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ORIGINAL ARTICLE: EDITORS' CHOICE

# Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence

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**Abstract**
*Introduction and hypothesis* The minimally invasive tension-free vaginal tape (TVT) operation has become the "gold standard" of incontinence surgery. The aim of the present study was to evaluate the long-term effect of the tape material and to assess the continence status 17 years after surgery
*Methods* A cohort of 90 women operated upon with the TVT procedure at three Nordic centers has been prospectively followed for 17 years. All of the women alive according to national registries were contacted and invited to visit the clinics for evaluation. Pelvic examination was performed to reveal any adverse effects of the tape material. Objective and subjective continence status were assessed by a cough stress test and the patients' global impression of improvement as well as by condition-specific quality of life questionnaires.
*Results* Seventy-eight percent of the potentially assessable women were evaluated either by a clinic visit or by a telephone interview. One case of a minimal, symptom-free tape extrusion was seen. No other tape complications occurred. Over 90 % of the women were objectively continent. Eighty-seven per cent were subjectively cured or significantly improved.
*Conclusion* The TVT operation is durable for 17 years, with a high satisfaction rate and no serious long-term tape-induced adverse effects

**Keywords** Tension-free vaginal tape · Stress urinary incontinence · Long term follow-up

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## Introduction

The new minimally invasive surgical procedure for the treatment of female stress urinary incontinence, the tension-free vaginal tape (TVT), was introduced to clinicians all over the world in the late 1990s. At that time reports of up to 3 years' follow-up had been published [1–3]. The reports showed high efficacy and safety. The tape material used in the TVT operation was from the beginning a type 1 mesh, characterized by a monofilament, polypropylene, large pore size structure [4]. The success of the TVT procedure resulted in the development of numerous copies and modifications. Some modifications utilized meshes other than type 1, which in a number of cases resulted in problems with erosion, fistulation, and rejection reactions [5–7]. During recent years different kinds of meshes have been used in vaginal surgery in order to improve the results of the correction of urogenital prolapse [8]. An increasing number of studies report high complication rates caused by the vaginally implanted meshes, including type 1 meshes [9]. This has resulted in a warning by the USA-based Food and Drug Association (FDA) in July 2011 stating that complications caused by vaginal surgery with meshes are not uncommon, that risk factors have not been identified, and that results are not better than those obtained using traditional methods [10]. Although mesh material has been utilized in surgery for decades, with good results and tolerability, for example, in hernia surgery, the performance of meshes used in vaginal surgery, where meshes are implanted under mucosal tissue, seems to be very different. In the TVT procedure a type 1 mesh is implanted under the vaginal mucosa at the mid-urethra. One of the first cohorts of women receiving a TVT operation because of primary stress urinary incontinence has been followed prospectively since 1995. Reports at 5, 7, and 11 years' follow-up revealed high efficacy with no adverse effects of the tape material [11–13]. As the polypropylene tape material stays largely

unchanged throughout the years, a concern regarding how the tape performs in aging, atrophying, and even retracting tissue has risen. Therefore, we wanted to clinically examine our initial 1995 cohort 17 years after implantation of the tension-free vaginal tape, in order to detect complications caused by the tape and also to assess the continence status of these already elderly and even frail women.

## Materials and methods

The study population consisted initially of 90 consecutive women diagnosed with primary stress urinary incontinence. This prospective observational trial was conducted in three Nordic centers: Helsinki University Central Hospital in Helsinki, Finland, Danderyd Hospital in Stockholm, Sweden, and Uppsala University Hospital in Uppsala, Sweden. The women were recruited and operated upon using the TVT procedure between 1 January 1995 and 15 August 1996. The trial was approved by the ethics committees of the three participating centers separately, and all women consented to participating in the trial.

Only women with no prior incontinence surgery and with a positive stress test and urodynamically proven stress incontinence, with no detrusor over-activity and a urethral maximal closure pressure >20 cm $H_2O$ were included.

The TVT operation was performed in a standard manner under local anesthesia using between 70 and 100 cc of 0.25 % prilocaine with epinephrine as described in detail earlier [1, 12, 13]. An intra-operative cough test was utilized to avoid excess tensioning of the tape. The patients were asked to cough strongly at a bladder volume of 300 ml. A few drops of saline were allowed to escape the external urethral meatus. Cystoscopy was performed twice after each retropubic pass of the trocar to detect bladder injuries. The TVT set was identical to the presently commercially available one (TVT, Gynecare, Johnson & Johnson, Somerville, NJ, USA) with the exception that the trocar was 6 mm in diameter instead of the present 5 mm.

Evaluation 17 years after surgery focused on possible adverse reactions caused by the tape material and on the subjective and objective continence status.

The women were invited to visit the clinics for a thorough pelvic examination, concentrating on the tape situation by careful inspection and palpation, observing signs of erosion, extrusion, fistulation, other tissue reactions and prolapse (estimated by the Baden–Walker scale) [14]. The examinations and interviews were performed by independent doctors or nurses not involved in the early phases of the study. Post-void residual (PVR) urine volume measurements were performed using ultrasound.

Since most of the women did not consent to undergoing invasive urodynamics and/or cystoscopy, objective cure was assessed by performing a stress test in the same manner as pre-operatively and during the 5, 7, and 11 years follow-up visits [11–13]. Subjective success was assessed by the Patients Global Impression of improvement (PGII) and the following condition-specific Quality of Life (QoL) questionnaires: the Incontinence Impact Questionnaire-short form (IIQ-7) [15], the Urogenital Distress Inventory-short form (UDI-6) [15], the Urinary Incontinence Severity Score (UISS) [16]. The PGII included questions on if the women felt they were cured or if their incontinence had significantly improved or if they felt the incontinence was unchanged or worse. A visual analog scale (VAS) from 0 to 100, where 0 represented no urinary problems and 100 unbearable urinary symptoms, both pre-operatively and at the 17-year follow-up visit was also used. The women were asked if they experienced leakage on straining and if they would recommend the operation to a friend.

The Statistical Package for Social Sciences (IBM, SPSS Statistics19.0) was used for statistical analysis. A $p$ value< 0.05 was considered to indicate statistical significance.

## Results

Figure 1 shows the flow chart of the study. From the initial cohort of 90 women, 79 were still alive according to national registries. Of these 79 women 5 had such an impairment of their mental capacity that they were not able to cooperate. Sixteen women could not be reached. Thus, 58 women could be invited to visit the clinics for complete evaluation. Twelve of these 58 women chose to be interviewed by telephone and not to visit the clinic because of frailty or because they lived a long distance away.

Of the women who potentially could have been assessed, 58 out of 74 (78.4 %) were evaluated in some way.

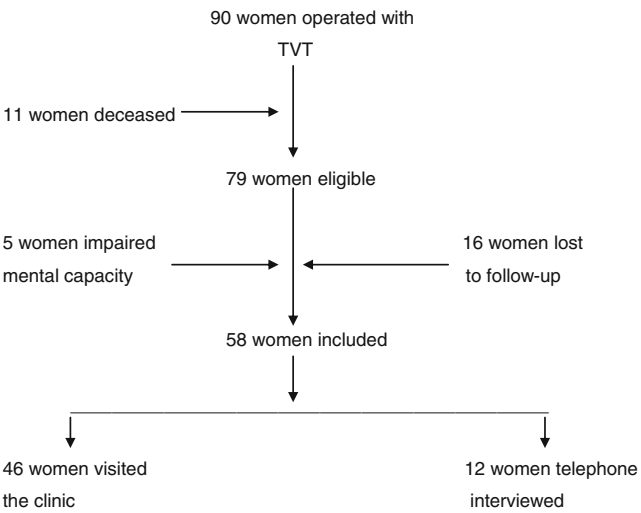


**Fig. 1** Flow chart of the study

Forty-six women were evaluated according to the protocol at the clinics. One of these 46 women had had a repeat mid-urethra tape operation 15 years after her primary operation because of recurrent stress incontinence and although she had a negative stress test she still suffered from leakage with signs of urgency according to the UDI-6 questionnaire. However, she did report improvement in her continence status, but has been regarded as a failure in the present analysis.

The mean follow-up was 201 months (16 years and 9 months) with a range between 185 and 213 months. The mean age of the women at the time of the 17-year follow-up visit was 69±9 years (range 51–89)

On examination only 1 woman, aged 69 years, had a small symptom-free exposure of the tape on the right side para-urethrally. The woman had not attended the 11-year follow-up visit and at her 7-year visit no tape exposure was seen. Her vaginal mucosa was atrophic and she was prescribed local estrogen therapy. She was continent and highly satisfied with the operation. No other adverse effects, signs or reactions of the tape material could be detected among the women examined.

Objective cure, defined as a negative stress test, was seen in 42 out of 46 women (91.3 %). Two of the women with a positive stress test were regarded as failures, while one woman considered herself significantly improved, even though she had minimal leakage at her stress test. Figure 2 includes the percentage of women with a negative stress test available for clinical investigation at their 5-, 7-, 11-, and 17-year follow-up visits respectively. The data from the stress tests at earlier follow-ups are derived from the respective publications [11–13]. Only one woman out of those who had been assessed on the different occasions during the 17-year follow-up had undergone a repeat incontinence operation, which was a TVT obturator procedure, 15 years after the primary operation.

The results of the condition-specific quality of life questionnaires are seen in Table 1. A clear answer on all questions could not be obtained from some of the women contacted by telephone; hence the number of reported answers varies between the different questionnaires. The PGII

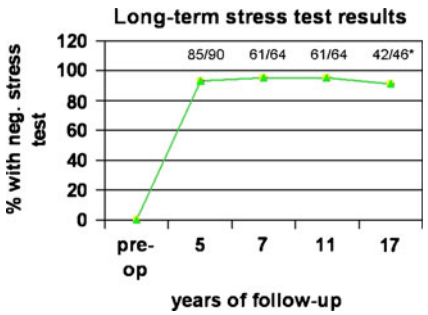


**Fig. 2** Cough stress test results during 17 years of follow-up after a trans-vaginal tape (TVT) operation. *number of performed stress tests per available women

**Table 1** Results of condition-specific quality of life questionnaires at 17 years' follow-up

| Questionnaire | *n* | Scores (median and range) |
|---|---|---|
| DIS (0–20) | 56 | 4.0 (0–14) |
| UISS (0–100) | 56 | 5.0 (0–75) |
| UDI-6 (0–18) | 55 | 3.0 (0–15) |
| IIQ-7 (0–21) | 55 | 0.0 (0–16) |
| VAS (0–100) | 55 | |
| Preoperative | | 75.0 (35–100) |
| Postoperative | | 9.0 (0–100) |

*DIS* Detrusor Instability Score, *UISS* Urinary Incontinence Severity Score, *UDI-6* Urogenital Distress Inventory-short form, *IIQ-7* Incontinence Impact Questionnaire-short form, *VAS* visual analog scale

revealed that 48 out of the 55 women (87.2 %) regarded themselves cured or significantly better than before surgery, 5 out of 55 (9.1 %) experiencing no change and 2 out of 55 (3.6 %) worse than before surgery. To the question, do you experience leakage during straining, 42 out of 53 (79.2 %) answered no and 50 out of 51 (98 %) would recommend the TVT procedure to a friend. Table 2 shows the women's subjective perception of their continence status compared with preoperative conditions. The criteria used for subjective evaluation were similar at the 7- [12], 11- [13], and 17-year follow-up visits, but slightly different at the 5-year visit [11]. Table 3 shows the clinical data of the 7 women whose incontinence was either worse or unchanged. Of these women all reported moderate or severe urgency incontinence in their UDI-6 questionnaire. Three were contacted by telephone with no stress test available; 2 women had a positive stress test.

The median PVR was 16 ml (range 0–550). One woman suffering from Parkinson's disease had on one measurement occasion a PVR of 550 ml; however, she did not complain of retention problems. One woman with a grade three cystocele who complained of voiding difficulties had a PVR of 317 ml. She was managed by fitting a prolapse ring. Three women had a grade three genital prolapse observed at the 17-year follow-up visit, 2 with a rectocele and 1 with the above-mentioned cystocele. Three women had undergone prolapse surgery between the 11- and 17-year follow-up visits, 1 anterior colporrhaphy, 1 posterior colporrhaphy, and 1 vaginal hysterectomy.

**Table 2** Patients' global impression of improvement at 5, 7, 11, and 17 years of follow-up

| | 5 years | 7 years | 11 years | 17 years |
|---|---|---|---|---|
| Percentage cured or improved | 95.3 | 97.6 | 97.0 | 87.2 |
| Number available for evaluation | 85/90 | 78/80 | 67/69 | 48/55 |

**Table 3** Clinical data of women with worsening of or no change in their incontinence status compared with the pre-operative condition

| Patient number | Age (years) | Stress test | UDI-6 |
|---|---|---|---|
| 1 | 84 | Negative | Severe urgency incontinence, symptoms initiated by posterior colporrhaphy operation in 2008 |
| 2 | 79 | NA | Severe urgency incontinence, spinal stenosis |
| 3 | 68 | Positive | Severe urgency incontinence, obesity, BMI 47 |
| 4 | 70 | NA | Moderate urgency incontinence, anticholinergic medication |
| 5 | 73 | Negative | Severe urgency incontinence, obesity, BMI >40 |
| 6 | 56 | Positive | Severe urgency incontinence, anticholinergic medication |
| 7 | 69 | NA | Moderate urgency incontinence, DM, obesity |

*NA* not available because of telephone contact, *BMI* body mass index, *DM* diabetes mellitus

## Discussion

The present 17-year follow-up report is so far the longest follow-up of the performance of the tension-free vaginal tape surgical procedure for treatment of female stress urinary incontinence. The greatest challenge of such a long-term follow-up is to retrieve a representative number of the women of the initial cohort for a clinical evaluation. Seventy-four of the initial cohort of 90 women (82 %) were potentially available for follow-up. Of these women 78 % could be contacted and participated in the 17-year evaluation, either through a telephone interview or by a visit to the clinic. The actual percentage of those lost to follow-up was thus 22 %, which we feel is fairly low for a period of almost two decades. Although we naturally cannot know the health or continence status of the 16 women lost to follow-up we believe that the satisfaction figures we have obtained from the women evaluated is rather representative of the performance of the TVT procedure.

The objective cure rate, assessed by the stress test, was 91 % and showed no decline between 5 and 17 years' follow-up. The corresponding subjective perception of either cure or improvement was over 87 %, with a slight decline during the last 6 years, probably mostly due to urgency incontinence and not to late recurrence of stress incontinence, as indicated by the data shown in Table 3. Published long-term results of the TVT procedure, in cohorts other than the one reported here, include a few reports on 7 to 11 years of follow-up. Three of them include more than 100 women each visiting the clinics an average of between 7.5 and 11.5 years after the operation and showing similar high objective cure rates, ranging from 84 to 90 % [17–19], as the present report. One 10-year telephone interview follow-up study of 52 women reported a 65 % subjective overall cure rate, with 79 % regarding themselves cured of stress incontinence [20]

A weakness of the present study is the fact that urodynamics were not performed as the women did not consent to such an invasive examination. It is therefore difficult to know if the decline in subjective satisfaction during the last 6 years of follow-up is due to urgency symptoms, as suggested by the data on the 7 women not satisfied with their continence status or if they had mixed incontinence, with a component of recurrent stress incontinence, which certainly is the case in two of the women.

An important observation is that there seems to be no shrinkage of the TVT mesh over time, as suggested by PVR volumes within normal ranges, except for 2 patients with concomitant diseases (Parkinson's, grade III cystocele).

The TVT operation was introduced as a highly standardized procedure in order to be able to train doctors to perform the operation in a manner proven to give good objective and subjective results [1, 2]. When first introduced to clinicians in the Nordic countries, structured training was provided before the surgeon was encouraged to adopt the new technique in clinical practice. The standardized procedure included elements to keep the procedure minimally invasive. Such elements were performing the operation under local anesthesia, which allowed performance of an intra-operative cough test, utilized to avoid tightening of the tape to the extent of causing voiding difficulties or even imposing a risk of tape erosion into the urethra.

The mesh complications seen in association with urogenital prolapse surgery that have alerted the FDA might not be caused by the mesh material itself. As long as a type I material is used the complications could be the result of improper training of the surgeon, resulting in an inappropriate surgical technique or choosing the wrong indication or wrong patient for the graft procedure.

The present report suggests that using a type I, macroporous, monofilament, lightweight, and soft polypropylene mesh, the risk of mesh complications even 17 years after implantation under the vaginal mucosa is negligible provided the surgery is performed by a trained and experienced surgeon. Age-induced atrophy of the vaginal mucosa exerts a risk of tape material extrusion into the vagina over time and can be treated or even avoided by local estrogen therapy [21]. The single tape complication seen during the present prospective observational trial during a 17-year period was in a completely asymptomatic, continent and highly satisfied 69-year-old woman with an atrophic vaginal mucosa, who missed her 11-year follow-up visit, but had no tape exposure 7 years post-operatively.

The present report suggests that the TVT operation for the treatment of female stress urinary incontinence is a

durable procedure, with an efficacy lasting even beyond 17 years. When the operation is performed adhering to the originally developed technique the risk of complications, and especially tape material-related problems, seems to be small. It is to be noted that the amount of implanted mesh with the TVT operation is small compared with the amount mostly used during urogenital prolapse surgery. This fact might make a difference to tissue performance and therefore we feel that mesh use for the treatment of urinary incontinence in the manner of a TVT operation is not associated with the problems seen in prolapse surgery. This observation could serve as a reason for a shift in the use of mesh for prolapse surgery from larger, covering meshes to smaller, tape-like suspending ones [22]. On the other hand it might, however, be possible for larger meshes in prolapse surgery to perform as well as that in the TVT operation provided the surgical technique and the mesh material used are optimized and that the procedures are utilized with the right indications.

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**Conflicts of interest** CGN and CF have acted as consultants for Astellas, Ethicon, and Pfizer.

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