

Role of Transobturator Tape in the Treatment of Mixed Urinary Incontinence in Women

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ABSTRACT

BACKGROUND

Globally, urinary incontinence (UI) is frequently observed in women and impairs every aspect of her life. Mixed urinary incontinence (MUI) refers to the presence of both stress (SUI) and urgency urinary incontinence (UUI). There are variable cure rates of midurethral slings (MUS) procedures in MUI. Thus, the present study was performed to evaluate the effectiveness of transobturator tape (TOT) technique, influence of outside-in TOT on objective and subjective cure rates and quality of life, and to assess the post-operative complications in women with MUI.

METHODS

This was a prospective interventional study involving 31 women who had undergone TOT procedure for MUI at Department of Urology, Sri Ramachandra Medical Centre & Sri Ramachandra Medical College Hospital, Chennai, over the last 2 years. The study was performed over a period of 25 months (i.e., September 2016 to September 2018). MUI was diagnosed on the basis of urodynamic tests such as pressure flow study. Urodynamic evaluation was done using Laborie urodynamic device. All patients filled in the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) both pre-operatively and post-operatively (at 6 months). Incontinence bothersome scale (IBS) was used to evaluate post-operative satisfaction and if the IBS score was > 80, patient was considered to be satisfied. All patients were routinely evaluated at 2 weeks post-operatively and then on the 6th month post-operatively with pelvic examination, cough stress test (CST), IBS score, and ICIQ-SF.

RESULTS

Majority of patients belonged to the age group of 41-50 years (35.4%) and were post-menopausal (61.3%). Post-operatively, there was a significant decrease in the number of patients with symptoms related to both SUI and UUI (< 0.05). Moreover, there was significant postoperative increase in Pdet Qmax (< 0.05) and a reduction of maximum flow (Qmax) (< 0.05). Subjective and objective SUI cure was achieved in 90.32% and 87.09% patients, respectively. While, subjective UUI cure was achieved in 70.96% patients. VAS score > 80 was observed in 77.41% patients. Only 5 patients developed post-operative complications including dyspareunia, severe groin pain, recurrent UTI, and urinary retention.

CONCLUSIONS

During follow-up, TOT procedure was found to be highly successful in the treatment of MUI. There was no incidence of injury to urethra or bladder, and no complications related with bowel or nervous system. Hence, TOT will definitely improve MUI control, decrease women's dissatisfaction, and improve quality of life.

KEYWORDS

Midurethral Slings, Mixed Urinary Incontinence, Transobturator Tape, Urinary Incontinence

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BACKGROUND

International Continence Society (ICS) defines urinary incontinence (UI) as an involuntary passage of urine.¹ Whereas, mixed urinary incontinence (MUI) is the simultaneous presence of both stress urinary incontinence (SUI) and urgency urinary incontinence (UUI) and is linked to both effort, exertion, sneezing, or coughing as well as urgency.²

UI is highly prevalent in women and adversely affects every aspect of woman's life i.e., physical, psychological, and social resulting in low self-esteem, embarrassment, and decreased productivity at work place.^{3,4} However, as compared to women suffering from SUI, women with MUI are at least two-fold more likely to be worried by the symptoms.⁵ Primarily, SUI is most prevalent, but during late adulthood, MUI is an extremely predominant subtype.⁶

Predominant symptom, that is most troublesome to the patients, generally determines the treatment.⁷ Non-surgical treatment is considered as the first-line treatment and includes weight loss, behaviour modification, pelvic floor muscle training, reduced fluid intake, caffeine moderation, biofeedback, anti-incontinence devices, and pharmacological treatment.^{2,7,8} While, surgical treatment is an option for women with stress-predominant MUI or with equal components of SUI and UUI, and not responding to non-surgical interventions. These includes urethral bulking agents, retropubic suspensions, bladder neck slings, or midurethral slings.^{2,8} Among these surgical methods, midurethral sling (MUS) procedures such as transobturator tape (TOT) and tension-free vaginal tape (TVT) are most widely used.² Some studies have reported that TOT is more promising to result in total resolution of MUI, due to its less obstructive nature.^{9,10} However, no significant difference in outcomes is validated by a recent meta-analysis.¹¹

Available data reports variable cure rates of MUI after MUS surgery.¹¹⁻¹⁴ Moreover, such data from the perspective of adult Indian women is lacking. Thus, the present study was performed with an objective of evaluating the effectiveness of TOT in the treatment of women with MUI. Secondary objectives of the present study were to determine the influence of outside-in TOT on objective and subjective cure rates and quality of life, and to assess the postoperative complications in women with MUI.

METHODS

This was a prospective Interventional study involving 31 women, attending Department of Urology, Sri Ramachandra Medical Centre & Sri Ramachandra Medical College Hospital, Chennai. The study was performed over a period of 25 months (i.e., September 2016 to September 2018). The study commenced only after the approval of Institutional Ethics Committee.

Women aged 21 years or more; diagnosed both clinically and urodynamically as a case of MUI; had failed 3 months of conservative treatment; and having positive pad test & cough stress test were included in the study. While, women with presence of pelvic organ prolapse (> stage 1); known history of neurological disorder; urodynamically proven impaired

bladder contractility; previous urethral reconstruction; morbid obesity (BMI > 40 Kg/m²); and pregnancy were excluded. A total of 31 women who underwent transobturator taping procedure for MUI in our institution over the last 2 years were requested to participate in this study. On acceptance, written informed consent was obtained. All the women were evaluated through a thorough history, pelvic examination with focused neurological examination, ultrasound scan of the abdomen with post-void residual (PVR), pad and cough stress test, urodynamic evaluation & cystoscopy. MRI of the pelvis & spine was reserved for women with abnormal focused neurological examination.

Patient characteristics included in the study were age, body mass index (BMI), menopausal status, parity with mode of delivery, previous pelvic surgical history, the number of pads used per day, symptom duration, pre- and post-operative urodynamic study (UDS) parameters, intra-operative parameters, post-operative complications and surgical outcomes.

Urodynamic tests such as pressure flow study were performed in all patients for the diagnosis of MUI. Urodynamic evaluation was done using Laborie urodynamic device. A sterile 8F dual channel cystometry catheter was placed into the urethra and a rectal catheter with 10 ml balloon was placed into the rectum. The urinary bladder was filled with saline solution at the rate of 40 ml/min and the patient was asked to cough after each 100 ml filling. Urinary incontinence occurring in this time was detected, detrusor instability during the filling phase was also noted. Abdominal leak-point pressure was measured in all patients and recorded. On confirming a diagnosis of MUI, a free-flow without catheter was performed. All patients filled in the International Consultation on Incontinence Questionnaire-Short form (ICIQ-SF) pre-operatively and post-operatively at 6 months. All patients, after obtaining anaesthetist clearance, underwent outside-in TOT procedure as described by Leval.¹⁵ All surgeries were done under regional/general anaesthesia. Post-procedure cystoscopy was done to assess urethra and bladder. All patients were monitored with the Foley catheter for bladder drainage for 48-72 hours.

Incontinence bothersome scale (IBS) was used to evaluate post-operative satisfaction. Where, 0 represented very dissatisfied/intolerable urinary complaints and 100 represented very satisfied/no urinary problems. If the IBS score was > 80, patient was considered to be satisfied. All patients were routinely evaluated at 2 weeks post-operatively and then on the 6th month post-operatively with pelvic examination, cough stress test (CST), IBS score, and ICIQ-SF.

- Objective cure: negative CST with no need for pads or any form of surgical intervention.
- Subjective cure: 0 point on ICIQ-SF and an IBS score of > 80.

Statistical Analysis

Categorical data was expressed as absolute numbers and percentages and the continuous data was expressed as mean ± standard deviation (SD). Statistical analyses were performed with SPSS 17.0 (SPSS version 17.0, Chicago, IL, USA). A p-value of ≤ 0.05 was considered as statistically significant.

RESULTS

Table 1 depicts the demographic profile and risk factors of the study population. Majority of patients i.e., 11 each, belonged to the age group of 41-50 years and had BMI in the range of 25-29.9 Kg/m². The mean age and the mean BMI of the patients were 51.90±10.46 years and 27.2±4.35 Kg/m², respectively. Majority of the women i.e., 19 were post-menopausal. Majority of women i.e., 25 had a past history of vaginal delivery and the mean parity was 2.38±1.12. Majority of the patients i.e., 19 used ≤ 4 pads per day and the mean pads used per day was 4.03±1.79. Among patients with past history of pelvic surgeries, majority i.e., 5 had caesarean section. Majority of the patients i.e., 17 had symptoms for 1-5 years and the mean symptoms duration was 4.45±1.95 years.

Parameters	Number of Patients	Percentage of Patients
Age Group (in Years)		
31-40	5	16.2
41-50	11	35.4
51-60	6	19.4
61-70	9	29.0
BMI (in Kg/m²)		
15-19.9	2	6.4
20-24.9	8	25.8
25-29.9	11	35.5
30-34.9	8	25.8
35-39.9	2	6.4
Menopausal Status		
Pre-menopausal	12	38.7
Post-menopausal	19	61.3
Parity		
0	1	3.2
1	4	12.9
2	13	41.9
> 2	13	41.9
Mode of Delivery		
Vaginal	25	80.6
LSCS	5	16.2
Nulliparous	1	3.2
Prior Pelvic Surgeries		
None	23	74.2
Caesarean section	5	16.2
Vaginal hysterectomy	2	6.4
Abdominal hysterectomy	1	3.2
Symptoms Duration (in Years)		
< 1	2	6.4
1 - 5	17	54.9
> 5	12	38.7
Number of Pads Used		
1 - 4 pads	19	61.3
> 4 pads	12	38.7

Table 1. Demographic Profile and Risk Factors of the Study Population

UDE Parameters	Pre-Operative	Post-Operative	p
Cystometric capacity (ml)	396.90 ± 46.98	371.96 ± 43.50	< 0.05
Detrusor over-activity	26 (83.87%)	23 (74.19%)	xx
PdetQmax (cmH ₂ O)	16.35 ± 1.99	25.22 ± 4.32	< 0.05
Qmax (ml/s)	25.54 ± 5.50	18.45 ± 5.22	< 0.05
Urodynamic SUI	31 (100%)	4 (12.90%)	< 0.05
Abdominal Leak Point Pressure	98.48 ± 7.75	-	-

Table 2. Pre- and Post-Operative Urodynamic Parameters

Data expressed as mean ± SD, absolute numbers, and percentage; p-value ≤ 0.05 was considered as statistically significant. Please write the specific statistical test used.

Pre-Operative ICIQ-SF Score		
Score	N = 31	Percentage (%)
≤ 15	17	54.8
> 15	14	45.2
Intra-operative Parameters		
Parameters	Mean ± SD	Range
Operative time (in minutes)	29.83 ± 5.08	20 - 40
Hospital stay (in days)	1.61 ± 0.61	1 - 3

Table 3. Pre-Operative ICIQ-SF Score and Intra-Operative Parameters

ICIQ-SF - International Consultation on Incontinence Questionnaire-Short form. Please write post-operative ICIQ-SF score as well & whether there was any statistically significant change.

Post-Operative Complications	n (%)
Grade I	
Dyspareunia	2 (40)
Grade II	
Severe groin pain	1 (20)
Recurrent UTI	1 (20)
Grade III a	
Urinary retention	1 (20)
Total	
Total	5 (100)

Table 4. Post-Operative Complications as per Modified Clavien Classification System

Outcome Measures	n (%)
Subjective SUI cure	28 (90.32)
Objective SUI cure	27 (87.09)
Subjective UUI cure	22 (70.96)
Patient satisfaction (IBS> 80)	24 (77.41)
Total	31 (100)

Table 5. Outcomes of the Patients at the Postoperative 6th Month

SUI- stress urinary incontinence; UUI - urgency urinary incontinence; IBS- Incontinence bothersome scale.

Table 2 depicts pre- and post-operative urodynamic parameters. Post-operatively, there was a significant decrease in the number of patients with symptoms related to both SUI and UUI (<0.05). Moreover, there was significant postoperative increase in PdetQmax (< 0.05) and a reduction of maximum flow (Qmax) (< 0.05).None of the patients had a significant PVR either pre- or post-operatively.

Table 3 depicts pre-operative ICIQ-SF score and intra-operative parameters. Majority of the patients i.e., 17 had a score of ≤ 15 and the mean ICIQ-SF score was 15.03±1.88. Post-operative ICIQ-SF score was less than 3 in all patients post TOT repair.

Table 4 depicts post-operative complications according to modified Clavien classification system. In the immediate post-operative period, 1 patient developed severe groin pain requiring prolonged analgesics. One patient developed urinary retention, requiring Foley's catheterisation, and was very-well able to pass urine 1 week after catheter removal. One patient had recurrent UTI, on urine culture E. Coli was identified and was treated with oral Levofloxacin 500 mg OD for 2 weeks. Since her symptoms persisted, she was further prescribed oral Nitrofurantoin 200 mg BD for 2 weeks. During follow-up after 6 months, 2 patients complained of persisting dyspareunia, which was managed conservatively with local application of oestrogen.

Table 5 depicts surgical outcomes among patients at the post-operative 6th month. Subjective cure from SUI and UUI was seen in 28 and 22 patients, respectively. Patients with persisting UUI were prescribed Solifenacin 5 mg OD and performed better. Objective cure from SUI was noticed in 27 patients, and 1 patient had negligible leak which was detected on UDS, but not perceived by the patient. The overall patient satisfaction assessed through the IBS score of >80 was noted in 24 patients.

DISCUSSION

Global epidemiological studies have reported increasing prevalence of UI with increase in age, but each subtypes of UI has a different order of prevalence as per the age group involved. As per available evidence, prevalence of SUI (mean = 13%) is most during the 5th decade of life, and then decreases. While, prevalence of UUI (mean = 5%) and MUI (mean = 11%) is low during young age (20-30 years), but

steadily increases with age.⁶ MUI may result from two separate pathologies involving combination of bladder dysfunction and a leaky urethral sphincter, or principally involving a leaky urethral sphincter, leading to passage of urine into the proximal urethra, thereby resulting in both reflexive detrusor contractions and urgency incontinence, as well as stress incontinence, in between.⁷ Extensive literature search failed to retrieve any data regarding epidemiology and risk factors related exclusively to MUI in Indian women. Various epidemiological studies in India have reported variable prevalence of MUI. Agarwal et al.,¹⁶ Bhanu et al.,¹⁷ and Singh et al.,¹⁸ reported the prevalence of MUI as 38%, 34.6%, and 16.8%, respectively. This may be due to different settings and study population.

The muscle fiber to connective tissue ratio and muscle fiber diameter in the urethral sphincter decreases with increase in age. Thus, similar age-related changes may develop in the pelvic floor, resulting in deficient support in old women and ultimately UI.³ In the present study, majority of the patients (35.4%) belonged to the age group of 41-50 years and had a mean age of 51.90±10.46 years. Similarly, Abdel-Fattah et al. Reported the mean age of 55.14±10.97 years in women with MUI.¹³ Biswas et al. Reported the mean age of 61.91±9.69 years and maximum prevalence in ≥ 70 years-old women.¹⁹ Thus, mean age and age group of our study participants correlate well with the studies cited in literature. In the present study, majority of the patients (61.3%) had achieved menopause. However, contrary to our finding, Singh et al. Reported that 22.5% of the patients were post-menopausal.¹⁸ Kirss et al. in their study reported high prevalence of UI in post-menopausal women, where only 21.17% of post-menopausal women had MUI.²¹⁰ Thus, increasing age and postmenopausal status are important risk factors of UI. In the univariate analysis, we found no significant risk factor for persistence of SUI. Mean age of > 60 years and menopause were significant predictive factors for persistence of UUI ($p = 0.008$ and $p = 0.04$, respectively). Mean age > 60 years ($p = 0.009$) was predictive of persistence of overall incontinence.

Increased BMI is linked to greater prevalence of SUI, due the reason that increased abdominal pressure on the bladder area, results in the greater risk of SUI. Moreover, chronically elevated abdominal pressure may lead to stressed pelvic floor.³ In the present study, majority of the patients (35.4%) had a BMI in the range of 25-29.9 Kg/m² and a mean BMI of 27.2±4.35 Kg/m². Similarly, Abdel-Fattah et al. Reported the BMI of ≥ 30 kg/m² in 44.0% women with MUI.¹³ Contrary to the present study, Biswas et al. Reported that the majority of patients (70.1%) had a normal BMI (18.5-24.9 Kg/m²). Studies have demonstrated inverse relationship between parity and strength of pelvic floor muscles. Thus, as the number of deliveries increase, the strength of pelvic floor muscles decreases.³ In the present study, majority of the patients (83.8%) had a parity of ≥ 2. Similarly, Biswas et al. reported that the majority of patients (54.2%) had a parity of ≥ 4. Singh et al. reported that multiparity is associated with UI and 17.6% multiparous women had MUI.

Incidence of UI is more with vaginal deliveries than caesarean, due to increased chances of weakness of pelvic floor muscles. Caesarean delivery usually protects the functions of pelvic nerve and muscle.³ In the present study, majority of the patients (80.6%) had vaginal delivery, thus

supporting the findings in the literature. Similarly, Singh et al. reported that maximum prevalence of UI was among patients with vaginal delivery (26.84%), which was significantly higher than nulliparous women (9.42%) and women with caesarean deliveries (8.59%).¹⁸ These findings demonstrate that the mechanical strain during the labor may further increase the risk related to the pregnancy itself. Moreover, history of gynaecological surgery such as LSCS and hysterectomy increases the chances of trauma to the urinary tract, thereby increasing the risk of UI. Majority of the women (74.2%) in the present study, had no past history of pelvic surgeries, while majority of women with past history of pelvic surgery had LSCS (16.2%). Similar to the present study, Biswas et al. Reported that only 10.7% patients had a past history of gynaecological surgery and 4.5% had past history of LSCS.¹⁹

The mean duration of symptoms were 4.45±1.95 years. There was a significance delay in asking for medical help. From the data collected, it appears that most women tend to seek treatment between 1-5 years after the onset of symptoms. Reasons for this delay could be ranging from personal to economical to logistical.²¹ In patients with MUI, urodynamic studies (UDS) are generally recommended before invasive procedures and surgery and they predict treatment outcome.⁷ In terms of treatment success and patient satisfaction, pre-operative UDS has not been found superior to office evaluation of UUI before surgery.²² In the present study, UDS failed to identify SUI in 3 patients, but we have done TOT based on positive cough stress test and SUI history. Also, we could not confirm detrusor over-activity (DO) in 7 patients who had incontinence with strong urge. When there is a disagreement between the UDS and the patient's symptoms, UDS findings are not superior to the patient's symptoms. Inability to report DO or SUI on UDS does not exclude the importance of patient's symptoms.²³

In the present study, on UDS, 28 women had demonstrable SUI pre-operatively, whereas only 4 women had SUI post-operatively, where it was negligible in one patient (4 ml) and she did not notice the leak. UUI disappeared in 23 patients (74.2%); urgency, which was present pre-operatively in all 31 patients, persisted in 9 patients (29%) ($p < 0.05$). Frequency, which was present pre-operatively in 26 patients, persisted in 6 patients (19.3%) ($p < 0.05$). There were no patients with worsening of over-active bladder (OAB) symptoms. All patients with post-operative storage symptoms were treated with Solifenacin 5 mg and had a good clinical response.

The urodynamic data revealed a statistically significant postoperative increase in PdetQmax ($p = 0.02$) and a reduction of maximum flow (Qmax) ($p = 0.03$). No obstruction, according to the Blaivas and Groutz nomogram, was observed in any patient post-operatively.²⁴ The mean procedural time was 29.83±5.08 minutes, including an additional cystoscopy at the end of the procedure. This was similar to mean operative time of TVT reported by Abouassaly et al.²⁵

The present study demonstrates that patients with MUI, who have not responded to conservative treatment, can achieve a significant improvement of both the stress and the urge components following a TOT procedure. The surgical management of women with MUI is a subject of debate among clinicians. Some authors have published positive

results, even though, cure rates following MUS were significantly lower in patients with MUI than in patients with pure SUI.^{11,26,27} Cure rates of SUI do not differ from that in patients with pure SUI, but 30–70% still suffer from urgency symptoms.^{27,28} Cure rates are even lower in patients with urge predominant MUI.^{27,28}

In a meta-analysis, Jain et al. evaluated retropubic TVT and TOT in patients with MUI, and reported no significant difference in overall subjective cure of SUI and urinary urgency, frequency and UUI.¹¹ However, a RCT comparing TVT and TOT in MUI patients in terms of all storage symptoms revealed cure rates of 31% after TVT and 55% after TOT.²⁹ In a prospective RCT comparing TVT and TOT in patients with SUI or MUI, Nyssonen et al. reported that a large proportion of patients with MUI found the operation beneficial for urge symptoms. In a median follow-up of 46 months, the subjective and objective cure rates in TOT group were 81% and 74%, respectively. Urge symptoms were relieved in 70% of patients in MUI subgroup.³⁰ In another study, Gamble et al. assessed the efficacy of transobturator, retropubic or bladder neck sling in 305 women with MUI and concluded that transobturator slings had the lowest rate of persistent DO.³¹

Abdel-Fattah et al. in a RCT compared outside-in and outside-in TOT in 66 patients with MUI and reported a subjective success rate of 73.8%, with a clinically significant improvement in quality of life (QoL) of 86.7%. The cure rates of urgency and urgency incontinence were 50.1% and 56.5%, respectively and there were no significant differences between the two groups.¹⁴ Results of the present study are consistent with the findings in the literature, as the cure rates of urgency and UUI were lower than that of SUI. Significant relationship between DO and failure of TOT surgery finds its mention in some studies. Jain et al. in their meta-analysis observed that studies which excluded patients with DO reported higher cure rates for UUI.¹¹ Similarly, Paick et al. found that coexisting DO increases the risk of both persistent urgency and UUI.³² Findings of the present study concur with these studies.

In the present study, overall complication rate of 16.92% was comparable to other studies with the complication rates ranging from 10.5% to 31.3%.^{33,34} It has been advocated that de novo urgency rate is lower in TOT compared to other midurethral sling procedures.³⁴ None of the patients experienced worsening of UUI. Various studies have demonstrated that the transobturator tape is very much away from the pudendal nerve, obturator vessels and nerve, and the femoral vessels. The risk of lower urinary tract injury or other visceral injury is negligible with this approach when compared to TVT.^{35,36} In a study involving 107 SUI patients, de Leval demonstrated no injuries related to bladder or urethra and absence of vascular or neurologic complications.¹⁵

In the present study, none of the patients had signs and symptoms of vaginal, urethral, or bladder injury or erosions; or persistent pain during the 6 months follow-up period. Prolonged postoperative groin pain was seen in 1 patient in this study. The cause for the postoperative pain with this procedure was probably due to a less predictable, more lateral passage of the needle and thus, a closer exit to the obturator nerve in the groin. Oral analgesics were sufficient and she was pain-free during the follow-up at 3 months.

The strengths of the present study are the prospective design; the inclusion of women with only MUI with predominant SUI; UDS were performed both pre- and post-operatively; and pre- and post-operative assessment of symptoms with validated questionnaires. The limitations of the study were short duration of the follow-up and absence of a control group.

CONCLUSIONS

TOT procedure was found to be highly successful in the treatment of MUI during follow-up. The outside-in transobturator technique is simple, quick, and safe. It allows the accurate passage of the tape with minimal dissection. Both menopause and age over 60 are risk factors for failure of surgery. Surgeons should take this into account when counselling the patient on the likelihood of persistence of UUI and SUI symptoms. Finally, TOT will definitely improve MUI control, increase women's satisfaction, and improve their quality of life. However, long-term comparative studies are needed to assess the efficacy of TOT in patients with MUI.

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