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Cost-Effectiveness Aspects of Defibrillators: Decreasing the Financial Burden

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Decreasing the Financial Burden

The financial burden on society to treat and prevent sudden cardiac death (SCD) is enormous. ICDs effectively reduce SCD and are recommended for secondary and primary prevention of SCD from VT/VF. Unfortunately, ICDs are expensive and add to demands to healthcare budgets in even the most developed nations. In this article, we look at the cost-effectiveness of ICDs in different scenarios.

Cost-efficiency can be defined as achieving the maximal increment in benefit for a fixed amount of resources, and is typically expressed as an incremental cost effective ratio (ICER), the ratio of changes in costs to the changes in effects. Cost-effectiveness analysis is a complex form of economic analysis that often includes “cost-effectiveness”, “cost-benefit” and “cost-utility” analyses. These analyses commonly measure effectiveness in Quality-Adjusted Life Years (QALYs).

Data on the Effectiveness of ICDs

Firstly, it is important to examine data on the effectiveness of ICDs. Among secondary prevention trials, “Antiarrhythmics Versus Implantable Defibrillators” (AVID) showed a greater survival rate with ICD than without - 89.3 % versus 82.3% at one year, 81.6 % versus 74.7 % at two years, and 75.4 % versus 64.1 % at three years. The other trials, Canadian Implantable Defibrillator Study (CIDS) and Cardiac Arrest Study Hamburg (CASH) also showed a reduction in mortality with ICDs. A meta analysis of AVID, CIDS and CASH trials showed a 28% reduction in mortality with ICD.

Among the primary prevention trials, the patient populations studied were:

(a) Ischaemic cardiomyopathy, left ventricular ejection fraction (LVEF) < 35%, asymptomatic nonsustained VT, inducible and nonsuppressible VT for the Multicentre Automatic Defibrillator Implantation Trial (MADIT);

(b) Ischaemic cardiomyopthay, LVEF < 40%, non-sustained VT, inducible VT for the Multicentre Unsustained Tachycardia Trial (MUSTT);

(c) Ischaemic cardiomyopathy, LVEF < 30% for the MADIT-II trial, and

(d) Ischaemic and non-ischaemic cardiomyopathy, LVEF < 35%, NYHA heart failure class II-III for the Sudden Cardiac Death in Heart Failure Trial (SCDHeFT).

MADIT, MUSTT, MADIT-II and SCDHeFT demonstrated a reduction in mortality with ICDs by 19% over two years, 31% over five years, 6% over two years, and 7% over five years, respectively. Among the patients with severe congestive heart failure (CHF) needing cardiac resynchronisation therapy (CRT), the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure Trial (COMPANION) trial showed lower (36%) relative reduction in all-cause mortality with CRT-D (ICD combined with CRT) when compared with optimised medical therapy.

Applying Cost-Effectiveness to ICDs

The MADIT and AVID trials reported ICERs of 27,000, and 66,677 dollars per year of life-saved during four and three year follow-up periods, respectively. As regards comparison with amiodarone, Owen et al showed the cost range per QALY varying from 37,300 to 74,400 dollars for mortality reduction by 20% and 40% respectively by ICD therapy in high risk patients. Likewise, Caro et al demonstrated that compared to amiodarone, ICDs decreased deaths from 37.0% to 29.7% during five years at a net cost of 26,222 to 20,008 euros per patient, yielding a cost-benefit ratio of 0.17 for the population in the UK and 0.14 for the population in France. This translated into more than a five to one return on investment.

Prevention Cheaper than the Cure

Compared to amiodarone and other common cardiovascular drugs, the upfront total cost of ICDs is high. However, when compared on a ‘cost-per-day-of-use’, the cost of ICD therapy becomes low given the fact that ICDs keep the patients alive for a long period. The fact that four major countries in Europe spend annually, 6.14 billion euros for statins, 2.71 billion euros for ACE-inhibitors, 1.94 billion euros for calcium channel blockers and 0.90 billion euros for betablockers, compared to 0.49 billion euros on ICDs, further highlights the cost-effectiveness of ICDs.

The risk of further cardiac arrest in the survivors of SCD remains high, with a mortality rate of over 45% at two years. Secondary prevention trials, AVID, CASH and CIDS have shown survival benefits with ICD therapy amounting to a 25% relative risk reduction for all-cause and a 50% relative risk reduction for arrhythmic mortality to compared with antiarrhythmic drug therapy. The estimated cost effectiveness ratios per life-year added were 66,677 and 139,000 dollars from the AVID and CIDS trials respectively.

For “primary” prevention, data from MADIT-II, SCDHEFT, and meta-analysis and review of several trials demonstrate that ICDs are cost-effective, and that the cost-effective ratio would remain below 100,000 dollars per QALY as long as the ICD reduced mortality for seven or more years. However, these analyses do not factor in issues such as inappropriate shocks, device-related complications such as infection needing antibiotic therapy or surgery or both, device malfunction needing component or generator change, etc. Repeated and prolonged hospitalisation for post-ICD care may thus in the long term cancel out the beneficial cost-effectiveness of ICD. Furthermore, cost-effective data analyses cannot be extrapolated from one country to the other.

Cost-Effectiveness of ICDs in CRT-D for CHF

Given the non-uniform design and nature of ICD trials in patients with CHF, it is difficult to form a unanimous conclusion on cost-effectiveness of ICDs including CRT-D for CHF. In SCDHEFT trial, ICDs compared to medical therapy alone, reduced all-cause mortality from 29% to 22% with lifetime cost-effectiveness and cost-utility ratios of 38,389 dollars per life-year saved and 41,530 dollars QALY, respectively.

Of note, in the SCDHEFT trial, only single lead ICDs were implanted in outpatient settings, thus reducing the upfront cost of ICDs. In this trial, the cost-effective ratio was also sensitive to extrapolation beyond the empirical five-year trial data: 127,503 dollars per life-year-saved at five years, 88,657 dollars per life-year-saved at eight years, and 58,510 dollars per life-year-saved at 12 years. There was a significant interaction between ICD treatment and CHF functional class, such that despite incremental cost no incremental benefit was noted in class III.

Cost-Effectiveness of ICDs in Elderly Patients

For practical purposes patients above age 65 years are considered elderly. In this patient population, there was lower or no statistically significant survival benefit from the ICDs as observed in MADIT-II and SCDHeFT trial respectively. In their analysis of healthcare costs and outcomes of ICDs for primary prevention of SCD in the elderly, Groeneveld et al showed significant reductions in mortality with ICD, but with a higher median hospital costs, by approximately 41,500 dollars, both in the first 30 days and at one year after initial hospitalisation, and with a higher outpatient and physician costs by approximately 1,800 dollars at 6 months. These additional healthcare costs of ICD implantation were deemed comparable to published cost-effectiveness models that have projected ICDs to be cost-effective.

Conclusion

Many landmark clinical studies have shown ICD therapy to be highly effective in the treatment of SCD. Economic analyses also support the cost-effectiveness of ICDs. Additionally, a further decline in the cost of the devices has occurred recently. One would therefore hope that on balance the healthcare budget of many nations would allow and promote ICD therapy for prevention of SCD for high risk patients as a standard therapy.

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