Prevalence and Presentation of Externalized Conductors and Electrical Abnormalities in Riata Defibrillator Leads After Fluoroscopic Screening

Report From the Netherlands Heart Rhythm Association Device Advisory Committee

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Background—The Riata family of implantable cardioverter-defibrillator (ICD) leads is prone to a specific insulation abrasion characterized by externalization of conductor cables. The objective of this study was to determine the prevalence of externalized conductors and electrical abnormalities in Riata ICD leads by fluoroscopic screening and standard ICD interrogation.

Methods and Results—All ICD implantation centers were contacted by the Netherlands Heart Rhythm Association Device Advisory Committee to identify all patients with an active Riata ICD lead and to perform fluoroscopic screening of the lead. In addition, the electrical integrity of the lead was assessed. As of March 1, 2012, data for 1029 active Riata leads were available; 47% of these were 8-F Riata and 53% were 7-F Riata ST. Externalized conductors were observed in 147 leads (14.3%). Proportion of externalized conductors was higher in 8-F Riata compared with 7-F Riata ST (21.4% vs 8.0%; P<0.001). Median time from implantation to detection of externalized conductors was 65.3 months. The estimated rates of externalized conductors were 6.9% and 36.6% at 5 and 8 years after implantation, respectively. Of the 147 leads with externalized conductors, 10.9% had abnormal electrical parameters vs 3.5% in nonexternalized leads (P<0.001).

Conclusions—The prevalence of externalized conductors in Riata leads is significantly high (14.3%) using fluoroscopic screening. The majority of externalized conductors are not detectable with standard ICD interrogation. Screening with fluoroscopy is reasonable. (Circ Arrhythm Electrophysiol. 2012;5:1059-1063.)

Key Words: complications ■ implantable cardioverter-defibrillator ■ insulation ■ lead failure

Insulation abrasion is the most common cause of implantable cardioverter-defibrillator (ICD) lead failure.1 Recently, several reports of a unique failure mechanism observed in the 8-F Riata and 7-F Riata ST family of ICD leads (St Jude Medical) have been published.2–6 High-voltage and low-voltage conductor cables wear through the silicone insulation, ie, inside-out abrasion, and appear outside the lead body (externalized conductors). Distribution of the Riata and Riata ST silicone leads was stopped in 2010, and subsequently the leads were classified as a Food and Drug Administration class I recall in December 2011. The rate of leads with externalized conductors appeared to exceed the manufacturer quoted values. Previous studies have found a rate of externalized conductors up to 15%, including leads with normal electrical function but that exhibit externalized conductors.7–10 However, the prevalence and clinical sequelae of conductor externalization are still unclear.

In addition, the rate of externalized conductors over service time after implantation is unknown. We report the Riata advisory experience from an independent group of investigators who represent all ICD implant centers in the Netherlands.

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Methods

Study Population and Data Collection

On January 4, 2012, the Device Advisory Committee of the Netherlands Heart Rhythm Association issued a recommendation to identify all patients with an active Riata or Riata ST silicone high-voltage defibrillation lead and to perform fluoroscopic screening of the lead. All 31 Dutch ICD implantation centers were contacted to collect data in a standardized format, eg, lead model, serial number, date of implantation, date of screening, presence of externalized conductors, location of externalized conductors, presence of electrical...
dysfunction, and type of electrical dysfunction. Examples of fluoroscopic images of externalized conductors were made available by the Dutch Society of Cardiology. These images could be used as a tool on how to identify externalized conductors.

The study included patients with an indwelling active Riata (models 1570, 1580, 1581, and 1582) or Riata ST (models 7000, 7001, 7002, and 7040) high-voltage defibrillation lead in one of the Dutch ICD implantation centers. A full list of the participating Dutch ICD implantation centers can be found in the Online Data Supplement material. The respective leads were implanted between July 2002 and November 2008.

**Fluoroscopy and ICD Interrogation**

Fluoroscopy in the electrophysiology or intervention laboratory was performed in all patients. Cine loops of the high-voltage defibrillation lead were obtained in antero-posterior, left-anterior-oblique, and right-anterior-oblique projections, with additional projections or other magnification settings as needed for better identification of conductor externalization. The lead was screened at full length from pocket region to the tip in the right ventricle. At each ICD implant center, the cine loops were examined at the time of image acquisition and reviewed by the local board-certified cardiologist with extensive experience in device implantation and lead cine fluoroscopy. In case of questionable conductor externalization, local investigators were advised to consult members of the Device Advisory Committee for adjudication of the cine loops. In addition, ICD interrogation was performed in every patient with measurements of low-voltage and high-voltage impedances, sensing and threshold values, as well as pocket manipulation and pectoral muscle maneuvers. Episodic history was reviewed for inappropriate detection of sensing events, ie, noise and oversensing.

**Definitions**

Electrical dysfunction of the lead was considered if it met 1 of the following Criteria: (1) the presence of nonphysiological signals on the intracardiac ventricular electrogram; (2) increase in pacing impedance to >2000 Ω or to greater than double the increase in stable baseline impedance; (3) decrease in pacing impedance to <200 Ω or to less than half of stable baseline value; or (4) change in high-voltage impedance to >200 Ω or <25 Ω. The presence of externalized conductors was defined as conductor cables visible outside the lead body on fluoroscopy in any of the views.

**Statistical Analysis**

The data are presented using descriptive statistics. Normality of distribution was determined by the Kolmogorov-Smirnov test. Continuous variables are expressed as mean±SD, if normally distributed; otherwise, variables are expressed as median and interquartile range. Continuous data were analyzed with Student t test or Mann-Whitney U test, when appropriate. Categorical data are expressed as percentages and compared with the χ² test or Fisher exact test when appropriate. Rates of externalized conductors were estimated by life-table analysis with 95% CIs. Statistical analysis was performed using Stata version 12 SE for Windows (StataCorp) and PASW version 18 (IBM). P<0.05 was considered statistically significant.

**Results**

By March 1, 2012, 1029 patients with an active Riata or Riata ST high-voltage defibrillation lead were screened at the Dutch ICD implantation centers. The models and respective numbers of the screened leads are presented in Table 1. The models of the 7-F Riata ST family were more prevalent (57%), and the majority of screened leads had a dual-coil design (57%). The median time from implant to date of fluoroscopy was 59.7 months (interquartile range, 50.2–71.1 months). In our study, the median time from implant to screening was longer for Riata leads compared with Riata ST leads (71.7 vs 51.1 months; P<0.001).

<table>
<thead>
<tr>
<th>Model</th>
<th>N (%)</th>
<th>Diameter (F)</th>
<th>Sensing Coils</th>
<th>Fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riata 1570</td>
<td>89 (8.6)</td>
<td>8</td>
<td>True bipolar</td>
<td>Dual Passive</td>
</tr>
<tr>
<td>Riata 1571</td>
<td>2 (0.2)</td>
<td>8</td>
<td>True bipolar</td>
<td>Dual Passive</td>
</tr>
<tr>
<td>Riata 1580</td>
<td>236 (22.9)</td>
<td>8</td>
<td>True bipolar</td>
<td>Dual Active</td>
</tr>
<tr>
<td>Riata 1581</td>
<td>45 (4.4)</td>
<td>8</td>
<td>True bipolar</td>
<td>Dual Active</td>
</tr>
<tr>
<td>Riata 1582</td>
<td>110 (10.7)</td>
<td>8</td>
<td>True bipolar</td>
<td>Single Active</td>
</tr>
<tr>
<td>Riata ST 7000</td>
<td>161 (15.6)</td>
<td>7</td>
<td>True bipolar</td>
<td>Dual Active</td>
</tr>
<tr>
<td>Riata ST 7001</td>
<td>55 (5.3)</td>
<td>7</td>
<td>True bipolar</td>
<td>Dual Active</td>
</tr>
<tr>
<td>Riata ST 7002</td>
<td>330 (32.1)</td>
<td>7</td>
<td>True bipolar</td>
<td>Single Active</td>
</tr>
<tr>
<td>Riata ST 7040</td>
<td>1 (0.1)</td>
<td>7</td>
<td>True bipolar</td>
<td>Dual Passive</td>
</tr>
</tbody>
</table>

The presence of externalized conductors was observed in 147 of 1029 patients (14.3%). Table 2 provides data for the leads with externalized conductors. The following models and respective numbers of Riata or Riata ST leads presented with externalized conductors: 1570 (n=14), 1580 (n=41), 1581 (n=7), 1582 (n=41), 7000 (n=8), 7001 (n=8), and 7002 (n=28), respectively. A higher proportion of the 8-F Riata family had externalized conductors than the 7-F Riata ST family (21.4% vs 8.0%; P<0.001). The distribution of time from implant to detection of externalized conductors by fluoroscopic screening is presented in Figure 1. The median time from implant to detection of externalized conductors was 65.3 months (interquartile range, 54.0–72.3 months). The median time to detection of externalized conductors was longer for Riata leads compared with Riata ST leads (70.1 versus 53.2 months; P<0.001).

Life-table analysis was performed to estimate the rate of externalized conductors in Riata and Riata ST leads as function of service time after implantation. The estimated rates of externalized conductors are shown in Figure 2. The rates of externalized conductors were 6.9% (95% CI, 5.3%–8.9%) and 36.6% (95% CI, 30.6%–43.4%) at 5 and 8 years after implantation, respectively. The estimated rate of externalized conductors is higher for 7-F Riata ST leads compared with 8-F Riata leads at 5 years after implantation (12.2% [95% CI, 8.9%–16.6%] versus 3.5% [95% CI, 2.1%–5.6%]; P<0.001).

Table 3 presents the location of externalized conductors. The majority of insulation defects presenting with externalized conductors were located near the annulus of the tricuspid valve (114 of 148 specified defects [77%]). Four defects
were observed above the level of the right atrium in the vena anonyma (n=2) and superior caval vein (n=2).

Of the 147 leads with externalized conductors, 16 (10.9%) had abnormal electrical parameters. The majority of electrical parameters (88%) were attributed to abnormal impedance measurements: 5 high-voltage impedance and 9 low-voltage impedance. The proportion of abnormal electrical parameters was higher in leads with externalized conductors than those without externalization (10.9% vs 3.5%; \( P < 0.001 \)).

### Discussion

The results of this study show a high prevalence of conductor externalization (14.3%) at fluoroscopic screening of 1029 patients with an active Riata or Riata ST lead in 27 Dutch ICD centers. The rate of externalized conductors may increase with longer service time and can reach 36.6% at 8 years of service time. Conductor externalization was significantly more frequent in 8-F Riata than in 7-F Riata ST. No significant differences in the prevalence of conductor externalization between the single-coil and dual-coil leads were observed. The predilection location of inside-out abrasion with externalized conductors was mainly at the annulus of the tricuspid valve and in the right atrium, but also externalization in the anonymous vein was seen.

Our study results matched those of 2 prospective studies with externalization rates of 11.5% and 15%, respectively.\(^8,10\) Compared with these data, the lead failure rate was 20-times to 100-times higher as reported by the manufacturer (0.63%)\(^7\) and published in 2 performance articles of the Riata lead family (0.13% and 0.21%, respectively).\(^11,12\) The main reason for this discrepancy could be explained by the definition of adverse events that were defined as those that required lead revision, extraction, or replacement. Without systematic fluoroscopically screening, the rate of conductor externalization was obviously underestimated.\(^6\) However, 1 single-center study showed a prevalence of conductor externalization of 33% (29/87) when electrical dysfunctions were present or lead extraction was necessary.\(^13\)

Abnormal electrical parameters were documented in 11% (16/147) of our patients with lead extrusion; this rate was significantly higher than in patients with Riata leads without conductor externalization (3.5%; \( P < 0.001 \)). Electrical dysfunctions of the low-voltage circuit could lead to oversensing with inappropriate shock and loss of capture, whereas damage of the high-voltage circuit could lead to short-circuits with failure to defibrillate. Furthermore, adverse events such as ventricular tachyarrhythmias could be produced by mechanical irritation of the endocardium of the floating externalized conductor. An analysis of the Food and Drug Administration’s Manufacturers and User Facility Device Experience (MAUDE) database showed a higher rate of death caused by lead failure of Riata and Riata ST leads when compared with 9-F ICD leads.\(^14\)

### Clinical Implication

Leads under advisory may vary considerably with regard to their potential for failure. The clinical implications of failure and timing of failure can be variable and different among patients. As a result, the management also can vary significantly, from close surveillance to a complex reoperation.
involving lead extraction. Analysis of the Accufix (Teletronics) pacing lead advisory showed a 10-fold increase in complications when leads were extracted compared with leaving the recalled lead in place.15 This observation showed that careful consideration must be used in the setting of an advisory before device replacement or lead extraction. Amin et al16 proposed a Markov decision-analysis model to compare risks and benefits for elective device replacement in devices under advisory. Their findings suggested that the main factor affecting whether a device should be removed is the estimated risk of device failure. In contrast, lead advisories represent an entirely distinct problem compared with device advisories. A clinical decision model for leads under advisory is not available because of limited data for the best management strategy for leads under advisory. Data are lacking on the risks of ICD lead extraction, timing of failure, and the lack of information about the ultimate failure rate of the lead under advisory, which can change over time. Considering the failure rate, the current data clearly show that the rate of externalization is progressive in time. However, the Riata recall is more complex compared with the recall of the Medtronic Sprint Fidelis ICD lead.17,18 The Sprint Fidelis concerned a conductor fracture with electrical dysfunction. However, the Riata recall is more complex compared with the recall of the Medtronic Sprint Fidelis ICD lead.17,18 The Sprint Fidelis concerned a conductor fracture with electrical dysfunction in the majority of the patients.17 Whereas management of leads in the context of electrical abnormality is clear, there is no consensus on the management of leads with conductor externalization without overt evidence of electrical dysfunction. There are many questions still unanswered regarding the Riata recall, for example, in which patients should extraction of the lead be considered? Our data show that externalized conductors with intact electrical properties have to be considered as lead failure. The inner thin coating of ethylene tetrafluoroethylene prevents initial electrical malfunctioning of the leads. However, erosion of this ethylene tetrafluoroethylene insulation is suggestive because electrical abnormalities are triple in externalized leads as compared with nonexternalized leads. Furthermore, it is not known whether the ethylene tetrafluoroethylene coating in externalized conductors can withstand high-voltage shock. Do we need to wait for electrical dysfunction? Our data demonstrate that the combination of electrical and fluoroscopic data are mandatory for the management of these patients. The different electrical modes of failure, such as impedance and pacing threshold changes or electrical noise, are probably late signs of Riata lead dysfunction. Fluoroscopic screening is accurate, feasible, and poses a low risk to patients who undergo screening. Given this low risk, it may be considered in patients with an active Riata lead. The Netherlands Heart Rhythm Association Device Advisory Committee in association with the Dutch Health Authorities recommended annual fluoroscopic screening of patients who have an active Riata or Riata ST lead.

Limitations

Several limitations of the present study warrant consideration. First, the design was cross-sectional, which limits the analysis of the exact time of externalization of conductors. However, life-table analysis clearly demonstrated the relation between service time and the rate of externalized conductors. Second, we did not have any data for the deceased patients with a Riata or Riata ST lead. The number of externalized conductors in this patient group is unknown, and any possible relation between externalized conductors and mortality could not be analyzed.

Conclusion

When systematically performing fluoroscopy in patients with a Riata or Riata ST lead, the overall rate of externalized conductors is significantly higher than previously reported. The rate of externalized conductors will increase over service time of the implanted lead. Conductor externalization can be easily missed with routine ICD interrogation because many cases are functionally silent. Currently, it is still unknown how to manage patients with insulation failure and externalized conductors in the absence of abnormal electrical parameters. Clinical studies are needed to determine the best management of patients who have Riata and Riata ST leads with externalized conductors but without overt evidence of electrical dysfunction. Screening with fluoroscopy is reasonable.

Disclosures

None.

References


**CLINICAL PERSPECTIVE**

The Riata family of implantable cardioverter-defibrillator leads is prone to a specific insulation abrasion characterized by externalization of conductor cables, and the leads were placed under a class I recall by the Food and Drug Administration in December 2011. In this study, we determined the prevalence of externalized conductors and electrical abnormalities using a national screening program consisting of fluoroscopic and electrical assessment in all patients with an active Riata lead. As of March 1, 2012, data for 1029 active Riata leads were available. Conductor externalization was observed in 147 leads (14.3%), with estimated rates of externalized conductors of 6.9% and 36.6%, at 5 and 8 years after implantation, respectively. Of the 147 leads with externalized conductors, 10.9% had abnormal electrical parameters. A clinical decision model for leads under advisory is not available because of limited data on the best management strategy for leads under advisory. Whereas management of leads in the context of electrical abnormality is clear, there is no consensus on the management of leads with conductor externalization without overt evidence of electrical dysfunction. Considering the progressive failure rate of conductor externalization, and considering that the majority of externalized conductors are not detectable with standard implantable cardioverter-defibrillator interrogation, screening with fluoroscopy is reasonable.
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SUPPLEMENTAL MATERIAL

Dutch ICD implantation centres participating in fluoroscopic screening

Academic Medical Centre, Amsterdam, P.F.H.M. van Dessel; Albert Schweitzer Hospital, Dordrecht, L. van Woerkens; Amphia hospital, Breda, M.A. Alings; Atrium hospital, Heerlen, G. Paulussen; Canisius Wilhelmina Hospital, Nijmegen, L. Bouwels; Erasmus Medical Centre, Rotterdam, D.A.M.J. Theuns; Flevoziekenhuis, Almere, N.R. Bijsterveld; HagaZiekenhuis, the Hague, R. Robles de Medina; Isala Klinieken, Zwolle, A. Elvan; Kennemer Gasthuis, Haarlem, R. Tukkie; Leiden University Medical Centre, Leiden, L. van Erven; Maasstad Hospital, Rotterdam, B. Dijkman; Maastricht University Medical Centre, Maastricht, Y. Blaauw; Medical Centre Alkmaar, Alkmaar, G.P. Kimman; Medical Centre Haaglanden, the Hague, H. Ramanna; Medical Centre Leeuwarden, Leeuwarden, M. Aardema; Medisch Spect Twente, Enschede, M.F. Scholten; Rijnstate Hospital, Arnhem, R. Derksen; St. Antonius hospital, Nieuwegein, L.V.A. Boersma; St. Lucas Andreas Hospital, Amsterdam, W.G. de Voogt; Tweesteden Hospital, Tilburg, J. Widdershoven; Vlietland Hospital, Schiedam, H. Spierenburg; VU University Medical Centre, Amsterdam, C.C. de Cock; University Medical Centre, Utrecht, M. Meine; University Medical Centre Groningen, Groningen, A. Maass; University Medical Centre Nijmegen, Nijmegen, J. Smeets.