Automated Vulnerability Testing Identifies Patients With Inadequate Defibrillation Safety Margin

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Background—Implantable cardioverter-defibrillator system efficacy is tested at implant by induction of ventricular fibrillation (VF). Defibrillation safety margin can be assessed without VF induction using upper limit of vulnerability methods, but these methods have required manual determination of T-wave timing.

Methods and Results—To test the feasibility of an inductionless system of implant testing, a multicenter prospective study of an automated vulnerability safety margin system was conducted, which measured T-wave timing using an intracardiac electrogram during a ventricular pacing train. The system delivered up to 4 T-wave shocks of 18 J. Lack of VF induction by all 4 shocks was considered evidence of defibrillation adequacy. Patients subsequently underwent conventional defibrillation testing to meet a standard implant criterion. The 95% lower CI for defibrillation success at 25 J for noninduced patients was found using Bayesian statistics. Sixty patients were enrolled at 6 centers. Vulnerability testing and defibrillation success results were obtained from 54 patients. Vulnerability testing induced VF in 10 (19%) patients, of whom 2 required system revision. All patients not induced by vulnerability testing were successfully defibrillated twice at $\leq 25$ J. The Bayesian credible interval was 97% to 100% for the population success rate of defibrillation at 25 J for automated vulnerability safety margin noninduced patients.

Conclusions—An automated system identified all patients who failed conventional safety margin testing, while inducing only 19% of patients. Although limited by sample size, this study suggests the feasibility of automated implant testing that substantially reduces the need for VF induction in patients receiving implantable cardioverter-defibrillators. (Circ Arrhythm Electrophysiol. 2012;5:1073-1080.)

Key Words: defibrillation ■ implantable cardioverter-defibrillator ■ upper limit of vulnerability

Defibrillation testing is performed at implantable cardioverter-defibrillator (ICD) implantation to ensure adequate defibrillation efficacy and sensing of ventricular fibrillation (VF).1,2 This is commonly done by defibrillation safety margin (DSM) testing, which determines whether 2 successive induced episodes of VF can be defibrillated with shocks at least 10 J below the maximum device output. Major complications or deaths associated with defibrillation testing are rare but have been reported.3,4

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A potential alternative to intentionally inducing VF and defibrillating it is to assess the defibrillation efficacy by measuring the upper limit of vulnerability (ULV) at ICD implantation.5-11 The ULV is the energy threshold at which shocks can no longer induce VF. The ULV has been shown to be a reproducible estimator of the shock strength associated with 90% probability of successful defibrillation,11 and the energy of a noninducing shock can, therefore, be a reliable test of ICD system efficacy. In many patients, ICD implant testing can be performed without induction of VF using methods based on the ULV.5,6,11,14

Clinical assessment of the ULV is performed by delivering shocks coupled to overdrive ventricular pacing trains, usually at 500 ms. The pacing trains are necessary to establish a controlled electrophysiological substrate. Shocks induce VF only if they are delivered while the heart is actively repolarizing, during the vulnerable period, as shown in Figure 1. Shocks nearest in energy to the ULV will only induce VF near the peak of the vulnerable period. Assessment of the ULV involves identifying an electrocardiographic marker with a timing near the peak of the vulnerable period and delivering a series of shocks with coupling intervals that span timings near that marker. Generally, the marker used has been the peak of the latest peaking T wave on the surface 12-lead ECG. Because identification of the timing of this marker requires equipment,
Although TR does not precisely correspond to the peak of the T-wave shocks are delivered at a predetermined energy. Several studies suggest that the system timing marker for the vulnerable period, and a sequence of T-wave shocks are delivered at a predetermined energy. The interval from the R wave to the peak of the vulnerable zone, is an internal marker of repolarization. The interval from the R wave to the activation-recovery interval, which is the peak of the derivative of the intracardiac T wave, is an internal marker of repolarization. The interval from the R wave to the activation-recovery interval is often called the recovery time and is denoted as TR. TR is used as a reliable marker for the timing of the peak of the vulnerable zone.16,17

A new method for ICD testing has been developed in which vulnerable period timing is automatically determined by calculating TR from the far-field ICD electrogram. TR is used as the timing marker for the vulnerable period, and a sequence of T-wave shocks are delivered at a predetermined energy. Because the ULV defines the boundary between inducing and noninducing shock energy, noninduction of VF by this shock at the upper limit of vulnerability induces VF is sometimes called the peak of the vulnerable zone.

Because VF sensing is also assessed during ICD implant testing, some investigators have suggested induction of VF to test sensing if sinus rhythm R-wave amplitudes are small (usually <7 mV).14 A secondary objective, therefore, was to assess sinus R-wave amplitude as a screen for patients who may have poor VF sensing performance. We hypothesized that patients with VF undersensing will have small R-wave amplitudes in sinus rhythm. The study was an acute, prospective, nonrandomized, multicenter feasibility study.

**Methods**

**Patients**

Patients were candidates for this study if they were eligible to receive a Virtuoso ICD or Concerto cardiac resynchronization therapy defibrillator implant (Models D154AWG, D154VWC, C154DWK, or C164AWK; Medtronic, Inc, Minneapolis, MN), had a superior vena cava defibrillation coil, had a right ventricular defibrillation lead placed in the right ventricular apex, were >18 years of age, and were willing and able to give informed consent. The study was approved by the Institutional Review Board of each institution.

Patients were excluded for any of the following: frequent ventricular sensed intervals of <500 ms occurring at rest, pacemaker dependency, right-sided ICD systems, long-QT syndrome, Brugada syndrome, hypertrophic cardiomyopathy, congenital heart disease, use of intravenous inotropes, class IV heart failure, known elevated defibrillation threshold >35 J, use of class Ia, Ic, or III antiarrhythmics with the exception of amiodarone and procainamide, enrollment in a concurrent study that might confound the results of this study, or pregnancy.

**System Description**

The AVSM system consists of an investigational software for the Medtronic programmer that implements the automated implant test and downloadable ICD software. The recovery time, TR, is calculated by the downloaded software from the ICD far-field electrogram. Determination of TR has been described in detail previously.16,17 TRp is the peak of the derivative of the far-field intracardiac T wave and is calculated numerically after the electrogram is filtered. Because numerical differentiation amplifies high-frequency signal components, conventional numerical peak detection on a differentiated signal generally produces unstable results. A stable approximation to the peak of the derivative is the weighted mean of the derivative signal (the center of area to TR determined by the signal maximum. TRp has been shown to be very close to the visually identified peak of the derivative and to produce numerically stable results.17

TRp timing is automatically calculated from the T waves after the final 2 complexes invoked by an 8-pulse, 500-ms pacing train (8 V, 1.5 ms). Up to 4 additional pacing trains are initiated under physician control, each followed by an 18-J biphasic shock so that the waveform of the T-wave shock matches the waveform of defibrillation.
shock. T-wave shocks are aborted if there is evidence of loss of capture. The T-wave shock trains are separated by a minimum of 1 minute. The coupling of the shock to the final pulse in the pacing train is automatically determined by the software based on the calculated $T_p$. To ensure that the most vulnerable intervals are included in the shock range, the shock couplings range from 50 ms before the calculated $T_p$ to 10 ms after the calculated $T_p$, in 20-ms intervals. The couplings chosen are based on the results of a previous pilot study and adjusted to compensate for software delays in the ICD. If VF is not induced, the test takes $\approx$ 5 minutes to run. Because AVSM operates as a screen, the T-wave shock energy of 18 J was set conservatively low to be highly sensitive to patients requiring $>25$ J to defibrillate, with the trade-off that some patients with induced VF would have sufficient DSMs.

At the discretion of the investigator, a 12-lead surface ECG was collected simultaneously with telemetered device electrograms to allow comparison between $T_p$ and surface T-wave peaks.

### Protocol

Standard implant or change-out procedures were followed up to the point of defibrillation testing. A diagram of the procedure for vulnerability and defibrillation testing is shown in Figure 3. The first and second rescue defibrillation shocks were programmed to 22 J and 25 J, whereas defibrillation therapies 3 through 6 were programmed at the discretion of the investigator. After completing the AVSM test (4 noninducing 18-J T-wave shocks or any VF induction while delivering T-wave shocks during the vulnerable period), additional VF inductions were performed so that all patients had at least 2 induced VF episodes to determine the DSM. The additional VF inductions were performed for all subjects using the investigator’s method of choice, usually a 1- to 2-J T-wave shock or 50-Hz burst pacing. Implant criterion was at least 2 of 3 defibrillation successes at $\leq 25$ J (giving a 10-J safety margin). If an ICD system failed the defibrillation implant criterion, the investigator could conduct additional testing and revise the system.

Sinus rhythm R-wave amplitudes were recorded at implant. Consistent with standard implant guidelines, we called for a minimum R-wave amplitude of 5 mV for newly implanted ventricular leads or 3 mV for chronic leads. Ventricular sensitivity was set to a maximum R-wave amplitude of 5 mV for newly implanted ventricular leads or 3 mV for chronic leads. Ventricular sensitivity was set to a less-sensitive value of 1.2 mV during VF inductions.

### Data Analysis

For the AVSM protocol, a VF induction was defined to be a sustained polymorphic ventricular arrhythmia with cycle length $\leq 320$ ms, which was detected and had VF therapy delivered by the ICD.

To quantify VF undersensing, we examined all induced VF episodes for clear deflections on the ventricular tip-ring electrogram which were not sensed by the ICD. A 5-second delay in detection caused by undersensing was considered to be clinically significant.

The recorded 12-lead ECGs were measured post hoc to find $T_{peak}$, the peak of the latest peaking monophasic T wave that is opposite in polarity from the R wave. $T_{peak}$ is used for setting T-wave shock timings using standard ULV methods. Figure 4 shows an example of $T_{peak}$ and $T_p$ measurements for 1 patient.

### Statistical Analysis

We used a 2-sided exact binomial test to calculate the 95% CI for successful defibrillation at 25 J for patients in whom VF was not induced with the AVSM test. To draw conservative conclusions about population behavior, we used only results of the first VF episode. Using Bayesian statistical analysis, we also calculated the probability of defibrillation success at an energy of $\leq 25.1$ J, given AVSM noninduction. Analogous to the 95% CI used in conventional (frequentist) statistics, the Bayesian 95% credible interval we calculated showed the predicted range of that probability. This analysis used noninformative Jeffreys priors and the results of both defibrillation tests. The correlation between $T_p$ and $T_{peak}$ was calculated using a Pearson correlation. SAS version 9.2 for Windows was used for statistical analyses.
Results

Sixty patients were enrolled from 6 centers in the United States. Patient demographics were typical for patients implanted with standard or cardiac resynchronization ICDs (Table 1). The right ventricular defibrillation leads used were Models 6945, 6947, or 6949 (Medtronic, Inc, Minneapolis, MN) or Model 7120 (St. Jude Medical, St. Paul, MN). Table 2 lists patients excluded from data analysis, along with the reason for exclusion. None of the 6 exclusions was caused by failure of the AVSM software. All were excluded for typical reasons in a multicenter study.

VF Induction and Defibrillation

The collected induction and defibrillation data from 54 patients are summarized in Table 3. The AVSM test induced sustained VF in 10 patients (19%), nonsustained VF lasting for 4.2 seconds in 1 patient (2%), and no arrhythmias in 43 patients (80%).

All 44 patients (81%) in whom sustained VF was not induced by the AVSM test were defibrillated at shock energies of \( \leq 25 \) J. Of these, all 43 patients (80%) in whom the test induced no VF were also defibrillated at 22 J, and the 1 patient in whom nonsustained VF was induced required 25 J. Conversely, 4 of the 10 patients (40%) in whom the AVSM test induced sustained VF had at least 1 defibrillation failure at 22 J, and 2 (20%) had defibrillation failures at \( \geq 25 \) J. In the 2 patients with defibrillation failures at 25 J, the investigator was unwilling to reattempt 22 J and 25 J defibrillations before system modification, so it was not possible to verify whether the patients would have failed 2 of 3 defibrillation attempts.

For all 44 ICD systems that passed the AVSM test, the calculated 95% CI for successful defibrillation at 25 J was 92% to 100%. The CI for the 38 patients not on antiarrhythmic drugs other than digoxin was 91% to 100%. The corresponding 95% Bayesian credible intervals for the population success rate of defibrillation at 25 J were 97% to 100% and 97% to 100%, respectively.

TR and Tpeak Results

Loss of capture did not occur during pacing trains, but 1 patient had a single fusion beat. TR measurements were available from stored ICD data for 54 patients. TR during the initial pacing train occurred at 381 \( \pm 19 \) ms. The distribution of TR measurements is shown in Figure 5.

In all patients, TR was measured late on the upstroke of the T wave. Figure 6 shows an example of the right ventricular coil-can electrogram and the corresponding derivative signal on which the automatic TR measurement is made. Note that the center of area does not necessarily occur at the peak of the derivative signal. TR timing was not significantly different for patients in whom AVSM induced or did not induce VF (372 \( \pm 21 \) ms [n=10] versus 382 \( \pm 18 \) ms [n =44]; \( P=0.15 \)).

Of the 10 patients in whom the AVSM test induced VF, 2 patients were induced with the first T-wave shock at TR−30 ms, 7 with the second T-wave shock at TR−10 ms, none with the third T-wave shock at TR−50 ms, and 1 with the fourth T-wave shock at TR+10 ms. The interval from TR to the inducing shock was −12 \( \pm 11 \) ms. The range of pace-to-shock coupling intervals that induced VF ranged from 331 to 415 ms.

Corresponding Tpeak and TR measurements were available for 44 patients. Tpeak was collected in these patients as supplementary data and was not used to validate the algorithm, because prior studies had shown that Tpeak and TR measurements were not significantly different for patients in whom AVSM induced or did not induce VF.
identified slightly different sections of the vulnerable zone.\textsuperscript{16,17} \(T_R\) was 382 $\pm$ 20 ms, and \(T_{\text{peak}}\) was 367 $\pm$ 28 ms. The mean difference (\(T_R - T_{\text{peak}}\)) was 15 $\pm$ 21 ms. Figure 7 shows the correlation between \(T_R\) and \(T_{\text{peak}}\) (\(r=0.65\)). Consistent with the earlier retrospective analysis, \(T_R\) was generally slightly later than \(T_{\text{peak}}\).\textsuperscript{17}

### Relationship Between Sinus R-Wave Amplitude and VF Sensing

At least 1 undersensed event occurred in 42 of the 109 analyzed VF episodes (39%), with greater numbers of undersensed events occurring exponentially less often (Figure 8). No episode had as many as 6 undersensed events (25% of events in the 24-beat detection window). Undersensed events were not confined to patients with sinus R-wave amplitudes <7 mV; patients with R-wave amplitudes as large as 13 mV had undersensed events, and the 2 patients with sinus R-wave amplitudes <7 mV had adequate VF sensing. The undersensed events never led to >2.5-second delay in detection. Undersensing in patients with large R waves was because of rapid changes in amplitude between consecutive deflections. These results occurred with ventricular sensitivity set to 1.2 mV; undersensed events should be less common at a nominal sensitivity of 0.3 mV.

### Discussion

The principal finding of this prospective, multicenter study is that an automated method based on the ULV served as an effective screen for patients who have inadequate DSMs, often without the induction of VF. AVSM avoided VF induction in 85% of patients who passed subsequent confirmatory defibrillation testing, while identifying all patients with inadequate DSMs.

ICD implant testing is designed to assure appropriate device function at the time of clinical arrhythmia. Complications associated with DSM testing are rare, but there is increasing controversy over whether the risks of testing are justifiable, especially in primary prevention patients, many of whom may have no other episodes of VF.\textsuperscript{1,19–23} However, a combination of anatomic and physiological factors still contributes to a small percentage of patients being inadequately protected at the time of implant.\textsuperscript{1} No reliable method has been established for identifying these patients in advance, and there are no current guidelines for when ICD testing may be avoided.
and little prospective clinical data to assess the clinical safety question.\textsuperscript{1,2,3,20,21}

ULV-based testing methods have the potential to significantly reduce VF inductions at ICD implantation testing, while providing adequate sensitivity to detect patients requiring system revision. Vulnerability testing has the advantage that it screens for inadequate ICD DSM, yet significantly reduces the likelihood that a particular patient will experience an episode of VF compared with conventional defibrillation testing. Those patients who avoid VF induction will still experience four 18-J T-wave shocks. Although the 72 J of total energy delivered to the patient is somewhat greater than the \( \approx 54 \text{ J} \) that would be delivered during nominal DSM testing (induction energy-rescue energy for 2 episodes of VF), it is important to note first that the individual shocks are smaller than DSM rescue shocks, second that they are delivered into a nonischemic substrate, and third that at least 1 single-center study has found no evidence of increased myocardial damage from T-wave shocks that assess ULV, compared with defibrillation shocks that assess defibrillation threshold.\textsuperscript{24}

Those patients who fail the vulnerability screen (in this study, the 19% who were induced by AVSM testing) receive high-voltage ICD therapy, which begins the process of conventional defibrillation testing and thus have effectively the same experience as if AVSM testing had not been attempted. Therefore, the sensitivity of the screen can be made high, without exposing patients who fail the screen to any incremental risk relative to conventional testing.

ULV-based testing historically has consisted of identifying the repolarization period, or vulnerable zone, by manually measuring the timing of the T wave on surface ECGs, requiring extra time, additional equipment, and operator expertise during implant testing. With ULV testing, incorrect determination of T-wave timing could result in inadvertently delivering test shocks outside the vulnerable period. The result could be false reassurance of defibrillation efficacy. Thus, although ULV testing has been shown to be effective in numerous clinical trials,\textsuperscript{5-15} the extra steps and implanters’ lack of experience with the technique have hindered the wider clinical application of ULV as a screening test. An automated ULV system would have the benefit of assuring acceptable defibrillation function without the need for VF induction in most patients and without the obstacles posed by manual application of the technique.

Proof-of-concept studies were performed to develop a system that could be implemented in the ICD or programmer and would identify the vulnerable zone by automated analysis of the far-field electrogram of ICD.\textsuperscript{16,17} As in those studies, the automatically determined timing, \( T_{\text{Vul}} \), was close to the timing determined from the surface ECG, \( T_{\text{peak}} \). The present study establishes the clinical feasibility of using the automatically identified vulnerable zone in an automated system of ICD implant testing, the AVSM system. Using 18-J T-wave shocks, 100% of patients who passed AVSM testing had adequate DSMs. In contrast, 40% of patients who failed AVSM (4 of 10) had at least 1 unsuccessful defibrillation.

Although the sample size was limited, Bayesian statistical analysis of the primary results predicted that between 97% and 100% of patients not induced by AVSM would be defibrillated at 25 J. This compares favorably with the results of the Arrhythmia Single Shock Defibrillation Threshold Testing Versus Upper Limit of Vulnerability: Risk Reduction Evaluation study in which passing a 14-J vulnerability safety margin test with shock timing determined from the surface ECG had a 98.4% positive predictive accuracy for successful defibrillation at 21 J (10-J safety margin) in 394 patients.\textsuperscript{6}

VF induction at implant is also used to assess VF sensing. Often, VF inductions have been considered necessary in patients with sinus rhythm R-wave amplitudes <5 to 7 mV.\textsuperscript{5,6,14} This study found that clinically significant undersensing did not occur in any patient but found sporadic VF undersensing in patients with sinus R-wave amplitudes as large as 13.9 mV and adequate VF sensing in all patients with amplitudes between 3 and 7 mV. A significant number of induced VF episodes (39%) had at least 1 undersensed event, but only half that many (21%) showed at least 2 undersensed events, and the pattern continued for greater numbers of undersensed events. This suggests that the likelihood of large numbers of undersensed events, and therefore a clinically significant detection delay, is vanishingly small. It also shows an almost random pattern in the occurrence of undersensed events, rather than VF sensing being consistently poor. This not only demonstrates that sinus R-wave amplitude is a poor predictor of VF sensing but also suggests that implant testing for the purpose of evaluating VF sensing provides limited information. Sporadic VF undersensing never resulted in a detection delay >2.5 seconds, even at the reduced ventricular sensitivity value used for testing. The correlation between VF undersensing and R-wave amplitude at implant has been studied retrospectively in a much larger population with similar results.\textsuperscript{25} Standard practice calls for a minimum R-wave amplitude of 5 mV during initial lead placement. Our evidence suggests that no additional requirement on R-wave amplitude is necessary to ensure adequate VF detection, at least for patients with true bipolar sensing, as in this study.

Limitations
Because this was a feasibility study, sample size was necessarily limited. In particular, only 2 patients were found to

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**Figure 8.** Percentage of ventricular fibrillation episodes with undersensed depolarizations. The bars show the percentage of episodes with exactly \( n \) undersensed depolarizations. No episodes had \( >5 \) undersensed events. The line shows the cumulative percentage of episodes with \( n \) or fewer depolarizations. This number decreases exponentially, with roughly half as many patients having 1 additional event. This suggests that undersensed events are statistically independent, rather than part of a repeatable pattern of inadequate sensing.
require system revision. However, statistical analysis demonstrated the principal end point with >97% confidence. Several classes of patients were excluded from the study. In some cases, such as class IV heart failure or medical instability, the exclusion was not specifically related to the algorithm. The exclusion of rapid intrinsic rhythms was based on the inability to create a stable rhythm by overdrive pacing, as required for ULV-based testing. The exclusion of repolarization abnormalities such as long-QT or Brugada syndrome was because the vulnerable zone is intrinsically related to repolarization and there has been insufficient study of how these abnormalities affect vulnerable zone determination. These considerations also excluded patients on some antiarrhythmic medications. Single-coil and right-sided lead systems, as well as many patients with congenital abnormalities, use a different shock vector, which could also have an impact on exact vulnerable zone timing. Patients with single-coil systems likely could use the system but might need a slightly different timing range for T shocks and would have to be studied separately. The number of patients affected by these exclusions is relatively small, and this method could, therefore, be used on the vast majority of the ICD patient population.

**Conclusions**

This multicenter, prospective study was the first to use an automated system for ICD implant testing without VF induction. The AVSM test correctly identified all subjects with failed defibrillation, while inducing VF in only 19% of subjects. All subjects who passed the AVSM test were defibrillated successfully twice at ≤25 J. The AVSM algorithm provides a simplified practical tool for assessing DSM without inducing VF in most patients. It eliminates the need for any additional setup or expertise and substantially reduces the procedure time required by ULV or vulnerability safety margin testing based on the surface ECG. The results from the current pilot support the feasibility of conducting a pivotal trial to study AVSM as a practical screening tool for patients with high defibrillation threshold at the time of implantation.

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Defibrillation threshold testing at implantable cardioverter-defibrillator (ICD) implant is done to assure appropriate device function. Complications when inducing ventricular fibrillation (VF) are rare but do occur. However, upper limit of vulnerability (ULV)-based testing methods have the potential to significantly reduce VF inductions and still provide adequate sensitivity to detect patients with a high DSM who would require system revision or additional management strategies. In fact, ULV-based testing would allow most patients to undergo ICD implant testing without any VF induction. This method has been studied extensively in clinical trials, with documentation of both correlation to DFT and reproducibility. The traditional way of performing ULV-based testing requires identification of the vulnerable zone by manual measurement, which has required extra time, additional equipment, and operator expertise. These extra steps have hindered a wider clinical use of ULV as a method for ICD implant testing. This multicenter, prospective study is the first study to evaluate an automated system for inductionless implant testing based on ULV, thus removing the requirement for any manual measurements. Using an automated algorithm of T-wave timing measured on intracardiac electrograms, a vulnerability safety margin system could be established, which successfully identified all patients who failed conventional ICD testing, while inducing VF in only 19% of patients at implant. These results suggest that automated vulnerability safety margin testing could provide a practical tool for physicians at the time of ICD implant testing, allowing for a safety margin assessment without the need for VF induction.
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