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Differences in patient characteristics, clinical practice and outcomes of cardiac implantable electric device therapy between Japan and the USA: a cross-sectional study using data from nationally representative administrative databases

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ABSTRACT

Objectives To identify differences in patient characteristics, clinical practice and outcomes of cardiac implantable electronic device (CIED) therapy between Japan and the USA.

Design A cross-sectional study.

Setting Nationally representative administrative databases from Japan and the USA containing hospitalisations with first-time implantations of pacemakers, implantable cardioverter-defibrillators (ICD) and cardiac-resynchronisation therapy with or without defibrillators (CRTP/CRTD).

Participants Patients hospitalised with first-time implantations of CIEDs.

Outcome measures In-hospital mortality, in-hospital complication and 30-day readmission rates.

Results Overall, 107 339 (median age 78 (71–84), 48 415 women) and 295 584 (age 76 (67–83), 127 349 women) records with CIED implantations were included from Japan and the USA, respectively. Proportion of women in defibrillator recipients was lower in Japan than in the USA (ICD, 21% vs 28%, p<0.001; CRTD, 24% vs 29%, p<0.001). Length of stay after CIED implantation was longer in Japan than in the USA for all device types (conventional pacemaker, 8(7–11) vs 1 (1–3) days, p<0.001; leadless pacemaker, 5 (3–9) vs 2 (1–5) days, p<0.001; ICD, 8 (7–11) vs 1 (1–3) days, p<0.001, CRTP, 9 (7–13) vs 2 (1–4) days, p<0.001; CRTD, 9 (8–14) vs 2 (1–4) days, p<0.001). In-hospital mortality after CIED implantation was similar between Japan and the USA ((OR) (95% CI), conventional pacemaker 0.58 (0.83 to 1.004); ICD 0.77 (0.57 to 1.03); CRTP 0.85 (0.51 to 1.44); CRTD 1.11 (0.81 to 1.51)), except that after leadless pacemaker implantation in Japan was lower than that in the USA (0.32 (0.23 to 0.43)). 30-day readmission rates were lower in Japan than in the USA for all device types (conventional

pacemaker 0.55 (0.53 to 0.57); leadless pacemaker 0.50 (0.43 to 0.58); ICD 0.54 (0.49 to 0.58); CRTP 0.51 (0.42 to 0.62); CRTD 0.57 (0.51 to 0.64)).

Conclusions International variations in patient characteristics, practice and outcomes were observed. In-hospital mortality after CIED implantation was similar between Japan and the USA, except in cases of leadless pacemaker recipients.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Using representative nationwide administrative databases, differences in patient characteristics, clinical practices and outcomes between Japan and the USA were reported.

⇒ However, despite extensive coding conversions between Japan and the USA, coding patterns could be influenced by differences in healthcare reimbursements.

⇒ Precise clinical information such as procedural details or pacemaker settings was not available.

⇒ Rates of readmission were underestimated in the Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination (JROAD-DPC) group because patients admitted to one hospital would not be consistently tracked when readmitted to another hospital using the JROAD-DPC, while patients admitted to different hospitals in the same state would be tracked in the Nationwide Readmission Database.

⇒ An event adjudication board did not evaluate if the complications or readmissions were related to the cardiac implantable electronic device implantation.

INTRODUCTION

Cardiac implantable electronic devices (CIEDs), including conventional pacemakers, leadless pacemakers and implantable

cardioverter-defibrillators (ICDs), and cardiac resynchronisation therapy, with and without defibrillators (CRTD and CRTP, respectively), improve patient quality of life and survival, and are increasingly implanted worldwide.[1–5] Better understanding of the international differences in patient backgrounds, healthcare systems and clinical outcomes using real-world large databases is important for better design, interpretation and implementation of clinical studies to improve healthcare practice in each country; however, to our knowledge, no study has directly compared patient characteristics or clinical outcomes post-CIED implantation among different countries.

Recently, administrative claims databases have been frequently used to investigate evidence in contemporary clinical practice.[6–8] Unlike clinical trials or registries conducted by specialists working in academic centres, claims databases provide comprehensive data that include a wide range of patients from a variety of hospitals.

Therefore, we obtained individual patient data from nationally representative administrative databases from two different countries that adopt different healthcare systems: Japan, where all citizens are covered by public insurance, and the USA, where healthcare coverage is provided through a combination of private and public health insurance (online supplemental files 1 and 2). Indications for CIED implantation are similar in both the countries,[1–5] except for some differences in CRT implantation (online supplemental file 3).

In this study, we investigated international differences in patient characteristics, clinical practice, costs and outcomes of CIED implantation therapy between Japan and the USA.

METHODS

Data sources
We obtained administrative electronic health records of Japan and the USA. These nations were selected because of the availability of a high-quality source of nationally representative electronic health records. Characteristics of and differences in the databases are summarised in online supplemental file 2.

Japan: The Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination (JROAD-DPC) is an administrative inpatient database that covered over 800 Japanese Circulation Society certified training hospitals during the study period.[8–12] The JROAD-DPC includes hospitalisation records with detailed patient demographics, weight, height, diagnoses based on the 10th revision of the International Statistical Classification of Diseases (ICD-10) codes, diagnostic and therapeutic procedures, drugs, length of stay, total charges, in-hospital outcomes and rehospitalisation during the same fiscal year.

The JROAD-DPC contains six categories of diagnoses based on the ICD-10 codes. Furthermore, detailed names of diagnoses that cannot be identified using ICD-10 codes alone were also listed. One diagnosis was coded for each of the following: 'main diagnosis', 'admission-precipitating diagnosis', 'most resource-consuming diagnosis' and 'second most resource-consuming diagnosis'. Additionally, a maximum of 10 diagnoses were coded for each of the following: 'comorbidities present at the admission' and 'conditions arising after admission'. The validity of the diagnoses of JROAD-DPC was proven in a previous study.[9] To adjust with the Nationwide Readmission Database (NRD), which does not contain a variable differentiating conditions present before or developed after admission, baseline characteristics were collected using diagnoses in any category in the JROAD-DPC group. Complications were identified from diagnosis of 'conditions arising after admission' or procedures performed after CIED implantation. Body mass index (BMI) was calculated using weight and height.

The USA: Data were obtained from the US Agency for Healthcare Research and Quality, which includes the Healthcare Cost and Utilisation Project and NRD.[13 14] The NRD includes hospitalisation data from 30 geographically dispersed States, accounting for 60% of all US hospitalisations with all payer types. The NRD is binned per discharge data during one calendar year, and uses a patient-level ID to track patient admissions to any hospital within the same state during the calendar year, and the discharge weight was provided to obtain the national estimates. Each admission record in the NRD contains patient demographics, length of stay, total charges, diagnoses and procedures performed during hospitalisation based on the ICD-10-Clinical Modification/Procedure Coding System. The NRD does not contain a variable differentiating conditions present before and developed after admission.

The ICD-10 codes used are summarised in online supplemental file 4.

Study population
The flow chart presented in figure 1 presents the initial participants, exclusion criteria and final participants. We included admissions with CIED implantation, which were either conventional pacemakers, leadless pacemakers, ICDs, CRTPs or CRTDs. Transvenous ICDs (TV-ICDs) and subcutaneous ICDs (S-ICDs) could be distinguished only in JROAD-DPC. For conventional pacemakers, ICDs, CRTP or CRTDs, only cases in which the generator and leads were implanted on the same day were included. Records with discharge in the last month of the fiscal year in each country were excluded to ensure a 30-day follow-up after discharge. CIED implantations in outpatient setting were not included in the study.

Clinical variables
Data on frequently occurring comorbidities among patients requiring CIED implantations (congestive heart failure (CHF), ischaemic heart disease (IHD), atrial fibrillation (AF), ventricular tachycardia (VT), ventricular fibrillation (VF), atrioventricular block (AVB), sick sinus syndrome (SSS), diabetes, hypertension, chronic
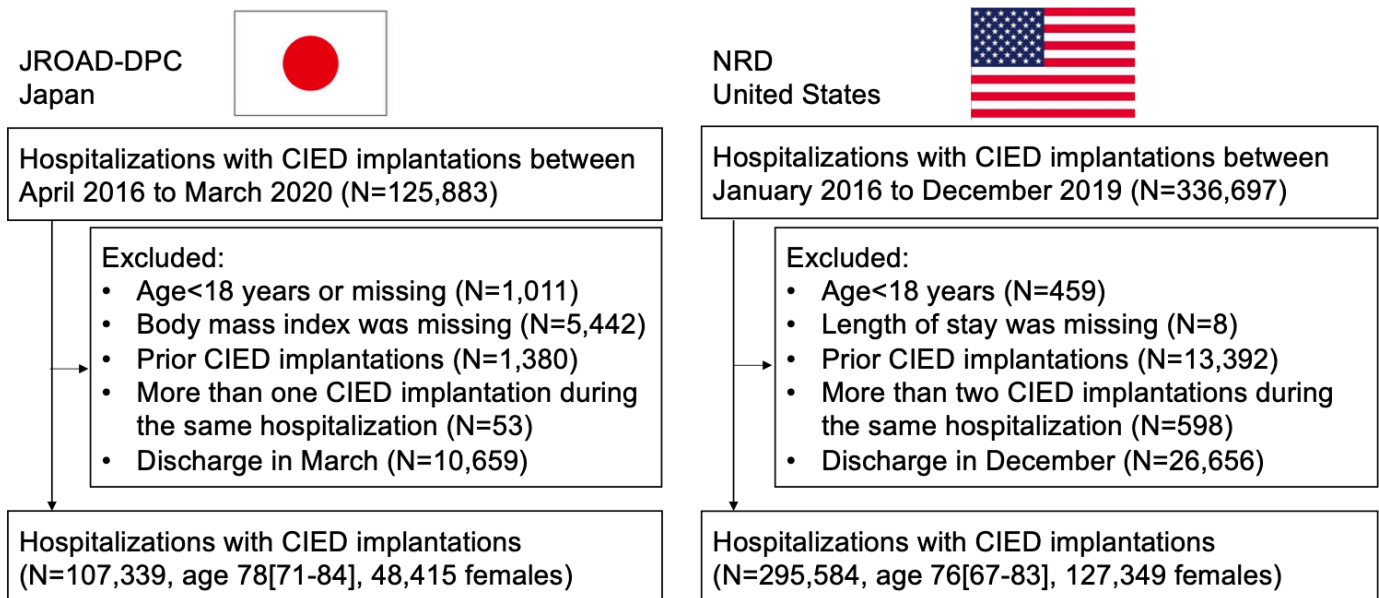
JROAD-DPC
Japan

NRD
United States

Hospitalizations with CIED implantations between April 2016 to March 2020 (N=125,883)

Excluded:
- Age<18 years or missing (N=1,011)
- Body mass index was missing (N=5,442)
- Prior CIED implantations (N=1,380)
- More than one CIED implantation during the same hospitalization (N=53)
- Discharge in March (N=10,659)

Hospitalizations with CIED implantations (N=107,339, age 78[71-84], 48,415 females)

Hospitalizations with CIED implantations between January 2016 to December 2019 (N=336,697)

Excluded:
- Age<18 years (N=459)
- Length of stay was missing (N=8)
- Prior CIED implantations (N=13,392)
- More than two CIED implantations during the same hospitalization (N=598)
- Discharge in December (N=26,656)

Hospitalizations with CIED implantations (N=295,584, age 76[67-83], 127,349 females)

Figure 1 Study flow chart. CIED, cardiac implantable electronic devices; JROAD-DPC, Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination; NRD, Nationwide Readmission Database.

kidney disease (CKD), dialysis treatment) were extracted using relevant diagnostic codes (online supplemental file 4). Patients with obesity were identified using diagnostic codes in the NRD, while BMI higher than 30 was defined as obesity in JROAD-DPC records.

In-hospital outcomes

The primary endpoint was all-cause in-hospital mortality after CIED implantation. Other endpoints were cardiac effusion and/or tamponade, haemothorax, pneumothorax and red blood cell (RBC) transfusions. The in-hospital complication rate was a composite of all complications and in-hospital deaths. Procedure codes used to extract complications are summarised in online supplemental file 4. The length of hospital stay, length of stay after CIED implantation and total charge during hospitalisation were identified. For JROAD-DPC, the conversion rate of ¥110 for US$1 was considered, based on the average exchange rate during the study period.

Outcomes related to 30-day readmission

All-cause readmissions and heart failure readmissions, and readmissions with CIED-related infections within 30 days of discharge were also analysed. Only the first elective or non-elective readmission within 30 days of discharge from the index admission for CIED implantation was included in the analysis. In JROAD-DPC, we defined readmission due to heart failure or CIED-related infection as a readmission record coded with heart failure or CIED-related infections in the 'main diagnosis', 'admission-precipitating diagnosis' or 'most resource-consuming diagnosis'. In the NRD, heart failure or CIED-related infectious readmission was defined as a readmission record coded with diagnosis of heart failure or CIED-related infections. The definition of infections related to CIED implantation is listed in online supplemental file 4.

Statistical analysis

Categorical data are presented as frequencies and percentages, and continuous data are presented as medians (IQR). The χ^2 test and Wilcoxon rank-sum test were used to compare categorical and continuous data, respectively. Cochran-Armitage trend test was performed to analyse annual trends for in-hospital mortality, overall complication and 30-day readmission. For NRD, the discharge weight was used to obtain the national estimates, which were used for national annual trend analyses. To compare (1) in-hospital mortality rate, (2) in-hospital complication rate between Japan and the USA for each CIED implantation, multivariable logistic regression analyses adjusted for age, sex and 11 clinically relevant characteristics (CHF, IHD, AF, VT, VF, AVB, SSS, diabetes, CKD, dialysis treatment and obesity) were performed after merging individual patient data from JROAD-DPC and NRD. Multivariable logistic regression analysis, adjusted for the occurrence of complications during the index admission and the same variables used for analysis of in-hospital mortality, was performed in patients who survived the index admission for CIED implantation to identify factors associated with 30-day all-cause readmission. History of hypertension was not included in the analyses due to collinearity. All statistical comparisons were two sided, with statistical significance set at p<0.05. All analyses were performed using STATA V.16.0 (StataCorp).

Patient and public involvement

None.

RESULTS

A total of 107 339 (median age 78 (71–84), 48 415 women) and 295 584 (median age 76 (67–83), 127 349 women)

hospitalisation records with CIED implantations were included from the JROAD-DPC and the NRD, respectively (figure 1).

Baseline characteristics and outcomes of CIED recipients

Baseline characteristics of the patients are presented in table 1, online supplemental files 5 and 6.

Compared with NRD, the proportion of women in JROAD-DPC was comparable in conventional pacemaker recipients (49% vs 48%), leadless pacemaker recipients (45% vs 45%), and CRTP recipients (41% vs 39%), but was >5% lower in ICD recipients (21% vs 28%) and CRTD recipients (24% vs 29%). In leadless pacemaker recipients, the proportion of patients aged >85 years was higher in Japan than in the USA (39% vs 26%) (figure 2). In the NRD, 17% of leadless pacemaker recipients were aged ≤65 years, while only 3.3% were aged ≤65 years in the Japanese population. While the proportion of defibrillator recipients aged >85 years was small in the JROAD-DPC (TV-ICD, 1.6%; S-ICD, 0.2% and CRTDs, 1.4%), 3.2% of ICD recipients and 5.4% of CRTD recipients were aged >85 years in the NRD (figure 2, online supplemental file 7). The proportion of patients with CRTP aged >85 years was lower in the JROAD-DPC group than in the NRD group (12% vs 19%). The proportion of patients with history of IHD, diabetes, CKD and obesity was higher in the USA than in Japan for all device types.

The length of stay after CIED implantation was longer in Japan than in the USA for all device types (table 2).

In case of CIEDs other than leadless pacemakers, more than 75% of the patients were hospitalised for ≥7 days in Japan. Conversely, in the USA, the median length of stay after conventional pacemaker or ICD implantation was 1 day, and after CRTP or CRTD implantations was 2 days. In leadless pacemaker recipients, the median length of stay after implantation was shorter than that in conventional pacemakers in Japan (5 (3–9) vs 8 (7–11) days), but not in the USA (1 (1–3) vs 2 (1–5) days).

Medical costs during hospitalisation were 3.5–9.4 fold higher in the USA than in Japan, with the largest difference in leadless pacemaker recipients (JROAD-DPC vs NRD: 15 325 (13 324–21 376) vs 143 670 (94 698–240 708) US dollars) and the smallest difference in CRTD recipients (61 672 (58 373–69 955) vs 217 757 (148 002–326 230)).

The in-hospital mortality and in-hospital complication rates with leadless pacemaker implantation were lower in the JROAD-DPC group than in the NRD group (1.4% vs 5.6% and 4.3% vs 12%, respectively). The proportion of patients requiring RBC transfusion after device implantation was higher in JROAD-DPC than in NRD among conventional pacemaker, ICD, CRTP and CRTD recipients. The rates of 30-day readmission for any cause were lower in the JROAD-DPC than in the NRD for all devices (conventional pacemakers, 6.1% vs 12%; leadless pacemakers, 7.5% vs 19%; ICDs, 7.0% vs 15%; CRTPs, 7.6% vs 15% and CRTDs, 8.0% vs 16%).

In-hospital mortality and overall complication rates

In-hospital mortality rate and complication rate among leadless pacemaker recipients in NRD were relatively high, 5.6% and 12%, respectively, but they showed decreasing trends overtime (P for trend <0.001 and <0.001, respectively) (online supplemental file 8). There were decreasing or increasing trends in some other device recipients, but absolute change of the proportion during the study period was as small as within 2.0%. In multivariable logistic regression analysis, leadless pacemaker implantation in Japan was associated with a decreased risk of in-hospital mortality (OR 0.32, 95% CI 0.23 to 0.43) (figure 3). In other devices, in-hospital mortality rates were similar between the JROAD-DPC and NRD. Moreover, CIED implantation in Japan was associated with a decreased risk of in-hospital complications in conventional pacemaker (OR 0.58, 95% CI 0.55 to 0.61), leadless pacemaker (OR 0.41, 95% CI 0.34 to 0.50) and ICD (OR 0.50, 95% CI 0.43 to 0.58) recipients. The in-hospital complication rate was not significantly different between Japan and the USA among CRTP and CRTD recipients.

Thirty-day readmission

In multivariable logistic regression analysis, all-cause 30-day readmission rates were significantly lower in Japan than in the USA (figure 3) in all device types. Furthermore, 30-day readmission due to heart failure or infections related to CIEDs was significantly lower in Japan than in the USA.

Factors predicting all-cause 30-day readmission for any cause were generally similar across CIEDs; female sex, history of heart failure, IHD, AF and CKD were associated with an increased risk of 30-day readmission for all device types (online supplemental file 9). Occurrence of complications during the index admission was associated with higher risk of 30-day readmission among conventional PM, ICD and CRTD but not among leadless PM and CRTP recipients.

DISCUSSION

To our knowledge, this study is the first attempt to compare patients who underwent CIED implantation using nationally representative claims databases across countries, providing insights into differences in patient characteristics, length of stay, medical cost, in-hospital clinical outcomes and 30-day readmission rate. We have used in-hospital mortality and all-cause 30-day readmission as our measures of outcomes, because these were the most reliable outcomes, when comparing the outcomes obtained from two different databases from different countries.

Differences in patient characteristics

In defibrillator recipients (ICD or CRTD), the proportion of women was lower in Japan than in the USA. Women have been under-represented in most randomised controlled trials or registries of ICD therapy, partly

Table 1 Baseline characteristics of patients

Baseline characteristics	Conventional pacemaker		Leadless pacemaker		ICD		CRTP		CRTD	
	JROAD-DPC	NRD	JROAD-DPC	NRD	JROAD-DPC	NRD	JROAD-DPC	NRD	JROAD-DPC	NRD
	N=85 561	N=210664	N=3989	N=7764	N=10 605	N=46 113	N=1995	N=8781	N=5189	N=22 262
Age, years, median (IQR)	80 (74–85)	78 (70–85)	83 (78–88)	79 (70–86)	65 (52–73)	66 (56–74)	78 (71–83)*	77 (69–84)*	70 (63–76)	71 (62–78)
Female	42 267 (49)	101 216 (48)	1801 (45)†	3524 (45)†	2269 (21)	12 663 (28)	814 (41)‡	3420 (39)‡	1264 (24)	6526 (29)
Heart failure	40 352 (47)	59 215 (28)	1656 (42)	3831 (49)	5982 (56)	30 868 (67)	1890 (95)	6159 (70)	4799 (92)	19 324 (87)
Ischaemic heart disease	21 826 (26)	93 932 (45)	665 (17)	3841 (50)	5012 (47)	33 295 (72)	686 (34)	5394 (61)	2045 (39)	15 846 (71)
Atrial fibrillation	25 339 (30)	88 965 (42)	1874 (47)	4982 (64)	2249 (21)	16 555 (36)	709 (36)	5059 (58)	1664 (32)	10 007 (45)
Ventricular tachycardia	1241 (1.5)	9004 (4.3)	42 (1.1)	540 (7.0)	5778 (55)	24 200 (53)	99 (5.0)	779 (8.9)	2472 (48)	7023 (32)
Ventricular fibrillation	328 (0.4)	1354 (0.6)	8 (0.2)	120 (1.5)	3811 (36)	9341 (20)	14 (0.7)§	123 (1.4)§	404 (7.8)¶	1907 (8.6)¶
Atrioventricular block	47 171 (55)	106 392 (51)	1430 (36)**	2985 (38)**	402 (3.8)	3197 (6.9)	567 (28)	4304 (49)	677 (13)	4407 (20)
Sick sinus syndrome	32 201 (38)	98 258 (47)	1443 (36)	3174 (41)	419 (4.0)	3 749 (8.1)	180 (9.0)	1967 (22)	172 (3.3)	1974 (8.9)
Diabetes	19 699 (23)	74 655 (35)	979 (25)	2993 (39)	2816 (27)	17 766 (39)	602 (30)	3314 (38)	1752 (34)	9697 (44)
Hypertension	67 052 (78)	177 813 (84)	3264 (82)	6589 (85)	9 144 (86)	37 663 (82)	1911 (96)	7607 (87)	5047 (97)	19 017 (86)
Chronic kidney disease	8894 (10)	58 982 (28)	587 (15)	3177 (41)	923 (8.7)	13 398 (29)	343 (17)	3308 (38)	744 (14)	8610 (39)
Dialysis	3229 (3.8)	4313 (2.0)	340 (8.5)††	750 (9.7)††	433 (4.1)	1172 (2.5)	108 (5.4)	169 (1.9)	243 (4.7)	617 (2.8)
Obesity	3190 (3.7)	35 465 (17)	126 (3.2)	1313 (17)	672 (6.3)	10 055 (22)	78 (3.9)	1552 (18)	282 (5.4)	4524 (20)

Categorical data are presented as frequencies and percentages.
P values for comparison between the JROAD-DPC and the NRD were <0.001 otherwise listed below.
*P=0.51.
†P=0.80.
‡P=0.13.
§P=0.01.
¶P=0.07.
**P=0.01.
††P=0.04.
CIED, cardiac implantable electronic devices; CRTD, cardiac resynchronisation therapy with defibrillator; CRTP, cardiac resynchronisation therapy without defibrillator; ICD, implantable cardioverter-defibrillator; JROAD-DPC, Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination; NRD, Nationwide Readmission Database.
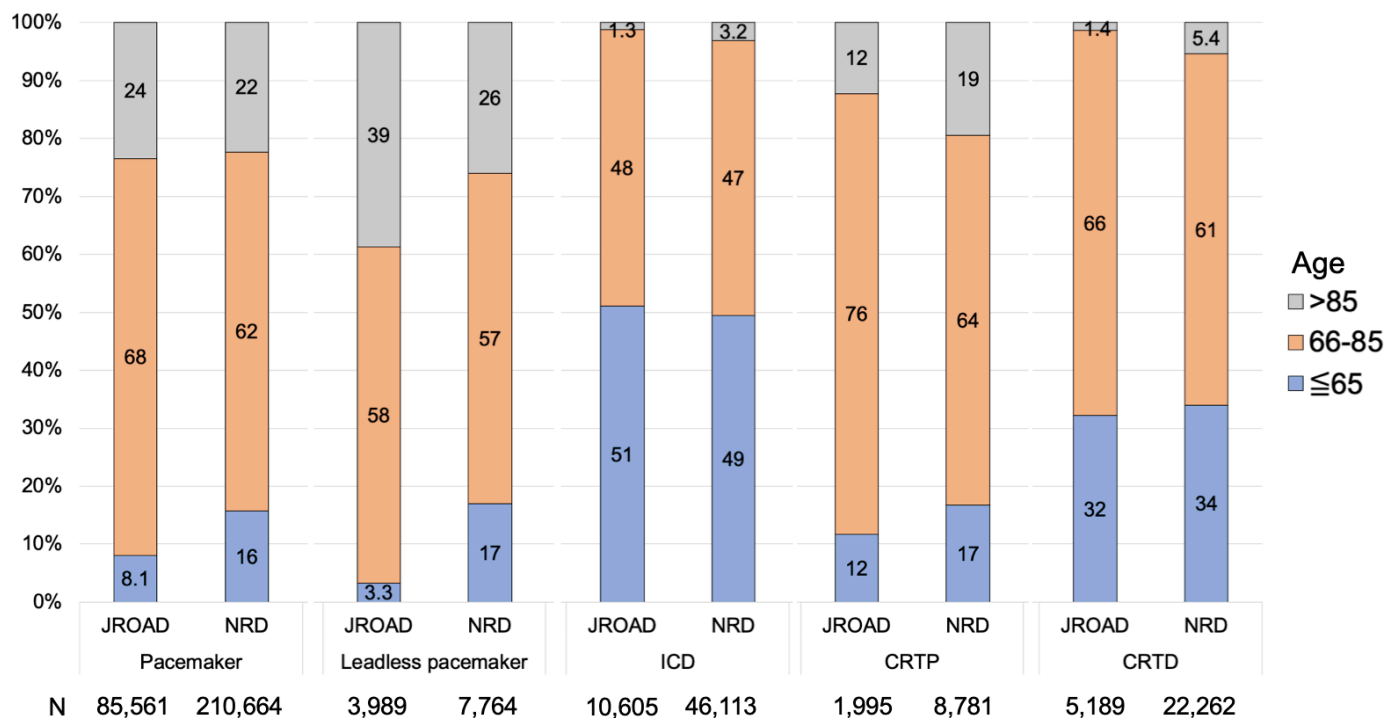
Figure 2 Proportion of patients in each age group by device type in JROAD-DPC and NRD. CIED, cardiac implantable electronic devices; CRTD, cardiac resynchronisation therapy with defibrillator; CRTP, cardiac resynchronisation therapy without defibrillator; JROAD-DPC, Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination; ICD, implantable cardioverter-defibrillator; NRD, Nationwide Readmission Database.

because of a lower incidence of sudden cardiac death or underlying coronary artery disease; the most common cause of spontaneous cardiac death had been fatal ventricular arrhythmia.[15–20] However, women also underwent less appropriate therapy for VT/VF than men, and thus, were less likely to be referred for ICD therapy.[12 13] Further investigation is warranted to determine why the female proportion was lower in defibrillator recipients in Japan than in the USA.

In NRD, 1467 (3.2%) ICD and 1205 (5.4%) CRTD recipients were aged >85 years, whereas only few Japanese defibrillator recipients were aged >85 years. According to the latest guidelines, ICD is a class-I recommendation for patients with history of haemodynamically unstable VT or VF if survival >1 year is expected.[3 4 21] Proportion of patients undergoing defibrillator implantation for primary prevention has been reported to be low in Japan; this might be related to the fact that proportion of very elderly patients who received ICD or CRTD was low.[22] ICD therapy benefits in the very elderly population should be further investigated; however, age alone should not preclude ICD implantation. Compared with the USA, proportion of patients with a history of IHD was lower in Japan, which is consistent with previous reports of lower prevalence in Japan than that in the Western countries.[23–25]

Differences in in-hospital outcomes

After adjustment for patient comorbidities, in-hospital mortality post-CIED implantation was similar between Japan and the USA, except for leadless pacemaker

recipients. Consistent with previous reports,[26 27] in-hospital mortality and complication rates for leadless pacemaker recipients in NRD were relatively high, but they revealed a decreasing trend overtime. These changes are likely due to the operator's learning curve, which has been reported as an important factor for quality of leadless pacemaker implantation.[28] Since insurance coverage for leadless pacemakers was introduced later in Japan than in the USA or Europe, it is possible that implantations in Japan were performed with caution with regard to patient selection and complication prevention. Unlike in Japan, where almost all CIED implantations are performed in an inpatient setting, approximately half of the leadless pacemaker implantations are performed in outpatient settings in the USA, which are not included in the NRD.[29] Pacemaker recipients in inpatient settings might have a greater number of comorbidities than those in outpatient settings, leading to greater risk of complications.

The proportion of patients receiving RBC transfusion after CRTD implantation was higher in Japan than in the USA except for leadless pacemaker recipients. In JROAD-DPC, more than 50% of the CIED recipients were administered an anticoagulant or antiplatelet agent before or during hospitalisation; this proportion was >70% among CRT recipients. Although the proportion of underweight patients in Asia is higher, doses of anticoagulant or antiplatelet drugs are not specified depending on the body weight; therefore, a higher risk of bleeding was reported in underweight individuals on anticoagulant therapy.[30 31] Further investigation is needed to determine

Table 2 Outcomes in CIED recipients

	Conventional pacemaker		Leadless pacemaker		ICD		CRTP		CRTD	
	JROAD-DPC	NRD	JROAD-DPC	NRD	JROAD-DPC	NRD	JROAD-DPC	NRD	JROAD-DPC	NRD
In-hospital outcome	N=85 561	N=210664	N=3989	N=7764	N=10 605	N=46 113	N=1995	N=8781	N=5189	N=22 262
Overall complication	2410 (2.8)	9807 (4.7)	172 (4.3)	890 (12)	211 (2.0)	2 034 (4.4)	106 (5.3)*	467 (5.3)*	252 (4.9)†	1 262 (5.7)†
In-hospital death	716 (0.8)	2 039 (1.0)	57 (1.4)	437 (5.6)	59 (0.6)	425 (0.9)	22 (1.1)‡	109 (1.2)‡	61 (1.2)§	274 (1.2)§
Cardiac tamponade	251 (0.3)	3 312 (1.6)	27 (0.7)	264 (3.4)	28 (0.3)	933 (2.0)	9 (0.5)	180 (2.0)	27 (0.5)	547 (2.5)
Pneumothorax or haemothorax	353 (0.4)	2 795 (1.3)	3 (0.1)	57 (0.7)	27 (0.3)	421 (0.9)	6 (0.3)	107 (1.2)	16 (0.3)	281 (1.3)
RBC transfusion after CIED implantation	1364 (1.6)	2 301 (1.1)	113 (2.8)¶	263 (3.4)¶	120 (1.1)**	375 (0.8)**	84 (4.2)	103 (1.2)	178 (3.4)	255 (1.2)
Length of stay										
Length of stay, days	11 (9–18)	4 (2–7)	9 (5–20)	6 (3–12)	17 (10–28)	6 (3–10)	15 (10–27)	5 (3–9)	17 (11–30)	6 (3–10)
Length of stay after CIED implantation, days	8 (7–11)	1 (1–3)	5 (3–9)	2 (1–5)	8 (7–11)	1 (1–3)	9 (7–13)	2 (1–4)	9 (8–14)	2 (1–4)
Medical cost, US dollars††	15 636 (14 050–18 468)	84 797 (55 044–141 431)	15 325 (13 324–21 376)	143 670 (94 698–240 708)	48 163 (44 276–59 480)	190 528 (126 961–292 300)	28 362 (25 698–35 039)	145 773 (97 680–232 611)	61 672 (58 373–69 955)	217 757 (148 002–326 230)
Readmission	N=84 845	N=208625	N=3932	N=7327	N=10 546	N=45 688	N=1 973	N=8 672	N=5 128	N=21 988
30-day all cause readmission	5224 (6.1)	24 262 (12)	299 (7.5)	1361 (19)	743 (7.0)	6922 (15)	152 (7.6)	1286 (15)	415 (8.0)	3424 (16)
30-day heart failure readmission	783 (0.9)	10 689 (5)	61 (1.5)	814 (11)	116 (1.1)	5 117 (11)	56 (2.8)	965 (11)	149 (2.9)	2 915 (13)
30-day readmission due to CIED-related infection	533 (0.6)	2992 (1.4)	15 (0.4)	234 (3.2)	96 (0.2)	765 (1.7)	50 (1.0)‡‡	144 (1.6)‡‡	18 (0.9)	369 (1.7)

Categorical data are presented as frequencies and percentages.

P values for comparison between the JROAD-DPC and the NRD were <0.001 otherwise specified below.

*P=0.99.
†P=0.02.
‡P=0.61.
§P=0.74.
¶P=0.11.
**P=0.001.
††For the JROAD-DPC, conversion rate of 110 Japanese yen equivalent to US$1 US dollar was used based on the average exchange rate during the study period.
‡‡P=0.02.

CIED, cardiac implantable electronic devices; CRTD, cardiac resynchronisation therapy with defibrillator; CRTP, cardiac resynchronisation therapy without defibrillator; ICD, implantable cardioverter-defibrillator; JROAD-DPC, Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination; NRD, Nationwide Readmission Database; RBC, red blood cell.
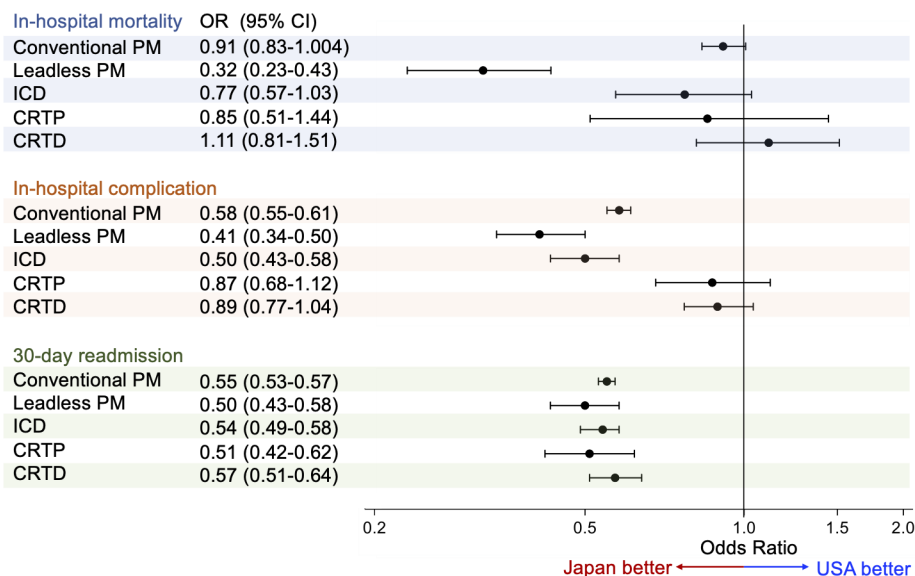
In-hospital mortality	OR (95% CI)
Conventional PM	0.91 (0.83-1.004)
Leadless PM	0.32 (0.23-0.43)
ICD	0.77 (0.57-1.03)
CRTP	0.85 (0.51-1.44)
CRTD	1.11 (0.81-1.51)
In-hospital complication	
Conventional PM	0.58 (0.55-0.61)
Leadless PM	0.41 (0.34-0.50)
ICD	0.50 (0.43-0.58)
CRTP	0.87 (0.68-1.12)
CRTD	0.89 (0.77-1.04)
30-day readmission	
Conventional PM	0.55 (0.53-0.57)
Leadless PM	0.50 (0.43-0.58)
ICD	0.54 (0.49-0.58)
CRTP	0.51 (0.42-0.62)
CRTD	0.57 (0.51-0.64)

Odds Ratio — Japan better ← → USA better (axis: 0.2, 0.5, 1.0, 1.5, 2.0)

Figure 3 Adjusted ORs for outcomes after CIED implantations in JROAD-DPC. Adjusted ORs to estimate in-hospital mortality, in-hospital complication and 30-day readmission after CIED implantations in JROAD-DPC (NRD as the reference standard). CIED, cardiac implantable electronic devices; CRTD, cardiac resynchronisation therapy with defibrillator; CRTP, cardiac resynchronisation therapy without defibrillator; JROAD-DPC, Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination; ICD, implantable cardioverter-defibrillator; NRD, Nationwide Readmission Database; PM, pacemaker.

other factors associated with RBC transfusion post-CIED implantation.

Differences in length of stay after CIED implantation and 30-day readmissions

Occurrence of complications during the index admission was associated with higher risk of 30-day readmission among conventional PM, ICD and CRTD but not among leadless PM and CRTP recipients. In leadless PM and CRTP recipients, comorbidities that could lead to a decline in general condition, such as a history of heart failure or CKD, were identified as factors associated with 30-day readmissions. In these populations, readmissions seemed to be closely related to the patients' original condition rather than to complications that arose during the index admission.

The length of hospital stay after CIED implantation was significantly longer in Japan than in the USA for all device types. In Japan, hospitalisation cost calculation includes the length of hospital stay, with the hospital receiving perdiem reimbursement for up to 30 days for pacemaker and ICD implantations and 60 days for CRT implantation.[12] If additional medical care was needed, the coverage period is even longer. The amount of medical expenses paid by patients is capped depending on their financial situation, and in most cases, hospitalisations involving CIED implantation exceed this limit. Hence, the amount paid by patients does not change depending on the length of hospital stay. Therefore, both hospitals and patients have little financial incentive to shorten hospital stays. Based on the reports that most of the potentially fatal complications occur within 3 days,[32] and that same-day discharge after CIED implantation was not associated with higher risk of complications or readmission compared with

overnight hospital stay,[33] hospitalisation period for CIED implantation in Japan is very long. In Japan, patients are usually discharged after confirming that the wound has healed, and that heart failure did not develop due to the physiologic change by a new CIED or an invasion by implantation surgery. Incidence of 30-day readmission due to heart failure or infections related to the devices was lower in Japan compared with the USA. Further investigations are needed to confirm if the low readmission rate in Japan is related to the longer inpatient monitoring post-CIED implantation.

Study limitations

Our study has limitations. First, despite extensive coding conversions between Japan and the USA, coding patterns could be influenced by differences in healthcare reimbursements. Second, complications may be missed or inadequately documented in administrative claims. For example, certain device-related complications such as elevated pacing thresholds do not have specific diagnostic codes. Third, any sudden death occurring outside the hospital before readmission was not included in the analysis. Fourth, precise clinical information, such as echocardiography/laboratory data, procedural details or pacemaker setting information, was not available. Therefore, we were unable to explore the impact of technical factors on the endpoints. Fifth, complication rates might be overestimated in the NRD group because the NRD does not have variable differentiating conditions present before admission and developed during hospitalisation. However, we assumed that the conditions analysed as complications, such as cardiac tamponade, pneumothorax or haemothorax, at the time of admission were rare. Sixth, rates of readmission were underestimated in

the JROAD-DPC group because patients admitted to one hospital would not be consistently tracked when readmitted to another hospital using the JROAD-DPC. Meanwhile, patients admitted to different hospitals in the same state would be tracked in the NRD. Seventh, an event adjudication board did not evaluate if the complications or readmissions were related to the CIED implantation. Finally, CIED implantations in outpatient settings were not included, and outpatient clinic visit after discharge were not analysed.

CONCLUSIONS

Among inpatient defibrillator recipients, the proportion of women and very elderly were lower in Japan compared with the USA. Length of stay post-CIED implantation was significantly longer in Japan than in the USA. In-hospital mortality post-CIED implantation was similar between Japan and the USA, except among leadless pacemaker recipients. 30-day readmission rates were significantly lower in Japan. Further investigations are needed to verify if the low readmission rate in Japan is related to longer inpatient monitoring post-CIED implantation.

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