Journal of Geriatric Cardiology | JGC
RESEARCH ARTICLE
J Geriatr Cardiol 2021; 18(7): 505–513

Leadless cardiac pacemaker implantations after infected pacemaker system removals in octogenarians

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https://doi.org/10.11909/j.issn.1671-5411.2021.07.006

ABSTRACT

Background Management of pacemaker (PM) infections among advanced aged patients possesses particular clinical challenges due to higher rates of concurrent cardiovascular disease and medical comorbidities. Novel leadless cardiac pacemakers (LCPs) may provide new opportunities for better management options in this population, however, there is limited data especially in Asian populations to guide the decision making.

Methods We reviewed 11 octogenarians (median age: 86 [minimum 82–maximum 90] years; male: 73%; median body mass index (BMI): 20.1 kg/m^2) who received Micra Transcatheter Pacing System (Medtronic Inc, Minneapolis, MN) implantations following transvenous lead extractions (TLEs) for PM infections.

Results All patients had more than two medical comorbidities (average 3.7 comorbidities). The indications for LCP implantations were atrioventricular block in four patients, atrial fibrillation bradycardia in five, and sinus node dysfunction in two. Eight patients (73%) were bridged with temporary pacing using active fixation leads (median interval of 14.0 days), while one with severe dementia underwent a concomitant LCP implantation and TLE during the same procedure. Successful TLEs and LCP implantations were successfully accomplished in all without any complications. The median time from the TLE procedure to discharge was 22 days (minimum 7–maximum 136). All patients remained free of infections during a mean follow-up period of 17.2 ± 6.5 months.

Conclusions LCP implantations were safe and effective after removing the entire infectious PM system in all octogenarians. The novel LCP technology may offer an alternative option for considering a re-implantation strategy after transvenous PM infections in elderly patients, particularly those with severe frailty and PM dependency.

The incidence of cardiac pacemaker (PM) infections among patients with an advanced age has been increasing owing to the continually widening indications and growing number of generator replacements.[1–3] In current clinical practice, there is a class l indication for removing all hardware in the case of a proven or suspected device infection, and after a recovery window, a new conventional PM is implanted in PM dependent patients.[1,4,5] However, this management for the elderly population is one of the most sensitive issues, since they possess particular clinical challenges due to higher rates of concurrent cardiovascular disease and medical comorbidities.[6–10]

Recently, the implantation of a Micra Transcatheter Pacing System (Medtronic Inc, Minneapolis, MN) has emerged as a new option for PM re-implantations after the removal of infectious PMs.[11–17] Without the use of leads and a device pocket, this leadless cardiac pacemaker (LCP) potentially reduces the

risk of pocket infections and lead associated endocarditis.[16,17] However, there have not been enough data supporting the feasibility of leadless PM implantations following the removal of infectious PMs in people with an older age, particularly in octogenarians. Furthermore, there has been no data regarding those therapeutic strategies in Asian populations who have a low body mass index (BMI) and are at a higher risk of a transvenous lead extraction (TLE) procedure. Therefore, in this case series, we sought to characterize the procedure for LCP implantations following TLEs of infected PMs in octogenarians at 2 Japanese high-volume centers.

METHODS

Study Population

This case series included octogenarians receiving LCP implant procedures following TLEs of infectious conventional cardiac PM leads between June 2017 and June 2020 at Tokyo Women's Medical University and Shinshu University, which are tertiary referral centers for TLEs in Japan. The indication for a TLE was a device-related infection with a class 1 indication according to the Heart Rhythm Society expert consensus statement on cardiovascular implantable electronic device lead management and extractions.[1] Device-related infections were defined as clinically proven or suspected infections of the PM pocket or lead.[1] Transthoracic and transesophageal echocardiography was performed to evaluate the presence of vegetations due to endocarditis or lead involvement. The demographic data including the age, sex, body mass index (BMI), pacing indication, cardiovascular disease history, and medical comorbidities were also obtained from the medical records. This study conformed to the Declaration of Helsinki on human research. The study was approved by the ethics committee of both institutions and written informed consent was obtained from every patient.

TLE Procedures

Before the TLE procedures, all patients underwent cardiac CT and angiography to assess any extravascular or extracardiac lead positioning, to identify the sites of any venous occlusions or stenoses, and to assess the regions of lead mobility and adherence. All the procedures were performed by experienced electrophysiologists under conscious sedation or general anesthesia in the cardiac surgery operating room with cardiovascular surgeon backup. A temporary pacing wire was inserted from the femoral vein before the procedure. The invasive arterial pressure and intracardiac or transesophageal echocardiography monitoring were recorded and cardiopulmonary bypass equipment was always on standby during the procedure.

All leads were extracted transvenously through a subclavian or femoral approach using the following four techniques: (1) manual traction using a normal or locking stylet; (2) laser-assisted lead extraction using an excimer laser sheath (GlideLight, Philips, Netherland); (3) mechanical sheath extraction using a non-powered polypropylene Byrd dilator sheath (Cook Medical, USA) or a bidirectional rotational mechanical sheath (Evolution RL, Cook Medical, USA); or (4) a snare-assisted lead extraction using various snare tools such as Goose neck snare (Medtronic, Minneapolis, MN, USA), Needle's eye snare (Cook Medical, USA), or Lassos (Osypka, GmbH, Grentzig-Whylen, Germany).[18] Following manual traction, a mechanical sheath extraction and/or laser-assisted lead extraction was selected based on whether there was a venous occlusion or stenosis, lead-lead or lead-tissue adherence, or extensive calcification. Alternatively, among those with severe adhesions in the subclavian, innominate, or superior vena cava veins, a femoral approach using the snaring technique was applied once the tip of the lead was detached from the tissue. After the removal of the entire system, an active-fixation pacing lead was implanted from the right jugular vein and connected to the explanted PM for temporary pacing until the implantation of the LCP.

Complete success was defined as the successful removal of all the leads without any remnants in the cardiovascular space.[1] Major complications were defined as outcomes that were life threatening, or resulted in significant or permanent disability, procedure-related deaths, or required surgical intervention.[1] Minor complications were defined as events related to the procedure that required medical intervention or minor procedural intervention.[1]

LCP Implantations

The infection status of each patient was evalu-

ated carefully and the decision regarding the use of antibiotics and the duration of their administration was made based on the 2017 HRS expert consensus statement on CIED lead management and extractions.[1] All the LCP implantations were performed by experienced electrophysiologists under conscious sedation and pain control with opioid agents. The device was delivered into the right ventricle by a deflectable catheter through a percutaneous femoral approach. In three cases (#4, #5 and #11) without temporary pacing using an active-fixation pacing lead, a temporary pacing wire was inserted into the right ventricular apex from the femoral vein for backup pacing and as an anatomical landmark. Once the catheter was positioned in the right ventricle, a suitable site of attachment in a septal position was identified according to the standard anatomical landmarks, and the location was then confirmed by injecting contrast medium into the right ventricle with two complementary radiological projections. The device fixation was determined adequate when at least two of four tines of the LCP were anchored to the myocardium. Following the device placement in the right ventricle, electrical measurements such as the pacing thresholds, pacing impedance, and R-wave amplitude were checked. If an adequate deployment was confirmed, the device was released from the tether, otherwise repositioning to another site of the right ventricle was attempted. A figure of eight stitch was used to guarantee correct hemostasis at the femoral cannulation site and was removed on the next day. The device data including the pacing capture threshold, pacing impedance, and R-wave amplitude were collected prospectively, and electrocardiography and chest radiography were performed to exclude any procedural adverse events before the hospital discharge.

All patients were scheduled in the setting of regular care visits at one month and then every six months after the LCP implantation. Further, they underwent a clinical follow-up including laboratory tests for signs of ongoing infections at the local satellite clinics.

RESULTS

Baseline Characteristics

Between June 2017 and June 2020, 11 octogenarians (median age of 86, male 73%) underwent an LCP implantation after a total PM system removal due to an infection. The baseline characteristics of the population are shown in Table 1. The indication for the initial pacemaker implantation was atrioventricular block in four patients, bradycardia as-

Table 1 Baseline characteristics.

Variable	*N* = 11
Age, yrs	86 (82–90)
Male	8 (73%)
BMI, kg/m^2	20.1 (17–31)
Pacing indication	
Sinus node dysfunction	2 (18%)
Atrioventricular block	4 (36%)
Atrial fibrillation bradycardia	5 (45%)
Cardiovascular disease history	
Coronary artery disease	3 (27%)
Open-heart surgery	1 (9%)
Transcatheter aortic valve implantation	1 (9%)
Tricuspid valve regurgitation	
Moderate	5 (45%)
Severe	2 (18%)
Medical comorbidities	
Dementia	5 (45%)
Hypertension	9 (82%)
Diabetes	5 (45%)
Chronic kidney disease	8 (73%)
Old cerebral infarction	3 (27%)
COPD	2 (18%)
Anemia	7 (64%)
Number of medical comorbidities	
2	2 (18%)
3	5 (45%)
≥ 4	4 (36%)
LVEF	59.3% ± 8.7%
Left atrial dimension, mm	44.8 ± 8.7
BNP, pg/mL	160.6 ± 112.6
eGFR, mL/min per 1.73 m^2	49.7 ± 15.2
HGB, g/dL	10.5 ± 1.1
Oral anticoagulant	5 (45%)
Antiplatelets	4 (36%)

All data are expressed as the mean ± SD or median (minimum-maximum) or *n* (%). BMI: body mass index; BNP: brain natriuretic peptide; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; HGB: hemoglobin; LVEF: left ventricular ejection fraction.

sociated with permanent atrial fibrillation (AF) in five including three that were completely pacemaker dependent with no escape rhythm, and sinus node dysfunction with no escape rhythm in two. Seven of 11 patients (64%) had moderate or severe tricuspid valve regurgitation (TR). All patients had more than two medical comorbidities (average 3.7 comorbidities). Five of 11 patients (45%) had dementia including two with severe dementia that required physical restraints.

PM Infections

The characteristics of the pacemaker infections in all patients are summarized in Table 2. Ten patients (91%) were diagnosed with a pocket infection identified by typical local inflammatory changes such as erythema, swelling, and/or erosions of the skin, but differed in their severity. There were two patients (#8 and #11) who had evidence of a positive blood culture. The pocket tissue culture was positive in eight patients (73%). The transesophageal echocardiography revealed small lead vegetations less than 2cm in one patient (#1). The lead tip culture taken during the TLE procedure was positive in five patients (45%).

TLE Procedures

The TLE procedures are summarized in Table 3. Preprocedural venography demonstrated an occlusion in the ipsilateral subclavian vein in seven patients (64%). Nine patients (82%) underwent procedures under general anesthesia while two underwent them under conscious sedation (#2 and #4) considering the risk of general anesthesia due to their medical comorbidities. In two patients (#2 and #4) with a short lead dwelling time, a complete lead removal could be achieved with only a snare technique. Seven patients used an excimer laser sheath technique and seven a mechanical sheath technique including five with a non-powered polypropylene sheath, one with a bidirectional rotational mechanical sheath, and one with both techniques. There were no patients that required open-heart surgery support. The mean procedural duration was 162.7 ± 68.4 min. Complete success was achieved in all TLE procedures. There were no major or minor complications among the patients.

LCP Implantations

The LCP implantation procedures are summarized in Table 4. Temporary pacing with an active fixation lead was instituted in 8 patients (73%) as a bridge to the LCP implantation. The median interval from the TLE procedure to the LCP implantation procedure was 14.0 days. One patient with a transcatheter aortic valve replacement (#2) exhibited persistent inflammatory signs (fever and increased CRP) even after a complete device system

Table 2 Summary of the symptoms and bacteriology.

Patients	Age (year)	Sex	BMI (kg/m^2)	Systemic symptom			Pocket symptom			Lead involvement	
				Fever	Increased CRP	Blood culture	Redness & swelling	Device exposure	Pocket culture	Vegetation	Lead culture
1	86	M	24.6				+	+	+ (MSSA)	+	+ (MSSA)
2	90	F	19.6	+	+						
3	82	M	17	+	+		+		+ (Anaerobic GPR)		
4	82	M	19.7	+	+		+		+ (MSSA)		
5	83	M	25.5				+		+ (CNS)		
6	86	M	18.2	+	+		+	+	+ (MSSA)		
7	90	F	18.1				+				
8	89	F	23	+	+	+ (MSSA)	+	+	+ (MSSA)		+ (MSSA)
9	82	M	22.9				+	+			+ (*P.acnes*)
10	86	M	20.6				+	+	+ (MSSE)		+ (MSSE)
11	87	M	31.3	+	+	+ (MRSE)	+		+ (MRSE)		+ (MRSE)

BMI: body mass index; CNS: coagulase negative Staphylococci; GPR: Gram Positive Rods; F: female; M: male; MSSA: Methicillin-Susceptible Staphylococcus Aureus; *P.acnes*: *Propionbacterium acnes*; MSSE: methicillin-susceptible Staphylococcus Epidermidis; MRSE: methicillin-resistant staphylococcus epidermidis; PM: pacemaker.

Table 3 Summary of the transvenous lead extraction procedures.

Patients	PM mode	No. of leads	Dwell time (year)	Ipsilateral vein occlusion	TLE tools				Result of TLE	Procedural duration (min)
					Mechanical sheath	Evolution	Laser sheath	Snare		
1	DDD	2	10.3	+	+			+	Success	173
2	DDD	2	2	+				+	Success	91
3	DDD	2	7.9	+	+	+	+		Success	181
4	DDD	2	2.2					+	Success	108
5	VVI	1	5.5	+			+	+	Success	91
6	DDD	2	4.9	+	+		+		Success	116
7	DDD	2	1.2				+		Success	144
8	DDD	2	15.4	+		+			Success	230
9	DDD	2	17.0		+		+		Success	166
10	VVI	1	5.2		+		+		Success	166
11	DDD	2	12.6	+	+		+		Success	324

AF: atrial fibrillation; CAVB: complete atrioventricular block; DDD: dual chamber pacemaker; PM: pacemaker; SSS: sick sinus syndrome; TLE: transvenous lead extraction; VVI: single chamber pacemaker.

Table 4 Summary of leadless cardiac pacemaker implantation procedures.

Patients	PM indication	Temporary pacing	Location of deployment	Number of deployments	R-wave amplitude (mV)	Impedance (Ω)	Pacing threshold (V)	Skin to skin implantation time (min)	Time from the TLE to re-implant (days)	Time from the TLE to discharge (days)
1	CAVB	+	Low septum	1	16.8	650	0.75	25	10	19
2	SSS	+	High septum	1	6.8	570	1.0	31	132	136
3	AF Brady	+	Mid septum	1	8.4	590	0.5	13	11	34
4	CAVB		Mid septum	1	2.7	490	0.5	15	0	7
5	AF Brady		Mid septum	1	8.9	630	0.38	19	18	22
6	AF Brady	+	Mid septum	2	5.9	560	0.38	42	8	14
7	CAVB	+	Mid septum	2	12.6	650	1.13	55	21	26
8	SSS	+	Low septum	2	4.0	500	2.0	70	30	36
9	AF Brady	+	Low septum	2	–	540	0.75	60	21	27
10	AF Brady	+	Mid septum	2	–	610	0.63	50	8	29
11	CAVB		Mid septum	2	–	580	0.5	60	14	17

AF: atrial fibrillation; CAVB: complete atrioventricular block; PM: pacemaker; SSS: sick sinus syndrome; TLE: transvenous lead extraction.

removal and required 132 days to undergo a new LCP implantation. One patient with PM dependency and severe dementia (#4) underwent a simultaneous TLE procedure and LCP implantation to avoid temporary pacing leads as a bridge to a permanent PM implantation and required intravenous vancomycin for four weeks, which was highly effective for treating the causative methicillin-sensitive Staphylococcus aureus. In all 11 patients, a successful LCP implantation was achieved with no major or minor procedural complications including no access site complications. The mean LCP implantation time was 40 ± 20.3 min. All patients were discharged after the implantation without any fever or signs of a re-infection. The median time from the TLE procedure to discharge was 22 days (minimum 7—maximum 136 days).

Follow-up

The device parameters at the time of the implantation, discharge, and after 6 months of follow-up visits are listed in Table 5. During a mean follow-up of 17.2 ± 6.5 months, none of the patients had any recurrence of the infection. Only one patient (#2)

Table 5 Device parameters of the leadless pacemakers at the time of implantation, discharge, and after 6 months of follow-up visits.

	At implant	At discharge	At 6 months of follow-up
Pacing threshold (V)	0.74 (0.38–2.00)	0.83 (0.50–1.38)	1.00 (0.50–2.00)
R-wave amplitude (mV)	6.6 (2.7–16.8)	7.2 (4.7–10.6)	9.1 (6.3–10.7)
Impedance (Ω)	579 (490–650)	487 (410–580)	460 (400–490)

All data are expressed as the mean (minimum-maximum). The pacing thresholds were achieved at a pulse duration of 0.24 ms.

died at the age of 92 due to a gastrointestinal hemorrhage 13.0 months after the implantation.

DISCUSSION

Pacemaker Infections in Octogenarians

In our case series, the rate of pocket infections was high in comparison to systemic infections. The elderly population is characterized by unique features that may contribute to a risk of a pocket infection: (1) degenerated subcutaneous tissue, due to aging and emaciation, may cause skin compression necrosis; (2) those with dementia may manipulate and scratch the pacemaker site resulting in skin injury; and (3) multiple device exchange procedures can be a risk for a pocket infection. Since the patients in our case series were not always associated with a low BMI, the high rate of a pocket infection might have been due to a combined mechanism.

TLE Procedures in Octogenarians

An increasing age is reflected by higher rates of comorbidities and this makes the device management most challenging.[1,4,5] In a community-based study, approximately 70% of device recipients were 65 years of age or older and more than 75% had one or more coexisting medical condition.[4,5] In fact, all patients in our cohort had more than two medical comorbidities. These comorbidities have been shown to be associated with the rise in the incidence of TLE procedure complications. In addition, the octogenarian population, especially in the Asian regions, had a low BMI level that was more likely to be associated with major adverse events related to the TLE procedure.[19] Nonetheless, there have been several reports that have compared the safety and efficacy of TLEs between octogenarians and the younger population. Rodriguez, *et al*.[20] compared the clinical outcome of TLE procedures between 118 patients in the octogenarian group and 388 in the younger group and showed that there was no significant difference with respect to the proportion of minor (P = 0.65), major (P = 0.56), and total (P = 0.50) complications.[20] In a multicenter retrospective study that consisted of 150 octogenarians and 698 non-octogenarians who underwent TLEs, the periprocedural mortality and major adverse events were similar between the two groups despite the higher prevalence of medical comorbidities in the octogenarians.[21] Another multicenter study showed the outcomes of TLEs in 1 060 patients in a younger population (21–70 years) and 192 octogenarians, and again the major adverse events were similar between the two cohorts (1.6% *vs*. 1.51%).[22] These findings suggested that octogenarians who have an indication for a TLE should not be denied the procedure based on age alone.

LCP Implantations in Octogenarians

A previous report from the Micra post-approval registry proposed octogenarians with an age of more than 85 years old as a risk factor for a perforation during LCP implantations.[12] They proposed that most patients who developed perforations had more than one risk factor including an older age, low BMI, female sex, congestive heart failure, non-AF indication, and chronic lung disease. However, although the number was small, our experience suggested the safety profile of LCP implantations even in octogenarians. Furthermore, all patients could achieve a successful deployment with only 1 or 2 device deployment attempts. There might be one explanation supporting this favorable outcome. In our cohort, 5 of 11 patients (45%) had permanent AF and all these patients had a giant left atrium with a left atrial dimension of more than 50 mm. Seven of 11 patients (64%) had moderate or severe tricuspid valve regurgitation, suggesting a right atrial volume overload. The previous transvenous leads might worsen the regurgitation owing to mechanical interference with the tricuspid valve

closure.[23] This anatomical remodeling in the right atrium might allow for a safer manipulation of the LCP catheter delivery system.[12]

The LCP may have several advantages for a re-implantation strategy after a conventional PM infection in octogenarians. First, the small surface area of the LCP and its location completely within the intracardiac space, could lead to a potential benefit in preventing a relapse of an infection.[24] Second, patients with dementia may have the risk of self-manipulation of the PM within the pocket resulting in pocket trouble.[25] Furthermore, patients with severe frailty with a low BMI might have the risk of skin thinning that could cause exposure of the generator. The use of a small intracardiac LCP eliminates all risk of pocket trouble and infections and the necessity for an infection-prone pectoral generator replacement.[11,12] Third, in our cohort, 7 of 11 patients (64%) had ipsilateral subclavian vein occlusions in the preprocedural venography. Re-implantation of a PM without using the collateral subclavian vein may have been of benefit, especially in patients who had a risk of future hemodialysis considering a patent vascular access.

Simultaneous LCP Implantation and TLE Procedure

In our series, there was one patient who underwent a simultaneous LCP implantation and PM removal during the same procedure. Beurskens, *et al.*[13] recently reported a case series of 17 patients who underwent a simultaneous TLE and LCP implantation procedure in the setting of an active infection. They demonstrated either the safety or freedom from recurrent infections during a mean follow-up of 16 months. Kypta, *et al.*[14] also presented two cases in whom a Micra implant was safe and feasible even though the implant had been performed before the removal of an infected PM system within the same procedure. Furthermore, a subanalysis of the Micra post-approval registry demonstrated that among 105 patients with prior device infections, 39 (37.1%) received a Micra implant on the same day of the TLE procedure.[15] This strategy has the benefit of avoiding temporary pacing leads as a bridge to a permanent PM implantation. A previous study reported that temporary transvenous leads are associated with maintaining and causing a recurrence of device infections with an odds ratio of 2.5.[10] It can also avoid the risk of self-removing their temporary pacing lead in patients with severe dementia. However, there are some concerns about performing TLEs and LCP implants on the same day, since the current evidence about the outcome of this approach seems relatively weak for guaranteeing the safety in a population at high risk of an infection. Therefore, prospective randomized data on the LCP therapy for managing device infections should be required to determine the optimal timing and recovery window for performing an LCP implantation after a TLE of an infected PM.

Limitations

Our case series showed the feasibility of our therapeutic strategy for managing infected PMs in the most advanced aged population of patients needing permanent cardiac pacing. However, there were several limitations to our clinical investigation. First, because of the small population and absence of a control group receiving a traditional PM, the present results cannot be used to assess any causal relationship between the variables explored. However, this explorative study allowed the evaluation of the feasibility of an LCP implantation in our clinical setting and in patients with broad clinical indications. Second, our two centers had a high volume of LCP implantations and TLEs with experienced operators, which may have led to more favorable outcomes. The small sample size made it difficult to draw any conclusions regarding the mortality in this population. Therefore, multicenter registries and studies with a large study population are essential in the future. Finally, though there were no signs of a reinfection at the 17.2 month follow up, LCP infections may occur at a later stage. Furthermore, since we used the available echocardiography, blood cultures, and clinical symptoms to identify the device infection, the diagnosis of an LCP infection might have been missed.

CONCLUSIONS

In this observational study of our case series, all octogenarians experienced safe and effective transcatheter LCP implantations after the removal of the entire infectious PM system despite high rates of medical comorbidities. This novel LCP techno-

logy may offer an alternative option in considering the re-implantation strategy after a transvenous PM infection even among Asian populations with an advanced age who need permanent cardiac pacing.

ACKNOWLEDGMENTS

We would like to thank Mr. John Martin for his linguistic assistance in the preparation of this manuscript.

DISCLOSURE STATEMENT

The authors have no conflict of interest to disclose.

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Please cite this article as: Higuchi S, Okada A, Shoda M, Yagishita D, Saito S, Kanai M, Kataoka S, Yazaki K, Tabata H, Kobayashi H, Shoin W, Okano T, Yoshie K, Ejima K, Kuwahara K, Hagiwara N. Leadless cardiac pacemaker implantations after infected pacemaker system removals in octogenarians. *J Geriatr Cardiol* 2021; 18(7): 505–513. DOI: 10.11909/j.issn.1671-5411.2021.07.006