The assessment of defibrillation (DFT) efficacy has long been the standard of care during defibrillator implantation. To ensure an acceptable DFT safety margin, early defibrillator systems frequently required that the shock polarity and the location, type, or number of electrodes had to be altered. Advances in defibrillator and lead technology have resulted in lower and more consistent DFT thresholds in the range of 10 J, with an infrequent requirement to modify the DFT system. Yet, one can make an argument for and against continuation of DFT testing at the time of defibrillator implantation. The goal of this paper is to address both the data that do support and the data that do not support continuation of DFT testing at the time of device implantation. Scientifically, DFT testing should be abandoned only when prospective evidence demonstrates that defibrillator implantation without testing is as safe and has the same mortality benefits as implantation with testing. The most attractive aspect of eliminating DFT efficacy testing is that more patients may have the opportunity to be treated with this life-saving therapy. Perhaps there are alternative strategies to improve accessibility to defibrillator therapy without possibly eroding its effectiveness. In the end, will lives be saved or lost if we discontinue DFT efficacy testing and lower the barriers to implantable defibrillator therapy? (J Am Coll Cardiol 2004;44:88–91) © 2004 by the American College of Cardiology Foundation

**Is Defibrillation Testing Required for Defibrillator Implantation?**

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The assessment of defibrillation (DFT) efficacy has long been the standard of care during defibrillator implantation. To ensure an acceptable DFT safety margin, early defibrillator systems frequently required that the shock polarity and the location, type, or number of electrodes had to be altered. Advances in defibrillator and lead technology have resulted in lower and more consistent DFT thresholds in the range of 10 J, with an infrequent requirement to modify the DFT system. Yet, one can make an argument for and against continuation of DFT testing at the time of defibrillator implantation. The goal of this paper is to address both the data that do support and the data that do not support continuation of DFT testing at the time of device implantation. Scientifically, DFT testing should be abandoned only when prospective evidence demonstrates that defibrillator implantation without testing is as safe and has the same mortality benefits as implantation with testing. The most attractive aspect of eliminating DFT efficacy testing is that more patients may have the opportunity to be treated with this life-saving therapy. Perhaps there are alternative strategies to improve accessibility to defibrillator therapy without possibly eroding its effectiveness. In the end, will lives be saved or lost if we discontinue DFT efficacy testing and lower the barriers to implantable defibrillator therapy? (J Am Coll Cardiol 2004;44:88–91) © 2004 by the American College of Cardiology Foundation

**HISTORY OF DFT TESTING**

Defibrillation efficacy traditionally has been performed with successive DFT attempts using approximately 20 J in a device that delivered 25 to 30 J (1,2). A safety margin of 10 J was required for the implantation of the earliest defibrillators. The inventors and early researchers of the implantable defibrillator selected 10 J for the safety margin based on the maximum available energy of 25 J and on a few animal and human studies that suggested early DFT systems would generally be effective with <15 J (Mower MM, personal communication, 2003) (5,6). The initial implants required successful DFT with the maximum device output of 25 J, which therefore assumed a 10-J safety margin (M. M. Mower, personal communication, 2003). The 10-J safety margin was subsequently confirmed in patients with an implantable defibrillator (7) and validated as defibrillators were demonstrated to reduce mortality (8–11) and because patients with inadequate DFT safety margins were thought to have a higher mortality rate (12,13). As technology improved, DFT thresholds were substantially reduced. Most studies of new DFT systems required documentation of a 10-J safety margin, with only the rare study requiring testing beyond documentation of an adequate safety margin (14). Today, our general impression is that only a small percentage of physicians do more than confirm a 10-J safety margin at implant.

**THE DFT SYSTEMS**

Current implantable defibrillator systems provide an average DFT threshold of 8 to 10 J. These systems use one or two intracavitary DFT electrodes while the defibrillator pulse generator functions as a subcutaneous electrode (active can). Only in unusual cases does the DFT system need to be modified to achieve adequate DFT efficacy, for example, with the addition of another subcutaneous DFT electrode, reversal of shock polarity, and/or with the use of a pulse generator with greater delivered energy (15). The frequency
with which these approaches are used to achieve adequate DFT efficacy is probably around 5%.

TECHNIQUES FOR DETERMINING DFT EFFICACY

Defibrillation efficacy may be assessed in various ways. The most time-honored approach confirms a 10-J safety margin. Considerably less frequently, a step-down DFT protocol that uses decrementing energy levels for subsequent DFT attempts until DFT fails or an abbreviated step-down protocol that is terminated after two or three DFT attempts have been used. Determining the upper limit of vulnerability as an alternative to direct DFT testing has been proposed (16,17). The upper limit of vulnerability demonstrates DFT efficacy by estimating the DFT threshold from the lowest energy level that will not induce ventricular fibrillation (VF) with a “shock on T” (16). Each of the aforementioned techniques that assess DFT efficacy will identify the infrequent patient in whom modification of the DFT system is required to achieve an adequate DFT safety margin.

Documentation of DFT efficacy provides an additional safety evaluation of the lead position and the system’s ability to sense, detect, and defibrillate VF. The induction of VF at the time of defibrillator implantation poses little risk. Although precise data are not available, the intraoperative mortality rate is probably in the range of 0.1%.

DFT TESTING OR NOT

What is the rationale for abandoning DFT testing? First, the probability of a high DFT threshold and a failed implant is quite small. Second, the majority of ventricular arrhythmias treated by an implantable defibrillator are ventricular tachycardia. The cardioversion energy for ventricular tachycardia is probably significantly less than the DFT energy required for VF (18). In addition, the probabilistic nature of DFT suggests that shocks less than the determined threshold, when repeated several times, have some probability of success even in the much less likely event of VF (4,19). Thus, even the infrequent patient with a high DFT threshold who does receive a DFT system that is incapable of defibrillating VF at the time of device implantation may not succumb to an episode of VF. Indeed, defibrillator testing is withheld in some patients with profound left ventricular dysfunction, a group where DFT testing is arguably the most necessary. Next, the determination of DFT efficacy requires additional anesthetics, and the shocks themselves may cause hemodynamic compromise (20). Finally, DFT testing may be a barrier to implantable defibrillator therapy in regions with few or no electrophysiologists. It may be argued that other physicians, such as those currently implanting pacemakers, would more readily implant defibrillators if not for the requirement of DFT testing.

What are the arguments for continued DFT testing? First, all the data supporting increased survival with implantable defibrillators were attained with some assessment of DFT efficacy at implant (8–11). Arguably, the requirement for testing was essential in demonstrating device efficacy. Second, there is no doubt that some patients receive a more effective DFT system because DFT testing is performed. For instance, patients with a frank inability to defibrillate are identified, and corrective measures such as the use of a higher energy device, addition of electrodes, or reversal of shock polarity can be used (15). Ensuring that the system provides effective DFT and appropriate sensing of VF is intuitively very compelling, although not proven to improve survival. There are no data that specifically demonstrate increased mortality among patients with high DFT thresholds. Epstein et al. (12) observed that 42% of patients with an elevated DFT threshold who were treated with an implantable defibrillator died suddenly. However, the two-year mortality rate was 20%. An annual mortality rate in an implantable defibrillator population from the early 1990s of approximately 10% may not be considered excessive, and it may be possible that patients who cannot be defibrillated easily have intrinsically higher mortality rates independent of defibrillator usage. Third, an accurate estimate of the DFT threshold should facilitate programming of shocks to a multiple of the DFT threshold, allowing lower energy shocks (3,4). This may result in less syncope and near-syncope and improve post-shock hemodynamics (20). Finally, the medico-legal implications of an unexplained death or documented failure to defibrillate are uncertain. Arguably, failure by the physician to verify DFT efficacy may be a compelling argument that the implant procedure fell below the standard of care, a position that would be supported by many electrophysiologists.

What evidence would be required to establish equivalence or superiority of a strategy of no testing versus current DFT testing? Data from a randomized trial would probably be required. Patients undergoing defibrillator implantation would be randomized to DFT testing or no DFT testing. It seems obvious that mortality should be the primary end point, or at least a major component of the primary end point, if a composite primary end point was developed. Factors such as cost and procedural complications can be readily assessed but are unlikely to be acceptable as sole primary end points. To estimate the number of patients required for a randomized mortality study, the first assumption is that 5% of patients will not be successfully defibrillated with the maximum output of a standard device that uses the usual lead position and shock polarity. Second, <75% of this 5% of patients will receive appropriate therapies after implant (i.e., 3.75% of the total number of
patients who receive an implantable defibrillator). If 25% of appropriate shocks are for VF and represent excess mortality, then the rate of excess mortality as a result of not assessing DFT efficacy would be 25% of 3.75% of patients, or about 1% of initial implants. If the usual death rate for implantable defibrillator patients is 10% per year, a reasonable estimate, the study population would need to differentiate between mortality rates of 10% and 11%. Using these assumptions, which probably overestimate the frequency of high DFT thresholds and the frequency of VF, approximately 29,000 patients would need to be randomized to achieve a statistical power of 80%. Although different assumptions can be made and a creative study design can reduce the sample size, it is clear that such a study would involve a large number of patients.

A looming question is who will do the implantation procedure with the study? If the goal is to demonstrate that experienced defibrillator implanters can safely and effectively implant a defibrillator without DFT efficacy testing, then these physicians should implant the devices and position the leads. If the goal is to demonstrate that experienced pacemaker implanting physicians without defibrillator implantation experience can safely and appropriately implant defibrillators, then these physicians should participate in the trial and at least perform the implants in the patients randomized to implantation without DFT efficacy testing. This would allow the study to test the hypothesis that physicians with pacemaker implantation experience, but not defibrillator implantation experience, can implant defibrillators with an appropriate mortality rate.

CONCLUSIONS

The assessment of DFT efficacy at the time of implant has long been the standard of care. It is intuitively reasonable to ensure that the system has an acceptable DFT safety margin at the time of implant. One might ask simply whether the downsides of ensuring device sensing and DFT capability are sufficient to discontinue this practice. DFT efficacy testing may be minimally assessed with as few as one or two inductions of VF with only rare complications. The expertise involved in performing this task should not be outside the capabilities for an implanting team involved in the care of patients requiring these devices. With the evolution of devices that defibrillate more efficiently and predictably, it is fair to ask whether initial DFT testing is still necessary. Scientifically, this question should be answered only with prospective evidence that demonstrates at least equivalent patient safety, equivalent mortality reduction, and cost savings. Proponents of eliminating DFT testing need to demonstrate the safety and benefits of such a strategy with objective evidence before this element of defibrillator implantation is abandoned. The most attractive aspect of eliminating DFT efficacy testing is that more patients may have the opportunity to be treated with this life-saving therapy. Perhaps there are alternate strategies to improve accessibility to defibrillator therapy without possibly eroding its effectiveness. In the end, will lives be saved or lost if we discontinue DFT efficacy testing and lower the barriers to implantable defibrillator therapy?

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