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The Entirely Subcutaneous Implantable Cardioverter-Defibrillator

Initial Clinical Experience in a Large Dutch Cohort

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Objectives The purpose of the study was to evaluate the efficacy and safety of the entirely subcutaneous implantable cardioverter-defibrillator (S-ICD).

Background A new entirely S-ICD has been introduced, that does not require lead placement in or on the heart. The authors report the largest multicenter experience to date with the S-ICD with a minimum of 1-year follow-up in the first 118 Dutch patients who were implanted with this device.

Methods Patients were selected if they had a class I or IIa indication for primary or secondary prevention of sudden cardiac death. All consecutive patients from 4 high-volume centers in the Netherlands with an S-ICD implanted between December 2008 and April 2011 were included.

Results A total of 118 patients (75% males, mean age 50 years) received the S-ICD. After 18 months of follow-up, 8 patients experienced 45 successful appropriate shocks (98% first shock conversion efficacy). No sudden deaths occurred. Fifteen patients (13%) received inappropriate shocks, mainly due to T-wave oversensing, which was mostly solved by a software upgrade and changing the sensing vector of the S-ICD. Sixteen patients (14%) experienced complications. Adverse events were more frequent in the first 15 implantations per center compared with subsequent implantations (inappropriate shocks 19% vs. 6.7%, $p = 0.03$; complications 17% vs. 10%, $p = 0.10$).

Conclusions This study demonstrates that the S-ICD is effective in terminating ventricular arrhythmias. There is, however, a considerable percentage of ICD related adverse events, which decreases as the therapy evolves and experience increases. (J Am Coll Cardiol 2012;60:1933–9) © 2012 by the American College of Cardiology Foundation

Implantable cardioverter-defibrillators (ICDs) are widely used to prevent fatal outcomes associated with life-threatening arrhythmic episodes in a variety of cardiac diseases (1–4). Traditionally, ICDs have been implanted transvenously by creating a pocket in the subclavicular area and gaining vascular access to reach the heart. This approach, although considered the standard of care for pacing and ICD therapy, has its drawbacks, such as short- and long-term vascular complications, and complications associated with obtaining venous access. This can prolong the procedure and occasionally results in failed ICD implantation. Also, in case of device infection, the presence of intracardiac leads is a risk for endocarditis, which can lead to major morbidity and mortality (5). Additionally, implanted transvenous leads are subject to mechanical stress associated with heart motion, body motion, and patient anatomy. This can influence lead longevity. Lead fractures and inside-out abrasions in commonly used leads such as Sprint Fidelis (Medtronic Inc., Minneapolis, Minnesota) and Riata demonstrate that even modern leads are susceptible to lead failure. Clinical management in these patients is difficult and potentially harmful (6,7). Lead failure either generates inappropriate shocks or impedes appropriate therapy. Therefore, despite decades of innovations in lead design, lead complications (e.g., lead dislodgement, lead fracture,

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Abbreviations and Acronyms

ATP = antitachycardia pacing

ICD = implantable cardioverter-defibrillator

LVEF = left ventricular ejection fraction

mVT = monomorphic ventricular tachycardia

S-ICD = subcutaneous implantable cardioverter-defibrillator

TV-ICD = transvenous implantable cardioverter-defibrillator

VF = ventricular fibrillation

VT = ventricular tachycardia

or infection) remain a major limitation in the use of transvenous ICDs (TV-ICD). A different approach to ICD implantation might alleviate these concerns.

Recently, a new subcutaneous ICD (S-ICD) was introduced in Europe (8). The S-ICD is unique in that its implantation is entirely subcutaneous, eliminating the need for lead placement in or on the heart and simplifying the implant procedure by using anatomical landmarks instead of fluoroscopy imaging. We report the burgeoning and largest experience to date with the S-ICD with a minimum of 1-year follow-up in the first 118 patients who were treated with this novel technology in the Netherlands.

Method

Study design. This study was conducted in 4 high-volume ICD-implanting hospitals in the Netherlands. The study was performed using routine files of consecutive patients implanted with an S-ICD. All patients were aware of the innovative aspects, limitations, and potential advantages and disadvantages of the device. Patients who had an S-ICD implanted prior to the CE approval provided written informed consent and the use of the device was approved by the Medical Ethical Committee. Permission of the Medical Ethical Committee was not required for retrospective analysis of stored data.

Study population. Patients were eligible for an S-ICD if they had a class I or IIa ICD indication for ICD therapy according to the American Heart Association/American College of Cardiology/European Society of Cardiology 2006 guidelines (9) for primary or secondary prevention of sudden cardiac death. Patients with an indication for bradycardia or antitachycardia pacing (ATP) or resynchronization therapy were not considered for S-ICD implantation. Patients were selected for S-ICD implantation by 3 criteria: 1) patient preference; 2) after complications of a transvenous system that made reimplantation of a TV-ICD unattractive; and 3) when the physician deemed S-ICD implantation more appropriate than a transvenous system (e.g., because of a young age of the patient). Forty patients have been previously reported (8,10). Patients included in the IDE (Investigational Device Exemption) Clinical Study (NCT01064076) or PRAETORIAN (Prospective, RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter-defibrillator therapy) trial (NCT01296022) (11) were left out from our analysis. T-waveform analysis using the customized measurement screening tool was performed and deemed acceptable in all patients. All patients were implanted between December 2008 and April 2011.

Implantation. The S-ICD (Cameron Health S-ICD System, Cameron Health, San Clemente, California) consists of 3 components: the SQ-RX Pulse Generator, the Q-TRAK Subcutaneous Electrode, and the Q-TECH Programmer. Antibiotic prophylaxis consisted of intravenous flucloxacillin (1,000 or 3,000 mg) or cephazoline (1,000 or 2,000 mg) given before the procedure. General anesthesia or local anesthesia in combination with conscious sedation was used. The S-ICD was implanted without fluoroscopy using anatomical landmarks only. An additional suture sleeve at xiphoid position was used from September 2009 after the first 20 patients in this study. Due to a relative high incidence of inappropriate shocks in the earlier implanted S-ICD patients (8), a software upgrade was applied to all devices since October 2009. This software upgrade was designed to decrease oversensing by adjusting the detection profiles of the system in the conditional zone to allow for a slightly longer refractory period. At least 1 defibrillation testing was done with 65 J in all patients. Polarity was reversed in case of failure. After implantation a chest x-ray was performed to check correct positioning of the ICD and subcutaneous lead. Patients were mobilized immediately after the procedure. Most patients were discharged on the day of the procedure or on the following day.

Device programming. Most device settings in the S-ICD are automated. The device has 3 sensing vectors, and will automatically select the optimal vector during implantation. Thereafter, a template is made to store the QRS morphology, referred to as an automatic setup. A conditional discrimination zone incorporating a feature-extraction technique was programmed between rates of 170 and 250 beats/min to distinguish supraventricular tachycardia from ventricular tachycardia (VT). Shock therapy was programmed at maximum output (80 J), with potential transthoracic post-shock pacing therapy for 30 s.

Follow-up. All patients visited the ICD outpatient clinic at least within 2 months after implantation. Thereafter patients were evaluated at the outpatient clinic at intervals of 6 months. Additional follow-up visits took place on indication, for instance after shock therapy or complications. Careful history taking was done and all arrhythmic events were routinely examined every visit in the follow-up period.

Statistical analysis. Categorical data are displayed as percentages. Continuous data are described as mean ± SD. To compare the inappropriate shock and complication rate between first and later implants Fisher's exact test was used. We considered p values <0.05 statistically significant.

Results

Patient characteristics. From December 2008 to April 2011 of the approximately 1,300 patients who had a ICD

Table 1 Patient Characteristics of Patients Implanted With an S-ICD (n = 118)

Male	89 (75)
Age at implant, yrs	50 ± 14
Clinical disease	
Ischemic cardiomyopathy (n = 118)*	45 (38)
Dilated cardiomyopathy (n = 118)*	22 (19)
Nonischemic/nondilated cardiomyopathy (n = 118)*	8 (6.8)
Inherited cardiac disease (n = 118)*	27 (23)
Congenital heart disease (n = 118)*	1 (0.8)
Idiopathic VF (n = 118)*	15 (13)
Other cardiac history	
Hypertension (n = 117)*	14 (12)
Diabetes mellitus (n = 117)*	14 (12)
Atrial fibrillation (n = 118)*	13 (11)
Moderate/severe valvulopathy (n = 84)*	11 (13)
Previous CABG (n = 118)*	11 (9.3)
Nonsustained VTs (n = 116)*	24 (21)
ECG	
PR interval, ms)	170 ± 29
PR interval >200 (n = 118)*	13 (11)
QRS interval, ms	102 ± 17
QRS interval >120 (n = 118)*	11 (9.3)
LVEF	41 ± 15
Primary prevention	38 ± 12
Secondary prevention	50 ± 14
NYHA functional class	
I (n = 114)*	86 (75)
II (n = 114)*	23 (20)
III (n = 114)*	5 (4.4)
IV (n = 114)*	0 (0.0)
Medication	
Beta-blocker (n = 117)*	71 (61)
ACE inhibitor/ARB (n = 117)*	58 (50)
Oral anticoagulants (n = 56)*	22 (39)
ICD indication	
Primary (n = 118)*	71 (60)
Secondary	
VF in history (n = 118)*	39 (33)
Polymorphic VT in history (n = 118)*	2 (1.7)
Monomorphic VT in history (n = 118)*	6 (5.1)

Values are n (%) or mean ± SD. *Number of persons for whom there were available data.

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CABG = coronary artery bypass graft; ECG = electrocardiogram; ICD = implantable cardioverter-defibrillator; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; S-ICD = subcutaneous implantable cardioverter-defibrillator; VF = ventricular fibrillation; VT = ventricular tachycardia.

indication without the need for bradycardia or tachycardia pacing, 118 patients (9%) were selected and received an S-ICD. Patient characteristics are displayed in Table 1. The largest subgroup of patients was diagnosed with ischemic cardiomyopathy (n = 45 [38%]) and 27 patients (23%) received an ICD because of an inherited cardiac disease. More than half of the patients (n = 71 [60%]) received an ICD for primary prevention, of whom 24 patients (mean left ventricular ejection fraction [LVEF] of 56%) had an inherited arrhythmia syndrome. There were 6 patients with a secondary prevention indication because of monomorphic VT (mVT). The mean LVEF was 41% (38% in patients with S-ICDs implanted for primary prevention, 50% for secondary prevention). The mean age at implantation was 50 years (range 10 to 83 years). Thirteen patients (11%) previously had a TV-ICD explantation because of lead or device malfunction (n = 8 and n = 1, respectively), infection (n = 2), thrombotic occlusion (n = 1), and a complicated implantation of a TV-ICD (n = 1).

General anesthesia was used in 56 patients (47%); the rest were given local anesthesia in combination with conscious sedation. All induced tachyarrhythmias were successfully detected and converted into sinus rhythm. The mean rates of the programmed conditional zone were between 190 ± 9 and 228 ± 11 beats/min.

Follow-up. The mean follow-up period was 18 ± 7 months (177 patient-years). Two patients died during follow-up, 1 because of end-stage lung carcinoma and 1 because of end-stage heart failure. The latter patient, with a QRS duration of 100 ms, did not qualify for biventricular pacing.

In 8 patients, a total of 9 episodes of spontaneous sustained VT (n = 4) and 36 episodes of spontaneous ventricular fibrillation (VF) occurred (n = 4). All episodes were appropriately detected, and shock therapy was immediately successful in 98% of the episodes. One patient had an mVT that accelerated due to the shock delivered. The episode ended spontaneously without the necessity of another shock. Another patient had 6 successfully converted episodes of mVT. The S-ICD was explanted because the referring cardiologist preferred a transvenous system, as ATP was deemed necessary. Of the 6 patients implanted for secondary prevention after an episode of mVTs, no appropriate shocks occurred, but 1 patient had a nonsustained episode of mVT. In total, nonsustained VT episodes were registered in 12 patients (10%).

In 15 patients (13%) a total of 33 inappropriate shocks occurred (Table 2). Eleven inappropriate shocks in 9 patients were due to T-wave oversensing of which 3 shocks were prior to a software upgrade. In the other cases, T-wave oversensing was solved by changing the sensing vector of the S-ICD system during exercise testing (n = 7) or making a new template during exercise testing (n = 1). One patient received 15 shocks on double counting because of a newly developed complete right bundle branch block, which was solved by making a new template. One patient had an inappropriate shock because of noise sensing caused by transcutaneous electrical nerve stimulation therapy. One patient received an inappropriate shock due to atrial flutter, with a ventricular rate in the unconditional zone. Three patients experienced inappropriate shocks due to myopotential sensing caused by lead migration in 2 of the 3 patients. No inappropriate shocks occurred due to atrial fibrillation or other supraventricular tachycardias in the conditional zone.

Clinically significant ICD complications, defined as clinical events requiring surgical correction or hospitalization, occurred in 16 patients (14%). Dislocation of the subcuta-

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Table 2 S-ICD Related Adverse Events

	Patients	Episodes
Inappropriate shocks		
Total number	15 (100)	33 (100)
Number pre-software upgrade	6 (40)	7 (21)
Cause		
T-wave oversensing	9 (60)	11 (33)
Myopotentials	3 (20)	4 (12)
Double counting	1 (6.7)	15 (45)
Atrial flutter	1 (6.7)	2 (6.1)
TENS therapy	1 (6.7)	1 (3)
Complications		
Total number	16 (14)	
Cause		
Lead dislodgement	3 (2.5)	
Device dislodgement	1 (0.8)	
Infection	7 (5.9)	
Premature battery depletion	2 (1.7)	
Skin erosion	2 (1.7)	
Explantation because of need for ATP	1 (0.8)	

Values are n (%).

ATP = antitachycardia pacing; S-ICD = subcutaneous implantable cardioverter-defibrillator; TENS = transcutaneous electrical nerve stimulation therapy.

neous lead occurred in 3 patients, which resulted in inappropriate shock therapy in 2 patients. In all cases of lead dislocation, the parasternal part of the lead migrated 1 to 2 cm caudally. This prompted the introduction of an additional suture sleeve at xiphoid level, after which dislocation was no longer observed. There were 2 patients who had skin erosion at the location of the S-ICD generator requiring surgical revision. Seven patients had an infection of the S-ICD, requiring extraction of the device. Detailed information about these patients is described in Table 3. At least 3 of these patients had predisposing factors for developing infections. In 3 of these patients, an S-ICD was reimplanted in the same anatomical position 3 months later after treatment with antibiotics.

Inappropriate shocks and complications were more frequently observed in the first 15 patients per center who were implanted with the S-ICD than in subsequent patients (inappropriate shocks 19% vs. 6.7%, p = 0.03; complications 17% vs. 10%, p = 0.10) (Fig. 1).

Discussion

This study describes the largest cohort of patients to date, with 177 patient-years of follow-up, who received an entirely S-ICD for primary or secondary prevention. All induced tachyarrhythmias during defibrillation threshold testing were successfully converted. After 18 months of follow-up 98% of the spontaneous VT/VF events were successfully converted into sinus rhythm. One patient had an mVT, which accelerated due to initial shock therapy, but then had spontaneous termination. It is well known that shock therapy from a TV-ICD can also accelerate mVTs (11,12). The spontaneous termination of this arrhythmic

Table 3 Characteristics of Patients With S-ICD Infections

Patient	A	B	C	D	E	F	G
Age, yrs	51	59	53	36	23	43	14
Diagnosis	Ischemic CMP	iVF	Ischemic CMP	TGA	Genetic arrhythmia syndrome	Ischemic CMP	Dilated CMP
ICD indication	Primary prevention	Secondary prevention	Primary prevention	Primary prevention	Primary prevention	Primary prevention	Secondary prevention
Predisposing factors	—	Poor cicatrization e.c.i.	—	Small hematoma	Manipulation suture in wound	DM and obesity (large breast over pocket wound)	Ongoing leg infection after treatment compartment syndrome and ECMO
Manifestation	Redness, pus, and pain	Redness, pus, and large wound (tip visible)	Redness, pain, and fever	Redness and pain	Redness, pain, and fever	Redness, pus, and little wound	Redness and pus
Start site	Xiphoid	Sternomanubrium	Sternomanubrium	Sternomanubrium	Sternomanubrium	Pocket	Pocket
No. of days post implant	28	34	37	24	28	12	126
Systemic or local infection	Local	Local	Systemic	Local	Systemic	Local	Local
Lead and/or generator	Lead and generator	Lead	Lead	Lead	Lead and generator	Lead and generator	Generator
Infective organism	*S. Aureus*	*S. Aureus*	*S. Aureus*	*S. Aureus*	*S. Aureus*	Unknown	*S. Aureus*
Antibiotics	Flucloxacillin iv.	Flucloxacillin iv.	Flucloxacillin iv.	Flucloxacillin iv.	Flucloxacillin iv.	Flucloxacillin iv.	Flucloxacillin iv.
Reimplantation	TV-ICD	TV-ICD	TV-ICD	S-ICD	S-ICD	S-ICD	TV-ICD

CMP = cardiomyopathy; DM = diabetes mellitus; e.c.i. = e causa ignota; ECMO = extracorporeal membrane oxygenation; ICD = implantable cardioverter-defibrillator; iv. = intravenous; iVF = idiopathic ventricular fibrillation; S-ICD = subcutaneous implantable cardioverter-defibrillator; TGA = transposition great arteries; TV-ICD = transvenous implantable cardioverter-defibrillator.

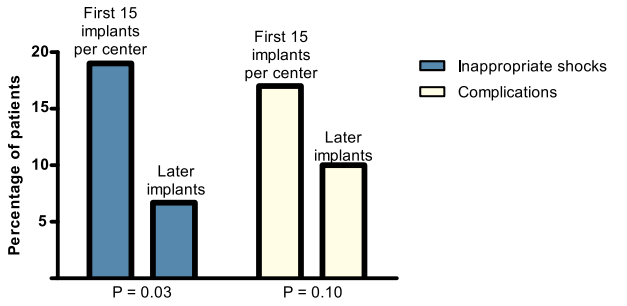

Figure 1 **Comparison of Inappropriate Shock and Complication Rate Between First and Later S-ICD Implants**

Inappropriate shocks and complications occurred more frequently in the first 15 patients per center who were implanted with the subcutaneous implantable cardioverter-defibrillator (S-ICD) than in subsequent patients (inappropriate shocks 19% vs. 6.7%; complications 17% vs. 10%).

episode prevented additional shocks. These results confirm the earlier reported very reliable shock efficacy of the S-ICD.

The decision to implant an S-ICD was mainly on the basis of 3 selection criteria: 1) patient preference; 2) after complications of a transvenous system; and 3) when the physician deemed S-ICD implantation more appropriate (e.g., because of a young age of the patient). This explains the relative younger age of these patients and the high percentage of patients with inherited diseases at baseline compared with conventional ICD populations in other studies (1,3,4). Most (89%) of these patients with inherited diseases had a prophylactic S-ICD implantation. The mean ejection fraction of these patients was 56%. This also accounts for the relatively high mean LVEF in our study population (41% in general; 38% in the primary prevention and 50% in the secondary prevention category).

Patients with a primary as well as secondary prevention had S-ICDs implanted. In the secondary prevention group, 6 patients had a history of mVTs. None of these 6 patients experienced appropriate shocks. On the other hand, 4 other patients received appropriate shocks on mVT, of which 1 of them had 6 successfully converted episodes of mVT. The latter patient had his S-ICD replaced by a TV-ICD to allow ATP. The lack of ATP capabilities in the S-ICD may be a possible limitation of the system, although this remains debatable. Decreasing the rate of painful ICD shocks for VT is an accepted reason to program ATP. Inappropriate intervention for self-terminating rhythms such as nonsustained VT may occur when ATP is used empirically (13). Several studies have demonstrated that ATP terminates around 80% of the slow and fast VTs, with acceleration rates between 1% and 5% (13,14). Remarkably, earlier studies testing ATP in induced VTs had lower success rates and higher acceleration rates (15–18). Additionally, the PAINFREE Rx II (Pacing Fast VT Reduces Shock Therapies II) trial had higher syncopal events in the ATP arm, perhaps due to acceleration of nonsustained VT by ATP (13). Moreover, most patients with an out-of-hospital cardiac arrest have VF (19), where ATP is not indicated. Nevertheless, patients with frequent therapy refractory sustained mVTs, although small in number, might benefit from ATP and therefore seem less suitable for the S-ICD.

Inappropriate shocks were observed in 15 patients (13%), comparable to the rate of inappropriate shocks in TV-ICDs (20). Six patients experienced inappropriate shocks before upgrading the software, which specifically aimed to reduce the inappropriate shock rate. T-wave oversensing was the main cause of inappropriate shock therapy before and after the upgrade. The S-ICD has a morphology based sensing algorithm and depends on a significant difference in the ratio between R- and T-wave for appropriate sensing. Before implant, in all patients a T-waveform analysis, to screen the QRS to T-wave ratio for correct sensing, was performed. This analysis is performed in supine and standing position during rest and therefore relatively slow heart rate. In all patients this analysis was deemed acceptable. During the automatic setup during implantation the device selects the best of 3 possible vectors on the basis of this R- to T-wave ratio and a template is made to store the QRS morphology and R- to T-wave ratio. Usually this setup is performed in rest. We noticed, however, that during or shortly after exercise a different QRS to T-wave ratio developed in 6 patients causing 8 exercise-related inappropriate shocks caused by T-wave oversensing. By choosing a different sensing vector or making a new template during an exercise test in these patients, further inappropriate shocks were prevented. Therefore, it might be recommended to perform the automatic setup routinely during an exercise test, when the patient is mobilized again. Also, 1 patient experienced inappropriate shocks due to double counting after newly developed right bundle branch block. It would be useful if the device would be able to create an automatic template on a daily basis, to prevent shocks for newly developed intraventricular conduction delay. Further analysis should be done to identify patients with an S-ICD who are at increased risk for T-wave oversensing.

In total, 14% of the patients experienced ICD-related complications, similar to the complication rate in transvenous ICD trials (1,4). Three patients had lead dislocations causing inappropriate sensing and shock therapy in 2 of them. All dislocations were due to caudal migration of 1 to 2 cm of the parasternal part of the lead. An additional suture sleeve was introduced to fixate the lead at the level of the xiphoid incision. After the introduction of this suture sleeve no lead dislocations have occurred. This study therefore demonstrates that the introduction of this suture sleeve at the xiphoid level was successful in preventing lead dislocations.

Seven patients had an infection that mandated the removal of the device system. This relatively high infection rate of 5.9% might partly be due to the fact that part of these patients were at increased risk for infection: 1 was a diabetic

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and 1 had an ongoing limb infection, which seemed to be the hematogenous source of the infection and 1 manipulated his wound. It should be noted that because of the novelty of the device there are no experienced implanters. This might have led to a prolonged implantation procedure time causing an increased infection rate, as in TV-ICDs implantation procedure time is directly related to infection risk (21). In most cases, infections in the S-ICD were only skin-deep (in our study only 2 S-ICD infections were systemic) and were therefore easily managed, whereas removal of infected transvenous devices and leads are associated with a significant risk of morbidity and mortality (22). In 3 patients, 3 months after explantation and treatment with antibiotics, reimplantation of a new S-ICD was successful.

Premature battery depletion occurred in 2 patients within 2 years. These 2 devices were part of a specific subset of devices for which a field safety advisory was reported. The risk for premature battery depletion was due to a specific condition within an individual battery cell, as reported by Cameron Health (23).

Skin erosion was seen in 2 patients. In 1 patient the pocket was probably not wide enough which led to complaints of pain especially during excessive movement of the left arm. After surgical revision of the pocket this problem was resolved. The larger generator of the S-ICD might have led to these pocket complications. With downsizing the S-ICD generator, pocket-related complications might be further reduced in the future. However, it is important to note that although the generator size of TV-ICDs has dramatically decreased, skin erosions have not disappeared in these patients.

The substantial implantation-related complications and long-term complications associated with lead longevity and subsequent risk of system extractions encountered in transvenous systems resulted in the development of an entirely S-ICD. However, as we demonstrate, the subcutaneous position of the S-ICD brought new limitations, such as inappropriate shocks due to oversensing. One can only speculate about the decrease in long-term complications compared with TV-ICDs and this has to be proven in the future in clinical trials. However, lead fractures were not observed in 177 patient-years of follow-up, which is less than found in TV-ICDs (24).

Moreover, an interesting observation in this Dutch experience is that relatively more inappropriate shocks and complications occurred in the first 15 implanted patients per center. There appears to be both a physician- and device-related learning curve. The software upgrade, the introduction of the suture sleeve at xiphoid level at implantation to prevent lead migration, the knowledge of preventing inappropriate shocks by applying vector and template changes in some patients, and the creation of a wide enough pocket in the left axillary region to prevent skin erosion seem to decrease complication and inappropriate shock rates substantially. Evolving experience will hopefully solve more of the complexities, which arise with developing a new ICD system.

Conclusions

This retrospective study suggests that the S-ICD is effective in terminating ventricular arrhythmias, but it also draws attention to some limitations due to its subcutaneous position. Inappropriate therapy is an important issue in the S-ICD. However, both inappropriate shocks and device-related complications seemed to be related to a learning curve of both the device and the physician. Our study demonstrates that the S-ICD is a viable alternative to conventional ICD systems in selected patients. Randomized comparative trials with the S-ICD and TV-ICD will further define the role of the S-ICD as an adjunctive or primary therapy in patients at risk for sudden cardiac death.

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REFERENCES

1. The Antiarrhythmics Versus Implantable Defibrillators (AVID) Investigators. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. N Engl J Med 1997;337:1576–83.
2. Kadish A, Dyer A, Daubert JP, et al. Prophylactic defibrillator implantation in patients with nonischemic dilated cardiomyopathy. N Engl J Med 2004;350:2151–8.
3. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877–83.
4. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225–37.
5. Sohail MR, Uslan DZ, Khan AH, et al. Management and outcome of permanent pacemaker and implantable cardioverter-defibrillator infections. J Am Coll Cardiol 2007;49:1851–9.
6. Hauser RG, Kallinen LM, Almquist AK, Gornick CC, Katsiyiannis WT. Early failure of a small-diameter high-voltage implantable cardioverter-defibrillator lead. Heart Rhythm 2007;4:892–6.
7. Hauser RG, McGriff D, Retel LK. Riata ICD lead failure: analysis of explanted leads with a unique insulation defect. Heart Rhythm 2012;9:742–9.
8. Bardy GH, Smith WM, Hood MA, et al. An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 2010;363:36–44.
9. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: a report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. J Am Coll Cardiol 2006;48:e247–346.
10. Dabiri AL, Theuns DA, Valk SD, et al. Clinical experience with a novel subcutaneous implantable defibrillator system in a single center. Clin Res Cardiol 2011;100:737–44.
11. Olde Nordkamp LR, Knops RE, Bardy GH, et al. Rationale and design of the PRAETORIAN trial: A Prospective RAndomizEd comparison of subcuTaneOus and tRansvenous ImplANtable cardioverter defibrillator therapy. Am Heart J 2012;163:753-60.e2.

12. Abello M, Merino JL, Peinado R, et al. Syncope following cardioverter defibrillator implantation in patients with spontaneous syncopal monomorphic ventricular tachycardia. Eur Heart J 2006;27:89–95.
13. Wathen MS, DeGroot PJ, Sweeney MO, et al. Prospective randomized multicenter trial of empirical antitachycardia pacing versus shocks for spontaneous rapid ventricular tachycardia in patients with implantable cardioverter-defibrillators: Pacing Fast Ventricular Tachycardia Reduces Shock Therapies (PainFREE Rx II) trial results. Circulation 2004;110:2591–6.
14. Wathen MS, Sweeney MO, DeGroot PJ, et al. Shock reduction using antitachycardia pacing for spontaneous rapid ventricular tachycardia in patients with coronary artery disease. Circulation 2001;104:796–801.
15. Gillis AM, Leitch JW, Sheldon RS, et al. A prospective randomized comparison of autodecremental pacing to burst pacing in device therapy for chronic ventricular tachycardia secondary to coronary artery disease. Am J Cardiol 1993;72:1146–51.
16. Hammill SC, Packer DL, Stanton MS, Fetter J. Termination and acceleration of ventricular tachycardia with autodecremental pacing, burst pacing, and cardioversion in patients with an implantable cardioverter defibrillator. Multicenter PCD Investigator Group. Pacing Clin Electrophysiol 1995;18:3–10.
17. Kantoch MJ, Green MS, Tang AS. Randomized cross-over evaluation of two adaptive pacing algorithms for the termination of ventricular tachycardia. Pacing Clin Electrophysiol 1993;16:1664–72.
18. Calkins H, el-Atassi R, Kalbfleisch S, Langberg J, Morady F. Comparison of fixed burst versus decremental burst pacing for termination of ventricular tachycardia. Pacing Clin Electrophysiol 1993;16:26–32.
19. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation, 1980–2000. JAMA 2002;288:3008–13.
20. van Rees JB, Borleffs CJ, de Bie MK, et al. Inappropriate implantable cardioverter-defibrillator shocks incidence, predictors, and impact on mortality. J Am Coll Cardiol 2011;57:556–62.
21. de Oliveira JC, Martinelli M, Nishioka SA, et al. Efficacy of antibiotic prophylaxis before the implantation of pacemakers and cardioverter-defibrillators: results of a large, prospective, randomized, double-blinded, placebo-controlled trial. Circ Arrhythm Electrophysiol 2009;2:29–34.
22. Margey R, McCann H, Blake G, et al. Contemporary management of and outcomes from cardiac device related infections. Europace 2010;12:64–70.
23. Majkrzak R. Product Advisory: SQ-RX Pulse Generator, Model Number 1010. Cameron Health [online]. 2012. Available at: http://physician.cameronhealth.com/product-advisories.htm. Accessed on March 5, 2012.
24. Maisel WH, Kramer DB. Implantable cardioverter-defibrillator lead performance. Circulation 2008;117:2721–3.

Key Words: heart rhythm disturbances ■ ICD ■ implantable cardioverter-defibrillator ■ subcutaneous ■ ventricular arrhythmia.