A systematic review on the use of prophylactic mesh during primary stoma formation to prevent parastomal hernia formation

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**CRD summary**
The authors concluded that despite certain methodological flaws and small patient populations, studies of the use of a prophylactic mesh at the primary operation appeared to show a reduction in the incidence of parastomal hernia. The authors' conclusions were appropriately cautious and appear likely to be reliable.

**Authors' objectives**
To assess the efficacy of prophylactic mesh at primary operation in reducing incidence of parastomal hernia.

**Searching**
MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) were searched between January 1980 and January 2010 without language restrictions; some search terms were reported. Bibliographies of retrieved papers were searched.

**Study selection**
Randomised controlled trials (RCTs) that compared prophylactic mesh to no mesh at primary stoma formation were eligible for inclusion.

The included studies used either a biological or composite mesh. The mesh was placed in a sublay position in two trials and in the retromuscular plane in one trial. Two trials recruited only patients who underwent permanent end colostomy primarily for rectal cancer or faecal incontinence; one trial recruited only patients having a temporary loop ileostomy. Mean ages ranged from 42.6 to 71 years. Mean body mass index ranged from 25.6 to 27.3kg/m². Two trials used clinical and radiological follow-up to detect parastomal hernia and the other studies used clinical follow-up only.

Titles and abstracts were screened by one reviewer. Two reviewers independently screened the full papers. Disagreements were resolved by discussion.

**Assessment of study quality**
Study quality was assessed using a validated Delphi list. Studies were given a score out of nine: a yes response scored one; no or don't know scored zero. Seven criteria were presented in a study quality results graph; the review authors did not describe how a score of 9 was obtained.

One reviewer performed the assessments and the results were checked by a second reviewer.

**Data extraction**
Data were extracted to calculate a risk ratio (RR) with a 95% confidence interval (CI).

One reviewer extracted data which were checked by a second reviewer.

**Methods of synthesis**
A meta-analysis was performed to calculate a pooled risk ratio with a 95% confidence interval. The authors stated they used a random-effects model but the forest plot indicated that a fixed-effect model was used. Heterogeneity was assessed using the $I^2$ statistic.

**Results of the review**
Three RCTs were included (128 participants, range 20 to 54). All trials were described as being of good quality (Delphi scores of 7). The authors reported that the groups appeared similar at baseline, that all studies made use of consecutive sealed envelopes and that all used an intention-to-treat analysis. None of the studies clearly described blinding techniques and timing of randomisation. Follow-up ranged from 12 to 83 months.
Fewer patients in the mesh group developed a parastomal hernia compared with the control group and the difference was statistically significant (RR 0.25, 95% CI 0.13 to 0.48; three RCTs; I²=36%).

Authors' conclusions
Despite certain methodological flaws and a small patient population, this meta-analysis was the best available evidence to demonstrate that use of a prophylactic mesh at the primary operation reduced the incidence of parastomal hernia.

CRD commentary
The review addressed a clear question supported by reproducible eligibility criteria (although no population criteria were reported). Relevant studies were found by searching electronic databases without language restrictions; it was unclear whether unpublished studies were sought. Suitable methods were employed to reduce the risks of reviewer error and bias during data extraction and assessment of study quality; only one reviewer selected titles and abstracts during study screening so the possibility of reviewer error and bias at this stage of the review could not be ruled out. Study quality was assessed and the assessment was used in interpreting the results of the review. Sufficient study details were provided and appropriate methods were used to pool data and assess heterogeneity.

The authors noted the possible limitations of the included trials and appropriately incorporated them into their conclusions, which appear likely to be reliable.

Implications of the review for practice and research
Practice: The authors stated that confirmatory studies were needed before prophylactic mesh could be recommended routinely.

Research: The authors stated a need for a large randomised double-blind trial with long-term follow-up to confirm their results. They added that any future study should try to address the optimal type of mesh and the best anatomical location for its placement.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.