Clinical effectiveness of bare-metal stenting compared with balloon angioplasty in total coronary occlusions: insights from a systematic overview of randomized trials in light of the drug-eluting stent era

CRD summary
This review compared stenting with percutaneous transluminal coronary angioplasty (PTCA) for total coronary occlusion. The authors concluded that stenting reduces major adverse cardiac events compared with PTCA, but increases periprocedural minor myocardial damage. Incomplete reporting of review methods and the lack of an adequate validity assessment mean that the robustness of the authors' conclusion cannot be confirmed.

Authors' objectives
To compare bare-metal stenting with percutaneous transluminal coronary angioplasty (PTCA) in the management of patients with total coronary occlusion.

Searching
MEDLINE and the Cochrane CENTRAL Register were searched from 1994 to December 2004 using the reported keywords. Reference lists and conference proceedings (2000 to 2004) of four named societies were screened and experts were contacted for details of other relevant trials. No language restrictions were applied.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) that analysed data on an intention-to-treat basis were eligible for inclusion. The duration of follow-up ranged from 6 months to 6 years.

Specific interventions included in the review
Studies that compared stenting versus PTCA were eligible for inclusion. In the included studies, patients treated with stenting received aspirin plus an oral anticoagulant for 1 to 3 months or double antiplatelet therapy for 1 month. Patients treated with PTCA generally received only aspirin; one PTCA study administered ticlopidine in addition to aspirin. Crossover from PTCA to stent was not allowed in any study.

Participants included in the review
Studies of patients with coronary artery occlusion that had lasted at least 3 days were eligible for inclusion. Studies of patients with acute myocardial infarction (MI) (defined as less than 72 hours after the onset of MI) were excluded. The mean age of the participants in the included studies was 59.3 years. Where reported, overall, 77.8% of the participants were men and 19.2% had diabetes. The minimum duration of occlusion ranged from 3 to 30 days and the proportion of patients with a previous MI ranged from 32 to 68%. In all of the included studies, patients were allocated to treatments only after successful crossing of the artery occlusion.

Outcomes assessed in the review
The primary review outcome was the incidence of major adverse cardiac events (MACE), defined as a composite of death, MI and repeated revascularisation, in the medium term (4 to 12 months) and long term (more than 2 years). The review also assessed each component of the composite outcome separately, as well as angiographic results.

How were decisions on the relevance of primary studies made?
One reviewer conducted the searches. Abstracts and titles were screened and full reports of potentially relevant studies were evaluated for inclusion. The authors did not state how many reviewers performed the selection.
Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
Two reviewers independently extracted the data onto a structured form. Any disagreements were resolved through consensus. For each study, dichotomous outcomes were extracted as proportions and percentages and continuous outcomes were extracted as means.

Methods of synthesis
How were the studies combined?
Pooled odds ratios (ORs) with 95% confidence intervals (CIs) were calculated for dichotomous data using both fixed-effect (Mantel-Haenszel) and random-effects (DerSimonian and Laird) models. Only results for the random-effects model were reported in the review. Weighed mean differences with 95% CIs were calculated for continuous outcomes using a random-effects model (DerSimonian and Laird). The number-needed-to-treat was calculated, along with its 95% CIs, from pooled random-effects risk differences.

How were differences between studies investigated?
Heterogeneity was assessed using the chi-squared statistic. Studies that reported long-term (more than 2 years) follow-up were analysed separately. Subgroup analyses were used to evaluate the effects of oral anticoagulant versus thienopyridine, older versus more recent studies, and the monitoring of cardiac enzymes after treatment.

Results of the review
Nine RCTs (n=1,409) were included.

Midterm follow-up (9 RCTs).
There was no significant difference in death rates between stenting and PTCA (0.4% versus 0.7%, p=0.6). Stenting was associated with a significant increase in the rate of MI (6.7% versus 3.4%; OR 2.06, 95% CI: 1.22, 3.46, p=0.006) and a significant reduction in the risk of repeat revascularisation (17% versus 32%; OR 0.41, 95% CI: 0.31, 0.53, p<0.0001).

MACE were significantly less common after stenting compared with PTCA (23.2% versus 35.4%; OR 0.49, 95% CI: 0.36, 0.68, p=0.0001).

Angiographic restenosis was significantly less common after stenting compared with PTCA (41.1% versus 60.9%; OR 0.36, 95% CI: 0.23, 0.57, p<0.0001), as was the reocclusion rate (6.8% versus 16.0%; OR 0.36, 95% CI: 0.22, 0.59, p<0.0001).

Long-term follow-up (4 RCTs).
MACE were significantly less common after stenting compared with PTCA (30.7% versus 45.5%; OR 0.42, 95% CI: 0.22, 0.79, p=0.007).

The number-needed-to-treat with stenting compared with PTCA was 7 (95% CI: 5, 10) to prevent one revascularisation and 10 (95% CI: 7, 20) to prevent one reocclusion. No significant heterogeneity was found for any of the above analyses. The results were similar across subgroup analyses.

Authors' conclusions
Compared with PTCA, stenting reduces MACE, repeated revascularisation, and angiographic restenosis and reocclusion. However, these adverse effects are still frequent and stenting increases periprocedural minor myocardial damage.
CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched and attempts were made to reduce language and publication bias. Methods were used to minimise reviewer errors and bias in the extraction of data, but it was unclear whether similar steps were taken when selecting the studies. Only RCTs that reported the results of an intention-to-treat analysis were included, but there was no systematic assessment of study quality.

The characteristics of the participants and interventions were adequately reported. Statistical heterogeneity was assessed and the studies were appropriately combined using meta-analyses. Subgroup analyses were used to examine the influence on the results of several factors. Although the authors’ conclusions appear to be supported by the data presented, the incomplete reporting of review methods and the lack of an adequate validity assessment mean that the robustness of the authors’ conclusion cannot be confirmed.

Implications of the review for practice and research
Practice; The authors stated that coronary collaterals should be taken into account in routine clinical practice, owing to the potential for periprocedural myocardial necrosis and effects on long-term patency. They do not recommend the routine use of glycoprotein IIB/IIA inhibitors (especially at the start of stenting) since they may expose patients to the risk of cardiac tamponade; this recommendation does not appear to be based on data evaluated in the review.

Research: The authors stated that well-conducted registries and RCTs are required to determine the effectiveness of drug-eluting stents (DES), and a future RCT comparing DES with bare metal stents should be undertaken with between 170 and 225 patients per treatment arm. They also stated that there is a need to evaluate new interventions to reduce repeated revascularisation and periprocedural MI associated with stenting. Further research should also examine the benefits and harms of percutaneous interventions on infarct-related artery occlusions.

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