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ORIGINAL ARTICLE

Micra AV leadless pacemaker implantation after transcatheter aortic valve implantation

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Abstract

Background: Transvenous pacemaker (PM) implantation is a complication in patients undergoing transcatheter aortic valve implantation (TAVI). Recently, a second generation of leadless PMs able of atrioventricular (AV) synchronous pacing has been introduced and could be an alternative when ventricular pacing is required after TAVI. Real-world data on Micra AV after TAVI are still lacking. Our aim was to determine the per- and post-procedural outcomes in patients with Micra AV leadless PM implantation after TAVI.

Methods: A total of 20 consecutive patients underwent Micra AV leadless PM implantation after TAVI between November 2020 and June 2021.

Results: The main indication for ventricular pacing was high-degree AV block (55% of patients) and left bundle branch block (LBBB) associated with prolonged HV interval (45% of patients). At discharge, mean (SD) ventricular pacing threshold was 0.397 ± 0.11 V at 0.24 ms and ventricular impedance was 709.4 ± 139.1 Ω. At 1-month follow-up, 95% of patients were programmed in VDD pacing mode. Mean (SD) ventricular pacing threshold was 0.448 ± 0.094 V at 0.24 ms. In patients with ventricular> pacing > 90% ($n = 5$), mean AM-VP was 72.5% ± 8.3%. Pacing threshold at 1 month was not significantly different compared to discharge ($p = .1088$). Mean (SD) impedance was 631.0 ± 111.9 Ω, which remained stable at discharge ($p = .0813$). No procedural complications occurred during implantation. At 1-month follow-up, two patients displayed atrial under-sensing.

Conclusions: Micra AV leadless PM implantation after TAVI is associated with a low complication rate and good device performance at 1-month post-implantation.

KEYWORDS
leadless pacemaker implantation, outcome, transcatheter aortic valve implantation

1 | INTRODUCTION

Transcatheter aortic valve replacement is associated with a risk of post-procedural complications, including the occurrence of atrioventricular (AV) conduction disturbances requiring pacemaker (PM) implantation.[1,2] The incidence of PM implantation after transcatheter aortic valve replacement ranges from 3.4% to 25.9%.[3] Furthermore, the number of transcatheter aortic valve implantation (TAVI) procedures is increasing rapidly and the typical patient is shifting to those with a lower surgical risk.[4–6] Conventional transvenous PM implantation has a complication rate of 8.2% within 90 days of hospital discharge.[3,7,8] Complications include lead-related reintervention (dislodgement, malposition, subclavian crush syndrome), infections (superficial, pocket, or systemic infections), pneumothorax, haemothorax, brachial plexus injury, cardiac perforation, coronary sinus dissection, hematoma, tricuspid regurgitation, PM syndrome, or diaphragmatic stimulation requiring reintervention. PM implantation after a TAVI procedure remains a matter of concern in elderly and frail patient populations.

Leadless PMs are a novel alternative to conventional transvenous PMs for the treatment of bradyarrhythmias.[3] First generation leadless PMs function in VVI(R) mode and restrict indications to patients with atrial fibrillation or infrequent pacing (e.g. paroxysmal atrioventricular block (AVB)). Studies have shown a low risk of short- and long-term complications and high successful implantation rates.[9–11] Recently, second-generation leadless PMs, which function in VDD mode (using a three-axis accelerometer to detect atrial contraction), have been introduced, extending the indications to patients with AVB with preserved sinus node function.[12,13] The MARVEL study confirmed the safety and feasibility of these devices and demonstrated their efficacy in atrioventricular synchrony (AVS) in patients with third-degree heart block.[13] AVS was maintained 70%–90% of the time, depending on the patient's position and activity.

The aim of the current study was to evaluate the per- and post-procedural complications and to determine the electrical performance of Micra AV leadless PMs in patients previously implanted with a TAVI.

2 | METHODS

2.1 | Study population

This prospective, observational study of 20 consecutive patients was approved by the institutional review board (IRB number: COS-RGDS-2021-09-009-MECHULAN-A). Patients were informed about the study and gave their written consent before inclusion. The medical records of the patients were screened. Data were collected, including: demographic and anthropometric information, comorbidities, electrocardiogram (ECG), operative data, complications, and device interrogation data.

The aims of the study were to describe the procedural results and to evaluate the immediate and 1-month outcomes. Complications were defined as per- and post-procedural hematoma or hemorrhage, events at the puncture site, infection, pneumothorax, cardiac effusion and/or perforation, embolism, thrombosis, PM dislodgement, AVS dysfunction, increase in ventricular threshold, and atrial undersensing.

2.2 | Leadless pacemaker implantation

Trained operators performed all implantation procedures. Leadless PMs (Micra AV, MC1AVR1; Medtronic, Dublin, Ireland) were implanted in the right ventricle via femoral vein access (Figure 1). After obtaining access to the right femoral vein, the catheter system containing the leadless PM (Micra AV) was passed through the 23F sheath under fluoroscopic guidance into the right atrium. The steerable delivery catheter was then carefully introduced into the right ventricle. After successful deployment, a "pull and hold" fixation test was performed. Pacing parameters were tested with a target capture threshold of <1 V at a pulse width of 0.24 ms. The femoral puncture site was closed with a "figure-of-eight" suture. Device interrogation and programing were scheduled for the day of implantation, at discharge and at 1-month follow-up.

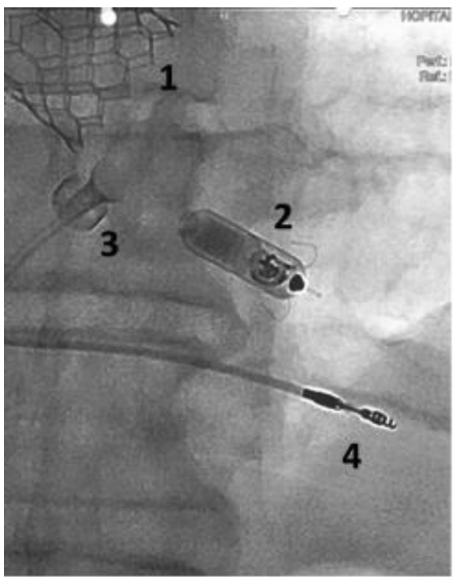

FIGURE 1 Fluoroscopy view of a Micra AV leadless pacemaker during implantation. TAVI valve is marked by **1**, **2** indicates the Micra AV, **3** indicates the MICRA deployment catheter and **4** is the temporary pacing lead

2.3 | Statistical analysis

The results are presented as mean ± SD, or number and percentage. The Shapiro–Wilk test was used to determine normality of the data. The Mann–Whitney test (unpaired data, two-tailed) was used for non-normally distributed data and an unpaired *t*-test was used to compare normally distributed groups of data. A *p*-value < .05 was considered statistically significant.

All data analyses were performed using GraphPad Prism 7 (GraphPad Software, La Jolla, CA).

3 | RESULTS

3.1 | Baseline characteristics

A total of 20 patients underwent Micra AV leadless PM implantation between November 2020 and June 2021 (mean (±SD) age: 81.2 ± 6.8 years, 25% (*n* = 5) female). Concomitant comorbidities were diabetes mellitus (40%), hypertension (80%), chronic obstructive pulmonary disease (25%), coronary artery disease (35%), chronic kidney disease (25%), and cancer (5%). The characteristics of the patients are summarized in Table 1.

3.2 | Procedural characteristics

Nineteen patients (95%) underwent TAVI intervention due to aortic valve calcification; the remaining patients underwent a valve-in-valve procedure. The majority of patients (55%) received SAPIEN 3 valves. A transfemoral approach was used in 85% of patients while the others underwent a transaortic approach (Table 2). Over half (60%, *n* = 12) of the patients had temporary transvenous pacing (Table 3). The main indication for pacing was high-degree AVB in 55% of patients and left bundle branch block (LBBB) associated with prolonged HV interval in the other 45%. Leadless PM implantation was chosen in agreement with the patients mainly because of the high risk of infection and hematoma, and preserved left ventricular ejection fraction (LVEF: mean (SD) value: 59% ± 5.98%). Mean (SD) time between TAVI and leadless PM implantation was 4.75 ± 2.02 days. All implantations were successful; in one patient, a second device had to be used due to steerable sheath dysfunction. General anesthesia was used in 60% of patients; the others were placed under moderate/conscious sedation. Mean (SD) duration of the implantation procedure was 42.1 ± 20.3 min. The position in the right ventricle was the septal region in 19 patients (95%) and the apex in one (5%). Leadless PM implantation required a mean (SD) fluoroscopy time of 6.7 ± 9.37 min and a dose of 2.42 ± 3.17 mGy.cm2. A right ventricular pacing threshold of <1 V at 0.24 ms was achieved in all patients. No procedural complications were observed. Patients were discharged 2.6 ± 1.1 days after leadless PM implantation with a mean hospital stay of 9.25 ± 1.65 days. Pacing parameters for the 20 patients were a mean pacing threshold of

TABLE 1 Characteristics of the study population at inclusion

Characteristic	Total (*N* = 20)
Age (years)	
Mean ± SD	81.2 ± 6.8
Median (IQR)	80.5 (78.2–85.0)
Sex (female), *n* (%)	5 (25)
Body mass index (kg/m^2)	
Mean ± SD	28.0 ± 5.6
Median (IQR)	27.6 (23.8–30.7)
NYHA classification, *n* (%)	
II	1 (5)
III	19 (95)
Pre-TAVI LVEF (%)	
Mean ± SD	57.7 ± 7.0
Median (IQR)	60 (52.5–60)
EuroSCORE	
Mean ± SD	2.7 ± 1.9
Median (IQR)	2.1 (1.4–3.3)
Comorbidities, *n* (%)	
Diabetes	8 (40)
Hypertension	16 (80)
COPD	5 (25)
Coronary artery disease	7 (35)
Cancer	1 (5)
Chronic kidney disease	5 (25)

Abbreviations: COPD, chronic obstructive pulmonary disease; EuroSCORE, European System for Cardiac Operation Risk Evaluation; IQR, interquartile range; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; SD, standard deviation; TAVI, transcatheter aortic valve implantation.

TABLE 2 Characteristics of TAVI

Characteristic	Total (*N* = 20)
Type of valve, *n* (%)	
SAPIEN 3 (Edwards Lifesciences)	11 (55)
EVOLUT R (Medtronic)	4 (20)
EVOLUT PRO (Medtronic)	3 (15)
ACURATE NEO (Boston Scientific)	2 (10)
Approach for TAVI, *n* (%)	
Transfemoral	17 (85)
Transaortic	3 (15)
Valve size[a] (mm)	
Mean ± SD	27.8 ± 3.5
Median (IQR)	27.5 (26–29)

Abbreviations: AVB, atrioventricular block; BBB, bundle branch block; ECG, electrocardiogram; IQR, interquartile range; SD, standard deviation; TAVI, transcatheter aortic valve implantation.

[a]Except for the two ACURATE NEO (size L for both).

TABLE 3 Micra AV leadless pacemaker procedure characteristics

Characteristics	Total ($N = 20$)
Temporary pacing, *n* (%)	12 (60)
Indication for Micra AV implantation, *n* (%)	
High-grade AVB	11 (55)
LBBB with prolonged HV intervals	9 (45)
Time from TAVI to Micra AV implantation (days)	
Mean ± SD	4.8 ± 2.0
Median (IQR)	4.5 (3–6)
Pre-MICRA LVEF (%)	
Mean ± SD	59 ± 6.0
Median (IQR)	60 (56.3–63.8)
Type of anesthesia, *n* (%)	
Moderate/conscious sedation	8 (40)
General anesthesia	12 (60)
Implantation duration (min)	
Mean ± SD	42.1 ± 20.3
Median (IQR)	37.5 (28.3–45.8)
Device location, *n* (%)	
RV apex	1 (5)
RV septum	19 (95)
Fluoroscopy duration (min)	
Mean ± SD	6.7 ± 9.4
Median (IQR)	3.77 (2.07–5.89)
Fluoroscopy dose (mGy.cm^2)	
Mean ± SD	2.42 ± 3.17
Median (IQR)	1.44 (0.47–2.9)
Complication at implantation, *n*	0

Abbreviations: AVB, atrioventricular block; IQR, interquartile range; LBBB, left bundle branch block; RV, right ventricle; SD, standard deviation.

0.397 ± 0.11 V at 0.24 ms (Figure 2A) and an impedance of 709.4 ± 139.1 Ω (Figure 2B). No device-related complication was observed.

3.3 | Electrical performance of Micra AV at follow-up

At 1-month follow-up, 19 patients were seen at the PM clinic and one was followed-up by remote monitoring. At follow-up, 19 were programmed in VDD pacing mode and one in VVI 50 BPM to avoid ventricular pacing due to long PR interval. Mean ventricular pacing threshold was 0.448 ± 0.094 V at 0.24 ms (Figure 2C). Pacing threshold at 1 month was not significantly different compared to discharge ($p = .1088$) (Figure 2A). Mean impedance was 631.0 ± 111.9 Ω, which was stable compared to discharge ($p = .081$) (Figure 2B). ECGs showed that 17/19 patients (one patient was followed up remotely) displayed sinus rhythm (89.5%) and one had atrial fibrillation with normal conduction (5.3%). Six out of 19 patients had ventricular pacing. Among these, four had sinus rhythm followed by ventricular pacing, one had ventricular pacing with retrograde atrial conduction due to sinus node dysfunction and one had AV dissociation due to atrial under-sensing. Mean ventricular pacing was stable between implantation and 1-month follow-up (at discharge: 64.6% ± 35.1% vs. 46.6% ± 40.1%, respectively; $p = .156$).

For patients with ventricular> pacing > 90% ($n = 5$), the percentage AM-VP (atrial mechanical event-ventricular pacing reflecting AVS during ventricular pacing) was 72.5% ± 8.3%. Regarding patients with complete heart block, one was dissociated at 1-month follow-up due to atrial under-sensing. This patient was successfully reprogrammed. Another patient was admitted 12 days after discharge for acute heart failure due to TAVI mismatch; AV dissociation due to atrial under-sensing was recorded and was reprogramed. Overall, no other leadless PM complications were observed during follow-up.

4 | DISCUSSION

To our knowledge, this is the first study to evaluate Micra AV leadless PM implantation after TAVI in real life. Our main finding was that implantation of a leadless PM was safe and was associated with no procedural complication. Two patients had atrial under-sensing during follow-up and were adequately reprogrammed.

TAVI is an approved treatment for patients with a high surgical risk and, more recently, a moderate surgical risk.[6] Patients referred for TAVI are typically of advanced age and have multiple comorbidities, and the requirement for PM implantation is a well-recognized complication. Limiting the complications after PM implantation is, therefore, a major issue and a leadless PM is a promising alternative. Studies concerning the first generation of leadless VVI PMs demonstrated their safety and efficacy.[9,14] El-Chami et al. reported a low rate of major complications at 12 months (2.7%), a high success rate (99.1%), and stable electrical parameters over time. They also reported that the risk of major complications was significantly lower for patients with transvenous PM implantation up to 12 months' post-insertion.[14] Moore et al. compared the outcomes of leadless single chamber PMs in 10 patients and conventional single-chamber PMs in 23 patients after TAVI. The authors found that leadless PMs performed as well as conventional PMs and were associated with less tricuspid regurgitation and bleeding during the implantation procedure.[15] These results were confirmed by Garweg et al. in 170 patients.[16] Leadless PMs have been successfully inserted after valve intervention without major procedure-related complications and with excellent electrical performance at 12 months follow-up. Recently, a large-scale study was performed on 15,408 patients, comparing characteristics and complications in patients implanted with leadless VVI PMs and transvenous VVI PMs.[11] The authors observed that patients who received a leadless PM had a higher rate of pericardial effusion and/or perforation but lower rates of other device-related complications or requirements for device revision at 6 months.

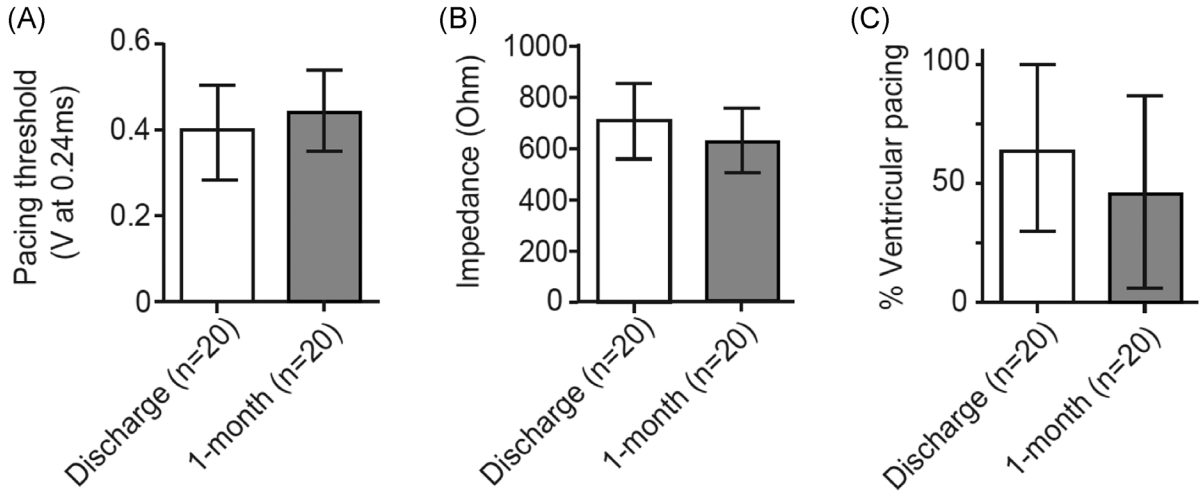

FIGURE 2 Micra AV leadless pacemaker measurement at discharge and at 1-month follow-up. (A) Pacing threshold (V) at 0.24 ms. (B) Impedance (Ω). (C) Percentage ventricular pacing. Data shown are means ± SD

The use of leadless single-chamber ventricular PMs is restricted to patients with AVB and atrial fibrillation. New generation dual-chamber PMs providing AVS open up the indications to patients with sinus rhythm and AVB. The MARVEL2 study assessed the efficacy of synchronous AV pacing in patients with third-degree AVB and normal sinus rhythm.[12] In this study, the AVS algorithm was downloaded into an already implanted leadless PM device. The authors observed a mean AVS of 89.2%, which is higher than that in the present study (72.5%) in patients with pacing > 90%. In this study, AVS was measured using the percentage AM-VP. AM-VP corresponds to the percentage of ventricular pacing preceded by a detected atrial mechanical event. In the MARVEL2 study, AVS was calculated directly from surface ECGs and was considered to meet if the timing of the ventricular marker was within 300 ms of the P-wave. A study is required to show that the AM-VP sequence provides an estimation of AVS level. Our study shows a mean AVS of 72.5%, which is lower than with conventional dual-chamber PMs. This may be a concern in patients requiring ventricular pacing. It is well known that permanent pacing after TAVI decreases after discharge due to AV conduction recovery.[17] In our study, patients implanted for LBBB had a low risk of permanent ventricular pacing. Regarding patients with complete AVB after TAVI they were at high risk of complications for conventional dual-chamber PMs due to severe comorbidities (COPD, diabetes, chronic kidney disease, or cancer). Our study suggests that the TAVI population could benefit from the advantages of Micra AV leadless PMs despite lower AVS.

5 | CONCLUSION

Micra AV leadless PMs appear to be an interesting alternative to conventional PMs and are associated with a low complication rate, stable right ventricular threshold, and efficient AV synchronization. A leadless PM could, therefore, be a suitable option for patients after TAVI.

5.1 | Limitations

This was a single-center study and was limited in its sample size. Further studies are required to confirm these results.

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