A meta-analysis of specifically designed randomized trials of sirolimus-eluting versus paclitaxel-eluting stents in diabetic patients with coronary artery disease

CRD summary
This meta-analysis of individual patient data concluded that sirolimus-eluting stents reduced the risk of needing a repeat operation compared with paclitaxel-eluting stents. The two stents were comparable for death, heart attack and stent thrombosis. The conclusions reflect the evidence presented, but the small number of participants and wide confidence intervals suggest the findings should be considered provisional.

Authors' objectives
To compare the long-term efficacy and safety of sirolimus-eluting stents and paclitaxel-eluting stents in patients with diabetes and coronary artery disease.

Searching
The authors searched PubMed, ClinicalTrials.gov and Cochrane Central Register of Controlled Trials (CENTRAL), together with several internet sources and conference proceedings (listed in the paper). Relevant recent reviews and editorials were screened. The last search was done in May 2010. No search terms were reported. No language restrictions were reported.

Study selection
Randomised controlled trials (RCTs) that compared sirolimus-eluting and paclitaxel-eluting stents in patients with diabetes and coronary artery disease were eligible for the review. The primary efficacy outcome was target lesion revascularisation. The primary safety outcome was a composite of death and myocardial infarction (MI). Stent thrombosis was a secondary outcome.

Included trials recruited patients with a mean age between 60 and 70 years. The proportion of patients receiving insulin ranged from 13% to 37%. Late lumen loss was the most common primary outcome.

The authors did not state how trials were selected for inclusion.

Assessment of study quality
Individual patient data (IPD) were checked for consistency, queries were resolved and the final database entries were verified by the responsible trial investigator. Quality of included trials was evaluated based on adequacy of allocation concealment, use of intention-to-treat analysis and outcome assessment.

The authors did not state how the quality assessment was performed.

Data extraction
Investigators supplied IPD on date of randomisation, treatment allocation, type of treatment of diabetes, event status and date of last follow-up visit. Data for surviving patients were censored at the date of last contact.

Methods of synthesis
The log rank test was performed and hazard ratios (HRs) and associated 95% confidence intervals (CIs) were calculated for each outcome. Pooled hazard ratios were calculated using a random-effects (DerSimonian and Laird) model. Heterogeneity was assessed using the Cochran test and I² statistic.

Results of the review
Six RCTs with 1,183 participants were included. Median follow-up was 3.9 years (inter-quartile range 3.4 to 4.5 years). Results of trial quality assessment were not reported.

Use of sirolimus-eluting stents was associated with a statistically significant 35% reduction in risk of target lesion
revascularisation (HR 0.65, 95% CI 0.47 to 0.91). There was no significant difference between groups for the composite of death or myocardial infarction (HR 1.04, 95% CI 0.74 to 1.45) or stent thrombosis (HR 0.95, 95% CI 0.65 to 1.39). There was no significant heterogeneity for any of the outcomes.

Authors' conclusions
In patients with diabetes and coronary artery disease, use of sirolimus-eluting stents led to a sustained reduction in risk of target lesion revascularisation compared with paclitaxel-eluting stents. The two stent types were comparable for risk of stent thrombosis, myocardial infarction and death.

CRD commentary
The review question and inclusion criteria were clear. The search covered a range of relevant sources of both published and unpublished trials. Search terms were not reported so the ability of the search to detect all relevant trials was unclear. Similarly the process of selecting trials was not reported so the risk of errors or bias at this stage was unclear. Quality of included trials was assessed but no results were reported. No trials were omitted because of lack of IPD. Appropriate methods were used to check the quality of the IPD supplied. The meta-analysis used standard methods for time to event data. Statistical heterogeneity was assessed and reported as low for all outcomes.

Overall, the authors' conclusions reflect the evidence presented. However, the small number of included patients and the wide confidence intervals surrounding the estimates suggest that estimates of treatment effect should be regarded as provisional. In particular, the findings for death, myocardial infarction and stent thrombosis may represent no evidence of a difference rather than evidence of no difference. The review involved a specific patient population and the findings may not be generalisable to other patient groups or stent types.

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

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