687

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ANTERIOR COMPARTMENT PROLAPSE: SHORT TERM RESULTS AND QUALITY OF LIFE IN WOMEN RANDOMISED TO MESH OR TRADITIONAL REPAIR

Hypothesis / aims of study

The primary aim was to determine the rate of surgical failure to correct anterior compartment vaginal prolapse using either traditional repair or repair with vaginal mesh. The secondary aim was to evaluate pre- and post-operative Quality of Life (QoL) using a validated questionnaire.

Study design, materials and methods

Women presenting with anterior compartment prolapse of at least POPQ stage 2 were eligible. Block randomisation to anterior mesh (Prolift, Johnson & Johnson) or traditional anterior repair by midline plication was undertaken for each hospital. The randomisation code was broken preoperatively to allow procurement of mesh where required and to ensure a gynaecologist competent in the mesh technique was available. The booking gynaecologist undertook preoperative POPQ staging, (1) procedures were performed in accordance with hospital rostering requirements (the operator could be someone else) and where possible a gynaecologist or gynaecology registrar other than the operator undertook postoperative POPQ evaluation. The PQOL questionnaire (2) was used to evaluate QoL pre- and post-operatively. Additional procedures for middle and/or posterior compartment prolapse and/or for urinary incontinence were determined at booking at the discretion of the gynaecologist. Analysis was by intention to treat.

Surgical failure was defined as a post-operative POPQ stage of 2 or more for the anterior compartment. A power calculation estimated 132 procedures were required for an 80% chance of detecting a 20% difference in the rate of surgical failure (Sigma Stat 2.03). Statistical analysis was by the unpaired t-test or Kruskall Wallis test with Dunns' post hoc comparison (Graph Pad Prism for Mac OS X) unless otherwise specified.

All participants gave informed consent.

Results

Forty-six women enrolled in the trial, of which two withdrew after randomisation before surgery and three are yet to have operations. Data up to the 6-month postoperative follow up visit are presented for 35 women (19 mesh, 16 traditional) with six lost to follow up (3 in each group). Previous surgery included: hysterectomy (9 mesh, 4 traditional), anterior compartment procedures (2 mesh, 4 traditional), middle and posterior compartment procedures (1 mesh and 5 traditional). Women in the mesh group were younger (mean, SD 57,14 vs 67, 7 – $p < 0.01$). There were no differences in parity, weight, smoking history, duration of surgery or hospital stay, or change in Hb concentration pre- to postoperatively.

Table 1: Additional Surgical Procedures (n):

	Vaginal hysterectomy	Sacrospinous colpopexy	Posterior repair	Midurethral sling
Mesh	3	2	13	4
Traditional	10	1	11	2

One woman randomised to mesh had only a TVT procedure and no repair, otherwise the allocation was correctly followed. There was no difference in preoperative baseline POPQ staging for anterior, middle or posterior compartments (Table 2, $p > 0.17$) nor for QoL domains (Table 3, $p > 0.4$). Both groups showed significant improvements postoperatively in POPQ staging of the anterior and middle compartments ($p < 0.0001$) with no difference between groups and no difference observed in the posterior compartment pre- and postoperatively. Surgical failure occurred in 9/19 mesh and 7/16 traditional cases (p=1, Fisher's exact test). Allocation of non-attendees to surgical failure did not materially alter this comparison. There was no difference between groups in baseline or postoperative PQOL domains ($p > 0.4$) but there was substantial and equivalent improvement in QoL observed in both groups for 7 of the 8 domains (Table 3, $p < 0.006$). The domain General Health showed no change (Table 3, $p > 0.38$). There was no correlation between surgical success or failure and postoperative QoL parameters (Spearman correlation – data not shown). There were no immediate surgical complications. Two women in the mesh group required excision of segments of mesh that had eroded per vaginum, one woman in the traditional group has been reoperated for a posterior compartment recurrence, and one woman in the mesh group required a TVT to manage severe postoperative stress urinary incontinence.

Table 2. Pre- and post-operative POPQ staging of prolapse by compartment (n). Patients randomised to anterior mesh or traditional anterior vaginal repair with additional procedures at the discretion of the surgeon.

Stage of prolapse	Anterior		Middle		Posterior	
	Mesh	Traditional	Mesh	Traditional	Mesh	Traditional
Stage 0: pre-op	0	0	7	6	7	4
post-op	4	6	13	11	8	8
Stage 1: pre-op	0	0	5	2	3	5
post-op	6	3	6	4	4	4
Stage 2: pre-op	8	11	7	6	9	7
post-op	9	7	0	1	7	3

Stage 3: pre-op post-op	11 0	5 0	0 0	1 0	0 0	0 1
Stage 4: pre-op post-op	0 0	0 0	0 0	1 0	0 0	0 0

Table 3. The median (interquartile range) values for the PQOL domains.

Domain	Mesh		Traditional	
	Preoperative	Postoperative	Preoperative	Postoperative
General Health	25 (0-25)	25 (0-25)	25 (25-50)	25 (0-25)
Life Affect	67 (33-100)	33 (0-33)	67 (58-100)	0 (0-33)
Role Limitations	32 (16-66)	0 (0-0)	32 (0-70)	0 (0-0)
Physical and Social Limitations	23 (7-51)	0 (0-0)	20 (7-56)	0 (0-0)
Personal Relations	25 (0-71)	0 (0-12)	67 (50-100)	0 (0-33)
Emotions	33 (19-69)	0 (0-11)	55 (11-69)	0 (0-0)
Sleep and Energy	33 (16-70)	16 (0-32)	33 (16-66)	16 (16-33)
Severity Measures	25 (17-44)	0 (0-8)	28 (8-50)	0 (0-8)

Interpretation of results

We found no difference in short-term outcome for either surgical failure or QoL. Surgical failure occurred in an almost identical 43% and 47%. Surgical failure was not predictive of QoL, which showed considerable improvement regardless of the postoperative POPQ stage or the type of procedure employed.

Concluding message

In the short term mesh is not superior to traditional repair for unselected women presenting with anterior compartment prolapse. Long-term data are needed. POPQ stage 2 does not appear to be a satisfactory definition of surgical failure.

References

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Is this study registered in a public clinical trials registry?	**No**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of the Central Northern Adelaide Health Service**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**