The high cost of implantable defibrillators

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Introduction

Recently updated practice guidelines suggest that a wider spectrum of patients with established cardiovascular disease should be strongly considered for an implantable cardioverter defibrillator (ICD) to prevent sudden cardiac death and enhance life expectancy. The broadening of the indications for prophylactic ICD use reflected in these guidelines poses challenges to clinicians and health policy makers.

ICDs were initially used only in patients who had been successfully resuscitated from an episode of ventricular tachycardia (VT) or ventricular fibrillation (VF). In this small, high-risk population, three randomized clinical trials showed that ICD therapy reduced overall mortality by 20–25% in relative terms. As a consequence of this consistent evidence, there is no controversy that the small number of patients who survive a cardiac arrest should receive an ICD.

Most victims of sudden cardiac death, however, have not had prior episodes of sustained VT or VF. Many more lives could be saved if ICDs were implanted prophylactically in patients at increased risk of sudden death. Randomized clinical trials conducted in ‘primary prevention populations’ (i.e. patients with established cardiac disease, but no history of sustained ventricular arrhythmia) have had mixed results: most trials found patients assigned to an ICD had significantly reduced mortality, but several trials failed to document a benefit with the ICD therapy.

Current clinical guideline recommendations are heavily influenced by the largest and the most recent of the primary prevention trials, MADIT II and SCD-HeFT, which showed a clear and significant improvement in survival with the ICD therapy. On the basis of the nominal eligibility criteria for these trials, there are potentially millions of patients with cardiovascular disease who could benefit from ICD implantation. However, several years after the publication of these pivotal trials, the most eligible patients have not received an ICD. One reason for the slow change in clinical practice is the high cost of the ICD devices and the anticipated economic burden on national health-care budgets. ICDs are expensive devices, with acquisition prices in the USA ranging from ~$18 000 for the simplest devices to over $35 000 for ICDs with biventricular pacing capabilities. But, even in the USA, where Medicare reimbursement has been broadened to include virtually all patients who meet the MADIT II or SCD-HeFT eligibility criteria, the growth in the use of ICDs over the last several years has been unexpectedly modest. Although the expense of the ICD therapy is a legitimate concern, this factor does not fully explain why the strategy of implanting ICDs for primary prevention of sudden cardiac death, a major public-health problem in all the developed countries, has seen only limited implementation to date.

Net cost and cost effectiveness of ICDs

Several randomized clinical trials have measured medical resource use and cost among patients assigned to an ICD or to alternative therapy. The results of these studies are quite consistent: patients assigned to ICD have substantially higher early costs due to the cost of the ICD device and implantation, and they continue to have significantly higher costs over several years of follow-up (Table 1). The...
The high long-run cost of the ICD therapy is not surprising. Although a few therapies ‘pay for themselves’ by reducing complications that are costly to treat, the ICD prevents sudden out-of-hospital death, a complication that costs little or nothing to treat. In addition, monitoring an ICD and treating device complications increase the long-term cost of patient management.

A further notable feature of the ICD therapy is that the great majority of the lifetime cost of therapy occurs at the time of initial implantation, but the benefits take years to accrue. Finally, much of the cost of the ICD therapy is paid to one of several for-profit medical device companies to purchase the equipment. In contrast, the majority of the cost of other expensive cardiac procedures, such as coronary bypass surgery, is paid to not-for-profit hospitals. This distinction is viewed as important by some observers and may influence attitudes about increasing use of ICDs.

The cost of a therapy cannot be judged without considering its clinical effectiveness in the target population. On the basis of plausible assumptions about the long-term clinical benefits, cost-effectiveness analyses suggest that ICDs provide health benefits with an efficiency that is comparable to other well-accepted forms of health care.\textsuperscript{9–11,13} Thus, clinical trial data suggest that for primary prevention in selected populations with moderate systolic dysfunction, ICDs produce a survival benefit that is large enough to be considered cost effective over the long run (12 years or more of therapy). Should these data be enough to mandate general acceptance of ICD therapy for all eligible patients?

### Policy issues

Health economics research shows that adoption of new medical technologies is the primary reason that health-care costs are increasing much faster than inflation in all the developed countries.\textsuperscript{14} Each country struggles with the dilemma of how to pay the higher cost of medical advances, which are typically more effective than the existing technology. Some commentators have argued that any single new therapy, such as ICDs, adds so little to the national health-care budget that the therapy should be provided to anyone who might benefit.\textsuperscript{15} The total effect of multiple new therapies, however, is the main force driving higher health-care costs. The challenge to health policymakers is to foster development and dissemination of genuinely effective new therapies but to control the growth of costs to an affordable level.

Health-care systems may not be able to afford to purchase all nominally cost-effective therapies because the added cost exceeds the available funds. The overall cost of a therapy to the health-care system depends on the number of affected patients and the absolute cost of the treatment. An expensive therapy that will be used in 1000 patients a year may be more affordable to the health-care system than a less expensive therapy that will be used by 100 000 patients a year. Nevertheless, a health-care system would rather spend a fixed budget on therapies that benefit many patients: all else being equal, it seems fairer to spend 20 000€ to buy effective drugs for 100 patients than to buy an ICD for one patient. Equity in distribution of health-care resources must be considered as well as efficiency in allocating health-care resources.

Although the percentage of a gross domestic product devoted to medical care is often discussed in the media, the general public places a high value on health and may be willing to pay more for better health care. Policy makers, as representatives of society, must grapple with the relative desirability of spending more on health care rather than on education, social welfare, transportation, defence, environmental protection, and so forth. The fact that society is often ill prepared to engage in meaningful dialogue on these trade-offs is one of the reasons that the health policy of many countries seems quixotic and poorly reflective of collective values.

### Improving cost effectiveness

Do ICDs really need to be as expensive as they are?\textsuperscript{16} This question highlights the complex interplay between the device manufacturers, electrophysiologists who implant ICDs, and third-party payors. Although it might be possible to save money by using simpler, less fully featured ICDs, as were tested in SCD-HeFT, electrophysiologists currently prefer to use newer more complex (and more expensive) devices. The reluctance to use simpler, cheaper devices, we believe, derives from a combination of factors. First, few data directly compare the different features of ICDs with regard to their effects on outcomes. The standards for device regulatory approval, in fact, are more often based on the demonstrated device function rather than the long-term clinical outcomes. Second, the training of electrophysiologists emphasizes pathophysiological reasoning over empirical testing in clinical trials (it should be noted that this is generally true of many technology-based specialties). Thus, when manufacturers add new features to their devices that make pathophysiological sense, physicians may adopt them without demanding empirical proof of improved outcomes. Further, few outside the device industry understand the relationship between individual device features and the differential prices of devices. Finally, there is a tendency for physicians to equate older less sophisticated technology with lower quality medical care. Despite general concern about the high price of devices, no ‘customer’ for ICDs is currently providing a strong incentive for device companies to develop more economical devices.

In some respects, the contrast between new and older generation ICDs is similar to the contrast between bare metal stents and newer drug-eluting stents. In both cases, the newer technology produces a less eventful clinical course (perhaps less shocks due to antitachycardia pacing for ICDs, less restenosis with repeat procedures for
drug-eluting stents). But in both cases, there is no evidence that the eventual outcome of the patient, as defined by survival or major morbidity events, is meaningfully improved by using the newer technology. When first released, drug-eluting stents were hailed as breakthrough devices and quickly adopted in much of North America and Western Europe. Emerging data now suggest that drug-eluting stents may have an increased risk of late stent thrombosis and death. Recent recalls of some models of ICDs suggest that the complex engineering involved in the most recent generation of devices may also contain the potential for unintended patient harm. Electrophysiologists are as reluctant to use lower-tech ICD devices to save money as interventional cardiologists are to use bare metal stents for the same purpose. However, current standards for regulatory approval of complex medical devices may be insufficient to define whether ‘newer’ is really equivalent to ‘better’.

If we cannot save money by using less expensive ICDs, perhaps it is possible to reduce costs by restricting the number of patients who get an ICD. This strategy has intuitive appeal to many clinicians, since it appears to offer a win-win option: no one has to get ‘inferior’ technology and lower risk patients can avoid an unneeded procedure. In large clinical trials, the vast majority of patients who undergo prophylactic ICD implantation never receive an ‘appropriate shock,’ even after several years of follow-up. It seems logical to conclude that if an ICD does not fire over a reasonable period of time, it was not needed in the first place. A variety of methods have been proposed to separate the patients who will benefit from an ICD from those who fit the major clinical trial criteria but will not be likely to benefit. Methods to identify individuals at high risk of sudden death would provide ‘more bang for the buck’ from prophylactic ICD implantation.

However, two practical problems stand in the way of general implementation of this appealing solution. First, no risk stratification technique or strategy has been properly validated for this purpose in a large-scale clinical trial of ICD therapy. Although it might seem that a test that stratifies mortality risk in a similar cohort would perform suitably well for this purpose, one should be sceptical of equating the partitioning of mortality risk in general with the efficient and accurate partitioning of ICD therapeutic benefit. Second, selecting a smaller, higher-risk population for the ICD therapy will increase the proportion of treated patients who use the ICD but will decrease the public health impact (in terms of total number of sudden deaths in the population that are prevented). This is because many patients who will experience sudden death will appear at low risk by all testing methods currently available up until the day they die.

Other barriers to ICD use

There are several barriers other than cost to widespread adoption of prophylactic ICD implantation. Many potentially eligible patients have advanced cardiac disease, substantial co-morbidity, and poor quality of life. These patients may not wish to have an ICD implanted, as they might fear sudden cardiac death less than a protracted final illness. Patients may also not wish to undergo the discomfort of an ICD implantation or the inconvenience of additional visits to monitor the device. Still other patients may be concerned about the chance of device malfunctions or complications or about inappropriate ICD shocks, which may degrade quality of life significantly. An informed patient may reasonably decide not to undergo a prophylactic ICD implantation.

Many regions do not have enough physicians with expertise in heart rhythm disorders and skills to perform ICD implantations for the large ‘primary prevention population’. There are difficult physician workforce issues around ICD implantation and management and appropriate concerns that less skilled physicians will not be able to match the results achieved by the specialists who provided ICD management in clinical trials. Procedure-based therapies often work less well in widespread practice, where patients would not meet entry criteria for randomized trials, and treatment is provided by less expert physicians.

Conclusion

Greater use of ICDs in primary prevention populations will strain the budgets of many health-care systems. The high cost of each ICD device and the large population of potentially eligible patients will entail expenditures that require either increasing overall health-care budgets or cutting back on other services. This impact would be mitigated by lower cost ICDs or better methods to identify the smaller number of patients who actually benefit from the device.

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References

Clinical vignette

Myocardial metastasis of a bronchial carcinoid

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A 78-year-old woman was admitted to the Intensive Care Unit for cardiogenic shock due to cardiac tamponade. She had no past medical history and was previously healthy. Transthoracic two-dimensional echocardiography performed after pericardial drainage demonstrated a myocardial infiltrative mass localized in the septum (Panel A, four-chamber apical view, arrow) and in the left ventricle (LV) inferior wall (Panel B, parasternal short axis, arrow). Cardiac valves were normal. Pathological examination of pericardial fluid did not reveal abnormal cells. A lower lobe right pulmonary mass was diagnosed using chest CT scan (Panel C, arrow). Magnetic resonance imaging (Panel D, four-chamber view, and Panel E, short-axis view) demonstrated not only the septal, anteroseptal (Panels D and E, arrow), and the inferior masses associated with circumferential pericardial effusion but also masses localized in the LV lateral wall and in the free wall of the right ventricle (head arrow, Panels D and E, respectively). Bronchial endoscopy failed to biopsy the pulmonary mass. However, histological analysis of a myocardial biopsy performed by thoracotomy diagnosed a metastasis of a differentiated bronchial carcinoid. A somatostatin treatment was introduced. After 1 year of follow-up, despite a preserved healthy state, the patient suddenly expired. The cause of death was supposed to be ventricular arrhythmia as a consequence of tumoural invasion. In conclusion, myocardial metastasis is an unusual clinical presentation of bronchial carcinoid particularly with a preserved health. These data are in contrast with the clinical deterioration often described in patients with malignant tumours and metastatic myocardial invasion. Asterisk indicates pericardial effusion. LV, left ventricle; RV, right ventricle.