

EDITORIAL COMMENT

Reappraisal of Implant Testing of Implantable Cardioverter Defibrillators*

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For more than 20 years, detection and defibrillation of ventricular fibrillation (VF) have been tested at the implantation of implantable cardioverter defibrillators (ICDs). In this issue of the *Journal*, Strickberger and Klein (1) question this practice. They propose that abandoning ICD testing should permit reduced training requirements for implanters and hence greater access to life-saving ICDs. Although implant testing attracts modest interest, training requirements attract great interest because they may substantively affect who implants ICDs and the economics of the medical device industry.

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THE RELATIONSHIP BETWEEN IMPLANT TESTING AND TRAINING REQUIREMENTS FOR IMPLANTERS

The principal argument of Strickberger and Klein (1) for abandoning defibrillation testing is that it limits access to ICDs. They begin by suggesting that the requirement for implant testing creates a barrier to ICD therapy “in regions with few or no electrophysiologists” and hence limited capacity to perform such testing. Then, they extrapolate this argument to the national level. Finally, they propose a study to “demonstrate that physicians without defibrillator implantation experience can safely and appropriately implant defibrillators [without testing].” These arguments rely on several questionable assumptions.

First, no study has established that a shortage of trained implanters creates a barrier to ICD therapy, even in remote regions. High cost, lack of expert consensus on indications, lack of perceived benefit by patients or physicians for primary prevention, disparities in insurance coverage, or other factors may be more important.

Second, the authors assume that more implant capacity will result in better outcomes on a national level by servicing unmet need, but they provide no estimate of either need or present capacity. A work-time study sponsored by the North American Society of Pacing and Electrophysiology-Heart Rhythm Society determined that electrophysiologists have substantial excess implant capacity. They perform an

average of three implants per month, spending only 12% of their time in implant-related activities (G. Naccarelli, personal communication, January 2003), but a recent study (2) estimated that ICDs were underused in urban areas despite a concentration of electrophysiologists who have unused implant capacity. If we make the conservative assumption that an electrophysiologist can implant two ICDs per week with testing, present implant capacity probably is in the range of two to three times the present volume. Once this capacity is saturated, it is not axiomatic that “more is better.” After a threshold fraction of patients undergo coronary interventions, more interventions do not consistently improve outcomes (3).

Third, although the authors focus on implant testing, their implicit thesis is that a putative shortage of electrophysiologists is the principal barrier to ICD therapy. Having an insufficient supply of electrophysiologists perform all ICD care except implantation will not remove this barrier. Thus, the authors’ fundamental assumption is that physicians who are not trained to perform defibrillation testing can nevertheless provide comprehensive, quality care to patients at risk for sudden death, but proficiency at implant testing is only one of a number of differences between training requirements for ICD and pacemaker implantation (4). Both VF induced by inappropriate therapy for supraventricular tachycardia and untreated ventricular tachycardia due to programming errors have caused sudden deaths in ICD recipients (5). Multiple unnecessary shocks delivered because of suboptimal programming may have a major adverse effect on quality of life. To be meaningful, the authors’ study must test their fundamental assumption, that physicians without electrophysiologic training can provide comprehensive care for ICD patients, including selection, preoperative evaluation, implantation, programming, troubleshooting, follow-up, and management of drug-device interactions and recurrent ventricular tachyarrhythmias. Their proposed trial does not address this comprehensive issue.

Fourth, the authors assume that the outcome of their study will not be influenced strongly by the type of implant testing used. However, different testing methods result in different recommendations about programming or system revision, and experts disagree about which method is best. Before considering a multicenter study of testing versus no testing, it would be prudent either to identify optimal testing or demonstrate that a clinically relevant range of testing strategies results in similar outcomes.

The authors demonstrate that a randomized controlled trial will be large, expensive, and time consuming. We need better data in at least four key planning areas before considering one: 1) What is the optimal method for implant testing? 2) Does implant testing limit access to indicated ICDs? If so, to what degree? 3) How safe is a trial of “no testing” in a large prospectively selected subset of ICD recipients? Detection of VF may be unreliable if the R-wave

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is small. The high rate at which left-sided pectoral ICDs with right ventricular, apical defibrillation electrodes pass the 10-J safety margin is in part due to implant testing. Success rates $\geq 95\%$ are achieved only after implanters change shock waveform, lead position, or generator position in $\sim 10\%$ of patients (6). Defibrillation thresholds (DFTs) are higher with right pectoral implants. Even with left pectoral implants, experts disagree about whether lead positions other than the apex have consistently low DFTs. Some of these situations cannot be anticipated preoperatively. 4) How will the study test the fundamental assumption that physicians without electrophysiologic training can provide comprehensive care for ICD patients?

ALTERNATIVE PERSPECTIVE

An alternative perspective is that implant testing should be re-evaluated to determine the optimal balance between implant safety and long-term benefits of ICD therapy. The accuracy of defibrillation testing increases with the number of VF episodes. Serious complications are rare with limited, safety-margin testing (7), but a comprehensive assessment of defibrillation efficacy is not performed in humans, because the risks of many VF episodes, including death, are considered unacceptable.

However, limited testing provides limited assurance of reliable defibrillation. The commonly used, 10-J safety margin identifies only $\sim 50\%$ of patients who have unreliable defibrillation (8). Increases in DFTs that compromise defibrillation efficacy occur in up to 15% of patients who are programmed to a 10-J safety margin (9). Implantable cardioverter defibrillators reduce the risk of sudden death only by $\sim 50\%$ (10). In one study of ICD recipients, more than half of sudden deaths were caused by shock failure or post-shock electromechanical dissociation (5). Some of the former may be prevented by a more specific implant criterion and some of the latter by programming lower, patient-specific shock strengths that cause less post-shock mechanical dysfunction. Even if it were practical to implant ICDs that deliver uniformly effective shocks, unnecessarily strong shocks would cause serious mechanical dysfunction in many patients (7).

Strict, conventional defibrillation implant criteria subject all patients to multiple VF episodes and a significant fraction to unnecessary system revisions and retesting. There is an inverse relationship between the fraction of patients who pass any defibrillation implant criterion and the subsequent success rate for conversion of spontaneous device-detected VF (8). Given the high, a priori probability of successful defibrillation at implants performed by trained implanters, the rules of conditional probability dictate that many patients with reliable defibrillation will not pass a highly specific implant criterion.

Thus, the implanter's dilemma is that programming based on more specific testing may increase long-term benefits of ICD therapy—but only at the price of greater

implant risk and complexity. Experts disagree on optimal implant criteria because they disagree about the trade-off between accuracy and risk. In this context, “no testing” is one end of a continuum that progresses with increasing rigor through limited safety-margin testing and DFT testing to research DFT testing used only in animals.

New testing methods improve the predictive accuracy of implant testing with fewer or no episodes of VF. Bayesian defibrillation testing is the most efficient method (11). Testing based on the upper limit of vulnerability permits the assessment of defibrillation efficacy without inducing VF in 80% to 90% of implants (12–14). An interleaved Bayesian combination of defibrillation and vulnerability testing is one method to maximize the information derived from implant testing. Clinical studies will be required to determine whether new implant testing methods can improve outcomes.

FINANCIAL CONSIDERATIONS

A “no-testing” standard will have financial implications for implanters, insurers, and industry. Some ICD manufacturers favor reduced training requirements as a major opportunity for increasing sales. They focus on “no testing” as a first step. Implantable cardioverter defibrillator manufacturers have funded key clinical ICD studies and may fund future studies of implant capacity, unmet need, and barriers to therapy. When evaluating such studies, assumptions, methods, and funding must be considered critically.

THE BIG PICTURE

The implantation of ICDs is only one step in the therapeutic use of a technologically complex system that can cause serious short-term and long-term complications. Implantable cardioverter defibrillator therapy is a key element, but only one element, in a complex chain of comprehensive antiarrhythmic therapy.

Both the reliable sensing of VF and safe and effective defibrillation are crucial for effective ICD therapy, but neither can be assured at implant without some risk to the patient. Ideal implant testing would identify both the optimal ICD system for each patient and its optimal programming, without the need for either VF or shocks. Until such a method is developed, implanters will benefit from new, practical, evidence-based guidelines on optimal use of available methods. In the short term, guidelines may recommend less testing, more testing, or different (e.g., vulnerability) testing, depending on the clinical situation. In the long term, they may recommend no testing if supported by the level of evidence proposed by the authors. The goal of reassessing implant testing should be to determine the optimal balance between implant safety and long-term benefits of ICD therapy. To abandon implant testing is to squander a valuable opportunity to improve outcomes for ICD patients.

Available evidence indicates that nationwide ICD

implant capacity is not presently restricted by either the requirement for implant testing or training requirements for implanters. There are no waiting lists for ICDs. Although implant capacity should be sufficient for unmet need, excess implant capacity should not drive need. The analysis of barriers to therapy for prevention of arrhythmic death should include all steps in the complex chain required for safe, effective, and comprehensive antiarrhythmic therapy.

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