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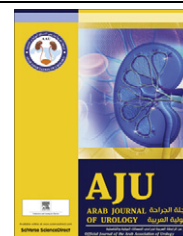
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URODYNAMICS/FEMALE UROLOGY

ORIGINAL ARTICLE

Transobturator vaginal tape (inside-out) for stress urinary incontinence after radical cystectomy and orthotopic reconstruction in women

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KEYWORDS

Transobturator vaginal tape;
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Outcome;
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ABBREVIATIONS

PVR, post-void residual urine volume;
SUI, stress urinary incontinence;
TVT(-O), tension-free

Abstract Objectives: To evaluate the safety and clinical efficacy of the transobturator vaginal tape ‘inside-out’ (TVT-O) procedure for managing new-onset stress urinary incontinence (SUI) after radical cystectomy (RC) and orthotopic W-neobladder construction in women.

Patients and methods: Between January 2004 and June 2010, 57 women were treated with RC and orthotopic ileal neobladder reconstruction. Six of these patients (median age 44 years, range 39–62; grade 2 muscle-invasive squamous cell carcinoma in four and transitional cell carcinoma in two) developed de novo SUI that was moderate in four and severe in two. The median (range) duration of SUI was 11 (9–18) months. All six patients underwent TVT-O for control of their SUI.

Results: Four patients were completely dry day and night (three of them can initiate voiding and one cannot, and uses intermittent catheterization). One patient improved, as assessed by using fewer pads (from 5–7 pads to 1 pad/day and night). She can initiate voiding but has minimal leakage only on moderate exertion. One

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vaginal tape (inside-out); RC, radical cystectomy; CIC, clean intermittent self-catheterisation

patient who had severe SUI showed no improvement. Patients were followed for a mean (range) of 18 (17–32) months, with no deterioration in the continence status.

Conclusion: These encouraging results confirm the safety and clinical efficacy of TVT-O for managing new-onset SUI after RC and ileal neobladder construction, although a larger survey and a longer follow-up are needed.

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Introduction

The continence status after orthotopic urinary diversion is still a challenge and persistent urinary leakage is considered one of the most important functional complications of the neobladder. Since it was first introduced by Delorme in 2001, with a reported 90.6% cure rate [1], transobturator mid-urethral tapes became more popular with many urologists, because they are safe and effective. The transobturator vaginal tape 'inside-out' (TVT-O), by being passed through the obturator foramen, thus avoiding the retropubic space and by the more horizontal support, made the system safer, and postoperative voiding dysfunction and difficulty less likely [2,3]. All of these advantages raised the idea of using it to treat women with new-onset stress urinary incontinence (SUI) following an orthotopic bladder reconstruction after radical cystectomy (RC). The TVT-O procedure aims to provide backing support to the urethra, avoid the risk of urethral and neobladder injuries, and avoid entering the retropubic space; we present our experience with this procedure in women with de novo SUI after neobladder reconstruction.

Patients and methods

Between January 2004 and June 2010, 57 women with primary urinary bladder carcinoma (squamous cell carcinoma in 36, 63%; TCC in 21, 37%) were treated with RC and orthotopic ileal W-neobladder reconstruction. Six patients (11%) developed SUI that was persistent and that did not respond to conservative management. Their median (range) age was 44 (39–62) years. The tumour was grade 2 muscle-invasive squamous cell carcinoma in four and TCC in two (Table 1). The median (range) duration of incontinence was 11 (9–18) months. Before

surgery all six patients had good urinary control and had no evidence of pelvic prolapse. Their history was significant only for hysterectomy in one patient and vaginal deliveries in all. Three weeks after RC the urethral catheter was removed from all patients, and immediately they complained of SUI that required several pads. Physical examination, in addition to cystoscopy and cystography, showed an average pouch capacity and no evidence of fistulae. The severity of incontinence was classified objectively using a 24-h pad test, with mild, moderate and severe SUI defined as 1.3–20 g, 21–74 g and > 75 g of leakage on this test, respectively [4]. Four patients had moderate degrees of SUI, and two had severe SUI (Table 1). The total number of pads/day was recorded for all patients and ranged from 3–5 pads/day for moderate and > 5 pads/day for severe cases.

All patients were evaluated urologically for pouch capacity, residual urine volume and the integrity of the upper urinary tract by a plain abdominal film, IVU, abdominal ultrasonography and a urodynamic evaluation. Renal function tests (blood urea and serum creatinine) were normal in all patients. The demographic and urodynamic data of the six patients are shown in Table 1.

All patients underwent a TVT-O procedure to control their SUI, after they were counselled about the surgical procedure and the possible complications, success rate and the other alternatives for urinary control. They provided written informed consent and we obtained approval from the local ethical committee for the study.

Technique

The TVT-O procedure was conducted with the patient under spinal anaesthesia. The tape was inserted using the same technique described by de Leval [5], with the Ethicon TVT obturator system (Gynecare, Johnson

Table 1 The patients' demographic and urodynamic data.

Patient No.	Age (years)	Degree of SUI	Type of cancer	Pouch capacity (mL)	PVR (mL)	ALPP (mL/cm H ₂ O)
1	39	Moderate	SCC	470	0	81
2	43	Moderate	SCC	510	0	76
3	62	Moderate	TCC	360	60	65
4	54	Moderate	TCC	490	30	69
5	51	Severe	SCC	530	50	30
6	42	Severe	SCC	410	30	27
Mean	48.5	–	–	462	28	61

ALPP, abdominal leak-point pressure; SCC, squamous cell carcinoma.

and Johnson, USA). With the patient in a dorsal lithotomy position and hips hyper-flexed to maintain patient comfort, the coccyx being flush to the edge of the table, a Foley urethral catheter was inserted to empty the pouch and to provide a landmark in the urethra. A reference exit point was located by tracing a horizontal line at the level of the urethral meatus and a second line parallel and 2 cm above the first line. The reference skin was marked at an exit point on this second line 2 cm lateral to the fold of the thigh. Using an Allis clamp for traction, a 1 cm midline vaginal incision was made starting 1 cm proximal to the urethral meatus. This was initiated using sharp dissection with scissors orientated on the horizontal plane starting from the vaginal incision using a 'push-spread' technique to the inferior pubic ramus (not entering the pelvic cavity to avoid injuring the pouch). The dissection was stopped after the obturator membrane had been perforated. A safety winged guide was then inserted, through which the tape, loaded on a helical passer, was passed along it to be exited at the previously marked exit point. The technique was repeated on the other side. We ensured that the mesh lay flat under the urethra, and made final adjustments to the mesh, then cut the end of the tape at the skin level. The vaginal and skin incisions were closed using polyglactin 2/0 sutures. All tapes were inserted without tension and the urethral catheter was left for 24 h. During a median (range) follow-up of 18 (17–32) months the patients were evaluated as before. A successful repair was defined as the patient being socially continent (dry or requiring no more than one pad per day, even with exercise), and that the patient was satisfied with the result.

Results

The mean (range) pouch capacity was 462 (360–530) mL, and the abdominal leak-point pressure was 61 (27–76) mL/cmH₂O, according to the severity. All six patients had significant SUI that failed to improve over time, for up to 9 months after surgery. The upper tract was normal by IVU in four patients and mild residual dilatation was recorded in the other two. No special difficulties were encountered during tape insertion, and there were no significant or particular complications, like pouch and urethral trauma or injury of other pelvic structures in any of the patients.

Using the definition of success, four patients were completely dry day and night. Three patients initiated voiding and only one could not; the latter was treated using clean intermittent self-catheterisation (CIC), which was feasible and easy when using a clean 10-F feeding tube, with no reported difficulties or complications to evacuate the pouch. One patient improved, as assessed by using fewer pads (reduced from 5–7 pads to 1 pad/day and night). She can initiate voiding but has minimal leakage only on moderate exertion, and

only occasional night-time leakage at 3 and 9 months, respectively, after TVT-O surgery. One patient who had severe SUI showed no improvement and has refused any further surgery. There was no deterioration in the continence status over the follow-up, and no significant change in PVR or pouch capacity.

Discussion

SUI after RC and orthotopic ileal neobladder construction in women is a stressful situation, with a reported incidence of 30–60% [6]. Nevertheless, SUI is probably the most important factor for patient satisfaction. We evaluated the role of the TVT-O for managing SUI in six patients after RC and an orthotopic ileal neobladder. The procedure was successful in five patients, with variable degrees of improvement in SUI. Four patients were completely dry day and night, with three able to initiate voiding and one using CIC. One patient improved, using fewer pads, and can initiate voiding but with minimal leakage on moderate exertion and occasional night-time leakage, at 3 and 9 months, respectively, after surgery. These results were maintained over the follow-up of 17–32 months with no deterioration in the continence status.

There were no significant complications (pouch and urethral trauma or injury of other pelvic structures) in any of the patients. We wrapped an omental flap around the new bladder neck to increase the continence rate and decrease the risk of pouch-vaginal fistula during creation of the urethro-ileal anastomosis. This omental flap raises the pouch from the pelvic floor, which helps to avoid pouch perforation during TVT-O tape insertion.

Many authors have tried to examine the problem of persistent SUI after RC and orthotopic neobladder reconstruction. Transurethral bulking agents like collagen were tried, with variable results. Although being a minimally invasive procedure, inserting transurethral bulking agents has the drawback of recurrent incontinence and the need for multiple periodic injections [7]. Moreover, it carries the risk of major complications, e.g. a new-onset vesicovaginal fistula was reported after transurethral collagen injection [8]. Also, fibrosis from the previous surgery and the absence of bladder neck limits the space for and effect of collagen injection, giving a success rate of only 50–60% [7]. Another alternative is to use a pubovaginal sling, but it has the potential for bowel or neobladder injury, as insertion requires dissection in the retropubic space, and has a high rate of hyper-continent. Quek et al. [9] tried autologous rectus fascia pubovaginal slings in two patients; the result was disappointing, with significant complications arising from dissection in the retropubic space, including one entero-pouch fistula and one enterotomy resulting in an enterocutaneous fistula, sepsis and subsequent death. The same authors tried transvaginal pubovaginal slings, using dermal grafts with infrapubic bone anchors in another two patients. Both patients became hypercontinent,

mandating the use of CIC, with complete daytime continence and only occasional night-time leakage at 3 and 9 months after sling surgery. From these previous trials we decided that transurethral bulking agents are insufficient and the use of pubovaginal slings with dissection in the retropubic space is risky, with potential fatal complications and should be avoided.

The TVT procedure is a minimally invasive suburethral sling procedure now widely used for managing female SUI, since its introduction by Ulmsten et al. in 1996 [10]. However, the standard TVT procedure was unsuitable for the present patients, as it uses a retropubic route and thus risks several complications resulting from penetration of the tape or its supporting needle in the bladder, urethra, bowel, or neurovascular structures [11,12]. Although the 'outside-in' transobturator approach has been used for placing mid-urethral tapes, with the aim of avoiding the retropubic and pelvic spaces [13], bladder perforation has been reported [14]. To avoid or at least to minimise the occurrence of these injuries, the TVT-O was first described by de Leval [5] to pass from underneath the urethra, through the obturator foramen, and towards the thigh folds, without entering the pelvic region at any time during the procedure. Moreover, the TVT-O was reported to be a safe and efficient treatment for female SUI, with high cure rates comparing favourably with those of the TVT [15].

Hence we used the TVT-O to manage women with de novo SUI after orthotopic W-neobladder reconstruction, aiming to restore their continence, with no injury to pelvic structures by avoiding retropubic dissection. Being less invasive, quicker and with minimal vaginal dissection the TVT-O procedure is suitable for those patients who have had previous major surgery.

Although the present study is limited by including only six patients and a short follow-up, it provides a potential treatment alternative for SUI in this unique patient group. Our developing experience suggests that TVT-O is an attractive and safe treatment option for managing women with SUI after orthotopic W-neobladder substitution. However, hypercontinence and the need for CIC should be discussed with the patient before surgery, to ensure a satisfactory outcome with appropriate expectations.

In conclusion, our encouraging results confirm the feasibility of the TVT-O for managing SUI after RC and ileal neobladder urethral diversion in women, but a larger study with longer follow-up are needed.

Conflict of interest

The authors declare that they have no conflict of interest.

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