

Original Article

An Evaluation of Use of Trans-Obturator Tape (TOT) Sling Procedure in the Current Surgical Management of Female Stress Urinary Incontinence

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Abstract

Objective: To assess the role of TOT sling procedure in current surgical management of female Stress Urinary Incontinence (SUI) in terms of post-operative results, cost effectiveness, patient acceptance and complications.

Method: From June 2006 to September 2008, 30 patients of SUI were treated surgically by TOT-sling procedure. Pre-operatively the patients were evaluated by thorough history taking, clinical examination and different diagnostic test depending upon the individual clinical scenario. Patients were explained in their own language the nature of procedure and the principle behind it. Any complication(s) (intra/postoperative) were noted. After discharging the patients they were followed up by at least 3 visits (follow-up visits) at 1, 3 & 6 month interval. Any complications of the procedure and patient acceptance were evaluated at each follow-up.

Results: The mean age of the total patients (n=30) was 39.5 yrs and 28 (93.33%) were multiparous. Involuntary loss of urine on straining was the most common complaint present in 25 (83.33%) patients and 22 (73.33%) patients were having duration of symptoms less than 3 yrs. 9 (30%) patients were having mild cystocele pre-operatively which resolved after surgery. All the 30 (100%) patients were continent post-operatively while 7 (23.33%) were having lower urinary tract symptoms (LUTS). No major intra/post-operative complication was seen but, urgency, dysuria, fever and haematuria was seen post-operatively which resolved after few days. The operative time was 24 ± 3.8 minutes and catheter was removed on 2.7 ± 1.7 days post-operatively. Hospital stay was 6 ± 2.4 days (3 – 11) and approx. Cost of the treatment was $\text{Rs}3253 \pm 360$ (2700,3900).

Conclusion: TOT Sling procedure is currently the Gold Standard for management of female SUI. It is very important to diagnose SUI and rule out other causes of incontinence because only the former one (Genuine SUI) is improved by TOT sling and other types may be even worsened by this procedure.

Key Words: Assessment, TOT Sling, Efficacy, Post-op results, Cost effectiveness, Patient acceptance, Complications.

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Introduction

The international continence society (ICS) defines the symptom of urinary incontinence as “*the complaint of any involuntary loss of urine*”^[1] Stress urinary incontinence (SUI) has an observed prevalence of between 4% and 35%^[5] Stress urinary incontinence (SUI) is the involuntary leakage of urine during exertion (exercise or movements such as coughing, sneezing, and laughing). SUI is often seen in women after middle age (with repeated pregnancies and vaginal deliveries)^[3] In genuine stress incontinence, the assumption is that the intrinsic structure sphincter itself is intact and normal. However, it loses efficiency because of excessive mobility and loss of support. Thus the anatomic feature of genuine SUI is consistently that of hypermobility or lowering of the position of the vesicourethral segment or a combination of two factors. Numerous risk factors for SUI have been identified. Aging, obesity, and smoking appear to have consistent causal relationships with the condition, whereas the roles of pregnancy and childbirth remain controversial.^[5] Post menopausal atrophy also causes stress incontinence and urethral syndrome.^[8]

Diagnostic procedures for stress urinary incontinence are as:

- Abdominal Ultrasound
- Uroflowmetry
- Cystogram
- Filling cystometrogram (CMG)
- Abdominal leak point pressure (ALPP)
- Videourodynamics

Treatment of SUI consists of conservative, pelvic floor muscle training (PFMT), pharmacologic treatment (Imipramine, Duloxetine, Estrogens). The principal treatment of SUI is proper suspension and support of the vesico-urethral segment in a normal position. There were numerous approaches in the past to restore the normal position and providing adequate support, some vaginal and some supra-pubic. Then can tension free vaginal tape (TVT) in mid to late 1990s. But TVT was associated with vascular injuries and bowel perforations. In order to avoid these complications delorme^[2] described the trans-obturator tape (TOT).

Methods

Our study was a prospective study conducted on 30 patients of clinically and investigation proved SUI, who were managed in the department of urology Sher-i-Kashmir Institute of Medical Sciences Srinagar, Kashmir with effect from June 2006 to September 2008. The patients underwent a thorough history taking, general physical examination, systemic and local examination. All baseline and special/specific investigations (urodynamic study, lateral cystogram and cysto-pan endoscopy), were conducted on the patients depending upon each patients clinical scenario and the need for the specific investigation. TOT procedure was performed in all these patients. The final data was analyzed as per the standard statistical method. All patients undergoing TOT sling procedure were informed about the ease, simplicity and safety of the procedure compared to other previous surgeries and complications associated with those. All the patients in our study have TOT sling procedure performed under spinal anaesthesia,

though general or local anaesthesia can also be used. The patients were placed in the modified lithotomy position with the feet placed squarely in the boots of the Allen stirrups. Patients were catheterized with a Foleys self retaining catheter to empty the bladder. After giving spinal anaesthesia patient is placed in modified lithotomy position and parts are draped. Two vertical lines are drawn on each side of the labial fold. At the base of the clitoris a horizontal line is drawn. The points at which these lines intersect each other corresponds to the obturator membranes and subsequent entry of the TOT needle through the obturator foramen. After retracting the labial fold an incision of 1.5 cm is made 1 cm proximal to the external urethral meatus in the anterior vaginal wall. Just behind urethra lateral dissection is made on both sides elevating the vaginal wall and taking care not to injure urethra and bladder. Any bleeding can be controlled by pressure only. Ischio pubic rami is felt with the index finger and tunneler device (TOT needle) is introduced from outside in with finger acting as a guide. Tip of the TOT needle is brought out from the incision in the vaginal wall and threads of the TOT tape are fed through the eye of the TOT needle. TOT needle is withdrawn through the same path taking along with it one end of the TOT tape through the incision in groin. Same procedure is repeated on the other side also. The urethral segment is correctly placed in relation to the second part of the urethra maintaining the distance of one instrument thickness between the tape and the urethra. Both ends of the TOT tape are cut just beneath the skin incisions in the groin. ASD is applied on skin incisions in groin. Vaginal cavity is packed with betadine soaked gauze, which is to be removed on 1st postoperative day. Patients were advised to start normal daily routine activities after discharge from hospital, to maintain local hygiene, to avoid straining and lifting heavy weights for 3 – 4 weeks, to avoid sexual activity for 4 – 6 weeks. In our studied patients the mean followup was 9 months ranging from 3 – 36 months. After the patients were discharged from the institute, they were followed up by at least three visits (follow-up visits) at 1 month, 3 month, and 6 month. Cost effectiveness of the procedure was noted. Observations were made regarding the post operative results assessed by clinical examination, cough stress test (full bladder), uroflowmetry and post void residual urine volume. Any complications of the procedure were noted at each visit. The patient acceptance of the procedure was also noted at each interaction with the patient and graded as excellent, good, average and poor.

Observations

The total number of patients evaluated in our study was 30. The age of the patients was in the range of 25 to 53 years (39.5 ± 7.5 years)

Table 1. Age range of patients (n = 30)

Age (yrs)	N	% age
≤ 30	4	13.3
31 – 40	13	43.3
>40	13	43.3
Mean ± SD	39.5 ± 7.5 (23 – 53)	

All the patients admitted were married and having issues. The distribution of parity can be seen below in Table 2.

Table 2. Distribution parity of patients (n = 30)

Parity	N	% age
<2	2	6.66
2 – 4	25	83.33
>4	3	10.0

Involuntary loss of urine on straining was present in 25 (83.33%) patients out of 30 (n = 30). After admission, patients were evaluated by different tests to diagnose stress urinary incontinence and rule out other causes of incontinence. The results are summarized in table 3 below.

Table 3. Investigations in studied patients

Investigation	Result	N	% age
USG abdomen	Normal	27	90
	*Abnormal	3	10
Lateral cystogram	Normal	14	46.77
	**Abnormal	16	53.33
Urodynamic study	***Abnormal	9	30
	Not done	21	70
Cysto-pan endoscopy	Normal	15	50
	****Abnormal	9	30
	Not done	6	20

* Post void residual urine (PVRU) volume > 100 ml.

** Loss of posterior vesicourethral angle.

*** Low abdominal leak point pressure (ALPP).

Decreased functional urethral length

Low urethral closure pressure.

**** Mild cystocele.

Preoperatively all the patients had clinically proven SUI. Postoperatively Foleys catheters were removed to see whether the patients were continent or not. Postoperative results of all the patients who were subjected to TOT sling procedure are briefed in table 4.

Table 4. Post operative results

Result	N	% age
Fully continent	30	100
Mild symptoms (LUTS)	7	23.3
Poor results (incontinent)	0	0

After the catheter removal there were no major postoperative complications seen in TOT sling procedure. The minor complications associated with the procedure which then gradually subsided over few days are summarized in Table 5.

Table 5. Post operative complications

Complication	N	% age
Urgency	9	30
Dysuria	6	20
Fever	3	10
Haematuria	2	6.6

After the patients were discharged from the Institute they were followed up by at least 3 visits (post-op) at 1 month, 3 month and 6 month. Observations were made regarding post – op complications. The patient acceptance of the procedure was also noted at each interaction with the patient and graded as excellent, good, average and poor. Table 6 shows the satisfaction of different patients at follow up.

Table 6. Patient satisfaction

Satisfaction	N	% age
Excellent	22	73.33
Good	6	20.0
Average	2	6.66
Poor	0	0

Discussion

In our study 28 (93.33%) patients were multiparous (more than 1 delivery) and 26 (86.66%) patients were above the age of 30 years. 25 (83.33%) patients were having the chief complaint of involuntary loss of urine on straining and 22 (73.33%) patients were having duration of symptoms less than 3 years. 9 (30%) patients were having mild cystocele preoperatively which was resolved after TOT sling procedure. In our study the mean follow up was 9 months ranging from 3 – 26 months. Of the 30 patients who were operated (undergone TOT sling procedure) all 30 (100%) patients were continent postoperatively after removal of Foleys catheter, 7 (23.3%) had mild lower urinary tract symptoms (LUTS). No intraoperative complication or injury occurred in our studied patients. Our results are comparable and even better than the study [4] in which the mean follow up was 16 months (range 12 – 33). Of the total patients who had undergone TOT sling procedure in this study 79% were completely cured (continent), 13% improved, and in 7% patients the surgical procedure failed. 2.4% patients had postoperative urinary retention in this study where as no procedure failed in our study and none of our patient had postoperative urinary retention. The operative time in our study is 34.0 ± 33.8 minutes (30 – 40). When compared to a study [7] the operative time in that study for the TOT procedure was 15 minutes, but, only 92% were shown to have recovered from stress incontinence within a month, 3% improved and 5% had surgical treatment failure. But, in our study all the patients were continent at discharge and surgical failure rate was 0. In addition in this study [7] 3 intraoperative complications resulting in bladder injury were seen where as no intraoperative complication or injury occurred in our study. On follow up visits the patients acceptance of the procedure was noted at each interaction with the patient and graded as excellent, good, average and poor. Although, all 30 patients were continent when asked whether they would submit to this procedure again and recommend/ suggest this procedure to other patients of SUI 28 (93.33%) patients answered yes. In our study the hospital stay was 6 ± 2.4 days (3, 11) and approximate cost of the treatment (including the TOT tape, antibiotics and hospital charges) was rupees 3253 ± 360 (2700, 3900). When compared to a cross sectional study[6] to estimate cost of routine care for female urinary incontinence, health related quality of life and willingness to pay for incontinence improvement they have to pay rupees \$900 annually (Rupees 40,500 approximately) for

incontinence routine care which is more than 10 times the cost of TOT sling procedure in our patients.

Conclusion

SUI is more common in multiparous (93.33%) women than nulliparous, It is very important to diagnose SUI and rule out other causes of incontinence as only the former one (Genuine SUI) which is associated with urethral hypermobility is improved by TOT sling and other types may be even worsened by this procedure. *TRANSOBTURATOR TAPE* (TOT) sling procedure is the gold standard for current surgical management of female stress urinary incontinence. TOT is simple, minimally invasive and cost effective procedure for current surgical management for female stress urinary incontinence. When performed after proper training TOT sling procedure has 100% success rate (continence) and is associated with only minor postoperative complications which resolves within few days.

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