Sirolimus-eluting stents vs paclitaxel-eluting stents in patients with coronary artery disease: meta-analysis of randomized trials


CRD summary
This review compared the efficacy and safety of sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) in patients with coronary artery disease. The authors concluded that SES had a lower risk of restenosis and target vessel revascularisation than PES, but there were no differences in mortality, myocardial infarction, or stent thrombosis. The authors appropriately highlighted the need for studies with longer-term follow-up.

Authors' objectives
To compare the efficacy and safety of sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) for percutaneous treatment in patients with coronary artery disease (CAD).

Searching
PubMed and the Cochrane CENTRAL Register were searched from January 2003 to April 2005; the search terms were not reported. Conference proceedings, recent reviews and editorials from major medical journals were checked. Internet searches were also conducted. Trials published as abstracts were included.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion. The studies had to report follow-up results of at least 6 months after the index percutaneous coronary intervention.

Specific interventions included in the review
Studies that compared SES and PES in head-to-head comparisons were eligible for inclusion in the review.

Participants included in the review
Studies of patients with symptoms or objective signs of myocardial ischaemia due to CAD, who were undergoing percutaneous coronary intervention, were eligible for inclusion.

Outcomes assessed in the review
The primary outcome of interest was target lesion revascularisation. Binary restenosis, stent thrombosis, myocardial infarction (MI), mortality, and the composite of death or MI were also of interest. Full definitions for each outcome were given in the paper.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected studies, with any disagreements resolved by consensus.

Assessment of study quality
The trials were assessed for concealment of treatment allocation, blinding, and analysis according to the intention-to-treat principal. The authors did not state who performed the validity assessment.

Data extraction
Two reviewers independently extracted the data from the primary studies, with any disagreements resolved by consensus. Odds ratios (ORs) and their 95% confidence intervals (CIs) were extracted for each study.
Methods of synthesis

How were the studies combined?
Pooled ORs and their 95% CIs were calculated using the Mantel-Haenszel fixed-effect method and the DerSimonian and Laird random-effects method. Publication bias, with respect to the primary outcome of interest, was assessed by using a funnel plot and the Begg and Mazumdar adjusted rank correlation test (see Other Publications of Related Interest).

How were differences between studies investigated?
The Cochran Q test and the I-squared statistic were used to explore between-study differences.

Results of the review
Six RCTs (n=3,669) were included in the review.

Compared with PES, SES were associated with statistically significant reductions in target lesion revascularisation (5.1% with SES versus 7.8% with PES; OR 0.64, 95% CI: 0.49, 0.84) and angiographic restenosis (9.3% with SES versus 13.1% with PES; OR 0.68, 95% CI: 0.55, 0.86). No statistical differences were shown between the treatment groups in stent thrombosis (0.9% with SES versus 1.1% with PES; OR 0.85, 95% CI: 0.46, 1.59), mortality (1.4% with SES versus 1.6% with PES; OR 0.85, 95% CI: 0.50, 1.46), or the composite of death or MI (4.9% with SES versus 5.8% with PES; OR 0.84, 95% CI: 0.63, 1.12). No significant heterogeneity was found between trials.

No evidence of publication bias, with respect to target lesion revascularisation, was shown in the funnel plot or the rank correlation test.

Authors’ conclusions
In patients with CAD presenting with various angiographic and clinical risk profiles, those who were receiving SES had lower risk of restenosis and target vessel revascularisation than those receiving PES. There was no difference in mortality, MI, or thrombosis. Studies with longer-term follow-up are required.

CRD commentary
The review question was clear in terms of the study design, intervention and outcomes. The literature search covered two databases and no restrictions on the form of study publication were made. However, the authors did not state whether their search was restricted by language. Efforts were made to reduce reviewer error and bias in the methods used to select the primary studies and extract the data. The methodological quality of the primary studies was assessed; although no individual trial information was presented, the authors reported that the primary studies were of adequate quality. The data synthesis was appropriate and statistical heterogeneity between the studies was assessed. The authors' conclusions appear to be supported by the evidence presented and are likely to be reliable.

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

Research: The authors suggested that studies with longer-term follow-up are required.

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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.