How Much Scrutiny and Stress Can the Fidelis Lead Withstand?

Avi Fischer, MD

The implantable cardioverter-defibrillator lead has undergone numerous design and manufacturing changes over the last 25 years aimed at improving patient care and outcomes. It is widely accepted that implantable cardioverter-defibrillator leads, similar to pacemaker leads, have a finite life. The design of an implantable cardioverter-defibrillator lead is more complex than that of a pacemaker lead, and the propensity for failure is greater. Estimates of the rate of failure vary, but during follow-up at 10 years, the failure rate may be as high as 20%. Factors that affect implantable lead performance include the implanting physician, the patient, and specific characteristics related to lead design. Most lead failures are multifactorial.

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In October 2007, Medtronic voluntarily discontinued sales of the Sprint Fidelis family of leads because of a trend toward decreased survival of the lead compared with an earlier model, the Sprint Quattro. At the time of discontinuation, the lead had been implanted in 268,000 patients worldwide; by October 2010, an estimated 166,000 Fidelis leads remained active worldwide. Fidelis lead failure can be traced to fracture of the pace/sense electrodes, the shocking coils, or both. Failure is usually the result of fracture of either the cable to the anode (ring electrode) near the lead tip or the coil to the cathode (tip electrode) near the anchoring sleeve. The most common complication of lead fracture is rapid oversensing of electrical noise and delivery of inappropriate shocks, but failure to deliver bradycardia pacing and antiarrhythmia pacing due to elevated impedance or inhibition of pacing by oversensing has also been reported. The most concerning complication when fracture of the high-voltage electrode occurs, however, is failure to deliver the lifesaving therapy intended: defibrillatory shock(s).

Since the first reports of failure of this lead, numerous case reports and series have substantiated an increasing incidence, while editorialists in the lay and professional press focused on broader outcome issues in managing patients with Fidelis leads. Among these are the risks and costs associated with their revision and extraction. A recent PubMed search with the key word “Fidelis lead” returned a list of >35 publications between April 2007 and August 2010. Pressing clinical questions in managing patients with Medtronic Fidelis leads are how to identify those prone to failure, how to minimize delivery of inappropriate therapy after failure, and, increasingly, what to do when patients with functioning Fidelis leads present for pulse generator generator replacement.

In the current issue of Circulation, Hauser et al add to the growing literature on this particular lead. The authors should be commended for their continued efforts to advance the understanding of the mechanisms of lead failure and improve management of patients with advisory leads. The authors analyzed retrospective data from 2691 patients followed at 3 US centers with either Sprint Fidelis or Quattro leads; some may have been selected for inclusion in previous analyses of lead survival. Not surprisingly, in this analysis, Fidelis leads failed significantly more frequently than Quattro leads. Between 2001 and 2009, the failure rate for Fidelis leads was 2.81%/y versus 0.43%/y for Quattro leads (P<0.0001); Fidelis lead survival was 87% at 4 years compared with 98.7% during the same period for the Quattro lead. As in previous reports, Fidelis lead failure increased with time and mainly was due to failures of the pacing and sensing electrodes; a small number of failures involved the high-voltage coils. The authors found a higher risk of fracture in the 113 patients (11% of the cohort) in whom the leads had been implanted for arrhythmias associated with either hypertrophic cardiomyopathy, arrhythmogenic right ventricular dysplasia, or channelopathy, conditions associated with implantation of defibrillators in younger patients. The authors indicate that there were no reported deaths or other serious injuries in this cohort, although, arguably, inappropriate shocks occurring in 42% of lead failures would be considered quite serious to those who received them.

It is important to bear in mind that the authors defined “lead failure” in this study as a lead exhibiting “electric noise, or abnormal impedance, or if it could not sense R-waves and/or provide effective electric therapy due to an apparent structural defect such as a conductor fracture or insulation breach.” Although valid, this definition differs from those used in other publications focused on Fidelis lead failure (including 1 from an institution participating in this study) that identify specific increases in impedance measures (>1500 for the pacing and sensing portion of the leads, >200 for the defibrillating portions of the lead, or 100% from baseline), or an abrupt sudden increase in long-term pacing or defibrillation impedance (>20% increase over a 24-hour period), or inappropriate shock(s) secondary to oversensing of artificial electric potentials. The authors do not specify whether header-connector problems or other potential causes...
of lead failure were excluded during surgical exploration. They acknowledge that “the cause of most lead failures was not verified by return product analyses.” This is important because data suggest that a proportion of Fidelis leads explanted for “lead fracture” and returned in their entirety for analysis may not have fractures. Differences between the findings in this and other series, reports from the Medtronic System Longevity Study, and Carelink-Plus data in this respect may thus reflect variations either in thresholds for diagnosis of lead failure or in the criteria used to define fracture.

An important message from this analysis is that the risk of Fidelis lead malfunction is higher in younger and female patients, substantiating earlier observations that women and patients aged <50 years are at greater risk of both Fidelis and Quattro lead failure and that better left ventricular systolic performance is an independent predictor of Fidelis lead failure. The available evidence suggests a relationship of lead failure to physical activity and better ventricular systolic function. This should be considered as patients with Fidelis leads approach elective generator replacement and in the design of new electrodes for use in patients whose cardiac disease permits a high level of physical activity despite their need for protection against potentially lethal ventricular tachyarrhythmias. The indications for device-based therapy in these patients are associated with greater life expectancy than dilated cardiomyopathy, and hence there is a need for a greater number of generator changes over the course of the patient’s lifetime and greater exposure to lead failure.

More work is needed to better identify patients who would benefit from replacement of leads that function properly when the generator is replaced. Current recommendations for management of patients with Fidelis leads include regular clinical follow-up on a quarterly schedule, careful evaluation of lead properties, utilization of the Lead Integrity Alert to detect impending fracture, and prompt intervention at the first sign of lead failure. On the basis of available data, prophylactic replacement of Fidelis leads in selected patients at the time of pulse generator replacement may be reasonable when the benefits outweigh the risks. Although lead replacement is associated with known complications, the risks are closely related to operator experience, and major adverse events appear to be mitigated when lead replacement is performed by experienced operators in high-volume centers. Replacement of functional Fidelis leads should be considered at the time of elective generator replacement in younger and active patients, taking into account individual patient characteristics. The risks in the individual patient depend on the chance of a Fidelis failing over time and the potential clinical consequences associated with Fidelis failure. The new data from Hauser et al underscore the importance of age and disease state in addition to the frequency of ventricular arrhythmias, pacemaker dependency, other clinical factors, and the patient’s individual values and preferences in deciding whether to explant a functioning Fidelis lead.

Disclosures
Dr Fischer has consulted for and received honoraria from Medtronic, Boston Scientific, St Jude Medical, and Spectranetics.

References
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