Cost-effectiveness of a microvolt T-wave alternans screening strategy for implantable cardioverter-defibrillator placement in the MADIT-II-eligible population

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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 examined the cost-effectiveness of risk stratification with microvolt T-wave alternans (MTWA) in hypothetical 65-year-old patients eligible for an implantable cardioverter-defibrillator (ICD), in comparison with ICDs for all patients and medical therapy, from the perspective of US society. Risk stratification with MTWA improved the cost-effectiveness of ICDs. The clear presentation of the study findings and the appropriateness of the sensitivity analyses enhance the robustness of the authors’ conclusions, although more details on the clinical and economic sources would have been useful.

Type of economic evaluation
Cost-utility analysis

Study objective
The objective of the study was to examine the cost-effectiveness of risk stratification with microvolt T-wave alternans (MTWA) in hypothetical 65-year-old patients with ischaemic heart disease and left ventricular ejection fraction ≤30%, who were eligible for an implantable cardioverter-defibrillator (ICD). These patients represented the eligible population for the Second Multicenter Automatic Defibrillator Implantation Trial (MADIT-II).

Interventions
The three strategies examined were medical therapy, ICDs for all patients and risk stratification with MTWA. Under the last option, patients who tested MTWA non-negative (positive and indeterminate) received ICDs, while those who tested MTWA negative received medical therapy alone.

Location/setting
USA/hospital.

Methods
Analytical approach:
A Markov model was developed to assess the long-term clinical and economic impact of the three strategies under examination. A lifetime horizon was considered. The authors stated that a societal perspective was adopted in the study.

Effectiveness data:
The clinical data were derived from a selection of known relevant studies. Key estimates on clinical characteristics of the patient population and effectiveness of the strategies under examination were derived from the MADIT-II. Data on the accuracy of MTWA for risk stratification were taken from several prospective studies. Mortality risk was taken from the MADIT-II, supplemented by other published evidence. Other clinical estimates (e.g. complications) came from published studies, but details of the design and other characteristics of these studies were not reported. The key clinical outcome was the reduction in sudden cardiac death with the three strategies under analysis.

Monetary benefit and utility valuations:
Utility valuations were derived from published reports (details not given). The data were taken from patients with stroke or sudden cardiac death.
Measure of benefit:
The summary benefit measure was the quality-adjusted life-years (QALYs). Future benefits were discounted at an annual rate of 3%. The expected life-years (LYs) were also reported, although they were not combined with the costs.

Cost data:
The individual cost items considered in the analysis were not reported since the costs were presented as macro-categories. These included the cost of ICD and its potential complications, the cost of death and loss of productivity due to disability. The resource use data were mainly taken from published studies, details of which were not given. The unit costs were obtained from several sources, including Medicare, hospital cost accounting, the Duke database and other published studies. The costs were in US dollars ($). An annual discount rate of 3% was applied. The price year was 2004.

Analysis of uncertainty:
A univariate sensitivity analysis was performed on all model inputs using published ranges. Specific two-way sensitivity analyses were carried out on selected model inputs (i.e. mortality hazard ratio for MTWA testing and annual mortality rate). A multivariate sensitivity analysis was also conducted using a second-order Monte Carlo simulation. The probabilistic distributions assigned to model inputs were described.

Results
The lifetime costs were $157,993 with ICDs for all patients, $136,449 with MTWA risk stratification and $80,782 with medical therapy.

The expected QALYs were 7.246 (8.2 LYs) with ICDs for all patients, 7.004 (8.0 LYs) with MRWA risk stratification and 5.863 (6.7 LYs) with medical therapy.

Relative to medical therapy, the incremental cost per QALY gained was $55,800 with ICDs for all patients and $48,800 with MTWA risk stratification.

Relative to MTWA risk stratification, the incremental cost per QALY gained with ICDs for all patients was $88,700.

The sensitivity analysis identified the most influential parameters such as the effectiveness of MTWA, the rate of MTWA negative screen, the costs and effectiveness of ICDs, and patient risk for arrhythmic death. However, the incremental cost per QALY for MTWA versus medical therapy was always between $42,000 and $62,000, while the strategy of ICDs for all never resulted in less than $50,000 per QALY gained with respect to MTWA.

The probabilistic sensitivity analysis indicated that the incremental cost per QALY gained with MTWA over medical care had a 100% probability of being <$100,000 and a 55% probability of being <$50,000. The corresponding values for the ICD for all compared with MTWA were 26% and 0%.

Authors’ conclusions
The authors concluded that risk stratification with MTWA improved the cost-effectiveness of ICD in patients with ischaemic heart disease and left ventricular ejection fraction ≤ 30%, while implanting ICDs in all patients was not cost-effective from the perspective of US society.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear and appropriate. The strategies under examination are likely to be relevant to other health care systems.

Effectiveness/benefits:
The primary studies appear to have been identified selectively rather than through a review of the literature. However, much of the clinical evidence was taken from a randomised controlled trial, which should have ensured high internal validity. MTWA performance for risk stratification was taken from prospective studies, given the lack of clinical trials. The authors did not address the issue of heterogeneity among the sources used to derive the clinical data, nor did they...
provide details of the methods used to combine the estimates. In terms of the derivation of the benefit measure, the authors did not provide details of the approach used to estimate utility valuations. Nevertheless, it was stated that some conservative assumptions were made. QALYs are a validated benefit measure, which are highly generalisable.

Costs:
There was little information on the cost analysis. The authors reported the perspective of the analysis, but the costs were presented as macro-categories and a detailed breakdown of the cost items was not given. The resource quantities and unit costs were taken from typical sources for the US context, but were not reported separately. This may hamper replication of the study in other locations. The use of discounting and the price year were reported.

Analysis and results:
The synthesis of the costs and benefits was appropriately performed. The authors undertook an extensive sensitivity analysis which addressed both specific and general aspects of uncertainty in the study. The results of both the base-case and the sensitivity analyses were presented clearly.

Concluding remarks:
The clear presentation of the study findings and the appropriateness of the sensitivity analyses enhance the robustness of the authors’ conclusions, although more details on the clinical and economic sources would have been useful.

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Bibliographic details

Other publications of related interest


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