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PROLAPSE REPAIR BY VAGINAL ROUTE USING A NEW PROTECTED LOW-WEIGHT POLYPROPYLENE MESH: PRELIMINARY RESULTS OF A PROSPECTIVE MULTICENTRE STUDY

Hypothesis / aims of study

Recent publications have shown that the results of prolapse repair via vaginal approach could be improved when meshes are used as tissue support (1). However, non protected heavy-weight meshes are often associated to complications such as delayed healing or erosions (2). The aim of this large multicentre study was to evaluate the clinical results of an innovative low-weight polypropylene mesh protected by an absorbable hydrophilic film in the prolapse repair by vaginal route.

Study design, materials and methods

This study included a consecutive series of 174 patients surgically treated for a genital prolapse between March 2003 and March 2004 in 13 centres. The study was approved by the Local Ethical Committee. All the patients were operated via a vaginal route with a specially designed mesh: UgytexTM (Sofradim, France). Ugytex is a low-weight (38g/m²) and highly porous (average porosity: 89%, pores over 1.5mm) polypropylene monofilament mesh offering tissue ingrowth and connective differentiation for a stable and long-term support. The mesh is coated with a hydrophilic film composed of atelocollagen, polyethylene glycol and glycerol. The absorbable coating protects delicate pelvic viscera from the risk of acute inflammation during the healing's inflammatory peak. The main outcomes of this study were the rate of cured patients and the rate of complications related to the mesh. Prolapse severity was evaluated using the POP-Q system. In order to evaluate the patient's quality of life, the validated PFDI and the PFIQ questionnaires have been used preoperatively and during follow-up (3).

The present study is based on the analysis of the first 40 patients evaluated with at least 6 months follow-up. Mean age was 61.7 years old (37-83). 8 patients (20%) were treated for recurrence. 24 patients had preoperatively normal sexual activity (60%). Preoperatively, cystocele were grade II in 16 patients (44.4%), grade III in 15 (41.7%) and grade IV in 5 (13.9%). Rectocele were grade II in 11 patients (58%), grade III in 4 (21%) and grade IV in 4 (21%). Preoperatively, mean POPDI and POPIQ were 113/300 and 45/300, respectively. Anterior, posterior and anterior/posterior repair with that mesh were performed in 21, 4 and 15 patients, respectively. Vaginal hysterectomy was associated in 13 patients (32.5%).

<u>Results</u>

The mean operative time was 65 minutes (25-120). Mean hospitalisation stay was 4.1 days (1-8). At day 3 the pain measured by the patient using a visual analogic scale (range 0 to 10) was reduced to 0.78 ± 1.4 . Mean follow-up was 9 months (6-12). At 6 month follow-up, 37/40 patients were subjectively cured (92.5%) with a recurrence rate of 2/36 (5.6%) for cystocele and 1/19 (5.3%) for rectocele. Postoperatively, mean POPDI and POPIQ were significantly improved: 22/300 (p<.001) and 10/300 (p<.01), respectively. There was no postoperative infection of the mesh. There was no vaginal erosion reported in this first series of 40 patients. In the following series of 131 patients, 6 delayed healings or early mesh exposure were reported at the one-month follow up (4.5%). Only 3 of them had necessitated a simple partial excision of the mesh. One can note that 22/24 women returns to postoperative sexual activity, 3 de novo dyspareunia were reported but only one complaint with significant pain (4.5%).

Interpretation of results

Genital prolapse repair via vaginal approach is a simple and safe technique, with short hospitalisation stay and low postoperative pain. The obtained results can be favourably compared to the existing literature (1,2). Vaginal erosions rate is lower and postoperative sexual function is preserved. Longer follow-up is required to confirm these encouraging preliminary results.

<u>Concluding message</u> This new low-weight polypropylene mesh protected by a hydrophilic absorbable film for vaginal repair of genital prolapse seems to be well tolerated while maintaining low recurrence rates.

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