
Chapter 7

**Result of the Tension-free Vaginal Tape (TVT)
in patients with concomitant pelvic surgery,
a two year follow-up study, analysis from the
Netherlands TVT database**

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ABSTRACT

Objective: This study assessed the long-term outcome of TVT in women with concomitant pelvic surgery.

Material and Methods: A prospective cohort study of 809 746 patients in 51 hospitals was undertaken. The Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) were used to measure the results of the TVT. Fifty-nine patients with concomitant prolapse surgery were compared with 687 women with TVT only.

Results: IIQ/UDI mean scores decrease statistically significant in both groups after the TVT. The success rates of 'no leakage at all' is comparable for both groups. But aHowever in a larger amount of women with concomitant surgery no change of the incontinence after TVT was found. After a follow-up of two years a statistical difference in UDI & IIQ scores could be identified.

Conclusion: TVT is effective for women without and with concomitant prolapse surgery, after 2 years a difference in UDI & IIQ scores could be identified.

INTRODUCTION

The estimated prevalence of urinary incontinence in women aged 18 years and older varies between 23% and 57%^{1,2}. About half of these women suffer from stress urinary incontinence (SUI). Urinary incontinence in combination with pelvic prolapse is reported up to 80%^{3,4}. Until 1995 the “gold standard” for stress urinary incontinence surgery was the Burch colposuspension⁵. More recently, TVT^{6,7} has become the first choice as surgical treatment for stress urinary incontinence in many women because it has proven to be as successful as the Burch colposuspension^{8,9}. A vaginal approach to both prolapse and incontinence is therefore nowadays possible.

Therefore it is surprising that the efficacy of the TVT in conjunction with other reconstructive pelvic floor surgery has not often been addressed. In this study we present the outcome and two years follow-up of the TVT procedure in women with concomittant surgery by means of objective (patient self reported) results on their health status with the aid of disease specific HRQOL questionnaires (the Incontinence Impact Questionnaire (IIQ) and the Urogenital Distress Inventory (UDI)).

MATERIAL AND 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.

Study design

A standardized history was taken and physical examination was performed preoperatively and again at two, six, twelve and twenty-four months postoperative. Investigative preoperatively 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 Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) before and at two, six, twelve and twenty-four 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 gynecologist's and urologist's, were blinded to the individual results of these questionnaires. The long form IIQ & UDI are disease specific health-related quality of life (HRQOL) questionnaires¹⁰. These questionnaires consist of 19 questions (UDI) and 30 questions (IIQ). Uebersax et al¹¹ validated a short form for both questionnaires (IIQ-7 & UDI-6), which consists of seven and six questions respectively. These questionnaires were translated into Dutch and validated for the female population in the Netherlands². All items in the questionnaires are on a four 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, while the UDI indicates the type of bother women experience.

Inclusion and exclusion criteria

Included were women who were willing to participate in the study and who had an indication for TVT. Excluded were women: with a history of prolapse and/or incontinence surgery, with recurrent and difficult to treat urinary tract infections, those who had a 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 questionnaire 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^{6,7}. All surgeons were qualified to per-

form vaginal surgery and received a brief training in TVT. The operation was carried out under local anesthesia, spinal analgesia or general anesthesia.

Outcome measures

The primary outcome measurement 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 a secondary outcome measure to define success or failure for SUI¹². Women who have a lower score on the UDI question score postoperative compared with preoperative were considered to be improved.

Statistical analysis

The data was anonymously processed by a research physician (TMB) and the research team secretary. Statistical analysis was performed with SPSS 11.5 for Windows. The Chi-square 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 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 of 809 women. Fifteen women were excluded, 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). In 59 women (7.3%) concomitant surgery was performed and were the subject of this analysis. The surgical procedures performed concomitant to the TVT were: vaginal hysterectomy for uterine descent (n=7), anterior repair (n=15), posterior repair (n=28) and anterior with posterior repair (n=9). Of these 59 patients 15 women underwent prior surgery, 6 women had prior prolapse repair: 3 women a vaginal hysterectomy, 5 underwent a colporrhaphy anterior, 3 women a colporrhaphy posterior. One Women underwent a sacrocolpopexy and rectopexy. Seven women underwent previous incontinence surgery, all underwent a Burch colposuspension. One Women underwent a re-Burch and 1 woman a underwent a Marchall-Marchetti-Kranz (MMK) suspension after a Burch. Two women underwent both prior incontinence and prolapse surgery. One Burch colposuspension with a colporrhaphy anterior and colporrhaphy posterior and one woman a MMK with abdominal hysterectomy with colporrhaphy anterior and posterior.

The mean age at the time of TVT was 56,2 years (SD 10.4; range 32 - 82). One woman was nulliparous. The mean parity was 2.7 (SD 1.1; range 0 - 6). Of all women 70.6% was postmenopausal and 28.3% of all women used hormone replacement therapy. The mean operating time of the TVT and concomitant surgery was 50 minutes (SD 27.4; range 20-150).

General anesthesia was used in 47.3%, spinal in 16.4%, local analgesia in 36.4%. In teaching hospitals 34 (58%) and in non teaching hospitals 25 (42%) of the surgery was performed.

The mean pre and postoperative values of the IIQ-7 and UDI-6 quality of life questionnaires are listed in table 1. The response rate for these outcome parameters was 72.9% at 2 years follow-up. Both IIQ and UDI mean scores decrease statistically significant after TVT at the two months. Thereafter, no statistical difference was found comparing the changes between two and six, six and twelve months and twenty-four months follow-up in the UDI scores. However, a statistical significant (but small) decline in the mean IIQ score at 12 months was observed, which at 24 months had disappeared.

The results for outcome parameter two are listed in table 2. The follow-up rates were the same as for outcome parameter 1 and are noted in table 3. After 2 months the continence rate stated by the women with concomitant surgery is 64.2%. This increased to 69.2% after 12 months to 76.5% after 36 24 months. For women without concomitant prolapse surgery the success rate also increased in time. The difference lies in the larger amount of women with concomitant surgery in whom no change of the incontinence was found.

In table 3 the two groups were compared, the groups did not significantly differ in, parity and preoperative IIQ & UDI scores. The two groups did differ significantly in age (56.2 versus 51.2, $p=0.000$) and post menopausal state (70.6 versus 45.7, $p=0.000$).

The mean IIQ and UDI scores of women with concomittant pelvic surgery were compared with the mean IIQ and UDI scores of women without prior surgery (table 3). These two groups were the same as for outcome parameter two. The results show that after a follow-up of two years a statistical difference in UDI & IIQ scores could be identified.

DISCUSSION

Co-existing urinary incontinence and pelvic organ prolapse has been reported in 15-80%^{3,4}. Choe et al and Bai et al reported that 60-63% of patients with urinary stress incontinence also had pelvic organ prolapse^{4,13}.

With the TVT as first choice for incontinence surgery, TVT in conjunction with other pelvic surgery is becoming more popular. Especially because the two can be performed in one session without an abdominal incision. Therefore it is remarkable that not many studies describe the success rate of this combination. The intra and postoperative complication rates of this combined surgery have been described before¹⁴. The complication rate of our study group in comparison with women undergoing TVT without concomitant surgery was comparable¹⁴. Tamussino et al and Partoll et al described a longer period of postoperative residual volumes for patients undergoing concomitant surgery^{15,16}. This was not demonstrated by Sokol et al¹⁷. Deval et al described a higher rate of bladder perforations when concomitant surgery was performed¹⁸.

Few studies have stratified for TVT versus TVT in conjunction with prolapse surgery. No significant difference in success was found in these studies¹⁸⁻²⁰. One study described a lower success rate for TVT with cystocele repair of 38% against 67% in patients without a cystocele repair. However this was not significant probably due to the small amount of patients²¹. Another study described a lower success rate for TVT with colporrhaphy anterior but no statistical analysis was performed²². Tape migration has been described when performing a colporrhaphy anterior combined with TVT²³. Migration from mid urethral to bladder neck can influence the outcome²⁴. We could not find a statistical difference for those women who had undergone a colporrhaphy and TVT. This may be due to small numbers (n= 15) but also because several participating surgeons made separate incisions for the introduction of the TVT and the anterior colporrhaphy to prevent this migration. We could not compare these two approaches due to the small sample size.

Partoll et al described 37 patients who underwent TVT and concomitant prolapse surgery¹⁶. After a follow-up of 11 months the overall success rate for urinary incontinence was 94.6%. Success was defined as dry at a standing stress test with a comfortably full bladder and no stress incontinence episodes were reported verbally by the patient or noted in a voiding diary. Jomaa reported in 2001 on 32 women undergoing TVT and colporrhaphy anterior and/or posterior²⁵.

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Table 1. Mean UDI scores and mean IIQ scores (N=59)

	Mean UDI-scores (SD)	P-value	Mean IIQ-scores (SD)	P-value
Preoperative	63.3 (18.0)		58.4 (21.0)	
2 months postoperative	29.8 (21.9)	0.000	20.6 (23.5)	0.000
6 months postoperative	29.5 (20.7)	0.000	19.1 (24.2)	0.000
12 months postoperative	25.3 (18.6)	0.000	13.1 (18.8)	0.000
24 months postoperative	31.5 (22.6)	0.000	21.2 (22.6)	0.000

Wilcoxon's signed rank-test.

SE is standard deviation.

★ Significant P-value < 0.05, compared to the preceding value.

The values presented are the mean scores on the UDI subscales.

A high score means more bother

Table 2. Continence status- women's reply to the UDI question: "do you experience urinary leakage during physical activity, coughing or sneezing?", compared to their preoperative status

	2 months	6 months	12 months	24 months
Concomitant surgery(n=59)				
no leakage	64.2%	63.8%	69.2%	67.5%
improved	17.9%	22.2%	23.1%	20.0%
no change	17.9%	11.7%	5.2%	12.5%
worsened	0%	2.8%	2.5%	0%
No concomitant surgery(=687)				
no leakage	68.3%	71.9%	71.9%	67.7%
improved	23.0%	22.8%	24.9%	28.3%
no change	7.6%	4.2%	2.6%	3.6%
worsened	1.1%	1.1%	0.6%	0.4%

Table 3. Differences in mean UDI and IIQ scores between women with concomitant surgery (N=59), and women who had no concomitant surgery (N=687)

	UDI		IIQ		p-value	follow-up
	concomitant surgery	no concomitant surgery	concomitant surgery	no concomitant surgery		
pre-operative	63	59	58	58	1.000	
2 months postoperative	30	25	21	16	0.771	50.80%
6 months postoperative	30	23	19	13	0.185	64.40%
12 months postoperative	25	21	13	12	1.000	67.80%
24 months postoperative	32	23	21	13	0.022*	72.90%

One-way Anova with post hoc Bonferroni correction, * Significant P-value < 0.05.