

Leadless pacemaker implant with concomitant atrioventricular node ablation: Experience with the Micra transcatheter pacemaker

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Abstract

Background: The feasibility and outcomes of concomitant atrioventricular node ablation (AVNA) and leadless pacemaker implant are not well studied. We report outcomes in patients undergoing Micra implant with concomitant AVNA.

Methods: Patients undergoing AVNA at the time of Micra implant from the Micra Transcatheter Pacing (IDE) Study, Continued Access (CA) study, and Post-Approval Registry (PAR) were included in the analysis and compared to Micra patients without AVNA. Baseline characteristics, acute and follow-up outcomes, and

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electrical performance were compared between patients with and without AVNA during the follow-up period.

Results: A total of 192 patients (mean age 77.4 ± 8.9 years, 72% female) underwent AVNA at the time of Micra implant and were followed for 20.4 ± 15.6 months. AVNA patients were older, more frequently female, and tended to have more co-morbid conditions compared with non-AVNA patients ($N = 2616$). Implant was successful in 191 of 192 patients (99.5%). The mean pacing threshold at implant was 0.58 ± 0.35 V and remained stable during follow-up. Major complications within 30 days occurred more frequently in AVNA patients than non-AVNA patients (7.3% vs. 2.0%, $p < .001$). The risk of major complications through 36-months was higher in AVNA patients (hazard ratio: 3.81, 95% confidence interval: 2.33–6.23, $p < .001$). Intermittent loss of capture occurred in three AVNA patients (1.6%), all were within 30 days of implant and required system revision. There were no device macrodislodgements or unexpected device malfunctions.

Conclusion: Concomitant AVN ablation and leadless pacemaker implant is feasible. Pacing thresholds are stable over time. However, patient comorbidities and the risk of major complications are higher in patients undergoing AVNA.

KEYWORDS

AV node ablation, leadless pacemaker, Micra

1 | INTRODUCTION

Atrioventricular nodal ablation (AVNA) and pacing (“ablate and pace”) is sometimes required for the treatment of atrial fibrillation (AF) complicated by medically refractory tachycardia.^{1,2} This approach is largely reserved for patients who fail catheter ablation or who are not considered candidates for AF ablation,³ which is not uncommon in octogenarians and in patients with advanced structural heart disease.^{3,4} While an ablate and pace approach can be very effective, lead dislodgment and device infection in patients who were rendered pacemaker dependent remain important concerns.⁵

Leadless pacemakers (LP) reduce lead and pocket related complications encountered with transvenous pacemakers (TV-PPM).^{6–8} This potential benefit over TV-PPM in addition to the advantage of using a single femoral venous puncture to implant a LP and concomitantly perform an AVNA makes the use of leadless pacing as part of the “ablate and pace” approach an appealing strategy. Small studies have reported on the safety and efficacy of a simultaneous LP and AVNA.^{9,10} Accordingly, we sought to assess the safety and efficacy of concomitant AVNA and Micra pacemaker implantation in a large cohort of patients enrolled in clinical trials.

2 | METHODS

2.1 | Patient cohort and setting

Patients enrolled in the Micra Transcatheter Pacing (IDE) Study, Continued Access (CA) study, and Post-Approval Registry (PAR) were included in this analysis and stratified by the presence or absence of AVNA at the time of Micra implantation. The methodologies and results of these studies have been previously published.^{6,7}

These studies were sponsored by Medtronic and enrolled patients with Class I or II pacing indications¹¹ with no co-morbidity restrictions. The Micra IDE study was designed to obtain regulatory FDA approval for the Micra Transcatheter Pacing System (TPS)⁷ and excluded patients with an existing cardiac implantable electronic devices (CIEDs). The long-term results showed excellent safety and efficacy of Micra.¹² The Micra CA study allowed continued access to Micra while under review by FDA. The Micra PAR studied the performance of Micra in a real-world setting, in clinical practice outside of clinical trials. Both the Micra CA and PAR studies allowed participation of patients with pre-existing CIEDs. Initial results of the PAR were published confirming the safety and efficacy of Micra in a large patient population.^{6,13} The 9-year follow-up period in the Micra PAR is ongoing. The study protocols were approved by the ethics

TABLE 1 Baseline medical history and implant characteristics

Patient characteristic	AVNA (N = 192)	No AVNA (N = 2616)	p-value ^a
Age			
Mean ± standard deviation	77.4 ± 8.9	75.5 ± 13.0	.53
Median	78.0	78.0	
25th Percentile - 75th Percentile	73.0-84.0	71.0-84.0	
Female	71.9% (138/192)	37.5% (980/2615)	<.001
Co-morbidities			
Atrial tachyarrhythmias	98.4% (189/192)	75.1% (1963/2615)	<.001
CHF	29.7% (57/192)	14.6% (383/2615)	<.001
COPD	27.6% (53/192)	10.2% (268/2615)	<.001
CAD	27.1% (52/192)	24.9% (651/2615)	.49
Hypertension	79.7% (153/192)	68.9% (1803/2615)	.001
Diabetes	27.1% (52/192)	27.5% (719/2615)	.93
Renal dysfunction	26.6% (51/192)	21.1% (551/2615)	.08
Dialysis	7.8% (15/192)	7.0% (184/2615)	.66
Prior CIED	0.5% (1/192)	11.8% (308/2615)	<.001
Condition that precludes the use of TV-PPM	14.1% (27/192)	19.8% (519/2616)	.06
Pacing indication (%)			
Bradyarrhythmia with AF	94.3% (181/192)	60.9% (1591/2611)	< 0.001
Sinus node dysfunction	3.1% (6/192)	12.5% (327/2611)	
AV Block	1.6% (3/192)	12.9% (338/2611)	
Syncope	0.0% (0/192)	11.3% (294/2611)	
Other	1.0% (2/192)	2.3% (61/2611)	
Not reported	0.0% (0/192)	0.0% (0/2611)	
LVEF^b			
Mean ± standard deviation	56.7 ± 8.0	57.1 ± 9.3	.20
Median	55.0	59.0	
25th-75th percentile	50.0-60.0	53.0-62.0	
Implant success	99.5% (191/192)	99.2% (2596/2616)	1.00
Follow-up (months)			
Mean ± standard deviation	20.4 ± 15.6	25.2 ± 15.3	
Median	19.0	24.5	
25th-75th Percentile	5.8-30.0	14.3-35.5	
Procedure duration (min)			
Mean ± standard deviation	47.6 ± 30.9	32.8 ± 24.2	<.001
Median	41.0	27.0	
25th-75th percentile	27.0-62.0	20.0-39.0	
Fluoroscopy duration (min)			
Mean ± standard deviation	11.7 ± 28.7	9.2 ± 15.2	.001
Median	8.0	6.4	
25th-75th percentile	5.0-12.1	4.1-10.5	
Anticoagulation strategy (%)			
Not on OAC	22.6% (43/190)	34.9% (910/2604)	<.001
Interrupted OAC	50.0% (95/190)	38.6% (1005/2604)	
Continued OAC	27.4% (52/190)	26.5% (689/2604)	

Abbreviations: AF, atrial fibrillation; AVNA, atrioventricular nodal ablation; CAD, coronary artery disease; CHF, congestive heart failure; CIED, cardiac implantable electronic device; COPD, chronic obstructive pulmonary disease; LVEF, left ventricular ejection fraction; OAC, oral anticoagulation; TV-PPM, transvenous pacemaker.

^ap-value from Wilcoxon Rank sum test (age, LVEF, procedure duration, fluoroscopy duration), or Fisher's exact test (categorical variables).

^bLVEF was available for 129 patients with AVNA and 1805 patients without AVNA.

committee at each center, and all patients provided written informed consent. An independent committee of physicians adjudicated all adverse events.

Baseline demographics, medical comorbidities, procedural characteristics, and study outcomes were collected on study case report forms. Device diagnostic data contained in interrogation files were obtained from study centers as they were collected.

2.2 | Objective

The objective of this analysis was to assess the safety and performance of Micra when AVNA was performed at the time of device implant. The safety outcomes included major complications and system revisions through 36 months postimplant. In brief, major complications were defined as any events related to Micra device or procedure that resulted in death, permanent loss of device function, hospitalization, prolonged hospitalization, or system revision.⁷ Device electrical performance was also assessed through 24-months following implant.

2.3 | Statistical analysis

Patients enrolled in the Micra IDE, CA, or PAR studies with AVNA were identified. The Micra IDE and CA databases were locked before reporting their results. The Micra PAR database was frozen for this analysis on March 2, 2020. Baseline characteristics and comorbidities were compared between those with and without AVNA using *t*-tests or the Wilcoxon Rank sum test (continuous variables) or Fisher's exact test (categorical variables). A logistic regression model was used to compare the rate of acute (within 30 days of implant) major complications between groups. Cox proportional hazards

models were used to compare the risk for major complication and system revisions through the 36-months postimplant follow-up period. Logistic regression models and Cox models using propensity score overlap weights were used to adjust for differences in comorbid conditions between groups. Specifically, these weights estimate the probability of treatment with the opposing therapy based on observed characteristics. To calculate the propensity score, the probability for each patient to receive AVNA was estimated using a logistic-regression model that included baseline characteristics found in Table S1. The resulting propensity scores were used to derive a weight for each patient to adjust for patient differences between AVNA status. Analyses using propensity score overlap weights place the most emphasis on patients who are considered the most "exchangeable" (i.e., patients with similar or equal probability of receiving [or not receiving] AVNA based on observed characteristics) and the least emphasis on patients who are least likely to be treated with the opposing therapy.¹⁴ Standardized mean differences were used to assess balance among covariates included in the propensity model following weighting.

Device electrical parameters including pacing impedance and pacing capture thresholds (PCTs) were obtained from follow-up visits and device interrogation uploads. The Micra device stores the minimum and maximum weekly pacing impedance and pacing capture threshold in device memory. For electrical parameters obtained from interrogation uploads, the mean weekly pacing impedance was used for analysis, while the maximum weekly PCT was used for analysis. All PCTs were standardized to a pulse duration of 0.24 ms (nominal setting) using the Micra strength duration curve. Device electrical parameters were compared at implant and follow-up visits by AVNA status using a mixed effects linear regression model. Additionally, the mean, 10th and 90th percentile for maximum PCT was computed weekly during the first 12-weeks following implant for the subset of patients with AVNA.

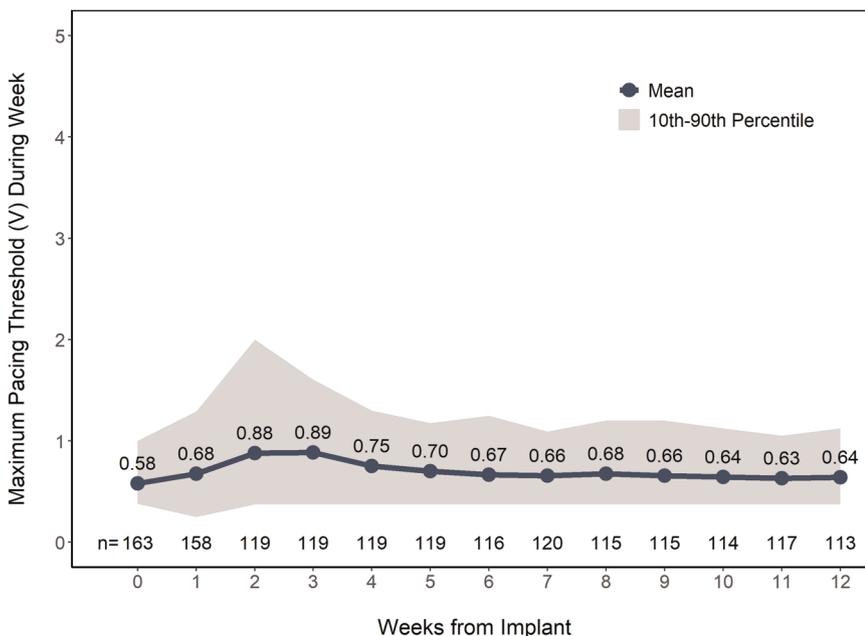


FIGURE 1 Maximum weekly pacing capture thresholds in patients with concomitant atrioventricular nodal ablation following implant procedure. Mean pacing capture thresholds standardized to a pulse duration of 0.24 ms. Gray shaded area represents 10th–90th percentile intervals. N values represent the number of patients with data available at each timepoint

p-values less than .05 were considered statistically significant. All analyses were performed using SAS v9.4 (SAS Institute) or R v4.0.2 (www.r-project.org).

3 | RESULTS

3.1 | Patients

The cohort included a total of 2817 patients who underwent a Micra implant attempt across the three studies of which 192 had AVNA, 2616 did not have AVNA. In nine patients the AVNA status was unknown and these subjects were excluded from further analysis. Of the 192 patients with AVNA, 40, 42, and 110 came from the Micra IDE, CA, and PAR studies, respectively, representing 5.5%, 15.2%, and 6.1% of each study's population. Patients with

AVNA had an average follow-up of 20.4 ± 15.6 months with 34 (17.7%) patients having more than or equal to 36 months of follow-up compared with an average of 25.2 ± 15.3 for patients without AVNA. Patients with AVNA were more likely female, and had more co-morbidities including heart failure, chronic obstructive pulmonary disease, and hypertension compared with patients without AVNA (Table 1). One (0.5%) of the 192 patients with AVNA had a prior cardiac implantable electronic device compared with 11.8% of patients without AVNA ($p < .001$) and 14.1% and 19.8% of patients, respectively had a condition precluding transvenous pacemaker implant ($p = .06$).

Among the 2808 patients where AVNA status was known, 99.5% of the 192 patients with AVNA were successfully implanted compared with 99.2% of patients without AVNA ($p = 1.00$). Median procedure time was significantly greater in patients with AVNA compared with those without (41 min, interquartile range [IQR]: 27.0–62 min vs.

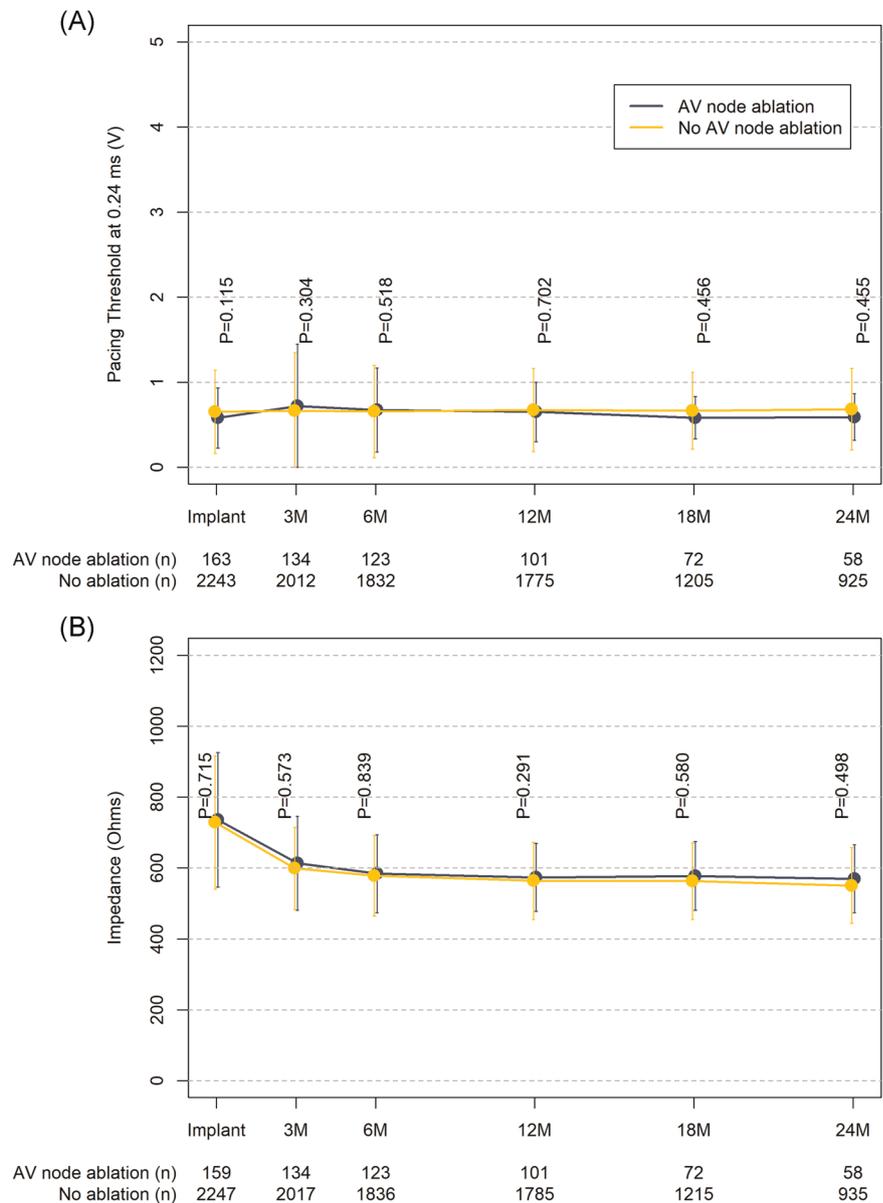


FIGURE 2 Electrical performance over time by concomitant atrioventricular nodal ablation status. (A) Pacing capture thresholds standardized to a pulse duration of 0.24 ms. (B) Impedance. Error bars represent the standard deviation. n values represent the number of patients with data available at each timepoint

27 min, IQR: 20–39 min, $p < .001$). Similar results were observed for fluoroscopy duration (8.0 min, IQR: 5.0–12.1 min vs. 6.4 min, IQR 4.1–10.5 min, $p = .001$). The median percentage of RV pacing was 99.7% (IQR 98.6%–99.9%) in the AVNA group as compared with 59.1% (IQR: 10.0%–97.2%) in the non-AVNA group ($p < .001$).

3.2 | Electrical performance

Pacing capture threshold (PCT) at implant was 0.58 ± 0.35 V at a pulse duration of 0.24 ms among patients with AVNA compared to 0.65 ± 0.49 in patients without AVNA ($p = .12$). The maximum weekly PCT among AVNA patients increased to an average of 0.89 V with a lower 10th and upper 90th percentile of 0.38 V and 1.60 V, respectively, at 3 weeks postimplant and declined to an average of 0.64 V (10th–90th percentile: 0.38 V–1.12 V) by Week 12 among those patients with electrical data available for analysis (Figure 1). Pacing capture thresholds and impedance were not different between patients with and without AVNA through 24-months postimplant (Figure 2A,B) where electrical data were available for analysis.

3.3 | Safety

Table 2 displays major complications by AVNA status. The majority of major complications (72%) in both groups occurred within 30-days of implant. The rate of acute major complications in the 192 patients with AVNA was 7.3% compared with 2.0% in the 2616 patients without AVNA ($p < .001$). The difference in major acute complications was driven by a higher rate of cardiac effusions, thrombosis events, pacing issues and other major complications (which included heart failure, acute myocardial infarction, pacemaker syndrome, etc.)

in patients with AVNA compare with those without AVNA (Table 2). The weighted analysis balanced the baseline characteristics used in the propensity model in the subset of 2764 patients with all baseline measurements available for constructing the overlap weights (Table S1). Similar results were observed after adjusting for differences in baseline patient condition (Table S2, 6.8% vs. 1.9%, $p = .046$).

The risk for major complication through 36-months was significantly higher in the AVNA group compared with patients without AVNA (Figure 3A, hazard ratio: 3.81, 95% confidence interval [CI]: 2.33–6.23, $p < .001$) and this difference persisted after adjustment for differences in baseline characteristics (Figure 3B). There were three cardiac effusions in the AVNA group, two cases required pericardiocentesis, and one case required no intervention. Among patients without AVNA, there were 16 cardiac effusions, four required surgical repair of which two resulted in death, nine required pericardiocentesis, and in the remaining three cases, no interventions were taken. Details of the deaths have previously been reported.⁶ There were no cases of device dislodgement or embolization in the AVNA group during the follow-up period (Table S3). However, there were three instances of device micro-dislodgment and one device embolization in patients without AVNA, of which all four events occurred either during the implant procedure (device embolization) or within the acute period. There were no macrodislodgments.

There were three intermittent loss of capture events that all occurred within 30 days of implant in patients with AVNA (Table S3). All three resulted in a revision (percutaneous retrieval) of the Micra device, of which two patients received a new Micra device and one patient received a transvenous system. Loss of capture was reported in eight cases in seven patients without AVNA of which one occurred before tether release, five occurred within 30 days of implant and two occurred after 30 days. Six of the eight events required revision of the Micra device.

TABLE 2 Major complications by concomitant AVNA status

No. events (no. patients, %)	Concomitant AVNA ($n = 192$)		No AVNA ($n = 2616$)		p -value (acute) ^b	p -value (total) ^c
	Acute	Total ^a	Acute	Total ^a		
Total major complications	15 (14, 7.3%)	21 (20, 11.8%)	61 (53, 2.0%)	85 (77, 3.3%)	<.001	<.001
Cardiac effusion/perforation	3 (3, 1.6%)	3 (3, 1.6%)	15 (15, 0.6%)	16 (16, 0.6%)	.112	.132
Events at groin puncture site	1 (1, 0.5%)	2 (2, 1.1%)	15 (15, 0.6%)	16 (16, 0.6%)	.926	.460
Thrombosis	2 (2, 1.0%)	2 (2, 1.1%)	3 (3, 0.1%)	3 (3, 0.1%)	.016	.014
Pacing issues ^d	5 (5, 2.6%)	5 (5, 3.1%)	15 (13, 0.5%)	21 (19, 0.8%)	.002	.008
Cardiac rhythm disorder	0 (0, 0.0%)	0 (0, 0.0%)	1 (1, < 0.1%)	3 (3, 0.1%)	.356	.996
Infection	1 (1, 0.5%)	1 (1, 0.6%)	2 (2, 0.1%)	4 (4, 0.2%)	.117	.240
Other ^e	3 (3, 1.6%)	8 (8, 5.3%)	10 (10, 0.4%)	22 (22, 1.0%)	.032	<.001

Abbreviations: AVNA, atrioventricular nodal ablation; MI, myocardial infarction.

^aTotal percentages are estimated from the Cox regression model.

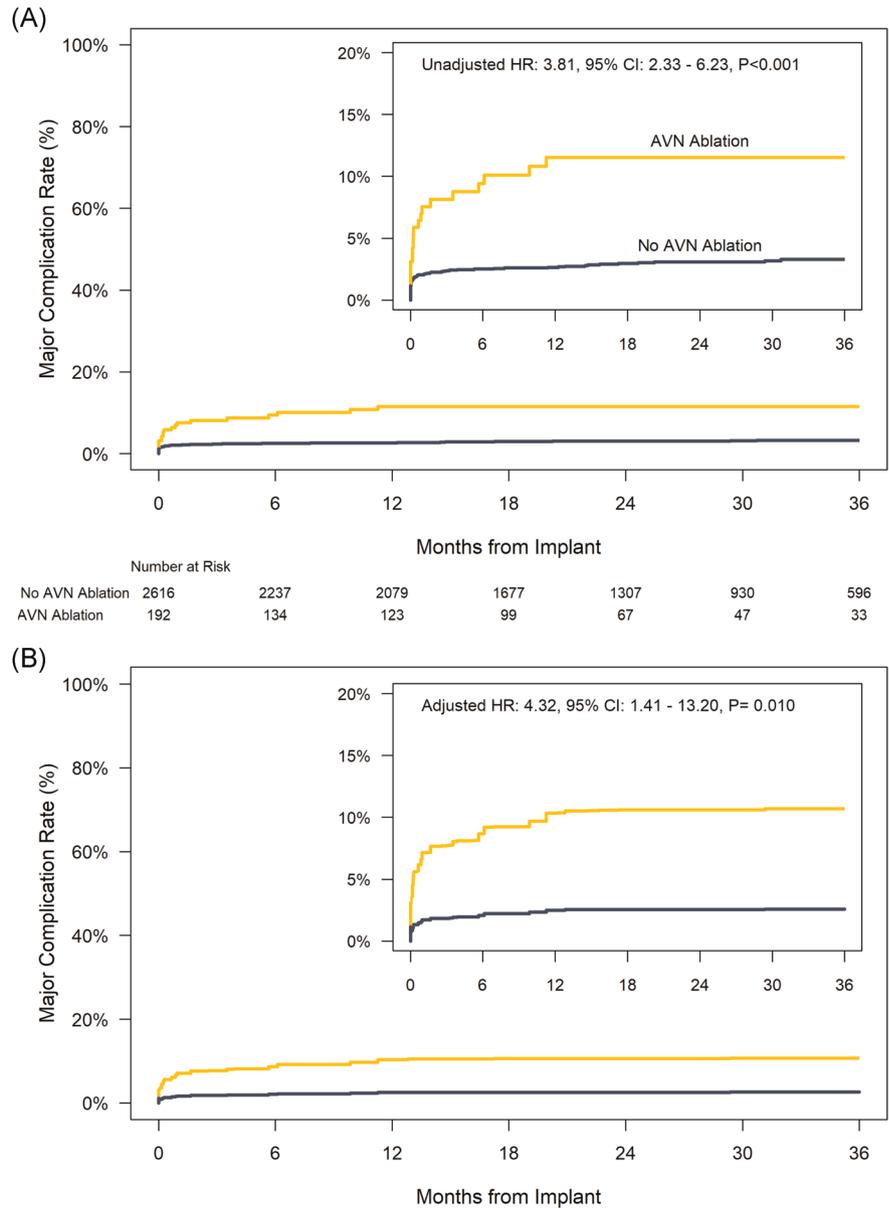
^b p -value comparing acute major complications from the logistic regression model.

^c p -value for comparing total major complications from Cox regression model at 36-months postimplant.

^dIncludes device loss of capture, undersensing, device dislodgement, and device embolization.

^eOthers include congestive heart failure, acute MI, pacemaker syndrome, syncope, pulmonary edema, etc.

FIGURE 3 Major complication rates through 36-months postimplant for patients with and without concomitant atrioventricular nodal ablation. (A) Unadjusted (univariate) comparison. (B) Comparison adjusted for differences in baseline characteristics using overlap weights. HR = hazard ratio from Cox model. CI = confidence interval



There were six procedure-related deaths, of which two occurred in patients with AVNA. One death was caused by metabolic acidosis in a 77-year-old female patient with end stage renal disease. The second death was caused by retroperitoneal bleeding in a 92-year-old female with low body mass index (19.2 kg/m^2), hypertension, and COPD. The remaining four deaths occurred in patients without AVNA. Two resulted from cardiac tamponade, one from RV failure (possible from acute infarct), and one from pulmonary edema in a patient with severe aortic valve disease. All six procedure-related deaths have been described previously in detail.^{6,7}

3.4 | System revisions

There were 10 system revisions for any reason in 9 (4.7%) of the patients with AVNA and 64 system revisions in 62 (2.4%) of the

patients without AVNA (Table 3). The risk for system revision for any reason through 36-months was 2.72 times higher on a univariate basis (95% CI: 1.34–5.51, $p = .005$) in patients with AVNA compared with those without AVNA and trended higher after adjustment for differences in baseline characteristics (Figure 4A,B). The most common reasons for system revision in both groups were device upgrade or high pacing thresholds (including loss of capture). The most common action taken with the Micra device was to leave the device in place and program it to OOO mode. There were three system revisions for infection in patients without AVNA. In two patients the Micra was prophylactically removed following prosthetic valve endocarditis. The third patient had their Micra implant following removal of an infected cardiac resynchronization therapy (CRT)-pacemaker. After the infection cleared, their Micra was programmed to OOO and following implant of a new CRT-pacemaker system. However, their new transvenous system became infected and was

TABLE 3 System revision by concomitant AVNA status

System revisions	AVNA (n = 192)	No AVNA (n = 2616)
Total system revisions	10 (9, 4.7%)	64 (62, 2.4%)
Reason for system revision		
Device upgrade	4 (4, 2.1%)	25 (25, 1.0%)
Transvenous single chamber IPG	0 (0, 0.0%)	1 (1, < 0.1%)
Transvenous dual chamber IPG	0 (0, 0.0%)	4 (4, 0.2%)
ICD	0 (0, 0.0%)	1 (1, < 0.1%)
CRT-pacemaker	4 (4, 2.1%)	13 (13, 0.5%)
CRT-ICD	0 (0, 0.0%)	6 (6, 0.2%)
High threshold	5 (4, 2.1%)	19 (18, 0.7%)
Pacemaker syndrome	0 (0, 0.0%)	5 (5, 0.2%)
Battery ERI ^a	0 (0, 0.0%)	3 (3, 0.1%)
Cardiac failure	1 (1, 0.5%)	2 (2, 0.1%)
Infection	0 (0, 0.0%)	3 (3, 0.1%)
Dislodgement	0 (0, 0.0%)	2 (2, 0.1%)
Heart transplant	0 (0, 0.0%)	1 (1, < 0.1%)
Other	0 (0, 0.0%)	4 (4, 0.2%)
Type of system revision		
Programmed to OOO	5 (5, 2.6%)	44 (44, 1.7%)
Explanted	3 (3, 1.6%)	11 (11, 0.4%)
Programmed to backup	2 (2, 1.0%)	4 (4, 0.2%)
Heart transplant	0 (0, 0.0%)	1 (1, < 0.1%)
Repositioned	0 (0, 0.0%)	1 (1, < 0.1%)
Therapy resumed	0 (0, 0.0%)	1 (1, < 0.1%)
Not reported	0 (0, 0.0%)	2 (2, 0.1%)

Note: Numbers reflect the number of events (number of unique patients, percentage of unique patients).

Abbreviations: AVNA, atrioventricular nodal ablation; CRT, cardiac resynchronization therapy; ERI, elective replacement indicator.

^aERI due to elevated pacing thresholds.

removed necessitating resumption of pacing therapy from the Micra device.

4 | DISCUSSION

This is the largest study to date examining simultaneous leadless pacemaker implant and AVNA. The results show that simultaneous LP/AVNA appears to be safe and feasible, despite the higher rate of observed complications and device revision as compared with patients undergoing LP implant alone.

The complications observed in the LP/AVNA group appear to be mostly related to the LP implantation and do not involve the simultaneous performance of the AVNA. For example, the rate of pericardial effusion in the simultaneous LP/AVNA group was 1.6% versus 0.6% in the LP group. Similarly, it is unlikely that the higher rate of microdislodgment or changes in pacing capture thresholds over time are due to the AVNA itself, particularly

since the mean capture threshold was numerically lower in the LP/AVNA patients.

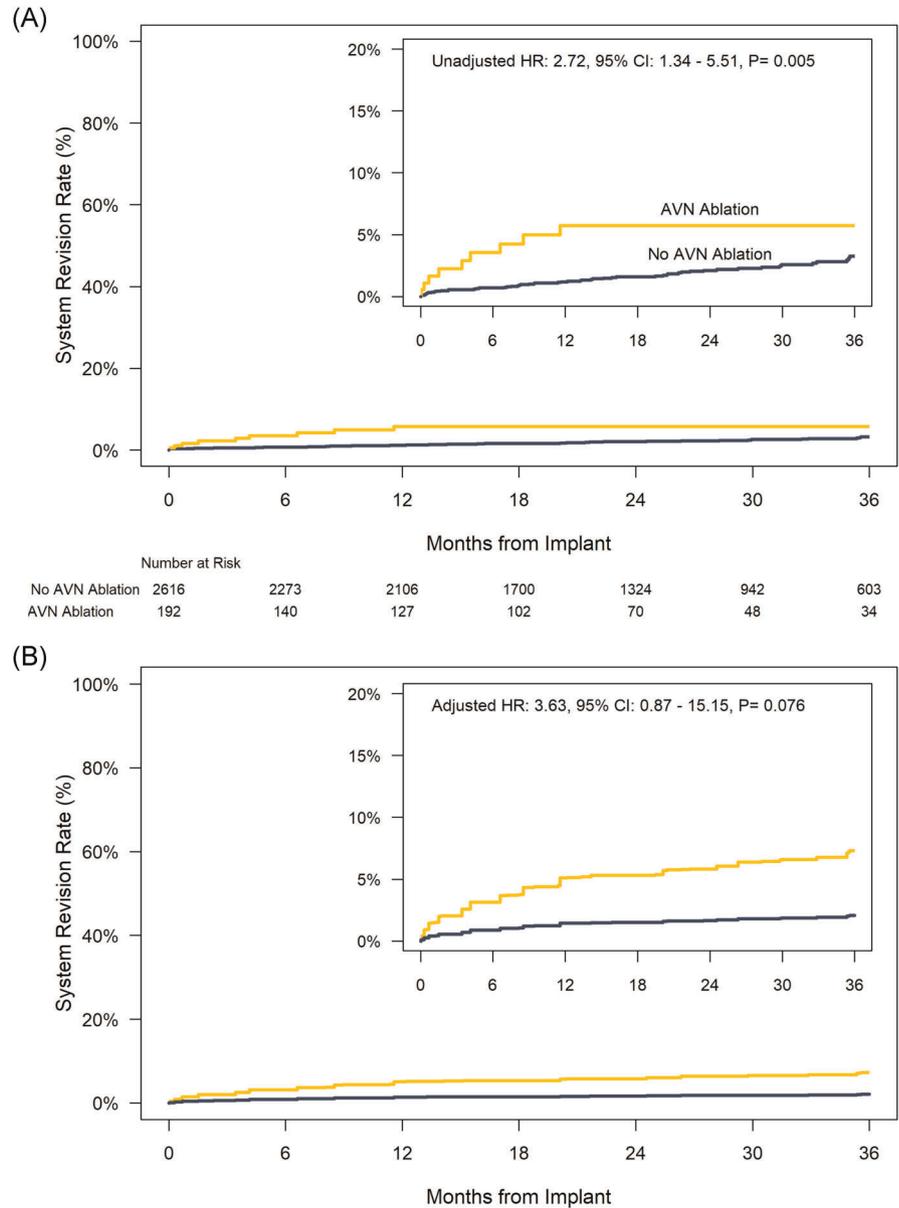
The increased rate of complications in the AVNA cohort is not entirely unexpected, as those undergoing LP/AVNA were older and had more risk factors known to be associated with complications including female sex, concomitant AF (requiring attendant anticoagulation), heart failure, end stage renal disease, and COPD.¹⁵ Despite adjusting for baseline comorbidities, the overall rate of complications remained higher in the LP/AVNA group. This could be due to either the added complexity in a LP/AVNA procedure or the difference could be due to residual confounding that is not entirely corrected by the propensity weighting techniques.

Simultaneous LP implantation and AVNA via a single femoral venous puncture is a strategy with potential advantages over TV-PPM and AVNA. LPs are associated with lower dislodgment rates and infection rate as compared to TV-PPMs. These two complications have devastating consequences in pacemaker dependent patients. It is likely that performing two simultaneous procedures will always carry higher risk than performing one procedure, but one must weigh this against the risk of performing two procedures that requires similar access entry point separately. Patients referred for an ablate and pace approach are typically an elderly population with multiple comorbidities as seen in this study. Despite adjusting for baseline comorbidities, the total complication rates remained greater in the AVNA group. As mentioned previously, it is likely that there are some confounding factors that we did not account for that could explain the higher rate of complications in this group. It is interesting to note that the individual adjusted major complication rates (rates of pericardial effusion, groin complications, and pacing issues) were not different between the two groups (Table S3), though propensity weighting resulted in a lower effective sample size.

There are a few previously published reports regarding the safety and feasibility of this approach.^{9,10,16} Similar to our international cohort, these small reports also suggest that this approach is safe and feasible. For instance, Martinez-Sande et al.¹⁶ reported on 27 patients who received simultaneous LP and AVNA. Three patients experienced complications (11%) as compared with 5.5% complication rate in their cohort (127 patients) of patients that received LP without a concomitant AVNA. None of these complications were related to the AVNA procedure.

It is also worth noting that the higher rate of system revisions in the LP/AVNA group is not only related to changes in thresholds but also due to heart failure and requirement for upgrade to a CRT system. Patients with AVNA typically have higher rate of RV pacing as compared with patients receiving LP who are not pacemaker dependent. High burden of RV pacing predisposes to heart failure and left ventricular dysfunction.¹⁷ In this study, the median percentage of RV pacing was 99.7% (IQR 98.7%–99.9%) in the AVNA group as compared with 59.1% (IQR: 10.0%–97.2%) in the non-AVNA group ($p < .001$). In patients with an expected high percentage of RV pacing, an approach of utilizing physiologic pacing or CRT as a first-line strategy for pacing may be beneficial, especially in patients

FIGURE 4 System revision rates for any reason through 36-months postimplant for patients with and without concomitant atrioventricular nodal ablation. (A) Unadjusted (univariate) comparison. (B) Comparison adjusted for differences in baseline characteristics using overlap weights. HR = hazard ratio from Cox model. CI = confidence interval



with an LVEF $\leq 50\%$.¹⁸ It is worth noting that the mean LVEF in the AVNA group was $56.7 \pm 8.0\%$, which may explain physicians' choice of a leadless system rather than CRT or a pacing system that provides physiologic pacing. Although three of the 129 patients in the AVNA group had an LVEF $\leq 40\%$, none required CRT upgrade or underwent system revision. The higher rate of system revision due to rise in thresholds in the LP/AVNA group may also be partly explained by the lower threshold for revising a pacing system in pacemaker dependent patients.

In this study, no patients in either group died due to loss of capture. However, 2.1% of patients had a system revision for elevated thresholds in the LP/AVNA group during follow-up. Therefore, it is an imperative recommendation for new implanters or in the case of a challenging implant with suboptimal electrical characteristics¹⁹ to delay the AVNA until the LP is mature and thresholds are stable.

4.1 | Limitations

Despite adjusting for baseline measured differences with propensity-based methods; residual confounding due to unmeasured factors cannot be ruled out in an observational study. Also, the effective sample size of our adjusted analysis was small due to the large differences in patients' profiles between the two groups. This led to wider confidence intervals for our adjusted comparison. It is also important to note that this study does not have a comparison group of patients undergoing AVNA weeks to months post LP implant. Therefore, we cannot compare a strategy of simultaneous versus staggered LP/AVNA. Similarly, there was not a comparator group of patients undergoing concomitant AVNA with TV-PPM implant; therefore, it is unknown whether such patients also experience a higher rate of complications. Nevertheless, this is the largest multicenter study evaluation the safety of concomitant LP and AVNA.

5 | CONCLUSION

Simultaneous LP and AVNA appears to be a safe approach for treating a subgroup of patients with AF. Thresholds remain stable over time with a low risk of needing a system revision. Patients referred for an ablate and pace have a higher comorbidity burden and performing LP with AVNA concomitantly is associated with a higher complication rate than solely implanting a LP without AVNA.

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DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions.

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

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