A novel cause of inappropriate subcutaneous implantable cardioverter-defibrillator therapies after a generator change

Timothy M. Markman, MD,* Jeffrey Smietana, MD,*
Andrew E. Epstein, MD, FAHA, FACC, FHRS*†

*From the *Division of Cardiovascular Medicine, Section of Cardiac Electrophysiology, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, and †Cardiology Division, Corporal Michael J. Crescenz VA Medical Center, Philadelphia, Pennsylvania.*

Introduction

Implantable cardioverter-defibrillators (ICDs) effectively prevent deaths resulting from ventricular tachyarrhythmias.[1,2] Because of complications and lead failures associated with transvenous ICD systems, an entirely extravascular subcutaneous ICD (S-ICD) was developed.[3] A large, multicenter, randomized trial suggested that the S-ICD was noninferior to traditional transvenous ICD systems with respect to delivering appropriate therapy, avoiding inappropriate therapy, and avoiding device-related complications,[4] although the interpretation of these data has been questioned.[5] The FDA issued a class I recall of the S-ICD lead Model 3501 on December 2, 2020 for an increased risk of lead fracture that could result in the inability to defibrillate ventricular arrhythmias and the potential for inappropriate shocks.[6] Beyond the recalled lead, inappropriate shocks remain a concern for S-ICDs primarily due to oversensing T waves and myopotentials, or lead fracture, and have been reported to occur in 5%–13% of patients.[7–10]

KEY TEACHING POINTS

- Inappropriate shocks remain a limitation of subcutaneous implantable cardioverter-defibrillators (ICDs) and common causes include oversensing of myopotentials, oversensing T waves, and undersensing of the QRS, which results in automatic changes in the gain and subsequent oversensing of noise.
- High-frequency electrical noise artifacts on subcutaneous ICDs can result in appropriate therapy and may be caused by lead fracture, loose set screws, improper insertion of the lead into the header of the generator, movement of the suture sleeve over the primary electrode, or interaction of the lead with metal.
- Inadequate connection between the lead and the header of the generator is a rare cause of electrical noise and inappropriate subcutaneous ICD therapy. This must be considered and carefully evaluated by removing, cleaning, and reinserting the lead into the header to evaluate for resolution of noise so that needless system extraction can be avoided.

Case report

A 42-year-old man with Brugada syndrome underwent implantation of an S-ICD in 2016 (lead model 3401). He had not experienced any shock or syncope since implantation. Owing to premature battery depletion, he presented for generator change, which was performed without acute procedure complication (model A219 EMBLEM™). At the generator change, defibrillation threshold testing was performed successfully; the shock impedance was 79 ohms. Four weeks after generator change, the patient experienced an S-ICD shock at home while standing in his kitchen, after which he presented to a local emergency department, where he had another S-ICD shock several hours later while awaiting device interrogation. At the time of his second shock he was lying supine on the hospital stretcher and telemetry revealed normal sinus rhythm.

KEYWORDS Cardiac implantable electronic devices; Implantable cardioverter-defibrillator; Implantable cardioverter-defibrillator malfunction; Inappropriate shocks; Subcutaneous implantable cardioverter-defibrillator

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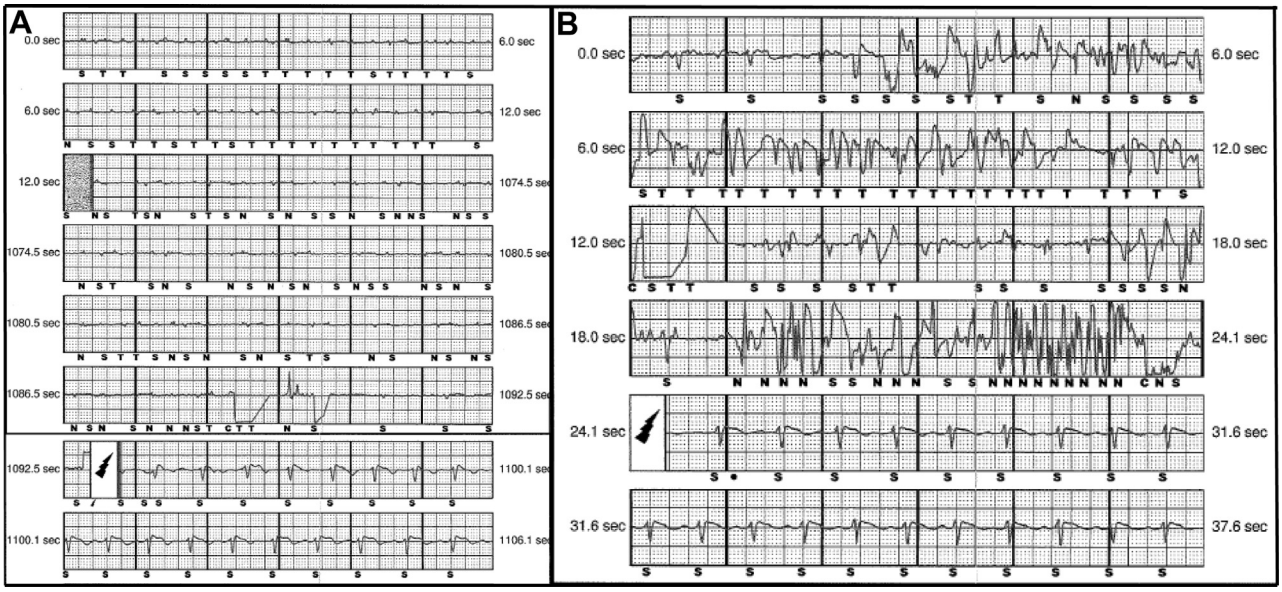

Figure 1 Subcutaneous implantable cardioverter-defibrillator electrograms of inappropriate shocks. **A:** The first inappropriate shock occurred while standing. The device was sensing in the "Alternate" vector with low-amplitude signals and oversensing that had occurred for greater than 15 minutes followed by a brief period of electrical noise artifact before the shock was delivered. **B:** The second inappropriate shock occurred while supine in the emergency department. The device was sensing in the "Alternate" vector with high-frequency noise that lasted for approximately 20 seconds prior to the shock.

Device interrogation identified 2 inappropriate S-ICD shocks that occurred approximately 10 hours apart. Sensing was programmed to the "Alternate" vector for both shocks and the SMART Pass filter was programmed off. The first shock occurred in the setting of low-amplitude signal with associated oversensing that had occurred for greater than 15 minutes followed by a brief period of electrical noise artifact before the shock was delivered (Figure 1A). The second

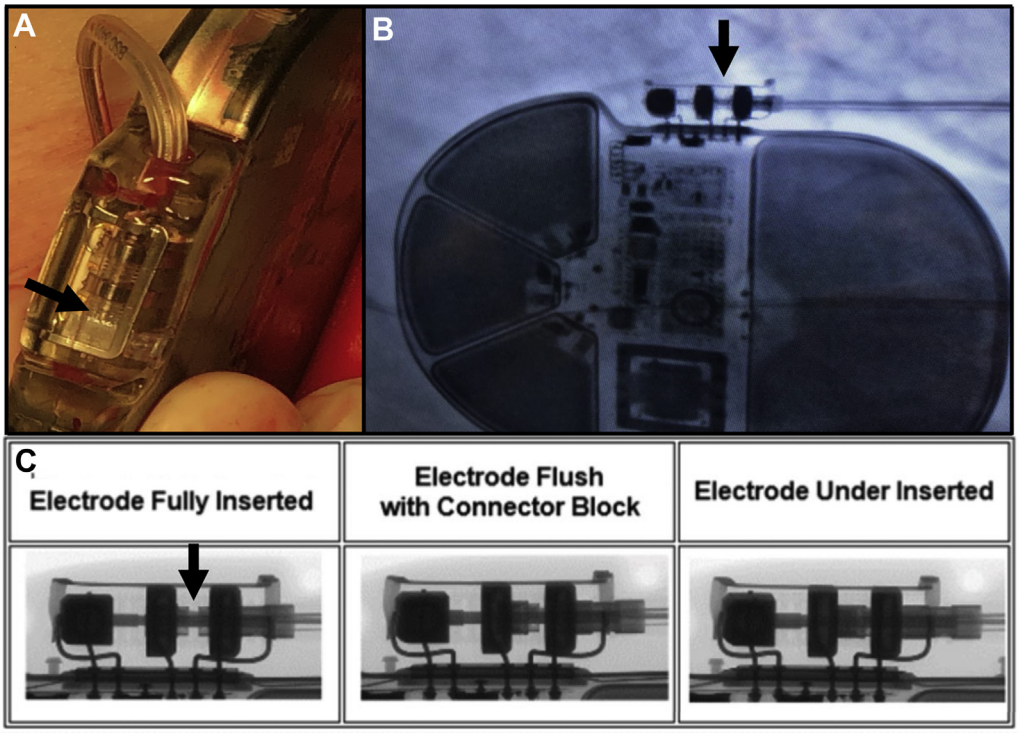

Figure 2 Inspection of the subcutaneous implantable cardioverter-defibrillator at the time of device revision. **A:** Visual inspection of the device suggested that the lead was fully inserted in the header (*arrow showing radiolucent marker*). **B:** Cine fluoroscopy of the header suggested the lead was fully inserted in the header (*arrow*) when compared to panel C. **C:** Images showing the fluoroscopic appearance of fully (*arrow showing radiolucent marker*) and incompletely inserted leads (Courtesy of Boston Scientific, with permission).

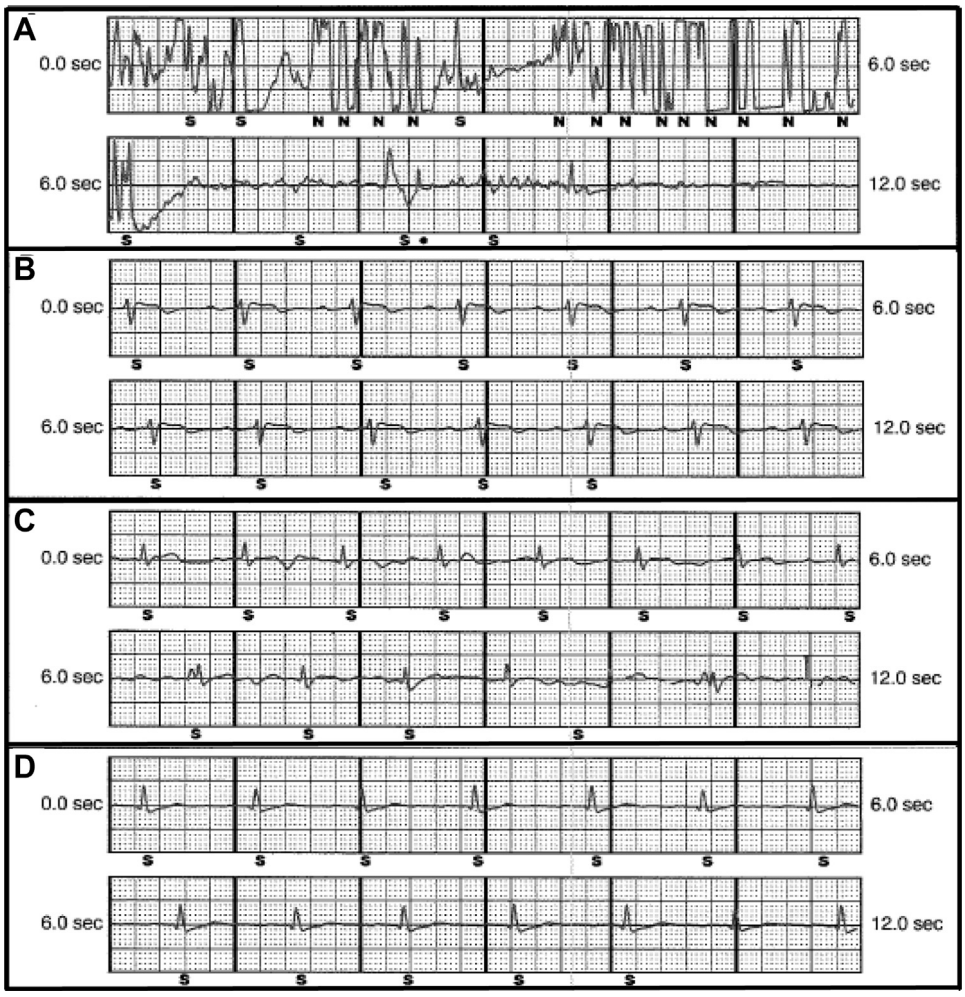

Figure 3 Electrograms recorded during device revision. **A:** Noise similar to the clinical episodes was easily reproduced with manipulation of the lead within 5 centimeters of the header when sensing in the "Alternate" vector. **B–D:** After removing the lead from the header, cleaning it, and reinserting it fully, device and lead manipulation in the "Alternate" (**B**), "Secondary" (**C**), and "Primary" (**D**) vectors elicited no electrical noise artifact.

shock occurred in the setting of high-frequency electrical noise artifact that lasted approximately 20 seconds prior to the shock (Figure 1B).

The following day, the patient was taken to the electrophysiology laboratory for evaluation of the device and possible extraction. In the preoperative area, manipulation of the lead and pulse generator were performed while sensing in "Primary," "Secondary," and "Alternate" vectors. No electrical noise artifacts were detected in standing, sitting, or supine positions. Cine fluoroscopy of the lead and generator revealed no evidence of lead fracture and the suture sleeve for the lead was separated from and not touching the primary, proximal electrode. The pocket was opened, the generator inspected, and the lead appeared to be fully inserted into the header (Figure 2A). Pulling on the lead showed that it was not movable within the header. Cine fluoroscopy of the generator and header showed appropriate placement of the lead within the header (Figure 2B and 2C). Manipulation of the lead within several centimeters of the header elicited reproducible electrical noise artifact similar to that recorded in association with the inappropriate S-ICD shock (Figure 3A). A screwdriver was inserted into the header and the set screw was confirmed to be securely tightened. The lead was removed from the header and visual inspection revealed no apparent debris. While lead failure was suspected, on the off-chance that the lead was imperfectly seated in the header, the lead was cleaned with saline and gauze and reinserted into the header. Further manipulation resulted in no additional noise in any vector (Figure 3B–3D). The device was repositioned in the pocket and there was no additional noise noted. During 4 months of follow-up, there were no inappropriate therapies and there was no noise detected on the device.

Discussion

S-ICDs were developed to avoid complications that are associated with transvenous ICDs, including those related to lead insertion or long-term complications such as endocarditis. While early studies suggested that S-ICDs can be used safely and effectively, there has been increasing concern that these devices may be prone to inappropriate ICD shocks, which are

associated with impaired quality of life as well and increased mortality.[8,11] The most commonly reported causes of inappropriate shocks from S-ICDs are oversensing of myopotentials, followed by T-wave oversensing and undersensing of QRS, which results in automatic changes in the gain and subsequent oversensing of noise.[8] Other reported mechanisms include P-wave oversensing and rate-dependent aberrancy with R-wave double counting. S-ICDs offer limited programming options compared to transvenous devices when inappropriate shocks occur, and device extraction has been reported in 5% of patients owing to refractory oversensing issues.[9]

Here we present the case of a novel mechanism of inappropriate shocks following S-ICD generator change in a patient with an older model lead (3401) that was not included in the December 2020 recall. The device-recorded electrograms prior to therapy were consistent with several potential mechanisms of inappropriate therapy, including a fractured lead, a loose set screw, improper insertion of the lead into the header of the generator, and intermittent movement of the suture sleeve over the primary electrode. Interaction of the lead with metal, such as sternal wires, could be an alternative hypothesis, although this patient did not have any such material implanted.

Cine fluoroscopy identified no apparent fracture and the suture sleeve was not overlapping the primary sensing electrode, although both of these explanations remained possible, as the fracture may not have been visible on fluoroscopy and the lead could have been mobile within the suture sleeve. The decision was made to open the pocket and inspect the device visually to determine whether a problem with the lead-header interaction was present and to subsequently extract the device if no reversible etiology could be identified. On visual inspection the lead was fully inserted in the header, and on cine fluoroscopy of the pulse generator the lead appeared to be adequately positioned within the header. A loose set screw was unlikely to be the cause of the noise artifacts because pulling on the lead demonstrated that it was not movable within the header and when the screwdriver was inserted into the header, the set screw was confirmed to be tightly sealed. Given the reproducibility of the noise with manipulation of the lead, a fracture was initially suspected. After the lead was cleaned and reinserted, the electrical noise artifacts disappeared immediately and were not present in any vector. This confirmed that there had been inadequate connection between the lead and the header, despite the contrary visual and fluoroscopic evidence. Additionally, low-amplitude electrograms as seen in Figure 1 were no longer observed after reinsertion of the lead into the header. This suggested that the low-amplitude signals were likely the result of insufficient electrode contact owing to inadequate insertion of the lead into the generator. Electrograms recorded during the second episode were of substantially higher amplitude, which may have been due to dynamic changes in the lead-header connection or because of position changes, which have been shown to significantly affect signal amplitude.[12]

There is no evidence that this problem could have been detected prior to the inappropriate shocks, as the lead appeared to be well inserted into the header, and there was no problem with sensing or noise at the time of implant and shock impedance at the time of defibrillation threshold testing was excellent. Furthermore, despite careful assessment of the S-ICD system, had the lead not been cleaned and reinserted, a fracture would have been assumed to be present, resulting in an unnecessary device extraction and implantation of a transvenous ICD. It is important that electrophysiologists be aware of this rare cause of inappropriate shocks and that inadequate lead-header interactions be assessed when other causes are not identified.

Conclusion

S-ICDs are an important tool for the treatment of sudden cardiac death, although inappropriate shocks remain a limiting factor in the adoption of this device. Abnormal lead-header interactions that are otherwise not identifiable can cause inappropriate shocks. Implanting physicians must be aware of this entity and evaluate lead-header interactions.

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