Tension-free vaginal tape procedure for treatment of USI: subjective and objective efficacy evaluation

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Summary

Urinary incontinence is a frequent functional disease affecting 5% to 25% of women. It is commonly believed that urinary stress incontinence (USI) is caused by anatomical defects, thus it can be treated by restoring anatomy. More than 100 surgical techniques have been proposed for genuine stress incontinence treatment. The tension free vaginal tape procedure (TVT) for the treatment of genuine IUS in women was first reported in 1996 by Ulmsten *et al.*

The purpose of this study was to evaluate objective and subjective efficacy of the TVT procedure in different types of female urinary incontinence. From February 2000 to December 2001, 52 patients with urinary incontinence underwent the TVT procedure in the Obstetric and Gynecology Department of Avezzano Hospital, Italy.

No difference in the cure rates was found between patients undergoing the TVT alone or associated with anterior and/or posterior colporrhaphy. In accordance with many authors we can affirm that the TVT sling technique is easy to use, the time for surgery is relatively short, and the procedure is free of complications and provides a satisfactory outcome.

Key words: Urinary stress incontinence (USI); TVT; Urodynamic.

Introduction

Urinary incontinence is a frequent functional disease affecting 5% to 25% of women [1, 2]. It is commonly believed that urinary stress incontinence is caused by anatomical defects, thus it can be treated by restoring anatomy [3]. The pathophysiology of USI seems to be on the incomplete pressure transmission to the proximal urethra due to anatomic descent of the urethrovescical junction [4]. More than 100 surgical techniques have been proposed for genuine stress incontinence treatment [5]; in fact, incontinence surgery can be performed by laparotomy (e.g., Burch Technique), but it is associated with high postoperative morbidity and long hospital stays [6]. To avoid laparotomic disadvantages and complications, many authors recommend laparoscopic or transvaginal approaches for IUS treatment [7-11].

The tension free vaginal tape procedure (TVT) for the treatment of genuine IUS in women was first reported in 1996 by Ulmsten *et al.* [12]. It is a minimally invasive procedure that can be performed under local or spinal anesthesia (on request) making it possible for the patient to cough and thereby aid the surgeon in adjusting the suburethral sling to control the leakage [13], and it requires only short hospitalization. In addition TVT is effective on the midurethra rather than the urethrovescical junction, and it does not need fixed anatomic structure anchoring [14]. The objective cure rate for this procedure varies between 80% and 90% according to different studies [12, 15, 16].

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Materials and methods

From February 2000 to December 2001, 52 patients with urinary incontinence underwent the TVT procedure in the Obstetric and Gynecology Department of Avezzano Hospital. Patient characteristics are summarized in Table 1. The severity of urinary incontinence was classified according to the Baden-Walker scale: grade 1, urinary incontinence when coughing or sneezing; grade 2, urinary incontinence when running or picking up an object from the floor; grade 3, urinary incontinence when walking or stair climbing.

The inclusion criteria were the diagnosis of urodynamically proven genuine stress incontinence associated or not to an intrinsic sphincter deficiency and the presence of urethral hypermobility (straining urethral angle 30° or greater from the horizontal). Exclusion criteria were the absence of a urodynamic complete test, and the absence of urethral mobility (i.e. neurological bladder defects causing incontinence).

Urodynamic evaluation included urethro-cystometry, static and dynamic urethral closure pressure, maximum cystometric capacity and Valsava leak point pressure. Genuine stress incontinence was diagnosed if the patient showed observable urine leakage with stress but in absence of simultaneous detrusor activity during cystometry. Detrusor instability, in fact, corresponds to the presence of detrusor contraction and urine loss during cystometry. Intrinsic detrusor deficiency accords with a maximum urethral closure pressure of less than 20 cm/H_2O at maximum cystometric capacity. Among our 52 patients, seven (13.4%) showed a reduction in MUCP (maximum urethral closure pressure) with a mean value of about 19.7 cm/H_2O.

Patients were considered to have a mixed incontinence when they both symptoms of stress and urge incontinence (due to a bladder over activity or to a sphincter's closure defect) diagnosed with a complete urodynamic investigation. Seven patients (13.4%) showed mixed incontinence. Four patients of 52 (7.7%) had previously undergone other incontinence surgery such as the Burch procedure. Five patients (9.6%) showed mild cysto-

cele, six patients (11.5%) showed rectocele, three patients (5.7%) showed both cystocele and rectocele. The other 31 patients (59.6%) showed genuine stress incontinence (Table 1).

Thirteen patients out of 52 (25%) had grade 1 urinary incontinence, 20 patients of 52 (38.4%) had grade 2, and 19 patients of 52 (36.5%) had grade 3 (Table 2).

Bonney's test was positive (+) in 12 patients (23% - IUS 1), (++) in 31 patients (59.6% - 16 with IUS 2, 10 with IUS 3, 5 with mixed incontinence), and (+++) in nine patients (17.3% - 7 with USI 3, and 2 with mixed incontinence) (Table 3).

Surgery was performed under spinal anesthesia in 49 patients (94.2%), local anesthesia in two patients (3.8%) and only one patient (1.9%) asked for general anesthesia.

Two small incisions, 1 cm apart, were made in the skin above the superior rim of the pubic bone; the anterior vaginal wall was incised at the level of the midurethra, starting 1-1.5 cm under the urethral meatus. After paraurethral dissection of the vaginal wall, the urethra and bladder were pushed to the opposite side of the trocar insertion using a Foley catheter equipped with a metal guidewire. A prolene mesh tape was introduced with the trocar through the urogenital diaphragm underneath the midurethra (to create an artificial pubourethral ligament) into the retropubic space just behind the internal pubic bone up to the skin incision [17-20]. The same procedure was utilized for the other side and cystoscopy was subsequently performed to verify the absence of bladder injury. After filling the bladder with 300-350 ml of saline solution, the mesh tape was adjusted without tension until no urinary leakage occurred when the patient coughed. The plastic sheath covering the prolene tape was removed, and the abdominal incisions were sutured. No fixation of the mesh tape was required. Colpotomy was sutured with absorbable sutures. A Foley catheter was inserted into the bladder for 24 hours [20].

Table 1. — *Patient characteristics.*

Characteristics	No. of patients
Mean age	56.7 ± 10.3
Mean parity	2.05 ± 1.3
Nulliparous	9 (17.3%)
Pluriparous	36 (69.2%)
Postmenopausal status	28 (53.8%)
Genuine IUS (urethral hyprmobility)	31 (59.6%)
Mixed incontinence	7 (13.4%)
Cystocele	5 (9.6%)
Rectocele	6 (11.5%)
Cysto-rectocele	3 (5.7%)
Previous incontinence surgery	4 (7.7%)

Table 2. — *USI/mixed incontinence grade.*

	Grade 1		Grade 2		Grade 3	
	N	%	N	%	N	%
USI (45)	12/45	26.6	16/45	35.5	17/45	37.7
MIXED (7)	1/7	14.2	4/7	57.1	2/7	28.5
Total	**13/52**	**25**	**20/52**	**38.4**	**19/52**	**36.5**

Table 3. — *Bonney's test.*

	+	++	+++
No. of patients	12 (°)	31 (*)	9 (^)
%	23	59.6	17.3

(°) all patients with USI 1.
(*) 16 patients with USI 2; 10 patients with USI 3; 5 Patients with Mixed Incontinence.
(^) 7 patients with USI 3; 2 Patients with mixed incontinence.

Table 4. — *Hospitalization.*

Hospitalization days	No of patients	Motivation
6	4	• 3 bladder perforations • 1 urinary retention (300 ml three weeks after surgery)
4	3	• 3 urinary retentions (150 ml during the 1st week after surgery)
2	45	No problems
Mean 2.4 ± 1.1 (from 2 to 6 days)	–	–

Table 5. — *Complications.*

Complications	%	No
Perioperative complications	5.7	3/52
Early postoperative complications (§) (urinary retention*)	7.7	4/52
Overall complication rate	13.4	7/52

(§) 0% urinary infections; 0% urinary bleeding
(*) 1 patient of 4 (25%) need for section without removal of the TVT tape

Anterior colporrhaphy was necessary in three patients (5.7%) of five presenting cystocele, posterior colporrhaphy was necessary in four patients (5.7%) of six presenting rectocele, and both anterior and posterior colporrhaphy were necessary in only two patients (3.8%) of three presenting cisto-rettocele.

After the withdrawal of the catheter, the residual urine volume was evaluated; voiding difficulties were defined as a residual volume of 150 ml or greater after spontaneous micturition. Mean hospitalization was 2.4 ± 1.1 days (from 2 to 6 days) (Table 4).

Ciprofloxacin tablets were prescribed for three or five days.

Follow-up was done at one, six, 12 and 18 months postoperatively when possible. Patients were considered objectively cured if continent at the clinical stress tests, and if there was no sign of urine retention or residual volume greater than 150 ml.

Patient satisfaction about the TVT results was registered using a subjective questionnaire of ten items concerning the total number of daily and night micturitions, urge symptoms, incontinence seriousness in terms of life quality worsening, subjective grade of incontinence, remedies or cures used for the incontinence, discomfort and shame of the patient affected by incontinence, pain during or after the TVT surgery, irritation from the catheter, and satisfaction/dissatisfaction for the TVT surgical result.

Results

The mean operative time was 25.28 ± 5.8 minutes (range from 20 to 40). Among the 52 patients, 49 asked for spinal anesthesia, one asked for total anesthesia and two underwent local anesthesia. The operative and postoperative complications are shown in Table 5.

The perioperative complication rate was 5.7% (3 patients of 52) and was the result of a bladder injury (perforation) during the trocar insertion into the retropubic space. This was probably due to the wrong position of the patient's legs, which have to be positioned almost at the same level as the trunk. All were diagnosed with the systematic cystoscopy. Extraction and reinsertion of the trocar were successfully performed. The Foley catheter was left in the bladder for three days to have total restoration of the bladder damage.

Early postoperative complications such as urinary retention, occurred in 7.7% (4 patients of 52); three patients had a spontaneous remission within the first postoperative week, and only one patient showed a residual urinary volume of 300 ml after four weeks, so a section without removal of the TVT tape was necessary and effective. None showed urinary infection or bleeding.

Patients (7) affected by mixed incontinence were treated with anticholinergic therapy which was effective in all of them. No tape infection or healing defect of the vaginal wall occurred.

Among the seven patients (13.4%) having a mean reduction in MUCP (maximum urethral closure pressure) with a mean value of 19.7 cm/H_2O, six (85.7%) showed a complete restoration of continence after TVT, while only one (14.2%) still showed mild residual incontinence.

The overall complication rate was 13.4% (7 patients of 52).

Mean hospitalization was 2.4 days (from 2 to 6 days) (Table 4).

Subjective and objective cure rates are shown in Table 6.

The subjective cure rate was 80.6% (25 patients of 31) in women with genuine stress incontinence and 42.8% (3 patients of 7) in women with mixed incontinence.

The objective cure rate based on clinical stress tests was 87% (27 patients of 31) in women with genuine USI and 57.1% (4 patients of 7) in women with mixed incontinence. No difference in the cure rates was found between patients undergoing the TVT alone or associated with anterior and/or posterior colporrhaphy.

Table 6. — *Subjective and objective cure rates.*

Characteristics	USI (No. 45)	%	Mixed Incontinence (No. 7)	%
Subjective				
• cured	38	84.4	3	42.8
• improved	4	8.8	2	28.5
• no change	3	6.6	2	28.5
• became worse	0	0	0	0
Objective (stress tests):				
• cured	40	88.8	3	42.8
• improved	5	11.1	4	57.1
• failed	0	0	0	0

Discussion

Most surgical procedures for the treatment of USI fall into one of three groups of surgery: needle suspension of the bladder neck, retropubic urethropexy, and pubovaginal sling [14].

TVT is the most used pubovaginal sling technique and is now considered an alternative to classic surgical methods because it is very easy to learn, has a low incidence of perioperative and postoperative complications, and gives a high objective and subjective success rate.

The mechanism of action of the TVT may be related to an improvement in urethral closure under stress, without anatomic change in bladder neck position. Anatomically the urethra lies suspended in a "hammock" of the anterior vaginal wall and is immobilized by a forward contraction of the pubococcygeus muscle and pubourethral ligament [21]. TVT is thus based on a new integral theory which emphasizes the role of the vaginal anterior wall and the midurethra in bladder function and urethral opening and closure [18]. Urinary continence is achieved by creating a dynamic kinking of the midurethra.

The ideal anti-incontinence procedure limits the amount of urethral obstruction necessary to stop urine loss during a Valsalva maneuver or during cough. TVT seems an ideal technique even to achieve this goal.

Published series report 80% of continence two years after TVT, which is analogous to results achieved with Burch colposuspension. Considering both methods, TVT is better tolerated by patients, has very low perioperative risks, fewer days of hospitalization and lower postoperative complications.

The use of the TVT method gives, in many cases, a better possibility of improving the quality of life even in women who previously would not have been recommended for surgery (i.e., cardiopathic women >75 years old, patients ASA 3-4 risk for total anesthesia, etc.), than with older surgical techniques because this technique can be performed under local or spinal anesthesia.

Our results are excellent in terms of both subjective and objective cure rates, so this study demonstrates that the TVT procedure is a safe and effective surgical method for the treatment of urinary incontinence in women.

According to many authors we can affirm that the TVT sling technique is easy to use, the time for surgery is relatively short, and the procedure is free of complications and provides a satisfactory outcome.

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