Failure of Lead Integrity Alert to detect implantable cardioverter-defibrillator lead-system failure in a pacemaker-dependent patient

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Introduction

Transvenous implantable cardioverter-defibrillator (ICD) leads are prone to failure and are a significant cause of morbidity and mortality related to ICD systems.[1–3] ICD lead conductor failures may result in adverse clinical consequences such as inappropriate ICD shocks and inhibition of pacing.[4,5] Lead Integrity Alert (LIA; Medtronic, Inc, Minneapolis, MN) was developed to reduce inappropriate ICD shocks due to rapid oversensing by providing an advance warning on right ventricular (RV) lead fracture.[6,7] The algorithm has incremental sensitivity for lead failure over lead impedance alone and has a low false-positive rate, but the false-negative rate is uncertain.[8,9] We report a case of LIA failure to identify RV lead-system failure resulting in inhibition of pacing in a pacemaker-dependent patient.

KEY TEACHING POINTS

- Lead Integrity Alert (LIA) remains a sensitive tool to diagnose implantable cardioverter-defibrillator (ICD) lead fracture, but is limited owing to algorithm criteria.
- A thorough understanding of the LIA algorithm and its limitations may help clinicians appropriately manage patients with clinically suspected ICD lead failure.
- Nonphysiological high-rate nonsustained episodes and changes in lead impedances, in absence of LIA alert, should trigger further investigation if there is clinical suspicion for lead failure.

Case report

A 69-year-old man with history of nonischemic cardiomyopathy, hypertension, dyslipidemia, and prior cardiac resynchronization therapy ICD implant presented to the clinic with recurrent dizzy spells and episodes of loss of consciousness that began several weeks earlier. He denied any prodrome, angina, or exercise limitations. His medications included unchanged doses of carvedilol, lisinopril, amlodipine, tamsulosin, aspirin, simvastatin, and sildenafil (as needed) for several years. His pulse rate was 76 beats per minute and blood pressure was 152/88 mm Hg with no orthostatic changes. Approximately 7 years prior to presentation, he developed symptomatic complete heart block and cardiomyopathy with a left ventricular (LV) ejection fraction of 30%. He underwent cardiac resynchronization therapy defibrillator implant (ICD lead: Medtronic 6947 Sprint Quattro DF-1 connector). Echocardiogram from 2 years prior to the current presentation was notable for recovered LV ejection fraction. One year prior to the onset of his current symptoms, he underwent an apparently uncomplicated ICD pulse generator replacement.

Evaluation of his ongoing symptoms was notable for a device interrogation that showed stable right atrial, RV, and LV pacing thresholds and impedances. A single high-rate ventricular episode was recorded by the ICD 2 months prior to the onset of symptoms, consistent with oversensing (Figure 1). He denied any exposure to electromagnetic interference. The Sensing Integrity Counter (SIC) recorded 32 short V-V intervals detected over a 5-month time period. There was no electrogram noise elicited with provocative maneuvers. An RV lead-system failure was suspected, but a lead revision was deferred owing to stable threshold and impedance and failure of the LIA to detect a lead failure. An event monitor was placed with a plan to follow up with the patient in 1 month for repeat device interrogation.

Three weeks later, 2 episodes of ventricular asystole (longest 9 seconds) were recorded on his event monitor at about 1 AM during sleep (Figure 2). The patient was advised to proceed to the emergency room. A repeat device interrogation was notable for appropriate ICD function, no triggering of the LIA, only 1 additional short V-V interval on the SIC,

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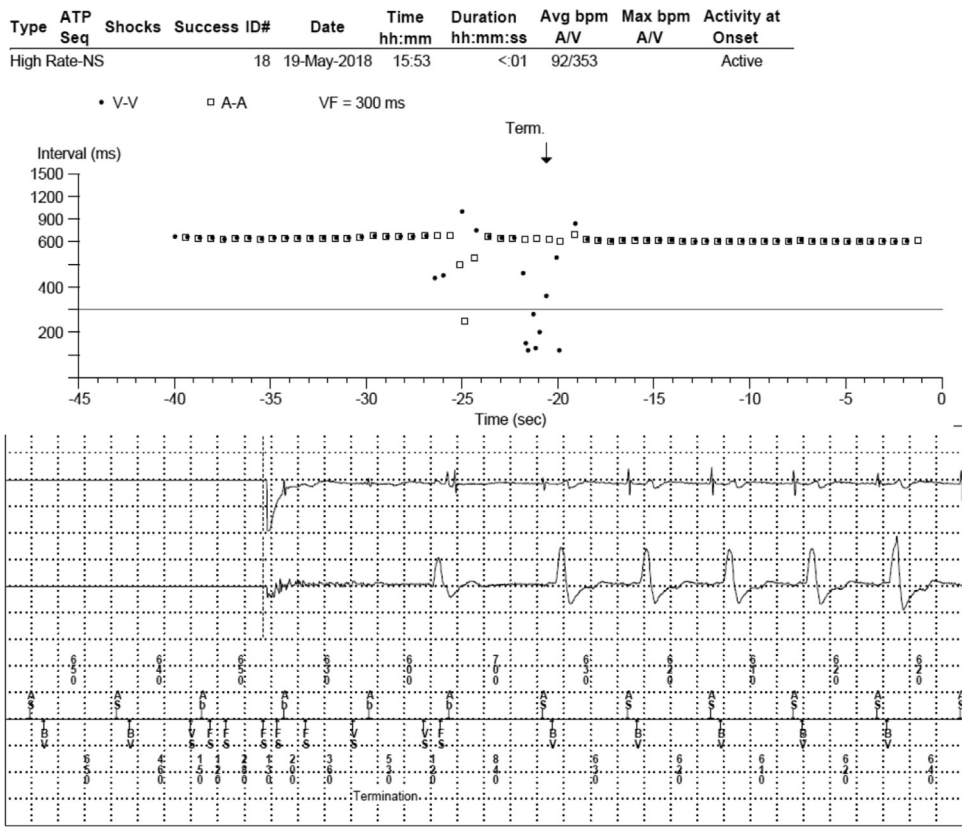


Figure 1 A single high-rate ventricular episode recorded 2 months prior to the onset of the patient's symptoms, consistent with oversensing owing to probable electrical noise.

and no high-rate nonsustained episodes. The RV lead impedance trends were carefully inspected. In retrospect and notably, there was a modest short-term rise in bipolar impedance over the past few months and an increase in variability of the RV bipolar impedances that exceeded the baseline measurement by 350 ohms at times over the past 15 days

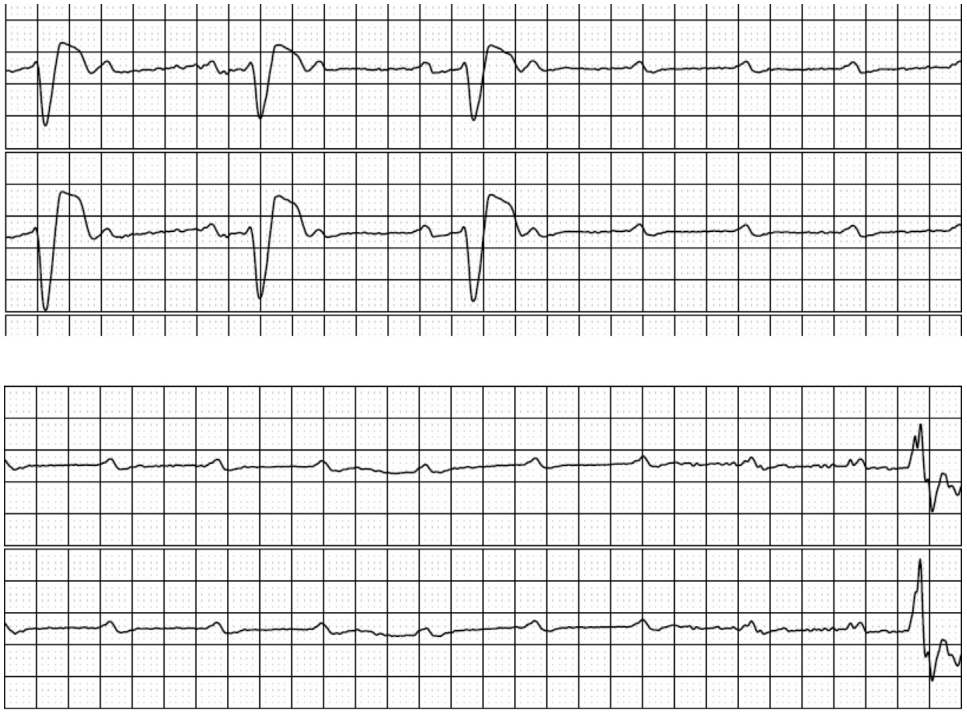
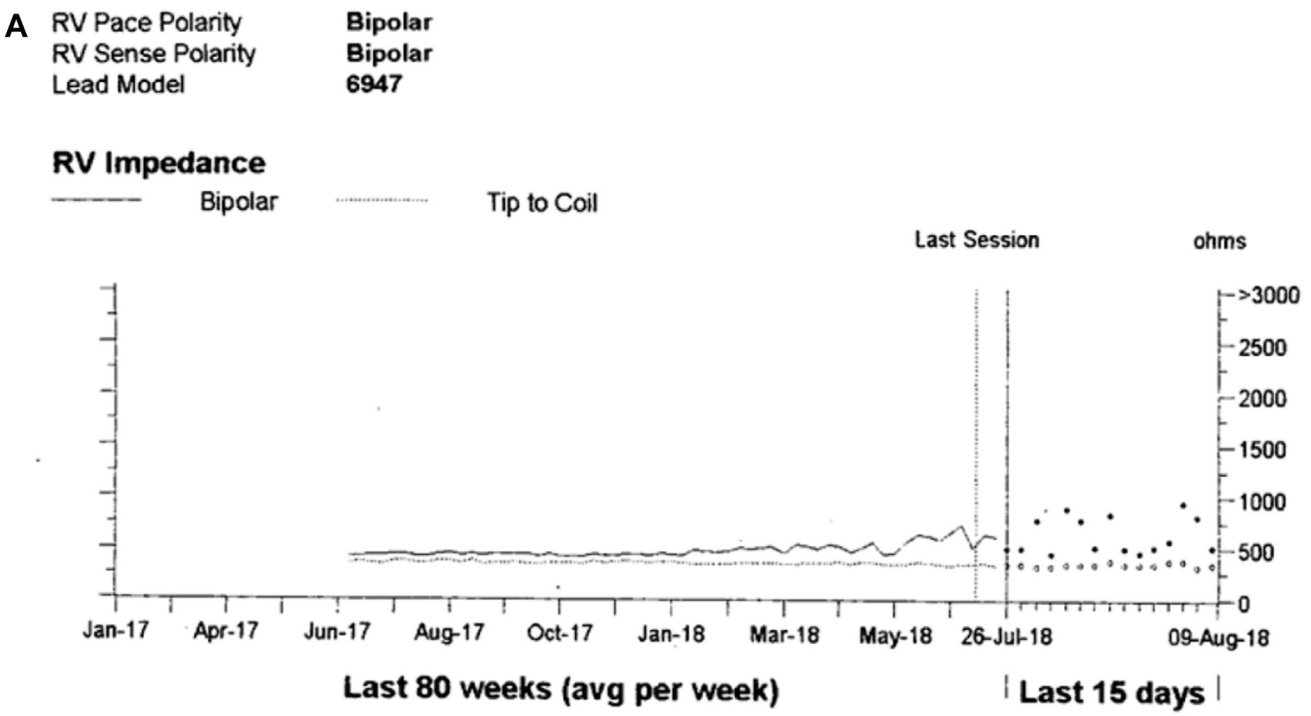


Figure 2 Event monitor recorded a 9-second asystole episode during nighttime.



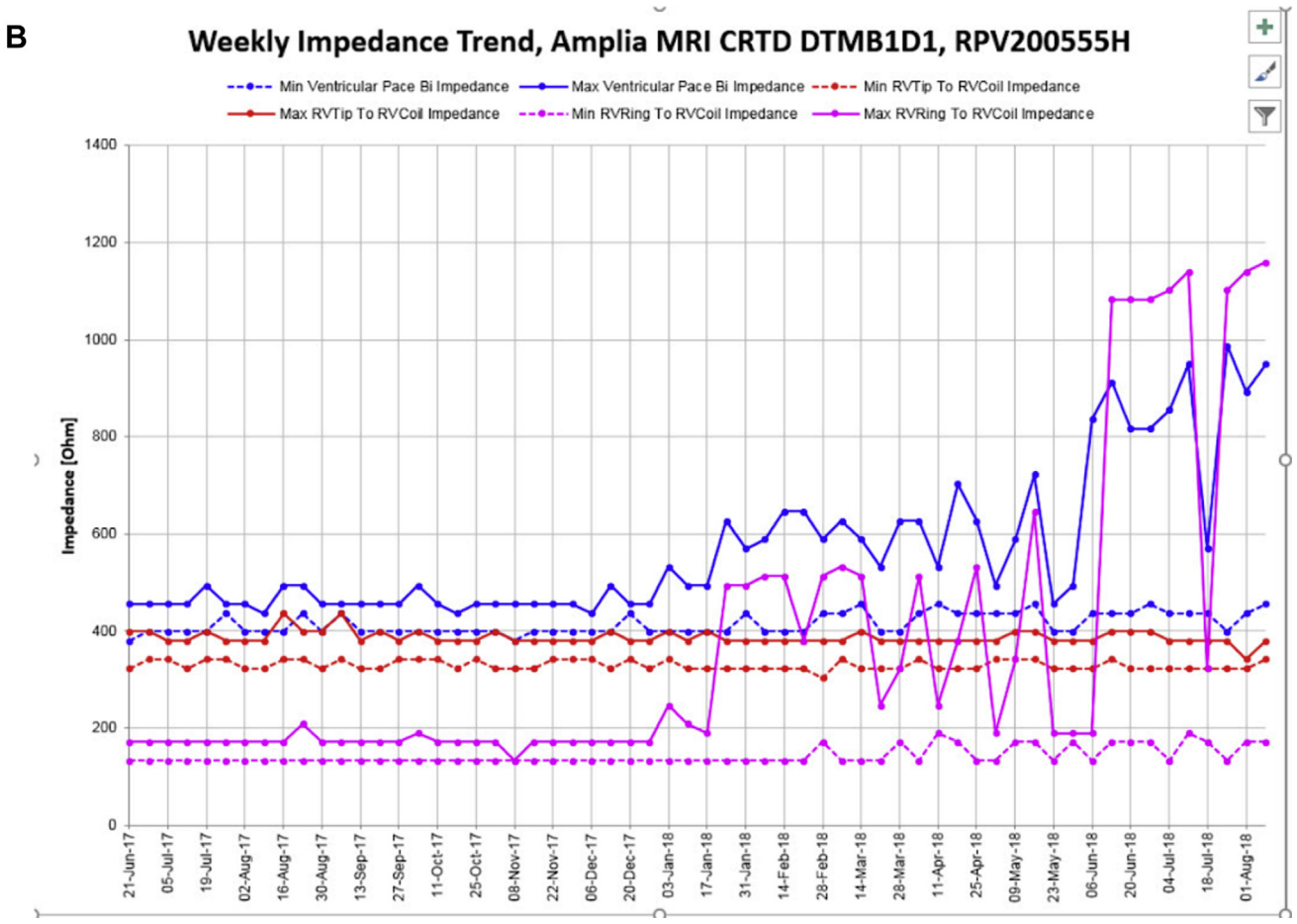


Figure 3 **A:** Right ventricular (RV) bipolar and tip-to-coil lead impedance trends averaged weekly over the last 80 weeks and daily over the past 15 days prior to presentation. **B:** Manufacturer performance data analysis showing biweekly measurements (minimum and maximum) of the RV bipolar, ring-to-coil, and tip-to-coil impedances. Notable are the trends demonstrating variable increases in the RV bipolar and ring-to-coil maximum impedances, which are not seen on the RV tip-to-coil impedances.

(Figure 3A). The absolute bipolar impedance never exceeded the threshold for an impedance alert of 1000 ohms and there were no major changes in RV tip-to-coil impedance trends. An RV pace-sense lead failure was diagnosed based on his symptoms in association with clear evidence of ventricular oversensing and prolonged ventricular pauses on the event monitor. These findings of oversensing and increased impedance trends are indicative of a pace-sense ICD lead failure owing to either a RV ring conductor fracture or a connection problem between the lead and the ICD generator.[10] A magnified x-ray image of the ICD header suggested incomplete insertion of the RV IS-1 pace-sense pin into the device header, which was supported by review of additional fluoroscopic images of the header (Supplementary Figure 1); ICD revision was undertaken and intraoperatively, the ICD was inspected for a loose set screw or pin before disconnection of the lead. None of these abnormal findings could be confirmed by the operator. In light of the patient's pacemaker dependence, the prolonged duration from the last ICD generator change before the onset of the current problem (greater than 1 year), and a preoperative discussion with the patient, it was elected to proceed with abandonment of the current lead and implantation of a new ICD lead.

A subsequent 30-day event monitor was unremarkable for any asystole. His symptoms resolved after the lead revision and during an additional 21 months of uneventful close follow-up.

The performance data collected from the device were sent to the manufacturer for further investigation. The manufacturer analysis was notable for variability in the biweekly maximum RV lead pacing impedance trends only seen on the RV bipolar and RV ring-to-coil impedances, but not on the RV tip-to-coil impedances or atrial or LV lead impedances (Figure 3B). Review of these data confirmed the oversensing and variable RV impedance trends and was consistent with a lead fracture of the RV ring conductor or a connection problem between the ring electrode and the ICD. Notably, these detailed impedance trend plots are not available to the user via standard programmer or remote monitoring interrogation.

Discussion

This is the first case to report the failure of LIA to detect a clinically significant lead-system failure. In the present case, the LIA did not trigger because of insufficient SIC counts and high-rate nonsustained episodes.

As part of the LIA, the device continuously monitors for a potential RV lead fracture using lead impedance measurements for both RV pacing lead polarities, the SIC, and high-rate-nonsustained episode data. It identifies a potential lead fracture if at least 2 of the following criteria have been met within the past 60 days: (1) an RV pacing lead impedance measurement for either polarity is less than 50% or greater than 75% of the baseline impedance, (2) the ventricular SIC is incremented by at least 30 within a period of 3 consecutive days or less, and (3) the device senses 2 high-rate NS episodes with a 4-beat average R-R interval of $<$220 ms within 60 days or $\geq$5 beats, but less than programmed ICD detection.[6]

This case highlights that ICD lead-system failure still can occur even with a negative LIA. Although subtle impedance changes were seen in this case, the LIA requires 2 out of 3 criteria be met and failed to trigger owing to an insufficient SIC number or high-rate nonsustained episode. Although the LIA appears to be a very sensitive algorithm for detection of a lead failure, the "true" false-negative rate has not been previously reported. The LIA algorithm was designed and validated to detect lead failure, and not lead-system failure. Thus, clinicians should be aware that lead-system failures can still occur even without an LIA. Clinical judgment and ancillary tests, such as an event monitor in our case, may help diagnose and treat patients in whom a lead-system failure is clinically suspected. Turning pre-EGM "on" may have helped with the diagnosis in our case, but this feature should be eventually turned off to prevent excessive battery depletion. A diagnostic warning provided by the programmer or remote monitor may be helpful to the clinician when 1 of 3 LIA criteria are met to alert to the possibility of a lead failure but sufficient criteria have not been met yet to trigger the LIA, owing to the specifics of the algorithm. Although this will likely increase the number of false-positives, the clinician may simply choose to intensify the frequency of monitoring or seek additional lead performance trends via manufacturer analysis in response to such a diagnostic warning rather than proceed with urgent lead revision. High-resolution radiography may help identify header connection problems related to incomplete pin insertion into the header, which—as suggested by this case—can manifest in some cases quite late well beyond the perioperative period.[10] A switch in RV sensing polarity from RV true bipolar (tip-to-ring) to integrated bipolar (tip-to-coil) may have prevented clinical oversensing events in this case.

This case emphasizes that a thorough understanding of the LIA algorithm and its limitations may help clinicians appropriately manage patients with clinically suspected ICD lead-system failure. LIA remains a sensitive tool to diagnose ICD lead fracture, but it should not be relied on exclusively as false-negatives are possible owing to algorithm criteria. Nonphysiological high-rate NS episodes and changes in lead impedances, in the absence of LIA alert, should trigger further investigation in a patient with clinically suspected lead-system failure.

Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrcr.2020.08.021.

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