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Sensitivity and specificity of the subcutaneous implantable cardioverter defibrillator pre-implant screening tool

Mehmood Zeb [a,c,*], Nick Curzen [a,c], Venugopal Allavatam [b], David Wilson [a,b], Arthur Yue [a], Paul Roberts [a], John Morgan [a,c]

[a] Wessex Cardiac Unit, Southampton University Hospitals NHS Trust, United Kingdom
[b] Boston Scientific, United Kingdom
[c] Faculty of Medicine University of Southampton, United Kingdom

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ABSTRACT

Background: The sensitivity and specificity of the subcutaneous implantable cardioverter defibrillator (S-ICD) pre-implant screening tool required clinical evaluation.
Methods: Bipolar vectors were derived from electrodes positioned at locations similar to those employed for S-ICD sensing and pre-implant screening electrodes, and recordings collected through 80-electrode PRIME®-ECGs, in six different postures, from 40 subjects (10 healthy controls, and 30 patients with complex congenital heart disease (CCHD); 10 with Tetralogy of Fallot (TOF), 10 with single ventricle physiology (SVP), and 10 with transposition of great arteries (TGA)). The resulting vectors were analysed using the S-ICD pre-implant screening tool (Boston Scientific) and processed through the sensing algorithm of S-ICD (Boston Scientific). The data were then evaluated using 2×2 contingency tables. Fisher exact and McNemar tests were used for a comparison of the different categories of CCHD, and $p < 0.05$ vs. controls considered to be statistically significant.
Results: 57% of patients were male, mean age of 36.3 years. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the S-ICD screening tool were 95%, 79%, 59% and 98%, respectively, for controls, and 84%, 79%, 76% and 86%, respectively, in patients with CCHD ($p = 0.0001$).
Conclusion: The S-ICD screening tool was comparatively more sensitive in normal controls but less specific in both CCHD patients and controls; a possible explanation for the reported high incidence of inappropriate S-ICD shocks. Thus, we propose a pre-implant screening device using the S-ICD sensing algorithm to minimise false exclusion and selection, and hence minimise potentially inappropriate shocks.

1. Introduction

Implantable cardioverter defibrillators (ICDs) are considered to be the most effective treatment for primary and secondary prevention of sudden cardiac death (SCD) [1–5]. The main function of ICD is to sense and terminate potentially fatal ventricular arrhythmias. However, the conventional transvenous ICDs carry risks of a variety of complications [6–8]. These complications include procedural (bleeding, pneumothorax, vascular damage and myocardial perforation), short-term (infection, thrombosis) and long-term (lead failure, inappropriate shocks) factors [8].

The use of transvenous ICD is conservative in patients with congenital heart diseases (CHD) because of the anatomical challenges and higher risk of lifelong complications; despite the fact that these people experience a high rate of SCD at young age and would benefit most from ICD [9,10]. The totally subcutaneous implantable cardioverter defibrillator (S-ICD) has been developed, and used in a selected number of patients because of the limitations of transvenous ICD. S-ICDs are entirely subcutaneous, and aim to reduce complications through avoidance of the use of intracardiac leads [11–13]. However, despite these advantages, the S-ICD is limited by the inability to provide anti-tachy pacing (ATP) and can provide post-shock brady pacing for 30 s only [11]. Additionally, selection for S-ICD implant is based on pre-implant electrographic body surface mapping [14].

The S-ICD consists of a pulse generator (SQ-RX® pulse generator, Boston Scientific) [14], implanted subcutaneously in the left mid-axillary line at the level of the fifth and sixth intercostal spaces [14]. The L-shaped S-ICD lead (Q-TRAK® lead, Boston Scientific) is inserted subcutaneously and has two segments, (i) a horizontal segment which is attached to the S-ICD pulse generator and continues as (ii) a vertical segment parallel to the left sternum edge [14]. This configuration offers three sensing vectors (Fig. 1) [11,15]. Pre-implant screening identifies the most appropriate sensing vector, which is then confirmed by post-implant device interrogation. However, the current generation of S-ICD does not automatically select the sensing vector. The S-ICD uses

* Corresponding author at: Clinical Cardiology Research Fellow, Wessex Cardiothoracic Unit, Southampton University Hospitals, Tremona Road, Southampton SO16 6YD, United Kingdom.
E-mail address: mehmoodzeb@hotmail.com (M. Zeb).

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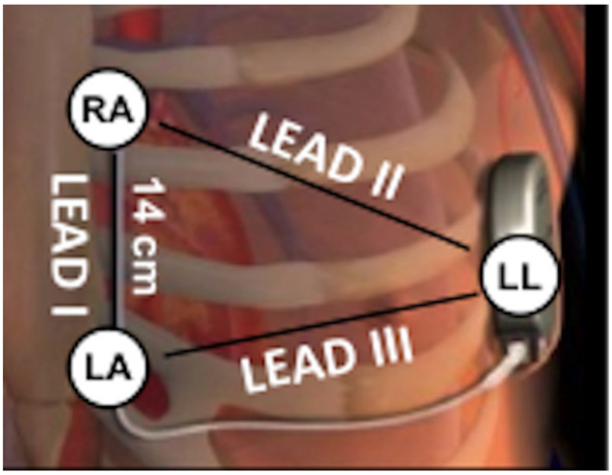

Fig. 1. S-ICD generator and lead position. This figure shows the position of subcutaneous sensing arrays and location of bipolar three lead ECG placement to generate Lead I, Lead II and Lead III for S-ICD pre-implant screening [ECG = electrocardiology, S-ICD = subcutaneous implantable cardioverter defibrillator]. Reproduced with permission from Boston Scientific Inc.

subcutaneous electrocardiogram (ECG) signals to monitor cardiac output and discriminate between shockable and non-shockable rhythms [15].

Early trials of S-ICD defibrillation ability have demonstrated effective termination of VT and VF similar to transvenous ICDs [11,15]. However, recent clinical studies have reported inappropriate shocks in at least 7–13% cases within one year of implant suggesting that the sensing algorithm requires further evaluation [11,12,15–21].

Bellardine et al. have demonstrated a good correlation between subcutaneous and the corresponding transcutaneous body surface ECGs [22], suggesting that it is feasible to study the sensing algorithm of S-ICD through surface ECG measurements. Additionally, patient selection for S-ICD implant is based on pre-implant screening; carried out using a three-lead surface ECG, acquired in both supine and standing postures. The ECG tracings are then mapped out using the Boston Scientific screening tool; intended to identify patients with acceptable sensing characteristics [14,15]. However the diagnostic and discriminatory ability (sensitivity and specificity) of the pre-implant screening tool against the sensing algorithm of S-ICD is not known.

In this study we have tested the sensitivity and specificity of the pre-implant screening tool against the sensing algorithm of the S-ICD in six postures (standing, sitting, supine, left lateral, right lateral, prone) for three vectors. Four subgroups were considered; including normal adults and adults with complex congenital heart diseases (Tetralogy of Fallot (TOF), transposition of great arteries (TGA) and single ventricle physiology (SVP)).

2. Method

This observational study was conducted at the tertiary care cardiology centre of our university teaching hospital. Patients were identified from their records upon presentation to the inpatient and outpatient departments and anonymised by assignment of a unique ID number.

This study received approval from an independent review board of the Southampton University Hospital & South West Hampshire Research Ethics Committee B (REC 08/H0504/55).

2.1. Study population

All the subjects were aged 18 years or over and had the ability to give informed consent.

Forty patients were recruited into the following subgroups.

1. Ten adults with morphologically normal heart on transthoracic echocardiography and cardiac magnetic resonance imaging (half of these patients had assessment with late gadolinium enhancement at the discretion of the attending radiologist and showed no abnormality).
2. Ten adults with TOF.
3. Ten adults with TGA.
4. Ten adults with SVP.

Patients in arrhythmias and paced rhythm were excluded from the study.

2.2. Electrocardiographic data collection

Electrocardiographic body surface mapping was performed through 80-electrode ECG (PRIME®-ECG Verathon Inc.); consisting of an on-board computer and flexible plastic anterior and posterior electrode vests, as described previously [23,24]. The anterior vest contains 64 electrodes and the posterior vest contains 16 electrodes, thus enabling the recording of 80 simultaneous ECG signals [23,24]. The vests are arranged in vertical strips referenced to their anatomical landmarks. In each subject, 80-electrode ECGs were recorded in six postures (standing, sitting, supine, left lateral, right lateral, prone), for 10 s, at a sweep speed of 25 mm/s, and a sampling rate of 1 kHz. Adequate adhesion of individual ECG skin electrodes and good quality signal collection were ensured through prior skin preparation, shaving hair where necessary and using alcohol wipes. Three bipolar vectors were created from electrodes at locations mimicking the placement of the S-ICD sensing electrodes as recommended by the manufacturers (Boston Scientific) for pre-implant screening (Fig. 1) [14]. The bipolar vectors Lead I, Lead II and Lead III were derived, representing surface ECG equivalent of Boston Scientific sense vectors (Primary = Lead III, Secondary = Lead II, Alternate = Lead I). Each vector was created at gain 5, 10, 15 and 20 mm/mV.

2.3. Screening tool and bipolar vector analysis

The manufacturer of the currently available S-ICD (Boston Scientific) recommends pre-implant screening through surface ECG in all patients considered for S-ICD. A pre-implant screening tool is used to identify patients with acceptable sensing characteristics, prior to the implant of S-ICD. This is a printed chart, containing six profiles of varying morphology, with a horizontal line passing through all the colour profiles to adjust with the baseline. Each colour profile has an identical window above and below the baseline; to account for positive or negative amplitude of the R-wave and T-wave. Each window is subdivided by dotted lines and the peak of the R-wave has to lie within this sub-window for of one of the six profiles to be appropriate for sensing. Additionally, the trailing T-wave has to be contained within the same colour profile as the R-wave for the vector to be appropriate for sensing (Fig. 2) [14]. This screening tool was used to evaluate each vector. A coloured map from the screening tool that best matched the amplitude and duration of the QRS complex and the T-wave was determined. For biphasic signals, the larger peak was used. The left-hand edge of the selected coloured map was aligned with the onset of the QRS complex. The horizontal line on the coloured template was used as a guide for isoelectric baseline alignment. The QRS peak had to be within the window bounded by the dotted line and the peak of the coloured profile (Fig. 2). If, when printed at the maximum 20 mm/mV gain, the QRS peak did not reach the minimum boundary (dotted line) of the smallest coloured profile, the vector was considered unacceptable. If the entire QRS complex and trailing T-wave were contained within the coloured profile, the vector/posture combination was considered suitable. If any portion of the QRS complex or trailing T-wave extended outside the coloured profile, the sense vector was considered unacceptable. All vectors were examined individually at four gain settings (5, 10, 15 and 20 mm/mV);