

Subcutaneous implantable defibrillator: a therapeutic alternative for prevention of sudden cardiac death

*Desfibrilador implantable subcutáneo: una alternativa
terapéutica para la prevención de la muerte súbita cardiaca*

Juan Simon Rico-Mesa,* Laura Duque,* Juan Carlos Díaz,** Jorge E Velásquez,**
Julián Aristizábal,** Jorge Marín,** William Uribe,** Mauricio Duque**

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* Department of
Cardiovascular Diseases.
** Cardiologist and
electrophysiologist,
Department of
Cardiovascular Diseases,
CES Cardiología.

CES University,
Medellín, Colombia.

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Juan Simon Rico-Mesa,
Laura Duque
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ABSTRACT

The transvenous implantable cardiac defibrillator (T-ICD) is currently considered the standard of care for prevention of sudden cardiac death in patients with structural cardiac disease or channelopathies. However, the use of these devices is associated with a significant increase of short and long-term complications, mostly related to intravascular leads. The subcutaneous implantable cardiac defibrillator (S-ICD) is a novel alternative for high-risk patients susceptible to intravascular lead complications, with a similar efficacy as T-ICD. Multiple ongoing clinical trials involving the S-ICD are expected to provide additional information about safety, use and benefits in the clinical setting.

RESUMEN

El desfibrilador cardiaco implantable transvenoso (DCI-T) se considera actualmente el tratamiento estándar para la prevención de la muerte súbita cardiaca en pacientes con enfermedad cardiaca estructural o canalopatías. Sin embargo, el uso de estos dispositivos se asocia con un aumento significativo de complicaciones a corto y largo plazo, principalmente relacionadas con derivaciones intravasculares. El desfibrilador cardiaco implantable subcutáneo (DCI-S) es una alternativa novedosa para pacientes de alto riesgo susceptibles a complicaciones intravasculares, con una eficacia similar al DCI-T. Se espera que varios ensayos clínicos en curso que involucran al DCI-S brinden información adicional sobre seguridad, uso y beneficios en el entorno clínico.

INTRODUCTION

Sudden cardiac death (SCD) represents one of the leading causes of death worldwide, particularly in patients who have channelopathies, arrhythmogenic hereditary disorders (i.e: Brugada syndrome, long or short QT syndrome) and structural cardiomyopathies (including ischemic and non-ischemic cardiomyopathy). The use of an implantable cardiac defibrillator (ICD) in conjunction with medical therapy have demonstrated a significant reduction of all-cause mortality, currently being the most effective strategy in reducing SCD, for both primary and secondary prevention.¹⁻⁴ Two types of ICD are

available: First, the transvenous implantable cardiac defibrillator (T-ICD), which uses an intravascular lead for arrhythmia detection and cardiac stimulation; Second, the subcutaneous implantable cardiac defibrillator (S-ICD), which is composed of a pulse generator capable of detecting lethal ventricular arrhythmias and delivering high-energy depolarizing shocks through a subcutaneous parasternal lead.⁵ Since the first implant performed by Dr. Michel Mirowski back in the 70's,⁶ the T-ICD has been widely studied and has undergone significant improvements. Previous T-ICD required thoracotomy for their implantation. In contrast, modern devices use intravascular leads. This has enabled electrophysiologists to

implant devices with a safer and less morbid technique, leading to a rapid increase in the number of devices implanted. In fact, between 2006 and 2014, a total of 158,649 ICD have been implanted in the United States (US), according to the National Cardiovascular Data Registry.⁷ Because of innovation in circuit and battery technology, current devices are smaller, more durable and easier to implant.⁸ Nonetheless, the uptrend in T-ICD implants have resulted in an increased short and long-term complications, including procedure-related complications (infection, hematoma, pneumothorax, cardiac tamponade, venous thrombosis) and lead-related complications (lead displacement, dysfunction and increasing pacing threshold due to myocardial fibrosis at the implant site).^{3,9,10} Since intravascular leads are the most fragile and failure-prone component of the device, the development of an ICD with a totally subcutaneous lead is expected to reduce the number of lead-related complications. Unfortunately, these devices have limited pacing capabilities, therefore, appropriate patient selection is crucial.

In the following review article, we present an illustrative case-scenario, followed by an in-depth review of the topic.

CASE SCENARIO

A 45-year-old male with past medical history remarkable for ischemic cardiomyopathy with a left ventricular ejection fraction (LVEF) of 25% and end stage renal disease (ESRD) on hemodialysis, was referred to the electrophysiology service for implantation of an ICD because of non-sustained ventricular tachycardia (VT) found on a 24-hour Holter monitor. Would this patient benefit from an S-ICD?

IS THERE A NEED FOR AN S-ICD?

Early complications associated with T-ICD implant occur in 3.8% of the patients, including infection (1.5%), hematoma (1.2%) and pneumothorax (1.1%).¹¹ Particularly, lead-related complications data from the US national registry of ICD systems reported complication rates significantly lower compared to previous clinical trials (MADIT II, SCD-HeFT Trials),

including cardiac tamponade in 0.12%, lead perforation in 0.16%, lead displacement in 2.84% and all-cause mortality in 0.03%.¹² In addition, young female patients may have a higher incidence (as high as 20% during a 10-year follow-up) of lead dysfunction.¹³ Thus, intravascular leads are responsible for a significant percentage of all device-related complications, spurring the need for an alternative device.

DEVICE CHARACTERISTICS AND IMPLANT

The S-ICD consists of a pulse generator, located subcutaneously between the anterior and mid-axillary line at the fourth intercostal space. The pulse generator is connected to a single lead with two distal electrodes separated by an 8cm coil. The electrodes are used for rhythm detection, while the coil delivers electrical shocks for the treatment of ventricular arrhythmias (*Figure 1*). The lead is tunneled through the subcutaneous tissue, running from the pulse generator to the xiphoid process and then running parallel to the left side of the sternum, fixed with non-absorbable sutures to reduce the risk of lead displacement, thus reducing the risk of ineffective or inappropriate



Figure 1. Subcutaneous ICD characteristics. The pulse generator is connected to a single lead, which has two electrodes (proximal and distal) and a single coil. This figure belongs to Boston Scientific: <http://www.bostonscientific.com/en-US/products/defibrillators/emblem-s-ICD-system/physician-resources.html>

shocks. The first-generation S-ICD's pulse generator had a volume of 70 cm³, which has been reduced to 59.5 cm³ in second-generation devices. However, implantation requires enough subcutaneous tissue to provide appropriate protection of the device and reduce the risk of extrusion (*Figure 2*), which could be a limiting factor in thin individuals. Placement of the generator in an intermuscular pocket (between the anterior surface of the Serratus anterior muscle and the posterior surface of the *Latissimus dorsi* muscle) could potentially solve this problem, with a low risk of procedure-related complications (hematomas, device erosion or infection).¹⁴⁻¹⁶

Once pulse generator implantation is achieved, the lead is placed without the need of fluoroscopy. The two electrodes (located at the level of the xiphoid process and at the distal tip of the lead) and the pulse generator create three electrocardiographic (ECG) vectors: the first one, running from the distal electrode to the pulse generator; the second, from the proximal electrode to the pulse generator; the third, from the distal to the proximal electrode (*Figure 3*). The software automatically selects the ECG lead that provides the best QRS to T-wave signal, reducing the risk of double counting and inappropriate shocks.

After the device implantation, a defibrillation test (DFT) must be performed using a 65 J shock. Although routine DFT has been abandoned during T-ICD implants, the increased energy required for a successful defibrillation using subcutaneous devices (due to a higher resistance

to current flow, as opposed to a low resistance when the defibrillating coil is in direct contact with the myocardial surface) along with a lack of trials comparing outcomes with and without DFT in patients with an S-ICD make DFT mandatory. Since the S-ICD provides fixed 80J shocks (with the possibility of delivering a reverse polarity shock if necessary) a successful DFT (i.e: one in which a 65J shock could successfully end VF) would theoretically guarantee a 15J safety margin for future shocks.

HOW TO CHOOSE THE MOST SUITABLE PATIENT FOR AN S-ICD IMPLANT?

Device and patient characteristics must be considered when deciding whether or not a patient is suitable for an S-ICD implant. Unlike the T-ICD, S-ICD cannot double as a pacemaker (although it can provide 30 seconds of transthoracic pacing after a shock using 200mA biphasic pulse) and should not be considered in patients who require cardiac pacing. This absence of pacing capabilities includes a lack



Figure 2. Pocket location for insertion of the pulse generator.

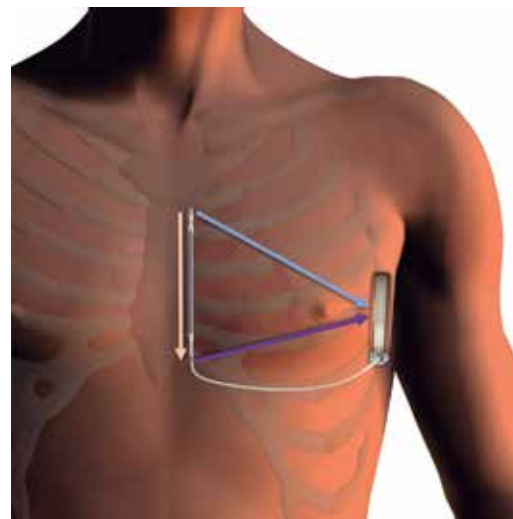


Figure 3. Location of the device and its lead once implanted. The position of the electrodes allows the construction of 3 electrical register vectors: distal electrode to pulse generator; proximal electrode to pulse generator and distal electrode to proximal electrode. Image taken and modified from <http://www.bostonscientific.com/en-US/products/defibrillators/emblem-s-ICD-system/physician-resources.html>.

of anti-tachycardia pacing (ATP). Currently, ATP is widely used for VT termination. In the MADIT-RIT Trial, the use of ATP in VT up to 200 beats per minute (a significant increase from the previous limit of 170 beats per minute) significantly decreased inappropriate shocks and all-cause mortality.¹⁷ Therefore, the S-ICD should not be considered in patients with VT easily terminated with ATP or in patients who benefit from pacing (i.e: bradycardia, AV block or those who require Cardiac Resynchronization Therapy (CRT) for heart failure). However, simultaneous use of S-ICD with pacing devices (leadless pacemakers, transvenous pacemakers or resynchronization devices) have important limitations. Particularly, pacing from the apex produces significant distortion of the QRS-complex and T-wave morphology, limiting the number of patients suitable for S-ICD implant. Patients with biventricular pacing and septal pacing are more likely to meet screening criteria than patients with apical right ventricular (RV) pacing (80%, 67% and 37-46%, respectively).¹⁸

As previously stated, thin patients have a risk of device extrusion due to insufficiently thick subcutaneous tissue, however, that is not an absolute contraindication although it should be taken into consideration upon implantation. Unfortunately, there is no standardized measure of the minimum appropriate thickness upon implantation of an S-ICD and any decision is based on the implanting electrophysiologist's point of view. On the other hand, patients with a high risk of lead-related complications (previous device infections, young males, athletes, patients on hemodialysis) have a greater probability to benefit from an S-ICD. Most studies included patients with prior T-ICD infection, channelopathies (such as Brugada syndrome, short and long QT syndrome) or hypertrophic cardiomyopathy.^{19,20} A pooled analysis from the IDE Trial and the EFFORTLESS Registry of S-ICD patients demonstrated the safety of the S-ICD. The pooled analysis had a sample of 882 patients, with a mean age of 50.3 ± 16 years and a mean LVEF of $39.4 \pm 17.6\%$, 618 of them with device placement for primary prevention and a mean follow-up of 651 ± 345 days.²¹ The S-ICD is also effective in patients on renal replacement therapy (RRT) such as hemodialysis, who usually have very

limited vascular access and are at an increased risk of developing central venous stenosis and intravascular infection.^{22,23} First-generation devices have an average battery durability of five years. However, battery depletion has been reported below the expected threshold in 29% of patients at the time of explant.^{24,25} Second generation S-ICD (EMBLEM) devices have an average battery durability of 7.3 years.²⁶

Once the patient is considered suitable for S-ICD implantation, a screening test must be performed. This screening method evaluates sensing vectors in order to determine the ability to discriminate the QRS complex and the T-wave). This is done using a specially designed tool, made of transparent plastic with different color profiles (*Figure 4*). Subsequently, a rhythm strip is obtained by placing the ECG electrodes in a similar position to the device electrodes, enhancing the stimulation of the future sensing vectors (*Figure 5*). A description of the electrodes implantation is provided below:

- One electrode located at the fifth intercostal space, in the left mid axillary line. This represents the future location of the device generator.
- One electrode located 1 cm to the left of the base of the xiphoid process. This represents the future location of the proximal electrode.
- One electrode located in a left parasternal position, 14 cm above the previous electrode (the tool includes a ruler to allow appropriate measurement). This represents the future location of the distal electrode.

Once the electrodes are implanted, a 10-20 second rhythm strip with each of the three vectors (using the ECG leads I, II, and III) is registered. This is done by using an amplitude gain of 5-20 mV. The baseline should be stable for adequate measurement and records should be taken in supine and standing positions. Each of the QRS complexes, including premature ventricular complexes and QRS complexes stimulated by pacemakers, are evaluated to determine if the vector is appropriate for arrhythmia discrimination (*Figure 4*). At least one of the leads must have adequate measurements in each of the anatomical positions recorded,

otherwise the patient is not considered suitable for treatment with the S-ICD due to the risk of misinterpretation of the ECG.

In previous studies, approximately 85.2% of the patients were suitable candidates for S-ICD placement based on the results of the screening test.²⁷ Of note, screening could even

provide additional information regarding the need of changing the vector's polarity and lead repositioning.²⁸ In patients with congenital cardiomyopathy, performing screening on both sides of the sternum prior to the S-ICD implantation could potentially predict the risk of device failure and guide proper lead placement.²⁹

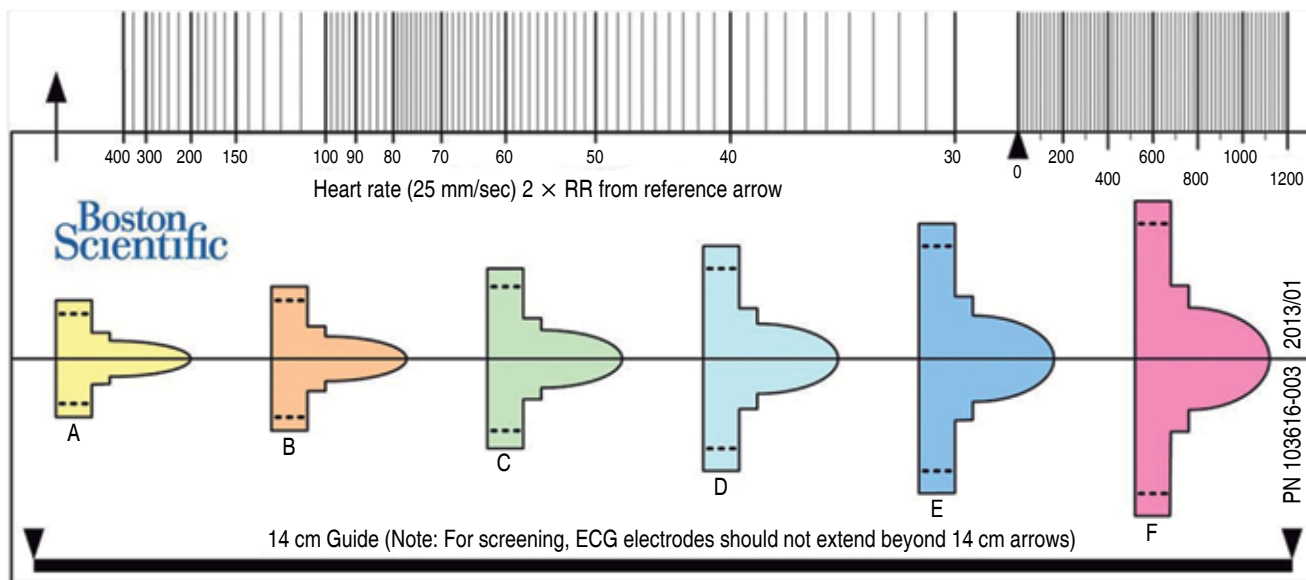


Figure 4. Screening tool. Different QRS to T-wave signal templates (figures A to F) are observed, which are crossed by a baseline. To use it, a profile of the appropriate size is chosen (according to the size of the QRS complex) and the left border of the template is placed at the beginning of the QRS complex, placing the baseline of the ECG trace at the baseline of the template. In the bottom part, two arrow-heads indicate the 14 cm that separate the proximal and distal electrodes.

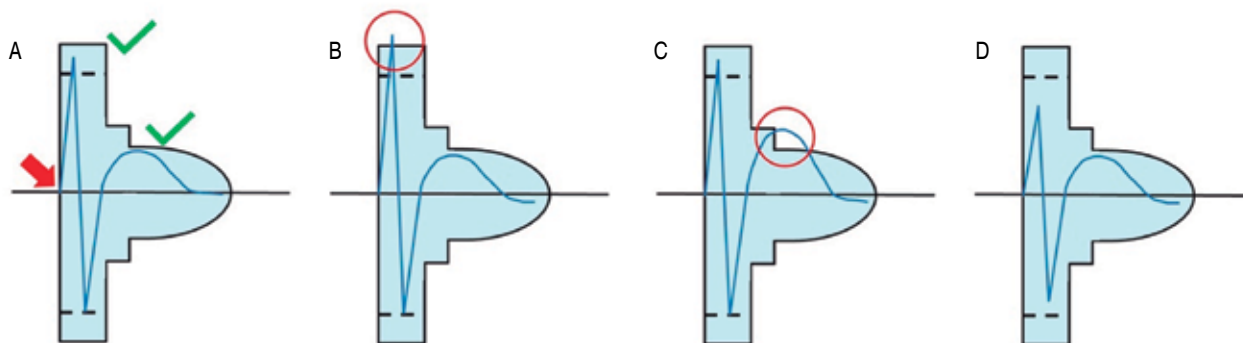


Figure 5. Evaluation of the QRS complex and the T-wave using the template. A) Once the appropriate template size is selected, the beginning of the QRS complex is aligned with the left border of the template (red arrow) and the ECG baseline with the line crossing through the profile. Appropriate QRS and T-wave morphology are determined when the QRS complex exceeds (superior or inferiorly) the dashed line without exceeding the template limit and the T-wave does not exceed the final part of the template. B) The QRS complex exceeds the template, and a larger template should be used for evaluation. C) The T-wave exceeds the template, which could lead to double counting and inappropriate shocks. D) Low voltage QRS complex that does not exceed the dotted line. In this case, a smaller template must be selected.

CLINICAL EFFICACY AND SAFETY OF S-ICD

Although there are no trials evaluating a direct comparison safety and efficacy between S-ICD and T-ICD, the S-ICD has demonstrated significant efficacy in well-known studies, showing a similar efficacy to the T-ICD in terms of termination of ventricular arrhythmias.

Both the EFFORTLESS Registry (NCT01085435) and the IDE Trial (NCT 01064076) assessed the capacity of the S-ICD for detecting ventricular arrhythmias and providing effective shock therapy. A total of 59 episodes of ventricular rhythms (VF and VT) susceptible of being shocked were registered in both trials, with the S-ICD demonstrating a high rate of arrhythmia termination (90.1% after the first shock and 98.2% after the second shock, similar to the T-ICD), with an 11.1% complication rate during a three year follow-up period.²¹ These include pocket infections, cable migration, device erosion, inappropriate shocks and hematoma.²¹

- 1) Infection: Infection rates vary widely, ranging from 1.3 to 9.9% and appear to be inversely associated with number of procedures performed by the implanting electrophysiologist and center volume.³⁰⁻³⁶ There have been no reports of infective endocarditis or cardiac injury with the S-ICD, probably related to the lack of an intravascular lead.³⁷
- 2) Inappropriate shocks and rhythm identification algorithms: early studies revealed an elevated risk of inappropriate shocks due to inadequate detection and rhythm discrimination algorithms, with most inappropriate shocks secondary to detection of supraventricular arrhythmias (25%).^{34,35} Other causes of inappropriate shocks include myopotentials, electrode migration (0.85% of the S-ICD patients) and P-wave oversensing (Figure 6).³⁷ Changes in rhythm detection algorithms have since reduced the risk of inappropriate shocks.^{38,39} Nonetheless, T-wave over-sensing still poses a significant risk of inappropriate shocks, but proper electrocardiographic preoperative screening as described and the use of exercise stress

test reduce this risk.^{28,40} Clinical conditions that modify normal T-wave morphology such as left ventricular overload or hypertrophy, early repolarization, complete or incomplete bundle branch blocks and ischemia, may tamper the S-ICD ability for arrhythmia discrimination and result in inappropriate shocks.^{41,42} Current rates of inappropriate shocks (ranging from 7-13%) for the S-ICD are higher than rates reported for T-ICD, which is currently the device's main drawback.^{43,44} Further improvements in detection algorithms are expected in order to reduce inappropriate shocks.

- 3) Minor complications associated with device implantation: hematoma (0.2%) and device erosion (1.8% for first generation devices) are less common complications associated with device implant.^{19,21,37} Second generation devices appear to have a lower rate of device erosion due to a smaller volume compared to first generation devices. Despite these minor complications, the results of the IDE Trial led to its approval in Europe in 2008³⁰ and FDA approval in 2012. In fact, only one S-ICD model is currently available (EMBLEM, Boston Scientific, Marlborough, Massachusetts, US).

GUIDELINE RECOMMENDATIONS

The recently updated ESC guidelines for SCD prevention include the S-ICD as an alternative to T-ICD for SCD prevention in patients without bradycardia, pacing dependency or need of a CRT (class «IIa», level of evidence C).⁴⁵ Moreover, it is recommended as an alternative to T-ICD in patients with difficult or no venous access, patients with device-related infections (after removal of infected leads) and in young patients who are candidates for long-term prevention of SCD due to the high cumulative risk of lead dysfunction over the patient's lifetime (class «IIa», level of evidence «C»).⁴⁵ The AHA/ACC guidelines for prevention of SCD and ventricular arrhythmias and the guidelines for heart failure management don't include the S-ICD as a recommended therapy.⁴⁶ The recently published Canadian Cardiovascular Society/Canadian Heart Rhythm Society 2016 Implantable Cardioverter-Defibrillator Guidelines consider the use of the S-ICD should be limited

due to the higher rate of inappropriate shocks and lack of long-term studies, but should be considered in patients with congenital heart

disease which limit access to the ventricles or result in significant right to left shunting (due to an increased risk of thromboembolic complications

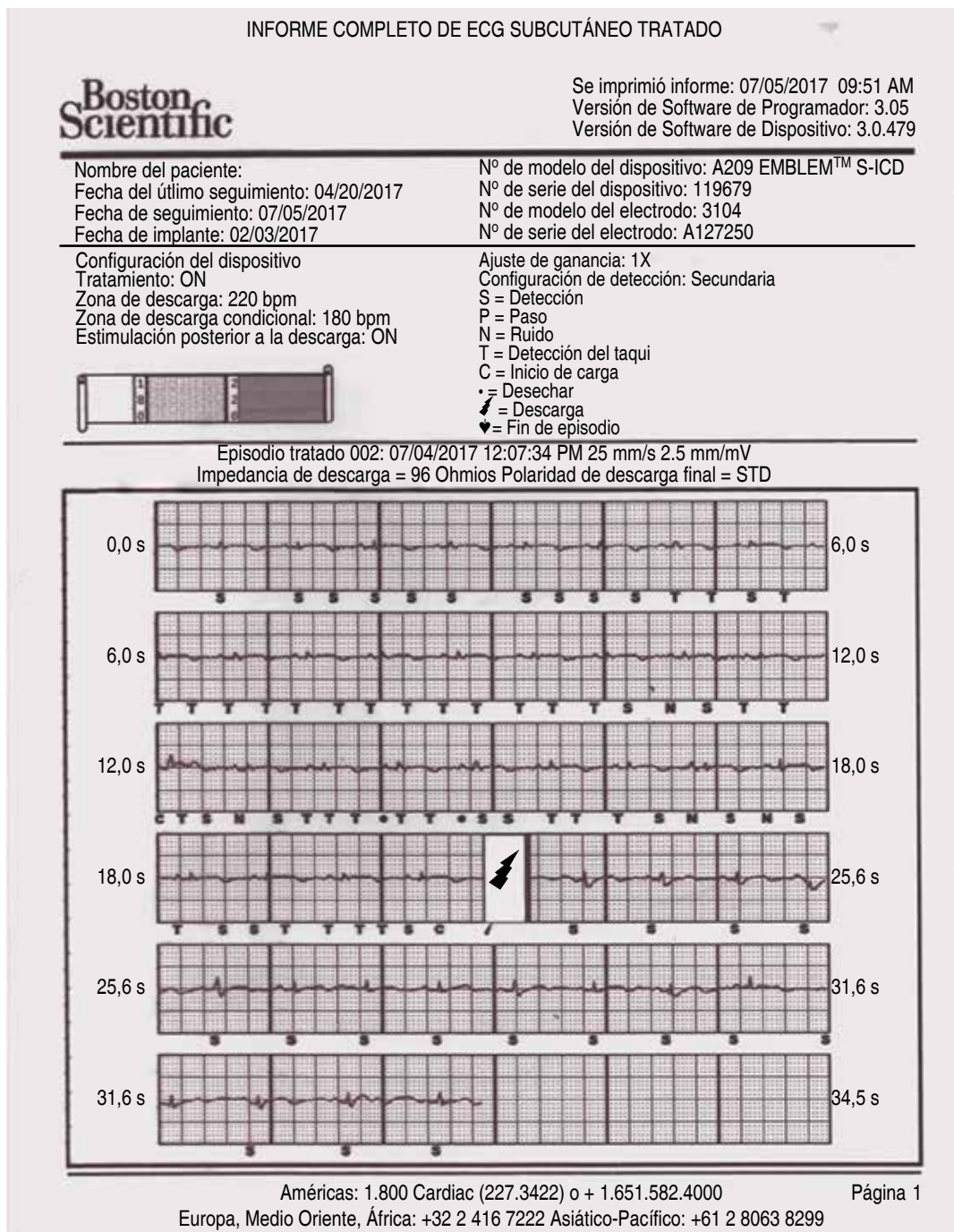


Figure 6. Device interrogation report of a patient with inappropriate shocks. Low QRS-complex voltage in the selected sensing lead allowed for double and triple counting due to P-wave and T-wave oversensing. Manual programming using the primary vector as the sensing lead successfully resolved P-wave and T-wave oversensing.

associated with an intravascular lead) and in patients who have absence of a pocket site (due to either previous device infections or the presence of indwelling catheters).⁴⁷

COMPARATIVE EFFICACY OF SUBCUTANEOUS VERSUS TRANSVENOUS DEVICES

No direct comparisons have been performed between the transvenous and subcutaneous

ICD, therefore, comparative superiority or non-inferiority of either device cannot be established. The advantages and disadvantages of the S-ICD Vs. T-ICD are presented in *table I*. In addition, *table II* summarizes when to consider and S-ICD as a recommended choice, a reasonable choice or when to avoid it. The on-going PRAETORIAN Trial (NCT01296022) is expected to recruit 850 patients with a class «I» and «IIa», level of recommendation «B» for ICD implantation, who will be randomized

Table I. Advantages and disadvantages of the S-ICD.

Advantages	Disadvantages
Easy implantation without using vascular access for lead implantation	Absence of anti-tachycardia pacing
No need for fluoroscopy	Absence of anti-bradycardia pacing function
Similar shock efficacy to T-ICD	Larger pulse generator (59.5 cm ³) than most T-ICD
Easy extraction of the device	Shorter battery longevity than some T-ICD
Suitable option for patients with prior device related infections	
Risk reduction of lead failure in the mid-term	
Reduced risk of implant related complications (pneumothorax, cardiac tamponade, infections)	

Table II. When to consider an S-ICD as a recommended choice, as a reasonable choice or avoid it.⁴²

S-ICD as a recommended choice	S-ICD as a reasonable choice	Avoid the S-ICD
Pediatric patients with difficult venous access	Moderate risk of infection (i.e.: prosthetic heart valves)	Indication for permanent pacing
Grown-up congenital heart disease patients with difficult venous access	Hypertrophic cardiomyopathy	Indication for CRT
History of previous of device infection or endocarditis	Inherited channelopathies and arrhythmogenic syndromes (short and long QT, Brugada)	Indication for ATP (recurrent sustained monomorphic VT)
Patients candidates for heart transplantation	Young patients with a long-life expectancy	Failure in Pre-implantation screening protocols
Patients with high risk of endovascular lead's infection	Primary prevention in ischemic and non-ischemic dilated cardiomyopathy	Previous implantation of unipolar pacemaker
Risk reduction of lead failure in the mid-term	Secondary prevention after ventricular fibrillation	Anatomic limitations (Pectus excavatum, thin subcutaneous tissue)
Reduced risk of implant-related complications (pneumothorax, cardiac tamponade, infections)		

to S-ICD or T-ICD implantation. The primary endpoint will be ICD-related adverse events and is scheduled to be completed by December 2019.⁴⁸

CASE SCENARIO RESOLUTION

Since the patient had multiple risk factors for lead-related complications (young age, hemodialysis, high risk of SCD), he was considered a suitable candidate for S-ICD implantation. Although the patient had previous non-sustained VT on Holter monitoring, the risks associated with an intravascular lead in young patients on hemodialysis outweighed the potential benefits of ATP. The procedure was undertaken uneventfully under local anesthesia, with a total procedure time of 35 minutes. During follow-up, the patient hasn't had device-related complications or shocks.

CONCLUSION

Current evidence supports the use of S-ICD as an effective strategy for the prevention of sudden death, with detection and termination rates of ventricular arrhythmias greater than 98%. Patients most likely to benefit the most include young population, patients with a low risk of short-term shocks, patients with a past medical history of infections associated with cardiac stimulation devices, patients with conditions that limit vascular access for lead placement (i.e: congenital heart defects with vessel transposition or vascular anatomical variants that hinder vascular access) and patients with a history of implant-related complications. Additionally, patient selection must consider the lack of ATP and anti-bradycardia pacing associated with S-ICD devices. Second generation devices have a longer longevity, smaller generator size and optimization of arrhythmia detection software. Current limitations include the significant rate of inappropriate shocks, inability to work as a pacemaker and the high costs. The final results of the EFFORTLESS Registry, PRAETORIAN Trial and IDE Trial will fill the gaps in clinical knowledge allowing for precise recommendations in the different scenarios and standardization of the use of S-ICD.

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Correspondence to:

Dr. Juan Simon Rico-Mesa,
Research Fellowship in Echocardiography
and vascular unit laboratory
Mayo Clinic College of Medicine, Rochester,
Minnesota, USA.
Mayo Clinic, 200 First St SW, Rochester,
MN 55905.
Tel: +1 507 398 02 30
E-mail: mesa.juan@mayo.edu