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# THE LONG-TERM EFFECTIVENESS AND LATE SEQUELAE OF THE TENSION-FREE VAGINAL TAPE PROCEDURE FOR FEMALE URINARY INCONTINENCE

Hypothesis / aims of study

To evaluate the outcome of tension-free vaginal tape (TVT) during the 10.5 years of follow-up.

Study design, materials and methods

This is a follow-up study concerning 191 patients operated on using TVT between January 1998 and May 2000. The procedure was performed by two surgeons, though vast majority (90%) was performed by one surgeon. Altogether 127 women (66%) had stress urinary incontinence (SUI) whereas 64 (34%) had mixed incontinence. Thirty nine (20%) patients had recurrent incontinence. Thirty four (18%) patients with concomitant surgery were also included in the study. The diagnosis of incontinence was based on the Urinary Incontinence Severity Score (UISS), the Detrusor Instability Score (DIS) and physical examination including a supine stress test. Urogynecological ultrasonography was performed on patients with a history of mixed incontinence. The TVT procedure was performed as previously described under local (82%) or spinal (18%) anesthesia (1). After a mean of 10.5 years follow-up the assessment included gynecologic examination and a supine stress test with comfortably filled bladder. Subjective outcome was evaluated with UISS, DIS, a visual analog scale (VAS 0-100), EuroQoL-5D (EQ-5D), EQ-5D VAS and short versions of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) (2, 3). Negative stress test defined objective cure.

Results

So far 124 (65%) of 191 patients have been evaluated at a mean of 10.5 years postoperatively. A total of 108 patients (57%) answered the questionnaires and visited the outpatient clinic. The remaining 16 (8%) patients who were not willing or able to attend the follow-up visit just returned the questionnaires. Eighteen (9%) patients were deceased during the follow-up.
The mean follow-up time was 126.5 months (108-145). The mean age at the follow-up was 69 years (48-93) and mean BMI 27 (19-38). Sixty-eight (63%) patients had chronic illnesses requiring medication. Fifty seven patients (53%) used estrogen therapy either vaginal, systemic or combined. During the 10.5 years follow-up 18 patients had undergone gynecological operations such as hysterectomy (5), prolapse repair (4), trans-obturator tape procedure (TOT) (6) and one transurethral injection therapy for recurrent SUI. The TVT tape was cut under the urethra in two patients; one due to urinary retention a year after the operation and another due to pain 8 years afterwards. Resection of the tape from the bladder on cystoscopy was performed twice in one patient nine years postoperatively.
The stress test was negative in 99 (92%) of 108 patients at the objective evaluation but six (5.6%) patients had undergone another operation for SUI during the follow-up. Stress test was positive in six (5.8%) patients.
Three of the six patients with positive stress test performed also a 24 h pad test. One patient had a leakage of 21 g per 24 h and the other two less than five grams. No late tape rejections occurred. The results of the questionnaires are shown in table 1.

Table 1. The results of questionnaires after a mean of 10.5 years postoperatively.

| | mean ± SD | range |
|---|---|---|
| IIQ-7 (7-28) | 9.8 ± 4.6 | 7-28 |
| UDI-6 (6-24) | 10.6 ± 3.9 | 6-23 |
| EQ-5D VAS (0-100) | 70 ± 21 | 10-100 |
| EQ-5D (6-18) | 8.5 ± 1.9 | 6-16 |
| VAS (0-100) | 28 ± 30 | 0-100 |
| UISS (0-100) | 19.6 ± 21.9 | 0-90 |
| DIS (0-20) | 6.4 ± 3.9 | 0-16 |

Interpretation of results

These are preliminary results of the ongoing follow-up study of 191 patients operated on for SUI using TVT a mean of 10.5 years ago. Although among the study population there were great number of patients with mixed incontinence and recurrent SUI and even patients with concomitant surgery were included, the objective and subjective cure remained high 10.5 years after the TVT procedure in 124 patients. Tape related problems were rare.

Concluding message

The TVT procedure is effective and safe during the follow-up a mean of 10.5 years.

References


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| ***Specify source of funding or grant*** | **None** |
| ***Is this a clinical trial?*** | **Yes** |
| ***Is this study registered in a public clinical trials registry?*** | **No** |
| ***Is this a Randomised Controlled Trial (RCT)?*** | **No** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **Yes** |
| ***Specify Name of Ethics Committee*** | **Ethics Committee of the Hospital District of Southwest Finland.** |
| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |