Is Defibrillation Testing Necessary for Implantable Transvenous Defibrillators?

**Defibrillation Testing Should Not Be Routinely Performed at the Time of Implantable Cardioverter Defibrillator Implantation**

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

Because the implantable cardioverter defibrillator (ICD) was introduced into clinical practice, insertion of these devices has typically involved defibrillation testing (DT). However, DT has never been shown to independently improve patient outcomes. The rationale for DT has always been that the induction of ventricular fibrillation (VF) immediately after ICD insertion allows the implanting team to verify that the ICD can appropriately sense VF and deliver a high-energy shock that can effectively terminate this arrhythmia. The first ICD systems were complex, using epicardial patches and monophasic shock waveforms, thus accurate sensing and termination of VF were frequently in question. However, the ICD evolved over time, with the introduction of transvenous systems, biphasic waveforms, and active cans, which made failure to sense and treat VF much less common. Modern ICDs are also capable of delivering energies >40 J, thus many have started to question the rationale for DT in the modern era.

Response by Russo et al on p 351

During the past 10 years, there has been a dramatic shift in practice, such that DT is performed in <50% of ICD implants in some jurisdictions. This change was not driven by the results of randomized trials, but by changing opinions of clinicians, based on the following insights from observational studies: (1) intraoperative DT is usually successful and clinicians do not always act on unfavorable results; (2) intraoperative DT is an unproven surrogate for clinical shock efficacy; (3) the likelihood of a failed appropriate clinical shock is low and does not appear lower among patients who have DT; and (4) DT is associated with uncommon, but serious complications and adds cost and complexity to the ICD implant procedure. A large randomized evaluation of DT will soon be completed; however, the observational data seem to suggest that it may not demonstrate a benefit of DT. Pending on the results of this trial, DT should not be routinely performed at the time of ICD implantation, as the benefits of DT are unproven, whereas its hazards are real.

Intraoperative DT Is Usually Successful and Clinicians Do Not Always Act on Unfavorable Results

The main rationale of conducting DT at the time of ICD implantation is that if the ICD fails to terminate an episode of induced VF, then the ICD system can be modified to make it more effective. Thus, any potential benefit of DT would only be realized by those patients whose ICD fails to terminate VF at the time of intraoperative testing. However, recent registries and clinical trials show that in 90% to 95% of cases, the initial ICD configuration successfully terminates VF and when measured, the defibrillation threshold is far below the maximum output of modern devices (Table 1). Even among patients with advanced heart failure, in whom observational
studies suggest an increased risk of failed DT, the likelihood of failed intraoperative DT is low. In a substudy of RAFT (Resynchronization for Ambulatory Heart Failure Trial), 96% of patients with New York Heart Association class II heart failure and a broad QRS had successful termination of VF with their initial ICD configuration. In Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), a substudy of DT demonstrated that all 717 patients had a defibrillation threshold of ≤30 J, and 97.8% of patients had a threshold of ≤20 J.

Thus, only a small fraction of patients having ICD implantation could potentially benefit from DT, as only those in whom DT fails would receive an intervention as a result of DT. However, a recent Canadian survey suggests that among the 7% of patients who did not achieve a 10-J safety margin with their initial ICD system configuration, this safety margin was only achieved in 56% of patients before completion of the ICD implant procedure. Physicians were often unable or unwilling to modify the ICD system to achieve a 10-J safety margin, calling into question the value of performing DT in the first place. This registry documented that unwillingness to modify the ICD system was driven by both safety concerns and lack of conviction that DT is useful.

**Intraoperative DT Is an Unproven Surrogate for Clinical Shock Efficacy**

When DT is conducted today, ≥70% of the time this involves only a single induction of VF. However, the likelihood of success for a single ICD shock at a given shock energy is probabilistic. Thus, a single failed shock 10 J below the maximum ICD output does not necessarily imply a poor long-term ICD efficacy. More rigorous DT using multiple shock protocols has shown that a safety margin of only 5.2±1.1 J is associated with a 97.3% rate of successful conversion of clinical ventricular arrhythmias. Conversely, intraoperative DT with a single shock may not identify all cases in which future ICD shock success.

One must also recognize that intraoperative DT is only a surrogate for clinical shock efficacy. Clinical VF may be associated with other clinical abnormalities, such as myocardial ischemia, heart failure decompensation, and electrolyte disturbances, which could make the response to defibrillation different from that of induced VF. Although one might assume that clinical ventricular arrhythmias would be more difficult to terminate, in the case of antitachycardia pacing, there is some evidence to suggest that these arrhythmias may actually be easier to terminate than induced VF. As well, it should be emphasized that VF represents only 10% to 15% of clinical ventricular arrhythmias in ICD patients. Thus, intraoperative DT typically evaluates a different ventricular arrhythmia than is observed in clinical practice.

The concept of intraoperative DT is predicated on the assumption that something can be done for patients with failed DT that will improve not only the acute success of DT but also long-term clinical shock efficacy and ultimately patient survival. There is only limited high-quality data to show that interventions to improve defibrillation efficacy actually work. Data to support the use of azygous or coronary sinus coils are limited to case reports and small series, and a recent study of programmable shock waveform failed to show a reduction in defibrillation threshold using tilt-based programming. There is a reasonably large (n=177) series demonstrating that the addition of a subcutaneous lead can reduce defibrillation threshold by ≈10 J, although this study cannot determine whether acute improvements in intraoperative defibrillation threshold improve the success of defibrillation for clinical arrhythmias. Finally, a series of 965 consecutive ICD recipients observed that 7.1% of patients failed to have 2 consecutive successful shocks at ≥10 J below maximum ICD output, but that with a variety of interventions, all patients were able to meet this standard before the end of the ICD implant procedure. However, at the time of subsequent, routine, predischarge DT, 38.5% of patients in whom a failed DT was corrected again failed to meet the standard. Conversely, 2.0% of patients meeting the standard for DT at implant failed to do so when re-evaluated predischarge. These data call into question the reproducibility of DT and its value as a surrogate to predict long-term clinical shock success.

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**Table 1. Results of Defibrillation Threshold Testing in Selected Cohort Studies and Randomized Trials**

<table>
<thead>
<tr>
<th>Author</th>
<th>Study Type</th>
<th>Time Frame</th>
<th>Sample Size</th>
<th>DFT (J), Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pires and Johnson</td>
<td>Consecutive cohort</td>
<td>1996–2004</td>
<td>835</td>
<td>13.5±4</td>
</tr>
<tr>
<td>Russo et al</td>
<td>Consecutive cohort</td>
<td>1997–2003</td>
<td>1139</td>
<td>17±6</td>
</tr>
<tr>
<td>Hohnloser et al</td>
<td>RCT</td>
<td>1999–2003</td>
<td>91</td>
<td>10±5</td>
</tr>
<tr>
<td>Shorofsky et al</td>
<td>Cohort</td>
<td>2003</td>
<td>44</td>
<td>8±5</td>
</tr>
<tr>
<td>Gold et al</td>
<td>RCT</td>
<td>1997–1999</td>
<td>636</td>
<td>7.9±3.7</td>
</tr>
</tbody>
</table>

DFT indicates defibrillation threshold; and RCT, randomized controlled trial.
Likelihood of a Failed Appropriate Clinical Shock Is Low and Does Not Appear Lower Among Patients Who Have DT

In the current era, ICD shocks are highly effective at terminating clinical ventricular arrhythmias, including ventricular tachycardia and VF. In a consecutive series of 835 American patients, first shock efficacy was 91%. The success of shocks for clinical arrhythmia was the same for patients who underwent full defibrillation threshold testing (91%; n=129), limited evaluation of defibrillation safety margin (91%; n=503), and for patients who did not have any form of DT (92%; n=203). In this series, all clinical ventricular arrhythmias were successfully treated with ≤2 ICD shocks. All-cause mortality was higher among patients not having DT; however, there was a bias toward not performing DT among individuals with greater comorbidity. A more recent observational study of 2120 consecutive Italian patients found similar results. More than 2 years of follow-up, the rate of failed appropriate ICD shock was only 0.5% among the 1284 patients who did not have DT and 0.8% among the 836 patient who did (P=0.28). This study also demonstrated a similar and low rate of sudden or instantaneous death among patients who did not have DT (0.8%) and those who did (1.2%) and documented only a single case of death after documented ineffective shock in each group. Furthermore, details of the 25 failed appropriate shocks suggest that in 11 of these cases, other issues, such as acute coronary syndrome, cardiogenic shock, or cardiac rupture, were likely.

DT Is Associated With Uncommon But Serious Complications and Adds Cost and Complexity to the ICD Implant Procedure

Among physicians, there is concern about the safety of inducing VF and delivery of high-voltage shocks to ICD recipients who typically have significant structural heart disease and often many additional medical conditions. Several reports of variable size and methodology suggest that although uncommon, serious complications can occur in patients undergoing DT; however, issues of patient selection and statistical power make it difficult to address causation. A retrospective review of 15,254 Canadian patients having ICD implantation between 2000 and 2006 documented 3 deaths that were thought to be the direct result of DT as well as 5 strokes (0.03%) and 27 patients (0.18%) who required external cardiac massage or >1 external rescue shock. In the smaller, prospective CREDIT (Canadian Registry of ICD Implant Testing Procedures) registry, 0.4% of patients having DT experienced stroke. Finally, the most recent and perhaps the best observational data come from the SAFE-ICD (SAFEty of two strategies of ICD management at implantation) registry, which prospectively documented only a single embolic event among 836 consecutive patients having DT, 4 cases of cardiac arrest, 1 case of cardiogenic shock, and only 2 deaths from any cause in the perioperative period. Again, the rates of all complications were not significantly different from patients having ICD implantation without DT; however, patients having DT were substantially younger, had better cardiac function and less comorbidity. Only a single small randomized trial of DT has been performed, which did not observe any stroke, embolism, or acute heart failure and only 4 cases of prolonged hypotension among 75 patients randomized to receive DT. However, the results of a much larger (n=2500) randomized trial will be available in 2014.

In addition to the risk of complications, the conduct of DT is associated with increased resource utilization, including the involvement of an anesthesiologist, the use of intravenous anesthetic agents, and the need for an overnight stay in hospital. This was associated with an increased cost of $800, or 3% of the total ICD implant costs. Finally, there is ongoing debate that the delivery of ICD shocks may increase the risk of death. In the SCD-HEFT trial, 22% of patients received ≥1 appropriate ICD shock and these patients had a substantial increased risk of death from any cause (hazard ratio, 5.68; 95% confidence interval, 3.97–8.12). However, this analysis cannot conclude that shocks actually cause death, as ICD shocks may have simply been a marker for more advanced cardiac disease. However, the recent Multi-centre automatic defibrillator implantation trial to reduce inappropriate therapy (MADIT-RIT) study randomized patients to conventional ICD programming or programming designed to prevent ICD shocks and found that each of 2 new programming algorithms reduced the rate of inappropriate shocks by =80% and the risk of all-cause mortality by =50%. These data seem to support the concept that ICD shocks could increase mortality; however, only a modest number of total shocks were prevented in MADIT-RIT (n=82 shocks prevented for 1.4 years among 500 patients in the high-rate therapy arm), which raises suspicion that the prevention of 18 deaths during the same period may have involved the play of chance. These findings await confirmation by the Shockless Implant Evaluation (SIMPLE) trial, which will prevent ≥1500 shocks among patients randomized to DT. If ICD shocks do indeed increase the risk of death, then SIMPLE should be well-positioned to detect this.

Current Practice and Recommendations

During the past decade, observational data have called into question the current role of DT. In an era where the ICD is highly effective at terminating ventricular arrhythmias, including ventricular tachycardia and VF, the administration of DT among individuals with greater comorbidity may not result in greater efficacy but may increase patient safety and resource utilization.

Table 2. Proportion of ICD Recipients Receiving Intraoperative Defibrillation Testing

<table>
<thead>
<tr>
<th>Author</th>
<th>Region</th>
<th>Time Frame</th>
<th>Sample Size</th>
<th>Proportion Having Defibrillation Testing, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christ et al</td>
<td>Germany</td>
<td>1998–2004</td>
<td>965</td>
<td>100</td>
</tr>
<tr>
<td>Pires and Johnson</td>
<td>USA</td>
<td>1996–2004</td>
<td>835</td>
<td>75.7</td>
</tr>
<tr>
<td>Brignole et al</td>
<td>Italy</td>
<td>2005</td>
<td>7857</td>
<td>70.0</td>
</tr>
<tr>
<td>Healey et al</td>
<td>Canada</td>
<td>2006–2007</td>
<td>361</td>
<td>64.0</td>
</tr>
<tr>
<td>Healey et al</td>
<td>Canada</td>
<td>2007–2008</td>
<td>2173</td>
<td>58.4</td>
</tr>
<tr>
<td>Brignole et al</td>
<td>Italy</td>
<td>2008–2009</td>
<td>2120</td>
<td>39.4</td>
</tr>
</tbody>
</table>

ICD indicates implantable cardioverter defibrillator.
effective at terminating both induced and clinical ventricular arrhythmias, the small but measurable risks of DT-related complications have become more relevant. In many regions of the world, physicians have moved dramatically away from DT at the time of ICD implantation (Table 2). Despite significant variation between regions (Table 2) and between individual centers within regions, there is a clear trend for less DT over time (Table 2). Thus, many ICD clinicians also seem to feel that the balance of risks and benefits no longer favor the routine conduct of DT. A large randomized trial will soon provide additional insights; however, unless it ultimately demonstrates a clear benefit for DT, it seems that clinicians are justified to implant defibrillators without the routine need for DT.

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Disclosures
Dr Healey has received grant support from Boston Scientific to fund the Shockless Implant Evaluation Trial, which is evaluating the role of intraoperative defibrillation testing. The other author reports no conflicts.

References
Routine Defibrillation Testing Is Not Necessary

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

Andrea M. Russo, MD and Mina K. Chung, MD

Healey and Brambatti argue that defibrillation testing (DT) is no longer necessary at the time of implantable cardioverter-defibrillator insertion based on observational data and opinions of clinicians, which have resulted in a dramatic shift in clinical practice. In contrast, multiple prospective randomized clinical trials that have documented the efficacy of implantable cardioverter-defibrillators for the primary and secondary prevention of sudden cardiac death have all involved the induction of ventricular fibrillation at the time of implantation to demonstrate effective arrhythmia termination. We must ask ourselves why observational data and subjective opinions might supersede clinical trial evidence?

The authors argue that DT should not be performed because implanting physicians do not act on unfavorable results, based on a survey performed in Canada. In fact, observational studies and clinical trials have demonstrated that this is not the case. System modifications performed at implantation to enhance defibrillation efficacy result in effective defibrillation in 67% to 100% of cases, as discussed in our article. However, one cannot argue that there is no reason to perform DT, if the implanting physician does not plan to revise the system based on results of testing.

We agree that the benefits of DT related to clinical shock efficacy during follow-up and affect long-term mortality are currently unproven with modern-day implantable cardioverter-defibrillator technology. We do know that the first shock success rate for spontaneous ventricular tachycardia/ventricular fibrillation in ventricular fibrillation zone in patients who passed implant criteria has been shown to be 83% to 92%, not 100%. However, we do not know whether clinical shock efficacy would be even lower in patients identified to have high defibrillation energy requirements at the time of implantation, representing 2% to 12% of patients in prior studies, if devices known to fail implantation criteria were not modified. We would argue that most clinicians who perform DT do this with the intent of correcting the system to achieve an adequate safety margin, recognizing that there is a paucity of data to prove or refute this statement.

All-cause mortality or procedure-related adverse events seem to be more common among patients who do not undergo DT; however, this likely represents selection bias, in that DT is likely omitted in sicker patients with greater comorbidities. This is why prospective randomized trial data are needed to prove or disprove the need for DT.

Although the Shockless IMPLAnt Evaluation (SIMPLE) trial may not answer the mortality question, it will help address questions related to first shock efficacy and adverse events in patients who undergo DT versus those who do not. We commend Dr Healey on the design of this important prospective randomized trial to answer this question and look forward to the results of SIMPLE. However, until these results become available, DT should be considered a standard part of initial implantable cardioverter-defibrillator implantation for patients without contraindications.

Key Words: defibrillation, electric implantable cardioverter-defibrillators
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