

SURGERY OF FEMALE URINARY INCONTINENCE USING TRANS-OBTURATOR TAPE (TOT): A PROSPECTIVE RANDOMISED COMPARATIVE STUDY WITH TVT.

Aims of Study

TVT is now considered as gold standard technique to treat stress urinary female incontinence. It give good results but has some morbidity and some life threatening complications have been described. A new technique described in France by Delorme, the TOT is said to reduce these complications. The aim of this study isto evaluate the results and morbidity of the trans-obturator tape by comparing it with a classical technique TVT.

Methods

We have started, in septembre 2001, a prospective randomised and comparative study concerning 200 patients with stress incontinence associated or not with prolapse. The study is still going on. The first 102 patients operated the first year have been evaluated with a mean follow up of 6,17 months.

Preoperatively, standardized uro-gynaecologic questionnaire was fulfilled, urodynamics and ultrasound are performed in every patient. Before the operation the technique is randomly drawn using blinded envelopes containing the same number of TOT and TVT procedures. If prolapse surgery is associated, the sub urethral tape is put at the end of the operation.

In the TOT procedure, a sagitttal 2 cm vaginal incision is made at mid urethra. After paraurethral bilateral dissections of the vaginal wall up to the pelvic fascia, a small incision is made bilaterally one centimetre lateral the ischio-coccygeus ramus at the level of the clitoris. A specific needle is used to perforate the obturator membrane and keeping close contact with the bone, turns around the ischio-coccygeus ramus. A finger tip is introduced in the space between the vagina and urethra up to the pelvic fascia and waits for the tip of the needle. The needle follows the finger up to the vaginal incision. A Prolene tape obtained by cutting a tape 11 mm large and 30 cm long from a mesh 30X30 cm is attached to the needle which is then removed from the obturator foramen. The same technique is used on the other side to pass the other extremity of the tape. Cystoscopy is performed and stress test, is used to position the tape under the urethra in the same way as TVT.

The follow up consisted of a clinical evaluation, a one-hour pad test, uroflowmetry, residual urine as well as a self questionnaire evaluating the subjective results.

Results

The study concerns 48 TOT and 54 TVT. There is no difference between the two groups concerning age, history and associated surgery. Urinary complications are more frequent in TVT group, 5 bladder perforation and 1 urethral laceration versus zero bladder injury in the TOT group. No haematoma in either group. The results on stress incontinence is the same in both groups, 93% of patients in TVT group are cured, versus 96 % in TOT group. Urge incontinence is cured in 60% of patients in TVT group and 80% in TOT group. De novo urge incontinence is present in 7% of TVT group and 4% of TOT group. Frequency is cured in 70% of patients in TVT group and 79 % of TOT group. De novo frequency happened in 19% and 3% of patients respectively. Five patients in TVT group and 1 patient in TOT group had retention and needed lateral section of the tape. They restored satisfactory micturation and are dry. The Prolene° tape is well tolerated in both group, we did not find any exposition of the materiel.

In France the TVT costs 371,52 Euros and a Prolene° mesh 80,49 E, the net economy for the hospital is 291 Euros per operation. In our department we operate 150 patients per year which means an annual economy of 43 650 E.

Conclusions

Mid sub urethral Prolene tape put in a similar way to TVT up to fascial penetration gives the same results on stress incontinence cure rates. The TOT does not pass through the Retzius space and reduce significantly urinary complications and hematomas. It eliminates completely

life threatening complications such as intestinal perforation or large vessels traumas. It seems in this preliminary study that the TOT creates less irritative bladder symptoms. This is to be confirmed in the remaining cases. The home made trans-obturator tape gives the same results as TVT procedure and allows substantial economy to hospital and the society. This economic and safe technique can thus be proposed to treat urinary female incontinence.