



The Outcome of TVT-O Procedure with Cough Test in Theatre under Local Anaesthesia and Sedation in Women with or without Intrinsic Sphincter Deficiency: Retrospective Case Series of 111 Women

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Abstract

Aim: To assess the outcome of TVT-O procedure performed under local anaesthesia and sedation, with a cough test, on patients with urodynamic stress urinary incontinence with or without intrinsic sphincter deficiency.

Methods: A retrospective study analysing the outcomes of 111 women between December 2004 and April 2013. The primary outcome was the resolution of stress urinary incontinence. The secondary outcomes were resolution of urge symptoms, detrusor over activity and occurrence of post-operative complications.

Results: The success rate was 99.1% in 106 out of 111, who were followed-up (Range: 6-208 weeks, Average: 23 weeks), including the 30 women (27%) with intrinsic sphincter deficiency. The resolution of urge symptoms and detrusor overactivity occurred in 93% and 85% of women respectively. Urinary retention occurred in 2 women (1.8%). Upper thigh pain occurred in 1.8%, and resolved by 6 weeks. Three women (2.7%) complained of dyspareunia at 6 weeks post-operatively and two of them required tape division. One of these two cases was the only case of mesh exposure in the study (0.9%). There were no other significant complications.

Conclusions: Our study demonstrated a subjective cure rate of stress urinary incontinence in 99.1% in patients undergoing the TVT-O procedure under sedation and local anaesthesia, performed with cough test in theatre. It shows low rates of urinary retention and high cure rates for symptoms of detrusor overactivity. These results compare favourably to other published studies.

Keywords

Intrinsic sphincter deficiency, Mid-urethral slings, Stress urinary incontinence, Tension free vaginal tape obturator, TVT-O.

Burch colposuspension used to be the gold standard for its treatment. Nowadays, Synthetic Midurethral Slings (SMS) have become the procedure of choice [2]. The Tension-Free Vaginal Tape (TVT) was the first introduced by Ulmsten in 1996 [3]. To avoid the potential serious complication of injury to the bowel or major blood vessels, Delorme and de Leval introduced the transobturator system [4,5].

In women with SUI with no intrinsic sphincter deficiency (ISD), TVT and TVT-O tape procedures have equivalent cure rates [6]. The transobturator route is associated with fewer complications and less reoperation rate when compared to Burch colposuspension [7,8].

The TVT procedure by Ulmsten was performed under local anaesthesia (LA) with a cough provocation test intraoperatively, thus allowing for the optimal tension of the tape to be achieved. The use of LA in TVT-O could not be located in any published papers, apart from the first author's previous publication [9]. Studies comparing spinal Vs general anaesthesia have found no difference in outcomes in terms of safety and efficacy [10,11].

This study aims to describe the intraoperative and postoperative outcomes of TVT-O procedures performed exclusively under sedation and LA by one surgeon.

Methods

This is a retrospective review of 111 consecutive patients who underwent the procedure of TVT-O (Gynecare, Ethicon) at Darwin Private Hospital, Australia between December 2004 and April 2013. The main author (NG) performed all 111 procedures. The fourth author (AM) was the specialist anaesthetist who administered the sedation in the majority of these patients. This study has ethics approval granted by the Medical Advisory Committee of Darwin Private Hospital.

All patients underwent a preoperative evaluation including

Introduction

Stress urinary incontinence (SUI) is very common in women [1].

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medical history, physical examination, Urinalysis and Urodynamic Assessment (UDA). The patient's notes were analysed retrospectively and recorded on a purpose made master sheet. The data collected included age, parity, mode of previous deliveries, 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. Preoperative UDA was performed in all patients by the author and included uroflowmetry and filling cystometry. In this study, ISD was identified by the following conditions: SUI on valsava or cough at less than 60cm H₂O or MUCP less than 20cm H₂O.

Women diagnosed with Urodynamic Stress Incontinence (UDSI) were referred for physiotherapy to undergo Pelvic Floor Exercises (PFE) preoperatively. Women, who had no improvement with PFE, were offered TVT-O and cystoscopy under sedation and LA with the cough test to be performed in theatre. In women with preoperative diagnosis of ISD, the procedure of TVT versus TVT-O was discussed with them. They were informed that in women with a preoperative diagnosis of ISD the TVT procedure may have a higher cure rate than TVT-O; However the TVT has the potential rare risk of bowel or major blood vessels injury. The choice of each woman was respected.

The postoperative assessment was performed at approximately six weeks post-procedure, including a detailed history and a physical examination to assess persistence of SUI or other urinary symptoms and for potential complications including mesh exposure. In this study, the procedure was considered to have failed if the patient reported persistence of SUI and or demonstrable urinary leakage on performing the cough test. UDA was not used postoperatively to assess the outcome of the procedure.

Description of local anaesthesia and sedation

The anaesthetic goal is to provide good surgical conditions and patient comfort with the ability to wake the patient to allow for the cough test during surgery. Patients are usually anxious about the idea of waking prior to the end of surgery and a large component of the pre-operative anaesthetic consult involves explaining the procedure and easing their concerns. Routine monitoring of ECG and pulse oximetry is applied. Oxygen is given via Hudson mask at 6L/min. Intravenous access is established and surgical antibiotic prophylaxis is given. The patient is given 3-4mg of midazolam and 50mcg of fentanyl. An initial propofol dose of 30-50mg is given followed by additional propofol increments (usually up to 120mg) are given until the patient stops responding to the LA injections by the surgeon. Care is needed to avoid inducing apnoea. When the patient is unresponsive to pain, propofol at 20mls/hour is given by infusion until the injection of LA is complete.

Local anaesthesia is administered for analgesia, vasoconstriction and hydrodissection to the area of the suburethral vaginal incision, the expected passage of paraurethral lateral dissection, the obturator foramen and muscles and to the exit point on the skin of the inner upper part of the thigh on both sides. The LA agent used is a total of 80-100ml of 0.25% prilocaine with adrenaline (1:200,000). Occasionally extra propofol increments 20-30mg will be needed during the procedure if the patient wakes prematurely. Once the tape is inserted on both sides the propofol infusion is stopped to give it time to wear off, while acystoscopy is performed. The woman is then gently woken by saying her name and shaking her shoulders. Cough provocation test is then performed and when the procedure is completed the patient is taken to recovery for routine post-surgical care. Postoperatively, women had no recollection of the surgery or experiencing pain during it, and only recall being instructed to cough.

Description of procedure & cough provocation test

All the TVT-O procedures were performed in a similar technique originally described by de Leval [5], with the exception that the obturator membrane is not perforated with the scissors, but initially with the winged guide, and later on with the spiral trocar. Once the tape has been inserted on both sides, sedation is ceased and the

bladder is filled with normal saline to a volume similar to that at which SUI was demonstrated during the preoperative UDA. Arigid 30 or 70-degree cystoscopy is performed to rule out any bladder or urethral injury. When the patient is awake enough, the operative table is tilted head up about 30 degrees, and the patient is instructed to cough strongly whilst the tape tension is held loosely into position beneath the urethra using a pair of Metzenbaum scissors. Initially leaking upon coughing is demonstrated, and alternative 1-2mm traction on the two ends of the tape allows repositioning of the mid portion of the tape to maintain a closer contact with the ventral aspect of the urethra. The practice of the principal author ensures that the cough test is performed following each pull, and the adjustment ceases once the patient just stops leaking. Once this is achieved the bladder is emptied via an in-out catheter and vaginal skin is sutured using interrupted 3/0 vicryl suture material. No indwelling catheter is left in-situ. Initially, it was the surgeon's practice for patients to be admitted overnight. However, after the first twenty operations, they were all routinely discharged home on the same day unless there was a medical or social reason for admission. Postoperative review in the clinic at 6 weeks was arranged prior to discharge.

Results

Patient characteristics

The average age of patients was 51 years (range 39-79) and the majority of women were referred by their GP (88%), with 12% presenting after referral by other gynaecologists. The parity was not clear in 4 women. Of the 107 women with clearly documented parity, all but 2 women (1.9%) were nulliparous and 105 women (98.1%) were multiparous with an average parity of 2.8 (range 0-7 children). Past mode of delivery was variable with 91 women (85%) having had only vaginal deliveries, eleven women (10%) having had both a vaginal and caesarean delivery and only 3 women (2.8%) had exclusively caesarean deliveries. All 111 patients (100%) had symptoms of SUI with only 40 women (36%) presenting exclusively with SUI symptoms. Twenty eight patients (25%) in this study perceived their SUI symptoms to be severe. Seventy one women (64%) had also urge symptoms. The other commonly reported urinary symptoms were: urge incontinence in 49 (44%), urgency in 62 (56%), frequency in 31 (28%) and nocturia in 36 (32%) of women. Other urinary symptoms reported by the women included, leakage during intercourse (4 patients), dysuria (2 patients), dribbling (1 patient) and suprapubic pain (1 patient). Furthermore, 12 patients (11%) were confirmed to have a pre-operative UTI based on mid-stream urine sample. Eight patients (7%) had undergone previous surgery for SUI, none of them by the main author. Four had undergone a Burch colposuspension, one had undergone a sling (type unknown) and in three other patients the type of previous operation could not be verified. One third of the women (37) had previously undergone a hysterectomy. Nineteen women (17%) had a POP repair in the past (Table 1).

Physical examination and UDA

Clinical examination revealed that 57 women (51%) also had POP with 12 women (11%) reporting symptoms that may be related to POP and 45 women (41%) presenting with asymptomatic POP.

Preoperative UDA confirmed that all 111 women (100%) in this study had SUI. Eighty women (72%) had HMBN. Thirty women (27%) had ISD, 20 of them (18%) were in association with HMBN while 10 of them (9%) were diagnosed with ISD alone. ISD is defined as a Valsalva leak point pressure of less than 60mm H₂O or a maximum urethral closure pressure (MUCP) of less than 20cm H₂O [12]. One woman (0.9%) did not fit into the diagnosis of ISD or HMBN. Thirteen women (12%) had detrusor overactivity (DO).

The mean MUCP was 40cm H₂O, with a range of 14-122cm H₂O. There were 15 patients (14%) with a MUCP of <20cm H₂O. Five of these patients also had leaking on valsava or cough at pressure of <60cm H₂O. Nineteen patients (17%) had leakage on valsava or cough at pressures of <60cm H₂O (Table 2).

Table 1: Patient characteristics

Characteristics	Number	
Age (years)	51 (Range 39 -79)	
Parity (median [range])	2.8 (Range 0-7)	
Vaginal only	91	85%
Caesarean only	3	2.8%
Both	11	10%
Nullipara	2	1.9%
History of caesarean	14	13%
Presence of SUI	111	100%
Urgency	62	56%
Urge incontinence	49	44%
Frequency	31	28%
Nocturia	36	32%
Preoperative UTI	12	11%
Previous surgery for SUI	8	7%
Previous Hysterectomy	37	33%
Previous POP surgery	19	17%

POP: Pelvic Organ Prolapse, UTI: Urinary Tract Infection,

SUI: Stress Urinary Incontinence.

Table 2: Preoperative physical examination and Urodynamic assessment

	Number	
Presence of POP	57	51%
Asymptomatic	45	79%
Symptomatic	12	21%
UDSUI	111	100%
MUCP (cm H ₂ O)	Average 40	Range 14-122
10-19	15	14%
20-29	26	23%
30-39	22	20%
40 - 99	45	41%
>100	3	3%
HMBN only	80	72%
HMBN + ISD	20	18%
ISD only	10	9%
Leaking on Valsalva or Cough at 60cm H ₂ O	19	17%
No HMBN and No ISD	1	1%
DO	13	12%

UDSUI: Urodynamic Stress Urinary Incontinence, MUCP: Maximal Urethral Closure Pressure, HMBN: Hypermobile Bladder Neck, ISD: Intrinsic Sphincter Deficiency, DO: Detrusor Overactivity.

Hospital stay and intraoperative and short-term complications

The TVT-O and cystoscopy procedures were successfully completed under LA and sedation in all 111 patients. Two women were previously excluded from the study due to their preoperative planned mode of anaesthesia. One woman had a spinal anaesthesia, as she was suffering from sleep apnoea and lung cancer. The other woman had general anaesthesia because of morbid obesity.

All women in the study had their surgery in the afternoon, 73 women (65.8%) were discharged on the same day (within 4 hours of surgery). There were 32 patients (28.8%) who had an elective pre-planned admission overnight. This included the first 20 women (18%) when it was the routine practice. Most of the other admissions were because the patients were either from a rural location or did not have a responsible adult to look after them overnight. In one patient, preoperative anxiety was the indication for planned admission.

Only 2 patients (1.8%) had an unplanned postoperative hospital admission. One patient required admission for 48 hours because of pain in the upper thigh. The second patient experienced urinary retention. This patient's Post Void Residual (PVR) was approximately 400ml twice in the evening post-procedure, and a Foley's indwelling catheter inserted overnight. On removal of the catheter the following morning, the repeated PVR were approximately 300ml. The patient demanded for the tape to be divided, in spite of advice to allow more time for the resolution of the urinary retention, and after tape

Table 3: Perioperative and hospital detail

Outcomes	Number
Type of anaesthesia	
Sedation and LA	111 (100%)
Intraoperative complications	0 (0%)
Hospital admission	
Discharged same day	77 (69.3%)
Planned admission	32 (28.8%)
Emergent admission†	2 (1.8%)
Thigh pain	2 (1.8%)
Post operative urinary retention	2 (1.8%)
Sling release‡	1 (0.9%)

† One patient thigh pain and one patient with urinary retention.

‡ Sling divided in the patient with urinary retention at patient request.

Table 4: Patient outcomes

Outcomes	Number	
Average duration of follow-up (weeks)	23 (Range 6 – 208)	
Patient report of symptoms at 6 weeks		
Cure of SUI	106/106 (100%)	5 lost follow-up
Cure of Urge	66/71 (93%)	1 lost follow-up
Cure of DO	11/13 (85%)	
De novo DO	0/98 (0%)	
Upper thigh pain	0/106 (1.8%)	
Dyspareunia	3/106 (3.8%)	
Post operative mesh exposure	1/106 (0.9%)	
Need to divide or to excise mesh	3/106 (2.8%)	
Post operative UTI	2/106 (1.8%)	

SUI: Stress Urinary Incontinence, DO: Detrusor Overactivity, UTI: Urinary Tract Infection.

division the retention resolved (Table 3). There was one further case of short-term urinary retention that resolved spontaneously, bringing the rate of urinary retention within the cohort to 1.8%. This patient already had a planned overnight admission due to her residing in a rural location and was discharged to her community after 48 hours with education about Intermittent Self-Catheterisation (ISC). Her bladder chart showed low PVR and the ISC stopped at one week post discharge.

In this study, there were no complications such as bladder or urethral perforation, blood loss greater than 200ml, blood transfusion or any other significant adverse event.

Follow up and late post-operative complications

Most of the patients were reviewed approximately 6 weeks after surgery. The follow up rate was 95.5% with only 5 patients lost to follow up (4.5%). Women were routinely discharged to their referring doctor following the 6-week review. Two patients were assessed by their referring gynaecological specialist. Some women were seen back by the main author either for further reviews or due to consultations for other unrelated gynaecological conditions. The average duration of follow-up was 24 weeks and the range was 6-208 weeks. The average duration between procedure and time of audit was 208 weeks (4 years) and the range was 18-454 weeks (8 years 38 weeks).

Table 4 summarizes the outcome of the procedure. Of the 106 who completed their follow up at 6 weeks, all of them reported complete resolution of preoperative SUI, which is a 100% cure rate. During the audit period, only the woman who demanded post-operative division of the tape reported a return of her SUI symptoms, approximately 8 months after surgery, but only during episodes of severe sneezing due to hay fever. Hence, the long-term cure rate of SUI in this study is 99.1%.

Of the 71 patients who had reported urge symptoms pre-operatively, 66 patients (93%) had complete resolution of symptoms, while 5 patients (7%) had persistent urge symptoms. Of the 13 patients diagnosed with symptoms of DO pre-operatively 11 reported complete resolution of symptoms (85%), with 2 patients (15%) experiencing persistent DO. There were no women with de novo DO

at 6 weeks post-operatively. Two women (1.8%) who experienced pain in the upper thigh had complete resolution by 6 weeks. There were 2 women (1.8%) who developed UTI within the first 6 weeks.

There were also three women (2.7%) who complained of dyspareunia at 6 weeks post-operatively. One woman was given an appointment in 3 months to check on any persistence of symptoms but did not attend for follow up. The second woman was the only patient in the cohort who developed mesh exposure at the vaginal incision site. She had intercourse at 18 days post procedure, despite being advised to wait for a minimum of 4 weeks. She underwent an excision of the exposed part of the mesh 11 weeks post-operatively. The third patient did not have mesh exposure but underwent a mesh excision due to symptoms of dyspareunia as she reported discomfort at the time of sexual intercourse, and her partner also felt the mesh. On palpation there was tenderness over the central part of the mesh and this part was excised 36 weeks after the initial surgery. Both women were followed up at 6 weeks post mesh excision and remained free from SUI symptoms with complete resolution of dyspareunia. There were no other significant long term post-operative complications in the study, including neurological, vascular, bladder or urethral injury.

Discussion

In 2008 the 4th International Consultation on Incontinence concluded that the TVT procedure was more effective than the Burch colposuspension as treatment for SUI [13]. A 2009 Cochrane review concluded that SMS operations had significantly less de novo urgency and urgency incontinence, shorter operating time, hospital stay and time to return to daily activities when compared with colposuspension [14]. Between 2005 and 2011 studies comparing TVT and TVT-O confirmed that the transobturator approach for SUI were less favourable than the retropubic approach with respect to objective cure rate (84 vs 88%, CR 0.96, CI 95% 0.93-0.99, 17 trials, n = 2,434) despite no differences in subjective cure rate [15,17]. However, there was less voiding dysfunction, blood loss, bladder perforation (0.3% versus 5.5%, RR 0.14, 95% CI 0.07 to 0.26) and shorter operating time with the transobturator route [16]. Bladder injuries and voiding difficulties were more common with TVT, but vaginal injuries and mesh exposure were more common with transobturator approaches [17].

This paper aims to suggest that the success rate of TVT-O is aided by the use of sedation and LA, thus allowing for an individualised approach to tape adjustment, based on direct real time feedback from the patient during the intraoperative cough test. The use of general or spinal anaesthesia would not allow for same feedback, although studies comparing spinal and general anaesthesia have found no difference in outcomes or cure rates between the two modalities [10,11]. Yet, the original technique described by Ulmsten for TVT was performed under LA with a cough provocation test to help achieve the optimal tape tension. It is well documented in pelvic floor teaching that the accuracy of adjustment of the sling is critical to its success, as the difference between postoperative continence and incontinence may only be 2mm [18]. Hence the mode of anaesthesia may have potential implication for the success rate of transvaginal sling procedures.

All 111 procedures were performed successfully under LA and sedation with minimal impact on patient recovery, discomfort and postoperative complications. At 6-week follow up this study has 100% cure rate for SUI for all of the 106/111 patients who were followed up, including the woman who requested division of the tape 24 hours post surgery. This patient reported a return of her SUI symptom, approximately 8 months after surgery, mainly during episodes of severe sneezing due to hay fever. Hence the long term cure rate for SUI in this audit is 99.1%.

A recent prospective observational study with a 10-year follow up of 63 women showed a subjective, objective and urodynamic cure rate of 89.7%, 93.1% and 91.4% respectively [19]. Nilsson et al. reported an 11-year follow up data of TVT in 90 women that demonstrated objective and subjective cure rates of 90% and 77% respectively [20].

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. There was no urethral or bladder injury. One patient had vaginal sulcus laceration. The immediate cure rate in this study was reported as 91% [21]. The authors of the above study followed their 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 [22]. A smaller 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 [23].

In this study, there were no major intraoperative or immediate complications in the form of bladder or urethral perforation, vessel or bowel injury, haemorrhage, or blood transfusion. The two immediate postoperative complications were groin pain in two women (1.8%), which completely resolved by 6 weeks and urinary retention in 2 women (1.8%). Cheng and colleague reported a urinary retention rate of 11.6% with groin pain being the major complaint in 25 out of 103 patients (24.3%). One patient required mesh excision due to erosion and 3 required tape release [24]. In our study there was one case of immediate post-operative tape division (0.9%) at the request of the patient and 2 cases of mesh excision (1.8%), one of which was performed for mesh exposure as a result of intercourse on day 18 post-surgery and the other for dyspareunia. In this study, cystoscopy was performed routinely for all women. Most published studies report no intraoperative bladder perforation. Despite this, it has been reported in a few studies. In his study, Pushkar et al. reported that 3 women (0.6%) out of 537 experienced bladder perforation during TVT-O procedure [25]. In another two studies, the risk was surprisingly higher, occurring in 6 out of 100 women, and 2 (3%) out of 69 women experienced bladder perforation during TVT-O procedure [26,27].

Our cure rate for urge symptoms was 93% and 85% for DO which was considerably higher than those reported elsewhere in the literature. There were no cases of de novo DO. Lim et al. examined outcomes after 1 year showing a decrease in urge incontinence from 59% to 35%, with a rate of de novo DO of 4.8% [28]. Jakimiuk et al. reported the incidence of de novo urge incontinence in their cohort was 13.5%. None of these cases were performed under LA [23,25]. In a similar sized study, with a 10 year follow up, de novo overactive bladder was reported by 30.1% and 18.9% of patients at 3 month and 10 years up respectively [19].

Prior studies show that ISD and low MUCP have a negative effect on the cure rate after continence surgery. Our study included 30 patients (27%) with ISD with or without HMBN. Fifteen of them (13.5%) had MUCP less than 20cm H₂O, with 5 having leakage on Valsalva. Most previous trans-obturator studies excluded patients with ISD. The TVT procedure has a significantly greater success rate than the TVT-O in women with ISD [29,27]. In our study, all the 30 patients who had ISD were cured at 6 weeks follow up visit. A study by Schierlitz, included women with ISD comparing TVT vs TVT-O showed that 20% of women in the TVT-O group needed repeat surgery within 3 years to correct SUI, compared to only 1.4% of women in the TVT group [30]. Miller et al. compared the Monarc procedure with TVT in patients with borderline MUCP. The study concluded that in women with preoperative MUCP of 42cm H₂O or less, the MONARC was nearly 6 times more likely to fail than TVT [31]. In our study 63 women (59%) had a MUCP of less than 40cm H₂O and all had cure of their SUI symptoms. Unfortunately there has been no subgroup analysis within the larger randomised studies to support this and many studies investigating SMS have previously excluded women with ISD.

We acknowledge the limitations of this study, which does not allow for randomisation or comparison between different modes of analgesia. Another limitation of this study is that our results are based on relatively short follow up periods, subjective reporting and clinical examination only, rather than validated questionnaires or

postoperative UDA.

TVT-O under sedation and LA with intraoperative cough test is a highly effective option for the treatment of female SUI with or without ISD. We have demonstrated high subjective cure rates of 99.1% in the 111 patients who underwent the TVT-O procedure under sedation, which compares very favourably to other published studies. We propose that our method of performing the procedure under sedation and LA allowed for the benefits of an intraoperative cough test, which may contribute to this high resultant cure rate for SUI and DO, and a lower rate of post-operative urinary retention and de-novo DO. Prospective comparative randomised controlled trials are necessary to validate these apparent benefits in this study.

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