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What determines a successful tension-free vaginal tape? A prospective multicenter cohort study: Results from The Netherlands TVT database

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Objective: The objective of this study was to report which preoperative and intraoperative factors influence the success of the tension-free vaginal tape procedure for stress urinary incontinence.
Study design: This was a prospective cohort study of 809 patients. In 28 teaching hospitals and 13 local hospitals, 54 gynecologists and urologists performed the tension-free vaginal tape procedure.
Results: Before treatment and 2 years postoperatively, the following question from the Urogenital Distress Inventory for stress urinary incontinence was selected to define success or failure: "Do you experience urinary leakage during physical activity, coughing, or sneezing?" Secondary outcome measurement was the outcome of the doctor's question, "Do you leak during physical activity, coughing, or sneezing?" asked at the 2-year follow-up. Response rate was 78.7%. The success rate was significant higher in all analyses when the surgeons had performed more than 20 tension-free vaginal tape procedures ($P = .003$; beta = 1.918 [95% confidence interval 1.24-2.97]). General anesthesia had a negative effect on the success of the tension-free vaginal tape ($P = .032$; beta = 2.21 [95% confidence interval 1.07-4.55]).
Conclusions: Inexperience of the surgeon with the tension-free vaginal tape procedure and general anesthesia had a negative effect on the result. We believe that the tension-free vaginal tape should be performed only by experienced surgeons.

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Stress urinary incontinence (SUI) is a common condition in the female population.[1] During the last century, a variety of surgical procedures have been developed as treatment for this condition. Many of these procedures have disappeared because of poor long-term results. Until 1995 the golden standard of SUI surgery was the Burch colposuspension.[2] By now this procedure has been mostly replaced by the tension-free vaginal tape (TVT). The TVT has become the first choice as surgical treatment for stress urinary incontinence in women. The procedure was introduced by Ulmsten and colleagues in 1995.[3,4] TVT is a minimally invasive procedure based on one of the concepts of the integral theory for female incontinence: the midurethral support. TVT has proven to be as successful as the Burch colposuspension.

Assessing the efficacy of the surgery for incontinence represents a challenging issue. Black and Downs[5] analyzed the outcome of several incontinence procedures. They concluded that the methodological quality of the few prospective studies that have reported on the effectiveness of surgery for SUI is poor. Additionally, they conclude that the value of surgery and the effectiveness of different procedures are unclear. Since the introduction of TVT, many studies have described the results of TVT. However, the criticism of Black and Downs still stands for most of these reports. Ward and Hilton[6,7] compared the Burch colposuspension and TVT in a prospective, well-conducted study. Besides this comparative study, there are only a few studies that have determined prospectively the outcome of TVT. To our knowledge not one publication reports on the prognostic factors for success or failure of the TVT procedure.

In this article we present the results of a multicenter study on the long-term outcome of TVT. The focus of this report is on the pre- and intraoperative factors influencing the success of the TVT procedure for SUI.

Material and methods

Between March 2000 and September 2001, all patients with an indication for the TVT procedure were asked to participate in this study. Inclusion criteria were urodynamic proven stress incontinence or SUI at history/physical examination. The urodynamic investigations were performed according to the standards recommended by the International Incontinence Society.[8] Exclusion criteria were recurrent and difficult-to-treat urinary tract infections, predominant symptoms of urge urinary incontinence (defined as urge incontinence being more prevailing than the stress incontinence), detrusor overactivity at cystometry, postvoiding bladder retention (more than 150 mL), bladder capacity less than 200 mL, or a physical/mental impairment. Intrinsic sphincter deficiency (ISD) was defined when the maximum urethral closing pressure (MUCP) was less than 20 cm H_2O ISD and MUCP greater than 20 cm H_2O at preoperative urodynamics.

All participating gynecologists and urologists were qualified to perform vaginal surgery and had a short training in performing TVT by an experienced surgeon.

The TVT was performed as described by Ulmsten.[3] The operation was carried out under local anesthesia using 0.25% prilocaine with adrenalin and sedation, spinal analgesia, or general anesthesia.

Before and at 2, 6, 12, and 24 months after surgery, a standardized history, physical examination, and urine culture were performed. At the same time intervals, all patients were asked to complete the short version of the Urogenital Distress Inventory (UDI). The questionnaires, a postage-paid return envelope, and instructions were send to the patient by mail. The UDI is a disease-specific, health-related quality-of-life questionnaire. Uebersax et al[9] validated a short form for this questionnaire (UDI-6), which consists of 6 questions. These questionnaires were translated in the Dutch language and validated in The Netherlands by van der Vaart et al.[10] All items in the questionnaires consisted of a 4-step ordered category scale from "not at all" to "greatly." The answers were transformed to a scale from 0 (no complaints) to 100 (very bothered). Registration of mode of anesthesia, intraoperative, and direct postoperative complications was performed by the surgeon.

The number of TVTs that every surgeon performed was counted. Groups were formed of the first 10 TVTs, 11 to 20 TVTs, and more than 20 TVTs each surgeon performed.

Ethics

This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg as primary research center and all other coworking hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Outcome measures

According to the recommendation of the International Incontinence Society, the question "Do you experience urinary leakage during physical activity, coughing, or sneezing?" was selected from the UDI as primary outcome measure to define success or failure for SUI.[8] Success was defined as the answer was "no." The questionnaires, a postage-paid return envelope, and instructions were sent to the patient by mail. The questionnaires were anonymously processed in a database. Researchers as well as participating gynecologist and urologists were blinded to the individual results of these questionnaires.

The secondary outcome measure was the answer to the doctor's question "Do you leak during physical