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ORIGINAL PAPER

Follow-up of the first patients with a totally subcutaneous ICD in Germany from implantation till battery depletion

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

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Abstract

Background The subcutaneous ICD is a promising treatment option in patients at risk for sudden cardiac death. Approved in 2009, the first S-ICD® in Germany was implanted in June 2010. Although large prospective registry studies have shown safety and efficacy of the system, there is a lack of long-term data with regard to battery longevity of the S-ICD®. Therefore, we report follow-up of our first initial S-ICD® cases from implantation till battery depletion.

Materials and methods All S-ICD® patients with device replacement for battery depletion in our large single-center S-ICD® registry were included in this study. Baseline characteristics, appropriate and inappropriate shocks, and complications were documented in a median follow-up of 75.9 ± 6.8 months.

Results Twenty-eight patients with S-ICD® systems were included in this study. Of these patients, 21 were male and 7 were female, with an overall mean age of 41.9 ± 12.6 years. Primary prevention of sudden cardiac death was the indication in 19 patients (67.9%). Ventricular tachycardia was adequately terminated in two patients (7.1%). In 7 patients, non-sustained ventricular arrhythmias were not treated. A total of three inappropriate shocks occurred in three patients (10.7%). Mean time from implantation till battery depletion was 65.8 ± 8.1 months. Only one patient presented premature elective replacement criteria because of rapid battery depletion. No lead-related complication occurred during follow-up and no complications were seen regarding device replacement. In one patient (3.6%), the system was explanted without replacement due to patient's preference.

Conclusion The estimated battery longevity of S-ICD® of about 5 years was reached in all but one patient. Compared to larger S-ICD® registry studies, frequency of inappropriate shocks was relatively high in the initial S-ICD® cases. Both technological improvement as well as programming and operators' experience have led to a reduction of complications. Replacement of the S-ICD® seems to be a safe and effective procedure.

Keywords Subcutaneous ICD · Longevity · Battery depletion · Device replacement

Abbreviations

ATP	Antitachycardia pacing
ERI	Elective replacement indicator
ICD	Implantable cardioverter defibrillator
SCD	Sudden cardiac death
S-ICD®	Subcutaneous implantable cardioverter defibrillator
SVT	Supraventricular tachycardia
T-ICD	Transvenous implantable cardioverter defibrillator
VF	Ventricular fibrillation
VT	Ventricular tachycardia

Introduction

The subcutaneous ICD (S-ICD®, Boston Scientific, Natick, Massachusetts) has been established as valuable treatment option in prevention of sudden cardiac death in wide range of underlying cardiac diseases [1–3]. After European approval in 2009 [4], the first S-ICD® in Germany was implanted at our center in June 2010. Since then, 216 S-ICD® implantations were performed at our institution. The number of S-ICD® implantations is continuously increasing [5]. Reasons for this increase are the advantages of the

✉ Gerrit Frommeyer
gerrit.frommeyer@ukmuenster.de

[1] Department of Cardiology II-Electrophysiology, University Hospital Münster, Munster, Germany

S-ICD® system compared to transvenous ICD systems. No venous access is required, so the venous system is protected. In particular, young patients at risk for sudden cardiac death may profit most from the S-ICD®, because, in this patient collective, several lead changes can be expected during follow-up duration with a transvenous system. In case of system infection, removal of the S-ICD® is a simple procedure, because all components (pulse generator and tripolar shock lead) are implanted subcutaneously. Typical procedural and long-term complications of transvenous ICD systems (i.e., vascular lesions, pneumothorax, cardiac tamponade, and electrode dislocation) can be avoided.

Despite its advantages, there are important limitations of S-ICD® therapy. 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 antitachycardia pacing (ATP) are no suitable candidates for S-ICD® therapy [6]. Furthermore, there is still a lack of long-term data regarding S-ICD® performance (i.e., appropriate and inappropriate therapies) and battery longevity of the system. Therefore, we analyzed the long-time follow-up of our first S-ICD® patients from the initial implantation till battery depletion.

Materials and methods

The study was conducted in accordance with the guidelines of the Declaration of Helsinki and its later amendments. Between June 2010 and December 2017, a total of 216 S-ICD® systems were implanted at our institution. In 28 patients, the battery of the S-ICD® system reached the elective replacement indicator (ERI). All patients with device replacement for battery depletion were included in this study. Patient characteristics were summarized in Table 1. In all patients, we performed an intraoperative defibrillation test [7]. In case of an unsuccessful test, the shock vector was changed to reverse or system components (pulse generator or lead) were repositioned using fluoroscopy. For follow-up, the patients were examined at 6 weeks after implantation and every 3 months subsequently. All appropriate and inappropriate shocks and complications were documented.

Statistical analysis

Categorical data are presented as frequencies; continuous variables are expressed as mean and standard deviation (SD). The Kaplan–Meier method was used to estimate the time of first occurrence of appropriate and inappropriate shocks. Data transformation and all statistical analyses were performed using the IBM SPSS Statistics 20.0 for Windows (IBM Corporation, Somers, NY, USA).

Table 1 Baseline characteristics

Baseline characteristics	Total ($n=28$)
Male (n)	21 (75.0%)
Age (years)	41.9 ± 12.6
Body mass index (kg/m^2)	25.9 ± 4.2
Left ventricular ejection fraction (%)	51.4 ± 13.3
Functional NYHA class (n)	
NYHA I	17 (60.7%)
NYHA II	11 (39.3%)
Primary prevention	19 (67.9%)
Underlying heart disease (n)	
CAD	3 (10.7%)
DCM	9 (32.2%)
HCM	9 (32.2%)
Electrical	3 (10.7%)
Idiopathic VF	2 (7.2%)

Results

A total of 28 patients with S-ICD® of our center were included in this study. Median age was 41.9 ± 12.6 years. The overall mean follow-up duration from the initial implantation till last follow-up appointment was 75.9 ± 6.8 months. Indications for S-ICD® are summarized in Fig. 1. The most frequent indications for ICD therapy were dilated and hypertrophic cardiomyopathy (each 35%). Primary prevention was the indication in 67.9% of the patients. One patient (58.8 y/o male, DCM, secondary prevention, recurrent VT, and mildly reduced ejection fraction 40%), had a prior transvenous ICD system. Due to endocarditis, the system was explanted and changed to a subcutaneous system. No deaths were observed during the follow-up.

Most often, the primary sensing vector was chosen initially (57.1%) (Table 2). In 35.8% of the patients, the optimal sensing was seen in the secondary vector, and in 7.1% of the patients, the alternate vector was favorable. Dual-zone programming was only present in 67.9% of all patients. However, after the initial 20 cases, all patients received a dual-zone programming in our patient collective. The conditional shock zone was programmed at a median rate of 200 beats/min (range 190–210 beats/min), and the shock zone was programmed at a median rate of 235 beats/min (range 200–240 beats/min). At the time of initial implantation, in 24 of 28 patients, the first defibrillation test was effective. In one patient, defibrillation testing could not be performed due to a thrombus in the left atrial appendage. In three patients (10.7%), a reversed shock polarity led to an effective intraoperative defibrillation, while, in one patient, repositioning of the pulse generator was necessary.

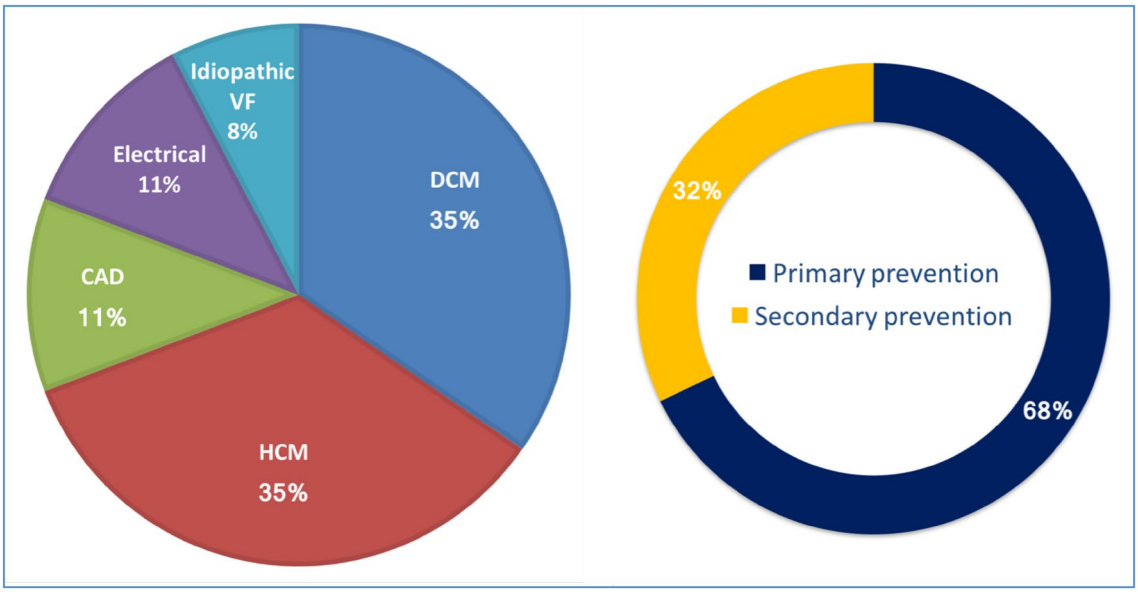

Fig. 1 Indications for ICD therapy

Table 2 Results of intraoperative defibrillation test and spontaneous episodes in the follow-up

Results	Total ($n=28$)
Sensing vector (n)	
Primary	16 (57.1%)
Secondary	10 (35.7%)
Alternate	2 (7.2%)
Dual-zone programming (n)	19 (67.9%)
Effective test ≤ 65J with first shock (n)	23 (82.3%)
Effective test after changing polarity ("reversed") (n)	3 (10.7%)
Effective test after repositioning of the lead (n)	1 (3.5%)
No defibrillation test due to a intracavitary thrombus (n)	1 (3.5%)
Spontaneous termination of VT/VF (episodes/pat)	9/7
Non-sustained oversensing (episodes/pat)	9/3
Appropriate therapies (episodes/pat)	2/2
Inappropriate shocks (episodes/pat)	3/3

During follow-up, two patients experienced an appropriate therapy delivery. In total, three inappropriate shocks occurred in three patients. Inappropriate shocks occurred earlier in follow-up than appropriate therapies (Fig. 2). Interestingly, 18 therapies in 10 patients were withheld. Regarding these events, nine episodes in seven patients were withheld due to spontaneous termination of VT/VF. On the other hand, another nine episodes in three patients were stopped before shock delivery due to non-sustained oversensing. The leading cause of inappropriate shocks was T-wave oversensing in two cases. The remaining inappropriate shock occurred due to a position-dependent oversensing during fine atrial fibrillation in a left-side position. In all three patients with inappropriate shock, the sensing vector was manually changed and an exercise treadmill test was performed with the programmed vector, to exclude T-wave oversensing at higher heart rates. In none of these patients, further inappropriate therapies were seen till battery depletion of the device. The inappropriate shock rate in the initial cases was 0.017 per patient-year.

During a median follow-up of 10.5 ± 11.4 months after device replacement, only the patient mentioned above with position-dependent oversensing received an inappropriate shock. In this patient, another vector change was performed inadvertently in the automatic setup prior to discharge. The vector was changed to the initial vector, in which the patient received an inappropriate shock due to posture-depending oversensing of fine atrial fibrillation in a left-side position.

Median time from the first implantation till device replacement due to battery depletion was 65.8 ± 8.1 months. Only one patient had premature ERI after 32.1 months. A 48 y/o female patient with the early repolarization syndrome and family history of sudden cardiac death received a S-ICD® for primary prevention. The device was explanted after battery depletion without replacement due to patient's preference. In a follow-up of 72.3 months, no episodes were stored in the memory of the subcutaneous ICD. However, explantation of the S-ICD® was performed without any difficulty. All devices were tested again. Of note, no ineffective defibrillations were observed at testing during device replacement. All patients with regular battery depletion received the

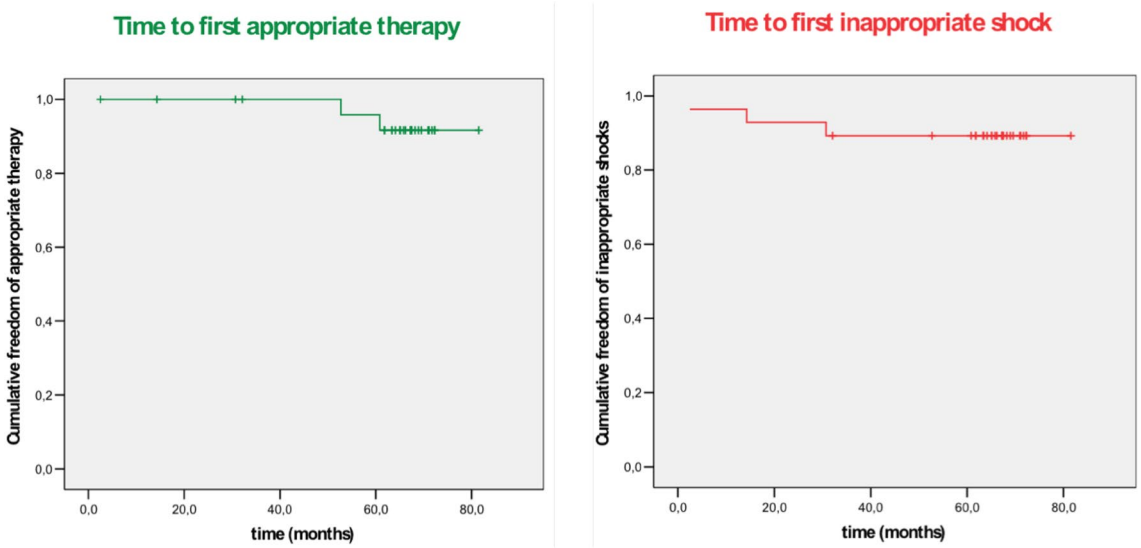

Fig. 2 Kaplan–Meier analysis of time to first appropriate and inappropriate therapy. Inappropriate shocks occurred mainly in the first half of follow-up, while the first appropriate therapy was delivered in the second half of the follow-up

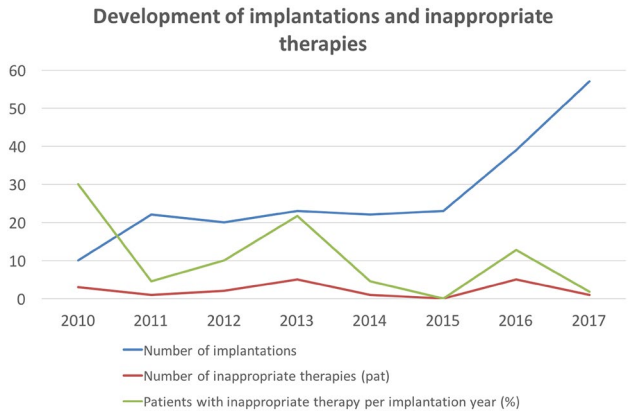

Fig. 3 Development of implantations and frequency of inappropriate therapies over the years. Whereas implantations are increasing rapidly after 2015, the percentage of inappropriate therapies in S-ICD® patients is constantly decreasing over time according to operators' experience and developments of device technology. The INSIGHT™ algorithm was introduced in 2015, and the SMART-PASS-filter became available in 2016

second generation of the S-ICD® at time of device replacement (Boston Scientific, EMBLEM S-ICD). Several device updates as well as new development of the device [INSIGHT™ and SMART Pass technology, Boston Scientific] had led to a reduction of inappropriate therapies over time (Fig. 3).

Perioperative complications occurred rarely. Only one patient needed re-operation due to a massive pocket hematoma while starting effective anticoagulation with warfarin at time of the initial S-ICD® implantation. No peri- or postoperative complications were seen after device replacement.

Discussion

The present study contributes important data of the subcutaneous ICD with regard to longevity of the system and its performance in the long-term follow-up. The advantage of this study is the rather long follow-up time of 75.9 ± 6.8 months. The estimated battery life-time was reached in all but one patient. Results from the European Regulatory Trial Cohort [8] showed longevity of S-ICD®-systems of 5.0 years, which is slightly shorter than the results of our study. In that study, the authors reported five cases of premature battery depletion. We have observed only one premature ERI in our patient collective, so far.

One patient decided to disclaim prevention of sudden cardiac death with an ICD after battery depletion of the S-ICD® system. The patient had electrocardiographic pattern of the early repolarization and a family history of sudden cardiac death. However, in a long-term follow-up of 72.3 months, there were no episodes documented in the S-ICD® memory and no symptoms or syncope occurred during this follow-up. Device explantation was an easy and uncomplicated procedure. The S-ICD® might, therefore, an interesting treatment option in patients with intermittent risk of sudden cardiac death or in patients in which the risk cannot be thoroughly assessed, as it was the case in our patient.

The overall complication rate in this study was rather low. However, one patient under effective anticoagulation developed a massive pocket hematoma at the 20th postoperative day that required re-operation. No infections of the S-ICD® occurred in the first cases of our experience. There were also no lead-associated complications. Besides the technical aspects of the system, in a previous study of our institution,

patients with S-ICD® described an equal or even better quality of life compared to patients with transvenous systems [9].

Compared to other large transvenous ICD studies [10, 11], our patient collective was rather young with a median age of 41.9 years. The reason for this is a different distribution of indications for ICD implantation. While, in transvenous ICD studies, there is a high proportion of patients with coronary artery disease, the most frequent underlying heart disease in our S-ICD® patient collective was non-ischemic and hypertrophic cardiomyopathies [12]. Another difference to transvenous ICD patients is the relatively good ejection fraction with a median of 51.4% due to a high percentage of young patients with electrical heart disease and idiopathic ventricular fibrillation in this collective. Despite the relatively high ejection fraction, we observed a rate of 7.1% appropriate therapies, which is more frequent as, e.g., in the MADIT-RIT trial (4.8%) [11].

Appropriate and inappropriate therapy

The overall inappropriate shock rate was 10.7%, which was slightly higher than those of the EFFORTLESS registry with an inappropriate shock rate of 8.3% [1]. However, in two of three patients with inappropriate shock, the S-ICD® was programmed with a shock zone only. A pooled analysis of the IDE and EFFORTLESS registry [13] showed that programming a dual-zone (i.e., adding a conditional shock zone with morphology discrimination algorithm) significantly reduced the occurrence of inappropriate shocks. Furthermore, there is also a significant learning curve when starting implantation of the subcutaneous ICD [14]. Both, advancements of device technology (introducing adiscrimination algorithm and an additional high-pass filter) as well as operators' experience have significantly reduced T-wave oversensing [15]. After the first 20 S-ICD® implantations, dual-zone therapy was programmed in all patients.

Main reason for inappropriate therapy was T-wave oversensing in two patients. In both patients, no further oversensing episodes occurred after changing the sensing vector. Kooiman et al. [16] analyzed management of T-wave oversensing. In their study, as well, in 87.5% of patients with T-wave oversensing, no inappropriate shocks recurred after reprogramming the sensing vector or therapy zones. Our data underline the importance of having at least two valuable sensing vectors in screening to have the option of changing the sensing vector after inappropriate therapy.

Compared to transvenous ICD collectives, the inappropriate shock rate is still significant. In the MADIT-RIT study [11], the inappropriate shock rate was 3.1% in the group with delayed therapy. However, inappropriate ATP delivery in this group occurred in 5.1%, in combination with inappropriate shocks, the rate of inappropriate therapies was 8.2% in the delayed therapy arm. In contrast to transvenous ICD systems, the therapy delay in the subcutaneous ICD is not programmable. We observed nine episodes in seven patients that were withhold due to spontaneous termination of VT/VF. Therefore, the S-ICD® may reduce appropriate therapies of discrete episodes of ventricular arrhythmias.

Complications regarding device replacement

Based on our results, device replacement seems to be a simple and safe procedure. No perioperative complications were present. Of note, no ineffective defibrillation was observed during defibrillation testing at time of replacement, while in four patients reversed shock polarity or generator replacement was necessary at time of implantation. Unfortunately, one patient received an inappropriate shock after device replacement. In this patient (45 y/o male with dilated cardiomyopathy and severely reduced ejection fraction), the automatic setup was performed prior to discharge and the suggested vector was programmed. Inadvertently, the suggested vector was the same vector as in the explanted system, in which the first inappropriate shock occurred. Therefore, after device replacement, automatic setups should be applied with careful attention to avoid sensing vector selection by the device.

Conclusion

The estimated battery longevity of S-ICD® of about 5 years was reached in all but one patient. Compared to large S-ICD® registry studies, frequency of inappropriate shocks was relatively high in the initial S-ICD® cases. Technological improvements as well as programming and operators experience have led to a lower complication rate. Replacement of the S-ICD® seems to be a safe and uncomplicated procedure. Long-term data of S-ICD® performance underline the promising and valuable properties of these devices for safe prevention of sudden cardiac death.

Compliance with ethical standards

Conflict of interest FR, JK, LE, and GF received travel grants and lecture honoraria from Boston Scientific within the last 12 months.

References

1. Lambiase PD, Barr C, Theuns DA et al (2014) Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-ICD Registry. Eur Heart J 35(25):1657–1665
2. Weiss R, Knight BP, Gold MR et al (2013) Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 128:944–953

3. Brouwer TF, Yilmaz D, Lindeboom R et al (2016) Long-term clinical outcomes of subcutaneous versus transvenous implantable defibrillator therapy. J Am Coll Cardiol 68:2047–2055
4. Bardy GH, Smith WM, Hood MA et al (2010) An entirely subcutaneous implantable cardioverter-defibrillator. N Engl J Med 363:36–44
5. Friedman DJ, Parzynski CS, Varosy PD et al (2016) Trends and in-hospital outcomes associated with adoption of the subcutaneous implantable cardioverter defibrillator in the United States. JAMA Cardiol 1:900–911
6. Priori SG, Blomström-Lundqvist C, Mazzanti A et al. 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: the task force for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death of the European Society of Cardiology (ESC). Europace 2015,17(11):1601–1687
7. Frommeyer G, Zumhagen S, Dechering DG et al (2016) Intraoperative defibrillation testing of subcutaneous ICD systems—a simple issue? J Am Heart Assoc 4(3):e00318. https://doi.org/10.1161/JAHA.115.00318
8. Theuns DA, Crozier IG, Barr CS et al (2015) Longevity of the subcutaneous implantable defibrillator. Long-term follow-up of the European Regulatory Trial Cohort. Circ Arrhythm Electrophysiol 8:1159–1163
9. Köbe J, Hucklenbroich K, Geisendörfer N et al (2017) Posttraumatic stress and quality of life with the totally subcutaneous compared to conventional cardioverter-defibrillator systems. Clin Res Cardiol 106:317–321
10. Healey JS, Hohnloser SH, Glikson M et al (2015) Cardioverter defibrillator implantation without induction of ventricular fibrillation: a single-blind, non-inferiority, randomised controlled trial (SIMPLE). Lancet 385:785–791
11. Moss AJ, Schuger C, Beck CA et al (2012) Reduction in inappropriate therapy and mortality through ICD programming. N Engl J Med 367:2275–2283
12. Frommeyer G, Dechering DG, Zumhagen S et al (2016) Long-term follow-up of subcutaneous ICD systems in patients with hypertrophic cardiomyopathy: a single-center experience. Clin Res Cardiol 105:89–93
13. Burke MC, Gold MR, Knight BP et al (2015) Safety and efficacy of the totally subcutaneous implantable defibrillator: 2-year results from a pooled analysis of the IDE study and EFFORTLESS registry. J Am Coll Cardiol 65:1605–1615
14. Knops RE, Brouwer TF, Barr CS et al (2016) The learning curve associated with the introduction of the subcutaneous implantable defibrillator. Europace 18:1010–1015
15. Brisben AJ, Burke MC, Knight BP et al (2015) A new algorithm to reduce inappropriate therapy in the S-ICD system. J Cardiovasc Electrophysiol 26:417–423
16. Kooiman KM, Knops RE, Olde Nordkamp L et al (2014) Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to T-wave overesensing can be prevented: Implications for management. Heart Rhythm 11:426–434