Heparin-bonded circuits improve clinical outcomes in emergency coronary artery bypass grafting


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
Two different strategies for the treatment of emergency coronary artery bypass grafting (EM-CABG) were compared. The conventional non-heparin bonded circuits (NHBC) with full anticoagulation protocol (FAP) and activated clotting time (ACT) > 480 seconds was compared with heparin-bonded circuits (HBC) and a lower anticoagulation protocol (LAP) with ACT > 280 seconds.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of patients undergoing EM-CABG. Only patients undergoing CABG following catheterisation laboratory emergencies were included. This inclusion criteria was based on the Society of Thoracic Surgeons National Cardiac Surgery Database registry and was defined as coronary artery bypass grafting immediately following catheterisation, because of acute percutaneous transluminal coronary revascularisation failure, or critical anatomy with significant haemodynamic instability. No other inclusion or exclusion criteria were reported.

Setting
The setting for the study was not clear. The authors stated that a review of consecutive patients entered into a national registry was used. However, the authors also stated that patients in the HBC/LAP group were treated at a tertiary setting, in a University Medical Centre in Boston, MA, USA.

Dates to which data relate
Clinical outcomes data were collected by a retrospective review of registry data. Data for the NHBC/FAP patients were collected between 1993-1995, while data for the HBC/LAP patients were collected between 1995-1997. No dates were given for the price data used.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
A retrospective cost analysis was carried out on the same 206 patients, for whom the outcomes were evaluated.
Study sample
An integrated blood conservation strategy was developed and applied to all patients undergoing CABG (emergency and non-emergency) over a four-year period, 1993-97. Data were collected prospectively. For this current study a retrospective analysis of the 206 consecutive patients who had undergone EM-CABG, was carried out. The study sample included 81 consecutive patients (1993-1995) who received NHBC/FAP, while the following 125 consecutive patients (1995-1997) had received HBC/LAP.

Study design
A before and after study was carried out on 2 groups of patients undergoing EM-CABG. Patients were followed-up to discharge and no loss to follow-up was reported.

Analysis of effectiveness
The analysis included all patients identified in the case review and selected for the evaluation: 206 in total.

The primary clinical outcomes reported in the analysis were:

- mortality;
- return to operating room for bleeding;
- perioperative myocardial infarction;
- postoperative inotropes;
- cerebrovascular accident/transient ischemic attack;
- pulmonary complications;
- vascular complications;
- atrial fibrillation;
- renal dysfunction (Cr>2.5);
- myocardial infarction and cerebrovascular accident/transient ischemic attack and vascular complications;
- any complication.

Effectiveness results
There was no statistically significant difference between the groups for:

- mortality: NHBC/FAP 7.40%, HBC/LAP group 2.40%;
- return to operating room for bleeding: NHBC/FAP 2.47%, HBC/LAP 1.60%;
- cerebrovascular accident/transient ischemic attack: NHBC 2.40%, HBC/LAP 1.60%;
- vascular complications: NHBC 1.20%, HBC/LAP 1.60%;
- atrial fibrillation: NHBC 37.0%, HBC/LAP 27.2%; or
- renal dysfunction (Cr>2.5): NHBC 6.20%, HBC/LAP 5.60%.

There was a statistically significant difference between the groups for:
perioperative myocardial infarction: NHBC 12.3%, HBC/LAP group 3.20% (95% CI: 0.27, 0.07 - 0.97; p=0.002);

postoperative inotropes: NHBC 38.1%, HBC/LAP 19.2% (95% CI: 0.37, 0.17 - 0.75; p=0.004);

pulmonary complications: NHBC 12.3%, HBC/LAP 4.80% (95% CI: 0.11, 0.01 - 0.85; p=0.05);

myocardial infarction and cerebrovascular accident/transient ischemic attack and vascular complications: NHBC 16.0%, HBC/LAP group 6.40% (95% CI: 0.36, 0.14 - 0.91; p=0.017).

any complication: NHBC group 28.4%, HBC/LAP group 12.8% (95% CI: 0.37, 0.16 - 0.82; p=0.012).

**Clinical conclusions**

The authors reported that the use of HBC/LAP was safe, and, compared to NHBC/FAP, resulted in a decrease in clinical thromboembolism and also effectively improved clinical outcomes.

**Measure of benefits used in the economic analysis**

No summary measure of benefits was reported. The outcomes were reported in a disaggregated way, and as such this was a cost-consequences analysis.

**Direct costs**

Resource quantities and costs were reported separately. The direct costs of the hospital were used in the analysis. The direct costs reported were blood bank costs of blood typing and administration, intensive care unit (ICU) stay, and additional non-ICU stay. The cost of the length of stay included room and board only. It was not reported what the cost or charge was based on. Details of the components of blood units for a transfusion were given, but the source of the prices was not reported. Hospital charges and costs were reported. Only incremental direct costs were reported based on the differences in average resource use between HBC & NHBC patients. Discounting was not required due to the short time frame of the study (less than one year). The dates of the price data were not specified.

**Statistical analysis of costs**

No statistical analysis of cost was reported.

**Indirect Costs**

Indirect costs were not reported.

**Currency**

US dollars ($). No currency conversions were undertaken.

**Sensitivity analysis**

No sensitivity analysis was carried out.

**Estimated benefits used in the economic analysis**

The reader is referred to the effectiveness results reported earlier.

**Cost results**

The difference in costs between NHBC and NHBC/LAP was given as $4,751.50 (charge data) and $4,533.60 (cost data). No sensitivity analysis of costs was reported.
Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The authors concluded that the use of HBC/LAP in EM-CABG was both safe and more cost-effective than the conventional NHBC/FAP.

CRD COMMENTARY - Selection of comparators
No explicit justification was given for the comparator used. The authors reported that the relevance of NHBC was under debate. In addition, the registry data indicated that NHBC might have been replaced by HBC/LAP. You, as a user of this database, should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a before and after comparative study design, which may result in biased or inaccurate data. As the authors noted, the study design used does not control for the impact of other variables on outcomes, such as experience or improvement over time. The patient groups were not comparable at analysis in terms of pre-operative or intra-operative care or predicted mortality, which may introduce selection bias. The authors reported the use of multivariate statistical analysis to control for the impact of confounding variables and assess whether the treatment was an independent predictor of outcome. However, it is not clear if the factors that differed between the groups at baseline were included in this analysis. The authors did not adjust the level of statistical significance for multiple comparisons. The authors did not report whether the sample size was sufficient to detect statistically significant differences. Insufficient information was reported to determine whether the study sample was representative of the study population. These factors make it difficult to assess the validity of the estimates of effectiveness.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit and included only short term outcomes up to discharge from the index hospital admission. The analysis was therefore categorised as a cost-consequences study and did not assess the long term impact of the two interventions on patients’ health or well being.

Validity of estimate of costs
The authors reported resource use and costs separately, but noted that only a limited number of costs to the hospital were included, which might have affected the results of the cost analysis. In particular, the costs excluded were more likely to have been affected by practice variation. Costs were not discounted, which was appropriate, given the short time frame of the analysis. The source and year for the price data were not reported. No statistical or sensitivity analysis of costs was conducted to assess the robustness of differences between the groups.

Other issues
The authors interpreted the results of their study with reference to other published literature and discussed issues that could affect the generalisability of the results to other settings, such as differences in treatment protocols and clinical practice.

Implications of the study
The authors concluded that HBC/LAP was safe and effective and reduced hospital stays. On this basis the authors recommended the use of HBC/LAP in all patients undergoing EM-CABG.

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