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Development of Risk Stratification Predictive Models for Cervical Deformity Surgery

BACKGROUND: As corrective surgery for cervical deformity (CD) increases, so does the rate of complications and reoperations. To minimize suboptimal postoperative outcomes, it is important to develop a tool that allows for proper preoperative risk stratification.
OBJECTIVE: To develop a prognostic utility for identification of risk factors that lead to the development of major complications and unplanned reoperations.
METHODS: CD patients age 18 years or older were stratified into 2 groups based on the postoperative occurrence of a revision and/or major complication. Multivariable logistic regressions identified characteristics that were associated with revision or major complication. Decision tree analysis established cutoffs for predictive variables. Models predicting both outcomes were quantified using area under the curve (AUC) and receiver operating curve characteristics.
RESULTS: A total of 109 patients with CD were included in this study. By 1 year postoperatively, 26 patients experienced a major complication and 17 patients underwent a revision. Predictive modeling incorporating preoperative and surgical factors identified development of a revision to include upper instrumented vertebrae > C5, lowermost instrumented vertebrae > T7, number of unfused lordotic cervical vertebrae > 1, baseline T1 slope > 25.3°, and number of vertebral levels in maximal kyphosis > 12 (AUC: 0.82). For developing a major complication, a model included a current smoking history, osteoporosis, upper instrumented vertebrae inclination angle < 0° or > 40°, anterior diskectomies > 3, and a posterior Smith Peterson osteotomy (AUC: 0.81).
CONCLUSION: Revisions were predicted using a predominance of radiographic parameters while the occurrence of major complications relied on baseline bone health, radiographic, and surgical characteristics.

KEY WORDS: Adult cervical deformity, Complication, Corrective spine surgery, Predictive model, Risk stratification

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Adult cervical deformity (CD) is a debilitating condition, with adverse effects on quality of life and daily activities. CD may result from a variety of etiologies but frequently presents in the context of neuromuscular disease, proximal junctional kyphosis after thoracolumbar surgery, and spondyloarthropathies.[1-4] The goals of CD corrective surgery are to restore ideal alignment and improve general function.[5-7] Advancements in surgical technology, operative approaches, and perioperative management have allowed more dramatic corrections over the past decade, and patients previously considered ineligible for such interventions are now regularly receiving these procedures.[8-11] The combination of more intensive surgical interventions and higher-risk patients means that the prevalence of adverse events after CD surgery, including complications and reoperations, remains quite high.[12-14]

ABBREVIATIONS: CBVA, Chin brow vertical angle; **CCI,** Charlson Comorbidity Index; **CD,** cervical deformity; **cSVA,** cervical sagittal vertical axis; **LIV,** lowermost instrumented vertebrae; **mJOA,** modified Japanese Orthopaedic Association; **PI-LL,** pelvic incidence minus lumbar lordosis; **PT,** pelvic tilt; **SRS,** Scoliosis Research Society; **SVA,** sagittal vertical axis; **TS-CL,** T1 slope minus cervical lordosis; **UIV,** uppermost instrumented vertebrae.

Recently, investigators have proposed risk stratification models specific to adult spinal deformity.[15] These studies relied on patient demographic, surgical, and radiographic parameters to inform surgical decisions and optimize perioperative management.

Risk factors in the context of thoracic and lumbar deformity may be dramatically different from those in the setting of CD. Furthermore, the surgical approaches and instrumentation used are different. It is, therefore, unclear that risk stratification models developed among patients with thoracolumbar scoliosis or kyphosis are applicable to individuals with CD.

In this context, we sought to develop risk stratification models to identify factors that may lead to revision surgery or major complication after adult CD surgery. We used a prospective multicenter database of consecutively enrolled adult patients with CD, previously used to study postoperative patient outcomes and associated risk factors.

METHODS

Study Design and Data Collection

This study represents a retrospective review of prospectively collected data on patients with CD who received surgical intervention at 1 of 13 contributing centers between 2013 and 2017. Database inclusion criteria consisted of patients age 18 years or older and radiographic evidence of CD, defined as the presence of at least one of the following: cervical kyphosis (C2-7 Cobb angle > 10°), C2-7 sagittal vertical axis > 4 cm, chin-brow vertical angle > 25°, or T1 slope minus cervical lordosis > 10°. Before patient enrollment, Institutional Review Board approval was obtained at each participating center, and consent was obtained from each patient before enrollment in the study. The database is routinely audited, monitored, and updated by dedicated research coordinators at each institution ensuring a high standard of quality control for the curated data. Minimum patient follow-up for this study was 1 year postoperation.

Data Collection and Radiographic Assessment

Demographic and surgical parameters were collected using standardized data forms at baseline evaluation and all follow-up encounters. Demographic information included age, sex, body mass index, and Charlson Comorbidity Index. Operative characteristics consisted of number of levels fused, estimated blood loss, operative time, surgical approach, performance of decompression and osteotomy, and length of stay. In addition, patient-reported outcome measures were administered at baseline and follow-up visits including Neck Disability Index, Numeric Rating Scale Neck, EuroQol-5D-3L, and the modified Japanese Orthopaedic Association questionnaires. Minimal clinically importance difference thresholds were applied to evaluate improvement in outcomes using previously published values.[16-18]

Full-length free-standing lateral spine radiographs (36-in. cassette) were collected and assessed at baseline and 1 year follow-up. SpineView (ENSAM, Laboratory of Biomechanics) software was used to analyze radiographs using standardized and validated techniques previously published in the literature. Spinopelvic radiographic parameters included pelvic tilt (angle between vertical and sacral midpoint to the center of the 2 femoral heads); pelvic incidence and lumbar lordosis mismatch; and sagittal vertical axis (C7 plumb line relative to the posterosuperior corner of S1). Cervical spine parameters assessed included cervical lordosis (C2-C7 angle), cervical sagittal vertical axis (C2 plumb line relative to the posterosuperior corner of C7), T1 slope (T1S), C2 slope (C2S), T1 slope minus cervical lordosis, and McGregor slope.

Patients with complete baseline and at least 1 year health-related quality-of-life and radiographic data were included. We surveyed for complications and need for revision procedures up to 2 years after surgery as reported in the data set by participating centers. Complications were defined as major if they substantially prolonged hospitalization, involved an invasive intervention, had prolonged or permanent morbidity, or resulted in death during the first 730 days of follow-up.[15] Reasons for undergoing a surgical revision in this cohort included distal junctional kyphosis, instrumentation failure, sensory nerve deficit, spinal cord deficit, or development of a deep infection.

Classification of CD

Preoperative CD severity was assessed using the Ames CD classification.[19] This system consists of a CD descriptor that identifies the apex of the deformity and 5 modifiers (Figure 1). Patients were assigned a CD descriptor based on radiographic review and were stratified by deformity severity for each of the modifiers. Postoperative improvement in an Ames modifier was defined as being classified as a lower grade than preoperatively, i.e. from grade 2 to 0 or 1 or from grade 1 to 0.

Deformity severity was also assessed using the Scoliosis Research Society-Schwab adult spinal deformity classification system.[20] The system uses a coronal curve descriptor and 3 sagittal modifiers (Figure 2). Patients were stratified by deformity severity for each of the radiographic modifiers preoperatively. Improvement was defined as being classified as a lower grade postoperatively.

Statistical Analysis

Patients with complete baseline and 1-year health-related quality-of-life and radiographic data were included. All baseline demographic, radiographic, and surgical variables characteristics were considered in the model. Independent t tests and χ^2 analyses were used to compare continuous and categorical factors, respectively. Patients were stratified into 2 groups based on index surgery postoperative outcome: (1) revision and (2) major complication. A bivariate analysis was conducted using preoperative surgical factors to determine associations with any of the 2 outcomes. A multivariable logistic regression was used to identify independent surgical, radiographic, and baseline functional characteristics associated with a revision or major complication. The conditional inference tree machine learning technique was used to establish optimal cutoffs for each predictive variable included in the final model. The final model's predictive capacity was quantified by using area under the curve (AUC) and receiver operating curve characteristics controlling for age, comorbidities, and surgical invasiveness. Statistical analysis was performed using SPSS software (version 21.0, IBM).

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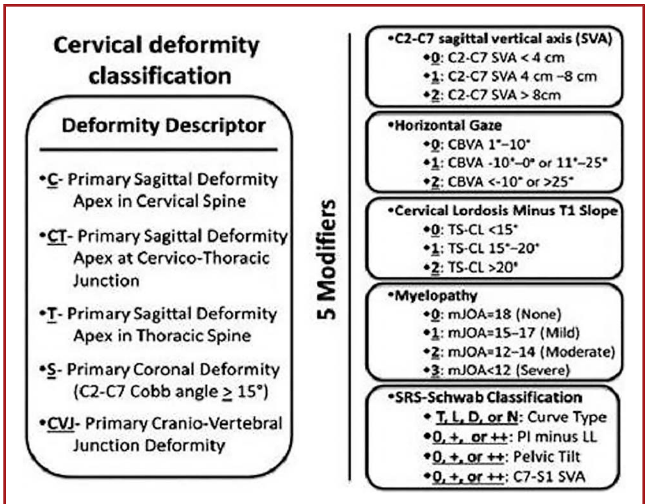

FIGURE 1. *The Ames classification system for CD consists of a deformity descriptor and 5 modifiers. CBVA, chin-brow vertical angle; CD, cervical deformity; CT, computed tomography; CVJ, cranio-vertebral junction; mJOA, modified Japanese Orthopaedic Association; SVA, sagittal vertical axis; TS-CL, T1 slope minus cervical lordosis.*

RESULTS

Cohort Demographic Overview

We included 109 patients with CD who met inclusion criteria. The mean patient age was 61.5 ± 10.4 years, body mass index of 28.0 ± 6.7 kg/m^2, and Charlson Comorbidity Index of 1.1 ± 1.4, with 66.1% of patients being female.

Cohort Surgical Details

Operatively, patients had a mean level fused of 7.9 ± 3.9, estimated blood loss of 829 ± 852 mL, and operative time of 397.7 ± 214.1 minutes. By surgical approach, 49.5% were posterior-only, 14.7% anterior-only, and 35.8% underwent an anterior–posterior approach.

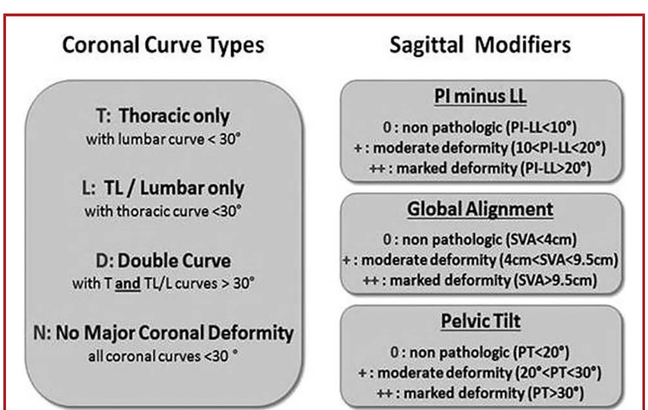

FIGURE 2. *The Scoliosis Research Society-Schwab classification system for adult spinal deformity consists of a coronal deformity type and 3 sagittal modifiers. PI-LL, pelvic incidence and lumbar lordosis mismatch; PT, pelvic tilt; SVA, sagittal vertical axis; TL/L, thoracolumbar/lumbar.*

Baseline Characteristics Between Adverse Outcome Groups

Baseline demographic, surgical, and radiographic details are compared between the need for revision cohorts and incidence of major complication cohorts in Tables 1 and 2, respectively.

Baseline and Follow-up SRS-Schwab and Ames CD Modifiers

Baseline and 1-year follow-up classification in Scoliosis Research Society-Schwab and Ames CD modifiers for the entire cohort are provided in Tables 3 and 4, respectively.

Postoperative Radiographic Alignment Improvement

Changes in both classification schemas are compared between the need for revision cohorts and incidence of major complication cohorts in Table 5.

Postoperative Adverse Events

Postoperatively, 26 (23.9%) patients experienced a major complication and 17 (16.2%) patients underwent a subsequent revision. Instrumentation location for lowermost instrumented vertebrae (LIV; odd ratio [OR]: 1.8 [1.2-3.6], $P = .004$) and upper instrumented vertebrae (UIV; OR: 1.6 [1.1-2.3], $P = .009$) was significantly associated with undergoing a revision after index surgery. The development of a postoperative major complication was significantly associated with baseline osteoporosis (OR: 4.0 [1.2-13.0], $P = .023$).

Risk Stratification Model

Predictive modeling incorporating preoperative and surgical characteristics controlling for age, comorbidities, and invasiveness identified several factors associated with the risk of revision, including UIV > C5 (OR: 7.9 [1.6-38.2] $P = .010$), LIV > T7 (OR: 57.8 [3.4-996.4] $P = .005$), more than 1 unfused lordotic cervical vertebrae (OR: 4.33 [0.99-18.91] $P = .051$), baseline T1 slope > 25.3° (OR: 3.6 [0.8-16.3] $P = .093$), and more than 12 vertebral levels in maximal kyphosis (OR: 8.6 [1.9-37.7] $P = .005$), AUC: 0.821 (Table 6). The factors influential of major complications included a current smoking history (OR: 6.5 [0.9-45.1] $P = .058$), osteoporosis (OR: 4.0 [1.2-13.0] $P = .023$), UIV inclination angle < 0° or > 40° (OR: 4.5 [1.5-13.8] $P = .009$), anterior diskectomies > 3 (OR: 4.6 [1.3-15.5] $P = .015$), and a posterior Smith Peterson osteotomy (OR: 1.25 [0.97-1.61] $P = .081$), AUC: 0.811 (Table 7).

DISCUSSION

The heterogeneous clinical presentation and etiologies behind CD makes it difficult to prognosticate risk factors for outcomes

TABLE 1. Baseline Demographic, Surgical, and Radiographic Differences Between Revision and No Revision Patients

	Revision	No revision	*P*-value
Basic demographics			
Age (yr)	61.6	61.2	.860
Sex (% female)	59%	68%	.458
BMI (kg/m²)	27.4	28.1	.708
CCI	0.85	1.15	.481
Surgical characteristics			
Estimated blood loss (mL)	956.5	827.7	.575
Operative time (min)	418.5	393.9	.672
Number of levels fused	8.1	8.0	.955
Radiographic alignment			
PT (°)	21.0	19.2	.578
PI-LL (°)	1.1	−0.1	.808
SVA (mm)	−17.6	−2.6	.428
cSVA (mm)	60.9	45.2	.036
TS-CL (°)	44.3	39.2	.437

BMI, body mass index; CCI, Charlson Comorbidity Index; cSVA, cervical sagittal vertical axis; PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SVA, sagittal vertical axis, TS-CL, T1 slope minus cervical lordosis.

after surgery. Our results demonstrated that instrumentation location was significantly associated with patients undergoing a revision. Radiographic predictors of revision were T1 slope and the number of vertebral levels in maximal kyphosis. A statistical model predicting major complications consisted of patient smoking status and osteoporosis. Surgical predictors in the model included the inclination angle of the UIV, number of anteriorly performed diskectomies, and a posterior Smith Peterson osteotomy.

TABLE 2. Baseline Demographic, Surgical, and Radiographic Differences Between Major Complication and No Major Complication Patients

	Major complication	No major complication	*P*-value
Basic demographics			
Age (yr)	61.4	61.6	.922
Sex (% female)	62%	67%	.581
BMI (kg/m²)	27.3	28.3	.550
CCI	1.18	1.07	.746
Surgical characteristics			
Estimated blood loss (mL)	1090.6	747.1	.073
Operative time (minutes)	464.4	376.9	.069
Number of levels fused	8.5	7.7	.389
Radiographic alignment			
PT (°)	16.8	20.2	.190
PI-LL (°)	−1.4	0.6	.618
SVA (mm)	−0.03	−6.12	.692
cSVA (mm)	47.2	46.8	.946
TS-CL (°)	42.0	38.4	.456

BMI, body mass index; CCI, Charlson Comorbidity Index; cSVA, cervical sagittal vertical axis; PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SVA, sagittal vertical axis; TS-CL, T1 slope minus cervical lordosis.

TABLE 3. Baseline and Follow-up SRS-Schwab Modifiers for the Entire Cohort

SRS-Schwab Modifiers	Preoperatively			Postoperatively		
	0	+	++	0	+	++
PI-LL	74.1%	18.5%	7.4%	77.3%	8.0%	14.8%
SVA	78.5%	15.0%	6.5%	69.7%	19.1%	11.2%
PT	51.9%	35.2%	13.0%	63.3%	15.2%	21.5%

PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SRS, Scoliosis Research Society; SVA, sagittal vertical axis.

The location of the UIV and LIV were significantly associated with revisions in our study. Although it has been previously noted that extending the construct to the axis has substantial benefits,[21] others have considered it a move with elevated risks of complications.[22] Perhaps in our population, the risk of revision outweighed the potential benefit of stability. Baseline sagittal deformity marked by the number of vertebrae in maximal kyphosis was determined as a predictor of undergoing revision surgery. Severe kyphosis in a patient with CD presents a difficult situation for surgeons to achieve optimal alignment goals.[23-25] Techniques attempted by Shen et al[26] have had correction rates >80% in the kyphotic region of patients with severe CD. In addition, Virk et al[25] found patients who had a Flat neck deformity fared better with greater correction of horizontal gaze. Our model recommends this deformity at thresholds to be considered at significantly greater odds of undergoing revision surgery by 1 year postoperatively. This emphasizes the importance of risk stratifying and addressing a baseline deformity as each case may require unique correction goals to avoid complications and promote better outcomes.

Additional work specific to cervical malalignment has shown that despite substantial improvement in pain and disability after surgical intervention, postoperative incidence of a major complication such as distal junctional kyphosis remains high at 23.8% with preoperative T1 slope minus cervical lordosis, sagittal vertical axis, cervical kyphosis, and cervical lordosis being significant predictors.[27-29] Furthermore, a recent study by Smith et al[29] demonstrated that additional consideration toward a combination of demographic, radiographic, and surgical characteristics is needed with increased awareness toward optimizing patients for surgery. Smoking was included in our model because it has been found to been significantly associated with increased odds of major complications after spine surgery.[30,31] Although not independently significant in our cohort, it increased the validity of our model and should be considered when evaluating a patient for CD correction. Osteoporosis has been associated with increased rates of complications after spine surgery because of

TABLE 4. Baseline and Follow-up Ames CD Modifiers for the Entire Cohort

	Preoperatively				Postoperatively			
Ames Cervical Deformity Modifiers	**0**	**1**	**2**	**3**	**0**	**1**	**2**	**3**
cSVA	52.8%	47.2%	0%		69.7%	13.5%	16.9%	
CBVA	20.2%	45.2%	34.6%		19.2%	52.9%	27.9%	
TS-CL	7.7%	3.8%	88.5%		11.0%	11.0%	78.0%	
mJOA	9.1%	37.4%	34.3%	19.2%	18.5%	28.3%	31.5%	21.7%

CBVA, chin-brow vertical angle; CD, cervical deformity; cSVA, cervical sagittal vertical axis; mJOA, modified Japanese Orthopaedic Association; TS-CL, T1 slope minus cervical lordosis.

poor bone density resulting in decreased fixation strength.[32,33] The development of a postoperative major complication was significantly associated with baseline osteoporosis in this cohort. Promoting bone health and understanding the risk of elective spine surgery are critical for patients and surgeons alike when evaluating preoperative bone density. Little exist in the literature on the UIV inclination angle in CD surgery, but Lafage et al[34] highlighted important findings when studying adult spinal deformity. They found a more posterior UIV inclination was present in patients who developed proximal junctional kyphosis. In this cohort, anterior and posterior extremes of UIV inclination were determined by conditional inference tree machine learning to be at increased odds of a major complication. Although poorly understood, these findings may serve as a basis for further study on the influence of angles of inclination and instrumented vertebrae in CD surgery. In addition, excessive anterior diskectomies and a posterior Smith–Peterson osteotomy were included in the model predicting a major complication. In a selective analysis of our cohort, this threshold for anterior diskectomies remained significant when testing patients who only underwent a combined (anterior posterior) approach procedure. In a previous retrospective review, Smith–Peterson osteotomy use was included in a model used to predict postoperative cervical malalignment,[35] and the finding in our study indicates the use of this osteotomy technique in CD correction escalates postoperative risks.

TABLE 5. Postoperative Radiographic Alignment Improvement or Deterioration for Revision and Major Complication

Radiographic Parameters	**Same**	**Improved**	**Deteriorated**	**Same**	**Improved**	**Deteriorated**	***P*-values**
			SRS-Schwab modifiers				
	Major complication			No major complication			
PI-LL	86.4%	0.0%	13.6%	83.3%	6.1%	10.6%	.476
SVA	60.0%	15.0%	25.0%	77.6%	7.5%	14.9%	.285
PT	73.7%	5.3%	21.1%	85.0%	8.3%	6.7%	.187
	Revision			No revision			
PI-LL	93.3%	6.7%	0.0%	81.4%	4.3%	14.3%	.286
SVA	91.7%	0.0%	8.3%	70.4%	9.9%	19.7%	.279
PT	88.9%	11.1%	0.0%	80.3%	7.6%	12.1%	.526
			Ames CD modifiers				
	Major Complication			No Major Complication			
cSVA	50.0%	25.0%	25.0%	53.7%	29.9%	16.4%	.676
CBVA	76.0%	3.8%	8.0%	68.4%	16.5%	15.2%	.641
TS-CL	65.2%	21.7%	13.0%	73.6%	20.8%	5.6%	.471
mJOA	42.1%	36.8%	21.1%	56.1%	22.7%	21.2%	.432
	Revision			No revision			
cSVA	28.6%	50.0%	21.4%	59.4%	23.2%	17.4%	.076
CBVA	66.7%	13.3%	20.0%	70.6%	16.5%	12.9%	.756
TS-CL	86.7%	6.7%	6.7%	69.7%	22.4%	7.9%	.353
mJOA	41.7%	33.3%	25.0%	54.2%	25.0%	20.8%	.718

CD, cervical deformity; cSVA, cervical sagittal vertical axis; mJOA, Modified Japanese Orthopaedic Association; PI-LL, pelvic incidence minus lumbar lordosis; PT, pelvic tilt; SRS, Scoliosis Research Society; SVA, sagittal vertical axis; TS-CL, T1 slope minus cervical lordosis.

TABLE 6. Predictive Model of Undergoing a Revision

Factors	Odds ratio	CI	*P*-value
UIV > C5	7.9	1.6-38.2	.010
LIV > T7	57.8	3.4-996.4	.005
Unfused lordotic cervical vertebrae > 1	4.33	0.99-18.91	.051
Vertebral levels in maximal kyphosis > 12	8.6	1.9-37.7	.005
Baseline T1 slope > 25.3°	3.6	0.8-16.3	.093
			AUC = .821

AUC, area under the curve; LIV, lowermost instrumented vertebrae; UIV, uppermost instrumented vertebrae.

Our current work adds to the existing literature by presenting baseline and surgical factors associated with revisions and major complications derived from a multicenter cohort of patients treated for CD in the modern period of surgical instrumentation and relying on current technical approaches.

Limitations

Foremost, the retrospective nature of this work means determinations may be confounded by selection and indication bias, as well as clustering at the provider and institutional level. There may be restricted clinical variation and truncation that cannot truly be evaluated given the study design. Furthermore, given the limited event rate, our methodologic approach was of necessity exploratory. Although the work is able to identify factors that merit further consideration in robust analysis, we caution that all of the parameters identified here may not be clinically actionable.

We acknowledge several potential shortcomings associated with this effort. Although we accrued many patients from different centers and surgeons, there remains the potential for selection and expertise bias, as well as patient clustering, to confound results. Because this multicenter study follows specific inclusion criteria, we understand there is inherent selection bias as not all patients with CD were consented and enrolled in the study. Given the tedious checks for data at each follow-up time point, the number of patients enrolled at each site is limited to properly maintain the quality of information gathered. This can limit the generalizability of this study to single centers nationwide as the breadth of cases may not be fully representative of the CD population. Furthermore, given that the study design is limited to 1 year postoperatively, there is also the prospect of a surveillance bias, and we cannot ensure that all possible outcomes and events during postsurgical care for CD are adequately represented in this cohort. Although derived from the experience across 13 centers, we cannot be certain that the outcomes and trends presented here are fully translatable, and the findings may not be uniformly applicable to all health care contexts, especially those that are dramatically different from the contributing members of the International Spine Study Group. There may be restricted clinical variation and truncation that cannot truly be evaluated given the study design. Furthermore, given the limited event rate, our methodologic approach was of necessity exploratory. Although the work can identify factors that merit further consideration in robust analysis, we caution that all of the parameters identified here may not be clinically actionable. This is an area of future investigation that should be observed closely going forward.

TABLE 7. Predictive Model of a Major Complication

Factors	Odds ratio	CI	*P* value
Current smoker	6.5	0.9-45.1	.058
Osteoporosis	4.0	1.2-13.0	.023
UIV inclination angle < 0° or > 40°	4.5	1.5-13.8	.009
Anterior diskectomies > 3	4.6	1.3-15.5	.015
Posterior Smith–Peterson osteotomy	1.25	0.97-1.61	.081
			AUC = .811

AUC, area under the curve; UIV, uppermost instrumented vertebrae.

CONCLUSION

Major adverse events are not uncommon after adult CD correction. Risk stratification models were developed to predict with high accuracy the occurrence of these common significant postoperative events. Revisions and major complications were predicted with an accuracy > 80% using a predominance of radiographic and surgical variables.

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