Cost-effectiveness of rehabilitation after an acute coronary event: a randomised controlled trial


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 two cardiac rehabilitation strategies for patients who had suffered an acute coronary syndrome (ACS). The strategies were conventional care (CC) and conventional care plus an exercise-based rehabilitation programme (C+R). The additional care consisted of a 6-week package of thrice-weekly sessions, each comprising 60 to 90 minutes of supervised exercise, combined with 45 minutes of education (12 occasions) and 45 minutes of psychosocial counselling (6 occasions). The sessions were conducted in groups (maximum 15 people), with additional one-to-one counselling provided if necessary.

Type of intervention
Treatment and rehabilitation.

Economic study type
Cost-utility analysis.

Study population
The population comprised patients who had been admitted to hospital for an ACS event. The inclusion criteria were patients aged less than 75 years who were self-caring, adequately literate in the English language, and residing in the geographical area of the health service, with consent given by their specialists. Patients who presented with uncompensated heart failure, uncontrolled arrhythmias, severe and symptomatic aortic stenosis, or other conditions precluding physical activity, were excluded.

Setting
The setting was tertiary care, specifically two tertiary teaching hospitals in the Central Sydney Area Health Service, NSW, Australia. The economic study was carried out in Australia.

Dates to which data relate
The dates to which the effectiveness evidence and resource use data referred were not reported. The patients were recruited over a 2-year period and were followed up for 12 months. The price year was 1998.

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

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients that provided the effectiveness data.
Study sample
Of the 375 patients who were eligible for the study, 113 (30%) were randomised between C+R (n=57) and CC (n=56). Reasons for non participation were detailed, the main one being no interest (n=105). Another 2,337 (86%) screened individuals were considered ineligible, mainly because they lived outside of the area health service (n=1,347). Sample size calculations were adequately reported.

Study design
The study was a randomised controlled trial that was conducted in two tertiary teaching hospitals. Consecutive patients were recruited over a 2-year period after an episode of uncomplicated acute myocardial infarction or recovery from unstable angina. The participants were followed up for 12 months. Central randomisation was performed using dynamic balancing, hierarchically stratified according to relevant patient or site characteristics.

Analysis of effectiveness
The analysis of the clinical study was conducted on an intention to treat basis. The primary health outcomes were quality of life measures estimated at baseline, and at 6 and 12 months, using the standard Medical Outcomes Study Short Form-36 (SF-36) questionnaire and the disease-specific Utility-Based Quality of Life-Heart questionnaire (UBQ-H). The randomised groups were well balanced for baseline characteristics. During follow-up, two patients in the conventional group died, one from cardiogenic shock and the other with respiratory failure. All patients from the rehabilitation group survived to 12 months. Direct patient follow-up data were available in the population at risk for 109 of the 113 patients (96%) at 6 months and 105 of the 111 patients (95%) at 12 months. Only one patient was lost entirely to follow-up.

Effectiveness results
Both groups showed a general improvement in the SF-36 domain scores. The domain scores improved from baseline at 6 and 12 months, with non significant advantages for rehabilitation across domains except for “physical function,” where a significant advantage was seen at 12 months, (p=0.04). The utility results are shown in the 'Estimated Benefits Used In The Economic Analysis' section.

Clinical conclusions
Improvement in self-reported physical function suggested higher levels of daily physical activity in response to rehabilitation during follow-up. The size of the difference equated to 2 of 10 tasks of daily living performed with little or no limitation, compared with substantial previous limitation, and would therefore be clinically important. Similar subjective improvements in physical function after rehabilitation have been found and confirmed by objective improvements in functional capacity. These results support the notion that early exercise-based rehabilitation counters functional cardiac impairment.

Measure of benefits used in the economic analysis
The outcome measure used in the economic analysis was the quality-adjusted life-years (QALYs). The QALYs were calculated for the intervention period based on UBQ-H scores at baseline, 6 and 12 months for each patient. The UBQ-H was developed specifically for use in coronary artery disease and has been validated in this clinical situation. The UBQ-H was used to assign the patient's utility (preference) for their current health state and to calculate QALYs by treatment arm, integrating UBQ-H utility scores (0 to 1 scale) and survival by treatment arm using the quality-adjusted survival analysis method.

Direct costs
The direct costs included all cardiovascular hospitalisations, pharmaceuticals, tests, consultations, rehabilitation, patients' expenses and ambulance costs. The cost of admission for defibrillator implantation in the conventional group was excluded. The authors presented the mean total cost per patient and the incremental costs. Hospitalisation costs were based on the diagnosis-related group category reference and length of stay. All other cost categories were valued...
according to official Australian government schedules. The patients and their general practitioners provided health resource use data by completing comprehensive questionnaires at 6 and 12 months. Medical records were used to determine and verify all outpatient medical data and to complete information not available from the patient. Discounting was appropriately not carried out because of the short study period. The quantities and the costs were estimated on the basis of actual data. The dates when the resources were measured were not reported. The price year was 1998.

**Statistical analysis of costs**
The costs were treated stochastically. Shapiro-Wilk tests were used to test for normally distributed data. Unpaired t tests, chi-squared tests and Mann-Whitney U-tests for non-normal data were used for comparisons between groups at baseline. For differences between groups over time, longitudinal multiple regression and repeated-measures ordinal regression analyses were undertaken.

**Indirect Costs**
No indirect costs were included.

**Currency**
Australian dollars (AUD).

**Sensitivity analysis**
One-way sensitivity analyses were performed to determine resilience to variations around the base-case estimates. Ninety-five per cent confidence intervals (CIs) for incremental utility were estimated by bootstrapping the sampled distribution of incremental utility with 10,000 replicates re-sampled with replacement from treatment and control populations.

**Estimated benefits used in the economic analysis**
Baseline estimates (CC versus C+R group) of health-related utility elicited using the UBQ-H were not significantly different (0.9599 and 0.9593, respectively; p=0.47).

Utility scores increased progressively relative to this base level in both treatment arms over 12 months.

At 6 months, the mean incremental improvement in health utility was 0.012 (95% CI: 0.002 to 0.023) for CC and 0.016 (95% CI: 0.006 to 0.026) for C+R, (p=0.78).

At 12 months, there was a non significant improvement from baseline of 0.010 (95% CI: -0.001 to 0.022) for CC and a significant improvement of 0.026 (95% CI: 0.013 to 0.039) for C+R.

While the estimated improvement in utility was higher in C+R patients at 12 months, the difference between improvements in CC and C+R was not significant, (p=0.38).

Using utility estimates at 6 and 12 months, and published survival effects at 1 year of 21.2% applied to the base risk mortality of 5.7% in an Australian population after uncomplicated acute myocardial infarction, the estimated gain in QALYs was 9.289 per 1,000 up to 12 months.

**Cost results**
These additional costs of rehabilitation were partially offset by lower costs for medication (AUD 117), ambulance (AUD 143) and other consultations (AUD 66).

Overall, resource use at 12 months was non significantly higher for the rehabilitation group by an amount of AUD 395 per patient, (p=0.74).
Synthesis of costs and benefits
The base-case incremental cost-effectiveness ratio for C+R relative to CC was AUD 42,535 per QALY saved in the study population.

This base-case analysis estimated life-years accrued to 1 year, including within-study utility effects and the reported treatment effect of rehabilitation on mortality.

The incremental cost per QALY saved was most sensitive to variations in the utility scores.

At the upper 95% confidence limit for QALYs saved, the expected cost per QALY saved was $19,690, but rehabilitation treatment was dominated at the upper boundary and was therefore not cost-effective.

Varying the relative risk reduction or the base-rate mortality had moderate effects on the cost-effectiveness results.

Assuming no treatment effect on baseline survival increased the cost per QALY to AUD 70,580 (attributable to effects on quality of life alone), while extending the time horizon for up to 3 years reduced the cost per QALY to AUD 27,030.

Authors' conclusions
The results of the study favoured the idea that rehabilitation services should be made available and routinely offered to all survivors of acute coronary syndromes (ACS). The advantages in quality of life were mostly non significant, but the cost of delivering rehabilitation services was low. The estimated incremental cost per quality-adjusted life-year (QALY), derived under conservative assumptions, was consistent with those accepted by decision-making public authorities.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It reflected standard practice in the authors' setting. You should decide whether these strategies are relevant in your own setting, or whether other comparators from other techniques and types of care could also be relevant.

Validity of estimate of measure of effectiveness
This was a randomised controlled trial that was performed in two tertiary teaching hospitals. The study design was appropriate for the study question. Sample size and power calculations were reported. The authors reported that their conclusions might be subject to random error because of the small sample size, the incomplete compliance with rehabilitation, and the use of pre-thrombolysis estimates for the mortality benefits of exercise-based rehabilitation.

Validity of estimate of measure of benefit
The authors reported the methods used to produce the QALY estimates.

Validity of estimate of costs
The relevant costs for the perspective adopted appear to have been included in the analysis. The costs and the quantities were not reported separately, which would have helped the analysis to be extrapolated to other settings. The sources of the resource use data were questionnaires and medical records, which might be prone to bias. All these factors could affect the robustness of the cost results. A statistical analysis of the costs was carried out. Discounting was appropriately not undertaken since the study period was short. The price year was reported.

Other issues
The authors made some comparisons with the findings from other studies. They stated that this trial was one of the first randomised evaluations worldwide of the cost-effectiveness of cardiac rehabilitation in a broad cross-section of typical
patients with ACS. The issue of generalisability was thus addressed. The authors stated that the major limitations of the study were the relatively small sample size, incomplete compliance with rehabilitation, and the use of pre-thrombolysis estimates for the mortality benefits of exercise-based rehabilitation. In addition, extrapolation to wider patient populations was limited by the low eligibility rate and the high refusal rate of those eligible.

**Implications of the study**

These results are important, mainly due to the fact that a very low proportion of Australian patients have access to rehabilitation programmes after an ACS. Other strategies for the delivery of cardiac rehabilitation, with more explicit cooperation between rehabilitation specialists and physicians, might achieve better health outcomes and further improve cost-effectiveness.

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