Defibrillation testing is mandatory in patients with subcutaneous implantable cardioverter–defibrillator to confirm appropriate ventricular fibrillation detection

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BACKGROUND The subcutaneous implantable cardioverter–defibrillator (S-ICD) remains a new technology requiring accurate assessment of the various aspects of its functioning. Isolated cases of delayed sensing of ventricular arrhythmia have been described.

OBJECTIVE The purpose of this multicenter study was to assess the quality of sensing during induced ventricular fibrillation (VF).

METHODS One hundred thirty-seven patients underwent induction of VF at the end of the S-ICD implantation.

RESULTS VF induction was successful in 133 patients (97%). Mean time to first therapy was 16.2 ± 3.1 seconds, with a substantial range from 12.5 to 27.0 seconds. Four different detection profiles were arbitrarily defined: (1) optimal detection (n = 39 [29%]); (2) undersensing with moderate prolongation of time to therapy (<18 seconds; n = 68 [51%]); (3) undersensing with significant prolongation of the time to therapy (>18 seconds; n = 19 [14%]); and (4) absence of therapy or prolonged time to therapy related to noise oversensing (n = 7 [6%]). In some of the patients in the last group, despite induction of VF the initial counter was never filled, the device did not charge the capacitors, and the shock was not delivered because of a sustained diagnosis of noise (n = 5). A manual shock by the device or an external shock had to be delivered to restore the sinus rhythm.

CONCLUSION Our study demonstrated a marked sensing delay leading to prolonged time to therapy in a large number of S-ICD patients. A few worrisome cases of noise oversensing inhibiting the therapies were detected. These results support the need for systematic intraoperative defibrillation testing.

KEYWORDS Complication; Defibrillation testing; Noise; Subcutaneous implantable cardioverter–defibrillator; Undersensing

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Introduction

The subcutaneous implantable cardioverter–defibrillator (S-ICD) represents an efficient alternative to a transvenous device in patients who do not require pacing and who are at risk for device-related complications over their lifetime.[1–3] The S-ICD is entirely extrathoracic and leaves the heart and vasculature untouched. Avoiding the intravascular space with an S-ICD completely modifies the sensing characteristics compared to the "near-field" sensing of a transvenous system because subcutaneous signals have lower amplitude, longer duration, and lower frequency

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Table 1 Patient baseline characteristics

No. of patients	137
Age (years)	48 ± 15
Male	96 (70%)
Ischemic heart disease	52 (38%)
Hypertrophic cardiomyopathy	18 (13%)
Brugada syndrome	17 (12%)
Idiopathic VT/VF	17 (12%)
Dilated cardiomyopathy	16 (12%)
Myocarditis	6 (4%)
Arrhythmogenic right ventricular cardiomyopathy	5 (4%)
Long QT syndrome	4 (3%)
Noncompaction cardiomyopathy	2 (2%)
Mean ejection fraction (%)	47 ± 16
Primary prevention implant	77 (56%)

Values are given as mean ± SD or n (%) unless otherwise indicated.
VF = ventricular fibrillation; VT = ventricular tachycardia.

content with greater postural variation. The S-ICD remains a new technology that requires scrutiny of the different characteristics of its functioning and demonstration of a comparable efficacy with an extensively validated reference. Cases of delay in sensing and treating of ventricular arrhythmia episodes have been described.[4] The results of the SIMPLE (Shockless IMPLant Evaluation) study question the value of perioperative defibrillation testing (DFT) in individuals undergoing transvenous ICD implantation.[5] In contrast, DFT is systematically performed at implant of an S-ICD to confirm appropriate sensing and successful 65- J termination of induced ventricular fibrillation (VF). Extensive data on the quality of sensing during intraoperative DFT in S-ICD patients are limited.[6,7]

In this multicenter observational study, the quality of sensing in 137 consecutive patients with an S-ICD undergoing intraoperative defibrillation tests was systematically evaluated.

Methods

Patients

The study was approved by the Institutional Committee on Human Research at the authors' institution, and all patients provided informed consent for S-ICD implantation and testing. One hundred thirty-seven consecutive S-ICD systems were implanted in 4 institutions and were retrospectively analyzed. Patient baseline characteristics are summarized in Table 1.

Implantation procedure

Implantation was performed with the patient under general anesthesia using a technique involving 2 or 3 incisions and placement of the midaxillary pulse generator under the subcutaneous tissue or intermuscularilly.[8]

Intraoperative defibrillation test

The device automatically selected the sensing vector. All patients underwent standardized intraoperative defibrillation test by delivery, via the programmer, of a 50-Hz DC burst for 4–10 seconds. During the induction, the number of zones (1 single shock zone or 1 shock zone and 1 conditional zone) and the zone cutoffs were programmed according to the physician's choice as follows: (1) 1 single zone programmed from 170–200 bpm (n = 77); (2) 2 zones with a conditional zone from 170–200 bpm and a shock zone from 200–230 bpm (n = 56); and (3) 2 zones with a conditional zone at 220 bpm and a shock zone at 240 bpm (n = 4). The first shock energy was programmed to 65 J, and the second shock energy was programmed to 80 J in reversed polarity followed by external rescue shocks if ineffective.

Sensing with an S-ICD

The S-ICD system senses subcutaneous signals from a dipole defined as primary (proximal electrode ring to can), secondary (distal electrode ring to can), or alternate (distal to proximal electrode) vector. After implantation, the system automatically selects the optimal vector for detection and gain combination based on the R- to T-wave amplitude ratio to avoid QRS and T-wave oversensing.

To minimize undersensing of VF and to prevent T-wave oversensing, the device operates with a low sensing floor (0.08 mV or 80 μV) and a low high-pass filter (3 Hz) that cannot be altered in any manner.

The S-ICD sensing algorithm comprises 3 phases:

1. The sensed event detection phase filters the input signal and generates sensed events for further analysis. The S-ICD uses automatic sensitivity adjustment to reduce T-wave oversensing and sensing refractory periods to prevent R-wave double-counting with different profiles. The sensing threshold is adjusted based on the amplitude of the preceding 2 QRS complexes. Once an elevated heart rate is certified, threshold stringency is progressively relaxed as the heart rate increases. The refractory period and the decay profile are more sensitive in the shock zone than in the conditional zone. Therefore, addition or removal of a tachycardia detection zone alters the sensing profile on a beat-to-beat basis.
2. The certification phase classifies the sensed events as certified QRS complexes or as suspected oversensing events and calculates an accurate ventricular rate. A waveform algorithm uses frequency and slew rate analysis to ensure the signal is cardiac in origin and to reject myopotentials and electromagnetic interference, corresponding to the "N" (noise) marker on the electrogram (EGM). The intervals associated with the noise events are discarded. The remaining sensed events are then passed through 4 certification algorithms to recognize and correct for R-wave double-counting and T-wave oversensing. A dot "•" marker on the EGM labels the uncertified "oversensed" events. The S-ICD measures heart rate as the rolling average of 4 consecutive certified intervals.
3. The decision phase detects VF and ventricular tachycardia (VT) and discriminates the latter from a supraventricular tachycardia (SVT). In the shock zone, the device detects VF using only rate and duration. In the conditional zone, the device also uses SVT–VT discrimination based on "static" EGM morphology (comparison with sinus template), QRS duration, and "dynamic" EGM morphology.