Drug-eluting stents versus bare-metal stents in saphenous vein graft interventions: a systematic review and meta-analysis

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CRD summary
The review concluded that, compared with bare-metal stents, drug-eluting stent use was associated with improved clinical outcomes with no evidence of increased myocardial infarction or thrombosis in patients with saphenous vein grafts percutaneous coronary interventions. The poor quality of some of the included studies and variation across studies limit the reliability of the authors’ conclusions.

Authors’ objectives
To evaluate the benefits and safety of bare-metal stents compared with drug-eluting stents in patients with saphenous vein graft percutaneous coronary interventions.

Searching
MEDLINE, EMBASE, the Cochrane Library, CINAHL, BIOSIS Previews, and the US Food and Drugs Administration (FDA) website were searched to December 2009. Search terms were reported. Reference lists of eligible studies and relevant reviews were scanned.

Study selection
Randomised controlled trials (RCTs) and cohort studies that examined the use of drug-eluting stents versus bare-metal stents during saphenous vein graft interventions were eligible for inclusion. Studies with historic controls were included. Studies that reported only ultrasound or quantitative angiography data were excluded if they did not provide discernible clinical outcomes.

The relevant outcomes were all cause mortality, major adverse cardiac events, target vessel revascularisation, target lesion revascularisation, myocardial infarction and stent thrombosis.

The included studies compared bare-metal stents versus paclitaxel, sirolimus, tacrolimus and zotarolimus eluting stents. The mean age of patients ranged from 64.9 to 73 years. Most studies did not require angiographic follow-up. The use of embolic protective devices ranged from 1.6 to 100% (where reported). The definition of major adverse cardiac events varied between studies.

Two authors independently performed study selection and disagreements were resolved by discussion or consultation with a third reviewer.

Assessment of study quality
Quality assessment was undertaken using the criteria devised by Juni et al, and a modified Newcastle Ottawa scale. Quality items including blinding, loss to follow-up, and allocation concealment were assessed.

The authors did not state how many reviewers performed quality assessment.

Data extraction
Two reviewers independently extracted data on clinical outcomes and adverse events, and used the data to calculate odds ratios (OR) and 95% confidence intervals (CI).

Methods of synthesis
A random-effects meta-analysis was undertaken to obtain pooled odds ratios and 95% confidence intervals. Heterogeneity was assessed using $\Gamma^2$ and graded as low ($\Gamma^2=25\%$), moderate ($\Gamma^2=50\%$) or high ($\Gamma^2=75\%$). Subgroup analyses were undertaken for type of study design, type of controls (historic versus concurrent controls), and the
frequency of use of distal embolic protection device. The absolute risk reduction (ARR) and number needed to treat (NNT) were also calculated. Publication bias was assessed using funnel plots.

**Results of the review**

Twenty-three studies were included in the review (n=5,324 patients): four RCTs and 19 cohort studies (eight of which used a historical control group only). The study sample size ranged from 39 to 1,128 patients. The length of follow-up ranged from six to 48 months. The quality of the included studies was variable, with most studies failing to blind patients, assessors and carers; most had complete follow-up.

For drug-eluting stents, there was a statistically significantly lower rate of all-cause mortality (OR 0.72, 95% CI 0.58 to 0.89; I²=5.0%; 22 studies), target lesion revascularisation (OR 0.57, 95% CI 0.40 to 0.82; I²=53%; 17 studies), target vessel revascularisation (OR 0.56, 95% CI 0.40 to 0.77; I²=67%; 20 studies) and major adverse cardiac events (OR 0.61, 95% CI 0.47 to 0.79; I²=66%; 21 studies) compared with bare-metal stents. There was no difference in the rates of recurrent myocardial infarction or stent thrombosis. The use of with drug-eluting stents was not associated with increased complications in the treatment of saphenous vein graft lesions.

There were no treatment group interactions in the subgroup analyses, although there was moderate heterogeneity across studies. All-cause mortality was higher with drug-eluting stents in the RCTs (OR 2.33; 95% CI 0.31 to 17.77).

Funnel plot publication bias assessment was inconclusive.

**Authors’ conclusions**

Compared with bare-metal stents, drug-eluting stent use was associated with improved clinical outcomes with no evidence of increased myocardial infarction or thrombosis in patients with saphenous vein grafts percutaneous coronary interventions.

**CRD commentary**

Inclusion criteria for the review were broadly defined. Several relevant data sources were searched. It was not clear if non-English language studies were included, which made the risk of language bias difficult to determine. Publication bias was assessed but was inconclusive. Attempts were made to reduce reviewer error and bias during study selection and data extraction, but it was not clear these applied to quality assessment.

Quality assessment, based on standard criteria, indicated the variable quality of the included studies, which the authors acknowledged. A random-effects meta-analysis was undertaken and statistical heterogeneity was assessed, which appeared appropriate. Subgroup analyses were pre-specified, but there was heterogeneity across studies.

The review was generally well conducted, but the poor quality of some of the included studies and heterogeneity in some analyses limit the reliability of the authors’ conclusions.

**Implications of the review for practice and research**

**Research:** The authors stated that large RCTs with longer follow-up are needed to assess the durability of benefits. Double-blind RCTs are also needed to determine the impact of angiographic follow-up and the generalisability of results.

**Practice:** The authors did not state any implications for practice.

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