Shock Efficacy of Subcutaneous Implantable Cardioverter-Defibrillator for Prevention of Sudden Cardiac Death

Initial Multicenter Experience

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Background—Recently, subcutaneous implantable cardioverter-defibrillator (S-ICD) has become available. The aim of our study was to assess the efficacy of S-ICD in a clinical setting.

Methods and Results—Between June 2010 and July 2011, 40 consecutive patients (42±15 years; body mass index, 27±6 kg/m²; left ventricular ejection fraction, 47±15%; 28 men) received an S-ICD for primary (n=17) or secondary prevention (n=23 [58%]) at 3 institutions in Germany. Intraoperative defibrillation efficacy testing failed in 1 patient with severely reduced left ventricular ejection fraction; testing was effective in all other patients. All episodes stored in the S-ICD were analyzed for appropriate and inappropriate detection, as well as effective shock delivery to convert ventricular tachyarrhythmia into sinus rhythm. During a median follow-up of 229 (interquartile range, 116–305) days, 4 patients experienced 21 episodes, with correct detection of ventricular tachyarrhythmia and subsequent shock therapy. A total of 28 shocks were delivered in these 4 patients. Mixed logistic regression modeling revealed a shock efficacy of 96.4% (95% CI, 12.8%–100%). The efficacy of first shocks, however, was only 57.9% (95% CI, 35.6%–77.4%). Four episodes were incorrectly classified as ventricular tachyarrhythmia, which led to inappropriate shock delivery in 2 patients.

Conclusions—Ineffective shock delivery may occur in patients with S-ICD, even after successful intraoperative testing. Multicenter trials are required with close monitoring of safety and efficacy end points to identify patients who may be at risk for shock failure. (Circ Arrhythm Electrophysiol. 2012;5:913-919.)

Key Words: implantable cardioverter-defibrillator • ventricular tachyarrhythmia • implantable cardioverter-defibrillator shock failure • defibrillation threshold • subcutaneous implantable cardioverter-defibrillator

Implantable cardioverter-defibrillator (ICD) therapy is established as the best option to prevent sudden cardiac death because of ventricular tachyarrhythmia in patients with both a primary and a secondary prevention indication. However, with the increasing application of transvenous ICDs and higher patients’ life expectancy, long-term technical difficulties, such as lead failure or device infection, have become important issues in clinical practice. In addition, complications during lead placement, such as lead dislocation, perforation, or pneumothorax, bear a substantial perioperative risk.

The subcutaneous ICD (S-ICD) offers an alternative, novel approach to avoid lead-associated complications. A first report from a single center has shown a promising device performance, with a sensitivity of 100% to detect ventricular tachyarrhythmia and 100% cardioversion efficacy. Here, we report an initial multicenter experience with patients offered the S-ICD for both primary and secondary preventions of sudden cardiac death.

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Methods

Patients
The study included all 40 consecutive patients (42±15 years [range, 19–73 years]; 28 men [70%]) undergoing S-ICD implantation between June 2010 and July 2011 at the Department of Cardiology/Electrophysiology of the University Heart Center at the University Medical Center Hamburg-Eppendorf (13 implants), Germany; the Department of Cardiology and Angiology, Division of Experimental and Clinical Electrophysiology, Hospital of the Westfälische Wilhelms-University, Münster (20 implants), Germany; and the Department of Cardiology, Heart Center Brandenburg in Bernau, Berlin (7 implants), Germany. Pertinent characteristics of the 40
patients are listed in Table 1. Of note, the majority of our patients had an indication for secondary prevention (n=23; 58%).

**Patient Selection**

Files of all patients receiving an S-ICD between June 2010 and July 2011 at the participating institutions were reviewed for this report. Patients were selected for an S-ICD if they fulfilled the indication criteria specified by the American College of Cardiology/American Heart Association/European Society of Cardiology guidelines for primary or secondary prevention of sudden cardiac death.1 According to the recommendations given by the manufacturer, the S-ICD was not implanted in patients with symptomatic bradycardia, incessant ventricular tachycardia, or documented spontaneous, frequently recurring ventricular tachycardia that was reliably terminated with antitachycardia pacing. Patients with pacemakers were also classified as not suitable for an S-ICD. ECG morphology was preoperatively screened in accordance with the recommendations of the manufacturer to exclude patients with atrioventricular block, bundle branch block, and long-QT interval.

S-ICD therapy was offered to all patients who fulfilled the criteria mentioned above; therefore, the patients’ preference was 1 decision factor on transvenous ICD versus S-ICD. Also, patients with previous transvenous ICDs and an indication for removal were given the choice for another transvenous ICD or the S-ICD. Magnetic resonance tomography or transthoracic echocardiography was performed to assess left ventricular ejection fraction.

**Table 1. Clinical Characteristics and Outcome**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>40</td>
</tr>
<tr>
<td>Age, years±SD</td>
<td>42±15</td>
</tr>
<tr>
<td>Body mass index, kg/m²±SD</td>
<td>27±6</td>
</tr>
<tr>
<td>Height, cm±SD</td>
<td>180±10</td>
</tr>
<tr>
<td>Weight, kg±SD</td>
<td>88±21</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>28 (70.0)</td>
</tr>
<tr>
<td>Previous transvenous ICD, n (%)</td>
<td>10 (25.0)</td>
</tr>
<tr>
<td>Secondary prevention, n (%)</td>
<td>23 (57.5)</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>9 (22.5)</td>
</tr>
<tr>
<td>Non-ischemic cardiomyopathy, n (%)</td>
<td>9 (22.5)</td>
</tr>
<tr>
<td>Other structural heart disease, n (%)</td>
<td>10 (25)</td>
</tr>
<tr>
<td>Hypertrophic cardiomyopathy</td>
<td>5 (12.5)</td>
</tr>
<tr>
<td>Myocardial inflammation</td>
<td>2 (5)</td>
</tr>
<tr>
<td>Arrhythmogenic right ventricular cardiomyopathy</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Univentricular heart disease</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Valvular cardiomyopathy</td>
<td>1 (2.5)</td>
</tr>
<tr>
<td>Idiopathic ventricular arrhythmia, n (%)</td>
<td>12 (30)</td>
</tr>
<tr>
<td>Ejection fraction, %</td>
<td>47±15</td>
</tr>
<tr>
<td>Patients discharged with an S-ICD</td>
<td>39</td>
</tr>
<tr>
<td>Patients with shock therapy, n (%)</td>
<td>4/39 (10.3% [95% CI, 2.9%–24.2%])</td>
</tr>
<tr>
<td>VT/VF episodes, n</td>
<td>21</td>
</tr>
<tr>
<td>Delivered S-ICD shocks, n</td>
<td>28</td>
</tr>
<tr>
<td>Explanation of S-ICD and switch to transvenous ICD, n (%)</td>
<td>4/40 (10% [95% CI, 1.6%–20.4%])</td>
</tr>
</tbody>
</table>

ICD indicates implantable cardioverter-defibrillator; VT, ventricular tachycardia; VF, ventricular fibrillation; S-ICD, subcutaneous ICD.

**Subcutaneous ICD System**

A commercially available S-ICD system (pulse generator model SQ-RX 1010 and subcutaneous lead model Q-Trak 3010, both from Cameron Health Inc, San Clemente, CA) was used in all patients. The 3mm tripolar Q-Trak 3010 parasternal lead is made of polycarbonate urethane 55D. The electrode is positioned subcutaneously parallel to the left of the sternal midline, and the pulse generator is positioned between the midaxillary line and the anterior axillary line, as described previously.2 Sensing is assured by 2 sensing electrodes that are integrated into the lead and placed at the manubriosternal junction (distal electrode) and the xiphoid process (proximal electrode). The 8-cm shocking coil is located between the proximal and distal electrodes.

By including the active generator, the following vectors are feasible to detect the electric activity of the heart: (1) a primary vector, with sensing from the proximal electrode to the surface of the active generator, (2) a secondary vector, with sensing from the distal electrode to the surface of the active generator, (3) an alternate vector, with sensing from the proximal to distal electrode. The S-ICD system automatically selects the most appropriate vector for rhythm detection and for prevention of double QRS counting and T-wave oversensing.

Rhythm detection and classification in the S-ICD are based on consecutive interval counting and morphology analysis of the sensed signal. In addition to an obligatory zone for the detection of ventricular arrhythmia where detection is made only by heart rate, a second optional discrimination zone adding a feature extraction technique can be programmed to discriminate supraventricular from ventricular tachycardia and to prevent inappropriate shock delivery because of supraventricular tachycardia. Although testing is performed with 65-J shocks, the device delivers nonadjustable 80-J shocks in case of spontaneous episodes to guarantee a safety margin. If the first shock fails to terminate tachycardia, shock polarity is reversed for the second shock delivery. Maximum therapy consists of 5 shock deliveries. In contrast to transvenous ICD systems, the S-ICD does not have the option for antitachycardia pacing. However, the S-ICD is capable of ventricular postshock pacing for 30 seconds after a shock, using a 200 mA biphasic transthoracic pulse.

**Implantation Procedure**

Implantation was performed according to the recommendations of the manufacturer, with the patient under general anesthesia. Antibiotic prophylaxis was given intravenously directly before the procedure. The patient’s left arm was abducted to provide unrestricted access to the axilla. The device pocket was prepared in the left axilla, as described in previous reports.3 Lead placement was performed and checked intraoperatively with support from a manufacturer-employed technician. Using a tunneling tool, the lead was advanced subcutaneously first to the xiphoid process and then parallel to the sternum up to the manubrium. A fixation sleeve was inserted to fix the lead proximally at the xiphoid process. The distal tip of the lead was fixed to the fascial tissue at the manubrium. Device functionality was tested in all patients with a 65-J shock, as described in previous reports.3

**Programming**

The devices were programmed individually according to the patient’s clinical characteristics. Two therapy zones were available: one shock zone that as a general rule started at 200 beats per minute in all patients and an optional therapy zone starting at 170 to 200 beats per minute, in which an ECG-based discrimination feature attempts to differentiate supraventricular from ventricular arrhythmia.

**Classification of Episodes**

Stored episodes were categorized as appropriate detection if ventricular arrhythmia was correctly identified and as inappropriate detection if a supraventricular rhythm or oversensing was incorrectly classified as ventricular episodes. Ventricular tachycardia was defined as monomorphic if the morphology of all QRS complexes obtained via the intracardiac signal remained stable throughout the episode. Ventricular tachycardia was defined as polymorphic if the QRS complexes had...
Definition of Shock Efficacy, First Shock Efficacy, and Inappropriate Shocks

Effective shock therapy was defined as the successful conversion of a detected episode of ventricular tachyarrhythmia with any of a maximum of 5 shocks. Effective first-shock therapy was defined as the successful conversion of a detected episode of ventricular tachyarrhythmia with the first shock delivered. An inappropriate shock was defined as any shock given to treat episodes that were incorrectly, according to the classification of the episodes mentioned above, classified as a ventricular arrhythmia by the device.

Follow-Up

A follow-up interrogation of the device was performed 1 day after the implantation. Correct positioning of the device and lead was verified with an anteroposterior and lateral x-ray of the thorax. All initial postoperative controls, as well as the verification of correct lead placement, were performed in the presence of a manufacturer-employed technician.

After hospital discharge, follow-ups were obtained at 1 month and every 3 months thereafter. During follow-up visits, clinical events were assessed, and the S-ICD was interrogated to check signal quality, lead impedance, and ECG storage.

Patients were also seen, and the device interrogated, in between scheduled visits in cases of discomfort or immediately after a presumed discharge of the device. After an ICD shock, the correct position of device and lead were again checked by x-ray.

Data Analysis

To discern appropriate from inappropriate detection and effective from ineffective therapy, all episodes have been collected centrally at the University Heart Center Hamburg-Eppendorf. The episodes were evaluated independently by 4 cardiologists (A.A., S.B., C.B., and L.E.) from the 3 sites. Continuous variables are presented as mean±1 SD or as median and interquartile range, where appropriate. Categorical variables are presented as counts and percentages.

Analysis of efficacy of shock treatments was performed using a mixed logistic regression model, allowing for cluster effects on patient level. Adjusted rates and 95% CIs were calculated both for efficacy of terminating an episode in total and with the first shock only. Two-sided P values <0.05 were considered statistically significant. We used STATA 12, procedure xtollogit for the mixed regression model and SPSS for Windows (release 17.0; SPSS Inc, 1993–2007, Chicago, IL) for statistical analyses.

Results

Arrhythmias During Follow-Up and Efficacy of Shock Therapy

During a median follow-up of 229 (interquartile range, 116–305) days, S-ICD activity was recorded in 4 of the 40 patients (10.0%, 95% CI, 2.9%–24.2%). All 4 patients were seen at 1 center (Hamburg). A total of 25 episodes were retrieved from these patients’ devices (Figure 1). The characteristics of patients with S-ICD shock therapy and the description of episodes are given in Table 2. In 21 of 25 episodes, ventricular tachyarrhythmia with regular initial detection was correctly identified, and a total of 28 shocks were delivered. The S-ICD successfully terminated 11 episodes of ventricular arrhythmia with a single 80-J shock, and 2 shocks were necessary to terminate ventricular arrhythmia in 3 episodes. One episode of electrical storm could not be terminated after a maximum of five 80-J shocks. This patient survived because of timely resuscitation and external shock deliveries. A spontaneous conversion to sinus rhythm occurred in 3 episodes. The documentation of 2 episodes in the same patient stopped incorrectly because of undersensing during resuscitation and chest compression after 1 and 2 ineffective shocks, respectively. One episode ended before S-ICD discharge because of a defibrillator shock given externally. We calculated an overall S-ICD shock efficacy of 96.4% (95% CI, 12.8%–100%), indicating that 96.4% is the best estimate for the average shock efficacy of the S-ICD in an arbitrary patient.

The efficacy of first shocks, however, was only 57.9%, with a 95% CI ranging from 35.6% to 77.4%; this indicates with 95% confidence that the true efficacy rate of a first S-ICD shock is at best 77.4%.

Four episodes were incorrectly classified as ventricular tachycardia, with inappropriate shock delivery in 2 patients (Figure 1). One episode showed inappropriate detection in the VF zone because of T-wave oversensing without shock delivery; 1 episode illustrated inappropriate detection of chest compression during resuscitation without shock delivery, and 2 patients had sinus tachycardia with consecutive inappropriate shock delivery.

Detailed Description of Episodes for Patient No. 1

Patient No. 1 (male, 43 years; weight, 140 kg; body mass index, 35 kg/m²) had an indication for secondary prevention after he survived VF. The patient’s ejection fraction was 55%, and no signs of structural heart disease, long-QT syndrome, or Brugada syndrome were found. Seventy-nine days after uneventful implantation of the S-ICD, the patient had to be resuscitated because of an electrical storm due to incessant VF. The S-ICD initially recognized the onset of VF and exhausted therapy with 5 maximum energy shocks. However, these multiple shock deliveries did not terminate ventricular tachyarrhythmia. The device continued to monitor the patient’s rhythm because the detected rate decreased over time as low-amplitude VF continued and extensive chest compression during resuscitation mimicked a lower heart rate. Multiple external shocks failed to restore normal sinus rhythm. Throughout the event, arrhythmia reinitiation occurred; 3 S-ICD system shocks successfully terminated VF; whereas 3 other S-ICD system shocks were ineffective; finally, VF was permanently terminated by a maximum energy 80-J S-ICD system shock.

No technical fault of the S-ICD was found, and chest x-ray showed appropriate position of both lead and device. Nevertheless, it was decided to explant the S-ICD and implant a transvenous ICD system because of the severity of ventricular arrhythmia. At 5 months after the implantation of the transvenous system, the patient’s clinical course was uneventful.

Detailed Description of Episodes for Patient No. 2

Patient No. 2 (male, 20 years; body mass index, 24 kg/m²) received an S-ICD for secondary prevention after having survived idiopathic VF. During a follow-up of 280 days, he experienced multiple tachyarrhythmic episodes; 37 days after implantation of the S-ICD, he had VF that was detected and treated appropriately with an 80-J shock (Figure 2). At 177 days after implantation, during a routine follow-up visit, sinus tachycardia was detected in the VF zone because of T-wave sensing but without inappropriate shock delivery. Finally, at 280 days...
after implantation, the patient experienced multiple episodes of rapid polymorphic ventricular tachycardia induced by premature ventricular beats. Regular detection and therapy occurred during 1 episode. However, in another episode, undersensing of low-amplitude ventricular arrhythmia led to a delay in shock delivery, with two 80-J shocks failing to interrupt ventricular arrhythmia (Figure 3). Interestingly, S-ICD electrogram documentation stopped after the second ineffective shock, which was technically explained by the fact that sinus rhythm occurred spontaneously during charging for the next shock, with subsequent termination of electrogram recording.

After these multiple episodes of tachyarrhythmia, regular signal quality and lead impedance were verified. Chest x-rays showed lead and device positions identical to the positions after implantation. After analysis of the tachyarrhythmic episodes, it was decided to explant the S-ICD because of the undersensing of low-amplitude ventricular tachyarrhythmia and the 2 unexplained ineffective shocks. A transvenous 40-J ICD system was implanted with a dual-coil lead and tested successfully for defibrillation efficacy. Two weeks after implantation of the transvenous ICD, the patient received multiple appropriate and effective ICD shocks because of fast ventricular tachycardia.

### General Postsurgical Outcome

S-ICD implantation was successful in all patients but 1. In this 23-year-old male patient with a weight of 126 kg (body mass index, 37 kg/m²), dilated cardiomyopathy, and a left ventricular ejection fraction of 15%, successful defibrillation efficacy testing could not be achieved during implantation and after 4 days, neither with initial nor reversed shock polarities. After implantation, histological analysis of a heart biopsy revealed subacute myocardial inflammation. The S-ICD was subsequently explanted and exchanged for a transvenous ICD. Initially, defibrillation efficacy testing with the transvenous system was also not successful; however, it was achieved 2 weeks later.

During follow-up, no deaths occurred. In 2 of 39 patients (5.1%; 95% CI, 0.6%–17.3%) discharged with an S-ICD, the device had to be explanted and replaced with a transvenous ICD, because the S-ICD had failed to effectively terminate ventricular arrhythmia, as described above. In patient No. 4, it was decided to exchange the S-ICD for a transvenous ICD to treat recurrent ventricular tachycardia with antitachycardia pacing.

### Other Peri- and Postoperative Complications

Implantation and postoperative outcomes of the other 36 patients were uneventful. No procedure-related complications,

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**Table 2. Characteristics and Episode Details of Patients With S-ICD Shock Therapy**

<table>
<thead>
<tr>
<th>Patient</th>
<th>BMI (kg/m²)</th>
<th>Indication</th>
<th>Time of episode: Days after implantation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Male, 43 y</td>
<td>35</td>
<td>Secondary, idiopathic VF</td>
<td>79 d</td>
<td>Electrical storm because of incessant VF, 8 ineffective shocks, external shocks nonoperative, finally 3 effective shocks</td>
</tr>
<tr>
<td>2. Male, 20 y</td>
<td>24</td>
<td>Secondary, idiopathic VF</td>
<td>1. 37 d 2. 177 d 3. 280 d</td>
<td>Ad 1: Appropriate detection and effective shock therapy of VF Ad 2: T-wave oversensing, no therapy Ad 3: 2 effective and 3 ineffective shock deliveries in recurrent polymorphic VT</td>
</tr>
<tr>
<td>3. Male, 35 y</td>
<td>26.3</td>
<td>Secondary, fast idiopathic VT</td>
<td>62 d</td>
<td>Appropriate detection and effective shock therapy of VT</td>
</tr>
<tr>
<td>4. Male, 38 y</td>
<td>27.5</td>
<td>Secondary, ischemic heart disease, VF</td>
<td>1. 185 d 2. 403 d</td>
<td>Ad 1: Appropriate detection and effective shock therapy of VT Ad 2: Appropriate detection and effective shock therapy in 5 episodes, spontaneous conversion in 2 episodes</td>
</tr>
</tbody>
</table>

S-ICD indicates subcutaneous implantable cardioverter-defibrillator; BMI, body mass index; VF, ventricular fibrillation; VT, Ventricular tachycardia.
such as infection, lead dislocation, or hematoma, were observed. Chest x-rays revealed correct positions of lead and device in all patients but 1 in whom the device was repositioned successfully.

Discussion

Main Findings
In 40 patients followed for a median of 229 days who had received an S-ICD at 3 German centers, S-ICD performance was analyzed during 21 spontaneous episodes of ventricular arrhythmia occurring in 4 patients. Two young patients with idiopathic VF experienced shock failure and delayed therapy. One patient had a VF storm that was not terminated by multiple S-ICD shocks. The other patient showed a delay of the finally effective therapy because of undersensing of low-amplitude ventricular tachycardia; two 80-J shocks failed to interrupt the ventricular arrhythmia. Seven of 21 ventricular episodes were treated with >1 shock to terminate ventricular arrhythmia. Testing of the devices showed no malfunction. Both patients with failed or delayed shock therapy were converted to a transvenous ICD.

The present study comprises an unusually large number of patients with idiopathic VF (30%). Also, compared with other previously published studies of the S-ICD, the 58% prevalence in our population of an indication for secondary prevention is rather high; it contrasts with 22% and 33% previously reported. Our patients’ mean age of 42 years was younger compared with contemporary transvenous ICD registries or the published mean age of the S-ICD system so far. However, recently, Jarman et al reported on an even younger population, including pediatric patients, with a mean age of 20 years, in whom cases of delayed shock delivery for ventricular tachycardia treatment were observed. Finally, at 47%, the mean ejection fraction in our patients was higher compared with previous prospective S-ICD reports and conventional ICD registries.

The reasons for these differences may be physician- or patient-based selection bias. Young patients are probably more likely to be offered and to accept a new, more expensive technology because of their longer life expectancy. Nevertheless, because all implants in the 3 centers participating in this study were included in the analysis, our data reflect the real life use of the S-ICD in the first year after its approval in Germany. Another remarkable finding is the fact that nearly 25% of our patients previously had a transvenous ICD explanted because of device-related complications. Thus, patients with repeated lead dislocation or more difficult venous access (eg, because of infection or venous occlusion) may be more likely to be selected for an S-ICD.

Ineffective Shock Delivery in S-ICD and Transvenous ICDs
Overall conversion efficacy of the S-ICD in our study was 96.4%, which is in the range of shock efficacy rates of transvenous ICD systems. In a recent large cohort analysis, conversion efficacy for spontaneous arrhythmia episodes among patients who received right and left pectoral transvenous
implants was 97% and 100%, respectively. In that study, successful conversion was defined as the restoration of baseline rhythm with either the first or the second shock. In our study, first-shock efficacy was only 57.9%; however, the upper limit of the 95% CI indicates that first-shock efficacy may be as high as 77.4%.

Ineffective shock delivery is a life-threatening situation rarely noticed with current transvenous ICD systems. It is mainly observed in patients with ICD dysfunction, lead dislocation, structural heart disease such as hypertrophic cardiomyopathy, reduced ejection fraction, electrical storm, metabolic decompensation, and Brugada syndrome. An initial report by Bardy et al showed that the S-ICD successfully detected and treated all 12 episodes of spontaneous sustained ventricular tachycardia. However, these episodes occurred in only 3 patients, with 1 patient experiencing an electrical storm. Another study by Dabiri et al reported 11 ventricular tachyarrhythmias occurring in 4 patients during a median follow-up of 286 days, which were all treated successfully.

Intraoperative Failure of Defibrillation Conversion Testing
We observed 1 intraoperative failure of defibrillation testing, both with initial and reversed polarity. The failure of defibrillation threshold testing was probably because of the deteriorated electric conductivity in this severely obese patient. Furthermore, a severely reduced left ventricular ejection fraction as a result of myocardial inflammation was found in this patient. Intraoperative failure of defibrillation testing has not been described in previous S-ICD reports and is rarely observed with modern transvenous ICD systems.

Inappropriate Shock Therapy With the S-ICD
Inappropriate detection of ventricular arrhythmia occurred in 10% of our patients, of whom 5% suffered inappropriate shock therapy during follow-up. The latter incidence is lower than that reported for subcutaneous ICDs in a recent single-center study. This can be mainly explained by a software update for the devices we used, which specially addressed sensing during myopotentials. Dabiri et al mentioned 5 (16%) of 31 patients with inappropriate shocks; however, 2 patients had events before the software update to reduce sensing during myopotentials. Interestingly, no inappropriate shocks occurred in the pilot study. No data exist comparing the incidence of inappropriate shocks in the S-ICD with that in transvenous ICDs.

Study Limitations
The present study was not a randomized trial; therefore, a comparison of the shock efficacy of the S-ICD with that of the transvenous ICD is not allowed. Furthermore, the number of patients treated is fairly small. Of the 40 patients, 23 were implanted with an S-ICD for secondary prevention, and spontaneous episodes analyzed occurred in 4 patients who had all received the S-ICD for secondary prevention. The mean follow-up of 221 days is rather short compared with trials investigating transvenous ICDs. Finally, there was no clinical events committee.

Conclusions
Ineffective shock delivery may occur in patients with subcutaneous ICD, even after successful intraoperative testing. Larger and long-term multicenter trials are needed, with close monitoring of safety and efficacy end points to identify patients who may be at risk for shock failure. Hence, it is of great importance to ensure proper device function and patient safety.
importance to conduct a prospective study to work out clinical and electrophysiological parameters that might predict ineffective therapy.

Disclosures

None.

References


CLINICAL PERSPECTIVE

Transvenous implantable cardioverter defibrillators (ICDs) are associated with relevant acute (lead dislocation, perforation, pneumothorax) and long-term complications (lead failure, device infection). The subcutaneous ICD is a novel alternative to transvenous ICDs, which is easily implanted without transvenous access. In this study, we evaluated the performance of the subcutaneous ICD in 40 consecutive patients; 4 of these patients, all with an indication for secondary prevention, experienced a total of 21 spontaneous episodes of ventricular tachyarrhythmias. At 96%, the overall shock efficacy seemed promising, yet we observed failed shock deliveries in 1 patient and delayed, though eventually effective, therapy in another. First-shock efficacy was only 58%. In all cases of failed and delayed therapy, there were no signs of technical faults of the subcutaneous ICD. Our study indicates a need for large clinical registries to identify optimal candidates for the subcutaneous ICD and suggests that the transvenous ICD should presently be preferred in patients with an indication for secondary prevention.
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