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DEVICES

Low-voltage shock impedance measurements: A false sense of security

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Abstract

Background: Implantable cardioverter defibrillators use low-voltage shock impedance measurements to monitor the lead integrity. However, previous case reports suggest that low-voltage shock impedance measurements may fail to detect insulation breaches that can cause life-threatening electrical short circuits.

Methods and results: We report six cases of insulation breaches in transvenous defibrillation leads that were not obvious during standard interrogations and testing of the lead beforehand. In two cases, an electrical short circuit during commanded shock delivery for internal electrical cardioversion resulted in a total damage of the ICD generator. In one of these cases, commanded shock delivery induced ventricular fibrillation, which required external defibrillation. In two cases, a shock due to ventricular tachycardia was aborted as the shock impedance was less than 20 Ω. However, in both cases the tiny residual shock energy terminated the ventricular tachycardia. In contrast, in one case the residual energy of the aborted shock did not end ventricular fibrillation induced at defibrillator threshold testing. In one case, the ICD indicated an error code for a short circuit condition detected during an adequate shock delivery.

Conclusions: This case series illustrates that low-voltage shock impedance measurements can fail to detect insulation breaches. These data suggest that in patients without a contraindication, traditional defibrillator threshold testing or high voltage synchronized shock at the time of device replacement should be considered.

KEYWORDS
electrical short circuit, implantable cardioverter defibrillator, lead insulation failure, shock impedance

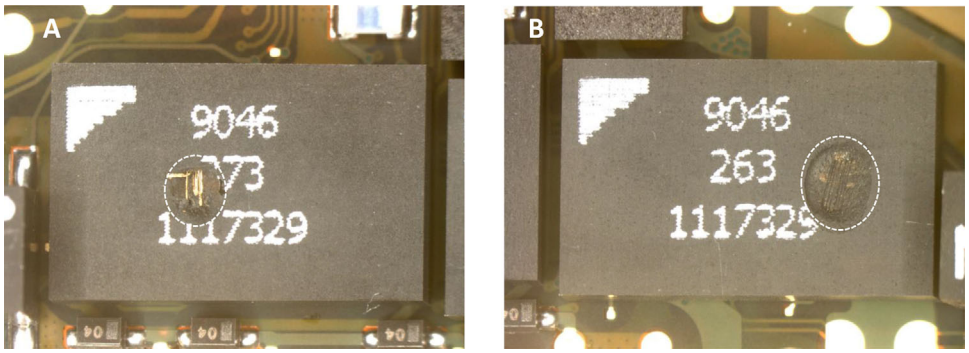

FIGURE 1 A and B, In an explanted Lumax 340 VR-T, both high-voltage circuits are damaged (white circles). The surface of the ICD was intact. The internal wiring and connections inside the circuitry have evaporated, and the integrated circuit housing has burst open [Color figure can be viewed at wileyonlinelibrary.com]

1 | INTRODUCTION

A high-voltage (HV) electrical short circuit in patients with an implantable cardioverter defibrillator (ICD) is a serious complication, as it is accompanied by failure to deliver shock therapy. Following two main mechanisms of electrical short circuit have been described: (a) external insulation breaches, caused by can-lead insulation abrasion or compression (most commonly between RV-coil cable and can); (b) Internal breaches, caused by cyclical forces exerted by lead cables on silicone insulation.

Historically, HV circuit integrity was confirmed by impedance measurement during an actual shock. However, ICDs currently use low-voltage measurements of shock impedance to monitor lead integrity. These weak, subthreshold test pulses avoid myocardial and skeletal muscle stimulation and are below the pacing and pain threshold.[1,2]

ICDs measure low-voltage shock-circuit impedance intermittently and alert in case of out-of-range values. Up to now, the performance of low-voltage shock-circuit impedance measurements for identifying insulation breaches has not been studied systemically. However, several case reports document failure of low-voltage shock-circuit impedance measurements to reliable assess the structural integrity of the leads.[3–5] In contemporary ICDs of meanwhile all manufacturers, an overcurrent detection is used in addition, which can prevent a shock releasement into the HV short circuit.

In this report, we discuss six cases of electrical short circuits in defibrillator leads that occurred unexpectedly as device interrogation showed normal interrogation values beforehand.

2 | CASE 1

A 67-year old male patient with ischemic heart failure with severely impaired left ventricular ejection fraction (LVEF) and inducible ventricular tachycardia at electrophysiology study had undergone implantation of a transvenous single-chamber ICD (Lumax 300 VR-T, Biotronik) with a Biotronik Linox TD 65/16 lead in June 2008. In 2011 an additional right ventricular pace-sense lead (Biotronik) was implanted due to an isolated pace-sense problem in the defibrillation lead with inappropriate shock delivery. The ICD was later replaced with a Lumax 340 VR-T (Biotronik) in July 2013 due to battery depletion. Defibrillation threshold testing (DFT) was not performed after the procedure. No electrical abnormalities of the system were observed during the follow-ups. In April 2016 the patient was referred to our hospital for electrical cardioversion of an atrial tachycardia. Device interrogation before internal electrical cardioversion showed stable interrogation values (RV sensing: 14.2 V; RV pacing threshold: 0.5 V / 0.4 ms; pacing impedance: 563 Ω; shock impedance: 82 Ω). Internal electrical cardioversion with 40 J induced ventricular fibrillation which had to be terminated by external defibrillation (270 J) as communication with the ICD via the programmer was unsuccessful afterwards. The ICD was explanted and returned to the manufacturer for analysis. On manufacturer examination, no visual abnormalities were found on the device body. However, analysis revealed damaged HV circuits (Figure 1). We speculate that excessive currents by electrical short circuit due to lead insulation defects destroyed the device.

3 | CASE 2

A 58-year old male with dilated cardiomyopathy was implanted with a single-chamber ICD (device: Lumax 340 VR-T; RV lead: Linox SD 65/18 lead; Biotronik) in April 2013 for primary prevention. Electrical parameters during in-office follow-ups had been stable (12/2013: RV sensing: 10.5 V; RV pacing threshold: 0.5 V / 0.4 ms; pacing impedance: 823 Ω; shock impedance: 43 Ω). In addition, a remote monitoring system with daily transmissions (Biotronik Home Monitoring) was utilized. Data sent via the remote monitoring system on January 28th in 2014 exhibited no abnormalities with a pacing and shock impedance reading of 714 and 43 Ω, respectively (Figure 2A). The next day, the patient was referred to the hospital for electrical cardioversion of atrial fibrillation. After internal electrical cardioversion, communication with the device via the programmer was no longer possible. Thus, the ICD system was explanted and sent to the respective manufacturer for further analysis. An X-ray showed no lead abnormalities (Figure 2B). However, inspection of the lead showed an abrasion of the insulation 12-cm distal to the IS-1 connector pin (Figure 2C). In addition, a burn mark

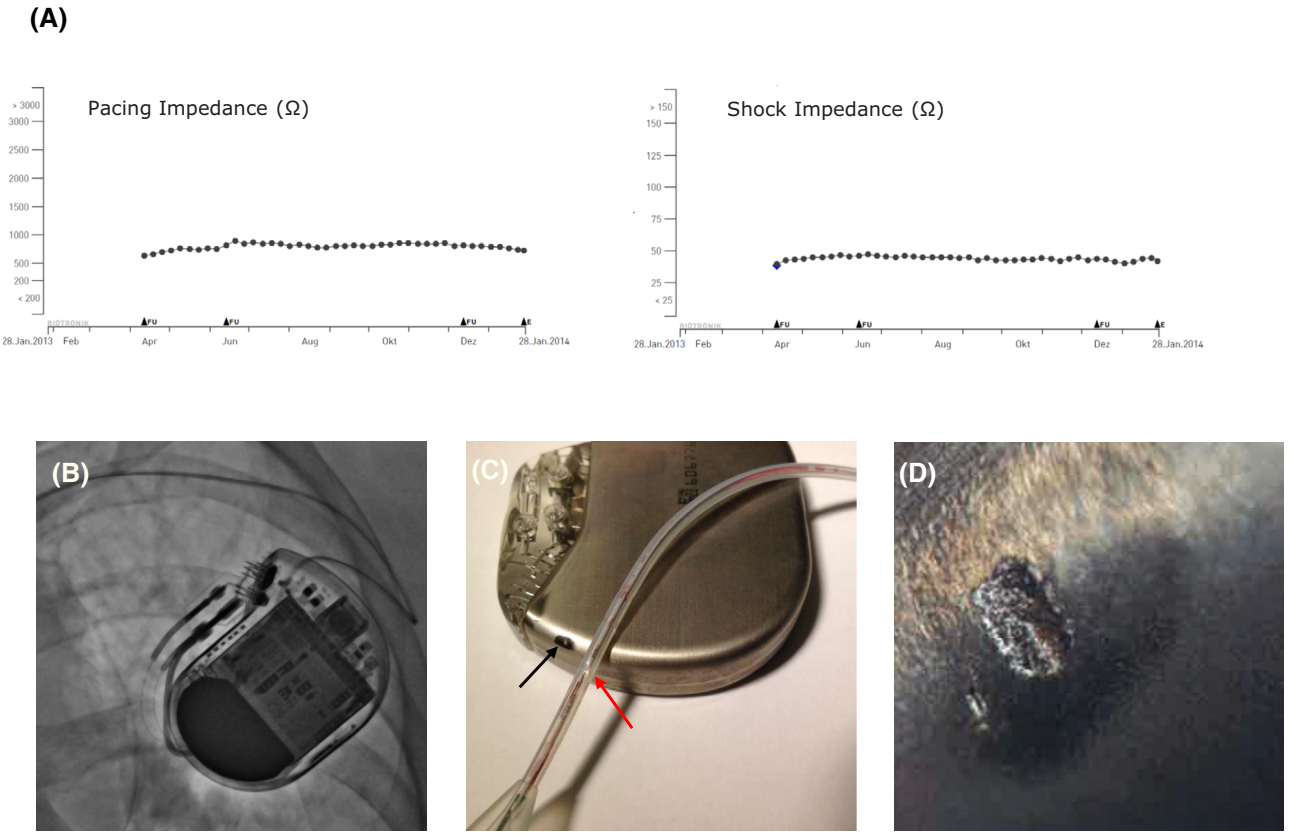

FIGURE 2 A, Pacing and low-voltage shock impedance trends were unsuspicious before internal electrical cardioversion. B, A preoperative X-ray showed no lead abnormalities. C and D, Surface arc mark on the edge of the generator, which suggests an HV electrical short circuit. C, Partial isolation defect of the defibrillator lead [Color figure can be viewed at wileyonlinelibrary.com]

was found on the device surface (Figure 2C,D). Manufacturert's analysis report revealed a shock output into a low-impedance shock path with a damaged shock output stage and subsequent discharge of the battery.

4 | CASE 3

A 47-year old male with a history of postprocedural occlusion of the left circumflex artery during a mitral valve repair and subsequent moderately impaired LVEF (40%) had undergone implantation of a transvenous single-chamber ICD (device: Teligen 100 VR; RV lead: Endotak Reliance G lead; Boston Scientific) in June 2009 due to recurrent ventricular tachycardia. Electrical parameters during in-office follow-ups showed no abnormalities in pacing impedance, pacing threshold, and shock impedance. In September 2014, the patient presented to the pacemaker clinic with an ICD shock on the previous day. At ICD interrogation, the device indicated an error code (fault code 1004) for a short circuit condition detected during shock delivery. Shock delivery was adequate due to a ventricular fibrillation episode (initial ventricular tachycardia which could not be terminated by antitachycardia pacing and degenerated into ventricular fibrillation). Shock impedance measurement was less than 20 Ω, whereas all other electrical parameters (RV sensing: 11.1 mV; RV pacing threshold: 1.8 V / 0.8 ms; pace-sense impedance: 781 Ω) were in the normal range. According to the manufacturert's recommendation, the ICD was explanted, the lead abandoned, and a new ICD lead and generator implanted. The explanted device and the proximal lead segment were sent to the manufacturer for further examination. Visual inspection of the device identified an arc mark on the device surface. Review of the device memory revealed that a shorted lead fault was recorded. An X-ray of the device showed a damage of the internal high voltage fuse. The damage to the fuse most likely occurred during shock delivery into the shorted shock lead. Analysis of the returned proximal lead segment showed that the identification tag was buckled and cracked. However, no further damage was noted, and the lead segment passed electrical testing. As analysis of the returned lead segment did not identify characteristics indicating a shorted lead, the segment of the lead remaining within the patient is likely to be damaged as an arc mark on the generator was found.

5 | CASE 4

A 72-year-old male with ischemic cardiomyopathy was implanted with a transvenous dual-chamber ICD (device: Lumax 340 DR; RV

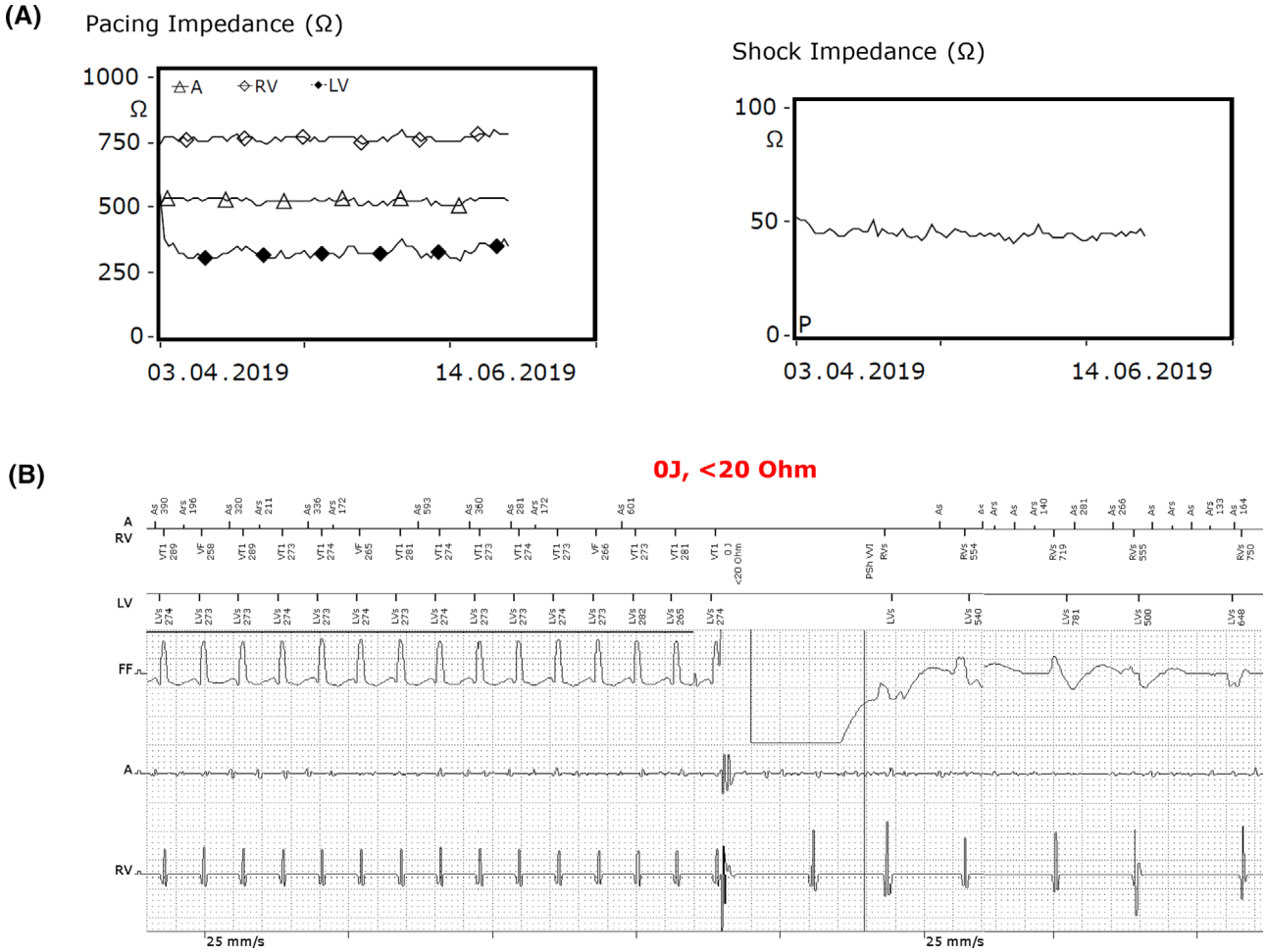

FIGURE 3 A, No abnormalities were detected in pacing impedance and low-voltage shock impedance values beforehand. B, Ventricular tachycardia detection with charging of the capacitors to 40 J. The shock was aborted ("0 J") as the shock impedance was <20 Ω. The released tiny residual energy terminated the ventricular tachycardia [Color figure can be viewed at wileyonlinelibrary.com]

lead: Linox S65; Biotronik) in 2008 for secondary prevention after resuscitation due to ventricular fibrillation. At the time of implantation, no DFT testing was performed due to a left ventricular thrombus. In-office follow-ups revealed several ventricular tachycardia and ventricular fibrillation episodes, terminated by either ATP or shock delivery (last shock 07/2016). In 2012, the device was upgraded to a cardiac resynchronization therapy defibrillator (CRT-D; device: Lumax 540 HF-T; Biotronik). Due to battery depletion, the generator was replaced in April 2019 with an Inlexa 3 HF-T hardware (Biotronik) without DFT testing. During the follow-ups before and after the generator exchange, CRT-D interrogation parameters exhibited no abnormalities (Figure 3A). In June 2019, the patient experienced an ICD shock and was referred to the hospital for further management. CRT-D interrogation revealed a ventricular tachycardia (cycle length: 300 ms), which was treated adequately by shock delivery following two failed ATP attempts. However, the shock was aborted as the shock impedance was <20 Ω, indicating a potential HV lead issue. Remarkably, the released tiny residual energy terminated the ventricular tachycardia (Figure 3B). All other device interrogation values were within the normal range (low-voltage shock impedance reading 40 Ω). In consultation with the manufacturer, a new RV-lead (Plexa Pro MRI S65; Biotronik) was implanted, and the old lead abandoned. Due to the excessive current protection system, the CRT-D generator could be reused and was not subjected to further examinations by the manufacturer.

6 | CASE 5

A 74-year old male with ischemic cardiomyopathy had undergone implantation of a single-chamber ICD (device: Epic™+ VR V-196; RV lead: Riata 1580; St. Jude Medical) in 2006 for secondary prevention. In 2013, the patient underwent a generator exchange (Lumax 540 VR-T; Biotronik) without lead replacement. During a routinely in-office follow-up in April 2018, the programmer could not communicate with the device anymore. As device interrogation was unsuccessful, an ICD box exchange to an Itrevia 5 VR-T (Biotronik) was carried out. However, as the electrical parameters (RV sensing, RV pacing threshold, pace-sense impedance, and shock impedance) showed no abnormalities beforehand, the ICD lead was not replaced.

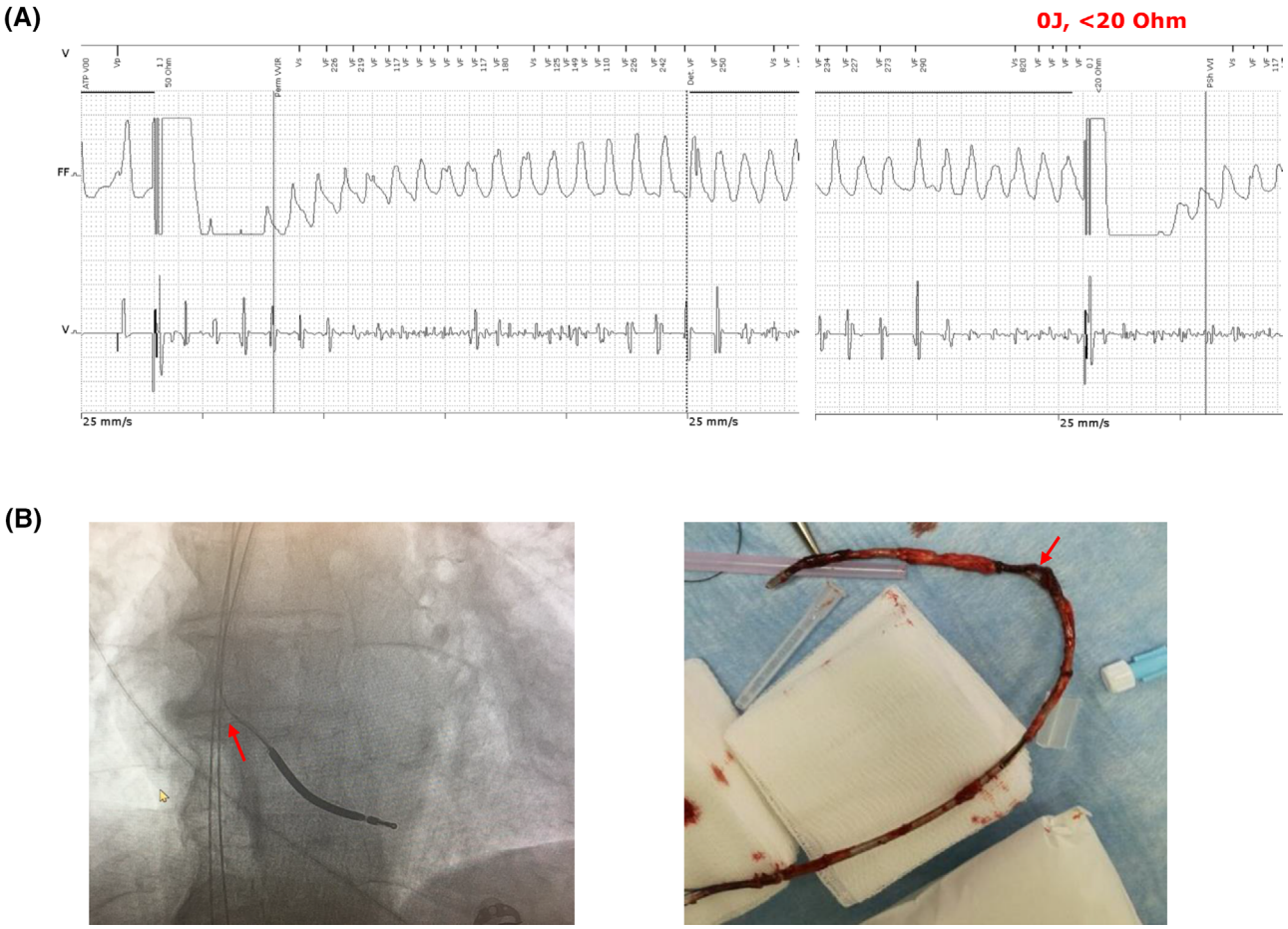

FIGURE 4 A, During DFT testing, ventricular fibrillation was induced by a 1 J shock on the T wave. Shock impedance measured by the 1 J shock was 50 Ω. After ventricular fibrillation detection and charging, the shock was aborted ("0 J") by the excessive currents protection system. The released tiny residual energy did not terminate ventricular fibrillation. B, A cable externalization was revealed on a preoperative X-ray (left, red arrow) and after lead extraction (right, red arrow) [Color figure can be viewed at wileyonlinelibrary.com]

Lead-related electrical parameters after connection of the new generator were unsuspicious (RV sensing: 19.1 mV, RV pacing threshold: 0.8 V / 0.4 ms, pacing impedance: 607 Ω, and shock impedance: 62 Ω). During DFT testing, ventricular fibrillation was induced by a 1 Joule shock on the T wave. Shock impedance measured by the 1 J shock was in the normal range with an impedance reading of 50 Ω. After ventricular fibrillation detection, both the first shock and the following programmed two were aborted (0 J, <20 Ω; Figure 4A). Ongoing ventricular fibrillation was successfully terminated by an external shock. DFT testing was repeated after reprogramming the shock path. At the second DFT testing, ventricular fibrillation was induced by a high frequency burst. Like during the first DFT testing, both the first shock and the following two (0 J and <20 Ω, respectively) were aborted. An external shock was administered, and the ongoing ventricular fibrillation terminated. As a chest X-ray showed evidence of a cable externalization (Figure 4B), the Riata 1580 lead was extracted, and a new ICD lead (Protego Pro MRI S 65; Biotronik) placed. Subsequent DFT testing went without complications.

7 | CASE 6

An 88-year-old male with ischemic cardiomyopathy with moderately impaired LVEF (40%) underwent implantation of a left-sided transvenous dual-chamber ICD (device: Lumax 300 HF-T, Biotronik; RA lead: Selox JT53, Biotronik; RV lead: Linox S65/18, Biotronik; LV port closed with a blind plug) in February 2009 for secondary prevention. In 2016, a device replacement with an Itrevia 7 DR-T (Biotronik) was performed due to battery depletion. After the generator exchange, no electrical abnormality of the system was observed during follow-up. Most important, low-voltage shock impedance measurements were stable and in the normal range (Figure 5A). In January 2019, the patient presented to the hospital due to an ICD shock delivery. Device interrogation showed a ventricular tachycardia (cycle length: 267 ms) with shock delivery. However, the shock was aborted as the shock impedance was less than 20 Ω. Even though the shock has been aborted, the released tiny residual energy terminated the ventricular tachycardia (Figure 5B). Thus, the indication for placement of a new RV-lead was made.

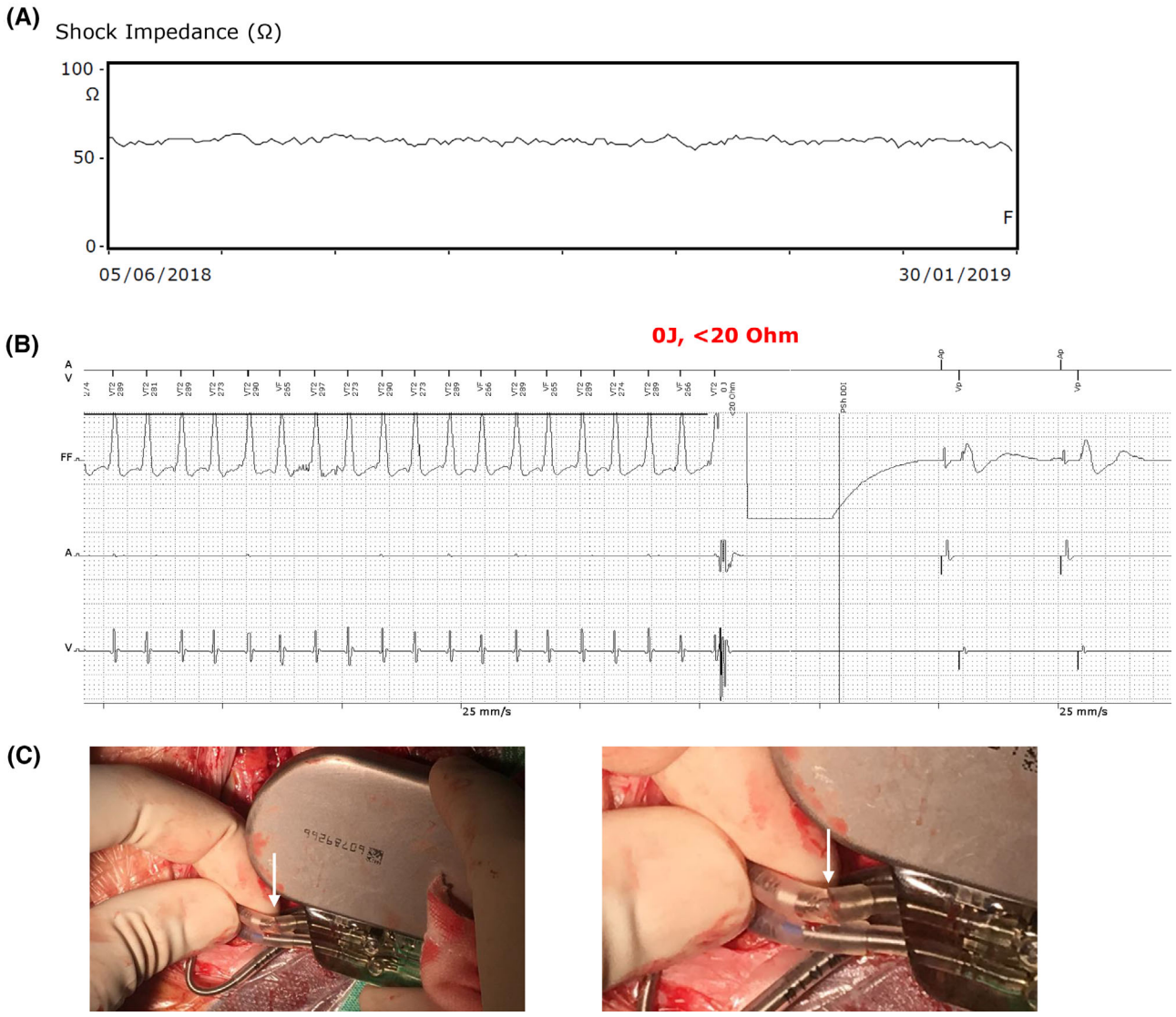

FIGURE 5 A, Low-voltage shock impedance values beforehand were in the normal range. B, Detection of a stable ventricular tachycardia (VT) in the ventricular fibrillation (VF) zone. After charging of the capacitor to 40 J, the shock was aborted ("0 J") by the excessive current protection system. The released tiny residual energy terminated the ventricular tachycardia. C, The ICD lead shows partial insulation defect. The lead failure occurred not only on the silicone outer insulation, but also on the ethylene tetrafluoroethylene of the RV coil conductor [Color figure can be viewed at wileyonlinelibrary.com]

During the operation, a sharp cut on the RV defibrillator lead at the junction between the lead and the generator box was observed (Figure 5C). As the subclavian vein venography revealed a total occlusion of the left subclavian vein, the lead was abandoned and a dual-chamber ICD (Ilivia 7 DR-T; Biotronik) implanted from the right side.

8 | DISCUSSION

We here present six cases with HV electrical short circuits in defibrillator leads that were unsuspected owing to normal lead parameters during standard interrogation with low-voltage shock impedance measurement. HV electrical short circuits cause the interruption of shock delivery and result in the failure of the device to deliver appropriate therapy to terminate life-threatening arrhythmias. In two of the reported cases, HV electrical short circuits occurred when shock delivery was commanded. In one of these cases, a commanded shock for internal electrical cardioversion induced ventricular fibrillation, and the arrhythmia had to be terminated by an external shock. In one case, the device indicated an error code for a short circuit detected during adequate shock delivery to terminate a ventricular fibrillation episode.

In the last years, device manufacturers developed special algorithms to protect the implant from irreversible damage due to excessive current flow through the shock electrodes. These algorithms measure the current through the HV defibrillation circuit at the onset of shock delivery to verify lead integrity. If the current flow during shock delivery exceeds a certain limit, the protection hardware immediately

disconnects the charged capacitors from the ICD lead, and the ongoing shock delivery is stopped. An aborted ICD shock due to an abnormally high current caused by a shorted lead will be depicted in Biotronik devices by the values "0 J" and "<20 Ω". However, a partial release of energy is possible until the time of circuit separation. The amount of residual energy is only measured and displayed in ICDs from Medtronic (Minneapolis, MN) and is usually between 0.3 and 4 J. Following effects can be observed: (a) the residual energy is sufficient to terminate the ongoing ventricular arrhythmia (Case 4 and Case 6) (b) the residual energy has no effect and the ventricular arrhythmia is ongoing (Case 5), and (c) the residual energy has a proarrhythmic effect, and a ventricular tachycardia accelerates to ventricular fibrillation.

In the event of an insulation breach, a commanded shock for internal electrical cardioversion can induce ventricular fibrillation in ICDs without excessive current flow protection. In these cases, the shock is not aborted, and the full energy of the capacitor discharged. The shock energy is, in part, released into the generator and can destroy the HV circuits. Due to the uncoordinated discharge of the capacitor, part of the released shock energy can hit the vulnerable phase of the heart and induce ventricular fibrillation (Case 1).

The overcurrent detection algorithm prevents the self-destruction of the ICD in the event of a shorted ICD lead in the HV part. The ICD can be interrogated after this event, the root cause can be uncovered, and the right measures can be taken into the further clinical considerations. Herewith, it is usually sufficient to exchange the defective ICD lead, whereas the generator can be reused.

Our case series contains five ICDs from Biotronik and one ICD from Boston Scientifc (Table 1). The ICDs in Case 1 and 2 have no overcurrent detection. In Case 1, the ICD lead demonstrated failure due to an internal short circuit in the ICD electrode, and therefore no arc mark was visible on the surface of the ICD generator. In Case 2 an arc mark was observed on the edge of the ICD housing. In Case 3, the shock was aborted (0 J, <20 Ω), but nonetheless an arc mark was visible on the can, and the HV fuse has burned through. As the ICDs in Case 1, 2, and 3 were destroyed, a box exchange was necessary. The ICDs/CRT-D in Case 4, 5, and 6 were technically intact and could be reused after exchanging the defective ICD electrode.

Kleemann et al previously reported that the annual rate of ICD lead defects reaches 20% in 10-year-old leads regardless of the manufacturer.[6] Moreover, previous studies found an accumulation of HV short circuits after device replacements, possibly because of physical stress to the implanted lead during the replacement procedure.[3,7] Out of our six cases, four patients had a history of generator replacement beforehand. Noteworthy, low-voltage shock impedance measurements prior and after box exchange were unsuspicious. In general, a single-coil ICD system is of advantage in comparison to a dual-coil system for preventing HV short circuits, as a single-coil system has only one HV conductor inside the ICD lead.

ICD interrogation with monitoring changes in pacing impedance and detecting occurring oversensing has been shown to reduce the morbidity of lead failure associated with the pace-sense function.[8,9] However, previous single case reports show failure of the HV circuitry and failure to defibrillate despite nominal low-voltage shock impedance measurements.[4,10] Analyzing both internal and external insulation breaches, Shah et al reported that three of four patients with Durata ICD leads (St. Jude Medical, St. Paul, MN) presented with failure of HV shock therapy or death without a history of electrical malfunction.[11] With the goal to assess internal insulation breaches in Durata ICD leads, Hauser et al searched the Food and Drug Administration Manufacturer and User Facility Device Experience database.[12] The authors found that Durata ICD leads are susceptible to internal insulation breaches, and low-voltage measures of shock impedance may be insufficient to detect insulation breaches. To study the disparity in insulation breaches despite nominal subthreshold impedance values, Swerdlow et al simulated in-pocket, coil-can abrasions in vitro.[13] This study showed that direct metal-metal contact of the breached conductor to the ICD housing is necessary for reliable low-voltage shock impedance measurements.

Currently, DFT testing at implantation or generator replacement is rarely performed. The reason for DFT testing at implantation was initially related to the need to determine the actual DFT and to demonstrate an adequate safety margin. Previous studies have shown that the risk of DFT testing associated complications is extremely low with a total of three death and five strokes in a total of over 19 000 implants.[14] The need to reliably assess lead integrity provides a new argument for a routine use of DFT testing or delivery of a commanded HV synchronized shock at the time of generator replacement.

8.1 | Unmet needs and possible solutions

There is an urgent need to early identify HV insulation breaches which might be undetected by low-voltage shock impedance measurements and could lead to shock delivery failure. Previous in vitro studies evaluated novel methods using high frequency transmission line impedance measurements, which might be a promising approach to detect outer insulation breaches with intact inner insulation.[15,16]

9 | CONCLUSION

Low-voltage measures of shock impedance are insensitive to detect insulation breaches that can cause failure to deliver shock therapy. This applies to defibrillators from all manufacturers. As previous studies report that leads with insulation breaches were able to deliver 20 J or 23 J shocks, but shorted during maximum output shocks, a maximal output shock is currently necessary to diagnose a presumed insulation defect.[3,4] Thus, DFT testing or HV synchronized shock should be considered at the time of generator exchange.

AUTHOR CONTRIBUTIONS

Study concept and design: Parwani, Lacour, Franke, Hohendanner, Heinzel, Boldt, Blaschke, and Blaschke. Drafting of the manuscript: Parwani, Lacour, Franke, Hohendanner, Heinzel, Boldt, Kucher, and Pieske. Data collection: Reichert, Klein, Beiert, Supryn, Rangasamy, Kull, and Blaschke. Analysis and interpretation of data: Kucher.

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