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Original Article

Ten-Year Subjective Outcome Results of the Retropubic Tension-Free Vaginal Tape for Treatment of Stress Urinary Incontinence

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ABSTRACT **Study Objective:** To assess the 10-year subjective outcome of use of retropubic tension-free vaginal tape (TVT).
Design: Structured telephone interview (Canadian Task Force classification II-3).
Setting: Universitiy-affiliated tertiary medical center.
Patients: Sixty consecutive women with urodynamically confirmed stress urinary incontinence (SUI) who underwent retropubic TVT surgery during 2000. At surgery, their mean (SD) age was 62.4 (9.3) years, and parity was 2.9 (1.3).
Interventions: Retropubic TVT, with 10-year subjective outcome questionaire.
Measurements and Main Results: Of the 60 patients, 52 (87%) were available for 10-year follow-up. Preoperatively, all patients reported substantial SUI, and 28 (54%) also had concomitant urge urinary incontinence (UUI). At 10 years postoperatively, 34 women (65%) considered their condition cured, 6 (12%) believed it was improved, and 12 (23%) thought surgery had failed. Eleven women (21%) reported SUI, 22 (42%) had UUI (de novo UUI in 9), and 8 (15%) had recurrent urinary tract infections. Two women (4%) underwent repeated TVT. Of the various perioperative variables, only postoperative impaired bladder emptying was a statistically independent risk factor for long-term failure (odds ratio, 6.4; 95% confidence interval, 1.3–30.1).
Conclusions: Ten-year subjective outcome of retropubic TVT are less favorable than previously reported. Early postoperative impaired bladder emptying is the most significant risk factor for long-term failure. Journal of Minimally Invasive Gynecology (2011) 18, 726–729 © 2011 AAGL. All rights reserved.

Keywords: Long-term outcome; Stress urinary incontinence; TVT

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Urinary incontinence is a common condition that adversely affects the quality of life in many women worldwide. Reported prevalence ranges from 4.5% to 53.0%, with an early peak in midlife of 30% to 40% and a subsequent steady increase in later life of 30% to 50% [1–3]. Approximately 50% of all women with incontinence have stress urinary incontinence (SUI). However, mixed stress and urge urinary incontinence (UUI) predominates in elderly women [3–5].

Surgical intervention is considered the most efficient and lasting approach to treatment of SUI. A wide variety of surgical techniques have been described, among which the midurethral sling procedures have gained worldwide popularity. The retropubic tension-free vaginal tape technique (TVT), originally introduced by Ulmsten et al [6] in 1996, was the first minimally invasive midurethral sling procedure for treatment of SUI. Since the introduction of TVT, studies have confirmed its efficacy, safety, and medium-term durability [7–9]. Surgical interventions for correction of SUI are usually undertaken in midlife. However, people all

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over the world are now living longer. By 2050, one of every 5 persons living in the United States will be aged 65 years or older, and the total number of older Americans is expected to be 82 million [10]. Similarly, the 2050 life expectancy of US women at birth is expected to be 85.6 [11]. It is, therefore, important to assess the durability and long-term outcome results of anti-incontinence interventions such as TVT in later life. Such studies are scarce; only 2 studies from Scandinavia have reported outcomes at 11 years after TVT [12,13].

The objectives of the present study were to assess the 10-years subjective outcome of retropubic TVT for treatment of SUI and to explore possible predictors of long-term success.

Patients and Methods

Sixty consecutive women with urodynamically confirmed SUI who underwent retropubic TVT surgery during 2000 were enrolled. The study protocol was approved by the local hospital Helsinki committee. All procedures were performed by 2 experienced surgeons (R.G., D.G.) at a single university-affiliated tertiary medical center. Women who required concomitant anterior or apical pelvic organ prolapse repair and those with urodynamic occult SUI were excluded. All women underwent a full urodynamic evaluation before and after surgery. The methods, definitions, and units conformed to the standards proposed by the International Continence Society [14]. Stress testing was performed at 150 mL and incrementally at 50 mL until SUI was demonstrated or maximum cystometric capacity was attained. Urodynamic SUI was defined as involuntary loss of urine during increased intraabdominal pressure without a change in detrusor pressure. The TVT procedure was performed in strict accordance with the technique and instruments described by Ulmsten et al [6] with the exception of mode of anesthesia; all surgical procedures were performed with the patient under general or regional (spinal) anesthesia. Patients were closely observed during their hospital stay. Special attention was taken to evaluate and document early postoperative complications. Postoperatively, patients were scheduled for evaluation at 1, 3, 6, and 12 months and annually thereafter for up to 5 years. Each follow-up visit included medical history, focused questioning about the occurrence and severity of lower urinary tract symptoms, pelvic examination with a full bladder, stress test (Valsalva maneuver), uroflow, and sonographic measurement of postvoiding residual urine volume. Urodynamic evaluation was routinely performed at 3 months after surgery. Patients who developed lower urinary tract symptoms after this time underwent a full clinical evaluation including repeated urodynamic testing. Patients who developed postoperative recurrent urinary tract infections (UTIs), or de novo overactive bladder also underwent urethrocystoscopy to exclude iatrogenic injury. Recurrent UTIs were defined as at least 3 episodes of UTI in the last 12 months, with at least 1 documented at culture. Overactive bladder was defined as urinary urgency, with or without urge incontinence, usually with frequency and nocturia. All preoperative, perioperative, and postoperative data were prospectively documented and stored in a computerized database.

The 10-year subjective outcome of the TVT procedure were assessed using a structured telephone interview conducted by a research nurse (G.R.) after obtaining patient approval. Women were asked about frequency and severity of various lower urinary tract symptoms, primarily nocturia, urinary frequency, urinary urgency, UUI, SUI during various activities, and voiding difficulty. Episodes of incontinence were further categorized as daily, frequently (at least once a week), infrequent (at least once a month), and rare (less than once a month). Patients were also asked about other possible long-term postoperative complications such as recurrent UTIs and vaginal erosions, whether they consulted a physician about these symptoms, whether they received further treatments (pharmaceutical, surgical, or other), whether they were interested in further evaluation and treatment, what their global satisfaction was (cure, improvement, or failure), and whether they would recommend TVT surgery to a friend with a similar problem.

Possible clinical and urodynamic predictors of long-term surgical success or failure were analyzed from the computerized database. Statistical analysis was performed using the *t* test for continuous data or the Fisher exact test for categorical data; $p < .05$ was considered statistically significant. Data are given as mean (SD) or percentage according to the variables. Preoperative and perioperative variables that were statistically significant at univariable analysis were entered into a multivariable logistic regression model to identify independent risk factors. Multivariable analysis was performed using commercially available software (SPSS version 15.0; SPSS, Inc., Chicago, IL).

Results

Of the 60 patients, 52 (87%) were available for 10-year follow-up. Preoperatively, all patients reported significant SUI, and 28 (54%) also had concomitant (UUI). At surgery, mean (SD) patient age was 62.4 (9.3) years, and parity was 2.9 (1.3). Previously, 9 women (17%) had undergone total abdominal hysterectomy; 5 (10%), vaginal hysterectomy; and 5 (10%), anti-incontinence surgery (4, Burch procedure, and 1, Raz procedure).

In 3 patients, intravesical passage of the polypropylene (Prolene) tape occurred. In 1 of these patients, the complication was diagnosed 15 months postoperatively. This late manifestation was most probably due to late bladder erosion, although a misdiagnosed intraoperative bladder perforation cannot be excluded. The tape was excised endoscopically. Nine patients (17%) had postoperative voiding difficulties that necessitated catheterization for longer than 48 hours. No loosening procedures were performed. All but 1 patient resumed spontaneous voiding within 2 weeks postoperatively. One patient experienced impaired bladder emptying for 2 months, and pressure flow studies revealed bladder outlet obstruction. This was treated via combined transvaginal