Defibrillator Implantation Without Induction of Ventricular Fibrillation
Good Enough?

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An increasing number of cardiac electrophysiologists are fortunate not to have endured the challenges of implanting monophasic waveform cardioverter-defibrillators (ICDs). With early technology, ICDs were routinely tested during the implantation procedure and then again before discharge, with a not-infrequent need for system revisions. With transvenous, high-output devices and biphasic shocks, the number of patients who have an inadequate defibrillation safety margin (DSM) has become so small that questions have been raised about the need for testing at all. However, given the fact that ICDs are designed to be potentially lifesaving, it is incumbent on physicians to obtain a high level of assurance that the device will work as designed if needed. It also should be noted that all clinical trials of ICD therapy for the prevention of sudden cardiac death incorporated testing for the adequacy of the DSM.

Despite the fact that we usually call the sequence of induction of ventricular fibrillation (VF) and defibrillation at different energies in the electrophysiology laboratory “defibrillation threshold testing,” it is, in fact, usually a DSM that is determined. Particularly with the typical protocol of 2 defibrillations at a minimum of 10 J below the maximum output of the device, a true probability curve for defibrillation is determined.1 Particularly with the typical protocol of 2 defibrillations at a minimum of 10 J below the maximum output of the device, a true probability curve for defibrillation success cannot be constructed. Regardless, this protocol is well accepted in practice. An alternative approach is upper limit of vulnerability testing, which closely correlates with the defibrillation threshold.2 This method requires only 1 initiation of VF, but strictly performed, multiple shocks may need to be delivered before VF is induced and the energy corresponding to the upper limit of vulnerability is determined.

In the present issue of Circulation, Day et al3 present the results of the Arrhythmia Single Shock Defibrillation Threshold Testing Versus Upper Limit of Vulnerability: Risk Reduction Evaluation (ASSURE) study. In this study, 426 patients undergoing ICD implantation, including generator changes, for standard indications were prospectively studied to determine the efficacy of DSM testing with a single induction of VF and delivery of a 14-J shock versus a vulnerability safety margin (VSM) approach. The latter differs from upper limit of vulnerability in that only a single energy (14 J) is tested, albeit 3 separate times at different intervals related to the peak of the paced T wave. VSM testing will not result in induction of VF if the upper limit of vulnerability is ≤14 J.

By the design of the study, both DSM and VSM were tested in every patient in a randomized fashion, with 2 subsequent “confirmatory” tests at 21 J. Patients who passed the initial DSM or VSM test, regardless of the outcome of the other test, and passed both confirmatory tests were followed up in the study with a first shock for VF set at 21 J. Patients who did not pass both the initial and confirmatory tests were followed up in a registry and had revisions to their system as necessary to achieve an adequate safety margin. Given that the maximum output of the ICDs was 31 J, the 2 confirmatory tests at 21 J mirror clinical practice for DSM testing and allow direct comparison with study results. Because the goal of the study was to evaluate the predictive value of DSM with VSM for successful shock delivery in follow-up, it is the study patients rather than the registry patients who are of greatest interest.

For DSM, 338 of 343 patients who passed the initial DSM test also passed the 21-J confirmatory tests (98.5%); for VSM, the numbers were almost identical (317 of 322, 98.4%). The fact that a handful of confirmatory tests in each case failed reinforces the probabilistic nature of this testing. Even the flat part of the defibrillation success curve indicates a 99% success rate, and the energy associated with that level can never be determined exactly. Therefore, the single tests, either DSM or VSM, in each case provided an acceptable level of assurance that an adequate safety margin was present. The results also indicate that, if these procedures were adopted into clinical practice, ≈1.5% of patients would be deemed to have successful testing but would have failed the standard approach of testing 2 shocks at 10 J below the maximum output of the device.

When patients were crossed over to the alternate testing procedure, 65 patients who had passed either DSM or VSM failed the other technique. Of these patients, 60 of 64 passed the two 21-J confirmatory shocks, which is a failure rate of 6.3%. One patient apparently did not have 21-J testing data available. A failure rate of >6% is a bit concerning because these patients would not be detected in clinical use of this approach and they indicate a borderline safety margin.
Whatever the results of acute testing, the key point is whether the potentially life-threatening arrhythmias that developed in follow-up were appropriately detected and terminated. Because the initial shocks were programmed to 21 J, more information was obtained about the adequacy of the safety margin than if 31-J shocks were programmed. In ASSURE, over a follow-up period of 9.5±4.5 months, there were 45 treated episodes (25 VF, 17 ventricular tachycardia, and 3 polymorphic ventricular tachycardia) in 25 patients. Among the patients in the analysis cohort who had passed all initial testing and who had their first shock energies set to 21 J, 32 of 37 episodes of spontaneous fast ventricular tachycardia/VF (86%) were terminated with 21-J shocks, and 100% were terminated with 31-J second shocks when necessary.

A limitation of the study is the relatively short follow-up period and the low number of spontaneous arrhythmias for which shock efficacy could be evaluated. In particular, it is not clear whether any spontaneous arrhythmias occurred in the 10 patients who passed the initial DSM or VSM test and then failed either of the 21-J confirmatory tests. These are the patients who would potentially be at risk if this new approach was adopted because the confirmatory tests would not be performed in clinical practice. These 10 patients would have been followed up in the registry, in which there were only 8 arrhythmic episodes in 98 patients, and only 6 of these terminated with an initial 31-J shock.

Because VSM testing usually does not result in VF induction, the adequacy of sensing cannot be directly determined. In ASSURE, there was a requirement that the intrinsic R-wave amplitude be at least 7 mV for an initial implant and 5 mV for a generator replacement to have a reasonable level of assurance that sensing during VF would be adequate. The direct assessment of sensing during VF that is possible during DSM is therefore a distinct advantage of this approach.

In addition to the observed success rates with either approach, other important factors include the time involved with testing and the safety of the testing. The typical approach used in practice of 2 inductions and defibrillations with 15 to 30 minutes. The DSM time was lower simply because 1 induction was performed instead of 2. The VSM method requires 3 shocks, but because VF was not induced with successful testing, only 1 minute was allowed to elapse between shocks. The VSM method is also a little more cumbersome in that a 12-lead ECG machine should be connected to the patient, and someone needs to measure the time to the peak of the T wave to set the timing of the T-wave shocks correctly. If only 3 ECG leads were recorded, 4 T-wave shocks were delivered to allow for underestimation of the peak of the T wave.

Simplification of the testing procedure during ICD implantation may allow greater hemodynamic stability, which is highly desirable given the poor ventricular function of many patients indicated for ICD therapy. Among 87 patients studied at a single center (to ensure standardization of anesthesia delivery), there were no instances of hypotension among patients tested with VSM, whereas 2 patients tested with DSM had transient drops in blood pressure that recovered quickly.

The results of ASSURE confirm the findings of the Low Energy Safety Study (LESS). In that study, among 720 patients undergoing initial ICD implantation, 318 patients were programmed to a maximum output of 31 J in follow-up. Of these 318 patients, 254 had successful defibrillation with a 14-J shock at the first VF induction. Over a follow-up period of 24±12 months, there were 112 ventricular tachycardia/VF episodes in 31 patients. There was no difference in the success of the first and second shocks (when needed) for termination of spontaneous ventricular tachyarrhythmias whether the patient had an initial success with 14 J or underwent more systematic testing.

So, what have we learned from these studies? We know from clinical experience that the practice of inducing VF at least twice and defibrillating the patient with a shock set at least 10 J below the maximum output of the device is a quick and reliable method of estimating the DSM, even if it tends to overestimate the true defibrillation threshold. Both LESS and ASSURE show that a single induction of VF with defibrillation at 14 J appears to be as reliable in predicting efficacy in follow-up, assuming a device with a maximum output of at least 31 J. ASSURE also has shown that a VSM approach, in which no induction of VF is necessary if the 14-J test is above the upper limit of vulnerability, appears to predict efficacy in follow-up equally well. However, the small number of arrhythmias in follow-up means that some caution is necessary in accepting this conclusion, and further study would be helpful. Other caveats are the minor inconvenience of having a 12-lead ECG machine attached to the patient and determining the timing of the peak of the T wave (or a 3-lead ECG and delivery of a fourth shock) and the fact that sensing is not directly tested. However, if avoidance of VF induction is desirable because of marginal hemodynamic stability, the VSM approach should be considered. Even here, success may be expected in only 76% of the patients, and further testing is still necessary. Given that there is still a small percentage of patients who fail DSM testing (6.2% in 1 series), some assessment that defibrillation will be adequate for the spontaneous arrhythmias that develop in follow-up is essential with ICD therapy, whatever the testing approach used during implantation.

Disclosures
Dr Curtis has received a research Grant from Medtronic; has served on the speakers’ bureau for Medtronic, Boston Scientific, and St Jude Medical; and has served as a consultant or on the advisory board for Medtronic and St Jude Medical.

References


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