

LAPAROSCOPIC SACRAL COLPOPEXY VERSUS ANTERIOR VAGINAL MESH IN PATIENTS WITH PELVIC ORGAN PROLAPSE WITH HIGH-RISK OF RECURRENCE: A RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study

Severe anterior and apical POP are considered a risk factor for pelvic organ prolapse (POP) recurrence [1]. The aim of the study was to compare laparoscopic sacral cervico/colpopexy (LSC-CS) with anterior vaginal mesh (AVM) for the correction of anterior vaginal wall associated with apical POP (uterine or vault) in women with advanced POP stage.

Study design, materials and methods

A prospective randomised controlled trial (RCT) was designed in a tertiary university hospital from January 2011 to March 2016. The inclusion criteria were: women requiring POP surgery with primary or recurrent symptomatic POP (stage 3 or greater anterior POP with a stage 2 or greater apical POP). Given a 77% anatomic success rate for LSC-CS [2], the sample size necessary to detect a difference of 25% in anatomic success rates, having a β error of 0.2 and an α error of 0.05, was 52 patients per arm. Considering a drop-out rate of 15%, 120 patients were included in the study (60 per group). Surgical success (primary composite outcome) was defined as: 1) vaginal apex descent no more than one-third into vaginal canal or anterior or posterior vaginal wall not beyond the hymen; 2) no bothersome vaginal bulge symptoms; and 3) no retreatment for POP at 1 year. Secondary outcomes included patient satisfaction, PFDI, ICIQ-UI-SF, intraoperative variables, immediate and late postoperative morbidity, adverse effects, complications and reinterventions. Dyspareunia was evaluated by question number 11 of the *Pelvic Organ Prolapse/Incontinence Sexual Questionnaire* (PISQ-IR). Urinary, bowel and POP symptoms were evaluated with the Spanish validated version of two questionnaires: *International Consultation on Incontinence questionnaire-Short Form* (ICIQ-UI-SF) and the *Pelvic Floor Distress Inventory-20* (PFDI-20).

Results

Surgical success was achieved in 79% with LSC-CS and 76% with AVM (NS) (Table 1). No statistically significant differences were found among POP-Q anterior vaginal wall points between groups, whereas better results were obtained with LSC-CS in posterior vaginal wall points and total vaginal length. Intraoperative outcomes were similar in the two groups, except for the operating time (78.1 ± 35.0 minutes for LSC-CS and 44.3 ± 18.4 minutes for AVM group; $p < 0.001$). Anatomical correction was also analyzed, as well as subjective and objective intraoperative and postoperative outcomes incontinence and dyspareunia. Worse results were found in the CRAD-8 in the LPSC-CS group, due to constipation symptoms. Three patients (7%) explained dyspareunia de novo (% of sexually active at baseline) in the LSC-CS group, while 7 women (19%) in the AVM group (NS). Late postoperative complications and reinterventions were similar in both groups. Two reinterventions (3%) were performed in the LSC-CS group for complications of the mesh, whereas 3 (5%) in the AVM.

Table 1.-Results of surgery success at one year comparing laparoscopic sacrocolpopexy (LSC-CS) and anterior vaginal mesh (AVM) surgical techniques N(%).

	LSC-CS (n=58)*	AVM (n=58)*
Composite surgery success	46 (79%)	44 (76%)
Subjective success	57 (98%)	54 (93%)
Anatomic success	46 (79%)	44 (76%)
Apical success	57 (98%)	55 (95%)
Anterior success	50 (86%)	51 (88%)
Posterior success	56 (97%)	50 (86%)
Reintervention for POP recurrence	1 (2%)	3 (5%)

*Two patients of each group were missing due to lack of follow-up.

Interpretation of results

- 1) Anterior and apical POP correction with LSC-CS or AVM shows similar results based on questionnaires or the POP-Q system. The apical compartment can be successfully corrected vaginally, although TVL and point C are higher in the LSC-CS.
- 2) *De novo* dyspareunia was more frequent in the AVM group (NS), whereas constipation was significantly more prevalent in the LSC-CS group.
- 3) The number of complications and reinterventions in both groups were similar.

Concluding message

The surgical success rate of both LSC-CS and AVM was similar in the treatment of POP in patients with advanced stage apical and anterior compartment prolapse. A longer follow-up is compulsory in this type of study.

References

1. (1) Vergeldt TFM, Weemhoff M, IntHout J, Kluivers KB. Risk factors for pelvic organ prolapse and its recurrence: a systematic review. *Int Urogynecol J.* 2015;26:1559-1573.
2. (2) Maher CF, Feiner B, DeCuyper EM, Nichlos CJ, Hickey K V., O'Rourke P. Laparoscopic sacral colpopexy versus total vaginal mesh for vaginal vault prolapse: a randomized trial. *Am J Obstet Gynecol.* 2011;204:360.e1-360.e7.

Disclosures

Funding: Dr. Eduardo Bataller was a consultant for AMS (Astora, women's health). The Elevate® Anterior kits were donated by AMS as a grant for the study without any other support or supervision. **Clinical Trial:** Yes **Registration Number:** The study has been registered at Clinical Trials Registry.gov (NCT01097200). **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** CEIm Hospital Clinic de Barcelona **Helsinki:** Yes **Informed Consent:** Yes