

# Three-Year Follow-Up of Tension-Free Vaginal Tape Compared With Transobturator Tape in Women With Stress Urinary Incontinence and Intrinsic Sphincter Deficiency

Lore Schierlitz, FRANZCOG, Peter L. Dwyer, FRANZCOG, Anna Rosamilia, FRANZCOG, Christine Murray, CNC, Elizabeth Thomas, CNC, Alison De Souza, FRANZCOG, and Richard Hiscock, FANZCA

**OBJECTIVE:** To compare the efficacy of tension-free vaginal tape (TVT) to transobturator tape in the treatment of women with stress urinary incontinence (SUI) and intrinsic sphincter deficiency at 3-year follow-up.

**METHODS:** One hundred sixty-four women were randomized to either TVT or transobturator tape after diagnosis of urodynamic stress incontinence and intrinsic sphincter deficiency. Concomitant pelvic organ prolapse surgery was not an exclusion criterion. The primary outcome assessed at 3-year follow-up was symptomatic stress incontinence requiring repeat surgery. Secondary outcomes were quality-of-life parameters assessed by validated questionnaires and numerical success score.

**RESULTS:** One hundred sixty-four women were enrolled in the study. At 3 years, 15 of the 75 (20%) women in the transobturator tape group underwent repeat surgery to correct SUI compared with one of the 72 (1.4%) in the TVT group. In other words, if TVT had been used exclusively, repeat surgery would have been avoided in one in six patients. The risk ratio of repeat surgery was 15 (95%

confidence interval 2–113;  $P < .001$ ) times greater in the transobturator tape group. In the transobturator tape group, the median time to repeat surgery was 15.6 months compared with 43.7 months for TVT ( $P < .001$ ). The quality-of-life outcomes did show an improvement in both groups before and after surgery but no difference between the two slings in the Urogenital Distress Inventory short form, the Incontinence Impact Questionnaire short form, and a patient-rated numerical success score.

**CONCLUSION:** The long-term cure rates for retropubic TVT are significantly greater than for transobturator tape in women with urodynamic stress incontinence and intrinsic sphincter deficiency. Urethral functions tests such as urethral closure pressure and Valsalva leak point pressures are of value in determining what surgery to perform.

**CLINICAL TRIAL REGISTRATION:** Australian New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://www.anzctr.org.au), ACTRN12608000093381.

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**LEVEL OF EVIDENCE: I**

Women with intrinsic sphincter deficiency associated with stress urinary incontinence (SUI) often have greater severity of symptoms compared with those without intrinsic sphincter deficiency. This may be the result of the urethral closure mechanism functioning poorly as a result of aging, neurological etiology, or previous surgery. The surgical success rates for treatment of intrinsic sphincter deficiency are lower compared with those with SUI and normal urethral function. Patients with intrinsic sphincter deficiency therefore pose a greater challenge in management for the clinician.<sup>1</sup>

From the Department of Urogynecology, Mercy Hospital for Women, Heidelberg, and the Department of Urogynecology, Monash Medical Centre, Clayton, Australia.

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Corresponding author: Lore Schierlitz, FRANZCOG, Department of Urogynecology, Mercy Hospital for Women, 163 Studley Road, Heidelberg 3084, Victoria, Australia; e-mail: [lschierlitz@mercy.com.au](mailto:lschierlitz@mercy.com.au).

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Minimally invasive synthetic slings have now become the most common procedure performed for SUI replacing the pubovaginal fascial sling and Burch colposuspension. Tension-free vaginal tape (TVT) was the first synthetic midurethral sling introduced and prospective studies show long-term cure rates greater than 77% for SUI.<sup>2</sup> Tension-free vaginal tape has shown to be equivalent in efficacy to the Burch colposuspension with less side effects and a quicker recovery time.<sup>3,4</sup> Traditionally, the pubovaginal fascial sling was considered the procedure of choice for women with intrinsic sphincter deficiency. Bulking agents are an option for those women not suitable for major surgery or as second-line approach. After the TVT procedure, a cure rate of 74% and improvement of 12% were described in women with intrinsic sphincter deficiency.<sup>5</sup>

Transobturator midurethral tapes were introduced to minimize the complications of the retropubic slings, which include injury to the bladder, major vessels, and bowel. Transobturator midurethral tape has shown similar safety and efficacy to TVT in a recently published randomized trial,<sup>6</sup> meta-analyses, and in retrospective series.<sup>7-9</sup> Unfortunately, data about intrinsic sphincter deficiency cannot be extrapolated from these previous studies because the numbers of patients with intrinsic sphincter deficiency were small, not analyzed separately, or patients with intrinsic sphincter deficiency were excluded.

The aim of this study was to compare the long-term efficacy of retropubic TVT with transobturator midurethral tape in women with SUI and intrinsic sphincter deficiency. We have previously reported the 6-month data and found that the objective success rate of TVT was greater in these patients compared with transobturator midurethral tape.<sup>10</sup> The 3-year follow-up will provide more information on the long-term outcomes of midurethral slings in this patient group. We hypothesize that transobturator tape will continue to have higher objective and subjective failure rates than retropubic TVT.

## MATERIALS AND METHODS

Prospective ethics approval was granted by the review boards of both participating tertiary hospitals. Women who had failed conservative management for SUI and who were diagnosed with intrinsic sphincter deficiency on urodynamic studies were invited to participate. Informed consent was obtained and women were randomized to either the TVT or transobturator midurethral tape procedure by computer-generated allocation. Detailed descriptions of the study methods including inclusion and exclusion criteria and surgical technique have been previously reported in the 6-month findings.<sup>10</sup> All definitions

and methods conform to the standards recommended by the International Continence Society.<sup>11,12</sup>

The preoperative and postoperative protocol included urogynecological history and examination, a 3-day bladder diary, and 24-hour pad weight test. Multichannel urodynamic testing was performed before and again at 6 months after surgery. This was repeated later if the patient developed new-onset incontinence symptoms. Urodynamic testing included uroflowmetry, urethral pressure profilometry before cystometry and at bladder capacity (400–500 mL if tolerated), and pressure voiding study. The abdominal leak point pressures were established by direct visualization with cough and Valsalva in semirecumbent and standing positions. Validated quality-of-life questionnaires were completed preoperatively and postoperatively to assess subjective improvement. These included the Urogenital Distress Inventory short form and the Incontinence Impact Questionnaire short form. Patients also completed a numerical success score ranging from 0 to 100 (0 equals complete failure to 100 equals cure) to evaluate the symptomatic improvement after their sling procedure.

Patient follow-up took place at 6 months, 12 months, and yearly thereafter. The 3-year primary end point was symptomatic stress incontinence considered as failure requiring a repeat procedure on request of the patient. Complications at 3 years including voiding dysfunction, as well as change in quality of life as assessed by the Urogenital Distress Inventory short form, Incontinence Impact Questionnaire short form, and numerical success score were recorded. For all trial participants symptomatic of recurrent SUI confirmed by urodynamic assessment, we applied the standard practice of our unit to offer repeat surgery. This was usually a retropubic sling, TVT, inserted as described in the previous article.<sup>10</sup>

Sample size calculations assumed an 80% success in the TVT group with an effect of 20%, 80% power, and  $\alpha$  at 0.05. Ninety-one patients were required in each group. Recruitment started in 2004 and stopped in 2007 as a result of slow accrual of patients with intrinsic sphincter deficiency.

The median (25th–75th percentile), mean (standard deviation), or count (%) was used to present the data according to distribution (assessed by graphical methods). Testing of the hypothesis based on postoperative–preoperative difference scores for the total quality-of-life scores (Urogenital Distress Inventory short form and Incontinence Impact Questionnaire short form) used unpaired and paired *t* tests for between- and within-group analyses. Wilcoxon sign rank test and Wilcoxon rank-sum test were used for Urogenital Distress Inventory short form subscores.

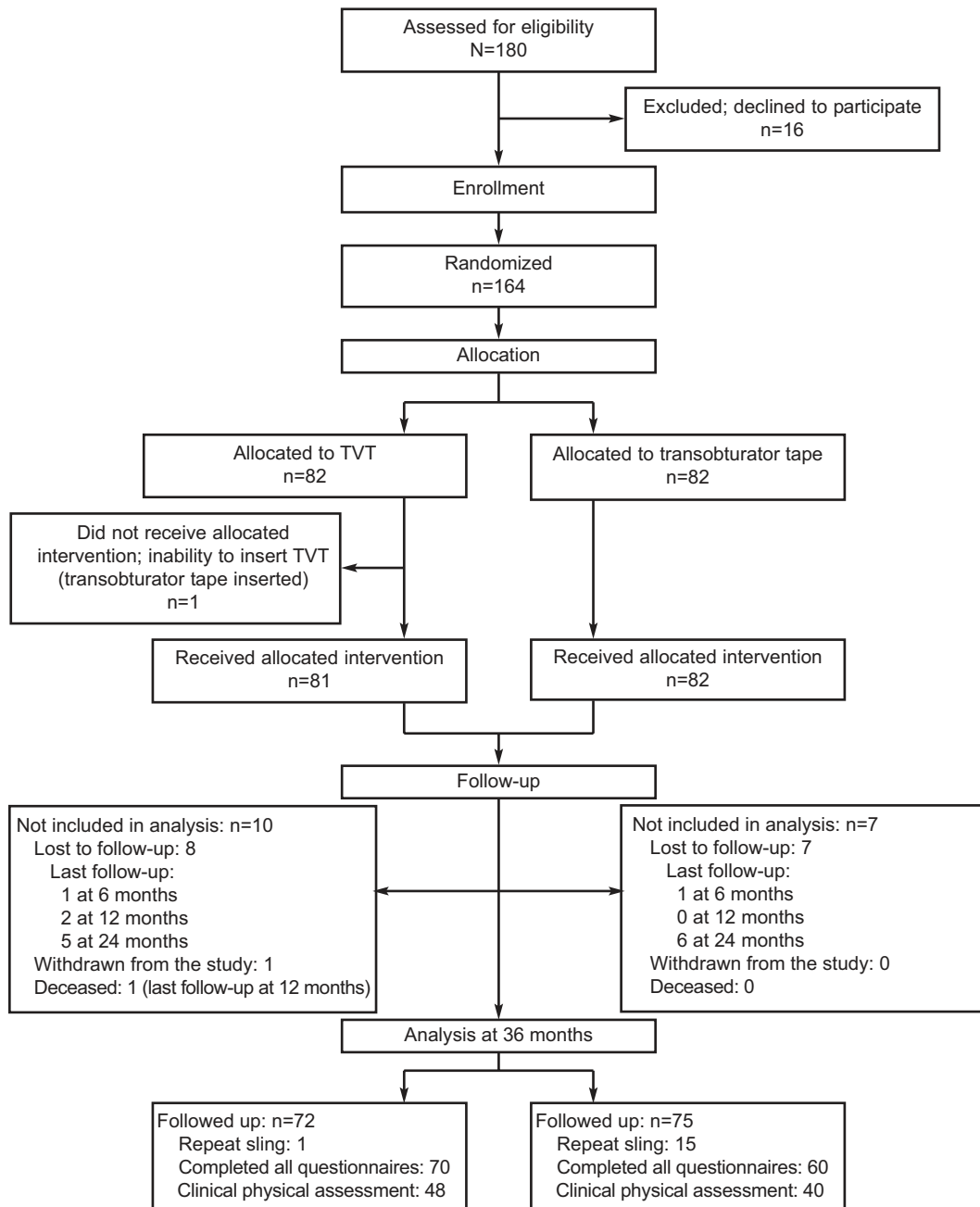


Count data used Fisher's exact test for between-group comparisons. Significance level was set at .05, and adjustment comparisons using Holm's stepdown procedure were made where appropriate.<sup>13</sup> Time to request for repeat surgery is presented graphically using Kaplan-Meier survival curve, and between-

group difference was tested using both the log-rank test and Cox proportional hazards regression.

## RESULTS

One hundred eighty women were eligible and 16 women declined to participate in the trial. One hundred



**Fig. 1.** Flow of participants through the trial. TVT, tension-free vaginal tape. Modified from Schierlitz L, Dwyer PL, Rosamilia A, Murray C, Thomas E, De Souza A, et al Effectiveness of tension-free vaginal tape compared with transobturator tape in women with stress urinary incontinence and intrinsic sphincter deficiency: a randomized controlled trial. *Obstet Gynecol* 2008;112:1253–61.

Schierlitz. TVT Compared With Transobturator Tape. *Obstet Gynecol* 2012.



sixty-four women consented to participate and were randomly allocated to either TVT (n=82) or transobturator tape (n=82). The progress of the participants is shown in the flow chart (Fig. 1). During the 3-year review period, eight women were lost to follow-up in the TVT group and seven in the transobturator tape group. In the group randomized to TVT, one patient requested withdrawal from the trial and one patient died. With the exception of one patient allocated to TVT, all women received their allocated sling. This patient's procedure was abandoned as a result of repeated bladder perforations and a transobturator tape was substituted. Because analysis was by intention to treat, this patient continued to be followed up in the TVT arm (Fig. 1).

No significant difference was detected in the demographic data between the two groups. This included analysis for parity, age, body mass index, menopause, and hormone replacement use. One-third of participants in both groups underwent surgery for concomitant prolapse (Table 1). Blood loss, operating time, catheter duration, and length of stay in the hospital were similar between groups. Complications, both intraoperative and postoperative, have been previously described.<sup>10</sup>

At 3-year follow-up, 15 of 75 (20%) of women in the transobturator tape group required further surgical treatment to correct SUI compared with one of 72 (1.4%) in the TVT group. The intention-to-treat analysis revealed that 15 of 82 (18.3%) women in the transobturator group compared with one of 82 (1.2%) in the TVT group (Fisher's exact test,  $P<.001$ ) had repeat surgery. The incident rate difference is 17.1% (95% confidence interval [CI] 8.4–25.8%). Therefore, if TVT was used in all patients, repeat surgery would be avoided in one in six

patients. The Kaplan-Meier curve of time to request for repeat surgery is presented in Figure 2. The log-rank test of equal survivorship rejects the null hypothesis of no difference ( $P<.001$ ) and concludes that the failure rate is higher in the transobturator tape group. This can be quantified as a hazard ratio that looks at the instantaneous hazard of failure, having survived up to the point under consideration; this is 15 (95% CI 2–113,  $P<.001$ ) times greater for the transobturator tape group compared with the TVT group.

Of 16 women who received further sling surgery, only two participants in the transobturator arm had normal urodynamic studies at the 6-month follow-up and the remaining 14 patients had urodynamic stress incontinence. One patient in the TVT group underwent a repeat TVT procedure at 43.7 months, whereas the median time to repeat surgery for the transobturator tape group was 15.6 (11.8–41.4) months ( $P<.001$ ). All patients except one in the transobturator tape group had a repeat TVT procedure. This one patient had a groin infection requiring partial sling removal and a subsequent insertion of a fascial pubovaginal sling. Nine of the 16 women (56%) who underwent repeat surgery were cured, four of 16 (25%) reported minimal leakage, and three of 16 (19%) remained unchanged.

Seventeen patients (10 TVT and seven transobturator tape) originally declined repeat urodynamic testing at 6 months because they felt cured by subjective assessment. After 3 years, all 10 women who received a TVT continued to be asymptomatic for SUI compared with five women receiving the transobturator sling. One participant in the transobturator tape arm did experience SUI after 24 months; had SUI on urodynamic assessment and elected to have a

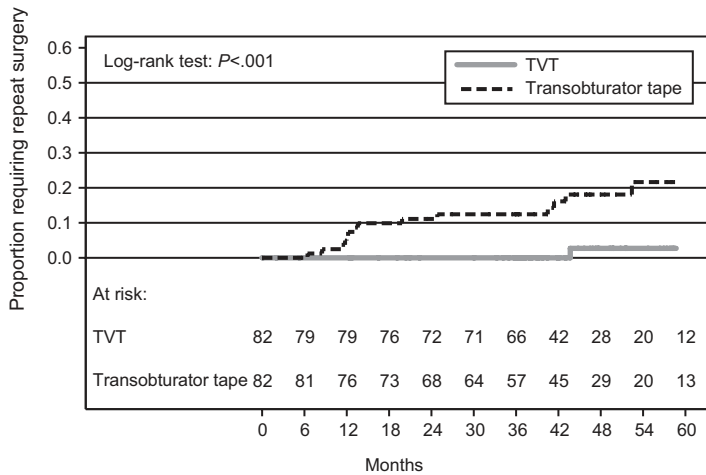
**Table 1. Demographics, Preoperative Characteristics, Concomitant Surgery Performed, and Outcomes With Tension-Free Vaginal Tape or Transobturator Tape**

	Tension-Free Vaginal Tape (n=82)	Transobturator Tape (n=82)	P
Age (y)	60±11.5	60±10.9	
Parity	3 (2–4) [0–6]	3 (2–4) [0–6]	
Body mass index (kg/m <sup>2</sup> )	26 (23–30) [18–40]	28 (24–31) [18–46]	
Menopausal status			
Premenopausal	16 (20)	14 (17)	
Postmenopausal without hormone therapy	51 (62)	54 (66)	
Postmenopausal with hormone therapy	15 (18)	14 (17)	
Prior incontinence procedures	6 (7)	10 (12)	
Concomitant prolapse surgery	29 (35)	26 (32)	
TVT or TOT alone	53 (65)	56 (68)	
Stress urinary incontinence at 6 or 12 mo postoperatively	13 (16.3)	23 (28)	.09
Repeat sling procedure at 6 mo	0 (0)	9 (13)	<.001
Repeat sling procedure at 36 mo	1 (1.2)	15 (18.3)	<.001

TVT, tension-free vaginal tape; TOT, transobturator tape.

Data are mean±standard deviation, median (25th–75th percentile) [minimum–maximum], or n (%) unless otherwise specified.





**Fig. 2.** Kaplan-Meier figure showing log-rank test of survivorship. TVT, tension-free vaginal tape. Schierlitz. TVT Compared With Transobturator Tape. *Obstet Gynecol* 2012.

repeat sling inserted. One further participant had SUI on examination but felt the symptom was not bothersome to warrant further surgery.

Overall, there was a high level of satisfaction demonstrated by the median numerical success scores of 90 in both groups at 36 months with no significant difference between the two groups. The baseline quality-of-life assessment (Urogenital Distress Inventory short form, Incontinence Impact Questionnaire short form) did not differ between groups. On average, the overall mean Urogenital Distress Inventory short form and Incontinence Impact Questionnaire short form scores improved by 5.8 (standard deviation, 4.34) and 6.0 (standard deviation, 5.48), respectively ( $P < .001$ ); no between-group difference was found (Table 2). Analysis of question 2 relating to urinary urgency and question 3 relating to SUI in the Urogenital Distress Inventory short form also showed significant improvement within

both groups and no difference between groups (Table 2). In the group of patients that failed the first sling procedure, the quality-of-life questionnaire difference scores did not change after the initial unsuccessful surgery but did improve significantly after successful repeat surgery.

## DISCUSSION

Only a handful of studies have evaluated the efficacy of transobturator slings compared with TVT in women with SUI and intrinsic sphincter deficiency. The multivariable analyses of three observational studies have failed to demonstrate intrinsic sphincter deficiency as an independent risk factor for sling failure with use of TVT.<sup>14-16</sup> However, Stav et al retrospectively assessed 1,225 women who received a midurethral sling (955 retropubic, 270 transobturator tape) for SUI, showing an odds ratio of 1.9 for

**Table 2.** Quality-of-Life Questionnaire Scores at 36 Months

	Tension-Free Vaginal Tape				Transobturator Tape				Between-Group Difference	Between-Group P
	Baseline	Follow-Up	Difference Score	Within-Group P	Baseline	Follow-Up	Difference Score	Within-Group P		
Numbers	76	70	66		78	71	68			
UDI 6 total	10 (7-12) [2-16]	3 (1-6) [0-13]	-5.8±4.28	<.001*	10 (8-12) [4-16]	4 (1-7) [0-17]	-6.0±4.43	<.001*	0.2 (-1.3 to 1.7)	.78
Question 2	2 (1-3) [0-3]	1 (0-1)	-1 (-2 to 0)	<.001*	2 (1-3) [0-3]	1 (0-2)	-1 (-2 to 0)	<.001*		.50
Question 3	3 (2-3) [0-3]	0 (0-1) [0-3]	-2 (-3 to 1)	<.001*	3 (2-3) [0-3]	0 (0-1) [0-3]	-2 (-3 to 1)	<.001*		.69
IIQ 7 total	8 (4-12) [0-21]	0 (0-4) [0-21]	8.3±5.21	<.001*	11 (5-15) [0-19]	0 (0-3) [0-20]	7.2±5.65	<.001*	2.1 (0.3-4.3)	.03
Numerical success score	—	90 (80-99)	—	—	—	90 (70-99)	—	—		.32

UDI 6, Urogenital Distress Inventory short form; IIQ 7, Incontinence Impact Questionnaire short form; —, no value taken preoperatively.

Data are median (25th–75th percentile) [minimum–maximum] or mean±standard deviation unless otherwise specified.

Hypothesis testing: within-group testing used paired *t* test for total scores (UDI 6 and IIQ 7) and sign rank test for UDI subscores questions 2 and 3; between-group testing used unpaired *t* test for total scores and rank sum test for UDI subscores questions 2 and 3, and numerical success score.

\* Statistically significant after adjustment for multiple comparisons.



intrinsic sphincter deficiency as a significant independent risk factor for sling failure.<sup>17</sup> Goktolga et al showed the 87% success of TVT at 6 months reduced to 74% at 5 years in patients with intrinsic sphincter deficiency.<sup>18</sup> Miller et al found that the transobturator sling had a six times greater failure rate compared with TVT in women with low maximum urethral closure pressure (less than 40 cm H<sub>2</sub>O). The finding was confirmed by Guerette et al.<sup>19,20</sup>

In our previously published study, it was shown that patients with SUI and intrinsic sphincter deficiency fared significantly worse with transobturator tape compared with TVT at the 6-month follow-up; further surgery was required in 13% of the transobturator tape group compared with 0% in the TVT group. At 3-year follow-up, this is confirmed with the significant finding of 18.3% of the transobturator tape group compared with 1.2% in the TVT group receiving further surgery ( $P<.001$ ). The majority of all participants receiving further surgery showed SUI at the 6-month urodynamic assessment (14 of 16), but only nine participants reported bothersome SUI requesting further treatment at 6 months. Initially asymptomatic SUI became bothersome resulting in further surgery in seven participants, all but one in the transobturator tape group. Additionally, the failures in the transobturator tape group occurred significantly earlier than in the TVT group. All asymptomatic women who initially declined urodynamic assessment at 6 months in the TVT arm ( $n=10$ ) continued to be asymptomatic in the subsequent follow-up, whereas two of seven in the transobturator tape arm developed recurrent SUI, resulting in one participant receiving repeat surgery (TVT).

Possible explanations for the higher success rate of TVT compared with transobturator tape may be the difference in sling axis<sup>21,22</sup> and the more distal location of the transobturator tape as seen on ultrasonography resulting in more urethral kinking during straining in the TVT group.<sup>23</sup> There is the possibility that increased sling tension at the time of surgery may be responsible for the higher success rate of TVT. However, the study clinicians sought to achieve tension-free placement of both slings. Furthermore, the rate of voiding difficulty with the need for tape loosening or division was similar in both groups (TVT 3.6%, transobturator tape 2.4%) as previously reported.<sup>10</sup> These findings did not change with the 3-year follow-up.

A significant improvement was detected between preoperative and postoperative subjective measures (quality-of-life questionnaires and numerical success score) within groups, but no difference was detected between groups at 6-month follow-up. This remained

the same for Urogenital Distress Inventory short form and the numerical success score in the group of participants in both arms. In the Incontinence Impact Questionnaire short form, we found a significant difference between the groups because the transobturator tape group showed a greater improvement at 36 months. This may be the result of the higher baseline score (although not statistically significant) in the transobturator tape group compared with the TVT group before surgery. Urogenital Distress Inventory short form scores and scores of question 3 assessing SUI did not show any difference between the groups. This may indicate that other aspects of urogenital well-being that are captured by Incontinence Impact Questionnaire short form may be responsible for this difference. In the group of patients who failed the first sling procedure, the quality-of-life questionnaire difference scores did not change after the initial unsuccessful surgery but did improve significantly after successful repeat surgery.

These findings have important implications for the significance of intrinsic sphincter deficiency as a poor prognostic indicator for continence surgery and, if confirmed by other studies, the importance and relevance of the urodynamic assessment generally. In particular, this relates to measurements of urethral function such as urethral closure pressure and Valsalva leak point pressures to guide clinicians not only when to perform surgery, but what surgery.

The study limitations already discussed at the time of 6-month follow-up include failure to reach recruitment numbers according to initial power calculation and a nonblinded study design. The limitations of the 3-year follow-up study consist of further participants being lost to follow-up. The number of patients who withdrew or were lost to follow-up (dropouts) is higher in the TVT group and a conservative assessment of any bias may be performed by classifying all dropouts as failures. Using this in the analysis, 11 of 22 patients are coded as failures in the TVT and transobturator tape groups, respectively, which results in an incident rate difference of 13.4% (95% CI 1.3–25.5%,  $P=.03$ ). This still demonstrates both a clinically important and statistically significant difference. Under these assumptions, if TVT was used in all study patients, repeat surgery would be avoided in one in eight patients.

In conclusion, the 3-year follow-up findings indicate that women with SUI and intrinsic sphincter deficiency are significantly less likely to require repeat surgery if the TVT sling is used compared with the transobturator sling. Thus, TVT is the preferred option in this cohort of patients. This study has focused



on women with intrinsic sphincter deficiency because they have the most severe symptoms in the spectrum of female SUI and the worst surgical outcomes. Our findings at 6 months of increased failure with the transobturator approach are continued in the 3-year follow-up.

Prospective randomized trials of TVT and transobturator tape (and all other sling procedures that are becoming increasingly available) are most important in patients with normal sphincter function and intrinsic sphincter deficiency to determine efficacy and safety profiles in each subgroup. This study supports the contention that not all slings are equal or equivalent; furthermore, these findings therefore do not necessarily apply to other transobturator slings or TVT exact. Despite the challenges of follow-up, this is important information for both the clinician and patient and aids their decision-making regarding midurethral sling selection. It is essential to verify that short-term outcomes translate into long-term benefit without added complication.

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