

# **A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery**

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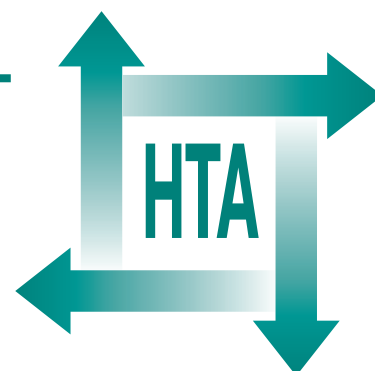
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## **Executive summary**

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## Executive summary

### Objectives

To compare the (a) clinical and (b) cost-effectiveness of minimally invasive direct coronary artery bypass grafting (MIDCAB) and percutaneous transluminal coronary angioplasty (PTCA) with or without stenting in patients with single-vessel disease of the left anterior descending coronary artery (LAD).

### Design

Multi-centre randomised trial without blinding. The computer-generated sequence of randomised assignments was stratified by centre, allocated participants in blocks and was concealed using a centralised telephone facility.

### Setting

Four tertiary cardiothoracic surgery centres in England.

### Participants

Patients with ischaemic heart disease with  $\geq 50\%$  proximal stenosis of the LAD, suitable for either PTCA or MIDCAB, and with no significant disease in another vessel.

### Interventions

Patients randomised to PTCA had local anaesthetic and underwent PTCA according to the method preferred by the operator carrying out the procedure.

Patients randomised to MIDCAB had general anaesthetic. The chest was opened through an 8–10-cm left anterior thoracotomy. The ribs were retracted and the left internal thoracic artery (LITA) harvested. The pericardium was opened in the line of the LAD to confirm the feasibility of operation. The distal LITA was anastomosed end-to-side to an arteriotomy in the LAD. All operators were experienced in carrying out MIDCAB.

### Main outcome measures

The primary outcome measure was survival free from cardiac-related events. Relevant events were death, myocardial infarction, repeat coronary revascularisation and recurrence of symptomatic angina or clinical signs of ischaemia during an exercise tolerance test at annual follow-up. Secondary outcome measures were complications, functional outcome, disease-specific and generic quality of life, health and social services resource use and their costs.

### Results

Participants were recruited from November 1999 to December 2001; 1091 of 12,828 consecutive patients undergoing a diagnostic angiogram or elective PTCA had proximal stenosis of the LAD. Of the 1091, 127 were eligible and consented to take part; 100 were randomised and the remaining 27 consented to follow-up.

All randomised participants were included in an intention-to-treat analysis of survival free from cardiac-related events, which found a non-significant benefit from MIDCAB (hazard ratio = 0.77, 95% confidence interval 0.38 to 1.57,  $p = 0.47$ ). Cumulative rates of cardiac-related events at 12 months were estimated to be 7.1 and 9.2% for MIDCAB and PTCA, respectively. There were no important differences between MIDCAB and PTCA with respect to angina symptoms or disease-specific or generic quality of life.

The total NHS procedure costs were £1648 and £946 for MIDCAB and PTCA, respectively. The costs of resources used during 1 year of follow-up were £1033 and £843, respectively.

### Conclusions

We found no evidence that MIDCAB was more effective than PTCA. However, the trial did not have sufficient power and we cannot rule out this possibility. The procedure costs of MIDCAB

were considerably higher than those of PTCA. Given the small and non-significant differences in effectiveness between MIDCAB and PTCA and the considerably higher costs of MIDCAB, it is unlikely that MIDCAB represents a cost-effective use of resources in the reference population.

Recent advances in cardiac surgery mean that surgeons now tend to carry out off-pump bypass grafting via a sternotomy instead of MIDCAB. At the same time, cardiologists are treating more patients with multi-vessel disease by PTCA. Future primary research should focus on this comparison. Other small trials of PTCA versus MIDCAB have

now finished and a more conclusive answer to the original objective could be provided by a systematic review.

## Publication

Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, *et al.* A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery. *Health Technol Assess* 2004;**8**(16).

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The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the 'National Knowledge Service' that is being developed to improve the evidence of clinical practice throughout the NHS.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 96/04/06. As funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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