Executive summary

Intravascular ultrasound-guided interventions in coronary artery disease: a systematic literature review, with decision-analytic modelling, of outcomes and cost-effectiveness

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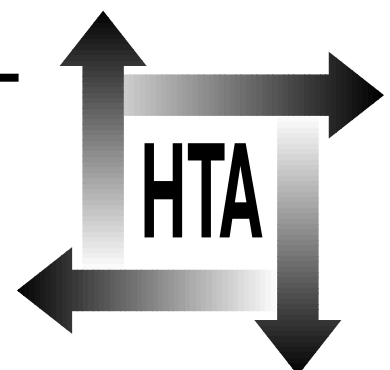[5] Division of Public Health, Nuffield Institute for Health, Leeds, UK
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Background

Intravascular ultrasound (IVUS) is the generic name for any ultrasound technology used *in vivo* within the blood vessels. More specifically, intracoronary ultrasound enables imaging of the coronary arteries from within the lumen. This review concentrates on the role of intracoronary ultrasound as an adjunct to interventional cardiology.

Objectives

- To identify the literature on IVUS for guiding coronary interventions, and to synthesise evidence about outcomes compared with outcomes when IVUS guidance has not been used.
- To use this evidence, together with other information about costs and outcomes, to model the cost effectiveness of IVUS guidance.
- To synthesise the evidence on the reproducibility of measurements of cross-sectional area made using IVUS.

Methods

Data sources
- Electronic searches of MEDLINE, EMBASE, Science Citation Index, Index to Scientific and Technical Proceedings, Engineering Compendex, Engineering Page One, Cochrane Library, Inside (British Library), 1990–98.
- Contacting experts and centres of expertise, 1990–99.
- Internet search, 1990–99.

Study selection
Studies of IVUS-guided coronary interventions performed on humans were included in the review. Non-English language studies were also included when they covered IVUS-guided stenting or angioplasty. Control evidence regarding outcomes without IVUS guidance was sought only from randomised controlled trials (RCTs). Studies investigating the reproducibility of measurements of cross-sectional area were included only if the results were expressed in terms of the mean and standard deviation of paired differences.

Data extraction
Checklists that covered study details, patient characteristics and results were completed independently by three reviewers. Consensus was reached on any disagreements. Local data were gathered on the costs of IVUS-guided stenting.

Data synthesis
Overall event rates were calculated by pooling patient results from the included studies. A decision-analytic model was used to combine information from the literature with cost estimates, in order to predict cost-effectiveness in terms of cost per restenosis event avoided by the use of IVUS guidance. The analysis was performed from the perspective of the healthcare provider. Sensitivity analysis was undertaken. A simple extrapolation was made to long-term outcome so that cost–utility (using quality-adjusted life years (QALYs)) could be estimated. The minimum detectable change in cross-sectional area was estimated from the reproducibility results.

Results

Only one study on IVUS-guided angioplasty satisfied the inclusion criteria, and there were no studies on IVUS-guided atherectomy or other IVUS-guided interventions that satisfied the inclusion criteria. Of the 15 articles on IVUS-guided stenting that satisfied the inclusion criteria, seven presented data on outcomes at 6 months post-intervention. The angiographic restenosis rate was $16 \pm 1\%$. This compared with $24 \pm 2\%$ derived from five articles on stenting without IVUS guidance. Data for follow-up periods longer than 6 months were presented in only two studies.

Data from a total of five studies were included in the decision-analytic model. The cost per restenosis event avoided was £1545. After extrapolation to long-term outcome, the calculated cost per QALY was £6438. The baseline QALY gain was only 0.03 years. Sensitivity analysis resulted in large differences between the best- and worst-case scenarios, for example, from a saving of £5000 to a cost of £24,000 per restenosis event avoided.

The smallest changes in cross-sectional area that could be measured were 1.6 mm^2 by a single observer and 1.9 mm^2 by different observers.

Conclusions

Implications for healthcare
* The evidence available is too weak for there to be any reliable implications for clinical practice.

Recommendations for research
* An adequately powered, well-designed RCT comparing the long-term outcomes of stenting, with and without IVUS guidance.
* An RCT to compare acute and subacute thrombosis rates and long-term outcome of high pressure stent implantation strategies with and without IVUS guidance.
* An RCT to compare the long-term outcome of therapy guided by IVUS against the 'intention-to-stent' approach using angiographic guidance.
* Studies of cost and cost-effectiveness based on the results of these RCTs, which follow guidelines for the measurement and valuation of costs.
* There is a strong case for a prospective audit of all stenting procedures carried out in the UK to commence as soon as possible, along clearly defined lines that address the gaps in currently available data.
* Updating of the decision model presented here when results are available from trials currently underway.
* Monitoring of expert opinion (horizon scanning) to identify future roles for IVUS, and early implementation of adequately powered RCTs to test emergent applications.
* Measures to facilitate modelling should include the development of guidelines to authors about the style of data presentation necessary, support for supplementary data to be held on web servers, and routine collection of registry and local data.
* A structured review of the therapeutic and outcome impact of using IVUS to detect calcification and eccentric lesions.

Publication

NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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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.

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