DEVICE THERAPY

COMPLEX CASE STUDY

Inappropriate Shocks Due to Externalized Riata Implantable Cardioverter-Defibrillator Lead Conductors with Normal Lead Parameters

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Case 1

The patient is a 51-year-old male with severe non-ischemic cardiomyopathy treated with an implantable cardioverter-defibrillator (ICD) (Atlas + HF V343, St. Jude Medical, Sylmar, CA) for primary prevention of sudden death in January 2006. The patient received a model 1582, single-coil, 8 French ICD lead (Riata, St. Jude Medical). Despite cardiac resynchronization therapy (CRT), the patient had progressive heart failure and underwent implantation of a left ventricular assist device (LVAD, HeartMate II, Thoratec Corp., Pleasanton, CA) in June 2011.

In September 2011, the patient presented after an ICD shock. The patient did not have any acute symptoms prior to his shock. Interrogation of the event showed multiple episodes of non-physiologic recordings in the right ventricular (RV) electrograms classified as ventricular fibrillation (VF), one of which led to an inappropriate, spurious ICD shock (Figure 1). The question was raised whether the electrical noise on the RV sensing lead may have been related to device–device interaction with the patient’s recently implanted LVAD. Lead parameters for capture threshold, sensing, and shock impedance were stable without any abnormalities. Detailed review of the RV pacing lead impedance trend did reveal a recent minor decrease of about 150 ohms, but the lead impedance had remained within the normal physiologic range (>200 and <2000 ohms) (Figure 2a). Notably, as well, the bipolar LV lead impedance also decreased simultaneously, suggesting that this change in RV pacing impedance may have been related to changes in volume status rather than indicative of a lead insulation problem.

The patient’s ICD was nearing elective replacement indicator status due to expected battery depletion, and he was brought in for lead assessment and generator changeout in January 2012. Fluoroscopy of the Riata ICD lead revealed externalization of the conductors occurring proximal to the defibrillation coil in the inferior right atrium near the tricuspid annulus (Figure 3a). Subsequent detailed review of the patient’s prior chest radiographs clearly showed that the conductors on the ICD lead had externalized more than 1 year earlier, sometime between March 2009 and December 2010 (Figure 2b,c) and that this insulation failure had occurred between 41 and 59 months after lead implant. Of note as well, the appearance on radiographs of external ICD lead conductors had occurred prior to the minor changes in RV pacing lead impedance noted above. Owing to the diagnosis of insulation abrasion failure and the occurrence of an inappropriate shock, a new ICD lead was placed in the RV at the time of the generator replacement procedure.

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Figure 1: Electrograms of inappropriate shock from patient in case 1. Intermittent nonphysiologic signals are classified as ventricular fibrillation prior to the shock.

Figure 2: Impedance trends over time. (a) Case 1. While there is a minor drop in right ventricular (RV) lead impedance prior to the first RV lead noise, the left ventricular (LV) lead impedance drops as well, suggesting volume rather than lead change. The bracket is the time window in which the conductors first became externalized, the dashed arrow is the time the patient received a left ventricular assist device, and the solid arrow is the time the RV lead noise first appeared. (b) Case 2. The RV lead impedance shows a gradual and minor, subtle decline over time. The sudden rise in impedance in the last measurement is from an interrogation done of the device after it was explanted and disconnected from the leads.
Case 2

The patient is a 69-year-old male with nonischemic cardiomyopathy implanted with a single chamber ICD (Atlas+ VR V193, St. Jude Medical) in September 2005 for primary prevention of sudden death. The patient received a model 1582, single-coil, 8 French ICD lead (Riata, St. Jude Medical).

In July 2010, the patient developed spontaneous, asymptomatic ventricular tachycardia (VT) with a cycle length (CL) of approximately 320 ms, leading to several ICD shocks. He was seen at that time, confirming the ventricular arrhythmia, but it also was noted that there was noise on the RV pace/sense electrogram channel that developed immediately after the shocks were delivered. Lead parameters were normal, and device manipulation did not reproduce any noise. It was decided to observe the patient’s device while treating his VT medically.

In January 2012, the patient presented again after the sudden onset of multiple ICD shocks. Interrogation of the device again showed VT with a CL of 320 ms. After this VT was successfully defibrillated via the ICD, the patient had significant noise in the RV lead, being classified as VF leading to several additional therapies (Figure 4). Lead parameters for capture threshold, sensing, and shock impedance were all stable without any abnormalities. Detailed review of the RV lead pacing impedance revealed a minor gradual decrease of about 100 ohms at the time that the first RV lead noise appeared (Figure 2b). The pacing lead impedance, however, remained within normal limits (>200 and <2000 ohms).

Fluoroscopy revealed externalization of the conductors on the patient’s single coil Riata high-voltage lead proximal to the defibrillation coil in the inferior right atrium near the tricuspid annulus. The lead was replaced, and the patient was upgraded to a CRT defibrillator device.

Discussion

The St. Jude Medical Riata and Riata ST silicone leads recently have been noted to be subject to insulation abrasion failures leading to a Food and Drug Administration (FDA) class I recall in December 2011. The conductor cables in these high-voltage leads may wear through the silicone insulation from inside-out and can be seen outside the lead body (externalized conductors) on fluoroscopy or after extraction. Although a true estimate of the risk of this failure mode with Riata leads is uncertain at this point in time, the incidence rate is reported by the manufacturer at 0.63%. However, recent reports by implanters and those following patients with these devices suggest that the actual incidence of these failures is considerably higher than that estimated by the manufacturer based on returned product analysis.

Many of the findings in both of the currently reported cases are consistent with what is known about inside-out, insulation abrasion failures in Riata leads. The Riata 1582 leads used in both of these patients were single-coil, 8-Fr ICD leads with pure silicone outer insulation. Among Riata leads included in the FDA recall, the single coil, 8-Fr silicone leads appear to be most susceptible to this mode of failure. Also consistent with prior reports, detection of the abnormality occurred in these two patients only after their leads had been in place for at least 5 years. The location of externalized conductors on fluoroscopy was near the tricuspid annulus proximal to the defibrillator coil in both cases. This location is typical for Riata abrasion failures, presumably due to the inexorable, long-term mechanical stress on the lead from the heart motion. In addition, as emphasized previously, this failure mode can result in inappropriate, spurious shocks due to detection of electrical noise and may not be preceded by any significant abnormalities in ICD electrical parameters. The risk of electrical abnormalities appears to be 30–50%, with up to 30% of patients receiving inappropriate shocks.
The Riata ICD lead is no longer being manufactured or implanted. However, there were over 200,000 of these leads sold worldwide. At this juncture, it is still unclear what should be done routinely in patients who have Riata leads implanted with or without externalized conductors. St. Jude Medical currently is conducting the Riata Lead Evaluation Post-Market Study designed to determine the incidence of externalized cables in Riata®/Riata® ST silicone leads and the electrical performance of leads with externalized cables (ClinicalTrials.gov Identifier NCT01507987). Several observations in the cases reported here might have relevance for the management of these patients.

Despite externalization of electrical conductors for more than 1 year in both cases, there were no major changes in lead parameters outside the normal limits that usually would result in concern or further investigation for a potential lead problem. Thus, in a patient with one of these leads, one cannot be assured that the conductors have not exteriorized beyond the outer insulation even when lead parameters including impedance measurements remain within the normal range. This may be due to the intact ethylene tetrafluoroethylene (ETFE) insulation on the individual conductor cables. This finding in the Riata lead is in contrast to Sprint Fidelis ICD leads (Medtronic), which often demonstrate marked changes in lead impedance or other non-invasive parameters prior to a lead conductor fracture. These observations have been utilized in development of a lead integrity alert algorithm in Medtronic ICDs as a monitoring mechanism to identify lead fractures as early as possible and to prevent inappropriate ICD shocks. An ICD algorithm for early identification of Riata ICD lead failure thus far has not been developed. In this regard, it is notable that in retrospect both of these patients manifested minor, subtle decreases in RV pacing impedance over time that preceded the onset of electrical noise, but in both cases impedances remained in the normal physiologic range. This may have been related to breakdown in the integrity of the silicone insulating material covering the conductor cables without disruption of the ETFE coating. However, as noted above, because other alterations can affect impedance measurements, the clinical utility, specificity and predictive value of small, time-dependent decreases in pacing impedance in a patient with a Riata ICD lead remains to be determined prospectively.

The long-term, electrical reliability and performance of a Riata lead in which the conductors have exteriorized beyond the silicone insulation but the ETFE remains intact is not yet known. Whether such a lead can withstand continued, long-term mechanical abrasion due to the heart motion or the effects of delivery of one or more high voltage shocks remains uncertain. The observations in the present cases suggest that when the conductors are exteriorized beyond the silicone, although there is a risk of an abnormal electrical event, development of a lead integrity alert algorithm in Medtronic ICDs as a monitoring mechanism to identify lead fractures as early as possible and to prevent inappropriate ICD shocks. An ICD algorithm for early identification of Riata ICD lead failure thus far has not been developed. In this regard, it is notable that in retrospect both of these patients manifested minor, subtle decreases in RV pacing impedance over time that preceded the onset of electrical noise, but in both cases impedances remained in the normal physiologic range. This may have been related to breakdown in the integrity of the silicone insulating material covering the conductor cables without disruption of the ETFE coating. However, as noted above, because other alterations can affect impedance measurements, the clinical utility, specificity and predictive value of small, time-dependent decreases in pacing impedance in a patient with a Riata ICD lead remains to be determined prospectively.

Figure 4: Electrograms of ventricular tachycardia (VT) and noise from patient in case 2. A true VT episode is treated appropriately and this is followed by noise with very high gain likely due to low amplitude signals during the preceding VT event. The noise seen here did lead to several implantable cardioverter-defibrillator shocks.
this risk may be low and may not represent an urgent or life-threatening situation. Notably in the first case, the exteriorized conductors were present on radiographs for at least a year or more before electrical noise became manifest and resulted in an inappropriate shock. Furthermore, even after the first appearance of electrical noise in this patient, no further noise or inappropriate shocks occurred during an additional 4 months of observation. In the second case, lead-related electrical noise and an inappropriate shock only became manifest immediately after delivery of an appropriate, high-voltage shock for spontaneously occurring, sustained VT. Noise did not manifest again or result in any inappropriate shocks or changes in impedance outside the normal range for another 18 months until the recurrence of VT and need for another appropriate high-voltage ICD shock. However, whether it is safe and for how long one can rely on a Riata lead that has an externalized conductor that can be seen under fluoroscopy but has not manifested any electrical abnormalities is uncertain. Furthermore, the routine use of fluoroscopic surveillance of all Riata leads still is a matter of debate.

In summary, these two cases highlight the emerging issues surrounding implanted Riata ICD leads that are likely to remain an important, clinical problem during ICD follow-up and management for many years to come. The observations in these cases may have significant implications for the role of routine fluoroscopy and management of leads with externalized conductors but normal lead parameters. Riata lead insulation abrasion failures can occur without significant lead parameter changes and the first clinical manifestation may be electrical noise or spurious ICD shocks. Such an inappropriate event in a patient with an implanted Riata lead should prompt detailed fluoroscopic evaluation of the lead especially in the region around the tricuspid valve to avoid subsequent inappropriate ICD shocks. The only apparent lead parameter change prior to an inappropriate shock in a patient with a Riata lead may be minor, subtle decreases in RV pacing impedance that remain in the normal range. Therefore, even small changes in lead impedance within the normal range of these parameters in a patient with a Riata lead may be sufficient to warrant fluoroscopy of the leads to avoid inappropriate ICD shocks. The routine use of detailed fluoroscopic assessment of Riata leads also seems reasonable at the time of elective ICD generator replacement for upgrades and/or battery depletion, even in the absence of an inappropriate shock or impedance changes, especially because it appears that these failures become manifest on average about 5 years after implantation. Replacement of leads with externalized conductors but normal electrical parameters at the time of generator replacement seems reasonable because of the risk of inappropriate shocks. Patients with one of these high-voltage leads without externalized conductors seen under fluoroscopy require close monitoring and lifetime follow-up. Future studies will help clarify the optimal strategy for managing patients with Riata ICD leads.

References