

CERVICAL SPINE

Development of a Modified Cervical Deformity Frailty Index

A Streamlined Clinical Tool for Preoperative Risk Stratification

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Study Design. Retrospective review.

Objective. Develop a simplified frailty index for cervical deformity (CD) patients.

Summary of Background Data. To improve preoperative risk stratification for surgical CD patients, a CD frailty index (CD-FI) incorporating 40 health deficits was developed. While novel, the CD-FI is clinically impractical due to the large number of factors needed for its calculation. To increase clinical utility, a simpler, modified CD-FI (mCD-FI) is necessary.

Methods. CD patients (C2-C7 Cobb > 10°, CL > 10°, cSVA > 4 cm, or CBVA > 25°) > 18 year with preoperative CD-FI component factors. Pearson bivariate correlation assessed relationships between component deficits of the CD-FI and overall

CD-FI score. Top deficits contributing to CD-FI score were included in multiple stepwise regression models. Deficits from model with largest R² were dichotomized, and the mean score of all deficits calculated, resulting in mCD-FI score from 0 to 1. Patients were stratified by mCD-FI: Not Frail (NF, < 0.3), Frail (0.3–0.5), Severely Frail (SF, > 0.5). Means comparison tests established correlations between frailty category and clinical outcomes.

Results. Included: 121 CD patients (61 ± 11 yr, 60%F). Multiple stepwise regression models identified 15 deficits as responsible for 86% of the variation in CD-FI; these factors were used to construct the mCD-FI. Overall, mean mCD-FI was 0.31 ± 0.14. Breakdown of patients by mCD-FI category: NF: 47.9%, Frail: 46.3%, SF: 5.8%. Compared with NF and Frail, SF patients had the longest inpatient hospital stays ($P=0.042$), as well as greater baseline neck pain ($P=0.033$), inferior Neck Disability Index scores ($P<0.001$) and inferior EQ-5D scores ($P<0.001$). Frail patients had higher odds of superficial infection (OR:1.1[1.0–1.2]), and SF patients had increased odds of mortality (OR:8.3[1.3–53.9]).

Conclusion. Increased frailty, assessed by mCD-FI, correlated with increased length of stay, neck pain, and decreased health-related quality of life. Frail patients were at greater risk for infection, and severely frail patients had greater odds of mortality. This relationship between frailty and clinical outcomes suggests that mCD-FI offers clinical utility as a preoperative risk stratification tool.

Key words: cervical deformity, complications, deformity, frailty, frailty index, health deficit, mortality, outcomes, risk, risk index, spine.

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Deformity of the cervical spine is often debilitating, with severe cases characterized by cervical sagittal malalignment, myelopathy, dysphagia, and loss of horizontal gaze.¹ Given the wide range of etiologies and

presentations for cervical deformity (CD), surgical management is exceptionally complex, frequently requiring multi-segment fusions, multiple surgical approaches, osteotomies, and long operative times.² While CD-corrective surgery has been studied to improve patient health status, postoperative complication rates remain high, especially for high-risk patient populations including the severely frail.³

Frailty, defined as a multisystem impairments associated with decreased physiologic reserve for coping with normal age-related stressors, has consistently been characterized in the literature as a strong predictor of adverse outcomes following spine surgery.⁴⁻⁶ As such, a number of studies have developed pathology-specific frailty indices as tools for preoperative risk stratification.^{7,8} Recently, Miller *et al*³ developed a novel adult cervical deformity frailty index (CD-FI) which correlated increased patient frailty with longer hospital stays, higher complication rates, and increased risk of non-home discharge. While effective in correlating patient frailty with clinical outcomes, the clinical application of this CD-FI is limited as its calculation requires a complete set of 40 discrete health deficits, 17 of which are derived from patient-reported outcome measures, and thus subject to individual bias. A simpler and less biased CD frailty assessment tool is necessary; however, such a frailty index has yet to be developed.

Given the drawbacks of the Miller *et al* CD-FI, the goal of this study was to develop a simpler, modified cervical deformity frailty index (mCD-FI) that relied less on patient-reported factors and more on objective, physician-reported health deficits. Additionally, to assess the utility of this mCD-FI as a preoperative risk stratification tool, we sought to identify correlations between mCD-FI score and

postoperative clinical outcomes, including complication incidence, health-related quality of life, and mortality.

MATERIALS AND METHODS

Data Source

This study used a prospectively collected, multicenter database of consecutively enrolled CD patients to construct a simple, mCD-FI. Patients in the database were enrolled from 2013 to 2017 at 13 participating spine surgery centers across the United States. All participating surgery centers obtained Institutional Review Board approval prior to patient enrollment, and all participating patients provided consent prior to enrollment. Inclusion criteria for the database was age ≥ 18 years, and radiographic evidence of cervical deformity, as defined by the presence of at least one of the following on baseline imaging: cervical kyphosis (C2–7 Cobb angle $>10^\circ$), cervical scoliosis (C2–7 coronal Cobb angle $<10^\circ$), C2–7 sagittal vertical axis (cSVA) >40 mm or chin-brow vertical angle (CBVA) $>25^\circ$. Additional inclusion criteria for the present analysis included complete data for each of the 15 component health deficits comprising the mCD-FI (Table 1). Patients with active tumors or infections were excluded from the study.

Modified Cervical Deformity Frailty Index Development

To develop a simplified mCD-FI, the present study first reconstructed the CD-FI previously published by Miller *et al*.³ Briefly, 40 candidate health deficits in the database associated with frailty were selected as determined by Searle *et al*.⁹ These deficits were dichotomized into scores of 0 or 1, and the mean score of all deficits was calculated, yielding a

TABLE 1. Final Multiple Stepwise Regression Model Predicting Overall Patient Cervical Deformity Frailty Index (CD-FI) Score

Health Deficit	Standardized Coefficient (β)	Standard Deviation (SD)	P Value
Lung disease	0.033	0.013	0.010
BMI <18.5 kg/m ² or >30 kg/m ²	0.015	0.008	0.054
Diabetes	0.04	0.011	<0.001
Depression	0.02	0.009	0.024
Liver disease	-0.101	0.057	0.077
Rheumatoid arthritis	0.058	0.015	<0.001
Venous disease	0.099	0.068	0.149
Unsteady gait	0.022	0.007	0.004
Bladder incontinence	0.031	0.012	0.010
Leg weakness	0.04	0.008	<0.001
≥ 4 Comorbidities	0.151	0.039	<0.001
Anxiety (EQ-5D-3L)	0.098	0.008	<0.001
Bowel incontinence	0.044	0.008	<0.001
Difficulty sleeping >6 h (SWAL-QOL 9B)	0.056	0.008	<0.001
Inability to walk (EQ-5D-3L)	0.043	0.01	<0.001
$R^2 = 0.860$			
Health deficits identified in this model were used to calculate the modified cervical deformity index score (mCD-FI). BMI indicates body mass index.			

CD-FI score ranging from 0 to 1. To simplify the Miller *et al.* CD-FI, each of the 40 component health deficits comprising the frailty index, were assessed as independent predictors for overall CD-FI score via linear regression modeling. Top physician-documented and patient-reported health deficits predicting CD-FI score were then selected and included in multiple stepwise regression models. To minimize overfitting and model saturation, only 19 deficits were included in the stepwise regression analysis.¹⁰ Deficits derived from the stepwise model with the largest R^2 were included in the mCD-FI (Table 1). Patient mCD-FI score was similarly constructed by calculating the mean score of all component deficits, resulting in a final mCD-FI score from 0 to 1.

Statistical Analysis

Patients were grouped by mCD-FI score according to previously published guidelines: not frail (NF, <0.3), frail (0.3–0.5), and severely frail (SF, >0.5).⁹ Study outcome measures were length of hospital stay, complication incidence, and patient-reported health-related quality of life scores, including those from the Neck Disability Index and EuroQol-5D-3L (EQ-5D) questionnaires. Differences in patient characteristics and outcome measures were assessed across frailty groups using chi-squared tests and one-way analysis of variance with Tukey *post hoc* tests, as appropriate. Binary logistic regression assessed the relationship between frailty category and complication occurrence. All analysis was performed using SPSS software (v23.0, Armonk, NY). Statistical significance was set to $P < 0.05$.

RESULTS

Study Sample

Overall, 121 cervical deformity patients were included in the present analysis, presenting with mCD-FI scores ranging from 0.00 to 0.67, and a mean overall mCD-FI score of 0.31 ± 0.14 . By frailty severity, 47.9% of patients were categorized as not frail, 46.3% were frail, and 5.8% were severely frail. Differences in age, sex, body mass index, and comorbidity burden were observed across frailty groups (Table 2). Specifically, while NF patients were significantly older than frail patients ($P = 0.004$), SF patients presented with the greatest overall comorbidity burden, including significantly higher CCI scores ($P = 0.040$), higher rates of depression ($P < 0.001$), and higher rates of pulmonary disease ($P = 0.003$). Procedural characteristics, including operative time, estimated blood loss (EBL), surgical approach, and utilization of osteotomy did not differ across frailty groups (Table 2). While severely frail patients showed the greatest preoperative C7-S1 sagittal vertical axis malalignment ($P = 0.041$), there were no other statistically significant differences in alignment across patient frailty groups (Table 2).

Complication Incidence Across Frailty Groups

Table 3 shows differences in complication rates across patient frailty groups. Of note, as compared with NF

patients, frail patients showed significantly higher odds of developing a vascular complication (OR: 1.1 95% CI: 1.001–1.158) or superficial surgical site infection (OR: 1.1, 95% CI: 1.001–1.158). Regression analysis showed Severely Frail patients to have a significantly increased risk of both cardiac arrest (OR: 18.8, 95% CI: 1.05–339.17) and mortality (OR: 8.3, 95% CI: 1.28–53.94) as compared with Frail and NF groups.

Clinical Outcomes Across Frailty Groups

Increasing frailty was significantly associated with deterioration in patient-reported measures of neck pain, neck disability, and overall health-related quality of life (Table 4). Length of hospital stay showed a significant increase across frailty groups: NF 5.6 ± 3.6 days; Frail: 8.4 ± 11.5 days; SF: 14.0 ± 17.9 days ($P = 0.042$). Rates of non-routine discharge, including discharge to inpatient rehab or a skilled nursing facility, also increased across frailty groups, although this trend did not reach statistical significance (NF: 20.7%, Frail: 27.3%, SF: 57.1%, $P = 0.109$).

Case Examples

Figure 1A to C presents preoperative lateral radiographs for NF, Frail, and SF patients, respectively. The Not Frail patient was a 72-year-old male with a mCD-FI score of 0.20 (Figure 1A). The patient was discharged home following an uncomplicated 4-day hospital stay. The Frail patient was a 65-year-old female with a mCD-FI score of 0.40, who, following surgery, developed a superficial surgical site infection (Figure 1B). This patient was discharged home after a 4-day hospital stay. The Severely Frail patient was a 65-year-old female with a mCD-FI score of 0.53 (Figure 1C). Following surgery, the severely frail patient developed both upper airway edema and a minor neurologic complication. Following a 5-day hospital stay, this patient was discharged to inpatient rehabilitation. Table 5 shows mCD-FI score calculations for the NF, Frail, and SF patients included in the case example. For all patients, mCD-FI score was calculated as the mean of all component deficits, with deficit absence recorded as 0 and deficit presence recorded as 1.

DISCUSSION

Evidence-based risk assessment tools play an important role in preoperative patient counseling, complimenting clinical insight to provide both patients and physicians with a more accurate prediction of outcomes following surgery. Recent risk assessment tools have focused on frailty as a means of stratifying patients, using validated methodologies to develop pathology-specific frailty indices that correlate with postoperative clinical outcomes.^{6,8,9} These indices count health deficits, including symptoms, comorbidities, disabilities, and radiographic abnormalities, to ultimately assess patient frailty level. Frailty indices have been developed and validated for surgical spine patients, with a number of studies showing significant independent associations between increased frailty and higher complication rates,

TABLE 2. Differences in Demographic, Comorbidity, Procedural, and Preoperative Radiographic Characteristics of 121 Cervical Deformity Patients by Frailty Status, as Assessed by Modified Cervical Deformity Frailty Index (mCD-FI) Score

	Not Frail n = 58	Frail n = 56	Severely Frail n = 7	P Value
Demographic and comorbidity characteristics				
Age (yr)	64.1 ± 9.1	57.8 ± 11.3	62.5 ± 9.1	* 0.005
Sex (% female)	48.3%	71.4%	71.4%	* 0.034
BMI (kg/m ²)	26.9 ± 5.1	30.2 ± 8.9	39.5 ± 6.6	* <0.001
Charlson comorbidity index	0.70 ± 1.06	0.86 ± 1.21	2.00 ± 2.45	* 0.040
Depression	15.5%	48.2%	71.4%	* <0.001
Diabetes mellitus	8.6%	17.9%	14.3%	0.345
Osteoporosis	12.1%	16.1%	28.6%	0.482
Smoking status (% smokers)	8.8%	7.3%	0.0%	0.705
Pulmonary disease	10.3%	3.6%	42.9%	* 0.003
Procedural characteristics				
Operative time (min)	510 ± 354	487 ± 330	344 ± 198	0.468
Estimated blood loss (cc's)	954 ± 1096	700 ± 610	396 ± 333	0.136
Levels fused	8.4 ± 5.1	7.4 ± 3.6	7.4 ± 4.4	0.546
Surgical approach				
Anterior only	20.7%	14.3%	28.6%	0.516
Posterior only	46.6%	48.2%	42.9%	0.958
Combined	32.8%	37.5%	28.6%	0.816
Utilization of osteotomy	51.7%	58.9%	42.9%	0.605
Preoperative radiographic characteristics				
C2-C7 SVA (mm)	41.6 ± 21.7	34.8 ± 18.4	39.2 ± 19.8	0.203
TS-CL (°)	41.2 ± 19.6	34.9 ± 14.0	34.6 ± 17.4	0.216
C0-C2 lordosis (°)	34.1 ± 11.9	31.7 ± 14.0	36.4 ± 0.95	0.578
McGregor's Slope (°)	5.5 ± 14.6	2.1 ± 12.6	-2.6 ± 0.8	0.321
C7-S1 SVA (mm)	-4.9 ± 59.1	13.8 ± 65.7	65.7 ± 107.1	* 0.041
Pelvic tilt (°)	22.1 ± 9.1	18.9 ± 16.0	24.2 ± 16.0	0.198
PI-LL (°)	2.4 ± 17.2	-37.4 ± 14.4	-30.2 ± 13.0	0.145
Thoracic kyphosis (°)	-42.3 ± 17.2	-37.4 ± 14.3	-30.1 ± 13.1	0.096
Lumbar lordosis (°)	53.6 ± 14.5	51.8 ± 17.6	40.7 ± 22.9	0.244

Bolded and asterisked values denote statistical significance to $P < 0.05$.

higher reoperation rates, and longer postoperative hospital stays.^{11,12} While a CD-FI exists in the literature, the index is limited in clinical utility due to the full set of 40 health deficits necessary for the index's calculation, and subject to bias due to the index's inclusion of multiple subjective patient-reported disability scores.³ There is a need for a simpler, less biased CD patient frailty assessment tool; however, no such frailty index currently exists in the literature. As such, the goal of this study was to simplify the existing CD-FI, creating a clinically-meaningful mCD-FI.

Using multiple stepwise regression models, our study identified 15 health deficits as responsible for 86% of the variation in CD-FI score (Table 1). These deficits ultimately comprised the mCD-FI. Given that only 15 health deficits are needed to calculate a patient's mCD-FI score, the mCD-FI offers applicability in a wider range of clinical settings as compared to the previously published CD-FI, which cannot be calculated without a complete set of 40 variables.

Calculating a 15-variable mCD-FI is more practical, and requires less time for both data collection and analysis. Additionally, the physician-documented health deficits included in the mCD-FI are general enough to be captured in routine preoperative systems review, and the complete 15-factor index provides sufficient scope to capture a wide range of clinical states, as suggested by the broad range of mCD-FI scores in our patient population (0.00–0.67).

Importantly, as compared with the previously published CD-FI, calculation of the mCD-FI relies less on patient-reported health-related quality of life questionnaires to assess health deficits. Whereas the previously published CD-FI incorporates 17 health deficits derived from patient-reported outcome questionnaires, the present mCD-FI only incorporates three: difficulty sleeping >6 hours per night (as assessed by the Swallowing Quality of Life Questionnaire), anxiety, and difficulty walking (both assessed by the EQ-5D). As patient-reported outcome

TABLE 3. Differences in Overall and Specific Complication Incidence Across Not Frail, Frail, and Severely Frail Cervical Deformity Patient Groups

	Not Frail n = 58	Frail n = 56	Severely Frail n = 7	P Value
Complication incidence				
Any complication	65.5%	60.7%	57.1%	0.826
Reoperation	22.4%	7.1%	14.3%	0.072
Any infection	3.4%	8.9%	0.0%	0.363
Deep incisional SSI	3.4%	1.8%	0.0%	0.773
Superficial SSI	0.0%	7.1%	0.0%	0.091
Urinary tract infection	0.0%	1.8%	0.0%	0.557
Other infection	0.0%	1.8%	0.0%	0.557
Cardiopulmonary	8.6%	8.9%	14.3%	0.884
Pneumonia	1.7%	1.8%	0.0%	0.939
Respiratory failure	3.4%	5.4%	0.0%	0.747
Tachycardia	2.7%	0.0%	0.0%	0.578
Cardiac arrest	0.0%	1.8%	14.3%	*0.020
Other cardiac event	3.4%	3.6%	0.0%	0.880
Neurologic	25.9%	19.6%	28.6%	0.690
C5 motor deficit	5.2%	1.8%	0.0%	0.528
Mental status change	6.9%	7.1%	0.0%	0.768
Nerve root motor deficit	3.4%	3.6%	14.3%	0.380
Nerve sensory deficit	5.2%	3.6%	0.0%	0.777
Radiculopathy	3.4%	5.4%	0.0%	0.747
Gastrointestinal	3.4%	1.8%	0.0%	0.773
Ileus	3.4%	0.0%	0.0%	0.331
Perforated ulcer	0.0%	1.8%	0.0%	0.557
Vascular	0.0%	7.1%	0.0%	0.091
Instrumentation failure	5.2%	5.4%	0.0%	0.823

Bolded and asterisked values denote statistical significance to $P < 0.05$.

questionnaires have shown to be inadequate in discriminating small-to-moderate differences in health status, decreased reliance on patient-reported health deficits lends the mCD-FI increased objectivity, and less susceptibility to bias.^{13,14} Furthermore, increased reliance on objective, physician-reported health deficits also provides increased reliability in the mCD-FI's calculation. Future studies should investigate the inter-rater reliability of the mCD-FI.

Our analysis demonstrates the utility of the mCD-FI in predicting clinical outcomes following CD-corrective surgery. Not only was increased frailty associated with significant increases in hospital length of stay, but mCD-FI score appeared to be associated with complications of increasing severity. Specifically, as compared with not frail patients (mCD-FI score < 0.3), frail patients (mCD-FI from 0.3 to 0.5) had significantly higher odds of developing superficial site infection and vascular

TABLE 4. Differences in Patient-Reported Neck Disability, Pain, and Health-Related Quality of Life Across Cervical Deformity Frailty Groups

	Not Frail n = 58	Frail n = 56	Severely Frail n = 7	P Value
Patient-reported clinical outcomes				
Neck Disability Index	40.3 ± 16.9	55.5 ± 15.7	64.6 ± 13.5	*<0.001
EQ-5D	0.77 ± 0.06	0.70 ± 0.06	0.66 ± 0.04	*<0.001
Numeric rating scale: neck pain	6.28 ± 2.51	7.27 ± 2.45	8.29 ± 2.06	*0.033
Numeric rating scale: back pain	4.79 ± 2.78	5.29 ± 3.37	6.71 ± 3.09	0.265

Bolded and asterisked values denote statistical significance to $P < 0.05$.

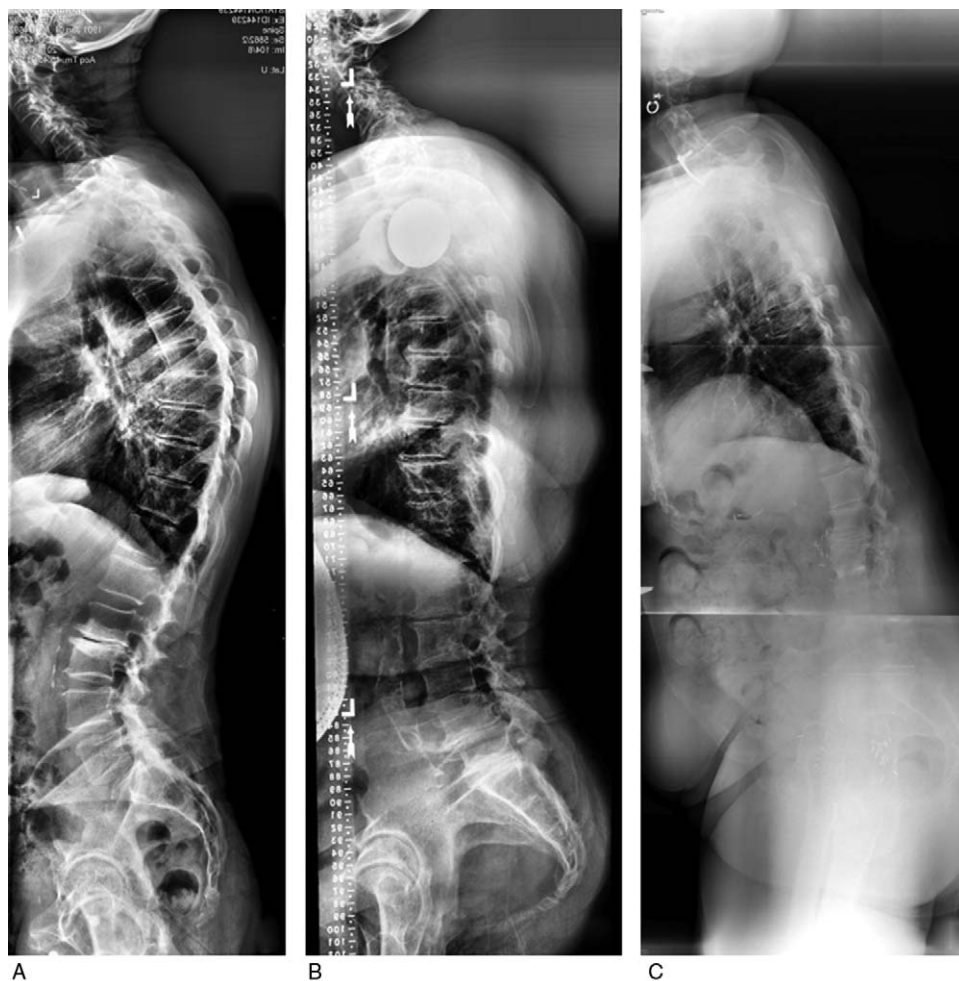


Figure 1. Preoperative lateral radiograph case examples for Not Frail (A), Frail (B), and Severely Frail (C) surgical cervical deformity patients. The mCD-FI scores were 0.20, 0.40, and 0.53, for the Not Frail, Frail, and Severely Frail patients, respectively.

complications following surgery. Similarly, as compared with both frail and not frail patients, severely frail patients (mCD-FI > 0.5) showed significantly higher odds of cardiac arrest and mortality. Taken as a whole, these results suggest the mCD-FI has utility as a tool for objective quantification of surgical risk for cervical deformity patients. The present frailty index can be used to improve both patient counseling and selection, as well as preoperative surgical planning. Future prospective investigations should continue to investigate the clinical utility of the mCD-FI, and assess the mCD-FI's external validity.

Indeed, as our quantification of frailty also includes modifiable factors like anxiety, unsteady gait, and leg weakness, the mCD-FI may also assist in setting surgical goals that reduce postoperative patient frailty. Previous research has shown that CD-corrective surgery and concomitant reduction in myelopathy severity is associated with significant improvements in gait impairment.¹⁵ Other adult spinal deformity studies also show a significant relationship between superior postoperative frailty score and clinical outcomes, including improvements in health-related quality of life.^{11,16} Our study similarly shows a significant relationship between mCD-FI score and health-related quality of life, suggesting frailty reduction should be considered a key goal of CD-corrective surgery. In this sense, the modifiable

factors of the mCD-FI have the potential to guide surgeons in the preoperative planning process.

We acknowledge a number of limitations in our analysis. Calculation of frailty using the present methodology requires complete data for all 15 health deficits. Thus, mCD-FI score cannot be calculated for patients with missing or unavailable data. Additionally, although the cervical deformity patient population we used in our outcomes assessment is larger or comparable in size to previously published cervical deformity studies, our 121 patient sample size is still small, thus reducing the statistical power of our stepwise predictive modeling and our findings.¹⁷⁻²⁰ This lack of statistical power is reflected in the wide confidence intervals of our multivariate analyses. Despite these limitations, the present study offers a simple, clinically relevant tool for preoperative patient risk stratification.

CONCLUSION

This study presents a 15-factor frailty assessment instrument for surgical cervical deformity patients. Increased patient frailty, as assessed by the mCD-FI, was associated with increased hospital stay, inferior health-related quality of life, and significantly greater risk of perioperative complication. Specifically, frail patients showed higher odds of

TABLE 5. Calculation of mCD-FI Scores for the Not Frail (NF), Frail, and Severely Frail (SF) Patients Included in the Case Example of Figure 1

mCD-FI Health Deficit	Patient A (NF)	Patient B (Frail)	Patient C (SF)
Lung disease	0	0	0
BMI <18.5 kg/m ² or >30 km/m ²	0	1	1
Diabetes	0	1	0
Depression	0	0	1
Liver disease	0	0	0
Rheumatoid arthritis	0	0	0
Venous disease	0	0	0
Unsteady gait	1	1	1
Bladder incontinence	0	0	1
Leg weakness	0	0	1
≥4 Comorbidities	0	0	0
Anxiety (EQ-5D-3L)	0	1	1
Bowel incontinence	0	0	0
Difficulty sleeping >6 h (SWAL-QOL 9B)	1	1	1
Inability to walk (EQ-5D-3L)	1	1	1
mCD-FI score (mean of deficits)	0.20	0.40	0.53

developing infection or vascular complications, while severely frail patients showed higher odds of cardiac arrest and mortality. Given the relationship between frailty score and clinical outcomes, we suggest that the mCD-FI can be used to compliment clinical insight as an evidence-based preoperative risk assessment tool for patients undergoing CD-corrective surgery.

➤ Key Points

- ❑ Frailty is an important consideration in the preoperative risk stratification of surgical cervical deformity patients.
- ❑ The mean mCD-FI in this population of 121 surgical cervical deformity patients was 0.31 ± 0.14 .
- ❑ Frail patients (mCD-FI between 0.3 and 0.5) had increased risk for superficial site infection and vascular complications; severely frail patients (>0.5) had increased odds of cardiac arrest and mortality.
- ❑ Increasing mCD-FI score was associated with longer inpatient hospital stay and inferior health-related quality of life.
- ❑ The mCD-FI may serve as a valuable tool for preoperative risk stratification to improve outcomes following CD-corrective surgery.

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