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Incontinence Outcomes in Women Undergoing Primary and Repeat Midurethral Sling Procedures

Alison M. Parden, MD, Jonathan L. Gleason, MD, Victoria Jauk, MPH, Rachel Garner, MD, Alicia Ballard, MD, and Holly E. Richter, PhD, MD

Department of Obstetrics and Gynecology, Division of Urogynecology and Pelvic Reconstructive Surgery, University of Alabama at Birmingham, Birmingham, Alabama

Abstract

Objective—To assess stress urinary incontinence (SUI) and other lower urinary tract symptom outcomes in women undergoing a repeat midurethral sling compared to those undergoing primary midurethral sling.

Material and Methods—Cure was defined as responses of “not at all” or “somewhat” to both questions of the SUI subscale of the Urogenital Distress Inventory-6 (UDI-6); symptom impact was assessed using the Incontinence Impact Questionnaire-7. Multivariable models were created controlling for baseline Medical Epidemiologic and Social Aspects of Aging questionnaire urge score and UDI-6 stress subscale score.

Results—1316 subjects had charts available for review. 135/1316 (10.2%) had undergone prior midurethral sling. 799/1329 (60%) questionnaires were returned, with 92 having undergone prior midurethral sling. Median follow-up time was 36.4 months with a range of 11.4 to 71.5 months. Cure rates were 71% (95% CI 67.7%, 74.3%), in the primary midurethral sling group and 54% (95% CI 43.8%, 64.2%) in the repeat MUS group ($p<0.001$). Repeat midurethral sling women had significantly greater improvement on symptom specific QOL compared to primary midurethral sling women (-28.87 ± 37.6 versus -18.42 ± 32.73 , $p=0.01$). Multivariable analyses revealed that women in the repeat midurethral sling group had increased risk of SUI failure (OR 1.7, 95% CI: 1.1, 2.8).

Conclusion—Women undergoing repeat midurethral sling had almost 2 times the odds of stress incontinence treatment failure, but greater improvement in symptom impact on QOL to women undergoing a primary midurethral sling. This information can help counsel patients regarding their expectations of repeat midurethral sling surgery for recurrent SUI.

Introduction

Stress urinary incontinence (SUI), the involuntary leakage of urine with increases in abdominal pressure, affects up to 35% of the female population.(1,2) SUI can be treated with both non-surgical and surgical treatments, but the only documented long term curative treatment is surgery. The most common surgical treatment performed in the United States is the midurethral sling. (3,4)

The retropubic midurethral sling approach was first described by Ulmsten in 1996 and the transobturator approach was later introduced in 2002.(5,6) A midurethral sling is now

Corresponding Author: Holly E. Richter, PhD, MD, Department of Obstetrics and Gynecology, University of Alabama at Birmingham, 1700 6th Av South, Suite 10382, Birmingham, AL 35233, Phone: 205-934-1704, Fax: 205-975-8893, hrichter@uabmc.edu.

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considered the gold standard for SUI treatment with over 103,000 performed annually.(3) Success rates of these procedures at 12 months range from 77–90% reflecting differences in definition of success.(4) Due to the large number of midurethral sling procedures performed, an estimated 23,600 women will have recurrence of SUI after a midurethral sling annually in the United States (US).

The optimal management for recurrent SUI after midurethral sling is unknown. Currently there is little published data on outcomes of repeat midurethral sling for SUI. The largest study to date is a cohort study of 77 patients which reported a stress incontinence cure rate of 62%. There are also two case series with 29 and 31 patients which report cure rates ranging from 67–77%. (7–9) Despite this dearth of data, the most common management for recurrent SUI is a repeat midurethral sling. (10,11)

Given the lack of supportive data for repeat midurethral sling as a treatment for recurrent SUI our primary aim was to assess and compare continence outcomes of women undergoing primary and repeat midurethral sling. We also aimed to compare lower urinary tract symptoms, patient satisfaction and patient impression of improvement between women undergoing primary and repeat midurethral sling. We hypothesized that women undergoing a repeat midurethral sling would have similar outcomes to those undergoing a primary midurethral sling.

Methods and Materials

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 UAB Institutional Review Board approved all data collection.

Preoperative clinical and demographic information, including history of prior midurethral sling, urodynamic parameters, and preoperative symptom distress and impact questionnaires, were abstracted from the clinic charts. Cases were defined as any women who had documentation of a prior midurethral sling and controls were defined as any women who had no history of having had a prior midurethral sling. 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. Women who had more than one prior sling procedure during the study period were identified and were sent only one questionnaire. These women were included in the repeat midurethral sling group.

The retropubic sling used as a primary or repeat procedure 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.(4) Procedures were performed by four attending surgeons during the study period. The data was not extracted by the surgeons and was entered into a password-protected database that was not accessed by the surgeons.

The primary outcome of “cure” was defined as an answer of “not at all” or “somewhat” 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?” (12) 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.(13) Urgency urinary incontinence (UUI) symptoms were measured by

using the MESA urge subscale score which ranges from 0–18 where higher scores represent worse urge incontinence.(13) 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. (12,14)

Symptom specific impact on quality of life (QOL) was assessed using the Incontinence Impact Questionnaire (IIQ-7).(12,14) 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. (15,16) 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.”

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 baseline urgency UI symptoms as measured by the MESA urge scale and UDI-6 stress subscale score. 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 1428 women were eligible and 1316 (92%) had charts that were available for review. A total of 135/1316 (10%) were identified as having had a prior midurethral sling. Questionnaires were mailed to all 1316 patients and 799/1316 (61%) responded with 92/135 (68%) having undergone a repeat midurethral sling responding. Mean time from surgery was 37.9 ± 16.3 months with range 11.4–71.5 months and there was no difference in mean follow-up time between groups (*p* = 0.10). Baseline clinical and demographic characteristics, index surgery information and baseline symptoms are presented in Table 1. Questionnaire non-responders were younger, more overweight, and less likely to have undergone a prior hysterectomy or other prolapse surgery (Table 2).

Women undergoing a repeat midurethral sling were more likely to have undergone a prior hysterectomy, had other pelvic surgery, and had higher rates of anticholinergic use (*p* 0.001). The repeat midurethral sling group also had less prolapse at POPQ Point C; the primary MUS group underwent more concurrent prolapse surgery. The primary midurethral sling group had a larger estimated blood loss, and there was no difference in rate of TVT verses TOT for primary and repeat midurethral sling groups (Table1).

Women undergoing a repeat midurethral sling reported worse baseline stress incontinence by MESA stress subset, higher MESA urge scores, and higher impact on QOL by IIQ-7 as compared to the primary midurethral sling cohort. Both groups demonstrated high rates of urodynamic SUI, and there was no difference in baseline leak point pressures between the two groups (Table 1).

Continence cure rates were (505/707) 71% (95% CI 67.7%, 74.3%) in the primary midurethral sling group and (50/92) 54% (95% CI 43.8%, 64.2%) in the repeat MUS group

($p < 0.001$). There was no difference between groups in the improvement of SUI, UII or overall urinary symptom distress (Table 2). However, women undergoing a repeat midurethral sling had significantly greater improvement on symptom specific QOL as compared to primary midurethral sling women (-28.87 ± 37.6 versus -18.42 ± 32.73 , $p = 0.01$). There was no difference in median patient satisfaction or global impression of improvement between groups (Table 3). In the multivariable model comparing continence cure rates in women undergoing primary versus repeat midurethral sling, adjusting for baseline MESA urge incontinence score and UDI-6 stress score, the women undergoing a repeat midurethral sling were almost twice as likely to report failure (OR 1.7, 95% CI 1.1–2.8). Adding concurrent prolapse surgery to the model did not change the failure rate (OR 1.7, 95% CI 1.02–2.9).

Comparing characteristics of women in the repeat midurethral sling group with treatment failure to those with treatment success, revealed lower rates of prior hysterectomy (78.6% vs 94.0%, $p = 0.029$) in cases of treatment failure, but no difference in rates of prior prolapse surgery or type of prior midurethral sling. Women with treatment failure had higher baseline MESA urge incontinence scores (9.8 ± 4.6 versus 6.7 ± 4.8 , $p = 0.003$). There was no difference in baseline valsalva leak point pressures or prolapse by POPQ point C.

Discussion

Women who underwent a repeat midurethral sling were almost twice as likely to report stress continence failure even after adjusting for baseline urgency and stress UI symptoms and concurrent prolapse surgery compared to women undergoing a primary midurethral sling procedure. This finding suggests that there may be other cause(s) of SUI failure in the repeat midurethral sling group, such as neurovascular injury or dysfunction from their previous surgery, that we were not able to robustly measure and analyze. Despite the higher success rate in the primary midurethral sling group there was no difference between groups in the degree of SUI symptom improvement, patient satisfaction or impression of improvement. Similar satisfaction and impression of improvement between groups likely reflects that the groups had similar degrees of improvement, which both exceed the minimum clinically important differences for the measures. (17) It is unclear what factors are directly reflected by the subjects' responses, but clearly this is a complex issue involving physiologic, social and psychological interactions. Women undergoing a repeat midurethral sling also reported a significantly greater improvement in symptom specific impact on quality of life as compared to women undergoing primary midurethral sling.

To date, there is very little published data on repeat midurethral sling outcomes. Stav et al published the largest cohort study that included 77 repeat midurethral slings and 1,035 primary midurethral slings. (7) They reported subjective success of 86% for the primary midurethral slings versus 62% for the repeat midurethral slings at a mean follow-up 50 ± 24 months. Their higher success rate may be attributed to information bias as their outcome was a single question on the UDI-6 that was assessed by telephone interview. They also reported that women undergoing a repeat midurethral sling had a higher rate of baseline intrinsic sphincter deficiency, while in the current study there was no difference between groups in baseline leak point pressure. They also reported a higher rate of de novo UII in the repeat group after the procedure (27% vs 14%); however, it is unclear how this was assessed as they did not report baseline measures on their subjects. In our study, there was no difference in the change in MESA urge subset score between groups. Finally, their study did not include any measure of symptom specific impact on quality of life. (7)

Our finding of significantly greater improvement in symptom specific quality of life in the repeat midurethral sling group, despite a lower success rate, is interesting. Primary and

repeat midurethral sling groups demonstrated similar improvements in all UI symptoms, but women in the repeat group started with worse symptoms. This implies that any degree of improvement may be more impactful if symptoms are worse at baseline, even if success as defined by the lack of moderately bothersome UI is not met. Also, the prior failed midurethral sling procedure may heighten patient's perceived appreciation of any symptom improvement after a repeat procedure. This may also help to explain why participants reported similar satisfaction rates among groups.

It has been widely reported that women with mixed UI have worse incontinence outcomes after midurethral sling procedures. (18) In our study, women with a prior failed midurethral sling reported higher baseline urgency UI symptoms, but were significantly more likely to experience stress incontinence treatment failure even when controlling for baseline UUI symptoms. When looking just at women who underwent a repeat midurethral sling, those that reported failure had significantly higher rates of baseline UUI. How much this impacts their outcome is unclear, but it is important to recognize that women undergoing repeat midurethral sling report higher UUI symptoms which complicates their treatment outcomes and efforts must be made to appropriately treat these concurrent symptoms pre- and post-operatively.

This study has limitations including incomplete medical records and inherent non-responder bias. This study is strengthened by a relatively high response rate of 61%, clear and robust outcome measures, and the largest sample size in the current literature.

Conclusions

Women undergoing a repeat midurethral sling have significantly lower stress incontinence cure rates than women undergoing a primary midurethral sling, making them almost twice as likely to report failure. Despite this, women who underwent repeat midurethral sling had greater improvement in symptom specific impact on QOL and reported similar satisfaction and impression of improvement to women undergoing a primary midurethral sling. This data will be useful to help counsel patients that they should see improvement, but that additional therapies, such as credible adjunctive behavioral therapies and/or medication therapy, may be necessary to optimize lower urinary tract symptom outcomes.

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Table 1

Baseline Characteristics of Women Undergoing Primary and Repeat MUS.

Demographics/Characteristics	Primary MUS (n=707)	Repeat MUS (n=92)	p Value
Age (years) *	60.6 ± 11.7	59.8 ± 10.7	0.517
Race [£]			
Caucasian	654 (93.2)	89 (96.7)	0.462
African-American	40 (5.7)	2 (2.2)	
Other	8 (1.1)	1 (1.1)	
BMI [£] (kg/m ²)			
Normal (<25)	215 (30.5)	29 (31.5)	0.972
Overweight (25–29)	284 (40.5)	36 (39.1)	
Obese (≥30)	205 (29)	27 (29.4)	
Vaginal Deliveries [£]	661 (94.0)	86 (93.5)	0.836
Smoker [£]	56 (8.0)	10 (11)	0.329
Menopause [£]	573 (81.0)	74 (80.4)	0.888
Prior Hysterectomy [£]	440 (62.3)	80 (87)	<0.0001
Prior surgery for repair of prolapse [£]	217 (31.2)	64 (69.6)	<0.0001
Anticholinergic for OAB [£]	62 (8.8)	18 (19.6)	0.001
POPQ Point C [†]	−5 (−8, −2)	−7 (−9, −4)	0.001
POPQ Point Ba	0 (−2, 2)	−1 (−2, 0)	<0.0001
Stress UI Demonstrated by Urodynamics [£]	480 (96.8)	78 (97.5)	<0.9999
Abdominal Valsalva LPP [£] (cmH ₂ O)	441 (109.8)	74 (102.9)	0.065
Index TVT [£]	636 (90.1)	85 (92.4)	0.481
Index TOT [£]	70 (9.9)	7 (7.6)	
Concurrent Prolapse Surgery [£]	496 (70.1)	39 (42.4)	<0.0001
Concurrent Cystocele Repair [£]	344 (48.7)	19 (20.7)	<0.0001
Concurrent Hysterectomy [£]	156 (22.0)	2 (2.2)	<0.0001
Cystotomy with trocar [£]	37 (5.3)	9 (9.8)	0.080

Demographics/Characteristics	Primary MUS (n=707)	Repeat MUS (n=92)	p Value
Estimated Blood Loss (cc) *	100.9 ± 111.4	68.3 ± 64.2	<0.0001
Baseline UDI6 Score *	53 ± 25.9	63.9 ± 27.3	0.0004
Baseline IIQ-7 Score *	42.8 ± 28.5	61.2 ± 29.7	<0.0001
Baseline MESA Urge Score *	5.8 ± 4.3	8.2 ± 5.0	<0.0001
Baseline MESA Stress Score *	14.5 ± 8.3	20.3 ± 6.8	<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=799)	Non-Responders (n = 517)	p Value
Age (years) *	60.5 ± 11.6	58.7 ± 13.4	0.014
Race [£]			
Caucasian	745 (93.6)	470 (91.3)	0.273
African-American	42 (5.3)	36 (7.0)	
Other	9 (1.1)	9 (1.8)	
BMI [£] (kg/m ²)			
Normal (<25)	244 (30.6)	143 (27.8)	0.003
Overweight (25–29)	322 (40.4)	175 (34.1)	
Obese (>=30)	232 (29.1)	196 (38.1)	
Vaginal Deliveries [£]	749 (94.0)	488 (95.1)	0.376
Menopause [£]	648 (80.9)	399 (77.6)	0.151
Prior Hysterectomy [£]	522 (65.2)	304 (58.9)	0.022
Prior surgery for repair of prolapse [£]	283 (35.9)	139 (27.3)	0.001

* mean ± SD

[£]
n (%)

BMI=Body mass index

Table 3

Changes in Scores Pre- and Post MUS

Questionnaires	Primary MUS (n=707)	Repeat MUS (n=92)	p Value
UDI-6 [*]	-22.87 ± 30.41	-23.23 ± 36.98	0.933
IIQ-7 [*]	-18.42 ± 32.73	-28.87 ± 37.60	0.017
MESA-SUI [*]	-7.03 ± 9.88	-8.48 ± 9.85	0.204
MESA-Urge [*]	-0.853 ± 4.69	-1.12 ± 5.21	0.614
PSQ [†]	1 (1-2)	2 (1-2.5)	0.186
PGI-I [†]	2 (1-3)	2 (1-3.5)	0.505

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