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Original article

## In-hospital complications after implantation of cardiac implantable electronic devices: Analysis of a national inpatient database in Japan

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### ABSTRACT

**Background:** Complications after implantation of cardiac implantable electronic devices (CIEDs), including permanent pacemakers (PMs) and other CIEDs, are associated with increased patient mortality and healthcare costs. This study aimed to investigate overall complications after implantation of CIEDs, analyze the associated risk factors, and compare complications after PM implantation between hospitals that performed only PM implantations (PM-only hospitals) and hospitals that implanted other CIEDs, as well as PMs (all-CIED hospitals).

**Methods:** Using the Japanese Diagnosis Procedure Combination database, we retrospectively collected data on inpatients who underwent CIED implantation from 1 July 2010 to 31 March 2014.

**Results:** A total of 77,324 patients were identified, including 64,951 patients with PMs and 12,373 with other CIEDs. The overall incidences of in-hospital complications were 2.5% in patients with PMs and 2.1% in those with other CIEDs. The incidences of pocket infections, pocket problems, device- and lead-related problems, and sepsis were 0.9%, 0.5%, 0.4%, and 0.3%, respectively. The crude proportion of complications after PM implantation was higher in the PM-only hospitals than in the all-CIED hospitals (3.1% vs. 2.1%), but the multivariable logistic regression analysis showed no significant difference (odds ratio, 1.29; 95% confidence interval, 0.99–1.68).

**Conclusion:** After adjusting for patient backgrounds, the occurrence of complications after PM implantation was not significantly different between patients in PM-only hospitals and those in all-CIED hospitals.

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### Introduction

Cardiac implantable electronic devices (CIEDs), including permanent pacemakers (PMs), implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy devices with or without defibrillators (CRTDs or CRTPs), are implanted globally, and their use is increasing [1].

Many studies on complications after CIED implantation have focused on infections [2–5] and few have examined non-infectious complications [6]. A previous study also showed that non-infectious complications including hematomas or lead dislocation requiring reoperation were associated with an increased

probability of infectious complications [7]. Moreover, complications after CIED implantation were associated with increased mortality and healthcare costs [8]. It is therefore important to take overall complications into consideration in the perioperative management of patients undergoing CIED implantation.

Previous studies have shown mixed results in terms of the factors associated with CIED complications [5,9–17]. One reason for this is geographical variations in practice patterns worldwide. In Japan, PMs can be implanted at any hospital with a cardiac department and a lot of PM implantations are performed at these hospitals. We defined PM-only hospitals as those that implanted PMs, but no other CIEDs. In contrast, CRTPs, ICDs, and CRTDs can only be implanted at advanced hospitals that satisfy strict criteria, including performing more than 50 ablations per year and employing more than two full-time cardiac surgeons, and we defined these hospitals as all-CIED hospitals. It remains unclear if

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the incidences of overall complications after PM implantation differ between PM-only hospitals and advanced hospitals.

Using a Japanese national inpatient database, this study aimed to (i) investigate in-hospital complications after the implantation of CIEDs in a nationwide clinical setting, (ii) analyze the risk factors associated with CIED complications, and (iii) compare in-hospital complications after the implantation of PMs between PM-only and all-CIED hospitals.

## Methods

### Data source

We analyzed data from the Japanese Diagnosis Procedure Combination database. Details of this database have been described elsewhere [18]. In brief, the database contains information on inpatients collected from approximately 1000 hospitals across Japan, accounting for approximately 7 million patients annually, which represents approximately 50% of all acute-care inpatients in Japan. The database includes administrative claims and discharge abstract data, including the following information: hospital identification number; patient sex and age; body weight and height; dates of hospitalization and discharge; emergency or elective admission; main diagnoses, pre-existing comorbidities at admission, and complications during hospitalization, coded with the International Classification of Diseases, Tenth Revision (ICD-10) codes and text data in Japanese; procedures performed; drugs used; and discharge status.

Informed consent was not obtained because of the anonymous nature of the data. The present study was approved by the Institutional Review Board at The University of Tokyo.

### Study protocol

We extracted data on inpatients who underwent CIED implantation, including implantation of a PM, CRTD, ICD, or CRTD from 1 July 2010 to 31 March 2014. We excluded patients who received any type of surgery before CIED implantation, and those who received non-cardiac surgery after CIED implantation. We also excluded patients who had complications at the time of the admission.

We identified post-procedural complications for each patient using the following ICD-10 codes and text data in Japanese: sepsis (A40,A41); infective endocarditis (I30,I31,I32,I33,I38); pocket infection (T793,T814,T941); lead infection (T814); pocket trouble [combination of hematoma and vascular injury (T810,T812) and anastomotic failure (T813)]; lead perforation (T820); pneumothorax (T812); and mechanical device/lead trouble (T821). We defined the composite outcome as any of the above complications after admission.

We also examined patient age, sex, body mass index (BMI), use of anti-thrombotic drugs (either anti-coagulant or anti-platelet drug), use of a temporary pacemaker, status of admission (emergency admission), and use of hemodialysis. BMI was categorized as underweight (<18.5 kg/m<sup>2</sup>), normal weight (18.5–24.9 kg/m<sup>2</sup>), overweight (25.0–29.9 kg/m<sup>2</sup>), or obese (≥30.0 kg/m<sup>2</sup>) according to the World Health Organization definition [19]. Patient age was categorized as ≤49 years, 50–59 years, 60–69 years, 70–79 years, or ≥80 years. We also extracted data on comorbidities at admission, including diabetes mellitus (ICD code, E10–14) [20] and chronic obstructive pulmonary disease (J43.9) [21], which were reported to be associated with complications in previous studies.

Hospital volume was defined as the annual number of device implantations performed at each hospital, and was categorized

into tertiles (low-, medium-, or high-volume). Hospital volume was calculated separately for PMs and other CIEDs.

### Statistical analysis

Patient characteristics and in-hospital complications were presented for all patients and for those receiving PMs or other CIEDs. Categorical variables were expressed as numbers and proportions. The proportions of complications were compared between patients receiving PMs and those receiving other CIEDs using  $\chi^2$ , *t*-tests, and Fisher's exact tests. We performed multivariable logistic regression analyses to examine the associations between overall in-hospital complications in all patients, those receiving PMs, and those receiving other CIEDs, separately, and various factors, including patient characteristics (age, BMI, sex), comorbid conditions (diabetes mellitus, hemodialysis, chronic obstructive pulmonary diseases), use of antithrombotics, temporary pacemaker, and status of admission (emergency or elective admission). For all-patient analysis, we also included device type (PM and other CIED). For PM-group analysis, we included hospital type (PM-only hospitals or all-CIED hospitals) and hospital volume for PM. For the analysis of patients with other CIED, we included hospital volume for other CIED. We fitted a generalized estimating equation with the regression models to adjust for within-hospital clustering.

All statistical analyses were conducted using IBM SPSS version 22 (IBM Corp., Armonk, NY, USA). A *p*-value <0.05 was considered significant.

## Results

We identified 91,784 patients who underwent CIED implantation during the study period. We excluded the following: (i) 10,915 patients who had additional surgery before CIED implantation or non-cardiac surgery after implantation; (ii) 2431 patients who had complications at admission; and (iii) 765 patients with invalid data. We included a total of 77,673 eligible patients (65,223 patients with PM alone, 7167 with ICD, 1093 with CRTD, and 4190 with CRTD) in this study. We divided the eligible patients into the patients receiving PMs (*n* = 65,223) and those receiving other CIEDs (*n* = 12,450).

The patient characteristics for all patients, those receiving PMs and those receiving other CIEDs are summarized in Table 1. More than 70% of the patients were aged ≥70 years. Less than 4% had hemodialysis, about 20% had diabetes, and <1% had chronic obstructive pulmonary disease. Overall, 43% of the study population was administered at least one antithrombotic drug, and >58% of those receiving other CIEDs had at least one antithrombotic drug. Among patients receiving PM about 40% had their implantation at PM-only hospitals.

Table 2 shows the characteristics of patients receiving PM implantation among PM-only hospitals and all-CIED hospitals. PM-only hospitals were more likely to be small, have more elderly emergent patients, and use temporary PMs.

Details of the complications are shown in Table 3. Among infectious complications, pocket infection occurred most frequently, followed by sepsis. Among non-infectious complications, the most prevalent complication was pocket trouble (including hematoma and vascular injury), followed by device- and lead-related problems. Lead perforation and pneumothorax occurred in 0.1% and 0.2%, respectively. The incidence of overall complications was higher in patients receiving PMs than in those receiving other CIEDs (2.5% vs. 2.1%, *p* = 0.003). Table 4 shows the details of complications in patients receiving PM implantation according to hospital type. The crude proportion of complications after PM

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