Management of the Patient With Implantable Cardioverter-Defibrillator Lead Failure

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A 52-year-old man was brought to the emergency department because of multiple implantable cardioverter-defibrillator (ICD) shocks. His existing dual-chamber pacemaker was upgraded from a biventricular ICD 4 years ago. The ECG in the emergency department showed sinus tachycardia with left bundle-branch block at a rate of 135 bpm. In the emergency department, the patient received 5 additional shocks without a change in rhythm. A donut magnet was placed over the ICD. Interrogation revealed evidence of a lead fracture, and tachycardia therapies were disabled. The high-voltage lead was a Medtronic Sprint Fidelis ICD lead. Admission to the hospital was recommended for definitive correction of his problem.

ICD Lead Failure

This case illustrates the most common presentation of an ICD lead failure and the resulting management challenges. Lead failure is typically thought of as an intrinsic design or construction defect leading to an adverse clinical event. However, any adverse clinical event mediated through malfunction of an ICD lead represents lead failure. An ICD lead failure can occur in any patient, even with leads that have a proven record of reliability.

Incidence

The overall incidence of ICD lead failure is difficult to assess because of its underreporting and the absence of strict reporting requirements. Random component failures in individual patients are especially difficult to quantify, but some studies suggest a failure rate of ≈0.58%/y among modern ICD leads. Leads that have undergone manufacturer advisory or Food and Drug Administration alerts have a much higher incidence of failure. Examples of ICD leads with high failure rates include the Guidant Endotak DSP (model 0125) and the Medtronic Transvene (model 6936). The 6936 lead had a 90% survival rate at 4 to 5 years and a nearly 60% survival rate at 8 to 9 years. Therefore, lead failure rates are not linear over time. The recent recall of the Medtronic Sprint Fidelis leads is a much larger clinical problem. An estimated 205,600 leads were implanted in the United States, and an estimated 151,100 leads are in active use. It is estimated that only a small number of the remaining leads were explanted or abandoned. Most were likely to belong to patients who expired (unrelated to lead malfunction) or were lost to follow-up. The Medtronic Product Performance Report (available at www.medtronic.com/crm/performance.html) shows an estimated survival rate of 94.2% at 48 and 57 months, implying a stabilization of the incidence of lead failure. One independent study suggests that the incidence of Sprint Fidelis failure is as high as 3.75%/y and that the rate of failure does not plateau. In this study, the lead had an 87.9% lead survival at 3 years.

Mechanisms of Lead Failure and Clinical Presentations

A basic understanding of lead design is needed to understand the mechanisms of lead failure, clinical manifestations, and management. Modern transvenous ICD leads use a multiflumen design with the conductors arranged in parallel rather than coaxial. Figure 1 shows a schematic diagram of a true bipolar and integrated bipolar lead. The components of an ICD lead include the conductors, insulation materials, defibrillation coils, lead electrodes, fixation mechanism, yoke (branch point of individual conductor elements; see Figure 1), and lead connectors. Failure can occur in any component of the ICD lead. In a true bipolar...
lead, the ring electrode and defibrillation coil have independent conductors. In an integrated bipolar lead, the distal defibrillation coil also serves as the ring electrode. Therefore, in an integrated bipolar design, failure of the conductor to the distal (right ventricular) coil will necessitate replacement of the entire lead. A newer lead design incorporates an in-line arrangement to form a single connector pin (instead of 2 or 3 pins), the proposed DF-4 (or IS-4) connector. This design eliminates the yoke. Currently, this lead design is offered only by St. Jude Medical, Inc. The Medtronic Sprint Fidelis lead has well-described mechanisms of failure. Fracture of the conductor to the ring electrode accounts for 90% of failures. Only 10% of failures are due to fracture at the DF-1 connector segment or the proximal portion of the right ventricular coil.

ICD lead failures can occur as a result of body/lead interaction, improper implantation technique, and intrinsic design defects. Subclavian crush syndrome, exit block, and metal ion oxidation are examples of lead failure caused by the interaction of the lead and the body. Subclavian crush syndrome is associated with a medial access site with the lead passing through the costoclavicular ligament, resulting in conductor fracture. Exit block occurs in the chronic phase of lead-myocardium interface maturation as a result of the formation of scar tissue. Progressively increasing capture threshold can result in the need for lead revision. Metal ion oxidation, calcification, and environmental stress cracking are examples of biochemical processes that lead to insulation failure. Insulation failures generally occur as random events rather than systematic failures caused by lead design. The Twiddler syndrome, in which the patient consciously or unconsciously manipulates the device within the pocket, resulting in twisting of the lead, can result in lead fracture or insulation defects. Implantation technique can affect lead performance and long-term reliability. Excessively tight lead coiling within the pocket, repeated extension and retraction of the fixation helix, and overtorquing of the lead are examples of practices that can contribute to lead failure.

ICD lead failures generally have serious and immediate consequences. Inappropriate shocks are the most common and dramatic expression of lead failure and can lead to morbidity (physical and psychiatric) and mortality. Other manifestations of lead failure include high pacing or shock impedance, which can result in failure to pace the heart or to deliver shock therapy, and a variety of abnormal diagnostic parameters such as nonphysiological V-V intervals. These abnormalities are usually discovered during routine office follow-up or by device-based monitored alerts. Some ICDs will emit audible tones when abnormally high or low impedance is measured during routine daily (automated) device measurements and diagnostics.

**Short-Term Management**

The short-term management of ICD failure presenting with inappropriate shocks requires immediate device interrogation and reprogramming. The short-term management of ICD lead failure is based on the clinical condition of the patient and the underlying rhythm.

A donut magnet should be applied until reprogramming with the manufacturer’s programmer can be performed. The magnet should be placed directly over the device and secured to the skin by tape. In most cases, an audible tone is emitted from the ICD indicating proper magnet application. When a magnet is applied to an ICD, detection will be disabled (as long as the magnet remains applied). Magnet application will not alter the pacing (bradycardia) parameters of the device.

**Long-Term Management and Monitoring**

Figure 2 summarizes the most important factors that should be weighed in determining long-term management. First, the suspected mechanism of lead failure and lead design need to be considered. Suspected insulation defects can rarely be managed conservatively, and an invasive approach is needed. This is also true for a lead with a DF-4 connector pin or...
an integrated bipolar lead with a conductor fracture involving the distal coil. In fact, in most cases of lead failure, a new lead needs to be implanted, sometimes accompanied by extraction of the existing leads. A new pace/sense lead alone can be added if there is an isolated fracture of the ring electrode conductor. This may be the appropriate strategy in older patients, patients with multiple comorbidities, or patients for whom lead extraction is prohibitively high risk. Switching sensing electrodes by using intact or previously abandoned lead components may also be appropriate. Both approaches may be preferable to placing a new defibrillation lead. Adding another defibrillation coil in the heart raises a theoretical concern about shunting of current to the abandoned lead. Defibrillation threshold testing is indicated in such cases. The disadvantages of adding new leads without removal of the failed leads include multiple leads crossing the tricuspid valve, lead-to-lead interaction, and an increased risk of future lead-related problems. If lead extraction became necessary in the future, the complexity and risks would be higher with more leads. Management in every case needs to be individualized.

Remote monitoring may be performed with proprietary Internet-based software and equipment specific to each manufacturer. This approach facilitates close monitoring of patients with failing leads. In cases of lead advisories, very specific parameters are tracked to identify or monitor failing leads. For example, the lead-integrity algorithm is a downloadable RAMware (Medtronic, Inc.) that should be added to all ICDs with a Fidelis lead. It uses a combination of changes in lead impedances, short V-V intervals, and trending data to generate alerts for pending lead failures to decrease the risk of inappropriate shocks.

### Lead Extraction

Lead extraction in patients with a failed ICD lead should be carefully considered. The Table summarizes the 2009 Heart Rhythm Society consensus recommendations for a nonfunctional, noninfected ICD lead. There are no examples of ICD leads (on advisory) with a failure mechanism that represents an immediate threat to patient safety if left in place. There are conflicting data about whether the morbidity and mortality of ICD lead extraction are increased compared with pacemaker lead extraction. However, most studies suggest that morbidity is higher. Complications of lead extraction can be catastrophic, with fatal outcomes despite immediate surgical intervention. Major complications include cardiac or vascular avulsion, pulmonary embolism, stroke, cardiac tamponade, and retained ICD lead fragments. Lead dislodgement or unintended damage to other existing leads may also occur. Passive fixation leads and dual coil leads may be more difficult to extract because of increased adhesions. Lead extraction should be performed only in high-volume centers by operators with experience using multiple extraction techniques.

### Table. Indications for Lead Extraction in Patients With Lead Failure

<table>
<thead>
<tr>
<th>Condition</th>
<th>Indications</th>
</tr>
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<tbody>
<tr>
<td>A design characteristic or failure mechanism that poses an immediate (Class I) or potential (Class IIa) threat to the patient if the lead is left in place.</td>
<td></td>
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<tr>
<td>A lead that interferes with the operation of the implanted device (Class I)</td>
<td></td>
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<tr>
<td>Implantation of another lead would result in &gt;4 leads on 1 side and &gt;5 leads through the superior vena cava (Class IIa)</td>
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### Summary

With expanding ICD indications and improved patient survival, ICD lead failure will continue to be a source of morbidity. The majority of cases will require invasive management, potentially leading to further complications. Systematic monitoring and reporting of lead failures will help mitigate the impact of design-related lead failure. The Heart Rhythm Society has recently published a set of guidelines addressing the monitoring, detecting, and reporting of lead malfunction and failure.

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### References

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