

Coronary artery stents: a rapid systematic review and economic evaluation

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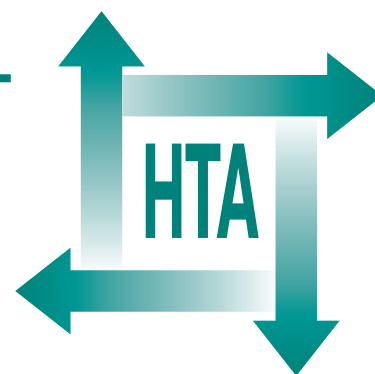
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Executive summary

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Executive summary

Objectives

To assess the effectiveness and cost-effectiveness of the use of coronary artery stents in patients with coronary heart disease (CHD).

Specifically, the review compares the use of:

- stent versus percutaneous transluminal coronary angioplasty (PTCA)
- stent versus coronary artery bypass graft (CABG)
- drug-eluting stents (DES) versus non-DES.

Background

CHD is a major cause of morbidity and mortality in the UK. Treatment models include medical management, percutaneous interventions (PCI) and surgery. Although PCI provides initial relief of symptoms, there is a high rate of restenosis and need for repeat treatment. There has been rapid evolution of treatment in the area of coronary artery stents, including the development of drug-eluting stents (DES).

The rapid developments in stenting in the treatment of coronary artery disease (CAD) have made it necessary to re-examine the available research evidence to inform national guidance.

Methods

The review was conducted following accepted guidelines for conducting systematic reviews, including the identification of clinical and economic studies, application of inclusion criteria, quality assessment of included studies and data extraction and analysis.

Inclusion criteria

Randomised controlled trials that include comparisons of PTCA versus PTCA with stent, stent versus CABG and non-DES versus-DES in patients with CAD in native or graft vessels and those with stable angina or acute coronary

syndrome (ACS) and unstable angina were included in the review. Data on the following outcome measures were included in the review: combined event rate or event-free survival, death, acute myocardial infarction (AMI), target vessel revascularisation, repeat treatment (PTCA, stent or CABG) and binary restenosis.

Full economic evaluations that compared two or more options and considered both costs and consequences, including cost-effectiveness, cost-utility analysis or cost-benefit analysis undertaken in the context of high-quality randomised controlled trials, were included in the review.

Clinical findings

Sixty-eight studies fulfilled the inclusion criteria. These included 50 studies comparing the use of stents with PTCA, six comparing stents with CABG and 12 comparing DES eluting stents with non-DES. No studies were identified that compared DES with PTCA or DES with CABG.

Studies included a variety of stent designs and eluting drugs. In the surgical trials both standard and minimally invasive surgical techniques were reported.

Mortality is a rare event and none of the included studies was powered to assess effectiveness of the treatment in relation to this outcome. The primary outcome in all studies was either a composite end-point such as major adverse cardiac (and/or cerebrovascular) events, a composite event rate made up of death, AMI and revascularisation or revascularisation rate.

Definition of revascularisation rates varied across studies, with some including all target lesion or vessel revascularisation (whether need was clinically or angiographically identified), others reporting only clinically driven rates and others reporting a mix of both. No studies reported total revascularisation (e.g. repeat treatments carried out on target vessels or lesions and treatment to any other vessel). ▶

Studies were not powered to assess effectiveness across groups of high-risk patients (i.e. patients with diabetes, patients with long lesions). Data on subgroups of high-risk patients have been presented within study reports but were not available for further analysis.

Existing quality of life data suggest that revascularisation procedures reduce the patient's quality of life for a short period only.

PTCA versus stent

Data analysis was carried out with studies grouped according to patient characteristics (non-specific, AMI, totally occluded vessels and small vessels).

Stents are more effective than PTCA in preventing adverse events and revascularisations. These results confirm the trends presented in the previous review that informed the national guidance.

Stent versus CABG

All studies were a comparison of bare metal stents with surgery. Studies comparing drug-eluting stents with CABG have commenced but no reports of results are currently available.

Analysis of data was carried out considering patients with single- and multiple-vessel disease. Studies in the former group were small and did not report results that could be used in the analysis past 6-month follow-up.

In multiple-vessel disease there was no evidence of a difference in mortality (at 1 year) between patients treated surgically and those receiving a stent. Longer term data from these studies are now becoming available. Patients treated surgically required fewer revascularisations.

Stent versus DES

Data are limited by the lack of reporting of longer term outcomes. There is no evidence of a difference in mortality between patients receiving DES and those treated with bare metal stents at 1 year.

There is a reduction in event rate at 9 and 12 months in patients treated with DES. This event rate is primarily made up of increased revascularisation rates in patients treated with bare metal stents. Two-year outcome data from one study indicate that this benefit of DES continues over the longer term.

Economic evaluation

The existing economic literature in this area is limited and of variable quality and relevance. The nature of CAD as a life-long condition means that outcomes and costs should be considered over extended time periods. In our view, the submitted company models were inadequate in this respect.

We developed an economic model based on extrapolation of trends in mortality and revascularisation from clinical trials data to a 5-year time horizon. This proved sufficient to indicate long-term trends in cost-effectiveness:

- Bare metal stenting versus CABG in multivessel disease
CABG is initially more expensive and may have higher immediate risks, but over time the cost differential is reduced and long-term outcomes favour CABG over stenting.
- DES versus CABG in multiple-vessel disease
Here the situation is not qualitatively different from bare metal stenting. Reduced costs from fewer repeat revascularisations is more than offset by the higher costs of stents and the improved efficacy of the new stents does not eliminate the long-term outcome advantage of CABG.
- DES versus bare metal stenting in single-vessel disease
This leads to substantially higher costs with a very small outcome benefit, so that DES would not normally be considered a cost-effective alternative.

DES might be considered cost-effective if one or more of the following options apply:

- The additional cost of DES (compared with ordinary stents) was substantially reduced.
- The outcome benefits from the use of DES are much improved.
- The use of DES is targeted on the subgroups of patients with the highest risks of requiring reintervention.

Implications for the NHS

The net cost implications to the NHS, depending on which patients receive DES, range from £4.2 million to £23 million per year, at current levels of stent provision. ►

Recommendations for further research

This review indicates a need for research in a number of areas:

- Long-term clinical studies that focus on significant outcomes such as mortality.
- Further studies on (a) differences among plain stents (this might be possible from a systematic review, but is not addressed in the current review), (b) head-to-head comparisons within DES (new trial data required), (c) CABG compared with DES (already planned) and (d) evaluation of newer non-DES against DES.
- Evaluation of the effects of revascularisation procedures and especially repeat

revascularisation procedures on the patient's quality of life.

- Development and testing of risk assessment tools to identify patients likely to need further revascularisations.
- The rapid rate of change in this area suggests that a further review should be undertaken in 12–18 months.

Publication

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