

Retrospective Review

The TVT-O Procedure with the cough test in theatre: Preliminary retrospective case series study in the first 25 women

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Abstract: This retrospective case series analyses the outcomes of the first 25 women with stress urinary incontinence (SUI) who were treated by the procedure of TVT-O under local anaesthesia and sedation with the cough test performed in theatre. The study addresses the intraoperative, immediate and medium term postoperative complications and cure rate in absence and presence of intrinsic sphincter deficiency (ISD). In this study all 25 procedures were performed successfully under local anaesthesia and sedation. There were no intraoperative complications or postoperative urinary retention. The short term complication was groin pain in two women (8%) which completely resolved by 6 weeks post surgery. Of the women who had their surgery in the morning 86% were discharged on the same day (within 10 hours). Regarding the only woman on the morning list that was discharged the following day, the delay in her discharge was planned preoperatively due to her medical history. There was only one woman (4%) with intermediate long term complications who developed pain in the vagina that required excision of a small part of the tape. This did not affect her cure from SUI. Two women (8%) developed mild urinary urgency that did not require any further management. 10 women (40%) in the study had ISD with or without hypermobile bladder neck and five out of them had maximum urethral closure pressure less than 20 cm H₂O. Only one woman was lost to follow up, all the remaining 24 women (with and without ISD) were cured from SUI in their last follow up (average 13.4 weeks).

Key words: TVT-O; Stress urinary incontinence; Intrinsic sphincter deficiency.

INTRODUCTION

Stress urinary incontinence (SUI) is a common problem in women. An epidemiological study has showed that 30% of women aged 50 years old have urinary incontinence and that of these up to 70% have complaints of SUI.¹ The tension-free vaginal tape procedure (TVT) has revolutionized the treatment of female stress urinary incontinence (SUI).² Five years later Delmore described an outside-in transobturator approach for the surgical placement of suburethral tapes.³ This new approach aims to avoid the potential complications associated with the retropubic approach such as injury to bowel, or major blood vessels and reduce the risk of injury to bladder or urethra. In 2003, de Leval J described the inside-out transobturator approach to insert the tape (TVT-O) It is advocated that this inside-out approach results in a more precise placement of the tape and this may further minimize the potential risks of perforation of the bladder and urethra that may happen with outside-in approach.⁴ Suburethral slings are the preferred surgical treatment of SUI in presence of intrinsic sphincter deficiency (ISD). This is a retrospective case series analyzing the first 25 cases of the TVT-O procedures performed under sedation and local anaesthesia at Royal Darwin Hospital and Darwin Private Hospital. The study described the outcome of the procedure by looking at the intraoperative, immediate and medium term post procedure periods with particular analysis on its effect on SUI with or without ISD. The results shall be compared with other studies.

STUDY DESIGN, MATERIAL AND METHODS

The study sample included the first 25 consecutive women who underwent the procedure of TVT-O (Gynecare) and cystoscopy performed under sedation and local anaesthesia December 2004 to October 2007 at two hospitals in Australia (Royal Darwin Hospital and Darwin Private Hospital). The main author (NG) performed 23 procedures and the remaining two were performed under his direct supervision.

The patients' notes were analyzed retrospectively on a purpose made master sheet. The data collected included referral source, age, parity, presenting symptoms, previous hysterectomy or surgery for SUI or pelvic organ prolapse

(POP), presence or absence of POP or hypermobile bladder neck (HMBN) during pelvic examination.

The data of preoperative urodynamic assessment (UDA) which was performed preoperatively in all patients was also tabulated. The UDA included uroflowmetry and filling cystometry. Intrinsic sphincter deficiency were identified in the following conditions: urinary incontinence on Val-salva or cough leak point pressure less than 60 cm H₂O or maximum urethral closure pressure (MUCP) of 20 cm H₂O or less. On diagnosis of urodynamic stress incontinence (UDSI) all women were advised on pelvic floor exercises (PFE) preoperatively and referred for physiotherapy. Women who had either been performing PFE or had no improvement with the same, were offered TVT-O and cystoscopy under sedation and local anaesthesia with the cough test to be performed in theatre. Women were also advised to continue PFE postoperatively. In women with preoperative diagnosis of ISD, the procedure of TVT versus TVT-O was discussed with them. They were informed that women with preoperative diagnosis of ISD the TVT procedure may have a higher cure rate than TVT-O; on the other hand, TVT has the potential risk of bowel or major blood vessels injury compared to TVT-O. The choice of each woman was respected.

Intraoperative complications such as bladder or urethral perforation, blood loss greater than 200 mls, blood transfusion or any other significant adverse event were tabulated.

Immediate postoperative complications that were evaluated included urinary retention, infection, thromboembolic events, return to theatre, blood transfusion or any other specific complication.

The medium term post operative assessment was performed at about six weeks post procedure. This included a detailed history, with special reference to the effect of the procedure on preoperative urinary symptoms and a physical examination to assess potential complications such as mesh erosion and/or recurrence of SUI. In this study, the procedure was considered to have failed if the patient reported persistence of stress leak and/or there was demonstrable urinary leakage on performing the cough test. UDA was not used postoperatively to assess the outcome of the procedure. The results of this study were compared with that of international studies.

Description of the local anaesthesia and sedation and cough test

In all the 25 women the procedure was planned to be performed under sedation and local anaesthesia. Patients are to be sedated first using a bolus of 1-2 mg midazolam, followed by propofol 1% infusion at a rate of 20-40 mls/hour titrated to effect. Then administration of local anaesthesia to the area of the suburethral vaginal incision, paraurethral lateral dissection, expected tape passage through the Obturator foramen and muscles and the exit on the skin of the inner upper part of the thigh on both sides. The local anaesthetic agent used was a total of 80-100 ml of 0.25% prilocaine with adrenaline (1:200,000). A small bolus of propofol (10-30 mg) and/or alfentanil (100-200 mcg) may be used when required in some patients during penetration of Obturator membranes. Once the tape is inserted on both sides, this is followed immediately by cessation of all sedation while cystoscopy is being performed to rule out any bladder or urethral injury. The bladder is filled to a volume similar to the volume when SUI was demonstrated during the preoperative UDA. When the patient is awake enough, the operative table is tilted head up about 30 degrees, then the patient is instructed to cough strongly and the tape is very slowly adjusted to the point when the urinary leakage just stops. Once this is achieved the table is returned back to the horizontal plane and vaginal skin is sutured using 2 or 3 interrupted 3/0 vicryl suture material. Then bladder is emptied via an in-out catheter and the patient transferred from the theatre with no indwelling catheter. Patient discharge is on the same day when the procedure is performed in the morning or on the following day when performed in the afternoon. Postoperative review in the clinic at 6 weeks post surgery is arranged prior to discharge.

RESULTS

History

Seventy two per cent of the patients were performed at the private hospital and 20 % were referred by other gynaecologists. The average age of patients was 52 years (range 39-66) with average parity of 3 (range 1-6). All women had at least one vaginal delivery in the past. Two women had one caesarean section (CS) and one woman had 2 CS as well as vaginal deliveries. All 25 patients (100%) had symptoms of SUI. The other reported urinary symptoms were: urge incontinence in 5 (20%), urgency in 9 (36%), frequency in 6 (24%) and nocturia in 5 (20%) patients. Three patients (12%) had undergone previous transabdominal surgery for SUI, one of which was confirmed to have been a Burch colposuspension and in two others this could not be verified. Ten women (40%) had undergone a hysterectomy and 6 (24%) POP repair in the past (Tab. 1).

Physical examination and UDA

Fifteen patients (60%) had POP, mostly 1st degree. All 15 patients had cystocele which was either alone or combined with another type of prolapse: 3 women had cystocele alone, 8 had cystocele and rectocele, 2 had cystocele, rectocele and uterine prolapse and 2 had cystocele, rectocele and vaginal vault descent. Most of these women had no specific symptoms related to the POP they had.

Hypermobility of the bladder neck were seen in 21 women (84%). Ten women (40%) in this study had ISD, 6 (60%) of them were in association with HMBN and 4 (40%) of them were ISD alone. Of the ten women with diagnosis of ISD 5 women (50%) had MUCP < 20 cm H₂O, 4 women had leakage on valsalva and the remaining patient had leakage on valsalva and the cough leak point pressure was less than 60 cm H₂O, this patient was lost to follow up. Two women (8%) had Detrusor instability (DI) (Tab. 2).

TABLE 1. – *Patients History.*

	<i>Number</i>	<i>%</i>
Public	7	28%
Private	18	72%
GP referral	20	80%
Specialist Ref	5	20%
Age	39-66 years	
Parity	1-6	3
Presence of SUI	In all women	100%
Urgency	9/25	36%
Urge incontinence	5/25	20%
Frequency	6/25	24%
Nocturia	5/25	20%
Previous surgery for SUI	3/25	12%
Previous Hysterectomy	10/25	40%
Previous POP repair	6/25	24%

Intraoperative and short term Complications and Hospital Stay

In all 25 women the TVT-O and cystoscopy procedures were successfully completed under local anaesthesia and sedation. There were no intraoperative complications such as bladder or urethral perforation, excessive blood loss and none developed post-operative urinary retention. One woman experienced two episode of nocturnal enuresis on the 2nd and 7th postoperative and day that resolved after administration of 1 mg tolterodine orally for two weeks. When the patient was reviewed 5 weeks later she was asymptomatic with no nocturia or SUI. Two patients (8%) developed significant pain in the upper thigh that required inpatient stay for 48 hours. They were pain-free by 6 weeks post surgery.

Of the women who had their surgery in the morning 86% were discharged on the same day (within 10 hours). The only one in this group who was discharged the following day, was an elective delayed discharge based on her medical history: This patient was on warfarin due to multiple heart conditions including an artificial pace maker. She was switched to Clexane preoperatively, and an indwelling urinary catheter was left overnight. Residual urine was < 50 ml the following morning and she was discharged home without any complications. Two of the women on the afternoon list were discharged on the same day (within 6 hours). A total of 23/25 (92%) were discharged within 24 hours of their surgery with only 2 patients (8%) required admission for more than 24 hours because of significant pain in the upper thigh that required more analgesia & physiotherapy. Both were discharged within 48 hours (Tab. 3).

TABLE 2. – *Preoperative physical examination and UDA.*

	<i>Number</i>	<i>%</i>
Presence of POP	15	60%
HMBN	21	84%
ISD	10	40%
HMBN + ISD	6	24%
ISD alone	4	16%
DI	2	8%

HMBN = Hypermobility bladder neck; ISD = Intrinsic sphincter deficiency; DI = Detrusor instability.

TABLE 3. – Intraoperative and short term complications and Hospital stay.

	Number	%	Comments
Intraoperative complications	0	0%	
Short term Urinary retention	0	0%	
Short Term DI	0	0%	One woman had 2 episode of nocturnal enuresis on the 2nd and 7th postoperative and day that resolved by the time she was reviewed 5 weeks later
Short term postoperative complications	2	8%	2 patients (8%) developed significant pain in the upper thigh that resolved by 6 weeks post surgery
AM list	7	28%	
Discharge of AM list on same day	6/7	86%	
PM List	18	72%	
Discharged on the same day	2/18	11%	
Discharged next morning	14/18	78%	
Discharged within 48 hours	2/18	11%	

Follow Up

Most of the patients were reviewed about 6 weeks post surgery, however 15 patients (60%) were reviewed again after this routine six weeks post surgery check-up visit. These further follow up visits were for either further reviews or due to consultations for other unrelated gynaecological conditions. Only one woman was lost to follow up. The average duration of follow-up was 13.4 weeks and the range was 4-52 weeks. The average duration between procedure and time of audit was 53 weeks and the range was 7-156 weeks. As early cases performed nearly 3 years ago, the absence of re-referral supports the assumption of a longer term successful post operative outcome right up to the time of audit.

In all these visits patients were assessed by history taking and pelvic examination to check for recurrence of SUI or other urinary symptoms and also to examine for any evidence of mesh erosion. Two patients were assessed by their referring gynaecological specialist who updated our records by the clinical assessment of the patient. Cure was diagnosed when patients express no further SUI and also in most patients negative cough test was performed in the outpatient clinic. One patient was lost to follow up; all the remaining 24 patients had no further SUI in their last consultation and were considered cured (Tab. 4).

There were two women (8%) who developed mild urgency and both patients did not wish to have repeat UDA nor any medication for the same. The only significant complication in this series happened to a patient who had TVT-O seven months following a total Prolift procedure.⁵ She presented herself about 3 months following the TVT-O complaining of pain inside the vagina. There was no recurrence of her SUI. Clinical examination revealed a tender spot on the right side of the lower anterior vaginal wall where the TVT-O mesh penetrates the Obturator membrane; there was no evidence of mesh erosion, granuloma formation or recurrence of the prolapse. The patient was admitted as a day procedure where she was examined under anaesthesia; there was no evidence of mesh erosion. The vaginal skin was incised over the tender spot described above and about 1 cm of the TVT-O mesh was excised up to where it penetrates the Obturator mem-

brane. The vaginal skin was then well mobilized before it was sutured. When she was reviewed in the out patient clinic, the patient was asymptomatic with no further pain or recurrence of SUI. On further review 6 weeks later there was no recurrence of pain in the vagina, but occasional pain in right lower quadrant when bending over. She is due for a further review in 6 months time from her last visit.

DISCUSSION

The TVT procedure has recently replaced Burch colposuspension as the gold standard surgical procedure for treatment of SUI. A systematic review of seven randomized trials of TVT or laparoscopic Burch colposuspension for treatment of SUI showed no significant difference for the two procedures in the rate of complications and subjective cure rates at 18 months but the objective cure rates was in favour of the TVT procedure. The TVT was associated with a shorter operative time and hospital stay.⁶ Several studies have noted that transobturator approaches had similar success rates to TVT. Bladder injuries and voiding difficulties were more common with TVT, but vaginal injuries and mesh erosion were more common with transobturator approaches.⁷ Several studies have shown that TVT-O has a shorter operative time than TVT.⁸⁻¹⁰

In this study all 25 procedures were performed successfully under local anaesthesia and sedation. There were no any intraoperative complications or postoperative urinary retention. The short term complication was groin pain in two women (8%) which completely resolved by 6 weeks post surgery. Of the women who had their surgery in the morning 86% were discharged on the same day (within 10 hours). The only woman on the morning list that was discharged the following day, the delay in her discharge was planned preoperatively due to her medical history. There was only one woman (4%) with intermediate long term complications who developed pain in the vagina that required excision of small part of the tape. This did not affect her cure from SUI. Two women (8%) developed mild urinary urgency that did not require any further management. One woman was lost to follow up and the remaining 24 women in the study were cured from SUI following the TVT-O procedure.

In a recent prospective observational study of 44 women who underwent TVT-O and had follow up visits at 3 and 12 months after surgery, 42.8% were cured, significant improvement in 17.1%, no improvement in 20% and deterioration in 8.7%. There was one bladder perforation. Significant haemorrhage occurred in 2 patients that required intervention. Three

TABLE 4. – Follow up and intermediate-term outcome.

	Number	%	Comments
Duration of FU			Average = 13.4 weeks Mean = 4-2 weeks
Duration to Audit			Average = 53 weeks Mean = 7-156 weeks
Intermediate-term urinary retention	0	0%	
Intermediate-term urgency	2	8%	Two woman developed mild urgency
Other intermediate-term complications	1	4%	Pain in the vagina required excision of part of the tape (see text)
No further USI at follow up	24	100%	One woman was lost to follow up

women (6.8%) had high residual urine >150 ml after removal of the urethral catheter, so it had to be re-inserted for one more day. The mean hospitalization was 3.75 days. The incidence of de novo urge incontinence was 13.5%. Five patients (11.4%) complained of groin pain but this was resolved at follow up at 3 and 12 months. It was described in this study that in 39 cases the operation was performed under subarchnoid anaesthesia, in 4 cases under extradural anaesthesia and in one patient under general anaesthesia.¹¹

In another prospective observational study from Belgium 102 women had TVT-O procedure and followed up for at least one year. 70.6%, 28.4% and 1% received spinal, general and local anaesthesia respectively. The woman who had local anaesthesia had sedation also. There was no urethral or bladder injury. One patient had vaginal sulcus laceration. There was no mesh erosion. Some patients complained of transient groin pain. The range of hospital stay was 1-4 days with a median of 1 night. Two patients had high residual urine that required placement of suprapubic catheter in one patient and intermittent self catheterization in the other one. It was reported that at their last visit the 2 women were cured of SUI with absent high residual urine and no de novo urge symptoms. Two women who underwent concomitant surgery for pelvic organ prolapse developed complete urinary retention that required immediate tape release. The tape was sectioned in another 2 women because of recurrent urinary tract infection and/or urgency associated with chronic retention 4 and 7 months after the TVT-O respectively. The cure rate in this study was reported as 91%.¹² The authors of the above study followed the same patients for a minimum of 3 years. There was no erosion or persistent pain noted, disappearance and improvement of SUI were observed in 88.4% and 9.3% respectively.¹³

In a study comparing the Monarc versus the TVT-O procedure in 50 patients in each group, all the procedures were performed under sedation and local anaesthesia. In the TVT-O group the post operative complications were: 1 case of urinary tract infection, another woman had transient urinary retention, 4 patients had pain in the thigh and one patient had de novo urgency. The overall cure rate at one year was 94%.¹⁴

Prior studies show that low MUCP has a negative effect on the cure rate after continence surgery.¹⁵

In our study 10 patients (40%) had ISD with or without HMBN. Five (50%) of them had MUCP less than 20 cm H₂O, 4 had leakage on Valsalva, the remaining patient (who was lost to follow up) had leaking on Valsalva and cough leak point pressure less than 60 cm H₂O. All nine patients who attended their follow up were cured by the procedure of TVT-O and cough test performed in theatre.

Miller et al., compared the transobturator procedure (Monarc, American Medical System) with that of TVT in patients with borderline MUCP. In this study MUCP of 20 cm H₂O or less was exclusion criteria for transobturator tape (Monarc) but not TVT. The borderline MUCP was considered as 42 cm H₂O or less. The study conclusion was: In women with preoperative MUCP of 42 cm H₂O or less, the MONARC was nearly 6 times more likely to fail than TVT at 3 months after surgery.¹⁶

CONCLUSION

TVT-O under local anaesthesia and sedation is very effective and safe surgical treatment of SUI in women with or without ISD. Our results achieved 100% cure rate with limited complications which compares very favourably with other studies.

We acknowledge the small number of the patient in this study and the relatively short term follow up period. We are looking forward to a large prospective randomized control-

led study to compare the outcome in women with SUI in whom the TVT-O procedure is to be performed with and without the cough test in theatre. Also within each group, the outcome is compared in women with and without ISD.

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