

## The Efficacy of Transobturator Tape (TOT) in Treatment of Mixed Urinary Incontinence in Females

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### ABSTRACT

**Background:** mixed urinary incontinence (MUI) is defined as the complaint of involuntary loss of urine, associated with urgency and also with effort. Urodynamic studies (UDS) are widely considered the gold standard investigation for determining the type of incontinence.

**Aim of the Work:** It evaluates the safety and efficacy of transobturator tape (TOT) procedure in treatment of women with mixed urinary incontinence.

**Patients and Methods:** this study was carried out at Ain Shams Urology Department and National institute of urology and nephrology in the period from October 2017 to may 2018. This Study included 20 female patients with MUI who failed to respond to medical treatment and other forms of conservative methods. Post operative evaluation was carried out at 2 weeks, 3, and 6 months following operation.

**Results:** Our study showed statistically significant cure rate for urge component 12 cases (60%), and also significant cure rate for stress component 17 cases (85%), no statistically significant difference in the cure rate depending on the age factor by dividing the patients into two groups group below forty (11 cases) and group above forty (9 cases).

**Conclusion:** our study showed statistically significant cure rate for urge component 12 cases (60%), and also significant cure rate for stress component 17 cases (85%). The limitations in our study were small number of patients and short time of postoperative follow-up. We advocate that the TOT procedure should always be tried in the management of mixed urinary incontinence in female population as it is an effective and simple procedure.

**Keywords:** Transobturator Tape, Mixed Urinary Incontinence, Urodynamic studies

### INTRODUCTION

Mixed urinary incontinence (MUI) is defined as the complaint of involuntary loss of urine, associated with urgency and also with effort or physical exertion or on sneezing or coughing<sup>(1)</sup>. MUI is common, with an estimated prevalence of 30% of all women with urinary incontinence<sup>(2)</sup>. Women with MUI are twice as likely to be bothered by their symptoms as compared to those with SUI alone<sup>(3)</sup>. Urodynamic studies (UDS) are widely considered the gold standard investigation for determining the type of incontinence. UDS findings provide valuable information for the confirmation or rejection of the clinical diagnosis and play a crucial role in the determination of the therapeutic strategy<sup>(4)</sup>. Women with both stress and urgency urinary incontinence can be challenging to manage. It is important to determine which component is more bothersome as it will help in directing treatment. UDS are frequently advocated prior to surgery in patients with MUI, as leakage with stress and urgency often coexists. In patients without detrusor overactivity there is some limited data suggesting they have a higher chance of resolution of their urgency symptoms after a sling than those with urodynamic detrusor overactivity. In patients with a predominant stress component, the midurethral sling (MUS) has been shown to improve urgency and urge urinary incontinence (UUI)<sup>(5)</sup>. Management of

women with MUI is relatively more difficult, as it involves addressing both the SUI and overactive bladder (OAB) symptoms. Conservative management is usually the first line, including pelvic floor muscle training, bladder retraining, and pharmacological treatment. If the above fails, surgery for SUI may be contemplated in women with predominant SUI symptoms; a number of options are usually discussed with the patient including MUS. Transobturator tension-free vaginal tapes (TO-TVT) have been described in 2001 and 2003<sup>(6)</sup> and have rapidly gained wide popularity among surgeons due to the avoidance of the blind retro-pubic pathway. It was also hypothesized that TO-TVT could be preferred in women with MUI compared to retro-pubic tension-free vaginal tapes (RP-TVT) due to the more horizontal position of the tape and consequently, less postoperative OAB symptoms<sup>(3)</sup>. In a recent systematic review and meta-analysis *Jain et al.*<sup>(7)</sup> examined the effectiveness of MUS in women with MUI. The authors showed that MUS is associated with reasonable overall subjective cure rates (56.4%) in women with MUI. However, the cure rate for the urge component (30% to 85 %) was lower than that for the stress component (85% to 97%).

### AIM OF THE WORK

The aim of the present study is to evaluate the safety and efficacy of TOT procedure in

treatment of women with MUI using subjective and objective measures.

## PATIENTS AND METHODS

This study was carried out at Ain Shams Urology Department and National institute of urology and nephrology in the period from October 2017 to May2018. The study was approved by the Ethics Board of Ain Shams University and an informed written consent was taken from each participant in the study. This Study included 20 female patients with MUI who failed to respond to medical treatment and other forms of conservative methods. 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. 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. **1) Voiding Diary:** 3 days voiding diary. **2) Laboratory investigations:** 1) Urine analysis, culture and sensitivity if needed. 2) Routine pre-operative laboratory investigations, (CBC, Blood sugar, Creatinine). 3) Imaging Studies: All patients were assessed by abdomino-pelvic ultrasonography to evaluate the upper urinary tract and estimation of postvoid residual urine. **1) Urodynamic examination:** 1) Uroflowmetry, 2) Filling cystometry, 3) Pressure flow study. **Inclusion Criteria:** 1) Age: 18-60. 2) Body Mass Index (BMI): <35. 3) Failed Medical Treatment. 4) Incontinence: Mixed Urinary Incontinence (MUI). **Exclusion Criteria:** 1) Associated pathology that may induce similar symptoms e.g. urinary tract infections, stones and tumors. 2) Central or peripheral neurological pathology. Such as multiple sclerosis. 3) Presence of other gynaecological pathology that needs hysterectomy. 4) Advanced pelvic organ prolapse ( $\geq$  stage 2). 5) Pregnancy. 6) Patients who are surgically unfit. 7) Detrusor under-activity. 8) Detrusor over-activity. 9) Obstructed flow. 10) Significant post-void residual urine. **Statistical analysis:** SPSS (Statistical Package for the Social Science, SPSS Inc., Chicago, IL, USA) version 16 for Microsoft Windows. Statistical significance was established at a p-value of less than 0.05.

## RESULTS

**Table (1):** Showing post-operative follow up of urge incontinence in the 1<sup>st</sup> six months

Daily episodes of Urge incontinence	Pre		Post 3 months		Post 6 months		Chi-Square	
	N	%	N	%	N	%	X <sup>2</sup>	P-value
None	0	0	12	60	12	60	22.54	<0.001*
<3.	1	65	7	35	7	35		
>3.	7	35	1	5	1	5		
Total	2	10	20	100	20	100		
	0	0						

\* means the data is statistically significant.

The differences between pre and post operative results were clinically significant.

**Table (2):** Showing post-operative follow up of stress incontinence in the 1<sup>st</sup> six months.

Daily episodes of Stress inc.	Pre		Post 3 Month		Post 6 Month		Chi-Square	
	N	%	N	%	N	%	X <sup>2</sup>	P-value
None	0	0	17	85	17	85	44.266	<0.001*
<3.	11	55	2	10	2	10		
>3.	9	45	1	5	1	5		
Total	20	100	20	100	20	100		

\* means the data is statistically significant.

The differences between pre and post operative results were clinically significant.

**Table (3):** Showed difference between QMAX in the Pre and postoperative evaluation.

	Qmax (ml/s)		Comp.	P-value
	Range	Mean±SD		
Pre	13.2-27.1	21.432±3.474		
Post 3 Month	18.7-24.5	21.732±1.598	P1-P2	0.624
Post 6 Month	18.7-24.5	21.612±1.564	P1-P3	0.752

\* means the data is statistically significant.

The differences between pre and post operative results were insignificant.

**Table (4):** Showed difference between P.V.R.U. in the pre and post operative evaluation.

	P.V.R.U. (cc)		Comp.	P-value
	Range	Mean±SD		
Pre	10-35	19.000±7.606		
Post 3 Month	15-40	25.714±7.032	P1-P2	0.416
Post 6 Month	20-45	25.000±7.338	P1-P3	0.350

\* means the data is statistically significant.

The differences between pre and post operative results were insignificant.

## DISCUSSION

We treated 20 female patients using TOT set by outside to inside technique to evaluate the safety and efficacy of TOT for the treatment of MUI. Post operative evaluation was carried out at 2 weeks, 3, and 6 months following operation. At each visit all patients were subjected to clinical assessment, history to assess the presence of any possible complication, incontinence and quality of life questionnaires (intermountain healthcare questionnaire), 3 days voiding diary, examination for the presence of complication, and Cough stress test. Abdomino-pelvic ultrasonography at 3<sup>rd</sup> and 6<sup>th</sup> month postoperatively was done. Uroflowmetry was done at 3<sup>rd</sup> and 6<sup>th</sup> month, cystometry and or pressure flow study was performed when needed (presence of urge or obstructive symptoms, reduced Q max, or residual urine more than 100 ml). In our study, the mean duration of surgery was 15 minutes +3.5 minutes. In a study done by **Magon and Chopra** <sup>(8)</sup>, a total of 59 patients were applied TOT by outside-in technique, the mean duration of surgery was 21.69 minutes, **Taweele and Rabah** <sup>(9)</sup> reported mean surgery duration of 18 minutes. **Purnichescu et al.** <sup>(10)</sup> reported a mean duration of 23 minutes. In our study, all patients had minimal blood loss less than 100 cc, hence they did not need blood transfusion. In a study done by **Magon and Chopra** <sup>(8)</sup> the mean blood loss was 76.78 ml, **Taweele and Rabah** <sup>(9)</sup> reported an average intra-op blood loss of 57 ml. In our study, all patients stayed post operative at the hospital for 24 hours without occurrence of fever and then all were discharged. In our study, all procedures passed smoothly without adverse events, but at 2 weeks post-operative clinical examination revealed 2 patients with vaginal infection (10%), that responded to medical treatment. In a study done by **Law et al.** <sup>(11)</sup> on 218 women who underwent TO-TVT, 96 (44%) women had SUI only and underwent TO-TVT alone, while 122 (56%) had SUI and POP and underwent TO-TVT with concomitant PFR surgery: 88 women receiving TO-TVT alone and 101 women receiving TO-TVT with concomitant pelvic floor repair surgery were followed up for 5 years after operation, showed that the long-term complication rate of TO-TVT is low. The most commonly

encountered morbidity was de-novo DO after TO-TVT (9% at 5 years). The higher percentage of women developing de-novo DO at 5 years (9.0%) when compared with 1 year (5.4%) could be attributed to ageing. This difference also suggested that more women had de-novo DO in the prolapse group (14.3%) than in the TO-TVT alone group (4.5%) as the mean age of the prolapse group was higher. study also showed low rates of mesh erosion and voiding dysfunction after operation, and concomitant surgery didnot impose higher complication rates. In a study done by **Kaelin-Gambirasio et al.** <sup>(12)</sup> included 233 consecutive women who underwent TOT procedure for pure stress or mixed urinary incontinence with mean follow-up 27 months: Follow-up information was available for 225 (96.6%) women. It showed that there were few per operative complications. Forty-eight women (21.3%) reported late complications including *de novo* or worsening of preexisting urgencies (10.2%), perineal pain (2.2%), *de-novo* dyspareunia (9%), and vaginal erosion (7.6%).The overall proportion of women satisfied by the procedure was 72.1%. The percentage of women satisfied was significantly lower in women who experienced erosion (29.4%) compared to women who did not (78.4%). **Athanasiou et al.** <sup>(4)</sup> reported 7% de-novo urgency 7 years after TVT-O but **Angioli et al.** <sup>(13)</sup> found a 5-year de-novo urgency rate of 6.4%. Our study showed after follow up of urge incontinence component 12 cases (60%) cured, 1 case (5%) improved and 7 cases (35%) not improved. It also showed that the patients who had less than three urge inc. episodes (13 cases, 65%) showed cure rate 53.8% (7 cases). Patients who had three or more than three urge inc. episodes, they were 7 cases (35%) who showed cure rate 71.4% (5 cases). The study showed that there is no significant difference in the cure rate between patients who had less than or more than three urge inc. episodes. Our study showed after six months post-operative follow up of SUI component for 20 female patients 17 cases cured (85%), and 3 cases not improved (15%). It also showed that No significant difference between patients who had less than or more than three incontinence episodes in the cure rate of SUI: Patients who had less than three stress inc. episodes (11 cases, 55%) showed cure rate 81.8% (9 cases), while patients who had stress inc. episodes three or more than three, they were 9 cases (45%) which showed cure rate

88.88% (8 cases). Our study showed no statistically significant difference depending on the age factor by dividing the patients into two groups group below forty (11cases) and group above forty (9 cases). In a study done by *Yonguc et al.* (14) on 193 women who underwent TOT procedure for, Patients were divided into two groups in terms of incontinence type. Group 1 consists of patients with SUI (105) and group 2 with MUI (67), All patients were evaluated at 3 and 12 months and annually, Two groups were retrospectively compared for patient satisfaction, objective and subjective cure rates: There was no significant difference between the objective cure rates in two groups; however subjective cure and patients satisfaction rates were significantly higher in SUI group ( $P<0.05$ ). Study concluded that TOT procedure seems to be effective and safe in the surgical treatment of MUI after 5 years follow-up. In a retrospective cohort study done by *Lee et al.* (2), 237 women with MUI who underwent TOT surgery to asses the impact of TOT treatment on OAB symptoms with a particular focus on nocturia. Of these, 86 patients (36.4%) had preoperative nocturia, Of these 70 subjects eligible for analysis; TOT treatment resulted in an overall significant improvement in OAB symptoms including nocturia. Frequency-volume charts revealed that TOT treatment significantly decreased the actual number of nightly voids (ANV) and the nocturnal bladder capacity index (NBCi) in the entire cohort. However, in a subgroup of women with nocturnal polyuria, there was no significant change in ANV or NBCi after the sling operation. Correlation analysis of the whole cohort revealed that the postoperative changes in NBCi correlated positively with postoperative changes in ANV. The nocturia- persisting group was more likely to have nocturnal polyuria and lower preoperative functional bladder capacity compared with the nocturia-improved group. This study demonstrated that the TOT procedure resulted in an overall significant improvement in OAB symptoms including OAB-related nocturia in patients who presented with MUI.

## CONCLUSION

Our study showed statistically significant cure rate for urge component 12 cases (60%), and also significant cure rate for stress component 17 cases (85%). The limitations in our study were small number of

patients and short time of postoperative follow-up. We advocate that the TOT procedure should always be tried in the management of mixed urinary incontinence in female population as it is an effective and simple procedure.

## CONFLICTS OF INTEREST

There are no conflicts of interest.

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