A Better Method for Preventing Adverse Clinical Events Caused by Implantable Cardioverter-Defibrillator Lead Fractures?

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In October 2007, the Medtronic Sprint Fidelis implantable cardioverter-defibrillator (ICD) lead was voluntarily withdrawn from the market by the manufacturer because of a higher-than-expected fracture rate. Most Sprint Fidelis fractures involve the pace-sense component of the lead, which may cause oversensing of electrical artifacts, undersensing of ventricular depolarizations, and/or loss of ventricular capture. Approximately 10% to 20% of Sprint Fidelis fractures involve the high-voltage conductor, which may compromise defibrillation. The most common clinical consequence of pace-sense conductor fracture is inappropriate shocks, which often occur in painful clusters and without warning. Inappropriate shocks may be proarrhythmic and lethal, and patients who experience them may suffer psychological sequelae. ICD lead failures are more likely to result in oversensing than pacemakers because the ICD pulse generators use high-sensitivity amplifiers to effectively detect ventricular fibrillation (VF). In this issue of Circulation, Swerdlov et al describe a new algorithm that may avoid or reduce inappropriate shocks and other serious adverse events in patients with failed Sprint Fidelis and possibly other high-voltage leads. If this algorithm proves to be safe and effective, it will be an important advance in ICD therapy.

Fracture of a transvenous high-voltage ICD lead was first observed in the original CPI Endotak model in 1988. Patients who had this lead suffered multiple inappropriate shocks, and it was withdrawn from clinical trial. Since then, conductor fractures and insulation disruption have challenged engineers and physicians to develop improved designs and implant techniques. Progress has been made, but not without setbacks. The Medtronic Transvene lead, a coaxial polyurethane design introduced in 1993 and implanted in >24,000 patients, exhibited both insulation degradation and conductor fractures; these failures typically appeared ≥4 years after implant and most commonly presented as inappropriate shocks. A mismatch between the terminal pin of the Boston Scientific Endotak DSP and the pulse generator connector header resulted in insulation and conductor defects when the pin punctured the lead; again, inappropriate shocks were the usual consequence. Surgical methods have contributed to lead failure, including subclavian venous access techniques that may entrap leads and cause crush fractures. Additional lead failures associated with inappropriate shocks have been the result of poorly designed or applied suture sleeves, iatrogenic damage during implant, insulation erosion in the pocket, unique patient factors (such as age and activity level), and normal wear and tear.

The long-term survival of ICD leads and the incidence of various failure mechanisms are poorly characterized because there is no standard definition of lead failure and no universal approach to gathering and analyzing data. The consequence is a wide range of reported failure rates and mechanisms. For example, during a median follow-up of 2.6 years at a single center, Kleeman et al found that 148 of 990 ICD leads (15%) failed, 12% as a result of fracture. Of interest, only 33% of their observed lead failures presented with inappropriate shocks or other clinical signs, and the remainder were diagnosed at routine follow-up or intraoperatively by impedance measurements. In contrast, Eckstein and colleagues in a multicenter study of 1317 leads found just 38 lead failures (2.9%) during a median follow-up of 6.4 years. However, more than three quarters of these failures presented as inappropriate shocks, and 24% of them were caused by lead fracture. The differences between these 2 recent studies illustrate how difficult it is to make definitive statements about the clinical performance of ICD leads.

Nevertheless, inappropriate shocks are the hallmark of ICD lead failure. Of 350 ICD lead failures that have been reported to the Multicenter Registry over the past 10 years, 165 (47%) were heralded by inappropriate shocks caused by conductor fractures (n=94; 57%), insulation defects (n=44; 27%), and/or active fixation malfunctions (n=9; 5%). Oversensing was documented in 94% of the leads that precipitated these shocks, but only 21% of them were found to have abnormal pacing impedances. These and other ICD lead problems have prompted the development of noninvasive diagnostic tools that assess lead integrity and that may alert patients and their caregivers when flaws are detected, preferably before they cause adverse clinical events. Current Medtronic ICDs perform daily automatic pacing and high-voltage conductor impedance measurements by delivering subthreshold synchronized pulses between electrodes; the resultant voltage and current values are used to calculate impedance. The impedance measurements are nominally...

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taken at 3 AM, and, if they are out of normal range, an audible alert is emitted by the pulse generator at 8 AM.

Recently, we reported that impedance monitoring alone, as implemented in Medtronic ICDs according to the manufacturer’s recommendations, failed to prevent inappropriate shocks in our patients whose Sprint Fidelis leads fractured. Of the 12 inappropriately shocked patients, 4 had no substantial increase in lead impedance before receiving shocks, 3 were shocked <3 hours after their lead impedances exceeded the alert threshold, and 2 did not hear the 8 AM alert. However, all of them had evidence of oversensing from <1 day to 3 weeks before being shocked. Oversensing in these patients was manifested by excessive short-interval counts or noise on the stored intracardiac electrogram. Thus, lead impedance changes often occurred too late to provide a timely warning of impending inappropriate therapy. Our study also suggested that lead noise may be a useful early indicator of Sprint Fidelis fracture. Indeed, Gunderson and colleagues in 2004 demonstrated that the combination of rapid oversensing detection and abnormal impedance could provide an early warning of impending lead failure with 83% sensitivity and 100% specificity. The oversensing measures included a counter for nonphysiological short intervals <140 ms and nonsustained ventricular tachycardia (VT) <200 ms.

The Lead Integrity Algorithm (LIA) described in the present study by Swerdlow and coworkers builds on the foundational methods described by Gunderson et al, so that an abnormal change in lead impedance or evidence of lead noise initiates a sequence of actions by the ICD, namely, (1) the number of intervals to detect (NID) VT or VF is set to 30 of 40 to reduce the likelihood of inappropriate shocks; (2) the audible patient alert is triggered and repeats every 4 hours; and (3) a wireless Internet-based message is sent to a monitoring center provided that the system is activated, and the response to magnet application changes from the normal continuous tone. The LIA’s impedance is calculated using a weekly average of maximum and minimum impedances, and the threshold for an alert is adjusted automatically. This approach provides a patient-specific impedance threshold that is continuously updated, which differs from the original method in which the threshold is manually adjusted by programming during implant or follow-up. Compared with optimal impedance monitoring, the authors found that the LIA would provide most patients with a 3-day warning of inappropriate shocks.

In its October 2007 letter to physicians, Medtronic recommended programming the NID to 18 of 24 intervals to reduce the likelihood of inappropriate shocks due to a Sprint Fidelis fracture. This NID setting also incidentally reduces unnecessary shocks in many patients who have self-terminating VT/VF without substantially delaying therapeutic shocks. Increasing the NID to 30 of 40 in response to the LIA alert will further decrease the incidence of inappropriate shocks, but the obvious risk is a further delay in therapy for true VT/VF (increasing specificity while potentially decreasing sensitivity). Although the risk may be minimal, physicians should recognize that the LIA was validated on the bench utilizing data from several Medtronic proprietary databases. It was not tested in patients who had the algorithm downloaded into their ICDs. The NID performance in this study could have been affected by the data sets extracted from stored diagnostics and electrograms. Moreover, the safety of increasing the NID to 30 of 40 intervals for VF detection was inferred from the results of the Medtronic-sponsored Primary Prevention Parameters Evaluation (PREPARE) study, a nonrandomized, historically controlled, prospective, multicenter investigation of patients who received ICDs for primary prevention of sudden death and who had not had a sustained VT or VF episode requiring ICD therapy. It is possible that patients who have ICDs for secondary prevention or who have received ICD therapy for VT or VF could be placed at risk with an NID that is automatically set to 30 of 40 intervals. The authors emphasize the importance of a prompt clinical response to the LIA, ie, disabling VT/VF detection and performing a lead assessment, but the real-world effectiveness of the new alert features is unproven. Hence, although the results of this study are compelling, they are not definitive, and the LIA should be evaluated thoroughly in a prospective clinical trial that examines its performance in a diverse patient population.

Medtronic began implementing the LIA in the United States in mid 2008 after receiving approval from the Food and Drug Administration. However, patients are undergoing RAMware downloads on the basis of limited safety and efficacy data, and the Food and Drug Administration has not announced that it is requiring Medtronic to conduct a follow-up study. Although it is reasonable to apply the LIA in primary prevention patients who have Sprint Fidelis leads and who have not required antiarrhythmic pacing or shocks for VT or VF, the suitability of this novel algorithm for other patients who have Sprint Fidelis leads is less certain. Physicians should evaluate each patient and determine whether the LIA is appropriate on the basis of the indication for ICD implantation, subsequent therapy history, and other clinical variables, including the use of antiarrhythmic agents. The LIA is designed primarily for patients who have Sprint Fidelis leads, and its performance in patients who have other high-voltage leads is unknown. Furthermore, as the authors observe, this is the first downloadable RAMware that triggers real-time changes in VF detection. This function requires postimplementation surveillance to determine whether the installed RAMware is performing as expected.

The LIA algorithm will be a significant improvement in device therapy for sudden cardiac death if it is proven to be safe and effective in clinical studies. It offers the potential to avoid a major complication of ICD therapy and to prevent pain and anxiety. However, this advance is not a victory. There will always be a role for early indicators of lead failure, but the medical community, industry, and regulators should strive for a single goal, namely, to provide patients with leads that are so reliable, well tested, and durable that the LIA and similar fail-safe techniques are rarely needed.

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References


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