

PROMIS physical health domain scores are related to cervical deformity severity

ABSTRACT

Introduction: The aim of this study was to evaluate the association of available cervical alignment components through the Ames cervical deformity (CD) classification parameters with the Patient-Reported Outcomes Measurement Information System (PROMIS) physical health domain metrics.

Methods: Surgical CD patients (C2–C7 Cobb $>10^\circ$ or C2–C7 sagittal vertical axis [cSVA] >4 cm or T1 slope minus cervical lordosis (TS-CL) $>15^\circ$) ≥ 18 years with available baseline (BL) radiographic and PROMIS were isolated in a single-center spine database. Patients were classified according to the Ames CD modifiers for cSVA and TS-CL (low deformity [Low], moderate deformity [Mod], and severe deformity [Sev]). Descriptives and univariate analyses compared population-weighted PROMIS scores for Pain Intensity (PI), Physical Function (PF), and Pain Interference (Int) across CD modifiers. Conditional tree analysis with logistic regression sampling determined the threshold of PROMIS scores for which the correlation with Ames radiographic cutoffs was most significant. Reported cutoff values for Mod (cSVA: 4–8 cm; TS-CL: 15–20°) and Sev (cSVA: >8 cm; TS-CL: $>20^\circ$) disabilities were used.

Results: Two hundred and eight patients (58.8 years, female: 51%, 29.6 kg/m², Charlson Comorbidity Index: 1.19). BL cSVA modifier by severity: 83.2% Low, 16.8% Mod. No patients met criteria for severe cSVA. BL TS-CL modifier by severity: 18.8% Low, 22.1% Mod, 59.1% Sev. Mean baseline PROMIS scores were as follows: PI score: 89.6 ± 15.4 , PF score: 11.9 ± 13.1 , Int score: 56.9 ± 6.8 . PI did not differ between cSVA and TS-CL severity. Mod cSVA patients and Mod/Sev TS-CL modifier groups trended toward lower PF scores and higher Int scores. A PI score of >96 (odds ratio [OR]: 0.658 [0.303–1.430]), a PF score of <14 (OR: 1.864 [0.767–4.531]), and an Int score of >57.4 (OR: 1.878 [0.889–3.967]) were predictors of Mod cSVA. A PI score of >87 (OR: 1.428 [0.767–2.659]), a PF score of <14 (OR: 1.551 [0.851–2.827]), and an Int score of >56.5 (OR: 1.689 [0.967–2.949]) were predictors of Sev TS-CL.

Conclusions: PROMIS physical health domains were related to the Ames CD classification. Certain BL PROMIS thresholds can be connected to the severity of CD.

Keywords: Ames classification, cervical deformity, health-related quality of life, Patient-Reported Outcomes Measurement Information System

KATHERINE E PIERCE, HADDY ALAS, AVERY E BROWN, COLE A BORTZ, BROOKE O'CONNELL¹, DENNIS VASQUEZ-MONTES¹, BASSEL G DIEBO², RENAUD LAFAGE³, VIRGINIE LAFAGE³, AARON J BUCKLAND¹, PETER G PASSIAS

Departments of Orthopaedic and Neurosurgery, Division of Spinal Surgery, NYU Medical Center, NY Spine Institute, ¹Department of Orthopaedic Surgery, NYU Langone Orthopedic Hospital, ²Department of Orthopedic Surgery, SUNY Downstate, ³Department of Orthopaedics, Hospital for Special Surgery, New York, NY, USA

Address for correspondence: Dr. Peter G Passias, Departments of Orthopaedic and Neurosurgery, Division of Spinal Surgery, NYU Medical Center, NY Spine Institute, New York, NY, USA.
E-mail: pgpassias@yahoo.com


INTRODUCTION

Evaluation and treatment of cervical deformities is challenging, due to its heterogeneous malalignment and symptomatic presentation. To effectively diagnose and treat the condition, a classification system of deformity severity was proposed by Ames and the International Spine Study Group (ISSG) and stands as the most widely studied novel system for classifying CD.^[1] Comprised of sagittal, regional, and global alignment aspects, the parameters in the

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Ames-ISSG classification include moderate and severe cutoffs, the mismatch between T1 slope and cervical lordosis, C2–C7 sagittal vertical axis (cSVA), horizontal gaze, myelopathy severity, and the SRS-Schwab Classification for adult spinal deformity.^[1]

However, in order for proper recommendation and validation of the classification system, the suggested radiographic alignment cutoffs must have a relationship with patient-reported outcomes (health-related quality of life [HRQLs]).^[2] There has been progress in understanding the relationship between cervical sagittal malalignment and HRQLs, including the 36-Item Short-Form Health Survey (SF-36) and the Neck Disability Index (NDI).^[3] NDI remains as the most commonly employed metric of evaluating neck pain for patients undergoing cervical deformity (CD) corrective surgery.^[4] However, this modality has an inherent drawback: the NDI may be altered by the presence of parallel pain and dysfunction in the spine regions adjacent to the cervical spine.^[5] The NDI also lacks a strong connection to the CD disease itself, by rather assessing the cervical spine pathology as a whole, affecting its overall reliability and reproducibility in this condition.^[6] These factors suggest the need for a novel approach to gathering patient-reported outcomes.

Pioneered by the National Institutes of Health, the Patient-Reported Outcomes Measurement Information System (PROMIS) uses computerized adaptive testing to effectively capture patient outcomes.^[7] The system algorithmically selects question items based on previous responses, allowing for a more precise and efficient modality of patient symptom reporting.^[8] There are three domains in the PROMIS outcome assessment that has been connected to established patient outcome metrics: Pain Intensity (PI), Physical Function (PF), and Pain Interference. The PROMIS domain of PF specifically has been shown to negatively correlate with the NDI.^[9,10] However, there is a paucity in the literature investigating the relationship between PROMIS physical health domain metrics and established Ames CD radiographic classification.

This study aimed to assess the association of available cervical alignment components through the Ames CD classification parameters with PROMIS physical domains to evaluate the PROMIS metric in CD severity classification.

METHODS

Study design and data source

This is a retrospective analysis of a database containing spine patients presenting to a single academic institution from September 2012 to June 2018. Institutional Review Board

approval was obtained. The study inclusion criteria required operative CD patients, greater than 18 years of age with available baseline (BL) radiographic and PROMIS data. CD was defined as the presence of one of the following radiographic criteria: C2–C7 Cobb angle $>10^\circ$ or C2–C7 sagittal vertical axis >4 cm or TS-CL >15 , in addition to a clinical diagnosis of deformity.

Data collection

Demographic and clinical information was collected including age, sex, body mass index (BMI), comorbidities, and the Charlson Comorbidity Index (CCI) scores at the time of initial presentation. Operative data were reviewed per surgical medical records including surgical approach, fusion status, total operative time, and estimated blood loss (EBL). The following outcome assessments were administered through a tablet at BL: PROMIS instruments of PI, Pain Interference, and PF. These PROMIS instruments use a computer-adaptive algorithm to assess patient-reported capability, where each questionnaire item is selected based on previous item answers. Each of the PROMIS domains score on a scale from 0 to 100, where higher Pain Intensity and Pain Interference scores indicate inferior outcomes and higher Physical Function score indicates superior outcomes.

Radiographic analysis utilized full-length free-standing lateral spine radiographs (36' long cassette) at BL. Validated software (SpineView®; ENSAM, Laboratory of Biomechanics, Paris, France) investigated the images at a single center with standard techniques. The parameters explored included the regional cervical alignment parameters of cSVA and the mismatch between the T1 slope and C2–C7 lordosis (TS-CL).

Statistical analysis

Descriptive analyses determined the overall cohort's demographic and surgical profile. Patients were classified according to the CD classification proposed by Ames and the ISSG. The modifiers assessed in this study included cSVA and TS-CL. Each modifier encompasses cutoffs for low deformity (Low), moderate deformity (Mod), and severe deformity (Sev). Proposed cutoff values for Low (cSVA: <4 cm, TS-CL: $<15^\circ$), Mod (cSVA: 4–8 cm; TS-CL: $15\text{--}20^\circ$), and Sev (cSVA: >8 cm; TS-CL: $>20^\circ$) disabilities were used in the present analysis. Mean comparison and analysis of variance assessed differences between population-weighted PROMIS scores for Pain Interference, PI, and PF across CD modifiers. Random forest analysis generated 20,000 conditional inference trees to determine the cutoff values of possible thresholds of PROMIS scores for which the correlation with Ames radiographic cutoffs for cSVA and TS-CL had the lowest *P* value. This was accomplished through the iteration of multivariate regression equations. All statistical analyses were

run using the R statistical software package (R, version 3.2., R Foundation for Statistical Computing, Vienna, Austria) of the SPSS software (v23.0, Armonk, NY, USA). All analyses were two-sided, and the level of significance was set to $P < 0.05$.

RESULTS

Cohort demographic and surgical overview

Two-hundred and eight CD patients met the study inclusion criteria. The mean age was 58.8 years, with a mean BMI of 29.6 kg/m², and 51% of patients were female. The mean CCI score was 1.19, where 46.2% of patients had a history of hypertension, 15.9% had diabetes mellitus, and 3.4% had chronic obstructive pulmonary disease. At BL, the average PROMIS scores were 89.6 ± 15.4 for PI, 11.9 ± 13.1 for PF, and 56.9 ± 6.8 for Pain Interference.

Overall, 66.8% of patients underwent fusion, with an average number of levels fused of 3.7 ± 4.2. By surgical approach, 79.3% of cases were posterior only, 5.7% were anterior only, and 14.9% were combined. The mean operative time was 231.2 ± 147.7 min, and the mean EBL was 451.5 ± 795.9 ccs.

Cohort by Ames-International Spine Study Group modifiers

The average cSVA for the cohort was 28.5 ± 13.3 mm (categorized as Low modifier), whereas TS-CL was 23.5 ± 9.31° (Sev). BL cervical cSVA Ames-ISSG modifier by severity: 83.2% Low and 16.8% Mod, where no patients met radiographic criteria for severe cSVA modifier. TS-CL Ames-ISSG modifier by severity included 18.8% Low, 22.1% Mod, and 59.1% Sev.

Relationship between Ames-International Spine Study Group modifiers and Patient-Reported Outcomes Measurement Information System

PROMIS domain scores for PI did not differ between cSVA and TS-CL modifier severity groups. Mod cSVA patients and Mod/Sev TS-CL modifier groups both trended toward lower PF scores and higher Pain Interference scores, though this was not statistically significant ($P > 0.05$). Scores across cSVA and TS-CL Ames-ISSG severity groups are listed in Table 1.

Reported Outcomes Measurement Information System thresholds by Ames-International Spine Study Group modifiers

Conditional tree analysis determined thresholds for PROMIS scores that were independent predictors of modifier severity. cSVA cutoffs were found for Low-to-Mod severity of CD Ames-ISSG modifiers, due to the inherent lack of the severe deformity category in the present cohort. A PI score of >96 (odds ratio [OR]: 0.658 [0.303–1.430]), a PF score of <14 (OR: 1.864 [0.767–4.531]), and a Pain Interference

Table 1: Average Patient-Reported Outcomes Measurement Information System scores of Pain Intensity, Physical Function, and Pain Interference across Ames-International Spine Study Group cervical deformity modifiers, C2–C7 sagittal vertical axis, and T1 slope and C2–C7 lordosis

PROMIS domain	Low deformity	Moderate deformity	Severe deformity	P
cSVA				
Pain Intensity	89.8±14.9	88.9±17.8	-	0.744
Physical Function	12.1±13.1	11.0±13.4	-	0.663
Pain Interference	56.8±6.6	11±13.4	-	0.692
TS-CL				
Pain Intensity	86.3±19.9	91.9±10.3	89.8±15.3	0.248
Physical Function	13.4±14.4	11.9±13.5	11.4±12.6	0.704
Pain Interference	56.1±8.5	57±6.6	57.2±6.4	0.668

cSVA - C2–C7 sagittal vertical axis; TS-CL - T1 slope and C2–C7 lordosis; PROMIS – Patient-Reported Outcomes Measurement Information System

score of >57.4 (OR: 1.712 [0.811–3.616]) were predictors of Mod cSVA. While cutoffs of ≤96 for PI, PF >14, and <57.4 Pain Interference for Low cSVA.

A PI score of >87 (OR: 1.428 [0.767–2.659]), a PF score of <14 (OR: 1.551 [0.851–2.827]), and a Pain Interference score of >56.5 (OR: 1.689 [0.967–2.949]) were predictors of Sev TS-CL. Moderate TS-CL deformity severity thresholds for PROMIS domains were as follows: 83–87 for PI, 15–27 for PF, and 31–56.5 for Pain Inference. A PI score of <83, PF score of ≥28, and Pain Interference score of <31 were the thresholds for Low TS-CL deformity. All ordinal regression values and thresholds for PROMIS scores are shown in Table 2.

DISCUSSION

With the increased incidence of CD diagnoses and the development of severity classification systems, such as the one proposed by Ames and the ISSG, modalities by which deformity can be assessed are vital to proper treatment.^[1] There is currently a lack of a CD-specific patient outcome measurement.^[6] The NDI legacy questionnaire is the most common metric for evaluating CD quality of life, but the PROMIS item banks offer less item redundancy and alteration by proximal regions of the spine, as well as lower administrative burden.^[5] PROMIS tools have been validated in various orthopedic subspecialties and have outperformed traditional legacy HRQLs.^[11–14] Specifically, the PROMIS metric has been found to have a strong correlation with the NDI and is presented in the literature as a superior modality to quantifying neck pain.^[10,15] Thus, the main goal of this study was to assess the relationship between the PROMIS metric and the Ames CD classification system.

There have been few studies to measure the relationship between Ames cervical radiographic parameters and

Table 2: Ordinal regression values and thresholds for Patient-Reported Outcomes Measurement Information System physical domains of Pain Intensity, Physical Function, and Pain Interference by the Ames-International Spine Study Group cervical deformity modifiers, C2-C7 sagittal vertical axis, and T1 slope and C2-C7 lordosis

Ames modifier	PROMIS domain	Modifier severity	Cutoff	OR	Lower CI	Upper CI	P
cSVA	Pain Intensity	Low	≤96	1.519	0.699	3.297	0.291
		Moderate	>96	0.658	0.303	1.430	0.291
	Physical Function	Low	≥14	0.536	0.221	1.303	0.169
		Moderate	<14	1.864	0.767	4.531	0.169
	Pain Interference	Low	≤57.4	0.532	0.252	1.125	0.099
		Moderate	>57.4	1.878	0.889	3.967	0.099
TS-CL	Pain Intensity	Low	<83	2.569	1.090	6.053	0.031
		Moderate	83-87	1.796	0.721	4.475	0.209
		Severe	>87	1.428	0.767	2.659	0.261
	Physical Function	Low	≥28	2.649	1.034	6.788	0.042
		Moderate	15-27	2.506	1.117	5.620	0.026
		Severe	≤14	1.551	0.851	2.827	0.152
	Pain Interference	Low	<31	9.081	0.802	102.811	0.075
		Moderate	31-56.5	1.526	0.790	2.946	0.209
		Severe	>56.5	1.689	0.967	2.949	0.065

cSVA - C2-C7 sagittal vertical axis; TS-CL - T1 slope minus C2-C7 lordosis; PROMIS - Patient-Reported Outcomes Measurement Information System; OR - Odds ratio; CI - Confidence interval

HRQLs.^[16-18] Recently, Passias *et al.* found no significant relationship between the Ames-ISSG modifiers and the modified Japanese Orthopedic Association (mJOA), NDI, or the EuroQol-5 Dimension.^[6] In the current study, we found that there was no strong correlation between PROMIS physical health domains and Ames-ISSG deformity severity groups for cSVA and TS-CL modifiers (All $P > 0.200$). However, both cSVA and TS-CL modifiers trended toward lower PROMIS PF and higher Pain Interference scores with increasing deformity severity. This trend, but lack of a strong connection, falls in line with the few previous assessments of HRQLs and the Ames-ISSG CD classification.^[17,18]

The present study developed cutoffs for the PROMIS physical health domain metrics in concordance with the cSVA and TS-CL Ames-ISSG severity categories through conditional tree analysis. These cutoff points can be applied to patient care and were significant or approaching significance for most parameters. Predictably, larger PROMIS PI and Pain Interference scores and smaller PF measures coincided with increased CD severity. The cSVA modifier demonstrated more dramatic PROMIS physical health modality cutoffs for moderate deformity, necessitating a PI score of >96, a PF score of <14, and a Pain Interference score of >57.4. The aforementioned cSVA PROMIS cutoffs are strikingly similar to the TS-CL modifier values for severe deformity, where the conditional tree analysis found a PI score of >87, PF score of ≤14, and Pain Interference score of >56.5.

There is an inherent relationship between the TS-CL and cSVA cervical parameters. In a study by Boissière *et al.*, it

was proposed that cervical lordosis determined the cSVA, whereas Lee *et al.* determined that the T1S was the driver of cSVA, where a larger degree compensated a greater cervical lordosis for overall cervical sagittal alignment.^[19,20] Recently, Goldschmidt and the ISSG proposed an equation demonstrating the relationship between the two parameters: $cSVA = (1.1 \times T1S) - (0.55 \times CL)$.^[21] The connection between radiographic factors, via the Ames-ISSG cervical sagittal parameters, with patient-reported outcomes (PROMIS modalities), can be utilized for diagnosis and severity-specific treatment.

With greater degree of TS-CL and increased distance of the cSVA, PROMIS PI and Pain Interference scores increased, whereas the domain of PF scores presented as inversely proportional to severity by Ames-ISSG CD classification. As the moderate Ames-ISSG category for cSVA and severe TS-CL presented similar relationships to the PROMIS physical health domain metrics, there is a need for further investigation into deformity categories by cervical parameters and their association to HRQLs. Future studies into CD severity classifications should understand the connection and compensation of the parameters with malalignment, as well as the radiographic relationship with patient-reported outcomes. PROMIS physical health domain metrics present as a worthy metric to quantifying the patient view in the Ames-ISSG CD severity.

Our study is not without limitations. This is a retrospective review of patient-reported outcomes, which yields itself to possible selection bias and information bias. Further, the

cohort did not contain any patients who fall into the severe deformity category for cSVA in the Ames-ISSG classification. Therefore, cutoffs for PROMIS physical health modalities were not created.

CONCLUSIONS

PROMIS physical health domain metrics of PI, PF, and Pain Interference were related to cervical malalignment parameters of the Ames CD classifications system. Certain BL PROMIS thresholds can be connected to the severity of CD.

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Conflicts of interest

There are no conflicts of interest.

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