

Title:	Implantable cardioverter defibrillators for prevention of sudden cardiac death, 2006
Agency:	Medical Services Advisory Committee (MSAC) Australian Government Department of Health and Ageing, MDP 106 GPO Box 9848 Canberra ACT 2601 Australia http://www.msac.gov.au
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Aim

To assess the safety, effectiveness and cost effectiveness of implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy with implantable cardioverter defibrillators (CRT-D) for prevention of sudden cardiac death and the circumstances under which public funding should be supported for them.

Conclusions and results

Safety. ICD implantation is successful in about 98 per cent of patients. Complications at implantation are uncommon and there is no reported difference in mortality within 30 days of implantation between patients receiving ICD plus optimal pharmacological therapy (OPT) compared with patients receiving OPT alone. With the exception of perforation, which was infrequently reported, most complications are unlikely to be serious. Complications within 30 days of ICD implantation include inappropriate shocks, lead dislodgement, pneumothorax and infection. Longer-term data examining the safety of ICD plus OPT suggest similar complications to those that arise early.

Effectiveness

Eight randomised trials have generally reported favourable benefits from ICD plus OPT in relation to all-cause mortality over relatively long periods of follow-up. The patient populations selected varied between the randomised trials. The results from the two largest trials, SCD-HeFT and MADIT II, indicate that ICD plus OPT reduces the risk of death from any cause by between 23 per cent (hazard ratio = 0.77, 95% CI: 0.62-0.96) and 31 per cent (hazard ratio = 0.69, 95% CI: 0.51-0.93) compared with OPT alone over mean follow-up durations of up to 60 months. In both these studies patients with NYHA class IV heart failure were excluded. Patients in MADIT II had a prior MI and LVEF \leq 30 per cent. However, they were not required to have symptomatic heart failure. In contrast, SCD-HEFT included patients with or without prior MI, NYHA class II or III heart failure and LVEF \leq 35 per cent. Results from the COMPANION trial suggest treatment with CRT-D plus OPT is effective at reducing all-cause mortality (hazard ratio = 0.64, 95% CI: 0.48-0.86) after one year of follow-up.

Cost-effectiveness

Over the patients' lifetimes, it is expected that ICD therapy will result in an incremental cost per life year saved of \$18,681 based on public hospital costs and \$44,479 based on private hospital costs; and CRT-D therapy will result in an incremental cost per life year saved of \$13,786 based on public hospital costs and \$34,870 based on private hospital costs. Sensitivity analysis showed that the conclusion of the analysis is robust to most plausible variations in key parameters of the model. However, there is significant uncertainty regarding cost-effectiveness associated with assumptions regarding long-term mortality rates.

Recommendations

MSAC recommended that public funding should be supported for the use of ICD therapy (in patients who have received OPT) with left-ventricular ejection fraction of less than or equal to 30 per cent or with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left-ventricular ejection fraction less than or equal to 35 per cent. Public funding for CRT-D therapy is beneficial and appropriate for patients with chronic heart failure (who have received OPT) associated with moderate to severe symptoms (NYHA III and IV), sinus rhythm, a left-ventricular ejection fraction of less than or equal to 35 per cent and a QRS duration greater than or equal to 120ms.

Method

A systematic review of ICD therapy and CRT-D therapy for the prevention of sudden cardiac death was conducted. The literature was searched up to July 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.

Produced by Sarah Hancock, Phil Hider, Robert Weir, Susan Bidwell, Sarah Hogan, Wasan Ali, Jacqueline Lawson and Ray Kirk – NZHTA, Department of Public Health and General Practice, University of Otago.