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External Validation of the European Spine Study Group-International Spine Study Group Calculator Utilizing a Single Institutional Experience for Adult Spinal Deformity Corrective Surgery

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ABSTRACT

Background: The International Spine Study Group (ISSG) and the European Spine Study Group (ESSG) developed an adult spinal deformity (ASD) risk calculator based on one of the most granular, prospective ASD databases. The calculator utilizes preoperative radiographic, surgical, and patient-specific variables to predict patient-reported outcomes and complication rates at 2 years. Our aim was to assess the ISSG-ESSG risk calculator's usability in a single-institution ASD population.

Methods: Frail ([F], 0.3 > 0.5) ASD patients were isolated in a single-center ASD database. Basic demographics were assessed via χ^2 and *t* tests. Each F patient was inputted into the ESSG risk calculator to identify individual predictive rates for postoperative 2-year health-related quality of life questions (HRQL) outcomes and major complications. These calculated predicted outcomes were analyzed against those identified from the ASD database in order to validate the calculator's predictability via Brier scores. A score closer to 1 meant the ISSG-ESSG calculator was not predictive of that specific outcome. A score closer to 0 meant the ISSG-ESSG calculator was a predictive tool for that factor.

Results: A total of 631 ASD patients were isolated (55.8 ± 16.8 years, 26.68 kg/m^2, 0.95 ± 1.3 Charlson Comorbidity Index). Of those patients, 7.8% were frail. Fifty percent of frail patients received an interbody fusion, 58.3% received a decompression, and 79.2% underwent osteotomy. Surgical details were as follows: mean operative time was 342.9 ± 94.3 minutes, mean estimated blood loss was 2131.82 ± 1011 mL, and average length of stay was 7.12 ± 2.5 days. The ISSG-ESSG calculator predicted the likelihood of improvement for the following HRQL's: Oswestry Disability Index (ODI) (86%), Scoliosis Research Society (SRS)-22 mental health (71.1%), SRS-22 total (87.6%), and major complication (53.4%). The single institution had lower percentages of improvement in ODI (24.6%), SRS-22 mental health (21.3%), SRS-22 total (25.1%), and lower presence of major complication (34.8%). The calculated Brier scores identified the calculator's predictability for each factor was as follows: ODI (0.24), SRS-22 mental health (0.21), SRS-22 total (0.25), and major complication (0.28).

Conclusions: All of the variables had low Brier scores, indicating that the ISSG-ESSG calculator can be used as a predictive tool for ASD frail patients.

Level of Evidence: 3.

Other and Special Categories

Keywords: adult spinal deformity (ASD), risk calculator, Brier scores, International Spine Study Group (ISSG), European Spine Study Group (ESSG), Oswestry Disability Index (ODI), Scoliosis Research Society (SRS) questionnaire, complication risk

INTRODUCTION

The large projected rise in the US elderly population between 2010 and 2050 will likely increase the prevalence of adult spinal deformity (ASD).[1] Given the association of age with the development of ASD, this shift in population growth will also increase the societal burden of this condition.[1] In an era of increasing healthcare costs and progressive budget constraints, there is a demand for providing value in care.[2] Although surgical treatments have proven effective in correcting malalignment and improving function in patients with ASD, these treatments are costly and are associated with high complication rates and a frequent need for unanticipated reoperations, making delivery of value-based care challenging.[1,2]

Predictive analytics are employed in many fields where large datasets are available. Utilization of predictive analytics in health care can allow for identification of patients at high risk for complications and surgical failures.[2] The European Spine Study Group (ESSG) and International Spine Study Group (ISSG) utilized 2 large, observational cohort studies of surgical ASD patients to develop a specific risk calculator that develops prediction models for surgical success in ASD management. The calculator utilizes preoperative radiographic, surgical, and patient-specific variables in order to predict patient-reported outcome measures and complication rates at 1 and 2 years.[2] This calculator can allow spine surgeons to predict which ASD patients are most likely to benefit from surgery and which patients are most likely to require revision surgery, which could have profound implications for treatment planning, patient counseling, and payment decision-making.[3]

The creation of this calculator involved the analysis of prospective, multicenter ASD datasets from both the ESSG and ISSG.[3] However, the accuracy and reliability of this calculator have not yet been assessed in a single institution. The purpose of this study is to utilize this risk calculator to create predictive models and compare its results to patient outcomes at a single institution to validate whether the ESSG-ISSG calculator can be used as a reliable predictive tool for outcomes related to ASD surgery.

MATERIALS AND METHODS

Study Design

This study is a retrospective analysis of consecutive ASD patients. All patients were enrolled at a single spine center from May 2009 to May 2020, following study approval by the Institutional Review Board. Patients provided informed consent prior to enrollment. Patients eligible for study enrollment were >18 years old seeking either operative or nonoperative treatment for ASD, defined radiographically as baseline scoliosis >20° (measured by major coronal Cobb angle), sagittal vertical axis ≥5 cm, pelvic tilt (PT) ≥25°, and/or thoracic kyphosis (TK) >60°. Patients included in this analysis also had complete data for all the component health deficits in the modified ASD Frailty Index (mASD-FI).

Development of the mASD-FI

This study modifies the 40-factor ASD-FI published by Miller et al in 2017.[4,5] ASD-FI score was calculated for each patient. Pearson bivariate correlation then assessed the relationships between each of the 40 component health deficits and overall ASD-FI score (R^2 = 0.71). The top statistically significant, clinically relevant health deficits identified in this correlation analysis were included in a multiple linear regression model predicting overall ASD-FI score (Table 1). This multiple linear regression model was limited to 10 independent health deficits to minimize model saturation and overfitting. The 10 factors comprising this statistically significant model were ultimately included in the mASD-FI (R^2 = 0.68). Frail patients [F] were defined as having a score 0.3 > 0.5.

Table 1. Factors used to create the Modified Frailty Index.

Frailty Factors
Body mass index <18.5 or >30
Heart disease
Work status
Depression
Diabetes
Hypertension
Osteoporosis
Blood clots
Bladder incontinence
Bowel incontinence

ESSG Calculator

The ESSG risk calculator was created through the utilization of the largest and most granular, prospective, mutually compatible, multicenter ASD datasets from the ISSG as well as from the ESSG. The patients used to create this preoperative risk tool were collected from 57 surgeons at 23 sites. A total of 2286 patients were used to train the models that led to the calculator's creation. The calculator has both a preoperative model and a postoperative model that can be utilized to predict likelihood of improvement in the Scoliosis Research Society (SRS)-22 and Oswestry Disability Index (ODI), and development of postoperative major complications by 1 year. The current study utilized the preoperative model, which utilized an array of patient characteristics split up into 4 categories: (1) 12 basic patient demographics, (2) 9 radiographic parameters, (3) 8 health-related quality of life questions (HRQL), and (4) 9 surgical characteristics. Examples of how the calculator appears can be seen in Figures 1–4.

Statistical Analysis

A total of 631 ASD patients were filtered by frailty status and then analyzed for basic demographics and surgical characteristics via χ^2 and *t* test as appropriate. Each individual frail patient with the required baseline parameters necessary was inputted into the ESSG risk calculator in order to identify individual predictive rates for postoperative 2-year HRQL outcomes as well as major complications. These calculated predicted

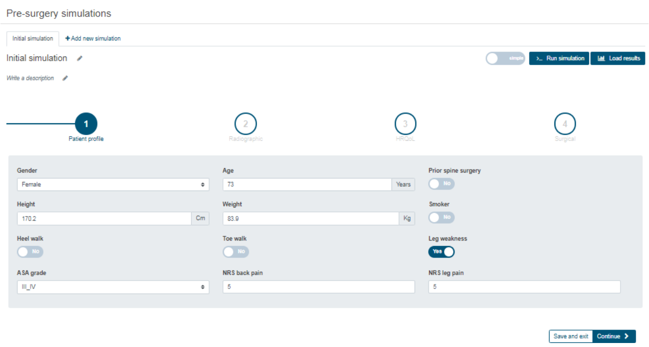

Figure 1. Basic demographics of a sample patient utilizing the European Spine Study Group-International Spine Study Group calculator.

outcomes were analyzed against those identified from the single-surgeon ASD database in order to validate the calculator's predictability in a single-center institution. Brier scores were calculated for each variable in order to validate the calculator's predictability in quality. The Brier score is a quadratic scoring rule used to measure the difference between observed and predicted risk. It is calculated as the sum of squared differences between the binary outcome (Y) and the predicted risk (p): $(Y - p)^2$. A score closer to 1 indicates a poor predictive tool for a specific outcome. A score closer to 0 indicates a valid predictive tool for that factor.

RESULTS

Cohort Overview

A total of 631 ASD patients met inclusion criteria. The mean ± SD age for included patients was 55.8 ± 16.8 years, the mean body mass index was 26.68 kg/m^2, and the mean ± SD Charlson Comorbidity Index was 0.95 ± 1.3. Of these patients, 7.8% (n = 49) were frail. By surgical characteristics, 50% of frail patients received an interbody fusion, 58.3% received a decompression, and 79.2% underwent osteotomy. The mean ± SD operative time was 342.9 ± 94.3 minutes, estimated blood loss was 2131.82 ± 1011 mL, and length of stay was 7.12 ± 2.5 days.

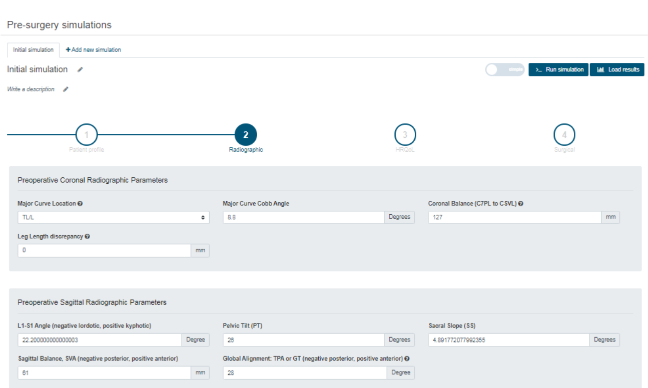

Figure 2. Radiographic alignment of a sample patient utilizing the European Spine Study Group-International Spine Study Group calculator.

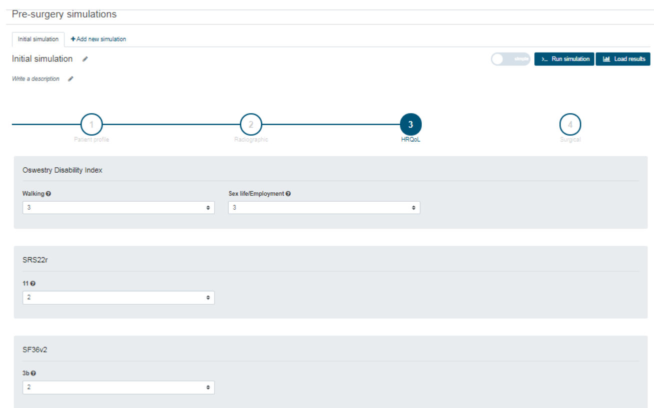

Figure 3. Health-related quality of life metrics of a sample patient utilizing the European Spine Study Group-International Spine Study Group calculator.

Radiographic Measurements

By radiographic parameters at baseline, the average PT was 27.8°, pelvic incidence 50.6°, pelvic incidence minus lumbar lordosis 28.5°, and T4-T12 TK –35.1°. By 2 years, frail patients had a significantly decreased PT (24.3°) and pelvic incidence minus lumbar lordosis (7.5°), but developed a greater TK (–50.5°; all $P < 0.05$). Pelvic incidence was not significantly different by 2 years (50.7°; $P > 0.05$).

Complication Data

About 74% (n = 36) of the frail ASD patients developed a postoperative complication (22.2% ajor and 77.8% minor). Specific complications included: 14.2% cardiopulmonary (n = 6), 10.7% implant-related (n = 5), 14.2% infection (n = 6), 35.7% neurologic (n = 18), 14.2% operative (n = 6), and 17.8 % (n = 9) radiographic related. Of these ASD patients, 22.2% received a reoperation, with 50% due to implant complications

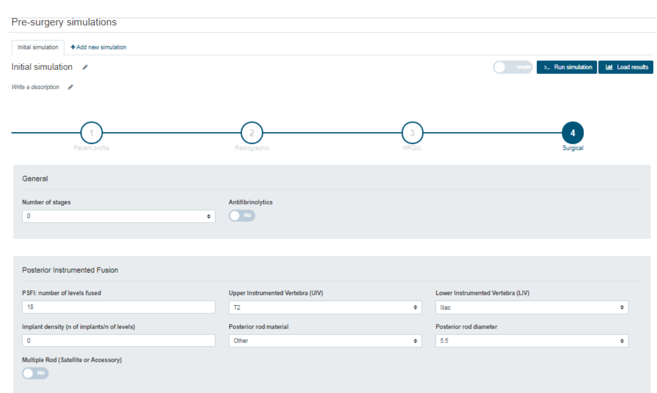

Figure 4. Planned surgical characteristics of a sample patient utilizing theEuropean Spine Study Group-International Spine Study Group calculator.

Table 2. Brier scores for the European Spine Study Group calculator.

	Predicted	Observed	Brier Score
Likelihood of improvement in ODI	89.2%	79.2%	0.0013
Likelihood of improvement in SRS-22 mental health	71.1%	66.7%	0.0019
Likelihood of improvement in SRS-22 subtotal	87.6%	83.3%	0.0018
Major complication at 2 y	53.4%	34.8%	0.034

Abbreviations: ODI, Oswestry Disability Index; SRS, Scoliosis Research Society.

and 50% due to radiographic, infectious, or neurologic complications.

HRQL Measures at Baseline and 2 Years

At baseline, frail patients had an average ODI of 51.1, SRS-activity of 2.4, SRS-pain of 2.1, SRS-appearance of 1.9, SRS-mental health of 2.9, and an SRS-total of 2.2. By 2 years, these patients significantly increased in SRS-activity (3.7), SRS-pain (3.5), SRS-appearance (3.3), SRS-mental (3.7), and SRS-total (3.6; all $P < 0.05$). ODI was not significantly different by 2 years (28.3, $P = 0.056$). By 2 years 60% of these frail patients achieved their minimum clinically important difference (MCID) for ODI.

ESSG Calculator Predictability

The ESSG calculator predicted the likelihood of improvement for the following HRQLs at 2 years: ODI (86%), SRS-22 mental health (71.1%), SRS-22 total (87.6%), and major complication (53.4%). The single institution had lower percentages of improvement in ODI (24.6%), SRS-22 mental health (21.3%), SRS-22 total (25.1%), and lower presence of major complication (34.8%). The calculated Brier scores (Table 2) identified the calculator's predictability for each factor: ODI (0.0013), SRS-22 mental health (0.0019), SRS-22 total (0.0018), and major complication (0.034).

Case Example

A 73-year-old woman underwent posterior spinal fusion from T2 to the ilium. The patient's comorbidities included anemia, blood clots, arthritis, depression, heart disease, and osteoporosis. The patient presented with the following baseline scores: ODI = 60, SRS-22 total = 2.04, SRS-22 mental health = 3.4, and SRS-22 pain = 1.5. Radiographically, the patient presented with L1-S1 of 22°, PT = 26.2°, spinal stenosis = 4.89°, and a T1 pelvic angle = 28.4° (Figure 5). Utilizing the patient's baseline demographics, radiographic alignment, surgical variables, and HRQL measures, the calculator predicted 86% chance of improvement for ODI, 90% for SRS-22 total score, 72% for SRS-22 mental health, and 88% for SRS-22 pain. The calculator also predicted a 45% chance of developing a major complication 2 years postoperatively. By 2 years, the patient improved in ODI (52), SRS-22 total (2.8), SRS-22 mental health (4.0), and SRS-22 pain (1.6). The patient also developed a major complication secondary to infection within 2 years. Follow-up radiographs are shown in Figure 6.

DISCUSSION

The ESSG-ISSG calculator was created to predict outcomes related to ASD surgery. It utilizes preoperative radiographic, surgical, and patient-specific variables to determine the likelihood of improvement in patient-reported outcomes such as ODI and SRS-22r as well as major postoperative complications at 2 years. The creation of this calculator utilized the largest and most granular, prospective, multicenter ASD datasets from 57 surgeons at 23 different sites. Our study aimed to utilize this calculator on a cohort of ASD patients from a single institution to validate the accuracy and

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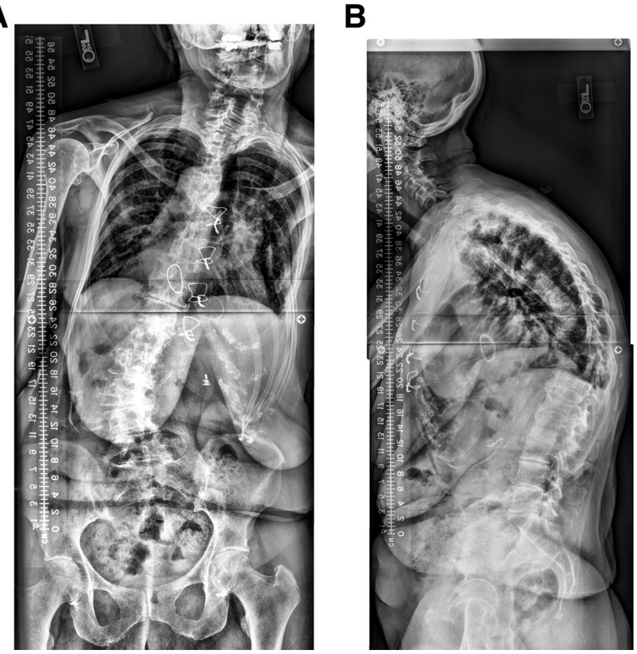

Figure 5. (A) Case example: baseline full standing coronal radiograph, (B) case example: baseline full standing lateral radiograph.

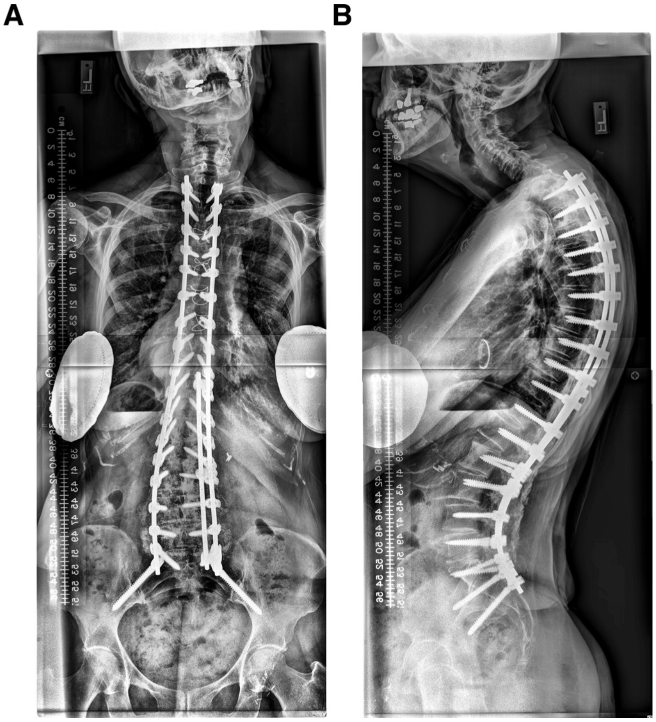

Figure 6. (A) Case example: follow-up coronal radiograph, (B) case example: follow-up lateral radiograph.

reliability of the predictive models created by the ESSG-ISSG calculator.

Recent studies have shown that the disease burden associated with ASD is substantial compared to that of other severe chronic conditions such as diabetes, congestive heart failure, chronic lung disease, or arthritis.[1,3] Over the past few decades, improvements in technique, implant selection, and biologics have improved our ability to treat ASD.[1] Despite these advances, surgical treatment for ASD remains a significant physiologic burden for the patient, given the large number of spinal levels exposed, osteotomies for sagittal correction, high blood loss in the setting of advanced age, and pre-existing medical comorbidities.[1,6] In our analysis, ASD patients who underwent surgical management at our institution had a mean operative time of 6 hours, an average length of stay in the hospital of 7 days, and mean estimated blood loss of approximately 2100 cc. Our findings highlight that these procedures place the patient under substantial physiological burden and have significant costs associated with them.[6] Accurately predicting outcomes and complications prior to surgery can profoundly impact outcomes by minimizing complications and the need for reoperation, which will subsequently reduce cost as well.[3,6]

Studies have shown that nonoperative management of ASD has no significant impact on HRQL measures, whereas surgery is associated with HRQL notable long-term improvements.[6–9] The ESSG-ISSG calculator predicts the likelihood of improvement in specific HRQL measures such as ODI, SRS-22r, and major complications at 1 and 2 years. This can allow spine surgeons to preoperatively assess which patients will benefit most from surgery and which patients should delay or forego surgery to avoid major complications. In our analysis, we calculated the baseline and 2-year ODI and SRS-22r and recorded major complications at 2 years for frail patients and compared our findings to the predictive models created by the ESSG-ISSG calculator. Through use of Brier scores, we determined that the current proposed risk calculator is able to accurately predict outcomes in ODI, SRS-22 total, SRS-22 mental health, and major complications. Therefore, our analysis validates that the ESSG-ISSG calculator can be reliably used as a predictive tool for outcomes and complications in surgical management of ASD.

Current preoperative risk stratification tools consist of the Charlson Comorbidity Index, American College of Surgeons - National Surgical Quality Improvement Program (ACS-NSQIP) calculator, SpineSage, and American Society of Anesthesiology (Table 3). Mannion et al reported that an increasing American Society of Anesthesiology score is associated with a higher incidence of perioperative complications, and other studies have found that a score >2 is an independent risk factor for medical complications after spine surgery.[10,11]

Similarly, the Modified Frailty Index-5 and Modified Frailty Index-11 is popularly used to risk stratify patients who are undergoing various surgical procedures and has been reported to strongly predict mortality and postoperative complications. Despite the overwhelming evidence supporting the utility of each of these risk tools in predicting certain outcomes,[12–15] their predictability is limited because they are not able to take various patient characteristics into account. The ESSG-ISSG calculator captures such basic demographics, baseline patient-reported outcome measures, and surgical characteristics. While other risk stratification tools allow for greater applicability among different types of patients, the specificity of the ESSG-ISSG calculator for ASD patients allows for more reliable predictability. Since the surgical management of ASD has such a profound physiologic burden and is associated with a plethora of potentially debilitating complications, the authors feel that having a more specific tool to predict outcomes in ASD is imperative to enhance patient care, improve postoperative outcomes, and reduce the significant costs associated with complications.

As with most studies that are retrospective in nature, this study was subject to selection biases and confounding variables. Utilization of a cohort of patients from a single institution may result in a biased patient population due to relatively small sample size. With our sample size and

Table 3. Comparing the ESSG-ISSG calculator with other commonly used risk stratification tools.

Predictive Tool	Factors Used to Predict Outcomes	Measured Outcome
ESSG-ISSG calculator	Twelve basic patient demographics: gender, age, height, weight, smoking history, prior spine surgery, heel walk, toe walk, leg weakness, ASA grade, NRS back pain, NRS leg pain Nine radiographic parameters: major curve location, Cobb angle, coronal balance, leg length discrepancy, L1-S1 angle, pelvic tilt, sacral slope, sagittal balance, global alignment 8 HRQL questions Nine surgical characteristics: number of stages, use of bone graft, use of antifibrinolytics, number of levels fused, upper instrumented vertebra, lower instrumented vertebra, implant density, posterior rod material, posterior rod diameter	Major complications, reinterventions, readmissions, and patient-reported outcomes including SRS-22, Oswestry Disability Index, SF36v2
Charlson Comorbidity Index	Age, history of MI, CHF, PVD, DM, CKD, CVA/TIA, AIDS, liver disease, connective tissue disease, peptic ulcer disease, hemiplegia, solid tumor, leukemia, lymphoma	Estimated 10-y survival based on medical comorbidities
ACS-NSQIP Calculator	Age, BMI, functional status, ASA class History of HTN, DM, CHF, COPD, acute kidney injury, CKD requiring dialysis, smoking, ascites, sepsis, disseminated cancer	Postoperative risk of any complications, severe complications, cardiac complications, and death
SpineSage[T]	Age, BMI, gender, diagnosis Level (cervical, thoracic, lumbar), Approach (anterior, lateral, posterior) Previous spine surgery, revision surgery, previous cardiac complications History of CVA/TIA, COPD, asthma, HTN, rheumatoid arthritis, kidney disease, cancer, syncope/seizure, anemia, bleeding disorder, DM, CHF	Expected complication rates after various types of spine surgery
ASA	Patients clinically classified into 1 of the following categories based on multiple factors: I: normal healthy patient II: mild systemic disease III: severe systemic disease IV: severe systemic disease constant threat to life V: moribund patient not expected to survive without the operation	Preoperative risk of undergoing anesthesia
mFI-5	CHF within 30 d of surgery Partially or totally dependent functional health status at time of surgery History of DM, COPD or pneumonia, HTN	Occurrence of adverse postoperative outcomes
mFI-11	Functional status, history of HTN, DM, MI, PVD, CVD, cerebrovascular disease ± neurologic deficit, impaired sensorium, respiratory problems, other cardiac problems	Occurrence of adverse postoperative outcomes

Abbreviations: ASA, American Society of Anesthesiology; BMI, body mass index; CHF, congestive heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; CVA, cerebrovascular accident; CVD, cardiovascular disease; DM, diabetes mellitus; ESSG, European Spine Study Group; HTN, hypertension; ISSG, International Spine Study Group; mFI, modified frailty index; MI, myocardial infarction; NRS, numeric rating scale; PVD, peripheral vascular disease; TIA, transient ischemic attack.

available data, there were 2 limiting preoperative elements that were recorded but were adjusted for in our analysis, such as the ODI sex life question and the implant density. Since the patients that appear in our clinic have traditionally low baseline quality of life, we gave a "3" for the sex life question when omitted from their datasheet, as this reflects the growing literature of sexual and physical dysfunction related to spinal deformities.[16,17] In prior research, implant density has shown to have no appearance of negatively impacting clinical or demographic outcomes in a clinically meaningful way; for this reason, we gave patients missing this parameter a "0" as it would not affect their outcomes and would allow us to have great capture and usability of the ESSG calculator.[18] Additionally, the single-institution data had poor follow-up for SRS at 2 years, which limits our conclusions for the calculator's predictability for improvement in this outcome. Although this study represents a step forward, no prospective randomized studies have been performed at a single institution to validate the reliability and accuracy of the ESSG-ISSG calculator. Due to more than half of our patients reaching their MCID for ODI, future studies focusing on the calculator's utility in patients achieving their MCID for various HRQLs should be further investigated. Well-designed prospective studies employing this calculator are warranted to further validate and establish its utility.

CONCLUSION

The newly developed ESSG-ISSG risk assessment tool has a wide application in single institutions as it accurately predicts 2-year outcomes for various SRS-22 questionnaires and development of major complications. All of the variables had low Brier scores, indicating that the ISSG-ESSG calculator can be used as a predictive tool for ASD frail patients.

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Ethics Approval: The current study has been performed in accordance with the ethical standards in the 1964 Declaration of Helsinki. It has also been carried out in accordance with relevant regulations of the US Health Insurance Portability and Accountability Act (HIPAA). Details that might disclose the identity of the subjects were omitted.

IRB Approval: Institutional Review Board approval was obtained for enrollment of patients.

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