

Results of tension-free vaginal tape procedure in patients with or without colporrhaphy

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Abstract We investigated the clinical results and the ultrasonic morphological characteristics of tension-free vaginal tape (TVT) surgery combined with anterior or posterior colporrhaphy in relation to the results after TVT procedure without prolapse repair. Seventy-two women with stress incontinence and other pelvic floor defects underwent the tension-free vaginal tape procedure in conjunction with anterior or posterior colporrhaphy. Another 212 patients with stress incontinence without genital prolapse underwent TVT procedure alone. The study was designed as a prospective investigation. The follow-up was performed 3 months after surgery. The protocol included a standardized questionnaire, gynecological examination, stress test and pad test. The position of the tape was evaluated by introital ultrasound. No differences were found when comparing the groups of patients in terms of complication rates, the rates of improvement or cure of stress incontinence and patient satisfaction. Also, no differences in the characteristics of the tape were identified on ultrasound examination. Additional colporrhaphy does not influence clinical and morphological outcome after TVT and can easily be performed in conjunction with the TVT procedure.

Keywords Tension-free vaginal tape · Stress incontinence · Colporrhaphy · Genital prolapse

Petros and Ulmsten [1] proposed the integral theory, postulating that stress incontinence may arise from laxity in the vagina or its supporting ligaments. This theory of female urethral closure mechanisms suggests that the urethra

is sealed in its midportion and not at the bladder neck. The aim of the tension-free vaginal tape (TVT) procedure is to reinforce the support of the midurethra by the pubourethral ligaments. It is a simple, minimally invasive procedure with a relatively quick recovery. As a result of this the procedure has achieved worldwide popularity and revolutionized incontinence surgery.

Urinary stress incontinence and genital prolapse are caused as a result of pelvic relaxation and therefore other surgical procedures used to correct these are often performed simultaneously to TVT. Only a few studies exist that investigate the combination of TVT with other pelvic surgery. Therefore, the aim of this prospective observational study was to investigate the clinical results and the structural characteristics of the tape by using ultrasound in women with or without concomitant anterior or posterior colporrhaphy.

Materials and methods

Between January 2001 and December 2003, 315 patients underwent the TVT procedure in our department. Two hundred and sixteen patients underwent the TVT procedure alone, in 40 patients the TVT procedure was combined with anterior colporrhaphy and in 32 patients with posterior colporrhaphy. Twenty-seven patients were excluded because of missing follow-ups ($n=11$) or additional surgeries other than colporrhaphy ($n=16$). The surgical technique was similar to that described by Ulmsten et al. [2], but with a minor modification [3]. The tape was inserted before repairing the cystocele or rectocele and adjusted after finishing the colporrhaphy. The posterior colporrhaphy was performed by site-specific fascial repair in combination with reconstruction of the perineal body. The anterior colporrhaphy was performed with a midline incision

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beginning in the area of the bladder neck. Cystocele was corrected by plication of the fascia of the bladder. In cases of anterior colporrhaphy, we inserted the TVT through a separate small sagittal incision. All the TVT procedures were carried out by the same surgeon (F.F.).

The follow-up was carried out after 3 months (range 2–9 months) using a standardized questionnaire, gynecological examination, a stress test in the supine and upright position with a comfortably filled bladder (about 250 ml), and a 24-hour-pad test in accordance with the procedures of the International Continence Society [4]. A woman was considered dry if the results of the stress tests with an adequately full bladder were negative and no stress incontinent episodes were reported verbally by the women or recorded in her questionnaire and the pad test was <5 mg/die. The position of the tape was evaluated by introital ultrasound (as we described previously [5]). The position of the tape was established by its site in relation to urethral length (% meaning 0% for a position at the bladder neck and 100% under the external urethral orifice) and to the quarters of the urethra. The distance of the tape to the urethra was defined as the space between the border of the tape and the hypoechoic center of the urethra. This hypoechoic zone corresponds to the longitudinal smooth muscle layer and the mucosa.

Some patients had previously undergone incontinence surgery with methods other than TVT (Table 1). There were no relevant differences within the three groups in terms of the body mass index. TVT alone was performed in all cases with the exception of one patient under local anesthesia with intravenous analgesic sedation (Remifentanyl, Ultiva; GlaxoSmithKline). The additional anterior or posterior colporrhaphy operations were carried out using spinal or general anesthesia. All patients suffered from genuine stress incontinence grades 1–3 of the Ingelman-Sundberg scale

[6], according to which there were no relevant differences among the groups. The basic characteristics of the patients are shown in Table 1.

Statistical analysis was performed using the Mann–Whitney *U* test and χ^2 test ($p < 0.05$ was accepted as statistical significance).

Results

The clinical outcomes after TVT with or without concomitant surgery are described in Table 2. In summary, there were no significant differences among the groups relating to the complication rates, the improvement or cure of stress incontinence, and the subjective satisfaction of the patients. The objective cure rate was 90% in women after isolated TVT procedures, 97% after TVT procedures and anterior colporrhaphy, and 85% in patients after TVT and posterior colporrhaphy. Improvement of stress incontinence was found in 9%, in 3%, and in 12% respectively. None of the differences were statistically significant.

The majority of patients across all groups were satisfied with the surgical procedures; 92.5–94% of these patients reported the result to be “good” or “very good.”

In addition, the incidence of typical complications during and after a TVT procedure was investigated in the various groups. A typical surgical complication of the TVT procedure is an injury to the bladder. In our study groups, this complication occurred in 1.4% of cases during an isolated TVT procedure, in 3% during a TVT procedure with a posterior colporrhaphy and in no cases in the combination TVT and anterior colporrhaphy. All cases of bladder injury were uneventful.

We saw a postoperative hematoma in the retropublic space in 10% of cases after TVT and anterior colporrhaphy.

Table 1 Basic characteristics of patients. TVT tension-free vaginal tape

	TVT (<i>n</i> =212)	TVT with anterior colporrhaphy (<i>n</i> =40)	TVT with posterior colporrhaphy (<i>n</i> =32)
Age (years)	61	66	73
Previous incontinence surgery (%)			
Colposuspension	18	3	4
Needle suspension	4	0	1
Body mass index	27.6	29.3	28.9
Analgesia (n)			
Local	215	0	1
Spinal	0	38	22
General	1	2	3
Additional surgery (n)			
Hysterectomy	0	1	2
Vaginal fixation	0	2	5
Posterior colporrhaphy	0	3	0
Colpocleisis	0	2	0

Table 2 Clinical outcome after TVT operation with or without concomitant colporrhaphy. *NS* not significant

	TVT (<i>n</i> =212)	TVT with anterior colporrhaphy (<i>n</i> =40)	TVT with posterior colporrhaphy (<i>n</i> =32)	Statistics
Stress incontinence (%)				
Cured	90	97	85	
Improved	9	3	12	
Not changed	1	0	3	NS
Patient satisfaction (%)				
Good or very good	93	92.5	94	
Moderate	5.5	7.5	3	
Poor	1.5	0	3	NS
Complications (%)				
Bladder injury	1.4	0	3	
Hematoma	4.2	10	3	
Evacuation of hematoma	1	2.5	3	
Residual urine volume (>50 ml)	5	10	9	
Cutting of the tape	0.5	2.5	0	
De novo urinary urge	8	20	5	NS

The difference in this occurrence for TVT alone (4.2%) and TVT with posterior repair (3%) was not statistically significant. But in only one patient out of the group undergoing posterior repair (3%) and one out of the group undergoing anterior repair (2.5%) did surgical removal of the hematoma have to be undertaken. This was necessary for 1% of those who had the TVT procedure alone.

New micturition disturbances with postoperative onset, with more than 50 ml of residual urine, occurred more often in the groups undergoing the combination therapy (9–10%). After TVT alone, this happened in 5% of cases. These figures have been found not to be statistically significant. Where there was persistent residual urine volume with clinical symptoms, the tape was cut through on one side periurethrally. This was needed in 2.5% of cases after TVT with anterior repair, 0.5% after TVT alone, and not at all after TVT with posterior repair.

A de novo urge incontinence occurring after insertion of TVT was not rare. Within the group that underwent TVT with anterior repair the incidence was 20%. In the other

groups the rates for this problem were under 10%. The differences were statistically not significant.

In addition, we evaluated the sonographic characteristics of the tape. There was no difference between the three groups in the position of the tape in relation to the length of the urethra and the distance of the tape to the urethra (Table 3).

Discussion

In our study the success rate of the TVT procedure in treating urinary stress incontinence was between 85 and 97% without significant differences amongst the groups. Published studies [7–11] have reported objective success rates after TVT procedures with concurrent prolapse surgeries and/or hysterectomy of between 91 and 95% (Table 4). The published outcomes of combined surgeries are comparable to our results and to the worldwide results of the isolated TVT procedure [12–14]. However, there is one exception. Pang et al. [15] reported a low cure rate of

Table 3 Sonographic attributes of the tape with or without concomitant surgery

	TVT (<i>n</i> =212)	TVT with anterior colporrhaphy (<i>n</i> =40)	TVT with posterior colporrhaphy (<i>n</i> =32)	Statistics
Position of the tape in relation to the urethra length (mean, %)	62	61	60	NS
Position of the tape in relation to the quarter of the urethra (mean, %)				
Inner or outer quarter	84.5	78.5	78	NS
Middle quarters	15.5	21.5	22	NS
Distance of the tape to the hypoechoic center of the urethra (mean, mm)	4.3	4.4	4.5	NS

The position of the tape was established by its site in relation to urethral length (%) and to the quarters of the urethra. The distance of the tape to the urethra was defined as the space between the border of the tape and the hypoechoic center of the urethra (mm)

Table 4 Combined TVT and prolapse repair: review of the studies

Reference	Number	Period of follow-up (months)	Combination of TVT and	Cure rate (%)
[7]	55	18	Vaginal hysterectomy Anterior colporrhaphy Posterior colporrhaphy Sacrospinous fixation	91
[8]	32	24	Anterior colporrhaphy Posterior colporrhaphy Anterior and posterior colporrhaphy	93
[9]	35	11	Vaginal hysterectomy Anterior colporrhaphy Posterior colporrhaphy McCall culdoplasty LeFort colpocleisis Sacrospinous fixation	95
[10]	81	25	Hysterectomy	93
[11]	186	25	Vaginal hysterectomy Pelvic floor reconstruction	91

43% at 1-year follow-up and a lower cure rate in patients with additional cystocele repair than in patients without anterior colporrhaphy.

The bladder perforation rate during TVT procedures in combination with other surgical procedures is between 0 and 13% [7–9, 14–16]. This complication could easily be managed by more lateral reinsertion of the TVT needle and by placing a transurethral Foley catheter for about 4 days. No higher risk of bladder perforation during the TVT procedure with concomitant prolapse surgery was found in our study or in the literature.

A typical postoperative complication can be transient urinary retention, which occurred in 11–43% of cases [7, 8, 14, 15]. Prolonged catheterization, placement of a suprapubic catheter, the use of a Hegar dilator for pushing the proximal urethra or even sectioning the transvaginal tape may be needed, according to the extent of the problematic symptoms. Partoll [9] reported that the time to resumption of normal voiding was significantly increased in women who underwent anterior repair of a cystocele. In contrast to this, two studies did not identify any correlation between urinary retention with the need for drainage and vaginal vault surgery [17, 18].

Reported de novo postoperative urinary urge incontinence is between 10 and 30.4% [7, 8, 14, 15]. In our study we found most de novo urgency in the group undergoing TVT and anterior colporrhaphy. We suppose that the reason for this is the manipulation of the closeness of the bladder.

We propose that the precision work of tape adjustment should be undertaken after the prolapse reconstructive procedure has been completed. This order of procedure was identical in other studies [7–9, 15, 16, 19]. However, the technique of tape insertion combined with anterior colporrhaphy was different. In accordance with our management, Meschia et al. [19] inserted the tape via a separate

sagittal vaginal incision. In contrast, Pang et al. [15] and Jomaa [8] inserted the tape through an extension of the anterior vaginal wall incision. Lo et al. [7] performed the TVT procedure after the coaptation of the paravesical fascia during the anterior colporrhaphy. We believe that the position of the tape around the middle of the urethra is more stable when two incisions are performed. Partoll [9] described tape migration in patients with the TVT procedure and anterior colporrhaphy performed via a single vaginal incision.

In our study we described the position of the tape using introital ultrasound. A combination of TVT and anterior colporrhaphy by two incisions resulted in the same sonographic characteristics of the tape as with TVT alone. In a former study, with over 300 patients, after TVT we defined a normal position of the tape between 40 and 80% of the urethral length and a distance to the hypoechoic center of the urethra of ≥ 3 mm [5]. Patients with persistent stress incontinence often demonstrate a position outside the range of 40–80% of urethral length, and patients with voiding dysfunction regularly have a narrowness of < 3 mm. Therefore, we suggest that ultrasound is an important investigation after TVT procedures in patients with these problems.

Female urinary stress incontinence is frequently associated with cystocele or rectocele. A vaginal approach cystocele or rectocele repair is often preferred because the problems can be simultaneously treated. In summary, the TVT procedure performed with concurrent pelvic reconstructive surgery is a safe and effective treatment for urinary stress incontinence with co-existing vaginal pelvic prolapse. Furthermore, in this study, it has been demonstrated that patients undergoing simultaneous colporrhaphy and TVT have identical morphological tape characteristics on ultrasound examination to those undergoing TVT alone.

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