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PRELIMINARY RESULTS OF PERI-OPERATIVE AND 3-MONTH OUTCOMES FROM A WORLD-WIDE OBSERVATIONAL REGISTRY OF TENSION-FREE VAGINAL TAPES IN WOMEN WITH STRESS URINARY INCONTINENCE

Hypothesis / aims of study

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 single-incision tapes. Whilst there is a wealth of long-term data for TVT[1], there is a need to generate long-term evaluation for newer modifications. TVT-WORLD is an international prospective observational registry established in 2007 for GYNECARE TVT*, TVT*-Obturator and TVT-SECUR* Systems. Here we report preliminary peri-operative and short-term outcome results.

Study design, materials and methods

This prospective registry is currently being conducted in 24 sites across 7 countries. Prior to initiation of enrolment at each site, ethics committee approval was obtained. Written informed consent was obtained from all patients prior to their participation in the registry.

Women diagnosed with stress urinary incontinence (SUI) who are suitable candidates for a TVT system, as according to the relevant Instructions for Use (IFU) can be invited to participate in this evaluation. Diagnosis of SUI is to be confirmed by a positive cough stress test and / or urodynamic assessment prior to surgery.

Patients are evaluated at baseline, peri-operatively, and thereafter at up to 3, 6 and 12 months, and then annually to 5 years. Peri-operative data are collected, including pain, as assessed by a verbal pain score (0=low pain to 10=high pain) at time of discharge or 24 hours post-procedure, whichever occurred first. Effectiveness evaluations include objective assessment by standing stress test at 12 months, subjective assessment using the internationally validated Incontinence Quality of Life instrument (I-QOL). All device-related and procedure-related adverse events are collected.

Results

Here we report interim results from the first 563 women included from 19 sites (12 US, 1 Canada, 1 South Korea, 1 Singapore, 1 Austria, 1 UK and 2 South Africa) by 13 February 2008. 352 (62.5%) were TVT SECUR patients; 90 (16.0%) TVT-O and 121 (21.5%) TVT. In the 352 TVT SECUR patients, ”Hammock“ placement was used in 247 women (70.2%), and “U“ placement in 105 women (29.8%). Three patients withdrew consent following the TVT SECUR procedure, and 1 patient following TVT-O. One TVT patient and 3 TVT-O patients have been considered lost to follow up.

The demographics and medical history of patients in the 3 groups appeared to be well balanced for age, weight, menopausal status, and previous gynaecological surgeries. There were similar proportions of SUI (66.8%, 65.3%) to mixed incontinence (33.2%, 34.7%) in the TVT SECUR and TVT groups, respectively; in the TVT-O, the proportion was 55.6% with SUI and 44.4% with mixed. The proportion of patients with intrinsic sphincter deficiency was 4.0%, 3.3% and 13.2% in the TVT SECUR, TVT-O and TVT groups, respectively.

As the proportion of patients with concurrent surgery was higher in the TVT-O group (44.4%) compared to TVT SECUR (17.9%) and TVT (21.5%), the peri-operative data to time of discharge have been analysed two ways, the second of which is reported here: 1) for all patients and 2) for patients without any concurrent surgery. The median surgical duration was 15.5, 27 and 22 minutes for TVT SECUR, TVT and TVT-O, respectively. The use of local anaesthesia with sedation was higher in TVT SECUR group (73.5%) compared to TVT and TVT-O (41.8% and 45.5%, respectively). Discharge from hospital on the same day as surgery occurred in 85.5% TVT SECUR patients compared with 74.2% for TVT and 72.0% for TVT-O. Normal voiding at discharge was reported in 92.4% for TVT SECUR, 89.0% (TVT) and 96.0% (TVT-O). Median post-operative pain was 1 for TVT SECUR, 2 for TVT and 0 following TVT-O.

The I-QOL data are summarised 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].

Table 1: I-QOL* Scores for Patients with 3 Month Follow Up

	TVT-SECUR (n=259)	**TVT-O (n=66)**	**TVT (n=59)**
Baseline (mean±SD)	49.2 (23.5)	54.4 (24.8)	43.0 (22.7)
3 Month (mean±SD)	83.1 (18.9)	83.7 (21.0)	70.4 (28.5)
Mean change from baseline	34.1 (24.9)	29.0 (27.2)	30.2 (23.9)
#Proportion of patients change >MCID**	215/249 (86.3%)	54/63 (85.7%)	27/30 (90.0%)

*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 3-month follow-up.

Complications included: 1 bladder perforation (0.8%) during a TVT procedure; 1 vaginal laceration during a TVT SECUR procedure (0.3%); bleeding in excess of 200 ml was reported in 1 (0.3%) TVT SECUR patient; mesh exposure in 4 TVT SECUR (1.1%) and 3 TVT patients (2.5%); voiding dysfunction in 3 TVT SECUR (0.9%) and 1 TVT patients (0.8%); haematoma in 3 TVT SECUR (0.9%) and 1 TVT-O (1.1%); de novo urgency in 2 (0.6%) TVT SECUR patients; worsening urge incontinence in 1 (0.8%) TVT patient.

Interpretation of results

These early interim results from this prospective evaluation are biased to the use of TVT SECUR. As a result, comparison to TVT and TVT-O data (which are only from 9 of the sites) must be treated with care due to the limited number of these devices included in this dataset.
Peri-operative results with TVT SECUR suggest that this procedure may be performed quickly under local anaesthesia with sedation. Median post-operative pain scores demonstrate that TVT SECUR is well tolerated in terms of post-operative pain, and the majority of patients can be discharged from hospital on surgical day. Early post-procedure I-QOL data suggest that the majority of TVT SECUR patients report clinically meaningful improvement in symptoms. Complication rates appear low.

Concluding message

These early results suggest that TVT SECUR is well-tolerated and safe to use. Follow up continues to assess the long-term effectiveness of this novel single-incision sling.

References

1. Long-term results of the tension-free vaginal tape operation in an unselected group of 129 stress incontinent women. Acta Obstet Gynecol Scand, 2006; 85(4): 482-7.
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Specify source of funding or grant	**This registry is sponsored by Ethicon Inc, A Johnson & Johnson Company. Each participating site is paid for inclusion of patients, and transcription of data onto the electronic case report forms.**
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; NCT00453739**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Oakwood Healthcare System IRB, 18101 Oakwood Blvd, Dearborn, MI 48124, US is the IRB for Dr Khandwala. All other sites have also appropriate local IRB approval in place, and details are available, if required.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**