Reduced postoperative blood loss and transfusion requirement after beating-heart coronary operations: a prospective randomised study
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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
The use of coronary bypass, with or without cardiopulmonary bypass, on patients with coronary artery disease undergoing first-time coronary artery bypass graft (CABG).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with coronary artery disease undergoing first-time CABG under the supervision of the same consultant. The patients were judged eligible for operation on the basis of their medical history and the most recent angiogram. Eligibility was based on the following exclusion criteria:

- pre-existing coagulopathy or other disorders of haemostasis, such as a low platelet count, known platelet dysfunction, or history of bleeding tendencies;
- a left ventricular ejection fraction of less than 30%;
- a recent myocardial infarction (less than 1 month);
- reoperation;
- a prior stroke or transient ischaemic attack;
- respiratory or renal impairment; and
- coronary artery disease involving branches of the circumflex artery.

Setting
The setting was secondary care. The economic study was conducted at the Royal Infirmary, Bristol, UK, and in the USA.

Dates to which data relate
The effectiveness and resource data were collected between March 1997 and August 1998. The price year was not stated.
Source of effectiveness data
The effectiveness data were derived from a single study.

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
Two hundred patients with coronary artery disease were prospectively randomised to receive on-pump treatment (100 patients) and off-pump treatment (100 patients). Power calculations were used to determine the sample size. It was estimated that, in order to detect a clinically meaningful reduction in the length of postoperative stay (a 1-day reduction) with a probability of 0.9 and choosing a 5% significance level, 100 patients per group would be required. From a total of 538 patients who underwent first-time CABG, 200 patients remained eligible for the study after the exclusion criteria had been applied. The baseline characteristics of the study population were compared in terms of the following: age, body surface, gender, presence of diabetes, extent of coronary disease, left ventricular function, number of grafts per patient, and graft distribution.

Study design
This was a randomised, prospective study conducted at a single centre. Randomisation was performed using numbered, sealed, opaque envelopes. The treatment allocation for a patient was determined by opening the next envelope the evening before the operation. The duration of the follow-up was not explicitly stated, but the patients were observed for the duration of the postoperative stay. For conventional CABG, this amounted to 7.31 (+/- 1.6) days. Two patients allocated to the off-pump group crossed over to the on-pump group at the beginning of the operation because, haemodynamically, their heart did not tolerate the surgical manoeuvres to expose the target anastomotic site.

Analysis of effectiveness
The effectiveness was analysed on an intention to treat basis. The main health outcome used in the analysis was postoperative blood loss, which was identified as total chest tube drainage and transfusion requirement. Haematologic indexes and clotting profiles were also analysed. The authors stated that groups were similar in terms of their age, body surface, gender, presence of diabetes, extent of coronary disease, left ventricular function, number of grafts per patient and graft distribution. However, no statistical comparison of the two groups was presented in this paper.

Effectiveness results
The mean ratio of postoperative blood loss between the groups was 1.64 (95% confidence interval: 1.39 - 1.94). This suggested that the average blood loss was 1.6 times higher in the on-pump group than in the off-pump group.

A blood transfusion was not required in 70% of the patients in the off-pump group, compared with only 48% in the on-pump group, (p<0.05).

Less than 5% of the patients in the on-pump group required fresh frozen plasma and platelet transfusion, compared with 30% (plasma) and 25% (platelets) in the on-pump group, (p<0.05 in both instances).

There was no difference between the groups with respect to the preoperative and intraoperative patient variables.

Clinical conclusions
Compared with the off-pump group, the average postoperative blood loss was significantly higher in the on-pump group. Consequently, the need for blood, fresh frozen plasma and platelet transfusions was significantly higher in the on-pump group.
Modelling
The haematologic and coagulation indexes were analysed using a mixed linear model, proposed by Proc Mixed in the SAS software.

Measure of benefits used in the economic analysis
The authors did not provide a summary measure of benefits. A cost-consequences analysis was therefore performed.

Direct costs
The direct hospital costs of transfusion were considered. The total (intraoperative and postoperative) number of units of red blood cells, fresh frozen plasma, and platelets were recorded for each patient. The costs were then calculated from the number of units transfused. Discounting was irrelevant because of the short duration of the study. The quantities and the costs were estimated from the actual data collected in the authors’ institution. The resources used were collected between March 1997 and August 1998. The price year was not stated.

Statistical analysis of costs
The transfusion costs were presented as the mean value (+/- standard error of the mean). The two groups were compared using the unpaired t test.

Indirect Costs
The indirect costs were not considered.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The mean transfusion cost per patient was higher in the on-pump group than in the off-pump group. The cost was $184.8 (+/-$35.2) per patient in the on-pump group versus $21.47 (+/-$6.9) in the off-pump group, (p<0.01).

Synthesis of costs and benefits
The costs and the benefits were not synthesised due to the cost-consequences approach adopted in the analysis.

Authors' conclusions
Compared with conventional revascularisation with cardiopulmonary bypass and cardioplegic arrest, coronary artery bypass graft (CABG) on the beating heart was associated with a significant reduction in the postoperative blood loss, transfusion requirement and transfusion-related cost.

CRD COMMENTARY - Selection of comparators
The comparator was off-pump treatment on the beating heart, as opposed to on-pump treatment with conventional
cardiopulmonary bypass and cardioplegic arrest. The reason for this choice was clear, both treatment alternatives were used in the authors' setting. You should consider if this applies to your own setting.

Validity of estimate of measure of effectiveness
The analysis used results from a randomised, single-centre prospective trial. This was appropriate for the study in question. The study sample seems to have been representative of the study population. Power calculations were used to determine the sample size. The groups of patients seem to have been comparable in terms of their baseline characteristics, although no statistical analysis relating to this was performed. An extensive statistical analysis was conducted on the effectiveness data. These features of the effectiveness analysis suggest that the results were of high validity.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of benefits. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
All the categories of cost relevant to the perspective adopted were included in the analysis. The total (intraoperative and postoperative) number of units of red blood cells, fresh frozen plasma, and platelets were recorded for each patient, and the costs were subsequently calculated from the number of units transfused. Thus, the quantities and the costs were presented separately. Appropriate statistical analyses were conducted on the costs. The price year, however, was not stated.

Other issues
Appropriate comparisons were conducted with relevant studies dealing with the same topic. The issue of generalisability of the costs was not addressed, as no sensitivity analysis was conducted. The authors do not appear to have presented their results selectively. The authors stated that their omission of the analysis of the coagulation and haematologic indexes in the original study design could represent a limitation.

Implications of the study
The authors state "Given that nearly 10% of the 3.2 million annual recipients of red blood cell transfusions in the US are patients undergoing CABG, the routine implementation of the off-pump coronary operation should have significant implications in terms of reducing cost and postoperative complications related to blood-product transfusion”.

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Other publications of related interest

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