Original article

Long term follow up of the transobturator tape procedure for the treatment of stress urinary incontinence in a tertiary institution in South Africa

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Abstract: The transobturator tape (TOT) procedure has become the preferred procedure in managing female stress urinary incontinence (SUI) as it is safer than the tension-free vaginal tape (TVT) which was the "gold standard" since 1995. Ours is the first study looking at the continence status eight years after TOT surgery. The objectives of this series were to describe the long-term effectiveness over a maximum period of 8 years and to describe the associated complications. Records of patients of attending the urogynaecology unit at the tertiary Charlotte Maxeke Johannesburg Academic Hospital who underwent the TOT procedure from April 2005 to April 2010 were included. The study population included women who complained of stress urinary incontinence (SUI) and were diagnosed objectively in keeping with the definition by the International Continence Society (ICS). Follow-up was as per the clinic protocol. One-hundred and twenty women had a TOT procedure. The median age of the women in the group was 55.3 years. One case of bladder injury and 2 cases of vaginal perforation occurred intraoperatively. During the follow-up period 1 woman presented with tape erosion, 7 with sling failure, and 2 patients had de-novo detrusor instability. This descriptive study demonstrates a low intra-operative complication rate, a high subjective and objective cure rate and a low risk of complications up to 8 years (median 5 years and 8 months) of follow-up. We therefore recommend this procedure for the management of genuine SUI in women. We believe that the time has arrived for a new "gold standard".

Key words: Stress urinary incontinence; Transobturator tape; Tension-free transvaginal tape; 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 a physiologically, emotionally and physically devastating condition and can adversely affect a woman's quality of life. SUI is estimated to affect up to one-third of women older than 18 years of age with a median age of 45 years.[2] In 2001, Delorme described the Trans-Obturator Tape (TOT)[3] as a mid-urethral sling for the surgical treatment of SUI. This minimally invasive procedure, termed "outside-in," in which the tape is inserted underneath the middle of the urethra between the two obturator foramina, has almost replaced the Tension-free Vaginal Tape (TVT) which was introduce by Ulmsten in 1995,[4] as it is safer due to the minimal risk of entry into the retro-pubic space.[3] The TOT has a low risk of bladder injuries, vascular injuries and post-operative voiding difficulties[5, 6, 7] as compared to the TVT.

Although cystoscopy is mandatory with a TVT, it is not always recommended for the TOT technique.[8, 9]

The TOT approach has been found to have high success rates with an objective and subjective cure rate of 90% and 97% respectively.[9, 10]

The objectives of this case series were to assess the durability and the long-term effectiveness of the procedure over a period of up to eight years of follow-up, and to describe the complications associated with the TOT procedure; and their management.

MATERIALS AND METHODS

The study was conducted at a tertiary urogynaecology unit in Johannesburg, South Africa, with the approval of the Human Research Ethics Committee of the University of the Witwatersrand. All women who underwent a TOT procedure in the unit from April 2005 to April 2010 were included in the study. Study participants were women with SUI. The diagnosis of SUI was based on subjective complains of involuntary leakage of urine on effort, sneezing or coughing without symptoms, suggesting an overactive bladder (as recommended by ICS).[1]

Objective bedside investigations included a cough test (performed in the lithotomy or standing position with a comfortably filled bladder), residual volume and urine dipstick to exclude infection. Uro-dynamic studies (UDS) were not routinely performed in patients with pure SUI following a history, clinical and bedside investigations; but were mandatory for patients who presented with overactive bladder (OAB) symptoms.

The surgical technique was originally described by Delorme in 2001.[3]

Postoperative evaluations were scheduled for 1 week, 6 weeks, 6 months, 1 year and annually thereafter. Evaluations included a cough stress test, a vaginal examination and residual volume. If a patient presented with overactive bladder (OAB) symptoms during follow-up, UDS were performed.

A 24-hour pad test was not performed. Patients unable to present at the clinic were contacted telephonically to assess subjective cure. Patients were contacted by a qualified nurse working in the uro-gynaecology clinic and asked if symptoms were present, however the patients were not subjected to a formal questionnaire. All patients who reported dissatisfaction with the procedure or on-going symptoms were asked to return to the clinic for further assessment.

Patients were considered objectively cured if they did not demonstrate stress urinary incontinence during the stress provocation test (cough test) and were deemed not to have urinary retention if a residual volume of less 100 ml was recorded. Tape erosion and de-novo urinary incontinence were considered as failures.

Subjective success rates were measured as the patient's satisfaction with the procedure during follow-up. The definition of a cure of SUI was the disappearance of subjective and objective leakage.

Descriptive statistics were performed, showing the frequencies and percentages for categorical variables and the means, standard deviations and ranges for continuous variables.

RESULTS

One-hundred and twenty women underwent a transobturator tape procedure during the study period, of which 24 were associated with other surgical procedures. The follow-up period ranged between 36 to 96 months (3 years to 8 years). Patient characteristics, previous operations and concurrent operations during TOT procedures are summarized in Table 1. The mean patient age was 55.3 years. Pure stress urinary incontinence was found in 118 patients. Two patients with mixed urinary incontinence with predominant stress symptoms were included in this study.

TABLE 1. – Demographic and previous surgical characteristics of women in the study.

Age (years)	55.3 (range 31-84)
Parity	2.1 (range 1-6)
Previous operations:	
· Anterior repair	14
· Total abdominal hysterectomy	38
· Vaginal hysterectomy	12
· Posterior intravaginal slingoplasty	1

Concurrent operations during TOT procedures are presented in Table 2.

TABLE 2. – Concurrent operations performed during transobturator procedure.

Procedure	Number of patients
Posterior IVS	3
Vaginal hysterectomy	5
LAVH*	3
Anterior repair	2
Posterior repair	4
Laparoscopic sterilization	2
Removal of IUCD+	1
Removal of Labial cyst	1
Laparoscopy cystectomy	2
Fenton vulvoplasty	1

Five different types of slings were used during the study period and are shown in Table 3.

TABLE 3. – Transobturator mid-urethral slings used in the study.

Type of sling	Frequency of use
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%)

All the operations were successfully completed. Intra-operative complications are presented in Table 4.

TABLE 4. – Intra-operative complications encountered during insertion of the transobturator tape.

Complication	Frequency
Bladder perforation	2 (1.6%)
Vaginal perforation	2 (1.6%)
Bleeding	0
Urethral perforation	0

Seven sling failures occurred. Four failures were diagnosed with positive cough test, 3 patients at six months and 1 at the one year follow up. During the follow up, three patients in addition to the four confirmed failures complained of subjective urinary leakage. The three patients were reinvestigated. Bed-side investigations failed to demonstrate leakage. In addition, vaginal examinations and residual volumes were normal. UDS performed on the 3 women also failed to demonstrate leakage. De novo detrusor instability was noted in two patients and was treated successfully with antimuscarinics. Sling erosion was diagnosed in one patient at the six months follow-up. Excision of the sling was performed, followed by local application of estrogen vaginal cream. All complications were diagnosed in the first year post-operatively. During the follow up period no other major complications were reported except for occasional cases of urinary tract infections, which were treated successfully with antibiotics.

TABLE 5. – Complications after insertion of transobturator tape between 36 to 96 months of follow-up.

Complication	Frequency
Tape erosion	1 (0.6%)
Sling failure	7 (5.8%)
De novo UI	2 (1.6%)

Follow-up data was censored at the end of April 2013 when the last patient who underwent TOT procedure completed 3 years of follow-up. At the last follow-up (range 36-96 months) 10 cases were considered as treatment failure (according to the definition of stress specific cure) with subjective cure rate of 90.4%. The objective cure rate was 93.3% as 3 patients failed to demonstrate urinary leakage on clinical examination (negative cough test with comfortable filled bladder) and no leakage of urine was noted during urodynamic studies.

DISCUSSION

The present study with a follow-up of more than five years is the longest known follow-up study conducted on the TOT surgical procedure for treatment of female stress urinary incontinence. Of the original 120 women, 104 (86.7%) were potentially available for follow-up. The percentage of those lost to follow-up was 13.3% which is fairly low for the study period covered.

Although it was not possible to assess the continence status of the 14 women lost to follow-up, we believe that the success rates we have obtained from the women evaluated is representative of the performance of the TOT procedure especially since all the complications occurred in the first year following the procedure.

Our results show that the TOT is an effective, safe procedure for treating SUI. The objective cure rate of SUI, defined as the disappearance of SUI, was 93.3% during the follow up period. Success rates are similar to other such reported series.[11, 12] There is a decreased risk of intra-operative complications with the TOT as compared to the TVT, particularly bladder perforation.[5,6,7] In our series, bladder perforation occurred in two patients (1.6%), and this is similar to other reported rates of 0 – 1.5%.[5,7,9,11] The two patients in this series with bladder perforations had had previous anterior repairs. Of significance is that the bladder perforations occurred during the dissections following vaginal incision and not during the insertion of the tape. Bladder injury during the insertion of the tunneler as seen in TVT should be distinguished from the bladder injuries during the creation of the para-urethral tunneler as seen in transobturator tape insertion.

The bladder repairs and two concomitant anterior repairs were performed in this study without cystoscopy. Instead catheterization with a methylene blue solution was performed demonstrating absence of leakage. Two vaginal perforations were diagnosed during the insertion of the tunnel-

er, corrected by repositioning and re-passing of the tunneler and the tape, without complications.

No major intraoperative complications such as bowel and vessel injuries were reported in our study, confirming the results of other studies that indicate 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.[7]

There was minimal bleeding in our series as opposed to other published studies, which reported bleeding in excess of 200ml in 3.3% and 5.2% respectively.[7,13]

Routine uro-dynamic studies (UDS) were not performed to confirm the diagnosis of SUI in 120 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 the cough test is a useful and reliable tool in the diagnosis of SUI.[14] It is recommended that women with clearly defined clinical diagnosis of SUI do not need routine UDSprior to surgical intervention.[15] In our setting, UDS is limited to the patients with the history of OAB symptoms. Important considerations in the use of UDS include cost, discomfort and lack of reproducibility of the procedure.[16] A recent systematic review has failed to show that performing uro-dynamic studies improves the outcome of anti-incontinence surgery.[17] In a study by Nager et al.[18] 10% of the women with positive cough (stress) tests on clinical examination did not have SUI on urodynamic studies. Their conclusion was that the stress test is more sensitive than UDS. In a limited resource setting clinical assessment alone is adequate as it is our intention to treat the patient not the findings of the UDS.

De novo detrusor instability was noted in two patients and was treated successfully with oxybutynin.

The four failures, diagnosed with a positive cough test at six months and one year of follow up were managed by reinserting a new sling. All the complications that occurred where diagnosed within the first year following the insertion of the TOT. There was no decline in the efficacy of the procedure over time demonstrating its durability in spite of aging of the study population.

Sling erosions may be secondary to surgical technique and may relate to the sling material used. The low rate of erosion in this study is because all 5 slings used were polypropylene Type 1 meshes (macroporous, monofilament), and the technique of application was correct. The strength of this study lies on the fact that the same surgeon (AC) performed all the TOTs.

Urinary retention following TOT placement has been reported in the literature as between 1.5 to 15% respectively.[10,19,20] There were no cases of urinary retention in this series. Post-operative groin or thigh complications with TOT that were found in other studies[5,12] did not occur in this study.

A sub-analysis performed by Cheng Yu Long[20] found that TVT appeared to be more painful and the possible cause was that the exit point of the TVT needle is closer to the adductor muscle and the obturator neurovascular bundle compared with the outside-in TOT. Groin or thigh pain has been found to be more common with TVT-O inside-out procedures with a reported incidence of 16%-17%.[21,22] 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 to the ischiopubic ramus.[23] Tapes placed with the "inside out" technique were found further from the ischiopubic ramus, and closer to the obturator canal.[24]

Two patients with UDS-demonstrated mixed urinary incontinence (MUI) were cured after TOT, in keeping with the other studies showing a 91% improvement with MUI where the stress was the most bothersome symptom.[25]

CONCLUSION

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 maximum of 8 year follow up period, with a median of 5 years and 8 months. In the presence of this good, long-term results, the TOT procedure can be recommended for the management of female stress urinary incontinence.

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