Effectiveness and safety of drug-eluting stents in vein grafts: a meta-analysis

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CRD summary
The review concluded that observational studies suggested that use of drug-eluting stents for vein graft stenosis had favourable effects, but that results from such studies should be interpreted with caution and randomised trial data were inconclusive. Limitations in the conduct and reporting of the review left a degree of uncertainty surrounding the reliability of the conclusions.

Authors' objectives
To compare the safety and effectiveness of drug-eluting stents with bare-metal stents for the treatment of vein graft stenosis.

Searching
PubMed and Cochrane Central Register of Controlled Trials (CENTRAL) were searched between 2003 and February 2009 for studies published in English; search terms were reported. Reference lists were searched.

Study selection
Randomised controlled trials (RCTs) and observational studies (follow-up duration ≥6 months) that compared the effectiveness and safety of drug-eluting stents with bare-metal stents for vein graft stenosis were eligible for inclusion. Studies had to report clinical outcomes. Major advance cardiac events, all-cause mortality, myocardial infarction, target-lesion revascularisation and target-vessel revascularisation were the main outcomes of interest.

All studies were of patients with de novo lesions in a vein graft; lesion lengths ranged from 8.7mm to 19.3mm and mean ages of vein grafts from 7.5 to 12.9 years (in treatment arms, where reported). Most studies included sirolimus-eluting stents, paclitaxel-eluting stents or both as interventions. Where reported, all studies also used heparin (sometimes with bivalirudin) and glycoprotein IIb-IIIa inhibitors. Most participants were male. Mean age (by treatment group) ranged from 65 to 73 years. Many participants had hypertension and/or diabetes mellitus. Following treatment, dual antiplatelet therapy (acetylsalicylic acid and clopidogrel) was recommended for at least three to six months in all studies. Use of embolic protection devices varied between studies.

The authors did not state how many reviewers selected studies.

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

Data extraction
Data were extracted in order to calculate odds ratios (ORs) with 95% confidence intervals (CI).

Two reviewers independently extracted data. Disagreements were resolved by a third reviewer.

Methods of synthesis
Meta-analyses of pooled odds ratios and 95% CIs were performed using a random-effects model and reported by study design.

Results of the review
Eighteen observational studies (n=3,421) and two RCTs (n=155) were included. Sixteen observational studies were retrospective and two were prospective. Follow-up periods ranged from six to 34 months.

Observational studies: Compared with bare-metal stents, drug-eluting stents were associated with a decreased risk of major advance cardiac events (OR 0.50, 95% CI 0.35 to 0.72; 15 studies), and reduced mortality (OR 0.69, 95% CI 0.45 to 0.99; 12 studies).
0.53 to 0.91; 16 studies), target-vessel revascularization (OR 0.54, 95% CI 0.37 to 0.79; 16 studies) and target-lesion revascularization (OR 0.54, 95% CI 0.37-0.78; 12 studies). There was no significant difference between treatments in terms of myocardial infarctions.

Pooled results from the two RCTs showed no significant differences between treatments for any outcome.

**Authors' conclusions**
Observational studies suggested that use of drug-eluting stents for vein graft stenosis had favourable effects, but results from these studies should be interpreted with caution. Corresponding randomised controlled trial data were inconclusive.

**CRD commentary**
The review addressed a clear question and was supported by appropriate inclusion criteria. Attempts to identify relevant studies were limited to searching two electronic databases for studies published in English, so it is possible that relevant studies were missed and the review may have been subject to publication or language bias (acknowledged by the authors). Suitable methods (such as independent duplicate processes) were employed to reduce risks of reviewer error and bias for data extraction; the authors did not report on whether such methods were used during study selection. Study quality was not appraised, so it was not possible to assess the strength of the evidence (although most studies were observational). Sufficient study details were provided, but it was unclear whether pooling data by meta-analysis was appropriate there was no assessment of clinical or statistical heterogeneity.

The authors' conclusions were suitably cautious in reflecting the seemingly limited evidence, but shortcomings in the conduct and reporting of the review left a degree of uncertainty surrounding their reliability.

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

**Research:** The authors stated a need for large multicentre RCTs to examine use of drug-eluting stents in vein grafts and reported that a study (BASKETSAVAGE) was ongoing, with results expected in 2014. They added that, with respect to stent thrombosis, the long-term effect of drug-coated devices and polymers in locations more lipid rich, softer and prone to rupture needed to be clarified.

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