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Female Urology – Incontinence

Midterm Prospective Evaluation of TVT-Secur Reveals High Failure Rate

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Abstract

Background: TVT-Secur has been described as a new minimally invasive sling for women's stress urinary incontinence (SUI) management, showing promising results in short-term studies.
Objective: Our goal was to evaluate the outcome of this procedure after a midterm follow-up.
Design, setting, and participants: A prospective evaluation involved 45 consecutive patients presenting SUI associated with urethral hypermobility. Fourteen patients preoperatively reported overactive bladder (OAB) symptoms, but none had objective detrusor overactivity. Eight patients had low maximal urethral closure pressure (MUCP). Four patients had pelvic organ prolapse (POP).
Intervention: Patients with POP were treated under general anesthesia by Prolift and TVT-Secur procedure. The 41 other patients received TVT-Secur under local anesthesia on an outpatient basis. All interventions were made by the same surgeon.
Measurements: Postoperative assessment included pad count, bladder diary, clinical examination with stress test, evaluation of satisfaction with the Patient Global Impression of Improvement (PGI-I) scale, and evaluation of side effects. Patients were classified as cured if they used no pads, had no leakage, and had a PGI-I score $\leq$2; as improved in case of reduction of SUI symptoms >50% and PGI-I score $\leq$3; and as failure otherwise.
Results and limitations: Mean postoperative follow-up was 30.2 $\pm$ 9.8 mo (range: 11–40 mo). Short-term evaluation showed a 93.5% success rate, but, at last follow-up, only 18 (40%) patients were cured, while 8 (18%) were improved, and 19 (42%) failed. Twelve patients underwent implantation of TVT or transobturator tape during follow-up. Age, MUCP, or OAB were not associated with failure. Side effects were limited to five cases of de novo OAB and three cases of urinary tract infection. This work is limited by the absence of a comparison group.
Conclusions: Our experience shows that despite its good short-term efficacy, TVT-Secur is associated with a high recurrence rate of SUI. Therefore, TVT-Secur does not seem appropriate for SUI first-line management in women.

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1. Introduction

The prevalence of urinary incontinence in women varies with age from 10–40% [1,2]. This condition, in certain social domains, affects quality of life [3]. Stress urinary incontinence (SUI), defined by the International Continence Society as an involuntary loss of urine with effort or exertion or on sneezing or coughing [4], is frequently reported by women. It can be pure or associated with overactive bladder (OAB) symptoms; the latter is called *mixed incontinence*. Mechanisms underlying SUI can be intrinsic sphincter deficiency, bladder neck hypermobility, or both [1].

SUI management is based on surgical options in case of failure of noninvasive therapies. Placement of a suburethral sling is the gold standard for the management of SUI associated with urethral hypermobility [5,6]. TVT and transobturator tape (TOT) are widely used in this indication with a high success rate and few complications [7–9].

In 2006, to minimize the risk of postoperative pain and organ perforation, a new generation of suburethral slings was described that avoided skin incision to pull out and tension the sling. The first available device, the so-called mini-sling, was the TVT-Secur [10]. Evaluation of this device through prospective short-term series has shown controversial results compared with other tension-free techniques. To our knowledge, all available published reports present <15 mo of follow-up data, concern 32–154 patients, and show an overall success rate between 62–100% at 1 yr [11–17]. Although preliminary series have shown promising results [12,17], other authors have reported an overall success rate of 70% on SUI and mild degradation of results after 1 yr [13].

Therefore, longer follow-up is needed and indications of this device still remain to be assessed. Our aim was to present our 3-yr experience with TVT-Secur in current clinical practice, focusing on the sustainability of the results.

2. Materials and methods

2.1. Patients

From September 2006 to March 2007, 45 consecutive patients underwent TVT-Secur implantation in our institution. A prospective evaluation was conducted. The following data were preoperatively collected: age; complete medical history; results of clinical examination with cough test; clinical evidence of urethral hypermobility; and preoperative urodynamics, which included maximal urethral closure pressure (MUCP), cystomanometry, and urine flow rate. Four patients had organ prolapse stage 3 in the Pelvic Organ Prolapse Quantification (POP-Q) system with associated SUI and underwent combined placement of a Prolift and a TVT-Secur. Fourteen patients had mixed incontinence with OAB symptoms; 11 of them were treated by anticholinergics at the time of surgery. No patient had objective detrusor overactivity (DO) on urodynamics, and all presented urethral hypermobility. Eight patients had a MUCP <40 cm H_2O. All patients did appropriate pelvic floor muscle exercises that failed to improve symptoms. Patients' characteristics are presented in Table 1.

2.2. Procedures

Forty-one patients were managed on an outpatient basis, received the sling under local anesthesia, and were discharged after surgery without catheter. All these patients received the TVT-Secur sling according to the procedure described elsewhere [12]. Four patients were hospitalized for 24 h and operated on under general anesthesia with a 24-h catheterization because of combined placement of a Prolift anterior mesh and a TVT-Secur sling. Mean operating time was 15 min under local anesthesia and 1 h under general anesthesia.

Table 1 – Preoperative data

Variable	Data
Age, yr, mean plus or minus SD (range)	60.3 ± 10.6 (35–87)
Preoperative symptoms	
Mixed incontinence (SUI and OAB), *n* (%)	14 (31)
Pure SUI, *n* (%)	31 (69)
Pads per day, mean plus or minus SD (range)	1.4 ± 0.7 (0–3)
Urodynamics	
Maximal urethral pressure closure, mean plus or minus SD (range)	54.6 ± 22 (20–100)
ISD (MUCP <40 cm H_2O), *n* (%)	8 (18)
Q_{max}, mean plus or minus SD (range)	24.8 ± 4.7 (16–33)
DO on urodynamics, *n* (%)	0

SUI = stress urinary incontinence; OAB = overactive bladder; ISD = intrinsic sphincter deficiency; MUCP = maximum urethral pressure closure; Q_{max} = urine flow rate; DO = detrusor overactivity.

2.3. Perioperative evaluation and follow-up

Follow-up for continence and satisfaction was done at 1, 3, 6, and 12 mo and yearly thereafter. Each visit included evaluation of pad usage, clinical examination with stress test, validated Patient Global Impression of Improvement (PGI-I) scale [18], and assessment of side effects possibly related to the procedure.

The main criterion for analysis was efficacy on SUI symptoms. Patients were considered cured in case of no pad usage, no stress-related leakage, and PGI-I score of 1 or 2. Improvement was defined as a reduction >50% of leakage episodes associated with a satisfaction level of 1, 2, or 3 according to PGI-I. Other cases were classified as failure. Further medical and/or surgical management of cases presenting failure was also assessed during follow-up.

2.4. Statistical evaluation

Statistical evaluation was conducted with XLStat2009 for Windows (Addinsoft, Paris, France). Quantitative values were compared with the Mann-Whitney test. We evaluated the durability of the results by assessing a Kaplan-Meier analysis with respect to the recurrence of pad use or SUI episodes on bladder diary during the follow-up period.

3. Results

Forty-five patients underwent the placement of a TVT-Secur sling for SUI. All patients operated on under local anesthesia were discharged the day of surgery, and the four patients who had combined Prolift placement and sling implantation were discharged at day 1. No perioperative complication was noted.

3.1. Follow-up

Mean postoperative follow-up was 30.2 ± 9.8 mo (range: 11–40 mo). Evaluation of efficacy showed that at last follow-up, 18 (40%) patients were cured, 8 (18%) patients were improved,

Table 2 – Evolution of results during follow-up ($n = 45$)

	First follow-up, *n*	6 mo follow-up, *n*	Last follow-up, *n*
Cured	28	24	18
Improved	11	8	8
Failure	6	13	19

and 19 (42%) patients were classified as failure, either because of recurrent or persistent pad usage, leakage at clinical examination, or nonsatisfaction. Table 2 shows the evolution of the results at 1 and 6 mo and at last follow-up.

Fig. 1 represents the evolution of patients initially cured during follow-up. At first postoperative evaluation, 28 patients were cured with no leakage, and 17 patients had persistent SUI (improved in 11 and failed in 6). Recurrence of SUI occurred in 10 of the 28 cases initially cured. These types of failure can be late onset until 24 mo. Among the six patients having presented a late onset failure (after 6 mo), three had preoperative OAB, three had pure SUI, none had prolapse, and none had a MUCP <40 cm H_2O. Satisfaction results at last follow-up are presented in Fig. 2.

Twelve patients underwent supplementary surgery for SUI, with a TVT placement in 10 cases and TOT in 2 cases. Eleven of them were cured at last follow-up, and one failed. Other patients presenting failure underwent reeducation and/or adjuvant therapy with duloxetin and/or intravaginal pads. Thirteen of the 14 patients presenting OAB symptoms preoperatively were still suffering from OAB at last follow-up and were taking oral anticholinergic medication. Univariate analysis showed that failure was not significantly linked with age ($p = 0.17$), low MUCP <40 cm H_2O ($p = 0.71$), or OAB ($p = 0.51$). Patients who underwent combined surgery with Prolift and TVT-Secur were all cured at last follow-up, with no recurrence of organ prolapse.

3.2. *Side effects*

De novo urgency and OAB symptoms appeared in five patients and required medical management by trospium chloride. No other side effect was noted during follow-up, except three cases of urinary tract infection treated with antibiotics.

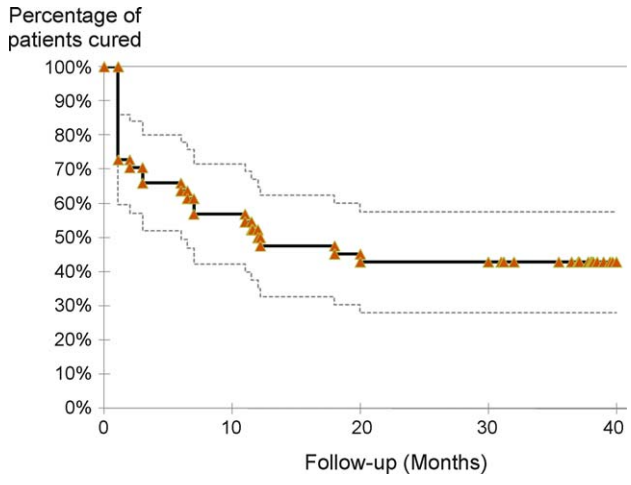

Fig. 1 – Survival without recurrence of pad usage, any stress urinary incontinence episode, and any degradation of satisfaction.

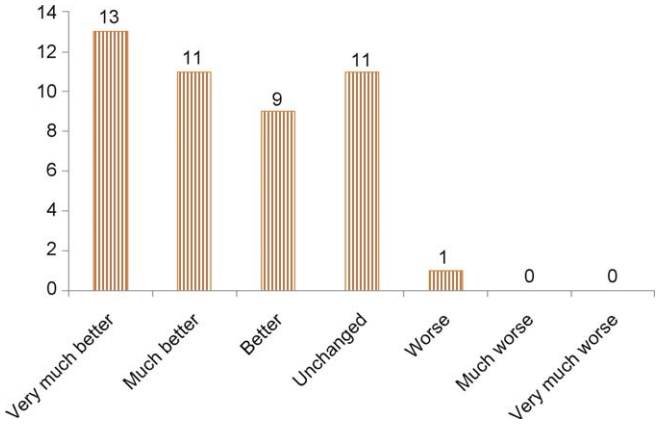

Fig. 2 – Patient's Global Impression of Improvement Scale-I results at last follow-up. Number of patients for each class is noted at the top of each column.

4. Discussion

Management of SUI by suburethral slings expanded rapidly after the first description of the TVT technique in 1996 [19]. Indeed, this approach avoids a number of complications linked to such abdominal surgeries as colposuspension [19,20,22], is regarded as a successful technique to treat SUI, and has an estimated cure rate of around 80% in long-term follow-up studies [21]. TOT, introduced several years later, brought additional security by avoiding penetration of the retropubic space and thus also avoiding several complications, such as bladder perforation, hematoma, or pelvic organ injury [20]. However, the TOT approach is associated with postoperative thigh pain, and obstruction, infection or erosion can also happen [23–25]. Complications are therefore seen as an important outcome for further innovative slings [26]. New so-called minimally invasive devices have been developed to limit groin pain after sling placement while aiming at comparable success results. TVT-Secur minimizes operative dissection and risk of injury of periurethral elements and pelvic organs as well as the risk of nerve or adductor muscle damage.

In our experience, this innovative device failed to demonstrate high clinical efficacy on SUI symptoms. After 30 mo, numerous patients in our series presented recurrence of urinary leakage. Overall, only 40% of patients remained cured at last follow-up, whereas 42% failed and 18% were improved. Twelve patients of 45 required additional TOT or TVT surgery. All but one patient who underwent supplementary surgery were dry at last follow-up, in line with the data recently published by Liapis et al about TVT as a secondary procedure after initial failure of midurethral sling for SUI [27].

Data analysis shows two different patterns of failure. The first is a primary failure, diagnosed at the first

postoperative visit (13% of our cases). This kind of event is well known by all practitioners in the field of sling surgery and is usually related to technical failure (sling misplacement, failure of the device itself, bad patient selection, learning curve [27]). However, all procedures were led by an experienced surgeon, and no erosion or sling misplacement was demonstrated. Furthermore, a similar proportion of short-term failure has already been reported in the literature about TVT-Secur. Indeed, failure rate was 6.5% at 2 mo for Debodinance et al. [13], 15% at 14 mo for Oliveira et al. [15], 21% at 13 mo for Meschia et al. [17], and 8–20% at 1 mo according to Neuman [28]. Finally, a recent report on short-term results of TVT-Secur by Lee et al shows a cure rate of 84% based on stress test versus 76.4% based on satisfaction questionnaires [29]. Some other papers [11,12] report a cure rate >95% at 1 mo, but in selected cases (eg, excluding patients presenting low MUCP and/or OAB symptoms preoperatively).

The second pattern of failure emerging from our data analysis after a 3-yr follow-up is of greater significance and is linked to the long duration of our prospective evaluation. We observed recurrence of symptoms in 33% of patients initially cured, leading to pad use, decrease of satisfaction, and/or objective leakage at clinical examination. At last follow-up, only 40% of patients remained cured. Twelve patients underwent further surgical management with TVT or TOT slings. All but one of these reinterventions led to satisfactory results, indicating that traditional sling would have been preferred as a first-line treatment in these patients.

To our knowledge, this high rate of recurrence has not been described previously, and can be explained by several factors. The first one is the follow-up duration of our study, since no longer evaluation has yet been published in the available literature. The other is the heterogeneity of our cohort, including patients with OAB, low MUCP, or prolapse. No link could be shown between these variables and failure in univariate analysis, but statistical significance is very low given the small number of patients. However, this kind of series is more able to reflect daily practice than carefully selected populations usually presented for the evaluation of a new device. The last reason could be the failure of the device itself (self-fixing secure tip), since it had not been evaluated yet in long-term studies. The system may not resist periurethral tissue modifications with time, and slip and lose its efficacy.

Side effects were limited to postoperative pain in 10 patients, de novo OAB symptoms in 5 patients, and urinary tract infection in 3 patients, easily managed by antibiotics. These data compare favorably to previous studies.

This evaluation is limited by the small number of patients treated and patient-selection criteria, which were very large to reflect daily practice. Moreover, the design of this study is prospective but did not include a comparison group. However, these results, if confirmed on larger series, should lead us to reconsider indications of this device. Our results should encourage authors who have presented large series based on short-term evaluation to present their results with updated follow-up.

5. Conclusions

Our midterm experience evaluating TVT-Secur for SUI in women shows that this new technique is safe and quick and is associated with limited and mild side effects. However, under current clinical conditions, if results are satisfactory in the short term, they are not sustainable. Indeed, a significant degradation over time was assessed with an overall failure rate of 42% at 3-yr follow-up. These results demonstrate the importance of a long follow-up when a new device is evaluated in the field of urinary incontinence. Indications of TVT-Secur for SUI in women should be reconsidered.

Author contributions: Jean-Nicolas Cornu had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Haab.
Acquisition of data: Peyrat, Sèbe.
Analysis and interpretation of data: Cornu, Sèbe.
Drafting of the manuscript: Cornu.
Critical revision of the manuscript for important intellectual content: Sèbe, Cussenot.
Statistical analysis: Ciofu, Peyrat.
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References

[1] Norton P, Brubaker L. Urinary incontinence in women. Lancet 2006; 367:57–67.
[2] Lasserre A, Pelat C, Guéroult V, et al. Urinary incontinence in French women: prevalence, risk factors, and impact on quality of life. Eur Urol 2009;56:177–83.
[3] Coyne KS, Wein AJ, Tubaro A, et al. The burden of lower urinary tract symptoms: evaluating the effect of LUTS on health-related quality of life, anxiety and depression: EpiLUTS. BJU Int 2009;103: 4–11.
[4] 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. Am J Obstet Gynecol 2002;187:116–26.
[5] 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.
[6] Wilson TS, Lemack GE. Transvaginal surgery for stress incontinence. In: Carlin B, Leong F, eds. Female Pelvic Health and Reproductive Surgery. New York, NY, USA: Marcel Dekker; 2002. p. 137–50.
[7] 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 2007; 52:663–79.

[8] Jeon MJ, Jung HJ, Chung SM, Kim SK, Bai SW. Comparison of the treatment outcome of pubovaginal sling, tension-free vaginal tape, and transobturator tape for stress urinary incontinence with intrinsic sphincter deficiency. Am J Obstet Gynecol 2008;199:76.e1–4.

[9] Hsiao SM, Chang TC, Lin HH. Risk factors affecting cure after mid-urethral tape procedure for female urodynamic stress incontinence: comparison of retropubic and transobturator routes. Urology 2009;73:981–6.

[10] Molden SM, Lucente VR. New minimally invasive slings: TVT Secur. Curr Urol Rep 2008;9:358–61.

[11] Solà V, Ricci P, Pardo J. Third generation sub-mid urethral mesh: experience with 110 TVT-Secur. Arch Esp Urol 2009;62:376–86.

[12] Tartaglia E, Delicato G, Baffigo G, et al. Third-generation tension-free tape for female stress urinary incontinence. J Urol 2009;182: 612–5.

[13] Debodinance P, Amblard J, Lucot JP, Cosson M, Villet R, Jacquetin B. TVT Secur: prospective study and follow up at 1 year about 154 patients. J Gynecol Obstet Biol Reprod (Paris) 2009;38:299–303.

[14] Martan A, Svabík K, Masata J, Koleska T, El-Haddad R, Pavlikova M. Correlation between changes in ultrasound measurements and clinical curative effect of tension-free vaginal tape-SECUR procedure. Int Urogynecol J Pelvic Floor Dysfunct 2009;20:533–9.

[15] Oliveira R, Silva A, Pinto R, et al. Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence. BJU Int 2009;104:225–8.

[16] Jiménez Calvo J, Hualde Alfaro A, Raigoso Ortega O. Our experience with mini tapes (TVT Secur and MiniArc) in the surgery for stress urinary incontinence. Actas Urol Esp 2008;32:1013–8.

[17] Meschia M, Barbacini P, Ambrogi V, Pifarotti P, Ricci L, Spreafico L. TVT-secur: a minimally invasive procedure for the treatment of primary stress urinary incontinence. One year data from a multicentre prospective trial. Int Urogynecol J Pelvic Floor Dysfunct 2009;20:313–7.

[18] Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003;189:98–101.

[19] 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.

[20] Novara G, Galfano A, Boscolo-Berto R, et al. Complication rates of tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials comparing tension-free midurethral tapes to other surgical procedures and different devices. Eur Urol 2008;53:288–309.

[21] Lee K-S, Choo M-S, Doo CK, et al. The long term (5-years) objective TVT success rate does not depend on predictive factors at multivariate analysis: a multicentre retrospective study. Eur Urol 2008;53:176–83.

[22] Liapis A, Bakas P, Creatsas G. Burch colposuspension and tension-free vaginal tape in the management of stress urinary incontinence in women. Eur Urol 2002;41:469–73.

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

[24] Neuman M. TVT obturator: short-term data on an operative procedure for the cure of female stress urinary incontinence performed on 300 patients. Eur Urol 2007;51:1083–8.

[25] Bhargava S, Chapple CR. Rising awareness of the complications of synthetic slings. Curr Opin Urol 2004;14:317–21.

[26] Daneshgari F, Kong W, Swartz M. Complications of mid urethral slings: important outcomes for future clinical trials. J Urol 2008;180:1890–7.

[27] Liapis A, Bakas P, Creatsas G. Tension-free vaginal tape in the management of recurrent urodynamic stress incontinence after previous failed midurethral tape. Eur Urol 2009;55:1450–8.

[28] Neuman M. Perioperative complications and early follow-up with 100 TVT-Secur procedures. J Minim Invasive Gynecol 2008;15: 480–4.

[29] Lee K-S, Lee Y-S, Seo JT, et al. A prospective multicenter randomized comparative study between the U- and H-type methods of the TVT SECUR procedure for the treatment of female stress urinary incontinence: 1-year follow-up. Eur Urol 2010;57:973–9.