

Combination of a leadless pacemaker and subcutaneous defibrillator: First in-human report



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Introduction

Although transvenous pacemakers and implantable cardioverter-defibrillators (ICD) have long been the standard of care, they are not without significant drawbacks. In recent years, major advances have been achieved in leadless pacemaker technology¹ and entirely subcutaneous ICD (S-ICD) systems² that obviate intracardiac leads and hence carry the potential to reduce associated complications. Unlike standard ICDs, the S-ICD is devoid of antibradycardia pacing capabilities. Nevertheless, certain patients, such as those lacking vascular access for transvenous lead insertion, may benefit from leadless devices with both pacing and ICD functions. Herein, we present the first patient in whom the leadless pacemaker and S-ICD were used in combination.

Case presentation

A 70-year-old man with coronary artery disease, mechanical prosthetic aortic and mitral valves, permanent atrial fibrillation, and a left ventricular ejection fraction of 30% was referred to our institution for a primary prevention ICD. He was on long-term dialysis therapy via a catheter tunneled to the right internal jugular vein. On preprocedural venography, complete obstruction of the left subclavian vein was noted along with severe stenosis of the right subclavian vein. In the absence of pacemaker indications, the patient was further assessed for an S-ICD. During the screening test, T-wave oversensing was registered with the subcutaneous

lead positioned along the left sternal border. However, no such T-wave oversensing occurred with the lead to the right of the sternum. An S-ICD (Model SQRX; Boston Scientific, Malborough, MA) was therefore implanted under general anesthesia, with the can placed in a left lateral position over the fifth and sixth intercostal space. The defibrillation lead was tunneled towards the xiphoid process and then cranially to the right of the sternum. Ventricular fibrillation (VF) was induced and a 65 J shock effectively restored sinus rhythm. The procedure was well tolerated and without complication.

Seventeen months later, the patient presented to the emergency room with syncope and complete atrioventricular block. A temporary pacemaker was placed by means of a right-sided femoral approach. In light of the vascular access constraints, a leadless pacemaker (Nanostim system; St Jude Medical St. Paul, MN) was then inserted with an 18F introducer in the right femoral vein and implanted at the apex of the right ventricle. The threshold was 2 V at 0.4 ms, R-wave 7 mV, and lead impedance 960 ohm. As displayed in [Figure 1](#), during testing the pacemaker was programmed at maximum output (6.5 V @ 0.5 ms) and no oversensing or double counting was detected by the S-ICD in all 3 configurations (primary, secondary, alternate). The programmed automatic configuration was therefore retained. Although VF was not re-induced, an 80 J shock was delivered by the S-ICD on QRS timing, which did not result in mode reversion, shutdown, or dislodgment of the pacemaker. Moreover, no noise (ie, from modulated pacing pulses) was perceived by the S-ICD during pacemaker interrogation and programming ([Figure 2](#)). The chest radiograph in [Figure 3](#) shows the position of the S-ICD and leadless pacemaker in anteroposterior and lateral views. At 6 months of follow-up, the patient's evolution continues to be uneventful, with 12% ventricular pacing (0.5 V at 0.4 ms, R-wave 12 mV, and lead impedance 540 ohm), no recurrent syncope, and no S-ICD shock.

KEYWORDS Subcutaneous defibrillator; Leadless pacemaker; Venous thrombosis; Primary prevention; Ischemic cardiomyopathy; Dialysis

ABBREVIATIONS ICD = implantable cardioverter-defibrillator; PM = pacemaker; S-ICD = subcutaneous implantable cardioverter-defibrillator; VF = ventricular fibrillation

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Discussion

To our knowledge, this is the first case reported of a leadless pacemaker implanted in combination with an S-ICD. A few prior reports have described S-ICD systems in patients with

KEY TEACHING POINTS

- A subcutaneous implantable cardioverter-defibrillator may potentially be used in combination with a leadless pacemaker.
- Some careful attention must be brought to device interaction.
- This strategy carries the potential of pacing and defibrillation for patients in whom standard transvenous approaches are not feasible or desirable.

transvenous and epicardial pacemakers.^{3,4} When these 2 technologies are used together, pacemakers must be programmed to stimulate in a bipolar mode in order to avoid double counting by the S-ICD. Functionally, a leadless pacemaker operates in a fashion similar to a standard bipolar VVIR pacemaker. Even when programmed to maximum output, no oversensing was detected by the S-ICD. In

addition, we were concerned over the potential for leadless pacemaker dysfunction after delivery of an S-ICD shock. We therefore tested this scenario by delivering a maximum-output shock from the S-ICD. No device interactions were noted, as the leadless pacemaker continued to function as programmed during and after the shock. Since VF was not re-induced after pacemaker implantation, we could not exclude the possibility that VF undersensing by the pacemaker may lead to pacing spikes that are more prominently seen by the S-ICD, as its detection algorithm filters out finer subcutaneous electrocardiographic signals.

In conclusion, our case demonstrates that an S-ICD may potentially be used in combination with a leadless pacemaker to provide pacing and ICD functions without intracardiac leads. However, given that unexpected behavior may occur during VF, electromagnetic interference, or sensing vector changes, a more formal safety assessment with regard to possible device interactions is required before widespread adoption. This combined leadless strategy carries the potential to widen our therapeutic armamentarium for patients who have indications for pacemakers and ICDs but in whom

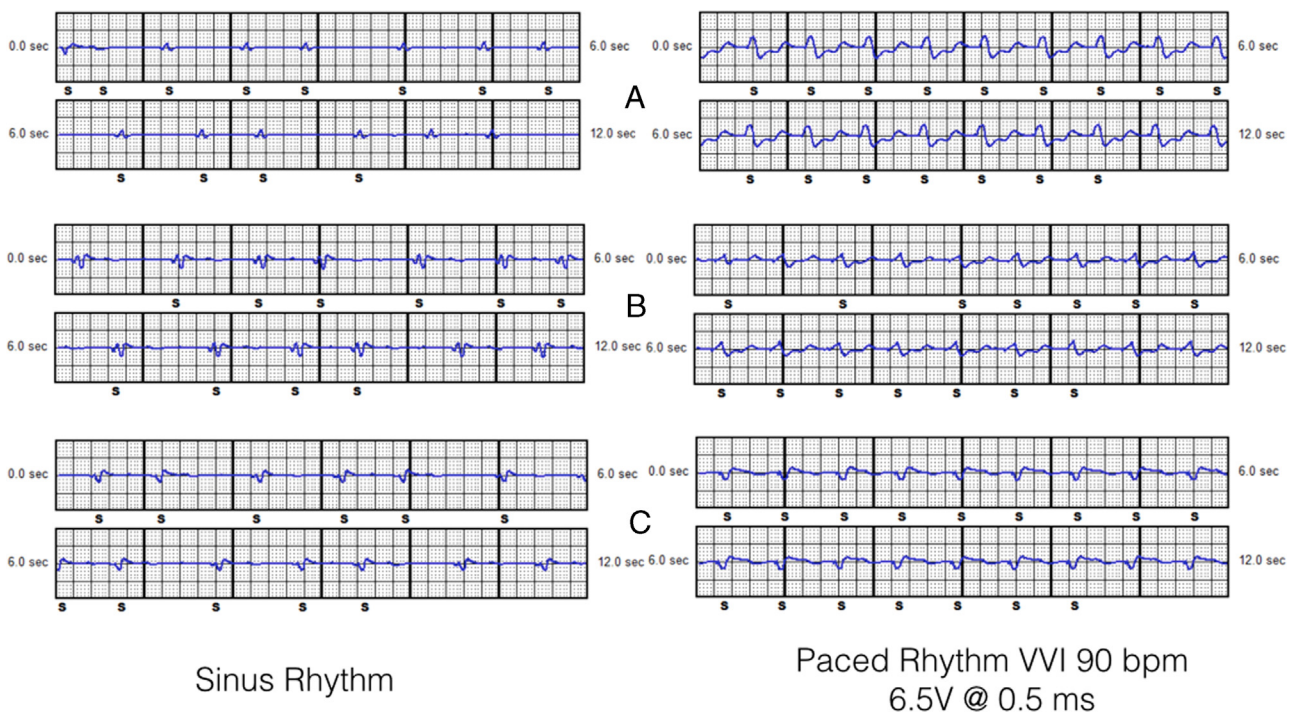


Figure 1 Subcutaneous implantable cardioverter-defibrillator electrogram recordings during spontaneous sinus rhythm (*left*) and during VVI 90 bpm maximum output (6.5 V @ 0.5 ms) pacing (*right*) are shown in the following 3 configurations: **A:** primary configuration; **B:** secondary configuration; **C:** alternate configuration.

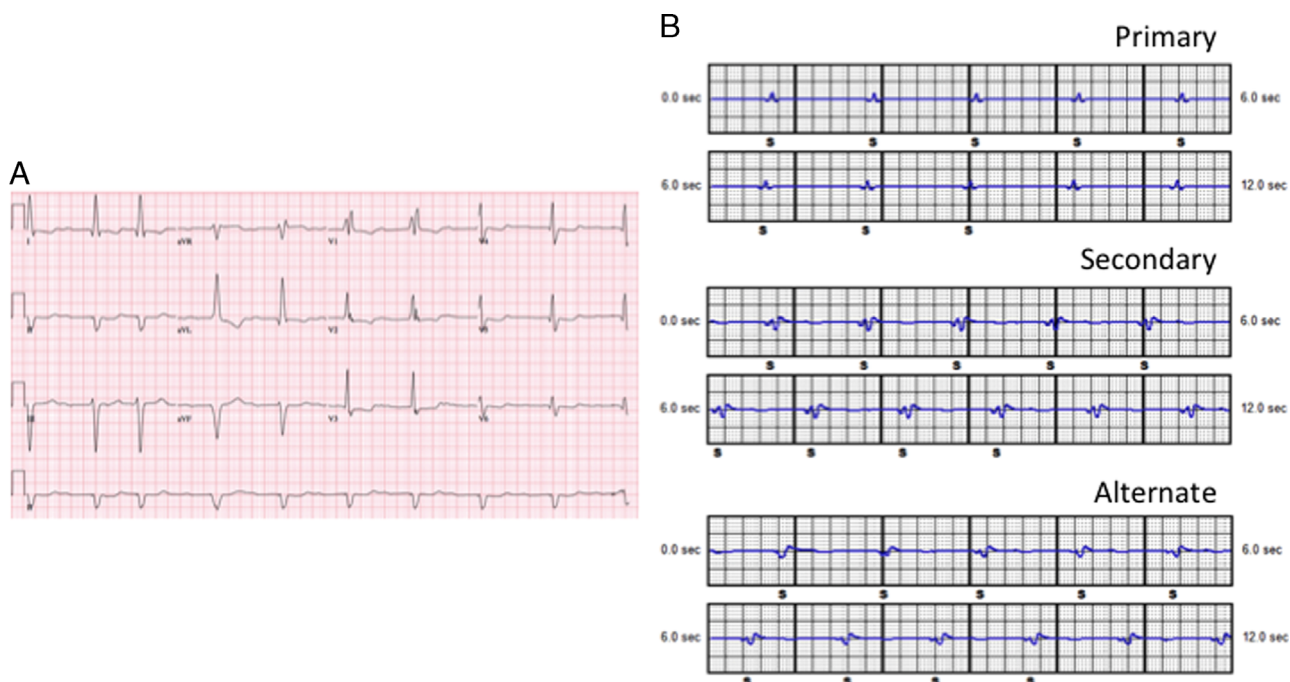


Figure 2 Recordings during interrogation and programming of the leadless pacemaker. **A:** A 12-lead electrocardiographic recording showing the absence of noise from modulated pacing pulses. **B:** Subcutaneous implantable cardioverter-defibrillator recordings in primary (*upper panel*), secondary (*middle panel*), and alternate (*lower panel*) configurations during interrogation and programming of the leadless pacemaker, likewise demonstrating the absence of detected interference.

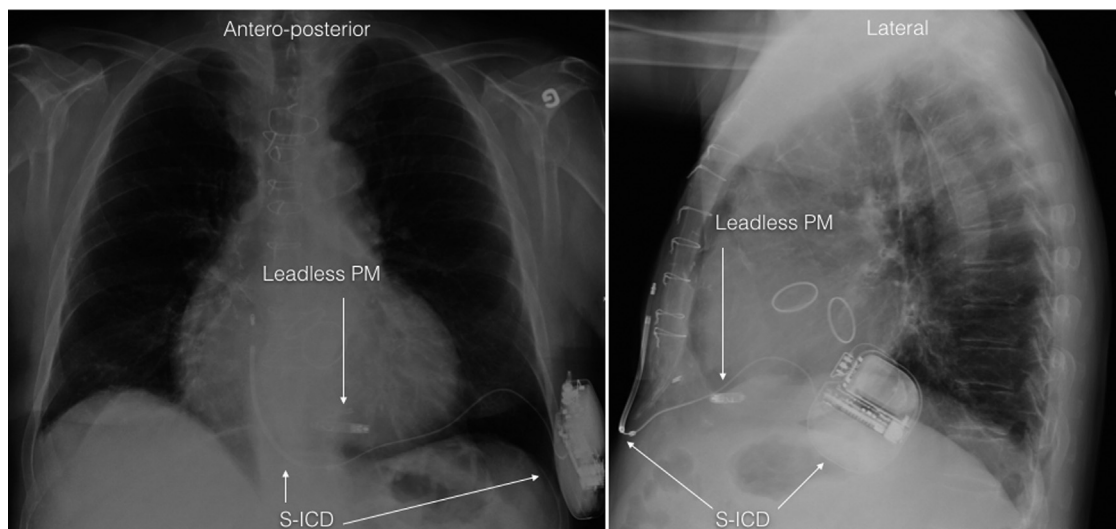


Figure 3 Chest radiograph. Shown are anteroposterior and lateral views of the leadless pacemaker (PM) and subcutaneous implantable cardioverter-defibrillator (S-ICD) systems.

standard transvenous approaches are not feasible or desirable.

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