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ORIGINAL PAPER

Long-term follow-up of subcutaneous ICD systems in patients with hypertrophic cardiomyopathy: a single-center experience

Gerrit Frommeyer[1] · Dirk G. Dechering[1] · Sven Zumhagen[1] · Andreas Löher[2] · Julia Köbe[1] · Lars Eckardt[1] · Florian Reinke[1]

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Abstract
Background The totally subcutaneous implantable defibrillator (S-ICD) was introduced as a new alternative to conventional implantable defibrillators and is employed worldwide. This system is especially attractive for young patients. However, in patients with hypertrophic cardiomyopathy (HCM), T-wave oversensing may occur. To address the question whether the S-ICD system is suitable for HCM patients, the data of a standard of care prospective single-center S-ICD registry were evaluated.
Methods and results In the present study, 18 HCM patients who received an S-ICD for primary ($n = 14$) or secondary prevention ($n = 4$) and a minimal follow-up duration of 6 months were analyzed. The mean follow-up duration was 31.7 ± 15.4 months. Ventricular arrhythmias were adequately detected in 4 patients (22 %). In 7 patients (39 %), T-wave oversensing was noticed and led to at least one inappropriate shock in 4 patients (22 %). Further adverse events included surgical revision due to a mobile sensing electrode and resulting noise detection as well as one case of early battery failure requiring pulse generator change.
Conclusion Patients with HCM and S-ICD systems have an increased risk of T-wave oversensing and inappropriate shock delivery. Thorough monitoring as well as exercise tests may help to improve device settings and thereby prevent T-wave oversensing.

Keywords S-ICD · Sudden cardiac death · Hypertrophic cardiomyopathy · T-wave oversensing · Device complications

Introduction

The implantable cardioverter defibrillator (ICD) is routinely employed for primary and secondary prevention of sudden cardiac death [1, 2]. The totally subcutaneous implantable defibrillator (S-ICD, Boston Scientific, Natick, MA, USA) has been introduced as a new alternative to the conventional transvenous defibrillator system. The obvious advantages of this system are described as a reduction of lead complications and systemic infections. The subcutaneous ICD system can particularly be considered in patients with congenital heart disease [3], other rare entities impeding transvenous lead implantation [4], or electrical heart disease [5, 6]. Young patients with hypertrophic cardiomyopathy (HCM) also represent suitable candidates for S-ICD implantation [7].

The early results of the worldwide EFFORTLESS registry suggested an appropriate system performance. Occurrence of arrhythmic events and inappropriate shocks resembled those reported for conventional transvenous ICD systems [8]. Comparable results were described in the 2-year follow-up of the same cohort [9]. Of note, a trend toward a reduction of inappropriate shocks was reported after 2 years follow-up. Nonetheless, common problems in the S-ICD patient population such as inappropriate sensing due to muscular noise and T-wave oversensing [10–14] or

✉ Gerrit Frommeyer
Gerrit.Frommeyer@ukmuenster.de

[1] Division of Electrophysiology, Department of Cardiovascular Medicine, University of Münster, Münster, Germany

[2] Division of Cardiac Surgery, Department of Cardiothoracic Surgery, University of Münster, Münster, Germany

high defibrillation thresholds [15] may occur. Especially in patients with HCM, inappropriate shock deliveries due to T-wave oversensing remain a clinical challenge [16]. Data from the EFFORTLESS registry suggest a hazard ration of 4.6 for inappropriate shocks in patients with HCM [16]. In the present study, the single-center experience of 18 HCM patients who received an S-ICD system and had a minimal follow-up duration of 6 months was systematically evaluated.

Methods

The study conforms to the declaration of Helsinki and later amendments. Between July 2010 and June 2015, 102 S-ICD systems were implanted at our institution. Among these, 18 patients with HCM and a minimal follow-up duration of 6 months were analyzed. Patient baseline characteristics are summarized in Table 1. All patients underwent preoperative ECG screening [17, 18] and an intraoperative defibrillation test. An ineffective first shock required further tests in either reverse polarity or after repositioning of the subcutaneous lead and/or the pulse generator. Devices were routinely programmed to a detection rate of 220 bpm (conditional shock zone) and 240 bpm (shock zone) (Table 2).

Results

Regular follow-up

18 HCM patients of a mean age of 35 ± 19 years received an S-ICD system. The mean follow-up duration was 31.7 ± 15.4 months. 3 patients presented hypertrophic obstructive cardiomyopathy (HOCM), while 15 patients did not display signs of obstruction of the left ventricular outflow tract (HNCM). The mean left ventricular ejection fraction was 62.8 ± 5.7 %. 14 of 18 patients (78 %) received the S-ICD system as a primary prophylaxis of sudden cardiac death, while ventricular arrhythmias had already occurred in 4 patients (22 %). In 9 of 18 patients (50 %), the primary sensing vector was recommended while the secondary sensing vector was chosen in 7 patients (39 %) and the alternative sensing vector in 2 patients (11 %). Ventricular fibrillation could be induced in 17 of 18 patients during intraoperative defibrillation test. In 1 patient, sustained ventricular fibrillation was not inducible and the patient did not accept postoperative defibrillation tests. In 15 of 17 patients (88 %), the first defibrillation test with 65 J was effective. In 2 of 12 patients (12 %), ventricular fibrillation was not terminated by the first internal shock. In these patients, further tests with 65 J and reversed polarity effectively terminated ventricular fibrillation.

Table 1 Baseline characteristics

Age (years)	35 ± 19
Male sex (*n*)	15 (83 %)
Primary prevention (*n*)	14 (78 %)
Secondary prevention (*n*)	4 (22 %)
HOCM (*n*)	3 (17 %)
HNCM (*n*)	15 (83 %)
LVEF (%)	63 ± 6

LVEF left ventricular ejection fraction

Table 2 Ventricular arrhythmias and T-wave oversensing in HCM patients with an S-ICD system ($n = 18$)

Detection of ventricular arrhythmias	4 (22 %)
Occurrence of T-wave oversensing	7 (39 %)
Inappropriate shock delivery due to T-wave oversensing	4 (22 %)

T-wave oversensing and inappropriate shocks

In this cohort, T-wave oversensing occurred in 7 of 18 patients (39 %). In 3 patients, these episodes were short and did not lead to inappropriate shock delivery while 4 of 18 patients (22 %) experienced at least one inappropriate shock.

In 2 of these 3 patients without shock delivery, the sensing vector was changed from secondary to primary after occurrence of T-wave oversensing during ergometer test. In the third patient, T-wave oversensing occurred during non-sustained slow ventricular tachycardia. Thereafter, no further episodes occurred and, therefore, no changes have been programmed.

Among patients who encountered inappropriate shocks due to T-wave oversensing, 3 patients experienced more than 1 shock. In one of these patients, supraventricular tachycardia with concomitant T-wave oversensing led to delivery of 3 successive inappropriate shocks. Here, the sensing vector was altered from secondary to primary. In another patient, T-wave oversensing during sexual activity led to delivery of 5 successive shocks. The last shock resulted in ventricular fibrillation that was appropriately detected and terminated by another 80 J shock. Extensive ergometer tests led to programming of the alternative sensing vector. Thereafter, no T-wave oversensing occurred. Another patient experienced one inappropriate shock due to T-wave oversensing during sinus tachycardia as well as another episode with inappropriate shock delivery in the presence of triple count due to p-wave and T-wave oversensing. In this case, oversensing was present in all

possible sensing vectors during ergometer test. Therefore, the S-ICD system was explanted and replaced by a conventional transvenous defibrillator system [19].

Detection of ventricular arrhythmias and further adverse events

Ventricular arrhythmias were appropriately detected in 4 patients. In 3 patients, non-sustained fast ventricular tachycardia was detected but the episodes terminated spontaneously before a shock could be delivered. Therefore, the charging process was interrupted. In another patient, one episode of sustained polymorphic ventricular tachycardia was appropriately detected and terminated with the first 80 J shock. Further adverse events included surgical revision due to a mobile sensing electrode and resulting noise detection as well as one case of early battery failure requiring pulse generator change after 32 months without shock delivery.

Discussion

In the present single-center registry, a significant proportion of S-ICD recipients with HCM experienced inappropriate shocks as a result of T-wave oversensing. T-wave oversensing occurred in 39 % of HCM patients. In 1 patient, explantation of the S-ICD system and implantation of a transvenous ICD system were necessary. Ventricular arrhythmias were adequately detected and effectively terminated if necessary.

T-wave oversensing

In the present study, an increased incidence of T-wave oversensing in patients with HCM was observed as compared with the recently published data from the EFFORTLESS registry [16]. In this multi-center registry, 8.3 % of 581 patients experienced inappropriate shocks. However, the follow-up duration of 21 ± 13 months was significantly shorter than in the present registry (31.7 ± 15.4 months). In accordance with the latest results of the EFFORTLESS registry, in most cases, reprogramming of the sensing vector from secondary to primary configuration prevented further T-wave oversensing. However, in one case programming of the alternative sensing vector was necessary.

A low *R/T* ratio represents a major risk factor for the occurrence of T-wave oversensing in this patient cohort. Alterations of the *R/T* ratio in the subcutaneous ECG may occur during follow-up and result in T-wave oversensing. These alterations occur most likely during exercise testing [18]. Changing of the sensing vector in patients with inappropriate shock deliveries resulted in an increased *R/T* ratio, especially during exercise test. Other abnormalities such as bundle branch block or repolarization abnormalities can also play a role. These scenarios should normally be detected during the preoperative screening process. Nonetheless, T-wave alterations are more likely in HCM patients [20, 21] and, therefore, increase the risk of oversensing. Furthermore, a reduced *R/T* ratio can be observed in the presence of obesity [18]. T-wave alterations may also be a result of drug-induced QT-prolongation [22].

Studies in patients with conventional transvenous defibrillator systems suggest that the rate of inappropriate shocks in usual defibrillator patient cohorts may be lowered to approximately 5 % by programming higher detection rates as well as increased detection intervals [23–25]. Although the detection intervals of the S-ICD system are fixed to 18/24, the longer charging period leads to a comparable time to therapy as conventional transvenous ICD systems. However, in the present study all S-ICD systems were programmed to detection rates of 220 bpm. Therefore, significant modifications of the detection rate to extend time to therapy were not possible.

Implications

According to the significantly elevated incidence of T-wave oversensing and inappropriate shocks in HCM patients, these patients should be selected thoroughly and monitored closely. A recent screening analysis of QRS/T-wave morphology suggested HCM as an independent predictor for non-suitability for S-ICD systems [18]. The results of our registry further support this finding but also suggest that differentiated programming of sensing vectors depending on results of exercise tests may reduce the rate of inappropriate shocks. The majority of patients included in the present registry were implanted long before the latest recommendations were published [16]. At any rate, exercise-based optimization of the S-ICD system should be thoroughly performed in HCM patients to reduce the risk of T-wave oversensing. This should include examination of all three sensing vectors during exercise test as well as acquisition of subcutaneous ECG templates [26]. Exercise testing after S-ICD implantation is of particular interest because surface ECGs employed for preoperative screening cannot be regarded as adequate surrogates for subcutaneous ECGs during exercise [27].

Of note, new sensing algorithms may further reduce the susceptibility to T-wave oversensing [28] although the suggested algorithms have not yet been evaluated in prospective studies. A thorough preoperative screening in combination with these algorithms may solve the problem of T-wave oversensing in the future (Fig. 1).

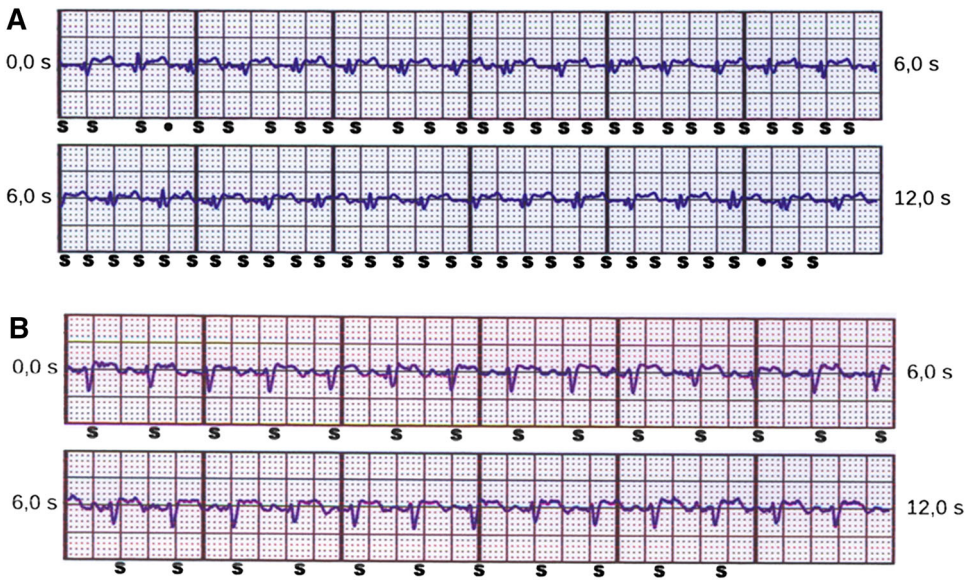

Fig. 1 **a** Representative example of T-wave oversensing during exercise test. **b** No T-wave oversensing after changing the sensing vector in the same patient

Conclusion

The present study underlines that patients with HCM who receive an S-ICD system possess a significant risk for T-wave oversensing. Often, T-wave oversensing can be avoided by changing the sensing vector. Although preoperative ECG screening is thoroughly performed, T-wave oversensing can still occur and lead to inadequate shock delivery eventually. An increased probability of T-wave oversensing can be observed in the presence of low R-wave signals. This is especially important in patients with HCM because T-wave abnormalities may occur frequently [20] and thereby lead to alterations of the *R*/*T* ratio. Therefore, the vector with the highest discrimination between R- and T-waves in different positions and during exercise test should be chosen.

In case of repeated inappropriate shocks and reproducible occurrence of oversensing during exercise tests in all sensing vectors, a switch to a conventional ICD system should be discussed.

Compliance with ethical standards

Conflict of interest G.F., D.G.D., S.Z., J.K., L.E., and F.R. received travel grants and lecture honoraria from BIOTRONIK, Boston Scientific, Medtronic, Sorin Group and St. Jude Medical.

References

1. Connolly SJ, Hallstrom AP, Cappato R, Schron EB, Kuck KH, Zipes DP, Greene HL, Boczor S, Domanski M, Follmann D, Gent M, Roberts RS (2000) Meta-analysis of the implantable cardioverter defibrillator secondary prevention trials. Avid, cash and cids studies. Antiarrhythmics vs implantable defibrillator study. Cardiac arrest study hamburg. Canadian implantable defibrillator study. Eur Heart J 21:2071–2078
2. Nanthakumar K, Epstein AE, Kay GN, Plumb VJ, Lee DS (2004) Prophylactic implantable cardioverter-defibrillator therapy in patients with left ventricular systolic dysfunction: a pooled analysis of 10 primary prevention trials. J Am Coll Cardiol 44:2166–2172
3. Backhoff D, Muller M, Ruschewski W, Paul T, Krause U (2014) Icd therapy for primary prevention of sudden cardiac death after mustard repair for d-transposition of the great arteries. Clin Res Cardiol 103:894–901
4. Kolb C, Lennerz C, Semmler V, Jilek C (2013) Primary prevention of sudden cardiac death with an entirely subcutaneous defibrillator in a patient with a large right atrial thrombus. Clin Res Cardiol 102:169–170
5. Alcalde M, Campuzano O, Sarquella-Brugada G, Arbelo E, Allegue C, Partemi S, Iglesias A, Oliva A, Brugada J, Brugada R (2015) Clinical interpretation of genetic variants in arrhythmogenic right ventricular cardiomyopathy. Clin Res Cardiol 104:288–303
6. Bobinger T, Kallmunzer B, Kopp M, Kurka N, Arnold M, Hilz MJ, Huttner HB, Schwab S, Kohrmann M (2015) Prevalence and impact on outcome of electrocardiographic early repolarization patterns among stroke patients: a prospective observational study. Clin Res Cardiol 104:666–671
7. Yamazawa H, Takeda A, Takei K, Furukawa T (2014) Primary prevention of sudden cardiac death in a low-risk child with familial hypertrophic cardiomyopathy: the role of cardiac magnetic resonance imaging. Clin Res Cardiol 103:75–77
8. Lambiase PD, Barr C, Theuns DA, Knops R, Neuzil P, Johansen JB, Hood M, Pedersen S, Kaab S, Murgatroyd F, Reeve HL, Carter N, Boersma L (2014) Worldwide experience with a totally subcutaneous implantable defibrillator: early results from the effortless s-icd registry. Eur Heart J 35:1657–1665
9. Burke MC, Gold MR, Knight BP, Barr CS, Theuns DA, Boersma LV, Knops RE, Weiss R, Leon AR, Herre JM, Husby M, Stein KM, Lambiase PD (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

10. Aziz S, Leon AR, El-Chami MF (2014) The subcutaneous defibrillator: a review of the literature. J Am Coll Cardiol 63:1473–1479
11. Dabiri Abkenari L, Theuns DA, Valk SD, Van Belle Y, de Groot NM, Haitsma D, Muskens-Heemskerk A, Szili-Torok T, Jordaens L (2011) Clinical experience with a novel subcutaneous implantable defibrillator system in a single center. Clin Res Cardiol 100:737–744
12. Olde Nordkamp LR, Abkenari LD, Boersma LV, Maass AH, de Groot JR, van Oostrom AJ, Theuns DA, Jordaens LJ, Wilde AA, Knops RE (2012) The entirely subcutaneous implantable cardioverter-defibrillator: initial clinical experience in a large dutch cohort. J Am Coll Cardiol 60:1933–1939
13. Jarman JW, Todd DM (2013) United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: important lessons to learn. Europace 15:1158–1165
14. Weiss R, Knight BP, Gold MR, Leon AR, Herre JM, Hood M, Rashtian M, Kremers M, Crozier I, Lee KL, Smith W, Burke MC (2013) Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator. Circulation 128:944–953
15. Guenther M, Kolschmann S, Knaut M (2015) Substernal lead implantation: a novel option to manage dft failure in s-icd patients. Clin Res Cardiol 104:189–191
16. Olde Nordkamp LR, Brouwer TF, Barr C, Theuns DA, Boersma LV, Johansen JB, Neuzil P, Wilde AA, Carter N, Husby M, Lambiase PD, Knops RE (2015) Inappropriate shocks in the subcutaneous icd: incidence, predictors and management. Int J Cardiol 195:126–133
17. Groh CA, Sharma S, Pelchovitz DJ, Bhave PD, Rhyner J, Verma N, Arora R, Chicos AB, Kim SS, Lin AC, Passman RS, Knight BP (2014) Use of an electrocardiographic screening tool to determine candidacy for a subcutaneous implantable cardioverter-defibrillator. Heart Rhythm Off J Heart Rhythm Soc 11:1361–1366
18. Olde Nordkamp LR, Warnaars JL, Kooiman KM, de Groot JR, Rosenmoller BR, Wilde AA, Knops RE (2014) Which patients are not suitable for a subcutaneous icd: incidence and predictors of failed qrs-t-wave morphology screening. J Cardiovasc Electrophysiol 25:494–499
19. Frommeyer G, Dechering DG, Zumhagen S, Kobe J, Eckardt L, Reinke F (2015) Limitations in s-icd therapy: reasons for system explantation. Clin Res Cardiol. doi:10.1007/s00392-015-0880-x
20. Sakamoto N, Sato N, Oikawa K, Karim Talib A, Sugiyama E, Minoshima A, Tanabe Y, Takeuchi T, Akasaka K, Saijo Y, Kawamura Y, Hasebe N (2015) Late gadolinium enhancement of cardiac magnetic resonance imaging indicates abnormalities of time-domain t-wave alternans in hypertrophic cardiomyopathy with ventricular tachycardia. Heart Rhythm 12:1747–1755
21. Flett AS, Maestrini V, Milliken D, Fontana M, Treibel TA, Harb R, Sado DM, Quarta G, Herrey A, Sneddon J, Elliott P, McKenna W, Moon JC (2015) Diagnosis of apical hypertrophic cardiomyopathy: T-wave inversion and relative but not absolute apical left ventricular hypertrophy. Int J Cardiol 183:143–148
22. Verrier RL, Nieminen T (2010) T-wave alternans as a therapeutic marker for antiarrhythmic agents. J Cardiovasc Pharmacol 55:544–554
23. Tan VH, Wilton SB, Kuriachan V, Sumner GL, Exner DV (2014) Impact of programming strategies aimed at reducing nonessential implantable cardioverter defibrillator therapies on mortality: a systematic review and meta-analysis. Circ Arrhythm Electrophysiol 7:164–170
24. Moss AJ, Schuger C, Beck CA, Brown MW, Cannom DS, Daubert JP, Estes NA 3rd, Greenberg H, Hall WJ, Huang DT, Kautzner J, Klein H, McNitt S, Olshansky B, Shoda M, Wilber D, Zareba W, Investigators M-RT (2012) Reduction in inappropriate therapy and mortality through icd programming. N Engl J Med 367:2275–2283
25. Gasparini M, Proclemer A, Klersy C, Kloppe A, Lunati M, Ferrer JB, Hersi A, Gulaj M, Wijfels MC, Santi E, Manotta L, Arenal A (2013) Effect of long-detection interval vs standard-detection interval for implantable cardioverter-defibrillators on antitachycardia pacing and shock delivery: the advance iii randomized clinical trial. JAMA 309:1903–1911
26. Kooiman KM, Knops RE, Olde Nordkamp L, Wilde AA, de Groot JR (2014) Inappropriate subcutaneous implantable cardioverter-defibrillator shocks due to t-wave oversensing can be prevented: implications for management. Heart Rhythm Off J Heart Rhythm Soc 11:426–434
27. Bellardine Black CL, Stromberg K, van Balen GP, Ghanem RN, Breedveld RW, Tieleman RG (2010) Is surface ecg a useful surrogate for subcutaneous ecg? Pacing Clin Electrophysiol PACE 33:135–145
28. Brisben AJ, Burke MC, Knight BP, Hahn SJ, Herrmann KL, Allavatam V, Mahajan D, Sanghera R, Gold MR (2015) A new algorithm to reduce inappropriate therapy in the s-icd system. J Cardiovasc Electrophysiol 26:417–423