

Eleven years prospective follow-up of the tension-free vaginal tape procedure for treatment of stress urinary incontinence

C. G. Nilsson · K. Palva · M. Rezapour · C. Falconer

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Abstract The aim of this study was to evaluate the long-term effectiveness and safety of the tension-free vaginal tape (TVT) procedure. In a Nordic three-center prospective observational cohort study, 90 women with primary stress incontinence had a TVT operation performed in local anesthesia. Assessment included a 24-h pad test, a stress test, physical examination, and a visual analog scale for assessing the degree of bother. Patient's global impression of cure was obtained, and condition specific quality of life questionnaires were used. Seventy-seven percent of the initial cohort of 90 women and 89% of those alive and capable of cooperating were assessed 11.5 years after the TVT operation. Ninety percent of the women had both a negative stress test and a negative pad test being objectively cured. Subjective cure by patients global impression was found in 77 %, 20% being improved and only 3 % regarded the operation as a failure. No late-onset adverse effects of the operation were found, and no case of tape erosion was seen. The TVT procedure is safe and effective for more than 10 years.

Keywords Long-term · Stress incontinence · TVT procedure

C. G. Nilsson (✉) · K. Palva
Department of Obstetrics and Gynecology,
Helsinki University Central Hospital,
Haartmaninkatu 2,
Helsinki, POB 140, 00029 HUS, Finland
e-mail: carl.nilsson@hus.fi

M. Rezapour
Uppsala University Hospital,
Uppsala, Sweden

C. Falconer
Danderyd Hospital, Karolinska Institutet,
Stockholm, Sweden

Introduction

Prevalence of female stress and urge urinary incontinence increases with age [1]. With an increasing life expectancy of women in the developed world the number of women suffering from stress urinary incontinence is growing rapidly. Demographic data in reports on surgical treatment of female stress urinary incontinence mostly show that the average age at which the incontinence operations are performed is around 50 years. The first surgical intervention because of urinary incontinence is thought to be the most successful one [2]. It therefore becomes ever more important to acquire knowledge of the durability and long-term results of primary performed incontinence procedures. Long-term prospective reports on the effectiveness of incontinence surgery are scarcely available. Longer than 10 years of follow-up of the traditional incontinence operations, as fascial slings and colposuspension, have mostly been retrospective with the limitations it imposes on the interpretation of the results [3, 4]. The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence is the first modern minimally invasive mid-urethra sling operation and the only one thus far with reports on cure rates with follow-up periods of 5 years or more [5, 6].

The TVT procedure was developed during the early 1990s and introduced as a minimally invasive operation in 1996 [7]. Many reports since then have shown that the TVT procedure is effective in many different groups of patients, with cure rates between 80% and 90% during follow-up periods of more than 3 years [8–11]. No consensus exists on the definition of long-term follow-up according to what can be found in the literature on incontinence surgery, but 5 years or more is mostly regarded as long-term. The 5 years follow-up data on a prospectively investigated first

Table 1 Age distribution, in percent, of the total cohort and those evaluated at 11 years postoperatively

	Total initial cohort (%), <i>n</i> =90	Evaluated cohort (%), <i>n</i> =69
<50	45.2	5.8
51–60	28.6	31.9
61–70	19.0	39.1
71–80	4.8	18.8
81–90	2.4	4.3

cohort of 90 women receiving the TVT procedure was published in 2001 [5], and the 7 years results of the same cohort were published in 2004 [6].

As 12 years have elapsed since the first TVT operations were performed on this initial cohort, an effort was made to evaluate as many of these patients as possible. We report in this paper the 11 years durability of the effectiveness of the TVT procedure.

Materials and methods

The study population consisted of 90 consecutive women suffering from urinary stress incontinence. Three Nordic centers, one in Finland (the Helsinki University Central Hospital) and two in Sweden (the Danderyd Hospital in Stockholm and the Uppsala University Hospital), participated in this prospective observational trial. The TVT procedures were performed between January 1st 1995 and August 15th 1996. The study was approved by the ethics committee of all three centers, and all women consented on participating in the study.

Inclusion criteria were a history of stress incontinence, a positive cough stress test performed in a semilithotomy position with a comfortably filled bladder (200–300 ml), and a urodynamically proven stress incontinence. Women with prior incontinence surgery or a need for concomitant surgery were excluded. Women showing detrusor activity during the urodynamic examination and women with a maximal urethral closure pressure less than 20 cm H₂O were also excluded.

The TVT operations were carried out as described in detail previously [7]. All operations were performed in local infiltration anesthesia using 0.25 % prilocaine with adrenaline (epinephrine).

The TVT set used was identical with the presently commercially available one with the exception that the TVT needle was 6 mm in diameter instead of the present 5-mm needle.

Cystoscopy was performed twice during the operation and after each retropubic pass of the TVT needle to detect bladder injury. Adjustment of the tape was performed by using the cough test.

A few drops of saline were allowed to escape at the external meatus of the urethra on vigorous coughing.

Evaluation 11 years after the TVT operation included a cough stress test performed in the same manner as preoperatively, a 24-h pad weighing test, residual urine volume measurements, and a gynecological examination where careful attention was paid to detect tape erosion or adverse tissue effects caused by the polypropylene material.

Subjective outcome of the TVT surgery was assessed by the following condition-specific validated questionnaires: the Incontinence Impact Questionnaire—short form (IIQ-7) [12], the Urogenital Distress Inventory (UDI-6) [12], the Urinary Incontinence Severity Score (UISS) (13), and the Detrusor Instability Score (DIS) [13]. A visual analog scale (VAS) [14], where 0 represents no urinary problems and 100 unbearable urinary complaints, was used both preoperatively and at 11 years follow-up. The Patients Global Impression (PGI) of the patients' continence status was assessed by asking the women if they felt that they were cured or improved of their incontinence or if they felt that the treatment had failed. The women were also asked directly if they experienced leakage on straining. Objective cure was defined as a negative stress test and a negative 24-h pad test (less than 8 g per 24 h), while subjective cure was defined by the patients global impression of her continence status.

The Statistical Package for Social Sciences (SPSS for Windows 15.0) was used for statistical analysis. For analysis of continuous variables, the paired-samples *t* test was used. The chi-square test was applied for the categorical variables. A *p* value <0.05 was considered to indicate statistical significance.

Table 2 New medical conditions, surgical procedures or medications, which might affect urinary continence since last follow-up at 7 years and the continence condition of these women

Continence status	Medical condition	Surgery	Medication
Cured, <i>n</i> =53	4/53 (7.5%)	3/53 (5.7%)	0/53 (0.0%)
Improved, <i>n</i> =14	3/14 (21.4%)	3/14 (21.4%)	4/14 (28.6%)
Failed, <i>n</i> =2	1/2 (50.0%)	1/2 (50.0%)	1/2 (50.0%)

Table 3 Nature of new medical conditions, surgery, and medication

	Cured	Improved	Failed
Surgery	Cystocele repair Rectocele repair Colorectal resection	Cystocele repair Rectocele repair Hysterectomy with cysto- and rectocele repair	Spinal disc-prolapse
Medical condition	Asthma Spinal stenosis Colon carcinoma Back problems	Multiple sclerosis Diabetes mellitus Diverticulosis	Spinal disc-prolapse
Medication		Anticholinergics Anticholinergics Anticholinergics Anticholinergics	Furosemide

Results

Of the original 90 women, 69 (77 %) could be evaluated either by the protocol when they visited the clinic or outside the clinics by interview, mail, and/or home visits. Six women had died from reasons not related to the TVT procedure; seven women were disabled to such a degree that they could not be interviewed. Eight women were lost to follow-up. Fifty-three women were seen at the clinics and 16 contacted outside the clinics.

The median time of follow-up was 141 months (range, 127–160), which is an average of 11 1/2 years. The age distribution of the total cohort and that of those evaluated 11 years after the operation is seen in Table 1. Tables 2 and 3 shows the number and nature of acquired medical conditions, surgeries performed, and initiated medications since last follow-up visit and the continence status of these women.

The cough stress test was negative in 95.3 % (61/64) of the women, and 90.2 % had a negative pad test (55/61). Of these women, 90.2 % had both a negative stress test and a negative pad test and thus regarded objectively cured.

By PGI, 77 % (53/69) regarded themselves as cured, 20% (14/69) as improved, and 3% (2/69) thought the treatment had failed. Asked if experiencing leakage on straining 93%

(64/69) claimed they were dry; 97% were prepared to recommend the TVT operation to a friend.

The results of the condition specific quality of life questionnaires are shown in Table 4.

The VAS score was highly significantly improved compared to preoperative values ($p < 0.001$).

No patient needed catheterization, and 93.1% had a post-void residual urine volume less than 100 ml. No case of tape erosion or adverse tissue reaction caused by the polypropylene tape was detected on careful vaginal examination.

Discussion

The average time of follow-up of the women of the present prospective observational trial was 11 1/2 years, the longest period of follow-up thus far reported for the modern mid-urethra sling operations. Every patient of the initial cohort of 90 could understandably not be assessed according to the initial protocol. Six had died of reasons unrelated to the TVT procedure, mostly because of illnesses related to high age (the oldest woman would have been 98 years of age). Seven patients were severely disabled and incapable of participating in any respect, and another 16 were living in nursing homes at which they were contacted and evaluated as extensively as possible, but without reaching full assessment according to the protocol. Only eight patients (8.9%) were completely lost to follow-up.

We, however, succeeded in getting at least a subjective evaluation of the continence condition of 77% of the original total group of women and of 89% (dead and severely disabled excluded) of women potentially available to follow-up. Of these, 93% claimed they were dry during straining, and 77% regarded themselves as cured of their incontinence.

Of those women who performed both the stress test and the 24-h pad test, 90% were objectively cured, defined as

Table 4 Results of condition specific QoL questionnaires at eleven years of follow-up

Questionnaire	Scores (median and range)
DIS (0–20)	2.0 (0–14)
UISS (0–100)	5.0 (0–80)
UDI-6 (0–18)	3.0 (0–12)
IIQ-7 (0–21)	0.0 (0–16)
VAS (0–100)	
Preoperative	75 (35–100)
Postoperative	6.0 (0–90)*

* $p < 0.0001$

having both a negative stress test and a negative pad test. Both the subjective and objective cure rates are high and at the same level as have been reported extensively with the TVT procedure in larger patient materials but with shorter periods of follow-up [15–18]. It has, however, to be pointed out that one of the exclusion criteria for initially participating in the present trial was a low pressure urethra (maximal urethral closure pressure <20 cm H₂O), and thus, some of potentially poorly performing patients were ruled out. This fact might contribute to the high success rate. On the other hand, the cohort suffered preoperatively of moderate or severe stress incontinence as measured by the 24-h pad test and by the VAS score [5].

The results are reassuring and show that there is no decline in efficacy of the TVT procedure over time, even when we are dealing with an aging population, as 62% of the women of this trial were more than 60 years old at the time of their 11 years follow-up visit.

The women's subjective apprehension of the success of their surgical treatment is naturally based on their general experience of urinary symptoms, some being caused by a true failure of the operation to cure incontinence, but some by later acquired conditions not necessarily related to the initial treatment. The data shown in Tables 2 and 3 suggest that new illnesses increase the risk of having urinary symptoms, which affects patients' global impression of treatment success. The tables also show that five patients have had prolapse surgery, which accounts for 7% of the study population, a figure not greater than the risk of having prolapse surgery in a general population [19]. The above-mentioned circumstances might explain the difference between subjective and objective cure rates of the present report, as 77% thought that their incontinence was cured 11 years after the initial operation, while 20% regarded themselves as improved and only 3% thought that the initial treatment had failed.

Synthetic mesh material might cause tissue reactions and erosion into nearby structures like the urethra, the bladder, or the vagina. As the non-absorbable polypropylene material of the TVT tape is thought to stay intact over time, but there certainly are changes in the aging tissues in which the tape is implanted, there has been a fear of seeing late-onset erosion problems.

It is therefore also reassuring that we did not find a single case of tape erosion, tissue reactions, or other adverse effects of the tape during at the most up to 13 years of follow-up.

The results of the condition-specific quality of life (QoL) questionnaires filled in by the women indicate that urinary problems do not affect their quality of life very much. On the contrary, one gets the impression that the women are rather content and that this at least partly might be due to the beneficial and long-lasting effect of the TVT operation.

We feel that the results of our long-term prospective follow-up of the effectiveness of the TVT operation are reassuring and that no distinct decline in cure rates occurs over a time period of 11 years. It is also encouraging to see that no late adverse effects of the polypropylene tape material was found and that erosion of the tape into adjacent tissues did not occur.

Results of the present kind should be able to achieve at any clinic where surgeons are offered systematic training and proper patient selection is undertaken.

Conflicts of interest None.

References

- Sandvik H, Hunskaar S, Seim A, Hermstad R (1993) Validation of a severity index in female urinary incontinence and its implementation in an epidemiologic survey. *J Epidemiol Community Health* 47(6):497–499
- Jarvis GJ (1994) Surgery for genuine stress incontinence. *Br J Obstet Gynaecol* 101:371–374
- Feyereisl J, Dreher E, Henggi W, Zikmund J, Schneider H (1994) Long-term results after Burch colposuspension. *Am J Obstet Gynecol* 171:647–652
- Alcalay M, Monga A, Stanton SL (1995) Burch colposuspension: a 10–20 year follow up. *Br J Obstet Gynecol* 102:740–745
- Nilsson CG, Kuuva N, Falconer C, Rezapour M, Ulmsten U (2001) Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. *Int Urogynecol J* 12(Suppl 2):5–8
- Nilsson CG, Falconer C, Rezapour M (2004) Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. *Obstet Gynecol* 104:1259–1262
- Ulmsten U, Henriksson L, Johnson P, Varhos G (1996) An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 7:81–85
- Rezapour M, Ulmsten U (2001) Tension-free vaginal tape (TVT) in women with recurrent stress urinary incontinence—a long-term follow up. *Int Urogynecol J* 12(Suppl2):9–11
- Rezapour M, Falconer C, Ulmsten U (2001) Tension-free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)—a long-term follow up. *Int Urogynecol J* 12 (Suppl2):12–14
- Ulmsten U, Johnson P, Rezapour M (1999) A three-year follow up of tension-free vaginal tape for surgical treatment of female stress urinary incontinence. *Br J Obstet Gynecol* 106:345–350
- Olsson I, Kroon U (1999) A three-year postoperative evaluation of tension-free vaginal tape. *Gynecol Obstet Invest* 48:267–269
- Ubersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA (1995) Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and urogenital distress inventory. *Continence program for women research group. NeuroUrol Urodyn* 14:131–139
- Kauppila A, Alavaikko P, Kujansuu E (1982) Detrusor instability score in the evaluation of stress urinary incontinence. *Acta Obstet Gynecol Scand* 61:137–141
- Stach-Lempinen B, Kujansuu E, Laippala P, Metsänoja R (2001) Visual analog scale, urinary incontinence severity score and 15D- psychometric testing of three different health-related quality-of-life instruments for urinary incontinent women. *Scand J Urol Nephrol* 35:476–483

15. Nilsson CG, Kuuva N (2001) The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence. *BJOG* 108:414–419
16. Mescia M, Pifarotti P, Gernasconi F, Guercio E, Maffiolini M, Magatti F, Spreafico L (2001) Tension-free vaginal tape: analysis of outcome and complications in 404 stress incontinent women 2001. *Int Urogynecol J* 12:24–27
17. Levin I, Groutz A, Pazner D, Lessing JB, Gordon D (2004) Surgical complications and medium-term outcome results of tension-free vaginal tape: a prospective study of 313 consecutive patients. *Neurourol Urodyn* 23:7–9
18. Holmgren C, Nilsson S, Lanner L, Hellberg D (2007) Frequency of de novo urgency in 463 women who had undergone the tension-free vaginal tape (TVT) procedure for genuine stress urinary incontinence—a long-term follow up. *Eur J Obstet Gynecol Reprod Biol* 132:121–125
19. Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clark AL (1997) Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol* 89:501–506