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Mossa M[1], Ahuja S[1]
***1.*** *Benenden & Maidstone Hospitals*

# HOW SECURE IS TVT SECUR?

Hypothesis / aims of study

Urodynamic stress incontinence is defined as the leakage of urine through an incompetent urethra in the absence of a detrusor contraction.[1] Prior to the introduction of tension-free vaginal tape (TVT) in the mid to late1990's, Burch Colposuspension was the gold standard for the surgical treatment of stress incontinence. Newer techniques have been developed in the hope of producing good long term success, lesser complications, shorter hospital stay and lower morbidity and hence quick return to normal activity.

Since the development of the TVT in 1996, there has been an explosion in marketing of similar devices using different mesh types and applicators. These have not generally been subjected to randomised controlled trials, have no long-term data from case-cohort studies and do not have the same evidence base. Although the long term results (5–7 year outcome) of TVT are known (81.3% and 82% cure rate)[2] there are concerns over the safety of TVT. Most of these complications are related to the penetration of the retropubic space.

Delorme described the transobturator tape (TOT) with an aim to achieve similar success rates as the TVT but with reduced morbidity and complications.[3] A recent metanalysis reported that bladder injuries and voiding difficulties were lower, but the risk of vaginal erosions and groin pain was higher with TVT-O/TOT as compared to TVT.[4]

The TVT Secur system is the newest product from the TVT (Tension Free Vaginal Tape) family. The tape has been designed with a special applicator system with no need for external skin incisions. A preclinical trial assessed the performance of this mesh in a sheep model in terms of tissue integration and pull-out forces.[5]

The device may be placed in either a "U" or "Hammock" approach under the mid-urethra depending on surgeon preference. Both approaches require a midurethral vaginal incision and may be performed under local, regional or general anaesthetic. The tape is still placed sub-urethrally and works in the same way as the TVT and TOT by supporting the urethra without any tension. At the time of conducting this study, there was only one clinical trial reporting the use of the TVT Secur system, which included 15 women. All the patients were seen between one and three months at follow-up and the reported cure rate was 93%.[6]

Study design, materials and methods

We carried out a retrospective study of 23 cases operated on between January and July 2007. All cases had been diagnosed to have moderate to severe genuine stress incontinence on urodynamic assessment. The aim of our study was to assess the short term outcomes and the complication rates of the TVT-Secur system.

All the 23 cases were operated on by the same surgeon, with suburethral placement of the tape in a 'hammock' fashion. Two women (9%) had history of stress incontinence surgery in the past. Three cases (13%) underwent an additional prolapse surgery at the same time.

Results

There were 2 (9%) cases of vaginal sulcus injury intraoperatively. Postoperative analgesia was prescribed only on patients' request in the 20 women, who did not have additional surgical procedures. None of those patients reported any degree of pain or requested analagesia.

The women were followed up clinically at 6 weeks and by urodynamic assessment at 3 months postoperatively. Out of the 23 cases 18 (78.2 %) cases reported subjective improvement or cure on the first clinical follow up. 22 out of 23 cases had follow up urodynamic assessment at 3 months postoperatively. Of those, 16 cases (77.2%) were confirmed to have objective cure by urodynamic assessment. There were no voiding difficulties in any of the 23 cases. There were 3 (13%) cases of tape erosion or exposure. However, all 3 cases only needed trimming of the tape and re-suturing of the vaginal skin under local anaesthetic. There was 1 case with ongoing stress incontinence confirmed on urodynamic assessment and she required a transobturator tape subsequently.

Interpretation of results

The subjective & objective cure rates of this procedure seem to be lower than the well established mid-urethral procedures such as TVT and TVTO. The tape erosion/exposure rate in this study is disappointingly high (13%). However all the 3 cases were within the first 10 cases performed by the surgeon, hence could be related the learning curve. It was noted that the immediate and long term postoperative periods were pain free.

Concluding message

Our small pilot study invites for a prospective randomised controlled study in order to answer the question: "*HOW SECURE IS TVT SECUR".*

References

1. The standardization of terminology of lower urinary tract dysfunction: report from the standardization committee of the ICS. *Neurourol Urodyn* 2002; 21: 167–78.
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| ***Specify source of funding or grant*** | **Benenden Hospital. Kent. Uk.** |
| ***Is this a clinical trial?*** | **No** |
| ***What were the subjects in the study?*** | **HUMAN** |
| ***Was this study approved by an ethics committee?*** | **No** |
| ***This study did not require eithics committee approval because*** | **It is a retrospective study of the outcome of an existing surgical procedure.** |

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| ***Was the Declaration of Helsinki followed?*** | **Yes** |
| ***Was informed consent obtained from the patients?*** | **Yes** |