Original Article

Transobturator Tape in Treatment of Stress Urinary Incontinence: It is Time for a New Gold Standard

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Abstract

Background: Stress urinary incontinence (SUI) can significantly impair the quality of life. A variety of treatments, both medical and surgical, have been used to manage it. The transobturator sling, which is a subfascial sling, is relatively a new surgical technique with minimal access. **Aim:** The objective of this study was to evaluate the effectiveness of transobturator tape (TOT) in the treatment of female SUI and to analyze functional results. **Materials and Methods:** A total of 59 patients were applied TOT by outside-in technique and various outcome parameters recorded. These patients were followed up 6 months after surgery. **Results:** Success rate of TOT was 93.2% (95% CI: 86.4–99.5). A total of 51 patients (86.4%) were completely satisfied, whereas 4 (6.8%) were partially satisfied and 4 were unsatisfied with surgical outcome. The procedure-related complications were few and could be managed in the same sitting. **Conclusion:** The transobturator approach is an effective treatment of SUI with low morbidity, and it has all the potential to be the new Gold Standard in the treatment of female SUI.

Keywords: Stress urinary incontinence, sling, transobturator tape

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Introduction

Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations studied.[1] An estimated prevalence for urinary incontinence is nearly 30% in women aged 30–60 years, with approximately half of the cases attributed to SUI.[2,3] The treatment for this problem include initial conservative therapies (i.e., lifestyle interventions, pelvic floor muscle training, and bladder training), followed by surgery, which is an option for women whose quality of life is still impaired after a diagnosis of genuine stress incontinence has been confirmed.

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In 1998, Nickel *et al*. from Holland reported a successful sling procedure using a polyester ribbon passed through the obturator foramen and around the urethra for treatment of refractory urethral sphincter incompetence in female dogs.[4] In France in 2001, Delorme introduced the transobturator sling procedure in humans.[5] Thousands of procedures have been performed in Europe and more recently in the United States, and lately this newer, seemingly safer approach to the tension free tape sling procedure is picking up in India.

In transobturator tape (TOT) placement, through small incisions placed in the groins and in the vagina under the urethra, the mesh can be placed under the urethra in the correct position without having to pass needles blindly through the retropubic space, as in transvaginal tape (TVT). The space that the needle passes through has been extensively studied and has been found to be a very safe space to work in. The mean operative time is significantly shorter in the transobturator sling and risk of bladder injury and of postoperative urinary retention is also considerably lower than other sling procedures.[6] The TOT is a tension-free sling as the resting urethral angle is not changed by the procedure, nor is it necessary to correct urethral hypermobility.[7]

One of the most important and not well-recognized advantages of the TOT as compared with other mid-urethral sling procedures is the lower rate of *de novo* urge/urge incontinence.[8] As far as sexual activity is concerned, there is no significant change in patients' sexual life as regards frequency of intercourse and pleasure and/or pain during penetration, whereas there is a significant decrease in coital incontinence.[9]

Materials and Methods

This was a prospective experimental study to see the outcome measures in patients of SUI treated with transobturator sling. The study population comprised Indian patients attending the gynecology OPD at a tertiary care teaching hospital and the patients were recruited from October 2008 to March 2010. It was an experimental design to see the efficacy of TOT in SUI and study intra-operative parameters, intra- and postoperative complications, and patient satisfaction. In this study, there were no controls and no comparisons were made.

All patients attending gynecology OPD at a tertiary care teaching hospital, who complained of de novo involuntary passage of urine on coughing, laughing, straining, or any other action suggestive of increase in intra-abdominal pressure, were subject to a thorough history taking and physical examination. Patients with history suggestive of urge incontinence were excluded and were treated for the same. In addition, the patients who had a co-existing pelvic organ prolapse or any other gynecological problem which required treatment and was planned to be corrected in the same surgical sitting were excluded. Furthermore, patients who had previously undergone corrective surgery for stress incontinence were also excluded. Patients who were pregnant were excluded. Only non-pregnant patients with a history suggestive of genuine stress incontinence, who had never undergone any previous corrective surgery for the same, and for whom no other gynecological surgery was planned in the same sitting were included in this study and considered for final recruitment.

All the patients diagnosed with SUI and a positive Bonney's test were explained about their disease, and the available modes of treatment including non-surgical and surgical options were discussed. Patients who were willing for an operative procedure, either initially or after failure in relief of symptoms after a trial of pelvic floor muscle training and were desirous of a TOT placement were the patients who were finally recruited for this study.

After they were declared fit for anesthesia, surgery was planned on a mutually convenient date and patient was admitted the night before. An informed consent was taken. Part preparation was done in the morning before sending to operation theater. Thereafter, on the day of surgery, a transobturator sling was applied using a TOT by outside-in technique.

The time taken for the surgical procedure was recorded and noted for every patient. The blood loss at the time of surgery was assessed by using pre-weighed swabs and estimating their difference in weight before and after surgery. In addition, the quantity of blood drained by negative suction, if any, was estimated by noting its volume in the suction drainage chamber.

Postoperative analgesia was given as per patient demand and based on VAS of pain (Visual assessment score of Pain or Visual Pain Score, VPS), NSAIDs were given for VAS £5/10, and opioids were given for VAS of >5/10. Patients were discharged when they had passed the urine freely and they felt confident to look after themselves. The period of their hospital stay was noted and recorded.

All patients were given extensive advice at the time of discharge which specifically stressed to avoid squatting and intercourse for 4 weeks. They were told to use chair-style toilet seat only and not to squat while micturation or while defecating. They were also stressed upon the requirement of an adequate fluid intake so as to prevent urinary infections and also avoid constipation. Telephonic communications were established with patients and they were called for a follow-up at 4 weeks after surgery and then at 3 and 6 months. Telephonic reminders were given to patients who did not come within 1 week of the date of follow-up. At the follow-up visits, they were specifically asked about the relief of symptoms for which they underwent surgery, any chronic pain, and their overall satisfaction with the surgical outcome.

Statistics study

All the data were recorded and in the end was analyzed and outcomes were derived. All these accumulated data were statistically analyzed using appropriate statistical techniques, Student's "*t*" test and SPSS (Statistical Package for Social Scientists) version 16 statistical software.

TOT is an established and safe procedure for treatment of SUI. This was an observational study and there were no controls kept.

Results

Out of 59 patients included in the study, 55 slings were successful and 4 had a surgical failure (6.8%) in terms of persistence of stress incontinence postsling fixation.

Total success rate of transobturator sling fixation in the study was 93.2% (95% CI: 86.4–99.5). No apparent cause could be found for failure of surgery in these four cases. A total of 51 patients which constituted 86.4% of patients under study were completely satisfied with the surgical outcome, whereas 4 patients (6.8%) were partially satisfied and an equal number of patients, i.e., 4 were unsatisfied with the surgical outcome, the same patients in whom the surgery was not successful.

Age and parity

The mean age of the patients operated for SUI under this study was 46.2 years (SD 11.2 years; range 24–70 years). Out of the total 59 patients, 33 were premenopausal (55.9%) and 26 were postmenopausal (44.1%). Out of total 59 transobturator slings applied, only 1 (1.7%) was in a nulliparous woman, 8 (13.6%) were in primiparous women and 50 (84.7%) were in multiparous women.

Duration and blood loss in surgery

The mean duration of surgery was 21.69 minutes (SD 6.41 minutes), and the mean blood loss was 76.78 ml (SD 19.25 ml), which was calculated by using pre-weighed swabs.

Complications

There were few procedure-related complications which were managed intra-operatively, and thereafter the TOT was applied after the repair of the injury and intra-operative cystoscopy was done. There was intra-op bladder injury in one case and intra-op urethral injury in one case.

Hospital stay

Thirty-three patients (55.9%) required opioid analgesia in postoperative period and the rest 26 were managed with NSAIDs. Out of 59 patients, 27 (45.8%) were discharged within 24 hours of surgery, 30 (50.8%) between 24 and 72 hours postop, and only 2 (3.4%) had to stay hospitalized for more than 3 days and both these were the patients who had intra-operative bladder/urethral injury which was repaired simultaneously in the same sitting itself.

TOT fixation is a minimally invasive surgery for treatment of SUI. It has a high success rate as quoted in the literature and the total success rate of transobturator sling fixation in this study was also 93.2%.

This is a procedure which can be accomplished in a very small hospitalization period and in a short operative time. The mean duration of surgery in this study was 21.69 minutes (SD 6.41 minutes), and as far as hospitalization was concerned, in this study 45.8% patients were discharged within 24 hours of surgery, another 50.8% were discharged between 24 and 72 hours postop, and only 3.4% patients had to stay hospitalized for more than 3 days and these were the patients who had intra-operative complications. Average stay of 57 patients in this study (excluding the two extremes who prolonged stay because of bladder/urethral injury) was 1.6 days.

There is a very small blood loss associated with the surgery and mean blood loss in this study was 76.78 ml. Also, the postoperative analgesic requirement is also adequately met with NSAIDs in almost half of the cases. These again are predictors of an early postoperative recovery.

TOT seems to be a surgery with good relief of symptoms and results in great satisfaction levels in the patients. In this study, 86.4% of patients were completely satisfied with the surgical outcome, whereas 6.8% were partially satisfied and only 6.8% were not satisfied with the surgical outcome and these were the patients in whom the surgery was not successful.

Discussion

TOT application was successful in 93.2% cases in this study and it failed in 6.8% cases. Delrome in 2001 reported on 40 patients in whom TOT was applied for the first time, 39 patients had no incontinence postsurgery and 1 patient had improvement in symptoms.[5] DeTayrac in 2004 reported a 1-year cure rate of 84% with the TOT procedure.[6] In a series of 117 patients with a median follow-up of 16.3 months, Spinosa in 2005 reported subjective complete and partial satisfaction rates of 92.3% and 4.2%, respectively.[10] In 2007, Latthe *et al*. quoting their experience in Britain in a series of 135 patients who were applied TOT reported the subjective level of complete cure and improvement reported by patients were 89.6% and 8.8%, respectively.[11] Taweel *et al*. reported a 92% cure or improvement rate after 12 months and 85% after 24 months by an objective assessment and a patient satisfaction rate of 88% at 1 year by subjective assessment.[12]

The mean age of the patients operated for SUI under this study was 46.2 years (SD 11.2 years; range 24–70 years). The mean age of patients reported by Taweel in his series was 52 ± 9 years (range 34–70 years).[12] Moore *et al*. in their study had patients with an average age of 56.8 years with an SD of 11.7.[13] Isabelle *et al*. in their analysis of 233 cases had patients with an average age of 57.9 years (SD 13.2 years).[14]

In this study, the mean duration of surgery was 21.69 minutes (SD 6.41 minutes), and mean blood loss was 76.78 ml (SD 19.25 ml). Purnichescu *et al*. reported a mean

duration of 23 minutes.[15] Taweel reported mean surgery duration of 18 minutes.[12] Moore *et al*. reported the mean operative time for sling placement as 12.4 minutes.[13] Taweel reported an average intra-op blood loss of 57 ml (SD 22 ml),[12] whereas Moore *et al*. reported 36 ml in their study.[13]

Out of 59 patients studied in this study, 27 (45.8%) were discharged within 24 hours of surgery, 30 (50.8%) between 24 and 72 hours postoperatively, and only 2 (3.4%) had to stay hospitalized for more than 3 days. The average stay of 57 patients in this study (excluding the two extremes who had to stay because of bladder/urethral injury) was 1.6 days. Purnichescu *et al*. from France reported mean duration of hospitalization in the cases of isolated TOT as 1.25 days.[15] Isabelle *et al*., for women who had only TOT procedure, reported the mean hospitalization as 2.2 days.[14]

In our series of 59 patients, there was one bladder and one urethral injury intra-operatively. In both the cases, the injury was repaired by standard surgical techniques and TOT was applied. Cystoscopy was done after the complete procedure to confirm success of repair. Lateral vaginal injury was encountered in two patients (3.4%), which was identified at the time of the injury, and the tunneler (TOT needle) was removed and correctly reinserted without further consequence. Unrecognized, vaginal laceration may predispose patients to mesh extrusion. Therefore, in our opinion, it is mandatory to inspect the lateral vaginal wall after passing the needle through transobturator foramen. In the immediate postoperative period, only one patient (1.7%) had transient urinary retention after removal of urinary catheter, which was relieved by recatheterization and subsequently had successful voiding on the next day.

No patient in this study had vascular, neural, or bowel injury. The most important step to avoid erosion and voiding dysfunction was found to be tape adjustment without any tension or any contact with the urethra. There were no complaints of thigh pain in our series, which confirms findings of a meta-analysis published in BJOG in 2007 by Latthe *et al*.; that the outside-in technique is usually not associated with this specific symptom.[16] None of the patients had developed erosion in the period of study till the last follow-up, which is probably due to the use of the tape material made of non-woven polypropylene mono filament with macropores.

Obstructive voiding dysfunction is the most commonly reported complication of some other mid urethral sling placements like TVT. Because the TOT is positioned horizontally across the urethra, it provides less chance for static urethral kinking and the associated urethral obstruction that may follow. In this series, no patient developed urethral obstruction requiring complete or even partial tape release.

One of the most important and not well recognized advantages of the TOT as compared with other mid-urethral sling procedures is the lower rate of de novo urge/urge incontinence. In the transobturator approach, the path of the tape, crossing the obturator foramen, muscle, and fascia, reproduces the natural suburethral suspension by reinforcing the rotational pivot point, restoring continence while sparing the rertropubic space. Sparing the retropubic space may preserve any periurethral nerve fibers that may be associated with urethral function and stability. Second, the TOT is associated with a lower risk of urethral obstruction as compared with other mid-urethral sling procedures. The transobturator sling procedure spares the retropubic space and thus also eliminates the risk of major bowel, neural, and vascular complications which have been reported with the TVT. In this study, there was no incidence of de novo urgency/urge incontinence.

Another important advantage of TOT is that since it is not possible anatomically to over tighten the tape, there is hardly any reported incidence of urinary retention because of mechanical obstruction, whereas obstructive voiding dysfunction is the most commonly reported complication of some other mid urethral sling placements like TVT. In the present series, no patient developed urethral obstruction.

Conclusions

To conclude, the transobturator approach is an effective treatment of SUI with low morbidity. There are enough data in the literature to support the use of the transobturator approach as a good alternative to the retropubic access, and it has all the potential to be the new Gold Standard in the treatment of female SUI.[17]

Treatment for female SUI has seen revolutionary changes in the last 10 years, with new minimally invasive techniques that have been proven safe and effective. The TVT sling was first developed and then the TOT sling followed, which provided a safer means to place a tension-free mesh tape sling with seemingly equivalent cure rates and lower rates of complications. TOT seems to be the surgery of future for treatment of SUI with a potential to replace the present gold standard (Burch colposuspension) because it is a minimally invasive surgery with small incisions, vaginal route, and minimal blood loss. It has fewer complications (such as de novo urge incontinence or voiding difficulties) than other surgical options for management of SUI. Cystoscopy is not mandatorily required for TOT, which was not

the case with many of its predecessors like TVT where cystoscopy must be performed. It promises a high cure rate and good patient satisfaction. It promises a faster recovery and a quick return to work or back to be with family.

However, the limitations of our study were the time period for which the patients were followed and in view of the same any long-term morbidity or long-term satisfaction level of the patients treated could not be recorded and analyzed. Although there have been studies quoted in the literature which have followed up patients for almost up to 2 years after TOT application, it is still felt desirable that larger trials with bigger sample size and with a longer duration of follow-up for evaluating long-term success of TOT are required. Further, comparative trials comparing TOT with other surgical options available for treatment of SUI shall be able to give it its right place of honor in the treatment of SUI. It has all the potential to be the new Gold Standard in the treatment of female SUI.

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