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

Running title: Theuns et al.; Externalisation in Riata leads

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Abstract:

**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 on 1029 active Riata leads was available; 47% of these were 8-F Riata and 53% 7-F Riata ST. Externalized conductors were observed in 147 leads (14.3%). Proportion of externalized conductors was higher in 8-F Riata compared to 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 versus 3.5% in nonexternalized leads (P < 0.001).

**Conclusions** - The prevalence of externalized conductors in Riata leads is significant high (14.3%) using fluoroscopic screening. The majority of externalized conductors are not detectable with standard ICD interrogation. Screening with fluoroscopy is reasonable.

**Key words:** complications; implantable cardioverter-defibrillator; insulation; lead failure
Introduction

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, Sylmar, CA, USA) have been published.\(^2\)\(^-\)\(^6\) High-voltage and/or low-voltage conductor cables wear through the silicone insulation, i.e. 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 (FDA) Class I recall in December 2011.\(^7\) 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.\(^8\)\(^-\)\(^10\) 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 centres in the Netherlands.

Methods

Study population and data collection

On January 4, 2012, the Device Advisory Committee of the Netherlands Heart Rhythm Association (NHRA) 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 implantable cardioverter-defibrillator (ICD) implantation centres were contacted to collect data in a standardized format, e.g. lead model, serial number, date of implantation, date of screening, presence of externalized conductors, location of externalized conductors.
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 (model 1570, 1580, 1581, and 1582) or Riata ST (model 7000, 7001, 7002, and 7040) high-voltage defibrillation lead in one of the Dutch ICD implantation centres. A full list of the participating Dutch ICD implantation centres can be found in the supplemental 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 centre, 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- and high-voltage impedances, sensing and threshold values as well as pocket manipulation and pectoral muscle manoeuvres. Episode history was reviewed for inappropriate detection of sensing events, i.e. noise and oversensing.

**Definitions:** Electrical dysfunction of the lead was considered if it met one of the following
criteria, 1) the presence of nonphysiological signals on the intracardiac ventricular electrogram; 2) increase in pacing impedance to > 2000 Ω or greater than double rise 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 by median and interquartile range (IQR). Continuous data were analyzed with Student’s t test or Mann-Whitney U test, when appropriate. Categorical data are expressed as percentages and compared with the Chi-square test or Fisher’s exact test when appropriate. Rates of externalized conductors were estimated by life-table analysis with 95% confidence intervals (CIs). Statistical analysis was performed using Stata version 12 SE for Windows (StataCorp, College Station, TX) and PASW version 18 (IBM Corp., Somers, NY). A P value < 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 centres. 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 (53%), 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 (IQR, 50.2 to 71.1 months). In our
study, the median time from implant to screening was longer for Riata leads compared to Riata ST leads (71.7 vs. 51.1 months; \( P < 0.001 \)).

The presence of externalized conductors was observed in 147/1029 patients (14.3%). Table 2 provides data on 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 (IQR, 54.0 to 72.3 months). The median time to detection of externalized conductors was longer for Riata leads compared to Riata ST leads (70.1 vs. 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% to 8.9%) and 36.6% (95% CI, 30.6% to 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 to 8-F Riata leads at 5 years after implantation (12.2% [95% CI, 8.9% to 16.6%] versus 3.5% [95% CI, 2.1% to 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; 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 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 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 to two prospective studies with an externalization rate of 11.5% and 15%, respectively.\(^8\)\(^,\)\(^10\) Compared to these data the lead failure rate was 20 to 100 times higher as reported by the manufacturer (0.63%)\(^7\) and published in two performance papers 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 which were defined as those that required lead revision, extraction or replacement. Without systematic fluoroscopically screening, the rate of conductor externalization was obviously underestimated.\(^6\) On the other hand, one single centre 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 a 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 FDA’s MAUDE database showed a higher rate of death caused by lead failure of Riata and Riata ST leads when compared to 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 can also vary significantly, from close surveillance to a complex reoperation involving lead extraction. Analysis of the Accufix (Teletronics, Eaglewood, CO, USA) pacing lead advisory showed a 10-fold increase in complications when leads were extracted compared to leaving the recalled lead in place.\(^{15}\) This observation showed that careful consideration must be employed in the setting of an advisory prior to device replacement or lead extraction. Amin et al. proposed a Markov decision analysis model to compare risks and benefits for elective device replacement in devices under advisory.\(^{16}\) 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 to device advisories. A clinical decision model for leads under advisory is not available due to limited data on the best management strategy for leads under advisory. Data is 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. The Sprint Fidelis concerned a conductor fracture with electrical dysfunction in the majority of the patients. While 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, e.g. in which patients extraction of the lead should be considered? Our data show that externalized conductors with intact electrical properties has to be considered as lead failure. The inner thin coating of ethylene tetrafluoroethylene (ETFE) prevents initial electrical malfunctioning of the leads. However, erosion of this ETFE insulation is suggestive as electrical abnormalities are triple in externalized leads as compared to non externalized leads. Furthermore, it is not known whether the ETFE 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 is 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 of the 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 on 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 as 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.

Conflict of Interest Disclosures: None.

References:


2. Duray GZ, Israel CW, Schmitt J, Hohnloser SH. Implantable cardioverter-defibrillator lead
disintegration at the level of the tricuspid valve. *Heart Rhythm.* 2008;5:1224-1225.


### Table 1. Characteristics and distribution of screened Riata and Riata ST leads

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

### Table 2. Riata and Riata ST leads with externalized conductors

<table>
<thead>
<tr>
<th>Model</th>
<th>N (%)</th>
<th>Percentage of implanted leads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Riata 1570</td>
<td>14 (9.5)</td>
<td>15.7</td>
</tr>
<tr>
<td>Riata 1580</td>
<td>41 (27.9)</td>
<td>17.4</td>
</tr>
<tr>
<td>Riata 1581</td>
<td>7 (4.8)</td>
<td>15.6</td>
</tr>
<tr>
<td>Riata 1582</td>
<td>41 (27.9)</td>
<td>37.3</td>
</tr>
<tr>
<td>Riata ST 7000</td>
<td>8 (5.4)</td>
<td>5.0</td>
</tr>
<tr>
<td>Riata ST 7001</td>
<td>8 (5.4)</td>
<td>14.5</td>
</tr>
<tr>
<td>Riata ST 7002</td>
<td>28 (19.0)</td>
<td>8.5</td>
</tr>
</tbody>
</table>
Table 3. Location of externalized conductors in single- and dual-coil Riata and Riata ST leads

<table>
<thead>
<tr>
<th>Location</th>
<th>Defect, N</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Single-coil models</strong></td>
<td></td>
</tr>
<tr>
<td>Proximal of RA</td>
<td>2</td>
</tr>
<tr>
<td>RA</td>
<td>21</td>
</tr>
<tr>
<td>RA-to-RVC</td>
<td>14</td>
</tr>
<tr>
<td>Annulus TV</td>
<td>12</td>
</tr>
<tr>
<td>TV-to-RVC</td>
<td>22</td>
</tr>
<tr>
<td><strong>Dual-coil models</strong></td>
<td></td>
</tr>
<tr>
<td>Proximal of SVC</td>
<td>2</td>
</tr>
<tr>
<td>SVC-to-RVC</td>
<td>49</td>
</tr>
<tr>
<td>RA</td>
<td>9</td>
</tr>
<tr>
<td>Annulus TV</td>
<td>8</td>
</tr>
<tr>
<td>TV-to-RVC</td>
<td>9</td>
</tr>
<tr>
<td><strong>Not specified</strong></td>
<td>7</td>
</tr>
</tbody>
</table>

RA = right atrium; RVC = right ventricular coil; SVC = supraventricular coil; TV = tricuspid valve

Figure Legends:

**Figure 1.** Distribution of time from implant to detection of externalized conductors.

**Figure 2.** Estimated rates of externalized conductors over time after implantation. The error bars represent the 95% confidence intervals.
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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.