Comparison by meta-analysis of drug-eluting stents and bare metal stents for saphenous vein graft intervention

Lee MS, Yang T, Kandzari DE, Tobis JM, Liao H, Mahmud E

CRD summary
This review concluded that there was evidence to support use of drug-eluting stents for treatment of saphenous vein graft lesions. The risk of missing data and the likely limitations of the included studies and pooled effect sizes mean the findings of the review may not be reliable.

Authors’ objectives
To compare the safety and efficacy of drug-eluting stents in comparison with bare-metal stents for the treatment of saphenous vein graft disease.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched from January 2003 to February 2009. Search terms were reported. Only studies in English published in peer-reviewed journals were eligible for inclusion in the review.

Study selection
Randomised controlled trials (RCTs) and observational studies that compared sirolimus-eluting stents and/or paclitaxel-eluting stents with bare-metal stents for saphenous vein graft were eligible for inclusion in the review. Eligible studies had to follow-up patients for at least six months after the index saphenous vein graft intervention.

Sixty-three per cent of the included studies assessed a combination of sirolimus-eluting and paclitaxel-eluting stents, 21% assessed only sirolimus-eluting stents and the rest assessed only paclitaxel-eluting stents. Drug-eluting stents were usually either Cypher or Taxus. Participant age ranged from 66 to 74 years. The proportion of men ranged from 55% to 100%. The proportion of participants with diabetes ranged from 12% to 54%. The proportion of patients with hypercholesterolaemia ranged from 42% to 98%. Where reported, between 19% and 65% of patients underwent a previous percutaneous coronary intervention and ejection fractions ranged from 42% to 72%. Stent length ranged from 12.1mm to 2,029.3mm and stent diameter ranged from 1.84mm to 4.2mm. Mean length of follow-up was 20 months (range six to 48 months). Distal embolic protection was evident in between 1.6% to 71.2% of participants. The primary endpoint in the included studies was target vessel revascularisation. Secondary end points were death, myocardial infarction and stent thrombosis.

The authors did not state how papers were selected for the review.

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

Data extraction
Two reviewers independently extracted study data. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated.

Methods of synthesis
Studies were grouped according to outcome. Pooled odds ratios with 95% CIs were calculated using a fixed-effect analysis. Studies were pooled using a random-effects model to analyse heterogeneity. Statistical heterogeneity was calculated using the Q statistic.

Results of the review
Nineteen studies (n=3,420) were selected for inclusion: two RCTs (n=155) and 17 registries (n=3,265). Sample size ranged from 39 to 482.
In comparison with bare-metal stent patients, patients with a drug-eluting stent had a significantly lower rate of target vessel revascularisation (OR 0.59, 95% CI 0.49 to 0.72; 19 studies; p=0.0001 significant heterogeneity) and myocardial infarction (OR 0.69, 95% CI 0.49 to 0.99; 15 studies; p=0.03 significant heterogeneity). There were no significant differences between the two groups with respect to mortality (18 studies) and stent thrombosis (six studies); there was no evidence of significant statistical heterogeneity. Further analyses using a random-effects model showed similar results.

**Authors' conclusions**
The findings supported use of drug-eluting stents for saphenous vein graft lesions.

**CRD commentary**
This review assessed a clearly defined review question. Relevant electronic databases were searched for eligible studies. There were risks of publication and language biases as only studies published in English were included in the review. Some attempt was made to reduce risks of reviewer error and bias by multiple reviewers extracting study data; it was unclear whether similar precautions were used when selecting studies for inclusion. The reliability of the data was unclear given the lack of any assessment of methodological quality; inclusion of a large amount of registry data made the study findings likely to be at risk of bias. There was evidence of significant statistical heterogeneity and clinical differences were evident between the studies.

The reviewers had previously received funding from a number of different pharmaceutical companies including Shering-Plough, Boston Scientific, Bristol-Myers Squibb, Medtronic, Cordis, Johnson & Johnson and Abbott Vascular.

The risk of missing data and the likely limitations of the included studies and pooled effect sizes mean the findings of the review may not be reliable.

**Implications of the review for practice and research**
The authors did not report any implications for practice or research.

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