

## SHORT-TERM CLINICAL AND QUALITY OF LIFE OUTCOMES IN WOMEN TREATED BY THE TVT-O PROCEDURE.

### Hypothesis / aims of study

The TVT-O (Ethicon, Somerville, NJ, USA) is a transobturator suburethral synthetic sling used in the treatment of female stress urinary incontinence (SUI). The transobturator approach purportedly avoids visceral and major vascular injuries as well as eliminating the need for routine cystoscopic examination during insertion (1). The aim of this study was to prospectively assess subjective and objective cure rates (primary outcomes) of the TVT-O procedure. Secondary outcomes assessed were the safety and efficacy of this device focussing on complications, patient satisfaction with surgery, and impact on patients' quality of life.

### Study design, materials and methods

A prospective analysis was made of 100 consecutive patients who underwent the TVT-O procedure. All patients had stress urinary incontinence (SUI) or mixed urinary incontinence confirmed by a pre-operative urodynamic study. Patients were required to complete four standardized quality of life questionnaires preoperatively and 6 months postoperatively. These were the Short Urogenital Distress Inventory (SUDI), Short Incontinence Impact Questionnaire (SIIQ), AQoL, and EuroQoL. At the six-month postoperative review, a urogenital history, a visual analogue score for patient satisfaction, a uroflow study and a urinary stress test (with the patient advised to present with a "comfortably" full bladder) were performed. Outcome measures included pre and post-operative comparison of urodynamic parameters, operative complications, postoperative symptomatology, quality of life analysis, and patient satisfaction.

### Results

The results are detailed in table 1. Concomitant surgery was performed in 49 patients. These procedures included: Anterior vaginal repair (31), posterior vaginal repair (42), vaginal hysterectomy (11), hysteropexy / colpopexy (39), anal sphincteroplasty (4), hysteroscopy and curettage (2), vaginoplasty (1), cystodistension (1), and haemorrhoidectomy (1).

Table 1:

Variable	Pre-operative	Post-operative
Age (mean)	55.5 years	
Parity (mean)	2.7	
Postmenopausal (%)	55	
HRT (%)	19	
SUI (%)	100	
Mixed Urinary Incontinence (%)	58	4
Urge Urinary Incontinence (%)	58	33
De novo		
Urge Urinary Incontinence (%)		2
Flow rate, Qmax (mean)	26.8ml/s	27.6ml/s
Residual urine (mean)	34.9ml	28.8ml
Prior Pelvic Surgery (%)	46	
Prior Anti-incontinence surgery (%)	15	
Voiding difficulty (%)	1	0
High satisfaction (%)		90
Subjective cure (%)		92
Objective cure (%)		95

Operative complications included: haematoma (1), wound infection (1), urinary tract infections (2), paraurethral vaginal mesh erosion (1), urethral irritation (1), groin discomfort (4), dyspareunia (2), and recurrent vaginal prolapse (2). There were no cases of postoperative voiding difficulty ( $Q_{max} < 15\text{ml/s}$  & residual volume  $>100\text{ml}$ ), vascular, bladder or other visceral injuries. 8% reported post-operative stress urinary incontinence but only 5% had positive stress tests, representing a 92% subjective and 95% objective cure rate. The incidence of urge urinary incontinence was also reduced by 25% postoperatively, and only 2% had de novo urge urinary incontinence. Quality of life analysis revealed an improvement in mean SUDI & SIIQ scores from 48.17% to 14.32%, and 41.92% to 12.52% respectively. 61% of patients reported an improvement in their general level of health in the postoperative EuroQol questionnaire, and Visual Analogue Scores (VAS) indicated high patient satisfaction (VAS above 80%) in 90% of patients.

#### Interpretation of results

Preliminary results indicate that the TVT-O procedure is a safe and effective treatment for female stress urinary incontinence. The short-term subjective & objective cure rates appear comparable to the traditional retropubic TVT procedure (2). There appears to be a reduction in the prevalence of de novo urge incontinence and post-operative voiding difficulty with the TVT-O procedure when compared with reported prevalence of this problem with the TVT procedure (2). The overall complication rate was low, patient satisfaction was high, and quality of life was improved after treatment.

#### Concluding message

In the short-term, at least, the TVT-O appears to have performed favourably as a safe and effective alternative to the other traditional treatments for female stress urinary incontinence.

1. Novel surgical technique for the treatment of female stress incontinence: transobturator vaginal tape inside-out.  
Eur Urol 2003 Dec; 44(6):124-30
2. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence.  
BMJ 2002; 325(67):789