

Executive summary

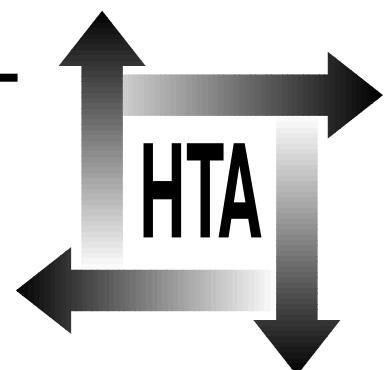
**Coronary artery stents in the
treatment of ischaemic heart disease:
a rapid and systematic review**

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Executive summary

Background

Coronary artery stents are prosthetic linings inserted into coronary arteries via a catheter to widen the artery and increase blood flow to ischaemic heart muscle. They are used in the treatment of ischaemic heart disease (IHD).

IHD is a major cause of morbidity and mortality (123,000 deaths per annum) in the UK and a major cost to the NHS. Clinical effects of IHD include subacute manifestations (stable and unstable angina) and acute manifestations (particularly myocardial infarction [MI]). Treatment includes attention to risk factors, drug therapy, percutaneous invasive interventions (PCIs) (including percutaneous transluminal coronary angioplasty [PTCA] and stents) and coronary artery bypass graft surgery (CABG).

In the last decade there has been a steady and significant increase in the rate of PCIs for IHD. In the UK, rates per million population increased from 174 in 1991 to 437 in 1998. Stents are now used in about 70% of PCIs. Data from the rest of Europe suggest there is potential for PCI and stent rates to increase considerably. In the UK there is evidence of under-provision and inequity of access to revascularisation procedures.

Objectives

The following questions were addressed.

1. What are the effects and effectiveness of elective stent insertion versus PTCA in subacute IHD, particularly stable angina and unstable angina?
2. What are the effects and effectiveness of elective stent insertion versus CABG in subacute IHD, particularly stable angina and unstable angina?
3. What are the effects and effectiveness of elective stent insertion versus PTCA in acute MI (AMI)?
4. What are best estimates of UK cost for elective stent insertion, PTCA and CABG in the circumstances of review questions 1 to 3?
5. What are best estimates of cost-effectiveness and cost-utility for elective stent insertion relative to PTCA or CABG in the circumstances of review questions 1 to 3?

Methods

A systematic review addressing the objectives was undertaken.

Data sources

A search was made for RCTs comparing stents (inserted during a PTCA procedure) with PTCA alone or with CABG in any manifestation of IHD. The search strategy covered the period from 1990 to November 1999 and included searches of electronic databases (MEDLINE, EMBASE, BIDS ISI, The Cochrane Library), Internet sites, and handsearches of cardiology conference abstracts and 1999 issues of cardiology journals. Lead researchers and local clinical experts were contacted. Manufacturers' submissions to the National Institute for Clinical Excellence were searched.

The search strategy was expanded to look for relevant economic analyses and information to inform the economic model (including searching MEDLINE, the NHS Economic Evaluation Database and the Database of Abstracts of Reviews of Effectiveness). Searches focused on research that reported costs and quality of life data associated with IHD and interventional cardiology.

Study selection

For the review of clinical effectiveness, inclusion criteria were: (i) RCT design; (ii) study population comprising adults with IHD in native or graft vessels (including patients with subacute IHD or AMI); (iii) procedure involving elective insertion of coronary artery stents; (iv) elective PTCA (including PTCA with provisional stenting) or CABG as comparator; (v) outcomes defined as one or more of: combined event rate (or event-free survival), death, MI, angina, target vessel revascularisation, CABG, repeat PTCA, angiographic outcomes; (vi) trials that had closed and reported results for all or almost all recruited patients.

For the economic evaluation, studies of adults with IHD were included if they were of the following types: studies reporting UK costs; comparative economic evaluation combining both costs and outcomes; economic evaluations reporting costs and outcomes separately for the years 1998 and 1999 (to ensure current practice was included).

Data extraction

For the review of clinical effectiveness, data were extracted into data extraction forms and RCT quality was assessed using standard methods. Decisions relating to data extraction and quality were made by two independent reviewers. Disagreements were resolved by discussion and with the aid of a third party if there was any residual discrepancy. The quality assessment of cost-effectiveness analyses was based on a pre-determined check-list.

Data synthesis

For the review of clinical effectiveness, abstracted data were collated in summary tables. Whenever possible, analysis was on an intention-to-treat basis. Meta-analyses were carried out when adequate data were available.

For the economic evaluation, cost data and health economic assessments were documented and evaluated.

Results

Effects and effectiveness

Thirty-five RCTs which fulfilled the study criteria were found: 25 compared stent with PTCA for subacute IHD; three compared stents with CABG for subacute IHD; seven compared stents with PTCA following AMI. In general, the trials were open to bias, which introduced uncertainty. Despite this, convincing evidence of impact was identified in the following.

1. Elective stent insertion versus PTCA in subacute IHD for:
 - event rates (generally death, MI, repeat PTCA and CABG) – odds ratio (OR), 0.68 (95% confidence interval [CI], 0.59 to 0.78)
 - repeat PTCA – OR, 0.57 (95% CI, 0.48 to 0.69)
2. Elective stent insertion versus PTCA in AMI for:
 - event rates (generally death, MI, repeat PTCA and CABG) – OR, 0.39 (95% CI, 0.28 to 0.54)
 - repeat PTCA – OR, 0.44 (95% CI, 0.26 to 0.74).

There was no clear evidence of impact on deaths, MI or CABG in comparison (1) or (2) above. Although trials were identified, there was insufficient evidence to draw any conclusions on the effectiveness of elective stent insertion versus CABG in subacute IHD.

Costs and economic analyses

The information identified contributes only to conclusions concerning elective stent insertion compared with PTCA in subacute IHD. There was wide variation in the estimates of cost, cost-effectiveness and cost-utility. Cost estimation, particularly for wider costs, was generally poor. It was probably conducted best in the context of the cost-effectiveness studies. These generally showed that cost/event-free survivor for elective stenting was equivalent to or less than that of PTCA. They support the view that higher initial costs of stents are outweighed by savings from reduced requirement for repeat PTCA. The majority of cost-utility studies reported cost/QALY estimations in the range of £20,000–£30,000. Reasons why these estimates should be treated with caution were identified.

The efficiency of the use of stents compared with CABG in subacute IHD or stents compared with PTCA in AMI is unknown.

Conclusions

In subacute IHD (especially stable angina and unstable angina), there is evidence for the effectiveness of elective stents in reducing the need for repeat PTCA. This appears to represent an efficient use of resources. However, this assertion could be made with more confidence if the resource neutrality of stents could be confirmed using more rigorously derived cost data. There is currently insufficient evidence to assess the effectiveness of the extension of stent use to patients with baseline risks or indications different from those of the patients in the trials reviewed (for review question 1).

Recommendations for further evaluation and research

1. For many important stenting applications, research is ongoing and a reassessment of research evidence and health economic evaluations in 1–2 years' time would be valuable.
2. Further research on the use of stents is needed to: acquire better cost data, using explicit micro-costing; investigate the impact of stents on severity of angina and quality of life; evaluate the effectiveness of newer technologies.
3. It is very important to establish clearly the effectiveness and efficiency of stents compared with CABG, and even though there is considerable ongoing research in this area, further targeted research may be valuable.

Publication

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