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# Cost-Benefit Analysis of Preventing Sudden Cardiac Deaths with an Implantable Cardioverter Defibrillator versus Amiodarone

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## ABSTRACT

**Objectives:** To conduct a cost-benefit assessment of prevention of sudden cardiac deaths with an implantable cardioverter defibrillator (ICD) versus amiodarone from the perspective of the health-care systems in the UK and France.
**Methods:** Course after implantation with an ICD or taking amiodarone was modeled using discrete event simulation; 1000 pairs of identical patients were simulated 100 times for each analysis. Rates of life-threatening arrhythmia and death from other causes were assumed identical, but the case fatality of arrhythmia and hospitalization differ between treatments. Rates were based on published data, primarily from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Direct medical costs (in 2004 Euros) and lives saved were estimated over 5 years. The monetary value of a life (UK €2.1 million, France €2.0 million) was applied to this benefit and examined relative to the net investment required.
**Results:** ICDs decreased deaths during the 5 years from 37.0% to 29.7% at a net cost of €26,222 to €20,008 per patient, yielding cost-benefit ratios of 0.17 (UK) and 0.14 (France)—more than a 5 to 1 return on investment. Sensitivity analyses showed ICDs represent value for money whenever a life is valued at least at €274,000.
**Conclusion:** In these European countries where society values a life at more than €2 million, ICDs are a worthwhile investment compared with amiodarone for primary prevention of sudden cardiac deaths in patients with heart failure.
*Keywords:* cost-benefit analysis, ICD, implantable cardioverter defibrillator, sudden cardiac deaths.

## Introduction

The implantable cardioverter defibrillator (ICD) is the most effective way to prevent a ventricular arrhythmia from being fatal [1]. It is a life-preserving device—without it few patients experiencing ventricular arrhythmias arrive in hospital soon enough to survive [2]. ICDs have been recommended for several years for patients with prior ventricular arrhythmias (so-called secondary prevention of sudden cardiac death [SCD]) [1,3]. Most recently, indications for ICD have been expanding as clinical trials have shown improved survival in patients with serious heart disease who have not yet suffered a ventricular arrhythmia (so-called primary prevention of SCD) [4]. The direct economic consequences of this expansion can be considerable, however. For example, the results of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) led to the expansion of coverage in the United States, and it is expected that Medicare beneficiaries eligible for an ICD will increase by one-third, to nearly 500,000—an additional 25,000 patients will be implanted in the first year of coverage, and potentially up to 2500 lives will be prolonged [5].

Even before primary prevention was being considered, there was already evidence that ICDs have not been uniformly adopted, and that this is probably due to economic, as well as clinical, concerns [1,6]. Various cost-effectiveness analyses of ICD use have been completed [7–10] and have generally concluded that the cost-effectiveness of ICD use is borderline, except when patients are at high risk of SCD. This conclusion is largely due to the methods selected for the analyses: Cost-effectiveness studies use duration of life, often adjusted to reflect the average quality of life, as the measure of benefit. This leads, in our opinion and that of others [11], to undervaluing of the benefit when the intervention tends to be for more elderly patients, especially if they are chronically ill and thus likely to have their survival "quality-adjusted" downward. Although cost-effectiveness analyses are prevalent in health technology assessments, the morality of valuing a person's life less because they are older or ill is questionable. In this article, we provide a different view of the economic desirability of ICD use for primary prevention of SCD by carrying out a cost-benefit assessment compared with amiodarone in the UK and France. This

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method was chosen because it places an equal value on each life saved.

## Methods

### *Data and Sources*

Because no single data source provided all of the required age-dependent arrhythmia and mortality inputs, these were derived by combining data from two sources. The major source for inputs was the published results of the SCD-HeFT [4]—individual patient data were not made available to us. The SCD-HeFT was a randomized, controlled, primary prevention trial of 2521 patients with mild to moderate heart failure (New York Heart Association class II/III) and ejection fractions of 35% or less. All the patients were receiving optimal medical therapy before enrollment (beta-blocker, diuretic, statin, and ACE inhibitor). Patients were assigned to ICD (N = 829), amiodarone (N = 845), and placebo (N = 847); median follow-up was 3.8 years. The 5-year mortality in the placebo group was 36.1%. When amiodarone was compared with placebo, there was no significant difference, whereas those receiving an ICD had a 23% reduction in mortality, an absolute decrease of 7.2% after 5 years. Other information obtained from the trial was the initial age distribution and all-cause mortality over 5 years.

The second major source—for mortality rates in five age groups and the probability of developing severe amiodarone toxicity—was a published meta-analysis of trials of amiodarone based on individual patient data [12,13]. Thirteen trials (N = 6252) were included in the meta-analysis, which evaluated the effect of prophylactic amiodarone on all-cause death and fatal arrhythmia after myocardial infarction or congestive heart failure (22%). The mean follow-up was 1.4 years.

## Model

A discrete event simulation was designed to follow a patient's course after implantation with an ICD or initiation of amiodarone for primary prevention of SCD (Fig. 1). Individual patients were created by assigning unique characteristics to each one: For example, each patient was assigned an age based on the SCD-HeFT population [4], which had a median age of 60.1 years (25th percentile 51.7 years, 75th percentile 68.5 years). Then each patient was "cloned" to ensure comparison of identical cohorts. One clone received an ICD, the other amiodarone, and both also received optimal medical therapy (beta-blocker, diuretic, statin, and ACE inhibitor). The rate of life-threatening arrhythmia was the same for the clones. If a severe arrhythmia occurred, the model determined whether the patient survived the event and then whether a hospitalization occurred, and these consequences differed depending on which treatment the patient was on: The probabilities were lower with an ICD. Survivors of an event were exposed to a higher rate of life-threatening arrhythmia for the following 6 months. Each patient with an ICD may develop postimplantation complications (lead- and device-related), which may lead to hospitalization for a reoperation or revision. Patients on amiodarone may develop severe drug toxicity. A patient with amiodarone toxicity was assumed to be hospitalized and a probability of death was assigned. The age-dependent hazard of death from causes other than severe arrhythmia was the same for each of the treatments. When a patient died or reached the end of

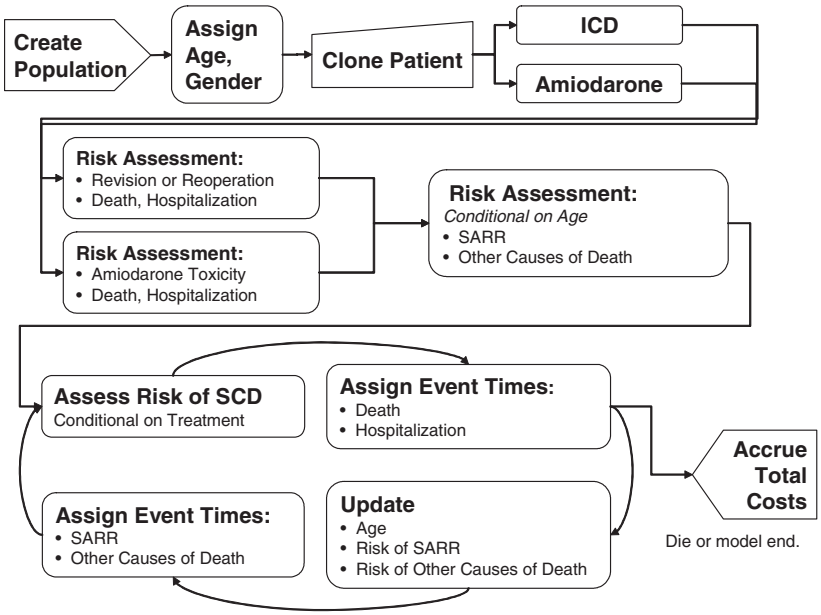


**Figure 1** Schematic representation of model implemented as a discrete event simulation.