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RETROSPECTIVE STUDY ON TENSION-FREE VAGINAL TAPE OBTURATOR

Hypothesis / aims of study

Stress urinary incontinence affects up to 20% of women and is a social stigma. Multiple behavioral and surgical treatments exist; however, midurethral slings are becoming the gold standard for correction of stress urinary incontinence (1). Several reports have confirmed high cure rates using the minimally invasive tension-free vaginal tape approach (2,3).

The TVTO procedure has come to be considered the therapy of choice by many surgeons for the treatment of female SUI because the retropubic route of TVT instrument insertion has been associated with complications due to damage of the bladder pelvic organs, nerves and vessels. The TVT-O procedure was developed with the aim of decreasing the rate of complications, avoiding damage to the urethra and pelvic organs, and achieving reproducible results.

The aim of this study is to report the 3 year efficacy and complications of the tension free vaginal tape obturator (TVTO) procedure in the treatment of female stress urinary incontinence.

Study design, materials and methods

All women undergoing the TVTO procedure between January 2004 and December 2006 by the same urogynaecologist from the department of urogynaecology were recruited in the study. Pre operative evaluation consisted of history taking , pelvic examination, erect stress test(EST), and urodynamic study(UDS) . Post operative evaluation consisted of history taking, pelvic examination and cough test at 6 months,1 year, 2 years and 3 years. In addition UDS was repeated at 6 months following surgery.

Operative details documented included duration of surgery, type of anaesthesia, concomitant surgery and blood loss. Perioperative complications like excessive blood loss and bladder perforation were also recorded.

Post operative details recorded included length of stay in hospital, no of days requiring catheterization, presence of fever of > 37.5 C and groin or thigh pain were recorded including whether the patients were readmitted and the reasons for this.

Results

There were a total of 422 patients who had a TVTO procedure done. 3 patient case notes were unavailable for review. Out of the remaining 419 cases, 176(42%) had an isolated TVTO procedure and 243(58%) had TVTO with concomitant surgery. 332(79.2%), 277(66.1%), 234(55.8%) and 185(44.2%) came for review at 6 months, 1 year, 2 years and 3 years respectively.

The length of stay in hospital ranged from 0 to 15 days. The patients staying in hospital for less than a day were day surgery cases. A single patient stayed for 15 days due to voiding difficulty The duration of surgery ranged from 5 to 51 minutes and 7 to 223 minutes for the isolated TVTO procedure and TVTO with concomitant surgery respectively.

247 (58.9%) had general anaesthesia, 166(39.6%) had a regional block , 5(1.2%) had local anaesthesia and type of anaesthesia was not available from the case record in 1 patient.

Operative blood loss ranged from less than 10ml to 1100 ml. Intraoperatively 2(0.5%) had an end blood loss of more than 1 litre. Both patients had concomitant hysterectomy. Bladder perforation occured in 2(0.5%) out of 419 patients. The number of patient catheterization days post operatively ranged from 0 to 15 days.

During the initial post operative period 39(9.3%) had a temperature > 37.5 degrees but only 12(2.9%) had a temperature ranging from 38.0 to 38.2 degrees. 5(1.2%) had voiding difficulty requiring catheterization for more than 2 days. 151(36 %) had pain in the thigh or groin. 135(89.4%) and 16(10.6%) out of these 151 had thigh and groin pain respectively.

7(2.1%),3(1.1%) and1(0.4%) had voiding difficulty at 6 months,1 year and 2 years respectively.

There were no patients with voiding difficulty at 3 years follow up. 9(2.7%), 1(0.4%),1(0.4%) and 1(0.5%) had pain at 6 months,1 year,2 years and 3 years respectively. 16(4.8%), 6(2.2%), 4(1.7%) and 1(0.5%) had erosion at 6 months,1 year,2 years and 3 years respectively. 21(6.3%), 18(6.5%), 21(9%) and 7(7.6%) developed de novo frequency, urgency and urge incontinence at 6 months,1 year,2 years and 3 years respectively

No patients had any major or life threatening complications. There was 1 readmission for acute urinary retention.

The subjective cure rate was 91.6%, 91.7%, 89.7% and 87.6% at 6 months, 1 year, 2 years and 3 years respectively. The subjective improvement rate was 7.2%, 7.2%, 8.5% and 10.3% at 6 months, 1 year, 2 years and 3 years respectively. The objective cure rate by cough test was 94.3%, 94.2%, 93.2% and 92.4% at 6 months, 1 year, 2 years and 3 years respectively. The objective cure rate at 6 months by urodynamic study was 93.5%. The objective cure rate at 6 months was 94.3% by cough test but 93.5% by urodynamic study.

Interpretation of results

There were minimal intraoperative complications with a 0.5% bladder perforation rate and a 0.5% significant operative blood loss rate of 1 litre or more. In the immediate postoperative period, 2.9% had significant pyrexia of 38.0 degrees and above, with 1.2% of patients developing voiding dysfunction. From 6 months to 3 years there was a reduction in the voiding dysfunction rate from 2.1% to 0.4% as well as the vaginal tape erosion rate from 4.8% to 0.5%. There were no life threatening complications and only one readmission.

The subjective and objective cure rates were approximately 90% which agrees with the present accepted rates.

Concluding message

The TVTO is an efficacious method for treating stress urinary incontinence with minimal complications .

References

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Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**