Economic evaluation of a randomised trial of early return to normal activities versus cardiac rehabilitation after acute myocardial infarction


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 interventions assessed were early return to normal activities (ERNA) and standard rehabilitation (REHAB) after acute myocardial infarction (AMI).

Patients who had been diagnosed with AMI, but who were at low risk of experiencing further cardiac events, were encouraged to return to normal activities about 2 weeks after the infarction without formal rehabilitation (ERNA). Patients in the comparator group were encouraged to return to normal activities after rehabilitation, about 6 to 12 weeks after infarction (REHAB).

Type of intervention
Rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged less than 75 years who had been diagnosed with AMI, but who were at low risk of experiencing another cardiac event. Low-risk patients had to satisfy the following criteria:

- a negative exercise stress test (<2 mm ST segment change) with at least 7 Metabolic Equivalents achieved at the initial exercise test or, in manual workers, a workload equivalent to levels achieved at work before the AMI;

- a left ventricular ejection fraction of at least 40%;

- no inducible ventricular tachycardia in patients with left ventricular ejection fraction less than 40%;

- no unstable angina after the AMI; and

- no severe cardiac failure.

The patients and their doctors gave their consent to participate in the trial.

Setting
The setting was secondary care. The economic analysis was carried out in Sydney, Australia.

Dates to which data relate
The effectiveness and resource use data related to 1994 to 1997. The price year was 1999.
Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The same patient sample provided both the effectiveness data and the cost data. The costing was carried out prospectively.

Study sample
Power calculations were reported. At each time point up to 6 months, the study had at least 70% power to detect a 10-point difference in the health-related quality of life scales, and at least 60% power to detect a 20% difference in return to normal activities. The authors stated that the power of the analyses in the paper was actually higher than this, because they used appropriate statistical methods for analysing longitudinal data.

Of 1,201 AMI patients aged less than 75 years, 187 patients satisfied the inclusion criteria. However, 45 of these did not consent to be randomised to treatment. Thus, 142 patients were randomised to either REHAB (n=70) or ERNA (n=72).

Study design
This was a randomised controlled trial (RCT) that was conducted in a single centre. The patients were followed up clinically for 6 months, and by questionnaire for 12 months. There were 9 time periods during the 12 months at which patients should have been assessed (every week for 6 weeks, then at 12 weeks, 6 months and 1 year post infarction). Thirteen patients did not complete any questionnaires. Thus, the effective sample was 129 (69%) of the 187 eligible patients. Any patient who missed a questionnaire and all subsequent ones were described as lost to follow-up. The loss to follow-up was:

at 3 months, 15 in the ERNA group and 15 in the REHAB group;
at 6 months, 19 in the ERNA group and 17 in the REHAB group; and
at 12 months, 34 in the ERNA group and 33 in the REHAB group.

The completion and dropout rates were similar in the two groups.

Analysis of effectiveness
The analysis of effectiveness was conducted on the basis of treatment completers only. The health outcomes included four health-related quality of life domains and four measures of return to normal activities. The health-related quality of life domains were physical abilities, distress, usual activities and self-care. Patient-perceived health-related quality of life was estimated using a cardiovascular extension of the Health Measurement Questionnaire (see Other Publications of Related Interest). Return to normal activities provided a measure of return to level of health before the AMI. It was assessed on the basis of:

whether the patient undertook any hours of paid work;
whether the patient resumed the pre-AMI hours of paid work;
whether the patient resumed any hours of unpaid activities; and
whether the patient resumed their pre-AMI hours of unpaid activities.

The sample size for the return to work measures was 76, as these were the patients who had been in paid work before their AMI. Of these, 65 (86%) provided information on their hours of paid work during the follow-up. The sample size for the measure of return to any unpaid normal activities was 119 patients. Of these, 110 patients provided information
on hours of unpaid work before and after their AMI.

The only statistically significant difference between the two groups at baseline, in terms of patient characteristics, was that more patients in the REHAB group lived alone (97 versus 84%, p=0.02).

**Effectiveness results**

The only statistically significant difference between the two patient groups was the return to any paid work in the first 6 weeks after AMI, which was higher in the ERNA group than in the REHAB group. This was shown in a graph, (Wilcoxon test, p=0.007, log rank, p=0.04).

The mean scores for quality of life were shown graphically and appear to have been similar for both groups. The mean scores were low, indicating good quality of life in each patient group. There was no statistically significant difference between the two groups in any of the dimensions of quality of life.

There was a significant effect of time for each dimension, (p<0.001), and a significant interaction between time and group for distress, (p=0.007), and usual activities, (p=0.004).

**Clinical conclusions**

The authors concluded that the rehabilitation programme did not improve health outcomes for this category of patients.

**Measure of benefits used in the economic analysis**

No summary measure of benefits was calculated. In effect, the authors carried out a cost-consequences analysis.

**Direct costs**

Discounting was not carried out since the costs were incurred during less than 2 years. The costs of REHAB (i.e. assessment, counselling, education and exercise) were broken down according to price and quantity of sessions. They consisted of staff costs, building costs, equipment costs, consumables and overheads, which were not individually broken down into prices and quantities. The authors also included the transport costs of the patients attending the rehabilitation sessions, but these also were not broken down into prices and quantities. Other health service resource costs were calculated for the 12 months after the AMI, but details of these were not given in the paper. In addition, there was no breakdown into prices and quantities, as they did not differ significantly (statistically) between the two patient groups. These costs consisted of phone calls, hospital readmissions, gated heart pool scan, exercise stress test, other diagnostic tests, and visits to a general practitioner, specialist doctors, or other health professionals. The cost of the rehabilitation programme was obtained using data from the hospital and from the patients. The other costs to the health system during the follow-up period were obtained from patient questionnaires and patient records. The price year was 1999. Resources were measured between 1994 and 1997.

**Statistical analysis of costs**

No statistical analysis of the costs was carried out.

**Indirect Costs**

No indirect costs were measured.

**Currency**

Australian dollars (Aus$).

**Sensitivity analysis**
No sensitivity analysis was carried out.

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

Cost results
The authors reported the cost of any difference in resources used between the two patient groups. The only difference turned out to be the cost of the rehabilitation programme (i.e. Aus$393.68 per patient treated)

The costs were calculated for 12 months.

The costs of adverse effects would have been included in the calculation of the health service resources used.

Synthesis of costs and benefits
The cost and benefits were not combined as this was, in effect, a cost-consequences analysis.

Authors' conclusions
For this sample of low-risk patients, the cost of this particular rehabilitation programme could not be justified by any benefit in clinical outcomes.

CRD COMMENTARY - Selection of comparators
The authors justified their choice of the comparator (a cardiac rehabilitation programme) on the grounds that it was current practice. You should decide if the particular rehabilitation programme used in this study represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a single study that obtained information from patient questionnaires and from clinical follow-up at 6 weeks and 6 months. The study design, an RCT, was appropriate for the study question. Power calculations were reported. Hence, the sample size should have been appropriate to detect significant differences in outcomes between the groups. The authors were aware that the number of patients for whom complete follow-up data were available was fewer than one would like. The study sample appears to have been representative of the study population (i.e. low-risk AMI patients). The patients in the two groups were shown to be comparable in all but one respect, more patients in the ERNA group lived with at least one other person. In general, the analysis of effectiveness was handled credibly, but it would have been helpful had the results been presented numerically as well as graphically.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The health benefits are therefore those associated with the effectiveness outcomes.

Validity of estimate of costs
It was unclear which cost perspective the authors adopted, as they included health system and patient expenses but did not include any indirect costs, even though they had obtained information on the amount of paid and unpaid work that the patients had undertaken. The authors' conclusion, that the expense of the rehabilitation programme was not justified, would have been strengthened had the indirect costs been included. This is because their inclusion would have shown an increase in the amount of paid and unpaid work during the first 6 weeks in the ERMA group, compared with the REHAB group. The unit costs were not reported separately from the resource quantities. Although the authors
had calculated quantities of health system resources used in addition to the rehabilitation sessions, they did not report them. The resource use quantities were obtained from a single study, while the prices were taken from the authors' setting. No statistical or sensitivity analyses of the quantities or prices were performed. These facts limit the generalisability of the results to other settings. The price year was given.

Other issues
The authors made appropriate comparisons of their results with the findings from other studies and differentiated their study from others in which the 'no rehabilitation' patients still received limited rehabilitation. However, they did not address the issue of generalisability to other settings. The authors did not present the full details of their results, although it was unclear whether this would have altered any conclusions, and their conclusions reflected the scope of the analysis. The authors were aware of, and acknowledged, certain limitations of their study. In particular, the fact that there were limited data for the follow-up period, which was limited to 12 months. Further, there was no assessment of patient compliance with medication.

Implications of the study
The authors concluded that, for the category of low-risk patients defined in the study, the cardiac rehabilitation programme does not produce any clinical benefits but it does increase expenses. The use of this programme cannot, therefore, be justified.

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