

## TENSION-FREE VAGINAL TAPE (TVT) REVISITED – OUTCOMES OF TVT AND THE INFLUENCE OF DIFFERENT ANAESTHETIC APPROACHES

### Hypothesis / aims of study

To evaluate the Efficacy, Patient Satisfaction and complications of TVT for surgical treatment of Urodynamic Stress Incontinence (USI), and to assess whether the type of Anaesthesia used affects postoperative outcomes.

### Study design, materials and methods

The study population consisted of 98 consecutive women who had TVT procedure in our Unit between May 2002 and February 2004. All patients had initial preoperative assessment- full structured history, gynaecological examination, urinalysis, completion of symptoms/QoL questionnaire, a stress test in lying and standing positions with bladder volume of approx 300mls, one week voiding diary and residual urine measurements. They all had urodynamic evaluation preformed by medium fill dual channel subtracted cystometry with simultaneous pressure and flow voiding studies; those with previous/failed bladder neck surgery had videocystography.

Postoperative evaluations were carried out at 3 and 6 months, and after 36 months postage-paid return envelope questionnaires with instructions were posted to the patients. The questionnaire was designed to obtain specific responses from the women with regard to their intraoperative and postoperative experiences, patient satisfaction or otherwise, any postoperative or ongoing adverse event or complications, with specific additional questions with visual analogue scale (VAS) to assess Quality of Life (QoL). Patient perceptions of changes in their symptoms and treatment outcome were measured with questions modified from our Unit urogynaecology questionnaire, and from the generic SF-36 and the disease specific Bristol female lower urinary tract symptoms questionnaire (1,2). Cure was defined as no postoperative stress urinary incontinence, both subjectively and objectively.

The operations were performed as described previously (3), and were carried out under Local infiltration Anaesthesia + IV sedation (54 patients), General Anaesthesia (23 Patients), or Spinal/Epidural anaesthesia (9 patients). All patients received prophylactic antibiotics irrespective of anaesthesia type, and they all had post-void residuals less than 100mls, measured by bladder scan, before discharge from hospital. TVT was performed by/or under supervision of two experienced urogynaecologists. Data was entered into a database and analysed using SPSS 14.0.

### Results

Out of the 98 women, 89 responded to our questionnaire (91% response), but three of these responders were excluded because of incomplete data. Of the 86 women evaluated, 69(80.2%) were cured 3 years after the operation ( no urinary leakage subjectively or objectively), and 5(5.8%) were significantly improved, representing an overall 86% success rate. Of the 69 women who were cured, the majority 44 (64%) had their TVT performed under Local infiltration Anaesthesia (LA) with intraoperative cough test performed when placing/adjusting the tape.

The median age was 56.5 years, and median operating time (all anaesthetic groups) was 30 mins (range 20-60mins). The overall patient satisfaction within all anaesthetic groups was 91.5%, and the median VAS score overall was 9 ( range 0-10; SD 1.931 ). Patient satisfaction was very similar in the three anaesthetic groups ( GA =Gen Anaesthesia, SE= Spinal/Epidural, and LA ), with no statistically significant difference, and so also was the VAS scores. There was no major vascular injury or haematoma. There were 8(9%) bladder perforations; these occurred mostly with the trainees and all perforations were recognised at operation and needle/tape correctly repositioned and patient catheterised for 24-48 hrs with no adverse sequelae. There were no bowel injuries.

19 women had complained of 'cystitis-like' symptoms postoperatively and were prescribed additional antibiotics, but the MSU results received subsequently confirmed UTI in only 5 women(5.8%); 12 of these 19 women were in the GA or SE group and were routinely catheterised postoperatively. The other documented complications in this series included 'de novo' Urgency in 5(5.8%) women, tape erosion in 4(4.65%), and dyspareunia in 5 women.

Excision/trimming of exposed tape was carried out for the women with tape erosion and they all remained continent with no loss of TVT efficacy. Four of the 5 women with dyspareunia had additional procedure for prolapse at same time as TVT (12 of the total 86 women had concomitant prolapse surgery and these were performed under GA or SE).

The mean hospital stay for those who had TVT alone was 0.9 days (for the LA group), 2.23 days (for the GA group), and 2.4 days for the SE group. The overall mean hospital stay (all groups) was 2 days. The majority of the patients who were operated under LA were able to micturate spontaneously within 4-6 hrs without catheterisation, There was no patient with long term (>10 days) urinary retention or voiding difficulty in any of the anaesthetic groups.

### Interpretation of results

The success rate of TVT in our Unit is comparable with published results. The length of stay is longer in the GA and SE groups even when additional prolapse surgery has not been performed at same time as TVT. 'Cystitis-like' symptoms/UTI was more prevalent in the GA and SE groups, who were also more likely to be catheterised.

Dyspareunia was more prevalent when additional prolapse surgery was performed at the same time as TVT. The overall Patient satisfaction and the VAS score were very similar with no statistically significant difference amongst the various anaesthetic groups. However, according to the results in our study, better outcomes were achieved in terms of cure rate, shorter hospital stay, and less chance of cystitis/UTI when TVT procedure is performed under LA , with hydrodissection and good quality intraoperative cough test.

### Concluding message

The TVT procedure is a safe and effective method to cure stress urinary incontinence irrespective of the type of Anaesthesia used. Surgeons should be encouraged to use local anaesthesia preferably, whenever possible, to achieve better outcomes and in particular, to reduce the length of hospital stay. There is a significant rate of intraoperative complications, which do not cause further problems when identified and treated or corrected during surgery. Some of the postoperative complications require only minor correction ( such as trimming/excision of exposed tape ) and do not influence the continence rate.

## References

1. BMJ 1993;306:1437-40
2. Brit J Urol 1996, 77, 805-12
3. Int Urogynecol J 1996,7: 81-86

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<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>Service development rather than a clinical trial, therefore ethical committee approval was not required, but the study details and questionnaires were passed through our Trust Research &amp; Development.</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>