European Spine Journal (2018) 27:2331–2338
https://doi.org/10.1007/s00586-018-5575-3

ORIGINAL ARTICLE

External validation of the adult spinal deformity (ASD) frailty index (ASD-FI)

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Received: 2 October 2017 / Revised: 22 February 2018 / Accepted: 27 March 2018 / Published online: 30 March 2018

Abstract

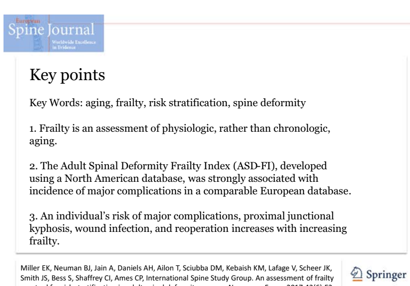
Purpose To assess the ability of the recently developed adult spinal deformity frailty index (ASD-FI) to predict odds of perioperative complications, odds of reoperation, and length of hospital stay after adult spinal deformity (ASD) surgery using a database other than the one used to create the index.

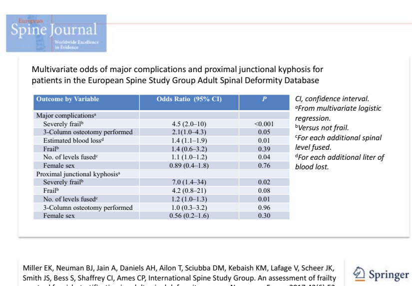
Methods We used the ASD-FI to calculate frailty scores for 266 ASD patients who had minimum postoperative follow-up of 2 years in the European Spine Study Group (ESSG) database. Patients were enrolled from 2012 through 2013. Using ASD-FI scores, we categorized patients as not frail (NF) (< 0.3 points), frail (0.3–0.5 points), or severely frail (SF) (> 0.5 points). Multivariable logistic regression, adjusted for preoperative and surgical factors such as operative time and blood loss, was performed to determine the relationship between ASD-FI category and odds of major complications, odds of reoperation, and length of hospital stay.

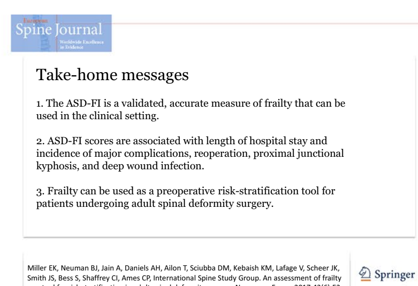
Results We categorized 135 patients (51%) as NF, 90 patients (34%) as frail, and 41 patients (15%) as SF. Overall mean ASD-FI score was 0.29 (range 0–0.8). The adjusted odds of experiencing a major intraoperative or postoperative complication (OR 4.5, 95% CI 2.0–10) or having a reoperation (OR 3.9, 95% CI 1.7–8.9) were higher for SF patients compared with NF patients. Mean hospital stay was 2.1 times longer (95% CI 1.8–2.4) for SF patients compared with NF patients.

Conclusions Greater patient frailty, as measured by the ASD-FI, is associated with longer hospital stays and greater odds of major complications and reoperation.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.







Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00586-018-5575-3) contains supplementary material, which is available to authorized users.

Extended author information available on the last page of the article

Keywords Adult spinal deformity · Comorbidities · Complications · Frailty index · Functional status · Preoperative risk stratification

Introduction

In the last several decades, the physiologic diagnosis of frailty has been gaining support in geriatric research as a preferred measure for characterizing aging and predicting mortality. People age at different rates, which leads to discrepancies between physiological age and chronological age. Frailty is "a medical syndrome with multiple causes and contributors that 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). It has been shown to be a better predictor of decline in self-management ability than chronological age [2].

Frailty has been shown to be a better predictor of adverse events than age alone in general surgery [3–5]. Adult spinal deformity (ASD) surgery is associated with high complication rates necessitating adequate preoperative risk assessment and increasing chronological age is a known risk factor for complications, morbidity, and mortality after ASD surgery [6, 7]. Patients who experience a major complication are less likely to achieve a minimum clinically important difference in health-related quality-of-life scores [8, 9]. The ASD frailty index (ASD-FI) was developed using a prospective, surgeon-maintained database of patients with ASD according to the methods of Mitnitski et al. [10] and Searle et al. [11] for developing frailty indices using pre-existing patient databases. It uses the following criteria: (1) variables whose prevalence increases with age are selected, (2) only variables related to health status can be included, (3) variables are eliminated if the prevalence saturates too early, (4) the variables selected cover a range of systems, including motility, activities of daily living, independence, cognitive function, mood, and comorbidities, and (5) at least 30 distinct variables meeting all of these qualifications must be included. The ASD-FI was shown to be strongly associated with greater odds of major complications and longer hospital stays in the database in which it was developed [12].

The purpose of our study was to externally validate the ASD-FI in a prospective, surgeon-maintained database of patients with ASD. The ASD-FI was examined for associations with complication incidence, reoperation incidence, and length of hospital stay after ASD surgery. We hypothesized that frailty would be strongly associated with these three outcomes of interest.

Materials and methods

Patient population

Patient data were obtained from a multicenter database of patients with ASD, maintained by the European Spine Study Group (ESSG). Institutional review board approval for patient inclusion in this database was obtained by each site that contributed patient information. Each patient provided written consent to be included in the database. The inclusion criteria for the ESSG database are identical to those of the database in which the ASD-FI was developed [the International Spine Study Group (ISSG) ASD database], as follows: age 18 years or older; and surgery for ASD between 2010 and 2014, defined as scoliosis (major curve $\geq 20°$), thoracic kyphosis $\geq 60°$, pelvic tilt $\geq 20°$, or sagittal vertical axis > 5 cm. Of the 42 variables included in the original ASD-FI, 36 were recorded in the ESSG database and were included in this analysis. In the ESSG database, 266 patients had minimum 2-year follow-up and were included in the analysis.

Frailty index

Of the 42 variables from the ISSG database that were used to create the ASD-FI, 36 were available in the ESSG database and were used to calculate frailty in this study (Table 1). Each variable, or deficit in health, was recorded as a binary value (e.g., presence vs. absence of osteoporosis). The mean score of all deficits was calculated, resulting in a frailty score between 0 and 1. Patients with scores of less than 0.3 were considered not frail (NF), those with scores ranging from 0.3 to 0.5 were considered frail, and those with scores greater than 0.5 were considered severely frail (SF). These cut-points were set on the basis of precedent in the frailty literature [13].

Data analysis

The primary outcome of interest was major perioperative complications, which 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. [14, 15] and McDonnell et al. [16]. These complications included intraoperative vascular, visceral, or neurologic injury; deep wound infection; pulmonary embolism; junctional failure; and other similar complications [15]. Secondary outcomes included length

Table 1 Factors included in the adult spinal deformity frailty index

Health deficits	Questionnaire (question no.)
Documented by physician	
> 3 medical problems	
Body mass index < 18.5 or > 30	
Cancer	
Cardiac disease	
Currently on disability[a]	
Depression	
Diabetes	
Hypertension	
Kidney disease[a]	
Liver disease	
Lung disease	
Osteoporosis	
Peripheral vascular disease	
Previous blood clot (DVT/PE/stroke)	
Nervous system disorders[a]	
Smoking	
Patient-reported	
Bladder incontinence	
Bowel incontinence	
Deteriorating health this year	SF-36v2 (2)
Difficulty climbing 1 flight of stairs	SF-36v2 (3e)
Difficulty driving a car[a]	LSDI (3)
Difficulty getting dressed	LSDI (1/2); SF-36v2 (3j)
Difficulty getting in/out of bed[a]	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	LSDI (8); SF-36v2 (3j)
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	ODI (3); SF-36v2 (3c)
Inability to travel > 1 h	ODI (9)
Inability to walk without assistive device	ODI (4)
Loss of balance[a]	
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	

DVT deep vein thrombosis, *LSDI* Lumbar Stiffness Disability Index, *ODI* Oswestry Disability Index, *PE* pulmonary embolism, *SF-36v2* Short Form-36, version 2, *SRS-22r* Scoliosis Research Society-22r questionnaire

[a]These variables were not available in the European Spine Study Group database and were excluded from this analysis

of hospital stay, reoperation, proximal junctional kyphosis, deep wound infection, and surgical/medical complications. Surgical complications included intraoperative and immediate postoperative complications. Medical complications included those unrelated to surgical technique, including stroke, deep venous thrombosis, pulmonary embolus, pneumonia, and urinary tract infection.

Statistical analysis

Statistical analyses were performed using Small Stata, version 14.1, software (StataCorp LP, College Station, TX) and SAS, version 9.4, software (SAS Institute Inc., Cary, NC). Univariable log-transformed linear or Poisson regression (for continuous variables) and logistic regression (for binary variables) analyses of all independent variables not already included in the frailty calculation (e.g., demographic and surgical parameters such as race and number of levels fused) were performed, followed by multivariable analysis of all independent variables with *P* values less than 0.3. Variables were eliminated until the maximum supportable number of variables was reached. Age was not included as an independent variable because chronological age and frailty are strongly correlated. There is too much overlap between age

Table 2 Characteristics of patients in the European Spine Study group adult spinal deformity database by frailty status

Variable	Not frail (*n* = 135)		Frail (*n* = 90)		Severely frail (*n* = 41)		*P*
	Mean (SD)	No. (%)	Mean (SD)	No. (%)	Mean (SD)	No. (%)	
Age at surgery, year	43 (1.7)		57 (1.8)		62 (2.6)		< 0.001[a]
Female sex		95 (70)		73 (81)		35 (85)	0.60[b]
ASA PSC							
1		78 (58)		33 (37)		6 (15)	< 0.001[a]
2		49 (36)		50 (56)		24 (59)	
3		8 (5.9)		7 (7.8)		11 (27)	
4		0 (0)		0 (0)		0 (0)	
CCI							
0		106 (79)		47 (52)		14 (34)	< 0.001[a]
1		18 (13)		20 (22)		10 (24)	
2		6 (4.4)		14 (16)		7 (17)	
3		1 (0.7)		7 (7.8)		7 (17)	
4		3 (2.2)		0 (0)		1 (2.4)	
5		1 (0.7)		2 (2.2)		1 (2.4)	
6		0 (0)		0 (0)		0 (0)	
7		0 (0)		0 (0)		0 (0)	
8		0 (0)		0 (0)		1 (2.4)	
Operative time, h	5.0 (0.2)		4.3 (0.2)		5.1 (0.4)		0.02[a]
EBL, l	1.4 (0.1)		1.6 (0.1)		1.7 (0.2)		0.06[a]
LOS, day	9.6 (0.5)		11 (1.1)		19 (3.5)		0.24[a]
Procedure							
Interbody fusion		27 (20)		33 (37)		13 (32)	0.02[b]
Decompression		32 (24)		36 (40)		18 (44)	0.01[b]
3-column osteotomy		30 (22)		18 (20)		7 (17)	0.76[b]
No. of instrumented vertebrae	10 (0.3)		9.7 (0.5)		9.3 (0.7)		0.27[a]
≤4		11 (8.1)		14 (16)		7 (17)	
5–8		35 (26)		21 (23)		9 (22)	
9–12		48 (36)		33 (37)		43 (51)	
13–16		37 (27)		15 (17)		5 (12)	
≥17		4 (3.0)		7 (7.8)		4 (9.8)	
Major complication		31 (23)		32 (36)		18 (44)	0.02[b]

ASA American Society of Anesthesiologists, *CCI* Charlson Comorbidity Index, *EBL* estimated blood loss, *LOS* length of hospital stay, *PSC* physical status classification, *SD* standard deviation

[a]From Kruskal–Wallis *H* test

[b]From Pearson χ^2 test

and frailty to include both in a single multivariate analysis. Age and frailty are both measures of aging and only one can be included. Because of the skewed distribution of length of hospital stay, Poisson regression analyses were used for this variable and the results were log transformed.

Results

Using the ASD-FI, 135 patients (51%) were classified as NF, 90 (34%) as frail, and 41 (15%) as SF. The mean ASD-FI score was 0.29 (range 0–0.8). Frail and SF patients were significantly older than NF patients and had higher Charlson Comorbidity Index (CCI) and American Society of Anesthesiologists scores (all $p < 0.001$). There were significantly fewer decompressions ($p = 0.01$) and interbody fusions ($p = 0.02$) performed in the NF cohort compared with the frail and SF cohorts. There were no significant differences in the number of spinal levels fused or the number of three-column osteotomies performed among the three frailty groups (Table 2).

On univariable analysis, frail patients had higher odds [odds ratio (OR) 1.8; 95% confidence interval (CI), 1.0–3.3] of experiencing a major complication compared with NF patients. Similarly, SF patients had higher odds (OR 2.6; 95% CI 1.3–5.5) of experiencing a major complication compared with NF patients (Table 3). On multivariable analysis, SF patients had higher odds of experiencing a major complication (OR 4.5; 95% CI 2.0–10.0) than NF patients (Table 4).

Comparable analyses were performed for all secondary outcomes of interest. Compared with NF patients, SF patients had higher odds of developing proximal junctional kyphosis (OR 3.1; 95% CI 1.0–9.9), developing a wound infection (OR 8.4; 95% CI 2.7–26), and requiring reoperation (OR 3.5; 95% CI 1.6–7.6) (Table 3). On multivariable logistic analyses, SF patients had higher odds of reoperation (OR 3.9; 95% CI 1.7–8.9), proximal junctional kyphosis (OR 7.0; 95% CI 1.4–34), and wound infection (OR 9.7; 95% CI 2.3–41) than NF patients (Table 4). On univariable analysis, frail patients had longer hospital stays (OR 1.2; 95% CI 1.1–1.3) compared with frail patients, as did SF patients (OR 2.0; 95% CI 1.8–2.1). On multivariable linear analysis, frail patients had longer hospital stays (OR 1.4; 95% CI 1.3–1.6) compared with NF patients, as did SF patients (OR 2.1; 95% CI 1.8–2.4) (Table 4).

Discussion

The population of ASD surgical candidates is aging as average life expectancy increases and surgical techniques improve [17]. As patients become older, it is important to understand the effect of aging on surgical outcomes. Adverse events, although sometimes unpredictable, are strongly affected by patient characteristics, presence of comorbidities, surgical technique, procedure modifications, and surgeon skill. Although older age has been shown to be a risk factor for complications [17], longer hospital stays, and overall worse outcomes after ASD surgery, many patients have a much different physiologic age than chronological age. This difference is now being quantified through the concept of frailty.

Many methods of calculating frailty have been proposed and validated, enabling providers to choose the method that best works for their patients. The ASD-FI was created using the validated method of Searle et al. [11] to assess frailty in existing patient databases. In a series of 1000 iterations, the slope of deficit accumulation (0.03 per year) and the submaximal limit at about two-third of the deficits tested were insensitive to the precise composition of the index demonstrating validity of their methods [11]. The number of variables ensures statistical reliability of a new frailty index. By meeting these criteria, a new index will have good comparability to other frailty indices and will be considered an

Table 3 Univariate analysis of outcomes of patients in the European Spine Study Group adult spinal deformity database

Outcome	Frail vs. not frail			Severely frail vs. not frail		
	Odds ratio	95% CI	*P*	Odds ratio	95% CI	*P*
Complication type[a]						
Infection	1.9	0.5–6.3	0.32	8.4	2.7–26	< 0.001
Major	1.8	1.0–3.3	0.04	2.6	1.3–5.5	0.01
Proximal junctional kyphosis	1.3	0.4–4.0	0.64	3.1	1.0–9.9	0.05
Overall	1.2	0.7–2.1	0.45	2.8	1.3–6.0	0.01
Reoperation[a]	2.3	1.2–4.4	0.01	3.5	1.6–7.6	0.002
Length of hospital stay[b]	1.2[c]	1.1–1.3	< 0.001	2.0	1.8–2.1	< 0.001

CI confidence interval

[a]From univariate logistic regression

[b]From univariate Poisson regression with lognormal transformation

[c]Regression coefficient

Table 4 Multivariate analysis of outcomes of patients in the European Spine Study Group adult spinal deformity database

Outcome by Variable	Odds ratio	95% CI	*P*
Deep wound infection[a]			
Severely frail[b]	9.7	2.3–41	0.002
Operative time[d]	1.5	1.2–2.0	0.003
Frail[b]	1.2	0.2–6.6	0.83
No. of levels fused[c]	1.1	0.9–1.2	0.36
Decompression performed	0.87	0.3–2.6	0.80
Female sex	0.82	0.3–2.6	0.74
Lumbar interbody fusion performed	0.51	0.2–1.2	0.12
Length of hospital stay[e]			
Severely frail[b]	2.1[f]	1.8–2.4	< 0.001
Disc degeneration preoperatively	1.5[f]	1.2–1.8	< 0.001
Frail[b]	1.4[f]	1.3–1.6	< 0.001
3-column osteotomy performed	1.3[f]	1.1–1.5	0.003
Decompression performed	1.2[f]	1.0–1.3	0.03
Operative time[d]	1.1[f]	1.0–1.1	< 0.001
Lumbar interbody fusion performed	0.93[f]	0.8–1.1	0.29
Estimated blood loss[g]	0.89[f]	0.6–1.0	0.002
Female sex	0.88[f]	0.8–1.0	0.11
Major complications[a]			
Severely frail[b]	4.5	2.0–10	< 0.001
3-column osteotomy performed	2.1	1.0–4.3	0.05
Estimated blood loss[g]	1.4	1.1–1.9	0.01
Frail[b]	1.4	0.6–3.2	0.39
No. of levels fused[c]	1.1	1.0–1.2	0.04
Female sex	0.89	0.4–1.8	0.76
Proximal junctional kyphosis[a]			
Severely frail[b]	7.0	1.4–34	0.02
Frail[b]	4.2	0.8–21	0.08
No. of levels fused[c]	1.2	1.0–1.3	0.01
3-column osteotomy performed	1.0	0.3–3.2	0.96
Female sex	0.56	0.2–1.6	0.30
Reoperation[a]			0.37
Severely frail[b]	3.9	1.7–8.9	0.001
3-column osteotomy performed	1.8	0.9–3.7	0.13
Frail[b]	1.4	0.6–3.3	0.45
Estimated blood loss[g]	1.3	1.0–1.8	0.06
No. of levels fused[c]	1.1	1.0–1.2	0.08
Operative time[d]	0.94	0.8–1.1	0.44

CI confidence interval

[a]From multivariate logistic regression

[b]Versus not frail

[c]For each additional spinal level fused

[d]For each additional hour of operative time

[e]From multivariate Poisson regression with lognormal transformation

[f]Regression coefficient

[g]For each additional liter of blood lost

accurate measurement of frailty. Although it may be possible to distill the index down to fewer variables in the future, a "gold standard" is needed from which to compare accuracy of frailty measures with fewer variables. The modified frailty index has not been shown to be an accurate measure of frailty. Variables relating to spinal deformity were not excluded because spinal deformity itself, as a significant deficit in health, contributes to increasing frailty.

The ESSG and ISSG data yielded comparable results in terms of greater odds of complications and major complications, as well as longer hospital stays with greater frailty. This was expected, given that these databases have the same inclusion criteria and differ only on nationality (the ISSG is based in North America and the ESSG in Europe). In both databases, SF patients were shown to have much higher odds of adverse events than NF patients.

Another study investigated the use of the modified frailty index in spine surgery patients using the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database, which showed a strong association between Modified Frailty Index Score and complication incidence [18]. However, the modified frailty index was not created using a validated method and has not been shown to correlate with standard frailty indices. Although it is potentially another good risk stratification tool, like the ASA classification [19], it is not necessarily a measure of frailty. Our study was designed to address the limitations of this study by using a validated method for creating a statistically accurate and comprehensive frailty index and by using a prospectively collected patient database, including data on a specific patient population for 2 years after surgery. Our study and the NSQIP study support the use of frailty in preoperative risk stratification. Whereas the NSQIP study was limited by a short follow-up period, a less standardized patient population, heterogeneity of surgical invasiveness, and a modified frailty index, our study had 2 years of follow-up, a surgeon-maintained database of a specific patient population, comparable recorded surgical invasiveness, and a comprehensive frailty index. The consistency of results between the ESSG and ISSG databases supports the use of the ASD-FI as a tool for preoperative risk stratification to improve patient counseling and surgical planning.

Conclusion

The ASD-FI was developed using a validated protocol in the ISSG ASD database. In this database, frail and SF patients had significantly higher odds of incurring major complications than NF patients. The current study using the ESSG database supports these results. Frailty was strongly associated with odds of major complications, proximal junctional kyphosis, deep wound infection, and reoperation after ASD surgery. This external validation of the ASD-FI supports its use as a component of preoperative risk assessment.

Funding Funding for the European Spine Study Group database was provided by DePuy Synthes.

Compliance with ethical standards

Conflict of interest None of the authors has any potential conflict of interest.

Ethical statement Institutional review board approval for patient inclusion in this database was obtained by each of the sites that contributed patient information. Each patient signed a consent document before inclusion.

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