



ORIGINAL ARTICLE

A survey of the implementation rate of cardiac rehabilitation for patients with heart disease undergoing device implantation in Japan

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Abstract

Background: The effect of cardiac rehabilitation (CR) on patients undergoing device implantation (DI) for arrhythmias has been reported; however, the implementation status of these patients has not been clarified. This study aimed to verify the implementation status of CR for patients with heart disease who have undergone DI using real-world data.

Methods: This was an observational study using a nationwide administrative database associated with the diagnosis procedure combination (DPC) system in Japan (2014–2018). Subjects were patients with heart disease (70 667 cases) who underwent DI during the above scheduled hospitalization period. The overall rate of CR and the background factors of the subjects were verified.

Results: The CR rate for patients with heart disease who underwent DI during hospitalization was 23%, and the CR rate for patients with comorbid heart failure who underwent DI was only 32%. It was confirmed that progressing age was associated with a higher CR implementation rate. The lower the Barthel index score at the time of admission, the higher the CR implementation rate.

Conclusions: CR was performed for only one-quarter of all the patients during admission for DI and just one-third of the patients for DI with heart failure. Most of these patients were elderly and had a decreased ability to perform activities of daily living. The DPC data are subject to various limitations, and further research is necessary.

KEYWORDS

arrhythmia, cardiac rehabilitation, diagnosis procedure combination database, implantable cardiac devices, Japan

1 | INTRODUCTION

Cardiac disease is the second leading cause of death in Japan, and the number of patients with this condition is increasing. Arrhythmia is a major cause of sudden death among patients with cardiac disease. Treatment for arrhythmia includes drug therapy with antiarrhythmic drugs and non-pharmacotherapies such as catheter ablation and device implantation, and the goal of these treatments is to improve the prognosis and the quality of life of patients. Among these treatments, device implantation, which has been covered by insurance in Japan since 1974, increased to having been used in a total of 79972 cases in 2021, possibly due to the evolution of smaller, lighter implantable devices such as cardioverter defibrillators and cardiac resynchronization therapy devices. Various device implantation procedures are recommended by the JCS/JHRS 2019 guideline on non-pharmacotherapy of cardiac arrhythmias.¹

Conversely, cardiac rehabilitation (CR) is also performed for patients with cardiovascular diseases such as acute myocardial infarction, after cardiac surgery, and after heart failure, and its effectiveness has been recognized. In addition, comprehensive CR involvement not only improves exercise tolerance but also the quality of life and mental health of patients. In Japan, medical treatment is provided according to the medical fee system set by the Ministry of Health, Labour, and Welfare, and CR may be provided to some patients within the scope of the requirements set forth by this system.

The guidelines are yet to be established regarding CR for patients with arrhythmias, who are often restricted in their activities to prevent the occurrence of arrhythmias. In contrast, CR after device implantation is recommended by the Guideline on Rehabilitation in Patients with Cardiovascular Disease,² and the effects of CR on patients undergoing device implantation for arrhythmias have been recently reported.³⁻⁷ Although there have been reports of trends in the dissemination of CR using diagnosis procedure combination (DPC) data in Japan,⁸ only patients hospitalized for myocardial infarction, angina pectoris, heart failure, peripheral vascular disease, and cardiovascular surgery are eligible for the program, while the

implementation status of CR after device implantation has not yet been clarified. In particular, an analysis of the implementation of CR after device implantation using a large database may yield important and useful information reflecting the current status in medical practice. The purpose of this study was to verify the implementation status of CR among patients with heart disease who have undergone device implantation using real-world data.

2 | METHODS

2.1 | Subjects

This was an observational study using a nationwide administrative database associated with the DPC system in Japan. The subjects were patients with heart disease who had undergone device implantation, such as pacemaker implantation, implantable cardiac resynchronization therapy, implantable cardioverter defibrillator therapy, and implantable cardiac resynchronization therapy with a defibrillator. Of the 124882 patients, 70667 were included in the study, with the exclusion of patients under 15 years of age, those having undergone device implantation during unscheduled hospitalization, and those having undergone pacemaker generator replacement surgery (Figure 1).

This study was approved by the institutional review board of the University of Occupational and Environmental Health, Japan (Approval Code: R2-007), which waived the requirement for informed consent.

2.2 | Data source

The DPC is a case-mix patient classification system launched by the Ministry of Health, Labour, and Welfare of Japan in 2002. It contains information about hospitalized patients, such as date of birth, admission, discharge, sex, primary injury (ICD-10 code), complications,

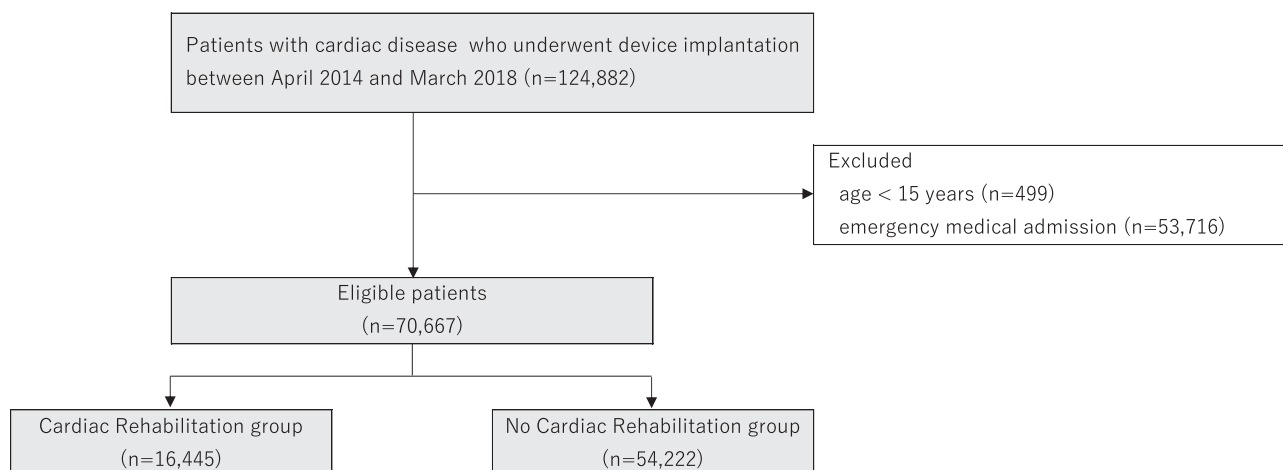


FIGURE 1 Flow diagram of patient recruitment and the study process

comorbidities (using the Charlson comorbidity index), surgical procedures, other key indicators, and patient status at discharge. The database stores the data of 7 million patients annually from more than 1000 participating hospitals.^{9,10} Furthermore, the database includes the data of more than 50% of all acute-care inpatients and 90% of all tertiary-care emergency hospitals in Japan.¹⁰ During this study, we used the case data of patients discharged between April 2014 and March 2018.

2.3 | Statistical analysis

The CR [CR (+)] group was defined as patients for whom some rehabilitation fee was calculated during hospitalization, while the no CR [CR (-)] group was defined as patients for whom no rehabilitation fee was calculated. The unpaired *t*-test and the chi-squared test were used to compare the characteristics of the CR (+) and the CR (-) groups. All statistical analyses were performed using STATA version 16 (Stata). A *p*-value of <.05 was considered statistically significant.

3 | RESULTS

The study included 70 667 patients with cardiac disease who underwent device implantation (Figure 1). Table 1 presents the baseline characteristics of the patients. After device implantation, 16 445 patients (23%) underwent CR. The mean age of patients who underwent CR was 77 years, and the mean age of patients who did not undergo CR was 75 years. The mean age of patients in the CR group was significantly older.

The implanted devices in the CR (+) group included pacemakers in 13 030 patients (79%), implantable cardioverter defibrillator in 958 patients (6%), cardiac resynchronization therapy pacemaker in 581 patients (4%), and cardiac resynchronization therapy defibrillator in 1887 patients (11%), respectively. In the CR (+) group, a smaller proportion of patients received a pacemaker and a larger proportion of patients received cardiac resynchronization therapy compared to the CR (-) group.

Patients in the CR (+) group were more likely to have various comorbid heart diseases or other diseases than patients in the CR (-) group. In addition, patients in the CR (-) group were more prone to atherosclerotic risk factors than patients in the CR (+) group.

The Barthel Index score, which is a measure of activities daily living (ADLs), was more than 85 points for 80% of patients at hospital admission. The mean Barthel Index score of the CR (+) group was 85 points, while that of the CR (-) group was 93 points. The mean Barthel Index score was significantly lower in the CR (+) group.

The total length of hospital stay was more than 8 days for 92% of cases. The total length of hospital stay was more than 8 days for 99% of CR (+) group; however, it was more than 8 days for 90% of the CR (-) group. The total length of the hospital stay was significantly longer for the CR (+) group. The outcome at discharge of patients were home in 92%, transfer to other hospitals in 5%, nursing

home admission in 2%, and death in 1%. The outcome at discharge was 81% home and 13% transfer to other hospitals for the CR (+) group, and 95% home discharge and 3% transfer to other hospitals for the CR (-) group. Of the CR (+) group, a smaller proportion were discharged to the house and a larger proportion had transferred to other hospital compared to the outcomes in the CR (-) group.

Implementation rates of CR according to the hospital volume were comparable when divided into groups of <65 cases per year, 65–125 cases per year, 126–205 cases per year, and 206 or more cases per year.

Table 2 shows the percentage of the status of disease-specific rehabilitation fees in patients who underwent rehabilitation. A total of 69% of patients were undergoing CR fees, and 31% of the patients were undergoing non-CR fees.

4 | DISCUSSION

Although device implantation for patients with heart disease has an important role in the treatment of arrhythmia, the implementation status of CR after device implantation in Japan is not clear yet. During this study, patients undergoing pacemaker replacement had a shorter duration of hospital stay, and patients admitted for device implantation during emergency admissions were excluded from the study because this may have prolonged the duration of the hospital stay and was likely to affect the outcome. This analysis aimed to help clarify the problems that need to be solved, and the results offer important implications for future decisions regarding treatment and medical policies for CR after device implantation among patients with heart disease.

The results of this study indicated that the implementation rate of CR after device implantation in Japan was 23% ($n = 16\,445$), and the implementation rate of CR after device implantation in patients with comorbid heart failure was only 32% ($n = 9262$). It was reported that the implementation rates of CR after myocardial infarction, heart failure, and cardiac surgery in Japan were 66%, 47%, and 77%, respectively.¹¹ The implementation rate of CR after device implantation was low compared to these rates. The rate of CR after device implantation in Japan did not differ according to hospital volume. CR after device implantation is recommended by the 2021 Revision of the Guidelines for Cardiovascular Disease Rehabilitation,² and various meta-analyses have suggested the safety and efficacy of exercise.^{12–17} However, the provision of CR after device implantation in Japan may not be widespread, at least during the perioperative phase, regardless of the hospital volume.

Patients who underwent CR after device implantation were older and had lower Barthel Index scores at hospital admission than those who did not. Moreover, the CR (+) group had longer hospital stays and were transferred to other hospitals at a higher rate than the CR (-) group. These results suggest that for the subjects in the CR (+) group whose abilities to perform ADLs had been declining or were likely to decline before hospital admission, CR was proactively conducted to maintain and improve the physical functions of

TABLE 1 Patient characteristics

	All		CR(+)		CR(-)		p-value
	n	(%)	n	(%)	n	(%)	
Number of patients	70 667		16 445		54 222		
Age (years), mean (SD)	75.2	(11.6)	77.1	(11.7)	74.6	(11.5)	<.001
Sex							
Male	38 302	(54)	8 235	(50)	30 067	(55)	
Female	32 365	(46)	8 210	(50)	24 155	(45)	
Device implantation							<.001
Pacemaker	60 239	(85)	13 030	(79)	47 209	(87)	
Implantable cardioverter defibrillator	3 916	(6)	958	(6)	2 958	(5)	
Cardiac resynchronization therapy	1 614	(2)	581	(4)	1 033	(2)	
Cardiac resynchronization therapy with defibrillator	4 917	(7)	1 887	(11)	3 030	(5)	
Comorbidity of heart disease							<.001
Ischemic cardiomyopathy	15 623	(22)	4 271	(26)	11 352	(21)	
Valvular disease	5 329	(8)	2 754	(17)	2 575	(5)	
Heart failure	28 588	(41)	9 262	(56)	19 326	(36)	
Cardiomyopathy	4 662	(7)	1 471	(9)	3 191	(6)	
Atherosclerotic risk factors							<.001
Hypertension	34 093	(48)	7 776	(47)	26 317	(49)	
Diabetes mellitus	634	(1)	191	(1)	443	(1)	
Dyslipidemia	10 831	(15)	2 302	(14)	8 529	(16)	
Smoking history	20 043	(28)	4 333	(26)	15 710	(29)	
Medication							<.001
Beta blockers use	8 459	(12)	3 006	(18)	5 453	(10)	
Amiodarone use	4 426	(6)	1 938	(12)	2 488	(5)	
Comorbidity							<.001
Charlson comorbidity index: 0	24 985	(35)	4 110	(25)	20 875	(38)	
Charlson comorbidity index: 1	25 770	(37)	6 381	(39)	19 389	(36)	
Charlson comorbidity index: ≥ 2	19 912	(28)	5 954	(36)	13 958	(26)	
Activities of daily living at admission							
Barthel index (points), mean (SD)	89.0	(25)	84.7	(31)	93.3	(20)	<.001
Length of stay							<.001
Total length of hospital stay: 1-7	5 377	(8)	184	(1)	5 193	(10)	
Total length of hospital stay: ≥ 8	65 290	(92)	16 261	(99)	49 029	(90)	
Duration of hospital stay (days), mean (SD)	23.7	(54)	33.6	(95)	13.8	(14)	<.001
Discharge destination							<.001
Home	65 110	(92)	13 350	(81)	51 760	(95)	
Other hospital	3 486	(5)	2 118	(13)	1 368	(3)	
Nursing home	1 561	(2)	633	(4)	928	(2)	
Death	477	(1)	328	(2)	149	(0)	
Other	32	(0)	16	(0)	16	(0)	
Number of cases at the individual centers							
Hospital volume: 1-65	18 231	(26)	4 213	(26)	14 018	(26)	.769
Hospital volume: 66-125	16 666	(24)	3 623	(22)	13 043	(24)	.783
Hospital volume: 126-205	18 490	(26)	4 080	(25)	14 410	(26)	.779
Hospital volume: 206	17 280	(24)	4 529	(27)	12 751	(24)	.738

TABLE 2 Status of disease-specific rehabilitation fee

	Number of cases	(%)
Cardiac rehabilitation fees	11 367	69.1
Non-cardiac rehabilitation fees	5078	30.9

more severely challenged patients. CR after device implantation was regarded as an assistive intervention to be implemented with the aim of hospital discharge. However, it is necessary to recognize that CR after device implantation is, in fact, a treatment with established evidence of improving the long-term prognosis. Many patients have restricted activity and reduced exercise tolerance before device implantation and a gradual decline in physical activity after device implantation.¹⁸ CR after device implantation has been reported to improve not only physical function but also exercise tolerance, quality of life, mental health, and the re-hospitalization rate of patients with full independence performing ADLs.^{19–32} Furthermore, the implementation of CR is also important for evaluating chronotropic incompetence during exercise. During this study, the rate of those hospitalized for more than 8 days was more than 90% even among the CR (-) group after device implantation. As length of hospital stay is sufficiently long, CR should be recommended for most patients after device implantation, regardless of whether they can independently perform ADLs. We believe that CR during hospitalization is feasible and will contribute to reducing anxiety and increasing activity to improve the life expectancy after discharge, thus maximizing the benefits of device implantation surgery.

Additionally, regarding the medical fee calculation for rehabilitation after device implantation, 69% ($n = 11\,367$) of patients were charged a CR fee and 31% ($n = 5078$) of patients were charged for other disease-specific rehabilitation fees. If not considered CR, then there is no comprehensive multidisciplinary intervention or safe practice under ECG monitoring supervision, and the patient benefits described by previous studies may not be expected. Rehabilitation is differentiated according to disease by the Japanese medical fee system, and each disease has its own criteria. This situation can be attributed to the fact that the current medical fee calculation conditions for left ventricular ejection fraction less than 40% and brain natriuretic peptide more than 80 pg/mL are criteria assumed mainly for patients with myocardial infarction and heart failure. The subjects of this study were patients with stable cardiac disease who were admitted for the purpose of device implantation; therefore, these criteria for calculation of CR do not apply here. The current criteria, which exclude stable cardiac disease, may have resulted in the lower rate of CR after device implantation. It will be necessary to collect data on CR after device implantation to provide more evidence.

This study had some limitations. First, it was a retrospective, database-based cohort study; thus, limited data were available. Therefore, the specific treatment and other details provided during CR were unknown. Second, this study did not distinguish between CR before and CR after device implantation. Patients who underwent CR before device implantation had lower ventricular function and heart failure before hospital admission, which may have affected the

length of the hospital stay and outcomes after implantation. Third, the DPC data used during this study were large Japanese administrative data, but they represented a subset of all Japanese hospitals; thus, it is necessary to make careful generalizations. Finally, because this study only examined the implementation rate of CR after device implantation, we were unable to determine its effectiveness. In accordance with the purpose of this study, only univariate analysis was performed with no multivariate analysis; hence, the effects of confounding factors may not have been excluded. In the future, it will be necessary to verify the effectiveness of CR after device implantation in Japan by performing longitudinal and interventional studies based on long-term data.

5 | CONCLUSIONS

CR was performed for only one-quarter of all patients after device implantation and just one-third of the patients for device implantation with heart failure. Most patients were elderly and had impaired ability to perform ADLs. These results suggest that the subjects in this study underwent general rehabilitation to maintain and improve their physical function. Additionally, the calculation criterion for CR in Japan may have caused the lower rate of CR after device implantation. It is necessary to promote the importance of CR after device implantation and improve its implementation rate. The DPC data are subject to various limitations, and further research is necessary.

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FUNDING INFORMATION

Not applicable.

CONFLICT OF INTEREST

The authors have no conflicts of interest to disclose.

ETHICS APPROVAL STATEMENT

This study was approved by the institutional review board of the University of Occupational and Environmental Health, Japan (Approval Code: R2-007), and the research protocol followed the guidelines of the Declaration of Helsinki.

CLINICAL TRIAL REGISTRATION

Not Applicable.

PATIENT CONSENT STATEMENT

This study was deemed that written informed consent from the participants was unnecessary by the institutional review board.

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