Prospective blinded evaluation of a novel sensing methodology designed to reduce inappropriate shocks by the subcutaneous implantable cardioverter-defibrillator

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BACKGROUND Most inappropriate shocks from the subcutaneous implantable cardioverter-defibrillator (S-ICD) are caused by cardiac oversensing. A novel sensing methodology, SMART Pass (SP; Boston Scientific Corporation, Natick, MA), aims to reduce cardiac oversensing.

OBJECTIVE The purpose of this study was to evaluate the effect of SP on shocks in ambulatory S-ICD patients.

METHODS Patients implanted in 2015–2016 and enrolled in a remote patient monitoring system were included and followed for 1 year. Shocks were adjudicated by 3 independent blinded reviewers as appropriate or inappropriate. Shock incidence was calculated for patients with SP programmed enabled or disabled at implantation, censoring patients when SP programming changed or at the last transmission. The SP setting (enabled vs disabled) was modeled as a time-dependent Cox regression variable.

RESULTS The cohort consisted of 1984 patients, and a total of 880 shocks were adjudicated. At implantation, SP was enabled in 655 patients (33%) and disabled in 1329 patients (67%). SP reduced the risk for the first inappropriate shock by 50% ($P < .001$) and the risk for all inappropriate shocks by 68% ($P < .001$) in multivariate analysis adjusted for age and device programming. The incidence of inappropriate shocks was 4.3% in the SP enabled arm vs 9.7% in the SP disabled arm. The incidence of appropriate shocks was similar (5.2% vs 6.6%; $P = .18$) along with the time to treat the first appropriate shock (17.4 seconds vs 16.7 seconds; $P = .92$) for SP enabled vs disabled, respectively.

CONCLUSION This prospective blinded evaluation of the SP filter demonstrates that enabling the SP filter results in a significant reduction of inappropriate shocks by the S-ICD without a negative effect on appropriate shocks.

KEYWORDS Appropriate shocks; Inappropriate shocks; Subcutaneous ICD

Introduction

The implantable cardioverter-defibrillator (ICD) is an established therapy to prevent sudden cardiac death.[1,2] Despite the effectiveness in reducing arrhythmic mortality, conventional ICD systems have been associated with morbidity because of short- and long-term complications with endovascular leads.[3–5] To address these complications, an entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) system was developed with no leads within or on the heart.[6] Several studies have demonstrated the feasibility and safety

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of the S-ICD system in detecting and terminating life-threatening ventricular arrhythmias.[7–9] Despite the safety and efficacy of the S-ICD system, the main cause of morbidity in S-ICD patients is the inappropriate shock, primarily caused by cardiac oversensing.[10,11] An initial update in the morphology-based sensing algorithm in the S-ICD reduced inappropriate charges because of T-wave oversensing by ~40%.[12] In order to reduce inappropriate shocks further, a new high-pass filter (SMART Pass [SP], Boston Scientific Corporation, Natick, MA) available within the S-ICD system was activated for cardiac sensing.

We evaluated the effect of SP on shocks in ambulatory S-ICD patients. For the purpose of this study, events in S-ICD patients enrolled in the LATITUDE remote follow-up system (Boston Scientific) were used in order to allow real-life events to be evaluated.

Methods

Study design

The LATITUDE remote patient monitoring system was market released in February 2006 for CRT-D and ICD devices. In 2015, the EMBLEM S-ICD system (Boston Scientific) was added to the LATITUDE network system. Device data are transmitted wirelessly from the implanted device to a central server via interaction with the LATITUDE communicator in the patient's home. Data are available through a secured website for review by the patient's health care provider. Participating centers are engaged in a data processor agreement that governs the use of LATITUDE data, and each patient signed a data authorization form that allows the use of anonymous data for research purposes. The study cohort consisted of patients who received an S-ICD between January 2015 and December 2016. For the purpose of the study, patients had to be enrolled in the European LATITUDE remote monitoring system. LATITUDE allows for limited demographic data, and as such, this study design focuses on events as it relates to programming.

The SP filter was approved on April 20, 2016, with CE Mark approval of the EMBLEM MRI (model A219) device, and the first implantation occurred on April 25, 2016. The SP filter was retroactively available for A209 devices through a firmware upgrade. The SP filter could be programmed active following the device setup process and selection of the optimal sensing vector.

Sensing of the S-ICD system and SP

The S-ICD system uses 3 sensing electrodes to record cardiac electrical activity: (A) superior to the sternal defibrillation coil; (B) inferior to the sternal defibrillation coil; and (C) pulse generator (CAN) implanted left-lateral at the midaxillary line. These electrodes represent 3 vector projections of cardiac electrical conduction, which resembles the signal characteristics of the standard surface electrocardiogram (ECG): primary, B to CAN; secondary, A to CAN; alternate, A to B. One of the 3 available vectors is selected (on the basis of the optimal QRS-to-T wave ratio) for use as a configuration for sensing. Each detected cardiac signal is sent through several noise detection and 4 double detection algorithms to determine whether oversensing is present.

Two generations of the S-ICD system—EMBLEM A209 and EMBLEM-MRI A219—can apply an additional high-pass filter to the sensing methodology, SP, in order to reduce inappropriate therapy. SP enables the high-pass filter for cardiac sensing only while continuing to use the wide-band ECG for rhythm discrimination purposes (Figure 1). The high-pass filter is activated if the sense vector signal characteristically meets the minimal QRS amplitude requirement (≥0.5 mV). The activated filter is a first-order high-pass filter with corner frequency between 8 and 9 Hz and a roll-off rate of 20 dB/decade. Such a filter allows maximum reduction around the corner frequency and a gradual reduction at lower frequencies, thereby not affecting signals at higher frequencies (>10 Hz). Based on the fundamental frequency of T waves (<9 Hz) and QRS complexes (>10 Hz) observed on surface and subcutaneous electrocardiograms (S-ECGs), SP is more likely to reduce most T waves while allowing accurate sensing of the QRS complex owing to the improved QRS-to-T wave ratio.[13] In an effort to avoid undersensing of low-amplitude ventricular arrhythmias, SP is specifically designed to auto deactivate in the presence of low-amplitude signals (0.25 mV, SP filtered), whether cardiac or noncardiac.

Event adjudication

Before adjudication, all device-stored events were de-identified of patient data and reviewers were blinded to the SP setting (enabled vs disabled). The event adjudication committee composed of 3 investigators experienced in S-ICD and S-ECG interpretation. Two investigators (D.A.M.J.T. and T.F.B.) reviewed the events independently. In case of discordance, the third investigator (V.A.) was consulted to reclassify the event and provide a final decision.

Categories for rhythm classification were polymorphic ventricular tachycardia (PVT)/ventricular fibrillation (VF), monomorphic ventricular tachycardia (MVT), normal sinus rhythm, sinus tachycardia (ST), atrial fibrillation (AF), and supraventricular tachycardia (SVT). Shocks delivered for PVT/VF or MVT above the programmed detection rate were classified as appropriate. Shocks delivered for all other rhythms were classified as inappropriate, including PVT and MVT below the lowest programmed detection rate with oversensing. Reviewers applied standard definitions for ventricular arrhythmias: (1) *MVT* was defined as stable single QRS morphology from beat to beat; (2) *PVT* was defined as changing or multiform QRS morphology from beat to beat; and (3) *VF* was defined as a rapid irregular ventricular activity with marked variability in waveforms, usually with a ventricular rate of >300 betas/min. To assess the interobserver variability, the Cohen's κ statistic and percent agreement between reviewers were calculated.

Therapy characteristics were also evaluated. *Time to therapy* was defined as the interval from the onset of the arrhythmia until delivery of the first shock using the stored