Cost-effectiveness analysis of intravascular ultrasound guided percutaneous coronary intervention versus conventional percutaneous coronary intervention

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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
Intravascular ultrasound (IVUS) and coronary angiography (CAG) guided percutaneous coronary intervention (PCI) was compared to PCI guided by CAG alone.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised male patients referred for PCI of a de novo lesion on a native coronary artery. The mean age of patients was 57 and ranged from 33 to 73. Patients were excluded if they did not wish to participate, if follow-up was deemed unlikely, if patients had an acute myocardial infarction less than 3 months prior to scheduled PCI, if patients had suffered from unstable angina within a month of the procedure, if patients had a left bundle branch block, if patients had a trial fibrillation, if patients had an elevated level of serum creatinine (greater than 200 micromol/l), if patients had thyrotoxicosis or if patients had polycythemia. Patients in whom PCI proved impossible due to a total exclusion that could not be crossed with a guided wire, were subsequently excluded, as were patients in whom no IVUS pullback could be performed.

Setting
The setting was secondary care. The economic analysis was carried out in Odense, Denmark.

Dates to which data relate
The dates for the effectiveness evidence and the resource use data were not reported. The price year was 1997.

Source of effectiveness data
The evidence/estimate for final outcomes was derived from a single study.

Link between effectiveness and cost data
Costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were not reported. The method of sample selection was not described, although the initial study sample, namely men referred for PCI of a de novo lesion on a native coronary artery, appears
to have been appropriate for the clinical study question. 108 patients were included in the study, with 54 in the CAG guided group and 54 in the IVUS guided group. The percentage of patients who refused to participate, or who were excluded from the study, was not reported.

Study design
The study was a randomised controlled trial carried out in a single centre. Patients were randomised to each intervention group on a 1:1 basis. The method of random allocation was not reported. The duration of follow-up was 6 months or earlier in case of recurrence of angina. The median follow up time was 26 weeks in both groups. 2 patients were lost to follow-up in the CAG group and 3 were lost to follow-up in the IVUS group. In the CAG group, the PCI operator was blinded to the IVUS result. The same operator, unblinded to patient randomisation, performed on-line and off-line analysis. Blinding was not possible as any patient with more than two IVUS pullbacks (pre-interventional and post-interventional) could only have been randomised to IVUS guided PCI.

Analysis of effectiveness
The analysis of the clinical study was presented on both an intention to treat and treatment completer basis. The primary health outcomes reported in the analysis were: restenosis (defined as QCA diameter stenosis 50% or more), recurrence (defined as QCA diameter stenosis greater than or equal to 50% and coronary flow reserve (CFR) less than 2.5 and presence of angina), recurrence (defined as QCA diameter stenosis greater than 50%, fractional flow reserve (FFR) less than 0.75 and presence of angina), and target vessel revascularisation (TVR). The groups were shown to be comparable at analysis.

Effectiveness results
Restenosis (defined as QCA diameter stenosis 50% or more) occurred in 13 (25%) patients in the CAG group and 8 (16%) in the CAG and IVUS guided group (NS).

Recurrence (defined as QCA diameter stenosis greater or equal to 50% and CFR less than 2.5 and presence of angina) occurred in 10 (20%) patients in the CAG group and 5 (11%) in the CAG and IVUS guided group, (p<0.05).

Recurrence (defined as QCA diameter stenosis greater than 50%, FFR less than 0.75 and presence of angina) occurred in 7 (20%) of the CAG guided group and 2 (5%) of the CAG and IVUS guided group, (p<0.05).

TVR (target vessel revascularisation) occurred in 18 patients in the CAG group (35% of treatment completers, 33% on intention to treat basis) and in 10 patients in the CAG and IVUS guided group (20% of treatment completers and 19% on intention to treat basis), (p=0.07).

Clinical conclusions
Patients randomised to IVUS guided PCI experienced an improved clinical outcome, with lower angina levels than patients in the CAG guided group and a lower need for re-intervention.

Measure of benefits used in the economic analysis
No summary health benefit was used in the economic analysis, therefore a cost-consequences analysis was performed.

Direct costs
Discounting was not carried out as the study was carried out over a period of less than two years. Quantities were reported separately from costs. The quantity/cost boundary adopted was that of the hospital. Direct costs included the cost of utensils (balloons and stents), the cost of labour (doctors, technicians, secretary), the cost of equipment, the cost of extra hospitalisation days and the cost of PCI or CAG. Direct cost data were based on patient data and on interviews and surveys for the estimation of labour time. Unit prices were obtained from the hospital accounting and supply system or from the invoices for utensils. The dates during which the costing was conducted, were not reported. The
**Statistical analysis of costs**  
No statistical analysis of costs was reported.

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

**Currency**  
Danish kroner (DKr).

**Sensitivity analysis**  
Sensitivity analyses were not carried out.

**Estimated benefits used in the economic analysis**  
See effectiveness results above.

**Cost results**  
The total cost for the CAG group was DKr2,301,589 and DKr2,149,366 in the IVUS and CAG guided group. IVUS guided procedures cost DKr152,223 less than CAG guided procedures.

**Synthesis of costs and benefits**  
Costs and benefits were not combined.

**Authors' conclusions**  
The increased benefits measured as cost savings resulting from less restenosis outweigh the cost increase from performing the IVUS guided PCI as opposed to CAG guided PCI.

**CRD COMMENTARY - Selection of comparators**  
A justification was given for the comparator used, namely CAG guided PCI. This was the standard procedure at the study hospital. You, as a user of this database, should decide if this is a widely used health technology in your own setting.

**Validity of estimate of measure of effectiveness**  
The analysis was based on a randomised controlled trial, which was appropriate for the study question. The study sample was representative of the study population. Patient groups were shown to be comparable at analysis. Analyses were presented for treatment completers and on an intention to treat basis. Some weaknesses in the analysis of effectiveness were that no power calculations were performed to determine the sample size, and the percentage of patients excluded from the study or who refused to participate was not reported.

**Validity of estimate of measure of benefit**  
The estimation of benefits was obtained directly from the effectiveness analysis. The choice of estimates was justified.
Validity of estimate of costs
In general the costing was well conducted and reported. All categories of cost relevant to the perspective adopted appear to have been included in the analysis. For each category of cost, all relevant costs were included in the analysis. Costs were reported separately from quantities. The price year was reported, discounting was appropriately not conducted, and charges were not used to proxy prices. Some weaknesses in the costing were that no statistical or sensitivity analyses were performed.

Other issues
The authors made appropriate comparisons of their findings with those from other studies, but the issue of generalisability to other settings was not addressed. The authors did not appear to present their results selectively. The study considered male patients undergoing PCI and this was reflected in the authors’ conclusions. The authors acknowledged that a larger number of patients would diminish the influence of outliers in the costing.

Implications of the study
The increased benefits measured as cost savings resulting from less restenosis outweigh the cost increase from performing the IVUS guided PCI as opposed to CAG guided PCI.

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