Coronary artery bypass grafting with cardiopulmonary bypass versus off-pump cardiopulmonary bypass grafting: does eliminating the pump reduce morbidity and cost?


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 health technology intervention studied was off-pump coronary artery bypass grafting (OPCAB) in patients with disease involving the posterior descending or circumflex coronary arteries. OPCAB was performed through a sternotomy incision. Conduits for coronary artery bypass grafting (CABG) including the left internal mammary artery, radial artery, and saphenous vein were harvested in a standard fashion.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with disease involving the posterior descending or circumflex coronary arteries who were considered candidates for either procedure. Patients with the following contraindications to either procedure were excluded: left main coronary artery stenosis, reoperation with patent grafts, or significant left ventricular hypertrophy or dilatation.

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

Dates to which data relate
Effectiveness and resource use data were collected from January through December 1999. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

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

Study sample
Power calculations were used to determine the sample size (sample size calculations were performed using data from the literature; the authors assumed a total cost of $20,000 (SD, 4,000) and calculated the sample size needed to detect a $4,000 difference between groups; these calculations revealed a power level of 87% for accrual of 40 patients (20 per
group) and a power level of 99% for accrual of 80 patients (40 per group)). The study sample consisted of a total of 80 patients who represented a subgroup of 600 coronary revascularisations per year in the study hospital. The OPCAB group constituted 40 patients with a mean (SD) age of 64.9 (7.7) years; as compared with the 40 patients in the CABG/CPB group with a mean (SD) age of 64.6 (7.6) years.

**Study design**

The study was a prospective cohort study, carried out in a single centre. The duration of the follow-up appears to have been until discharge from hospital. No patients appear to have been lost to follow-up; except for two OPCAB patients who required conversion to CABG with CPB to complete their revascularisation. The attending surgeon, in consultation with the patient made the decision as to which procedure was performed on an individual basis. For patients undergoing OPCAB, angiography was performed within 48 hours after surgery to determine early graft patency. All patient data were collected according to the Society of Thoracic Surgeons national cardiac surgery database (STS.NCSD). After surgery, both groups of patients were admitted to the intensive care unit (ICU). The patients were extubated as soon as clinically indicated. An early extubation protocol was employed for both groups of patients. The patients were transferred from the ICU and discharged to home when clinically indicated by the attending surgeon.

**Analysis of effectiveness**

The principle used in the analysis of effectiveness was intention to treat. The clinical outcome measures were patency rate, perioperative outcomes (including number of vessels grafted, procedure time, time to extubation, chest tube output, and transfusion of blood products) and postoperative outcomes regarding need for reoperation for bleeding and incidence of complications including myocardial infarction, stroke, renal failure, mediastinitis, atrial fibrillation, and death. The study groups were comparable in terms of baseline characteristics; except for the fact that patients requiring four or more grafts were more likely to undergo CABG with CPB; thirty-six (90%) CABG with CPB patients had circumflex grafts placed, while 28 (70%) OPCAB patients had circumflex grafts placed.

**Effectiveness results**

The effectiveness results were as follows:

The OPCAB patients underwent grafting of 2.7 (SD, 0.7) vessels per patient compared with 3.6 (SD, 0.8) vessels per patient in the CABG/CPB group, (p<0.0001).

All bypassable circumflex coronary arteries were grafted in each group.

Chest tube output was lower for the OPCAB group compared with the CABG/CPB group (419 +/- 169 versus 588 +/- 476 mL, p=0.036).

Time to extubation and transfusion of blood products did not differ between the two groups.

Angiography demonstrated 105 of 108 (97%) grafts were patent in the OPCAB group.

In terms of postoperative outcomes, there were no differences between the OPCAB group and the CABG/CPB group with regard to the incidence of reoperation for bleeding, myocardial infarction, stroke, renal failure, mediastinitis, atrial fibrillation, or death.

**Clinical conclusions**

At the time of postoperative angiography, 97% of the grafts in the OPCAB group were patent. With these results, this study documents that postoperative angiography after OPCAB is not routinely necessary, obviating any associated complications. The study found no differences in the incidence of postoperative complications between the OPCABG and CABG/CPB groups.

**Measure of benefits used in the economic analysis**
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

**Direct costs**
Costs were not discounted due to the short time horizon of the cost analysis. Resource use quantities were reported separately from the costs. Cost items were reported separately. The cost analysis covered the hospital costs in surgery, the ICU, and inclusive from the time of surgery to discharge. Costs incurred during the postoperative coronary angiograms or catheter-based interventions were not included in the analysis of the OPCAB group, as angiography was utilised for the study to determine graft patency. The perspective adopted in the cost analysis was not specified. The price year was not given.

**Statistical analysis of costs**
It was reported that analysis of variance was used to analyse continuous variables (which include costs). Regression analysis was used to investigate the correlation between the number of vessels grafted per patient and the cost from surgery to discharge for both groups.

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

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was conducted.

**Estimated benefits used in the economic analysis**
Not applicable.

**Cost results**
The mean (SD) total cost from surgery to discharge was $17,110 (7,057) in the OPCAB group compared to $17,963 (7,233) in the CABG/CPB group, (p=0.360), the differences, therefore, being non-significant. The number of vessels grafted showed a positive correlation to total costs in both groups.

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

**Authors’ conclusions**
While OPCAB provided satisfactory early graft patency, there was no significant difference between OPCAB and CABG with CPB with regard to cost, length of stay, or incidence of complications. In this study, eliminating CPB did not reduce morbidity or cost after CABG.

**CRD COMMENTARY - Selection of comparators**
A justification was given for the choice of the comparator. It was the conventional procedure used in the context in question. You, as a database user, should consider whether this is a widely used health technology in your own setting.
Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results was hampered by the non-randomised nature of the study design (the attending surgeon determined which procedure was performed on a particular patient). As acknowledged by the authors, this introduces the possibility of selection bias. Furthermore, the preoperative coronary artery pathology appears to have played a role in patient selection: patients requiring four or more grafts were more likely to undergo CABG with CPB. Notably, 90% of CABG with CPB patients had circumflex grafts placed, while this was the case in only 70% of OPCAB. However, the study groups were comparable with regard to other baseline characteristics. The study groups appear to have been representative of a low-risk population with multivessel coronary artery disease who were candidates for either OPCAB or CABG with CP.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore of cost-consequences design.

Validity of estimate of costs
Good features of the cost analysis, likely to enhance its validity, were as follows: costing was performed prospectively; resource use and cost profiles were reported separately; statistical analyses were performed on resource use and cost data. However, the following characteristics may have adversely affected the validity of the cost analysis: the price year and perspective adopted in the cost analysis were not specified; the sources of cost data and whether they were based on charges or true costs were not reported; the effects of alternative procedures on indirect costs were not addressed. As a consequence, cost results may not be generalisable outside the study setting.

Other issues
With regards to the above-described limitations of the study design, and lack of sensitivity analysis and statistical analysis of the costs, some degree of caution may need to be exercised in interpreting the study results. The issue of generalisability to other settings or countries was not addressed, although appropriate comparisons were made with other studies. The issue of the degree to which the study sample was representative of the study population was discussed in the authors' comments. The authors acknowledged that, because the rates of many complications are very low (in the range of 1% to 5%) in the low-risk population, to show a significant difference between groups would require a sample size of well over 1,000 patients. It was also noted that morbidity and cost after CABG appear to be driven by factors beyond the use of CPB: the preoperative risk profile of the patient and decisions made by the surgeon in the operating room.

Implications of the study
The authors noted that:

questions not addressed by this study include whether OPCAB procedures can be confirmed prospectively to benefit selected subgroups of patients requiring CABG: the elderly, the calcified ascending aorta, renal insufficiency, or patients requiring reoperative bypass grafting; and whether OPCAB can reduce cognitive dysfunction after bypass grafting compared with CABG with CPB;

long-term follow-up is necessary to determine whether the need for reinterventions and subsequent cardiac events will differ between OPCAB and CABG with CPB patients.

the study of the appropriate application of OPCAB procedures to patients undergoing CABG should be a productive area of study for many years.

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