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## Frailty Is Associated with an Increased Risk of Complications and Need for Repeat Procedures after Sling Surgery in Older Adults

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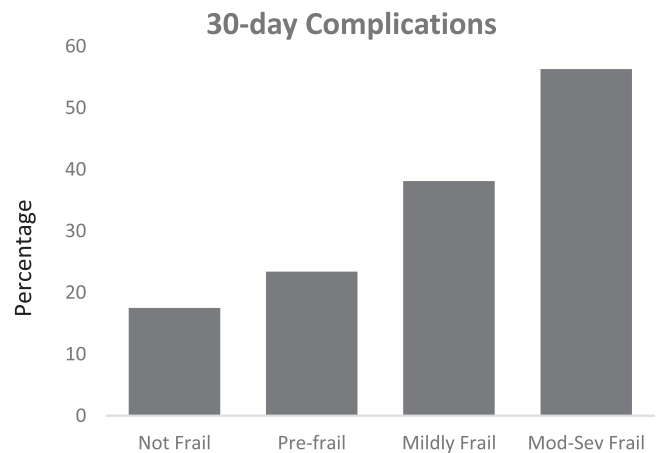
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**Study Need and Importance:** As the population ages in both the United States and worldwide, there is an increased need to better understand how to care for aging adults who present with urinary incontinence. Rather than assuming age is a surrogate for risk, frailty accounts for underlying vulnerability that can lead to increased risk of complications and poor outcomes in response to surgery. Currently, there are very limited data on outcomes in older, and frail older, adults as these patients are often excluded from clinical trials.

**What We Found:** Using the validated Claims-Based Frailty Index, female Medicare beneficiaries over the age of 65 years undergoing sling surgery were stratified into 4 previously established categories of frailty. The risk of complications significantly increased with increasing frailty category (see figure). Additionally, frail women were more likely to undergo a repeat procedure for either persistent urinary incontinence or obstructed voiding 1 year after sling placement. After adjusting for age and comorbidities, frailty remained independently associated with these increased risks.

**Limitations:** Given that this is a study using Medicare claims data, valuable clinical information such as the severity and degree of bother from urinary




**Figure.** Rates of 30-day complications after sling placement stratified by frailty ( $p < 0.001$ ). *Mod-Sev*, moderately to severely.

incontinence prior to sling placement was not known. Additionally, degree of improvement in symptoms and quality of life after surgery was not captured.

**Interpretation for Patient Care:** Aside from just age and comorbidities, it is important to incorporate frailty into the surgical decision-making process to help risk-stratify and prognosticate outcomes in older adults contemplating sling surgery.

## Frailty Is Associated with an Increased Risk of Complications and Need for Repeat Procedures after Sling Surgery in Older Adults

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**Purpose:** Sling surgery is the gold standard treatment for stress urinary incontinence in women. While data support the use of sling surgery in younger and middle-aged women, outcomes in older, frail women are largely unknown.

**Materials and Methods:** Data were examined for all Medicare beneficiaries  $\geq 65$  years old who underwent sling surgery with or without concomitant prolapse repair from 2014 to 2016. Beneficiaries were stratified using the Claims-Based Frailty Index (CFI) into 4 categories: not frail (CFI  $< 0.15$ ), prefrail ( $0.15 \leq \text{CFI} < 0.25$ ), mildly frail ( $0.25 \leq \text{CFI} < 0.35$ ) and moderately to severely frail (CFI  $\geq 0.35$ ). Outcomes included rates and relative risk of 30-day complications, 1-year mortality and repeat procedures for persistent incontinence or obstructed voiding at 1 year.

**Results:** A total of 54,112 women underwent sling surgery during the study period, 5.2% of whom were mildly to moderately to severely frail. Compared to the not frail group, moderately to severely frail beneficiaries demonstrated an increased adjusted relative risk (aRR) of 30-day complications (56.5%; aRR 2.5, 95% CI: 2.2–2.9) and 1-year mortality (10.5%; aRR 6.7, 95% CI: 4.0–11.2). Additionally, there were higher rates of repeat procedures in mildly to severely frail beneficiaries (6.6%; aRR 1.4, 95% CI: 1.2–1.6) compared to beneficiaries who were not frail.

**Conclusions:** As frailty increased, there was an increased relative risk of 30-day complications, 1-year mortality and need for repeat procedures for persistent incontinence or obstructed voiding at 1 year. While there were fewer sling surgeries in performed frail women, the observed increase in complication rates was significant. Frailty should be strongly considered before pursuing sling surgery in older women.

**Key Words:** urinary incontinence, stress; aging; frailty; frail elderly; suburethral slings

STRESS urinary incontinence (SUI) is a common clinical condition that affects up to 53% of women over the age of 60 years.<sup>1</sup> Sling surgery, often considered the gold standard treatment, is the most commonly performed operation to treat SUI the United States.<sup>2–4</sup> As

the population ages, there will be an increase in older women with SUI seeking surgical treatment who are also frail, meaning that they have additional vulnerabilities and an increased risk for poor health outcomes in response to stressors such as

### Abbreviations and Acronyms

AP = anterior/posterior

aRR = adjusted relative risk

CCI = Charlson Comorbidity Index

CFI = Claims-Based Frailty Index

CPT® = Current Procedural Terminology

ICD = International Classification of Diseases

POP = pelvic organ prolapse

SUI = stress urinary incontinence

TOMUS = Trial of Mid-Urethral Slings

TUG = Timed Up & Go test

UTI = urinary tract infection

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**Editor's Note:** This article is the third of 5 published in this issue for which category 1 CME credits can be earned. Instructions for obtaining credits are given with the questions on pages 1357 and 1358.

surgery.<sup>5</sup> While sling surgery is generally regarded as a relatively safe and low-risk procedure, most outcomes data are limited to younger and middle-aged women.

However, very little is known about surgical outcomes in frail older adults undergoing this common procedure. While 1 study looked at outcomes of sling surgery in Medicare beneficiaries over the age of 65, the impact of frailty on outcomes was not examined.<sup>6</sup> There is a growing body of literature indicating that frailty is associated with an increased risk of complications after many types of surgery, including urological procedures.<sup>7–10</sup> Given the paucity of data on outcomes of sling surgery in frail women, it remains unknown whether it is reasonable to perform this type of surgery in this particularly vulnerable population or if it should be avoided entirely.

In order to address this gap in knowledge, we used a 100% cohort of fee-for-service Medicare claims for female beneficiaries, inclusive of all ages and all levels of frailty, who underwent sling surgery with or without concomitant pelvic organ prolapse (POP) repair from 2014 to 2016 in the United States. Using the Claims-Based Frailty Index (CFI), we examined short-term outcomes including 30-day complications, both overall and for rates of urinary tract infections (UTIs) specifically, along with 1-year outcomes including 1-year mortality and need for repeat procedures for either obstructed voiding or persistent incontinence at 1 year following sling surgery. Findings of this study will help better define the risks of sling surgery in all older women of who may be considering surgical correction of SUI.

## MATERIALS AND METHODS

### Subjects and Database

We used a 100% cohort of female Medicare beneficiaries undergoing sling surgery from 2014 to 2016. Specifically, we used the Medicare Inpatient, Outpatient, Carrier and Master Beneficiary Summary files to include all fee-for-service care for female Medicare beneficiaries ages 66 and older who underwent sling placement during this time period. Sling surgery was identified using the Current Procedural Terminology (CPT®) code 52788 in the Carrier file. Concomitant POP repair was identified using CPT codes for hysterectomy, anterior/posterior (AP) repairs, apical repairs and colposcleisis surgeries (supplementary table 1, <https://www.jurology.com>). Institutional Review Board approval was obtained for this study (IRB No. 17-23783).

### Outcome Measures

Both 30-day and 1-year outcomes were assessed. Thirty-day outcomes included 30-day complications, both overall and for UTI separately, as UTI is a well-known complication of sling surgery.<sup>6,11,12</sup> Additionally, since

UTI is a more minor complication, it was assessed independent of more serious complications. One-year outcomes included 1-year mortality and the need for repeat procedures (for both urinary incontinence and for outlet obstruction) at 1 year. Thirty-day complications were identified using the International Classification of Diseases (ICD)-9 and ICD-10 diagnosis codes from the Medicare Files, consistent with the existing literature.<sup>9,10,13,14</sup> Complications included infection (including UTI), cardiovascular, renal, pulmonary, nervous system including stroke, deep venous thrombosis or pulmonary embolism, delirium, wound complications, postoperative hemorrhage, postoperative shock, complications secondary to anesthesia, other complications and reoperation. One-year mortality was determined using the date of death from the Master Beneficiary Summary file.

We assessed procedures to address both persistent SUI and obstructed voiding. Repeat SUI procedures included repeat sling placement (CPT 52788) or urethral bulking (CPT 51715). Procedures to correct obstructed voiding included removal or revision of sling (CPT 57287) and urethrolisis (CPT 53500) procedures.

### Covariates

To measure frailty, we used the CFI, which was developed and validated specifically for use with Medicare data.<sup>15–17</sup> This index utilizes a weighted deficit accumulation model that takes into account 93 different variables including 52 ICD-9 codes, 25 CPT-4 codes and 16 Healthcare Common Procedure Coding System level II codes. This CFI allows for assessment of risk for adverse health outcomes that are not otherwise quantified using demographic characteristics and traditional comorbidity measures in Medicare data. Using this index, we stratified female beneficiaries into 4 established categories based on level of frailty: not frail (CFI <0.15), prefrail (0.15 < CFI < 0.25), mildly frail (0.25 ≤ CFI < 0.35), and moderately to severely frail (CFI ≥ 0.35), consistent with the literature.<sup>16</sup>

Demographic data including age and race were obtained from the Medicare Carrier files. Information on comorbidities was abstracted from the Medicare Inpatient, Outpatient and Carrier files in the year preceding sling surgery and was used to calculate the Charlson Comorbidity Index (CCI).<sup>18</sup>

### Statistical Analyses

Univariate analysis was performed by standard descriptive statistics. For categorical variables, numbers and percentages were reported and Pearson  $\chi^2$  tests were performed. For continuous variables, mean ± SD or median with (25%–75%) were presented and ANOVA performed.

Relative risk was calculated by using generalized estimating equations to explore the association between frailty and the outcome variables of interest (30-day complications, 30-day UTIs, 1-year mortality and repeat procedures for persistent incontinence or obstructed voiding within 1 year of surgery) adjusting for age, race, CCI, concomitant POP repair and type, and calendar year. Both univariate and multivariate models were created. Due to the small number of repeat procedures at 1 year, beneficiaries in the mild and moderate to severe frailty

categories were combined into a single category for these analyses.

For all analyses,  $p=0.05$  on a 2-sided significance test with a 5% level was considered statistically significant. Analyses were performed using SAS® statistical software v9.4.

**RESULTS**

A total of 54,112 women ages 66 years and older underwent sling surgery during the study period. The mean±SD age was 73.6±5.6 years, and 92.3% of women were White. The mean±SD CCI in the cohort was 1.6±1.9. Most female beneficiaries were not frail (46.2%) or prefrail (48.7%), while only 4.8% and 0.4% were characterized as mildly and moderately to severely frail, respectively. Both age and mean CCI increased with increasing CFI categories, while rates of concomitant POP repair declined with increasing CFI categories (table 1).

**30-Day Complications**

All 30-day complications are shown in supplementary table 2 (<https://www.jurology.com>). As CFI category increased, rates of all 30-day complications also steadily increased, and moderately to severely frail female beneficiaries demonstrated

the highest rate of 30-day complications at 56.5%. UTIs, which were observed in 15.7% of all women within 30 days of sling surgery, represented the most common postoperative complication in this cohort. Similar to all 30-day complications, as CFI categories increased, rates of 30-day UTI increased accordingly, with moderately to severely frail women demonstrating the highest rates of UTI at 37.7% (fig. 1).

After UTI, cardiovascular complications were the next most frequently observed complication in female Medicare beneficiaries. While cardiovascular complications were uncommon in beneficiaries who were not frail (0.5%) they increased to 2.4%, 8.6% and 19.9% in prefrail, mildly frail and moderately to severely frail beneficiaries, respectively ( $p < 0.001$ ). Both pulmonary (not frail: 0.8%; prefrail: 1.9%; mildly frail: 5.1%; moderately to severely frail: 9.4%;  $p < 0.001$ ) and renal (not frail: 0.8%; prefrail: 1.7%; mildly frail: 3.6%; moderately to severely frail: 6.3%;  $p < 0.001$ ) complications also increased significantly with increasing CFI category.

Results of multivariate analysis for 30-day complications and 30-day UTIs are shown in table 2. After adjusting for age, comorbidity, race, concomitant POP

**Table 1. Characteristics of baseline cohort stratified by CFI**

	Total	Not Frail (CFI 0.15)	Prefrail (0.15≤CFI<0.25)	Mildly Frail (0.25≤CFI<0.35)	Moderately to Severely Frail (CFI ≥0.35)	p Value
No. subjects (%)	54,112 (100.0)	25,012 (46.2)	26,326 (48.7)	2,583 (4.8)	191 (0.4)	
No. yrs age (%):						<0.001
66–69	17,468 (32.3)	9,676 (38.7)	7,230 (27.5)	534 (20.7)	28 (14.7)	
70–74	17,424 (32.2)	8,478 (33.9)	8,202 (31.2)	690 (26.7)	54 (28.3)	
75–79	11,655 (21.5)	4,689 (18.8)	6,254 (23.8)	659 (25.5)	53 (27.8)	
80–85	5,296 (9.8)	1,653 (6.6)	3,177 (12.1)	430 (16.7)	36 (18.9)	
≥85	2,269 (4.2)	516 (2.1)	1,463 (5.6)	270 (10.5)	20 (10.5)	
Mean±SD yrs age	73.6±5.6	72.5±5.0	74.4±5.8	76.1±6.4	77.0±6.5	<0.001
Median yrs age (IQR)	72.6 (69.0–77.1)	71.50 (68.4–75.4)	73.5 (69.6–78.1)	75.5 (70.8–80.4)	76.4 (72.3–81.7)	<0.001
No. race (%):						<0.001
White	49,943 (92.3)	23,232 (92.9)	24,128 (91.7)	2,405 (93.1)	178 (93.2)	
Black	1,542 (2.9)	553 (2.2)	914 (3.5)	66 (2.6)	9 (4.7)	
Other	2,627 (4.9)	1,227 (4.9)	1,284 (4.9)	112 (4.3)	4 (2.1)	
No. CCI (%):						<0.001
0–1	33,047 (61.1)	20,065 (80.2)	12,613 (47.9)	364 (14.1)	5 (2.6)	
2–4	16,614 (30.7)	4,590 (18.4)	10,780 (41.0)	1,189 (46.0)	55 (28.8)	
>4	4,451 (8.2)	357 (1.4)	2,933 (11.1)	1,030 (39.9)	131 (68.6)	
Mean±SD CCI	1.6±1.9	0.8±1.1	2.1±1.9	4.1±2.5	6.7±2.8	<0.001
Median CCI (IQR)	1.0 (0.0–2.0)	0.0 (0.0–1.0)	2.0 (1.0–3.0)	4.0 (2.0–6.0)	6.0 (4.0–8.0)	<0.001
No. procedure yr (%):						0.040
2014	18,949 (35.0)	8,891 (35.6)	9,083 (34.5)	902 (34.9)	73 (38.2)	
2015	17,075 (31.6)	7,908 (31.6)	8,265 (31.4)	844 (32.7)	58 (30.4)	
2016	18,088 (33.4)	8,213 (32.8)	8,978 (34.1)	837 (32.4)	60 (31.4)	
No. concomitant POP repair (%):						<0.001
Sling only (no POP)	17,170 (31.7)	6,525 (26.1)	9,383 (35.6)	1,150 (44.5)	112 (58.6)	
AP repair with sling	10,495 (19.4)	4,423 (17.7)	5,485 (20.8)	560 (21.7)	27 (14.1)	
Apical repair with sling	2,673 (4.9)	1,389 (5.6)	1,198 (4.6)	78 (3.0)	8 (4.2)	
AP+apical repair with sling	9,865 (18.3)	4,596 (18.4)	4,831 (18.4)	414 (16.0)	24 (12.6)	
Hysterectomy+AP repair with sling	3,801 (7.0)	2,204 (8.8)	1,500 (5.7)	93 (3.6)	4 (2.1)	
Hysterectomy+apical repair with sling	2,564 (4.7)	1,710 (6.8)	813 (3.1)	39 (1.5)	2 (1.1)	
Hysterectomy+AP+apical repair with sling	5,912 (10.9)	3,611 (14.4)	2,182 (8.3)	111 (4.3)	8 (4.2)	
Colpocleisis with sling	1,632 (3.0)	554 (2.2)	934 (3.6)	138 (5.3)	6 (3.2)	



**Figure 1.** Rates of 30-day complications and 30-day UTI after sling placement stratified by frailty ( $p < 0.001$  for both). *Mod-Sev*, moderately to severely.

repair and type, and calendar year, compared to female beneficiaries who were not frail, those who were prefrail, mildly frail, moderately to severely frail had an adjusted relative risk (aRR) of any 30-day complication of 1.2 (95% CI: 1.2–1.3;  $p < 0.001$ ), 1.8 (95% CI: 1.7–1.9;  $p < 0.001$ ), and 2.5 (95% CI: 2.2–2.9;  $p < 0.001$ ), respectively. Additionally, moderately to severely frail women also demonstrated the highest relative risk of UTI within 30 days of sling surgery (aRR 2.4, 95% CI 1.9–2.9;  $p < 0.001$ ), compared to women who were not frail (table 2).

### One-Year Mortality

Overall, 1-year mortality was 0.9% after sling surgery in this cohort of female Medicare beneficiaries. This ranged from 0.3% among nonfrail beneficiaries and increased with increasing CFI to 10.5% among moderately to severely frail beneficiaries ( $p < 0.001$ ). On multivariate analysis, compared to female beneficiaries who were not frail, those who were prefrail, mildly frail and moderately to severely frail had an aRR of 1-year mortality of 1.9 (95% CI:

1.5–2.5,  $p < 0.001$ ), 3.4 (95% CI: 2.4–4.8,  $p < 0.001$ ), and 6.7 (95% CI: 4.0–11.2,  $p < 0.001$ ), respectively (table 2).

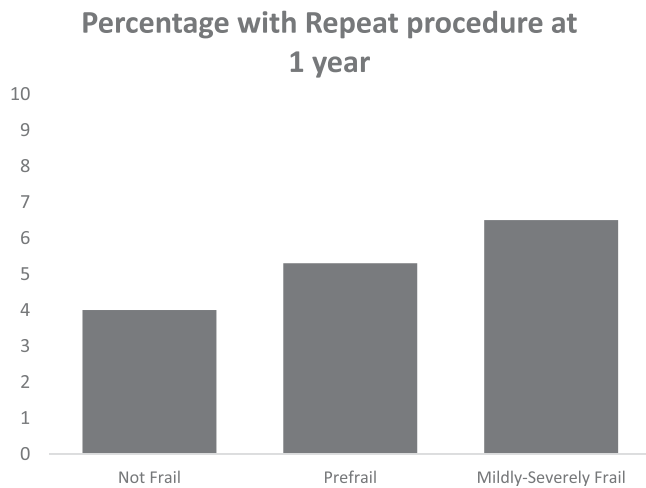
### Repeat Procedures at 1 Year

Overall, 4.8% of women in the cohort underwent a repeat procedure for persistent incontinence or obstructed voiding at 1 year, with slightly more procedures being done for persistent incontinence (2.9%) than for obstructed voiding (2.1%). As CFI category increased, there was also a corresponding increase in the percentage of these repeat procedures (fig. 2). On multivariate analysis, compared to female beneficiaries who were not frail, beneficiaries who were prefrail and mildly to severely frail demonstrated an increased aRR of 1.2 (95% CI: 1.1–1.3,  $p < 0.001$ ) and 1.4 (95% CI: 1.2–1.6,  $p < 0.001$ ) for undergoing a repeat procedure at 1 year, respectively (table 3). Separate multivariate analyses were performed for anti-incontinence and obstructed voiding procedures individually, which indicated similar trends (data not shown).

**Table 2.** Relative risk of 30-day complications, UTI and 1-year mortality

	Basic Statistics			Univariate Model RR		Multivariate Model RR			
	No. Observed (%)	No. Events (%)	p Value	RR (95% CI)	p Value	Global p Value	RR (95% CI)	p Value	Global p Value
30-Day complications (including UTI):			<0.001			<0.001			<0.001
Not frail (CFI <0.15)	25,012 (46.2)	4,379 (17.5)		Referent			Referent		
Prefrail (0.15 ≤ CFI < 0.25)	26,326 (48.7)	6,138 (23.3)		1.3 (1.3–1.4)	<0.001		1.2 (1.2–1.3)	<0.001	
Mildly frail (0.25 ≤ CFI < 0.35)	2,583 (4.8)	977 (37.8)		2.2 (2.0–2.3)	<0.001		1.8 (1.7–1.9)	<0.001	
Moderately to severely frail (CFI ≤ 0.35)	191 (0.4)	108 (56.5)		3.2 (2.8–3.7)	<0.001		2.5 (2.2–2.9)	<0.001	
30-Day UTIs			<0.001			<0.001			<0.001
Not frail (CFI <0.15)	25,012 (46.2)	3,281 (13.1)		Referent			Referent		
Prefrail (0.15 ≤ CFI < 0.25)	26,326 (48.7)	4,488 (17.0)		1.3 (1.3–1.4)	<0.001		1.2 (1.2–1.3)	<0.001	
Mildly frail (0.25 ≤ CFI < 0.35)	2,583 (4.8)	662 (25.6)		2.0 (1.8–2.1)	<0.001		1.7 (1.5–1.8)	<0.001	
Moderately to severely frail (CFI ≤ 0.35)	191 (0.4)	72 (37.7)		2.9 (2.4–3.5)	<0.001		2.4 (1.9–2.9)	<0.001	
1-Yr mortality:			<0.001			<0.001			<0.001
Not frail (CFI <0.15)	25,012 (46.2)	85 (0.3)		Referent			Referent		
Prefrail (0.15 ≤ CFI < 0.25)	26,326 (48.7)	298 (1.1)		3.3 (2.6–4.2)	<0.001		1.9 (1.5–2.5)	<0.001	
Mildly frail (0.25 ≤ CFI < 0.35)	2,583 (4.8)	96 (3.7)		10.9 (8.2–14.6)	<0.001		3.4 (2.4–4.8)	<0.001	
Moderately to severely frail (CFI ≤ 0.35)	191 (0.4)	20 (10.5)		30.8 (19.3–49.1)	<0.001		6.7 (4.0–11.2)	<0.001	

Models adjusted for age, race, CCI, concomitant POP repair and calendar year.



**Figure 2.** Repeat procedures at 1 year stratified by CFI (p <0.001).

**DISCUSSION**

In this study, increasing CFI category was associated with an increased relative risk of 30-day complications, 30-day UTIs, and 1-year mortality following sling surgery. Importantly, CFI was independently associated with these increased risks even after adjusting for age, CCI, and concomitant POP repair demonstrating the value of assessing frailty independently. To date, this is the first study that has utilized the CFI with a 100% cohort of Medicare beneficiaries undergoing sling surgery with or without concomitant POP repair to assess surgical outcomes. Our findings underscore the importance of considering and measuring frailty in the preoperative setting, as an emerging body of evidence demonstrates the

negative association that frailty has on the risk of postoperative complications.<sup>7–10</sup>

In general, reported rates of serious complications following sling surgery are low. In the Trial of Mid-Urethral Slings (TOMUS), which compared transobturator to retropubic sling placement in 597 women, there were no reported cardiovascular complications, pulmonary complications, or death within 1 year of surgery.<sup>19</sup> This differs significantly from the findings in our study in which cardiovascular complications, pulmonary complications, and 1-year mortality were observed. These complication rates increased significantly with increasing frailty in moderately to severely frail women who experienced high rates of cardiovascular complications (19.9%), pulmonary complications (9.4%), and 1-year mortality (10.5%). Notably, the study population in the TOMUS trial had an average age of 53 years, which differs significantly from the average age of 74 years in our study. This is not unique to the TOMUS trial; most data regarding outcomes of sling surgery do not account for the heterogeneity of older women with SUI, as they are generally not included in these types of trials. Our study uses real-world data examine surgical outcomes in older women to allow for more appropriate risk stratification and patient counselling prior to surgical intervention.

Another recent study compared outcomes of sling surgery in women with and without frailty. This study found that frail women were more likely to have increased length of stay after sling surgery, but overall rates of serious complications after surgery were low in both groups.<sup>20</sup> Importantly, the

**Table 3.** RR of repeat sling surgery, urethral bulking, sling revision or urethrololysis at 1 year

Variable	Basic Statistics			Univariate Model RR			Multivariate Model RR		
	No. Observed (%)	No. Events (%)	p Value	RR (95% CI)	p Value	Global p Value	RR (95% CI)	p Value	Global p Value
Total	54,112 (100.0)	2,617 (4.8)							
CFI:			<0.001			<0.001			<0.001
Not frail (CFI <0.15)	25,012 (46.2)	1,006 (4.0)		Referent			Referent		
Prefrail (0.15 ≤ CFI <0.25)	26,326 (48.7)	1,428 (5.4)		1.4 (1.3–1.5)	<0.001		1.2 (1.1–1.3)	<0.001	
Mildly/moderately to severely frail (CFI ≥0.25)	2,774 (5.1)	183 (6.6)		1.6 (1.4–1.9)	<0.001		1.4 (1.2–1.6)	<0.001	
Age (yrs):			<0.001			<0.001			0.009
65–69	17,468 (32.3)	746 (4.3)		Referent			Referent		
70–74	17,424 (32.2)	848 (4.9)		1.1 (1.0–1.3)	0.008		1.1 (1.0–1.2)	0.020	
75–79	11,655 (21.5)	623 (5.3)		1.3 (1.1–1.4)	<0.001		1.2 (1.1–1.3)	0.001	
80–85	5,296 (9.8)	279 (5.3)		1.2 (1.1–1.4)	0.002		1.2 (1.0–1.3)	0.028	
≥85	2,269 (4.2)	121 (5.3)		1.3 (1.0–1.5)	0.020		1.2 (1.0–1.4)	0.116	
Race:			<0.001			<0.001			<0.001
White	49,943 (92.3)	2,472 (4.9)		Referent			Referent		
Black	1,542 (2.8)	58 (3.8)		0.8 (0.6–1.0)	0.035		0.8 (0.6–1.0)	0.026	
Other	2,627 (4.9)	87 (3.3)		0.7 (0.5–0.8)	<0.001		0.7 (0.6–0.9)	0.001	
CCI:			<0.001			<0.001			0.101
0–1	33,047 (61.1)	1,477 (4.5)		Referent			Referent		
2–4	16,614 (30.7)	868 (5.2)		1.2 (1.1–1.3)	<0.001		1.1 (1.0–1.2)	0.188	
>4	4,451 (8.2)	272 (6.1)		1.4 (1.2–1.6)	<0.001		1.2 (1.0–1.3)	0.037	

RR associated risk factors for repeated procedure (CPT 53500, 51715, 57288, 57287) at 1 year. Model adjusted for concomitant POP repair and calendar year.

population in this study was significantly younger than the population in our study with a mean age of 56.4 versus 73.6 years. Additionally, our study stratified women into 4 categories of frailty and included more complete data of all fee-for-service Medicare beneficiaries. These 2 studies taken together emphasize the importance of assessing frailty in all women but demonstrate that accounting for frailty is particularly important in more elderly populations.

The rate of repeat procedures after sling surgery seen in our study is slightly lower than what has been previously reported where 8% of women required a procedure to relieve obstruction.<sup>6</sup> This may be due to the fact that the authors of that study accounted for additional CPT codes, such as placement of urethral catheter and urethral dilation. However, these codes, particularly urethral catheterization, are known to be unreliable so may explain the lower number of repeat procedures seen in our study.<sup>21</sup> Regardless, the rates of repeat procedures seen in our study were not ubiquitous in women over 66, and also increased with increasing CFI category. The most notable finding is that frailty was independently associated with this difference in observed rates. One possibility is that frailty represents additional vulnerability towards poor post-operative outcomes, including surgical failures. Another possibility is that frail older adults have more issues with underactive bladders,<sup>22</sup> leading to an increased risk of retention with sling placement. Looking only at age treats older adults as a homogenous group while using frailty helps to account for differences on an individual level.

In the clinical setting, a practical assessment of frailty is the use of the Timed Up & Go test (TUG). TUG is performed by asking patients to stand from a seated position in a chair, walk at their normal pace 10 feet to a mark on the floor, turn around, return to the chair and sit back down. A time of  $\leq 10$  seconds, 11–15 seconds and  $\geq 15$  seconds corresponds to not frail, prefrail and frail categories. TUG has been used

in urological practice to help stratify patients into categories of frailty.<sup>23</sup>

A major strength of this study is the use of a large national 100% sample of female Medicare beneficiaries undergoing sling surgery; however, it does not capture preoperative clinical information such as the type or severity of incontinence, results of urodynamic testing (if performed), or post-void residual volumes. Additionally, we were unable to assess outcomes such as patient satisfaction or improvements in quality of life after surgery or determine the reason for the patient's repeat procedure at 1-year. Despite these limitations, the data used in this study are ideal for assessing real-world outcomes of sling surgery in women ages 65 and older, as they capture data on all women with all levels of frailty, the majority of whom may not have met criteria for clinical trials. Another limitation is that procedure code 57288 captures all sling types including synthetic (retropubic, transobturator, and single incision) and autologous fascia pubovaginal slings which carry different risk benefit profiles. However, it is reasonable to assume that the breakdown of sling type would not be different among groups.

## CONCLUSIONS

In this study, we found that increasing frailty, as determined by the CFI, was associated with an increased relative risk of 30-day complications including UTIs, 1-year mortality and the need for repeat procedures for persistent incontinence and obstructed voiding at 1 year. While there were far fewer sling procedures performed in mildly and moderately to severely frail women, the increase in observed complication rates among this frail older cohort was significant and clinically important. These data highlight the notion that frailty should be strongly considered when making decisions regarding sling surgery in older women.

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## EDITORIAL COMMENT

Evidence continues to emerge that frailty, rather than chronological age, may be a better prognostic indicator of postoperative morbidity and mortality. Indeed, in the current study, increasing degrees of frailty were strongly associated with an increased risk of 30-day complications, 1-year mortality and need for additional surgery at 1 year after undergoing a sling. The findings are timely and bring up additional questions. First, is a formal measure of frailty necessary prior to sling surgery? The authors of the current study found that only 5.1% of the >54,000 women ages >65 years undergoing slings met the criteria for mild, moderate or severe frailty. One interpretation of this finding is that sling surgeons are already prescreening their operative candidates for surgical risk without a formal measure of frailty and excluding the frailest from surgery. Subsequently, fewer women at higher risk for postoperative complications are undergoing slings. Second, if a preoperative measure of frailty is used, which measure is most useful? The authors' choice of a claims-based frailty index is dependent on accurate coding of multiple International Classification of Diseases-

9, Current Procedural Terminology and Healthcare Common Procedure Coding System variables. This, like other claims-based metrics, is detailed but may be challenging to apply prospectively. Other measures, such as the Modified 5-Item Frailty Index used in the study by Medendorp et al,<sup>1</sup> used the presence of 5 comorbidities (congestive heart failure, diabetes mellitus, chronic obstructive pulmonary disease or pneumonia, partially dependent or totally dependent functional health status at time of surgery and hypertension) and lends itself to easier evaluation using standard electronic health record technology. The simplest measure may be the Timed Up & Go test, an objective measure of frailty that has also been implemented in multiple fields, including urological surgery.<sup>2</sup> While this option is certainly reproducible in the office setting, it may be time-consuming in a busy practice.

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## REPLY BY AUTHORS

We believe that frailty should be measured and considered in the perioperative decision-making process for all older adults undergoing all types of surgical procedures, including slings. Although the percentage of frail older adults undergoing sling surgery was relatively low in our study, these data demonstrated a dose-response relationship between increasing levels of frailty and worse postoperative outcomes not only among the most frail individuals. Therefore, identification of frailty, and even prefrail states, allows for helpful risk stratification and prognostication across the frailty spectrum. We

appreciate the reference to our prior work using Modified 5-Item Frailty Index and the Timed Up & Go test (TUG) to measure frailty, and we continue to advocate the use of the TUG in clinical practice. We have previously published that the TUG is well suited for a busy clinical practice as it takes (on average) less than 1 minute to perform and record in the electronic medical record and adds valuable insight into physical function and frailty.<sup>1</sup> We continue to measure TUG for all adults ages 65 years and older presenting to our office for routine care and consider it to be the fifth vital sign.

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