Clinical outcomes of sirolimus-eluting stents versus bare metal stents in ST-segment elevation myocardial infarction patients: a meta-analysis


CRD summary
The authors found that sirolimus-eluting stents were associated with a lower rate of major adverse cardiac events than bare-metal stents in the management of patients with ST-segment elevation myocardial infarction over one year of follow-up. Large trials are required to compare long-term outcomes. The review was well conducted and these conclusions appear reliable.

Authors' objectives
To compare the safety and effectiveness of sirolimus-eluting stents and bare-metal stents in the management of ST-segment elevation myocardial infarction.

Searching
PubMed, EMBASE, ISI Web of Science and the Cochrane Central Register of Controlled Trials were searched. No language restrictions were applied. Conference proceedings from the American College of Cardiology, American Heart Association and European Society of Cardiology were also searched. Search dates were from January 2003 to February 2008. Relevant articles from major medical journals for the previous year were checked, as were three relevant Internet-based sources.

Study selection
Randomised controlled trials (RCTs) comparing sirolimus-eluting stents with bare-metal stents for the management of ST-segment elevation myocardial infarction patients were eligible for inclusion. Included trials had to reported follow-up for at least six months. The primary review outcome was major adverse coronary event, a composite of death, recurrent myocardial infarction or repeat revascularisation (target vessel revascularisation or target lesion revascularisation). Secondary outcomes were death, recurrent myocardial infarction, repeat revascularisation or stent thrombosis (safety outcome). Stent thrombosis was defined by Academic Research Consortium criteria. Target vessel revascularisation and target lesion revascularisation were defined in detail in the review.

Nearly all participants in the review had received primary percutaneous coronary interventions, but one trial included some patients who had received percutaneous coronary interventions plus thrombolysis. The drug protocol in the included trials was clopidogrel or ticlopidine for three to 12 months and indefinite aspirin, after the index procedure. Most trials included all deaths in the definition of major adverse coronary event, but some trials included only target-vessel-related deaths. Duration of follow-up was one year in all the included studies, apart from one which had a follow-up of six months.

Two reviewers independently selected studies for inclusion, with disagreements resolved by consensus.

Assessment of study quality
The following aspects of study validity were apparently assessed: randomisation, masking of allocation and follow-up rate. It appeared that two reviewers assessed the quality of the included trials.

Data extraction
Data were extracted on an intention-to-treat principle. Odds ratios were calculated from the numbers of events in the control and intervention groups of each study, with 95% confidence intervals.

Two reviewers independently extracted study data, with disagreements resolved by consensus.

Methods of synthesis
Trials were grouped according to outcome and pooled odds ratios, with 95% confidence intervals, were calculated using the Mantel-Haenszel fixed-effect model. Statistical heterogeneity was assessed using the Χ² test and publication bias was assessed for both primary and secondary outcomes, using a funnel plot and the adjusted rank correlation test of Begg and Mazumdar.

**Results of the review**

Seven randomised controlled trials (RCTs) were included in the review (n=1,973 participants, range 120 to 712). The review authors stated that six trials reported adequate methods of randomisation and allocation concealment and had a follow-up rate of over 95%. One trial was double-blinded and four trials were single-blinded. One unpublished RCT did not give details of randomisation or allocation concealment.

**Sirolimus-eluting stents versus bare-metal stents** (seven RCTs): In the sirolimus-eluting stents group there was a significantly lower rate of major adverse coronary event (odds ratio 2.45, 95% confidence interval (CI): 1.88, 3.19, \( p<0.00001 \)) and repeat revascularisation (odds ratio 3.30, 95% CI: 2.37 to 4.60; \( p<0.00001 \)) than in the bare metal stents group. There was no statistically significant difference between the groups in the rates of death (odds ratio 1.39, 95% CI: 0.84 to 2.30), recurrent myocardial infarction (odds ratio 1.45, 95% CI: 0.87 to 2.41) or stent thrombosis (odds ratio 1.61, 95% CI: 0.79 to 3.26). There was no evidence of significant statistical heterogeneity nor of publication bias.

**Authors' conclusions**

Sirolimus-eluting stents were associated with a lower rate of major adverse coronary event than bare-metal stents in the management of patients with ST-segment elevation myocardial infarction over one year of follow-up. Large trials are required to compare long-term outcomes.

**CRD commentary**

The objectives and inclusion criteria of the review were clear. Relevant sources were searched for published and unpublished studies, with no language restrictions. Steps were taken to reduce the risk of reviewer bias and error by having more than one reviewer independently select studies, extract data and assess study validity. Relevant criteria appear to have been used for validity assessment, but it was unclear whether some references in the text referred to allocation concealment or to blinding. The statistical techniques used to combine trials appear suitable. Appropriate methods were used to test for statistical heterogeneity and publication bias. Other potential limitations, such as the lack of long-term data and use of a strict definition of stent thrombosis used, were well addressed in the text. The review was well conducted and the authors' conclusions appear reliable.

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

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that larger RCTs with longer follow-up are needed to determine the role of sirolimus-eluting stents for ST-segment elevation myocardial infarction patients and to compare the long-term safety of sirolimus-eluting stents and bare-metal stents.

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