Repeat Synthetic Mid Urethral Sling Procedure for Women With Recurrent Stress Urinary Incontinence

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Purpose: We reported and compared the outcomes of repeat mid urethral sling with primary mid urethral sling in women with stress urinary incontinence. Materials and Methods: A total of 1,225 consecutive women with urodynamic stress incontinence underwent a synthetic mid urethral sling procedure (955 retropubic, 270 transobturator) at our institution between 1999 and 2007. Of the patients 91% (1,112) were interviewed via telephone call with a structured questionnaire and were included in the analysis. Mean \pm SD followup was 50 \pm 24 months (range 12 to 114). A comparison between repeat (77, mean age 62 ± 12 years) and primary (1,035, mean age 60 \pm 13 years) mid urethral sling groups was performed. Repeat sling was placed without removal of the previous sling. **Results**: The preoperative incidence of intrinsic sphincter deficiency was higher in patients who had a repeat mid urethral sling (31% vs 13%, p <0.001). The subjective stress incontinence cure rate was 86% and 62% in the primary and repeat group, respectively (p < 0.001). The repeat retropubic approach was significantly more successful than the repeat transobturator approach (71% vs 48%, p = 0.04). The rates of sling related and general postoperative complications were similar between the primary and the repeat groups. However, de novo urgency (30% vs 14%, p < 0.001) and de novo urge urinary incontinence (22% vs 5%, p s 14%, p 14%, p<0.001) were more frequent in the repeat group compared with the primary group.

Conclusions: A repeat synthetic mid urethral sling procedure has a significantly lower cure rate than a primary mid urethral sling procedure. The repeat retropubic approach has a higher success rate than the repeat transobturator approach. The incidence of de novo urgency and urge incontinence are significantly higher in repeat procedures.

Key Words: recurrence; urinary incontinence, stress; suburethral slings; reoperation

MINIMALLY invasive mid urethral slings are now the first line surgical treatment for female SUI. However, 5% to 20% of treated patients experience surgical failure with recurrent or persistent SUI.¹⁻³ To date there is no general consensus to our knowledge on the management of recurrent SUI after a failed MUS. There is a paucity of data on repeat sling after a failed primary MUS. A few small studies with relatively short followup have previously addressed this issue.⁴⁻⁹ We evaluated the efficacy and safety

Abbreviations and Acronyms BMI = body mass index ISD = intrinsic sphincter deficiency MUCP = maximal urethralclosure pressure MUS = mid urethral sling SUI = stress urinary incontinence TOV = trial of voidTVT = tension-free vaginal tape UDI = Urogenital Distress Inventory UUI = urge urinary incontinence VLPP = Valsalva leak point pressure

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* Correspondence: Urogynaecology Department, Mercy Hospital for Women, 163 Studley Rd., Heidelberg, Victoria 3084, Australia (telephone: +61 3 95238380; FAX: +61 3 94162472; e-mail: stavkobi@yahoo.com.au). of retropubic and transobturator slings as secondary therapy in a large group of women with recurrent SUI after MUS. A comparison between repeat MUS and primary sling was performed.

METHODS

After receiving approval from our institutional ethics board we reviewed the medical records of 1,225 consecutive women (mean age 60 \pm 12.9 years) who underwent MUS surgery from May 1999 to August 2007. The assessment included demographics, comprehensive medical history, lower urinary tract symptoms evaluation, physical examination, bladder diary, urodynamics and surgical reports. A detailed proforma was used for documentation of the preoperative data. All definitions are used according to the recommendations of the International Continence Society.¹⁰ Intrinsic sphincter deficiency was defined as maximum urethral closure pressure of 20 cm H₂O or less¹¹ and/or a pressure increase from baseline required to cause incontinence (Δ Valsalva or cough leak point pressure) of 60 cm H₂O or less.¹²

Of the slings 955 (78%) were retropubic (TVT 87%, AdvantageTM sling 11%, SPARCTM 2%) and 270 (22%) were transobturator (MonarcTM 91%, TVT obturator 9%). Sling type was chosen according to surgeon preference. All slings were performed in the standard manner as previously described.^{13–15} Retropubic hydrodissection using local anesthetic and normal saline injection was done in all retropubic slings. Intraoperative cystoscopy was routinely performed in all retropubic and transobturator slings. Repeat slings were placed without removal of the previous sling.

Trial of void was performed immediately at the end of the surgery in patients who had an isolated sling procedure. An indwelling urethral catheter was left routinely for 24 hours in patients who had concomitant vaginal prolapse surgery or if bladder injury had occurred. A failed TOV was defined as a post-void residual volume greater than 150 ml or urinary retention. Patients in whom 2 consecutive trials failed were treated with intermittent self-catheterization.

Postoperatively patients were scheduled for evaluation at 6 weeks, 6 and 12 months, and annually thereafter. However, most of the patients did not attend the clinic after 2 or 3 followup visits. Therefore, to complete this study patients were interviewed via telephone calls with a structured questionnaire examining urinary symptoms, pain and the need for further continence surgery (see Appendix). The questionnaire included questions from previously validated questionnaires, that is the Urogenital Distress Inventory,¹⁶ Pelvic Floor Distress Inventory¹⁷ and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire.¹⁸ Of the patients 91% (1,112) completed the questionnaire and were included in the analysis. The remaining patients could not be contacted due to death (21) or change of residence (92). Minimum followup was 12 months (mean 50 \pm 24, range 12 to 114). Subjective cure was considered in those women who had no further continence surgery and who responded no to the question of leaking urine during physical activity, coughing or sneezing (see Appendix, question 2).

Data were analyzed with SPSS® software (version 16.0) and p < 0.05 was considered significant. Patients were divided into 2 groups of those who had primary MUS and those who had repeat MUS for recurrent or persistent SUI. Chi-square tests and t tests were performed to compare the 2 groups for categorical and continuous variables, respectively. Group size was sufficiently large to use parametric tests by the central limit theorem. The main outcome measures were subjective cure, perioperative morbidity and long-term complications.

RESULTS

Of the study population 77 patients (7%) had repeat MUS (mean age 62 ± 12 years) and 1,035 (93%) had primary sling (mean age 60 ± 13 years). Average time between primary and repeat sling was 2.1 ± 0.5 years. Comparison of demographics, and clinical, surgical, postoperative and followup variables between the 2 groups is summarized in table 1. Patients who had a repeat sling had significantly more ISD and a significantly lower preoperative MUCP on preoperative urodynamics compared with women who had a primary sling.

Followup was significantly longer in the primary sling group (51 \pm 24 vs 40 \pm 19 months, p <0.001). The overall continence rate was 73% (810). The overall subjective cure rate was 85% (primary sling group 86%, repeat sling group 62%, p <0.001). Of the primary sling group 94% and of the repeat group 81% (p <0.001) responded yes to the question, "Would you recommend this operation to someone else with incontinence?" (see Appendix, question 9). The incidence of de novo UUI was significantly higher in the repeat group (22% vs 5%, p <0.001).

The comparison between repeat transobturator and repeat retropubic slings is presented in table 2. Mean MUCP and VLPP values were higher in the transobturator group. More patients were diagnosed as having ISD in the retropubic group but this did not reach statistical significance. The subjective cure rate was significantly higher in patients who had a repeat retropubic sling procedure (71% vs 48%, p = 0.04). More patients with a repeat retropubic sling had de novo urge incontinence but this did not reach statistical significance.

The subjective cure rates of repeat retropubic sling after failed retropubic and failed obturator sling were 67% and 74%, respectively (p = 0.53). The subjective cure rates of repeat transobturator sling after failed retropubic and failed obturator sling were 53% and 40%, respectively (p = 0.26). Thus, the type of the previous primary sling had no impact on the success rate. A comparison between cured and failed cases in the repeat group showed that 29% of the cured cases had transob-

Table 1. Comparison of demographics, and clinical and surgical characteristics

	Primary	Repeat*	p Value
	Demographics + clinical variables		
Mean \pm SD age	60 ± 13	62 ± 12	0.34
Mean \pm SD BMI	28.4 ± 4.7	29.2 ± 5.3	0.14
No. sexually active (%)	594 (57)	39 (51)	0.09
No. postmenopausal (%)	820 (79)	64 (83)	0.41
No. diabetes mellitus (%)	118 (11)	9 (11)	0.22
No. previous cerebrovascular accident (%)	5 (0.5)	1 (1.3)	0.09
Mean \pm SD overall deliveries	2.7 ± 1.4	2.5 ± 1.2	0.09
No. previous cesarean section (%)	77 (7)	3 (4)	0.25
No. previous prolapse surgery (%)	317 (31)	31 (40)	0.08
No. previous hysterectomy (%)	401 (39)	30 (39)	0.21
No. previous colposuspension (%)	109 (10)	3 (4)	0.01
No. urgency (%)	410 (40)	33 (43)	0.44
No. UUI (%)	300 (29)	26 (34)	0.31
Mean \pm SD pads/day	2.1 ± 1.9	2.29 ± 1.8	0.19
	Preop urodynamics		
No. urodynamics diagnosis (%):			
SUI	861 (83)	60 (78)	0.24
Mixed type incontinence	174 (17)	17 (22)	
Mean \pm SD ml post-void residual vol	17 ± 39	14 ± 18	0.49
Mean \pm SD cystometric capacity	465 ± 83	472 ± 60	0.51
Mean \pm SD cm H ₂ O MUCP	39 ± 17	31 ± 15	< 0.001
Mean \pm SD cm H ₂ O Δ VLPP	66 ± 26	61 ± 29	0.21
No. with ISD (%)	134 (13)	24 (31)	< 0.001
No. experienced surgeon (%)	<i>Operative</i> 646 (62)	48 (62)	0.98
No. anesthesia (%):	040 (02)	40 (02)	0.50
Local + sedation	359 (35)	22 (29)	
Regional	187 (18)	13 (17)	0.44
General	489 (47)	42 (54)	0.++
No. sling type (%):	403 (47)	12 (01)	
Retropubic	818 (79)	48 (62)	0.01
Transobturator	217 (21)	29 (38)	0.01
No. concomitant prolapse surgery (%)	391 (38)	13 (17)	< 0.001
No. bladder perforation (%)	31 (3)	2 (3)	0.84
	Postop + followup	2 (0)	0.04
Mean \pm SD days hospitalization [†]	1.05 ± 1.9	0.95 ± 1.5	0.27
No. failed TOV (%)†	72 (11)	7 (11)	0.37
No. sling division (%)	13 (1)	1 (1)	0.54
Mean \pm SD mos followup	51 ± 24	40 ± 19	< 0.001
No. subjective cure rate (%)	894 (86)	48 (62)	<0.001
No. urgency (%):	001 (00)	10 (02)	(0.001
De novo	149 (14)	27 (30)	< 0.001
Persistent	279 (68)	23 (70)	0.41
Resolution	131 (32)	10 (30)	0.44
No. UUI (%):		()	0.11
De novo	49 (5)	17 (22)	< 0.001
Persistent	219 (73)	18 (69)	0.24
Resolution	81 (27)	8 (31)	0.17
No. de novo voiding difficulty (%)	70 (7)	3 (4)	0.33
No. de novo dyspareunia (%)	32 (3)	2 (3)	0.81

* Variables in the repeat group represent data before repeat MUS.

† In patients who had isolated sling procedure.

turator MUS compared to 52% in the failed group (p = 0.04, table 3).

DISCUSSION

A mid urethral sling has a high success rate for female stress urinary incontinence. However, up to 20% of treated patients experience surgical failure with recurrent or persistent SUI.¹⁻³ The reason for failure of the primary MUS is unclear but may be related to improper adjustment of the sling at the placement or misplacement of the suburethral tape.

Treatment options for recurrent SUI after MUS procedures are retropubic suspension, urethral

	Retropubic	Transobturator	p Value
No.	48	29	
Mean \pm SD age	62 ± 12	61 ± 13	0.98
Mean \pm SD BMI	29.7 ± 5.5	28.4 ± 5.0	0.29
No. postmenopausal (%)	43 (90)	21 (72)	0.06
No. urodynamics diagnosis (%):			
SUI	34 (71)	26 (90)	0.07
Mixed type incontinence	14 (29)	3 (10)	
Mean \pm SD cm H ₂ O MUCP	29 ± 15	35 ± 15	0.12
Mean \pm SD cm H ₂ O VLPP	57 ± 30	84 ± 19	0.006
No. with ISD (%)	18 (38)	6 (21)	0.12
No. experienced surgeon (%)	33 (69)	15 (52)	0.13
No. concomitant prolapse surgery (%)	7 (14)	6 (21)	0.34
No. failed TOV (%)*	5 (10)	2 (7)	0.26
Mean \pm SD mos followup	35 ± 20	42 ± 17	0.11
No. subjective cure rate (%)	34 (71)	14 (48)	0.04
No. de novo UUI (%)	13 (27)	4 (14)	0.17

Table 2. Comparison of retropubic and transobturatorapproach in the repeat group

* In patients who had isolated sling procedure.

bulking agents, a pubovaginal sling procedure, a shortening of the pre-implanted tape, artificial urethral sphincter or repeat MUS.¹⁹ Since the MUS procedure is simple and has a high primary success rate, repeat MUS is an attractive option for initial MUS failure.

The first report on repeat retropubic sling was in 2002. The authors described 2 cases of repeat TVT slings for patients with recurrent SUI, and concluded that this option was feasible and safe.⁸ Subsequently 4 case series of repeat MUS were published. Villet et al described 3 cases of repeat retropubic MUS.⁹ At short-term followup (4 and 12 months) 2 patients were continent. Tsivian et al described 12 repeat cases (5 TVT, 4 intravaginal slingplasty, 3 transobturator sling) after a failed MUS procedure.⁵ At a mean followup of 23.2 months 11 patients (91.7%) were continent after repeat MUS. Moore et al presented a case series of 5 patients who had transobturator slings placed for SUI that failed and subsequently had TVT slings placed for persistent SUI.⁷ All 5 patients had successful treatment of incontinence with the TVT sling procedure with a mean followup of 17 months. The last case series was published in 2008. Eandi et al described 10 cases of repeat TVT after a failed MUS procedure.⁶ At a mean followup of 16 months 4 patients achieved complete continence and another 3 reported significant improvement. These case series have small sample sizes and a relatively short followup.

To date the largest study on repeat MUS was published in 2007 by Lee et al.⁴ Their series included 29 repeat cases (13 retropubic and 16 transobturator) and at a mean followup of 18.1 months the cure rate was 75.9%. In the current study the efficacy and safety of retropubic and transobturator slings as secondary therapy in women with recurrent SUI after MUS was evaluated. Comparison between repeat (77, mean followup 40 months) and primary MUS (1,035, mean followup 51 months) revealed a significantly higher cure rate in the latter group (62% vs 86%, p <0.001). Previous reports demonstrated high rates of ISD in patients with failed MUS ranging from 30% to 100%.^{6,7} Consistent with these findings the incidence of ISD was significantly higher in the repeat group compared with the primary MUS group (31% vs 13%, p <0.001).

Interestingly despite having a higher incidence of ISD and lower mean MUCP, patients who underwent repeat retropubic MUS had a higher subjective cure rate than those in the repeat transobturator group (71% vs 48%, p = 0.04). Lee et al reported similar trends with repeat retropubic MUS having a higher success rate than repeat transobturator MUS (92.3% vs 62.5%).⁴ This did not attain statistical significance due to a small sample size. In the series of 12 patients with repeat MUS described by Tsivian et al the only procedure to fail was the transobturator sling.⁵

In this study the rates of sling related and general postoperative complications were similar between the primary and the repeat sling group. There were no differences in bladder perforation rate, hospitalization time, incidence of de novo voiding difficulty and dyspareunia. However, the rates of de novo urinary urgency and UUI were significantly higher in the repeat group compared with the primary group (30% vs 14%, 22% vs 5%, p < 0.001). Previous studies demonstrated that the rate of de novo urgency in repeat cases is high,

Table 3. Comparison of treatment success and failure in therepeat group

	Success	Failure	p Value
No.	48	29	
Mean \pm SD age	61 ± 14	60 ± 15	0.87
Mean \pm SD BMI	27.7 ± 5.1	28.4 ± 6.3	0.18
No. postmenopausal (%)	41 (85)	23 (79)	0.16
No. urodynamics diagnosis (%):			
SUI	37 (77)	23 (79)	0.72
Mixed type incontinence	11 (23)	6 (21)	
Mean \pm SD cm H ₂ O MUCP	32 ± 17	34 ± 18	0.23
Mean \pm SD cm H ₂ O VLPP	69 ± 38	63 ± 34	0.19
No. with ISD (%)	15 (31)	9 (31)	0.88
No. experienced surgeon (%)	30 (62)	18 (62)	0.79
No. concomitant prolapse surgery (%)	9 (19)	4 (14)	0.25
No. failed TOV (%)*	4 (8)	3 (10)	0.36
Mean \pm SD mos followup	42 ± 23	41 ± 17	0.29
No. sling type (%):			
Retropubic	34 (71)	14 (48)	0.04
Transobturator	14 (29)	15 (52)	
No. de novo UUI (%)	10 (21)	7 (24)	0.31

* In patients who had isolated sling procedure.

ranging from 13% to 23%.^{4,5} De novo urge incontinence after repeat MUS has not been previously reported.

This study has the limitations consistent with the retrospective nature of its design, although documentation using the same standardized proforma for more than 10 years would suggest that the data were of consistent quality. Furthermore, clinical objective measures to evaluate success were not used. However, patients were interviewed with a structured questionnaire based on validated questionnaires and this study had a high response rate of 91%.

To our knowledge this study represents the largest series of repeat MUS (77) with the longest followup (40 \pm 19 months) in the current literature. In addition, this is the only comparative study between primary and repeat MUS. It would be important to

APPENDIX

Followup Questionnaire

confirm our findings with a well designed prospective study to investigate the outcome of repeat mid urethral slings.

CONCLUSIONS

In this study repeat synthetic mid urethral sling procedures had a significantly lower cure rate than primary procedures (62% vs 86%, p <0.001). When a prior mid urethral sling failed a retropubic approach was associated with a higher success rate compared to a transobturator approach for the repeat sling (71% vs 48%, p = 0.04). Rates of general and sling related complications were similar between primary and repeat MUS procedures. However, the incidence of de novo urgency and urge incontinence was significantly higher in repeat procedures (22% vs 5%, p <0.001).

Question	Questionnaires	
1 Do you experience any urine leakage?	UDI ¹⁶	
No; Yes		
2 Do you experience urine leakage related to physical activity, coughing or sneezing? No; Yes	UDI ¹⁶	
3 Do you experience a strong feeling of urgency to empty your bladder? No; Yes	UDI ¹⁶	
4 Do you experience urine leakage related to the feelings of urgency? No; Yes	UDI ¹⁶	
5 Do you usually experience difficulty emptying your bladder? No; Yes	PFDI-20 (Pelvic Floor Distress Inventory ¹⁷)	
6 Are you sexually active?	Nonspecific	
No; Yes (if yes – please complete question 7)		
7 Do you feel pain during sexual intercourse? No; Yes	PISQ (Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire ¹⁸)	
8 Did you have another surgery for incontinence since your last one at our medical center? No; Yes (if yes - when and what type)	Nonspecific	
9 Would you recommend this operation to someone else with incontinence? No; Yes	Nonspecific	

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