**Economic outcome of off-pump coronary artery bypass surgery: a prospective randomized study**

Ascione R, Lloyd C T, Underwood M J, Lotto A A, Pitsis A A, Angelini G D

**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**
Off-pump (beating heart) coronary artery bypass surgery in patients undergoing first-time coronary artery bypass grafting.

**Type of intervention**
Treatment.

**Economic study type**
Cost-effectiveness analysis.

**Study population**
The study population was patients undergoing first-time coronary artery bypass grafting. Exclusion criteria were impaired left ventricular function (ejection fraction less than 30%) as assessed by angiography, recent myocardial infarction (less than 1 month), raised serum creatinine (greater than 130 micro mol/L), combined valve surgery, respiratory impairment, previous stroke or transient ischemic attack (TIA), and coagulopathy. Patients with coronary disease involving branches of the circumflex artery distal to the first obtuse marginal branch and posterior branches originating from the left system were also excluded from the study. In these patients it was felt to be technically too difficult for adequate revascularisation at the beginning of the authors' experiences with off-bypass surgery.

**Setting**
The setting was hospital. The economic analysis was carried out in Bristol, UK.

**Dates to which data relate**
No dates were reported.

**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 not used to determine the sample size. A total of 200 patients were randomly assigned in equal numbers to either the on-pump group (mean (SD) age 61.8 (8.59) years) or the off-pump group (mean (SD) age 62.9 (9.61) years).
Study design
The study was a randomised, controlled trial carried out in a single centre. The duration of the follow-up appears to have been until discharge from hospital. The study appears to have had no loss to follow-up, although it was reported that two patients in the off-pump group were converted to conventional surgery at the start of procedure because they did not tolerate the usual manoeuvres to expose the target anastomotic site. Patients were prospectively randomised into two groups by card allocation. Suitability for discharge from intensive care unit (ICU) and high dependency unit (HDU) followed unit protocol and was based on the judgement of an independent anaesthetist, cardiac surgeon, and the ICU nursing staff.

Analysis of effectiveness
The principle used in the analysis of effectiveness was intention to treat. The health outcome measures were postoperative outcomes, including mortality, acute renal failure (ARF), chest infection, transient stroke, reopening, inotrope requirement, myocardial infarct, total blood loss (mL), transfusion requirement, and intubation time (hours). Operative characteristics, such as number of distal anastomoses, conduit usage, and operative times were also reported. The study groups were found to be comparable in terms of their baseline characteristics.

Effectiveness results
The effectiveness results were as follows:

The study groups were not significantly different in terms of the number of deaths, ARF, transient stroke, reopening, and myocardial infarct.

The number of cases with chest infection was 22 in the on-pump group versus 8 in the off-pump group, (p<0.01).

The use of inotropic support was significantly greater in the on-pump group; 23 cases versus 6 cases, (p<0.001).

The mean (SD) total blood loss (mL) was 1,094.5 (660.4) in the on-pump group, and 769.8 (378.5) in the off-pump group, (p<0.01).

Transfusion requirements were higher in the on-pump group and were as follows: packed cells, 1.16 +/-1.6 units (on-pump) versus 0.28 +/-0.57 units (off-pump), (p<0.001); fresh-frozen plasma (FFP), 1.25 +/-2.84 units (on-pump) versus 0.07 +/-0.46 units (off-pump), (p<0.001); and platelets, 0.43 +/-1.0 units (on-pump) versus 0.04 +/-0.22 units (off-pump), (p<0.01).

Intubation time (hours) was 12.72 (21.99) in the on-pump group versus 7.16 (3.51) in the off-pump group, (p<0.05).

Operative characteristics were similar between the two study groups.

Clinical conclusions
Morbidity was significantly higher in the on-pump group. This study shows that off-pump coronary revascularisation is a safe and effective surgical technique when compared with conventional on pump coronary surgery.

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

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities were reported separately from the costs and cost items were reported separately. The cost analysis covered the variable and fixed costs during operative and postoperative care. The total cost for each patient was determined by adding the operation materials, bed
occupancy, transfusion, and complication management costs. The perspective adopted in the cost analysis was not explicitly reported but is likely to have been that of the National Health Service (NHS). The price year was not given. The following costs were not included in the cost analysis: professional fees, preoperative costs, theatre and perfusionist staff, drug costs, hospital administration, building, and maintenance costs.

**Statistical analysis of costs**
The unpaired t test was used to compare the groups in terms of costs.

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

**Currency**
US dollars ($). The exchange rate from UK pounds sterling to US dollars was not reported.

**Sensitivity analysis**
No sensitivity analysis was carried out.

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

**Cost results**
The mean (SD) total cost per patient was $3,731.6 (1,169.7) in the on-pump group versus $2,615.13 (953.6) in the off-pump group; (p<0.001). The cost reductions were distributed from the operating theatre to postoperative management.

**Synthesis of costs and benefits**
Costs and benefits were not combined since the use of the off-pump technique was the dominant strategy.

**Authors’ conclusions**
Off-pump revascularisation offers a safe, cost-effective alternative to conventional coronary revascularisation with cardiopulmonary bypass and cardioplegic arrest.

**CRD COMMENTARY – Selection of comparators**
A justification was given for the choice of the comparator; it was the conventional treatment 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 is likely to be high owing to the randomised nature of the study design, the comparability of the study groups, and the fact that the effectiveness analysis was based on intention to treat. However, the following may be regarded as limitations: power calculations were not performed to justify the sample size; the study was deemed to have relatively small number of patients with complications to infer definite benefits from either technique. The study sample appears to have been representative of the study population. One limitation of the study was that the dates for the effectiveness data collection were not reported.

**Validity of estimate of measure of benefit**
No summary benefit measure was identified in the economic study and, as such, the study was of cost-consequences design.

Validity of estimate of costs
The validity of the cost analysis was enhanced by the fact that: sufficient details of methods of cost estimation (including quantities of resource use and cost units) were given; statistical analyses were performed on resource use and cost data; the cost data appear to be based on true costs rather than on charges (although this was not explicitly reported). However, the price year and perspective adopted in the cost analysis were not explicitly specified; the effects of alternative treatment strategies on indirect costs were not addressed; it was acknowledged that costs in the operative and postoperative management of patients are generally absorbed across the department, and segregation of costs is occasionally difficult to specify. These features tend to limit the generalisability of the cost results to other settings.

Other issues
The authors’ conclusions appear to be justified given the uncertainties in the data. The issue of generalisability to other settings was not addressed, although some comparisons were made with other studies. The degree to which the study sample was representative of the study population was not addressed in the authors’ comments.

Implications of the study
In terms of clinical practice the results suggest the clinical and economic benefits of off-pump coronary revascularisation. Economic benefits appear to extend into the postoperative management phase. However, there is a need to assess the long-term outcomes of the off-pump technique (to evaluate whether the cost reduction is truly effective by being translated to long-term outcomes).

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