Implantation of Cardioverter Defibrillators Without Induction of Ventricular Fibrillation

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Background—The upper limit of vulnerability (ULV) is the weakest shock at which ventricular fibrillation (VF) is not induced by a T-wave shock. This study tested the hypothesis that a vulnerability safety margin based on the ULV can be used as an implantable cardioverter-defibrillator implantation criterion.

Methods and Results—Implantable cardioverter-defibrillators were implanted in 80 patients if T-wave shocks did not induce VF and the baseline-rhythm R wave was ≥7 mV. The T-wave shock was 10 J in the first 45 patients (group A) and 15 J in the last 35 patients (group B). After inductionless implantations, the first VF shock was programmed to the T-wave shock plus 5 J. If T-wave shocks induced VF, the ULV was measured and the first shock was programmed to the ULV+5 J. Inductionless implantations were performed in 58 patients (72%), 28 in group A (62%) and 30 in group B (86%; P=0.04). If T-wave scanning had been done at 15 J in group A patients, inductionless implantations could have been performed in 84% of them. At 3 months, VF was induced twice during electrophysiological study in 75 patients (94%). All VFs were detected in ≤4.7 s and were terminated by the first shock. During follow-up, 197 of 198 appropriate first shocks for rapid ventricular tachycardia or VF (99%) were successful in patients who had inductionless implantations (95% confidence intervals, 97% to 100%).

Conclusion—Inductionless implantations can be performed in >80% of implantable cardioverter-defibrillator recipients using a vulnerability safety margin based on a T-wave scan at 15 J. (Circulation, 2001;103:2159-2164.)

Key Words: defibrillation, defibrillators, implantable, shock

The most widely accepted method for implantable cardioverter-defibrillator (ICD) implantation requires inducing ventricular fibrillation (VF) to ensure that the ICD will sense, detect, and defibrillate VF. Rarely, inducing VF may result in serious complications1–3 or death.1 Under most conditions, sensing and detecting VF is reliable if the baseline R wave has sufficient amplitude.4,5 The present study tests the hypothesis that a vulnerability safety margin based on the upper limit of vulnerability (ULV) could ensure consistent defibrillation without inducing VF and thus be used as an ICD implant criterion.

The ULV is the weakest shock at which VF is not induced when a shock is delivered during the vulnerable phase of the cardiac cycle. The ULV hypothesis of defibrillation links the ULV to the minimum shock strength that defibrillates reliably.6 The ULV approximates the shock strength that defibrillates with a 90% probability of success.7 Shocks programmed to the ULV+3 J or ULV+5 J defibrillate induced VF consistently, both acutely7 and chronically.8 Shocks at the ULV+5 J convert spontaneous ICD-detected VF reliably.9

This study’s primary end points were detection and defibrillation of induced VF 3 months after implantation. Secondary end points were the detection and defibrillation of spontaneous, rapid ventricular tachycardia (VT) and VF.

Methods

Patients

Patients were candidates for this study if they had initial, left pectoral ICD implantation, agreed to postoperative testing at 3 months, and did not have a pacemaker or other implanted electronic device. All gave written, informed consent according to a protocol approved by the Human Subjects Committee. A total of 80 of 131 consecutive eligible patients participated in the study. Patient characteristics are shown in Table 1.

Implant Procedure

Technique

An active-can ICD (Medtronic model 7227, 7229, 7271, or 7273) and a dual-coil, integrated-bipolar ventricular defibrillation lead with a sensing interelectrode distance of 12 mm (Medtronic model 6942 or 6945) were inserted through a left pectoral incision, as described previously.10 The tip of the ventricular lead was placed at the right ventricular apex if the R wave was ≥7 mV and the pacing threshold was <1.0 V. Otherwise, the lead was placed at the closest position to the apex that had an R wave ≥7 mV and a pacing threshold <1.0 V. The value of 7 mV was selected on the basis of 2 assumptions. (1) The minimum chronic R wave amplitude necessary for reliable sensing of VF at a sensitivity of 0.3 mV is 3 to 4 mV.4,11 and (2) the amplitude of the chronic R wave decreases by ~40% from implantation.12 If the sinus rhythm R wave was <7 mV, VF was induced to testing detection.
TABLE 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
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<tbody>
<tr>
<td>Age, y</td>
<td>63±11</td>
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<tr>
<td>Sex, male/female</td>
<td>55/25</td>
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<tr>
<td>Cardiac disease, n</td>
<td></td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>52</td>
</tr>
<tr>
<td>Myocardial or valvular disease</td>
<td>24</td>
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<tr>
<td>No structural disease</td>
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<tr>
<td>LV ejection fraction*</td>
<td>0.34±0.11</td>
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<tr>
<td>Indication for ICD, n</td>
<td></td>
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<tr>
<td>Sustained monomorphic VT</td>
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<tr>
<td>Sustained polymorphic VT</td>
<td>1</td>
</tr>
<tr>
<td>VF</td>
<td>34</td>
</tr>
<tr>
<td>Syncope and inducible sustained VT†</td>
<td>8</td>
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<tr>
<td>Nonsustained VT and inducible sustained VT†</td>
<td>8</td>
</tr>
<tr>
<td>Antiarrhythmic drugs at implantation, n</td>
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<tr>
<td>Amiodarone</td>
<td>16</td>
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<tr>
<td>Digoxin</td>
<td>13</td>
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<tr>
<td>Sotalol</td>
<td>14</td>
</tr>
<tr>
<td>β-Blockers</td>
<td>39</td>
</tr>
<tr>
<td>Calcium-channel blockers</td>
<td>4</td>
</tr>
</tbody>
</table>

Values are mean±SD or No. of patients. n=80 patients.

*Left ventricular ejection fraction was measured by contrast angiography in 36 patients and radionuclide ventriculography in 44 patients.

†Prior myocardial infarction and left ventricular ejection fraction <35%.

Vulnerability Testing
If the rhythm R wave was ≥7 mV, the T wave was scanned at 10 J in the first 45 patients (group A) and at 15 J in the last 35 patients (group B). The shock strength was liberalized to 15 J in group B on the basis of an analysis of the results of 3-month electrophysiological studies in the first 40 patients. Clinical variables shown in Table 1 did not differ significantly between groups.

The main features of the T-wave scan have been reported previously. Pacing was performed via the right ventricular electrode. The baseline drive (S1) was delivered at a cycle length of 500 ms. All 12-lead electrocardiographic leads were recorded simultaneously, and the lead with the latest-peaking, monophasic T wave was selected. The first T-wave shock was delivered after 8 S1s at the peak of this T wave. The right ventricle was the anode for the first phase of biphasic shocks. If VF was not induced, subsequent shocks were delivered 20 ms and 40 ms before and 20 ms after the peak. There was a 1-minute recovery period between shocks that did not induce VF. If VF was not induced by these 4 shocks, the ICD was implanted.

If any of the T-wave shocks induced VF, defibrillation was performed with a shock 10 J greater than the T-wave shock. If this shock failed, a 200-J external shock was delivered. There was a 4-minute recovery period after each VF episode. The T-wave shock was then increased by 5 J and the T-wave scan was repeated. This process was repeated until none of the 4 shocks induced VF. The ULV was recorded as the shock strength that did not induce VF. The lead was repositioned at least once if the ULV was ≥25 J.

ICD Programming
Up to 3 detection zones were programmed: 1 zone (VF) was programmed in 8 patients, 2 zones (VF and VT) were programmed in 18 patients, and 3 zones (VF, VT, and fast VT) were programmed in 54 patients. The VF detection interval was 284±19 ms, and the fast VT detection interval was 323±11 ms. This latter value is comparable to the programmed VF detection interval in studies of 2-zone ICDs. The minimum autotuning sensitivity was 0.3 mV.

The first fast VT therapy was 1 trial of antiarrhythmia pacing. The second fast VT therapy (first shock) and first VF shock were set to 5 J greater than the lowest tested shock strength that did not induce VF. This was 15 J in group A patients in whom VF was not induced, 20 J in group B patients in whom VF was not induced, and the ULV+5 J in patients in whom VF was induced. The second shock was 10 J greater than the first shock, and subsequent shocks were 30 to 35 J.

Chronic Electrophysiological Study
Patients were studied 3 months postoperatively, as described previously. Detection of VF and efficacy of the first programmed shock were tested twice in trials separated by 4 minutes. VF was induced by a 2-J T-wave shock. The time for detection of VF was measured manually at 25 mm/s on stored electrograms from the T-wave shock to the VF detection marker. Because detection amplifiers were saturated for ~0.5 s after the T-wave shock, the measured detection time slightly overestimates the true detection time.

Follow-Up
Patients were followed from the date of implantation until the date of study closure or reprogramming of the first VF shock. The first shock strength was increased by 10 J if patients had acute myocardial infarction, exacerbation of heart failure by >1 New York Heart Association class, or unsuccessful first shocks. The cardiac rhythms detected in the fast VT and VF zones were classified using previously reported, prospective criteria for stored detection intervals and electrograms. Each appropriate first VF shock was analyzed using stored postshock intervals and electrograms. VT and fast VT shocks were not analyzed.

Statistical Analysis
Data are presented as mean±SD. Basic comparative statistics were calculated using the 2-tailed, paired t test, or χ2 test. P<0.05 was used to reject the null hypothesis for single comparisons.

Results
Inductionless Implantations
The flow chart in Figure 1 shows that inductionless implantations were performed in 58 patients (72%). More group B patients underwent inductionless implantations than group A patients (86% versus 62%, P=0.04). There were no operative deaths. Four minor perioperative complications did not require surgical intervention.
VF at Implantation

VF was induced to assess sensing in 2 patients who had R waves ≤7 mV, despite lead repositioning. T-wave scans did not induce VF in these patients.

The ULV was determined at implantation because vulnerability testing induced VF in 20 patients. Of 16 group A patients, the ULV was 15 J in 10 patients, 20 J in 5 patients, and 25 J in 1 patient. If T-wave scanning had been done at 15 J in group A, inductionless implantations would have been performed in 38 of the 45 patients (84%), which is similar to the percentage of patients in group B who had inductionless implantations. The ULV was 20 J in all 4 group B patients in whom it was measured.

The ventricular lead was repositioned in 16 patients because of pacing thresholds >1.0 V, in 18 patients because the R wave was ≤7 mV, and in 2 patients because of ULVs ≥25 J.

Acute Versus Chronic R Waves

Table 2 shows the amplitudes of baseline-rhythm R waves measured at implantation by direct connection to the electrodes with those measured 3 months later by telemetry from the ICD. Chronic R waves were lower than acute R waves for both active-fixation and passive-fixation leads (P<0.001). For the 78 patients with R waves ≥7 mV at implantation, the lowest chronic R wave was 4.1 mV on a passive lead.

Overall, chronic R-waves <5 mV were present in 3 of 43 active leads (7%) and in 3 of 37 passive leads (8%, P=0.8).

Chronic Electrophysiological Study

An electrophysiological study was performed at 87±9 days in 75 of 80 patients (94%), including 55 of the 58 patients (95%) who underwent inductionless implantations. In these 55 patients, induced VF was detected in ≤4.7 s (Figure 2). The mean detection time was 3.7±0.5 s. The interval between the T-wave shock and the first VF electrogram was 0.4±0.1 s.

All first shocks were successful; these included 110 shocks in the 55 patients who underwent inductionless implantations (95% confidence intervals, 97% to 100%), 4 shocks programmed based on vulnerability safety margins in 2 patients in whom VF was induced to assess sensing, and 36 shocks in 18 patients programmed to the ULV 15 J. The high-voltage lead impedance was 37±8 Ω versus 39±7 Ω at implantation (P=0.07).

Follow-Up

The duration of follow-up was 17±4 months in group A and 8±4 months in group B. Total follow-up for patients who had inductionless implantations was 616 months (476 months for the 28 patients in group A and 240 months for the 30 patients in group B). One patient died of heart failure and one had a cardiac transplant. Six other patients were censored at the time first shocks were reprogrammed because of exacerbation of heart failure by 2 functional classes (4 patients), failed first shock and exacerbation of heart failure by 2 classes (1 patient), and acute myocardial infarction (1 patient).

First-Shock Efficacy for Spontaneous VT/VF

In patients who had inductionless implantations, there were 84 appropriate first shocks in the VF zone (Figure 3) and 114 in the fast VT zone. Details are summarized in Table 3.
Overall, 197 of 198 first shocks (99%) were successful (95% confidence intervals, 97% to 100%). The only ineffective shock occurred during treatment with intravenous amiodarone and lidocaine for VT storm associated with exacerbation of heart failure: antitachycardia pacing accelerated monomorphic VT in the VT zone to polymorphic VT.

In patients in whom VF was induced at implantation, there were 18 appropriate first shocks in the VF zone and 21 in the fast VT zone, all of which were successful. (95% confidence intervals, 92% to 100%).

Detection Times and Syncope
The time to detection of the 84 appropriate arrhythmias in the VF zone was 4.8 ± 0.5 s (range, 2.9 to 6.1 s). The longest detection time was caused by VT on the boundary of the VT and VF zones, not undersensing. One patient with a ULV of 20 J had syncope before a first shock after antitachycardia pacing accelerated VT into the VF zone. The patient who had a failed first shock had syncope before the successful second shock.

Discussion
The principal finding of this study is that inductionless implantations can be performed in >80% of ICD recipients using a vulnerability safety margin based on a 4-shock T-wave scan at 15 J. First shocks were programmed below maximum output in >90% of patients. The 95% confidence intervals for first-shock success were 97% to 100%, for both induced VF at 3 months after implantation and spontaneous VT/VF in the fast VT/VF zones of clinically stable patients.

Previous Implantation and Programming Strategies
Strategies based on defibrillation safety margin, defibrillation threshold, and ULV and have been compared.9 The defibrillation safety margin strategy limits fibrillation-defibrillation testing to the minimum necessary to confirm a safety margin between the ICD’s maximum output and the shock strength required for consistent defibrillation.2,9,16 Patient-specific strategies based on the defibrillation threshold 2 and ULV 9 permit programming shocks that are strong enough to defibrillate but not strong enough to cause unnecessary 17 or prolonged 18 myocardial depression and unnecessary conduction block.19 They prevent avoidable battery depletion if sustained or self-terminating arrhythmias cause capacitors to charge frequently, and they may reduce the risk of syncope during capacitor charging. However, the defibrillation threshold method requires multiple fibrillation-defibrillation episodes, and the ULV method requires 1 VF episode as well as multiple T-wave shocks.9

Vulnerability Safety-Margin Strategy
The principal goal of ULV and defibrillation threshold implantation strategies is to identify patients who have low defibrillation energy requirements. In the present study, these patients were identified accurately by 4 T-wave shocks without inducing VF. This vulnerability safety-margin strategy resulted in a first-shock success rate as good as9,13 or better than9,10 those reported for other methods of implant testing.

Why Is VF Induced at ICD Implantation?
VF is induced to ensure the detection of VF, an adequate defibrillation safety margin, and appropriate function of the
ICD generator. ICD generator failures are extraordinarily rare.

**When Should Detection of VF Be Tested at Implantation?**

Detection of VF depends both on the electrode’s sensing bipolar and the ICD’s sensing circuit and detection algorithm. Interactions of ICDs with implanted electronic devices require testing VF sensing. Otherwise, a baseline-rhythm R wave $\geq 5 \text{ mV}$ ensures rapid detection of VF at a nominal sensitivity of 0.3 mV. Under-sensing VF can occur rarely, despite an adequate R wave, if the amplitude of the VF signal varies rapidly. Implant testing may not exclude this remote possibility because VF electrogram patterns have limited reproducibility. Redetection of VF may fail after an unsuccessful shock, but this has been reported only with closely-spaced (6 mm), integrated bipolar leads.

The present study shows that the detection of VF is reliable with the lead, sensing circuit, and detection algorithm used if the baseline R wave is $\geq 7 \text{ mV}$. Because R-wave amplitude may decrease as leads mature, postimplantation testing may be more useful than implantation testing.

**When Should Defibrillation Be Tested at Implantation?**

More than 95% of patients treated with active-can, left-pectoral ICDs pass defibrillation implantation criteria. However, in up to 11% of patients, the shock polarity, lead position, or generator position was changed after failed defibrillation to meet these criteria. Thus, a measure of defibrillation efficacy at implantation is necessary to ensure an acceptable defibrillation safety margin. Vulnerability safety-margin testing provides such a measure without inducing VF in most patients. If T-wave scanning had been performed at 15 J in all patients in the present study, VF would have been induced in only 12 patients (15%), 2 of whom required lead repositioning.

**Implantation Morbidity Shocks Versus VF**

Some complications of implantation testing, such as intracardiac VF, cerebral hyperperfusion, and myocardial ischemia, are directly related to VF or circulatory arrest rather than to shocks. Prudence dictates that VF and circulatory arrest be induced only when they provide a specific benefit. Patients at higher than usual risk for VF induction include those in whom external defibrillation is unreliable, those with clinical history of only ventricular fibrillation: implications for use of implantable defibrillator. Circulation. 1995;91:1996–2001.

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