Insight into the mechanism of failure of the Riata lead under advisory

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BACKGROUND Cable externalization and insulation abrasion are known to occur with the St Jude Medical Riata leads under advisory. The distribution of these abnormalities and how they relate to clinical presentation have not been well described.

OBJECTIVE In this study, we sought to determine the relationship between structural lead failure and clinical presentation by using the analysis of returned Riata products in Canada.

METHODS The analyses of returned Riata products in Canada were obtained from St Jude Medical, Sylmar, CA. These data were correlated with the clinical presentation of patients just before lead removal from service.

RESULTS As of May 1, 2013, there were 263 returned Riata leads in Canada. Of these, 43 (16.8%) were found to have insulation abrasion that was due to either lead-can or lead-other device interaction (70%) or inside-out abrasion (27.9%). The predilection of lead-to-can abrasion was seen in the Riata 7-F leads (84.2% vs 58.4%; $P = .07$), while inside-out abrasion was more common in the Riata 8-F leads (37.5% vs 15.8%; $P = .12$). Electrical abnormalities were frequent (20 of 31 [65.4%]) and most often due to electrical noise (45.2%), although inappropriate shocks were present (25.8%). Death occurred in 1 of 43 (2.3%) of those patients with an insulation defect in the lead-can abrasion group.

CONCLUSION Lead-can abrasion is the most common form of insulation defect in the Riata group of leads under advisory. Management of this group of leads under advisory should not neglect the issue of lead-can abrasion, in addition to detection of cable externalization.

KEYWORDS Device advisory; Implantable cardioverter-defibrillator; Lead failure

ABBREVIATION ICD = implantable cardioverter-defibrillator

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Introduction

The Riata lead advisory was announced on November 28, 2011, by St Jude Medical after the lead had been removed from the market the previous year.[1] This advisory describes the possibility of conductors within the implantable cardioverter-defibrillator (ICD) lead becoming externalized owing to an "inside-out" abrasion mechanism. The underlying defect for this is attributed to weakness of silicone that surrounds the conductors. The implications of this novel mechanism of lead failure are a cause of concern because of the theoretical possibility of abnormal electrical conductance if this faulty lead is left in place and mechanical complications resulting from externalized conductors or interaction with subsequent implanted leads.[2] The rate of conductor externalization has been found to occur in up to 25% of these leads and has been observed to occur more commonly in the 8-F Riata lead.[3,4] Electrical lead failure is far less common and does not always occur in the presence of cable externalization.[5,6] We have previously reported on electrical lead failure and have found a rate of 4.6% over a 5-year follow-up,

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but cable externalization was present only in 8% of leads.[7] These findings have led to uncertainty as to the failure mechanism of the Riata lead and the purported importance of cable externalization. This study was performed to determine the failure mechanism of the Riata lead by examining returned products in Canada and correlating them to the clinical presentation.

Study design

The Queen Elizabeth II Health Sciences Centre Ethics Review Board approved the study. A list of returned products for the Riata and Riata ST leads under advisory (models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042) from Canada was obtained from St Jude Medical, Sylmar, CA. This list was complete as of May 13, 2013. Data on returned products obtained directly from St Jude Medical included primary (and secondary, if available) root cause as determined by laboratory analysis by St Jude Medical, date of implantation and explantation, medical center of original implantation, presence of lead-to-can abrasion or intravascular/intracardiac abrasion, and distance from abrasion site to connector pin in lead-to-can abrasion, and distance from distal lead tip to abrasion site in the case of intravascular/intracardiac abrasion. Each Canadian center documented as having returned a Riata lead and found to have insulation abrasion through St Jude Medical's analysis was contacted to obtain the clinical information surrounding the lead removal. These data included age, sex, body mass index, indication for ICD, date of implantation, left ventricular ejection fraction, New York Heart Association class (if a history of heart failure was present), diabetes, atrial fibrillation, evidence of cable externalization before explantation, number of leads at original implantation, presence of cardiac resynchronization therapy, previous pacemaker, active vs passive fixation, single coil vs dual coil, procedural time, venous access, percent pacing, lead impedances, threshold, sensing at baseline and before extraction, presence of electrical noise, inappropriate shocks due to electrical noise, and complications from lead removal.

Statistical analysis

Continuous variables were analyzed as mean ± SD. Categorical variables were analyzed as percentages, unless otherwise specified. Differences among groups were determined using the χ^2 test or the Fisher exact test; 2-sided P values $<.05$ were considered statistically significant.

Results

There were 263 returned products included in the present analysis, as of May 13, 2013, from Canada (Table 1). The cause for the returned product, as determined by laboratory analysis by St Jude Medical, is given in Table 2. One death occurred in a patient with a normal lead owing to early perforation post-implantation. A total of 43 leads (16.3%) were found to have insulation abrasion (Table 3). The mean lead dwell time was 4.9 ± 2.5 years (range 0.22–10.2 years). The occurrence of electrical lead failure was significantly associated with a longer dwell time ($P < .0001$; Figure 1). The most common form of abrasion was insulation abrasion due to a lead-to-can or lead-to-another device interaction (70%); the remainder was due to inside-out abrasion (27.9%); 1 cause for abrasion could not be determined. The distribution of type of insulation abrasion varied according to lead model: abrasion due to lead-to-can or lead-to-device interaction was lower among the 8-F models than the 7-F models (58.4% vs 84.2%, respectively; $P = .07$), while there was a predilection of inside-out abrasion among the 8-F models than the 7-F models (37.5% vs 15.8%, respectively; $P = .12$). Abrasion of the ethylene tetrafluoroethylene, a fluorine-based plastic used to insulate conductor cables, was noted in 2 reports, one in the case of lead-to-can abrasion and the other in the case of inside-out abrasion. In the cases of lead-to-can abrasion, the distance from the connector pin to the site of abrasion was available in 58% of the returned products; the mean distance from the connector pin to the site of abrasion was 15.9 ± 6.5 cm. No reports of insulation defects underneath the shock coil were seen. In the case of inside-out abrasion, distance from the distal tip of the lead to the site of abrasion was available in 19 leads; 9 (47%) were found to have 2 areas of cable externalization. The mean distance from the distal tip of the lead to the site of abrasion was 14.9 ± 9.5 cm.

Table 1 Returned product evaluation: Distribution of lead models

Model	n (%)
1560, 1561, 1562	1 (0.38)
1570, 1571, 1572	17 (6.5)
1580, 1581, 1582	124 (47.1)
1590, 1591, 1592	10 (3.8)
8 F (total)	152 (57.8)
7000, 7001, 7002	98 (37.2)
7040, 7041, 7042	13 (4.9)
7 F (total)	111 (42.2)
Single coil	29 (11.0)
Dual coil	234 (89.0)
Active fixation	173 (65.8)
Passive fixation	90 (34.2)
Total	263

Table 2 Primary root causes for returned products: Riata and Riata ST leads under advisory

Cause	n (%)
Damage at the time of implantation or explantation	64 (24.3)
Problem with helix retraction or stylet insertion	53 (20.2)
Insulation abrasion	43* (16.3)
Normal	100† (38.0)
Packaging/labeling anomaly	2 (0.76)
Workmanship anomaly	1 (0.38)
Total	263

*Two deaths in this group.
†One death in this group due to acute lead perforation.