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DEFORMITY

External Validation of the Adult Spinal Deformity (ASD) Frailty Index (ASD-FI) in the Scoli-RISK-1 Patient Database

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Study Design. Analysis of a prospective multicenter database.

Objective. To assess the ability of the recently created Adult Spinal Deformity (ASD) Frailty Index (ASD-FI) to predict odds of major complications and length of hospital stay for patients who had more severe preoperative deformity and underwent more invasive ASD surgery compared with patients in the database used to create the index.

Summary of Background Data. Accurate preoperative estimates of risk are necessary given the high complication rates currently associated with ASD surgery.

Methods. Patients were enrolled by participating institutions in Europe, Asia, and North America from 2009 to 2011. ASD-FI scores were used to classify 267 patients as not frail (NF) (<0.3), frail (0.3–0. 5), or severely frail (SF) (>0.5). Multivariable logistic regression, adjusted for preoperative and surgical covariates such as operative time and blood loss, was performed to determine the relationship between ASD-FI category and incidence of major complications, overall incidence of complications, and length of hospital stay.

Results. The mean ASD-FI score was 0.3 (range, 0–0.7). We categorized 105 patients as NF, 103 as frail, and 59 as SF. The adjusted odds of developing a major complication were higher for SF patients (odds ratio = 4.4; 95% CI 2.0, 9.9) compared with NF patients. After adjusting for covariates, length of hospital stay for SF patients increased by 19% (95% CI 1.4%, 39%) compared with NF patients. The odds of developing a major complication or having increased length of stay were similar between frail and NF patients.

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Conclusion. Greater patient frailty, as measured by the ASD-FI, is associated with a longer hospital stay and greater risk of major complications among patients who have severe preoperative deformity and undergo invasive surgical procedures.

Key words: adult spinal deformity, complications, deformity complexity, external validation, frailty, length of hospital stay, personalized preoperative risk stratification, physiologic age, risk factors, surgical invasiveness.

Level of Evidence: 2

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Frailty is a relatively new physiologic diagnosis and measurement of aging. In terms of health and risk of death, people age at different rates. Frailty is "characterized by diminished strength, endurance, and reduced physiologic function that increases an individual's vulnerability for developing increased dependency and/or death".[1(p.392)] Compared with chronological age, frailty has been shown to be a better predictor of decline in self-management ability than chronological age.

More recently, frailty has been adopted by the surgical community as a better predictor of adverse events, longer hospital stay, and worse discharge disposition than chronological age.[2–4] Given the high rate of complications in spine deformity surgery, adequate preoperative evaluation and risk assessment using the best predictors of adverse events is essential. The Adult Spinal Deformity (ASD) Frailty Index (ASD-FI) was developed using a prospective, surgeon-maintained, ASD patient database to assess the value of frailty as part of preoperative patient evaluation in terms of association with worse outcomes. The index was developed using a previously validated methodology established by Mitnitski *et al*[5] and Searle *et al*[6] for assessment of frailty in pre-existing patient databases. The ASD-FI was found to be strongly associated with greater incidence of major complications and longer hospital stay in the database in which it was developed (the International Spine Study Group [ISSG] Adult Spinal Deformity Database)[7] and in an external database with identical patient inclusion criteria (the European Spine Study Group [ESSG] Adult Spinal Deformity Database) (unpublished data). The purpose of this study was to externally validate the ASD-FI in a prospective, surgeon-maintained, ASD patient database with different patient inclusion criteria. We hypothesized that the ASD-FI would correlate similarly, with greater incidence of major complications and longer length of hospital stay in an external, complex ASD patient database.

MATERIALS AND METHODS

Patient Population

After external validation of the ASD-FI in the ESSG ASD database (which has inclusion criteria identical to those in the database with which the index was developed),[7] another database of patients who have more severe preoperative deformity and who underwent more invasive surgical procedures was selected to validate the index (unpublished data). Institutional review board approval for patient inclusion in this database was obtained by each of the sites that contributed patient information. The inclusion criteria for ISSG and ESSG are as follows: 1) age 18 years or older; and 2) surgery for ASD, defined as scoliosis (major curve $\geq 20^\circ$), thoracic kyphosis $\geq 60^\circ$, pelvic tilt $\geq 20^\circ$, or sagittal vertical axis >5 cm. In the Scoli-RISK-1 database, in addition to being 18 to 80 years of age, patients undergoing surgery for ASD were included if they met any one of the following criteria: 1) primary scoliosis and/or kyphosis with a major curve $>80^\circ$ in the coronal or sagittal plane; 2) congenital or revision spinal deformity undergoing corrective spinal osteotomy; 3) preoperative myelopathy caused by spinal deformity; 4) ossification of the ligamentum flavum or posterior longitudinal ligament with concomitant deformity requiring reconstruction and decompression; or 5) a planned surgical procedure, including a 3-column spinal osteotomy from C7 to L5, inclusive. A total of 272 patients were enrolled.[8] For this subanalysis, 267 patients who had at least 75% of all frailty variables recorded were included.

Frailty Index

The 40 variables selected in the ISSG ASD database for the ASD-FI were used to calculate frailty in the Scoli-RISK-1 database; however, seven of these variables were unavailable in the Scoli-RISK-1 database. Some of these were replaced by comparable comorbidities (kidney disease substituted for liver disease), and scoring was calculated with 36 variables (Table 1). Each variable, or health deficit, was recorded as a binary value (*e.g.*, presence *vs.* absence of osteoporosis). The mean score of these deficits was calculated, giving a frailty index score between 0 and 1. Patients with scores <0.3 were considered not frail (NF), those with scores of 0.3–0.5 were considered frail, and those with scores >0.5 were considered severely frail (SF). These cut-off values were based on maximum separation of mortality curves per previous research.[9]

Data Analysis

The primary study outcome was the incidence of major complications. As with the original study, major complications were defined as those that substantially changed the expected path to recovery and were potentially life-threatening, required reoperation, or caused permanent injury per Glassman *et al*[10] and McDonnel *et al*.[11] These complications included intraoperative vascular, visceral, or neurologic injury; postoperative deep wound infection; pulmonary embolism; junctional failure; and other similar complications.[12] Secondary outcomes were length of hospital stay and overall complication incidence.

Statistical Analysis

All statistical analyses were performed using SAS, version 9.4, software (SAS Institute Inc, Cary, NC). First, univariable linear regression (for continuous variables) and logistic regression (for binary variables) analyses of all independent

TABLE 1. Factors Included in the Adult Spinal Deformity Frailty Index

Health Deficits
Documented by physician
>3 Medical problems
Anemia†
Body mass index <18.5 or >30 kg/m^2
Cancer
Cardiac disease
Currently on disability*
Depression*
Diabetes
Hypertension
Kidney disease†
Liver disease*
Lung disease
Osteoporosis
Peripheral vascular disease*
Previous blood clot (deep vein thrombosis/pulmonary embolism/stroke)
Nervous system disorders†
Smoking status
Patient-reported (questionnaire, question no.)
Bladder incontinence
Bowel incontinence
Deteriorating health this year (SF-36v2, 2)
Difficulty climbing 1 flight of stairs (SF-36v2, 3e)
Difficulty driving a car (LSDI, 3)*
Difficulty getting dressed (SF-36v2, 3j; LSDI, 1/2)
Difficulty getting in/out of bed (LSDI, 6)*
Difficulty sleeping >6 h (ODI, 7)
Difficulty walking 100 yards (SF-36v2, 3i)
Difficulty with light activity (SF-36v2, 3b)
Feeling downhearted/depressed most of the time (SF-36v2, 9f; SRS-22r, 16)
Feeling tired most of the time (SF-36v2, 9i)
Feeling worn out most of the time (SF-36v2, 9g)
General health: fair/poor (SF-36v2, 1)
Inability to bathe without assistance (SF-36v2, 3j; LSDI, 8)
Inability to cheer up often (SF-36v2, 9c; SRS-22r, 7)
Inability to do normal work/schoolwork/housework (ODI, 10; SRS-22r, 9/12)
Inability to lift heavy objects (SF-36v2, 3c; ODI, 3)
Inability to travel >1 h (ODI, 9)
Inability to walk without assistive device (ODI, 4)
Loss of balance*
Not in excellent health (SF-36v2, 11d)
Personal care dependency (ODI, 2)
Restricted activity level (SRS-22r, 5)
Restricted social life (ODI, 8; SRS-22r, 14/18)
Weakness

**These variables were unavailable in the Scoli-RISK-1 Database and were excluded from that analysis.*

†These variables were unavailable in the International Spine Study Group database and were added for analysis in the European Spine Study Group and Scoli-RISK-1 databases.

LSDI indicates Lumbar Stiffness Disability Index; ODI, Oswestry Disability Index; SF-36v2, Short Form-36, version 2; SRS-22r, Scoliosis Research Society-22r questionnaire.

variables not already included in the frailty calculation (demographic and surgical parameters such as race and number of levels fused) were performed. Second, a multivariable analysis of all independent variables included in the analysis of the ISSG database was performed. Because of the skewed distribution of length of hospital stay, this variable was log-transformed for analysis. $P < 0.05$ was considered statistically significant.

RESULTS

The mean ASD-FI score was 0.3 (range, 0–0.7). We classified 105 patients as NF, 103 as frail, and 59 as SF. The mean (± standard deviation) age was 57 (±15) years, and 67% of patients were women. Sixty-two percent of patients had undergone previous spine surgery. Seventy-six percent of patients had undergone 3-column osteotomies. The mean estimated blood loss was 2.6 (±2.0) L, the mean operative time was 7 (±3) hours, and the mean number of levels fused was 12 (±4) (Table 2).

The median length of hospital stay was 9 days (range, 4–108 days), with a median intensive care unit stay of 1 day (range, 0–51 days). The median length of hospital stay was 8 days for NF patients, 9 days for frail patients, and 10 days for SF patients. On univariable regression analysis, frailty was not significantly associated with length of hospital stay, with a 4% (95% CI: −14, 25) increase for frail patients and a 12% (95% CI: −9.8, 39) increase for SF patients compared with NF patients (Table 3). After adjusting for covariates, SF patients had a 19% (95% CI: 1.4, 39) longer hospital stay than did NF patients (Table 4).

Complications occurred in 76% of patients, and 37% of patients had a major complication. When stratified by frailty, complication rates increased from 65% for NF patients to 78% for frail patients and 92% for SF patients ($P < 0.001$). Major complication rate followed a similar pattern, with 27% for NF patients, 37% for frail patients, and 58% for SF patients ($P < 0.001$). On univariable analysis, SF patients had higher odds (odds ratio [OR] = 3.7; 95% CI: 1.9, 7.3) of developing a major complication than NF patients (Table 3). On multivariable analysis, the adjusted odds of incurring a major complication were higher for SF patients (OR = 4.4; 95% CI: 2.0, 9.9) than for NF patients (Table 4). The difference in major complication rates between frail and NF patients was not statistically significant.

DISCUSSION

In our analysis of complex patients undergoing highly invasive procedures for ASD, we found that frailty was associated with major complication incidence and length of hospital stay. This study was conducted to evaluate whether frailty continued to be strongly associated with complication incidence in a surgical patient database with different inclusion criteria than the database in which the ASD-FI was developed. The associations between frailty and major complications or length of hospital stay in the Scoli-Risk-1 database are not as strong as those seen in the ISSG and ESSG databases on univariable analysis, which is likely related to the higher risk of major surgical complications with increased invasiveness, which mitigates the impact of patient factors.

TABLE 2. Characteristics of Patients in the Scoli-RISK-1 Adult Spinal Deformity Database

Characteristic	No. (%) (n = 267)	Mean (Standard Deviation)
Patient factors		
Age at surgery, yr		57 (15)
Female sex	179 (67)	
Frailty		0.33 (0.17)
Previous spine surgery	166 (62)	
Surgical factors		
Operative time, h		7 (3)
Estimated blood loss, mL		2600 (2000)
Length of hospital stay, d		15 (15)
Intensive care unit stay, d		2 (5)
Procedure		
3-column osteotomy	202 (76)	
No. of levels fused		12 (4)
Complication incidence		
Major	100 (37)	
Minor	173 (65)	
Any	202 (76)	

This study builds on the background provided by the development and analysis of the ASD-FI in the ISSG ASD patient database[7] using the method of Searle *et al*.[6] The ESSG and ISSG databases were comparable in terms of major complication incidence, complication incidence, and length of hospital stay. This was expected, given that these two databases had the same inclusion criteria and differed only by patient nationality (the ISSG and ESSG databases are based in North America and Europe, respectively). With the results of the present study, three prospectively collected patient database studies have now found that SF patients have a much higher risk of major complications and a much longer length of hospital stay than NF patients.

ASD surgery is associated with a high rate of complications; therefore, adequate preoperative risk stratification is important. Older chronological age is a known risk factor for surgical complications, but age is an imperfect measure of physiologic status because patients may have a much older or younger physiologic age than chronological age. This difference in physiologic age is now being quantified through the concept of frailty. The ASD-FI was created using a validated method for the development of frailty indices previously shown to be an accurate measurement of frailty with good correlation with other frailty assessments such as the Fried phenotype. In this proposed method, frailty indices were consistent when at least 30–40 variables were included. If the number of deficits included was less than 10, frailty estimates were unstable and imprecise.[6]

The modified frailty index was developed by analyzing the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database and identifying 11 recorded variables that corresponded to 16 of the 70 variables in the Canadian Study of Health and Aging Frailty Index.[13] The results of the study, which proposed the use of frailty indices, suggest that using only 11 variables to assess frailty is imprecise and may not yield reliable assessments of frailty.[6] This modified frailty index has been shown to correlate with complication incidence in the NSQIP database.[14–16] Although the modified frailty index has been shown to be another useful risk stratification tool similar to the American Society of Anaethesiologists score, it is not yet established whether this is an accurate measure of frailty. Additionally, although these studies had large patient populations, the use of large national databases has several recognized limitations. First, the use of Current Procedural

TABLE 3. Univariable Analysis of Outcomes of Patients in the Scoli-RISK-1 Study Group Adult Spinal Deformity Database

	Frail *vs.* Not Frail		Severely Frail *vs.* Not Frail	
Complication Type	OR (95% CI)	*P*	OR (95% CI)	*P*
Major	1.6 (0.9, 2.9)	0.114	3.7 (1.9, 7.3)	<0.001
Minor	1.4 (0.8, 2.5)	0.240	2.1 (1.0, 4.3)	0.037
All	1.9 (1.0, 3.5)	0.041	5.9 (2.2, 16)	<0.001

CI indicates confidence interval; OR, odds ratio.

TABLE 4. Multivariable Analyses of Outcomes of Patients in the Scoli-RISK-1 Adult Spinal Deformity Database

Outcome	OR (95% CI)	% Change (95% CI)	*P*
Major complications*			
Estimated blood loss (per 500-mL increase)	1.1 (1.0, 1.2)		0.026
Frailty			0.002
Not frail	Referent		
Frail	1.5 (0.8, 3.0)		0.218
Severely frail	4.4 (2.0, 9.9)		<0.001
No. of levels fused (per 1-level increase)	1.0 (1.0, 1.1)		0.234
Operative time (per 30-min increase)	1.1 (1.0, 1.2)		0.006
Previous spine surgery	0.8 (0.4, 1.5)		0.442
Region			0.003
North America	Referent		
Asia	0.7 (0.3, 1.7)		
Europe	3.5 (1.6, 7.7)		
Length of hospital stay†			
3-column osteotomy performed		7.0 (−7.5, 24)	0.360
BMP used		3.8 (−10, 20)	0.610
Estimated blood loss (per 500-mL increase)		2.2 (0.6, 3.9)	0.008
Male sex		−17 (−27, −6.0)	0.004
Frailty			0.100
Not frail	Referent		
Frail		6.5 (−6.9, 22)	0.359
Severely frail		19 (1.4, 39)	0.033
Operative time (per 30-min increase)		4.7 (3.4, 5.9)	<0.001
Region			<0.001
North America	Referent		
Asia		181 (136, 234)	
Europe		50 (26, 78)	

**From multivariable logistic regression.*
†From multivariable regression with log transformation.
BMP indicates bone morphogenic protein; CI, confidence interval.

Terminology[17] codes to identify patients can lead to inclusion discrepancies and does not allow stratification by surgical invasiveness. Second, complication incidence was analyzed for only 30 days after surgery. Third, large national databases have been shown to underestimate complication rates.[18] Our study was designed to address the limitations of the modified frailty index. The ASD-FI was developed using a method validated for creating accurate, precise measurements of frailty that correlate with other frailty assessments. The Scoli-Risk-1 is a surgeon-maintained patient database that allows for accurate complication analyses up to 2 years after surgery. Additionally, given the strict inclusion criteria, a consistent patient population could be selected. Among the 3 databases, 950 patients have been analyzed using the ASD-FI. The consistent results support the use of the ASD-FI as a tool for preoperative risk stratification to improve patient counseling and surgical planning. This confirms the external validity of the ASD-FI and indicates that it can be used even with modifications of the variables included according to available data.

Limitations of this study include a relatively small patient population compared with studies using large national databases and the use of a larger, more cumbersome index. To create an accurate measurement of frailty, we needed to include at least 30–40 variables in the ASD-FI. However, the ASD-FI could still be used clinically in the form of a patient survey sent before each clinic visit to generate a frailty score that can be used during preoperative risk-benefit discussions. Current research is focused on prospective use of this tool.

CONCLUSION

In patients with a high degree of preoperative deformity who underwent invasive ASD surgery, frailty was associated with major complication incidence and length of hospital stay. This external validation of the ASD-FI supports its use as a component of preoperative risk assessment that would allow surgeons to counsel patients more effectively about their risk of adverse outcomes after surgery. Additionally, this would allow surgeons to tailor the invasiveness of

surgical procedures according to risk of complications. In conclusion, frailty assessments are strongly associated with complication risk and would make a valuable addition to current preoperative risk assessments.

➢ Key Points

- ❑ The ASD-FI, developed in another database as a method to quantify physiologic age, was strongly associated with incidence of major complications and length of hospital stay in an international patient database with more complex patients and procedures.
- ❑ Preoperative frailty assessments may be used to improve the risk-stratification process.
- ❑ Frailty indices may more appropriately define expected quality metric ranges before surgery and hospital admission.

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