Fluoroscopic Screening of Asymptomatic Patients Implanted With the Recalled Riata Lead Family

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Background—The Food and Drug Administration recently issued a class I recall of the St. Jude Medical Riata implantable cardioverter-defibrillator lead presumably because of increased risk of electric failure and mechanical separation via inside-out abrasion. We sought to examine the incidence and time dependence of inside-out abrasion in asymptomatic patients implanted with the Riata lead.

Methods and Results—Asymptomatic patients implanted with the Riata lead at our institution were offered voluntary fluoroscopic screening in 3 views. Electric testing of the Riata lead with provocative isometric muscle contraction was performed at the time of fluoroscopic screening. Of the 245 patients undergoing fluoroscopic screening, 53 (21.6%) patients showed clear evidence of lead separation. Of these externalized leads, 0%, 13%, and 26% had a dwell time of <3 years, 3 to 5 years, and >5 years, respectively (P=0.037). Externalized leads had a significantly pronounced decrease in R-wave amplitude (−1.7±2.9 mV versus +0.35±2.5 mV; P<0.001), and more patients with externalized leads had ≥25% decrease in R-wave amplitude from baseline (28.0% versus 8.1%; P=0.018). One patient with externalization exhibited new noise on near-field electrogram.

Conclusions—The Riata lead exhibits time-dependent high rates of cable externalization exceeding 20% at >5 years of dwell time. Externalized leads are associated with a more pronounced decrease in R-wave amplitude, which may be an early marker of future electric failure. The use of fluoroscopic and electric screening of asymptomatic patients with the Riata lead remains controversial in the management of patients affected by the recent Food and Drug Administration recall. (Circ Arrhythm Electrophysiol. 2012;5:809-814.)

Key Words: fluoroscopy ■ implanted cardioverter-defibrillators ■ recall ■ Riata lead ■ screening

Implantable cardioverter-defibrillator (ICD) leads are medical devices with inherently complex designs. Differences in lead design have resulted in some ICD leads exhibiting high rates of premature failure. In particular, smaller caliber ICD leads have more often displayed signs of premature failure. Most recently, the Riata family (St. Jude Medical Inc, Sylmar, CA) of leads has come under intense scrutiny. The Riata lead family consists of 8F and 7F (Riata ST) leads with silicone external insulation. These leads were initially introduced to the market in late 2001. In 2008, experiences of lead conductor externalization started being reported. Soon thereafter, several studies reported premature Riata lead failure, including electric failure with noise leading to inappropriate shocks, as well as changes in lead threshold, impedance, and sensing parameters. The mechanism of lead failure and conductor externalization was attributed to conductor cables exerting pressure on the inner luminal surface, leading to inside-out insulation defects because of the lead’s silicone-only insulation design. Subsequently, Riata family leads were placed under class I Food and Drug Administration recall in December 2011. More than 200,000 Riata leads have been implanted globally, and it is estimated that ≈80,000 Riata leads remain active in the United States. Currently, there are no published studies investigating the optimal approach to the clinical management of patients with active Riata leads. In 2011, a study of all Riata leads implanted at the J.W. Goethe University in Germany found 30 of 357 (8%) Riata leads to have failed within 42 months of follow-up, with 7 of these 30 failures consisting of lead externalization. Subsequently, a report from Northern Ireland found nearly 15% of patients to have lead
externalization. Most recently, a report from Switzerland found ≥12% prevalence of Riata lead externalization on fluoroscopic screening. The purpose of the present study is to examine the rates and time dependence of Riata lead externalizations and failures obtained through a comprehensive fluoroscopic and electric screening program initiated at the University of Pittsburgh Medical Center (UPMC). This report represents early data on Riata lead externalizations and failure in the United States since the class I Food and Drug Administration recall was announced a few months ago.

Methods

Patient Population

All patients followed within the UPMC network of hospitals with an active Riata ICD lead were identified and offered voluntary fluoroscopic and electric screening of their ICD lead (n=369). Of those, 245 (66%) agreed to be screened and were included in this study, which was approved by the Institutional Review Board of the University of Pittsburgh. The patients who did not agree to be screened were similar to those who were screened with respect to age (P=0.455), sex (P=0.107), percentage of ICD implantation for secondary indication (P=0.509), percentage of 8F Riata leads (P=0.144), ejection fraction (P=0.327), and lead dwell time (P=0.325). Demographic and clinical characteristics were obtained from medical records review.

Cine fluoroscopy of the Riata lead was performed in 3 views: right anterior oblique (20°–45°), posteroanterior, and left anterior oblique (20°–45°) projections at a rate of 15 to 30 frames per second. Image magnification was left to the discretion of operators who were all electrophysiologists experienced in ICD lead implantations. All fluoroscopic images were stored in the UPMC imaging digital electronic archives. Lead conductor externalization was defined as the appearance of conductors outside the lead body on fluoroscopy in any of the views. After lead fluoroscopy, all leads were classified as (1) externalized if they exhibited a clear separation of a conductor cable from the lead body, (2) indeterminate if there was a suspicion of early separation, or (3) normal if the lead appeared to be of normal structure, with uniform conductor spacing and lead width in all 3 projections. Attempts to examine the integrity of the entire lead were made, with analysis of the lead being limited by coiling in the pocket and superposition of adjacent leads. All leads that were externalized or suspicious were then reviewed by the same experienced implanters for final adjudication. In all instances, the second reviewer agreed with the original cine-fluoroscopic reading.

ICD interrogation was performed within a week of fluoroscopic screening. Standard lead parameters, including R-wave sensing amplitude, pacing and high-voltage impedance, and ventricular capture threshold, were obtained. In addition, isometric maneuvers were performed to elicit inappropriate noise on either the near-field or far-field channels. Isometric testing included 7 maneuvers performed with the arm ipsilateral to the device: (1) rubbing and moving of the device in the pocket; (2) pushing against resistance in an attempt to extend the arm forward; (3) pulling against resistance; (4) abdication at the shoulder against resistance; (5) adduction at the shoulder by putting both hands against each other; (6) back and forth movement of the ipsilateral arm mimicking a vacuum cleaner; and (7) rotational movement of the extended and elevated ipsilateral arm mimicking cleaning a window. These maneuvers were performed while monitoring the near-field (right ventricular tip-right ventricular ring) as well as the far-field (Can–superior vena cava (SVC) coil Can–distal coil or SVC coil–distal coil) channels. Electric parameters were compared with baseline values defined as first lead parameters recorded ≥30 days after initial lead implantation. Far-field noise was defined as high-amplitude (≥25% of the R-wave amplitude), nonphysiological signal seen on any of the far-field channels spontaneously or during isometric testing. Near-field noise was defined as any nonphysiological signal seen on the bipolar ventricular channel, regardless of the amplitude or actual detection by the device. Nominal device settings were maintained during isometric testing in each patient.

Analytical Techniques

All continuous variables are presented as mean±SD and were compared using Student t test and ANOVA test. All categorical variables are presented as absolute numbers and percentages and were compared using the χ2 test. Only leads with confirmed externalization by our fluoroscopic classification were considered externalized for the purposes of statistical analyses. Time-dependent rates of lead externalization were evaluated using predetermined time intervals (<3 years, 3–5 years, and >5 years) from the date of lead implantation, as well as by evaluating the externalization rates around the median or by tertiles of dwell time. A 2-sided P value <0.05 was considered statistically significant. All statistical analyses were performed on SPSS 10.1 (IBM Corporation, Armonk, NY).

Results

Baseline Characteristics

Table 1 shows the baseline demographics of screened patients and details of their ICD systems. A total of 245 patients underwent screening, with a mean age of 65±12 years at the time of lead implantation (71±12 years at the time of screening) and a mean lead dwell time of 5.7±1.5 (median, 5.6) years. Of the whole cohort, 11% of patients were pacemaker dependent. Riata leads consisted of the 8F Riata (n=187; models 1580 and 1581) and 7F Riata ST (n=58; models 7000 and 7001) connected to ICD generators manufactured by St. Jude Medical (62%), Medtronic Inc (27%), and Boston Scientific Inc (11%).

Table 1. Baseline Characteristics of Patients and ICD System

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Externalized (n=53)</th>
<th>Nonexternalized (n=190)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years at implantation</td>
<td>62±13</td>
<td>66±12</td>
<td>0.020</td>
</tr>
<tr>
<td>Age, years at screening</td>
<td>68±13</td>
<td>72±12</td>
<td>0.046</td>
</tr>
<tr>
<td>Sex (men)</td>
<td>64%</td>
<td>68%</td>
<td>0.66</td>
</tr>
<tr>
<td>Race (white)</td>
<td>93%</td>
<td>88%</td>
<td>0.38</td>
</tr>
<tr>
<td>Primary indication</td>
<td>71%</td>
<td>72%</td>
<td>0.36</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>62%</td>
<td>61%</td>
<td>0.54</td>
</tr>
<tr>
<td>Pacemaker dependence</td>
<td>12%</td>
<td>11%</td>
<td>0.28</td>
</tr>
<tr>
<td>Previous appropriate ICD</td>
<td></td>
<td></td>
<td>0.70</td>
</tr>
<tr>
<td>therapy</td>
<td>17%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>ATP</td>
<td>14%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Shock</td>
<td>24±8</td>
<td>27±12</td>
<td>0.20</td>
</tr>
<tr>
<td>Left-sided implant</td>
<td>90%</td>
<td>89%</td>
<td>0.94</td>
</tr>
<tr>
<td>Apex</td>
<td>62%</td>
<td>69%</td>
<td></td>
</tr>
<tr>
<td>Septum</td>
<td>38%</td>
<td>31%</td>
<td></td>
</tr>
<tr>
<td>Access type</td>
<td></td>
<td></td>
<td>0.94</td>
</tr>
<tr>
<td>Cephalic</td>
<td>12%</td>
<td>11%</td>
<td></td>
</tr>
<tr>
<td>Auxillary</td>
<td>88%</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>Lead model</td>
<td></td>
<td></td>
<td>0.029</td>
</tr>
<tr>
<td>7000, 7001</td>
<td>13%</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>1580, 1581</td>
<td>87%</td>
<td>74%</td>
<td></td>
</tr>
<tr>
<td>Lead length</td>
<td></td>
<td></td>
<td>0.66</td>
</tr>
<tr>
<td>60 cm</td>
<td>14%</td>
<td>21%</td>
<td></td>
</tr>
<tr>
<td>65 cm</td>
<td>86%</td>
<td>79%</td>
<td></td>
</tr>
</tbody>
</table>

ICD indicates implantable cardioverter-defibrillator; RV, right ventricular.
Riata leads in our patient cohort were implanted between April 24, 2002, and March 9, 2010. Leads were implanted in 8 hospitals, 89% of which were within the UPMC network. Twenty-four physicians implanted all leads, with a range of 1 to 66 leads per physician. Seven physicians implanted a large majority (74.7%) of Riata leads.

**Fluoroscopic Screening**

Of the 245 screened, 190 leads (77.6%) showed no separation and 53 (21.6%) leads exhibited clear externalization. In the case of 2 (0.8%) leads, fluoroscopic screening was inconclusive after review by 2 electrophysiologists. Figure 1 shows the distribution of externalized and normal leads by dwell time. None of the 53 externalized leads had a dwell time ≤3 years. Although 10 externalized leads had a dwell time of 3 to 5 years, the majority (n=43) were ≥5 years old. Figure 2 shows the percentage of externalized leads by dwell time, according to predefined time cutoffs. Externalization increased with greater lead dwell time, as observed in 10 of 77 leads (13.0%) that were 3 to 5 years old and in 43 of 165 leads (26.1%) that were ≥5 years old (P=0.037). This time dependence is further confirmed when analyzing the data around the median of the dwell time. The rate of externalization was 17 of 121 (14.0%) for leads with dwell times ≤5.6 years versus 36 of 123 (29.3%) for those with dwell times >5.6 years (P=0.003). Analyzing the data by tertiles demonstrates externalization rates of 12.7%, 31.0%, and 21.0% for tertiles 1, 2, and 3, respectively, P=0.018 with cutoffs of 5.0 years and 6.2 years between tertiles. The difference between tertiles 2 and 3 was not statistically significant (P=0.14), suggesting a possible plateau in externalization rates after 6.2 years from the implantation date.

The Riata lead externalization was seen in all projections in 59% of patients and in only a subset of views in the remaining 41%, suggesting that a reduced set of views may lead to missing externalization in some patients. When present, externalization was seen in 80%, 75%, and 84% of right anterior oblique, posteroanterior, and left anterior oblique projections, respectively. Omitting the posteroanterior view resulted in missing externalization in 1 patient (2%).

As shown in Table 1, lead externalization was associated with younger age (62±13 years versus 66±12 years; P=0.020) and with the implantation of 8F Riata leads (87% of externalized leads versus 73% of nonexternalized leads were 8F Riata leads; P=0.029).

**ICD Interrogation**

Table 2 shows the electric parameters of the Riata lead from device interrogation at fluoroscopic screening and baseline values obtained shortly but >30 days after lead implantation. Externalized leads exhibited more pronounced decrease in R-wave amplitude than normal leads (−1.3±2.6 mV versus +0.4±2.5 mV; P=0.002), and more externalized leads showed >25% decrease from baseline in R-wave amplitude (29% versus 7%; P=0.003).

Isometric maneuvers were performed on 28 of 53 patients with externalized Riata leads and on 81 of 192 patients without externalized cables. Of a total of 109 patients undergoing isometric maneuvers, 1 patient (0.9%) with externalized cables exhibited new noise on near-field electrograms during isometric maneuvers and had his lead replaced. Far-field noise was noted during isometric maneuvers in 6 of 28 patients with externalized cables and in 31 of 81 patients without externalized cables and was deemed a nonspecific finding. Figure 3 shows examples of far-field and near-field noise elicited by isometric maneuvers.

**Discussion**

This study represents the first US report of Riata lead screening for conductor externalization in asymptomatic patients. The main findings of our study are as follows: (1) the Riata lead
Our study screened more patients than previously reported externalizations; and (5) electric screening forces are not present, then no externalization takes place or occurs to the forces that contribute to conductor externalization. Interestingly, in the present study, leads ≥6.2 years old did not show a higher percentage of externalization compared with leads 5 to 6.2 years old. This suggests a possible plateau in externalization rates, which is likely reflective of unfavorable conditions and forces that, if present, result in externalization within a finite period of time. If, however, these unfavorable forces are not present, then no externalization takes place or does so slowly relative to the observation period of this study.

Role of Fluoroscopic Screening in the Clinical Management of Riata Patients

There are several basic principles of screening used to ascertain whether a particular screening test should, or should not, be used: (1) Is the disease or condition medically important and well defined?; (2) Is the screening test accurate and feasible?; and (3) Is there a clear intervention or treatment available at the time of diagnosis? In terms of relevance, Riata lead externalization and premature failure have quickly emerged as the latest large-scale medical device malfunction. Although initial reports on the performance of the Riata leads in several registries did not reveal abnormally high rates of lead-related adverse events,\textsuperscript{10,11} albeit with limited follow-up, European studies in late 2011 identified the problem of Riata lead externalization and reported its prevalence as ranging from 2% to 15%. Our data contribute to the understanding of the natural history of the Riata lead in showing a significantly higher, time-dependent rate of lead externalization exceeding 20%, as well as association between externalization and more pronounced R-wave diminution over time.

Unfortunately, no observational studies to date have defined the natural history of externalized Riata leads. Data presented by representatives of St. Jude Medical at the Riata Summit (2012, Rochester, MN) reported that the majority (>85%) of externalized Riata leads returned to St. Jude Medical for analysis functioned normally with intact ethylene tetrafluoroethylene insulation around conductor cables.\textsuperscript{7} Whether externalized leads are necessarily destined to eventual lead failure is an important clinical question that warrants further study.

As for the question of screening accuracy, our data suggest that fluoroscopic screening of Riata leads, when done according to a predefined protocol using multiple views, is...
definitive and accurate at assessing lead externalization. Only 2 of 245 (0.8%) screening procedures were inconclusive. In the absence of other diagnostic modalities, multiplanar fluoroscopic evaluation remains the method of choice for diagnosing Riata lead externalization.

The issue of feasibility is complex. From the perspective of the patient, fluoroscopic screening is not difficult. The examination is noninvasive and requires a small time commitment. There are no inherent procedural risks, with the exception of exposure to a minimal dose of radiation estimated to be ≤1
mSv, although the exact radiation dose per patient from the current cine-fluoroscopic screening was not measured. From the perspective of the caretakers, fluoroscopic screening represents additional workload and cost to the medical system, involving a sizable team of medical professionals (eg, physicians, nurses, radiology technologists, and schedulers). Nontrivial resources are required to adequately provide this service.

Several options are available to patients found to have externalized Riata leads. Conservative approaches to externalized leads include observation with or without more frequent monitoring of lead parameters and consideration of lead replacement at the time of elective generator change. More aggressive approaches include immediate prophylactic lead replacement, with or without extraction of the externalized Riata lead. The ultimate clinical course of action depends on patient (eg, age, comorbid conditions, device indication, pacemaker dependence, ipsilateral venous occlusion, and personal wishes) and physician and institutional (eg, expertise in device/lead explanation) factors. The clinical value of fluoroscopic screening of Riata leads, however, remains highly controversial.

In summary, our data show an alarmingly high externalization rate of Riata leads at fluoroscopic screening. Furthermore, fluoroscopic screening is conclusive in the majority of cases, poses little risk to patients who undergo screening, and allows for discussion of several therapeutic options should externalization be present. In the absence of observational studies detailing the natural history of externalized leads, fluoroscopic screening remains, to date, controversial.

Study Limitations

Our study has some limitations. First, it was performed at a single institution, and thus its results may not reflect the experience with Riata leads elsewhere. However, it did include patients implanted by 24 different physicians at several hospitals, thus offering some interoperator variability, despite being a single-center study. Second, although fluoroscopic screening is feasible, accurate, and safe as it subjects patients to a low risk associated with a small dose of radiation, the actual dose of radiation per patient was not measured, and it remains unclear how the mere knowledge of externalization should guide further clinical action. The use of fluoroscopic screening of Riata leads remains, therefore, controversial, particularly in that it is unlikely to be able to uncover in-pocket abrasions of insulation on high-voltage conductors, which is likely a significant mechanism of failure in Riata leads.

Conclusions

With multiple view fluoroscopic screening of asymptomatic Riata leads, ≥20% of leads exhibit cable externalization, and this appears to be a time-dependent phenomenon. There remains uncertainty regarding the progression of externalized leads toward overt electric failure. However, given the accuracy, safety, and feasibility of fluoroscopic screening, it may be considered in patients who have an indwelling active Riata lead, particularly for high-risk subsets where failure may be catastrophic, including pacemaker-dependent patients and secondary prevention cohorts.

Disclosures

None.

References


CLINICAL PERSPECTIVE

The Riata defibrillator lead family (St. Jude Medical, Sylmar, CA) was placed under class I recall by the Food and Drug Administration in December of 2011 because of an increase rate of separation of the lead cables from the Silicone insulation (the so-called lead externalization) and higher than expected electric failure. In this study, we investigated these patterns of failure using a screening program implemented at our institution, consisting of fluoroscopic imaging, as well as isometric maneuvers, and demonstrated high overall rates of externalization of the Riata lead (≥20%), associated with longer dwell times and more pronounced decline in sensing parameters. Leads that were implanted for <3 years had no externalizations documented, whereas those implanted for >7 years had a 26% rate of externalization. These data have implications as to the management of patients implanted with the Riata lead.
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_Circ Arrhythm Electrophysiol_. 2012;5:809-814; originally published online July 11, 2012; doi: 10.1161/CIRCEP.112.973081

_Circulation: Arrhythmia and Electrophysiology_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 1941-3149. Online ISSN: 1941-3084

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