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Original article

Single-center experience with percutaneous extraction of cardiac implantable electric devices

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ABSTRACT

Background: The estimated incidence of infected cardiac implantable electric devices (CIED) has recently increased to 1–2% in Japan. Extraction of long-term implanted devices is generally difficult. There are few reports about lead extraction in Japan. We describe our experience with and outcomes of lead extraction using excimer lasers, mechanical sheaths, and manual extraction.

Methods: We retrospectively analyzed the characteristics, types of devices, and indications for extraction in 29 patients with 67 leads who required CIED lead extraction at Shinshu University Hospital between April 2014 and October 2016. Mean patient age was 71 years and 25 patients were male. The indications for device extraction were infections ($n = 25$) and non-functioning leads ($n = 4$).

Results: A total of 67 leads (active fixation lead, $n = 28$; passive fixation lead, $n = 39$) had been implanted for a median duration of 6.3 ± 5.6 years. Extractions were performed using an excimer laser sheath ($n = 26$), laser with mechanical sheath ($n = 7$), only mechanical sheath (Cook Vascular Inc., Leechburg, PA, USA) ($n = 1$), and manually ($n = 1$). The procedure was successful in all patients. There were no major or minor complications during extraction. There was no recurrence of infection after infected device extraction. Two patients were implanted with subcutaneous implantable defibrillators after extraction of the implantable cardioverter defibrillator (ICD).

Conclusions: CIED lead extraction, especially of those that are adherent to the subclavian vein, can be successfully performed in Japanese subjects using an excimer laser and mechanical sheath, without complications.

Introduction

The rate of infected cardiac implantable electric devices (CIEDs) has been estimated as 1–2% of devices in Japan [1,2].

High infection rates (2.77%) have been particularly observed in infection-experienced institutions [3]. The number of hospitalizations related to CIED infection increased 3.1-fold between 1996 and 2003, and more importantly, CIED infections increased the risk of in-hospital death by >2-fold [4]. Infection rates of CIED range from 1% to 2% [3–5].

Some reports indicate that coagulase-negative Staphylococcus and other Staphylococcus species account for 42% and 25% of CIED infections, respectively [6]. Known risk factors for CIED infection include diabetes mellitus, steroid medication, renal failure, advanced age, temporary pacemakers, and generator exchange, which expose patients to a greater risk of infection compared with initial device implantation [7]. Antibiotic prophylaxis and new device implantations are associated with a lower risk of infection, and earlier removal of an infected device results in better outcomes [8].

The guidelines for dealing with CIED infections published by the Heart Rhythm Society [1] indicate that infected devices must be removed as soon as possible [9,10]. In Japan, infected CIEDs have historically been removed using transvenous manual extraction or open heart surgery [2]. However, surgical removal can be too invasive, especially in patients who are elderly or who have significant co-morbidities [11,12].

The excimer laser sheath (Spectranetics, Colorado Springs, CO, USA) was approved for lead extraction in Japan in 2010 [2], while

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the mechanical sheath was approved in 2016. Transvenous laser and mechanical lead extraction are associated with lower complication rates and higher success rates than manual transvenous extraction [13]. Here, we describe our experience with lead extraction using an excimer laser sheath and mechanical sheath at a single institution.

Methods

We retrospectively evaluated 29 consecutive patients who had undergone CIED lead extraction at Shinshu University Hospital, Japan, between 2014 and 2016. The indications for lead extraction were based on the Heart Rhythm Society criteria [1] and included patients who were unable to tolerate open cardiac surgery or general anesthesia. We analyzed the characteristics of the patients and devices, indications for lead extraction, types of CIED infection, complications associated with device extraction, and procedure outcomes from their medical records. Definitions of the results of the extraction procedure are based on the Expert Consensus Statement of the Heart Rhythm Society [1].

We began performing the lead extraction procedure in our hospital in 2011, and we have previously published a paper on the initial experience of 13 patients between 2011 and 2014. Our indication for lead extraction was limited to device infection at the beginning, and all leads were extracted by the excimer laser sheath. In the present study, all lead extraction procedures were performed by one co-author (M.S.) who is an expert in lead extraction. This study began in 2014 when he joined our hospital.

The study proceeded with all co-authors in compliance with the ethical standards described in the Declaration of Helsinki under informed consent.

Extraction procedure

Leads have been extracted using excimer lasers for several years at selected hospitals in Japan. Use of the excimer laser sheath for this purpose requires rigorous training to meet the necessary proficiency criteria, which we completed at Tokyo Women's Medical University Hospital. Approval for use of the mechanical sheath for CIED extraction, as well, was only given after the doctors underwent the required training.

Leads were extracted from patients under general anesthesia in an operating room. The patients were electrocardiographically monitored and assessed by transesophageal echocardiography. An open-heart surgery kit with a standby pump oxygenator was prepared by a cardiac surgeon. We opened and drained the pocket containing the CIED and removed the implanted generator (if present). Fibrotic tissues surrounding the leads were excised and the area was dissected to expose them. An LLD locking stylet (Spectranetics, Colorado Springs, CO, USA) was advanced to each lead tip. Two ties of silk suture material were secured around the outer insulation of the leads. A 12Fr laser sheath was passed over the lead body until the first binding site was reached. Encapsulated adherent tissue was ablated using laser bursts and the sheath was advanced to the next binding site. All bound tissue was dissected by the sheath and, when it reached the lead tip, the lead was extracted by countertraction [9].

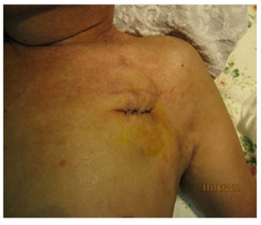
In cases in which a mechanical sheath was used, a locking stylet (Liberator, Cook Medical Inc., Bloomington, IN, USA) was delivered to the tip of the lead. A polypropylene mechanical dilatorsheath (Evolution, Cook Medical Inc.) was passed over the lead. The size of the sheath ranged from 7 to 14Fr. The sheath was advanced by rotating it alternatively clockwise and counter-clockwise with two or three turns. During dilation, smooth traction was applied in order to keep the lead under tension, while avoiding myocardial wall invagination or coil lengthening and lead damage [9]. Thereafter, the pocket was closed with 2-0 VICRYL sutures (Johnson and Johnson, New Brunswick, NJ, USA) and the patients were transferred to the intensive care unit for 24 hours.

Results

Fig. 1 shows the characteristics of the 29 patients with 67 leads (mean age, 72.0 ± 17.2 years; range, 15–83 years; 25 males) from whom 61 leads were extracted. As shown in the figure, the median duration after initial implantation was 6.3 ± 5.6 years. Of the 67 leads, 28 of them were active fixation leads (of which seven were shock leads) and 39 were passive fixation leads (two of which were shock leads). The indications for device extraction were infection (n = 25, 86%) and non-functioning or recalled leads (n = 4, 13.8%).

There were four types of devices: pacemakers (n = 19, 65.5%), cardiac resynchronization therapy pacemakers (CRTP) (n = 1, 3%),

	(n=29)
Age (years)	72.0±17.2
Male	25 (86%)
BMI (kg/m^2)	21.1±3.6
Indication for lead extraction	
Infection	25 (86%)
pocket infection/sepsis	21/4
non-functioning or recalled lead	4 (13.8%)
Device type	
Pacemaker	19 (65.5%)
CRTP	1 (3%)
ICD (dual coil)	5 (17.2%)
CRTD	4 (13.8
Implant duration, years	6.3±5.6
No. of leads (no. extracted)	67 (61)
Shock leads (dual)	9
Post generator exchange	23 (79%)
Active fixation lead	28 (shock 7)
Passive fixation lead	39 (shock 2)



Risk factors

Steroid therapy: 1 (3%)
CRF on HD: 1 (3%)
No. of leads >2: 8 (28%)
High age (≥70 yrs.): 21 (72%)
Post GE: 23 (79%)

Fig. 1. Baseline characteristics of 29 study patients. BMI, body mass index; CRTP(D), cardiac resynchronization therapy pacemakers (defibrillator); CRF on HD, chronic renal failure on hemodialysis; GE, generator exchange.

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