Hypothesis / aims of study

TVT-O is the second generation of tension-free vaginal tapes. It is a modification of former transobturator method TOT to eliminate the risk of damage of urethra and the need of larger preparation of the tissues. However this method brings new complaints of patients such as groin pain. It was suggested by Hinoul [1] that the position of the legs might be important to the insertion pathway. Unfortunately this study builds this theory on one sole case, which lacks any statistical power. We hypothesize that the pathway of the TVT-O will be different if the legs are in improper position and that the groin pain might be explained by the distance of the TVT-O tape from the obturator nerve.

Study design, materials and methods

We used a total of nineteen female cadavers - fourteen formalin-embalmed and five fresh frozen. TVT-O was placed as recommended by the manufacturer in the instructions. The only way this placement deviated from the recommended procedure was in the position of the legs of the formalin-embalmed bodies, due to the rigidity of the limbs. It was necessary for the flexion in the hip joint to be 30° instead of 90°. This was also the reason for the inclusion of fresh frozen cadavers, since the position of legs is important according to Hinoul and our hypothesis. The legs at fresh frozen cadavers were positioned as recommended (90° flexion in the hip joint). After the insertion dissection of the adductor region was performed same as abdominal dissection and distances to the obturator nerve were measured as a safety parameter. For statistical analysis we used 5% level of significance alpha, and the data were processed by the system R. To compare the difference between the group of fresh frozen and formalin-embalmed bodies we used the t test and Wilcoxon-paired test. Due to the small number of bodies in both groups, we tried to estimate the number of bodies needed for comparison of mean differences between groups. We used two sample t test, where one group has three times more objects than the other group, approximately. We made a rough estimate of standard deviation SD from given data as 0.8 cm. At a 5% level of significance and with the power of the test 80%, the numbers of fresh frozen bodies and embalmed female bodies needed to detect the mean difference delta of 0.5 cm, we would need 27 fresh frozen bodies and 82 embalmed female bodies. In our study, we would be able to detect a mean difference of approximately 1.5 cm.

Results

In total we examined 38 trajectories and fixation sites of TVT-O. At the formalin-embalmed bodies the mean distance to the anterior branch of obturator nerve was 8.57 mm (SD 6.91 mm) on the left side and 7.14 mm (SD 7.52 mm) on the right side. The mean distance to the posterior branch was 8.36 mm (SD 6.51 mm) on the left side and 8.93 mm (SD 7.12 mm) on the right side. There was significant statistical difference in the distance to the obturator nerve between the group of fresh-frozen bodies and formalin-embalmed bodies. At the fresh-frozen bodies the mean distance to the anterior branch was 24 mm (SD 4.18 mm) on the left and 23 mm (SD 5.7 mm) on the right. The mean distance to the posterior branch was 23 mm (SD 5.7 mm) on the left and 23 mm (SD 4.47 mm) on the right. TVT-O never penetrated through the fascia of obturator internus muscle and the contact with the nerve always occurred in the adductor region (Fig. 1).
Position of TVT-O depends on position of the legs during the procedure. Nevertheless, all the contacts with the nerve occurred in the adductor region. This might be explanation why partial extirpation of the pelvic part of TVT-O might fail to bring relief [2]. It seems to be obvious that the contact of the tape might cause irritation which might be called groin pain. However until successful extirpation of the tape from the adductor region with documented direct contact with either branch of the obturator nerve during live surgery it will be just a theory that is supported by cadaver study.

Concluding message
TVT-O is dependent on position of the legs. The contact occurs in adductor region, therefore extirpation of the pelvic part of the TVT-O might fail to relieve the pain.

References

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Is this a clinical trial? No

What were the subjects in the study? NONE