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SAFETY OF INSIDE-OUT TRANSOBTURATOR APPROACH FOR URINARY STRESS INCONTINENCE TREATMENT :

PROSPECTIVE MULTICENTRIC STUDY OF 994 PATIENTS – FRENCH TVT-O(REGISTRY.

Hypothesis / aims of study

Evaluate the safety of inside out transobturator approach for surgical treatment of urinary stress incontinence (USI) using TVTO® (Gynecare) sub urethral sling

Study design, materials and methods

This study was prospective and multicentric (89 investigators: 48 gynaecologic surgeons and 41 urologic surgeons). Diagnosis of prolapse associated with USI was an exclusion criterion. 994 patients were included in this study. Mean age was 57.7 years old (27-93). Nine % of patients (n=92) had previous surgical treatment of USI (21 cases of previous of retro pubic or transobturator sub urethral sling/ 2.1%). Five % of patients had previous gynaecologic surgery. Sixty four % of patients were menopausal (26% of hormonal replacement treatment). Concerning clinical data, Boney test was done for 80.6% and positive for 94.8% of cases. Ulmsten test was done for 72.5% and positive for 97.4% of cases. Urinary urgencies were noticed for 20.6% of case. Concerning preoperative urodynamic investigations, mean of maximal urethral closure pressure was 48.6 (6-70). Surgical procedure was an isolated cure of USI without other associated surgical procedure. Each patient was followed up 4 weeks after surgery.

Results

Concerning surgical procedure, cure of USI was performed under general anaesthesia for 54%, spinal anaesthesia for 40% and local anaesthesia for 6 %. We used prophylactic antibiotherapy for 83% of cases. Procedure started with hydro dissection in 24 % of cases. In order to place the sling, cough test was done in 26% of cases. No cystoscopy was performed. Mean operation time was 17 minutes (4-120). No bladder injury was noted. We observed 13 cases (1.3%) of vaginal wall perforation in the lateral cul de sac. One case of urethral injury was noted (0.1%). Abnormal bleeding was noticed for 21 cases (estimated bleeding between 50 and 400 ml). No one required any transfusion. Bladder catheter was leaved in place for 24 hours in 73.7% of cases.

Postoperative moderate pain was noted in 14.8% of cases; most of time bilateral (62.8%) and located at the upper thigh (70.9%). Urinary infection, haematoma and ecchymose were observed in 18 (1.8%), 7 and 18 patients respectively. Rate of re intervention was 0.8%: one case of haemorrhage that occurred 6 hours after surgery and required transfusion of 2 units of red cells; 7 cases of urinary retentions required a release mesh procedure between 2 and 9 days after initial procedure (one urethral dilatation and 6 tension reduction of the sling). All patients were reviewed 1 to 3 months after operation. No perineal neurological complication was encountered. Forty-seven patients complained of residual pain (4.7%). This symptom was located at the upper part of thigh in 51%. No one required opiod or non-opiod analgesic medical treatment. Concerning functional results, patients were completely cured in 892 of cases (89.7%). USI was significantly reduced for 79 cases (7.9%); reduced for 11 cases (1.1%) and not modified for 12 cases (1.2%). Concerning urinary urgencies, we observed 137 de novo cases (3.7%). The intensity of these symptoms was reduced for 75 cases (7.5%) and worth for 17 cases (1.7%). Dysuria was noticed in 17.4% (173/94). Six patients have been re operated: 2 cases of vaginal erosion (partial resection of the tape); 2 sections of the tape and 2 drainage of perineal abscess.

Interpretation of results

The absence of major peri and postoperative complication stressed the safety of this technique (no vascular or digestive complication) compare to retro pubic procedure. Concerning functional evaluation and USI, the results are promising and seem equivalent to retro pubic tape.

Concluding message

These results confirm the very low morbidity of the inside out trans obturator approach: no bladder injury in this large study. Functional results have to be confirmed by long term follow up and randomised control trial compared retro pubic and transobturator approach.

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