Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave oversensing can be prevented: Implications for management

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BACKGROUND Inappropriate shocks (IASs) complicate implantable cardioverter-defibrillator (ICD) therapy. The management of IASs in patients with a subcutaneous ICD (S-ICD) differs from that in patients with a conventional ICD because of different sensing algorithms and programming options.

OBJECTIVE To describe the management of IASs in patients with an S-ICD.

METHODS Patients were implanted with an S-ICD between February 2009 and July 2012. The prevalence data and clinical determinants of IASs were prospectively collected. In the case of T-wave oversensing (TWOS), an exercise test was performed, and all possible sensing vectors were screened for TWOS. The absence of TWOS defined a suitable vector.

RESULTS Eleven of 69 patients (54% men; mean age 39 ± 14 years; 73% primary prevention) received IASs after 8.9 ± 10 months of implantation (10.8% annual incidence rate). In 8 cases, TWOS caused IASs. Seven of these IASs occurred during exercise and 1 during atrial fibrillation with a high ventricular rate. To manage TWOS, in 7 of 8 patients the sensing vector was changed and in 5 of 8 patients the (un)conditional zone was changed. Hereafter, IASs recurred in 3 of 8 patients, in 2 because of programming errors. Hence, after reprogramming, we observed no IASs in 87.5% of the patients with TWOS during a follow-up of 14.1 ± 13 months.

CONCLUSIONS IASs due to TWOS in the S-ICD can be managed by reprogramming the sensing vector and/or the therapy zones of the device using a template acquired during exercise. Exercise-optimized programming can reduce future IASs, and standard exercise testing shortly after the implantation of an S-ICD may be considered in patients at an increased risk for TWOS.

KEYWORDS Implantable cardioverter-defibrillator; Subcutaneous ICD; ICD sensing; ICD programming; Inappropriate shocks; T-wave oversensing

ABBREVIATIONS **BBB** = bundle branch block; **ECG** = electrocardiogram/electrocardiography; **IASs** = inappropriate shocks; **ICD** = implantable cardioverter-defibrillator; **LVEF** = left ventricular ejection fraction; **RBBB** = right bundle branch block; **S-ICD** = subcutaneous implantable cardioverter-defibrillator; **TV-ICD** = transvenous implantable cardioverter-defibrillator; **TWOS** = T-wave oversensing

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Introduction

The implantable cardioverter-defibrillator (ICD) reduces mortality in survivors of cardiac arrest and patients at high risk for sudden cardiac death.[1] Despite the significant reduction in mortality, there is also a risk for serious complications owing to ICD therapy. Among those are acute and long-term complications related to the transvenous lead and the occurrence of inappropriate shocks (IASs) due to lead failure, supraventricular arrhythmias, or oversensing of myopotentials or electromagnetic interference.[2] Supraventricular arrhythmias have been found to be the most common cause of inappropriate therapy in patients with a transvenous ICD (TV-ICD).[3] An entirely subcutaneous ICD (S-ICD) was developed with the potential to reduce or prevent complications associated with the implantation and long-term performance of transvenous leads. However, this remains an assumption because no long-term data are available on the performance of the subcutaneous lead.

The S-ICD was approved for general use within Europe in 2009 and within the United States in 2012 as an alternative to the TV-ICD in patients with an ICD indication but without an indication for bradycardia pacing, cardiac resynchronization therapy, or the need for antitachycardia pacing. Safety and efficacy of the S-ICD have been described previously.[2,4] Multicenter experience[5–9] showed that in 295 patients with an S-ICD, 27 (9.2%) received a total of 68 IASs during a mean follow-up of 11.2 (range 8–18) months. The rate of

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IASs in patients with a TV-ICD has been reported as 7% and 13% after 1 and 2 years, respectively.[10] However, contemporary programming has reduced the number of IASs.[11,12] IASs as complication from ICD therapy can have adverse effects on the quality of life, psychological stress, or even the induction of ventricular arrhythmias.[13] The most common cause of IASs in the S-ICD was double counting of the cardiac signal owing to T-wave oversensing (TWOS).[5–9] Hence, IASs due to TWOS appear to be a considerable problem in patients with an S-ICD. The sensing algorithm and programming options of the S-ICD are different from those of a TV-ICD. The most important differences are that the S-ICD uses the extracardiac (subcutaneous) electrocardiogram (ECG) for sensing and the TV-ICD uses the bipolar intracardiac ECG. The sensing algorithm in the S-ICD is fixed and can only be modified indirectly by changing the frequency of the therapy zones. In addition, the discrimination algorithm is fixed and can only be affected by changing the stored template. Therefore, the management of IASs in patients with an S-ICD is different from that in patients with a conventional ICD. We report the management of IASs in patients with an S-ICD in a single center with a large cohort of patients with an S-ICD.

Methods

Study population and data collection

From 100 patients implanted with an S-ICD between February 2009 and July 2012, we selected patients (n = 69) who had a class I or IIa indication for ICD therapy according to AHA/ACC/ESC 2008 guidelines,[14] without an indication for bradycardia pacing, cardiac resynchronization therapy, or antitachycardia pacing. Patients (n = 31) participating in the ongoing PRAETORIAN trial[15] (NCT01296022; a randomized, multicenter efficacy trial comparing S-ICD and TV-ICD) were excluded because IASs are included in the end points of that study and the protocol does not permit double publication of patients. Patients (n = 39) participating in the retrospective EFFORTLESS Registry[16] (NCT01085435; an observational study of factors that affect clinical outcome and cost-effectiveness of the S-ICD) were for that reason not excluded.

Three patients underwent S-ICD implantation before Conformité Européenne (CE) approval and gave written informed consent. After CE approval, the S-ICD was used as clinical practice and patient provided procedural consent. Approval for this retrospective study by the institutional review board was not required.

All patients underwent a screening ECG preimplantation and were found suitable for S-ICD implantation on the basis of the ECG screening tool (Figure 1). The screening ECG was obtained by recording the ECG from the location of the 3 sensing electrodes of the S-ICD (Figure 2) and mimics the sensing vectors used by the S-ICD: primary (proximal electrode to can), secondary (distal electrode to can), and alternate (distal electrode to proximal electrode). An ECG recording of these 3 vectors was obtained for at least 10 seconds in both a supine and a standing position. Initially, screening was performed with at least 1 acceptable QRS-T complex in at least 1 sensing vector in a supine and a standing position as recommended by the user manual at that time.[19] However, when multiple QRS-T complexes were found unsuitable, the S-ICD was considered contraindicated in that patient. After CE approval, the manufacturers' recommendation changed and more stringent ECG screening for T-wave analysis was implemented. Now, all QRS-T complexes for the duration of at least 10 seconds should be suitable in both supine and standing positions. Left ventricular ejection fraction (LVEF) was determined by using magnetic resonance imaging or transthoracic echocardiography, creatinine levels in blood by using ECG, and the use of cardiac/psychotropic medication were obtained from the patients' medical record. The choice of these variables was based on their direct and indirect effects on the morphology of the R and T waves on the surface ECG.[17,18]

Implantation and device programming

Forty-two patients underwent the procedure under general anesthesia and 27 patients under local anesthesia and conscious sedation. Antibiotic prophylaxis was administered according to local protocol. No fluoroscopy was used. A lowest effective defibrillation test was performed at least once, with a minimum shock of 65 J unless contraindicated. In the case of failure of the first shock, a second shock was automatically programmed at 80 J with reversed polarity.

During implantation, an incomplete automatic setup was performed, the automatically chosen sensing vector was programmed, and a QRS morphology template was acquired.

Discrimination between ventricular tachycardia and supraventricular tachycardia in the conditional zone (which can be programmed between 170 and 240 beats/min) is based on rate and morphology. If an average of 4 sensing events meets the programmed rate of the conditional zone, the fixed discrimination algorithm discriminates "similar" from "dissimilar" sensing events on the basis of programmed template, beat-to-beat similarity, and QRS width. The unconditional zone (170–250 beats/min) uses exclusively rate criteria for detection. Selection and programming of the therapy zones was at the discretion of the implanting physician. A complete automatic setup was performed, and the automatically chosen sensing vector and newly acquired template were programmed on the first postoperative day. Patients were seen within 2 weeks and after 2 months of implantation. Thereafter, patients visited the outpatient clinic semiannually.

Follow-up

Data from every follow-up visit and unplanned visits were stored in the clinical database system. Up to April 1, 2010, an automatic setup was performed at every routine visit and the suggested vector was programmed. After April 1, 2010, we performed only the automatic setup predischarge as advised