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Increasing lead burden correlates with externalized cables during systematic fluoroscopic screening of Riata leads

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Abstract

Purpose—Riata and Riata ST defibrillator leads (St. Jude Medical, Sylmar, CA, USA) have been recalled due to increased risk of insulation failure leading to externalized cables. As this mechanical failure does not necessarily correlate with electrical failure, it can be difficult to diagnose. Fluoroscopic screening can identify insulation failure. Studies have suggested that insulation failure is predominantly seen in 8-Fr, single-coil models. Our patients have exclusively dual-coil leads and a high proportion of 7-Fr leads.

Methods—Fluoroscopic screening was performed in 48 patients with recalled Riata leads. Twenty-three patients had 8-Fr Riata leads and 25 patients had 7-Fr Riata ST leads. Images were recorded in at least three projections and studies were reviewed by seven attending electrophysiologists.

Results—Externalized cables were seen in ten patients (21 %), and another five patients (10 %) had abnormal cable spacing. All device interrogations showed normal parameters. Patients with abnormal leads had more leads *in situ* (2.5 ± 0.7 vs. 1.6 ± 0.8 leads; $P=0.002$) and a higher rate of nonischemic cardiomyopathy (80 vs. 24 %; $P=0.03$). There were no differences between the groups with regards to patient age, body mass index, lead age, lead parameters, or vascular access site. There was no difference with regard to lead size ($P=0.76$).

Conclusions—The Riata family of leads has a high incidence of mechanical failure, as demonstrated on fluoroscopic screening. In this study, the 7-Fr models were just as likely to mechanically fail as the 8-Fr models. Increasing lead burden and a diagnosis of nonischemic cardiomyopathy correlated with insulation failure.

Keywords

Implantable cardioverter-defibrillator; Fluoroscopy; Defibrillation; Recall; Inappropriate shocks

1 Introduction

A class I recall was initiated for the Riata and Riata ST leads (St. Jude Medical, Sylmar, CA, USA) in December of 2011 [1]. These defibrillator leads have increased risk of failure due to a unique insulation defect. The silicone insulation on these leads is prone to “inside-out erosion” whereby the cables of the lead can become exteriorized [1, 2]. While the Riata and

Riata ST leads have been shown to have a higher electrical failure rate than other models, the relationship between the externalized cables and electrical failure is not clear. Over the last several years, case reports have appeared in the literature describing electrical failure of these leads in the setting of exteriorized cables as seen on fluoroscopic examination of the lead [3–6]. However, there have also been cases of leads with externalized cables with completely normal electrical function [7, 8]. This is presumed to be due to an ethylene–tetrafluoroethylene coating on the cables themselves which acts as a secondary insulator [2].

As the device interrogations in patients with externalized cables are often normal, it is difficult to screen for the outer insulation defects. In addition, plain chest radiographs have been shown to be insensitive for detecting externalized cables [7]. The movement during the cardiac cycle as seen on fluoroscopy is usually needed to see the cables separate from the rest of the lead. Thus, it is difficult to know the incidence of this mechanical defect. Kodoth *et al.* systematically examined Riata and Riata ST leads by fluoroscopy and reported their results at the European Society of Cardiology Scientific Sessions in 2011 [9]. They demonstrated that 15 % of their patients had externalized cables. However, 80 % of leads were electrically normal at the time of fluoroscopic screening. A large proportion of their population had 8-Fr Riata single-coil leads. It has been speculated that their findings may be limited to these particular models [10].

Our population of patients has a larger proportion of 7-Fr Riata ST leads and all of our patients have dual-coil leads. To determine the rate of mechanical and electrical failures, we systematically screened our population of patients with Riata and Riata ST leads with device interrogation and fluoroscopy. We determined clinical and lead characteristics associated with structural lead abnormality.

2 Methods

2.1 Patient population

Between 2003 and 2007, 184 Riata and Riata ST leads were implanted at the University of Virginia. Review of our records demonstrates that 42 of the patients are deceased. An additional 73 patients are now followed up at other institutions. Four patients experienced electrical failure of their lead prior to this study (three with noise on the lead and one with rising pacing impedance) and were taken out of service. Thus, there were 65 patients with active St. Jude Riata and Riata ST leads that were being followed up by our institution at the time of the Food and Drug Administration (FDA) recall.

After the recall was initiated, all 65 patients were contacted and offered an outpatient visit to discuss the advisory and undergo recommended device interrogation and reprogramming [11]. At the visit, recall data was reviewed as well as current St. Jude Medical and FDA recommendations. All patients were offered fluoroscopic screening of their lead. Comprehensive interrogation was performed of all devices. If there were abnormal fluoroscopic findings, isometric maneuvers were performed during interrogation to attempt to illicit lead noise. Informed consent was obtained as this is not part of current recommendations, and there is radiation exposure. This study was approved by the Institutional Review Board of the University of Virginia.

2.2 Fluoroscopic imaging

The cine fluoroscopic images were recorded in at least three views. The leads were initially surveyed from the generator to the lead tip in an anterior–posterior projection. Images were also recorded in the left anterior oblique and right anterior oblique views. Further images were recorded per the operator's discretion. The leads were classified according to three

categories: (1) normal appearance; (2) abnormal cable spacing; and (3) externalized cables. A lead was determined to have externalized cables when one or more cables were concluded to be obviously external to the body of the lead. A lead was determined to have abnormal cable spacing when there was movement of one or more cables away from the main body of the lead on frame-by-frame analysis [12]. This was felt to denote early or threatened erosion. All studies were reviewed by seven attending electrophysiologists and each study was classified by consensus.

2.3 Statistical analysis

Continuous variables are expressed as the mean±standard deviation. Categorical variables are expressed as numbers and percentages. The statistical significance of differences between groups was tested using the unpaired Student's *t* test or Fisher's exact test. Univariable and multivariate logistic regression analysis was performed to predict positive fluoroscopic screening (Minitab 16, State College, PA, USA). Continuous variables assessed included patient age, height, body mass index, number of leads, lead parameters, and lead age. Categorical variables assessed included gender, vascular access site, diagnosis, and delivery of shocks. Significant univariate predictors ($P<0.10$) were tested in the multivariate model, and the final multivariate model was constructed using a stepwise algorithm ($P<0.05$). The maximum number of covariates included in the final model was constrained to two based on the number of observed events to avoid overfitting. Interobserver variability for the fluoroscopic outcome was assessed using the Shrout–Fleiss intraclass correlation coefficient ICC(3,1).

3 Results

Of the 65 patients with active Riata or Riata ST leads contacted regarding the advisory, 48 were seen in clinic and agreed to fluoroscopic screening of their leads. The screenings took place in January and February 2012. The patient characteristics are given in Table 1. All patients had dual-coil leads. The 8-Fr Riata lead was present in 23 patients and the 7-Fr Riata ST lead was present in 25 patients. There was excellent agreement in the assessment of the fluoroscopic abnormalities (ICC=0.957).

Externalized cables were seen in ten patients (21 %), and an example is shown in Fig. 1. Another five patients (10 %) were determined to have abnormal cable spacing, likely denoting early or partial erosion, and an example is shown in Fig. 2. The remaining 33 (69 %) had normal fluoroscopic appearance. All externalized cables lay between the shock coils involving the heel of the lead in the right atrium. One patient had externalization above the proximal shocking coil in addition to between the coils (Fig. 3). One of the leads with abnormal cable spacing was electively extracted using a laser sheath. This patient also had a malfunctioning atrial lead and rapid battery depletion and was referred for revision of the entire system. After extraction, a small area of cable externalization was seen just proximal to the distal coil, in the same area as seen on fluoroscopic screening (Fig. 4).

On device interrogation, all of the leads were electrically normal. There was no evidence of noise with isometric provocative maneuvers. There were no differences in R wave amplitude, threshold, or impedance between the normal and abnormal leads (Table 1). High voltage testing was not performed.

In univariate analysis, the major significant difference between the two groups was the number of pacing leads *in situ* (Fig. 5). The patients with abnormal leads had an average of 2.5 ± 0.7 leads, while normal patients had an average of 1.6 ± 0.8 leads ($P=0.002$). The patients with abnormal leads were more likely to have nonischemic cardiomyopathy (80 vs. 24 %; $P=0.03$) and a higher percentage of right ventricular pacing (63 vs. 25 %; $P=0.01$).

In multivariable analysis, the only significant predictors were the number of leads ($P=0.025$) and nonischemic cardiomyopathy ($P=0.035$). The higher percentage of right ventricular pacing reflects the presence of biventricular devices and did not remain an independent predictor.

On univariate analysis, there were some interesting trends. There were more women in the abnormal group (60 vs. 21 %; $P=0.13$). The leads were older in the abnormal group (5.9 ± 1.1 vs. 5.4 ± 1.1 years; $P=0.12$). Importantly, there were no differences between the normal and abnormal groups with regards to patient age, 7- or 8-Fr lead size, access site, or clinical shock delivery (Table 1).

4 Discussion

This study demonstrates a high rate of mechanical failure in the Riata and Riata ST lead. Previous studies have led to speculation that this problem may be predominantly in 8-Fr Riata single-coil leads [2, 10]. Our study showed no differences between the 7- and 8-Fr leads, and all of our leads were dual-coil; other recent studies have demonstrated similar findings [12]. Like most studies, we demonstrated that the predominant site of failure is in the right atrium at the heel of the defibrillator lead [2, 7, 12, 13]. We also found that an increased number of leads *in situ* correlates with failure. This is interesting as the mechanism of insulation failure is “inside-out erosion” as opposed to external abrasion. The cables are somewhat mobile within the body of the lead, and it may be that other leads provide hinge points that increase the internal abrasion. We also found that nonischemic cardiomyopathy was strongly associated with mechanical failure. Patients with nonischemic cardiomyopathies often have greater left ventricular dilatation and this could play a role in lead position and motion within the heart. Unfortunately, we do not have serial echocardiography data to confirm this hypothesis.

While 21 % of patients had mechanical failure of the lead by fluoroscopic examination, all of the patients we screened had normal function electrically on device interrogation. The relationship between this unique mode of insulation failure and actual electrical failure is not at all clear [14]. Studies have clearly shown that the rate of electrical failure in the Riata and Riata ST leads is higher than other models [15]. However, that electrical failure rate is not nearly as high as our study has shown the mechanical failure rate to be. It may be that the externalized cables are a marker of the insulation defect but the actual appearance of externalized cables fluoroscopically may not be necessary for failure of the insulation and electrical malfunction. Furthermore, interrogation is not helpful in diagnosing externalized cables and may not be helpful in diagnosing imminent electrical failure of the device either [13, 16].

More information is needed regarding the Riata leads [14]. The natural history of this lead with or without externalized cables is unclear at the present time. St. Jude Medical has developed a study to follow-up patients with externalized cables, which started just last December 2011. As shown for the case of the Medtronic Sprint Fidelis lead, which was recalled in 2005, it is difficult to predict whether the failure rate of a faulty lead will plateau or continue to climb over years [17]. We will be gathering data regarding the Riata and Riata ST leads for years to come, and clinical recommendations will continue to evolve.

How to use this fluoroscopic screening information in clinical practice is an important question. The FDA has recently updated recommendations to include fluoroscopic screening of Riata leads [18]. They do not recommend replacement of leads with externalized cables, but state that decisions should be “individualized” based upon patient history and severity of the fluoroscopic abnormality. This is driven, again, by the fact that many of these leads seem

to function normally electrically despite externalized cables. Studies of prior advisory-related lead and generator replacements have shown higher complication rates from the replacements than the patients would expect as the result of continued use of the product [19, 20]. Each advisory presents a distinct clinical problem, and overreaction to this kind of data is a real concern. Continued analysis of Riata lead data, such as the findings presented in the current analysis, will be critical to inform long-term management decisions.

Patient disclosure is an important part of this process. The findings were discussed with the 15 patients who were found to have abnormal leads by fluoroscopic examination, and we did not recommend routine lead replacement. All patients with Riata and Riata ST leads were placed on home monitoring, and programming changes were made as recommended by the company [11]. Patients with abnormal leads were offered monthly remote monitoring evaluation. Two of the patients were due for generator change and, after discussion, elected to have a new lead placed at the time of generator change. Another patient with a biventricular device had noise on his atrial lead and rapid battery depletion. He was referred for extraction and replacement of his atrial and implantable cardioverter–defibrillator leads and generator. The remaining 12 patients were comfortable with a plan for watchful waiting. They will be screened again at the time of generator change or in 12 months.

4.1 Limitations

This is a single-center study involving a relatively small number of patients. Factors, such as gender and the age of the lead, may be significant predictors in a larger sample size. There are likely many other variables involved in cable externalization that a study of this size would be unable to identify. Leads were implanted by six different operators, but implantation technique cannot be ruled out as a factor. Although the determination of abnormal fluoroscopic findings is qualitative and subject to reader interpretation, measures of interobserver variability confirmed excellent agreement among raters.

5 Conclusions

Both Riata and Riata ST defibrillator leads are at high risk for mechanical failure, as assessed by fluoroscopic screening. Externalized cables do not necessarily correlate with electrical failure. Increasing lead burden was an independent predictor of externalized cables by fluoroscopic screening in this study and may be an important factor in lead failure. Further data is needed to determine the natural history of this lead family.

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Fig. 1.
Externalized cables as seen on fluoroscopic screening of a Riata lead

Fig. 2.
Abnormal cable spacing as seen on fluoroscopic screening of a Riata lead

Fig. 3. Fluoroscopic images from a single Riata lead with multiple insulation defects, including proximal to the superior vena cava coil (**a**) and between the shock coils (**b**)

Fig. 4.
Extracted lead that had been judged to have abnormal cable spacing by fluoroscopic screening

Fig. 5.
Relationship between lead burden and externalized cables as detected by fluoroscopic screening

Table 1

Patient characteristics fluoroscopic appearance

	Normal	Abnormal	P value
Number of patients	33	15	
Age (years)	60±10	57±15	0.68
Female	7 (21 %)	9 (60 %)	0.13
Body mass index (kg/m ²)	31±6	30±7	0.66
Ischemic cardiomyopathy	15 (45 %)	2 (13 %)	0.20
Nonischemic cardiomyopathy	8 (24 %)	12 (80 %)	0.03
Secondary prevention indication	9 (27 %)	2 (13 %)	0.48
Age of lead (years)	5.4±1.1	5.9±1.1	0.12
7-Fr lead	18 (55 %)	7 (47 %)	1.0
8-Fr lead	15 (45 %)	8 (53 %)	0.79
Atrial lead <i>in situ</i>	13 (39 %)	13 (87 %)	0.14
Left ventricular lead <i>in situ</i>	7 (21 %)	9 (60 %)	0.13
Total number of leads <i>in situ</i>	1.6±0.8	2.5±0.7	0.002
Number receiving shocks	13 (39 %)	4 (27 %)	0.76
Access site			
Cephalic	7 (21 %)	5 (33 %)	0.51
Subclavian	15 (45 %)	7 (47 %)	1.0
Axillary	5 (15 %)	1 (7 %)	0.67
Lead parameters			
R wave	11.7±4.0	10.6±3.0	0.40
Threshold	0.9±0.4	0.85±0.3	0.45
Pacing Impedance	441±124	460±94	0.61