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


Authors' objectives
To synthesise evidence about outcomes of coronary interventions when intravascular ultrasound (IVUS) is used, compared with outcomes when it is not.

Searching
MEDLINE, EMBASE, the Cochrane Library and BRLII were searched from 1990 to March 1999; the Science Citation Index, Index of Scientific and Technical Proceedings, Engineering Compendex and Engineering Page One, all on BIDS, were also searched over the same time interval. Additional material was identified by contacting experts and centres of expertise, by searching the Internet from 1990 to 1999, and by handsearching reference lists of all retrieved articles; source journals not included in the electronic sources were also searched. Full details of search strategies are provided.

Study selection
Study designs of evaluations included in the review
For studies of IVUS-guided interventions, all study designs were included. Only reviews, non-human studies and case reports were excluded. For control studies only randomised controlled trials (RCTs) and systematic reviews were included. Studies were excluded if they had fewer than 10 patients included, investigated technical performance only, and provided only registry data or safety data.

Specific interventions included in the review
Any IVUS, i.e. any ultrasound technique used in vivo within the blood vessels. Information on a control was based on studies of coronary interventions without IVUS. In practice, studies directly comparing a coronary intervention procedure with and without IVUS were not found and, therefore, data were gathered from studies of percutaneous transluminal angioplasty (PTCA), with or without stenting. Studies where the intervention included any of the following criteria were excluded from the review: doppler only; therapeutic or diagnostic use of IVUS; radial catheter approach (include only femoral approach); not an IVUS-guided intervention.

Participants included in the review
Any patients undergoing a coronary intervention. A study was excluded from the review of IVUS if any of the following criteria applied: not coronary arteries; transplant recipients; only one named coronary artery included; registry data; safety data only.

Outcomes assessed in the review
Angiographic re-stenosis at 6 months and major adverse cardiac event (MACE) at 1 year.

How were decisions on the relevance of primary studies made?
Two reviewers applied the validity criteria to control-arm studies. The authors do not state how may of the reviewers were involved in the validity assessment of the IVUS studies, nor if there was any independent duplication or checking of this validity assessment.

Assessment of study quality
An assessment of validity was performed according to five criteria: a unique patient population, i.e. not included in any other study included in the review; at least 85% of patients followed-up; there was some clinical follow-up (6 months for study of re-stenosis); adequate study information was included, i.e. at least clinical event rate specified for restenosis, or at least angiographic criteria definition specified; the proportion of patients for whom IVUS was planned that are actually receiving IVUS is specified, i.e. intention to treat analysis. Systematic reviews of stenting or PTCA were critically appraised by one member of the study team according to the criteria developed by NHS Centre for...
Reviews and Dissemination (see Other Publications of Related Interest no.1) and Sackett et al. (See Other Publications of Related Interest no.2). The individual studies identified from these reviews were then critically appraised. Two reviewers applied the validity criteria to control-arm studies. The authors do not state how many of the reviewers were involved in the validity assessment of the IVUS studies, nor if there was any independent duplication or checking of this validity assessment.

**Data extraction**

Two clinician team members and the main reviewer independently performed the data extraction of the IVUS studies. The data extraction for the control studies was performed by one team member only. Other data and economic data were also extracted by one team member only. Categories of data extracted included: reference identification, patient characteristics (including details of cardiovascular disease, characteristics of coronary lesion, design and nature of study. Full details are given in the results tables in the report.

**Methods of synthesis**

How were the studies combined?
A narrative synthesis was undertaken where studies were grouped by research question:

1. Does IVUS guidance improve outcomes compared with the procedure without IVUS guidance?
2. Is the technology cost-effective in the application?
3. Is there any morbidity associated with the use of IVUS?
4. What is the failure rate of IVUS examination in the application?
5. IVUS-guided optimisation of PTCA.
6. Other IVUS-guided coronary interventions.
7. IVUS-guided therapy for in-stent re-stenosis.
8. What are the in vivo intra- and inter-observer reproducibility of measurements made using IVUS?

For the quantitative data (re-stenosis rate), the results from all eligible studies were pooled to calculate an overall rate. No test was applied to compare the different arms of the review (intervention versus control) due to the different inclusion criteria.

How were differences between studies investigated?
Each study is summarised in the text and in tables. When data from studies were pooled quantitatively, heterogeneity was not formally investigated.

**Results of the review**

Fifteen studies of IVUS-guided intervention were included in the review. Of these, 7 presented data on outcomes at 6-month follow-up. A total of 9 articles provided information for the control arm of this review: 5 were new RCTs, and 4 were studies included in the IVUS part of the review but also provided control information.

Only one study on IVUS-guided angioplasty satisfied the inclusion criteria; studies on IVUS-guided atherectomy or other IVUS-guided interventions did not satisfy the inclusion criteria. From the 15 articles on IVUS-stenting that satisfied the inclusion criteria, 7 presented data on outcomes at 6-months post-intervention. The angiographic re-stenosis rate was 16 plus or minus 1%. This compared with 24 plus or minus 2% derived from 5 articles on stenting without IVUS guidance. Data for follow-up of more than 6 months were presented in only 2 studies. From the details provided in the results tables it is unclear how the overall figures for re-stenosis in the two arms of the study were obtained.
Cost information
No economic evaluation studies were identified. A decision-modelling exercise was performed. Data from a total of 5 studies were included in the decision-analytic model. The cost per re-stenosis event avoided was £1,545. After extrapolation to long-term outcome, the calculated cost per QALY (quality-adjusted life gain) was £6,438. The baseline QALY gain was only 0.03 years. Sensitivity analysis resulted in large differences between the best and worst-case scenarios, e.g. from a saving of £5,000 to a cost of £24,000 per re-stenosis saved.

Authors’ conclusions
None of the studies included in this review were sufficiently well designed or performed to return clear evidence on what would appear to be a simple question, i.e. if IVUS-guided stent deployment results in statistically-significantly larger stent minimal luminal dimensions, then does this translate into reduced re-stenosis rates?

CRD commentary
The review addressed an appropriate question. The inclusion criteria in terms of study designs were very broad. Given that there were no studies that directly addressed the main question of the review, two parallel reviews were conducted; one for the intervention and one of the control. It was not stated clearly in the report that this is what had been done, and the whole review is poorly presented and difficult to follow. Given that the only conclusion that can be justified is that RCTs are required, the decision to conduct the 'control' review seems questionable. The validity assessments appeared suitable for the very general inclusion criteria used in this review. Study details are presented in the review, and the method of quantitative synthesis appears appropriate for the main review given that none of the included studies was a randomised comparison. However, the details do not allow a full understanding of the source of the data for the calculation of the overall re-stenosis rate. In addition, it appears inappropriate that pooling was performed without assessing statistical heterogeneity. Given that the data comparing the intervention and control came from different reviews, it is unsurprising that the results of the sensitivity analysis were hugely different between the best- and worse-case scenarios. The authors' conclusions follow from the findings of the review.

Implications of the review for practice and research
Practice: The authors state 'the evidence available is too weak for there to be any reliable implications for clinical practice'.

Research: The authors make the following recommendations 'an adequately powered, well designed RCT comparing the long-term outcomes of stenting, with and without IVUS guidance; an RCT to compare acute and sub-acute 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'.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.