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ORIGINAL ARTICLE

Incontinence-related quality of life and sexual function following the tension-free vaginal tape versus the "inside–out" tension-free vaginal tape obturator

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Abstract The objective of this cohort study was to compare morbidity, quality of life, and sexual function in stress-incontinent women treated with tension-free vaginal tape (TVT) versus tension-free vaginal tape obturator (TVT-O) in a group of 329. Preoperative scores of the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) were compared to those from a mailed, postoperative questionnaire. The Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ-12) and three additional questions were also included in the mailing. Of the initial 329 patients, 239 (73%) completed the questionnaire with a mean follow-up of 14.7 months. Complications, return to normal voiding, and operative time were less in the TVT-O group. Postoperative PISQ-12 scores and improvements in the UDI-6 and IIQ-7 were comparable between groups. The TVT-O procedure appears to be as effective in improving incontinence-related quality of life as the TVT. No differences in sexual function were demonstrated between groups.

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Introduction

Numerous randomized clinical trials [1–5] have shown the tension-free vaginal tape (TVT) to be equally or more efficacious than traditional surgical procedures for female stress urinary incontinence (SUI). Many feel that these trials, the minimally invasive nature of the procedure, and its favorable long-term objective success [6] have established TVT as a new gold standard in the treatment of SUI. In addition to these objective outcomes, improvements in quality-of-life outcomes with TVT are also well established [7–10]. Postoperative sexual function following this procedure has also been investigated with some studies showing favorable results [11–13]. Despite the overwhelming data supporting the use of the retropubic TVT procedure, many surgeons have started using obturator midurethral slings to treat their patients with SUI.

In an effort to improve the safety and ease of a midurethral sling while maintaining efficacy, Delorme [14] developed an "outside–in" transobturator sling (T.O.T.) in 2001. While this technique did seem to minimize bladder perforations [15], some lower-urinary-tract injuries were still reported [16]. In 2003, this led de Leval [17] to develop an "inside–out" transobturator vaginal tape (TVT-O) procedure in which the passing needle started under the midurethra and was directed away from the bladder through the obturator foramen. While initial data on the "inside–out" sling has been favorable, it is limited to case series [18] and comparative trials with short-term follow-up [19] or minimal quality-of-life data [20–21].

The majority of comparative studies published on obturator slings have been on the "outside–in" technique [15, 22–26].

Given this paucity of research comparing the "inside–out" obturator technique to the retropubic TVT using patient-derived outcomes, we sought to compare these two techniques by assessing perioperative morbidity and longer-term outcomes with validated incontinence-related quality-of-life and sexual function instruments.

Materials and methods

In this ambidirectional cohort study [27], we identified 329 consecutive women with SUI in our practice in whom we had placed a midurethral sling as a sole procedure between January 2004 and March 2006 (women with incontinence and symptomatic pelvic-organ prolapse who had a sling and concomitant prolapse repair were not included in this study). Three attending surgeons (MM, VRL, and BW) performed all the cases. The decision to place a TVT or TVT-O (Gynecare, Ethicon, Johnson & Johnson, Somerville, NJ, USA) was based on physician preference in each individual case; but given some early reports of outcomes with "outside–in" transobturator slings, we tended to minimize the use of TVT-O in patients with maximum urethral-closure pressures (MUCP) ≤40 cm H_2O and/or Valsalva leak point pressures (LPP) ≤60 cm H_2O [28]. TVT was performed as initially described by Ulmsten et al. [29]. TVT-O was performed as described by de Leval [17]. The cough test was used to set the slings in all cases done under local or regional anesthesia. All patients had either a positive standing stress test in the office and/or urodynamic SUI. The decision to proceed with preoperative urodynamic testing was left up to physician discretion; the general policy in our practice is to order testing in patients whom we think may have intrinsic sphincter deficiency (ISD) or detrusor overactivity based on our clinical impression, and/or those with a history of prior pelvic radiation or incontinence surgery. In these cases, LPPs were obtained at an infused volume of 200 ml in a semireclined position, and MUCPs were measured with 8F microtip catheter transducers.

Urodynamic data, demographics (height and weight were measured by office staff, race was self-reported on our intake form), medical history, evaluation of urethral mobility, pelvic organ prolapse quantification, perioperative morbidity data, and responses to the short forms of the Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) [30] (which we started including in our new-patient packets in January 2004) were collected in a retrospective chart review. The UDI-6 is a six-item questionnaire used to assess the distress caused by various urogenital symptoms, and the IIQ-7 is used to measure the psychosocial impact of urinary incontinence on activities of daily living. The long forms of the UDI and IIQ are significantly correlated with both the number of incontinent episodes per week and the pad-weight test, and short forms scores on these instruments are highly correlated with those of the long forms [31]. The UDI-6 can be divided into three subscales: Irritative Symptoms, Obstructive/Discomfort, and Stress Symptoms.

In June 2006, we mailed these same questionnaires to these patients. If more than two items from these questionnaires were missing, scores were not calculated, and these patients were counted as nonresponders. Our primary outcome of interest was change in the UDI-Stress Symptoms subscale score. Of all the instruments we used, this was chosen as our primary outcome because it has been shown to be the most sensitive to change with the TVT procedure [7–8, 32]. However, we also chose to use other instruments to measure secondary outcomes because this approach is recommended by the National Institute of Diabetes and Digestive and Kidney Diseases [33]. In our postoperative survey, we also included the short form of the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ-12) [34] and four additional questions, "Have any doctors had to 'loosen' or 'release' your sling since your original surgery because it was too tight and you had trouble emptying your bladder?", "Do you feel that this surgery has cured your stress urinary incontinence?", and "Have you been sexually active in the last six months?" Response options for these questions were "Yes" or "No." If they answered "Yes" to the last question, they were asked to complete the PISQ-12. Since no preoperative assessment of sexual function was available, the following question was added to the end of the PISQ-12, "How has this surgery affected your sexual activity?" Response options this question were, "No effect or change," "Positive effect," "Negative effect," or "Not applicable (not sexually active)." Questionnaires were mailed twice, and our research nurse (RH) then called those who did not reply and administered the questionnaires verbally.

Univariate analysis comparing baseline and outcome data between the TVT and TVT-O groups was conducted using the Pearson chi-square statistic for categorical data, the independent-samples *t* test for continuous data, and the paired-samples *t* test for repeated measures. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) 15.0 for Windows (SPSS, Chicago, IL, USA).

We performed a power calculation to determine if we had enough patients in our cohort to detect a 25-point difference between groups in our primary dependent variable, change in UDI-Stress Symptoms subscale score. This power calculation was based on a previous study [8] that found a difference in the UDI-Stress subscale between

TVTs performed with and without an intraoperative cough test. This study was powered to detect a 33-point difference. Given previously documented [22] similarities in objective cure rates between obturator and retropubic slings, we decided to increase the clinical relevance of the current study by giving it the power to detect an even smaller difference in scores. We determined that group sample sizes of 70 in each arm were required to achieve an 80% power to detect this 25-point difference between the TVT and TVT-O groups with an α of.05 using a two-tailed test. Our study protocol was approved by the Institutional Review Board of Abington Memorial Hospital.

Results

TVT was performed in 97 and TVT-O in 232 women during our study period. Of these 329 women who underwent midurethral sling placement, 239 (73%) completed the postoperative survey with a mean follow-up time of 14.7 (±6.9) months. There were no statistically significant differences between responders and nonresponders in terms of demographics, preoperative quality-of-life measures, urodynamic results, and perioperative morbidity with one exception; the mean age of survey responders was 4 years older than that of nonresponders (54.8±13.1 vs 50.8±12.4, P=0.02).

Baseline characteristics of the TVT and TVT-O groups are compared in Table 1. Patients in the TVT group tended to have worse measurements on their urodynamic testing as well as a higher incidence of other characteristics associated with ISD including more advanced age. Otherwise, demographics between groups were comparable.

Perioperative data and outcomes from short-term office follow-up are compared in Table 2. None of the patients in our cohort had concomitant surgeries, and 309 (93.9%) were done under intravenous sedation and local anesthesia. Operative time and complications were significantly less in the TVT-O group. Catheters were removed and remained out when patients were able to void adequately (defined as a void greater than 200 ml with a postvoid bladder scan residual of <200 ml). The average time to adequate void was shorter in the TVT-O group. Three patients in each group needed operative release of their sling, and there were no erosions. Office follow-up was significantly longer in the TVT-O group.

There was no statistically significant difference in the proportion of each group that responded to the survey (73.2% of TVTs and 71.6% of TVT-Os, P=0.63), but the mean follow-up was longer in the TVT-O group. Statistically significant changes were found when comparing pre- to postoperative scores on the IIQ-7 and the UDI-6 within each sling group. When comparing the extent of improvement between the TVT and TVT-O groups on these measures, no differences were found (Table 3). Patients did not complete the PISQ-12 preoperatively, but postoperative scores were very similar between groups. This applied to the overall PISQ-12 score, as well as the individual questions that are related to urinary incontinence and pain. In terms of the additional nonvalidated questions asked on the questionnaire, there was no difference between groups in the effect of surgery on sexual function, and no additional cases of sling release were found. Subjective cure rates were comparable between groups, but there was a trend toward greater success with the TVT-O.

Subanalysis of patients with ISD (defined as MUCP ≤20 [35] and/or LPP ≤60 cm H_2O [36]) revealed no differences in baseline characteristics as were seen in the general population. Improvement in quality-of-life measures and subjective cure rates also showed no statistically significant differences, although in this smaller subpopulation of patients there was a trend towards higher subjective cure rates in the TVT group (84.6 vs 50.0%, P=0.15). When using the less-stringent MUCP cut-off of ≤40 cm H_2O suggested in previous studies [26, 28] of "outside–in" obturator slings, quality of life and subjective cure outcomes were very similar between the TVT and TVT-O groups (all P>0.50). However, when looking at patients with traditionally defined [35] low-pressure urethra (MUCP ≤20 cm H_2O, ignoring LPP measures), a statistically significant difference was found between the subjective cure rates of the TVT and the TVT-O groups (100 vs 33.3%, P=0.01). No differences in sexual function as measured by the PISQ-12 were found in any of these subanalyses.

Discussion

This study revealed significant improvements in incontinence-related quality-of-life measures following both the TVT and TVT-O procedures. In a general population of stress-incontinent women, the degree of improvement between sling types was similar. Likewise, there were no differences in sexual function between groups as measured by condition-specific, validated questionnaires. The TVT-O group had a statistically lower rate of intraoperative complications, quicker operating times, and faster return to normal voiding (although possibly not clinically significant). But in a subanalysis of patients with urodynamic findings associated with ISD, there was a trend toward more favorable quality-of-life outcomes and subjective cure rates in the retropubic TVT group.

Our analysis benefited by a large sample size with an average follow-up of greater than 1 year. The use of

Table 1 Baseline characteristics

	TVT (n=97)	TVT-O (n=232)	P value
Age	56.9±12.7	52.5±13.0	0.01
BMI	29.3±6.1	30.4±7.0	0.22
Parity	2.2±1.3	2.2±1.4	0.77
Race (white)	95 (97.9)	229 (98.7)	0.83
Tobacco use	7 (7.2)	27 (11.6)	0.21
Sexually active preoperatively	59 (60.8)	164 (70.7)	0.09
Prior hysterectomy	39 (40.2)	68 (29.3)	0.28
Prior surgery for incontinence	21 (21.6)	24 (10.3)	0.02
Prior surgery for prolapse	3 (3.1)	11 (4.7)	0.72
Preoperative urgency	74 (76.2)	144 (62.1)	0.02
Urethral hypermobility	75 (77.3)	198 (85.3)	0.19
POP-Q stage			
0	57 (72.2)	153 (72.5)	0.29
1	22 (27.8)	52 (24.6)	
2	0 (0)	6 (2.8)	
Preoperative urodynamics	71 (73.2)	126 (54.3)	<0.01
Preoperative MUCP	34.4±20.4	61.4±23.6	<0.01
Preoperative LPP	77.6±20.3	89.9±24.3	0.04
Preoperative ISD	16 (22.5)	4 (3.2)	<0.01
Preoperative IIQ-7	43.2±25.6	38.9±26.3	0.27
Preoperative UDI-6			
Total	56.6±18.3	49.4±20.2	0.01
Stress subscale	81.7±20.9	75.6±24.2	0.08
Irritative subscale	65.3±30.9	51.6±32.6	<0.01
Obstructive subscale	22.2±26.9	20.9±26.6	0.73

Values are presented as mean±SD for continuous data and as n (%) for categorical data.
POP-Q Pelvic Organ Prolapse Quantification system (values not available for all patients); *MUCP* maximum urethral closure pressure and *LPP* leak point pressure, both measured in cm H_2O; *ISD* intrinsic sphincter deficiency (defined as MUCP ≤20 and/or LPP ≤60; denominator only includes patients who underwent urodynamic testing in each group); *IIQ-7* short form of the Incontinence Impact Questionnaire; *UDI-6* short form of the Urinary Distress Inventory.

validated quality-of-life and sexual function questionnaires was likewise a strength. We also investigated "subjective" cure rates. While some may consider these outcomes less important than "objective" ones, many studies of female stress incontinence have found subjective cure to be a more rigorous definition of success than objective cure [1, 26]. This study did suffer from a number of limitations, however. Group selection was not randomized and, in fact,

Table 2 Perioperative data and office follow-up outcomes

	TVT (n=97)	TVT-O (n=232)	P value
Anesthesia/analgesia			
Local with sedation	91 (93.8)	218 (94.0)	0.16
General	4 (4.1)	4 (1.7)	
Regional	2 (2.1)	10 (4.3)	
Operative time (min)	33.0±7.4	27.0±15.9	<0.01
Intraoperative complication	2 (2.5)	0 (0)	0.02
Estimated blood loss	26.9±6.2	26.1±11.3	0.57
Discharged to home same day	97 (100)	232 (100)	–
Postoperative day of first void	0.5±1.1	0.1±0.4	<0.01
Length of office follow-up (month)	3.1±3.5	5.0±5.0	<0.01
Slings needing release	3 (3.1)	3 (1.3)	0.27
Erosion	0 (0)	0 (0)	–
De novo urgency	3 (3.8)	14 (6.6)	0.35
Preoperative urgency resolved	43 (58.1)	71 (49.2)	0.70

Values are presented as mean±SD for continuous data and as n (%) for categorical data.

Table 3 Survey outcomes—comparison between groups

	TVT (n=71)	TVT-O (n=166)	P value
Follow-up time survey (month)	13.1±5.5	15.4±7.4	0.02
Change from pre- to postoperative score			
IIQ-7	26.0±31.1	25.4±29.6	0.92
UDI-6			
Total	36.5±26.2	32.5±22.9	0.34
Stress subscale	61.2±37.7	59.6±34.6	0.79
Irritative subscale	39.9±34.2	29.6±32.9	0.07
Obstructive subscale	10.4±28.9	8.4±26.2	0.66
Sexually active in the last 6 months	37/71 (52.1)	108/166 (65.1)	0.05
Sexually active patients who completed the PISQ-12	36/37 (97.3)	103/108 (95.4)	0.68
Postoperative PISQ-12 score	96.5±16.9	97.6±14.2	0.75
Question number 5 of the PISQ-12 (~pain with intercourse)	3.1±1.0	3.2±1.1	0.65
Question number 6 of the PISQ-12 (~incontinence with sex)	3.7±0.7	3.7±0.7	0.63
Question number 7 of the PISQ-12 (~fear of incontinence)	3.6±0.7	3.7±0.8	0.70
Effect of surgery on sexual function[a]			
No effect	19/36 (52.8)	64/105 (61.0)	0.18
Positive effect	14/36 (38.9)	39/105 (37.1)	
Negative effect	3/36 (8.3)	2/105 (1.9)	
Subjective cure	55/71 (77.5)	143/165 (86.7)	0.08

Values are presented as mean±SD for continuous data and as x/n (%) for categorical data.
PISQ-12 Short form of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; *IIQ-7* short form of the Incontinence Impact Questionnaire; *UDI-6* short form of the Urinary Distress Inventory.
[a] Two patients in the TVT-O group answered "no effect" on this isolated question regarding the effect of surgery on sexual function but declined to complete the PISQ-12.

was subject to selection bias in that more patients with severe incontinence were included in the TVT group. We tried to minimize this bias in our analysis by stratifying patients into a general population and an ISD population. In addition, in our analysis of quality-of-life measures, we calculated not only absolute pre- to postoperative change but also the percent change in score in an effort to control for differences in preoperative symptom severity. Finally, we had greater than 20% loss to follow-up and did not perform an intention-to-treat analysis. It is possible that more failures chose not to respond to our questionnaire, but the percent of patients lost to follow-up was equally divided between the two sling groups.

This investigation adds to a growing body of literature that shows similar efficacy in obturator and retropubic midurethral slings while minimizing the untoward risks associated with the latter [15, 19, 25, 26]. The lateral direction of needle and sling guidance of the TVT-O in contrast to the more cephalad direction of the TVT appears to decrease the risk of a bladder perforation while making a bowel perforation almost impossible (although an extremely large trial would be necessary to confirm a decreased risk in this potentially disastrous but rare complication). There has been a fear that this lateral pass near the anterior sulcus of the vagina and inner surface of the ischiopubic ramus might lead to adverse sexual effects. Theoretical complications include intraoperative neurological damage (since the inside–out approach heads in the direction of the dorsal nerve of the clitoris) and postoperative erosion of mesh in the vaginal sulcus. No such increased risk of adverse sexual effects has been demonstrated in our study.

It has been postulated that this obtuse angle of an obturator sling under the urethra, in contrast to the more acute angle of the retropubic TVT, may contribute to less circumferential compression of the urethra. Miller et al. [26] hypothesized that this decrease in compressive forces may fail to prevent postoperative stress incontinence in "outside–in" obturator slings in patients with lower MUCPs. They and others [28] found this cut-off point to be around 40 cm H_2O, while we found it to be at the more conventional value of low-pressure urethra, 20 cm H_2O. There are too many uncontrolled variables between studies to speculate on the reason for this disparity. Nonetheless, the similarities in the findings of these investigations, whether the "outside–in" or "inside–out" approach is used, should serve as a caution in the use of obturator slings in patients with low urethral-closure pressures until longer-term results from prospective randomized trials are available.

The balance of efficacy and safety is an issue that individual clinicians must struggle with every day. Quality-of-life measures and other patient-assessed outcomes help

to prevent the oversimplification of these complex issues. While we cannot definitively conclude from a non-randomized investigation that one type of sling is superior or inferior to another, this study demonstrates that the TVT-O yields outcomes similar to the retropubic TVT in a large cohort of stress-incontinent women when it is used sparingly in patients with clinical risk factors for—or urodynamic evidence of—ISD. While it is certainly possible that the outcomes in the TVT-O cohort might have been even more favorable if they had all undergone the retropubic TVT; it is also possible that more clinically significant complications would have occurred as well. Ongoing randomized trials [19] should help to elucidate the balance of long-term efficacy and safety in regards to the various midurethral slings now available and provide more information on how to determine which procedure is the "best fit" for an individual patient. In the meantime, we hope that this study may help with patient selection for clinicians who are looking to introduce obturator slings into their surgical armamentarium without a significant drop in the outcomes they are having with the retropubic TVT.

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