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

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Executive summary

Health Technology Assessment 2005; Vol. 9: No. 36
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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relevant studies and experts were contacted for advice and peer review and also to identify additional published and unpublished references.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

The research findings from the NHS R&D Health Technology Assessment (HTA) Programme directly influence key decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC) who rely on HTA outputs to help raise standards of care. HTA findings also help to improve the quality of the service in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’ that is being developed to improve the evidence of clinical practice throughout the NHS.

The HTA Programme was set up in 1993. Its role is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care, rather than settings of care.

The HTA Programme commissions research only on topics where it has identified key gaps in the evidence needed by the NHS. Suggestions for topics are actively sought from people working in the NHS, the public, service-users groups and professional bodies such as Royal Colleges and NHS Trusts.

Research suggestions are carefully considered by panels of independent experts (including service users) whose advice results in a ranked list of recommended research priorities. The HTA Programme then commissions the research team best suited to undertake the work, in the manner most appropriate to find the relevant answers. Some projects may take only months, others need several years to answer the research questions adequately. They may involve synthesising existing evidence or conducting a trial to produce new evidence where none currently exists.

Additionally, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme is able to commission bespoke reports, principally for NICE, but also for other policy customers, such as a National Clinical Director. TARs bring together evidence on key aspects of the use of specific technologies and usually have to be completed within a short time period.

Criteria for inclusion in the HTA monograph series

Reports are published in the HTA monograph series if (1) they have resulted from work commissioned for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

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.

The research reported in this monograph was commissioned and funded by the HTA Programme on behalf of NICE as project number 03/32/01. The protocol was agreed in July 2003. The assessment report began editorial review in July 2004 and was accepted for publication in December 2004. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme, NICE or the Department of Health.

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.
Printed on acid-free paper in the UK by St Edmundsby Press Ltd, Bury St Edmunds, Suffolk.