Original article

Acute and Long-term Results After Contemporary Subcutaneous Implantable Cardioverter-defibrillator Implantation: A Single-center Experience

Miguel A. Arias, Marta Pachón, Finn Akerström, Alberto Puchol, Cristina Martín-Sierra, and Luis Rodríguez-Paladí

Unidad de Arritmias y Electrofisiología Cardiaca, Servicio de Cardiología, Hospital Virgen de la Salud, Toledo, Spain

Article history:
Received 3 July 2017
Accepted 11 September 2017
Available online 6 December 2017

Keywords:
Subcutaneous defibrillator
Cardiac arrest
Ventricular arrhythmias

ABSTRACT

Introduction and objectives: The subcutaneous implantable cardioverter-defibrillator (S-ICD) has emerged as an alternative to the transvenous defibrillator. The incidence of complications is similar, with inappropriate shocks (IS) being more frequent than those occurring with contemporary programming of transvenous defibrillators. Several improvements have been implemented after the S-ICD was approved for use in Europe in 2009. This study reports the results of S-ICD use in a single center, whose experience began late, at the end of 2013.

Methods: Prospective observational study including consecutive patients with defibrillator indication and no indication for either permanent pacing or cardiac resynchronization who underwent S-ICD implantation. Implant data and long-term follow-up were analyzed.

Results: An S-ICD was implanted in 50 patients who were deemed suitable after electrocardiographic screening. The median age was 46.9 ± 15 (range, 15-78) years and 72% were male. Thirty eight percent had left ventricular ejection fraction ≤ 35%. The most frequent heart disease was ischemic heart disease (34%), followed by hypertrophic cardiomyopathy (18%). The intermuscular technique was used, with 3 incisions in 10% and 2 incisions in the remaining 90%. Ventricular fibrillation was induced in 49 patients, with 100% effectiveness in their conversion. After a mean follow-up of 18.1 (range, 2.3-44.8) months, there were no late complications requiring surgical revision, the rate of IS was 0%, and 1 patient (2%) experienced appropriate shocks.

Conclusions: Improvements in technology, implant technique and device programming, along with appropriate patient selection, have led to outstanding acute and long-term results, especially regarding the absence of both IS and complications requiring surgical revision.

© 2017 Sociedad Española de Cardiología. Published by Elsevier España, S.L.U. All rights reserved.

Resultados agudos y a largo plazo tras implante contemporáneo de desfibrilador subcutáneo: experiencia en un centro

RESUMEN

Introducción y objetivos: El desfibrilador subcutáneo (S-ICD) surge como alternativa al transvenoso. La incidencia de complicaciones es similar, y los choques inapropiados (CI) son más frecuentes que lo observado con programaciones contemporáneas en los transvenosos. Tras aprobarse en 2009 en Europa, se han implementado diversas mejoras. Se expone el resultado en un centro con el implante de S-ICD, cuya experiencia se inició tardíamente, a finales de 2013.

Métodos: Estudio prospectivo observacional con inclusión de pacientes consecutivos con indicación de desfibrilador y sin indicación de estimulación permanente o resincronización cardiaca, a los que se implantó un S-ICD. Se analizaron datos del implante y seguimiento a largo plazo.

Resultados: Se implantó un S-ICD a 50 pacientes que habían superado el cribado electrocardiográfico pertinente. La media de edad era 46,9 ± 15 (15-78) años, y el 72% eran varones. El 38% presentaba una fracción de eyeción del ventrículo izquierdo ≤ 35%, y la cardiopatía isquémica fue la más frecuente (34%), seguida de la miocardiopatía hipertrófica (18%). Se usó la técnica intermuscular, con 3 incisiones en el 10% y 2 en el 90%. Se indujo fibrilación ventricular a 49 pacientes, con eficacia del 100% en su conversión. Tras un seguimiento medio de 18,1 (2,3-44,8) meses, no se produjeron complicaciones tardías que requirieran revisión quirúrgica ni CI (0%), y 1 paciente (2%) recibió choques inapropiados.

Palabras clave:
Desfibrilador subcutáneo
Muerte súbita
Arritmas ventriculares

SEE RELATED CONTENT:
http://dx.doi.org/10.1016/j.rec.2018.05.018
* Corresponding author: Unidad de Arritmias y Electrofisiología Cardiaca, Hospital Virgen de la Salud, Avda. Barber 30, Planta Semisótano, 45004 Toledo, Spain.
E-mail address: maapalomares@secardiologia.es (M.A. Arias).

https://doi.org/10.1016/j.rec.2017.11.006
1885-5857/© 2017 Sociedad Española de Cardiología. Published by Elsevier España, S.L.U. All rights reserved.
METHODS

Patients

From October 2013 to April 2017, patients were selected for S-ICD implantation if they had a standard indication for ICD therapy, namely, no indication for cardiac resynchronization therapy or permanent cardiac pacing. The reason why an S-ICD was chosen instead of a transvenous ICD varied during the inclusion period according to the latest evidence available on this new therapy in the literature.
Follow-up

Face-to-face follow-ups were performed 3 months after the implantation and then every 6 to 12 months. In addition, using the Latitude system from Boston Scientific, remote follow-up was performed in patients who were implanted with second- and third-generation devices.

Statistical Analysis

Data were analyzed using SPSS software (version 20.0; IBM Corp.; Armonk, New York, United States). Continuous variables are expressed as mean ± standard deviation and categorical variables as absolute values and percentages.

RESULTS

Patient Characteristics

In total, 56 patients were selected for S-ICD implantation; 6 of these did not ultimately receive an S-ICD for the following reasons: 3 because the preimplantation electrocardiographic screening was unsuccessful, 1 because the patient opted not to undergo device implantation, 1 because the patient preferred a transvenous ICD, and 1 because the patient required permanent pacemaker implantation. The general characteristics of the remaining 50 patients are detailed in Table 1 and the type of heart disease and type of indication are shown in Figure 1. Initial data on the first 8 patients to receive an S-ICD in our center have already been published.13 The mean age was 46.9 ± 15 (15-78) years and the mean body mass index was 25.5 ± 4.1 (16.5-35.0). Slightly more than a third of patients (38%, 19 patients) had a left ventricular ejection fraction ≤ 35%. All patients were in New York Heart Association function class I or II. Five patients (10%) already had a transvenous ICD; the reasons for S-ICD implantation were defibrillation lead dysfunction in 2 patients and infection of the previous system in 3.

Preimplantation Electrocardiographic Screening

Resting electrocardiographic screening was performed in all patients. The screening results are shown in Figure 2.

Implantation, Induction Testing, and Final Programming Data

All implantations were performed in the electrophysiology laboratory by 4 cardiologists with extensive implantation experience with all types of electronic cardiac devices. Only 1 of the patients was anticoagulated at the time of implantation, because this patient already had a mechanical tricuspid valve.14 The S-ICD was implanted satisfactorily in all 50 patients (100%).

Figure 1. Underlying heart disease in patients who received a subcutaneous defibrillator (A) and type of indication (B). ARVC, arrhythmogenic right ventricular cardiomyopathy.
2 with the lead in the right parasternal position (4%) and the remainder with the lead in the left (96%) (Figure 3). The first 10 patients (20% of the total) received a Cameron S-ICD SQ-RX 1010 device, the next 18 (36%) an Emblem S-ICD A209, and the final 22 (44%) an Emblem MRI S-ICD A219. The basic implantation characteristics are described in Table 2. Induction testing and ventricular fibrillation detection (Figure 4A) was performed in all patients except 1 (2%; due to left ventricular apical thrombus), with 100% effectiveness for the S-ICD; only 2 patients required a second maximum-energy shock (80 J) with reversed polarity after an ineffective 65-J shock with standard polarity. The mean duration of ventricular fibrillation therapy was 16.7 ± 2.8 (13.4-26) seconds. A sustained ventricular arrhythmia was not achieved in 4 of the 45 patients (8.8%) who underwent this procedure, even after up to 3 attempts with up to 5 seconds of continuous current with the device. Two zones were programmed with the following heart rate cutoffs: the conditional zone with thresholds of 220 bpm in 4 patients, 200 bpm in 3, 180 bpm in 8, and 170 in 1; and the shock zone with thresholds of 250 bpm in 45 patients and 240 bpm in 5. The most common programming was that of a conditional zone from 200 bpm and a shock zone from 250 bpm (36 patients, 72% of the total).

**Complications and Follow-up**

In total, 96% of patients were free of periprocedural complications. Periprocedural complications occurred in 2 patients (4%).

![Figure 2. Results of preimplantation electrocardiographic screening.](image)

![Figure 3. Chest radiography of a patient with right parasternal lead implantation (A) and of a patient with left parasternal implantation (B).](image)

<table>
<thead>
<tr>
<th>Table 2: Implantation and Induction Testing Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General anesthesia</strong></td>
</tr>
<tr>
<td>Sedation</td>
</tr>
<tr>
<td>2-incision technique</td>
</tr>
<tr>
<td>3-incision technique</td>
</tr>
<tr>
<td>Left parasternal lead</td>
</tr>
<tr>
<td>Right parasternal lead</td>
</tr>
<tr>
<td><strong>Total implantation time, min</strong></td>
</tr>
<tr>
<td>Vector chosen for induction</td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>Alternative</td>
</tr>
<tr>
<td><strong>Induced sustained VF</strong></td>
</tr>
<tr>
<td>1st 65-J shock effectively inducing VF</td>
</tr>
<tr>
<td>Effectiveness of induced VF defibrillation</td>
</tr>
<tr>
<td>Discharge impedance, Ω</td>
</tr>
<tr>
<td>Pseudoshock pacing</td>
</tr>
<tr>
<td><strong>Final programmed vector</strong></td>
</tr>
<tr>
<td>Primary</td>
</tr>
<tr>
<td>Secondary</td>
</tr>
<tr>
<td>Alternative</td>
</tr>
<tr>
<td><strong>Hospital discharge the next day</strong></td>
</tr>
</tbody>
</table>

VF, ventricular fibrillation. Values represent No. (%) or mean ± standard deviation.
Figure 4. A: Postimplantation ventricular fibrillation induction with effective conversion to sinus rhythm with a 65-J subcutaneous defibrillator shock. B: Periprocedural inappropriate shocks due to rapid atrial fibrillation with intermittent wide complexes; dual-zone programming, conditional at 180 bpm and shock at 250 bpm. C: Nonsustained monomorphic ventricular tachycardia that triggered device therapy; dual-zone programming, conditional at 200 bpm and shock at 250 bpm. D: Episode classified as nonsustained ventricular tachycardia due to oversensing of nonphysiological signals generated by movement of the upper left extremity in a patient; dual-zone programming, conditional at 200 bpm and shock at 250 bpm.

One patient, after induction of ventricular fibrillation that was correctly detected and effectively treated with the first shock and after wakening from the anesthesia and with dual-zone device programming (180 and 250 bpm), developed a state of intense agitation leading to rapid atrial fibrillation, with intermittent wide complex rhythms (aberrant or ventricular complexes); in addition, signal oversensing occurred and 2 ISs were delivered (Figure 4B), with sinus rhythm established once the agitation resolved. In another patient, minutes after pocket closure, a hematoma was detected in the generator pouch requiring immediate surgical wound revision; an internal active bleeding site was detected, which was cauterized without incident.

In all patients, chest radiography performed the next day confirmed the correct position of the system and no complications were observed. Most patients were discharged the following day; when not, it was for reasons unrelated to the implantation and none of these patients had been admitted originally for the procedure. There was no incidence of premature battery depletion. All patients who received a second- or third-generation device (40 patients, 80% of the total) were supplied with a Latitude monitor for remote in-home monitoring.

In total, 33 patients (66%) were followed up for more than 1 year after implantation. After a mean follow-up of 18.1 (2.3-44.8) months, only 1 patient (2%) showed ventricular arrhythmia episodes requiring appropriate device shocks and 3 (6%) were recorded to have had asymptomatic self-limiting ventricular tachycardia after receiving a shock (Figure 4C), detected prematurity upon activation of a Latitude system alert. Notably, there were no ISs during follow-up of the 50 patients (0%).

The initially programmed sensing vector was changed in only 1 patients, 18 months after implantation, due to noise that activated a shockless alert, which was reproduced upon movement
of the left upper extremity (Figure 4D). One patient died (2% mortality rate) 10 months after the implantation due to noncardiac causes, a vesical neoplasm; the rate of late complication-free survival was 98% and no patient required surgical revision of the system. Three months after implantation, 1 patient (2%) developed an infection of the parasternal wound after the 2-incision technique, with positive cultures for Staphylococcus aureus; the infection resolved after intravenous antibiotic therapy.

**DISCUSSION**

**Main Findings**

This single-center experience with the delayed introduction of S-ICD implantation shows highly favorable results, with an acceptable periprocedural complication rate and no late complications requiring surgical revision of the implanted system. Even more notable is the lack of ISs during follow-up, which exceeded 1 year in 60% of patients. In line with previous data, the therapy was 100% effective for induced ventricular arrhythmias.

**Patient Characteristics**

Similar to what was seen in the main series published on patients with S-ICDs,15–17 the mean patient age (46.9 years) was less than that typically seen in registries of patients who received an ICD, including a Spanish registry.16 To a large extent, the lower age was due to a higher percentage of patients with arrhythmogenic right ventricular cardiomyopathy, Brugada syndrome, or hypertrophic cardiomyopathy (38% of the total). These diseases are nonetheless associated with a higher risk of inappropriate therapies in patients with an ICD and, in relation to S-ICD specifically, are also associated with a higher frequency of worse detection of cardiac signal and potential dynamic changes in the QRS-T and, thus, an increased likelihood of ISs.15–22c

Chronic ischemic heart disease was the most common underlying disease in this cohort (34%); 46% of patients had left ventricular systolic dysfunction and the rate of implantations in primary prevention was higher than that generally seen in Spain for ICDs,18 but was similar to that observed in the main S-ICD series 15–17 In a cohort of 856 patients with an S-ICD and after a mean follow-up of more than 600 days, Boersma et al.23 reported no differences in S-ICD performance according to whether the indication was primary or secondary prevention and, in primary prevention, it was independent of whether the left ventricular function was depressed, findings that were corroborated in the present cohort.

**Implantation Procedure and Related Complications**

The 2-incision surgical technique was used from the sixth patient in the series, with intermuscular placement of the generator in all patients. There was 1 periprocedural hematoma (2%) and 1 infection (2%) during follow-up that did not require surgical revision. In the largest series published on patients with S-ICDs,17 the 30-day rate of device- or procedure-related postimplantation complications was 4.7% in 1637 patients. This rate was 4.5% in the pooled analysis of the IDE and EFFORTLESS studies,24 with a 3-year complication rate of 11.1% in 882 patients; the rate of infection requiring surgical revision was higher (1.7% of patients). The new 2-incision technique simplifies the procedure by avoiding superior parasternal incision, which reduces the procedural time. In this series, with 90% of implantations performed with the 2-incision technique, the mean procedural time was 59.8 minutes, whereas in the S-ICD PAS study,17 with only 52.2% of procedures performed using this technique, the time was 77.3 minutes. In addition, there are esthetic and comfort benefits for the patient, the risk of infections and erosions is minimized, and it has been shown to be safe, with minimum long-term risk of dislodgments.3,7,8 Moreover, the intermuscular placement of the generator, between the anterior surface of the serratus anterior and the posterior surface of the latissimus dorsi muscles, not only has esthetic advantages, but also reduces pocket complications and IS frequency.9 Additionally, placement of the generator on the muscle without underlying fat tissue would lower the defibrillation threshold.25 In this series, 100% of induced ventricular fibrillations were defibrillated with the device, 95.6% with the first programmed shock (65 J). For this reason, there is disagreement about whether to perform induction and defibrillation testing in patients with an S-ICD implant,26,27 particularly those with intermuscular implantation.27

**Device Therapies**

The most notable result of the present study is the absence of ISs during follow-up, which may be for multiple reasons.

In the first published experiences with the S-ICD,1 one of the main limitations was a rate of ISs (particularly due to T wave oversensing and supraventricular arrhythmias with heart rates exceeding the programmed detection zone) markedly higher than that observed with transvenous ICD with contemporary programming. A 2-year pooled analysis of the patients in the IDE and EFFORTLESS studies28 revealed that dual-zone programming—1 conditional and 1 shock—instead of a single shock zone was associated with a highly significant reduction in the IS rate. Thus, the dual-zone programming in all patients in the present series has probably contributed to the complete lack of ISs during long-term follow-up.

On the other hand, Olde Nordkamp et al.21 determined an IS incidence of 8.3% in 581 patients after a mean follow-up of 21 months but found that hypertrophic cardiomyopathy and history of atrial fibrillation were independently associated with higher risk of ISs. In the present work, only 1 patient had history of atrial fibrillation and just 18% had hypertrophic cardiomyopathy.

Because our experience with these devices was later than in other countries, most of the patients benefited from device software updates aimed at significantly reducing signal oversensing, and thus ISs. This has partially contributed to the observed rate of ISs and the differences with previous series. T wave oversensing was reduced by an estimated 40% with the introduction of the ACWADD algorithm, with an additional 40% reduction in ISs with the SMART Pass algorithm. The long-term results of ongoing studies that recruited patients at a similar time to our study, such as the S-ICD PAS17 (begun in August 2013), will show the true rate of ISs after the implementation of the device software updates in a larger population of patients.

Only 1 patient received appropriate shocks during follow-up, and the therapies were effective. The effectiveness of S-ICD to terminate spontaneously-induced malignant ventricular arrhythmia episodes was very high and similar to that seen with transvenous ICDs.24

**Limitations**

The main limitations of the present work are as follows: a) its inclusion of a low number of patients and those who were not
WHAT IS KNOWN ABOUT THE TOPIC?

- Although S-ICD is a therapy with equivalent effectiveness to transvenous ICD that avoids the complications of endovascular leads, it was associated with higher incidence of ISS in the first published series.
- Improvements have been implemented in device programming, implantation technique, and software to reduce the incidence of complications. The effects of these improvements are still unknown.

WHAT DOES THIS STUDY ADD?

- The present work allows an approximation of complications with contemporary S-ICD implantation by including most of the improvements implemented in the therapy since its release on to the market.
- In the long-term, with a mean follow-up of almost 18 months, there were no ISS or complications requiring surgical revision, which confirms better results vs those of the initial studies with this therapy.

REFERENCES