

## Voiding Dysfunction

# Efficacy and Safety of the TVT-SECUR<sup>®</sup> and Impact on Quality of Life in Women with Stress Urinary Incontinence: A 2-Year Follow-Up

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**Purpose:** As recently reported, the short-term results of the tension-free vaginal tape SECUR<sup>®</sup> (TVT-S) procedure seem to be similar to those of the conventional trans-obturator tape (TOT) procedure. However, results of efficacy and satisfaction with TVT-S are insufficient in patients with more than 1 year of follow-up. Therefore, we evaluated the results of the TVT-S procedure in women with stress urinary incontinence (SUI) during 2 years.

**Materials and Methods:** We evaluated 51 patients with clinical and urodynamic diagnoses of SUI who underwent the TVT-S procedure from March 2008 to February 2009. Preoperative evaluation included a history, cough stress test with full bladder, urodynamic study, and incontinence quality of life (I-QoL) questionnaire. Following the post-operative period, urinary incontinence status was examined through a physical examination and the I-QoL questionnaire was completed in an outpatient setting or by telephone.

**Results:** Data from 2 years of follow-up were available for 46 of 51 patients. The cure rate was 80.4% at 1 month after TVT-S and 76.0% at 2 years after TVT-S. The cure or improvement rate was 93.5% at 1 month after TVT-S and 86.8% at 2 years after TVT-S. The mean total I-QoL score increased by 42 points at 1 month after TVT-S ( $p < 0.026$ ) and by 32 points at 2 years after TVT-S ( $p < 0.013$ ). Most patients reported significant improvements in quality of life. At the 2-year follow-up, there were no significant complications related to TVT-S.

**Conclusions:** The results of this study suggest that TVT-S is an efficient and safe procedure for the improvement of both the quality of life of the patients and the SUI itself.

**Key Words:** Minimally invasive surgical procedures, Treatment outcome, Urinary stress incontinence

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## INTRODUCTION

Stress urinary incontinence (SUI) adversely affects the quality of life and well-being of approximately 15% of the female population [1]. The treatment options for SUI include retropubic suspensions and slings, transobturator tape procedures, injectable bulking agents, and less commonly, artificial urinary sphincter placement [2]. The ret-

ropubic tape has been shown to be effective for many years, but exposes the patient to serious complications, such as bladder perforation, principally because of the use of the retropubic space for the fixation of the tape [3]. In an attempt to avoid the retropubic space, the second generation of slings, the transobturator tape, was introduced. The recent generation of midurethral slings, the tension-free vaginal tape SECUR<sup>®</sup> (TVT-S, Gynecare, Ethicon, Somerville,

NJ, USA), which was introduced in 2005, attempts to lower the number of complications by involving only a small vaginal incision and no exit wound.

As recently reported, the short-term results of the TVT-S procedure seem to be similar to those of the conventional 'outside-in' technique of the transobturator route for suburethral tape placement, i.e., the transobturator tape (TOT) procedure. However, results of efficacy and satisfaction with TVT-S are lacking in patients with long-term follow-up [4]. Therefore, we evaluated the long-term results of the TVT-S procedure in women with SUI.

## MATERIALS AND METHODS

This study was conducted in the urology division at our national university hospital between March 2008 and February 2009. During this period, the TVT-S procedure was performed for all patients with clinical and urodynamic diagnoses of SUI who needed anti-incontinence surgery. Patients who had urinary tract infection, urogynecological malignancy, or neurogenic bladder were excluded from the study. The population consisted of 51 women who underwent the TVT-S procedure. The surgery was done under general or spinal anesthesia by one experienced surgeon. The surgical approach of the TVT-S procedure was through the U approach. The patients included in the study had SUI or stress-predominant mixed urinary incontinence proven by urodynamic study. Preoperative evaluation included a history, cough stress test with full bladder, urodynamic study, and incontinence quality of life (I-QoL) questionnaire. All subjects underwent a pelvic examination in the seated semilithotomy position with a Valsalva maneuver. The pelvic organ prolapse quantification (POP-Q) standard scoring system was adopted for staging. Because the degree of POP was minimal, surgical management for pelvic organ prolapse was not performed. Following the postoperative period, urinary incontinence status was examined through a physical examination, and the I-QoL questionnaire was completed in an outpatient setting or by telephone.

Cure was defined as the absence of any episodes of involuntary urine leakage during stressful activities and a stress test. Improvement was defined as a significant reduction in urine leakage, such that it did not require further treatment.

Statistical analysis of the data was performed by using Student's t-test. SPSS ver. 17.0 (SPSS Inc., Chicago, IL,

USA) was used for the data analysis. Statistical significance was set at  $p < 0.05$ .

## RESULTS

The population included 46 patients. Five patients were excluded because of loss to follow-up. The mean age of the population was 57.89 years (range, 38-85 years), mean parity was 3.07 (range, 1-6), mean body mass index was 25.54 kg/m<sup>2</sup> (range, 21-35 kg/m<sup>2</sup>), and mean symptom duration was 5.09 years (range, 1-15 years). The mean follow-up period was 25.16 months (range, 24-34 months). Urge urinary incontinence was present in 5 patients (10.8%). Stamey symptom grade 1 was present in 27 patients (58.6%) and grade 2 was present in 19 patients (41.4%). POP was present in 17 patients (36.9%), and 2 patients (4.3%) had undergone a previous anti-incontinence surgery. The mean maximum flow rate was 26.32 ml/s (range, 10-48 ml/s), and mean postvoid residual volume was 17.53 ml/s (range, 10-70 ml/s). Mean Valsalva leak point pressure was 85.16 cmH<sub>2</sub>O (range, 50-95 cmH<sub>2</sub>O), and mean maximum urethral closure pressure was 52.53 cmH<sub>2</sub>O (range, 13-74 cmH<sub>2</sub>O) (Table 1).

**TABLE 1.** Clinical characteristics of the patients treated with the TVT-S

Variables	Values
Mean age (yr)	57.89 (41-77)
Mean parity (range)	3.07 (1-6)
Mean BMI (kg/m <sup>2</sup> )	25.54 (21-35)
Mean symptom duration (yr)	5.09 (1-15)
Mean follow-up (mo)	25.16 (24-34)
No. with presence of urge urinary incontinence (%)	5 (10.8)
No. Stamey symptom grade	I (%) 27 (58.6) II (%) 19 (41.4)
No. with presence of POP (%)	17 (36.9)
No. with history of previous anti-incontinence surgery (%)	2 (4.3)
Mean maximum flow rate (ml/s)	26.32 (10-48)
Mean postvoid residual volume (ml)	17.53 (10-70)
Mean VLPP (cmH <sub>2</sub> O)	85.16 (50-95)
Mean MUCP (cmH <sub>2</sub> O)	52.53 (13-74)

TVT-S: tension-free vaginal tape-Secur, BMI: body mass index, POP: pelvic organ prolapse, VLPP: Valsalva leak point pressure, MUCP: maximum urethral closure pressure

**TABLE 2.** Comparison of preoperative and postoperative I-QoL scores

Subscales	Baseline	1 month	2 years	p-value <sup>a</sup>	p-value <sup>b</sup>
I-QoL Total	35.44	77.31	67.57	<0.026	<0.013
Avoidance and limiting behaviors	36.80	76.94	73.52	<0.034	<0.021
Psychosocial impacts	39.61	79.89	65.35	<0.045	<0.046
Social embarrassment	25.78	73.28	71.23	<0.001	<0.023

I-QoL: incontinence quality of life, <sup>a</sup>: comparison of baseline vs 1 month, <sup>b</sup>: comparison of baseline vs. 2 years

**TABLE 3.** Surgical outcomes of TVT-S

	1 month	2 years
Success		
Cure (%)	80.4 (37/46)	76.0 (35/46)
Improvement (%)	13.1 (6/46)	10.8 (5/46)
Failure (%)	6.5 (3/46)	13.2 (6/46)

TVT-S: tension-free vaginal tape-Secur

**TABLE 4.** Results of urodynamic study in the cure or improvement group compared with the failure group

	Cure or improvement group (n=40)	Failure group (n=6)
Mean maximum flow rate (ml/s)	26.43	25.58
Mean postvoid residual volume (ml)	15.32	32.26
Mean VLPP (cmH <sub>2</sub> O)	87.27	71.09
Mean MUCP (cmH <sub>2</sub> O)	52.64	51.79

VLPP: Valsalva leak point pressure, MUCP: maximum urethral closure pressure

The preoperative mean total I-QoL score was 35.44. One month after the operation, the mean total I-QoL score was 77.31 (Table 2). Two years after the operation, the mean total I-QoL score was 67.57. Mean total I-QoL scores increased 42 points at 1 month and 32 points at 2 years after TVT-S ( $p < 0.026$ ,  $p < 0.013$ ) (Table 2). Most patients reported significant improvements in quality of life.

The overall cure rate was 80.4% at 1 month after TVT-S and 76.0% at 2 years after TVT-S. The overall cure or improvement rate was 93.5% at 1 month and 86.8% at 2 years after TVT-S. The failure rate was 6.5% at 1 month and 13.2% at 2 years after TVT-S (Table 3).

Results of urodynamic study in the cure or improvement group compared with the failure group were obtained. In the cure or improvement group, mean maximum flow rate, mean Valsalva leak point pressure, and mean maximum urethral closure pressure were higher than in the failure group. Mean postvoid residual volume was lower in the cure or improvement group (Table 4). The statistical significance of these differences could not be determined, however, because of the limited number in the failure group.

Three patients (6.5%) had urinary retention after surgery, which was managed with temporary clean intermittent catheterization. De novo urgency developed in 4 patients (8.6%). Among 5 patients who had urge urinary incontinence before the operation, 2 patients had persistent urge urinary incontinence. No vaginal or urethral erosion was identified. At the 2-y follow-up, there were no significant complications related to TVT-S.

## DISCUSSION

Before 1996, SUI was optimally treated with one of several forms of retropubic colposuspension, the pubovaginal sling,

injectable bulking agents, or needle suspension [2]. Although associated with acceptable "cured/dry" rates, each of these procedures is subject to inherent complications, is cumbersome to perform or difficult to learn, or is associated with unacceptable morbidity [5-7]. The TVT, whose design was determined from the integral theory's focus on midurethral continence, offered a less-invasive, outpatient-based treatment option for SUI [3]. However, the TVT procedure has been associated with specific risks, including bladder, bowel, and vascular injury, owing to the blind passage of the trocars through the retropubic space [8]. In response to these risks, the TVT procedure was modified, and the TOT procedure was introduced in 2001 [9]. Instead of transgressing the retropubic space, the TOT procedure passes the trocars blindly through the obturator foramen in an "inside-out" or "outside-in" fashion that thus obviates the risk of injury to the retropubic organs. Although promising, the TOT procedure has been associated with a small, but defined, risk of prolonged leg pain, ostensibly owing to passage of the transvaginal mesh through the obturator foramen proper [10]. The conventional TOT approach has resolved some of these problems by passing the obturator fossa to avoid getting in the retropubic space, so that the tape is far enough away from the bladder, vessels, and bowel [11]. However, even this revolutionary approach is associated with some complications, such as thigh pain, hematoma due to significant intraoperative bleeding, and postoperative bladder outlet obstruction [12].

TVT-S was planned to reduce the invasiveness of the tape procedure by developing a new tape. The principal idea of this novel technique was to introduce a midurethral sling from a single incision without passing the retropubic space or the obturator foramen and its related nerves and vessels [13]. The TVT-S procedure utilizes a shorter sling (8 cm) that is anchored directly to the retropubic fascia (U method) or the obturator internus muscle (H method). These steps lead to less dissection, lower amounts of synthetic material, and possibly fewer complications. Exit points are unnecessary, which reduces the immediate and persistent pain.

Gagnon and Tu reported that improvement in incontinence symptoms was much higher with the U Method than with the Hammock technique [14]. The success rate increased with time, reaching a statistically significant difference at 6 months with 100% (22/22) improvement compared with 69% (11/16) for the Hammock technique. The U Method seems to offer better support to the urethra and a stronger fixation of the mesh. The tightness applied to the tape during the surgery is also important for obtaining good results [14]. Accordingly, the surgical approach of the TVT-S procedure was through the U approach in our study.

A small number of published articles are available on the TVT-S. Reported success rates for the TVT-S are about 80% [14]. To our knowledge, the first report came from Martan et al in January 2007 [15]. At 1 to 3 months of follow-up, they reported a cure rate of 93% in 15 patients, 10 with the Hammock technique. In 2008, Debodinance et al published

an article on 110 patients with a dry rate of 70.4% at 2 months [16]. This report actually revealed a low cure rate compared with conventional midurethral slings, but the technique was the Hammock technique in 85.5%. More recently, Oliveira et al reported, in January of 2009, good success rates in 107 patients with a mean follow-up of 15 months. The patients were either dry or improved in 85% [17]. In our study, the overall cure or improvement rate was 93.5% at 1 month after TVT-S and 86.8% at 2 years after TVT-S. Oliveira et al reported that the cure rate was 83% after TVT-O, 67% after TVT-S, and 87% after Mini-Arc [18]. The fact that TVT-S has been associated with lower success rates deserves some consideration. TVT-S has a long learning curve. Even among experienced surgeons, consistent positioning of the TVT-S tip maybe difficult. Moreover, mesh detachment from the introducer blades requires a twisting movement that may enlarge the internal obturator muscle area where the TVT-S tip is inserted, thus compromising mesh adhesion [18]. But, according to Jeong et al, there was no significant difference in cure rate or patient satisfaction between the TVT-S and MONARC procedures after more than 1 year of follow-up [4]. In our study, the TVT-S procedure was shown to offer relatively good results and a significant improvement in quality of life among women with SUI.

Because the questionnaire is a subjective measure, it should be convenient and easily understood. The I-QoL is easily self-administered and takes approximately 5 minutes for the average patient reading at a fifth-grade level to complete [19]. It is available in 16 different language versions and has been validated in four European countries as well as in the United States [20]. Also, we used the Korean version of the I-QoL. The I-QoL questionnaire is a targeted condition-specific questionnaire that assesses the effect and distress of specific symptoms of SUI [21,22]. The I-QoL contains 22 items, each with a five-point, Likert-type response scale, yielding a total score and three subscale scores. The potential advantage of the I-QoL over previous measures is its applicability to patients over a range of ages and with varying types and severities of SUI.

In our study, based on the outcome of the I-QoL, the patients experienced a significant improvement in their quality of life with the TVT-S procedure.

## CONCLUSIONS

The TVT-S procedure has a cure rate similar to that of the current TVT or TOT procedures, and the TVT-S procedure can be performed safely. From our experience, the TVT-S procedure offers a good success rate and a significant improvement in quality of life among women with SUI. We suggest that the TVT-S procedure is an efficient surgical treatment for improving the aspect of the quality of life of patients as well as SUI itself. However, controversy remains about the difference in success rates of the TVT-S procedures between medical centers. Also, the TVT-S procedure has a long learning curve.

## Conflicts of Interest

The authors have nothing to disclose.

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