Coronary stents: an appraisal of controlled clinical studies
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Authors' objectives
To assess the clinical efficacy and effectiveness evidence for the elective or emergent use of coronary stents.

Searching
MEDLINE and HEALTH databases were searched from 1990 to 1996 (search terms given). HSTAR, ECRINET, HSResearch and Federal Research in Progress were also searched from 1990 to 1996 and Current Contents up to October 1996. Contact with experts was made to identify published and unpublished studies and reference lists of all retrieved articles were made.

Study selection
Study designs of evaluations included in the review
Controlled studies only were included; uncontrolled case series were excluded.

Specific interventions included in the review
Coronary stents: elective stenting versus percutaneous transluminal coronary angioplasty (PTCA) or emergent stenting versus prolonged angioplasty.

Participants included in the review
Patients with de novo or restenotic coronary artery lesions. The average age of patients in the included trials ranged from approximately 53 to 63 years, and about 80% of trial participants were male. Rates of previous myocardial infarction (MI) in included studies varied from 20 to 51%. The proportion of patients with Class III/IV angina (where stated) varied from approximately 50 to 70%.

Outcomes assessed in the review
The primary outcomes which were identified as being of importance were angina and changes in symptoms, functional status, myocardial infarction and mortality.

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 authors performed the selection.

Assessment of study quality
Each study was formally assessed using a checklist of standard quality criteria. Three researchers performed the quality assessment.

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

Methods of synthesis
How were the studies combined?
A narrative review was undertaken.

How were differences between studies investigated?
Differences between the studies were not discussed formally. However, some differences were highlighted in the
narrative review of studies.

**Results of the review**

Twelve controlled studies were included: 6 for elective stenting (n=6,602) and 6 for emergent stenting (n=1,134).

Health outcomes: the included studies reported no improvement in health outcomes resulting from elective use of stents, or from the emergent use of coronary stents in managing complications of PTCA or failed PTCA, though this may be due to a lack of statistical power in the primary studies. There appeared to be significant harms associated with the use of stents, in terms of vascular complications, deaths and recurrent symptomatic closures.

Intermediate outcomes: in elective patients, stents may have reduced the need for revascularisation, though this finding may have been due to lack of blinding in the study reporting this outcome. In emergent stenting, there was no difference found in terms of reduced need for subsequent CABG or repeat PTCA. There is no strong evidence that stents reduce rates of restenosis in either elective or emergent stenting.

Overall, the review included only two randomised controlled trials and the evidence was of weak quality.

**Cost information**

Yes. Five papers comparing the costs of using stents versus PTCA were identified. All of the papers concluded that stents were the more expensive of the two options for the management of coronary artery disease. The initial higher costs of using stents were associated with longer hospital stay, higher costs of the device itself, the need for pre- and post-stent dilatations, increased vascular complications, and increased laboratory and drug costs.

One key cost analysis compared the cost of stents and PCTA at 1-year follow-up using a subset of patients from the STRESS study (Stents Restenosis Study). This reported a revascularisation rate of 33% for PCTA versus 19% for stents (p=0.02). Assuming no significant differences in length of hospital stay, rates of revascularisation procedures and re-hospitalisations, in patients with no vascular and bleeding complications, the cost difference between stents and PTCA at 1 year was close to US $1,062. This was based on device unit cost of around US $900, but did not include the cost of antiplatelet treatment or outpatient follow-up.

**Authors’ conclusions**

There is an absence of valid research evidence that stents reduce the incidence of angina, MI, coronary heart disease, or all causes mortality.

**CRD commentary**

This review was based on clear inclusion criteria and used a thorough search for both published and unpublished studies. However, by limiting the review to only articles published in English or French relevant information may have been excluded. Three researchers independently appraised the evidence for the clinical effectiveness part of the review, but only one researcher appraised the economic and anticoagulation literature. The analysis of the clinical effectiveness studies was also assessed but the quality of the economic studies was not. Although the differences between the studies was not formally discussed, certain differences were mentioned and, in view of these differences, a narrative presentation of the results was appropriate. Overall, this was a reasonable quality review and the authors findings would appear to follow from the evidence presented.

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

Coronary stents should be the subject of continual evaluation. The methodological quality of subsequent trials in this area should be rigorously assessed.

**Bibliographic details**

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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.