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ORIGINAL PAPER

Single-incision needleless mini-sling technique for female stress urinary incontinence: A comparative study with standard transobturator inside-out technique

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Summary *To evaluate the safety and efficacy of surgeon-tailored polypropylene mesh (STM) through a needle-less single incision mini-slings (SIMS) vs. standard trans-obturator tape (TOT) in the treatment of female stress urinary incontinence (SUI).*

Methods: We conducted an open-label randomized controlled trial that included women with SUI. Eligible women were randomized in a 1:1 ratio to receive either standard TOT or SIMS techniques. All procedures were performed using a surgeon-tailored polypropylene mesh and monofilament tape.

Results: A total of 60 women were included. The mean operative time was significantly longer in the standard TOT group. The mean bleeding rate was significantly higher in the standard TOT group (87.6 ± 10.6 cc) compared to the SIMS group (60.0 ± 8.1 cc). There was no urethral injury in both groups. Transient thigh pain occurs in 12 cases (40 %) of the standard TOT and no cases in the SIMS group (p < 0.001). After three months, there was no significant statistical difference between the result of the two groups as regard to cure or improvement rate. No failed cases were reported in both groups (p = 0.64). Likewise, there was no significant difference between the two groups regarding patients' satisfaction rate.

Conclusions: SIMS was not inferior to standard TOT. STM SIMS is a mini-invasive, relatively safe, reproducible, easy to perform in a short time, with excellent patient tolerability and minimal pain, allowing early return to work and economically effective surgical procedure for the treatment of female stress urinary incontinence.

KEY WORDS: *Contasure-needleless; Single-incision needleless mini-sling; Stress urinary incontinence; Transobturator inside-out.*

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INTRODUCTION

Stress urinary incontinence (SUI) is a complaint of involuntary urine leakage triggered by coughing, sneezing, exertion, or effort. According to age, geographic location, and race, SUI prevalence varies from 5 to 61%, with yearly incidence rates of 4-11% and remission rates of only 4-5% (1-3). Particularly in developing countries, SUI continues to be a substantial health burden (3). There have been several surgical methods developed throughout time to treat female SUI, including *tension-free vaginal tape* (TVT) and *trans-obturator tape* (TOT) (4, 7). Both of these surgical approaches are widely accepted for the treatment of SUI. However, TOT became more popular owing to its same cure rate and lower incidence of complications, such as urinary tract infections, pelvic hematoma, and bladder/vaginal perforation (8, 9). The TOT sling method is regarded as the gold standard in the treatment of female SUI (10).

Retropubic polypropylene mesh supports the urethra without tension, which was originally used in the initial approach, has now been modified to provide the same therapeutic benefits with fewer complications (11, 12). By avoiding the retropubic area, the TOT helps prevent hematoma and bladder perforation development in this area (13). These *mid-urethral slings* (MUS) procedures, however, also have complications owing to the blind transit of the introducer needles via obturator foramen. Although groin pain has been reported to occur at a rate of 2-7.5% in certain studies, more significant complications such as vascular injury may also occur (11). A novel minimally invasive technique for treating SUI, known as *single incision mini-slings* (SIMS), was proposed as a way to reduce postoperative pain and eliminate blind passing trocars via the Retzius space and obturator canal with less mesh (14, 15). In this study, we aimed to evaluate the safety and efficacy of *surgeon-tailored polypropylene mesh* (STM) through a needleless SIMS vs. standard TOT in the treatment of female SUI.

METHODS

The local ethics committee approved the protocol of the current trial of *Faculty of Medicine for girls, Al-Azhar University* (FMG-IRB) met at *Faculty of Medicine for Girls, Nasr City, Cairo, Egypt* (Registration Number: 29042019). Only women who were able to read and sign the informed consent were included. All procedures run in compliance with the standards of the Declaration of Helsinki (16). The reporting of the present manuscript followed the CONSORT statement (17).

Study design and patients

We conducted an open-label randomised controlled trial that included women with SUI, who were scheduled to undergo surgical management at *Al Zahraa University Hospital in Cairo, Egypt*, from February 2019 to June 2022. Adult women with a confirmed diagnosis of SUI through a positive stress test were included if they exhibited no response to pelvic floor exercise. There were no restrictions regarding the severity of SUI or the presence of cystocele. We excluded women with tumours of the

genitourinary organs, infection, neurogenic bladder, and pregnant women. Eligible women were randomised in a 1:1 ratio to receive either standard TOT or SIMS techniques. All procedures were performed using a surgeon-tailored polypropylene mesh and monofilament tape.

Preoperative assessment

Preoperatively, all women were assessed for the presentation, duration, and severity of SUI through the questionnaire described by *Sand et al.* (18). Besides, patients were evaluated for associated genitourinary or neurological conditions and bowel habits. General medical, obstetric, and gynaecological histories were evaluated as well. All women underwent routine physical examination and preoperative laboratory assessment, including *complete blood count* (CBC), liver and renal functions, bleeding profile, and urine culture. Abdominopelvic ultrasonography was performed for all women to assess post-void residual urine. All patients underwent cytometry preoperatively via *Andromeda Urodynamic* apparatus.

Surgical procedures

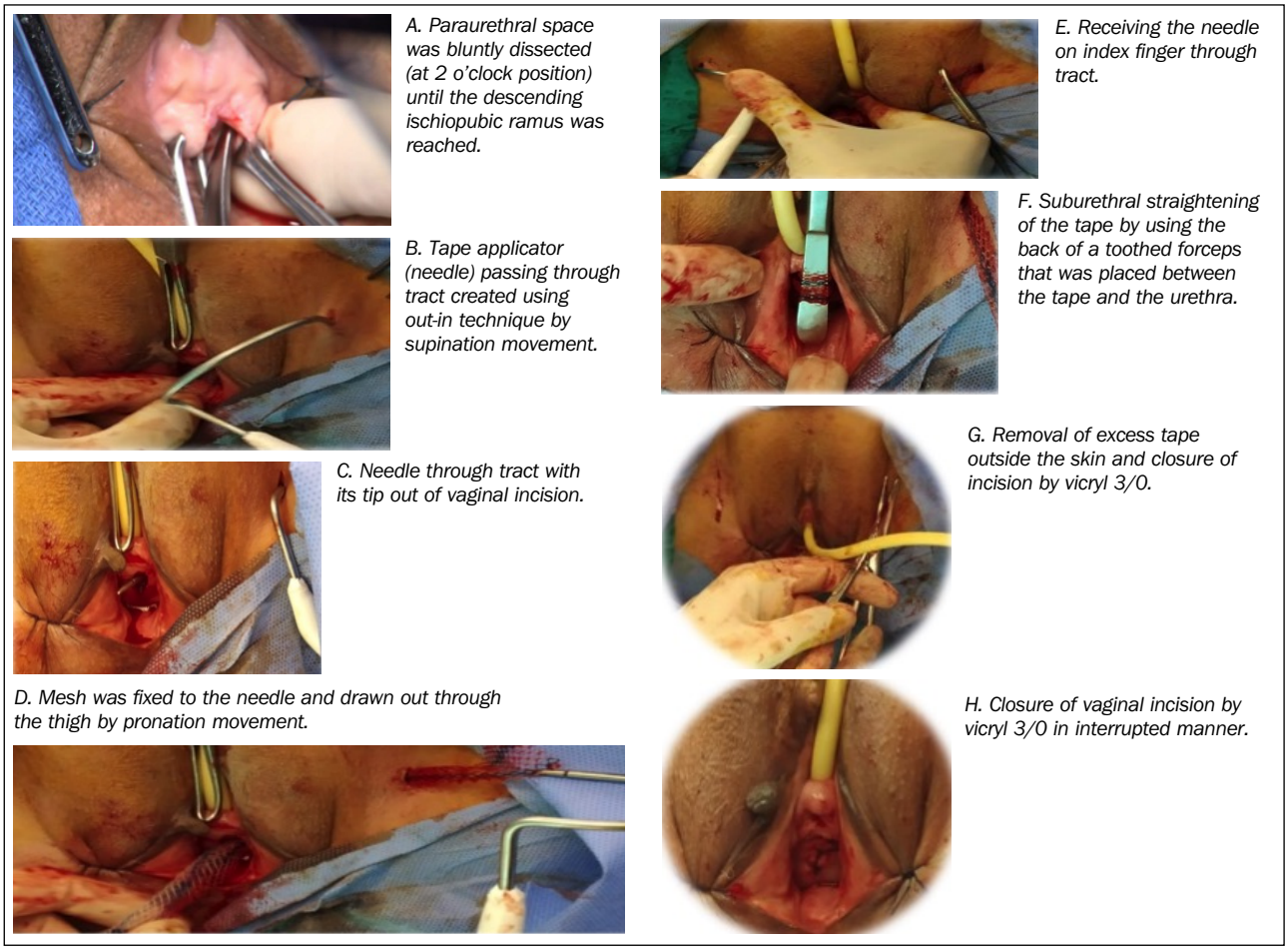
In both groups:

– patients received prophylactic antibiotics one hour before the procedure (1gm 3rd generation cephalosporin intravenously);
– procedures were performed under spinal anesthesia and in lithotomy position, with a 16 F bladder catheter insertion;
– labia were retraced using a 3.0 silk stay suture;
– a vaginal incision was done;
– Allis clamps were applied at each side of the midline to suspend the anterior vaginal wall;
– hydrodissection of the vaginal mucosa was performed;
– vaginal wall was incised 1 cm on the sagittal line starting 1 cm below the urethral meatus.

In the standard TOT group:

– the mesh was prepared using a 30 x 30cm monofilament mesh;
– periurethral fascia was dissected laterally using Metzenbaum scissors toward the inferior pubic ramus at each side;
– a skin incision was made at the adductor longus tendon base parallel to the clitoris;
– a needle was passed from this incision to the vaginal incision;
– surgeon-tailored mesh was fixed to the needle and guided throughout the thigh;
– to obtain a tension-free procedure a non-toothed forceps was placed between the sling and the urethra to avoid twisting of the tape;

Figure 1 (A-H).
Standard transobturator tape (TOT) procedure.



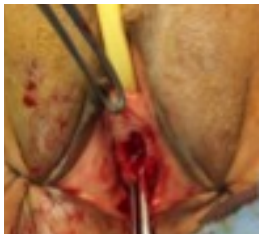
– the patient was asked to cough to assess the correction of stress incontinence;
– a 3-0 vicryl suture was used to close the skin and vaginal incisions in sub-cuticular and interrupted fashions, respectively;
– the vagina was packed with a povidone-iodine-soaked pack, and the urethral catheter was connected to closed-bag drainage (Figure 1).

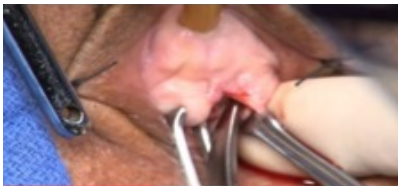
In the SIMS:
– the mesh was prepared using 15 x 15 cm monofilament mesh (*polypropylene mesh; Prolene, Ethicon Ltd., UK*) to prepare T-pocket shaped strips of a total length of 12.5 cm;
– dissection was made bilaterally to reach the ischiopubic ramus;
– the T-pocket shaped mesh was then folded into surgical forceps, which were introduced at 45 degrees to the dissected paraurethral space until the internal obturator fascia was penetrated;
– the surgeon opened the forceps to extend the T-pocket shaped mesh and removed the pulling sutures after full positioning;
– a 3-0 vicryl suture was used to close the vaginal incisions in an interrupted fashion. The vagina was packed with a povidone-iodine-soaked pack, and the urethral catheter was connected to closed-bag drainage (Figure 2).

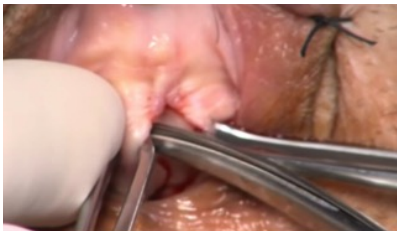
Figure 2 (A-L).
Needle-less single incision mini-sling (SIMS).

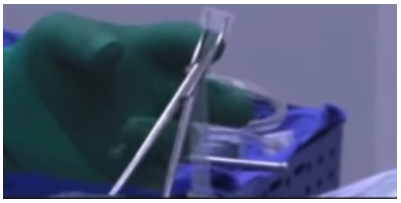

A. Polypropylene mesh 30 x 30 cm that will be tailored as tapes.

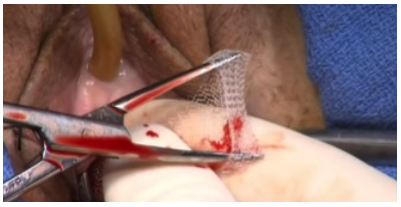

B. Polypropylene strips or tapes (surgical tailored mesh) each one 1 cm x 30 cm prepared for package and sterilization by plasma machine.

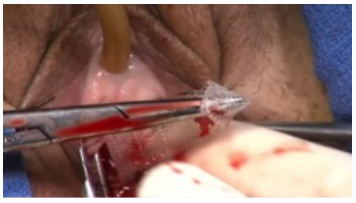

C. Suburethral longitudinal midline incision of anterior vaginal wall in presence of urethral catheter.

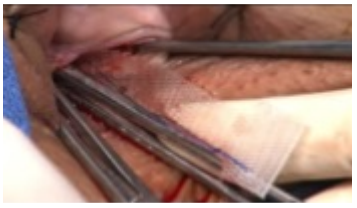

D. Paraurethral space blunt dissection at 2 o'clock position until the descending ischiopubic ramus was reached.

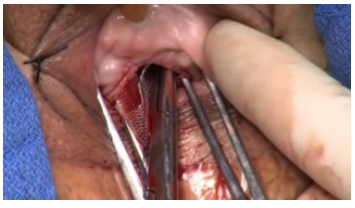

E. Paraurethral spaces blunt dissection (at 10 o'clock position) until the descending ischiopubic ramus was reached.

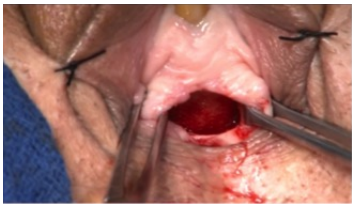

F. Hyperextention of the STM T pocket by the forceps.

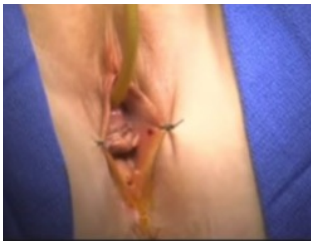

G. Hyperextention of the T pocket of STM by the forceps at other end of the STM tape.


H. By hyperextension and closure of the forceps the STM was folded into surgical forceps by placing the forceps inside the T- Pocket followed by opening and closing the forceps.


I. Forceps with the folded mesh was introduced by a controlled push at 45° from the horizontal plane in the previous dissected paraurethral space until a "crack" was felt that signified the penetration of the internal obturator fascia.


J. The T-pocket was then extended inside the internal obturator muscles by opening the forceps. The forceps were then closed and pulled off the vagina.


K. Visualization of suburethral tape untwisted before closure of the wound.


L. Closure of vaginal incision by vicryl 3/0 interrupted suture.

Women in both groups received routine postoperative care, and the vaginal pack and catheter were removed 12 hours after the operation in uneventful cases.

Follow-up and study's outcomes

All women were followed biweekly in the first postoperative month, then every month for three months. The follow-up visits consist of subjective assessment of SUI symptoms through the SUI questionnaire and urodynamic studies. The surgical outcome was categorized according to the questionnaire and *abdominal leak point pressures* (ALLP) into: success, in which there is no urinary leakage with stress and patient's satisfaction; improve; in which there was leakage with severe exertion only; and failed, in which there is a persistent leakage and patient's dissatisfaction.

Statistical analysis

Retrieved data were summarized and processed with IBM SPSS statistical software (version 25). Descriptive statistics were used to describe continuous and categorical data, respectively. The hypothesis of significant difference between the techniques regarding postoperative outcomes and complications was tested using the Chi-square test, with Fisher exact whenever needed. The association between technique and continuous data was tested using the Mann-Whitney test. P-value < 0.05 was regarded as statistically significant.

Results

A total of 60 women were included in the present study. The mean age of the standard and SIMS groups was 45.6 ± 7.9 and 42.3 ± 6.6 years old, respectively. None of the patients was nulliparous. The mean number of deliveries in the standard group was 3.6±1.7, compared to 3.9 ± 1.1 deliveries in the SIMS group. Two patients had *cesarean section* (CS) in addition to their vaginal deliveries. Seven cases had associated preoperative urinary tract infection. Almost 90% of the patients had no previous surgery, three patients (5%) underwent an abdominal hysterectomy, and three patients (5%) underwent previous vaginal prolapse repair surgery. Nine (30%) patients had grade I cystocele in the standard group, and six (20%) patients had grade II cystocele. Five (16.6%) patients had grade I cystocele on examination in the SIMS group. The mean duration of symptoms was 2.73 ± 1.36 years (range 1-5 years). Four cases only (6.67%) in both groups had an ALPP less than 50 ml, which indicate intrinsic sphincteric deficiency. The preoperative urodynamic studies showed a mean bladder capacity of 382.76 ± 34.26 ml. No patient had detrusor overactivity or significant residual urine preoperatively (Table 1).

The mean operative time was significantly longer in the standard TOT group (17.0 ± 2.9 min) compared to the SIMS group (10.7 ± 1.8 min). The mean bleeding rate was significantly higher in the standard TOT group (87.6 ± 10.6 cc) compared to the SIMS group (60.0 ± 8.1 cc). One case (3.33%) had bladder injury in the SIMS group, which needed cystoscopy revealing a small bladder injury that was repaired immediately by vicryl 4/0 in two layers. There was no urethral injury in both groups. None of the studied patients developed intraoperative vaginal wall laceration (Table 2).

Concerning early complications, re-catheterisation was not needed in any patient as there was no retention of urine or significant residual urine postoperatively. The incidence of postoperative *urinary tract infection* (UTI) was 10% and was treated medically according to culture and sensitivity. Three patients (two in the standard TOT and one in the SIMS group) developed a vaginal discharge. Postoperative wound infection was not found in any cases. None of the studied patients developed urine retention. In terms of late complications, transient thigh pain occurs in 12 cases (40%) of the standard TOT and no cases in the SIMS group (p < 0.001). After three months from operation, vaginal discharge was reported in two cases (6.7%) treated with the appropriate antibiotics, antifungals, and frequent vaginal douches. Five cases (20%) had urinary tract infection which was treated medically according to culture and sensitivity. Dyspareunia, vaginal erosions and de novo urgency were not reported during postoperative follow up (Table 2).

After three months, there was no significant statistical difference between the result of the two groups as regard to cure or improvement rate, wherein the standard TOT group, 27 cases (90%) and three cases (10%) were succeeded and improved, respectively, compared to 28 cases (93.33%) and two cases (6.66%) in the SIMS group. No

Table 1.
Preoperative data of both groups.

Variables		STM standard TOT N = 30 %	STM SIMS N = 30 %	P-value
Age (years)	Mean ± SD	45.6 ± 7.9	42.3 ± 6.6	P = 0.086
Delivery	Normal vaginal delivery	3.6 ± 1.7	3.9 ± 1.1	P = 0.561
	Cesarean section	0.07 ± 0.25	0.03 ± 0.18	
Menopausal status	Pre menopause	20 (66.7%)	24 (80%)	P = 0.243
	Post menopause	10 (33.3%)	6 (20%)	
Surgical history	Patients with no previous surgery	25 (83.3%)	29 (96.7%)	P = 0.163
	Previous vaginal prolapse repair surgery	3 (10%)	0 (0%)	
	Previous abdominal hysterectomy	2 (6.7%)	1 (3.3%)	
Per vaginal examination	Normal	15 (50%)	25 (83.3%)	P = 0.008*
	Mild cystocele	9 (30%)	5 (16.7%)	
	Moderate cystocele	6 (20%)	0 (0%)	
Severity of preoperative incontinence rate	Mild (0-1 pad/day)	2 (6.7%)	3 (10%)	P = 0.707
	Moderate (2-3 pad/day)	14 (46.7%)	16 (53.3%)	
	Severe (4-5 or more pad/day)	14 (46.7%)	11 (36.7%)	
ALLP	< 50 ml	2 (6.66%)	2 (6.66%)	
	51-100 ml	12 (40%)	16 (53.33%)	
	101-150 ml	14 (46.66%)	12 (40%)	
	151-200 ml	2 (6.66%)	0 (0%)	

Table 2.
Operative time and complication of both groups.

Variables	STM standard TOT N = 30	%	STM SIMS N = 30	%	P-value
Operative time (minutes)					P = 0.000*
· 8-11	0	0.0	20	66.7	
· 12-18	22	73.3	10	33.3	
· 19-25	8	26.7	0	0.0	
Operative time (minutes), Mean ± Sd	17.0 ± 2.9		10.7 ± 1.8		P = 0.000*
Intra-operative complications					P = 0.313
Bladder injury	1 (3.3%)		0		
Bleeding rate (CC), Mean ± SD	87.6 ± 10.6		60.0 ± 8.1		P = 0.000*
Vaginal wall laceration	0		0		
Early postoperative complications					P = 0.000*
· Groin pain	12 (40%)		0 (0%)		
· Urinary tract infection	2 (6.7%)		1 (3.3%)		
· Vaginal infection	2 (6.7%)		1 (3.3%)		
· Urine retention	0 (0%)		0 (0%)		
Late postoperative complications					P = 0.554
· Mesh erosions	0		0		
· De novo urgency	0		0		
· Dyspareunia	0		0		
· Vaginal discharge	1 (3.34%)		1 (3.34%)		
· Urinary tract infection	3 (10%)		2 (6.7%)		

failed cases were reported in both groups (p = 0.64) (Figure 3). Likewise, there was no significant difference between the two groups regarding patients' satisfaction rate. In the standard TOT group, 23 cases (76.7%) were very satisfied, compared to 22 cases (73.3%) in the SIMS group (p = 1.00).

Discussion

In this study, we included two comparable groups of women with no significant differences in terms of age, BMI, parity, or menopausal status. In addition, there were no significant differences in results of pelvic examination or cough stress test between women of both groups before surgery. However, in terms of operative time, STM SIMS needed a mean operative time of 10.7 minutes, which was significantly less than the mean operative time (17 minutes) needed by the STM standard TOT procedure. Similarly, *Hasan et al.*, demonstrated that the mean operative time of the mini-sling procedure was 8.3 minutes compared to 16.5 minutes in the standard TOT procedure (5). The mean operative time of the single incision TOT procedure was nine minutes and seven minutes in the studies conducted by *Cabrera et al.* (19) and *Navazo et al.* (20), respectively.

Regarding intraoperative blood loss, our findings showed that the standard TOT was associated with significantly higher procedure-related blood loss compared to STM SIMS. In the Hasan et al. study, single incision TOT patients had a lower average than regular TOT patients (51.5 *vs.* 123.1 ml), respectively (5). According to a study done by *Magon* and *Chopra* on 51 individuals, the average volume of blood loss in the conventional TOT was 78.76 ml (21). *Dobson et al.* showed that the blood loss was more than 100 ml in 71% of cases (22). *Moore et al.* reported an average intraoperative blood loss of 57 ± 22 ml in the standard TOT and 36 ml in the single incision TOT (23).

In our study, the early postoperative complications were more common in the standard TOT, including groin pain, UTI, and vaginal infection. However, intraoperative complications and late postoperative complications were similar in both groups. Likewise, in the *Hasan et al.* trial, there was no significant difference in iatrogenic organ injury and postoperative complications between the two groups (5). When *Amati et al.* completed their investigation, they found that just one patient in each group had a bladder injury that could be attributed to the simultaneous surgery. In the group of standard TOT, there was one case (3.3%) catheterized for two weeks due to intraoperative bladder injury (24). *Navazo et al.* reported a mean catheterization time of 2.02 days (20). *Cabrera et al.* mentioned that after the standard TOT, the mean catheterization time was 1.52 days in 5 patients with acute retention (19). Retention that needed catheterization for more than 24 hours following routine TOT resolved spontaneously in less than two days in one case described by *Magon and Chopra* (21). It has been found that the prevalence of dyspareunia after SIMS ranges from 3 to 8% (*Richter et al.*) (25). In our study, it was observed that neither group suffered from urge incontinence, voiding difficulties, urine retention, urethral or bladder erosions, or dyspareunia. According to *Karakeçi et al.*, postoperative dyspareunia occurred in 21% of patients in the *midurethral sling* (MUS) group and 20% of patients in the SIMS group (26). According to several clinical trials, the percentage of voiding problems after SIMS ranged from zero to eight percent (27, 29). The proportion of patients experiencing pain after the procedure was reported to reach up to 15.5% (25). Although the groin and leg pain spontaneously resolved within a few weeks in many cases, it may be prolonged in some patients. During the short mid-term follow-up, *Karakeçi et al.* preferred the SIMS technique since it caused less groin pain (26). Also, SIMS was preferred and recommended by more incontinence-suffering women (30, 31). SIMS has reduced complication rates due to little retropubic dissection and the absence of blind needle and mesh path in the groin region (26).

Patients were released from the hospital within 24 hours following surgery in our study with no significant differences in postoperative hospital stays between the two techniques. In the study of *Magon and Chopra*, the average hospitalization time was 1.6 days; 45.8% of patients were released within 24 hours after surgery, 50.88% were discharged between 24 and 72 hours after surgery, and only 3.4% of patients had to remain in the hospital for more than three days because of intraoperative complications (21). Postoperative hospital stay was not significantly different between the two procedure (standard TOT: 2.95 days and single-incision TOT: 2.65 days), with a mean of 1.04 days including both procedures when there were no concomitant operations and of 2.65 days when there were concomitant operations (24).

STM standard TOT patients had an objective cure rate of 90% after three months, with a 10% improvement and no failed cases reported, while STM SIMS patients had an objective cure rate of 93.33% after three months, with a 6.66% improvement and no failed cases reported. Cabrera et al. studied 230 women who had undergone single incision TOT and found that 86% of them were

objectively cured after a year, with 6% showing improvement and 8% being classified as failures (19), while Navazo et al. studied 120 women who had undergone single incision TOT and found that 84% were objectively cured after a year, with 8% showing improvement (20). There were no failed cases in the initial case series performed by *Delorme et al.* on 32 women who had undergone the conventional TOT and had a cure rate of 90.6% at one year (32). At one year following the standard TOT operation, the objective cure rate was 88-92% and the subjective cure rate was 68-90%, according to published studies (33).

In conclusion, our study showed that SIMS was not inferior to standard TOT. STM SIMS is a mini-invasive, relatively safe, reproducible, and economically effective surgical procedure for the treatment of female stress urinary incontinence. The STM for SIMS was easy to insert in a short time operation. It demonstrated excellent patient tolerability with minimal pain, early return to work and normal activity, and low morbidity when compared to STM standard TOT. STM SIMS should be considered as a low-cost alternative to the available commercial kits in the treatment of female SUI, mainly for public health systems with few financial resources. Randomized controlled studies with a longer duration of follow-up are needed to confirm our results.

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