

Seal plug damage causing inappropriate detection and therapy in a subcutaneous defibrillator system



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Introduction

Subcutaneous implantable cardioverter-defibrillator (S-ICD) systems have been introduced to clinical electrophysiology within the past decade as an alternative to the implant of traditional transvenous devices in the management of patients with increased risk for ventricular tachyarrhythmias and sudden cardiac death.¹ These devices have the unique ability to terminate ventricular tachycardia (VT) and/or ventricular fibrillation (VF) with no direct contact between the implanted hardware and the vasculature or the endocardium. The electrical discharge is delivered between a can that is implanted in the left lateral thoracic region and a coil that is placed lateral to the left edge of the sternum, anterior to the rib cage.²

Although initial reports indicated an acceptable rate of inappropriate sensing and therapies when this technology is compared to traditional transvenous systems,³ novel mechanisms of noise oversensing that may lead to inappropriate detection and shocks have recently been reported.^{4,5} The present report illustrates a mechanism of noise oversensing triggered by fluid entrapment within the device header secondary to a physical breach of the seal plug.

Case report

A 25-year-old woman with an established history of recurrent syncope of unknown etiology, palpitations, and frequent ventricular ectopy suffered a witnessed out-of-hospital VF arrest.

Her subsequent cardiac work-up demonstrated a structurally normal heart and normal resting electrocardiographic findings. She was referred to the University of Wisconsin Inherited Arrhythmia Clinic for phenotyping and genetic analysis. She fortunately made a full neurological recovery; an implantable cardioverter-defibrillator (ICD) was recommended for secondary prevention of sudden cardiac death.

An S-ICD system was chosen based on her lack of pacing requirements and her young age, in the hope of avoiding

long-term complications associated with indwelling endovascular hardware, such as venous thrombosis, systemic infection, and the potential need for lead revisions and/or extractions.

An S-ICD system was successfully implanted with no immediate periprocedural complications. Upon implantation, routine visual inspection of the device and lead system was unremarkable. The device selected the secondary vector for ventricular sensing (lead tip to can).

As per protocol, following the device implant VF was induced via the 50-Hz pulse method; adequate sensing of VF wavelets was noted. The first 65-J shock effectively restored sinus rhythm with a shock impedance of 33 ohms. The total time to therapy delivery (including detection interval and charging time) was 15 seconds.

The device was programmed with 2 therapy zones: a VT (conditional) zone with a rate cutoff of 220 beats/min and a VF (shock) zone with a rate cutoff of 240 beats/min, with all shocks programmed at the standard output (80 J).

The patient was discharged home the following day with recommendation to return to the Device Clinic 2 weeks later for a routine wound check and system interrogation. Five days after implant, however, the patient received a shock from her device while at home in her usual state of health. She returned to the hospital and a device interrogation revealed lead noise with evidence of noise oversensing. In addition to the episode that led to the shock, 4 other “nonsustained VF” episodes had been recorded over the few days that followed the procedure. All of these events indicated the occurrence of noise oversensing (Figure 1).

A 2-view (posteroanterior and lateral) chest radiograph was obtained and revealed that the system remained stable in its positioning (Figure 2), with no obvious evidence of lead fracture, dislodgment, or discontinuity of the circuit.

The patient was brought back to the electrophysiology laboratory for inspection of the S-ICD system. The set screw was tight and the lead tip completely inserted in the device header. The decision was then made to proceed with an S-ICD pulse generator replacement and the originally implanted generator was returned to the manufacturer for evaluation.

A comprehensive analysis of the returned device revealed the presence of a hole in the seal plug, shown in detail in Figure 3. The analysis concluded that the hole in the seal

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KEY TEACHING POINTS

- Subcutaneous defibrillators (subcutaneous implantable cardioverter-defibrillator systems) are used for sudden cardiac death prevention in appropriate patient populations.
- Subcutaneous implantable cardioverter-defibrillator systems are subject to malfunctions such as noise oversensing.
- Seal plug damage and air or fluid trapping in the device header may be oversensed as ventricular tachyarrhythmias and lead to inappropriate therapies (including shocks).
- Remote monitoring transmissions play an important role in minimizing the risk of delayed recognition of abnormal device behavior compared to traditional in-office checks.

plug introduced air and/or fluid around the lead tip and contributed to the observed noise oversensing events that were followed by inappropriate therapy delivery.

Discussion

Inappropriate ICD shocks have been associated with increased morbidity and mortality risks.⁶ Their occurrence has significantly decreased in the current era of high-voltage cardiac implantable electronic devices, owing to both optimized programming strategies and technological developments aimed at minimizing the total number of therapies delivered by implantable defibrillators.

In addition, continuous scrutiny aided by postmarket approval studies has also led to enhanced surveillance and early recognition of devices and/or leads at higher risk of malfunction, leading to manufacturer recalls and advisory statements.^{7,8}

The EFFORTLESS S-ICD Registry has previously reported that 48 of 581 S-ICD patients (8.3%) experienced 101 inappropriate shocks.⁹ The most common reported cause for inappropriate S-ICD therapies has traditionally been T-wave oversensing. As these devices become more commonly implanted by the electrophysiology community, new causes of inappropriate therapy, such as the one described in this report, are expected to surface and will likely contribute to a better understanding of these devices' potential limitations.

It is important to recognize that this modality of noise oversensing, triggered by entrapment of air bubbles or fluid within the lead-header interface, has been previously described with traditional (transvenous) ICD systems, leading to similar clinical manifestations.¹⁰ Interestingly, the electrograms that illustrate our patient's events appear remarkably similar to a recent report of inappropriate shock by an S-ICD system.¹¹ Whether these are isolated events or triggers for additional manufacturing precautions remains to be seen.

Similar to transvenous ICD systems, subcutaneous defibrillators can have the inherent risk of inappropriate discharges mitigated by adequate programming methods. These include the adoption of dual-zone programming ("conditional" zone and "shock" zone, with proprietary morphology discriminators applied in the former), which has been known to contribute to better specificity in terms of withholding therapy for treatment of supraventricular arrhythmias that do not require external cardioversion or defibrillation.

Unique to the S-ICD system is the need for preoperative screening. This process utilizes surface electrocardiographic parameters that evaluate the patient's cardiac signals in 3

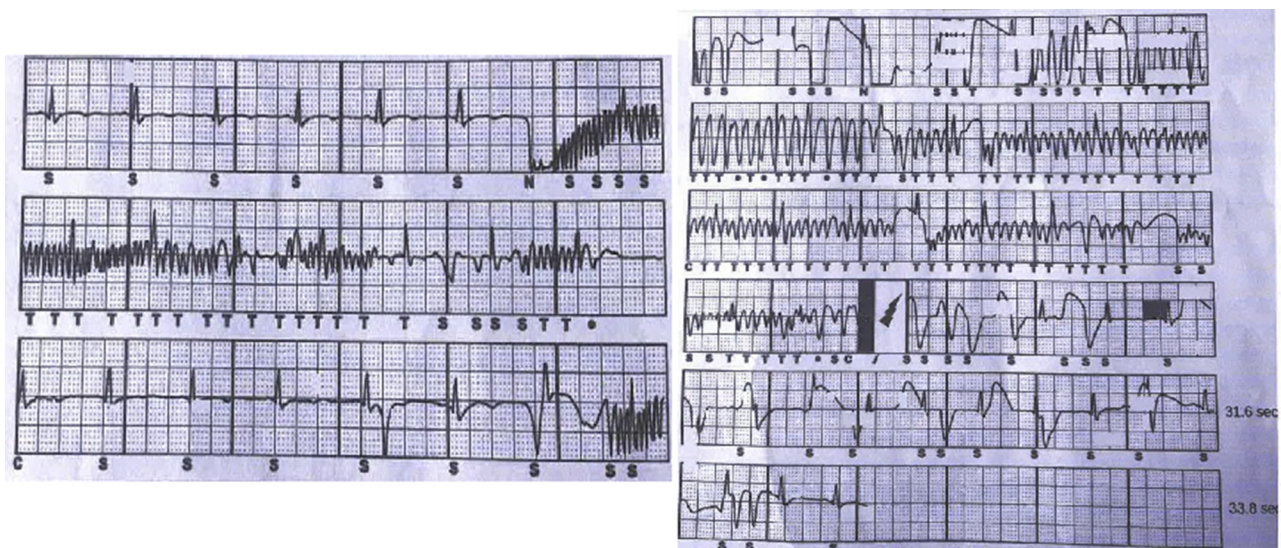


Figure 1 Intermittent noise oversensing noted on postoperative day 2 (left) and continuous noise oversensing noted on postoperative day 5 (right). The marker channel indicates that the device mislabels noise as ventricular tachyarrhythmia, leading to the inappropriate shock (lightning bolt).

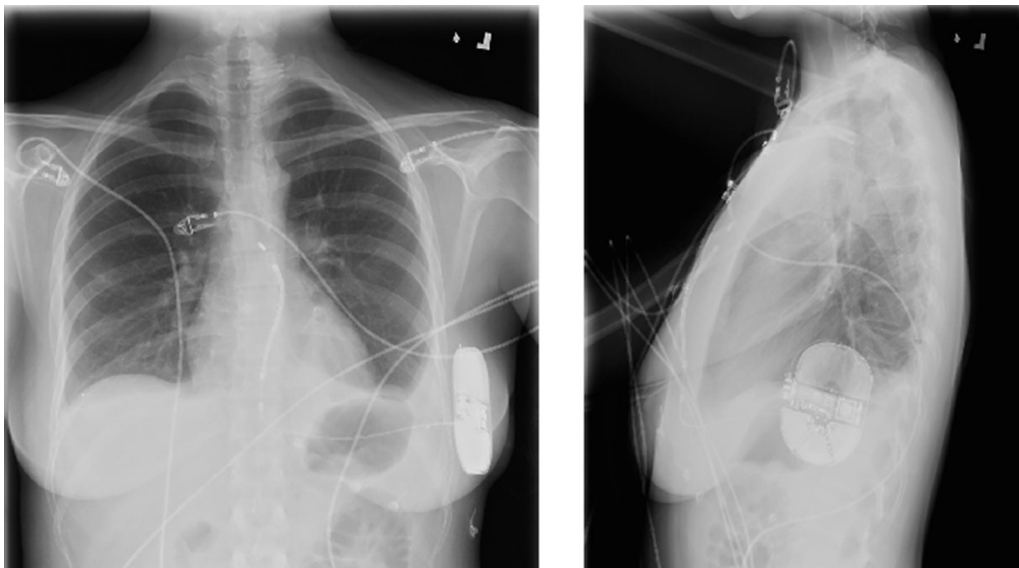


Figure 2 Chest radiograph post-device implant (posteroanterior and left lateral projections).

vectors that aim to simulate the device's 3 sensing vectors: primary (lead ring to can), secondary (lead tip to can), and alternate (lead tip to ring). In addition, the QRS complexes and T waves must fit within predetermined templates that are intended to avoid future episodes of T-wave oversensing or QRS complex double-counting (such as noted with significant intraventricular conduction delays that cause excessive QRS complex prolongation).

In addition, exclusive to the S-ICD remote monitoring system is the fact that remote transmissions occur every 7 days. This feature may result in delayed recognition of abnormal device behavior, such as observed in our case report.

During the implantation of any defibrillator system, which typically includes the pulse generator and its associated electrode(s), air or fluid may become entrapped in the device header. Therefore, noise oversensing can occur if fluid or air bubbles penetrate the header and interact with the electrode sensing elements.

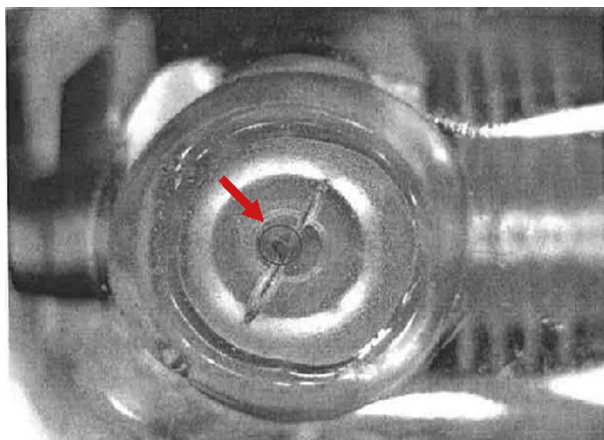


Figure 3 Magnified view of the device header exhibiting a hole (center of circle) in the seal plug.

In the S-ICD device, the seal plug is positioned over the tip, or distal connector block. A hole in the seal plug can cause noise artifact involving the secondary and/or alternate vectors, as the lead tip is part of the sensing circuit in both those vectors. The resultant deflections are rapid in rate and medium-frequency in appearance, and have been reported to cause intermittent pacing inhibition in transvenous devices.¹²

Seal plug damage has been reported in other Boston Scientific devices (transvenous cardiac implantable electronic devices). As per the manufacturer's report, "oversensing of this type is sporadic and unlikely to cause either extended inhibition of anti-bradycardia pacing or inappropriate shocks in a defibrillator. This form of oversensing is rarely seen beyond implant and disappears once the seal plug returns to its normal closed position, the entrapped air has dissipated, and pressure equilibrium within the header has been achieved."¹³

In our case, the manufacturer analysis results indicated the presence of damage to the set screw seal plug. This puncture could have been the consequence of a perforation of the header plastic material by the sharp wrench tool or subsequent damage caused by other surgical instruments following device placement in the pocket. The seal plug damage likely resulted in bodily fluid intrusion in the header and, subsequently, the reported clinical observations of noise oversensing by the S-ICD system. Damage to seal plugs may also occur during the initial insertion of the torque wrench.

Conclusion

Our report indicates that the intrinsic characteristics of the delicate seal plug and the sharp torque wrench used for lead fixation to the subcutaneous defibrillator device header may lead to inadvertent tearing of the seal plug and the potential for introduction of air bubbles and/or fluid into the device header.

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