

---

*Chapter 3*

**What determines a successful TVT?  
A prospective multicenter cohort study, results  
from the Netherlands TVT database**

Steven E. Schraffordt Koops  
Tanya M. Bisseling  
H. Jorien van Brummen  
A. Peter M. Heintz  
Harry A.M. Vervest

*American Journal of Obstetrics and Gynecology* 2006, January 194:65-74.

## **ABSTRACT**

**Objective:** The objective of this study was to report which preoperative and intraoperative factors influence the success of the tension-free vaginal tape procedure for stress urinary incontinence.

**Study Design:** This was a prospective cohort study of 809 patients. In 28 teaching hospitals and 13 local hospitals, 54 gynecologists and urologists performed the tension-free vaginal tape procedure.

**Results:** Before treatment and 2 years postoperatively, the following question from the Urogenital Distress Inventory for stress urinary incontinence was selected to define success or failure: "Do you experience urinary leakage during physical activity, coughing or sneezing?". Secondary outcome measurement was the outcome of the doctor's question, "Do you leak during physical activity, coughing or sneezing?" asked at two-year follow-up. Response rate was 78.7%. The success rate was significant higher in all analyses when the surgeons had performed more than 20 tension-free vaginal tape procedure ( $P = .003$ ; beta 1.918 [95% confidence interval 1.24-2.97]). General anesthesia had a negative effect on the success of the TVT ( $P = .032$ ; beta 2.21 [95% confidence interval 1.07-4.55]).

**Conclusion:** Inexperience of the surgeon with the tension-free vaginal tape procedure and general anesthesia had a negative effect on the result. We believe that the tension-free vaginal tape procedure should only be performed by experienced surgeons.

## **INTRODUCTION**

Stress urinary incontinence (SUI) is a common condition in the female population<sup>1</sup>. During the last century, a variety of surgical procedures have been developed as treatment for this condition. Many of these procedures have disappeared because of poor long-term results. Until 1995 the golden standard of SUI surgery was the Burch colposuspension<sup>2</sup>. By now this procedure has been mostly replaced by the tension-free vaginal tape (TVT). The TVT has become the first choice as surgical treatment for stress urinary incontinence in women. The procedure was introduced by Ulmsten and colleagues in 1995<sup>3,4</sup>. TVT is a minimally invasive procedure based on one of the concepts of the integral theory for female incontinence: the midurethral support. TVT has proven to be as successful as the Burch colposuspension.

Assessing the efficacy of the surgery for incontinence represents a challenging issue. Black and Downs<sup>5</sup> analyzed the outcome of several incontinence procedures. They concluded that the methodological quality of the few prospective studies that have reported on the effectiveness of surgery for SUI is poor. Additionally, they conclude that the value of surgery and the effectiveness of different procedures are unclear. Since the introduction of TVT, many studies have described the results of TVT. However, the criticism of Black and Downs still stands for most of these reports. Ward and Hilton<sup>6,7</sup> compared the Burch colposuspension and TVT in a prospective, well-conducted study. Besides this comparative study, there are only few studies that have determined prospectively the outcome of TVT. To our knowledge not one publication reports on the prognostic factors for success or failure of the TVT procedure. In this article we present the results of a multicenter study on the long-term outcome of TVT. The focus of this report is on the pre- and intra operative factors influencing the success of the TVT procedure for SUI.

## **MATERIALS AND METHODS**

Between March 2000 and September 2001, all patients with an indication for the TVT procedure were asked to participate in this study. Inclusion criteria were urodynamic proven stress incontinence or SUI at history/physical examination. The urodynamic investigations were performed according to the standards recommended by the International Incontinence Society<sup>8</sup>. Exclusion criteria were 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 overactivity at cystometry, postvoiding bladder retention (more than 150 ml), bladder capacity less than 200ml, or a physical/mental impairment. Intrinsic sphincter deficiency (ISD) was defined when the maximum urethral closing pressure (MUCP) was less than 20 cm H<sub>2</sub>O at preoperative urodynamics. All participating gynecologists and urologists were qualified to perform vaginal surgery and had a short training in performing TVT by an experienced surgeon. The TVT was performed as described by Ulmsten<sup>3</sup>. The operation was carried out under local anesthesia using 0.25% prilocaine with adrenalin and sedation, spinal analgesia, or general anesthesia.

Before and at 2, 6, 12, and 24 months after surgery a standardized history, physical examination, and urine culture was performed. At the same time intervals, all patients were asked to complete the short version of the urogenital distress inventory (UDI). The questionnaires, a postage-paid return envelope, and instructions were sent to the patient by mail. The UDI is a disease specific, health-related quality of life (HRQOL) questionnaire. Uebersax et al<sup>9</sup> validated a short form for this questionnaire (UDI-6), which consists of 6 questions. These questionnaires were translated in the Dutch language and validated in the Netherlands by van der Vaart et al<sup>10</sup>. All items in the questionnaires consisted of a 4-step ordered category scale from "not at all" to "greatly". The answers were transformed to a scale from 0 (no complaints) to 100 (very bothered). Registration of mode of anesthesia, intraoperative, and direct postoperative complications was performed by the surgeon.

The number of TVTs that every surgeon performed was counted. Groups were formed of the first 10 TVTs, 11-20 TVTs, and over 20 TVTs each surgeon performed.

### *Ethics*

This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg as primary research center and all other co-working hospitals as required by Dutch law. Written informed consent for this study was obtained from all women.

### *Outcome measures*

According to the recommendation of the International Continence Society, the question "Do you experience urinary leakage during physical activity, coughing, or sneezing?" was selected from the UDI, as primary outcome measure to define suc-

cess or failure for SUI<sup>8</sup>. Success was defined as the answer was “no”. The questionnaires, a postage-paid return envelope, and instructions were send to the patient by mail. The questionnaires were anonymously processed in a database. Researchers as well as participating gynecologist and urologists were blinded to the individual results of these questionnaires.

The secondary outcome measure was the answer to the doctor’s question “Do you leak during physical activity, coughing, or sneezing?” asked at 2-year follow-up. The answer “no” was defined as success. All other answers, as well as improved were considered as failure.

As tertiary outcome measure, both questions were combined. Women who had answered to be dry in the written questionnaire as well as to the oral question at  $\chi^2$ -year follow up were defined to be a success.

#### *Statistical analysis*

All data were processed anonymously by a research physician (T.M.B.) and the secretary of the research team. Statistical analysis was performed with SPSS 11.5 for Windows. Proportions relating to subjects in different groups were compared by  $\chi^2$  test. Categorical variables were compared with a 2-sided Fisher exact test. Interval variables were compared by a Student t-test. Univariate odds ratios (OR) and 95% confidence intervals (CI), as well as P-values were calculated for risk factors.

Subsequently multivariate logistic regression analysis was used to construct a prediction model to determine pre- and intraoperative factors that independently influenced the incontinence rate. Logistic regression is a technique that can be used to evaluate the performance of multiple variables in a diagnostic model. Selection of variables is usually performed with a significance level of 5%. However, the incorrect exclusion of a factor would be more deleterious than including too many factors. Multivariate analysis included therefore all variables with a *P* value less than .10 in the univariate analysis.

## RESULTS

The procedures took place in 41 different hospitals in which 54 gynecologists and urologists performed the TVT procedure. Among the 41 hospitals, there were 3 university hospitals, 25 teaching hospitals, and 13 local hospitals. Of all TVTs 58% were performed in teaching hospitals. In total 809 women participated in the study. Patient characteristics are shown in table 1.

One hundred and thirty-one women had previous incontinence or prolapse surgery. In the group that had undergone prior incontinence surgery, there were 9 patients who had undergone 2 prior incontinence procedures and 1 patient who had undergone three prior incontinence procedures (Burch, re-Burch and hysterectomy with concomitant Raz sling procedure). At preoperative evaluation 49.8% of all women said to have frequency (defined as >8 voids per day) and 62.6% had nocturia of more than once. Of all operated women, 94.1% had daily SUI. In 86.9% of all women, urodynamics were performed. In 5.8% intrinsic sphincter deficiency was diagnosed. In 6.3% detrusor overactivity was diagnosed. Despite the fact that this was an exclusion criteria for this study, surgeons performed a TVT on these patients. We believe it worthwhile to include these patients in this analysis.

The mean operating time for only the TVT procedure was 32.4 minutes (SD 11.2). Fifty-nine women had simultaneous prolapse surgery: vaginal hysterectomy for uterine descent (n = 7), anterior repair (n = 15), posterior repair (n = 28), and anterior and posterior repair (n = 9). TVT was combined with nonurogynecological procedures like , for example, sterilization in 7.8% of all women. These combined procedures were performed under general anesthesia. The incidence of intraoperative complications was 6.2% (n = 50) and have been described elsewhere <sup>11</sup>. Local anesthesia was used in 80%, spinal in 8.3% and general anesthesia in 11.7%.

The response rate for the primary outcome parameter was 78.7% at 2-year follow-up. Twenty-six patients were excluded for the study, for the reason: refused to take further part in the study (n = 22), diseased (n = 3), and did not fully complete the questionnaire (n = 1). Table 2 shows the univariate and multivariate analysis of the primary outcome. For this outcome measurement, the total success rate was 66%. The success rate was statistical significantly increased when the surgeon's experience was more than 20 TVTs performed.

Table 3 shows the univariate and multivariate analysis of the secondary outcome. The follow-up for the second measurement outcome was 78.5%. Excluded from the study were 26 patients: 22 women refused to take further part in the study, 3 patients had diseased, and 1 did not fully complete the questionnaire. Six hundred eleven patients came at the doctor's follow-up at 2-years. The success rate was 78%. The success rate was statistical significantly higher in the univariate and multivariate analysis when the surgeon's experience exceeded 20 TVTs. Success was negatively effected by general anesthesia.

The follow-up for the tertiary measurement outcome was 66.3%. The overall success rate was 64%. The outcome of this tertiary measurement was comparable with that of the secondary measurement.

## COMMENT

Not many articles describe prospectively the influence of preoperative and intraoperative factors that influence the success for stress incontinence of the TVT.

In this study we observed that the experience of the surgeon significantly contributes to the success rate of the TVT procedure. The type of hospital setting did not make a difference for the outcome of the surgery. Twelve of the 51 surgeons performed more than 20 TVTs. In this group an effect of the learning curve was observed. An association between the learning curve for the TVT procedure and the complication rate has been described before<sup>11-13</sup>. However, only Grouz et al<sup>12</sup> suggest an effect of the learning curve on the final outcome of TVT. But with only 30 patients and only 1 surgeon, proper statistics cannot be performed.

A second observation in our study is a less successful outcome after general anesthesia (GA). In a retrospective study of 173 patients, Murphy et al<sup>14</sup> performed a univariate analysis of the TVT's performed by 2 surgeons. No difference voiding dysfunction was found between the group with GA and without GA. However, no data on the final outcome for were mentioned. Kunde and Varma<sup>15</sup> observed a success rate of TVT under GA of 72%. Unfortunately, no comparison with a TVT under local anesthesia was performed. It is difficult to explain these contradictory findings. The advantage of local analgesia is that the cough-stress test can be performed to adjust the tape. Although we are aware that a cough-stress test is of limited value (as shown by Barry<sup>16</sup> and Kuan-Hui Huang<sup>17</sup>), the advantage of the cough test is also not present when using spinal analgesia. In this group we did not observe a detrimental outcome. Furthermore, the negative influence of GA was not observed in outcome measurement 2. Nevertheless, general anesthesia and local anesthesia also differ with regard to somatic, sympathetic, and parasympathetic discharge.

How nervous input to the bladder is altered between general and local anesthesia may be important to how a TVT is tensioned. However, from this study and the other previously mentioned studies, the neural influence cannot be reliably determined. Rezapour et al<sup>18</sup> reported on another possible risk factor: ISD. ISD is believed to be more difficult to cure than other forms of SUI<sup>19</sup>. Rezapour found no improvement on stress incontinence in 7 of 49 patients. Five of these patients were older than 70 years and had an ISD. In our analysis preoperative ISD at urodynamic testing did not seem to influence the final success of the TVT. It should be noted, though, that this outcome was interpreted from the results of only 6% of the total group.

No difference was found in all outcome parameters for patients who had or had not undergone urodynamic testing, although this might suggest that urodynamic testing is not worthwhile. We think this is untrue. Those doctors who choose not to perform urodynamic testing before surgery could have been very certain about the diagnose SUI without detrusor overactivity because of the history and physical examination. So only for these cases, preoperative urodynamic testing does not change the outcome.

A number of studies have been published on concomitant prolapse surgery with the TVT<sup>11, 17, 20-23</sup>. Most state that TVT can be performed safely and effectively with con-

comitant surgery. Pang et al <sup>24</sup> published a retrospective study of 45 patients with a follow-up of 1 year using the stress test and urodynamics as an objective outcome measurement. The success rate in patients undergoing concomitant cystocele repair was 38%; in the noncystocele group, the success rate was 67% ( $P = .19$ ). We could not confirm this finding. In our data 15 patients underwent an anterior repair with the TVT. No difference was found in the final outcome for SUI in comparison with the group (N = 421) undergoing TVT only.

In conclusion, this study reports on the prognostic factors determining success of the TVT procedure for SUI. General anesthesia seems to have a negative effect on the result; however, this observation was not constantly present in all outcome variables. Experience of the surgeon determines a successful outcome of the TVT. In fact, many traditional variables thought to be of importance in incontinence surgery appear not to be related to a successful outcome. Therefore, we believe that in the hands of an experienced surgeon the TVT is a clinically safe and effective method to cure stress urinary incontinence.



## REFERENCES

1. HANNESTAD YS, RORTVEIT G, SANDVIK H, HUNSKAAR S. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. *Epidemiology of Incontinence in the County of Nord-Trøndelag. J Clin Epidemiol* 2000;53:1150-7.
2. BURCH JC. Cooper's ligament urethrovesical suspension for stress incontinence. Nine years' experience—results, complications, technique. *Am J Obstet Gynecol* 1968;100:764-74.
3. ULMSTEN U, HENRIKSSON L, JOHNSON P, VARHOS G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 1996;7:81-5; discussion 85-6.
4. ULMSTEN U, PETROS P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol* 1995;29:75-82.
5. BLACK NA, DOWNS SH. The effectiveness of surgery for stress incontinence in women: a systematic review. *Br J Urol* 1996;78:497-510.
6. WARD K, HILTON P. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. *Bmj* 2002;325:67.
7. WARD KL, HILTON P. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: two-year follow-up. *Am J Obstet Gynecol* 2004;190:324-31.
8. ABRAMS P, CARDOZO L, FALL M, et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. *Neurourol Urodyn* 2002;21:167-78.
9. UEBERSAX JS, WYMAN JF, SHUMAKER SA, MCCLISH DK, FANTL JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Continence Program for Women Research Group. Neurourol Urodyn* 1995;14:131-9.
10. VAN DER VAART CH, DE LEEUW JR, ROOVERS JP, HEINTZ AP. Measuring health-related quality of life in women with urogenital dysfunction: the urogenital distress inventory and incontinence impact questionnaire revisited. *Neurourol Urodyn* 2003;22:97-104.
11. SCHRAFFORDT KOOPS SE, BISSELING TM, HEINTZ APM, VERVEST HAM. Prospective analysis of complications of tension-free vaginal tape (TVT) from The Netherlands TVT Study. *Am J Obstet Gynecol* 2005, July 193: 45-52.
12. GROUTZ A, GORDON D, WOLMAN I, JAFFA AJ, DAVID MP, LESSING JB. Tension-free vaginal tape for stress urinary incontinence: Is there a learning curve? *Neurourol Urodyn* 2002;21:470-2.
13. KUUYA N, NILSSON CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand* 2002;81:72-7.
14. MURPHY M, HEIT MH, FOUTS L, GRAHAM CA, BLACKWELL L, CULLIGAN PJ. Effect of anesthesia on voiding function after tension-free vaginal tape procedure. *Obstet Gynecol* 2003;101:666-70.
15. KUNDE D, VARMA R. Feasibility of performing TVT operation for stress urinary incontinence under general anaesthesia. *J Obstet Gynaecol* 2002;22:663-5.

16. BARRY CL, DIETZ HP, RANE A, WILSON PD. Is the cough test necessary? A case control series of two techniques of TVT adjustment. *Neurourol Urodyn* 2004;23:492-493.
17. HUANG KH, KUNG FT, LIANG HM, HUANG LY, CHANG SY. Concomitant surgery with tension-free vaginal tape. *Acta Obstet Gynecol Scand* 2003;82:948-53.
18. REZAPOUR M, FALCONER C, ULMSTEN U. Tension-Free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)—a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct* 2001;12 Suppl 2:S12-14.
19. US Department of Health and Human Services. Urinary incontinence in adults: acute and chronic management. *Clin Pract Guideline* 1996;2:51-61.
20. PARTOLL LM. Efficacy of tension-free vaginal tape with other pelvic reconstructive surgery. *Am J Obstet Gynecol* 2002;186:1292-5; discussion 1295-8.
21. GROUTZ A, GOLD R, PAUZNER D, LESSING JB, GORDON D. Tension-free vaginal tape (TVT) for the treatment of occult stress urinary incontinence in women undergoing prolapse repair: a prospective study of 100 consecutive cases. *Neurourol Urodyn* 2004;23:632-5.
22. GORDON D, GOLD RS, PAUZNER D, LESSING JB, GROUTZ A. Combined genitourinary prolapse repair and prophylactic tension-free vaginal tape in women with severe prolapse and occult stress urinary incontinence: preliminary results. *Urology* 2001;58:547-50.
23. JOMAA M. Combined tension-free vaginal tape and prolapse repair under local anaesthesia in patients with symptoms of both urinary incontinence and prolapse. *Gynecol Obstet Invest* 2001;51:184-6.
24. PANG MW, CHAN LW, YIP SK. One-year urodynamic outcome and quality of life in patients with concomitant tension-free vaginal tape during pelvic floor reconstruction surgery for genitourinary prolapse and urodynamic stress incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2003;14:256-60; discussion 259-60.



**Table 1. Baseline characteristics of all 809 women participating in the study**

<b>GENERAL DATA</b>			
	<b>number or mean</b>	<b>percentage</b>	<b>missing patient</b>
<b>age</b>			
mean age in years	51.3 (20-82)		missing 6
<i>categories</i>			
20 - 30 years	8	1.0%	
31 - 40 years	807	13.3%	
41 - 50 years	284	35.4%	
51 - 60 years	254	31.6%	
61 - 70 years	117	14.6%	
71 - 80 years	28	3.5%	
older than 80 years	5	0.6%	
<b>parity</b>			
nulliparity	17	2.1%	missing 0
multiparity	792	97.9%	
<b>menopausal status</b>			
premenopausal	432	53.4%	missing 0
postmenopausal	377	46.6%	
HRT usage	128	33.9%	
<b>previous urogynecological surgery</b>			
no previous urogynecological surgery	678	84.0%	missing 2
previous prolapse surgery	65	8.0%	
previous incontinence surgery	50	6.1%	
previous incontinence and prolaps surgery	16	2.0%	
<b>mean operating time in minutes</b>	32.4		
<b>DIAGNOSIS PRIOR TO TVT</b>			
<b>type of incontinence</b>			
stress incontinence	577	79.6%	missing 84
mixed incontinence	148	20.4%	
<b>day time frequency</b>			
< 8 voids per day	300	50.2%	missing 211
> 8 voids per day	298	49.8%	
<b>night time frequency</b>			
no nocturnal micturition	237	37.4%	missing 167
once or more per night	396	62.6%	
<b>severity of incontinence</b>			
daily episodes	646	94.1%	missing 123
weekly episodes	39	5.7%	
monthly episodes	1	0.1%	
<b>pelvic floor status</b>			
cystocele	327	46.6%	missing 107
rectocele	166	23.6%	
prolapse of uterine cervix of vaginal vault	161	22.9%	
urethral hypermobility	513	73.1%	
<b>loss at cough test</b>			
yes	629	93.7%	missing 183
no	42	6.3%	

---

**PREOPERATIVE URODYNAMIC STUDY**

<b>urodynamic investigation performed</b>			missing 0
yes	703	86.9 %	
no	106	13.1%	
<b>urodynamic stress incontinence</b>			missing 158
yes	529	81.3%	
no	122	18.7%	
<b>detrusor overactivity at urodynamics</b>			missing 187
yes	41	6.3%	
no	611	93.7%	
<b>intrinsic sphincter deficiency</b>			missing 106
yes	41	5.8%	
no	662	94.2%	
<b>uroflowmetry</b>			missing 287
peak flow (ml/s; value $\pm$ sd)	26.6 (21.3)		
<i>flow pattern</i>			
continuous flow	473	90.6%	
interrupted flow	49	9.4%	

**SURGICAL DATA**

---

<b>simultaneous procedures</b>			missing 0
TVT only	687	84.9%	
TVT combined with prolaps surgery	59	7.3%	
TVT with non-urogynecological surgical procedures	63	7.8%	
<b>type of anesthesia</b>			missing 64
local anesthesia (with sedation)	596	80.0%	
spinal analgesia	62	8.3%	
general anesthesia	87	11.7%	
<b>type of hospital setting</b>			missing 0
no. of TVT in 28 teaching hospitals	469	58.0%	
no. of TVT in 13 non-teaching hospitals	340	42.0%	

---

**Table 2. Univariate and Multivariate Analysis of determinants for the outcome of TVT. Success is defined as 'dry' at the postal question 2 years post operatively**

	univariate analysis				multivariate analysis	
	success (n = 408)	failure (n = 209)	OR [95% CI]	p-value	$\beta$	OR [95% CI] p-value
<b>general data</b>						
age (years $\pm$ sd)	51.19	51.17	0.58	0.937		
parity					t	
nulliparity	7	3	30.0 %	1.000		
multiparity	401	206	66.1 %		X <sup>2</sup>	
<b>menopausal status</b>						
premenopausal	203	106	65.7 %	34.3 %		
postmenopausal	172	86	66.7 %	33.3 %		X <sup>2</sup>
<b>urogynecological history</b>						
no previous urogynecological surgery	350	171	67.2 %	32.8 %		
previous prolapse surgery	31	13	70.5 %	29.5 %		X <sup>2</sup>
previous incontinence surgery	20	12	48.8 %	51.2 %		
previous incontinence and prolapse surgery	7	4	63.6 %	36.4 %		
<b>mixed incontinence</b>						
stress	310	148	82.4 %	17.6 %		
mixed	66	37	80.0 %	20.0 %		X <sup>2</sup>
frequency						
< 8 voids per day	160	80	66.7 %	33.3 %		
> 8 voids per day	153	69	68.9 %	31.1 %		X <sup>2</sup>
<b>incontinence episodes</b>						
daily	333	166	66.7 %	33.3 %		
weekly	27	4	87.1 %	12.9 %		X <sup>2</sup>
monthly	1	0	100.0 %	0.0 %		
<b>urodynamic investigation performed</b>						
yes	335	157	68.1 %	31.9 %		
no	46	27	63.0 %	37.0 %		X <sup>2</sup>
<b>stress in continence at urodynamics</b>						
yes	251	116	68.4 %	31.6 %		
no	56	33	62.9 %	37.1 %		X <sup>2</sup>
<b>detrusor overactivity at urodynamics</b>						
yes	15	9	62.5 %	37.5 %		
no	296	139	68.0 %	32.0 %		X <sup>2</sup>
<b>intrinsic sphincter deficiency</b>						
yes	20	10	66.7 %	33.3 %		
no	361	174	67.5 %	32.5 %		X <sup>2</sup>

<b>flow pattern preoperative</b>									
continuous flow	223	67.4%	108	32.6%					
non continuous flow	24	70.6%	10	29.4%	0.86[0.34-1.86]	0.848	X <sup>2</sup>		
<b>simultaneous procedures</b>									
TVT only	336	68.3%	156	31.7%					
TVT with prolaps surgery	21	60.0%	14	40.0%	1.44 [0.71-2.80]	0.350	X <sup>2</sup>		
TVT with other surgical procedures	24	63.2%	14	36.8%	1.26 [0.63-2.49]	0.589			
<b>pelvic floor status prior to TVT</b>									
cystocele									
no cystocele	170	66.9%	84	33.1%	0.89 [0.61-1.31]	0.559	X <sup>2</sup>		
cystocele	159	69.4%	70	30.6%					
rectocele									
no rectocele	275	70.2%	117	29.8%	1.44 [0.92-2.20]	0.128	X <sup>2</sup>		
rectocele	67	62.0%	41	38.0%					
prolaps of uterine cervix of vaginal vault									
no prolaps of cervix of vaginal vault	272	68.0%	128	32.0%	1.09 [0.70-1.71]	0.730	X <sup>2</sup>		
prolaps of cervix of vaginal vault	72	66.1%	37	33.9%					
urethral hypermobility									
no hypermobility	261	69.6%	114	30.4%	1.61 [0.93-2.78]	0.108	X <sup>2</sup>		
hypermobility	37	58.7%	26	41.3%					
<b>type of hospital setting</b>									
no. of TVT in teaching hospitals	228	67.9%	108	32.1%	1.05 [0.73-1.50]	0.855	X <sup>2</sup>		
no. of TVT in non-teaching hospitals	153	66.8%	76	33.2%					
<b>type of anesthesia</b>									
local anesthesia (with sedation)	287	68.2%	134	31.8%					
spinal analgesia	31	66.0%	16	34.0%	1.11 [0.59-2.09]	0.744	X <sup>2</sup>		
general anesthesia	42	72.4%	16	27.6%	0.82 [0.44-1.50]	0.550			
<b>surgeon's experience</b>									
learning curve effect									
first 10 procedures for each surgeon	129	61.7%	80	38.3%					
next 10 procedures for each surgeon	79	67.5%	38	32.5%	0.78 [0.48-1.25]	0.337			
more than 20 procedures for each surgeon	173	72.4%	66	27.6%	0.615 [0.41-0.92]	<b>0.020</b>			1.918 1.24-2.97 <b>0.003</b>
<b>loss at cough test</b>									
yes	230	71.0%	94	29.0%					
no	99	66.0%	51	34.0%	1.26 [0.83-1.91]	0.285	X <sup>2</sup>		
no cough test performed	24	63.2%	14	36.8%	1.35[0.67-2.71]	0.460			

t= s-Student-t test

X<sup>2</sup> = Fisher exact Test; statistically significant differences are highlighted

Values are mean (SD), number (%) and Odds Ratio [95% CI]

**Table 3. Univariate and Multivariate Analysis of determinants for the outcome of TVT. Success is defined as 'dry' at the doctors question two years postoperative**

	UNIVARIATE ANALYSIS				MULTIVARIATE ANALYSIS	
	success (n = 478)	failure (n = 133)	OR [95% CI]	p-value	statistical method	$\beta$ [95% CI] p-value
<b>general data</b>						
age (years $\pm$ sd)	51.3	50.6	(0.89)	0.474	t	
<b>categories</b>						
20-40	64	21	24.7%			
41-50	174	48	21.6%	0.84 [0.47-1.51]		
51-60	157	37	19.1%	0.72[0.39-1.32]	X <sup>2</sup>	
61-70	66	24	26.7%	1.11 [0.56-2.19]		
71-80	15	3	16.7%	0.61 [0.16-2.31]		
>80	2	0	0.0%	0.75 [0.67-1.01]		
<b>parity</b>						
nulliparity	11	1	8.3%			
multiparity	467	132	22.0%	3.11[0.39-24.30]	X <sup>2</sup>	
<b>menopausal status</b>						
premenopausal	241	66	21.5%			
postmenopausal	204	53	20.6%	1.05[0.70-158]	X <sup>2</sup>	
<b>urogynecological history</b>						
no previous urogynecological surgery	408	108	20.9%			
previous prolapse surgery	33	11	25.0%	1.26[0.62-2.57]	X <sup>2</sup>	
previous incontinence surgery	28	12	30.0%	1.62[0.80-3.29]	X <sup>2</sup>	
previous incontinence and prolapse surgery	9	2	18.2%	0.84[0.18-3.94]		
<b>mixed incontinence</b>						
stress	365	84	18.7%			
mixed	67	35	34.3%	2.27[1.42-3.64]		1.84 0.96-3.54 0.066
<b>frequency</b>						
< 8 voids per day	195	44	18.4%			
> 8 voids per day	175	51	22.6%	1.29[0.82-2.03]		
<b>incontinence episodes</b>						
daily	384	104	21.3%			
weekly	30	4	11.8%	0.49[0.17-1.43]		0.272
monthly	1	0	0.0%	0.78[0.75-0.82]		1.000



<b>urodynamic investigation performed</b>									
yes	423	78.2%	118	21.8%	0.98[0.53-1.79]	1.000			
no	55	78.6%	15	21.4%					
<b>stress incontinence at urodynamics</b>									
yes	311	78.5%	85	21.5%	1.32[0.79-2.17]	0.289			
no	75	73.5%	27	26.5%					
<b>detrusor overactivity at urodynamics</b>									
yes	17	68.0%	8	32.0%	0.58[0.23-1.37]	0.218			
no	375	78.6%	102	21.4%					
<b>intrinsic sphincter deficiency</b>									
yes	29	85.3%	5	14.7%	0.61[0.23-1.59]	0.394			
no	449	77.8%	128	22.2%					
<b>flow pattern preoperative</b>									
continuous flow	294	78.2%	82	21.8%	1.11[0.51-2.44]	0.837			
non continuous flow	29	76.3%	9	23.7%					
<b>simultaneous procedures</b>									
TVT only	421	79.4%	109	20.6%	1.99[0.99-3.86]	0.054			
TVT with prolaps surgery	29	65.9%	15	34.1%					
colporaphia anterior									
TVT with other surgical procedures	28	75.7%	9	24.3%	1.24[0.57-2.71]	0.537			
<b>pelvic floor status prior to TVT</b>									
cystocele									
no cystocele	229	81.2%	53	18.8%	1.32[0.87-1.99]	0.206	X <sup>2</sup>		
cystocele	200	76.6%	61	23.4%					
rectocele									
no rectocele	337	81.0%	79	19.0%	1.58[1.00-2.49]	0.051	X <sup>2</sup>		
rectocele	97	72.9%	36	27.1%					
<b>prolaps of uterine cervix of vaginal vault</b>									
no prolaps of cervix of vaginal vault	343	80.7%	82	19.3%	1.64[1.05-2.58]	<b>0.038</b>	X <sup>2</sup>	1.25	0.66-2.37
prolaps of cervix of vaginal vault	94	71.8%	37	28.2%				0.489	
<b>urethral hypermobility</b>									
no hypermobility	321	80.3%	79	19.8%	1.51[0.85-2.71]	0.201	X <sup>2</sup>		
hypermobility	51	72.9%	19	27.1%					
<b>type of hospital setting</b>									
no. of TVT in teaching hospitals	291	80.2%	72	19.8%	1.32[0.89-1.94]	0.164	X <sup>2</sup>		
no. of TVT in non-teaching hospitals	187	75.4%	61	24.6%					

<b>type of anesthesia</b>									
local anesthesia (with sedation)	365	81.1%	85	18.9%					
spinal analgesia	39	72.2%	15	27.8%	1.65[0.87-3.13]	0.147	X <sup>2</sup>		
general anesthesia	47	68.1%	22	31.9%	2.01[1.15-3.51]	<b>0.017</b>		2.21	1.07-4.55
<b>surgeon's experience</b>									<b>0.032</b>
learning curve effect									
first 10 procedures for each surgeon	162	74.3%	56	25.7%			X <sup>2</sup>		
next 10 procedures for each surgeon	96	74.4%	33	25.6%	0.99[0.60-1.64]	1.000			
more than 20 procedures for each surgeon	220	83.3%	44	16.7%	0.58[0.37-0.90]	<b>0.018</b>		0.55	0.32-0.96
<b>loss at cough test</b>									<b>0.035</b>
yes	299	82.4%	64	17.6%					
no	116	74.8%	39	25.2%	1.57[0.99-2.47]	0.055			
no cough test performed	28	71.8%	11	28.2%	1.84[0.87-3.88]	0.128			

Values are mean (SD), number (%) and Odds Ratio [95% CI]

statistically significant differences are highlighted

t= student-t test

X<sup>2</sup> = Fisher exact Test;