Drug-eluting stents perform better than bare metal stents in small coronary vessels: a meta-analysis of randomised and observational clinical studies with mid-term follow up

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CRD summary
This review concluded that the treatment of small coronary vessels with drug-eluting stents was safe and effective in the medium term, regardless of the drug used. Despite some limitations in reporting, the authors' conclusions seem reliable.

Authors' objectives
To compare the performance of drug-eluting and bare-metal stents in small coronary vessels.

Searching
PubMed, Cochrane Central Register of Controlled Trials (CENTRAL), mRCT, BioMed Central, ClinicalTrials.gov, Cardiosource, and Web of Science were searched up to January 2010; search terms were reported. Proceedings of the annual meetings of four major cardiology associations were also searched. Experts in the field were contacted.

Study selection
Randomised controlled trials (RCTs), RCT subgroups and observational studies of percutaneous coronary interventions that compared a drug-eluting stent with a bare-metal stent to treat vessels with a diameter of less than 3mm were eligible for inclusion. Studies had to have a follow-up period of at least six months. The primary endpoint was target vessel failure, defined as target vessel revascularisation or any death or myocardial infarction that could not be attributed to a vessel other than the target vessel by the end of the follow-up period. The secondary endpoints were: major adverse cardiovascular events (defined as death, myocardial infarction, or target vessel revascularisation as a composite or single outcome); definite or probable stent thrombosis; and late lumen loss or binary restenosis at angiographic follow-up.

In the included studies, most of the drug-eluting stents used sirolimus; others used paclitaxel or everolimus. The mean reference vessel diameter was 2.22mm in the drug-eluting stent group and 2.27mm in the bare-metal stent group. The mean age of included patients ranged from 61 to 67 years, the percentage of men ranged from 59% to 79, 19% to 100% had diabetes, 12% to 86% had stable angina, and zero to 45% had myocardial infarction (where reported).

The authors did not report how many reviewers selected the studies.

Assessment of study quality
Study quality was evaluated using the methods recommended by the Cochrane Collaboration, which covered selection, performance, detection and attrition biases.

The authors did not report how many reviewers performed the quality assessment.

Data extraction
Data were extracted to calculate odds ratios for binary outcomes and mean differences for continuous outcomes, both with 95% confidence intervals. For studies with multiple assessments over time, a single time point was chosen.

The authors did not report how many reviewers performed the data extraction.

Methods of synthesis
A DerSimonian and Laird random-effects meta-analysis was used if there was heterogeneity between studies, otherwise an inverse variance fixed effect model was used. Statistical heterogeneity was assessed with $X^2$ and $I^2$.

Analyses were stratified to explore heterogeneity by using the type of study (randomised or not), length of follow-up (more or less than 360 days) and the type of drug-eluting stent.

Publication bias was assessed using a funnel plot and Egger's test.
Results of the review

Twelve studies (3,182 patients) were included in the review (three RCTs, five RCT subgroups and four observational studies). The mean follow-up period was 377 days.

**Target vessel failure** (ten studies): Rates of target vessel failure were significantly lower with drug-eluting than with bare-metal stents (OR 0.37, 95% CI 0.29 to 0.47). There was moderate heterogeneity ($I^2=46.9\%$), but no evidence of publication bias.

**Major adverse cardiovascular events** (ten studies): Rates of major adverse cardiovascular events were significantly lower with drug-eluting than with bare metal stents (OR 0.36, 95% CI 0.29 to 0.45). There was low heterogeneity ($I^2=31.9\%$).

**Target vessel revascularisation** (nine studies): Rates of target vessel revascularisation were significantly lower with drug-eluting than with bare-metal stents (OR 0.28, 95% CI 0.21 to 0.37). There was moderate heterogeneity ($I^2=49.9\%$). Event rates appeared to be lower for sirolimus stents (OR 0.20, 95% CI 0.14 to 0.30) than for paclitaxel stents (OR 0.49, 95% CI 0.32 to 0.74).

**Binary restenosis** (nine studies): Rates of binary restenosis were significantly lower with drug-eluting compared than with metal-stents (OR 0.16, 95% CI 0.12 to 0.20). There was moderate heterogeneity ($I^2=42.7\%$).

**Late lumen loss** (nine studies): This was significantly smaller for drug-eluting stents (mean difference -0.46mm, 95% CI -0.55 to -0.38), although heterogeneity was high ($I^2=81.5\%$).

No statistically significant differences between stent types were seen for mortality, myocardial infarction or stent thrombosis for pooled studies or in stratified analyses.

Authors’ conclusions

The treatment of small coronary vessels with drug-eluting stents was safe and effective in the medium term, regardless of the drug used.

CRD commentary

This review had clearly reported selection criteria, which meant that the review could be replicated. A number of databases were searched and efforts were made to locate unpublished studies, although it was not clear if papers in all languages were included to reduce the chance of language bias. It was unclear how many reviewers performed the study selection, data extraction and quality assessment, so the chance of reviewer error or bias could not be ruled out.

Although study quality was assessed, the results were not reported, so the risk of of bias was unclear. Results were pooled using appropriate meta-analysis methods. Generally, the heterogeneity was moderate to low.

Despite some limitations in reporting, the authors’ conclusions seem reliable.

Implications of the review for practice and research

**Practice**: The authors stated that drug-eluting stents should be considered the treatment of choice in a restenosis-prone clinical setting.

**Research**: The authors stated that a large-scale RCT with long follow-up was needed to verify whether these results were maintained for more than one year. More research was also needed into newer drug-eluting stents in this population.

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