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SINGLE INCISION POSTERIOR TRANSVAGINAL MESH PROCEDURE WITHOUT CONCURRENT SURGERY – NATIONAL PROSPECTIVE MULTICENTRE STUDY

Hypothesis / aims of study

Attitudes towards transvaginal meshes in prolapse surgery have changed to more cautious since FDA announcement in 2011 [1]. However, not all patients suffering from vaginal prolapse will be helped with traditional operative techniques and alternative methods are needed. Furthermore, apical support in posterior prolapse repair has been evidenced to play crucial role in preventing reprolapse formation [2].

Elevate®Posterior is a transvaginal method in treatment of posterior vaginal prolapse using lightweight mesh with trocar free apical fixation system. The aim of this study was to investigate the safety and efficacy of this method. Secondly we wanted to evaluate the effect of this surgical method on non-affected anterior vaginal compartment. The study hypothesis is that complications are acceptable and both objective and subjective outcomes are satisfying.

Study design, materials and methods

This prospective multicentre national study included patients with symptomatic posterior vaginal wall prolapse POP-Q stage II or more. Recruitment of the patients was accomplished in four university and four central hospitals in Finland between September 2010 and August 2013. Exclusion criteria were concomitant surgery, immunosuppressive treatment of any kind, previous or forthcoming bowel operation with low anastomosis creation and previous vaginal radiation therapy.

A total of 111 patients fulfilled the inclusion criteria. Baseline and three months follow-up data was gathered from standardized and detailed interviews and gynaecological examinations. POP-Q measurements were performed. Impact of the intervention to quality of life was measured by two validated questionnaires: Pelvic Floor Dysfunction Inventory-20 (PFDI-20) and Pelvic organ prolapse/urinary Incontinence Sexual Questionnaire (PISQ-12).

The used mesh in Elevate®Posterior kit is knitted macroporous polypropylene monofilament. The mesh has low density (25.5g/m^2) and small fiber diameter (1/3000 inch). In the operative technique the mesh is attached to both sacrospinous ligaments with special self-fixating tips. Otherwise the placement of the mesh follows the normal use of transvaginal meshes.

Two definitions were used to determine objective cure: POP-Q stage ≤ I in posterior compartment and postoperative leading edge at or above the hymen. De novo formation of anterior vaginal wall prolapse was defined as stage ≥ II prolapse and postoperative leading edge beyond the hymen in anterior compartment in patients with preoperative anterior stage 0-I. Subjective cure was defined as absence of bulge symptoms.

Sample size was calculated with G*Power program. The used tests measuring the outcome scores were paired t-test, Fisher´s exact test or Mann-Whitney U-test, when appropriate.

Results

Median age was 63 years (47-87), body mass index 27 kg/m^2 (19-44), and median parity was 2 (0-12). Prior hysterectomy had been carried out in 74% of the patients. A total of 91% of the postmenopausal women used local oestrogen. Most of the preoperative posterior prolapses were stage III (70%) and preoperative leading edge at or above the hymen was observed in 88% of the patients. A total of 46% of the prolapses were recurrences.

Intraoperative and immediate postoperative complications were few and minor in character. At three months 109 patients were reached. POP-Q measurements Ap, Bp and C were significantly better at three months than in baseline. Posterior stage ≤ I prolapse was obtained in 92 (84%) patients. Posterior leading edge at or above the hymen was reached in 107 (98%) patients. De novo anterior vaginal wall prolapse stage ≥ II was seen in 14 (15%) patients while de novo anterior leading edge beyond the hymen was identified in three (3.2%) patients. Both Aa and Ba POP-Q measurements were significantly worse at three months than preoperatively in patients with preoperative anterior vaginal wall stage ≤ I. Of the 102 (92%) patients who suffered from bulge symptoms at baseline, 84 (86%) reported the symptom to be disappeared at three months.

For postoperative complications, one mesh exposure of 1 mm size was detected at the follow-up. Other complications were granulation tissue (4.6%), hematoma (2.8%), urinary tract infection (1.8%) and pain (3.7%). Both PFDI-20 and PISQ-12 scores were better at the follow-up compared to baseline.

Interpretation of results

This study shows that Elevate®Posterior method is effective when both objective and subjective cure are evaluated in three months follow-up. Our result is consistent with previously reported data on the same mesh [3]. The trend of de novo prolapse formation in untreated vaginal compartment was noticed. In hands of experienced surgeons the incidence of intraoperative and postoperative complications is rare and insertion of lightweight mesh is safe in terms of mesh extrusion rate as well. Denying concomitant hysterectomy in our study and high percentage of local oestrogen use among study patients may lower mesh

exposure rate in our study compared to other studies involving transvaginal mesh. According to our study results Elevate®Posterior method improves quality of life and sexual functions.

Concluding message

Single incision Elevate®Posterior is effective method in treatment of posterior vaginal wall prolapse. The rates of intra- and postoperative complications are low. Elevate®Posterior is a noteworthy choice when tranvaginal mesh is considered for posterior vaginal wall reconstruction. However, longer follow-up is needed to draw sustainable conclusions.

References

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