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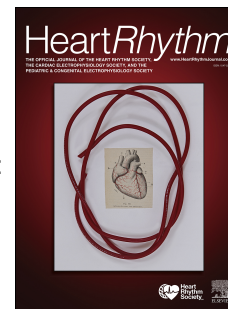
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Personalized Screening Before Subcutaneous Cardioverter Defibrillator Implantation: Usefulness and Outcomes in Clinical Practice – The S-ICD Screening SIS Prospective Study

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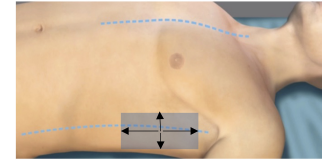
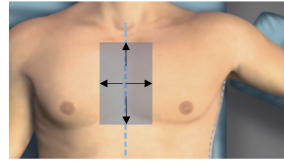
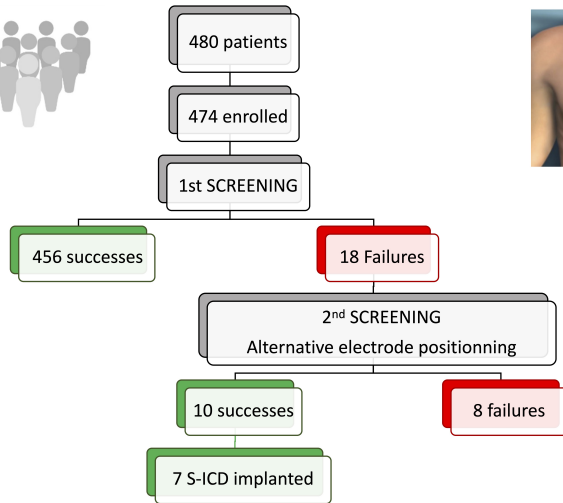
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**Personalized screening before subcutaneous cardioverter defibrillator implantation: usefulness and outcomes in clinical practice.**  
 – The SIS prospective study –



**CONCLUSION**

- Initial screening success : 96 %
- After alternative screening : 98 %
- No initial concerns regarding sensing / detection
- *BUT* at one year 3/7 patients with inappropriate shocks

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1 *Original Clinical*

2  
3 **Personalized Screening Before Subcutaneous Cardioverter**  
4 **Defibrillator Implantation: Usefulness and Outcomes in Clinical**  
5 **Practice – The S-ICD Screening SIS Prospective Study**

6  
7 Running title: Personalized Screening Before S-ICD Implantation

8  
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47 **Conflict of Interest:** R Garcia received research grants from Boston Scientific.

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49  
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1 **ABSTRACT (WC=244)**

2 **Background** – Electrocardiographic (ECG) screening prior to S-ICD implantation is  
3 unsuccessful in around 10% of cases. A personalized screening method, by slightly moving  
4 the electrodes, to obtain a better R/T ratio has been described to overcome traditional  
5 screening failure.

6 **Objective** – To assess to what extent a personalized screening method improves eligibility for  
7 S-ICD implantation and evaluate the inappropriate shock rate after such screening success.

8 **Methods** – All consecutive patients eligible for an S-ICD implantation were prospectively  
9 recruited across 20 French centers between December 2019 to January 2022 (NCT04101253).  
10 In case of traditional screening failure, patients received a second personalized screening. If at  
11 least one vector was positive, the personalized screening was considered as successful, and  
12 the patient was eligible for implantation.

13 **Results** – 474 patients were included in the study (mean age  $50.4 \pm 14.1$  years; 77.4% men).  
14 Traditional screening was successful in 456 (96.2%) cases. This figure rose to 98.3% (n=466;  
15  $P=.002$ ) when personalized screening was performed. All patients implanted after successful  
16 personalized screening had correct signal detection on initial device interrogation.  
17 Nevertheless, after one year follow-up, 3 (43%) of the 7 patients implanted with personalized  
18 experienced inappropriate shock (vs 18 (4.2%) out of the 427 patients with traditional  
19 screening and S-ICD implantation  $P=.003$ ).

20 **Conclusion** – Traditional S-ICD screening was successful in our study in a very high  
21 proportion of patients. Considering the small improvement in success of screening and a  
22 higher rate of inappropriate shock, a strategy of personalized screening cannot be routinely  
23 recommended.

24 **Keywords** – Subcutaneous Implantable Cardioverter Defibrillator; Screening; Inappropriate  
25 shock; Sudden Cardiac Death; Complication.

1 **ABBREVIATIONS**

- |   |        |   |
|---|--------|---|
| 2 | ATP    | Anti-Tachycardia Pacing                             |
| 3 | ECG    | Electrocardiogram                                   |
| 4 | OR     | Odds Ratio  |
| 5 | S-ICD  | Subcutaneous Implantable Cardioverter Defibrillator |
| 6 | TV-ICD | Transvenous Implantable Cardioverter Defibrillator  |

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## 1 INTRODUCTION

2 The subcutaneous implantable defibrillator (S-ICD) has become a common alternative to the  
3 transvenous defibrillator (TV-ICD) in recent years. Initially, this approach was proposed  
4 mainly for younger patients with hereditary channelopathies, or when it was impossible to  
5 implant a transvenous defibrillator. However, the indications have gradually been extended to  
6 all patients who benefit from TV-ICD implantation and without anticipated need for either  
7 bradycardia or anti-tachycardia pacing (ATP).

8 Screening is mandatory before implantation in order to assess the adequacy of specific  
9 electrocardiographic vectors used by the S-ICD to analyze cardiac signals and thereby  
10 determine suitability for S-ICD implantation. In clinical practice, approximately 10% of  
11 patients are excluded for S-ICD device implantation due to failed screening<sup>1-4</sup>. The causes are  
12 mainly related to R wave amplitude (low or high) and low R/T wave ratio. Determinants for  
13 screening failure have not yet been clearly identified. Also, electrocardiogram (ECG)  
14 electrode position affects R and T wave amplitude.<sup>5</sup>

15 It has been shown that S-ICD implantation can still be successfully performed in some  
16 cases where initial screening failed.<sup>7</sup> This observation suggests an imperfect concordance  
17 between signals obtained with transcutaneous versus subcutaneous electrodes, or between the  
18 position of ECG electrodes during screening and the final position of the subcutaneous  
19 generator and lead electrodes.

20 It is common in clinical practice for physicians to slightly move the ECG electrode  
21 positions, to obtain a better R/T ratio allowing to change a failed screening to a success and  
22 increasing the number of patients eligible for S-ICD; however, this approach has never been  
23 scientifically studied.

24 The objectives of the SIS study were to assess to what extent such a personalized  
25 screening, by slightly varying electrode positions, could improve screening rates, to look for



1 factors predictive of initial screening failure and to assess the rate of inappropriate shocks  
2 during the first year after S-ICD implantation.

3

4

## 5 **METHODS**

### 6 *Study Design*

7 This prospective observational multicenter study was carried out in 20 secondary and tertiary  
8 French Cardiology centers routinely performing TV-ICD and S-ICD implantations.

9       Between December 2019 and January 2022, all adult patients eligible for implantation  
10 of an S-ICD for primary or secondary prevention were prospectively and consecutively  
11 included in the study, regardless of the underlying indication. All patients had a class I or IIa  
12 indication for ICD therapy. The exclusion criteria were contraindications to S-ICD  
13 implantation, such as the need for pacing or resynchronization therapy and refusal of consent.

14       The study protocol was approved by the French Ethics Committee (Comité de  
15 Protection des Personnes Sud Est VI, reference CPP: AU 1570, reference ID-RCB : 2019-  
16 A01900-57) in December 2019. The study was conducted in accordance with the Helsinki  
17 Declaration as revised in 2013, the Good Clinical Practice (GCP) guidelines of the  
18 International Conference on Harmonisation (ICH–E6, 17/07/96) and local regulatory  
19 requirements (NCT04101253). The patients provided their written informed consent to  
20 participate in this study.

21

### 22 *Screening Protocol*

23 Routine traditional screening was conducted by a Boston Scientific technical representative  
24 under supervision of the implanting physician or by the physician himself, using the  
25 Automated Screening Tool of the Boston Scientific Zoom 3120 programming system.

1 Electrodes were positioned as recommended in the mid axillary line and left parasternal. In  
2 case of screening failure, right parasternal position was tested. Successful screening was  
3 defined as having at least one lead fitting within the screening template in both supine and  
4 sitting positions.

5         If all three vectors failed, a personalized screening was performed, involving the  
6 placement of the electrodes in slightly different positions, at the discretion of the implanting  
7 physician, taking into account the patient's anatomy and the possibilities for implant  
8 positioning. The parasternal electrodes could move in right/left and cranio/caudal directions,  
9 while the axillary electrode could also move in a cranio/caudal or posterior direction (**Figure**  
10 **1**). Electrode displacement was up to 2 cm in the different directions, depending on thoracic  
11 anatomy and implantation requirements. As above, successful screening for the personalized  
12 approach was defined as the presence of at least one lead fitting the screening template in both  
13 the supine and standing positions.

14         The type of device (S-ICD or TV-ICD) finally implanted after the personalized  
15 screening protocol was left to the physician's discretion and the patient's preference after  
16 discussion of the advantages and disadvantages of each device in the specific context. If  
17 personalized screening also failed, the patient was considered ineligible for S-ICD. When S-  
18 ICD implantation was chosen, generator and lead placement were guided by the electrode  
19 positioning in the successful screening procedure. Every S-ICD implantation was performed  
20 after marking the best positioning of the system on the patient's skin. S-ICD programming for  
21 primary prevention was mostly (94.7%) dual zone and consisted in setting a conditional zone  
22 programmed at 220 beats per minutes and a shock zone at 250 beats per minute. For  
23 secondary prevention, programming was at the discretion of the cardiologist and adapted to  
24 rate of the ventricular arrhythmia leading to S-ICD implantation.

25

## 1 ***Study Endpoint***

2 The primary endpoint was the percentage of patients who had a positive personalized  
3 screening after usual screening failure.

4 The following data were collected: demographic variables, height, weight,  
5 electrocardiographic and echocardiographic parameters, underlying etiology, vectors  
6 validated in the first and second screening protocols, electrode location and procedural data.

7 A one-year clinical follow-up was performed.

8

## 9 ***Statistical Analysis***

10 Categorical variables are expressed as percentages (%) and 95% CI (exact method).

11 Quantitative variables are expressed as the median and interquartile range (IQR).

12 Comparisons were performed using the  $\chi^2$  test or Fischer's exact test, as appropriate, and the

13 McNemar test was used for paired data. Logistic regression was performed to obtain

14 independent predictors of traditional S-ICD screening failure. The search for a statistical link

15 between vectors validated during screening and occurrence of inappropriate shocks was

16 performed with the U test of Mann-Whitney-Wilcoxon. The relationship between screening

17 technique and occurrence of inappropriate shocks was performed with the Fischer's exact test.

18 For all comparisons, p value  $<0.05$  was considered significant. All statistical analyses were

19 conducted using SAS software version 9.4 (SAS Institute, Cary, NC, USA).

20

21

## 22 **RESULTS**

### 23 ***Study Population***

1 Among 480 potentially eligible patients, 474 (98.8%) were finally included in the analysis  
2 (**Figure 2**; mean age  $50.4 \pm 14.1$  years, 77.4% men, 44.9% ischemic cardiomyopathy and  
3 70.3% primary prevention indication). Demographic data are detailed in **Table 1**.

4 Initial traditional screening was successful in 96.2% [94.1%; 97.7%]. Of the 18  
5 patients who failed the traditional screening protocol, 10 (55.6%) had a successful  
6 personalized screening protocol after electrode repositioning. Individuals from the traditional  
7 screening success group were taller than those who failed traditional screening and tended to  
8 have shorter QRS duration and ischemic cardiomyopathy less frequently (**Table 1**). Overall  
9 screening success after the personalized protocol was 98.3 % [96.7%; 99.3%], which was  
10 significantly higher than that obtained with traditional screening alone ( $P=.002$ ). (**Figure 2**)

11 In the traditional screening, primary, secondary and supplementary vectors were  
12 validated in respectively, 90.1%, 85.7% and 52.4%. A total of 35 (7.7 %) had one validated  
13 vector, while 257 (56.3%) had 2 acceptable vectors and 164 (36.0%) 3 vectors.

14 Parameters predictive of traditional screening failure were ischemic cardiomyopathy  
15 ( $OR=3.8$ , 95% CI [1.01-14.4],  $P=.05$ ), height ( $OR=0.91$ , 95% CI [0.85-0.97],  $P=.01$ ) and  
16 QRS duration ( $OR=1.03$ , 95% CI [1.00-1.05],  $P=.03$ ). Conversely, age, sex, weight, body  
17 mass index, left ventricular ejection fraction, heart rate, PR interval and type of prevention  
18 (primary vs. secondary) were not associated with traditional screening failure (**Table 2**).  
19 Of the 10 patients who underwent successful personalized screening, the primary vector was  
20 validated in 5 (50%), the secondary vector in 5 (50%) and the supplementary vector in 4  
21 (40%). In 7 (70%) patients, a single vector was validated, while 2 vectors were validated in 2  
22 (20%) patients and 3 vectors were accepted in one (10%) patient.

23

24 ***Follow-up and Outcomes***

1           Among the 456 patients with traditional screening success, 444 (97.4%) had a S-ICD  
2 implanted, 9 had a transvenous ICD implantation (pacing required n=3; patient's choice n=6),  
3 and 3 did not undergo implantation due to left ventricular ejection fraction recovery. Seven  
4 (70.0%) out of the 10 patients who had successful personalized screening underwent S-ICD  
5 implantation; 2 had TV-ICD and 1 did not have ICD implantation after a discussion between  
6 physician and patient. The 7 patients who underwent S-ICD implantation after successful  
7 personalized screening had an initial and 2-month S-ICD interrogation that revealed normal  
8 functioning with a correct signal detection.

9           After one year follow-up, 3 (43%) out of the 7 patients experienced inappropriate  
10 shock (vs 18 (4.2%) out of the 427 patients with traditional screening and S-ICD implantation  
11  $P=.003$ ). As compared to patients without inappropriate shock, those in the inappropriate  
12 shock group were older (56 [55-62] vs. 46.5 [26.5-66.5]), males were more represented  
13 (100% vs 50%) and left ventricular ejection fraction was lower (22.5 [20-25] vs. 50 [34-70]).  
14 Each patient received 2 inappropriate shocks (6 shocks in total). In 2 patients, the  
15 inappropriate shocks were due to myopotential oversensing and T wave oversensing  
16 respectively on the primary detection vector. The problem was resolved after changing  
17 detection to secondary vector and no further inappropriate shocks occurred in these two  
18 patients after reprogramming during 1 year of follow up. In the last patient, inappropriate  
19 shocks occurred while detection was programmed on the supplementary vector. This patient  
20 had an initial repositioning of the parasternal electrodes 1 centimeter towards the left side.  
21 Due to poor detection on all 3 vectors in this patient, it was decided to explant the S-ICD.  
22 Atrial fibrillation was not responsible for inappropriate shock in the personalized screening  
23 group.

24           In the study population as a whole, the rates of appropriate and inappropriate shocks  
25 were 4.4% and 4.8% respectively at one year. There was no association between the number

1 of vectors validated during screening and the occurrence of inappropriate shocks during  
2 follow-up (P=.95). Finally, no lead malfunction responsible for inappropriate shock was  
3 observed during follow up.

4

## 5 **DISCUSSION**

6 The main conclusion of this prospective multicenter study is that traditional screening was  
7 successful in 96% of the cases, demonstrating that the S-ICD is suitable for the vast majority  
8 of patients requiring an ICD. In case of initial screening failure, personalized screening with  
9 electrode repositioning allowed a significant but small increase in the success rate of  
10 screening. However, implantation of an S-ICD after personalized screening resulted in a 10-  
11 fold higher rate of inappropriate shock as compared to implantation after traditional method.

12 To the best of our knowledge, this is the largest real-life prospective study specifically  
13 analyzing S-ICD screening. Our results showed a much higher success rate than previously  
14 reported. The failure rate of S-ICD screening varies depending on the underlying etiology.  
15 Previous studies have reported that approximately 85% of patients with a primary or  
16 secondary prevention indication for an ICD have a surface ECG suitable for S-ICD  
17 implantation when assessed using an ECG template.<sup>8</sup> The rate is slightly lower in patients  
18 with congenital heart disease<sup>9</sup> and Brugada syndrome.<sup>10</sup> There is also some variability in  
19 screening success depending on the screening tool used (ECG template or automated  
20 screening tool).<sup>11,12</sup> Some have reported variability even when the same screening method  
21 was used, with a significant percentage of 'eligible' vectors becoming ineligible when patients  
22 are screened repeatedly.<sup>13</sup>

23 Thus, a non-negligible percentage of S-ICD candidates are unable to undergo S-ICD  
24 implantation either because of screening failure or because, the fear of a screening failure  
25 leads the clinician to go directly to TV-ICD implantation even before screening. However,

1 our study has shown that the vast majority of patients are suitable for an S-ICD by traditional  
2 screening.

3 We also have demonstrated in this study that using a personalized screening method  
4 with electrodes placed in a slightly different location according to patient anatomy, led to a  
5 modest but significant increase in screening success rate. However, a high rate of  
6 inappropriate shocks was noted in patients who were implanted after traditional screening  
7 failure, but personalized screening success. Usually, the location of the lead and generator is  
8 determined radiographically during implantation. Therefore, they can be placed in a different  
9 position to that tested with the personalized screening.

10 In patients with a positive traditional screening, a minor shift in the position of the  
11 lead or defibrillator will likely have no consequences on the quality of detection. On the other  
12 hand, if correct detection is only obtained in a very specific position, even a small  
13 displacement of the lead or defibrillator could lead to a deterioration in the quality of  
14 detection and therefore a greater risk of inappropriate shock. Therefore, physicians should  
15 carefully evaluate the risk-benefit in a case before applying a personalized screening method.

16 In cases with a clear contra-indication to TV-ICD and traditional S-ICD screening  
17 failure, personalized screening could be considered, combined with extra care during  
18 implantation to ensure that the generator and the lead are placed at the exact position where the  
19 screening has been done.

20 In previous studies, the presence of a bundle branch block, prolonged QRS duration  
21 and high-amplitude T waves predicted traditional S-ICD screening failure<sup>9-11</sup>. In our study, in  
22 addition to QRS duration, a history of ischemic cardiomyopathy and patient height and were  
23 predictors of traditional screening failure. These have not been described before but must be  
24 interpreted with caution given the low rate of screening failure in our study. It is possible that

1 ischemic cardiomyopathy might have been a marker for both QRS and repolarization  
2 modifications which then reduced the rate of screening success.

3         Our results must be interpreted in the context of the limitations of our study. This was  
4 a proof-of-concept study to assess the feasibility of a personalized screening method based on  
5 initial reports of screening failure rates. The low rate of traditional screening failure was  
6 probably due to a low rate of patients with hypertrophic cardiomyopathy, Brugada syndrome  
7 and Long QT syndrome.<sup>14,15</sup> In addition, the number of patients who were ultimately  
8 ineligible for S-ICD was small (n=18). Moreover, there was no control group for comparison  
9 in patients with conventional screening failure. Finally, a systematic or common protocol for  
10 electrode repositioning could not be implemented as cardiac anatomy and resulting electrical  
11 signal had large interindividual variations, necessitating a truly individualized or personalized  
12 approach. Further analysis will provide information on the screening and S-ICD vectors  
13 recorded before and after implantation, as well as an understanding of the variability in signal  
14 recording.

15

## 16 **CONCLUSIONS**

17 Traditional S-ICD screening was successful in our study in a very high proportion of patients.  
18 Considering the small improvement in success of screening and a higher rate of inappropriate  
19 shock, a strategy of personalized screening cannot be routinely recommended. If it is  
20 performed in an occasional case with a mandatory indication for S-ICD, greater diligence and  
21 closer follow-up will be necessary to avoid inappropriate shocks.

22

## 23 **DECLARATION OF GENERATIVE AI IN THE WRITING PROCESS**

24 During the preparation of this work the authors did not use AI.



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3

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1 **TABLE AND FIGURE LEGENDS**

2 **Table 1: Baseline Characteristics of Participants**

3 **Table 2: Logistic Regression assessing Parameters associated with Traditional Screening**

4 **Failure.**

5 **Figure 1: Illustration of Personalized Screening Method**

6 **Figure 2: Flow Chart**

7

8

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1 **REFERENCES**

- 2
- 3 1. Weiss R, Knight B, Gold M, et al. Safety and efficacy of a totally subcutaneous  
4 implantable-cardioverter defibrillator. *Circulation* 2013;128:944–953.
- 5
- 6 2. Lambiase PD, Barr C, Theuns D, et al. EFFORTLESS Investigators. Worldwide experience  
7 with a totally subcutaneous implantable defibrillator: early results from the EFFORTLESS S-  
8 ICD Registry. *Eur Heart J* 2014;35:1657–1665.
- 9
- 10 3. Burke MC, Gold M, Knight B, et al. Safety and efficacy of the totally subcutaneous  
11 implantable defibrillator: 2-year results from a pooled analysis of the IDE study and  
12 EFFORTLESS Registry. *J Am Coll Cardiol* 2015;65:1605–1615.
- 13
- 14 4. Groh CA, Sharma S, Pelchovitz D, et al. Use of an electrocardiographic screening tool to  
15 determine candidacy for a subcutaneous implantable cardioverter-defibrillator. *Heart Rhythm*.  
16 2014 Aug;11(8):1361-6
- 17
- 18 5. Kania M, Rix H, Ferencic M, et al. The effect of precordial lead displacement on ECG  
19 morphology *Med Biol Eng Comput*. 2014; 52(2): 109–119.
- 20
- 21 6. Thomas JA, Perez-Alday E, Hamilton C, Kabir M, Park E, Tereshchenko L. The utility of  
22 routine clinical 12-lead ECG in assessing eligibility for subcutaneous implantable cardioverter  
23 defibrillator. *Comput Biol Med*. 2018 Nov 1;102:242–250
- 24
- 25 7. Brouwer TF, Kooiman K, Nordkamp L, Halm V, Knops R. Algorithm-Based Screening  
26 May Improve Patient Selection for the Subcutaneous Implantable Defibrillator. *JACC Clin*  
27 *Electrophysiol*. 2016 Oct;2(5):605–614.
- 28
- 29 8. Randles D, Hawkins N, Shaw M, Patwala A, Pettit S, Wright D. How many patients fulfil  
30 the surface electrocardiogram criteria for subcutaneous implantable cardioverter-defibrillator  
31 implantation? *Europace*. 2014 Jul: 16(7):1015–1021.
- 32
- 33 9. Zormpas C, Silber-Peest, Eiringhaus J, et al. Eligibility for subcutaneous implantable  
34 cardioverter-defibrillator in adults with congenital heart disease *ESC Heart Fail*. 2021  
35 *Apr*;8(2):1502–1508.
- 36
- 37 10. Conte G, Kawabata M, Asmundis C, Taravelli. High rate of subcutaneous implantable  
38 cardioverter-defibrillator sensing screening failure in patients with Brugada syndrome: a  
39 comparison with other inherited primary arrhythmia syndromes. *Europace*. 2018 Jul  
40 1;20(7):1188–1193.
- 41
- 42 11. Francia P, Ziacchi M, Filippo P, et al. Subcutaneous implantable cardioverter defibrillator  
43 eligibility according to a novel automated screening tool and agreement with the standard  
44 manual electrocardiographic morphology tool *J Interv Card Electrophysiol*. 2018  
45 *Jun*;52(1):61–67
- 46
- 47 12. Chang SC, Patton K, Robinson M, Poole J, Prutkin J. Subcutaneous ICD screening with  
48 the Boston Scientific ZOOM programmer versus a 12-lead ECG machine. *Pacing Clin*  
49 *Electrophysiol*. 2018 May;41(5):511–516.
- 50

- 1 13. Wiles BM, Morgan J, Allavatam V, ElRefai M, Roberts P. S-ICD screening revisited: do  
2 passing vectors sometimes fail? *Pacing Clin Electrophysiol.* 2022 Feb;45(2):182–187.  
3
- 4 14. Bögeholz N, Pauls P, Güner F, et al. Direct comparison of the novel automated screening  
5 tool (AST) versus the manual screening tool (MST) in patients with already implanted  
6 subcutaneous ICD. *Int J Cardiol.* 2018;265:90-96.  
7
- 8 15. Sakhi R, Yap SC, Michels M, et al. Evaluation of a novel automatic screening tool for  
9 determining eligibility for a subcutaneous implantable cardioverter-defibrillator. *Int J Cardiol.*  
10 2018;272:97-101.  
11

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**Table 1: Baseline Characteristics of participants**

	All participants	Traditional screening success (n=456)	Traditional screening failure (n=18)	P-value
Age (years)	52 [39-62]	51.5 [39-62]	55 [52-64]	0.13
Male sex :	367 (77.4%)	354 (77.6%)	13 (72.2%)	0.57
Weight (kg)	78[68-89]	78[68-89]	80[67-88]	0.93
Height (cm)	174[168-180]	174[169-180]	169.5[164-174]	0.02
Left ventricular ejection fraction (%)	33[27-53]	33[27-53]	35[31.5-52.5]	0.30
Heart rate (beats/min)	66[59-77]	66[58-77]	71.5[60-77]	0.32
PR interval (ms)	164[149-186]	165[150-186]	161[138-182]	0.40
QRS duration (ms)	101.5[90-116]	101[90-115]	113[95-129]	0.12
Indication of implantation				
Primary prevention	333 (70.3%)	319 (70.0%)	14 (77.8%)	0.60
Secondary prevention	141 (29.7%)	137 (30.0%)	4 (22.2%)	
Underlying cardiac disease				
Ischaemic cardiomyopathy	213 (44.9%)	200 (43.9%)	13 (72.2%)	-
Dilated cardiomyopathy	92 (19.4%)	92 (20.2%)	0	
Hypertrophic cardiomyopathy	49 (10.4%)	48 (10.5%)	1 (5.6%)	
Brugada syndrome	32 (6.8%)	32 (7.0%)	0	
Long QT Syndrome	2 (0.4%)	2 (0.4%)	0	
Catecholaminergic VT	1 (0.2%)	1 (0.2%)	0	
Idiopathic VF	39 (8.2%)	39 (8.6%)	0	
Congenital heart disease	6 (1.3%)	4 (0.9%)	2 (11.1%)	
ARVC	11 (2.3%)	10 (2.2%)	1 (5.6%)	
Valvular diseases	11 (2.3%)	11 (2.4%)	0	
Others	18 (3.8%)	17 (3.7%)	1 (5.6%)	
Abbreviations : ARVC, arrhythmogenic right ventricular cardiomyopathy; VF, ventricular fibrillation, VT, ventricular tachycardia Results are expressed as median [IQR=Q1-Q3] for quantitative variables and number, percentages (%).				

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1 **Table 2:** Logistic regression assessing parameters associated with traditional screening failure.  
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	Univariate logistic regression		Multivariate logistic regression	
	OR (95% CI)	P value	OR (95% CI)	P value
Age (per 1 year increase)	1.03 (0.99;1.06)	0.15	1.00 (0.96;1.05)	0.95
Sex - woman	1.34 (0.47;3.83)	0.59	—	—
Height	0.94 (0.89;0.99)	0.02	0.91 (0.85;0.97)	0.01
Weight	1.00 (0.97;1.03)	0.92	—	—
Body mass index	1.06 (0.98;1.15)	0.16	1.08 (0.99;1.18)	0.10
Left ventricular ejection fraction	1.01 (0.98;1.04)	0.61	—	—
Heart rate	1.01 (0.98;1.04)	0.64	—	—
PR interval	0.99 (0.98;1.01)	0.32	—	—
QRS duration	1.02 (1.00;1.04)	0.06	1.03 (1.00;1.05)	0.03
Secondary prevention	0.67 (0.22;2.06)	0.48	—	—
Ischaemic cardiomyopathy	3.33 (1.17;9.49)	0.02	3.82 (1.01;14.4)	0.05
<i>Non-significant results in univariate analysis (<math>p&gt;0.20</math>) were removed from the multivariate logistic regression. Abbreviations: CI, confidence interval; OR, odds ratio</i>				

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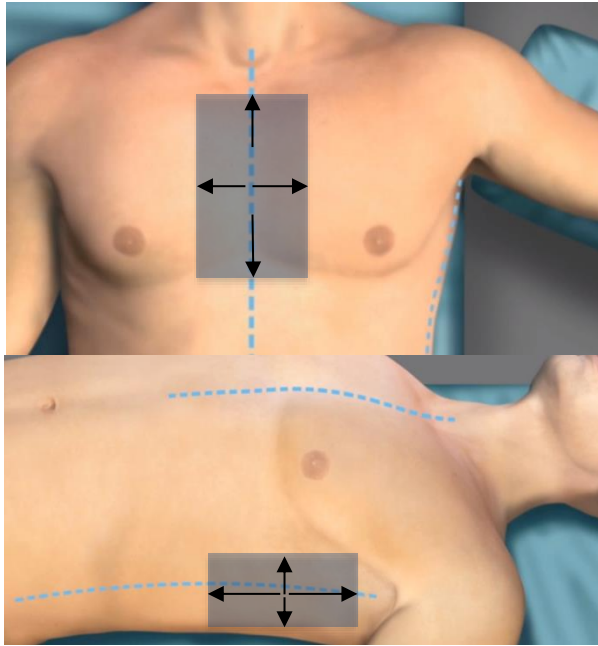
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1 **Figure 1: Illustration of personalized screening method**

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Figure 2: Flow chart

