

Long-term results of tension-free vaginal tape and pubovaginal sling in the treatment of stress urinary incontinence in female patients

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Summary

Objectives: To report the long-term outcome of tension-free vaginal tape (TVT) and pubovaginal sling (PVS) in the treatment of stress urinary incontinence (SUI) in female patients. **Materials and Methods:** The long-term objective and subjective results of female patients who were previously randomized in a single blind study to two arms, TVT or PVS, between 2000 and 2004, were evaluated. The patients were asked if they were satisfied with the results of the procedure and if they would recommend it to a friend or relative. The assessment included a physical examination and cough-induced stress test. Satisfaction levels were assessed by Likert-type scale. Cure was described as absence of urine leakage in any circumstances, while improvement was characterized as subjective improvement of SUI without complete resolution. **Results:** One hundred women with SUI underwent surgery at the present medical center between 2000 and 2004. A total of 52 patients were followed clinically for objective and subjective assessment. Seventeen were interviewed only by telephone. The objective cure rate was 81.5% and 84%, where as subjective cure rate was 70.3% and 71.9%, for TVT versus PVS, respectively ($p > 0.05$). After an average follow-up of 10.5 years, there was no difference in clinical outcome, satisfaction scores, and postoperative complications between the two groups. **Conclusion:** Both TVT and PVS are safe and effective treatments for SUI in female patients, with acceptable success rate in long term follow-up.

Key words: Tension-free vaginal tape (TVT); Pubovaginal sling (PVS); Stress urinary incontinence (SUI).

Introduction

Stress urinary incontinence (SUI) is defined as the complaint of involuntary urinary leakage through the urethra during physical exertion, laughing, coughing or sneezing [1]. It is a widespread problem with a prevalence of 12.8% to 46.0% in women [2] and more common in young and middle-aged individuals [3, 4]. Several studies have reported the negative impact of SUI on the quality of life [5-7]. Over the years, several operations have been developed to cure or improve the SUI problem. Their principal mechanism of correction is to increase the pressure in the urethra during an increase of the intra-abdominal pressure [8-11]. In 2001, the pubovaginal sling (PVS) became the dominant anti-incontinence procedure [12]. At present, the appliance of urethral slings were introduced as a gold standard in the treatment of SUI [13-15]. Tension-free vaginal tape (TVT) was introduced at 1995 and was soon implemented as a standard minimally invasive procedure, with a reported success rate of 84 to 95% [16].

In this study, the authors report the long term results of two different techniques, TVT and autologous rectus fascia

sling, which were performed in the present center.

Materials and Methods

Between 2000 and 2004, 100 patients with the complaint of SUI (abdominal leak point pressure = 60-90 cm H₂O) were randomized (single-blind study) to be treated with either TVT (n = 48) or autologous rectus fascia pubovaginal sling (n = 52) at a single institute (Shahid Labbafinejad Medical Center, Tehran, Iran).

Inclusion criteria were as follows: one-hour pad test (> two-gram leak), positive cough-induced stress test, urodynamic confirmation of type II SUI (abdominal leak point pressure of 60-90 cm H₂O), urethral hyper mobility, and a competent bladder neck [2]. Exclusion criteria were: recurrent urinary tract infection, high-grade uterine prolapse, high grade rectocele and enterocele, cystocele grade II or greater, detrusor overactivity, low capacity or low compliance in urodynamic, low flow rates (< 15 ml/s), residual urine > 100 ml, trabeculated bladder mucosa on cystoscopy, and a history of pelvic fracture that might negatively affect urethral function. Women with mixed urinary incontinence were not excluded if their urodynamic studies showed normal compliance, normal capacity, and stable bladder.

All surgeries were performed by a single surgeon, experienced in both techniques. The TVT procedure was performed as described by Ulmsten *et al.* [17]. The rectus fascia pubovaginal sling surgery was performed with Pfannenstiel incision and an eight-

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Table 1. — Subjective results of ten years' follow-up in the tension-free vaginal tape and pubovaginal sling groups.

	TVT (n=37)	PVS (n=32)	<i>p</i>
Cure	26 (70.3%)	23 (71.9%)	0.92
Improvement	4 (10.8%)	4 (12.5%)	
Failure	7 (18.9%)	5 (15.6%)	

PVS: pubovaginal sling; TVT: tension-free vaginal tape.

Table 2. — Objective results of ten years' follow-up in the tension-free vaginal tape and pubovaginal sling groups.

	TVT (n=27)	PVS (n=25)	<i>p</i>
Positive stress test	5 (18.5%)	4 (16%)	0.11

PVS: pubovaginal sling; TVT: tension-free vaginal tape.

cm long and 1.5-cm wide strip of the rectus fascia was harvested. Another incision was performed in the vaginal wall mucosa for the replacement of the fascia around the urethra and the arms of the harvested graft were transferred through the abdominal incision and thigh, in a tension free manner. Cystourethroscopy was performed to check for possible urethral or bladder perforation.

Medium-term results have been reported in a previous article [18], while this study focused on the long-term objective and subjective clinical results. The available patients were asked if they were satisfied with the outcome and if they would suggest the procedure to a friend or relative. Also, they were asked if they preferred to undergo the same procedure in case of recurrence. The assessment included a physical examination and cough-induced stress test, and the satisfaction scores were assessed by a Likert-type scale, as follows: 1 (completely dissatisfied), 2 (mostly dissatisfied), 3 (neutral), 4 (mostly satisfied), or 5 (completely satisfied). Cure was characterized as no urine leakage in any circumstances while improvement was defined as the subjective improvement of SUI without complete resolution. Failure was described as leakage of urine most of the times.

Complications such as voiding dysfunction, de novo urgency and urge incontinence, history of vaginal, urethral and bladder erosion and dyspareunia were recorded. Data were analyzed with the SPSS software (Statistical Package for the Social Sciences, Version 19, using Fisher exact test. A *p*-value < 0.05 was considered statistically significant, with a confidence interval of 95%.

Results

Sixty-nine out of 100 patients were available (37 patients in the TVT and 32 in the PVS group, respectively). A total of 52 patients were followed clinically by objective and subjective evaluation. Seventeen women refused to present at the clinic for the visit and were assessed only by telephone interview. The authors had a 31% loss to longer follow-up because of four deaths and changes of address and telephone number in other cases.

After an average 10.5 years follow-up, the subjective cure rate was 70.3% and 71.9%, improvement rate was 10.8% and 12.5%, whereas failure rate was 18.9% and 15.6% for the TVT versus the PVS (*p* = 0.92), respectively, as shown in Table 1. The stress test was positive in 18.5% of TVT and

Table 3. — Satisfaction scores were assessed by Likert-type scale of ten years' follow-up in the tension-free vaginal tape and sling groups.

	TVT (n=37)	PVS (n=32)	<i>p</i>
Completely dissatisfied	5 (13.5%)	2 (6.3%)	0.11
Mostly dissatisfied	11 (29.7%)	3 (9.4%)	
Neutral	1 (2.7%)	4 (12.5%)	
Mostly satisfied	9 (24.3%)	11 (34.4%)	
Completely satisfied	11 (29.7%)	12 (37.5%)	

PVS: pubovaginal sling; TVT: tension-free vaginal tape.

Table 4. — Outcome of ten years' follow-up in tension-free vaginal tape and sling groups.

	TVT (n=37)	PVS (n=32)	<i>p</i>
De novo urgency	6 (16.2%)	6 (18.8%)	0.78
Urge incontinence	3 (8.1%)	2 (6.3%)	0.57
Vaginal erosion	2 (5.4%)	0	0.49
Urethral erosion	0	0	-
Bladder erosion	1 (2.7%)	0	0.53
Dyspareunia	5 (13.5%)	3 (9.4%)	0.71
Voiding dysfunction	7 (18.9%)	7 (21.9%)	0.76
Surgical revision	1 (2.7%)	1 (3.1%)	0.71
Satisfied	22 (67.6%)	20 (62.5%)	0.65

PVS: pubovaginal sling; TVT: tension-free vaginal tape.

16% for PVS patients (*p* = 0.11), respectively (Table 2). There was no difference in the satisfaction scores between the two groups (*p* = 0.11) (Table 3). In total, 67.6% of patients in the TVT and 62.5% in the sling group were satisfied and suggested the procedure to their friends (*p* = 0.65) (Table 4). De novo urgency and urge incontinence (self-reported by the patient without urodynamic confirmation) was not statistically different in the TVT and sling groups, respectively (Table 4).

Seven patients in each group reported changes in voiding pattern, from feeling of abrupt transient stop in the urinary stream or the need to change posture from sitting to semi-standing or bending forward to help emptying the bladder (*p* = 0.76). One patient in the TVT group suffered from left-side suprapubic small keloid scar formation, which was in the route of needle passage. There were two cases of vaginal erosion (5.4%) in the TVT group, and after conservative treatment by topical estrogen, one of them required surgical repair by mucosal reapproximation. Another case of bladder erosion in the TVT group benefited from partial excision, as well. The rate of dyspareunia was the same for both groups (*p* = 0.71). One patient in each group complained of difficult voiding which was unresponsive to medical management, finally requiring treatment by urethrolisis at one year post-operation (*p* = 0.71).

Discussion

The search for the optimal surgical technique for SUI is still under way. The TVT procedure has been introduced as a safe and effective procedure in the treatment of SUI with acceptable success rate (73-82%) [3, 4, 7, 19-21].

Most reports have been of short and medium term follow-up and very few evaluated the results in long-term studies. Recognized complications are bladder, bowel and blood vessel injury, postoperative de novo urgency, and urge incontinence [16].

The ten-year results of the study by Seratiet *et al.* demonstrate that TVT is a highly effective procedure in the treatment of female SUI with low postoperative complications. In their report the ten-year subjective, objective, and urodynamic cure rates were 89.7%, 93.1%, and 91.4%, respectively [22].

Nilson *et al.* reported 90% and 77% objective (negative cough test or a 24-hour pad test of < eight grams) and subjective (based on the Patient Global Impression of Improvement index) cure rates in a mean follow-up of 11 years [23].

Liapis *et al.* reported in their 2008 studied the efficacy and the complications of TVT, after five-year follow-up. The objective cure rate was 83%. However, at seven-year follow-up, the objective cure rate reduced to 80% [24].

Accordingly, the reported objective and subjective cure rate of TVT after a mean follow-up of 11.5 years were 84% and 77% respectively, in the study of Olsson *et al.* [25].

Abdel-Fattah *et al.* compared TVT with PVS in 142 patients and reported equal success rates (90%) at three-year follow-up for both procedures [19]. Also, Wadie *et al.* compared TVT with autologous fascial sling at a short-term follow-up and reported equal success rates for both procedures [3]. Doo *et al.* reported the results of TVT in two groups by urodynamically proven SUI, according to the Valsalva leak point pressure (VLPP). Thirty-one patients had a VLPP < 60 cm H₂O while 64 a VLPP > 60 cm H₂O, with five-year follow-up. Cure rates were 51.6% and 82.8%, respectively. They concluded that the success rate in the intrinsic sphincter deficiency group was significantly lower [26].

In the present study, 100 women with SUI and a VLPP of 60-90 cm H₂O were randomized, either to the TVT or to the autologous rectus fascia sling procedure. The results of the medium-term follow-up were reported in the year 2008 [18]. There was no significant difference between the two procedures in the treatment of SUI after medium-term follow-up (longer than one year). Mean follow-up time was 38.5 and 40 months in the TVT and sling group, respectively. The objective cure rate was 88% and 83% in the TVT versus sling group ($p = 0.78$), respectively, using a cough-induced stress test. Long-term subjective follow-up was possible in more than two-thirds of patients.

At long-term (8-12 years) follow-up, 70.3% (26 out of 37 patients) and 71.9% (23 out of 32 patients) in the TVT

versus the PVS group, respectively, reported cure of SUI and the difference was not statistically significant ($p = 0.92$). Also, there was no difference in clinical outcome and postoperative complications between the two groups.

Conclusion

Both TVT and PVS procedures are safe and effective techniques in the treatment of SUI, without statistically significant difference between the two surgical methods.

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