

Title:	Cardiac resynchronisation therapy for severe heart failure, 2006
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Aim

To assess the safety, effectiveness and cost effectiveness of cardiac resynchronisation therapy for severe heart failure and the circumstances under which public funding should be supported for it.

Conclusions and results

Safety. CRT is associated with an acceptable short-term safety profile. Implantation is successful in about 90 per cent of patients. Fatalities at implantation are rare (<1%) and although complications may arise in approximately 6 per cent of implantations, most are unlikely to be serious. These commonly involve lead problems such as dislodgement and infection that require the patient to undergo a repeat procedure, but are usually not life threatening. Reliable data about the longer term safety of CRT is not available.

Effectiveness

Four well-designed, multi-centre, randomised controlled trials have consistently reported similar favourable benefits from CRT plus optimal pharmacological therapy (OPT) in relation to patient quality of life. The largest trial, COMPANION, assessed the impact of CRT plus OPT using a composite endpoint that included all-cause mortality and hospitalisation. The trial was stopped early and although the intervention group was associated with a 24 per cent reduction in all-cause mortality, the result was not statistically significant (hazard ratio = 0.76, p=0.06, 95% CI: 0.58-1.01). In another large trial, the MIRACLE study, the mortality rates during follow-up appear to be lower in the CRT plus OPT group compared with the OPT alone group. However, this trial, along with the third study, lacked sufficient statistical power to reliably assess this issue. The fourth major trial had sufficient statistical power to assess mortality and the study recorded a significant 36 per cent (hazard ratio: 0.64, 95% CI: 0.48-0.85, p<0.001) reduction in all-cause mortality over a relatively long duration of follow-up (mean 29 months). The results from a meta-analysis that included 6-12 month mortality data from the four randomised controlled trials indicated that CRT was associated with a statistically significant reduction of 21 percent in the relative risk of mortality (RR=0.79, 95% CI: 0.63-0.98). The benefits from CRT plus OPT appear to be clinically significant in appropriately selected patients, especially in relation to quality of life, reduction in mortality and improvements in the rate of hospitalisation, particularly for cardiovascular events and worsening heart failure. Long-term data supporting the benefits of therapy are available up to a mean 29 months follow-up period.

Cost-effectiveness

Over a patient's lifetime, CRT is expected to be associated with an increase of 1.52 discounted (2.74 undiscounted) life years and 1.54 discounted (2.63 undiscounted) quality-adjusted life years. The expected five-year incremental cost per life year saved was estimated to be \$35,436, based on public hospital data, and \$63,861, based on private hospital data. The expected 15-year incremental cost per quality-adjusted life year (QALY) saved was estimated to be \$25,362, based on public hospital data, and \$45,706, based on private hospital data. These estimates are based on conservative projections. Sensitivity analysis showed that the conclusion of the analysis is robust to plausible variations in key parameters of the model.

Recommendations

MSAC recommended that public funding should be supported for the use of cardiac resynchronisation therapy in patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria-sinus rhythm, a left ventricular ejection fraction of less than or equal to 35% and a QRS duration greater than or equal to 120ms.

Method

A systematic review of the cardiac resynchronisation therapy for severe heart failure was conducted. The literature was searched up to April 2005 using Medline, Embase, Current Contents, Science Citation Index, Cochrane Library, DARE, and various website sources. Study selection criteria were stipulated and standard checklists were used to appraise study quality.

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