Review Article

Subcutaneous implantable cardioverter defibrillator. Clinical evidence and recommendations

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ABSTRACT

Currently, implantable automatic defibrillators (ICD) have demonstrated unobjectionable effectiveness in the primary and secondary prevention of sudden cardiac death (SCD) in the population of patients with high-risk heart diseases. However, its application is not free from complications, difficulties and inconveniences mainly related to intravascular catheters, which are more prevalent in a subgroup of selected patients, such as young active patients, patients with susceptibility to infections and with absent or difficult intravascular access. In response to this problem, the subcutaneous cardioverter defibrillator (S-ICD) emerged in 2009, a completely extracardiac and extrathoracic device, whose design has been optimized in recent years and which, despite its limitations, such as the absence of a pacemaker, has proven an efficacy not inferior to that of the conventional ICD, without the complications inherent to the procedure of handling it and the permanence of intravenous catheters. This makes the S-ICD a useful and effective option, being ideal for those patients who do not require anti-bradycardia or anti-tachycardia cardiac stimulation or cardiac resynchronization.

PREFACE

This review suggests a very special time for Argentine electrophysiology.

Currently, in 2024, 38 years have elapsed since the first implantable cardioverter defibrillator was implanted for the first time in Argentina and Latin America, thanks to the work by Drs. Ricardo Pesce, Elina Valero de Pesce, and Dr. Mariano Favaloro. Our greatest acknowledgement to all of them.

In year 1986, implants were surgical and therapies were administered in a blind manner. The procedure had a considerable rate of complications and perioperative mortality, which turned it into a strategy implemented exceptionally.

Nowadays, we see how medical knowledge and technological input have changed the history of patients with high risk of sudden cardiac death. Endocavitary cardioverter defibrillator implants have meant a qualitative advancement, becoming a safe and predictable alternative, with excellent results in terms of effectiveness, complications and survival. This has made it possible for the range of patients reached by this therapy to increase significantly. We have gone in this short period of time, from treating terminally ill patients to treating in primary prevention.

I celebrate the work by Drs. Rosmiro Javier Fernández and Daniel Víctor Ortigoza, member of the committee on Arrhythmias and Electrophysiology of FAC, who made this magnificent review, showing the evolution of ventricular defibrillation that was started already 38 years ago in Argentina, by medicine eminent figures.

Dr. Fernando Scazzuso
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INTRODUCTION

In the Western world, cardiovascular disease constitutes the main cause of death, with sudden cardiac death (SCD) being the culprit event in 60% of cases.[1] So much so, that in developed countries, mortality by cardiac arrest exceeds the summation of mortality by lung cancer, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV/AIDS (human immunodeficiency virus/acquired immunodeficiency syndrome), domestic fires, traffic accidents, prostate cancer, suicides and Alzheimer's disease.[2] In the West, the epidemiology of SCD is closely linked to CAD, which is responsible for up to 75-80% of cases of SCD.[3] Implantable cardioverter defibrillators have consistently proven to be superior to the best pharmacological therapy available for the prevention of SCD in patients with previous cardiac arrest (secondary prevention) and for patients in high risk,

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with depressed ventricular function or an arrhythmogenic condition (primary prevention). For this reason, implantable cardioverter defibrillators (ICD) are the gold standard of SCD prevention.[2]

Transvenous ICD (TV-ICD) has shown benefits; however, to this date there are numerous complications inherent to the system, mostly related to the intravascular catheters used, whose incidence has been reported to be between 1 and 14%, according to the different publications.[4] To prevent these complications, among other reasons, in year 2008 the completely subcutaneous ICD (S-ICD) emerged. It was approved to be commercialized in the European Union in 2009 and in 2012 in the United States. [5]

COMPLICATIONS ASSOCIATED TO INTRAVASCULAR CATHETERS

Conventional ICDs are exposed to a wide variety of complications, with the most frequent and significant ones being those related to intravascular catheters.

We could start by mentioning acute complications, inherent to the implant technique for catheters, which go from the difficulty to reach venous access, which may significantly prolong the time of the procedure and the exposition to X-rays, and in some cases lead to failure, catheter shifting, exposing patients to surgical reinterventions and more severe complications, such as pneumothorax, hemothorax, cardiac perforation and tamponade. The incidence of complications is estimated in 1.5% of ICD implants.[4,6]

As these are intravascular devices, catheters are susceptible to thrombogenicity and infection. Mainly Staphylococcus and Streptococcus are the bacterial species involved, which create a biofilm on the surface of the catheter and lead to infectious endocarditis, which cannot be eradicated by antibiotic treatment and requires extraction of the device. On the other hand, ICD pocket infection is one of the most frequent complications, whose incidence increases in up to 3% after repeated generator exchanges.[5] It also requires extraction of the device to prevent infectious endocarditis. This is a risky procedure, mainly in old implants, which due to the phenomena of thrombosis, fibrosis and adherence of catheters, may make extraction difficult, with a risk of perforation, valve disruption and death, with a rate of major complications of between 1 and 4%, and mortality of 0.8% in the more experienced centers.[2,7]

Furthermore, the presence of thrombi adhered to catheters has been observed using intracardiac ultrasound in 30% of cases, which contraindicates its use in patients with venous-systemic shunt, and increases the risk of thromboembolism thrice in patients with patent foramen ovale.[1]

Another potential complication related to intracardiac leads is valve dysfunction caused by the catheter passing through the tricuspid annulus. A study showed a worsening in tricuspid regurgitation in 15% of implanted resynchronizers, which was correlated with worse clinical and echocardiographic response to cardiac resynchronization therapy (CRT).[8]

Finally, we should mention the catheter failures related to the long-term deterioration of its components. This wear and tear mainly affects insulating materials (polyurethane and silicone) and is due to the repetitive mechanical movement occurring beat to beat when going through the tricuspid annulus, and to friction when going through the costoclavicular ligament, when subclavian puncture is used as access (subclavian crush syndrome), and in the fixation point at the level of the pectoralis major.[4] The incidence of this type of failures increases according to the time elapsed since the implant, which may reach 20% in 10 years according to some studies and it is more prevalent in young patients (younger than 50 years) with intense physical activity.[4,8] These defects may cause an increase in impedances, oversensing and inappropriate shocks, requiring surgical review and electrode replacement.

The National Cardiovascular Data Registry of the US reported that women with TV-ICD have a greater risk of post-implant complications than men, with a higher rate of hospital readmissions within 6 months and a greater risk of acute complications such as pneumothorax and cardiac perforation.[9] This same registry also showed a higher risk of infections related with TV-ICD in the population of patients in hemodialysis.[10]

TECHNICAL CONSIDERATIONS OF S-ICD

Unlike conventional transvenous ICDs (TV-ICD), whose system has intravascular/intracavitary leads, S-ICDs are entirely extracardiac and extrathoracic devices. They have 2 main components *(Figure 1)*.

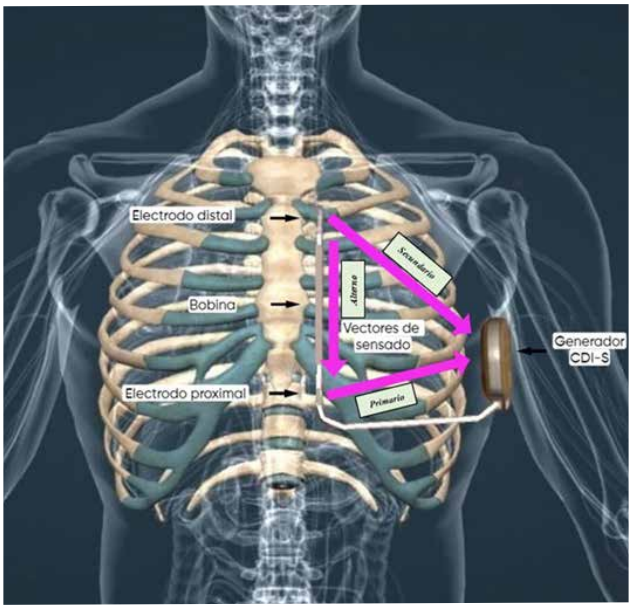


FIGURE 1.
Graphic representation of S-ICD and its components
Position of S-ICD (subcutaneous implantable cardioverter defibrillator) and graphic representation of the generator, the catheter and its leads (proximal, distal and the coil). The 3 sensing vectors available are represented: primary (inferior), secondary (superior) and alternate (medial). Purple arrows.

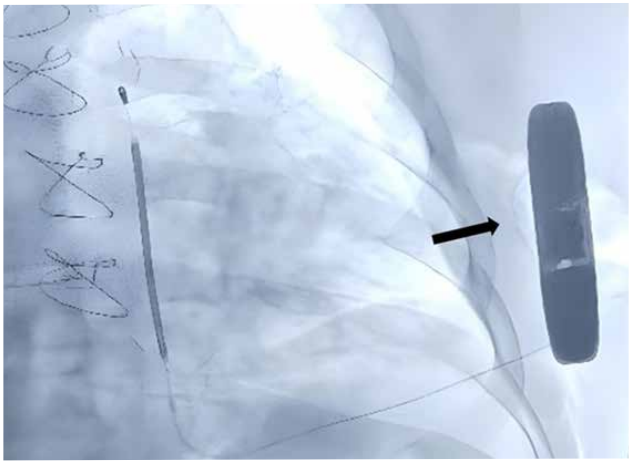


FIGURE 2.
Radioscopy image of patient with S-ICD (subcutaneous implantable cardioverter defibrillator indicated by black arrow). Courtesy of Dr. Ignacio Mondragón. ICBA, Buenos Aires.

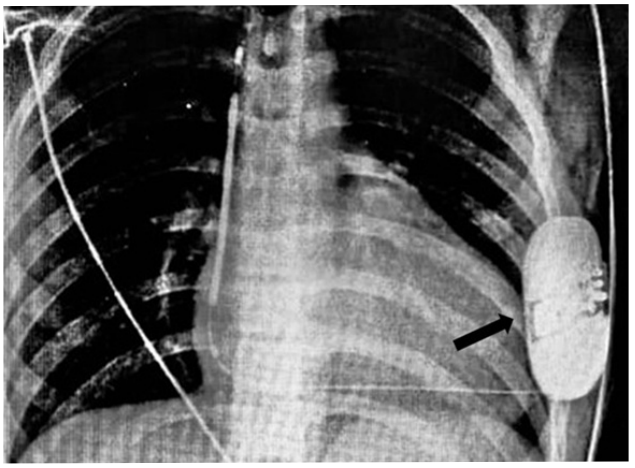


FIGURE 3.
The S-ICD generator is in a submuscular plane (black arrow) and the catheter has a right parasternal trajectory.
Courtesy of Dr. Mónica Benjamín, Hospital Argerich, Buenos Aires.

- A generator, whose weight and volume is greater than in TV-ICD, with a capacity of providing high-energy shocks, of up to 80 Joules, and pacemake after shock, at 50 bpm for 30 seconds if asystole is detected for more than 3.5 seconds. The generator design was optimized from the original versions, that had 145 g of weight, 65 ml of volume and an estimated useful life of 5 years, to current versions (third generation), with 130 g of weight, 59.5 ml of volume, and an estimated useful life of 8.7 years.[11]
- A single subcutaneous catheter of 3 millimeters of diameter (9 French) and 45 cm of length, which is channeled through the lateral chamber where the generator is placed medially, up to the xiphoid process, where it is fixed, and later it is tunneled in a cephalic direction (at 1 to 2 centimeters to the left or right, in a parallel line to the sternum), trying to place the distal end of the catheter close to the sternal manubrium. This subcutaneous catheter has 2 leads along its parallel trajectory to the sternum (a proximal one and a distal one) with sensing capacity. The defibrillation coil extends between the 2 sensing electrodes, which along with the generator close the defibrillation circuit (active case).[2]

There is a huge difference between the subcutaneous and transvenous ICDs implant techniques. In intravascular devices, the generator is generally located in the left infraclavicular region, and the placement of the lead(s) requires venous access toward the right ventricle, through the subclavian, axillary or cephalic veins. In contrast, the generator of the subcutaneous device is located laterally in the chest, at the level of the 5th or 6th left intercostal space, and the lead is tunneled subcutaneously from the pocket of the generator to the left parasternal edge in the conventional technique.[2]

The standard implant procedure of the generator and catheter entails 3 incisions: a lateral one for the generator, and two parasternal ones for the catheter.

The first incision is made laterally, parallel to the inframammary fold, at the level of the 5th or 6th intercostal space, between the mid and anterior axillary lines. The aim of this incision is the creation of the generator's pocket. The second incision of 1 to 1.5 cm is located medially, adjacent to the left edge of the xiphoid process. Subsequently, the lead is tunneled, from the lateral incision up to the xiphoid one, using the appropriate tools and is held with nonabsorbable sutures to maintain the fixation in the long term, and thus prevent lead migration. A third superior left parasternal incision is made at the level of the sternal manubrium, repeating the tunneling and fixation procedure of the lead at this level *(Figure 2)*.[2]

There are alternatives to this technique: locating the generator submuscularly and the catheter in a right parasternal position, as shown in the radiographic image in *Figure 3*. On the other hand, the third incision is prone to causing discomfort in patients, and in turn, there are aesthetic consequences as it is more visible, and furthermore, it is more prone to infection. These issues led to the development of a technique with just 2 incisions, which means the lead tunneling and release in a cephalic direction through an 11 French peel-away introducer for the left parasternal edge, not requiring a third incision. The cost of obviating the third incision and lead distal fixation is a greater chance of electrode dislodging, although currently, the rate of dislodgement is very low with this technique.[12]

Another aspect to underscore is that more than 95% of the procedures can be done using only anatomical references, not requiring fluoroscopic guide, which means an additional advantage for operators, medical staff and patients. [12]

Currently, the technique that has shown best results, and therefore, the one most used, is the so-called intermuscular implant technique with 2 incisions, consisting of the combination of the lead fixation technique with 2 incisions already described, and positioning the generator at

an intermuscular plane, between the serratus anterior and the latissimus dorsi, instead of the classical subcutaneous pocket. This technique has displayed a decrease in the risk of pocket-related complications, such as erosion and infection, and in turn decreases the risk of device migration and achieves better cosmetic results for patients, being particularly useful in obese and very thin patients.[13]

PRE-IMPLANT SCREENING

Unlike conventional cardioverter defibrillators, a pre-implant screening using surface leads is a crucial requirement when applying S-ICD. This is because of S-ICD susceptibility to undersensing (due to the distance of the subcutaneous lead and the heart) and to double counting the cardiac signal by T-wave oversensing, generating a high risk of inappropriate shock. Patients failing the screening (check-up) should not be selected for S-ICD implant.

Several groups have evaluated the eligibility of patients based on standard screening, observing a rate of lack of selection between 7 and 10%. The least eligible patients are those with hypertrophic cardiomyopathy and congenital heart diseases. On the other hand, a screening methodology has been proposed both in rest and during exercise to decrease the rate of T-wave oversensing.[2]

Kooiman et al, made an elegant study, where they observed that 7 in every 8 inappropriate shocks by T-wave oversensing occurred during exercise and 1 during atrial fibrillation of high response, proposing exercise screening in patients in high risk of T-wave oversensing.[14]

PROGRAMMING

S-ICD was designed with a high level of automaticity. Unlike TV-ICD, which presents more than 100 programmable parameters, S-ICD has less than 10, among which the following can be mentioned: sensing vector, detection heart rate in each of the 2 zones, post-shock pacing (on/off), polarity of the following shock and delay time between each shock. The third generation devices also have the activation option of high-frequency filter: the Smart Pass filter.

In the first experiences, a single detection zone was programmed, with an HR above 200 bpm, with no rhythm discrimination, so the rate of inappropriate shocks was around 20% in 3 years. With the addition of a conditional second detection zone, a decrease was achieved in inappropriate shocks of up to 11.7% in 3 years.[15] The analysis of the IDE study ratifies the importance of programming 2 zones, which reduces the rate of inappropriate shocks by supraventricular arrhythmia by 70%.[15] Furthermore, it was proven that the addition of a second detection zone, with an active discrimination algorithm does not extend the detection time, nor increases the incidence of syncope.[16]

Several studies on TV-ICD showed the importance of programming of high heart rates of detection and a prolonged detection time to reduce the amount of shocks, as a direct relationship was observed between the number of shocks with an unfavorable evolution of patients. Because of this, a conditional zone of 200 bpm and a non-conditional zone of between 220 and 230 bpm are suggested.[2]

The last generation of S-ICD has incorporated, between its sensing and arrhythmia discrimination tools, a high-frequency filter called Smart Pass. This filter activates when the sensed signal reaches a minimum width ≥0.5 mV and is capable of discriminating the signals corresponding to QRS (>10 Hz) from those of T wave (<9 Hz). A prospective study has shown that the Smart Pass filter availability in S-ICD leads to a significant decrease in inappropriate shocks, not affecting performance in terms of appropriate shocks.[17]

This filter has proven to be so effective, that its implementation turned supraventricular tachycardia into the main cause of inappropriate therapies, just as with TV-ICD.[18]

The interventions to prevent recurrent inappropriate shocks include: a proper implant technique, optimization of sensing vector, addition of a conditional zone if there is none, Smart Pass filter activation, modification of detection rate, obtaining a reference template during exercise test.

Other interventions available are the optimization of antiarrhythmic treatment and eventually, radiofrequency ablation, and in selected cases, surgical intervention could be necessary to reposition the catheter or the generator.[2]

DISADVANTAGES OF S-ICD

Many of the S-ICD design characteristics that make it superior to TV-ICD also entails limitations and disadvantages *(Table 1)*.

As this is an entirely extracardiac device, it depends on far-field sensing algorithms for the detection and diagnosis of heart rhythm. This fact implies the need to perform a pre-implant screening in all patients, so as to guarantee a reliable sensing and to prevent oversensing and inappropriate shocks, which would mean a screening failure, and therefore, the exclusion of 7 to 8% of patients candidates to this therapy.[1]

Another negative aspect is the size and weight of the generator of the S-ICD, presenting approximately twice the volume and weight in comparison to TV-ICD, as it requires high-energy shocks (80 J), and therefore, batteries with more capacity. This detail could be a problem, mainly in children and patients with low subcutaneous cellular tissue, which may favor skin erosion, decubitus lesions and pocket infection.[6] However, the advancements in the design have achieved an acceptable generator weight and volume of 130 g and 59.5 ml in the most recent versions.[2]

The limited longevity of the battery is a consequence of the need to apply high-energy shocks (80 J) to achieve an effective therapy, and it is still a weak point in comparison with TV-ICD. With technological improvements, longevity could be significantly extended, from 5 years in the first models, to 8.7 years in third-generation ones, according to a remote follow-up study.[19]

The rate of inappropriate shocks represented a disadvantage in the first-generation S-ICDs, but, as mentioned abo-

TABLE 1.
Summary of the S-ICD and TV-ICD devices (single-chamber)

	S-ICD	TV-ICD
Pre-implant	Requires screening	Does not require screening
Generator implant	Subcutaneous or intermuscular	Subcutaneous or submuscular
Catheter implant	Subcutaneous, 2 vs 3 incisions technique	Transvenous, requires intravascular access
Battery longevity	7.3 – 8.7 years	11-12 and more than 13 years
Generator size	59.5 cm3, 130 g	30 cm3, 68.9 g
Energy discharge	Up to 80 J	Up to 42 J
Energy required to defibrillate	36.6 ± 19.8 J	11.1 ± 8.5 J
Capacitor charge time	Long (14.6 ±2.9 sec)	Shorter (7.1 ±1.8 sec)
Shock wave	Biphasic	Biphasic
Shock tilt	Fixed 50%	Fixed 50%
Permanent pacemaker capacity (ATP/antibradycardia/CRT)	Not available	Available
Risk of infection in 4 years	0.9%	1.9%
Catheter failures/ complications	1.4%	6.6%
MRI compatibility	Yes	Yes
Atrial arrhythmia monitoring	Yes (AFib-detection algorithm)	Yes (several programmable options)
Remote monitoring	Yes	Yes

Adaptado de Tan y cols[21]

ve, with technological and programming improvements, a significant reduction in it was achieved, being currently comparable with that of TV-ICD, although the mechanisms are different, with T-wave oversensing being predominant in S-ICD.[1]

Another disadvantage is the chance of a greater discomfort produced by the high-voltage therapies required for an effective shock of the S-ICD and being more harmful than those of TV-ICD. However, it seems there is little correlation between shock voltage and the discomfort provoked, as this is a phenomenon that mainly depends on sensitivity and individual pain threshold in each patient.[6] On the other hand, as to the myocardial damage caused, studies in animals showed that S-ICD shocks were less damaging for the myocardium than those generated by TV-ICD, with less troponin I elevation when comparing subcutaneous 80 J shocks with intracardiac 35 J in pigs.[20] Although this phenomenon still has to be tested in humans, which at first sight may appear as a disadvantage, it could rather be an advantage.

The charge and shock therapy time is significantly higher in S-ICD compared with TV-ICD. However, evidence has not shown negative clinical consequences in relation to this phenomenon. In fact, the more prolonged detection times correlated with favorable clinical outcomes in patients with TV-ICD (SIMPLE trial). Both types of devices are the foundation for current programming.

Undoubtedly, the greater disadvantage and the Achilles heel of S-ICD currently still is the inability for permanent pacing and ventricular oversensing as anti-tachycardia pacing (ATP). This limitation restricts S-ICD indication to patients without current or future pacing indication, including cardiac resynchronization therapy and patients with no monomorphic VT that could benefit from ATP.[1] Nevertheless, there are data from the SCD-HeFT trial indicating that the yearly rate of reverted VT episodes thanks to ATP is very low: <2% per year, interestingly less than the risk of complications by transvenous catheters. Moreover, there is evidence showing more mortality associated to the acceleration of tachycardia treated by ATP from a study with remote ICD monitoring.[2] Finally, the emerging technology of leadless cardiac pacing and its combination with S-ICD is a promising solution for this limitation. This new concept proved to be reliable and effective, with an excellent performance in an 18-month follow-up, in a pre-clinical study in animals.[21] Currently, there is an ongoing trial in humans, in its clinical phase, that will evaluate safety, performance and effectiveness of combined S-ICD and leadless pacemaker.[19]

CLINICAL EVIDENCE AND RECOMMENDATIONS

Since its approval in the European Union in 2009 to this date, use of S-ICD for sudden cardiac death prevention has grown exponentially, exceeding 100,000 around the world.[2] Numerous clinical and preclinical studies haven proven its safety and efficacy in the treatment of ventricular arrhythmias.

The first clinical trials date back from 2008. Bardy et al. made the first pilot study in human phase with S-ICD and proved that the posterolateral position of the generator was capable of offering an optimal and safe defibrillation chronically, although with defibrillation thresholds significantly greater than those of TV-ICD.[15]

Since the moment when it was ready to be sold, plenty of studies have been published on different clinical conditions and populations of patients. Among the most relevant ones, we can mention:

In 2009, 2 large prospective trials, with similar design and endpoints studied the efficacy and safety of S-ICD: the IDE study enrolled 308 patients, and the EFFORTLESS trial, 568 patients. The population of patients included were mainly young patients, with higher ejection fraction in comparison with other studies with TV-ICD, and 70% had indication as primary prevention. Both trials were analyzed jointly and showed a high efficacy in spontaneous VT/VF cardioversion, with 90% efficacy in the first shock and total efficacy of 98%. In turn, the rate of complications was low. A point to highlight is that programming was evaluated in one and two zones (conditional zone) of detection, showing a rate of inappropriate shocks in 3 years of 20.5% with programming

TABLE 2.
Recommendations for S-ICD implant – 2022 European Guidelines for Sudden Cardiac Death[25]

Recommendations	Clase (a)	Level (b)
Implanting a subcutaneous cardioverter defibrillator should be considered as an alternative to the transvenous implantable cardioverter defibrillator in patients with indication of ICD, when pacing for bradycardia, cardiac resynchronization therapy or antitachycardia pacing are not necessary.	IIa	B

(a) Recommendation class (b) Level of evidence

TABLE 3.
Recommendations for S-ICD implant – 2017 AHA Guidelines on Sudden Cardiac Death[26]

Recommendations	Clase (a)	Level (b)
S-ICD implant is recommended in patients meeting ICD criteria, and that have inadequate vascular access or high risk of infection, and in whom cardiac pacing for bradycardia, antitachycardia pacing or resynchronization are not necessary or expected.	I	B
S-ICD implant is recommended in patients meeting ICD criteria, and in whom cardiac pacing for bradycardia, antitachycardia pacing or resynchronization are not necessary or expected.	IIa	B
S-ICD should not be implanted in patients with cardiac pacing indication due to bradycardia, indication for antitachycardia pacing or resynchronization.	III	B

(a) Recommendation class (b) Level of evidence

in one zone in comparison with 11.7% with programming in two zones. The main cause for inappropriate shocks was T wave oversensing.[15] In 2018, the Propensity Score was published, a study comparing the rate of complications, appropriate and inappropriate shocks between the population of patients with VT-ICD from the SIMPLE trial vs the population with S-ICD from the EFFORTLESS trial. There were no significant differences in the endpoints evaluated. In regard to the rate of complications related to catheters, as expected, it was significantly less in the S-ICD group (0.3% vs 2.3% in 3 years). A remarkable datum is that a higher rate of inappropriate shocks was observed with S-ICD, 11.9% vs 7.9% in the TV-ICD group, that did not have statistical significance. The main cause of inappropriate shocks was supraventricular arrhythmia in TV-ICD and oversensing in S-ICD.[23] We should highlight that the evaluated devices were mostly (60%) of the first generation, with no Smart Pass filter available to minimize inappropriate shocks due to oversensing.

Between 2011 and 2017, the PRAETORIAN trial was carried out, which was the first noninferiority randomized prospective trial, comparing S-ICD vs TV-ICD. There were 876 patients with ICD indication, but without cardiac pacing indication, randomized to S-ICD or TV-ICD. During a mean follow-up of 49 months, noninferiority was proven for the primary aim of complications related to the device and inappropriate discharges. The rate of inappropriate discharges was 9.7% in the S-ICD group and 7.3% in the TV-ICD group (HR 1.43; 95% CI 0.89-2.30). There were no differences observed either, in the secondary aim of death and appropriate discharges; but the trial did not have enough statistical power to show noninferiority for this second aim.[6] We should point out that more than 80% of the patients included had class I and II of NYHA and were younger than in other previous trials with ICD. Currently, there is an ongoing extension of the PRAETORIAN XL trial follow-up (not published yet), with the aim of establishing the superiority of S-ICD over TV-ICD.

The UNTOUCHED trial was a prospective, multicenter, non-randomized trial, published in 2021, evaluating the incidence of inappropriate shocks by S-ICD of second and third generations in 1111 patients with indication as primary prevention for sudden cardiac death. This study showed a high efficacy and safety with contemporary devices and the lowest rate reported of inappropriate shocks, 3.1% yearly, with programming in 2 zones of detection and the algorithms of morphology discrimination (Smart Pass filter).[16]

The ATLAS trial was prospective, randomized and controlled, published in 2022, which revealed a rate of catheter-related complications within 6 months that was 93% less in S-ICD in comparison with TV-ICD (0.4% vs 4.8%). On the other hand, there were no differences in performance in terms of failed shocks and rate of inappropriate shocks between both devices.[23]

POSTAPPROVAL is the largest trial, made to this date and with a more prolonged follow-up. It was published in August 2023, and it is a multicenter trial directed by the FDA, and designed to evaluate the safety and efficacy of S-ICD in a population more adjusted to the real world. There were 86 centers from the US participating, which enrolled 1643 patients, with a 5-year follow-up, and proved that S-ICD is a safe and efficient device in a long-term follow-up, with a rate of complications of 7.3% per year and 13.5% in 5 years.[22]

Nowadays, the weight of the evidence available supports using S-ICD for primary and secondary prevention of sudden cardiac death, as long as the need for cardiac pacing is not present or expected, whether due to bradycardia, antitachycardia pacing or resynchronization therapy. The last American and European guidelines gave S-ICD a class IIa indication, with level of evidence B. Also, the American Guidelines consider a class I indication in patients that also present inappropriate vascular access and high risk of infection *(Tables 2 and 3)*.[3,24,25] We have to highlight that the last Guidelines were written before the publication of the most recent trials, and therefore, the level of recommendation of S-ICD therapy should be increased in the next update.[21]

SELECTION OF PATIENTS FOR S-ICD

Most candidates to ICD in primary prevention are also eligible for S-ICD implant. The patients requiring cardiac pacing for an extended time should not be considered for S-ICD. However, evidence shows that, if pacing is not needed at the time of the implant, the future chance of needing it is low, and if it so happened, there is always the alternative of adding a transvenous or leadless pacemaker.[2]

The need for antitachycardia pacing (ATP) as indication to implant TV-ICD, although supported by guidelines, remains controversial. Although ATP is clinically effective in some patients to prevent unnecessary shocks, extending the detection time and/or programming high VT detection could be equally effective. On the other hand, predicting which patients will benefit from ATP is hard to define. If the data from the SCD-HeFT trial are observed, the tachycardias that were treated effectively by ATP were scarce, with an incidence of less than 2% per year, which is less than the rate of failures of transvenous catheters.[2]

There is a large population of patients, in whom the implant of transvenous devices is not possible or it is difficult. This would be the case of pediatric or adult patients with congenital heart diseases, many of which lack venous accesses. The risk of sudden cardiac death could be high in these patients, depending on the underlying heart disease and S-ICD emerges as a first-line option. On the other hand, by pre-implant venogram, a study has proven the presence of stenosis or obstruction in the central venous system in 7% of patients, particularly in those with previous permanent transvenous catheters; therefore, in patients with multiple damaged or dropped catheters, a change to S-ICD is a reasonable option.[26] Something similar occurs with patients in hemodialysis, in whom central venous access is usually a great hindrance.

Patients with high risk of infection represent another population to take into account for S-ICD implant. Those with endocarditis or infection in IV devices, in whom the risk of recurrent infection is high, are excellent candidates to S-ICD after extraction. Patients in hemodialysis, those who are diabetic, immunosuppressed and oncological also are included in this group of patients, and therefore, should be considered for S-ICD.[1]

Another piece of information to take into account in the selection of patients for S-ICD is age. Young patients are a population that could benefit mainly with S-ICD, given the chance of complications associated to catheters over their life.

Young patients with hereditary arrhythmic syndromes also result in a population appealing for S-ICD, in whom the risk of developing bradycardia and need for permanent pacing is low. In this group, patients are included who present: long QT syndrome, short QT syndrome, early repolarization syndrome, and some patients with arrhythmogenic right ventricular cardiomyopathy. These patients are prone to developing polymorphic VT and VF rather than monomorphic VT.[1] This group also includes patients with Brugada syndrome, in whom evidence has reported a high rate of failures in transvenous catheters of up to 2% per year, which is 4 times more than in the general population, and over the course of the life of these patients, the risk of complications related to transvenous devices may reach up to 9%.[26] For this reason, patients with Brugada syndrome are first-line candidates for S-ICD.

Patients with hypertrophic cardiomyopathy, who usually have high defibrillation thresholds with TV-ICD, also represent a group to take into account for S-ICD.[21] Both patients with Brugada syndrome and those with hypertrophic cardiomyopathy have electrocardiographic characteristics that may potentially predispose to double counting of QRS and T wave respectively, with the subsequent risk of inappropriate shocks. Therefore, a careful pre-implant screening is necessary in this group of patients.[1]

A study evaluated the experience of S-ICD in teenagers and young adults, demonstrating its safety and efficacy in this population. Although there was also evidence of a higher rate of inappropriate shocks in younger patients, this same trend is observed with VT-ICD.[27]

Finally, for patients with indication of ICD implant temporarily, as those in a waiting list for heart transplant, S-ICD represents an advantageous alternative, preventing venous fibrosis, and it facilitates extraction during surgery.[1]

Figure 4 summarizes the most important factors to take into account in the selection of patients candidates to S-ICD implant.

LIMITATIONS

The initial aim of this article was to make a short review about S-ICD, focused on recommendations and selection of patients. The bibliographical search process started revealing a large amount of material, which, given its richness

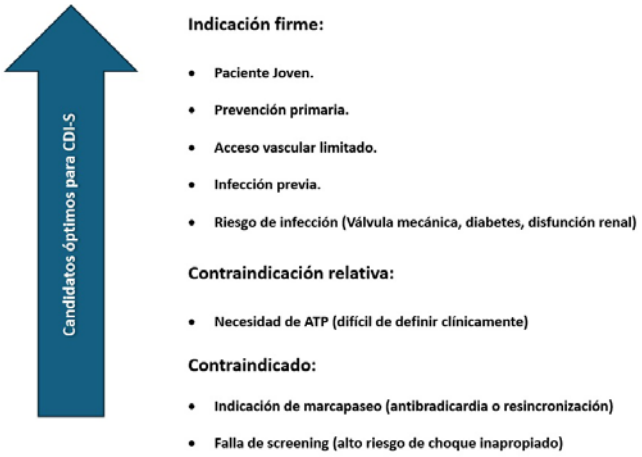


FIGURE 4.
Flowchart of S-ICD (subcutaneous implantable cardioverter defibrillator) indications, showing the direction of indications of the device for the patients that benefit the most.
Adapted from Mc Leod et al[2].

and pertinence was difficult to leave aside, consequently producing a more extensive publication, and perhaps less concise and friendly for reading than intended.

CONCLUSION

Since its release in 2009 to this date, S-ICD has gone from being an emerging therapy, with limited indications, to a sound, safe and effective alternative to TV-ICD in primary and secondary prevention, in a wide population of patients, averting the multiple complications inherent to permanent intravascular catheter implants. However, this technology still presents limitations, such as the absence of pacing, restricting its use to patients not requiring antibradycardia or antitachycardia pacing. Ideal candidates are patients with limited vascular access and in whom life expectancy or their clinical conditions turns them more susceptible to intravascular catheter-related complications. In spite of this, a promising scenario is observed for a not-too-distant future, with technological advancements and the emergence of leadless pacing, which could be coupled with S-ICD, thus turning it into a comprehensive tool for the prevention of sudden cardiac death, antitachycardia pacing, and even cardiac resynchronization.

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