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ONE YEAR RESULTS FROM A WORLD-WIDE REGISTRY OF TVT-SECUR™ IN WOMEN WITH STRESS URINARY INCONTINENCE (SUI)

Hypothesis / aims of study

To evaluate the long-term objective and subjective outcomes of the single incision sling (SIS), GYNECARE TVT SECUR™ across a broad spectrum of international surgical centres.

Since the introduction of tension-free vaginal tape (TVT) for the treatment of stress urinary incontinence (SUI) over a decade ago, there have been modifications to the technology, including the trans-obturator approach (TVT-O) and, more recently, the introduction of a SIS. While there is a wealth of long-term data for TVT, there still exists a paucity of data on the newly introduced SISs. A prospective, multicentre registry was established to gather long-term evidence for these mid-urethral sling systems. Here we report interim results on the SIS, TVT SECUR™.

Study design, materials and methods

TVT-WORLD is an international prospective observational registry established in 2007 for GYNECARE TVT™, TVT™-Obturator and TVT-SECUR™ Systems. Women were enrolled at 29 sites across 9 countries. A diagnosis of SUI or stress predominant mixed incontinence was to be confirmed by either a pre-operative positive cough stress test and / or urodynamic assessment. The surgeon was to determine the sling type; GYNECARE TVT, TVT-Obturator or TVT-SECUR.

Data were collected at baseline, peri-operatively, and at 3, 6 and 12 months. The primary outcomes measures were a Standing Cough Stress Test (SCST) and the Incontinence Quality of Life instrument (I-QOL) at 12 months. Postoperative voiding pattern and pain scores were collected where 0 = no pain and 10 = worst pain imaginable. Device and or procedure related adverse events were also collected.

Results

676 women with SUI underwent a TVT SECUR. ”Hammock“ placement was used in 64.9% and “U“ placement in 35.1%. Mean age was 54 years (SD 11.6) and mean BMI was 28 (SD 6.1). 58% were postmenopausal. 38.6% had a prior hysterectomy and 9.3% previous continence surgery. 65.5% had SUI, while 34.5% had mixed incontinence with predominant symptoms of SUI.

In patients without concomitant surgery (81.3%) mean surgical duration was 17.9 minutes (SD 11.2). 67.7% required local anesthesia with sedation only. Day surgery occurred in 87.5%. Normal voiding at discharge was 90.2%. Mean postoperative pain-score was 1.4 (SD 1.9, score 0 to 10). For all patients, the mean number of days to return to social life was 11.5 days (SD 14.1), to employment: 16.1 days (SD 29.5) and to sexual activity: 44.9 days (SD 40.0).

Mean change from baseline in I-QOL to 1 year was 36.1 (95%CI: 34.0-38.2). The improvements in I-QOL observed at 3 months appeared to be maintained at 12 months (Mean score: Baseline 48.4 (SD 23.4, n=652): 3 months 83.5 (19.6, n=563) and 12 months 85.2 (20.2, n=542)).

At 1 year, TVT SECUR met patients’ expectations in 87.6% of patients. 81.4% reported satisfaction with the outcome, while 18.6% were not. Objectively, leakage upon SCST was observed in 10% patients after 6 months and in 15.2% (95%CI: 11.5%-18.9%) at 1 year.

SCST results and I-QOL data are detailed in Table 1. Relevant Peri-operative and postoperative complications are included in Table 2.

Interpretation of results

Peri-operative results suggest that TVT SECUR may be performed quickly, comfortably, and safely under local anaesthesia with sedation. Median post-operative pain scores demonstrate that TVT SECUR is well tolerated in terms of postoperative pain, and the majority of patients can be discharged from hospital on the same day of surgery. Objective cure rate determined by cough stress test was 84.8%, which was accompanied by significant and sustained improvements in subjective assessment using the I-QOL.

Concluding message

This prospective study reports on the largest series to date of TVT SECUR patients with a follow up of one year. Objective cure rate determined by cough stress test was 84.8%, which was consistent with patient satisfaction (81.4%); these were accompanied by a significant improvement in the quality of life that did not seem to deteriorate over a period of one year.

Table 1: SCST and I-QOL* Scores for Patients with 12 Month Follow Up

SCST One Year Results	**TVT-SECUR (n=355)**

Negative SCST	301 (84.8%) 95% CI (81.1%-88.5%)

Mean I-QOL scores (SD)	**TVT SECUR**
Baseline	48.4 (23.4); n=652
12 Month	85.2 (20.2); n=542
Change from baseline[#]	36.1 (25.1); n=537

*I-QOL scores using a 100-point scale (with 100 the best possible and 0 the worst possible QOL)
#Data are calculated excluding missing data. Some patients did not complete I-QOL at 12-month follow-up.

Table 2: Complications:

	TVT SECUR (n=676)
Bladder perforation	1 (0.1%)
Excess bleeding	4 (0.6%)
Urinary retention	2 (0.3%)
Urinary tract infection	5 (0.7%)
Voiding dysfunction	6 (0.9%)
Wound infection	1 (0.1%)
De novo urgency	16 (2.4%)

Specify source of funding or grant	**Fully sponsored by Ethicon Women's Health and Urology**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**www.clinicaltrials.gov NCT00453739**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**UK sites MREC** **US sites Western Institutional Review Board** **All other sites received local EC approval**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**