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# Same-Day Pacemaker Reimplantation in Patients with Pacing Dependency after Infected Pacemaker Extraction: Feasibility and Long-Term Outcomes

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## Abstract

**Background:** Infection is a common complication of pacemaker implantation. Affected patients must undergo device removal; however, the optimal timing of new pacemaker reimplantation after infected pacemaker removal is still under debate. Some patients require reimplantation as soon as possible; however, the safety of same-day reimplantation is controversial.

**Objective:** We sought to evaluate the safety and outcomes of same-day reimplantation in patients diagnosed with pacemaker device infection after lead extraction.

**Methods:** We recruited patients who underwent same-day pacemaker reimplantation at our center after complete lead extraction due to infection between May 2014 and December 2018.

**Results:** A total of 24 patients (median age, 72 years; range, 3 to 92 years) underwent same-day reimplantation after successful pacemaker extraction. All patients demonstrated isolated pocket infection and were pacemaker-dependent. The average follow-up period was 59.7 ± 16.5 months. Two patients died 3 years after the procedure due to sudden non-cardiac death. None of the patients developed reinfection.

**Conclusion:** In this study, same-day reimplantation of a new pacemaker was safe and feasible in patients with isolated pocket infection after extraction of the infected pacemaker.

**Keywords: Pacemaker; Isolated pocket infection; Reimplantation; Device-related complications**

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## Introduction

With progressive population aging and the expanding indications for Cardiovascular Implantable Electronic Devices (CIEDs), the use of pacemakers has increased exponentially over recent decades [1]. With this increase, there has also been substantial growth in the number of CIED complications, especially infectious complications. Antibiotic treatment and complete extraction of the infected CIED are the two dominant methods to control infectious complications [2-4]. However, these interventions are not easy to perform, and the optimal timing for CIED reimplantation after infected CIED removal is still uncertain [5]. Current management strategies have mainly been examined in the context of a population age group distributed between 18 to 75 years old. As such, there is limited evidence on the optimal management strategies in octogenarians and children, due to the high incidence of cardiovascular diseases and medical comorbidities in these groups [6]. In this study, we aimed to describe our experience in the treatment of isolated pocket infection by pacemaker removal with same-day reimplantation of a new pacemaker.

## Materials and Methods

Peking University People's Hospital (PUPH) is the largest tertiary center for CIED management in China. All patients who underwent lead extraction and reimplantation of a new pacemaker on the same day as leads removal for infection between May 2014 and December 2018 at PUPH were included. Patients who did not undergo device reimplantation or did not survive to hospital discharge were excluded from the study. Among all included patients, we compared those who underwent device reimplantation within 48 h of lead extraction with those who received device reimplantation

more than 72 h after lead extraction. Demographic data were collected, including age, sex, and medical history, indications for CIED implantation, clinical status, and cardiac rhythm. The study was approved by the ethics committee of Peking University, and all patients provided written informed consent.

The definition and classification of CIED infection were based on the 2010 scientific statement from the American Heart Association on CIED infections and their management [2]. Isolated pocket infection was diagnosed if signs of inflammation were confined to the generator pocket, including local erythema, warmth, fluctuance, tenderness, or hardware protrusion through the skin, with negative blood cultures. Systemic infection was classified as an increase in the white blood cell count and/or a positive blood culture and/or visible vegetation during cardiovascular ultrasound examination. In fact, this study only included patients with isolated pocket infection.

Before the procedure, all patients were treated with intravenous antibiotics from admission to discharge once blood cultures were obtained. Intravenous antibiotics were administered throughout the extraction and reimplantation procedure. After discharge, patients received a 10-day course of oral antibiotics.

Transvenous lead extraction was conducted in the hybrid operating room. All patients underwent lead extraction and new device implantation by an experienced electrophysiologist, with a cardiac surgeon as a back-up. Radial artery sheaths were placed for hemodynamic monitoring, and a temporary pacing catheter was advanced from the femoral vein into the right ventricular apex for pacing support during the procedure. Removal by simple traction was first attempted, and if unsuccessful, more advanced tools were deployed. These tools included locking stylets, mechanical dilator sheaths (Evolution®; Cook Medical), and laser sheaths (Spectranetics). A combination of all of the above or surgical device removal was implemented based on the lead dwell time, the number of leads, and the surgeon's preference. Complete extraction was defined as removal of the entire lead, while partial extraction was defined as removal of most of the lead components, except for the electrode tip and <4 cm of the wire or insulation.

The indication for reimplantation was thoroughly reevaluated before the procedure. The contralateral pectoral was the first choice of placement for the replacement device. Alternatively, the iliac vein or epicardium was considered. After complete lead extraction, the reimplantation region was prepared in a sterile fashion. With the temporary pacing catheter still in place in the femoral vein, the new pacemaker device was implanted.

Post-implantation device interrogation was performed before hospital discharge to identify stable and satisfactory lead parameters. All patients were subsequently followed up by regular care visits at our center. Routine follow-up with device interrogation was arranged at 2 weeks, 3 months, 6 months, and 12 months, and every 6 months thereafter. For patients living in remote areas, survival and functional status information were obtained by telephone.

## Results

### Patients' baseline characteristics

Between May 2014 and December 2018, a total of 693 patients were referred to the PUPH for infected pacemaker lead extraction. Twenty-four of these patients (17 males; age range, 3 to 92 years) underwent contralateral implantation on the same day as lead extraction, and as such, these patients met the inclusion criteria for the present study. The clinical and demographic characteristics of the patients are shown in Table 1. The population age distribution varied greatly. For example, the population included a 3-year-old child, three elderly patients (>85 years of age), and two patients who were unable to function independently due to central nervous system diseases.

**Table 1:** Baseline characteristics.

| Patients | N=24 |
|---|---|
| Age (yrs), median (range) | 72 (3-92) |
| Gender, Male | 17 (71%) |
| **Comorbid conditions** | |
| Coronary artery disease | 6 (25%) |
| Heart failure | 3 (12.5%) |
| Diabetes mellitus | 8 (33.3%) |
| Chronic kidney dysfunction | 6 (25%) |
| Congenital heart disease | 2 (8.3%) |
| Anticoagulation | 4 (16.7%) |
| Stroke | 3 (12.5%) |
| Parkinson's disease | 1 (4%) |
| LV ejection fraction (%, mean ± SD) | 59.5 ± 12.3 |
| **Antibiotic prior to extraction** | |
| Cefmetazole | 22 |
| Levofloxacin | 2 |

**Table 2:** Original pacemakers implant and lead extraction data.

| Indication | |
|---|---|
| Heart block | 17 |
| Sinus node dysfunction | 6 |
| Atrial fibrillation with long RR interval | 1 |
| Last procedure before lead extraction | |
| Contralateral implantation | 9 |
| Due to malfunction | 3 |
| Due to infection | 6 |
| Ipsilateral Lead revision/insertion | 4 |
| Generator replacement | 8 |
| Mean time from first implantation (yrs, mean ± SD) | 6.2 ± 5.5 (0.5-18) |
| Combine RV lead perforation | 1 |
| Number of treated leads | 58 |
| Extraction tools (leads number) | |
| Locking style | 12 |
| Laser combined snare | 9 |
| Snare | 20 |
| Evolution | 4 |
| Simple traction | 11 |
| Open chest | 2 |

Original pacemaker implantation data are shown in Table 2. The reason for extraction was isolated pocket infection in all patients. However, before being transferred to PUPH, most patients (21/24 [87.5%]) underwent at least two device-related procedures, including eight patients who underwent at least one generator replacement

**Table 3:** Procedural characteristics and outcomes.

| Reimplantation site | |
|---|---|
| Contralateral site | 22 |
| Abdomen | 1 |
| Epicardium | 1 |
| Long-term outcomes | |
| Follow-up duration(months, mean ± SD) | 59.7 ± 16.5 |
| Infection recurrence | 0 |
| Death | 2 |
| Sudden non-cardiac deaths | 2 |

for battery depletion, four patients who required ipsilateral lead revision or new lead insertion, and nine patients who had a bilateral implantation history and in the original side with the resident leads. Considering the complexity of the patients with bilateral implantation, detailed clinical data are shown in Table 3. One patient combined right ventricular lead asymptomatic perforation, which was founded by accident before lead extraction.

### Lead extraction

Fifty-eight leads were extracted from 24 patients (mean, 2.3 leads/patient, range, 1-5 leads/patient). The mean implantation time for the oldest dwelled leads was 6.2 ± 5.5 years (range, 6 months to 18 years). Eleven leads were removed with simple traction, twenty leads required the use of a snare, and nine leads required a snare combined with a laser sheath. The patient with combined right ventricular lead perforation underwent open chest lead extraction. All leads were completely and successfully removed, with no severe procedure-related complications.

### Pacemaker reimplantation

The reasons for same-day pacemaker reimplantation were complex and unusual. All patients were pacemaker-dependent. Six patients were scheduled for same-day reimplantation due to their vulnerable physical fitness, including one three-year-old child, three elderly patients (>85 years of age), and two patients who were unable to function independently due to diseases of the central nervous system. Two patients could not undergo temporary ventricular lead implantation due to subclavian vein occlusion at the infected site. Thus, we decided to implant a new pacemaker system on the same day. Two patients had obvious pacemaker syndrome, which manifested as an acute decrease in cardiac output and blood pressure during single right ventricular pacing.

Nine patients had a bilateral implantation history. Three of them were scheduled to undergo removal of the original infected leads, but the contralateral leads were accidentally dislocated during transvenous lead extraction. Interim decisions were made to reimplant the leads on the uninfected dislocated side. The patient with bilateral pocket infection was scheduled for abdominal implantation of a VVI pacemaker (Table 4).

### Follow-up and outcomes

At short-term follow-up, no intraoperative deaths occurred in the study population. Three VVI pacemakers and 21 DDD pacemakers were reimplanted. The pacing threshold, sensing, and impedance parameters were acceptable in all implanted leads during the procedure, postoperatively, and before discharge. There were no acute complications related to device reimplantation.

At long-term follow-up, all patients were followed up at the electrophysiology outpatient clinic at PUPH. The mean follow-up time was 59.7 ± 16.5 months (median, 58.5 months; range, 34 to 88 months). Two patients who were >85 years old with several comorbidities died 3 years after the initial surgery due to sudden non-cardiac death. There were no instances of new pacemaker infection, including no lead-related infections and no local infections of the new contralateral pocket.

## Discussion

The main finding of this study was that same-day reimplantation of a new CIED is safe and feasible in patients with isolated pocket infection after extraction of an infected pacemaker. During a mean follow-up of 59.7 ± 16.5 months, which to our knowledge is the longest follow-up period to date, none of the 24 patients who were

**Table 4:** The detail information of patients had bilateral implantation history.

| Patient | Sex | Age | PMH | Indication for PM | Original implantation site | Original implantation time | Abandoned leads number | Reason for bilateral implantation | Contralateral implantation time | Infection site | Infection time | Extracted leads number | TLE tools | Complications during TLE | Reimplantation site |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | F | 77 | HBP, CHD, DM, RA renal artery stenosis | SSS | left | 13 years | 2 | RV lead dislocation | 8 years | right | 7 years after contralateral implantation | 4 | laser sheath combined snare | Transient hypotension | left |
| 2 | M | 86 | DM, HF | AVB | left | 11 years | 0 | infection after generator replacement | 2 years | both sites | 1.8 years after contralateral implantation | 2 | locking style | none | abdomen |
| 3 | M | 68 | HBP | SSS | right | 14 years | 3 | infection after generator replacement | 5 years | right | 4.8 years after contralateral implantation | 5 | laser sheath combined snare | contralateral leads dislocated | left |
| 4 | M | 71 | NONE | SSS | left | 12 years | 1 | malfunction | 3 years | right | 2.8 years after contralateral implantation | 3 | snare | none | left |
| 5 | M | 74 | HBP, OSASH | AVB | right | 1 years | Move the pulse generator to the left chest and connect the original electrode to the subcutaneous tunnel | infection | 7 months | left | 1 month after contralateral implantation | 2 | simple tract | none | right |
| 6 | M | 76 | kidney stone | SSS | left | 16 years | 2 | infection | 9 years | right | 1.6 years after contralateral replacement | 4 | snare | none | left |
| 7 | M | 73 | DM | AVB | right | 18 years | 2 | malfunction | 11 years | both sites | 10 years after contralateral implantation | 4 | open chest | none | epicardium |
| 8 | M | 46 | | AVB | left | 7 years | 2 | infection | 2 years | left | | 4 | evolution | contralateral leads dislocated | right |
| 9 | F | 65 | | AVB | left | 10 years | 2 | malfunction | 4 years | left | | 4 | snare | contralateral leads dislocated | right |

diagnosed with isolated pocket infection experienced recurrence.

The rate of CIED infection is increasing in parallel with population aging, as is the number of CIED implantation procedures. Pacemaker replacement and aging are strong factors predisposing to pacemaker infection [1]. In the present study, the overall rate of a second procedure was up to 28%, and a quarter of patients were aged >80 years.

Antibiotic therapy and complete extraction of the infected CIED system constitute the current treatments for CIED infection management [3]. Despite standardized protocols for CIED infection being established since 2010 [2], improper treatments are still used in parts of China. This may be due to a lack of recognition of infection and inadequate preparation for complete extraction. Six patients underwent removal of only the infected pulse generator, not the entire system, before a new device was implanted on the contralateral side. During CIED removal on the infected side in patients with bilateral CIEDs, the contralateral leads were dislocated in three patients. Thus, such inappropriate treatments could not solve the infection on the original side and very likely contaminated the healthy contralateral side, increasing the complexity of surgery and economic loss [7].

In principle, patients with infected CIEDs are treated using two separate procedures, one for lead extraction and one for reimplantation. Current guidelines recommend that CIED reimplantation in patients with positive blood cultures should be delayed for 72 h to allow blood cultures to return to negative. In patients with isolated pocket infection, however, guidelines do not address the optimal reimplantation time owing to the paucity of literature exploring the timing of CIED replacement and reinfection risk [3]. In addition, even though the use of an active fixation lead connected to an external pulse generator has proven safe in pacemaker-dependent patients after transvenous lead extraction, these temporary leads require maintenance and are associated with infection recurrence [8,9].

Recent studies have shown that there is no significant correlation between the timing of reimplantation and survival in patients with isolated pocket infection [5,10]. In a prospective study of 434 patients who underwent complete system removal due to CIED infection, 23 patients underwent same-day reimplantation, and the reinfection rate was as low as in the delayed reimplantation group [11]. Another study by Mountantonakis et al. [12] included 15 patients who underwent reimplantation of a new device on the contralateral side on the same day as lead extraction for isolated pocket infection. There was no infection of the new system at a mean follow-up of 39.6 months. In a study by Spanish scholars, a new system was implanted on the contralateral side in the same procedure in 152 patients and in a second procedure in 57 patients, with no difference in relapse after 1 year of follow-up [13].

At our center, the strategies for pacemaker reimplantation and lead extraction are carefully discussed on a case-by-case basis by an experienced CIED management team, including, as a minimum, an electrophysiologist and a cardiothoracic surgeon. Certain factors are considered, including the extent of infection, degree of pacing dependency, presence of bilateral subclavian vein occlusion, physical fitness to sustain a second procedure (octogenarians, children, patients who cannot take care of themselves for other reasons), and VVI syndrome. The factors that determine the final decision are not always isolated. In fact, for cases of simple local pocket infection, the proportion of patients who underwent same-day reimplantation was 3.5% (24 of 693) at our center.

Leadless pacemakers have become an excellent alternative to traditional CIEDs in these challenging cases, such as in patients with recurrent device infection, occlusion of the subclavian venous access, or bilateral implants [14,15]. Some centers attempt simultaneous reimplantation of a new leadless pacemaker and lead extraction. For example, in a study by El-Chami et al. [16], 40 patients (37.1%) underwent leadless pacemaker implantation during the same procedure as device removal, with no recurrent device-related infections after a mean follow-up period of 8.5 months. Zhang et al. [17] also performed leadless pacemaker reimplantation immediately after removal of an infected pacing system in eight patients with pocket infection. Kypta et al. demonstrated the feasibility of Micra system implantation just before conventional pacemaker lead extraction during the same procedure in two patients. Both of these studies indicate that it is safe and feasible to implant leadless pacemakers without delay in patients with isolated pocket infection after transvenous lead extraction. However, more research is required to support this conclusion. Our approach to same-day traditional pacemaker implantation might provide an empirical basis to support this strategy.

## Study Limitations

This study has some limitations that should be noted. First, it was a small single-center retrospective study with a degree of selection bias. Second, the small sample size of our study meant that a multivariate analysis was unsuitable.

## Conclusion

In this study, same-day reimplantation of a new pacemaker during lead extraction for isolated pocket infection was feasible and was not associated with long-term adverse outcomes. To ensure the safety of same-day reimplantation, it is necessary to ensure that there is no bacteremia during transvenous lead extraction, which should be confirmed in future prospective studies.

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