

The big short: A lifesaving alternative to a catastrophic lead failure



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Introduction

The development of an electrical short circuit represents critical failure in the function of an implantable cardioverter-defibrillator (ICD) system. The Food and Drug Administration issued a class I recall of St. Jude Medical Riata and Riata ST leads in 2011 owing to higher-than-expected failure rate, including “inside-out abrasion.” However, externalized conductors do not necessarily cause electrical malfunction.^{1,2} Despite heightened surveillance and stable electrical parameters in follow-up, these leads can fail suddenly and without warning.^{3–8} In this report, we describe successful rescue of a patient utilizing an automatic shocking-vector adjustment algorithm following catastrophic short circuit between high-voltage (HV) coil and generator in the prepectoral pocket.

Case report

A 50-year-old man with ischemic cardiomyopathy and paroxysmal atrial fibrillation without known history of ventricular ectopy underwent implantation of a primary prevention dual-chamber ICD in 2007 via left subclavian access. Implanted hardware included a Tendril SDX 1488TC (St. Jude Medical, Sylmar, CA) in the right atrial appendage, a Riata 7000 (St. Jude Medical) in the right ventricular (RV) apex, and an Atlas 2+ DR V-268 (St. Jude Medical) pulse generator. Initial defibrillation threshold testing demonstrated successful defibrillation at 15 J with a shock impedance of 45 ohms. The patient did not require HV therapy during the lifetime of the first device. Sensing, pacing, and impedance thresholds remained stable (sensed R waves >12 mV, RV pacing thresholds 0.5–1.0V @ 0.5 ms, and RV lead impedance 510–600 ohms) when measured in

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KEY TEACHING POINTS

- Leads do not always fail by the same mechanism that prompted a Food and Drug Administration recall. This case highlights a Riata (St. Jude Medical, Sylmar, CA) lead failure due to a can-to-high-voltage (HV) conductor cable short circuit in the prepectoral pocket rather than intravascular conductor cable externalization.
- Diverted implantable cardioverter-defibrillator shocks deliver some energy to the myocardium despite episode rhythm strip and device reporting “0 J” or “no therapy delivered.” This phenomenon is evidenced by cardiac rhythm changes in both the atrium and ventricle after therapy was diverted owing to out-of-range HV impedance.
- We highlight the use of creative software/programming solutions to mitigate catastrophic failures. In this case, DynamicTx OCD was able to make use of the presence of a dual-coil RV lead to exclude the can from the shocking vector, bypassing what would otherwise have been a lethal short circuit.

follow-up. Notably, HV circuitry was not routinely evaluated during longitudinal follow-up.

The patient underwent generator replacement when his battery reached elective replacement indicator in 2014. Prior to the procedure, the leads were evaluated under fluoroscopy in anteroposterior and left anterior oblique views without evidence of cable externalization. Generator change (Ellipse DR CD2411-36C; St. Jude Medical) was uneventful and intraoperative lead measurements were unchanged from prior. Ventricular fibrillation was induced utilizing a direct current fiber and the arrhythmia was successfully terminated with 25 J after a failed 15 J shock.

He had no clinically significant ventricular arrhythmias until 2019 when he developed ventricular tachycardia at a cycle length of 240 ms that satisfied ventricular fibrillation zone

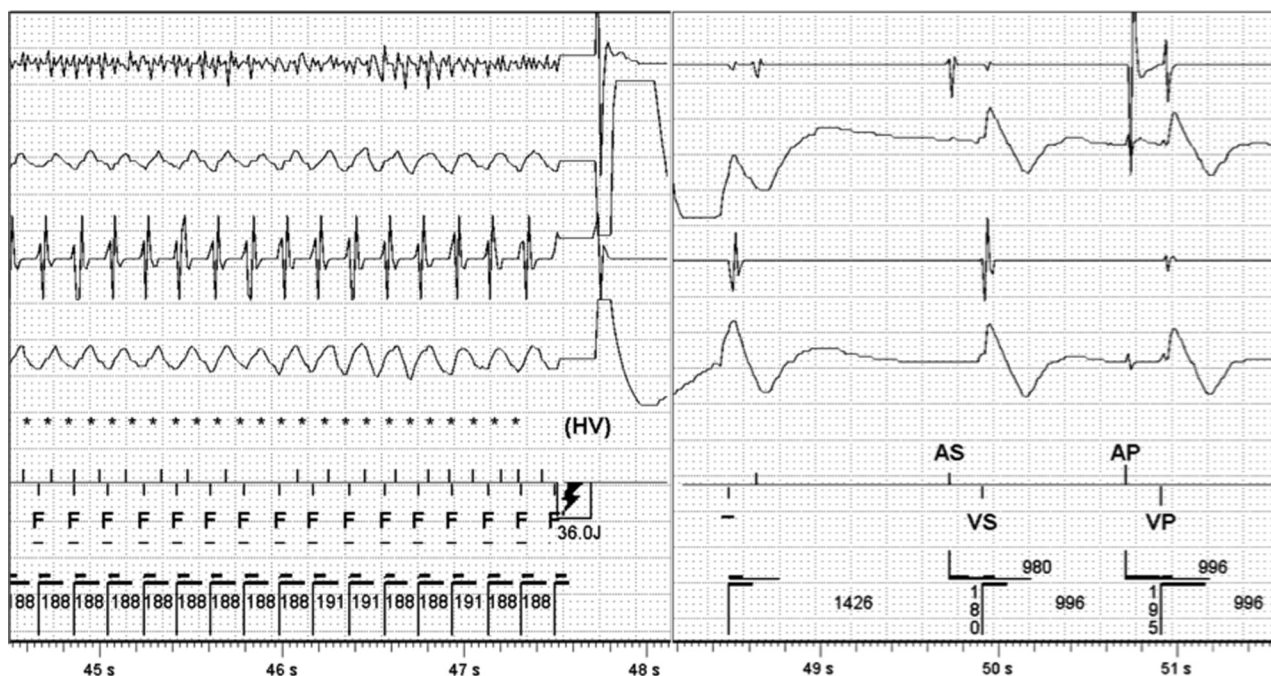


Figure 2 Final shock delivered through right ventricular coil to superior vena cava coil configuration with conversion of both atrial fibrillation and ventricular fibrillation.

An automated remote transmission was performed summarizing device therapy and noting HV lead warning (Figure 3). The patient was instructed to seek further evaluation in the emergency department, at which point he was admitted to the cardiology service for ICD system revision. Upon visual inspection during the procedure, an insulation defect was noted on the RV HV coil proximally in the pocket without arc mark on the surface of the ICD generator (Supplemental Figure 1). Again, no conductor externalization was noted under fluoroscopy. Laser lead extraction was attempted; however, the lead demonstrated extensive

mechanical damage and was unable to be removed in its entirety. Ultimately, a new RV ICD lead and single-chamber generator were implanted with the Riata lead abandoned in place.

Discussion and conclusion

Serious adverse events, including death, have been linked to Riata and Riata ST ICD leads.^{3,4,8-10} Among catastrophic events, electrical short circuits are particularly lethal, as they may occur abruptly during shock delivery, thus failing to defibrillate as the first sign of lead malfunction.

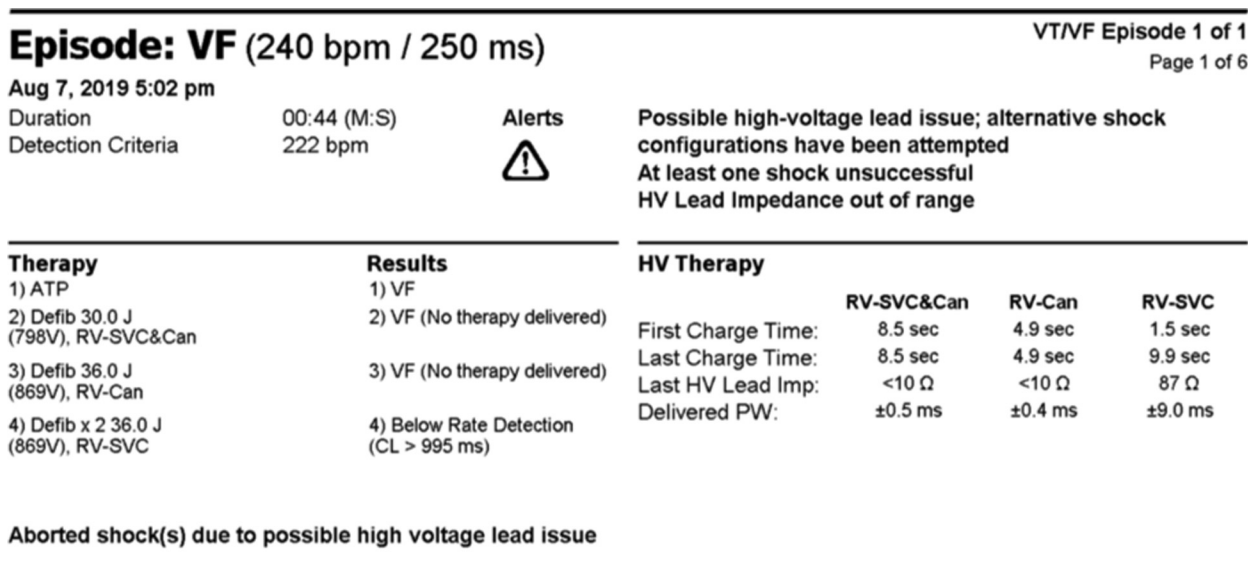


Figure 3 Automated remote device transmission communicating high-voltage (HV) lead warning and failed delivery of shock therapy. The summary documents attempted shock vector, charge time, measured HV impedance, and result of each trialed therapy.

Largely in response to prior HV lead failure leading to generator overstress, pulse generators equipped with DynamicTx OCD, an overcurrent protection and automated dynamic shocking vector algorithm, were released beginning with the St. Jude Assura and Ellipse platforms in 2013. During delivery of a sufficiently high load (shock of at least 180 V), this algorithm detects “overcurrent” (>60 amperes) produced by HV impedances less than 20 ohms or greater than 200 ohms. When these parameters are met, therapy is truncated and the shock vector is temporarily reprogrammed for the next prescribed device therapy. Arrhythmia detection must be satisfied once again for the device to recharge and deliver a shock through the adjusted vector. This sequence can be repeated up to 6 times in an attempt to successfully convert a patient from a ventricular arrhythmia in the setting of a malfunctioning lead. Notably, this algorithm requires the presence of both SVC and RV coils to provide alternative vectors to supplement reversal of shock polarity.

Upon replacement of his generator in 2014, the patient received a device with DynamicTx OCD capabilities. Review of a device interrogation performed in clinic 2 years prior to admission revealed stable lifetime HV impedances for multiple vectors: RV to can, 66–97 ohms; RV to SVC, 64–105 ohms; SVC to can, 60–115 ohms; RV to SVC/can (therapies), 57 ohms. Included in the same report, the 1-year HV lead impedance curve for RV to SVC/can configuration was stable between 70 and 110 ohms without apparent outliers. Annual office evaluation and quarterly remote lead integrity monitoring remained otherwise unremarkable. Despite having an apparently normal Riata lead with stable electrical parameters, his ICD system demonstrated nearly fatal failure. In this case, the device appropriately detected a ventricular arrhythmia. When a shock of 30 J (798 V) was attempted via RV coil to SVC/can configuration, HV impedance was found below the detection limit (<10 ohms). Therapy was aborted to prevent energy shunting with catastrophic generator failure. Interestingly, while the episode summary notes “0 J” delivered, sufficient energy was delivered to the myocardium to accelerate the ventricular rate and convert the atrial rhythm to atrial fibrillation. Utilizing the DynamicTx OCD algorithm, a second shock vector attempted to deliver 36 J (869 V). HV impedance was also found below the detection limit in this configuration (RV coil to can). A third vector was trialed in 2 consecutive shocks at 36 J. In this final configuration (RV coil to SVC coil), HV impedance measured 87 ohms and energy was delivered without truncation; although the first shock in this vector was not successful, the second shock terminated both the ventricular and atrial tachyarrhythmias. The site of electrical short was presumed to be between the RV HV cables and the pulse generator within the pocket, given the normal impedance upon elimination of the can as a cathode. This was corroborated by a visually apparent insulation breach in the RV HV coil proximally in the subcutaneous pocket found at time of system revision.

Several cases of failed delivery of shock therapy have been reported to date.^{4,6–8,10} Frequently, there are no signs of device charring, insulation breach, or other physical defects to suggest location of electrical failure.^{6–8} The incidence of internal abrasion short circuit underneath the SVC shock coil is debated, though it may account for some portion of ICD system malfunction.^{3,9,11} Abrasion occurring between the lead and the can in the pocket accounts for up to 43% of electrical failures in the Riata lead family.³ Can abrasions are not detectable by noninvasive monitoring until they produce an out-of-range impedance and may not be evident at pulse generator change by visual inspection alone.¹⁰ Although lead impedances are evaluated noninvasively through routine follow-up and daily automated device self-diagnostics, the low current used in these algorithms may not sufficiently stress the system to detect electrical short circuit.^{4,10} There are currently no recommendations or expert consensus regarding defibrillation threshold testing during follow-up or at generator exchange with ICD systems integrating Riata family leads.

While much interest has been directed toward externalized conductors in the Riata and Riata ST leads,^{12,13} the development of this mechanical defect does not directly correlate with the presence of electrical failure or a higher incidence of unexpected patient death. In 1 study examining patient death by lead failure, 22 of 133 deaths were attributed to Riata or Riata ST leads. None of these leads showed externalized conductors, and lead failure was largely attributed to can abrasion.⁹ Inside-out abrasion does herald an inherent design flaw in a lead prone to malfunction by a variety of mechanisms. These leads may harbor multiple insulation defects distributed along the length of each single lead, as found in more than 65% of cases studied.³ Though the number of active Riata leads will decline, we expect patients will continue to benefit from novel device algorithms. The newer Durata ICD lead, with its added siloxane-based polyurethane outer insulation, was designed to mitigate conductor externalization. Recent reports, however, raise the possibility that internal insulation breaches observed in the Riata family may also affect the Durata lead performance.¹⁴

This case highlights a number of important teaching points. First, recalled leads do not always fail by the same mechanism that prompted the recall. In this case, a Riata lead failed owing to a can-to-HV conductor cable short circuit rather than intravascular conductor cable externalization. Second, contrary to being reported as 0 J, diverted ICD shocks deliver some energy to the myocardium, as evidenced by cardiac rhythm changes in both the atrium and ventricle after a diverted therapy. Third, we highlight the use of software/programming solutions to mitigate catastrophic failures. In this case, the DynamicTx OCD algorithm was able to make use of the presence of a dual-coil RV lead to exclude the can from the shocking vector, bypassing what would otherwise have been a lethal short circuit. This algorithm provides a unique solution to the challenge of managing, in real time, lead failure in a previously normally functioning system.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hrcr.2020.07.022>.

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