Cost-benefit analysis of preventing sudden cardiac deaths with an implantable cardioverter defibrillator versus amiodarone

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
The study evaluated the economic value of an implantable cardioverter defibrillator (ICD) in comparison with amiodarone therapy for the primary prevention of sudden cardiac death in patients with heart failure, using a cost-benefit analysis. The authors demonstrated the economic desirability of the ICD in both France and the UK. The quality of the study methodology was good, with satisfactory reporting of information about the methods and results.

Type of economic evaluation
Cost-benefit analysis

Study objective
The primary objective of the study was to determine the economic value of an implantable cardioverter defibrillator (ICD), compared with conventional amiodarone therapy, for the prevention of sudden cardiac death in patients with heart failure who have not yet suffered a ventricular arrhythmia (primary prevention). The study used a cost-benefit framework to assign an equal value to each life saved by an ICD, regardless of the patients’ age or health condition.

Interventions
The study examined use of an ICD and amiodarone for the primary prevention of sudden cardiac death. Patients in both strategies also received optimal medical therapy that included beta-blockers, diuretics, statins and angiotensin-converting enzyme inhibitors.

Location/setting
UK/France. Hospital.

Methods
Analytical approach:
A discrete event simulation model was developed in order to estimate, on the basis of individual simulations, the costs and benefits of the two strategies using published evidence. The time horizon of the analysis was 5 years. The authors stated that the perspective was that of the health care system.

Effectiveness data:
The clinical data were derived from two recent, relevant studies. The first one was a randomised clinical trial (RCT) of 2,521 patients receiving ICD, amiodarone or placebo. The second was a meta-analysis of 13 trials of amiodarone. Other clinical data, such as adverse events, were derived from manufacturers or other published studies. The case-fatality rate of a severe arrhythmia according to treatment was the main clinical input of the model. Several equations were used to estimate the individual risk of clinical events.

Monetary benefit and utility valuations:
The value of a life saved was calculated using the willingness-to-pay (WTP) approach. Sources for WTP for immediate loss of life were obtained from the Department of Transport for the UK, and from research commissioned by the French government for France.

Measure of benefit:
The benefit measure was the monetary value of the number of lives saved. An annual discount rate of 3.5% was used.
for the UK and 3% for France.

Cost data:
The main cost categories were hospitalisations (for initial and subsequent operations), ICD (lead and device) and medications (optimal therapy, amiodarone and treatment of toxicity). The costs in the two countries were derived from national health agencies and national drug databases. Resource consumption was derived from published evidence, but no details of this were provided. The costs were in euros (EUR) and the price year was 2004. The annual discount rate was 3.5% in the UK and 3% in France.

Analysis of uncertainty:
A univariate deterministic sensitivity analysis was undertaken on key model inputs such as age, case-fatality rates, arrhythmia rates and hospitalisation rates. The ranges of values under examination were presumably based on published data. A threshold analysis was conducted in order to estimate the WTP break-even point at which the cost-benefit ratio was equal to 1 (costs equal to benefits).

Results
The costs and benefits were synthesised by calculating their ratio, for which a value of less than one indicated a good result since it suggested that the value of the benefits exceeded the net direct costs.

The cumulative additional net costs of the ICD over amiodarone over 5 years for 1,000 hypothetical patients were EUR 26.1 million in the UK and EUR 20.0 million in France.

Since the ICD was predicted to prevent 73 premature deaths, the value of lives saved with the ICD over amiodarone over 5 years for 1,000 hypothetical patients was EUR 153.1 million in the UK and EUR 135.5 million in France. Thus, the cost-benefit ratio was 0.17 in the UK and 0.14 in France, suggesting the high economic desirability of the ICD over amiodarone. The net benefit (value of lives saved minus net cost) was valued at EUR 127 million in the UK and EUR 115 million in France.

The break-even point representing the value of a life at which the benefits just equalled the net costs was found to be EUR 359,210 for the UK and EUR 274,083 for France. This indicated that ICD treatment represented a very worthwhile investment.

The sensitivity analysis showed that the base-case results were robust to variations in key model inputs.

Authors’ conclusions
The authors concluded that the use of an ICD as primary prevention for sudden cardiac death in patients with heart failure who have not yet suffered a ventricular arrhythmia was a cost-effective alternative to amiodarone in both the UK and France.

CRD commentary
Interventions:
The choice of the interventions was appropriate as they are the relevant comparators in the two countries as well as in other settings.

Effectiveness/benefits:
The selective identification of specific sources of data was intended to ensure that the most relevant sources were used for the two countries. Thus, a review of the literature was not required. The design of the main primary sources was reported, but there was little information about the sources of other model inputs. In general, the use of an RCT and a meta-analysis of RCTs represent two valid sources of data, and this is a strong feature of the current analysis. The derivation of the benefit measure was appropriately reported.

Costs:
The analysis of the costs was performed satisfactorily. Extensive details of the unit costs, sources of costs and resources, price year, discounting and inflation adjustment were reported, which enhances the possibility of replicating the
analysis in other settings or time periods. The most relevant sources of data for each country were used. The assumptions made in the economic analysis were explicitly reported.

**Analysis and results:**

The approach used to combine the costs and benefits was consistent with the cost-benefit framework. The results of both the base-case and sensitivity analyses were clearly reported. The issue of uncertainty in the model parameters was addressed explicitly by sensitivity analyses and implicitly by the type of decision model applied, which takes into account variability at a patient level. The authors discussed the advantages and potential limitations of using a cost-benefit analysis rather than the most commonly used cost-effectiveness approach.

**Concluding remarks:**

Overall, the study methodology was robust and clearly presented in terms of both the methods and results. The authors’ conclusions appear appropriate.

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**Bibliographic details**


**Other publications of related interest**


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