

Efficacy of the inside-out transobturator tension-free vaginal tape (TVT-ABBREVO) for the treatment of stress urinary incontinence after a 12-month follow-up

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Abstract

The aim of this study was to evaluate the efficacy of the inside-out tension-free vaginal tape transobturator approach or TVT-Obturator system (TVT-ABBREVO) in women with stress urinary incontinence (SUI). This is a prospective single arm study of women with SUI who underwent a TVT-ABBREVO procedure. The inclusion criterion was a diagnosis of SUI urodynamically proven without detrusor over activity. SUI was defined as involuntary urine leakage with stress in the absence of detrusor over activity with or without intrinsic sphincter deficiency. Before, and 12 months after surgery women received urodynamic test, pelvic examination, and a personal interview using the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ). The primary outcome was the incidence of incontinence through cough stress test during the urodynamic exam. A total of 90 women were included in the analysis. Our analysis showed that the incidence of incontinence through cough stress test during the urodynamic exam was significantly less 12 months after the intervention (100% vs 3%; P-value = 0.001). Moreover, we found a significantly improvement of the quality of life measured by UDI score (13±4.5 vs 7.3±2.2 points; P-value 0.01) and IIQ score (14±5.7 vs 8.1 vs 3.1 points; P-value 0.02). No intra-operative complications were noticed. TVT-ABBREVO significantly reduced the incidence of stress urinary incontinence. In the authors' experience, this technique resulted technically simple and provided high objective and subjective long-term efficacy, a clinically meaningful improvement in patient quality of life, and an excellent safety profile.

Introduction

Urinary incontinence (UI) affects approximately 35% of women, depending on age, etiology and the definition of incontinence used.¹ UI is associated with poor self-rated health and decreased quality of life.² The annual cost attributed to UI is several thousand dollars per resident with incontinence.^{3,4}

The inside-out tension-free vaginal tape transobturator approach or TVT-Obturator system (TVT-ABBREVO), is a new minimally invasive surgery used for the treatment of female stress urinary incontinence (SUI).⁵ Urodynamic measures of urethral function have been studied before in attempts to characterize the effectiveness of pubovaginal slings and laparoscopic colposuspension.⁶ So far, the effect of TVT-ABBREVO procedure on urodynamic measures of urethral function and on urodynamic continence indices remains unknown.

Objective

The aim of this study was to evaluate the efficacy, urodynamically proven, of the TVT-ABBREVO procedure.

Materials and Methods

This is a prospective single arm study of women with SUI diagnosed both clinically and urodynamically who underwent a TVT procedure between January 1, 2012 and December 31, 2014. The inclusion criterion was a diagnosis of SUI urodynamically proven without detrusor over activity. SUI was defined as involuntary urine leakage with stress in the absence of detrusor over activity with or without intrinsic sphincter deficiency. Only women with at least history of 1-year incontinence were included in the study.

Exclusion criteria included absence of preoperative urodynamic testing and lost to follow-up. Women with uterus' or bladder's prolapse and women with severe urinary tract obstruction were also excluded. All women included in the study provided a written informed consent to participate in the study. Data were collected with patient consent and were anonymized before the analysis.

The TVT-ABBREVO procedures were performed according to the technique of de Leval.⁷ All women received antibiotic prophylaxis (*i.e.*, cefazolin 1 gram *e.v.*) before the surgery. The procedure was performed with the women under epidural anesthesia. A 12-cm-long polypropylene tape was used

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during the operations. The procedures were performed by one on the author (C.R.).

Before, and 12 months after surgery women received urodynamic test, pelvic examination, and a personal interview using the Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ).^{8,9} Urodynamic studies, including spontaneous uroflowmetry, filling and voiding cystometry were performed according to the recommendation of the International Continence Society,¹⁰ with a 6-channel urodynamic monitor (MMS; UD2000, Enschede, The Netherlands).

The primary outcome was the incidence of incontinence through cough stress test during the urodynamic exam. The secondary outcome was the incidence of incontinence through the McGuire test (*i.e.*, voluntary increase in abdominal pressure by pushing) during the urodynamic exam. We also assessed as secondary outcome the mean score of UDI and IIQ test before and 12 months after the TVT-ABBREVO.

Statistical analysis was performed by using Statistical Package for Social Sciences (SPSS) v. 19.0 (IBM Inc., Armonk, NY, USA). Discrepancies were resolved by discussion. Data were shown as means ± standard deviation or as number (percentage). Categorical variables were compared using the chi-square or Fisher exact test. Within-group comparison was undertaken using Wilcoxon and Mann-Whitney tests. P-value <0.05 was consid-

ered statistically significant.

Sample size calculations were assessed a priori. We observed that with an α of 0.05 and 80% power, a sample size of around 50 to 70 women is required to detect a significant difference in the urodynamic difference before and after TVT procedure.⁷ The study was performed following the STROBE guidelines.¹¹

Results

A total of 190 women were assessed for eligibility. 100 were excluded: 30 did not receive preoperative urodynamic testing, while 30 were lost in follow-up and 40 had bladder prolapse or uterus prolapse. 90 women were included in the analysis.

Table 1 shows the characteristics of the included women. None of them had history of prior pelvic surgery. No injury, intraoperative or postoperative complications were noticed. No mesh related events, including extrusion, were noticed during the follow-up period.

Our analysis showed that the incidence of incontinence during the urodynamic exam was significantly less 12 months after the intervention using the cough stress test [100% (n=90) vs 3% (n=3); P-value = 0.001; Figure 1] and the McGuire test [100% (n=90) vs 0% (n=0); P-value <0.001]. Only one woman (3%) developed urge incontinence 12 months after the intervention (Table 2).

Moreover, we found a significantly improvement of the quality of life measured by UDI score (13±4.5 vs 7.3±2.2 points; P-

value 0.01) and IIQ score (14±5.7 vs 8.1 vs 3.1 points; P-value 0.02). None of the included women reported urinary obstruction symptoms 12 months after the procedure.

Discussion

This study showed that TVT procedure significantly reduced the incidence of incontinence through cough stress test during the urodynamic exam 12 months after the intervention. However, in addition to relatively small sample size, the lack of a comparison group may limit the study's utility for clinical practice decision making.

In 1996, Petros and Ulmesten introduced a new surgery for the treatment of female SUI, the TVT procedure. Based on the integral theory, continence can be achieved by placing a vaginal tape situated directly below the mid-urethra without tension to reinforce the weakened pubo-urethral ligament. A systematic review and meta-analysis showed that TVT procedure seems to be the best choice for USI in comparison with laparoscopic colposuspension.¹² TVT procedure have revolutionized the surgical treatment of female SUI. The inside-out TVT transobturator approach has been developed about 15 years ago with the goal of minimizing the risk of urinary track injuries associated with retropubic and outside-in transobturator tape. Recently, this approach was modified by de Leval with the goal of reducing the incidence of postoperative groin pain and the risk of obturator nerve injury.⁷

Therefore, TVT-ABBREVO is the latest advancement among mid urethral slings for treatment of female stress urinary incontinence. It offers lesser post operative groin pain compared to other transobturator slings due to the shorter tape length and lesser paraurethral dissection.¹³ Our findings concurred with the study by Capobianco *et al.* They found that TVT-ABBREVO resulted technically simple and provided high objective and subjective long-term efficacy.¹³

In summary, this study showed that TVT-ABBREVO procedure significantly reduced the incidence of incontinence. In the authors' experience, this technique resulted technically simple and provided high objective and subjective long-term efficacy, a clinically meaningful improvement in patient quality of life, and an excellent safety profile.

Table 1. Characteristics of the included women.

	Included women N = 90
Number of children	2±1.4
Age	61±8.9
BMI	28.3±4.4
Smoking	15 (17%)
Sport activity	15 (17%)
Parity	2.7 (1-4)
Gravidity	3.1 (1-6)
Hysterectomy	0 (0%)
Duration of incontinence (months)	15±3.2
Urge incontinence	0 (0%)
Pollakiuria	12 (13%)
Dysuria	12 (13%)
Menopausal	45 (50%)
History of chronic constipation	18 (20%)
Use of hormone replacement therapy	0 (0%)

Data are presented as mean±standard deviation or as number with percentage or as median with range.

Table 2. Outcomes of the included women during the urodynamic exam 12 months after the TVT-ABBREVO procedure for stress urinary incontinence.

	Included women N = 90
Symptomatology unchanged	3 (3%)
Cough test positive	3 (3%)
McGuire test positive	0 (0%)
De novo overactive bladder	3 (3%)
Normal postoperative urodynamics	84 (93%)

Data are presented as mean±standard deviation or as number with percentage or as median with range.

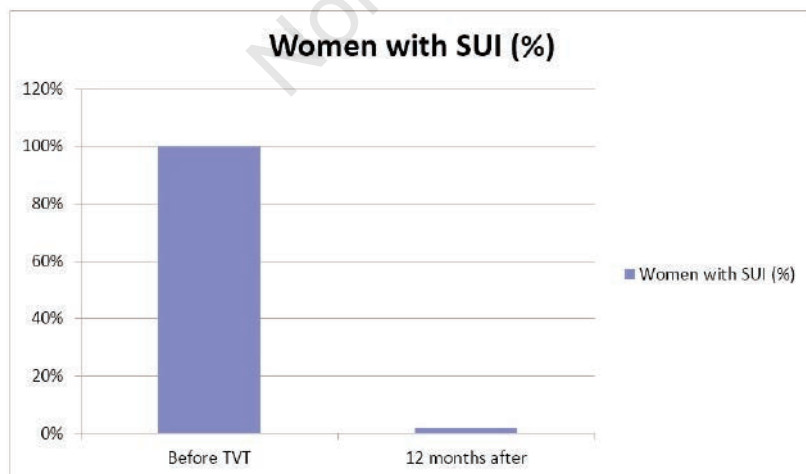


Figure 1. Percentage of women with stress urinary incontinence through cough stress test during the urodynamic exam before and 12 months after the TVT-ABBREVO procedure. Data are presented as percentage. Total number of included women (n=90). SUI, stress urinary incontinence.

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