Long-term outcome after sirolimus-eluting stents versus bare metal stents in patients with diabetes mellitus: a patient-level meta-analysis of randomized trials

CRD summary
This review concluded that, compared with bare metal stents, Sirolimus-eluting stents effectively reduced the risk for major cardiac events, and were safe in diabetic patients with coronary artery disease. Although there was a lack of reporting on study quality, the authors’ conclusions reflect the evidence presented and appear likely to be reliable.

Authors’ objectives
To compare the efficacy of sirolimus-eluting stents with bare metal stents in patients with coronary artery disease and diabetes mellitus.

Searching
PubMed, Cochrane Central Register of Controlled Trials (CENTRAL) and www.ClinicalTrials.gov were searched up to July 2010. Several websites on clinical trials in cardiology were searched. Search terms were not reported. Several relevant conference proceedings were searched and reference lists of relevant reviews were screened for additional studies. Experts in the field were contacted for any unpublished relevant trials.

Study selection
Randomised controlled trials (RCTs) that compared drug-eluting stents with bare metal stents, with a mean follow-up period of at least 12 months were eligible for inclusion. Participants had to be patients with coronary artery disease and diabetes mellitus. The primary outcome was the incidence of major cardiac events (including death, myocardial infarction and target lesion re-intervention). Secondary outcomes were all-cause mortality, myocardial infarction, target lesion re-intervention and stent thrombosis.

All of the included studies evaluated sirolimus-eluting stents as the drug-eluting stent. The mean age of patients from individual trials ranged from 60 to 70 years. The recommended length of postprocedural thienopyridine therapy ranged from three to 12 months. The median length of follow-up ranged from 1.1 to five years (median 4.2 years). Included studies were published between 2005 and 2008.

The authors did not state how many reviewers assessed studies for inclusion.

Assessment of study quality
The quality of studies was assessed using the following criteria: allocation concealment, intention-to-treat analysis and blind assessment of outcomes. All individual patient data were checked for consistency.

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

Data extraction
Individual patient data were obtained from trial investigators to enable the calculation of hazard ratios (HRs) with 95% confidence intervals (CIs). Studies in which the event of interest was not observed in either treatment group were excluded from the analysis. When only one treatment group of an individual trial had no event of interest, 0.5 was added to each cell of the 2x2 table for this trial to enable the calculation of the treatment effect estimate and its standard error.

Methods of synthesis
Survival analyses were performed using the Mantel-Cox method (stratified by trial on the basis of individual patient data), with hazard ratios and 95% confidence intervals calculated by the log-rank test. Data for surviving patients were censored on the date of last follow-up. The pooled hazard ratios with 95% confidence intervals were calculated using the DerSimonian and Laird random-effects model. Statistical heterogeneity was assessed using the Cochran test and I² statistics. Survival curves were presented as non-stratified Kaplan-Meier curves across all trials.
Results of the review

Four RCTs were included in the review (583 patients). Individual patient data were available for all RCTs.

Compared with bare metal stents, sirolimus-eluting stents were associated with a significant reduction in the rate of major cardiac events (HR 0.48, 95% CI 0.36 to 0.63) and repeat revascularisation (HR 0.27, 95% CI 0.18 to 0.41). There were no significant differences in the outcomes of death/myocardial infarction, all-cause mortality and stent thrombosis between the two groups.

No significant heterogeneity was observed in the outcomes.

Authors' conclusions

Sirolimus-eluting stents effectively reduced the risk for major cardiac events, and were safe in diabetic patients with coronary artery disease.

CRD commentary

This review's inclusion criteria were clear. Several relevant databases were searched. Efforts were made to find both published and unpublished studies, which reduced the risk of publication bias. The authors did not state whether any language restriction was applied to the search, which made it difficult to assess the risk of language bias. Trial investigators were contacted for individual patient data. It was unclear whether sufficient attempts were made to minimise errors and biases in the review process. The authors stated that they performed a formal quality assessment, but study quality was not reported. All individual patient data were checked for consistency.

Statistical heterogeneity was assessed and the chosen method of synthesis appeared to be appropriate. As all included trials evaluated sirolimus-eluting stents, findings from this review were not generalisable to other drug-eluting stents. Although there was a lack of reporting on study quality, the authors' conclusions reflect the evidence presented and appear likely to be reliable.

Implications of the review for practice and research

The authors did not state any implications for practice and research.

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