IJC Heart & Vasculature 35 (2021) 100841

Contents lists available at ScienceDirect

IJC Heart & Vasculature

journal homepage: www.journals.elsevier.com/ijc-heart-and-vasculature

The potential impact of acute coronary syndromes on automatic sensing system in Subcutaneous-ICDs

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ARTICLE INFO

Article history:
Received 13 June 2021
Received in revised form 2 July 2021
Accepted 5 July 2021

Keywords:
S-ICD
Automated sensing system
Acute coronary syndrome
STEMI
CCS

ABSTRACT

Background: The Subcutaneous-ICD (S-ICD) is emerging as a suitable option for most ICD candidates, however some open issues regarding the sensing algorithm still remain.
Objectives: We aimed to examine the performance of the S-ICD sensing algorithm in patients hospitalized for ST elevation myocardial infarction (STEMI), non ST elevation acute coronary syndrome (NSTE-ACS) or chronic coronary syndrome (CCS), before and after revascularization.
Methods: We performed a S-ICD automated screening on 75 patients, 21 hospitalized for STEMI, 23 for NSTE-ACS and 31 for CCS, before and after percutaneous revascularization, regardless their eligibility to ICD implantation.
Results: Patients did not differ in clinical, electrocardiographic and echocardiographic parameters. Rates of screening pass were significantly lower in STEMI patients compared to NSTE-ACS and CCS (5% vs 56.7% vs 81% respectively, p < .0001). The viability of the primary vector was lower in STEMI patients compared to NSTE-ACS and CCS (33% vs 56% vs 71%, p .027 respectively). After revascularization, there were no more significant differences between groups. Pairing subjects at baseline and after revascularization, STEMI subjects percentages of screening success were respectively 5% and 81% (p < .001) and the rates of primary vector viability were 33% and 81% (p .002). STEMI was the only independent predictor of screening failure at multivariate logistic regression analysis (odds ratio 10.68 confidence interval 2.77–41.38, p = .001)
Conclusion: The performance of the S-ICD and possible malfunction detections in the context of an acute ischemic event deserve further evaluation. Adequate patient selection and the development of dynamic device programming are warranted.

1. Introduction

Since its Introduction in the 1980s, the Implantable cardioverter defibrillator (ICD) has significantly reduced mortality in patients at risk for sudden cardiac death (SCD) [1]. Despite several improvements over time, device-related complications and malfunctions have been reported.

These are mainly related to the intravascular lead: lead failure rates approach 40% at 5 years [2] and bacteria species are able to create biofilms in contact with leads, rendering antibiotics ineffective and prompting extraction.

These complications and the need of specific patient populations (e.g. pediatric patients and those at high risk for bacteremia) led to the development of a non-endovascular defibrillator system. In 2012 the Food and Drug Administration (FDA) approved the first entirely subcutaneous implantable cardioverter defibrillator (S-ICD) that has been recommended in the current guidelines of the European Society of Cardiology (ESC) and of the American Heart Association/American College of Cardiology/ Heart Rhythm Society (AHA/ACC/HRS) for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death [3,4].

The S-ICD is progressively emerging as a suitable option for most ICD candidates with a primary prevention indication. In patients without need for pacing, it has been shown to reduce the risk of systemic infection and lead failure compared to

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https://doi.org/10.1016/j.ijcha.2021.100841
2352-9067/

transvenous (TV)-ICD [5]. More recently, the S-ICD was also found to be non inferior to TV-ICD with regard to device-related complications and inappropriate shocks [6]. However, it does not acquire endocardial electrograms but subcutaneous signals that resemble those of the surface electrocardiogram (ECG), more susceptible to postural variation. The S-ICD is able to process the waveform to identify the QRS as distinct from the T wave and P wave. Therefore, patients should always be screened before S-ICD implantation to ensure adequate QRS and T wave sensing and to avoid both undersensing of intrinsic QRS and T wave oversensing (TWOS). Particularly TWOS is the predominant cause of inappropriate shocks in the S-ICD population [7,8].

We aimed to examine the performance of the S-ICD sensing algorithm in patients hospitalized for Acute Coronary Syndromes

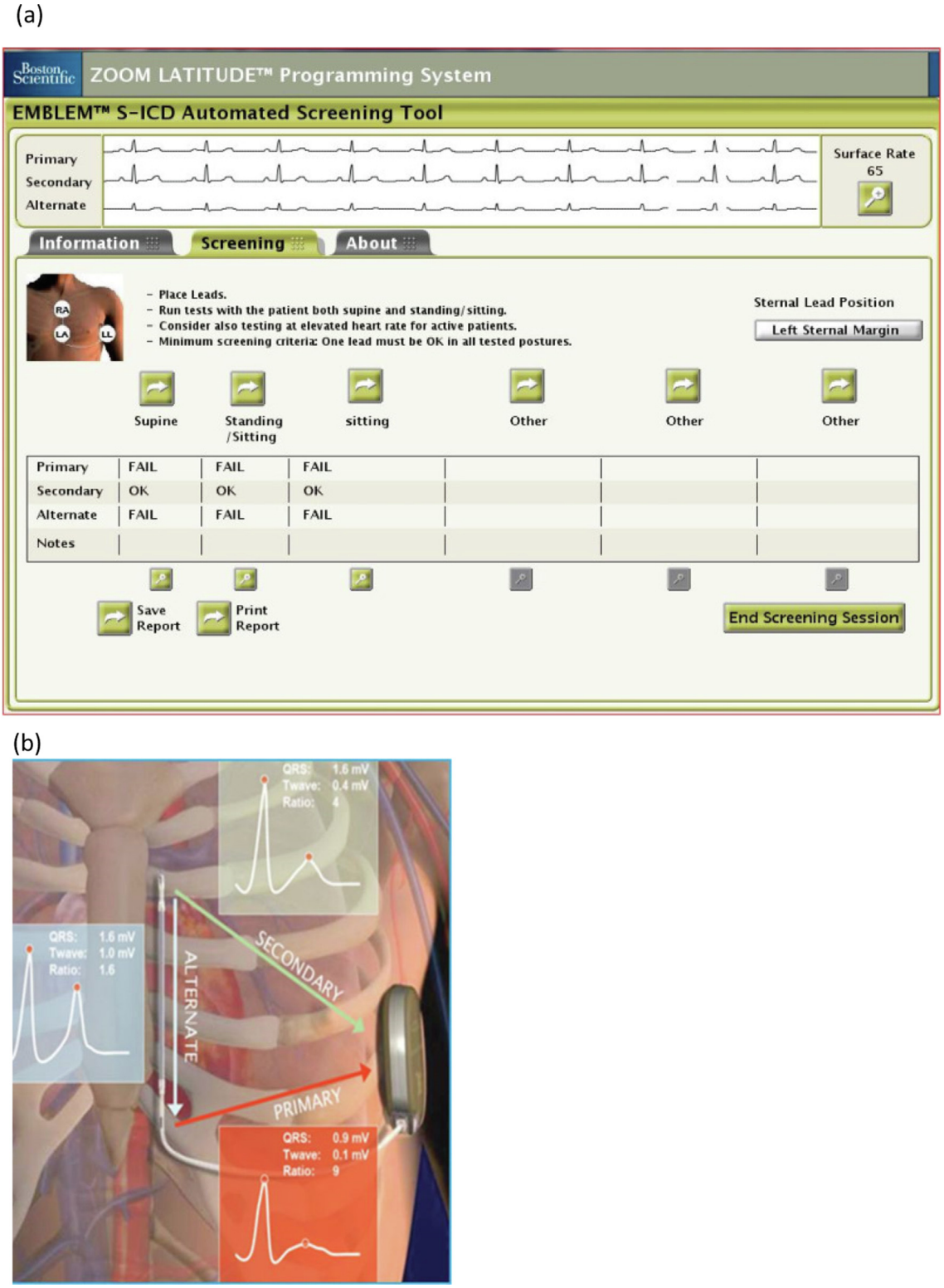

Fig. 1. (a) S-ICD automated screening tool and (b) Surface skin electrodes placement to perform the S-ICD screening.

(ACS), STEMI and NSTE-ACS groups, or Chronic Coronary Syndromes (CCS). These two settings, in fact, have different impacts on QRS morphology and duration. Our aim was to compare the rates of S-ICD screening success or failure in these populations, at baseline and after coronary revascularization procedure.

2. Materials and methods

2.1. Study population

We prospectively enrolled 75 patients fulfilling the following inclusion criteria: age >18 years, hospitalized for either ACS or CCS and who underwent percutaneous revascularization, regardless their eligibility to ICD implantation. Patients presenting with left bundle branch block or with a paced rhythm were considered ineligible. Baseline evaluation included demographics and medical history, clinical examination, electrocardiographic and echocardiographic variables.

2.2. Study protocol

Patients underwent two S-ICD screening procedures, the first upon arrival in the department and the latter after revascularization, before discharge. Mean time from arrival to first s-ICD screening was 130 min in ACS group and 364 min in CCS group; mean time from coronary revascularization to second screening was 4.4 days in ACS patients and 1.9 days in CCS patients. In STEMI patients, the screening procedure was done while preparing the catheterization laboratory and did not delay door-to-balloon times.

The Model 3120 Programmer (Boston Scientific, Natick,MA) was used to screen the patients, adopting the recently developed automated screening tool (AST) with the Vector Select™ algorithm to reduce subjectivity [9] (Fig. 1).

The surface skin electrodes were placed to match the location of the implanted S-ICD (Fig. 1b): can (midaxillary line, fifth intercostal space), proximal sensing electrode (1 cm left lateral to the xiphoid process) and distal sensing electrode (14 cm cranial to the proximal electrode). A ground electrode was placed in the right lower abdomen. The three resulting vectors were named primary (proximal to can), secondary (distal to can) and alternate (distal to proximal).

Before and after coronary revascularization, screening was performed in supine and erect/sitting posture; eligibility of all vectors was assessed automatically and data regarding QRS amplitude were obtained. Screening was considered successful if at least one vector was viable both in supine and erect/sitting posture.

Two operators performed the s-ICD screening, blinded to the acute or chronic setting of the groups.

Table 1
General findings in STEMI, NSTEMI and CCS patients.

	STEMI (21)	NSTEMI (23)	CCS (31)	P
Age (years)	67 ± 12	71 ± 10	70 ± 7	ns
Males n (%)	16 (76.2%)	16 (69.6%)	27 (87.1%)	ns
BMI (kg/m^2)	25 ± 4	28 ± 4	27 ± 5	ns
Diabetes mellitus n (%)	7 (33.3%)	7 (31.8%)	11 (35.5%)	ns
Arterial Hypertension n (%)	9 (42.9%)	21 (91.3%)	26 (83.9%)	**<0.0001**
CVD Family History n (%)	10 (47.6%)	7 (31.8%)	15 (48.4%)	ns
COPD n (%)	2 (9.5%)	4 (18.2%)	5 (16.1%)	ns
HR (bpm)	76 ± 16	77 ± 17	67 ± 14	ns
Atrial Fibrillation n (%)	0 (0.0%)	2 (9.1%)	2 (6.5%)	ns
QRS duration (msec)	101 ± 23	112 ± 35	98 ± 25	ns
RBBB n (%)	0 (0.0%)	3 (13.6%)	6 (19.4%)	ns
R wave lead I baseline (mV)	0.729 ± 0.259	0.748 ± 0.351	0.826 ± 0.280	ns
T wave lead I baseline (mV)	0.186 ± 0.174	0.128 ± 0.120	0.176 ± 0.168	ns
R wave lead I after revascularization (mV)	0.534 ± 0.261	0.729 ± 0.388	0.595 ± 0.383	ns
T wave lead I after revascularization (mV)	0.133 ± 0.146	0.139 ± 0.170	0.106 ± 0.177	ns
R/T ratio lead I baseline	1.92 ± 4.14	4.55 ± 4.68	3.70 ± 4.33	ns
R/T ratio lead I after revascularization	2.03 ± 3.52	2.18 ± 5.18	2.93 ± 3.49	ns
Troponin I peak (ng/ml)	53.44 ± 87.59	9.37 ± 18.59	NA	**0.023**
ST elevation site n (%)				
Anterior	10 (47.6%)	NA	NA	
Lateral	1 (4.8%)	NA	NA	
Inferior	10 (47.6%)	NA	NA	
Number of diseased vessels n (%)				ns
1	7 (33.3%)	9 (39.1%)	14 (45.2%)	
2	6 (28.6%)	6 (26.1%)	10 (32.3%)	
3	8 (38.1%)	8 (34.8%)	7 (22.6%)	
Culprit lesion n (%)				ns
LAD	11 (52.4%)	11 (47.0%)	12 (38.7%)	
LCX	1 (4.8%)	8 (34.8%)	7 (22.6%)	
RCA	9 (42.8%)	4 (18.2%)	12 (38.7%)	
LVEF < 50% baseline n (%)	12 (57.1%)	11 (47.8%)	9 (29%)	ns
LVEF baseline (%)	48 ± 11	49 ± 14	55 ± 13	ns
LVEDV baseline (ml)	99 ± 30	107 ± 54	99 ± 26	ns
LVESV baseline (ml)	53 ± 25	60 ± 45	46 ± 23	ns
LVEF after revascularization (%)	52 ± 10	57 ± 13	57 ± 12	ns
LVEDV after revascularization (ml)	97 ± 36	101 ± 51	103 ± 27	ns
LVESV after revascularization (ml)	49 ± 30	52 ± 43	46 ± 25	ns
Time to reperfusion (min)	65 ± 25	236 ± 100	380 ± 156	**<0.001**
Time to screening at baseline (min)	58 ± 24	196 ± 86	350 ± 150	**<0.001**
Time to screening after revascularization (days)	4.3 ± 1.6	2.0 ± 1.1	1.6 ± 0.6	**<0.001**

Abbreviations: STEMI: ST elevation myocardial infarction; NSTEMI: non-ST elevation myocardial infarction; CCS: chronic coronary syndromes; BMI: body mass index; CVD: cardiovascular disease; COPD chronic obstructive pulmonary disease; HR: heart rate; RBBB: right bundle branch block; LAD: left anterior descending; LCX: left circumflex; RCA: right coronary artery; LVEF: left ventricular ejection fraction; LVEDV: left ventricular end diastolic volume; LVESV: left ventricular end systolic volume;

None of the patients were deemed eligible for ICD based on the present guidelines during hospitalization.

All patients provided written informed consent for their screening procedure and use of their anonymized medical information for research. This research was done at a single center and was approved by the Institutional Review Board.

2.3. Statistical analysis

Differences in proportions were compared by means of chi-square analysis or Fisher's exact test, as appropriate. Differences in proportions for paired data were compared with the McNemar test.

Continuous variables were compared by means of unpaired Student's *t*-test or analysis of variance (ANOVA) as appropriate. Changes pre and post treatment were evaluated with paired Student's *t* test or repeated measures ANOVA as appropriate. Bonferroni post hoc test was used for multiple comparisons.

The independent association of variables with baseline screening pass or failure was also assessed by multivariate logistic regression, in which variables with univariate P value $\leq$0.1 were included.

Descriptive statistics are presented as means ± SD, and categorical variables are reported as percentages.

A P value <.05 was considered significant for all tests. All statistical analyses were performed using IBM SPSS Statistics 23 software for Windows.

3. Results

3.1. General findings

A total of 75 consecutive patients were enrolled between July and October 2019. 44 presented with an ACS, of whom 21 were diagnosed with STEMI and 23 with NSTE-ACS; 31 patients were admitted for a CCS. Table 1 reports general and demographic data in STEMI, NSTE-ACS and CCS patients; there were no significant differences between clinical, electrocardiographic and echocardiographic parameters, apart from significantly higher troponin I peak levels in STEMI patients compared with the NSTE-ACS group that reflect infarct size. All the patients were treated with percutaneous coronary intervention. Mean time from admission to revascularization was 65 min for STEMI patients, 236 min for NSTE-ACS and 380 min for CCS.

3.2. S-ICD specific screening variables and vectors

Table 2 summarizes S-ICD screening variables. At baseline, rates of screening pass were significantly lower in STEMI patients compared to NSTE-ACS and CCS subjects (5% vs 57% vs 81% respectively, p < .0001). In these subgroups, the viability of the primary vector was lower in STEMI patients compared to NSTEMI and CCS (33% vs 56% vs 71%, p .027 respectively). Moreover, the absolute number of viable vectors, in both positions, was lower in the STEMI group compared to the other two groups. After coronary revascularization, there were no significant differences between groups in screening pass percentage, vector viability and number of viable vectors (Fig. 2)

When conducting the analysis on paired subjects at baseline and after revascularization, we found that in STEMI subjects the percentages of screening success were respectively 5% and 81% (p < .001), the rates of primary vector viability were 33% and 81% (p .002) and the rates of secondary vector viability were 38% and 67% (p .07). No differences were noted in the same variables in the NSTE-ACS and CCS groups at baseline and after revascularization (Fig. 2).

STEMI as clinical presentation was the only independent predictor of screening failure at multivariate logistic regression analysis (odds ratio 10.68 confidence interval 2.77–41.38, p = .001) (Tables 3 and 4).

4. Discussion

Data from a recent RCT showed that the S-ICD was non inferior to the TV-ICD with respect to the cumulative incidence of device-related complications. However, patients with a S-ICD had a higher

Table 2
S-ICD screening and vector variables.

	STEMI (21)	NSTEMI (23)	CCS (31)	P
Screening pass baseline n (%)	1 (4.8%)	13 (56.5%)	25 (80.6%)	**<.0001**
Screening pass after revascularization n (%)	17 (81.0%)	19 (82.6%)	30 (96.8%)	ns
Primary vector baseline n (%)	7 (33.3%)	13 (56.5%)	22 (71.0%)	**.027**
Primary vector viability after revascularization n (%)	17 (81.0%)	18 (78.3%)	25 (80.6%)	ns
Secondary vector viability baseline n (%)	8 (38.1%)	14 (60.9%)	19 (61.3%)	ns
Secondary vector viability after revascularization n (%)	14 (66.7%)	18 (78.3%)	25 (80.6%)	ns
Viable vectors supine baseline n (%)				**.004**
0	11 (52.5%)	6 (26.1%)	1 (3.2%)	
1	2 (9.5%)	1 (4.3%)	7 (22.6%)	
2	4 (19.0%)	10 (43.5%)	14 (45.2%)	
3	4 (19.0%)	6 (26.1%)	9 (29.0%)	
Viable vectors supine after revascularization n (%)				ns
0	3 (14.2%)	2 (8.7%)	0 (0.0%)	
1	0 (0.0%)	3 (13.0%)	3 (9.7%)	
2	9 (42.9%)	8 (34.8%)	11 (35.5%)	
3	9 (42.9%)	10 (43.5%)	17 (54.8%)	
Viable vectors sitting baseline n (%)				**<.0001**
0	20 (95.2%)	9 (39.2%)	6 (19.4%)	
1	0 (0.0%)	1 (4.3%)	3 (9.6%)	
2	0 (0.0%)	8 (34.8%)	15 (48.4%)	
3	1 (4.8%)	5 (21.7%)	7 (22.6%)	
Viable vectors sitting after revascularization n (%)				ns
0	3 (14.3%)	4 (17.4%)	1 (3.2%)	
1	2 (9.5%)	4 (17.4%)	4 (12.9%)	
2	8 (38.1%)	8 (34.8%)	15 (48.4%)	
3	8 (38.1%)	7 (30.4%)	11 (35.5%)	

Abbreviations: STEMI: ST elevation myocardial infarction; NSTEMI: non-ST elevation myocardial infarction; CCS: chronic coronary syndromes.

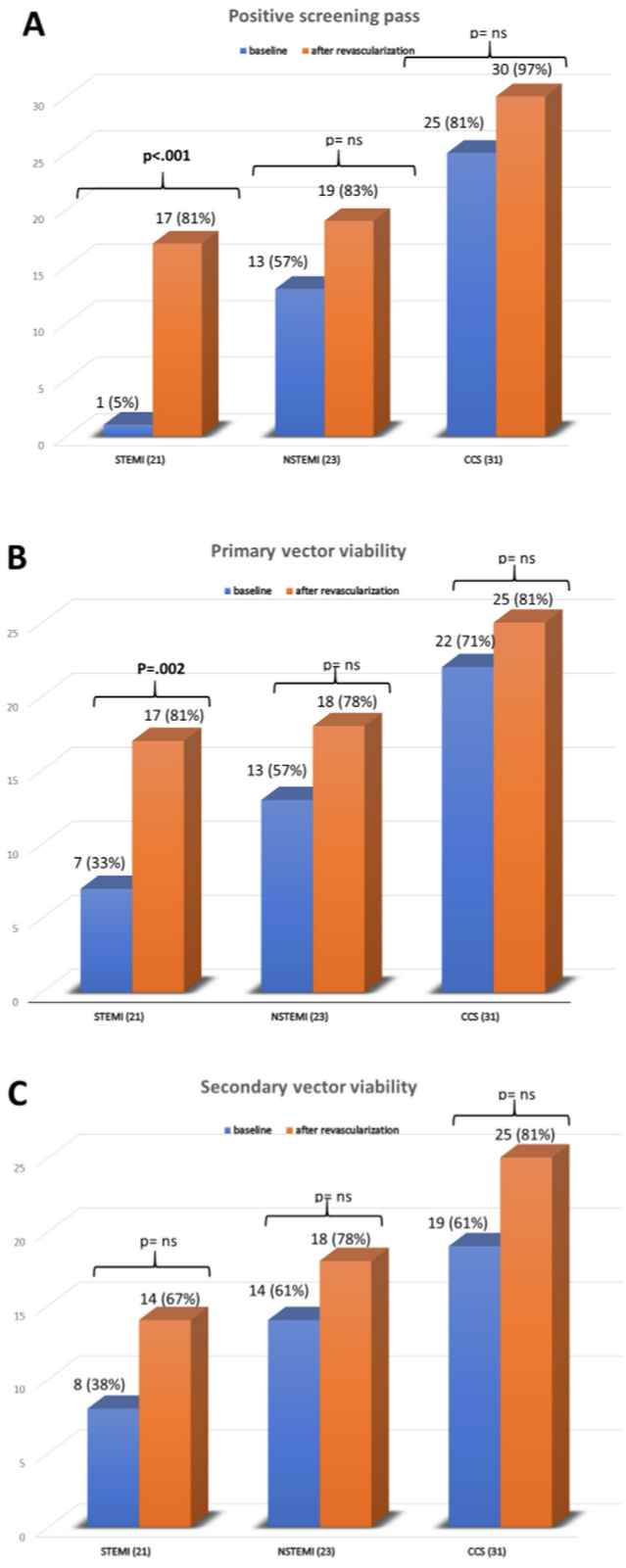

Fig. 2. Paired subjects at baseline and after revascularization.

Table 3
Variables associated with screening failure at univariate regression logistic analysis.

	OR	95% CI	P
Gender	0.58	0.56–1.80	ns
Diabetes mellitus	0.37	0.14–1.01	ns
Arterial Hypertension	0.10	0.03–0.40	**.001**
CVD Family History	0.60	0.24–1.50	ns
COPD	0.55	0.15–2.08	ns
Sinus Rhythm	0.92	0.14–7.94	ns
Atrial fibrillation	0.25	0.03–2.35	ns
RBBB	2.40	0.55–10.42	ns
LVEF < 50%	3.73	1.38–10.04	**.009**
ACS	8.00	2.69–23.75	**<.0001**
STEMI	47.50	5.87–384.64	**<.0001**
NSTEMI	0.77	0.29–2.07	ns
Anterior ST elevation	2.90	0.16–12.54	ns
Inferior ST elevation	12.67	1.51–105.96	**.002**
Lateral ST elevation	3.17	0.24–14.57	ns

Abbreviations: OR: odds ratio; CI: confidence interval; CVD: cardiovascular disease; COPD chronic obstructive pulmonary disease; RBBB: right bundle branch block; LVEF: left ventricular ejection fraction; ACS: acute coronary syndromes; STEMI: ST elevation myocardial infarction; NSTEMI: non-ST elevation myocardial infarction.

Table 4
Association of variables with screening failure in multivariable logistic regression analysis.

	OR	95% CI	p
LVEF < 50%	1.21	0.43–3.43	ns
STEMI	10.68	2.77–41.38	**.001**

Abbreviations: OR: odds ratio; CI: confidence interval; LVEF: left ventricular ejection fraction; ACS: acute coronary syndromes; STEMI: ST elevation myocardial infarction.

cumulative incidence of inappropriate shocks, although the trial was not powered for this comparison [6].

Given the lack of long-term evidence, several questions remain unanswered with particular regard to the S-ICD safety and efficacy. The present study is the first to evaluate the performance of the S-ICD sensing algorithm and the changes of the vectors in an acute and a stable ischemic setting.

To the best of our knowledge, this is the first demonstration of S-ICD screening failure in patients with ACS before coronary revascularization. Moreover, at baseline, ACS patients presented with less viable vectors compared to CCS patients. These results could be directly related to the S-ICD sensing algorithm, based on vectors' morphology and QRS/T waves ratio. As reported in literature [10], these ECG parameters are typically altered in subjects with ST elevation/depression and hyperacute/inverted T waves. This is especially evident in patients presenting with ST segment elevation on ECG and consequently the diagnosis of STEMI was the only independent predictor of screening failure at multivariate logistic regression analysis in our study. Interestingly, inferior STEMI was a predictor of screening failure at univariate analysis; this result may be related to the position of the three screening vectors that approximately reflect leads I, II and aVF of the surface ECG, whereas other infarcted areas such as the anterior and lateral walls usually produce more pronounced changes in precordial leads. Similarly to STEMI, patients with Brugada syndrome present a higher rate of screening failure as compared with other cardiac channelopaties [11].

ST modifications in different ischemic settings may be transient and usually occur over a timespan of roughly two weeks: in our study, after revascularization and consequent ECG normalization, ACS patients had significantly higher screening pass rates (increasing from 33% to 82%) and there were no more relevant differences when comparing them to CCS patients.

Therefore, our study raises the important issue whether the S-ICD is going to properly sense and treat ventricular arrhythmias in a high-risk ischemic scenario, when they are most likely to occur. The two most feared complications could be QRS undersensing, resulting in VT/VF undertreatment, or TWOS leading to inappropriate shocks.

According to data from S-ICD registry [12,13], indication for S-ICD is mainly due to common cardiomyopathies such as ischemic ones, compared to earlier S-ICD recipients who were younger and with channelopathies [14,15]. Particularly, in very recent registries, approximately one third of subjects presented with diagnosis of ischemic cardiomyopathy. The setting is changing and other issues may deserve attention, such as acute ischemic events and the chance of malfunction during such episodes.

Ventricular tachycardia/fibrillation conversion rate is 90% at first shock and 98–100% within 5 shocks. Inappropriate shock rates range from 13% to 21% among literature, TWOS being the main underlying cause. However, the timing of TWOS (exercise, acute ischemic event or other), was not reported in the main studies [12–14]. Dynamism of TWOS has not been explored till now, and may represent a weakness of the present sensing algorithm in acute changes of the ST/T segment.

The performance of the S-ICD and possible malfunction detections in the context of an acute ischemic event warrant further evaluation. In the meantime, based on the results of our study, it seems reasonable that patients carriers of an S-ICD and presenting with an ACS should be carefully monitored in the acute setting, may have their device checked during the event and after treatment, with sensing vector optimization if necessary.

In the next future, vector sensing refinement will be essential to broaden S-ICD eligibility. One limit is the variability in real life, according to different settings, timing and disease. As recently described, one improvement could come from the reconstruction of the QRS-T wave morphology of an 8 lead ECG based on the 3 vectors, to obtain a personalized ECG for every patient [16,17]. On top of that, however, it is necessary that vector sensing of the S-ICD evolve into a dynamic rather than static process, able to adjust according to the multiple possible changes of the QRS-T wave complex of patients, in different settings of the cardiomyopathy.

4.1. Limitations

The main limitation of our study is the relatively small sample size. Moreover, because none of our patients was actually implanted with a S-ICD, we can only make assumptions on the possible behavior of the device during an ACS based on screening data. In fact, we acknowledge that sensing failure would be a rather more critical issue in clinical setting than screening failure, but given the setting of the study and the impossibility to detect sensing failure in patients without a device, we used it as a possible surrogate for undersensing and/or TWOS.

A recent paper by Bogeholz and colleagues demonstrated that the AST did not predict the finally selected sensing vector better than the manual screening tool (MST) [18]; therefore another limitation worth mentioning of our study is that the screening was only performed automatically and we cannot provide any correlation between the AST and the MST.

We also have to recognize that ECG alterations in STEMI patients usually evolve over a timespan of roughly two weeks but our patients had a relatively short length of stay (4.3 days was median time before pre-hospital discharge screening); hence it is possible that the best moment to screen these ischemic subjects may be after complete ECG evolution an stabilization.

5. Conclusion

In conclusion, the S-ICD appears as a promising alternative to the TV-ICD, overcoming complications related to the endovascular lead. Nevertheless, the superficial nature of the sensed signal still represents the ‘‘Achille’s heel” of the device. While new algorithms are continuously studied and released, adequate patient’s selection and dynamic device programming play a paramount role to avoid complications, especially in high risk vulnerable patients.

Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.

Acknowledgements

None.

Funding

None.

References

[1] M. Mirowski, P.R. Reid, M.M. Mower, L. Watkins, V.L. Gott, J.F. Schauble, et al., Termination of malignant ventricular arrhythmias with an implanted automatic defibrillator in human beings, N. Engl. J. Med. (1980), https://doi.org/10.1056/NEJM198008073030607.

[2] W.H. Maisel, M. Moynahan, B.D. Zuckerman, T.P. Gross, O.H. Tovar, D.B. Tillman, et al., Pacemaker and ICD generator malfunctions: Analysis of food and drug administration annual reports, J. Am. Med. Assoc. (2006), https://doi.org/10.1001/jama.295.16.1901.

[3] S.G. Priori, C. Blomstrom-Lundqvist, A. Mazzanti, N. Bloma, M. Borggrefe, J. Camm, et al., ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death the Task Force for the Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the Europea, Eur. Heart J. 2015 (2015), https://doi.org/10.1093/eurheartj/ehv316.

[4] S.M. Al-Khatib, W.G. Stevenson, M.J. Ackerman, W.J. Bryant, D.J. Callans, A.B. Curtis, et al., AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death, Circulation 2018 (2017), https://doi.org/10.1161/CIR.0000000000000549.

[5] G.F. Lewis, M.R. Gold, Safety and efficacy of the subcutaneous implantable defibrillator, J. Am. Coll. Cardiol. (2016), https://doi.org/10.1016/j.jacc.2015.11.026.

[6] R.E. Knops, L.R.A. Olde Nordkamp, P.P.H.M. Delnoy, L.V.A. Boersma, J. Kuschyk, M.F. El-Chami, et al., Subcutaneous or transvenous defibrillator therapy, N. Engl. J. Med. (2020), https://doi.org/10.1056/NEJMoa1915932.

[7] L.R.A. Olde Nordkamp, T.F. Brouwer, C. Barr, D.A.M.J. Theuns, L.V.A. Boersma, J. B. Johansen, et al., Inappropriate shocks in the subcutaneous ICD: Incidence, predictors and management, Int. J. Cardiol. (2015), https://doi.org/10.1016/j.ijcard.2015.05.135.

[8] E.P. Zeitler, D.J. Friedman, Z. Loring, K.B. Campbell, S.A. Goldstein, Z.K. Wegermann, et al., Complications involving the subcutaneous implantable cardioverter-defibrillator: Lessons learned from MAUDE, Hear Rhythm (2019), https://doi.org/10.1016/j.hrthm.2019.09.024.

[9] P. Francia, M. Ziacchi, P. De Filippo, S. Viani, A. D'Onofrio, V. Russo, et al., Subcutaneous implantable cardioverter defibrillator eligibility according to a novel automated screening tool and agreement with the standard manual electrocardiographic morphology tool, J. Interv. Card. Electrophysiol. (2018), https://doi.org/10.1007/s10840-018-0326-2.

[10] G.S. Wagner, P. Macfarlane, H. Wellens, M. Josephson, A. Gorgels, D.M. Mirvis, et al., AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram. Part VI: Acute Ischemia/Infarction A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation, J. Am. Coll. Cardiol. (2009), https://doi.org/10.1016/j.jacc.2008.12.016.

[11] G. Conte, M. Kawabata, C. De Asmundis, E. Taravelli, F. Petracca, D. Ruggiero, et al., High rate of subcutaneous implantable cardioverter-defibrillator sensing

screening failure in patients with Brugada syndrome: A comparison with other inherited primary arrhythmia syndromes, Europace (2018), https://doi.org/10.1093/europace/eux009.

[12] L. Boersma, C. Barr, R. Knops, D. Theuns, L. Eckardt, P. Neuzil, et al., Implant and Midterm Outcomes of the Subcutaneous Implantable Cardioverter-Defibrillator Registry: The EFFORTLESS Study, J. Am. Coll. Cardiol. (2017), https://doi.org/10.1016/j.jacc.2017.06.040.

[13] A.F.B.E. Quast, V.F. van Dijk, S.C. Yap, A.H. Maass, L.V.A. Boersma, D.A. Theuns, et al., Six-year follow-up of the initial Dutch subcutaneous implantable cardioverter-defibrillator cohort: Long-term complications, replacements, and battery longevity, J. Cardiovasc. Electrophysiol. (2018), https://doi.org/10.1111/jce.13498.

[14] R. Weiss, B.P. Knight, M.R. Gold, A.R. Leon, J.M. Herre, M. Hood, et al., Safety and efficacy of a totally subcutaneous implantable-cardioverter defibrillator, Circulation (2013), https://doi.org/10.1161/CIRCULATIONAHA.113.003042.

[15] J.W.E. Jarman, D.M. Todd, United Kingdom national experience of entirely subcutaneous implantable cardioverter-defibrillator technology: Important lessons to learn, Europace (2013), https://doi.org/10.1093/europace/eut016.

[16] D.G. Wilson, P.L. Cronbach, D. Panfilo, S.E. Greenhut, B.P. Stegemann, J.M. Morgan, Reconstruction of an 8-lead surface ECG from two subcutaneous ICD vectors, Int. J. Cardiol. (2017), https://doi.org/10.1016/j.ijcard.2017.01.117.

[17] P.D. Lambiase, Editorial: Automating subcutaneous ICD screening and future sensing refinements, Int. J. Cardiol. (2018), https://doi.org/10.1016/j.ijcard.2018.07.144.

[18] N. Bögeholz, P. Pauls, F. Güner, N. Bode, A. Fischer, D. Dechering, et al., Direct comparison of the novel automated screening tool (AST) versus the manual screening tool (MST) in patients with already implanted subcutaneous ICD, Int. J. Cardiol. (2018), https://doi.org/10.1016/j.ijcard.2018.02.030.