Impact of myocardial protection during coronary bypass surgery on patient outcome

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 intervention examined in the study was continuous coronary perfusion with warm blood enriched with the ultra-short acting beta-blocker esmolol (ES) to improve functional and structural myocardial protection in patients undergoing coronary artery surgery.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with isolated coronary artery disease subjected to primary coronary artery surgery.

Setting
The setting was a hospital. The economic study was carried out at the Clinic for Cardiothoracic Surgery of the University of Cologne in Germany.

Dates to which data relate
No dates or price years were reported.

Source of effectiveness data
The source of effectiveness data was a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not reported. A sample of 150 consecutive eligible patients who underwent ES and who were selected at the study hospital were enrolled in the ES group. The mean age of the ES group was 64.1 (+/- 8.3) years (range: 62.8 - 65.4 years; 119 men). A further group of 150 patients with a mean age of 64.3 (+/- 8.9) years (range: 62.9 - 65.7 years; 115 men) who underwent CP and were matched for age, gender, preoperative left ventricular function, number of emergent operations, history of renal failure and history of neurological symptoms was selected and included in the CP group.
Study design
This was a retrospective cohort study with matched controls, carried out in a single centre (the Clinic for Cardiothoracic Surgery of the University of Cologne). Patients in the control group were matched with those retrospectively selected in the intervention group. Length of follow-up was not clearly stated. No loss to follow-up was reported.

Analysis of effectiveness
All patients included in the study were accounted for in the clinical analysis. The health outcomes assessed in the analysis were intraoperative data, such as cardiopulmonary bypass time, aortic cross-clamp time, and distal anastomoses, and several post-operative data, such as dopamine, dobutamine, epinephrine, norepinephrine, intra-aortic balloon pump (IABP), left ventricular assist device (LVAD), perioperative myocardial infarction (MI), creatinine increase, hemofiltration or dialysis, supraventricular arrhythmias, ventricular arrhythmias, neurological disorders, reoperation, white blood cell count (WBCmax), mechanical ventilation, intensive care unit (ICU) stay, readmission to ICU, hospital mortality, and hospital stay. Study groups were shown to be comparable at baseline, due to the matching procedure.

Effectiveness results
Intraoperative data: in the ES group cardiopulmonary bypass time was 103 mins. (+/-32) (95% CI: 98 - 108) and in the CP group it was 109 mins. (+/-37) (95% CI: 103 - 115);

aortic cross-clamp time was 60 mins. (+/-20) (95% CI: 57 - 63) in the ES group and 58 mins. (+/-19) (95% CI: 55 - 61) in the CP group; and

the number of distal anastomoses was 3.4 (+/-1) (95% CI: 3.2 - 3.5) in the ES group and 3.7 (+/-1.1) (95% CI: 3.5 - 3.8) in the CP group.

Only the difference in terms of number of distal anastomoses reached statistical significance at the 5% level.

As regards the post-operative data, only the number of patients requiring readmission to ICU were statistically different across the study groups, while the remaining outcomes produced similar results. 3 patients required readmission (2.2%; 95% CI: 0 - 4.2%) in the ES group and 13 (8.7%; 95% CI: 4.2% - 13.2%) in the CP group, (p=0.01). Hospital stay was 12.3 days (+/-4.8; 95% CI: 11.5 - 13) in the ES group and 13.5 days (95% CI: 12.9 - 14.1) in the CP group, (p=0.0013)

Clinical conclusions
The authors concluded that clinical outcomes were generally similar in patients treated with both myocardial protection approaches. Only hospital stay, readmission to ICU and the number of distal anastomoses led to more favourable results (in terms of statistical significance) in the group of patients treated with esmolol.

Measure of benefits used in the economic analysis
Health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis, thus a cost-consequences analysis was performed.

Direct costs
Discounting was not relevant as the time horizon of the study was short. Unit costs and quantities of resources were not reported separately. Only the procedural costs of the intervention were considered, and thus the acquisition costs of esmolol and cardioplegia solution were included in the analysis. The cost of one hospital day was also reported. The source of unit cost data was not reported. The estimation of resources was based on actual data derived from patients’ charts. The cost/resource boundary appears to have been that of the hospital. The period of collection of quantities of resources was not reported and no price year was given.
Statistical analysis of costs
Statistical analyses of costs were not performed.

Indirect Costs
Indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was conducted.

Estimated benefits used in the economic analysis
Please refer to the effectiveness results reported earlier.

Cost results
Procedural costs were $60 per patient in the ES group and $120 per patient in the CP group. As the cost of one hospital day was about $370, total costs savings in the ES group compared with the CP group were about $59,000 for the 150 patients.

Synthesis of costs and benefits
This was not relevant as a cost-consequences analysis was carried out.

Authors' conclusions
The authors concluded that the beta-blocker technique may represent a safe, effective and cheaper alternative to standard crystalloid cardioplegia for myocardial protection during primary coronary artery surgery.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator was clear. Crystalloid cardioplegia was selected as it represented the standard approach for myocardial protection during coronary artery surgery. You, as a user of this database, should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness was based on a retrospective matched cohort study, which appears appropriate for the study question. Patients in the control group were selected to match those in the intervention group. Study groups were comparable at baseline due to the matching procedure performed. However, as no randomisation was performed, the impact of bias and confounding factors cannot be excluded. The study sample appears to have been representative of the study population. However, length of follow-up was not reported and power calculations were not performed. The authors acknowledged that the sample was underpowered to detect statistically significant differences in terms of some outcome measures, such as mortality.

Validity of estimate of measure of benefit
Health outcomes were left disaggregated and a cost-consequences analysis was carried out. Please refer to the comments reported earlier.
Validity of estimate of costs
The perspective adopted in the study was not explicitly stated, but appears to have been that of the hospital where the study was carried out. The main economic analysis included only the direct costs associated with the procedures (drugs). Quantities were derived from patients' charts, but the source of unit cost data was not stated. No dates were reported and the price year was not given. No statistical analysis of costs or quantities was performed. These issues reduce transparency and limit the external validity of the economic analysis.

Other issues
The authors made some comparisons of their findings with those from other studies. The issue of the generalisability of the study results was not addressed and sensitivity analyses were not conducted. Because of this, and given that unit costs and the price year were not reported, the external validity of the analysis was limited. The study enrolled a sample of patients undergoing coronary artery surgery and this was reflected in the conclusions of the study. The authors presented the effectiveness results in detail, although costing was selectively reported.

Implications of the study
The authors stated that their study showed the economic superiority of the beta-blocker esmolol over crystalloid cardioplegia in myocardial protection, while no relevant difference was found in terms of clinical outcomes. However, other studies found different results and the authors concluded that "the questions (1) if myocardial protection during routine coronary artery surgery impacts clinical patient outcome and (2) which specific myocardial protection technique is most-effective and efficient remain to be elucidated".

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