Chapter 5

The effectiveness of Tension-free Vaginal Tape (TVT) and quality of life measured in women with previous urogynecological surgery: Analysis from The Netherlands TVT database

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Abstract

Objective: Long-term outcome of tension-free vaginal tape (TVT) in women with a history of surgery for urinary incontinence and/or prolapse.

Study design: Prospective cohort study of 809 women. Twenty-eight teaching and 13 local hospitals, 54 gynaecologists and urologists performed the TVT's.
The Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) were used to measure the results of the TVT procedure (preoperative, at 2, 6, 12, 24, and 36 months postoperative). 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 assess stress urinary incontinence.

Results: The decrease in IIQ/UDI mean scores was statistically significant. The UDI scores of women with a history of previous prolapse and/or incontinence surgery were not statistically different to the scores for primary cases after 3 years follow-up ($p = 0.193$).

Conclusions: TVT is effective for women with recurrent stress urinary incontinence and/or previous prolapse surgery.

INTRODUCTION

Urinary incontinence is a common condition in the female population. The estimated prevalence in women aged 18 years and older varies between 23% and 57%[1, 2]. Until 1995 the golden standard of stress urinary incontinence (SUI) surgery was the Burch colposuspension[3]. The Tension-free Vaginal Tape (TVT) has become the first choice for surgical treatment for SUI in women. The procedure was introduced by Ulmsten and Petros in 1995[4, 5]. This minimally invasive procedure is based on one of the concepts of the integral theory for female incontinence: improving mid urethral support. TVT has proven to be as successful as the Burch colposuspension [6, 7]. Many results have been reported on the outcome of the TVT. However, only few report on the effectiveness of the TVT in more complicated cases with prior surgery for prolapse and/or incontinence. In addition to this, most studies addressing incontinence surgery use nonvalidated questionnaires, postoperative continence status on a visual analogue scale (VAS), micturition diary, pad weighing tests, interviewing women and urodynamic evaluation. Most of these measurements are subject to bias.
In this study we present the outcome and follow-up of three years of a low-tension mid-urethral sling (TVT) in women with previous incontinence or prolapse surgery, by means of objective (patient self-reported) health-related quality of life (HRQoL) questionnaires (the Incontinence Impact Questionnaire [IIQ] and the Urogenital Distress Inventory [UD]).

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 coworking hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

Study design
A standardized history was taken and physical examination was performed preoperatively and again at 2, 6, 12, 24, and 36 months postoperatively. Investigative preoperative multi-channel urodynamics was not mandatory and left to the gynecologist's or urologist's discretion.
All women were asked to complete the short version of the IIQ-7 and the UDI-6 before and at 2, 6, 12, 24, and 36 months after the procedure. The questionnaires, a postage-paid return envelope, and instructions were sent to the patient by mail. The questionnaires were processed anonymously. Researchers, as well as participating gynecologists and urologists, were blinded to the individual results of these questionnaires. The long form IIQ and UDI are disease-specific HRQoL questionnaires[8]. These questionnaires consist of 19 questions (UDI) and 30 questions (IIQ). Uebersax et al[9] validated a short form for both questionnaires (IIQ-7 and UDI-6), which consists of 7 and 6 questions, respectively. These questionnaires were translated into Dutch and validated for the Dutch female population[2]. All items in the questionnaires are on a 4-step ordered category scale from "not at all" to "greatly" impaired. The total score is transformed to a scale from 0-100 (a higher score means more bothered). The IIQ measures the implications of urinary incontinence for normal daily functioning, whereas the UDI indicates the type of bother women experience.

Inclusion and exclusion criteria
Included were women who were willing to participate in the study, who had an indication for TVT, and had a history of previous incontinence or prolapse surgery. Excluded were women who had recurrent and difficult to treat urinary tract infections, predominant symptoms of urge urinary incontinence (defined as urge incontinence being more prevailing than the stress incontinence), detrusor over activity at cystometry, post voiding bladder retention (>150 ml), bladder capacity less than 200ml, or a physical/mental impairment that 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.

Surgical procedure

The procedures took place in 41 different hospitals by 54 gynecologists and urologists. Of the 41 hospitals, 3 were university hospitals, 25 were teaching and 13 were non-teaching hospitals. TVT (Gynecare, Ethicon Inc, Sommerville, New Jersey, USA) was performed as described by Ulmsten[4, 5]. The operation was carried out under local anesthesia, spinal analgesia or general anesthesia.

Outcome measures

The primary outcome measurements were the IIQ and UDI scores.

According the recommendation of the ICS, the question "Do you experience urinary leakage during physical activity, coughing or sneezing?" was selected from the UDI, as secondary outcome measure to define success or failure for SUI[10]. Women who have a lower score on the UDI question score postoperatively were considered to be improved.

Statistical analysis

All the data were anonymously processed by a research physician (TMB) and the research team secretary. Statistical analysis was performed with SPSS 11.5 for Windows (SPSS Inc, Chicago, IL). The ÃÇ test was used to compare proportions relating to subjects in different groups. Categorical variables were compared with a 2-sided Fisher exact test. The Student *t* test was used as a statistic to compare interval variables. To analyze 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. To analyze statistical differences between groups, the one-way ANOVA test with a Post Hoc Bonferroni correction was used.

RESULTS

The original database comprised data for 809 women. Fifteen women were excluded for the study, for the following reasons: refused to take further part in the study (n=13), diseased (n=1), did not fully complete the questionnaire (n=1). There were 131 women who had previous incontinence and/or prolapse surgery and were the subject of this analysis. The operative history of these 131 women is shown in table 1. Fifty women had prior incontinence surgery. In this group there were 9 women who had undergone 2 prior incontinence procedures and 1 woman who had undergone 3 prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). There were 16 cases with a history of both prolapse and incontinence surgery. In this group, 1 woman had undergone a Burch colposuspension twice; 1 woman had undergone a Stamey suspension followed by a Burch colposuspension. Sixty-five women had a history of prolapse surgery only. Two women had undergone prolapse surgery twice.
The TVT was combined in 6.1% of cases with non-urogynecological procedures, for example, sterilization; in 15 women (11.5%) it was combined with prolapse surgery. This concomitant prolapse surgery was performed in 6 women with previous prolapse surgery, in 7 women with previous incontinence surgery and in 2 women, who had both prior prolapse and incontinence surgery. General anesthesia was used in 14.1% of women, spinal in 7.8%, local analgesia in 78.1%. The mean age at the time of TVT was 55.5 years (SD 10.5; range 33 – 82yrs). One woman was nulliparous. The mean parity was 2.5 (SD 1.1; range 0 - 9). Of all women, 68.1% were postmenopausal and 23% of all women used hormone replacement therapy. The mean operating time of the TVT was 36 minutes (SD 15.5; range 20 -120 minutes).
The patient characteristics of the two groups are shown in table 2.
The results for outcome parameter 2 for both groups are listed in table 3. After 2 months the improved rate stated by women on the UDI question: "Do you experience urinary leakage during physical activity, coughing or sneezing?", compared to their pre-operative status is 86.1%. This increased to 92.9% after 36 months. The control group showed an improved rate of 92% after a follow-up of 3 years.
The UDI scores of women with recurrent SUI (n = 50) improved from preoperative mean score of 65 to 31 at 2 months, and to 28 at 36 months. In women with prior prolapse surgery (N=65), the UDI score improved from preoperative 59, to 26 at 2 months, and to 25 at 36 months. Women with a history of both prolapse and incontinence surgery (N=16) had improved UDI scores from preoperative 77, to 24 at 2 months, and to 33 at 36 months. No statistical differences were found in the outcome of the UDI among the 3 groups.
The mean preoperative and postoperative values of the IIQ-7 and UDI-6 QOL questionnaires of both groups are listed in table 4. The response rates for these outcome parameters was 79.3% at 3 year follow-up. The UDI scores of the previous-surgery group were significant higher pre-operatively. Both IIQ and UDI mean scores at the postoperative visit compared with the preoperative values decreased for both groups, which was statistically significant after TVT. The difference between the

UDI scores of the two groups at twelve months and at twenty-four months follow-up was statistically significant. For the IIQ score, no difference was found between preoperative values. A significant difference was found at 6 and 24 months follow-up. The results show that after a follow-up of 3 years, no statistical difference in UDI and IIQ scores between both groups could be identified.

COMMENT

Women with prior surgery for incontinence or prolapse represent a group of patients who are difficult to cure surgically. In this study group, 10 (7.6%) women had undergone more than 1 operation for incontinence before the TVT indicating the difficulty to cure these patients. Burch colposuspension and sling procedures have been used for women with recurrent stress incontinence. Success rates of 85 to 90% at 3 to 4 years follow-up are published, but this surgery is associated with high complication rates such as significant urinary retention and haemorrhage[11-13]. These complication rates are lower with the TVT procedure [14].

Only a few articles describe the outcome of the TVT after prior incontinence surgery[15-21] and prolapse surgery[17, 22]. Most studies do not report a difference in success rates between primary and secondary cases of incontinence surgery[23-25]. The success rate of the secondary cases reported is 84% to 89%, but objective judgment of these studies is complicated. The groups are small, the outcome parameters are all different, the definition of repeat or secondary surgery is not uniform and sometimes the level of statistical significance is not reported[19, 26, 27].

Liapis et al[15] described cure rates of 90% in women with recurrent stress urinary incontinence with a preoperatively mobile urethra. The success rate was only 33% in patients with a fixed urethra. Rezapour et al[28] found a complete cure in 74% and improvement in another 12% in women with stress incontinence and intrinsic sphincter deficiency (ISD).

In a previous publication[29] we showed no difference between women with or without ISD either. Data regarding the success rate in women with intrinsic sphincter deficiency (ISD) (either defined by a low pressure urethra or fixed urethra) are conflicting.

This study assessed a well-defined group of secondary incontinence and/or prolapse cases. A significant improvement was found for all outcome parameters, which shows that TVT is a successful treatment in secondary cases for recurrent incontinence and/or prolapse. No statistical difference was found in the UDI outcome parameter comparing 2 large groups with and without previous urogynecological surgery after a follow up of 3 years of all women. The groups compared at 12 and 24 months showed a significant difference in UDI. No statistical difference was found at 36 months this might be due to the number of patients included. The improvement of the group with prior surgery is encouraging because in this group, the preoperative UDI scores were significantly higher than for the other groups, indicating more preoperative bother.

The QOL scores are equally good for both groups after 3 years follow-up. A trend between both groups was found at all follow-up visits but was only significant different at 6 and 24 months. In conclusion, patients with prior pelvic surgery perform very well after a TVT but a slight difference in quality of life was noted.

Previous retropubic surgery is associated with more intraoperative complications[30, 31]. In a previous publication, we reported a higher intraoperative complication rate during the TVT procedure for women with prior prolapse surgery[14].

In conclusion, this study shows that the TVT is a valuable tool for women with recurrent stress urinary incontinence, prior prolapse surgery, or both. Therefore, we think the TVT should be recommended for the treatment of recurrent stress urinary incontinence in women with previous incontinence and/or prolapse surgery.

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Table 1. Operative history of women

Women with previous incontinence surgery (n = 50)	
Burch colposuspension	44
Abdominal hysterectomy	21
Vaginal hysterectomy	6
Raz procedure	4
Stamey procedure	6
MMK procedure	5
Women with previous prolapse surgery (n = 65)	
Vaginal hysterectomy, anterior and posterior colphoraphia	16
Vaginal hysterectomy & anterior colporrhaphy	13
Vaginal hysterectomy & posterior colporrhaphy	1
Anterior colporrhaphy	1
Anterior & posterior colporrhaphy	12
Posterior colporrhaphy	3
Sacrocolpopexy	4
Abdominal hysterectomy	12
Vaginal hysterectomy	3
Women with previous incontinence and prolapse surgery (n = 16)	
Burch colposuspension	13
Abdominal hysterectomy	4
Vaginal hysterectomy	2
Raz procedure	1
Stamey procedure	2
MMK procedure	2
Vaginal hysterectomy, anterior and posterior colporrhaphy	3
Vaginal hysterectomy & anterior colporrhaphy	2
Anterior colporrhaphy	5
Posterior colporrhaphy	3
Anterior & posterior colporrhaphy	3
Sacrocolpopexy	1

Table 2. Patient characteristics

	prior surgery	no prior surgery	p-value
age	55.5 (10.5)	50.5(10.2)	0.000
parity	2.5 (1.1)	2.4(1.1)	0.518
menopausal state			
premenopausal	31.90%	57.50%	0.000
postmenopausal	68.10%	42.50%	
HRT use			
yes	23.40%	16.00%	0.070
no	76.60%	84.00%	
simultaneous procedures			
TVT only	82.40%	85.40%	
TVT with prolapse surgery	11.50%	6.50%	0.112
TVT with other surgical procedures	6.10%	8.10%	
Type of Anesthesia			
local anesthesia (with sedation)	78.10%	80.30%	
spinal analgesia	7.80%	8.40%	0.685
general anesthesia	14.10%	11.20%	

Values are mean (SD) or %,Chi square test and Student-t test were used where appropriate.

Table 3. Continence status- women's reply to the UDI questionnaire, on the question: "Do you experience urinary leakage during physical activity, coughing or sneezing?", compared to their preoperative status

Prior surgery	**2 months**	**6 months**	**12 months**	**24 months**	**36 months**
improved	86.1%	90.5%	92.4%	90.1%	92.9%
no change	11.1%	6.0%	5.4%	8.8%	7.1%
worsened	2.8%	3.6%	2.2%	1.1%	0.0%
No prior surgery					
improved	91.2%	93.8%	95.5%	95.0%	92.6%
no change	7.9%	5.3%	3.9%	4.4%	6.3%
worsened	0.9%	0.9%	0.6%	0.6%	1.1%

Table 4. Differences in mean UDI and IIQ scores between women with no history of prolapse/incontinence surgery (N=678) and women with prior urogynecological surgery (N=131)

	UDI			IIQ		
	previous surgery	no previous surgery	p-value	previous surgery	no previous surgery	p-value
preoperative	63.4	58.3	0.007*	61.4	58.1	0.108
2 months postoperative	27.8	25.5	0.334	17.0	15.9	0.705
6 months postoperative	27.5	23.4	0.114	19.5	12.2	0.011*
12 months postoperative	26.0	21.5	0.011*	15.2	11.5	0.140
24 months postoperative	28.3	23.1	0.018*	20.2	12.2	0.003*
36 months postoperative	27.4	24.5	0.193	15.2	13.6	0.527

Student-T test. * Significant P-value<0.05