Cost-effectiveness of implantable cardioverter defibrillators in Brazil in the public and private sectors

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study assessed the cost-effectiveness of an implantable cardioverter defibrillator (ICD), compared with usual therapy, to prevent death from chronic heart failure. The authors concluded that from both private and public perspectives, the cost of the ICD was high relative to its benefits, and strategies to improve this ratio should be pursued. There were a few limitations to the methods and reporting, but overall the authors’ conclusions appear to be appropriate.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study assessed the cost-effectiveness of an implantable cardioverter defibrillator (ICD), compared with usual therapy, to prevent death from chronic heart failure.

Interventions
The two primary prevention strategies were an ICD that connected to a single chamber, plus the usual therapy, compared with the usual therapy alone.

Location/setting
Brazil/secondary care.

Methods
Analytical approach:
The evaluation was based on a decision tree and a Markov model of the success of implantation and the annual risk of death and complications. A 20-year time horizon was used. The authors stated that a third-party payer perspective was adopted, with the public payer analysed separately from the private health care payer. A subgroup of patients who were at a higher risk of arrhythmia was analysed separately.

Effectiveness data:
The effectiveness of the ICD was from clinical trials and meta-analyses, identified by a search in the MEDLINE database. The complication rates came from reviews of the literature and meta-analyses of published clinical trials and observational studies, in particular international cohort and registry studies. For general ICD patients, the risk of death came from a meta-analysis of primary prevention trials, and the reduction in mortality was assumed to be constant over time. For the subgroup of patients with more severe disease, these estimates were from the Multicenter Automatic Defibrillator Implantation Trial (MADIT-1). The annual probability of lead replacement was from a cohort study, with a 10-year follow-up and this rate was assumed to be constant after seven years. The generator was assumed by the authors to be replaced every five years. Long-term survival with usual therapy alone was from an out-patient chronic heart failure patient cohort study in a Brazilian hospital and was extrapolated to 20 years using country-specific life tables.

Monetary benefit and utility valuations:
The utility estimate for heart failure was based on published international studies. Based on published international studies, the authors assumed that there was no difference between the ICD group and the usual therapy group.
Measure of benefit:
The summary measures of benefit were quality-adjusted life-years (QALYs) and life-years. These were discounted at an annual rate of 3%.

Cost data:
The costs included ICD implantation and related procedures, such as generator replacement; ICD complications, such as hospitalisation for lead replacement; and annual costs, such as ICD follow-up and maintenance. These costs were from a number of sources including the public Hospital Admission Authorization of the Brazilian Public Health System, health insurance companies' reimbursements, and a Brazilian city public and private hospital. All costs were presented in 2007 Brazilian reais (BRL) and discounted at an annual rate of 3%.

Analysis of uncertainty:
Univariate sensitivity analyses, on all parameters, and bivariate sensitivity analyses, on ICD costs and effectiveness and frequency of generator replacement, were performed to identify the most influential parameters for the incremental cost-effectiveness ratios (ICERs). The results were presented in a table and graphically on an incremental cost-effectiveness plane.

Results
In patients with general heart failure, the ICD plus usual therapy was associated with a mean of 6.15 QALYs (6.99 life-years) compared with 5.23 QALYs (5.95 life-years) for usual therapy alone. The costs were BRL 96,131 with the ICD and BRL 33,408 without it, from the public payer perspective, and BRL 184,824 with the ICD and BRL 101,330 without it, from the private payer perspective.

The ICER with the ICD, compared with no ICD, was BRL 68,318 per QALY or BRL 60,121 per life-year gained, from the public perspective, and BRL 90,942 per QALY or BRL 80,029 per life-year gained, from the private perspective.

The parameters that had the greatest impact on the ICERs (for both perspectives) were the ICD effectiveness, the frequency of generator replacement, and the costs of the ICD and its implantation. Variations in the discount rate and the utility for a patient with chronic heart failure had a moderate impact on the results. A lower (better) cost-effectiveness ratio was obtained with a more effective or cheaper ICD, or a longer period between generator replacement.

For the subgroup of patients with more severe disease, the ICERs were BRL 23,739 per QALY gained from the public perspective, or BRL 33,592 per QALY gained from the private perspective. These were within the cost-effectiveness threshold of three times the per capita gross domestic product of Brazil (BRL 40,545).

Authors’ conclusions
The authors concluded that from both private and public perspectives, the cost of the ICD was high relative to its benefits, and strategies to improve this ratio should be pursued. More favourable estimates were found for patients with more severe disease.

CRD commentary
Interventions:
The ICD intervention and the comparator (usual care) seem to have been appropriate, as they were included in randomised controlled trials. Usual care was relevant for the authors’ setting, but it was not described, which may limit the generalisability of these results to other settings.

Effectiveness/benefits:
The authors reported the clinical effectiveness data and referenced their sources. A review of the literature was undertaken, but the details were not reported, making it unclear if the search was systematic and unclear if the best available evidence was used. The data were from potentially high quality sources, such as meta-analyses, but these were not fully reported. For some inputs, such as mortality due to infection, the authors conducted meta-analyses and reported their inclusion criteria. QALYs were an appropriate benefit measure, as chronic heart failure can affect survival and quality of life. The sources for the utilities were given, but the methods used to elicit them were not. The authors assumed that the ICD had no effect on quality of life, but this assumption might not have been generalisable to
a Brazilian population. It was assumed that minor complications had no impact on utility and little explanation for this assumption was provided.

Costs:
The analysis of the costs was consistent with the authors' stated perspectives. The cost data were reported and were generally from Brazilian sources and populations. A breakdown of cost items and the resource quantities were not provided, which might hinder the replication of the analysis for other settings. The authors reported the price year and the currency and appropriately discounted future costs.

Analysis and results:
The analytic approach was satisfactorily described and the model structure was reported in full, with a diagram. More details on the modelling methods and assumptions were available elsewhere (Ribeiro, et al. 2009, see 'Other Publications of Related Interest' below for bibliographic details). The results were clearly and fully reported, as were those of the incremental analysis. The authors conducted univariate and bivariate sensitivity analyses; a probabilistic sensitivity analysis would have captured the full impact of parameter uncertainty on the ICER. The authors compared their results with those of other published Brazilian economic evaluations, and against various hypothetical cost-effectiveness thresholds. They reported a number of limitations to their study including the assumption of a constant benefit from the ICD over time, the use of utility data from non-Brazilian populations, and the lack of a conclusion on the impact of the ICD on the quality of life in international literature.

Concluding remarks:
There were a few limitations to the methods and reporting, but overall the authors’ conclusions appear to be appropriate.

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Other publications of related interest

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