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Management of recurrent stress urinary incontinence after Burch and sling procedures

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Abstract

Introduction—To examine treatment options selected for recurrent stress urinary incontinence (rSUI) in follow-up after Burch, autologous fascial and synthetic midurethral sling (MUS) procedures.

Methods—We performed a secondary analysis of the SISTER and ToMUS trials of participants who underwent primary stress urinary incontinence (SUI) treatment (without prior SUI surgery or concomitant procedures). Using Kaplan-Meier analysis, retreatment-free survival rates by initial surgical procedure were compared. Mean MESA (Medical Epidemiologic and Social Aspects of Aging) stress index was also compared between those retreated for rSUI compared to those not retreated.

Results—Half of the women in the SISTER trial met inclusion criteria for this analysis (329/655, 174 Burch and 155 fascial sling), as did 444/597 (74%) of subjects in ToMUS (221 transobturator midurethral sling (TMUS), and 223 retropubic midurethral sling (RMUS). Types of surgical retreatment included autologous fascial sling (19), synthetic sling (1), and bulking agent (18). Five-year retreatment free survival rates (and standard errors) were 87% (3%), 96% (2%), 97% (1%) and 99% (0.7%) for Burch, autologous fascial sling, TMUS, and RMUS groups respectively ($p < 0.0001$). For all index surgery groups, the mean MESA stress index at last visit prior to retreatment for those retreated ($n = 23$) was significantly higher than mean MESA stress index at last visit for those not retreated ($n = 645$) ($p < 0.0001$).

Conclusion—In these cohorts, 6% of women after standard anti-incontinence procedures were retreated within 5 years, mostly with injection therapy or autologous fascial sling. Not all women with rSUI chose surgical retreatment.

Keywords

Recurrent stress urinary incontinence; Surgical treatment; Female

INTRODUCTION

The management of recurrent stress urinary incontinence (rSUI) is controversial and there is a paucity of literature on the best “rescue” procedure for those women who require

retreatment for stress urinary incontinence (SUI) following a primary SUI surgery. The lack of evidence informing the optimal management of rSUI is likely due to a focus over the past decade on evaluating outcomes for primary procedures such as Burch, fascial slings, transobturator and retropubic midurethral slings, and more recently mini slings for stress-predominant urinary incontinence. With the increasing utilization of mid-urethral slings (MUS) to surgically treat SUI, there are relatively low numbers of failed procedures, making feasibility of prospective clinical trials a challenge. Given the lack of quality data on the optimal management of rSUI, most surgeons rely on their own experience or opinion. While some experts advocate injectable therapy, others have little hesitation to perform another synthetic sling over a pre-existing one, such as a retropubic after a transobturator or vice versa, or a retropubic or transobturator following a mini sling(1). The autologous fascial sling may be preferred by clinicians who still view it as the best “last resort” option. A fascial sling may also be preferred by patients who wish to avoid another synthetic or who are concerned by the FDA notifications of 2008 and 2011. (2–4).

Considering the dearth of data on the management of rSUI, the aim of this analysis was to describe the treatment options selected by patients and their physicians for women after unsuccessful primary surgical SUI treatment.

MATERIAL AND METHODS

The Urinary Incontinence Treatment Network (UITN) is an NIH-funded research network comprised of nine clinical study sites and a Data Coordinating Center (DCC). The UITN conducted 2 large randomized trials comparing surgical procedures for SUI. The Stress Incontinence Surgical Treatment Efficacy Trial (SISTEr) compared the Burch and autologous fascial sling for treatment of SUI⁴ and the Trial of Midurethral Sling (ToMUS) compared the retropubic and transobturator MUS for treatment of SUI⁵. Each study actively followed the study participants for 24 months after surgery and then invited the participants to enroll in an extension study for an additional 3 years of follow-up. Data from these trials were used for this secondary analysis exploring treatment for rSUI. We included trial participants without previous SUI treatment procedure who did not undergo a concomitant surgery for anterior prolapse repair or hysterectomy at the time of the index study surgery. Women who underwent a takedown of their original SUI procedure for obstruction were not excluded. There is no universally accepted definition of recurrent stress urinary incontinence⁶; but included in this study were women who sought out retreatment (surgical or non-surgical) for persistent or recurrent SUI.

Outcome measures included surgical and non-surgical retreatments for rSUI, number of surgical retreatments, types of first and/or second retreatments, as well as time between study surgery and first retreatment. The independent variable was type of initial surgery (fascial sling, Burch, retropubic MUS (RMUS) or transobturator MUS (TMUS)). The secondary outcome was the Medical Epidemiologic and Social Aspects of Aging Project (MESA) stress index (range 0–100), with a higher score indicating more incontinence(5) at baseline, 6 months, 12 months, and annually for as many visits as completed. Co-variables studied were: age, menopausal/hormonal (HRT) status, parity, previous hysterectomy, and smoking status.

Statistical analysis

In addition to descriptive statistics on participants included in these two trials, Kaplan-Meier time-to-retreatment analysis was used to assess the differences among the procedures in rates of retreatment over time. For the secondary outcomes, we used the ANOVA to compare the mean MESA stress index levels at the last visit prior to retreatment or the last study visit whichever occurred first.

RESULTS

Of the 655 women enrolled in SISTEr, 329 (50%) had no previous SUI treatment procedures and no concomitant surgery for anterior prolapse repair or hysterectomy at the time of index study surgery (174 Burch, 155 fascial sling). Of these, 228 (69%) consented to the extended follow-up study. Of the 597 TOMUS participants, 444 (74%) met the same inclusion criteria (221 transobturator (TMUS) and 223 retropubic (RMUS)). Of those, 311 (70%) consented to the extended follow-up study. Baseline characteristics by surgery group are displayed in Table 1.

Forty-eight women received 63 treatments for rSUI (Table 2 a). Surgical retreatments (n=35 women) included fascial sling (19), synthetic sling (1), tightening of a previous sling (1) and bulking agent (18). Seventeen women in the Burch group had 20 surgical retreatments (10 fascial sling and 10 injection), four women in the autologous fascial sling group had 4 surgical retreatments (1 fascial sling, 1 synthetic sling, 1 tightening of previous sling, 1 bulking agent injection), 10 women in the TMUS group had 11 surgical retreatments (6 fascial slings and 5 bulking agent injection) and four women in the RMUS group received 4 surgical retreatments (2 fascial sling and 2 bulking agent injection). Four women received both surgery and an injection, three in the Burch group and one in the TMUS group.

More than half of the retreatments (35 of 63) occurred early, in the first 12 months following surgery (Table 2 b). For the Burch group, 9/18 women had early treatments including five who received injectable agents, two who received a sling, one who received both, and one who received pelvic muscle rehabilitation and a pharmacologic agent. For the fascial sling group, 4/8 women had early treatment: one received an injectable agent, one received a vaginal device, one received pelvic muscle rehabilitation and one received 4 treatments (sling tightening, pharmacologic agent, pelvic muscle rehabilitation and other). In the 10/15 women in the TMUS group treated early, 4 had an injectable agent, two received a sling, one received both, one received a pharmacologic agent, one received a vaginal device and two received pelvic muscle rehabilitation. Finally, in the 4/9 women in the RMUS group treated early, one received a sling, two received pelvic muscle rehabilitation, and one received 3 treatments (a sling, pelvic muscle rehabilitation and a vaginal device).

The Kaplan Meier time-to retreatment analysis indicated that the four groups had significantly different survival distributions ($p<0.0001$). Five-year retreatment free survival rates (and their standard errors) were 87% (3%), 96% (2%), 97% (1%) and 99% (0.7%) for the Burch, autologous fascial sling, TMUS and RMUS groups respectively (Figure 1 with Table 3).

Follow-up MESA stress index scores were available for 23 (48%) of those retreated and 645 (89%) of those not retreated (Table 4). For all index surgery groups, the mean MESA stress index at last visit prior to retreatment for those retreated was significantly higher than the mean MESA stress index at last visit for those not retreated ($p<0.0001$) and the difference in MESA stress index at follow-up between those retreated and those not retreated differed significantly across the surgery groups ($p=0.003$). Among those retreated, women who received surgical retreatment ($n=17$) had higher MESA stress index scores than those retreated non-surgically ($n=6$), but the difference did not reach statistical significance ($p=0.19$).

DISCUSSION

Availability of data from two large studies, the SISTER and TOMUS trials, allowed us to examine our network's clinical management for rSUI following the study intervention. We found that over half of women who were retreated for rSUI were re-treated within the first year following their original procedure and that about half chose an injectable agent over a fascial or synthetic sling. Severity of SUI symptoms, as measured by the MESA Stress index, prior to retreatment may have affected the choice of therapy; those surgically retreated had higher scores than those retreated by non-surgical means, although the difference was not statistically significant. So the choice made about management of rSUI was from women well-educated on incontinence matters, bothered by incontinence (either persistent or recurrent) to various degrees, and cared for by experts who had access to a large range of incontinence treatment modalities in their specialized centers. No management guidelines for rSUI were circulated among the UITN participating centers. Therefore the findings reflect true real life practice, with no external biases.

A recent systematic review and meta-analysis of randomized controlled trials (RCT) on the surgical management of rSUI (6) examined data on 350 women in 10 randomized-controlled trials with a mean follow-up of 18.1 months. The authors of this review concluded that there is "a poor level of evidence in this field". Most recent studies advocate using a different type of synthetic mid-urethral sling for the re-intervention than the mid-urethral sling used for the initial procedure⁷. However, there are no prospective, randomized trials assessing the optimal treatment approach for rSUI.

Our study looking back at the management of rSUI is limited by its descriptive nature as we do not know how many women qualified for, but declined, retreatment. The complexity of patient decision making in this setting is poorly understood. We did not collect data regarding treatment counseling or the reasons one procedure was chosen over another by the surgeon or the patient. Clinically, it is likely that a surgeon or a patient might choose an injectable over a repeat sling to prevent further voiding dysfunction, to avoid another surgical procedure with a need for recovery, or because of minimal SUI bother. These trials were multicentered and involved urogynecologists and urologists, which may affect the generalizability of the study findings. It is possible also that surgeons and patients may have chosen a fascial sling after a Burch or any type of sling failure due to a belief that the fascial sling may provide benefit without additional synthetic material. Furthermore, there is no data on patients' voiding performance and on how this information might have influenced

the treatment decision. Clearly, the generally held concept that injectable agents may not always be durable did not prevent patients/physicians from opting for this retreatment modality. Possibly this indicates either a low level of bother or patient preference to avoid a more major corrective surgery. A repeat sling of any material after failure of a prior sling may not be attractive to a patient. Furthermore, the limited data on the use of a secondary synthetic sling suggests a modest success rate, probably in the range of 70–75% (7). Women who sought out retreatment (surgical or non-surgical) had either persistent or recurrent SUI and our data did not allow to distinguish between them. However, a large number of women underwent early retreatment, suggesting indirectly that this might have been a persistent issue in several of them. Finally, this descriptive study on rSUI retreatment does not provide data on how these retreated women responded to their selected retreatment therapy.

CONCLUSION

In these cohorts, 6% of women were retreated for rSUI within 5 years following their initial standard anti-incontinence procedure. However, not all women with rSUI chose to have surgical retreatment. Injection therapy and autologous fascial slings were the most common forms of secondary treatment.

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Figure. 1.
Kaplan-Meier retreatment free survival for each index procedure.

Table 1

Selected baseline characteristics by surgery group.

	Burch N=174	Fascial Sling N=155	TMUS N=221	RMUS N=223	p-value
	<i>Mean (sd)</i>	<i>Mean (sd)</i>	<i>Mean (sd)</i>	<i>Mean (sd)</i>	
Age	52.9 (10.7)	52.0 (10.4)	52.2 (11.5)	51.7 (9.9)	0.71
Stress index	71.9 (16.1)	71.4 (16.5)	72.0 (15.8)	71.3 (16.2)	0.96
Urge index	35.0 (21.9)	33.1 (20.9)	35.5 (21.6)	31.0 (21.3)	0.13
IIQ	169.4 (102.6)	156.3 (100.9)	148.3 (96.4)	143.0 (95.6)	0.05
UDI	144.1 (50.1)	146.0 (45.2)	132.5 (42.3)	126.3 (45.4)	<0.0001
	<i>N (%)</i>	<i>N (%)</i>	<i>N (%)</i>	<i>N (%)</i>	
HRT use					0.01
Pre-menopausal	43 (25%)	47 (31%)	74 (34%)	74 (33%)	
No HRT	65 (37%)	51 (33%)	92 (42%)	95 (43%)	
HRT	66 (38%)	56 (36%)	54 (25%)	54 (24%)	
Previous hysterectomy	68 (39%)	52 (34%)	48 (22%)	66 (30%)	0.002
Smoking status					0.22
Never smoker	99 (57%)	66 (43%)	116 (52%)	110 (49%)	
Former smoker	52 (30%)	57 (37%)	74 (33%)	77 (35%)	
Current smoker	23 (13%)	32 (21%)	31 (14%)	36 (16%)	
Prolapse stage					0.0001
0	11 (6%)	9 (6%)	22 (10%)	25 (11%)	
1	54 (31%)	43 (28%)	96 (43%)	83 (37%)	
2	88 (51%)	77 (50%)	93 (42%)	105 (47%)	
3	17 (10%)	18 (12%)	8 (4%)	6 (3%)	
4	4 (2%)	8 (5%)	2 (1%)	4 (2%)	
Concomitant surgery	54 (31%)	42 (27%)	28 (13%)	26 (12%)	<0.0001

Stress index and Urge index ranges: 0–100

30 items IIQ (Incontinence Impact Questionnaire) score range: 0–400

UDI: Urogenital distress inventory score range: 0–300

Table 2

a. Retreatments received by study surgery						
Type of treatment	Burch N=174	Fascial Sling N=155	TMUS N=221	RMUS N=223	Total N=773	
Burch	0	0	0	0	0	0
Fascial Sling	10	1	6	2	19	19
Synthetic MUS	0	1	0	0	1	1
Tightening of fascial sling	0	1	0	0	1	1
Needle suspension	0	0	0	0	0	0
Suburethral plication	0	0	0	0	0	0
Collagen or other bulking agent	10	1	5	2	18	18
Other surgical procedure	0	0	0	0	0	0
Alpha-agonists	0	0	0	0	0	0
Other pharmacologic	2	1	1	0	4	4
Pelvic muscle rehabilitation	2	5	2	6	15	15
Vaginal device insertion	1	1	1	1	4	4
Other non-surgical treatment	0	1	0	0	1	1
Total number of treatments	25	12	15	11	63	63
Women who received 1 or more retreatment	18	8	13	9	48	48
Women who received any surgical retreatment	17	4	10	4	35	35
b. Retreatments received within 12 months of surgery by study surgery						
Type of treatment	Burch N=174	Fascial Sling N=155	TMUS N=221	RMUS N=223	Total N=773	
Burch	0	0	0	0	0	0
Sling	3	0	3	2	8	8
Synthetic sling	0	0	0	0	0	0
Tightening of previous sling	0	1	0	0	1	1
Needle suspension	0	0	0	0	0	0
Suburethral plication	0	0	0	0	0	0
Collagen or other bulking agent	6	1	5	0	12	12
Other surgical procedure	0	0	0	0	0	0

b. Retreatments received within 12 months of surgery by study surgery					
Type of treatment	Burch N=174	Fascial Sling N=155	TMUS N=221	RMUS N=223	Total N=773
Alpha-agonists	0	0	0	0	0
Other pharmacologic	1	1	1	0	3
Pelvic muscle rehab	1	2	2	3	7
Vaginal device insertion	0	1	1	1	3
Other non-surgical treatment	0	1	0	0	1
Total number of treatments	11	7	12	6	36
Women who received 1 or more retreatments	9	4	10	4	27
Women who received any surgical retreatment	8	2	7	2	19

Table 3

Retreatment Free Survival Rates, standard errors and 95% confidence intervals at 24 and 60 months by surgery.

	n	24 Months			60 Months		
		Survival rate	Standard error	95% Confidence Interval	Survival rate	Standard error	95% Confidence Interval
Burch	174	0.92	0.02	0.88, 0.97	0.87	0.03	0.81, 0.93
Fascial Sling	155	0.99	0.01	0.97, 1.00	0.96	0.02	0.93, 1.00
TMUS	217	0.98	0.01	0.96, 1.00	0.97	0.01	0.94, 0.99
RMUS	221	0.99	0.007	0.98, 1.00	0.99	0.007	0.98, 1.00

Table 4

Adjusted mean (and standard error) MESA stress index* at baseline and follow-up by retreatment for rSUI and primary surgery.

	Retreated			Not retreated		
	n	Baseline	Follow-up**	n	Baseline	Follow-up**
Burch	9	74.9 (6.6)	34.3 (12.4)	128	71.5 (1.7)	15.5 (3.2)
Fascial Sling	6	79.2 (8.0)	47.5 (14.9)	128	71.2 (1.7)	9.4 (3.2)
TMUS	3	85.0 (11.4)	70.3 (21.1)	192	72.2 (1.4)	12.7 (2.6)
RMUS	5	62.0 (8.8)	23.0 (16.4)	197	71.3 (1.4)	8.2 (2.6)

* MESA stress index ranges from 0 – 100 with higher scores indicating greater stress incontinence⁵

** Follow-up was defined as last visit before retreatment for those retreated or last visit for those not retreated.