Cost-effectiveness of intracoronary ultrasound for percutaneous coronary interventions

Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two methods of stenting, either with angiographic guidance only (ANGIO) or with intravascular ultrasound (IVUS), were studied. Stenting was performed when either the angiographic assessment deemed it necessary (greater than 35% residual diameter stenosis or severe dissection), or there was a failure to reach the predefined IVUS lesion lumen area of more than 65% of the surrounding reference area. The IVUS intervention was performed with a combined IVUS/variable diameter balloon catheter. Glycoprotein IIb/IIIa receptor antagonists were not administered in the trial.

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who were undergoing percutaneous coronary interventions. No other information on the patients was given.

Setting
The setting was secondary care. The economic study was carried out in Germany.

Dates to which data relate
The dates to which the effectiveness and resource evidence related were not given. The price year used was 1996.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The main costing was carried out prospectively on the same patient sample as that used in the effectiveness study. However, some of the costs were estimated using sources from other patient groups.

Study sample
No power calculations to determine the sample size were reported. There was no sample selection, all those patients undergoing planned percutaneous coronary interventions were included. All of the patients gave written informed consent. There were 269 patients in the study as a whole. The distribution of patients between the groups was not mentioned.
Study design
This was a randomised controlled trial with a 2-year follow-up, which was conducted in a single centre. The method of randomisation was not stated. The hospital staff assessed the patient outcomes. The assessment was carried out blind. No loss to follow-up was reported.

Analysis of effectiveness
The authors did not state whether the basis of the analysis was intention to treat or per protocol. The primary health outcome was the incidence of major adverse cardiac events (MACE). Data were provided separately for deaths, myocardial infarction and clinically-driven target vessel revascularisation (TVR). There was no information given on the comparability of the two groups.

Effectiveness results
The proportion of patients suffering from MACE was 19.8% in the IVUS group and 31.1% in the ANGIO group, (p=0.04).

The proportion dying was 3.2% in the IVUS group and 2.7% in the ANGIO group, (p=0.77).

The proportion suffering myocardial infarction was 0.8% in the IVUS group and 3.4% in the ANGIO group, (p=0.16).

The proportion suffering from TVR was 17.4% in the IVUS group and 29.1% in the ANGIO group, (p=0.02).

Clinical conclusions
The authors concluded that the clinical results were superior in the IVUS group. This was clearly illustrated by the difference in MACE rates between the two groups.

Measure of benefits used in the economic analysis
The measure of benefit used in the economic analysis was the MACE-free survival gained. MACE-free survival was defined as the percentage of the group without MACE after 2 years. MACEs occurring in the second year were discounted at a rate of 3%.

Direct costs
Discounting was carried out at 3%. The price year used was 1996. The costs of initial hospitalisation and cardiac-related hospitalisations during the 2-year follow-up were estimated from actual data from the study. The medication costs were calculated using a model that assumes that the current American College of Cardiology/American Heart Association/American College of Physicians/American Society of Internal Medicine guidelines for the treatment of chronic stable angina. Non-cardiac medication was not included in the costs.

Statistical analysis of costs
Statistical tests (and p-values) on the differences in the costs were reported.

Indirect Costs
Discounting was carried out at 3%. The costs were estimated from another study (see Other Publications of Related Interest). The price year was 1996.

Currency
US dollars ($). The costs were originally calculated in German marks (DM) then converted into dollars. The exchange rate was $1.00 = DM2.00.
Sensitivity analysis
A sensitivity analysis on the cost difference between IVUS and ANGIO was carried out. The variables investigated were the time for the IVUS procedure, the additional cost of the combination device, the duration of the initial hospitalisation, the total number of IVUS procedures performed, stent rates and IVUS revascularisation.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The cost per patient was $15,947 (+/- 8,545) in the IVUS group and $16,103 (+/- 9,954) in the ANGIO group, (p=0.89).

Synthesis of costs and benefits
The incremental cost-effectiveness ratio for IVUS guidance was -$1,417 per MACE-free survival gained. IVUS dominated ANGIO as it was cheaper and more effective.

In a bootstrap analysis, 55.3% of the replications showed that IVUS was the dominant strategy, while 43.2% of the replications showed that IVUS improved effectiveness but increased the costs.

Authors’ conclusions
Intravascular ultrasound (IVUS) was the dominant procedure since it lowered the costs and produced better outcomes for the patients.

CRD COMMENTARY - Selection of comparators
The choice of the comparator, ANGIO, was justified by the authors’ claim that it is considered to be the best available alternative to IVUS. You should consider if it is the most appropriate comparator in your setting.

Validity of estimate of measure of effectiveness
The source of the effectiveness data was a randomised controlled trial. This is the best type of broad design. However, the authors did not report sufficient data from the study, nor did they give the numbers in the different patient groups. It is hard to say whether there was any possibility of selection bias as the randomisation procedure was not described and the baseline characteristics of the two groups were not reported. The authors reported that physicians and nurses involved in patient management after the interventions were blind to the patient group. For the results, only percentages were reported. It is hard to assess the external validity of the study as few patient characteristics were reported.

Validity of estimate of measure of benefit
The measure of benefits, difference in MACE-free survival, was taken directly from the effectiveness analysis but was not defined clearly. The authors did not show exactly how they had used the effectiveness data in the benefit measure. The authors stated that they had discounted the effectiveness data by 3%, which would have been appropriate for the second year.

Validity of estimate of costs
All the relevant categories of costs were included given the societal perspective adopted. In addition, the authors included an estimate of the indirect costs, which was useful. The cost data were taken from a single study, although the authors did use other sources for the indirect costs and for the quantities of the medication used. The costs and the quantities were not reported separately. This limits the usefulness of the cost data for other health care decision-makers.
The authors did not report the years for which the costs were calculated, although they did give a price year.

Other issues
The authors made appropriate comparisons of their results with the findings of other studies. However, they did not address the issue of generalisability to other settings. As already mentioned, the authors did not provide sufficient detail on the patients. They did not present their results selectively, but they did not provide them in sufficient detail.

The authors discussed several limitations to their study. They thought that the unique, variable-diameter, focal design of the combination balloon catheter may have caused particularly good results for IVUS at their hospital. They also stated that the clinical experience with IVUS criteria was limited, but did not state any implications of the research results. Finally, they pointed out that in the study the rate of stenting was rather low compared with current practice, although they also stated that the 50% stent rate was similar to that reported in other published trials.

Implications of the study
The authors gave several reasons why their results might not be replicated by other researchers, therefore implying that further research would be helpful to check the generalisability of their results.

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Other publications of related interest

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Subject indexing assigned by NLM

MeSH
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