

# A novel screening test for inappropriate shocks due to myopotentials from the subcutaneous implantable cardioverter–defibrillator

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**BACKGROUND** The subcutaneous implantable cardioverter-defibrillator (S-ICD) is effective in preventing sudden cardiac death. Compared with transvenous ICDs, S-ICDs have a lower rate of inappropriate shocks (IASs) for supraventricular arrhythmias, but such shocks for T-wave oversensing (TWO) and extracardiac myopotentials are more common. No screening tests to identify patients at risk for IAS due to myopotential interference (MPI) currently are available.

**OBJECTIVE** The purpose of this study was to assess the efficacy of a tube exercise test (TET) developed to detect MPI post S-ICD implantation.

**METHODS** TET includes 3 different maneuvers using an exercise tube. S-ICD electrograms were recorded to assess MPI while patients performed each of the maneuvers.

**RESULTS** TET was performed in 43 patients, and MPI was observed in 12 patients (28%). In 10 of the 12 TET-positive patients, the positive vector corresponded with a vector that did not show TWO on

standard S-ICD preoperative screening. During median follow-up of 672 days (interquartile range 465–805 days), 3 patients (7%) experienced IAS due to MPI. Importantly, the vector at the time of IAS in all 3 patients passed standard preoperative screening for TWO but was positive with TET. Sensitivity and specificity of TET were 100% and 78%, respectively, and positive and negative predictive values were 25% and 100%, respectively.

**CONCLUSION** Postimplant screening for MPI identified patients at increased risk for IAS. TET may be helpful for guiding optimal programming to prevent IAS.

**KEYWORDS** Exercise test; Inappropriate shock; Myopotential interference; Oversensing; Subcutaneous implantable cardioverter-defibrillator

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## Introduction

The subcutaneous implantable cardioverter–defibrillator (S-ICD) is an alternative to the transvenous ICD for prevention of sudden cardiac death. It reduces device-related complications, such as lead failure, venous obstruction, and systemic infection.<sup>1–4</sup> The S-ICD has a low rate of inappropriate shocks (IASs) for supraventricular arrhythmias, but this is offset by an increased risk of shocks for oversensing, most commonly from T waves (T-wave oversensing [TWO]).<sup>5</sup>

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TWO and supraventricular arrhythmias are the most studied mechanisms of IAS. Dual-zone programming<sup>6,7</sup> and an improved discrimination algorithm<sup>8,9</sup> reduce such shocks. However, extracardiac oversensing, which is the second most common cause of oversensing, has not been well studied, and strategies for predicting or preventing IAS from myopotential interference (MPI) are not available. In the present study, we developed a novel tube exercise test (TET) to assess MPI in S-ICD patients.

## Methods

### Study population

From February 2016 to November 2018, 63 S-ICD implantations (model A 209 [n = 24] and model A 219 [n = 39]; Boston Scientific, St. Paul, MN) were performed at Hirosaki University Hospital (Hirosaki, Japan). Of the patients in this cohort, 43 underwent TET and constitute the study

## KEY FINDINGS

- A novel tube exercise test (TET) includes 3 different maneuvers using an exercise tube for isometric exercise of the upper limbs. Exercise 1 is a horizontal movement of the arms. Exercise 2 is a horizontal periodic movement while both arms are raised. Exercise 3 is a vertical periodic movement using the left arm. This test is a reliable screening method to identify patients at risk for inappropriate shock due to myopotential interference (MPI).
- The results of the TET test did not correlate with those of the standard S-ICD screening test for T-wave oversensing. Thus, the standard screening test would not be useful for predicting MPI.
- The 3-incision technique was an independent predictor of MPI by TET, whereas the 2-incision technique may reduce the risk of MPI.

population. The study was approved by the Ethics Committee of Hiroasaki University, and all patients provided written informed consent for participation.

Patient selection was based on Japanese Circulation Society Guidelines,<sup>10</sup> and patients met standard indications for S-ICD implantation, which included passing preimplantation ECG screening for TWO in at least 1 sensing vector in both supine and standing positions using the manual screening tool (MST). The final vector of the patient was programmed by the device implanter based on the automated algorithm in the pulse generator.

### TET

The TET includes 3 different maneuvers using an exercise tube that were performed after S-ICD implantation (Figure 1). The test is performed by isometric exercise of the upper limbs as follows. Exercise 1 is a horizontal movement of the arms. Exercise 2 is a horizontal periodic movement while both arms are raised. Exercise 3 is a vertical periodic movement using the left arm. Patients are instructed to move the tube as quickly as possible.

TET is performed >10 days post S-ICD implantation to avoid disturbing the device incision. During each exercise, subcutaneous electrograms (S-ECG) are recorded in each of the 3 vectors from the implanted S-ICD. The test is classified as positive when MPI is observed visually and sensed by the device, as documented by an “S” marker, in at least 1 vector (Figure 2). Classification of TET response was made by 2 independent investigators.

### Data collection

Demographic and clinical data were submitted to a central database. Data included age, sex, baseline heart disease, body mass index (BMI), history of ventricular tachycardia

(VT) and/or ventricular fibrillation (VF), previous cardiac implantable electronic device infection, left ventricular ejection fraction, atrial fibrillation, and procedural characteristics. After device implantation, follow-up visits at the device clinic were scheduled for every 1–3 months, and device-related data were collected at those visits. All patients used a remote monitoring system (LATITUDE Patient Management System; Boston Scientific). Shock data are collected from the remote monitoring system by automatic monthly transmission. Device-related data also are collected during unplanned visits to an outpatient clinic or hospital for device shocks.

All shocks were analyzed by at least 2 investigators, who were blinded to the results of TET and classified by consensus. Shocks were classified as appropriate if they were due to a ventricular tachyarrhythmia. IASs were subclassified by the presence of MPI. The incidence of MPI by TET and the relationship between the results of TET and IAS due to MPI were assessed.

### Statistical analysis

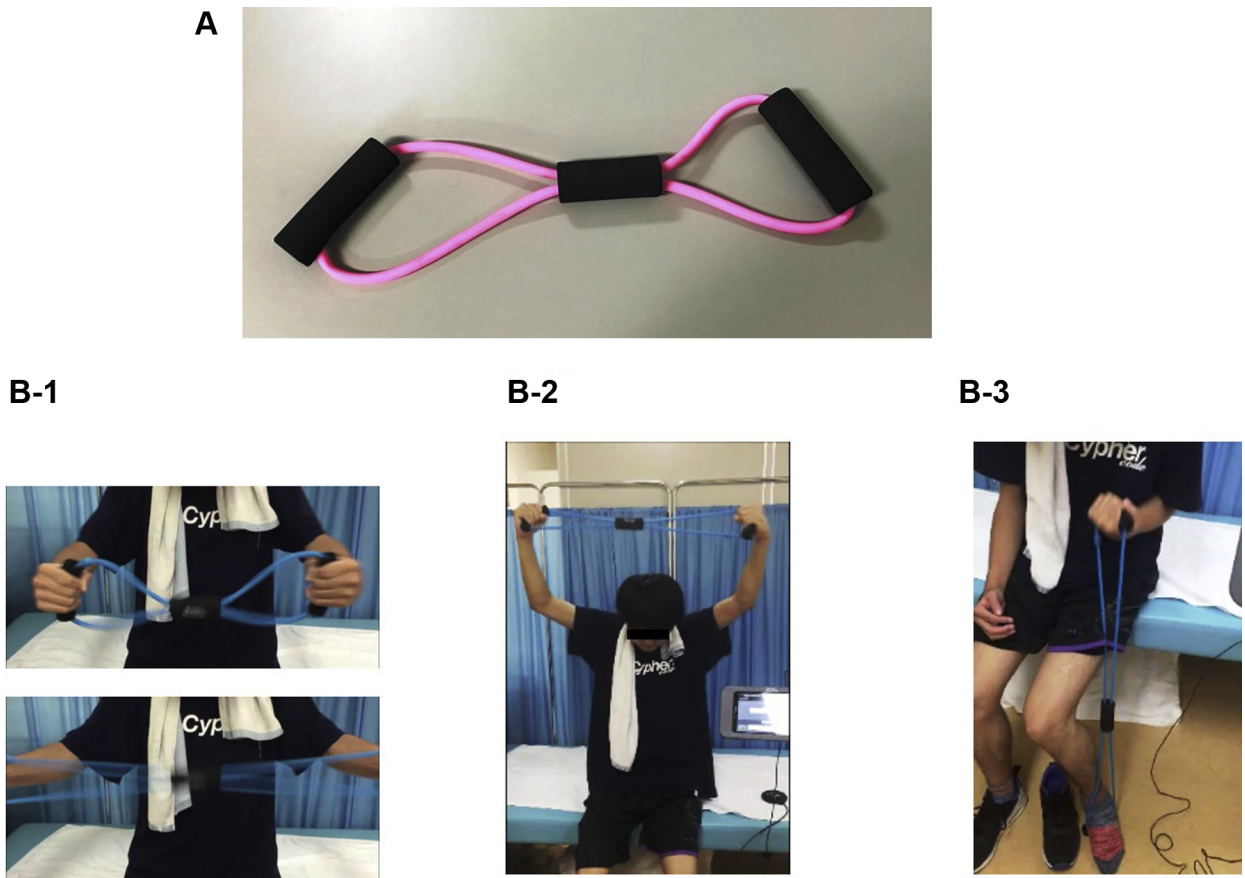
Data are expressed as median (interquartile range) or n (%). Continuous data were compared using the Mann–Whitney U test. Categorical variables are summarized as frequency and percentage and were compared using the Fisher exact test. To investigate the predictors of MPI by TET, univariate and multivariate analyses using nominal logistic regression analysis were performed using the variables of age, sex, BMI, and type of incision technique. Statistical analysis was performed using JMP 13 (SAS Institute, Cary, NC).  $P < .05$  was considered significant.

## Results

### Clinical characteristics and operative procedure

Of the 63 patients implanted with an S-ICD during the study period, 43 underwent TET. The reasons for not performing TET were patient’s inability to exercise; patient’s failure to comply with the exercise protocol; or patient was lost to follow-up. Clinical and implantation characteristics are listed in Table 1. Median age of the population was 62 (47–66) years, and >70% of patients were male. Twenty-two patients (51%) had a history of VT/VF, and 3 patients (9%) had a previous infection. The underlying arrhythmia substrate was ischemic cardiomyopathy in 16 patients (37%), idiopathic VF in 8 (19%), Brugada syndrome in 6 (14%), hypertrophic cardiomyopathy in 5 (12%), and dilated cardiomyopathy in 2 (5%). Mean left ventricular ejection fraction was 50%, and 4 subjects (9%) had atrial fibrillation.

Procedural characteristics are listed in Table 1. The S-ICD lead was placed in the left parasternal position in 42 patients (98%). The procedure was performed with intermuscular 2-incision technique in 22 patients or 3-incision technique in 21 patients. Defibrillation test was performed in 40 patients (93%). In all patients, VF was induced and successfully terminated by a single 65-J shock. Median time to shock therapy was 13.6 seconds, and median postshock impedance of



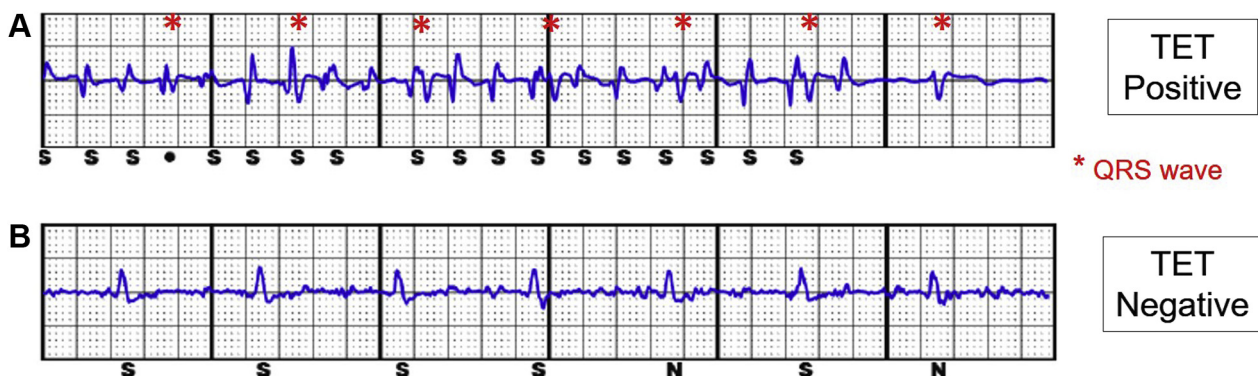
**Figure 1** The tube exercise test (TET) includes 3 different maneuvers using an exercise tube and is performed after S-ICD implantation. In each exercise, the patient periodically moves the upper limbs. **A:** Exercise tube. **B-1:** Exercise 1: horizontal movement. **B-2:** Exercise 2: horizontal movement while both upper limbs are raised. **B-3:** Exercise 3: vertical movement.

the S-ICD lead was 67Ω. No perioperative implantation-related complications occurred.

**Incidence of MPI with TET**

MPI with TET was observed in 12 patients (28%) in at least 1 vector. Characteristics of patients with positive TET (n = 12) were compared to those with negative TET (n = 31) (Table 1). The 3-incision technique was performed more commonly in patients with positive TET (n = 9 [75%])

than in those with negative TET (n = 12 [39%]) (P = .03). No differences in the other clinical characteristics were observed. The relationships between sensing vector and MPI with TET are shown in Figure 3. MPI was observed in 6 cases (14%), 7 cases (16%), and 7 cases (16%) in the primary, secondary, and alternate vector, respectively. A higher rate of MPI with TET exercise 1 was observed in the alternate vector. There were no differences in MPI from the 3 exercises in the other vectors.



**Figure 2** Criteria for the tube exercise test (TET). **A:** TET positive. Myopotentials were observed visually and sensed by the device. “S” markers show documented QRS waves (asterisks) and myopotentials. **B:** TET negative. Myopotentials were not sensed by the device.

**Table 1** Comparison of baseline characteristics between TET-positive and TET-negative patients

Variable	All patients (n = 43)	TET		P value
		Positive (n = 12)	Negative (n = 31)	
Age (y)	62 (47–66)	53 (33–65)	62 (54–67)	.17
Male gender	31 (72)	9 (75)	22 (71)	.79
BMI (kg/m <sup>2</sup> )	25.3 (22.4–27.7)	24.3 (21.4–27.3)	25.4 (22.6–27.7)	.52
History of VT/VF	22 (51)	8 (67)	14 (45)	.20
Previous CIED infection	3 (9)	1 (8)	2 (7)	.85
LVEF (%)	50.0 (34.8–66.3)	48.8 (33.2–67.1)	50.0 (35.0–63.6)	.97
Atrial fibrillation	4 (9)	0 (0)	4 (13)	.17
Operation procedure				
Left lead position	42 (98)	12 (100)	30 (97)	.42
Three-incision technique	21 (49)	9 (75)	12 (39)	.03
Defibrillation test	40 (93)	11 (92)	29 (94)	.83
Time to therapy (s)	13.6 (12.3–15.0)	14.8 (11.5–17.5)	13.4 (12.5–14.5)	.58
Shock impedance (Ω)	67 (58–79)	64 (55–77)	68 (58–82)	.33

Values are given as median (interquartile range) or n (%).

BMI = body mass index; CIED = cardiac implantable electronic device; LVEF = left ventricular ejection fraction; TET = tube exercise test; VF = ventricular fibrillation; VT = ventricular tachycardia.

### IAS and its relationship with TET

During median follow-up of 672 days (465–805 days), 5 patients experienced IASs, 3 (7%) due to MPI and the other 2 (5%) due to supraventricular tachyarrhythmia above the rate cutoff of the conditional zone (Figure 4). No IAS due to TWO occurred in this cohort. In 2 of 3 patients with IAS due to MPI, the SMART Pass algorithm was not active at the time of the shock. In 1 patient, this algorithm was not available in the device at that time. In the other patient, the algorithm was active at first but was automatically turned off because of low R-wave amplitude (<0.25 mV). All 3 patients with IAS due to MPI had a positive TET. Moreover, no negative TET patients had an IAS due to MPI (Table 2). Sensitivity and specificity of the TET were 100% and 78%, respectively. Positive and negative predictive values were 25% and 100%, respectively.

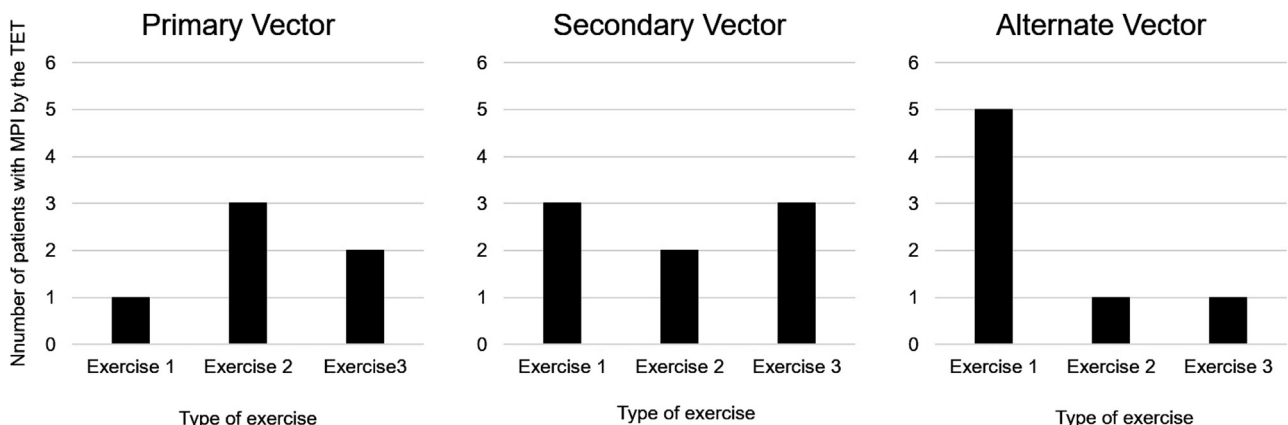
The details of the sensing vector in the TET-positive patients are listed in Table 3. The vectors that passed in S-ICD preoperative screening for TWO did not correlate with those associated with MPI. In 2 of the 12 TET-positive

patients, the selected device failed the preoperative vector as an optimal vector (patients 3 and 6); that is, the vector that did not pass in S-ICD preoperative screening for TWO was selected by the device algorithm.

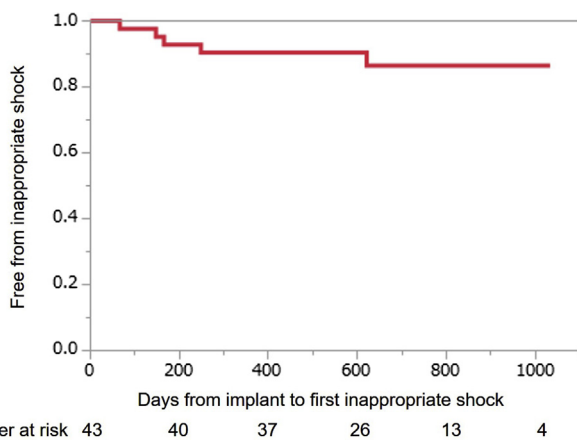
In 10 of the 12 TET-positive patients, the TET-positive vector passed S-ICD preoperative screening. However, in only 6 of the 12 TET patients (no. 1, 3, 5, 9, 10, and 12), the optimal vector determined by the device was TET negative. Importantly, in all 3 patients with IAS due to MPI (no. 4, 5, and 8), the positive programmed vector at the time of IAS was TET positive and passed preoperative screening.

### Predictor of MPI by TET

Univariate and multivariate analyses using nominal logistic regression analysis revealed that the 3-incision technique was an independent predictor of MPI by TET (Table 4). Kaplan–Meier analysis showed a nonsignificant trend for time to IAS due to MPI between the 2- and 3-incision techniques (log-rank  $P = .08$ ) (Figure 5). One possible explanation for the lack of statistical significance is the difference in



**Figure 3** Relationship between sensing vector and myopotential interference (MPI) by tube exercise test (TET). A higher rate of MPI with exercise 1 was observed in the alternate vector.



**Figure 4** Kaplan–Meier curve for subcutaneous implantable cardioverter–defibrillator patients free from inappropriate shocks (IASs). Three patients (7%) experienced IAS due to myopotential interference and the other 2 patients (5%) due to supraventricular tachyarrhythmia.

follow-up duration. Specifically, patients who underwent the 3-incision technique had a significantly longer follow-up period than those who had undergone the 2-incision technique [median 805 (734–958) days vs 548 (448–613) days;  $P < .01$ ]. This finding is expected because we transitioned from the 3- to the 2-incision technique over the course of patient enrollment in this study.

**Discussion**

The primary results of this study are that TET is a reliable method for identifying patients at risk for IAS due to MPI. About 30% of patients had positive TET, including all patients with IAS due to MPI. The 100% specificity indicates that a negative TET places patients at very low risk for IAS from MPI. In addition, the standard preoperative ECG screening tool and device algorithm for choosing a vector do not protect from IAS due to MPI. In >80% of TET-positive patients, the TET-positive vector corresponded with a vector that passed standard S-ICD preoperative screening designed to prevent TWO. Moreover, in 2 of 3 patients with IAS due to MPI, the device was programmed to the optimal vector determined by the device-based algorithm, which is also designed to enhance sensing and prevent TWO. These results indicate that the current preoperative screening algorithms do not prevent IAS due to MPI.

Most studies of IAS have focused on TWO and supraventricular arrhythmia. However, noncardiac oversensing,

including myopotential or electromagnetic interference, is well recognized in S-ICD patients. Olde Nordkamp et al<sup>11</sup> reported that 9% of IASs were due to noncardiac oversensing. Quast et al<sup>12</sup> reported that 15% of IASs are due to noise. However, neither study reported the distribution of IAS from MPI compared with other sources of noise, such as electromagnetic interference. We previously reported that the incidence of IAS due to MPI was 5%.<sup>13</sup> Interestingly, Theuns et al<sup>9</sup> reported fewer IAS events due to noncardiac oversensing with SMART Pass. However, the cause of IAS was not provided in their study. Recently, Noel et al<sup>14</sup> reported that 9% of patients had an oversensing event (IAS and inappropriate charges) involving MPI. From these results, it is estimated that approximately 10% of patients have MPI. Of note, the S-ICD will report MPI only if it is of sufficient duration and rate to result in device charging. Accordingly, the incidence of MPI likely is underestimated by these studies.

van den Bruck et al<sup>15</sup> recently reported that myopotentials were induced during exercise in >90% of patients. In their study, exercise consisted of isometric chest press, lifting and holding a 20-kg weight, and side plank exercise. The incidence of IAS was not reported, so the correlation between the exercise regimen and shocks cannot be assessed. Their rate of MPI was 3 times higher than noted in our series. There are several possible reasons for these discrepant results. First, the more aggressive exercise regimen used by van den Bruck et al was not as standardized as the TET. Second, in their study, a test was classified as positive when MPI was documented as sensed (“S” marker) or noise (“N” marker) by the device. In contrast, we only used signals classified as sensed (“S” marker) that would result in device shocks. Given the much lower rates of IAS due to MPI noted in the present study and in previous reports,<sup>11–14</sup> the specificity of this test likely is very low.

An interesting and unexpected finding was the observation that a 3-incision technique for S-ICD implantation was the only predictor of MPI. Knops et al<sup>16</sup> first described the usefulness of the 2-incision technique, which avoids the superior parasternal incision. The procedure is safe, effective, less invasive, and simpler, and it shortens implant time.<sup>17</sup> Ferrari et al<sup>18</sup> reported a single-center experience with an intermuscular 2-incision technique in 14 patients. During mean follow-up of 9 months, no procedure-related complications, appropriate shocks, or IASs were observed. Subsequently, Migliore et al<sup>19</sup> reported a multicenter experience with an intermuscular 2-incision technique of 36 patients. During mean follow-up of 10 months, no IASs were observed. More recently, Migliore et al<sup>20</sup> showed that 3 of 101 patients implanted with an S-ICD using an intermuscular 2-incision technique had IAS due to oversensing cardiac (n = 1), noncardiac (n = 1), and a combination of both cardiac and noncardiac signals (n = 1) during median follow-up of 21 months. They concluded that the 2-incision technique seemed to be associated with a low risk of complications, such as IAS. Our results also support that the 2-incision technique may reduce the risk of MPI. The mechanism for the lower risk with the 2-incision technique is not clear, but not

**Table 2** Sensitivity and specificity of TET for detection of inappropriate shock due to MPI

	IAS due to MPI (+) (n = 3)	IAS due to MPI (-) (n = 40)
TET positive (n = 12)	3	9
TET negative (n = 31)	0	31

IAS = inappropriate shock; MPI = myopotential interference; TET = tube exercise test.

**Table 3** Details of the sensing vector in TET-positive patients

Pt no.	Sex	Disease	Passed vector in preoperative screening	Optimal vector selected by device	Programmed vector	TET-positive vector	IAS due to MPI (vector at the time of IAS)	Incision technique
1	M	Brugada	S	S	S	P		3
2	F	IVF	PS	P	P	P		3
3	M	ICM	A	P	S	A		3
4	M	Brugada	S	S	S	SA	+ (S)	3
5	M	ARVC	PSA	A	P	PS	+ (P)	3
6	M	ICM	S	P	P	P		3
7	F	IVF	PS	S	S	SA		3
8	M	ICM	PS	P	P	PS	+ (P)	3
9	M	IVF	SA	S	S	A		3
10	M	ICM	PS	P	P	S		2
11	F	ICM	PSA	S	S	S		2
12	M	ICM	PSA	P	P	A		2

A = alternate vector; ARVC = arrhythmogenic right ventricular cardiomyopathy; F = female; ICM = ischemic cardiomyopathy; IVF = idiopathic ventricular fibrillation; M = male; P = primary vector; Pt = patient; S = secondary vector; other abbreviation as in Table 1.

sewing the distal tip of the electrode to the fascia may be associated with lower sensitivity to underlying myopotentials. Furthermore, lead position and depth may be related to sensing of pectoral muscle myopotentials. In this regard, a case report showed that positioning the lead over the midsternum avoided IAS due to MPI.<sup>21</sup> In the present study, lead position and depth were appropriate as seen on postoperative x-ray films taken in the supine and standing positions regardless of incision technique. However, we routinely placed the lead to the left or occasionally to the right side of the sternum, so sensing of MPI with midsternal lead placement cannot be assessed.

The implant technique used in this study was an intermuscular technique that recently had become more popular because of greater patient comfort and for cosmetic reasons.<sup>18–20</sup> Its use is preferred in Japanese patients because they have lower body surface area on average than many other populations. It is unlikely that the intermuscular position of the pulse generator contributed to a higher incidence of MPI because the alternate vector was affected as often as the primary and secondary vectors. The alternate vector does not include the pulse generator in the sensing vector.

Furthermore, we cannot exclude that the learning curve of the 3-incision technique is related to IAS. Consistent with this possibility, Knops et al<sup>22</sup> demonstrated that the performance of S-ICD implanters stabilized after 13 implants. However, we are currently using the 2-incision technique,

so we cannot determine whether operator experience is related to the incidence of IAS.

The MST was used in our study, whereas the automated screening tool (AST) is now widely used clinically. Three studies compared the MST and the AST for determining eligibility for an S-ICD.<sup>23–25</sup> Two studies, including the largest study to date,<sup>23</sup> showed no difference between MST and AST for determining eligibility for an S-ICD.<sup>23,24</sup> The third study demonstrated that AST is associated with a higher pass rate than MST, especially in the primary and secondary vectors.<sup>25</sup> If this latter finding is confirmed, then the AST is expected to increase the number of vectors that pass the screening ECG test and thus allow more options for reprogramming to other vectors. This makes TET screening even more applicable to patients, as the proportion of patients who can be reprogrammed to TET-negative vectors should increase.

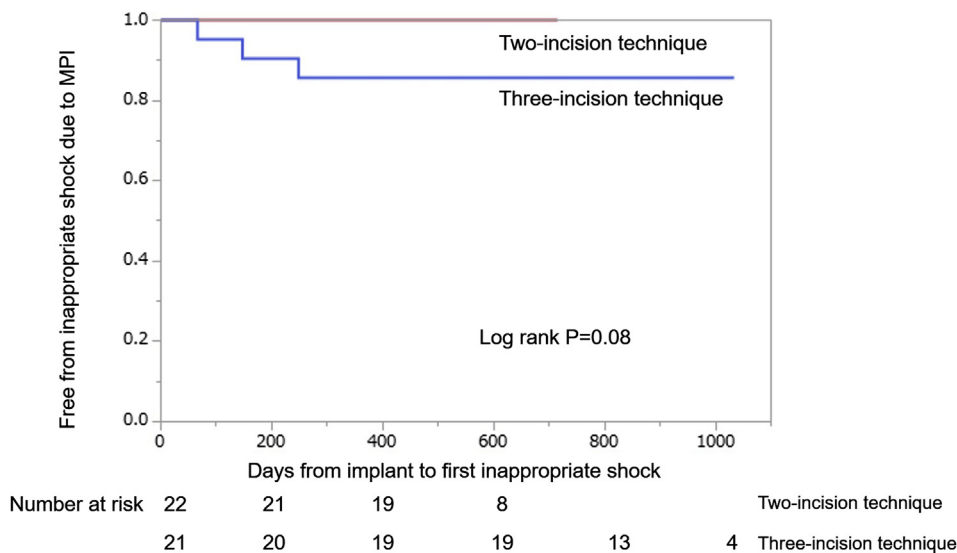
### Clinical implications

Approximately one-third of the patients had MPI with TET. In addition, all patients with IAS due to MPI had a positive TET, so a negative test is reassuring. Importantly, the vectors in which MPI were noted do not correlate with those showing TWO. Thus, the standard S-ICD screening test would not be useful for predicting MPI. These findings indicate that choosing a vector with both TWO-negative and TET-negative results may help prevent IAS. In support of this

**Table 4** Predictor of myopotential interference by tube exercise test

Variable	Univariate analysis		Multivariate analysis	
	Odds ratio (95% CI)	P value	Odds ratio (95% CI)	P value
Age	0.97 (0.94–1.01)	.17	0.97 (0.93–1.02)	.24
Male gender	1.23 (0.27–5.61)	.79	1.03 (0.19–5.35)	.98
BMI	0.94 (0.79–1.13)	.50	0.99 (0.80–1.23)	.92
Three-incision technique	4.75 (1.07–21.1)	.03	5.05 (1.08–23.6)	.03

BMI = body mass index; CI = confidence interval.



**Figure 5** Comparison between 2- and 3-incision techniques of the incidence of inappropriate shocks (IAS) due to myopotential interference (MPI) in patients with a subcutaneous implantable cardioverter–defibrillator. Kaplan–Meier analysis showed a trend that did not reach statistical significance for the time to IAS due to MPI between the 2 techniques (log-rank  $P = .08$ ).

strategy, each of the patients with IAS due to MPI were re-programmed to a TET-negative vector, and no further IAS due to MPI was noted.

TET is performed after S-ICD implantation. If TET is positive, we recommend changing the sensing vector to a TET-negative vector if that vector passed the screening ECG test. This is a simple and noninvasive approach. However, if the TET-negative vector does not pass the screening ECG test, then we advise patients to avoid movements or exercises that are similar to those of the TET, and we program to a vector that does not show device-based oversensing if possible. More invasive approaches, such as revising the lead position to a midsternal location or implanting a transvenous system, can be considered, but given the low positive predictive value of TET, such interventions likely would not be pursued in the absence of shocks. Further clinical studies are needed to determine the best approach for these patients.

### Study limitations

First, this was a relatively small, observational study with the limitations associated with such a design. Moreover, the event rate was low. Second, TET was not performed by all patients, primarily the patients with reduced activity levels. MPI will be low in such patient groups. Third, not all devices in this study had the more advanced discrimination algorithm and filtering of the newer model S-ICD (SMART Pass algorithm), which may be protective for MPI as it was inactive in 2 of 3 patients who received IAS. However, this algorithm has limitations. It is inactivated in the presence of small sensed R waves, as occurred in 1 of the 3 IAS patients in our series. Moreover, the magnitude of MPI reduction with SMART Pass is unknown. Finally, this was a single-center study of Japanese patients with a relatively low BMI

compared with patients in other S-ICD trials. However, BMI was not associated with MPI in this study.

### Conclusion

For patients with an S-ICD, postimplant screening for MPI is predictive of those who may have IAS due to MPI. TET may be useful in guiding the choice of programmed sensing vector to reduce IAS.

### Acknowledgments

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