Meta-analysis comparing drug-eluting stents with bare metal stents

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CRD summary
This review compared the use of bare metal stents and drug-eluting stents (paclitaxel or sirolimus) for coronary artery stenosis. There was no difference in effect on mortality or overall myocardial infarction. The authors concluded that the treatments were similar and excluded, with confidence, the possibility of any clinically relevant differences. These conclusions are supported by the data presented.

Authors' objectives
To investigate the effects of drug-eluting stents (DES) compared with bare metal stents (BMS) in the treatment of coronary artery lesions.

Searching
MEDLINE, EMBASE and the Cochrane Controlled Trials Register were searched; the search terms were given. The last date of searching was May 2004. Abstracts from major meetings and the bibliographies of identified studies and reviews were checked.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared the effects of DES (paclitaxel or sirolimus) with BMS were eligible for inclusion. Studies that incorporated other drugs in the DES were excluded. The stent types were generally similar within studies, and both polymer and non-polymer coated stents were used. Further details of the types of stent used were provided. Concomitant therapies included aspirin and heparin and, in some studies, clopidogrel, ticlopidine or cilostazol.

Participants included in the review
Studies on people undergoing coronary stent placement were eligible for inclusion. In the included studies, the mean age of the patients ranged from 60 to 65 years and the proportion of males ranged from 69 to 88%. The prevalence of co-morbidities (diabetes, hypertension, hyperlipidaemia or prior myocardial infarction) was reported.

Outcomes assessed in the review
The outcomes of interest were death (all cause or cardiac), myocardial infarction (combined, and Q-wave and non-Q-wave separately) and stent thrombosis. The events were assessed at 12 months where possible, or closest to 12 months in the range 6 to 12 months.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Two reviewers independently extracted the data. Any discrepancies were resolved by discussion and consensus with a third reviewer. Risk differences (RDs) and 95% confidence intervals (CIs) were calculated for each study and outcome.
Methods of synthesis
How were the studies combined?
Pooled estimates of RD were calculated using both a fixed-effect model and a random-effects model. Fixed-effect results were reported. Studies were excluded from the analysis if there were no events in either comparison arm.

How were differences between studies investigated?
Heterogeneity was investigated using the Q statistic. Subgroup analyses were performed, based on type of drug and use of polymer coatings.

Results of the review
Ten RCTs (5,066 participants) were included. Of these, six used paclitaxel-eluting stents and four used sirolimus-eluting stents.

There was no significant heterogeneity between the studies for any of the outcomes.

There were no significant differences between the two treatment groups for mortality (RD 0.12%, 95% CI: -0.34, 0.58, P=0.60), myocardial infarction (RD 0.04%, 95% CI: -0.72, 0.81, P=0.91), Q-wave myocardial infarction (RD 0.36%, 95% CI: -0.04, 0.77, P=0.08), non-Q-wave myocardial infarction (RD -0.26%, 95% CI: -0.93, 0.43, P=0.46) or thrombosis (RD 0.29%, 95% CI: -0.08, 0.66, P=0.13).

The subgroup analyses showed no clear differences in these results when paclitaxel and sirolimus trials, and polymer and non-polymer coated stents, were analysed separately.

Authors' conclusions
Sirolimus- and paclitaxel-eluting stents, and BMS are similarly effective at one year of follow-up. The possibility of considerable differences in effects is excluded with confidence.

CRD commentary
The inclusion criteria for this review were clearly stated. Several relevant databases were searched and efforts were made to identify unpublished studies. The methods of the review (study selection, data extraction) were not described and the authors did not discuss any quality assessment. It is therefore possible for error or bias to be introduced during the review process. This, or any methodological flaws in the included studies, might have affected the results of the review. Where the methods were not fully reported these factors cannot be assessed. Statistical methods of pooling the trial data were appropriate and clearly described. The authors' conclusions are supported by the data presented.

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

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