JACC: CASE REPORTS VOL. 2, NO. 2, 2020

EDITORIAL COMMENT

New Therapy, New Complications*

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With the introduction of every new technology, we must learn how to omitclar and deal with new types of complications. That was exactly what happened to Elder and Al Hashimi (1), who were kind enough to share their experience in this issue of *JACC: Case Reports*, which we have read with a great interest. Their case presents an uncommon mechanical complication of defibrillation threshold testing (DFT) following subcutaneous implantable cardioverter-defibrillator (S-ICD) implantation, resulting in a left subcapital humerus bone fracture. The investigators clearly presented and discussed a possible mechanism of its origin, resulting from a forceful pectoral muscle twitch related to ventricular fibrillation induction and high-voltage shock delivery.

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Since the introduction of ICD in the early 1980s, routine defibrillation testing of cardiac implantable electronic devices evolved from DFT to safety margin testing in the modern era. The primary objective of such tests has been to confirm the ICD's ability to sense, properly detect, and deliver shock terminating the arrhythmia with adequate safety margin. Safety margin testing is based on confirming a successful defibrillation at shock with delivered energy output below the maximum for the tested device (safety margin is typically ≥10 J). In the early years of first-generation ICD devices, the risk of failing to successfully terminate arrhythmia was higher and mainly related to technological imperfection (i.e., monophasic shock, epicardial patches). Along with the advances of ICD systems (i.e., biphasic shocks, reversed polarity, change of the vector, modification of defibrillation waveforms), the success of defibrillation has been greatly enhanced, and the mean defibrillation thresholds were reduced.

Currently, the majority of patients receiving conventional ICDs do not benefit from routine DFT (2,3). Although it may be safe and well tolerated, it does not improve survival or improve the delivered shocks' efficacy (4–6). When DFT is performed, the risk-to-benefit ratio and its questionable effect on long-term clinical outcomes should always be taken into account. The lack of correlation between induced and spontaneous ventricular arrhythmias and potential risk of complication (i.e., inability to convert, complications related to general anesthesia, prolonged resuscitation, stroke, or death) undermine routine DFT utility. It is reasonable to omit DFT in patients undergoing an initial left pectoral conventional ICD implantation procedure where appropriate device parameters are obtained and the right ventricular lead is well positioned with the use of fluoroscopy (3).

Nonetheless, there are some specific clinical scenarios in which DFT in conventional ICDs should be strongly considered. These include right pectoral transvenous ICD implantation or ICD pulse generator reimplantation, intraoperative concerns regarding ICD system integrity, suboptimal sensing (R-wave <5 mV), initiation of amiodarone in the setting of a marginal defibrillation threshold margin, patients with a higher incidence of ventricular arrhythmias (e.g., secondary prevention), and implantation of a fully subcutaneous ICD system (7).

Currently, the maximum output of the S-ICD device is 80 J and implant testing typically is performed at 65 J, with a successful defibrillation indicating a safety margin of 15 J. Patients receiving S-ICD should routinely undergo DFT, given that there is limited evidence available regarding the efficacy and safety of not performing DFT in this population (3,7,8).

*Editorials published in *JACC: Case Reports* reflect the views of the authors and do not necessarily represent the views of *JACC: Case Reports* or the American College of Cardiology.

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ISSN 2666-0849 https://doi.org/10.1016/j.jaccas.2019.10.044

Current guidelines still give Class I recommendation for DFT testing during S-ICD implantation (9). However, a recent analysis of the National Cardiovascular Data Registry, which includes data for more than 8,000 patients, demonstrated that DFT testing at the time of S-ICD implantation is performed only in 71% of cases and is mainly driven by facility preference to a greater extent than patient factors (10).

In the EFFORTLESS S-ICD (Evaluation of Factors Impacting Clinical Outcome and Cost Effectiveness of the S-ICD) registry, 861 patients underwent DFT testing at the time of implantation, and only 0.5% had an inadequate safety margin (11). In a small observational study of 178 patients by Peddareddy et al. (12), there was no significant difference in first shock efficacy among patients who had DFT testing at the time of S-ICD implantation compared with those who did not. In another small study, Al-Ghamdi et al. (13), when compared with 30 consecutive patients who received an S-ICD and single-chamber transvenous ICD during the same period, there was no significant difference in mortality. Without randomized trials to confirm these observational data, we still should follow the guidelines. We should always keep in mind an important technical distinction in S-ICD compared with transvenous systems. Subcutaneous ICD has a fixed lower-sensing floor of 0.08 mV and a low high-pass filter of 3 Hz, which can present issues regarding the appropriate detection and treatment of ventricular arrhythmias (10). The DFT is considered to be the ultimate test of optimal system positioning.

In a recent multicenter study, le Polain de Waroux et al. (8) assessed the quality of sensing during induced ventricular fibrillation in the 137 patients who underwent the S-ICD implantation. They observed a marked sensing delay, leading to prolonged time to therapy in a large number of S-ICD recipients (undersensing with moderate prolongation <18 s of time to therapy in 51%; undersensing with significant prolongation of the time to therapy >18 s in 14%), whereas optimal detection was noted only in 29% of cases (8). Finally, in 4% of the patients, the device failed to recognize and treat ventricular fibrillation due to noise oversensing at the time of implantation, which was resolved by changing the sensing vector. In their conclusions, the investigators strongly suggested that their results support the need for systematic intraoperative defibrillation testing mainly because of a marked sensing delay led to prolonged time to therapy in a large number of patients who received S-ICD.

In a study by Frommeyer et al. (14), the investigators found that in 25% of S-ICD cases, the primary intraoperative DFT was not successful; however, in most cases, it could be achieved by changing shock polarity or optimizing its vector by lead or pulse generator repositioning.

It should also be mentioned that some risk factors, such as obesity or overweight, have inadequate safety margins in S-ICD implantation. An analysis of the S-ICD IDE (Investigational Device Exemption) study found higher body mass index to be associated with a higher rate of first shock failure during device implantation (15). It is also suspected that increased adipose tissue leads to higher lead impedance measurements. A case report of high DFT testing with S-ICD lead position in the fat layer demonstrated improved shock effectiveness by repositioning the lead to just above the sternum (16).

These results strongly support the continued need for intraoperative defibrillation testing in the S-ICD population but, over time, with continued enhancement of technology, DFT in these patients might be simplified as well. The ongoing PRAETORIAN-DFT (Prospective Randomised Comparative Trial of Subcutaneous Implantable Cardioverter-Defibrillator Implantation With and Without Defibrillation Testing) trial will randomize patients with S-ICDs to DFT and non-DFT groups, and the results should shed some light on this issue (17).

Apart from obligatory DFT in the population of patients who received S-ICDs, other common problems are present. Lead or pulse generator migration often requires surgical revision or changes in device settings. Inappropriate sensing due to chest muscle noise, oversensing of T waves, and inadequate shocks require dedicated programming.

S-ICDs are being implanted worldwide with growing evidence regarding their efficacy and safety; therefore, Elder and Al Hashimi (1) have proposed that an adducted position of the arm before DFT in S-ICD recipients to prevent the described complication is especially important to improve the overall safety of S-ICD implantation.

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KEY WORDS complication, defibrillation threshold testing, device implantation, humerus fracture, subcutaneous implantable cardioverter-defibrillator