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THE OPTIMAL ANTERIOR REPAIR STUDY (OARS): A TRIPLE ARM RANDOMIZED DOUBLE BLINDED CLINICAL TRIAL OF STANDARD COLPORRHAPHY, PORCINE DERMIS OR POLYPROLYLENE MESH AUGMENTED ANTERIOR VAGINAL WALL REPAIR.

Hypothesis / aims of study

The high rate of recurrence after anterior vaginal wall prolapse repair is well described in the literature.[1] Growing evidence suggests that the use of graft reinforced repairs may result in higher cure rates.[2&3] However, the optimal graft material (xenograft versus synthetic) remains unclear. The objective of this study was to compare cure rates of traditional anterior colporrhaphy to graft augmented vaginal paravaginal repairs using porcine dermis or polypropylene mesh in a randomized double blinded clinical trial.

Study design, materials and methods

Institutional Review Board approval was obtained for this randomized, double blind clinical trial of 99 women ≥ 18 years of age with at least stage 2 anterior vaginal wall prolapse (as measured by POP-Q point Ba ≥ -1). The study was performed at two clinical sites by 1 of 4 fellowship trained urogynecologists between July 2006 and September 2008. Subjects were randomly assigned to one of three treatment arms: 1) Standard anterior colporrhaphy (AC) using midline plication with delayed absorbable suture. 2). Vaginal paravaginal repair using free hand formed porcine dermis graft (Pelvicol TM) (P) 3). Vaginal paravaginal repair using free formed polypropylene mesh (M). All graft material was secured to the arcus tendineus fascia pelvis using a Capio ™ device with permanent monofilament suture. Concomitant procedures including hysterectomy, colpopexy, posterior colporrhaphy and incontinence operations were performed at the surgeon's discretion.

Baseline characteristics were obtained including demographics, medical and surgical history, physical examination measures (including POP-Q measures) [4], and validated quality of life instruments. Outcomes were assessed at 6 weeks as well as at 6, 12 and 24 months, post-operatively. The primary outcome was anatomic success; defined as anterior vaginal wall prolapse of stage 1 or less with a minimum of 1 year follow up. Failure could occur at anytime and was defined by a point Ba ≥ -1 with or without re-operation. Symptomatic recurrence was defined as subjective complaint of "bulge or pressure" *and* the presence of stage 2 anterior prolapse. Secondary outcomes included impact on quality of life and degree of bother as measured using the PFIQ and PFDI. Sexual function was also assessed using PSIQ, Complications including peri-operative infection, blood loss, urinary retention as well as long term complications of graft erosion and re-operation were recorded. Power calculations were based on previously published data of anatomic cure rates of 50 and 85% respectively between AC and M assuming a two-tailed hypothesis test with 5% type I error and 80% power. 33 patients would be needed to detect at least a 35% difference in recurrent stage 2 or greater prolapse.

Proportion of subjects with anatomic success was compared across groups using chi-squared statistics. Median QOL scores were compared using Mann Whitney U test. T-tests were used for continuous variables and chi-square or fisher exact tests were used for categorical factors to analyze demographics and baseline characteristics.

Results

Thirty-two women were randomized to anterior colporrhaphy, 36 to polypropylene mesh and 31 to porcine dermal graft. There was no difference between groups between groups in terms of clinical history and demographic data. A total of 78 women had completed a minimum 1 year follow up at the time of these analyses. The mean follow-up period for these women was 20 months +/-6 months. In these subjects, the cure rate was 53.8%, 62.5% and 89.3% in the anterior colporrhaphy, porcine dermis graft and polypropylene mesh groups, respectively. (Table 1) All groups had a reduction in their prolapse and urinary symptom severity and degree of bother without significant differences between groups. The symptomatic recurrence rate of anterior wall prolapse was 7% overall; with 3 in the colporrhaphy (11.5%), 3 in porcine dermis (12.5%) group and 1 (3.6%) in the synthetic mesh group. There was no significant difference in the quality of life scores.(Table 1). Graft erosion rates in the mesh group were 14% compared to 4% in the porcine group, only one of which required excision. There was no difference in estimated blood loss or post-operative hematocrit. No deaths or serious adverse events occurred. The two patients who elected to undergo re-operation for recurrent anterior wall prolapse were in the porcine dermis group.

	Colporrhaphy N = 26 Median (range)	**Porcine** N = 24 Median (range)	**Mesh** N = 28 Median (range)	**Colporrhaphy and Porcine** P value	**Colporrhaphy And Mesh** P value	**Mesh and Porcine** P value
Cure	14 (53.8%)	15 (62.5%)	25 (89.3%)	0.53	0.004	0.022
Delta POPDI	-33 (-79 to 8)	-46 (-100 to 8)	-33 (-100 to -8)	0.061	0.788	0.138
Delta UDI	-25 (-90 to 13)	-38 (-100 to 46)	-21 (-92 to 13)	0.924	0.903	0.813
Delta POPIQ	-14 (-76 to 0)	-33 (-95 to 3)	-29 (-100 to 0)	0.064	0.447	0.320
Delta UIQ	-21 (-81 to 10)	-33.3 (-91 to 38)	-14 (-100 to 0)	0.129	0.932	0.347
Delta PSIQ	-0 (-32 to 20)	-5 (-24 to 11)	0 (-28 to 14)	0.401	0.397	0.124

Mann Whitney U test used to calculate p-values.

Interpretation of results

In this preliminary analysis of women randomized to 3 different approaches to anterior prolapse repair, it appears that mesh is superior to both traditional and porcine grafted approaches. Although, a slightly higher success rate was seen in the porcine group compared to the standard repair, this difference was not statistically significant, likely due to the fact that the study was not powered to assess this relationship.

Concluding message

Anterior repair with mesh augmentation offers higher cure rates than colporrhaphy alone.

References

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Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**