Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator

Christopher A. Groh, MD, Shishir Sharma, MD, Daniel J. Pelchovitz, MD, Prashant D. Bhave, MD, John Rhyner, MD, Nishant Verma, MD, Rishi Arora, MD, Alexandru B. Chicos, MD, Susan S. Kim, MD, Albert C. Lin, MD, Rod S. Passman, MD, FHRS, Bradley P. Knight, MD, FHRS

From the Division of Cardiology, Department of Medicine, Northwestern University, Chicago, Illinois.

BACKGROUND An electrocardiographic (ECG) screening test has been developed to identify patients being considered for a totally subcutaneous implantable cardioverter-defibrillator (S-ICD) at risk for T-wave oversensing.

OBJECTIVE The purpose of this study was to determine the proportion of potential S-ICD recipients who fail the ECG screening test and to identify predictors of failure.

METHODS Patients who already have an ICD but are not receiving antibradycardia pacing are representative of patients who might be considered for an S-ICD. One hundred such outpatients were enrolled in the study. Surface rhythm strips were recorded along the sensing vectors of the S-ICD system and the screening template applied. Clinical and standard ECG characteristics of patients who failed the test were compared to those who passed.

RESULTS Patients had the following characteristics: 72% male, age 57 ± 16 years, body mass index 29 ± 6 kg/m^2, left ventricular ejection fraction 43% ± 17%, QRS duration 109 ± 23 ms, QTc interval 447 ± 39 ms, 44% had coronary disease, and 55% had heart failure. Among the 100 patients, 8% failed the screening test. There were no differences in patient clinical characteristics and most standard ECG measurements. However, patients with T-wave inversions in standard ECG leads I, II, and aVF had a 45% chance of failing.

CONCLUSION Eight percent of potential S-ICD patients were not eligible for the S-ICD after failing the screening test designed to identify patients susceptible to T-wave oversensing. Patients with T-wave inversions in leads I, II, and aVF on a standard ECG were 23 times more likely to fail. More work is needed in S-ICD sensing algorithms to increase patient eligibility for the S-ICD.

KEYWORDS Subcutaneous implantable cardioverter-defibrillator; T-wave oversensing; Defibrillator screening; Implantable cardioverter-defibrillator; Inappropriate shocks

ABBREVIATIONS **ECG** = electrocardiogram; **ICD** = implantable cardioverter-defibrillator; **S-ICD** = subcutaneous implantable cardioverter-defibrillator; **TWI** = T-wave inversion

(Heart Rhythm 2014;11:1361–1366)

Introduction

Implantable cardioverter-defibrillator (ICD) systems have been proven to be effective in decreasing mortality in carefully chosen patient populations.[1] Until recently, the only means of implanting a defibrillating system was to place high-voltage leads on either the epicardial aspect of the heart via a surgical approach or on the endocardial aspect of the heart via a transvenous approach. Totally subcutaneous implantable cardioverter-defibrillator (S-ICD) systems have been developed and have been shown to be effective in detecting and terminating ventricular fibrillation in multiple studies.[2–6] Despite the proven efficacy of the S-ICD, this device carries the risk of T-wave oversensing and subsequent inappropriate shock delivery, as also occurs with transvenous ICDs.[7] Inappropriate shocks have been associated with reduced quality of life and increased mortality in some studies.[8] Consequently, a screening template has been designed by the S-ICD manufacturer (Boston Scientific, Natick, MA) to identify these susceptible patients based on a modified preimplantation surface waveform in the 3 S-ICD sensing vectors. The purpose of this study was to determine how often patients pass this screening test and if there were any clinical or standard electrocardiographic (ECG) predictors of failure.

This study was supported by a grant from Boston Scientific. Dr. Knight receives honoraria for speaking and for consulting for Boston Scientific.
Address reprint requests and correspondence: Dr. Bradley P. Knight, Center for Heart Rhythm Disorders, Bluhm Cardiovascular Institute, Northwestern Memorial Hospital, Northwestern University, Feinberg School of Medicine, 251 E Huron St, Feinberg 8-503E, Chicago, IL 60611. E-mail address: bknight@nmff.org.

1547-5271/$-see front matter http://dx.doi.org/10.1016/j.hrthm.2014.04.025

Methods

Study population

The Northwestern University Institutional Review Board approved this study. Written informed consent was obtained from each subject prior to enrollment in the study. To identify a patient population that would be representative of patients who might be potential candidates for the S-ICD system, patients who had previously undergone implantation of a transvenous ICD for primary or secondary prevention and who were not receiving bradycardia pacing and did not have an indication for pacing were identified during a routine outpatient device interrogation between July 1, 2013 and December 6, 2013. A total of 103 patients consented to the study. Three patients were excluded after ICD interrogation when the screening waveform demonstrated pacing or an indication for pacing (i.e., heart rate <40 bpm), for a total enrollment of 100 patients.

Screening waveform

Screening waveforms were obtained using the Boston Scientific Zoom Latitude Programmer (Boston Scientific, Natick, MA). ECG leads were placed in the standard manufacturer configuration for the Boston Scientific S-ICD system (Figure 1). Electrode placement was 1 cm lateral to the xiphoid process (LA), 14 cm cranial to the xiphoid process on the chest wall (RA), and either the fifth or sixth intercostal space on the left midaxillary line (LL). A ground electrode was placed on either the clavicle or a soft tissue location on the right lower extremity. This electrode configuration was designed to mimic the sensing vectors available on the S-ICD. Using the Zoom Latitude Programmer, screening waveforms were initially obtained in the supine position at gains of 5, 10, and 20 mV for a period of 10 seconds at a paper speed of 25 mm/s in each of the 3 lead vectors (Figure 1). This process was repeated in the standing position. Candidacy was determined via the Boston Scientific screening template (Figure 2A). A patient qualified if the ECG screening template passed in any same lead supine and standing, at any gain, and without significant morphologic changes in QRS complexes. Either the maximal R or S wave in the QRS complex was required to fit between horizontal dashed and solid lines and the width of the complex within the vertical solid lines in a template box (Figure 2B). The associated T wave was also required to fit within the trailing outline of the template box with the isoelectric line determined by the preceding T-P segment (Figures 2B and 3). If any QRS complex aside from artifact beats was clipped by voltage parameters, the respective lead tracing was excluded at that gain but still was eligible for review at other gains and positions (supine/standing). If any QRS complex was clipped at a specific gain, the respective lead tracing was excluded at that gain, but the patient was still eligible for review at other gains and positions (supine/standing). Similarly, if any QRS complex was too small to fit in the smallest colored template, the respective lead tracing was excluded at that gain, but the patient was still eligible for review at other gains and positions (supine/standing). However, if a QRS complex was clipped at the lowest gain in all 3 leads, the patient would fail the screening test and was ineligible. Each QRS–T-wave association was reviewed across every tracing with all complexes required to meet the above standards for candidacy. The tracings were reviewed by a minimum of 2 reviewers, with screening failures confirmed by a third reviewer.

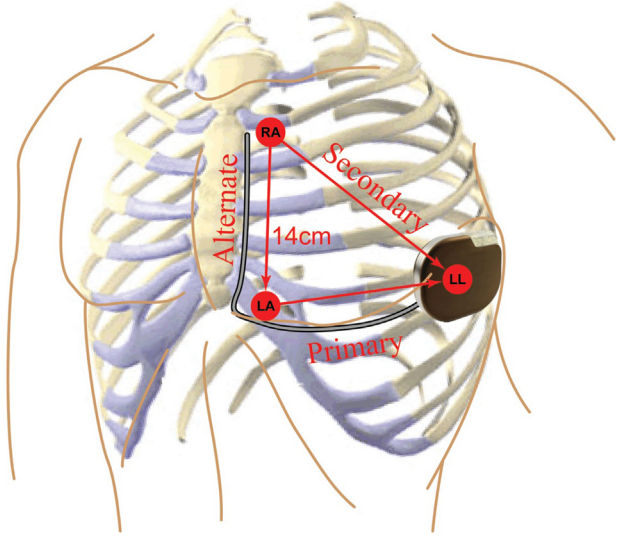

Figure 1 Diagram of subcutaneous implantable cardioverter-defibrillator lead vectors and placement of the surface electrodes (*red circles*) during screening. The primary lead vector extends from 1 cm left lateral of the xiphoid process (LA) to the fifth or sixth intercostal space in the left midaxillary line (LL). The secondary lead vector is formed from 14cm cranially to LA (RA) to LL. The alternate lead vector extends from RA to LA.

ECG analysis

Additional analysis was performed on the patient's most recent surface ECG. Leads I, II, and aVF were assessed because these leads shared the most similar vectors with the S-ICD system (Figure 1). Maximum QRS amplitude (absolute maximum deflection from isoelectric line), T-wave amplitude, presence of T-wave inversion (TWI), and discordancy of QRS/T-wave amplitude all were assessed on the surface ECGs. Additional parameters obtained include QRS duration, QT interval, QTc (as determined by Bazett formula), QRS axis, and T-wave axis.

Statistical analysis

Continuous and normally distributed data are reported as mean $\pm$ SD; categorical data are expressed as percentages. Independent Student t test and χ^2 test were used to compare continuous and categorical data, respectively. $P < .05$ was considered significant.

Results

Patient characteristics

The demographic and clinical characteristics of the patients are listed in Table 1. After application of the screening template, 8 patients failed S-ICD candidacy. Comparative