Short-stay intensive care after coronary artery bypass surgery: randomized clinical trial on safety and cost-effectiveness


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 study compared the early discharge (under 8 hours) of post-surgical coronary artery bypass graft (CABG) patients from intensive care (IC) to medium care (MC), compared with an overnight stay in intensive care (i.e. usual care).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised all CABG patients admitted to one hospital over 2 years. Exclusion criteria included age over 78 years, ejection fraction less than 30%, Stage 3 obesity, haemodialysis, pulmonary hypertension, recent cardiovascular accident, recent myocardial infarction, cardiogenic shock, need for inotropic therapy, ongoing infarction, or the need for an intra-aortic balloon pump. Other reasons for exclusion were the inability to give informed consent, the inability to speak, read or understand the Dutch language, and emergency surgery.

Setting
The setting was inpatient and outpatient care. The economic study was carried out in the Netherlands.

Dates to which data relate
The effectiveness and resource use data were obtained between March 2001 and March 2003. The price year was 2001.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

Study sample
The authors reported that 300 patients were needed in each group to ensure that the study had 80% power to detect an IC readmission difference of 5% between the two groups. All high-risk individuals were excluded from the analysis. One thousand and sixty-two patients were admitted to the hospital for CABG surgery. Of these, 380 patients were excluded, 181 because they were identified as high-risk patients and 179 for other reasons (e.g. unable to speak Dutch or unable to give informed consent). A total of 702 patients (66.1%) were eligible for inclusion and were asked to give informed consent. Of the eligible patients, 102 refused to participate (14.6%) and 600 (55.5%) gave informed consent. Finally, 300 were allocated to the control group and 300 to the SSIC group. Three patients were excluded from the analysis (2 from the SSIC group and 1 from the control group).
Study design
The study was a single-blinded, randomised controlled trial that was conducted in a single centre. Randomisation was generated by a computer before the study started. The results of the randomisation process were entered into numbered, opaque envelopes and sealed with tape. Research nurses not involved in the treatment assigned consecutive patients once written consent and baseline measures had been obtained. The nurses in IC opened the envelopes immediately postoperatively. Patients and the surgical team were blinded to the group assignment. The length of follow-up for each patient was 30 days or less. There appears to have been no loss to follow-up.

Analysis of effectiveness
The primary health outcomes were IC readmission and total hospital stay. The secondary outcomes included quality of life scores and postoperative morbidity and mortality. The analysis was conducted on an intention to treat basis. The groups were shown to be comparable at baseline.

Effectiveness results
IC readmission was 1.34% (n=4) in the control group and 2.68% (n=8) in the SSIC group. The difference was not statistically significant, (p= 0.241; 95% confidence interval, CI: -0.9% to 2.9%).

The mean postoperative total hospital stay was 8.5 days in the control group and 8.1 days in the SSIC group. The difference was not statistically significant, (p=0.807; 95% CI: -0.4 to 1.2).

No statistically significant differences were found between the two groups in terms of postoperative morbidity and 30-day mortality.

Clinical conclusions
Early discharge from IC to MC for low-risk CABG patients is comparable, in terms of IC readmission, with postoperative overnight IC stay.

Measure of benefits used in the economic analysis
The measure of health benefit used was the delta quality-adjusted life-month (QALM). Quality of life was assessed at day 1 and day 30 using the EuroQol instrument (EQ-5D). The EQ-5D includes five 3-level dimensions: morbidity, self-care, usual activities, pain and mood. The patient’s answers to the five EQ-5D items were used to express a single utility value ranging from 0 to 1. In the absence of a series of Dutch population-based utility weights, an English series was used instead. The delta QALM was then calculated by subtracting the utility measured at the end of the follow-up from the baseline utility score, then dividing by two.

Direct costs
The direct costs to the hospital, which performed the CABG surgery, and the district hospital, which appear to have been used for outpatient procedures in the follow-up period, were included in the analysis. The resource use of clinical and outpatient procedures in the main hospital was obtained from the hospital billing system. Data on outpatient procedures in the district hospitals were obtained through questionnaires. The number of hours or days of inpatient hospital stay in the different departments in the University hospital were obtained from medical records, while data on low-care inpatient stays in the district hospitals were obtained from discharge letters. The unit costs of inpatient days were calculated according to Dutch guidelines for costing. The nursing costs were calculated on the basis of actual salary and occupation figures for the different departments. Guideline prices were used for specialist and resident costs. The cost of material and laundry was based on average use by a CABG patient. Medication costs were based on the cost calculation of a random sample of 50 patients in each group. A shadow price was used to assess the cost of the first hours of MC treatment in the IC department for the SSIC patients. The costs and the quantities were not reported separately. The price year was 2001. Discounting was not necessary given the short follow-up period.
Statistical analysis of costs
A non-parametric bootstrap sampling method with 1,000 replications was used to assess the statistical significance of cost (and quality of life) differences between the two groups.

Indirect Costs
Productivity costs were not considered.

Currency
Euro (EUR).

Sensitivity analysis
In six one-way analyses, the unit costs of hospital inpatient days were varied with minimum and maximum cost estimates. A non-parametric bootstrap method was used to estimate the probability that the SSIC group dominated the control group. The shadow price of the MC stay for SSIC patients was replaced by the IC price. In addition, a multivariate analysis was conducted on the costs in order to evaluate a worst-case scenario for the SSIC group.

Estimated benefits used in the economic analysis
The SSIC group's quality of life improved more than that of the control group. The delta QALM was 0.0253 (+/- 0.1424) for the SSIC group versus 0.0015 (+/- 0.1388) for the control group. The difference in the delta QALM was statistically significant, (p=0.0238; 95% CI: 0.0012 to 0.0464).

Cost results
The mean total costs were EUR 4,625 in the SSIC group and EUR 5,441 in the control group.

The mean difference was EUR -816 (95% CI: -1,581 to -174).

Synthesis of costs and benefits
The costs and benefits were combined using an incremental cost-effectiveness ratio (ICER). The bootstrap results for the ICER showed that SSIC was dominant over the control group in 98% of cases, with the quality of life improving more for SSIC patients than for control patients and their costs being lower.

The sensitivity analysis showed that the results were robust, with 97% of the bootstrapped ICERs lying in the same quadrant as in the base-case analyses.

Authors' conclusions
Short-stay intensive care (SSIC) is a safe and cost-effective approach. It can be considered an alternative to conventional postoperative intensive care treatment for low-risk coronary artery bypass graft (CABG) patients.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. It was chosen because it reflected current practice in the authors' setting. You should decide if it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a randomised controlled trial, which was suitable to address the study question. With the exception of the exclusion of the high-risk patients, the study sample was representative of the study population. In addition, the patient groups were shown to be comparable at baseline. The method of randomisation and blinding, the
length of the study and the loss to follow-up were all reported, suggesting that the internal validity of the study is likely to be high. Power calculations were reported and an appropriate sample size was used.

**Validity of estimate of measure of benefit**
The measure of benefit used in the analysis was the QALM. The utilities were taken from a published source using the five EQ-5D items.

**Validity of estimate of costs**
The analysis of the costs was performed from the perspective of the hospital. Relevant cost categories and all relevant costs appear to have been included in the analysis. Discounting was not performed, but was not necessary given the short duration of follow-up. The authors evaluated uncertainty in the cost data jointly with the effectiveness data by random sampling observations, to produce a CI around the ICER. The costs and the quantities were not reported separately, which reduces the generalisability of the study results.

**Other issues**
The authors compared their findings with those from other studies which, in general, showed the results to be in agreement. They noted that the ability to generalise their study will be limited as the analysis was a single-centred study. The authors do not appear to have presented their results selectively. The analysis excluded high-risk patients and this was reflected in the conclusions. The authors reported a number of further limitations to their study. For example, only one moment of decision to transfer SSIC patients from IC to MC was taken. The authors acknowledged that it might have been more effective had the decision to transfer also been taken at later stages.

**Implications of the study**
The authors suggested that SSIC should be considered an alternative for conventional postoperative IC treatment for low-risk CABG patients.

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