Bypass surgery versus stenting for the treatment of multivessel disease in patients with unstable angina compared with stable angina


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
The use of percutaneous coronary intervention (PCI) with stent implantation and coronary artery bypass grafting (CABG) for the treatment of multivessel disease.

Type of intervention

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with multivessel disease and a left ventricular ejection of at least 30%. Patients with left main stem stenosis, prior CABG or PCI, a transmural myocardial infarction (MI) within the previous week, a history of prior cerebrovascular accident (CVA), or concomitant severe hepatic or renal disease were excluded. Patients were also excluded if they had a need for other major surgery, had intolerance or contraindication to acetyl salicylic acid or ticlopidine, or leucopenia, neutropenia or thrombocytopenia were present. Patients were classified as having stable angina (Canadian Cardiovascular Society class 1 through 4), silent ischaemia, or unstable angina (Braunwald classification I B, C through III B, C). The patients had at least two de novo coronary lesions located in different vessels.

Setting
The setting was a hospital. The economic study was carried out in The Netherlands.

Dates to which data relate
The collection of effectiveness and resource use data started in April 1997. No price year was reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study, the analysis being based on a subgroup of patients enrolled in a trial published earlier (see Other Publications of Related Interest).

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not reported. The patients were enrolled from April 1997 to June
1998 and were allocated to the study groups. Of the 755 patients with stable angina, 374 were assigned to PCI and 381 to CABG. The mean age in the PCI group was 61 (+/- 10) years (range: 35 - 83) and 75% were men. The mean age in the CABG group was 62 (+/- 10) years (range: 32 - 81) and 77% were men. Of the 450 patients with unstable angina, 226 were assigned to PCI and 224 to CABG. The mean age in the PCI group was 61 (+/- 10) years (range: 30 - 78) and 80% were men. The mean age in the CABG group was 61 (+/- 10) years (range: 34 - 82) and 75% were men.

**Study design**
This was a randomised controlled trial. The number of centres in which the trial was carried out was not reported. The methods of randomisation and assessment were not specified, but further details were provided in the study published earlier (see Other Publications of Related Interest). The patients were followed for one year in the present study. The loss to follow-up was not reported.

**Analysis of effectiveness**
The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcomes were death, CVA, MI (Q-wave and non-Q-wave), CABG, repeat PCI, and no major adverse cardiac and cerebrovascular events (MACCE). The study groups were shown to be comparable at baseline.

**Effectiveness results**
After PCI, the rate of death was 2.4% in stable patients and 2.7% in unstable patients. The corresponding rates after CABG were 3.2% (stable) and 2.2% (unstable), respectively.

After PCI, the rate of CVA was 2.1% in stable patients and 0.4% in unstable patients. The corresponding rates after CABG were 1.3% (stable) and 3.1% (unstable), respectively.

After PCI, the rate of Q-wave MI was 4.3% in stable patients and 5.3% in unstable patients. The corresponding rates after CABG were 2.9% (stable) and 4.9% (unstable), respectively.

After PCI, the rate of non-Q-wave MI was 0.8% in stable patients and 0.4% in unstable patients. The corresponding rates after CABG were 0 (stable) and 0.9% (unstable), respectively.

After PCI, the occurrence of CABG was 3.7% in stable patients and 6.2% in unstable patients. The corresponding occurrences after CABG were 0.3% (stable) and 0.9% (unstable), respectively.

After PCI, the rate of repeat PCI was 13.1% in stable patients and 10.6% in unstable patients. The corresponding rates after CABG were 3.2% (stable) and 2.7% (unstable), respectively.

After PCI, the rate of no MACCE was 73.5% in stable patients and 74.3% in unstable patients. The corresponding rates after CABG were 89.2% (stable) and 85.3% (unstable), respectively.

There were statistically significant differences between all bypass patients versus stented patients in terms of the occurrence of CABG and repeat PCI, and between stable and unstable angina bypass surgery versus stable and unstable stented angioplasty.

**Clinical conclusions**
Compared with stable patients, there was no difference in the rate of major adverse events in unstable patients treated with either PCI or CABG. However, the overall need for repeat vascularisation was significantly higher in stented patients than in CABG patients.

**Measure of benefits used in the economic analysis**
The benefit measure used in the economic analysis was the MACCE event-free survival. It was derived from the effectiveness analysis using the Kaplan-Meier method.
**Direct costs**
No discounting was carried out as the costs were measured over one year. The unit costs and the quantities of resources were not reported separately. The costs were divided into procedural costs (procedure and initial hospitalisation), follow-up costs (diagnostic tests and rehospitalisation), and medication. The cost/resource boundary was not explicitly stated, but appears to have been that of the hospital. The source of the cost data was not reported, although the unit costs were estimated in The Netherlands. The resource use was estimated using actual data obtained from the trial. No price year was reported.

**Statistical analysis of costs**
Statistical analyses of the total costs were carried out to test for statistical significance of the results.

**Indirect Costs**
The indirect costs were not included in the analysis.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analyses were performed.

**Estimated benefits used in the economic analysis**
The difference in MACCE event-free survival between CABG and PCI was 11% for patients with unstable angina and 15.7% for patients with stable angina. The difference was not statistically significant.

**Cost results**
The total direct medical costs in stable patients were $12,960 for CABG and $10,368 for PCI. The corresponding costs in unstable patients were $14,783 (CABG) and $11,156 (PCI), respectively. The difference between CABG and PCI was $2,592 in stable patients and $3,627 in unstable patients. The difference did not reach statistical significance.

**Synthesis of costs and benefits**
An incremental analysis was performed to combine the costs and benefits. Compared with CABG, the incremental cost-effectiveness ratio in favour of PCI was $16,530 (95% confidence interval: 8,270 - 31,563) for patients with stable angina and $32,983 (95% confidence interval: 13,389 - 122,316) for patients with unstable angina.

**Authors’ conclusions**
There was no statistically significant difference between stable and unstable patients in terms of the costs and cost-effectiveness at one year. However, overall stenting was a cost-effective alternative to surgery, although the rate of repeat vascularisation of both stable and unstable angina was significantly higher in patients with stents.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear. CABG and PCI were selected as they represented two interventions commonly used to treat patients with multivessel disease. You should assess whether they are currently implemented in your own setting.
Validity of estimate of measure of effectiveness  
The analysis of the effectiveness used a randomised clinical trial, thus ensuring a high internal validity for the analysis. However, most of the details of the study were published in a different paper (see Other Publications of Related Interest). The authors noted that the present study was a subanalysis. Thus, there was a lack of sufficient power to detect statistically significant differences between the study groups.

Validity of estimate of measure of benefit  
The benefit measure used in the economic analysis was the MACCE event-free survival, which was obtained from the effectiveness analysis. It represents a widely used health measure in the treatment of patients with cardiovascular disease and should, therefore, have good validity.

Validity of estimate of costs  
The perspective of the analysis was not explicitly stated, although it is likely to have been that of the hospital. Only the direct costs were included in the analysis. The unit costs and the quantities of resources were not reported and no price year was given. Thus, reflation exercises to other settings would be difficult. Statistical analyses were carried out on the total costs.

Other issues  
The authors made limited comparisons of their findings with those from other studies. The issue of the generalisability of the study results to other settings was not addressed and sensitivity analyses were not carried out. Thus, the external validity of the study was limited. In addition, the authors noted that the study populations could not be representative of all patients with multivessel disease, due to the specific inclusion and exclusion criteria. The authors pointed out some limitations of the analyses, which have been highlighted already.

Implications of the study  
The main implication of the study was that the outcomes and costs were similar among stable and unstable angina patients. However, compared with CABG, there was a greater need for repeat vascularisation in both groups of patients who underwent stent implantation.

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None stated.

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Other publications of related interest  

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