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Yehia Abdel Salam Wafa

Department of Obstetrics and Gynecology, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.

Ahlam El Said Kamel

Department of Obstetrics and Gynecology, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.

Mahmoud Salaheldin Said Ahmed Khalifa

*Department of Obstetrics and Gynecology, Faculty of Medicine for boys, Al-Azhar University, Cairo, Egypt.,
dr.m.salah.1988@gmail.com*

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A Comparative Study of Outside-in and Inside-out Transobturator Tape Procedures for Female Stress Urinary Incontinence: 5-year Outcomes

Yehia Abdel Salam Wafa, Ahlam El Said Kamel,
Mahmoud Salaheldin Said Ahmed Khalifa*

Department of Obstetrics and Gynecology, Faculty of Medicine for Boys, Al-Azhar University, Cairo, Egypt

Abstract

Background: In the surgical treatment of female urodynamic stress incontinence, the transobturator approach for tension-free suburethral vaginal tapes has witnessed a significant increase in its utilization over the course of the past 7 years. This method, which avoids the blind entrance into the retropubic region but uses the same suburethral hammock principle as the retropubic tension-free vaginal tape (TVT), was first published by Delorme in the year 2001. The retropubic TVT is a technique developed by the same researcher. It considerably lowers the likelihood of visceral injury occurring.

Aim and objectives: Comparing the tension-free vaginal tape 'inside-out' (TVT-O) and 'outside-in' [transobturator tape (TOT)] surgeries for the treatment of female stress urinary incontinence (SUI) over the course of a 5-year period is an important step in the study process.

Patients and methods: This retrospective cohort study was done at outpatients' urogynecological clinic, Obstetrics and Gynecology Department, Ahmed Maher Teaching Hospital from February 2022 until February 2023. During this study, 116 women were enrolled, after consenting each of them and divided into two equal groups, 58 in each group.

Results: Success rate, women's satisfaction, recommendation to other cases with SUI, and readiness to undergo the same procedure if same symptoms recur were statistically significant better among TOT outside-in cases compared with TVT-O inside-out ones.

Conclusion: TOT and TVT-O are effective and safe in treating female SUI. However, our study concluded that outside-in TOT procedure is favorable than TVT-O one with higher success rate and women's satisfaction.

Keywords: Stress urinary incontinence, Transobturator tape, Vaginal surgery

1. Introduction

Incontinence of urine that occurs involuntarily after physical activity, sneezing, or coughing is referred to as stress urinary incontinence (SUI).¹

When looking at women of all ages, stress has a mean prevalence of 50 % as a cause of urine incontinence.² When noninvasive treatments for SUI, such behavioral and cognitively retraining, physiotherapy, and planned voiding regimes, have failed, surgery is the gold standard.³

Zyczkowski and colleagues pioneered the tension-free vaginal tape (TVT) method in 1996. Delorme

then presented the transobturator tape (TOT), which was created to avoid the uncommon but potentially fatal consequences of intestinal perforation and significant vascular damage, both of which have been associated with TVT.⁴

There are a number of sling methods now in use, most of which have been implemented very recently. Both TOT technique and 'inside-out' (TVT-O), appear to be similarly clinically successful and safe when treating female SUI, at least in short-term studies.⁵

Cure rates after 6–12 months for outside-in mid urethral sling were from 83.2 to 90 %, while those for inside-out slings were 87.0–88.2 %.⁶

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* Corresponding author. Postal: 11884.
E-mail address: dr.m.salah.1988@gmail.com (M.S.S. Ahmed Khalifa).

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Surgical results of TOT operations for the treatment of SUI were compared between the TVT-O and 'outside-in' TOT approaches over a 5-year period in this study.

2. Patients and methods

This study analyzed data collected from the urogynecology clinic of Ahmed Maher Teaching Hospital's Obstetrics and Gynecology Department from February 2022 to February 2023.

Population analysis: female patients of TOT and TVT who suffered from stress incontinence:

Inclusion criteria: all included individuals have been clinically diagnosed with true SUI.

Exclusion criteria: detrusor overactivity or non-contraction, a PVR more than 100 ml, pregnancy, neurological disease, an active urinary or vaginal infection, a negative stress test, a maximum cystometric capacity less than 300 ml, urogenital malignancy, a fistula, or pelvic radiation are all contraindications.

Sample size: to achieve 80 % power and 95 % confidence, 116 women were enrolled after obtaining their informed permission and randomly assigned to one of two groups ($n = 58$ in each).

2.1. Ethical considerations

Patient information and informed consent: before enrollment, the patient was provided with information about the study and gave her informed permission after being briefed on the study's purpose, procedures, and potential outcomes.

Study interventions and procedures:

Urodynamic testing (using Aquarius 120 filling cystometry), urinalysis, uroflowmetry, voiding cystometry, and urethral pressure profiles were all part of the preoperative evaluations. Stamey Grade 7 was used to calculate a SUI grade. The cases of 116 women with SUI who underwent TOT or TVT-O were studied. The outside-in Obtryx™ – Halo technique and the inside-out TVT-O procedure were used throughout operations. Both were carried out in accordance with accepted practices, intra-operative prophylactic antibiotics were given to all patients. When patients' PVRs after urination were less than 150 ml after surgery, they were released. Surgical outcome evaluations at the 5-year mark, with follow-up interviews for each patient conducted over the phone. Patients were asked to fill out a questionnaire after surgery. Definitions of both 'cure' and 'improvement' of SUI were established, and success rates for each were calculated. Cases were requested to rate their overall happiness on a scale from 'very satisfied' to 'not satisfied.' Treatment outcomes following sling surgery were evaluated using two satisfaction gradings ('satisfied' and 'so-so') and the impact of preoperative variables was considered.

2.2. Statistical analysis

SPSS Inc. (Chicago, Illinois, USA), version 23.0 (statistical program for the social sciences) was used to analyze the collected data. For parametric (normal) data, we report the mean \pm SD and ranges, while for nonnormally distributed variables (nonparametric

Table 1. Group comparison based on demographic information.

Demographic data	TOT (N = 58) outside-in	TVT-O (n = 58) inside-out	Test value	P value
Age (years)				
Mean \pm SD	42.59 \pm 4.12	41.59 \pm 5.84	1.065	0.289
Range	36–49	33–50		
Weight (kg)				
Mean \pm SD	78.10 \pm 8.85	78.95 \pm 11.47	–0.444	0.658
Range	65–91	62–96		
Height (cm)				
Mean \pm SD	161.57 \pm 5.16	159.00 \pm 5.97	1.855	0.192
Range	157–168	154–166		
BMI (kg/m ²)				
Mean \pm SD	30.97 \pm 3.85	32.24 \pm 3.79	–1.819	0.143
Range	27–35	26–38		
Duration of SI (years)				
Mean \pm SD	2.95 \pm 0.85	3.04 \pm 1.12	–1.246	0.266
Range	2–4	2–5		

TOT, transobturator tape; TVT-O, tension-free vaginal tape inside-out.

Using: t independent sample t test for mean \pm SD.

Using: χ^2 : χ^2 test for n (%) or Fisher's exact test, when appropriate.

P value more than 0.05 is insignificant.

Table 2. Group comparisons based on responses to questions designed to gauge the severity of incontinence.

Questions used to assess the degree or urinary incontinence	TOT (N = 58) outside-in	TVT-O (N = 58) inside-out	Test value	P value
How often do you experience urinary leakage?				
Median (IQR)	3 (2–4)	3 (2–4)	0.556	0.579
Range	1–4	1–4		
How much urine do you lose each time?				
Median (IQR)	2 (1–2)	2 (1–2)	0.593	0.554
Range	1–2	1–2		
Total Score severity of index				
Mean ± SD	4 (3–8)	4 (3–8)	0.743	0.459
Range	1–8	1–8		
Severity index [n (%)]				
Slight (1–2)	7 (12.1)	9 (15.5)		
Moderate (3–4)	28 (48.3)	32 (55.2)	1.417	0.492
Severe (6–8)	23 (39.7)	17 (29.3)		

IQR, interquartile range; TOT, transobturator tape; TVT-O, tension-free vaginal tape inside-out. Using: U, Mann–Whitney test for nonparametric data ‘median (IQR).’

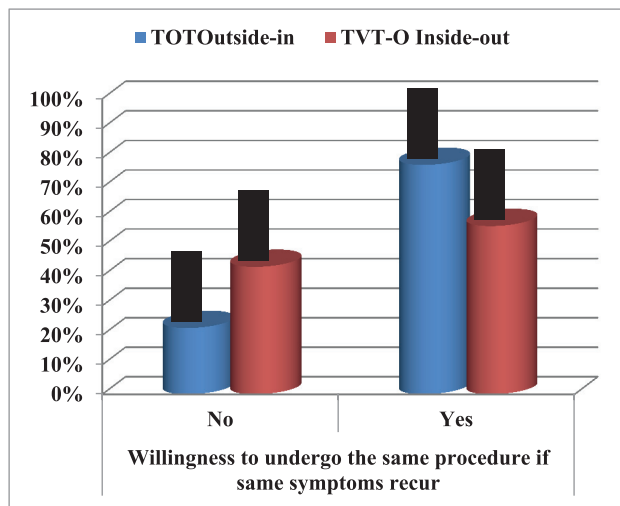


Fig. 1. Groups were compared based on their desire to repeat the surgery if their original symptoms returned.

data), we report the median and interquartile ranges. Quantitative and percentage data were also provided for qualitative characteristics. The Kolmogorov–Smirnov and Shapiro–Wilk tests were used to check for data normality.

3. Results

Table 1.

According to the demographic data we collected (age, weight, height, BMI, and number of SI ‘years’), there is no statistically significant difference between the groups ($P > 0.05$; Table 2).

No statistically significant difference in severity index for questions used to determine the degree of urine incontinence was found across groups ($P > 0.05$; Fig. 1, Tables 2 and 3).

When comparing groups with and without vaginal hysterectomy, sacrospinous ligament suspension, and postrepair, there is no statistically significant difference ($P > 0.05$; Table 4).

Table 5 shows statistically significant increase frequency of success in TOT outside-in was 55 (94.8 %) women's comparing to 45 (77.6 %) women's for TVT-O inside-out, with P value of 0.007 and statistically significant increase frequency of cured in TOT outside-in was 47 (81 %) women's comparing to 37 (63.8 %) women's for TVT-O inside-out, with P value of 0.038.

While, statistically significant increase frequency of failed in TVT-O inside-out was 13 (22.4 %)

Table 3. Analyzing the correlation between groups with and without simultaneous vaginal surgery.

Concomitant vaginal surgery	TOT (N = 58) outside-in [n (%)]	TVT-O (N = 58) inside-out [n (%)]	Test value	P value
Vaginal hysterectomy				
No	52 (89.7)	55 (94.8)	1.084	^{FE} 0.298
Yes	6 (10.3)	3 (5.2)		
Sacrospinous ligament suspension				
No	52 (89.7)	49 (84.5)	0.689	0.406
Yes	6 (10.3)	9 (15.5)		
Post repair				
No	35 (60.3)	32 (55.2)	0.318	0.573
Yes	23 (39.7)	26 (44.8)		

TOT, transobturator tape; TVT-O, tension-free vaginal tape inside-out.

Table 4. Success rates across different groupings are compared.

Success	TOT (N = 58) outside-in [n (%)]	TVT-O (n = 58) inside-out [n (%)]	Test value	P value
Success	55 (94.8)	45 (77.6)	7.250	0.007*
Cured	47 (81.0)	37 (63.8)	4.315	0.038*
Improved	8 (13.8)	8 (13.8)	0.000	1.000
Failed	3 (5.2)	13 (22.4)	7.250	^{FE} 0.007*

TOT, transobturator tape; TVT-O, tension-free vaginal tape inside-out.

*: Statistically significant at $P \leq 0.05$.

Table 5. Postoperative data comparisons between groups.

Postoperative data	TOT (n = 58) outside-in	TVT-O (n = 58) inside-out	Test value	P value
Duration of surgery (min)				
Mean \pm SD	18.31 \pm 3.08	18.64 \pm 3.29	-0.554	0.581
Range	13–23	14–24		
Duration of catheter stay (days)				
Mean \pm SD	1.02 \pm 0.56	1.05 \pm 0.65	-0.231	0.818
Range	0–2	0–2		
Duration of hospital stay (days)				
Mean \pm SD	1.78 \pm 0.60	2.09 \pm 0.62	-1.925	0.099
Range	1–3	1–3		

TOT, transobturator tape; TVT-O, tension-free vaginal tape inside-out.

Using: *t* independent sample *t* test for mean \pm SD.

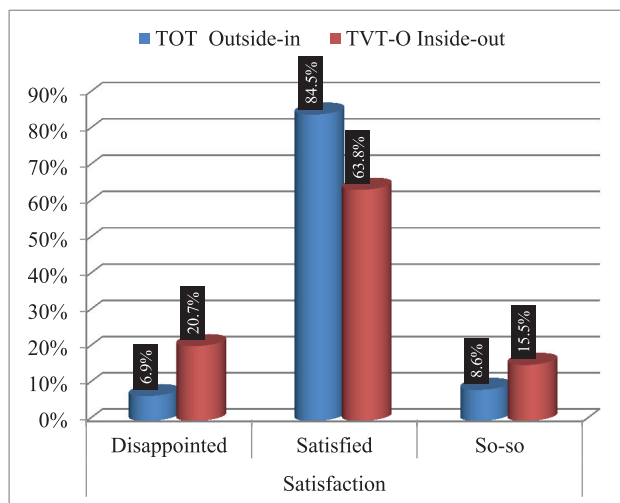


Fig. 2. Comparison between groups according to satisfaction.

women's comparing to three (5.2 %) women's for TOT outside-in, with *P* value of 0.007.

Postoperative statistics including operation duration (min), catheter stay (days), and hospital stay (days) show no statistically significant difference among groups ($P > 0.05$; Fig. 2, Table 6).

De-novo urgency, recurrent urinary tract infections, and inguinal discomfort consequences show no statistically significant difference ($P > 0.05$).

4. Discussion

Urinary incontinence, or the involuntary loss of bladder control, can lead to sanitary and hygiene-related issues. About 22 % of Caucasians over the age of 18 and between 36.1 and 47.1 % of Koreans suffer from SUI.⁷

Table 6. Analysis of complication rates across groups.

Complications	TOT (N = 58) outside-in [n (%)]	TVT-O (N = 58) inside-out [n (%)]	Test value	P value ^{FE}
De-novo urgency				
No	53 (91.4)	56 (96.6)	1.368	0.242
Yes	5 (8.6)	2 (3.4)		
Frequent urinary infection				
No	55 (94.8)	55 (94.8)	0.000	1.000
Yes	3 (5.2)	3 (5.2)		
Inguinal pain				
No	58 (100.0)	57 (98.3)	1.009	0.315
Yes	0	1 (1.7)		

TOT, transobturator tape; TVT-O, tension-free vaginal tape inside-out.

Our research showed that there were no significant differences among groups in terms of demographics, period of stress incontinence, parity, menopausal status, preoperative urodynamic parameters, degree of urinary incontinence, concomitant vaginal surgery, or postoperative data such as surgical, catheter, and hospital lengths of stay.

There was a statistically significant upgrading in success rate, female satisfaction, readiness to suggest the operation to other patients with SUI, and willingness to perform the same surgery if the same symptoms recurred among TOT outside-in cases compared with TVT-O inside-out cases.

Quality of life declines for the estimated 35 % of adult women worldwide who suffer from SUI.⁸

Stress incontinence is often treated nonsurgically at first (with behavioral therapy, pelvic floor exercises, or incontinence devices), but individuals who continue to have symptoms may be candidates for surgery. As a less invasive method with a cure rate comparable to Burch colposuspension (TVT) has been the standard therapy.⁹

TOT, on the other hand, was developed as an alternative to TVT due to its risk of problems, and it has a success rate that is comparable to that of TVT.¹⁰

After 5 years of follow-up, we found similar success and cure rates of 94.8 and 77.6 % in the current trial.

The TVT-O cure rate was lower than that previously demonstrated by Cheng and Liu.¹¹

In a prior research, Lee et al.¹² prospectively compared TVT-O to TOT for the treatment of SUI in 100 females.

Cure rates were similar in the TVT-O and TOT groups (86 vs. 92 %, retrospectively) about 1 year after surgery. Both groups showed significant improvements in QoL indicators related to incontinence after treatment. The TVT-O group had a lower cure rate than the TOT group, although the difference was not statistically significant.

Disparities between objective and subjective outcomes increased from 1 year's follow-up to 5 years'. Lee et al.¹³ found in 2010 that there was no statistically significant difference in the short-term cure rates of TVT-O (94 %) and Monarc (90 %) between the two treatments.

Debodinance¹⁴ showed similar success rates for both treatments in a short-term follow-up analysis.

Our surgical results were worse than those seen in the aforementioned trials after accounting for a longer follow-up period. Our study's decreased success rate in curing incontinence may be attributable to the larger prevalence of individuals with mixed urine incontinence in the TVT-O group.

Mixed urine incontinence has been proven to alter the long-term consequences of surgery, as demonstrated by Marcelissen and Van Kerrebroeck.¹⁵

After 2–5 years, 85 % of women with stress incontinence are completely cured after undergoing the TVT surgery. However, the cure rate for women with mixed incontinence remains at just 60 % for the first 4 years following surgery, dropping rapidly to 30 % in years 4 and 5.

In the present study, the TVT-O needle was rotated at the transobturator foramen more intensely than usual to decrease thigh discomfort, which may have contributed to the decreased cure rate. Ford et al.¹⁶ found that in the first 6 h after surgery, patients who had undergone the inside-out treatment felt much higher discomfort than those who had undergone the outside-in approach.

Instead of utilizing an objective assessment, such as a cough test, we determined the severity of pee leakage by a telephone interview and Sandvik questionnaires. Patients may not have understood the concept of stress urinary symptoms with urge urine incontinence despite being interviewed by a qualified interviewee.

Our investigation found that 8.6 % of TOT patients and 3.4 % of TVT-O patients had de-novo urgency, like the percentages reported in a 5-year follow-up study by Angioli et al.¹⁷ (2/37 participants, 6.4 %).

Our study's overall complication rates for both operations were comparable to those seen in earlier studies.

Several variables, including as advanced age and medical comorbidities, have been hypothesized to affect the outcome of treatment following surgery for SUI. Lower urinary tract factors, the severity of incontinence, and any history of incontinence-correcting surgery.¹⁸

Clinical applications of urethral function parameters such as maximum urethral closure pressure and lower pelvic pressure are often where prognostic information about the outcome of anti-incontinence operations is obtained. However, study conducted by Richter et al.¹⁹ and Nilsson and Kuuva²⁰ discovered that there was no link between urethral function tests and the postoperative success of midurethral slings.

It is important to note that the study had some significant limitations: it was hospital-based, so the sample size was small in relation to the study outcomes; it was not a multicentric study, so there was a high risk of publication bias; and it did not represent any specific community.

The quality of evidence was lower in retrospective studies compared with prospective studies, and controls are frequently recruited by convenience

sampling, making them unrepresentative of the community at large and vulnerable to biases such selection bias, recollection bias, and misclassification.

4.1. Conclusion

TOT and TVT-O are both effective and safe therapy options for the management of urinary incontinence brought on by emotional or physical stress in women. The findings of our research, on the other hand, suggest that the outside-in TOT treatment is preferred to the inside-out TOT method (TVT-O), both in terms of the success rate and the level of pleasure that was expressed by the women.

Conflicts of interest

There are no conflicts of interest.

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