



Original Article

Outcomes of single- or dual-chamber implantable cardioverter defibrillator systems in Japanese patients



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ABSTRACT

Background: There are no criteria for selecting single- or dual-chamber implantable cardioverter defibrillators (ICDs) in patients without a pacing indication. Recent reports showed no benefit of the dual-chamber system despite its preference in the United States. As data on ICD selection and respective outcomes in Japanese patients are scarce, we investigated trends regarding single- and dual-chamber ICD usage in Japan.

Methods: Data from a total of 205 ICD recipients with structural heart disease (median age, 63 years) in two Japanese university hospitals were reviewed. Patients with bradycardia with a pacing indication and permanent atrial fibrillation at implantation were excluded.

Results: Single- and dual-chamber ICDs were implanted in 36 (18%) and 169 (82%) patients, respectively. Non-ischemic cardiomyopathy dominated both groups. Seventeen dual-chamber patients developed atrial pacing-dependency over 4.5 years, and it developed immediately after implantation in 14. Although preoperative testing showed no sign of bradycardia in these patients, their pacing rate was set higher than it was in patients who were pacing-independent (61 vs. 46 paces per min, $p < 0.01$). Two single-chamber patients (5%) underwent atrial lead insertion.

While inappropriate shock equally occurred in both groups (7 vs. 21 patients, single- vs. dual-chamber, $P=0.285$), device-related infection occurred only in dual-chamber patients (0 vs. 9 patients, $P=0.155$). No differences in death or heart failure hospitalization were observed between groups.

Conclusions: Dual-chamber ICDs were four-fold more common in Japanese patients without a pacing indication. No benefit over single-chamber ICD was observed. Newly developed atrial pacing-dependency seemed to be limited and could have been overestimated due to higher pacing rate settings in dual-chamber patients.

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1. Introduction

There have been no clear established criteria for the selection of single- or dual-chamber implantable cardioverter defibrillators (ICDs) in patients without a pacing indication. In the United States, dual-chamber ICDs are predominantly used [1–3], but the reason for this trend is unclear. Potential benefits of dual-chamber ICD systems, such as superior supraventricular tachycardia (SVT) discrimination with atrial sensing [4,5] or physiological pacing for potential future bradycardia development [6], could encourage the physicians' preference. Recent studies, however, demonstrated that not only did

dual-chamber ICDs have no additional benefit over single-chamber ICDs but that they also resulted in a higher incidence of lead malfunctions or other adverse events [3]. These data shed light on the importance of careful consideration when selecting dual-chamber ICDs in patients without a pacing indication.

The proportion of non-ischemic cardiomyopathy (NICM) in the Japanese ICD cohort is higher than that of ischemic cardiomyopathy (ICM) [7]. The different background of these patients might affect physicians' decisions on ICD selection and lead to different clinical courses. As data on dual- or single-chamber ICD selection and respective outcomes in Japan are scarce, the aim of this study was to understand the Japanese trend in ICD selection and clinical outcomes.

2. Materials and methods

2.1. Patient selection

Two hundred seventy-seven consecutive patients (median age 68 years; interquartile range [Q1–3], 53–74 years; 69 women) who underwent ICD implantation and were followed from November 1994 to December 2013 in two Japanese university hospitals (Kyorin University Hospital, Tokyo, and the University Hospital at the University of Occupational and Environmental Health, Kitakyushu, Japan) were reviewed. Exclusion criteria were: (1) idiopathic ventricular tachycardia (VT)/fibrillation (VF), including Brugada syndrome and long QT syndrome; (2) known sinus node or atrioventricular node dysfunction with a pacing indication; and (3) permanent atrial fibrillation (AF) at the time of implantation. The remaining patients were then categorized into two groups according to the ICD type (i.e., single-chamber ICD and dual-chamber ICD). Decisions regarding ICD implantation were made according to the most recent Japanese guidelines for cardiac-implantable devices at the time of implantation [8–10]. The types of ICD and the settings of the pacing and antitachycardia therapy were selected based on the operators' decisions. Although neither university hospital had standard criteria for ICD type selection, operators referred to the patients' information on the use of negative chronotropic medications and results of preoperative testing. Every researchers involved in this study acted in conformity with the Declaration of Helsinki (adopted by the 18th WMA General Assembly, Helsinki, Finland).

2.2. Preoperative testing

Data from preoperative transthoracic echocardiography and 24-hour ambulatory monitoring within 6 months prior to implantation were evaluated.

2.3. Follow-up

All patients were followed in the outpatient device clinic every 3–4 months, and the devices were interrogated at each clinic visit or remotely. When bradycardia was observed, the pacing mode or a lower rate adjustment was considered in addition to the discontinuation of medication if necessary. A pacing rate change was attempted in patients for whom the tachyarrhythmia was believed to have been triggered by bradycardia. Additionally, the pacing mode was changed in case of a lead malfunction, such as an increased pacing threshold or progression of AF from a paroxysmal to persistent form. When the pacing ratio was 80% or more in the atria and/or in the ventricle, we defined it as an atrial or ventricular pacing dependency. Decisions regarding additional lead insertion or an upgrade to a cardiac resynchronization therapy defibrillator (CRTD) were made by the electrophysiological team after a detailed discussion. The patients were advised to visit the hospital when they experienced any shock delivery, palpitations, or other issues, such as skin redness or erosion.

2.4. Data collection

Data collection was closed by the end of December 2013. The pacing and therapy histories were collected from medical records at the outpatient device clinic. The follow-up period was defined as the period from the day of the initial ICD implantation to the last day that the physician contacted the patient before December 2013. When a patient underwent a CRTD upgrade, data collection was closed on the day of the upgrade.

2.5. Statistical analysis

Normally distributed continuous variables were expressed as the mean and standard deviation. Non-normally distributed variables were expressed as the median and first to third interquartile range (Q1–3). Categorical data were expressed as absolute numbers and/or percentages. Comparisons between the two groups were assessed by the two-tailed *t*-test or Mann–Whitney *U*-test according to a variable distribution. A Chi-squared test or Fisher's exact test was performed for the comparisons of categorical data. Statistical significance was set at $p < 0.05$. All analyses were performed with SPSS statistical software (SPSS Inc., Chicago, IL, USA).

3. Results

3.1. Patient demographics

Among the 277 ICD patients who underwent initial implantation at one of two hospitals, 72 were excluded from the study for the following reasons: idiopathic VT or VF in 39 patients (26 with a single-chamber ICD), permanent AF in 26 patients, sick sinus syndrome in five patients, and atrioventricular block in two patients. Three of the excluded 72 patients had previously received a pacemaker and then underwent an ICD upgrade. Therefore, the remaining 205 patients (median age, 63 years; Q1–3, 56–75 years; 59 women) were enrolled in the study. Single- and dual-chamber ICDs were selected in 36 (18%) and 169 (82%) patients, respectively (Fig. 1). There were no significant differences between the two groups with regard to age, sex, and proportion of NICM (Table 1). Patients with a primary prevention indication tended to receive a dual-chamber system (17% in the single- vs. 33% in the dual-chamber group, $P=0.048$). Patients in the dual-chamber group were more frequently taking class III antiarrhythmic drugs (mostly amiodarone), although it was not statistically significant (31% and 48%, $P=0.053$). Beta blockers were more frequently used in the dual-chamber group (36% and 58%, $P=0.014$).

Table 1 shows the results of preoperative testing. Echocardiography and 24-hour ambulatory monitoring data were available in 168 (82%) and 108 (53%) patients, respectively. While left ventricular systolic function was lower in the dual-chamber group (left ventricular ejection fraction, 54% vs. 46%; $P=0.034$), the total heart beats per day and maximum, mean and minimum heart rates were similar between the two groups. There was no evidence of bradycardia on 24-hour ambulatory monitoring in either group.

3.2. Follow-up

The mean duration of follow-up was 56 months (Table 2). A total of 65 (32%) ICD generators were exchanged, and three patients (1.4%, all in the dual-chamber group) were upgraded to CRTD (one patient at the time of the generator exchange and two patients due to worsening heart failure). Apart from the left ventricular lead insertion for CRTD, a total of 13 leads were added in 12 patients. Nine patients (two in the single- and seven in the dual-chamber group) had ventricular shock leads re-implanted due to lead malfunction (four for lead fractures and five for

insulation abrasions). Six of them were Riata leads (St. Jude Medical, Inc., Sylmar, CA) and three were Sprint Fidelis leads (Medtronic, Inc., Minneapolis, MN). One patient underwent lead implantation due to ventricular under-sensing. One atrial lead was re-implanted because of a high pacing threshold. Two atrial leads were newly implanted at the time of the generator exchange in patients who initially received single-chamber ICDs.

3.3. Device-related infections, other device-related adverse events, and death or heart failure hospitalizations

No patients in the single-chamber group experienced any device-related infections. In contrast, nine patients in the dual-chamber

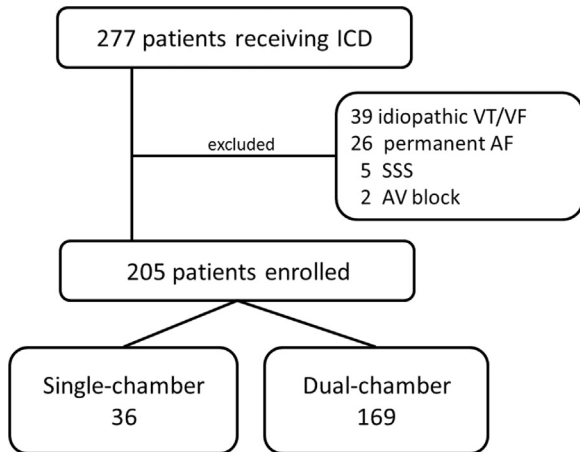


Fig. 1. Selection of the study participants. After excluding patients with idiopathic ventricular fibrillation/tachycardia, permanent atrial fibrillation, and sinus node or atrioventricular node dysfunction, a total of 205 patients were enrolled in the study. AV, atrioventricular; ICD, implantable cardioverter defibrillator; SSS, sick sinus syndrome; VF, ventricular fibrillation; VT, ventricular tachycardia.

Table 1
Demographic data.

	Total (n=205)	Single-chamber n=36	Dual-chamber n=169	Difference
Age at implantation, median (Q1–3)	63 (56–75)	61 (51–73)	68 (58–75)	P=0.099
Female sex, n (%)	59 (29)	11 (31)	48 (28)	P=0.796
Non-ischemic cardiomyopathy, n (%)	117 (57)	19 (53)	98 (58)	P=0.566
Primary prevention, n (%)	62 (30)	6 (17)	56 (33)	P=0.048*
Preoperative SVT Documentation, n (%)	35 (17)	3 (8)	32 (19)	P=0.125
Height (m), mean ± SD	1.62 ± 0.10	1.63 ± 0.10	1.62 ± 0.19	P=0.771
Weight (kg), mean ± SD	58.9 ± 12.0	58.7 ± 10.6	59.4 ± 12.3	P=0.787
BSA (m ²), mean ± SD	1.6 ± 0.2	1.6 ± 0.2	1.6 ± 0.2	P=0.697
BMI (kg/m ²), mean ± SD	22.5 ± 3.4	22.1 ± 2.9	22.6 ± 3.5	P=0.483
Medication at the time of implantation, n (%)				
Class I antiarrhythmic drug	14 (7)	2 (6)	12 (7)	P=0.736
Class III antiarrhythmic drug	92 (45)	11 (31)	81 (48)	P=0.053
Calcium channel blocker	42 (20)	9 (25)	33 (21)	P=0.462
Beta blocker	111 (54)	13 (36)	98 (58)	P=0.014*
TTE at implantation, mean ± SD				
LVEF (%)	47 ± 17	54 ± 15	46 ± 18	P=0.034*
LVDd (mm)	53 ± 10	51 ± 9	53 ± 10	P=0.467
LVDs (mm)	53 ± 10	51 ± 9	40 ± 13	P=0.193
LAD (mm)	39 ± 13	39 ± 9	40 ± 8	P=0.085
24-hour ambulatory ECG monitoring, mean ± SD				
Total heart beat (/day)	96,350 ± 18,119	94,491 ± 12,009	96,826 ± 19,409	P=0.601
Minimum HR (bpm)	54 ± 16	50 ± 7	55 ± 17	P=0.107
Average HR (bpm)	67 ± 13	66 ± 9	68 ± 14	P=0.455
Maximum HR (bpm)	99 ± 22	99 ± 18	99 ± 23	P=0.981

BMI, body mass index; BSA, body surface area; ECG, electrocardiogram; HR, heart rate; LAD, left atrial dimension; LVDd, left ventricular diastolic dimension; LVDs, left ventricular systolic dimension; LVEF, left ventricular ejection fraction; Q1–3, first to third interquartile range; SD, standard deviation; SVT, supraventricular tachycardia; TTE, transthoracic echocardiography.

* Statistically significant.

group (5%) experienced device-related infections requiring long-term antimicrobial therapy, although this difference was not statistically significant ($P=0.155$). Four of nine patients required lead extraction. All body habitus markers, except for body mass index (BMI), were not significantly different between patients with infections and those without infections (BMI, 19.9 kg/m² in patients with infection vs. 22.3 kg/m² in patients without infection; $P=0.033$, not shown in the Tables). Death or heart failure admissions were similarly observed in the two groups.

3.4. Antitachycardia therapy history

The incidence of tachyarrhythmia therapy is shown in Table 2. Antitachycardia therapy was initially programmed for the VF zone only in 51 patients and for both the VT and VF zones in 154 patients. The proportions of the zone settings were similar between the two groups (VF zone only, 36% in the single-chamber group vs. 22% in the dual-chamber group; $P=0.086$). Inappropriate shocks due to SVT or sinus tachycardia were similarly observed in patients with single- and dual-chamber group patients. The causes of inappropriate shocks were AF or other SVT ($n=5$) and sinus tachycardia ($n=2$) in the single-chamber group, and AF or SVT ($n=17$), sinus tachycardia ($n=2$), and noise oversensing ($n=2$) in the dual-chamber group. The antitachycardia zone settings were not associated with the incidence of inappropriate shocks ($P=0.167$, not shown in the Tables).

3.5. Initial and subsequent pacing settings

The initial pacing mode in the single-chamber group was VVI, and the pacing rate was set to 40–60 paces per minute (ppm). In the dual-chamber group, 151 patients (89%) had a DDD or DDI mode, including DDD with an algorithm that minimized right ventricular pacing (eight patients), and the lower pacing rate

Table 2
Follow-up data.

	Total (n=205)	Single-chamber (n=36)	Dual-chamber (n=169)	Difference
Follow-up period (months)	56 ± 35	64 ± 39	54 ± 34	P=0.130
Setting changes				
Additional lead insertion, n (%)	13 (6)	4 (11)	9 (5)	P=0.147
Pacing setting change, n (%)	29 (14)	3 (8)	26 (15)	P=0.270
Time from implant to setting change (months), median (Q1–3)	37 (21–80)	89 (89–104)	35 (20–74)	P=0.009*
Adverse events				
Lead malfunction, n (%)	14 (7)	2 (6)	12 (7)	P=0.739
Infection, n (%)	9 (4)	0 (0)	9 (5)	P=0.155
Skin complications, n (%)	14 (7)	4 (11)	10 (6)	P=0.267
Death and hospitalization				
Death (all causes), n (%)	47 (23)	5 (14)	42 (26)	P=0.155
Death <i>d/t</i> cardiac cause, n (%)	12 (6)	1 (3)	11 (7)	P=0.613
Admission <i>d/t</i> heart failure, n (%)	33 (16)	5 (14)	28 (17)	P=0.587
Therapy history				
Initial antitachycardia therapy zone, n (%)	VF only 51 (25) VT 154 (75)	VF only 13 (36) VT 23 (64)	VF only 38 (22) VT 131 (78)	P=0.086
Duration from implant to inappropriate shocks (months), median (Q1–3)	24 (9–61)	56 (13–75)	23 (7–44)	P=0.220
Appropriate shock, n (%)	39 (19)	8 (22)	31 (18)	P=0.625
Appropriate ATP, n (%)	44 (21)	5 (14)	39 (23)	P=0.206
Inappropriate shocks, n (%)	28 (14)	7 (19)	21 (12)	P=0.285
Newly diagnosed SVT, n (%)	50 (24)	8 (22)	42 (25)	P=0.996

ATP, anti-tachycardia pacing; *d/t*, due to; Q1–3, first to third interquartile range; SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.

* Statistically significant.

ranged from 40 to 80 ppm. Eighteen patients in that group (11%) had a VVI mode with a pacing rate of 40 or 50 ppm.

The pacing mode or rate was changed in three patients in the single-chamber group (8%) and 26 in the dual-chamber group (15%) during the follow-up period ($P=0.270$). Among the three patients in the single-chamber group, two underwent an additional atrial lead insertion and the pacing mode was changed to DDD at the time of the generator exchange: one patient with obstructive hypertrophic cardiomyopathy underwent a single- to dual-ICD upgrade 90 months after the initial implantation for short AV interval pacing to reduce the outflow pressure gradient of the left ventricle, and the other patient with paroxysmal AF and an old myocardial infarction had an atrial lead implanted for the overdrive pacing. In the dual-chamber group, the DDD mode was changed to VVI in one patient because of a high atrial pacing threshold. Seven patients developed paroxysmal or persistent AF, and the DDD mode was changed to DDI or VVI. Two patients had the pacing rate decreased for unknown reasons. Although the pacing rate was increased to improve bradycardia or to inhibit premature beats triggering SVT or ventricular arrhythmias in 16 patients, 13 of them were still pacing-independent at the time of study closure.

The interval from implantation to setting change was 89 (Q1–3; 89–104) months in the single-chamber group and 35 (Q1–3; 20–74) months in the dual-chamber group, respectively, indicating that setting changes were attempted at a significantly earlier stage in dual-chamber patients ($P=0.009$).

3.6. Atrial and ventricular pacing dependency

Information on the atrial pacing ratio at the time of implantation and the follow-up closure was available in 34 patients (94%) in the single-chamber group and 161 in the dual-chamber group (95%).

Seventeen patients in the dual-chamber group (11%) had developed atrial-pacing dependency (atrial-pacing ratio $\geq 80\%$) by the end of follow-up, and 13 of them (76%) had developed it

immediately after implantation. A comparison between the patients who were atrial-pacing dependent or independent is shown in Table 3. Patients in both categories were demographically similar. Although the 24-hour ambulatory monitoring data were similar without any sign of bradycardia, the initial pacing rate was programmed significantly higher in patients who were pacing-dependent (61 ppm vs. 49 ppm, $p < 0.001$). Progressive bradycardia requiring atrial pacing in the mid-course of the follow-up was observed only in four patients in the dual-chamber group (2%).

Ventricular pacing dependency (ventricular pacing ratio $\geq 80\%$) by the end of follow-up was observed in 18 patients (7% of all patients). All but one patient were in the dual-chamber group.

4. Discussion

4.1. Main findings

This observational study revealed that: (1) dual-chamber ICDs accounted for more than 80% of the total ICD implantations in two Japanese university hospitals; (2) the incidence of inappropriate shocks and other adverse events were similarly low in the single- and dual-chamber ICD groups; (3) 11% of the dual-chamber ICD recipients developed an earlier atrial-pacing dependency with a higher pacing rate; (4) newly developed pacing dependency seemed to be limited in both groups; and (5) no differences were observed in the incidence of death or heart failure hospitalization in either group.

4.2. Trends for dual- and single-chamber ICD selection

Dual-chamber ICDs were selected four-fold more frequently as compared to single-chamber ICDs in the two university hospitals in Japan. Although similar trends were reported in recent studies from the United States that revealed that dual-chamber ICDs were used 1.5–2 times more frequently [1–3], the preference for dual-

Table 3
Dependent/independent atrial pacing in the dual-chamber group.

	Ap-dependent (n=17)	Ap-independent (n=144)	Differences
Age at implantation, median (Q1–3)	69 (64–77)	66 (56–75)	P=0.163
Follow-up period (months), mean ± SD	53 ± 41	56 ± 33	P=0.725
Female sex, n (%)	7 (41)	40 (28)	P=0.250
Non-ischemic heart diseases, n (%)	11 (65)	83 (58)	P=0.576
Primary prevention, n (%)	5 (29)	47 (33)	P=0.774
Target only VF, n (%)	3 (18)	31 (22)	P=0.711
Preoperative SVT documentation, n (%)	5 (29)	27 (18)	P=0.298
Medication at the time of implantation, n (%)			
Class I antiarrhythmic drug	2 (13)	8 (6)	P=0.294
Class III antiarrhythmic drug	12 (75)	71 (49)	P=0.051
Calcium channel blocker	5 (31)	27 (19)	P=0.0262
Beta blocker	8 (50)	85 (61)	P=0.408
24-hours ambulatory ECG monitoring, mean ± SD			
Total heart beat	96,986 ± 21,885	98,080 ± 18,776	P=0.893
Minimum HR (bpm)	58 ± 14	56 ± 17	P=0.790
Average HR (bpm)	67 ± 15	69 ± 13	P=0.812
Maximum HR (bpm)	84 ± 16	99 ± 23	P=0.172
Pacing setting			
Initial pacing rate (ppm), mean ± SD	61 ± 9	47 ± 8	P<0.001*
Pacing setting change, n (%)	4	21	P=0.335
Newly diagnosed SVT, n (%)	4	36	P=0.833

ECG, electrocardiography; HR, heart rate; Q1–3, first to third interquartile range; SD, standard deviation; SVT, supraventricular tachycardia; VF, ventricular fibrillation.

chamber systems was more distinct among physicians in Japan. There were several demographic differences between the previous studies and our study. While previous cohorts received ICDs primarily for primary prevention, 70% of our cohort received ICDs for secondary prevention. Additionally, while the proportions of NICM in the previous studies were at most 30% [1,3], more than 50% of the patients in our study had NICM. These differences are, however, unable to explain the reason for the selection of dual-chamber ICDs. In our cohort, we intentionally excluded patients with pacing dependency at the time of implantation, as previous studies had shown that approximately 20–40% of patients with dual-chamber ICDs were pacing-dependent [1]. The extent of the preference for a dual-chamber system in Japan far exceeded our expectations.

4.3. Incidence of inappropriate shocks and adverse events

Inappropriate therapy was experienced by 14% of the total cohort during 4.5 years of follow-up (2.9%/yr), which was comparable to that reported in previous studies [11,12]. Although better SVT discrimination is expected from dual-chamber ICDs, whether this is true remains controversial [4,5,12–14]. A recent report from Denmark demonstrated a higher risk of inappropriate therapy associated with dual-chamber ICDs [14]. Conflicting results among the previous studies may be attributed to the different endpoints, namely inappropriate detection or therapies and different programming. Leenhaldt et al. reported that fine-tuning the device programming, such as a higher rate setting of the VT

zone, could have prevented half of the inappropriate therapies that occurred in 11% of their cohort during a mean 22-month follow-up period [15]. Friedman et al. also demonstrated a low incidence of inappropriate shocks (2% in a year) not only in patients with dual-chamber ICDs but also in those with single-chamber ICDs after optimal programming [16]. These recent reports suggest that individualized optimal programming is essential, regardless of the ICD type. As inappropriate shocks are experienced at various times during follow-up, updating the antitachycardia therapy programming might be useful for preventing future inappropriate therapies. Recently, a new type of ICD ventricular lead with a floating atrial sensing bipole has been launched. This lead might offer good sensitivity and specificity for SVT discrimination with no additional implantation time [17].

In this study, device-related infections were observed only in patients with dual-chamber ICDs, in agreement with previous studies [18,19]. Although such a tendency was not observed in recent studies with large numbers of patients [1,3], this difference might be accounted for by the low incidence of infections (0.02–0.6%) with a very short follow-up period (< 90 days).

Overall, mortality, hospital admissions, and incidence of adverse events occurred at similar rates in the two groups. Almendral et al. reported that dual-chamber ICDs were associated with fewer clinically significant adverse events, including all-cause mortality, invasive interventions, hospitalization for cardiovascular causes, inappropriate shocks, and sustained symptomatic atrial tachycardia [13]. In contrast, others reported worse clinical outcomes in dual-chamber ICD patients [1,3]. Our study was not designed to determine the superiority of dual-chamber ICDs or the non-inferiority of single-chamber ICDs, and therefore we cannot draw any such conclusions. At least, no clear advantages of dual-chamber ICDs were observed.

4.4. Additional lead insertion and/or pacing setting changes

Among the 36 patients who received a single-chamber ICD, only two patients (6%) were upgraded to a dual-chamber ICD during the follow-up period, and one patient was still pacing-independent even after the upgrade. Among the 169 dual-chamber ICD recipients, only 11% had developed atrial-pacing dependency. These results seem to suggest that the necessity of an atrial lead for future atrial pacing is very limited in NICM-dominant Japanese ICD patients. Furthermore, the majority of the atrial-pacing dependency that developed shortly after the implantation was due to the higher pacing rate setting. It is possible that these patients became atrial-pacing dependent due to the unnecessarily high pacing rate setting.

In 1997, Anderson et al. reported that atrial pacing reduced the incidence of AF in the setting of sick sinus syndrome [20]. This idea, to some extent, could motivate physicians to set a high atrial pacing rate. Subsequent studies, including the DAVID-II trial, however, failed to demonstrate any superiority of atrial pacing with regard to AF prevention in patients with a low ejection fraction without bradycardia [21,22]. In this study, the incidence of newly developed AF was documented equally in the atrial-pacing dependent and independent patients, in agreement with those studies, suggesting that atrial pacing failed to prevent AF effectively.

Pacing mode and rate changes were attempted at an earlier stage in the dual-chamber group as compared to in the single-chamber group. This difference may simply be due to the programming flexibility that the dual-chamber system provides. Most of the reprogramming was aimed at increasing the atrial-pacing ratio in the dual-chamber group; however, the reprogramming might have been unnecessary because most patients were still pacing-independent after the change.

The lack of advantages of the dual-chamber system on the incidence of adverse events, a limited number of patients who truly required atrial pacing, and a limited impact of pacing reprogramming might suggest that the dual-chamber ICD system has been overused. Careful consideration seems to be necessary for future ICD implantation.

4.5. Limitations

The number of patients in this study was limited. We expect that future analyses using the Japanese registry would be taken place.

Additionally, because of the nature of this observational study, the selection of the ICD type, pacing mode, lower rate settings, and timing/reasons for setting changes were entirely dependent on the physicians' decisions and therefore could be biased. In most cases, the reasons for the decisions were unclear.

We analyzed data from a limited number of preoperative tests. More intensive testing, such as 24-hour ambulatory monitoring or exercise testing, which potentially uncovers chronotropic incompetence, could predict the future development of symptomatic bradycardia.

5. Conclusion

Although dual-chamber ICDs were selected four-fold more frequently in NICM-dominant Japanese ICD cohort that initially had no bradycardia, our study failed to demonstrate a benefit for dual-chamber ICDs over single-chamber ICDs in terms of inappropriate shock reduction and incidence of device-related adverse events. Death or heart failure hospitalization was also equally observed in both the single- and dual-chamber groups. Newly developed atrial-pacing dependency seemed to be limited and could have been overestimated due to the unnecessarily higher pacing rate settings in some patients in the dual-chamber group. Single-chamber ICD seems to be sufficient in most patients. Careful consideration when selecting the type of ICD is required for future implantation.

Conflict of interest

Dr. Soejima is a member of the steering committee for Micra, Medtronic.

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None.

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