Prevalence of subcutaneous implantable cardioverter-defibrillator candidacy based on template ECG screening in patients with hypertrophic cardiomyopathy

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BACKGROUND Subcutaneous implantable cardioverter-defibrillator (S-ICD) is a promising option for patients with hypertrophic cardiomyopathy (HCM). Patients with HCM can present markedly abnormal electrocardiograms (ECGs), and there are no data on what percentage of patients with HCM fail the prerequisite S-ICD vector screening.

OBJECTIVE The purpose of this study was to determine the failure rate of the prerequisite vector screening using 1 or 2 acceptable vectors stratified for risk profile for sudden cardiac death and predictors of failure.

METHODS ECG recordings from consecutive patients with HCM simulating the S-ICD sensing vectors were analyzed with the S-ICD screening tool. Eligibility was defined by 1 or 2 appropriate vectors. Medical history, ultrasound characteristics, and 12-lead ECG characteristics were analyzed and the individual arrhythmic risk at 5 year was determined to study potential predictors of failure.

RESULTS One hundred sixty-five (118 men; mean age 51 ± 16 years) patients were analyzed. Twenty-two patients (13%) had a high risk of sudden cardiac death, 33 (20%) had intermediate to high risk, and 110 (67%) had low risk. Twenty-six patients (16%) had no suitable vector, including 8 of 22 high-risk patients (36%). The primary cause of failure was high T-wave voltages in 25% of the vectors analyzed. T-wave inversions in >2 leads on the surface 12-lead ECG (odds ratio 15.6; 95% confidence interval 4.9–50.3; $P < .001$) and prior myectomy (odds ratio 8.4; 95% confidence interval 2.1–33.1; $P = .002$) were significantly associated with screening failure in a multivariable model.

CONCLUSION Currently available preimplant screening algorithms recommended by the manufacturer are associated with a significant failure rate in patients with HCM, particularly in the high-risk subgroup.

KEYWORDS Subcutaneous implantable cardioverter-defibrillator; Hypertrophic cardiomyopathy; T-wave oversensing; Defibrillator screening; Inappropriate shocks; Sudden cardiac death

ABBREVIATIONS **ECG** = electrocardiogram/electrocardiographic; **HCM** = hypertrophic cardiomyopathy; **ICD** = implantable cardioverter-defibrillator; **LBBB** = left bundle branch block; **LV** = left ventricle/ventricular; **S-ICD** = subcutaneous implantable cardioverter-defibrillator; **TWI** = T-wave inversion

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Introduction

Hypertrophic cardiomyopathy (HCM) is an inherited heart muscle disorder and a leading cause of sudden cardiac death (SCD) in young adults.[1,2] Patients at high risk of SCD benefit from prophylaxis with an implantable cardioverter-defibrillator (ICD). However, because of their young age at implantation, patients with HCM are likely to suffer from long-term device-related complications. The subcutaneous implantable cardioverter-defibrillator (S-ICD)[3] eliminates the need for lead placement in or on the heart and is expected to reduce intravascular lead-related complications, such as pneumothorax, venous thrombosis, and cardiac perforation.[4,5] As the S-ICD uses a morphology-based rhythm discrimination algorithm, abnormal QRS complexes and T waves can cause sensing issues, resulting in inappropriate shocks.[6–10] To avoid S-ICD implantation in patients who are likely to experience such problems, the manufacturer has developed a prerequisite electrocardiographic (ECG) screening to identify unsuitable

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ECG morphologies. This is possible because surface and subcutaneous ECGs are highly correlated with similar R-wave amplitudes and signal-to-noise ratios.[9,10] Current recommendations state that only patients who pass the screening in at least 1 vector should be considered eligible for S-ICD implantation.

The S-ICD may be a promising option for patients with HCM who are generally young, do not require pacing, and have an increased risk of endovascular lead-related complications.[8] However, there are no data on the prevalence of screening failure in patients with HCM in whom the ECG is often markedly abnormal, particularly in those with severe phenotypes who are potentially at higher arrhythmic risk.[11] In case of an inappropriate shock due to QRS double counting or T-wave oversensing, the availability of second suitable sensing vector may reduce the chance of reoccurrence of a second inappropriate shock.

In the present study, we therefore assessed a cohort of patients with HCM, with and without an ICD indication, consecutively seen at 2 referral centers and determined the failure rate of the prerequisite vector screening using both 1 and 2 suitable vectors stratified for high- and low-risk profile for SCD.

Methods

Study population

We assessed a cohort of 165 patients with HCM (118 men; mean age 51 ± 16 years) from 2 European tertiary referral centers (Azienda Ospedaliera-Universitaria Careggi in Florence, Italy, and Academic Medical Center in Amsterdam, The Netherlands) from March to November 2014. Patients with right bundle branch block or left bundle branch block (LBBB) were also included. The diagnosis of HCM was based on ultrasound characteristics: a hypertrophied, nondilated left ventricle (LV) (wall thickness of $\leq$15 mm) in the absence of another cardiac or systemic disease capable of producing a similar degree of hypertrophy.[12] For all patients, informed consent to participate in the study was obtained and the local ethics committee approved the study protocol.

Echocardiography

Comprehensive 2-dimensional and Doppler echocardiographic studies were performed in each patient using commercially available instruments. LV hypertrophy was assessed by 2-dimensional echocardiography, and the site and extent of maximal wall thickness were identified. Peak instantaneous LV outflow gradient, due to mitral valve systolic anterior motion and mitral-septal contact, was estimated with continuous wave Doppler under standard conditions.[12]

Electrocardiogram collection and analysis

Standard 12-lead ECG was performed in all patients, and parameters such as P-wave amplitude, P-Q interval, QRS duration, maximal QRS amplitude, ST-segment characteristics, corrected QT interval, amplitude and voltage of the largest T wave, and left ventricular hypertrophy indexes (Sokolow, Cornell, and Romhilt-Estes) were assessed.

For the evaluation of S-ICD candidacy, specific ECG recordings were obtained using limb lead electrodes to simulate the S-ICD sensing vectors. The left arm and right arm electrodes were positioned 1 cm lateral to the left sternal border and, respectively, 1 cm above the xiphoid process and no more than 14 cm superior to the left arm electrode. The left leg electrode was positioned in the fifth intercostal space on the midaxillary line and the neutral electrode on the lower torso to ensure other lead positions were undisturbed. The resulting augmented leads (leads I, II, and III) correspond to the alternate, secondary, and primary vectors of the S-ICD, respectively. Ten- to 20-second rhythm strips were recorded using these 3 leads at 5 and 10 mm/mV gains in both supine and erect positions, or at 20 mm/mV, if deemed appropriate.

Screening ECGs were analyzed using the template of the Patient Screening Tool provided by the manufacturer (Boston Scientific). The tool consists of 6-colored templates that correspond to the 6 S-ICD automatic gain morphology templates of the discrimination algorithm. The screening template was placed over a single QRS-T complex. The horizontal line on the template was aligned with the isoelectric line, and the left edge of the template was aligned with the onset of the QRS complex. To fit the template, no part of the QRS-T complex may lie outside the colored shape and the maximum amplitude of the QRS complex must cross the dashed line. For validation of data analysis, ECGs in Florence were analyzed by 2 independent blinded observers and their assessment of S-ICD eligibility was compared. When there was a disagreement, ECG for that patient was adjudicated by a third independent observer. All 3 observers received training before using the surface ECG screening template.

Criteria for eligibility and screening failures

Successful vector screening at any of the 3 gain settings in both erect and supine postures was defined in 2 ways: (1) as 1 suitable vector ("1-vector rule"); (2) as $\geq$2 suitable sensing vectors ("2-vector rule"). *Vector screening failure* was defined as nonfitting of at least 1 QRS-T complex in the 10- to 20-second ECG strip. Reasons of failures were recorded for every single analyzed vector and categorized into 3 groups: (1) high T-wave voltages; (2) high R-wave voltages; and (3) low QRS complex voltages (Figure 1).

SCD prediction model

The novel validated algorithm HCM Risk-SCD was used to estimate the risk of SCD.[13] A low-risk patient group was defined by a 5-year risk of $<4\%$; an intermediate to low-risk patients group was defined by a 5-year risk of $4\% \leq x < 6\%$; and a high-risk patient group was defined by a 5-year risk of $\geq 6\%$.[1,13] Such an approach was used as the only available, independently validated methods for SCD quantification in HCM.[13,14]

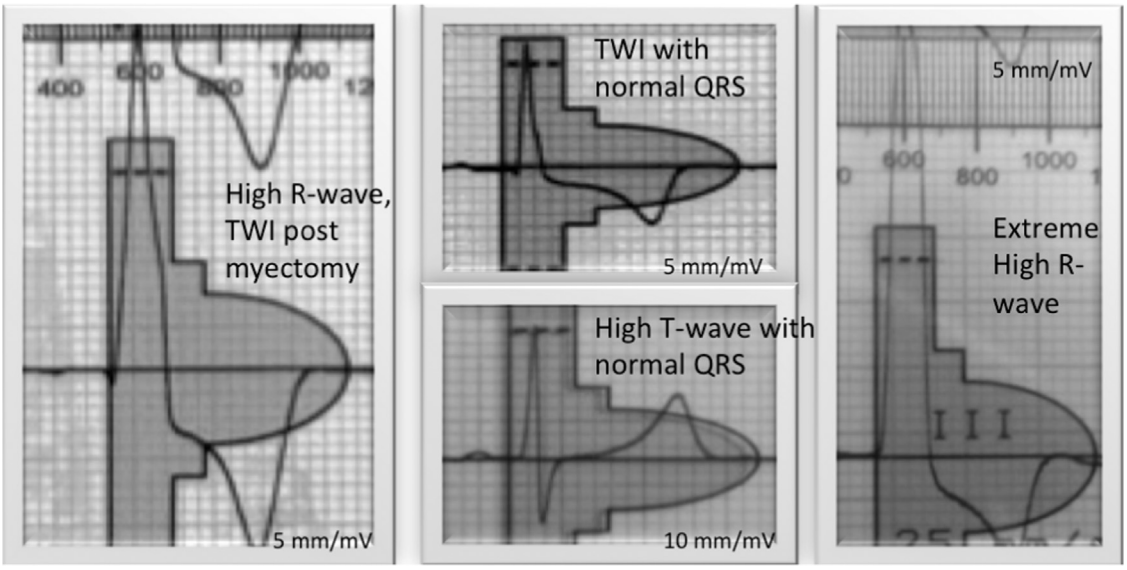

Figure 1 Paradigmatic example of an inappropriate QRS/T-wave morphology not fulfilling the preimplant screening for the subcutaneous implantable cardioverter-defibrillator. TWI = T-wave inversion.

Statistical analysis

Continuous and normally distributed data are represented as mean ± SD; categorical data are expressed both as numbers and as percentages. Continuous variables were compared using the independent Student *t* test, whereas categorical data were assessed among groups using the χ^2 test or the Fisher exact test, as appropriate. Not normally distributed data were expressed as median with interquartile ranges and compared between groups using the Mann-Whitney *U* test. Multivariable logistic regression was used to examine the predictors of screening failure for the S-ICD. Initially, potential risk factors were evaluated using univariate analyses; a *P* value of $<.10$ was used as criteria to include it in the multivariable logistic regression model to control confounding effects. *P* values are 2-sided, and a *P* value of $<.05$ was considered significant. The SPSS software (version 21.0, SPSS Inc., Chicago, IL) was used for statistical analysis.

Results

Patients characteristics and risk profile

A total of 165 patients (mean age 51 ± 16 years) were screened for the S-ICD (Table 1). Thirty-four patients (23%) were women; 44 (27%) were younger than 40 years; and 121 (73%) were 40 years and older. Twenty-two patients were in New York Heart Association functional class higher than I; the mean LV ejection fraction was 63% ± 9%; 32 patients (19%) had a history of atrial fibrillation, and 39 patients (24%) had a basal left ventricular outflow tract obstruction of ≤30 mm Hg. Twenty-two patients (13%) had a history of surgical myectomy; 6 patients (3.5%) had a history of percutaneous alcohol septal ablation; and 2 patients (1%) had a history of both. Forty-one patients (24%) already carried a transvenous ICD for primary (n = 38) or secondary (n = 3) SCD prophylaxis. Twenty-two patients (13%) were stratified as high risk (5-year risk >6%; mean 7.6% ± 1.7%), 33 as intermediate to moderate risk (5-year risk 4% ≤x<6%; mean 4.778% ± 0.581%), and 110 as low risk (5-year risk ≤4%; mean 2.730% ± 0.646%) (Table 1).

By design, high-risk patients had a higher prevalence of syncope ($P = .008$), nonsustained ventricular tachycardia ($P < .001$), and family history of SCD ($P < .001$) and exhibited greater maximal LV wall thickness ($P = .012$) and left atrial diameter ($P = .006$) as compared with low-risk patients. In addition, patients in the high-risk group were younger ($P = .032$) and more often carried an ICD ($P < .001$).

Interobserver agreement and adjudication

ECGs in Florence (n = 137) were analyzed by 2 independent blinded observers (N.M. and C.F.). An agreement was reached in 132 (96%). When there was a disagreement, the ECG for that patient was adjudicated by a third independent observer (I.O.). The use of 20 mm/mV gain has been necessary in 6 patients (4%).

Results of morphology screening

A total of 1008 vectors were analyzed, and overall 564 of 1008 (56%) failed screening. Main causes of failure were high T-wave voltages in 248 vectors (25%), low QRS voltages in 183 vectors (13%), and high R-wave voltages in 133 vectors (18%). The secondary sensing vector was the most likely to fail (36%), followed by a primary sensory vector (35%), whereas an alternate sensing vector had the lowest failure rate (29%) (Table 2).

Results of screening for the S-ICD using the 1-vector rule

Twenty-six patients (16%) failed the morphology screening in all vectors: failure was disproportionately prevalent in the high-risk subgroup (n = 8 of 32 [36%]) as compared with the

Table 1 Demographic and clinical characteristics based on 5-year SCD risk

Variable	Total screened (N = 165)	Low risk of SCD (<4% at 5 y) (n = 110)	Intermediate to moderate risk of SCD (4% ≤x<6% at 5 y) (n = 33)	High risk of SCD (≥6% at 5 y) (n = 22)	*P* Low risk/ intermediate risk	*P* Low risk/ high risk	*P* Intermediate/ high risk
Age (y)	51 ± 1	51 ± 15	47 ± 15	45 ± 15	.120	<.001	.432
Sex: male	118 (70)	73 (70)	27 (81)	18 (86)	.045	.022	.870
NYHA class >I	22 (13)	12 (11)	8 (24)	2 (10)	.320	.670	.481
LV ejection fraction (%)	63 ± 9	63 ± 4	65 ± 9	64 ± 9	.565	.502	.683
LVOT obstruction at rest (≥30 mm Hg)	39 (24)	20 (18)	13 (39)	7 (32)	.023	.030	.654
Atrial fibrillation	32 (19)	17 (15)	8 (24)	7 (33)	.112	.694	.448
ICD implanted	41 (24)	18 (17)	12 (36)	11 (50)	.561	<.001	.471
Prior myectomy	22 (12)	12 (11)	7 (21)	3 (14.3)	.780	.373	.060
Prior alcohol septal ablation	6 (3)	6 (6)	0	0	.336	.588	1
Prior myectomy and alcohol septal ablation	2 (1)	2 (2)	0	0	1	1	1
Prior aborted cardiac arrest	5 (3)	3 (3)	1 (3)	1 (4.7)	1	.213	.875
Syncope	19 (11)	11 (10)	3 (9)	5 (23.8)	.454	.008	.869
NSVT	55 (32)	23 (21)	14 (42)	18 (81)	.040	<.001	.125
LVMWT (mm)	21 ± 6,15	19 ± 5	23.9 ± 6.5	24.7 ± 7.6	.016	.012	.348
LA diameter (mm)	43 ± 7	42 ± 7	43 ± 7	48 ± 6	.137	.006	.019
LVOT gradient (mm Hg)	8 (5 25)	8 (5 25)	14 (5 60)	8 (5 45)	.021	.124	.991
Fx of HCM	66 (39)	40 (37)	7 (21)	13 (57)	.555	.965	.361
Fx of SCD	48 (28)	21 (19)	14 (42)	13 (62)	.684	<.001	.392
Individual risk of SCD at 5 y (%)	3.598 ± 2.065	2.730 ± 0.646	4.778 ± 0.581	7.666 ± 1.790	<.001	<.001	<.001

Values are presented as mean ± SD or as n (%).

Fx of HCM = family history of hypertrophic cardiomyopathy; Fx of SCD = family history of sudden cardiac death; ICD = implantable cardioverter-defibrillator; LA = left atrium; LV = left ventricular; LVMWT = left ventricular maximal wall thickness; LVOT = left ventricular outflow tract; NYHA = New York Heart Association; NSVT = nonsustained ventricular tachycardia; SCD = sudden cardiac death.

low-risk subgroup (n =12 of 110 [11%]; $P = .041$). The calculated individual risk of SCD at 5 years was significantly higher in patients who fail than in eligible patients (3.409% ± 1.885% for eligible patients vs 4.498% ± 2.702% for failure patients; $P = .006$). This result was largely driven by the fact that among the various risk factors analyzed in the

Table 2 Comparison of clinical parameters between eligible patients and failure patients using the 1-vector rule

Variable	Eligible (n = 139)	Failures (n = 26)	*P*
Age	50.3 ± 16	53 ± 18	.291
Syncope	16 (12)	3 (12)	.510
NSVT	43 (31)	12 (46)	.116
LVMWT (mm)	20.9 ± 5.7	22 ± 7.8	.149
LA diameter (mm)	42 ± 6.7	46 ± 7.7	.002
LVOT maximum gradient (mm Hg)	8 (5.14)	11 (5.42)	.003
Fx of HCM	58 (42)	7 (27)	.543
Fx of SCD	41 (30)	7 (27)	.694
Prior aborted CA	5 (4)	1 (4)	.577
ICD implanted	28 (20)	11 (42)	.126
Myectomy	12 (9)	10 (38)	<.001
Alcohol septal ablation	3 (2)	3 (12)	1
Myectomy and alcohol septal ablation	1 (1)	1 (4)	
Individual risk at 5 y (%)	3.409 ± 1.885	4.498 ± 2.702	.006

Values are presented as mean ± SD or as n (%).

CA = cardiac arrest; Fx of HCM = family history of hypertrophic cardiomyopathy; Fx of SCD = family history of sudden cardiac death; ICD = implantable cardioverter-defibrillator; LA = left atrium; LVMWT = left ventricular maximal wall thickness; LVOT = left ventricular outflow tract; NSVT = nonsustained ventricular tachycardia.

Table 3 Comparison of electrocardiographic parameters between eligible patients and failure patients using the 1-vector rule

Variable	Total (N = 165)	Eligible (n = 139)	Failures (n = 26)	*P*
HR (betas/min)	62 ± 11	61 ± 10	65 ± 15	.156
P-wave length (ms)	117 ± 22	118 ± 22	113 ± 38	.613
PQ-wave length (ms)	180 ± 35	181 ± 34	175 ± 39	.851
Maximum QRS voltage measured (mm)	152 ± 103	152 ± 102	152 ± 106	.254
Corrected QT interval (ms)	421 ± 50	420 ± 50	419 ± 45	.248
TWI in >2 leads	53 (32)	35 (25)	18 (69)	<.001
T-wave voltage (mm)	67 ± 42	63 ± 42	80 ± 45	.039
T-wave length (ms)	270 ± 77	274 ± 77	258 ± 86	.208
QRS/T ratio	2.6 ± 1.8	2.8 ± 1.9	1.9 ± 1.1	.036
QRS/T ratio <1.36	45 (27)	33 (24)	12 (46)	.020
Positivity to Sokolow index	49 (30)	44 (31)	15 (57)	.026
Positivity to Cornell index	74 (45)	64 (46)	9 (34)	.323
R-E index	5.6 ± 2.8	5.6 ± 2.7	5.16 ± 3	.330

Values are mean ± SD or as n (%).
HR = heart rate; R-E = Romhilt-Estes; TWI = T-wave inversion.

European Society of Cardiology risk score, screening failure patients had a higher prevalence of resting LV outflow obstruction ($P = .003$) and left atrial diameter ($P = .002$). Conversely, no significant differences were present between the 2 groups with regard to age ($P = .4$), maximal LV wall thickness ($P = .149$), syncope ($P = .5$), nonsustained ventricular tachycardia ($P = .116$), and family history of SCD ($P = .694$). In addition, myectomy proved to be a potent predictor of screening failure ($P < .001$), whereas alcohol septal ablation did not have an impact on screening outcome (Table 3).

Twelve-lead ECG analysis and predictors of failure

The results of the ECG analysis for the study population are presented. T-wave inversion (TWI) in >2 leads on the 12-lead ECG was the strongest discriminator between those who failed and those who passed the preimplant screening ($P < .001$). Furthermore, screening failures more often had a positive Sokolow Index ($P = .026$), higher maximal T-wave voltage ($P = .039$), and an overall lower QRS/T ratio ($P = .036$) and were more likely to have a QRS/T ratio of <1.36 ($P = .020$).

Univariate analysis showed TWI in >2 leads, QRS/T ratio <1.36, and myectomy to be associated with preimplant screening failure. In multivariable logistic regression analysis, only TWIs in >2 leads on the surface 12-lead ECG (odds ratio 15.6; 95% confidence interval 4.9–50.3; $P < .001$) and prior myectomy (odds ratio 8.4; 95% confidence interval 2.1–33.1; $P = .002$) independently predicted screening failure.

Two-vector rule

When candidacy was tested on the basis of 2 successful vector screening, 72 patients (44%) proved not eligible at the S-ICD screening ECG, including 15 high-risk patients (71%) and 42 low-risk patients (38%). Thus, the introduction of a second vector in preimplant evaluation resulted in 46 additional screening failures as compared to the 1-vector rule (Figure 2).

A SCD risk profile comparison between eligible and failure patients using the 1-vector rule is given in the Online Supplement.

Discussion

Since its introduction in 2012, the S-ICD has come to represent an appealing alternative to the transvenous ICD in patients with HCM who are often young, do not require pacing, and face considerable infectious risk related to recurrent device substitutions over their lifetime.[4,5] Recent data from the EFFORTLESS S-ICD Registry identify patients with HCM as one of the subsets at a higher risk of inappropriate shocks because of T-wave oversensing.[15,16] While risk can be reduced by appropriate preimplant screening, this unavoidably occurs at the cost of limiting the use of S-ICD. Our data show that 16% of the consecutive patients with HCM are not eligible for the device according to current manufacturer recommendations. This is in contrast with prior studies of general cardiac patients, showing that only 8% of individuals may not be eligible for the implantation.[17,18] Furthermore, our data are in disagreement with a recent work

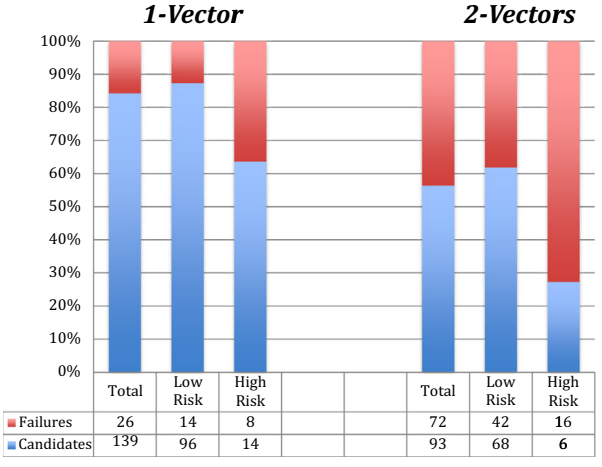

Figure 2 Eligibility rates evaluated using the 1-vector rule vs 2-vector rule.

by Francia et al,[19] showing a low failure rate in a small cohort of patients with HCM. However, the SCD risk profile for this cohort is not provided, nor are the predictors of failure identified, so the discrepancy may be largely due to patient selection.

Two population studies, 1 from the Netherlands[17] and 1 from North America,[18] were performed according to the currently recommended 1-vector rule', and the screening failure rate was 7% and 8%, respectively. In the Dutch cohort, increased body weight, prolonged QRS duration, R/T ratio <3 on the surface ECG lead with the largest T wave, and HCM were significantly associated with screening failure.[17] Conversely, in the North American cohort reported by Groh et al,[18] TWI was the only predictor of screening failure.

The only study performed according to the previously recommended 2-vector rule, by Randles et al,[20] reported a 15% failure rate in an unselected cardiac patient cohort, with QRS duration as the only predictor of failure. This is in sharp contrast with the 44% of patients with HCM who fail the screening using the 2-vector rule, supporting the view that conclusions regarding patients with HCM cannot be inferred from other populations and that specific studies are required. This concept is all the more relevant, as the patients with HCM most likely to fail the screening are also the most likely to benefit; that is, those stratified as high risk of SCD are 8/22 (36%). In our cohort, patients who failed the screening showed a calculated high risk of SCD (4.5% $\pm$ 2.7% at 5 years) (Table 3). Conversely, patients at lower risk failed the screening less often, but were also, by definition, less likely to require primary prophylaxis with an ICD. This discrepancy reflects the fact that, on average, the ECG is progressively more abnormal (and thus likely to fail template-based screening) as the phenotypic expression of HCM becomes more severe.[11]

Interestingly, the QRS/T ratio was not the best predictor of failure in multivariable logistic regression analysis. Our regression model showed that TWIs in >2 leads on the surface ECG and prior myectomy were associated, respectively, with a 15- and 8-fold increase in the likelihood of failing the test. Mere inversion of the T wave should not cause the T wave to fall outside the template window because the window is symmetric along its horizontal axis with equal space above and below the baseline for the T wave. However, it appears that TWI is associated with ST-segment depression and a change in T-wave morphology (especially in patients with HCM) that causes the peak of the T wave to occur later as compared to when the T wave is not inverted, resulting in a T wave peaking outside the window.[21]

Preliminary data from the EFFORTLESS S-ICD Registry[15,16] suggested T-wave oversensing and low-amplitude signals to be the main causes of inappropriate shocks. In this respect, we report that high-voltage T waves and low-amplitude QRS complexes were also the major contributor to vector screening failure, thereby also limiting the S-ICD choice for patients with HCM.

The current European Society of Cardiology guidelines for HCM state that 2 eligible vectors have to be identified before the implantation in order to offer alternative vector choice in case of inappropriate shock occurrence.[1] However, our study clearly shows that the choice of a second implant vector increases the number of patients that fails S-ICD candidacy, from 16% to 44% in the entire cohort and from 36% to 72% in the high-risk subgroup. Furthermore, it is important to consider that S-ICD candidates with HCM may need to carry the device for many years, given the normal life expectancy associated with the disease. Thus, potential modifications in ECG morphology over time may impact the accuracy of arrhythmia detection. Definite data are lacking regarding the natural history of ECG morphology in patients with HCM. In our experience, the overall pattern remains generally stable over lifetime, with changes limited to mild increases in conduction times. However, patients at high arrhythmic risk are likely to be at high risk of disease progression leading to LV dysfunction, fibrosis, and subsequent changes in the ECG (mostly, occurrence of LBBB).[11] Furthermore, this subset would be more likely to benefit from pacing and antitachycardia pacing, favoring the implantation of a transvenous ICD. Similar considerations apply to obstructive patients who are candidates for surgical myectomy (often resulting in LBBB) or alcohol septal ablation (resulting in right bundle branch block). Thus, a subset of patients with HCM may exhibit sufficient dynamic evolution of the ECG as to raise concerns regarding arrhythmia detection by the S-ICD. This requires further study and warrants periodic reevaluation of candidacy in implanted patients.

Ultimately, our findings indicate the need for caution when considering patients with HCM for the implantation of the S-ICD. These individuals not only exhibit a higher failure rate compared to previously studied populations[17–19] but also have a limited choice of alternative vectors in case of sensing problems, especially in the high SCD-risk subgroup. This suggests the need for disease-specific preimplantation screening criteria (including simple measures such as the introduction of 2.5 mm/mV gain) and customized arrhythmia detection algorithms taking into account the specific ECG abnormalities found in these patients.

Patients with HCM would likely benefit from improvements in the discrimination algorithm that can reduce oversensing caused by the large T waves, such as the addition of a 2.5 mm/mV gain setting. Further studies are clearly needed to validate the safety and efficacy of arrhythmias detection of the 1-vector method and how inappropriate discharges can be managed, for example, by changing the vector in patients with 2 suitable vectors.

Conclusion

Currently available preimplant screening algorithms recommended by the manufacturer are associated with a significant failure rate in patients with HCM, particularly in the high-risk subgroup.

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Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.hrthm.2015.09.007.

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CLINICAL PERSPECTIVES

The present study characterizes for the first time the prevalence of subcutaneous implantable cardioverter-defibrillator candidacy in a large cohort of patients with hypertrophic cardiomyopathy (HCM), stratified for their risk of SCD, consecutively referred to 2 international centers. Specific clinical and instrumental predictors of screening failure have been described for patients with HCM. In addition, the study clearly shows that the choice of a second implant vector, as suggested in the occurrence of an inappropriate shock, increases the number of patients that fails subcutaneous implantable cardioverter-defibrillator candidacy. The authors aim that patients with HCM and high arrhythmic risk would likely benefit from improvements in the discrimination algorithm in order to potentially reduce the oversensing often caused by large inverted T waves. Ultimately, we specifically designed an algorithm taking into account clinical and instrumental characteristics of high-risk patients with HCM to better support the physician in the device selection.