Primary stent implantation compared with primary balloon angioplasty for acute myocardial infarction: a meta-analysis of randomized clinical trials

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Authors' objectives
To compare the effectiveness of coronary stenting to balloon angioplasty (PTCA) as primary revascularisation for acute myocardial infarction (AMI).

Searching
Searches were conducted of MEDLINE (from 1990 to December 2000) and the scientific session abstracts in Circulation, Journal of the American College of Cardiology and the European Heart Journal (from 1995 to 2000). In addition, the reference lists of identified trials and reviews were checked for relevant studies.

Study selection
Study designs of evaluations included in the review
Only randomised controlled studies were included.

Specific interventions included in the review
Comparisons of coronary stenting and balloon angioplasty were included. The stents used in the trials were Palmaz-Schatz (with and without heparin), Gianturco-Roubin, Gianturco-Rubin II, Witkot-GX, TensumIII, Witkor and MultiLink (Duet). In the included trials, the use of thrombolytics as adjunctive treatment was 'infrequent'. One trial compared the efficacy of stents and PTCA alone, and in combination with a platelet glycoprotein IIb/IIIa inhibitor (abciximab). In another small trial this drug was used in 48% of each group.

Participants included in the review
Patients with AMI. In the included studies, the participants were eligible for inclusion at 6, 12 or 24 hours following an AMI event and with vessel diameters less than 2.5 to 4.5 mm. Patients with cardiogenic shock were included in 4 of the smaller trials, but were excluded from the others. Some studies included patients with evidence of ongoing ischaemia and with heart failure.

Outcomes assessed in the review
The outcomes assessed were death, reinfarction, target vessel revascularisation (TVR), and a composite of major adverse cardiac events (MACE; i.e. death, reinfarction and TVR). The outcomes were assessed at 6 months or more (taken from the longest follow-up reported in the individual trials).

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.

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

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

The following data were extracted: the number of sites the study was undertaken at; the number of patients randomised to each treatment; the time of symptoms onset; vessel diameter; first-choice stent; crossover (%); duration of follow-up; and outcomes, i.e. death, reinfarction, TVR and MACE. The data were extracted on an intention-to-treat principle. The
odds ratio (OR) and 95% confidence intervals (CIs) were calculated using the method of Woolf (see Other Publications of Related Interest no.1), to assess the comparative effectiveness of primary stenting versus angioplasty in each individual trial. The authors of the studies were contacted for missing data.

**Methods of synthesis**

**How were the studies combined?**
The pooled ORs and 95% CIs were calculated using the Mantel-Haenszel fixed-effect model (see Other Publications of Related Interest no.2).

**How were differences between studies investigated?**
Heterogeneity was examined using the Breslow-Day test (See Other Publications of Related Interest no 2). A subgroup analysis was performed, excluding the abciximab arms of one large trial. A sensitivity analysis was also performed to assess the stability of overall estimates when one very large trial was omitted.

**Results of the review**

Nine trials (4,120 participants) were included.

In comparing stenting to PTCA, there was no statistically-significant difference in mortality or reinfarction up to 6 to 12 months after AMI; the OR was 1.04 (95% CI: 0.75, 1.44) for mortality and 0.71 (95% CI: 0.47, 1.08) for reinfarction. There was evidence that primary stenting was superior to PTCA in reducing the need for TVR (OR 0.43, 95% CI: 0.36, 0.52), and also for MACE (OR 0.52, 95% CI: 0.44, 0.62). The main component influencing this favourable composite outcome (MACE) was the effect on TVR. The subgroup analysis showed similar results, except that the difference in reinfarction rate between the two treatments was further widened to approaching statistical significance (OR 0.61, 95% CI: 0.38, 1.00). The sensitivity analysis (excluding one very large study) showed no substantial changes to the main summary results. No statistically-significant heterogeneity was observed across the studies.

**Authors' conclusions**
The evidence showed that after AMI, primary stenting is superior to primary angioplasty in reducing TVR over a 6- to 12-month follow-up period. However, with regard to the 'hard' end points of death and reinfarction, the trials show no clear difference between stenting and angioplasty.

**CRD commentary**
The aims of the paper were clearly identified. Only MEDLINE was searched and the search terms were not described, although the reviewers did search relevant abstracts and reference lists. It was not mentioned whether the search was restricted to English language articles or not. Two trials were excluded because of insufficient data, and there was no mention of whether the authors of these trials were contacted for missing information. It is therefore possible that relevant studies were missed. The methods used for the study selection, data extraction and quality assessment processes were not described. There was little information on the participants in the individual trials. In addition, the authors pointed out that most of the trials included only 'lower risk' patients, in that those with cardiogenic shock were excluded and the overall death rate was low. It may, therefore, be difficult to generalise from these results. Heterogeneity was appropriately investigated.

Overall, bearing in mind the above comments, the evidence would seem to support the authors’ conclusions.

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

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

**Research:** The authors state that further research is needed to determine whether a small but important difference in mortality exists between these two treatments. Emphasis should be put on including patients at a higher risk.
Bibliographic details

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Other publications of related interest

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.