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

Running title: Liu et al.; Fluoroscopic Screening of Riata Leads

Jeffrey Liu, MD1; Rohit Rattan, MD1; Evan Adelstein, MD1; William Barrington, MD, F HRS1; Raveen Bazaz, MD1; Susan Brode, MD1; Sandeep Jain, MD, F HRS1; G. Stuart Mendenhall, MD1; Jan Nemec, MD1; Eathar Razak, MD1,2; Alaa Shalaby, MD, F HRS1,2; David Schwartzman, MD, F HRS1; Andrew Voigt, MD1; Norman C. Wang, MD1; Samir Saba, MD, F HRS1

1University of Pittsburgh Medical Center
2Pittsburgh Veterans Affairs Healthcare System, Pittsburgh, PA

Address Correspondence to:
Samir Saba, MD, F HRS
Director, Cardiac Electrophysiology
University of Pittsburgh Medical Center
200 Lothrop Street, PUH B535
Pittsburgh, PA 15213
Tel: (412) 647 6272
Fax: (412) 647 7979
E-mail: sabas@upmc.edu

Journal Subject Codes: [106] Electrophysiology
Abstract:

Background - The Food and Drug Administration (FDA) recently issued a class I recall of the St. Jude Medical Riata™ implantable cardioverter-defibrillator (ICD) lead because of increased risk of electrical failure presumably 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. Electrical testing of the Riata lead with provocative isometric muscle contraction was performed at the time of fluoroscopic screening. Of 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 - 5 years, and >5 years, respectively (p=0.037). Externalized leads had significantly pronounced decrease in R-wave amplitude (-1.7±2.9 mV vs. +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% vs. 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 dwell time. Externalized leads are associated with more pronounced decrease in R-wave amplitude which may be an early marker of future electrical failure. The use of fluoroscopic and electrical screening of asymptomatic patients with the Riata lead remains controversial in the management of patients affected by the recent FDA recall.

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 8 French (Fr.) and 7 Fr. (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 electrical 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 (FDA) recall in December 2011. More than 200,000 Riata leads have been implanted globally and it is estimated that approximately 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. Specifically, the value of fluoroscopic screening of Riata leads to uncover externalization in asymptomatic patients remains unclear. 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 approximately a 12% prevalence of Riata lead externalization on fluoroscopic screening.
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 electrical 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 FDA recall was announced 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 electrical 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), gender (p=0.107), percentage of ICD implantation for secondary indication (p=0.509), percentage of 8 Fr. 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 (RAO, 20° to 45°), postero-anterior (PA), and left anterior oblique (LAO, 20° to 45°) projections at a rate of 15-30 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 of 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 at examining the integrity of the entire lead was 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 implanter 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) abduction at the shoulder against resistance; 5) adduction at the shoulder by putting both hands against each other and pushing; 6) back and forth movement of the ipsilateral arm mimicking operating 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 (RV tip-RV ring) as well as the far-field (Can - SVC coil Can – distal coil, or SVC coil - distal coil) channels. Electrical parameters were compared to 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), non-physiologic signal seen on any of the far-field channels spontaneously or during isometric testing. Near-field noise was defined as any non-physiologic signal seen on the bipolar ventricular channel.
regardless of 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 ± standard deviation and were compared using student’s t-test and ANOVA test. All categorical variables are presented as absolute numbers and percentages and were compared using the Chi-square 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 two-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 the screening) and a mean lead dwell time of 5.7±1.5 years (median = 5.6 years). Of the whole cohort, 11% of patients were pacemaker-dependent. Riata leads consisted of the 8 Fr. Riata (n=187; models 1580 and 1581) and 7 Fr. 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%).

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**

Out of 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. While 10 externalized leads had a dwell time of 3 - 5 years, the majority (n = 43) were ≥5 years old. Figure 2 shows the percentage of externalized leads by dwell time, according to pre-defined time cutoffs. Externalization increased with greater lead dwell time, as it was observed in 10 of 77 leads (13.0%) that were 3 - 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 17/121 (14.0%) for leads with dwell times ≤5.6 years versus 36/123 (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 RAO, PA, and LAO projections, respectively. Omitting the PA 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 8 Fr. Riata leads (87% of externalized leads versus 73% of non-externalized leads were 8 Fr. Riata leads, p=0.029).

**ICD Interrogation**

Table 2 shows the electrical 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 vs. 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. Out of a total of 109 patients undergoing isometric maneuvers, one 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 6/28 patients with externalized cables and in 31/81 patients without externalized cables and was deemed a non-specific finding. Figure 3 shows examples of far-field and near-field noise elicited by isometric maneuvers.

**Discussion**

This study represents the first United States report of Riata lead screening for conductor externalization in asymptomatic patients. The main findings of our study are: (1) The Riata lead exhibits a high definitive externalization rate exceeding 20% at > 5 years dwell time; (2) Riata lead externalization is time-dependent but appears to possibly plateau at approximately 6 years; (3) Externalized leads have more pronounced R wave amplitude decreases from baseline values; (4) Multiple fluoroscopic views are needed to detect externalization; (5) Electrical screening of
Riata patients with isometric maneuvers may elicit noise on the near-field channel in a small subset of patients.

**Riata Externalization and Time Dependence**

In this study, more than 20% of all Riata leads followed within the UPMC network of hospitals exhibited lead externalization, which is a markedly higher percentage than previously reported externalization rates from Germany (2%)\(^6\), Northern Ireland (15%)\(^7\) and Switzerland (11.5%)\(^8\).

Our study screened more patients (n=245) than the Northern Ireland and Swiss studies (n=165 and n=52, respectively). Furthermore, our approach used high resolution cine fluoroscopy in multiple views to screen all patients instead of biplane chest radiography and proceeding to fluoroscopy only if conventional radiography was suspicious, which was the method used in the Swiss study. By proceeding directly to multi-planar fluoroscopy, we likely increased the sensitivity of detecting externalized leads that may possibly have been undetected when using chest radiography as the initial screening test. This may also be the reason why the Northern Ireland group who also employed high resolution fluoroscopy on all subjects reported a higher externalization rate as compared to the Swiss group. On the other hand, Erkapic et al. reported a markedly lower prevalence of Riata lead externalization in a study which did not mandate that all patients with Riata leads undergo prophylactic fluoroscopic screening. This may explain the lower rates of externalizations detected in that study.

In the present study, we also found significant time-dependence of Riata lead externalization. None of the 53 externalized leads in this study were within three years of implantation and the majority of externalized leads were between 5 and 6.2 years old (in the second tertile by dwell time). The lead dwell-times in our present study are comparable to those of others: mean time to screening was 3.98 ± 1.43 years after lead implantation in the Northern
Ireland study and 6.6 ±1.2 years in the Swiss study. The observed time-dependent nature of lead separation is not surprising. The mechanism of Riata lead mechanical malfunction involves conductor cables coated with ethylene tetrafluoroethylene (ETFE) exerting pressure on the inner luminal surface of the lead, particularly in regions of lead flexion, which ultimately results in ‘inside out’ silicone insulation breach. Thus, the more time elapsed from implantation equates longer exposure 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 to leads 5 - 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 employed9: (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 has quickly emerged as the latest large scale medical device malfunction. While initial reports on the performance of the Riata leads in several registries did not reveal abnormally high rates of lead-related adverse events10,11, 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%-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 ETFE insulation around conductor cables\(^5\). 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, multi-planar 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 exam is non-invasive 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 \(\leq 1\) mSv, although the exact radiation dose per patient from the current cine-fluoroscopic screening was not measured. From the perspective of the care takers, fluoroscopic screening represents additional workload and cost to the medical system, involving a sizable team of medical professionals (e.g. physicians, nurses, radiology technologists, and schedulers). Non-trivial 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 (e.g. age, co-morbid conditions, device indication, pacemaker-dependence, ipsilateral venous occlusion, and personal wishes) and physician and institutional (e.g. expertise in device/lead explantation) factors. The clinical value of fluoroscopic screening of Riata leads remains, however, 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 inter-operator variability despite being a single center study. Secondly, 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 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 towards overt electrical 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 pacer-dependent patients and secondary prevention cohorts.

Conflict of Interest Disclosures: None

References:


8. Schmutz M, Delacretaz E, Schwick N, Roten L, Fuhrer J, Boesch C, Tanner H. Prevalence of
asymptomatic and electrically undetectable intracardiac inside-out abrasion in silicon-coated
Riata and Riata ST implantable cardioverter-defibrillator leads. *Int J Cardiol.* 2012; Jan 9 (ePub
ahead of print).


O, Beau SL, Herre JM. Clinical performance of the St. Jude Medical Riata defibrillation lead in a
Table 1. Baseline Characteristics of Patients and ICD System

<table>
<thead>
<tr>
<th></th>
<th>Externalized (N=53)</th>
<th>Non-Externalized (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>Gender (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 Therapy</td>
<td></td>
<td></td>
<td>0.70</td>
</tr>
<tr>
<td>ATP</td>
<td>17%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Shock</td>
<td>14%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Ejection Fraction</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>RV lead Position</td>
<td></td>
<td></td>
<td>0.62</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>Axillary</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>
### Table 2. Electrical Parameters of Screened Riata Leads

<table>
<thead>
<tr>
<th></th>
<th>Externalized Leads (N=53)</th>
<th>Non-Externalized Leads (N=192)</th>
<th>P Value</th>
<th>Adjusted P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R wave (mV)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>11.2±3.3</td>
<td>10.6±3.2</td>
<td>0.46</td>
<td>0.89</td>
</tr>
<tr>
<td>Screening</td>
<td>9.9±4.0</td>
<td>10.9±3.3</td>
<td>0.28</td>
<td>0.94</td>
</tr>
<tr>
<td>Change from Baseline</td>
<td>- 1.3±2.6</td>
<td>+ 0.4±2.5</td>
<td>0.002</td>
<td>0.002</td>
</tr>
<tr>
<td><strong>Pacing Impedance (Ω)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>462±96</td>
<td>462±79</td>
<td>0.99</td>
<td>0.96</td>
</tr>
<tr>
<td>Screening</td>
<td>418±95</td>
<td>422±89</td>
<td>0.78</td>
<td>0.78</td>
</tr>
<tr>
<td>Change from Baseline</td>
<td>-33±90</td>
<td>-40±87</td>
<td>0.69</td>
<td>0.82</td>
</tr>
<tr>
<td><strong>Shock Impedance (Ω)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>46±6</td>
<td>43±7</td>
<td>0.13</td>
<td>0.13</td>
</tr>
<tr>
<td>Screening</td>
<td>50±8</td>
<td>47±9</td>
<td>0.051</td>
<td>0.064</td>
</tr>
<tr>
<td>Change from Baseline</td>
<td>+4±9</td>
<td>+5±8</td>
<td>0.94</td>
<td>0.72</td>
</tr>
<tr>
<td><strong>Pacing Threshold (V at 0.5 ms)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>1.07±0.83</td>
<td>0.92±0.46</td>
<td>0.20</td>
<td>0.28</td>
</tr>
<tr>
<td>Screening</td>
<td>1.03±0.50</td>
<td>0.98±0.41</td>
<td>0.44</td>
<td>0.46</td>
</tr>
<tr>
<td>Change from Baseline</td>
<td>-0.09±0.77</td>
<td>+ 0.06±0.49</td>
<td>0.19</td>
<td>0.21</td>
</tr>
</tbody>
</table>

(*) P value adjusted for lead dwell time
Figure Legends:

**Figure 1.** Bar graph showing the distribution of externalized (blue) and non-externalized (red) Riata leads by time from lead implantation to fluoroscopic screening, binned by 6-month intervals. Note that none of the externalized leads have been implanted for less than 3 years and that the distribution is skewed to the right for the externalized compared to the non-externalized leads.

**Figure 2.** Bar graph demonstrating the time-dependence of externalization of Riata leads.

**Figure 3.** Example of near-field (panel A) and far-field (panel B) noise elicited during isometric maneuvers in two Riata patients one with (panel A) and one without (panel B) cable externalization. The arrow in panel A shows the low amplitude noise seen on the near-field channel but not detected by the device.
Rates of Externalization of Riata Leads

P=0.037

- 0 of 3 (0%)
- 10 of 77 (13%)
- 43 of 165 (26%)

Riata Lead Dwell Time

Percentage of Patients
1: Markers
2: V Bipolar AutoGain (3.6 mm/mV)
3: Custom SVC-Can AutoGain (10.0 mm/mV)

Sweep Speed: 25 mn
Fluoroscopic Screening of Asymptomatic Patients Implanted with the Recalled Riata Lead Family
Jeffrey Liu, Rohit Rattan, Evan Adelstein, William Barrington, Raveen Bazaz, Susan Brode, Sandeep Jain, G. Stuart Mendenhall, Jan Nemec, Eathar Razak, Alaa Shalaby, David Schwartzman, Andrew Voigt, Norman C. Wang and Samir Saba

Circ Arrhythm Electrophysiol. published online July 11, 2012;
Circulation: Arrhythmia and Electrophysiology is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2012 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-3149. Online ISSN: 1941-3084

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circep.ahajournals.org/content/early/2012/07/11/CIRCEP.112.973081

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Arrhythmia and Electrophysiology can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Arrhythmia and Electrophysiology is online at:
http://circep.ahajournals.org//subscriptions/