Efficacy and safety of drug-eluting stents in ST-segment elevation myocardial infarction: a meta-analysis of randomized trials


CRD summary
This review compared the use of drug-eluting stents to bare-metal stents in patients with ST-segment elevation myocardial infarction. Drug-eluting stent use was found to significantly decrease target-vessel revascularisation at one to two years of follow-up. Insufficient information was presented about the quality of the studies, which makes it difficult to draw conclusions about the reliability of the authors’ conclusions.

Authors’ objectives
To assess the effectiveness and safety of surgical implantation of drug-eluting stents compared to bare-metal stents in patients undergoing primary angioplasty for ST-segment elevation myocardial infarction (STEMI).

Searching
The databases MEDLINE and Cochrane Central Register of Controlled Trials were searched for from January 1990 to October 2007, as were abstracts from four relevant journals. Searches were also undertaken for oral presentations and/or expert slide presentations for the period from January 2002 to October 2007 using relevant websites. There were no language restrictions. Search terms were reported.

Study selection
Completed randomised controlled trials (RCTs) comparing the use of drug-eluting stents to bare-metal stents in patients undergoing primary angioplasty for ST-segment elevation myocardial infarction (STEMI) were eligible for inclusion. Exclusion criteria were: lack of follow-up in more than 10% of the enrolled patients; trials of less than 50 patients; ongoing trials; trials for which data could not be retrieved; and trials that included patients with both STEMI- and non-STEMI.

The drug-eluting stents included in the trials were sirolimus-eluting, Cypher, paclitaxel-eluting, Endeavor and Taxus. The bare-metal stents included Express-2, Vision and Liberte. Patients in the majority of the included trials were treated with glycoprotein IIb/IIIa inhibitors and received six to 12 months of dual oral antiplatelet therapy. The clinical outcomes of interest were mortality, re-infarction, stent thrombosis (defined by the reviewers as recurrent myocardial infarction with angiographic proof of vessel occlusion) and target vessel revascularisation.

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
Data were extracted to permit the calculation of odds ratios (OR) with 95% confidence intervals (CI). In the event of incomplete or unclear data, authors were contacted. The reviewers assessed the data using intention-to-treat analyses.

Two reviewers extracted data independently and any differences were resolved by discussion.

Methods of synthesis
The pooled odd ratios and 95% confidence intervals for the outcomes were calculated using a Mantel-Haenszel fixed-effect model. The Breslow-Day test was used to evaluate the statistical heterogeneity across the trials. Had statistically significant heterogeneity been observed, a DerSimonian and Laird random-effects model would have been used. The reviewers explored potential publication biases by linear regression and visual appraisals of funnel plots.
Results of the review

Eleven RCTs (n=3,607 patients) were included in the review. Four trials had follow-up of more than 18 months; in the remaining seven trials, follow-up was 12 months or less.

There were statistically significant differences decreases in target vessel revascularisation at 12 months follow-up in the group treated with drug-eluting stents compared to patients who received bare-metal stents (5.0% compared to 12.6%; OR 0.36; 95% CI: 0.28 to 0.47). In addition, the beneficial effects of drug-eluting stents on target vessel revascularisation continued to be statistically significant compared to bare-metal stents at 18 to 24 months follow-up (5.9% compared to 13.5%; OR 0.40; 95% CI: 0.26 to 0.60). In sensitivity analyses evaluating the effect of routine angiography, no interaction was found between the numbers of patients presenting for angiographic follow-up (those not lost to follow-up) and the outcomes assessed.

There were no significant differences between drug eluting stents and bare metal stents for the following outcomes: mortality, re-infarction and stent thrombosis.

No statistically significant heterogeneity was observed for any outcome.

Authors' conclusions

In selected patients who underwent primary angioplasty, the use of sirolimus- and paclitaxel-eluting stents was associated with a significant beneficial reduction in target-vessel revascularization at one-year and two-year follow-up compared to bare-metal stents. No specific safety concerns emerged from the data presented.

CRD commentary

The review addressed a clear question and the criteria for the inclusion of studies in the review were clearly stipulated. The search was adequate and was designed to minimise language and publication biases. The authors reported using methods designed to reduce reviewer bias in the extraction of data but not in the selection of studies.

No assessment of validity was reported, which made it difficult to assess the reliability of the evidence from included studies.

The authors' conclusions reflect the results of the review but, in the absence of a validity assessment, it is difficult to determine their reliability.

Implications of the review for practice and research

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

Research: The authors stated that further trials with long term follow-up (recommended to be three to five years) in patients with STEMI are necessary to confirm the safety of drug-eluting stents in primary angioplasty. Research is also required on new emerging stent technologies.

Funding

None.

Bibliographic details


PubMedID

18394731
DOI
10.1016/j.ijcard.2007.12.040

Original Paper URL
http://www.internationaljournalofcardiology.com/article/S0167-5273(08)00044-2/abstract

Indexing Status
Subject indexing assigned by NLM

MeSH
Angioplasty, Balloon, Coronary; Drug-Eluting Stents; Humans; Myocardial Infarction /drug therapy; Randomized Controlled Trials as Topic; Treatment Outcome

AccessionNumber
12009104131

Date bibliographic record published
22/07/2009

Date abstract record published
14/10/2009

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.