Cost-effectiveness of measuring fractional flow reserve to guide coronary interventions
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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
Three strategies for the management of patients with intermediate coronary lesions and no prior functional study were examined. The strategies were:

deferring the decision for percutaneous coronary intervention (PCI) to obtain a nuclear stress imaging study (NUC strategy);

measuring functional flow reserve (FFR) at the time of angiography to help guide the decision for PCI (FFR strategy); and

stenting all intermediate lesions (STENT strategy).

Type of intervention
Diagnosis and treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised hypothetical patients with chest pain who underwent coronary angiography before stress perfusion imaging, and who had an intermediate coronary lesion of unclear physiologic significance. Only patients with single-vessel disease were considered.

Setting
The setting was a hospital. The economic study was conducted in the USA.

Dates to which data relate
The effectiveness data were derived from studies published between 1995 and 2001. No dates for resource use were reported. The price year was 2000.

Source of effectiveness data
The effectiveness evidence was derived from published studies and the authors' assumptions.

Modelling
A decision tree model was constructed to evaluate the costs and benefits of the three strategies under examination. The structure of the tree was depicted graphically, but no details of the model were provided.
Outcomes assessed in the review
The health outcomes evaluated from the published literature were:

the percentage of lesions producing ischaemia,

the relief of angina with medical therapy,

the relief of angina with PCI,

the duration of angina relief,

the utility for living with angina,

the sensitivity and specificity of nuclear imaging,

the sensitivity and specificity of FFR,

the risk of death from PCI, and

the median survival period for a 55-year-old patient.

Study designs and other criteria for inclusion in the review
No formal literature review appears to have been performed. The design of the primary studies was not stated.

Sources searched to identify primary studies
Not stated.

Criteria used to ensure the validity of primary studies
Not stated.

Methods used to judge relevance and validity, and for extracting data
Not stated.

Number of primary studies included
The model inputs were derived from 9 primary studies.

Methods of combining primary studies
Not stated.

Investigation of differences between primary studies
Not stated.

Results of the review
The proportion of lesions producing ischaemia was 47%.

The relief of angina with medical therapy was 29%.

The relief of angina with PCI was 70%.
The duration of angina relief was 4 years.

The utility for living with angina was 0.9.

The sensitivity was 0.88 and the specificity 0.96 for both nuclear imaging and FFR.

The risk of death from PCI was 0.3%.

The median survival period for a 55-year-old patient was 20 years.

**Methods used to derive estimates of effectiveness**
The authors made some assumptions for the decision model.

**Estimates of effectiveness and key assumptions**
The main assumption was that measuring FFR increased the risk of death by 0.015, while nuclear stress imaging did not increase the risk.

**Measure of benefits used in the economic analysis**
The summary benefit measure used in the economic analysis was the quality-adjusted life-years (QALYs). These were obtained by combining survival data derived from the decision model and the utility adjustment estimated from the literature. A 3% annual discount rate was used.

**Direct costs**
A 3% annual discount rate was applied because the costs were incurred over a long time. The unit costs were reported, but details of resource use were not. The health services considered in the economic analysis were FFR (wire, adenosine and professional fee), nuclear stress imaging, angina treatment, angiography and PCI. The cost/resource boundary was that of the health care system. The costs were estimated using data derived from a hospital cost accounting system and published data. Resource use was estimated using actual data from two series of consecutive patients undergoing the study procedures. All the costs were expressed in 2000 values.

**Statistical analysis of costs**
The costs were treated deterministically in the base-case.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
To evaluate the robustness of the estimated cost-effectiveness ratios, one-way sensitivity analyses were conducted on almost all of the model inputs. In particular, all variables were varied within the confidence intervals, when available, or within reasonable published ranges. Medicare reimbursement rates were used in place of the hospital costs. Threshold analyses were also performed to determine what relative sensitivity or specificity of FFR for nuclear stress imaging was necessary for the NUC strategy to become financially attractive (less than $50,000 per QALY).
Estimated benefits used in the economic analysis
The total (discounted) QALYs gained per patient were 14.7962 with the NUC strategy, 14.7940 with the FFR strategy, and 14.7761 with the STENT strategy. Thus, the benefits obtained with the three strategies were similar.

Cost results
The estimated costs per patient were $13,190 with the NUC strategy, $11,395 with the FFR strategy, and $15,225 with the STENT strategy. Therefore, compared with the FFR option, the NUC strategy cost an extra $1,795 and the STENT strategy cost an extra $3,830.

Synthesis of costs and benefits
The costs and benefits of the NUC and STENT strategies were compared with the FFR option by calculating the incremental cost-effectiveness ratio (ICER). However, FFR dominated the STENT option that cost more and was less effective (fewer QALYs), while the ICER of NUC relative to FFR was $808,000. Thus, FFR was the most cost-effective strategy. This conclusion was robust to almost all of the variations examined in the sensitivity and threshold analyses. Only when the specificity of FFR was decreased to less than 74% did the NUC strategy become financially attractive (ICER less than $50,000 per QALY).

Authors’ conclusions
Measuring fractional flow reserve (FFR) at the time of initial angiography, to evaluate the functional significance of an intermediate coronary lesion, was the most cost-effective strategy. It saved costs in comparison with the STENT strategy (stenting all intermediate lesions) and NUC strategy (deferring the decision for percutaneous coronary intervention to obtain a nuclear stress imaging study). It also provided comparable improvements in terms of the quality-adjusted life-years (QALYs).

CRD COMMENTARY - Selection of comparators
The authors stated that NUC represented the standard strategy for the management of patients with intermediate coronary lesions, while the FFR and STENT options represented two alternative strategies. You should decide whether they represent valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness estimates came from published studies, but it seems that a formal review of the literature was not undertaken. The authors did not describe the search methods or the designs of the primary studies. Thus, it was not possible to evaluate the quality of the data used in the decision tree. In addition, it was unclear whether the authors considered the impact of differences in the primary studies when estimating the effectiveness. These issues limit the internal validity of the analysis. Some assumptions were also made and uncertainty was tested in the sensitivity analysis.

Validity of estimate of measure of benefit
QALYs were used as the summary benefit measure. These appear to have been appropriate for estimating the impact of the study interventions on the quality of life and survival. The utility weights were obtained from a published study, but it was not stated whether the utilities were estimated from patients or from the general population. Appropriate discounting was performed. The use of QALYs permits the benefits of the interventions examined in the present study to be compared with those of other health technologies.

Validity of estimate of costs
The perspective adopted in the study was explicitly stated. It appears that all the relevant categories of costs have been included in the economic evaluation. The unit costs were reported, although details of the resources used were not. The price year was reported, thus facilitating reflation exercises in other settings. The sources of the cost and resource use data were provided. Alternative costs were used to estimate the robustness of the cost estimates. Sensitivity analyses
were conducted on the key economic inputs. Discounting was relevant and was appropriately performed. The economic analysis appears to have been conducted credibly.

Other issues
The authors made some comparisons of their findings with those from other studies, which were described in detail. Consistent results were observed. The issue of the generalisability of the study results to other settings was not addressed, but extensive sensitivity analyses were conducted and model inputs were varied over reasonable ranges. Consequently, the external validity of the analysis was increased. The study referred to patients with intermediate coronary lesions and this was reflected in the conclusions of the analysis. The authors did not describe the decision model used in the analysis.

Implications of the study
The study results suggested that patients with intermediate coronary lesions should undergo FFR to guide the decision for further interventions, thus saving costs and slightly improving survival in comparison with alternative treatments.

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