Chapter 4

Quality of life before and after TVT, a prospective multicentre cohort study, results from the Netherlands TVT database

Steven E. Schraffordt Koops
Tanya M. Bisseling
A. Peter M. Heintz
Harry A.M. Vervest

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Abstract

Objective: To asses the long-term outcome of the tension-free vaginal tape procedure in women with isolated stress urinary incontinence (SUI).

Design: Prospective cohort study.

Setting: Twenty-eight teaching hospitals and 13 local hospitals with 54 gynaecologists and urologists performing the surgery.

Sample: Eight hundred and nine participants.

Main outcome measures: The Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) were used to measure the results of the TVT procedure (pre-operative at 2, 6, 12 and 24 months post-operative).
According the recommendation of the International Continence Society (ICS), the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI to asses SUI.

Results: Both IIQ and UDI mean scores decreased significant after TVT, indicating an improvement in quality of life. Subjective improvement can improve for up tol two years post-operatively.

Conclusions: This is the largest study that used these validated disease-specific questionnaires to asses the long term outcome of the TVT procedure. This study shows a statistically significant and clinically relevant long term improvement of the quality of life after a TVT for women with SUI.

Introduction

The estimated prevalence of urinary incontinence in women aged 18 years and older varies between 23% and 57% [1, 2]. Around half of these women suffer from stress urinary incontinence (SUI). Until 1995 the "gold standard" for SUI surgery was the Burch colposuspension [3]. More recently, TVT[4, 5] has become the first choice as surgical treatment for SUI in many women because it has proven to be as successful as the Burch colposuspension [6, 7].

Assessing the efficacy of surgery for incontinence represents a challenging issue and Black and Downs examined the methodological quality of the few prospective studies that have reported on the effectiveness of surgery for stress incontinence, found it to be poor[8], and concluded that the value of surgery and the relative effectiveness of different procedures were therefore unclear. Ward and Hilton compared the Burch colposuspension and TVT in a well-designed prospective, randomised study but the criticism of Black and Downs still hold true for many published reports on TVT and other surgery. There are only few studies that have prospectively determined the outcome of TVT by assessing the influence of this procedure on quality of life with the aid of disease specific validated health-related quality of life (HRQoL) questionnaires[9, 10].

In this article we present the results of a multicentre study on the long term outcome of TVT in women as a primary treatment of urodynamic stress incontinence, assessed with validated disease specific questionnaires.

METHODS

Between March 2000 and September 2001, women with an indication for a TVT procedure were asked to participate in this study. The study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Included were women who were willing to participate in the study and who had an indication for TVT. Excluded were women with concomitant urogynaecological surgery, a history of previous incontinence or prolapse surgery, recurrent urinary tract infections, significant symptoms of urge urinary incontinence, a history of or detrusor overactivity at cystometry, post-voiding bladder retention (>150 ml), a bladder capacity less than 200 ml or a physical/mental impairment which would make participation impossible. If more than two items on the IIQ or the UDI were not answered, the total score was not calculated and was not included in the results.

A standardised history was taken and physical examination was performed pre-operative and at 2, 6, 12 and 24 months post-operatively. Investigative pre-operative multi-channel urodynamics was not mandatory and left to the gynaecologist's or urologist's discretion. Urodynamical investigations were eventually carried out in 549 women (87%).

All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6). The questionnaires, a postage-paid return envelope and instructions, were sent to the patient by mail. The questionnaires were anonymously processed in a database. Researchers as well as participating gynaecologists and urologists were blinded to the individual results of these questionnaires. The long form IIQ (30 questions) and UDI (19 questions) are disease specific HRQoL questionnaires[11]. A short form for both questionnaires has been validated which consists of seven and six questions respectively (IIQ-7 & UDI-6 [12]). These questionnaires were translated into Dutch and validated for the Dutch female population[2]. All items in the questionnaires are on a four-step ordered category scale from "not at all" to "greatly" impaired. The UDI is subdivided in three domains: stress incontinence, irritative and obstructive/discomfort and the IIQ measures the implications of urinary incontinence for normal daily functioning. The total score of every domain is transformed to a scale from 0-100 (a higher score means more bothered).

The procedures took place in 41 different hospitals by 54 gynecologists and urologists. Of the 41 hospitals there were 3 university hospitals, 25 teaching and 13 non-teaching hospitals. TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) was performed as described by Ulmsten[4]. The operation was carried out under local anaesthesia using 0.25% prilocaïne with adrenalin, spinal analgesia or general anaesthesia.

The primary outcome measures were the scores on the IIQ and UDI, with improvement defined as a lower score on follow up questionnaires. Secondary outcomes included the response to question three from the UDI: "do you experience urinary

leakage during physical activity, coughing or sneezing?" as a subjective record of success or failure for SUI as recommended by the International Continence Society (ICS)[13]. We also asked the patients directly "do you leak during physical activity, coughing or sneezing?" at each follow up visit. The answer "no" was defined as success. All other answers were considered as failure. The physical demonstration of urine loss coughing found during physical examination with a full bladder at follow up was used as an objective measure of cure.

Statistical analysis was performed with SPSS 11.5 for Windows. The ¯Ç test was used to compare proportions relating to subjects in different groups. Categorical variables were compared with a two-sided Fisher exact test. The Student *t* test was used as a statistic to compare interval variables. To analyse matched and paired data, the Wilcoxon's signed-rank test was used. The mean difference was chosen to be significant at the 0.05 level. Data are presented as mean [SE].

RESULTS

The original database comprised data from 809 women. One hundred and thirty-one women had previous incontinence or prolapse surgery and were excluded from the analysis reported here. Another 44 women had simultaneous prolapse surgery and were also excluded, leaving 634 women for analysis. Among these women, TVT was combined in 8.7% with non-urogynecological procedures like for example sterilisation. The mean age at the time of TVT was 50 years [10]. Only 15 women were nulliparous. The mean parity was 2.4 [1.1]. Forty-one percent of women were postmenopausal and 15% used hormone replacement therapy. The mean operating time was 32 [10] minutes. The follow up was at least two years for all women.

Twenty-six women were excluded from the study: 22 declined to take further part in the study, 3 had intercurrent illness, and 1 did not fully complete the questionnaire.

Both IIQ and UDI mean scores decreased significantly after TVT (Table 1). This improvement occurred up to six months after surgery and became stable after that. Mean IIQ and UDI scores at all follow up measurements showed no difference between women over or under 70 years of age. The secondary outcome measures are shown in Table 2.

Between 20% and 60% of the women who did not attend in person for follow up one or more times did return the questionnaires for the study. There was no consistent difference in reported outcomes between these women and the women who attended for full follow up.

Discussion

This study followed a large number of women for two years after TVT surgery, with the primary assessment performed with disease specific quality of life questionnaires. As might be expected, from the work of others, urinary incontinence has a profoundly negative impact on the quality of life of women[9, 14, 15]. The TVT procedure produced a lasting improvement in quality of life scores.

Our results show that women with residual SUI directly after surgery can improve for up to two years post-operatively, which is considered a 'long term' follow up by the WHO International Consultation on Incontinence[16]. At two years, 80% of patients reported cure of their stress incontinence. Another large study using the UDI and IIQ to asses the outcome of TVT confirmed a significant improvement in quality of life after a TVT[9]. In this study the follow up was done only once with a follow up of mean 22.1 months (range 6.1 - 49.8), although three quarters of the 114 patients underwent concomitant prolapse surgery, which may have contributed to the outcome, and contributed to the reported improvement in quality of life.

Mukuherjee and Constantine [17] used the validated Kings quality of life questionnaire to asses the medium term outcome of TVT, six months after surgery. Women with a normal BMI (<25) had a 85% cure rate, while obese women (BMI>25) had a cure rate of 90%. Our data showed a lower improvement on the quality of life after a TVT for all women participating in our study, but the longer follow up in our study and the differences between the questionnaires used could be the reason for the difference in outcome.

Inevitably, a longer follow-up means a greater drop out rate. In our study the drop out rate after two years for the follow up in clinic is about 34%. Normally, no information is gathered from those patients who fail to attend for follow up in research studies, and the (possibly incorrect) assumption is then made that these women performed the same as the attendees. Hilton even suggests to consider these non-attendees as failures[18]. In our study, however, we had some information via the UDI and IIQ. We found a small difference between the groups who did and did not show up in clinic but did fill in the questionnaires. The improvement rates in the "lost to follow-up" group were 5%-8% lower, but to consider this group a failure seems inappropriate.

Walsh et al.,[10] in a prospective study using quality of life questionnaires, found a difference in improvement of stress incontinence between women older than 70 years and women younger than 70 years. The improvement was greater in the younger group. The authors explained this by a higher incidence of intrinsic sphincter deficiency in the older group. We could not confirm this difference in improvement for different age categories.

This study reports the outcome of the tension-free vaginal tape procedure by means of the disease specific health related quality of life IIQ-7 and the UDI-6 questionnaires. A statistically significant and clinical relevant long term improvement of the quality of life after a TVT for women with SUI was found.

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Table 1. Mean IIQ & UDI scores

	Response rate (%)	Mean IIQ-scores (SE)	p*	Mean UDI-scores (SE)	p*
Preoperative	91.8	58 (0.8)		58 (0.8)	
2 months postoperative	67.4	15 (1.1)	0.000*	25 (0.9)	0.000*
6 months postoperative	69.7	12 (0.9)	0.022*	23 (0.9)	0.027*
12 months postoperative	73.1	11 (0.8)	0.760	21 (0.8)	0.300
24 months postoperative	77.3	12 (0.9)	0.180	23 (0.9)	0.060

Data are mean (standard error)
Wilcoxon's signed rank-test.
*analysis compared to the preceding value.

Table 2. Secondary outcome measures

	Response rate	**improved**	**no change**	**worsened**
Question 3⋆				
2 months	67.4%	91.6 %	7.4 %	1.0 %
6 months	69.7%	94.4 %	4.7 %	0.9 %
12 months	73.1%	95.7 %	3.6 %	0.7 %
24 months	77.3%	95.3 %	4.0 %	0.6 %
Direct question#		no leakage	leakage	
2 months	91.6%	88.5%	11.5%	
6 months	62.0%	88.5%	11.5%	
12 months	56.8%	84.1%	15.9%	
24 months	76.2%	80.1%	19.1%	
Observed leak§		no	yes	
2 months	91.6%	98.1%	1.9%	
6 months	62.0%	97.0%	3.0%	
12 months	56.8%	95.0%	5.0%	
24 months	76.2%	97.1%	2.9%	

⋆ Data are the percentage of patients responding to the question from the UDI: "do you experience urinary leakage during physical activity, coughing or sneezing?"
Data are percentages of the answer to the doctors question "do you leak during physical activity, coughing or sneezing?" asked at follow up.
§ Data are percentages of patients were loss of urine upon coughing was found during physical examination with a full bladder at follow up.