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Initial Experience of Percutaneous Extraction of Infected Cardiac Implantable Electric Devices Using Excimer Laser

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Background : The estimated incidence of infected cardiac implantable electric devices (CIED) has recently increased to 1 % - 2 %. Prompt removal of infected devices improves survival rates. We describe our initial experience of lead extraction from infected devices using an excimer laser that was approved for this application in 2010.

Methods and results : We retrospectively analyzed the characteristics, type of devices and leads, as well as indications and complications in 13 patients with CIED infection between 2011 and 2014 at our hospital.

The clinical presentation comprised isolated pocket infection (n=12), lead endocarditis (n=3) and methicillin-resistant *Staphylococcus aureus*-positive blood cultures. The patients had been implanted with a total of 29 leads (atrial, n=13 ; ventricular, n=16) for a median duration of 10.2±5.2 years. The procedure was successful in all patients, but two patients who developed recurrent infection required repeated removal of devices and an implant device from epicardial cardiac muscle. Acute cardiac tamponade occurred in one patient after ventricular lead extraction due to perforation of the right ventricle. This patient required an emergency thoracotomy, but was discharged one month after the procedure.

Conclusion : Infected CIED leads can be quickly extracted using an excimer laser. *Shinshu Med J 63 : 103—108, 2015*

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Key words : device infection, complication, cardiac tamponade, septic embolism, generator exchange

I Introduction

The rate of CIED infection has recently increased worldwide and affects an estimated 1 %-2 % of devices in Japan[1)2)]. The number of hospitalizations related to CIED infection increased 3.1-fold between 1996 and 2003, and more importantly, CIED infection has increased the risk of in-hospital death >2-fold[3)]. Infection rates of CIED range from 1 % to 7 %[3)4)]. Known risk factors for CIED infections include diabetes mellitus, steroid medication, renal failure, advanced age, temporary pacemakers and generator exchange[5)], which exposes patients to increased risk of infection compared with initial device implantation[6)].

Antibiotic prophylaxis and new device implantation are associated with a low risk of infection and earlier removal of an infected device results in better outcomes[7)]. Some reports indicate that coagulase-negative *Staphylococcus* and other *Staphylococcus* species account for 42 % and 25 %, respectively, of CIED infections[8)].

The guidelines for dealing with CIED infection published by the Heart Rhythm Society[3)] indicate that infected devices must be removed as soon as

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possible[9)10)]. Infected CIED in Japan have historically been removed using trans-venous manual traction or open heart surgery[2)] but surgical removal can be too invasive, especially for 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)]. Transvenous laser lead extraction is associated with lower complication rates than manual transvenous extraction and high success rates.

Here, we describe our initial experience of lead extraction using an excimer laser sheath to treat CIED infection at a single institution.

II Methods

We retrospectively studied 13 consecutive patients after they had undergone CIED lead extraction using an excimer laser at Shinshu University Hospital, Japan between 2011 and 2014. Indications for lead extraction were based on the Heart Rhythm Society criteria[3)].

Patients who were unable to tolerate open cardiac surgery or general anesthesia, or who had giant vegetations in leads or valves, were excluded. We percutaneously extracted leads using the excimer laser when surgical removal was considered too invasive and manual extraction was likely to be less successful.

We analyzed the characteristics of the patients and devices, types of CIED infection, and complications associated with device extraction.

The study proceeded in compliance with ethical standards included in the Declaration of Helsinki.

III Extraction Procedure

Leads have been extracted using excimer lasers for four years at selected hospitals in Japan. Use of the excimer laser sheath for this purpose requires rigorous training to meet specific criteria, which we completed at the Tokyo Women's Medical University Hospital.

We extracted leads from patients under general anesthesia in an operating room. The patients were electrocardiographically monitored and assessed by transesophageal echocardiography. An open-heart surgical kit was prepared by a cardiac surgeon with a standby pump oxygen generator.

Plastic surgeons opened and drained the pocket and removed the generator (if present). Fibrotic tissues surrounding the leads were excised and the area was exfoliated to expose them.

An LLD locking stylet (Spectranetics, Colorado Springs, CO, USA) was advanced to each lead tip. A 12 Fr laser sheath was passed over the lead body until the first binding site was reached. Encapsulated adhesive 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 counter traction[7)].

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.

IV Results

Table 1 shows the characteristics of the 13 patients (mean age, 65.0±21.6 y; 11 males) from whom 29 leads were extracted using the excimer laser.

The mean number of leads and the median duration after initial implantation were 2.2±0.4 and 10.2±5.2 y, respectively. Of the 29 leads, 13 were located in the right atrium and 16 were located in the right ventricle. Patients no. 2, 3 and 10 had at least one ICD coil lead, which might have been prone to powerful adhesion and require more careful extraction. Importantly, CIED infection was primarily diagnosed after generator exchange in 11 patients (84.6 %), but not after initial implantation in two others, in accordance with the known risks associated with the exchange procedure. Indications for initial device implantation widely varied depending on the disease (**Table 2**). **Table 3** shows local symptoms at the site of the pacemaker pocket[13)], echocardiographic findings, and the results of cultured blood and extracted leads[3)7)]. At least one

Table 1 Patient characteristics

Case No	Age	Sex	Number of Leads (n)	Times after Implantation (y)	Device type	Infection after GE	Time after GE (M)
1	55	M	2	13	PM	+	7
2	43	M	3	4	ICD	+	2
3	82	M	2	7	ICD	+	2
4	70	M	2	10	PM	+	4
5	20	M	3	7	PM	+	2
6	68	M	2	13	PM	−	
7	76	M	2	13	PM	+	6
8	79	M	3	14	PM	+	1
9	36	M	2	16	PM	+	41
10	57	M	2	2	ICD	−	
11	83	F	2	20	PM	+	4
12	92	M	2	9	PM	+	2
13	85	M	2	5	PM	+	4

M : Male F : Female ICD : implantable cardioverter difibrillator
PM : pacemaker GE : generator exchange

Table 2 Indications for device implantation

Case No	
1	Sick sinus syndrome
2	Vf (Brugada syndrome)
3	VT (DCM)
4	Complete atrio-ventricular block
5	Advanced atrio-ventricular block
6	Sick sinus syndrome
7	Complete atrio-ventricular block
8	Complete atrio-ventricular block
9	Complete atrio-ventricular block
10	VT (OMI)
11	Sick sinus syndrome
12	Sick sinus syndrome
13	Sick sinus syndrome

Vf : Ventricular fibrillation DCM : Dilated cardiomyopathy VT : Ventricular tachycardia
OMI : Old myocardial infarction

culture from all patients was positive. Samples from pocket sites of 12 patients were positive except for one in which only blood cultures were positive. However, device infection was still suspected because that patient had developed sepsis due to *Staphylococcus* species according to the guidelines of the Heart Rhythm Society (2009).

The device was exteriorized in eight patients, among whom one required emergency extraction to prevent systemic infection. Three patients had pocket infection without device exteriorization and one had no pocket infection. Preoperative blood cultures were positive in only one patient and transesophageal echocardiography detected vegetations in two others. In contrast, pocket tissues or leads in all patients were mostly positive for methicillin-resistant *Staphylococcus epidermidis*, which was cultured from the CIED pockets of nine patients and from the lead tips of three others.

Leads were completely extracted from all patients with a 100 % success rate. The only major adverse event was acute cardiac tamponade in

Table 3 Pacemaker pocket, echocardiographic findings and result of culture

Case No	Pocket symptom	TEE	Blood culture	Pocket culture	Lead culture
1	Exteriorization	Negative		MRSE	Negative
2	Exteriorization	Negative		MRSE	Negative
3	Exteriorization	Negative		MRSE	Negative
4	Exteriorization	Negative		S. aureus	Negative
5	Exteriorization	Vegetation		MRSE	MRSE
6	Local infection	Vegetation		MRSE	Negative
7	Exteriorization	Vegetation		MRSE	MRSE
8	Local infection	Negative		MRSE	Negative
9	Local infection	Negative		MRSE	MRSE
10	No pocket infection	Negative	MRSE		MRSE
11	Exteriorization	Negative		P. aeruginosa	Negative
12	Exteriorization	Negative		Candida	Negative
13	Impending ext	Negative		MRSE	Negative

Impending ext, impending exteriorization ; MRSE, Methicillin-resistant S epidermidis ; P. aeruginosa, Pseudomonas aeruginosa ; S. aureus, Staphylococcus aureus ; TEE, Transthoracic echocardiography.

Table 4 Perioperative period

Case No.	Anesthesia time (hour)	Procedure Time (hour)	Length of ICU stay (day)	Bleeding (ml)	Blood transfusion
1	6.51	4.12	1	150	−
2	5.50	3.52	1	I50	−
3	6.23	4.18	1	60	−
4	6.21	4.27	1	100	−
5	6.36	4.27	1	50	−
6	8.16	6.52	1	100	−
7	5.25	3.40	1	100	−
8	5.4	3.2	1	100	−
9	3.15	1.51	1	100	−
10	4.9	1.38	1	50	−
11	9.16	7.51	35	1600	+
12	5.11	3.31	1	20	−
13	4.5	5.39	1	40	−

patient no. 10 (7.8 % of all patients). This patient was discharged at 30 days after on-pump, beating-heart cardiac repair. Patient no. 3 developed systemic infection (7.8 % of all patients) with septic lung embolisms after pacemaker re-implantation.

The mean procedural duration of CIED extraction was 4.0±1.7h, the average stay in the intensive care unit was 24 hours and an average of 201 mL of blood was lost during the procedure (**Table 4**). The cause of bleeding was almost always pocket debridement except for cardiac tamponade. The amount of blood loss during procedures was generally ＜200 mL.

Importantly, infection recurred in patients no. 7 and 9, both of whom required subsequent implantation of an epicardial pacemaker via thoracotomy. A newly re-implanted pacemaker became infected in Patient no. 7, and this was again retrieved one month later. Patient no. 9, who had collagen disease that was being treated with high-dose steroid, required temporary pacing after the initial pacemaker extraction, and then developed a high fever with increased C-reactive protein levels under antibiotic therapy. Cultures of the extracted temporary lead were positive for methicillin-resistant *Staphylococcus epidermidis*.

Ⅴ Discussion

We showed that extraction of infected CIED from a series of 13 patients using an excimer laser was clinically expedient and completely successful. Various patient characteristics, indications for device implantation, and duration after initial implantation did not appear to restrict application of the excimer laser. The success rates of lead removal and in-hospital death due to CIED infection were 100 % and 0 %, respectively, which were superior to the findings of the LExIcon trial (96.5 % and 0.3 %, respectively).

Total lead extraction rates with and without the excimer laser sheath in the original PLEXES trial were 95 % and 64 %, respectively[11]. Using the laser significantly reduced the mean amount of time required to successfully extract leads compared with non-laser techniques. Life-threatening complications developed in three patients in whom leads were extracted with the laser, including one who died, and in none of those whose leads were removed without a laser. The rate of major adverse events directly related to the procedure in the LExIcon trial was 1.4 %[4], including death (0.28 %), and the clinical success rate was 97.7 %. Considering these findings, excimer laser extraction can significantly reduce procedural duration and achieve substantially high extraction rates. Clinicians should, however, carefully consider complications, among which the reported incidence of death and fatal injury can be up to 1 %[3], and that of major complications, including superior vena cava laceration or massive pulmonary embolism, is about 1 %[14)–17)]. In fact, one of our patients (patient no. 10) developed cardiac tamponade, which accounted for a complication incidence of 7.8 % among our small patient cohort.

The risks must always be weighed against the success rate of lead extraction[18)19)]. The risk of life-threatening complications indicates that lead extractions should proceed only with the appropriate equipment and personnel required to address all potential situations, including thoracotomy, sternotomy and cardiopulmonary bypass. Potential complications are discussed in preoperative meetings when we schedule lead extractions and we aim to extract leads without incurring adverse events.

Ⅵ Conclusion

Infected CIED and leads can be extracted from patients using an excimer laser with high success rates and a significantly reduced surgical duration. However, appropriate strategies are essential to prevent device infection and rare but serious complications.

Ⅶ Conflict of Interest

None to declare.

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