

Don't Just Do Something, Stand There? Unraveling the Complexities of Riata

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As electrophysiologists we confront the challenge of articulating the risks and benefits of various management options to our patients and their families. Weighing the upfront risk typically associated with an interventional procedure against potential adverse events in the long term is a vexing problem that we frequently face in clinical practice. This discussion involves both the immediate risks of an intervention (doing something) and the protracted risks of observation (standing there). Assessing the risk-benefit ratio of intervening today versus possibly intervening tomorrow when a device malfunction has already occurred is challenging to the experts in the field, let alone patients and their families. It is therefore not too surprising that we often find ourselves, after a long discussion in which we present the salient medical facts and evidence-based reasoning to our patients, we face the question, "What would you do if I was your family member?" Management of implantable cardioverter-defibrillator leads with a known high rate of failure is anxiety-producing for both patients and physicians.

See Article by Parkash et al

Many of our patients continue to live with the St Jude Medical Riata family of leads, which were placed under US Food and Drug Administration advisory in 2011. These leads have well-described design problems associated with a tendency toward inside-out abrasion, resulting in conductor cable externalization. They also display an increased rate of electrical failure, although the rate of failure and its relationship to conductor cable externalization have been debated. Although most observational studies have shown a significantly increased risk of electrical failure in the setting of cable externalization,¹ the relationship remains unclear, and causality has proved difficult to demonstrate. The value of screening for cable externalization either by fluoroscopy or by chest radiography has been questioned, especially because the risk of developing electrical failure over time is substantial, even in the absence of structural abnormality.

In this issue of *Circulation: Arrhythmia and Electrophysiology*, Parkash et al² report on a prospective Canada-wide

registry examining the performance of the Riata family of defibrillator leads and the clinical management and outcomes of patients living with it. The registry followed close to three quarters of the ≈5000 Riata leads implanted in Canada, with a mean follow-up time of 8 years. The major findings were as follows: (1) the rate of electrical failure was 5.2% at 8 years; (2) conductor externalization was seen more commonly in the larger 8F lead; (3) multivariate predictors of electrical failure included conductor externalization, higher left ventricular ejection fraction, younger age, higher body weight, and passive fixation-designed leads; and (4) lead revision (and especially lead extraction) were associated with a high rate of major complications.

Putting these findings in perspective, the rate of electrical failure in the present analysis was lower compared with what was reported recently in a meta-analysis published by Zeitler et al¹ where electrical failure rates were 6.3% over shorter follow-up period. The electrical failure rate reported by Prakash et al is clearly higher, however, than that of the widely used Endotak Reliance (Boston Scientific) and Sprint Quattro (Medtronic Corp) implantable cardioverter-defibrillator leads, which have an estimated electrical failure rate of 0.29% to 0.45% per year or 2.3% to 3.6% at 8 years follow-up.³ The authors found a higher rate of both electrical failure and conductor externalization in the 8F versus 7F Riata leads, similar to previous reports.⁴ Importantly, Prakash et al report no acceleration in the rate of electrical failure of the lead over the course of the observational study, which seems to be inconsistent with earlier concerns that the Riata failure rate would increase exponentially with time, which would have had dreadful management implications. Conductor cable externalization occurred in 9% of the minority of leads in which a radiographic evaluation was performed. This is lower than previously reported,^{1,4} which may in part be because of underdetection because of predominate use of chest radiography as opposed to more sensitive cine fluoroscopy.

The high rate of complications related to Riata lead revision in this cohort should give us pause. Riata lead revision for any reason was associated with a 9.7% risk of a major complication, with the strategy of lead extraction being associated with significantly higher risk of complications than abandonment (18% versus 5%). The incidence of cardiac perforation and SVC injury during lead extraction was 4.2%. This is in contrast to 3 previous publications from high-volume centers reporting that the rate of major complications associated with extraction of the Riata lead was 0%,⁵ 0.87%,⁶ and 2%.⁷ Similar to previous observational studies, infection postlead revision was a significant problem, occurring in 3.4% of patients. Whether prophylactic measures such as the addition of an antibiotic eluting pouch can mitigate this risk is the subject of ongoing investigation.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

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The report by Prakash et al is a stark reminder of the significant upfront risk associated with Riata lead revision, including extraction, and may encourage a more conservative approach to these patients. However, there are several important caveats. First, the rate of major complications associated with lead extraction is highly dependent on operator expertise and facility volume, close collaboration with cardiothoracic surgery, and other clinical factors. Although the rate of major complications with lead extraction was higher than in previous observational studies, details such as operator volume and Riata dwell time are not provided in the present report. Clearly, lead extraction presents upfront risks, but the magnitude of those risks remains unclear, and extraction may confer long-term benefits, especially in younger patients. Second, although the authors make the case that in their cohort the rate of Riata lead failure is linear and somewhat lower than many previously published studies and that only 1 patient was confirmed to have died because of failure of the device to deliver life-saving high voltage therapy, this by no means demonstrates the relative safety of this lead. The incidence of high-voltage circuit failures cannot be known, given that this testing was not routinely performed. And, as the authors acknowledge, even if performed it does not guarantee appropriate defibrillation function at a later date. Finally, the nature of the Riata lead itself, with its tendency toward abrasion and structural degradation over time, may expose patients to unique risks. Thrombosis,⁸ embolization,⁹ and prolapse of cables into the pulmonary artery¹⁰ have all been reported in association with conductor cable externalization. These mechanical complications may increase in frequency as time passes.

Prakash et al should be commended for giving us additional data which will further inform our discussions with patients facing the dilemma of what, if anything, to do about the Riata lead, especially at the time of elective generator replacement. Ultimately, appropriate decision making depends partly on a frank and open discussion with our patients about what is known and what is not known. However, in addition, it should incorporate patients' preferences based on their wishes, beliefs, and values and their perceptions of risks and benefits. Only after we get better at integrating all these essential parameters into the decision-making process do we get closer to tailoring individual management strategies for individual patients and will we be able to better answer the question: "What would you do if I was your family member?"

Disclosures

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