


Eligibility for subcutaneous implantable cardioverter-defibrillator in adults with congenital heart disease

Christos Zormpas^{1,2}, Ann Sophie Silber-Peest², Jörg Eiringhaus^{1,2}, Henrike A.K. Hillmann^{1,2}, Stephan Hohmann^{1,2}, Johanna Müller-Leisse^{1,2}, Mechthild Westhoff-Bleck², Christian Veltmann^{1,2} and David Duncker^{1,2*} 

¹Hannover Heart Rhythm Center, Department of Cardiology and Angiology, Hannover Medical School, Carl-Neuberg-Str. 1, Hannover, D-30625, Germany; ²Department of Cardiology and Angiology, Hannover Medical School, Hannover, Germany

Abstract

Aims Patients with adult congenital heart disease (ACHD) carry an increased risk for sudden cardiac death. Implantable cardioverter-defibrillator (ICD) therapy may be challenging in these patients due to anatomical barriers, repeated cardiac surgery, or complicated transvenous access. Thus, the subcutaneous ICD (S-ICD) can be a promising alternative in this patient population. Patients with ACHD show significant electrocardiogram (ECG) abnormalities, which could affect S-ICD sensing because it depends on surface ECG.

Methods and results One hundred patients with ACHD were screened for S-ICD eligibility. Standard ECG-based screening test and automated S-ICD screening test were performed in all patients. Sixty-six patients (66%) were male. Underlying congenital heart disease (CHD) was mainly CHD of great complexity (71%) and moderate complexity (29%), including repaired tetralogy of Fallot (20%), which was the most common entity. Thirty-seven patients (37%) already had a pacemaker (23%) or ICD (14%) implanted. Automated screening test identified 83 patients (83%) eligible for S-ICD implantation in either left parasternal position (78%) or right parasternal position (75%). Absence of sinus rhythm, QRS duration, and a paced QRS complex were associated with S-ICD screening failure in univariate analysis. Receiver operating characteristic curve and multivariate analysis revealed a QRS duration ≥ 148 ms as the only independent predictor for S-ICD screening failure.

Conclusions Patients with ACHD show satisfactory eligibility rates (83%) for S-ICD implantation utilizing the automated screening test, including patients with CHD of high complexity. S-ICD therapy should be considered with caution in ACHD patients with a QRS duration ≥ 148 ms and/or need for ventricular pacing.

Keywords Subcutaneous implantable cardioverter-defibrillator; Adult congenital heart disease; S-ICD screening test; Tetralogy of Fallot

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*Correspondence to: David Duncker, Hannover Heart Rhythm Center, Department of Cardiology and Angiology, Hannover Medical School, Carl-Neuberg-Str. 1, D-30625 Hannover, Germany. Tel: +49 511 532 3817; Fax: +49 511 532 8475. Email: duncker.david@mh-hannover.de

Introduction

Patients with adult congenital heart disease (ACHD) show an elevated risk for sudden cardiac death (SCD).^{1–3} Current guidelines recommend an implantable cardioverter-defibrillator (ICD) implantation for primary prevention in patients with ACHD with reduced systemic ventricular function [ejection fraction (EF) $\leq 35\%$] or in high-risk patients with

tetralogy of Fallot (TOF). For secondary prevention, the ICD is indicated after haemodynamically not tolerated ventricular tachycardia or aborted SCD.^{4–6}

Conventional ICD systems require transvenous access in order to sense and terminate ventricular tachyarrhythmias, which can be challenging in patients with ACHD due to anatomical barriers, repeated cardiac surgery, or complicated transvenous access.^{7–10} In case of device infection or lead

failure, necessary extraction of the complete ICD system is associated with high morbidity and mortality in patients with ACHD.^{9,11,12} Transvenous access to the right ventricle in patients with ACHD may be impossible either anatomically or due to palliative or corrected cardiac operation. In case of relevant shunting, intravascular material should be avoided because of the increased risk of embolism. The subcutaneous ICD (S-ICD) offers a promising alternative to transvenous ICDs, as it does not require vascular access.

However, patients with ACHD usually show significant electrocardiogram (ECG) abnormalities, which could potentially affect S-ICD eligibility, because S-ICD detection is based on surface ECG. To date, there has been a limited series of studies assessing S-ICD eligibility in patients with ACHD using an ECG-based S-ICD screening test only.^{13–15} The present study aims to elucidate S-ICD eligibility rates in patients with ACHD utilizing both the ECG-based and the automated S-ICD screening test.

Methods

Patients with ACHD presenting for routine follow-up in the Adult Congenital Heart Center at Hannover Medical School were included in the study in a prospective non-randomized manner. Patients were included in the study according to the complexity of the underlying congenital heart disease (CHD), because risk stratification for SCD in these patients is not well established. The study protocol complied with the Declaration of Helsinki and was approved by the local ethics committee. All patients gave written informed consent.

A standard 12-lead ECG and a transthoracic echocardiography were performed in all patients. ECG was performed in accordance with international standards.¹⁶ Baseline parameters were recorded including underlying disease, prior cardiac operation, body mass index, and chest circumference. Classification of the underlying anatomy and complexity of lesion was performed according to 2018 American Heart Association/American College of Cardiology guidelines for the management of patients with ACHD.¹⁷

Subcutaneous implantable cardioverter-defibrillator screening test

In all patients, two S-ICD screening tests, that is, the standard ECG-based screening and the automated screening test, were performed to evaluate S-ICD eligibility. For the ECG-based screening test, the ECG limb leads (left arm, right arm, and left leg) were placed as previously described.¹⁸ The test was performed in left and right parasternal positions and was repeated in supine and upright position. S-ICD ECGs were recorded at gains of 5, 10, and 20 mV at a paper speed of

25 mm/s using an ECG device (MAC 5500, GE Healthcare, Chicago, IL, USA).

The automated screening test was performed to assess vector eligibility with the screening template using the Latitude Programmer Model 3120 (Boston Scientific, Natick, MA, USA). ECG electrodes were positioned at the same positions as for the ECG-based screening.¹⁸

Subcutaneous ICD eligibility was defined as at least one eligible vector in left or right parasternal position in both supine and upright positions. Reason for failure of the ECG-based screening test was manually evaluated by an experienced cardiologist. In case of the automated screening test, the programming device does not provide an explanation of test failure. Thus, the reason for vector failure in the automated test cannot be retraced.

Statistical analysis

Categorical variables are presented as numbers and percentages and were compared among subgroups using χ^2 test or regression analysis, as appropriate. For comparison of continuous variables, the non-parametric Wilcoxon test or Kruskal–Wallis test was used, as appropriate. In order to illustrate the diagnostic ability of parameters, receiver operating characteristic curve analysis was applied. Multivariate analysis was performed using binary logistic regression analysis. Continuous variables are presented as mean \pm standard deviation. Values of $P < 0.05$ were considered statistically significant. Statistical analysis was conducted using SPSS Version 26 (IBM, Armonk, NY, USA).

Results

The study included 100 patients with ACHD between November 2018 and June 2020. *Table 1* summarizes the baseline characteristics of the patients included. Twenty patients (20%) had a repaired TOF, which presented the most common underlying CHD in the present study.

Characteristics of the 12-lead electrocardiogram

All patients received a standard 12-lead ECG. Fifteen patients (15%) had a paced QRS complex. *Table 2* summarizes recorded ECG parameters.

Eligibility for subcutaneous implantable cardioverter-defibrillator implantation

Utilizing the automated S-ICD screening test, 83 patients (83%) had at least one eligible vector and were consequently

Table 1 Baseline patient characteristics

Parameter	n = 100
Age (years)	38.1 ± 12.2
Male, n (%)	66 (66)
Chest circumference (cm)	96.6 ± 11.9
Body mass index (kg/m ²)	25.8 ± 5.3
Underlying heart disease, n (%)	
• CHD of great complexity	71 (71)
○ Transposition of the great arteries	24 (24)
○ Conduits, valved or non-valved	9 (9)
○ Pulmonary vascular obstructive disease	9 (9)
○ Pulmonary atresia	5 (5)
○ Double-outlet ventricle/single ventricle	4 (4)
○ Tricuspid atresia	3 (3)
○ Other	17 (17)
• CHD of moderate complexity	29 (29)
○ Tetralogy of Fallot	20 (20)
○ Other	9 (9)
Mustard procedure, n (%)	13 (13)
Fontan procedure, n (%)	7 (7)
• Tricuspid atresia	3 (3)
• Single ventricle	2 (2)
• Other	2 (2)
Devices	
• Transvenous pacemaker, n (%)	23 (23)
• Transvenous ICD, n (%)	13 (13)
• Pacemaker dependent, n (%)	15 (15)
• S-ICD, n (%)	1 (1)
Ejection fraction of systemic ventricle (%)	48.0 ± 9.2

CHD, congenital heart disease; ICD, implantable cardioverter-defibrillator; S-ICD, subcutaneous implantable cardioverter-defibrillator.

Table 2 Twelve-lead ECG parameters recorded from 100 patients with ACHD

Parameter	n = 100
Atrial rhythm, n (%)	
• Sinus rhythm	74 (74)
• Atrial fibrillation	18 (18)
• Paced	8 (8)
Heart rate (b.p.m.)	67.1 ± 14.3
Cardiac axis (°)	16.2 ± 86.1
PR interval (ms)	171.3 ± 34.7
QRS duration (ms)	133.9 ± 37.9
QRS morphology, n (%)	
• QRS duration <120 ms	51 (51)
• RBBB	31 (31)
• LBBB	1 (1)
• IVCD	2 (2)
• Paced	15 (15)
QTc interval (ms)	454.9 ± 52.4

ACHD, adult congenital heart disease; ECG, electrocardiogram; IVCD, intraventricular conduction delay; LBBB, left bundle branch block; RBBB, right bundle branch block.

found eligible for S-ICD implantation. *Figure 1* summarizes the results of each screening test with regard to the number of eligible vectors in left and right parasternal positions, respectively.

Ninety patients (90%) showed S-ICD eligibility with either the ECG-based or the automated screening test. Seventy-eight patients (78%) had both a positive ECG-based and a positive automated screening tests. Of the seven

patients having a positive ECG-based screening test but negative automated screening test, all showed only one eligible vector with the ECG-based screening test. All patients with Mustard procedure ($n = 13$) were found eligible with the automated screening test. *Figure 2* provides an overview of the S-ICD eligibility rates according to each screening method performed.

Eight patients (8%) were found eligible in the left parasternal but not in the right parasternal position, while 5 patients (5%) were found eligible in the right parasternal but not in the left parasternal position. [Correction added on 03 March 2021, after first online publication: In the preceding sentence, the number of patients has been corrected in this version.]

Subcutaneous implantable cardioverter-defibrillator screening test failure

Reasons for S-ICD screening failure in the ECG-based screening test were a high amplitude of the QRS complex (47.6%), T-wave oversensing (29.1%), low amplitude of the QRS complex (21.8%), and a broad QRS complex not fitting in the QRS–T-wave template of the screening tool (1.5%).

In three patients (3%), the automated screening test yielded no result, and thus, these patients were also considered ineligible for S-ICD implantation.

Predictors for failure of automated screening test

In the univariate analysis, sinus rhythm ($P = 0.030$), QRS duration ($P < 0.001$), and a paced QRS complex ($P < 0.001$) were found to be relevant regarding S-ICD eligibility with the automated screening test (*Table 3*). In order to elucidate the diagnostic yield of QRS duration to predict S-ICD eligibility, receiver operating characteristic curve analysis was performed. A cut-off value of 148 ms QRS duration showed the best sensitivity (0.824) and specificity (0.265) and thus revealed that patients with a QRS duration ≥ 148 ms were more likely to fail the automated S-ICD screening test. *Table 4* provides results of the multivariate analysis performed, in which a QRS duration ≥ 148 ms was found to be the only independent parameter predicting failure of the automated screening test.

Discussion

The present study is the first to assess S-ICD eligibility in 100 patients with ACHD using the automated S-ICD screening tool. The main findings of the study are as follows:

- S-ICD eligibility rate of 83% was found in patients with ACHD using the automated screening test.
- A QRS duration ≥ 148 ms was the only independent predictor for failure of the automated screening test.

Figure 1 Eligible subcutaneous implantable cardioverter-defibrillator vectors according to electrocardiogram (ECG)-based and automated screening test in left and right parasternal positions ($n = 100$).

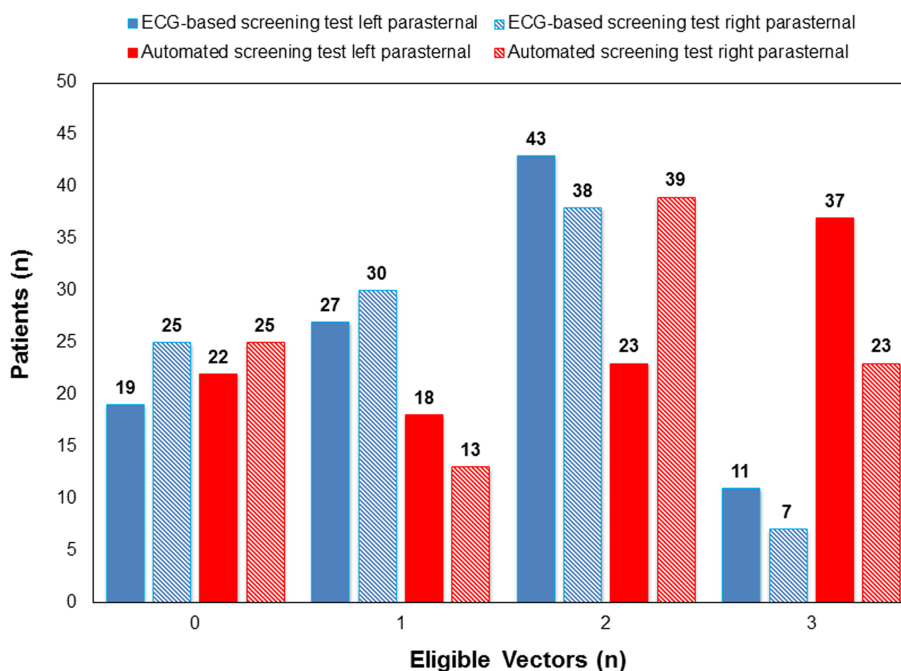
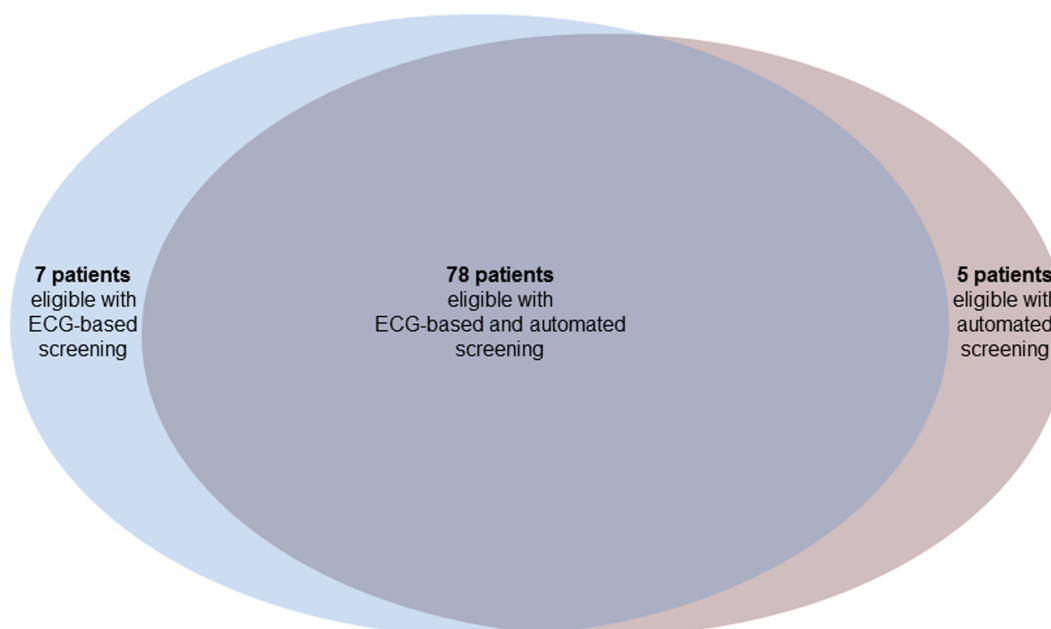


Figure 2 Proportional Venn diagram of 90 patients with adult congenital heart disease eligible for subcutaneous implantable cardioverter-defibrillator implantation according to each screening test performed. ECG, electrocardiogram.



Patients with ACHD show high morbidity and mortality, of which a high rate is attributed to SCD.¹⁻³ S-ICD therapy is safe and efficient in patients with heart failure in general^{19,20} as

well as patients with ACHD²¹⁻²³ and could overcome several limitations of the transvenous systems in this patient population. In a recent study of Willy *et al.*, 20 patients with ACHD

Table 3 Univariate analysis of recorded parameters between patients eligible and ineligible for subcutaneous implantable cardioverter-defibrillator implantation according to the automated screening test

Parameter	Eligible <i>n</i> = 83	Ineligible <i>n</i> = 17	<i>P</i> -value
Age (years)	36.5 ± 11.4	34.3 ± 7.5	0.756
Male, <i>n</i> (%)	55 (66.3)	11 (64.7)	0.903
Chest circumference (cm)	96.3 ± 12.3	94.5 ± 11.3	0.191
Body mass index (kg/m ²)	25.7 ± 5.7	25.0 ± 3.5	0.223
Sinus rhythm, <i>n</i> (%)	65 (78.3)	9 (53.0)	0.030
Cardiac axis (°)	19.9 ± 79.9	34.0 ± 83.5	0.957
QRS duration (ms)	122.8 ± 32.6	170.6 ± 30.1	<0.001
Paced QRS complex, <i>n</i> (%)	8 (9.6)	7 (41.2)	<0.001

Table 4 Multivariate analysis of parameters associated with failure of automated S-ICD screening test

	OR	95% CI for OR	<i>P</i> -value
Sinus rhythm	0.981	0.117–8.228	0.981
QRS duration ≥148 ms	0.102	0.024–0.432	0.002
Paced QRS complex	0.480	0.049–4.732	0.530

CI, confidence interval; OR, odds ratio; S-ICD, subcutaneous implantable cardioverter-defibrillator.

and an implanted S-ICD were evaluated.²¹ Patients included in this study had a median EF of 46.5%. S-ICD therapy was shown to be safe and effective in this small patient cohort. Similarly, Moore *et al.* evaluated S-ICD safety and effectiveness in a small cohort of 21 patients with ACHD and reported satisfactory conversion rates of induced ventricular fibrillation intraoperatively as well as adequate rhythm discrimination during follow-up.²³

The present study aimed to include patients with complex CHD rather than focusing on patients' ventricular function alone. Recruitment of patients included patients with complex CHD, predominantly repaired TOF (20%), and impaired systemic ventricular function (median EF 48.0%). Moreover, 13% had undergone Mustard procedure, and 7% had Fontan circulation. These patients often show significant ECG abnormalities.²⁴ In particular, patients with TOF often show a wide QRS complex,²⁵ and a QRS duration of >180 ms has been identified as risk factor for SCD in this patient cohort.²⁶ A transvenous or epicardial pacemaker system is often already implanted and could potentially impact the S-ICD screening test. Thus, analysing S-ICD eligibility in these patients with the automated screening test is of clinical importance.

Previous studies have reported S-ICD eligibility rates in patients with ACHD varying from 75.4–93.5% using the ECG-based screening test.^{14,15,27} In accordance with these data, the present data showed an overall S-ICD eligibility rate of 83% using the automated screening test, similar to the

85% rate found with the ECG-based screening test in the present study. Interestingly, patients with very complex cardiac anatomy after Mustard procedure (100%) and Fontan procedure (85.7%) showed high S-ICD eligibility rates.

Patients with Fontan circulation (*n* = 7) as well as patients with already implanted transvenous leads (*n* = 36), namely, multiple leads, lack transvenous access or show high incidence of venous obstruction, respectively.²⁸ Thus, these patients could benefit from S-ICD implantation.

In the present study, both the ECG-based screening and the automated screening test were performed, because the results of the two tests may differ, and rarely, the automated screening test yields no result.¹⁸ This was observed in three patients (3%) evaluated with the automated screening test. Thus, the less time-consuming automated screening test could be performed first, and the ECG-based screening test could remain as an alternative only for patients found ineligible with the automated screening test in order to reduce screening workload. Nevertheless, the aim of the present study was to assess S-ICD eligibility utilizing the automated screening test and not to compare the two methods.

Right parasternal position has been proposed as favourable in patients with ACHD.²⁹ In the present study, eight patients (8%) were found eligible in the left parasternal but not in the right parasternal position, while 5 patients (5%) were found eligible in the right parasternal but not in the left parasternal position. [Correction added on 03 March 2021, after first online publication: In the preceding sentence, the number of patients has been corrected in this version.] Previous studies have shown even higher S-ICD eligibility rates in the right parasternal position.^{30,31} Because of the special heart anatomies of ACHD patients, it is not groundless to address both parasternal positions, and this should be further examined.

Studies in pacemaker or cardiac resynchronization therapy recipients have shown lower S-ICD eligibility rates in comparison with patients with intrinsic atrioventricular nodal conduction.^{32,33} Nevertheless, the coexistence of a pacemaker and/or cardiac resynchronization therapy with an S-ICD appears to be feasible in selected cases. Thus, if ventricular pacing is necessary, S-ICD should be implanted only after careful screening of all possible pacing options. In the present study, univariate analysis showed that QRS duration (*P* < 0.001) and a paced QRS complex (*P* < 0.001) were associated with S-ICD eligibility when utilizing the automated screening test. Multivariate analysis revealed that a QRS duration ≥148 ms, regarding either paced or intrinsic QRS complex, is the only independent parameter predicting failure of automated screening test. Taking these data together, ACHD patients with a QRS duration ≥148 ms are less probably eligible for S-ICD implantation. In these patients, S-ICD should not be primarily considered but only in the absence of a transvenous access.

Limitations

In the present study, S-ICD eligibility was tested in ACHD patients for the first time utilizing the automated screening test. However, one major limitation is that positive S-ICD eligibility could not be verified through S-ICD implantation. As a consequence, actual potential S-ICD sensing failure could not be evaluated and actual S-ICD eligibility remains only on a theoretical level. Focusing on the automated screening test, the test provides a dichotomic result for S-ICD eligibility. Thus, reason for screening failure is not provided and cannot be examined.

The present study lacked a control group. Thus, only previously published data in patients with heart failure without CHD served as comparison.

Conclusions

Utilizing the automated S-ICD screening test in a patient population with predominantly complex CHD showed an S-ICD eligibility rate of 83%. Thus, S-ICD implantation seems possible in the majority of ACHD patients. A QRS duration ≥ 148 ms was found to be an independent predictor for S-ICD screening failure with the automated screening test.

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Conflict of interest

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