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Leadless pacemaker implant in patients with pre-existing infections: Results from the Micra postapproval registry

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Abstract

Introduction: Leadless pacemakers may provide a safe and attractive pacing option to patients with cardiac implantable electronic device (CIED) infection. We describe the characteristics and outcomes of patients with a recent CIED infection undergoing Micra implant attempt.

Methods and Results: Patients with prior CIED infection and device explant with Micra implant within 30 days, were identified from the Micra post approval registry. Procedure characteristics and outcomes were summarized. A total of 105 patients with prior CIED infection underwent Micra implant attempt ≤30 days from prior system explant (84 [80%] pacemakers and 13 [12%] ICD/CRT-D). All system components were explanted in 93% of patients and explant occurred a median of 6 days before Micra implant, with 37% occurring on the day of Micra implant. Micra was successfully implanted in 99% patients, mean follow-up duration was 8.5 ± 7.1 months (range 0-28.5). The majority of patients (91%) received IV antibiotics preimplant, while 42% of patients received IV antibiotics postprocedure. The median

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length of hospitalization following Micra implant was 2 days (IQR, 1-7). During follow-up, two patients died from sepsis and four patients required system upgrade, of which two patients received Micra to provide temporary pacing support. There were no Micra devices explanted due to infection.

Conclusion: Implantation of the Micra transcatheter pacemaker is safe and feasible in patients with a recent CIED infection. No recurrent infections that required Micra device removal were seen. Leadless pacemakers appear to be a safe pacing alternative for patients with CIED infection who undergo extraction.

KEYWORDS

cardiac implantable electronic device infection, leadless pacemakers, Micra, permanent pacing, transcatheter pacemaker

1 | INTRODUCTION

A significant increase in the rate of cardiac implantable electronic device (CIED) infections has been observed in the United States.[1,2] CIED infections are associated with a significant increase in hospital length of stay, cost, and mortality.[3–5] The average hospital length of stay for patients with pacemaker-related infections ranges from 15.5 to 24 days.[3] The cost associated with such admissions is significant, exceeding $28 000 in the U.S. and €23 000 in France.[4] More importantly, the 1-year mortality after pacemaker infections can exceed 35%.[3,5] Furthermore, the risk of reinfection after reimplantation is around 2% and exceeds 11% in patients who had only partial removal of the original device.[6]

Leadless pacemakers eliminate pocket-related infections and have the potential to reduce lead-related endocarditis. In the Micra leadless pacemaker investigational device exemption (IDE) study and post approval registry (PAR) no Micra device-related infections or any infections requiring device removal were observed.[7–9] Hence, Micra in the setting of device infection might be an appealing pacing alternative after CIED removal.

In this study we sought to determine the outcomes of patients enrolled in the Micra PAR with history of CIED infections that were implanted with a Micra pacemaker following prior system explant.

2 | METHODS

The design and rationale for of the Micra PAR study (ClinicalTrials.gov identifier: NCT02536118) have been reported previously.[9,10] Briefly, the aim of the Micra PAR is to further evaluate short- and long-term safety and performance of the Micra transcatheter pacing system (TPS) when used in the "real-world" setting following commercial release. All patients intended to be implanted with a market-approved Micra device without restriction due to comorbidity or prior CIED status at participating centers were eligible for enrollment. Since the goal of this analysis was to analyze outcomes in clinical practice outside of an investigational clinical trial, patients that participated in the premarket trial (ie, IDE) or continued access (CA) study and consented to long-term follow-up in the PAR were excluded from this analysis. All adverse events potentially related to the Micra system or procedure are required to be reported upon awareness. The study is sponsored by Medtronic, plc (Mounds View, MN), the protocol was approved by the ethics committee at each investigational site, and all patients provided written informed consent. Adverse events were adjudicated by a Clinical Events Committee comprised of n = 9 independent physicians.

Enrollment into the Micra PAR is closed with a total of 1820 patients that underwent attempted Micra implant at 180 investigational sites in 23 countries. The study's 9-year follow-up period is ongoing. For the purposes of this analysis, enrolled Micra PAR patients with evidence of a recent CIED infection and CIED explant within 30-days before Micra implant attempt were identified and included in the analysis. Explants were determined to be complete if all previously implanted system components were recorded as being removed and partial if only a portion of the system components were recorded as being removed (eg, two of three components).

2.1 | Objective

The objective of the present analysis is to report on outcomes in patients receiving a Micra device following recent CIED infection. Safety was assessed by summarizing major complications defined as events related to the Micra TPS or procedure resulting in death, permanent loss of device function, hospitalization, prolonged hospitalization by 48 hours or more, or system revision. Of particular interest for this analysis was the incidence of infection requiring device removal, thus reasons for any Micra system revision were also summarized. Medical history, implant characteristics, and electrical performance were also evaluated.

2.2 | Statistical methods

Patients with a history of CIED infection and/or reason for CIED explant reported as "infection" who had a full or partial CIED system explant within 30-days of their Micra implant attempt were identified. Summary statistics were obtained and reported using mean and standard deviation for continuous variables, and frequencies and percentages for categorical variables. The Kaplan-Meier method was used to estimate the all-cause mortality rate during follow-up. All analyses were conducted with SAS version 9.4 (SAS Institute, Cary, NC) or the R statistical package (R Project for Statistical Computing, Vienna, Austria).

3 | RESULTS

The Micra PAR database was frozen for analysis on 1 August 2018. A total of 1820 patients were consented and underwent Micra implant as part of the Micra PAR registry of which 105 (5.8%) from 59 study centers had a prior CIED infection and underwent a Micra implant attempt within 30 days of their prior system explant.

TABLE 1 Baseline characteristics and prior CIED system information

Subject characteristics	Subjects, *N* = 105
Age, y	
Mean ± standard deviation	72.7 ± 14.7
Sex (% male)	69 (65.7%)
Cardiovascular disease history (n, %)	
Atrial arrhythmias	60 (57.1)
Cardiomyopathy	28 (26.7)
Congestive heart failure	16 (15.2)
Coronary artery disease	26 (24.8)
Hypertension	51 (48.6)
Myocardial infarction	6 (5.7)
Pulmonary hypertension	3 (2.9)
Coronary artery intervention	17 (16.2)
Pacemaker dependent	33 (31.4)
Other comorbidities n (%)	
COPD	17 (16.2)
Chronic lung disease	18 (17.1)
Diabetes	34 (32.4)
Renal dysfunction	29 (27.6)
Dialysis	13 (12.4)
Condition precluding transvenous system	83 (79.0)
Pacing indication n (%)	
Bradyarrhythmia with AF	52 (49.5)
Sinus node dysfunction	11 (10.5)
AV block	23 (21.9)
Syncope	12 (11.4)
Other	6 (5.7)
Not reported	1 (1.0)
Previous CIED system (%)	
Pacemaker	74 (70.5)
CRT-pacemaker	10 (9.5)
ICD	5 (4.8)
CRT-ICD	8 (7.6)
Not reported	8 (7.6)
Prior system status (%)	
All components explanted	98 (93.3)
Partially explanted	7 (6.7)

Abbreviations: AV, atrioventricular; CIED, cardiac implantable electronic device; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator.

Table 1 summarizes the baseline characteristics of the cohort. The mean age was 72.7 ± 14.7 years, 57.1% of patients had atrial tachyarrhythmias, 32% had diabetes, and 27.6% had renal dysfunction, of which 13 (45%) required dialysis. Investigators reported that 83 patients (79.0%) had a condition that precluded the use of transvenous pacing systems, of which 11 (13%) had stenosed/occluded subclavian veins and 4 (5%) had a need to preserve the subclavian vein (ie, dialysis). AF with bradycardia was the main indication for pacing in this cohort (49.5%) followed by atrioventricular block with intact sinus function (21.9%) (Table 1). There were 33 patients (31.4%) considered to be pacemaker dependent (escape rhythm ≤30 bpm) by the implanting physician.

Prior CIED systems at the time of explant included single or dual chamber transvenous pacemakers (70.5%), cardiac resynchronization therapy pacemakers (CRT-P; 9.5%) and CRT-defibrillators (CRT-D) or defibrillators in 13 (12.4%) patients (Table 1). All infected CIED components present at baseline were explanted in 93.3% of patients, in the remaining 6.7%, only partial explant of components occurred.

The Micra system was successfully implanted in 104 (99%) of the 105 patients. The unsuccessful implant attempt occurred in an 82-year-old male with an entire dual chamber pacemaker system explanted on the day of implant attempt. The implanter reported that the device could not be adequately positioned to achieve an acceptable pacing threshold due to the patient's dilated ventricle.

The mean time between CIED extraction and Micra implant attempt was 6.5 ± 7.2 days with 37.1% of patients receiving their Micra implant on the day of CIED extraction (Table 2). The majority of pacemaker dependent patients (51.5%) had their Micra implant on the day of CIED extraction, whereas Micra implant was a median of 7 days following CIED explant for the 72 patients that were not pacemaker dependent ($P = 0.015$). Preimplant intravenous antibiotics were administered for 91.4% patients and 41.9% received intravenous antibiotics postimplant. After discharge oral antibiotics were prescribed for 13.3% of patients. Median hospitalization following Micra implant was 2 days (IQR, 1-7). Average implant pacing threshold was 0.6 + 0.4 V among 82 patients with thresholds reported. Of the 95 implant procedures reporting the number of positioning attempts, 89.5% of devices were positioned with less than equal to three attempts. Mean follow-up duration was 8.5 ± 7.1 months (range 0-28.5 months).

Six major complications occurred in four patients that were related to the Micra procedure or system (Table 3). These complications have been reported previously.[10]

One patient developed an effusion requiring pericardiocentesis. Another patient had three complications. After the release of Micra, a rise in threshold was noted and retrieval was attempted. During the retrieval the device became entangled in the patient's inferior vena

TABLE 2 Micra implant procedure

Subject characteristics	Subjects (N = 105)
Implant success (%)	
Yes	104 (99.0)
No	1 (1.0)
Days from prior system explant to micra procedure (days)	
Mean ± standard deviation	6.5 ± 7.2
Median	6.0
25th Percentile–75th Percentile	0–10
Subjects with measure available (N,%)	105 (100.0)
Infection prevention strategy (N,%)	
Not reported	2 (1.9)
Preoperative IV antibiotics	96 (91.4)
Preoperative oral antibiotics	8 (7.6)
Betadine use	26 (24.8)
Chlorhexidine use	58 (55.2)
Intraoperative antibiotics	16 (15.2)
Postoperative IV antibiotics	44 (41.9)
Postdischarge oral antibiotics	14 (13.3)
Implant Duration (min)	
Mean ± standard deviation	33.2 ± 18.5
Median	26.5
25th Percentile–75th Percentile	21–42
Subjects with measure available (N,%)	90 (85.7)
Fluoroscopy duration (min)	
Mean ± standard deviation	9.9 ± 9.5
Median	7.4
25th Percentile–75th Percentile	5–12
Subjects with measure available (N,%)	93 (88.6)
Deployments (N,%)[a]	
1	56 (53.3)
2	23 (21.9)
3	6 (5.7)
4–5	5 (4.8)
6–10	4 (3.8)
>10	1 (1.0)
Not reported	10 (9.5)
Pacing threshold (mV @ 0.24 ms)	
Mean ± standard deviation	0.6 ± 0.4
Median	0.5
25th Percentile–75th percentile	0–1
Subjects with measure available (N,%)	82 (78.1)
R-wave amplitude (mV)	
Mean ± standard deviation	9.6 ± 4.5
Median	9.1
25th Percentile–75th percentile	6–12
Subjects with measure available (N,%)	73 (69.5)
Impedance (ohms)	
Mean ± standard deviation	751.5 ± 207.5
Median	710.0
25th Percentile–75th percentile	616–820
Subjects with measure available (N,%)	85 (81.0)
Total hospital duration (days)	
Mean ± standard deviation	17.9 ± 16.0
Median	14.0
25th Percentile–75th percentile	6–27
Subjects with measure available (N,%)	105 (100.0)
Days from Micra procedure to discharge (days)	
Mean ± Standard deviation	4.9 ± 6.3
Median	2.0
25th Percentile–75th percentile	1–7
Subjects With measure available (N, %)	105 (100.0)

[a]Denominator for percentage is number of patients reporting deployments.

cava filter and led to vascular trauma. This required surgical repair. The patient subsequently developed an abdominal wall (surgical wound) infection that was treated successfully with antibiotics. This patient received a new Micra device at the time of retrieval of his first Micra. Two other patients developed pacemaker syndrome and required a device upgrade. The first patient was a 78-year-old male with a prior CRT-P device that developed pacemaker syndrome 41 days post implant. A final Micra device interrogation indicated high percentage RV pacing (98.9%). The patient's Micra device was programmed to OOO (off mode) and the patient received a CRT-D. The second patient was a 37-year-old female with a prior ICD who developed pacemaker syndrome 49 days postimplant; the percentage of ventricular pacing was not available. The patient's Micra device was programmed to OOO and the patient received a dual chamber pacemaker.

There were three additional system revisions that were not associated with Micra-related major complications. The first patient underwent a heart transplant 435 days after implant. The second patient was a 47-year-old female with a prior CRT-D that underwent a successful Micra extraction attempt and device upgrade 13 days after Micra implant. The 3rd patient was a 69-year-old male with a prior CRT-D whose device was programmed to OOO and upgraded to a transvenous system 140 days after Micra implant. Micra was used to provide temporary pacing support while the CIED infection cleared in the two patients with prior CRT-D devices.

There were no recurrent infections requiring Micra removal during the follow-up period.

A total of 10 deaths occurred during follow-up resulting in a mortality rate of 14.2% through 12-months after implant (Figure 1).

TABLE 3 Major complications in 105 patients with prior CIED infection and extraction who underwent Micra implant attempt

Adverse event keyterm	No. events (No. subjects, %)
Total major complications	**6 (4, 3.81)**
Cardiac effusion/perforation	**1 (1, 0.95)**
Pacing issues	**1 (1, 0.95)**
Elevated thresholds	1 (1, 0.95)
Infection	**1 (1, 0.95)**
Abdominal wall infection	1 (1, 0.95)
Other	**3 (3, 2.86)**
Complication of device removal	1 (1, 0.95)
Pacemaker syndrome	2 (2, 1.90)

Abbreviation: CIED, cardiac implantable electronic device.
The first bold is number of subjects and second one is percentage.

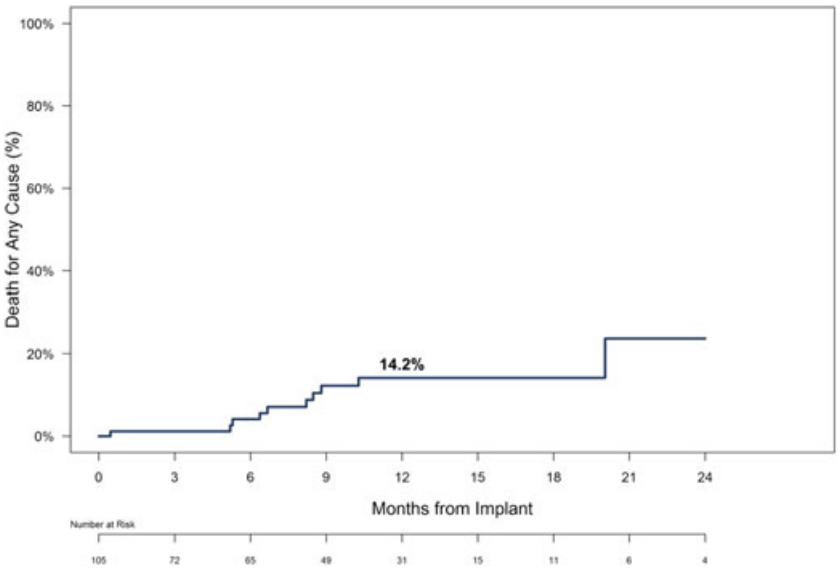

FIGURE 1 Kaplan-Meier survival curve following micra implant. All cause death rate for patients implanted with a Micra device within 30 days of CIED extraction due to infection. Kaplan-Meier rate at 12 months postimplant is depicted. CIED, cardiac implantable electronic device

None were adjudicated to be related to Micra device or implant procedure. Two of the 10 deaths were due to sepsis that occurred 14 and 161 days postimplant, both patients had complete extraction of all CIED components before Micra implant. These patients had multiple comorbidities including cardiomyopathy, renal dysfunction, and diabetes.

4 | DISCUSSION

This is the largest study to date evaluating the outcomes of patients implanted with a leadless pacemaker after extraction of an infected CIED. The use of Micra leadless pacemakers in this setting appeared safe with no recurrent device (Micra)-related infections. By eliminating the subcutaneous pocket, leadless pacemakers reduce the chance of bacterial translocation into the pacemaker locale. In addition, the small surface area of Micra (~546 mm^2) as compared to a TV lead (~3500 mm^2) and its tendency for encapsulation[11] might reduce the chance of device related endovascular infection. In addition, Micra is located completely within the intracardiac space, where blood pressure, velocity, and turbulence are higher. Other devices located completely within the intracardiac space, such as MitraClip, Watchman, and patent foramen ovale closure devices, exhibit an extremely low infection rate, which Micra may share. Hence, the use of this leadless pacemaker in patients with prior CIED infection may lead to potential benefit.

A small study of 17 patients that received a leadless pacemaker after extraction of an infected CIED system, showed no recurrent infection during a mean follow-up of 16 months.[12] Similarly, the use of Micra TPS after extraction of pre-existing pacing system in six patients with device infection proved safe without recurrence of any infection after 12 weeks of follow-up.[13]

The data presented in this manuscript also show that Micra is a safe alternative in patients after extraction of infected CIED. No Micra infection was observed and no systemic infection that required device removal was encountered. This is an important finding especially in this patient population at high risk of recurrent infection.[6] Another notable observation is the low mortality rate through 1-year (14.2%). Mortality in patients with TV CIED infection after extraction is on average 20% at 1-year and in some studies exceeds 35%.[3,5] Whether this finding is related to a low reinfection rate with Micra requires further investigation. Two patients died of sepsis during follow-up, in both cases all components of the prior CIED system were extracted. These two deaths were considered unrelated to Micra. It is conceivable however that the death from sepsis occurring 14 days post Micra implant is still related to the original infection. The second death from sepsis occurred 161 days from Micra implant in a patient with multiple comorbidities including cardiomyopathy, chronic kidney disease, and diabetes. The death was adjudicated as unrelated to Micra device or procedure.

Patients enrolled in this study had multiple comorbidities. Around 80% of these patients had a condition that precluded the use of a traditional transvenous device. This could explain why patients with pre-existing ICD or CRT devices (22% of our cohort) had Micra implant after CIED extraction (Table 1). It is also possible that the indication for an ICD or CRT in these patients no longer existed at the time of CIED extraction.

The Micra pacemaker was implanted on average 6.5 days after device extraction, however 37.1% of patients had Micra implanted during the same procedure. Simultaneous reimplantation of a new pacing system after extraction of CIED for isolated pocket infection has been shown in single center studies to be feasible and not associated with increase in complications.[14]

5 | STUDY LIMITATIONS

This study does not compare the outcome of Micra vs transvenous pacemakers in patients with prior CIED infection. Also, the decision to implant a Micra pacemaker as well as the timing of implant was

left to the discretion of the implanting physician. Patients were followed for a mean of 8.5 months; hence long-term infection recurrence might have been missed. In addition, no data were collected on the type and severity of the infection (ie, type of infection, presence or absence of bacteremia, and or endocarditis and type of antibiotics used). In addition, we cannot rule out that patients with less severe infection were more likely to be enrolled in this registry therefore introducing an important source of selection bias. It is, however, the largest report on the outcomes of patients with history of CIED infection implanted with a leadless pacemaker.

6 | CONCLUSION

The Micra leadless pacemaker is a safe and feasible pacing option in patients with history of CIED infection. Its intracardiac location, small surface area, and tendency for encapsulation might provide an advantage in this patient population at risk of recurrent infections.

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