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Incontinence Outcomes After “Second Primary” Compared to Repeat Midurethral Sling for Recurrent and Persistent Stress Urinary Incontinence

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Abstract

Introduction and hypothesis: The current study aims to assess the continence rate of a “second primary” midurethral sling (MUS) in women with recurrent/persistent stress urinary incontinence (SUI) after sling excision compared to a historical cohort who underwent a repeat MUS.

Methods: A retrospective cohort study of women who underwent excision of a primary MUS and placement of a “second primary” MUS from 2009–2016 compared to a historical cohort who underwent a repeat MUS from 2006–2009. The primary outcome was continence rate, defined as “not at all” or “somewhat” to Urogenital Distress Inventory (UDI-6) SUI subscale questions. Secondary outcomes included assessment of symptom severity (UDI-6), symptom specific quality of life, Incontinence Impact Questionnaire (IIQ-7), Medical and Epidemiologic Aspects of Aging (MESA), and Patient Global Impression of Improvement (PGI-I).

Results: Survey responses were available for 23/64 (36%) in the “second primary” MUS group versus 88/135 (65%) in the historical cohort. Mean follow-up in months, second primary: 41.8 ± 26.1 versus repeat: 36.2 ± 14.1 , $p=0.16$ and age (years): 56.4 ± 10.7 versus 59.8 ± 10.8 , $p=0.19$. Continence rates were 48% in “second primary” versus 56% in the repeat group ($p=0.50$). Both groups had significant improvement in questionnaire scores postoperatively with no intergroup

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differences. Multivariable analysis demonstrated that odds of success did not differ between groups (adjusted odds ratio: 0.73, 95% confidence interval: 0.27–1.99).

Conclusions: In women with recurrent/persistent SUI, repeat and “second primary” MUS demonstrate similar success outcomes and improvement in UI symptom distress and QOL.

Continued research is needed for this increasingly important clinical question.

Brief summary

In women with recurrent/persistent SUI, repeat and “second primary” MUS demonstrate similar success outcomes and improvement in urinary incontinence symptom distress and quality of life.

Keywords

midurethral sling; “second primary”; stress urinary incontinence

Introduction

Stress urinary incontinence (SUI), or the involuntary leakage of urine with increased abdominal pressure such as with coughing, laughing, sneezing, or physical exertion, affects a large subset of the female population and can have a negative impact on quality of life (QOL) and health outcomes [1]. The prevalence of SUI is difficult to isolate as symptoms are often widely under-reported; however, 4–35 percent of women in the United States are impacted by SUI [2]. The gold standard of surgical treatment for SUI is considered the midurethral sling (MUS). Despite treatment with a primary MUS, up to 20 percent of women will experience recurrent or persistent SUI [3–5]. The current literature would suggest that the efficacy of a second MUS may not be as high as a primary sling, with reported success or continence rates for a second MUS ranging from 50–70% compared to 70–90% in those with a primary MUS [6–9]. Currently, there is minimal evidence-based consensus on how to treat patients with persistent or recurrent SUI when a primary MUS fails.

The most common surgical approach is a second sling placed over the original sling in situ (a repeat sling) [4]. Alternatively, the primary sling may be excised, and a second MUS is placed (a “second primary” sling). Limited data exists addressing the surgical treatment of recurrent/persistent SUI, especially on “second primary” slings, as most of the published data are based on repeat slings leaving the index sling intact. A better understanding of these outcomes is needed of these two surgical approaches, as increasingly women are presenting with recurrent/persistent SUI after a primary MUS.

The primary aim of this study was to assess the continence rate of a “second primary” MUS in women with recurrent/persistent SUI after sling excision compared to women in a historical cohort who underwent a repeat MUS (“sling over sling”) placement. Secondary aims of the study were to assess symptom severity, QOL, and patient impression of improvement in women undergoing a “second primary” versus repeat MUS. The hypothesis was that there is no difference in continence rates after repeat and “second primary” sling procedures.

Materials and Methods

A retrospective cohort study of two exposure groups was performed after Institutional Review Board approval. The exposure groups were 1) a historical cohort of all women who underwent a repeat MUS procedure (without excision) from 2006 to 2009 with a minimum follow-up time of 12 months and 2) women who underwent excision of a primary MUS and delayed placement of a “second primary” MUS from 2009 to 2016. Patients were captured by utilizing Current Procedural Terminology (CPT) codes (57288 and 57287). The only exclusion criterion was age less than eighteen years old. All repeat and “second primary” MUS (with excision of the index MUS) procedures were performed at this institution by Female Pelvic Medicine and Reconstructive Surgery board certified urogynecologic surgeons. The index procedure may have been performed at an outside institution.

Patient demographics were abstracted from the electronic medical record and included patient age, race, body mass index (BMI), smoking status, menopausal status, obstetric history, medical history, prior gynecologic surgical history, and vaginal estrogen and/or anticholinergic use. Sling type, time from second sling placement to follow-up, reason for removal, concurrent urogynecologic surgery and surgical complications, and estimated blood loss were also collected.

Validated questionnaires were mailed to the “second primary” group to assess symptom-specific distress and impact as well as perception of UI symptom improvement. In the historical cohort (the repeat sling) group, the same set of questionnaires had been mailed and collected [8]. The Urogenital Distress Inventory (UDI-6), scored from 0 to 100, was used to measure urinary symptom distress with higher scores indicating worse symptom distress [10, 11]. The Incontinence Impact Questionnaire (IIQ-7), also scored from 0 to 100, was used to evaluate symptom-specific effect on QOL with higher scores indicating a greater impact on QOL [10, 11]. The Medical and Epidemiologic Aspects of Aging (MESA) questionnaire stress subscale, scored 0 to 27, and urge subscale, scored 0 to 18, were used to measure stress and urge incontinence symptoms, respectively, with higher scores representing worse symptoms [12]. Finally, the Patient Global Impression of Improvement (PGI-I) questionnaire was used to evaluate the patient’s overall impression of their urinary leakage condition after surgery, with seven options ranging from 1 “very much better” to 7 “very much worse” [13, 14].

For the symptom-specific distress and impact scores (UDI-6, IIQ-7, and MESA stress and urge subscales), the change in scores from baseline (collected prior to their second MUS procedure) was compared between groups. The primary outcome was rate of continence, defined as responses of “not at all” or “somewhat” to both SUI subscale questions of the UDI-6: “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?”.

Demographic and clinical characteristics were reported using frequencies and percentages for categorical variables, means and standard deviations for normally distributed continuous values, and medians and interquartile ranges for non-normally distributed continuous variables. Statistical analysis included Student’s *t*-test, Wilcoxon’s rank-sum test, Chi-

square test, and Fisher's exact test as appropriate. All p -values < 0.05 were considered statistically significant. All statistical analysis was generated using SAS software, Version 9.4 of the SAS System for Windows (SAS Institute, Cary, NC).

Results

The historical cohort of 135 patients underwent repeat MUS procedures. Of those, 88 patients (65.2%) responded to the validated questionnaires. This cohort was compared to the "second primary" MUS cohort composed of 64 patients. Of those, 23 patients (36.0%) responded to the questionnaires. Additionally, demographic characteristics were compared between survey responders and non-responders in the "second primary" cohort.

Mean time interval between placement of second sling and follow-up was 36.2 ± 14.1 months in the repeat group and 41.8 ± 26.1 months in the "second primary" group ($p = 0.16$). The mean age was 59.8 ± 10.8 and 56.4 ± 10.7 years for the repeat and "second primary" groups, respectively ($p = 0.19$). As outlined in Table 1, baseline demographic characteristics were similar (all $p > 0.05$) between groups except for smoking status (11.5% repeat versus 30.4% "second primary," $p < 0.05$). Most patients were post-menopausal ($p = 0.61$) and had previously had a hysterectomy in both groups ($p = 0.51$). Demographics between survey responders and non-responders in the "second primary" group were also similar except for BMI ($p = 0.02$, Table 2). The most common reason for MUS removal was vaginal mesh exposure, and there was no difference between groups ($p = 0.44$, Table 2).

Index sling types were similar with 54% retropubic (RP) and 46% transobturator (TO) in repeat group compared to 45% RP and 55% TO in "second primary" group ($p = 0.47$). Most second slings were RP (repeat 93% vs. "second primary" 91%, $p = 0.67$). Some patients underwent concurrent prolapse repair at the time of their second sling, with concomitant rectocele repair being significantly more common in the repeat sling group (35.2%) compared to the "second primary" group (13.0%, $p = 0.04$). Bladder injury via cystotomy with trocar at the time of surgery and estimated blood loss (EBL) were similar between groups ($p = 0.27$ and 0.97 , respectively). The median baseline questionnaire scores (UDI-6, IIQ-7, MESA-Stress, and MESA-Urge) are summarized in Table 1. Overall, results were similar between groups (all $p > 0.05$).

Continence rate was 56% in the repeat sling group and 48% in the "second primary" group ($p = 0.50$). Multivariable analysis controlling for sling type, smoking, prolapse surgery, BMI, and anticholinergic use, demonstrated that the odds of having success did not differ between groups, adjusted odds ratio: 0.73, 95% confidence interval: 0.27–1.99. There were no significant differences between groups in change in UDI-6, IIQ-7 and MESA stress and urge outcome scores (all $p > 0.05$, Table 3). There was a significant difference in median PGI-I score with the repeat sling group score of 2 (IQR: 2.5) correlating to a response of "much better" compared to the "second primary" group score of 3 (IQR:3) correlating to a response of "a little better" ($p = 0.03$, Table 3).

Discussion

This study sought to estimate continence rate outcomes in women undergoing excision of a primary sling with delayed placement of a “second primary” sling compared to outcomes in women undergoing placement of a repeat sling as demonstrated from a historical cohort [8]. The current study showed that there was no difference in continence rate, surgical complications, or patient-reported symptom change between a repeat and “second primary” MUS. However, a significant difference in patient-global impression of improvement was noted with increased perceived improvement noted in the repeat MUS group compared to the “second primary” MUS group.

There is a paucity of high-quality data regarding the efficacy of MUS in women with persistent or recurrent SUI when the initial sling fails. Steele et al. evaluated the continence rate after placement of repeat MUS with concurrent excision/lysis of a primary MUS (n=11) compared to repeat MUS without excision (n=24) with median follow-up duration of 67 (11–149) months and showed concurrent excision of the primary sling and immediate placement of a second sling did not improve subjective outcomes compared to repeat MUS with continence rates of 64% and 71% for “second primary” sling and repeat MUS, respectively ($p=0.71$) [18]. These findings are consistent with the current study which has a larger sample size (n=111) demonstrating no difference in continence rate between a “second primary” and repeat MUS even with delayed placement of second sling.

There are other studies examining surgical outcomes of the subsequent sling for the treatment of recurrent/persistent SUI. A wide range of “success” rates have been reported in the current literature, likely due to the heterogeneity of the study populations, follow-up durations, types of the subsequent MUS, and the definition of success used in the published studies.

Kociszewski et al. examined the continence rate (defined using 1 hour pad test) in women after excision of primary sling and placement of a second MUS (“second primary”) compared to those undergoing a primary MUS placement and found a continence rate of 88% at six-month follow-up [16]. The mean time to follow-up in the current study was significantly longer (approximately 42 months with the continence rate of 48%), which could account for some of the difference noted in SUI symptoms. Additionally, the two studies differed in the definition of success.

Another study by Stav et al. identifying predictors for MUS failure with an overall follow-up of 50 months included 77 of 1112 women who had previous MUS. Of 77 subjects, 48 women (62%) reported no subjective stress incontinence [7]. Verbrugghe et al. reported a similar subjective continence rate (63.5%) after a repeat MUS with a mean follow-up time of 44.8 (range 3–104) months [17]. These rates are comparable to the continence rate (56%) in women undergoing a repeat MUS (the original sling in situ) in the current study. However, in the study by Stav et al, the status of the index sling (whether previously excised or not) was not addressed. Similarly, of 80 patients in Verbrugghe et al.’s study, 5% had previously undergone sling “release” and 7.5% sling excision.

The current literature suggests a decreased efficacy of a second MUS in women with persistent or recurrent stress urinary incontinence. An increase in urgency urinary incontinence after repeat MUS may contribute to patients' perceptions of persistent stress urinary incontinence. Multiple studies have noted increased urinary urgency and/or urgency incontinence after repeat MUS ranging from 8–30% [17, 18]. The current data is consistent with prior studies as demonstrated by the increase in MESA-Urge scores in the “second primary” group. These urgency symptoms may confound the patient-reported symptoms related to SUI and the actual persistence of SUI. Smoking may also represent an additional confounder in the perception of symptom severity, as smoking was significantly more prevalent in the “second primary” group (11.5% repeat versus 30.4% “second primary,” $p < 0.05$). Additionally, obesity is an important risk factor for SUI and may represent an additional confounder as the non-responder group was significantly more obese than the responder group ($p = 0.02$, Table 2). However, continence rates were adjusted for smoking status and BMI in the current study.

The current study is limited in its retrospective, survey-based design and patient population size. However, given the limited patient population that requires and seeks a second sling procedure, it is important to evaluate the available population. Additionally, while a survey-based design may increase possible recall bias, the use of validated questionnaires filled out by the patient herself serves to minimize this effect. Responder versus non-responder analysis was also included to address potential selection bias with respect to follow-up in the repeat MUS group. Finally, the low survey response rate of the “second primary” group may limit generalizability.

Despite these limitations, strengths of our study include the direct clinical application and need for research on this topic. Additionally, a well-characterized and published historical cohort and validated patient questionnaires were used to compare the two surgical cohorts. Patients undergoing a repeat MUS secondary to recurrent SUI after prior removal due to vaginal mesh exposure, sling pain or other indications may be inherently different in their perception of SUI from those patients undergoing repeat MUS secondary to recurrent SUI after an initial sling placement. This highlights the need for randomized trial data in patients with recurrent/persistent SUI after a primary MUS.

In conclusion, there was no difference in continence rates between repeat MUS and “second primary” sling groups, although there was a statistically significant difference in patient impression of improvement favoring repeat MUS. This study may help in decision-making and counseling for patients with recurrent/persistent SUI considering surgical therapy. Further research, including randomized trial data, is warranted to assess surgical outcomes in patients desiring a second MUS procedure for recurrent/persistent SUI.

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Table 1.

Baseline characteristics of women undergoing repeat versus “second primary” midurethral sling

Demographics	Repeat MUS <i>n</i> = 88	“Second Primary” MUS <i>n</i> = 23	<i>p</i> -value
Age (years)	59.8 ± 10.8	56.4 ± 10.7	0.19
Race			1.00
African American	2 (2.3)	0 (0)	
Caucasian	85 (96.6)	23 (100.0)	
Asian/Other	1 (1.1)	0 (0)	
Body Mass Index (kg/m ²)			0.38
Normal (<25)	27 (30.7)	4 (17.4)	
Overweight (25–29)	34 (38.6)	12 (52.2)	
Obese (≥ 30)	27 (30.7)	7 (30.4)	
Vaginal deliveries ^{*1}			0.40
0–1	14 (15.9)	6 (27.3)	
2	45 (51.1)	11 (50.0)	
3 or more	29 (33.0)	5 (22.7)	
Smoker ^{*1}	10 (11.5)	7 (30.4)	0.046
Menopause ^{*2}	83 (94.3)	17 (89.5)	0.61
Vaginal estrogen ^{*2}	61 (72.6)	19 (82.6)	0.33
Prior Hysterectomy	77 (87.5)	19 (82.6)	0.51
Prior surgery for prolapse	61 (69.3)	11 (47.8)	0.06
Anticholinergic use for Overactive Bladder	16 (18.2)	7 (30.4)	0.25
Mean Valsalva Leak Point Pressure (cmH ₂ O) ^{*3}	104.0 ± 49.1	94.2 ± 43.4	0.43
First Sling Type ^{*4}			0.47
Retropubic	40 (54.1)	9 (45.0)	
Transobturator	34 (45.9)	11 (55.0)	
Second Sling Type			0.67
Retropubic	82 (93.2)	21 (91.3)	
Transobturator	6 (6.8)	2 (8.7)	
Concurrent Prolapse Surgery	38 (43.2)	5 (21.7)	0.06
Concurrent Apical Surgery	18 (20.5)	2 (8.7)	0.24
Concurrent Cystocele Repair	18 (20.5)	4 (17.4)	1.00
Concurrent Rectocele Repair	31 (35.2)	3 (13.0)	0.04
Cystotomy with trocar	8 (9.1)	4 (17.4)	0.27
Median Estimated blood loss (cc) ^{*5}	50 (75)	50 (75)	0.97
Mean number of months to follow-up	36.2 ± 14.1	41.8 ± 26.1	0.16
Median Baseline UDI-6 Score ^{*4}	66.7 (45.8)	66.7 (50.0)	0.96

Demographics	Repeat MUS <i>n</i> = 88	“Second Primary” MUS <i>n</i> = 23	<i>p</i> -value
Median Baseline IIQ-7 Score ^{*4}	61.9 (47.6)	52.4 (19.0)	0.30
Median Baseline MESA-Stress Score ^{*3}	85.2 (33.3)	87.0 (24.1)	0.98
Median Baseline MESA-Urge Score ^{*3}	44.4 (44.4)	47.2 (25.0)	0.55

UDI= Urogenital Distress Inventory, scored 0 to 100, higher scores indicating worse symptoms

IIQ = Incontinence Impact Questionnaire, scored 0 to 100, higher scores indicating greater impact on quality of life

MESA= Medical and Epidemiologic Aspects of Aging, stress subscale scored 0 to 27 and urge subscale scored 0 to 18, higher scores indicating worse symptoms

Data are mean ± standard deviation, *n* (%), or median (interquartile range) unless otherwise specified

^{*1} 1 missing,

^{*2} 4 missing,

^{*3} 21 missing,

^{*4} 17 missing,

^{*5} 3 missing

Table 2.

Baseline characteristics of survey responders versus non-responders of “second primary” midurethral sling

Demographics and Characteristics	Responders <i>n</i> = 23	Non-responders <i>n</i> = 47	<i>p</i> -value
Age (years)	56.4 ± 10.7	53.8 ± 10.9	0.35
Race			0.59
Caucasian	23 (100.0)	42 (89.3)	
African American	0 (0)	2 (4.3)	
Asian	0 (0)	2 (4.3)	
Other	0 (0)	1 (2.1)	
Body mass index (kg/m ²)			0.02
Normal (<25)	4 (17.4)	7 (14.9)	
Overweight (25–29)	12 (52.2)	10 (21.3)	
Obese (≥ 30)	7 (30.44)	30 (63.8)	
Smoker	7 (30.4)	12 (26.1)	0.70
Hypertension	12 (52.2)	24 (51.1)	0.93
Diabetes mellitus	1 (4.4)	5 (10.7)	0.66
Chronic obstructive pulmonary disease	1 (4.4)	3 (6.4)	1.00
Median Number of vaginal deliveries	2 (1)	2 (2)	0.77
Menopause	17 (89.5)	29 (74.4)	0.30
Prior hysterectomy	19 (82.6)	38 (80.9)	1.00
Prior prolapse surgery	11 (47.8)	17 (36.2)	0.35
Previous sling type			0.73
Retropubic	9 (45.0)	19 (40.4)	
Transobturator	11 (55.0)	28 (59.6)	
Repeat sling type			0.25
Retropubic	21 (91.3)	46 (97.9)	
Transobturator	2 (8.7)	1 (2.1)	
Reason for removal (May choose multiple)			0.44
Mesh exposure	14 (60.9)	25 (53.2)	
Pain	5 (21.7)	17 (36.2)	
Recurrent symptoms	4 (17.4)	4 (8.5)	
Other	0 (0)	1 (2.1)	

Data are mean ± standard deviation, n (%), or median (interquartile range) unless otherwise specified

Table 3.

Change in scores pre- and post- midurethral sling procedures and impression of improvement

Questionnaires	Repeat MUS n = 88	“Second Primary” MUS n = 23	p-value
UDI-6 ^{*1}	−20.8 (54.2)	−8.3 (30.0)	0.37
IIQ-7 ^{*1}	−28.6 (57.1)	−19.1 (66.7)	0.13
MESA-Stress ^{*2}	−25.9 (63.0)	−14.8 (72.2)	0.35
MESA-Urge ^{*2}	−2.8 (38.9)	11.1 (50.0)	0.52
PGI-I	2 (2.5)	3 (3)	0.03

UDI= Urogenital Distress Inventory, scored 0 to 100, higher scores indicating greater symptom distress

IIQ = Incontinence Impact Questionnaire, scored 0 to 100, higher scores indicating greater impact on quality of life

MESA= Medical and Epidemiologic Aspects of Aging, stress subscale scored 0 to 27 and urge subscale scored 0 to 18, higher scores indicating greater severity of symptoms

PGI-I = Patient Global Impression of Improvement (post- midurethral sling scores only)

Data are median (interquartile range) unless otherwise specified

^{*1} 17 missing,

^{*2} 21 missing