Original Article

What are the major drivers of outcomes in cervical deformity surgery?

ABSTRACT

Background Context: Cervical deformity (CD) correction is becoming more challenging and complex. Understanding the factors that drive optimal outcomes has been understudied in CD correction surgery.

Purpose: The purpose of this study is to assess the factors associated with improved outcomes (IO) following CD surgery.

Study Design/Setting: Retrospective review of a single-center database.

Patient Sample: Sixty-one patients with CD.

Outcome Measures: The primary outcomes measured were radiographic and clinical "IO" or "poor outcome" (PO). Radiographic IO or PO was assessed utilizing Schwab pelvic tilt (PT)/sagittal vertical axis (SVA), and Ames cervical SVA (cSVA)/TS-CL. Clinical IO or PO was assessed using MCID EQ5D, Neck Disability Index (NDI), and/or improvement in Modified Japanese Orthopedic Association Scale (mJOA) modifier. The secondary outcomes assessed were complication and reoperation rates.

Materials and Methods: CD patients with data available on baseline (BL) and 1-year (1Y) radiographic measures and health-related quality of life s were included in our study. Patients with reoperations for infection were excluded. Patients were categorized by IO, PO, or not. IO was defined as "nondeformed" radiographic measures as well as improved clinical outcomes. PO was defined as "moderate or severe deformed" radiographic measures as well as worsening clinical outcome measures. Random forest assessed ratios of predictors for IO and PO. The categorical regression models were utilized to predict BL regional deformity (Ames cSVA, TS-CL, horizontal gaze), BL global deformity (Schwab PI-LL, SVA, PT), regional/global change (BL to 1Y), BL disability (mJOA score), and BL pain/function impact outcomes.

Results: Sixty-one patients met inclusion criteria for our study (mean age of 55.8 years with 54.1% female). The most common surgical approaches were as follows: 18.3% anterior, 51.7% posterior, and 30% combined. Average number of levels fused was 7.7. The mean operative time was 823 min and mean estimated blood loss was 1037 ml. At 1 year, 24.6% of patients were found to have an IO and 9.8% to have a PO. Random forest analysis showed the top 5 individual factors associated with an "IO" were: BL Maximum Kyphosis, Maximum Lordosis, C0-C2 Angle, L4-Pelvic Angle, and NSR Back Pain (80% radiographic, 20% clinical). Categorical IO regression model (R^2 = 0.328, P = 0.007) found following factors to be significant: low BL regional deformity (β = –0.082), low BL global deformity (β = –0.099), global improve (β = 0.532), regional improve (β = 0.230), low BL disability (β = 0.100), and low BL NDI (β = 0.024). Random forest found the top 5 individual BL factors associated with "PO" (80% were radiographic): BL CL Apex, DJK angle, cervical lordosis, T1 slope, and NSR neck pain. Categorical PO regression model (R^2 = 0.306, P = 0.012) found following factors to be significant: high BL regional deformity (β = –0.108), high BL global deformity (β = –0.255), global decline (β = 0.272), regional decline (β = 0.443), BL disability (β = –0.164), and BL severe NDI (>69) (β = 0.181).

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Conclusions: The categorical weight demonstrated radiographic as the strongest predictor of both improved (global alignment) and PO (regional deformity/deterioration). Radiographic factors carry the most weight in determining an improved or PO and can be ultimately utilized in preoperative planning and surgical decision-making to optimize the outcomes.

Keywords: Cervical deformity, patient reported outcomes, radiographic outcomes

INTRODUCTION

Cervical deformity (CD) refers to malalignment of the normal lordotic curve of the cervical spine with the most common CD being cervical kyphosis.[1] Smith *et al*. attempts to define CD as at least one of the following: cervical kyphosis, cervical scoliosis, C2-7 cervical sagittal vertical axis (cSVA) >4 cm, or chin-brow vertical angle (CBVA) >25°.[2] There are multiple etiologies of CD which can result in pain or possibly neurologic or physical impairment.[3]

Indications for surgical deformity correction are not well defined. Indications include progressive myelopathy, severe radiculopathy, other severe neurologic deficit, and severe functional impairment (i.e., dysphagia), severe mechanical pain, and progressive kyphotic deformity.[4-6] Surgical management attempts to relieve pain, decompress neurologic elements, realign the cervical spine, improve horizontal gaze, and improve function. The outcomes of CD correction are poorly defined.[7] Greater degree of surgical CD correction has been associated with improved patient-reported outcomes.[8] Radiographic cervical parameters have been previously correlated with patient outcomes. One study found significant correlation between baseline (BL) C2-7 SVA values of 5 cm or more and worse outcomes on health-related quality of life (HRQL) assessments.[9] In addition, positive sagittal malalignment has been linked to poor Neck Disability Index (NDI) scores.[10]

Recent study showed myelopathy to be a strong independent driver of patient-oriented outcome measures.[11] This retrospective study attempts to use full BL and 1-year (1Y) radiographic measures as well as HRQL measures to predict if a patient will have an “improved outcome (IO),” “poor outcome (PO),” or “null outcome.”

MATERIALS AND METHODS

Data overview

Patients with a clinical diagnosis of cervical spine deformity, greater or equal to 18 years of age, undergoing cervical fusion procedures by a single spine surgeon were included in the dataset. The database required radiographic evidence of CD, defined as cervical kyphosis (C2-7 sagittal Cobb angle >10°), cervical scoliosis (C2-C7 coronal Cobb angle >10°), C2-C7 SVA (C2-C7 SVA) >4 cm, or CBVA >25°, measured with preoperative radiographs. Institutional Review Board approval was obtained prior to enrolment and every patient gave consent before data collection.

Patients included underwent a cervical osteotomy and had full BL and 1-year radiographic and HRQL data. Those who underwent reoperation for an infection were excluded.

Data collection

Basic BL data were collected before operative intervention, including age, gender, body mass index, and comorbidity burden (otherwise described as the Charlson Comorbidity Index).

Surgical data were also collected for the analysis, such as total number of levels fused, surgical approach, decompression type, and osteotomy type: Three column osteotomy, Ponte osteotomy, and facet osteotomy. Patient-reported outcomes were collected and recorded in the dataset, including the NDI, Modified Japanese Orthopedic Association Scale (mJOA), and Euro-QOL 5-Dimension questionnaire (EQ5D).

BL up to 1-year postoperative radiographs were measured using validated software programming (SpineView; ENSAM Laboratory of Biomechanics, Paris, France) at a single academic center. Cervical sagittal alignment and balance was evaluated using C2-7 Cobb angle for cervical lordosis (CL: angle between the lower endplates of C2 and C7), cSVA (cSVA: C2 plumb line offset from the postero-superior corner of C7), and the mismatch between T1 slope and CL (TS-CL). Global sagittal alignment measures assessed included thoracic kyphosis (TK: angle between the lower endplates of T4 and T12), lumbar lordosis (LL: angle between the lower endplates of L1 and S1).

Outcome measures

Patients were classified as having a postoperative IO, PO or null outcome. To define these outcome measures, patients were required to have three categories fulfilled of radiographic outcome, clinical outcome, and complication/reoperation outcome. The radiographic outcomes were classified as the software requirements specification (SRS)-Schwab adult spinal deformity severity modifiers and the Ames-ISSG CD modifiers. The clinical outcomes were derived from the HRQLs of NDI, mJOA and EQ5D. Finally, the complication/reoperation outcome depended on the presence or absence of a postoperative complication or reoperation.

An IO was defined as improved in all three outcomes: radiographic, clinical, and complication/reoperation. The radiographic outcome for the IO patients included having a 1-year postoperative "0" SRS-Schwab modifier category for (pelvic tilt [PT] <20°) and SVA (SVA <4 cm), along with a "0" Ames-ISSG cSVA (cSVA <4 cm) and T1 slope minus cervical lordosis (TS-CL <15°). Their clinical outcome required having met the minimal clinically important difference for EQ5D (a BL to 1-year difference of >0.09) and NDI (a BL to 1-year difference of <15), as well as improvement in the patient's Ames-ISSG mJOA modifier. For the last category, these patients did not have a postoperative complication or reoperation.

For the PO, the opposite of every category was utilized for definition. The radiographic outcome had + or ++ SRS-Schwab PT and SVA modifier severity (>20° and >4 cm, respectively, as well as "1" or "2" 1-year Ames-ISSG cSVA and TS-CL modifier severity (>4 cm and 15°, respectively). The clinical outcome for PO had no patients meeting MCID for either EQ5D or NDI, as well as worsening in their Ames-ISSG mJOA modifier. Meanwhile, these patients did experience a complication or reoperation after their procedure.

Statistical analysis

Descriptive statistics provided basic means and characteristics of our patient cohort. Chi-square analyses assessed significance of categorical variables. Random forest assessment generated 10,000 conditional inference trees to determine the top five preoperative factors associated with an outcome (IO and PO).

Categorical linear regression model predicted the following impact on our IO and PO: BL regional deformity, BL global deformity, regional change, global change, BL disability, and BL pain function. BL regional deformity was defined via the Ames-ISSG CD modifiers, where preoperative Low deformity was a "0" in cSVA, TS-CL, and CBVA modifiers, while High was "2" Ames-ISSG severity in cSVA and TS-CL modifiers. BL global deformity was defined as the SRS-Schwab modifiers of "0" SVA, PI-LL and PT at BL for Low, and High for "++" in those radiographic parameters. Regional change was defined as BL to 1-year improvement ("1" or "2" to a respective "0" or "1") or decline ("0" or "1" to a respective "1" or "2") in Ames-ISSG modifier severity. Global change included BL to 1-year improvement (+ or ++ to a respective "0" or +) or decline ("0" or + to a respective + or ++) in SRS-Schwab modifier severity. BL disability was defined via mJOA scores, where Low was a "0" and High as "1" or "2" in Ames-ISSG modifier severity. Finally, the BL Pain/Function category was defined via the BL NDI scores, where low included those who had preoperative scores from 0 to 28, and severe as >50.

All statistic tests were run on the Statistical Analysis was performed using SPSS software (v21.0, Armonk, NY, USA), with a $P < 0.05$ noted as statistically significant.

RESULTS

Cohort overview

At 1 year, 24.6% were classified with an IO and 9.8% of the cohort had a PO. Overall, there were 61 patients included in our study. The mean age for the cohort was 55.8 years, with 54.1% as female. The surgical approach breakdown included 18.3% as anterior approach, 51.7% posterior approach, and 30% who underwent combined anterior-posterior approach. The average total levels fused was 7.7, with mean operative time of 823 min. Estimated blood loss for the cohort averaged around 1037 ml.

Radiographic overview

Patients presented radiographically at BL with an average PT of 16.2 ± 8.02, PI-LL of-3.46 ± 11.9, SVA: –5.05 ± 59.8, TS-CL: 23.0 ± 14.1; cSVA: 26.8 ± 15.7. At 1 year post operatively, patients presented with an average PT of 13.4 ± 7.34, PI-LL of –5.47 ± 13.6, SVA:-4.70 ± 40.8, TS-CL: 21.0 ± 8.26; cSVA: 25.7 ± 10.7.

Random forest variables

Our random forest with conditional inference tree analysis showed the top five individual factors associated with those that were classified with an IO were: BL maximum kyphosis, BL maximum lordosis, C0-C2 angle, L4 pelvic angle, and NRS back pain. This amounted to 80% radiographic factors and 20% clinical.

The random forest for the PO demonstrated the top five individual BL factors to be 80% radiographic and 20% clinical. These factors included BL cervical lordosis apex, the DJK angle, cervical lordosis, T1 slope, and BL NRS neck pain.

Categorical regression models

The IO categorical regression model had an R^2 value of 0.328 ($P = 0.007$), including low BL regional deformity ($\beta = -0.082$), low BL global deformity ($\beta = -0.099$), global improvement ($\beta = 0.532$), regional improvement ($\beta = 0.230$), low BL disability ($\beta = 0.100$), and low BL NDI ($\beta = 0.024$).

Categorical PO regression model demonstrated an R^2 value of 0.306 ($P = 0.012$), comprised of high BL regional deformity ($\beta = -0.108$), high BL global deformity ($\beta = -0.255$), global decline ($\beta = 0.272$), regional decline ($\beta = 0.443$), high BL disability ($\beta = -0.164$), and BL severe NDI (>69) ($\beta = 0.181$).

DISCUSSION

Restoration of cervical sagittal alignment is challenging, complex, and poses risk for major complications as well as poor patient-reported outcomes. Although outcomes can range widely, CD corrective surgery results in overall high patient satisfaction and appears to be an effective option when conservative measures fail.[1,2] Understanding the factors that drive optimal outcomes has been understudied in CD corrective surgery. Previous research has revealed the determinants of patient outcomes are multifactorial and include a combination of patient, surgical, and radiographic parameters.[2] In our study of 61 patients undergoing CD correction, we found that radiographic factors carry the most weight in determining an IO or PO. Our findings can ultimately be utilized in preoperative planning and surgical decision-making to optimize the outcomes.

In the present study, random forest demonstrated the top 5 individual factors associated with IO to be BL maximum kyphosis, BL maximum lordosis, C0-C2 angle, L4 pelvic angle, and NSR back pain. Furthermore, random forest demonstrated the top five individual factors associated with PO to be BL CL Apex, DJK angle, cervical lordosis, T1 slope, and NSR neck pain. These define the variables of highest yield for the spine surgeon as it pertains to predicting patient outcomes after CD correction surgery.

Few studies have attempted to characterize the determinants of outcomes following CD corrective surgery. A study by Tang *et al*. found disability of the neck increases with progressive cervical malalignment. Specifically, they found a correlation between cSVA >40 mm and worse outcomes on HRQL measures.[3] It has been found that postoperative improvements in cervical regional alignment positively correlate with improves HRQL measures.[4] Smith *et al*. found residual global sagittal malalignment (C7-S1 SVA) was associated with worse outcomes based on NDI2. Furthermore, a study by Passias *et al*. demonstrated the relationships between myelopathy, global sagittal realignment, and HRQL measures following CD correction. They concluded that improvement in myelopathy symptoms, as assessed by mJOA, is a key driver of patient-reported outcomes following corrective surgery and demonstrates the importance of correcting sagittal alignment in these patients.[5] However, Kato *et al*. found no significant differences in postoperative outcomes regardless of achievement of deformity correction in patients with myelopathy, and concludes aggressive realignment in these patients may not be necessary.[6] One contributing factor to this inconsistency may be related to current HRQL metrics not being deformity-specific. Current metrics can fail to fully assess a patient's deformity and outcomes, making analysis of CD patients challenging and unreliable.[8]

Researchers have previously explored determinants of poor operative outcomes. One such study by Protopsaltis *et al*. prospectively attempted to characterize factors leading relating to failure to radiographically correct cervical alignment. Failure to correct cSVA was associated with revision surgery, worse preoperative C2 PT angle, concurrent thoracolumbar deformity, and failure to correct secondary, thoracolumbar drivers of deformity. Early postoperative DJK was also a major determinant of these radiographic failures.[9] Further studies have similarly determined that the location and subsequent correction of the primary driver of the deformity is an important determinant for clinical and radiographic outcomes.[10] Furthermore, a recent study by Bortz *et al*. determined severe preoperative malalignments were the strongest indicators of nonroutine discharge following corrective surgery. These preoperative alignments included C1 Slope >14, TS-CL ≥57, and cSVA ≥40 mm 10.

In the present study, we found radiographic factors to carry the most weight in determining an improved or PO. In both IO and PO groups, change in global (SRS-Schwab modifier severity) and regional (Ames modifier severity) radiographic measures from BL to 1-year following surgery most strongly correlated with operative outcome. This was more strongly correlated than BL radiographic measures and clinical HRQL measures. Therefore, it is believed that these radiographic measures are the key drivers of outcomes.

This study has accompanying limitations due to its retrospective nature and relatively small patient population. In addition, there is not currently a CD specific outcomes measure; therefore, more general measures needed to be used to assess patient outcomes. We highlight the most significant factors associated with IOs after CD correction surgery. Furthermore, based on our results, we found that radiographic variables carry more predictive value in terms to outcomes as compared to preoperative clinical variables. Clinical research in this area is sparse, and further studies are needed to fully characterize the determinants of outcomes in CD corrective surgery.

CONCLUSION

Categorical weight demonstrated radiographic as the strongest predictor of both improved (global alignment) and poor outcome (regional deformity/deterioration). Radiographic factors carry the most weight in determining an improved or poor outcome, and can be ultimately utilized in pre-operative planning and surgical decision making in order to optimize outcomes.

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Conflicts of interest

Peter G Passias MD – Reports personal consulting fees for Spinewave, Zimmer Biomet, DePuy Synthes, and Medicrea outside the submitted work.

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