

TENSION – FREE VAGINAL TAPE: THE INSIDE-OUT TRANS-OBTURATOR TECHNIQUE IN THE TREATMENT OF STRESS URINARY INCONTINENCE IN WOMEN

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ABSTRACT

Aim: The objective of this study was to assess the effectiveness and safety of stress urinary incontinence (SUI) treatment in women with placement of tension-free transobturator vaginal tape using the inside out technique (TVT-O).

Methods: Thirty eight patients with clinically and urodynamically - proved SUI constituted the subjects of this study. The transobturator inside-out tension-free urethral suspension in which a synthetic tape is passed from underneath the urethra, through the obturator foramen, towards the thigh fold, without entering the pelvis, was performed. The tape is positioned without tension under the mid-urethra.

Results: Mean operative time was 18 minutes (range: 13 – 25 minutes). With the exception of only one case (2.6%) of a significant (> 200 ml) bleeding, no other intra-operative complication was reported. Also, no hematoma or wound infection was noticed after the procedure. Five patients (13.2%) developed significant pain in the upper thigh which required injectable analgesics and inpatient stay for 24 - 48 hours post-operatively. Two patients (5.3%) developed urine retention which necessitated intermittent self catheterisation for 3 - 4 weeks. Three patients (7.9%) reported de novo urgency at 6th weeks. In two of them, this symptom disappeared spontaneously at the 3rd month. The remaining patient had her tape, eventually, cut under a general anaesthetic. Only one case (2.6%) of mesh erosion, which was repaired surgically, has been noted in this study. Two patients (5.3%) reported persistence of their SUI. Therapeutic failure diagnosis was confirmed on urodynamic assessment (UDA). All of the 36 women who attended their last follow up visit reported no further SUI and, therefore, were considered cured.

Conclusion: The experience gained through this study indicates that the TVT-O procedure for treating SUI in women is associated with a very low morbidity and high rates of success. However, further studies in larger populations with longer follow up are warranted to determine the presumed efficacy and significantly decreased morbidity of this procedure.

Keywords: Stress urinary incontinence, Transobturator, TVT-O

INTRODUCTION

SUI is defined as “the complaint of involuntary leakage of urine, through the urethra, on effort, sneezing or coughing without rise in detrusor pressure”.^{1, 2} It is a common problem which has a significant impact on the quality of life for many women. SUI is variably estimated to affect between 4% and 35% of adult women.³⁻⁵

The exact causes of SUI are not precisely known. However, numerous risk factors have been identified. Aging, obesity, and smoking appear to have consistent causal relationships with the condition, whereas the roles of pregnancy and childbirth remain, to some extent, controversial.¹

In an ideally supported urogenital tract, increases in intra-abdominal pressure are equally transmitted to the bladder and urethra. In women who are continent, these increases in pressure resulting from cough, laugh or sneeze are countered by supportive tissue tone provided by the levator ani muscles and vaginal connective tissue while in those with a weakened support, these forces are not countered. This leads to funneling of the urethrovesical junction, a patent

urethra, and in turn, urine leakage. Also, loss of urethral support results in reduced urethral closing pressures, inability to resist increases in bladder pressure and finally, incontinence.³

Treatment for SUI includes initial conservative therapies, and surgery is indicated when the former fail or are not feasible or desirable. More than 200 surgical procedures have been described for the treatment of SUI.³

The gold-standard surgical treatment of SUI has been a retro-pubic approach using either a Burch retro-pubic urethropexy or Marshall-Marchetti-Krantz (MMK) procedure.⁶ Laparoscopic Burch was successfully first performed in 1991.⁷

The retro-pubic tension-free vaginal tape (TVT) procedure first described by Ulmsten et al.⁸ has then replaced Burch colposuspension as the gold standard surgical procedure for treatment of SUI.⁹ There are, however, concerns over the safety of the TVT procedure. A Finnish series of 1455 women treated for SUI demonstrated several vascular injuries, while another study reported a case of right external iliac artery injury.^{10, 11} In addition, two deaths due to serious vascular

injuries have been reported as have bladder and bowel perforations.^{12, 13} Most of these complications are related to the penetration of the retro-pubic space.

In order to avoid the complications of the TVT procedure but keep the principle of a minimally invasive procedure, the outside in trans-obturator procedure (TOT) has been described.¹⁴ It has been suggested that this procedure marked the beginning of a new, simpler, and innocuous form of treating SUI in women.¹⁵⁻¹⁷

A further modification to the surgical technique, which allows the passage of a trocar and tape through the obturator foramen from inside to the outside (TVT-O) has later been described.¹⁸ It was claimed that this further reduced any risk of damage to the urethra and bladder.

The objective of this study was to assess the effectiveness and safety of SUI treatment in women with placement of tension-free trans-obturator vaginal tape using the inside out (TVT-O) technique.

SUBJECTS AND METHODS

This study was carried out over the period from May 2008 to April 2009 at Countess of Chester Hospital, Chester, England, UK. Thirty eight patients with clinically and urodynamically - proved SUI constituted the subjects of this study. Patients with mixed urinary incontinence, voiding disorders, major pelvic organ prolapse, previous SUI surgery, or detrusor over-activity were excluded. Approval of the local hospital ethical committee has been sought.

Cases were identified from the theatre register, and case notes retrieved from medical records. These were reviewed and patients' data were collected using a purpose-designed proforma.

A detailed history was taken and a thorough clinical examination was performed. A pre-operative UDA in order to confirm the diagnosis of SUI and to exclude patients who should not have the TVT-O procedure (e.g. those with voiding disorders) was arranged for all patients.

After confirming the diagnosis of SUI on UDA, patients were referred for physiotherapy and advised on pelvic floor exercises. Women who had no improvement were counselled regarding having the TVT-O procedure. All participants were fully informed about the benefits and risks of the procedure, and a signed consent was obtained from them before the operation.

The mode of anaesthesia was discussed pre-operatively with all patients and their individual choices were respected in the light of their suitability. At the beginning of the procedure, an indwelling Foley's catheter was inserted in the bladder but cystoscopy was not performed.

The TVT-O procedure was carried out using the technique pioneered by de Laval.¹⁸ Patients scheduled to the morning list were planned to be discharged on the same day while those on the afternoon one were discharged the following day.

Cure was defined as the absence of urine leakage, no pad use, and a negative cough test. In this study, the procedure was considered to have failed if the patient reported persistence or recurrence of stress urinary leak and/or there was demonstrable leakage on performing the cough test. With the exception of only 2 cases, UDA was not routinely used postoperatively to assess the outcome of the procedure.

Patients were seen at 6 weeks and then further reviewed at 3, 6, and 12 months postoperatively. At each visit, women were interviewed with emphasis on the effect of the procedure on preoperative urinary symptoms, postoperative complications and the need for further therapy – if any. Physical examination to check for persistence or recurrence of SUI and assess potential complications such as mesh erosion ...etc. was carried out.

RESULTS

A total of 38 patients were operated on using the TVT-O inside-out technique between May 2008 and April 2009. Table 1 shows the demographic data while Table 2 illustrates the operative data of all patients.

With the exception of only one case (2.6%) of a significant (> 200 ml) intra-operative bleeding which did not require extra-ordinary intervention, no injury to the bladder, urethra, bowel, nerves, or any other intra-operative complication was reported in this study (Table 3). Also, no hematoma or wound infection was noticed after the procedure.

Five patients (13.2%) developed significant pain in the upper thigh which required injectable analgesics and inpatient stay for 24 - 48 hours post-operatively (Table 3). Pain was not reported by any of the patients 6 weeks after the operation. All cases, except 5, were discharged within 24 hours.

Two patients (5.3%) developed urine retention which necessitated intermittent self catheterisation for 3 weeks in one and 4 weeks in the other (Table 3). Both patients were totally free of this complaint at the first follow up visit 6 weeks post procedure.

Three patients (7.9%) reported de novo urgency at the 6th week follow-up visit (Table 3). In two of them, this symptom disappeared spontaneously at the 3rd month visit. The remaining patient was commenced on Oxbutynine orally for 3 months. Despite that, her complaint persisted and

eventually her tape was cut under a general anaesthetic. All 3 patients reported no further SUI. Only one case of mesh erosion (2.6%) was noted in this study (Table 3). This patient was advised to abstain from intercourse. Local application of estrogen cream to allow a layer of vaginal mucosa to grow and cover the sling was tried for 9 weeks. However, when conservative management failed, surgical repair was performed under a general anaesthetic. The vaginal flaps around the site of erosion were mobilised, the extruded part of the mesh was removed and the remaining mesh was carefully examined for signs of infection. The vagina was finally closed to cover the defect using 2/0 vicryl sutures. However, this patient was totally cured of her SUI.

Two out of 38 patients (5.3%) reported, at the 6th week follow-up visit, persistence of their SUI which was still present at 3 months. Therapeutic failure diagnosis was confirmed on UDA. One of these 2 patients opted to be referred to another hospital for further treatment, and the other one was lost for further follow-up (Table 4).

All of the remaining 36 women who attended their last follow up visit reported no further SUI and, therefore, were considered cured (Table 4). The absence of re-referral following the 12th month follow up visit supports the assumption of a longer term successful post operative outcome.

Table 1. Demographic data

Demographic data	Mean	Range
Age (years)	53.2	42 – 71
Parity	3	2 -7
BMI (kg/m ²)	23.4	21 – 33
Duration of SUI (months) *	16.9	10 – 24
	No	%
Smoking	6	15.8
Background medical disorders	8	21.0

* SUI: Stress urinary incontinence

Table 2. Operative data

Operative data	No	%
Mode of anaesthesia:-		
- Spinal analgesia	33	86.9
- General anaesthesia	5	13.2
	Mean	Range
Operative time (minutes)	18	13 – 25
Hospital stay (Hours)	17	10 – 48

Table 3. Intra-operative and Post-operative complications

Intra-operative and Post-operative complications	No	%
Intra-operative complications:-		
- Significant (>200 ml) bleeding	1	2.6
Post-operative complications:-		
- significant pain in the upper thigh	5	13.2
- urine retention	2	5.3
- de novo urgency	3	7.9
- mesh erosion	1	2.6

Table 4. TVT-O outcome @ 12 months post procedure

Cured		Not cured (failed procedure)	
No	%	No	%
36	94.7	2	5.3

DISCUSSION

For the purpose of this study, patients with mixed urinary incontinence, voiding disorders, major pelvic organ prolapse, previous SUI surgery, or detrusor over-activity, were excluded. The reason for that was to avoid the effect of these variables on the outcome of the TVT-O procedure and also to simplify the comparison with other studies and make it more meaningful.

Several studies have shown that TVT- O has a short operative time.¹⁹⁻²¹ This was the case in this study where the mean operative time was 18 minutes with a range of 13 – 25 minutes.

Jakimiuk et al.,²² reported 4.5% incidence of significant (> 200 ml) intra-operative bleeding with the TVT-O procedure, while Neuman²⁰ noted that intra-operative bleeding is less frequent with the procedure. In this study, only one case (2.6%) of significant intra-operative bleeding was reported. This, however, might be due to the small sample size of this study.

No cases of bladder penetration were noted in this study. This is in agreement with previous studies which also reported no bladder penetration in relation to an “inside-out” transobturator procedure.^{23, 24}

Retention of urine was noted to happen following TVT-O at a rate ranging between 2.8% and 6.8%.^{18, 22} This was the case in this study, where two cases (5.3%) of urine retention were noted.

One of the recognised complications after the TVT-O procedure is de novo urgency. Previous studies have shown an incidence of 2 - 13.5%.^{22, 25} In this study, 3 cases (7.9%) of de novo urgency were reported.

The incidence of mesh erosion following TVT-O procedure is low.^{25 - 27} In this study, only one case (2.6%) of mesh erosion was reported. The management of mesh complication is an individualised approach. The choice of the technique should be based on the type of mesh complication, location of the erosion, its magnitude and severity and associated recurrence of SUI and/or urinary retention.²⁷

An overall cure rate between 88.4% and 98.7% was noted following the TVT-O procedure.^{20, 28} The short-term data presented in this study are in agreement with the previously reported efficacy of the TVT-O procedure with an early cure and improvement rate of 94.7%. However, in view of the small number of cases and the relatively short (12 months) follow-up period in this study, the quoted early cure and improvement rate should be interpreted with caution.

CONCLUSION

The experience gained through this study indicates that the TVT-O procedure for treating SUI in women is associated with a very low morbidity and high rates of success. Encouraging data are in hand to support the use of this approach as a first choice for the treatment of SUI in women. However, further studies in larger populations with longer follow up are warranted to determine the presumed efficacy and significantly decreased morbidity of this procedure.

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