Evidence for use of coronary stents: a hierarchical Bayesian meta-analysis

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CRD summary
This review compared routine coronary stenting with standard percutaneous transluminal coronary angioplasty (PTCA). The authors concluded that routine coronary stenting is safe but is not associated with reduced mortality, acute myocardial infarction or coronary artery bypass grafting in comparison with PTCA with provisional stenting, and that the reduction in restenosis rate is small. The authors’ conclusions are likely to be reliable.

Authors’ objectives
To compare routine coronary stenting with standard percutaneous transluminal coronary angioplasty (PTCA).

Searching
MEDLINE was searched to June 2002 for studies reported in any language; the search terms were given. Handsearches of general medical and cardiology journals (9 journals listed) and reference lists in identified studies and recent reviews were also conducted. The reviewers also consulted agencies known to perform systematic reviews.

Study selection

Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared routine coronary stenting with PTCA were eligible for inclusion. Studies of primary angioplasty for acute myocardial infarction were excluded. The included studies used various types of stent (further details were provided).

In most studies some patients crossed over from PTCA to stenting.

Participants included in the review
Studies of patients with stable and unstable angina were included. The participants in the included studies had various types of lesions, including large and small native vessels, occluded and restenosed native arteries, and bypass grafts. The mean age of the participants ranged from 52.1 to 66 years and the proportion of female patients ranged from 12.5 to 66%.

Outcomes assessed in the review
All of the studies included in the review assessed total mortality, myocardial infarction and repeat angioplasty. Angiographic restenosis, coronary artery bypass surgery, repeated PTCA and freedom from angina were also assessed. In all but three studies, patients underwent angiographic follow-up at 6 to 12 months and reported results as the number of patients with a recurrent blockage exceeding 50% at the site of the original intervention. All of the included studies followed up patients for at least 6 months (range: 6 to 12).

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

Assessment of study quality
The authors reported on blinding, intention-to-treat analysis and losses to follow-up, but no formal validity assessment was described.
Data extraction
Two reviewers independently extracted the data and reached consensus through discussion. The extracted data included the number of patients in each treatment group, the rate of stent crossover, and whether angiographic follow-up was performed. All data were extracted on an intention-to-treat basis, so that patients who were crossed over were analysed as being in their assigned group.

Methods of synthesis
How were the studies combined?
The studies were combined using a Bayesian hierarchical random-effects meta-analysis (further details were provided). Pooled odds ratios (ORs) and 95% equal-tailed credible intervals (CrIs) were calculated for each outcome.

The results of meta-analyses were presented in forest plots. The association between the crossover rate and repeat angioplasty rates was explored by plotting the difference in repeat angiography rates between treatment arms in individual studies against the percentage crossover to stenting. Angiographic restenosis rates for stenting of occluded and nonoccluded lesions were compared.

How were differences between studies investigated?
The Bayesian analysis modelled variability among trials. The meta-analysis also took account of variability among studies in the anatomic lesion, rate of crossover stenting and the type of stent. The analysis was adjusted for potential bias due to a lack of blinding by assuming a constant ratio of repeated angioplasties-to-angiographic restenosis in each treatment group. This allowed the upper bound for the OR for repeated PTCA to be estimated.

Results of the review
Twenty-nine RCTs (n=9,918) were included.

All of the studies analysed data on an intention-to-treat basis. Almost no patients were lost to follow-up. Blinding was not applicable given the nature of the interventions.

There was no statistically significant difference between routine stenting and standard PTCA for death or myocardial infarction (OR 0.90, 95% CrI: 0.72, 1.11), or the need for coronary artery bypass surgery (OR 1.01, 95% CrI: 0.79, 1.31).

Stenting significantly reduced the rate of restenosis (OR 0.52, 95% CrI: 0.37, 0.69) and the need for repeat PTCA (OR 0.59, 95% CrI: 0.50, 0.68).

The rates of crossover from PTCA to stenting ranged from 0 to 65%.

A smaller percentage of patients with documented angiographic stenosis originally assigned to stents underwent a second percutaneous intervention compared with those assigned to the PTCA group (68.6% versus 77.8% for the original PTCA group). After adjusting for the potential bias due to lack of blinding, the authors estimated that stents reduced repeated angioplasty by a smaller margin than the unadjusted estimates (OR 0.90, 95% CrI: 0.68, 1.18).

Six studies reported angina status. Angina disappeared or was reduced in 67% of the stent group versus 61% of the PTCA group (difference 6%, 95% CrI: 3, 9).

Authors' conclusions
In the setting of RCTs, routine coronary stenting was safe but was not associated with reductions in mortality, acute myocardial infarction or coronary artery bypass grafting when compared with standard PTCA with provisional stenting. An association between stenting and reduced restenosis rates and the subsequent need for repeat PTCA may have been overestimated in the trials, owing to the lack of study blinding.

CRD commentary
The review question was clear but the inclusion criteria were explicitly defined only for the study design and intervention. Several relevant sources were searched, the search terms were stated and attempts were made to minimise language bias. No attempt was made to locate unpublished studies, thus raising the possibility of publication bias. The methods used to select the studies were not described, so it is not known whether any efforts were made to reduce errors and bias. Two reviewers independently extracted the data and this reduces the potential for bias and errors. Although validity was not formally assessed, the reviewers commented on the type of analysis and drop-outs.

The data were combined in a meta-analysis that modelled some of the characteristics that varied within and among studies. Estimates of repeat angioplasty rates were estimated before and after adjusting for potential bias due to a lack of blinding. The authors' conclusions are likely to be reliable.

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

**Practice:** The authors stated that individual health care systems must determine whether the limited benefits from routine stenting outweigh the additional costs.

**Research:** The authors stated that research is required to determine the role of drug-eluting stents.

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