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TRANSOBTURATOR TENSION FREE SLING OPERATION FOR FEMALE GENUINE STRESS INCONTINENCE - OUR EXPERIENCE

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ABSTRACT: OBJECTIVES: 1. To evaluate the effectiveness of Trans-Obturator vaginal tape in the treatment of genuine female urinary stress incontinence. 2. To analyze functional results and quality of life after 12 months follow up. **DESIGN:** Prospective Observational study. **METHODS:** 25 women with clinical and urodynamic features of genuine stress incontinence fulfilling the inclusion and exclusion criteria were enrolled in this study and underwent TOT operation. The follow-up was done upto 12 months subjectively by UDI-6 and objectively by UDS and physical examination. Chi square test, Wilcoxon matched pair test was used for statistical analysis. A value was considered statistically significant at $p < 0.05$. **RESULTS:** Our objective assessment demonstrated 100% cure rate after 12 months. However, the subjective assessment using the UDI-6 demonstrated 90% cure or improvement rate after 12 months. **CONCLUSION:** The outside to in Trans-Obturator approach is a very effective treatment of SUI with low morbidity.

KEYWORDS: GSI (Genuine stress incontinence), TOT (Trans obturator tape), UDI-6 (Urinary distress inventory-6), UDS (Urodynamic study), SUI (Stress urinary incontinence).

INTRODUCTION: Stress urinary incontinence (SUI) is defined as involuntary urine leakage on effort or exertion (e.g., on sneezing or coughing) without rise in detrusor pressure.¹ Female urinary incontinence is a common problem and its prevalence increased with age.² The most usual type of UI is Stress Urinary Incontinence (SUI). SUI has a significant impact on the quality of life for many women, although estimate of prevalence vary widely due to inconsistency lies in the definition of SUI and differences in population studied. Hampel et al., in a large meta-analysis in 1997 and then in 2004 reported an estimated prevalence for urinary incontinence of 30% in women aged 30-60 years, with approximately half of the cases attributed to SUI.^{2,3} Conservatively treatment options, including pelvic floor exercise, physiotherapy, lifestyle changes and medication, can be helpful in mild cases, but the treatment of moderate to severe SUI symptoms, however often requires operative means. Traditional operation alternatives, including open colposuspension and suprapubic slings, are very invasive procedures associated with many complications, where the long term results of less invasive operations like needle colposuspension procedures, have poor. Although retropubic urethropexy has been widely used and is very effective, the newer midurethral, tension free sling procedures are very popular, effective and easier to perform. Tension free slings are surgical procedures using a polypropylene mesh to support the midurethra without tension, a technique first described by Ulmsten et al. The original technique used a retropubic approach, but the transobturator approach, as described by Delorme later in year 2001 is becoming the most common tension free sling technique performed worldwide for primary SUI.⁴⁻⁶

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METHODS AND MATERIALS: This is a prospective study conducted in Calcutta National Medical College and Hospital from Nov 2011 to Oct 2012. The patients were selected after taking proper history of leakage of urine on stress, Pad test and clinical examination including stress test, Bonney's test and also pelvic examination, urine analysis, urodynamic studies including filling and voiding cystometry and pressure flow studies, leak point pressure (LPP). Patients with urge incontinence or mixed incontinence or pure intrinsic sphincter deficiency were not included in the study. The history of SUI or demonstration of SUI during physical examination or urodynamic studies constituted the indication for the TOT procedure, in which two tiny incisions are made in the skin just inside the upper thigh (labio-crural fold) at the level of glans clitoris and another small longitudinal incision over the vagina just beneath the mid urethra. A small tunnel is opened by gentle dissection on each side of the urethra, after which a specially designed instrument is used to position the tape under the urethra up to the two other incisions through obturator foramen from outside to inside to place the sling suburethrally under regional anesthesia. The tape will rest completely tension free under the urethra like a hammock, supporting it during straining so that there is no leakage of urine. The cough test – sometimes the position of the tape is checked with a cough test, the bladder is filled by the surgeon, you will be asked to cough to see if any leakage occurs, and the tape will then be repositioned until no leakage is seen with coughing. The tape ends are trimmed to fit just under the skin. The tiny incisions are sutured with dissolvable stitches. A catheter may be required until the anesthetic block wears off, but not always. The operation is covered with antibiotics. All patients were required a minimal follow up done at 6 months and 12 months interval subjectively by UDI-6 and objectively by UDS and physical examination. We defined the cure of SUI as the disappearance of subjective and objective SUI using UDI-6 and urodynamic study and negative cough test on physical examination. Improvement of SUI was objectively defined as a decrease in leakage using the pad weight test and subjectively as a decrease in the UDI-6 score.

Chi square test, paired t test was used for statistical analysis. Per-operative and post-operative complications were also taken into account.

RESULTS AND ANALYSIS: 25 women were recruited in this study who fulfilled the inclusion criteria and underwent TOT procedure. The mean age was 50 years (range 35-61) and minimal follow up was one year. The mean operative time was 35 +/- 5 minutes (range 30-45 min), with an average amount of bleeding 75 cc ± 25 cc.

Age group (years)	No (n=25)
30-40	2
41-50	10
>50	13

Table 1: Distribution of patients according to age

P value: Significant (0.02)

As summarized in Table 1, stress urinary incontinence is more pronounced as age of the female increased and which is statistically significant in higher age group.

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Parity	No (n=25)
P ₁	2
P ₂	9
≥P ₃	19

Table 2: Distribution of patients according to parity

P value: Significant (0.01)

As summarized in Table 2, stress urinary incontinence is more pronounced as the parity of the female increased and which is statistically significant in higher parity group.

BMI	No (n=25)
19-24.9	10
25-29.9	12
≥30	3

Table 3: Distribution of patients according to BMI

P value: Not significant (0.06)

As summarized in Table 3, stress urinary incontinence is more pronounced in overweight patient (BMI 25-29.9) and there is no relationship of SUI with BMI in this study group and it is not statistically significant.

Mode of Delivery	No (n=25)
VD+ Forceps	17
VD+ LSCS	4
LSCS	4

Table 4: Distribution of patients according to mode of delivery

P value: Significant (0.001)

As summarized in Table 4, stress urinary incontinence is more pronounced in those female had history of vaginal delivery or instrumental delivery than cesarean section and which is statistically significant.

Perioperative and Postoperative Complication	n= 25
Bladder injury	0
Lateral vaginal injury	0
Urethral injury	0
Vaginal erosion	0
Urinary tract infection	4 (16%)
De novo urgency	1 (4%)
Transient retention	(8%) 2
Pore site infection	1 (4%)

Table 5: Complications incurred with the transobturator vaginal tape

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As summarized in Table 5, among the 25 patients 4 patients suffered from urinary tract infection, 1 patient suffered from De novo urgency, 2 patients suffered from transient retention and 1 patient port site infection occurred which was managed conservatively.

Sensation to Void	preoperative mean value (ml)	postoperative mean value (ml)	Paired t test & p value
First desire	239.92±73.44	251.2±68.51	0.0146 (S)
Normal desire	406.48±89.20	417.12±93.52	0.0026(S)
Cystometric capacity	505.6±80.10	536±52.59	0.0080 (S)

Table 6: Distribution of patient according to pre & post-operative filling cystometry

The above table reveals that first & normal sensation of desire is improved significantly on post-operative urodynamic study. The cystometric capacity also improved in significant amount post-operatively.

Variable	Preoperative mean value (ml)	Postoperative mean value (ml)	Paired t test & p value
Qmax	14.28±3.18	19.8±4.08	<0.0001 (S)
Residual vol.	159.04±41.53	124.4±23.28	0.0001 (S)

Table 7: Distribution of patient according to pre & post-operative voiding cystometry

The above table reveals that maximum urine flow rate is improved significantly on post-operative urodynamic study. The residual volume diminished in significant amount post-operatively.

Variable	Preoperative	Postoperative	Paired t test & p value
Pdet AT Qmax	38.76±13.59	34.76±13.29	<0.0001 (S)

Table 8: Distribution of patients according to pre & post-operative pressure flow study

The above table reveals that detrusor pressure (Pdet=Pves=Pabd) at maximum urine flow rate diminished in significant amount post-operatively.

Variable	Pre-operative (cm of H2O)	Postoperative (cm of H2O)	Paired t test & p value
Mean Leak Point Pressure	74.2±20.16	122.16±18.17	<0.0001 (S)

Table 9: Distribution of patients according to pre & post-operative leak point pressure (LPP) (abdominal LPP on cough)

The above table reveals that mean leak point pressure increased in significant amount post-operatively. So, our objective assessment by UDS demonstrated a 100% cure rate.

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	CURED	IMPROVED
6 Months	20/25 (80%)	5/25 (20%)
12 Months	23/25 (92%)	2/25 (8%)

Table 10: SUBJECTIVE ASSESMENT BY UDI-6

However, the subjective assessment using the UDI-6 demonstrated 92% cure rate after TOT procedure.

DISCUSSION: Bladder symptoms affect women of all ages. However, bladder problems are most prevalent among older women.² Difficulty with bladder control results in higher rates of depression and limited activity levels. Stress urinary incontinence (SUI) is common in women, and the prevalence peaks at around the age of 50 years.^{2,3} In our study more than 50% women aged 50 yrs. are suffering from SUI and it is statistically significant.

The principal known risk factors are age, body mass index (BMI) and parity.⁷ Parity is a risk factor for SUI only among young women; the association is highest among those 20–34 years and non-existent after 65 years.^{7,8} The effects of pregnancy and delivery on continence may therefore fade with time. In our study SUI is more common in overweight (BMI 25-29.9) patient and SUI also more common those who has parity more than 3 and it is statistically significant.

Several studies report that SUI occurs less often after caesarean than vaginal deliveries.⁹ The medical community has begun discussing the possible benefits of elective Caesarean section to prevent future continence problems, and some obstetricians would choose caesarean over vaginal deliveries for themselves or their partners because of fear of SUI. Postpartum studies also have found that the prevalence of SUI is lower after caesarean delivery,^{9,10} we also found protective effect against SUI by caesarean section in our population. Only a few studies, however, have investigated the association between mode of delivery and SUI around menopause. The survey of Rortveit et al analyzed the association between prevalence of SUI (pure or mixed) and mode of delivery (vaginal only versus caesarean section only) according to age group. SUI prevalence was higher among those aged 30–39 years who delivered vaginally (19%) compared with those delivered by caesarean (10%, OR=2.1, 95%CI: 1.45–3.13) but the difference was not significant among those aged 40–49 years (24% versus 18%) or 50–64 years (27% versus 20%).¹⁰ In the study by Kuh et al of 1333 women aged 48 years, SUI prevalence was slightly higher among women with only vaginal deliveries compared with women delivered only by caesarean section (52% versus 44%) but again the difference was not significant. Several hypotheses may explain the discrepancies between these data and ours.

Although it is effective and easy to perform, the retropubic placement of suburethral tension-free vaginal tape has been associated with a number of perioperative and postoperative complications, including bowel, vascular and bladder injuries.^{11,12}

In our series, we treated patients with pure stress incontinence with hypermobility and excluded patients with intrinsic sphincter deficiency without hypermobility. None of our patients had mixed or urge incontinence. So far none of the patients developed erosion, which is likely due to the use of the non-woven polypropylene mono filament with macropores. This material allows for good fibroblasts colonization of the tape, which is essential in preventing erosion and local infection.

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In our study no urethral or bladder injury happened during TOT procedure. Bladder injuries occurred in women who underwent concomitant vaginal surgery, while urethral injuries occurred in women undergoing secondary procedures¹¹ Abdel-Fattah and colleagues found that lower urinary tract injury only occurred with the outside-in technique.¹² In a recent literature review by Sivanesan and colleagues, several cases of bladder injury were reported; they recommend cystoscopy in cases of associated pelvic surgery or presence of prolapse, previous retropubic surgery or in cases where it is difficult to insert the tapes.¹¹ In our practice we are considering abandoning the cystoscopic examination. This change will result in shorter operative time and lower procedure cost.

Although urine retention and voiding dysfunction are thought to be less common after the transobturator approach, the rates vary from 0% to 15.6%.^{11,12} In our series, 4% of patients developed denovo urgency. No patients developed urinary retention, except transient retention(8%) that was relieved in a day. 16% of patients developed UTI postoperatively and 2% of patients suffered from pore side infection, but both of these complication responded well with proper antibiotic treatment.

We did not have any complaints of thigh pain in our series, which confirms recent findings of a meta-analysis that the outside-in technique is usually not associated with thigh pain.¹³

In our study it reveals that first & normal sensations of desire are improved significantly on postoperative urodynamic study. The cystometric capacity also improved in significant amount postoperatively. The pre-operative first desire to void during filling cystometry was 239.9 ± 73.4 ml & postoperative first desire is 251.2 ± 68 . ($p=0.0146$). Average normal desire to void was 406.4 ± 89.2 ml preoperatively & 419.1 ± 93.5 ml postoperatively ($p=0.0026$). Preoperatively average cystometric capacity was 505 ± 80.1 ml & 536 ± 52.5 ml ($p=0.0080$). In our study all patient improved significantly in postoperative period.

Study also reveals that preoperative Qmax is 14.2 ± 3.1 ml/s and postoperative mean value is 19.8 ± 4.08 ml/s ($p < 0.0001$). Preoperative residual volume was 159.04 ± 41.53 ml & postoperative residual volume is 124 ± 23.28 ml ($p=0.0001$). The mean value of Qmax is 20ml/s, which is almost same with normal values described by Abrams et al.¹³ This figure showed statistically significant rise after surgical correction.

In our study detrusor pressure at maximum urine flow rate is 38.7 ± 13.5 (cm of H₂O) preoperatively & 32.7 ± 13.2 (cm of H₂O) postoperatively ($p < 0.0001$) it is seen that detrusor pressure at maximum flow rate is significantly diminished postoperatively. It is due to proper selection of patient for surgery by urodynamic study.

Mean leak point pressure is 74.2 ± 20.1 cm H₂O in preoperative period & 122.1 ± 18.1 cm of H₂O postoperatively ($p < 0.0001$).

From different studies it is seen that abdominal leak point pressure measurements are used frequently to evaluate urethral function in patient with stress incontinence. A tentative diagnosis of intrinsic urethral sphincter deficiency may be made from LPP. At present however a low abdominal leak point pressure (<65 cm H₂O) appears to be most widely accepted method of diagnosis.¹⁴

In our study It reveals that leak point pressure improved after TOT procedure of genuine urinary stress incontinence.

The subjective global satisfaction rate recorded at 12 months is 92%. And our objective assessment by UDS demonstrated a 100% cure rate. As is often the case, the rate of our subjective assessment is lower than the one observed during the objective clinical examination.¹⁵

CONCLUSION: On the basis of the present work, the following conclusions can be drawn-

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1. The outside to in TOT operation is an effective and safe anti-incontinence procedure for treating female genuine stress urinary incontinence.
2. The general applicability of the TOT procedure is good.

We have enough data to support the use of the transobturator approach as a good alternative the retropubic access.

Yet, large follow-up in larger population should assess the long-term reliability of this attractive procedure.

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