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CHANGES IN ULTRASOUND MEASUREMENTS AFTER TENSION-FREE VAGINAL TAPE-SECUR* PROCEDURE

Hypothesis / aims of study
The aims of this study were to compare ultrasonographic findings of the urethra and the tape position and mobility following both TVT–S procedures. The hypotheses were that the TVT-S procedures restrict urethral mobility and that the restriction might change over time.
Study design, materials and methods
Eighty-five women with previously untreated stress urinary incontinence were recruited to participate in a clinical study. Their mean age was 55.5 (SD-11.0) years, mean body mass index (BMI) 28.2 (SD-5.0), and mean parity 2.0 (SD-1.1). The tape was placed 46 times in the “hammock” position and 39 times in the “U” position. Determination of the position of the tape was by surgeon choice, with no difference in indication for both approaches and without information about patient status.
The US (ultrasound) examinations were performed before the operation (time point 0) and again twice afterwards. The effect of the TVT-S procedure was evaluated only by US examination approximately one week after the operation (time point 1), and then after three months (time point 2) by US examination and objectively by cough test (cured patient = negative test). Subjective assessment of the efficacy was based on the International Consultation on Incontinence Questionnaire – Short form (ICIQ-UI SF) filled in before and three months after the surgery. Hence we can distinguish short-term effects (time point 1 compared to time point 0) and medium-term effects (time point 2 compared to time point 0) of the operation; we also explore the effects of healing by comparing time point 2 measurements to those of time point 1.
The first and second US examinations were performed on all 85 patients (before and one week after the operation), the third US examination three months after surgery on 70 (82%) patients only. Eighty-one (95%) patients sent us the completed questionnaire ICIQ-UI SF.
The urogynecologic perineal ultrasound (US) examination was performed on patients in the supine position with the bladder filled with 300 ml of sterile saline. The US examination was performed at rest and at maximum Valsalva maneuver to determine the vector of movement. We measured the position of the urethrovesical junction (UVJ) and the point of the urethra (U) 17 mm away from the UVJ, in order to assess the middle third of the urethra. The rotation of the urethra axis and the tape axis is defined as the angle between the urethra axis/the tape axis at rest and during Valsalva maneuver. All data were processed and statistical analysis performed in statistical environment R, version 2.5.1. Continuous data were summarized as mean with standard deviation and as median. Changes in time and differences between groups were compared using t-test, Wilcoxon test or Fischer exact test; the level of significance was set to 0.05.
Results
Objective assessment by cough test showed that 53/85 (62%) of our patients were completely dry, and in 32/85 (38%) of patients leakage of urine persisted. Subjective assessment by the ICIQ-UI SF questionnaire showed that 39/81 (48%) of our patients were completely dry, 24/81 (30%) of patients improved and in 18/85 (22%) of patients leakage of urine remained the same as before the operation. We found no statistically significant differences in these results between patients with the tape in the "hammock" and the "U" position.
Results of US measurements were analyzed from several points of view.
Short-term effects: The mobility of the urethra is restricted to an important and statistically significant extent (UVJ-5.6 mm, U-4.6 mm; p-level<0.05). The rotation of the urethra axis is restricted by the operation as well – while it rotated by 33 degrees before the operation, the tape restricts the rotation to 21 degrees. The tape moves concordantly with the urethra and rotates by 22 degrees during the Valsalva maneuver.
Medium-term effects: The mobility of the urethra is restricted to a lesser extent than one week after operation, but the restriction of the mobility is at a statistically significant level when compared with the mobility of the urethra before the operation (UVJ-3.8 mm, U-4.3 mm; p-level<0,05). The rotation of the urethra axis is significantly greater than immediately after the operation: during the Valsalva maneuver it rotates by 32 degrees. The tape still moves concordantly with the urethra and rotates by 28 degrees.
We found no difference between the US measurements of patients with "hammock" and "U" position of the tape.
Interpretation of results
The curative rates of TVT-S were low, irrespective of which of the two approaches was used, compared with published curative rates for TVT and TVT-O.
From the early US examination we observe restriction of the mobility of the bladder neck and urethral point. But the mobility of UVJ and U point falls partially to preoperative values at the 3-month follow up. We may speculate that these changes might be due the effects of healing (possibly resorbtion of hematoma in the surrounds of the urethra) or loosening of fixation after resorption of the resorbable part of the implant. However, it is possible that some patients performed a less effective Valsalva maneuver at the first week time point control due to postoperative pain.
Concluding message
In conclusion, the objective and subjective curative rate of TVT – S procedure is low irrespective of the position of the tape. It seems that this is caused by insufficient restriction of urethral mobility. The restriction weakens within the first 3 months after surgery.

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Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**

Specify Name of Ethics Committee	**Local Medical Ethical Committee of the General Faculty Hospital, Prague, Czech Republic**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**