

RESULTS OF RETROPUBIC AND TRANSOBTURATOR PLACEMENT OF SUB-MID URETHRAL TAPES (M.U.T.) IN FIRST INTERNATIONAL REGISTRY: RESULTS ON 984 PATIENTS AT 3 AND 12 MONTHS.

Hypothesis / aims of study

To evaluate the efficacy and safety of the same type I polypropylene M.U.T by two different approaches for the first time by surgeons in different countries, it was proposed to systematically and prospectively register pre, per and post-operative characteristics of patients operated for stress urinary incontinence (SUI) with or without a combined prolapse cure (C.P.C.).

Study design, materials and methods

By the end of February 2007, 42 surgeons from Finland, France, Italy, Spain, South Africa, and UK had enrolled 984 patients, mean age 60 years (26-90), in the registry. Within this group, 68% of patients reported genuine SUI, 14% SUI with urgencies and 18% mixed incontinence. 89% of patients had no previous surgery for SUI or prolapse. Physical examination revealed visible, minimum or no urethral hypermobility in 60%, 30% and 10% of cases respectively. The MUT implantation was mainly performed utilising the transobturator route (79%) and a CPC was made in 40% of patients.

Results

Evaluation of the procedure was reported in 984 patients, stated as easy in 928 (96%) and difficult in 39 (4%) patients. Per-operative complications occurred in 44 (4.4%) patients: 1 urethral perforation, 10 bladder perforations, and 8 vaginal sulcus perforations. At discharge, 984 files were completed: an adverse event was recorded in 21 (2%) patients and pain, evaluated using a visual scale, was noted as absent, normal and important in 446 (49%), 445 (48.39%) and 13 (1.4%) patients respectively. At 3 months follow-up, among 745 evaluated patients, 601 (80.67%) were dry, 112 (15%) significantly improved and 32 (4.2%) slightly improved, same or worse. Physical examination revealed a tape extrusion in 3 (0.4%) patients. To assess prognostic factors, the population was analysed in subgroups; dry patient rates were: 82.4% in young versus 77.14% in old patients, 81.73% in no previous surgery versus 71.95% in previously operated patients, 72.29% in BMI over 30 versus 82.74% in BMI 0-29 patients, 84% in obvious urethral hypermobility patients versus 68% in patients with none, 85% in genuine SUI patients versus 66% in mixed patients, 73.52% in low closure pressure (0-30 cm H₂O) versus 82.85% in over 40 cm H₂O patients, and 82% in patients with CPC versus 79% in patients having only a MUT implantation. At 12 months follow up in 166 patients reported 148 (89%) were dry, 11 (1%) significantly improved and 7 (4%) slightly improved, same or worse. Physical examination revealed tape extrusion in 1 patient (0.6%),

Interpretation of results

Results confirm efficacy and safety of this polypropylene type I MUT at 3 and 12 months. Per operative adverse events were considered minor and of low incidence (4.4%). Few tape extrusions have been reported at 3 and 12 months (0.4% and 0.6% respectively). No statistically significant differences were found within the subgroups selected, However from these results patients may have a less successful outcome if; previously operated, with a BMI >30, with no obvious urethral hypermobility, with mixed incontinence, and with a urethral closure pressure 0-30 H₂O. This needs to be further examined with longer follow up and a larger patient cohort.

Concluding message

This study is the first international prospective analysis of efficacy and associated complications of the same M.U.T. implanted by 2 different surgical routes. Results confirm efficacy and safety of this polypropylene type I MUT at 3 and 12 months. It is planned to enter 2000 patients into this registry to further statistically compare the prognosis factors and the retropubic and the transobturator routes.

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