The effects and costs of implantable cardioverter defibrillator therapy

A review of the evidence on the effects and costs of implantable cardioverter defibrillator therapy in different patient groups, and modelling of cost-effectiveness and cost–utility for these groups in a UK context

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Executive summary

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Executive summary

Background

In September 2000, the National Institute for Health and Clinical Excellence (NICE) published guidance on the use of implantable cardioverter defibrillators (ICDs) for arrhythmias. That guidance relied heavily on a small number of relatively large-scale randomised controlled trials (RCTs) of ICDs compared with conventional management conducted principally in North America. Questions remain about the generalisability of their results to the UK, particularly the associated analyses of cost-effectiveness. This study was designed not simply to update the existing systematic review of published literature, but also to collect original data relating to the UK to use with international trial data to model the cost-effectiveness of ICDs in a UK context. Thus, this report contains a combination of an updating of the systematic review evidence on the effectiveness, health-related quality of life (HRQoL) and cost-effectiveness of ICDs; compilation of new data on the service provision in the UK; and on the clinical characteristics, survival, quality of life and costs of ICD patients in the UK, and a new cost-effectiveness model using both international RCT and UK-specific data.

Updated systematic reviews of studies of effectiveness, quality of life and cost-effectiveness

Objectives

To update the earlier review on clinical effectiveness and cost-effectiveness of ICDs compared with conventional therapy of patients at risk of sudden cardiac death (SCD) due to arrhythmias.

Methods

Electronic databases and reference lists were searched from November 1999 to March 2003 for RCTs, systematic reviews and meta-analyses following recognised principles. Cost-effectiveness studies pre-dating the availability of RCT data were excluded.

Results

Five original clinical studies meeting these criteria were identified that had been published since the previous review: three RCTs of effectiveness (CASH, MADIT II and CAT) and two RCT-based studies of HRQoL (based on the AVID and CIDS trials). In addition, there was one systematic review and one meta-analysis of secondary prevention trials. Eight economic studies were appraised, of which four were directly based on an RCT, two on specific registries/databases and two models used multiple sources. None of the economic analyses could be directly applied to the UK.

Conclusions

There is increasingly strong RCT evidence for the survival benefits of ICDs compared with medical management of ventricular arrhythmias following survival of cardiac arrest and in preventing SCD in those at high risk. The evidence on impact on HRQoL is conflicting and relatively weak. The estimates of cost-effectiveness vary considerably, not least because of the different time-horizons considered and the need to make assumptions on long-term relative effectiveness.

Data on service provision in the UK

Objectives

To review the current use of, and service provision for, ICDs in the UK.

Methods

Multiple published data sources were used and a survey of ICD centres was conducted.

Results

The multiple sources of routine data available (including the national ICD database) provide an imperfect picture of the need for and use of ICDs. Implantation rates have been rising to a rate of around 20 per million population. Mean age is increasing and most ICDs are implanted into men aged 45–74 years. There is significant geographical variation. A survey of 41 UK centres provided additional evidence, particularly of variation in level of activity and resourcing.

Conclusions
Rates of implantation of ICDs in 2000 were less than half of the target suggested by the NICE guidelines, and capacity to increase these rates is constrained by a variety of factors.

Data on clinical characteristics, survival, quality of life and costs of ICD patients in the UK

Objective
To describe the clinical characteristics, survival, quality of life and resource use/costs in a sample of UK patients.

Methods
Basic data were obtained from two major implanting centres including 535 patients (about 10% of overall UK activity) implanted between 1991 and 2002, and retrieval of fuller data, on patient characteristics, management and resource use, from patient notes for a sample of 426 patients was attempted. A cross-sectional survey collected HRQoL data (using the Nottingham Health Profile, Short Form 36, Hospital Anxiety and Depression questionnaire, EuroQoL 5 Dimensions and disease-specific questions) on a sample of 229 patients.

Results
Most detailed data were obtained for 380 patients (89%). The postal survey produced a 73% response rate. Demographic characteristics of these patients were similar to ICD recipients in the UK as a whole and patients included in secondary prevention RCTs. Mean actuarial survival at 1, 3 and 5 years was 92%, 86% and 71%, respectively. Patient age at implantation and functional status significantly affected survival.

Levels of most of the HRQoL measures were lower than for a UK general population There was no evidence of a change with time from implantation. Patients who had suffered ICD shocks had significantly poorer HRQoL. Most patients nevertheless expressed a high level of satisfaction with ICD therapy.

Mean initial costs of implantation showed little variation between centres (£23,300 versus £22,100) or between earlier and more recent implants. There appeared to be greater variation between patients presenting along different pathways. Postdischarge costs (tests, medications and follow-up consultations) and costs of additional hospitalisations were also calculated.

Conclusions
These data showed the degree of similarity of the UK ICD recipients to those in the secondary prevention trials, and identified the main characteristics that appear to be systematically related to survival [age at implant and left ventricular ejection fraction (LVEF)], to HRQoL (number of shocks) and to costs of implantation (patient pathways). These data provide key parameter values for the UK relevant model of cost-effectiveness.

Cost-effectiveness model for the UK

Objective
To estimate the cost-effectiveness of ICDs compared with antiarrhythmic drug treatment in the UK, in secondary prevention patients at risk of SCD.

Methods
A Markov model combined UK patient data with data from published RCTs to estimate incremental costs per life-year or quality-adjusted life-year (QALY) gained.

Results
Over a 20-year horizon, mean discounted incremental costs were £70,900 (£35,000–142,400). Mean discounted gain was 1.24 years (0.29–2.32) or 0.93 QALYs. Cost-effectiveness was most favourable for men aged over 70 years with an LVEF below 35%. If the treatment effect were to continue, then the cost per life-year over a lifetime might fall to around £32,000.

Conclusions
Although there is considerable uncertainty involved in modelling beyond the experience of the trials, the results suggest that ICDs, as currently applied in the UK, are not cost-effective by conventional standards.

Addendum

Objective
To summarise and discuss new primary and secondary research published while the main study was under review.

Methods
A systematic review of published work during 2003–2005 was undertaken. ▶

Results

Five RCTs of ICDs, a meta-analysis and, a cost-effectiveness analysis of ICDs used in primary prevention, and a meta-analysis of ICDs in patients with non-ischaemic cardiomyopathy have been published recently. These trials provide confirmation of survival benefit of ICDs used in primary prevention in both ischaemic and non-ischaemic cardiomyopathy patients. Costs per QALY ranged from US$34,000 in older trials (MADIT, MUSTT) to controls being both less expensive and more effective (CABG Patch, DINAMIT). More recent trials estimated cost per QALY between $50,300 and $70,200. The inconsistency in evidence for a HRQoL benefit has not been resolved and further work on risk stratification is necessary.

Conclusions

Overall, the survival benefit and cost-effectiveness estimates for primary prevention patients are similar to those for secondary prevention patients in the UK.

Overall conclusions

The evidence of short- to medium-term patient benefit from ICDs is strong but cost-effectiveness modelling indicates that the extent of that benefit is probably not sufficient to make the technology cost-effective as used currently in the UK. One reason is the high rates of postimplantation hospitalisation. Better patient targeting and efforts to reduce the need for such hospitalisation may improve cost-effectiveness.

Recommendations for further research

Further cost-effectiveness modelling, underpinned by an improved ICD database with reliable long-term follow-up, is required. This can now begin fully to address the cost-effectiveness of primary prevention, particularly as the results from other primary prevention trials are added to those from MADIT II.

The absence of a robust measure of the incidence of SCDs is noted. This may be an area where further organisational changes with improved data collection would help. However, to be effective this will require the co-ordination of information from a wide range of sources, including the records of pathology services and coroners' offices.

Publication

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NHS R&D HTA Programme

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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.

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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.

The research reported in this monograph was commissioned by the HTA Programme as project number 99/23/04. The contractual start date was in July 2001. The draft report began editorial review in May 2004 and was accepted for publication in January 2006. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. 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.

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