

Original Article

Experience of tension-free vaginal tape for the treatment of stress incontinence in females with neuropathic bladders

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Study design: Retrospective.

Objective: To evaluate the safety and efficacy of the tension-free vaginal tape (TVT) for the treatment of stress incontinence in females with neuropathic bladders.

Setting: London Spinal Injuries Unit, Stanmore & Institute of Urology, London, UK.

Methods: Twelve women (mean age 53.3 years; range 41–80 years) with neuropathic bladder dysfunction and stress urinary incontinence were treated with tension-free vaginal tape (TVT) between November 1997 and December 2000. The group consisted of women with: (i) traumatic spinal cord injuries ($n=3$); (ii) post lumbar spinal surgery ($n=6$); (iii) spinal stenosis ($n=3$). Four of the 12 patients had previously failed surgery for stress incontinence. All patients underwent pre- and post-TVT evaluation with video-urodynamic studies.

Results: Mean follow-up was 27.1 months (range 17–54 months). Three patients were voiding spontaneously (stress voiding) before surgery and continued to do so post-operatively. The remaining 9 were performing clean intermittent self-catheterisation before the insertion of TVT and continued to do so after the surgery. At follow up 10 patients (83.3%) were dry. The procedure failed in one patient and the other complained of mild leakage, but she reported a decrease in the number of pads used. One patient developed detrusor hyperreflexia on post-operative video-urodynamics but there was no evidence of stress incontinence. One patient had a bladder perforation on insertion of TVT, managed successfully with extended use of a urethral catheter post-operatively. Three patients developed post-operative urinary tract infection successfully treated with oral antibiotics.

Conclusions: Tension-free vaginal tape insertion is minimally invasive, safe and effective for the treatment of stress incontinence in females with bladder neuropathy with intrinsic sphincter deficiency. Previous surgery for incontinence did not affect post-operative complications or outcome.

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Keywords: neuropathic bladders; stress incontinence; video-urodynamics; tension free vaginal tape

Introduction

Urinary stress incontinence is a major disabling feature in females with neurovesical dysfunction.¹ The incidence in this group is unknown; however 10–20% of females in the general population are known to be affected.² The neuropathic group have additional and unique problems compared to the general population with stress incontinence. Specifically, neuropathic patients may have detrusor hyperreflexia combined

with a weak external urethral sphincter in an upper motor neurone injury, or they may have an acontractile bladder with a weak urethral sphincter in a lower motor neurone injury. Additionally, this sphincter deficiency may be combined with urethral hypermobility.³

The aim of treatment of stress incontinence with a neuropathic bladder is distinct from that in neurologically intact persons. Incontinence in these patients is influenced by the presence of detrusor overactivity or acontractility, and the loss or diminution of vesical sensory function impacts on

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the management options. In the presence of detrusor hyperreflexia it is imperative to suppress the bladder adequately with anticholinergics before correction of the stress incontinence. On the other hand in acontractile bladder dysfunction many patients need to perform clean intermittent self-catheterisation (CISC) in order to effect bladder emptying and avoid the sequelae of residual urine in the bladder. Consequently, the need to perform CISC is an acceptable outcome post-operatively in neuropathic patients after surgery for stress incontinence, which obviously is not a desirable outcome in the non-neuropathic patients.

The treatment options for stress incontinence include pharmacological therapy, periurethral injections, pubovaginal slings, and insertion of an artificial urinary sphincter. Pharmacological therapy comprises of treatment with pseudoephedrine hydrochloride, which is thought to increase the muscular tone of the bladder neck and urethra. However, the effectiveness is extremely variable and it is associated with troublesome cardiovascular side effects. Peri-urethral injections have been successfully used as bulking agents in the short term, but long-term results are poor.⁴ The artificial urinary sphincter is effective in controlling stress incontinence. However it is a major surgical procedure and its restricted mechanical life, potential for infection and high cost limits its potential advantages.⁵ Pubovaginal slings have gained increased approval in the treatment of stress incontinence in females over the last decade.⁶ Autologous or cadaveric fascia has been used but there have been problems with fascial harvesting⁷ and infection.⁸ Ulmsten has added a new dimension in the treatment of female stress incontinence with the introduction of a synthetic polypropylene tension-free vaginal tape (TVT).⁹ The placement of the TVT at the mid-urethral level is based on anatomical and pathophysiological studies¹⁰ and supported by the findings of Zaccharin¹¹ for the role of pubourethral ligaments in maintaining continence.

This study retrospectively evaluated the safety and efficacy of tension free vaginal tape to restore continence in selected female patients with urodynamically defined stress urinary incontinence of neurogenic origin.

Materials and methods

We retrospectively analyzed the case records of all females with stress urinary incontinence of neurogenic origin that underwent the TVT procedure at our institution between November 1997 and December 2000. Twelve patients were identified, with a mean age of 53 years (range 41–80 years). The cause of neuropathic bladder dysfunction in these patients is shown in Table 1. It should be noted that any patient who had incompletely suppressed detrusor hyperreflexia on conventional anticholinergic medication was not offered a TVT, but had an alternative procedure such as an augmentation cystoplasty performed.

All 12 patients had stress incontinence demonstrated on pre-operative video-urodynamic studies (VUDS). VUDS confirmed the absence of urge incontinence in all the patients. One patient demonstrated detrusor hyperreflexia corresponding to a suprasacral spinal cord lesion, which was corrected by complete detrusor suppression with anticholinergic medication prior to the procedure. The remaining eleven patients had either hypo- or acontractile bladders.

The method of bladder drainage prior to surgery in all these patients was noted; three patients voided by *cr de manoeuvre* (suprapubic compression) and the remaining nine performed clean intermittent self-catheterisation. Four patients had undergone previous procedure for stress incontinence without benefit (Colposuspension; $n=2$, PolydimethylsiloxaneTM injection into the external urethral sphincter; $n=2$).

All patients had surgery performed under spinal anaesthesia. A single dose of prophylactic intravenous

Table 1 Patient profile, complications, and follow-up

Patient no.	Age (yrs)	Aetiology	Complications	F/U (mths)
1	41	T12 incomplete SCI	–	54
2	44	L1 complete SCI	UTI	20
3	46	L4 incomplete SCI	Bladder perforation	17
4	41	Disc surg L1/L2	–	23
5	59	Disc surg L2/L3/L4	–	20
6	55	Disc surg L5/S1	UTI	25
7	69	Disc surg L5/S1	–	18
8	64	Disc surg L5/S1	–	20
9	50	Disc surg L5/S1	–	41
10	41	Spinal stenosis L5/S1	Postoperative DH	54
11	50	Spinal stenosis L5	–	17
12	80	Spinal stenosis L5/S1	UTI	17

F/U: follow-up; L: lumbar; T: thoracic; S: sacral; SCI: spinal cord injury; UTI: urinary tract infection; Surg: surgery; DH: detrusor hyperreflexia

Gentamicin 120 mg was administered at induction. A single surgeon performed the operation and all but one of the patients were discharged after one day. The actual TVT (Gynaecare™) device is a 1 cm × 45 cm strip of polypropylene mesh that is attached to two 0.6 cm diameter curved stainless steel insertion needles. The insertion of the TVT was performed as a variation of the technique previously reported by Ulmsten.⁹ The bladder was completely emptied before the procedure by urethral catheterisation. The anterior vaginal wall was incised longitudinally over the urethra; two further 1 cm incisions were made on the abdominal wall 1 cm above the pubic tubercles on each side. The periurethral space was dissected by sharp dissection through to the endopelvic fascia. This step of the procedure is at variance with the original description of the procedure, wherein blind insertion of a probe is used to create a tract for the introduction of the TVT needles. The curved TVT insertion needle was then manoeuvred along the side of urethra and out through the incisions in the abdominal wall, guided by a finger placed in the vagina to assess the position of the urethra and the bladder neck – both structures obviously to be avoided. This was performed bilaterally. Cystoscopy was then performed to exclude inadvertent bladder perforation.

Initially, we started by using a provocative cough test to confirm correction of the stress incontinence, with adjustment of sling tension where necessary. More recently a 32 Ch Hegar's dilator was additionally placed between the tape and the urethra in order to prevent anatomical over-correction of the urethra. After confirmation of satisfactory positioning, the ends of the tape protruding through the abdominal incisions were cut down to the subcutaneous plane and a single stitch applied to each incision. The patients were then left with a urethral catheter *in situ* for 24 hours. Post-operatively the post-void residual volume was checked on the patients who were voiding spontaneously to ensure adequate bladder emptying. Additionally those patients performing CISC pre-operatively were re-assessed post-operatively to ensure ease of self-catheterization. Eleven of the 12 patients were followed up by clinical review at 3, 6 and 12 months, and videourodynamic studies at 3 months and then on an annual basis. The one remaining patient was followed up clinically at similar intervals but refused VUDS. She was symptomatically cured of incontinence and failed to see the need for a repeat invasive test, having experienced a urinary infection following a urodynamic study in the past.

Results

The operative notes and clinical follow-up of all 12 patients and video-urodynamic traces of 11 patients were examined. One patient refused post-operative video-urodynamic studies as explained above. All

patients have been followed up for a mean of 27.1 months (17–54 months).

The intraoperative cough test showed immediate correction of stress leakage after insertion of the TVT in all patients. Ten patients (83.3%) reported complete correction of their stress incontinence after the TVT, with no need for the use of incontinence pads postoperatively. One patient (8.3%) reported significant improvement in her symptoms, with a reduction of pad usage per 24 hours. This was significant and described by the patient as a 'success'. The procedure failed in one patient (8.3%) with no clinical improvement of her symptoms and urodynamic confirmation of persistent stress incontinence. One patient developed new onset post-operative detrusor hyperreflexia demonstrated on urodynamics that was absent pre-operatively; this was effectively corrected with anticholinergic medication, following which she reported complete resolution of her incontinence.

Per-operative cystoscopy revealed one bladder perforation (8.3%) which was easily corrected by withdrawal of the TVT introducer needle and re-insertion in a more lateral position. The urethral catheter was left *in situ* postoperatively for 3 days in this patient, and the postoperative period was otherwise unremarkable (except delayed discharge on post-operative day 5). The eventual outcome was satisfactory in this patient. Three patients (25%) had a single episode of post-operative urinary tract infection that was successfully treated with a course of oral antibiotics. The three patients who voided spontaneously or by suprapubic compression continued to do so post-operatively without any problems. One of the nine patients performing CISC experienced transient difficulty with insertion of the catheter. This resolved completely within 3 days, suggesting self-limiting post-operative peri-urethral oedema as the cause. The patients were discharged at a mean of 1.3 days (range 1–5 days) post-operatively. The results are summarised in Table 2.

Discussion

This series is the first to evaluate the effectiveness of TVT in patients with stress urinary incontinence of neurogenic origin. Our results demonstrate an excellent outcome following this procedure, with complete correction of incontinence in 83.3% ($n = 10$). A further

Table 2 Outcomes of TVT

	Number	Post op. VUDS	Change in bladder management
Dry	10	9	None
Improved	1	1	None
Failed	1	1	None

VUDS: video-urodynamic study

8.3% ($n=1$) reported significant improvement in the degree of stress incontinence. In the latter, VUDS results showing decreased urinary leakage, together with a decrease in number of pads used by the patient may be taken as an indication of success. Redefined in this way, the overall success rate in this series is 91.6%, which compares favourably to other authors.^{12,13} However this group of patients is different, as all patients had neuropathic bladders. In this series previous surgery for incontinence had neither any effect on the outcome nor did it result in any serious complications, which is similar to a recently reported series.¹⁴

One must be aware that insertion of TVT in neuropathic patients may exacerbate bladder dysfunction:

- It may result in new onset of detrusor hyperreflexia or lead to exacerbation of pre-existing hyperreflexia – it has been suggested that this may be due to the activation of the voiding reflex by stimulation of the afferent receptors in the proximal urethra.¹⁵
- Patients who are stress voiding pre-operatively may find it necessary to perform CISC post-insertion of TVT.
- Those patients performing CISC pre-operatively may be unable to do so post-operatively due to excessive tape tension in which case the TVT has to be incised in order to relieve bladder outlet obstruction without compromising bladder neck support.

The present study showed an 8% incidence of new onset detrusor hyperreflexia (as demonstrated on VUDS), which is slightly higher (6.4%) than in non-neuropathic patients.¹⁶ In the patient with pre-existing hyperreflexia there was no worsening of the condition on VUDS and additionally her stress incontinence was cured. Also there was no significant increase of intravesical pressures post-operatively in those patients who had been stress voiding. One patient experienced transient urethral obstruction which self-resolved and was attributed to post-operative oedema.

The commonly reported complications have been bladder perforation with a rate up to 6%,¹² severe bleeding and obturator nerve injury.¹⁷ We did encounter a single bladder perforation, which was immediately recognised intra-operatively and corrected by lateral repositioning of the introducer needle and extended urethral catheterization for 5 days post-operatively.

We conclude that tension-free vaginal tape insertion is minimally invasive, safe and effective for the treatment of stress incontinence in females with bladder neuropathy and intrinsic sphincter deficiency. However longer-term follow-up with randomised trials to compare TVT with other established anti-incontinence surgery is required in this group.

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