Clinical Research in Cardiology (2019) 108:1234–1239
https://doi.org/10.1007/s00392-019-01455-5

ORIGINAL PAPER

Feasibility of entirely subcutaneous ICD™ systems in patients with coronary artery disease

Kevin Willy[1] · Markus Bettin[1] · Florian Reinke[1] · Nils Bögeholz[1] · Christian Ellermann[1] · Benjamin Rath[1] · Patrick Leitz[1] · Julia Köbe[1] · Lars Eckardt[1] · Gerrit Frommeyer[1]

Received: 7 January 2019 / Accepted: 13 March 2019 / Published online: 21 March 2019

Abstract

Background The subcutaneous ICD (S-ICD™) is an important advance in device therapy for the prevention of sudden cardiac death (SCD). Although current guidelines recommend S-ICD™ use, long-term data are still limited, especially in subgroups. Among several cardiac diseases that prone to SCD, coronary artery disease (CAD) carries several peculiarities that may hamper S-ICD™ therapy in this cohort. CAD can lead to an ischemic cardiomyopathy (ICM) with a reduced left-ventricular ejection fraction (LVEF) and bundle branch blocks, which can be difficult for ICD sensing and discrimination of arrhythmia. CAD is mainly driven by risk factors such as diabetes mellitus, which put these patients at an elevated risk for infectious complications of cardiac devices. Furthermore, in ICM myocardial scars are frequent and are a potential substrate for ventricular tachycardia, which may be accessible for antitachycardia pacing. At the moment, it remains unclear if there is a value of S-ICD™ therapy in this subgroup. Therefore, this study analysed patients with CAD.

Materials and methods All S-ICD™ patients with CAD as the main indication for ICD implantation ($n = 45$ patients) in our large-scaled single-center S-ICD™ registry ($n = 249$ patients) were included in this study. Baseline characteristics, appropriate and inappropriate shocks, and complications were documented in a mean follow-up of 22.5 ± 8.3 months.

Results Primary prevention of SCD was the indication for implantation of an S-ICD™ in 28 patients (62%). Of all 45 patients with an overall mean age of 58.1 ± 11.4 years, 40 were male (88%). The mean LVEF was 37.7 ± 12.6%. Three episodes of ventricular arrhythmia (one monomorphic, one polymorphic, one ventricular fibrillation) were adequately terminated in three patients (7%). In only one patient, oversensing resulting in an inappropriate shock was observed, which could be managed by changing the sensing vector. 15 of the examined 45 patients previously had a transvenous ICD, which was explanted due to system-related infections. In only two patients, S-ICD™ was changed to transvenous ICD because of the need of antibradycardia stimulation. There were no S-ICD™ system-related infections.

Conclusion The S-ICD™ seems to be a valuable option for the prevention of SCD in CAD patients. Patients with systemic infections of a transvenous ICD and, therefore, a need for an alternative might benefit from the absence of intracardiac leads as the S-ICD™ is safe and works flawlessly in these patients. Inadequate shock delivery was very rare, while every episode of ventricular arrhythmia was terminated by the first shock.

Keywords Subcutaneous ICD · Coronary artery disease · Sudden cardiac death

Introduction

The S-ICD™ (Boston Scientific, Natick, Massachusetts) has been established as a valuable treatment option in the prevention of SCD for a wide range of underlying cardiac diseases [1–4]. Positive results and experiences have led to a class IIa recommendation in the current guidelines [4]. Patients with CAD, however, are not considered typical S-ICD™ candidates yet as they often display features which let physicians tend to opt for a transvenous ICD system, e.g.

Kevin Willy and Markus Bettin contributed equally.

✉ Gerrit Frommeyer
gerrit.frommeyer@ukmuenster.de

[1] Clinic for Cardiology II: Electrophysiology, University Hospital Münster, Münster, Germany

need for stimulation and ATP. Due to the missing pacing options, the system cannot be recommended in patients with symptomatic bradycardia. Besides, patients with need for cardiac resynchronization therapy or patients who are expected to profit from ATP are no suitable candidates for S-ICD™ therapy [4]. CAD is mainly driven by several well-known risk factors, particularly hypertension and diabetes mellitus. Many patients with an advanced CAD which has led to an ICM come into question for a primary preventive ICD. Peri- and postoperative mortality of these patients is possibly aggravated due to factors such as obesity and diabetes, which have shown to increase the risk for endocarditis [5]. Moreover, in patients with ischemic heart disease, BBB can impede the adequacy of discrimination algorithms [6].

While the main concern about S-ICD™ is inappropriate shock delivery due to the oversensing of T-waves or even P-waves [7, 8] and the missing option for ATP, the main problem of transvenous ICD systems are device-related infections occurring in about 6% of all patients and lead failure occurring in even 17% according to a large long-term dutch study [9]. Systemic infections of transvenous ICD systems remain a huge dilemma, especially in patients with history of VA. These patients are in urgent need for a protection against future arrhythmias if a transvenous ICD has to be explanted and could profit from an early re-implantation of an S-ICD™. Regarding the high prevalence of patients with ischemic heart disease as the indication for ICD implantation, it is worth analysing data of the performance of S-ICD™ in these patients, especially in patients where the S-ICD™ has replaced a transvenous ICD. The aim of the present study was to assess the outcome of S-ICD therapy in patients with coronary artery disease. In particular, appropriate and inappropriate therapy deliveries as well as therapeutic safety should be assessed (Fig. 1).

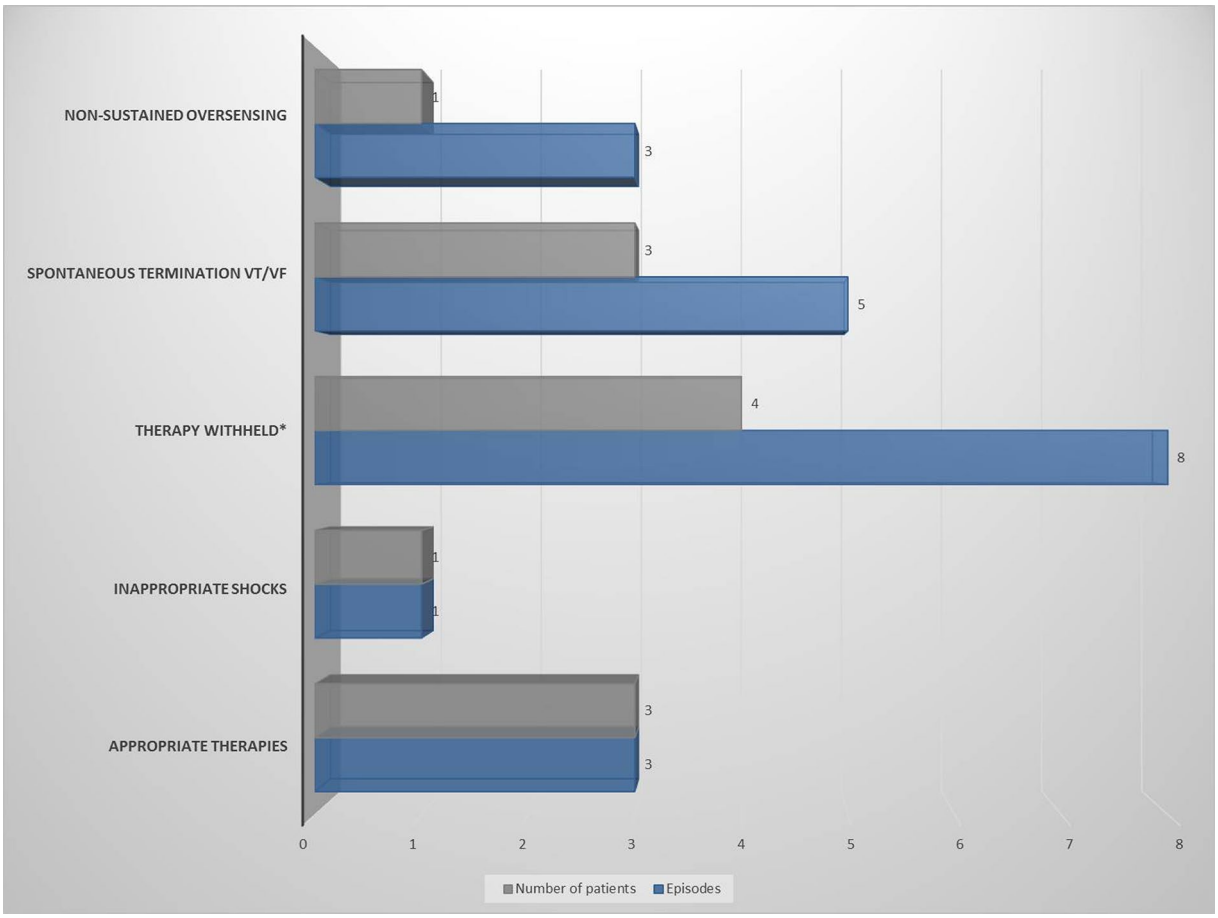

Fig. 1 Performance of the S-ICD. Both, inappropriate shocks and episodes of non-sustained oversensing all occurred in one patient. In this patient, the problem could be solved by changing the sensing vector. (*Therapy withheld = appropriate and inappropriate episodes which terminated spontaneously before ICD-discharge)

Materials and methods

The study was conducted in accordance with the guidelines of the Declaration of Helsinki. Between June 2010 and July 2018, a total of 249 S-ICD™ systems were implanted at our institution. In the present single-center retrospective study we enrolled all patients with CAD receiving an S-ICD™ for primary or secondary prevention of SCD. Indication for ICD implantation was in accordance to the current ESC guidelines. Patients with documented VT (< 200 bpm), that could reliably be terminated with ATP as well as patients with symptomatic bradycardia were excluded from this study. Patient characteristics are summarized in Table 1. Prior to implantation, S-ICD™ screening was performed with the manual and/or automated screening tool. Patients were considered eligible for S-ICD™ implantation, if there was at least one suitable vector. In all patients, an intraoperative defibrillation test was performed. In case of an unsuccessful test, the shock vector was changed to reversed polarity, the shock energy was raised or, if necessary, system components were repositioned intraoperatively using fluoroscopy. A treadmill test was performed routinely after the implantation procedure for vector optimization and exclusion of exercise-related oversensing. For follow-up, patients were examined at six weeks after implantation and every three to six months subsequently. Adverse events were documented during regular follow-up in three to six months' intervals.

Data transformation and statistical analysis was performed using GraphPad PRISM 6.0 (San Diego, CA, USA) and the SPSS Statistics, version 20.0 (SPSS, Inc., Chicago, IL, USA). Continuous variables are presented as mean and standard deviation (SD), while categorical data are expressed as frequencies.

Table 1 Patient baseline characteristics

Baseline characteristics	Total ($n = 45$)
Male (*n*)	40 (88.9%)
Age (years)	58.1 ± 11.4
Left ventricular ejection fraction (%)	37.7 ± 12.6
Primary prevention (*n*)	28 (62.2%)
Prior transvenous ICD (*n*)	15 (33.3%)
Reasons for explantation of prior transvenous ICD	
CDRIE (*n*)	15
Oversensing (*n*)	2

Results

45 S-ICD™ patients with CAD were investigated during a mean follow-up of 22.5 ± 8.3 months. All S-ICD™ systems were implanted in general anaesthesia with a mean implantation time of 38 ± 12.6 min.

Of the 45 patients, 40 were male (88%) and 5 female (12%). The mean age was 58.5 ± 11.4 years. The mean LVEF was 37.7% (primary prevention 31.1%, secondary prevention 47.4%). Of these 45 patients, 28 (62%) were implanted because of primary prevention (LVEF < 35%), 17 (38%) because of previous sustained ventricular arrhythmia (four monomorphic ventricular tachycardia, three polymorphic tachycardia and ten ventricular fibrillation). All of the patients with a VT as indication for S-ICD™ implantation had a history of transvenous ICD lead-related endocarditis (CDRIE).

15 patients received an S-ICD™ after a transvenous ICD was explanted due to CDRIE. In one of these patients there was also oversensing of the transvenous ICD, resulting in inappropriate shock delivery.

In two patients, the S-ICD™ system was changed to a transvenous system. One of them developed an indication for cardiac resynchronization therapy (CRT) and the other one because of syncope due to sinus arrest and, therefore, a need of antibradycardia pacing.

Two patients died during the observation period. Both deaths had no relation to the implanted S-ICD™ (one because of a pneumonia and sepsis, the other one during surgery due to an aortic dissection).

There were three appropriate shock deliveries in three patients, all of them terminating VA with the first shock. One episode was a monomorphic VT (350 ms), the other one polymorphic (300 ms) and the third one ventricular fibrillation.

In one patient, an inappropriate shock occurred due to T-wave-oversensing, which could be addressed by changing the sensing vector.

Altogether, no need for surgical revision occurred during observation time. In three patients, elective replacement of the S-ICD™ was performed due to battery depletion after a median longevity of 6.5 years (± 1 month). There were no adverse events concerning the generator replacement. In most cases, the primary sensing vector was chosen initially (48.8%, Table 2). In 42.2% of patients, the optimal sensing was given in the secondary vector, and in 9% of patients, the alternate vector was favourable. Conditional shock zone was programmed at a median rate of 200 bpm (range 180–220 bpm) and the shock zone was programmed at a median rate of 230 bpm (range 200–250 bpm). During the initial implantation, in 40 of 45 patients, the first defibrillation test was successful. In

Table 2 Clinical outcome

Results	
Initial sensing vector at time of implantation (*n*)	
Primary	22 (48.9%)
Secondary	19 (42.2%)
Alternate	4 (8.9%)
Operation related S-ICD complications (*n*)	1 (2.2%)
Pocket hematoma managed conservatively	1 (100%)
Successful defibrillation test (*n*)	45 (100%)
After changing generator position	1 (2.2%)
After switching shock polarity ("reversed")	4 (8.9%)
S-ICD explantation and conversion to transvenous ICD	2 (4.4%)
Death during follow-up	2 (4.4%)

four of the other five patients, shock delivery was effective after changing to reverse shock polarity. In the remaining patient, the shock delivery was effective with an elevated energy of 80 Joule (usually 65 Joule).

Discussion

Data on S-ICD™ performance in patients with CAD are sparse. While the number of S-ICD™ implantations in patients with electrical heart diseases, such as Brugada syndrome, increases progressively, the decision for the right device in patients with ICM remains difficult for clinicians [10]. This is mostly due to the fact that many of the electrical heart diseases are initially manifested through ventricular fibrillation which requires shock delivery anyway. On the other hand, in patients with ICM, the probability of the occurrence of monomorphic VT is higher and could be addressed by ATP.

In our cohort, there were three appropriate shocks (in 6.6% of all patients) overall, which is comparable to mid-term results from the EFFORTLESS study in which 5.8% in the first year and 13.5% in the first five years of the patients received an appropriate therapy [10]. Every episode could be terminated by the first shock, in line with the results from other studies, which demonstrated high conversion rates of > 90% in spontaneously occurring tachycardia episodes [2, 3, 11]. Of the three reported VA episodes, two required immediate shock delivery (ventricular fibrillation or polymorphic VT). In one patient (2.2%), a monomorphic VT was reported, which could have possibly been treated by ATP (prior monomorphic VT (CL 350 ms) pre-implantation, sudden onset, proven myocardial scar), but the patient had rejected the implantation of a transvenous ICD for personal reasons. The very low rate of monomorphic VT in this patient cohort surprises, because a priori, one would expect that especially patients with ICM would be prone to this kind of arrhythmia because of the myocardial scar. In the pooled analysis [3] from the IDE study [1] and the EFFORTLESS Registry [2] with 882 patients, 37.8% of the patients had ICM and 34.6% suffered from previous myocardial infarction. There were also 13.7% of patients who had a previous transvenous ICD. As well as in our study, patients with recurrent VT reliably terminated with ATP were not included in this study. In only one patient in the pooled analysis study, the S-ICD™ was changed to a transvenous system for ATP treatment. In our study there was also one patient with an indication for a system change to provide ATP who refused to undergo the operation procedure. A study by Sweeney and colleagues [12] showed that treatment of VT with shocks is associated with increased mortality risk and higher tachyarrhythmia burden compared to episodes treated with ATP. However, in this study, devices were programmed conservatively. Several trials have shown the safety of decreased treatment rates for asymptomatic self-terminating VT episodes [13, 14]. In the MADIT-RIT study [13], increased detection times or high-rate therapy led to a reduction of inappropriate therapies and all-cause mortality. Due to the system, detection rates are not programmable in the S-ICD™, but are comparable to the delayed therapy time in the MADIT-RIT trial. Therefore, in many patients, therapy of self-terminating VT is withheld. In the present study, five VT-episodes ended before S-ICD™ discharge.

Given the reduction in quality of life due to ICD shocks, ATP remains an important part in the therapy of ventricular arrhythmia. Careful patient selection is mandatory to guarantee success of the S-ICD™ performance. In a previous study by Köbe et al. the S-ICD™ was non-inferior concerning the quality of life compared to transvenous ICDs [15]. Important of notice, in our study a large group of patients with an indication for secondary prevention of SCD were present. Patients with primary preventive indication have a lower risk of appropriate therapy. In a recent S-ICD™ study by Boersma and colleagues [16], comparing the S-ICD™ in primary and secondary prevention indication, the incidence of appropriate therapy was 5.0%. In our study as well, the incidence was 6.6%. Therefore, after the occurrence of a stable VT that may require ATP delivery, a system conversion to a conventional transvenous ICD device could be discussed. Alternatively, primary VT ablation could be considered to continue S-ICD therapy in case of a successful procedure. This approach could delay endocardial lead implantation, especially taking the elevated risk for infectious complications in the ICM subgroup into account. It remains a trade-off between the risks of transvenous lead complications versus the consequences of shock for VT that might be stopped by ATP. In our collective, therapies exceeding the possibilities of an S-ICD™ were rare (one case in 2 years' observation time) and, therefore, potentially expendable.

Inappropriate shocks

Inappropriate shocks appeared only in one patient (2.2%) and could effectively be addressed by re-programming of the ICD. Earlier studies, e.g. from the EFFORTLESS S-ICD™ registry, showed a quite high rate of inappropriate shocks of 7% per year for the first generation S-ICD™ (SQ-RX™ 1010; Cameron Health) [2]. Inappropriate shocks were mainly attributed to T-wave-oversensing (39%) and supraventricular tachycardia above the discrimination zone (24%), which could be lowered by dual-zone programming [3, 17]. After addition of the SMART pass filter and further advancements, contemporary studies have reported inappropriate shock rates of 3.5% per year [18]. A recently published analysis underlined that the risk of inappropriate therapy with transvenous and with subcutaneous ICDs are comparable [19]. In conclusion, the rate of inappropriate ICD therapy in our study was well below of those reported in literature and overall very low. Clinicians have a lot of options nowadays to prevent oversensing and inadequate shocks and to handle them if they occur.

Safety

The peri- and postoperative safety was high. There was no need for operative revisions and no perioperative mortality or a need for intensive care unit treatment. Only one significant postoperative hematoma occurred, which could be controlled by local therapy. No surgical revision was needed. Brouwer et al. showed a lower rate of lead-related complications in S-ICDs™ compared to transvenous ICDs, but patients with subcutaneous ICDs had more non-lead-related complications, which mostly consisted of inappropriate sensing (also if no inappropriate therapy resulted) and infections [19]. In contrast to these results, there were no wound infections requiring surgical intervention within our cohort. Recently reported intraoperative shock conversion rates were consistently very high so that in > 99% patients induced ventricular arrhythmia was terminated [1, 2, 17, 19, 20].

In our cohort, every induced ventricular arrhythmia was terminated. No adverse events occurred concerning intraoperative defibrillation. Battery longevity was as high or even higher as expected in line with previous publications from our clinic [21].

Limitations

The data displayed in this work is derived from a registry and is, therefore, only retrospective data and should be interpreted as such. There is no prospective data of S-ICD™ systems in patients with ICM yet, but the data from the registry is promising and definitely encourages further, prospective studies. An additional limitation resulting from the nature of this work is that there was no randomization or control group since data was derived from a registry. Patients were possibly preselected because of their past medical history, their health status and their age to receive an S-ICD™, which exposes a potential bias in these pleasant results. In future research, there have to be predefined inclusion criteria or even better randomized controlled evidence comparing different types of ICDs. Further evidence is expected by the ongoing PRAETORIAN trial [22]. Another interesting aspect would be to compare a wearable defibrillator bridging until re-implantation of a transvenous ICD versus a definite S-ICD™ implantation after completion of the antibiotic treatment in patients with device-related endocarditis.

Conclusion

Taking the results of this analysis, one can summarize that the S-ICD™ is a feasible therapy option for the prevention of SCD in the specific cohort of patients with ICM. Appropriate therapies were very effective and could terminate every episode with the first shock. Inappropriate shock delivery was very rare and could be managed by ICD reprogramming.

Especially in patients suffering from lead-related endocarditis, the implantation of an S-ICD™ as an alternative seems a valuable option, since this entity represented 33% of the patients in this analysis and S-ICD™ worked flawlessly in all of these patients and no further infectious complications occurred. All in all, also in primary prevention for SCD in patients with ICM, the S-ICD™ appears to evolve as a potential first option as event rates are low, especially concerning monomorphic VT, and safety and efficacy are high.

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