

Role of Trans Obturator Tape (TOT) in the Treatment of Urinary Incontinence

Original Article *Ahmed Gamal Eldin Abd El-Raouf¹, Ahmed Fahim Abdelrahim¹, Ahmed Sabry Mohamed¹ and Mona Ragab²*

¹Department of Urology- Al-Azhar University

²Department of Obstetrics & Gynecology Al-Galaa Teaching Hospital

ABSTRACT

Aim: To evaluate the role of trans obturator tape (TOT) insertion in the treatment of women with mixed urinary incontinence using subjective and objective measures.

Patient and Methods: Included 25 female patients with mixed urinary incontinence with failure of response to medical treatment and other forms of conservative methods underwent trans obturator tape insertion (TOT) and followed until six months postoperative.

Results: TOT was successful in treatment of stress urinary incontinence, but 60% successful in treatment of urge incontinence 6 months post-operative.

Conclusion: TOT is an effective operation for the treatment of stress urinary incontinence; however, large studies with long term follow-up are needed to confirm that finding.

Key Words: Surgical treatment; trans obturator tape; urinary incontinence.

Received: 10 October 2022, **Accepted:** 17 October 2022

Corresponding Author: Mona Ragab, Department of Obstetrics & Gynecology Al-Galaa Teaching Hospital, Egypt, Tel.: +20 10 0603 2451 , E-mail: dr_manmona@yahoo.com

ISSN: 2090-7265, November 2022, Vol.12, No. 4

INTRODUCTION

Stress Urinary incontinence (SUI) is the commonest type of urinary incontinence in women, representing 86% of cases of incontinence women, which is either genuine (50%) or mixed stress and urge incontinence (36%). SUI is the complain of involuntary leakage of urine on sneezing, exertion, effort or coughing^[1].

Several operations for relieving SUI have been done mostly acting on stabilizing the urethra and/or the bladder neck. In 1996, Ulmsten suggested a new surgical technique called the tension-free vaginal tape (TVT) for treatment of SUI^[2], while Delorme (2001), developed the trans-obturator tape approach (TOT) aiming to decrease the adverse of the retropubic approach by avoiding the entry into the retropubic space^[3].

Women with mixed urinary incontinence can be difficult to manage. It is important to determine which component is more problematic in order to guide the treatment plan. Urodynamic studies are usually done before surgery in cases with mixed urinary incontinence (MUI), which often coexists. In patients without overactive bladder there is some data suggesting they have a higher probability of

resolution of their symptoms after a sling than those with urodynamic overactive bladder. In patients who complain mainly of stress incontinence, the Mid-urethral sling (MUS) improves urgency and urge urinary incontinence (UUI)^[4].

The mechanism of action of these sling is different from that of traditional slings that were usually placed under the bladder neck to elevate it according to the pressure transmission theory. Using tension-free or low-tension slings avoids backwards displacement of the bladder neck into the abdominal-pelvic pressure zone but rather replaces the defective pubo-urethral ligament. In addition, to the restoration of the defective connection between the urethra and vagina, thereby restoring the sub-urethral hammock^[5].

The aim of the present study is to evaluate the role of trans obturator tape (TOT) insertion in the treatment of women with mixed urinary incontinence.

PATIENTS AND METHODS

This study was carried out at Al-Azhar university hospitals and the national institute of urology and nephrology in the period from March to December

2018. The study included 25 cases with mixed urinary incontinence with failure of response to conservative management. All patients were assessed before surgery using the following scheme:

Clinical Assessment

1- A detailed history was taken including symptoms of urinary incontinence. Also, the data that was obtained by answering questions of intermountain healthcare organization incontinence questionnaire as well as the quality of life questionnaire.

2-Physical examination:

- a. Abdominal examination for masses, hernia or distended bladder.
- b. Pelvic examination.
- c. Cough stress test.
- d. Assessment of the presence of prolapse whether vaginal or uterine.

Voiding Diary

3 days voiding diary.

Laboratory investigations

- Urine analysis, culture and sensitivity if needed.
- Routine pre-operative laboratory investigations, (CBC, Blood sugar, Creatinine)

Imaging Studies

All patients were assessed by abdominal-pelvic ultrasonography to evaluate the upper urinary tract and estimation of post-void residual urine.

Urodynamic examination

- Uroflowmetry.
- Filling cystometry.
- Pressure flow study.

Exclusion criteria included the following

1. Detrusor under-activity.
2. Detrusor over-activity.

3. Obstructed flow.
4. Significant post-void residual urine more than 100 cc.
5. Central or peripheral neurological pathology.
6. Presence of other gynecological pathology that needs hysterectomy.
7. Pregnancy.

All patients were admitted 1 day before operation. Informed consent was taken from all patients before operation. T.O.T. set (obtryx, boston company located in Boston, U.S.A.) which was used in all procedures included two halo and curved needle introducers. They are pairs of instruments, specific for the left and right sides. With a polypropylene monofilament non absorbable tape with tanged and detanged edges 0.66mm tape thickness, pore size 1182 um, fiber size(diameter) 0.15 mm weight 100(gm/m²), mesh length 44 cm, white color with plastic tape marks center and can be used to aid in intra-operative tensioning.

Surgical technique

The operation was done under spinal anesthesia.

1 gram of cephalosporin was given intravenously at the time of anesthesia induction, followed by 1 gram at the night after the procedure. The patient was placed in lithotomy position, legs on stirrups. Cleaning and draping of the operative field. Two nylon stitches were taken in the labia minora to expose the vulvar vestibule.

Catheterization of the bladder by 16 Fr Foley's catheter. The points of needle entry at the skin level were identified by tracking a horizontal line at the level of the urethral meatus. The inlet points were located 2 centimeters above this line and 2 centimeters outside the thigh folds. A 0.5 cm skin incision was made at the inlet points. The anterior vaginal wall was suspended with two Allis clamps on either side of the midline about 1 cm proximal to the urethral meatus. A midline incision of the vaginal wall was done at this level continuing proximally (towards the vaginal pouches) for a distance of 1 cm. Both vaginal mucosa and sub-mucosa were incised. Minimal para-urethral sub-vaginal dissection was done laterally with the blade, over a few millimeters distance, on either side (Figure 1).

(One Allis clamp grasps right labium major and minor while another Allis clamp holds the left margin of the sub-urethral vaginal incision, to properly expose the most posterior aspect of the right vulvar vestibulum. Fine dissection by scissors through the blade-initiated

dissection path, and then further, on a horizontal plane with a 45-degree angle relatively to the urethral sagittal plane, towards the upper portion of ischial-pubic ramus (Figure2).



Fig. 1: Median sagittal incision of the anterior vaginal wall

Proper exposure of the vulvar vestibule and respecting the specific direction of the dissection are important to avoid vaginal wall perforation. Once reaching the upper part of the ischial-pubic ramus - a bone contact is perceived - the right obturator membrane is perforated with the tips of the scissors and slightly opened. During the dissection, some bleeding can occur but the use of blood-aspirating device is usually sufficient. The introducer is pushed into the skin points, through the obturator membrane followed by the pre-formed dissection pathway until reaching the vaginal incision. (Figure 3a,b).

The open side of the introducer's gutter must be facing the patient. The introducer passes through the incised skin in upward downward followed by medial direction through the dissected pathway until it reaches the vaginal incision, fixation of the tape to the introducer (Figure 3c), then backward rotation movement in the opposite direction of entry of the introducer until the tape reaches the inlet skin



Fig.2: Showing fine dissection of the par urethral subvaginal tissue by scissors

point ,the same process is repeated on the other side.

When both ends of the tape become appear outside the skin (Figure 4). It is important to avoid twisting the tape. When both tubes have been exteriorized through the skin incisions the tape is then aligned under the junction between the middle and distal urethra and the tension adjusted by exerting a traction on the two ends of the tape and interposing a pair of scissors between the tape and the urethra so leaving a space avoiding any tension on the tape, the plastic sheaths can now be removed simultaneously then the ends of the tape are cut flush with the skin.

Postoperative Evaluation

Post-operative evaluation was done at 2 weeks, 3, and 6 months after the operation. At each visit all patients were subjected to:



Fig. 3A: Showing the introducer passing through inlet skin point

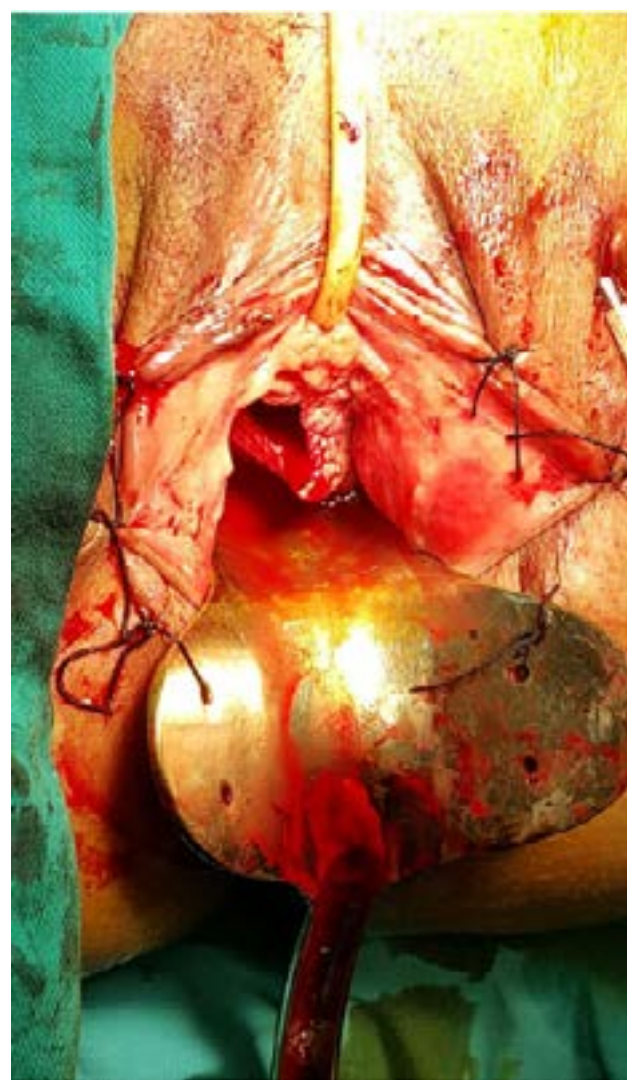


Fig. 3b: Showing introducer appears through vaginal incision



Fig. 3c: Showing tape fixed to the introducer



Fig. 4: Showing transobturator tape after fixation

Proper exposure of the vulvar vestibule and respecting the specific direction of the dissection are important to avoid vaginal wall perforation. Once reaching the upper part of the ischial-pubic ramus - a bone contact is perceived - the right obturator membrane is perforated with the tips of the scissors and slightly opened. During the dissection, some bleeding can occur but the use of blood-aspirating device is usually sufficient. The introducer is pushed into the skin points, through the obturator membrane followed by the pre-formed dissection pathway until reaching the vaginal incision. (Figure 3a,b).

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Postoperative Evaluation

Post-operative evaluation was done at 2 weeks, 3, and 6 months after the operation. At each visit all patients were subjected to:

(1) Clinical assessment

- Medical history to assess the presence of any possible complication.
- Incontinence and quality of life questionnaires.
- 3 days voiding diary.
- Examination for the presence of vaginal erosion, discharge, and chronic retention.
- Cough stress test.

(2) Imaging studies

- Abdominal- pelvic ultrasonography at 3rd and 6th month postoperatively.

(3) Urodynamic assessment

- Uroflowmetry was done at 3rd and 6th month.
- Cystometry and or pressure flow study was performed when needed (reduced Q max, presence of urge or obstructive symptoms, or residual urine more than 100 ml).

RESULTS

(Table 1) shows pre and post-operative evaluation of urge incontinence, stress incontinence and Cough stress

test. (Table 2) shows pre and post-operative evaluation of voiding diary, bladder capacity, Q max and PVRU test. (Table 3) shows the effect of age and number of pre-operative urge incontinence episodes on post-operative urge incontinence. (Table 4) shows the effect of age and number of pre-operative stress incontinence episodes on post-operative stress incontinence.

All procedures passed smoothly without adverse events. All patients had minimal blood loss less than 100cc, hence they did not need blood transfusion.

All patients had vaginal packs for 24 hours post – operatively, then removed. Urethral catheters were removed 24 hours post-operatively, all patients stayed at the hospital for 24 hours without occurrence of fever and then all were discharged.

Table 1: pre and post-operative evaluation of urge incontinence, stress incontinence and Cough stress test

	Pre-operative	Post-operative (3 Months)	Post-operative (6 Months)	P-value
Daily episodes of urge incontinence				
- None	0 (0 %)	15 (60 %)	15 (60 %)	<0.1*
- <3	16 (64 %)	9 (36 %)	9 (36 %)	
- >3	9 (36 %)	1 (4 %)	1 (4 %)	
Daily episodes of stress incontinence				
- None	0 (0 %)	22 (88 %)	22 (88 %)	<0.1*
- <3	13 (52 %)	2 (8 %)	2 (8 %)	
- >3	12 (48 %)	1 (4 %)	1 (4 %)	
Cough stress test				
- Negative	0 (0 %)	22 (88 %)	22 (88 %)	<0.1*
- Positive	25 (100 %)	3 (12 %)	3 (12 %)	

Data are presented as numbers (%)

Pearson Chi-square test was used*: Statistically significant (*p*-value <0.05)

Table 2: pre and post-operative evaluation of voiding diary, bladder capacity, Q max and P.V.R.U. test

	Pre-operative	Post-operative (3 Months)	Post-operative (6 Months)	P-value
Voiding diary (times) Diurnal & nocturnal	4.40 ± 0.866 (3 - 7)	4.36 ± 0.860 (4 - 7)	4.48 ± 0.918 (4 - 7)	0.746 ^a 0.627 ^b
Bladder cap.(cc) by pelvi-abdominal U/S	466 ± 42.622 (350 - 550)	472.8 ± 42.771 (400 - 570)	470 ± 40.825 (400 - 550)	0.516 ^a 0.647 ^b
Q max (ml/s)	21.432 ± 3.474 (13.2 - 27.1)	21.732 ± 1.598 (18.7 - 24.5)	21.612 ± 1.564 (18.7 - 24.5)	0.671 ^a 0.809 ^b
P.V.R.U. (cc)	19.0 ± 7.606 (10 - 35)	25.714 ± 7.032 (15 - 40)	25.0 ± 7.338 (20 - 45)	0.447 ^a 0.376 ^b

P.V.R.U. Post-Void Residual Urine

Data are presented as mean ± standard deviation and range

Paired t-test was used

a: *p*-value when comparing pre-operative with post-operative (3 Months)

b: *p*-value when comparing pre-operative with post-operative (6 Months)

Table 3: Effect of age and number of pre-operative urge incontinence episodes on post-operative urge incontinence

	Post-operative urge incontinence			<i>P-value</i>
	None	< 3 times	> 3 times	
Age				
- <40	9 (69.23 %)	4 (30.77 %)	0 (0 %)	0.433
- >40	6 (50 %)	5 (41.67 %)	1 (8.33 %)	
Pre-operative urge incontinence				
- <3	8 (50 %)	8 (50 %)	0 (0 %)	0.085
- >3	7 (77.78 %)	1 (11.11 %)	1 (11.11 %)	

Data are presented as numbers (%)

Pearson Chi-square test was used

Table 4: Effect of age and number of pre-operative stress incontinence episodes on post-operative stress incontinence

	Post-operative urge incontinence			<i>P-value</i>
	None	< 3 times	> 3 times	
Age				
- <40	13 (100 %)	0 (0 %)	0 (0 %)	0.158
- >40	9 (75 %)	2 (16.67 %)	1 (8.33 %)	
Pre-operative urge incontinence				
- <3	11 (84.62 %)	2 (15.38 %)	0 (0 %)	0.227
- >3	11 (91.67 %)	0 (0 %)	1 (8.33 %)	

Data are presented as numbers (%)

Pearson Chi-square test was used

At 2 weeks post-operative clinical examination revealed three patients with vaginal infection (12%), that responded to medical treatment.

DISCUSSION

The current study showed that TOT was successful treatment for stress urinary incontinence in all cases and up to six months postoperative; however, this was not the case in urge incontinence as cure rate dropped to 60%, while complications were few and managed conservatively (two cases of postoperative infection).

The results of the current study agreed with the results of Lee *et al* (2011) who reported a cure rate of 59.7% from urgency in women with MUI and predominant after insertion of MUS after 50 months of follow up^[6]. On multivariate analysis Lee *et al* found that the presence of overactive bladder on preoperative urodynamics increased the chance of persistent postoperative urgency, whereas trans obturator tension free vaginal tape insertion compared decreased this probability when compared to other types of MUS. Jain *et al* (2011) described a trend of decreasing cure rate of urgency symptoms with time, 81% - 100% cure from urge at 12 months versus 35% - 43% at 38-months follow up, while our study partially disagreed with this study, who also showed that MUS was associated with adequate overall subjective cure rates (56.4%) in women with MUI; however, the cure rate for overactive bladder (30% to 85 %) was lower as compared to SUI (85% to 97%) and decreased over time. Meta-analysis did not detect a significant difference in the overall subjective cure rate between retropubic tension-free vaginal tape (TVT) and trans obturator tape (TOT)^[7].

The mean duration of surgery in the current study was 15 minutes, which was comparable to that of Navneet Magon and Sanjiv VSM Chopra (2012) who had a mean duration of 21.69 minutes^[8], Purnichescu *et al.* (2007) who had a mean duration of 23 minutes^[9] and Moore *et al.* (2006) who had mean duration of 12.4 minutes^[10]. The current study had a mean blood loss of less than 100 ml. and no cases required blood transfusion which is also comparable to that of Navneet Magon and Sanjiv VSM Chopra (2012) who had a mean blood loss of 76.78 ml^[8], Al Taweel and Rabah (2010) who had a mean blood loss of 57 ml^[11], and Moore *et al.* (2006) who reported a mean blood loss of 36 ml^[10].

All cases in the current study were early discharged after 24 hours similar to the study done by Purnichescu *et al.* (2007) reported mean duration of hospitalization in the cases of TOT alone was 1.25 days^[7]; however, Kaelin-Gambirasio, *et al* (2009) had a mean hospital stay of 2.2 days for those who did TOT only^[12], and 50.8 % were discharged between 24 and 72 hours in the study done by (Navneet Magon and Sanjiv VSM Chopra in 2012^[8]).

The current study had only few postoperative complications namely postoperative infection in two cases (8%) managed conservatively; which is like the results of Navneet Magon and Sanjiv VSM Chopra (2012), who had one case of bladder injury and another case urethral injury detected intra-operatively, repaired by standard surgical techniques and TOT was applied (8). Lateral vaginal injury occurred in 2 patients (3.4%), which was also identified intraoperative, and the tunneler (TOT needle) was properly reinserted without further consequence. In the immediate

postoperative period, only a single patient (1.7%) had transient urinary retention after catheter removal, which was corrected by re-catheterization and subsequently successful voiding the following day; while Tracy *et al*, (2015) had 96 cases (44%) with USI only, who underwent TO-TVT alone, while 122 cases (56%) had USI and POP and did TO-TVT with concomitant Pelvic Floor Repair surgery, which showed that long-term complication rate of TO-TVT was low^[13]. The commonest postoperative morbidity of TO-TVT was de-novo overactive bladder (9% at 5 years). The explanation of such increasing rate for developing de-novo DO at 5 years (9.0%) when compared with 1 year (5.4%) could be due to increasing age. This difference also suggested that more women had de-novo overactive bladder in the prolapse group (14.3%) as compared to the TO-TVT alone group (4.5%) as the mean age of the former group was higher. Tracy *et al*, (2015) study also showed low rates of postoperative mesh erosion and voiding dysfunction, and concomitant surgery was not associated with higher rates of complications^[13]. Athanasiou *et al* (2014) reported 7% de-novo urgency after 7 years from TVT-O^[14].

The advantages of the current study that it was done in tertiary centers by experienced operators with follow-up up to six months postoperative; however, the limitation of the current study is the small number of cases done and the lack of long term follow-up of cases.

CONCLUSION

TOT is a successful procedure in the treatment of stress urinary incontinence; however, large studies with long term follow-up are needed to confirm that finding.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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