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MULTICENTRE RANDOMIZED TRIAL OF PELVICOLTM IMPLANT TO PREVENT RECURRENCE OF ANTERIOR VAGINAL WALL PROLAPSE IN WOMEN UNDERGOING PRIMARY SURGERY FOR GENITAL PROLAPSE

Hypothesis / aims of study
Our aim was to evaluate the efficacy of porcine skin collagen (Pelvicol™) implant in preventing recurrent anterior vaginal wall prolapse in patients undergoing primary surgery for pelvic organ prolapse.

Study design, materials and methods
All women with anterior vaginal wall prolapse > stage II planning to undergo primary pelvic reconstructive surgery were randomly selected to undergo anterior vaginal repair with or without Pelvicol™ implant reinforcement. 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 cervix) with the patient recumbent and straining down. Treatment assignment was given according to a computer-generated random list. The sample size was determined by a power analysis that was based on 18% difference in recurrence rate that was observed between patients receiving or not a synthetic mesh for anterior repair[1]. Assuming a 2-sided hypothesis test with a 5% type I error and 80% power, we estimated that a simple size of 90 patients in each study arm was necessary to detect a 15% reduction in recurrent cystoceles when implants were used.
Follow-up visits were scheduled after 3 and 6 months and every year thereafter and included a detailed urogynecologic history and pelvic examination.
The primary outcome measure was rate of anterior vaginal prolapse recurrence. The secondary outcome measure was the rate of complications observed for each procedure. All patients were informed about the trial aim and procedures and gave their informed consent. The Statistical Package fo Social Sciences was used for data analysis. Continuos data were reported as means + standard deviation (SD) and analysed with Student's t test. Categoric relationship were analysed by the χ^2 test with Yates' correction or Fisher exact test, as appropriate. Probability values of < 0.05 were considered statiscally significant.

Results
Between March 2003 and March 2004, 163 women agreed to partecipate and were enrolled in the trial. After random assignment 79 patients underwent anterior vaginal repair with Pelvicol™ implant reinforcement and 84 without. Patients had mean age of 64 $\pm$ 10 years, BMI 25 $\pm$ 3, and parity 2.2 $\pm$ 1. All reported symptoms of genital prolapse with 34 (21%) and 62 (38%) of them also reporting stress urinary incontinence or urgency/urge incontinence. 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. Overall the associated procedures performed at the time of operation included: vaginal hysterectomy with McCall culdoplasty in all the patients and posterior repair in 85 subjects (52%). No intra-operative complications occurred in both groups and the mean blood loss was 156 $\pm$ 105 ml. Resumption of spontaneous voiding was achieved after a mean of 3 $\pm$ 3.7 days and the average hospital stay was 5 $\pm$ 3 days.
Ninty-three women (44 in the Pelvicol™ group and 49 in the other) completed at least their three months follow-up visits and were included in the analysis. The mean length of follow-up for both groups was 6.5 months.
Most of the women were satisfied of their condition with only 6 subjects reporting symptoms of pelvic organ prolapse. Symptoms of stress urinary incontinence or urgency/urge incontinence were reported by 7 and 20 women respectively. Optimal anatomic outcomes at point Ba were observed in 32 women in both group (73% vs 65% p = 0.86). There were 2 subject that did not receive the Pelvicol™ implant showing a stage II anterior vaginal prolapse.

Overall there were 6 women with posterior recurrence (3 for each group) and none with unsatisfactory results at the upper vaginal segment. No infection or rejection of the porcine graft occurred during follow-up, but two women (5%) showed a defective healing of the vaginal wound that were managed in out-patient care.

<u>Interpretation of results</u>
Preliminary data of this ongoing randomized study show that Pelvicol^{TM} implant can be easily used as reinforcement of anterior colporraphy improving anatomic outcomes in the anterior vaginal compartment. However reactions to allograft materials can be distressing in some way to the patient and physician.

<u>Concluding message</u>
Porcine skin collagen implant may improve anatomic results when added to anterior colporraphy

<u>References</u>
1. Sand PK et al. Prospective randomized trial of polyglactin 910 mesh to prevent recurrence of cystoceles and rectoceles. Am J Obstet Gynecol 2001;184:1357-64