Cost-effectiveness of cardiac resynchronization therapy in patients with asymptomatic to mild heart failure: insights from the European cohort of the REVERSE (Resynchronization Reverses remodeling in Systolic Left Ventricular Dysfunction)


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.

CRD summary
This study assessed the cost-effectiveness of cardiac resynchronisation therapy (CRT) in addition to best medical therapy, compared with best medical therapy alone, for patients with mildly symptomatic heart failure or for asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. The authors concluded that CRT was cost-effective. The methods seem to have been appropriate and were clearly and transparently reported. The conclusions reached by the authors appear to be appropriate.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
The aim was to develop an economic model to assess the cost-effectiveness of cardiac resynchronisation therapy (CRT) in addition to best medical therapy, compared with best medical therapy alone, in a cohort of European patients with mild symptoms of heart failure, or no symptoms, with left ventricular dysfunction, having had symptoms in the past.

Interventions
CRT in addition to the best medical care was compared with best medical care alone, for patients with a QRS complex of 120 milliseconds or more, and a left ventricular ejection fraction of 40% or less. The content of best medical care was from the Resynchronization Reverses Remodeling in Systolic Left Ventricular Dysfunction (REVERSE) trial (Linde, et al. 2008, see 'Other Publications of Related Interest' below for bibliographic details).

Location/setting
Europe/secondary care.

Methods
Analytical approach:
A proportion in state model, with Monte Carlo Simulation, was constructed and used to combine data from a randomised controlled trial with published cost data. Time was measured in discrete units of one month and the time horizon was 10 years. The authors reported that a third-party payer perspective was taken.

Effectiveness data:
The evidence came from European patients in the REVERSE trial (Linde, et al. 2008). This was a multicentre, double-blind, randomised controlled trial of 287 patients, mainly from Denmark, France, Sweden, and the UK. There were 262 successfully implanted patients, who were randomly assigned (2:1) to have CRT switched on or not and they were followed-up for two years. The main clinical effectiveness estimate was the proportion of patients who had worsened at one year.

Monetary benefit and utility valuations:
Health-related quality of life estimates were from a previous model of CRT. This model used mapping to derive utility estimates, based on the European Quality of life (EQ-5D) questionnaire.

Measure of benefit:
The benefits were measured in quality-adjusted life-years (QALYs) and life-years gained. These were discounted at a rate of 3.5%.

Cost data:
The REVERSE trial provided overall resource use data from all European patients and combined this with unit costs from the UK. The device costs were from a 2007 National Institute for Health and Clinical Excellence (NICE) appraisal, inflated to 2008 values. Patients with the CRT off, who received CRT with an implantable cardioverter defibrillator (ICD) device were assigned the cost of an ICD implant. The cost of all device replacements was included. Drug prices were from the 2008 British National Formulary. All costs were discounted at a rate of 3.5%. They were reflated where necessary to 2008 and converted from UK pounds sterling to Euros (EUR).

Analysis of uncertainty:
A probabilistic sensitivity analysis was conducted, using parameter values from appropriate statistical distributions. Cost-effectiveness acceptability curves were generated. Deterministic analyses were performed to explore the impact of alternative parameter values and modelling assumptions on the model results.

Results
CRT with the device on, was associated with 7.34 life-years gained, compared with 6.39 life-years gained with the device off. CRT on was associated with 5.98 QALYs gained, compared with 5.18 QALYs gained with CRT off. CRT on cost EUR 28,081, compared with EUR 16,626 for CRT off.

Compared with the device turned off, CRT on was associated with an incremental cost per life-year gained of EUR 12,172 and an incremental cost per QALY gained of EUR 14,278.

The probabilistic sensitivity analysis estimated that at a threshold of EUR 33,300 per QALY gained, there was a 79.6% chance that CRT was cost-effective. The deterministic sensitivity analysis found that CRT became cost-effective after about 4.5 years and that it had a modest impact on all-cause mortality. The results were robust to changes in all the other parameters.

Authors' conclusions
The authors concluded that CRT was cost-effective for patients with mildly symptomatic heart failure or for asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms.

CRD commentary
Interventions:
The interventions were briefly described and appear to have been appropriate comparators. These comparators might be appropriate for other settings.

Effectiveness/benefits:
The effectiveness data were from a multicentre randomised controlled trial which should have been of high internal validity. The trial was described briefly and the original publication should be consulted to fully assess its quality. The measure of benefit was appropriate, as QALYs take account of both morbidity and mortality, but little information was provided on how the utility estimates were measured and derived. The source study should be checked to assess the quality and validity of these estimates.

Costs:
The perspective was clearly stated and all the cost categories relevant to this perspective appear to have been included. The resource use data were from the randomised controlled trial and should have been of good quality; they should be generalisable as they were from all European patients. The sources for the unit costs appear to have been appropriate. The costs were adjusted for inflation, but the methods of adjustment were not stated. These costs were appropriately discounted.

Analysis and results:
The model structure was described in sufficient detail. The results were adequately reported and an appropriate
incremental analysis was undertaken. The authors investigated the uncertainty in the model parameters through probabilistic and deterministic sensitivity analyses, which should have given a reasonable assessment of the uncertainty in the parameters and overall. The authors appropriately discussed a number of limitations to their study.

Concluding remarks:
The methods seem to have been appropriate and were clearly and transparently reported. The conclusions reached by the authors appear to be appropriate.

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Other publications of related interest
Linde C, Gold MR, Abraham WT, Daubert JC. Randomized trial of cardiac resynchronization in mildly symptomatic heart failure patients and in asymptomatic patients with left ventricular dysfunction and previous heart failure symptoms. Journal of the American College of Cardiology 2008; 52: 1834-1843.

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