

## RETROSPECTIVE COMPARATIVE STUDY OF 3 YEARS OUTCOME FOR TENSION FREE VAGINAL TAPE (TVT) AND TENSION FREE VAGINAL TAPE-OBTURATOR (TVT-O)

### Hypothesis / aims of study

The aim of this study was to compare the success and complication rates of the Tension free vaginal tape (TVT) with the Tension free vaginal tape-Obturator (TVT-O) for the treatment of female stress urinary incontinence over 3 years period

### Study design, materials and methods

This was a retrospective comparative study involving two groups – patients who underwent TVT in 2002-2004; and patients who underwent TVT-O in 2004-2006. Case records were reviewed and data collected included pre-operative evaluation through standardised clinical proforma, erect stress test (EST) and urodynamic findings. Intra-operative details collected included duration of surgery, bladder injuries and blood loss. Outcome of surgery in terms of complete cure or improvement was assessed at 6 months, 1 year and 3 years. The data was analysed and results were compared using Chi-square test.

### Results

This study involved 911 patients – 492 patients who underwent TVT in 2002-2004 (Group-I); and 419 patients who underwent TVT-O in 2004-2006 (Group-II). The cure rate at 6 months and 1 year for those in Group-I was 90.7% and 91.2% respectively; and the cure rate at 6 months and 1 year for those in Group-II was 92.7% and 92.8%. The pattern of success rate was maintained over 3 years with greater cure for the TVT-O group (89.7%) as compared to the TVT group (82%).

TVT-O had fewer patients with demonstrable leakage on UDS at 6 months (5.4%) as compared to TVT (16.7%). Mean hospital stay was longer for TVT (2.35±1.27days) as compared to TVT-O (1.56±1.27days). When performed alone without any concomitant surgery, TVT-O (n=178) took lesser time (14.2±6.9min) as compared to TVT (n=69) (28.73±16.79min).

With regards to surgery complications, bladder perforation occurred in fewer TVT-O patients (0.5%) as compared to TVT patients (4.3%). Prolonged catheterisation ≥7days was required for 7(1.67%) TVT-O patients and 12(2.4%) TVT patients. Contrary to popular belief, voiding difficulty in the form of slow flow or incomplete emptying was more common with TVT-O (3.8%) as compared to TVT (1%), and the difference was noted persistently over 6 months, 1 year and 3 years.

### Interpretation of results

Comparing the two groups (Group-I and Group-II) using Chi Square test-TVTV and TVT-O were comparable in terms of success rates at 6 months ( $p=0.80$ ) and 1 year ( $p=0.85$ ). However at the end of 3 years, TVT-O was found to be associated with better success rates than TVT ( $p<0.001$ ).

Peri-operative complications including bladder perforation were significantly more with TVT ( $p<0.001$ ). Need for prolonged catheterisation ≥7 days was more common with TVT, though this was not statistically significant ( $p=0.49$ ). There were also more voiding difficulties reported in the TVT-O group than TVT group at 6 months, 1 year and 3 years ( $p<0.001$ ).

### Concluding message

TVT-O surgery seems to be comparable with TVT in terms of 1 year success rate. Also, TVT-O was found to be associated with lesser perioperative complications in the form of lesser blood loss, fewer days of hospitalisation and shorter operative time. The 3 years cure rate for TVT-O was found to be significantly better than TVT. However as compared to the usual observation, long term voiding dysfunction was more common with TVT-O as compared to TVT. More long term data is awaited for better evaluation of such a difference.

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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>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Centralised Institutional Review Board (CIRB)</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>