

Surgical outcome of a repeat midurethral sling procedure after failure of a first procedure

Tae Heon Kim¹ · Hyun Wook You¹ · Dong-Soo Ryu² · Kyu-Sung Lee^{1,3}

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Abstract

Introduction and hypothesis Although there is no consensus on the management of persistent or recurrent stress urinary incontinence (SUI) after placement of a midurethral synthetic sling (MUS), a repeat MUS procedure is commonly performed with favorable results. The aim of this study was to evaluate the efficacy of a repeat MUS procedure compared to the primary procedure in women with SUI, and to investigate factors associated with the failure of the repeat procedure.

Methods We retrospectively analyzed data from 53 women who underwent a repeat MUS procedure and 102 women who underwent a primary MUS procedure at a single center. Success was defined as no urine leakage during physical activity based on the Sandvik questionnaire. Outcomes were assessed using the Sandvik Severity Index and Incontinence-Quality of Life (I-QOL) questionnaire. Multivariate logistic regression analysis was used to determine the factors predicting failure of the repeat procedure.

Results The success rate was 76.5 % for the primary MUS procedure (78/102 patients) and 69.8 % for the repeat MUS procedure (37/53 patients; $p=0.369$). The mean follow-up duration was significantly longer for the primary procedure (83.8 months vs. 54.6 months, $p<0.001$). SUI and all domain

scores of the I-QOL were significantly better following the repeat MUS procedure than following the primary procedure. In the multivariate analysis, SUI grade 3 was the only independent factor predicting failure of the repeat qq (odds ratio 7.610, $p=0.023$).

Conclusions A repeat MUS procedure after a failed primary MUS procedure was shown to be effective. However, a repeat procedure may be unsuccessful in patients with grade 3 SUI.

Keywords Urinary incontinence · Stress · Prostheses and implants · Reoperation

Introduction

Midurethral synthetic sling (MUS) placement is one of the most commonly performed procedures for the treatment of female stress urinary incontinence (SUI) [1–4]. The retropubic tension-free vaginal tape (TVT) procedure has an objective cure rate at 11 years of 84–90 % [5, 6], and the tension-free vaginal transobturator tape inside-out (TVT-O) and outside-in (TOT) procedures have comparable efficacy at 5 years [7, 8]. Despite the high success rates of MUS qqs, their widespread use has led to a greater absolute number of failures, as 5–20 % of treated patients show persistent or recurrent SUI following a failed MUS qq [1, 9, 10]. Treatment options for managing a failed MUS qq include transurethral injection of a bulking agent, retropubic suspension, a pubovaginal sling procedure, and a repeat MUS procedure [11, 12]. Of these, a repeat MUS procedure is considered a good option with favorable results [13–16]. However, few studies have attempted to assess the efficacy of repeat MUS procedures for the treatment of persistent or recurrent SUI with a short-term follow-up. Furthermore, little is known

✉ Kyu-Sung Lee
ksleedr@skku.edu

¹ Department of Urology, Samsung Medical Center, Sungkyunkwan University School of Medicine, 81 Irwon-Ro, Gangnam-gu, Seoul 135-710, Republic of Korea

² Department of Urology, Samsung Changwon Hospital, Sungkyunkwan University School of Medicine, Changwon, Korea

³ Department of Medical Device Management & Research, SAIHST, Sungkyunkwan University, Seoul, Korea

about the factors predicting the failure of repeat MUS procedures.

Extensive evidence to support the use of a repeat MUS procedure has not yet been provided, so we investigated the efficacy of a repeat MUS procedure in women with persistent or recurrent SUI compared to that in women undergoing a primary MUS procedure with a long-term follow-up. We also determined the factors predicting failure of the repeat MUS procedure.

Materials and methods

Between January 2005 and August 2012, 1,175 women underwent a primary MUS procedure for SUI of whom 67 underwent a repeat MUS procedure for persistent or recurrent SUI by a single surgeon (K.S.L.) at our institution. Persistent SUI was defined as early leakage associated with stress events that caused increased abdominal pressure less than 6 weeks after the primary MUS procedure. Recurrent SUI was defined as later leakage more than 6 weeks after the success of the primary procedure. After obtaining institutional review board approval, we conducted a retrospective review of medical records of all patients. We enrolled 53 out of the 67 patients who underwent a repeat MUS procedure and who could be followed for more than 1 year. Using 1,175 patients who underwent a primary MUS procedure, we matched approximately three patients to each patient with a repeat procedure based on age at operation, operation date, grade of SUI (using the Stamey Urinary Incontinence Scale [17]), abdominal leak pressure point, and body mass index. Patients who had more than one sling procedure during the study period were identified and allocated to the repeat procedure group. A total of 177 patients were selected as the primary procedure group. Because most patients were lost to follow-up within 1 year of MUS surgery, all patients were sent a letter explaining the purpose of the investigation, a questionnaire, and a stamped return envelope. If no reply was received, a structured telephone interview was conducted by a research nurse after obtaining patient approval. Ultimately, 102 patients who either returned the questionnaire or completed a telephone interview were enrolled as the primary procedure group, with a ratio of 1.0:1.9 between the two groups.

The retropubic (TVT) and transobturator (TVT-O or TOT) procedures used for primary or repeat MUS placement were performed as originally described [18–20]. In patients who underwent a repeat procedure, the type of MUS was chosen according to the primary MUS type, except in four patients. In other words, the transobturator procedure was performed in patients who had undergone a retropubic procedure as the primary procedure, and a retropubic procedure was selected in patients who had undergone a transobturator procedure. No

attempt was made to remove the previously placed sling at the time of the repeat procedure.

Preoperative assessment included detailed history, pelvic examination, uroflowmetry, post-void residual urine measurement, determination of SUI grade according to the Stamey Urinary Incontinence Scale, a 3-day voiding diary, and a urodynamic study (including filling cystometry, abdominal leak point pressure, maximum urethral closing pressure, and a pressure/flow study). Patients also completed the Sandvik questionnaire [21], the Incontinence Quality of Life (I-QOL) questionnaire [22], and the Bristol Female Lower Urinary Tract Symptoms Questionnaire-Scored Form (BFLUTS-SF) questionnaire [23], and these data were compared between the repeat procedure and primary procedure groups.

Patients with a successful MUS procedure were those who did not experience involuntary urine leakage during coughing or sneezing, or physical activities, based on the Sandvik questionnaire. SUI severity was assessed using the Sandvik Severity Index [21], which was obtained by multiplying two scored items, one evaluating the frequency and the other the amount of urine leakage; higher scores indicate greater SUI severity. The I-QOL questionnaire is scored as three domain scores (avoidance and limiting behavior, psychosocial impact, and social embarrassment) and a total I-QOL summary score, with higher scores representing better QOL [22]. The BFLUTS-SF has four items associated with filling symptoms, three items associated with voiding symptoms, and five items relating to urinary incontinence. Two items address sexual function and five address additional aspects of QOL [23]. All scales use simple additive scores. Postoperative data analyzed and compared between the two groups included the Sandvik Severity Index, I-QOL, BFLUTS-SF, and uroflowmetry parameters.

Statistical analysis

Categorical variables were compared using the chi-squared test or Fisher's exact test for two independent variables. Student's *t* test or the Mann-Whitney *U*-test was used to compare differences between the two groups. The paired *t* test or Wilcoxon signed ranks test were used to compare differences between preoperative and postoperative scores. Univariate and multivariate logistic regression analyses were performed to identify predictive factors associated with failure of a repeat MUS procedure; those with $p < 0.2$ were entered into a multivariate model to find independent predictors. All *p* values were two-sided and $p < 0.05$ was considered statistically significant. All data analyses were performed with SPSS® for Windows, version 21.0.

Results

Baseline characteristics of the two patient groups are summarized in Table 1. While no patients in the primary MUS procedure group had undergone a previous anti-incontinence procedure other than MUS placement, 7.5 % of patients (4/53) in the repeat MUS procedure group had undergone a different

anti-incontinence procedure such as transurethral injection of a bulking agent for SUI ($p=0.013$). Patients undergoing a repeat MUS procedure were more likely to have undergone a retropubic procedure, to have had lower maximum urethral closing pressure, and to have a higher Sandvik Severity Index than those undergoing a primary MUS procedure. Patients in the repeat procedure group reported significantly worse

Table 1 Baseline characteristics of patients who underwent primary and repeat MUS procedures

	Primary procedure ($n=102$)	Repeat procedure ^a ($n=53$)	<i>p</i> value
Age (years)	56.4±8.8	56.0±9.4	0.769
Body mass index (kg/m ²)	24.4±3.7	23.9±2.4	0.396
No. of vaginal deliveries	2.5±1.2	2.5±1.3	>0.9
Menopause	75 (73.5)	37 (69.8)	0.624
Previous hysterectomy	19 (18.6)	11 (20.8)	0.750
Previous anti-incontinence procedure other than MUS	0 (0)	4 (7.5)	0.013
Stress urinary incontinence grade ^b			
1	30 (29.4)	12 (22.6)	0.052
2	63 (61.8)	29 (54.7)	
3	9 (8.8)	12 (22.6)	
Midurethral sling type			
Transobturator	59 (57.8)	18 (34.0)	0.005
Retropubic	43 (42.2)	35 (66.0)	
Maximum flow rate (ml/s)	22.8±7.7	23.7±8.4	0.488
Voided volume (ml)	270.8±77.8	291.7±120.1	0.256
Postvoid residual volume (ml)	12.9±13.7	18.3±29.5	0.225
Urodynamic parameters			
Maximal cystometric capacity (ml)	417.9±64.9	428.1±79.7	0.394
Involuntary detrusor contraction	12 (11.8)	11 (20.8)	0.135
Maximum urethral closing pressure (cm H ₂ O)	39.1±12.5	33.5±12.0	0.013
ALPP (cm H ₂ O)	90.1±27.2	85.8±30.6	0.369
No. with ALPP ≤60 cm H ₂ O	18 (17.6)	11 (20.8)	0.638
Sandvik Severity Index	7.7±3.1	9.5±2.9	0.006
I-QOL questionnaire domain			
Avoidance and limiting behavior	49.3±25.3	42.7±26.3	0.157
Psychosocial impacts	53.2±28.6	37.7±28.3	0.003
Social embarrassment	37.0±29.1	28.0±27.1	0.079
Total score	64.3±23.0	55.6±23.2	0.037
BFLUTS-SF questionnaire scores			
Filling symptoms	5.6±2.9	5.5±3.2	0.811
Voiding symptoms	1.9±2.7	1.4±2.1	0.317
Incontinence symptoms	7.8±4.2	7.1±3.7	0.366
Sexual function	1.4±1.5	1.8±1.6	0.255
Quality of life	6.7±4.2	8.4±5.0	0.040

Values are means±standard deviation or number (%) of patients

ALPP abdominal leak point pressure, I-QOL Incontinence–Quality of Life, BFLUTS-SF Bristol Female Lower Urinary Tract Symptoms–Scored Form

^a Values are from before the repeat MUS procedure

^b Stamey Urinary Incontinence Scale

psychosocial impact, lower total preoperative I-QOL scores, and higher preoperative BFLUTS-SF QOL sum scores than those in the primary procedure group. Follow-up duration was significantly longer in the primary procedure group (83.8 ± 23.7 vs 54.6 ± 28.2 months, $p < 0.001$).

Of the 53 patients in the repeat procedure group, the transobturator approach had been used as the primary procedure in 69.8 % (37 patients) and the retropubic approach in 30.2 % (16 patients). The mean interval between the primary and repeat procedures in these patients was 26.7 ± 24.9 months. Of the 53 patients, 56.6 % (30 patients) and 43.4 % (23 patients) underwent the repeat MUS procedure due to persistent and recurrent SUI, respectively.

The success rate in the primary MUS procedure group was 76.5 % (78/102 patients) and 69.8 % in the repeat procedure group (37/53 patients; $p = 0.369$). Table 2 shows the symptom questionnaire scores and uroflowmetry parameters before and after the MUS procedure. The Sandvik Severity Index, I-QOL subdomain scores, and BFLUTS-SF subdomain scores, except the voiding symptoms score, significantly improved in both groups after the MUS procedure. There were no differences between the groups in the improvement of filling symptoms score, voiding symptoms score, or incontinence symptoms score by BFLUTS-SF. However, patients in the repeat MUS procedure group had significantly greater improvement on the Sandvik Severity Index, I-QOL subdomain scores, and sexual function and QOL score by BFLUTS-SF than those in the primary MUS procedure group. Maximum flow rates were significantly decreased in both groups, and postvoid residual urine volumes were significantly increased in the primary MUS procedure group.

Patients with a successful repeat procedure were significantly older and had more vaginal deliveries than those with a failed repeat procedure (Table 3, $p = 0.013$ and $p = 0.041$, respectively). Other preoperative parameters including the type of approach for the repeat procedure and SUI grade were not significantly different. Success rates in the repeat procedure group were 66.7 % (8/12), 79.3 % (23/29), and 50.0 % (6/12) among patients with SUI grades 1, 2, and 3, respectively.

Table 4 shows the univariate and multivariate analyses of factors potentially involved in predicting failure of the repeat MUS procedure. In the multivariate analysis, SUI grade 3 was the only independent factor predicting failure of the repeat MUS procedure (odds ratio 7.610, 95 % confidence interval 1.321 – 43.846, $p = 0.023$).

Discussion

In the last two decades, MUS placement has been increasingly used for the treatment of SUI. Although MUS procedures have a success rate greater 85 % [5–8], about 20 % of patients

will experience persistent or recurrent SUI [1, 9, 10], indicating the need for an appropriate secondary procedure. The reasons for failure of the primary MUS procedure are unclear but may be related to misplacement of the suburethral tape, inadequate tension on the tape, local fibrotic reactions, or healing abnormalities. Because of the lack of understanding of the etiology of persistent or recurrent SUI, the management of failure of the primary MUS procedure remains a challenge for urologists. Thus, there is no consensus on treatment of persistent or recurrent SUI, and various options have been introduced for managing patients with a failed MUS procedure [11, 12].

A repeat MUS procedure is commonly performed and is gaining popularity as a secondary procedure for treating persistent or recurrent SUI. Several studies have showed that a repeat procedure is an effective treatment for persistent or recurrent SUI after failure of primary MUS procedure. Lee et al. reported that a repeat MUS procedure had a cure rate of 75.9 % in 29 patients with failure of the initial procedure after a mean follow-up of 18.1 months [13]. Stav et al. [14] and Parden et al. [16] also found overall subjective cure rates following repeat MUS procedures of 62 % and 54 % with mean follow-up periods of 50 and 38 months, respectively. Another retrospective study in 80 patients showed subjective and objective cure rates following MUS procedures of 61.0 % and 63.5 %, respectively, with a mean follow-up of 44.8 months [15]. In a prospective study in 31 patients with recurrent SUI the overall objective cure rate was 74 % with a mean follow-up of 18.6 months [9]. In the present study, the repeat MUS procedure was successful in 37 of 53 patients (69.8 %) with recurrent or persistent SUI with a mean follow-up of 54.6 months. Although it is difficult to compare the findings of studies because differences in the definitions of success or cure, our results are similar to those reported previously [9, 13–16]. The success rate in this study was higher than those of other minimally invasive treatments for persistent or recurrent SUI. In previous studies [24, 25] in patients with a failed primary MUS procedure, transurethral injection of a bulking agent and shortening of the preimplanted tape have shown cure rates of 34.8 % and 46.7 %, respectively. In addition, in this study the Sandvik Severity Index score, and the total score and the scores for all domains of the I-QOL significantly improved after the repeat procedure (all, $p < 0.001$).

Although Stav et al. [14] and Parden et al. [16] found that the subjective cure rates of a repeat MUS procedure (62 % and 54 %, respectively; $p < 0.001$) were significantly lower than those of the primary procedure (86 % and 71 %, respectively; $p < 0.001$), in the present study the difference in the success rates between the repeat and the primary procedures was not statistically significant (69.8 % and 76.5 %, respectively; $p = 0.369$). This might be related to the differences in the procedures used to choose the repeat MUS procedure. Stav et al.

Table 2 Symptom questionnaires scores and uroflowmetry parameters before and after MUS procedures

	Primary procedure (<i>n</i> =102)	Repeat procedure (<i>n</i> =53)	<i>p</i> value
Sandvik Severity Index			
No. of patients	50	43	
Before procedure	7.7±3.1	9.5±2.9	
Change	-4.8±5.0	-8.3±3.6	<0.001
<i>p</i> value	<0.001	<0.001	
I-QOL questionnaire domain scores			
No. of patients	89	47	
Avoidance and limiting behavior			
Before procedure	49.3±25.3	42.7±26.3	
Change	22.2±32.6	39.5±24.9	0.002
<i>p</i> value	<0.001	<0.001	
Psychosocial impact			
Before procedure	53.2±28.6	37.7±28.3	
Change	23.8±33.8	48.7±27.7	<0.001
<i>p</i> value	<0.001	<0.001	
Social embarrassment			
Before procedure	37.0±29.1	28.0±27.1	
Change	32.1±39.1	48.2±27.7	0.006
<i>p</i> value	<0.001	<0.001	
Total I-QOL summary			
Before procedure	64.3±23.0	55.6±23.2	
Change	22.1±29.1	38.8±21.9	<0.001
<i>p</i> value	<0.001	<0.001	
BFLUTS-SF questionnaire scores			
No. of patients	85	46	
Filling symptoms			
Before procedure	5.6±2.9	5.3±3.1	
Change	-1.2±3.3	-2.1±2.5	0.070
<i>p</i> value	0.002	<0.001	
Voiding symptoms			
Before procedure	1.9±2.7	1.4±2.1	
Change	0.5±3.1	0.2±2.6	0.534
<i>p</i> value	0.131	0.654	
Incontinence symptoms			
Before procedure	7.8±4.2	7.0±3.8	
Change	-4.0±5.3	-4.9±3.2	0.223
<i>p</i> value	<0.001	<0.001	
Sex			
Before procedure	1.4±1.5	1.7±1.7	
Change	-0.8±1.7	-1.5±1.6	0.033
<i>p</i> value	0.001	<0.001	
Quality of life			
Before procedure	6.7±4.2	8.1±4.9	
Change	-2.9±5.3	-5.3±4.9	0.013
<i>p</i> value	<0.001	<0.001	
Maximum flow rate (ml/s)			
No. of patients	100	53	
Before procedure	22.8±7.7	23.7±8.4	
Change	-3.2±10.1	-3.1±8.5	>0.9
<i>p</i> value	0.002	0.009	
Postvoid residual volume (ml)			
No. of patients	100	51	
Before procedure	12.2±12.9	18.3±29.5	
Change	14.0±33.7	6.9±52.0	0.320
<i>p</i> value	<0.001	0.345	

Values are means±standard deviation

I-QOL Incontinence–Quality of Life, *BFLUTS-SF* Bristol Female Lower Urinary Tract Symptoms–Scored Form

Table 3 Characteristics of patients with a successful and a failed repeat procedure

	Success (n=37)	Failure (n=16)	p value
Age (years)	57.8±9.8	51.7±6.8	0.013
Body mass index (kg/m ²)	24.4±2.5	23.0±2.2	0.061
No. of vaginal deliveries	2.7±1.4	2.1±0.8	0.041
Menopause	26 (70.3)	11 (68.8)	>0.9
Persistent or recurrent			
Persistent	22 (59.5)	8 (50.0)	0.524
Recurrent	15 (40.5)	8 (50.0)	
SUI grade ^a			
1	8 (21.6)	4 (25.0)	0.378
2	23 (62.2)	6 (37.5)	
3	6 (16.2)	6 (37.5)	
Midurethral sling type			
Transobturator	11 (29.7)	7 (43.8)	0.322
Retropubic	26 (70.3)	9 (56.2)	
Urodynamic parameters			
Detrusor activity			
No involuntary contraction	30 (81.1)	12 (75.0)	0.716
Involuntary contraction	7 (19.9)	4 (25.0)	
ALPP			
≤60 cm H ₂ O	8 (21.6)	3 (18.8)	>0.9
>60 cm H ₂ O	29 (78.4)	13 (81.2)	

Values are means±standard deviation or number (%) of patients

ALPP abdominal leak point pressure

^a Stamey Urinary Incontinence Scale

Table 4 Univariate and multivariate logistic regression analyses to determine the factors predicting failure of the repeat MUS procedure

	Univariate		Multivariate	
	OR (95 % CI)	p value	OR (95 % CI)	p value
Age	0.918 (0.848 – 0.995)	0.038	0.899 (0.793 – 1.020)	0.098
Body mass index	0.777 (0.593 – 1.019)	0.068	0.803 (0.579 – 1.115)	0.190
No. of vaginal deliveries	0.571 (0.294 – 1.111)	0.099	1.158 (0.437 – 3.069)	0.768
Menopause	0.931 (0.261–3.316)	>0.9		
SUI grade				
1, 2	1.000 (reference)			
3	3.100 (0.814 – 11.808)	0.097	7.610 (1.321 – 43.846)	0.023
Involuntary contraction	1.381 (0.340 – 5.603)	0.652		
Midurethral sling type				
Transobturator	1.000 (reference)			
Retropubic	0.544 (0.162 – 1.831)	0.325		
Indication for repeat MUS procedure				
Persistent SUI	1.000 (reference)			
Recurrent SUI	1.467 (0.451 – 4.770)	0.524		
Abdominal leak point pressure				
>60 cm H ₂ O	1.000 (reference)	0.813		
≤60 cm H ₂ O	0.837 (0.191 – 3.673)			

[14] selected the MUS type for the repeat procedure according to surgeon preference, but we based the selection of MUS type for the repeat procedure on the type of surgery used during the failed primary procedure. This implies that the use of a different approach for the repeat procedure could improve the likelihood of success. Furthermore, there was a significantly higher amelioration of QOL assessed by using the I-QOL questionnaire after surgery in the repeat MUS procedure group than in the primary MUS procedure group (Table 2). This might have been associated with worse baseline symptom scores and the relatively short follow-up duration in those undergoing the repeat procedure (Table 1), or heightened patient appreciation of any symptom improvement after a repeat procedure [16].

In this study, the mean maximum flow rates after the repeat procedure were significantly decreased by 3.1 ml/s ($p=0.009$), while the mean postvoid residual urine volumes increased by 6.9 ml ($p=0.345$). There were no serious urination-related complications including obstructive voiding symptoms and urinary retention. Furthermore, there were no significant differences between preoperative and postoperative voiding symptom scores in the BFLUTS-SF questionnaire scores (Table 2, $p=0.654$). Based on our results, a repeat MUS procedure may be considered as an effective option for patients who experience persistent or recurrent SUI after a primary MUS procedure.

Few studies have addressed the risk factors for failure of a repeat MUS procedure. In several studies different predictors have been found to be associated with failure of a repeat procedure. Stav et al. demonstrated that the repeat transobturator sling procedure resulted in a lower cure rate than the retropubic sling procedure (48 % vs. 71 %, $p=0.04$) [14]. Lee et al. also found that the repeat transobturator sling procedure was associated with a lower cure rate than the retropubic sling procedure (63 % vs. 92 %), but the difference was not statistically significant ($p=0.09$) [13]. We found no differences in the rates of success and failure of repeat MUS procedures between the types of approach ($p=0.322$). Meyer et al. [26] also found that overall success rates of repeat MUS procedures did not differ between the retropubic approach (57 %) and transobturator approach (72 %; $p=0.2$). In the present study, SUI grade 3 was the only independent predictor of failure of the repeat MUS procedure (odds ratio 7.610, $p=0.023$). This finding suggests that those who have SUI grade 3 prior to a repeat procedure should be informed of the possibility of a poor outcome, and may be useful in the decision-making process in considering a repeat MUS procedure for persistent or recurrent SUI.

This study had several limitations. First is its retrospective nature, which is associated with both inherent and selection biases. Second, clinically objective measurement data to evaluate the success of repeat MUS procedures were not available. We evaluated success only according to subjective patient

responses. However, validated questionnaires were administered preoperatively and at the time of postoperative follow-up.

Conclusions

A repeat MUS procedure can benefit patients with persistent or recurrent SUI after a primary procedure, with a subjective success rate of 69.6 %. SUI grade 3 was the only independent predictor associated with failure of a repeat procedure. Therefore, patients who have SUI grade 3 prior to a repeat procedure should be informed of the possibility of a poor outcome.

Conflicts of interest None.

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