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Two-year follow-up of the transobturator vaginal tape procedure for treatment of female stress urinary incontinence

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Abstract
Objective: To evaluate the long-term cure rates and perioperative and post-operative complication rates after treatment of female urinary stress incontinence with the minimally invasive transobturator tape procedure.
Methods: Between 1/01/2007 and 31/12/2008, a transobturator vaginal tape was inserted in 30 women with clinical evidence of SUI. Preoperative evaluation included complete history, physical examination, urine analysis and a questionnaire assessing the subjective perception of the women on their continence status.
Results: Thirty consecutive women who fulfilled the inclusion criteria underwent TOT procedure. The mean age was 55years (range 41-60). The follow up time was of 2 years**.** One patient was lost to follow-up after 12 months and 2 women did not come for the 24-month evaluation. Our results demonstrate a 93.3% cure or improvement rate after 6 months, 93.1% after 12 months and 92.85% after 24 months. Mesh erosion was seen in 2 women (6.6%), whereas rate of urinary tract infection and transient retention of urine was 3.3% each.
Conclusion: The transobturator vaginal tape is a safe, easy and efficient surgical procedure for the treatment of female SUI.

Keywords: TOT, female SUI

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) is involuntary urine leakage on effort or exertion (e.g., on sneezing or coughing) without rise in detrusor pressure. SUI can have a significant negative impact on the quality of life (QOL) of not only those who suffer from the condition, but also potentially on those friends and family members whose lives and activities may also be limited.
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.
Midurethral slings are becoming the first-line surgical treatment for stress urinary incontinence (SUI) in women. The midurethral sling provides continence by creating functional kinking of the midurethra during increased intra-abdominal pressure and the associated rotational descent of the bladder neck and proximal urethra.
In 2001, Delorme described a new method of inserting the tape, which passes through the obturator foramen. The transobturator approach (TOT) for sub-urethral tension-free vaginal tapes has since gained wide popularity in the surgical treatment of SUI. This approach has a theoretical advantage of less obstruction and postoperative voiding dysfunction, as well as avoiding some of the complications, such as bladder perforation and bowel perforation [2].
SUI is often seen in women after middle age (with repeated pregnancies and vaginal deliveries) [3]. Post menopausal atrophy also causes stress incontinence and urethral syndrome [4]. Stress urinary incontinence (SUI) has an observed prevalence of between 4% and 35% [5].

Method
All female women with SUI undergoing TOT from January 2007 to December 2008 were prospectively evaluated. The procedure was done under general or regional anesthesia.

All women were required to have a minimal follow-up of 24 months. Women with urge incontinence or pure intrinsic sphincter deficiency were excluded. All women were evaluated with history, physical examination including pelvic examination, urinalysis and a questionnaire assessing the subjective perception of the women on their continence status. The history of SUI or the demonstration of SUI during physical examination constituted an indication for the TOT procedure.

The women who presented with pelvic organ prolapse and SUI underwent vaginal total hysterectomy and TOT procedure. Both procedures were carried out as if done differently with separate vaginal incisions. A pair of surgical grade stainless needles coated with ziroconium nitride, handles of Delrium, eye was at the tip of the needle for inserting & locking the sling, reuseable and autoclavable, of LOTUS surgical company were used. The slings used were made of polypropylene, 34 cms long, width of 1.8 cms, ends of the slings were tapered & had slit for locking in the needle eye and slings were self locking, and it was also manufactured by LOTUS surgical company.

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.

We defined the cure of SUI as the disappearance of subjective and objective SUI after 12 months and negative cough test on physical examination after 24 months. Any complications of the procedure were noted at each visit.

Observations

Thirty consecutive women who fulfilled the inclusion criteria underwent TOT procedure. Table 1 shows that the mean age in study population was 55years (range 41-60). The follow up time was of 2 years. The mean duration of incontinence symptoms was of 14 months.

Table 1: Subject characteristics

	Value
Mean Age (years)	55 (41- 60)
Parity (mean)	2 (0-4)
Menopausal at time of surgery (%)	48.8 %
Duration of incontinence symptoms (months)	14 (3-24)
Follow up time (months)	24

Table 2 depicts that cure rate after 6 months was 93.33%, after 1 year was 93.1 % and after 2 years it was 92.85%. Failure rate was 3.3%. The women who didn't improve after 1 year were offered revision sugery, but they were not ready.

Table 2: Cure Rate after 1 year and 2 years

	Cured	**Improved**	**Failed**
After 6 months	28 (93.3%)	1 (3.3%)	1(3.3%)
After 1 year	27 (93.1%)	1 (3.3%)	1 (3.3%)
After 2 years	26 (92.85%)	1 (3.3%)	1 (3.3%)

Table 3 shows that most common complication was mesh erosion (6.6%), followed by transient retention of urine and urinary tract infection (3.3%). 1 procedure failed in our study and our 1 patient had postoperative urinary retention.

Table 3: Complications incurred with TOT

Perioperative & postoperative complications	**N %**
Excessive bleeding	1(3.3%)
Bladder injury	0
Lateral vaginal injury	0
Urethral injury	0
Mesh erosion	2 (6.6%)
Urinary tract infection	1 (3.3%)
De novo urgency	0
Transient retention	1 (3.3%)

Table 4 shows that 12 women (40%) presented with pelvic organ prolapse associated with SUI, in whom vaginal total hysterectomy with anterior repair and TOT procedure were done. 60% women presented with only SUI, in whom only TOT procedure was done.

Table 4: Total number of pelvic organ prolapse in study population

S	**SUI with Pelvic organ prolapsed**	**SUI without Pelvic Organ prolapsed**
Total no. of women	12 (40%)	18 (60%)

Discussion

The mean age in study population was 55years (range 41-60). The most common complication was mesh erosion (6.6%), followed by transient retention of urine and urinary tract infection (3.3%). In a study conducted by Edoardo Tartaglia *et al* none of the 32 women had any surgical complication, postoperative pain or blood loss greater than 100 cc. Some minor complications were recorded and the sling eroded in 1 case. Urinary continence was achieved in all patients after surgery and at assessments 12 to 18 months later. All patients confirmed immediate satisfaction with continence and pain on the questionnaire [6]. Our results are comparable and even better

than the study [7] 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 1 procedure failed in our study and our 1 patient had postoperative urinary retention. When compared to a study [8], 92% were shown to have recovered from stress incontinence within a month, 3% improved and 5% had surgical treatment failure. But, in our study surgical failure rate was 3.3%. In addition in this study [8] 3 intraoperative complications resulting in bladder injury were seen where as in our study there was excessive bleeding intraoperatively in 1 patient, 1 patient developed UTI, 1 patient had urinary retention post-operatively and in 2 cases mesh eroded.

Conclusion

The transobturator approach is an effective treatment of SUI with low morbidity. Thus far, we have enough data to support the use of the transobturator approach as a good alternative to the retropubic access. 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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