Evaluating and improving the cost-effectiveness of the implantable cardioverter-defibrillator

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.

Health technology
Implantable cardioverter-defibrillator (ICD) versus electrophysiology (EP) guided drug therapy for severe ventricular arrhythmias.

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis

Study population
Patients with ventricular arrhythmia.

Setting
Hospital and community. The economic study was carried out in Baltimore, USA.

Dates to which data relate
The effectiveness analysis data were collected from 1980 to 1987. For resource use, published reports were used. Probabilities of ICD complications were obtained from reports published between 1988-1992 and in 1985, results of EP testing corresponded to 1988. For probabilities used in the Markov model, a review of literature published in the period 1985 to 1992 was used. Charges used relate to the period 1989 to 1992.1993 prices were used.

Source of effectiveness data
Effectiveness data were derived from a single study, literature review, and expert opinion.

Link between effectiveness and cost data
The costing was not undertaken on the same patient sample as that used in the effectiveness study. The costing was undertaken retrospectively.

Study sample
Power calculations were not used to determine the sample size. The intervention group consisted of a total of 218 patients who underwent ICD implantation and, for whom, the time of first appropriate ICD discharge (defibrillation) was determined. The same 218 patients also formed the controls, but, in this instance, the time of first appropriate ICD discharge was assumed to be the time of death without ICD.
Study design
Case series (each individual was his/her own control), performed in a single centre. The analysis was carried out on the whole sample and by stratification according to mean ejection fraction (EF).

Analysis of effectiveness
The analysis of effectiveness was based on intention to treat. The primary health outcome was life expectancy. Life expectancies were computed from Kaplan-Meier curves after discounting survival probabilities at a constant rate using a specified formula.

Effectiveness results
ICD had a discounted mean life expectancy after implantation of 3.78 years, the corresponding figure for EP-guided drug therapy being 2.06 years. No p values or confidence intervals were provided.

Clinical conclusions
Life expectancy improved in patients with ICDs compared with EP-guided therapy.

Modelling
A 1-month cycle Markov decision model over a 6-year horizon was used in estimating benefits and costs.

Outcomes assessed in the review
The clinical probabilities related to ICD, EP-guided drug therapy, complications, rehospitalisation, tests and visits in year 1 and subsequent years which were assessed from a review of published reports. The clinical probabilities related to ICD were the probabilities of being alive and early mortality. The clinical probabilities relating to EP-guided drug therapy were EP testing, initial hospitalisation and rehospitalisation. The probabilities relating to complications were the probability of requiring general anaesthesia, explant leads, replacement generator, and lead replacement. The probabilities related to tests and visits were the probability of 24-hour ambulatory ECG, stress tests, and outpatient visits.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
8 studies were the main sources of the clinical probabilities used in the Markov model.

Methods of combining primary studies
Investigation of differences between primary studies
Not reported.

Results of the review
The values of the clinical probabilities related to ICD were: alive, 0.966, early mortality, 0.034. For complications arising with ICD the probabilities were: complications (overall), 0.058; complications requiring general anaesthesia (overall), 0.22; explant leads, 0.56; new implant, 0.44; complications requiring local anaesthesia (overall), 0.78; explant generator, 0.75; new implant generator, 0.25. The probabilities of lead replacement were, 0.02 (year 1 and subsequent years). The probability of rehospitalisation with ICD was 0.7 (year 1) and 0.5 (subsequent years). For tests and visits associated with ICD the probabilities were: 24-hour ambulatory ECG, 0.8 (year 1) and 0.6 (subsequent years); stress tests, 1.0 (year 1) and 0.4 (subsequent years); and outpatient visits, 6.9 (year 1 and subsequent years). For EP-guided drug therapy the clinical probabilities were: EP testing, initial hospitalisation, 1.0; rehospitalisation (year 1), 1.2; and rehospitalisation (subsequent years), 1.0. These data formed the principal inputs to the Markov model.

Methods used to derive estimates of effectiveness
Expert opinion was used to estimate the probability of repeat EP.

Estimates of effectiveness and key assumptions
The value adopted for the probability of repeat EP was 0.15. Two key assumptions were made in the analysis:

1. It was assumed that without ICD, the first shock equalled death, and
2. "Event-free curve of mortality/first shock was in fact a "control" group for EP-guided drug therapy".

Measure of benefits used in the economic analysis
The measure of benefit used was Life-Years gained. The Markov model was used because of the difficulty in carrying out randomized clinical trials. Kaplan-Meier survival curves were computed for both groups.

Direct costs
Costs were discounted. Quantities and costs were analysed separately. Quantities measured were those of testing, professional fees, operating costs, cost of complications, and overhead costs. The boundary adopted was that of the hospital. Quantities used were obtained mainly from previously published reports. The estimation of costs was based on charges from the Michigan Medicare discharge abstracts. The resources used were reported in studies published in 1985 and 1988-1992. The price year was 1993.

Indirect Costs
Not considered.

Currency
US dollars ($)

Sensitivity analysis
One way sensitivity analyses were performed based on the following parameters: first appropriate discharge as 100% of probability of death (without ICD), perioperative mortality, battery life, discount rate, standard error of charges for
initial and repeated hospitalizations, number of repeat hospitalizations and visits.

**Estimated benefits used in the economic analysis**

1.72 incremental life-years were gained with intervention, at a discount rate of 5%. The duration of benefits, for both strategies, was 6 years since intervention (ICD).

**Cost results**

Total charges (discounted at 5%) were $146,797 for ICD and $93,340 for EP-guided drug therapy.

**Synthesis of costs and benefits**

Cost-effectiveness was $31,100 per year of life saved. The sensitive parameters were: the assumption of 100% probability of death at a first appropriately determined discharge (shock), with a sensitive value of less than 38%; an assumed discount rate of 10% increased the marginal cost-effectiveness to a value of $40,300; an assumed battery life of 2 years (instead of 4) yielded $41,800.

**Authors' conclusions**

Use of first-ICD discharge data provides a method of determining ICD cost-effectiveness, which is consistent with that of other techniques.

**CRD COMMENTARY - Selection of comparators**

The rationale for choice of comparator was clear.

**Validity of estimate of measure of benefit**

The internal validity of the effectiveness results may be open to doubt due to the assumptions made by the authors, principally that the first ICD discharge in the EP-guided therapy group would have resulted in death for 100 percent of patients.

**Validity of estimate of costs**

The resource utilisation and charge items included were fully reported but it should be noted that by using charges as a proxy for costs the generalisability of the results to other settings is limited as charges may overestimate the cost-effectiveness of the results.

**Other issues**

The results may need to be treated with some caution. The authors note that only 70 percent of patients were receiving antiarrhythmic drugs which may have the effect of biasing the results in favour of ICD. The issue of generalisability to other settings or countries was not addressed. An analysis of endocardialICD was also performed, but since this relied on a very small sample size, it is not reported in this abstract.

**Implications of the study**

If ethical to do so, a randomized controlled trial should be performed to validate these results.

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