A quantitative estimate of bare-metal stenting compared with balloon angioplasty in patients with acute myocardial infarction: angiographic measures in relation to clinical outcome

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CRD summary
This review compared bare-metal stenting with balloon angioplasty after acute myocardial infarction. The authors concluded that bare-metal stenting was superior to balloon angioplasty for angiographic outcomes (reocclusion, restenosis, target vessel revascularisation), but that clinical outcomes were similar (mortality, reinfarction). Trial quality was not reported and longer follow-up may be needed. These cautious conclusions appear reliable.

Authors' objectives
To quantify the treatment effect of bare-metal stenting compared with balloon angioplasty on angiographic measures of infarct-related artery patency in relation to clinical outcomes in patients with acute myocardial infarction (AMI).

Searching
MEDLINE and EMBASE (both from 1990 to February 2006) and the Cochrane Library (Issue 2, 2005) were searched; the search terms were listed. There were no language restrictions. In addition, relevant reviews and reference lists of retrieved studies were examined.

Study selection
Study designs of evaluations included in the review
Studies were eligible if they were randomised controlled trials (RCTs).

Specific interventions included in the review
Studies were eligible if they assessed bare-metal stenting in comparison with balloon angioplasty. Studies of rescue angioplasty, of interventions carried out more than 48 hours after the onset of symptoms, of coronary artery bypass grafts/small vessels, or of drug-eluting stents or thrombectomy devices, were excluded. In the included trials, the interventions occurred between less than 6 hours and less than 48 hours after symptom onset. The use of concomitant medication with respect to antiplatelet treatment and use of abciximab varied between trials. The rates of repeat angiography were roughly the same in the comparison groups of each trial. Two trials included all vessel sizes, while the others looked at medium-calibre vessels.

Participants included in the review
Studies were eligible if they assessed patients with objectively diagnosed AMI. Studies including only patients with cardiogenic shock were excluded. Demographic data were not provided.

Outcomes assessed in the review
Studies were eligible if they reported core laboratory data on quantitative angiographic analysis and clinical outcomes at follow-up. Primary angiographic outcomes of interest included the rates of reocclusion (defined as a completely occluded lesion), restenosis (defined as a stenosis of more than 50%) and sub-acute thrombosis at angiographic follow-up. Secondary angiographic outcomes included thrombolysis in myocardial infarction (TIMI) flow 3 after coronary intervention as a measure of successful infarct-related artery perfusion, and quantitative coronary angiographic parameters after the coronary intervention and at follow-up. Clinical outcomes at the latest available follow-up included all-cause mortality, myocardial reinfarction, target vessel revascularisation, emergency coronary bypass grafting and bleeding complications.

How were decisions on the relevance of primary studies made?
Two authors independently evaluated studies for eligibility. Any disagreements were resolved by consensus.

Assessment of study quality
The authors did not report how they assessed trial validity, or how many authors were involved in the validity
assessment. It appears that there was some assessment of the randomisation techniques employed in the trials. The analysis was not weighted using quality scoring, as the authors considered that there were no validated quality scales and that the use of subjective rating scales might lead to bias.

**Data extraction**

Two authors independently extracted the data using a pre-specified data extraction form. Authors of primary studies were contacted for additional or missing information. Any discrepancies were resolved by consensus. Odds ratios (ORs) with 95% confidence intervals (CIs) were calculated for dichotomous variables.

**Methods of synthesis**

How were the studies combined?

Only outcome measures reported on an intention-to-treat basis were used in the analysis. Angiographic follow-up results of less than 6 months after the acute event were not included in the pooled analysis. The data were pooled in a meta-analysis. ORs for dichotomous data were combined using both the Mantel Haenszel fixed-effect model and a random-effects model.

How were differences between studies investigated?

Heterogeneity was assessed with a significance level set at 0.1, but details of the assessment were not reported.

**Results of the review**

Ten RCTs (n=6,192) were included in the review.

Significant heterogeneity was observed when assessing post-procedural TIMI flow 3, restenosis, reinfarction and target vessel revascularisation, so the results were presented using the random-effects model.

No significant difference between bare-metal stenting compared with balloon angioplasty was found with respect to the rates of multi-vessel disease (52% versus 51%), TIMI flow 0/1 before angioplasty (71% versus 74%), TIMI flow 3 after angioplasty (94% versus 93%), emergency coronary artery bypass grafting (2% versus 2%), or bleeding complications (defined as bleeding requiring transfusion or surgical repair, and intracerebral haemorrhage); 2% versus 2%).

Reocclusion was significantly less frequent after bare-metal stenting than after balloon angioplasty (7 trials): 6.7% versus 10.1% (OR 0.62, 95% CI: 0.40, 0.96, p=0.03). Similarly, there was significantly less restenosis after bare-metal stenting than after balloon angioplasty (7 trials): 23.9% versus 39.3% (OR 0.45, 95% CI: 0.34, 0.59, p<0.001). There was no significant difference in sub-acute thrombosis between the groups (6 trials): 1.7% versus 1.7% (OR 0.82, 95% CI: 0.42, 1.59, p=0.55).

There was no significant difference in all-cause mortality between the bare-metal stenting and balloon angioplasty groups. The OR for mortality at the longest available follow-up was 1.03 (95% CI: 0.82, 1.30, p=0.79). Similarly, there was no significant difference between the interventions in reinfarction rate (defined as recurrent chest pain with new ST segment elevation and recurrent increase of cardiac enzymes); the OR at the longest available follow-up was 0.86 (95% CI: 0.54, 1.37, p=0.54).

Target vessel revascularisation rates were 12.2% in the bare-metal stenting group and 19.2% in the balloon angioplasty group (OR 0.50, 95% CI: 0.37, 0.69, p<0.001).

**Authors’ conclusions**

Compared with balloon angioplasty supported by provisional stenting, routine bare-metal stenting results in a significant benefit in terms of reocclusion and restenosis. There were no differences in sub-acute thrombosis between the groups, but there were benefits from bare-metal stenting with respect to target vessel revascularisation. However, no differences were seen in mortality or reinfarction rates, but follow-up may not have been long enough to detect relevant benefits.

**CRD commentary**

This review had clearly stated inclusion criteria with respect to the study design, participants, interventions and
outcomes. The authors searched two relevant databases and efforts were made to identify supplemental information. The study selection and data extraction processes were conducted in duplicate, thus reducing the potential for error and bias. However, as the authors considered that quality could not be reliably assessed, no validity assessment of the studies was included.

Study details were tabulated. The authors cautioned that the interpretation of the data may be limited by the clinical heterogeneity between the trials. Some of the studies were designed to randomise patients after successful balloon angioplasty, and changing trends in concomitant pharmacotherapy and in stent technology may have resulted in differences between earlier and later trials. Given the limitations of the available evidence, the authors’ conservative conclusion and recommendation for further research seem appropriate and reliable. Overall, the conclusions appear to be consistent with the data presented.

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

Practice: The authors stated that the results support bare-metal stent placement in AMI.

Research: The authors stated that the discrepancy between angiographic and clinical outcome measures has important implications for future studies investigating further technical improvements, such as drug-eluting stents and devices for distal protection of the affected vessel.

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