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POSSIBLE COMPLICATIONS OF THE TVT-S VAGINAL TAPE IN THE H-POSITION

Hypothesis / aims of study

TVT-S is the third generation of tension-free vaginal tapes. There are two possible insertion methods: the H-position and the U-position. It was claimed that this tape, using less foreign material, would achieve higher efficacy and a reduction of the complication rate in comparison to the previous methods [1]. The aim of the study was to evaluate the fixation site of the TVT-S tape and to explain possible haemorrhagic complication [2]. We hypothesize that fixation site will be crucial for long-term efficacy of the method.

Study design, materials and methods

We used a total of nineteen female cadavers - fourteen formalin-embalmed and five fresh frozen. TVT-S was placed in the H-position 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-fixated 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 might be important for proper insertion; the previous methods - especially trans-obturator tapes - are known to depend on it. After the insertion abdominal dissection of the lesser pelvis was performed, distances to the obturator nerve were measured as a safety parameter, and the site of fixation was examined. 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-fixated bodies we used the *t* test and Mann-Whitney 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 1.3 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 71 fresh frozen bodies and 214 embalmed female bodies. In our study, we would be able to detect a mean difference of approximately 2 cm.

Results

In total we examined 38 trajectories and fixation sites of TVT-S. The mean distance from the obturator nerve was 2.94 cm (SD 1.14 cm) on the left and 3.04 cm (SD 1.20 cm) on the right. None of the tests for differences in the distance to the obturator nerve and the fixation site between the group of fresh frozen bodies and formalin-embalmed bodies was significant.
In half of the cases the inserter penetrated into the lesser pelvis with the following results. In eleven cases the inserter was prevesical, i.e. between the urinary bladder and the fascia of obturator internus muscle. Four times the inserter was in the wall or inside the urinary bladder. In three cases the inserter was subvesical, underneath the urinary bladder pointing toward the uterus. In one case during the subvesical placement the inserter was in contact with the varicose uterine vein (Fig. 1). Subfascial placement (between the fascia of obturator internus muscle and obturator internus muscle) occurred eight times. In one case the inserter was almost in contact with variable nutritive vessels for obturator internus muscle (Fig. 2).

Fig. 1
1 left external iliac artery, *2* left obturator nerve, *3* varicose left uterine vein, *4* uterus, *5* inserter, *6* urinary bladder.

Fig. 2
1 anastomosis between right obturator artery and deep epigastric artery, *2* right obturator artery and vein, *3* nutritive vessels for obturator internus muscle, *4* fascia of obturator internus muscle, *5* urinary bladder

Interpretation of results

TVT-S appears to be less depending on position of the legs during the procedure. Nevertheless, frequency of the perforation of the fascia of obturator internus muscle is alarming and is quite similar to long-term efficacy published by clinicians. In case of inserting the tape into lesser pelvis possible complications, as perforation of the urinary bladder or haemorrhage, can occur. In the case of perforation of the fascia of obturator internus muscle, haemorrhage will be less likely to stop by self-compression. The rate of perforation of the urinary bladder is in contrast with our clinical praxis. With 160+ TVT-S done we witnessed perforation of urinary bladder only once. The difference might be explained by fixed position of the urinary bladder in embalmed bodies.

Concluding message

TVT-S has a high risk of placement into the small pelvis with risk of injury to vessels, urinary bladder and variable anatomical structures. Excessive movement with the inserter might cause severe complications. Position of the legs seems to be less important for TVT-S than for previous methods. TVT-S minimally endangers the obturator nerve.

References

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