

# Frailty is a Risk Factor for Postoperative Complications in Older Adults with Lumbar Degenerative Disease: A Prospective Cohort Study

Yan Zhang<sup>1,\*</sup>, Qixing Wu<sup>2,\*</sup>, Mingming Han<sup>2</sup>, Chengwei Yang<sup>2</sup>, Fang Kang<sup>2</sup>, Juan Li<sup>2</sup>, Chengwen Hu<sup>1</sup>, Xia Chen<sup>1</sup>

<sup>1</sup>Department of Nursing, The First Affiliated Hospital of USTC, Division of Life Sciences and Medicine, University of Science and Technology of China, Hefei, People's Republic of China; <sup>2</sup>Department of Anesthesiology, The First Affiliated Hospital of USTC, Division of Life Sciences and Medicine, University of Science and Technology of China, Hefei, People's Republic of China

\*These authors contributed equally to this work

Correspondence: Xia Chen; Chengwen Hu, Email [chenxiaahslyy@163.com](mailto:chenxiaahslyy@163.com); [huchengwen318@126.com](mailto:huchengwen318@126.com)

**Objective:** Frailty, representing the physiological reserve and tolerance of the body, serves as a crucial evaluation index of the overall status of the older adults. This study aimed to investigate the prevalence of preoperative frailty and its impact on postoperative outcomes among older adults with lumbar degenerative disease in China.

**Patients and Methods:** In this prospective study, a total of 280 patients aged 60 and above, diagnosed with lumbar degenerative disease and scheduled for surgical intervention were enrolled. The prevalence of frailty pre-surgery was evaluated using the Tilburg Frailty Indicator (TFI) and the modified Frailty Index 11 (mFI-11). The primary outcome was postoperative complication within 30 days post-surgery. The secondary outcomes were the length of hospital stay, hospital costs, reoperation within 30 days post-surgery and unplanned readmission within 30 days post-discharge. Both univariable and multivariable logistic regression were employed to screen and identify the risk factors predisposing patients to postoperative complications.

**Results:** A total of 272 older adults were included in the study ultimately. The frailty detection rates of TFI and mFI-11 were 15.8% (43/272) and 10.7% (29/272) respectively. Thirty-four patients (12.5%) encountered complications. Significantly elevated rates of complications, prolonged hospital stays, increased hospital costs, and heightened readmission rates were observed in the frail group compared to the non-frail group ( $P < 0.05$ ). Univariable analysis showed that the potential factors related to complications are TFI, mFI-11 and albumin. Multivariable logistic regression revealed that TFI was an independent risk factor for postoperative complications (OR=5.371, 95% CI: 2.338–12.341,  $P < 0.001$ ).

**Conclusion:** Frailty was an independent predictor of postoperative complications in older adults undergoing lumbar fusion surgery. Frailty assessment should be performed in such patients to improve preoperative risk stratification and optimize perioperative management strategies.

**Keywords:** lumbar degenerative disease, older adults, frailty, postoperative outcome

## Introduction

Lumbar degenerative disease is a prevalent condition among the older adults,<sup>1</sup> leading to back or leg pain or associated neurological signs, thereby diminishing their independence and impeding quality of life. With advancements in anesthesiology and spinal surgery techniques, lumbar surgery for this group of patients is progressively gaining clinical acceptance.<sup>2</sup> Studies have indicated that the most rapid increase in the rate of spinal fusion surgery is occurring in patients over 60 years old.<sup>3,4</sup> However, older adults have decreased physiological function and more medical comorbidities. Under the joint action of aging and chronic diseases, the body's defense ability against various traumatic stress is

weakened. Additionally, patients experience prolonged disease duration and severe degenerative changes in the lumbar spine, contributing to a reportedly high incidence of perioperative complications and mortality.<sup>5</sup> Therefore, preoperative evaluation is essential for older adults. Presently, the American Society of Anesthesiologists(ASA) physical status is frequently utilized to determine the surgical and anesthesia-related risk for patients. However, it represents a subjective assessment of systemic diseases and survival probability, lacking consideration of the characteristics of older adults. The frailty assessment integrates the physiological and functional status of patients during the aging process, thereby offering pivotal information for risk assessment and planning. The consensus on preoperative assessment of older adults suggests that frailty should be an integral component of preoperative assessment.<sup>6</sup>

Frailty is a progressive age-related decline of the body system, which is defined as a condition in which the individual is in a vulnerable state at increased risk of adverse health outcomes and/or dying when exposed to a stressor.<sup>7</sup> It is a reversible process, especially in the early stage.<sup>8</sup> Early identification and timely, effective care provision can delay the progression of frailty and even restore the individual to their initial state. In several surgical cohorts, preoperative frailty is associated with unfavorable postoperative outcomes, as patients classified as frail exhibit higher incidence of complications and mortality.<sup>9–11</sup> However, there are few prospective reports on the prevalence of frailty in patients with lumbar degenerative disease or the effect of frailty on postoperative outcomes in this population in China, and clinical medical staff do not pay much attention to it. As the population ages, frailty is increasingly prevalent within this demographic. Given that frailty is a reversible, controllable process, this study aims to explore the preoperative frailty status of older adults with lumbar degenerative disease and its effect on postoperative outcomes through a prospective observational study, in order to attract the attention of medical staff to the frailty assessment of such patients and provide a reference for perioperative clinical decision-making.

## Materials and Methods

### Study Design and Population

This prospective, observational cohort study was approved by the Clinical Research Ethics Committee of The First Affiliated Hospital of the University of Science and Technology (No:2022-KY-120) and registered in the Chinese Clinical Trial Registry (<http://www.chictr.org.cn>; No:ChiCTR2300075058). Written informed consent was obtained from all patients or their families. The study was performed in accordance with the ethical standards of the Declaration of Helsinki. A total of 280 patients, aged over 60 years, diagnosed with lumbar degenerative disease and scheduled for elective surgery under general anesthesia were enrolled in the study. Patients with severe mental illness, language communication disorders, and inability to cooperate with the researchers for various reasons were excluded. In addition, patients who had completed preoperative visits but were discharged without surgical treatment, and those lost to follow-up post-discharge were considered dropouts and excluded from the analysis.

### Frailty Assessment

The Tilburg Frailty Indicator (TFI) and modified frailty index 11 (mFI-11) were used to evaluate frailty before surgery. TFI comprises three dimensions with a total of 15 items, namely physical dimension (8 items), psychological dimension (4 items) and social dimension (3 items). The total score ranged from 0 to 15, with a score higher than 5 defined as frailty.<sup>12</sup> The mFI-11 includes the following items: 1) dependent functional status, 2) diabetes mellitus, 3) chronic obstructive pulmonary disease or pneumonia, 4) congestive heart failure, 5) myocardial infarction, 6) percutaneous coronary intervention, stenting, or angina, 7) hypertension requiring medication, 8) impaired sensorium, 9) transient ischemic attack or cerebrovascular accident, 10) cerebrovascular accident with neurological deficits, 11) peripheral vascular disease. mFI-11 was calculated as number of items present divided by 11, thus obtaining a score of 0–1. Based on previous study, a score greater than 0.21 was defined as frail.<sup>13</sup>

### Data Collection

Demographic and clinical data of patients were obtained prospectively through the electronic medical record system, which included age, gender, Body Mass Index (BMI), history of chronic diseases and medication, laboratory indicators

(hemoglobin and albumin). Comorbidity means that patients have two or more chronic diseases, and polypharmacy means that they take more than five kinds of medication.<sup>14</sup> We also recorded the following surgical data: ASA physical status, surgical method, surgical segment.

## Outcome

Patients were followed up until 30 days after discharge. Post-discharge information was obtained through the electronic medical record system as well as follow-up contact by phone. The primary outcome was surgical complication within 30 days post-surgery. The secondary outcomes were the length of hospital stay (LOS), hospital costs, reoperation within 30 days post-surgery and readmission within 30 days post-discharge.

## Data Analysis

SPSS23.0 software was used for statistical analysis. Continuous variables are presented as mean±standard deviation. Student's *t*-test was used to compare the continuous variables with normality and homogeneity of variance and Yuan-Welch-*t* test was used to compare the continuous variables that did not meet normality or did not meet both normality and homogeneity of variance between the two groups; Categorical variables are presented as count and percentage and Chi-square test or Fisher exact test were used for comparisons. Univariable and multivariable logistic regression was used to identify risk factors for postoperative complications. Receiver operating characteristic (ROC) curve analysis was performed to assess the potential predictive ability of TFI, mFI-11 and the combination of them, and the area under the ROC curve (AUC) was used to reflect the predictive ability.  $P < 0.05$  was considered statistically significant.

## Results

A total of 280 patients aged 60 or above, scheduled for elective spine surgery from June 2022 to November 2022 were evaluated in this study. Among them, 6 refused surgery on the day of the scheduled surgery, 2 dropped out due to loss of follow-up post-discharge, the remaining 272 patients were included in final analysis. The average age was (68.22 ±5.32) years. Of these, 210 patients (77.2%) underwent Transforaminal Lumbar Interbody Fusion (TLIF). 62 patients (22.8%) underwent Minimally Invasive Transforaminal Lumbar Interbody Fusion (MIS-TLIF). The frailty detection rates of TFI and mFI-11 were 15.8% (43/272) and 10.7% (29/272) respectively. Characteristics of the patients are shown in Table 1.

**Table 1** Characteristics of Patients (n = 272)

Items	Overall
Age, years	68.22±5.32
Female sex	170 (62.5)
BMI, kg/m <sup>2</sup>	25.05±3.38
Comorbidity	94 (34.5)
Polypharmacy	25 (9.2)
Hemoglobin, (g/L)	126.44± 15.23
Albumin, (g/L)	38.96±3.46
Living alone	22 (8.1)
Smoking history	31 (11.4)
Drinking history	19 (7.0)
Comorbidity	94 (34.5)
Polypharmacy	25 (9.2)
TFI score≥5	43 (15.8)
mFI-11 score>0.21	29 (10.7)

**Note:** Data are presented as n (%) or mean±SD.

**Abbreviations:** BMI, body mass index; TFI, Tilburg Frailty Indicator; mFI-11, The modified frailty index 11.

**Table 2** Postoperative Complications of Patients (n = 272)

Items	n, %
Incision infection	13 (4.8)
Cerebrospinal leak	5 (1.8)
Deep venous thrombosis	4 (1.5)
Pulmonary infection	4 (1.5)
Cerebral infarction	3 (1.1)
Intestinal obstruction	2 (0.7)
Intraspinal hematoma	2 (0.7)
Stress gastric ulcer	1 (0.3)
Poor wound healing	1 (0.3)
Fat liquefaction	1 (0.3)
Nerve root edema	1 (0.3)
Nerve root injury	1 (0.3)
Other	1 (0.3)

**Note:** Data are presented as n (%).

No patient fatalities occurred during the study period. 34 patients (12.5%) developed complications within 30 days post-surgery. 5 patients had two postoperative complications and 29 had one postoperative complication. The top three complications were incision infection (4.8%), cerebrospinal fluid leakage (1.8%), deep venous thrombosis of lower limbs and pulmonary infection (both accounting for 1.5%), as presented in Table 2.

No matter which frailty assessment tools was used, a signifying higher incidence of postoperative complications and readmission was found in the frail group compared to the non-frail group ( $P < 0.05$ ) but no significant difference was found in the incidence of reoperation between the two groups ( $P > 0.05$ ). Frailty based on TFI lead to increased the length of hospital stay and cost ( $P < 0.05$ ), but this difference was not found in the results based on mFI-11, as shown in Table 3.

Univariable analysis showed that the potential factors for postoperative complications were TFI, mFI-11 and albumin. Incorporating these factors into multivariable logistic regression, TFI emerged as an independent risk factor for postoperative complications (OR=5.371, 95% CI: 2.338–12.341,  $P < 0.001$ ), as is outlined in Tables 4 and 5.

TFI and mFI-11 were included again by multivariable logistic regression to realize the combined application of TFI and mFI-11 in predicting the risk of adverse complications. According to the partial regression coefficients of TFI, mFI-11 and constant in multivariable logistic regression, the linear predictive value equation of adverse complications was Logit (Probability)= $-2.535+1.819*TFI+0.714*mFI-11$ . The prediction probability of adverse complications is calculated as follows: Probability =  $1/(1+e^{-x})$ , where e is an exponential function. Further analysis showed the AUC of TFI and mFI-11 in predicting postoperative complications was 0.679, 0.574 respectively. The AUC for combined used of TFI and mFI-11 was 0.703, higher than that of either mFI or TFI single indicator, as shown in Figure 1.

**Table 3** Comparison of Surgical Outcomes Between the Two Groups

	Total (n=272)	TFI		P value	mFI-11		P value
		Frail (n=43)	Non-frail (n=229)		Frail (n=29)	Non-frail (n=243)	
Complications	34 (12.5)	16 (37.2)	18 (7.9)	<b>&lt;0.001<sup>a</sup></b>	8 (27.6)	26 (10.7)	<b>0.009<sup>a</sup></b>
LOS, days	7.46±2.84	8.91±2.83	7.18±2.77	<b>&lt;0.001<sup>b</sup></b>	8.52±3.67	7.33±2.71	0.112 <sup>b</sup>
Hospital cost, 10,000 yuan	2.77±0.54	3.05±0.56	2.72±0.52	<b>0.001<sup>b</sup></b>	2.86±0.75	2.76±0.51	0.401 <sup>b</sup>
Reoperation	5 (1.8)	2 (4.7)	3 (1.3)	0.179 <sup>c</sup>	2 (6.9)	3 (1.2)	0.090 <sup>c</sup>
Readmission	12 (4.4)	7 (16.3)	5 (2.2)	<b>&lt;0.001<sup>a</sup></b>	4 (13.8)	8 (3.3)	<b>0.009<sup>a</sup></b>

**Note:** Data are presented as n (%) or mean±SD. <sup>a</sup>Denotes the use of Chi-square test; <sup>b</sup>Denotes the use of Yuan-Welch t-test with 10% Trimmed sample size; <sup>c</sup>Denotes the use of Fisher exact test. The bold indicates  $p < 0.05$ .

**Abbreviations:** TFI, Tilburg Frailty Indicator; mFI-11, The modified frailty index 11. LOS, length of hospital stay.

**Table 4** Univariable Analysis of Major Postoperative Complications

	Non-complication (n=238)	Complication (n=34)	P value
Age, years	68.29±5.17	67.74±6.39	0.559 <sup>a</sup>
Female sex	147 (61.8)	23 (67.6)	0.508 <sup>b</sup>
BMI, kg/m <sup>2</sup>	24.92±3.36	25.90±3.46	0.235 <sup>a</sup>
Comorbidity	80 (33.6)	14 (41.2)	0.386 <sup>b</sup>
Polypharmacy	22 (9.2)	3 (8.8)	0.937 <sup>b</sup>
Hemoglobin, (g/L)	127.05±15.09	122.18±15.74	0.081 <sup>c</sup>
Albumin, (g/L)	39.15±3.45	37.68±3.34	<b>0.021<sup>c</sup></b>
ASA≥III	222 (93.3)	32 (94.1)	0.854 <sup>b</sup>
TLIF	182 (76.5)	28 (82.3)	0.444 <sup>b</sup>
Surgical segment≥2	136 (57.1)	25 (73.5)	0.069 <sup>b</sup>
TFI	27 (11.3)	16 (47.0)	<b>&lt;0.001<sup>b</sup></b>
mFI-11	21 (8.8)	9 (26.5)	<b>0.009<sup>b</sup></b>

**Note:** Data are presented as n (%) or mean±SD. <sup>a</sup> Denotes the use of Yuan-Welch *t*-test with 10% Trimmed sample size; <sup>b</sup> Denotes the use of Chi-square test; <sup>c</sup> Denotes the use of Student's *t*-test. The bold indicates *p* <0.05.

**Abbreviations:** BMI, body mass index; ASA, American Society of Anaesthesiologists; TLIF, Transforaminal Lumbar Interbody Fusion; TFI, Tilburg Frailty Indicator; mFI-11, The modified frailty index 11.

**Table 5** Multivariable Logistic Regression Analysis of Major Postoperative Complications

Index	B	S.E.	Wald	P	OR	95% confidence interval
Constant	0.223	2.274	0.010	0.922	–	–
TFI	1.681	0.424	15.688	<b>&lt;0.001</b>	5.371	2.338–12.341
mFI-11	0.733	0.509	2.074	0.150	2.081	0.768–5.645
Albumin	–0.071	0.059	1.464	0.226	0.932	0.831–1.045

**Note:** The bold indicates *p* <0.05.

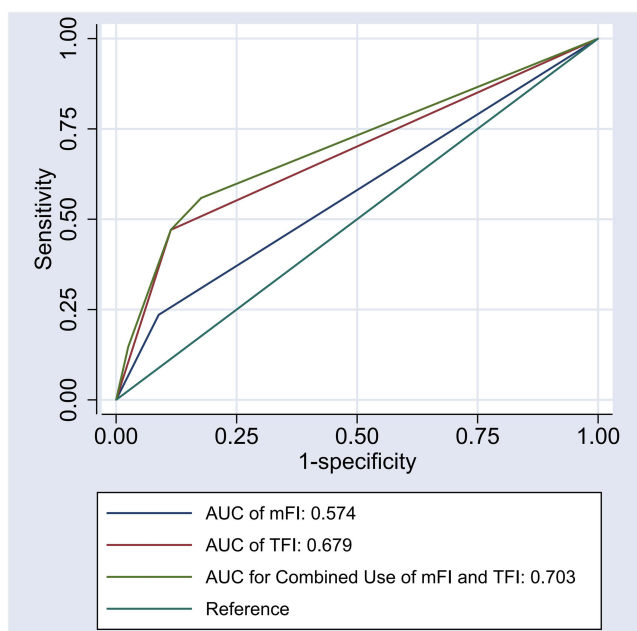
**Abbreviations:** TFI, Tilburg Frailty Indicator; mFI-11, The modified frailty index 11.

Further subgroup analysis showed that no statistically significant differences were found when comparing TLIF and MIS-TLIF with respect to postoperative complications in both frail and non-frail cohorts (*P* > 0.05), as depicted in Table 6.

## Discussions

In this study, we investigated the incidence of frailty in older adults with lumbar degenerative disease, as well as to analyzed the predictive factors associated with postoperative complications. The results revealed a significant association between frailty and adverse postoperative outcomes, identifying frailty as an independent risk factor for postoperative complications.

Numerous frailty measurement instruments based on different models of frailty have been developed.<sup>15</sup> The predominant instruments utilized in clinical settings can be categorized into three main groups: One is Fried Criteria<sup>16</sup> based on the biological model, which defines frailty as five phenotypes (unintentional weight loss, grip strength, fatigue, gait speed, low activity level); another is Frailty Index (FI)<sup>17</sup> based on the deficit accumulation model, which counts accumulated deficits across organ systems and assumes frailty is a state caused by the accumulation of health deficits; A third is TFI<sup>12</sup> that based on Integral Model of Frailty,<sup>18</sup> which defined frailty as "a dynamic state affecting an individual who experiences losses in one or more domains of human functioning (physical, psychological, social), which is caused by the influence of a range of variables and which increases the risk of adverse outcomes. To date, Several



**Figure 1** ROC curves for mFI-11, TFI and the combination of mFI-11 and TFI mFI-11, The modified frailty index 11; TFI, Tilburg Frailty Indicator.

kinds of frailty indices developed from the original FI such as mFI-11, the modified frailty index 5(mFI-5), Adult Spinal Deformity Frailty Index (ASD-FI) and other types of frailty assessment tools have been used in the spinal surgery literature (Table 7).<sup>19–27</sup> Among them, mFI-11 was the most commonly used one.<sup>28,29</sup> Due to the multidimensional characteristics of frailty<sup>30</sup> and overlap between frailty and elements of spinal pathology, the TFI was used to evaluate frailty together with mFI-11 in this study. TFI includes the assessment of physical, psychological and social dimensions, which avoids the influence of disease factors on the assessment of frailty and can comprehensively reflect the overall status of older adults with lumbar degenerative disease. The frailty detection rates of TFI and mFI-11 were 15.8% and 10.7%, higher than the 8% incidence of frailty in patients undergoing spinal surgery reported by Flexman et al<sup>31</sup> and lower than those reported in two other studies (19.6–29.2%).<sup>32,33</sup> These variations may be attributed to different types of spinal diseases of study population and methods of frailty measurement.

The incidence of postoperative complication in this study was 12.5%, aligning with figures reported by other studies (10%-16.4%).<sup>34–37</sup> The multivariable logistic regression confirmed that frailty based on TFI was an independent risk factor for postoperative complications (OR=5.371,  $P<0.001$ ). Despite the non-significant effect size of mFI-11 in predicting the risk of adverse complications (OR=2.081,  $P=0.150$ ), the clinical practicality of mFI-11 prompted the inclusion of both TFI and mFI-11 in a multivariable logistic regression to realize their combined application in predicting the risk of adverse complications. The subsequent evaluation, utilizing the ROC curve, demonstrated that the AUC for the combined application surpassed that of either mFI-11 or TFI as a single indicator. This outcome underscores the superior prediction efficiency of the combined application of mFI-11 and TFI, offering valuable insights for the clinical assessment of frailty in this population. It is worth noting that studies have confirmed that mFI-11 can predict postoperative complications in patients undergoing spinal surgery,<sup>38,39</sup> but there is no relevant study on the relationship

**Table 6** Subanalysis of MIS-TLIF versus TLIF Within Frail and Non-Frail Cohorts

	Frail (n=43)		P value	Non-frail (n=229)		P value
	MIS-TLif (n=5)	TLIF (n=38)		MIS-TLIF (n=57)	TLIF (n=172)	
Complication	2 (40.0)	14 (36.8)	0.891	4 (7.0)	14 (8.1)	0.785

**Note:** Data are presented as n (%).

**Abbreviations:** MIS-TLIF, Minimally Invasive Transforaminal Lumbar Interbody Fusion; TLIF, Transforaminal Lumbar Interbody Fusion.

**Table 7** Frailty Assessment Tools in Spine Surgery

Tools	Method of Assessment	Scoring
mFI-11 <sup>19,20</sup>	1) dependent functional status, 2) diabetes mellitus, 3) chronic obstructive pulmonary disease or pneumonia, 4) congestive heart failure, 5) myocardial infarction, 6) percutaneous coronary intervention, stenting, or angina, 7) hypertension requiring medication, 8) impaired sensorium, 9) transient ischemic attack or cerebrovascular accident, 10) cerebrovascular accident with neurological deficits, 11) peripheral vascular disease or ischemic rest pain	Number of items present divided by 11 to obtain a score of 0–1. The cutoff values varies by study but an increase of mFI-11 score implies increased frailty.
mFI-5 <sup>21,22</sup>	1) history of congestive heart failure within 30 days of surgery, 2) history of diabetes mellitus, 3) history of chronic obstructive pulmonary disease or pneumonia, 4) nonindependent functional status (partially or totally dependent in activities of daily living), 5) history of hypertension requiring medication	Number of items present Not frail: 0 Pre-frail: 1 Frail: ≥ 2
ASD-FI <sup>23,24</sup>	variables including comorbidities and disabilities	Number of items present divided by 40 to obtain a score of 0–1 Not frail: < 0.3 Frail: 0.3–0.5 Severely frail >0.5
FRAIL scale <sup>25,26</sup>	1) fatigue over the past 4 months; 2) ability to climb a flight of stairs unassisted; 3) ability to walk two blocks unassisted; 4) medical comorbidities; 5) loss of weight	Number of items present Not frail: 0 Pre-frail: 1–2 Frail: 3–5
FRIED criteria <sup>27</sup>	1) weight loss; 2) exhaustion; 3) physical inactivity; 4) slowness; 5) handgrip strength	Not frail: 0 Pre-frail: 1–2 Frail: ≥ 3

**Abbreviations:** mFI-11, The modified frailty index 11; mFI-5, The modified frailty index 5; ASD-FI, Adult Spinal Deformity Frailty Index.

between frailty based on TFI and postoperative complications of spinal surgery. However, Liu et al<sup>40</sup> have identified that frailty based on TFI emerged as a significant predictor of the post-operative quality of recovery and complications in patients with gynecologic cancer; Miao et al<sup>41</sup> have demonstrated the successful prediction of total complications among older adults with gastric cancer through the combined use of TFI with other factors, emphasizing the potential of TFI as a promising tool for frailty assessment and risk stratification in surgical populations. The trauma induced by lumbar surgery and anesthesia can incite diverse stress-related changes in the body. The magnitude of the stress response is affected by various factors, among which the existence of frailty should be considered, because it impairs the homeostatic compensatory mechanism needed to combat perioperative stress. With a substantial population affected by lumbar degenerative disease in China, this study underscores the necessity to comprehensively comprehend the preoperative physiological function and vulnerabilities of patients. This understanding should guide efforts aimed at optimizing preoperative frailty status and perioperative management strategies.

The study also revealed that frail patients may experience prolonged hospital stays, higher hospital costs, and increased readmission rates. Given the traumatic nature of spinal surgery, frail patients typically exhibit slow recovery and are predisposed to complications post-surgery. These complications necessitate additional medical interventions, leading to extended hospitalization and medical expenses.<sup>42</sup> It is easy to develop complications and lead to readmission if there are factors such as inadequate postoperative treatment and early discharge, combined with improper self-care post-discharge. In order to minimize all these adverse outcomes, make patients benefit from surgery to the greatest extent, medical staff should carry out a comprehensive geriatric assessment for older adults before surgery, formulate a reasonable rehabilitation nursing plan and discharge arrangements according to the situation of patients, and give correct nursing guidance to caregivers post-discharge. If possible, continuing nursing intervention can be carried out for patients with frailty.

Additionally, our subgroup analysis demonstrated no statistically significant difference in the incidence of postoperative complications in the frail group and the non-frail group when comparing TLIF and MIS-TLIF surgery, while the research of Ton et al<sup>43</sup> indicated frail patients who underwent multi-level lumbar fusions using a traditional open approach experienced a higher rate of surgical complications compared to other frail patients who underwent the same procedure using an MIS techniques. These findings offer orthopedic surgeons valuable insights into the potential benefits of minimally invasive techniques for older adults undergoing lumbar fusion surgery, especially those identified as frail. It is worth noting that our results differ from that mentioned above and may be affected by the relatively low sample size.

This study is not without limitations. First, it was conducted at a single center project, and the sample representativeness is insufficient. Second, the short follow-up period for patients may limit the depth of our findings. Extending the duration and scope of future follow-up could facilitate a more comprehensive analysis of frailty and its impact on patient prognosis. In addition, this study was only a prospective observation, and further intervention studies can be carried out in the future.

## Conclusions

In conclusion, our findings indicate that preoperative frailty in older adults with lumbar degenerative disease serves as an independent risk factor for postoperative complications, resulting in a cascade of adverse outcomes. This highlights the utility of frailty assessment in identifying high-risk patients and enhancing preoperative and postoperative management. Therefore, frailty should be included in the routine preoperative assessment of older adults with lumbar degenerative disease.

## Data Sharing Statement

The data that support the findings of this study are available from the corresponding author (Xia Chen), upon reasonable request.

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## Disclosure

The authors report no conflicts of interest in this work.

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