Evaluation of Transobturator Tension-free Vaginal Tapes in Management of Women With Recurrent Stress Urinary Incontinence

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OBJECTIVES To assess the efficacy of transobturator tapes in the treatment of women with recurrent urodynamic stress incontinence.

METHODS We performed a secondary analysis of a prospective, randomized, single-blinded study. A total of 341 women were recruited (April 2005 and April 2007) and randomly assigned to undergo "inside-out" TVT-O or "outside-in" TOT-ARIS. Of these women, 46 had undergone ≥1 previous continence procedures and were included in the present study. The preoperative assessment included a urodynamic assessment and completion of validated symptom severity and quality-of-life questionnaires. The primary outcome was the patient-reported success rate at 1 year as assessed using the Patient Global Impression of Improvement (very much/much improved). The secondary outcomes included changes in quality of life, sexual function, the objective success rates defined as negative findings on the standard 1-hour pad test, and a comparison between both routes of transobturator tapes. Multivariate analysis was performed to identify the risk factors for failure.

RESULTS All 46 women completed the 1-year follow-up period. The patient-reported success rate and objective cure rate was 69.6% and 76.5%, respectively, with no significant differences between the 2 transobturator routes ($P = .104$, odds ratio [OR] 2.933, 95% confidence interval [CI] 0.803-10.719; and $P = .077$, OR 4.524, 95% CI 0.849-24.109, respectively). Of the 46 women, 35 (76.1%) reported >10-point improvement on the total King's Health Questionnaire scores and 71% of sexually active women (n = 22) showed an improvement in the total 12-item Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire scores. On multivariate analysis, a maximal urethral closure pressure of <30 cm H_2O was the only independent risk factor for failure ($P = .016$, OR 9.206, 95% CI 1.511-56.104).

CONCLUSIONS Transobturator tapes have good patient-reported and objective success rates at 1 year of follow-up in women with previous failed incontinence surgery. A low maximal urethral closure pressure was the only independent predictor of failure. UROLOGY 77: 1070–1075, 2011. © 2011 Elsevier Inc.

Midurethral tension-free vaginal slings (MUSs) are now well established as the reference standard surgical treatment of female stress urinary incontinence (SUI). The retropubic transvaginal tape[1] (TVT) is the most widely popular MUS procedure worldwide, with >1 million procedures performed to date.[2] The TVT has been shown to be equally effective for colposuspension, as a primary continence surgery, with ≤5 years of follow-up[3] and to retain a relatively high long-term patient-reported success rate of 77% at 11 years.[4] The role of retropubic TVT as secondary continence surgery is, however, less clear. Despite this recognized uncertainty, only a small number of studies,[5-10] involving relatively small populations have attempted to assess TVT as a secondary continence procedure and showed patient-reported/objective success rates in range of 70%-80%.[5-7]

Transobturator tension-free vaginal tapes (outside-in[11] and inside-out[12] routes) are relatively newer and have gained wide popularity, primarily because of their comparable success rates to retropubic TVTs at 12 months of follow-up and their relatively safer route of insertion. They have been associated with lower rates of bladder

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injury,[13,14] and no cases of bowel or iliac vessels injuries have been reported, which can be of particular relevance to women with previous retropubic surgery and possible distorted anatomy. However, only a limited number of studies have attempted to assess the role of transobturator tapes in these women.[15-17] These were mainly retrospective studies[15,16] and with limited numbers, indicating a clear gap in the published data.

The aim of the present study was to evaluate the role of transobturator tapes in the treatmemt of women with recurrent SUI after one or more failed previous continence surgeries.

MATERIAL AND METHODS

A secondary analysis for a prospective single-blinded randomized study performed in a tertiary urogynecology center. The West of Scotland Research Ethics Committee approved the present study, and the protocol was registered at www.clinicaltrials.gov (March 2005). A total of 341 women were randomly assigned to undergo either "inside-out"[12] TVT-O (Ethicon, Somerville, NJ) or the "outside-in" transobturator tape (TOT) ARIS[11] (Coloplast, Minneapolis, MN), using opaque sealed envelopes, from April 2005 to April 2007.[18] Of the 341 women, 46 who had undergone one or more previous failed continence procedures, were the basis of the present analysis.

The women were included if they had SUI or mixed incontinence with predominant bothersome SUI symptoms and had failed or declined pelvic floor muscle training. The women were excluded if they had undergone concomitant surgery or had uterovaginal prolapse (pelvic organ prolapse quantification stage 2 or greater), predominant bothersome overactive bladder symptoms, or specific comorbidities, such as multiple sclerosis and diabetes. The preoperative assessment included detailed history, pelvic examination, urodynamic assessment (eg, free uroflowmetry, subtracted multichannel cystometry, and urethral pressure profile) and completion of the King's Health Questionnaire (KHQ),[19] Birmingham Bowel Urinary Symptom Questionnaire,[20] and Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire (PISQ-12).[21]

The procedures were performed as originally described.[11,12] We did not attempt to identify the previous tapes. The postoperative voiding assessment was done using a standard local protocol,[18] and satisfactory voiding was defined as a postvoid residual urine volume of $<$100 mL and a voided volume of $\geq$250 mL. The postoperative assessment was performed $\geq$12 months postoperatively by an independent clinician unaware of the treatment conditions. These parameters were reassessed with the addition of the Patient Global Impression of Improvement,[22] International Consultation on Incontinence Questionnaire-short form[23] questionnaires, and the International Continence Society standard 1-hour pad test. The primary outcome was the "patient-reported success," as assessed by Patient Global Impression of Improvement as "very much improved" or "much improved." The secondary outcomes were the objective cure, defined as negative pad test findings ($\leq$1 g gain), the effect on the women's quality of life (changes in the KHQ scores), and the effect on the women's sexual life (changes in the PISQ-12 total score). The outcomes were assessed in the whole cohort and were compared between the "outside-in" and "inside-out" transobturator routes.

Statistical analysis was performed using the Statistical Package for Social Sciences, version 17 (SPSS, Chicago, IL), with a significance level of 5%. The categorical variables were tested using the chi-square test and Fisher's exact test for the 2 independent variables. Wilcoxon tests were used to test for differences in the scores from preoperatively to postoperatively. The Mann-Whitney *U* test was used to compare the differences between the 2 groups. The factors associated with failure were assessed on univariate logistic regression analysis; those with P $<$1.0 were entered in a multivariate model to determine the independent predictors.

RESULTS

A total of 46 women with recurrent SUI and previous failed continence surgery were recruited and included in the present analysis ("outside-in," n = 18 vs "inside-out," n = 28). All women received the allocated treatment and completed the 12 months of follow-up. The median duration between the previous and repeat continence surgery was 4.8 years (range 6 month to 12 years), with 4 women describing persistent SUI from their initial surgery. The patient characteristics and details of the previous continence surgery are listed in Table 1.

The mean $\pm$ SD operative time was 16 $\pm$ 5.8 minutes (range 12-48). Of the 46 women, 4 (8.6%) had vaginal angle perforation requiring repair. One woman sustained a bladder injury (2%) and another a urethral injury (2%). Both women had undergone the "outside-in" route; the injury had occurred during dissection rather than at trocar insertion and was repaired during surgery with the insertion of a catheter for 7 days. Postoperatively, 5 women (10.8%) required catheterization; all had achieved satisfactory voiding within 2-14 days with no additional intervention. No cases of bleeding ($>$200 mL) or tape erosion were encountered. At 12 months of follow-up, 2 (5.7%) of 35 women had developed de novo urgency and 2 (18%) of 11 women had worsening of preoperative urgency; all were receiving antimuscarinic treatment at 12 months postoperatively. Of the 11 women, 6 (55%) had improvement or cure of preoperative urgency and 3 (27%) of the 11 women had no change.

All 46 women completed the 12-month follow-up, although 12 women declined to attend for the International Continence Society pad test and completed the questionnaires at home. Two women who initially did not attend their 12-month follow-up visit eventually completed the questionnaires at 18 and 21 months. The patient-reported success rates were consistently greater with the "inside-out" route; however, they did not reach statistical significance in any of the variables assessed (Table 2). The objective cure rate was greater for the "inside-out" route than for the "outside-in" route; however, the difference did not reach statistical significance, with a narrow margin (86.4% vs 58%, odds ratio [OR] 4.524, 95% confidence interval [CI] 0.849-24.109, P = .07). The patient-reported success rates and objective cure rates in our study were significantly lower than that for women undergoing TOT placement as "primary sur-

Table 1. Preoperative patient characteristics

Characteristic	Total Cohort	Inside-Out TVT-O	Outside-In ARIS	*P* Value
Patients (n)	46	28 (60.87)	18 (39.13)	
Age (y)				.637
Mean ± SD	55.81 ± 10.47	55.22 ± 9.70	56.73 ± 11.66	
Range	29-78			
BMI >30 kg/m^2	18 (39)	8 (28.6)	10 (55)	.090
Mixed incontinence	13 (28.3)	9 (32.1)	4 (22.2)	.694
MUCP <30 cm H_2O	10 (21.7)	6 (21.4)	4 (22.2)	1
Current antimuscarinic agents	7 (25.9)	3 (20.0)	4 (33.3)	.662
Previous hysterectomy	23 (50)	13 (46.4)	10 (55.6)	.763
Previous continence surgery				
Colposuspension	15 (32.6)	9	6	.442
Retropubic TVT	15 (32.6)	9	6	.442
Transobturator tapes	11 (24)	7	4	.372
Colposuspension and suburethral tape	5 (10.8)	3	2	.657

BMI = body mass index; MUCP = maximal urethral closure pressure.
Data in parentheses are percentages.

Table 2. Objective and patient-reported success rates

	Total	Outside-in ARIS	Inside-Out TVT-O	OR (95% CI)	*P* Value
PGI*	32/46 (69.6)	10/18 (55.6)	22/28 (78.6)	2.933 (0.803-10.719)	.104
Standard ICS 1-h pad test†	26/34 (76.5)	7/12 (58.3)	19/22 (86.4)	4.524 (0.849-24.109)	.077
Satisfaction Scale‡	31/43 (72.1)	10/16 (62.5)	21/27 (77.8)	0.476 (0.122-1.854)	.285
ICIQ-SF§	30/46 (65.2)	9/18 (50.0)	21/28 (75.0)	3.00 (0.852-10.567)	.087

OR, odds ratio; CI, confidence interval; PGI-I, Patient Global Impression of Improvement; ICIQ-SF, International Consultation on Incontinence Questionnaire-short form; ICS, International Continence Society.
* Success indicated by "very much improved or much improved."
† Cured indicated by pad gain of ≤1 g.
‡ Success indicated by score of ≥8/10.
§ Success indicated by "never leaked" or "leak few drops once or less per week."

Table 3. King Health Questionnaire scores before and after transobturator tape surgery and comparing outside-in versus inside-out routes

KHQ Variable	Median Difference (Pre-Post)	*P* Value	Approximate 95% CI	Median Difference (ARIS-TVT-O)	*P* Value	Approximate 95% CI
General health	0	.855	0.0, 12.5	0	.28	−24.99, −0.00
Incontinence effect	50	< .001*	33.3, 66.7	0	.832	−33.33, 33.34
Role limitation	50	< .001*	33.3, 58.3	0	.695	−33.35, 16.68
Physical limitation	50	< .001*	33.3, 58.3	0	.854	−33.33, 16.66
Social limitation	33.33	< .001*	22.2, 50.0	−11.11	.39	−33.33, 11.11
Personal relations	20.67	.001*	3.2, 36.5	0	.534	−33.33, 33.32
Sleep/energy	16.67	.001*	8.3, 33.3	−16.67	.44	−33.33, 16.66
Severity measures	41.67	< .001*	29.2, 54.2	−16.67	.222	−33.33, 8.33
Total	34.79	< .001*	25.8, 43.5	−7.72	.369	−23.93, 12.65

KHQ, King Health Questionnaire; CI, confidence interval.
* Statistically significant ($P < .05$).

gery"[18] (69.6% vs 81.5%,[18] $P = .0497$; and 76.5% vs 94%,[18] $P = .003$, respectively).

All 46 women completed the KHQ preoperatively and ≥12 months postoperatively. Of the 46 women, 35 (76.1%) had a ≥10 point improvement (range 16-50 points) in the total KHQ score, with no significant differences between the 2 groups (outside-in 66.7% vs inside-out 82.1%, $P = .236$, OR 2.300, 95% CI 0.580-9.113). Except for the general health domain, all domains of the KHQ and the total score showed statistically and clinically significant (≥10-point) improvement (Table 3) at 12 months, with no significant differences between the 2 groups. Similarly, 31 sexually active women completed a valid pre- and postoperative PISQ-12 (ie, ≤2 missing values). Of these 31 women, 22 (71.0%) showed an improvement in their total PISQ-12 score at 12 months (outside-in 69.2% vs inside-out 72.2%, $P = .856$, OR 0.865, 95% CI 0.181-4.141; Table 4).

Using univariate analysis, the various potential risk factors for failure of TOTs were assessed and found to be an insignificant association, including age, number of previous continence surgery, duration between previous and repeat continence surgery, urgency, and urgency incontinence. However, a body mass index of ≥30 kg/m^2, the route of insertion (inside-out vs outside-in), and low

Table 4. Prolapse/Incontinence Sexual Function Questionnaire scores before and after transobturator tape surgery and comparing outside-in versus inside-out routes

PISQ-12 Variable	Median Difference (Post-Pre)	*P* Value	Approximate 95% CI	Median Difference (ARIS-TVT-O)	*P* Value	Approximate 95% CI
Sexual desire frequency	0	.706	0.0, 0.5	0	1	−1.00, 1.00
Climax	0	.636	−0.5, 0.5	0	.439	−1.00, 1.00
Sexually excited	0	.683	−0.5, 0.5	0	.349	−0.00, 1.00
Variety of activities	0	.293	0.0, 0.5	0	.677	−1.00, 1.00
Pain during intercourse	0	.977	−0.5, 0.5	0	.983	−1.00, 1.00
Coital incontinence	1.5	< .001*	1.0, 2.0	0	.482	−1.99, 0.99
Fear of incontinence	1	.001*	0.5, 1.5	0	.709	−1.00, 1.00
Avoidance of sexual intercourse	0.5	.038*	0.0, 1.0	0	.255	−2.00, 0.00
Negative emotions	0.5	.012*	0.0, 1.0	0	.325	−2.00, −0.00
Erectile dysfunction	0	.386	−0.5, 0.0	0	.145	−1.00, 0.00
Premature ejaculation	0	.361	0.0, 0.0	0	.871	0.00, 0.00
Orgasm intensity	0.5	.094	0.0, 1.0	0	.413	−1.00, 0.00
Total score	5	.003*	2.0, 8.0	−5	.193	−9.99, 2.00

PISQ-12, Pelvic Organ Prolapse/Incontinence Sexual Function Questionnaire; CI, confidence interval.
* Statistically significant ($P < .05$).

maximal urethral closure pressure (MUCP) <30 cm H_2O were potential risk factors, with $P < .1$. On multivariate analysis, MUCP <30 cm H_2O was the only independent risk factor of failure ($P = .016$, OR 9.206, 95% CI 1.511-56.104).

COMMENT

The lack of understanding of the etiology of recurrent SUI means that the treatment of women with this condition represents a clinical and surgical dilemma that is set to increase. In the late 1990s, colposuspension was the reference standard procedure for SUI. Sivaslioglu et al[17] have recently shown a recurrence rate of 16% within 7 years after colposuspension. Other studies have shown recurrence rates of 5%-62%.[24-26] Recurrent SUI after MUS placement has been attributed to improper adjustment at the primary surgery, failure of the sling to fix in place, and/or the underlying pathologic features of SUI, such as intrinsic sphincter deficiency.[9]

All women in our study underwent transobturator tape insertion as a sole procedure; therefore, and unlike other studies,[6,16] we avoided the potential confounding effect of the concomitant prolapse repair on the outcome or complications of the procedure. The patient-reported success rate at 12 months was almost 70% (55.6% for outside-in TOT and 78.6% for inside-out TVT-O). This difference was not statistically significant; however, it is important to note that the study lacked the power to show a difference between the 2 groups. Biggs et al[15] reported a comparable 81% patient-reported success rate in 27 women who underwent TVT-O as secondary continence surgery. The latter study had a number of limitations; it was retrospective and had included women with concomitant prolapse repair. Our results with the "outside-in" TOT were comparable to the 62.5% and 62% rates reported for TOT after failed MUS[7] and colposuspension,[17] respectively. A possible theory for the greater success rate shown in our study with the "inside-out" route, although not significant, is the limited dissection behind the inferior pubic ramus, which might contribute to better fixing of the tape in position and, consequently, better urethral support.

The patient-reported success rate of 70% in our study was comparable to that of other studies of retropubic TVT as secondary continence surgery.[5-7] Liapis et al[5] have recently reported a 71% patient-reported cure rate for 31 women who underwent retropubic TVT after failed MUS placement. The objective cure rate of retropubic TVT (83%) reported by Lo et al[6] was significantly greater than our objective cure rate of 76.5% and also greater than that reported by Liapis et al[5] (77%). We believe that the patient-reported success rates, although rarely differentiating between the recurrence of SUI and the development of urgency incontinence, are much more clinically valuable than objective testing, which might overestimate the success of these procedures.

Comparing the patient-reported success rates and objective cure rates with women undergoing transobturator tapes as "primary surgery"[18]; significantly lower cure rates were seen in the repeat surgery group (69.6% vs 81.5%,[18] $P = .0497$ and 76.5% vs 94%,[18] $P = .003$, respectively). These results agree with those by Stav et al.[27] They retrospectively assessed 1225 women who had undergone MUS, including 77 women with repeat surgery, and a mean follow-up of 50 months. The patient-reported success rate was 86% and 62% in the primary and repeat surgery groups, respectively ($P < .001$). In their study, repeat retropubic TVT was significantly more successful than the repeat transobturator approach (71% vs 48%, respectively, $P = .04$). The latter study was limited by its retrospective nature and by the small number of women (n = 29) who underwent a transobturator tape procedure as repeat surgery compared to retropubic TVT.

The rate of perioperative complications in our study was low, reflecting the relative favorable safety profile of these procedures. Most complications were dissection-

related and easily repaired. Two cases of lower urinary tract injuries occurred during dissection and were unrelated to the trocar or route of insertion. This was comparable to 2 cases of lower urinary tract injuries that occurred in women with primary transobturator tape surgery[18] (4.5% vs 0.007%, respectively. $P = .081$). However, a much larger study would be required to detect a significant difference, knowing the rarity of this complication. Repeat retropubic TVT was associated with a greater incidence (9%) of lower urinary tract injuries in most studies.[6,28,29] The incidence of de novo urgency in our study (5.7%) was similar to the 5% reported by Lo et al[6] after repeat TVT. However, it was much lower than the 10%-13% reported by Van Baelen and Delaere[16] and Liapis et al[5] after TOT and TVT. Therefore, the current evidence on de novo urgency after secondary MUS surgery does not favor one approach of MUS over the other.

Our study is the only study to date to assess the effect of secondary MUS surgery on women's quality of life and sexual life. Kelleher et al[30] has shown that a 10-point improvement in KHQ scores would be reflected as a clinically significant improvement in quality of life. Except for the general health domain, the vast majority of women in our study reported clinically significant improvement in all KHQ domains and total KHQ score. Similarly, most sexually active women (71%) showed improvement in their sexual function postoperatively. These results are comparable to those from other prospective studies assessing the quality of life and sexual function after MUS placement as primary continence surgery.

Liapis et al[5] showed that a low MUCP did not affect the success rates of repeat TVT but that a combination of low MUCP and limited urethral mobility have significantly reduced the success rate. A major limitation in the latter study was the lack of multivariate analysis, raising the possibility that the difference in success rates might have been affected by other confounding factors. Our multivariate analysis has shown a low MUCP was the only independent risk factor for failure of transobturator tapes as secondary continence surgery. This finding is of clinical importance as it may affect our approach to investigation and surgical choice in these women. A recently published Canadian guidelines[31] highlighted that autologous slings and low-tension retropubic TVT are considered more optimal procedures compared with TOTs, in women with a combination of previous continence surgery and intrinsic sphincter deficiency, because they are more obstructive and exert more urethral pressure at time of stress.

The potential limitations in our study included that opaque, sealed envelopes for allocation concealment can be liable for flaws. However, we have taken every measure to avoid any tampering with the envelopes that were opened only on day of surgery by an independent nurse. The imbalance in numbers between both groups of TOTs resulted from the randomization process for the whole cohort (primary and secondary continence surgery) and, together with the relatively small cohort, has led to the lack of power to show a significant difference between both transobturator procedures. The results of the present study cannot be applied to women undergoing repeat continence surgery with concomitant prolapse repair. Nevertheless, the present study has a number of strengths; it is the largest prospective study to date to evaluate the success rate of TOTs in women with previous failed continence surgery and the first to address their impact on the quality of life and sexual function. The validity of the results are enhanced by the prospective randomized setting with robust inclusion/exclusion criteria, a standard postoperative assessment using validated tools, and the performance by an independent blinded clinician.

The research question of our study is of the utmost importance to the clinical community. The finding of an acceptable overall success rate (70%) for the TOT in women with previous failed continence surgery would open up new routes for treatment of recurrent stress incontinence, especially because TOTs avoid the blind passage into the retropubic space and therefore are associated with lower perioperative morbidity.

CONCLUSIONS

The results of our study have shown that TOTs are associated with good patient-reported and objective success rates at 12 months of follow-up in women with previous failed incontinence surgery, with a trend toward greater success rates with the inside-out route. Most women showed significant improvement in their quality of life with low rates of perioperative morbidity. A MUCP of <30 cm H_2O was the only independent predictor of failure.

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