Insulation Defects in Riata Implantable Cardioverter-defibrillator Leads

Akinori Sato¹, Masaomi Chinushi², Kenichi Iijima¹, Daisuke Izumi¹ and Hiroshi Furushima¹

Abstract

Background  The structures composing implantable cardioverter-defibrillator (ICD) leads have become more complicated and thinner with technological advances. Silicon insulation defects with and without clinically manifested electrical abnormalities have been reported in Riata leads (St. Jude Medical).

Objective  The aim of this study was to assess the incidence and clinical implications of insulation defects in Riata leads implanted at our hospital.

Methods  The subjects included 10 consecutive patients who received 8-French Riata ICD leads with dual-coil conductors (model 1580 or 1581) between 2006 and 2010 at our hospital. Operative records, chest X-rays and interrogation data were reviewed.

Results  In all cases, Atlas+ (St. Jude Medical) was used as an ICD generator and the Riata leads were implanted transvenously and fixed to the right ventricular apex. During a mean follow-up period of 52±9 (36-70) months, chest X-rays revealed insulation defects in Riata leads and conductor wires projecting from the bodies of the Riata leads in two of 10 (20%) patients. One of the patients received inappropriate ICD therapies due to T-wave oversensing based on attenuation of R waves and augmentation of T waves 41 months after implantation. In the other patient, an insulation defect without any clinically manifested electrical troubles was detected 50 months after implantation.

Conclusion  Riata leads have a high incidence of insulation defects, which may be occasionally accompanied by inappropriate ICD discharges. For patients with Riata leads, careful observation of any changes in the lead-electrical measurements and a routine chest X-ray follow-up are necessary.

Key words: insulation defect, Riata lead, implantable cardioverter-defibrillator, X-ray

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Introduction

Cardioverter-defibrillator implantation via the transvenous endocardial approach is an established treatment for patients suffering from ventricular tachycardia (VT) and/or ventricular fibrillation (VF). Current ICD leads have complicated structures; they are comprised of two high-voltage conductors (coils) for defibrillation and two electrode conductors (tip and ring) for pacing and sensing in the lead body. Nevertheless, as a result of recent technological advances, ICD leads have developed into thinner products to allow for less invasive transvenous implantation and insertion of multiple leads into one vein. Thin ICD leads have been reported to be linked to various problems such as lead fracture and cardiac perforation. Over 200,000 Riata and Riata ST ICD leads (St. Jude Medical, Sylmar, CA, USA) were implanted worldwide between 2002 and 2010. Recently, it has been announced that insulation defects are a special problem associated with these leads in Western countries, although the precise incidence and clinical details of the problems have not yet been clarified (1-4). The conductor cables in the leads are prone to erode the silicone insulation and project outside of the lead body. Externalized conductors may be detected on chest X-rays; however, the detection of an externalized conductor may not simply indicate a clinical prob-

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Table. Case Descriptions with an Implanted Riata Lead

<table>
<thead>
<tr>
<th>Case</th>
<th>Age (years)</th>
<th>Sex</th>
<th>Diagnosis</th>
<th>EF (%)</th>
<th>NYHA</th>
<th>ICD Lead</th>
<th>Insulation</th>
<th>Follow-up Period</th>
<th>Electrical Abnormality</th>
<th>Operation</th>
<th>1 month After</th>
<th>Last Clinic</th>
<th>ΔR(ope–last)</th>
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<td>1</td>
<td>70</td>
<td>M</td>
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<td>55</td>
<td>I</td>
<td>Atlas+ DR</td>
<td>Yes</td>
<td>43</td>
<td>7.8</td>
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<td>M</td>
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<td>78</td>
<td>I</td>
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<td>50</td>
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<td>10</td>
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<td>No</td>
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<td>12.0</td>
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</table>

M: male; F: female; EF: left ventricular ejection fraction; NYHA: New York Heart Association classification, ΔR(ope–last): Reduction rate of R-wave amplitude between at the operation and the last clinic, VT: ventricular tachycardia, BrS: Brugada syndrome, HCM: hypertrophic cardiomyopathy, DCM: dilated cardiomyopathy, LQT: long QT syndrome, VF: ventricular fibrillation, RĻ: ΔR(ope–last) is >30% or >3.0 mV, TWOS: T-wave oversensing, N/A: not applicable, *: significantly decreasing as compared to value at the operation.

To further study the characteristics of Riata lead problems in our country, we performed lead analyses and chest X-ray examinations in all 10 ICD patients who underwent implantation with Riata leads in our hospital.

Materials and Methods

Patients

This study included 10 consecutive patients (nine men, one woman) who underwent implantation of Riata high-voltage defibrillator leads (model 1580 or 1581, St. Jude Medical) with ICD generators. The patients received follow-up over 36 months at Niigata University Medical and Dental Hospital between 2006 and 2010. Both lead models were 8-French leads with dual-coil conductors. No other Riata models were used in our hospital. The data were analyzed retrospectively after a review of each patient’s medical record, including diagnosis, echocardiography data, implanted device model (ICD and lead) and operative information. Post-operative ICD interrogation data and the electrical performance of the Riata leads (including sensed R-wave amplitudes, pacing thresholds and bipolar lead impedances) were obtained in our ICD clinic every three months. Chest X-rays with posterior-anterior and lateral views were obtained at least once a year and carefully analyzed with adequate magnification to detect lead failures. The ethics committee of Niigata University Medical and Dental Hospital approved this study.

Statistical analysis

The values are expressed as the mean ± the standard deviation. Paired Student’s t-test was used to compare differences between paired variables, and p values <0.05 were considered to be statistically significant. All statistical analyses were performed using SPSS II software (ver. 11.0; SPSS Inc., Chicago, IL, USA).

Results

Patient population

The mean age of the 10 patients at Riata lead implantation was 59 ± 14 (range: 24-78) years. The mean height, weight and body mass index were 162.9±7.5 cm, 59.1±8.0 kg and 22.2±2.4, respectively. The diagnoses of the patients included Brugada syndrome (n=2), long QT syndrome (n=1), idiopathic VT/VF (n=2), hypertrophic cardiomyopathy (n=3), dilated cardiomyopathy (n=1) and cardiac sarcoidosis (n=1). All patients had ventricular tachyarrhythmia and/or syncopal episodes (Table). At the time of surgery, the mean left ventricular ejection fraction evaluated with echocardiogram was 60±12% and two of the patients were in chronic heart failure [New York Heart Association (NYHA) class II and III].

Operative data

All patients except two underwent ICD implantation for the first time. In these two patients (Cases 3 and 6, Table), additional Riata leads were implanted with new ICD generators to avoid inappropriate ICD discharge due to T-wave oversensing (TWOS) by the originally implanted defibrillator leads from another company. Nine 1580-model leads and one 1581-model lead were implanted. In all cases, Atlas+ (St. Jude Medical) was used as the ICD generator and the Riata lead was implanted from the subclavian vein using...
an extrathoracic puncture technique and fixed to the right ventricular (RV) apex with a screw. Dual-chamber ICDs were implanted in six patients and single-chamber systems were implanted in the other four patients. No complications occurred during ICD implantation and chest X-rays obtained immediately after implantation did not show any lead abnormalities, including insulation defects, dislodgement or cardiac perforation. The mean amplitude of the intracardiac R-waves immediately after implantation was 10.6±1.6 mV (range 7.8-12.0 mV), the mean pacing threshold immediately after implantation was 0.63±0.24 V (0.25-1.00 V) × 0.5 ms and the mean pacing impedance immediately after implantation was 487±66 ohms (385-580 ohms). In each case, before discharge from our hospital, the ICD was suitably programmed for the patient based on individual conditions.

Follow-up

The patients were followed for a mean time of 52±9 months. One death occurred in the study population. A patient with cardiac sarcoidosis and VT died 36 months after ICD implantation because of hepatic insufficiency due to viral hepatitis (Case 1, Table). However, chest X-rays and ICD interrogation data obtained one month prior to the death did not show any abnormalities of the Riata lead or ICD. The mean amplitude of the sensed R-waves measured one month after implantation did not change compared with that measured immediately after surgery (10.7±1.9 vs. 10.6±1.6 mV, p=0.988) (Table). However, the mean amplitude of the R waves measured at the last ICD clinic decreased slightly compared with that measured immediately after surgery (8.5±4.0 vs. 10.6±1.6 mV, p=0.044). R-wave reductions (reductions of more than 30% or 3.0 mV) were observed in three patients, while almost no changes were seen in the other six patients. In the one remaining patient, no continuous R-wave measurements were obtained due to frequent ventricular pacing for progressed atrioventricular block. The mean ventricular-pacing threshold and lead impedance of Riata measured immediately after surgery and at the last ICD clinic were not significantly different (0.63±0.24 vs. 1.00±0.65 V × 0.5 ms, p=0.067, 487±66 vs. 426±78 ohm, p=0.102, respectively).

As described below, during the follow-up period, chest X-rays revealed insulation defects in Riata leads in two of 10 (20%) patients (Cases 1 and 2, Table). The patients were two of the three patients who showed attenuations of R-wave amplitudes (reductions of more than 30% or 3.0 mV). In the remaining patient with an attenuation of R-wave amplitudes and the other seven patients, neither externalized conductors nor any clinically manifested electrical abnormalities of the leads were observed. No structural or electrical problems were detected in the atrial pacing leads implanted in the study subjects.

Case 1

A dual-chamber ICD (Atlas+ DR V-243, Tendril SDX 1688T atrial lead and Riata 1580 ventricular lead, St. Jude Medical) was implanted in a 70-year-old man with idiopathic VT that caused him to enter a hemodynamically unstable state. His clinical course had been stable. No episodes of ICD therapy were recorded in the device memory until two inappropriate discharges of anti-tachycardia pacing (ATP) were delivered due to TWOS 43 months after implantation (Fig. 1A). After the ATP discharges, chest X-rays obtained at the ICD clinic revealed an insulation defect in one of the surrounding lumens within the RV lead that had not been detected by chest X-rays taken one year prior (Fig. 1B). The externalized conductors were located between the two shock-coils in the right atrium. The patient’s R-wave amplitudes measured 7.8 mV immediately after implantation and 6.4 mV one month after implantation. A similar R wave amplitude (4.2-5.9 mV) was maintained before the TWOS episode. At that time of the TWOS episode, transient attenuation of the intracardiac R waves (from 7.8 to 2.0 mV, a 74% reduction) with a mild augmentation of T wave amplitudes (from 0.4 to 0.9 mV) (Fig. 1A) was recorded. However, other parameters of the lead analysis data measured before and after the inappropriate ATP therapy were mostly stable, and no noise interaction was recorded in the stored electrogram. We reprogrammed the ICD parameters as follows: the threshold start was changed from 62.5% to 75.0% and the VT-detection interval was lengthened from 20 to 30 intervals. The amplitudes of the sensed R-waves spontaneously recovered to 3.1 to 5.5 mV within a few weeks and inappropriate ATP discharge due to TWOS did not recur before the ICD re-operation. We implanted a new ICD RV lead (Durata 7122Q, St. Jude Medical) connected to a new ICD device (Fortify ST DR 2235-40Q, St. Jude Medical) in the patient.

Case 2

A single-chamber ICD (Atlas+ VR V-193 and Riata 1580 ventricular lead, St. Jude Medical) was implanted in a 59-year-old man who suffered from Brugada syndrome. The interrogation data obtained from the ICD did not show any ICD therapy. Chest X-rays obtained at an ICD clinic 50 months after implantation first showed that one of the conductors had protruded from the silicone insulation of the Riata body into the right atrium (Fig. 2). This patient showed attenuation of R-wave amplitudes (gradually decreasing to 3.0-5.0 mV six months after implantation followed by stable amplitudes thereafter), resulting in a 65% reduction of R-wave amplitudes measured at that ICD clinic compared to the R-wave amplitudes measured immediately after implantation (from 10.1 to 3.5 mV). However, the pacing threshold and pacing impedance were stable (0.5-0.75 V × 0.5 ms and 390-460 ohms), and no noise was recorded on the intracardiac monitor. Although the patient showed attenuation of R-wave amplitudes and had an externalized conductor, it was
Figure 1. Panel A: A stored intracardiac electrocardiogram of the ICD. Anti-tachycardia pacing (ATP) was delivered during sinus rhythm due to T-wave oversensing (marked by TX) (right panel). At the ATP discharge, transient changes in intracardiac electrograms were recorded and compared with those obtained at a previous ICD clinic (right and left panels). See details in the text. The upper trace indicates atrial intracardiac electrogram monitoring (A-EGM), the middle trace indicates ventricular intracardiac electrogram monitoring (V-EGM) and the lower lines indicate atrial and ventricular event markers accompanied by the numbers of the R-R interval. Panel B: Chest X-rays of posterior-anterior (PA) and lateral views (RL). The X-rays revealed an insulation defect (marked by arrows in the magnified sections) in a Riata lead proximal to the right ventricular defibrillation coil.

uncertain whether the externalized conductor was a cause of the R-wave amplitude attenuation. Until now, there were no clinically manifested problems associated with R-wave amplitude attenuation in this patient.

Discussion

Insulation defects in Riata leads

Riata ICD transvenous high-voltage leads (St. Jude Medical) have been implanted worldwide. Riata leads have a unique multi-lumen design in which one or two coil conductors and a ring conductor are packed independently into each silicon cavity surrounding a tip conductor. Recently, some instances of insulation damage in the Riata family have been reported (1-4). An information report from St. Jude Medical Co. indicated that externalized conductors may result from relative motion of conductor cables within the silicon insulation lumen, referred to as “inside-out” abrasion (5). A class I recall was announced by the U.S. Food and Drug Administration in November 2011 (6).

In our study, outer insulation defects were observed on X-rays obtained during the follow-up period (52±9 months) in two of 10 patients with Riata leads. In Case 1, the outer lead insulation defect occurred between 30 and 43 months after surgery because X-rays obtained at the ICD clinic 30 months after implantation showed normal findings. For the same reason, protrusion of the externalized conductor in Case 2 was estimated to have occurred between 39 and 50 months after ICD implantation. The incidence of outer insulation defects (20%) in our patients is higher than that (0.16-1.96%) of previous reports including large numbers of patients with Riata leads (1-3). This difference is probably due to the following: (i) this study included a very small number of patients, (ii) our follow-up period was longer than that used in previous studies and (iii) we performed X-ray assessment in all of our patients, including those with and without findings of lead electrical abnormalities.

Externalized conductors observed on chest X-ray do not necessarily cause clinically manifested electrical abnormalities if they are appropriately coated with ethylene tetrafluoroethylene (ETFE) inner insulation. In this study, intracardiac R-wave amplitudes decreased (by more than 30% or 3.0 mV) in three patients, and two of these three patients showed externalized conductors. It is possible that an insulation defect that was undetectable during the X-ray assess-
ment may occur in the remaining patient with R-wave attenuation and careful follow-up in this patient is mandatory. Disconnection of conductors and/or insulation damage are common causes of structural fractures of pacemaker and/or ICD leads. Disconnection of a conductor usually induces either pacing failure due to increased pacing-thresholds or sensing failure caused by noise interaction. On the other hand, abrupt decreasing lead impedance suggests insulation damage in implanted leads. Therefore, the pattern of R-wave attenuation seen in our patients seemed to be different from that usually observed in fractured leads (2). R-wave amplitude attenuation has been reported in other lead models and a mild degree of R-wave amplitude attenuation may be observed in normally working (structurally and functionally) pacemaker and ICD leads (7-10). However, as a result of attenuation of R-wave amplitudes with increases in T-wave amplitudes, TWOS-associated inappropriate ICD therapies developed in Case 1. Externalized conductors may be a cause of this phenomenon; however, similar TWOS episodes have been reported in other lead models without the occurrence of any lead structural abnormalities involving externalized conductors (7, 11-14). Therefore, up to now, it has been uncertain whether alternations of R-wave and/or T-wave amplitudes simply imply the presence of manifested (or latent) lead insulation defects in Riata leads.

Because Atlas+ICD generators do not have an alarm function to detect artificial electrical noise or sudden lead impedance changes in either high or low voltage conductors, electrical abnormalities in lead conductor fractures may not be noticed before the occurrence of cardiac events, inappropriate therapy, defibrillation delivery failure and/or pacing/sensing failure, etc. Scheduled X-ray assessments are reasonable to ensure early detection of externalized conductor insulation defects. However, it is uncertain how long a period and how often X-ray assessment is required in patients treated with Riata leads because the details of lead problems have not yet been clarified. Erkapic et al. reported that specific insulation failures occurred mainly in the tricuspid valve (2). It is important to pay particular attention to the curves around the tricuspid valves.

Until now, it has been uncertain when conductors would most likely become externalized and how externalized conductors could induce clinically manifested problems of lead failure. Therefore, both regular X-ray assessments and lead-electrical condition checks are required to prevent possible lead-associated complications in patients treated with Riata leads. In addition to the problems associated with R-wave and/or T-wave alterations, Hauser et al. reported that Riata lead-related deaths are associated with electrical short circuits between high-voltage components and other parts of the ICD system (low-voltage conductors, shock-coils and/or pulse generator cans) (15).

It is also unclear how to best treat patients with externalized conductors who do not show any clinically manifested electrical problems because the details of lead troubles have not been clarified. Currently, prophylactic explant and/or replacement of leads in such patients are not recommended (5, 16). Parvathaneni et al. recently reported that structural Riata lead failure detected with cine-fluoroscopy is time-dependent and occurs in 33% of patients (the mean follow-up period in this study was 5.9±3.5 years) (12). In addition, Hauser et al. assessed insulation defects in removed Riata leads and reported that the ETFE inner coating was found to be abraded in 22 of 43 Riata leads with externalized conductors (17). These reports suggest that the inner ETFE-coating may not be safe enough for long-term use. Therefore, it is possible that the number of Riata leads with externalized conductors and electrical abnormalities may increase during future follow-up. Possibly, prophylactic lead retraction and/or replacement of externalized conductors may become an appropriate strategy. However, the indications for these approaches need to be clarified by further
clinical studies.

Limitations

The limitations associated with this study include its retrospective design and the very small number of Riata leads implanted in our single hospital. Consequently, this study was not able to statistically demonstrate the longevity of Riata leads or any risk predictors of lead fracture.

Conclusion

In this study, two of 10 Riata leads with dual-coil conductors fractured in the silicon insulation over 52±9 months. Both patients with lead defects showed decreases in R-wave amplitudes and one patient experienced inappropriate ICD therapy due to TWOS. For all patients with ICDs using Riata leads, scheduled lead-electrical measurements must be monitored and chest X-rays examinations must be conducted primarily because the details of Riata lead problems have not yet been fully elucidated.

The authors state that they have no Conflict of Interest (COI).

References


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