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GENITAL PROLAPSE SURGICAL TREATMENT: ALWAYS HISTERECTOMY? PRELIMINARY RESULTS OF A TRIAL

Hypothesis / aims of study

To evaluate the long term efficacy and safety of hysteropexy with TFS mesh versus transvaginal hysterectomy for the treatment of stage two or higher uterine prolapse

Study design, materials and methods

Randomised controlled trial with 41 women with uterine prolapse, POP-Q stage 2 or higher pelvic organ prolapse, who underwent vaginal surgery between january 2010 and may 2012. They were randomized in two groups:

Group 1- transvaginal hysterectomy with McCall, perineal body reconstruction and vaginal anterior plastia (n=18).

Group 2- hysteropexy with TFS in cardinal and uterosacral ligaments, perineal body reconstruction and vaginal anterior plastia with TFS in tendinous arch. (n=23).

The mean age of the patients was 62 years (range 45-79 years). Mean

parity was 4 (range 0-8) and mean body mass index was 29,5 (range 20-39).

We performed pelvic floor 3 D ecographies before and 6 months after surgery. The patients answered surveys such as International Consultation on Incontinence Questionnaire - Short Form ICIQ-SF, Bladder Control Self-Assessment Questionnaire before and 12 months after surgery and a Likert scale for surgical satisfaction at 12 months.

Results

Median follow-up was 15 months on both groups (range 6-36 months). The primary outcome measure is recurrence of uterine prolapse defined as symptomatic prolapse:

uterine descent stage 2 assessed by pelvic organ prolapse quantification examination and prolapse complaints.

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 the vaginal hysterectomy group: at 12 months all patients were clinically asymptomatic but according to POP-Q classification only 6/16 patients (37,5%) have 0 score, nevertheless all patients improved their POP-Q score. Sexual activities improved in 5/8 patients (62,5%), 3/8 patients got worse and 8 patients did not have sexual activity. We recorded one rectal intrasurgery perforation that was repaired immediatelty and one vaginal stenosis at 6 months that needed surgical repair. At 12 months 15/16 patients were satisfied (93,75%): the only dissastified patient was the one with vaginal stenosis.

In the hysteropexy group: at 12 months 19 patients were clinically asymptomatic (90,4%) and 2 patients had symptomatic prolapse recurrence: one III grade hysterocel and one trachelocel that needed a vaginal hysterectomy and a trachelectomy respectively (recurrence rate 9.6%).

At 12 months 9/21 patients (42,8%) had POP-Q score 0. Sexual activities improved in 11/13 patients (84,6%),1/13 patients got worse, 1/13 patient stopped sexual activity and 8 patients did not have sexual activity. 1 patient needed vaginal TFS anchor removal due to dyspareunia. At 12 months all patients were satisfied (100 %).

In both groups all patients who needed suburethral slings for the urinary stress incontinence repairing were asymptomatic at 12 months. We did not observe any de novo urinary incontinence.

No statistical difference (P<0,05) was observed among the 2 groups above in terms of length of operation, amount of blood loss but hospital stay was statistically below in the hysteropexy group with 1,7 days as a mean against 2,5 days in the hysterectomy group. In both groups ICIQ-SF and Bladder Control Self-Assessment Questionnaire scores improved after surgery. Also hiatal area improvement was statistically significative (p<0,05) before and after surgery as much in contraction as in Valsalva in both groups.

Interpretation of results

Maybe TFS hysteropexy can be a good effective procedure to repair genital prolapse and an alternative to hysterectomy for treatment. Both together improve hiatal area.

Concluding message

We need more patients to make further conclusions and the trial is kept open. The hospital stay for TFS hysteropexy is shorter than vaginal hysterectomy.

Disclosures

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