Editorial Comment

Evolution, Evaluation, and Efficacy of Implantable Cardioverter-Defibrillator Technology

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The implantable cardioverter-defibrillator (ICD) has emerged as an accepted primary therapeutic option for patients at continuing high risk of potentially fatal arrhythmias. It is now evolving further into a group of alternative technologies for specific applications. During the history of ICD development, more than 10 years elapsed between the proposal of the concept and the initial clinical application followed by the first sizable clinical reports on the comparatively simple first-generation devices appeared less than 10 years ago. The subsequent rate of evolution of ICD devices has been an impressive testimony to the merged talents and goals of clinical scientists and industrial engineers in generating technologically advanced applications. From a single-function, nonprogrammable, committed-action, short-life device requiring thoracotomy for implantation, the direction is now toward multiple programmable functions with aborted-action decision capability, therapeutic pacing options imperceptible to the patient, and lead systems that can be placed transvenously and subcutaneously. Moving quickly from “last resort” therapy to a primary therapeutic option and in specific clinical circumstances the option of choice, ICD therapy is now beginning to offer a menu of choices responsive to the specific needs of individual patients.

Despite the attractive sophistication of the evolving technologies, their ability to deal with multiple contingencies, greater ease of implantation, and the potential for greater comfort and benefit to the patient, physicians must confront the issue that technological capabilities cannot be separated from two major factors that apply to any therapeutic intervention: 1) the impact on survival and 2) the impact on quality of life. In regard to the former, there are still no properly controlled studies to determine the extent to which ICD therapy prolongs life. Although many electrophysiologists who have been a part of the evolution of ICD therapy are convinced that survival benefit is being accrued, respected voices raise valid questions, and the issues continue to be debated. There is no doubt that ICD therapy can effectively and predictably convert ventricular tachyarhythmias with a very high success rate in clinical settings, probably resulting in reduced sudden death mortality, and we are among the majority who believe that this results in improved overall survival rates in high-risk patients. The magnitude of the improvement, however, which can be evaluated only by properly designed, concurrently controlled, randomized studies, remains unknown. This need is frustrated, at least in part, by the ethical question of use of placebo therapy in patients known to be at substantial risk of death. The confounding influence of competing risks is another difficult problem, which is not always appreciated. Patients at risk for sudden cardiac death are simultaneously at risk for nonsudden cardiac and noncardiac deaths; to the extent that a sudden death is replaced by another form of death, efficacy of the preventive intervention is neutralized. Limitations of positive controls (i.e., comparisons with another active therapy) and the impropriety of using historical controls in patients at risk for fatal arrhythmias are additional factors confounding valid measures of efficacy for prevention of death. The often quoted 30% 1-year and 45% 2-year recurrent cardiac arrest risk among survivors of out-of-hospital cardiac arrest derive from observational data from the early 1970s. The figures were imperfect natural history figures even then, although as close as possible to valid risk estimates for the time. All survival figures since then are even less perfect, and the current “natural history” is unknown. Several studies currently under way, which include design features controlling to a greater or lesser extent for various confounding factors, will provide some insight into the benefit of the ICD for specific subgroups. Only randomized, placebo-controlled studies, however, have the power to measure the magnitude of benefit accurately. These conflicting issues will not be resolved easily.

A measure of efficacy that has received only limited attention to date is the estimation of the effect of ICD therapy on duration of survival compared with other therapies, in contrast to survival to a predetermined end point in time. In the report by Newman et al., the ICD had no survival benefit over matched controls at 36 months of follow-up, but interval analysis of the survival curves indicated a relative benefit of ICD therapy for up to 24 months before the curves began to merge. Efficacy

See p 363

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expressed in terms of extension of life has been cited by others as well.10,19 In disease states in which survival beyond a specified interval is used to define cure of the underlying pathological process (e.g., the malignancies), a 3- or 5-year interval analysis has a different implication than for a disease state in which the underlying pathophysiological process continues while a single manifestation of that process remains controlled (e.g., tachyarrhythmic cardiac arrest risk in patients with coronary heart disease). Other manifestations not targeted by the intervention continue to exert their influence on outcome. Accordingly, interval analysis and extension of life have more meaning for the group of cardiovascular diseases than they do for some other disease states. Further analysis of the extension-of-life issue may provide better insight into the survival benefit of device therapy.

No analysis of therapeutic efficacy is complete without an estimation of the effects of therapy on quality of life. This is true in general and is particularly important when outcome is measured as extension of life rather than an open-ended prevention of death. ICD therapy has both positive and negative psychological impact on patients,20,21 but all of the data currently available address issues related to shock-only devices and not to potentially less disturbing tiered therapy. The latter benefit may be counterbalanced, in part, by the inconvenience and uncertainties of more complicated follow-up algoritms.

Two articles published in Circulation, one in a recent issue22 and one in this issue,23 report experiences with tiered-therapy ICDs22,23 and document the ability of the technology to achieve what it is designed to do. Bardy et al22 report that 80% of 623 true ventricular tachycardia (VT) episodes in 26 patients were successfully terminated by antitachycardia pacing (ATP) and that an additional 13% (78 episodes) were terminated by low-energy cardioversion. In the report by Fromer et al,23 initial ATP therapy terminated 91% of 1,204 spontaneous VT episodes in 43 of 102 patients. Both sets of data strongly support the efficacy of ATP therapy for appropriate arrhythmias. Among the populations enrolled in both studies, however, significant subgroups received no benefit from ATP/cardioversion capabilities. In the report by Bardy et al,22 the index arrhythmia leading to device therapy was ventricular fibrillation (VF) alone or in addition to VT in 29 of 50 patients, and in the Fromer et al report,23 36 had sustained VT clinically, and 66 had a history of survival from cardiac arrest or emergency cardioversion for ventricular tachyarrhythmias or both sustained VT and cardiac arrest survival. One patient had spontaneous nonsustained VT and inducible VF. Substantial numbers of survivors of VF would be less likely to benefit from ATP therapy. Because many cardiac arrests begin as monomorphic VT, however, it is conceivable that ATP may prevent the onset of accelerated VT or VF in this subgroup. Such a mechanism is important to define because it would justify the consideration of ATP therapy among subsets of patients whose index arrhythmia was VF. Data of this type will be required for the future and ideally will be acquired from memory analysis of implanted devices. In the meantime, it is important to recognize that only 73% of the patients in the report by Fromer et al23 had ATP function activated at the time of final programming and that only 26 of 50 patients in the report by Bardy et al22 received ATP therapy. Thus, although ATP therapy is clearly effective for appropriate arrhythmias, a more critical definition of appropriate patients would likely result in improved rates of effectiveness of this sophisticated function. Nonetheless, when ATP is appropriate, patients can be spared the discomfort of high-energy discharges.

Two other points require amplification. First, the problem of “device proarrrhythmia” is becoming more clearly defined. Even with the earlier shock-only devices, induction of secondary VTs as a result of inappropriate shocks or conversion from one form of VT to another was observed. However, they usually were not clinically relevant. With antitachycardia pacing and low-energy cardioversion, the concerns about accelerating VTs and conversion to VF are greater, and Bardy et al22 comment that acceleration of VT is an observed problem in some patients receiving ATP therapy. The second issue is the problem of complexity of patient management in regard to the programming and reprogramming requirements of complex devices. It is clear to all who have worked with devices having ATP capability that programming and long-term management are far more complex and require higher degrees of specialization than do the simple shock-only devices. Even among qualified electrophysiologists, a subculture who can communicate with these devices is developing. Given the complexity of the systems, it is likely that nonspecialized cardiologists or even some electrophysiologists having only limited familiarity with these systems will have difficulty managing these devices in the long term. This adds inconvenience and increased cost to long-term management and must be taken into consideration as a part of the quality-of-life issue. Nonuniform language is yet another problem. Subcultures tend to develop jargons, and we sense this in advanced ICD development, including the terminologies used among individual investigators,22,23 the corporations that develop devices, and the languages in the devices themselves. Some degree of uniformity would help the users considerably.

In conclusion, the advanced multiple-option devices now becoming available provide a major step forward in our ability to tailor device therapy to the needs of the individual patient. The patient with frequent recurrent episodes of sustained VT who can be spared the inconvenience and side effects of antiarrrhythmic drugs and the discomfort of high-energy shocks will receive a major benefit from these devices. In contrast, the individual with infrequent episodes of VF not initiated by sustained VT will receive no additional benefit over conventional device therapy. The question now is whether to direct efforts toward a universal therapeutic model in which standard complex devices could be used in the way that most benefits and least traumatizes the patient, or whether a selection of devices with different capabilities would be more appropriate. If cost, ease of long-term management, patient convenience, and patient comfort were equivalent, a universal device would be logical. It is not clear, however, that these requirements are on the horizon, and for the foreseeable future, the choice of a device that best meets these criteria should be made available for individual patients.
References


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