Transvenous Implantable Cardioverter-Defibrillator Leads
The Weakest Link
William H. Maisel, MD, MPH

Transvenous implantable cardioverter-defibrillator (ICD) lead development was an important advance in arrhythmia management. Their evolution has been critical to the wide acceptance of ICDs for the treatment of ventricular arrhythmias and the prevention of sudden cardiac death. Indeed, it is unlikely that the 20-fold increase in annual ICD implants observed during the past 15 years would have occurred without the advent of these leads. Compared with their epicardial predecessors, transvenous ICD leads are easier to implant, are less costly, and result in substantially decreased morbidity and mortality.

Modern ICD leads consist primarily of electrodes, conductors, and insulation, with a fixation mechanism and a connector to attach the lead to the myocardium and the ICD generator, respectively. ICD leads must withstand hundreds of millions of repetitive cardiac cycles, survive in the hostile environment of the human body, and allow high-voltage energy delivery for defibrillation at a moment’s notice. In total, the demands placed on ICD leads are unparalleled among implantable medical devices. Successful resuscitation of a potentially lethal ventricular arrhythmia by an ICD system depends on successful arrhythmia detection and timely delivery of therapy. Both the ICD generator and the lead are critical components of this system. Although ICD generator malfunctions have recently garnered much attention, failure of an ICD lead also can result in significant clinical events.

Oversensing can cause inhibition of pacemakers or inappropriate shocks, and failure to capture, premature battery depletion, or failure to defibrillate also can occur. Unlike ICD generators, which can be explanted and returned for manufacturer analysis when malfunction is suspected, ICD leads cannot be easily removed, because of the extensive scarring and fibrosis that occurs around the lead in the vasculature and heart. Verification of suspected lead malfunction is uncommon because of the substantial risks of lead extraction and the attendant electrode damage that may obscure malfunction analysis. Even when removed and returned to the manufacturer, returned product analysis tends to be a poor predictor of failure mode and failure rate. Assessment of potential lead failure, therefore, often depends on circumstantial evidence rather than direct visualization or confirmation of a lead abnormality. Definitions of verified and suspected pacemaker lead failure have been proposed and are applicable to ICD leads (TABLE).

Although lead reliability is affected by a number of bioengineering factors, including lead design, insulation durability, and manufacturing processes, lead performance is also impacted by patient and operator characteristics, such as implant route and implanting physician skill. These factors collectively make lead performance much more challenging than assessment of ICD generator performance. Because leads are rarely returned for postfailure analysis, assessment of lead reliability is most accurately assessed by prospective device registries. Passive lead-malfunction reporting (ie, relying on physicians to report lead failures when they occur), as used by most ICD manufacturers when reporting product performance, is subject to significant underreporting and, therefore, significant overestimation of device reliability.

In this issue of Circulation, Kleemann et al report on the reliability of ICD leads in 990 consecutive patients who underwent first implantation of an ICD between 1992 and 2005. Lead defect was defined as a severe lead failure that required surgical correction. Overall, 148 (15%) of ICD leads failed during follow-up, with estimated survival rates of 85% and 60% at 5 and 8 years after implant, respectively. Insulation defects were the most common cause of lead failure, with lead fracture, loss of ventricular capture, abnormal lead impedances, and sensing failure accounting for most of the other failure modes.

Importantly, the study results were not attributable to 1 or 2 “bad” leads. Although the investigation was not designed to compare the performance of different lead models, and although some underperforming leads were included in the study (eg, the Medtronic Transvene Model 6936/6966 ICD lead, which is known to be prone to premature failure), the report includes leads from 5 manufacturers, involving more than 20 lead models. The long-term follow-up is a strength of the study, but it does result in a cohort with a substantial number of older lead models. Therefore, the relevance of the results to modern ICD leads that have not yet been followed up on for extended periods is uncertain. In addition, most leads were implanted via the subclavian vein, an implant route known to be associated with a higher lead-complication rate. Nevertheless, the study findings are consistent with prior reports demonstrating similar failure rates and mechanisms.
Definitions of ICD Lead Failure

<table>
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<tr>
<th>Lead Failure Category</th>
<th>Definition</th>
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<tr>
<td>No structural failure</td>
<td>Lead functions normally, or has been discontinued for reasons unrelated to lead failure (e.g., patient death or infection)</td>
</tr>
<tr>
<td>Suspected structural failure*</td>
<td>One of the following clinical findings of malfunction without verified lead structural failure:</td>
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<td>- Loss of capture or markedly elevated thresholds</td>
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<td>- Loss of sensing, oversensing, or skeletal muscular stimulation</td>
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<tr>
<td>Verified structural failure*</td>
<td>One of the following findings of malfunction:</td>
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<td>- A visible conductor fracture or insulation defect seen at surgery</td>
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<td></td>
<td>- A change in the lead impedance, judged to be caused by conductor or insulation failure (abnormally low in those cases with insulation breakdown and “infinite” in those cases with conductor fracture)</td>
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<tr>
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<td>- An evident fracture seen on chest roentgenogram</td>
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<td>- Manufacturer’s returned product report confirming the failure</td>
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*Abnormality led to discontinued use (either surgically or noninvasively).

Hundreds of thousands of pacemaker leads have been recalled by the US Food and Drug Administration during the past 2 decades, with the majority of these recalls attributable to failure of the leads’ insulation. ICD leads have been plagued similarly by insulation failures, so it is not surprising that insulation defects were the most common abnormality observed in the study by Kleemann et al. Polyurethane and silicone are the 2 most widely used electrical insulators in ICD leads. Despite reports during the early 1980s that polyurethane pacemaker leads might experience premature degradation in vivo, many of the physical characteristics of this insulation remain attractive to manufacturers and implanting physicians, and polyurethane insulation is still used in many ICD transvenous leads. Its tensile and tear strength are greater than those of silicone, allowing for thinner insulation and smaller diameter leads. However, cracks on the inner insulation surfaces of polyurethane insulation, caused by metal oxidation, can markedly accelerate the failure process. To achieve the same durability and strength as polyurethane, silicone insulation must be thicker. This results in larger-diameter leads, which some implanting physicians do not favor. Some modern ICD leads use both silicone and polyurethane insulation. No matter what insulation or combination of insulations a manufacturer chooses, no two models of ICD leads are alike. The physical properties of a specific insulation vary with chemical structure, and lead reliability can be affected not only by the specific insulation used but also by the insulation-manufacturing process, lead manufacturing, and lead design.

One third of patients with lead failure presented with inappropriate shocks in the report by Kleemann et al. Methods to identify lead failure before clinical presentation are necessary, both to reduce the risk of inappropriate shocks and to prevent fatal events. Novel algorithms, such as the recognition of numerous short, nonphysiological ventricular intervals, or the recognition of a “mismatch” between far-field and intracardiac electrograms after signal processing, may identify lead malfunctions earlier and minimize clinical consequences. Notably, two thirds of lead defects are identified on routine device follow-up; this underscores the importance of routine care for ICD patients. Wireless technologies that permit automated, more frequent device checks should identify lead failures earlier and warn patients sooner.

The high rate of ICD lead failure and the need for invasive surgical procedures to correct many of the observed defects could challenge the tenet that ICDs are cost-effective. For example, a cost-effectiveness analysis of the Sudden Cardiac Death in Heart Failure Trial concludes that ICDs were cost-effective in that trial’s study population (New York Heart Association Class II or III heart failure with left ventricular ejection fraction no greater than 35%) “as long as the benefits of ICD therapy observed in the Sudden Cardiac Death in Heart Failure Trial persist for at least 8 years,” but this was based on the assumption that costs and complication rates observed during the first 5 years remain stable throughout the patient’s life. Although numerous ICD cost-effectiveness analyses have been performed, all underestimate the ICD lead–malfunction rate and fail to account for the substantial observed rates of ICD lead failure that necessitate costly lead revisions and alter the calculus of ICD cost-effectiveness. Future ICD cost-effective analyses must account for the observed moderate ICD lead–failure rates.

ICD lead reliability decreases over time and varies from model to model. As such, clinicians need more accurate and timelier lead-performance data, to clinically manage their patients appropriately. Although manufacturers have significantly improved product performance reporting for ICD generators in the wake of recent unfavorable press, ICD lead–performance reporting remains inadequate. For example, in their most recent product performance report, one manufacturer supplies only 6-month postimplant reliability data on fewer than 300 patients for an ICD lead that was approved for the US market in 2004 and that has been implanted in close to 100,000 patients. Other manufacturers fail to prospectively study lead reliability in a sufficient number of patients to adequately and accurately inform users of actual device performance. In short, better-designed lead-monitoring programs and more timely reporting of ICD lead performance must be required of manufacturers by the US Food and Drug Administration.

Even a thorough preapproval testing process cannot reproduce the real-life stress that a transvenous lead experiences during its years of service. Advances in lead technology require changes in lead design and manufacturing practices that may be met with unexpected increases in failure rates. Important ICD lead improvements have occurred and have
benefited many patients. However, these modifications must be accompanied by more robust postimplant lead surveillance so that unanticipated high failure rates may be detected as early as possible. The National Cardiovascular Data Registry ICD Registry may offer the opportunity to better monitor individual lead performance, although modifications to the registry would be required; these modifications could be accomplished at relatively little cost. More than a decade ago, a consensus report on pacemaker lead performance suggested target lead survival of more than 95% at 5 years after implantation and noted that the “better” leads demonstrated better than 95% survival at 10 years. Although these are realistic and reasonable goals for ICD lead performance, significant improvements in lead design, pre-market testing, and postmarket surveillance will be required to attain these target rates. Until then, ICD leads will remain the weakest link in an ICD patient’s chain of survival.

Disclosures
Dr Maisel is the chair of the US Food and Drug Administration’s Circulatory System Medical Device Advisory Panel.

References
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