

Predicting the combined occurrence of poor clinical and radiographic outcomes following cervical deformity corrective surgery

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OBJECTIVE Cervical deformity (CD) correction is clinically challenging. There is a high risk of developing complications with these highly complex procedures. The aim of this study was to use baseline demographic, clinical, and surgical factors to predict a poor outcome following CD surgery.

METHODS The authors performed a retrospective review of a multicenter prospective CD database. CD was defined as at least one of the following: cervical kyphosis (C2–7 Cobb angle > 10°), cervical scoliosis (coronal Cobb angle > 10°), C2–7 sagittal vertical axis (cSVA) > 4 cm, or chin-brow vertical angle (CBVA) > 25°. Patients were categorized based on having an overall poor outcome or not. Health-related quality of life measures consisted of Neck Disability Index (NDI), EQ-5D, and modified Japanese Orthopaedic Association (mJOA) scale scores. A poor outcome was defined as having all 3 of the following categories met: 1) radiographic poor outcome: deterioration or severe radiographic malalignment 1 year postoperatively for cSVA or T1 slope–cervical lordosis mismatch (TS-CL); 2) clinical poor outcome: failing to meet the minimum clinically important difference (MCID) for NDI or having a severe mJOA Ames modifier; and 3) complications/reoperation poor outcome: major complication, death, or reoperation for a complication other than infection. Univariate logistic regression followed by multivariate regression models was performed, and internal validation was performed by calculating the area under the curve (AUC).

RESULTS In total, 89 patients with CD were included (mean age 61.9 years, female sex 65.2%, BMI 29.2 kg/m²). By 1 year postoperatively, 18 (20.2%) patients were characterized as having an overall poor outcome. For radiographic poor outcomes, patients' conditions either deteriorated or remained severe for TS-CL (73% of patients), cSVA (8%), horizontal gaze (34%), and global SVA (28%). For clinical poor outcomes, 80% and 60% of patients did not reach MCID for EQ-5D and NDI, respectively, and 24% of patients had severe symptoms (mJOA score 0–11). For the complications/reoperation

ABBREVIATIONS AUC = area under the curve; CBVA = chin-brow vertical angle; CD = cervical deformity; CL = C2–7 lordosis; cSVA = C2–7 SVA; MCID = minimum clinically important difference; mJOA = modified Japanese Orthopaedic Association; NDI = Neck Disability Index; PI-LL = mismatch between pelvic incidence and lumbar lordosis; PT = pelvic tilt; SVA = sagittal vertical axis; TS-CL = mismatch between T1 slope and CL.

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poor outcome, 28 patients experienced a major complication, 11 underwent a reoperation, and 1 had a complication-related death. Of patients with a poor clinical outcome, 75% had a poor radiographic outcome; 35% of poor radiographic and 37% of poor clinical outcome patients had a major complication. A poor outcome was predicted by the following combination of factors: osteoporosis, baseline neurological status, use of a transition rod, number of posterior decompressions, baseline pelvic tilt, T2–12 kyphosis, TS-CL, C2–T3 SVA, C2–T1 pelvic angle (C2 slope), global SVA, and number of levels in maximum thoracic kyphosis. The final model predicting a poor outcome (AUC 86%) included the following: osteoporosis (OR 5.9, 95% CI 0.9–39), worse baseline neurological status (OR 11.4, 95% CI 1.8–70.8), baseline pelvic tilt > 20° (OR 0.92, 95% CI 0.85–0.98), > 9 levels in maximum thoracic kyphosis (OR 2.01, 95% CI 1.1–4.1), preoperative C2–T3 SVA > 5.4 cm (OR 1.01, 95% CI 0.9–1.1), and global SVA > 4 cm (OR 3.2, 95% CI 0.09–10.3).

CONCLUSIONS Of all CD patients in this study, 20.2% had a poor overall outcome, defined by deterioration in radiographic and clinical outcomes, and a major complication. Additionally, 75% of patients with a poor clinical outcome also had a poor radiographic outcome. A poor overall outcome was most strongly predicted by severe baseline neurological deficit, global SVA > 4 cm, and including more of the thoracic maximal kyphosis in the construct.

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KEYWORDS cervical deformity; poor outcome; complications; predictive analytics; sagittal malalignment

CERVICAL deformity (CD) includes a complex range of disorders with varying etiologies, from trauma, spondylosis, congenital conditions, and others.²² Although uncommon, severe CD can lead to debilitating consequences and can result in severe disability and pain related to neurological impairment.^{18,20} As opposed to thoracolumbar deformities, the CD literature lacks a strong agreement on the characterization and classification of the condition.²

As CD surgery has progressed, it has become increasingly more common for surgeons to operate on more challenging cases in higher-risk patients. There is a large amount in variability in both treatment techniques and surgical planning for CD that in part might contribute to the wide range of outcomes and complications experienced by patients.²¹ Additionally, CD patients are a distinct cohort from patients with thoracolumbar deformities, as they are more frail, have more heterogeneous pathologies, and oftentimes undergo more high-risk surgeries with unique complications, including C5 palsy and dysphagia.^{9,24} Increased age and presence of other comorbidities also put patients at risk of having poor outcomes following surgery; however, these high-risk patients are increasingly becoming more of the typical CD patient who undergoes surgical treatment. Additionally, baseline radiographic and clinical assessments influence postoperative outcomes and need to be taken into account when planning surgical procedures.¹⁹ One recent study showed that worse baseline malalignment was associated with inferior postoperative outcomes following CD corrective surgery.¹⁶ Other investigations have examined the importance of including the primary driver of the deformity in the construct, otherwise leading to residual malalignment and inferior health-related quality of life scores, which stresses the importance of preoperative alignment on postoperative outcomes.¹²

The use of predictive analytics in the field of spine surgery provides a means to determine patient-specific factors that predict a particular outcome of interest. Given that surgeons and their patients are invested in obtaining the most positive outcomes possible, determining specific factors that affect outcomes is of utmost importance.

Identifying patient-specific factors that predict a poor outcome after CD surgery may help to improve patient

outcomes. Therefore, the aim of this study was to use baseline demographic, clinical, and surgical factors to predict a poor overall outcome following CD corrective surgery.

Methods

Patient Population

This study is a retrospective review of a prospectively collected database of surgical CD patients enrolled from 13 sites within the United States from 2013 to 2017. Institutional review board approval was obtained at each participating site prior to study initiation, and informed consent was given by each included patient. Inclusion criteria for the database were patient age ≥ 18 years and radiographic evidence of CD at baseline assessment, defined as the presence of at least one of the following: cervical kyphosis (C2–7 Cobb angle > 10°), cervical scoliosis (C2–7 coronal Cobb angle > 10°), C2–7 sagittal vertical axis (cSVA) > 4 cm, or chin-brow vertical angle (CBVA) > 25°. CD patients meeting radiographic inclusion with available baseline and 1-year follow-up data were included in this study. Patients with active tumors or infections were excluded from the study.

Patient Inclusion and Exclusion

A total of 154 CD patients were included in the database used in this study. Of these patients, 65 were excluded because they did not have complete baseline and 1-year postoperative radiographic and clinical data. This limited our cohort to 89 patients included for analysis.

Data Collection

Demographic and clinical data collected included patient age, sex, BMI, prior cervical surgery, and Charlson Comorbidity Index. Surgical data collected included operative time, estimated blood loss, surgical approach, off-label use of bone morphogenetic protein–2, osteotomy use and number of osteotomies, levels fused, and instrumentation used.

Patients were evaluated using full-length free-standing lateral spine radiographs (36-inch-long cassette) at baseline and the 1-year postoperative follow-up visit. Radiographs were analyzed using dedicated and validated soft-

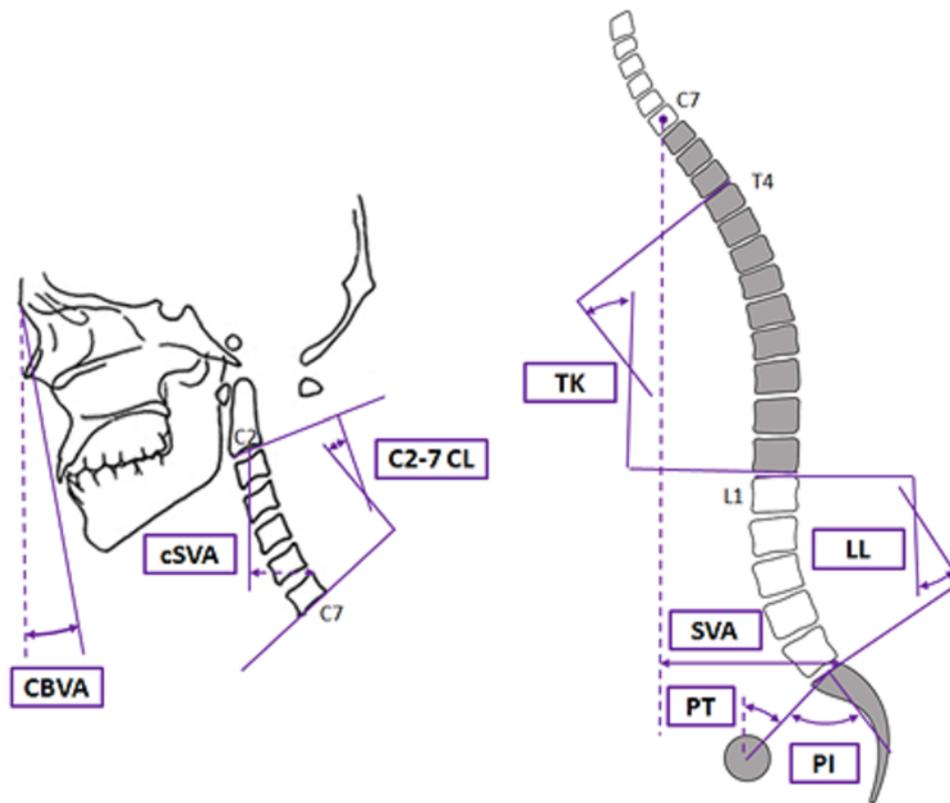


FIG. 1. Schematic of the measured sagittal alignment parameters for the cervical (**left**) and global spinopelvic (**right**) spinal regions. CBVA = chin-brow vertical angle; cSVA = cervical sagittal vertical axis; C2–7 CL = cervical lordosis; TK = thoracic kyphosis; LL = lumbar lordosis; SVA = sagittal vertical axis; PT = pelvic tilt; PI = pelvic incidence. Figure is available in color online only.

ware (SpineView, ENSAM, Laboratory of Biomechanics) at a single center with standard techniques.^{5,10,17} Measured cervical spine parameters included cSVA (offset from the C2 plumb line and the posterosuperior corner of C7), C2–7 lordosis (CL; Cobb angle between C2 inferior endplate and C7 inferior endplate), T1 slope minus CL (TS-CL; mismatch between T1 slope and CL), C2–T3 angle and SVA, and CBVA (angle subtended between the vertical line and the line from the brow to the chin). Measured spinopelvic parameters (Fig. 1) included sagittal vertical axis (SVA; C7 plumb line relative to the posterosuperior corner of S1), pelvic incidence minus lumbar lordosis (PI-LL; mismatch between pelvic incidence and lumbar lordosis), and pelvic tilt (PT; angle between the vertical and the line through the sacral midpoint to the center of the 2 femoral heads).

Defining a Poor Outcome

A poor outcome was defined as having all 3 of the following categories met: 1) radiographic poor outcome: deterioration (baseline to 1-year postoperative increase) or severe radiographic malalignment 1 year postoperatively for cSVA (> 8 cm) or TS-CL ($> 20^\circ$); 2) clinical poor outcome: failing to meet the minimum clinically important difference (MCID) for the Neck Disability Index (NDI) (defined as a change by 15 points or more) or having severe symptoms (modified Japanese Orthopaedic Association [mJOA] Ames modifier score 0–11); and 3) complications/

reoperation poor outcome: major complication, death, or reoperation for a complication other than infection.^{1,2} Major complications were defined as previously published: complications involving invasive intervention, prolonged or permanent morbidity, or a complication that resulted in death.²⁴

Statistical Analysis

Demographic and clinical variables were assessed using chi-square and t-tests for categorical and continuous variables, respectively. Univariate logistic regression followed by multivariate regression models was performed, and internal validation was performed by calculating the area under the curve (AUC). Two-sided p values < 0.05 were considered statistically significant. All statistical analyses were performed using IBM SPSS (version 23, IBM Corp.).

Results

Study Population

Eighty-nine patients with CD were included (mean age 61.9 years, female sex 65.2%, BMI 29.2 kg/m²; Table 1). The most common diagnoses for these CD patients were degenerative kyphosis (50.9%), cervical stenosis (12%), and iatrogenic kyphosis (10.9%). Patient comorbidities included depression in 30.3%, osteoporosis in 14.6%, and diabetes in 7.9%. Of all patients, 38.6% had a prior cervi-

TABLE 1. Overall cohort demographics and surgical details for the CD population in this study

	Mean or Frequency
Patient demographics	
Mean age, yrs	61.9
Female sex	65.2%
Mean BMI, kg/m ²	29.2
History of cervical spine surgery	38.6%
Osteoporosis	14.6%
Diabetes	7.9%
Depression	30.3%
Surgical details	
Mean no. of levels fused	7.61 ± 3.59
Mean EBL, mL	862.2 ± 887.1
Mean operative time, mins	376.6 ± 317.5
Surgical approach	
Anterior only	16.9%
Posterior only	49.4%
Combined	33.7%
3-column osteotomy	21.3%

EBL = estimated blood loss.

cal spine surgery. CD correction involved a mean (\pm SD) of 7.61 ± 3.59 levels fused, with an average operative time of 376.6 ± 317.5 minutes and estimated blood loss of 862.2 ± 887.1 mL. The surgical approach was anterior only in 16.9%, posterior only in 49.4%, and combined approach in 33.7%, with 21.3% of patients undergoing a 3-column osteotomy. In the overall cohort, 18 (20.2%) patients had a poor overall outcome (clinical, radiographic, and complications/reoperation) by the 1-year follow-up. The rate of osteoporosis was significantly higher for patients who had a poor overall outcome than for those who did not (33.3% vs 9.9%, $p = 0.021$). None of the other demographic, clinical, and surgical details were significantly different when compared between poor outcome patients and those without a poor outcome (all $p > 0.05$).

Pre- and Postoperative Radiographic Alignment

This cohort of CD patients had an average preoperative C2–7 lordosis of $-7.09^\circ \pm 21.02^\circ$, TS-CL of $37.32^\circ \pm 19.27^\circ$, and cSVA of 46.05 ± 24.91 mm (Table 2). Preoperative and 1-year postoperative changes in cervical, cervicothoracic, and global spinal alignment parameters are shown in Table 2. None of the cervical, cervicothoracic, and global alignment parameters differed at baseline between patients with and without an overall poor outcome, with the exception of pelvic tilt (Table 3). At 1 year postoperatively, patients with an overall poor outcome had worse cSVA, C2–T3 SVA, TS-CL, and C2 slope than patients without an overall poor outcome (all $p < 0.05$, Table 3).

Health-Related Quality of Life Scores and Baseline Neurological Status

At baseline, this CD cohort had an average NDI score of 48.5, EQ-5D of 0.73, and mJOA score of 13.5 (Table

TABLE 2. Radiographic assessment of the CD cohort at baseline and 1 year postoperatively

Radiographic Parameter	Preop	Postop	p Value
SVA, mm	2.67 ± 69.8	25.4 ± 70.03	<0.001
PT, °	19.5 ± 11.9	18.9 ± 11.3	0.314
PI-LL, °	1.25 ± 18.5	2.03 ± 18.44	0.484
C2–7 CL, °	-7.09 ± 21.02	6.96 ± 16.02	<0.001
cSVA, mm	46.05 ± 24.91	40.97 ± 17.89	0.008
C2–T3 angle, °	-17.09 ± 11.9	-1.57 ± 17.75	<0.001
C2–T3 SVA, mm	78.05 ± 40.22	76.61 ± 28.10	0.433
T4–12 thoracic kyphosis, °	39.1 ± 15.9	42.87 ± 15.28	<0.001
TS-CL, °	37.32 ± 19.27	28.10 ± 13.29	<0.001
C2 slope, °	37.81 ± 20.49	27.07 ± 14.25	<0.001

Boldface type indicates statistical significance.

4). Twenty-six percent of CD patients had no neurological deficit at baseline. At baseline, 54% of patients presented with hand numbness, 43.8% with weakness, 38.2% with gait impairment, and 36% with hand clumsiness.

Poor Outcome Clusters

In looking at the radiographic poor outcomes, 73% of patients worsened in TS-CL or remained severely malaligned postoperatively and 8% of patients worsened or had severe cSVA (Table 5). Eighty percent of CD patients failed to meet the MCID for EQ-5D, 60% failed to meet the MCID for NDI, and 24% of patients had a severe mJOA score (0–11) postoperatively. In looking at complications, 32% of the cohort experienced a major complication and 12% underwent a reoperation. The mortality rate of this cohort was 1%.

Seventy-five percent of patients who had a poor clinical outcome also had a poor radiographic outcome, 35% of patients with a poor radiographic outcome had a major complication, and 37% of patients with a poor clinical outcome experienced a major complication.

Predictive Model for an Overall Poor Outcome

Factors associated with an overall poor outcome (radiographic, clinical, and complications/reoperation) included the following independent baseline predictors: osteoporosis, baseline neurological status, use of a transition rod, posterior decompression, pelvic tilt, T2–12 thoracic kyphosis, T1 slope, C2–T3 SVA, C2–T1 pelvic angle (C2 slope), global SVA, and higher number of levels in maximal thoracic kyphosis.

An overall poor outcome was predicted with high accuracy (AUC 86%) using the following combination of factors in the final model: presence of baseline neurological deficit, osteoporosis, baseline global SVA > 4 cm, > 9 levels in maximal thoracic kyphosis, baseline C2–T3 SVA > 5.4 cm, and baseline pelvic tilt $> 20^\circ$ (Table 6).

Case Examples

Figure 2 displays a case example of a 69-year-old male patient with CD with a prior anterior fusion who was now undergoing a posterior fusion from C2 to T4. His risk fac-

TABLE 3. Preoperative and postoperative radiographic assessment of the CD cohort compared between patients with and without an overall poor outcome

	Not Poor Outcome (n = 71)	Poor Outcome (n = 18)	p Value
Baseline radiographic parameter			
SVA, mm	-0.64 ± 61.45	15.41 ± 96.58	0.388
PT, °	20.77 ± 10.4	14.51 ± 16.33	0.047
PI-LL, °	2.7 ± 16.04	-4.47 ± 25.84	0.143
C2–7 CL, °	-8.16 ± 18.63	-3.12 ± 28.56	0.384
cSVA, mm	43.8 ± 25.79	54.39 ± 19.8	0.120
C2–T3 angle, °	-16.89 ± 18.71	-17.86 ± 28.13	0.866
C2–T3 SVA, mm	73.67 ± 40.7	94.31 ± 34.82	0.060
T4–12 thoracic kyphosis, °	-38.06 ± 15.63	-43.18 ± 16.94	0.225
TS-CL, °	36.42 ± 18.29	40.67 ± 22.84	0.424
C2 slope, °	36.61 ± 19.58	42.25 ± 23.7	0.317
1-yr radiographic parameter			
SVA, mm	23.36 ± 57.83	29.56 ± 106.53	0.744
PT, °	20.04 ± 11.11	14.19 ± 11.29	0.050
PI-LL, °	3.65 ± 17.49	-4.38 ± 21.16	0.099
C2–7 CL, °	7.54 ± 15.16	7.52 ± 18.08	0.996
cSVA, mm	39.35 ± 17.41	49.15 ± 16.65	0.040
C2–T3 angle, °	0.13 ± 15.86	-5.04 ± 23.25	0.281
C2–T3 SVA, mm	74.2 ± 27.3	89.01 ± 26.57	0.048
T4–12 kyphosis, °	-41.71 ± 15.5	-47.72 ± 13.68	0.147
TS-CL, °	25.91 ± 12.15	35.29 ± 14.29	0.007
C2 slope, °	24.84 ± 12.68	34.31 ± 16.24	0.011

Boldface type indicates statistical significance.

tors for a poor outcome included the following combination of factors: baseline neurological deficit (weakness, gait impairment, hand muscle atrophy), baseline C2–T3 SVA of 84.7 mm, baseline pelvic tilt of 18.1°, and 12 levels in maximal thoracic kyphosis. Postoperatively, this patient had worsening TS-CL (preoperative: 54.4°; postoperative:

72.4°) and cSVA (preoperative: 56.9 mm, postoperative: 61.9 mm) malalignment, and failed to reach MCID for the mJOA score (preoperative: 10; postoperative: 11), although his NDI score improved (preoperative: 84; postoperative: 68). This patient developed distal junctional kyphosis by 6 months postoperatively and required a reoperation.

A case example of a 63-year-old female CD patient with a prior thoracolumbar fusion who was now undergoing a posterior fusion from C5-T2 is shown in Fig. 3.

TABLE 4. Baseline health-related quality of life (HRQOL) scores and neurological status of the CD cohort

Metric	Mean or Frequency
Mean HRQOL score	
Baseline NDI	48.5 ± 16.7
Baseline EQ-5D	0.73 ± 0.06
Baseline mJOA	13.5 ± 2.7
Neurological status	
Bladder issues	11.2%
Bowel issues	4.5%
Gait impairment	38.2%
Hand clumsiness	36%
Hand numbness	54%
Lhermitte's sign	6.7%
Bilateral paresthesia	23.6%
Weakness	43.8%
No deficit	26%

TABLE 5. Breakdown of each category for the poor outcomes for CD patients

Poor Outcome	Frequency
Radiographic	
TS-CL	73%
cSVA	8%
Clinical	
Failed to meet EQ-5D MCID	80%
Failed to meet NDI MCID	60%
mJOA score <12	24%
Complications/reoperation	
Major complication	32%
Reop	12%
Death	1%

TABLE 6. Final predictive model for predicting an overall poor outcome in CI patients*

Model Predicting a Poor Outcome	OR	CI
Baseline neurological deficit†	11.4	1.8–70.8
Osteoporosis	5.9	0.9–39
Baseline global SVA >4 cm	3.2	0.9–10.3
>9 levels in maximal thoracic kyphosis	2.01	1.1–4.1
Baseline C2–T3 SVA >5.4 cm	1.01	0.9–1.1
Baseline PT >20°	0.92	0.85–0.98

* AUC = 86%.

† Gait impairment, hand numbness and clumsiness, and weakness were the most common.

Her risk factors for a poor outcome included the following combination of factors: osteoporosis, baseline C2–T3 SVA of 107.9 mm, baseline SVA of 131.8 mm, and 12 levels in maximal thoracic kyphosis. Postoperatively, this patient had residual TS-CL (preoperative: 53.9°; postoperative: 26.7°) and cSVA (preoperative: 47.9 mm; postoperative: 41.9 mm) malalignment, failed to reach MCID for mJOA (preoperative score: 13; postoperative score: 10) and NDI (preoperative score: 62; postoperative score: 54), and experienced a postdischarge major mental status change.

Discussion

Outcomes after CD surgery are variable, with complications occurring commonly in complex deformity correction cases. With increased age, high comorbidity burden, and increased frailty, these CD patients are at high

risk of experiencing poor outcomes after surgery. There is limited literature regarding the specific baseline demographic, clinical, and surgical factors that can be used to predict a poor overall outcome following CD surgery. Therefore, in this investigation we developed a predictive model for this CD cohort to predict poor radiographic and clinical outcomes as well as complications. In our cohort of CD patients, 20.2% of patients experienced an overall poor outcome.

An overall poor outcome was predicted with high accuracy (AUC 86%) using a combination of demographic, clinical, and surgical factors. In looking specifically at the radiographic poor outcome, we found that 73% of patients had a severe TS-CL, while only 8% of CD patients had a severe cSVA by the 1-year follow-up. This suggests that TS-CL better captures the deformity of these patients and should be used above cSVA to gauge CD.^{1,2} Additional preoperative radiographic predictors of a poor outcome included severe C2–T3 SVA, global (C7–S1) SVA, and pelvic tilt. Given that these predictors take into account the global deformity of the spine beyond the cervical spine, these results suggest that severe full-spine malalignment impacts outcomes following CD corrective surgery and should be addressed appropriately. One recent study of surgical CD patients demonstrated that both cervical and global radiographic parameters were predictive of the postoperative complication of distal junctional kyphosis in the CD cohort.¹⁵ Other studies have also shown that global alignment affects the cervical spine and that in a thoracolumbar deformity population, both cervical and global sagittal alignment parameters are predictive of worse CD.^{13,14} Additionally, the predictor showed that having more than 9 vertebral levels in the preoperative maximal

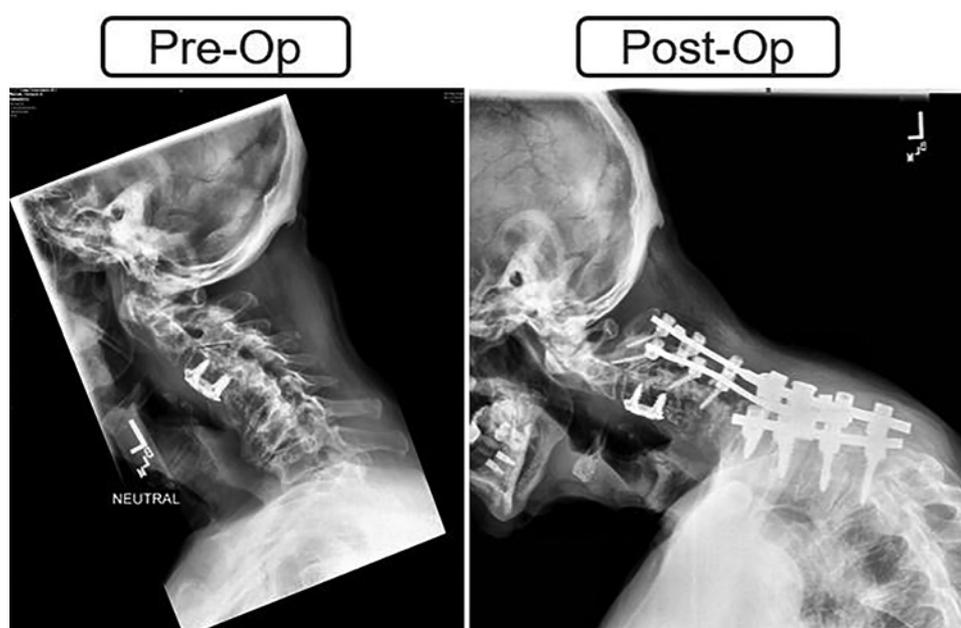


FIG. 2. Case example of a 69-year-old male patient with CD with a prior anterior fusion who underwent a posterior fusion from C2 to T4. His risk factors for a poor outcome included the following combination of factors: baseline neurological deficit (weakness, gait impairment, hand muscle atrophy), baseline C2–T3 SVA of 84.7 mm, baseline pelvic tilt of 18.1°, and 12 levels in his maximal thoracic kyphosis. Postoperatively, this patient had worsening TS-CL and cSVA malalignment, and failed to reach MCID for the mJOA score, but his NDI score improved. This patient developed distal junctional kyphosis by 6 months postoperatively and required a reoperation.

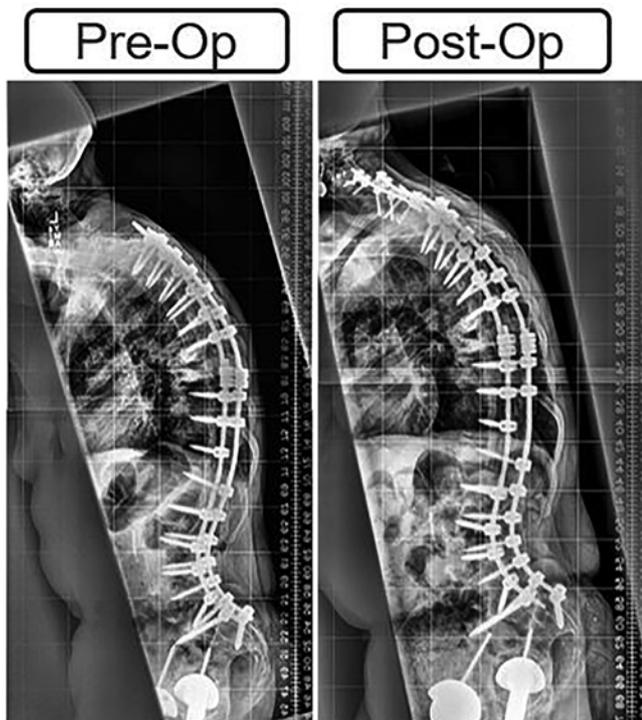


FIG. 3. Case example of 63-year-old female patient with CD with a prior thoracolumbar fusion who underwent a posterior fusion from C5 to T2. Her risk factors for a poor outcome included the following factors: osteoporosis, baseline C2–T3 SVA of 107.9 mm, baseline SVA of 131.8 mm, and 12 levels in her maximal thoracic kyphosis. Postoperatively, this patient had residual TS-CL and cSVA malalignment, failed to reach MCID for the mJOA and NDI scores, and experienced a postdischarge major mental status change.

thoracic kyphosis is an important consideration for surgical planning when determining the lowest instrumented vertebra and also in distal junctional kyphosis prediction in this cohort of patients.

Osteoporosis is a large problem globally, with more than 10 million individuals currently diagnosed, of whom about 80% are women.^{4,6,11} In our cohort of CD patients, osteoporosis was a strong predictor of a poor overall outcome (OR 5.9). Of our patients, 65% were women with an average age of 62 years, suggesting that this cohort is a high-risk group for osteoporosis. Previous studies on patients with degenerative thoracolumbar pathologies have shown a negative impact of osteoporosis on surgical outcomes given its impact on bone quality through negative bone remodeling and ultimate reduction in fusion rates and increased risk of fractures.^{3,7,8} However, limited literature exists that is specific to a CD population regarding the effects of osteoporosis on outcomes. This is the first study to date to report osteoporosis as a strong predictor of a poor overall outcome following CD corrective surgery. This highlights the important role of preoperative counseling and a multidisciplinary approach to osteoporotic patients to minimize poor outcomes.

Baseline neurological deficit was another significant predictor of an overall poor outcome, possibly resulting from changes in patients' neurological function and balance maintenance that might lead to altered postural alignment.

Their neurological compromise at baseline might also lead to decreased mobility, which would lead to a slower and poorer recovery. This could also in part be explained by the fact that the majority of these patients are elderly, with a high rate of osteoporosis and other age-related degenerative problems that can manifest in neurological symptoms such as cervical myelopathy. Additionally, a recent study demonstrated that CD has a substantial health impact on this population, with the CD patients in that study having a mean EQ-5D score that was comparable to the bottom 25th percentile of scores for other cohorts, including renal failure, stroke, and emphysema patients.²³ The substantial health impact of CD on these patients, in conjunction with previous studies that have shown that CD patients have a wide range of comorbidities and frailty indicators that put patients at risk for complications, could contribute to the occurrence of an overall poor outcome.⁹ It is also worth noting that although the rate of an overall poor outcome was 20.2%, when looking individually at the rates of a suboptimal outcome for each specific factor (radiographic, clinical, or complications/reoperation), the rates of poor outcomes are much higher. This study is investigating the worst possible outcome, where patients have severe radiographic and clinical outcomes, as well as a complication, reoperation, or death; however, the less-severe poor outcomes are still worth highlighting, given their negative effect on overall patient health.

Limitations

This study has several potential limitations. The retrospective nature of this study may in some ways limit our findings; however, the generalizability of our study is reasonable given the fact that the patients were enrolled from centers across the continental United States. Additionally, MR images were not available for all patients to assess pre- and postoperative muscle, disc, or ligamentous contributions to the deformity or neurological deficit. The EQ-5D is an overall health-related quality of life assessment tool, the mJOA scale is validated for use in myelopathy patients, and the NDI is not CD-specific. Thus, our results might suggest that the common outcome assessment tools used in the CD literature are not entirely appropriate to capture clinical improvement for CD patients. This study is also in part limited by the lack of granularity regarding neurological abnormalities. Additionally, selection bias may limit the study, as there were only 13 study centers over a 5-year period, not all patients were enrolled, and 65 patients were lost to follow-up. Future research should evaluate the combination of risk factors for improved predictive strength and to glean a better understanding of the relationship of these factors in combination that predicts a poor outcome after CD surgery.

Conclusions

A total of 20.2% of CD patients had an overall poor outcome by 1 year postoperatively, defined as severe radiographic alignment, a poor clinical outcome, and a complication, reoperation, or death. A poor outcome was predicted with high accuracy using a combination of clinical, neurological, surgical, and radiographic factors, most

notably osteoporosis, global SVA, and C2–T3 SVA. These results may assist in preoperative risk assessments and counseling for patients and surgeons in an attempt to mitigate the rates of poor outcomes in this population.

Appendix

Members of ISSG Involved in This Study

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 Ms. Horn: consultant for Medicea and SpineWave; scientific advisory board and speaking/teaching for Allosource, Zimmer Biomet, and Globus; and support of non–study-related clinical or research effort from CSFS and Aesculap. Dr. Lafage: direct stock ownership in Nemarix Inc.; speaking/teaching arrangements with AOSpine and DePuy Spine; and support of non–study-related clinical or research effort from DePuy Spine, NuVasive, K2M, and Stryker paid through ISSG and grants from SRS and NASS. Dr. Smith: consultant for K2M, AlloSource, Cerapedics, Zimmer Biomet, and NuVasive; support of non–study-related clinical or research effort from DePuy/Synthes/ISSG; royalties from Zimmer Biomet; and fellowship funding from NREF and AOSpine. Mr. Line: consultant for ISSG and AlloSource. Dr. Anand: consultant for Medtronic, direct stock ownership in Medtronic and Globus Medical, patent holder with Medtronic, and royalties from Globus Medical. Dr. Deviren: consultant for NuVasive, SeaSpine, Medi-

crea, Pfizer, Biomet, Guidepoint, and Alphatec and royalties from NuVasive. Dr. Mummaneni: consultant for Stryker; employee of UCSF, royalties from DePuy, honorarium from Globus, ownership in ISD/Spinicity, and grants from AANS/CNS/AOSpine and NREF. Dr. Daniels: consultant for Spineart, Stryker, and Orthofix and royalties from Springer. Dr. Park: consultant for Globus, NuVasive, Medtronic, and Allosource and royalties from Globus. Dr. Nunley: consultant for K2M; direct stock ownership in Amedica, Paradigm, and Spineology; patent holder with K2M and LDR/Zimmer Biomet; speakers bureau for K2M and LDR/Zimmer Biomet; Dr. Klineberg: consultant for DePuy Synthes, Stryker, Springer, Trevena, and Allosource; honoraria from K2M and AOSpine; and fellowship grant from AOSpine. Dr. Burton: consultant for Allosource and support of non-study-related clinical or research effort from Pfizer and DePuy. Dr. Schwab: consultant for MSD, K2M, Zimmer Biomet, NuVasive, and Medtronic; direct stock ownership in Nemaris Inc.; patent holder with MSD and K2M; support of non-study-related clinical or research effort from DePuy Spine, Stryker, K2M, and NuVasive (paid through ISSG); and speaking/teaching arrangements with MSD, K2M, NuVasive, and Zimmer Biomet. Dr. Bess: consultant for K2M and Allosource; royalties from K2M; and support of non-study-related clinical or research effort from K2M, Innovasis, NuVasive, DePuy, and Stryker. Dr. Shaffrey: consultant for Medtronic and NuVasive; direct stock ownership in NuVasive; and patent holder with Medtronic, NuVasive, and Zimmer Biomet. Dr. Ames: employee of UCSF; consultant for Medtronic, Stryker, Medtronic, K2M, and DePuy Synthes; and royalties from Stryker, Biomet Spine; DePuy Synthes; NuVasive; and Next Orthosurgical.

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Supplemental Information

Previous Presentations

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