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OUTCOME (POP-Q) OF PELVIC ORGAN PROLAPSE WITH PROLIFT® PROSTHESIS VS COLLAGEN PROSTHESIS (PELVICOL®) VS CLASSICAL ANTERIOR AND/OR POSTERIOR COLPORAPHY- PROSPECTIVE STUDY

Hypothesis / aims of study

To evaluate the outcome of pelvic organ prolapse (POP) repair with Prolift® prosthesis and compare the results with collagen prosthesis (Pelvicol®) and classical colporaphy.

Study design, materials and methods

We included in a prospective study, between June 2004 and December 2005, 29 patients undergoing surgery due to pelvic prolapse with transvaginal mesh (Prolift®) technique, (Group A) and 39 women (Group B) submmited to anterior repair with collagen porcine prosthesis (Pelvicol®). As control (Group C) we used 52 patients with hysterectomy and anterior and/or posterior classical colporaphy. POP-Q classification was applied for clinical evaluation before surgery and at 3 months post surgery in groups A and B. Group C was evaluated at least one year post surgery. We consider cured if the women don't had a prolapse grade II or higher (POP-Q), relapse if we had a Aa point lower than -1, and a de novo prolapse if we had any alteration in a compartment not operated before.

Results

In group A, 6 of the 29 women had a hysterectomy in the past. In 13 of 29 women we did not perform hysterectomy. In the group B, all the patients have a concomitant vaginal hysterectomy. The anatomical results are summarized in table

Table 1		Aa	Ва	С	VH	РВ	TVL	Ар	Вр
Α	Mean	-2,2	-2,4	-5,8	4,8	3,0	6,4	-2,1	-2,4
n=26	Std	1,0	1,1	2,5	0,8	0,4	3,7	0,9	1,3
В	Mean	-2,3	-3,0	-6,4	4,7	2,8	6,5	-1,2	-1,8
n=39	Std	0,9	0,8	1,4	0,9	0,7	2,6	1,3	1,7
С	Mean	-1,0	-0,9	-4,8	4,6	3,1	6,0	-1,5	-1,4
n=52	Std	1,4	1,7	2,3	0,7	0,9	2,0	1,3	1,7

The rates of cure, relapse or de novo prolapse for each group are summarized in table 2:

Table 2	Relapse %	<i>De novo</i> prolapse %	Cure %
Group A	14,3	7,1	78,6
Group B	42,2	15,6	42,2
Group C	65,4	25,0	9,6

Interpretation of results

The early anatomical outcome is better when we use prosthesis in the primary repair of the prolapse. The study show, with very rigid criteria, a high rate of relapse in the colporaphy group. The use of synthetic (polypropylene) mesh had a better anatomical result than the collagen prosthesis, but in this work we did not evaluate the functional outcome and the number of cases could not evaluate the late complications

Concluding message

We advocate the use of mesh's in the primary approach of the repair of anterior compartment prolapse if the risk or erosion or infection is not important. Further study's are needed for evaluate functional and long-term results of this techniques

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CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical

trials registry.

HUMAN SUBJECTS: This study did not need ethical approval because submitted to the university ethics committee; Integrated in a Ph D thesis but followed the Declaration of Helsinki Informed consent was obtained from the patients.