Drug-eluting balloons for de novo coronary artery disease: a meta-analysis of angiographic and clinical data
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CRD summary
This review concluded that angiographic and clinical data did not support use of drug-eluting balloons, especially for simple coronary lesions; further studies were required. Some of these findings were based on analyses that included small numbers of patients. The conclusions and the author's suggestion of further research appear reasonable.

Authors' objectives
To evaluate the effectiveness of drug-eluting balloons in the treatment of new coronary artery disease.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched up to December 2012. Search terms were reported. There were no language restrictions.

Study selection
Randomised controlled trials (RCTs) that assessed drug-eluting balloons alone or in combination with bare metal stents as an intervention for new coronary artery lesions were eligible. Studies were required to report angiographic or clinical outcome data and to have a minimum of one year follow-up. Intention-to-treat analysis was required. Primary outcomes were in-segment diameter stenosis (angiographic) and major adverse cardiovascular event (MACE) (clinical). MACE was defined as a composite of death, myocardial infarction and target lesion revascularisation.

Included studies used: drug-eluting balloons alone for small coronary lesions (with a bare metal stent as a "bail out"); or drug-eluting balloons plus systematic bare metal stent use for simple coronary or bifurcation lesions. Control groups were treated either with a bare metal stent alone or with a drug-eluting stent. Where reported, average ages ranged from 55 to 68 years and from 4% to 100% of patients with diabetes. Details of cardiovascular lesions and the balloons and stents used were presented.

Two reviewers independently assessed the studies for inclusion; disagreements were resolved through consensus.

Assessment of study quality
Risk of bias was assessed using relevant criteria such as randomisation method, allocation concealment, blinding and withdrawals and dropouts. They did not report how many reviewers were involved in the assessment.

Data extraction
Data were extracted to enable calculation of mean differences for continuous outcomes and relative risks (RR) for dichotomous outcomes, both with 95% confidence intervals (CI). Where data for the outcome of MACE were not available, data for the most similar outcome were used.

The authors did not state how many reviewers were involved in the data extraction.

Methods of synthesis
The studies were combined in meta-analyses to calculate pooled mean differences for continuous outcomes or pooled relative risks for dichotomous outcomes, each with 95% confidence intervals. Heterogeneity between studies was assessed using Cochran's Q and the I² statistic. A random-effects model analysis was used where I² was 50% or higher; otherwise a fixed-effect model was used. A post hoc subgroup analysis was conducted to explore treatment effects in different types of lesions including simple coronary lesions, small coronary lesions and bifurcation lesions. A sensitivity analysis excluded each study in turn.

Results of the review
Seven RCTs with 1,355 patients (sample size range 60 to 637) were included in the review. Risk of bias was low or
unclear (many criteria were not reported for some trials).

When comparing drug-eluting balloon plus bare metal stent to bare metal stent alone there was no significant difference between the treatment groups for either in-segment diameter stenosis (MD -2.59%, 95% CI -9.31 to 3.94; two RCTs; I²=0%) or major adverse cardiovascular events (RR 0.83, 95% CI 0.48 to 1.46; two RCTs; I²=0%).

When comparing drug-eluting balloon with or without bare metal stent to drug-eluting stent alone there was a worse angiographic outcome in the drug-eluting balloon groups (MD 10.64%, 95% CI 2.41 to 18.87; four RCTs; I²=77%) and a non-significant effect in the same direction for major cardiovascular events (RR 1.54, 95% CI 0.91 to 2.61; six RCTs; I²=54%).

Data for secondary angiographic and clinical endpoints were presented in the paper with broadly similar results.

A post hoc subgroup analysis by type of lesion found that for angiographic outcomes the combination of drug-eluting balloons and bare metal stents was worse than drug-eluting stents alone for simple lesions and for bifurcation lesions; results were not statistically significant for coronary artery lesions. For MACE the combination of drug-eluting balloons and bare metal stents was worse than drug-eluting stents alone for simple lesions but not for coronary artery lesions or bifurcation lesions.

Authors’ conclusions
Angiographic and clinical data did not support use of drug-eluting balloons, especially for simple coronary lesions. Further studies were required.

CRD commentary
The review question was clear and supported by relevant inclusion criteria. The search was adequate. The authors reported assessing the studies in duplicate for inclusion in the review but did not say whether this was also the case for quality assessment and data extraction. The risk of bias assessment appeared to use relevant criteria but was not used to inform the synthesis. Statistical pooling was reasonable although there was some heterogeneity in the analyses of trials with drug-eluting stents as comparators. Subgroup analyses involved some subgroups with very low numbers of patients.

The authors’ conclusions reflect the evidence presented but many of the findings were based on low patient numbers. This was particularly the case for trials that compared the treatment to bare metal stents alone, where patient numbers are very low. Given this, the authors' conclusions reasonably reflect the data and their call for further research is appropriate.

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

Research: The authors stated that further large scale studies were needed to assess newly developed drug-eluting balloons manufactured with modified techniques for the treatment of bifurcation lesions. They also stated a need for investigation of other revascularisation strategies and assessment of drug-eluting balloons in other complex coronary lesions. Longer-term follow-up (beyond one year) was recommended.

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