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EDITORIAL COMMENT

Defibrillation Testing

Should the Paradigm Shift?*

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In 3 decades of clinical use of the implantable cardioverter-defibrillator (ICD), defibrillation threshold (DFT) testing has remained an integral part of the implantation procedure. The prevailing rationale for the routine evaluation of DFTs has been to ensure appropriate sensing of ventricular fibrillation, system integrity, and effective defibrillation (1–3). Early ICD systems using monophasic waveforms with epicardial patches or transvenous leads were associated with a substantial incidence of elevated DFTs, requiring additional intervention to ensure clinical efficacy (1–3). Technically, the DFT is a probabilistic phenomenon requiring multiple shocks to determine with precision. Clinically, the DFT is commonly approximated with 1 or more shocks to terminate induced ventricular fibrillation and ensure a safety margin between the DFT and the maximum output of the ICD. Inadequate safety margins of <10 J between the DFT and maximum ICD energy delivery have been associated with worse clinical outcomes (3). Contemporary ICD systems using active cans, pectoralis pulse generators, biphasic waveforms, and intravascular high-voltage leads have considerably lowered the incidence of elevated DFTs (4–13). The reliability of current ICD systems has led implanting physicians to abandon the practice of routine testing of defibrillation efficacy before hospital discharge and annually. Observational studies also have noted an elimination of DFT testing in one-third of initial implants and two-thirds of replacements (14–16). Indeed, based on a growing body of evidence, the clinical utility of the determination of defibrillation efficacy during de novo implants has been questioned (4–13). With this background, it is appropriate to re-evaluate whether DFT testing still should be routinely performed at the initial ICD insertion procedure.

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Multiple arguments and lines of evidence support the routine evaluation of DFTs at ICD insertion (1–3). The prospective randomized trials demonstrating efficacy of the ICD for primary and secondary prevention of sudden death have required DFT testing. Evaluation of DFTs allows verification of sensing, integrity of the high-voltage system, and programming lower initial shock energy for ventricular fibrillation at 10 J over the DFT (1–3). Testing of defibrillation efficacy represent a historical standard of care, and eliminating the DFT testing may present a medical legal issue for the physician performing the implantation (1–3). However, the evidence supporting continued DFT testing is limited by the absence of a prospective randomized trial with appropriate clinical outcomes.

The arguments and evidence against the determination of the DFTs include the risks of major complications related to the testing (1–18). Death, stroke, myocardial infarction, and anesthesia-related complications related to DFT determination are reported in <1% of implants. However, registry and observational data may under-report the frequency of complications. Inadequate safety margins with current ICDs are very uncommon. Implant DFTs and safety margins have not been shown to predict long-term mortality or first shock efficacy for contemporary ICDs (1–18). Other cogent arguments have been advanced against DFT testing (19).

Predictors of high DFTs with ICD systems include ventricular dilation, increased left ventricular mass, severely impaired left ventricular function, heart failure, young age, increased body size, and single coil leads (4–7). Multiple measures can be employed in an attempt to lower the DFT and thereby increase the safety margin. These include lead repositioning, reprogramming polarity, altering waveform tilt, removing or adding a superior vena cava lead, adding a subcutaneous array, or implanting an azygous vein high-voltage lead. Given the probabilistic nature of the DFT and the absence of conclusive evidence that the DFT predicts clinical outcomes, some clinicians believe that the additional risk of these interventions may not be justified.

In this issue of the *Journal*, Brignole et al. (20) report the results of the SAFE-ICD (Safety of Two Strategies of ICD Management at Implantation) study, which provides additional evidence regarding DFT testing at initial implant. The investigators report results from a prospective observational study designed to evaluate the outcome of 2 strategies: performing defibrillation testing (DT+) versus not performing defibrillation testing (DT−) during de novo ICD implants (20). The 41 participating Italian centers continued their standard practices related to DFT testing for the 2,120 consecutive patients undergoing initial ICD insertion during a 1-year period (20). The primary endpoint, a composite of severe complications at ICD implant and sudden cardiac death or resuscitation, was not different in the 2 groups. During the 2 years of follow-up, it was reached in 1.72% of the DT+ patients and 1.02% of the DT− patients, with no difference on mortality (20). The authors conclude that event

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rates were similar and extremely low in both groups and that DFT testing has limited clinical relevance. The investigators note that these data support the strategy of omitting DFT during initial ICD implantation (20).

Although this study is important and adds additional insights, as an observational rather than randomized trial it does not provide conclusive evidence. The SAFE-ICD trial is the largest study evaluating the strategy of initial ICD implant with or without DFT testing (20). The multicenter design, enrollment of almost all eligible patients consecutively, and 2-year follow-up are strengths of the study (20). However, the absence of randomization resulted in confounding differences in the clinical profiles of patients enrolled in the 2 strategies (20). Patients undergoing DFT testing had a lower rate of class III or class IV heart failure, atrial fibrillation, higher ejection fraction, and less use of diuretics and digoxin (20). The study was powered to detect a difference in the 2 groups with the assumption that the primary endpoint would be reached in 2.5% of patients (20). With a lower than expected number of patients reaching this endpoint due to a low incidence of sudden death, ultimately, the study was underpowered to detect a difference in the 2 groups. It is noteworthy that 42% of ICDs placed were for cardiac resynchronization therapy and 29% for secondary prevention. Only 33% of cardiac resynchronization therapy ICDs and 37% of secondary prevention devices had DFT testing performed. Many prior observational studies have omitted DFT testing selectively in de novo ICD implants placed for primary prevention (3–18).

Although the SAFE-ICD study supports the paradigm shift toward elimination of DFTs at initial implants, it does not conclusively resolve the issue (20). The investigators make a meaningful contribution to the collective evidence that routine determination of DFTs has more risks than benefits for many patients at the time of initial ICD insertion (20). Indeed, the recently reported trends of eliminating DFT testing reflect the growing recognition by implanting physicians that routine DFT testing in selected patients is of limited clinical value (9,15). However, as an observational trial with the limitations noted, it does not provide definitive evidence that omission of DFT determination in all de novo ICD implants is clinically justified. More conclusive data are anticipated within 1 year from the results of a multicenter prospective trial that completed randomization of 2,500 patients in April 2011 to DFT testing versus no DFT determination (21). It is evident that the paradigm should not yet shift to elimination of DFT testing in all patients until more conclusive evidence is available. The safety of using this approach for high-risk patients remains unknown. In the meantime, implanting physicians will have to decide on the basis of the best available data, their experience, and judgment whether to omit DFT testing selectively in lower-risk patients.

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