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1. *Hopital Cochin*

LONG TERM FUNCTIONAL OUTCOMES FOLLOWING THE PLACEMENT OF A SINGLE INCISION POLYPROPYLENE MESH (ELEVATE ™) BY VAGINAL ROUTE

Hypothesis / aims of study
Genital prolapse is a common disease for which 1 for 10 women will underwent a surgery. In case of recurrent prolapse or prolapse stage 3/4, vaginal surgery using synthetic mesh can be done. Many polypropylene meshes are used even if surgeons have not evaluated their medium or long term results. Trials, which compare native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment in medium term, found better anatomical results in case of mesh placement but similar functional results in both groups. The aim of our study was to evaluate the long term (3 years) functional outcomes of patients who underwent vaginal prolapse surgery with non-absorbable mesh, knitted polypropylene light weight Elevate ™ (American Medical Systems: AMS).

Study design, materials and methods
This is a retrospective study which included 88 patients who underwent a vaginal surgical treatment of prolapse using mesh placement for prolapse POP-Q stage II to IV between 2012 and 2013. Patients were evaluated 8 weeks after the surgery and annually, using the POP-Q classification. We considered anatomical cure to have occurred when the POP-Q stage was equal to or less than 1 and functionnal cure in the absence of symptoms related to genital prolapse. In 2016, all patients were contacted postoperatively using a postal questionnaire at three years' follow-up. The questionnaire concerned overall satisfaction functional results, postoperative complications or surgical failure over the time according patient's point of view. Different validated questionnaires including PGI-I, PFIQ-7, PDFI-20 and PISQ-12 were used. Descriptive statistics are shown as medians and IQRs (interquartile range; 25th-75th).

Results
Demographic characteristics of the 88 patients included were: age 70 years' old (65 to 74.5), BMI 25.3 kg/m^2 (22.7 to 27.6), parity 2 (2-3), and the weight of the heaviest newborn 3500 g (3200-3825). The overall POP-Q preoperative evaluation showed no prolapse stage 0 or I, 22 prolapse stage II (24.7%), 82 prolapse stage III (92.1%) and 6 prolapse stage IV (6.7%). Seventy-eight patients (78.4%) had anterior mesh placement, 9(10.2%) only a posterior mesh and 8(9%) anterior and posterior meshes. In 3 patients (3.4%) mesh repair was not performed because of peroperative complications (2 bladder injuries in contact with ureteral meatus and one hemorrhage requiring transfusion). Concomitantly, a hysterectomy was performed in thirty nine patients (44.3%) and 26 (29.5%) had a mid-urethral sling. The complications observed in perioperative period were four cases of hematoma, 8 cases of postoperative urinary infection, five cases of bladder injury, two cases of re-operation to release mid urethral sling and two early re-operation for dehiscence of the vaginal vault sutures. Of the 88 patients included, 7(7.9%) were immediately lost of the follow-up after the intervention. The median follow-up period with clinical evaluation was 4 months (1-12 months). Follow-up longer than one year was assessed for 29 (33%) patients. 50 patients had no prolapse (stage 0) (56.2%), 12 had stage I prolapse (13.5%), 15 had prolapse stage II (16.8%), 3 had prolapse stage III (3.4%), and none had prolapse stage IV. The anatomical success rate was 79.8%. In the late postoperative period, two cases of mesh erosion occurred at 2 and 6 months after the surgery (2.2%). 13 (14.7%) patients suffered from *de novo* stress urinary incontinence. At 3 years' follow-up (2.2 to 3.3), the questionnaire for the evaluation of quality of life and satisfaction of the operation was answered by 39 patients (44.3%). The PFIQ-7 score was 14.3 (4.7-47.6), the PFDI 20-score was 31.2 (13.5-80.9), the PISQ-12 score was 13 (11.5 -17.5). Using a visual analogue scale (VAS) satisfaction of patients at 3 years was 90% (77.5-100). According to the PGI-I score, 74.2% were improved or very improved by surgery. No new case of mesh erosion or re-operation for prolapse recurrence have been reported by patients.

Interpretation of results
To date, no studie have reported long term (more than 3 years) functional outcomes of patients who underwent surgery for a prolapse using a non-absorbable mesh, polypropylene light weight Elevate ™. Our anatomical results were similar to those previously reported in the litterature. In an observational study including 115 patients, Korahanis et al. [1] reported an anatomical success rate of 95% and functional rate of 72% at one year follow-up (61% of the patients were lost to follow-up). Moore et al. [2] included sixty patients who were implanted using Elevate ™ with average follow-up of 13.4 months. They reported anatomical failure rate of 8% and a rate of functional failure of 1.6%. Stanford et al. [3], in a prospective multicenter study including 112 patients implanted using Elevate ™, with one year follow-up, reported satisfactory anatomical results for the anterior and apical compartment in 87.7% and 95.9% of the case, respectively. In our study, 3 years after the surgery, functional results were similar to those reported by Korahanis et al. one year after the surgery.

Concluding message
Despite a high rate of lost of follow-up, the long term (3 years) functional results after vaginal prolapse surgery using Elevate ™ are satisfaying for ¾ of the patients.

References
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Disclosures

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