Systematic review of the efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse

Jia X, Glazener C, Mowatt G, MacLennan G, Fraser C, Burr J

CRD summary
This review concluded that there was insufficient evidence to allow meaningful conclusions to be drawn on the efficacy of mesh or grafts in surgery for prolapse of the posterior or anterior vaginal wall. This was an appropriate conclusion for the limited evidence assessed.

Authors' objectives
To assess the efficacy and safety of mesh or grafts in surgery for anterior or posterior vaginal wall prolapse.

Searching
The search was for studies published in English from 1980 onwards. The databases searched were MEDLINE, EMBASE, BIOSIS Previews, Science Citation Index, Cochrane Central Register of Controlled Trials (CENTRAL), and Conference Proceedings Citation Index. NRR, Current Controlled Trials, and ClinicalTrials.gov, the Cochrane Database of Systematic Reviews, DARE, and the HITA database were searched. Conference proceedings of at least six relevant organisations were searched from 2005. Searches took place between April and July 2007; full details of the search strategies were available from the authors.

Study selection
Randomised controlled trials (RCTs), non-randomised comparative studies, case series with at least 50 patients, and registry reports were eligible for inclusion. Case series and registries with a follow-up of less than one year were only included in the assessment of safety. Studies had to assess the use of mesh or grafts in women undergoing anterior or posterior vaginal wall prolapse surgery. There were no restrictions on the type of mesh or graft. Studies of women having other concomitant surgery were eligible for inclusion provided that prolapse was the primary indication for surgery. Studies of women with prolapse resulting from pelvic trauma or congenital disease, or following the creation of a new vagina were excluded.

The primary outcomes were persistent prolapse symptoms (subjective failure), and recurrent prolapse at the original site (objective failure). Secondary efficacy outcomes were a new prolapse at another site, need for further prolapse surgery, persistent urinary symptoms, bowel symptoms or dyspareunia in women reporting these symptoms at baseline, operation time, and disease-specific quality of life. Safety outcomes comprised blood loss, damage to other organs during surgery, mesh or graft erosion, mesh or graft erosion necessitating further surgery, new urinary or bowel symptoms or dyspareunia and infection, and other potentially serious adverse effects.

Included studies used comparators of no mesh or graft or compared different types of mesh or graft. One reviewer assessed all studies for inclusion and a second reviewer was consulted in cases of uncertainty.

Assessment of study quality
Two reviewers independently assessed the validity of the RCTs; the studies with other designs were assessed by one reviewer. Published checklists that were appropriate for the study design were used. Studies reported as abstracts only were not assessed for validity.

Data extraction
Data to permit the calculation of relative risks, odds ratios, or mean differences, with their 95% confidence intervals, were extracted for the three subgroups of women undergoing the repair of the anterior wall, the posterior wall, or both, which included those patients where the data were not reported separately. Where reported, the loss to follow-up was collected. Two reviewers independently extracted the data from the RCTs; one reviewer extracted the data from studies of other designs.
Methods of synthesis
Meta-analysis was used to compare the efficacy and safety of mesh or graft versus no mesh nor graft, and to compare the different types of mesh or graft used. The crude event rates, with 95% confidence intervals, were calculated for all outcomes for each intervention category and by study design. A Bayesian binomial random-effects model was used to model the objective failure rates for repair of the anterior wall, which was the only outcome with sufficient data for such a model. Odds ratios with 95% credible intervals were calculated for the differences between interventions, adjusted for the study design. Indirect comparisons, adjusted for study design, of the different mesh graft types were modelled for this outcome. Statistical heterogeneity was assessed using the $\chi^2$ and $I^2$ statistics.

Results of the review
Forty-nine studies were included in the review; 17 were RCTs, seven were non-randomised controlled studies, 24 were case series, and one was a prospective registry. The quality of the six full-text RCTs was generally high, with adequate allocation concealment in four, and intention-to-treat analyses and follow-up of at least one year in all trials. The drop-out rates ranged from none to 30%.

Anterior prolapse: There was short-term evidence that any type of mesh or graft produced a statistically significant reduction in the objective prolapse recurrence rate compared with no mesh nor graft (RR 0.48, 95% CI 0.32 to 0.72, 10 RCTs). Non absorbable synthetic mesh had a statistically significant lower objective prolapse recurrence, but a higher erosion rate than either absorbable synthetic mesh or biological grafts. This finding was supported by the Bayesian analysis of objective failure. There was no statistically significant difference in subjective persistent prolapse symptoms between repair with an absorbable biological graft and repair without (two RCTs).

There was insufficient data to compare the other outcomes for any type of prolapse and for posterior prolapse.

Authors’ conclusions
The evidence for most outcomes was too sparse to permit meaningful conclusions. Rigorous long-term RCTs were required to determine the efficacy of using mesh or grafts.

CRD commentary
The review question and the inclusion criteria were clear. The authors searched a number of databases and other relevant sources, but the decision to limit the review to studies published in English might have introduced publication or language bias and relevant studies might have been missed. The authors reported using measures to reduce reviewer bias and error at each stage of the review process, but not for all studies. The assessment of validity appears to have had relevant criteria. The meta-analysis was reasonable and the authors’ conclusions were appropriately cautious given the limited evidence.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that rigorously designed and appropriately powered long-term RCTs were needed to assess the efficacy of mesh or grafts, and to compare different types of mesh or graft in surgery for prolapse of the posterior or anterior vaginal wall. These trials should have validated patient-reported outcomes and assess the cost-effectiveness, with at least five years of follow-up.

Funding
National Institute for Health and Clinical Excellence (NICE); and the Chief Scientist Office of the Scottish Government Health Directorates.

Bibliographic details