# A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry

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**BACKGROUND** First-in-man studies of leadless pacemakers have demonstrated high rates of implant success, and safety and efficacy objectives were achieved. Outside of the investigational setting, there are concerns, particularly over cardiac effusion and perforation, device dislodgement, infection, telemetry, and battery issues.

**OBJECTIVE** The acute performance of the Micra transcatheter pacemaker from a worldwide Post-Approval Registry is reported.

**METHODS** The registry is an ongoing prospective single-arm observational study designed to assess the safety and effectiveness of Micra in the post-approval setting. The safety end point was system- or procedure-related major complications at 30 days post implant. We compared the major complication rate with that of the 726 patients from the investigational study. Electrical performance was also characterized.

**RESULTS** The device was successfully implanted in 792 of 795 registry patients (99.6%) by 149 implanters at 96 centers in 20 countries. Through 30 days post implant, a total of 13 major complications occurred in 12 patients, for a major complication rate of 1.51% (95% confidence interval, 0.78%–2.62%). Major complications included cardiac effusion/perforation (1, 0.13%), device dislodgement (1, 0.13%), and sepsis (1, 0.13%). After adjusting for baseline differences, the rate of major complications in the registry trended lower than the investigational trial (odds ratio, 0.58, 95% confidence interval, 0.27–1.25; $P = .16$). Early pacing capture thresholds were low and stable.

**CONCLUSION** Performance of the Micra transcatheter pacemaker in a real-world setting demonstrates a high rate (99.6%) of implant success and low rate (1.51%) of major complications through 30 days post implant. In particular, the rates of pericardial effusion, device dislodgement, and infection were low, reinforcing the positive results seen in the investigational study.

**KEYWORDS** Acute performance; Leadless pacemaker; Real-world performance



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## Introduction

Pocket and lead-related complications are commonly encountered problems with traditional transvenous pacemakers (PPM).[1,2] Leadless pacemakers were designed to minimize or eliminate these adverse events.[3,4] The Micra transcatheter pacing system (TPS) investigational device exemption (IDE) study enrolled 745 patients.[3] In this study, the implant success rate was excellent (99.2%) and the major complication rate through 12 months post implant was low (4%).[5] This complication rate compared favorably with the complication rate (7.6%) seen in a prespecified transvenous PPM historical cohort. No TPS device dislodgements or infections were noted in these patients. In addition, device electrical parameters (capture thresholds, sensing, and impedance) were excellent and remained stable over 1 year of follow-up.[5] Although the results of the IDE study are reassuring, the novelty of the technology creates concerns over the reproducibility of these impressive initial findings. Concerns persist over the rate of pericardial effusion and the overall safety of Micra when implanted in the real world, outside the investigational setting. In this study, we report the acute performance of the Micra TPS with the initial patients from the ongoing worldwide Post-Approval Registry.

## Methods

### Study design

The Micra Post-Approval Registry is a prospective, nonrandomized, multicenter post-approval release registry designed to further evaluate the safety and effectiveness of the Micra TPS when used as intended, in "real-world" practice. The protocol was approved by the ethics committee at each of the participating centers. Adverse events were adjudicated by a clinical events committee comprised of independent physicians.

### Patients and procedures

Patients intended to be implanted with a Micra device are eligible for enrollment in the study. The study investigators intend to enroll approximately 1830 patients in the study, and enrollment is currently ongoing. All patients provided written and informed consent prior to implant.

The Micra TPS is a single-chamber ventricular pacemaker and is 93% smaller than a transvenous pacemaker system. The device has similar functionality and features to preexisting single-chamber pacemakers, including rate adaptive pacing, remote monitoring capabilities, and automated pacing capture threshold management, designed to maximize battery longevity. The device is implanted directly in the right ventricle through a femoral vein. The device is fixated in the myocardium via 4 flexible nitinol tines.

Enrolled patients underwent an implantation attempt and were followed in accordance with the standard care practices of their provider. Patient and device status are reported at implantation/pre–hospital discharge, 30 days post implant, and at least annually thereafter for a minimum of 9 years.

### End points

The aim of this interim analysis was to assess system- or procedure-related major complications through 30 days post implant. Using the same criteria as in the Micra IDE study, major complications were defined as events resulting in death, permanent loss of device function, hospitalization, prolonged hospitalization by 48 hours or more, or system revision. Electrical performance at implant/pre–hospital discharge was also characterized.

### Statistical analysis

The study is a pragmatic clinical trial designed to continuously monitor the performance of the newly market-released leadless pacemaker in the real-world clinical practice. The study primary objectives are to estimate acute and long-term safety performance of the Micra system. No statistical hypotheses were formulated. Study enrollment size was calculated to yield 500 Micra-implanted participants completing 9 years' postimplantation follow-up and to ensure reliable estimates could be achieved for individual complications occurring at an underlying rate of 1%.

All patients who underwent a Micra TPS implantation attempt after written consent were included in the analysis. Summary statistics were obtained and reported using mean and standard deviation for continuous variables, and frequencies and percentages for categorical variables. Rates of major complications related to the Micra system or implantation procedure were calculated using the binomial method, with 95% confidence intervals calculated using the exact method. We adopted the same definition for major complication from the IDE study to conduct the evaluations against the IDE study. Logistic regression was performed to adjust for potential risk factors when comparing the 2 cohorts.

## Results

### Patients

A total of 795 patients were enrolled from 96 centers in 20 countries, with the first implantation procedure occurring in July 2015. The database for the present analysis was frozen on January 31, 2017. Patients were mostly male (62.3%); the average age was 75.1 $\pm$ 14.2 years; and 104 patients (13.1%) had a previously implanted cardiac electronic implantable device (Table 1), which was an exclusion criterion in the IDE study. Types of previously implanted devices were transvenous pacemaker systems (73 patients), transvenous implantable cardioverter-defibrillators (13), epicardial systems (11), TPSs (1), and implantable cardiac monitors (6). In addition, 166 patients (20.9%) had $\geq$1 condition that precluded the use of a transvenous pacing system, including compromised venous access (72 patients), history of or risk of infection (70), need to preserve veins for hemodialysis (38), thrombosis (24), cancer (23), valvular issues/prosthetic valve (8), and other (13). Indications for implantation were bradyarrhythmia associated with permanent or persistent atrial tachyarrhythmia (57.7%), atrioventricular block (14.7%), syncope (14.1%), sinus node dysfunction

**Table 1** Baseline Characteristics

| Baseline Demographics and Clinical Characteristics | Patients With an Implant Attempt (N = 795) |
|---|---|
| Age, y, mean ± SD | 75.2 ± 14.2 |
| Male gender, n (%) | 495 (62.3) |
| LVEF, %, mean ± SD | 55.7 ± 9.7 |
| Hypertension, n (%) | 454 (57.1) |
| Atrial fibrillation, n (%) | 532 (66.9) |
| Diabetes, n (%) | 196 (24.7) |
| Condition that precludes the use of a transvenous pacemaker, n (%) | 166 (20.9) |
| Renal dysfunction, n (%) | 152 (19.1) |
| Previously implanted CIED, n (%) | 104 (13.1) |
| Coronary artery disease, n (%) | 132 (16.6) |
| LBBB, n (%) | 72 (9.1) |
| COPD, n (%) | 67 (8.4) |
| Congestive heart failure, n (%) | 46 (5.8) |

CIED = cardiac implantable electronic device; COPD = coronary artery disease; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction.

(8.0%), other indications without permanent or persistent atrial tachyarrhythmia (3.4%), and reason not specified (2.1%). The average follow-up duration was 1.8 ± 2.9 months (range, 0–14.9 months). Micra was successfully implanted in 792 patients (99.6%) by 149 physicians, of which 86.6% were implanters who had not previously implanted a Micra device. The device was implanted in the septum for 52.1% of implants, the right ventricular apex in 39.3% of implants, the right ventricular outflow tract in 1.9% of implants, and in an alternate location (including the apical-septum and low septum) in 6.3% of implants. Most implants (77.3%) required 2 or fewer deployments.

## Early safety

Through 30 days post implant, there were a total of 13 major complications in 12 patients, for a major complication rate of 1.51% (95% confidence interval [CI], 0.78%–2.62%). Major complications are shown in Table 2. There were 6 events at the groin puncture site (0.75%), including arteriovenous fistula (1 event), hematoma (2), incision site hemorrhage (1), persistent lymphatic fistula (1), and vascular pseudoaneurysm (1). There was 1 pericardial effusion/perforation major complication event, which required pericardiocentesis on the day of implantation and resolved the same day. One local device dislodgement (without embolization) was noted 2 days post implant; in this case, 2 tines were observed to not be embedded in tissue and 2 tines were positioned between the wall and papillary muscle. The same device was successfully repositioned at 50 days post implant, with normal pacing thresholds and no further issue noted at the time of repositioning. Sepsis was reported in 1 patient within 48 hours of the implant procedure and was successfully treated using intravenous antibiotics, without the need for device removal. There was no major complication related to telemetry or battery issues. No device embolization was observed.

**Table 2** Major Complications Through 30 Days Post Implant

| Adverse Event | No. (Patients, %) |
|---|---|
| Total Major Complications | 13 (12, 1.51) |
| Deep Vein Thrombosis | 1 (1, 0.13) |
| Events at Groin Puncture Site | 6 (6, 0.75) |
| Arteriovenous fistula | 1 (1, 0.13) |
| Hematoma | 2 (2, 0.25) |
| Incision site hemorrhage | 1 (1, 0.13) |
| Persistent lymphatic fistula | 1 (1, 0.13) |
| Vascular pseudoaneurysm | 1 (1, 0.13) |
| Cardiac Effusion/Perforation | 1 (1, 0.13) |
| Pacing Issues | 2 (2, 0.25) |
| Device dislodgement | 1 (1, 0.13) |
| Device pacing issue | 1 (1, 0.13) |
| Other | 3 (3, 0.38) |
| Chest pain | 1 (1, 0.13) |
| Pulmonary edema | 1 (1, 0.13) |
| Sepsis | 1 (1, 0.13) |

Major complication criteria were not mutually exclusive, and of the 13 major complications, 1 led to prolonged hospitalization, 4 led to hospitalization, 2 led to system revision, and 1 led to death (Table 3). None of the major complications resulted in loss of device function.

There were 22 deaths. None was related to the Micra system, and 1 was adjudicated as related to the implantation procedure. The patient was a 96-year-old male with aortic valvular disease who was undergoing an implantation attempt for complete atrioventricular block and who had no suitable access for transvenous pacing. The day after implantation, the patient developed pulmonary edema and could not be resuscitated. There was no evidence of tamponade or device migration, and the device was functioning normally at the time of his arrest. The pulmonary edema was thought to be related to the patient's valvular heart disease.

## Cardiac effusion/perforation events

There were 5 cardiac effusion/perforation events reported that were adjudicated as related to the system or procedure; none resulted in death. Three required no intervention. Two events required drainage or pericardial puncture or both, of which only 1 was associated with prolonged hospitalization. Thus, of the 5 events, 1 met the major complication criteria. In 4 of these 5 patients, the Micra was implanted at the septum, and in 1 patient, the Micra was implanted at the apex. Patients with cardiac effusion or perforation events had ≥1 of the following risk factors: advanced age (2 of 5 patients >75 years), female gender (4 of 5), low body mass index (1 of 5 <20 kg/m$^2$), and history of chronic obstructive pulmonary disease (2 of 5).

## Early electrical performance

Of the 701 patients with available pacing capture thresholds at implant, 87.2% had a pacing capture threshold ≤1.0 V and 97.0% had a pacing capture threshold ≤2.0 V (mean 0.6 ± 0.5 V at 0.24 milliseconds). Among the patients with available pacing capture thresholds available at 3 months (n = 39) and 6 months (n = 25), the average pacing capture

**Table 3** Components of Major Complications for Post-Approval and Investigational Studies

| Major Complication Criterion | 30-Day Event Rate | | Odds Ratio (Post-Approval vs Investigational) (95% CI) |
|---|---|---|---|
| | Post-Approval (n = 795) No. (Patients, %) | Investigational (n = 726) No. (Patients, %) | |
| Total Major Complications | 13 (12, 1.51%) | 24 (21, 2.89%) | 0.58 (0.27, 1.25)* |
| Death | 1 (1, 0.13%) | 1 (1, 0.14%) | 0.91 (0.06–14.66) |
| Hospitalization | 4 (4, 0.50%) | 9 (8, 1.10%) | 0.45 (0.14–1.51) |
| Prolonged hospitalization | 9 (8, 1.01%) | 16 (14, 1.93%) | 0.52 (0.22–1.24) |
| System revision | 2 (2, 0.25%) | 3 (3, 0.41%) | 0.61 (0.10–3.65) |
| Loss of device function | 0 (0, 0%) | 2 (2, 0.28%) | NE |

CI = confidence interval; NE = not estimable.

*Adjusted analyses for baseline characteristics (P = 0.16). Unadjusted results were similar (0.52, 95% CI: 0.25-1.05).

thresholds were 0.5 ± 0.3 V and 0.6 ± 0.3 V, respectively. The average impedance was 721 ± 181 Ω at implant, 634 ± 143 Ω at 3 months, and 572 ± 115 Ω at 6 months. The mean R-wave amplitude was 11.4 ± 5.3 mV at implant. Based on 54 participants who had a minimum of 180 days of pacing data, the preliminary estimate of median battery longevity is 14.9 years, although 40.7% of these patients had cumulative pacing <5%.

## Early safety versus the investigational cohort

Compared with patients from the IDE study, significantly fewer patients in the Post-Approval Registry had congestive heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disease, or atrial fibrillation (Supplemental Table 1). The mean left ventricular ejection fraction was significantly lower among patients in the Post-Approval Registry, and significantly more patients in the registry had no venous access for a transvenous pacemaker or had a previously implanted cardiac device, as the latter was an exclusion criterion in the IDE study.

The major complication rate trended lower in the registry compared with that of the IDE study (1.51% vs 2.89%; odds ratio, 0.515, 95% CI, 0.251–1.053; $P = .0691$), although this did not reach statistical difference. After adjusting for baseline characteristics, the major complication rate remained lower in the registry (odds ratio, 0.58, 95% CI, 0.27–1.25; $P = .16$). The reduction in major complications was associated with a decrease in events that led to hospitalization, prolonged hospitalization, or loss of device function (Table 3). Among the 795 patients in the registry, there were fewer cardiac effusion/perforation major complications, compared with the 726 patients from the IDE study (1 patient, 0.13% vs 10 patients, 1.38%). The number of major complications related to the groin puncture site was similar in both studies (6 events, 0.75% for the registry vs 5 events, 0.69% for the IDE study).

## Discussion

This interim report from the Micra TPS Post-Approval Registry has demonstrated a high level (99.6%) of successful implants with a low level (1.51%) of major complications. To our knowledge, this represents the first large-scale report of a TPS in the post-approval setting. These data closely mirror the findings of the Micra IDE study that demonstrated a similarly high level (99.2%) of implant success with a low level (2.89%) of major complications through 30 days.[5] Given the novelty of the technology and implantation technique, appropriate concern has been raised over the consistency of the implant success and complication rates as a wider adoption took place. However, results from this early interim report demonstrate impressive consistency with the results from the IDE study, even though 86.6% of implanters were new and did not implant Micra prior to this registry. Further, 77.3% of cases were successfully deployed with ≤2 deployments.

The patient demographics are slightly different between the groups, with the registry population having less congestive heart failure, coronary artery disease, hypertension, chronic obstructive pulmonary disease, and atrial fibrillation, but a higher percentage of patients had no venous access for a transvenous pacemaker. The mean ejection fraction within the registry group was lower, and there was a significant number of patients (13.1%) that had a previously implanted cardiac implantable electronic device. Of note, 20.9% of registry patients had a condition that precluded the use of a transvenous pacemaker. The primary indication for pacing in both studies was what would be considered a conventional single-chamber indication for pacing with permanent atrial fibrillation, although the percentage was slightly higher in the IDE study (64% vs 57.7%).

The outstanding electrical performance of Micra TPS has also been maintained within the registry population, with a 97% implant threshold of <2 V, and 87.2% had a pacing capture threshold ≤1 V, similar to what was reported for the IDE study.[6] The average impedance was 721 ± 181 Ω at implant, and the mean R-wave amplitude was 11.4 ± 5.3 mV. Longer-term follow-up in the IDE study has shown a trend to improvement of these parameters with time.

This registry has demonstrated a remarkably low level of major complications, and particularly noticeable is the low level of pericardial effusion and need for emergency cardiac surgery. There were 5 pericardial effusion/perforation events observed thus far in the registry population, only 1 of which met the criteria for a major complication. This may be reflective of the robust training program that is mandated prior to implantation of Micra TPS. A focus on training has been to implant the device on the septal aspect of the right

ventricle, where it is perceived that the risk of perforation might be lower compared with the risk in the true apex, which may include the thin free wall of the right ventricle. More patients had the Micra placed in a septal location in the Post-Approval Registry compared those in the IDE study (52% vs 33%). Additional focus has been placed on patient risk factors for perforation. Of note, patients with cardiac perforation/effusion events had at least 1 risk factor reported to be associated with cardiac injury in transvenous pacemaker implants.[7–9]

Consistent with all other leadless pacing data sets, there was no infection requiring extraction of the Micra. We suspect that the small size, lack of proximity to a cutaneous incision, and late encapsulation will all positively influence a reduced infection rate. Similarly, the rate of device dislodgement remains low, with only 1 recorded case in the registry cohort. Remarkably, across a combined 1521 patients from both the IDE and registry studies, this is the only reported macrodislodgement to date, for a raw rate of 0.066%. Even in this case, no embolization occurred. Among patients implanted with a transvenous pacemaker system in the FOLLOWPACE study, lead dislodgement was reported at a rate of 3.3% within 2 months of implant.[2]

The registry data mirror that of the IDE study, with a vascular/groin related complication rate of 0.75% overall. This is remarkably low when one takes into account that the delivery system is inserted using a 23F introducer sheath. Routine vascular ultrasound guidance for venous puncture may further lower this risk.

## Study limitations

Although the interim acute performance results of the registry data are very reassuring regarding the efficacy and safety of the Micra TPS, there are some limitations to the data. The registry was intended to include as many patients as possible over as many centers and geographies as possible. However, there may be some degree of bias in favor of the patients that are approached to join a registry by the recruiting physician, and whereas it is anticipated that this registry represents a real-world population, the data do not include all patients implanted with Micra TPS worldwide. Further, this report is an interim analysis with limited follow-up, including patients who had not yet been followed for 30 days, and it reflects the geographies of enrolled patients who were primarily from Europe. However, enrollment of patients in the United States is continuing, and patients in the registry will be followed for a minimum of 9 years. In addition, few patients had follow-up electrical data available, and thus battery projections are preliminary and based on only 54 patients.

## Conclusions

Initial results from the Micra TPS Post-Approval Registry have demonstrated a high level of implant success along with excellent electrical performance in short-term follow-up. Importantly, despite this therapy being available more broadly post-approval, the level of major complications remains low. This offers significant reassurance for leadless pacing as a therapy in moving forward but should not drive complacency in maintaining this high standard of clinical care.

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## Appendix

### Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.hrthm.2017.05.017.

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