A novel use of a subcutaneous implantable cardioverter-defibrillator algorithm to detect bradycardia

Timothy M. Markman, MD,* Joseph Brozoski, BSME, MBA,† Weeranun Bode, MD,* Saman Nazarian, MD, PhD, FHRS*

*From the *Division of Cardiovascular Medicine, University of Pennsylvania Perelman School of Medicine, Philadelphia, Pennsylvania, and †Boston Scientific, Minneapolis, Minnesota.*

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 and was approved in 2012 as an alternative to transvenous ICDs for the prevention of sudden cardiac death.[3,4]

Since its initial approval, the S-ICD system has added additional algorithms to reduce inappropriate shocks.[5] Despite the advantages of the entirely extravascular device and an overall favorable safety profile, limitations include ongoing concerns about inappropriate shocks due to potential oversensing and, aside from brief postshock pacing for up to 30 seconds, the inability of the device to provide pacing in the setting of bradycardia or as antitachycardia therapy.[6–8] The SMART Pass algorithm was developed in order to improve S-ICD arrhythmia discrimination and reduce the rate of inappropriate shocks (Figure 1).[9,10] There is currently no bradycardia detection algorithm available in the S-ICD.

Case report

A 70-year-old man with a history of ischemic cardiomyopathy with a left ventricular ejection fraction of 30% underwent implantation of an S-ICD in 2017 (generator model A219, lead model 3401) for primary prevention of sudden cardiac death. The device was programmed in the secondary vector sensing configuration and appropriate sensing was noted at implant. Defibrillation threshold testing was performed and successfully terminated ventricular fibrillation with a 65 joule shock at the time of implantation.

Since his implant, he underwent routine remote monitoring, with remote transmissions noting appropriate sensing in stored electrograms, and no ICD therapies had been delivered. Four years following implantation, a remote monitoring alert was triggered because the SMART Pass algorithm had been disabled. An electrogram was stored along with this alert, which was transmitted to our remote monitoring service. This electrogram revealed atrial fibrillation with a slow ventricular response and an 11-second pause (Figure 2). The patient reported a near-syncopal episode that corresponded to the time of the episode. Following discussion with the patient, he was initiated on apixaban for stroke prevention in the setting of atrial fibrillation. Given his symptomatic bradycardia, the anticipated need for bradycardia therapy, and the risk for inappropriate shocks in the setting of bradycardia,[11] he elected to undergo extraction of his existing S-ICD and implantation of a transvenous dual-chamber ICD.

Discussion

S-ICDs were developed to avoid complications that are associated with transvenous ICDs. Although early studies demonstrated that S-ICDs can be used safely, owing to increasing concern related to inappropriate ICD shocks, efforts have been made to improve the accuracy of tachyarrhythmia sensing.[12] A common cause of inappropriate ICD shocks is T-wave oversensing, which occurs when T waves are similar in amplitude to QRS complexes and the S-ICD detects both signals as ventricular events, resulting in inappropriate detection of tachycardia.[13] Initial improvements to the S-ICD, including a morphology-based sensing algorithm, improved inappropriate shocks due to T-wave oversensing by approximately 40%, but unfortunately these inappropriate therapies continued to occur.[14]

The SMART Pass algorithm was developed to further minimize T-wave oversensing using a high-pass filter with a corner frequency between 8 and 9 Hz and a roll-off rate

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KEY TEACHING POINTS

- Subcutaneous implantable cardioverter-defibrillators (S-ICDs) are limited by the inability to reliably monitor or provide pacing support for bradycardia.
- The SMART Pass algorithm on S-ICDs is designed to prevent T-wave oversensing and associated inappropriate shocks. The algorithm is deactivated when low-amplitude QRS complexes are detected or in the event of prolonged asystole.
- Deactivation of the SMART Pass algorithm provides a unique opportunity to identify bradycardia or prolonged pauses in patients with S-ICDs.

of 20 dB/decade (voltage gain decrease by a factor of 10 for each 10-fold increase in frequency) while continuing to use the wide-band electrocardiogram for rhythm discrimination purposes. This filter allows for a maximum reduction in T waves, which have a typical frequency <9 Hz, while minimally affecting the typical frequency range of QRS complexes, including during ventricular tachycardia and fibrillation.[9] This algorithm has been shown to effectively reduce T-wave oversensing by >60% compared to prior-generation algorithms.[9] Unfortunately, however, like all filtering schemes, this algorithm does have the potential, particularly at frequencies approaching the corner frequencies, to reduce the amplitude of QRS complexes, which could lead to undersensing of low-amplitude ventricular signals. For this reason, the SMART Pass algorithm is deactivated if either of the following 2 criteria are met: first, if sensed QRS complexes have an amplitude <0.25 mV for 5 consecutive complexes and at least 2 of these intervals are >1.4 seconds; and second, if the device senses >10 seconds of asystole. When either of these criteria are met, the SMART Pass algorithm is deactivated and a 44-second electrogram is captured (20 seconds prior to the event and 24 seconds after the event).[5] When remote monitoring is utilized, an alert will be generated notifying the care team that the SMART Pass algorithm had been deactivated and providing the electrogram for review.

Here we present the case of a novel use of the SMART Pass algorithm to detect a bradycardic episode. Owing to the prolonged pause that occurred during atrial fibrillation in this case (>10 seconds without a QRS complex), the SMART Pass algorithm was deactivated. Accordingly, this offered the unique ability to identify both atrial fibrillation and a symptomatic episode of bradycardia. By carefully reviewing the data provided by an algorithm that had not been designed for this purpose, the patient was appropriately treated for his atrial fibrillation as well as his symptomatic bradycardia. Extraction of the S-ICD and implantation of a transvenous dual-chamber ICD provided him with pacing support and avoided the risk of inappropriate shocks in the setting of bradycardia.[11]

Although this patient's atrial fibrillation and symptomatic bradycardia could have been detected with an alternative monitoring strategy, he had not yet reported symptoms that would have led to additional monitoring. While management of atrial fibrillation detected by cardiac implantable electronic devices with anticoagulation remains controversial, it is clear that patients with these cardiac implantable electronic devices develop atrial fibrillation at substantial rates and there is increasing evidence that rhythm control in patients with heart failure may provide a mortality benefit.[15–17] Patients with heart failure and transvenous ICDs who are noted to have atrial fibrillation are therefore closely monitored to determine when additional therapy may be indicated. Similarly, development of conduction system disease in this population is common and would be detected as

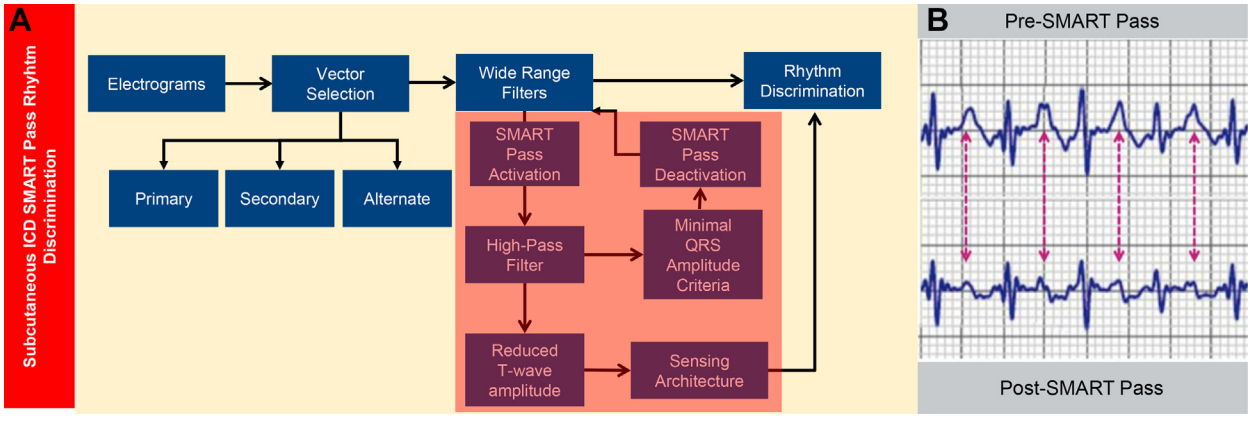

Figure 1 SMART Pass algorithm. **A:** The SMART Pass algorithm includes an additional high-pass filter (corner frequency between 8 and 9 Hz) and a roll-off rate of 20 dB/decade designed to reduce cardiac oversensing while maintaining an appropriate sensing margin of QRS complexes. The algorithm reduces the amplitude of low-frequency T waves with minimal effect on QRS amplitude to avoid undersensing of low-amplitude ventricular arrhythmias. **B:** Example of pre– and post–SMART Pass algorithm electrograms with substantially reduced amplitude of low-frequency T waves and minimally reduced amplitude of QRS complexes. Adapted from Boston Scientific SMART Pass Algorithm Inservice CRM-413109-AB, August 2016[10] (with permission).

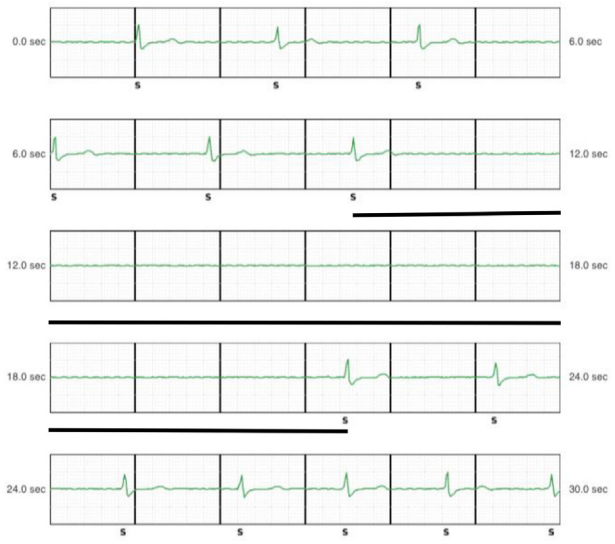

Figure 2 Subcutaneous implantable cardioverter-defibrillator electrograms at the time of SMART Pass algorithm deactivation. The device was sensing in the Secondary vector with adequate-amplitude QRS signals. The underlying rhythm is atrial fibrillation with irregular R-R intervals and without identifiable atrial activity. Owing to a period >10 seconds of no sensed QRS, the SMART Pass algorithm was deactivated and the electrograms were stored. The black line represents the 11.5 seconds without a sensed QRS complex. Electrograms are displayed at 25 mm/s speed and 5.0 mm/mV amplitude. S = sensed ventricular event.

increased pacing burden during routine follow-up of patients with transvenous devices.[18,19] Patients with S-ICDs, however, who are not felt to have an indication for pacing at the time of implantation, may also develop an indication for pacing over time. Although current S-ICD bradycardia detection is insufficient to be relied on for this purpose and additional monitoring strategies should be considered as indicated, careful attention to deactivation of the SMART Pass algorithm can provide initial documentation of significant bradycardia.

This case study identifies the unique application of an S-ICD algorithm to identify bradycardic episodes. Cardiac implantable electronic device algorithms are increasingly complex and variable between devices, and this case highlights the importance of understanding both the mechanism of this algorithm and the data it provides. Furthermore, as the volume of data provided in remote monitoring clinics continues to grow, it has become progressively more challenging to adequately review all available information. Patients with S-ICDs are unique among cardiac implantable electronic device patients in that they have no explicit bradycardia monitoring or pacing support. It is therefore beneficial for providers to be aware of the criteria in place for the SMART Pass algorithm and its ability to detect bradycardia episodes in the setting of algorithm deactivation. The proper use of a comprehensive remote monitoring strategy coupled with a detailed understanding of S-ICD algorithms are critical to providing optimal care for this population.

Conclusion

S-ICDs are an important tool for the prevention of sudden cardiac death, although they are limited by their inability to reliably monitor or provide pacing support for bradycardia. The SMART Pass algorithm, which is designed to prevent T-wave oversensing, provides a unique opportunity to detect and document bradycardic episodes when the algorithm is deactivated. Providers involved in the care of patients with S-ICDs, especially in the setting of remote monitoring programs, should be aware of this algorithm and the need to evaluate the electrograms when it is deactivated.

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