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Original Article

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

Masahiko Goya, MD[a,*,1], Michio Nagashima, MD[a], Ken-ichi Hiroshima, MD[a], Kentaro Hayashi, MD[a], Yu Makihara, MD[a], Masato Fukunaga, MD[a], Yoshimori An, MD[a], Masatsugu Ohe, MD[a], So-ichiro Yamazato, MD[a], Ko-ichiro Sonoda, MD[a], Kennosuke Yamashita, MD[a], Kouji Katayama [b], Tomoaki Ito [b], Harushi Niu [b], Kenji Ando, MD[a], Hiroyoshi Yokoi, MD[a], Masashi Iwabuchi, MD[a]

[a] Department of Cardiology, Kokura Memorial Hospital, Japan
[b] Department of Medical Engineering, Kokura Memorial Hospital, Japan

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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

* Correspondence to: Department of Cardiology, Kokura Memorial Hospital, Asano 3-2-1, Kokurakita-ku, Kitakyushu 802-8555, Japan. Tel.: +81 3 5803 5231; fax: +81 3 5803 0133.
E-mail address: mgoyamd@yahoo.co.jp (M. Goya).
[1] Present address: Department of Cardiovascular Medicine, Tokyo Medical and Dental University, Yushima 1-5-45, Bunkyo-ku, Tokyo 113-8519, Japan.

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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 ± 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, *n* (%)	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, n (%)	
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

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