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A new promising approach to urodynamic stress urinary incontinence care can help menopausal women

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Abstract

Introduction: The goal of this study is to evaluate the effectiveness of single-incision mini-sling in the surgical treatment of postmenopausal urodynamic stress urinary incontinence (SUI) compared to the standard trans-obturator mid-urethral sling.

Material and methods: This prospective study was carried out in two tertiary centres; Al-Azhar University Maternity & Urology Hospitals. A total of 120 postmenopausal women with urodynamic SUI were randomized to undergo either single-incision mini-sling (n = 60) or standard trans-obturator mid-urethral sling procedure (n = 60) from May 2019 until Oct 2021. Main outcome measures: efficacy was evaluated utilizing objective cure rate (cough stress test) and subjective cure rate (Sandvik incontinence severity index and International Consultations on Incontinence Questionnaire – Short Form), intraoperative and postoperative complications, and postoperative pain (using a visual analogue scale).

Results: The single-incision mini-sling (SIMS) and transobturator tape (TOT) groups had no statistically significant difference in subjective and objective cure rates ($p > 0.05$). Compared with the transvaginal tape O group, patients in the SIMS group had significantly less postoperative pain, shorter operative duration, and less intraoperative blood loss (all p-values < 0.05). No significant difference in perioperative complications was observed between both groups.

Conclusions: Single-incision mini-sling was superior to TOT in postmenopausal as SIMS is of similar effectiveness, more safe and minimally invasive with earlier ambulance.

Key words: single-incision mini-sling, trans-obturator mid-urethral sling, urodynamic stress urinary incontinence, postmenopausal women.

Introduction

Urinary incontinence is a serious social problem that affects more than 50% of postmenopausal women. The number of patients increases from year to year. This condition occurs in about 20–30% of young women, 30–40% in middle age, and up to 50% of women in old age [1]. Its impact on quality of life is significant, leading to physical and social limitations, shame, and increased rates of depressive symptoms. It is associated with significant physical morbidity, sexual dysfunction, loss of independence, and a reduction in psychological wellbeing, with consequent decreased participation in social and domestic activities [2]. Urinary incontinence affects 10–40% of women, with the most common type known as stress urinary incontinence (SUI) [3, 4].

The International Continence Society define SUI as any involuntary leakage of urine during increase abdominal pressure in the absence of detrusor contraction or an overactive bladder, e.g. during cough, sneezing, laughing, or lifting heavy objects [5]. It can be broadly divided into genuine stress incontinence (also referred to as urodynamic stress incontinence) caused by bladder neck weakness or an unstable bladder, or detrusor instability caused by an overactive detrusor muscle [6].

Risk factors for SUI include increased number of vaginal deliveries, previous vaginal surgery, obesity, chronic cough, depression, poor health, and stroke [4]. Treatment options include lifestyle modification, fluid management, avoiding constipation, pelvic muscle exercise, bladder training, topical vaginal oestrogen, con-

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tinence device, pessaries, pharmacotherapy, surgery, and stem cell therapy [7].

Surgical treatment for SUI has evolved continuously over the last 2 decades with the aim of providing a safe, effective, and truly ambulatory surgical procedure [8]. Standard mid-urethral sling (SMUS) including retropubic tension-free vaginal tapes and trans-obturator vaginal tapes have been the mainstay of surgical treatment over the last 2 decades. Single-incision mini-slings (SIMS) represent the third generation of mid-urethral slings, aiming to provide a truly mobile continence procedure that is as effective as the SMUS but with minimal morbidity [6]. As the operations are being improved and updated constantly, we are trying to find a treatment method that is effective, simple, easy to perform, with little trauma, and without long-term complications [9, 10]. The aim of the study is to assess the efficacy of a SIMS vs. SMUS transobturator tape (TOT) as a surgical procedure.

Material and methods

This randomized controlled trial was conducted in the urogynaecology units of 2 tertiary units: Al-Azhar University Maternity and Urology Hospitals, from May 2019 to Oct 2021. The study was approved by the Research Ethics Committee of the hospital, and all patients signed informed consent before surgery.

Patients diagnosed with urodynamic SUI and being candidates for surgical treatment were eligible for the study. The study excluded patients with overactive bladder, body mass index ≥ 30 kg/m^2, history of previous surgical procedures for treatment of SUI, voiding dysfunction, pelvic organ prolapse grade 2 or more, and patients with medical disorders of significance. A total of 178 patients were reviewed at the outpatient clinic, and 120 patients fulfilled the study criteria.

Initial assessment included full history, cough stress test, pelvic examination to quantify pelvic organ support according to the pelvic organ prolapse quantification system, urine analysis and culture, urodynamic study including uroflowmetry, post-void residual urine (PVR), multichannel cytometry, Valsalva leak point pressure, and urethral closure pressure. Patients were asked to complete International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF). Then patients were divided into 2 groups according to the computer-generated randomization table:

- Group I – 60 patients were operated upon using TOT,
- Group II – 60 patients were operated upon using SIMS.

Preoperative preparation

The patients were instructed to fast for at least 6 hours. Antibiotic prophylaxis was intravenous 1 g of third-generation cephalosporin one hour before starting the procedure.

Surgical procedure

All operations were done under regional anaesthesia in the dorsal lithotomy position. For Group I the Obtryx II system (Boston Scientific, Natick, MA, USA) was used, and the standard procedure of transvaginal tape (TVT-O) was followed using a halo needle and outside-in approach.

For Group II, the Solyx SIS system (Boston Scientific, Natick, MA, USA) was used, with a 2-cm incision into the anterior vaginal wall 1 cm from the urethral opening, bilateral dissection at 45° from the midline to the interior of the inferior pubic ramus, and a 9-cm-long macroporous polypropylene tape was passed into the obturator muscle using a delivery device and was anchored in place via self-fixation tips at either ends. The vagina was closed using polyglactin 2/0 sutures in a continuous manner.

For all patients the operative time, intraoperative blood loss, and any complications were recorded.

Postoperative care

After the end of the operation, a transurethral Foley's catheter was left in place for 6–12 hours until the patient recovered from the anaesthesia (because the procedures are minimally invasive with no need to increase the period of catheter insertion). Because the pain postoperative is minimal, just non-steroidal anti-inflammatory drugs were given if needed, and the visual analogue scale (VAS) was used to measure the patient's pain. A visual analogue scale score of 5/10 or more was considered as severe pain.

After removal of the urinary catheter, the patient was encouraged to void as early as possible. Once the patient had voided spontaneously, the PVR was measured. If the PVR is less than 100 cc and no difficulty in voiding occurred, then the patient was discharged.

Follow-up: visits were at 1, 3, 6, and 12 months post operation. The evaluation was carried out by taking new history of urinary symptoms, cough stress test, and measurement of PVR. At the 12-month visit the patients also underwent q urodynamic test and completed 2 questionnaires: the ICIQ-SF and the Sandvik Severity Index.

The primary outcome measure was objective cure rate at 12 months. The secondary outcomes were subjective cure rate, operative time, blood loss, and intraoperative and postoperative complications.

The objective cure rate for SUI was analysed using a cough stress test, with cure defined as a negative test. Subjective cure was defined as "Dry" on the Sandvik Severity Index. Improvement was defined as any answer other than "Dry" on the Sandvik Severity Index and 50%

or more decrease in symptoms based on the ICIQ-SF results. Post-void residual urine measurement was assessed by Nelaton catheter at each follow-up visit to show any variation from preoperative and to exclude postoperative retention (defined by PVR > 100 cc).

Statistical analysis

Retrieved data were recorded on an investigative report form. The data were analysed with SPSS® for Windows®, version 15.0 (SPSS, Inc., USA). Description of quantitative (numerical) variables was performed in the form of mean and standard deviation (SD). Description of qualitative (categorical) data was performed in the form of numbers and percentage. Analysis of numerical variables was performed using Student's unpaired *t*-test. Analysis of categorical data was performed using Fischer's exact test and the χ^2 test. The significance level was set at 0.05.

Results

Table 1. Demographic data

Parameters	TOT (n = 60)	Mini-sling (n = 60)	*p*-value
Age (years)	62.6 ±5.1	61.9 ±4.8	> 0.05
Parity	5.2 ±0.5	4.8 ±0.9	> 0.05
BMI [kg/m^2]	28.3 ±4.3	27.9 ±4.2	> 0.05
Incontinence period [years]	10.5 ±4.2	9.8 ±5.3	> 0.05

BMI – body mass index, n – number (percentage), SD – standard deviation, TOT – transobturator tape
Data presented as mean ±SD

Table 2. Preoperative data

Parameters	TOT (*n* = 60)	Mini-sling (*n* = 60)	*p*-value
Qmax [ml/sec]	29.1 ±3.8	28.8 ±3.7	> 0.05
PVR [ml]	27.4 ±2.5	29.6 ±3.1	> 0.05
Urodynamic			
VLPP [cm H^{2}O]	118.1 ±21.4	112.1 ±20.1	> 0.05
MUCP [cm H^{2}O]	81.1 ±10.3	77.1 ±9.6	> 0.05
FUL [cm]	1.8 ±0.9	2.0 ±0.3	> 0.05
ICIQ-SF	14 ±1.6	13 ±1.3	> 0.05

FUL – functional urethral length, ICIQ-SF – International Consultation on Incontinence Questionnaire-Short Form, MUCP – maximum urethral closure pressure, PVR – post-void residual urine, Qmax – maximum flow rate, SD – standard deviation, TOT – transobturator tape, VLPP – Valsalva leak point pressure
Data presented as mean ±SD

Table 3. Operative data

Parameters	TOT (*n* = 60)	Mini-sling (*n* = 60)	*p*-value
Estimated blood loss [ml]	52.8 ±7.2	18.9 ±6.9	< 0.05
Operative time (min)	26.1 ±4.2	11 ±3.9	< 0.05
Complications *n* (%)			
Bleeding	0 (0)	0 (0)	> 0.05
Vaginal perforation	3 (5)	1 (1.7)	
Urethral injury	0	0	
Bladder injury	0	0	

n – number (percentage), SD – standard deviation, TOT – transobturator tape
Data presented as mean ±SD

Table 4. Postoperative data

Parameters	TOT (*n* = 60)	Mini-sling (*n* = 60)	*p*-value
VAS	5.2 ±0.5	3.0 ±0.2	< 0.05
Pelvic haematoma	0	0	> 0.05
Urinary retention	3 (5)	2 (3.3)	> 0.05
Length of hospital stay (d)	1.2 ±0.1	1.0 ± 0.1	> 0.05
Mean time of return to activity	3.6 ±0.5	1.6 ±0.2	< 0.05

n – number (percentage), SD – standard deviation, TOT – transobturator tape, VAS – visual analogue scale
Data presented as mean ±SD

Table 5. Postoperative follow-up at 12 months

Parameters	TOT (*n* = 60)	Mini-sling (*n* = 60)	*p*-value
Objective cure rate (%)	89.2	81.9	> 0.05
Subjective cure rate (%)			
Cured	83	80	> 0.05
Improved	10	11	
Failed	7	9	
PVR [ml]	51.4 ± 9.1	54.1 ±10.4	> 0.05
Complications *n* (%)			
Voiding dysfunction	3 (5)	2 (3.3)	> 0.05
Mesh extrusion	1 (1.7)	1 (1.7)	
De novo urge	6 (10)	5 (8.3)	
Urodynamic			
Q-max [ml/s]	26.3 ±4.22	25.3 ±5.2	> 0.05
PVR [ml]	51.3 ±14.5	50.1 ±17.2	> 0.05
MUCP [H_2O]	87 ±31.2	91 ±38.2	> 0.05
FUL [cm]	3.2 ±0.73	2.9 ±0.81	> 0.05
ICIQ-SF	5.3	4.1	> 0.05
Sandvik severity index (%)			
Dry	78	80	> 0.05
Slight	12	10	
Moderate	4	3	
Severe	6	7	

FUL – functional urethral length, ICIQ-SF – International Consultation on Incontinence Questionnaire-Short Form, MUCP – maximum urethral closure pressure, n – number (percentage), PVR – post-void residual urine, Qmax – maximum flow rate, SD – standard deviation, TOT – transobturator tape, VLPP – Valsalva leak point pressure
Data presented as mean ±SD

Discussion

There are a few comparative studies on SIMS [11–14], but these studies are limited by short-term results and a lack of comparison between the SIMS technique and the standard treatments of SUI such as TOT.

It is difficult to imagine that a new device can show statistically significant improvements compared with the good present-day cure rates, which is why we chose a non-inferiority study to demonstrate that the results of the SIMS technique are not worse than those obtained with the TOT technique.

The main objective when analysing the results of a surgical technique for SUI should be the cure rate. However, it is difficult to define the cure rate with unique parameters that include both the objective and subjective results [15]. Therefore, in our study, we used a principal parameter of objective cure: a negative stress test in the lithotomy position.

No serious complications were reported, despite the description of serious complications in the literature; thus, both techniques seem to be safe.

One of the potential risks of the passage of the needles in the transobturator approach is injury to the neurovascular structures or tissues of the anatomical spaces we use. Although in our study we did not find any cases of injuries of this type, in the literature there are descriptions of injuries related to the needle passage [16]. With the SIMS technique, this morbidity should not exist because no anatomical space is crossed for its placement [17, 18]. In our study were not able to demonstrate this advantage, owing to the low incidence of these types of injuries, and a greater sample size would be required to find a difference.

In our study, there was a significant difference in the operative time, i.e. it was shorter in the SIMS group compared to the TOT group. In another study for TOT the mean duration of surgery was 21.69 minutes (SD 6.41 minutes) [19]. Other studies reported a mean surgery duration of 18 minutes for TOT [20]. This difference can be explained by the fact that all our operations were done in a teaching hospital, which is why the surgeon takes slow steps for better demonstration. This result is consistent with another study that reported a mean operation time of 24 min [21]. In contrast, some studies demonstrated no clinically significant difference in the operative time between both groups [22].

In this study, we reported significantly less intra operative blood loss in the SIMS group compared to the TVT-O group. This result agrees with another study which reported mean blood loss during the mini-sling operation of 27 + 16 ml [23]. This result disagrees with another study on 136 of patients, which showed no significant difference in intra-operative blood loss in both groups, with a *p*-value of 0.844 [24].

In the current study, there was a significant difference in both groups regarding post-operative pain by using VAS. Patients with SIMS had less pain. In a multicentre prospective study, patients with SUI (n = 137) were randomized to receive Ajust (n = 69) or TOT (n = 68) procedures, and the follow-up results showed that the post-operative pain in the Ajust group was significantly lower than the TOT group within 4 weeks after the surgery [25].

This can be explained by the fact that in the TOT surgical approach, postoperative pain was severe, long-lasting, covered a large area, and was often accompanied by pain in lower limbs, which was further aggravated during activity of lower limbs. It was suspected that the pain could be associated with the adductor tendon injury. Interestingly, in the SIMS procedure, the post-operative pain was mild and short-lasting compared to TOT. It was speculated that the reduced pain might be due to a limited puncture made only in the obturator membrane without any penetration in the obturator internus, and hence no tendon injury.

Our study showed no significant difference in length of hospital stay, but return to activity and work were significantly shorter in the SIMS group compared to the TOT group. This result is similar to another study that found post-operative hospital stay for SIMS was 2.25 ±0.74 days and for TVT-O 2.34 ±0.65 days [26].

Our results are consistent with a recent study that showed no significant difference between both studied groups in post-operative hospital stay period, with a mean duration of 1.04 days for both procedures [27].

In our study we did not report any serious complications in both study groups, and no urethral injury or nervous or vascular injuries. Only minor complications were found, and they were managed conservatively, with resolution in most cases. Patients with postoperative urinary retention were re-catheterized for 3 days, and all showed spontaneous voiding after removal of the catheter. One patient in the SIMS group with mesh extrusion received topical oestrogen cream with complete healing, while partial mesh excision was necessary in the TOT group.

Although no serious complications were reported in our study, the single-incision technique reduces the potential risk of transobturator technique of obturator nerve or vascular damage due to the passage of needles [28, 29].

In our study we noticed increasing satisfaction and cure rates among women of both groups. In a similar study, patients with SUI received SIMS surgery and were followed up for 29 months. The results showed that the postoperative objective cure rate was 86.3% [30].

In our study there was no significant difference between both groups as regard subjective cure rate. The value of SIMS in the management of female SUI could be supported by a recent meta-analysis which investigated 26 RCTs, including 3308 women, comparing SIMS with SMUS in the surgical management of SUI,

and found no evidence of significant differences between SIMS and SMUS in patient-reported cure rates, with a risk ratio of 0.94% (95% CI: 0.94–1.01) at a mean follow up of 18.6 months [31]. This supported our study, proving the non-inferiority of the SIMS procedure in comparison to SMUS.

Post-void residual urine > 50 ml after one year, which was in high normal range, was expected in this age group, with some weakness of the detrusor muscle.

The limitation of our study is the low number of patients and short follow-up period, so more research is needed to confirm our theory.

Conclusions

The Single-incision mini-sling shows less pain and a similar success rate in a short-term follow-up compared to TOT in the management of menopausal stress urinary incontinence.

Disclosure

The authors report no conflict of interest.

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