Off-pump vs conventional coronary artery bypass grafting: early and 1-year graft patency, cost, and quality-of-life outcomes

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 off-pump coronary artery bypass (OPCAB) versus conventional coronary artery bypass grafting (CABG) with cardiopulmonary bypass was examined.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients referred for primary, elective CABG surgery. Patients in cardiogenic shock requiring emergency surgery or preoperative intra-aortic balloon pump were excluded for cardiac reasons.

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

Dates to which data relate
The patients were enrolled from March 2000 to August 2001. However, the period during which the effectiveness and resource use data were collected was not reported. The price year was not given.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed prospectively on the same sample of patients as that used in the effectiveness study.

Study sample
Power calculations were performed. These showed that the sample considered in the study had 80% power at a 5% level of significance to detect an absolute difference (as small as 5%) in patency rates between groups in either direction. Of the 465 patients initially identified, 297 patients were asked to participate. Since 97 refused to participate, the study sample comprised 200 patients (67% of those screened and 43% of all referrals). However, 2 patients in the OPCAB group and 1 patient in the CABG group withdrew because of mitral valve disease. The final study sample comprised 98 patients in the OPCAB group and 99 patients in the CABG group. One patient in the OPCAB group and 3 patients in the CABG group crossed-over.
Study design
This was a prospective, randomised, blinded clinical trial that was carried out at a single centre, the Emory University School of Medicine in Atlanta, Georgia. Randomisation was based on a computer-generated random number table, and the patients were stratified by gender and diabetic status. Random assignment was performed separately within each stratum with randomly permuted block sizes of 4 and 6. The length of follow-up was one year. Twelve patients (8 in the OPCAB group and 4 in the CABG group) were lost to follow-up or withdrew from the study by one year. A further search of the US Social Security Index Death Index database showed that none of these 12 patients had recorded deaths. Patients, their families, referring cardiologists, and non-operative clinicians were blinded to the treatment strategy. A single, experienced OPCAB surgeon performed all of the procedures.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The outcome measures used in the economic evaluation were:

- the incidence of early and late complications, and death;
- graft patency;
- cardiac end points (myocardial infarction, stroke, recurrent angina, rehospitalisation or death); and
- quality of life, as assessed using the EuroQol 6 and the 36-item Medical Outcomes Short-Form, Health Survey (SF-36).

At baseline, the study groups were comparable in terms of their demographics and clinical characteristics. However, the rate of cerebrovascular accident was lower in OPCAB than CABG patients (1% versus 9.1%; p=0.02) and there were more patients in the Canadian Cardiovascular Society classification III/IV in the OPCAB group than in the CABG group (24.5% versus 12.1%; p=0.03).

Effectiveness results
The differences between the groups did not reach statistical significance for any of the outcome measures used in the effectiveness analysis.

In particular, the rate of death was 1% in the OPCAB group and 2% in the CABG group (odds ratio OR=0.50, 95% confidence interval, CI: 0.04 - 5.61) from baseline to 30 days, and 3.4% in the OPCAB group and 2.2% in the CABG group (OR 1.58, 95% CI: 0.26 - 9.73) from 30 days to the 1-year follow-up.

Also, the absolute difference in graft patency between the OPCAB and CABG groups was 1.3% (95% CI: -0.66 - 3.31; p=0.13) at 30 days and -2.2% (95% CI: -6.1 - 1.7; p=0.27) at 1 year.

Clinical conclusions
The effectiveness analysis showed that the two interventions were equally effective in terms of the main outcome measures.

Measure of benefits used in the economic analysis
No statistically significant differences in clinical and quality of life end points were found between the groups. In effect, a cost-minimisation analysis was carried out.

Direct costs
Discounting was not relevant since the costs were incurred during a 1-year timeframe. The unit costs were not presented separately from the quantities of resources used. The economic evaluation considered initial hospital charges, professional costs, and rehospitalisation costs (including physician charges). The cost/resource boundary of the third-
party payer appears to have been adopted, although it was not explicitly stated. The hospital costs were derived from Medicare formulation of the hospital bills. Cost-to-charge ratios were used to convert hospital charges into costs. Professional costs were derived from Current Procedural Terminology costs. Rehospitalisation costs that, in general, occurred at other hospitals were estimated from Medicare reimbursement rates. The quantities of resources used were estimated from the sample of patients included in the effectiveness study. However, data for 2 patients in the OPCAB group were truncated from the primary cost analysis because such patients had outlaying hospital costs due to severe non-cardiac co-morbidity. Accordingly, the 2 patients with the highest costs in the CABG group were also eliminated. The price year was not reported.

**Statistical analysis of costs**
The costs were presented as mean values. Bootstrap re-sampling techniques were used to determine a CI and to test the statistical significance of differences in the costs.

**Indirect Costs**
The indirect costs were not considered in the economic evaluation.

**Currency**
US dollars ($).

**Sensitivity analysis**
Sensitivity analyses were not performed.

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

**Cost results**
In the primary analysis (with truncated data), the average initial costs per patient were $18,796 (+/- 5,552) with OPCAB and $21,068 (+/- 5,030) with CABG. The difference was $2,272 (95% CI: 755 - 3,732; p=0.002).

The average total costs per patient over the 1-year follow-up period were $22,837 (+/- 9,707) with OPCAB and $24,792 (+/- 9,140) with CABG. The difference was $1,995 (95% CI: -766 - 4,727; p=0.08). Similar results were achieved when outliers were considered.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant since a cost-minimisation analysis was performed.

**Authors’ conclusions**
Off-pump coronary artery bypass (OPCAB) provided complete and durable revascularisation and was cost-effective relative to conventional coronary artery bypass grafting (CABG). However, it should be noted that the study results showed that the two surgical approaches were equally effective and that the difference in costs was not statistically significant over the 1-year follow-up.

**CRD COMMENTARY - Selection of comparators**
The choice of the two comparators under evaluation was appropriate as they reflected the conventional approach (CABG) and a newer surgical procedure (OPCAB). You should decide whether they are valid comparators in your own setting.
Validity of estimate of measure of effectiveness
The effectiveness evidence came from a well-conducted clinical trial, which was appropriate for the study question. The internal validity of the analysis was ensured by the robust design, which was based on a blinded assessment of the outcome, stratified random allocation of the patients to the study groups, the inclusion of consecutive patients, and the use of intention to treat as the basis for the analysis of the clinical study. The study groups were, in general, comparable at baseline and power calculations were performed to justify the size of the study sample. The study sample comprised unselected patients and was representative of the patient population. These issues tend to enhance the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-minimisation analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective adopted in the study was not explicitly stated, although it could have been that of the third-party payer. The authors noted that outpatient resource use data were not collected, even though inpatient costs represented a large proportion of expenses associated with the two surgical procedures. A cost-to-charge ratio was appropriately applied. There was no information on the costs and quantities of resources used, and a detailed breakdown of the cost items was not reported. The price year was not given. These aspects of the analysis limit the possibility of replicating the study and performing reflation exercises in other settings. Statistical analyses of the costs were performed, but the cost estimates were specific to the study setting and no sensitivity analyses were carried out.

Other issues
The authors reported the results from other studies and noted that controversial findings had been published. The issue of the generalisability of the study results was addressed. In particular, the fact that a single surgeon performed all the procedures limits the transferability of the study results to other surgeons. The study referred to patients undergoing elective CABG or OPCAB and this was reflected in the authors’ conclusions.

Implications of the study
The study results suggested that OPCAB and CABG were equally effective and costly from the perspective of the third-party payer. The authors stressed the need for a large, prospective clinical trial to evaluate the generalisability of the results observed in the current study and to better define the role played by OPCAB in patients with multi-vessel coronary artery disease.

Source of funding
None stated.

Bibliographic details

PubMedID
15100202

DOI
10.1001/jama.291.15.1841
Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Aged; Cardiopulmonary Bypass /economics; Coronary Artery Bypass /economics /methods; Costs and Cost Analysis; Female; Follow-Up Studies; Hospital Costs; Hospitalization /economics; Humans; Male; Middle Aged; Quality of Life; Treatment Outcome; Vascular Patency

AccessionNumber
22004008163

Date bibliographic record published
31/08/2005

Date abstract record published
31/08/2005