Clinical trials have documented the efficacy of implantable cardioverter-defibrillators (ICDs) for the primary and secondary prevention of sudden cardiac death. These trials have typically involved induction of ventricular fibrillation (VF) at the time of implantation to demonstrate effective arrhythmia termination. In fact, defibrillation testing (DT) was also performed at the time of implantation of ICDs in those patients whose data were used to seek approval of the US Federal Drug Administration for general use, and instructions for usage include labeling with DT. This is also the case for the recently approved subcutaneous ICD.

Response by Healey et al on p 346

Higher defibrillation thresholds (DFTs) were seen with older ICDs implanted using an epicardial approach, abdominal pulse generators, or monophasic waveforms. In contrast, modern technology now includes devices with biphasic waveform shocks and pectoral active can systems that result in more effective defibrillation. In addition, devices now have higher output, routinely delivering ≥35 J and also increasing the chance of effective defibrillation. Therefore, it has been suggested that these new defibrillation technologies may eliminate the need for DT.

Although the risk of failing defibrillation is now much lower, patients receiving ICDs today may have more comorbidities, more severe heart failure, and a higher risk of failing shocks. If a high defibrillation energy requirement is identified at the time of initial implantation, system revision is typically performed with the intent of increasing the likelihood that the ICD will effectively terminate ventricular tachycardia (VT) or VF when it occurs spontaneously. So, we need to ask ourselves, why would a physician implant this potentially life-saving device without testing?

Definition of DFT

The term DFT refers to the minimum shock strength that defibrillates. Historically, a threshold below a specific value has been used as an acceptable criterion for device implantation. There is a probabilistic nature of defibrillation. The clinical measurement of DFT has only fair reproducibility and represents an estimate of a point on the patient’s defibrillation probability-of-success curve. A variety of methods have been used to determine DFT. For example, a step-down approach may start with a first shock energy of 20 J. If this is successful, the first shock energy may be decreased to 15, 10, or 5 J in successive trials, until the first shock fails. If the 20 J shock fails, the first shock energy would be increased to 25 J with repeat testing.

With advancements in defibrillator technology, most centers now limit DT, and more limited implant criteria have been developed. A frequently used criterion for device implantation is safety margin testing, and an adequate safety margin for defibrillation may be defined as successful shock therapy at 10 J below the maximum output of the device. With modern devices, many implanting physicians may elect to induce VF only once or twice and may accept successful

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defibrillation at 20 or 25 J with an implanted device capable of delivering 35 J.

**Reasons to Perform DT**

With improved technology available in current generation devices and the expansion of ICD implantation to non-eletrophysiologists during the past decade, the need for DT has come under question. The potential benefits of DT are discussed in detail in this section.

**System Integrity and Reliable Sensing**

DT assesses the electric integrity of the connections between the leads and pulse generator and confirms reliable sensing, detection, and redetection in VF. Opponents of DT note that system integrity of connections can usually be evaluated by using low voltage pulses introduced during sinus rhythm, testing of pacing thresholds and impedances, and assessing recorded electrograms. R wave amplitude in the native rhythm correlates strongly with reliable sensing during VF. If the R wave during the underlying rhythm is ≥5 to 7 mV, sensing during VF is almost always adequate to ensure rapid detection. However, some inner insulation failures may only be detected after shock because some ICD leads may pass with normal shock impedance values at low voltage but fail with high voltage. Sauer et al reported that failure to sense is rare with intrinsic sensed R waves of >5 to 7 mV, but postshock redetection issues were more important with older integrated bipolar leads with short tip-to-coil spacing.

**Discovery of High DFTs Needing System Modification, Which Can Often be Easily Remedied at the Time of Implantation**

Review of the literature demonstrates a yield of discovering high DFTs needing system modification in 2.2% to 12% of implants (Table 1). For example, I study reported that 6.2% of ICDs required modification at implant to achieve a 10-J safety margin. If a high output device had been used upfront, only 3% of patients would have required system modification.

Unfortunately, although the sickest patients may be at highest risk for hemodynamic complications of DT, these patients represent the group at highest risk for DT failure. Cardiac resynchronization therapy (CRT) defibrillator patients are among those with the highest yield of DT. Mainigi et al reported that in 138 patients undergoing CRT defibrillator implantation, 12% had high DFTs, defined as a <10-J safety margin. Another study demonstrated that a high defibrillation energy requirement (<10-J safety margin) requiring system revision was seen in 28% of patients with New York Heart Association class IV compared with only 3% to 4% of patients with New York Heart Association class I to III heart failure (P<0.0001).

Once a high DFT is identified at the time of implantation, system revisions can be performed, and an adequate DFT can almost always be obtained. Studies report that 67% to 100% of patients who failed initial implant criteria achieved adequate safety margins for defibrillation following system modification.

System revisions may include moving the right ventricular coil, inactivating or activating the superior vena cava coil, adding an extra superior vena cava,azygous or subcutaneous

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>n</th>
<th>Implant Criteria</th>
<th>No. of Patients Not Meeting Implant Criteria</th>
<th>High DFT (% Implants)</th>
<th>Implant Criteria Met After Modifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russo et al20</td>
<td>2005</td>
<td>1139</td>
<td>10-J safety margin</td>
<td>71</td>
<td>6.2%</td>
<td>60 (85%)</td>
</tr>
<tr>
<td>Leong-Sit et al29</td>
<td>2006</td>
<td>168</td>
<td>10-J safety margin</td>
<td>16</td>
<td>9.5%</td>
<td>16 (100%)</td>
</tr>
<tr>
<td>Mainigi et al27</td>
<td>2006</td>
<td>121</td>
<td>10-J safety margin</td>
<td>14</td>
<td>12.0%</td>
<td>11 (79%)</td>
</tr>
<tr>
<td>Blatt et al29</td>
<td>2008</td>
<td>717</td>
<td>30 J (max 2 inductions)</td>
<td>0</td>
<td>0% (2.2% &lt;10-J safety margin)</td>
<td>NA</td>
</tr>
<tr>
<td>Day et al19</td>
<td>2008</td>
<td>1530</td>
<td>10-J safety margin</td>
<td>59</td>
<td>3.9%</td>
<td>59 (100%)</td>
</tr>
<tr>
<td>Havel et al26</td>
<td>2010</td>
<td>335*</td>
<td>10-J safety margin</td>
<td>155</td>
<td>4.6%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Healey et al17</td>
<td>2010</td>
<td>1268</td>
<td>10-J safety margin</td>
<td>2579</td>
<td>2.6%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Sauer et al18</td>
<td>2011</td>
<td>853</td>
<td>10-J safety margin</td>
<td>44</td>
<td>3.5%</td>
<td>Unknown</td>
</tr>
<tr>
<td>Healey et al14</td>
<td>2012</td>
<td>71</td>
<td>≤25 J</td>
<td>3</td>
<td>4.2%</td>
<td>3 (100%)</td>
</tr>
<tr>
<td>Lin et al24</td>
<td>2013</td>
<td>240</td>
<td>10-J safety margin</td>
<td>48</td>
<td>2.2%</td>
<td>32 (66.7%)</td>
</tr>
<tr>
<td>Keyser et al22</td>
<td>2013</td>
<td>716</td>
<td>≤21 J</td>
<td>28</td>
<td>3.9%</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>Vischer et al23</td>
<td>2013</td>
<td>309</td>
<td>10-J safety margin</td>
<td>7</td>
<td>2.3%</td>
<td>7 (100%)</td>
</tr>
</tbody>
</table>

DFT indicates defibrillation threshold; FU, follow-up; and NA, not applicable.

*Single coil.
†Dual coil.
electrode, changing to a higher output device, reversing polarity, or optimizing the biphasic waveform tilt. In view of data from the REPLACE study suggesting that major complication rates may be significant (15.3%) after ICD replacement with lead revision, such revisions might be best performed at the time of initial implantation.30

**Poor Predictive Value of Clinical Factors in Identifying Patients in Whom Defibrillation Is Likely to Fail at the Time of Implantation**

If we could predict which patients will have a high DFT or identify patients who would be most likely to have unsuccessful therapy at follow-up, we might be able to forego DT. Common patient-specific factors that are associated with higher DFTs include lower left ventricular ejection fraction,20,24,31 greater left ventricular size2,33 or mass,34,35 worse clinical heart failure,20,31–33,36 QRS duration ≥200 ms in CRT defibrillator implants,27 nonischemic cardiomyopathy,20 male sex,32,33,37 greater body surface area,32,33 right-sided pectoral implantation,18,39 hypertrophic cardiomyopathy,40 and certain drugs, such as amiodarone.20,31,32,41–44 However, the strengths of these associations are not consistent and vary between studies, with some studies demonstrating no good clinical correlates of high DFTs.41,45 Because there is no way to reliably predict which patients will have a high DFT at implant, testing is still recommended.

**Increased Assurance That Successful Defibrillation of VF Should Occur After the Patient Is Discharged**

Does implant DT predict effective defibrillation clinically? Data are limited. ICDs deliver ≤5 to 6 shocks for VT/VF so that subsequent shocks may be successful even if the first shock fails. However, there is still some benefit for first shock success because shocks are painful and prolonged VT/VF could lead to reduced organ perfusion or loss of consciousness.

We do know that implant testing is not a perfect predictor of clinical shock success. The first shock success rate for clinical VT/VF episodes is lower than success rates reported for induced VF. First shock success for spontaneous VT/VF in the VF zone for patients who passed implant criteria is only 83% to 92%,29,46–48 not 100% (Table 2). However, we do not know what these success rates would be if DT were not performed, and perhaps first shock success rates for VF might be worse.

Table 2. First Shock Success Rate for Spontaneous VT/VF in VF Zone in Patients Who Passed Implant Criteria

<table>
<thead>
<tr>
<th>Study</th>
<th>Implant Criterion</th>
<th>Programmed Output</th>
<th>% First Shock Success</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gold et al46</td>
<td>≤21 J</td>
<td>Max (31 J)</td>
<td>92</td>
</tr>
<tr>
<td>Sweeney et al47</td>
<td>10-J safety margin</td>
<td>DFT+10 J</td>
<td>87</td>
</tr>
<tr>
<td>Pires and Johnson48</td>
<td>10-J safety margin</td>
<td>DFT+10 J</td>
<td>91</td>
</tr>
<tr>
<td>Blatt et al29</td>
<td>none (≤30 J)</td>
<td>20 or 30 J</td>
<td>83</td>
</tr>
</tbody>
</table>

DFT indicates defibrillation threshold; VF, ventricular fibrillation; and VT, ventricular tachycardia.

A post hoc analysis of the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) is frequently used as justification for not performing DT at implantation. Baseline DFT data were available on 717 of 811 patients with the ICD in SCD-HeFT, and all had a DFT ≤30 J.29 There was no survival difference between patients with a DFT ≤10 J (n=547) compared with those with a DFT >10 J (n=170; P=0.41). First shock efficacy was 83.0%, and this did not differ in the high versus low DFT groups. However, the investigators chose an arbitrary cutoff of >10 J to define a high DFT. In addition, most patients with a high DFT still had a ≥10-J safety margin for defibrillation. In fact, only 16 patients had a <10-J safety margin in this study (Figure). It should be noted that patients enrolled in clinical trials may not always be representative of real-life or sicker patients, and many of these patients had devices implanted as elective same-day procedures. CRT patients were not included in SCD-HeFT. Although this study provides some interesting data, it may not be applicable to many patients with ICDs in clinical practice and, thus, results of this post hoc analysis should not be used as sole justification to omit testing.

**Discovery of Low DFTs That May Allow Programming Lower First Shock Energies**

Potential benefits of identifying lower DFTs might include lower programmed first shock energies that can result in faster charge times or a reduction in postshock ventricular dysfunction, although there are only limited clinical data to support such benefits. In a study of sudden death mechanisms in
patients with ICDs, postshock electromechanical dissociation occurred in 29% of sudden deaths. The authors suggested that many of these deaths resulted from ICD shocks that were too frequent, closely spaced, or too large. Animal models also have suggested myocardial dysfunction and damage, as well as death because of electromechanical dissociation, with high shock magnitudes, although these magnitudes were generally higher than those used clinically.

Assurance of a Safety Margin for Testing After Addition of Antiarrhythmic Drugs, Such as Amiodarone, That May Raise DFTs

In the years after implantation, it is possible that antiarrhythmic drugs may be added or left ventricular function may worsen, and these changes might increase DFTs. If the device was effective only at maximum output at initial implantation, without any safety margin for defibrillation, ineffective defibrillation may be more likely to occur in these patients compared with those who had a 10-J safety margin. Demonstration of an adequate safety margin at implantation may help to offset these changes during follow-up.

Assurance That Any Given Device Is Not a Lemon

Once detection of VT/VF occurs, the incidence of device failure to deliver programmed therapy is low. A search of the Manufacturer and User Facility Device Experience database from January 1, 2000, to June 28, 2013, of non-CRT ICDs revealed 5 devices that failed to deliver energy and 1 device with failure to power up and difficulty programming that appeared to be detected at the initial implant procedure. Therefore, this seems to be an extremely rare, although potentially serious problem.

Assessment of Certain Lead Failure Problems That May Only be Identified With Testing of the High Voltage System to Exclude a Short in the System

Although uncommon, shock impedances of the ICD lead measured with subthreshold test pulses may yield normal results, whereas shock impedances may be abnormal (>200 Ω) after DFT testing, identifying a concealed lead fracture, illustrated in a case report. There have also been case reports of electric abnormalities detected by DT but not by high voltage lead integrity testing in St Jude Medical Riata leads. Although DFT testing in patients with leads on advisory is not applicable to the general population of patients undergoing ICD implantation, this represents a special situation where DFT testing at implant would be informative.

Assessment for Device–Device Interaction in Patients With an Additional Cardiac Implantable Electric Device

Contemporary transvenous ICDs now all have the availability of bradycardia back-up pacing. However, early ICDs lacked this capability, requiring a separately implanted pacemaker for concomitant bradyarrhythmias. Permanent pacemaker–ICD interactions include oversensing or undersensing. Although oversensing of pacemaker output may result in inappropriate device therapy, the most serious and potentially life-threatening problem relates to ICD undersensing. The separately implanted pacemaker may not sense VF and may deliver pacing output during VF. These pacing stimuli are detected by the ICD, whereas the smaller VF signals remain undetected, and no shock is delivered.

Testing at the time of initial implantation detects these problems. The dedicated bipolar pacemaker can be programmed to minimize sensitivity and maximize output with induction of VF to exclude significant device interactions. This 2 device combination may be seen more frequently in upcoming years with approval of the totally subcutaneous ICD system (Cameron Health subcutaneous ICD) because the current model does not have bradycardia backup pacing (with the exception of postshock pacing).

Evidence-Based Medicine, Market Approval Studies, and Standard of Care

Clinical trials demonstrating a mortality benefit of ICD therapy have typically included some form of DT at the time of implantation. DT has been the standard of care, and the US Federal Drug Administration instructions for usage in device company manuals have included labeling with DT. In the absence of contraindications to testing, there are medical–legal implications of implanting devices without DT in the absence of justification.

The major primary and secondary prevention ICD trials typically incorporated DFT testing. The Multicenter Automatic Defibrillator Implantation Trial I (MADIT I) and MADIT II made every effort made to achieve 10-J safety margin. Although SCD-HeFT specified a maximum of 2 DFT inductions, few patients had a high DFT. The fact that all patients received effective defibrillation with ≤30 J suggests that these patients were less sick, without inclusion of CRT patients. In MADIT-CRT, devices were implanted according to the physician and center standard operating procedure, and testing details were not specified. In the Multicenter Unsustained Tachycardia Trial (MUSTT), intraoperative testing of VF energy requirements was mandated for implantation of ICDs. Confirmation of adequate defibrillation was repeated before hospital discharge if the DFT was >20 J; successful recognition and conversion of VT was also required. In the Antiarrhythmics Versus Implantable Defibrillator (AVID) trial, virtually all patients (99%) achieved an adequate DFT.

Potential Adverse Effects or Procedural Complications Related to DT

One of the most common reasons cited to avoid DFT testing at the time of implantation is related to the presumed increased risk for complications related to testing. However, this increased risk has never been proven in a prospective fashion. The risks of DT at the time of implantation could include those related to VF itself, which may lead to circulatory arrest and hypoperfusion. Risks may also be related to the shocks alone or to the anesthetic drugs that are required for DT.

Improved ICD technology has led to the need for fewer inductions of VF at the time of implantation testing, and...
procedure-related mortality is low. Using transvenous systems and biphasic waveforms, the perioperative mortality rate within 30 days of implantation is 0.2% to 0.4%. Recent data from the NCDR (National Cardiovascular Data Registry) ICD registry demonstrated an in-hospital mortality of <0.5%. Reports from 21 implanting centers in Canada estimate 3 of 19067 (0.016%) deaths related to DFT testing.

Although ICD implantation has well-known complications, without a large randomized prospective trial, it is often difficult to identify which complications are directly (or indirectly) related to DT itself. Risks that may be directly related to DT include stroke or transient ischemic attack because intracardiac thrombus may dislodge during conversion of atrial fibrillation in the absence of therapeutic anticoagulation, or hypotension could result in reduced cerebral perfusion. Persistent hypotension requiring hemodynamic support, multiple external defibrillations, pulseless electric activity, respiratory depression, or death may be direct results of DT or because of drugs used to perform testing. In contrast, DT may indirectly increase the risk for pneumothorax, perforation, tamponade, lead dislodgment, or infection because more leads may be placed and the procedure may be prolonged because of system revisions aimed at improving defibrillation efficacy. However, all of these complications may also occur in the absence of DT. Adverse events are driven primarily by mechanical complications or infection, most of which are not related to DT itself.

In a pilot study randomizing DT to no testing at the time of implantation in patients undergoing initial ICD implantation, the risk of perioperative complications was extremely low, regardless of whether or not DFT testing was performed. No significant difference in implant-related complications was demonstrated in the Safety of Two Strategies of ICD Management at Implantation (SAFE-ICD) study, a prospective observational study performed at 41 centers in Italy that was designed to evaluate the outcome of 2120 patients undergoing DT versus those who did not. The study was limited by absence of randomization, confounding differences in baseline characteristics, and the small number of patients reaching the primary end point but supports relative safety of DT. Other studies have demonstrated worse outcome of patients who did not undergo DT compared with those who did; however, this is likely because of selection bias in that sicker patients are more likely excluded from DT in nonrandomized trials.

**DFT Effect on Long-Term Mortality and Arrhythmic Death**

Early investigation demonstrated that a high DFT was associated with worse outcome, and arrhythmic death remained an important risk. With monophasic devices and a thoracotomy approach to implantation, the actuarial rate of sudden arrhythmic death was 16% for 5 years in patients with a high DFT (≥25 J). At that time, devices were implanted for secondary prevention indications, and defibrillation efficacy was lower with monophasic waveforms.

Factors that are dynamic and not present at the time of implantation, such as ischemia, progressive heart failure, metabolic abnormalities, drug effects, or ICD lead failures, may subsequently lead to increased DFTs, failed shocks, or sudden death. The most common mechanism of sudden death in patients with an ICD is VT/VF treated with an appropriate shock. Postmortem interrogation of ICDs revealed that 25% of sudden deaths in ICD patients were caused by failure to defibrillate VF. Multiple shocks may be required to defibrillate VF, and postdefibrillation electromechanical dissociation accounted for 29% of deaths in 1 study. Perhaps, this number of failed shocks or mortality might be even higher if implant DFT testing was not performed.

Some retrospective studies suggest no difference in mortality in patients who underwent DFT testing versus those who did not, although some studies were small with relatively short-term follow-up and few treated arrhythmic events, and each of these studies was not powered to address the end points of interest to the current debate. In a prospective observational study, there was also no difference in mortality between patients who underwent testing versus those who did not; however, large variations in the practice between centers was identified, and selection bias cannot be excluded. In contrast, 1 small retrospective study revealed a lower total survival in the no DFT group (69.1% versus 91.2%; P=0.004). However, multivariate analysis found only a trend toward increased risk of death in the no DFT group (hazard ratio, 3.18; 95% confidence interval, 0.82–12.41; P=0.095). In a much larger study (64227 initial ICD implantation procedures performed at 1261 facilities) in the NCDR ICD registry, patients who did not undergo DT had higher in-hospital mortality (0.61% versus 0.24%; P<0.001), even after multivariate analysis, although long-term mortality was not available. Similar findings were seen in a previous retrospective study where overall long-term survival was significantly lower in the no-testing group (58%) than in the DFT (74%) and safety margin testing (69%) groups (P<0.0005), and multivariate analysis confirmed that lack of ICD testing was an independent predictor of mortality. Although these results likely reflect exclusion of DFT testing in the sickest patients, these studies in total do not support harm from a strategy of DT. Because of marked differences in characteristics of patients who undergo testing compared with those who do not, whether there is any mortality difference or even a benefit from DFT testing can only be answered with a prospective randomized trial.

It should be noted that the absolute survival benefits of ICDs were 5.6% to 11% in AVID, MADIT II, and SCD-HeFT. If DFT testing does influence ICD shock efficacy during subsequent clinical events, it could be hypothesized that the absence of testing might counterbalance some of the survival benefit of ICD therapy. One study reported a high DFT in 12% of patients undergoing CRT defibrillator ICD implantation. Fortunately, >90% of the patients were able to achieve adequate safety margins with system modification or drug changes. With this strategy, elevated DFTs had no effect on 2-year mortality. Russo et al reported that long-term survival was not significantly different in patients requiring system modification compared with
those who did not require modification. Although this survival outcome could be interpreted to support lack of a need for DFT testing, perhaps the more valid interpretation is that the strategy of DFT testing and system revision in patients with high DFTs allowed successful achievement of similar survival to those patients with lower DFTs (ie, the strategy of DT worked).

**Potential Detrimental Effects of ICD Shocks on Long-Term Mortality**

Opponents of DFT testing purport that DT at the time of ICD implantation should be avoided because of potential adverse effects of shocks on outcome. Data suggest that patients receiving ICD shocks for clinical events, whether shocks are appropriate or inappropriate, are at increased risk for adverse outcomes, including mortality.\(^7^1\) Programming of ICD therapies with a detection rate of ≥200 bpm with a prolonged delay in therapy at ≥170 bpm, compared with conventional programming in MADIT-RIT, was associated with reductions in inappropriate therapy and all-cause mortality, consistent with the concept that clinical shocks might be detrimental.\(^7^1\)

However, a post hoc analysis of MADIT-CRT\(^7^2\) showed that increasing numbers of ICD shocks delivered during DFT testing were not associated with higher risk for heart failure or death (primary end point), heart failure alone, VT/VF, or death. In addition, delivery of high (>20 J) or low (≤20 J) energy shocks also were not associated with adverse clinical outcomes. This suggests that the ICD shocks themselves during DT may not be harmful. Another study also reported that ICD shocks delivered during induced ventricular arrhythmias do not increase the risk of death.\(^7^3\) The occurrence of spontaneous arrhythmias more likely explains the increased mortality risk of patients who receive shocks for clinical arrhythmias rather than risk related to the shocks themselves.

**Patients Who Should be Excluded From DFT Testing**

In the absence of prospective randomized trial data demonstrating that testing is no longer required, DFT testing is currently recommended for most patients who undergo initial ICD implantation. However, situations where testing should be omitted or deferred because of a high risk for complications include (1) presence of left atrial or left ventricular thrombus, (2) atrial fibrillation in the absence of therapeutic anticoagulation, (3) hemodynamic instability or requirement for pressor support, (4) severe aortic stenosis, (5) unvascularized severe proximal 3-vessel coronary artery disease or significant left main disease, (6) unstable angina or active ischemia, (7) recent stroke or transient ischemic attack, (8) respiratory issues that would preclude sufficient sedation, (9) known inadequate external defibrillation, and (10) inadequate anesthesia support. In some cases, patients may be tested at follow-up, such as after left atrial thrombus resolves or therapeutic anticoagulation is maintained. In other cases, such as unvascularized severe 3-vessel disease or left main disease, risk may preclude future testing.

**Current Practice Trends**

Recent studies have shown a trend toward ICD implantation without DFT testing.\(^7^4,7^5\) In addition, the use of this procedure in clinical practice varies by geographic region, hospital, physician training, and country.\(^6^2,7^5,7^7\) A decrease in DT has been noted over time with devices implanted without testing in 10.4% of patients in 2000 to 2002, 18.6% in 2003 to 2005, and 29.6% in 2006 to 2008 at a US university center.\(^7^4\) Only 25% of patients who did not have DT at implant underwent testing within 6 months postimplant. Studies from Italy and Canada demonstrated that 20% to 35% of devices were implanted without DT.\(^2^1,6^0,7^6,7^7\) In a later study in Italy, DT was performed in only 47%.\(^7^3\) There was a marked difference in testing between centers, suggesting physician preference. In the NCDR Registry, data from 64,227 initial ICD implant procedures performed at 1261 US facilities revealed that DFT testing was not performed in 29% of patients.\(^6^2\) There are currently no prospective data to support this dramatic shift in practice.

**Paucity of Randomized Trial Data**

It is clear that randomized trial data are needed to support or refute the need for DFT testing. Opponents of DT testing would suggest that more harm could be done to patients with rare complications because of VF inductions or system revisions performed at the time of implantation rather than by failure of untested systems that could have been prevented. Because of the probabilistic nature of defibrillation, the clinical measurement and identification of a high DFT at implantation may have limited reproducibility, perhaps leading to some unnecessary revisions. In addition, ICD shock failures during follow-up may be because of deterioration in substrate that could not have been prevented by revision of systems in patients with high DFTs measured during standard implantation testing. However, the clinical effect of not revising the systems with high DFTs cannot be readily tested because it will be unlikely that a randomized trial to test this could ethically or practically be performed. Moreover, the absolute survival benefit of 5.6% to 11% from ICDs in primary and secondary prevention trials was achieved in DT-tested ICDs and not nontested ICDs.

A randomized controlled pilot study comparing ICD implantation with and without intraoperative DT in 145 patients with heart failure and severe left ventricular dysfunction, a substudy of the Resynchronization for Ambulatory Heart Failure Trial (RAFT Trial),\(^2^5\) reported no significant differences between groups. Perioperative complications, failed appropriate shocks, and arrhythmic death were all uncommon, regardless of whether or not DFT testing was performed. This was a small study with too few events to answer the DFT question.

The Shockless IMPLant Evaluation (SIMPLE) trial is an international multicenter randomized, controlled trial of DT at the time of ICD implantation, aiming to enroll 2500 patients (NCT00800384).\(^7^8\) NORDIC ICD (NORDIC Implantable Cardioverter Defibrillator Study) (NCT01282918) is a randomized trial of DFT testing in Europe, with anticipated enrollment of 586 patients. A pilot study, Test-No Test-ICD (TNT-ICD),
planning enrollment of 100 patients, is also underway in the United States (NCT01905007). Although underpowered to detect a mortality difference, such trials can be useful in assessing the safety of DFT testing and first shock efficacy.

Conclusions

One of the most controversial and highly debated topics is related to the usefulness of DT at time of ICD implantation. The paucity of data from randomized controlled trials fuels this debate. Advancements in ICD technology have simplified the implantation procedure, and testing of ICDs seems to be safe in most patients. Modifications of the ICD system, such as lead repositioning or adding a subcutaneous lead, can easily be performed at initial implantation, improving defibrillation success. Although conclusive data are not currently available to demonstrate that this clearly translates into improved mortality or increased efficacy of therapy for clinical VT/VF, a number of data from randomized controlled trials fuels this debate. With few exceptions, most large clinical trials typically aimed for adequate DTs at implantation. If systems are not revised based on the results of DFT testing, it is unknown whether or not patients would have received the same benefit from ICD therapy in these trials.

To quote Dr Fisher, “The cost-risk inconvenience arguments against DFT testing at implant are largely specious. The mathematical risk arguments are largely philosophical. In the end, it boils down to whether the physician or patient wishes to accept a small chance that an untested device will fail, versus … why have a device and not have some assurance that it can defibrillate?”

Although DFT testing uses additional procedure time, and in the absence of studies demonstrating harm, the benefit may be a saved life. Thus, the easiest path may not always be the best approach.

Ongoing trials will not answer the mortality question but will help to address first shock efficacy and frequency of adverse events. Until then, DT should be considered a standard part of initial ICD implantation for patients without contraindications.

Disclosures

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References


**Key Words:** arrhythmias, cardiac defibrillators, implantable ventricular fibrillation
Response to Andrea M. Russo, MD, and Mina K. Chung, MD

Jeff S. Healey, MD, MSc, and Michela Brambatti, MD

Drs Russo and Chung have provided a comprehensive review of the arguments in favor of routine defibrillation testing (DT). They are correct in saying that DT may uncover rare system failures which would not be detected by other means. However; one must consider the uncommon nature of such failures, given the similarly uncommon risk of complications because of DT. History has taught us that attempts to mitigate small risks may result in a higher likelihood of adverse outcomes.1

The presumption that DT improves outcomes is predicated on the assumption that interventions taken in response to a failed DT improve clinical shock efficacy. However, in a recent registry, physicians took no action in response to a failed DT in >40% of cases. Even when actions are taken to correct failed intraoperative DT, a systematic evaluation found that many patients may still have an unsuccessful DT at the time of predischarge testing. Finally, it is a major assumption that optimizing the efficacy of implantable cardioverter-defibrillators therapy against induced arrhythmias has any influence on the effectiveness of the implantable cardioverter-defibrillators against clinical arrhythmias.

We disagree with Fisher’s statement that “mathematical risk arguments are largely philosophical” because the potential clinical consequences of conducting or not conducting DT can be clearly defined and reliable estimates of the frequency of these outcomes exist. For a patient to experience a fatal outcome related to an uncorrected, failed DT, the patient in question must have a clinical ventricular arrhythmia, which would have to be lethal, and have not one, but multiple failed clinical shocks. Investigators have considered each of these possible outcomes using formal decision analytical methods and have concluded that it is improbable that routine DT improves survival for typical implantable cardioverter-defibrillator recipients. Thus, such mathematical arguments can in fact provide clinicians with practical information.

Although it is true that DT was part of all of the landmark implantable cardioverter-defibrillator trials2 and remains part of the product labeling for these devices, it is reasonable for clinicians to adapt their practice based on high-quality observational data3 while they await the results of randomized controlled trials. Until such trials are completed, the intuition of many experienced physicians and their move away from routine DT should not be discounted.

References


Is Defibrillation Testing Necessary for Implantable Transvenous Defibrillators?: Defibrillation Testing Is Necessary at the Time of Implantable Cardioverter Defibrillator Implantation

Andrea M. Russo and Mina K. Chung

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