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ORIGINAL ARTICLE

Short and Long Term Follow up and Efficacy of Trans Obturator Tape for Management of Stress Urinary Incontinence

J. B. Sharma[1] · Karishma Thariani[1] · Rajesh Kumari[1] · Tanudeep Kaur[1] · Bharti Uppal[1] · Kavita Pandey[1] · Venus Dalal[1]

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Abstract

Background Stress urinary incontinence (SUI) is involuntary leakage of urine on raised intra- abdominal pressure which adversely affects quality of life usually requiring surgical treatment.

Methods This is a prospective study of efficacy, cure rates and complications of tension free transobturator tape (TOT) surgery on 85 women with SUI. Pre-operatively and 6 months post-operatively International consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) scores were calculated for all patients to know the severity of incontinence and efficacy of tape.

Results Mean age, parity, body mass index and mean duration of symptoms were 45.78 years, 2.68, 26.38 kg/m2 and 3.85 years, respectively. SUI was demonstrated in all cases on cough stress test and Bonney's test. Mean operative time, blood loss, post-operative analgesic injections, post- operative stay and post- operative catheterisation were 23.28 min, 45.50 ml, 1.2 injections, 1.2 days and 1.2 days. Various complications noted were excessive bleeding (3.52%), urinary retention (7.05%), urinary urgency (8.23%), urinary tract infection (2.35%), surgical site infection (1.17%), groin pain (28.23%) and mesh exposure (3.52%). At 6 months follow-up, the complete cure rate was 83.52% , partial cure rate was 11.76% and failure rate was found to be 4.70% whereas it was 79.16%, 12.0% and 8.33% respectively at 3 years follow up. 2 patients (2.35%) required burch colposuspension and 12 patients (14.11%) required pelvic floor exercises and duloxetine therapy for their symptoms. Mean pre- operative ICIQ-SF score reduced post- operatively (17.8 ± 4.67 to 2.71 ± 1.42) (p value = 0.001).

Conclusion Study demonstrates short and long-term efficacy and safety of TOT for surgical management of SUI.

Keywords Stress urinary incontinence (SUI) · Tension free transobturator tape (TOT) · International consultation on incontinence questionnaire – short form (ICIQ-SF score) · Cure rate

Introduction

Stress urinary incontinence (SUI) is involuntary leakage of urine due to raised intra-abdominal pressure by activities such as coughing, sneezing, laughing and other sporting activities [1, 2]. It has a world -wide prevalence of 30%, prevalence being 26.4% in U.S.A [1, 2]. Exact epidemiological data from India are scarce due to lack of good published studies and underreporting of the problem by the health care seekers. However, in some hospital-based surveys conducted in a tertiary level hospitals, the prevalence of urinary incontinence in India was found to be 21.8% out of which 73.8% was due to SUI [2]. This prevalence is lower than the reported worldwide prevalence. This could be largely because of unwillingness of Indian women to discuss this complaint due to embarrassment and shame and also because a large number of women consider incontinence to be a normal part of post-partum and age-related changes for which nothing can be done. Factors that may increase the risk of developing incontinence include obesity, increasing age, short interconception periods, high parity, manual labor,

J.B. Sharma: Professor, FRCOG, PhD, Karisma Thariani: Urogynaecology Fellow, MD, Rajesh Kumari: Associate Professor, MD, Tanudeep Kaur: Urogynaecology Fellow, MD, Bharti Uppal: Urogynaecology Fellow, MD, Kavita Pandey: Urogynaecology Fellow, MD, Venus Dalal: Senior resident, MD

✉ J. B. Sharma
jbsharma2000@gmail.com

[1] Department of Obstetrics and Gynecology, All India Institute of Medical Sciences, Room No. 3064A, III Rd Floor, Teaching block, New Delhi 110029, India

chronic obstructive pulmonary disease (COPD) and smoking [1, 2]. Child birth trauma can lead to muscle and ligament tears and injury to the supporting fascia and innervation of bladder and urethra leading to SUI. [1, 2].

Diagnosis of SUI is by good history taking, clinical examination and demonstration of leak by cough stress test, and Bonney's test which are performed with full bladder [1, 2]. Urodynamic studies may be useful for confirming the diagnosis and ruling out other conditions like detrusor overactivity and voiding dysfunction but are not routinely recommended due to cost effectiveness. [3, 4].

For mild to moderate, SUI, initial treatment is life style modification and other conservative measures like weight reduction, fluid and diet modifications and pelvic floor exercises [1, 5]. In some cases, drug treatment with Duloxetine may be started in the dose of 20–40 mg orally for 3–6 months [1, 5]. Vaginal oestrogens may be given for vaginal atrophy in post-menopausal women [6].

However, conservative treatments may not be effective in management of women with moderate to severe SUI. Many surgical procedures have been described for the management of SUI like retropubic colposuspension, midurethral slings (MUSs) and bulking agents [1, 2, 7–12]. Good quality evidence is available to suggest that mid urethral slings are safe and effective for the management of SUI when compared to other procedures [13–15]. The Cochrane review stated that irrespective of the route of tapes (retropubic or transobturator), they are highly effective in the short and medium term, and accruing evidence demonstrates their effectiveness in the long-term [16]. It also stated that there is no difference in the cure rates in transobturator tape passed medial to lateral opposed to that passed lateral to medial [16]. There is a lack of mid-term and long-term studies on effectiveness and adverse effects of transobturator tape not only from the western world but also from the Indian sub-continent [1, 2]. The Cochrane review illustrated the need to report long-term data to increase the evidence and provide insights into the long-term adverse effect profile of TOT. The aim of the present study was to observe the mid-term and long-term subjective and objective outcomes and any adverse effects of the transobturator tape inside-out technique for patients of pure SUI or mixed incontinence with predominant SUI.

Material and Methods

This was a combination of three prospective studies over 8 years period in a tertiary level referral hospital from January 2011 to January 2019 on 85 women with SUI diagnosed on history, clinical examination and International consultation on Incontinence Questionnaire – Short Form (ICIQ-SF). Ethical approval was taken from the Institutes Ethical Committee. The inclusion criteria were; women between 26 to 75 years of age with predominant SUI on clinical history, examination, ICIQ-SF and multichannel urodynamics in the absence of detrusor overactivity and voiding dysfunction and who were willing to participate in the study. Those women who were not willing to participate in the study or come for repeated follow-ups, those suffering with concomitant genital prolapse, predominant urge incontinence, previous failed surgery for incontinence, neurological disorders, bleeding disorders, uncontrolled diabetes mellitus, HIV and younger patients who had not completed their family were excluded from the study and were treated as per hospital protocol. Younger patients were initially put on conservative treatment and were not included in the study. We strictly followed the inclusion and exclusion criteria and thus the number of cases was slightly less.

Detailed history including symptoms, duration, obstetric history, medical history, drug history and past history was taken from all women. Detailed general physical and systemic examination including abdominal and neurological examination and local examination including per speculum and bimanual examination were done in all cases. Cough stress test and Bonney's test were done in all patients with full bladder. Baseline investigations including the complete blood count, liver function test, kidney function test, blood sugars, urine routine microscopy and culture were done in all patients. All the subjects underwent USG whole abdomen and pelvis to rule out any other co-existing pathology and evaluation of post void residual urine (PVR).

ICIQ-SF scores were calculated in all cases at admission. It was calculated by asking the patient how often she leaked, how much she leaked and asking her to rate on a scale of 0–10 how much did leaking of urine interfere with her everyday life. ICIQ-SF scores were calculated for all cases pre operatively and then 6 months post-operatively.

All patients underwent non-invasive uroflowmetry. Multichannel urodynamic testing was done only in selected cases where diagnosis was suspect or in patients who gave history suggestive of urgency or urgency urinary incontinence and voiding difficulties, but not in all cases due to financial and logistical constraints. All patients were counseled about various treatment options including conservative methods, Burch colposuspension and tension free transobturator tape procedure. A total of 85 women who were diagnosed to have predominant SUI (as mentioned above) and who underwent the tension free transobturator tape procedure were included in this study. We included patients with only SUI confirmed on history taking, clinical and urogynaecological examination, ICIQ score and confirmed by uroflowmetry or full urodynamics in selected cases.

Written informed consent was taken. All the surgeries were either done by or assisted by the first author using the inside-out approach after giving intravenous inj. Cefotaxime 1 gm and Inj. Metronidazole 500 mg. A 14 Fr per urethral

catheter (PUC) was placed before starting the procedure. A 1.5 cm longitudinal incision was given on the anterior vaginal wall sub-urethrally. Careful dissection of the para urethral and para vesical tissue was performed up to the ischiopubic ramus. Gynecare TVT- Abbrevo continence system (Ethicon Inc., Somerville, NJ, USA) was used in all cases (Figure 1). A specifically designed winged guide was inserted and held in place. Helical passer was inserted into the dissected tract over the winged guide (Fig. 2). Obturator membrane was pierced and exit point made 2 cm lateral to the inguinocrural fold at the level of 2 cm above the external urinary meatus. Same procedure was repeated on the other side. The tape was maintained under the urethra and tensioned just enough to allow the easy passage of a Kelly's clamp (Fig. 3). All the patients underwent a check cystoscopy post- operatively to rule out bladder and ureteric injury. Patients remained admitted overnight. Catheter was removed next morning, and the patients were discharged after they were able to void. PVR was checked after voiding, and voiding difficulty was defined as a PVR of more than 100 ml.

Patients were followed up at 1 week, 6 weeks and 6 months and then yearly for symptomatic relief and any complications. ICIQ-SF scores were calculated again at 6 months follow-up, and patients were examined for any demonstrable SUI on clinical examination.

Statistical Analysis

Data analysis was carried out, using statistical software SPSS IBM version 21.0. Descriptive measures—such as mean, standard deviation and range values—were calculated for continuous variables that were found to be approximate to the normal distribution. Median and interquartile range (IQR) values were calculated for skewed non-normal data. Categorical data were expressed as frequency and percent values. Changes in continuous variables from pre-operative to postoperative were tested, using a Student's t -paired test. A two-side probability of $p < 0.05$ was considered to be statistically significant.

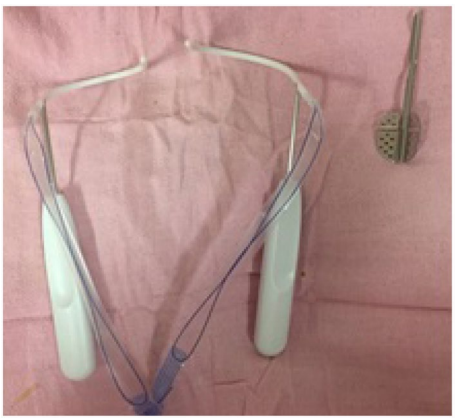

Fig. 1 Actual picture of Trans obturator tape (TVT- Abbrevo)

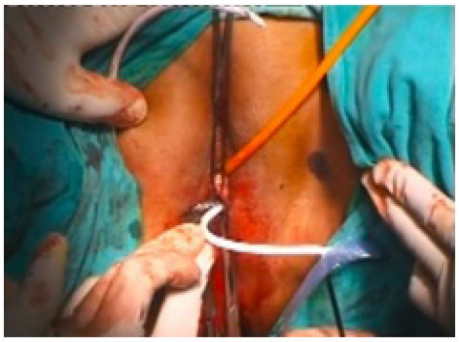

Fig. 2 TOT being inserted on the left side, helical passer being inserted into the tract over the winged guard

Results

A total of 85 women who underwent TOT procedure were enrolled in this prospective study. The characteristics of the patients is listed in table 1. The age ranged from 26 to 75 years with mean being 45.78 ± 11.25 years, parity ranged from 0 to 6 with mean being 2.68 ± 1.38, while body mass index ranged from 17.8 to 32.5 kg/m2 with mean being 26.38 ± 2.16 kg/m2. A total of 22 (25.88%) patients belonged to poor socio economic status, whereas 48 (56.47%) and 15 (17.64%) patients belonged to moderate and upper socio economic status, respectively. A total of 48 (56.47%) patients were post-menopausal. The symptoms, duration, past obstetric history and clinical examination findings are also given in table1.

All 85 (100%) patients complained of SUI with duration of SUI ranging from 0.6 to 6.5 years with mean being 3.85 ± 2.38 years. None of the patients had urgency urinary

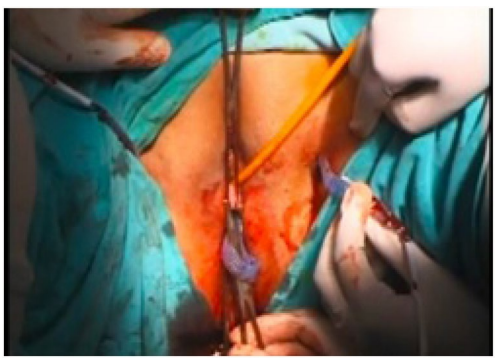

Fig. 3 Tensioning of the tape being done after insertion

Table 1 Characteristics of patients, symptomatology and clinical examination findings. ($n=85$)

S. No.	Parameter	Number	Range	Mean	SD	Percentage
1	Age (years)		26- 75 years	45.78	11.25	
2.	Parity		0-6	2.6	1.38	
3.	Body mass index(Kg/m^2)		17.8- 32.5	26.38	2.16	
4	*Socio economic status*					
	Lower	22				25.88
	Middle	48				56.47
	Upper	15				17.64
5.	Postmenopausal status	48				56.47
6.	*Symptoms*					
	1. SUI	85				100
	2. UUI (Urgency Urinary Incontinence)	0				0
	3. Associated genital prolapse Duration (in years)	0	0.6–6.5	3.85	2.38	0
7.	*Past obstetric history*					
	Normal vaginal delivery	69				81.17
	Instrumental delivery	12				14.11
	Cesarean section	4				4.70
8.	*Examination findings*					
	Cough stress test	85				100
	Bonney,s test	85				100

incontinence or associated genital prolapse, all such patients had been excluded from the study. In the past obstetric history, a total of 69 (81.17%) patients had vaginal delivery while 12 patients (14.11%) had history of instrumental delivery while only 4 (4.70%) patients had one or more cesarean section. Cough stress test and Bonney's test were present in all 85 (100%) patients.

The operative details of the patients are shown in table 2. The range of operative time was 18–40 min with the mean being 23.38 ± 5.87 min. Amount of blood loss ranged from 15 to 150 ml with mean being 45.50 ± 12.85 ml. The need

Table 2 Operative details of tension free transobturator tape procedure ($n=85$)

S. No	Parameter	Number	Range	Mean	SD	Percentage
1	Operative time (in minutes)		18–40	23.28	5.87	
2	Blood loss (in ml)		15–150	45.50	12.85	
3	Number of analgesic injections in post- operative period		1–3	1.2	0.4	
4	Post-operative hospital stay		1–4	1.2	0.38	
5	Post-operative catheterization (in days)		1–5	1.2	0.48	
6	*Complications:*					
	1. Excessive blood loss (> 100 ml)	3				3.52
	2. Urinary retention	6				7.05
	3. Urgency	7				8.23
	4. Urinary tract infection	2				2.35
	5. Surgical site infection	1				1.17
	Groin pain					
	< 1 week	24				28.23
	Persistent	4				4.70
	Mesh complications	3				3.52
7	*Surgery for complication*					
	Local vaginal mesh excision	2				2.35
	Cystoscopic excision of mesh from bladder neck	1				1.16

of analgesic injections ranged from 1 to 3 with mean being 1.2 ± 0.4. Post-operative hospital stay ranged from 1 to 4 days with the mean being 1.2 ± 0.38 days. While post-operative catheterization ranged from 1 to 5 days with the mean being 1.2 ± 0.48 days. Various per-operative and post-operative complications are also shown in table 2. The complications were excessive blood loss > 100 ml (3.52%), urinary retention (7.05%), urinary urgency (8.23%), urinary tract infection (2.35%), surgical site infection (1.17%), groin pain in the first week (28.23%), persistent groin pain (4.70%) and mesh complications in 3 patients (3.52%). In two patients, there was partial mesh erosion in the vagina with the patients presenting with vaginal pain, vaginal discharge and dyspareunia. On examination under anesthesia, the mesh was seen partially extruding in the vagina. The exposed mesh was removed under general anesthesia and vaginal mucosa was sutured over the defect. One patient had mesh perforation in the bladder neck presenting with slight hematuria and vaginal pain. It was managed by cystoscopic excision of mesh. All the 3 patients remained continent thereafter.

The success rate, pre- operative ICIQ-SF scores and post- operative ICIQ-SF scores are shown in Table 3. All 85 patients had one year follow-up whereas 48 (56.4%) had 3 years follow up. At 6 months complete cure was seen in 71 (83.52%) cases while partial cure was seen in 10 (11.76%) with 4 (4.70%) failures. Hence at 6 months the success rate was very high with only 4.70% failure rate. While at 3 years follow-up complete cure was seen in 38 (79.16%) cases, partial cure in 6 (12.5%) cases and failure in 4 (8.33%) cases. The success rate dropped slightly at 3 years with failure rate of 8.33% and partial cure rate of 12.5%. A total of 2 patients (2.35%) required a second procedure (Burch Colposuspension was done), and 12 patients (14.11%) required further treatment in the form of life style changes, fluid and diet modifications, pelvic floor exercises and Duloxetine therapy for residual SUI. Pre-operative ICIQ-SF score ranged from 16 to 20 with the mean being 17.80 ± 4.67 while post- operative ICIQ-SF score ranged from 0 to 18 with the mean being 2.71 ± 1.42. The decrease in ICIQ-SF score was significant ($p = 0.001$).

Hence, tension free transobturator tape was highly effective in surgical management of SUI in the present study.

Discussion

Stress urinary incontinence (SUI) has a high prevalence globally and is up to 21.8% in India where limited studies are available. [1, 2] It is seen in obese and parous women with chronic smoking and COPD being other risk factors. [1, 2] In the present study, mean BMI was 26.38 ± 2.16 kg/m2, and mean parity was 2.68, and history of vaginal delivery was present in 95.3% (81.17% spontaneous vaginal delivery, 14.11% instrumental delivery).

Diagnosis of SUI in the present study was made from history taking, clinical examination with demonstration of SUI on cough stress test. ICIQ-SF was filled in all the cases prior to surgery and again at 6 months after surgery. Urodynamic studies, though an objective method to diagnose SUI and an effective method to rule out detrusor overactivity are not recommended routinely due to high cost, non-availability of equipment in many places especially peripheral hospitals and need of expertise to perform the test [2–4]. In the present study, the pre- operative ICIQ-SF score ranged from 16 to 20 with mean being 17.8 ± 4.67. After the TOT procedure at 6 months follow-up, ICIQ-SF score ranged from 0 to 18 with the mean being 2.71 ± 1.42. The decrease in ICIQ-SF score was highly significant ($p = 0.001$) suggesting that TOT was highly effective in reducing the symptoms of SUI with very high cure rates.

Table 3 Pre-operative and post-operative ICIQ-SF score and success rate ($n = 85$)

S. No	Parameter	Number	Range	Mean	SD	Percentage
1	*Cure rate at 6 months*					
	Complete cure	71				83.52
	Partial cure	10				11.76
	Failure	4				4.70
2	*Cure rate at 3 years (n = 48)*					
	Complete cure	38				79.16
	Partial cure	6				12.5
	Failure	4				8.33
3	Pre-operative ICIQ-SF score		16–20	17.80	4.67	
4	Post-operative ICIQ-SF score		0–18	2.71	1.42	
5	Need for second surgical procedure for SUI	2				2.35
6	Need of conservative therapy/Duloxetine therapy	12				14.11

p value for pre-operative and post -operative ICIQ-SF-score 0.001 (Highly significant)

All patients were called for follow-up on yearly basis. On short-term follow-up in all 85 cases, complete cure rate was high (83.52%) while partial cure was seen in 11.76% cases with only 4 (4.7%) failures. On long-term follow-up of more than 3 years in 48 patients (other patients operated in last 3 years only), there was complete cure rate of 79.16%, partial cure rate of 12.5% and failure in 4 cases (8.33%). Our success rates are in line with the report from Lipais et al. [13], who assessed 74 women 4 years after TVT-O with 81% patient- reported success and 82% objective cure. Karmakar et al. reported a subjective cure rate of 71.6% at 9 years.

Only 2 patients (2.35%) required a second procedure (Burch Colposuspension was done), and 12 patients (14.11%) required further treatment in the form of life style changes, fluid and diet modifications, pelvic floor exercises and duloxetine therapy for residual SUI.

In the present study, TOT was found to be a minimally invasive procedure with mean operative time of only 23.38 min, mean blood loss of 45.50 ml, mean hospital stay of only 1.2 days and mean number of days requiring catheterisation of only 1.2 days. The complication rates were also less with excessive blood loss > 100 ml seen in 3.52%, urinary retention in 7.05%, urinary urgency in 8.23%, urinary tract infection in 2.35%, surgical site infection in 1.17%, groin pain in the 1st week in 28.23%) and mesh complications in 3.52% with two women requiring local vaginal excision of eroded mesh and one requiring cystoscopic excision of mesh from bladder neck.

The results of the present study are similar to many other studies from other countries as there is scarcity of data from the Indian subcontinent. [8, 12–14, 16–21].

Imamura et al.[22]in their systematic review and network meta-analysis of various randomized controlled trials observed Burch's colposuspension, mid-urethral slings and rectus fascial slings to be equally effective for SUI.

There has been a recent scare of adverse effects of synthetic mesh in western countries especially mesh erosion though the incidence is rare. [23–25] There has been a lot of adverse publicity about complications associated with synthetic mesh in western countries which has led to sudden ban on both manufacturing and use of mesh in certain countries like United Kingdom e.tc. In the present study, we observed a mesh complication rate of 3.52% (3), this was similar to the mesh erosion rates reported by Ulrich and Karmakar et al. [13, 26]. This emphasises the fact that surgeons should be vigilant about the possibility of mesh exposure/erosion during patient follow up.

Two of the 3 patients who had mesh complications, had partial vaginal exposure of mesh which was managed by local excision of the mesh from the vagina. One patient had mesh perforation in the bladder neck which was managed by cystoscopic excision of mesh. All the patients remained continent thereafter.

ICIQ-SF score was used in the present study to assess the effect of TOT. The score decreased significantly 6 months after the procedure and can be used to assess the efficacy of surgical procedure. Nystometal et al. in their study of performing ICIQ before and after treatment of SUI found it very useful and reproducible.[27].

Our study is one of the few available studies on short-term and long-term follow-up of transobturator tape from our country. The use of standardised evaluation techniques and questionnaires for evaluation and long-term follow-up is one of the strengths of our study. One of the limitations of our study is its relatively small sample size. The reason for this is our strict adherence to the inclusion and exclusion criteria. We enrolled women with only SUI or predominantly SUI after ruling out detrusor overactivity and voiding dysfunction on urodynamics in doubtful cases. Moreover, we also excluded young patients who had not completed their family and patients with uncontrolled or severe co-morbidities.

Conclusion: Tension free obturator tape is an effective and safe surgical treatment modality for SUI. However, large multicentre studies are recommended before its routine use in clinical practice.

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Compliance with Ethical Standards

Ethical Approval All procedures followed were in accordance with the Ethical Standard of the Responsible Committee on Human Experimentation and with the Declaration of HELSINKI of 1975, as revised in 2008. Informed consent was obtained from the patient. The study was conducted in department of Obstetrics and Gynecology in collaboration with department of Microbiology and Department of Medicine. The work is designed and was performed after taking ethical clearance from the Institutional ethical committee. Permission was taken by the institute's ethics committee.

Conflict of interest All the authors declare no conflict of interest. The authors have no financial disclosures to make**.**

Informed Consent Informed consent was taken from all patients for being involved in the study.

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About the Author

Dr JB Sharma, MD, DNB, FRCOG (London), PhD, MFFP FAMS, FICOG FIMSA, is a Professor in Department of Obstetrics and Gynecology, All India Institute of Medical Sciences, New Delhi. Before that he has worked as Professor in Maulana Azad Medical College, New Delhi. He has over 400 publications and has 150 peer reviewed articles in various journals of national and international repute. He is currently Editor in chief of Indian Obstetrics and Gynecology, Journal of Paediatrics, Obstetrics and Gynecology (JPOG) and Associate Editor of International Journal of Gynecology and Obstetrics, India. He has edited three books and has been awarded many times by Royal College of Obstetricians and Gynaecologists (RCOG), London. His special areas of interest include female genital tuberculosis, urogynecology and anemia in pregnancy.