Successful detection of a high-energy electrical short circuit and a "rescue" shock using a novel automatic shocking-vector adjustment algorithm

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Introduction

A high-voltage (HV) electrical short circuit can be a critical electrical failure in an implantable cardioverter-defibrillator (ICD) system because of the failed delivery of appropriate shocks against fatal arrhythmia. The Food and Drug Administration has classified the St Jude Medical Riata family of ICD leads (St Jude Medical, St Paul, MN) as a class I recall since 2011 because of the "inside-out abrasion" problem.[1] Currently, most of the externalized conductors are not related to an electrical malfunction.[2] However, several reports have pointed out the risk of HV short circuit in Riata leads caused by the inside-out abrasion underneath the shocking coils. In the present report, we describe a case of successful rescue of an HV short circuit via the implementation of the automatic shocking-vector adjustment algorithm that secures HV shock delivery when an HV electrical short circuit is detected.

Case report

A 33-year-old man was admitted for replacement of his ICD generator because of the depletion of its battery 6 years after the initial implantation. He had received a prophylactic ICD implant for the treatment of Brugada syndrome. The ICD system was implanted on the right side because his innominate vein was occluded. Atlas VR V-193 (St Jude Medical) and Riata 8-F dual-coil lead (1570-65; St Jude Medical) were used. During the initial operation, the right ventricular (RV) lead was implanted at the RV apex using the supraclavian approach. Thus, the proximal end of the RV lead was brought to the right chest wall via a subcutaneous tunnel across the right clavicle. Neither electrical failure nor externalized conductors had been detected. Lead measurements had been stable with a pacing impedance of 415–440 Ω and a pacing threshold of 0.75–1.25 V per 0.5 ms. Although R-wave sensing was low at the time of implantation (2.5–3.5 mV), it had been stable within 3.5–5.1 mV.

During the ICD generator change operation, Atlas VR was replaced with Ellipse VR (St Jude Medical) as a new generator. After the operation, defibrillation threshold testing (DFT) was performed. The superior vena cava (SVC) coil and the generator (CAN) were used as cathodes (default shocking configuration: RV to SVC/CAN). Ventricular fibrillation was induced using the direct current fibber method (2.0 seconds). However, the first attempted shock (650 V) was not delivered. Subsequently, the next detection sequence was implemented and the second attempt of an 875-V shock successfully terminated ventricular fibrillation (Figure 1). According to the test report (Figure 2), the first shock was abandoned with the recognition of a significant problem in the HV lead (HV impedance was < 10 Ω). However, immediately after the initial failed shock, another shocking configuration (RV to CAN) was automatically selected. Consequently, the second delivered shock at its maximum energy resulted in successful restoration of the sinus rhythm. We concluded that the successful rescue shock was delivered via execution of the Dynamic Tx overcurrent detection (OCD) algorithm with the detection of an HV electrical short circuit between the RV and SVC coils. After DFT, the ICD generator was explanted in order to investigate the mechanical failure or an electrical short circuit inside the subcutaneous pocket. However, no arc was found on the surface of the ICD generator and there was no apparent lead insulation break. Consequently, the ICD generator was replaced with a new Ellipse VR, and a new RV lead (Endotak Reliance G 4-site 0295-59, Boston Scientific, Natick, MA) was also placed at the RV apex via the right subclavian vein without removal of the Riata lead. The analysis of the

KEYWORDS Implantable cardioverter-defibrillator; High-voltage short circuit; Externalized conductor; Overcurrent detection; Automatic shocking-vector adjustment

ABBREVIATIONS **CAN** = implantable cardioverter-defibrillator generator; **DFT** = defibrillation threshold testing; **HV** = high voltage; **ICD** = implantable cardioverter-defibrillator; **OCD** = overcurrent detection; **RV** = right ventricle/ventricular; **SVC** = superior vena cava (Heart Rhythm Case Reports 2015;1:27–30)

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KEY TEACHING POINTS

- St Jude Medical Riata ICD leads recalled in 2011 are prone to externalize their conductor cables due to "inside-out abrasion." While most externalized conductors are not related to an electrical failure, several reports described a fatal high-voltage (HV) short circuit after long-term use because of the inside-out abrasion underneath the superior vena cava coil.
- HV short circuit could not be detected thorough routine follow-ups unless defibrillation threshold testing is performed. However, it is not currently recommended because of the potential risk of compromised hemodynamics or destruction of implantable cardioverter-defibrillator system.
- The automatic shocking-vector adjustment algorithm (Dynamic Tx) automatically finds a viable vector in the dual-coil setting and ensures the shock therapy if an HV short circuit is detected on the brink of the shock delivery.
- If the Dynamic Tx algorithm is available, defibrillation threshold testing can be revisited in order to unveil the HV short circuit of Riata dual-coil implantable cardioverter-defibrillator leads.

removed ICD generator (Ellipse VR) by the manufacturer did not reveal physical or electrical aberrations.

Discussion

Serious adverse events, including deaths linked to Riata leads, have been reported.[3–7] In these reports, the authors point to the risk of an HV short circuit caused by the inside-out abrasion underneath the shocking coils in the Riata lead family devices, though the incidence rate of internal abrasion short circuits underneath the SVC shock coil is quite low (0.06%).[8] The concern is that an HV short circuit may not be detected during a routine checkup unless DFT is performed.[4,5] Nevertheless, there are currently no recommendations or expert consensus regarding DFT during follow-up of Riata leads because of potential risks of compromised hemodynamics or failed rescue as well as overcurrent delivery, resulting in the destruction of the ICD system. Since we were concerned about the potential risk of unknown insulation break while no apparent defect was detected, DFT was performed after discussing the risk and benefit with the patient and among the device-care team. Consequently, we found that an apparently normal Riata lead had a fatal electrical failure demonstrating an HV short circuit and it occurred between the RV and SVC coils. The reasons are as follows: First, HV impedance between the RV coil and the SVC/CAN was below the detection limit, whereas during the second attempt, HV impedance between the RV coil and the CAN was within normal limits (74 Ω; Figure 2). Second, no physical defects (such as arc formation or burn injury) were found on the surface of the CAN and the RV shock lead or inside the subcutaneous pocket. These findings could not suggest that an HV short circuit occurred between the RV coil and the CAN because of an insulation break of the lead in the pocket. We expected that cables for the RV coil were electrically connected with the SVC coil because of an insulation defect and was short-circuited during the delivery of the first shock (Figure 3). However, strictly speaking, an arc could occur between the RV and SVC coils without physical contact at HV; therefore, it cannot be guaranteed that the RV coil cable and the SVC coil underwent a pure "electrical short."

We evaluated whether this is a specific problem of the Riata family. Kleeman et al[9] reported that the annual rate of ICD lead defects reaches 20% in 10-year-old leads among any type of ICD leads and that more than half of the lead defects involve insulation failure. We can hypothesize that any type of ICD lead can cause such an electrical failure after long-term use.

In the present case, the patient was saved from the failed shock delivery via the implementation of OCD together with the automatic shocking-vector adjustment algorithm (Dynamic Tx). This novel algorithm is exclusively adopted in ICD systems of Ellipse, Fortify Assura, Quadra Assura, and Unify Assura series (St Jude Medical). Importantly, it is feasible only if a dual-coil lead is implanted as well as the SVC coil is activated. When an overcurrent (>60 A) is detected on the brink of the shock delivery, OCD aborts the attempted shock delivery in order to preserve the destruction of the ICD system. Simultaneously, the Dynamic Tx algorithm checks for the compromised vector integrity and finds another viable configuration to ensure HV shock delivery (Figure 1). Thus, if an initial shocking-vector configuration (RV to SVC/CAN) failed, it is changed to "RV to CAN," followed by "RV to SVC" setting until the shock delivery is ensured. The sequence can be repeated at most 6 times. The Dynamic Tx algorithm is compatible with any type of dual-coil ICD leads.

We expect that the novel algorithm may overcome the limitation of detecting an HV short circuit as a fatal complication with long-term ICD use. Since the Dynamic Tx OCD algorithm is available, we routinely perform DFT during the box change operation in order to unveil the HV short circuit only if the algorithm is available with the newly replaced device and the Riata dual-coil lead is used. Although we should be prudent to perform DFT in every case, it should be a debatable issue. Especially in the generator replacement, we have a chance to consider the safety option of an additional placement or removal of ICD leads during the procedure if we can detect the existence of a possible HV short circuit by DFT.

With regard to clinical implications, implementation of the Dynamic Tx OCD algorithm is so far the only safety option for this type of fatal and undetectable electrical failure of ICD leads. To our knowledge, the present case report is

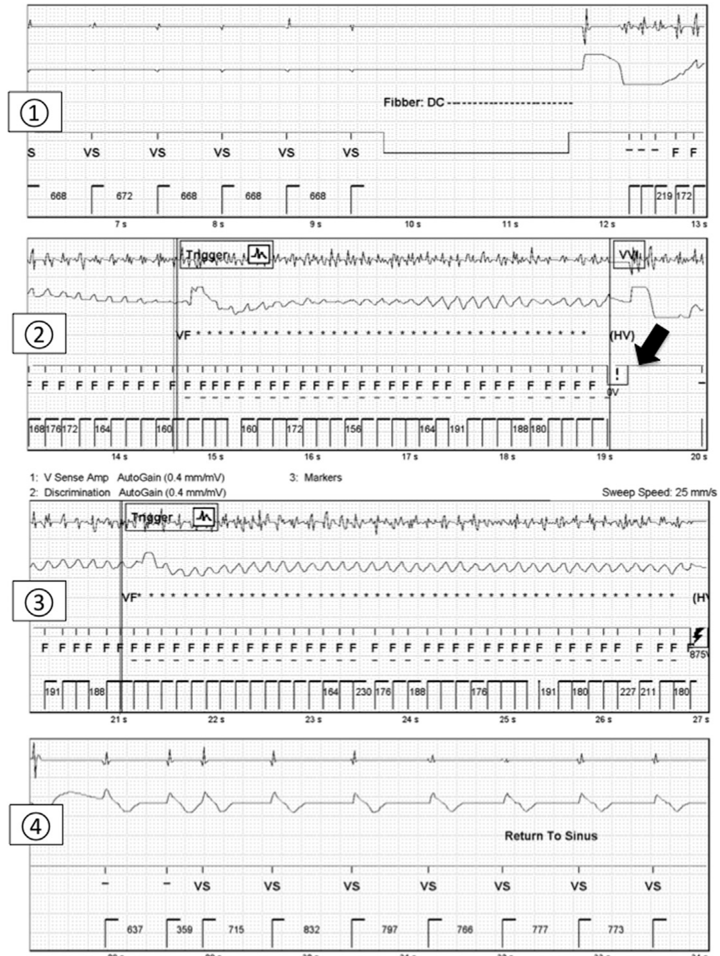
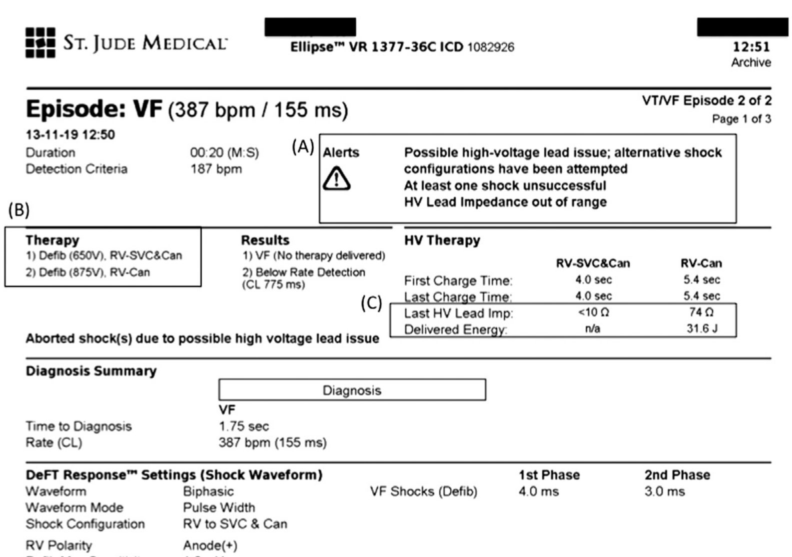


Figure 1 Intracardiac tracing during defibrillation threshold testing is shown. VF was induced ①. The first shock was implemented but failed to terminate VF. Note the exclamation point at the first shock. This mark denotes overcurrent detection. A high-voltage shock could not be delivered ("0 V") ②. Subsequently, the next detection and charging sequence was executed. VF was successfully terminated using maximum shock delivery (875 V) of the "RV-CAN" shocking-vector configuration ③④. CAN = implantable cardioverter-defibrillator generator; DC = direct current; HV = high voltage; RV = right ventricle; VF = ventricular fibrillation.



ST. JUDE MEDICAL [redacted] Ellipse™ VR 1377-36C ICD 1082926 [redacted] 12:51 Archive

Episode: VF (387 bpm / 155 ms)

VT/VF Episode 2 of 2
Page 1 of 3

13-11-19 12:50
Duration 00:20 (M:S)
Detection Criteria 187 bpm

(A) Alerts
Possible high-voltage lead issue; alternative shock configurations have been attempted
At least one shock unsuccessful
HV Lead Impedance out of range

(B)

Therapy
1) Defib (650V), RV-SVC&Can
2) Defib (875V), RV-Can

Results
1) VF (No therapy delivered)
2) Below Rate Detection (CL 775 ms)

HV Therapy

(C)

	RV-SVC&Can	RV-Can
First Charge Time:	4.0 sec	5.4 sec
Last Charge Time:	4.0 sec	5.4 sec
Last HV Lead Imp:	<10 Ω	74 Ω
Delivered Energy:	n/a	31.6 J

Aborted shock(s) due to possible high voltage lead issue

Diagnosis Summary

	Diagnosis
	VF
Time to Diagnosis	1.75 sec
Rate (CL)	387 bpm (155 ms)

DeFT Response™ Settings (Shock Waveform)

			1st Phase	2nd Phase
Waveform	Biphasic	VF Shocks (Defib)	4.0 ms	3.0 ms
Waveform Mode	Pulse Width			
Shock Configuration	RV to SVC & Can			
RV Polarity	Anode(+)			
Defib Max Sensitivity	1.0 mV			

Figure 2 The analyzed data of defibrillation threshold testing are presented. **A:** Alert messages. **B:** The second shock vector was changed (RV-CAN), and the delivered shock was at its maximum energy (875 V). **C:** HV impedances and delivered shock energies are shown. CAN = implantable cardioverter-defibrillator generator; CL = cycle length; HV = high voltage; RV = right ventricle; SVC = superior vena cava; VF = ventricular fibrillation.

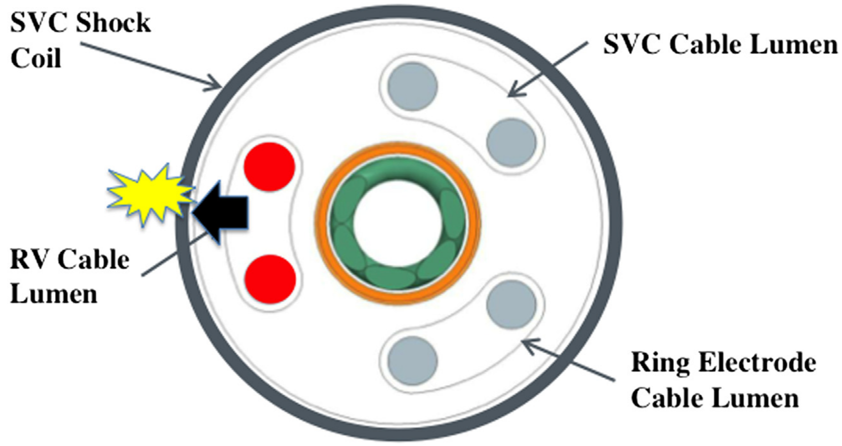


Figure 3 A possible mechanism of an HV electrical short circuit between the RV and SVC coils is demonstrated (courtesy of St Jude Medical). An internal abrasion of the lumen of an RV conductor cable could have occurred underneath the SVC coil. HV = high voltage; RV = right ventricular; SVC = superior vena cava.

the first to show the efficacy of this algorithm in clinical settings.

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References

1. FDA classifies voluntary physician advisory letter on Riata and Riata ST silicone defibrillation leads as class I recall. Heart Rhythm Society Web Site. http://www.hrsonline.org/Practice-Guidance/Device-Drug-Safety/Drug-Device-Lead-Safety/FDA-Classifies-Voluntary-Physician-Advisory-Letter-on-Riata-and-Riata-ST-Silicone-Defibrillation-Leads-as-Class-I-Recall. Published 2011. Accessed October 29, 2014.
2. Hayes D, Freedman R, Curtis AB, Niebauer M, Kay GN, Dinerman J, Beau S. Prevalence of externalized conductors in Riata and Riata ST silicone leads: results from the prospective, multicenter Riata Lead Evaluation Study. Heart Rhythm 2013;10:1778–1782.
3. Hauser RG, Abdelhadi R, McGriff D, Retel LK. Deaths caused by the failure of Riata and Riata ST implantable cardioverter-defibrillator leads. Heart Rhythm 2012;9:1227–1235.
4. Leong DP, van Erven L. Unrecognized failure of a narrow caliber defibrillation lead: the role of defibrillation threshold testing in identifying an unprotected individual. Pacing Clin Electrophysiol 2012;35:e154–e155.
5. Shah P, Singh G, Chandra S, Schuger CD. Failure to deliver therapy by a Riata lead with internal wire externalization and normal electrical parameters during routine interrogation. J Cardiovasc Electrophysiol 2013;24:94–96.
6. Webber MR, Allen RF, Stiles MK. Unheralded failure of Riata defibrillator lead at defibrillation threshold testing. J Arrhythm 2013;29:187–189.
7. Hauser RG, McGriff D, Retel LK. Riata implantable cardioverter-defibrillator lead failure: analysis of explanted leads with a unique insulation defect. Heart Rhythm 2012;9:742–749.
8. Tsung P. Product Performance Report—2014 First Edition. St Paul, MN: St Jude Medical; 2014. http://professional-intl.sjm.com/resources/product-performance/product-performance-reports/current. Accessed October 29, 2014.
9. Kleeman T, Becker T, Doenges K, Vater M, Senges J, Schneider S, Saggau W, Weisse U, Seidl K. Annual rate of transvenous defibrillation lead defects in implantable cardioverter-defibrillators over a period of >10 years. Circulation 2007;115:2474–2480.