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Repeat mid-urethral sling for recurrent female stress urinary incontinence

F. Meyer · J. F. Hermieu · A. Boyd · S. Dominique ·
L. Peyrat · F. Haab · V. Ravery

Abstract

Introduction and hypothesis The aim of the study was to assess the effectiveness of repeat mid-urethral sling after a failed primary sling for stress urinary incontinence.

Methods A total of 112 women with recurrent stress incontinence after primary mid-urethral sling underwent a repeat procedure between 2000 and 2011. All patients had a preoperative clinical and urodynamic evaluation. Outcomes were divided into three groups: cured (no more leaks), improved (decrease of leaks), or failed.

Results All patients had urethral hypermobility and 12.9 % had intrinsic sphincter deficiency [maximum urethral closure pressure (MUCP)≤20 cmH$_2$O]. Median MUCP was 41 cmH$_2$0. Overactive bladder was found in 5.7 % of women. The second sling placed was one of the following: retropubic Tension-free Vaginal Tape (49 %), transobturator tape (48 %), or mini-sling (3 %). No intraoperative morbidity was reported. After the second sling was placed, 68 (60.7 %) patients were subjectively cured and 18 (16.1 %) improved (76.8 % success overall) with a mean follow-up of 21 months. Success rates were 72.2 and 81.8 % for transobturator and retropubic slings, respectively, with no significant difference. Multivariable analysis showed higher odds of cure and improvement with the retropubic approach after adjusting for MUCP. Late complication rates were comparable to those observed after a first sling. Urodynamic parameters were not associated with postoperative success.

Conclusions Repeat mid-urethral sling for recurrent female stress urinary incontinence is nearly 77 % successful in a group of patients with persistent urethral hypermobility. A retropubic approach might be preferred for patients with low urethral closure pressures.

Keywords Stress urinary incontinence · Mid-urethral slings · Surgery failure · TVT · TOT

F. Meyer · J. F. Hermieu · S. Dominique · V. Ravery
Department of Urology, Bichat Hospital,
Paris, France

A. Boyd
INSERM UMR-S707,
Paris, France

L. Peyrat · F. Haab
Department of Urology, Tenon Hospital,
Paris, France

F. Meyer (✉)
Hôpital Xavier Bichat,
46 rue Henri Huchart,
75018 Paris, France
e-mail: francois.meyer@bch.aphp.fr

Introduction

In 1996 Ulmsten et al. (Tension-free Vaginal Tape®, TVT) [1] and in 2001 Delorme (Transobturator Tape®, TOT) [2] developed the concept of mid-urethral support based on the hammock hypothesis proposed by DeLancey [3]. Mid-urethral slings (MUS) drastically changed stress urinary incontinence (SUI) surgery in the mid-1990s, with excellent outcomes and a mini-invasive approach.

Although MUS are the reference treatment of SUI due to their high success rates, 5–20 % of women still experience surgery failure [4]. Several options have been proposed: second MUS, tape shortening, bulking agents, Adjustable Continence Therapy®, and artificial urinary sphincter. To date, there is no consensus on the management of MUS failure. Repeat sling might be an appropriate solution for women showing persistent urethral hypermobility but few studies have demonstrated their effectiveness. The aim of this study was to determine the outcomes of a repeat MUS after a failed primary sling for SUI and if there are any differences in outcome with respect to MUS used.

Materials and methods

Study population

We retrospectively included 112 female patients who received a second sling for recurrent SUI. Patients were operated on in two university hospitals based in Paris (Bichat and Tenon) between 2000 and 2011. Inclusion criteria were failure or recurrence after a first MUS and urethral hypermobility (visually determined by physical examination). Any type of MUS was allowed for the first procedure.

Data for this study were obtained from usual procedures. Biological material and clinical measures were obtained only for standard diagnosis following physicians' orders (no specific sampling, no modification of the sampling protocol, no supplementary question to the national standardized questionnaire). Data analyses were carried out using an anonymized database. According to the French Law of Public Health (CSP Art L 1121–1.1), such a protocol is exempt from written informed consent.

Evaluation

Preoperative assessment consisted of complete medical history, evaluation of lower urinary tract symptoms, physical examination, and urodynamic evaluation. Intrinsic sphincter deficiency was defined as maximum urethral closure pressure (MUCP) of 20 cmH$_2$O or less. In 24 cases (21.4 %) urodynamic evaluation had been performed outside of the hospital and was summarized in medical records but was not available for statistical analyses.

Patients were postoperatively scheduled for evaluation by their surgeon including interview and physical examination at 1 month, 6 months, and 1 year or more. Patients who did not attend the clinic after 6 months were contacted for a phone interview. They were submitted to a structured questionnaire based upon the Urinary Symptom Profile® [5] and the International Consultation on Incontinence Questionnaire Short Form® (ICIQ-SF) question 3 [6], evaluating stress, urge, frequency, obstructive symptoms, and quality of life. Patients who attended the clinic once within 6 months but could not be contacted afterwards were considered as lost to follow-up.

During follow-up, patients were then classified into three independent groups: (1) subjective cure, defined by the absence of leaks within the last month; (2) improvement, defined as the decrease in number of leaks and better quality of life; or (3) failure. Overall success was defined by the combination of cure and improvement.

Methods, definitions, and units conform to the standards jointly recommended by the International Urogynecological Association (IUGA) and the International Continence Society (ICS) [7, 8].

Statistical analysis

Baseline characteristics were summarized by means (SD) for continuous variables or counts (%) for discrete variables and then compared across MUS types using a Kruskal–Wallis, Pearson χ^2, or Fisher's exact test. Analysis of urodynamic findings was performed on patients whose data was available. Using either success (cure and improvement) or cure after surgery as an endpoint, a multiple logistic regression model was used to estimate odds ratios (OR) between MUS types, while adjusting for MUCP. To address the question of whether any bias was introduced due to patients with short-term follow-up, we performed sensitivity analyses examining the distribution of endpoints while only including patients with information for a minimum of 6, 12, and 24 months after intervention. Additionally, discrete follow-up time was also included in the multiple logistic regression model. All analyses were performed using Stata (v11.0, StataCorp, College Station, TX, USA) and $p < 0.05$ was considered significant.

Results

Description of the study population

Clinical and urodynamic preoperative characteristics are displayed in Table 1 and show typical values for this type of population. The previous sling was not removed except for 33 patients in whom it was removed or cut due to vaginal or urethral mesh exposure (20), voiding dysfunction (10), or de novo urgency (3).

The second MUS was one of the following: retropubic tape (49 %), transobturator tape (48 %), or a single-incision minisling (3 %). The sling type was chosen according to the surgeon's preference. Among the 12.9 % of patients with sphincter deficiency, there was 67 % of retropubic tapes, 25 % of

Table 1 Preoperative characteristics (mean±SD, range)

Characteristic	Value
Age (years)	55.5±12.3 (28–82)
BMI (kg/m^2)	26.3±5.1 (16–45)
Parity (number of children)	1.8±1.2 (0–6)
Menopause	80.6 %
Hysterectomy	31.6 %
Other pelvic intervention	13.4 %
Initial micturition sensation (ml)	251±117 (33–539)
Maximum bladder capacity (ml)	389±115 (135–850)
MUCP (cmH$_2$0)	41±19 (8–100)
Detrusor overactivity	5.7 %
Post-void residual (ml)	7.5±23.7 (0–150)

BMI body mass index

transobturator tapes, and 8 % of mini-slings. Details pertaining to the initial and second sling types are given in Table 2.

The population was divided in two groups: retropubic slings ($n=54$) and transobturator slings ($n=55$). There was no significant difference between retropubic and transobturator groups, except for proportion of patients with hysterectomy (22.9 vs 42.2 %, respectively, $p=0.047$) and detrusor overactivity (0 vs 11.4 %, respectively, $p=0.03$).

Clinical outcomes during follow-up

The mean follow-up was 21 months (median 12 months, range 1–108 months), with a total of 25 patients (22.4 %) lost to follow-up. In the entire study population, subjective cure rate was 60.7 % and improvement rate was 16.1 %, indicating an overall success of 76.8 %. Among the 20 patients with vaginal or urethral mesh exposure, 17 were cured (85 %), none was improved, and 3 had a second sling failure (15 %). We found that clinical and urodynamic pre-operative parameters had no effect on the outcomes in both uni- and multivariable analyses nor did the etiology of failure or the sequence in which the slings were placed (Table 3).

Table 4 displays results for patients whose follow-up was greater than or equal to 6, 12, and 24 months, showing that

Table 2 Distribution of slings used for the second intervention

	First intervention (%)	Second intervention (%)
Retropubic slings	44	49
TVT	90	100
IVS	4	
Swing	2	
SPARC	2	
Stratasis	2	
Transobturator slings	44	48
TOT (undetermined)	25	37
TVT-O	18	13
Monarc	18	34
Uratape	18	
ObTape	17	7
Aris	2	2
Uretex	2	
Obtryx		7
Single-incision mini-slings	10	3
TVT Secur	100	
Ajust		100
Undetermined slings	2	

IVS intravaginal slingplasty

long-term outcomes could be typically established after the first 6 months following surgery.

The cure and overall success rates were 65.4 and 81.8 % in the retropubic group and 57.4 and 72.2 % in the transobturator group, respectively. No significant difference was found between groups ($p=0.5$ and $p=0.2$, respectively). However, after adjustment for MUCP, patients having a retropubic approach had a 3.02-fold higher odds of cure ($p=0.05$) and a 2.86-fold higher odds of overall success ($p=0.02$) compared to the transobturator approach (Table 5). When additionally adjusting for follow-up time, the magnitude of effect remained the same for both cure (OR=2.72, $p=0.046$) or overall success (OR=2.81, $p=0.06$).

Complications associated with operation

There was no reported intraoperative morbidity, especially no bladder perforation or urethral injury. Postoperative complications were as follows: 8.9 % de novo urgency (2.7 % with urgency incontinence), 7.1 % temporary voiding dysfunction (successfully treated with clean intermittent catheterization), 3.6 % pelvic pain, and 2.7 % recurrent urinary tract infections. Five patients (4.5 %) had their sling removed because of three vaginal mesh exposures (2.7 %, none of them had vaginal or urethral mesh exposure after the first sling) and two complete retentions (1.8 %, 1 TOT, 1 TVT). None of the sling types were associated with an increased risk of complications.

Discussion

Currently, MUS are the preferred first-line treatment for female SUI. High cure rates over long periods are a clearly attainable goal, with one prospective evaluation reporting 90 % after 11 years [9]. Nevertheless, there remains 5 to up to 20 % risk of failure depending on the study population. Women with recurrent SUI who still have urethral hypermobility could technically benefit from a second MUS. We report that 76.8 % of patients have a successful second SUI, with the large majority completely resolving SUI. Furthermore, outcomes were typically determined within the first 6 months after surgery and were stable over time. To the best of our knowledge, this study represents the largest number of patients with repeat slings to date.

A literature review of studies since 2007 identified only seven case series of repeat MUS in which more than ten patients were included (Table 6). In three of seven studies, there was a heterogeneous distribution of first and second slings. Cure rates largely varied from 40 to 91.7 % with a weighted average of 64.9 %, while overall success rates similarly varied from 58 to 91.7 % with a weighted average of 76.6 %. In one of the more well-designed, prospective

Table 3 Univariable analysis for determinants associated with successful use of suburethral sling

	n	Improvement/resolution vs no improvement		Resolution vs no improvement/improvement	
		OR (95 % CI)	p value	OR (95 % CI)	p value
Type of suburethral sling	109				
TOT		1.00	**	1.00	**
TVT		1.73 (0.70–4.29)	0.2	1.41 (0.65–3.05)	0.4
MUS used first	98				
TOT		1.00	**	1.00	**
TVT		0.79 (0.31–1.97)	0.6	0.65 (0.29–1.50)	0.3
Duration between first and second MUS (per day increase)	112	1.00 (0.97–1.02)	0.8	1.00 (0.98–1.02)	0.9
Sequence of slings	95				
TOT-TOT	15	1.00	**	1.00	**
TOT-TVT	32	0.43 (0.08–2.29)	0.3	0.40 (0.09–1.71)	0.2
TVT-TOT	35	0.29 (0.06–1.53)	0.1	0.24 (0.06–1.02)	0.06
TVT-TVT	13	2.00 (0.16–25.11)	0.6	0.91 (0.15–5.58)	0.9
Preoperative characteristics					
Age (per 10 year increments)	112	1.10 (0.76–1.58)	0.6	0.89 (0.65–1.22)	0.5
Obesity	94				
Normal weight (BMI <25 kg/m^2)	42	1.00	**	1.00	**
Overweight (BMI 25–30 kg/m^2)	32	0.52 (0.18–1.51)	0.2	0.64 (0.25–1.66)	0.4
Obese (BMI >30 kg/m^2)	20	0.66 (0.18–2.37)	0.5	0.56 (0.18–1.68)	0.3
Parity (per number of deliveries)	82	1.52 (0.93–2.50)	0.1	1.40 (0.93–2.12)	0.1
Menopause	72	3.00 (0.86–10.45)	0.08	1.39 (0.43–4.51)	0.6
Detrusor overactivity	94	1.27 (0.13–12.03)	0.8	2.64 (0.28–24.67)	0.4
Overactive bladder	94	1.59 (0.17–14.40)	0.7	0.33 (0.06–1.91)	0.2
Post-void residual>50 ml	77	0.27 (0.04–2.10)	0.2	0.19 (0.02–1.88)	0.2
Maximum bladder capacity>400 ml	78	0.37 (0.11–1.20)	0.1	0.63 (0.24–1.64)	0.3
Initial micturition sensation>300 ml	64	2.30 (0.44–11.98)	0.3	2.27 (0.70–7.38)	0.2
MUCP≤20 cmH$_2$O	93	0.48 (0.13–1.83)	0.3	0.48 (0.14–1.72)	0.3

CI confidence interval, *BMI* body mass index

** no *p* value

studies, a much higher cure rate (74 %) was reported among 31 women with 18 months of follow-up [10]. Unfortunately, their data can only be extended to a specific population, as numerous exclusion criteria [body mass index (BMI)> 30 kg/m^2, associated urge incontinence or voiding dysfunction, concomitant pelvic floor surgery] arguably led to a population at low-risk of failure. With a subjective cure at 60.7 % and overall success at 76.8 %, our findings are similar to what has been previously described in the literature despite the aforementioned discrepancies. Our study

comprising 112 patients is the largest performed on repeat sling outcomes to date.

In our cohort, no clinical or urodynamic parameter was correlated to surgical outcomes. Currently, few studies have included multivariable analysis in which other factors predictive of sling success or failure were observed. Nonetheless, it should be noted that several factors have been previously identified for first sling failure (age, previous incontinence surgery, urge incontinence, BMI>25 kg/m^2, diabetes, intrinsic sphincter deficiency, overactive bladder [11]).

Table 4 Results for patients with a minimum 6 months of follow-up

Patients (n, %)	≥ 6 months: 85 (75.9 %)	≥ 12 months: 66 (58.9 %)	≥ 24 months: 37 (33.0 %)
Cured	48 (56.5 %)	35 (53.0 %)	20 (54.1 %)
Improved	16 (18.8 %)	13 (19.7 %)	8 (21.6 %)
Failed	21 (24.7 %)	18 (27.3 %)	9 (24.3 %)

Table 5 Multiple logistic regression of overall success and cure between MUS

	Overall success vs failed		Cure vs improvement + failed	
	aOR[a] (95 % CI)	p value	aOR[a] (95 % CI)	p value
Transobturator	1.00		1.00	
Retropubic	2.86 (0.99–8.26)	0.05	3.02 (1.15–7.93)	0.02

Overall success defined as improvement and cure combined

CI confidence interval

[a] After adjustment for MUCP

A large number of studies have compared transobturator and retropubic slings. In a recent meta-analysis, TVT appeared to be followed by significantly higher rates of objective continence rates than TOT, with no difference in subjective continence rates [12]. On the contrary, more intraoperative complications and storage lower urinary tract symptoms were observed with TVT than TOT slings. Studies on repeat slings have also aimed to compare the two approaches. Lee et al. found a trend toward higher success for the retropubic approach, although the difference between the two groups was not statistically significant [13]. Only Stav et al. demonstrated a significant difference in favor of the retropubic approach (71 vs 48 %, p=0.04) [14]. In our cohort there was no significant unadjusted difference between the two groups. On the other hand, after adjusting for closure pressure, retropubic

slings were significantly superior to the transobturator approach: the retropubic approach increased in effectiveness as the MUCP decreased. Several studies have already shown that retropubic slings are more effective in woman with intrinsic sphincter deficiency [15, 16]. A possible explanation is the U-shape of the retropubic tape, which may be more supportive and obstructive than the horizontal orientation of the transobturator tape.

One limitation of our study is its retrospective design, considering that prospective randomized controlled trials are difficult to perform for second-line surgery. Tenon and Bichat hospitals represent two reference centers for urogynecology in France, with similar and well-standardized methods of perioperative evaluation and operative procedures. Nonetheless, 21.4 % of patients had missing urodynamic data.

Nineteen patients had missing data on MUCP. It could be argued that significance after adjustment for this factor was more likely due to selection of the patient subpopulation. We performed a sensitivity analysis in which crude OR were calculated among those with MUCP data and found no substantial difference in either the magnitude of effect or significance.

Another limitation is the use of numerous types of slings. Hence, several different kinds of materials were compared (allowing the comparison of retropubic and transobturator approaches). Some have been withdrawn from the market due to their increased risk in vaginal or urethral mesh exposures, fistulas, or cellulitis (ObTape®, Uratape®, IVS®, etc.). Currently, the only recommended type of sling is nonwoven polypropylene.

Table 6 Literature review on second MUS for recurrent SUI

First author	No. of patients	1st MUS	2nd MUS	Results	Follow-up (months)
Tsivian (2007) [17]	12	TVT 75 % IVS 16.7 % TOT 8.3 %	TVT 41.7 % IVS 3.3 % TOT 25 %	Cure 91.7 %	23.2 (14–44)
Lee (2007) [13]	29	TVT 58.6 % TVT-O 20.7 % TOT 20.7 %	TVT 44.8 % TOT 55.2 %	Cure 75.9 %, improvement 6.9 %	18.1±8.4
Eandi (2008) [18]	10	TVT 50 % TOT 10 % TVT-O 40 %	TVT 100 %	Cure 40 %, improvement 30 %, failure 30 %	16 (6–33)
Van Baelen (2009) [19]	21	TVT 23.8 % TOT 76.2 %	TOT 100 %	Cure 53 %, improvement 5 %, failure 42 %	17 (3–38)
Palva (2009) [20]	20	TVT 100 %	TVT 100 %	Cure 55 %, improvement 20 %, failure 25 %	61 (34–100)
Liapis (2009) [10]	31	TVT 19.5 % TOT 22.5 % TVT-O 25.8 % TVT Secur 32.2 %	TVT 100 %	Cure 74 %, improvement 6.5 %, failure 19.5 %	18.6 (12–28)
Stav (2010) [11]	77	NS	TVT 62 %, TOT 38 %	Subjective cure 62 %	40±19

Despite a 22.4 % loss to follow-up, results were very stable regardless of minimal amount of follow-up time. We can therefore suppose that the outcomes of patients with less than 6, 12, or even 24 months of information would not have significantly altered the results of our study.

Conclusion

With 77 % overall success and low risk of complications, repeat slings are still a worthwhile therapeutic alternative in patients whose symptom is a social handicap. Moreover, we found that retropubic slings are more efficient than transobturator slings after adjusting for low MUCP. These data can be useful when choosing the approach after failure. However, the success of repeat slings is inferior to a first procedure.

Patients requiring a repeat sling should be carefully selected. Tape failure brings to light a great variety of situations that require rigorous assessment. Notwithstanding its simplicity, clinicians should not be driven to repeat MUS automatically when other solutions may be more appropriate (bulking agents, Adjustable Continence Therapy®, artificial sphincter).

Conflicts of interest   None.

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