Is combined resynchronisation and implantable defibrillator therapy a cost-effective option for left ventricular dysfunction?

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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.

CRD summary
This study investigated the cost-effectiveness of combined implantable defibrillator and cardiac resynchronisation for patients with New York Heart Association (NYHA) class III or IV heart failure, with left ventricular dysfunction. The authors concluded that the combined therapy was not cost-effective compared with cardiac resynchronisation alone, and the usual cardiac resynchronisation therapy was cost-effective. The methods were transparent and thorough and, assuming that the systematic review of clinical effectiveness was appropriately conducted, the authors' conclusions are a fair assessment.

Type of economic evaluation
Cost-utility analysis

Study objective
The aim was to assess the costs and health effects of combined cardiac resynchronisation and implantable defibrillator therapy. The population was a hypothetical cohort of patients, with an average age of 74 years and with heart failure, defined by a New York Heart Association (NYHA) level III or IV, with left ventricular dysfunction and evidence of electrical dyssynchrony.

Interventions
The study assessed combined cardiac resynchronisation and implantable defibrillator therapy compared with the usual cardiac resynchronisation therapy, which was compared with best medical care.

Location/setting
UK/secondary care.

Methods
Analytical approach:
A Markov model was used to synthesise the data from published clinical studies, national databases, and expert opinion. The analysis covered a lifetime and the authors stated that the study perspective was that of the UK NHS.

Effectiveness data:
The clinical efficacy for the two strategies was measured by the modified risks of death from heart failure, sudden cardiac death, hospitalisations, and complications from cardiac resynchronisation or combined treatment. A systematic review and meta-analysis, conducted alongside this evaluation, with authors common to both, was the source for these outcomes (Fox, et al. 2007, see 'Other Publications of Related Interest' below for bibliographic details).

Monetary benefit and utility valuations:
The utility scores for the different health states of heart failure were derived using the European Quality of life (EQ-5D) instrument and UK population values. These utilities were from two published studies.

Measure of benefit:
The measure of benefit was quality-adjusted life-years (QALYs) and these were discounted at an annual rate of 3.5%.

Cost data:
The direct medical costs were included for cardiac resynchronisation and implantable defibrillator devices, their associated surgery, the treatment of infections, treatment for lead displacement or failure, battery or unit replacement, heart transplant, non-elective hospitalisations, medications, and cardiologist follow-up appointments. Clinical opinion was used for the medication estimates. The unit costs were from national tariffs; the NHS Purchasing and Supplies Agency, the National Formulary, and the National Schedule of Reference Costs. All costs were discounted at 3.5% per year and were reported in UK pounds sterling (£) for the price year 2005, except those for drugs, which were reported for 2006.

Analysis of uncertainty:
The model parameters and assumptions were examined in one-way sensitivity analyses using 95% confidence intervals. Threshold analyses were undertaken for risk of cardiac death and the age at implantation. Probabilistic sensitivity analysis, with 1,000 Monte Carlo simulations, was performed. The sensitivity analysis results were presented in scatter plots on the cost-effectiveness plane, in cost-effectiveness acceptability curves, and in a cost-effectiveness frontier.

Results
Over the patients’ remaining lifetime, the total discounted costs were £32,687 for combined therapy, compared with £20,997 for cardiac resynchronisation, and £9,367 for medical therapy. The discounted QALYs were 4.09 for combined, 3.80 for cardiac resynchronisation, and 3.10 for medical therapy. The incremental cost per QALY gained was £40,160 (95% CI 26,645 to 59,391) for combined over cardiac resynchronisation therapy, and £16,738 (95% CI 14,630 to 20,333), for cardiac resynchronisation versus medical therapy.

The results were sensitive to many factors, but were most sensitive to patient age at implantation and the absolute annual risk of sudden death. Varying the model parameters simultaneously in a probabilistic sensitivity analysis showed that the mean incremental cost per QALY for combined therapy compared with cardiac resynchronisation was less than £30,000 in 26.3% of simulations, and in 91.3% of simulations for cardiac resynchronisation compared with medical therapy.

Authors’ conclusions
The authors concluded that combined cardiac resynchronisation and implantable defibrillator therapy was not cost-effective for UK patients with left ventricular dysfunction suitable for resynchronisation therapy, but was cost-effective if restricted to patients younger than 60 years or those at a 7% or higher annual risk of sudden cardiac death. The usual cardiac resynchronisation therapy was cost-effective.

CRD commentary
Interventions:
The patient cohort characteristics were clearly described, but the devices and the content of the best medical therapy were not described. Combined therapy might not be an option in other settings.

Effectiveness/benefits:
The utility values were directly from reports of other patients with heart failure conditions and were derived using a valid instrument, likely to produce good estimates. The efficacy of the two devices was from a meta-analysis of clinical trial data, and this study should be consulted to assess the internal validity of these clinical estimates.

Costs:
The perspective was that of the UK NHS and the analysis covered all the major direct medical resources, including complications from treatment, and device unit or battery replacements. The resource costs were from national UK sources, except for cardiac medication use, which was the opinion of experts.

Analysis and results:
The authors reported a number of limitations to their study, including the reduced generalisability when relying on randomised trial estimates, the reliance on indirect comparison data from trials, and the exclusion of some patients in the cardiac resynchronisation trials. The uncertainty was appropriately evaluated. The authors reported that their results were similar to those of other economic evaluations, but there was wide variability, which was attributed to the different time horizons analysed, with longer time horizons producing more favourable cost-effectiveness.
Concluding remarks:
The methods of this study were good and the study was well reported. Assuming that the systematic review of clinical effectiveness was appropriately conducted, the conclusions reached by the authors appear to be a good assessment of their analysis.

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