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Masata J[1], Martan A[1], Hubka P[1], Svabik K[1]
1. *Dept. of Obst. Gyn., Charles University Prague*

LONG-TERM FOLLOW UP (WITH A MINIMUM OF FIVE YEARS) COMPARING THE EFFICACY OF TVT-O AND TVT SECUR SYSTEM IN THE TREATMENT OF STRESS URINARY INCONTINENT WOMEN- RANDOMIZED TRIAL

Hypothesis / aims of study

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 single incision tension-free vaginal tapes has been introduced. The first tape of this type was TVT-Secur (TVT-S). The first published short-term results were promising, and the data showed similar efficacy as retropubic or transobturatory tapes. However, subsequent studies show lower efficacy than expected. Until now no long-term data referring to patients who have undergone this procedure has been published.

The aim of this study was to compare, with a minimum of five years follow-up, the 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 a total of 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 concern. Patients were randomized into three groups: TVT-O (68), TVT–S H approach (64) and TVT-S U approach (65). Based on pre-study statistical calculations it was indicated that the required sample size in each group was 65 patients.

All patients underwent complete urogynecological investigation before the procedure (clinical examination, urodynamics, ultrasound examination), and they filled in 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 than100 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, age < 18.

The peri-operative complications were monitored. 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), with the same examination 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; in all subsequent controls such cases appear as failures (LFCF – last failure carried forward analysis). Initially only a only two-year follow-up was planned for the study, but we subsequently added this long-term minimum five-year follow-up.

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 not significantly different, either. 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 Qmax 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 coupled with 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 and in the TVT-S U group 42.85ml (differences were statistically significant). Median follow up after surgery was 1.9 years.

The mean length of follow up was 5.9 years (SD±1.5) in the TVT-O group, 5.2 years (SD±2.2) in the TVT-S H group and 5.2 years (SD±2.0) in the TVT-S U group. For this final analysis we have available 162 (82.2%) women with minimum five-years follow-up; 20 (10.1%) patients were added as LFCF. For Last Observation Carried Forward analysis we used another 13 patients (3 with 3-years follow-up, 8 with 2 years and 2 with 1-year check-up).

Using the LOCF method, in the TVT-O group the stress test was negative in 92.6% of patients, in TVT S U in 67.7% and TVT-S H group in 64.1%. ($p<0.001$) (tab.1,2).

In the TVT-O group only two results were evaluated as a failure (2.8%), though in the TVT-S H group 15 patients were assessed in this way (23.4%), in the TVT-S U group failure occurred in 13 cases (20%) ($p<0.001$).

In the TVT-S groups incidence of tape protrusion was also higher: in the TVT-S H group there were 6 cases (9.4%) and in the TVT-S U group 4 cases (6.2%), compared to one case in the TVT-O group (1.4%). There were also statistically significant differences in assessment of QoL using the ICIQ, VAS, Likert scale and iQoL questionnaires, all favoring the TVT-O procedure.

Interpretation of results

In this minimum five-year follow-up we observed a further decrease in the subjective cure rate and an increase in the number of failures in the TVT SECUR group compared to the TVT-0 group, and this situation is different to that at two-year check-up. We also found greater deterioration in the quality of life in both TVT S groups compared to the results after two years. For TVT-O the cure rates were stable.

Concluding message

The use of SIMS TVT-S is connected with progressive decline of efficacy with increasing time after surgery, compare to stable cure rates following use of the standard transobturator midurethral sling (TVT-O).

Tab. 1 Long term subjective follow up, Quality of life (LOCF analysis)

	TVT-o	TVT-S H	TVT-S U	p
N	**68**	**64**	**65**	
Subjective cure rates				
Likert scale				
Cured (5)	60**(88.2%)**	**40(62.5%)**	44**(67.7%)**	0.001
Improved (4)	5**(7.4%)**	**11(17.2%)**	**7(10.8%)**	NS[b]
No change (3)	**2(2.9%)**	**11(17.2%)**	**12(18.5%)**	**0.005**
Worsened (1+2)	1**(1.5%)**	**2(3.1%)**	**2(3.1%)**	NS[b]
ICIQ	**3.3±4.7**	**6.2±6.1**	**6.0±5.6**	0.006[a]
VAS	**92.9 ± 18.9**	**77.5 ±33.8**	**77.7 ± 32.3**	**<0.001[a]**
VAS≥90	62**(91.2%)**	**41(64.1%)**	45**(69.2%)**	0.001[b]
iQoL	**98.8 ±16.2**	**88.6 ± 22.5**	**89.8 ± 21.2**	**0.008[a]**
Urgency	**30(46.8%)**	**29(46.7%)**	**24(42.1%)**	NS[b]
De novo Urgency	**10(14.7%)**	**8(12.5%)**	**5(7.7%)**	NS[b]
Urgency Cured	**34(50%)**	30**(46.9%)**	**30(46.2%)**	NS[b]
Urgency Incontinence	**23(33.8%)**	**12(18.8%)**	9**(13.8%)**	NS[b]
Urgency Incont. Cured	**22(32.4%)**	**10(9.4%)**	**12(18.5%)**	NS[b]

Tab. 2 Long term objective follow up (L0CF analysis)

	TVT-o	TVT-S H	TVT-S U	p
N	**68**	**64**	**65**	
Objective cure rates				
Stress test positive	6**(8.8%)**	**23(35.9%)**	**22(33.8%)**	**<0.001[b]**
Failure	**2(2.9%)**	**15(23.4%)**	**13(20%)**	**0.001[b]**
Tape erosion	2(3%)	6(9.4%)	4(6.2%)	NA[b]

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