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PORCINE DERMIS XENOGRAFT AS REINFORCEMENT FOR CYSTOCOELE STAGE III REPAIR: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

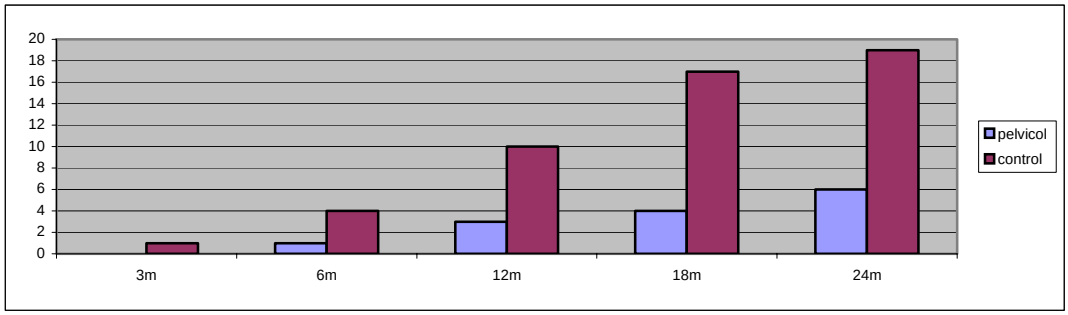
Vaginal cystocoele repair using native tissues results in a high recurrence rate. Synthetic implant materials such as Marlex or prolene meshes have shown to reduce the cystocoele recurrence rate. Biomaterials have been used as well, but only short term data are available. To evaluate the eventual advantages of biomaterials in this indication we designed a prospective randomised controlled trial comparing porcine dermis (Pelvicol ®) with polyglactin mesch (Vycril ®). The medium term results are presented (mean follow up 25 months)

Study design, materials and methods

Patients with a stage III cystocoele were enrolled after informed consent.The surgical procedure (Raz 4 defect repair) was standardized and performed by three surgeons. Patients were randomised in two groups.

In group I the cystocoele reduction was done by a plug of porcine dermis (Pelvicol) and the reapproximation of the perivesical fascia was reinforced with a porcine dermis overlay. In group II the same procedure was done with the use of a polyglactin mesh (Vycril). The pre operative assessment consisted of clinical examination with POP score, video urodynamic evaluation and two questionnaires (UDI-6 and IIQ-7). Primary outcome measure was clinical cystocoele recurrence defined as cystocoele stage II. Secondary measures were secondary prolaps, changes in UDI-6 and IIQ-7, complications and secondary surgery. Post-operative evaluation consisted of clinical examination with POP measurement and evaluation of questionnaires and registration of complications, adverse events and eventual subsequent surgery. This was done at 3, 6, 12, 18 and 24 months.

Results: In total 134 women were included between jan 2001 and December 2003. The mean follow up for group I (n=65) was 24,8 ± 5,3 months and for group II (n=69) 25,9 ± 6.4. The mean age was 70.09 (range 24-86) for group I and 69.47 (36-83) for group II. Both groups were matched. In group I 38 patients underwent a concomitant vaginal hysterectomy, 10 had a rectocoele repair and 17 had no concomitant surgery. In group II 41 had a vaginal hysterectomy, 13 had a rectocoele repair. The cumulative recurrence rate at 24 months in group I was 6 on 63 evaluable patients (9.5%) and 19 on 62 (30,6%). T-test p value 0.002.



Secondary repair of the recurred cystocoele was done in 3 patients in group I (4.7%) and in 9 (14.5%) in group II. There were no differences in peri-operative complication rate, nor in secondary prolapse rates of the mid or posterior compartments. UDI-6 and IIQ-7 showed an advantage for group I, without reaching statistical significance.

Interpretation of results

The use of porcine dermis (Pelvicol ®) results in a significant decrease of cystocoele recurrence in stage III cystocoele repair using the Raz 4-defect repair at 2 years follow up, compared to polyglactin mesh. It did not show any increase in complication rate.

Concluding message

Porcine dermis (Pelvicol ®) is useful and safe as reinforcing material in high grade cystocoele repair.