

A RANDOMIZED COMPARISON OF TWO VAGINAL PROCEDURES FOR THE TREATMENT OF STAGE TWO, OR HIGHER UTERINE PROLAPSE: HYSTERECTOMY WITH MESH VERSUS ONLY MESH IMPLANTATION.

Hypothesis / aims of study

To evaluate the long term efficacy and safety of transvaginal hysterectomy and implantation of a non- restorable synthetic prosthesis (mesh) for the treatment of stage two, or higher uterine prolapse

Study design, materials and methods

Randomised controlled trial with 61 women with uterine prolapse, POP-Q system, stage 2, or higher pelvic organ prolapse, who underwent vaginal surgery between April 2004 and December 2006. They were randomized in two groups :

Group 1- transvaginal hysterectomy and pelvic reconstruction floor with mesh (n=31).

Group 2- transvaginal reconstruction with mesh. (n=30) The mean age of the patients was 58 years (range 47-70 years). Mean parity was 4 (range 1-7) and mean weight was 75 kgr (range 60-82 kgr) .

Results

Median follow-up was 5 years on both groups. The primary outcome measure is recurrence of uterine prolapse defined as: uterine descent stage 2, or more assessed by pelvic organ prolapse quantification examination and prolapse complaints and/or redo surgery at 5 years follow up. Secondary outcomes are subjective improvement in the quality of life, operation time, intraoperative blood loss , complications following surgery, hospital stay and post-operative recovery and sexual functioning.

In group one: the severe pelvic prolapse, evaluated with the POP-Q System, was completely treated in all the patients and no recurrences were observed. Sexual activities improved in all patients. We recorded three vaginal erosions and one patient complained of a postoperative dyspareunia.

In group two: 5 had recurrent prolapse (recurrence rate 15%), 1 had severe de novo stress urinary incontinence and 5 patients underwent second surgery.

No statistical difference ($P < 0,5$) was observed among the above 2 groups in terms of length of operation, amount of blood loss and length of hospital stay. In both groups there were no major complications during, or after the operation.

Interpretation of results

Hysterectomy and use of mesh is a more effective procedure than only implantation of mesh for the reconstruction of high degree uterine prolapse.

Concluding message

Hysterectomy and use of mesh is a more effective procedure than only implantation of mesh for the reconstruction of high degree uterine prolapse.

Disclosures

Funding: NO FUNDING OR GRAND **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics not Req'd:** WE HAD THE APPROVAL OF ALL THE PATIENTS **Helsinki:** Yes **Informed Consent:** Yes