Failure rate of the Riata lead under advisory: A report from the CHRS Device Committee

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BACKGROUND A unique form of lead failure has been described in the Riata (8-F) and Riata ST (7-F) silicone defibrillation lead degradation of the outer insulation, resulting in the externalization of conductor cables.

OBJECTIVE To assess rates of lead revision due to lead failure in Riata leads affected by the Riata advisory.

METHODS Nineteen implantable cardioverter-defibrillator implant and follow-up centers were surveyed.

RESULTS As of March 1, 2012, there were 5043 known affected leads implanted in Canada. Data on 4358 (86.4%) leads were obtained; 65.3% of these were Riata (8-F) and 32.4% were Riata ST (7-F) leads. The median time from implant to last follow-up was 5 years. Electrical abnormalities were reported in 4.6% of the affected leads; 8.0% of these were found to have concomitant radiographic evidence of externalization. The rate of electrical failure was higher in the 8-F (5.2%) vs 7-F (3.3%) leads ($P = .007$). Oversensing with or without inappropriate shocks was reported in 39.8% of the leads with confirmed failure. Abnormally high or low impedance values (29.9%) and elevated pacing capture thresholds (43.8%) were frequently reported. One death (0.5%) attributed to lead failure was reported. Among the leads that were replaced, 21% were extracted. Two major complications (1.0%) were attributed to extraction of these leads.

CONCLUSIONS The overall rate of lead failure in the Riata (8-F) and Riata ST (7-F) leads is higher than previously reported by using passive surveillance data. The impact of recent advisories related to these leads is not yet apparent.

KEYWORDS Lead; Advisory; Complications

ABBREVIATIONS **ICD** = implantable cardioverter-defibrillator; **SVC** = superior vena cava

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Introduction

An advisory related to the Riata and Riata ST leads was announced on November 28, 2011, by St Jude Medical after these leads had been removed from the market the previous year.[1] This advisory described the possibility of conductors within the implantable cardioverter-defibrillator (ICD) lead becoming externalized owing to an "inside-out" abrasion mechanism. This is a novel failure mechanism not reported with other ICD leads. The implications of this novel mechanism of lead failure are concerning owing to the possibility of abnormal electrical conductance if a faulty lead is left in place and interacts with another ICD lead, potentially causing further abrasion with this lead.[2] Prior reports suggest a 0.7%–2.8%/y failure rate of the Riata/Riata ST lead, which is higher than other contemporary high-voltage leads.[3–6] Sites participating in the Canadian Heart Rhythm Society (CHRS) Device Committee were surveyed to investigate the rates of clinically important lead abnormalities, rates of lead failure, and clinical outcomes related to these issues.

Methods

Nineteen Canadian ICD implantation and 2 follow-up centers were approached to participate in a survey of electrical failure rates of the 2 Riata lead models under advisory. The Queen Elizabeth II Health Sciences Ethics Review Board approved the study. All centers agreed to participate in the survey process and obtained ethics approval, if necessary, in each respective center. Only leads that were actively followed in Canada were included (n = 5043).

Survey

The survey questionnaire was circulated to a working group identified to review it for clarity, content, and ease of use. The working group arrived at the final survey through consensus. Data were collected on the following Riata and Riata ST leads: 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042. The data collected in the survey were divided into 4 areas: (1) number of Riata leads implanted at each center by the lead model; (2) number of leads that were revised or found to have electrical lead failure classified by the model number; (3) number of patients with a lead abnormality by the model number; (4) deaths attributed to lead failure; (5) number of leads revised and reason for revision by the model number; (6) method of revision by the model number. At the time of this survey, detailed data on radiographic screening with either chest radiographs or fluoroscopy were not collected. Centers were indicated to include evidence of structural lead failure in conjunction with electrical lead failure (see Definitions).

Definitions

Lead failure was defined as a lead that does not perform its intended function owing to a specific structural or electrical failure and is removed from service owing to safety concerns.[7] *Structural failure* is defined as conductors outside the lead body owing to an abrasion-related breach of the outer insulation, which is visible radiographically.[1] *Electrical lead failure* is defined as one of the following: sudden change in impedance (HV or other; rise or drop >50% over a 3-month period) *or* inappropriate shocks/short RR intervals secondary to sensing of electrical noise artifacts from nonphysiologic potentials (seen as nonsustained ventricular tachycardia events) *or* sudden increases in pacing threshold for which no other cause was found.[8,9] A suspected electrical lead failure is a change in impedance that does not qualify in the above criteria. The local investigator at each center identified whether a lead was deemed as confirmed or suspected lead failure.

Outcomes

The main outcome of this survey was confirmed or suspected failure (electrical or structural) with a Riata lead under advisory.

Statistical analysis

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

Results

Of 5043 active Riata leads under advisory in Canada (as of March 2012), data were obtained on 4358 (86.4%) leads. The

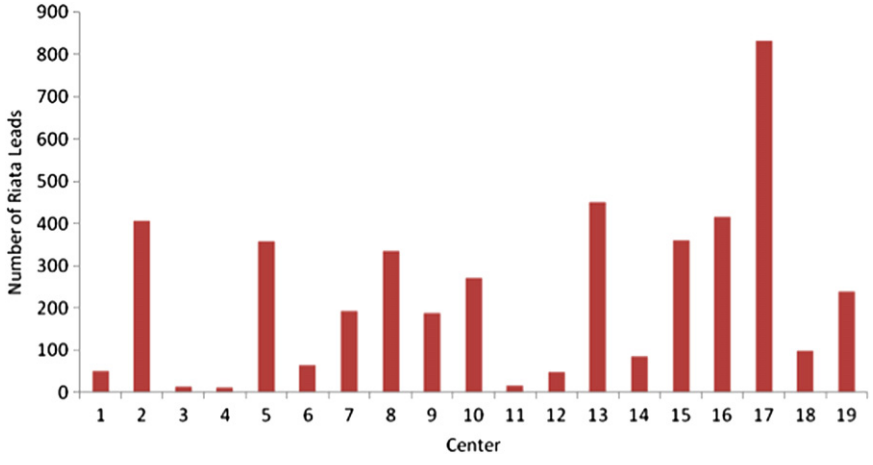

Figure 1 Volume of Riata leads at each center.