Original article

The management of stress urinary incontinence using transobturator tapes in a tertiary hospital in South Africa

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Abstract: Introduction and objectives: The aim of this case series was to assess the safety and efficacy of the TOT in treating SUI, as well as the intra- and postoperative complications and their management. Methods: Five different macroporous tapes were inserted by a single operator. Patients were assessed by history, positive cough test and intra- and postoperative complications; objective, subjective success rates have been recorded. Results: 120 patients with SUI were included. Intraoperative complications included 2 bladder and 2 vaginal perforations, which were diagnosed and managed intra-operatively. The follow up was between 3 and 63 months. Both objective and subjective cure rates of 94.5% were recorded. Positive results persist over a period of 5 years. Mesh erosion was noted in 1 case, 3 procedure failures and one de novo Detrusor Instability (DI) were found during the follow up period. Conclusion: TOT outside-in is a safe and effective procedure for SUI with low complications.

Key words: Complications; Outside-in Transobturator tape (TOT); Urinary stress incontinence; Urodynamic studies.

INTRODUCTION

Stress Urinary Incontinence (SUI) is defined as the involuntary leakage of urine on effort, exertion or coughing without a rise in detrusor pressure.[1] It is estimated to affect up to one-third of women older than 18 years, with a median age of 45 years.[2] The Tension-free vaginal tape (TVT) is a standard, minimally invasive procedure used to treat SUI, introduced by Ulmsten in 1995.[3] In spite of its proven efficacy of subjective and objective SUI cure of 90% at the 11-year follow up[4] TVT, has been found to be associated with intra and post operative complications such as urethral, bladder, bowel perforations, major blood vessel injuries as well as post operative voiding difficulties, de novo urgency and Urge Incontinence (UI).[5-9] In 2001, Delorme described the Transobturator tape (TOT)[10] as a mid urethral sling for the surgical treatment of SUI. This minimally invasive procedure, termed "outside-in"- in which the tape is inserted in an almost horizontal plane underneath the middle of the urethra, between the two obturator foramina- has almost replaced the TVT. The TOT technique has been safer, due to avoidance of entry into the retro-pubic space.[10] A modified technique ("inside-out") of TVT-O was introduced by de Laval in 2003.[11]

The Transobturator passage of the tape ensures that the retro-pubic space is not entered. Therefore this approach has a low risk of bladder injuries, vascular injuries and post-operative voiding difficulties.[5,12,13] The risks of complications seen with the retro-pubic approach (TVT) are avoided. Although cystoscopy is mandatory with a TVT, with the TOT technique it is not always recommended.[14,15]

The Transobturator (TOT) approach was found to have high success rates with an objective and subjective cure rate of 90% and 97% respectively and low morbidity.[15,16] The objectives of this case series were to assess the safety and efficacy of the TOT in the treatment of stress urinary incontinence in our hospital and to assess intra and postoperative complications associated with the TOT procedure and their management.

MATERIAL AND METHODS

Between April 2005 and April 2010, 114 female patients were diagnosed with SUI and were included in the study; two were included with mixed urinary incontinence (MUI) and four patients with overflow incontinence who agreed to Intermittent Self-Catheterization (ISC). All underwent TOT (outside-in) operations. The diagnosis of SUI was based on subjective complaints of involuntary leakage on effort, sneezing or coughing, without overactive bladder symptoms (as recommended by ICS).[1] Objective bedside investigations included a cough test, residual volume and urine dipstick to exclude infection.

Uro-dynamic studies were not systematically performed due to lack of availability but without exception was mandatory for those patients who were presented with overactive bladder (OAB) symptoms. The surgical technique was as described by Delorme in 2001.[10]

The Key Procedure Steps Are As Follows:

1. Place the patient in dorsal lithotomy position with the buttocks over the edge of the table and the hips flexed at 120º.
2. Insert a bladder catheter (Foley size 12-14) to empty the bladder and identify the urethra during the procedure.
3. Mark the tunneler insertion point through the obturator foramen on the lateral margin of the inferior ischiopubic ramus. The insertion point is not fixed as it depends on the depth of the lateral vaginal fornix, and must be at least 1cm above the horizontal line at the level of the urethra meatus and below the horizontal line at the level of clitoris.
4. Make a vaginal incision about 2cm long at the junction of the middle and lower third of the urethra (wide enough to insert a finger). Grasp each side of the incision with Allis' forceps and pull laterally to open a window. Separate the vaginal epithelium from the underlying periurethral fascia, using sharp and digital dissection in the direction of the inferior pubic ramus. If the index finger is in the incision, and the thumb is at the nearest point of the genito-crural fold, one may determine the entry point.
5. The incision that is made at this point should be big enough to fit the tunneler that will be used (3-5 mm).
6. Introduce the tip of the tunneler into the obturator skin incision. Pass the tunneler through the obturator membrane and muscle, keeping it close to ischiopubic ramus directed towards the meatus urethra. The tip of the tunneler should make contact with the finger inside the vagina incision. The tip of the tunneler must be brought out into the vaginal incision. With the tunneler in the in-

cision, the lateral vaginal fornix must be checked for perforation.
7. The tape must be inserted through the eye of the tunneler, pulled through the dissection and out of the obturator incision by reversing the tunneler.
8. This must be repeated on the other side of the patient, ensuring that the tape is not twisted and lies flat under the urethra. Once the positioning of the tape is confirmed, the vagina is close with bio-absorbable suture.
9. The lateral ends of the tape should be cut off and the inner thigh skin incisions are closed with an absorbable suture bilaterally.
10. A local modification included hospital stay for the patient, clamping the catheter the following day and removal on the second postoperative day. If residual volume was <100 ml, the patient was discharged.

Postoperative pain was assessed by Visual Analog Scale (VAS), which was simply and easily comprehended by the patient and the length of the postoperative hospital stay was recorded.

Postoperative evaluations were scheduled for 1 week, 6 weeks, 6 months, 1 year and yearly thereafter. Evaluations included: a cough stress test, a vaginal examination and residual volume. If a patient presented with Overactive Bladder (OAB) symptoms, Uro-Dynamic Studies (UDS) were performed. A 24 hour pad test was not performed. Patients were considered objectively cured if they had no stress urinary incontinence during the stress provocation test (Cough test) and did not have urinary retention if a residual volume of less than 100 ml was recorded. Subjective success rates were measured as the patients' satisfaction with the procedure during the follow-up. Cure rate of SUI was defined as a disappearance of subjective and objective leakage.

Descriptive statistics were performed showing the frequencies and percentage for categorical variables and the means, standard deviations and ranges for continuous variables. Inferential statistics were performed on some variables. The student's t-test was performed for differences in means on Gaussian distributed data, to determine the differences between operation times for those who had TOT alone and those who had additional operation. Spearman's correlation was also used to determine the relationship between duration of operation and days stayed in hospital. The maintenance of continence was shown using the Kaplan Meier curve. Statistical significance was ascertained at the 5% level hence a p-value of less than 0.05 rendered statistical significance. The analysis was performed using STATA 10.1.[17]

TABLE 1. – Patient Characteristics: Patients may have more than one previous operation.

Age (years)	mean	54.7 (±12.96)
	range	(29-87 years)
Parity	mean	2.6 (P1-P6)
Previous operations:		
Anterior repair		14
Posterior repair		9
Total abdominal hysterectomy		18
Vaginal Hysterectomy		10
PIVS		1
Concurrent operations during TOT procedures (n=22)		
Posterior IVS		3
Vaginal hysterectomy		3
LAVH		3
Anterior repair		2
Posterior repair		4
Laparoscopic sterilization		2
Removal of IUCD		1
Removal of Labial cyst		1
Laparoscopy cystectomy		2
Fento's procedure		1

RESULTS

Procedures were performed under spinal anesthesia in 98 cases and general anesthesia in 22. All the TOT's were performed at the Charlotte Maxeche Johannesburg Academic Hospital, and all cases were done by the same surgeon, the author. One hundred and twenty women underwent a TOT procedure during the study period, of which twenty two were associated with another surgical procedure. Patient's characteristics, previous operations and concurrent operations during TOT procedures have been summarized in table 1. The mean patient age was 54.7(±12.6) years. Pure stress urinary incontinence was found in 114 patients out of 120 patients. Two patients with mixed urinary incontinence and 4 patients with overflow incontinence who agreed to Intermittent Self Catheterization (ISC) were included in this study. Five different types of slings were used during the study period and are shown in table 2. All the cases were successfully completed. Intra-operative complications are presented in table 3.

The average operating time was 30 minutes (25-40). Some of the women had to undergo additional operations and this on average doubled the operating time e.g. the operating time for TOT had a mean of 21.2 minutes (SD±0.7). An additional operation increased the mean time of surgery to 40.3 (SD±2.8). Student's t-test showed a p-value<0.0001. This increase in time of operation lead to the statistically significant increase in the stay in hospital (Spearman's rho= 0.4323, p-value<0.0001).

The postoperative complications during the follow up period are presented in table 4. The postoperative hospital stay and pain (assessed by Visual Analogue Scale) are presented in table 5. The follow up period after TOT range from 3 to 63 months, and the condition appears in the parous women with average age of 42 years, with the majority of the women having either two or three children (Figure 1).

There were a total of five failures through out the 63 months of follow-up with a success rate of 94.5%. The x-axis shows the number at risk per each time point and the cases in brackets per each interval (Figure 2).

Follow-up data was censored at the end of July 2010 when the last patient who underwent TOT completed 3 months follow-up. At the last follow-up (range 3 to 63 months), 5 cases were considered treatment failure (according to the definition of stress specific cure).

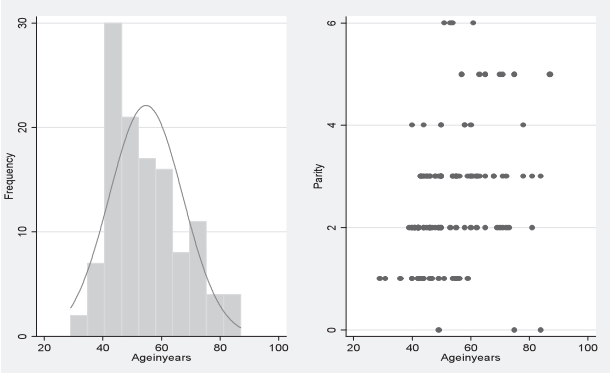

Figure 1. – Histogram of the Ages and the parity distribution across the ages.

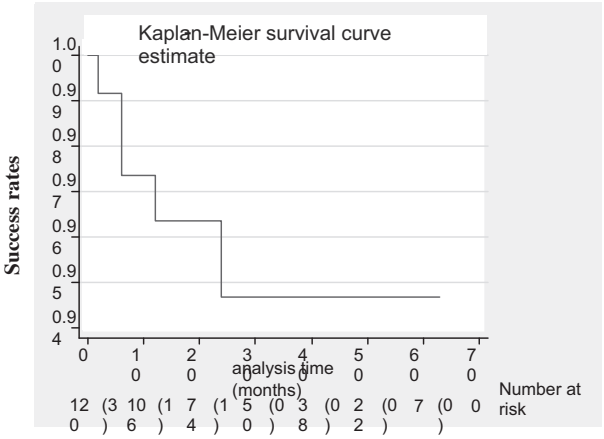

Figure 2. – Kaplan Meier survival curve for the development of any urinary incontinence after surgery.

DISCUSSION

The results from this study show that the TOT is a simple, effective and safe procedure for treating SUI. The cure rate of SUI, defined as the disappearance of subjective and objective SUI, was 94,5% during the follow up period. Success rates are similar to other reported series of retro-pubic or Transobturator mid urethral slings.[4,15,16,18] Routine uro-dynamic studies (UDS) were not performed to confirm the diagnosis of SUI in 114 patients with strongly suggestive SUI prior to surgery. Although this may be considered by some, as a weakness of this study, there is available evidence to demonstrate that cough test is useful and reliable tool in the diagnosis of SUI,[19] especially in countries with limited resources and in absence of symptoms indicating an Overactive Bladder (OAB). It is recommended that women with clearly defined clinical diagnosis of SUI do not need routinely UDS prior to surgical intervention.[20] We limit UDS to the patients with the history of OAB symptoms, those with RV > 100ml in absence of cystocele. This is supported by the literature that show that there is a little reason to delay surgery prior to treatment. Important issues also include cost, discomfort, constraint to the patient and lack of reproducibility.[21] A recent systematic review has shown there is no evidence that performing uro-dynamics does improve the outcome of anti-incontinence surgery.[22]

In our setting with limited resources, clinical assessment alone has place, as we have to treat the patient not the urodynamic findings. All cases were successfully completed. There has been a reported decreased risk of intra-operative complications with TOT as compared to TVT and particularly bladder perforation.[5,12,13] In our study, bladder perforation occurred in two patients, (1.6%) and this is in agreement with other reported rates of 0 –1.5%. [5,7,13,15,23] In the two patients in this study with bladder perforations, both had had a previous anterior repair, and both perforations were created at the time of vaginal dissections, not during tunneler insertion. In both patients, bladder perforation was diagnosed immediately, repaired in two layers and the procedure completed. Post-operative urethral catheterization was left in-situ for 10 days. Abdel-Fatah et al[24] reported 4 cases of urethral and bladder perforation in their series of 389 cases comparing TOT to TVT-O. He stated that all occurred in TOT "outside in" group, and no cases of bladder perforation ensued in the TVT-O "inside out" group. However, three of the perforations occurred during the dissections following vaginal incision, and only one bladder perforation during the insertion of the tape. If the correct technique is applied the risk of bladder perforation with the tunneler is minimal. Bladder injury during the insertion of the tunneler as seen in TVT should be distinguished from the bladder injuries during the creation of the par urethral tunnel as seen in transobturator techniques (TOT, TVT – O). It is evident from the literature that both Transobturator tape techniques are associated with lower risk of bladder perforation as compared to the retro-pubic techniques.[5,13,25] To be engaged in comparisons between TOT vs TVT-O undermine the transobturator technique of treating SUI and should be avoided. Because bladder perforation is one of the most common intraoperative complications of retro-pubic midurethral slings, cystoscopy is considered mandatory, whereas the use of cystoscopy with the Transobturator approach is not always recommended.[14,15]

Cystoscopy can be considered in women who have concomitant vaginal surgery or where the TOT procedure is considered difficult. Two bladder perforations repaired and two concomitant anterior repairs were performed in this study without cystoscopy. Instead a catheterization of a methylene blue test was performed demonstrating no leakage. Two vaginal perforations were diagnosed during the insertion of the tunneler. These were corrected by repositioning and re-passing of the tunneler and the tape, without complications. This complication can be avoided if the dissection is carried out away from the anterior vaginal wall as far as the iscio-public rami on each side. There was no bleeding in our series as opposed to others[13,25] who report bleeding in excess of 200 ml in 3. 3% and 5. 2% respectively in their series.

No major intraoperative complications such as bowel and vessel injuries were reported in this study, confirming the results of other studies that indicates the safety of this procedure. A recent report of the Austrian registry with data on 2,543 operations including 11 different tape systems, reported no bowel or major vessel injuries and low rates of intraoperative complications.[13]

Post-operative voiding problems found to be low (0.8%) in our study, in agreement with other studies.[5,23] De novo de-

Table 2. – Different TOTs used in the study.

IVS-O	Tyco	98	(81, 6%)
Aris	Mentor-Porges	16	(13, 3%)
Monarc	AMS	2	(1, 6%)
Obtryx	Boston Scientific	2	(1, 6%)
Intramesh	Cousin	2	(1, 6%)

Table 3. – Intra-Operative Complications.

Bladder perforation	2	(1,6%)
Vaginal perforation	2	(1, 6%)
Bleeding > 100 ml	0	
Urethral perforation	0	
Others	0	

Table 4. – Complications during follow-up.

Tape erosion	1	(0.8%)
Sling failure	3	(2.4%)
De novo UI	1	(0.8%)

Table 5. – Hospital Stay and Pain as Assessed by V.A.S.

Postoperative pain as assessed by VAS	Day 1: 2.9 (0-5) Day 2: 1.06 (0-3)
Postoperative Hospital stay (days)	2.1 (2-3 days)

trusor instability was noted in one patient and was treated successfully with antimuscarinics. This is definitely much lower than the rate reported with TVT.[5,7] It is suggested that the TOT is more horizontal as compared to the U-shape of retro-pubic slings, thereby making less contact with the urethra and so diminishing the likelyhood of this complication. Some expressed concern that the more horizontal axis of the TOT may translate into lower cure rates of SUI. The results of this study do not support such concerns.

Three failures with positive cough test were diagnosed at six months, one year and two years of follow up. All were managed by reinserting a new sling.

One patient in this series had sling erosion at the six-month follow up. Excision of the exposed portion of the sling was performed, followed by local application of estrogen vaginal cream for six weeks. Complete healing was achieved in 6 weeks follow up. Sling erosions may be secondary to surgical technique used and may relate to the sling material used. The low rates of erosion in this study is due to the fact that all 5 slings used were polypropylene Type 1 meshes (macro porous, monofilament), and the technique was correct. The strength of this study lies on the fact that the same surgeon performed all the TOT's (AC).

Urinary retention following TOT have been reported in the literature as between 1,5 to 15% respectively.[16,18] No cases of urinary retention occurred in this series. This may be attributed to the fact that in all cases the catheter was clamped on the first postoperative day, and removed on the second day before discharge. This not only allows bladder retraining but may also decrease tension of the sling in the immediate postoperative period.

Postoperative groin or thigh complications with TOT that were found in other studies[5,25] did not occur in this study. This study supports the evidence that such a complication is uncommon with TOT outside-in. Groin or thigh pain has been found to be more common with TVT-O inside out procedures with a reported incidence of 16%-17%.[11,26] A sub-analysis performed by Cheng Yu Long[12] found that TVT-O appear to be more painful and the possible cause was that the exit point of the TVT-O needle is closer to the adductor muscle and the obturator neurovascular bundle compared with outside-in TOT. Cadaver studies show that tapes inserted via the transobturator route using an 'outside in' technique have a lower risk of pudendal neurovascular bundle injury as the tape may be placed further from the obturator canal and closer ischiopubic ramus[27] Tapes placed with the "inside out" technique were found further from the ischiopubic ramus and closer to the obturator canal.[28]

Two patients with UDS demonstrated mixed UI were cured after TOT, thus keeping with the results of others that show 91% improvement with MUI where the stress was the most bothering symptom.[29] This study is in agreement with other epidemiological studies that show that SUI occurs more often in perimenopausal/postmenopausal women. The mean age of TOT in our study was 55,3 years (31-84 years).[30]

CONCLUSIONS

In summary, the TOT outside-in is a simple, effective, safe and minimally invasive procedure for treating SUI. It is associated with a low rate of complications and high success rate over a 5 year follow up period. The technique was found to be easier to teach registrars, offering them a good understanding of anatomical landmarks that are required to perform the procedure.

CONFLICT OF INTEREST

There are no conflicts of interest.

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