Comprehensive cardiac rehabilitation: a cost assessment based on a randomized clinical trial

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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 examined comprehensive cardiac rehabilitation (CCR) for patients with coronary heart disease (CHD) discharged from hospital. The intervention consisted of three lifestyle components (smoking cessation, physical training and dietary advice), as well as medical advice, for a 6-week period.

Type of intervention
Rehabilitation and secondary prevention.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with CHD discharged from the hospital.

Setting
The setting was outpatient. The economic study was carried out in Denmark.

Dates to which data relate
The clinical and economic data were gathered from March 2000 to March 2003. The costs referred to 2001 and 2002 prices.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that included in the effectiveness study.

Study sample
Power calculations, if performed, were not reported. The clinical study had 380 patients in the CCR group and 390 patients in the control group. Patients' demographics and reasons for eligibility or exclusion were not reported.

Study design
This was a prospective, open-label, randomised clinical trial that was carried out at the Department of Cardiology at Bispebjerg Hospital in Copenhagen. Details of randomisation and loss to follow-up were not reported. The patients were followed up for one year. Clinical outcomes were measured at baseline and at the end of the follow-up period (12
months). The number of patients with complete clinical data was 68 in the intervention group (i.e. CCR) and 69 in the control group. The authors stated that this sample was representative of the entire patient population.

Analysis of effectiveness
The analysis of effectiveness was restricted to those patients available at the end of the study period. The primary outcome measure was the patients' health-related quality of life (HRQL). This was estimated using two versions of the EQ-5D questionnaire: a visual analogue scale (VAS) and preference-weighted EQ-5D. Mortality was a secondary outcome of the clinical trial. The baseline comparability of the study groups was not discussed.

Effectiveness results
The average HRQL score when using the VAS was 0.710 in the intervention group and 0.657 in the control group (difference 0.057; p=0.06).

The average HRQL score when using the preference-weighted approach was 0.817 in the intervention group and 0.822 in the control group (difference -0.055; p=0.44).

Mortality was very low and similar between the two groups (the data were not reported).

Clinical conclusions
The effectiveness analysis showed that the patients’ quality of life was comparable between the CCR and the control groups.

Measure of benefits used in the economic analysis
No summary benefit measure was used in the economic analysis as the two interventions were equally effective, as demonstrated by the analysis of effectiveness. In effect, a cost-minimisation analysis was carried out.

Direct costs
The perspective of the economic analysis was not explicitly stated, but it appears to have been that of the Danish National Health System. Only the direct health care costs incurred during the study period were considered. Thus, future costs such as readmissions were not taken into consideration. Two macro-categories of costs were considered: remuneration of health care personnel (wages, pension, and vacation allowances) and other operational expenditures. Personnel costs included physicians, nurses, physiotherapists, secretaries and dieticians. The unit costs and the quantities of resources used were not presented separately. Resource consumption was derived directly from the sample of patients included in the clinical trial. The approach used to calculate costs within the constraints of the Danish health care system was described in detail (top-down approach). The lack of data meant that some assumptions had to be made. For example, it was assumed that the annual number of sequences in CCR was 250, based on an estimated full capacity of 300 sequences and assuming that 17% of patients would drop out. The costs were derived from the hospital department. Discounting was not relevant as the costs per patient were incurred during one year. The costs were estimated using 2001 and 2002 prices.

Statistical analysis of costs
Statistical analyses of the costs were not performed.

Indirect Costs
The indirect costs were not included in the economic analysis.

Currency
Euros (EUR).

**Sensitivity analysis**
A univariate sensitivity analysis was carried out to assess the robustness of the cost analysis to variations in wages, current costs other than wages, and number of treatment sequences, owing to the uncertain estimation of these data in the base-case analysis.

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

**Cost results**
The total costs using average data from the years 2001 and 2002 were EUR 243,998 in the intervention group and EUR 253,668 in the control group.

Considering the annual number of patient sequences at the authors’ institution and capacity of the rehabilitation ward, the cost per sequence was EUR 976 in the intervention group and EUR 294 in the control group (incremental cost of EUR 682 per sequence for CCR with respect to usual care).

The results of the sensitivity analysis confirmed the results of the base-case analysis, with the greatest uncertainty being around the number of patient sequences per year.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant given that a cost-minimisation analysis was carried out.

**Authors’ conclusions**
Comprehensive cardiac rehabilitation (CCR) delivered in the outpatient setting in Denmark was not likely to be a cost-effective strategy in comparison with usual care, which was similarly effective but cheaper.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear, as the new health care option was compared with usual care in the authors’ institution. CCR was partially described, although most details were probably reported in the original trial. You should decide whether they are relevant interventions in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The randomised design should limit the potential impact of selection bias. However, no information on the methods of sample selection and patient randomisation was provided. Data on quality of life were available for a small number of patients included in the study sample, but the authors stated that this was representative of the entire population. The authors did not report the use of power calculations, thus it was unclear whether the study had sufficient power to detect statistically significant differences between the groups. Overall, the limited information reported in the paper means that the validity of the clinical analysis is difficult to assess.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-minimisation analysis was conducted. Please refer to the comments reported in the 'Validity of estimate of measure of effectiveness' field (above).
Validity of estimate of costs
The perspective chosen for the cost analysis was not stated clearly. A breakdown of the cost items was provided. However, information on the unit costs and quantities of resources used was not given, which might limit the possibility of replicating the analysis in other settings. The authors noted that the estimation of costs required a complex calculation because of the peculiarity of the Danish health care system. Therefore, a top-down approach was used, although some approximations were made. If a more common source of costs had been used, such as diagnosis-related groups, the costs of the two strategies would have been the same. However, uncertainty in economic data was investigated in the sensitivity analysis. The period during which resource consumption and cost data were gathered was reported, thus facilitating refutation exercises in other time periods.

Other issues
The authors stated that their findings for the economic analysis were similar to those observed in a British health technology assessment, but different from those of a Chinese study. No comparable data on clinical effects were found. The issue of the generalisability of the study results to other settings was not addressed, and few sensitivity analyses were carried out. Therefore, the external validity of the analysis was low. The authors stated that caution will be required when interpreting the results of the analysis because of some methodological drawbacks, especially on the cost side of the analysis.

Implications of the study
The study results did not support the implementation of CCR in a hospital setting. In effect, hospitals should continue delivering conventional care to patients discharged with CHD. The authors stated that future studies should assess the impact of CCR on readmissions, long-term mortality, and total costs using a bottom-up approach.

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