Single-incision midurethral sling shows less pain and similar success rate in a short-term follow-up compared to the transobturator tape method in the treatment of stress urinary incontinence

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ABSTRACT

Objective: To compare the efficacy, complications, quality of life, and patient satisfaction rates in women treated for stress urinary incontinence (SUI) using the adjustable anchored single-incision midurethral sling (SIMS) and standard midurethral sling (MUS) procedures.

Material and methods: A total of 113 women between October 2012 and October 2016 underwent either the adjustable SIMS (n=54) or MUS (n=57) procedure. The postoperative pain profile was assessed using a 10-point visual analog scale at the fixed time-point quality of life and an additional postoperative 3rd week appointment. We asked our patients the following two questions to evaluate their satisfaction with surgery and their preference: "Would you have this kind of surgery again?" (Q1), and "Would you recommend this type of surgery to another patient with same symptoms?" (Q2). For the evaluation of patient complaints, the Incontinence Impact Questionnaire (IIQ-7) and Urinary Distress Inventory (UDI-6) were used before and after the procedure.

Results: Women in the SIMS group had a significantly lower postoperative pain profile for up to 3 weeks ($p<0.001$). There was no significant difference in perioperative complications and postoperative continence rates between the groups. With regard to Q1 and Q2, a significant difference was found between the groups ($p=0.003$ and $p=0.002$, respectively). While the questionnaire scores of the IIQ-7 and UDI-6 were also significantly improved at postoperative evaluations ($p<0.001$), there was no significant difference between the two groups.

Conclusion: SIMS is associated with a significantly improved postoperative pain profile and earlier return to work when compared to MUS.

Keywords: Mini-sling; patient satisfaction; single incision.

Introduction

Stress urinary incontinence (SUI) is defined as involuntary leakage of urine on effort or exertion, or on sneezing or coughing.[1] The treatment of SUI has been revolutionized over the past 2 decades with the advent of midurethral slings (MUS), and currently, the first-line surgical treatment for female SUI is the use of tension-free MUS.[2-4]

Single-incision midurethral slings (SIMS) were developed in an attempt to shorten the insertion trajectories to reduce complications.[5] Many studies reported that SIMS are an attractive alternative to standard MUS as they show comparable efficacy with less pain and a shorter recovery time.[6] While sufficient evidence on this topic is available for standard MUS, there are few and conflicting data for SIMS.

In this study, our aim was to compare the efficacy and complication rates of SIMS and transobturator MUS in the surgical treatment of SUI in women. In addition, the effects of both procedures on the quality of life and patient satisfaction levels were evaluated.

Material and methods

This was a multicentric retrospective cohort study approved by the institutional review board of Marmara University School of Medicine (Approval ID No: 09.2016.645). Informed consent was obtained from all patients.

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Study participants

Between October 2012 and August 2016, a total of 113 women who underwent surgical treatment for SUI either by SIMS (Ophira Promedon, Córdoba, Argentina) (n=56) or MUS (I stop, CL Medical, Lyon, France) (n=57) at three different urogynecology clinics were enrolled into the study. Preoperatively, all patients were evaluated by urine examination and using a voiding diary, uroflowmetry, and post-void residual urine measurement. The Q-tip test and cough test with a full bladder in lithotomy and at standing was performed to detect urethral hypermobility. Urodynamic testing was only performed to verify the diagnosis in a group of patients where the findings were inconclusive, in diabetics, and in mixed type of urinary incontinence. Patients with a history of previous surgery for SUI, a pelvic organ prolapse ≥stage 2, planned pregnancy, urge-type predominant mixed urinary incontinence, concomitant surgery (e.g., hysterectomy and/or other surgery for pelvic organ prolapse), severe mental or neurological disorders and who did not consult for follow-up were excluded.

Efficacy evaluations

The participants were divided into the MUS (transobturator tape) group or the SIMS group. Both groups were homogeneous considering age, urinary incontinence period, parity, and daily pad use. All patients underwent either the MUS or SIMS procedure as described previously.[7,8] Data such as age, menopausal status, the degree of symptom relief, surgery-related complications, difficulty in voiding due to obstruction, wound infection, mesh erosion, or hematoma were examined at the follow-up 12 months after the operation. Postoperative pain was defined as pain that limits the performance of daily activities such as washing, clothing, cooking, or taking food, despite the use of over-the-counter oral analgesics.[9] To assess postoperative pain, a visual analog scale (VAS) was applied on the 3rd day after the operation (0, no pain; 10, worst pain). The quality of life of the patients was evaluated using the validated Turkish translations of Urinary Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7), both of which assessed distress as an urinary incontinence-related symptom and the quality of life.[10] In addition, patients were asked to answer the following questions about surgery satisfaction and preference at the postoperative 3rd week visit: "Would you have this kind of surgery again?" (Q1) and "Would you recommend this type of surgery to another patient with same symptoms?" (Q2). Success was defined as the absence of leakage defined as "fully dry," decreased incontinence or slight leakage <1 pad as "improved," >50% improvement in incontinence severity as "more than 50% improvement," and cases where the leak continued or the pad use was ≥2 were labeled as "failure."

Statistical analysis

The IBM Statistical Package for the Social Sciences for Windows version 20.0 (IBM SPSS Corp.; Armonk, NY, USA) was used for statistical analysis. For continuous variables, the Mann-Whitney U test was used, while the chi-squared and Fisher's exact tests were used for categorical variables. The results were analyzed within the 95% confidence interval, and a *p*-value <0.05 was considered statistically significant.

Results

The mean follow-up was 19±7.52 (12 to 48) months for the MUS group and 27±14.33 (6 to 48 months) months for the SIMS group. The mean age was 49 ±6.41 (31-65) years and 50±7.49 (30-85) in the MUS and SIMS groups, respectively (p=0.879). The severity of preoperative incontinence rates was similar between the two groups (p=0.198). Table 1 shows the baseline characteristics of the patients in each group. Women in the SIMS group had a significantly lower postoperative pain profile at the 3rd week (p≤0.001). No significant difference in the postoperative continence rate was found between the two groups (p=0.268), and 86% of the patients in the MUS group and 82% patients in the SIMS group reported their continence status as "fully dry or improved." The VAS scores on the postoperative 3rd day were found to be significantly better in the SIMS group (p<0.001). However, there was no significant difference in perioperative complications and the postoperative continence rate between groups (Table 2). Groin pain was found to be significantly lower in the SIMS group (Figure 1). While the results of IIQ-7 and UDI-6 were found to be significantly improved at the postoperative period in the two groups, there was no significant difference between the groups (p=0.425 and p=0.536, respectively) (Table 3). A total of 49 patients in the

Table 1. Preoperative patient characteristics

Characteristic	MUS (n, %)	SIMS (n, %)	p
Patients	57	54	
Menopausal status	33 (57.89)	32 (59.25)	0.720
Severity of preoperative incontinence rate			0.198
Mild (1 ped/day)	1 (1.75)	2 (3.70)	
Moderate (2-3 pad/day)	21 (36.84)	28 (51.85)	
Severe (4-5 or more pad/day)	35 (61.40)	24 (44.44)	

MUS: midurethral sling; SIMS: single-incision mini-sling

SIMS group (90.7%) and 39 patients in the MUS group (68.4%) answered the question Q1 positively, and a significant difference was found between the groups (p=0.003). With respect to Q2, 50 (92.6%) patients in the SIMS group and 40 (70.2%) patients in the MUS group recommended surgery for other women with incontinence, and a significant difference was found between the groups (p=0.002). When we compared the satisfaction rates between the two groups following surgery, patients in the SIMS group reported a significantly high satisfaction rate compared to the MUS group (p=0.005). The patient satisfaction and surgery preference rates are presented in Table 4.

Discussion

The paradigm of SUI surgical treatment changed in the 1990s after the introduction of MUS by Petros and Ulmstein.[11] Historically, MUS can be divided into three categories. The first procedure is the retropubic tension-free vaginal tape, adopted by the

Table 2. Comparison of postoperative treatment outcomes and complications

Characteristic	MUS (n, %)	SIMS (n, %)	p
Postoperative continence rate			0.268
Fully dry	35 (61.40)	40 (74.07)	
Improved	14 (24.56)	11 (20.37)	
Failure	8 (14.04)	3 (5.56)	
Groin pain	57 (100)	7 (12.96)	<0.0001*
Groin pain duration			0.003*
Early period <10 days	39 (68.42)	1 (1.85)	
10-20 days	4 (7.01)	1 (1.85)	
Late period 21-90 days	10 (17.54)	- (0)	
>90 days	4 (7.01)	5 (9.25)	
VAS scores	3.8	0.2	<0.001*
Complications			
Extrusion rate	2 (3.50)	5 (9.25)	0.271
Infection rate	4 (7.01)	- (0)	0.118
Dyspareunia	12 (21.05)	11 (20.37)	0.852
Urination difficulty	10 (17.54)	3 (5.55)	0.911
Bleeding rate	5 (8.77)	1 (1.85)	0.746
Vaginal laceration	7 (12.28)	(0)	0.112
Perforation (bladder, urethra, etc.)	(0)	(0)	N/A
De-novo urge incontinence rate	(0)	2 (3.70)	0.242
Postoperative follow-up, median (range), month	19±7.52 (12-48)	27±14.33 (6-48)	0.010*

MUS: midurethral sling; SIMS: single-incision mini-sling; VAS: visual analog scale

Table 3. Comparison of Urinary Distress Inventory-6 (UDI-6) and Modified Incontinence Impact Questionnaire Short-Form-7 (IIQ-7) Scores before and 3 months following the Standard Midurethral Sling (SMUS) and Single-Incision Midurethral Sling (SIMS) procedures

Characteristic		Preoperatively	Postoperatively	p
UDI-6	SMUS (n=57)	13±3.15	8±6.39	0.536
	SIMS (n=56)	14±2.94	5±4.41	
IIQ-7	SMUS (n=57)	19±4.50	7.5±5.02	0.425
	SIMS (n=56)	16.5±4.55	5±3.62	

UDI-6: Urogenital Distress Inventory-6; IIQ-7: Incontinence Impact Questionnaire-7

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Table 4. Comparison of patient satisfaction and preference rates of surgery

Characteristic	MUS (n, %)	SIMS (n, %)	p
"Would you have this kind of surgery again?"			0.003*
Yes	39 (68.4)	49 (90.7)	
No	18 (31.6)	5 (9.3)	
"Do you recommend this type of surgery to patients who have stress incontinence?"			0.002*
Yes	40 (70.2)	50 (92.6)	
No	17 (29.8)	4 (7.4)	
Patient satisfaction			0.005*
Very pleased	28 (49.1)	43 (79.6)	
Moderately pleased	15 (26.3)	7 (13)	
Less satisfied	8 (14)	3 (5.5)	
Not satisfied	6 (10.5)	1 (1.8)	

MUS: midurethral sling; SIMS: single-incision mini-sling

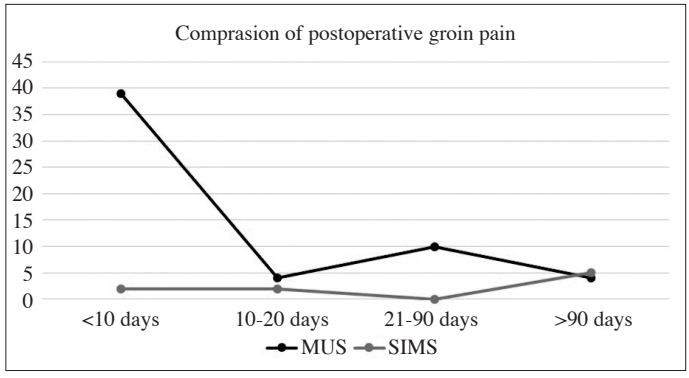

Figure 1. Comparison of groin pain duration
MUS: midurethral sling; SIMS: single-incision mini-sling

majority as the standard surgical SUI treatment. However, the nature of this procedure that allowed the surgeon to blindly enter the retropubic area predisposed patients to potential complications, such as vascular and bowel injuries, and perforation or dysfunction of the bladder.[12] This led to examining different sling methods with the introduction of the second generation of slings, that is, the transobturator MUS. Although the transobturator MUS has been reported to have similar efficacy as the retropubic MUS, this technique still has several adverse effects, such as persistent groin pain and *de novo* urgency.[13] Recently, SIMS has been introduced as the third-generation MUS to overcome the complications observed in MUS surgery. It has several advantages, such as less inguinal/groin pain because the adductor muscle is not perforated, short surgery duration, less tissue dissection, and less intense reaction to a foreign body due to the use of a short macropore and polypropylene tape.[14] However, an initially presented SIMS (TVT-Secur, TVT-S, Gynecare, Ethicon, Somerville, NJ, USA) fell short of expectations with low success and high re-operation rates.[14] It was implied that the main reasons for such a failure were the lack of a rigid fixation of the mesh to the obturator membrane and the muscle, as well as the absence of the post-insertion adjustability.[15] Until recently, studies comparing the success rates between the SIMS and MUS were usually performed using the TVT-S data, and in the majority of studies, the surgical success rate and patient satisfaction were shown to be lower with SIMS than those observed after the MUS surgery.[16,17] The introduction of SIMS that allows a firm insertion into the internal obturator muscle and for post-implantation adjustability of the tape were reported to yield better outcomes in terms of SIMS surgery and patient satisfaction. The SIMS Ophira (Promedon, Córdoba, Argentina) is one of the new mini-sling systems.

In a study by Mostafa et al.[18] no statistically significant difference between the SIMS and MUS groups was found with respect to patient-reported and objective success rates after 12 months. Likewise, Naumann et al.[19] reported restoring or improving the continence rate after the SIMS procedure as 86.3% post-operatively for up to 29 months. In the present study, we compared the efficacy and complications of SIMS and transobturator MUS surgeries, and we also examined postoperative patient satisfaction at three different urogynecology clinics. At a mean follow-up of 27 months, it was found that the SIMS and MUS methods were statistically comparable in terms of the success rate (p=0.268). This result is consistent with previous studies in the literature.[18-20] Therefore, it may be suggested that SIMS surgery is safe and effective in the treatment of female SUI in short-to-medium term.

Groin and leg pain are among the early complications of transobturator tape surgery. The proportion of patients experiencing pain after the procedure was reported to reach up to 15.5%.[21] Although the groin and leg pain spontaneously resolved within a few weeks in many cases, it may be prolonged in some patients. On the other hand,

randomized controlled trials have shown that the SIMS procedure has a low incidence of postoperative inguinal pain. [7] It is obvious that postoperative pain is an important parameter in patients' preference toward a type of the surgery among others. Schellart et al.[9] evaluated the effect of pain on the preference of SIMS vs. MUS and reported that patients with less pain or discomfort would have preferred even a lower cure possibility at the expense of a less invasive procedure. In our series, although the efficacy was the same for each procedure, having less groin pain led to preferring the SIMS procedure during the short mid-term follow-up. This satisfaction was also reflected in preference and higher recommendation of SIMS to other women with incontinence. A minimal retropubic dissection and lack of any blind passage of needles and mesh passage in the groin area led to low complication rates following the SIMS procedure.

The Urinary Distress Inventory and the Incontinence Impact Questionnaire forms have been used to evaluate the quality of life in patients with urinary incontinence. In the study by Golbasi et al.[22], which evaluated and compared the preoperative and postoperative results of patients who underwent the SIMS procedure with the Ophira device, the authors reported significant improvement in terms of the UDI-6 and IIQ-7 questionnaires. Similarly, in previous studies, it was emphasized that significant improvement was achieved in patients who underwent the MUS surgery.[23,24] In our study, while the results of IIQ-7 and UDI-6 were found to be significantly improved at the postoperative period in the two groups, there was no significant difference between the SIMS and MUS groups.

The VAS scores were used to determine the postoperative pain experience. In previous studies comparing SIMS with MUS surgeries, a significantly lower VAS score was found in patients who underwent SIMS.[18-21,25] Grison et al.[26] stated that this was only valid for the first week and that this difference disappeared after the 7th day; therefore the use of VAS scale after the 7th day was not significant. Thus, in the study by Djehdian et al.[27] no significant difference was found between the SIMS and MUS groups in terms of the VAS score on the 7th day. In our study, VAS scores for SIMS and MUS at the end of the 3rd day were found to be 0.2 and 3.8, respectively ($p<0.001$), where the difference was statistically significant. Similarly, a higher rate of patient satisfaction was observed in the SIMS group ($p=0.005$). The rate of recommending the procedure to patients with SUI was significantly higher for SIMS compared to MUS ($p=0.002$). These results suggest that one of the most important advantages of SIMS are the shorter blind passages, which causes less postoperative pain.

The prevalence of dyspareunia after SIMS was reported to vary between 3% and 8%.[21] In our study, postoperative dyspareunia was reported in 21.0% and 20.3% of the patients in the MUS and SIMS groups, respectively. This relatively high rate may be related to the high number of post-menopausal women operated in our cohort. In a meta-analysis comparing SIMS and MUS, a higher risk of mesh extrusion was reported in the SIMS group.[16] In our study, we also had a higher mesh extrusion in the SIMS group. This was attributed to its use at an earlier phase of the study where a learning curve was required. Nevertheless, almost every case of erosion occurred at the very beginning of the study when initial SIMS procedures were performed.

It was reported that *de novo* urgency following a SIMS procedure varies between 1.5% and 15.6%.[27-29] In our study, only 2 patients (3.7%) from the SIMS group developed *de novo* urgency, and all patients were managed by medical treatment. The rate of voiding difficulty following SIMS was reported to range between 0% and 8% in various case series.[27-30] In our study, it was found to be 5.5%, consistent with the literature. Only 1 patient developed urinary retention, which resolved after 4 weeks of clean intermittent catheterization, not requiring any additional intervention.

The limitation of the study is that it was performed retrospectively and with a relatively small sample size. However, we used several forms to assess questionnaires to evaluate patient satisfaction and operation preference rates. This might be especially important for the questions about pain, which had the potential to fail to thoroughly indicate the situation at the immediate postoperative period.

In conclusion, our study showed that SIMS was not inferior to MUS with regard to efficacy in the treatment of female SUI at short-to-midterm follow-up. Moreover, SIMS was shown to be associated with less pain compared to MUS at an early postoperative period, which increased the patient quality of life in this group. However, considering the lack of Level 1 evidence on the SIMS effectiveness, and suggestion that it should be used as part of a structured research program, obtained data regarding its efficacy and advantage of causing less pain found in this study need to be further validated in a larger and randomized controlled series.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Marmara University School of Medicine (Approval ID No: 09.2016.645).

Informed Consent: Written informed consent was obtained from all patients who participated in this study.

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