Safety and effectiveness of minimal-access versus conventional coronary artery bypass grafting in emergent patients

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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 minimal access versus conventional coronary artery bypass grafting (CABG) in emergency patients was examined. A detailed description of the two approaches was provided.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients requiring emergency CABG.

Setting
The setting was a hospital. The economic study was carried out in Taiwan.

Dates to which data relate
The effectiveness and resource use data were gathered from June 1996 to April 1998. The price year was not explicitly reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed retrospectively on the same sample of patients as that used in the clinical study.

Study sample
Power calculations were not reported. A sample of 63 patients who underwent emergency CABG was identified and included into the study. There were 10 patients in the MI group and 53 in the CS group. The mean age of the patients was 61.5 (+/- 11.4) years in the MI group and 61.8 (+/- 9.4) years in the CS group. The proportions of women in the two groups were 10% (MI) and 34% (CS), respectively. It was not stated whether some patients were excluded for any reason from the study sample, or refused to participate.

Study design
This was a prospective, randomised clinical trial. No information on the centre where the study took place was provided. The operation procedures were performed alternately every other week. Thus, patients were randomised according to the time when their operations were performed. The same doctor performed all the operations. The average length of follow-up was 19.7 (+/- 4.1) months in the MI group and 30.4 (+/- 9.8) months in the CS group. No patient was lost to the follow-up assessment.

**Analysis of effectiveness**

The analysis of the clinical study appears to have been conducted on an intention to treat basis, as all of the patients were accounted for in the clinical study. The outcome measures used were:

- the length of incisions,
- the number of distal anastomosis,
- cross clamping time,
- cardiopulmonary bypass,
- 24-hour drainage amount,
- internal mammary artery (IMA) use, mortality,
- predicted mortality (based on a Society of Thoracic Surgery program),
- the rate of major morbidity,
- intensive care unit (ICU) stay, and
- the length of postoperative stay.

The outcomes evaluated during the follow-up period were the rates of wound complications, late death and postoperative left ventricular ejection fraction (LVEF). The study groups were comparable at baseline in terms of their demographics and clinical characteristics, as none of the differences reached statistical significance.

**Effectiveness results**

The authors noted that no patients in the MI group required conversion to CS.

The length of incisions was 9.2 (+/- 0.3) cm in the MI group and 23.5 (+/- 1.2) cm in the CS group.

No statistically significant differences were observed in the number of distal anastomosis, cross clamping time, cardiopulmonary bypass, 24-hour drainage amount, mortality, rate of major morbidity, ICU stay, length of postoperative stay, and rates of wound complications, late death and postoperative LVEF.

The rate of IMA use was 100% in the MI group and 56% in the CS group, (p=0.001).

The predicted mortality was 23.98% in the MI group and 12.51% in the CS group, (p=0.001).

It was also reported that all patients in the MI group were satisfied with the cosmetic results of the limited thoracotomy incisions.

**Clinical conclusions**

The effectiveness analysis showed that MI led to lower predicted mortality and length of incisions in comparison with CS. Other aspects of the interventions were comparable.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was carried out.

Direct costs
Discounting was not relevant since the costs per patient were incurred during a short timeframe. The unit costs were not presented separately from the quantities of resources used. The health services included in the economic evaluation were grouped into the categories of operative fee, ward fee, laboratory fee, and transfusion fee. The cost/resource boundary of the study was not reported clearly. The source of the costs was not reported. Resource use was derived from data gathered between June 1996 and April 1998. The price year was not explicitly reported but it could have been 2000.

Statistical analysis of costs
Statistical analyses were performed to test the statistical significance of differences in the costs.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
New Taiwan dollars (NT$). In 2000, the average exchange rate between US dollars ($) and NT$ was $1 = NT$31.87.

Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
The estimated total fees per patient were NT$347,319 (+/- 87,602) in the MI group and NT$434,360 (+/- 83,583) in the CS group, (p=0.652).

With respect to the categories of costs, statistically significant differences were observed only in terms of transfusion fees. The transfusion fees were NT$9,406 (+/- 1,259) in the MI group and NT$12,059 (+/- 3,994) in the CS group, (p=0.003).

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant since a cost-consequences analysis was performed.

Authors' conclusions
Emergency coronary artery bypass graft (CABG) surgery could be accomplished using a minimally invasive technique, the efficacy, safety profile and economic impact of which were similar to those associated with conventional CABG.

CRD COMMENTARY - Selection of comparators
The selection of the comparators was appropriate since the standard approach (CS) was compared with a newer alternative strategy (MI). You should decide whether they are valid comparators in your own setting.
Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The authors described the randomisation approach. However, the two groups were quite unbalanced in some baseline characteristics, such as gender distribution, the proportion of smokers, and the proportion of patients with a percutaneous transluminal coronary angioplasty. These differences were not shown in the statistical analysis. Indeed, the main limitation of the study was the small sample size, which, as the authors noted, reduced the possibility of reaching statistically significant differences in outcome measures between the groups. The length of follow-up was appropriate to examine the long-term impact of the interventions. However, MI patients were followed for a significantly shorter timeframe. Limited information on the approach used to evaluate the outcome measures was provided. These issues tend to limit the internal validity of the study.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective adopted in the study was not reported. Hospital charges appear to have been used as a proxy for the costs. A detailed breakdown of the costs was not provided and the costs were presented as macro-categories. The unit costs and the quantities of resources used were not presented separately, which reduces the possibility of replicating the study. The source of the data was not reported. Standard statistical analyses of the costs were carried out, but the cost analysis could have been underpowered to detect statistically significant differences in the total costs, owing to the small sample size. The price year was not explicitly reported, although the authors stated that the exchange rate from Taiwan currency into US dollars was 2000. It was unclear whether costs were estimated using 2000 values.

Other issues
The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not performed, which reduces the external validity of the analysis. The authors highlighted the operative advantages of MI CABG over conventional CABG. The study referred to patients requiring emergency CABG and this was reflected in the authors’ conclusions.

Implications of the study
The study results suggested that a minimally invasive approach can be used in patients requiring emergency CABG. However, caution is required when interpreting the results of the study because of the limitations of the analysis.

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None stated.

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Other publications of related interest
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