

# Short-term outcomes of mini-sling *versus* transobturator tape in the surgical management of women with stress urinary incontinence. A randomized controlled trial

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## Abstract

The objective of this prospective randomized study was to assess the efficacy and safety of mini-sling in the management of female stress urinary incontinence (SUI) as compared to transobturator tape (TOT). A total of 42 female patients with SUI were included in this study. Patients were randomized into two equal

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groups, underwent either the TOT or the mini-sling procedure, and were followed up for 6 months. Compared to the TOT group, the mini-sling group had a statistically significant shorter operative time, less estimated blood loss, and a lower postoperative pain score. There was no statistically significant difference between both groups as regards postoperative fever, hospital stay, or vaginal erosion. The International Continence Index questionnaire showed a statistically significant improvement within each group after surgery, with the TOT group showing a statistically significant marginal improvement compared to the mini-sling group. Urodynamic testing showed no statistically significant difference between both groups regarding the first sensation of bladder filling, functional bladder capacity, maximal bladder capacity, postvoiding residual urine, and maximal flow rate. Both mini-slings and TOT were found to be safe and effective in treating female SUI with no clinically significant difference between both procedures.

## Introduction

Stress urinary incontinence (SUI) is a prevalent problem that impacts women's quality of life. It is defined by the International Continence Society as the involuntary loss of urine on effort, physical exertion, coughing, or sneezing.<sup>1</sup> The estimated prevalence for SUI is 24-45% in women over 30 years.<sup>2</sup> Diabetes, pregnancy, childbirth, and a higher body mass index (BMI) have been associated with an increased incidence of urinary incontinence.<sup>3</sup>

According to the prevailing theory, SUI is caused by a combination of weakening of the pelvic floor, bladder neck, and urethral sphincter muscles, as well as disruption of their supportive connective tissues. This lowers the urethral closure pressure and abdominal leak point pressure. Urethral hypermobility, which is associated with impaired anatomical support of the bladder neck and proximal urethra, is hypothesized to interfere with the transfer of pressure to the urethra, resulting in a reduction in extrinsic closure force, and eventually urine leakage.<sup>4</sup>

Both nonsurgical (*e.g.*, lifestyle adjustments, weight loss, Kegel exercises, vaginal pessaries or cones, and medications) in addition to surgical options are available.<sup>5</sup> The transobturator mid-urethral tape (TOT) was developed to reduce the prevalence of bladder, bowel, and major vascular injuries associated with traditional retropubic tapes.<sup>6</sup> Mid-urethral slings are currently the gold standard for the treatment of SUI in women.<sup>7</sup> A new generation of tapes known as single incision tapes or mini-slings was introduced in an effort to maintain the effectiveness of the treatment while minimizing the risk of some of the unintended side effects. Since only a single vaginal incision is made and a short tape is used that does not pass through the retropubic or obturator spaces, there is a significantly reduced risk of nerve or vessel injury as well as groin pain.<sup>7,8</sup> Clinical trials have demonstrated the safety and efficacy of

multi-incision slings, with a success rate of 70-80% in one year. Mini-slings' efficacy and safety for female SUI have not been adequately studied. Currently, it is uncertain how safe and successful mini-slings are for treating SUI in comparison to multi-incision slings.<sup>9</sup> The purpose of this research was to assess the safety and efficacy of mini-sling in the management of SUI in women as compared to TOT.

## Materials and Methods

After obtaining institutional ethical approval, this prospective randomized controlled study was conducted on 42 female patients with SUI or mixed urine incontinence, in which SUI was the dominant symptom and confirmed by a positive cough test. Patients were randomized into two equal groups and underwent either TOT or mini-sling between March 2021 and March 2023 (Figure 1). Women were not eligible for the study if they were older than 60 years old, were pregnant or planning to become pregnant, had previously undergone surgery for incontinence or pelvic organ prolapse (POP), had previously undergone pelvic irradiation, were receiving treatment with corticoids, had over 100 mL of postvoiding residual urine volume (PVRU), suffered from neurological conditions, for instance, multiple sclerosis, or had a history of genital, abdominal or pelvic cancer.

A comprehensive medical history was obtained, and a general and local pelvic examination was undertaken, including the presence and degree of any POP. Two expert surgeons performed the surgical procedures outlined below using DynaMesh® (Aachen, Germany) for the mini-sling and TOT. DynaMesh is made from polyvinylidene fluoride monofilament. All DynaMesh® implants are directly knitted and not cut from a flat mesh with a pore size of about 1.1 mm.<sup>10</sup>

### Preoperative assessment

Preoperatively, all women were assessed for the presentation, duration, and severity of SUI through the International Consultation on Incontinence Questionnaire (ICIQ): the patient was asked about the type of urinary incontinence, how often the urine leaks, how much urine leaks, and how much the leaking urine interferes with daily life. With the Female Sexual Function Index (FSFI), the patient was asked about arousal, desire, lubrication, orgasm, satisfaction, and pain. Besides, patients were evaluated for associated genitourinary or neurological conditions and bowel habits. General medical, obstetric, and gynecological histories were evaluated as well. All women underwent routine physical examination and preoperative laboratory assessment, including

complete blood count, liver and renal functions, bleeding profile, and urine culture. Abdominopelvic ultrasonography was performed for all women to assess postvoid residual urine. All patients underwent urodynamic testing preoperatively for study purposes.

### Interventions

In both groups, patients received prophylactic antibiotics 1 hour before the procedure (1 gm 3rd-generation cephalosporin intravenously). Foley's catheter (16 Fr) was inserted while the patient was in the lithotomy position and under spinal anesthesia. Labia were retraced using a 3.0 silk stay suture. The anterior vaginal wall was suspended with Allis clamps placed on either side of the midline, and hydrodissection of the vaginal mucosa was performed. The vaginal wall was incised 1 cm below the urethral meatus and 1 cm along the sagittal line.

As far as the surgical technique of mini-sling is concerned, the self-fixating mini-sling's tip was attached to a narrow mesh carrier, specifically made for introducing the device. The tip of the mesh was inserted into the obturator internus muscle after the tool and mesh were passed into the vagina. After that, the device was taken out, and the mesh was fixed to the muscle. The steps were repeated on the opposite side. Once the installation was finished, the mesh lay like a hammock beneath the urethra. The vaginal incisions were closed with an interrupted 3-0 Vicryl suture. The urethral

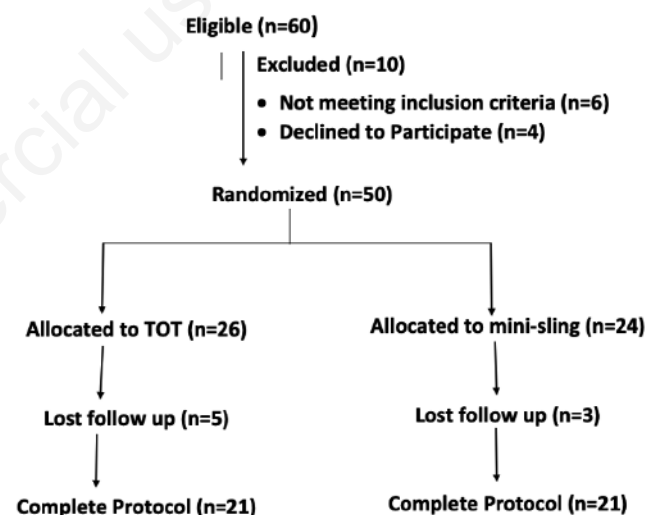


Figure 1. Consort flow diagram. TOT, transobturator tape.

Table 1. Characteristics of the patients.

		TOT group (n=21)	Mini-sling group (n=21)	p
Age (years)	Mean ± SD	48.05±5.43	47.19±5.16	0.603
	Median (IQR)	49 (44-52)	46 (44-51)	
	Range	38-58	35-55	
Parity	Mean ± SD	3.76±1.41	3.86±1.28	0.82
	Median (IQR)	4 (3-4)	4 (3-4)	
	Range	1-7	2-8	
BMI (kg/m <sup>2</sup> )	Mean ± SD	26.88±2.12	26.05±1.82	0.182
	Median (IQR)	26.8 (25.4-27.8)	25.8 (25.1-27.1)	
	Range	23-30.2	22.8-31.1	
Diabetes mellitus	Number (%)	3 (14)	4 (19)	0.5

SD, standard deviation; IQR, interquartile range; BMI, body mass index; TOT, transobturator tape.

catheter was attached to closed-bag drainage, and the vagina was packed with a povidone-iodine-soaked pack.

For what concerns the surgical technique of TOT, using Mayo scissors, the vagina was freed on both sides of the urethra over about 15 mm breadth, ending at the ischiopubic ramus. At the intersection of two lines (the horizontal one going by the clitoris and the vertical one representing the thigh crease), a puncture incision was performed. The needle was inserted into the skin incision until it penetrated the obturator membrane. Subsequently, the needle was rotated to a horizontal orientation, whereby the handle was directed towards the medial aspect. Steering the needle along the ischiopubic ramus while keeping constant contact with it was the safest method. The same steps were repeated on the other side, with the tape being gently inserted behind the urethra without any tension, producing a small gap between the tape and the urethra, measuring a few millimeters. This was achieved by inserting a mayo scissor between the tape and the urethra. A 3-0 vicryl suture was used to close the skin and vaginal incisions in subcuticular and interrupted fashions, respectively. The vagina was packed with a povidone-iodine-soaked pack, and the urethral catheter was connected to closed-bag drainage.

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

### Postoperative assessment

A negative cough-stress test was defined as the absence of urine leakage in the supine and standing positions with a 300-mL saline-filled bladder. In addition, the procedures were compared regarding operative time, complications, and postoperative pain. Surgery failure was defined as the need for a second procedure for either persistent symptomatic SUI or management of complications, including complete removal of the initial mesh. Postoperative pain was measured by the Numerical Rating Scale (NRS). Intraoperative blood loss was calculated using blood in the suction device and 30 cc per blood-soaked gauze. ICIQ, FSFI, and a postoperative urodynamic study were repeated at the 6-month appointment.

## Results

There was no statistically significant difference between both groups as regards age, BMI, parity, and diabetes mellitus (Table 1), and none of our cases had POP.

Compared to the TOT group, the mini-sling group had a statistically significant shorter operative time (7 *versus* 12 minutes,  $p < 0.001$ ), less estimated blood loss (EBL) (12 *versus* 60 mL,  $p < 0.001$ ), and a lower postoperative pain score (3 *versus* 4,  $p = 0.001$ ). Meanwhile, there was no statistically significant difference between both groups as regards postoperative fever, hospital stay, or vaginal erosion (Table 2). Concerning early complications, re-catheterization was not needed in any patient as there was no urinary retention. Postoperative wound infection was not found in any case.

ICIQ showed a statistically significant improvement of continence within each group after surgery, with the TOT group showing a statistically significant marginal improvement compared to the mini-sling group. Meanwhile, there was no statistically significant change in FSFI within each group or between both groups (Table 3).

There was no statistically significant difference in Valsalva leak point pressure between the TOT and the mini-sling groups before surgery (73±25 *versus* 79±27 cm H<sub>2</sub>O, respectively,  $p = 0.46$ ). Also, urodynamic testing showed no statistically significant difference within each group before or after surgery or between both groups with regard to the first sensation of bladder filling, functional bladder capacity, maximal bladder capacity, PVRU, and maximal flow rate (Q<sub>max</sub>) (Table 4).

## Discussion

Urinary incontinence is a major problem that impacts the different financial, social, and private aspects of a woman's life. Over the years, several surgical procedures have been performed, such as urethral bulking agents, bladder neck suspension, anterior vaginal wall repair, autologous sling, and mesh tapes. Due to their high success rates, mid-urethral slings are considered the first surgical option. With an 80% success rate, this minimally invasive procedure has a very low risk of recurrent symptoms and urinary dysfunction.<sup>11</sup>

**Table 2.** Perioperative data.

		TOT group (n=21)	Mini-sling group (n=21)	p
Operative time (min)	Mean ± SD	11.9±4.23	6.95±1.4	<0.001
	Median (IQR)	12 (10-14)	7 (6-8)	
	Range	5-21	4-10	
Estimated blood loss (mL)	Mean ± SD	59.52±47.27	12.14±6.04	<0.001
	Median (IQR)	50 (30-70)	10 (10-15)	
	Range	10-200	5-30	
Numerical rating pain score	Mean ± SD	4.1±1.64	2.57±0.93	0.001
	Median (IQR)	4 (3-6)	3 (2-3)	
	Range	2-6	1-5	
Postoperative fever (>37.8 C), n (%)		4 (19.05)	1 (4.76)	0.153
Hospital stay (days)	Mean ± SD	1.48±0.68	1.19±0.4	0.107
	Median (IQR)	1 (1-2)	1 (1-1)	
	Range	1-3	1-2	
Vaginal erosion	Number (%)	1 (4.76)	0 (0.00)	0.311

SD, standard deviation; IQR, interquartile range; TOT, transobturator tape.

The severity of SUI has been evaluated using different methods. The number of daily pads used has shown issues related to variations in volume. While 1-hour pad tests are most suited for establishing an initial diagnosis, 24-hour pad weight tests are most often used to evaluate treatment outcomes.<sup>12</sup> However, these are cumbersome and require a high degree of patient compliance. In our study, SUI was assessed subjectively using ICIQ and objectively using a cough stress test. A good correlation between the ICIQ and the 24-hour pad test has been documented by other studies.<sup>13,14</sup> In our study, both TOT and mini-sling proved to be safe and effective in treating SUI. The subjective improvement (ICIQ score) was slightly higher after TOT than after mini-sling procedures. In agreement with our study, a systematic review and meta-analysis showed that mini-slings were associated with inferior subjective and objective (negative cough stress test) cure rates when compared to standard mid-urethral slings in the short-term follow-up.<sup>15</sup> However, at their midterm follow-up, there was no evidence

of significant differences in patient-reported and objective cure between both procedures in agreement with other studies.<sup>16-20</sup>

In this study, the mini-sling group had less EBL and shorter operative time compared with TOT, which is in agreement with similar studies.<sup>18,20</sup> Meanwhile, other studies observed only a shorter operative time with no difference in EBL.<sup>19,21</sup>

The most frequent complications associated with surgical mesh slings for SUI repair, in descending order of frequency, include pain, mesh erosion through the vagina (also known as extrusion or exposure), infection, urinary problems, recurrent SUI, dyspareunia, bleeding, organ perforation, and neuro-muscular problems.<sup>9</sup> In our study, the mini-sling group had lower postoperative pain scores as compared to the TOT group, in agreement with the findings of similar studies.<sup>17-20</sup> This may be attributed to the passage of trocars through adductor muscles and the presence of three incisions (two in the groin, one vaginal) in TOT, which is not present in mini-sling.<sup>17</sup> On the other hand, Chang *et al.* reported no

**Table 3.** Patient-reported functional outcomes.

		TOT group (n=21)		Mini-sling group (n=21)		p
		Before	After	Before	After	
ICIQ	Mean ± SD	13.2±2.59	8.8±2.04	12.81±2.78	8.79±2.05	<0.001
	Median (IQR)	13.2 (12-14.6)	9 (8-10.1)	13.2 (11.5-14.8)	8.7 (7.9-10.5)	
	Range	7.4-19.2	4.2-11.8	6.7-17.1	4-12	
	Change		-4.4		-4.02	
	p		<0.001		<0.001	
FSFI	Mean ± SD	49.38±12.88	52.51±11.93	50.82±13.14	53.95±13.09	0.677
	Median (IQR)	47.6 (41-57.7)	53.8 (48.9-56.7)	53.2 (42.2-61.7)	53.9 (45.1-61)	
	Range	27.1-73.9	28.9-78.7	23.4-72	18.2-73.7	
	Change	3.13	3.13			
	p	0.418	0.443			

SD, standard deviation; IQR, interquartile range; ICIQ, International Continence Index Questionnaire; FSFI, Female Sexual Function Index; TOT, transobturator tape.

**Table 4.** Urodynamic findings before and after surgery.

		TOT group (n=21)		Mini-sling group (n=21)		p
		Before	After	Before	After	
First sensation of bladder filling (mL)	Mean ± SD	187.1±47.42	178.94±48.06	174±47.86	187.75±47.72	0.748
	Median (IQR)	182 (156.6-222.9)	169.5 (148-210)	175.7 (136-191.9)	188.8 (155.7-231.8)	
	Range	105.4-261.6	87.7-312	66.1-294.9	84.3-281.3	
	Change		-8.16		13.75	
	p		0.583		0.357	
Functional bladder capacity (mL)	Mean ± SD	281.86±44.2	293.42±39.27	275.03±59.62	290.34 ±43.58	0.584
	Median (IQR)	280.6 (263-303.5)	301.5 (276.2-314)	277.4 (235.8-310.1)	307.8 (259.4-322.9)	
	Range	208.7-372.5	209.1-382.4	160.2-371.6	220.3-356	
	Change		11.56		15.31	
	p		0.375		0.347	
Maximal bladder capacity (mL)	Mean ± SD	359.4±43.2	369.02±32.21	348.49±50.49	369.18±39.56	0.332
	Median (IQR)	367.2 (312.5-388.1)	367.8 (349.6-392.3)	351.3 (328.9-384.1)	374.7 (348-393.1)	
	Range	295.5-435.8	296.4-441	231.1-430.7	263.7-427.6	
	Change		9.62		20.69	
	p		0.418		0.147	
PVRU (mL)	Mean ± SD	86.29±17.79	76.67±18.38	90.24±26.52	76.76±18.55	0.08
	Median (IQR)	86 (73-101)	78 (65-92)	85 (79-102)	79 (66-91)	
	Range	57-115	41-104	40-159	30-106	
	Change		-9.62		-13.48	
	p		0.09		0.06	
Qmax (mL/sec)	Mean ± SD	24.37±8.35	26.16±6.58	26.59±8.27	27.22±6.73	0.647
	Median (IQR)	26.8 (19.2-29)	25.6 (22.1-29.7)	25.3 (22.2-30.6)	28.2 (25.2-30.4)	
	Range	3.3-37.5	13.5-39.3	8.3-41	14.6-37.7	
	Change		1.79		0.63	
	p		0.444		0.788	

SD, standard deviation; IQR, interquartile range; TOT, transobturator tape; PVRU, postvoiding residual urine; Qmax, maximal flow rate.

significant difference in pain scores between the two procedures.<sup>21</sup>

Mesh exposure after vaginal sling procedures is a frustrating but uncommon complication. Similar to the study conducted by Kokanali *et al.*,<sup>22</sup> mesh exposure occurred in 1/21 (4.7%) of the TOT group in our study, but not in any cases in the mini-sling group. This difference was not statistically significant. Cases who were more than 60 years old, recurrent, had previously undergone pelvic irradiation, or were on corticoid therapy were initially excluded from both groups to avoid potential bias that may arise from previously identified risk factors associated with a higher chance of mesh erosion.<sup>22</sup> Similarly, Maturana *et al.* found no differences in the rates of tape vaginal erosion and postoperative fever between both groups.<sup>23</sup>

Also, there was no statistically significant change in the FSFI within each group or between both groups, which is in agreement with the findings of the studies done by Emami *et al.*,<sup>20</sup> and AbdelFattah *et al.*<sup>24</sup>

Urodynamic testing showed no statistically significant difference within each group before or after surgery or between both groups regarding first sensation of bladder filling, functional bladder capacity, maximal bladder capacity, PVRU, and Qmax. Similar results were obtained by other studies.<sup>20,25</sup>

The current study was limited by being a single-center study with a short-term follow-up. Further comparative studies with larger sample sizes and longer follow-ups are still needed.

## Conclusions

Both mini-slings and TOT were found to be safe and effective in treating female SUI. Mini-sling has the advantage of being less invasive with a shorter operative time, less EBL, and less postoperative pain.

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