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A prospective randomized trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence

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KEY WORDS

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Objective: The purpose of this study was to prospectively and randomly compare tension-free vaginal tape (TVT) with transobturator suburethral tape (T.O.T.) for the surgical treatment of stress urinary incontinence (SUI) in women.

Study design: Sixty-one women with SUI were randomly assigned to either TVT (n = 31) or T.O.T. (n = 30). The preoperative evaluation included a quality-of-life questionnaire and a comprehensive urodynamic examination. The 1-year outcome included a detrusor pressure-uroflow study to compare bladder outlet obstruction.

Results: Patient characteristics, preoperative quality of life, and urodynamic evaluation were similar in the 2 groups. Mean operative time was significantly shorter in the T.O.T. group (15 min ± 4 vs 27 min ± 8, $P < .001$). No bladder injury occurred in the T.O.T. group versus 9.7% (n = 3) in the TVT group ($P > .05$). The rate of postoperative urinary retention was 25.8% (n = 8) in the TVT group versus 13.3% (n = 4) in the T.O.T. group ($P > .05$). The rates of cure (83.9% vs 90%), improvement (9.7% vs 3.3%), and failure (6.5% vs 6.7%) were similar for the TVT and T.O.T. groups, respectively. The 1-year outcome data were collected in 29 women of the TVT group and 27 women of the T.O.T. group. No vaginal erosion occurred in either of the groups. In terms of bladder outlet obstruction, no differences were found after TVT and T.O.T.

Conclusion: T.O.T. appears to be equally efficient as TVT for surgical treatment of stress urinary incontinence in women, with no reduction of bladder outlet obstruction at 1-year follow-up.

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Stress urinary incontinence (SUI) is a common functional pathologic condition occurring in women.¹ There

are a large number of surgical procedures for the treatment of female SUI, but few of these operations have been evaluated objectively in prospective studies. The rationale of the surgical treatment of SUI has changed over the passed few years; because the techniques using urethral suspension were responsible for acute urinary retention and chronic voiding troubles, techniques

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recreating a backboard between the urethra and the vaginal anterior wall were developed. The tension-free vaginal tape procedure (TVT; Gynecare, Ethicon, Issy-les-Moulineaux, France) has been used in the treatment of female SUI since 1995.² Although TVT has a high success rate, ranging from 84% to 95%,³⁻⁶ there are concerns regarding its operative safety in relation to bowel and major blood vessels injuries, bladder and urethral perforation,⁶ and postoperative voiding difficulties as transient urine retention in 8% to 17%,⁷⁻⁹ and urgency in 5% to 15%.⁸⁻¹⁰ Recently, a new surgical technique that uses the Uratape (Mentor-Porgès, Le Plessis-Robinson, France) called transobturator suburethral tape (T.O.T.) was introduced by Delorme.¹¹ Ninety percent of the patients were cured with no perioperative complications and no postoperative voiding difficulties.

To our knowledge, there is no prospective and randomized study comparing TVT with T.O.T. in the surgical treatment of SUI in women. Therefore, the aim of this study was to prospectively compare TVT with T.O.T. regarding clinical outcome and postoperative bladder outlet obstruction.

Material and methods

From January to November 2002, 61 women were prospectively, randomly assigned to either TVT or T.O.T.. Ethics approval was obtained from the local committee. Thirty-one women underwent the TVT procedure and 30 underwent the T.O.T. procedure. All women who had urodynamically proved genuine stress incontinence were candidates for inclusion. Surgery was only offered if conservative therapy was unsuccessful. Patients with predominant urge incontinence, urodynamic detrusor instability, or prolapse were excluded from the study. All subjects were given an explanation of the study and written informed consent was obtained. All patients underwent history and physical examination, urine dipstick and culture, and preoperative urodynamic examination, including urethral pressure profilometry, urethrocytometry, uroflometry, and postvoid residual volume measurement by a catheter. Patient characteristics, preoperative clinical and urodynamic data are summarized in Table I. Patients self-evaluated the severity of their incontinence symptoms with use of a visual analog scale (VAS) ranging from 0 to 10 (0 corresponding to no symptoms and 10 to the maximum severity). We evaluated the stage of SUI according to the Ingelman-Sundberg score.¹² Quality-of-life (QoL) assessment was carried out preoperatively and postoperatively with use of the Contilife questionnaire including 28 items and 6 scales: daily activities, effort activities, self-image, emotional impact, sexuality, and well-being. Contilife is a valid, reliable, and sensitive measure of the QoL of the patients.¹³

Women were randomized using numbered, opaque sealed envelopes containing computer-generated random allocations in a ratio of 1:1 in balanced blocks of 10. Envelopes were opened in the operating room by a nurse just before starting the procedure. All procedures were performed by 2 experienced surgeons. All subjects received intravenous prophylactic antibiotic therapy at the beginning of the operation.

TVT procedure

All TVT procedures were performed as was previously reported,¹⁴ except that the operation was carried out with the patient under general or spinal anesthesia. After bilateral paraurethral dissections of the vaginal wall, the trocar and tape was placed through the urogenital diaphragm into the retropubic space close to the back of the pubic bone up to the skin incision. The same procedure was performed on the other side. Cystoscopy was subsequently performed to verify the absence of bladder injury. Then, the tape was adjusted without tension in a U shape around the midurethra. We did not perform the cough stress test after adjustment of the tape. A Foley catheter was inserted into the bladder at the end of the procedure and removed the day after surgery.

T.O.T. procedure

In the T.O.T. group, the procedure was performed according to the technique of Delorme.¹¹ Spinal or general anesthesia was used according to the patient and/or anesthesiologist's preference. After the vagina was prepared with aqueous iodine, a 20-mm incision was made on the anterior vaginal wall and the middle urethra was identified. The dissection was stopped when the index finger inserted through the incision entered in contact with internal surface of the ischiopubic bone and obturator foramen. A 5-mm vertical skin incision was made on the internal surface of the thigh, a maximum of 10 mm above a horizontal line passing by the level of the urethral meatus, and 10 mm outside the ischiopubic ramus. A curved tunneling tool was introduced vertically just to perforate the superficial aponeurosis and the index finger of the contralateral hand was placed into the vaginal incision to check the path driving the tunneling device. Visual checks were conducted to control that the tunneling device had not perforated the lateral part of the vagina. The T.O.T. sling (Uratape, Mentor-Porgès, Le Plessis-Robinson, France) was inserted into the eye of the tunneling tool and passed backward through the obturator foramen by removing the device. The same operation was performed through the contralateral obturator foramen. The tape was placed in

Table I Patients characteristics, quality of life, preoperative clinical and urodynamic parameters

	T.O.T. (n=30)	TVT (n=31)	P value
Age	54.7 ± 11.9 (29-76)	53.6 ± 12.5 (35-79)	NS*
Body mass index (kg/m ²)	24 ± 3.2	25.2 ± 4.3	NS*
Parity	2.3 ± 0.8	2.0 ± 0.8	NS*
Menopausal status	18 (60)	16 (51)	NS [†]
Hormone replacement therapy	13/18 (72)	10/16 (62)	NS [†]
Previous surgery for SUI	4 (13.3)	1 (3.2)	NS [†]
Previous surgery for prolapse	4 (13.3)	1 (3.2)	NS [†]
Previous hysterectomy	2 (6.7)	5 (16.1)	NS [†]
Preoperative clinical parameters			
Duration of SUI (y)	4 ± 4.3	3.1 ± 1.4	NS*
Stage of SUI	1.6 ± 0.6	1.5 ± 0.6	NS*
Frequency (>8/d)	10 (33%)	9 (29%)	NS [†]
Nocturia (>2/night)	6 (20%)	5 (16%)	NS [†]
Voiding difficulties	3 (10%)	1 (3%)	NS [†]
Preoperative quality of life			
VAS (/10)	6.7 ± 1.3	6.5 ± 1.7	NS*
Daily activities (/10)	6.48 ± 2.15	7.06 ± 2.18	NS*
Effort activities (/10)	4.31 ± 2.63	4.17 ± 2.14	NS*
Self image (/10)	6.07 ± 2.08	5.95 ± 2.04	NS*
Emotional impact (/10)	4.88 ± 2.26	4.5 ± 2.19	NS*
Sexuality (/10)	8.73 ± 2.18	8.03 ± 2.93	NS*
Well being (/10)	4.44 ± 2.44	4.17 ± 2.31	NS*
Preoperative urodynamic parameters			
Qmax (mL/s)	36.2 ± 14.9	33.1 ± 11.2	NS*
Qmax < 15 mL/s	0	1 (3.2)	NS [†]
MUCP (cm H ₂ O)	55.3 ± 18	55.2 ± 21	NS*
ISD (MUCP < 30 cm H ₂ O)	4 (13%)	3 (9%)	NS [†]

Values are given as mean ± SD (range) and n(%). NS, Not significant; ($P > .05$). SUI, stress urinary incontinence; MUCP, maximal urethral closure pressure; VAS, visual analog scale; ISD, intrinsic sphincter deficiency.

*Student *t* test.

[†] χ^2 test.

a transversal, frontal plane between the urethra and vaginal anterior wall without any suspension action. No cystoscopy was required for the procedure, but all patients received indigo carmine intravenously at the beginning of the procedure to color urine in blue and to recognize any operative bladder injury. The Foley catheter was removed the day after surgery. Once the woman was able to void with residuals of less than 100 mL, she was discharged.

Follow-up evaluation was carried out after 6 weeks, 6 months, and 1 year. All patients were evaluated for follow-up by 2 independent physicians. They realized clinical examination and a cough stress test. The cough stress test was performed as follows: the patients were placed in the supine position and their bladders were filled to 250 mL, then the patients were asked to cough, and any positive leakage noted was a positive cough stress test. Then they performed uroflowmetry with detrusor pressure-uroflow study, in order to compare bladder outlet obstruction according to the nomogram of Blaivas.¹⁵ It is a 4-zone nomogram that classifies any pair of values of free Qmax (maximal flow) and pdet.max

(maximal detrusor pressure during uroflowmetry) into unobstructed (zone 0), mildly obstructed (zone 1), moderately obstructed (zone 2), and severely obstructed (zone 3). The secondary end point with respect to efficacy was the disappearance of the symptoms of SUI. We defined as “objectively cured” a patient who had no SUI and a negative stress test, “objectively improved” a patient who had improvement of SUI but positive stress test and “objectively failed” in the other cases. Subjective cure rates were self-evaluated by the patients as “very satisfied,” “satisfied,” or “not satisfied.”

Statistical analysis

All data analysis was carried out according to a pre-established analysis plan. Power analysis, based on a 40% incidence of moderate to severe obstruction after TVT, indicated that a total of 58 (29 patients in each group) would be required to demonstrate a 30% difference in bladder outlet obstruction (from 40% to 10%) between

TVT and T.O.T. with 80% power ($\alpha = .05$). Statistical analysis was performed using Student *t* test for parametric continuous variables, and the χ^2 test was appropriate for categorical variables. Excel (Microsoft, Redmond, Wash) and Statview (SAS Institute, Cary, NC) software were used for statistical analysis.

Results

There was no significant difference between the groups for age, parity, BMI, and previous surgery for incontinence or prolapse (Table I). Furthermore, there was no significant difference, with regard to duration, severity of the symptoms, quality of life, and preoperative urodynamic parameters. Preoperative clinical voiding dysfunction was not significantly different between the 2 groups (Table I).

Mean operative time was significantly shorter in the T.O.T. group (Table II). There was no significant difference in the type of anesthesia and duration of hospital stay between the groups. There was no major perioperative complication. There were 3 bladder perforations in the TVT group and none in the T.O.T. group. The day after surgery, urinary retention (postvoid residual volume more than 100 mL) occurred twice in the TVT group, even if that difference was not significant.

Statistical analysis failed to detect any significant differences between T.O.T. and TVT procedure with regard to objective and subjective cure rates (Table III). Twenty-seven (90%) and 26 (83.4%) women were objectively cured in the T.O.T. and the TVT groups, respectively ($P > .05$). Twenty-six (86.7%) and 30 (96.8%) women expressed to be satisfied or very satisfied in the T.O.T. and the TVT groups, respectively ($P > .05$). On quality of life, for any of the 6 scales, daily activities, effort activities, self image, emotional impact, sexuality, and well-being, T.O.T. and TVT were statistically equivalent (Table III).

A second operation was performed in each group. A lateral transection of the sling was required to treat urinary retention in one patient of the T.O.T. group 25 days after the procedure. A urethral erosion was diagnosed by urethroscopy 6 months after the procedure in a 44-year-old patient of the TVT group who complained of dysuria. The intraurethral piece of sling was cut by thin scissors and removed by a forceps under urethroscopic control. This woman is completely cured and satisfied at the current time.

There was no statistically significant difference between the T.O.T. and TVT procedures for postoperative urodynamic parameters concerning bladder outlet obstruction (Table IV). With regard to the Blaivas nomogram, there was no significant difference between the 2 groups (Figures 1 and 2). Only 1 patient had a severe obstruction in the TVT group, whereas none in the T.O.T. group did.

Table II Operation details, hospital stay, operative and postoperative and complications

	T.O.T. (n=30)	TVT (n=31)	P value
Duration of procedure (min)	14.8 ± 4.3	26.5 ± 7.7	<.001*
Hospital stay (d)	1.2 ± 1.3	1.1 ± 0.4	NS*
Operative complications			
Bladder perforation	0	3 (9.7)	NS†
Hemoglobin loss (g/dL)	1.1 ± 0.6	1.2 ± 0.5	NS*
Postoperative urinary retention			
PVR at day 1 > 100 mL	4 (13.3)	8 (25.8)	NS†
PVR at day 2 > 100 mL	3 (10)	2 (6.5)	NS†
PVR > 100 mL after than day 2	1 (3.3)	0	NS†
Postoperative complications			
Vaginal erosion	0	0	NS†
Urethral erosion	0	1 (3.2)	NS†
Obturator hematoma	1 (3.3)	0	NS†
Urinary infection	6 (20)	4 (12.9)	NS†

Values are mean ± SD and n(%). NS, Not significant; PVR, postvoid residual volume.

*Student *t* test.

†Chi-square test.

Comment

To our knowledge, this is the first randomized study comparing TVT with T.O.T. in the surgical treatment of SUI in women. In our study, the mean operative time was nearly 2 times longer in the TVT group (26.5 minutes vs 14.8 minutes). That difference is only due to the need of a cystoscopy during the TVT procedure. Bladder perforation is the most common complication occurring during TVT. Previous series reported an incidence between 0.8% and 21%.^{3-6,8,16-19} With the T.O.T. procedure, the risk of bladder perforation appears to be highly reduced. Dargent et al, who performed cystoscopy during the T.O.T. procedure at the beginning of their experience, reported no bladder injury in the first 71 patients.²⁰ Furthermore, we observed no bladder injury in the 30 T.O.T. of our study, despite a blue color test, versus 9.7% with TVT. However, one case of bladder injury was recently reported in a patient who had an associated cystocele.²¹ Overall, we do not recommend a cystoscopy during the T.O.T. procedure when it is performed in normal conditions, which means for patients with no associated cystocele.

We demonstrated that T.O.T. and TVT procedures are equally efficient to treat SUI with a mean follow-up of 12 months. The 90% objective cure rate of the T.O.T. procedure we observed is similar to cure rate of TVT reported by other authors, with ranges from 84% to 95%.^{3-6,8,14,16-19}

Table III Objective and subjective cure rates, postoperative voiding troubles, and quality of life

	T.O.T. (n=30)	TVT (n=31)	P value
Follow-up (mo)	12.1 ± 2.8 (7-17)	12.9 ± 3.1 (7-17)	NS*
Objective cure rates			
Cure	27 (90)	26 (83.9)	NS†
Improvement	1 (3.3)	3 (9.7)	NS†
Failure	2 (6.7)	2 (6.5)	NS†
Postoperative voiding troubles			
De novo urgencies	2 (6.7)	2 (6.5)	NS†
De novo voiding difficulties	5 (16.7)	7 (22.6)	NS†
Subjective cure rates			
Very satisfied	18 (60)	20 (64.5)	NS†
Satisfied	8 (26.7)	10 (32.3)	NS†
Non satisfied	4 (13.3)	1 (3.2)	NS†
Postoperative quality of life			
VAS (/10)	2.7 ± 2.5	1.4 ± 2.8	NS*
Daily activities (/10)	8.93 ± 1.88	7.86 ± 3.03	NS*
Effort activities (/10)	9.38 ± 1.62	9.25 ± 1.23	NS*
Self-image (/10)	9.18 ± 1.13	9.02 ± 2.78	NS*
Emotional impact (/10)	8.12 ± 2.2	8.25 ± 4.12	NS*
Sexuality (/10)	9.86 ± 0.54	9.92 ± 0.24	NS*
Well being (/10)	7.83 ± 2.17	8.10 ± 3.54	NS*

Values are mean ± SD (ranges) and n(%). NS, Not significant; VAS, visual analog scale.

*Student *t* test.

†Chi-square test.

Table IV Postoperative bladder outlet obstruction

	T.O.T. (n=27)	TVT (n=29)	P value
Free Qmax (mL/s)	24.4 ± 7.7	23.3 ± 8	NS*
Free Qmax < 15 mL/s	3 (11.1)	4 (13.8)	NS†
Detrusor pressure - uroflow studies			
No obstruction (zone 0)	19 (70.4)	17 (58.6)	NS†
Mild obstruction (zone 1)	5 (18.5)	7 (24.1)	NS†
Moderate obstruction (zone 2)	3 (11.1)	4 (13.8)	NS†
Severe obstruction (zone 3)	0	1 (3.5)	NS†

Values are mean ± SD and n(%). NS, Not significant.

*Student *t* test.

†Chi-square test.

Despite a high cure rate, the TVT procedure can be complicated by bladder outlet obstruction. This complication can appear in various clinical forms, such as urinary retention, voiding difficulties, and de novo urgencies or frequencies. Transient urinary retention incidence ranges from 2.3% to 27% after TVT.^{3-6,8,16-19} This is a consequence of an increasing urethral resistance created by the suburethral insertion of the tape. These retentions are usually partial and transient. Training in self-catheterization allows the patients to get through this difficult phase. If complete obstruction occurs, this should lead to transection of the tape. Long-term retention is a rare complication of TVT procedure.

Its incidence ranges from 0.6% to 3.8%.^{5,18,19} This risk is increased for patients previously operated on for SUI,²³ probably because of the temptation to provide excessive tension exerted on the urethra during the second procedure. However, voiding difficulties are frequent after TVT. Their incidence ranges from 5% to 38.9%.^{5,18} Since the introduction of the TVT procedure, some details of the initial concept changed. Most of the users stopped using the cough stress test as it led to postoperative urinary retention or voiding difficulties.⁸ It is now recommended to just place the tape beneath the urethra.

In our study, we observed a lower risk of postoperative urinary retention with T.O.T., but only for the day after surgery (13.3% vs 25.8%). This result was not statistically significant, probably because of the small number of patients in both groups. With a longer-term follow-up, we did not find any difference in bladder outlet obstruction. Moderate to severe obstruction occurred in 11.1% versus 17.3% in the T.O.T. and the TVT group, respectively. In another prospective randomized study comparing the TVT and the Pelvicol sling (Bard, Voisins le Bretonneux, France), prolonged postoperative urinary retention was 1.5% in the TVT group and 8% in the Pelvicol group.⁹ The use of another sling or a different route does not seem to decrease the suburethral resistance.

It is recommended that patients should be informed about the risk and carefully monitored for obstruction

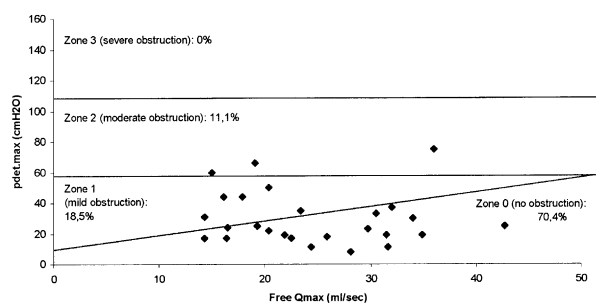


Figure 1 Blaivas nomogram for T.O.T.

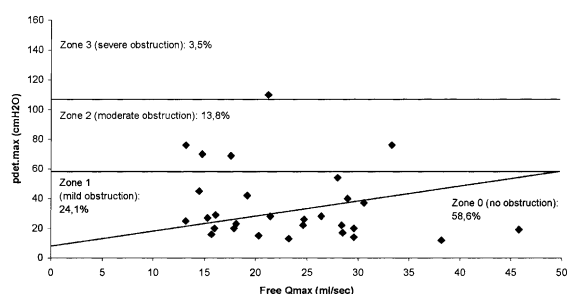


Figure 2 Blaivas nomogram for TVT.

symptoms after surgery. In cases where impaired bladder emptying or severe irritative symptoms occurred, conservative management may be used. These measures include self-catheterization, continued bladder drainage, urethral dilatation, and initiation of anticholinergic medications. Refractory voiding dysfunction after TVT or T.O.T. is a relatively uncommon situation and can be successfully managed with a simple release procedure. In most cases, the release procedure does not jeopardize overall improvement in symptoms of SUI.^{17,24}

To conclude, numbers of patient in this study were too small to reach significant difference between T.O.T. and TVT. Nevertheless, both techniques appear to be equally efficient and safe for the surgical treatment of SUI in women, with no difference of bladder outlet obstruction at 1-year follow-up.

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