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MEDIUM-TERM OUTCOME RESULTS AND SURGICAL COMPLICATIONS OF "INSIDE-OUT" TRANSOBTURATOR TVT (TVT-O): A PROSPECTIVE STUDY OF 119 CONSECUTIVE PATIENTS

Hypothesis / aims of study
The tension-free vaginal tape (TVT) procedure is safe and effective in treating female stress urinary incontinence (SUI). It has stood the test of time and some consider it as the new gold standard against which other procedures should be compared. However, the blind penetration of the retro-pubic space by the TVT applicators may cause some injuries, of which intraoperative bladder perforation is the most common. The new trans-obturator approach was developed to avoid the blind penetration of the retro-pubic space. Similarly to the retro-pubic TVT, the tape is placed in a mid-urethral position, thus procedure efficacy is expected to be comparable. However, contrary to the classic TVT, the retro-pubic space is avoided, thus major organ injuries are less likely to occur. The present study was conducted to assess the safety and medium-term effectiveness of the first 119 "inside-out" TVT-O procedures (GYNECARE TVT *Obturator System*, Somerville, NJ, USA) carried out in our Medical Center. Results were compared to a previous series of 313 consecutive retro-pubic TVT procedures carried out by our group.

Study design, materials and methods
A total of 119 consecutive women who underwent TVT-O surgery for urodynamically-proven SUI were prospectively enrolled. All patients underwent a full urodynamic evaluation before and after surgery. Surgical intervention was tailored according to clinical and urodynamic findings: Stress-incontinent women with normal pelvic anatomy underwent TVT-O only, whereas those with urogenital prolapse, and either overt or occult SUI, underwent combined TVT-O and prolapse repair. Patients were closely followed-up during their hospital stay. Special attention was taken in evaluating and documenting early postoperative morbidity. Postoperatively the patients were scheduled for evaluation at 1, 3, 6 and 12 months, and annually thereafter. All patients underwent a repeat urodynamic evaluation at 3 months postoperatively. Main outcome measures were procedure-related complications, perioperative morbidity, postoperative urodynamically-confirmed persistent SUI (symptomatic, or asymptomatic), persistent, or *de novo* overactive bladder (OAB) and bladder outlet obstruction (BOO).

Results
Mean follow-up of the patients was 19.9±5.7 months (range 12 to 30 months). The mean age and parity of the patients were 58.7 ± 11.8 years and 2.9 ± 1.4, respectively. Sixteen (14%) women had a previous hysterectomy and four (3%) had undergone anti-incontinence surgery (3-Burch, 1-Raz). Eighty-six (72%) patients presented with concomitant pelvic organ prolapse. Sixty-five (55%) patients had concomitant OAB.

The mean hospital stay was 4.2±3.2 days. Ten (8%) patients had immediate postoperative voiding difficulties necessitating catheterization for 7-14 days. No loosening procedure of the tape was undertaken. All resumed spontaneous voiding within two weeks postoperatively. Other early postoperative complications included fever in ten patients (8%, all but one had concomitant pelvic organ prolapse repair), and urinary tract infection in twelve (11%, all but two had concomitant pelvic organ prolapse repair).

Vaginal erosion of the prolene tape was diagnosed in two (1.7%) patients within one month postoperatively. The patients were treated by local excision of the eroded tape, with subsequent complete healing. Twelve (10%) patients had protracted thigh pain with spontaneous resolution within 3-6 months postoperatively. Ten (8%) patients developed recurrent urinary tract infections. Iatrogenic lower urinary tract injury was excluded by urethrocystoscopy.
Subjectively, eight (7%) patients had persistent postoperative mild SUI. However, postoperative urodynamic evaluation revealed asymptomatic sphincteric incontinence in seven (6%) additional patients. Of the 65 patients who had preoperative OAB, 55 (85%) still had persisting symptoms after operation. Four other patients (7% of patients who did not have preoperative OAB) developed *de-novo* OAB symptoms, one of whom was found to have BOO by pressure-flow studies. Outcome results of the TVT-O procedure were found to be identical with our retro-pubic TVT series, except for TVT-associated intraoperative bladder perforation and TVT-O associated postoperative thigh pain (Table 1).

Interpretation of results
Medium-term outcome results of the TVT-O procedure are comparable with the classic retro-pubic TVT. The TVT-O procedure is also associated with a short operation time and contrary to the retro-pubic TVT, no cystoscopy is needed, and bladder injury is unlikely to occur. However, postoperative protracted thigh pain is a troublesome complication and the patients should be informed accordingly.

Concluding message
Longer follow up and further anatomical research are required before the TVT-O can be considered a valid alternative to the classic retro-pubic TVT procedure.

Table 1:

Mean±SD, or N (%)	**TVT-Obturator; N=119**	**TVT; N=313**
Age (years)	58.7±11.8	63.8±10.7
Parity	2.9±1.4	2.9±1.6
Previous hysterectomy Previous anti-incontinence surgery Pelvic Organ Prolapse	16 (14%) 4 (3%) 86 (72%)	60 (19%) 13 (4%) 205 (65%)

Bladder perforation	0	16 (5%)
Follow up (months)	19.9±5.7	21.4±13.5
Catheterization >7days	10 (8%)	8 (3%)
Vaginal erosion	2 (1.7%)	4 (1.3%)
Protracted thigh pain	12 (10%)	0
Postoperative urodynamics:		
Subjective cure	93%	93%
Objective cure	87%	86%
Persistent OAB	85%	80%
De novo OAB	7%	8%
BOO	1 (0.8%)	3 (1%)

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HUMAN SUBJECTS: This study did not need ethical approval because No ethical approval was needed but followed the Declaration of Helsinki Informed consent was obtained from the patients.