Morbidity, cost, and six-month outcome of minimally invasive direct coronary artery bypass grafting

Magovern J A, Benckart D H, Landreneau R J, Sakert T, Magovern G J

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
Use of minimally invasive, direct coronary artery bypass grafting (MIDCABG) in patients undergoing elective left internal mammary artery (LIMA) to left anterior descending artery (LAD) bypass grafting. The MIDCABG procedure involves grafting the LIMA to the LAD through an anterior thoracotomy incision without arresting the heart, which thereby avoids both a sternotomy and cardiopulmonary bypass (CPB).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients aged less than 80 years undergoing elective LIMA to LAD bypass grafting. All cases were done on an elective or urgent basis, and emergency operations for acute myocardial infarction or failed angioplasty were excluded.

Setting
Hospital. The economic analysis was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data corresponded to the period between January 1995 and December 1996. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the final outcomes was based on a single study.

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

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of a total of 60 patients with a mean (SD) age of 63.2 (11.7) years in the MIDCABG group and 55 patients with a mean (SD) age of 63.3 (10) years in the CABG group.
Study design
This was a retrospective cohort study, carried out in a single centre. The duration of the follow-up was 6 months after the operation. Regarding loss to follow-up, it was reported that complete clinical follow-up of all patients in this series was obtained at 6 months after the operation and all MIDCABG patients underwent stress perfusion tests to identify myocardial ischemia. In the CABG series, no specific methods were used to confirm anastomotic patency or graft flow. Early in the MIDCABG series of patients no specific method was used to confirm graft patency. Starting in October 1996 (patient 50) a 20-MHz Doppler flow probe was used to evaluate systolic and diastolic flow velocity in the LIMA pedicle after construction of the anastomosis. The patients were stratified into low, average, high, or extremely high risk groups based on a preoperative clinical risk score that had been previously validated and published.

Analysis of effectiveness
The analysis of effectiveness appears to have been based on treatment completers only. The clinical outcomes were operative deaths, transfusion incidence, postoperative intubation time, the number of patients re-explored for bleeding, the number of patients who required ventilatory support for greater than 24/48 hours, the combined incidence of major morbidity, and 6-month follow-up outcome. The two study groups were found to be comparable in terms of age, sex, and preoperative risk level.

Effectiveness results
The effectiveness results were as follows:

There were no operative deaths in either group.

The MIDCABG patients had a lower transfusion incidence than the CABG patients (10/60 (17%) versus 22/55 (40%); p<=0.02) and a shorter postoperative intubation time (2.1 (4.2) versus 12.6 (9) hours; p<=0.0001).

One patient in each group was re-explored for bleeding.

Three CABG patients (3/55, 5%) required ventilatory support for greater than 48 hours, but no MIDCABG patient was ventilated for more than 24 hours.

The combined incidence of major morbidity was 9% for sternotomy (CABG) and 0% for MIDCABG.

At 6-month follow-up, 5 MIDCABG patients (5/60, 8%) had evidence of recurrent ischemia involving the left anterior descending artery, primarily the result of anastomotic stricture.

The overall incidence of recurrent angina in the CABG group was 1.8% (1/55), (p=0.20).

Clinical conclusions
The study data show that MIDCABG is as safe as traditional CABG for single-vessel coronary artery disease. With the same mortality level (no mortality), the study has shown that MIDCABG is less morbid than standard CABG. An important finding in the study results suggest that MIDCABG can be done with low morbidity even in high-risk surgical candidates. There was an 8% incidence of recurrent ischemia in the MIDCABG group, thus, there appears to be a definite incidence of early graft problems with MIDCABG caused primarily by anastomotic stricture.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported (see effectiveness results above).

Direct costs
Costs were not discounted due to the short time frame of the cost analysis. Quantities of length of stay were reported separately from the costs, but cost items were not reported separately. Cost analysis covered the hospital costs for each
patient, with the exception of overheads. The perspective adopted in the cost analysis appears to have been that of the hospital. The cost analysis was conducted retrospectively. The source of the cost data was the study hospital's computerised financial system. The cost analysis was based on true costs, reflecting resources used rather than estimated percentage of charges. The price year was not explicitly specified.

### Statistical analysis of costs

The Student's t test appears to have been used to compare the groups and subgroups in terms of length of stay and costs.

### Indirect Costs

Indirect costs were not considered.

### Currency

US dollars ($).

### Sensitivity analysis

No sensitivity analysis was carried out.

### Estimated benefits used in the economic analysis

See effectiveness results above.

### Cost results

The estimated mean (SD) hospital costs were $15,600 (4,200) for traditional CABG and $11,200 (3,100) for MIDCABG, (p<0.001).

The mean (SD) hospital cost for low or moderate risk (clinical risk score (CRS) lower than 5) category of the MIDCABG (n=47) patients was $9,360 (1,582) versus $12,200 (5200) for the CABG (n=42) patients, (p=0.01).

The corresponding values for the high or extremely high risk category (CRS greater than 5, n=13 in each group) were $16,120 (7,200) for the MIDCABG group and $26,800 (10,100) for the CABG patients, (p=0.01).

### Synthesis of costs and benefits

Costs and benefits were not combined.

### Authors' conclusions

This analysis shows that MIDCABG reduces the initial morbidity and cost of coronary bypass, but some patients require subsequent reintervention.

### CRD COMMENTARY - Selection of comparators

A justification was given for the choice of the comparator. It was the standard method in the context in question at the time of the study. You, as a database user, should consider whether this is a widely used health technology in your own setting.

### Validity of estimate of measure of effectiveness

The internal validity of the effectiveness results cannot be assured due to the retrospective nature of the study design, which, as the authors acknowledge, may have led to the introduction of systematic bias into the study. Another potential
bias-creating issue mentioned by the authors is that the MIDCABG operation is in a developmental stage and was compared with the results of an operation that has been developing for more than 25 years; therefore the study results should be viewed as a starting point rather than the final outcome. The results of MIDCABG will improve as experience grows and dedicated equipment is introduced. Adoption of patient selection criteria that exclude patients with very small (1 mm) or intramyocardial target vessels from MIDCABG will also improve the results of this procedure. One of the limitations of the effectiveness analysis was that none of the CABG patients had routine stress perfusion scans or angiography, and therefore the authors did not know the 6-month patency rate of these grafts. The two study groups were found to be comparable in terms of age, sex, and preoperative risk level. The study sample appears to have been representative of the study population (patients with single-vessel disease undergoing elective LIMA to LAD bypass grafting).

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was therefore of cost-consequences design.

**Validity of estimate of costs**
The validity of the cost results was enhanced by the following features of the cost analysis: quantities of length of stay for the groups and (risk) subgroups were reported separately from the costs; some details of methods of cost estimation were given; the perspective adopted in the cost analysis was implicitly specified; the cost analysis was based on true costs rather than charges; and statistical analysis was performed on resource use (length of stay) and cost data. However, the following limitations may apply: the price year was not given; the breakdown of hospital costs was not reported; the cost analysis was conducted retrospectively rather than prospectively; the effects of the two therapeutic modalities on indirect costs (productivity loss) were not addressed; and the cost results may not be generalisable outside the study setting.

**Other issues**
In view of the inherent limitations of the study design and the lack of sensitivity analysis, some degree of caution may need to be exercised in interpreting the study results. The issue of generalisability to other settings or countries was not addressed and appropriate comparisons do not appear to have been made with other studies. The issue of whether the study sample was representative of the study population was not fully addressed; it was reported that all the patients studied had single-vessel disease. A cost-utility approach may have been informative in the context in question by incorporating the subjective assessment of the patients in the analysis, as it was reported that there is conflict of interest between surgeons, who typically favour survival, graft patency and long-term outcome as the most important criteria by which to judge success, and patients and referring physicians who value low procedural morbidity and ease of recovery, in addition to survival. It was further mentioned that some patients may prefer MIDCABG or beating heart CABG over traditional CABG because of reduced morbidity and improved comfort, even if there is a small incidence of graft stenosis.

**Implications of the study**
Long-term follow-up is needed before MIDCABG can be judged better than traditional bypass, but the initial results are promising, especially in high-risk patients. From the study data, the authors could not determine whether the grafts were abnormal from the start or were compromised by a restenosis phenomenon. However, based on this experience, the authors are now obtaining routine intraoperative angiography as Doppler flow analysis of the bypass grafts. Only with these data can this new procedure be validated and established as an effective form of revascularisation. Another issue raised by MIDCABG is whether the beating heart approach can be applied to multivessel; ultimately MIDCABG will not be significant unless it can be applied to multivessel disease. It seems clear that a prospective study of traditional versus beating heart CABG for multivessel disease is needed to delineate the risks, benefits, and late outcome of these two approaches before traditional CABG is abandoned.

**Source of funding**
NHS Economic Evaluation Database (NHS EED)  
Produced by the Centre for Reviews and Dissemination  
Copyright © 2018 University of York
None stated.

**Bibliographic details**

**PubMedID**
9800810

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Case-Control Studies; Female; Follow-Up Studies; Hospital Costs /statistics & numerical data; Hospitals, General; Hospitals, University; Humans; Internal Mammary-Coronary Artery Anastomosis /economics /methods /mortality; Length of Stay /statistics & numerical data; Male; Middle Aged; Minimally Invasive Surgical Procedures; Morbidity; Pennsylvania; Postoperative Complications /epidemiology; Retrospective Studies; Risk Factors; Sternum /surgery; Time Factors; Treatment Outcome

**AccessionNumber**
21998001678

**Date bibliographic record published**
30/04/2001

**Date abstract record published**
30/04/2001