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Surgeon-tailored polypropylene mesh as a tension-free vaginal tape-obturator versus original TVT-O for the treatment of female stress urinary incontinence: a long-term comparative study

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Abstract

Introduction and hypothesis The objective of the study was to compare the safety and efficacy of surgeon-tailored polypropylene mesh (STM) through tension-free vaginal tape-obturator (TVT-O) versus original TVT-O in the treatment of stress urinary incontinence (SUI) aiming to decrease the cost of treatment. This is important in developing countries due to limited health care resources.

Methods A retrospective cohort study was done at the Urology and Gynecology Departments (dual-center), Cairo University from May 2007 to June 2010. Women evaluated by cough stress test, Stress and Urge Incontinence and Quality of Life Questionnaire (SUIQQ), maximum flow rate (Q_{\max}), and abdominal leak point pressure (ALPP) with follow-up for at least 48 months were included. Patients with post-void residual urine >100 ml, bladder capacity <300 ml, or impaired compliance were excluded. The effect of different factors on outcome was compared between both groups pre- and post-operatively using the paired *t*, Wilcoxon signed rank, McNemar, chi-square, Fisher's exact, independent *t*, or Mann-Whitney tests.

Results STM and TVT-O were inserted in 79 and 66 women, respectively. Intrinsic sphincter deficiency, ALPP, previous surgeries, associated urgency, urgency urinary incontinence (UUI), and prolapse were comparable in both groups. Operative duration was longer in STM by 10 min. No significant difference was found between both groups in

complications ($p=0.462$), cure ($p=0.654$), and different indices of SUIQQ. In STM, 74 (93 %) were cured and 3 (4 %) improved, while SUI persisted in 2 (2 %) patients. In TVT-O, 59 (89 %) were cured and 4 (6 %) improved, while failure was detected in 3 (4 %) patients.

Conclusions The 5-year outcome is comparable between STM and TVT-O. Furthermore, STM is more economical due to our resterilizable modified helical passers and the cheap polypropylene mesh.

Keywords Female stress urinary incontinence · Surgeon-tailored mesh · Polypropylene mesh · TVT-O, TOT · Cost

Abbreviations

ALPP	Abdominal leak point pressure
CST	Cough stress test
DO	Detrusor overactivity
ISD	Intrinsic sphincter deficiency
MUI	Mixed urinary incontinence
$P_{\det} Q_{\max}$	Detrusor pressure at maximum flow rate
PVRU	Post-void residual urine
Q_{\max}	Maximum flow rate
QOL	Quality of life
SUI	Stress urinary incontinence
SUIQQ	Stress and Urge Incontinence and Quality of Life Questionnaire
TOT	Transobturator vaginal tape outside-in
TVT	Tension-free vaginal tape
TVT-O	Transobturator vaginal tape inside-out
US	Abdominal and pelvic ultrasound
UUI	Urgency urinary incontinence
RCT	Randomized controlled trial

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Introduction

The tension-free vaginal tape (TVT) has been considered as a standard minimally invasive surgical treatment of female stress urinary incontinence (SUI) [1]. The use of needles with their passage through the retropubic space was associated with different complications including bladder injuries and potential bowel and major vascular injuries [2]. In order to reduce these risks, transobturator tapes were developed [3, 4]. Although a satisfactory outcome has been reported with these techniques, they are still expensive. They require special needles or passers and prefabricated slings. Their cost is problematic in developing countries. Therefore, we recently developed our procedure using the surgeon-tailored ordinary polypropylene mesh (STM) through the tension-free vaginal tape-obturator (TVT-O) technique as a low-cost alternative to the available commercial kits [5]. The aim of our study was to compare the safety and efficacy of our procedure versus original TVT-O in the treatment of female SUI.

Patients and methods

A retrospective cohort study on STM versus TVT-O was done at the Urology and Gynecology Departments (dual-center), Cairo University Hospitals. All women who underwent any of the two techniques for the treatment of SUI (involuntary loss of urine on effort or physical exertion, or on sneezing or coughing) in the period from May 2007 to June 2010 were identified from the surgical report database (Fig. 1). Inclusion criteria were the presence of complete perioperative data including preoperative urogynecologic history and examination including the Stress and Urge Incontinence and Quality of Life Questionnaire (SUIQQ) and cough stress test (CST), post-void residual urine (PVRU) evaluation using abdominal and pelvic ultrasound (US), free flowmetry (Q_{max}), and filling cystometry with assessment of detrusor pressure and detrusor overactivity (DO) and abdominal leak point pressure (ALPP). Intrinsic sphincter deficiency (ISD) was diagnosed on the basis of ALPP (≤ 60 cmH₂O). SUIQQ consists of the quality of life (QOL) index (0–16 score), SUI index (0–12 score), and urgency urinary incontinence (UUI) index (0–8 score) [6]. The presence of urgency (complaint of a sudden, compelling desire to pass urine which is difficult to defer), mixed urinary incontinence (MUI), or previous surgeries were not a contraindication provided that UUI (involuntary loss of urine associated with urgency) was not the predominant component of MUI. Patients with PVRU > 100 ml, bladder capacity < 300 ml, impaired bladder compliance, or neurological lesions were excluded. Patients with associated urogenital prolapse (according to Baden and Walker [7] classification) less than the third degree were included. The operative procedures were chosen according to the surgeon's preference among other

surgical techniques done in the same period for the treatment of SUI including TVT and transobturator vaginal tape (TOT). All surgeons had adequate experience in sling surgery. Associated prolapse repair was done for symptomatic patients.

Preparation of the polypropylene tape

The commercially available 11×6 cm nonabsorbable monofilament polypropylene mesh (Prolene[®], Polypropylene Mesh, Ethicon Ltd, Edinburgh, UK) (the same mesh used in herniorrhaphy) was tailored to form a strip (tape) of about 11 cm in length and 1.5 cm in width. A zero polypropylene suture was anchored to each end of the tape in a figure-of-eight fashion. The polypropylene suture was then inserted into the “eye” at the end of the passer.

Specifically designed surgical instruments (Fig. 2)

We modified the helical passers that were originally designed by de Leval [4]. They are pairs of stainless steel instruments, specific for the left and right sides, comprising a spirally shaped section and a handle. The spiral section comprises an open circular segment having a 3-cm radius terminated by two linear segments with a blunt tapered distal end. The passer is fenestrated at the tip, which allows the insertion of polypropylene sutures that were attached to both ends of the polypropylene tape [5].

Surgical technique

During induction of anesthesia (spinal) and positioning of the patient (lithotomy position with thighs in hyperflexion), the STM was prepared. A third-generation cephalosporin was administered before the procedure. A Foley catheter was inserted. Submucosal saline injection was done (hydrodissection) to elevate the vaginal mucosa easing the dissection. The technique was done similar to that originally described by de Leval [4] with some modifications. When the pointed tip of the passer appeared at the skin exit points (or alternatively, the skin was incised over the pointed tip of the passer), the polypropylene sutures were extracted from the passer. The passer was then removed by a backward rotational movement. The same technique was applied to the other side. The tape was then adjusted by simultaneously pulling on the polypropylene sutures on both sides without twisting. Tension was controlled by passing a clamp between the tape and the urethra. In order to prevent migration of the tape, the polypropylene sutures attached to both ends of the tape were passed through a French eye needle and then fixed to the deep fascia at the exit points in the groin by stitches (Fig. 2). The anterior vaginal wall was closed by interrupted absorbable 3-0 sutures.

Fig. 1 Flowchart of participants through each stage of the study. *STM* surgeon-tailored polypropylene mesh, *SUIQQ* Stress and Urge Incontinence and Quality of Life Questionnaire, *TVT-O* tension-free vaginal tape inside-out

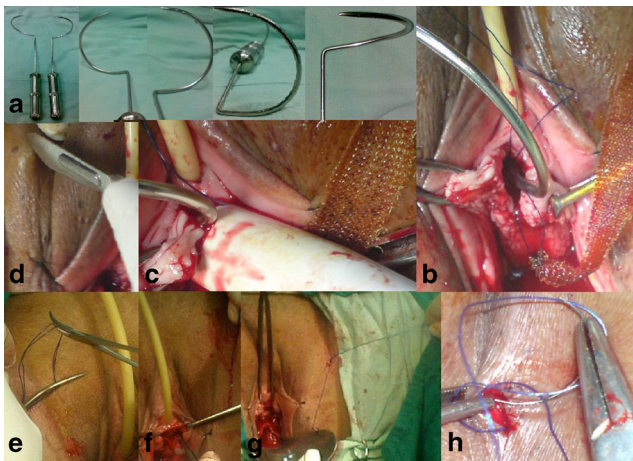
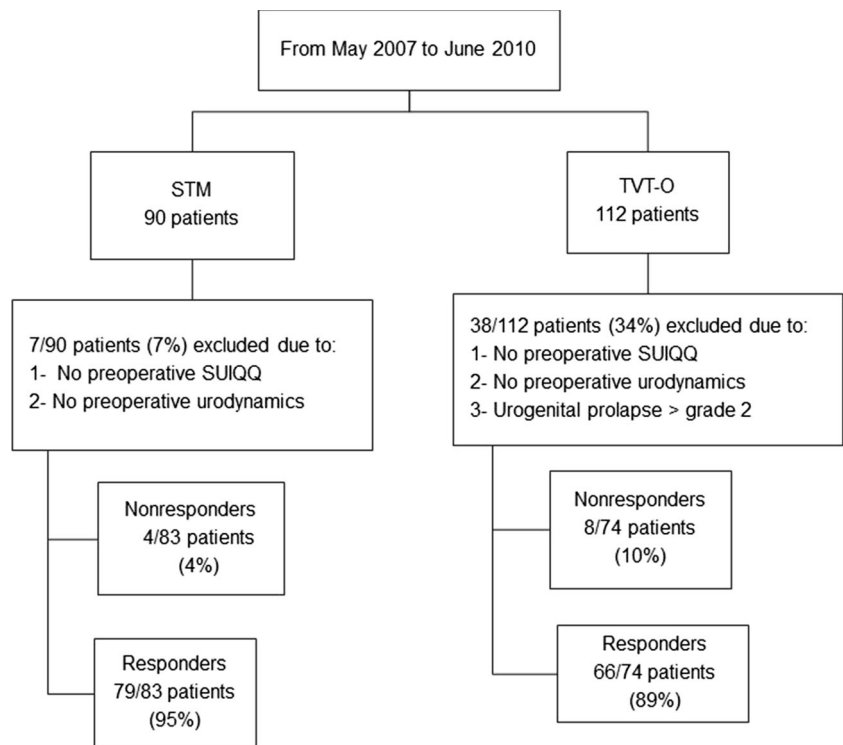


Fig. 2 The STM as a TVT-O. **a** Our specifically designed helical passers. **b** The STM is anchored with a zero polypropylene suture at each end in a figure-of-eight fashion. The polypropylene suture is then inserted into the eye at the end of the passer. **c** The helical passer is introduced into the previously dissected paraurethral space similar to the original TVT-O technique. **d** The skin is incised over the pointed tip of the passer. **e** The polypropylene suture is extracted from the passer after its passage through the exit points. The passer is then removed by a backward rotational movement. **f** The tape is then adjusted by simultaneously pulling on the polypropylene sutures on both sides without twisting. **g** In order to prevent migration of the tape, the polypropylene sutures attached to both ends of the tape are passed through a French eye needle and then fixed to the deep fascia at the exit points in the groin by stitches. Tension is controlled by passing a clamp between the tape and the urethra. **h** Closure of subcutaneous tissue

The second group of patients was treated with the inside-out transobturator tension-free vaginal tape (TVT-O) (Ethicon Inc., Somerville, NJ, USA) using the original technique [4].

Cystoscopy was performed in all cases in both groups to detect any possible injury. The urethral catheter was removed after 12 h. PVRU was evaluated by voiding trial and US. If PVRU exceeded 100 ml, the patient was discharged with indwelling catheter for 2 days and then reevaluated again. If associated prolapse surgery was done, the urethral catheter was maintained to the second postoperative day. The patients were followed up every 2 weeks for two visits and then every 6 months.

Assessment

After approval of the study by the Local Ethics Committee, these patients received a telephone call asking them to come for assessment of the 5-year outcome. An informed consent was taken from the responding patients (79 STM and 66 TVT-O) (Fig. 1). The operative reports and follow-up data were reviewed to record intraoperative and postoperative complications. Responding patients were evaluated by SUIQQ, examination, and Q_{max} . Cystometry with evaluation of ALPP was done for patients with persistent SUI.

Patients were considered cured if no leakage (during stress) was reported by symptoms and CST. If SUI was still present but milder (improved SUIQQ and ALPP) than preoperatively, the patients were considered improved. If SUIQQ or ALPP

were the same or worse than before surgery, the condition was reported as a failure.

Statistical analysis

All statistical calculations were done using the computer program SPSS (SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows. Comparison of quantitative variables between baseline and the 5-year follow-up was done with the paired *t* test (if normally distributed) or with the Wilcoxon signed rank test (if not normally distributed). Comparison of dichotomous variables was done with the McNemar test. Comparison of study groups was done using the chi-square (χ^2) test, Fischer's exact test, *t* test, or Mann–Whitney test as appropriate. A probability value (*p* value) < 0.05 was considered statistically significant.

Results

The perioperative data are presented in Tables 1 and 2. The two groups were nearly comparable without significant differences in menopausal status, previous surgeries, ALPP, presence of ISD or DO, presence of urgency or UUI, associated prolapse, associated prolapse repair, operative bleeding, and follow-up period, but patients in the STM group were older in age with significantly longer symptomatic periods and more frequent vaginal deliveries (Tables 1 and 2).

The operative duration was longer in the STM group by about 10 min (Table 1). No significant difference was found in the operative and postoperative complications. Postoperative vaginal discharge was treated with oral antibiotics, local metronidazole, and local antiseptics. The single case with urinary retention was catheterized for 2 days followed by relief of symptoms. The postoperative groin pain was treated by analgesics in both groups. It persisted for a few days in most patients, and disappeared completely within 4 weeks in all patients. We had no cases of erosions or mesh exposure (Table 1). The polypropylene sutures had been cut accidentally in two (2 %) patients in the STM group during extraction of the sutures outside the helical passer after its passage through the skin at the thigh folds. Withdrawal of the passer and reinsertion of new sutures into the end of the tape and reintroduction of the passer into the obturator canal again was then mandatory at this side. This prolonged the total operative time. The polypropylene sutures were felt subcutaneously in four (5 %) patients in the STM group with mild discomfort. There was no significant difference between both groups in cure, improvement, and failure rates (*p* = 0.654). Of the patients, 74 (93 %) were cured and 3 (4 %) improved, while SUI persisted in 2 (2 %) patients in the STM group; 59 (89 %) patients were cured, 4 (6 %) improved, and failure was detected in 3 (4 %) patients in the TVT-O group. The presence of

ISD, urgency, UUI, previous surgeries, associated urogenital prolapse, or associated urogenital prolapse repair did not lead to any significant difference in the outcome between both groups (Table 2).

The SUI, UUI, and QOL indices were significantly improved postoperatively in each group (Table 3). There was no significant difference between both groups in the postoperative SUI and QOL indices, although they were significantly worse preoperatively in the STM group (Table 3). There was no significant difference between both groups in UUI index and Q_{\max} either preoperatively or postoperatively (Table 3). Comparison between pre- and postoperative Q_{\max} showed no significant difference in the STM group, but it was significantly lower postoperatively in the TVT-O group, but not clinically significant as the difference was only 1 ml/s (Table 3).

Both groups showed significant postoperative improvement in the patients suffering from preoperative urgency or MUI (Table 3). Patients with persistent urgency or UUI had no obstructive symptoms or significant residual urine postoperatively. No postoperative de novo urgency or de novo UUI were reported. The cost of the mesh decreased markedly from US\$500 (TVT-O) to US\$10 (STM).

Discussion

Synthetic slings have increasingly been used in the form of commercially available kits for the treatment of female SUI with high efficacy [1–4, 8]. However, their cost-effectiveness has been questioned [9–11]. Many surgeons have used off-the-shelf polypropylene mesh and tailored it to overcome this cost [9–12]. This is very important in developing countries. The safety and efficacy of STM have been proven when used as a transobturator tape [10–12]. We developed our technique to decrease the cost of TVT-O using our modified helical passers to insert STM with acceptable safety and efficacy [5]. One study compared STM as TVT-O versus TVT [13]. The present study may be the first one that compares STM versus TVT-O.

Chen and colleagues used their modified helical needles to insert the 1 × 15 cm STM (Gynemesh) as TVT-O in 80 patients [12]. The mean operative time was 15 min (range 6–22). After 1 year of follow-up, the cure rate was 93.8 % and improvement was 6.2 % with no failure. Recatheterization was performed for 48 h in 3.8 % of patients due to urinary retention. Groin pain was reported by 15 patients (18.8 %) but relieved in all patients during the first postoperative month [12]. We had comparable results, but our operative time was longer by 10 min when compared to this study or other studies using the classic outside-in (TOT) or TVT-O techniques. Many factors prolonged our technique including the extraction of the polypropylene sutures out of the helical passers after their passage through the exit points, the bilateral fixation of these sutures

Table 1 Perioperative data

Variable	STM (79 patients)	TVT-O (66 patients)	<i>p</i> value
Age, years, mean \pm SD (range)	48.16 \pm 7.61 (31–65)	45.08 \pm 4.94 (33–56)	0.004 ^a
Parity, median (range)	4 (2–8)	3 (0–6)	0.007 ^a
Vaginal deliveries, median (range)	3 (0–8)	3 (0–6)	0.012 ^a
Premenopausal patients	33/79 (41 %)	34/66 (51 %)	0.241
Postmenopausal patients	46/79 (58 %)	32/66 (48 %)	
SUI duration, years, median (range)	6 (1–17)	3 (1–13)	<0.001 ^a
DO ^b	4/79 (5 %)	4/66 (6 %)	1
Preoperative UTI	6/79 (7 %)	5/66 (7 %)	0.997
ALPP, cmH ₂ O, median (range)	58 (20–120)	80 (30–120)	0.142
Cystocele	47/79 (59 %)	36/66 (54 %)	0.673
Grade 1	32/79 (40 %)	22/66 (33 %)	
Grade 2	15/79 (19 %)	14/66 (21 %)	
Rectocele	34/79 (43 %)	20/66 (30 %)	0.271
Grade 1	17/79 (21 %)	11/66 (16 %)	
Grade 2	17/79 (21 %)	9/66 (13 %)	
Uterine prolapse	4/79 (5 %)	7/66 (10 %)	0.228
Prolapse (total)	49/79 (62 %)	37/66 (56 %)	0.467
Operative time for tape insertion, min, median (range)	25 (15–35)	15 (9–22)	<0.001 ^a
Blood loss, ml, median (range)	40 (15–100)	45 (15–70)	0.056
Follow-up, months, mean \pm SD (range)	55.34 \pm 7.32 (48–72)	55.28 \pm 6.65 (48–71)	0.64
Complications			0.462
Vaginal discharge	4/79 (5 %)	3/66 (4 %)	1
Dyspareunia	1/79 (1 %)	1/66 (1 %)	1
UTI	2/79 (2 %)	3/66 (4 %)	0.660
Voiding difficulties	1/79 (1 %)	1/66 (1 %)	1
Groin pain	12/79 (15 %)	9/66 (13 %)	0.791
Retention of urine	0	1/66 (1 %)	0.455
Felt suture	4/79 (5 %)	0	0.126
Suture cut	2/79 (2 %)	0	0.501

ALPP abdominal leak point pressure, DO detrusor overactivity, SUI stress urinary incontinence, STM surgeon-tailored polypropylene mesh, TVT-O tension-free vaginal tape-inside out, UTI urinary tract infection

^aStatistically significant

^bThe involuntary contractions were mild (not exceeding 20 cmH₂O)

into the deep fascia at the exit points, and covering these nonabsorbable sutures with subcutaneous tissue. About 4 min or less were needed for STM tailoring with anchoring of polypropylene sutures into each end of the tape. This duration was not added to the operative time as preparation of the tape was done during positioning and induction of anesthesia.

Elgamasy and colleagues reported their early experience in the use of traditional polypropylene mesh (Vypro II) as TOT in 40 patients with a mean follow-up of 16.7 \pm 3.6 months. Associated prolapse repair was performed in 30 % of patients. The mean operative time was 40 min (30–50). The reported cure, improvement, and failure rates were 87.5, 5, and 7.5 %, respectively. Complications were remarkable bleeding (>200 ml) (5 %), early postoperative voiding difficulty (12.5 %), persistent voiding difficulty (5 %), vaginal

infections (10 %), dyspareunia (15 %), and mesh exposure with removal of the slings (7.5 %). Comparisons between preoperative and postoperative SUI and QOL scores together with Q_{max} showed significant decrease [11]. We had a comparable cure with fewer complications. We did not detect any case with mesh exposure, persistent voiding difficulty, remarkable bleeding, or need for removal of the sling. The Q_{max} showed significant decrease in the TVT-O group only (not STM) but this was not clinically significant. Similar to our study, Elgamasy and colleagues reported significant improvement in patients with preoperative MUI. It was cured in 10/13 patients (76.9 %). However, they reported 11.1 % de novo DO (3/27 patients) [11]. The overall cure of urgency and UII component in different studies on midurethral slings for the treatment of MUI was 30–85 % [14].

Table 2 Effect of ISD, associated urgency and UUI, previous surgeries, associated urogenital prolapse, and associated prolapse repair on the success rate

		No. of patients (%)	<i>p</i> value	Cure	I	F	<i>P</i> value
ISD	STM	42/79 (62 %)	0.061	38/42 (90 %)	2/42 (4 %)	2/42 (4 %)	0.274
	TVT-O	25/66 (37 %)		19/24 (76 %)	3/24 (12 %)	3/24 (12 %)	
Associated urgency	STM	43/79 (54 %)	0.866	41/43 (95 %)	1/43 (2 %)	1/43 (2 %)	0.453
	TVT-O	35/66 (53 %)		31/35 (88 %)	3/35 (8 %)	1/35 (3 %)	
Associated UUI (MUI)	STM	39/79 (49 %)	0.66	37/39 (95 %)	1/39 (2 %)	1/39 (2 %)	0.518
	TVT-O	35/66 (53 %)		31/35 (88 %)	3/35 (8 %)	1/35 (3 %)	
Surgical history (prolapse repair, surgery for SUI, or hysterectomy)	STM	8/79 (10 %)	0.361	6/8 (75 %)	1/8 (12 %)	1/8 (12 %)	0.498
	TVT-O	10/66 (15 %)		9/10 (90 %)	1/10 (10 %)	0	
Associated urogenital prolapse	STM	49/79 (62 %)	0.467	46/49 (94 %)	1/49 (2 %)	2/49 (4 %)	0.211
	TVT-O	37/66 (56 %)		31/37 (84 %)	4/37 (10 %)	2/37 (5 %)	
Associated cystocele	STM	47/79 (59 %)	0.673	44/47 (93 %)	1/47 (2 %)	2/47 (4 %)	0.218
	TVT-O	36/66 (54 %)		30/36 (83 %)	4/36 (11 %)	2/36 (5 %)	
Associated prolapse repair (anterior and/or posterior colporrhaphy)	STM	11/79 (14 %)	0.247	9/11 (81 %)	1/11 (9 %)	1/11 (9 %)	0.916
	TVT-O	14/66 (21 %)		11/14 (78 %)	1/14 (7 %)	2/14 (14 %)	

F failure, *I* improvement, *ISD* intrinsic sphincter deficiency, *MUI* mixed urinary incontinence, *STM* surgeon-tailored polypropylene mesh, *SUI* stress urinary incontinence, *TVT-O* tension-free vaginal tape-inside out, *UUI* urgency urinary incontinence

In a comparative study, Chen and colleagues randomized 150 women for modified TVT-O (95 patients) or TVT (55 patients) [13]. Their own self-designed helical needles were used with the same previously mentioned STM (Gynemesh) [12]. At 1 year postoperatively, the success rate was 94 % in TVT (80 % cure and 14 % improvement) and 95 % in STM

(87 % cure and 8 % improvement) with significant improvement in QOL but without any significant difference between both groups. The reported complications were bladder injuries (5 % in TVT), urinary retention (21 % in TVT and 8 % in STM), vaginal perforation (3 % in TVT and 2 % in STM), de novo urgency (10 % in each group), mesh exposure (2 % in

Table 3 The preoperative and postoperative scores according to SUIQQ, flow rates, urgency, and UUI

		STM	TVT-O	<i>p</i> value
SUI index	Preoperative	8.84±2.36 (4–12)	6.21±1.75 (4–10)	<0.001 ^a
	Postoperative	0.46±1.9 (0–11) <i>p</i> <0.001 ^a	0.65±2 (0–9) <i>p</i> <0.001 ^a	0.164
UUI index	Preoperative	2.62±2.83 (0–8)	2.27±2.37 (0–8)	0.367
	Postoperative	0.91±1.37 (0–6) <i>p</i> <0.001 ^a	1.03±1.75 (0–8) <i>p</i> <0.001 ^a	0.908
QOL index	Preoperative	6.14±2.32 (2–11)	5.02±2.06 (1–11)	0.005 ^a
	Postoperative	1.06±1.59 (0–6) <i>p</i> <0.001 ^a	1.42±2.36 (0–11) <i>p</i> <0.001 ^a	0.814
Q _{max} (ml/sec)	Preoperative	27.27±7.01 (12–41)	27.62±6.6 (13–40)	0.814
	Postoperative	27.24±5.87 (15–43) <i>p</i> =0.434	26.33±6.84 (12–38) <i>p</i> <0.001 ^a	0.619
Urgency	Preoperative	43/79 (54 %)	35/66 (53 %)	0.866
	Postoperative	27/79 (34 %) <i>p</i> <0.001 ^a	24/66 (36 %) <i>p</i> =0.001 ^a	0.784
UUI	Preoperative	39/79 (49 %)	35/66 (53 %)	0.66
	Postoperative	25/79 (31 %) <i>p</i> <0.001 ^a	23/66 (35 %) <i>p</i> <0.001 ^a	0.683

Values are presented as mean ± SD (range) or number of patients (%)

Q_{max} maximum flow rate, QOL quality of life, STM surgeon-tailored polypropylene mesh, SUI stress urinary incontinence, SUIQQ Stress and Urge Incontinence and Quality of Life Questionnaire, TVT-O tension-free vaginal tape-inside out, UUI urgency urinary incontinence

^a Significant

TVT and 1 % in STM), and postoperative pain (23 % in each group). The operative duration (45 ± 5 min in TVT versus 16 ± 9 min in STM), blood loss, and surgical cost were significantly reduced in the STM group compared with those in the TVT group [13]. Again, we had comparable cure with fewer complications in our study.

Our technique was also economical as it reduces the material cost from US\$500 to about US\$10. Furthermore, our modified helical passers were used for all STM cases as they are resterilizable instruments. Thus, they did not add to the treatment expenses. These advantages are very important in developing countries due to limited health care resources.

Lathe and colleagues reviewed the randomized controlled trials (RCT) that compared TVT-O (20 RCT) or TOT (18 RCT) versus TVT and 4 direct RCT of TVT-O vs TOT [15, 16]. The reported complications were groin and thigh pain (15.7 %), vaginal erosions (1 %), vaginal perforation (2.9 %), bladder perforation (0.09 %), voiding difficulties (3.6–5.5 %), and de novo urgency (8.9–18.3 %). The reported cure rates were from 78.7 to 95.4 %, while the mean operative time ranged from 16 to 29 min. Our results were nearly similar to these studies. On the other hand, we had other mild complications related to our modified technique. The figure-of-eight polypropylene sutures at the end of the tape were cut accidentally in two patients. This prolonged the total operative time. The polypropylene sutures were felt subcutaneously in four patients with mild discomfort.

Our study has some limitations, mainly because of nonrandom method of patient selection and the dual-center design with different surgeons. However, we do not think this caused bias because the two groups were similar when different parameters were compared preoperatively (Tables 1 and 2). However, the strengths of this study include that it is a cohort study on a good number of patients with uniform SUI, UI, and QOL assessment using validated standardized questionnaires and the use of urodynamic parameters to objectively evaluate the severity of incontinence and any associated DO. Another good point is that we used broader inclusion criteria that allowed patients with MUI and preoperative DO or urogenital prolapse to be included as these criteria are faced in daily practice. Despite reporting good results in the present study, further randomized controlled studies are needed to confirm these results.

Conclusions

This cohort study suggests that the 5-year objective and subjective outcomes of patients treated with STM are comparable to those treated with TVT-O. These results are also comparable with the results of TVT-O that were reported in the literature. Thus, this technique is a simple, safe, efficacious, and reproducible surgical procedure for the treatment of SUI.

Furthermore, this technique is more economical due to our resterilizable modified helical passers and the cheap ordinary polypropylene mesh. So, it 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 are needed to confirm our results.

Conflicts of interest None.

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Authors' contributions M. ElSheemy: protocol development, data collection and analysis, manuscript writing/editing. H. Fathy: protocol development, data collection. A. Hussein: protocol development, data collection. R. ElSergany: protocol development, manuscript editing. E. Hussein: protocol development, data collection.

References

1. Ulmsten U, Henriksson L, Johnson P, Varhos G (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 7(2):81–85
2. Boustead GB (2002) The tension-free vaginal tape for treating female stress urinary incontinence. *BJU Int* 89(7):687–693
3. Delorme E (2001) Transobturator urethral suspension: minimally-invasive procedure in the treatment of stress incontinence in women. *Prog Urol* 11(6):1306–1313
4. de Leval J (2003) Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol* 44:724–730
5. ElSheemy MS, Elsergany R, ElShenoufy A (2015) Low-cost transobturator vaginal tape inside-out procedure for the treatment of female stress urinary incontinence using ordinary polypropylene mesh. *Int Urogynecol J* 26:577–584
6. Kulseng-Hanssen S, Borstad E (2003) The development of a questionnaire to measure the severity of symptoms and the quality of life before and after surgery for stress incontinence. *BJOG* 110(11):983–988
7. Baden WF, Walker TA (1992) Fundamentals, symptoms, and classification. In: Baden WF, Walker T (eds) *Surgical repair of vaginal defects*. Lippincott, Philadelphia, pp 1–23
8. Novara G, Galfano A, Boscolo-Berto R et al (2008) Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. *Eur Urol* 53(2):288–308
9. Patel BN, Smith JJ, Badlani GH (2009) Minimizing the cost of surgical correction of stress urinary incontinence and prolapse. *Urology* 74(4):762–764
10. Shah DK, Paul EM, Amukele S, Eisenberg ER, Badlani GH (2003) Broad based tension-free synthetic sling for stress urinary incontinence: 5-year outcome. *J Urol* 170(3):849–851
11. Elgamasy AK, Elashry OM, Elenin MA, Eltaway HH, Elsharaby MD (2008) The use of polypropylene mesh as a transobturator sling for the treatment of female stress urinary incontinence (early experience with 40 cases). *Int Urogynecol J Pelvic Floor Dysfunct* 19(6):833–838

12. Chen X, Li H, Fan B, Yang X, Tong X (2009) An inexpensive modified transobturator vaginal tape inside-out procedure for the surgical treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 20(11):1365–1368
13. Chen X, Tong X, Jiang M et al (2011) A modified inexpensive transobturator vaginal tape inside-out procedure versus tension-free vaginal tape for the treatment of SUI: a prospective comparative study. *Arch Gynecol Obstet* 284(6):1461–1466
14. Jain P, Jirschele K, Botros SM, Latthe PM (2011) Effectiveness of midurethral slings in mixed urinary incontinence: a systematic review and meta-analysis. *Int Urogynecol J* 22(8):923–932
15. Latthe PM, Foon R, Tooze-Hobson P (2007) Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. *BJOG* 114(5):522–531
16. Latthe PM, Singh P, Foon R, Tooze-Hobson P (2010) Two routes of transobturator tape procedures in stress urinary incontinence: a meta-analysis with direct and indirect comparison of randomized trials. *BJU Int* 106(1):68–76