Influence of concomitant CABG and urgent/emergent status on mitral valve replacement surgery


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
Elective or urgent/emergent mitral valve replacement (MVR) surgery, with or without coronary artery bypass grafting (CABG), were examined.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing isolated primary MVR.

Setting
The setting was secondary care. The economic study was carried out at the Emory University Hospital, Atlanta (GA), USA.

Dates to which data relate
The effectiveness and resource use data were gathered from 1980 to 1997. The price year was 1997.

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

Link between effectiveness and cost data
The costing was performed prospectively on the same patients as were included in the effectiveness study.

Study sample
Power calculations, if performed, were not reported. The data for all eligible and consecutive patients who underwent elective or urgent/emergent MVR, with or without CABG, at the study centre from 1980 to 1997 were identified. An overall group of 1,844 patients was enrolled. Four groups of patients were considered:

- elective MVR with CABG (E MVR+CABG) was performed in 360 patients;
- elective MVR without CABG (E MVR-CABG) was performed in 1,332 patients;
66 patients underwent urgent or emergent MVR with CABG (U/E MVR+CABG); and
86 patients underwent urgent or emergent MVR without CABG (U/E MVR-CABG).

**Study design**
This was a prospective cohort study that was carried out in a single centre. Trained medical personnel recorded the clinical and procedural data prospectively on standardised forms. The follow-up period was 10 years. Follow-up information was obtained from communication (by letter or telephone) with the patients, their families and/or attending physicians. Information on patients who had died was obtained from the state bureau of records. Follow-up data were available for 1,719 patients (93% of those included in the initial sample).

**Analysis of effectiveness**
The analysis of the effectiveness was limited to those patients whose follow-up data were available. The outcomes used were:

- the rates of postoperative myocardial infarction (MI) and postoperative stroke,
- the rate of in-hospital mortality,
- the length of stay (LOS), and
- the 5- and 10-year survival rates (estimated using the Kaplan-Meier approach).

Multivariate correlates of survival were identified using the Cox model analysis.

Patients in the E MVR+CABG group were significantly older than those in the E MVR-CABG group, 65.4 (+/- 9.2) years versus 55.4 (+/- 14.4) years, (p<0.05). They were also more often male (47.5% female versus 64.2%), and more likely to have hypertension (53.0% versus 24.2%), class III-IV angina (36.0% versus 10.7%), and prior MI (35.0% versus 6.5%), (p<0.05). Similar baseline differences were observed when comparing U/E MVR+CABG and U/E MVR-CABG patients. U/E MVR+CABG patients were older (64.2 +/- 10.5 years versus 53.9 +/- 14.5 years), more often male (37.9% female versus 61.6%), and more likely to have hypertension (55.2% versus 21.0%), class III-IV angina (68.3% versus 25.9%) and prior MI (71.2% versus 22.0%). Patients in the E MVR-CABG had a significantly lower prevalence of class III-IV angina (25.9% versus 10.7%) and congestive heart failure (62.9% versus 79.3%), and a lower proportion with a history of prior MI (6.5% versus 22.0%), than did patients in the U/E MVR-CABG, (p<0.05). Similar baseline differences were observed when comparing E MVR+CABG and U/E MVR+CABG patients.

**Effectiveness results**
The postoperative MI rate was significantly lower in the E MVR-CABG group (0.4%) than in the E MVR+CABG group (1.7%), (p<0.05).

The postoperative MI rate was 0% in the U/E MVR groups (with or without CABG).

The postoperative stroke rates were 3.4% in the E MVR-CABG group, 8.4% in the E MVR+CABG group, 11.3% in the U/MVR-CABG group, and 9.4% in the U/E MVR+CABG group. Statistically significant differences were observed for E MVR-CABG versus E MVR+CABG, and for E MVR-CABG versus U/E MVR-CABG.

The in-hospital mortality rates were 5.9% in the E MVR-CABG group, 14% in the E MVR+CABG group, 20% in the U/E MVR-CABG group, and 40.6% in the U/E MVR+CABG group. Statistically significant differences were observed for E MVR-CABG versus E MVR+CABG, for E MVR-CABG versus U/E MVR-CABG, for U/E MVR-CABG versus U/E MVR+CABG, and for E MVR+CABG versus U/E MVR+CABG.

The LOS was 11.2 (+/- 9.4) days (range: 0 - 86) in the E MVR-CABG group, 14.8 (+/- 14.5) days (range: 0 - 120) in the E MVR+CABG group, 18.8 (+/- 24.3) days (range: 0 - 194) in the U/E MVR-CABG group, and 16.5 (+/- 18.2) days (range: 0 - 120) in the U/E MVR+CABG group.
days (range: 0 - 81) in the U/E MVR+CABG group. Statistically significant differences were observed for E MVR-CABG versus E MVR+CABG, and for E MVR-CABG versus U/E MVR-CABG.

The 5-year survival rates were 75.1% in the E MRV-CABG group, 57.2% in the E MVR+CABG group, 60.2% in the U/E MVR-CABG group, and 39.6% in the U/E MVR+CABG group.

The 10-year survival rates were 50.5% in the E MRV-CABG group, 31.6% in the E MVR+CABG group, 46.3% in the U/E MVR-CABG group, and 28.0% in the U/E MVR+CABG group.

The statistical analysis showed that correlates of in-hospital mortality were increasing age (odds ratio, OR=1.03, 95% confidence interval, CI: 1.02 - 1.05; p=0.0001), concomitant CABG (OR 2.06, 95% CI: 1.45 - 2.92; p=0.0001), and urgent/emergent status for MVR (OR 4.37, 95% CI: 2.87 - 6.66; p<0.0001).

Predictors of 10-year mortality were increasing age (OR 1.02, 95% CI: 1.01 - 1.02; p<0.0001), hypertension (OR 1.28, 95% CI: 1.09 - 1.46; p=0.01), prior MI (OR 1.27, 95% CI: 1.04 - 1.49; p=0.04), diabetes mellitus (OR 1.54, 95% CI: 1.31 - 1.78; p=0.0005), congestive heart failure (OR 1.19, 95% CI: 1.11 - 1.27; p=0.0001), concomitant CABG (OR 1.44, 95% CI: 1.23 - 1.64; p=0.0005), and urgent/emergent status (OR 1.40, 95% CI: 1.11 - 1.68; p=0.03).

Clinical conclusions
The study demonstrated that the addition of CABG or urgent/emergent status significantly increased morbidity and mortality in patients undergoing MVR. Therefore, better survival data were associated with patients not receiving CABG in elective surgery.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic evaluation. In effect, a cost-consequences analysis was conducted.

Direct costs
Discounting was not reported. The unit costs were not presented separately from the quantities of resources used. The perspective adopted in the economic evaluation was not reported, and neither the were the cost categories considered. Only the hospital costs were estimated. The costs were derived from charges provided by the hospital finance department. The charges were converted into costs using the cost-to-charge ratios obtained from the hospital cost report. Resource use data were estimated from the actual consumption of resources in the sample of patients used in the effectiveness analysis. All the costs were inflated to 1997 values using the Medicare cost inflation rate.

Statistical analysis of costs
The estimated costs in the study groups were compared using statistical tests.

Indirect Costs
The indirect costs were not included.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were carried out.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total hospital costs per patient were $23,890.11 (+/- 12,339.18) in the E MRV-CABG group, $33,215.72 (+/- 24,131.93) in the E MVR+CABG group, $31,981.18 (+/- 14,170.00) in the U/E MVR-CABG group, and $40,535.17 (+/- 32,464.85) in the U/E MVR+CABG group. Statistically significant differences were observed for E MVR-CABG versus E MVR+CABG, and for E MVR-CABG versus U/E MVR-CABG.

Synthesis of costs and benefits
Not relevant.

Authors’ conclusions
The addition of coronary artery bypass grafting (CABG) or urgent/emergent status to patients undergoing mitral valve replacement (MVR) significantly increased morbidity, mortality and the in-hospital costs.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. Elective or urgent/emergent MVR with or without CABG represented surgical procedures carried out at the authors’ institutions. You should decide whether they represent valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a prospective cohort study, which was appropriate for the study question. However, since patient allocation to the study groups was not randomised, the study groups were not balanced at baseline and selection bias could have affected the results of the effectiveness analysis. Some bias in the outcome assessment could have occurred due to the lack of a blinded design. The patients were enrolled from a single centre, therefore, caution is required when extrapolating the results to the overall population of patients requiring MVR.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis since, in effect, a cost-consequences analysis was conducted.

Validity of estimate of costs
The perspective of the study was not explicitly stated, but it appears to have been that of the health service payer. The costs were derived from hospital records and a breakdown of the cost categories was not reported. The authors limited their analysis to direct costs without providing details of the cost categories included in the analysis (e.g. operating room, physician fee, nursing). It would appear that relevant costs, such as outpatient and follow-up costs, were not included. The unit costs and the quantities of resources used were not presented separately. This lack of disaggregation limits the usefulness of the cost results. The price year was reported. A cost to charge ratio was used to estimate the true costs from patient bills. Statistical tests were carried out to compare the costs estimated in each study group. Discounting was likely to have been relevant since the length of follow-up for each patient was longer than two years.

Other issues
The authors compared their results with those obtained in other published studies. The main findings of the current analysis confirmed those reported in the literature. However, the issue of the transferability of the study results to other settings was not addressed. The authors did not perform any sensitivity analysis. One limitation of the analysis (i.e. cost data were derived from estimated cost-to-charge ratios) was noted.
Implications of the study
The main implication of the study was that emergency status and concomitant CABG may severely affect the long-term survival and costs for patients undergoing MVR. The authors suggested that careful preoperative scrutiny of the benefits versus resource use, along with proper conveyance of realistic survival expectations to the patient and his or her family, should be required for patients undergoing high-risk MVR.

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