ICD Leads Prone to Failure: Weighing the Risks at the Time of Pulse Generator Exchange

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ABSTRACT. Implantable cardioverter-defibrillators (ICDs) are used in large numbers in the United States and throughout the world. ICD manufactures are continually striving to improve the technology. This has led to a push for smaller, easier to implant pulse generators and high-voltage ICD leads. Consequently, unforeseen problems have been identified in post-marketing surveillance of these smaller defibrillator systems. Fortunately, the downsizing of pulse generators has not resulted in a drop in performance, although the push to reduce the size of the high-voltage ICD lead has resulted in the US Food and Drug Administration issued recall of the Sprint Fidelis and Riata/ Riata ST ICD leads for higher than predicted rates of lead failure. Presently, guidelines recommend against the routine extraction of functioning leads because of the risk of major complications. However, the choice to retain a functioning recalled lead at the time of pulse generator exchange is critically important. This paper will review the existing data on the Sprint Fidelis and Riata/Riata ST leads, current recommendations, and provide an update on ICD lead extractions to better prepare operators at the time of generator exchange.

KEYWORDS. implantable cardioverter-defibrillator malfunction, Riata, risk factor for implantable cardioverter-defibrillator lead failure, sprint fidelis.

Introduction

The first internal cardioverter-defibrillator (ICD) was successfully implanted in the 1970s and subsequently the number of implanted ICDs has grown exponentially. There are now more than 100,000 ICDs implanted in the United States annually, and many more worldwide. Since their advent, the push to create smaller, easier to implant devices has been a prominent market driver. This has led the industry to continually refine previous designs as well as create novel technology to meet the demands of the market. This has also led to the release of new devices based on limited studies of short duration. Consequently, unforeseen problems have arisen resulting in US Food and Drug Administration (FDA)-issued recalls.

The ICD system consists of a pulse generator and a high-voltage lead. Together, these elements create an ICD system that monitors the heart’s rhythm, and when a life-threatening arrhythmia is detected is capable of delivering a high-voltage shock. The effort to downsize the pulse generator has led to a smaller device that is easier to implant and more comfortable for patients without sacrificing battery life or function. Downsizing the high-voltage lead is desirable, presumably facilitating the implant procedure, reducing the incidence of lead crush, reducing venous occlusion, and improving extractability. Unfortunately, decreasing the size of high-voltage ICD leads has been associated with an alarming increase in lead failure rates, resulting in the FDA recall of two of these leads, the Sprint Fidelis and Riata/Riata ST ICD leads.

The decision to retain or extract these leads at the time of pulse generator exchange is a challenging one. Even in experienced hands, ICD lead extraction has a major adverse event rate approaching 1–1.5%. Thus, there is considerable controversy regarding management of patients with these leads. The difficult decision to reuse or replace a functioning recalled lead is often made at the time of ICD replacement.
ICD lead: history and structure

Since the first successful ICD implant in 1970s by Mirowski et al,1 the ICD has undergone a remarkable transformation. The first ICD systems were large and bulky, requiring implantation abdominally with leads attached to the epicardium. The implantation of an ICD required an extensive surgery and prolonged hospitalization. These early devices had limited battery life (<2 years) and minimal diagnostic capabilities, with only back-up ventricular pacing. They were also plagued by a high rate of complications, including infection and lead fracture. Advances in device technology have resulted in a smaller device, allowing for subcutaneous pectoral implantation of the pulse generator and endocardial implantation of the leads. These advances have made implantation much easier, dramatically reducing complications and improved battery technology has increased the expected battery life to >6 years.

The development of integrated leads incorporating both the rate-sensing electrodes and the defibrillation coils has led to the endocardial implantation of leads. Initially, ICD leads were constructed in a coaxial design with a central coiled conductor surrounded by an outside insulation layer, followed by an additional conductor surrounding both layers. Typically, the tip conductor was central, with the ring and defibrillator conductor being more peripheral.

Today, ICD leads are constructed in a multilumen fashion with conductors running in parallel through a single insulated lead. This design has reduced lead size and improved resistance to external forces. Although leads use this general configuration, leads vary in the orientation and spatial arrangement of the components in the lead (Figure 1).

In addition to the change in the spatial arrangement of the conductors in ICD leads, the choice of insulation can greatly affect the ICD lead. The choice of insulation includes silicone, polyurethane, or fluoropolymers. The choice of insulation greatly influences the long-term stability and function of the lead. Silicone is inert, biostable, and biocompatible, but has a high coefficient of friction and is soft, making it prone to damage after implantation due to lead–lead and lead–device contact. Polyurethane is biocompatible, has a high tensile strength, and a low coefficient of friction, but is prone to environmental stress and cracking. Fluoropolymers, polytetrafluoroethylene (PTFE) and ethylene-tetrafluoroethylene (ETFE), are the most biocompatible, have high tensile strength, but are stiff and prone to insulation micro-defects. Most leads today use a combination of insulations to take advantage of the beneficial properties of the particular insulation and limit their weaknesses.

Sprint Fidelis

The Sprint Fidelis lead developed by Medtronic was smaller in diameter (6.6 French) than previous models and was implanted in large numbers after it was introduced in the United States in September 2004. The lead was withdrawn from the market in October 2007 because of a higher than expected rate of failure during follow-up monitoring.2 During these 3 years, more than 268,000 Sprint Fidelis leads were implanted, and, even today, more than 100,000 patients still have an active Sprint Fidelis lead.3 Failure of the Sprint Fidelis lead often manifests as oversensing from fracture of the pace-sense conductor. Even with the enhanced monitoring recommended by the manufacturer, lead failure can lead to inappropriate shocks, loss of device function, and, in rare instances, death 4–7 (Figure 2).

A number of studies have shown the failure rate of the Sprint Fidelis ICD lead increases exponentially with time to more than 15% at 5 years. Failure rates in excess of 15%, which is much larger than those reported by the manufacturer, have recently been reported by our group and others.4,7,8 Studies examining non-recalled ICD leads have shown that younger age, preserved left ventricular ejection fraction, and female gender may be risk factors for lead failure.4,9–11 Morrison et al10 performed a retrospective

Figure 1: Cross-sectional anatomy of various implantable cardioverter-defibrillator leads.
analysis of their Fidelis cohort to determine risk factors for lead failure. They found an age <50 years to be predictive of failure. A similar study by Birnie et al. found that female gender and a history of lead malfunction were predictive of lead failure. They also found that axillary and subclavian lead introduction sites increased the rate of failure compared with cephalic placement.

Riata

St. Jude Medical released the 8 French Riata ICD lead in 2002, and more than 227,000 were implanted worldwide until the lead was removed from distribution in 2010. The smaller 7 French Riata ST lead was released in 2005. The Riata and Riata ST leads were constructed with a silicone rubber insulation and the high-voltage conductors insulated by an additional layer of ETFE. The Riata ST lead had an additional silicone–polyurethane co-polymer covering added in 2006 and was renamed the Optim. In 2008 the first report of issues with the Riata ICD lead were published, but it was not until the summer of 2011 in a study by Hauser et al. reported a series of lead failures in the Riata and Riata ST ICD leads. The study suggested the previous reports of insulation failure were not isolated events, but a unique pattern of failure that is more common than previously believed. The failure appears to be externalized conductors that result from an inside-out abrasion caused by the movement of the conductor cables within the leads’ lumen (Figure 3). Subsequently, St. Jude Medical issued a physician advisory letter on November 28 2011 on lead

Figure 2: Data from failed Fidelis lead. Note high pacing impedance, sudden onset of non-physiologic noise, and successive high voltage shocks.
Figure 3: (a) Extruded conductor coils in a Riata family lead. Note typical location proximal to distal coil. (b) Unexpected inside out coil erosion found in ICD pocket at time of extraction procedure. (c) Gross demonstration of extrusion proximal to distal high voltage coil.
failure, which was followed by a FDA-issued class I recall.\textsuperscript{13} Since St. Jude Medical released the physician advisory letter, a number of small studies have been published confirming Riata and Riata ST propensity for insulation failure and cable externalization. Although, imaging of the lead through fluoroscopy or chest radiograph shows a structural defect, the lead may continue to function normally. The Riata and Riata ST leads are constructed with pairs of conductors located in the outer silicone layer. These conductors are insulated with a small layer of polymer. The intact polymer coating covering the externalized conductors may explain the observation that these leads can continue to function normally albeit externalized. Consequently, the electrical parameters which predict lead failure have been difficult to define, and consensus on lead management has been evolving. However, there is an emerging consensus that electrical lead failure is likely the result of failure of both the silicone outer insulation and eventual abrasion of the ETFE polymer coating the cable in the proximity of a shocking coil, resulting in conductor-to-conductor shorting.\textsuperscript{12,14,15}

**Official recommendations**

Since Medtronic released the Physician Advisory letter informing doctors of the higher than expected rate of Sprint Fidelis ICD lead failure, the consensus on lead management has been continually evolving. Currently, ICD systems with a functioning Sprint Fidelis lead should have the Lead Integrity Alert uploaded and enabled with home monitoring to allow for early detection of lead failure. Medtronic recommends, “If a Fidelis pace-sense conductor fracture has occurred, we recommend implanting a new high voltage lead, with or without extraction of the Fidelis lead. It is no longer a recommended option to implant a pace-sense lead while maintaining use of the Fidelis high voltage conductors after a Fidelis pace-sense conductor fracture has
occurred.” Medtronic states, “Lead Model 6949 performance after device change-out is similar to lead performance without device change-out.” Although they suggest that in the event of a device change-out or upgrade procedure, with no manifestation of lead fracture, consider the patient age and lead model data, as well as patient life expectancy, comorbidities, ease of extraction related to implant time, and patient preference, in determining whether to reuse the Sprint Fidelis lead or abandon/extract the recalled lead.

As more and more reports are being published it is clear that the Riata/Riata ST leads are prone to structural failure and possibly electrical failure. Recently, new guidelines were released by the FDA encouraging the imaging of all leads to look for externalized conductors. They also suggest repeat imaging may be of clinical use, since failure appears to be time dependent. They do not have recommendations on the management of leads with structural defects but intact electrical function. Nor do they suggest Riata ST Optim (Durata) ICD leads are prone to failure, although a recent report suggests they may be.

**Generator exchange and lead extraction**

The literature shows that both the Sprint Fidelis and Riata/Riata ST ICD leads are prone to premature failure. Although the mechanism of failure is not similar, the uncertainty associated with both these leads results in similar clinical problems. Specifically, these leads fail in a time-dependent manner that results in the difficult decision at the time of generator exchange to retain a functioning lead or replace it.

Medtronic states that generator exchange is not associated with lead failure, but we recently published data showing that pulse generator exchange was associated with a fivefold increase in lead failure, with most occurring in the first 3 months after generator exchange.8 We were not the only group to note this, as Zuberi et al16 published a report describing two such cases. Additionally, Maytin and Epstein17 recently showed that >35% of Sprint Fidelis leads functioning normally at the time of elective extraction were noted to have evidence of conductor fractures with 20% having
Figure 6: (a–c) A lead extender (Cook Bulldog) is used to maintain control of all the conductor coils. This provides additional points of countertraction and helps prevent excessive prolapsing of extruded coil segments.
Figure 7: (a) Typical locations where dangerous adhesion points are often found. Careful control of extraction tools and angulation of the beveled tip helps prevent application of excessive forces to these areas. For removal of a fixed lead tip, countertraction helps provide better control, as opposed to application of laser energy (b).
more than one fracture. These data showing electrical stability prior to generator exchange in leads with “subclinical fractures” taken together with our data showing a high rate of failure after generator exchange strongly suggest the Sprint Fidelis lead should be abandoned during the procedure. In fact, the Canadian Heart Rhythm Society device committee has changed its position statement with regards to Sprint Fidelis leads. The committee had not recommended replacement, but now strongly recommends that replacement should be seriously considered. Unfortunately, there are no published data as of yet to guide the management of Riata/ Riata ST leads at the time of generator exchange.

The decision to extract a lead at the time of pulse generator exchange is a difficult choice. A number of factors must be weighed, including the patient’s age, life expectancy, comorbidities, lead implant time, and patient preference. Most hesitate at the choice of extraction due to risk of serious complications including death with rates anywhere from 1% to 8%. But more recent data published by Maytin and Epstein showed the Sprint Fidelis ICD lead extracted at high-volume centers resulted in no deaths or major complications, and minor complications at a rate less than 1%. These data and our experience with lead extraction leads us to believe that Sprint Fidelis ICD and Riata leads can be extracted in most case with acceptable risk under controlled conditions.

**Extraction procedure**

No center should consider extracting ICD leads until there is a full commitment to training of staff and physicians and adherence to published guidelines. Important safety criteria include appropriate anesthesia services and immediately available cardiothoracic surgeons. Many centers perform extractions in an operating room or hybrid operating room, while others utilize a well-equipped and staffed electrophysiology laboratory. Regardless of the location, it is essential all equipment, including emergency surgical equipment and blood products, be available in the extraction suite.

Specific extraction tools and techniques will vary from operator to operator, but certain technical tips can be provided to enhance safety and improve case flow. First, in cases where leads will be reimplanted, consideration of venous access is important (Figure 4). Up to a third of patients with chronically implanted leads may have a venous occlusion. When the central veins are patent, obtaining access with long wires prior to extraction of any lead is recommended. Careful attention to the point of venous entry will help avoid future lead crush or implant-related complications (Figure 5). Long wires allow the use of long sheathes when new leads are reintroduced. This helps protect portions of the innominate vein and superior vena cava that may be thinned and traumatized during extraction of the proximal lead from areas within the vessel lumen that are adherent to the lead.

Lead preparation is of particular importance. Leads that will be retained should be protected by reinforcing them with stylets. This will help minimize lead–lead interaction and facilitate separation of adherent leads during the extraction process. Prior to extraction, leads to be removed should be carefully prepared to facilitate extraction. Maintaining control of the conductor coils in the ICD leads is very helpful, and we consider it critical in the extraction of the Riata family of leads. The high tensile strength of these coils facilitates control of the distal lead, and, in the case of the Riata lead, helps to maintain tension on extruded coils that may otherwise be prolapsed and obstruct safe passage of the extraction tools (Figure 6).

Extraction sheaths may be manual or powered. Powered sheathes include a manually controlled rotating device, a radiofrequency-powered device, and the laser sheath. We have the most experience with the laser sheath, and it remains our preferred tool when powered extraction is necessary. Regardless of tools used, certain principles are always applied. These include constant attention to countertraction on the lead, careful maintenance of a coaxial relationship between the extraction sheath and the lead body, and avoidance of sudden lead movement, especially at the adhesion points found at the junction of the innominate–superior vena cava and the superior vena cava–right atrium. Removal of the lead from the RV attachment site is best performed by countertraction and not the powered sheath to avoid sudden advancement of the sheath and myocardial perforation (Figure 7).

**Conclusions**

The effort to make ICD leads smaller to allow for easier implantation and decrease the risk of implanted endovascular hardware has resulted in two FDA-mediated recalls affecting hundreds of thousands of patients, and left the public with a sense of apprehension in the viability of existing leads. The issues encounter by the Sprint Fidelis and Riata/Riata ST ICD leads has heightened the awareness in the field of the importance of detecting early signs of lead problems and bringing these issues to the forefront. In addition, this experience has exposed flaws in the post-marketing monitoring of new medical devices, especially ICD leads. The experience gained by the EP community in identifying at risk products and implementing clinical management strategies will be invaluable in the future as the market pressure to innovate will be ever present and unexpected medical device failure will be inevitable.

**References**