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RECTOCELE REPAIR USING BIOMATERIAL IMPLANTS –ANATOMIC OUTCOME ASSOCIATED WITH IMPROVEMENT OF OBSTRUCTIVE DEFECATION, FECAL INCONTINENCE AND VAGINAL DISCOMFORT: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

The last years has seen a new understanding and significant advances in the surgical treatment of rectocele and specific symptoms caused by rectocele like obstructed defecation, fecal incontinence and vaginal discomfort (symptomatic feeling of prolapse).Traditionally, rectocele has been treated with posterior colporraphy, which consists of midline plication of the rectovaginal fascia and the levator ani muscle, but this operation has been recognized as a cause of postoperative vaginal stenosis, dyspareunia and early recurrence. The aim of this study was to assess the safety and efficacy of posterior defect repair using biomaterial implants in patients with obstructed defecation, fecal incontinence or vaginal discomfort caused by rectocele.To evaluate the eventual advantages of two different biomaterials in this indication we designed a prospective randomized controlled trial comparing porcine dermis (Pelvicol™) with solvent-dehydrated human fascia lata (Tutoplast®). The short term results are presented (mean follow up 26,4 weeks).

Study design, materials and methods

Twenty-two consecutive women (mean age 57,8 years) with symptomatic rectocele of stage II and III were enrolled in a prospective, randomized study between July 2003 and September 2004. Patients were assessed preoperatively and postoperatively by clinical examination with pelvic organ prolapse quantification score (POP-Q) (1). Subjective assessment of bowel and vaginal function was made using standard questionnaires. The surgical procedure (2) was standardized and performed by one surgeon. Additional vaginal/abdominal repairs were made as necessary. Patients were randomized in two groups. In group I (n=12) the posterior defect repair was done by using a 4x7 cm piece of porcine dermis (Pelvicol™). In group II (n=10) the same procedure was done with the use of a 4x7cm piece of dehydrated human fascia lata (Tutoplast®). The patients were evaluated 6 months after surgery for anatomic improvement in the grade of their rectocele using POP-Q score and for functional improvement in their bowel and vaginal symptoms using standardized questionnaires. Objective cure was defined as POP-Q stage 0 or I, subjective cure was defined as no symptoms of evacuation disorder, fecal incontinence or vaginal discomfort.

Results

In total 22 women (mean age 57,8 years) were included between July 2003 and September 2004, the mean follow up 26,4 weeks.

In group I (n=12) (Pelvicol™) 10 patients underwent concomitant surgical procedures, 2 patients had no concomitant pelvic floor surgery. In this group 8 patients had preoperatively rectocele POP-Q stage II, 4 patients POP-Q stage III, postoperatively 9 patients POP-Q stage 0, 3 patients POP-Q stage I. These results showed a significant anatomic improvement (p=0,002) in group I, the anatomic cure rate was 100%

In group II (n=10) (Tutoplast®) 9 patients underwent concomitant surgery. In this group 6 patients had preoperatively rectocele POP-Q stage II, 4 patients POP-Q stage III, postoperatively 7 patients POP-Q stage O, 1 patient POP-Q stage I and 2 patients POP-Q stage II. In group II the results also showed statistical significance in anatomic improvement of rectocele (p=0,012), the anatomic cure rate was 80%.

Table 1 Objective results

	preoperatively n=12 Pelvicol™	postoperatively n=12 Pelvicol™	preoperatively n=10 Tutoplast®	postoperatively n=10 Tutoplast®
Stage 0	-	9	-	7
Stage I	-	3	-	1
Stage II	8	-	6	2
Stage III	4	-	4	-

In group I (n=12) preoperatively 11 patients complain of obstructive defecation symptoms, 4 patients complain of fecal incontinence, postoperatively 9 patients were cured of evacuation difficulties and no patient had fecal incontinence symptoms.
In group II (n=10) preoperatively 8 patients complain of obstructive defecation symptoms, 8 patients complain of fecal incontinence, postoperatively 7 patients were cured of evacuation disorder and 1 patient still indicated fecal incontinence.
In group I (n=12) preoperatively 9 patients, in group II (n=10) 8 patients complain of vaginal discomfort (symptomatic feeling of prolapse). Postoperatively in group I (n=12) 8 patients were cured and in group II (n=10) also 8 patients were cured of vaginal discomfort.

Table 2 Subjective results

	Functional improvement Group I, n=12, Pelvicol™	Functional improvement Group II, n=10, Tutoplast®
Obstructive defecation preop	11	8
Cured postop.	9	7
Not cured	1	1
Fecal incontinence preop.	4	8
Cured postop.	4	7
Not cured	0	1
Vaginal discomfort preop.	9	8
Cured postop.	8	8
Not cured	1	0

The comparison of anatomic and subjective results between group I (Pelvicol™) and group II (Tutoplast®) showed no significant difference in short term follow up. No perioperative or postoperative complications were seen.

Interpretation of results

Rectocele repair using porcine dermis (Pelvicol™) or solvent-dehydrated fascia lata (Tutoplast®) is a safe and effective procedure to correct the anatomical defect significantly associated with high cure rates of obstructive defecation symptoms, fecal incontinence and vaginal discomfort, with a low incidence of postoperative complications.

Concluding message

The short term results of this prospective study suggest that rectocele repair using biomaterial implants is a efficient surgical procedure for the treatment of bowel and vaginal symptoms caused by posterior vaginal wall prolapse. Long term follow up is needed to evaluate whether these results are durable.

References:

1.The standardization of terminology of female pelvic organ prolapse and pelvic floor dysfunction. Am J Obstet Gynaecol 175:10-17, 1996
2. Dermal graft-augmented rectocele repair. Int Urogynecol J 14:146-149, 2003