



Self-created transobturator tape treatment of stress urinary incontinence without prior urodynamic investigation



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ABSTRACT

Objectives: The purpose of this study was to evaluate and compare the results of tension free self-created transobturator tape (SCTOT) with the standard industrially created transobturator tape (ICTOT) in the treatment of stress urinary incontinence (SUI).

Study design: A prospective study of the treatment of SUI with SCTOT (67 patients) and ICTOT (47 patients) was performed. SCTOT was created from polypropylene mesh and monofilament sutures. The symptoms were evaluated before and after the surgery with the following: the Incontinence Impact questionnaire (IIC-7), the urogenital distress inventory (UDI-6), and the International Continence impact questionnaire short form (ICIQ5-SF). The overactive bladder symptom score (OABSS) was used to classify patients in the SUI or the mixed urinary incontinence (MUI) group. The follow up period was 18 months. Cure was defined as a negative stress test and no need for additional surgery.

Results: Objective cure was achieved in 56/67 (83.5%) participants in the SCTOT group and in 40/47 (85.1%) participants in the ICTOT group ($p > 0.05$). There was a significant improvement in IIC-7, UDI-6, ICIQ5-SF and OABSS in both groups. Improvement was better in the group with pure SUI than in patients with MUI, but this difference was not significant. Postoperative infection occurred in 5/67 (7.4%) participants and in 5/47 (10.6%) patients in the SCTOT and the ICTOT group, respectively. De novo overactive bladder symptoms occurred in 4/67 (5.9%) of the participants in the SCTOT group and in 3/47 (6.3%) of the patients in the ICTOT group. Operating time was longer in patients with SCTOT compared to those with ICTOT.

Conclusion: The results of the treatment with SCTOT are not inferior to the results of the treatment with ICTOT and other results reported in the literature.

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Introduction

Stress urinary incontinence (SUI) has a high prevalence that increases with advancing age and can reach a rate of 53.7% in females older than 40 years [1]. The most frequently used treatment for SUI is a tension free tape because of its surgical simplicity and high success rate [2]. The transobturator tape is considered more acceptable for everyday use, regardless of the slightly lower success rate, because a cystoscopy is not necessary and the occurrence of potentially life threatening complications is reduced [3].

The number of surgeries performed to treat SUI has increased in recent years. The high price of industrial tapes as well as the expensive and time-consuming urodynamic investigation are the most important limiting factors in everyday clinical use. Urodynamic investigation, although widely used, has no influence on the success rate and the ability to predict adverse effects of the surgery. For these reasons, although it was previously considered obligatory before surgery [4], urodynamic investigation is not considered obligatory before the primary treatment of SUI [5].

There are few reports about successful tape use without prior urodynamic investigation [6,7]. Self-created tension free supra-pubic slings have also been used successfully [8]. There are exceptional reports about the use of self-created transobturator tapes (SCTOT) in patients with SUI [9].

The aim of this study is to evaluate the results of the treatment of SUI, diagnosed based on pure clinical criteria, with SCTOT and

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compare the results to treatment with industrially created tension free tape (ICTOT).

Material and methods

A prospective study that included patients with clinical evidence of SUI was performed. The results of the surgery were evaluated in 67 patients treated with SCTOT and compared to the results of the surgery performed in 47 patients treated with ICTOT after complete follow-up. Fourteen patients in the SCTOT group and 4 patients in the ICTOT were excluded because of the incomplete follow-up. Two types of industrially created slings were used: the “T sling”- (Herniamesh, Torino, Italy), and the “TVT obturator” (Johnson & Johnson, Somerville, NJ, USA). The follow-up was 16–23 months (median 18 months). SUI was clinically diagnosed in all patients using a positive stress test in the supine position, and severity of incontinence was measured with the incontinence severity score [10]. In all patients, there was urethral hypermobility (Q tip test >30 degrees). Ultrasound measurement of residual urine was performed. Symptoms before and after the surgery were measured with the: urogenital distress inventory (UDI-6), Incontinence Impact Questionnaire (IIC-7) and Incontinence Impact questionnaire-short form (ICIQ5-SF). The overactive bladder symptom score was used to identify patients with mixed urinary incontinence (OBSS > 8) [11].

Associated pelvic organ prolapse (POP) was measured with the pelvic organ prolapse quantification system (POPQ). POPQ stage 0–1 was present in 24/67 (35.8%), stage 2 in 43/67 (64.2%) patients in SCTOT group. POPQ stage 0–1 was present in 11/47 (23.4%); stage 2 in 36/47 (76.6%) patients in ICTPT group. Patients with a prolapse stage 0–2 were included in the study, and the prolapse was corrected (natural tissue repair) in symptomatic patients only.

Demographic data collected in the study are shown in Table 1.

Patients with residual urine (>100 ml), pelvic organ prolapse more than stage 2, fixed urethra, radical surgery in the pelvis, or significant comorbidities were excluded from the study.

All surgeries were performed with spinal or laryngeal mask airway (LMA) anesthesia. Local infiltration was performed with saline for the preparation of tissues only. The standard prophylactic single dose of the second generation cephalosporin (cefuroxime 1.5 g) was administered prior to surgery.

A cure was defined as a negative stress test without the need for additional surgery during the follow-up.

ICTOT was placed according to the standard technique [12].

Surgical technique for the self-created sling

Sterile urine was confirmed before the surgery. Local estrogen therapy (Estriol 1% vaginal cream) was applied two times a week, several weeks before the surgery. The sling (15 cm × 1 cm) was created from the rectangular 15 cm × 10 cm macroporous polypropylene monofilament mesh weighing 48 g/m² (Pelvimesh®, Herniamesh, Torino, Italy). Monofilament sutures (PDS 2-0) were passed through both ends of the polypropylene mesh stripe to

make a “composite” sling consisting of monofilament suture–sling–monofilament suture (Fig. 1) (video). The middle of the polypropylene part of the sling was grasped with the forceps. It is important to hold the middle of the sling and to place the forceps just below the urethra, so that the sling is long enough to reach the obturator fascia and the skin surface bilaterally. Helicoid needles were passed through the upper middle part of the obturator foramen in the outside—in manner. Both ends of the monofilament sutures were passed through holes at the end of the needle in the vagina. Sutures were pulled outside and the middle of the sling was tension-free and placed below the urethra. The vagina was sutured, and the vaginal pack was left in situ for 24 h. Patients were discharged from the hospital after catheter removal and the confirmed volume of residual urine was less than 100 ml.

Results

Results of the treatment are shown in Fig. 2. Fifty six out of 67 (83.5%) patients and forty out of 47 (87.2%) in the SCTOT and ICTOT group were cured, respectively. There was no difference between groups ($p > 0.05$). There was no significant difference regarding cure rate between patients with SUI and MUI in both groups ($p > 0.05$) although cure rate remained lower in both groups for the patients with MUI. There was a significant decrease in the number of patients with OABSS > 8 after the surgery in both groups, however, this became significant later in the group of patients treated with ICTOT ($p < 0.05$). Symptom scores IIC-7, UDI-6, ICQ-SF-of, and OABSS are shown in Tables 2 and 3. Statistically significant improvement occurred after the surgery in both groups. There was a high variability of symptoms among the patients with MUI before the surgery (Tables 2 and 3).



Fig. 1. Self-created transobturator tape with the two PDS sutures.

Table 1

Demographic data in the investigated groups.

| | SCTOT | ICTOT |
|------------------------------|--------------|--------------|
| Total number of patients | 67 (100%) | 47 (100%) |
| Age (mean, range) | 67.3 (38–79) | 63.4 (41–82) |
| Post menopausal | 49 (73.1%) | 37 (78.7%) |
| Parity | 2.1 ± 0.6 | 1.9 ± 1.2 |
| Sexually active | 25 (37.3%) | 16 (34.1%) |
| Previous gynecologic surgery | 18 (26.8%) | 10 (21.2%) |

SCTOT—self created transobturator tape. ICTOT—industrially created transobturator tape.

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