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SMART pass will prevent inappropriate operation of S-ICD

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Abstract

Background: Compared to screening ECG before implantation of a subcutaneous implantable cardioverter-defibrillator (S-ICD), selectable vectors without T-wave oversensing increase after S-ICD implantation. Newer algorithms have recently become available to reduce T-wave oversensing, such as SMART pass (SP). With this function, more selectable vectors are identified after S-ICD implantation. However, this improvement in eligibility utilizing SP has not yet been well validated. We aimed to clarify S-ICD eligibility before and after S-ICD implantation with and without SP.

Methods: Participants comprised 34 patients implanted with an S-ICD at Okayama University Hospital and its affiliated hospitals between February 2016 and August 2017. A total of 102 S-ICD vectors were assessed for eligibility before and after S-ICD implantation, at rest and during exercise testing. Vector availability was evaluated in the presence and absence of SP after S-ICD implantation.

Results: Subcutaneous implantable cardioverter-defibrillator eligibility was significantly better after implantation even without SP than S-ICD screening before S-ICD implantation, both at rest (before 65.7% vs after 95.1%, $P < 0.01$) and during exercise (before 59.3% vs after 90.6%, $P < 0.01$). SP improved S-ICD eligibility during exercise (SP on 97.9% vs off 90.6%, $P = 0.03$). Multivariate analysis showed the prevalence of S-ICD eligibility increased significantly after S-ICD implantation compared to screening before implantation. SP further increased selectable vectors in multivariate analysis.

Conclusion: Available vectors increased significantly after S-ICD implantation compared to preoperative vectors as assessed by S-ICD screening ECG. T-wave oversensing during exercise has been an unresolved issue for S-ICD, but SP will help prevent inappropriate operation with S-ICD.

KEYWORDS

implantable cardioverter-defibrillator, inappropriate shock, SMART Pass, subcutaneous implantable cardioverter-defibrillator, T-wave oversensing

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1 | INTRODUCTION

The subcutaneous implantable cardioverter-defibrillator (S-ICD) was developed to avoid serious complications associated with the transvenous implantable cardioverter-defibrillator, while maintaining reliable detection and defibrillation of life-threatening arrhythmias.[1–3] Although the prevalence of selectable vectors is known to increase after implantation, how many vectors classified preoperatively as ineligible become available after S-ICD implantation has not been clarified. The most common problem with S-ICD systems in the real world is administration of inappropriate shocks because of T-wave oversensing.[4,5] To avoid this problem, the manufacturer has developed a system to identify patients likely to be unsuitable for S-ICD, using supine and standing ECG screening templates.

To avoid T-wave oversensing as one of the major factors underlying application of inappropriate shocks, the SMART pass (SP) algorithm was developed to minimize T-wave oversensing using a high-pass filter of 9 Hz. Although SP became available in November 2016 in Japan, the validity of SP is not well-known.

The present study aimed to clarify the change in the prevalence of eligible vectors after S-ICD implantation compared to that before operation. In addition, we assessed the degree to which the SP algorithm increases eligible vectors for S-ICD at rest and during a treadmill exercise test.

2 | METHODS

2.1 | Patients

All study protocols were approved by the Ethics Committee of Okayama University Hospital and its affiliated hospitals. All 34 patients who underwent S-ICD implantation at Okayama University Hospital and its affiliated hospitals between February 2016 and August 2017 were recruited. Of these, 17 patients (50%) experienced ventricular fibrillation (VF) or aborted cardiac arrest and 26 patients (76%) experienced syncope. We assessed the clinical characteristics of participants, including age, sex, body mass index (BMI), left ventricular ejection fraction (EF) from echocardiography and functional stage of the New York Heart Association (NYHA) classification of heart failure.

2.2 | S-ICD screening ECG at rest before S-ICD implantation

All 102 vectors from 34 patients were assessed for S-ICD eligibility using supine and standing ECG limb lead recordings which simulate the three S-ICD sensing vectors (primary, secondary, and alternate), as reported previously.[6] All ECG readings were analyzed by two independent blinded observers.

2.3 | Before S-ICD implantation, S-ICD screening ECG during exercise stress test

Of the 34 patients, 27 patients underwent exercise stress testing before S-ICD implantation. The remaining seven patients did not participate in exercise testing because of low back pain or leg pain. Thus, 81 vectors from 27 patients were evaluated for the suitability of S-ICD. The patients participated in a symptom-limited treadmill exercise test (TMT) under the Bruce protocol. Limb lead recordings simulated the 3 S-ICD sensing vectors and precordial leads were in the ordinary positions. The exercise test started with a warm-up stage at low workload, followed by successive 2-minutes stages with stepwise increments in workload. Tests were completed with a 5-minutes recovery phase after reaching peak exercise. ECGs were acquired every 1 minute during and after exercise testing up to 5 minutes into the recovery period. S-ICD eligibility was determined using the Boston Scientific screening template, at the following time points: (a) supine rest; (b) on standing; (c) at peak exercise; (d) at 1-minute recovery; (e) at 3-minutes recovery; and (f) at 5-minutes recovery. A vector was considered eligible when all points from ECG met the eligibility criteria during TMT.[7]

2.4 | Assessment of selectable vectors after S-ICD implantation

Vector eligibility was assessed at rest and during TMT with and without SP. A vector was considered selectable when T-wave oversensing was not observed.

Thirty-three patients participated in preoperative TMT after S-ICD implantation. We therefore assessed whether T-waves were oversensed with the device throughout the exercise stress test in 96 vectors of 32 patients. Exercise stress testing used the same protocol as S-ICD screening before implantation.

Furthermore, we compared ventricular fibrillation detection time of the device with and without SP during defibrillation testing at S-ICD implantation. Ventricular fibrillation detection time was defined as the duration from the induction of ventricular fibrillation to detection in the device.

2.5 | Statistical analysis

Categorical variables are presented as the number of patients (percentage), and continuous variables are summarized as median and range. For each variable, differences in categorical variables were evaluated using Fisher's exact test, and differences in continuous variables were evaluated using the Kruskal-Wallis test.

To account for correlations between vector ineligibility data within patients, we used multivariate generalized linear mixed-effect models (GLMMs) with random intercepts and logit link functions. Vector ineligibility data were compared between vectors (primary/secondary/alternate), status (exercise/rest), smart pass (on/off), and time (screening/S-ICD). Odds ratios (ORs) and the associated 95% confidence intervals and *P*-values were calculated using the GLMMs. To account for potential confounders, extended GLMMs including age, sex, BMI, EF, VF, and NYHA functional stage were also examined.

Furthermore, we constructed cross-tables of paired vector ineligibility data between conditions and calculated probabilities of

TABLE 1 Baseline characteristics of study participants

Male, n (%)	27 (79.4)
Age (y)	49 ± 17
BMI (kg/m^2)	24 ± 5
NYHA classification	1.3 ± 0.6
Ejection fraction	55 ± 17
Primary prevention	13 (38.2)
Episode of ventricular fibrillation	17 (50.0)
Episode of syncope	26 (76.5)
Disease	
Idiopathic ventricular fibrillation	10 (29.4)
Cardiomyopathy	8 (23.5)
Ischemic heart disease	7 (20.6)
Brugada syndrome	7 (20.6)
Long QT syndrome	2 (5.9)

BMI, body mass index; NYHA classification, New York Heart Association classification of heart failure.
Categorical variables are shown as the number of patients (percentage). Continuous variables are shown as mean ± SD.

ineligible results with 95% confidence intervals for each condition. Differences in probabilities and 95% confidence intervals were calculated. McNemar tests were also performed and *P*-values were calculated.

All tests were two-sided, and values of $P < 0.05$ considered significant. All analyses were exploratory and no multiplicity adjustments were performed. All statistical analyses were performed using R version 3.4.2 software (The R Foundation for Statistical Computing, Vienna, Austria).

3 | RESULTS

3.1 | Baseline characteristics of patients

Table 1 shows the baseline clinical characteristics of study participants. They tended to be middle-aged (mean, 49 ± 17 years) with preserved left ventricular EF. Almost 80% of patients were male and half of the patients experienced episodes of VF.

3.2 | Prevalence of selectable vectors in screening ECG and after S-ICD implantation—in overall analysis

Results of selectable vectors in screening ECG and after S-ICD implantation in the presence and absence of SP are shown in Figure 1. Five (4.9%) of 102 vectors were judged ineligible for S-ICD at rest after S-ICD implantation without SP, while the S-ICD screening algorithm judged 35 vectors (34.3%) as ineligible for S-ICD. Thus, 30 (29.4%) of the 102 vectors were decided to be erroneously considered ineligible from screening ECG before S-ICD implantation. Univariate analysis revealed that eligibility of vectors was significantly better after S-ICD implantation even without SP than that in screening ECG at rest ($P < 0.01$). When SP was switched on, almost all vectors judged ineligible during SP-off became eligible; of five vectors judged as ineligible after implantation of S-ICD during SP-off, four vectors became eligible after SP-on. Thus, only one (0.9%) of all 102 vectors remained ineligible with SP at rest. The exercise test performed in any phase of this study, before and after the implantation of S-ICD with and without SP, showed increased ineligible vectors compared to those obtained at rest. Before S-ICD implantation, the exercise increased ineligible vectors from 34.3% to 40.7%, and after S-ICD implantation with SP-off, unavailable vectors increased from five (4.9%) to nine vectors (9.4%) during the exercise test. Favorable effects on vector eligibility were added with SP during exercise. After SP was switched on, seven of the nine vectors became eligible, and finally, only two (2.1%) of all 96 vectors remained ineligible during exercise. No vectors that were considered eligible before implantation became ineligible after S-ICD implantation with SP. In addition, no patients became ineligible with S-ICD in any situation after implantation with or without SP.

3.3 | Prevalence of selectable vectors in screening ECG and after S-ICD implantation—in each vector analysis

We compared the ineligibility of the three individual vectors between in screening ECG and after S-ICD implantation. The

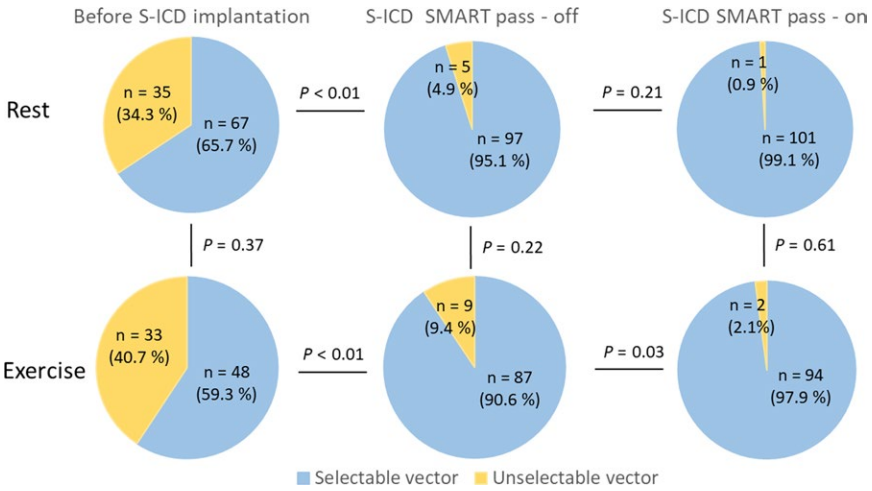

FIGURE 1 Prevalence of selectable vectors before and after S-ICD implantation. Selectable vectors are significantly increased after S-ICD implantation both at rest (upper row) and during exercise testing (bottom row). SP improves the selectivity of vectors during exercise testing (right column)

TABLE 2 Comparison of vector status (A: screening vs S-ICD; B: rest vs exercise)

Condition	n	Screening fail (CI)	S-ICD fail (CI)	Difference (CI)	McNemar *P*-value
(A)					
Rest					
Screening vs S-ICD, SP-off					
Primary	33	27.3 (15.1-44.2)	3.0 (0.2-15.3)	−24.2 (−42.1 to −6.6)	0.011
Secondary	33	24.2 (12.8-41.0)	0.0 (0.0-10.4)	−24.2 (−41.0 to −11.3)	0.005
Alternate	33	54.5 (38.0-70.2)	12.1 (4.8-27.3)	−42.4 (−60.1 to −21.8)	< 0.001
Screening vs S-ICD, SP-on					
Primary	34	26.5 (14.6-43.1)	0.0 (0.0-10.2)	−26.5 (−43.1 to −13.6)	0.003
Secondary	34	23.5 (12.4-40.0)	0.0 (0.0-10.2)	−23.5 (−40.0 to −11.0)	0.005
Alternate	34	52.9 (36.7-68.5)	2.9 (0.2-14.9)	−50.0 (−65.9 to −34.1)	<0.001
Exercise					
Screening vs S-ICD, SP-off					
Primary	26	34.6 (19.4-53.8)	7.7 (2.1-24.1)	−26.9 (−46.1 to −10.6)	0.008
Secondary	26	30.8 (16.5-50.0)	11.5 (4.0-29.0)	−19.2 (−39.5 to 0.9)	0.059
Alternate	26	57.7 (38.9-74.5)	7.7 (2.1-24.1)	−50.0 (−67.9 to −30.7)	<0.001
Screening vs S-ICD, SP-on					
Primary	26	34.6 (19.4-53.8)	0.0 (0.0-12.9)	−34.6 (−53.8 to −17.3)	0.003
Secondary	26	30.8 (16.5-50.0)	0.0 (0.0-12.9)	−30.8 (−50.0 to −13.9)	0.005
Alternate	26	57.7 (38.9-74.5)	3.8 (0.2-18.9)	−53.8 (−72.4 to −27.5)	<0.001
(B)					
Rest vs Exercise					
Screening					
Primary	27	29.6 (15.9-48.5)	33.3 (18.6-52.2)	3.7 (−9.2 to 18.3)	0.317
Secondary	27	29.6 (15.9-48.5)	29.6 (15.9-48.5)	0.0 (−15.4 to 15.4)	1.000
Alternate	27	51.9 (34.0-69.3)	59.3 (40.7-75.5)	7.4 (−6.0 to 23.4)	0.157
S-ICD, SP-off					
Primary	31	0.0 (0.0-11.0)	12.9 (5.1-28.9)	12.9 (0.5 to 28.9)	0.046
Secondary	31	0.0 (0.0-11.0)	12.9 (5.1-28.9)	12.9 (0.5 to 28.9)	0.046
Alternate	31	9.7 (3.3-24.9)	6.5 (1.8-20.7)	−3.2 (−18.2 to 11.0)	0.564
S-ICD, SP-on					
Primary	32	0.0 (0.0-10.7)	0.0 (0.0-10.7)	0.0 (−10.7 to 10.7)	NA
Secondary	32	0.0 (0.0-10.7)	0.0 (0.0-10.7)	0.0 (−10.7 to 10.7)	NA
Alternate	32	3.1 (0.2-15.7)	3.1 (0.2-15.7)	0.0 (−13.2 to 13.2)	1.000

Screening fail = prevalence of ineligible vector for S-ICD in Screening ECG; S-ICD fail = prevalence of ineligible vector for S-ICD after S-ICD implantation; Difference = S-ICD fail - Screening fail; CI = confidence interval.

number of ineligible vectors was significantly smaller for any of the vectors after S-ICD implantation compared to those in screening ECG (Table 2A).

Next, we compared ineligible vectors between rest and exercise. The number of eligible vectors tended to decrease after exercise in all three vectors, particularly after S-ICD implantation with SP-off. However, this tendency disappeared with SP-on, because many vectors estimated as ineligible during exercise with SP-off became eligible with SP-on (Table 2B).

The results of multivariate analysis are shown in Table 3. SP was independently associated with vector eligibility (OR 0.19, $P = 0.01$), and the alternate vector showed significantly higher ineligibility compared with the primary vector (OR 2.611, $P < 0.01$). Exercise also tended to show an association with vector ineligibility, but the relationship was not significant.

3.4 | Defibrillation test

Defibrillation testing was performed in 11 patients without SP and in 19 patients with SP. Time to detection did not differ significantly between groups (SP-on 9.5 ± 3.1 seconds vs SP-off 8.9 ± 2.5 seconds, $P = 0.62$). VF induced by DFT was treated successfully in all

patients at first operation, both with and without SP. The time to resumption of heart beat after VF termination also did not show any significant difference between groups (SP-on 1.1 ± 0.4 seconds vs SP-off 1.4 ± 0.4 seconds, $P = 0.53$).

4 | DISCUSSION

4.1 | Main findings

This pilot study estimated the effects of the SP algorithm on the eligibility of selected vectors for S-ICD. Of note, five (4.9%) of the 102 vectors were judged unavailable for S-ICD after implantation without SP, while 35 vectors (34.3%) considered ineligible for S-ICD on screening at rest before implantation; 30 vectors (29.4%) that were actually available for S-ICD were erroneously categorized unavailable by screening ECG before implantation. This result suggests that screening ECG may yield substantial underestimation of vector eligibility for S-ICD. When SP was switched on after the implantation, selectable vectors increased further.

Exercise tended to decrease the number of selectable vectors compared to the number at rest in screening ECG and after S-ICD implantation, and with and without SP. SP improved vector eligibility under all situations. Furthermore, patients who underwent S-ICD implantation were relatively young in this study, and their electrocardiograms could change due to ischemic heart disease or a conduction disturbance in the ventricle. Increasing selectable vectors by SP have the possibility of reducing inappropriate operations as a result of changes in the ECG over time.

4.2 | Screening scale vs actual selectable vector after S-ICD implantation

As mentioned above, the prevalence of eligibility was greater after S-ICD implantation both at rest and during exercise than that before implantation. Reasons for differences in eligibility between screening ECG before and after implantation must be considered. The first is the difference in sensing algorithms between screening ECG and the S-ICD. In a previous study, a new automated screening tool with the same sensing algorithm of the S-ICD provided a significantly higher eligibility rate than conventional screening ECG.[8] The present study did not use this new automated screening tool because the tool was not available throughout the entire study period. The lead system used for screening before implantation thus would not satisfactorily simulate the in situ leads of S-ICD. An alternative explanation is a difference in sensing position, as screening ECGs are recorded on the skin, whereas S-ICD ECGs are recorded under the skin. This difference in ECG sensing position could result in the differing eligibility of the vectors. In any case, the present results clarified that the screening scale before implantation was not satisfactory for selecting suitable vectors for S-ICD.

TABLE 3 Multivariate analysis using generalized linear mixed models

Coefficient	Odds ratio (CI)	*P*
Intercept	0.361 (0.201-0.649)	<0.001
Vector: secondary/primary	0.825 (0.409-1.665)	0.591
Vector: alternate/primary	2.611 (1.372-4.966)	0.003
Exercise/rest	1.518 (0.886-2.599)	0.128
SMART pass-on/off	0.190 (0.054-0.678)	0.010
Screening ECG/S-ICD	0.113 (0.058-0.218)	<0.001

4.3 | Usefulness of SP

Selectable vectors were increased with SP-on compared with SP-off. In particular, SP improved vector availability during exercise testing. The SP feature activates an additional high-pass filter of 9 Hz, instead of 3 Hz, designed to reduce cardiac oversensing while still maintaining an appropriate sensing margin. Thus, SP filtering reduces the amplitude of lower-frequency (slower-moving) signals such as T waves, by applying an additional high-pass filter. For higher-frequency (faster-moving) signals such as R waves, amplitudes remain almost unchanged.

We have previously reported that the amplitude of T waves increased during exercise testing, and some lead vectors were erroneously classified as unsuitable for S-ICD.[7] As a result, patients who were eligible at rest became ineligible during exercise testing. The most common cause of inappropriate shock from an S-ICD is reported cardiac signal oversensing (73%), such as T-wave oversensing.[4,9] S-ICDs tend to be implanted in younger patients because of their higher activity in daily life.[1] Improving T-wave oversensing with SP, resulting in decreasing inappropriate operation of the S-ICD, may offer an indispensable improvement to young patients with S-ICD.

Afzal et al did not observe any T-wave oversensing from the S-ICD during treadmill exercise testing while SP was on.[10] Since SP became available, we likewise have not experienced inappropriate therapy with the S-ICD due to T-wave oversensing, even in cases with a high T-wave that might be oversensed if SP was absent. SP could decrease T-wave voltage with the high-pass filter to the level below the trigger voltage of shock operation, resulting in a reduction in inappropriate shock.

In this study, even in the presence of SP, T-wave oversensing was still seen in two vectors during exercise. In our previous study, dramatic morphological changes were observed on S-ICD screening ECG during TMT before S-ICD implantation in patients with Brugada syndrome, as assessed using standard 12-lead ECG.[11,12] Subramanian et al confirmed these findings among high-risk Brugada syndrome patients on standard 12-lead ECG.[13] If the dramatic T-wave change during exercise exceeds the SP function to decrease T-wave amplitude, T-wave oversensing may occur.

The bandpass filter in ICD sensing circuits is designed to select a range of frequencies that reduces the amplitude of unwanted signals such as T waves, while retaining as much of the R wave as possible. However, using a high-pass filter of 9 Hz, we were concerned initially about undersensing VF. In this study, however, no significant

differences in detection time of VF during the defibrillation threshold time were seen between SP-on and SP-off.

4.4 | Limitations

Several limitations need to be considered when interpreting the results of this study. First, a relatively small number of participants was included. Although this study included patients from multiple centers, larger numbers of participants need to be investigated.

Second, we did not analyze how often inappropriate therapy with S-ICD actually occurred in this report. However, during follow-up, we experienced two cases of inappropriate S-ICD operation in 34 patients during the follow-up period (mean follow-up period 27.7 ± 5.4 months). Both cases of therapy operated without SP. No inappropriate therapy occurred with the SP switched on.

Whether the improvement in T-wave oversensing with SP in each vector clinically affects inappropriate therapy is unclear. The actual prevalence of inappropriate therapy with S-ICD in the presence of SP should be analyzed during follow-up.

Third, most inappropriate therapy with ICD is due to T-wave oversensing. However, although uncommon, inappropriate operation of the ICD due to myopotential oversensing has also been reported.[14] Since the frequency targeted by SP is the T wave, inappropriate operation from myopotentials cannot be prevented by SP.

5 | CONCLUSIONS

In this study, the availability of vectors was significantly better after S-ICD implantation than with preimplantation screening ECG at rest. SP improved the eligibility of S-ICD vectors not only at rest, but also during exercise. Because T-wave oversensing during exercise has been one of the serious problems resulting in inappropriate shock, particularly in younger patients with S-ICD, SP is likely to prove extremely helpful in preventing inappropriate operation of the S-ICD and thus to improve quality of life in patients with S-ICD.

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CONFLICT OF INTERESTS

The authors declare no conflict of interests for this article.

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