The cost of implantable defibrillators: how the perception of reality depends on perspective

Hein Heidbüchel*

University Hospital Gasthuisberg, Herestraat 49, B-3000 Leuven, Belgium

doi:10.1093/eurheartj/ehl518

Editorial

This editorial refers to 'The high cost of implantable defibrillators'† by M.A. Hlatky and D.B. Mark, on page 388 and 'The cost of implantable defibrillators: perceptions and reality'‡ by J. Camm et al., on page 392

The implantable cardioverter defibrillator (ICD) has been the subject of controversy since its very inception. Although Michel Mirowski had a visionary idea about how implantable devices could prevent arrhythmic sudden death, his vision immediately met criticism. Twenty-five years later, the skepticism has moved from issues of feasibility and effectiveness, raised by colleagues, to questions about cost and cost-effectiveness, asked by society. The discussion shows the evolution from evidence-based to value-based medicine.† By entering the health-economic arena, arguments have evolved from medically and scientific to economic and even ethical, where standards for evaluation are much less well defined than outcomes of randomized trials.

Two opinion papers in this issue of the journal‡,§ illustrate the persisting controversy around ICD therapy and its current stage. Both agree on the evidence that secondary ICD implantation (i.e. after a prior cardiac arrest or haemodynamically compromising ventricular tachycardia) and prophylactic ICD implantation in patients with compromised left ventricular function are more effective than the best actual medical therapy. But they diverge on the desirability for expansion of this treatment modality. Both articles ponder the arguments pro and contra, mainly concentrating on health-economic aspects. They look at the issue however from different perspectives which may explain their differing conclusions.

The first review article formulates the more classic, physician-based viewpoint. Camm et al.‡ wonder why, in the light of recent scientific evidence, not more prophylactic ICDs are implanted. They counter four 'perceptions' that might explain this discrepancy, although they do not make clear why they singled out these specific topics. The authors argue that the proportion of currently implanted ICD patients that benefits from the therapy is comparable with that of other well-accepted therapies, i.e. that patient selection (based primarily on left ventricular ejection fraction) is appropriate and should provide a clear and simple decision base. They reason that ICD therapy costs less than treatments for other (non-arrhythmic) conditions. Since the impact of more ICD therapy on the overall healthcare budget would be marginal (0.2%), this should not be a reason for not adapting it. Moreover, they argue that its overall cost could be recovered by addressing healthcare inefficiencies. Thus, from their perspective, there is no reason not to adapt the 'proven' management strategy. Their deliberately focused perspective, however, may have paradoxically led to a distorted perception of reality, the reverse of the intent that is expressed in the title of their article.

Cost-effectiveness issues require assessment from a wide perspective, including the views of patients and society at large. It is the dominant approach in the current opinion by Hlatky and Mark.§ These authors do not disagree with Camm et al. that ICDs are effective therapy, but argue that clinical efficacy does not necessarily imply public priority. Although money can be saved from corrected inefficiencies and the ICD budget may be small compared with the total healthcare budget, the following question remains: is implementing widespread ICD therapy a first choice for physicians, patients, and society? Spending money on healthcare contributes to overall economic activity, but it should be spent efficiently.† Patients have to weigh the possible disadvantages of therapy vs. its potential life-saving effect. In adopting this broader perspective, Hlatky and Mark touch upon some other explanations for the hesitance of society, physicians, and patients in implementing more generalized use of ICDs.

As mentioned, there is consistency among the majority of primary prevention ICD studies about its effectiveness. But calculated figures on cost-effectiveness in different trials vary significantly.⁵–⁶ Which is reality and which is just perception? Moreover, some ICD cost-effectiveness studies imply that a cost of ≤100,000 USD (~80,000 euro) would define it as good value for money, although literature consensus rather prefers a benchmark of 40,000 euro. ICD therapy falls only within that limit in subsets of patients.⁵–⁶ Although it may be comparable with other accepted treatments, it is still less cost-effective than other heart failure therapies in the same patient population, e.g. beta-blockade or ACE-inhibition are cheaper and have the additional potential to slow disease progression and/or reduce symptoms.⁷

Hlatky and Mark also note that private industry is the main and direct beneficiary of the ICD investment paid by society. Although this may be true in other fields of medicine, this
obvious relationship may explain hesitance of the (medical) community to embrace more widespread reimbursement of ICDs. Ironically, the argument is exemplified by the professional affiliation of one of the authors in the other article. Bringing this consideration into the public debate is worthwhile. It may help to delineate the responsibility of industry in controlling healthcare costs and guarantee sustainable development in this economic area. Available data are consistent that ICD cost-effectiveness is very much influenced by device longevity. However, device longevity is a poorly documented topic in medical literature. The current discussion may encourage clinical scientists to gather these data. Physicians are responsible to select models with the lowest long-term cost, for example, single-chamber ICDs whenever possible (as was the case in most prophyllactic trials). Industry needs to balance the willingness of society to invest more in ICD therapy with improved longevity and/or price reductions. Cost-effectiveness needs to be adjusted for the tolerability of the therapy by the patient, i.e. quality-adjusted. It remains unclear to what extent quality of life (QOL) is affected by ICD implantation. There even is no uniformity on whether the effect is positive or negative. Inappropriate shocks definitely lead to a decrease in QOL. Repetitive appropriate ICD discharges may have the same effect, while not necessarily prolonging life. Malfunction may require revisions, which by themselves have an 8% complication rate. The perceived disadvantages of ICD therapy may be even so important that patients or their treating physicians opt not to implant a device in some, as recently voiced by a large group of French doctors reviewing ICD implantation in patients with Brugada-ECG or -syndrome. There may be other cultural, medico-legal, and ethical factors that may explain different implant rates in the EU vs. the USA. These considerations cannot be excluded from ‘economic’ analysis of ICD therapy. It is important to further investigate this aspect so that reality and perception can be distinguished.

Another persistent issue in the debate is patient selection. There remains uncertainty, both among physicians and policymakers, about which patients benefit most from prophylactic ICD implantation. If those patients can be better prospectively defined, cost-effectiveness will evidently improve. On the other hand, the downside of more specific tests (or combinations of tests) is that they may result in lower sensitivity and hence a lower number of patients who will ultimately benefit from therapy. Camm et al. remind that current stratification schemes are reasonably accurate. However, the number of patients needed to be treated to prevent one casualty is 11 for a 3 year follow-up in MADIT-II and more than 14 for a 5 year follow-up in SCD-HeFT, unadjusted for QOL. It is primordial to better identify patients with a high and disproportionate risk of sudden cardiac death. Over the last years, despite intensive research, not much progress has been made in this field. Recently, promising results with microvolt T-wave alternans testing have led to new enthusiasm and may lead to improved cost-effectiveness.

The duration of the reduction in all-cause mortality associated with ICDs is undefined, although it has major impact on estimated lifetime cost-effectiveness. Understandably, clinical studies have a finite follow-up, and the SCD-HeFT data (the trial with the longest available follow-up) do show a mortality benefit up to the available follow-up of about 5 years. Beyond study end, sophisticated statistical techniques have been applied for extrapolation. This is no straightforward science in relatively old patient populations with high age-dependent death rates. No real data are available to prove a durable effect on mortality, less its magnitude. The total number of life-years saved may be lower than anticipated from relative mortality benefits derived from a few years of follow-up. We also do not know how the patients with advancing heart failure perceive the benefits from the device in the long term: heart failure symptoms will increase over time, as well as inappropriate shocks and reinterventions. They all have an impact on quality adjustments. More real data can advance the discussion beyond the speculation of current extrapolation. For this reason, ICD registries have been set up (as by the US Center for Medicare and Medicaid Services, later transferred to the American College of Cardiology) in order to assess predictors for optimal cost-effectiveness. Similar European initiatives are highly desirable.

There definitely is no winner in this debate of arguments, as is usual when complex issues are looked at from different perspectives. By publishing these papers, the Journal wants to stimulate and open up the discussion. It wants to encourage further research to improve knowledge about parameters that define incremental ICD cost-effectiveness: device longevity, long-term QOL, risk stratification, and sustainability of ICD benefit, to name but a few. Making the arguments explicit may help to reach consensus and will ultimately benefit all parties involved: providing doctors with more therapeutic tools, improved care for patients, a durable economic future for device industry, and well-spent money for society.

Conflict of interest: none declared.

References