



Original Article

Lead extractions in patients with cardiac implantable electronic device infections: Single center experience

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ABSTRACT

Background: Lead extraction using laser sheaths is performed mainly for cardiac implantable electronic device (CIED) infections. However, there are few reports concerning the management of CIED infections in Japan.

Methods and results: Lead extraction procedures were performed in 183 patients targeting 450 leads (atrial leads: 170, ventricular: 181, implantable cardioverter-defibrillators (ICDs): 79, and coronary sinus: 20). One hundred twenty patients (65.6%) presented with pocket infections without the presentation of an endovascular infection. Blood cultures were positive at least once in 63 patients (34.4%). Complete procedure success was achieved for 437 leads (97.1%) while partial removal occurred in nine, and failure in four leads. Major complications directly related to the procedure occurred in five patients (2.7%). Two of the four patients with a cardiac tamponade required a surgical repair. All patients received intravenous antibiotics, at least, one week after the procedure. Pocket or systemic infections were successfully controlled in 181 patients (98.9%). Coagulase-negative *staphylococci* (30.1%) and *Staphylococcus aureus* (37.1%) were the most common causes of CIED infections.

Conclusion: The current status of CIED infections in Japan seems to be similar to that previously reported from foreign countries. The optimal treatment of CIED infections involves the complete explantation of all hardware, followed by antibiotic therapy.

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1. Introduction

Roughly 40 years have passed since permanent pacemakers (PMs) became available in clinical medicine. More recently, implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy (CRT) have been introduced. The rate of device implantation is increasing with the aging of the general population and the indications are expanding [1]. Similar to other prosthetic materials, infections complicate a small proportion of patients with these devices. With the increase in device

implantation, the incidence of device infections has also been growing at a faster rate. We introduced the excimer laser system in 2009 for the transvenous removal of the implanted leads. However, there have been few reports [2–4] concerning the management of cardiac device infections. The purpose of this study was to review our single center experience and to clarify the current status of cardiac implantable electronic device (CIED) infections in Japan.

2. Material and methods

2.1. Study patients

All 183 patients with CIED infections who underwent a device and transvenous lead removal using an excimer laser system in Kokura Memorial Hospital from July 2009 through March 2014

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were reviewed. A CIED infection was defined using previously described criteria [5]. Briefly, a pocket infection was defined as the presence of local warmth, erythema, swelling, edema, pain, or discharge from the device pocket, or an erosion or impending erosion of the device. A bloodstream infection was defined as occult bacteremia despite appropriate antibiotic therapy. Device-related endocarditis was defined according to the Duke criteria [6]. Blood cultures were obtained from all patients on the day of admission; cultures were also obtained from the generator and the tip of the lead at the time of device removal. All patients gave their written informed consent. The indications for a lead extraction were decided based on the Heart Rhythm Society Expert consensus statement [5]. The baseline clinical characteristics, pathogens, results of the lead extraction procedures, and follow-up results were analyzed.

2.2. Lead extraction procedure

The procedures were performed in the cardiac catheterization laboratory or operation room under general or venous anesthesia according to the patient's condition. Careful monitoring with surface electrocardiograms, invasive arterial blood pressure monitoring, and transesophageal or intracardiac echocardiography were performed in all patients. There was cardiac surgical backup and stand-by percutaneous cardio-pulmonary support.

The lead extraction procedure has been previously described [7]. Briefly, the lead was prepared by inserting a locking stylet into the inner coil lumen when possible. Then, a suture was tied onto the insulation and the locking stylet. Next, the laser sheath was advanced over the lead. A laser application was performed at binding sites and the laser sheath was gradually advanced from one binding site to another until the tip of the lead was reached. Once abutting the myocardium, a combination of traction and counter-traction was performed and the lead was freed.

The definition of the outcome has been previously reported in the consensus statement [5]. Complete procedural success was defined as the "removal of all targeted leads and all lead material from the vascular space, with the absence of any permanently disabling complications or procedure-related deaths." Clinical success was defined as the "removal of all targeted leads and lead material from the vascular space, or retention of a small portion of the lead that did not negatively impact the outcome goals of the procedure." Failure was defined as the "inability to achieve either complete procedural or clinical success, or the development of any permanently disabling complications or procedure-related deaths."

Major complications were defined as "any of the outcomes related to the procedure that were life threatening or resulted in death, and in addition, any unexpected events that caused a persistent or significant disability, or any events that required a significant surgical intervention to prevent any of the outcomes listed above." Minor complications were defined as "any undesired events related to the procedure that required a medical intervention or minor procedural intervention to remedy, and did not persistently or significantly limit the patient's function, nor threaten their life or cause death".

2.3. Statistical analysis

The continuous variables are expressed as the mean \pm SD and were compared using a Student's *t*-test. A $P < 0.05$ was considered significant.

3. Results

3.1. Baseline characteristics

Two hundred twenty-two lead extraction procedures were performed between July 2009 and March 2014. One hundred eighty-three patients (mean 72.2 ± 14.3 years old, 131 males) had explantations of the devices, leads, or both due to infection complications. The patient characteristics are shown in Table 1. One hundred twenty patients (65.6%) presented with signs and symptoms of an infection involving the device pocket without the presentation of an endovascular infection. Blood cultures were positive at least once in 63 patients (34.4%). Twenty-six of 63 patients were diagnosed with infectious endocarditis according to Duke's criteria [6]. Among this cohort, 136 patients (74.3%) had a permanent PM, 45 (24.6%) had an ICD, and 19 (10.4%) had a biventricular PM with or without an ICD. The mean duration of the device implant and device explantation ranged from 2 to 417 months (91.9 ± 83.7 months). The mean duration of the implantation or last device replacement and device explantation was 30.5 ± 36.2 months. Twenty-seven patients (14.8%) had an early explantation (< 3 months), 45 (24.6%) had a late explantation (4–12 months), and 111 (60.7%) had a delayed explantation (> 12 months). Eighty (43.7%) patients underwent a device explantation due to a late infection more than 24 months after the device-related procedure.

Eighty-seven patients (47.5%) had a previous surgical intervention without full removal of all the hardware. Twenty-two patients received a device implantation on the ipsilateral side even though the infection was active in the PM pocket.

3.2. Lead extraction procedure

One to five leads were implanted in each patient, and a total of 450 leads were extracted. Twenty-five leads were extracted by manual traction; the remaining leads were extracted using an excimer laser sheath. The summary data of the extracted leads are shown in Table 2. Among the 450 leads extracted, the positions of the leads were the right atrium ($n=170$, 37.8%), coronary sinus ($n=20$, 4.4%), and right ventricle ($n=260$, 57.8%), and included 79 ICD leads. The mean implant duration was 88.5 ± 77.6 months in total, with 92.3 ± 76.4 months in the right atrium, 34.9 ± 27.6 months in the coronary sinus, and 102.5 ± 90.1 months in the right ventricle; 62.4 ± 35.5 were ICD leads Table 3.

Complete procedural success was achieved with 437 leads (97.1%), while partial removal in nine (2.0%), and failure with four

Table 1
Summary data of the baseline characteristics of the study patients.

Summary data of the patients	
No. of patients	183
Gender	Male: 131, female: 52
Male, <i>n</i> (%)	131 (72)
Age (years)	72.2 ± 14.3
BMI (kg/m ²)	22.1 ± 3.8
WBC	5970 ± 1620
Cr (mg/dl)	1.1 ± 1.4
CRP (mg/dl)	1.1 ± 2.8
Device type, <i>n</i> (%)	
Pacemaker	136 (74.3)
CRT-P	2 (1.1)
ICD	28 (15.3)
CRT-D	17 (9.3)

BMI: body mass index, WBC: white blood cell, Cr: serum creatinine, CRP: C-reactive protein, CRT: cardiac resynchronization therapy, P: pacing, ICD: implantable cardioverter defibrillator, D: defibrillator

Table 2
Summary data of 450 extracted leads.

	Number	Implant duration (Mo)
No. of extracted leads	450	88.5 ± 77.6
Atrial leads	170	92.3 ± 76.4
Active fixation atrial lead	53	
Passive fixation atrial lead	113	
Others	4	
Ventricular leads (except ICD)	181	102.5 ± 90.1
Active fixation ventricular lead	46	
Passive fixation ventricular lead	106	
Others	29	
Coronary sinus lead	20	34.9 ± 27.6
ICD lead	79	62.4 ± 35.5
Dual coil active fixation ICD lead	63	
Dual coil passive fixation ICD lead	10	
Single coil active fixation ICD lead	4	
Single coil passive fixation ICD lead	2	

Mo: months.

Table 3
Summary data of the pathogens isolated from the study patients.

Organism	No.	%
Aerobic Gram-positive		
Coagulase-negative <i>Staphylococcus aureus</i>	55	30.1
Methicillin-sensitive <i>Staphylococcus aureus</i>	48	26.2
Methicillin-resistant <i>Staphylococcus aureus</i>	20	10.9
<i>Streptococcus agalactiae</i>	1	0.5
<i>Enterococcus faecalis</i>	1	0.5
<i>Corynebacterium</i>	8	4.4
<i>Propionibacterium acnes</i>	3	1.6
Gram-Negative		
<i>Pseudomonas aeruginosa</i>	3	1.6
<i>Escherichia coli</i>	2	1.1
<i>Proteus mirabilis</i>	1	0.5
Anaerobes		
	4	2.2
Fungi		
<i>Candida</i> species	2	1.1
Others		
<i>Mycobacterium</i> species	2	1.1
Culture Negative		
	33	18

leads (0.9%) occurred. The mean implant duration of complete and partial removals was 86.1 ± 75.9 months and 162.0 ± 101.0 months, respectively ($p < 0.01$). In all cases of partial removal, only the tip of the lead remained in the myocardium without any complications and the desired clinical outcomes could be achieved. In two patients, open heart surgery was performed because of a large vegetation (Fig. 1). In those cases, the proximal portion of the leads was extracted using an excimer laser sheath from the PM pocket. With another four leads in two patients, the leads were also removed during open heart surgery due to cardiac tamponade encountered during the lead extraction procedure.

Major complications directly related to the lead extraction procedure occurred in five patients (2.7%, cardiac tamponade in four, and death within 24 h after the procedure due to uncontrollable bleeding from the vein in one patient). Two of the four patients with cardiac tamponades required a surgical repair. Further, minor adverse events occurred in seven more patients (3.8%, pneumothorax in two, blood transfusion in four, and pulmonary embolism in one patient). Four patients (2.2%) died during the index hospitalization. Two patients died because the systemic infection could not be controlled even after the removal of all implanted devices. One patient died during the hospital stay because of a cerebral infarction not related to the extraction procedure.

All patients received intravenous antibiotics, at least, one week after the procedure. Pocket or systemic infections were successfully controlled in 181 patients (98.9%).

A re-implantation of the device was performed 26.2 ± 12.9 days after the explantation. Fifteen of 183 patients (8.2%) did not require further device therapy, and devices were implanted in the remaining patients. Eight of these patients were transferred to another hospital for the re-implantation procedure. Two patients had recurrences of infection within one year after the explantation of the devices.

3.3. Microbiology

Coagulase-negative staphylococci (CNS, 30.1%, Fig. 2) and *Staphylococcus aureus* (37.1%) were the most common causes of CIED infections followed by the *Corynebacterium* species (eight patients). Gram-negative bacilli including *Pseudomonas aeruginosa* (three patients), *Escherichia coli* (two patients), and *Proteus mirabilis* were the pathogens in 3.8%. Seven patients had an anaerobic gram-positive bacillus species and two patients had a fungal (*Candida albicans*) infection. Thirty-three (18%) patients had localized inflammatory signs in the generator pocket or an erosion of

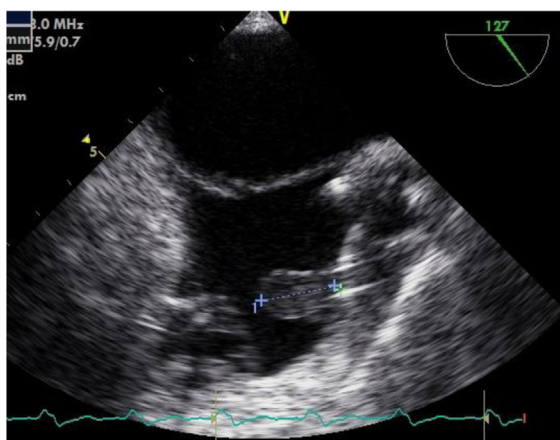


Fig. 1. Left: A vegetation (2.5 cm) attached to the leads was detected by transesophageal echo. Right: A vegetation removed by open heart surgery is shown.

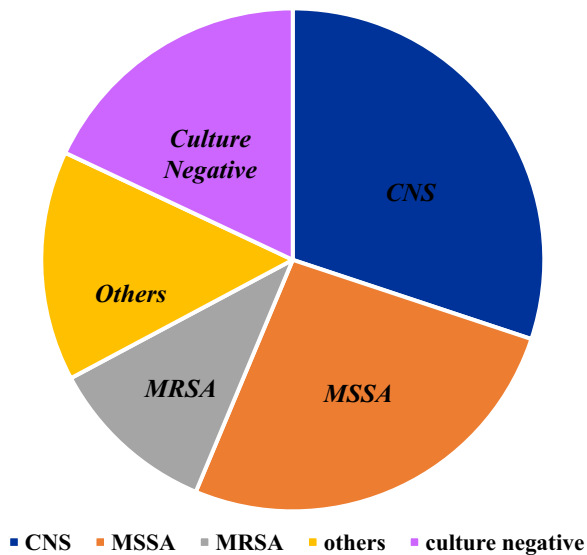


Fig. 2. Microbiology of the cardiac implantable electronic device infections ($n=183$).

the device/lead, but the cultures were negative. Thirty of these patients were receiving oral or intravenous antibiotics.

4. Discussion

Cardiac implantable electronic devices became available in the 1970s. The use of CIEDs continues to grow in Japan. The rate of device implantation is increasing with the aging of the general population and the expanding indications. Voigt et al. [1] reported that the rate of hospitalization for CIED infections have increased faster than the rate of CIED implants. This disproportionate increase is consistent with the findings of Cabell and colleagues [8] who demonstrated accelerating rates of cardiac device infections (including CIEDs, prosthetic valves, and ventricular assist devices) among Medicare beneficiaries from 1990 to 1999 [5]. Voigt et al. [1] suggested the reasons for such a disproportionate rise. First, while the age has remained relatively constant, there has been an increase in the prevalence of a coexistent morbidity in CIED recipients. Usilan et al. [9] have shown that population-adjusted PM implantation incidences have increased and that there has been an age-independent rise in comorbidities in PM recipients. Thus, the PM population may be becoming more susceptible to infections. Second, Voigt et al. speculated that a widespread and potentially indiscriminate CIED utilization for primary prevention of sudden cardiac death and the treatment of heart failure might play a role, primarily due to the disadvantaged health status and prevalent comorbidities of such recipients. Particularly, given the adverse impact of such comorbidities on the CRT response, a move to a more judicious application of CIEDs, in general, may be warranted. Interestingly a dramatic rise in CIED infections occurred beginning in 2001 and 2002 [1], when the positive results of the primary prevention defibrillator trials [10,11] were accepted by the medical community, followed by the adoption and increased rate of CRT device implantations.

The data concerning device infections and lead extractions from Japan are limited. Okamura et al. [2] reported their initial 40 cases. Ohmori et al. [3] reported a case of a thoracoscopy-guided lead extraction with an excimer laser sheath and Okada et al. [4] reported a case of a transjugular extraction using a snare technique. Our current study consisted of 183 patients, the largest cohort

in Japan, and, therefore, this study can clarify the status of device infections and lead extractions in Japan.

Klug et al. [12] reported that device-related infections occurred in 0.68% of patients within the first year after the de novo implantation or replacement. No data is available concerning the prevalence of CIED infections in Japan, however at Kokura Memorial Hospital, 1855 CIEDs were implanted between 2008 and 2012 (de novo implantations in 1,174 and replacements or upgrades in 681 patients). CIED infections occurred in 14 patients (0.75%). This data suggests that the prevalence of CIED infections seems to be similar in Japan.

As for the management of CIED infections, there have been no randomized controlled trials. The recommendations for a complete extraction of the device, route of administration, duration of antimicrobial therapy, and the timing of the placement of a new device are based on observational data and clinical experience. Observations from several medical centers universally support the complete removal of the device to cure the infection and reduce morbidity and mortality [13–15]. The relapse rate when a complete device removal is performed is 0–4.2%. On the contrary, when a partial removal or antibiotics are chosen, the relapse rate increases to 50–100% [9,13,16–19]. Removal of the generator without a lead extraction should be avoided.

Of the 183 CIED infection patients, 27 (14.8%) had an early infection (< 3 months after the procedure), 45 (24.6%) had a late infection (4–12 months after the device-related procedure), and 111 (60.7%) had a delayed infection (more than 12 months after the procedure). Of interest, 60 (43.7%) patients presented with an infection after an interval of more than 24 months after the device-related procedure. These durations are longer than those reported by Leckerkerker et al. [20]. As previously mentioned, almost half of the patients in this study had a previous surgical intervention without a full removal of all hardware and one-fourth of the patients underwent device implantation on the ipsilateral side even though the infection was active in the PM pocket. This might suggest a considerable number of patients were undertreated in Japan and at a risk of recurring infections, endocarditis, or fatal results.

Complete procedure success was achieved in 97.1% of the lead extractions in our study while partial removal occurred in 2.0%, and failure in 0.9%. Okamura et al. [2] reported the success rate of a complete removal was 97.1%. These two results were almost equally beneficial with those of the LExiCon study (complete removal: 96.5%) [21]. The mean implant duration of the partially removed leads was 162 ± 101 months (longest 338 months). Roux et al. [22] reported that a longer time from the implantation independently predicted a procedural failure. In this patient group, the mean implant duration of complete and partial removals was 86.1 ± 75.9 months and 162.0 ± 101.0 months, respectively ($p < 0.01$).

In our study, culture results were positive for *Staphylococcus aureus* in 37.1% of the patients, CNS in 30.1%, and other bacterial species in 14.8%. Tarakji et al. [23] reported their pathogens of CIED infections were CNS in 44.4% of the patients, Methicillin-sensitive *S. aureus* (MSSA) in 20.1%, and Methicillin-resistant *S. aureus* (MRSA) in 15.8%. Sohail et al. [17] reported CNS in 42%, MSSA in 25%, and MRSA in 4%. Margey et al. [18] reported MSSA in 30.8%, CNS in 20.5%, and MRSA in 5.1%. Leckerkerker et al. [20] reported *Staphylococcus aureus* in 25% and CNS in 29%. Our data and previously published data suggest that the *Staphylococcus* species continues to represent the most common pathogen of CIED infections, with 5–10% being methicillin resistant. The usefulness of the prophylactic use of antibiotics at the time of a device implantation was reported by de Oliveira et al. [24] Therefore many institutions continue to use beta-lactam antimicrobial agents at the time of implantation; however, this is not effective

against methicillin-resistant organisms. A single dose of vancomycin before the implantation might be better than that of beta-lactam antibiotics to prevent CIED infections in the selected patients such as MRSA carrier.

Two patients in this patient group (1.1%) had relapses within the first year. One patient had a dual chamber ICD due to ventricular tachycardia caused by a remote myocardial infarction. The ICD was successfully extracted for a pocket infection due to coagulase negative *Staphylococcus*. The pocket infection reappeared after re-implantation of an ICD on the ipsilateral side at a previous hospital. The pathogen of the second infection was *Pseudomonas aeruginosa*; indicating that the second pocket infection might not have been a recurrence of the initial pocket infection. The other patient had allergic dermatitis on the body and a VDD PM was implanted due to complete atrioventricular block. That patient was referred to our hospital under a diagnosis of device-related endocarditis. The device and all lead materials were completely removed and the patient underwent successful re-implantation of a device on the ipsilateral anterior chest after an intravenous antibiotic prescription for three weeks. This patient, however, was readmitted due to bacteremia after re-implantation of the device.

In our study, 8.1% of the patients no longer required device implantation or had reasonable alternatives after their devices were removed. Thus, the need for re-implantation in patients with an infected device should be carefully evaluated.

4.1. Limitations

Our study does have a few limitations. Ninety percent of our patients were initially treated by other institutions, and 47.5% had previously failed surgical attempts without a full removal. This study, therefore, has a potentially significant referral bias. This study consisted of the largest number of patients. However, this report was a single center experience. Further investigation with a larger patient group is required to clear up the present circumstances of CIED infections in Japan.

5. Conclusions

The current clinical status of CIED infections seems to be similar in Japan to that in foreign countries. The optimal treatment of infected PM and implantable defibrillator devices involves the complete explantation of all hardware, followed by antibiotic therapy. The excimer laser appeared to be safe and effective for extracting chronically implanted leads in Japanese patients. Conservative treatment without explantation of all hardware is frequently unsuccessful.

Conflicts of interest

All authors declare no conflicts of interest related to this study.

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