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REVIEW TOPIC OF THE WEEK

Implantable Cardiac Defibrillator Lead Failure and Management

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ABSTRACT

The implantable-cardioverter defibrillator (ICD) lead is the most vulnerable component of the ICD system. Despite advanced engineering design, sophisticated manufacturing techniques, and extensive bench, pre-clinical, and clinical testing, lead failure (LF) remains the Achilles' heel of the ICD system. ICD LF has a broad range of adverse outcomes, ranging from intermittent inappropriate pacing to proarrhythmia leading to patient mortality. ICD LF is often considered in the context of design or construction defects, but is more appropriately considered in the context of the finite service life of a mechanical component placed in chemically stressful environment and subjected to continuous mechanical stresses. This clinical review summarizes LF mechanisms, assessment, and differential diagnosis of LF, including lead diagnostics, recent prominent lead recalls, and management of LF and functioning, but recalled leads. Despite recent advances in lead technology, physicians will likely continue to need to understand how to manage patients with transvenous ICD leads. (J Am Coll Cardiol 2016;67:1358–68) © 2016 by the American College of Cardiology Foundation.

Implantable-cardioverter defibrillator (ICD) lead failures (LFs) are important to the practicing cardiologist because of the serious consequences if not diagnosed and treated promptly. This review summarizes LF mechanisms, assessment, and differential diagnosis, as well as management of patients with recalled leads or lead advisories. In this review, *mechanical LF* is used to refer to structural failure of lead materials, which may or may not be identified clinically. By contrast, *electrical LF* refers to mechanical failures that result in failure of the lead to perform its clinical roles of sensing, pacing, or defibrillation. We recognize that all LFs do not fit neatly into this dichotomy.

MATERIALS, DESIGN, AND FUNCTIONAL CONSIDERATIONS

Understanding the mechanisms of LF requires a basic familiarity with materials and structural design. The components of an ICD lead include the conductors, insulation materials, defibrillation coils, lead electrodes, fixation mechanism, yoke (branch point of individual conductor elements), and lead connector. Most newly implanted ICD systems use the DF-4 connection pin, rather than the previous, multicomponent yokes (DF-1 and IS-1). In the DF-4 design, the pace/sense conductor and defibrillation coil conductor(s) connect to a single, multi-interface connection pin. The advantages of this design are reduced pocket bulk and prevention of inadvertent reversal of high-voltage connections. To date, no systematic failures have been reported for DF-4 leads.

Although there are differences in details, most manufacturers use similar materials. All current ICD leads and most in service today are of the multilumen design (Figure 1). Cabled conductors are coated with PTFE (poly-tetrafluoroethylene) and ETFE (ethylene-tetrafluoroethylene) and placed in an insulating silicone cylinder with 3 to 6 lumens, which may be

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coated with polyurethanes or copolymer materials to accommodate conductors. Low-voltage conductors are typically composed of a multiphase alloy of nickel, cobalt, chromium silver, and molybdenum. High-voltage conductors contain a low-resistance core of silver or platinum.

A central coil conductor used for the pacing cathode (tip) allows for stylet insertion and facilitates extension or retraction of the fixation helix of active fixation leads. Conductors for the pacing anode (ring) and high voltage coils are arranged as parallel cables and distributed around the central coil. Differences in lead designs include symmetric versus asymmetric coil placement and location of cables, and location/inclusion of compression lumens (**Figure 2**).

All leads have at least 1 distal right ventricular (RV) shock coil. Dual-coil leads have a second shock coil, usually positioned in the superior vena cava (SVC). For left pectoral implants, there is no clinically significant difference in defibrillation efficacy between these 2 designs (1). Dual-coil leads may provide superior defibrillation for some right-sided implants, but they are associated with greater procedural extraction risk due to fibrotic tissue ingrowth into the proximal coil (2).

ICD leads have 2 types of sensing designs, both using the tip electrode as a cathode. The dedicated bipolar lead has a ring electrode as an anode dedicated to sensing. By contrast, the integrated bipolar lead uses the RV defibrillation coil, integrated with the shock circuit, as the anode. Therefore, a dedicated bipolar lead requires 1 more conductor than an integrated bipolar

ABBREVIATIONS AND ACRONYMS

EGM = electrogram

EMI = electromagnetic interference

FDA = Food and Drug Administration

ICD = implantable cardioverter defibrillator

LIA = lead integrity alert

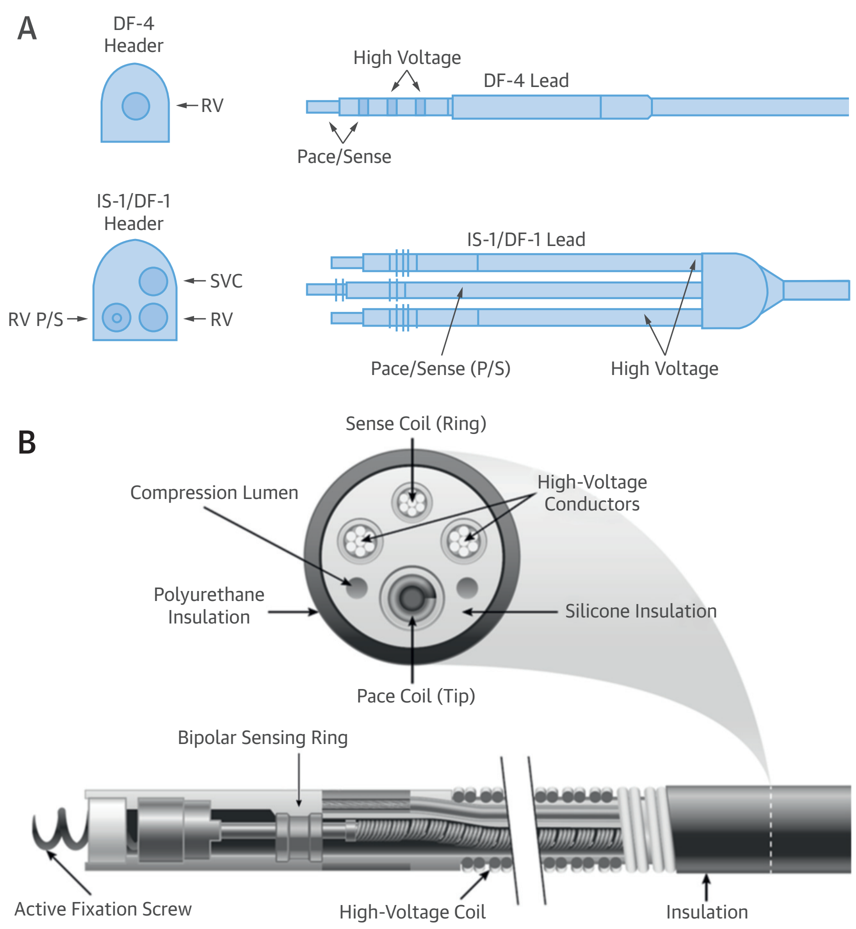
LF = lead failure

RV = right ventricular

SVC = superior vena cava

VF = ventricular fibrillation

FIGURE 1 **ICD Lead Design**



(A) DF-1 and DF-4 headers and leads. Schematic diagram of the DF-4 and earlier DF-1 connector. **(B)** Defibrillation lead schematic cross sections. Schematic diagram of multilumen ICD design. ICD = implantable cardioverter-defibrillator; P/S = pace/sense; RV = right ventricle; SVC = superior vena cava.