


# The clinical and cost-effectiveness of implantable cardioverter defibrillators: a systematic review

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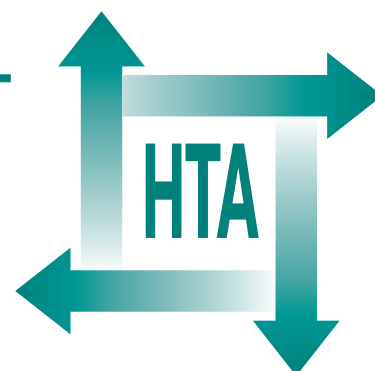
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## *Executive summary*

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## Executive summary

### Background

Sudden cardiac death occurs in approximately 100,000 people annually in the UK and is usually due to ventricular tachyarrhythmia. Increasing numbers of people are surviving a first episode of ventricular tachyarrhythmia and are at high risk of further episodes. Other risk factors for sudden cardiac death are prior myocardial infarction, coronary heart disease, genetic factors, poor cardiac function and heart failure. Treatments are aimed at either suppressing (anti-arrhythmic drug therapy) or terminating (implantable cardioverter defibrillator) the arrhythmia.

### Objectives

This review considers the clinical effectiveness and cost-effectiveness of implantable cardioverter defibrillators (ICDs) for arrhythmias.

### Methods

A systematic review of the literature on clinical and cost-effectiveness was undertaken.

### Data sources

The main electronic databases were searched with English language limits for periods up to November 2003. Bibliographies of related papers were assessed for relevant studies and experts were contacted for advice and peer review and also to identify additional published and unpublished references. Manufacturer submissions to the National Institute for Health and Clinical Excellence were reviewed.

### Study selection

Studies were included if they fulfilled the following criteria, which were applied independently by two reviewers, with any disagreements resolved through discussion:

- Intervention was implantable cardioverter defibrillators (ICDs).

- Participants were people at risk of sudden cardiac death due to arrhythmias, in secondary and primary prevention categories.
- Primary outcome was mortality, with quality of life (QoL) as the secondary outcome.
- Designs were systematic reviews of randomised controlled trials (RCTs), or individual RCTs, that assessed the effects of ICDs compared with anti-arrhythmic drug therapy.

### Data extraction and quality assessment

Data extraction and quality assessment were undertaken by one reviewer and checked by a second reviewer, with any disagreements resolved through discussion. The quality of RCTs was assessed using the Jadad criteria and the quality of systematic reviews was assessed using criteria developed by the NHS Centre for Reviews and Dissemination. The quality of economic evaluations was assessed by their internal validity (i.e. the methods used) using a series of relevant questions, and external validity (i.e. generalisability of the economic study to the population of interest) by modified standard criteria.

### Data synthesis

The clinical effectiveness and cost-effectiveness of ICDs for arrhythmias were synthesised through a narrative review with full tabulation of results of all included studies.

### Results

#### Number and quality of studies

Eight RCTs, two systematic reviews and a meta-analysis met the inclusion criteria of the review. The RCTs were of variable quality, with most trials having a Jadad quality score of 1/5 or 2/5, owing to the nature of comparing a device with drug therapy and the impossibility of double-blinding. The outcome measure of interest was mortality, which was reported as all-cause mortality in most trials and sudden cardiac death in some trials.

Eleven economic evaluations of ICDs for arrhythmias were identified. None were shown to have high internal and external validity. One unpublished study relevant to the UK was identified.

## Summary of benefits

The evidence suggests that ICDs reduce mortality in patients with previous ventricular arrest or symptomatic sustained ventricular arrhythmias, in patients who have not had a previous sudden cardiac episode or previous ventricular arrhythmia but have reduced left ventricular function due to coronary artery disease with asymptomatic non-sustained ventricular arrhythmia and sustained tachycardia that could be induced electrophysiologically, and in some patients with severe left ventricular dysfunction (ejection fraction <30%) after myocardial infarction.

QoL data are inconsistent but suggest that there is impaired QoL in patients who received numerous shocks from implanted devices.

## Costs and cost-effectiveness

Studies show that ICDs improve survival compared with drug treatment, but with considerably increased cost. Incremental cost per life-year gained ranges from US\$27,000 to Can\$213,543 and incremental cost per quality-

adjusted life-year from US\$71,700 to US\$558,000 in the published literature.

## Implications

The use of ICDs in the UK is increasing, but the technology is still under-utilised compared with other developed countries. Extending the current indications to patients with prior myocardial infarction and depressed heart function would impact on costs and service provision.

## Research recommendations

Further research is needed on the risk stratification of patients in whom ICDs are most likely to be clinically and cost-effective and the evaluation of shock frequency on QoL.

## Publication

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

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