Use of a discrimination algorithm to reduce inappropriate shocks with a subcutaneous implantable cardioverter-defibrillator

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BACKGROUND The subcutaneous implantable cardioverter-defibrillator system (S-ICD) uses a novel detection algorithm previously shown to discriminate induced tachyarrhythmias (ventricular vs supraventricular) effectively.

OBJECTIVE The purpose of this study was to evaluate the role of the S-ICD discrimination algorithm in reducing the incidence of spontaneous inappropriate shocks.

METHODS A total of 314 subjects underwent implantation with an S-ICD system as part of the S-ICD Clinical Investigation (IDE Trial). Subjects were grouped according to programming at discharge to either a single shock zone or 2 shock zones, with a discrimination algorithm in the lower rate zone.

RESULTS This cohort had 226 subjects (72%) with dual zone programming and 88 subjects (28%) with single zone programming. Over a mean follow-up period of 661 ± 174 days, inappropriate shocks occurred in 23 subjects from the dual zone subgroup (10.2%) and 23 subjects from the single zone subgroup (26.1%, $P < .001$), with 2-year inappropriate shock-free rates of 89.7% vs 73.6%;,respectively (hazard ratio 0.38, $P = .001$). Freedom from appropriate shocks did not differ between subgroups (92.2% vs 90.3%, hazard ratio 0.82, $P = .64$). Moreover, mean time to appropriate therapy did not differ between subgroups, and there was only 1 episode of arrhythmic syncope in the cohort.

CONCLUSION The addition of a second shock zone with an active discrimination algorithm was strongly associated with a reduction in inappropriate shocks with the S-ICD system and did not result in prolongation of detection times or increased syncope. These data support the use of dual zone programming as a standard setting for S-ICD patients.

KEYWORDS Subcutaneous implantable-defibrillator; Inappropriate shock; Inappropriate therapy; Supraventricular tachyarrhythmia; Oversensing; Rhythm discrimination

ABBREVIATIONS **ECG** = electrocardiogram; **ICD** = implantable cardioverter-defibrillator; **OR** = odds ratio; **S-ICD** = subcutaneous implantable defibrillator

(Heart Rhythm 2014;11:1352–1358)

Introduction

Implantable cardioverter-defibrillators (ICDs) provide effective therapy for primary and secondary prevention of sudden cardiac death.[1–4] However, implantation of endocardial leads is associated with significant procedural and long-term complications.[5–8] To address this problem, an entirely subcutaneous implantable cardioverter-defibrillator (S-ICD) was developed, potentially eliminating many of the complications associated with traditional transvenous ICDs.[9,10] This novel approach was demonstrated to provide reliable and effective detection and termination of ventricular arrhythmias.[9,11] The device programming provides for a shock zone where rhythms are analyzed strictly based on heart rate analysis and rhythm discrimination is not used. An

Dr. Gold reports consulting fees and research grants from Boston Scientific, Medtronic, St. Jude's Medical, and Sorin, as well as speaking fees with Sorin Group and Biotronik. Dr. Weiss reports consulting fees, speaking fees, and research grants from Biosense Webster, Biotronik, Boston Scientific, Medtronic, and St. Jude's Medical. Dr. Burke reports research grants, speaking fees, and consulting fees from Boston Scientific, Medtronic, and St. Jude's Medical. Drs. Smith and Knight report receiving consulting fees, speaking fees, and research support from Boston Scientific. Dr. Theuns reports receiving institutional grant support and a consulting fee from Boston Scientific. Dr. Leon reports receiving research grants from Boston Scientific. Mr. Carter and Mr. Husby are employees of Boston Scientific. The S-ICD System Investigational Device Exemption Clinical Study was sponsored in its entirety by Cameron Health, Inc., a subsidiary of Boston Scientific Corporation. Clinical Trial Unique identifier: NCT01064076. **Address reprint requests and correspondence:** Dr. Michael R. Gold, Medical University of South Carolina, 25 Courtenay Dr, ART 7031, Charleston, SC 29425-5920. E-mail address: goldmr@musc.edu.

optional conditional shock zone also can be programmed that uses a unique discrimination algorithm to classify rhythms as either shockable or nonshockable, if they are deemed to be supraventricular arrhythmias. We previously showed that the S-ICD discrimination algorithm was more effective than transvenous systems, programmed at nominal settings, for the discrimination of induced supraventricular arrhythmias.[12] However, little is known regarding the effectiveness of the conditional shock zone for arrhythmia discrimination and prevention of inappropriate shocks during treatment of spontaneous episodes with the S-ICD.[11] Accordingly, the present study evaluated the impact of device programming on inappropriate shocks.

Methods

The S-ICD System Clinical Investigation (S-ICD IDE Study) was a 330-patient, single-arm, prospective, nonrandomized, multicenter clinical trial. Details of the trial design and primary endpoints were published previously.[11] In brief, subjects were eligible for enrollment if they were 18 years of age or older and had a guideline indication for ICD implantation. Subjects then were required to pass a preoperative screening surface electrocardiogram (ECG) test. The screening ECG is a modified trichannel surface ECG that mimics the sensing vectors of the S-ICD system. This test is designed to assess the R wave to T wave ratio for appropriate signal characteristics and relationships.

The protocol and consent forms were reviewed and approved by the local Institutional Review Boards or Ethics Committees, and all subjects gave written consent for participation. A total of 314 subjects underwent implantation with the S-ICD system, which constitutes the cohort analyzed in this study.

Spontaneous episode categories

For analysis, all spontaneous shocks were classified as appropriate for ventricular tachyarrhythmias at rates that exceeded the lowest rate zone cutoff and inappropriate for other causes. Inappropriate shocks were subclassified as resulting from supraventricular arrhythmias above the shock zone cutoff, oversensing (T-wave oversensing, noise or myopotentials) or discrimination errors (supraventricular arrhythmias detected within the Conditional Shock zone). Shocks were classified by a clinical events committee.

S-ICD programming

The SQ-RX pulse generator (Boston Scientific; St. Paul, MN) is programmable as a single or dual zone device, as noted earlier. In the single zone configuration, shocks are delivered for detected heart rates above the programmed rate threshold. This zone is termed the *shock zone*. In the dual zone configuration, arrhythmia discrimination algorithms are active in the lower rate zone, termed the *conditional shock zone*.

The conditional shock zone evaluates rates detected from the lower tachycardia detection rate up to the shock zone rate cutoff. This zone is only activated during dual zone programming. With dual zone programming, the shock zone uses rate as the sole method for rhythm analysis, whereas the conditional shock zone uses a stepwise discrimination algorithm to distinguish shockable from nonshockable rhythms. The conditional shock zone has a morphology analysis process that is based on a normal rhythm transthoracic QRS:T wave template that uses up to 41 fiduciary points to reconstruct morphology for the template as well as the programmed targeted heart rate zones. Comparison of the template to the high rate rhythm ECG for discrimination constitutes the static waveform analysis. A good template match designates a sensed beat as supraventricular preventing a shock. A poor match to the static QRS:T morphology template moves the algorithm to a dynamic waveform analysis that compares single beat morphologies in groups of 4 beats for uniformity. A consistent dynamic waveform match moves the sensing to evaluate QRS width. If a tachycardia has a prolonged QRS width compared to the template width (>20 ms) and is of sufficient duration, then it will lead to a shock.

The system uses an initial 18 of 24 duration criteria prior to capacitor charging commencement; however, this duration is automatically extended following nonsustained ventricular tachyarrhythmia events. A confirmation algorithm is also used at the end of capacitor charging to ensure persistence of the ventricular arrhythmia prior to shock delivery.

Shocks for spontaneous (noninduced) episodes are delivered at a nonprogrammable 80 J regardless of the therapy zone of origination. For the IDE Study, programming of zones (single or dual) and the rate cutoffs for each zone were left to the discretion of the implanting physician. Subjects were categorized as single zone or dual zone based on programming values reported at the predischarge visit to create cohorts for this analysis. Programming throughout the follow-up period was left to the discretion of the physician.

Patient follow-up

Enrolled subjects who underwent implantation with an S-ICD system were followed until hospital discharge and at 30 days, 90 days, and 180 days postimplant. After the 180-day follow-up visit, subjects were followed semiannually until study closure. Device interrogations were performed at each scheduled visit. The S-ICD system was also interrogated between scheduled visits if a patient received shocks or experienced an adverse clinical event.

Statistical analysis

All statistical analyses were performed and independently validated using SAS Enterprise Guide, version 4.3 (SAS 9.3, SAS Institute, Inc.; Cary, NC). Data are presented as mean $\pm$ SD, unless noted otherwise. The event-free survivals from inappropriate shocks were compared between groups with the Kaplan-Meier method using the log-rank test and hazard ratios calculated. Unadjusted incidence rates were compared