TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up

ARTICLE *in* EUROPEAN UROLOGY · FEBRUARY 2008

Impact Factor: 13.94 · DOI: 10.1016/j.eururo.2007.08.021 · Source: PubMed

6 AUTHORS, INCLUDING:

Pierre Bonnet
University of Liège
62 PUBLICATIONS **678** CITATIONS
SEE PROFILE

Jean de Leval
University of Liège
29 PUBLICATIONS **1,195** CITATIONS
SEE PROFILE

EUROPEAN UROLOGY XXX (2007) XXX–XXX

available at www.sciencedirect.com
journal homepage: www.europeanurology.com

European Association of Urology

Female Urology - Incontinence

TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up

David Waltregny *, *Yves Gaspar*, *Olivier Reul*, *Wissem Hamida*, *Pierre Bonnet*, *Jean de Leval*

Department of Urology, University Hospital of Liège, Liège, Belgium

Article info

Article history:
Accepted August 10, 2007
Published online ahead of print on August 21, 2007

Keywords:
Female stress urinary incontinence
Suburethral slings
Transobturator
TVT-O

Abstract

Objectives: Medium-term results of transobturator tapes for the treatment of female stress urinary incontinence (SUI) are largely unknown. We analyzed the 3-yr results of a prospective, observational study designed to evaluate the safety and efficacy of the TVT-O procedure.

Methods: Preoperative and postoperative evaluations included physical examination, uroflowmetry and postvoid residual (PVR) measurement, and urinary symptoms and quality of life (QoL) questionnaires. Data were compared by means of the Wilcoxon matched pairs test.

Results: Between March 2003 and December 2003, 102 consecutive patients with clinical and urodynamic diagnoses of SUI who fulfilled inclusion and exclusion criteria underwent the TVT-O procedure; the latter was associated with pelvic organ prolapse treatment in 16 patients (15.7%). Three-year minimum follow-up (median, 40 mo) was available for 91 patients (89.2%). No erosion or persistent pain was noted. Four patients required tape release or section. Disappearance and improvement of SUI were observed in 88.4% and 9.3% of the patients, respectively. These cure rates were similar to those obtained 1 yr after the operation ($p = 0.55$). Frequency and urge symptoms were improved at 3 yr ($p < 0.005$). Whereas maximum flow rates were somewhat decreased ($p = 0.01$), the severity of obstructive symptoms and PVR volumes were not statistically different ($p = 0.11$ and $p = 0.32$, respectively). Incontinence severity and QoL scale scores were largely better than preoperative ones ($p < 0.001$) and did not differ from those reported at 1 yr ($p = 0.15$ and $p = 0.08$, respectively).

Conclusions: The TVT-O procedure is a safe and efficient treatment of female SUI, with maintenance of high cure rates after a 3-yr minimum follow-up.

* Corresponding author. Department of Urology, Central Building, Bat B35, level –1, CHU Sart Tilman Liège, B-4000 Liège, Belgium. Tel. +32 4 3667251; Fax: +32 4 3667258.
E-mail address: David.Waltregny@ulg.ac.be (D. Waltregny).

0302-2838/$ – see back matter doi:10.1016/j.eururo.2007.08.021

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

1. Introduction

Minimally invasive suburethral sling procedures have become a mainstay for the surgical treatment of women with stress urinary incontince (SUI). The tension-free vaginal tape (TVT) procedure introduced by Ulmsten [1] more than 10 yr ago is now considered by many surgeons to be the gold standard surgery for female SUI [2]. This surgical technique, which uses a retropubic route for the insertion of the tape, has been shown to be effective over a period of 7 yr, with objective and subjective SUI cure rates of around 80% [3]. Although the TVT procedure appears to be safe and efficacious at long-term, complications resulting from the penetration of the surgical device into pelvic organs, nerves, and vessels have been reported [2].

An alternative approach to the retropubic sling technique, the transobturator route, in which the tape is inserted through the obturator foramina either ''outside-in'' (TOT) [4] or ''inside-out'' (TVT-O) [5], has been proposed with the theoretical safety advantage of avoiding the pelvis. The results of several nonrandomized [6–11] and randomized [12–19] comparative studies indicate that retropubic and transobturator techniques may generate similar postoperative SUI cure rates. However, medium- and long-term results of transobturator tapes are currently lacking. Indeed, the vast majority of available studies including ours [5,20] have analyzed the outcomes after mean or median follow-up times less than 3 yr, generally not exceeding 12 mo [2].

To accurately evaluate the safety and efficacy of the TVT-O procedure, we initiated a prospective, observational study at our institution in March 2003. The 1-yr results of the first 102 patients who underwent the procedure have been previously reported [20]. The SUI complete cure rate was 91%, whereas SUI symptoms improved in 5% of the patients. The TVT-O procedure was also found to be associated with a low perioperative and short-term postoperative morbidity. Herein the same cohort of 102 consecutive patients were evaluated after a 3-yr minimum follow-up and results were compared with those obtained at 1-yr.

2. Methods

2.1. Design of the trial

The design of this prospective, observational trial has been previously detailed [20]. Briefly, since March 2003, all women with urodynamic stress incontinence who were offered a surgical treatment were candidates for inclusion in the trial if the following criteria were met: age between 25 and 85 yr, clinical and urodynamic diagnoses of SUI, positive stress test, and maximum cystometric capacity of 300 ml or greater. Patients with urodynamically proven detrusor overactivity or impaired bladder contractility, postvoid residual (PVR) 100 ml or greater, a contraindication to anesthesia, pregnancy, neurogenic bladder, or active urinary or vaginal infection were excluded from study.

Preoperative evaluation included detailed history, physical examination with a stress test, urine analysis, cystoscopy, and multichannel urodynamics. Preoperative evaluation of SUI, urgency, urge urinary incontinence (UUI), daytime frequency/nocturia, and lower urinary tract symptoms (LUTS) suggestive of bladder outlet obstruction was done with the use of the Measurement of Urinary Handicap (MUH) symptom-scoring questionnaire [21]. All patients were also asked to self-evaluate the severity of incontinence with a visual analogue scale graded from 0 to 10, with 0 corresponding to the absence of the symptom and 10 corresponding to the worst condition. Quality of life (QoL) was assessed at baseline with the use of the validated Ditrovie self-administered questionnaire [21].

The TVT-O procedure was performed in all patients as previously described [5]. Vaginal surgery or laparoscopic sacral colpopexy was performed simultaneously in women with symptomatic and/or significant (grade 3 or greater [22]) pelvic organ prolapse (POP). All patients were contacted by mail and/or telephone and invited to present to the follow-up visits, according to the follow-up chart of the study (Fig. 1). Follow-up evaluation at 1, 6, and 12 mo, and yearly thereafter included physical examination with a cough test, uroflowmetry with PVR measurement, and scoring of symptoms, QoL and visual analogue scales. To perform the cough test in the semilithotomy position, patients were invited to present with a full bladder. Postoperative complications were recorded, including urinary retention, the need for tape release/section, vaginal or urethral erosion, neurological complication, and persistent pain.

2.2. Definitions used

In this trial, cure of SUI was originally defined as the disappearance of subjective and objective SUI, as assessed both by SUI symptom scale scoring (no SUI reported by the patient) and by physical examination (negative cough test) [20]. In the current analysis, a significant proportion of patients denied the invitation to present to the follow-up visit but agreed to answer the MUH symptom-scoring questionnaire by phone interview. Moreover, in a few patients, the cough test was hardly interpretable because of a poorly filled bladder. Thus, since we had previously observed that none of the patients who reported SUI disappearance had a positive cough test, we decided to define cure of SUI as the disappearance of subjective SUI, as assessed by a SUI symptom scale score equal to 0. Symptom severity was arbitrarily considered as improved or worsened when symptom scale score had decreased or increased by at least 50%, respectively [20].

2.3. Statistical analysis

Comparisons between preoperative and postoperative symptoms, QoL and visual analogue scale scores, maximal flow

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

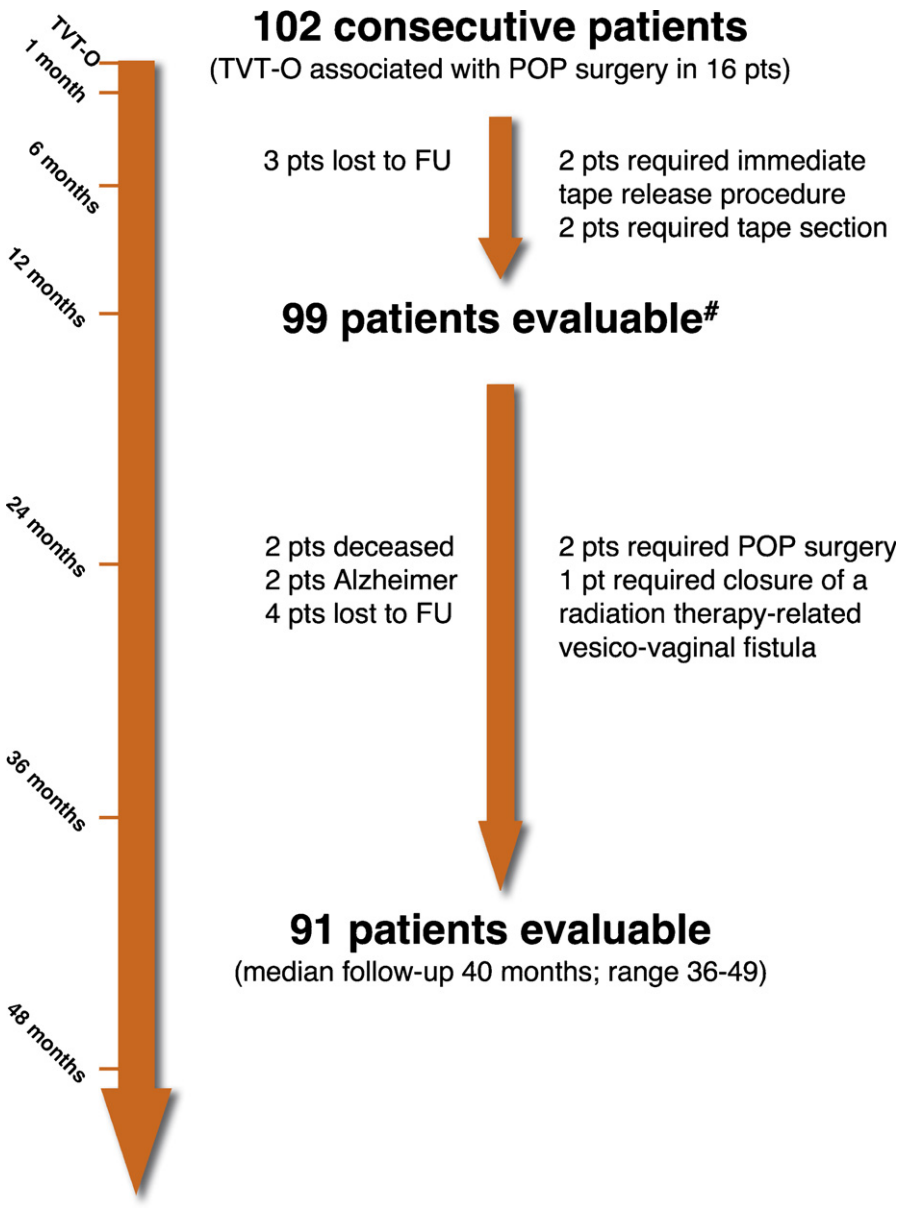

Fig. 1 – Progress of patients through trial.

rates (Q_{max}) and PVR volumes were performed with the Wilcoxon matched pairs test. Statistical tests were two-tailed and $p < 0.05$ was considered statistically significant.

3. Results

3.1. *Patients characteristics and progress through the trial*

Between March 2003 (ie, when the trial was initiated) and December 2003, 102 consecutive patients who fulfilled the inclusion and exclusion criteria underwent the TVT-O procedure. These patients were the focus of the current study because they were expected to have been followed at least 3 yr when this analysis was performed. Detailed baseline characteristics and 1-yr outcome of the patients analyzed herein have been previously reported [20]. The TVT-O procedure was associated with POP treatment in 16 patients (15.7%). Five of these patients did not complain of SUI. Rather, SUI presented after POP was reduced during vaginal examination (masked SUI).

The progress of the patients through the trial is shown in Fig. 1. In total, 11 (10.8%) of the 102 patients were either lost to follow-up or unevaluable at 3 yr. Three and 4 patients were completely lost to follow-up after the 1-mo and 1-yr visit, respectively. Four additional patients could not be evaluated after the

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

Table 1 – Analysis of subjective and objective SUI cure rates after 1-year and 3-year minimum follow-up (FU), using different assumptions about outcome for patients with missing data

Assumption	% (No./Total No.)					
	Cured only		Either cured or improved		With negative cough test	
	1-year FU	3-year FU	1-year FU	3-year FU	1-year FU	3-year FU
Women with data available at 3 years	90.9 (90/99)	87.9 (80/91)	95.9 (95/99)	96.7 (88/91)	91.9 (91/99)	90.2 (55/61)
Assuming all withdrawals are failures	88.2 (90/102)	78.4 (80/102)	93.1 (95/102)	86.3 (88/102)	89.2 (91/102)	53.9 (55/102)
Assuming all withdrawals are cured	91.2 (93/102)	89.2 (91/102)	96.1 (98/102)	97.1 (99/102)	92.2 (94/102)	94.1 (96/102)
Last observed result carried forward	91.2 (93/102)	88.2 (90/102)	96.1 (98/102)	96.1 (98/102)	92.2 (94/102)	93.1 (95/102)

1-yr visit. Two of them were dead, whereas the other two suffered from Alzheimer's disease. Among the 91 patients available for evaluation after a minimum follow-up of 3 yr, 30 (33%) declined the invitation to present at the visit. These 30 patients nevertheless agreed to be interviewed by telephone and declared that they were happy with the procedure, that their urinary condition was good/very good, and that they felt they did not require a follow-up visit. These reports were corroborated by the SUI symptom scores, which showed that all these patients, except one who was only improved, reported that they were cured. Indeed, all patients agreed to answer the MUH symptom scoring questionnaire as well as the self-administered incontinence severity and QoL questionnaires that were sent by postal mail. Overall, scores of symptoms, incontinence severity, and QoL scales were available for the 91 patients with a median follow-up of 40 mo.

3.2. *Objective and subjective SUI cure rates*

The impact of varying assumptions about losses to follow-up and missing data regarding SUI subjective and objective cure rates at 1-yr and 3-yr follow-up is given in Table 1. By analyzing only data available at 3 yr and ignoring dropouts, disappearance and improvement of SUI were observed, respectively, in 88.4% and 9.3% of the patients complaining of this symptom before the TVT-O procedure. One of the five patients with masked SUI developed SUI after a combined POP treatment and TVT-O procedure, and was considered as failed. Thus, in total, cure or improvement of SUI was reported by 87.9% and 8.8% of the patients, respectively. Similar subjective SUI cure and improvement rates were observed, either when it was assumed that all patients lost to follow-up or unevaluable patients were cured or when the data from the last available follow-up were substituted for all subsequent missing observations [23] (Table 1). At the last visit, the cough test was negative in all patients who reported disappearance of SUI. At 3 yr, 91.8% of the patients had a negative cough test when missing data were ignored (Table 1). Similar percentages were found when dropout patients were assumed to be cured or when results from the last cough test available at follow-up were imputed to substitute missing data (Table 1). Analysis of SUI subjective and objective cure rates with the assumption that all dropouts were failures yielded a worse outcome (Table 1).

3.3. *Comparisons between preoperative and postoperative data*

Table 2 shows the evolution of lower urinary tract symptoms (LUTS) after 3-yr minimum follow-up. Onset and worsening of urgency/UUI was reported

Table 2 – Postoperative urinary symptom evolution after 1-year and 3-year minimum follow-up

Symptom	% (No./Total No.)							
	Urgency		UUI		Frequency[a]		Obstruction[b]	
	1-year FU	3-year FU	1-year FU	3-year FU	1-year FU	3-year FU	1-year FU	3-year FU
Disappearance	78.1 (32/41)	71.1 (27/38)	73.7 (28/38)	71.4 (25/35)	46.1 (6/13)	60.0 (6/10)	55.6 (5/9)	75.0 (6/8)
Improvement	7.3 (3/41)	2.6 (1/38)	2.6 (1/38)	0.0 (0/35)	15.4 (2/13)	20.0 (2/10)	11.1 (1/9)	25.0 (2/8)
No change	12.2 (5/41)	21.0 (8/38)	23.7 (9/38)	22.9 (8/35)	38.5 (5/13)	20.0 (2/10)	33.3 (3/9)	0.0 (0/8)
Worsening	2.4 (1/41)	5.3 (2/38)	0.00 (0/38)	5.7 (2/35)	0.00 (0/13)	0.00 (0/10)	0.00 (0/9)	0.00 (0/8)
Onset	8.6 (5/58)	11.3 (6/53)	6.6 (4/61)	10.7 (6/56)	2.3 (2/86)	6.2 (5/81)	6.7 (6/90)	2.4 (2/83)

[a] Daytime frequency + nocturia.
[b] LUTS suggestive of bladder outlet obstruction.

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

by ±11% and ±5% of the patients, respectively, whereas 70–75% of the patients with preoperative urgency/UUI experienced either disappearance or improvement of these symptoms postoperatively. At the last visit, voiding difficulties were reported by less than 5% of the patients, whereas patients presenting these symptoms preoperatively reported improvement, the latter mainly in the group that underwent POP treatment. Comparisons between preoperative and postoperative urgency, UUI and daytime frequency/nocturia symptom scores showed a statistically significant decrease in the severity of these symptoms after 3-yr minimum follow-up (Table 3). There was no difference in intensity of LUTS suggestive of bladder outlet obstruction. Analysis of incontinence severity and impact of urinary symptoms on QoL showed a significant decrease in urinary leakage together with a significant improvement in QoL (Table 3). Uroflowmetry data were unavailable in the 30 patients who did not present to the follow-up visit and were uninterpretable in 2 other patients (Table 3). Q_{max} and PVR were slightly decreased and increased, respectively, after the procedure, with differences reaching statistical significance for Q_{max} only.

One-year and 3-yr postoperative data were also compared (Table 3). There was no significant difference in SUI cure rates between these two time points when all dropouts were ignored. Similarly, no difference was found when all dropouts were assumed to be cured or when the last available data were substituted for all subsequent missing ones (Wilcoxon matched pairs test $p = 0.92$ and $p = 0.55$, respectively). As compared with the 1-yr visit, urgency and UUI symptom scores were slightly increased at 3 yr. Daytime frequency/nocturia symptom scores were not different. Whereas Q_{max} and PVR did not differ, obstruction symptom scores were slightly decreased. There was no difference in incontinence severity and QoL scores.

3.4. *Complications*

Intraoperatively, only one complication—minor vaginal sulcus laceration—was recorded [20]. Within the first postoperative year, 4 patients required tape release or section [20]. One patient who had undergone pelvic radiation therapy 2 yr before the TVT-O procedure developed, 2 yr after TVT-O insertion, a vesicovaginal fistula that was unrelated to the TVT-O procedure and was successfully closed with the use of a Martius flap. Between the 1-yr and 3-yr visit, 2 patients developed symptomatic POP and were treated by laparoscopic sacral colpopexy. At the last visit, no complication or significant POP was

Table 3 – Preoperative and 1-year and 3-year postoperative urinary symptom scores, voiding parameters, incontinence severity scores and QOL scores

	Median preop (range) [mean ± SD]	Median 1-year postop (range) [mean ± SD]	Median 3-year postop (range) [mean ± SD]	*p* value[a]	
				Preop versus 3-year postop	1-year versus 3-year postop
Symptom scale scoring:					
SUI (max 8)	7 (0–8) [6.18 ± 1.68]	0 (0–8) [0.30 ± 1.1]	0 (0–6) [0.34 ± 1.01]	<0.0001	=0.5525
Urgency (max 4)	1 (0–4) [1.23 ± 1.28]	0 (0–4) [0.46 ± 0.81]	0 (0–4) [0.66 ± 1.07]	=0.0005	=0.0415
UUI (max 4)	0 (0–4) [1.08 ± 1.36]	0 (0–4) [0.45 ± 0.94]	0 (0–4) [0.61 ± 1.09]	=0.0036	=0.0669
Daytime frequency/nocturia (max 8)	1 (0–5) [0.98 ± 1.22]	0 (0–4) [0.46 ± 0.88]	0 (0–4) [0.42 ± 0.79]	=0.0006	=0.6204
LUTS suggestive of bladder outlet obstruction (max 4)	0 (0–4) [0.26 ± 0.74]	0 (0–3) [0.36 ± 0.72]	0 (0–2) [0.11 ± 0.38]	=0.1119	=0.0010
Visual analog scale scoring urinary incontinence severity (max 10)	6 (0–10) [5.66 ± 2.51]	0 (0–9) [0.74 ± 1.77]	0 (0–7) [1.06 ± 1.85]	<0.0001	=0.1550
Urinary symptom impact on QOL (10–50)	30 (10–46) [29.5 ± 9.21]	10 (10–46) [12.19 ± 4.88]	10 (10–37) [12.61 ± 5.09]	<0.0001	=0.0844
Voiding parameters:					
PVR (mL)[b]	0 (0–95) [9.2 ± 17.7]	5 (0–203) [19.6 ± 33.6]	0 (0–140) [13.7 ± 27.2]	=0.3202	=0.3806
Q_{max} (mL/sec)[c]	24 (7–68) [26.3 ± 12.2]	18 (3.7–49) [18.9 ± 9.0]	18 (5–53) [19.6 ± 11.0]	=0.0111	=0.7348

[a] Wilcoxon matched pairs test.
[b] Data missing on 31 patients.
[c] Data missing on 32 patients.

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

noted in the 61 patients who were examined. All patients were interviewed for symptoms suggestive of complications and for any intercurrent urogynecologic event. None presented symptoms suggestive of vaginal, bladder, or urethral erosion; neurologic complication; or persistent pain. One patient who had undergone radiation therapy for rectal cancer complained of recurrent lower urinary tract infections that were related neither to bladder outlet obstruction nor to tape erosion in the urethra or bladder.

4. Discussion

Suburethral tapes inserted via the transobturator route were pioneered in Europe a few years ago. These transobturator tapes have since been widely adopted for the treatment of SUI despite the lack of evidence for their long-term safety and efficacy. The same observation actually holds true for TVT, the gold standard surgery for female SUI, which gained wide popularity before medium-/long-term results of this technique became available. The views, practice, and preferences of urologists and urogynecologists worldwide with regard to transobturator tapes were recently surveyed by Abdel-Fattah and colleagues [24] via a postal/e-mail questionnaire. These authors reported that, whereas one third of the responding surgeons think that the transobturator approach for tension free vaginal tapes is the way forward for the management of SUI, the majority are awaiting studies with longer-term results. To our knowledge, the results of transobturator tapes after a 3-yr minimum follow-up have been reported in only one retrospective study that analyzed 24 patients who underwent an isolated TOT procedure and of whom 66.6% and 12.6% experienced complete cure and improvement of SUI, respectively, at 3-yr postoperatively. Whether these 3-yr SUI cure rates were similar to those obtained earlier during follow-up (eg, at 1 yr) has not been documented in that particular study.

In the current prospective study with a 3-yr minimum follow-up after the TVT-O procedure and an 11% dropout rate, complete cure of SUI was reported by 87.9% of the patients and SUI symptoms were considered to be improved in 8.8% of the patients. Objective SUI cure rate was 91.8%, with the limitation that physical examination with a cough test was performed in only two thirds of the patients at last visit. Globally, these subjective and objective cure rates compare favorably with those obtained at 3 yr after the TVT procedure [25–29]. However, it must be kept in mind that the methodology used to evaluate cure and improvement rates and patients' selection criteria were uneven among studies. It is thus difficult to precisely compare our study with those reported on TVT in the literature. Only the long-term results of randomized trials will allow drawing of definitive conclusions.

In this study, 1-yr and 3-yr data were analyzed in the same cohort of patients, allowing a longitudinal and paired evaluation of outcome. The most important finding of our study is that high SUI cure rates achieved at 1-yr follow-up persisted over a period of 3 yr. As compared with the 1-yr follow-up visit, urge symptoms were slightly but significantly increased at 3 yr. At this time, we do not have any firm explanation for this observation. This difference does not seem to be mechanistically related to changes in bladder outflow. Indeed, only 4 of the 91 patients evaluable at 3 yr reported LUTS suggestive of bladder outlet obstruction. Moreover, obstruction symptom scores at 3 yr remained low and, importantly, were lower than those at 1 yr, reflecting the fact that 2 patients underwent successful surgical treatment of symptomatic POP in this follow-up time interval. In addition, frequency symptom scores, Q_{max} and PVR did not differ between the 1-yr and 3-yr time points. Overall, differences in urge and obstruction symptoms appeared to have little impact on patient's self-evaluated incontinence severity and QoL since visual analogue scale incontinence severity scores and QoL scores were similar at 1 yr and 3 yr after the procedure. These findings support the notion that the positive impact of the TVT-O procedure maintains for at least 3 yr postoperatively. This information is certainly valuable for counselling patients before the surgery and for the design of prospective, randomized trials comparing the TVT-O procedure with other surgical treatments of SUI.

Several recent studies have demonstrated that the incidence of perioperative and short-term postoperative complications associated with the TVT-O procedure is low [9–11,13,14,17–20,30–32]. In the current study, no patient presented symptoms/signs suggestive of vagina, bladder, or urethral erosion; neurologic complication; or persistent pain at either 1-yr or 3-yr follow-up. Yet, 30 (33%) patients were not seen at the 3-yr visit. It cannot be ruled out that these patients might have developed an asymptomatic erosion. Nevertheless, tape-related erosions usually occur earlier in the postoperative period; the tape material used in our study was identical to the Gynecare TVT, which is associated with a low incidence of erosions. In those 61 patients who were examined, no complication was noticed.

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

Between the 1-yr and 3-yr time points, no specific TVT-O–related complication was recorded, suggesting that this procedure does not generate late complications. The main shortcoming of this study, as mentioned above, was that one third of the patients did not undergo physical examination at last follow-up.

5. Conclusions

The medium-term results of this prospective, observational study suggest that the TVT-O procedure is a safe and efficient treatment of female SUI, with maintenance, after a 3-yr minimum follow-up, of high cure rates comparing favorably with those reported for TVT.

Conflicts of interest

All authors have made a substantial contribution to the information or material submitted for publication. All have read and approved the final manuscript.

Jean de Leval is consultant for Gynecare. All authors declare that no funding or other agreement has limited their ability to fairly complete and publish this research study, and that they have had full control of the primary data and their interpretation. There has been no extrainstitutional funding for this study.

References

[1] 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.

[2] Latthe PM, Foon R, Toozs-Hobson P. Transobturator and retropubic tape procedures in stress urinary incontinence: a systematic review and meta-analysis of effectiveness and complications. BJOG 2007;114:522–31.

[3] Nilsson CG, Falconer C, Rezapour M. Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. Obstet Gynecol 2004;104: 1259–62.

[4] Delorme E. Transobturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001;11:1306–13.

[5] de Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. Eur Urol 2003;44:724–30.

[6] Fischer A, Fink T, Zachmann S, Eickenbusch U. Comparison of retropubic and outside-in transoburator sling systems for the cure of female genuine stress urinary incontinence. Eur Urol 2005;48:799–804.

[7] Palma P, Riccetto C, Herrmann V, et al. Transobturator SAFYRE sling is as effective as the transvaginal procedure. Int Urogynecol J Pelvic Floor Dysfunct 2005;16:487–91.

[8] Dietz HP, Barry C, Lim Y, Rane A. TVT vs Monarc: a comparative study. Int Urogynecol J Pelvic Floor Dysfunct 2006;17:566–9.

[9] Debodinance P. Trans-obturator urethral sling for surgical correction of female stress urinary incontinence: Outside-in (Monarc) versus inside-out (TVT-O). Are both ways safe? J Gynecol Obstet Biol Reprod (Paris) 2006;35:571–7.

[10] Sola V, Pardo J, Ricci P, Guiloff E, Chiang H. TVT versus TVT-O for minimally invasive surgical correction of stress urinary incontinence. Int Braz J Urol 2007;33:246–53.

[11] Neuman M. TVT and TVT-obturator: comparison of two operative procedures. Eur J Obstet Gynecol Reprod Biol 2007;131:89–92.

[12] Wang AC, Lin YH, Tseng LH, Chih SY, Lee CJ. Prospective randomized comparison of transobturator suburethral sling (Monarc) vs suprapubic arc (Sparc) sling procedures for female urodynamic stress incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2006;17:439–43.

[13] Liapis A, Bakas P, Giner M, Creatsas G. Tension-free vaginal tape versus tension-free vaginal tape obturator in women with stress urinary incontinence. Gynecol Obstet Invest 2006;62:160–4.

[14] Laurikainen E, Valpas A, Kivela A, et al. Retropubic compared with transobturator tape placement in treatment of urinary incontinence: a randomized controlled trial. Obstet Gynecol 2007;109:4–11.

[15] Daraï E, Frobert J-L, Grisard-Anaf M, et al. Functional results after the suburethral sling procedure for urinary stress incontinence: a prospective randomized multicentre study comparing the retropubic and transobturator routes. Eur Urol 2007;51:795–802.

[16] Porena M, Costantini E, Frea B, et al. Tension-free vaginal tape versus transobturator tape as surgery for stress urinary incontinence: results of a multicentre randomised trial. Eur Urol. In press. doi:10.1016/j.eururo.2007.04.059.

[17] Meschia M, Bertozzi R, Pifarotti P, et al. Peri-operative morbidity and early results of a randomised trial comparing TVT and TVT-O. Int Urogynecol J Pelvic Floor Dysfunct. In press. doi:10.1007/s00192-007-0334-8.

[18] Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007;51:1376–84.

[19] Lee KS, Han DH, Choi YS, et al. A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year followup. J Urol 2007;177:214–8.

[20] Waltregny D, Reul O, Mathantu B, et al. Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum followup. J Urol 2006;175: 2191–5.

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.021

[21] Marquis P, Amarenco G, Sapede C, et al. Elaboration and validation of a specific quality of life questionnaire for urination urgency in women. Prog Urol 1997;7:56–63.
[22] Villet R. Les prolapsus génitaux. In: Villet R, Buzelin J-M, Lazorthes F, editors. Les troubles de la statique pelvipérinéale de la femme. Paris: Vigot; 1995. p. 119–40.
[23] 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.
[24] Al-Singary W, Shergill IS, Allen SE, et al. Trans-obturator tape for incontinence: a 3-year follow-up. Urol Int 2007;78:198–201.
[25] Ulmsten U, Johnson P, Rezapour M. A three-year follow up of tension free vaginal tape for surgical treatment of female stress urinary incontinence. Br J Obstet Gynaecol 1999;106:345–50.
[26] Olsson I, Kroon U. A three-year postoperative evaluation of tension-free vaginal tape. Gynecol Obstet Invest 1999; 48:267–9.
[27] Debodinance P, Delporte P, Engrand JB, Boulogne M. Tension-free vaginal tape (TVT) in the treatment of urinary stress incontinence: 3 years experience involving 256 operations. Eur J Obstet Gynecol Reprod Biol 2002;105: 49–58.
[28] Lo TS, Horng SG, Liang CC, Lee SJ, Soong YK. Ultrasound assessment of mid-urethra tape at three-year follow-up after tension-free vaginal tape procedure. Urology 2004; 63:671–5.
[29] Meltomaa S, Backman T, Haarala M. Concomitant vaginal surgery did not affect outcome of the tension-free vaginal tape operation during a prospective 3-year followup study. J Urol 2004;172:222–6.
[30] Lim J, Cornish A, Carey MP. Clinical and quality-of-life outcomes in women treated by the TVT-O procedure. BJOG 2006;113:1315–20.
[31] Descazeaud A, Salet-Lizee D, Villet R, et al. TVT-O treatment of stress urinary incontinence: immediate and one-year results. Gynecol Obstet Fertil 2007;35:523–9.
[32] Juang C-M, Yu K-J, Chou P, et al. Efficacy analysis of trans-obturator tension-free vaginal tape (TVT-O) plus modified Ingelman-Sundberg procedure versus TVT-O alone in the treatment of mixed urinary incontinence: a randomized study. Eur Urol 2007;51:1671–9.

Editorial Comment on: TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-up

Giacomo Novara
Department of Oncological and Surgical Sciences, Urology Clinic, University of Padua, Padua, Italy
giacomonovara@libero.it,
giacomonovara@gmail.com

After the development of tension-free vaginal tape (TVT) as a minimally invasive treatment for patients with stress urinary incontinence (SUI), several devices have been introduced on the market to make the midurethral sling procedures even less invasive and to reduce the complications.

Although a recent meta-analysis of 14 randomized controlled trials showed the substantial equivalence of retropubic and trans-obturator tapes in terms of clinical efficacy [1], the best trial reported data only at a 16-mo follow-up [2]. Moreover, considering all the available nonrandomized studies, a single paper on trans-obturator tapes showed data at a follow-up duration as long as 18 mo [3].

In the present paper, Waltregny et al [4] reported on a small series of patients who had undergone placement of inside-to-out tension-free obturator tapes (TVT-O) for urodynamic SUI at a minimum follow-up of 3 yr. Compared to a previous report on the same cohort of patients (reference 20 in the paper), the present study showed that the short-term efficacy and safety of TVT-O were maintained at intermediate-term follow-up, which was definitely the main message of the paper. However, considering that most of the patients currently treated for SUI with midurethral slings are in their sixties or seventies, as well as the demographic distribution of the population in the western world, follow-up durations as long as 10 yr would be needed for the selection of the most appropriate surgical treatment.

The authors must be commended for their strength to handle the clinical data of the patients with incomplete follow-up data using sensitivity analyses. As clearly shown, the evaluation of only the patients with available follow-up, ignoring dropouts and those lost to follow-up, overestimates the efficacy of every procedure.

In the present study, both subjective and objective continence rates were reported. In the available literature heterogeneous definitions of continence rates are used. Prospective trials with more standardized criteria to evaluate continence and success rates after surgery for SUI are strongly needed, as recommended by the 3rd International Consultation on Incontinence [5].

Please cite this article in press as: Waltregny D, et al., TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-Up, Eur Urol (2007), doi:10.1016/j.eururo.2007.08.022

References

[1] Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W. Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. Eur Urol. In press.
[2] Zullo MA, Plotti F, Calcagno M, et al. One-year follow-up of tension-free vaginal tape (TVT) and trans-obturator suburethral tape from inside to outside (TVT-O) for surgical treatment of female stress urinary incontinence: a prospective randomised trial. Eur Urol 2007;51:1376–84.
[3] Abdel-Fattah M, Sivanesan K, Ramsay I, Pringle S, Bjornsson S. How common are tape erosions? A comparison of two versions of the transobturator tension-free vaginal tape procedure. BJU Int 2006;98:594–8.
[4] Waltregny D, Gaspar Y, Reul O, Hamida W, Bonnet P, de Leval J. TVT-O for the treatment of female stress urinary incontinence: results of a prospective study after a 3-year minimum follow-up. Eur Urol. In press. doi:10.1016/j.eururo.2007.08.021.
[5] Abrams P, Andersson KE, Brubaker L, et al. Recommendations for clinical research. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence, 3rd International Consultation on Incontinence. Plymouth, United Kingdom: Health Publications; 2005. p. 1624–6.

DOI: 10.1016/j.eururo.2007.08.022

DOI of original article: 10.1016/j.eururo.2007.08.021

Editorial Comment on: TVT-O for the Treatment of Female Stress Urinary Incontinence: Results of a Prospective Study after a 3-Year Minimum Follow-up

Antonella Giannantoni
Department of Urology and Andrology, University of Perugia, Policlinico Monteluce, Perugia, Italy
agianton@libero.it

In recent years different minimally invasive procedures have been introduced to treat stress urinary incontinence (SUI). Among suburethral slings, tension-free vaginal tape (TVT) has been reported to achieve a success rate ranging from 84% to 95%; complications included bladder, bowel, and major blood vessel injuries, as well as postoperative voiding difficulties and de novo urgency and urge incontinence [1]. To avoid pelvic complications, a new method of inserting the tape was introduced by Delorme in 2001 [2]. Since their introduction, TVT and trans-obturator tape (TOT), with their subsequent technical modifications, have been widely adopted and assumed by many urologists as the ''gold standard'' in the treatment of SUI. Indeed, this assumption has been adopted without a proper evaluation of their effectiveness and complications over time. To date, a number of studies have been published reporting the results of the effectiveness and safety of TVT and TOT in a short-term follow-up, but very few data are available about the results of these procedures over a medium long-term follow-up. Moreover, the results comparing TVT and TOT procedures in randomized controlled trials remain scarce.

In the present article, Waltregny and coauthors described the 3-yr results of a prospective, observational study designed to evaluate the efficacy and safety of inside out (TVT-O) procedure in the treatment of female SUI [3]. The present authors had previously reported the results of the same surgical procedure with a 1-yr follow-up [4]. In the present article, a 3-yr minimum follow-up (median: 40 mo) was available for 91 patients. Disappearance and improvement of SUI were observed in 88.4% and in 9.3% of patients, respectively, and these results were similar to those obtained 1 yr after surgery. At the 3-yr follow up, a significant improvement in the frequency of urge symptoms was observed, and obstructive symptoms and postvoid residual volume did not significantly differ as compared to those at 1 yr. Worth noting, at 3 yr of follow-up the quality of life scores remained largely better than those observed preoperatively, and they did not differ as compared to those reported 1 yr after surgery. Only four patients required tape release or section. Thus, Waltregny et al demonstrated that high cure rates can be maintained over a long-term period after the TVT-O procedure to treat female SUI and without any serious local or systemic complications.

The results reported in the present article help all clinicians involved in the treatment of female SUI to resolve the issue of long-term efficacy and safety of one of the main suburethral sling procedures. The present article demonstrates that both adequate sample size and accurate methodology are needed

to produce good quality and powered observational studies. For these reasons, Waltregny et al deserve my personal congratulations.

References

[1] Ulmsten U, Johnson P, Rezapour M. A three year follow up of tension-free vaginal tape for surgical treatment of stress urinary incontinence. Scand J Urol Nephrol 1995;29:75–82.

[2] Delorme E. Trans-obturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001;11:1306–13.

[3] Waltregny D, Gaspar Y, Reul O, Hamida W, Bonnet P, de Leval J. TVT-O for the treatment of female stress urinary incontinence: results of a prospective study after a 3-year minimum follow-up. Eur Urol. In press. doi:10.1016/j.eururo.2007.08.021.

[4] Waltregny D, Reul O, Mathantu B, et al. Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum follow up. J Urol 2006;175:2191–5.

DOI: 10.1016/j.eururo.2007.08.023

DOI of original article: 10.1016/j.eururo.2007.08.021