Pause-prevention pacing in an extravascular implantable cardioverter-defibrillator

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KEY TEACHING POINTS

- Sleep-related pauses discovered on cardiovascular implantable electronic devices could be related to obstructive sleep apnea, and patients may benefit from a sleep study to confirm diagnosis.
- Although the need for pacing in the primary prevention implantable cardioverter-defibrillator (ICD) population is low, a device with backup pacing therapy provides benefit if the patient develops a sudden bradycardia.
- Pause-prevention pacing should be programmed to "monitor" in all extravascular ICD patients regardless of their medical history so that pauses can be documented in the device diagnostics.

Introduction

The extravascular implantable cardioverter-defibrillator (ICD) is a novel therapy with a high-voltage lead implanted in the substernal space. The extravascular ICD Pivotal Study recently demonstrated that the system is both safe and effective for termination of ventricular arrhythmias.[1] One of the benefits of the extravascular ICD over other systems with extravascular placement is the ability to provide pause-prevention pacing. We present a case of repetitive prolonged pauses in a patient, with backup pacing. To our knowledge, this is the first reported case study demonstrating the use of this feature.

Case report

A 64-year-old man with NYHA functional class II congestive heart failure, ischemic cardiomyopathy, and systolic dysfunction (left ventricular ejection fraction 30%) was referred to electrophysiology for consideration of ICD implantation. Owing to his relatively young age, and the desire to keep hardware out of his vasculature, the patient was presented with the option of subcutaneous or extravascular ICD as an alternative to transvenous. The patient chose extravascular placement and chose to enroll in the extravascular ICD Pivotal Study mainly owing to smaller device size. Device implantation and testing was straightforward, with excellent R-wave sensing (1.9 mV) and a pacing capture threshold of 2.5 V @ 2.0 ms on the Ring 1 to Coil 2 pacing vector (Figure 1). Defibrillation testing was successful at 15 J. At the time of hospital discharge, the pause-prevention feature was programmed to "monitor" mode, to capture pauses of 5 seconds or greater in the device diagnostics.

The patient presented at the 6-month postimplant follow-up visit with 5 pause-prevention episodes. These episodes

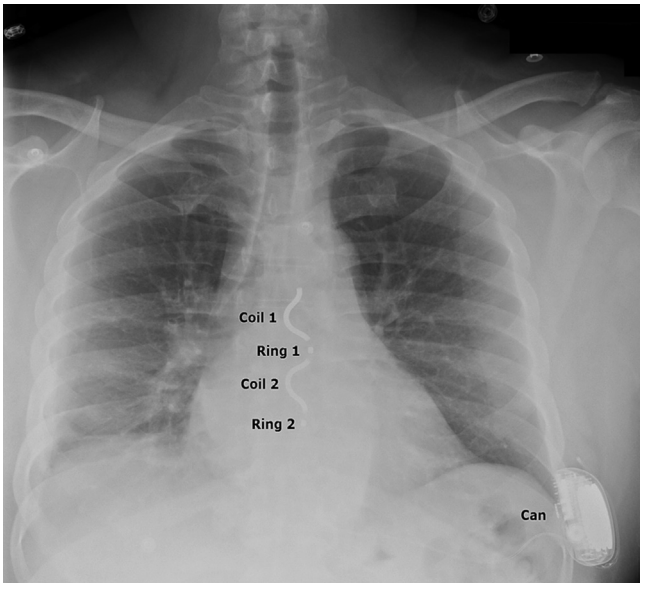

Figure 1 Postoperative chest radiograph showing this patient's implanted extravascular implantable cardioverter-defibrillator system with the electrodes labeled. Low-voltage bipolar pacing for pause prevention can be achieved in the Ring 1 to Ring 2 or Ring 1 to Coil 2 (primary) vector up to 8 V @ 8 ms. High-voltage bipolar pacing for pause prevention can be achieved in the Coil 2 to Coil 1 vector from 10 V up to 13 V with maximum pulse width of 10 ms. Sensing can be programmed to the Ring 1 to Ring 2 (primary), Ring 1 to Can, or the Ring 2 to Can vector. This patient is programmed to Ring 1 to Can sensing.

KEYWORDS Extravascular ICD; Pause; Pacing; Complete heart block; Obstructive sleep apnea
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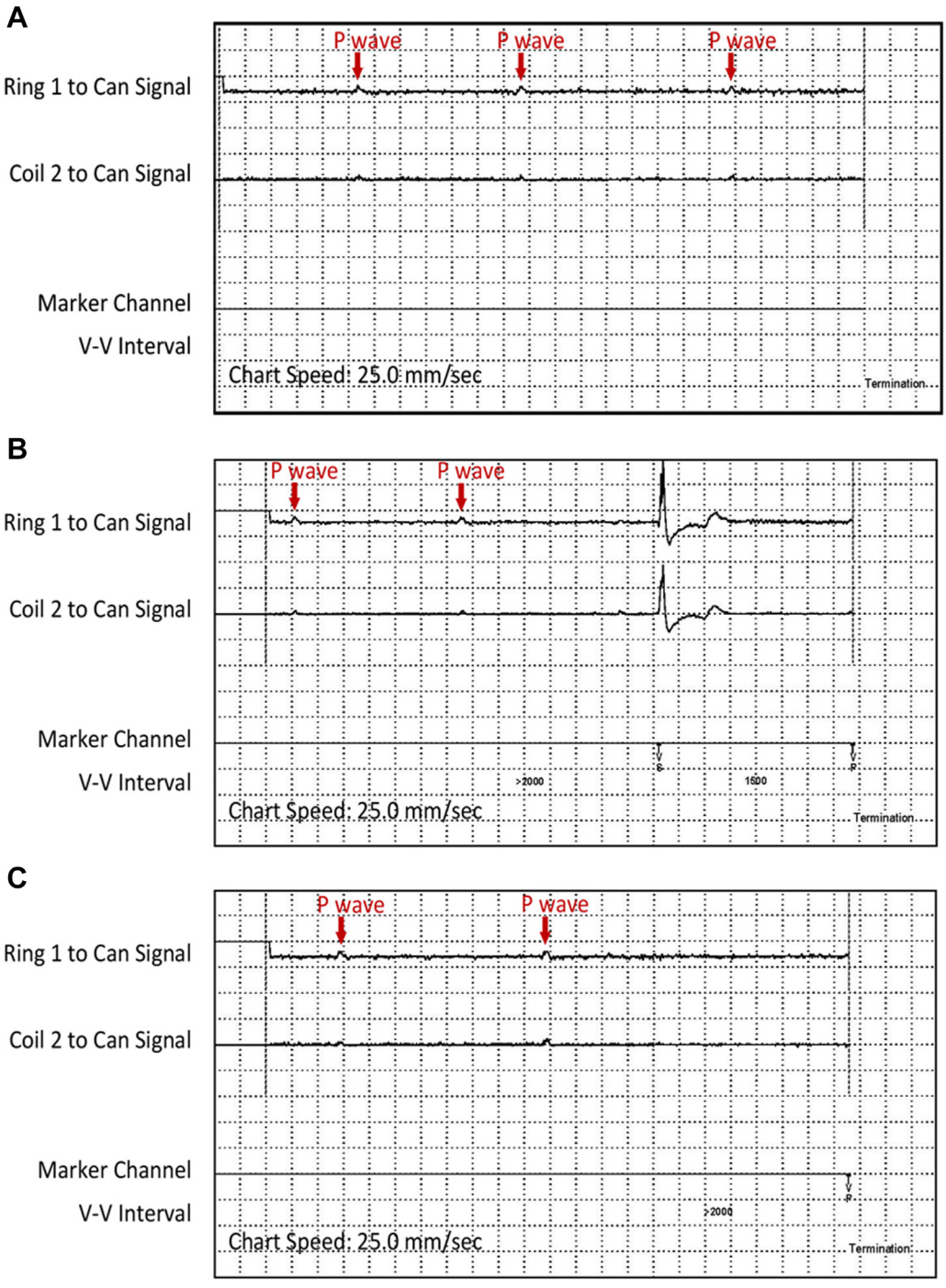

Figure 2 Electrograms (EGM) showing evidence of complete heart block before and after pause prevention was enabled. Two seconds of electrogram leading to the event are stored for each episode. **A:** This EGM was recorded while pause prevention was in "monitor" mode. Since no pacing therapy is programmed on, the marker channel shows "Termination" because the EGM recording has timed out. **B:** EGM recording after pause-prevention pacing was turned "on." A ventricular sense inhibits pacing after the 5-second asystole detect timer expires but before the first VVI escape interval expires. This is followed by a ventricular pace (VP) marker at 1500 ms (40 ppm). **C:** In this episode, the 5-second asystole timer and the VVI escape interval both expire, and a VP occurs. Owing to storage limitations, extravascular implantable cardioverter-defibrillator only records 2 seconds of EGM and Marker Channel prior to detection of a pause episode. Therefore, the EGM recording stops after the first VP marker.

occurred at various times on 3 different dates, and all during reported sleeping periods. The patient denied any symptoms. Episode electrograms showed sinus bradycardia with complete heart block, each lasting at least 5 seconds (Figure 2). The heart rate slowed down prior to nonconducted p waves and since this happened in sleep, it is likely related to alteration of the vagal tone. At the end of the visit, pause prevention was reprogrammed from "monitor" to "on." The pacing capture threshold at this visit was 8 V @ 6 ms on the Ring 1 to Coil 2 pacing vector (Figure 1). Therefore, the pause-

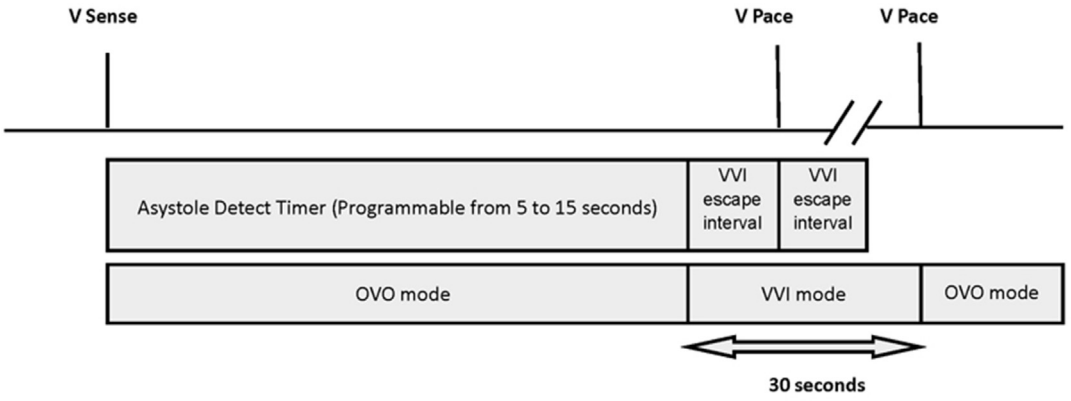

Figure 3 Pause-prevention feature operation.

prevention pacing output was programmed 10 V @ 2 ms on the Coil 2 to Coil 1 pacing vector (Figure 1). The patient was instructed to call the clinic if he had any symptoms.

Subsequent device checks through 18 months of follow-up revealed 12 more pause episodes that were detected and treated (Figure 2), for a device lifetime total of 17 episodes. Each pause-prevention episode stored by the device had 5 or fewer paces delivered. The patient denied any symptoms or pacing sensation and all episodes occurred during sleeping periods.

Discussion

Here we report on an early occurrence of pause-prevention pacing with an extravascular ICD. Through a mean 10.6 months of follow-up during the extravascular ICD Pivotal Study, only 17 out of 299 patients (5.7%) had the pause-prevention pacing therapy feature programmed as "on" through at least 1 follow-up visit. Among the patients with pause-prevention pacing therapy enabled, 2 patients had episodes of asystole treated, including this patient.[1]

The pause-prevention feature is designed to provide asystole detection and therapy. If a patient develops an indication for brady pacing it will provide a bridge to a device change. The device operates in OVO mode and monitors for long pauses in ventricular events. The pause detection is programmable from 5 to 15 seconds. When the feature is programmed "on," and a pause is detected, it will switch from OVO mode to VVI 40 ppm. It switches back to OVO mode after 30 seconds (Figure 3).

Many clinical studies have reported cardiac rhythm disturbances during the sleep period in patients with obstructive sleep apnea, such as heart block and atrial fibrillation. Significant resolution of such disturbances has been reported with treatment.[2–4] In this patient, the pauses were presumed to be associated with obstructive sleep apnea, which was confirmed by a sleep test. Even though sleep-related pauses are not an indication for permanent pacing, this patient already had a device with pacing capabilities. Therefore, we saw no harm in turning the pause-prevention pacing on to avoid pauses lasting longer than 5 seconds. It also gave the patient peace of mind. The patient waited 1 year to have the sleep test owing to insurance issues and still awaits treatment with a continuous positive airway pressure device. The pause-prevention feature continues to provide backup pacing while he waits for this therapy. It is worth noting that the pause-prevention pacing has had minimal impact to battery longevity. Estimated longevity at the 6-month visit was 9.8 years and at the 18-month visit was 8.7 years, demonstrating normal battery depletion.

Conclusion

We report a case of sleep-related heart block uncovered by an extravascular ICD system. Pause-prevention pacing was implemented until obstructive sleep apnea could be formally diagnosed and it continues to provide backup pacing until the patient can receive treatment. The need for bradycardia pacing in this patient population is low. However, this feature provides an advantage when a patient develops a sudden bradycardia.

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