

Clinical effectiveness and cost-effectiveness of immediate angioplasty for acute myocardial infarction: systematic review and economic evaluation

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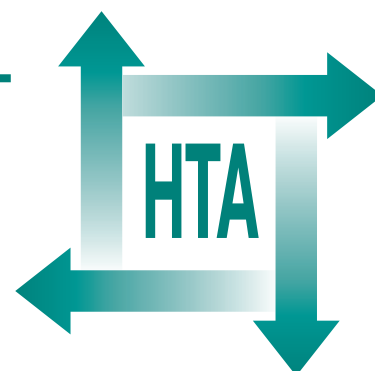
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Executive summary

Health Technology Assessment 2005; Vol. 9: No. 17

Health Technology Assessment
NHS R&D HTA Programme





Executive summary

Description of proposed service

This review examines the clinical and cost-effectiveness of immediate angioplasty in myocardial infarction, with thrombolysis as the main comparator.

Background

The blockage of a coronary artery (coronary thrombosis) can lead to a heart attack (acute myocardial infarction). There are several ways of trying to overcome this blockage. The methods include drug treatment to dissolve the clot (thrombolysis) and physical intervention, either by passing a catheter into the affected artery [angioplasty or percutaneous coronary intervention (PCI)], or bypassing the blocked section by cardiac surgery [coronary artery bypass grafting (CABG)].

Thrombolysis can be given in the community before the patient is sent to hospital, or delayed until after admission. Prehospital thrombolysis is not common in the UK.

Immediate angioplasty is not routinely available in the UK at present; it is much more common in the USA.

Objectives

To review the clinical evidence comparing immediate angioplasty with thrombolysis, and to consider whether it would be cost-effective.

Methods

This report was based on a systematic review of the evidence of clinical effectiveness and an economic analysis of cost-effectiveness based on the clinical review and on cost data from published sources and *de novo* data collection.

Data sources

The search strategy searched six electronic databases (including MEDLINE, Cochrane Library and EMBASE), with English-language limits, for

the periods up to December 2002. Bibliographies of related papers were assessed for relevant studies and experts contacted for advice and peer review, and to identify additional published and unpublished references.

Study selection

For clinical effectiveness, a comprehensive review of randomised controlled trials (RCTs) was used for efficacy, and a selection of observational studies such as case series or audit data for effectiveness safety in routine practice. RCTs of thrombolysis were used to assess the relative value of prehospital and hospital thrombolysis. Observational studies were used to assess the representativeness of patients in the RCTs, and to determine whether different groups have different capacity to benefit. They were used to assess the implications of wider diffusion of the technology away from major centres.

Data extraction

Data extraction and quality assessment were undertaken by one reviewer and checked by a second reviewer, with any disagreements resolved through discussion. The quality of systematic reviews, RCTs, controlled clinical trials and economic studies was assessed using criteria recommended by the NHS Centre for Reviews and Dissemination (University of York).

Study synthesis

Clinical effectiveness was synthesised through a narrative review with full tabulation of results of all included studies and a meta-analysis to provide a precise estimate of absolute clinical benefit. Consideration was given to the effect of the growing use of stents. The economic modelling adopted an NHS perspective to develop a decision-analytical model of cost-effectiveness focusing on opportunity costs over the short term (6 months).

Results and conclusion

Number and quality of studies, and summary of benefits

There were several good-quality systematic reviews, including a Cochrane review, as well as an individual patient meta-analysis and a number of

recent trials not included in the reviews. The results were consistent in showing an advantage of immediate angioplasty over hospital thrombolysis. The updated meta-analysis showed that mortality is reduced by about one-third, from 7.6% to 4.9% in the first 6 months, and by about the same in studies of up to 24 months. Reinfarction is reduced by over half, from 7.6% to 3.1%. Stroke is reduced by about two-thirds, from 2.3% with thrombolysis to 0.7% with PCI, with the difference being due to haemorrhagic stroke. The need for CABG is reduced by about one-third, from 13.2% to 8.4%.

Caution is needed in interpreting the older trials, as changes such as an increase in stenting and the use of the glycoprotein IIb/IIIa inhibitors may improve the results of PCI. There is little evidence comparing prehospital thrombolysis with immediate PCI. One good quality study from France showed that prehospital thrombolysis with PCI in those in whom thrombolysis failed was as good as universal PCI. Research on thrombolysis followed by PCI, known as facilitated PCI, is underway, but results are not yet available. Further caveats are needed. Trials may be done in select centres and results may not be as good in lower volume centres, or out of normal working hours. In addition, much of the marginal mortality benefit of PCI over hospital thrombolysis may be lost if door-to-balloon time were more than 1 hour longer than door-to-needle time. Conversely, within the initial 6 hours, the later patients present, the greater the relative advantage of PCI.

Cost-effectiveness

If both interventions were routinely available, the economic analysis favours PCI, given the assumptions of the model. Results suggest that PCI is more cost-effective than thrombolysis, providing additional benefits in health status at some extra cost and an incremental cost per unit change in health status under the £30,000

threshold in most instances. In the longer term, the cost difference is expected to be reduced because of higher recurrence and reintervention rates among those who had thrombolysis. The model is not particularly sensitive to variations in probabilities from the clinical effectiveness analysis.

However, very few units in England could offer a routine immediate PCI service at present, and there would be considerable resource implications of setting up such services. Without a detailed survey of existing provision, it is not possible to quantify the implications, but they include both capital and revenue: an increase in catheter laboratory provision and running costs. The greatest problem would be staffing, and that would take some years to resolve.

A gradual incrementalist approach based on clinical networks, with transfer to centres able to offer PCI, could be used. In rural areas, one option could be to promote an increase in prehospital thrombolysis, with PCI for thrombolysis failures.

Need for further research

There is a need for economic data on the long-term consequences of the treatment, the quality of life of patients after treatment and the effects of PCI following thrombolysis failure.

Publication

Hartwell D, Colquitt J, Loveman E, Clegg AJ, Brodin H, Waugh N, *et al.* Clinical effectiveness and cost-effectiveness of immediate angioplasty for acute myocardial infarction: systematic review and economic evaluation. *Health Technol Assess* 2005;9(17).

NHS R&D HTA Programme

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 Health and 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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Research suggestions are carefully considered by panels of independent experts (including consumers) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or designing a trial to produce new evidence where none currently exists.

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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 02/15/01. 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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ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.

Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.