Avoidance of defibrillation threshold testing at the time of internal defibrillator insertion: is it safe?

İnternal defibrilatör takılması sırasında defibrilasyon eşik testinden kaçınılması: Güvenli mi?

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This article consists of a subject review supported by a short-term pilot study which was conducted prospectively to shed light into the controversial question regarding the necessity of having the defibrillation threshold measured at the time of the implantable cardioverter defibrillator implantation. Answering this question will have an important impact on reducing the well-documented morbidity and mortality, making the operation simpler and cost-effective.

Keywords: Cardiac arrhythmia; internal defibrillator; ventricular fibrillation.

Implantable cardioverter-defibrillators (ICDs) have consistently been shown to reduce the death rate among people at risk for ventricular arrhythmias (primary prevention)

In the past, DFT testing has guarded against low DFTs since early devices often required altering their shock polarity and the location, number, or type of electrodes. However, advances in ICD technology and lead design have led studies to report excellent device performance without the need for threshold testing. 

In the early days of ICD development, the devices were prone to having overly high defibrillation thresholds, and DFT setting was an understood requirement to ensure reliable performance.

The aforementioned risks of the prophylactic procedure coupled with the increasing sophistication of ICD devices have sparked a debate in the literature regarding the necessity for DFT testing.

There has been substantial controversy in recent literature concerning the risks versus the benefits of the DFT procedure. In the early days of ICD development, the devices were prone to having overly high defibrillation thresholds, and DFT setting was an understood requirement to ensure reliable performance.

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Studies estimated that approximately 15% of patients with monophasic shocks required system modification for new high-voltage coils or epicardial patches.[3] However, with the advent of modern ICDs, defibrillation efficacy has risen due to high maximum output to DFT ratios, rapid charge times, and biphasic waveforms.[6,15,16]

Despite the rapid pace of ICD technology development, the risks of the DFT procedure have only begun to be studied in the past decade. Alarmingly, several recent studies have shown that serious complications are associated with this prophylactic procedure.[14,11] One study examined DFT testing-related outcomes associated with a total of 19,067 ICD implants performed in Canada between 2000 and 2006. The study found three deaths, five strokes, and 27 episodes of prolonged resuscitation, all attributable to threshold testing.[4] This may underrepresent the true risk of the procedure since the sickest patients were not tested.[4] Ironically, the sickest patients are the ones most at risk for defibrillation failure. In one series of peri-implant DFT testing, 12 patients required on average five to 17 shocks to defibrillate, and troponin elevation indicative of myocardial damage was reported in five patients postoperatively.[10] Also, death due to cerebrovascular stroke one day after DFT testing was reported in two patients out of 440 in a study of ICD-related complications.[12]

The need for general anesthesia, even for a short period, is also not without risk. This occurs particularly in patients with poor ventricular function and those with underlying lung disease or sleep apnea.[7]

Given the potentially lethal complications of the procedure, no matter how rarely they occur, and studies supporting the efficacy of modern ICDs, one might wonder whether DFT testing may actually precipitate more harm than it prevents. Indeed, several recent studies have supported the conclusions reached by our study.[8,9,13,17] Namely, a cohort study of 835 consecutive ICD patients revealed that successful ventricular arrhythmia normalization by the ICD did not significantly differ between patients undergoing normal DFT testing, limited defibrillation safety margin testing, and no testing.[8] In addition, threshold testing was not found to relate to long-term clinical outcomes in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Specifically, DFT testing data from 717 patients in the study suggests that threshold testing was irrelevant to successful ICD treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF).[9] Similarly, a European multi-center study enrolling 291 patients reported no significant differences between DFT-tested and untested patients in all-cause, cardiovascular, and sudden cardiac death mortality.[17] Furthermore, a formal decision analysis found that routine defibrillation testing may confer little significant survival advantage, with nearly identical five-year survival rates associated with DFT testing versus no testing.[14]

A pilot study was performed at our center to add some more data to this review in an attempt to verify whether DFT testing should be a necessary part of routine ICD implantation.

Sixty consecutive patients who required internal defibrillator insertion were enrolled at the Maritime Heart Center, Halifax, Nova Scotia, Canada. Defibrillator lead models included Medtronic Passive Fixation (6944), Medtronic Active Fixation (6947), St. Jude Passive Fixation (7170), and St. Jude active fixation (7120). Indications for ICD implantation included: ischemia-related ventricular arrhythmia (n=39), low ejection fraction prophylactic measures (n=18), and familial cardiomyopathy (n=3).

All patients underwent fluoroscopy-guided, transvenous single-lead defibrillator insertions. The criteria of accepted lead position were: (i) The tip of the lead is at the apex of the right ventricle, (ii) R wave sensing >8 mm, and (iii) pacing threshold <0.6 mV.

Devices were implanted by full-time cardiovascular surgeons. All patients signed an informed consent form before undergoing the procedure. Devices were tested in all patients. During DFT testing, VF was induced, and an adequate safety margin was defined as 10J below the maximum output of the ICD pulse generator.[7] All patients underwent arterial hemodynamic monitoring and general anesthesia for the duration of the testing.

No cases revealed poor defibrillator pacing or poor defibrillator thresholds. Neither repositioning of the leads nor ICD system modification was necessary.

This study, in spite the small number of patients, found that in a consecutive population of patients undergoing ICD implantation, DFT testing was unnecessary to ensure proper pacing and defibrillation. In all patients, the leads were in a good position as determined by fluoroscopic imaging, and the ICD had adequate pacing thresholds.

If DFT testing truly has limited efficacy in improving patient outcome, eliminating the testing step will free scarce healthcare resources that could be applied elsewhere. Indeed, a US trial found that the elimination of pre-hospital discharge testing resulted in a savings of $1,800 United States dollar per patient after six months, with no difference between groups in terms of ICD complication rates or unanticipated
hospital admissions.\textsuperscript{13} In a similar Canadian study, ICD insertion was found to be $844 Canadian dollars more expensive when DFT testing was performed versus no testing.\textsuperscript{18}

In addition to reliable modern ICD performance, the predictive value of DFT testing has also been criticized on several theoretical grounds. For instance, it has been argued that the induction of VF more closely resembles electrocution rather than clinical VF, which typically occurs due to myocardial ischemia.\textsuperscript{15,19} Furthermore, DFT testing is performed in deeply sedated patients, which is in contrast to spontaneous ventricular arrhythmias which are often triggered by electrolyte imbalances, worsening heart failure, high sympathetic tone, or ischemia.\textsuperscript{5} Thus, reasonable doubt can be cast on the validity of induced VF as a model for clinical arrhythmias.

Additionally, some studies suggest a significant proportion of implanted ICDs will never treat spontaneous VF.\textsuperscript{15,20} Many ICDs implanted for prophylactic purposes will predominantly treat ventricular tachycardia, which has a substantially lower cardioversion energy than the DFT required for VF.\textsuperscript{21} One study suggests that 40% of ICDs implanted for primary prevention of sudden cardiac death will not detect any sustained ventricular arrhythmias during their six-year battery life.\textsuperscript{15} As well, the probabilistic nature of defibrillation ensures that multiple successive shocks at less than the DFT have the potential to successfully terminate an episode of VF.\textsuperscript{22,23} It follows that even an unlikely patient with a high DFT detected during testing will not necessarily succumb to an episode of VF. Therefore, DFT testing may not, in most cases, confer utility in improving patient outcome.

The specialized nature of the DFT testing procedure may restrict therapy in regions where electrophysiologists are scarce. Perhaps if the testing step was not performed, a greater range of physicians would be able to implant ICD, including those currently implanting pacemakers.\textsuperscript{20}

From the above review, it can be concluded that the higher effectiveness of modern ICD devices coupled with the risks and costs associated with DFT testing clearly point to a revision in established practices. The elimination of DFT testing in current practice may be warranted if the lead is in a good position and has good pacing thresholds.

Finally, to support the above conclusion further, additional studies should aim to examine the relationship between DFT testing, mortality, and ICD performance as well as the long term prognosis.

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REFERENCES


