

RANDOMIZED COMPARISON BETWEEN INFRACOCYGEAL SACROPEXY (POSTERIOR IVS) AND SACROSPINOUS FIXATION IN THE MANAGEMENT OF VAULT PROLAPSE

Hypothesis / 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.

Study design, materials and methods

between February 2002 and December 2003, women with \geq stage II cuff prolapse (point C \geq -1), who required surgical treatment, were enrolled in the study. Pre-operative evaluation included history, urine culture and pelvic examination. At physical examination, pelvic floor defects were determined using the POP-Q system. 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 or infracoccygeal sacropexy, for the treatment of their condition. Treatment assignment was given according to a computer-generated random list. 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.

On the basis of a reported cure rate of 29% for sacrospinous ligament fixation[1] compared with a success rate of 66% for infracoccygeal sacropexy[2], 60 patients (30 in each group) were needed to achieve a power of 80% and an α level of 0.05. We assumed a dropout rate of approximately 10% and sought to enroll 66 subjects into the clinical trial.

Follow-up visits were scheduled at 3, 6, 12 and 24 months and included a detailed urogynecologic history and pelvic examination.

The primary outcome measure was rate of prolapse recurrence for each vaginal site. The secondary outcome measure was the rate of complications observed.

The Statistical Package for Social Sciences was used for data analysis. Continuous data were reported as means \pm standard deviation (SD) and analysed with Student's t test. Categorical relationships were analysed by the χ^2 test with Yates' correction or Fisher exact test, as appropriate. Probability values of < 0.05 were considered statistically significant.

Results

Overall 66 women agreed to participate and were enrolled in the trial. Study subjects had mean age 65.7 ± 8 (range 46-84) years, BMI 25 ± 2.8 , and vaginal parity 2 ± 1.1 (range 0-6). All, except one, were postmenopausal and none was using hormone replacement therapy at the time of operation. Previous hysterectomy was performed vaginally or abdominally in 52% and 48% 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 49 women (74%), the remaining received general anesthesia. Overall the associated procedures performed at the time of operation included: anterior repair in 37 patients, posterior repair in 50 subjects and douglasectomy in 26 women. No intra-operative complications occurred in both groups, the mean time for operation was 58 ± 17 min. for posterior IVS group and 69 ± 17 min. for sacrospinous fixation group and the mean blood loss was 56 ± 34 ml and 126 ± 21 ml respectively. Average hospital stay was 3 ± 1.1 days and 4 ± 1.7 respectively.

The median length of follow-up for the posterior IVS and sacrospinous group was 19 and 17 months respectively.

Optimal or satisfactory anatomic outcome at point C was observed in most of the patients with only 1 in IVS group having a stage II cuff prolapse. Eleven patients in the sacrospinous group (33%) and nine in the IVS group (27%) showed a \geq stage II anterior vaginal prolapse ($p=0.89$). Four (12%) and 6 (18%) subjects respectively had \geq stage II posterior vaginal prolapse ($p=0.80$). At three months follow-up 4 patients in the sacrospinous group complained of right

buttock pain that resolved spontaneously, one woman reported persistent severe dyspareunia. In the posterior IVS group 3 patients complained of pararectal pain with one having a pararectal abscess and one showing a vaginal vault erosion over the tape. At six months pain resolved spontaneously in 2 patients.

Interpretation of results

Overall optimal or satisfactory results in restoring vaginal anatomy were achieved in 64% and 58% ($p= 0.96$) of the patients undergoing sacrospinous fixation or posterior IVS. Both the procedures were highly effective in restoring anatomy in the upper vaginal segment.

Concluding message

Sacrospinous fixation and posterior IVS are equally effective in restoring anatomy at the upper vaginal segment

References

1. Benson JT, Lucente V, McClellan E. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: A prospective randomized study with long-term outcome evaluation. *Am J Obstet Gynecol* 1996; 175:1418-22
2. Papa Petros PE. Vault prolapse II: Restoration of dynamic vaginal supports by infracoccygeal sacropexy, an axial day-case vaginal procedure. *Int Urogynecol J* 2001; 12:296-303