

Inappropriate subcutaneous implantable cardioverter defibrillator shock due to incomplete sealing of the seal plug: a case report

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Background

A subcutaneous implantable cardioverter defibrillator (S-ICD) has several advantages over the transvenous ICD, including a reduced risk of lead-related mechanical complications and infection. However, inappropriate shock therapy is one of the most common adverse events associated with S-ICDs. We herein report a case of inappropriate shock therapy of S-ICD due to incomplete sealing of the seal plug.

Case summary

A 60-year-old man, who had been on haemodialysis with a history of myocardial infarction, was transferred to the hospital after successfully being resuscitated from ventricular fibrillation (VF). An S-ICD was implanted for secondary prevention. On the third and the seventh post-operative days, S-ICD shock therapy was delivered without any tachyarrhythmias. As device interrogation revealed reproducible noises in both the secondary and alternate vectors by tapping at the generator, the sensing vector was fixed to the primary vector. Two months after discharge, the patient died of VF after receiving appropriate S-ICD shock delivery seven times. The S-ICD was retrieved from the body, and it was revealed that the seal plug had incompletely sealed and returned to its normal closed position after reinsertion of a torque wrench.

Discussion

Seal plug damage is a rare complication but should be considered if noise oversensing is provoked only at the secondary and/or alternate vectors. In the present case, the inappropriate shock therapy might have been prevented if we had checked the seal plug carefully. Therefore, we advocate confirming the seal plug routinely after the removal of the torque wrench.

Keywords

Subcutaneous ICD • Seal plug damage • Inappropriate shock therapy • Noise oversensing • Case report

ESC Curriculum

5.10 Implantable cardioverter defibrillators • 8.6 Secondary prevention • 5.6 Ventricular arrhythmia

Learning points

- Inappropriate shock therapy is one of the most common adverse events associated with subcutaneous implantable cardioverter defibrillators (S-ICDs).
- Noise oversensing due to seal plug damage is rare but should be considered if it is provoked only at the secondary and/or alternate vectors.
- Seal plug damage might be able to be prevented by careful observation at the time of S-ICD implantation.

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Introduction

The subcutaneous implantable cardioverter defibrillator (S-ICD) system, which is safe and effective for preventing sudden cardiac death, has several advantages over the transvenous ICD system, including a reduced risk of lead-related mechanical complications and infection.^{1,2} Therefore, the S-ICD should be considered as an alternative to a transvenous ICD in patients with an indication for an ICD when pacing therapy for bradycardia support, cardiac resynchronization, or antitachycardia pacing is not needed (Class IIa) and may be considered as a useful alternative to the transvenous ICD when venous access is difficult, after the removal of a transvenous ICD for infections or in young patients (Class IIb).³

Timeline

3 years before	Patient started haemodialysis and had myocardial infarction.
12 days before	He was transferred to the hospital after recovery from cardiac arrest due to ventricular fibrillation (VF).
S-ICD implantation	Subcutaneous implantable cardioverter defibrillators (S-ICD) were implanted. The alternate vector was selected as the sensing vector according to automatic vector setup.
3 days later	Inappropriate shock was delivered. Tapping test showed no noise contamination. The sensing vector was not changed.
7 days later	Inappropriate shock was delivered again. Tapping test showed noise in the alternate and the secondary vectors. The sensing vector was changed to the primary vector.
16 days later	He was discharged from the hospital.
2 months later	He died of VF after appropriate shock delivery seven times. The S-ICD was retrieved from the body and the incomplete sealing of the seal plug was confirmed.

However, inappropriate shock therapy is one of the most common adverse events associated with ICDs. These are mainly due to supraventricular arrhythmias but occasionally related to noise, artefacts, and oversensing, of which external noise and lead/connector noise are the primary causes.⁴

We herein report a case of inappropriate shock therapy of S-ICD due to incomplete sealing of the seal plug.

Case presentation

A 60-year-old man, who had been on haemodialysis for 3 years due to diabetic nephropathy, had a history of myocardial infarction and stent implantation, and was receiving anticoagulants for chronic atrial fibrillation, developed cardiopulmonary arrest on the street. At the first contact of an emergency medical service, his initial rhythm was VF, which was successfully terminated by an automated external defibrillator. He was transferred to the hospital, where emergent coronary

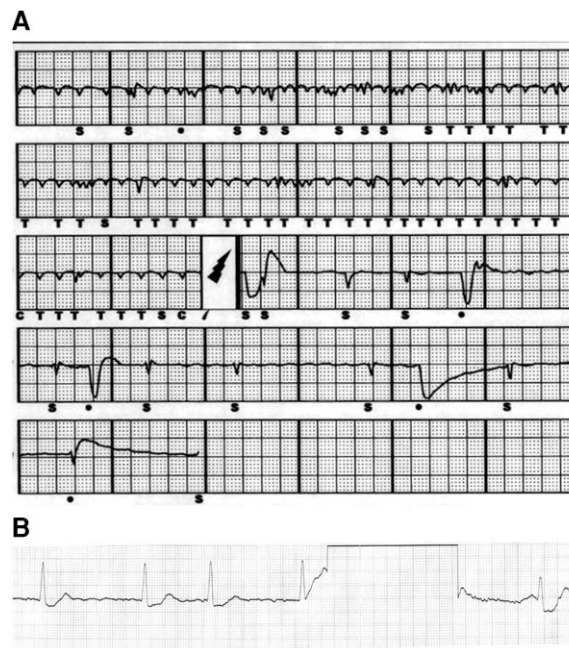


Figure 1 (A) Continuous noise oversensing observed on the seventh post-operative day. The marker channel indicates that the device mislabels noise as ventricular tachyarrhythmia, leading to inappropriate shock (lightning bolt). (B) The monitor electrocardiogram at the same time. The basic rhythm was atrial fibrillation and no ventricular tachyarrhythmia was observed.

angiography showed no significant progression of coronary artery stenotic lesions. Echocardiography showed the patient's left ventricular ejection fraction to be 41% with left ventricular diastolic and systolic dimensions of 53 and 40 mm, respectively, thus suggesting that the VF in this case was due to an old myocardial infarction with left ventricular dysfunction. He recovered without any neurological abnormality within a few days. The medical therapy at the time of admission was warfarin 1 mg, clopidogrel 75 mg, pitavastatin 4 mg, ezetimibe 100 mg, linagliptin 5 mg, repaglinide 0.75 mg, lanthanum carbonate 750 mg, and precipitated calcium carbonate 500 mg per day. There was no family history of sudden cardiac death. An electrocardiogram was not suggestive of long QT or Brugada syndrome.

An S-ICD was recommended for secondary prevention of sudden cardiac death rather than a transvenous ICD, because the patient did not require pacing therapy for bradycardia support, cardiac resynchronization, or antitachycardia pacing and therefore might have been at high risk for infection and venous access trouble due to diabetes and haemodialysis. A pre-screening test was performed in the supine and standing positions as well as on exercise. The primary vector sensing from the proximal sensing electrode ring on the subcutaneous electrode to the active surface of the device did not pass the pre-screening test, but both the secondary vector sensing from the distal sensing electrode ring on the subcutaneous electrode to the active surface of the device and the alternate vector sensing from the distal sensing electrode ring to the proximal sensing electrode ring on the subcutaneous electrode did pass.

An S-ICD with a left parasternal electrode was implanted without any complication by the two-incision technique. There were no artefacts during the tapping test at the proximal or distal electrodes. The alternate vector was selected according to the automatic vector setup. As per the protocol, VF was induced via the 50-Hz pulse method after

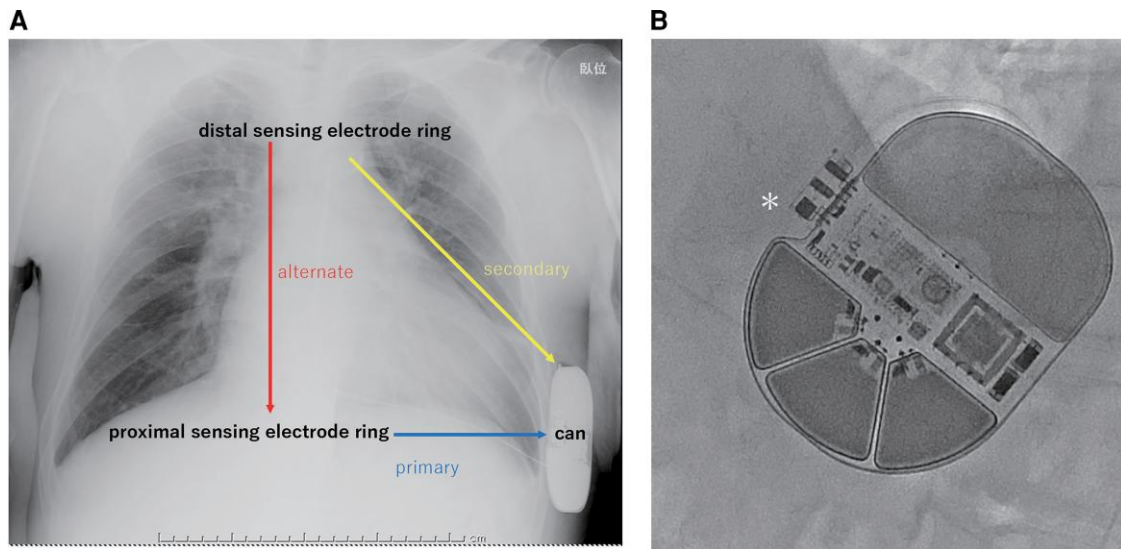


Figure 2 (A) Chest radiograph post-device implantation. Arrows indicate sensing vectors. (B) A fluoroscopic image of the S-ICD generator. Neither air entrapment nor loose pin was observed at the connector (*).

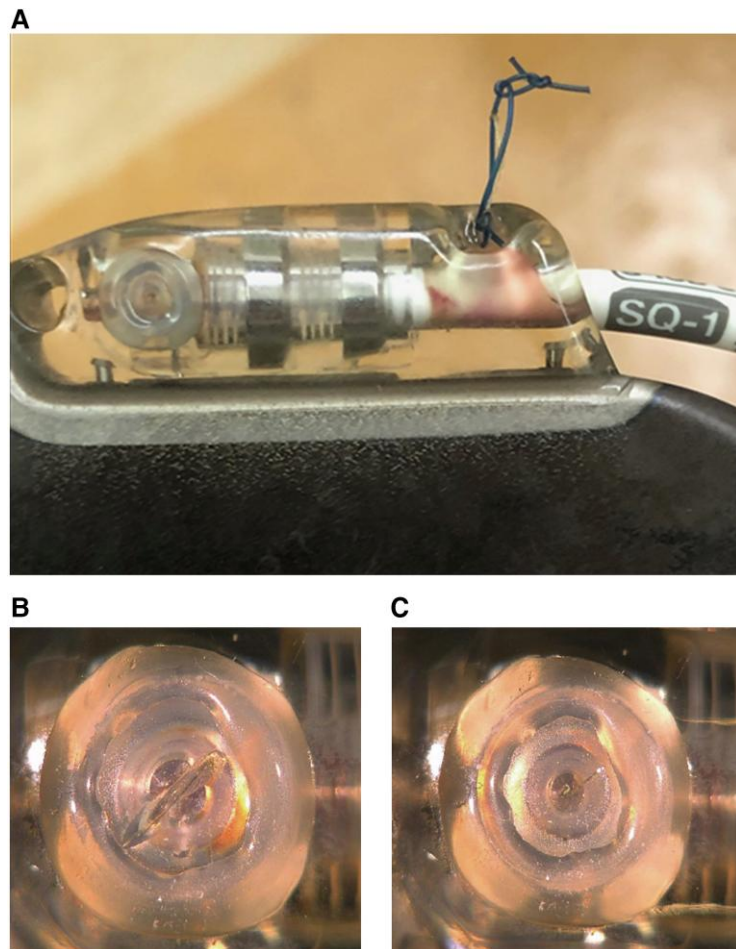


Figure 3 (A) The header of the removed device. The tip of the connector was inserted appropriately. There was no evidence of a loose pin. (B) The seal plug in close-up. The slit was slightly open. (C) The seal plug after reinsertion of a torque wrench. The slit was closed without any damage.

the device implantation, where adequate sensing of VF wavelets was observed. The first 65-J shock effectively restored sinus rhythm with a shock impedance of 33 ohms.

On the morning of the third post-operative day, S-ICD shock therapy was delivered. Because surface electrocardiogram monitoring revealed no tachyarrhythmias during the shock therapy, the lead noise was considered the cause of inappropriate shock therapy. Although air entrapment at the electrodes was suggested as a cause of the lead noise, tapping at either proximal or distal electrode resulted in no artefacts. Therefore, the possibility of air entrapment at the connector between the lead and the generator was considered, but provocative maneuvers failed to reproduce any artefacts including myopotential oversensing.

On the seventh post-operative day, inappropriate shock was delivered again (Figure 1). Device interrogation revealed that a reproducible noise could be detected by tapping at the generator but not at the proximal or distal electrodes. There was no obvious evidence of lead dislodgement, air entrapment around the devices, or a loose pin at the connector on fluoroscopic imaging (Figure 2). Because the reproducible noise was observed in both the secondary and alternate vectors, the sensing vector was changed from the alternate vector to the primary vector. Appropriate shock delivery without a sensing abnormality was confirmed by a defibrillation test. On the sixteenth post-operative day, the patient was discharged from the hospital with optimal medical therapy in accordance with the current guidelines, including amiodarone (200 mg per day), which was initiated in the current admission. No β -blocker therapy was introduced because of sinus bradycardia below 50 bpm.

Two months after the discharge, the patient died of VF after receiving appropriate S-ICD shock delivery seven times. The S-ICD was retrieved from the body (Figure 3A), and it was revealed that the seal plug was incompletely sealed (Figure 3B). However, after reinsertion of a torque wrench, the seal plug returned to its normal closed position without any damage (Figure 3C).

Discussion

Noise oversensing due to seal plug damage is a rare complication but has been reported in patients with transvenous ICDs⁵ as well as in those with S-ICDs.⁶ Seal plug damage causes air and/or fluid intrusion into the device connector. The noise oversensing has been attributed to the interaction between the fluid and the electrode-sensing elements. In the S-ICD device, the seal plug is positioned at the lead tip electrode. A hole in the seal plug can cause noise artefact involving the secondary and/or alternate vectors, as the lead tip is part of the sensing circuit in both of those vectors.⁶ Therefore, if noise oversensing is provoked only at the secondary and/or alternate vectors, seal plug issues should be considered.

In the present case, incomplete sealing of the seal plug caused lead noise and inappropriate therapy. The electrocardiograms illustrating our patient's events are similar to those previously reported.⁶ Because the seal plug returned to its normal closed position without any damage after reinsertion of a torque wrench, the inappropriate shock therapy might have been prevented if we had checked the seal plug carefully at the time of implantation. Therefore, we advocate confirming the seal plug routinely after the removal of the torque wrench.

Lead author biography



Tsuneki Ajimi, MD finished his medical studies at the Saga Medical School Faculty of Medicine, Saga University (Japan). He was trained in cardiology at the Saga University Hospital. Currently, he is working as a Chief physician at the Saiseikai Fukuoka General Hospital. His main field is interventional cardiology and critical care cardiology.

Supplementary material

Supplementary material is available at *European Heart Journal—Case Reports* online.

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Slide sets: A fully edited slide set detailing this case and suitable for local presentation is available online as [Supplementary data](#).

Consent: The authors confirm that written consent for submission and publication of this case including its images and associated text, was obtained from the patient's family in line with COPE guidelines.

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References

- Knops RE, Olde Nordkamp LRA, Delnoy PPHM, Boersma LVA, Kuschyk J, El-chami MF, Bonnemeier H, Behr ER, Brouwer TF, KaaB S, Mittal S, Quast AFBE, Smending L, Stuijt WVD, Weger A, Wilde KC, Bijsterveld NR, Richter S, Brouwer MA, Groot JR, Kooiman KM, Lambiase PD, Neuzil P, Vernooy K, Alings M, Betts TR, Bracke FAL, Burke MC, Jong JSSG, Wright DJ, Tijssen JGP, Wlode AMM. Subcutaneous or transvenous defibrillator therapy. PRAETORIAN trial. *N Engl J Med* 2020;**383**:526–536.
- Gold MR, Lambiase PD, El-Chami MF, Knops RE, Aasbo JD, Bongiorno MG, Russo M, Deharo JC, Burke MC, Dinerman J, Barr CS, Shaik N, Carter N, Stoltz T, Stein KM, Brisbane AJ, Boersma LVA. Primary results from the understanding outcomes with the S-ICD in primary. Prevention patients with low ejection fraction (UNTOUCHED) trial. *Circulation* 2021;**143**:7–17.
- Priori SG, Lundqvist B, Mazzanti A, Blom N, Bougrefre M, Camm J, Elliott PM, Fitzsimons D, Hatala R, Hindricks G, Kirchhof P, Kjeldsen K, Kuck KH, Madrid AH, Nikolaou N, Norekval TM, Spaulding C, Veldhuisen DJV. 2015 ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. *Eur Heart J* 2015;**36**:2793–2867.
- Powell BD, Asirvatham SJ, Perschbacher DL, Jones PW, Cha YM, Cesario DA, Cao M, Gilliam RT, Saxon LA. Noise, artifact, and oversensing related inappropriate ICD shock evaluation: ALTITUDE NOISE study. *Pacing Clin Electrophysiol* 2012;**35**:863–869.
- Cheung JW, Iwai S, Lerman BB, Mittal S. Shock-induced ventricular oversensing due to seal plug damage: a potential mechanism of inappropriate device therapies in implantable cardioverter-defibrillators. *Heart Rhythm* 2005;**2**:1371–1375.
- Barnett A, Eckhardt L, Leal MA. Seal plug damage causing inappropriate detection and therapy in a subcutaneous defibrillator system. *Heart Rhythm Case Rep* 2019;**5**:66–69.