Comparison of sirolimus- and paclitaxel-eluting stents in patients undergoing primary percutaneous coronary intervention for ST-elevation myocardial infarction: a meta-analysis of randomized trials

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CRD summary
This review concluded that sirolimus-eluting stents were superior to paclitaxel-eluting stents in reducing the incidence of restenosis in patients undergoing primary percutaneous coronary interventions for ST-segment elevation myocardial infarction, with non-significant differences for some other outcomes. The authors' conclusions reflect the evidence presented but, given the uncertain quality of the included studies, their reliability is unclear.

Authors' objectives
To compare sirolimus-eluting stents and paclitaxel-eluting stents in patients with acute ST-segment elevation myocardial infarction undergoing percutaneous coronary intervention.

Searching
PubMed, EMBASE and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched for relevant articles published from January 2001 to February 2010. No language restrictions were used. Search terms were reported. Four websites providing details on clinical trials within cardiology were also searched, as were abstracts from conference proceedings of three relevant societies (American College of Cardiology, American Heart Association, and the European Society of Cardiology). Relevant reviews and editorials from selected medical journals published recently were scanned for relevant articles.

Study selection
Eligible studies were randomised clinical trials that evaluated the outcome after sirolimus-eluting stent implantation compared with paclitaxel-eluting stents implantation for ST-segment elevation myocardial infarction. Eligible trials had to have a follow-up duration of at least six months following the procedure. Trials had to specifically enrol patients with ST-segment elevation myocardial infarction, or report outcomes for subpopulations of patients with ST-segment elevation myocardial infarction.

The primary outcome was target vessel revascularisation (definition provided in review). Other eligible outcomes included cardiac death, myocardial infarction, stent thrombosis, and binary restenosis (at least 50%).

Included trials were conducted in Korea, Italy and the Netherlands. Half of the included trials were multicentre; the other half were single-centre trials. In included trials, the mean age of patients ranged from 58 to 63 years; the proportion of men ranged from 69 to 86%. The proportion of participants with diabetes ranged from 6.5 to 29%; the proportion smoking ranged from 24 to 62%. From 27 to 54% of participants had hypertension. Other details were also reported.

The authors did not state how many reviewers performed the study selection.

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

Data extraction
Two reviewers independently extracted data required to enable calculation of odds ratios (ORs) and corresponding 95% confidence intervals (CIs) for the meta-analysis. Disagreements were resolved by consensus with a third reviewer. Absolute numbers were calculated when percentages were reported. Calculations were on an intention-to-treat (ITT) basis.

Methods of synthesis
Odds ratios (ORs) with 95% confidence intervals (CIs) were pooled using either Mantel-Haenszel fixed-effect or DerSimonian & Laird random-effects models, depending on the results of Q tests and $I^2$ statistics.

Sensitivity analysis was performed by assessing the effect of removing individual trials on the overall results. Publication bias was assessed through visual inspection of funnel plots.

**Results of the review**

Four trials were included in the review (n=1,105 patients; 550 in sirolimus-eluting stent group, 555 in paclitaxel-eluting stent group). These included two prospective randomised clinical trials and two subgroups from two other randomised clinical trials. Angiographic follow-up (where applicable) ranged from six to nine months; clinical follow-up ranged from one year to over four years.

Target vessel revascularisation was needed in 5.3% of patients in the sirolimus-eluting stent group compared with 7.6% in the paclitaxel-eluting stent group. There was a non-significant trend towards a reduction of target vessel revascularisation in sirolimus-eluting stent groups compared with paclitaxel-eluting stent groups.

There was a statistically significantly reduction of angiographic restenosis in sirolimus-eluting stent group compared with paclitaxel-eluting stent group (OR 0.38, 95% CI 0.19 to 0.74; three trials).

There was no statistically significant difference between groups for stent thrombosis, cardiac death and myocardial infarctions.

Heterogeneity was low, so fixed-effect models were used.

There was no evidence of publication bias from funnel plots.

**Authors’ conclusions**

Sirolimus-eluting stents were superior to paclitaxel-eluting stents in reducing the incidence of restenosis in patients that underwent primary percutaneous coronary intervention for ST-segment elevation myocardial infarction, with non-significant differences for target vessel revascularisation, cardiac death, myocardial infarction and stent thrombosis.

**CRD commentary**

The review question was clearly defined and the study selection criteria were clearly stated. The search was thorough and without language restrictions, which reduced the risk of publication and language bias. Although data were extracted independently by two reviewers, the number of reviewers performing study selection was not reported, so the risk of reviewer error and/or bias at this stage could not be ruled out.

No quality assessment was reported, so the risk of bias within trials was unknown, although all studies were randomised clinical trials. The reporting of included trial characteristics was thorough. A standard and appropriate approach to data synthesis was reported and used.

The authors’ conclusions reflect the evidence presented but, given the uncertain quality of the included trials, their reliability is unclear.

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

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

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