



Usefulness of a standard 12-lead electrocardiogram to predict the eligibility for a subcutaneous defibrillator

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ABSTRACT

Background: Currently, the eligibility for a subcutaneous implantable defibrillator (S-ICD) system relies on a pre-implant vector screening based on the automated screening tool (AST). We investigated which 12-lead ECG characteristics are associated with eligibility for an S-ICD in a heterogeneous population at risk for sudden cardiac death (SCD). The goal is to determine patient eligibility for S-ICD using the standard 12-lead ECG, thereby avoiding additional AST screening.

Methods: We evaluated the eligibility for an S-ICD in 254 consecutive patients at risk for SCD. We identified 12-lead ECG parameters which were independently associated with AST passing (≥ 1 vector) using multivariable logistical regression analysis in our derivation cohort. The final model was tested in a separate validation cohort. **Results:** The overall passing rate was 92% in our derivation cohort. Independent 12-lead ECG characteristics associated with AST passing were $QRS \leq 130$ ms, absence of QRS/T discordance in lead II and R/T-ratio ≥ 3.5 in lead II. Eighty-three of 254 patients (33%) fulfilled these three criteria and had a passing rate of 100%. Of the validation cohort, 37 of 60 patients (62%) fulfilled all three criteria and also had a passing rate of 100%. The interobserver agreement for applying the ECG model was 90% (Cohen's Kappa = 0.80).

Conclusion: Using the standard 12-lead ECG, we developed a simple screening model with a high specificity for S-ICD eligibility. Our results suggest that patients who fulfill the three ECG criteria do not need additional AST-screening.

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Introduction

The efficacy and safety of the subcutaneous implantable defibrillator (S-ICD) has been demonstrated in both primary and secondary prevention of sudden cardiac death (SCD) [1]. However, the advantage of the S-ICD is partially offset by the presence of inappropriate shocks that is mainly attributed to T-wave oversensing [1–4]. Therefore, it is recommended that every S-ICD candidate needs to be screened before S-ICD implantation to reduce the likelihood of T-wave oversensing. In current practice, the eligibility for a subcutaneous implantable defibrillator system relies on a pre-implant vector screening based on the automated screening tool (AST). Several studies have investigated the feasibility of AST for S-ICD eligibility screening [5–7].

Previous studies demonstrated several standard 12-lead ECG characteristics associated with the eligibility for an S-ICD. However, these associations were based on the manual ECG screening tool [8–10]. We

investigated which 12-lead ECG characteristics are associated with eligibility for an S-ICD in a heterogeneous population at risk for sudden cardiac death (SCD). The goal is to determine patient eligibility for S-ICD using the standard 12-lead ECG, thereby avoiding additional AST screening. Quick assessment of eligibility for an S-ICD based on a standard 12-lead ECG may be useful as the healthcare provider immediately knows if a patient is eligible for an S-ICD.

Methods

Study design

This was a retrospective study evaluating 12-lead ECG characteristics associated with AST passing in consecutive patients with cardiomyopathy, congenital heart disease, and inherited primary heart disease. The purpose of the present study was to develop a 12-lead ECG screening model which can identify patients who are eligible for an S-ICD, thereby omitting additional AST screening. The standard 12-lead ECG was acquired directly after the AST-screening. A patient was considered eligible for S-ICD if at least one sensing vector passed the AST in both

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supine and sitting posture. The screening model was developed using a derivation cohort. This derivation cohort consisted of 254 patients which was previously described by our group [7]. In this study we investigated the eligibility for S-ICD using both AST and manual ECG screening. In brief, all consecutive patients at risk for SCD were screened for their eligibility for S-ICD during their routine outpatient clinic using both AST and manual ECG screening between February and June 2017. Exclusion criteria were $\geq 3\%$ ventricular pacing, cardiac resynchronization therapy and patients with paced QRS-complex during screening.

Finally, the derived 12-lead ECG screening model was tested in an independent validation cohort consisting of implantable cardioverter defibrillator (ICD) candidates who underwent AST-screening in a clinical setting after June 2017. All included patients provided informed consent to participate in the study, and the study was approved by the institutional review board of the Erasmus Medical Center (MEC 2017-035).

ECG analysis

Standard 12-lead ECG characteristics, such as PR interval, QRS duration, presence of interventricular conduction delay and QT(c) interval (as determined by Fridericia formula), JTc ($JTc = QTc - QRS \text{ duration}$) were extracted from the baseline standard 12-lead ECG. Furthermore, maximum QRS and T-wave amplitude (absolute maximum deflection from the isoelectric line), absence of T-wave inversion (TWI) and QRS/T-wave discordance, and R/T-ratio were manually determined using E-scribe software (E-scribe™ ECG Workstation version 8.16.1). The characteristics were specifically analyzed in lead I, II and aVF, since these leads have a vector direction which are comparable to the primary, secondary and alternate sensing vector of the S-ICD, respectively. T-wave was considered inverted when the highest amplitude had a negative polarity and QRS/T-wave discordance was noticed when the T-wave had an opposite direction as the QRS complex. For the purpose of determining TWI and QRS/T-wave discordance the T-wave should be $\geq 0.1 \text{ mV}$.

ECG characteristics of the patients who passed the AST were compared to the patients who failed. Furthermore, a specific vector-based analysis was performed to investigate which ECG characteristics were associated with eligibility for S-ICD at the corresponding vector level.

Statistical analysis

Continuous data are presented as mean $\pm$ standard deviation or as median with interquartile range (25th and 75th percentile), where appropriate. Categorical variables are presented by frequencies and percentages. Differences between groups were analyzed with the unpaired Student's *t*-test, Chi-square test or the Fisher's exact test, as appropriate. Univariable and multivariable logistic regression analysis were performed to identify factors associated with AST passing. Any univariable variable with a *P*-value < 0.05 was entered in a multivariable forward conditional model. Inter-observer agreement between 2 observers (RS and SCY) was evaluated using Cohen's Kappa statistics. A *P*-value < 0.05 was considered statistically significant. Statistical analyses were performed using SPSS version 24.

Results

Baseline characteristics

A total of 254 consecutive patients were screened for their S-ICD eligibility using the AST. Among them 167 (66%) patients were males and the mean age of the study population was 51 ± 16 years. The majority of the patients had structural heart disease (SHD; $n = 194$, 76%). Inherited primary arrhythmia syndrome (IPAS) was present in 60 (24%) patients. Hundred and ten (43%) patients had an ICD at the time

of enrollment. The majority (64%) of the indications were for primary prevention.

Comparative demographic and clinical characteristics of those who passed ($n = 233$, 92%) and those who failed ($n = 21$, 8%) the AST are listed in Table 1. The passing rate varied from 83% for hypertrophic cardiomyopathy (HCM) to 100% for long QT syndrome (LQTS). There were no statistically significant differences in demographics, ICD indication, and underlying etiology between patients who passed and those who failed the screening. Detailed overview of the baseline characteristics has been previously reported by Sakhi et al. [7]

Patient based ECG analysis

ECG characteristics stratified by S-ICD eligibility are listed in Table 2. Patients who passed the screening had a higher proportion of QRS $\leq 130 \text{ ms}$ and QTc $\leq 450 \text{ ms}$ in comparison to those who failed the screening. When looking at specific leads, the patients who passed the screening had less TWI in lead II; less QRS/T-wave discordance in lead II and aVF; and a higher R/T-ratio in lead II and aVF in comparison to those who failed the screening.

Vector-based ECG analysis

The primary, secondary and alternate sensing vectors of 254 patients, both supine and sitting postures, were analyzed separately, resulting in 762 vectors. The primary sensing vector was the most appropriate (80%, $n = 204$), followed by the secondary vector (77%, $n = 196$) and the alternate vector (59%, $n = 151$). Results of the absolute QRS amplitude and R/T-ratio of lead I, lead II and lead aVF with the corresponding vectors are demonstrated in Fig. 1. Patients who passed the secondary or alternate vector had a higher absolute QRS amplitude in their corresponding leads (lead II and aVF, respectively) in comparison to those who failed (lead II: 0.92 mV versus 0.66 mV , $P < 0.01$; lead aVF: 0.81 mV versus 0.53 mV , $P < 0.01$). Furthermore, they also had a higher R/T-ratio in leads II and aVF (lead II: 3.88 versus 2.50 , $P < 0.01$; lead aVF: 4.77 versus 2.82 , $P < 0.01$). A R/T-ratio of ≥ 3.5 was deemed as the optimal cutoff based on the highest sensitivity and specificity for the specific leads (Fig. 1). A more detailed overview of ECG characteristics with the matching screening vectors are provided in supplementary material (Appendix A). Patients who passed the screening had a higher proportion of R/T-ratio ≥ 3.5 in lead II and aVF (Table 2).

ECG characteristics associated with S-ICD eligibility

Univariable and multivariable analysis for S-ICD eligibility are presented in Table 3. Univariable analysis demonstrated that QRS duration $\leq 130 \text{ ms}$, QTc duration $\leq 450 \text{ ms}$, absence of TWI in lead I and lead II,

Table 1
Demographics and clinical characteristics.

	Total (<i>n</i> = 254)	Pass (<i>n</i> = 233)	Fail (<i>n</i> = 21)	P-value
Male gender (%)	167 (66)	154 (66)	13 (62)	0.70
Age, years, $\pm$ SD	51 ± 16	51 ± 16	56 ± 16	0.17
BMI, kg/m^2 , $\pm$ SD	26.1 ± 4.5	26.0 ± 4.5	26.5 ± 5.0	0.68
Implantable	110 (43)	103 (44)	7 (33)	0.36
cardioverter-defibrillator				
Primary prevention	70 (28)	65 (28)	5 (24)	0.69
Secondary prevention	40 (16)	38 (16)	2 (10)	0.41
Cardiac diagnosis*				
Structural heart disease (%)	194 (76)	175 (75)	19 (90)	0.11
Cardiomyopathy	126 (50)	115 (49)	11 (52)	0.79
Congenital heart disease	68 (27)	60 (26)	8 (38)	0.22
Inherited primary arrhythmia syndrome (%)	60 (24)	58 (25)	2 (10)	0.11

Data are presented as mean $\pm$ SD, categorical data as *n* (%). BMI: body-mass index.

Table 2
Baseline 12-lead ECG characteristics.

	Total (n = 254)	Pass (n = 233)	Fail (n = 21)	P-value
Sinus rhythm (%)	229 (90)	209 (90)	20 (95)	0.41
PR interval (IQR) ^a	169 (152–189)	168 (151–187)	188 (161–193)	0.06
QRS ≤ 130 ms	200 (79)	193 (83)	7 (33)	<0.01
QT ≤ 450 ms	227 (89)	210 (90)	17 (81)	0.19
QTc ≤ 450 ms	223 (88)	208 (89)	15 (71)	0.02
JTc duration	294 (275–316)	295 (275–316)	289 (273–322)	0.36
Maximal QRS amplitude in mV (IQR)				
- Lead I	0.72 (0.49–0.99)	0.70 (0.49–0.99)	0.88 (0.55–1.00)	0.34
- Lead II	0.87 (0.60–1.18)	0.89 (0.63–1.20)	0.63 (0.45–1.01)	0.08
- Lead aVF	0.71 (0.48–1.00)	0.72 (0.50–1.03)	0.58 (0.34–0.87)	0.36
Absence of T-wave inversion (%)				
- Lead I	211 (83)	197 (85)	14 (67)	0.04
- Lead II	225 (89)	210 (90)	15 (71)	0.02
- Lead aVF	215 (85)	200 (86)	15 (71)	0.09
Absence of QRS/T-wave discordance (%)				
- Lead I	179 (70)	167 (72)	12 (57)	0.16
- Lead II	198 (78)	188 (81)	10 (48)	<0.01
- Lead aVF	163 (64)	156 (67)	7 (33)	<0.01
R/T-ratio per lead (IQR)				
- Lead I	3.87 (2.58–6.85)	3.88 (2.59–6.94)	3.44 (2.56–5.54)	1.00
- Lead II	3.52 (2.33–5.71)	3.61 (2.42–5.94)	2.52 (1.58–3.10)	0.02
- Lead aVF	3.66 (2.33–6.84)	4.08 (2.38–7.09)	2.36 (1.42–3.60)	0.02
R/T-ratio of ≥3.5 per lead (%)				
- Lead I	149 (59)	139 (60)	10 (48)	0.28
- Lead II	128 (50)	123 (53)	5 (24)	0.02
- Lead aVF	136 (54)	130 (56)	6 (29)	0.02

IQR = Interquartile range.

^a Only in patients with sinus rhythm.

absence of QRS/T-wave discordance in lead II and aVF, and R/T-ratio ≥3.5 in II and aVF were associated with AST passing based on ≥1-vector pass rule. Independent ECG characteristics associated with AST passing

were QRS ≤ 130 ms, absence of QRS/T-wave discordance in lead II and R/T-ratio ≥3.5 in lead II.

When applying the ECG criteria in the derivation cohort, 83 patients (33%) fulfilled all three ECG criteria. In these patients, the eligibility for S-ICD based on ≥1 vector passing rate was 100%. When using the more stringent ≥2 vector pass criteria for S-ICD eligibility, the passing rate was 96%.

Validation analysis

The 12-lead ECG screening model was evaluated in a validation cohort consisting of 60 ICD candidates who underwent AST-screening as part of their clinical workup for ICD implantation. The mean age of the validation cohort was 49 ± 17 years and the majority of the patients were male (76%). In total, 50 patients had SHD (83%) and IPAS was present in 10 (17%) patients. The ≥1 vector pass rate was 90% for this cohort, 6 patients (10%) failed the AST screening. When applying the derived screening model, 37 of 60 patients (62%) fulfilled all three 12-lead ECG criteria. The ≥1 vector pass rate was 100% for this selected cohort, thus all patients who fulfilled the three ECG criteria were eligible for S-ICD. Furthermore, when using the stringent criteria for S-ICD eligibility (≥2 vector pass rule) the eligibility increased from 78% to 89% in patients. The interobserver agreement of the screening model was good with a Cohen's Kappa of 0.80 and an overall agreement of 90%.

Follow-up of S-ICD patients

Of the patients who fulfilled all the three ECG criteria in the derivation cohort, 18 of 83 patients (22%) had an S-ICD. During a median follow-up of 66 months (interquartile range: 35–85 months), two patients experienced an inappropriate shock. One patient received an inappropriate shock due to R-wave attenuation and the other patient due to a supraventricular tachyarrhythmia detected in the shock zone. In the validation cohort, 28 of the 37 patients (76%) who fulfilled the three ECG criteria received an S-ICD and during a median follow-up of

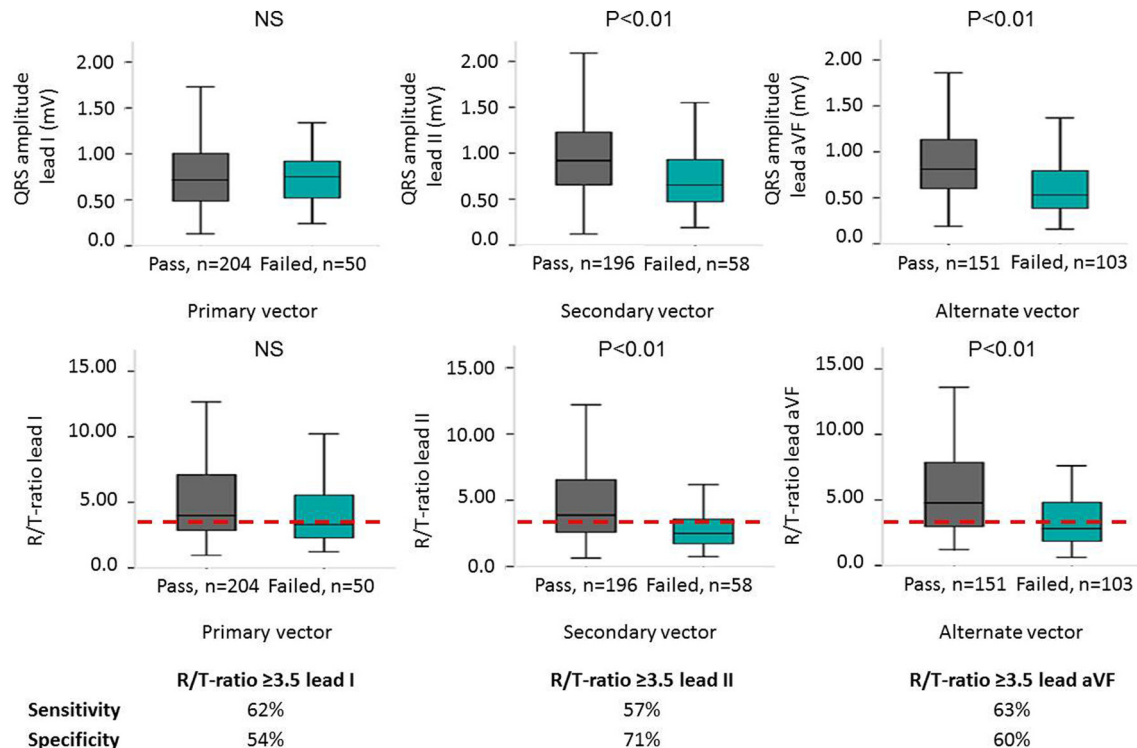


Fig. 1. Eligibility for S-ICD of the different screening vectors based on the QRS-amplitude and R/T-ratio of the corresponding leads. NS = no significant p-value.

Table 3
ECG characteristics associated with S-ICD eligibility.

Variables	Univariable		Multivariable	
	OR (95% CI)	P-value	OR (95% CI)	P-value
QRS $\leq$ 130 ms	9.65 (3.66–25.43)	<0.01	8.09 (2.88–22.77)	<0.01
QTc $\leq$ 450 ms	3.33 (1.18–9.54)	0.02		
Absence of T-wave inversion in lead I	2.74 (1.03–7.25)	0.04		
Absence of T-wave inversion in lead II	3.65 (1.29–10.33)	0.02		
Absence of QRS/T-wave discordance in lead II	5.05 (1.98–12.92)	<0.01	4.19 (1.49–11.74)	<0.01
Absence of QRS/T-wave discordance in lead aVF	3.95 (1.53–10.19)	<0.01		
R/T-ratio $\geq$ 3.5 in lead II	3.58 (1.27–10.01)	0.02	4.21 (1.27–13.95)	0.02
R/T-ratio $\geq$ 3.5 in lead aVF	3.16 (1.18–8.42)	0.02		

OR = odds ratio; CI = confidence interval.

11 months (interquartile range: 3–15 months) none of the patients experienced an inappropriate shock.

Discussion

The present study demonstrated that QRS duration $\leq$ 130 ms, absence of QRS/T-wave discordance in lead II and R/T-ratio $\geq$ 3.5 in lead II were independently associated with eligibility for S-ICD based on AST-screening. Interestingly, the eligibility for S-ICD was 100% in patients who fulfilled all three criteria in both the derivation and validation cohort.

Using the AST as a pre-implant screening tool, eligibility rates from 92% to 96% have been reported [5–7]. The study by Francia et al., reported eligibility rates of 94% and 80% when using $\geq$ 1-vector and $\geq$ 2-vector pass rule, respectively [5]. This is in line with the results of the present study (92% for $\geq$ 1-vector pass and $\geq$ 80% 2-vector pass). More recently, Bogeholz et al., found a $\geq$ 1-vector AST passing rate of 94% in

33 consecutive patients who already had an S-ICD system implanted [6]. Comparable results were demonstrated by Sakhi et al., in S-ICD patients in whom eligibility for S-ICD had already been determined with manual ECG screening ($n = 35$, 100% $\geq$ 1-vector pass rule) [7].

ECG characteristics associated with S-ICD eligibility

Previous studies have identified 12-lead ECG characteristics associated with S-ICD ineligibility based on manual ECG screening, such as prolonged QRS duration, low R/T-ratio, T-wave inversion and QRS/T-wave discordance [8–10]. Considering the high agreement between manual ECG screening and AST on a patient level, one would expect the same factors to be associated with S-ICD ineligibility based on AST [7]. We identified similar factors associated with S-ICD ineligibility: prolonged QRS duration, presence of QRS/T-wave discordance in lead II, and low R/T-ratio in lead II. Bogeholz et al. also demonstrated that

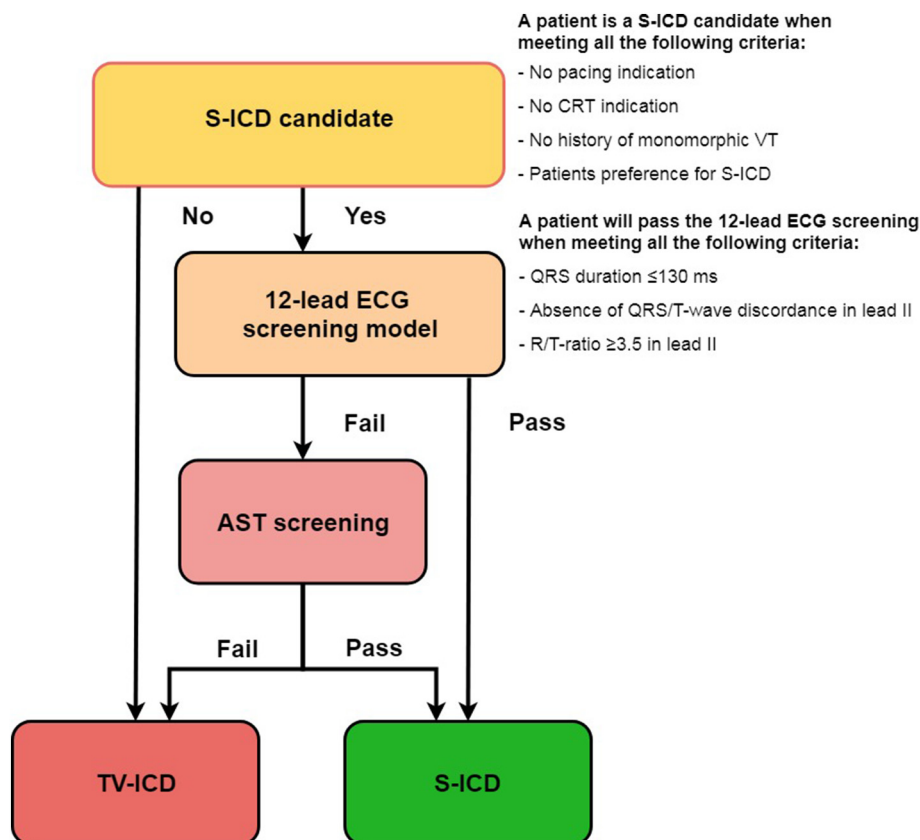


Fig. 2. Proposed screening procedure for S-ICD screening in daily clinical practice. CRT = cardiac resynchronization therapy; VT = ventricular tachycardia; TV-ICD = transvenous implantable cardioverter defibrillator.

prolonged QRS duration, presence of T-wave inversion and a low R/T-ratio were more common in patients who failed AST-screening.

The purpose of AST screening is to select patients who are at low risk of T-wave oversensing. Our proposed screening model achieves the same result albeit at the cost of sensitivity (patients who fail our screening model, may still be suitable based on AST). The identified ECG factors are probably associated with a normal repolarization with a good signal-to-noise ratio. It is known that prolonged QRS duration and QRS/T-wave discordance are associated with repolarization abnormalities. By excluding patients with repolarization abnormalities and a low R/T-ratio, it seems logical that the chance of T-wave oversensing is low.

Clinical implications

When a patient is a potential ICD candidate and does not have an indication for pacing, biventricular pacing or ATP then the patient is a potential candidate for an S-ICD. In clinical practice, a potential S-ICD candidate undergoes vector screening using AST and when at least 1 vector is suitable then we will discuss the pros and cons of transvenous and subcutaneous ICDs. Based on previous studies it is known that the S-ICD eligibility rate based on AST is relatively high (>90%). Some implanters have argued to abolish vector screening considering this high passing rate. Unfortunately, inappropriate shocks due to T-wave oversensing do occur and this should be prevented. We developed a simple screening model using the standard 12-lead ECG which can identify patients who have a very high likelihood to pass the vector screening based on AST. When patients fulfill all three ECG criteria, it seems safe to omit vector screening considering the 100% ≥ 1 vector passing rate and even 96% ≥ 2 vector passing rate. Despite the excellent specificity (100%), the sensitivity of the proposed screening model varied between 36 and 67%. This means that a substantial proportion of ICD candidates still requires AST screening. Based on the results of the present study, we propose a simple flowchart to determine eligibility for an S-ICD that can be easily implemented in daily clinical practice (Fig. 2).

Study limitations

Several limitations are important to highlight. It has been previously shown that S-ICD screening during exercise can identify T-wave oversensing and results in a greater failure rate, especially in certain patients with HCM [3,11,12]. We did not test our study population during exercise, therefore we cannot draw conclusions on the validity of our model in patients undergoing exercise testing as part of the screening. Furthermore, the combination of the small number of patients in the validation cohort and high passing rate may affect the accuracy of the specificity of our model. Therefore, the 12-lead ECG screening model should be validated in a larger population before widespread clinical adoption. Finally, the safety of the proposed algorithm can be evaluated when comparing the inappropriate shock rates of patient populations screened with the proposed algorithm versus AST only.

Conclusion

Using the standard 12-lead ECG we developed a simple screening model with a high specificity for S-ICD eligibility. Our results suggest

that patients who fulfill the three ECG criteria do not need additional AST-screening.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jelectrocard.2019.05.014>.

Declaration of Competing Interest

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