Meta-analysis of randomized controlled trials comparing open and laparoscopic ventral and incisional hernia repair with mesh

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CRD summary
This review compared open and laparoscopic ventral and incisional hernia repair with mesh. It concluded that laparoscopic repair was at least as effective, if not superior to, the open approach for a number of outcomes. The authors' conclusions are undermined by the poor quality and small sample sizes of the included trials, and should be interpreted with caution.

Authors' objectives
To compare the safety and effectiveness of open and laparoscopic ventral and incisional hernia repair with mesh.

Searching
MEDLINE, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for studies published between 1950 and January 2009. Search terms were reported. Reference lists of the included studies and previous systematic reviews were handsearched for additional studies. Abstracts of relevant meetings were also searched and an expert in the field contacted. Only studies reported in English were included.

Study selection
Randomised controlled trials (RCTs) that compared laparoscopic and open incisional or ventral hernia repair with mesh, and that included data on effectiveness and safety, were eligible for inclusion. There was no restriction on type of mesh, mesh placement and fixation technique used in eligible studies. Trials where the operative approach for hernia defects, including incisional, umbilical and spigelian hernia, were included provided that repair of the hernia defect was undertaken with a mesh prosthesis; those comparing treatment for patients undergoing surgery for inguinal hernia repair, and trials that did not use mesh a prosthesis, were excluded.

The primary outcome was hernia recurrence. Additional outcomes included effectiveness (duration of surgery, length of hospital stay and time to return to work) and safety (seroma formation, bleeding complications, bowel injury, wound infection not requiring mesh removal, and mesh infection requiring mesh removal).

In included trials, the mean size of the hernia ranged from 23.2 to 141.2cm². Hernia and operative characteristics from included trials were available in an online appendix.

Two reviewers independently screened citations for inclusion in the review; disagreements were resolved by consensus with a third reviewer.

Assessment of study quality
The authors used the US Preventive Services Task Force quality criteria to assess trial quality. Criteria included: method of randomisation; allocation concealment; blinding of patients/outcome assessors; similarity of patient characteristics at the start of the trial; outcomes defined a priori; calculation of sample size performed; achieved at least 80% follow-up; and used intention-to-treat-analyses. Based on these criteria, trials were classified as good, fair or poor quality.

It appeared that two authors performed the study quality assessment.

Data extraction
Two reviewers independently extracted relative risk (RRs) and their associated 95% confidence intervals (CIs) for dichotomous outcomes of interest, with the mean or median extracted for continuous variables. Disagreements were resolved through consensus with a third reviewer.
Methods of synthesis

Pooled relative risks and their 95% confidence intervals were calculated using a random-effects model. Heterogeneity was assessed using the $X^2$, $\tau^2$ and $I^2$ statistics.

Results of the review

Eight RCTS were included in the review (n=526 patients, treatment group size ranged from 11 to 85). Trial quality ranged from poor to fair. All trials reported the use of random allocation. None of the trials reported blinding the outcome assessors. Three trials undertook allocation concealment. Six trials described the method of randomisation. Six trials described results for all randomised patients. Two trials described loss to follow-up. One trial defined all trial outcomes a priori. Duration of follow-up ranged from six to 40.8 months.

There was no significant difference between the groups for hernia recurrence rates (RR 1.02, 95% CI 0.41 to 2.54; eight RCTs). The risk of wound infection not requiring mesh removal was significantly lower in patients undergoing laparoscopic repair (RR 0.22, 95% CI: 0.09 to 0.54; eight RCTs); there was a non-significant trend toward fewer haemorrhagic complications and infections requiring mesh removal for this procedure. Six of eight RCTs reported that laparoscopic surgery was associated with a significantly shorter hospital stay; the longest mean stay was 5.7 days for laparoscopic surgery versus longest mean stay of 10 days for open surgery. There was no significant difference between laparoscopic and open surgery in serosa formation, haemorrhagic complications or bowel injuries.

Authors' conclusions

Laparoscopic repair of ventral and incisional hernia was at least as effective, if not superior to, the open approach for a number of outcomes.

CRD commentary

The review addressed a focused question supported by clearly defined inclusion criteria. Relevant databases were searched, but the restriction to English language reported trials raised the possibility of language bias. Although potential sources of unpublished trials were searched, it was not clear if unpublished trials were included in the review, so publication bias could not be excluded. Appropriate steps were taken to minimise bias and errors for all stages of the review process.

Suitable criteria were used to assess trial quality; the majority of trials were of poor quality. The sample sizes in the included trials were small and, as acknowledged by the authors, the results may reflect the lack of statistical power. The methods used to pool results appeared to be appropriate. Heterogeneity was assessed and found to be present for continuous outcomes, but was absent for the dichotomous outcomes. The mean size of the hernias included this review were typically small, so the findings may not be generalisable to populations of patients with larger hernias. The results were clearly presented in the text and forest plots were used for each outcome assessed.

The authors' conclusions are supported by the data presented, but given the poor quality and small sample sizes of the included trials, the findings should be interpreted with caution.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that a large, multicentre RCT with rigorous methodology that compares laparoscopic hernia repair with open repair and assesses the long-term risk of hernia recurrence is required.

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