Implantable cardioverter-defibrillators (ICDs) have revolutionized the treatment of patients at risk for sudden cardiac death. In the nearly 3 decades since the first human ICD implant, millions of devices have been implanted worldwide and innumerable lives have been saved. 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 ICD lead are critical components of this system. The lead, in particular, is literally a lifeline whose purpose is to convey critical information about the heart’s rhythm to the ICD generator and, in turn, to deliver life-sustaining therapy when needed. Failure of an ICD lead may result in significant clinical events, including failure to pace, failure to defibrillate, inappropriate shocks, and even death.

ICD leads, like many medical technologies, have undergone a remarkable transformation. Epicardial leads, which necessitated a thoracotomy for lead placement, have given way to transvenous leads, which are easier to implant, less costly, and associated with decreased morbidity and mortality. Important advances in transvenous lead technology, such as the development of steroid elution, smaller diameter leads, novel insulations, and multipolar leads, have translated into meaningful clinical benefits for patients. Although modern ICD leads consist primarily of electrodes, conductors, insulation, and a fixation mechanism to attach the lead to the myocardium, lead design and performance vary from model to model. Indeed, monitoring of performance is critical not only to identify products with increased failure rates but also to provide physicians and patients with realistic expectations of device performance.

In the current issue of Circulation, Eckstein et al add to our understanding of ICD lead performance. The investigators conducted a retrospective analysis of 1317 consecutive patients who received ICD systems (including 38 different ICD lead models) at 3 centers in Germany between 1993 and 2004. Follow-up after implantation included noninvasive routine lead evaluation every 3 to 6 months. Lead failure was defined as a lead-related problem requiring surgical revision performed at the discretion of the treating physician. Abnormalities were classified as either structural (insulation defects or lead fracture) or functional (far-field sensing; T-wave or physiological oversensing, noise from contact with another lead, unstable impedance measurements, R-wave reduction, or loss of capture).

During a median follow-up of 6.4 years, 38 ICD leads required surgical revision, resulting in a reported cumulative ICD lead survival rate of 97.5% at 5 years. Compared with previous reports on ICD lead performance, this failure rate is low. This low rate could be due to underdetection of lead failures, a high clinical threshold for replacing a failed lead, a strict definition of lead failure, or the great skill of the implanting physicians. Interestingly, patients who underwent ICD lead revision for malfunction had an 8-fold higher incidence of experiencing another lead failure; this higher incidence underscores the important contribution of patient factors to ICD lead performance. Causes of malfunction were similar to those in prior published reports and most often were related to insulation defects and lead fractures. Inappropriate ICD therapies occurred in 76% of those patients who experienced a lead malfunction.

Like the Eckstein study, a number of prior published reports inform us about the reliability and durability of ICD leads (see Figure 1). Reported ICD lead “survival” varies from 91% to 99% at 2 years, 85% to 98% at 5 years, and 60% to 72% at 8 years. Several conclusions may be drawn from review of the data:

The definition of ICD lead “survival” or lead “performance” varies from study to study. Most commonly in published studies, lead malfunction is defined as electrical abnormalities on lead testing, a chest roentgenogram consistent with a fracture, or evidence of oversensing unrelated to cardiac signals. Other studies rely on physician clinical judgment and require replacement of the ICD lead in order to consider the lead to have malfunctioned. In most published studies, thresholds for action are poorly defined and ambiguous. The varying definitions make it difficult to compare study to study and lead to lead.

ICD lead performance varies by model. Although conceptually simple, ICD leads are complicated devices with lead designs that vary from model to model. These design differences may include variations in insulation, cable/conductor, length, diameter, and fixation mechanism. Pool-
lead performance definitions hinders data collection and well defined and understood, the lack of standardized ICD yielded varying results (Figure 1).

Figure 1. The results of selected studies of ICD lead performance are shown. To be included, studies had to (1) be published in a peer-reviewed journal after 1999, (2) provide follow-up for at least 18 months after implantation, and (3) statistically account for patients who had died or were lost to follow-up. The data point represents the point estimate of the study for ICD lead survival. The size of the data point is proportional to the total number of patients in the study. The white data point represents the study by Eckstein et al, published in the current issue of Circulation. The great variation observed in ICD lead survival is due to a variety of factors including variable study definitions of ICD lead malfunction, variable performance of different ICD lead models, and the impact of patient characteristics on physician implantation techniques on ICD lead performance. Primary author, year of publication, and number of patients in each study are displayed in the legend.

...ing ICD lead models for analysis, therefore, is potentially problematic, because occasionally individual ICD leads underperform relative to the average. On the other hand, understanding the average durability and reliability of an ICD lead is useful as a standard to which other leads may be compared.

Patient and physician characteristics affect ICD lead performance. Measuring lead performance is challenged by the impact of certain patient characteristics (such as size, activity, and anatomy) and physician characteristics (such as implantation skill, technique, and experience) on lead performance.

Clinical presentation of ICD lead failure varies. ICD lead malfunction may occasionally be catastrophic and life threatening, such as when the lead fails to deliver a needed high-voltage therapy. More often, patients present with inappropriate shocks or abnormal electrical parameters detected on routine testing. Some algorithms have been developed to detect lead abnormalities before they progress to a clinical lead failure, but unfortunately these are effective only in a minority of patients.

The tools available to detect impending ICD lead failure are limited. Fluoroscopy, x-ray, electrical testing, or direct visualization may be used to detect lead abnormalities, but in many respects these methods are too rudimentary and imprecise. Novel tools (eg, imaging and electrical) need to be developed to identify lead abnormalities sooner, both to prevent untoward clinical events and to better monitor lead performance earlier in the lifetime of the lead.

Given the aforementioned complexities of monitoring ICD lead performance and the weakness of the published studies, it is not surprising that reports of ICD lead performance have yielded varying results (Figure 1).

Whereas ICD lead malfunction mechanisms are generally well defined and understood, the lack of standardized ICD lead performance definitions hinders data collection and analysis, as well as communication about device performance. In the wake of recent high-profile ICD lead performance questions, such as those affecting the Medtronic Sprint Fidelis and the St. Jude Medical Riata ICD leads, the Heart Rhythm Society announced in March 2008 the formation of the Task Force on Lead Performance Policies and Guidelines. The task force will make recommendations to the US Food and Drug Administration, Congress, industry, physicians, and patients on lead performance, communication of lead performance, surveillance, threshold for activation of lead advisories, communication after abnormal performance is identified, clinical management of lead performance issues, and regulatory considerations.

A number of on-going efforts will greatly enhance our understanding of ICD lead performance in the coming months and years. The National Cardiovascular Data Registry ICD Registry will incorporate ICD leads, The US Food and Drug Administration is developing HeartNet, a sentinel network of electrophysiology laboratories throughout the United States, specially trained to report adverse events and device malfunctions, including those affecting ICD leads. Independent registries, such as the Multicenter Registry, continue to carefully monitor device performance and to provide early warning signals for devices whose performance expectations are not met. In addition, a number of ICD lead manufacturers have embarked on prospective ICD lead clinical studies and registries to better monitor ICD lead performance. Wireless remote monitoring of ICD lead function also offers enormous potential to identify performance issues early and to provide an automated warning system to improve patient safety (Figure 2).

ICDs are clinically proven to improve survival in select patients at risk for sudden cardiac death. Although ICD leads are a mature technology, monitoring of these devices remains critical to inform physicians and patients about device per-
performance and to identify underperforming products as early as possible. Ongoing efforts to standardize definitions of performance, improve timeliness of data collection, and enhance performance reporting are underway and will benefit the millions of patients who enjoy the benefits of these devices.

Disclosures

None.

References


Keywords: Editorials • death, sudden • defibrillation • registries • tachyarrhythmias