

Continuous ST-Monitoring Function of Implantable Cardioverter Defibrillator Detects Silent Ischemia in Patients With Coronary Artery Disease

Tetsuya Watanabe, MD, PhD; Keiji Hirooka, MD; Yoshio Furukawa, MD, PhD; Masanori Yabuki, MD, PhD; Akio Hirata, MD, PhD; Kazunori Kashiwase, MD, PhD; Ryu Shutta, MD; Takanao Mine, MD, PhD; Hiroya Mizuno, MD, PhD; Toshikazu Tanaka, MD, PhD; Takahiro Doi, MD, PhD; Akihiro Yoshida, MD, PhD; Yuji Okuyama, MD, PhD; Shinsuke Nanto, MD, PhD

Background—Newer implantable cardioverter defibrillators can monitor intracardiac ECGs, but their ability to detect ischemia is unclear. This study investigated the usefulness of implantable cardioverter defibrillators with an ST-monitoring function in coronary artery disease patients.

Methods and Results—We conducted a prospective study of implantable cardioverter defibrillator patients with the ST-monitoring function. One hundred seventy-three patients who received implantable cardioverter defibrillators for primary or secondary prevention of sudden cardiac death. All patients underwent medical examinations at least every 6 months, with standard 12-lead ECGs and device checks that included analysis of the ST-monitoring function. Myocardial perfusion imaging or coronary angiography was performed during the follow-up. The mean follow-up duration was 23.3 ± 7.7 months. Significant ST changes occurred in 15 patients (8.7%), of whom 14 were asymptomatic. The incidence of angina pectoris was significantly higher in the ST change (+) group than that in the ST change (−) group (28.6% versus 7.2%, $P=0.03$). In the patients who underwent myocardial perfusion imaging, the sensitivity, specificity, and negative predictive value of the ST-monitoring feature to detect ischemia were 75.0%, 72.5%, and 93.5%, respectively. The sensitivity, specificity, and negative predictive value of the ST-monitoring feature to predict residual stenosis evaluated using coronary angiography were 76.9%, 83.5%, and 97.5%, respectively. The percentage of patients with a septal right ventricular lead was significantly lower in the ST change (+) group than in the ST change (−) group (13.5% versus 33.5%, $P=0.01$).

Conclusions—If intracardiac ECGs ST changes are detected, it is necessary to use additional modalities even in asymptomatic patients.

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Recently, although the door-to-balloon time has improved significantly for patients undergoing primary percutaneous coronary intervention (PCI) for an acute myocardial infarction (AMI), the in-hospital mortality has remained virtually

unchanged.¹ Implantable cardioverter defibrillators (ICDs) have been widely recognized as effective devices for preventing sudden cardiac death from fatal arrhythmias.^{2,3} Despite the effectiveness of ICD therapy, delivering shock therapy can carry

From the Department of Cardiovascular Medicine, Yao Municipal Hospital, Osaka, Japan (T.W.); Cardiovascular Division, Osaka National Hospital, Osaka, Japan (K.H.); Division of Cardiology, Osaka General Medical Center, Osaka, Japan (Y.F.); Department of Cardiovascular Medicine, Higashi Takarazuka Satoh Hospital, Hyogo, Japan (M.Y.); Cardiovascular Division, Osaka Police Hospital, Osaka, Japan (A.H., K.K.); Division of Cardiology, Osaka Rosai Hospital, Osaka, Japan (R.S.); Cardiovascular Division, Department of Internal Medicine, Hyogo College of Medicine, Hyogo, Japan (T.M.); Department of Advanced Cardiovascular Therapeutics, Osaka University Graduate School of Medicine, Osaka, Japan (H.M., Y.O., S.N.); Department of Cardiology, Okazaki City Hospital, Aichi, Japan (T.T.); Department of Cardiovascular Medicine, Graduate School of Medicine, Kyoto University, Kyoto, Japan (T.D.); Division of Cardiovascular Medicine, Department of Internal Medicine, Kobe University Graduate School of Medicine, Hyogo, Japan (A.Y.).

Correspondence to: Tetsuya Watanabe, MD, PhD, Department of Cardiovascular Medicine, Yao Municipal Hospital, 1-3-1 Ryuge-cho, Yao, Osaka 581-0069, Japan. E-mail: t.watanabe252@gmail.com

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Clinical Perspective

What Is New?

- In this multicenter, prospective, observational study, use of implantable cardioverter defibrillators with an ST-monitoring function was safe, and it was effective for detecting asymptomatic myocardial ischemia.
- The ST-monitoring function has a high degree of sensitivity, specificity, and negative predictive value, even in comparison to myocardial perfusion imaging or coronary angiography.

What Are the Clinical Implications?

- The present study demonstrates the effectiveness of implantable cardioverter defibrillators of ST monitoring to detect myocardial ischemia.
- We should consider, if ST changes are detected on the intracardiac ECGs, to perform additional examinations, such as myocardial perfusion imaging or coronary angiography, even in asymptomatic patients.

a poor prognosis, especially in patients with ischemic heart disease. Therefore, avoiding unnecessary shock therapy is critical.^{4,5} In patients with ischemic heart disease who are at high risk of arrhythmic death, ischemia is an independent predictor of death and ICD therapy deliveries.⁶

Survivors of either a first or a recurrent AMI remain at a significantly higher risk of death compared with the general population. In particular, of those patients who develop a second AMI event, about one-third will die.^{7,8} Prevention of the recurrence of myocardial infarctions in patients with a history of AMI is important for improving prognosis.

Intracardiac ECGs are superior at detecting ischemia compared with body-surface ECGs and can detect ischemia earlier than surface ECGs.^{9–12} A comparison of the intracardiac ECG vectors of an ischemic state—from the tip of the right ventricle (RV) to the ICD can, from the tip of the RV to the right atrium (RA), and from the RA to the ICD can—showed that the ST change in the intracardiac ECG from the tip of the RV to the ICD can was sensitive.¹¹ A new ICD with ST monitoring has been introduced with a feature that enables it to monitor the intracardiac ECG throughout the battery life. The primary objective of this study was to evaluate the efficacy of the ST-monitoring feature in the Fortify ST, Fortify Assura ST, and Ellipse ST (St. Jude Medical, Inc, St. Paul, MN) family of ICD systems in patients with ischemic heart disease.

Methods

The data, analytic methods, and study materials will not be made available to other researchers for purposes of reproducing the results or replicating the procedure.

The ESTIMATION (Evaluation of the ST Segment Using the Automatic Monitoring Function) trial was a prospective, multicenter study in patients with ICDs with an ST-monitoring function. The study was conducted at 42 Japanese centers. Patients with coronary artery disease (CAD) who had ICDs implanted were prospectively enrolled from December 2011 to December 2014. This study was approved by the institutional review board/medical ethics committee of each participating center, and all patients provided signed informed consent.

After a run-in period of 3 months for algorithm optimization, the ST thresholds were programmed. When a rapidly progressive ST-segment shift met or exceeded the programmed detection threshold limit, the algorithm marked it as an ST episode and stored the date, time, heart rate, maximum ST shift, and duration of the event. Patients aged less than 20 years and those with complete atrioventricular block or Brugada syndrome were excluded. We enrolled 174 patients and the analysis was conducted in 173. One patient was excluded because no follow-up was performed after enrollment. Patients were eligible if they had received an ICD with the ST-monitoring function (ICD with ST monitoring; St. Jude Medical, Minnesota, MN, USA). At enrollment, all patients provided a comprehensive medical history and underwent a cardiovascular examination that included a resting 12-lead electrocardiography, chest radiography, fasting blood tests, and evaluation of the left ventricular (LV) ejection fraction (LVEF). All patients were seen at least every 6 months during the follow-up (3 months when possible) to check the device and inquire about symptoms. ST changes were defined as a difference between the equipotential interval and ST interval, and a positive/negative judgment was made according to the criteria specified by the device. The equipotential interval was defined as 94 to 148 ms before the peak of the R wave. The ST interval was defined as 72 to 126 ms from the terminal of the R wave. The stored ICD data were transferred to a central database for analysis. The tachyarrhythmias were then classified by the waveform on the intracardiac ECG.

Whenever possible, myocardial perfusion imaging (MPI) and coronary angiography (CAG) were performed during the follow-up period. MPI was performed using single-photon emission computed tomography with technetium-99m sestamibi during a standard maximum exercise test or pharmacological stress test with adenosine, dipyridamole, or dobutamine. Myocardial ischemia on MPI scans was visually interpreted by the consensus of 2 experienced observers.

The primary end point was to evaluate the sensitivity, specificity, positive predictive value, and negative predictive value in relation to the presence or absence of ST changes on the intracardiac ECG and conventional tests of myocardial ischemia. The secondary end point was to compare the effect of the RV lead position on the ST changes observed on the

intracardiac ECG and to examine the relationship between LV function and ST changes on the intracardiac ECG.

Device Description and Programming

All patients had an ICD equipped with the ST-monitoring function (Analyst DR/VR, Ellipse limited DR/VR, Fortify ST DR/VR, Fortify Assura DR/VR, Ellipse DR/VR; St. Jude Medical, Minnesota, MN, USA). Using a can-to-RV tip vector, the implantable device monitored the ST-segment of the sensed intracardiac ECG to detect and alert the patients to any excessive ST-segment shift events. The ST-monitoring function collects data from implantation to the first follow-up, and determines normal values and recommended values. ST monitoring requires 8600 events in the resting heart rate and 4 days to determine the recommended threshold of the ST shift. Data collection is not performed in consideration of fault current 4 hours immediately after implantation, and the ST recommended threshold cannot be obtained during follow-up within 4 days from implantation. Initially, the increasing/decreasing threshold is set to 100%. The ST increase/decrease threshold is expressed as a percentage of the R wave height. The threshold value for ST change detection was determined from the range (maximum value) of ST variation

generated in the ST part during the sampling period. A standard deviation of three times (99.72%, $\pm 3\sigma$) was used as the range of variation.

The ventricular tachycardia zone therapy was first anti-tachycardia pacing and then a shock.

Statistical Analysis

Continuous data are summarized as mean \pm SD, and categorical data are expressed as count and percentile. Pairwise group comparisons were tested using Student *t* test for continuous variables and Fisher exact test for categorical data. $P < 0.05$ was considered significant. All statistical analyses were performed using SAS Version 9.3 for Windows (SAS Institute Inc, Cary, NC).

Results

Patient Characteristics

In total, 173 CAD patients who were implanted with an ICD with the ST-monitoring function were analyzed. The clinical baseline characteristics are presented in Table 1. The average age of the study participants at baseline was 66.0 \pm 9.8 years.

Table 1. Patient Characteristics

Characteristic	Total (n=173)	ST Change (–) (n=158)	ST Change (+) (n=15)	P Value*
Age, y	66.0 \pm 9.8	66.4 \pm 9.6	65.0 \pm 12.4	0.69
Male sex, n (%)	158 (91.3)	146 (92.4)	12 (80.0)	0.37
BMI, kg/m ²	23.0 \pm 2.9	22.9 \pm 3.0	23.6 \pm 2.7	0.38
Diabetes mellitus, n (%)	73 (42.1)	68 (43.0)	5 (33.3)	0.28
Hypertension, n (%)	106 (61.3)	95 (60.1)	11 (73.3)	0.40
Hyperlipidemia, n (%)	103 (59.5)	94 (59.4)	9 (60.0)	0.40
CRF, n (%)	32 (18.4)	29 (18.3)	3 (21.4)	0.73
Laboratory data				
Hb level, g/dL	12.9 \pm 1.7	12.8 \pm 1.8	13.0 \pm 1.6	0.79
K level, mEq/L	4.3 \pm 0.5	4.3 \pm 0.5	4.2 \pm 0.5	0.83
BNP level, pg/mL	322.3 \pm 777.9	323.9 \pm 791.2	330.1 \pm 769.5	0.98
LVEF, %	45.4 \pm 15.2	44.0 \pm 14.8	54.9 \pm 15.2	0.02
Cardiac hypertrophy, n (%)	27 (15.6)	23 (14.5)	4 (26.6)	0.45
Atrial fibrillation, n (%)	38 (22.0)	38 (24.1)	0 (0)	0.04
Primary indication, n (%)	34 (19.7)	34 (21.5)	0 (0)	0.08
CCS classification (I/II/III/IV), n (%)	151/16/2/4 (87.3/9.2/1.2/2.3)	138/14/2/4 (87.3/8.8/1.3/2.6)	12/3/0/0 (80.0/20.0/0/0)	0.78
NYHA classification (I/II/III/IV), n (%)	99/63/9/2 (57.2/36.4/5.2/1.2)	87/61/8/1 (55.0/38.6/5.7/0.7)	11/2/1/1 (73.3/13.3/6.7/6.7)	0.06

Data are given as mean \pm SD or n (%). BMI indicates body mass index; BNP, brain natriuretic peptide; CCS, Canadian Cardiovascular Society; CRF, chronic renal failure; Hb, hemoglobin; K, potassium; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association.

*Difference between the ST change (–) and ST change (+) groups according to the Fisher exact test or Student *t* test.

Table 2. Characteristics of Patients With Coronary Artery Disease

Characteristic	Total	ST Change (–)	ST Change (+)	P Value
Ischemic heart disease				
OMI, n (%)	130 (75.1)	120 (75.9)	10 (66.7)	0.51
AP, n (%)	15 (8.7)	11 (7.0)	4 (26.7)	0.03
VSA, n (%)	34 (19.1)	27 (19.6)	3 (20)	1.00
Previous history of coronary intervention				
CABG, n (%)	33 (19.1)	32 (20.3)	2 (13.3)	0.74
PCI, n (%)	107 (61.8)	97 (61.4)	10 (66.6)	0.77
Previous target lesion of PCI				
LMT, n (%)	10 (5.8)	9 (5.7)	1 (6.7)	0.60
LAD, n (%)	95 (55.6)	87 (55.1)	8 (53.3)	1.00
RCA, n (%)	60 (34.7)	53 (33.5)	8 (53.3)	0.26
LCX, n (%)	51 (29.5)	49 (31.0)	2 (13.3)	0.23

AP indicates angina pectoris; CABG, coronary artery bypass grafting; LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; LMT, left main trunk; OMI, old myocardial infarction; PCI, percutaneous coronary intervention; RCA, right coronary artery; VSA, vasospastic angina.

Men comprised 91.3% of all the subjects, and the mean follow-up duration was 23.3 ± 7.7 months. During the follow-up, 2 patients died of heart failure and one of pneumonia. The ST-monitoring function recording was successful and interpretable in all patients, and no serious complications were observed during the recordings. Significant ST changes occurred in 15 patients (8.7% of all patients). The mean LVEF was significantly higher in the ST change (+) group than in the ST change (–) group ($54.9 \pm 15.2\%$ versus $44.0 \pm 14.8\%$,

Table 3. Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value of the ST-Monitoring Feature to Detect Ischemia

Relationship Between the Device ST Change and Ischemia Using MPI				
		MPI		Total
		(–)	(+)	
ST change	(–)	29	11	40
	(+)	2	6	8
	Total	31	17	48
		%	95% CI	
Sensitivity		75.0	34.9	96.8
Specificity		72.5	56.1	85.4
Positive predictive value		35.3	14.2	61.7
Negative predictive value		93.5	78.6	99.2
ROC-AUC		0.738	0.591	0.854

CI indicates confidence interval; MPI, myocardial perfusion imaging; ROC-AUC, receiver operating characteristic-area under the curve.

$P=0.02$). The mean hemoglobin level, brain natriuretic peptide level, cardiac hypertrophy, and New York Heart Association class did not differ significantly between the 2 groups.

Characteristics of Patients With CAD

The characteristics of the patients with CAD are presented in Table 2. The percentage with a previous history of coronary intervention and the target lesion of the previous PCI did not differ significantly between the 2 groups. The incidence of ischemia detected was unrelated to the coronary artery involved. The percentage of patients with angina pectoris (AP) was significantly higher in the ST change (+) group than in the ST change (–) group (26.7% versus 7.0%, $P=0.03$). The total in the first section of Table 2 exceeds 100% because some cases had more than one of the clinical features related to ischemic heart disease.

In the patients who underwent MPI, the sensitivity, specificity, positive predictive value, and negative predictive value of the ST-monitoring feature for detecting ischemia (Table 3) were 75.0%, 72.5%, 35.3%, and 93.5%, respectively. In the patients in whom the residual stenosis was examined using CAG, the sensitivity, specificity, positive predictive value, and negative predictive value of the ST-monitoring feature to detect residual stenosis were 76.9%, 83.5%, 30.3%, and 97.5%, respectively (Table 4).

Device Data

The device data are presented in Table 5. Most ICDs were implanted on the left side of the anterior chest (97.7%). The

Table 4. Sensitivity, Specificity, Positive Predictive Value, and Negative Predictive Value of the ST-Monitoring Feature to Detect Coronary Stenosis

Relationship Between the Device ST Change and Residual Stenosis				
		Residual Stenosis		Total
		(–)	(+)	
ST change	(–)	116	23	139
	(+)	3	10	13
	Total	119	33	152
		%	95% CI	
Sensitivity		76.9	46.2	95.0
Specificity		83.5	76.2	89.2
Positive predictive value		30.3	15.6	48.7
Negative predictive value		97.5	92.8	99.5
ROC-AUC		0.802	0.730	0.862

CI indicates confidence interval; ROC-AUC, receiver operating characteristic-area under the curve.

Table 5. Device Data

	Total	ST Change (–)	ST Change (+)	P Value
Device implant site, left side, n (%)	169 (97.7)	154 (97.4)	15 (100)	1.00
RV lead position apex/septum/other, n (%)	113/54/6 (65.3/31.2/3.5)	102/53/3 (64.5/33.5/2.0)	10/2/3 (66.7/13.3/20)	0.01
Ventricular pacing, %	4.8±14.8	4.2±12.5	11.2±29.0	0.36
AT/AF burden, %	2.9±20.5			
ST monitoring set point				
Upper limit threshold	65.5±38.8			
Lower limit threshold	64.8±40.6			
Equipotential interval				
Start, ms	143.7±21.7			
Duration, ms	60.0±11.8			
ST interval				
Start, ms	73.5±14.8			
Duration, ms	59.8±10.5			

Data are given as mean±SD or n (percentage). AT/AF indicates atrial tachycardia/atrial fibrillation; RV, right ventricular.

percentage of patients with atrial tachycardia/fibrillation was only 2.9%. The percentage with a septal RV lead position was significantly lower in the ST change (+) group than in the ST change (–) group (13.5% versus 33.5%, $P=0.01$). During the follow-up period, the ICDs detected ventricular tachycardia (VT)/ventricular fibrillation (VF) 55 times, of which 11 were inappropriate detections. The number of ST changes on the intracardiac ECG was twice that of the confirmed VT/VF episodes within 24 hours. Only one ST change was recognized on the intracardiac ECG within 24 hours after the detection of VT/VF.

Case Report

Case. A 70-year-old woman

The chief complaint was an intracardiac ECG disorder.

Present history

Ventricular fibrillation occurred in a 70-year-old woman with an old myocardial infarction and reduced LV function, in whom an ICD with intracardiac ECG monitoring (AnalyST, St. Jude Medical, St. Paul, MN) was implanted (Figure 1). She underwent a successful PCI using drug-eluting stents. She came to our hospital for a regular checkup in September 2013. We routinely measured her surface ECG and echocardiogram at rest. They revealed no change compared with the previous ones. We performed a routine check of her ICD. Unexpectedly, ST depression was recorded using the intracardiac ECG monitoring. Figure 2 shows the intracardiac ECG episode in this patient. A maximum ST change was found 5 days before her regular checkup, at which the patient had no significant

symptoms. Figure 3 shows the single-photon emission computed tomography stress and rest images. The anterior region exhibited viable ischemic myocardium. Cardiac catheterization was performed (Figure 4A). CAG demonstrated severe stenosis at the ostium of the left anterior descending coronary artery (LAD) (Figure 4B). PCI was performed from the left main coronary trunk to the LAD (Figure 4C). After the successful

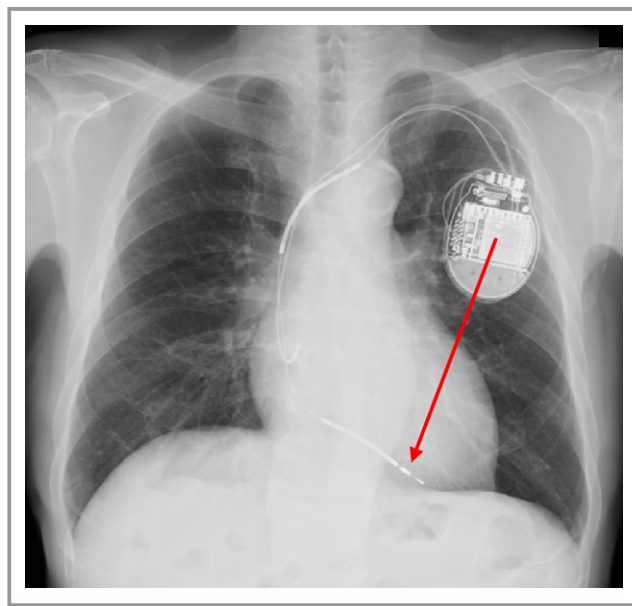


Figure 1. ST-monitoring feature of the implantable cardioverter defibrillator (ICD). Monitoring of the ST segment using the ICD, with an intracoronary electrogram from the ICD can to right ventricular tip lead.



Figure 2. Intracardiac ECG episode in the case described. ST depression was recorded using the intracardiac ECG monitoring. The upper panel shows the intracardiac ECG at baseline, the middle panel shows the ST shift onset, and the lower panel shows the maximum ST shift. The patient had no symptoms at that time.

PCI, no further ST depression was recorded using the intracardiac ECG monitoring (Figure 4D).

Discussion

The 4 main findings of the present study were as follows: (1) in the patients who underwent MPI, the sensitivity,

specificity, positive predictive value, and negative predictive value of the ST-monitoring feature to detect ischemia were 75.0%, 72.5%, 35.3%, and 93.5%, respectively; (2) in the patients in whom the residual stenosis was examined using CAG, the sensitivity, specificity, positive predictive value, and negative predictive value of the ST-monitoring feature to detect residual stenosis were 76.9%, 83.5%, 30.3%, and

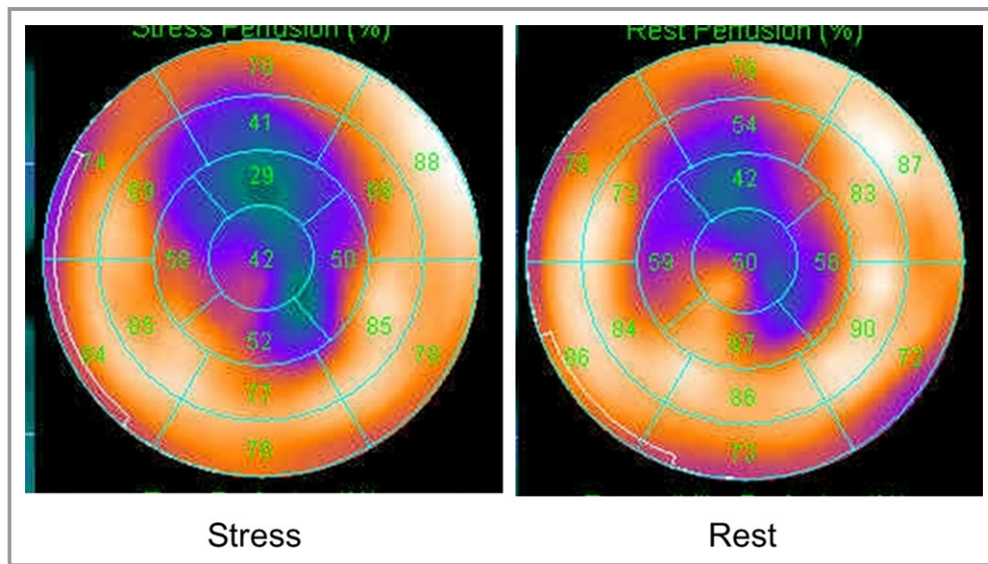


Figure 3. Myocardial perfusion imaging in the case described. ^{99m}Tc-myocardial single-photon emission computed tomography (SPECT) was performed. The image on the left is the stress image, and the image on the right is the rest image. ^{99m}Tc-myocardial SPECT reveals an ischemic region from the septum to the apex.

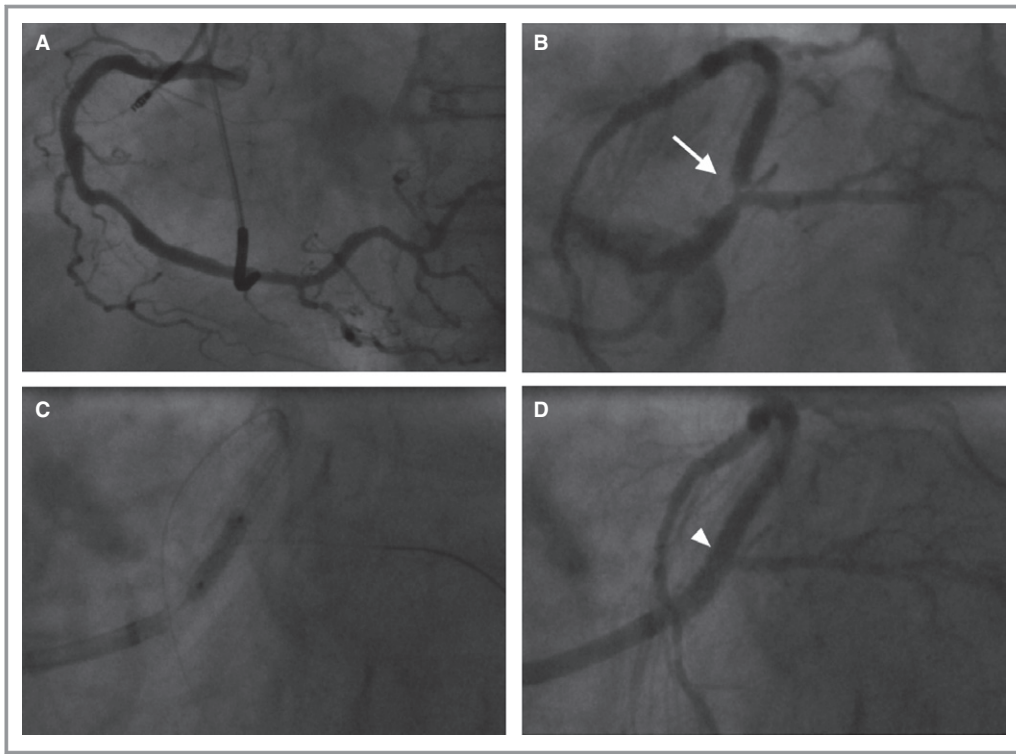


Figure 4. Cardiac catheterization in the case described. **A**, Multiple mild to moderate stenoses are recognized in the right coronary artery (left anterior oblique [LAO] 45, cranial [CRA] 0). **B**, Coronary angiogram demonstrates severe stenosis (arrow) at the ostium of the left anterior descending artery (LAD) (LAO 50, caudal 30). **C**, A drug-eluting stent (Xience 3.25×12 mm) was implanted from the left main trunk to the LAD ostium. **D**, After the stent treatment, the severe LAD stenosis disappeared (arrowhead). After the procedure, the patient was free from any further chest discomfort and no further ST depression was recorded using intracoronary electrogram monitoring.

97.5%, respectively; (3) the percentage with a septal RV lead position was significantly lower in the ST change (+) group than in the ST change (−) group; and (4) the percentage of patients with stable AP and the mean LVEF were significantly higher in the ST change (+) group than in the ST change (−) group. MPI and CAG could not be performed in all patients because of the general condition of the patients and renal dysfunction. However, CAG was performed in >85% of patients, and the sensitivity, specificity, and negative predictive value were highly clinically significant in the cases where we could conduct the examination. In addition, when at least ST change was observed, MPI-positive or residual coronary stenosis was recognized with a probability of $\geq 75\%$, which was considered useful for early diagnosis of myocardial ischemia even if it was asymptomatic.

The positive predictive value was low because of a few cases with positive ST changes. However, the sensitivity, specificity, and negative predictive value were high, even in comparison to MPI and CAG.

By using remote monitoring, this system can continuously observe the ST changes in the intracardiac ECG non-invasively and is considered to be a useful function.

Fischell et al reported intracardiac monitoring in 37 patients at high risk for an acute coronary syndrome. An implantable intracardiac ischemia detection device confirmed acute coronary syndrome in 4 patients.¹³ Approximately one-third of the asymptomatic patients with type 2 diabetes mellitus had significant CAD on coronary computed tomography angiography with a subsequent high risk for cardiac events.¹⁴ In our study, most of the patients did not have any chest pain (only one patient experienced chest pain) despite having ischemia, possibly as a result of the MPI or CAG. The Framingham Study determined that almost one-third of myocardial infarction patients had completely silent infarcts.¹⁵ Such infarcts were common in patients with angina and recurrent infarctions. Unrecognized infarctions were as likely as recognized ones to result in eventual death, heart failure, or stroke. Thus, unrecognized infarctions are common and have as serious a prognosis as typically symptomatic infarctions. In patients without chest symptoms, treatment was often delayed, which caused the prognosis to deteriorate. Intracardiac ECGs are more sensitive than the surface ECG in the detection of ischemia. By performing continuous intracardiac ECG monitoring, it is possible to detect symptomatic/

asymptomatic myocardial ischemia and to achieve early diagnosis and treatment. Improvement in the prognosis can then be expected. It is necessary to perform additional examinations, such as CAG, when an intracardiac ECG change is detected, even if asymptomatic.

The ALERTS (AngelMed for Early Recognition and Treatment of STEMI) trial tested the safety and effectiveness of the ST-monitoring device Guardian System. The primary effectiveness end point of the ALERTS trial was a composite of late presentation for confirmed events, new Q waves at 6 months, and cardiac or unexplained death. The primary effectiveness end point failed to meet statistical significance. However, the secondary end point of reduction in time to presentation reached statistical significance.¹⁶ Based on the results of the ALERTS trial, implantation of devices with only ST monitoring was not highly recommended, considering device infection and cost effectiveness. However, the continuous ST-monitoring function in this study was added to the function of the ICD, and there was no effect on cost and invasiveness to the patients.

In this study, the percentage with a septal RV lead position was significantly lower in the ST change (+) group than in the ST change (−) group. It has been reported that the can-to-RV apical tip vector was the most sensitive when comparing the ICD can-to-RV apical tip, ICD can-to-superior vena cava (SVC) and superior vena cava-to-RV apical tip as the myocardial ischemia assessment of the intracardiac ECG. These electrodes used for the leads were placed anatomically around the heart. The superior vena cava electrode was placed superiorly and dorsally to the heart, ICD can was placed superiorly and anteriorly, and RV apical tip electrode was placed diaphragmatically and anteriorly.^{11,12} When comparing the lead position in the case of the right ventricular septum and right ventricular apex, by considering a 3-dimensional electric vector with the ICD body, the apex lead position had an electrically large vector. Using an ICD can-to-RV apical tip vector, the implantable device monitored the ST-segment of the sensed intracardiac ECG to detect any excessive ST-segment shift events. When the RV lead is located on the right ventricular septum, the vector with the ICD can become small, so it is difficult to detect ST changes. Therefore, when using an ICD with an ST-monitoring function, it is better to place the RV lead in the apex of the right ventricle rather than on the right ventricular septum.

In the group with ST changes (+), the average LVEF was higher and the frequency of AP was higher than in the ST change (−) group. It has been reported that the residual myocardium is large if the ST changes are large during a dobutamine stress test.¹⁷ This seems to be more likely to detect ST changes in cases with a more viable myocardium.

ST depression increases with anemia and myocardial hypertrophy.^{18,19} In our study, the mean hemoglobin level, brain natriuretic peptide level, cardiac hypertrophy, and New

York Heart Association class did not differ significantly between the ST change (−) and ST change (+) groups. With the ICD system used in this study, the ST reference value for each patient seemed to be set after the implantation, so the original ST change was not considered to affect the ST determination directly.

Limitations

There were several limitations to this study. First, the result of the primary end point was established with a smaller sample size than we had assumed. Second, as this research was not a randomized study, it did not verify the effectiveness of the ST-monitoring system with regard to the prognosis. Myocardial ischemia may not be detected with the position of the RV lead. The rate of detection of ischemia because of MPI is not 100%, and there are also false positives; furthermore, MPI and CAG were not performed in all patients. Further studies will be needed to refine and extend the results of this study.

The continuous ST-monitoring system using the intracardiac ECG is safe and non-invasive, and it is effective for detecting asymptomatic myocardial ischemia. The ST-monitoring function has a high degree of specificity. If ST changes are detected on the intracardiac ECG, it is necessary to perform additional examinations, such as CAG or MPI, even in asymptomatic patients.

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Disclosures

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