Chapter 8

The prevalence of voiding difficulty after TVT, its impact on quality of life and related risk factors

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

International Urogynecology Journal 2006, in press

Abstract

Objective: To determine the prevalence of voiding difficulty (VD), quality of life and related risk factors after Tension-free Vaginal Tape (TVT).

Design: Prospective cohort study in 703 women undergoing a TVT procedure for stress urinary incontinence.

Main outcome measures: VD stated by women, Urogenital Distress Inventory (UDI-6) maximum flow rate, postvoid residual urine, necessity of postoperative catheterization, tape division, impact on quality of life (Incontinence Impact Questionnaire, IIQ-7).

Results: Postoperative catheterization (> 24 hours) was necessary in 11% and tape division in 1.3% of all patients. Twenty-six percent of women stated VD and 25% reported moderate to great impairment on the UDI-6 after 36 months. Women with abnormal voiding postoperative showed worse outcome on the quality of life. However, all women with and without voiding difficulties showed better scores in the IIQ postoperatively in comparison to preoperative. Preoperative existing voiding difficulty and concomitant prolapse surgery were found to be independent risk factors.

Conclusions: Symptoms of VD occured after TVT and caused less improvement on the quality of life.

INTRODUCTION

Until 1995 the "gold standard" for surgery for stress urinary incontinence (SUI) was the Burch colposuspension which resulted in good long term outcome[1, 2]. This procedure has mostly been replaced by the Tension-free Vaginal Tape (TVT) procedure. The TVT provides the same long term outcome, has lesser side effects and a much lower surgical impact on quality of life of women compared to the Burch colposuspension[3-7]. The TVT is based on the concepts of the Hammock Hypothesis and the Integral Theory[8-10], TVT provides reconstruction of the supporting tissue of the urethra using a polypropylene mesh without repositioning the bladder or securing the periurethral tissues to pelvic structures[5]. The TVT creates a dynamic kinking at the level of the mid-urethra without compressing the urethra at rest and hence, diminishing the obstructive nature of the sling procedure[11]. Nevertheless, voiding difficulty (VD) has been reported up to 60% after TVT and may impose a serious unfavorable outcome affecting quality of life in a negative way despite achieving urinary continence[7].

The aims of this study were to determine the prevalence, and risk factors for voiding difficulty after TVT with the use of objective parameters and validated quality of life questionnaires.

MATERIAL AND METHODS

Between March 2000 and September 2001 women with an indication for a TVT procedure were asked to participate in this study. This study was approved by the Medical Ethical Committee of the St. Elisabeth Hospital Tilburg (The Netherlands) 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.

Inclusion and exclusion criteria

Included were women with urodynamic proven SUI and who were willing to participate in the study. Excluded were women with predominant symptoms of urge urinary incontinence (defined as urge incontinence being more prevailing than stress incontinence), with recurrent and difficult to treat urinary tract infections, women who had a post void bladder retention (>150 ml), a bladder capacity less than 200 ml or a physical/mental impairment which would make participation impossible.

Study design

A standardized history was taken and physical examination was performed preoperatively, at 2, 6, 12, 24 and 36 months postoperatively. For this study the postoperative situation at 2 and 36 months was analyzed. Investigative preoperative multi-channel urodynamics was performed in all women. Flowmetry was carried out before and 2 months after TVT in respectively 552 and 182 women. Postvoid residual urine was determined preoperatively and at each visit postoperatively.

Women with a postvoid residual of more than 150 ml for more than 24 hours after surgery either stayed hospitalized until the postvoid residual was lower than 150 ml or left the hospital with a catheter (or learned self intermittent catheterization).

All women were asked to complete the short version of the Incontinence Impact Questionnaire (IIQ-7) and the Urogenital Distress Inventory (UDI-6) before surgery and at the at 2, 6, 12, 24 and 36 months postoperative. The questionnaires, a postage-paid return envelope and instructions were sent to the patient by mail. Researchers as well as participating gynecologists and urologists were blinded to the individual results of these questionnaires. The long form IIQ (30 questions) & UDI (19 questions) are disease specific health-related quality of life questionnaires[12]. A short form for both questionnaires has been validated and consists of seven and six questions respectively (IIQ-7 & UDI-6)[13]. These questionnaires were translated into Dutch language and validated for the Dutch female population[14]. 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. The IIQ measures the impact and implications of urinary incontinence for normal daily functioning. The total score of the IIQ-7 and UDI-6 and each domain is transformed to a scale from 0-100 (a higher score indicates more bother). 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. Among the 41 hospitals were 3 university hospitals, 25 teaching and 13 non-teaching hospitals. All surgeons were qualified to perform vaginal surgery, received a brief training in TVT and performed TVT as described by Ulmsten[5]. The operation was carried out under local anesthesia using 0.25% prilocaïne with adrenalin (and general sedation), spinal analgesia or general anesthesia. At the end of the procedure a Hegar sound number 7 was introduced in the urethra in order to detect any obstruction of the urethra.

Outcome measures and definitions

VD was defined by several parameters, which were used as outcome measures. The first outcome measure was the need of postoperative catheterization. Secondly, women were asked whether voiding went easy or difficult. Third, question 5 of the short form of the Urogenital Distress Inventory (UDI-6) informing about difficulty in emptying the bladder, was used. This question has four options for an answer: not impaired (score 0), slightly impaired (score 1), moderately impaired (score 2) or greatly impaired (score 3). The fourth outcome measure was the maximum flow rate, prior to and 2 months after TVT. The fifth was the postvoid residual urine.

Definitions used are according the recommendations of the International Continence Society[15]. Postoperative urinary retention was defined as the need of catheterization for more than 24 hours. Abnormal maximum flow rate was defined as a flow rate of less than 15 ml/s. Abnormal postvoid residual urine was defined as higher than 100 ml, except for the direct postoperative period where the level was set at 150 ml. Pelvic organ prolapse was dichotomized according to Baden-Walker classification[16]. Grade 0 was defined as no pelvic organ prolapse and grade ? 1 as a pelvic organ prolapse.

Statistical analysis

All data were anonymously processed by a research physician (TMB) and the secretary of the research team. Statistical analysis was performed with SPSS 11.5 for Windows.

Chi-square test was used to compare proportions relating to subjects in different groups. The Student t-test was used as a statistic to compare interval variables. To analyze paired data the Mc Nemar test was used for categorical variables. Multivariate logistic regression analysis was used to construct a prediction model to determine pre- and postoperative factors that independently influenced the voiding difficulty 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 < 0.10 in the univariate analysis.

The mean difference was chosen to be significant at the 0.05 level. Data are presented as mean ($\pm$ standard deviation) or numbers (%).

RESULTS

Data in this study are from the Dutch TVT database, which originally contained 809 women. For this study women in whom no urodynamic investigation prior to TVT was performed (n = 106) were left out of the analysis. This left 703 women for analysis.

The mean age at the time of surgery was 51.3 (± 10.1) years. The mean parity was 2.4 (± 1.0) and the median and range were 2.0 respectively 0 - 9, while only 16 women were nulliparous. 43.6% of women were postmenopausal and 13.9% used hormonal replacement therapy. Previous prolapse surgery was present in 61 (8.7%) women, previous incontinence surgery in 43 (6.1%) women, and prolapse and incontinence surgery in 15 (2.1%) women. The mean length of surgery was 34 (± 13.7) minutes. In 47 (6.7%) women TVT was combined with prolapse surgery and in 40 (5.7%) women non-urogynecological procedures, like for example sterilization, were carried out. Local anesthesia (with sedation) was used in 80.1%, spinal anesthesia in 8.2% and general anesthesia in 11.7%.

Postoperative catheterization due to urinary retention was necessary in 81 (11.5%) of women. Of these 81 women 66% voided normal within 2 days, 95% within 10 days, while in 4 women (5%) catheterization up to 90 days was needed. The mean length of catheterization was 5.07 (± 12.5, median 2) days. The mean number of voids before reaching a postvoid residual of less than 150 ml was 1.95 (± 1.04, median 2) in women after spontaneous voiding and 2.62 (± 0.9, median 3) in women who started voiding after catheterization ($p<0.001$). Tape division or adhaesiolysis of the tape due to permanent urinary retention was necessary 9 women (1.3%). Except for one woman, all voided normal afterwards and remained continent. Tape division was done in 5 women within 2 months after the TVT procedure, in 2 women between 2 and 6 months, and in another two women between 6 and 12 months. In one woman the removal of the tape resulted in an urethro-vaginal fistula.

In table 1 the prevalence of VD stratified by the various definitions and the response rates are presented. By omission women were not asked about VD prior to the surgical procedure. VD as assessed by the statement of the woman increased significantly between 2 and 36 months. The prevalence of women with an abnormal maximum flow rate and with abnormal postvoid residual urine increased significantly after 2 months.

In table 2 the changes in symptoms of voiding difficulty are listed. Significantly more women improved than developed voiding difficulty as assessed with the UDI after 36 months. The actual numbers of women having abnormal maximum flow rate or residual urine prior to TVT are low.

In table 3 the impact of the various parameters of voiding difficulty on quality of life is presented. All women improved significantly on the IIQ score 2 and 36 months postoperative. Women with difficulty emptying assessed with the UDI at 2 and 36 months scored lower at the IIQ then women without difficulty in emptying their bladder. Both groups though improved significantly compared to pre-operative scores on their quality of life. Women reporting voiding difficulty at 36 months

improved on their quality of life scores compared with pre-operative scores, but scored worse than women without voiding difficulty.
In table 4, a univariate and multivariate analysis are presented for possible risk factors in women reporting moderately to greatly impairment of voiding difficulty on the UDI at 36 months. After multivariate analysis two risk factors emerge for the development of voiding difficulty: preoperatively existing voiding difficulty and TVT with concomitant prolapse surgery.

Discussion

Voiding does not necessarily return to normal immediately after the TVT procedure. The need of postoperative catheterization ranges from 3% to 50% after TVT, while the length of catheterization may be up to 180 days postoperative as shown in table 5. Our data, being collected from a large multicenter study, are in accordance with other studies. It is apparent that in a small minority of women long-term postoperative catheterization, arbitrarily defined as more than 10 days, is necessary ranging between 0.6% in this study up to 11% in the study of Ward and Hilton[6].

The second way to determine VD is the number of voids before a normal postvoid residue is present. The median time to adequate spontaneous voiding was 2 days and is in agreement with other studies[17, 18]. In women needing postoperative catheterization the median time before reaching a postvoid residual of less than 150 ml was 3 days and statistically different from women with no need of postoperative catheterization. Despite this being a statistically significant difference, this has no clinical relevance. Longer periods have been observed in women undergoing TVT combined with prolapse surgery or when local or spinal analgesia is used[19-21].

A third method is the necessity of tape revision (either division or excision) or urethral dilatation due to permanent urinary retention, which ranges between 0.6 to 7.5% respectively 1.9 to 8% (table 5). The need of tape division in this study 1.3% and in accordance with findings in other studies[7, 21-25].

The fourth way to assess VD can be the reports of women (table 5). Difficult voiding as determined on the basis of what women report (either direct by oral history or by quality-of-life questionnaires) ranges between 4 to 78%. Often women do not directly state true VD, but more that voiding became less easy as in the study of Sander et al[26]. Difficult voiding may be present already prior to TVT: in this study in 30.9% and in Ward and Hilton's study in 79%, and after surgery this declines to 24.9 % respectively 60% [7].

The fifth way to asses VD can be with the aid of flowmetry. Reduced maximum flow rates are observed up to 43% after TVT. In this study, results indicate that the maximum flow rate diminished significantly after TVT. In women with a normal maximum flow rate prior to TVT, 37% developed an abnormal flow rate postoperative. However, we also found the opposite, abnormal flow rates returned to normal values after TVT in 50%. As far as postvoid residual urine values are concerned the same pattern was observed. Apparently VD may arise but can also resolve after a TVT procedure.

Several risk factors for the development of urinary retention and VD have been identified in literature. After multivariate analysis the following independent risk factors are described: increasing age[21], decreasing body mass index[21], previous incontinence surgery[21], low maximum flow rate[22, 25] and postoperative urinary tract infection[21, 22, 25]. In this study only preoperative existing VD, determined by the UDI-6, and simultaneously performed prolapse surgery could be identified as independent risk factors for developing VD after TVT. In a univariate analysis (but not after multivariate analysis) concomitant posterior repair was correlated to development of VD. This is

in agreement to Sokol et al. who found in a univariate analysis (but also not after multivariate analysis) that TVT with posterior repair was related to VD [21]. We feel that this may be due to low numbers. Voiding disorders might be attributed to surgical inexperience[27]. Wang et al. found more cases of urinary retention and obstructed voiding in their first 15 patients[25]. We found no differences between the first 10, second 10 or more than 20 procedures per surgeon, indicating no learning curve effect. Data about VD in literature are often difficult to interpret. This is due to the lack of proper definitions for VD, urinary retention and abnormal postvoid residue rates. Furthermore, the management of postoperative urinary retention is highly variable in the gynecologic community[28]. Finally the length of follow-up is quite different among all studies. These factors might in part explain the large differences in the need for postoperative catheterization and occurrence of VD after TVT as is shown in table 5.

VD may represent a major bothersome problem for women. For this reason we tried to determine the impact of difficult voiding on quality of life after TVT. Women reporting VD either during a visit to their physician or on the quality of life (IIQ-7) questionnaires have statistically significant higher IIQ-7 values after 36 months, indicating less improvement in quality of life than women without symptoms of voiding difficulty. Nevertheless, compared to their preoperative situation their IIQ-7 values are still significantly lower and hence, all women are still much better off after the TVT procedure. In more objective parameters like the maximum flow rate and postvoid residual urine this difference between normal and abnormal voiding was not found and women with or without these abnormal voiding parameters have an equal and statistically significant improvement in quality of life.

Several theories exist about the cause of urinary retention and VD after incontinence surgery. Peri-urethral edema, increased contractility or obstruction of the smooth urethral sphincter, inhibited relaxation of the striated urethral sphincter and suppressed contractility of the detrusor muscle have been suggested[29]. In all patients participating in this study, sounding of the urethra at the end of the TVT procedure was performed and never an anatomical obstruction was noted. Bladder neck position remains the same after TVT, this was demonstrated by the cotton swab straining angle (Q-tip test), perineal ultrasound and MRI studies[11, 30-32]. Urodynamic studies carried out before and after TVT showed increased stress maximum urethral closure pressure, decreased maximum flow rates and increased voiding detrusor pressure, mean detrusor pressure and mean urethral resistance postoperatively[31-35]. When no anatomical changes in the bladder neck support at rest occur, it is likely that the outflow resistance increases during voiding. No anatomical obstruction during surgery was observed in this study. We were unable to determine the cause of urinary retention and VD. However on the basis of above mentioned possible effects of TVT, increased outflow resistance seems a likely cause for the observed VD and reduced flow rates.

In conclusion, VD, irrespective how defined, may arise after a TVT procedure. In most women the clinical course of urinary retention after TVT is mild. Preoperative existing voiding difficulty and concomitant prolapse surgery were found to be independent risk factors. This study showed that quality of life after TVT was negatively

influenced by the existence of VD. However, all women with and without voiding difficulties showed better quality of life scores postoperatively in comparison to preoperative.

REFERENCES

1. BURCH JC (1961) Urethrovaginal fixation to Cooper's ligament for correction of stress incontinence, cystocele, and prolapse. Am J Obstet Gynecol 81:281-290
2. BURCH JC (1968) Cooper's ligament urethrovesical suspension for stress incontinence. Nine years' experience—results, complications, technique. Am J Obstet Gynecol 100:764-774
3. SCHRAFFORDT KOOPS SE, BISSELING TM, HEINTZ APM, VERVEST HAM (2006) Quality of life before and after TVT, a prospective multi centre cohort study, results from the Netherlands TVT database. BJOG 113:26-29
4. ULMSTEN U, PETROS P (1995) Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. Scand J Urol Nephrol 29:75-82
5. 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 Pelvic Floor Dysfunct 7:81-85
6. WARD K, HILTON P (2002) Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. BMJ 325:67-
7. WARD KL, HILTON P (2004) 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 190:324-331
8. DELANCEY JO (1994) Structural support of the urethra as it relates to stress urinary incontinence: the hammock hypothesis. Am J Obstet Gynecol 170:1713-1720
9. PETROS PE, ULMSTEN UI (1990) An integral theory of female urinary incontinence. Experimental and clinical considerations. Acta Obstet Gynecol Scand Suppl 153:7-31
10. PETROS PE, ULMSTEN UI (1993) An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol Suppl 153:1-93
11. 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 Pelvic Floor Dysfunct 7:81-85
12. LO TS, WANG AC, HORNG SG, LIANG CC, SOONG YK (2001) Ultrasonographic and urodynamic evaluation after tension free vagina tape procedure (TVT). Acta Obstet Gynecol Scand 80:65-70
13. SHUMAKER SA, WYMAN JF, UEBERSAX JS, MCCLISH D, FANTL JA (1994) Health-related quality of life measures for women with urinary incontinence: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. Continence Program in Women (CPW) Research Group. Qual Life Res 3:291-306
14. UEBERSAX 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 the Urogenital Distress Inventory. Continence Program for Women Research Group. Neurourol Urodyn 14:131-139
15. VAN DER VAART CH, DE LEEUW JR, ROOVERS JP, HEINTZ AP (2003) Measuring health-related quality of life in women with urogenital dysfunction: The urogenital distress inventory and incontinence impact questionnaire revisited. Neurourol Urodyn 22:97-104

16. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, van KP, Victor A, Wein A (2002) The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 21:167-178
17. Meschia M, Pifarotti P, Bernasconi F, Guercio E, Maffiolini M, Magatti F, Spreafico L (2001) Tension-Free vaginal tape: analysis of outcomes and complications in 404 stress incontinent women. Int Urogynecol J Pelvic Floor Dysfunct 12 Suppl 2:S24-S27
18. Murphy M, Heit MH, Fouts L, Graham CA, Blackwell L, Culligan PJ (2003) Effect of anesthesia on voiding function after tension-free vaginal tape procedure. Obstet Gynecol 101:666-670
19. Adamiak A, Milart P, Skorupski P, Kuchnicka K, Nestorowicz A, Jakowicki J, Rechberger T (2002) The efficacy and safety of the tension-free vaginal tape procedure do not depend on the method of analgesia. Eur Urol 42:29-33
20. Partoll LM (2002) Efficacy of tension-free vaginal tape with other pelvic reconstructive surgery. Am J Obstet Gynecol 186:1292-1295
21. Sokol AI, Jelovsek JE, Walters MD, Paraiso MF, Barber MD (2005) Incidence and predictors of prolonged urinary retention after TVT with and without concurrent prolapse surgery. Am J Obstet Gynecol 192:1537-1543
22. Hong B, Park S, Kim HS, Choo MS (2003) Factors predictive of urinary retention after a tension-free vaginal tape procedure for female stress urinary incontinence. J Urol 170:852-856
23. Karram MM, Segal JL, Vassallo BJ, Kleeman SD (2003) Complications and untoward effects of the tension-free vaginal tape procedure. Obstet Gynecol 101:929-932
24. Klutke C, Siegel S, Carlin B, Paszkiewicz E, Kirkemo A, Klutke J (2001) Urinary retention after tension-free vaginal tape procedure: incidence and treatment. Urology 58:697-701
25. Wang KH, Wang KH, Neimark M, Davila GW (2002) Voiding dysfunction following TVT procedure. Int Urogynecol J Pelvic Floor Dysfunct 13:353-357
26. Sander P, Moller LM, Rudnicki PM, Lose G (2002) Does the tension-free vaginal tape procedure affect the voiding phase? Pressure-flow studies before and 1 year after surgery. BJU Int 89:694-698
27. Bodelsson G, Henriksson L, Osser S, Stjernquist M (2002) Short term complications of the tension free vaginal tape operation for stress urinary incontinence in women. BJOG 109:566-569
28. Nguyen JK, Glowacki CA, Bhatia NN (2001) Survey of voiding dysfunction and urinary retention after anti-incontinence procedures. Obstet Gynecol 98:1011-1017
29. Fitzgerald MP, Brubaker L (2001) The etiology of urinary retention after surgery for genuine stress incontinence. Neurourol Urodyn 20:13-21
30. Halaska M, Otcenasek M, Martan A, Masata J, Voigt R, Seifert M (1999) Pelvic anatomy changes of TVT procedure assessed by MRI. Int Urogynecol J 10:S88-
31. Klutke JJ, Carlin BI, Klutke CG (2000) The tension-free vaginal tape procedure: correction of stress incontinence with minimal alteration in proximal urethral mobility. Urology 55:512-514

32. Mutone N, Mastropietro M, Brizendine E, Hale D (2001) Effect of tension-free vaginal tape procedure on urodynamic continence indices. Obstet Gynecol 98:638-645
33. Hardart A, Klutke JJ, Klutke CG, Carlin B (2000) Altered voiding after the tension-free vaginal tape procedure: Is increased resistance the mechanism of therapy? Obstet Gynecol 95:55S-
34. Moran PA, Ward KL, Johnson D, Smirni WE, Hilton P, Bibby J (2000) Tension-free vaginal tape for primary genuine stress incontinence: a two-centre follow-up study. BJU Int 86:39-42
35. Wang AC, Lo TS (1998) Tension-free vaginal tape. A minimally invasive solution to stress urinary incontinence in women. J Reprod Med 43:429-434
36. Ulmsten U, Falconer C, Johnson P, Jomaa M, Lanner L, Nilsson CG, Olsson I (1998) A multicenter study of tension-free vaginal tape (TVT) for surgical treatment of stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 9:210-213
37. 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 Gynaecol 106:345-350
38. Mishra VC, Mishra N, Karim OM, Motiwala HG (2005) Voiding dysfunction after tension-free vaginal tape: a conservative approach is often successful. Int Urogynecol J Pelvic Floor Dysfunct 16:210-214
39. Cetinel B, Demirkesen O, Onal B, Akkus E, Alan C, Can G (2004) Are there any factors predicting the cure and complication rates of tension-free vaginal tape? Int Urogynecol J Pelvic Floor Dysfunct 15:188-193
40. Minassian VA, Al-Badr A, Drutz HP, Lovatsis D (2004) Tension-free vaginal tape, Burch, and slings: are there predictors for early postoperative voiding dysfunction? Int Urogynecol J Pelvic Floor Dysfunct 15:183-187
41. Lukacz ES, Luber KM, Nager CW (2003) The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. Int Urogynecol J Pelvic Floor Dysfunct 14:179-184
42. Kuuva N, Nilsson CG (2002) A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. Acta Obstet Gynecol Scand 81:72-77
43. Abdel-Hady e, Constantine G (2005) Outcome of the use of tension-free vaginal tape in women with mixed urinary incontinence, previous failed surgery, or low valsalva pressure. J Obstet Gynaecol Res 31:38-42
44. Al-Badr A, Ross S, Soroka D, Minassian VA, Karahalios A, Drutz HP (2003) Voiding patterns and urodynamics after a tension-free vaginal tape procedure. J Obstet Gynaecol Can 25:725-730

Table 1. Prevalence of voiding difficulty stratified by various definitions prior to and at 2 and 36 months after TVT

	prior to TVT		after 2 months				after 36 months				
	N	%	follow-up	N	%	p-value#	follow-up	N	%	p-value#	p-value⋆
As reported by the women	na		93%				73%				
no voiding difficulty				486	82.8%			365	74.0%		
reporting voiding difficulty				101	17.2%	na		128	26.0%	na	< 0.001
Difficulty in emptying the bladder (UDI-6)			68%				73%				
not at all or slightly impaired	436	69.1%		335	71.1%			374	75.1%		
moderately to greatly impaired	195	30.9%		136	28.9%	0.467		124	24.9%	0.026	0.163
Maximum flowrate								na			
≥ 15 ml/s	461	83.5%		108	59.3%						
< 15 ml/s	91	16.5%		74	40.7%	<0.001				na	na
Residual urine											
≤ 100 ml	594	99.0%		364	90.5%			75	96.2%		
> 100 ml	6	1.0%		38	9.5%	< 0.001		3	3.8%	0.039	0.105

X^2 test was performed
= p-value which compared postoperative values with preoperative values
⋆ = p-value which compared 2 months postoperative values with 36 months postoperative values
na = not assessed

Table 2. Changes in symptoms of voiding difficulty

		2 months postoperative		36 months postoperative	
		%	p-value	%	p-value
Difficulty in emptying the bladder (UDI-6)					
not at all or slightly impaired preoperative	*remained unchanged*	73.7%		82.5%	
	worsened	26.3%	0.090	17.5%	0.034
moderately to greatly impaired preoperative	*remained unchanged*	35.0%		41.1%	
	improved	65.0%		58.9%	
Maximum flowrate					
≥ 15 ml/s preoperative	*remained unchanged*	62.8%			
	became < 15 ml/s	37.2%	<0.001		
< 15 ml/s preoperative	*remained unchanged*	50.0%			
	became ≥ 15 ml/s	50.0%			
Residual urine					
≤ 100 ml preoperative	*remained unchanged*	91.2%		95.8%	
	became > 100 ml	8.8%	<0.001	4.2%	0.625
> 100 ml preoperative	*remained unchanged*	0.0		0.0%	
	became ≤ 100 ml	100.0%		100.0%	

McNemar test was performed

Table 3. Changes in mean IIQ-7 score stratified by various definitions for voiding difficulty

	preoperative		after 2 months postoperative			after 36 months postoperative		
	IIQ-7 value mean (SD)	p-value#	IIQ-7 value mean (SD)	p-value#	p-value⋆	IIQ-7 value mean (SD)	p-value#	p-value⋆
As reported by the women								
no voiding difficulty at 2 months	59.4 (29.2)		14.6 (20.8)		< 0.001			
reporting voiding difficulty at 2 months	51.7 (19.8)	0.001	17.2 (22.7)	0.340	< 0.001			
no voiding difficulty at 36 months	56.6 (19.4)					11.1(17.8)		< 0.001
reporting voiding difficulty at 36 months	60.0 (19.2)	0.101				21.1 (24.6)	< 0.001	< 0.001
Difficulty in emptying the bladder (UDI-6)								
not at all or slightly impaired at 2 months	57.1 (20.0)		12.7 (19.3)		< 0.001			
moderately to greatly impaired at 2 months	58.6 (20.0)	0.452	24.7 (25.1)	0.001	< 0.001			
not at all or slightly impaired at 36 months	56.0 (19.5)					9.77 (15.3)		< 0.001
moderately to greatly impaired at 36 months	62.0 (19.3)	0.004				26.9 (26.8)	< 0.001	< 0.001
Maximum flowrate								
≥ 15 ml/s at 2 months	56.5 (20.5)		14.1 (20.0)		< 0.001			
< 15 ml/s at 2 months	57.7 (20.5)	0.711	13.0 (18.0)	0.751	< 0.001			
Residual urine								
≤ 100 ml at 2 months	57.9 (20.2)		16.4 (22.2)		< 0.001	9.50 (16.4)		< 0.001
> 100 ml at 2 months	58.0 (22.1)	0.967	14.4 (21.3)	0.653	< 0.001	1.59 (2.7)	0.412	0.085
≤ 100 ml at 36 months	55.8 (20.0)					9.50 (16.4)		< 0.001
> 100 ml at 36 months	60.3 (29.0)					1.59 (2.7)	0.412	0.085

= p-value, Student t-test was performed
⋆ = p-value, Paired T-test was peformed
SD = Standard Deviation

Table 4. Uni- and multivariate analysis of determinants of voiding difficulty as determined by UDI question 5 at 36 months

	UNIVARIATE ANALYSIS				MULTIVARIATE ANALYSIS			
	moderately to greatly impaired (n =124)		not at all or slightly impaired (n =374)		OR [95% CI]	*p*-value	B [95% CI]	*p*-value
General Data								
age (years ± sd)	52.6 (10.6)		51.1 (9.2)			0.138		
parity (mean ± sd)	2.5 (1.1)		2.4 (0.9)			0.091	2.35 [0.26-5.86]	0.446
Parity								
nulliparity	1	0.8%	7	1.9%	2.34 [0.28-19.25]	0.686		
multiparity	123	99.2%	367	98.1%				
menopausal status								
premenopausal	51	43.2%	191	54.1%	0.64 [0.42-0.98]	0.044	0.75 [0.46-1.22]	0.255
postmenopausal	67	56.8%	162	45.9%				
Urogynecological History								
no previous urogynaecological surgery	98	79.0%	319	85.3%		0.105		
previous prolapse surgery	10	8.1%	26	7.0%				
previous incontinence surgery	10	8.1%	24	6.4%				
previous incontinence and prolapse surgery	6	4.8%	5	1.3%				
hysterectomy								
incontinence episodes								
daily	97	92.4%	309	92.8%	1.06 [0.46-2.44]	0.833		
weekly	6	7.6%	24	7.2%				
intrinsic sphincter deficincy								
yes	10	8.1%	18	4.8%	1.74 [0.78-3.86]	0.181		
no	114	91.9%	356	95.2%				
Pelvic Floor Status prior to TVT								
cystocele								
no cystocele	62	58.5%	183	54.8%	0.86 [0.55-1.34]	0.575		
cystocele	44	41.5%	151	45.2%				
rectocele								
no rectocele	78	72.2%	273	79.4%	1.48 [0.90-2.42]	0.147		
rectocele	30	27.8%	71	20.6%				
prolaps of uterine cerix of vaginal vault								
no prolapse of cervix of vaginal vault	86	78.2%	277	80.3%	1.13 [0.67-1.92]	0.683		
prolapse of cervix of vaginal vault	24	21.8%	71	19.7%				
urethral hypermobility								
no hypermobility	102	100.0%	303	100.0%	n.a.	1,000		
hypermobility	0	0.0%	0	0.0%				

type of hospital setting								
no. of TVT in teaching hospitals	77	62.1%	231	61.8%	0.98 [0.65-1.49]	1,000		
no. of TVT in non-teaching hospitals	47	37.9%	143	38.2%				
Simultaneous Procedures								
TVT only	101	81.5%	343	91.7%		r		
TVT with prolapse surgery	13	10.5%	18	4.8%	2.45 [1.16-5.18]	0.027	3.03 [1.16-7.88}	**0.023**
TVT with other surgical procedures	10	8.1%	13	3.5%	2.61 [1.12-6.14]	0.040	2.01 [0.69-5.86]	0.199
Type of simultaneous prolaps procedure								
TVT only	111	89.5%	356	95.2%		r		
TVT with vaginal hysterectomy	0	0.0%	3	0.8%	n.a.	1,000		
TVT with anterior vaginal wall repair	2	1.6%	5	1.3%	1.28 [0.24-6.70]	0.673		
TVT with posterior vaginal wall repair	9	7.3%	6	1.6%	4.81 [1.68-13.81]	0.004	3.40 [0.28-41.21]	0.336
TVT with anterior & posterior repair	2	1.6%	4	1.1%	1.60 [0.29-8.87]	0.632		
Type of Anesthesia								
local anesthesia (with sedation)	95	80.5%	286	80.6%		r		
spinal analgesia	5	4.2%	39	11.0%	0.38 [0.15-1.01]	0.059	0.31 [0.08-1.21]	0.091
general anesthesia	18	15.3%	30	8.5%	1.81 [0.96-3.38]	0.081	1.21 [0.38-3.85]	0.750
Surgeon's Experience								
learning curve effect								
first 10 procedures for each surgeon	50	40.3%	129	34.5%				
next 10 procedures for each surgeon	21	16.9%	79	21.1%		0.417		
more than 20 procedures for each surgeon	53	42.7%	166	44.1%				
Pre-operative Voiding Difficulty								
voiding difficulty								
no voiding difficulty (on UDI-6 Q5)	57	49.6%	269	76.4%	3.29 [2.12-5.12]	**0.000**	3.26 [2.01-5.29]	**0.000**
voiding difficulty (on UDI-6 Q5)	58	50.4%	83	23.6%				
maximum flow rate								
normal max flow rate (>= 15 ml/s)	77	78.6%	258	84.9%	1.53 [0.86-2.72]	0.161		
abnormal max flow rate (< 15 ml/s)	21	21.4%	46	15.1%				
postvoid residue								
normal postvoid residue (< 100 ml)	103	98.1%	323	98.8%	1.57 [0.28-8.68]	0.636		
abnormal postvoid residue (> 100 ml)	2	1.9%	4	1.2%				

statistically significant differences are highlighted
Values are mean (SD). number (%) and Odds Ratio [95% CI]
r = reference group; n.a. = could not be determined

Table 5. Voiding difficulty after TVT in several studies

	this study		Ulmsten [36,37]		Ward [6,7]			Mishra [38]		Çetinel [39]		Minassian [40]	Lukacz [41]	Hong [22]			Kuuva [42]	Sokol [21]	Karram [23]	Klutke [24]	Wang [25]	Abd [43]
number of patients	703		131	50	175			52		75		63	103	375			1455	267	350	600	57	658
observation period (months)	2 -36				24					6-38			12						48		> 3	6
postoperative catheterization																						
needing catheterization (%)	10.9	0.6	3	10	38	5	6	19	4	9	3	50	37	5.9	1.6	1	2.3c	4.1				
length of catheterization																						
minimum (days)	1	11		1	1	11	29			1		9a	4b	1	15							
maximum (days)	10	90	3	14	10	28	180	90	> 90	30	> 30			14	31	> 34		> 42				
surgery for urinary retention																						
tape revision (%)	1.3				0.6									1.1				7.5d	1.7	2.8	1.7	
urethral dilatation (%)																		1.9	8			
report of voiding difficulty																						
oral history (%)	26																		4.9		26f	4.4
quality of life questionnaire (%)	24.9				60																	
flowmetry																						
decreased max flow rate (%)	40.7												43									
abnormal postvoid redisue (%)	3.8											50e						11.2				

a. mean 9 ± 2 days
b. is median value
c. complete urinary retention
d. tape revision in women with concomitant prolapse surgery was 3.7%
e. postvoid residue > 200 ml
f. combination of PVR > 100 ml, daytime and nighttime micturition frequency > 6 resp. > 2 and urinary stream considered abnormal by the woman