Systematic review of the clinical effectiveness of wound-edge protection devices in reducing surgical site infection in patients undergoing open abdominal surgery.
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CRD summary
This review concluded that wound–edge protection devices may have been efficient for reducing postoperative surgical site infections in patients who underwent open abdominal surgery, compared with standard care. The poor quality of the evidence indicated a need for a large good quality randomised controlled trial. This seems a reliable conclusion from a well-conducted review.

Authors' objectives
To evaluate the clinical effectiveness of wound-edge protection devices in reducing surgical site infection in patients undergoing open abdominal surgery.

Searching
MEDLINE, EMBASE, CINAHL, Web of Science and Cochrane Central Register of Controlled Trials (CENTRAL) were searched in November 2010 without any language restrictions; search terms were reported. The proceedings of the annual conferences of the Association of Coloproctology of Great Britain and Ireland and the Association of Surgeons of Great Britain and Ireland were searched. References were handsearched for additional studies. Manufacturers of devices and authors of relevant articles were contacted for information.

Study selection
Eligible randomised controlled trials, controlled trials, prospective cohort studies and case-control studies had to include patients who underwent elective or emergency open abdominal surgery using a wound-edge protection device which covered the incision edges with an impervious plastic sheet. Control groups had to use standard care and studies had to have clinically defined surgical site infection as a prespecified outcome. Purely bacteriological definitions of surgical site infection were excluded.

Most studies were in gastrointestinal surgery mostly colorectal surgery, others were generic abdominal surgery or appendicectomy. Interventions were plastic drapes and the actual type varied between studies. Control groups were no wound-edge protection device, standard retraction or incise drapes. Surgical site infection was prespecified as an outcome by all studies but the definitions of surgical site infection varied and only two studies used an internationally recognised definition (Centre for Disease Control and Prevention). The remaining studies used their own definitions and some included bacteriological results. Where stated, most studies followed up patients for one month.

Study selection was performed independently by two reviewers with disagreements resolved by a consensual decision.

Assessment of study quality
Study quality was assessed using the Cochrane Collaboration's Risk of Bias tool. This covered randomisation method, allocation concealment, blinding of patients and outcome assessors, addressing incomplete outcome data, selective reporting and other bias.

Assessment was performed independently by two reviewers with disagreements resolved by a consensual decision.

Data extraction
The numbers of patients with an surgical site infection were extracted and used to calculate risk ratios (RR) with 95% confidence intervals (CI).

Data were extracted by one reviewer and checked by a second.

Methods of synthesis
Results were combined using both fixed-effect and random-effects meta-analysis. Statistical heterogeneity was assessed
with the $I^2$ statistic. A subgroup analysis was used to look at the impact of contamination (clean, clean contaminated, contaminated and dirty surgical procedures) on the risk of an surgical site infection. Publication bias was assessed using a funnel plot.

**Results of the review**

Twelve studies were included (1,933 participants); ten were randomised controlled trials and two were controlled trials. All studies were considered to have been at medium or high risk of bias. Three studies had reported adequate randomisation methods, none reported adequate allocation concealment, two reported adequate blinding, four addressed incomplete outcome data, most were unclear for selective reporting, and eight studies were affected by other sources of bias (failing to report baseline comparability of groups or funding sources).

The use of wound-edge protection devices reduced the incidence of surgical site infection compared with control (RR 0.60, 95% CI 0.41 to 0.86) based on an analysis of all 12 studies with moderate heterogeneity ($I^2=54\%$). The result was similar when a fixed-effect model was used. The funnel plot showed some asymmetry indicating publication bias but the authors stated that this was due to two studies. Four studies reported results for the degree of contamination. The use of wound-edge protection significantly reduced SSIs in patients undergoing contaminated surgery (RR 0.37, 95% CI 0.23 to 0.61; three studies with no heterogeneity $I^2=0\%$) and dirty surgery (RR 0.55, 95% CI 0.36 to 0.86; three studies with moderate heterogeneity $I^2=51\%$). There was no difference between the groups for clean or clean contaminated surgery.

**Authors’ conclusions**

Wound-edge protection devices may have been efficient for reducing incidence of postoperative surgical site infections in patients who underwent open abdominal surgery, compared with standard care. The poor quality of the evidence indicated a need for a large good quality randomised controlled trial.

**CRD commentary**

This review had clearly defined inclusion criteria for study design, intervention, patients and outcome. The literature search covered several relevant databases, proceedings of conferences and efforts to contact device manufacturers. Searching was not limited by language so risk of publication or language bias was reduced, but the authors highlighted the fact that they may have failed to find some unpublished studies. Study selection, data extraction and quality assessment were carried out by two independent reviewers to reduce error and bias.

The quality of the evidence was assessed using a recognised checklist, details were reported in full and it was used in the evaluation of the pooled analyses. The methods of meta-analysis seemed appropriate, but the subgroup results were based on a small number of studies. This was a well-conducted review and its cautious conclusion and recommendation for research seem reliable.

**Implications of the review for practice and research**

**Practice:** The authors did not make any recommendations for practice.

**Research:** The authors stated that there was a need for high-quality, multi-centre, randomised controlled trials with economic evaluations to assess the appropriateness of introducing wound-edge protection devices as standard practice in open abdominal surgery.

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