Cost-effectiveness of implantable defibrillator as first-choice therapy versus electrophysiologically guided, tiered strategy in postinfarct sudden death survivors: a randomized study


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
Use of early implantation of implantable cardioverter-defibrillator (ICD) as first choice therapy in postinfarct sudden death survivors of out-of-hospital cardiac arrest caused by ventricular tachycardia (VT) or ventricular fibrillation (VF).

Type of intervention
Treatment and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
Postinfarct sudden death survivors of out-of-hospital cardiac arrest caused by VT or VF.

Setting
Hospital. The economic study was carried out in the Netherlands.

Dates to which data relate
Effectiveness and resource use data corresponded to study patients recruited between April 1989 and April 1993; the study finished on 1 January 1994. Cost results were reported in 3 scenarios using 1990, 1992, and 1993 as the price year.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costing was prospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not reported as being used to determine the sample size. The study sample consisted of 60 consecutive patients randomly allocated to the ICD group (n=29) or to the EP-guided group (n=31).

Study design
Randomized controlled trial, carried out in two centres. The median duration of follow-up was 729 days (range: 3 -
The study had no loss to follow-up. Stratified randomisation was performed in terms of left ventricular function.

**Analysis of effectiveness**
The principle used in the analysis of effectiveness was intention to treat. The primary clinical outcome was mortality; hazard ratio was used to compare the groups in terms of mortality; Cox proportional-hazards model was used to estimate the 95% confidence intervals. Secondary outcome measures (deemed to represent the quality of life aspects), which were not reported in great detail, were major nonfatal events (recurrent cardiac arrest and cardiac transplantation), functional NYHA class, exercise tolerance, left ventricular ejection function, duration of hospitalisation (initial and readmission), number of invasive procedures, and changes of antiarrhythmic therapy. The study groups were found comparable in terms of baseline characteristics.

**Effectiveness results**
Of the 31 patients in the EP-guided group, 10 had sole antiarrhythmic therapy, 5 had VT surgery after the failure of the initial antiarrhythmic therapy, and 16 had late ICD after the failure of the initial antiarrhythmic therapy and VT surgery (in one case). The early ICD group had 4 deaths versus 11 in the EP-guided group; (hazard ratio: 0.34); (95% CI: 0.11 - 1.08); (p=0.07). Seven patients died in the subgroup of patients who had sole antiarrhythmic therapy. In terms of secondary outcome measures, only the EP-guided group experienced recurrent cardiac arrest; and the early ICD group had significantly better outcomes with respect to exercise tolerance, duration of hospitalisation, number of invasive procedures, and changes of antiarrhythmic therapy. One case of cardiac transplantation occurred in the EP-guided group.

**Clinical conclusions**
The study results confirm that ICD is superior to drug therapy in terms of clinical effectiveness.

**Measure of benefits used in the economic analysis**
The benefit measure was total days alive for each study group.

**Direct costs**
Costs were not discounted "because the median follow-up was only 2 years". Quantities were not reported separately from the costs. Cost items were reported separately. Cost analysis covered the costs of hospitalisation; visits to outpatient clinics; all diagnostic investigations; and all therapeutic procedures, including drug treatment and domiciliary care. The perspective adopted in the cost analysis was that of Dutch private health insurance. Charges were used as opposed to real costs and were based on the lowest class scale rates of the Dutch private health insurance used by the billing department of the University Hospital Utrecht. The source of cost data was one of the study institutions. Cost results were estimated for the years 1990, 1992 and 1993.

**Indirect Costs**
Not considered.

**Currency**
US dollars ($).

**Sensitivity analysis**
A series of one-way sensitivity analyses was performed on hospitalisation charges (based on three different levels of hospital charges in 1990, 1992, and 1993), sudden death rate (lower rate), therapy efficacy assessment without EP testing, and exclusion of VT surgery as a therapeutic option.
Estimated benefits used in the economic analysis
The early ICD group had a range of total days alive of 837 at 1 month after randomization to 25,544 for the entire study period (month 1 to the end). The corresponding values for the EP-guided group were 930 at 1 month after randomization to 22,565 for the entire study period.

Cost results
For the year 1992 the early ICD group had a median total cost of $47,000 versus $47,500 in the EP-guided group. (The corresponding values for the subgroups of patients receiving sole antiarrhythmic therapy were $23,500, for VT surgery, $44,100, and for late ICD, $64,300). Total costs for the entire study period in terms of mean values were $56,067 for the early ICD group and $63,032 for the EP-guided group. The total costs had a range from $744,138 at 1 month after randomization to $1,625,949 for the early ICD group. The corresponding values for the EP-guided group were $297,053 at 1 month after randomization to $1,953,993 at the end of the study.

Synthesis of costs and benefits
The synthesis of costs and effects were achieved by calculating median cost per patient per day alive, and average (absolute) costs per day alive. The early ICD group had a median cost per patient per day alive of $63 versus $94 in the EP-guided group. (The corresponding values for the subgroups of patients receiving sole antiarrhythmic therapy were $196, for VT surgery, $84 and for late ICD, $97). The early ICD group had a range of cost per day alive of $889 at 1 month after randomization to $64 for the entire study period (month 1 to the end). The corresponding values for the EP-guided group were $319 at 1 month after randomization to $87 for the entire study period. The sensitivity analysis established the relative robustness of the cost-effectiveness results to changes in some variables of the assessment.

Authors' conclusions
In terms of cost-effectiveness, early ICD implantation is superior to the EP-guided therapeutic strategy in postinfarct sudden death survivors.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was its widespread use in the context in question. You, as a database user, should consider whether it is also a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The effectiveness results are likely to be internally valid in view of the use of a randomized design. However, it is not clear whether the sample size was appropriate for the study question.

Validity of estimate of costs
Quantities were not reported separately from the costs. Adequate details of methods of cost estimation were given. As acknowledged by the authors, indirect costs could have been included in the analysis. Charges were used as a proxy for costs and refer to the Dutch private healthcare insurance. The cost results may not, therefore, be generalisable to other settings.

Other issues
The authors’ conclusion appear to be justified given the uncertainties of the data. The issue of generalisability was not fully addressed. However, appropriate comparisons were made with other studies. With respect to the chronic nature of the disease, the use of a cost-utility framework may have been more appropriate.

Implications of the study
"Further studies comparing different scenarios (e.g., empirical amiodarone or other EP-guided drugs) must be performed to confirm or complement the findings of (this) study”.

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