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CLINICAL OUTCOMES IN PATIENTS UNDERGOING TVT-SECURTM FOR STRESS **URINARY INCONTINENCE: AN UPDATE**

<u>Hypothesis / aims of study</u> The TVT-SecurTM mid-urethral sling is a minimally invasive, single incision technique for stress urinary incontinence (SUI). Avoidance of the obturator or retropubic approach is postulated to reduce morbidity while attaining equal efficacy. Our 2008 interim analysis reported a 93% improvement rate. We now report on a larger series with longer follow-up.

Study design, materials and methods

A retrospective review of 125 women who underwent TVT-Secur[™] between 6/2006 and 7/2009 was conducted to evaluate demographics, voiding symptoms, urodynamics (UDS), prior treatments, concomitant procedures, pads per day (PPD), outcomes, and complications.

Results

Mean patient age was 59.1 years (29 - 88) with a mean follow-up of 11.3 months (1 - 39). SUI was documented on preoperative UDS in all patients. Mean valsalva leak point pressure was 85 cm H20 (9 - 220). Almost one-third (29%) of patients demonstrated detrusor overactivity preoperatively, however, by subjective appraisal 74% of patients reported mixed incontinence (MUI). 24.8% of patients had greater than 2 prior SUI surgeries and 47% underwent concomitant pelvic prolapse surgery. TVT-Secur[™] placement continued to demonstrate a significant reduction in mean PPD, from 2.76 to 0.34 (p=1.7e-13). 86% percent reported no pad use postoperatively. Despite the dramatic decrease in PPD, only 49% of patients conveyed complete cure with 44% indicating improvement of symptoms. 11 patients reported de novo urgency. 26.7% of women with pure SUI had denovo urgency, a decrease of 20% from 2008. The majority of women (62%) with MUI had significant improvement in urge component (p=.000015). Complications included 2 episodes of transient urinary retention, 6 urinary tract infections, and 6 (4.8%) mesh extrusions, of which one resolved with conservative management and 5 required mesh excision. 5 patients had subsequent bulking agent therapy and 3 women underwent autologous sling placement. 1 patient required urethrolysis. Anticholinergic refractory urgency required botox injections in 4 patients and interstim in 1 patient.

Interpretation of results

Our study found a dramatic decrease in PPD, with 86% of patients pad free post operatively. However, only half of patients conveyed complete cure with another 44% reporting improvement of symptoms. The rate of de novo urgency decreased in the pure SUI group by 20% compared to our 2008 interim analysis. MUI group continued to have improvement in their urgency. Our complication rate was low.

Concluding message

Our study suggests that TVT-SecurTM demonstrates comparable post operative improvement and patient satisfaction rates to common mid-urethral sling technologies. TVT-SecurTM continues to be an effective option for treating SUI with an acceptable morbidity profile.

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Is this a clinical trial?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Vanderbilt IRB
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes