Cost-effectiveness of implantable defibrillators after myocardial infarction based on 8-year follow-up data (MADIT II)

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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
The study assessed the cost-effectiveness of implantable cardioverter defibrillator (ICD) compared with conventional therapy in patients with an ejection fraction 30% or less after myocardial infarction. The authors concluded that ICD therapy could not be considered clearly cost-effective when compared to conventional medication therapy because of the high cost of initial ICD implantation and the lack of a morbidity-reducing effect. The study used valid and transparent methodology that enhances the robustness of the authors’ conclusions.

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

Study objective
The study assessed the cost-effectiveness of implantable cardioverter defibrillator (ICD) compared with conventional therapy in patients with an ejection fraction 30% or less after myocardial infarction. A budget impact analysis was carried out.

Interventions
ICD implantation was compared to conventional therapy of medications such as amiodarone, angiotensin-converting enzyme inhibitors and beta-blockers.

Location/setting
Germany/hospital.

Methods
Analytical approach:
The economic evaluation was based on a Markov model with a lifetime horizon. The perspective of the German statutory health insurance was adopted.

Effectiveness data:
A literature review in the MEDLINE database was used to identify relevant sources of evidence. Most of the studies were directly related to a clinical trial, the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II), the eight-year follow-up data from which had been released (see Other Publications of Related Interest). This trial was carried out at 71 USA and five European centres (Germany included) and included 1,233 patients (mean age 64 years). It was used as the main source for most inputs. Additional data were based on other published sources, mostly clinical trials. The probability of survival at four and eight years was a key input of the model. Various assumptions were made to extrapolate survival effects after the trial follow-up period.

Monetary benefit and utility valuations:
Utility valuations associated with heart failure were assumed to have been similar between intervention groups and were derived from a British study (313 patients) that used the EQ-5D instrument.

Measure of benefit:
Quality-adjusted life-years (QALYs) and life-years were used as summary benefit measures and were discounted at an annual rate of 3%.
Cost data:
The economic analysis included the costs of ICD implantation and battery replacement and revisions (including explantation where required), costs of outpatient follow-up after implantation (cardiologist visits and checks), costs of hospitalisations for heart failure and annual costs of heart failure. Unit costs were based on official reimbursement rates in the German health care system. Resource quantities were derived from published sources, including the MADIT II study. Costs were in Euros (€). The price year was 2009. A 3% annual discount rate was applied.

Analysis of uncertainty:
One-way sensitivity analyses were carried out on model inputs using published ranges of values. A Monte Carlo simulation was performed by assigning conventional probability distributions to model inputs. Cost-effectiveness acceptability curves were calculated for the net monetary benefit.

Results
Expected lifetime life years, QALYs and costs were 8.5, 5.3 and €101,860 with ICD and 6.7, 4.3 and €56,280 with conventional therapy. The incremental cost per QALY gained with ICD was €44,736. The incremental cost per LY gained was €33,105.

Budget impact analysis suggested that expenditure would range between €173 million and €1.7 billion per year depending on the proportion of patients with myocardial infarction who had a left ventricular ejection fraction 30 or less.

Sensitivity analysis showed that the most influential input was the assumption about the hazard ratio on mortality of ICD therapy versus conventional therapy from year five to year eight.

Authors' conclusions
The authors concluded that ICD therapy cannot be considered clearly cost-effective when compared with conventional medication therapy because of the high cost of initial ICD implantation as well as for the lack of a morbidity-reducing effect.

CRD commentary
Interventions:
The rationale for selection of comparators was clear. The proposed invasive strategy was compared against the conventional conservative approach for this specific patient population.

Effectiveness/benefits:
An appropriate approach was used to identify relevant sources of evidence. Methods and conduct of the literature review were not reported but the authors pointed out that many references found in MEDLINE were related to a single clinical trial that was a pivotal study for ICD and provided unique data on the follow-up of this patient population. Thus, the clinical inputs are likely to be valid. Other data were generally taken from clinical trials. QALYs were a valid benefit measure that allowed cross-disease comparisons with the benefits of other health care interventions. Utility valuations were assumed to have been similar between groups because no study had demonstrated a different quality of life in ICD patients. A valid instrument was used to elicit preferences. Undiscounted and discounted life-years were reported.

Costs:
Categories of costs included in the analysis were clearly reported and reflected the perspective stated by the authors. Intervention costs were based on average reimbursements of hospitals in German states. German diagnosis-related groups were used for hospitalisations. These values were representative of the authors' context. Resource use was partially taken from the MADIT II trial. It was unclear whether pooled estimates from the trial or data only were taken from German centres. Costs were varied in the sensitivity analysis. Other details such as price year and discount rates were provided.

Analysis and results:
The study results were presented clearly. An incremental approach was used to synthesise costs and benefits of alternative strategies. Conventional cost-effectiveness benchmarks were used. Deterministic and probabilistic
approaches were used to deal with the issue of uncertainty and the methods and results were presented. Key information on the simulation model was reported. The authors acknowledged some limitations of their analysis that might have underestimated or overestimated the benefits of ICD. It was stated that study results could not be transferred to other settings given potential differences in ICD prices, mortality and utility weights.

Concluding remarks:
The study used valid and transparent methodology that enhance the robustness of the authors’ conclusions.

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