Third-Generation Tension-Free Tape for Female Stress Urinary Incontinence

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Abbreviations and Acronyms

ISD = intrinsic sphincter deficiency

SUI = stress UI

TOT = tension-free transobturator tape

UI = urinary incontinence

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Purpose: We reviewed our experience with the TVT-Secur™ tension-free tape for stress urinary incontinence in females. We evaluated operative time, complications, the continence rate and patient satisfaction at followup. Ethics committee approval was not required.

Materials and Methods: A total of 32 hammock-shaped tape interventions were performed between November 2006 and April 2008 at our hospital. All patients had stress urinary incontinence, which was pure in 20 and associated with prolapse of other pelvic organs in 12. Each patient underwent urogynecological assessment with urodynamic evaluation and performed a quality of life questionnaire. We excluded from analysis all patients with intrinsic sphincteric deficiency. Patients were followed for continence and satisfaction. Therapeutic failure was defined as persistent urinary stress incontinence affecting quality of life, as reported by patients and on clinical examination.

Results: None of the 32 women had any surgical complication, postoperative pain or blood loss greater than 100 cc. Some minor complications were recorded and the sling eroded in 1 case. Urinary continence was achieved in all patients after surgery and at assessments 12 to 18 months later. All patients confirmed immediate satisfaction with continence and pain on the questionnaire.

Conclusions: TVT-Secur is a minimally invasive, safe and easy surgical technique for stress urinary incontinence in females. To compare this procedure to other tension-free techniques longer and more detailed followup is necessary in more patients. However, this tape may be associated with fewer complications.

Key Words: urethra; female; urinary incontinence, stress; suburethral slings; prolapse

It is estimated that the prevalence of UI is 10% to 25% in the female population between ages 15 and 64 years.[1] Of women older than 60 years 37% experience some form of UI.[2] Thus, we have assisted in developing treatment in terms of drugs and surgery.

Historically UI has been classified as SUI when a patient complains of involuntary leakage upon effort or exertion, sneezing or coughing, as urinary UI when the patient complains of involuntary leakage accompanied by or immediately preceded by urgency and as mixed UI when there is an association of the previous 2 types.[3,4] In males the primary continence mechanism is the prostatic and membranous portions of the urethra, as opposed to the entire shorter urethra that performs that function in females.[4] Moreover, urethral support in women derives from the 2 leaves of the levator ani, the endopelvic and pubocervical fasciae. This

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hammock supports and compresses the urethra when abdominal pressure increases. If thesesupporting structures are weakened, urethral hypermobility results.[4–8] SUI due to urethral hypermobility is referred to as type II. The other cause of urethral weakness may be ISD, which is type III SUI. Urethral hypermobility and ISD often occur in the same patient.

Surgical treatment for SUI has always aimed to improve the ability of the bladder outlet to resist increased abdominal pressure. According to the pressure equalization theory it was enough to pull the bladder neck and the proximal urethra up to balance the increase in abdominal pressure. It worked well and the improved urethral support benefited patients with urethral hypermobility and those with ISD.[9]

However, in the last 2 decades after newly acquired knowledge of pelvic anatomy the surgical approach changed, becoming step by step more specific and less invasive. At this time a theory of SUI treatment in females was proposed with use of a tension-free synthetic sling below the median urethra. According to the integral theory, urethral support weakness may affect the normal transmission of pelvic muscle strength to the urethra.[10] It was suggested to move surgery over the proximal urethra and position a tension-free sling below the median urethra without suspension. Although the sling was tension-free, it created strong ligamentous support that restored muscle strength to the urethra. Since then, TVT™ use has spread worldwide, becoming the gold standard for types I and II SUI in females.[10,11]

In 2003 the second generation of tension-free slings was launched. It consisted of a sling passing through the obturator hole (TOT), although the aim was the same. This technique had fewer complications than classic TVT with shorter operative and hospitalization time.[12]

In 2006 the third-generation TVT-Secur sling became available. Although there is no skin incision for pulling out the sling, the procedure is based on the usual mid urethral polypropylene tape support, which today is accepted as an easy and safe technique. The difference is that this sling fixes itself after positioning using 2 absorbable tips (fig. 1). An advantage is that it overcomes previous TVT and TOT complications, thigh pain and bladder outlet obstruction, and most of all the risk of visceral penetration caused by a needle.

PATIENTS AND METHODS

From November 2006 to October 2007 we enrolled in this study and treated 32 patients with types I and II SUI, of whom 12 also had cystocele, rectocele, hysterocele or vaginal vault prolapse and 20 had pure SUI. All patients underwent urogynecological assessment with urodynamic evaluation and the Wagner I quality of life 6 urology questionnaire. Thus, all patients with ISD, defined as

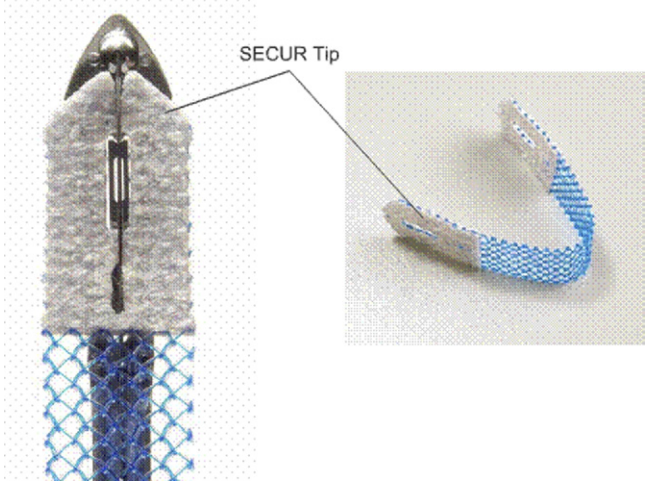

Figure 1. Sling with 2 absorbable tips for self-fixing

Valsalva leak point pressure less than 40 cm H_2O on urodynamics, were excluded from analysis.

Preoperatively all patients were given 1 gm ciprofloxacin and 1 gm metronidazole intravenously and underwent an iodine vaginal wash. Nine patients underwent cystopexy using anterior Prolift™ mesh. Two patients with vaginal vault prolapse underwent complete cystopexy using Total Prolift. One patient underwent hysterectomy and cystopexy with Total Prolift with a mean operative time of 1 hour 10 minutes. Ten patients who presented with SUI received a TVT-Secur sling only with a mean operative time of 10 minutes. TVT-Secur positioning was then performed in another 10 patients with pure SUI under local anesthesia using 20 ml 1% mepivacaine and 3 ml bicarbonate solution. This solution was infiltrated according to sling manufacturer recommendations as 10 to 13 ml under the urethra, and 15 ml on the right and left sides up to the internal obturator hole.

After incision of the anterior vaginal wall 1 cm below the urethral meatus accurate paraurethral dissection was carried about 2 cm. The sling was first introduced on the right side up to the ischiopubic bone and into the internal obturator muscle, where the tape edge was anchored by a needle holder instead of passing it through the obturator foramen, muscles and membrane, as for TOT (fig. 2, *A*). The left side was then introduced in the same way, creating a hammock-shaped sling. Finally, definitive sling tension was achieved by pulling the 2 tips as close to the urethra as the surgeon considered necessary.

Patient followup for continence and satisfaction was done at 1, 3, 6 and 12 months. At the final followup at 12 months data were recorded for study purposes. Criteria defining continence were absent stress incontinence affecting quality of life, as reported by patients on the questionnaire and on urodynamics. When minimal leakage occurred, it was not considered failure when considering the previous condition.

RESULTS

A total of 32 hammock-shaped TVT-Secur interventions were performed between November 2006 and