Effectiveness of a gentamicin impregnated collagen sponge on reducing sternal wound infections following cardiac surgery: a meta-analysis of randomised controlled trials

Creanor S, Barton A, Marchbank A

CRD summary
This review concluded there was some benefit in using gentamicin impregnated collagen sponges (along with systemic antibiotics) to reduce the risk of sternal wound infection after cardiac surgery, particularly for high-risk patients to reduce deep infection risks. High variation and a limited number of events in most analyses suggest that the authors' conclusions may not be reliable.

Authors' objectives
To examine the effectiveness of gentamicin impregnated collagen sponge to prevent sternal wound infections in patients after cardiac surgery.

Searching
PubMed, EMBASE, CINAHL and British Nursing Index were searched from inception to June 2011; search terms were reported. References of included articles were manually searched. No language or publication restrictions were applied.

Study selection
Eligible randomised controlled trials assessed the effectiveness of antibiotic sponges versus placebo or no intervention in cardiac surgery patients. The primary outcome of the review was any sternal wound infection; the secondary outcome was deep sternal wound infection.

Included trials were conducted in the USA, Finland and Sweden. Gentamicin sponge dose ranged from 130mg to 260mg and were used in addition to systemic antibiotics. Postoperative sternal wound infections were assessed; all trials used the Centers of Disease Control's definition of sternal wound infection. Trials either focused on patients who had received a coronary artery bypass graft or cardiac surgery by median sternotomy (an incision through the sternum).

Two reviewers selected studies for inclusion; this was done independently for full text articles.

Assessment of study quality
Only patient and assessor blinding was assessed.

The authors did not state how many reviewers assessed trial quality.

Data extraction
Outcomes (any sternal wound infection or deep sternal wound infection) were extracted from each trial to calculate odds ratios (ORs) with 95% confidence intervals (CIs).

The authors did not state how many reviewers extracted the data.

Methods of synthesis
Trials were pooled using a fixed-effect and random-effects models. $I^2$ (greater than 40% was considered significant) and $X^2$ were used to assess statistical heterogeneity.

Further planned analyses included only high-risk patients (people with diabetes mellitus and high body mass index) identified in trials.

Results of the review
Three RCTs were included in the review (3,994 patients). Of these, two trials included data on high-risk patients (2,887 patients). Follow-up ranged from two to three months. All three RCTs used blinded assessors; only one trial did not use patient blinding. Random-effects meta-analyses were reported for all results.
The pooled estimate was not statistically significant for any sternal wound infection, although it suggested some benefit for gentamicin impregnated collagen sponge in addition to systemic antibiotics. There was high heterogeneity ($\Omega^2=75\%$). The results were more consistent ($\Omega^2=0\%$) for deep sternal wound infections, suggesting some benefit for gentamicin, but this was not statistically significant.

For high-risk patients, there was no statistically significant difference for any sternal wound infection, and there was high heterogeneity ($\Omega^2=91\%$). However, for deep sternal wound infection, there was a statistically significant benefit found for gentamicin compared with control groups (OR 0.62; 95% CI 0.39 to 0.98; $\Omega^2=0\%$; two trials).

**Authors' conclusions**

There was some evidence for the benefit of using gentamicin impregnated collagen sponge in addition to systemic antibiotics to reduce the risk of sternal wound infection after cardiac surgery. This was particularly the case for deep sternal wound infection in high-risk patients.

**CRD commentary**

The review question and inclusion criteria were clear. The search provided a good coverage of relevant databases. Language restrictions were not applied, which reduced the risk of language bias. The authors acknowledged that only three RCTs were identified, so there was potential for publication bias. Acceptable methods were used to minimise error and bias in study selection, but it was unclear if such procedures were also used for quality assessment and data extraction.

There was a minimal quality assessment, so it was not possible to determine if there were any important limitations for the included trials. There was high heterogeneity for both analyses of any sternal wound infection, which limited the validity of the pooled estimates for these outcomes. The number of events was quite low for most analyses, which also limited the precision of the findings. A further limitation was the short follow-up period for most trials. In addition, the one statistically significant difference identified in the analyses would no longer have remained significant if multiple testing was taken into account.

High heterogeneity and a limited number of trials with a limited number of events in most analyses suggest that the authors' conclusions may not be reliable.

**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, high-quality RCT should be conducted to assess clinical and cost-effectiveness of gentamicin impregnated sponges.

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