

RANDOMIZED PROSPECTIVE TRIAL OF A COMPARISON OF THE EFFICACY OF TVT-O AND TVT SECUR SYSTEM IN THE TREATMENT OF STRESS URINARY INCONTINENT WOMEN – COMPARISON OF THE LONG- AND SHORT-TERM RESULTS

Hypothesis / aims of study

For many years there have been efforts to find an operative procedure for this condition that would, with minimum invasiveness, have the same effect and fewer complications. In 1996 Ulmsten and Petros described the method of tension-free vaginal tape (TVT), which is minimally invasive and has a comparable effect to Bruch colpo-suspension. Due to the retro-pubic trajectory during the tape insertion, serious perioperative complications were described, including injury of the major vessels and bowel injury – sometimes with fatal consequences. Despite the relative rarity of such complications, efforts were then made to minimize the risk of them occurring at all. In 2001 Delorme described the placement of the tape via the transobturator route (TOT - transobturator tape outside-in). The next transobturator modification was to place the tape inside-out (TVT-O, De Leval 2003).

Tape surgical methods are at present considered the gold standard for surgical treatment of stress urinary incontinence, but they are associated with some complications. In an attempt to reduce further the invasive nature of the procedure and the rate of complications, a new generation of tension-free vaginal tapes has been introduced, known as minitapes. The first tape of this type was TVT-Secur (TVT-S). It was expected that these tapes would be less invasive, the surgical procedure would require fewer tissue dissections, and there would be less post-operative pain while maintaining a similar degree of effectiveness. The first published short-term results were promising, and the data indicated similar efficacy as retro-pubic or transobturator tapes. However, subsequent studies showed lower efficacy than expected, and several case reports describing serious bleeding after this procedure were published.

The aim of this study was to compare the short term and long term efficacy of, and the complications involved in, the use of TVT-O and TVT SECUR systems, H and U approach (TVT-S) in the treatment of stress urinary incontinent women.

Study design, materials and methods

Between January 2007 and November 2009 197 women with proven urodynamic stress urinary incontinence were included in this prospective randomized trial. For randomization the envelope technique was used. Before enrolment to the study all patient signed informed consent documentation. Patients were randomized into three groups – TVT-O (68), TVT-S H approach (64) and in TVT-S U approach (65). Based on pre-study statistical calculations it was indicated that the required sample size in each group is 65 patients. All patients underwent a complete urogynecological investigation before the procedure (clinical examination, urodynamics, ultrasound examination), and they filled in the ICIQ and iQoL questionnaires. Surgery was only offered if conservative therapy was unsuccessful. Exclusion criteria were: predominant urge incontinence, urodynamic detrusor instability, previously failed anti-incontinence surgery, previous radiotherapy, postvoid residual volume (PVR) greater than 100 ml, bladder capacity less than 300 ml, stage II, III, or IV pelvic organ prolapse according to the International Continence Society pelvic organ prolapse quantification system, planned concomitant surgery, immobile urethra, age < 18.

The peri-operative complications were monitored. After the study the patients underwent a complete examination 3 months after surgery (the same examination as before the procedure). The next check-ups were provided one year and two years after surgery (or three years if the two-year check-up was omitted), and the investigation was the same as at the 3-month check-up, except for urodynamics.

Postoperative follow-up was terminated if the result of surgery was evaluated as a failure, and reoperation was offered.

Results

There were no significant differences in age, body mass index, parity, or history of surgery for gynecological disorders among the study participants. Preoperative urodynamic and QoL parameters were also not significantly different. The mean age was 56.3 (SD 10.0), mean BMI 26.9 (SD 4.5), mean parity 2.0 (SD 0.8), mean ICIQ 14.9 (SD 2.6) and iQoL 53.8 (SD 10.9), mean MUCP 43.7 cm H₂O (SD 16.8) and mean Q_{max} 27 ml/s.

There were no serious perioperative complications in the TVT-O group. In the TVT-S H group there was one bladder perforation and two incidents of blood loss over 500 ml (once required transabdominal surgical revision of bleeding in the Retzius space). The mean blood loss in the TVT-O group was 24.93 ml, in the TVT-S H group 56.80 ml and in the TVT-S U 42.85 ml (differences were statistically significant). Median follow up after surgery was 1.9 years.

At the end of the study the TVT-O group had a figure of 86.7 % subjectively continent, while the other figures were TVT-S U group: 58.4% and TVT-S H group: 70.3% (Tab. 1). Objective cure rate was also significantly better in the TVT-O group (91.1%) , compared to 67.7% and 68.7% in the other 2 groups respectively. In the TVT-O group only one result was evaluated as a failure - (1.4%), though in the TVT-S H group 12 patients were assessed in this way (18.7%), and 8 of them underwent further anti-incontinence procedures. In the TVT-S U group failure occurred in 9 cases (13.8%), and 7 of them underwent further anti-incontinent procedures. Three months after surgery the objective cure rate in the TVT-O group was 95.5%, in the TVT-S H group 82.8% and in the U group 78.5%. Subjective cure rates were also higher than at the end of survey (Tab.1).

In the TVT-S groups the incidence of tape protrusion was also higher: in the TVT-S H group there were 5 cases (7.8%) and in the TVT-S U group 4 cases (6.1%), compared to one in the TVT-O group (1.4%).

Tab. 1

Comparison of the surgical procedures

TVT-O	TVT S-H	TVT S- U	p
-------	---------	----------	---

ICIQ3	1.7/SD 2.9	2.9/SD 4,7	3.1/SD 4.0	0.087
ICIQL	2.8/SD 3.6	4.9/SD 5.8	4.6/SD 4.9	0.051
iQoL3	100.2/SD 10.9	96.2/SD 19.3	93.5/SD 13.9	0.0012
iQoLL	99.1/ SD 13.1	91.1/SD 22.4	94.6/SD 18.3	0.20
Positive ST 3	3	11	14	0.01
Positive ST L	5	20	20	<0.001
Subj. stress 3	5	12	16	0.03
Subj. Stress L	9	19	27	0.001
Failure 3	0	7	3	0,016
Failure L	1	12	9	0,001

3 – three months after surgery, L – last control, ST – stress test,
Subjective stress - Presence of leakage was based on evaluation of ICIQ questionnaire

Interpretation of results

Evaluation of the short term efficacy of new surgical techniques on a selective group of patient without comparison to standard procedure may be confusing. Three months after surgery there were relatively high objective cure rates in TVT-S patients (82.8% and 78.5% respectively). With increasing time from the surgery there was a significant decline in the cure rate. After TVT-O procedure the cure rate was stabile, and none of the patients required further anti-incontinence procedure. The only patient with failure required tape cutting for voiding difficulties, and after this procedure she remained continent.

Concluding message

Both short- and long-term follow-up revealed a significantly lower subjective and objective cure rate in the TVT SECUR group compared to the TVT-O group. There were no significant differences in the cure rates between the U and H approaches within the TVT–S group.

<i>Specify source of funding or grant</i>	IGA MZ CR grant No. NS10586-3/2009
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	Yes
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Ethics Committee of the General University Hospital in Prague
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes