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The impact of frailty on artificial urinary sphincter placement and removal procedures

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Abstract

Objectives: To determine whether frailty is associated with increased odds of 30-day surgical complications among men undergoing both artificial urinary sphincter (AUS) placement and removal procedures and to determine whether frailty was associated with increased odds of having an AUS removal procedure.

Methods: This is a retrospective cohort study of men undergoing AUS placement and removal procedures using data from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) from 2006–2013. Frailty was quantified using the NSQIP-FI (Frailty Index) and was applied to logistic regression models predicting 30-day complications (overall, major and minor) and the odds of having an AUS removal procedure (over an AUS placement procedure).

Results: We identified a total of 624 and 147 men undergoing AUS placement and removal procedures, respectively. NSQIP-FI of ≥0.27, but not age, was associated with major complications (aOR 3.5, 95% CI 1.2–9.9), while age ≥85 years, but not NSQIP-FI, was associated with minor complications (aOR 7.9, 95% CI 1.4–45.6). Men undergoing AUS removal procedures tended to be more frail compared to men undergoing AUS placement procedures (12.9% vs 6.1% had NSQIP-FI of ≥0.27, p<0.01).

Conclusions: Men undergoing AUS removal procedures are, on average, more frail compared to men undergoing AUS placement procedures. Frailty is associated with increased odds of major complications and with having an AUS removal procedure. These findings highlight the importance of incorporating measures of frailty, instead of age alone, into the perioperative decision-making process for adults considering these types of procedures.

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Keywords

geriatric; elderly; urethral sphincter; NSQIP

Introduction

Male stress urinary incontinence (SUI), defined as the involuntary loss of urine with effort or exertion,[1] is associated with significant detriments in quality of life[2] and costs of greater than $8–10 billion per year in the United States alone.[3] A history of prior prostate surgery, most commonly radical prostatectomy, is a major risk factor for the development of male SUI, and up to 20% of men undergoing these types of procedures ultimately undergo an intervention for SUI.[3–6] While a variety of interventions exist, the artificial urinary sphincter (AUS) is considered to be the gold standard definitive treatment for male SUI.[3–8]

Though overall success rates and satisfaction are high, the AUS is a procedure with many known potential complications.[5,9] Among the most severe of these complications are device infection and erosion, necessitating removal of the device in its entirety.[10] Known risk factors for device removal include diabetes, history of radiation or urethral stricture,[11] and higher American Society of Anesthesiologists (ASA) class.[11] However, there is reason to believe that frailty, a multifactorial syndrome associated with a reduction in physiologic reserve and an increased susceptibility to adverse events in response to stressors, may place men at heightened risk for device infection and erosion, leading to AUS removal. Some reasons why this may be the case include factors associated with frailty such as sarcopenia, changes in body composition, and malnutrition.[12] While frailty has been demonstrated to be associated with complications among men undergoing other types of urological procedures,[13,14] its association specifically with AUS surgery has not been studied.

In order to gain a better understanding of the role of frailty on outcomes related to AUS procedures, we performed a retrospective cohort study using data from the American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP) from 2006 to 2013. The objectives of this study were (1) to explore the relationship between frailty and complications for both AUS placement and removal procedures and (2) to determine whether frailty is more likely to be associated with men undergoing AUS removal as opposed to AUS placement procedures. Findings from this study will serve to further our understanding of the role of frailty in older men undergoing both types of AUS procedures and will offer potential insights into the importance of incorporating measures of frailty into the preoperative decision-making process.

Materials and Methods

Patients and Databases

We conducted a retrospective cohort study using ACS-NSQIP Participant Use Data Files from 2006–2013 to identify men undergoing AUS placement and AUS removal procedures. This study was deemed exempt by our institutional review board. The ACS-NSQIP Participant Use Data Files represent a prospectively maintained multicenter database composed of data extracted by trained and certified surgical clinical reviewers at each participating institution, with periodic audits performed to confirm inter-rater reliability. Extracted data include information on patient demographics, the surgical procedure, and 30-day postoperative outcomes.[15] Cases were identified in the ACS-NSQIP database using the following Current Procedural Terminology (CPT) codes: 53445 for AUS placement and 53446 for AUS removal.

Outcomes

We had two main outcomes in this study. The first outcome was to determine the incidence of 30-day complications among men undergoing AUS placement and removal procedures. Complications were evaluated overall and also stratified into major and minor complications, based existing categories in the literature.[14,16–18] Major complications included hospital readmission, return to operating room, sepsis, deep vein thrombosis, cerebrovascular accident [CVA], reintubation, renal failure, myocardial infarction [MI], pulmonary embolus, septic shock, wound dehiscence, cardiac arrest, deep wound infection, coma, and death. Minor complications included urinary tract infection [UTI], superficial wound infection, pneumonia, and blood transfusion. The second outcome of interest was to determine whether frailty was associated with men having an AUS removal procedure compared to an AUS placement procedure.

Covariates

We used the NSQIP frailty index (NSQIP-FI) as our measure of frailty, which was developed specifically for use with the NSQIP database. This frailty index was adapted from the Canadian Study of Health and Aging Functional Index which is a cumulative deficits model. The NSQIP-FI includes eleven factors – history of diabetes mellitus, impaired functional status, history of chronic obstructive pulmonary disease (COPD) or pneumonia, congestive heart failure within thirty days preoperatively, history of myocardial infarction within six months prior to surgery, history of percutaneous coronary intervention (PCI)/angina/cardiac surgery, hypertension requiring medication, peripheral vascular disease (PVD) or rest pain, impaired sensorium, history of transient ischemic attack (TIA), and history of cerebrovascular accident. The NSQIP-FI score is determined by summing the number of factors present and dividing by eleven, yielding a number such as 0.09 for 1 out of 11 deficits, 0.18 for 2 out of 11 deficits, etc. For the purposes of this study, we categorized frailty into the following ascending categories: 0, 0.09, 0.18, or ≥0.27 consistent with the literature.[19] The NSQIP-FI specifically assesses frailty and has been shown to correlate well with morbidity and mortality in surgical subspecialties including Urology.[14,20]

Additional covariates obtained from NSQIP data included demographic information such as patient age in years (categorized as <65, 65–74, 75–84, ≥85), race (white and non-white), and body mass index (BMI) (underweight [<18.5], normal [18.5–24.9], overweight [25–29.9], and obese [≥30]).

Statistical Analysis

Continuous data were reported as means with standard deviations and compared with Mann-Whitney tests and categorical data were reported as numbers with percentages and were compared using the Chi-square tests. The first study objective was to determine odds of complications, both (1) overall, and stratified by (2) major and (3) minor complications. Three separate logistic regression models were performed with each category of complications as the dependent variable (i.e., overall, major and minor complications) and with the type of procedure (AUS placement and AUS removal), age, race, BMI, and NSQIP-FI as the independent variables. The second study objective was to determine whether frailty was associated with having an AUS removed (versus having an AUS placed). In order to address this question, we performed a separate logistic regression where procedure type (AUS removal) was the dependent variable and age, race, BMI and NSQIP-FI were the independent variables. In order to determine whether there was an interaction between age and frailty, we ran a model with an interaction term between these two variables and found the interaction was not statistically significant (data not reported). Therefore, this term was left out of the final models. All analyses were performed using SAS, version 9.4.

Results

We identified a total of 624 individuals undergoing AUS placement procedures and 147 individuals undergoing AUS removal procedures, demonstrated in Table 1. Individuals undergoing AUS removal procedures were significantly older than those having AUS placement procedures (75.2±11.1 vs. 69.8±9.31 years, p<0.01), with 20.4% and 3.7% over the age of 85 years, respectively (p<0.01). There were no statistically significant differences in race or average BMI between men undergoing the two procedures, however, individual BMI categories did differ between groups. NSQIP-FI was significantly higher among individuals undergoing AUS removal, with 12.9% having a NSQIP-FI of ≥0.27 compared to only 6.1% among individuals undergoing AUS placement (p<0.01).

Predictors of postoperative complications

Table 2 shows results of the multivariate logistic regression models predicting the odds of any type of complication, and both major and minor complications in three separate models. The first model demonstrates that AUS removal procedures (compared to AUS placement procedures) were associated with increased odds of any complication (adjusted OR 1.9, 95% CI 1.1–3.5; p=0.03). Age, race, BMI and NSQIP-FI were not significant predictors of this outcome. The second model shows that NSQIP-FI of ≥0.27 was a significant predictor of major complications (adjusted OR 3.5, 95% CI 1.2–9.9; p=0.02), while neither type of procedure (i.e., AUS placement or removal) nor age were statistically significant. The third model shows that AUS removal procedures (adjusted OR 3.2, 95% CI 1.4–7.6; p<0.01) and age ≥85 (adjusted OR 7.9, 95% CI 1.4–45.6; p-0.02) were statistically significant predictors of minor complications, while frailty was not a significant predictor (NSQIP-FI ≥0.27 adjusted OR 1.0, 95% CI 0.2–6.5; p=0.97).

Determinants of having an AUS removal procedure

Table 3 depicts the multivariate logistic regression model predicting the odds of having an AUS removal procedure compared to having an AUS placement procedure. Age 75–84 years (adjusted OR 2.9, 95% CI 1.6–5.4; p<0.01) and age ≥85 years (adjusted OR 9.8, 95% CI 4.3–22.2; p<0.01), NSQIP-FI ≥0.27 (adjusted OR 2.4, 95% CI 1.1–5.5, p<0.04) and underweight BMI (adjusted OR 6.0, 95% CI 1.4–26.8, p=0.02) were associated with having an AUS removal procedure over an AUS placement procedure.

Discussion

This nationwide study on AUS surgery demonstrated that individuals undergoing AUS removal procedures were, on average, older and more frail compared to those having AUS placement procedures. Additionally, frailty (and not age) was associated with major complications while age (and not frailty) was associated with minor complications. The type of procedure (having an AUS removal compared to an AUS placement procedure) was associated with increased odds of both major complications and with complications overall. Finally, increased frailty and age were both associated with increased odds of undergoing AUS removal procedures (compared to AUS placement procedures).

This is the first study to assess the impact of frailty specifically on AUS surgery, either removal or placement. Other studies have evaluated the association of several non-frailty related factors with complications following AUS surgery. One study of 155 patients undergoing primary AUS placement evaluated multiple factors including age, BMI, and comorbidities (i.e., diabetes and hypertension), and found that none were significant predictors for repeat surgery on either univariate or multivariate analysis.[10] A prospective study of 386 patients with a minimum of 3 months follow up found that prior history of pelvic radiation, prior AUS erosion and history of urethral stent placement were associated with increased risk of AUS explantation.[21] Finally, a retrospective study of men undergoing AUS placement procedures found that pelvic irradiation, history of urethral stricture and higher ASA classification (reflecting increased comorbidities) increased the risk of subsequent explantation.[11]

Our prior work explored the impact of frailty on outcomes related to other types of urologic surgery. Our studies of multiple urologic procedures using the ACS-NSQIP database reported an increase in postoperative complications (both major and minor) and an increase in discharge to a skilled or assisted living facility associated with increasing NSQIP-FI score.[14,18] We also found an association between increased frailty and higher complications in pelvic organ prolapse surgery.[19]

This study is novel in that it investigates the role of frailty specifically with regard to AUS surgery. We found that increased frailty (and not age) was associated with major complications, while age (and not frailty) was associated with minor complications. This finding highlights the point that frailty may be a more valuable and dynamic predictor of worse outcomes/complications than age alone and that frailty may not be as problematic for relatively minor complications.

We also found that the type of procedure made a difference in the odds of complications, whereby AUS removal procedures (compared to AUS placement procedures) were associated with increased odds of both major complications and complications overall, but not with minor complications. This is interesting, as AUS removal procedures are more likely to be performed in the setting of infection or device erosion and it would make sense that poor tissue quality associated with these procedures may lend themselves to increased rates of minor complications such as wound and urinary tract infections. However, this was not the case in our study, but rather, we found that AUS removal procedures were associated with heightened risk of major complications such as hospital readmission, reintubation, renal failure, CVA, and cardiac arrest.

Interestingly, both age and frailty were significantly associated with device removal procedures (compared to device placement procedures). It makes sense that men undergoing device removal procedures were older than men undergoing device placement procedures, as one must first have a device placed in order to have it removed, making these men (by definition) older than those having the device placed. However, while frailty does tend to increase with increasing age, frailty is highly variable in its association with age, particularly among older age groups. Additionally, in our model, frailty was adjusted for age and there was no significant interaction between age and frailty when tested in a separate model. Therefore, the finding that frailty is significantly associated with device removal is meaningful and important.

There are many reasons why frailty may be associated with adverse outcomes related to AUS surgery. Possible contributing factors in frail older adults could include suboptimal tissue quality, issues with poor wound healing, and poor nutrition - all contributing to overall decreased resiliency and susceptibility to poor postoperative outcomes. These factors may ultimately result in increased likelihood of experiencing AUS erosion or infection, leading to subsequent device removal.

There are two important considerations in order to translate findings from this study into clinical practice: (1) how to best measure frailty in the clinical setting, and (2) once you have determined that a patient is frail, how to operationalize this information to improve patient outcomes. While the NSQIP-FI is well-suited for frailty measurement within the NSQIP database, other frailty indices are more easily adapted for use in the clinical setting. We have previously published on our use of the Timed Up and Go Tests (TUGT) as a parsimonious measure for frailty in an academic nononcologic urology practice.[22] Other measurement tools include the Fried frailty phenotype, consisting of 5 domains (unintentional weight loss, self-reported exhaustion, weakness, slow walking speed, and low physical activity),[23] and the Edmonton Frail Scale consisting of 9 domains (cognition, general health status, functional independence, social support, medication use, nutrition, mood, continence, and functional performance).[24]

Once it is determined that a patient is frail, this information is useful both for risk stratification and risk optimization. For risk stratification, knowledge of a frail phenotype is useful determine whether an individual is considered to be high- or low-risk for a procedure. This is helpful for patient counseling and in discussion of risks, benefits and potential alternatives to surgical treatment. In frail patients in whom the decision has already been made to proceed with surgery or in whom surgery is not elective (i.e., if they have an infected AUS device that needs removal), knowledge of a frail phenotype can be used to potentially optimize surgical prehabilitation, if there is time, in addition to peri- and post-operative care.

The findings of this study should be considered with certain limitations in mind. Due to the de-identified nature of the data source, we are unable to follow individual patients over time. Furthermore, based on these data we cannot tell whether or not some patients included in the AUS placement cohort are also included in the AUS removal cohort. However, we think that the potential number of patients included in both groups is likely to be low and would have a minimal impact on our study findings in light of the strengths of the database as a large heterogeneous national sample of procedures. Additionally, we cannot determine whether AUS procedures were primary procedures or repeat procedures, which are known to have higher odd of complications.[25] Another limitation of our study is that the ACS-NSQIP database itself is limited to specific predefined variables and does not contain certain other factors likely to influence surgical outcomes such as history of radiation therapy, testosterone levels, prior AUS erosions, or complications beyond thirty days postoperatively. However, with an increasing emphasis on quality-based care, the thirty-day complications have become an important metric with high visibility. Finally, our use of composite variables for major and minor complications puts equal statistical weight on adverse events within these groups, though clearly some complications have a greater clinical impact than others. Again, the role of complications in general as a metric for evaluating quality of care can mitigate this limitation and provide value to our findings.

Conclusions

This analysis of a nationwide database reveals the impact of frailty on postoperative complications from AUS surgery. These findings suggest that relying on age alone may be inadequate for risk stratifying patients prior to AUS surgery and that incorporating frailty into the perioperative decision-making process may be beneficial.

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Table 1.

Demographic characteristics of study cohort.

Variable	AUS placement (N=624)	AUS removal (N=147)	p Value
Age (Mean ± SD)	69.8 ± 9.31	75.2 ± 11.1	<0.01
Age Category (N (%))			
<65	151 (24.2%)	21 (14.3%)	<0.01
65–74	286 (45.8%)	34 (23.1%)	
75–84	164 (26.3%)	62 (42.2%)	
≥85	23 (3.7%)	30 (20.4%)	
Race (N (%))			
White	506 (90.0%)	122 (91.7%)	0.75
Non-White	56 (10.0%)	11 (8.3%)	
BMI (Mean ± SD)	29.5 ± 5.01	29 ± 7.06	0.10
BMI Category (N (%))			
Underweight (<18.5)	4 (0.6%)	5 (3.5%)	<0.01
Normal (18.5–24.9)	95 (15.3%)	32 (22.5%)	
Overweight (25–29.9)	275 (44.2%)	53 (37.3%)	
Obese (≥30.0)	248 (39.9%)	52 (36.6%)	
NSQIP-FI score (Mean ± SD (N))	0.10 ± 0.08 (N=624)	0.13 ± 0.10 (N=147)	<0.01
NSQIP-FI categories (N (%))			
0	159 (25.5%)	27 (18.4%)	<0.01
0.09	281 (45.0%)	55 (37.4%)	
0.18	146 (23.4%)	46 (31.3%)	
≥0.27	38 (6.1%)	19 (12.9%)	
Components of 11 item NSQIP FI (N (%))			
Diabetes mellitus	123 (19.7%)	42 (28.6%)	0.01
Partially/Totally dependent functional status	8 (1.3%)	16 (11.0%)	<0.01
History of severe chronic obstructive pulmonary disease or pneumonia	24 (3.8%)	9 (6.1%)	0.22
Congestive heart failure within 30 days preoperatively	3 (0.5%)	1 (0.7%)	0.76

Variable	AUS placement (N=624)	AUS removal (N=147)	p Value
Myocardial infarction in six months prior to surgery	0 (0.0%)	2 (2.4%)	<0.01
Any prior angina, percutaneous vascular intervention, or cardiac surgery	69 (18.8%)	28 (34.1%)	<0.01
Hypertension requiring medication	437 (70.0%)	98 (66.7%)	0.43
Peripheral vascular disease or rest pain	2 (0.5%)	1 (1.2%)	0.50
Impaired sensorium	0 (0.0%)	2 (2.4%)	<0.01
History of transient ischemic attack	21 (5.7%)	8 (9.8%)	0.18
History of cerebral vascular accident	6 (1.6%)	4 (4.9%)	0.07

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Table 2.

Multivariate logistic regression model predicting odds of complications overall and by major and minor complications.

	Complications overall				Major complications				Minor complications			
Variable	**N / total (%)**	**Odds Ratio**	**95% CI**	**p Value**	**N / total (%)**	**Odds Ratio**	**95% CI**	**p Value**	**N / total (%)**	**Odds Ratio**	**95% CI**	**p Value**
Procedure type												
AUS placement	43/560 (7.7%)	1.0			36/560 (6.4%)	1.0			14/560 (2.5%)	1.0		
AUS removal	24/130 (18.5%)	1.9	1.1–3.5	0.03	17/130 (13.1%)	1.7	0.9–3.4	0.11	14/130 (10.8%)	3.2	1.4–7.6	<0.01
Age												
<65	11/157 (7.0%)	1.0			10/157 (6.4%)	1.0			2/157 (1.3%)	1.0		
65–74	21/287 (7.3%)	1.0	0.4–2.1	0.92	19/287 (6.6%)	0.9	0.4–2.1	0.84	8/287 (2.8%)	2.0	0.4–9.9	0.39
75–84	26/201 (12.9%)	1.6	0.7–3.4	0.28	20/201 (10.0%)	1.2	0.5–2.8	0.68	11/201 (5.5%)	3.2	0.7–16.2	0.14
≥85	9/45 (20.0%)	2.4	0.8–6.7	0.11	4/45 (8.9%)	1.0	0.3–3.5	0.94	7/45 (15.6%)	7.9	1.4–45.6	0.02
Race												
White	58/623 (9.3%)	1.0			46/623 (7.4%)	1.0			25/623 (4.0%)	1.0		
Non-White	9/67 (13.4%)	1.6	0.7–3.6	0.30	7/67 (10.4%)	1.2	0.5–3.1	0.66	3/67 (4.5%)	2.0	0.6–7.4	0.29
BMI												
Underweight (<18.5)	3/9 (33.3%)	3.1	0.6–16.0	0.19	3/9 (33.3%)	3.6	0.7–18.9	0.13	0/9 (0.0%)	<0.1		
Normal (18.5–24.9)	12/115 (10.4%)	1.0			10/115 (8.7%)	1.0			5/115 (4.3%)	1.0		
Overweight (25–29.9)	29/284 (10.2%)	1.1	0.5–2.3	0.77	21/284 (7.4%)	0.8	0.4–1.9	0.68	15/284 (5.3%)	1.6	0.5–4.7	0.43
Obese (≥30.0)	23/282 (8.2%)	0.8	0.4–1.9	0.67	19/282 (6.7%)	0.7	0.3–1.6	0.40	8/282 (2.8%)	0.9	0.3–3.1	0.85
NSQIP-FI score												
0	12/158 (7.6%)	1.0			9/158 (5.7%)	1.0			4/158 (2.5%)	1.0		
0.09	24/301 (8.0%)	1.0	0.5–2.2	0.94	19/301 (6.3%)	1.2	0.5–2.7	0.71	9/301 (3.0%)	1.0	0.3–3.3	0.94
0.18	21/181 (11.6%)	1.4	0.7–3.1	0.38	16/181 (8.8%)	1.6	0.7–3.8	0.32	13/181 (7.2%)	2.2	0.7–7.5	0.19
≥0.27	10/50 (20.0%)	2.6	1.0–6.9	0.05	9/50 (18.0%)	3.5	1.2–9.9	0.02	2/50 (4.0%)	1.0	0.2–6.5	0.97

Table 3.

Logistic regression model predicting odds of having an AUS removal procedure over an AUS placement procedure.

Variable	N / total (%)	Odds Ratio	Lower 95% CI	Upper 95% CI	p Value
Age					
<65	17/157 (10.8%)	1.0			
65–74	30/287 (10.5%)	0.9	0.5	1.7	0.67
75–84	58/201 (28.9%)	2.9	1.6	5.4	<0.01
≥85	25/45 (55.6%)	9.8	4.3	22.2	<0.01
Race					
White	119/623 (19.1%)	1.0			
Non-White	11/67 (16.4%)	0.9	0.4	1.9	0.73
BMI					
Underweight (<18.5)	5/9 (55.6%)	6.0	1.4	26.8	0.02
Normal (18.5–24.9)	27/115 (23.5%)	1.0			
Overweight (25–29.9)	49/284 (17.3%)	0.9	0.5	1.5	0.57
Obese (≥30.0)	49/282 (17.4%)	0.9	0.5	1.7	0.80
NSQIP-FI score					
0	22/158 (13.9%)	1.0			
0.09	48/301 (15.9%)	1.0	0.6	1.9	0.94
0.18	44/181 (24.3%)	1.8	1.0	3.4	0.07
≥0.27	16/50 (32.0%)	2.4	1.1	5.5	0.04