Leadless pacemaker implantations after infectious pacemaker removals in octogenarians

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June 5, 2020

Abstract

Background: Management of pacemaker (PM) infections in patients with an advanced age is one of the most sensitive issues, since they possess particular clinical challenges due to higher rates of medical comorbidities. The novel leadless pacemaker (LP) requiring no transvenous lead or device pocket, may provide new opportunities for the management of PM infections among patients with an advanced age. Methods: We reviewed 8 octogenarians (median age of 86 [minimum 82 – maximum 90], male 63%) who received an LP implantation following a transvenous lead extraction (TLE) of an infectious PM. Results: All patients had more than 2 medical comorbidities. The indications for the LP implantations were atrioventricular block in 3 patients, atrial fibrillation bradycardia in 3, and sinus node dysfunction in 2. Five patients were bridged with a temporary pacing using an active fixation lead (median interval of 14.5 days), while one patient with severe dementia underwent a concomitant LP implantation and TLE during the same procedure. Successful TLEs and LP implantations were accomplished in all patients. There were no major or minor complications including vascular access troubles. All patients were discharged 2–8 days after the implantation. All patients stayed free of infection during the follow-up period of 6 months Conclusions: LP implantations were safe and effective after infected pacemaker removals in all 8 octogenarians. The novel LP technology may offer an alternative option in considering re-implantation of a PM even among patients with an advanced age and who are PM dependent.

Original article for JCE

Title: Leadless pacemaker implantations after infectious pacemaker removals in octogenarians

Short title: Micra implantations and TLEs in octogenarians

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Grant support: None Conflicts of interest: None

A total of 4171 words with 4 tables.

Abstract

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Methods:

We reviewed 8 octogenarians (median age of 86 [minimum 82 – maximum 90], male 63%) who received an LP implantation following a transvenous lead extraction (TLE) of an infectious PM.

Results:

All patients had more than 2 medical comorbidities. The indications for the LP implantations were atrioventricular block in 3 patients, atrial fibrillation bradycardia in 3, and sinus node dysfunction in 2. Five patients were bridged with a temporary pacing using an active fixation lead (median interval of 14.5 days), while one patient with severe dementia underwent a concomitant LP implantation and TLE during the same procedure. Successful TLEs and LP implantations were accomplished in all patients. There were no major or minor complications including vascular access troubles. All patients were discharged 2–8 days after the implantation. All patients stayed free of infection during the follow-up period of 6 months

Conclusions:

LP implantations were safe and effective after infected pacemaker removals in all 8 octogenarians. The novel LP technology may offer an alternative option in considering re-implantation of a PM even among patients with an advanced age and who are PM dependent.

(243/250 words)

Key words: octogenarian; transvenous lead extraction; leadless pacemaker; Micra transcatheter pacing system; infectious lead.

Introduction

The incidence of 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 for PM dependent patients.[1, 4, 5] However, these managements for the elderly population are 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-implantation after the removal of infectious PMs.[11-17] Without the use of leads and a device pocket, this leadless pacemaker (LP) potentially reduces the risk of a pocket infection and lead-associated endocarditis. However, there have been only few 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 is a concern that octogenarians are proposed as an important risk factor for perforations during LP implantations. [12] Therefore, we sought to investigate the feasibility and outcome of an LP implantation following a transvenous lead extraction (TLE) of an infected PM in octogenarians.

Methods

Study population

This case series included octogenarians receiving LP implant procedures following infectious conventional PM lead extractions between June 2017 and June 2019 at Tokyo Women's Medical University and Shinshu University, which are tertiary referral centers for TLEs. The indication for a lead extraction was a device-related infection with a class 1 indication for an extraction 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 further confirm the diagnosis of a device infection and to evaluate the presence of endocardial or pacing lead involvement. Demographic data including age, sex, body mass index, 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 and was approved by the ethical committee of both institutions. Written informed consent was obtained from every patient.

TLE procedures

Before the TLE procedures, all patients performed cardiac CT and angiography to assess any extravascular or extracardiac lead positioning, identify the sites of any venous occlusions or stenosis, and 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 4 techniques; (1) manual traction using normal or locking stylets, (2) laser-assisted lead extraction using an excimer laser sheath (3) a mechanical sheath extraction using a non-powered polypropylene 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), and 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 passive fixation lead became free. After the removal of the entire system, an active-fixation pacing lead was immediately implanted from the jugular vein and connected to an externalized PM until the time of the re-implantation in PM dependent patients.

Complete success was defined as the successful removal of all the targeted leads and all lead material from the vascular space.[1] Major complications were defined as outcomes that were life threatening, resulting 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]

LP implantation

All the LP 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 cases without temporary pacemaker using an active-fixation pacing lead, temporary pacemaker was inserted into the right ventricular apex from the femoral vein aiming for a 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 and filming in two complementary radiological projections. In case of the previous use of an active-fixation lead for temporary pacing after the TLE, we looked for an anchoring site for the LP that was not too close to the transvenous lead tip. The device fixation was considered adequate when the movement of at least 2 of 4 tines was confirmed. 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 pacing capture threshold, pacing impedance and R-wave amplitude were collected prospectively and electrocardiography and chest radiography were undergone for excluding the procedural adverse events before hospital discharge.

Patients were followed in the setting of regular care visits at our centers at 1 month and 6 months after LP implantation. Besides, they underwent clinical follow-up including laboratory tests for signs of ongoing infection at the satellite local doctors.

Results

Between June 2017 and June 2019, 8 octogenarians (median age of 86, male 63%) underwent LP implantations following PM removals due to infections. The baseline characteristics of the population are shown in Table 1. The indication for the initial pacemaker implantation was atrioventricular block in 3 patients, bradycardia associated with permanent atrial fibrillation (AF) in 3 including 2 that were completely pacemaker dependent with no escape rhythm, and sinus node dysfunction with no escape rhythm in 2. Five of 8 patients (63%) had moderate or severe TR. All patients had more than 2 medical comorbidities. Four of 8 patients (50%) had dementia including 2 with severe dementia that required physical restraints.

TLE procedures

The characteristics of the pacemaker infections and TLE procedures in all patients are summarized in Table 2. All 8 patients 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. Of those, in 2 patients (patients No.1 and No.2) lead involvement was revealed by transesophageal and transthoracic echocardiography but they had negative blood cultures. There was one patient (patient No.8) who had evidence of a positive blood culture for Staphylococcus aureus. Preprocedural venography demonstrated an occlusion in the ipsilateral subclavian vein in 6 patients (75%). Seven patients (88%) underwent TLEs under general anesthesia and 1 under conscious sedation (patient No.4). In two patients (patients No.2 and No.4) with a short lead dwelling time, a complete lead removal could be achieved by only using a snare technique. Four patients used an excimer laser sheath technique and four other patients used a mechanical sheath technique including 2 with a non-powered polypropylene sheath, 1 with a bidirectional rotational mechanical sheath, and 1 with both techniques. There were no patients that required open-heart surgery support. The mean procedural duration was 141.8 $\pm$ 49.7 minutes. Complete procedural success was achieved in all TLEs. There were no major or

minor complications among the patients.

LP implantations

The operative characteristics of LP implantations are summarized in Table 3. Temporary pacing with an active fixation lead was instituted in 5 patients as a bridge to the Micra implant. The median interval from the TLE procedure to the LP implantation procedure was 14.5 days. One patient with severe dementia (patient No.4) underwent a simultaneous TLE procedure and LP implantation. One patient (patient No.2) underwent a Micra implantation 132 days after the TLE procedure, since she had an intractable severe inflammatory sign even after a complete device system removal. All 8 patients achieved successful LP implantation with no major or minor procedural complications including no access site complications. The mean LP implant time was 33.8 ± 20.4 minutes. The mean electrical measurements of the LP were 8.3 ± 4.6 mV for the R-wave with an impedance of 580.0 ± 62.6 ohm and pacing threshold of 0.8 ± 0.24 V after an average of 1 or 2 device deployment attempts per patient.

Follow-up

All patients were discharged 2–8 days after the implantation after an unremarkable course without fever or signs of re-infection. The device parameters at the time of implantation, discharge and after 6 months of follow-up visits are listed in Table 4. During the 6 months follow-up, all patients had no signs of either recurrent infection or device parameter abnormality.

Discussion

TLE procedure in octogenarians

An increasing age is reflected by higher rates of comorbidities and this makes 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 2 medical comorbidities. These comorbidities have shown to be associated with the rise in the incidence of extraction procedure complications. In addition, octogenarian population displayed low BMI level that were more likely to experience major adverse events related to the TLE procedure. [19]

Nonetheless, there have been several reports that compared the safety and efficacy of TLE between octogenarians and the younger population. Rodriguez et al. 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 consisted of 150 octogenarians and 698 non octogenarians who underwent TLE, 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 that the outcomes of TLE in 1060 patients with younger population (21-70 years) and 192 octogenarians and again major adverse events were similar in the two cohorts (1.6% vs 1.51%).[22] These findings suggested that octogenarians who have an indication for TLE should not be denied the procedure based on age alone.

LP implantation in octogenarians

A previous report from Micra post-approval registry proposed octogenarians with an age of more than 85 years old as a risk factor for a perforation during LP implantation. [12] They proposed that most patients who developed perforations had more than 1 risk factor including an older age, low BMI, female sex, congestive heart failure, non-AF indication, and chronic lung disease. However, although the number is small, our experience suggested a safety profile of LP implantations even in octogenarians. Furthermore, all patients could achieve successful deployment with only 1 or 2 device deployment attempts. There might be one explanation supporting this favorable outcome. In this cohort, 4 of 8 patients (50%) had AF including 3 with permanent AF and all these patients had a giant left atrium with a left atrial dimension of more than 50mm. Furthermore, 5 of 8 patients (63%) had moderate or severe tricuspid valve regurgitation (TR), suggesting

an right atrial volume overload. The previous transvenous leads might help worsening the severity of the TR owing to the mechanical interferences with the tricuspid valve closure. [23] These anatomical remodeling in the right atrium might allow for a safer manipulation of the LP catheter system. [12]

The LP may have several advantages in considering it as a re-implantation strategy in octogenarians. First, the small surface area, occurrence of LP encapsulation, and 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 pacemaker pulse generator within the pocket resulting in pocket trouble.[25] Furthermore, patients with severe frailty might have the risk of skin thinning that could cause a generator exposure. The use of a small intracardiac LP eliminates all risks of pocket trouble and infections and the necessity of infection-prone pectoral generator replacements. [11, 12] Third, in our cohort, 6 of 8 patients (75%) 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 LP implantation and TLE procedure

In our series, there was one patient who underwent a simultaneous LP implantation and PM removal during the same procedure. Beurskens et al. recently reported a case series of 17 patients who underwent a simultaneous TLE and LP implantation procedure in the setting of an active infection. [13] They demonstrated either the safety or the freedom from recurrent infections during a mean follow-up of 16 months. Kypta et al. also presented two cases in a small series 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. [14] 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 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 leads in patients with severe dementia. However, there are some concerns about performing TLEs and LP implants on the same day, since the current evidence about the outcome of this approach seems relatively weak to guarantee the safety in a population at high risk of a reinfection. Therefore, prospective randomized data on the LP therapy in the management of device infections are required to determine the optimal timing and recovery window to perform an LP implantation after extractions of infected PMs.

Limitations

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 LP implantation in our clinical setting and in patients with broad clinical indications. Second, our center had a high volume of LP implantations and TLEs with experienced operators, which may have led to more favorable outcomes. The small sample size made it difficult to draw 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 sign of reinfection at the 6 months follow up, LP infection may occur at a later stage. Furthermore, we used available echocardiography, blood cultures, and clinical symptoms to identify device infection, the diagnosis of reinfection of the LP may have been missed.

Conclusion

In our case series, all 8 octogenarians experienced safe and effective transcatheter LP implantations after a conventional removal of infectious PMs. This novel LP technology may offer an alternative option in considering re-implantation of a PM even among patients with an advanced age who need ventricular pacing. Further, prospective, multicenter, larger-scale studies are needed to confirm and extend the current findings.

Acknowledgments

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

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