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A PROSPECTIVE RANDOMISED TRIAL COMPARING PELVICOL® AND VICRYL® FOR CYSTOCOELE REPAIR IN THE RAZ-COLPOSUSPENSION.

Aims of study

To compare the results of the Raz cystocoele repair (4 defect repair) concerning urinary symptoms, quality of life and cystocoele recurrence using a new technique where porcine dermis (Pelvicol®) is compared to the standard technique where a Vicryl® plug is used for reduction of the cystocoele. The porcine dermis was not only used as a plug to reduce the cystocoele, but also as an overlay once the pubocervical ligaments were repaired (plug and patch).

Study design, materials and methods

79 consecutive patients presenting with a cystocoele stage 3 or 4 (ICS classification) were randomised between a Raz procedure with Pelvicol® (Bard ltd.) or Vicryl® (Johnson & Johnson). The Urogenital Distress Inventory (UDI6) and Incontinence Impact Questionnaire (IIQ7) were used before operation and at the moment of follow-up consultations. In this ongoing study, 79 patients could be evaluated now. Because of concomitant prolapse problems, 20 patients also underwent a colporaphia posterior, 44 a vaginal hysterectomy and 12 a colpopexy. Statistical analysis was done using the student T test or chi-square test.

Results

Patients were comparable for age and follow-up: mean age 67.6 in the Pelvicol® and 68.6 for the control group, mean follow-up 241 and 294 days respectively. No complications such as erosion, rejection or infection were noted in both groups.

All patients had a significant improvement in UDI and IIQ scores after their operation. The scores did not differ significantly pre- or postoperatively between both groups. 78 % had stress-incontinence preoperatively in the Pelvicol® group and 63% in the control group. After operation, this was respectively 21 and 22%. Postoperative stress-incontinence was mild and did not bother the patients in all but one case: one patient in the Pelvicol® group received a suburethral sling as a second procedure. Preoperative urgency rate was 64% in the Pelvicol® and 65% in the Vicryl® group. This significantly improved in both groups to 3 and 7% respectively ($p<0.05$). Cystocoele recurrence did not differ significantly between the groups (Vicryl® 3 patients, Pelvicol® 1 patient). However, more patients ($p<0.05$) with stage 4 cystocoele (7/36) were randomised in the Pelvicol® group than in the Vicryl® group (2/43). Moreover, the degree of recurrent cystocoeles was more important in the Vicryl® group: one stage 1, one stage 2 and one stage 3. In the Pelvicol® group only one stage 1 cystocoele relapse was found. The overall recurrence rate was 5%.

Concluding message

The use of porcine dermis (Pelvicol®) does not induce more complications compared to Vicryl® during vaginal cystocoele repair. Our results suggest a tendency towards a lower urgency rate and cystocoele recurrence in the Pelvicol® group at a mean follow-up of 8 months.