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TWELVE-MONTH OBJECTIVE AND SUBJECTIVE OUTCOMES FROM A WORLDWIDE REGISTRY OF TENSION-FREE VAGINAL TAPES IN WOMEN WITH STRESS URINARY INCONTINENCE

Hypothesis / aims of study:

To evaluate the long-term objective and subjective outcomes from the family of GYNECARE TVT Systems 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 single-incision sling. While there is a wealth of long-term data for TVT[1], there is a need to generate long-term outcomes on the single incision TVT-SECUR™ sling.

Study design, materials and methods:

TVT-WORLD is an international prospective ethics committee approved observational registry established in 2007 for GYNECARE TVT™, TVT™-Obturator and TVT-SECUR™ Systems. Women are being enrolled at 29 sites across 9 countries. They must have a diagnosis of SUI or stress predominant mixed incontinence confirmed by either a pre-operative positive cough stress test and / or urodynamic assessment. The surgeon determines the choice of sling; GYNECARE TVT, TVT-Obturator or TVT-SECUR.

Data are collected at baseline, peri-operatively, and at 3, 6 and 12 months and then annually to 5 years. The primary outcomes measures are a Cough Standing Stress Test and the Incontinence Quality of Life instrument (I-QOL) at 12 months. Postoperative voiding pattern and pain scores are collected where 0 = no pain and 10 = worst pain imaginable. Device and or procedure related adverse events are also collected. Here we report the results of an interim data analysis completed in March 2009.

Results:

1281 women from Australia, Austria, Canada, Germany, Singapore, South Africa, South Korea, UK and the US were included in this interim analysis: 666 (51.9%) underwent TVT SECUR; 417 (32.6%) TVT and 198 (15.5%) TVT-O. Of those who underwent TVT SECUR, 430 (64.6%) had ”Hammock“ placement and 236 (35.4%) had “U“ placement. Baseline characteristics were similar across the 3 groups. There were similar proportions of SUI (65.3%, 66.7% and 56.6%) to mixed incontinence (34.7%, 33.3% and 43.4%) in TVT SECUR, TVT and TVT-O groups, respectively.

In patients without concomitant surgery (81.2% TVT-SECUR, 70.5% TVT and 53.5% TVT-O) mean surgical duration was: 17.9 (SD 11.2), 27.5 (13.6) and 24.7 (16.6) minutes; use of local anaesthesia with sedation occurred in 72.7%, 44.6% and 34.7% cases respectively. Day surgery occurred in 87.1%, 71.8% and 58.5% cases, respectively while normal voiding at discharge was present in 90.0%, 82.1% and 93.4% cases, respectively. Median postoperative VAS pain scores were similar across the 3 groups (0.0 TVT-SECUR, 2.0 TVT and 0.0 TVT-O).

TVT SECUR patients returned to normal activities quicker than those who received either TVT or TVT-O. Patients who indicated they were either satisfied or very satisfied with the outcome were similar across the groups; (85.4% TVT-SECUR, 79.6% TVT and 92.7% TVT-O).

Standing Cough Stress Test results and I-QOL data are detailed in Table 1. The majority of patients had improvement greater than the minimal clinically important difference (MCID) for within treatment group comparison of 6.3 points[2]. Peri-operative and postoperative complications are summarized 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 90.3%, accompanied by a significant improvement in the quality of life and comparable MCID results derived from different patient populations suggests TVT SECUR has objective and subjective success rates comparable to TVT and TVT-O. Longer-term follow up is ongoing.

Concluding message:

These 12-month results are equivalent to the standard mid urethral tapes, in terms of cure rate, quality of life improvement and safety.

Table 1: Standing Cough Stress Test and I-QOL* Scores for Patients with 12 Month Follow Up

	TVT-SECUR (n=247)	TVT (n=87)	TVT-O (n=47)

Negative Standing Cough Stress Test	223 (90.3%) 95% CI (86.6-94.0)	78 (89.7%) 95% CI (83.3-96.1)	46 (97.9%) 95% CI (93.7-100)

I-QOL	**Baseline n=642 12months n=405**	**Baseline n=351 12months n=125**	**Baseline n=182 12months n=77)**
Baseline (mean±SD)	48.5 (23.5)	38.3 (23.4)	52.0 (23.4)
12 Month (mean±SD)	84.3 (20.8)	84.2 (20.3)	83.5 (22.9)
Mean change from baseline	35.9 (26.6)	40.7 (25.5)	29.5 (26.3)
#Proportion of pts change >MCID**	357 (88.1%)	115 (92.0%)	64 (83.1%)

*I-QOL scores using a 100-point scale (with 100 the best possible and 0 the worst possible QOL)
**Within-treatment minimal clinically important improvement (MCID) is considered to be 6.3 points[2]
#Data are calculated excluding missing data. Some patients did not complete I-QOL at 12-month follow-up.

Table 2: Complications registered to date:

	TVT SECUR (n=666)	**TVT (n=417)**	**TVT-O (n=198)**
Bladder perforation	1 (0.2%)	5 (1.2%)	1 (0.5%)
Excessbleeding	3 (0.5%)	1 (0.2%)	0
Urinary retention	2 (0.3%)	6 (1.4%)	2 (1.0%)
Urinary tract infection	10 (1.5%)	7 (1.7%)	2 (1.0%)
Voiding dysfunction	6 (0.9%)	7 (1.7%)	1 (0.5%)
Wound infection	1 (0.2%)	2 (0.5%)	0
De novo urgency	18 (2.7%)	8(1.9%)	0
Mesh exposure	5 (0.8%)	7 (1.7%)	1 (0.5%)

References
1. Kuuva N, et al. Acta Obstet Gynecol Scand, 2006; 85(4): 482-7
2. Yalcin I, et al. Urology, 2006; 67:1304-1308

Specify source of funding or grant **Registry 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	**ClinicalTrials.gov Identifier: NCT00453739**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Trent Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**