



Original Article

Incidence of cardiac implantable electronic device infections and migrations in Japan: Results from a 129 institute survey

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ABSTRACT

Background: We conducted a survey of the infection burden associated with the implantation of cardiac implantable electronic devices (CIEDs) in Japan.

Methods: The institutes were selected using annual device implantation data provided by Medtronic Japan Co., Ltd. The data sampling period was from January 1 to December 31, 2013. Institutes were classified into Group P, at which only pacemakers were implanted, and Group A, at which other CIEDs were implanted. Group P was further classified into three sub-groups by implantation number. The infection rate was compared between groups using logistic regression analysis.

Results: A total of 129 of 138 institutes responded. The annual infection rate was 1.12% for overall CIEDs. The institute at which 15–29 pacemakers were implanted had a high infection rate (2.11%). No statistically significant difference was observed (adjusted $p=0.1131$). The overall migration rate was 0.50%. Complete removal of the CIED system was performed in 55.8% of patients who underwent implantation.

Conclusions: This survey was the first on CIED infection and migration in Japan. The CIED infection rate (1.12%) was similar to that previously reported. A high infection rate (2.77%) was observed in the infection experienced institutes.

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1. Introduction

Cardiovascular implantable electronic device (CIED) treatment is indispensable as cardiac treatment, and the implantation number of CIEDs has significantly increased over the past several years [1–3]. Increase in implantable cardioverter defibrillator (ICD) implantation is responsible for the increasing number of CIED implantations [4]. With this trend, augmenting CIED infection has become concerning. CIED infection has detrimental effects on mortality and increases financial burden [3–5]. Therefore, guidelines for the management of CIED infection were recently updated [5,6]. When a patient is diagnosed with CIED infection, even if the infection is restricted locally to the pocket, complete removal of the CIED system is required by guidelines [5,6]. However, a nationwide study on CIED infection has not been conducted in Japan. This survey is the first to investigate the current status of CIED infection and migration in Japan.

2. Methods

From October 27, 2014 to December 12, 2014, a survey on device infection and migration was conducted in Japan. The number of cases of device infection or migration after CIED implantation was assessed retrospectively. Respondents did not necessarily undergo CIED implantation. The institutes at which pacemakers, ICDs, cardiac resynchronization therapy pacemakers (CRT-Ps), or cardiac resynchronization therapy defibrillators (CRT-Ds) were implanted from January 1 to December 31, 2013 were selected using annual device implantation data provided by Medtronic Japan Co., Ltd. Patients who reported infection(s) during that period, and the infection or migration incidents that occurred from January 1, 2013 and December 12, 2014 were included in this study. The implant was not categorized based on whether it was a new or replacement device. All applicable events were counted regardless of manufacturer. The sample size was calculated based on the following assumptions. An 80% power at a significance level of 0.05 was the goal. The estimated annual infection rates are 0.6% for pacemakers [9], and for all other CIEDs, the estimated annual infection rate is 2.8%, which is derived from the infection rate of each device type and annual implant number. Estimation accuracy of the 95% confidence interval was set at $\pm 0.6\%$ for the pacemaker group and $\pm 2.8\%$ for all other CIEDs group. After applying an attrition rate of

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20%, 2052 and 432 subjects were found to be required to meet the above criteria. With regard to data collection, referred cases were excluded. Specific information collected was treatment for infection and complications due to migration. The questionnaire is shown in [Table 1](#), and the original language was Japanese.

Statistical analyses were performed with SAS Ver. 9.3. A *p*-value less than 0.05 was used to assess statistical significance.

3. Results

3.1. Institutes

A total of 138 institutes from each geographical area in Japan were randomly chosen. One hundred twenty-nine institutes responded to the survey. The response rate was 93.5%. A total of 84.5% (109 sites) of institutes at which only pacemakers were implanted and 15.5% (20 sites) at which other CIEDs were implanted responded to the survey. The total number of implantation cases was 3840: 3331 pacemaker cases (86.7%) and 509 other CIED cases (13.3%).

3.2. Infection burden

The duration that the survey covered was 1 year from January 1, 2013 to December 31, 2013. New device implantation and replacement were not distinguished in the analysis. We identified 43 cases of device infection. The overall infection rate was 1.12% (95% CI: 0.812–1.505); however, the rate was 2.77% at the sites with more experience with implantation.

The infection rates according to the device type were 1.08% in pacemakers and 1.38% in other CIEDs ([Table 2](#)). The infection rates according to institute type were 1.18% in the institutes at which only pacemakers were implanted and 1.05% in the institutes at which other CIEDs were implanted ([Table 3](#)).

Infection occurred within 1 year of implantation in 35 cases (81.4%) and more than 1 year in 8 cases (18.6%). Regarding treatments for infection, complete CIED system removal was performed in 24 cases (55.8%), generator removal in 11 cases (25.6%), administration or prolongation of antibacterial drugs or both in 7 cases (16.3%), and movement of the pocket to the opposite side in 1 case (2.33%) ([Fig. 1](#)).

Table 1
Survey questionnaire.

Question
The number of the CIED implantations in 2013
The number of CIED infection and migration.
The time infection occurred, within 1 year or more than 1 year
Treatment for infection
Complication due to migration
Treatment for migration

CIEDs: ICD, CRT-D, CRT-P.

Table 2
Comparison of the infection rate between pacemakers and other CIEDs.

Devices	Operation numbers	Infection numbers	Infection rate (%)	Exact-95% CI (min-MAX)	RR	<i>p</i> -Value ^a
Pacemakers	3331	36	1.081	0.758–1.493	1.27	0.5005
Other CIEDs ^b	509	7	1.375	0.555–2.813		
Total	3840	43	1.120	0.812–1.505		

CI, Confidence interval; RR, relative risk.

^a Fisher exact test.

^b other CIEDs: ICD, CRT-D, CRT-P.

3.3. Device migration

Nineteen device migration cases were identified. The overall migration rate was 0.50% (95% CI: 0.298–0.772). There were 19 complications due to device migration. These complications included lead dislodgment in 14 cases (73.7%), and perforation, lead fracture, and infection in 1 case each (15.8%), and an unknown complication in 2 cases (10.5%). Migration was treated by lead repositioning in 10 cases (52.6%), whole CIED system extraction and re-implantation in 2 cases (10.5%), and observation alone in 3 cases (15.8%). Lead extraction with an additional procedure was performed in 2 cases (10.5%).

4. Discussion

4.1. Quality and quantity of the survey

To review implant status as a whole, private annual device implantation data provided by Medtronic Japan Co., Ltd., were used in this survey. The private data may introduce bias; however, the data showed good correlation in the annual implantation number with the data from the Japan Arrhythmia Device Industry Association. The geographical area coverage rate of this survey was 93.6% (44 out of 47 prefectures). The variance of the annual implantation numbers among the institutes was 1–221. Out of randomly selected sites sampled from the above data, 93.5% of the institutes replied to the questionnaire. Therefore, the findings of this survey are well representative of the entire Japanese CIED infection rate, and this study is the first of its kind in Japan.

The data did not include personal data such as patients' demographics, physicians' experience, and details on the time of infection occurrence.

4.2. Infection burden

The overall infection rate was 1.12% and it was similar or lower than that previously reported in the USA and Europe [1,4,8,10,11]. In the European survey [7], the number of infection-free institutes was 27.1% (13/48). In this survey, 76.7% of the enrolled institutes did not experience device infection, and this rate is higher than that observed by the European survey. Nevertheless, the data from this survey cannot be compared with that from previous studies in the USA and Europe, because the background of the enrolled institutes may be different. One difference was that this survey included institutes with a low implant volume. The limitation of the European survey [7] was the low number of small volume institutes. The same survey showed that at 62.5% of the enrolled institutes, more than 200 devices were implanted per year. In contrast with this finding, less than 50 devices were implanted at 82.2% of the institutes in this survey and at 9.30% of the institutes, only 1 device per year was implanted. These findings reflect the number of small volume institutes in Japan. In a small volume institute, only 1 case of infection may reflect a high infection rate, e.g., the infection rate would be 100% at an institute at which only 1 implantation per year is performed if the patient contracts infection.

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