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Timing and mid-term outcomes of using leadless pacemakers as replacement for infected cardiac implantable electronic devices

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Abstract

Background Cardiac implantable electronic device (CIED) infections have a high morbidity and mortality and are an indication of device extraction. As a replacement, leadless pacemakers (LPs) may be preferable due to a low infection risk, but mid-term data on reinfections is lacking. Moreover, early LP reimplantation in pacemaker-dependent patients would circumvent the need for temporary pacemakers.

Methods We included all patients with LP implantation as a replacement for an infected CIED, between January 2013 and December 2021. The occurrence of reinfection was assessed during standard follow-up visits.

Results Twenty-nine patients (mean age 81 ± 9 years) were included, of which 21 (73%) had a pocket infection, 7 (24%) endocarditis, and 1 (3%) a systemic infection without endocarditis. All LP implantations were successful. LPs were implanted before extraction ($n=4$, 13%), simultaneously with extraction ($n=5$, 17%) and after extraction ($n=20$, 70%). No reinfection occurred during the follow-up of median 32 months (IQR 13–66 months). Repeat blood cultures obtained in 9 (30%) patients and transthoracic echocardiography in all 7 patients with pacemaker endocarditis were negative for reinfection. In a subset of 6 LPs extracted during follow-up due to early battery depletion, prophylactically after the battery advisory or due to non-capture (median 36 months (range 0–67 months) post-implantation), histopathologic examination of tissues around the LPs showed no signs of infection.

Conclusions After replacing infected CIEDs for an LP, no reinfections occurred in over 2.5 years follow-up. These results confirm that in case of CIED infection, the LP is an appealing replacement device. LP implantation before CIED extraction is feasible.

Keywords Leadless pacemaker · Infection · Cardiac implantable electronic device · Extraction

What's new?

- Leadless pacemakers (LPs) carry a very low infection risk and are therefore an appealing option in case of pacemaker infection. However, mid-term data on the recurrence of infections is lacking. Also, infected devices are usually replaced after extraction, but recent studies suggest that LPs can be safely implanted simultaneously to circumvent the use of temporary pacemakers and decrease hospitalization duration.
- In this study, LP implantations after, simultaneously with and even up to 4 days before extraction are reported. No reinfections were seen during more than 2.5 years follow-up.
- These results confirm that LPs are an attractive replacement option for infected pacemakers and suggest that LP implantation before extraction is feasible.

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1 Introduction

For patients with brady- or tachyarrhythmias, cardiac implantable electronic devices (CIEDs) are an established therapy. The use of conventional CIEDs is associated with a risk of mainly pocket- and lead-related complications [1, 2]. CIED infection is one of the most deadly complications and is a Class I indication for complete device extraction, i,e, leads and device [3]. After extraction, recent insights suggest that the use of leadless pacemakers (LPs), small pacemakers without leads, as replacement may be preferable. Currently, the only market-approved LPs are ventricular-only LPs [4]. LP infection was not described in the initial industry studies, and further only in three case reports, while > 150,000 have been implanted [5–9]. Also, LP infection was not seen in patients with endocarditis or bacteremia nor in retrieved tissue surrounding LPs [10, 11].

When LPs are used as a replacement in case of CIED infection, small studies showed no reinfections in the short-term, but mid-term data is lacking [12–14].

LP implantation before or simultaneously with extraction may bring additional advantages. Usually, CIEDs are reimplanted after complete extraction of the infected CIED and resolution of signs and symptoms [3]. Pacemaker-dependent patients stay hospitalized and temporary pacemakers are used as a bridge. Unfortunately, every added day of hospital stay is associated with an additional risk of nosocomial infections, decreased quality of life, and increased health costs, and temporary pacemakers by themselves are associated with a high number of complications [15, 16]. Patients that are not pacemaker-dependent may require separate hospitalizations for the extraction and implantation. Also, they may experience complications related to their rhythm disorder, such as asystole or bradycardia-induced ventricular arrhythmias. To circumvent these discomforts and risks, LPs are appealing to implant before or simultaneous with extraction due to the very low infection rate even in case of bacteremia. Current evidence suggests that simultaneous extraction and LP implantation is feasible [17, 18]. Even, in one patient, the LP was implanted one day before extraction, which makes the logistics easier and which may expedite the discharge date [14]. However, mid-term outcomes of both strategies are lacking. In this study, we describe our experience including mid-term outcomes after implanting LPs as a replacement for infected CIEDs, especially when implanted before or simultaneously with CIED extraction.

2 Methods

2.1 Design and patient population

In this retrospective cohort analysis, we included all consecutive patients who received an LP as a replacement for an infected conventional CIED in our tertiary extraction referral hospital (Amsterdam UMC Location University of Amsterdam, Amsterdam, The Netherlands) between January 2013 and December 2021. We excluded patients with LP implantation more than 1 year after infected CIED extraction. Baseline characteristics, procedural details, and follow-up data were collected from patient files. This study was approved by the Medical Ethical Committee of our hospital. All patients provided informed consent. A subset of these patients has been described previously [12].

All device-related complications, most importantly reinfections, were assessed during all follow-up visits, which were standard at 2 weeks, 2 months, 6 months, and every 6 months thereafter. Echocardiographic evaluation and cultures were performed when indicated.

2.2 Diagnosis and treatment

CIED infection was diagnosed according to the prevailing guideline or consensus document at the time of diagnosis. In this paper, we describe the infections according to the most recent international consensus document on CIED infections from 2019 [3]. Three types were distinguished: isolated pocket infection, CIED systemic infection without vegetation on leads or valves, and CIED endocarditis. Mainly transthoracic and transesophageal echocardiography and blood, pocket or lead tip (after extraction) cultures were used for the diagnosis. Cultures were deemed negative when no micro-organisms were cultured after 14 days.

The optimal extraction and reimplantation strategy, including reassessment of the indication, was determined by a multidisciplinary team consisting of electrophysiologists and cardiothoracic surgeons. When an LP was deemed the optimal option, it was implanted before, simultaneously with or after extraction of the infected CIED. Initially, the LP was implanted after extraction of the infected CIED and resolution of signs and symptoms of infection. Later, when the risk of LP infection was found to be very low in multiple studies, we started implanting LPs simultaneously with extraction. Because during those procedures, no LP dislocations occurred, we started to implant LPs before extraction, when this was deemed beneficial. When implanting LPs while leads were in situ, we chose the anatomic location of implantation similar to standard LP implantations, but not within the close proximity ($\pm$ 1 cm) of the transvenous lead. CIED extraction was performed by an electrophysiologist and cardiothoracic surgeon using manual traction, extraction stylets, and extraction lasers. Leads were abandoned when the risk of extraction was deemed too high. The LPs that we implanted were Nanostim (Abbott Medical Inc., Chicago, IL), Micra VR, and Micra AV (Medtronic, Mounds View, MN) LPs. The LPs were implanted following standard implantation procedures. In the case of LP implantation in the same session as CIED extraction, the LP was implanted prior to extraction of the ventricular lead, the atrial lead could have been extracted already. C-reactive protein (CRP, normal value 0–5 mg/L) was defined as CRP measured between 3 days prior to the first procedure (LP implantation/ CIED extraction) and the first procedure.

In case the LP was retrieved for any reason during follow-up, retrieved tissue surrounding the LP was evaluated by a pathologist at our center. This evaluation included staining with hematoxylin and eosin and screening for the presence of inflammatory cells. Also, tissues were stained with periodic acid-Schiff with diastase and Gram stains for evaluation of microorganisms. The full macroscopic and histopathologic examination was published previously [11].

2.3 Statistical analysis

Continuous variables were tested for normality. Normally distributed variables are expressed as mean and standard deviation and not normally distributed variables as median and interquartile range. Categorical variables are expressed as frequency and percentage. Student's *t*-test, Wilcoxon rank-sum test, and Fisher's exact test were used to compare groups. The data underlying this article will be shared on reasonable request to the corresponding author.

3 Results

3.1 Patients

We describe a total of 29 patients (mean age at LP implantation 81 ± 9, 26 (90%) male) with an infected CIED that was replaced by an LP. A Nanostim was implanted in 11 (38%) of the patients, a Micra VR in 17 (59%), and a Micra AV in 1 (3%). The LP was implanted before extraction in 4 (13%), simultaneously with extraction in 5 (17%) and after extraction in 20 (70%) patients. Demographic and clinical characteristics and a comparison between patients with an LP implantation before or simultaneously with extraction versus after extraction are shown in Table 1. Patients with an LP implantation before or simultaneously with extraction were significantly older and were more often pacemaker-dependent; also, most had an isolated pocket infection (not significant). According to the PADIT-score classification, 34% of patients were at high risk of reinfection (>3% in the year following implantation). The PADIT-score classes did not differ significantly between patients with an LP implantation before or simultaneously with extraction and patients with an LP implantation after extraction [19].

In 2 patients, the LP replaced an ICD due to the lack of defibrillation indication at the time of replacement. In 19 patients, the single-chamber LP replaced a dual-chamber transvenous CIED. This was justified in part by the lower infection risk, but in 5 patients also by the presence of permanent atrial arrhythmias at the time of CIED infection, in 2 patients by the low expected pacing frequency and in 1 patient by the unsuitable venous anatomy. In 8 other patients, the dual-chamber CIED was programmed to single-chamber modus days before the extraction to evaluate symptoms of pacemaker syndrome, which were absent in all. In 1 other patient, a Micra AV replaced the dual-chamber CIED.

The median time that the lead(s) were in situ at extraction was 6 years (IQR 3–15 years). In 28 patients, cultures were obtained: pocket cultures in 22 (76%) patients, blood cultures in 20 (69%) patients, and lead cultures in 6 (21%) patients. In 21 (72%) patients, one or more cultures were positive. The pathogen was most often *Staphylococcus aureus* (8; 28%) or other gram-positive cocci (10; 34%); gram-negative bacilli, *Proprionium acnes*, and a fungal pathogen were cultured in the others (1; 3% for all). Pre-extraction antibiotics were administered in at least 28 (97%) patients (it was unknown in 1), of which 13 (45%) orally and 15 (52%) intravenously. The median duration of pre-extraction antibiotics was 17 days (IQR 9–26 days). The extraction was complete in 25 (86%) patients, the atrial lead was abandoned in 2 (7%) patients and the ventricular lead was abandoned in 2 (7%) other patients. The only complication at extraction was a pocket bleeding in one patient. Of note, 6 (21%) of patients had a history of recurrent CIED infection followed by antibiotic therapy and/or revision or replacement of the CIED.

3.2 LP procedures

The median time between CIED extraction and LP implantation was 8 days (IQR 1–21 days) (Fig. 1). There were 12 pacemaker-dependent patients, and a temporary wire was used as a bridge in 4, all of whom received the LP after extraction. All LP implantations were successful. The mean pacing capture threshold at implantation was 1.3 ± 1.1 V at 0.40 ms (Nanostim) and 0.8 ± 0.8 V at 0.24 ms (Micra), R-wave amplitude was 9.2 ± 5.2 mV (not available in 2 (7%)) and impedance 824 ± 330 Ω. There were 2 LP-related procedural complications, both femoral artery bleedings. One LP could not be released and was exchanged for another. Also, one patient with a complete AV block had an in-hospital cardiac arrest due to asystole after transvenous pacemaker extraction but before LP implantation. A temporary pacemaker was initially not implanted due to a seemingly stable escape rhythm.

3.3 LP implantation before or simultaneously with extraction

In Table 2, we describe all 9 patients with an LP implantation before or simultaneous with the extraction of the infected CIED. Pocket infection was the indication for extraction in 8 (89%) and 1 (11%) device was extracted due to endocarditis. In the first 8 cases, this replacement strategy was chosen due to pacemaker dependence and no temporary pacing was used in all. In the last patient, the reason for this strategy was to minimize the number of hospitalizations in a 94-year-old patient. In Fig. 2, the course of an LP implantation before CIED extraction is shown (patient no. 8). Of interest, after inserting the introducer sheath with dilator over an extra stiff wire with a J-tip, the extra stiff wire could not be retrieved. Fluoroscopy showed that the extra stiff wire was in contact with the most caudal lead of the transvenous pacemaker (Fig. 2B). The dilator was then removed and the extra stiff wire was eventually removed using a single-loop snare.

Table 1 Demographic and clinical characteristics of all patients at leadless pacemaker implantation

Characteristics	All, $N=29$	Before or simultaneous, $N=9$	After, $N=20$	P-value
Age at implant, years (SD)	81 ± 8.5	88 ± 4.5	79 ± 8.1	0.002*
Male, no. (%)	26 (90)	7 (78)	19 (95)	0.22
Pacing indication, no. (%)				> 0.99
Bradycardia associated with persistent or permanent atrial tachyarrhythmia	15 (52)	5 (56)	10 (50)	
Complete AV block	8 (28)	3 (33)	5 (25)	
Sinus node dysfunction	5 (17)	1 (11)	4 (20)	
Second-degree type II AV block	1 (3)	0	1 (5)	
Pacemaker-dependent	12 (41)	8 (89)	4 (20)	0.001*
History of recurrent device infection	6 (21)	1 (11)	5 (25)	
Cardiovascular disease history, no. (%)				
Coronary artery disease	10 (34)	3 (33)	7 (35)	> 0.99
Cardiomyopathy	6 (21)	1 (11)	5 (25)	0.63
Supraventricular tachyarrhythmias	19 (66)	5 (56)	14 (70)	0.68
Pulmonary hypertension	0	0	0	
Previous cardiac surgery				
CABG	7 (24)	1 (11)	6 (30)	0.38
Valve surgery	6 (21)	2 (22)	4 (20)	> 0.99
Other	0	0	0	
Other comorbidities, no. (%)				
Hypertension	12 (41)	4 (44)	8 (40)	> 0.99
Diabetes	6 (21)	0	6 (30)	0.14
COPD	3 (10)	0	3 (15)	0.53
CVA	4 (13)	0	4 (20)	0.28
Renal failure	4 (13)	2 (22)	2 (10)	0.57
Time leads in situ at extraction, years	6 (3–15)	10 (2–14)	5 (2–16)	0.56
Infected device, no. (%)				0.44
DDD PM	17 (59)	6 (67)	11 (55)	
VVI PM	9 (31)	2 (22)	7 (35)	
DDD ICD	2 (7)	0	2 (10)	
Abdominal VVI PM	1 (3)	1 (11)	0	
Type CIED infection, no. (%)				0.57
Isolated pocket infection	21 (73)	8 (89)	13 (65)	
Systemic infection with endocarditis	7 (24)	1 (11)	6 (30)	
Systemic infection without endocarditis	1 (3)	0	1 (5)	
Micro-organism				0.35
S. aureus	8 (28)	3 (33)	5 (25)	
Other grampositive cocci	10 (34)	2 (22)	8 (40)	
Other	3 (10)	0	3 (15)	
Culture negative	7 (24)	4	3 (15)	
No cultures	1 (3)	0	1 (5)	
CRP before procedures, mg/L (IQR) ($n=19$)[#]	11 (4–25)	4 (3–8)	15 (5–31)	0.37
PADIT-score classification				0.68
Intermediate risk (1–3%)	19 (66)	5 (56)	14 (70)	
High risk (> 3%)	10 (34)	4 (44)	6 (30)	

*$p < 0.05$

[#]Normal value 0–5 mg/L

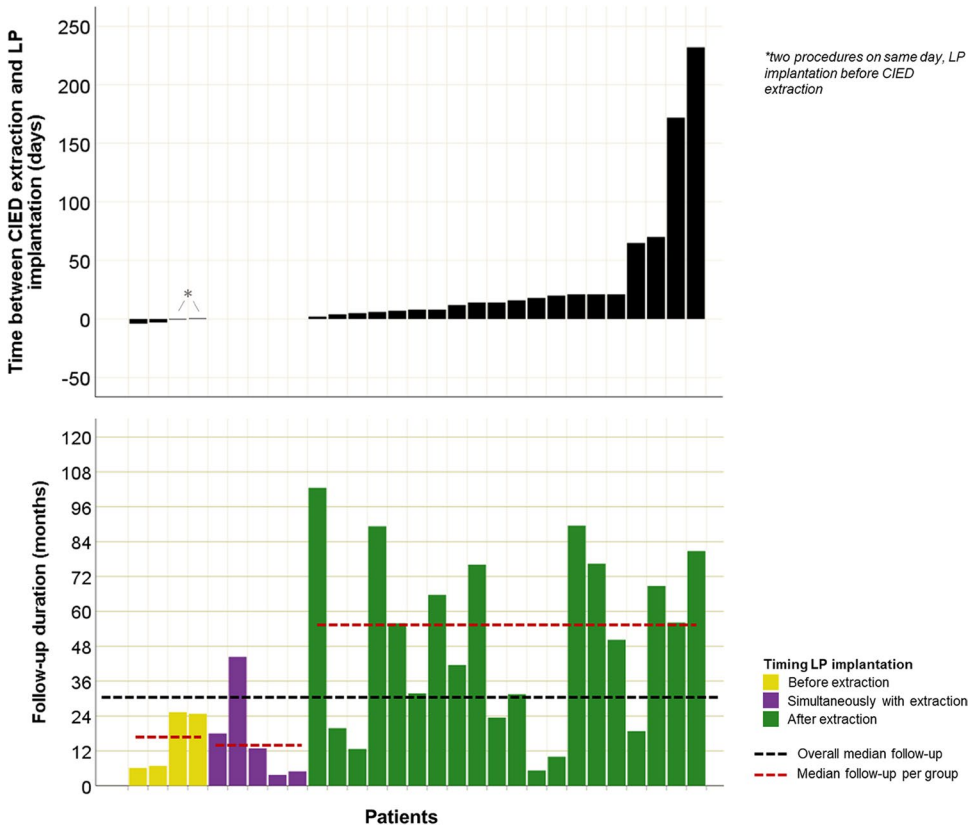

Fig. 1 Timing of leadless pacemaker (LP) implantation with respect to cardiac implantable electronic device (CIED) extraction (above) and follow-up duration (below). Each bar represents one patient

Table 2 LP implantation before or simultaneous with transvenous infected CIED extraction

Study no	Age at lp implant (years)	Timing procedures	Infected device	Type infection	Pathogen	Complete extraction	Reinfection during follow-up + months of follow-up
1	83	Same session: LP first	DDD TV-PM	Endocarditis	*S. capitis*	Yes	No, 44 months
2	85	Same session: LP first	DDD TV-PM	Isolated pocket infection	Culture-negative	Yes	No, 13 months
3	83	Same session: LP first	DDD TV-PM	Isolated pocket infection	Culture-negative	Yes	No, 18 months
4	87	Same session: LP first	VVI TV-PM	Isolated pocket infection	*S. aureus*	Yes	No, 3.8 months
5	95	LP implant 3 days before extraction	VVI TV-PM	Isolated pocket infection	*S. Aureus*	No, only generator	No, 6.9 months
6	86	Two sessions on the same day: LP first	DDD TV-PM	Isolated pocket infection	Culture-negative	Yes	No, 25 months
7	91	Two sessions on the same day: LP first	VVI abdominal PM	Isolated pocket infection	Culture-negative	No, only generator	No, 25 months
8	87	LP implant 4 days before extraction	DDD TV-PM	Isolated pocket infection	*S. schleiferi*	Yes	No, 6 months
9	94	Same session: LP first	DDD TV-PM	Isolated pocket infection	*S. aureus*	No, only generator and RV lead extracted	No, 5 months

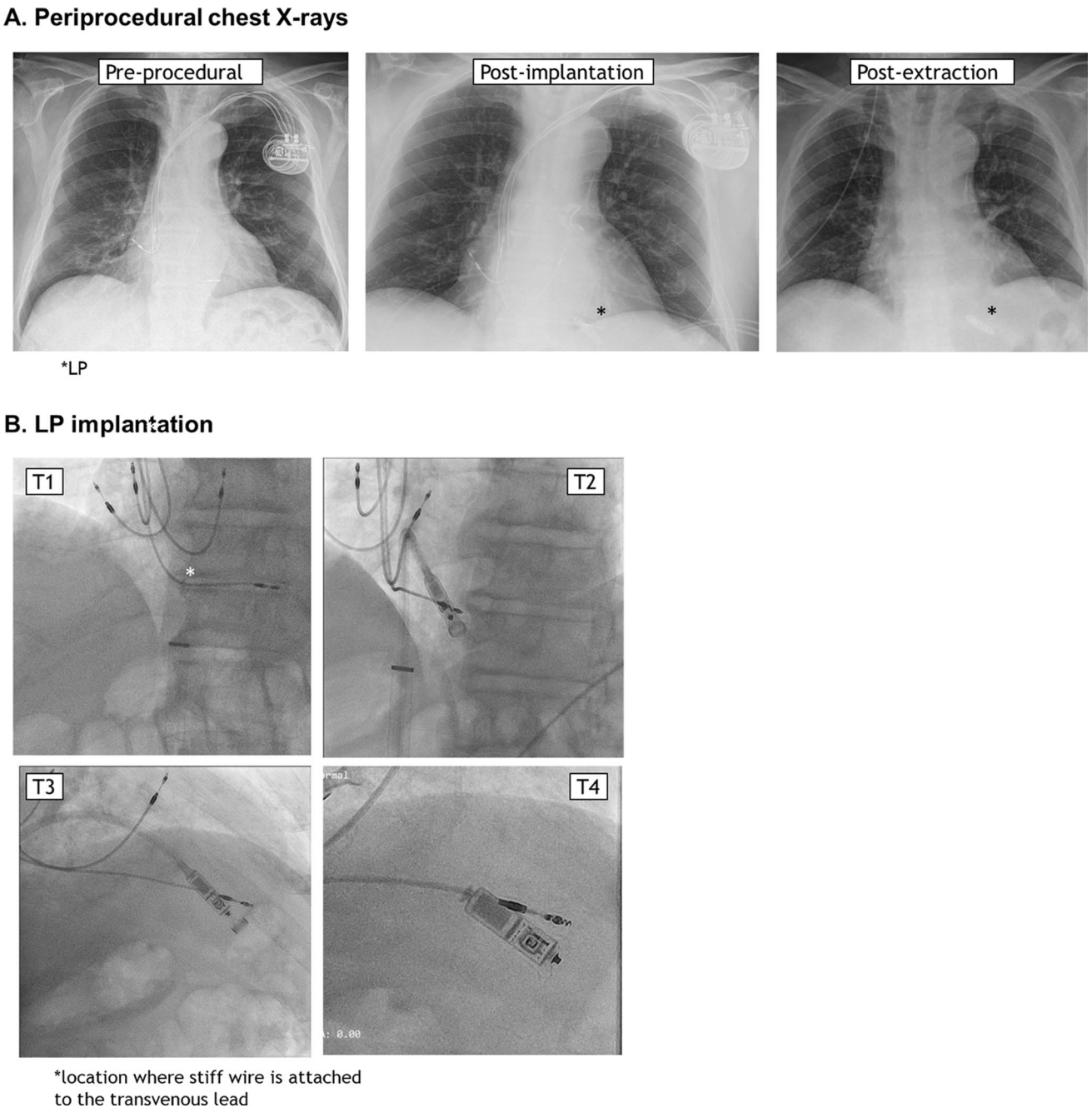

Fig. 2 Images from patient no. 8. **A** Periprocedural chest X-rays: left, pre-procedural; middle, after leadless pacemaker (LP) implantation; right, after transvenous pacemaker extraction. **B** LP implantation; T1, fluoroscopy still of stiff wire attached to transvenous pacemaker lead; T2 and T3, positioning of LP with delivery catheter; T4, LP in situ next to transvenous ventricular lead

3.4 Follow-up

The median follow-up duration was 32 months (IQR 13–66 months). In the 4 patients with LP implantation before infected CIED extraction, the median follow-up was 16 months (IQR 6.3–25 months); in the 5 patients with simultaneous LP implantation and infected CIED extraction 13 months (IQR 4.4–31 months) and in the 20 patients with LP implantation after CIED extraction 55 months (IQR 22–76 months) (Fig. 1). No reinfections occurred in all 29 patients. During follow-up, blood cultures were obtained in 9 patients (31%) and in 2 of those, pathogens were cultured. In one, 6 months after CIED extraction and LP implantation, *Proteus mirabilis* was cultured which was associated with osteomyelitis (the wound culture was also positive for *Proteus mirabilis*) and transthoracic echocardiography

showed no signs of endocarditis. The patient died soon afterwards. On the other, *Streptococcus mitis* was cultured due to mucositis and was treated successfully with antibiotics. In all 7 patients with endocarditis, echocardiography was available during follow-up and no signs of reinfection were seen. Six Nanostims were extracted due to early battery depletion, prophylactically after the battery advisory, or due to non-capture (median 36 months (range 0–67 months) after implantation). Histopathologic examination was performed on tissues surrounding the device in 5. These tissues were located at the docking button ($n=2$) or the fixation mechanism ($n=1$) and were undetermined in 2. No signs of infection were seen. In one case with an implantation-retrieval interval of 67 months, signs of active inflammation were seen, but no micro-organisms. Further, no device dislocations occurred and there were two device revisions: both were replacements of Nanostim LPs due to the battery advisory (replaced for a Micra in one and a transvenous pacemaker in the other). No upgrades to dual-chamber pacemakers or cardiac resynchronization therapy were necessary.

Of interest, in the 6 patients with a history of recurrent infections, the time from the first infection to the currently described infection was 9 months (IQR 3–23 months), while the follow-up duration after LP implantation was 49 months (IQR 24–93 months).

4 Discussion

The results of this study suggest that LP implantation as a replacement for an infected CIED is safe in the mid-term, even when the LP is implanted before or simultaneously with an infected CIED extraction. A strategy of LP implantation before or simultaneously with extraction circumvents the use of temporary pacemakers and number of hospitalizations necessary for the extraction and reimplantation process.

We describe the absence of reinfections during the currently longest reported follow-up (median more than 2.5 years) of LPs implanted as a replacement for an extracted CIED, in a population at intermediate or high risk of infection [19]. Our results are in line with previous studies, in which also not one reinfection necessitating LP extraction has been described [12–14, 18]. The reinfection rate of transvenous CIEDs following complete hardware removal is approximately 2% in the first 6 months, or 0,5% per year [20, 21]. For certain patients in our study who were reimplanted with LPs after the acute phase, though, the reinfection rate may have been only marginally increased. In addition, our results show that one may be more liberal with the timing of LP implantation, which could be useful for pacemaker-dependent patients. No reinfections were seen during more than 1-year follow-up in patients with LPs implanted simultaneously with CIED extraction, which is in line with previous studies with shorter-term follow-up durations [17, 18]. Even more, in case the LP was implanted before extraction in 4 patients, no reinfection was seen during median 1.5 years of follow-up. This was described in only one case previously and may be of additional benefit for logistic matters. Of note, the majority of patients with LP implantation before or simultaneously with extraction in this study had isolated pocket infections and the reinfection rate might be different in patients with systemic infections. No dislocations occurred in LPs implanted before or simultaneously with extraction. The early battery depletions of the Nanostim are a known problem which caused the cessation of Nanostim implantations since 2016 [22]. These results make LPs very appealing as replacement devices for CIED infections.

Our results also seem to apply to patients with recurrent CIED infections. There were 6 patients in this study with a recurrent infection. The time from the treatment of their first infection up to the reinfection was shorter than the follow-up duration after LP implantation. Therefore, we think that our follow-up duration was sufficiently long to detect a potential reinfection. Even more, one patient with a recurrent infection was implanted with an LP in the same session as the infected CIED extraction.

As the implantation of an LP while the transvenous leads are still in situ is an uncommon phenomenon, the novel strategy of implanting an LP before CIED extraction posed a challenge in one patient. When inserting the extra stiff wire, it became stuck around a transvenous lead. In our case, eventually, we could retrieve it with a single-loop snare. However, we think an extra stiff wire with a straight tip is preferable and caution must be taken not to make contact with the leads. If the extra stiff wire is stuck, this poses a significant risk to the patient.

A current limitation to LP therapy as a replacement for infected CIEDs is the restriction of LPs to ventricular-only pacing. The advantage of a smaller chance of reinfection should be weighed on an individual basis to the potential disadvantages of ventricular-only pacing. It is of utmost importance to first assess the pacing indication again; in our study, many subjects had developed permanent atrial arrhythmias, obviating the need for an atrial lead. When in doubt, our strategy is to program the transvenous pacemaker to ventricular-only pacing first, and then assess for symptoms indicating pacemaker syndrome. However, the first dual-chamber LP trial has already commenced and it is most likely that this technology will increase the use of LPs as a replacement for infected CIEDs.

In patients with an urgent need for pacing, an alternative strategy is to implant a contralateral transvenous pacemaker on the same day as lead extraction. The feasibility of this strategy was demonstrated in patients with pocket infections as well as patients with documented lead vegetations and bacteraemia [23, 24].

Although the risk of reinfection may be lower using this strategy compared to reimplantation at the ipsilateral site, it is probably higher than the very low risk of reinfection of LPs. On the other hand, LPs are currently only available for ventricular-only pacing, their use is low in younger patients due to little experience with retrievability and LPs are more expensive than transvenous pacemakers [25]. An individual decision should be made after weighing those (expected) advantages and disadvantages.

This study is limited by its retrospective design, although most information was gained as part of a prospective cohort study. Secondly, the timing of LP implantation was based on the physician's judgement for every individual patient, introducing the possibility of confounding by indication. However, it is more likely that the more liberal approach (LP implantation before or simultaneous with extraction) was performed more often over time due to the progressing knowledge of the low infection risk of LPs. Third, this study is limited by a small sample size.

5 Conclusion

In case of transvenous CIED infection, LP implantation before, simultaneously with, or after extraction is feasible with no reinfections during more than 2.5 years follow-up. A strategy of implanting the LP before or simultaneous with CIED extraction may help reduce the use of temporary pacemakers and the duration of hospitalization. Additionally, LP implantation before extraction may facilitate the logistics of this strategy and expedite the discharge date.

Data availability The data underlying this article will be shared on reasonable request to the corresponding author.

Declarations

Ethics approval This study was approved by the Medical Ethical Committee of our hospital.

Consent to participate All patients provided informed consent.

Conflict of interest RK reports consultancy fees and research grants from Abbott, Boston Scientific, Medtronic, and Cairdac and has stock options from AtaCor Medical Inc. FT received consulting honoraria from Abbott and Boston Scientific. The other authors did not have conflicts of interest.

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