Drug-eluting or bare metal stents for the treatment of saphenous vein graft disease: a Bayesian meta-analysis

CRD summary
The authors concluded that drug-eluting stents reduced risks of target vessel revascularisation and target lesion revascularisation compared to bare metal stents. Further research was needed to investigate mortality, stent thrombosis and myocardial infarction. The conclusions should be treated with caution due to the unclear quality of included studies, different findings from different study designs and potential for review bias.

Authors' objectives
To compare the effectiveness of drug-eluting stents with that of bare metal stents in the treatment of saphenous vein graft disease.

Searching
PubMed and The Cochrane Library were searched up to June 2010. Search terms were reported. Programmes of international meetings and bibliographies of selected studies were handsearched.

Study selection
Randomised controlled trials (RCTs) and observational studies that compared drug-eluting stents to bare metal stents for treating patients with saphenous vein graft disease were eligible for inclusion. Eligible studies needed to report outcomes for both drug-eluting and bare metal stent groups. Included studies of drug-eluting stents evaluated sirolimus-eluting stents, paclitaxel-eluting stents, tacrolimus-eluting stents and zotarolimus-eluting stents. Most patients were treated with aspirin. Where stated, peri-procedural clopidogrel treatment ranged from one month to more than six months. The mean age of patients was 69 years in the bare metal and 69.5 years in the drug-eluting stents group. Outcomes reported in the review were death from any cause, myocardial infarction (MI), target vessel revascularisation (TVR), target lesion revascularisation (TLR) and stent thrombosis. Follow-up ranged from six to 48 months. Drug-eluting stent groups had greater prevalence of chronic renal insufficiency and lower prevalence of acute coronary syndromes compared to bare metal stent groups.

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
The number of outcome events for each group was extracted at the longest available follow-up for each trial and used to calculate odds ratios (ORs) with 95% credible intervals (CrI). The number of events for death, myocardial infarction and TVR were combined in order to calculate the odds ratio for major adverse cardiac events (MACE).

Two reviewers independently extracted data for the review. Disagreements were resolved by consensus.

Methods of synthesis
Pooled odds ratios with 95% CrI intervals were calculated using a Bayesian hierarchical random-effects model. Low information prior distributions were used and selected independently from any information contained in the included studies. Separate models were calculated for randomised and non-randomised trials. Sub-analysis was conducted for the outcomes of TVR and MACE according to study duration (<18 months, 18 to 30 months, >30 months).

Results of the review
Twenty-five studies were included in the review (5,755 participants): two RCTs (155 participants), one secondary
Use of drug-eluting stents was associated with a significant reduction in risks of target vessel revascularisation (OR 0.55, 95% CrI 0.39 to 0.76; 20 studies, 4,130 participants) and target lesion revascularisation (OR 0.58, 95% CrI 0.37 to 0.87; 17 studies, 3,592 participants) compared to bare metal stents. There were no significant differences between groups for TVR and TLR when only RCTs were considered.

Use of drug-eluting stents was associated with a 38% reduction in the risk of major adverse cardiac events (OR 0.62, 95% CrI 0.46 to 0.81; 24 studies, 5,074 participants) compared to bare metal stents; this difference did not exist when only RCTs were considered.

Use of drug-eluting stents was not associated with a reduction in risks for mortality, myocardial infarction and stent thrombosis. However, drug-eluting stents significantly reduced mortality when only observational studies were considered, OR 0.75 (95% CrI 0.58 to 0.98; 21 studies, 4,949 participants).

Sub-analysis revealed that drug-eluting stents showed a significant reduction in risk of MACE and TVR from 18 to 30 months.

Authors’ conclusions
Drug-eluting stents reduced the risk of TVR and TLR compared to bare metal stents. Research was needed to investigate risks of mortality, stent thrombosis and myocardial infarction when drug-eluting stents were used.

CRD commentary
The review addressed a clear question. Inclusion criteria were well-defined for patients and intervention, but broad for study design. It was unclear whether inclusion criteria for outcomes were specified in advance. An appropriate search was carried out and attempts were made to identify unpublished material. Publication bias was not assessed and so could not be ruled out. It is unclear whether the search was restricted by language and so language bias could not be ruled out. Suitable steps were taken to minimise the risk of reviewer error and bias during data extraction; it was unclear whether similar steps were taken in the study selection stages. It appeared that no validity assessment was carried out.

Most of the included studies were of weaker design. This may have undermined the reliability of the results. Combining randomised and non-randomised studies in meta-analysis was not appropriate and the findings were not significant when only RCTs were considered. Credible intervals were wide for some outcomes. Statistical heterogeneity was not assessed and it was unclear whether the studies were sufficiently homogenous to combine.

The authors’ conclusions should be treated with caution due to the unclear quality of included studies, different findings from different study designs and potential for review bias.

Implications of the review for practice and research
Practice: The authors stated that these findings could not be generalised to newer generation drug-eluting stents.

Research: The authors stated that a large multicentred RCT was needed to compare the safety of drug-eluting stents, especially new generation platforms, with thin strut bare metal stents in saphenous vein graft atherosclerotic lesions.

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