

INITIAL EXPERIENCE WITH TVT-SECUR*SYSTEM PROCEDURE

Hypothesis / aims of study

The objective of this study is to present the TVT S System (tension-free vaginal tape secure system) a new, minimally invasive sling procedure for the treatment of stress urinary incontinence in women and to evaluate the complications and functional results of the TVT-S procedure and to determine possible reasons for these complications.

Study design, materials and methods

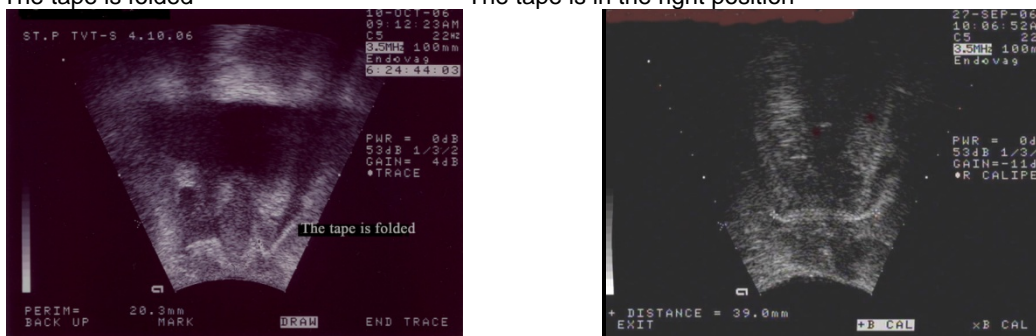
TVT-Secur* System Device - the mesh consists of a 1.1 x 8 cm PROLENE laser cut mesh tape, which is coated on both ends (2 cm on each end) with an absorbable fleece material. The sandwiched fleece is a composite of Vicryl and PDS (Polyglactin 910 and Poly-P-Dioxanon) which provides strong fixation without the use of sutures. This material is usually absorbable within 90 days, with PROLENE* remaining intact to provide long term fixation. A curved stainless steel inserter instrument and "release wire", anatomically designed for both the "U" and "hammock" tape position, is attached on both ends to the mesh. The prosthetic implant is placed under the midurethra, runs along, and is fixed in the "hammock" position into the obturator internus muscle. In the "U" tape position it is attached behind the pubic bone to the connective tissue of urogenital diaphragm. Forty women with proven and previously untreated stress urinary incontinence were recruited to participate in a clinical study. Their mean age was 55.5 [SD-11.23] years, mean body mass index (BMI) was 28.7 [SD-5.01], and mean parity was 1.9 [SD-0.94]. The tape was placed twenty-three times in a "hammock" position and seventeen times in a "U" position. All patients are currently between one and six months after the operation.

Results

The curative rate of TVT-SECUR*System procedure is 87.5 percent. When the tape was placed in the "hammock" position, the following complications of the TVT-S procedure were found. In three cases stress urinary incontinence persisted while perineal ultrasound examination ascertained that in two cases the tape was folded [Fig.1,2], although in a subjective assessment, even these patients observed a significant improvement. One patient suffered from pain in the vagina after this procedure. The causes of the pain were not ascertained, but they ceased of their own accord after a week. In two cases we found small vaginal erosion caused by the tape. When the tape was placed in the "U" position in two cases stress urinary incontinence persisted while perineal ultrasound examination ascertained that in these cases the tape was folded too.

Fig. 1,2

Ultrasound imaging of the lower urinary tract
The tape is folded The tape is in the right position



Interpretation of results

Our first experience with TVT-S procedure, including possible complications, post-operative care and curative rate, is positive. This procedure has supplemented the tape procedures that are already applied, and it will reduce the percentage of peri- and post-operative complications, primarily since it does not require skin incision and the amount of synthetic material that remains in the organism is smaller. Ultrasound examinations have determined that the tape may be slightly pulled back when extracting the inserters, which then causes persisting SI.

Concluding message

From our results we can conclude that placement of the tape with a fleece, and gentle removal of the inserter and possibly fixation of the fleece by forceps may protect the run out of the tape. These steps are crucial for the curative effect.

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Ethics Committee of General teaching hospital, Prague and followed the Declaration of Helsinki Informed consent was obtained from the patients.