODI), the Scoliosis Research Society-22r (SRS-22r), and the Distress and Risk Assessment Method (DRAM).

Full-length free-standing lateral spine radiographs were used to assess ASD patients at baseline and follow-up intervals, and analyzed with SpineView® (ENSAM, Laboratory of Biomechanics, Paris, France).^{11–13} Spinopelvic radiographic parameters assessed included pelvic tilt (PT: the angle between the vertical and the line through the sacral midpoint to the center of the two femoral heads), the mismatch between pelvic incidence and lumbar lordosis (PI-LL), and the sagittal vertical axis (SVA: C7 plumb line relative to the posteriosuperior corner of S1).¹⁴

Statistical Analysis

An unsatisfactory outcome was defined by the following categories met at 2-years: (1) clinical: deteriorating in ODI at 2-year follow up (2) complications/reoperation: having a reoperation and a major complication. Mechanical and radiographic complications were classified as major if involving invasive intervention or causing prolonged or permanent morbidity or mortality. These patients who met both criteria were deemed at high risk for poor outcomes postoperatively (HR). Baseline demographic, clinical, and radiographic information was utilized through univariate/multivariate analyses to assess predictive factors of HR patients in this cohort of adult spinal deformity patients. Pearson correlations determined the initial connection between patient factors and having incurred the HR criteria. Multivariate Logistic regression and Poisson regression were employed to create a predictive model for these patients. All analyses were performed using SPSS software (v23.0, Armonk, NY, USA). Statistical significance was set to $P < 0.05$.

RESULTS

Patient Cohort

Six-hundred and thirty-three adult spinal deformity patients met inclusion criteria. The mean age was 59.9 years, with 79% female. The average body mass index was 27.7 kg/m² with a Charlson comorbidity index of 1.74.

Baseline Radiographic and Clinical Profile

At baseline, mean sacral slope: 31.9°, pelvic tilt: 22.9°, pelvic incidence: 54.8°, PI-LL: 12.3°, SVA: 51.1 mm, and L1-S1: 42.5°. Baseline severe Schwab modifier incidence (++) : 39.2% PI-LL, 28.8% SVA, 28.9% PT. HRQL assessment at baseline demonstrated a mean ODI score of 43.9 ± 18.1, PCS score of 31.7 ± 10.1, SRS-22 Activity of 2.9 ± 0.89, and SRS-22 Pain of 2.4 ± 0.85.

Surgical Description

By surgical approach, 69.7% of cases were posterior-only, 0.6% were anterior-only, and 29.5% combined. Overall mean fusion length was 7.5 ± 2.1 levels, with an average operative time of 378 ± 134.2 minutes, and estimated blood loss of 1400 ± 1476 ccs. 63.4% of patients underwent osteotomy, and 56.8% underwent decompression. 18.2% of the cohort had a reoperation.

HR Patient Description

15.5% of patients deteriorated in ODI by 2 years, while 7.6% underwent a reoperation and had a major complication. 11 (1.7%) were HR. HR patients had were more comorbid in terms of

osteoarthritis (73%), heart disease (36%), and kidney disease (18%), all $p < 0.001$, compared to the remainder of the ASD population. Surgically, HR patients had an overall greater EBL (4431ccs), and underwent more osteotomies (91%), specifically Ponte (36%) and Three Column Osteotomies (55%), which occurred more at L2 (91%). HR patients underwent more PLIFs (45%) and had higher blood transfusion volume (2641ccs), all $p < 0.050$. (**Table 1**)

Model Predicting High Risk Patients Benefiting from Non-Operative Management

Multivariate regression revealed that the following factors significantly predicted HR status: baseline DRAM score in the 75th percentile, having kidney disease, a baseline right lower extremity motor score ≤ 3 , cSVA > 65 mm, C2 slope $> 30.2^\circ$, CTPA $> 5.5^\circ$, and meeting Schwab severe modifier (++) in PI-LL at baseline (**Table 2**). Out of the factors, greatest predictability for increased risk to operation was with cSVA greater than 65 at baseline (OR: 9.72, [6.38, 12.19], $p < .001$) and increased C2 slope at baseline (OR: 3.54, [.83, 2.04], $p < .001$).

DISCUSSION

Preoperative risk assessment is evidently important for all surgical specialties. In order to identify patients at risk of adverse outcomes, baseline risk-scoring assessments have been established in different capacities, both for a surgical patient population in general, and for adult spinal deformity patients specifically. Some commonly utilized systems include the American Society of Anesthesiologists (ASA) physical status classification, the Glasgow Coma Scale, and Charlson Comorbidity index.¹⁵⁻¹⁷ Systems specific to the ASD population, such as the frailty index developed by Miller and colleagues (ASD-FI), and the SRS-Schwab deformity

classification system, allow providers to directly categorize a patient during their preoperative visit and to understand the severity of their disease.^{8,10} Preoperative scoring systems allow for identification and potential optimization of physiologic risk factors as well as improved patient counseling on the risks and benefits of surgery.¹⁸ They have also been shown to correlate with morbidity and mortality following surgery.

Operative treatment for adult spinal deformity has been increasingly studied in the past decade, and reported to significantly reduce symptoms and functionality compared to a nonoperative cohort.^{19–21} Despite of the significant benefits of surgical intervention, proper risk assessment is essential given that major complications are still common due to the invasiveness of the procedures these patients are undergoing. Rarely, patients may experience a combination of several poor outcomes, an event that the present study sought to describe. We identified patients who present with a trifecta of unfortunate results following operative correction for their deformity: clinical deterioration as measured by the Oswestry Disability Index, incurring a major complication, and undergoing a reoperation in the follow up period. 1.7% of our ASD population fit the criteria for all three outcomes.

Those patients identified as HR had extensive medical histories, with 73% of them presenting with arthritis, and a third with heart disease. Bernstein et al. explored the relationship between rheumatoid arthritis (RA) in adult spinal deformity patients, noting that these patients experienced an exponentially higher rate than those without RA.²² Additionally, comorbidity burden in general has been linked to higher complication rates after ASD surgery.^{23–25} The HR patients had increased estimated blood loss, which has been shown in other studies to increase

risk for early post-operative complications. Furthermore, the HR patients underwent more invasive procedures, specifically, over half of the patients had a Three Column Osteotomy, which added to the comorbidity burden within these patients, and contribute to a larger risk profile.^{18,26,27}

We determined that a certain combination of preoperative factors was most predictive of incurring the status of not to operate upon in our ASD cohort. This included the previously mentioned arthritis, kidney disease, a poor lower extremity motor score, and concurrent malalignment in the cervical spine. The high-risk preoperative profile of these patients derives from their complex medical history, baseline neurologic dysfunction with lack of daily functionality, and concomitant deterioration of another region of the spine. Lower extremity functionality at baseline has been previously explored by Lenke and colleagues, who found that those with abnormal preoperative scores declined even further at follow up by 25.8%.²⁸ Moreover, patients with reciprocal changes in the cervical spine coinciding with the thoracolumbar deformity have an increased incidence of proximal junctional kyphosis, as well as higher need for an additional reoperation postoperatively. Thus, poor lower extremity motor score can be indicative of neurological deficit, with increased risk in patients with involvement in multiple myotomes^{29,30}.

The primary limitation of the present study is the retrospective design. We have tried to mitigate this limitation by evaluating patients with complications in a consecutive and multi-center study design. Further limitations lie in the small sample size and group numbers within the high risk

group. Additionally, poor outcomes generally were defined by surgical parameters. Patient satisfaction factors into the preoperative planning process and should be considered in when deciding benefits to operative management. Future study on this topic should include a prospective enrollment of consecutive cases and a larger patient pool.

CONCLUSIONS

When addressing adult spine deformities, a negative outcome of clinical deterioration, major complications, and reoperations is exceedingly rare, but does occur. Such poor outcomes tends to occur in severely comorbid patients with major baseline psychological distress scores, poor neurologic function, and concomitant cervical malalignment.

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Table 1. Comparison between NoOp and remainder of the cohort.

	NoOp	Remainder of ASD Cohort	p-value
Demographics			
Age (years)	63 years	59.9 years	0.467
Female (%)	64%	79%	0.208
BMI (kg/m ²)	29.9 kg/m ²	27.7 kg/m ²	0.226
CCI	2.64	1.73	0.083
History of Arthritis (%)	73%	41%	0.035
History of Cancer (%)	0%	11%	0.216
History of Diabetes (%)	18%	8%	0.216
History of Heart Disease (%)	36%	12%	0.017
History of Hypertension (%)	55%	38%	0.251
History of Kidney Disease (%)	18%	3%	0.003
History of Liver Disease (%)	0%	1%	0.705
History of Lung Disease (%)	0%	5%	0.44
History of Osteoporosis (%)	27%	15%	0.237
Surgical			
EBL (ccs)	4431.8 ccs	1528.1 ccs	<0.001
Osteotomies (%)	91%	62%	0.047
PSO (%)	36%	14%	0.043
3CO (%)	55%	19%	0.003
Corpectomies (%)	9%	1%	0.011
PLIF (%)	45%	5%	<0.001
Blood Transfusion (ccs)	2641 ccs	774.6 ccs	<0.001

Table 2. Model Predicting HR Patients.

Model Predicting HR Patients	Odds Ratio, 95% SI, p-value
DRAM score in the 75 th percentile	OR: 3.21, [1.87, 9.71], p<.001
Kidney Disease	OR: 1.19, [4.09, 10.57], p<.001
Right Lower Extremity Motor Score ≤ 3	OR: 1.05, [1.02, 5.29], p=.033
cSVA >65mm	OR: 9.72, [6.38, 12.19], p<.001
C2 slope >30.2°	OR: 5.56, [1.83, 7.14], p<.001
CTPA >5.5°	OR: 1.22, [.002,.84], p=.024
Meeting Severe Schwab PI-LL	OR: 2.11, [-.09,.98], p = .042