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Cost of a Recall of a Single-Center Experience Managing the Riata Defibrillator Lead

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Abstract

Riata and Riata ST defibrillator leads (St. Jude Medical, Sylmar, California) were recalled in 2011 due to increased risk of insulation failure leading to externalized cables. Fluoroscopic screening can identify insulation failure, although the relation between mechanical failure and electrical failure is unclear. At the time of the recall, the University of Virginia developed a screening program, including fluoroscopic evaluation, education sessions, device interrogation, and remote monitoring for patients with this defibrillator lead. The aim of this study was to review the outcomes of the screening program, including costs, which were absorbed by our institution. Costs were calculated using Medicare reimbursement estimates. Forty-eight patients participated in the screening program. At initial screening, 31% were found to have evidence of insulation failure but electrical function was normal in all leads. The cost of this program was \$35,358.72. The cost per diagnosis of mechanical lead failure was \$2,357.25. During 2 years of follow-up, 1 patient experienced Riata lead electrical failure without fluoroscopic evidence of insulation failure. Patients were more likely to have a lead revision if there was evidence of insulation failure. Lead revisions occurred at the time of generator change in 88% of patients with insulation failure but in only 14% of patients with a fluoroscopically normal lead ($p=0.04$). The cost of recall-related defibrillator lead revisions was \$81,704.55. In conclusion, our Riata screening program added expense without clear benefit to patients. In fact, patients may have been put at more risk by undergoing defibrillator lead revisions based solely on the results of the fluoroscopic screening.

In December 2011, a Class I recall was issued for the St. Jude Riata and Riata ST defibrillator leads (St. Jude Medical, Sylmar, California) due to increased risk of insulation failure, leading to externalized cables.¹ We developed a fluoroscopic screening program to evaluate patients for mechanical lead failure.² We have retrospectively evaluated the outcomes of our screening program and calculated the costs that this recall incurred for our patients. The initial screening program was covered entirely by the University of Virginia. The downstream costs were covered by a combination of University of Virginia, St. Jude, insurance, and the patients themselves. This analysis, of course, represents just the financial costs. Quantifying the impact of the anxiety and disruption that a recall causes for patients and providers is much more difficult.

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Methods

In January of 2012, we reviewed our device clinic records for patients with Riata and Riata ST leads. From 2003 to 2007, 184 Riata and Riata ST leads were implanted at the University of Virginia. Four patients had experienced electrical failure of their leads previously, and the leads had already been taken out of service. Seventy-three patients were being followed elsewhere and 42 patients had died previously. A total of 48 of the remaining 65 patients agreed to undergo screening. All screenings were performed in January 2012.

At the screening visit, recall data were reviewed as well as current St. Jude Medical and Food and drug Administration recommendations. All patients were offered fluoroscopic screening of their lead. Comprehensive interrogation was performed for all devices. All patients were placed on monthly remote device interrogations for at least 8 months. Informed consent was obtained as this is not part of current recommendations and there is radiation exposure. The results were reviewed with each patient in detail.

Cine fluoroscopic images were recorded in at least 3 views (anterior-posterior, left anterior oblique, and right anterior oblique). The leads were classified as normal, abnormal-cable spacing (suggesting threatened erosion), and externalized cables. Studies were reviewed by 7 attending electrophysiologists and each study classified by consensus. The complete fluoroscopic protocol has been published previously.²

In January 2014, the charts of all 48 patients who underwent screening were reviewed. Their charts were evaluated for device complications, including electrical or mechanical failure that had occurred in the 2 years since initial screening. Surveillance methods or surgical procedures that were driven entirely by either the fluoroscopic screening or because this was a recalled product were noted. After initial screening, further decision-making was made by the patient and their primary electrophysiologist. All patients underwent repeat fluoroscopy if they were due for a generator change.

For evaluation of the initial screening program, we obtained the Medicare reimbursement estimates for a level III established patient office visit, in-person device interrogation, cine fluoroscopy, and remote device monitoring. For this cost analysis, we only used 6 months of remote monitoring monthly to account for the normal quarterly device follow-up schedule. For downstream costs, we obtained the Medicare reimbursement estimates for the physician and technical fees for lead extraction and placement of a new implantable cardioverter-defibrillator (ICD) lead.

Continuous variables are expressed as mean $\pm$ SD. Categorical variables are expressed as numbers and percentages. The statistical significances between groups were tested using the unpaired Student *t* test or Fisher's Exact test. Interobserver variability for the fluoroscopic outcome was assessed using the Shrout-Fleiss intraclass correlation coefficient ICC(3,1). The study was approved by the Institutional Review Board of the University of Virginia.

Results

Of the 48 patients who underwent the initial screening, 10 (21%) had externalized cables, 5 (10%) had abnormal-cable spacing, and 33 (69%) were normal. There was good interobserver agreement in the assessment of the abnormalities (ICC = 0.957). All leads were functioning normally electrically regardless of their fluoroscopic status. Details regarding the fluoroscopic findings have been published previously.²

The costs associated with the initial screening program are given in Table 1. The per patient screening cost was \$736.64, with the total cost for the patient population of \$35,358.72. The cost per diagnosis of mechanical lead failure was \$2,357.25.

During the 2 years after the initial screening, 1 patient experienced electrical failure of the lead. This patient had normal fluoroscopic initial screening and continued to have normal fluoroscopic appearance even after the impedance and threshold were noted to be out of range. Eight patients died of causes unrelated to their devices, 1 in the fluoroscopically abnormal group and 7 in the normal group ($p = 0.4$).

In the 2 years after the initial screening, 9 patients (22%) had surgical interventions that were a direct result of the recall or the fluoroscopic screening. Five patients had a new ICD lead added, and 4 patients were referred for Riata ICD lead laser extraction and replacement. All these interventions were performed at the same time the patient was undergoing indicated generator replacement for battery depletion. Patients were more likely to have a surgical intervention if their fluoroscopic screening was abnormal. Of the 15 patients with abnormal screening, 7 (47%) underwent surgical revision, but of the 33 patients with normal screening 2 (6%) underwent surgical revision. ($p = 0.02$). For patients due for generator change, 88% of those with abnormal screening received an intervention versus 14% of those with normal screening ($p = 0.04$).

Importantly, there are 24 remaining patients in our follow-up groups who have not already had an intervention and have not yet come up for generator change. Of the patients with abnormal screening, 6 (40%) and 18 (54%) of the fluoroscopically normal patients have not reached replacement indication. If the rates of surgical intervention for the recalled lead continue for the remaining patients in each group and they all survive over the next several years, it would be anticipated that there will be 8 more lead revisions based solely on the existence of the recall or the fluoroscopic screening.

As all lead revisions were performed at the time of planned generator change, the estimated cost of the recall-related procedure was calculated as the cost of the lead revision minus that of a generator change (Table 2). The excess cost for addition of a new lead at the time of generator change per patient was \$7,666.31. The excess cost for lead extraction with lead replacement per patient was \$10,843.25. Total costs for all recall-related lead revisions were \$81,704.55. If there are 8 further lead additions, estimated additional cost would be \$61,330.48. If there are 8 further lead extractions with replacement, estimated additional cost would be \$86,746.00.

Discussion

The Riata Recall has been expensive for the medical system. The University of Virginia, Centers for Medicare and Medicaid Services, private insurance, and patients together have absorbed >\$100,000 to date dealing with screening, follow-up, and management of complications. Only 1 patient experienced actual electrical failure of their lead that was discovered during routine follow-up and not as part of our specialized screening program. Thus, the vast majority of this cost was due to the screening program or actions that were taken as a result of the recall or the fluoroscopic screening results. The per diagnosis cost of mechanical insulation failure from our screening program was \$2,357.25.

The difficulty with these numbers is that it is not clear that the diagnosis of mechanical insulation failure would correlate with electrical failure of the lead or, most importantly, harm to the patient. The Riata lead has an electrical failure rate and a mechanical failure rate that are higher than other leads. However, the relation between electrical and mechanical failure is not understood.^{3–6} Data suggest that patients with insulation failure are at increased risk of electrical failure.⁷ Many patients with insulation failure, however, continue to have electrically functional leads, which we confirmed in this study. In fact, although >30% of our patients had insulation failure by fluoroscopic screening, the only patient who had electrical failure of the lead had normal initial screening and continued to have normal fluoroscopic appearance of the lead after the impedance and threshold were abnormal. It is possible that replacing some of these leads may have prevented future complications; however, there is currently no data from this study and little data in the literature to support this conclusion.

Our screening program led to a number of invasive procedures. In 3 patients, abnormal fluoroscopy led to lead extraction, which is not necessarily a benign procedure. Riata externalized cables may make lead extraction more complicated.^{8,9} It could be speculated that our program put our patients at more risk than had we done nothing outside normal protocols. There is precedent for this. There have been recalls in which the interventions designed to protect patients from perceived risk caused harm. This was seen with the Accufix lead, in which ultimately more patients were harmed trying to take the lead out than to leave it in situ.¹⁰ It was seen with the Guidant Ventak ICD, in which patients who received generator changes had more problems than those who did not.¹¹

Recalls present a unique challenge to the medical system. A recall is issued when there is a systematic problem with a product. The implications of that problem are difficult to predict. It usually takes years after a product is recalled to understand the real danger that the problem presented to patients. This leaves patients and physicians in the difficult position of attempting to make appropriate decisions without adequate information. The Sprint Fidelis lead was recalled 4 years before the Riata.¹² There is still controversy about what to do with these leads. Official recommendations are to leave the leads in situ, but many experts are recommending replacing the leads at the time of generator change for patient's safety and cost effectiveness.^{13–15}

Two years after the Riata lead was recalled, the Food and Drug Administration changed recommendations to include fluoroscopic screening as an aid for clinical management.^{16–18} The Food and Drug Administration did not, however, recommend specific action based on the fluoroscopic findings and still does not recommend routine lead replacement. As of 2011, St. Jude Medical estimated that there were 79,000 of these leads left in service in the United States. Implementing a screening program such as ours for all these patients would add a financial burden of more than 50 million dollars to the health care system. This is a high cost for information of questionable clinical value.

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Table 1

Costs associated with the screening program

Variable	Professional Fee	Technical Fee	Total Cost
Level III Office Visit	\$38.18	\$73.68	\$111.86
Office Device Interrogation	\$32.50	\$33.95	\$66.45
Cine-Fluoroscopy	\$26.69	\$228.52	\$255.21
Remote Device Monitoring	\$50.52	\$0	\$50.52

Table 2

Downstream costs associated with recall-related procedures

Variable	Professional Fee	Technical Fee	Total Cost
Insertion of ICD	\$914.74	\$32,144.95	\$33,059.69
Lead Extraction	\$859.24	\$2,317.70	\$3,176.94
Generator Change	\$375.20	\$25,018.18	\$25,393.38