Is Defibrillation Testing Necessary?

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KEYWORDS

• Defibrillation testing • Implantable cardioverter defibrillator • Sudden cardiac death

KEY POINTS

- Whether or not defibrillation testing is necessary at the time of implantable cardioverter defibrillator (ICD) implantation is one of the most frequently debated topics in electrophysiology.
- With advancements in ICD technology, an inadequate safety margin for defibrillation at the time of implantation now occurs infrequently.
- Testing of ICDs seems safe in most patients, and modifications of the system are often easily performed at the time of the implantation procedure.
- Clinical trials demonstrating the efficacy of ICD therapy for the primary and secondary prevention of sudden cardiac death (SCD) all used some form of defibrillation testing at the time of implantation.
- The authors recommend that defibrillation testing be considered a standard part of initial ICD implantation in the absence of contraindications.

INTRODUCTION

ICDs are effective for the primary and secondary prevention of SCD in high-risk populations.[1–7] At the time of implantation, ventricular fibrillation (VF) is typically induced to demonstrate effective arrhythmia termination. Instructions for use of ICDs approved by the Food and Drug Administration (FDA) in the United States include recommendations for defibrillation testing at the time of implantation. Defibrillation testing, in the absence of contraindications, still seems to be the standard of care at most centers in the United States, with testing performed in 71% of patients, according to National Cardiovascular Data Registry (NCDR) data.[8]

With advanced technology, the practice of performing defibrillation threshold (DFT) testing has been questioned due to potential risks of testing as well as doubts about its ability to improve clinical shock efficacy or survival. Current technology includes biphasic waveform shocks, pectoral active can systems, and higher-output devices that result in higher defibrillation efficacy.[9–16]

In the absence of results of prospective randomized data, the topic of defibrillation testing continues to spark much debate. This article describes reasons to perform testing as well as reasons to avoid defibrillation testing at the time of initial ICD implantation.

DEFINITION OF DEFIBRILLATION THRESHOLD

The term, *DFT*, refers to the minimum shock strength that defibrillates.[17] This has been used as a patient-specific measure of defibrillation efficacy, and a threshold below a specific value has been used as a criterion for successful device

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implantation.[18,19] A detailed review of ICD implantation testing has been published.[20] Given the probabilistic nature of defibrillation, clinical measurement of DFT has only fair reproducibility and represents an estimate of a point on a patient's defibrillation probability-of-success curve.

A variety of methods have been used to determine DFT, including step-down, step-up, and binary search approaches. These methods often involved multiple VF inductions, however. With advancements in defibrillator technology, most centers now limit defibrillation testing and use safety margin testing. With this method, an adequate safety margin for defibrillation may be defined as successful shock therapy at 10 J below the maximum output of the device. Many implanting physicians may elect to induce VF only once or twice and, for example, accept successful defibrillation at 25 J with an ICD capable of delivering 35 J. In this article, the term DFT is used interchangeably with defibrillation safety margin testing, despite the differences in meaning.

REASONS TO SUPPORT DEFIBRILLATION TESTING

Assessment of System Integrity and Reliable Sensing

DFT testing can confirm the electrical integrity of connections between the leads and pulse generator, reliable sensing, and appropriate detection and redetection of VF.[21] Opponents of DFT testing, however, note that connection integrity can usually be evaluated without defibrillation testing by assessing low-voltage pulses introduced during sinus rhythm, pacing thresholds and impedances, and recorded electrograms. R wave amplitude in the native rhythm correlates well with reliable sensing during VF.[22,23] With modern ICDs, undersensing of spontaneous VF is rare if the native rhythm R wave is adequate ($\geq$5–7 mV). Some inner insulation failures may be detected, however, only by postshock oversensing, and some lead failures may pass with normal shock impedance values at low-voltage but fail with high-voltage testing. Postshock redetection issues are more important with older integrated bipolar leads with short tip-to-coil spacing.[24]

Discovery of High DFTs Needing System Modification

The primary goal of DFT testing is to increase the likelihood that the ICD will effectively terminate spontaneous ventricular tachycardia (VT) or VF and to identify patients who require system revision if implant testing demonstrates a high DFT.[21] The yield by defibrillation testing of discovering high DFTs needing system modification ranges from 2.2% to 12% of implants (**Table 1**). One study examining high DFTs at implantation suggests that an inadequate safety margin is more likely to occur with a single-coil compared with a dual-coil transvenous system (4.6% vs 2.6%, $P<.0001$).[25]

Although the sickest patients are likely at highest risk for hemodynamic complications of DFT testing, these patients are also at highest risk for DFT failure and thus have the highest yield of testing. In 138 patients undergoing cardiac resynchronization therapy (CRT) defibrillator implantation, 12% had a less than 10-J safety margin.[26] A less than 10-J safety margin requiring system revision was seen in 28% of patients with New York Heart Association (NYHA) class IV compared with only 3% to 4% of patients with NYHA class I-III heart failure ($P<.0001$).[27]

If a high DFT is identified, system revisions can be performed and an adequate DFT can almost always be obtained at the time of implantation. After system modification, 67% to 100% of patients who did not initially meet implant criteria achieved an adequate safety margin for defibrillation.[24,26–34] System revisions may include moving the right ventricular coil, capping off the superior vena cava (SVC) coil (in a dual-coil system), changing to a higher-output device, reversing polarity, optimizing the biphasic waveform, or adding an extra lead (such as a subcutaneous, transvenous SVC, or azygous lead). In addition, discontinuing drugs that may increase the DFT, such as amiodarone, may help. The REPLACE study demonstrated major complications occurring in 15.3% of patients undergoing ICD replacement with planned lead revisions[35]; therefore, such revisions might be best performed at the time of initial implantation.

Poor Predictive Value of Clinical Factors in Identifying High DFTs

Unfortunately, there is a poor predictive value of clinical factors in identifying patients who are likely to have ineffective defibrillation at implantation testing.[21] Factors that may influence defibrillation success include (1) patient characteristics (2) ICD system features (leads, shock waveform, and defibrillation pathway) (3) drug effects, in particular, chronic amiodarone, which has increased DFT in several studies[28,36–44]; and (4) implant-related factors or complications (such as pneumothorax, which may increase the DFT).

Common patient-specific factors that are associated with higher DFTs identified in multiple studies include lower left ventricular ejection fraction (LVEF),[28,32,36,45–48] larger left ventricular (LV) size[37,49] or mass,[50–53] worse clinical heart