

# Utilization of leadless pacemaker following transvenous lead extraction: A series of 10 successful cases



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## Introduction

Implantation rate of cardiovascular implantable electronic devices (CIED) is rising owing to improved diagnostic tools for bradyarrhythmias or ventricular arrhythmias, aging population, and growing indications. This comes with increasing pocket or systemic infections with each generator replacement and revisions necessitating device system extraction.

CIED infection is associated with high morbidity, protracted antimicrobial therapy, lengthy hospitalization particularly related to intensive care unit stays, and substantial financial burden to the healthcare system. In a large referral center in the United Kingdom (UK), the average cost of 84 patients undergoing transvenous lead extraction (TLE) ranged from £5139 for pacemaker to £24,318 for cardiac resynchronization therapy-defibrillator devices.<sup>1</sup> In another high-volume extraction center in the UK, Gould and colleagues<sup>2</sup> looked at 445 admissions for TLE over the course of 5 years and the mean length of stay for patients was  $16.3 \pm 15.2$  days.

The rate of reinfection in newly reimplanted transvenous pacemaker systems after extraction of infected CIEDs is about 2% and this rose to 11% if original hardware was retained in the pocket.<sup>3</sup> Leadless pacemaker (LP) is an alternative device for patients with bradyarrhythmia. This novel and advantageous technology supersedes the need for indwelling transvenous lead altogether, thus reducing the infection risk of conventional pacemakers. LP reimplantation

## KEY TEACHING POINTS

- Leadless pacemaker implantation reduces risks of device-related infections and complications following transvenous lead extraction.
- Long-term safety of leadless pacemaker utilization after transvenous lead extraction is demonstrable in this study.
- Transvenous lead extraction procedure is associated with significant complications and must be individualized.

following TLE in patients who are at high risk of reinfection or occluded venous system is appealing and has been performed concomitantly during or after extraction. LP utilization has been endorsed in specific subgroup of patients in the most recent 2021 European Society of Cardiology guidelines on cardiac pacing and cardiac resynchronization therapy.<sup>4</sup>

A simpler and less invasive technique of LP implantation through a small incision via the femoral vein where the pacemaker is preloaded on a delivery catheter, with the operator having minimal contact with the device, also mitigates against infection risks. To date, >50,000 LP Micra™ Transcatheter Pacing Systems (Medtronic Inc, Minneapolis, MN), the only available LP in the global market have been implanted worldwide,<sup>5</sup> and there have been no reported device-related infections in more than 2500 patients who were enrolled in the Micra pivotal and postapproval studies.<sup>6,7</sup> In a large observational study of a real-world population, LP implantation is also associated with lower rate of device reinterventions and chronic complications compared with *de novo* transvenous single-chamber ventricular pacemaker.<sup>8</sup>

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**Table 1** Summary of transvenous lead extraction cases followed by Micra leadless pacemaker implantation

Sex	Age	Mode of pacing, indication (temporary pacing during TLE)	No. of leads	Dwell time, years	Indication for TLE	Anesthesia	Venous entry for TLE	TLE tools used	TLE outcome (complication)	Time from TLE to reimplant, days	LOS in hospital, days
Female	21	VVI, CHB (TPW)	1	14	Pocket infection	General	Mixed	Laser and snare	Complete success	14	15
Male	40	DDD, CHB (-)	3*	19.3	Lead failure	General	Superior	Laser + Evolution	Clinical success (localized SVC dissection)	13	25
Male	51	DDD, SND (-)	2	14.4	Pocket infection + erosion	General	Mixed	Laser, snare + Evolution	Failure (Emergency open chest extraction of RV lead and atrial appendage repair)	14	20
Female	58	DDD, CHB (EPG)	2	7.3	Infective endocarditis	General	Superior	Laser	Complete success	11	45
Male	62	DDD, CHB (EPG)	2*	29.3	CIED bacteremia	General	Superior	Laser + Evolution	Complete success	4	32
Female	65	VVI, CHB (-)	1	1.7	Lead failure	General	Superior	Manual traction	Complete success	2	10
Male	72	DDD, 2:1 AV block (-)	2	3.6	Infective and lead endocarditis	Deep sedation	Superior	Manual traction	Complete success	0	65
Male	79	DDD, 2:1 AV block (-)	2*	8.1	Pocket erosion and infection	General	Mixed	Laser + snare	Complete success	7	34
Male	81	VVI, CHB (-)	2	1.1	Pocket erosion	Local	Superior	Manual traction	Complete success	10	16
Male	82	DDD, CHB (EPG)	2	20.5	Pocket infection	General	Superior	Laser + Evolution	Complete success	25	34

AV = atrioventricular; CHB = complete heart block; CIED = cardiovascular implantable electronic device; EPG = externalized pulse generator; LOS = length of stay; RV = right ventricle; SND = sinus node disease; SVC = superior vena cava; TLE = transvenous lead extraction; TPW = temporary pacing wire.

Asterisk (\*) denotes 1 passive lead.

Two reported rare cases of LP-related infections requiring percutaneous extraction have been reported at 120 days and 1 month after implantation.<sup>9,10</sup> A case series of 17 patients who had LP implantation (11 with Nanostim [St Jude Medical Inc, Saint Paul, MN] and 6 with Micra) after conventional pacing system extraction demonstrated no evidence of repeat infections either after early (less than a week) or late (more than a week) LP placement.<sup>11</sup>

There has been no consensus/guideline to support routine uptake of LP, likely owing to high costs of implantation, extra training skills, and time required by experienced operators potentially posing as barriers. A survey conducted in 52 centers in Europe echoed the aforementioned reasons as limiting factors in LP implantation.<sup>12</sup> There is a paucity of data on LP implantation after CIED extraction, although there are a few reported studies. Gonzales and colleagues<sup>13</sup> concluded LP implantation in comparison to externalized temporary transvenous right ventricular lead placement (9 vs 27 patients) is safe after CIED extraction, with shorter hospitalization and no reinfection in 90 days. In another study, a comparison of 23 patients who had prior TLE and subsequent LP implantation vs a control “naïve” population (n = 60) who had the same LP procedure revealed good outcome without device-related adverse events, stable electrical performance, and no repeat infections at median follow-up of 18 months.<sup>14</sup> Simultaneous LP implantation and CIED extraction have also shown to be achievable and sound in the context of active infection in a retrospective study of 17 patients.<sup>15</sup>

## Methods

We described 10 cases of transfemoral LP implantation in our tertiary referral center following TLE via either superior (entry site identical to implantation route) or mixed (femoral and superior approach combined when snare devices were used) venous entry. Decision to proceed to LP implantation after CIED extraction was at the discretion of the same operator who undertook device extraction. This study was conducted in accordance with local regulations and approved by the Institutional Review Boards Committee as part of a service evaluation study to assess the safety of the TLE scheme at our regional center. All patients provided written informed consent.

The operator is trained in wide-ranging skills of TLE, including laser-assisted technique, locking stylets, rotational mechanical dilator sheaths, and snare methods (needle’s eye and goose neck).

This study included 10 patients who received LP implantation following TLE of pacemaker system between April 2018 and August 2020 and followed up for at least 12 months in our tertiary regional referral center. Class 1 indication for TLE in our study population is pocket infection, valvular endocarditis, lead endocarditis, or failure. All patient details, including comorbidities, medications, indication of initial pacemaker implantations, duration of hospitalization, TLE technique, and procedures, were retrieved electronically and through medical notes.

The baseline demographics for each patient, pacing mode of initial pacemaker device implanted, indication of TLE, extraction tools used, outcomes, and time to LP implantation are detailed in [Table 1](#).

## Results

The operator carried out TLE and subsequent LP implantation procedures in the cardiac catheter suite with on-site immediate support from cardiothoracic surgeons and cardiopulmonary bypass facilities if required.

The majority of patients (80%) had pacemaker device system extraction attributed to infection. There was a wide range of age distribution (patients aged 21–82) with mean (SD) of 61 (19) years, and 70% of patients in the study were male. Left ventricular systolic function was preserved in all patients. Three patients had diabetes mellitus, 2 had chronic kidney disease without needing hemodialysis, and 3 were on oral anticoagulation therapy. A single complex patient had previous infective endocarditis requiring aortic valve prosthesis (porcine) coupled with extensive aortic root reconstruction.

Less than half (3 out of 10 patients) of the study cohort had a bridging pacing system with transvenous active-fixation right ventricular pacing lead (via extraction entry site) connected to externalized pulse generator during the TLE procedure until LP implantation and another patient had temporary transvenous ventricular pacing support via the femoral vein during CIED extraction.

Laser-assisted technique was the most frequently used tool during TLE cases of 19 leads (3 passive and 16 active), with 8 out of 10 patients requiring general anesthesia. Eight patients achieved complete procedural TLE success while another had clinical success complicated intraprocedurally with localized superior vena cava dissection diagnosed with direct venogram fluoroscopically without major hemodynamic embarrassment and settled with conservative supportive approach. One TLE procedural failure led to emergency open chest extraction of his broken passive-fixation right ventricular lead. He also required concomitant repair of right atrial appendage owing to perforation sustained, leading to hemodynamically significant pericardial tamponade and failed percutaneous drainage on the table. This led to lengthy hospitalization in the intensive care unit.

Time from device system extraction to LP implantation varied across all patients, ranging from concomitant procedure to at least 15 days or more. The average time interval from TLE to LP implantation was 10 days. The wide range of time difference to LP implantation is multifactorial owing to persistent inflammatory signs (fever and rising C-reactive protein) of patients or availability of cardiac catheter lab on the day of LP implantation. The patient with the longest wait (25 days) to LP implantation had severe infection and he was bridged with an externalized pulse generator owing to underlying complete heart block.

Another complex patient with the longest in-patient stay in the hospital (65 days) received concomitant LP

implantation at the time of TLE. He had recurrent infective endocarditis of redo bioprosthetic aortic valve, history of coronary bypass grafts, and previous aortic root reconstruction, which became infected during this episode, with abscess and fistula connection to the left atrium. He was subsequently turned down for surgery owing to high prohibitive surgical risks and managed with an extended course of intravenous antibiotics prior to LP procedure.

Patients who had TLE owing to infection appeared to have protracted hospitalization compared with noninfective causes. There was no mortality or adverse event related to device reinfection observed at follow-up of at least a year. Moreover, there is no evidence of long-term complication with LP device malfunction.

## Conclusion

Infection remains the commonest indication for TLE in our cohort. All leads were extracted predominantly with laser assistance. The majority of our patients were of young age. TLE procedure is associated with important risk and major complications. This study highlighted acceptable feasibility and safety in LP implantation following CIED extraction in infective or noninfective causes in carefully selected patients who were followed up for at least 12 months. Patients in our study seemed to have a long waiting time from TLE to LP procedures. There is emerging evidence that concomitant LP implantation and lead extraction are safe during active infection, particularly in patients who are pacemaker dependent.

## Discussion

Our small study without control group and decision made for LP implantation could be inherently biased by a single operator's experience and skills. Moreover, it is unknown whether the outcome would be dissimilar if all our patients had concomitant LP and TLE procedures. Randomized controlled trials of LP vs conventional transvenous pacing system post CIED extraction could be considered to guide future directions, although this can be challenging to conduct owing to complex selection of patients who are often unwell in the hospital with systemic infection or bacteremia.

Subsequent LP implantation in patients who have had TLE remains safe, although it will have to be undertaken by a subset of cardiologists with specialized skills who have undergone additional training time.

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