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Outcomes of Midurethral Sling Procedures in Women with Mixed Urinary Incontinence

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Abstract

Introduction and Hypothesis—To compare midurethral sling (MUS) urinary outcomes in women with stress urinary incontinence (SUI) only versus mixed UI (MUI).

Methods—A retrospective cohort study of women who underwent primary MUS surgery for SUI. MUI was defined as at least “moderately” bothersome urgency and stress incontinence on the Urinary Distress Inventory (UDI-6) subscale of the Pelvic Floor Distress Inventory-20 (PFDI-20). The primary outcome was SUI cure defined by a response of “No”, “not at all” or “somewhat” bothersome SUI on both of the 2 UDI-6 stress subscale items. Symptom impact was assessed using the Urinary Impact Questionnaire (UIQ-7). Multivariable models assessed the effect of MUI on SUI outcomes.

Results—1191 primary MUS procedures were reviewed. 715/1191 (60%) questionnaires were returned and 534/715 (75%) had completed baseline and follow-up questionnaires. Mean ($\pm$ SD) follow-up time was 35 $\pm$ 15 months. Women with MUI had a higher (worse) baseline total score on the UDI-6 ($p < 0.001$). A lower proportion of women with MUI had SUI success compared to the SUI only group (64% vs 84.5%, $p < 0.001$). On multivariable analyses, women in the MUI group had an increased risk of SUI failure (OR 2.5, 95%CI 1.6, 4.0) but greater improvements in UDI-6 (-31.6 ± 30.6 vs -15.5 ± 25.1), and UIQ-7 scores (-21.7 ± 35.3 vs -15.1 ± 28.2) compared to women with SUI only (all $p < 0.02$).

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Conclusions—Women with MUI are at increased risk of SUI failure after MUS compared to women with SUI only, but experience greater overall improvement in urinary symptoms impact on quality of life.

Keywords

incontinence outcomes midurethral mixed sling urinary

Introduction

Fifty percent of US women with urinary incontinence have mixed urinary incontinence (MUI) symptoms [1]. However, research in women with MUI is problematic because there is no commonly accepted definition of this condition. The International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology report defines MUI as “the complaint of involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing” [2]. Attempts to identify objective definitions of MUI that are clinically significant and reproducible have been unsuccessful [3,4]. Many women with MUI will undergo midurethral sling (MUS) procedures primarily for treatment of the stress incontinence component of their incontinence, however, outcomes of sling procedures in the MUI population are not well understood.

While it was once thought that women with mixed incontinence may be poor candidates for sling procedures because of the potential for worsening of overactive bladder symptoms (OAB), more recent trials suggest that over 50% of women with MUI undergoing MUS procedures have improvement of their OAB symptoms [5–7]. However, women with MUI have had higher stress incontinence failure rates compared to SUI alone women in secondary analyses of clinical trials [7]. These trials are limited in their applicability because they included only women with “stress-predominant” MUI, which has various definitions [6–9].

Our primary aim was to compare stress incontinence success rates after MUS procedures in women with MUI versus women with stress incontinence only in a tertiary care, academic, female pelvic medicine and reconstructive surgery practice. We hypothesized that women with MUI would have lower stress incontinence success rates than women with stress incontinence only. We also aimed to compare overall lower urinary tract symptom outcomes, symptom specific impact on quality of life outcomes, patient satisfaction and impression of improvement between women with MUI and stress incontinence only.

Materials and Methods

All women who underwent midurethral sling procedures from April 1, 2006 to December 31, 2009 by the Division of Urogynecology and Pelvic Reconstructive Surgery at the University of Alabama at Birmingham (UAB) were included in this retrospective cohort study. Midurethral sling procedures were identified by CPT code. The Institutional Review Board approved all data collection, and the study was exempted by the Carilion Clinic Institutional Review Board.

Preoperative clinical and demographic information, including urodynamic parameters, and preoperative symptom distress and impact questionnaires, were abstracted from the clinic charts. The exposure was MUI, which was defined as patient report of SUI and UUI. SUI was defined as patient report of at least moderate bother for both SUI questions on the UDI-6. UUI was defined as patient report of at least moderate bother to item #16 of the Pelvic Floor Distress Inventory, “Do you usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom”. Women in the SUI group responded “No” to UUI item #16, or “Yes” with symptoms either “not at all” or “slightly” bothersome. All participants had a positive stress test to confirm stress urinary incontinence. Minimum follow-up time was 12 months. All eligible patients were mailed questionnaires including measures of satisfaction and patient impression of improvement. All data were collected by mail; no questions were assessed by telephone. All women were undergoing a primary midurethral sling procedure.

Midurethral sling types included the retropubic and transobturator approaches. The retropubic sling used was the Tension-free Vaginal Tape (Gynecare, Somerville, NJ). The transobturator sling (TOT) used was the Monarc (American Medical System, Minnetonka, MN). All slings were performed as described [10]. Procedures were performed by four attending physicians during the study period. Surgeons were not involved in extracting or entering any data for this study.

The primary outcome of stress incontinence “cure” was improvement in SUI symptoms from baseline, which was defined as a response of either “No” SUI, or Yes and “not at all” or “somewhat” bothersome SUI to both questions of the UDI-6 stress subscale: “Do you usually experience small amounts of urine leakage (that is, drops)?” and “Do you usually experience urine leakage related to coughing, sneezing, or laughing?” [11]. Stress urinary incontinence symptoms were also assessed using the Medical Epidemiologic and Social Aspects of Aging (MESA) questionnaire stress subset scores ranging from 0–27 where higher scores represent worse stress incontinence. Urgency urinary incontinence (UUI) symptoms were also measured by using the MESA urge subscale score which ranges from 0–18 where higher scores represent worse urge incontinence [12]. Overall urinary symptom distress was measured using the UDI-6, which is scored from zero to one hundred, with higher scores reflecting greater symptom distress [11,13].

Symptom specific impact on quality of life (QOL) was assessed using the Incontinence Impact Questionnaire (IIQ-7) [11,13]. The IIQ-7 consists of 7 questions and is scored from zero to one hundred, where a higher score represents greater impact on QOL.

Patient satisfaction and patient impression of improvement were assessed using the Patient Satisfaction Questionnaire (PSQ), and Patient Global Impression of Improvement Questionnaire (PGI-I), respectively [14,15]. The PSQ consists of a single item, “How satisfied are you with your progress since your surgery?” where the three possible responses are “completely satisfied”, “somewhat satisfied”, and “not satisfied”. The PGI-I consists of a single item, “Circle the one response that best describes how your urinary tract condition is now, compared with how it was before you had surgery.” There are seven possible responses ranging from “very much better” to “very much worse.” Symptoms of pelvic

organ prolapse were assessed using the Pelvic Organ Prolapse Distress Inventory (POPDI-6) [16].

All questionnaires were collected preoperatively and again at follow-up and were scored using published protocols. Continuous variables were evaluated using Student t test and Wilcoxon rank-sum test where appropriate. The chi-square test of association and Fisher's exact test were used on categorical variables. Logistic regression was used to perform multivariable analysis controlling for age as a continuous variable, baseline MESA stress score, diabetes, and baseline POPDI-6 as a continuous variable. A p value of <0.05 was considered statistically significant. Statistical analyses were conducted using SAS version 9.1 (SAS Institute, Inc., Cary, NC).

Results

A total of 1191 primary MUS procedures were performed during the study period. Questionnaires were mailed to all 1191 patients and 715/1191 (60%) responded. Complete baseline and follow-up measures were available for 534/715 (75%). Mean time from surgery until the date that the questionnaire was completed was 34.7 ± 14.5 months with range 11.4–66.5 months. Women with MUI had longer time from surgery (35.9 ± 14.6 vs 33.4 ± 14.2 months, $p=0.048$). Baseline clinical and demographic characteristics, index surgery information and baseline symptoms are presented in Table 1. Women with MUI were older, and had a higher number of prescription medications, as well as a higher prevalence of diabetes and having had a prior hysterectomy (all $p<0.05$).

Women with MUI reported worse baseline overall incontinence by UDI-6 score, and worse baseline stress incontinence by MESA stress subset, higher MESA urge scores, and higher impact on QOL by IIQ-7 as compared to the SUI cohort. There was no difference in the prevalence of urodynamic stress urinary incontinence or abdominal leak point pressures between groups (Table 1). Eligible questionnaire non-responders (those who had completed baseline UII questions) were younger, more overweight, and less likely to have undergone other prolapse surgery (Table 2).

Stress continence cure rates were (184/289) 64%, 95% CI 58.0%, 69.0% in the MUI group and (207/245) 84.5%, 95% CI 79.4%, 88.5% in the stress incontinence only group ($p<0.001$). (Table 3). However, women with MUI had greater improvements in UII, overall urinary distress, and symptom specific impact on quality of life (-28.87 ± 37.6 versus -18.42 ± 32.73 ; $p=0.01$) (Table 3). On the PGI-I, women with MUI were less likely to describe their improvement as “much better” or “very much better” than women with SUI only (58.1% vs 74%; $p=0.0001$), and on the PSQ, women with MUI were less likely to report being “somewhat” or “completely” satisfied (78% vs 88.4%; $p=0.002$) (Table 3). In the multivariable model, women with MUI had an increased risk of SUI failure (OR 2.5, 95% CI 1.6–4.0), adjusting for baseline SUI symptoms, age, diabetes, hysterectomy, and baseline Pelvic Organ Prolapse Distress Inventory (POPDI-6) symptoms, and time to follow-up.

Discussion

Women with MUI had lower stress incontinence surgical success rates compared to women with SUI only (64% versus 84.5%, respectively) after midurethral sling. This risk for failure remains, even when controlling for worse baseline stress symptoms and other potential confounders (OR 2.5). Also, women with MUI reported less global improvement and satisfaction based on PGI-I and PSQ results. However, women with MUI have similar, if not greater, improvements in overall lower urinary tract symptoms, similar improvements in symptom specific impact on quality of life, and similar improvements in stress incontinence.

Our finding of increased risk of failure in women with MUI is similar to a prior report, which was a secondary analysis of a clinical trial comparing retropubic versus transobturator MUS procedures [10]. They found that increasing MESA urge score by 10 points was predictive of stress incontinence failure (OR 1.97, 95% CI 1.21–3.21). The OR of 2.5 that we report is higher, but this may be accounted for by their inclusion criteria of “stress predominant” urinary incontinence.

Lower success rates were seen in the MUI group (64% versus 84.5%), even when controlling for other known factors that would impact on SUI treatment outcomes, including baseline SUI symptom score. Therefore, we are not able to identify what factor is contributing to this lower success rate in the MUI group. Some have argued for, and some against, there being a common process in stress and urgency incontinence in women with MUI. Specifically, it has been proposed that proximal urethral funneling in women with SUI may cause detrusor overactivity [17]. The urethra plays a significant role in the pathophysiology of stress and urgency incontinence, warranting research efforts characterizing neurophysiologic function of the urethra in these patient cohorts.

Our cure rate is similar to a prior case-control study that reported 64% cure rates in women with MUI, and 86% in women with SUI [18]. Another case-control study of 137 women with MUI showed a higher overall cure rate of 85–95% [19]. This may be explained by the higher baseline UDI-6 scores in our sample, indicating worse baseline symptoms.

Improvement in overall urinary tract symptoms was similar between groups. The difference in overall improvement between groups on the UDI-6 (–16.1, Table 3) approaches some estimates of the Minimum Important Difference (MID) for the UDI-6. The MID for the UDI-6 has been reported as –22 to –6 in a population of women with SUI, or predominant SUI [20]. The MID for the UDI-6 is higher in women with urgency incontinence (–35 to –45) [21]. Our sample more closely aligns with the stress incontinence, or stress predominant population, as is reflected in baseline MESA subscale scores for stress and urgency incontinence (Table 1).

Despite similar overall improvements in overall urinary tract symptoms, women with MUI were not as satisfied as the SUI group. This finding supports our choice of definition for treatment success, and indicates that SUI improvement rates are a stronger driving force behind patient satisfaction and perception of improvement in women undergoing midurethral slings. It is likely that respondents in this study were thinking more specifically

about their stress incontinence outcome, and not taking into account their overall greater improvement in lower urinary tract symptoms, when reporting their satisfaction.

The strengths of this study include a relatively large sample size and high response rate for this study design. Further, the study is strengthened by an appropriate design for the question being asked. These data are also important and have good external validity because our sample includes all women undergoing MUS procedures in a tertiary care center by FPMRS surgeons, and is not limited to just women with SUI alone or “stress predominant” MUI. This study is limited by possible non-respondent bias, missing data amongst some respondents, and that the non-responders were slightly more obese and had more prior surgery for prolapse. We also do not have information on whether participants received additional incontinence treatments after the index surgery. Finally, we have two sling types represented in our sample. Two prior reports have demonstrated no difference in cure rates between retropubic and transobturator slings [21,22].

Women with MUI symptoms as defined, had lower stress incontinence success rates after MUS, compared to women with SUI alone. However, despite lower satisfaction rates with the MUS procedure, women with MUI have greater overall improvement in lower urinary tract symptoms, and similar improvements in SUI symptoms. Women with MUI should be counseled extensively prior to MUS procedures regarding stress incontinence and urgency incontinence outcomes. Future studies regarding potential combined pathophysiologic factors for SUI and UUI may lead to identification of the driving force behind lower stress incontinence success rates in women with MUI who undergo MUS procedures. Women with MUI symptoms may also benefit from perioperative behavioral and/or medication therapy and this needs to be tested with a randomized trial.

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Table 1

Baseline Characteristics of Women with MUI vs SUI only undergoing MUS.

Demographics/Characteristics	MUI (n=289)	SUI (n=245)	p Value
Age (years) *	61.5 ± 11.8	58.5 ± 11.6	0.004
Race [£]			
Caucasian	270 (94.4)	221 (90.2)	0.154
African-American	13 (4.6)	21 (8.6)	
Other	3 (1.1)	3 (1.2)	
BMI [£] (kg/m ²)			
Normal (<25)	82 (28.5)	81 (33.3)	0.279
Overweight (25–29)	116 (40.3)	100 (41.2)	
Obese (≥30)	90 (31.3)	62 (25.5)	
Vaginal Deliveries [£]	270 (93.8)	230 (93.9)	0.951
Diabetes [£]	43 (15)	18 (7.4)	0.006
Smoker [£]	25 (8.7)	16 (6.6)	0.361
Menopause [£]	235 (81.3)	189 (77.1)	0.235
Prior Hysterectomy [£]	195 (67.5)	142 (58)	0.023
Prior surgery for repair of prolapse [£]	94 (33.1)	69 (28.8)	0.284
Anticholinergic for OAB [£]	30 (10.4)	17 (6.9)	0.162
POPQ Point C [†]	−5 (−8, −2)	−4 (−7, −2)	0.328
POPQ Point Ba	0 (−2, 2)	0 (−1, 2)	0.271
Abdominal valsava leak point pressure (mmH2O) *	109.4 ± 91.7	111.9 ± 40.3	0.579
Stress UI Demonstrated by Urodynamics [£]	210 (98.1)	157 (96.3)	0.340
Index TVT [£]	270 (93.8)	228 (93.1)	0.749
Index TOT [£]	18 (6.3)	17 (6.9)	
Concurrent Prolapse Surgery [£]	208 (72)	170 (69.4)	0.513
Concurrent Cystocele Repair [£]	139 (48.1)	121 (49.4)	0.766
Concurrent Hysterectomy [£]	54 (18.8)	60 (24.5)	0.107

Demographics/Characteristics	MUI (n=289)	SUI (n=245)	p Value
Cystotomy with trocar [£]	18 (6.3)	14 (5.8)	0.814
Estimated Blood Loss (cc) *	94.3 ± 68.7	109.4 ± 159.3	0.172
Baseline UDI6 Score *	68.7 ± 18.8	36.5 ± 19.1	<0.0001
Baseline IIQ-7 Score *	53.5 ± 27.9	30.1 ± 23.4	<0.0001
Baseline MESA Urge Score *	7.9 ± 4.1	3.5 ± 3.4	<0.0001
Baseline MESA Stress Score *	17.1 ± 7.4	12.1 ± 8.3	<0.0001
Baseline POPDI Score *	48.6 ± 26.3	35.7 ± 23.9	<0.0001

* mean ± SD

[£] n (%)

[†] Median (interquartile range)

OAB=Overactive bladder

LPP=Leak point pressure

Table 2

Demographics of Responders and Non-Responders.

Demographics	Responders (n=534)	Non-Responders (n = 356)	p Value
Age (years) *	60.1 ± 11.8	58.4 ± 12.9	0.043
Race [£]			
Caucasian	491 (92.5)	331 (93.0)	0.972
African-American	34 (6.4)	21 (5.9)	
Other	6 (1.1)	4 (1.1)	
BMI [£] (kg/m ²)			
Normal (<25)	163 (30.7)	89 (25.1)	0.004
Overweight (25–29)	216 (40.7)	126 (35.6)	
Obese (>=30)	152 (28.6)	139 (39.3)	
Vaginal Deliveries [£]	500 (93.8)	334 (94.9)	0.501
Menopause [£]	424 (79.4)	282 (79.4)	0.990
Prior Hysterectomy [£]	337 (63.1)	204 (57.3)	0.082
Prior surgery for repair of prolapse [£]	163 (31.1)	86 (24.5)	0.034

* mean ± SD

[£] n (%)

BMI=Body mass index

Table 3

Changes in Questionnaire Scores Pre- and Post MUS

Questionnaires	MUI (n=289)	SUI (n=245)	p Value
UDI-6 [*]	-31.6 ± 30.6	-15.5 ± 25.1	<0.0001
IIQ-7 [*]	-21.7 ± 35.3	-15.1 ± 28.2	0.019
MESA-SUI [*]	-8.4 ± 10.2	-6.8 ± 9.5	0.064
MESA-Urge [*]	-1.87 ± 4.9	-0.34 ± 3.9	<0.0001
Patient impression “very much better” or “much better”	165 (58.1)	179 (74)	0.0001
Patient “completely” or “somewhat” satisfied	220 (78)	213 (88.4)	0.002

^{*} Mean ± SD[†] Median (interquartile range), postoperative only[£] n(%)