

Turning a blind eye to the far field: Are we burying the evidence? A case of abrupt catastrophic implantable cardioverter defibrillator lead failure causing sudden death



Stephen Tuohy, MD, Paul Ryan, BSc, Joseph Galvin, MD

From the Department of Cardiology, Mater Misericordiae University Hospital, Dublin, Republic of Ireland.

Introduction

Implantable cardioverter defibrillator (ICD) therapy is commonly used for the prevention of sudden arrhythmic death in high risk populations. A recognized complication of such therapy is lead failure, leading to potential inappropriate detection and delivery of high energy defibrillation shocks. Many modern devices utilize algorithms which can differentiate between lead noise and true arrhythmia, avoiding unnecessary therapies. However, the programming of these algorithms can be the difference between life and death. Below is presented a case of lead failure in which the default programming of the device's algorithms contributed to a catastrophic outcome which was potentially avoidable.

Case report

A 31-year-old male patient was admitted to the hospital with severe heart failure and cardiogenic shock in the setting of amphetamine-induced dilated cardiomyopathy and an ejection fraction (EF) of 5%–10%. After 10 weeks of in-hospital care with the administration of diuretics, inotropes, and intra-aortic balloon counterpulsation and the optimization of medications, his condition stabilized. However, his left ventricular (LV) systolic function remained severely impaired, with an EF of approximately 10%. As a consequence, he received a Protecta VR (Medtronic Corporation, Minneapolis, MN) single-

chamber ICD with Sprint Quattro (Medtronic Corporation, Minneapolis, MN) dual-coil lead prior to discharge. At the implantation of the device, the R-wave amplitude was 7.5 mV, the pacing threshold was 0.9 V at 0.4 milliseconds, and the pacing impedance was 784 ohms. The high-voltage lead impedance was 68 ohms through the right ventricular (RV) coil and 61 ohms through the superior vena cava (SVC) coil. Defibrillation testing was not performed, because of the presence of an LV apical thrombus in the preceding month and relative hemodynamic instability at the time of implantation. The device was programmed to detect ventricular fibrillation (VF) at rates >200 beats per minute (bpm), and the therapy to be delivered was a maximum of 6 × 35-J shocks with antitachycardia pacing (ATP) during charging. Alerts were programmed for RV lead integrity and RV lead noise, for RV pacing lead impedance out of range (<200 or >3000 ohms), and for RV and SVC defibrillation lead impedance out of range (<20 or >200 ohms). 'RV lead noise discrimination' (RVLND) was also programmed 'on' (by default) with an 'RV lead noise timeout' at the default value of 0.75 minute (see the Discussion section for further details).

A significant clinical improvement was noted, and the patient returned to work some months later. At heart failure clinic follow-up, LV EF had improved to 15%–20%, and he was walking up to a mile a day. Medical therapy was continually titrated until he was on optimal doses of beta-blockade, angiotensin-converting enzyme inhibitor, and aldosterone antagonist. The patient missed an ICD follow-up appointment 6 months post implant and was subsequently lost to ICD follow-up.

Three years after initial presentation, the patient died suddenly and unexpectedly, despite feeling well and having no symptoms when he was last seen, 30 minutes prior to his death. Postmortem interrogation of his explanted ICD demonstrated an abrupt failure of his RV pace-sense lead, with an abrupt rise in RV pace-sense lead impedance on the day of the patient's death. The impedance change was associated with detection of noise beginning with short (1 second) episodes of noise just 1 hour 53 minutes before

KEYWORDS Defibrillator; Ventricular fibrillation; ICD therapy; Sudden death; Lead fracture

ABBREVIATIONS ATP = antitachycardia pacing; bpm = beats per minute; EF = ejection fraction; EGM = electrogram; ICD = implantable cardioverter defibrillator; LV = left ventricle; RV = right ventricle; RVLND = right ventricular lead noise discrimination; SVC = superior vena cava; TWOS = T-wave oversensing; VF = ventricular fibrillation; VT = ventricular tachycardia (Heart Rhythm Case Reports 2016;2:6–10)

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KEY TEACHING POINTS

- Inappropriate ICD therapies due to lead noise can be fatal.
- Lead noise-discrimination algorithms have the ability to detect lead noise and withhold high-voltage therapies, but this function is limited by preprogrammed time-outs. These time-outs can be manually extended or disabled by the clinician. Such programming can be the difference between life and death (as in this case).
- Postmortem ICD interrogation should be indicated in cases of sudden unexplained death in an ICD recipient, as catastrophic system failures may be highlighted.

the patient’s death. Both lead noise and lead integrity alerts were noted shortly after the episode began. The duration of the noise episodes increased over the intervening period. The device transiently suppressed VF detection by recognizing the high rates as being noise (Figure 1) and due to the default time-out in the RVLND algorithm, VF would have been detected after 45 seconds of persistent noise. However, VF was actually detected after 8 seconds because of an interaction between the T Wave Discrimination algorithm and the RVLND algorithm, resulting in an even shorter suspension of VF detection, to only 8 seconds. The ICD proceeded to deliver a sequence of maximum output 35-J shocks, the third of which induced true VF (Figure 2). Three subsequent shocks failed to terminate the VF (Figure 3), and therapy was automatically discontinued, leaving the patient in VF from which he was not resuscitated.

Discussion

Inappropriate shocks are an unwelcome and potentially life-threatening complication of ICD therapy.¹ Recent advances

have dramatically reduced inappropriate shocks due to supraventricular arrhythmias.² Inappropriate shocks due to lead fracture or insulation break can be more difficult to prevent, particularly when lead failure is abrupt. The incidence of such events may be underestimated due to a relative paucity of postmortem ICD interrogations, even in cases of unexplained sudden death in ICD recipients.³ While such sudden deaths are often assumed to be spontaneous arrhythmic deaths, possibly with failure of ICD shocks to terminate episodes, the possibility of episodes being caused by the ICD is rarely considered.

ICD lead fractures may result in failure of detection and therapy delivery as well as lead noise that can result in unnecessary therapy delivery. The failure rate for Sprint Quattro leads has been shown to be 0.43% per year in a multicenter study.⁴ Many modern devices have incorporated features to detect noise and avoid inappropriate shocks, but the utility of lead noise-detection algorithms with suppression of tachyarrhythmia detection may be limited by their preprogrammed time-outs.

In this case, the patient had the quadruple misfortune of these events:

1. An abrupt lead fracture with immediate sensing of noise
2. Failure of the RVLND algorithm to prevent detection of VF
3. Induction of VF by one of the resulting shocks
4. Failure to defibrillate by 3 subsequent shocks, despite the fact that charge times, high voltage impedance, and delivered energy were all appropriate or normal

Although the alarms were programmed ‘on,’ the abruptness of lead failure made it extremely unlikely that the patient would have enough time to seek help in response to a device alarm.

The Medtronic RVLND algorithm differentiates RV lead noise from VT or VF by comparing a far-field electrogram (EGM) signal to near-field sensing.⁵ The algorithm instructs

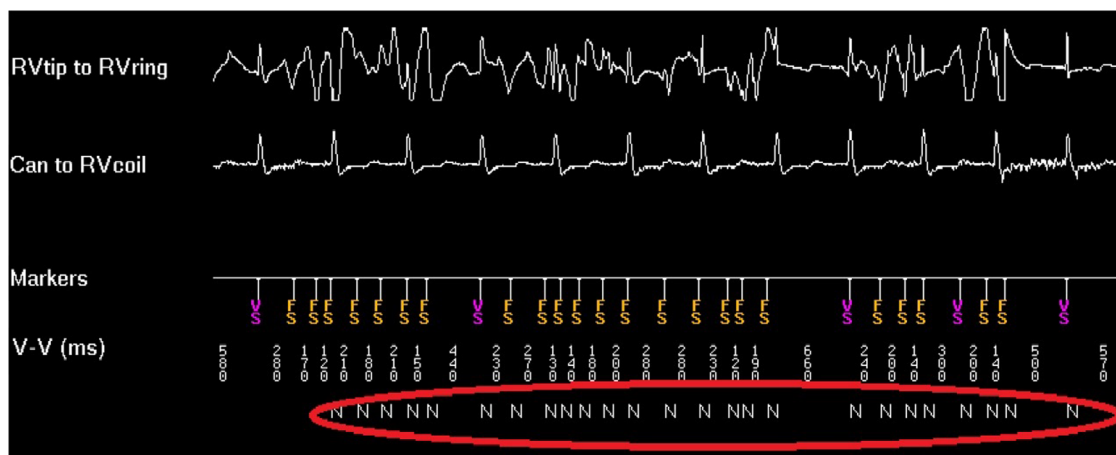


Figure 1 Initial right ventricular lead noise discrimination algorithm (RVLND) inhibiting therapy due to detection of noise (N). The far-field electrogram reveals a stable intrinsic rate.

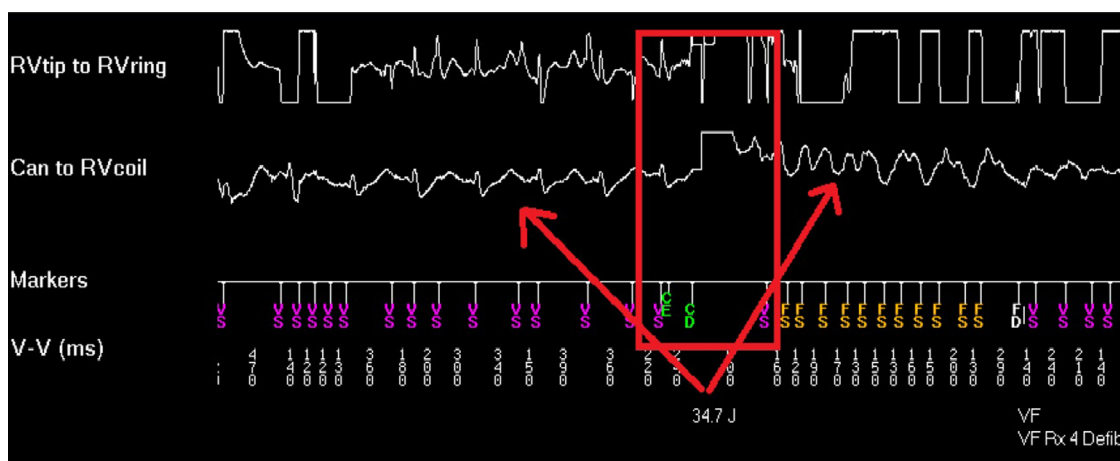


Figure 2 The third high-voltage therapy (red box) caused the patient's intrinsic rate to accelerate to a high-frequency (ventricular fibrillation [VF]) rate, which is clearly visible in the far-field can to right ventricular coil electrogram.

the device to withhold detection and therapy for ventricular rates of >200 bpm in the near-field (RV_{tip} to RV_{ring} bipole) electrogram (EGM) when there is significant discordance with the far-field (RV coil to can) EGM. The RV lead noise time-out function determines the duration for which detection and therapy is withheld. With the nominal programming configuration for this device, if oversensing persists for 45 seconds, the RVLND algorithm will stop withholding detection because of the preprogrammed time-out. This event would lead to subsequent detection and initiation of therapy if the oversensing persists. RVLND time-out is nominally programmed 'on' with a time-out of 45 seconds because approximately 88% of the lead noise episodes last <45 seconds.⁶ This time-out can be programmed to up to 120 seconds and may be programmed 'off,' which allows the device to withhold detection and therapy indefinitely in the setting of lead noise. This function is incorporated into the Medtronic Protecta, Evera, and Viva devices.⁵

Information from lead impedance, pacing threshold, and R-wave size are not incorporated into the algorithm.⁵ RVLND has both an audible alert and a programmable

wireless CareAlert, which is transmitted to CareLink if applicable. The audible alert continues to sound at regular intervals until the device is interrogated.⁵

Other manufacturers have similar but different algorithms. The St Jude Medical SecureSense algorithm is similar to the Medtronic RVLND algorithm with a comparison of the number of sensed signals between near- and far-field bipoles.⁷ If the near-field signal count is 10 greater than the far-field signal by the time of detection, therapy will be withheld. The St Jude Medical SecureSense algorithm can withhold therapy indefinitely, and the time-out is nominally programmed 'off.'⁷ It is possible that such a configuration could have led to VF detection being withheld indefinitely in a case such as this.

Boston Scientific have incorporated a Dynamic Noise algorithm that resets the sensing threshold when high-frequency, nonphysiological, low-amplitude signals are detected.⁸ According to Boston Scientific engineers, this algorithm is primarily used to detect external electromagnetic interference and is unlikely to have been effective in detecting high-amplitude noise, as in this case (written communication, July 1, 2014).

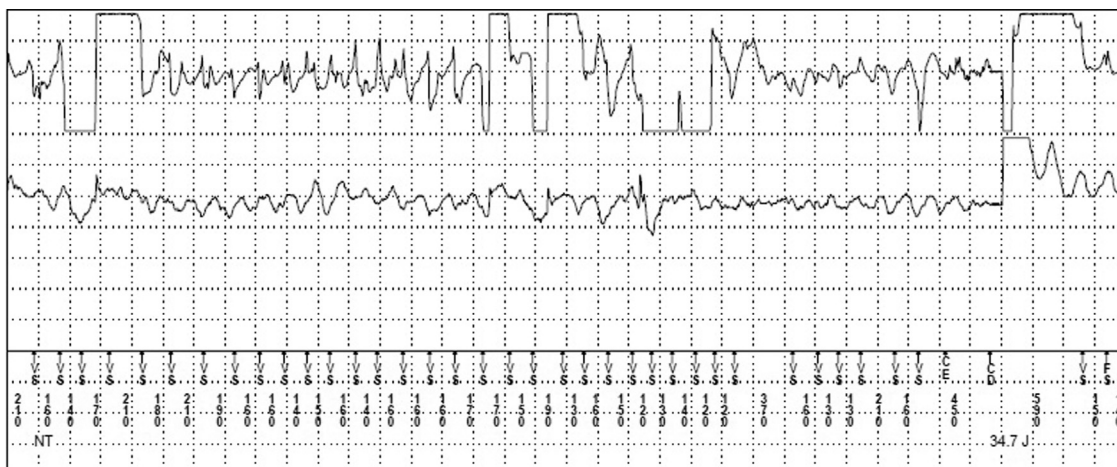


Figure 3 The fourth high-voltage therapy failed to terminate ventricular fibrillation.

The Biotronik SMART Detection⁹ and the Sorin PAR-AD+ algorithms¹⁰ are primarily focused on discrimination between supraventricular arrhythmias and ventricular arrhythmias and would have been unlikely to have prevented VF detection and therapy in this case, as they are not designed to detect lead noise.

Another contributory feature to this event was the interaction between the T Wave Discrimination and RVLND algorithms. As part of the Medtronic SmartShock Technology, the T Wave Discrimination algorithm was given precedence over the RVLND algorithm. According to Medtronic engineers, this feature was included to prevent unnecessary lead noise alerts caused by large near-field T waves corresponding to small far-field T waves (written communication, May 1, 2015). An unforeseen complication of this strategy was that fleeting recognition of T-wave oversensing (TWOS) during lead noise episodes inhibits RVLND processing. This interaction means that VF detection can occur despite lead noise having been recognized. This interaction has been recognized by the manufacturer, and all devices that have undergone a routine ICD interrogation since mid-2013 have had this interaction removed via a RAMware download. The RAMware download removes the specific interaction so that fleeting recognition of TWOS cannot inhibit RVLND. This change has also been incorporated into the more recent line of Medtronic devices that have SmartShock Technology 2.0. However, devices that have not undergone a routine interrogation since mid-2013 may still have this interaction present. In this case, the interaction allowed VF detection to occur sooner than the preprogrammed time-out, but this phenomenon is unlikely to have changed the outcome, as the period of lead noise was sustained for >15 minutes and VF would have been detected after 45 seconds if the interaction had not been present.

Refinements in current noise-detection algorithms are needed to prevent a recurrence of this type of case. A potential strategy may be to use the time-out as an opportunity to check lead and coil impedance and compare them with previous measurements. If there has been a sudden, prespecified change in these parameters and persistent discordance between near-field and far-field electrograms, then high ventricular rates detected can be assumed to be due to lead noise resulting from mechanical damage to the lead or its components.¹¹ In fact, the Medtronic lead integrity alert already uses short intervals and impedance changes to warn of likely lead or connector problems.⁵ In this circumstance, therapy could be withheld indefinitely with immediate and frequent sounding of a 'maximum loudness alarm,' possibly with an audio prompt to seek immediate medical attention. Frequent transtelephonic ICD interrogation may not be enough to protect patients from acute lead failure in these circumstances. Instant or near-instant loud warning alarms in cases of sudden onset, heavy burdens of lead noise may need to be developed.

Another issue that is highlighted by this case is the lack of routine postmortem ICD interrogation in cases of sudden

cardiac death. Pacemakers and ICDs are routinely explanted postmortem in many countries, particularly if cremation is planned. Postmortem ICD interrogation can help determine the cause of death (eg, ventricular tachyarrhythmias) and evaluate product reliability and malfunctions that may have contributed to a patient's death.¹²

A strong case can be made for mandatory postmortem interrogation of ICDs in the case of sudden death in ICD recipients. In this case, the ICD was interrogated postexplant, but the diagnosis of possible lead fracture was made at a time that was too late to allow inspection of the leads. In cases of abrupt lead failure, a postmortem chest radiograph could identify the site of lead fracture and should be considered.

Potential strategies for improving ICD handling of lead noise include the following:

- ICD manufacturers adapt the noise-detection algorithms on their devices to recognize significant excess counts on near-field compared to far-field channels as noise.
- In such cases, RV impedances could be checked prior to time-out of noise detection.
- Have an indefinite time-out if RV pacing lead impedance has changed significantly.
- Develop new high-volume alarms for such life-threatening situations.

Conclusions

ICDs have been a major advance in the prevention of sudden cardiac death in selected high-risk populations. Noise-discrimination algorithms can avoid inappropriate therapies, but their utility is limited by their preprogrammed time-outs. Cases such as this demonstrate that an unexplained sudden cardiac death indicates mandatory postmortem interrogation of the ICD rather than burying the evidence.

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