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RANDOMIZED COMPARISON BETWEEN POSTERIOR IVS AND SACROSPINOUS FIXATION IN THE MANAGEMENT OF VAULT PROLAPSE

Aims of Study

To assess the efficacy of two different transvaginal procedures in the management of patients with cuff prolapse and associated pelvic floor defects.

Methods

Between January 2002 and March 2003, 47 patients with stage \geq II cuff prolapse (point C \geq -1) were enrolled in the study. Pre-operative evaluation included history, urine culture, physical examination, stress test and urodynamic assessment. At physical examination, pelvic floor defects were determined using the standardized system (POP-Q) of the International Continence society. Measurements were made at different vaginal sites (anterior and posterior vagina and cuff) with the patient recumbent and straining down. Patients underwent either sacrospinous fixation (n=23) or posterior IVS, infracoccygeal sacropexy, (n=24) for the treatment of their condition. Treatment assignment was given according to a computergenerated random list. Envelops containing the study assignment were prepared in advance and sequentially labeled by a third party not involved in the study.

The associated pelvic floor defects were repaired using a standardized vaginal reconstructive technique that included, anterior and posterior repair and high closure of the Douglas-pouch when indicated. All patients were informed about the trial aim and procedures and gave their informed consent.

<u>Results</u>

Study subjects had mean age 63.9 ± 10 (range 52-80) years, BMI 25 ± 1.7 , and vaginal parity 2.1 \pm 1.4 (range 67). All were postmenopausal and none was using hormone replacement therapy at the time of operation. Eighteen patients (38%) had had previous hysterectomy for correction of genital prolapse. Vaginal or abdominal hysterectomy was performed in 45% and 55% of the cases respectively. There were no significant differences between the two groups with respect to any of these parameters and no difference in the severity of pelvic floor defects. Operation was performed under spinal anesthesia in 34 women (72%), the remaining received general anesthesia. Overall the associated procedures performed at the time of operation included: anterior repair in 30 patients, posterior repair in 34 subjects and douglasectomy in 15 women. No intra-operative complications occurred in both groups, the mean time for operation was 52 ± 13 min. for posterior IVS group and 66 ± 19 min. for sacrospinous fixation group and the mean blood loss was 54 ± 32 ml and 106 ± 41 respectively. Average hospital stay was 4 and 6 days respectively (one women in the sacrospinous group recovered for 13 days for medical reason).

The median length of follow-up for the posterior IVS and sacrospinous group was 11 and 12 months respectively.

Post-operative data were analysed only for women with at least 6 months of follow-up. Thus 32 patients were considered (16 in each group). Optimal or satisfactory anatomic outcome at point C was observed in all the patients with only 2 (one for each group) having a stage I cuff prolapse. Two patients in the posterior IVS group (12%) and three in the sacrospinous one (19%) showed a stage II anterior vaginal prolapse (point Ba = -1 or 0). Two patients (one for each group) showed a stage II posterior vaginal prolapse. At three months follow-up, 3 patients in the sacrospinous group complained of right buttock pain that resolved spontaneously at 6 months while one women at this time reported severe dyspareunia. In the posterior IVS group at three months follow-up, 3 patients complained of pararectal pain with one having also incontinence to liquid feces. At six months pain resolved spontaneously in 2 patients while fecal incontinence was still present.

Conclusions

Multiple studies have shown sacrospinous ligament fixation to be highly effective therapy for vaginal vault prolapse despite the fact that the marked vaginal retroversion subsequent to the procedure may predispose to recurrent cystocele. The aim of posterior IVS is to create articial uterosacral neoligaments by inserting a prolene tape along their anatomical pathway, without altering the vaginal axis. In our study both the procedures were highly effective in restoring anatomy in the upper vaginal segment but the results in the anterior vaginal compartment were not completely satisfactory.