

Safety and efficacy of the transobturator tape for stress urinary incontinence: short-term and medium-term results of 125 patients demonstrate a procedure-related learning curve

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Abstract Our aim was to assess the safety and efficacy of the transobturator tape (TOT) for the surgical treatment of female stress urinary incontinence. We report our initial experience in a district general hospital and study the learning curve effect. This is a retrospective study of the first 125 women to have the TOT procedure (Aris[®] Transobturator Tape). Short-term follow-up took place with the operating gynecologist in the clinic 3 months postoperatively, while medium-term follow-up was assessed by a patient questionnaire at 18–36 months (mean 23 months). Short-term success rate was 89.3%. Complications were bladder injury 2.4%, postoperative urinary tract infection 8.1%, transient voiding dysfunction 13.7%, tape erosion 4.1%, and de novo urgency 14%. Questionnaire response rate was 66%. Subjective cure at 18–36 months was 81.5% with 88.9% reporting an improvement in quality of life. Ten women underwent repeat TOT after primary procedure failure with 80% success. Tape erosion occurred up to 17 months postoperatively, thus overall incidence was 6.4%. The incidence of bladder injury, tape erosion, and tape failure was higher in the first 60 patients, thus we performed an analysis of these events by the number of procedures performed and demonstrated a definite learning curve. The TOT is a safe and effective surgical treatment for stress urinary incontinence; however, as for all new surgical procedures, there exists a learning curve.

Keywords Stress urinary incontinence · Transobturator tape

Introduction

Urinary incontinence is a common, distressing condition which affects women of all ages and can have a profound impact on quality of life. Women often have symptoms for a considerable amount of time before seeking a medical opinion. Stress incontinence is the complaint of involuntary leakage on effort or exertion or on sneezing or coughing, usually caused by weak or damaged muscles in the pelvic floor or sphincter [1]. Minimally invasive suburethral tape procedures which mimic the natural hammock to support the urethra are a very popular surgical treatment. The tension-free vaginal tape (TVT) was first described by Ulmsten in 1995. The transobturator tape (TOT) was introduced by Delorme et al. in 2001 and modified by de Leval in 2003 to allow insertion of the tape via the inside-out technique [2–4]. The transobturator route avoids blind entry into the retropubic space, thus, in comparison to the TVT, should carry less risk of bladder or bowel perforation, vascular injury, and major hemorrhage. For this reason, in contrast to the TVT, routine cystoscopy is not routinely required after TOT placement [5]. The procedure is relatively straightforward, can be inserted under local, regional, or general anesthesia, and performed as a day case procedure, thus minimizing hospital stay. However, TOTs are not without complications; these include bladder or urethral injury, tape erosion, de novo urgency, voiding dysfunction, groin or thigh pain, and abscess formation. There is now a wealth of evidence on their efficacy and safety and many randomized controlled trials have directly compared the retropubic and transobturator routes [6–8]. A 2007 systematic review and meta-analysis concluded that subjective cure rates at 2–12 months were similar for both TOT and TVT, that bladder injuries and voiding difficulties were less common with the transobturator route but that

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postoperative groin and thigh pain, vaginal injuries, and mesh erosions were more common [6].

The National Institute for Health and Clinical Excellence recommends that surgeons performing continence surgery should regularly audit outcomes, maintain careful audit data, and report adverse events. We report our initial experience of the TOT in a district general hospital where, previously, the TVT was the preferred surgical continence procedure.

Patients and methods

We conducted a retrospective study of 125 patients who opted for surgical management of their stress incontinence between July 2005 and April 2007. The patients were routinely referred to the gynecology clinic with symptoms of stress incontinence. All had detailed histories taken followed by pelvic examination. Midstream specimens of urine were sent to rule out urinary tract infection (UTI). All patients completed a frequency volume chart then underwent urodynamic studies.

The same tape was used for all patients; the Aris® Transobturator Tape by Coloplast UK inserted via the outside-in method. This is a synthetic, type 1 material—a macroporous, knitted polypropylene monofilament mesh of pore size $550 \times 170 \mu\text{m}$. There were two operating surgeons; both completed the same training, however, the vast majority of patients (113 of 125) were operated on by surgeon 1 with surgeon 2 performing the remaining 12 procedures.

All patients had a urinary catheter placed in theater prior to commencing the procedure. Post procedure cystoscopy was not routinely performed; only after complicated insertions or in cases of suspected bladder injury. Patients who had the TOT performed as a day case procedure with no concomitant surgical procedures had their catheters removed 2 h postoperatively. Those who had additional vaginal or pelvic floor surgery had their catheters removed after 24–48 h. After removal of the catheter, all patients had two post micturition bladder scans to check residual volumes. If both were less than 100 ml, the day case patients were discharged home. In cases where both volumes were more than 100 ml, then two further volumes were obtained and, if persistently high, the patient was commenced on distigmine bromide (Ubretid®, Rhône-Poulenc Rorer) 5 mg daily for 7 days. This is a long-acting anticholinesterase used in detrusor underactivity [9] which is also licensed short-term for postoperative urinary retention and has been used successfully in our experience. If residual volumes were greater than 300 ml, the patient had an indwelling urinary catheter replaced for a further 24 h. Length of hospital stay varied among those patients

who had additional surgical procedures, depending on the surgery performed and their recovery.

All patients were followed up as a minimum at 3 months postoperatively with uroflowmetry, residual volumes, and vaginal examination. Those in whom the tape was successful and who were symptom-free were discharged following this initial visit. Those who had postoperative complications or new or persisting symptoms had lengthier follow-up as appropriate. Medium-term follow-up was carried out at 18–36 months by a postal questionnaire and case note review. Success was defined as no stress leaks at all postoperatively. Failure was defined as no improvement in stress incontinence. Results were based on subjective cure.

Results

Age range

The patients were aged between 27 and 84 years. Forty-nine (39.2%) were ≤ 50 years old, 59 (47.2%) were aged between 51 and 69 years, while 17 (13.6%) were ≥ 70 years old.

Preoperative urodynamic results

All patients had preoperative urodynamic studies. Eighty-nine (71.2%) had urodynamic stress incontinence, while 36 patients (28.8%) had mixed (stress and urge) incontinence with stress being their predominant symptom.

Prior incontinence procedures

Only three patients had had prior continence surgery: one colposuspension, one TVT, and one suburethral buttressing.

Operative procedures

Fifty-seven patients (45.6%) underwent TOT placement as the only surgical procedure. Sixty-eight patients (54.4%) had concomitant surgical procedures, primarily vaginal hysterectomy and pelvic floor repair (Table 1).

Table 1 Concomitant surgical procedures

Procedure	Number	Percentage
Vaginal hysterectomy + pelvic floor repair	33	48.5
Pelvic floor repair	29	42.6
Sacrocolpopexy + pelvic floor repair	4	5.9
Laparoscopic sterilization	1	1.5
Refashioning of perineum	1	1.5
Total	68	100

Mode of anesthesia

Ninety-four patients had surgery performed under general anesthesia (75.2%), 23 under spinal anesthesia (18.4%), and eight under both general and spinal anesthesia (6.4%).

Intraoperative complications

We experienced one case of intraoperative hemorrhage (<200 ml) after tape placement. This necessitated tape removal to achieve hemostasis, following which the tape was replaced. Three patients suffered bladder injuries (2.4%). The first occurred during initial training and was unfortunately only diagnosed 3 months postoperatively at cystoscopy performed due to persistent dysuria. This confirmed a bladder injury below the right ureteric orifice. The patient underwent excision of the intravesical portion of the tape and remained continent. Since then, we have changed our practice and now leave the urinary catheter in situ for 2 h postoperatively (in day case patients having no concomitant surgery) to detect any hematuria which would indicate unrecognized bladder trauma. The remaining two patients had intraoperative bladder injuries diagnosed by cystoscopy performed due to suspicion. One patient had the tape removed and replaced correctly, while the other had the tape removed and not replaced as she had also undergone vaginal hysterectomy. This patient returned for the TOT procedure at a later date (outside of the study period).

Immediate postoperative complications

Fifty-seven patients had a TOT only; therefore, the catheter was removed 2 h postoperatively after which two post void residual urine volumes were measured. Four patients had persistently high residual urine volumes (>200 ml). Two were commenced on distigmine bromide. Two required recatheterization for a further 24 h. One had a proven UTI treated with antibiotics. The other had extremely high residual volumes >1,000 ml, so had the tape loosened prior to discharge with subsequent normal residual volumes. A total of three patients in this group had postoperative UTI (5.3%).

Sixty-eight patients had concomitant surgical procedures. One was excluded from further analysis as the TOT was removed following a bladder injury. Seven patients were treated for a postoperative UTI (10.4%). Thirteen patients had persistently high residual urine volumes (19.4%); 12 of whom were commenced on distigmine bromide, nine were also recatheterized for 24 h (10.4%), and two had the tape stretched prior to discharge. One patient had urinary retention which did not settle and necessitated intermittent self-catheterization (ISC) for 8 months after which time her symptoms resolved.

In summary, out of 124 patients, ten developed a postoperative UTI (8.1%) and 17 (13.7%) had transient voiding dysfunction which required intervention. Fifteen were commenced on distigmine bromide (12.1%), nine were recatheterized (7.3%), three had the tape loosened (2.4%), while only one had urinary retention necessitating ISC (0.8%). The incidence of voiding difficulty and UTI was higher in those patients who had concomitant vaginal surgery compared to those who did not (19.4% vs 7% and 10.4% vs 5.3%, respectively). The higher incidence of UTI may be due to increased catheterization time, whereas voiding difficulty may occur more commonly due to extensive dissection around the bladder with anterior repair and vaginal hysterectomy.

Efficacy: short-term follow-up at 3 months

Only two patients were lost to follow-up. One moved out of the area and the other repeatedly failed to attend appointments. A third patient was excluded from further analysis as the TOT was removed intraoperatively due to a bladder injury. Thus, 122 patients were reviewed at 3 months. One hundred nine patients were satisfied with the outcome of surgery (89.3%). One hundred four were completely dry (85.2%) and a further five (4.1%) experienced a significant improvement. Thirteen patients experienced no improvement in their stress symptoms at all (10.7%). Nine patients had pure stress incontinence (89.9% success rate for this group). The remaining four had mixed incontinence preoperatively with stress being their predominant symptom. The success rate for this group was 88.9%.

Late postoperative complications

Tape erosion occurred in five patients (4.1%). All were diagnosed on vaginal examination 3–4 months postoperatively. Three patients were symptomatic, having noticed rough areas in the vagina or experienced vaginal soreness, while two were asymptomatic. The site of tape erosion varied: three lateral and two midline erosions. Two patients had the TOT performed in isolation and three had concomitant vaginal surgery. Each patient underwent reburial of the eroded portion of the tape. Three of the five women had recurrent tape erosions at the same sites, 6–8 months after the initial TOT insertion. These women subsequently underwent excision of the eroded portion of the tape and closure of the vaginal defect. Four remained continent. Five patients (4.1%) reported personal or partner discomfort during intercourse which resolved with the use of lubricants. None had any evidence of tape erosion on examination. Eighty-nine patients had stress urinary incontinence preoperatively. The three patients excluded as explained above had stress incontinence, leaving 86 patients. Twelve reported de novo

urgency at 3 months (14%), nine of whom required treatment with anticholinergics (75%).

Effect of TOT on urgency

Thirty-two of the 36 patients with mixed incontinence were cured of their stress element. Seventeen patients (53.1%) reported that their urgency was also cured. Fifteen reported no effect on their urgency (46.9%). Nine continued on anticholinergics (60%), while six had only mild symptoms.

Medium-term follow-up: 18–36 months

Further follow-up data was collected by conducting a case note review and sending a postal questionnaire 18–36 months postoperatively (mean 23 months).

Case note review

A case note review was undertaken to identify any patients who had presented postoperatively with new or recurrent symptoms. The two main complications identified were recurrence of stress incontinence in patients who had initially reported success from the TOT and tape erosion. Two patients who had initially been continent following TOT insertion experienced a recurrence of their stress incontinence 9 and 15 months postoperatively. One had recurrent tape erosion and became incontinent after the eroded portion of the tape was excised.

Tape erosions were diagnosed in a further four patients. Two were diagnosed intraoperatively in patients attending for a repeat TOT procedure after the initial procedure had failed. Both were midline and both patients were asymptomatic of the erosion. The third patient was continent but experienced vaginal irritation 17 months postoperatively; lateral tape erosion was diagnosed and the eroded portion reburied. The fourth patient had been treated for tape erosion on two occasions and had a further recurrence. The incidence of tape erosion at 18–36 months was thus 6.4% with 50% of these women experiencing recurrent erosion.

Postal questionnaire

A postal questionnaire with a stamped addressed envelope was sent to 123 of the 125 patients. The questionnaire was anonymous. Eighty-one patients returned the questionnaire (66% response rate). The main results of the questionnaire were as follows: 90.1% of patients felt that their stress incontinence had improved postoperatively, 81.5% felt that their operation was successful at the time of responding to the questionnaire, 85.2% considered their operation successful initially (3 months postoperatively), 88.9% of patients reported that their quality of life had improved,

7.4% felt there was no difference, only 3.7% reported worsening in their quality of life (Fig. 1), 86.4% of patients were satisfied with the result of the operation overall, and 90.1% would recommend the procedure to another patient.

Learning curve analysis

All new surgical procedures have an associated learning curve. During the initial phase, complication rates and adverse events may be higher than average. We noted that many of the tape erosions and failed procedures occurred in patients operated on earlier in our experience, thus we wanted to investigate the learning curve effect. The technique of TOT placement was new to both surgeons who completed the same theoretical and practical training. Surgeon 1 performed the majority of procedures in this study (113 of 125), whereas surgeon 2 performed 12 of 125. In order to study the learning curve effect, we analyzed the results for surgeon 1 only, paying particular attention to the number of bladder injuries, tape erosions, and tape failures (see Table 2). As two patients were lost to follow-up, we have no outcome data in terms of whether they experienced tape erosion, success, or failure, so these two were excluded from this part of the analysis, leaving 111 patients. The patient whose tape was removed intraoperatively due to a bladder injury was excluded from tape erosion and success calculations. Overall incidence of bladder injury for surgeon 1 was two out of 111 (1.8%), tape erosion six out of 110 (5.4%), and success 97 out of 110 (88.2%). Figure 2 shows the learning curve effect on the incidence of bladder injury, tape erosion, and tape failure over time. As technical skill and confidence improve with the number of procedures performed, one would expect complication rates and adverse events to fall then plateau. The incidence of bladder injury was low—the peaks on the graph represent the occurrence of a single bladder injury as the actual numbers were very small. The incidence of tape erosion was 10% with the first ten procedures. After an initial decrease, this increased to 8% after 50 procedures then steadily fell to reach a plateau of 5–5.5%. The most striking finding was the marked decrease

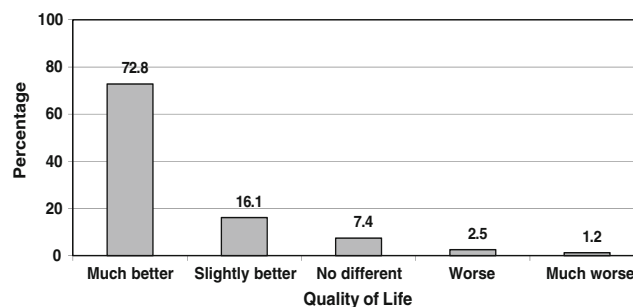


Fig. 1 Quality of life after TOT

Table 2 Learning curve analysis—surgeon 1

Number of procedures	Bladder injury (%)	Tape erosion (%)	Tape success (%)	Tape failure (%)
10	0	10	80	20
20	0	5	80	20
30	0	6.7	80	20
40	2.5	7.5	82.5	17.5
50	2	8	84	16
60	1.7	6.7	86.7	13.3
70	1.4	7.1	85.8	14.2
80	1.2	6.3	86.3	13.7
90	1.1	5.5	87.8	12.2
100	2	5	88	12
110	1.8	5.5	88.1	11.9

in the incidence of tape failure. The figure was unchanged until 40 procedures had been performed, then rapidly decreased to approximately 13% after 60 procedures. In summary, this learning curve analysis has shown that between 40 and 60 procedures were needed in order to observe a sustained and significant reduction in the above complications.

Discussion

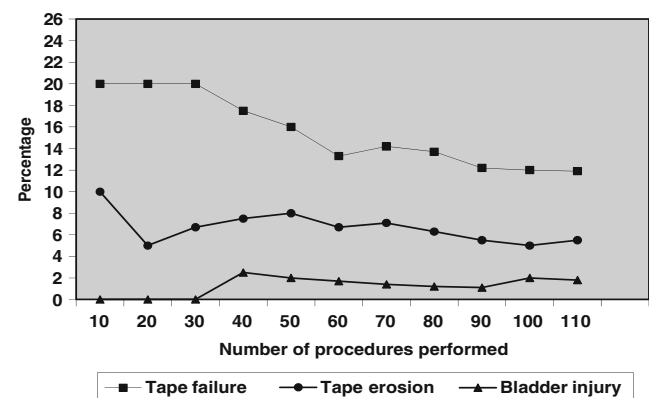
Many authors worldwide have now published their results and experiences with the TOT [10–22]. We report short-term success rates of 89.3% at 3 months which compares favorably to the patient-reported success at this time of 85.2%. At 18–36 months, subjective cure rates were 81.5%; however, 86.4% of patients were satisfied overall and 90.1% would recommend the procedure to another patient. Importantly, the vast majority of patients felt that the procedure had improved their quality of life (88.9%). While we recognize our study limitations, considering that this was a retrospective analysis and that our results are based on subjective cure with a self-designed questionnaire and not a validated quality of life questionnaire, the results are very encouraging. Since the study period, we have introduced the King's Health Questionnaire into our practice.

Although a successful treatment for female stress urinary incontinence, the TOT can be associated with significant complications of which patients must be counseled about preoperatively. The main complications are tape erosion, groin pain, bladder injury, and de novo urgency. Only one patient in our study suffered from postoperative groin pain which resolved spontaneously. We had no cases of wound infection, mesh infection, or groin abscess.

The incidence of bladder injury and tape erosion was slightly higher in our series compared to other published series. Bladder injury occurred in three of our patients (2.4%). The incidence of tape erosion into the vagina was 4.1% at 3 months rising to 6.4% at 18–36 months. There was no association with age or menopausal status and erosion as 62.5% of patients who experienced tape erosion were under the age of 50. Neither was there any increase in tape erosion in patients undergoing additional vaginal surgery; 50% had a TOT as a sole procedure and 50% had concomitant procedures. In addition, three out of four patients who had recurrent tape erosions underwent the TOT as a sole procedure. The safety of performing TOT procedures with concomitant prolapse surgery has been reported elsewhere [23, 24]. The observation that many of the above complications occurred early in our experience and that the incidence of these particular complications has been much lower in the 2 years since the study period prompted us to study the learning curve relating to the performance of the procedure as discussed above.

Bladder injuries are due to technical error, as are lateral erosions which most probably occur when dissection is too close to the vaginal wall. It is recommended that the vaginal sulci are systematically checked during and after TOT placement to avoid vaginal wall injury and subsequent erosion. Although the majority of women with tape erosions remained continent, we recommend that all patients have a pelvic examination at their initial follow-up visit to exclude asymptomatic tape erosion as it may lead to dyspareunia, mesh infection, sinus formation, abscess formation, and chronic pain and thus cause significant morbidity.

Fifteen patients failed to improve following TOT placement. Four (26.7%) had tape erosions treated surgically. There was no association with concomitant vaginal surgery; 53.3% of patients for whom the TOT failed to improve their symptoms had the TOT inserted as a sole procedure while 46.7% underwent additional vaginal

**Fig. 2** Learning curve effect on success and complications

surgery. All 15 patients with treatment failures were offered a repeat procedure. Five declined, ten accepted, and eight were successful (80%). Although our numbers are small, we have demonstrated success with repeat TOT procedures in cases of primary treatment failure. We have also demonstrated success in three patients with previous failed continence procedures with no intraoperative or postoperative complications in any of these patients. The patient whose tape was removed due to an intraoperative bladder injury returned to have the TOT reinserted; a successful outcome was achieved with no further complications.

One patient in our study became pregnant following surgery. At the time, there were no guidelines on the management of pregnancy or delivery following continence surgery. The patient was advised to have an elective Cesarean section due to the theoretical risk of disruption of the tape and recurrence of stress urinary incontinence following vaginal delivery. This was performed at 39 weeks gestation, 12 months following TOT insertion, and the patient remains asymptomatic. A paper has since been published on this subject. The authors report no significant increase in the risk of recurrence with vaginal delivery, thus we may counsel and advise our future patients differently [25].

Conclusion

The TOT is a safe, acceptable, and effective minimally invasive surgical treatment for stress urinary incontinence in women. It can be safely performed with other pelvic floor surgery. It can also be used successfully in patients who have had previous failed continence surgery. The incidence of adverse events is low; however, the procedure has an associated learning curve with the incidence of complications and failed procedures decreasing after approximately 40–60 procedures in our series. We await the results of further studies reporting more long-term data.

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