

Optimizing mechanically sensed atrial tracking in patients with atrioventricular-synchronous leadless pacemakers: A single-center experience



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BACKGROUND Atrioventricular (AV)-synchronous single-chamber leadless pacing using a mechanical atrial sensing algorithm produced high AV synchrony in clinical trials, but clinical practice experience with these devices has not yet been described.

OBJECTIVE To describe pacing outcomes and programming changes with AV-synchronous leadless pacemakers in clinical practice.

METHODS Consecutive patients without persistent atrial fibrillation who received an AV-synchronous leadless pacemaker and completed follow-up between February 2020 and April 2021 were included. We evaluated tracking index (atrial mechanical sense followed by ventricular pace [AM-VP] divided by total VP), total AV synchrony (sum of AM-ventricular sense [AM-VS], AM-VP, and AV conduction mode switch), use of programming optimization, and improvement in AV synchrony after optimization.

RESULTS Fifty patients met the inclusion criteria. Mean age was 69 ± 16.8 years, 24 (48%) were women, 24 (48%) had complete heart block, and 17 (34%) required $\geq 50\%$ pacing. Mean tracking index was $41\% \pm 34\%$. Thirty-five patients (70%) received ≥ 1

programming change. In 36 patients with 2 follow-up visits, tracking improved by $+9\% \pm 28\%$ (P value for improvement = .09) and $+18\% \pm 19\%$ ($P = .02$) among 15 patients with complete heart block. Average total AV synchrony increased from 89% [67%, 99%] to 93% [78%, 100%] in all patients ($P = .22$), from 86% [52%, 98%] to 97% [82%, 99%] in those with complete heart block ($P = .04$), and from 73% [52%, 80%] to 78% [70%, 85%] in those with $\geq 50\%$ pacing ($P = .09$).

CONCLUSION In patients with AV-synchronous leadless pacemakers, programming changes are frequent and are associated with increased atrial tracking and increased AV synchrony in patients with complete heart block.

KEYWORDS Leadless pacemaker; Mechanical atrial sensing; Atrioventricular synchrony; Complete heart block; Pacemaker programming

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Introduction

Leadless transcatheter pacing systems (TPS) offer an alternative to transvenous pacemakers, particularly for patients at an increased risk of infection or with limited venous access.¹ First-generation leadless pacing devices provided ventricular-only pacing, which significantly limited candidate selection to patients with chronic atrial fibrillation (AF) and atrioventricular (AV) block, patients with

paroxysmal sinus pauses or paroxysmal AV block with a very low expected pacing burden, or those with sufficient contraindication to placement of transvenous leads to justify sacrificing AV synchrony.

AV-synchronous pacing provides several advantages compared with ventricular-only pacing without AV synchrony, including avoidance of pacemaker syndrome and improved quality of life,^{2–4} especially in patients with high ventricular pacing burden.⁵ To expand the role of leadless pacing, an AV-synchronous pacing algorithm was developed which uses the device's 3-axis accelerometer to achieve mechanical sensing of atrial contraction.⁶ After initial feasibility trials, the algorithm was enhanced with auto-adjusting

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KEY FINDINGS

- In patients with atrioventricular (AV)-synchronous leadless pacemakers, programming changes are frequent. Despite programming optimization at the time of implant, 70% of patients required further adjustment of atrial sensing parameters during outpatient follow-up.
- In a majority of individuals implanted with AV-synchronous leadless pacemakers, atrial sensing was maximized during follow-up with programming lower A4 threshold than that selected immediately after the implant procedure.
- Programming changes improved atrial tracking in patients with complete heart block who received an AV-synchronous leadless pacemaker.

detection, enhanced atrial signal filters, mode switch algorithms, and expanded choice of accelerometer sensing vectors, which achieved high rates of AV synchrony and improved ventricular stroke volume during time-limited application in previously implanted first-generation leadless pacemakers.^{7,8}

The Micra AV™ leadless TPS (Medtronic, Minneapolis, MN) was subsequently released in February 2020 with nominal programming in a ventricular-pacing, atrial-tracking mode (VDD). Appropriate atrial sensing is predicated on appropriate discrimination of the atrial contraction mechanical signature. Device programming optimization of new leadless pacemakers is focused on maximizing atrial mechanical sensing by adjusting the signal discriminators for passive ventricular filling (A3) and atrial contraction (A4).

In the MARVEL 2 trial,⁸ mechanical atrial sensing allowed greater than 70% AV-synchronous pacing at rest among nearly 90% of participants with complete heart block. It has not yet been described how well this software performs with de novo device implantation in clinical practice outside of clinical trials. Accordingly, we describe our early single-institution experience with outpatient programming optimization of the AV-synchronous leadless TPS. Specifically, our objective was to describe the need for programming changes in atrial tracking parameters and improvement in atrial tracking after programming changes.

Methods

Patient selection

We conducted an observational retrospective cohort study involving patients at Duke University who received a leadless pacemaker equipped with mechanical atrial sensing (Micra AV; Medtronic, Minneapolis, MN). The study was approved by the Duke University Health System Institutional Review Board, and patient consent was waived in accordance with the retrospective nature of the study. The study was conducted in accordance with the Declaration of Helsinki.

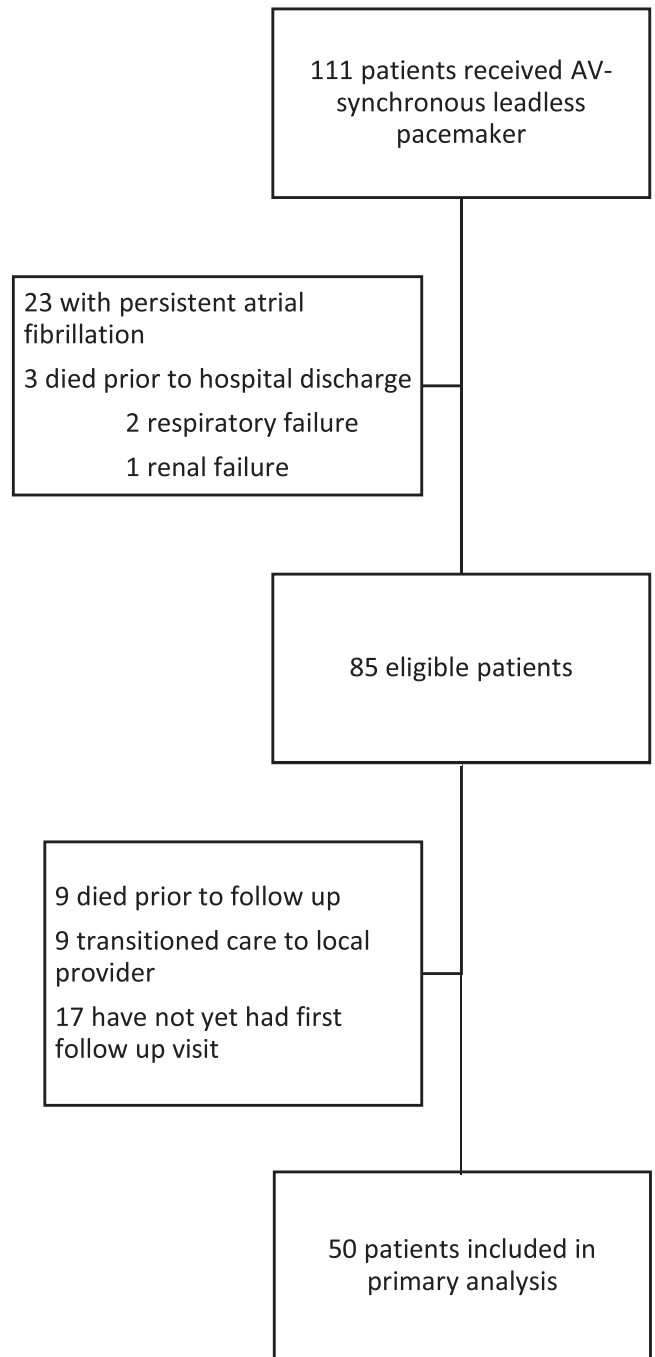


Figure 1 Cohort selection. AV = atrioventricular.

Patients were eligible for inclusion if they received a leadless pacemaker and completed at least 1 subsequent outpatient visit in a Duke University electrophysiology clinic between February 10, 2020, and January 31, 2021. Patients in persistent AF at implant were excluded from the study. Patients were included regardless of the degree of AV block. To assess the impact of changes in programmed parameters on atrial tracking, a subgroup was identified who met the above criteria and completed a second outpatient visit or remote interrogation before April 30, 2021.

Table 1 Baseline characteristics (N = 50 patients)

Age, years	69 ± 16.8
Women	24 (48%)
Indication for permanent pacing	
Sinus node dysfunction	8 (16%)
Sinus arrest / asystole	5 (10%)
High-grade AV block	9 (18%)
Complete heart block	24 (48%)
Tachy-brady syndrome	3 (6%)
Autonomic failure	1 (2%)
Postoperative state [†]	14 (28%)
Prior CIED	5 (10%)
Hypertension	33 (66%)
Heart failure	20 (40%)
Left ventricular ejection fraction	
>55	41 (82%)
41%–55%	5 (10%)
≤40	4 (8%)
Coronary artery disease	14 (28%)
CABG history	7 (14%)
Valve surgery	16 (32%)
Stroke	8 (16%)
Diabetes mellitus	14 (28%)
Chronic kidney disease	12 (24%)
On renal replacement therapy	6 (12%)
Acute kidney injury	2 (4%)
History of paroxysmal atrial fibrillation	13 (26%)
Prior atrial fibrillation ablation	3 (6%)
Active malignancy	3 (6%)
Bacteremia	7 (14%)
Endocarditis	6 (12%)
Prior transplant	6 (12%)
Heart	4 (8%)
Lung	1 (2%)
Kidney	1 (2%)
Time to first follow-up visit	2.3 ± 2.0 months

AV = atrioventricular; CABG = coronary artery bypass graft; CIED = cardiovascular implantable electronic device.

[†]Cardiac surgery (including transcatheter aortic valve replacement), during implanting admission prior to device placement.

Leadless pacemaker implantation

All implant procedures were performed by a cardiac electrophysiologist at Duke University Hospital using standard technique.⁹ Devices were interrogated prior to discharge, with manual atrial mechanical (MAM) test used to optimize atrial sensing features and maximize atrial tracking in sinus rhythm.

In-clinic device interrogation and optimization

Outpatient device interrogation was performed by a cardiac electrophysiology physician, nurse practitioner, or physician assistant, often in conjunction with attendant industry personnel. Baseline parameters from the first postimplant interval were recorded, including percentages of atrial mechanical sensed–ventricular pacing (AM-VP), AM-ventricular sensing (VS), VS, VP, AV conduction mode switch (time in VVI+ mode), and activity mode switch (time in VDIR mode). Appropriate activation of the device's advanced algorithms was assessed: AV synchrony mode switching, which provides backup pacing support at VVI 40 (VVI+ mode) to promote intrinsic AV conduction, when present; rate-responsive mode

switching, which transitions to VDIR mode with activity to provide rate-responsive pacing; and the rate-smoothing feature, which facilitates a consistent pacing rate during brief periods of atrial undersensing. Change in pacing mode (VDD, VDI, VVI, or VVIR), upper and lower pacing rates, pacing output, mode switch algorithms, and rate-responsive features were performed if clinically indicated. Adjustment of programmed device parameters was performed at the clinician's discretion. A MAM test was again used to optimize atrial sensing features, adjusting timing window and threshold amplitude for detection of mechanical A3 and A4 signals to maximize atrial tracking in sinus rhythm. Final parameters were recorded.

Data collection and analysis

Patient demographics, clinical factors, indication for permanent pacing, and procedural outcomes were abstracted from the electronic medical record. Device data (pacing statistics and programmed parameters) were collected from interrogation reports fully scanned into the medical record. The tracking index for each follow-up interval was defined as follows: the proportion of paced beats that track a mechanically sensed atrial contraction (calculated as AM-VP percentage divided by total VP percentage). Total AV synchrony was defined as the sum of AM-VS, AM-VP, and AV conduction mode switch percentages. In the subset of patients with more than 1 outpatient follow-up, change in tracking index and total AV synchrony were defined as absolute difference in each metric between first and second visit.

Descriptive statistical analyses were performed in SPSS. Continuous variables are presented as medians and 25th, 75th percentiles for variables without a normal distribution and means with standard deviations for normally distributed variables. Pre- and postadjustment pacing outcomes were compared via the Student *t* test for normally distributed variables and via the Wilcoxon rank sum test and McNemar test for variables without a normal distribution.

Results

Baseline characteristics

Overall, 111 patients received an AV-synchronous leadless pacemaker during the study period. Of these, 50 patients met study inclusion criteria, as illustrated in Figure 1. Baseline characteristics are detailed in Table 1. The mean age was 69 ± 16.8 years and 24 (48%) were women. Indications for permanent pacing included symptomatic sinus node dysfunction (16%), sinus arrest (10%), high-grade AV block (18%), complete heart block (48%), tachy-brady syndrome (6%), and autonomic failure (2%). Six patients (12%) had prior endocarditis or device infections. Six patients (12%) were on chronic immunosuppressive therapy owing to prior solid organ transplant and 3 (6%) were undergoing therapy for cancer. Thirteen (26%) had history of paroxysmal AF. There were no procedural complications related to leadless pacemaker implant.

Table 2 Atrioventricular synchrony metrics at first follow-up visit

	Number	Pacing burden (median)	Tracking index [†] (mean)	Total AVS [‡] (median)	>70% AVS, n (%)
Full cohort	50	10% [0%, 92%]	41% ± 34%	83% [49%, 98%]	32 (64%)
<50% pacing	33 (66%)	1% [0%, 9%]	37% ± 33%	96% [75%, 99%]	26 (79%)
≥50% pacing	17 (34%)	98% [93%, 100%]	47% ± 35%	59% [0%, 74%]	6 (35%)
VDD	40	8% [0%, 88%]	54% ± 28%	91% [74%, 99%]	32 (80%)
<50% pacing	28 (70%)	1% [0%, 9%]	46% ± 30%	97% [89%, 99%]	26 (93%)
≥50% pacing	12 (30%)	98% [93%, 100%]	67% ± 19%	69% [59%, 76%]	6 (50%)
CHB	24	73% [1%, 99%]	41% ± 31%	69% [16%, 96%]	12 (50%)
<50% pacing	11 (46%)	1% [0%, 6%]	37% ± 27%	96% [81%, 99%]	9 (82%)
≥50% pacing	13 (54%)	99% [95%, 100%]	43% ± 34%	59% [0%, 65%]	3 (23%)

AM-VP = atrial mechanical sensed – ventricular paced; AVS = atrioventricular synchrony; CHB = complete heart block.

[†]Tracking index = AM-VP / total VP.

[‡]Total AVS = sum of AM-VS, AM-VP, and AV conduction mode switch.

Initial programmed settings

At discharge following the leadless pacemaker implant procedure, 10 patients (20%), 5 of whom had complete heart block, were programmed in a nontracking mode (VDI, VVI, or VVIR). Among these 10 patients, 6 had been programmed in a nontracking mode following implant to prevent symptoms during AV conduction search in 2 patients, to minimize right ventricular (RV) pacing burden in 1 patient, and owing to underlying sinus bradycardia in 3 patients. Four had been transitioned to nontracking mode in the postprocedural period (3 owing to difficulties with the AV conduction mode switch algorithm and 1 to minimize RV pacing burden in a patient with infrequent sinus pauses).

Pacing burden and atrial tracking during follow-up

The first outpatient visit occurred at a mean follow-up of 2.3 ± 2.0 months after the implant procedure. The median pacing burden was 10% [0%, 92%] (Table 2), and 33 patients (67%) had <50% total RV pacing (median 1.2% [0%, 9%]). The remainder of the patients required ≥50% pacing (median 98% [93%, 100%]). Among patients with an implant indication of complete heart block, 46% required <50% pacing and 54% required ≥50% pacing. Three patients had incident AF or atrial flutter detected on 12-lead electrocardiogram or ambulatory monitor during the follow-up period.

The mean tracking index (AM-VP divided by total VP) was 37% ± 33% in those with <50% pacing and 47% ± 35% in patients with ≥50% pacing (Table 2, Figure 2). In

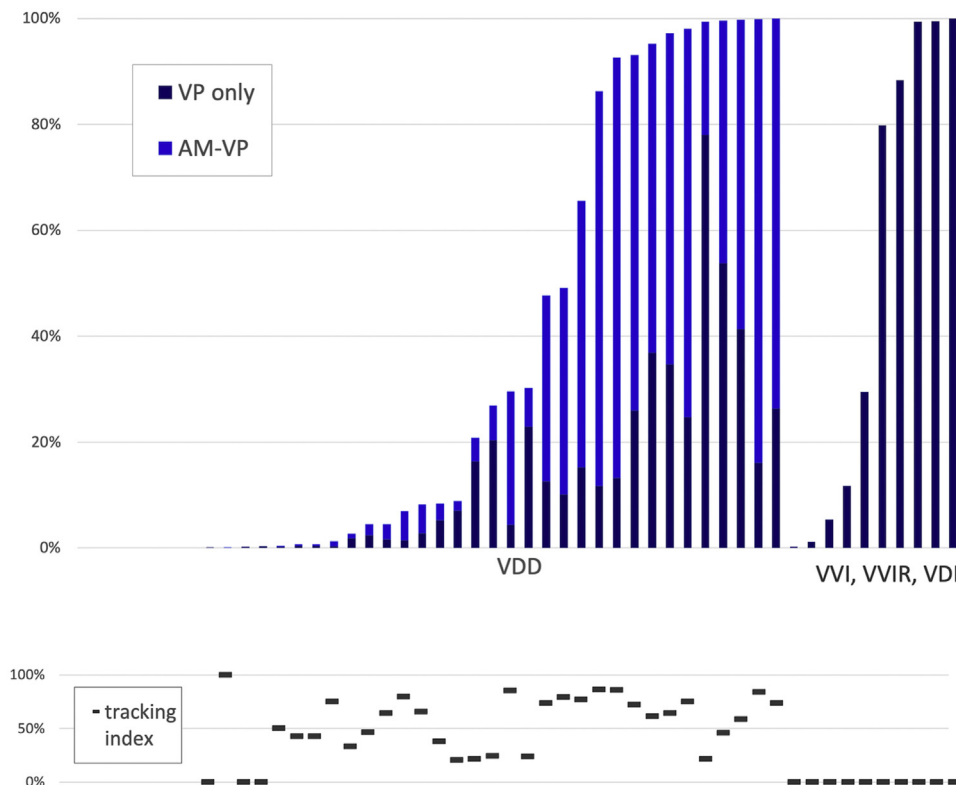


Figure 2 Cumulative pacing burden and tracking index for each patient at first follow-up. For each patient, pacing percentages representing successful tracking of atrial mechanical sensing (AM-VP) and nontracked ventricular pacing (VP) are plotted. Tracking index = AM-VP / total VP.

Table 3 Programmed parameter changes at first follow-up visit

Parameter adjustment	Number (%)
Mode	5 (10)
To tracking mode	4 (8)
To nontracking mode	1 (2)
Sensing vector	1 (2)
A3 Window	21 (42)
Increased	4 (8)
Decreased	17 (34)
Auto A3 window (turned off)	6 (12)
A3 Threshold	0 (0)
Auto A3 threshold (turned off)	1 (2)
A4 Threshold	23 (46)
Increased	2 (4)
Decreased	21 (42)
Auto A4 threshold (turned off)	4 (8)
PVAB	8 (16)
Increased	0 (0)
Decreased	8 (16)
PVARP	9 (18)
Increased	0 (0)
Decreased	1 (2)
Auto off	8 (16)
Lower rate limit	12 (24)
Increased	4 (8)
Decreased	8 (16)
Upper tracking rate	4 (8)
Increased	4 (2)
Decreased	0 (0)
Pacing output	8 (16)
Increased	1 (2)
Decreased	7 (14)
Rate smoothing	0 (0)
AV mode switch (turned on)	2 (4)
Rate responsive slope	0 (0)
No changes	15 (30)

AV = atrioventricular; PVAB = postventricular atrial blanking; PVARP = postventricular atrial refractory period.

13 patients with history of paroxysmal AF, the mean tracking index was $26\% \pm 27\%$ (Supplemental Table 1). The median total AV synchrony was 83% [49%, 98%] overall and 59% [0%, 74%] in those requiring $\geq 50\%$ pacing. In patients with complete heart block, the mean tracking index was $41\% \pm 31\%$, and median total AV synchrony was 69% [16%, 96%].

Programming changes during outpatient follow-up

A majority of patients (35/50, 70%) had device programming changes at their first postimplant outpatient follow-up visit (Table 3). The most frequent programming change was a decrease in minimum A4 sensing threshold (42%), followed by shortening of minimum A3 timing window (34%). The mechanical atrial sensing vector was changed in only 1 patient. Among patients with a history of complete heart block, 19 (79%) received at least 1 programming change, with 11 (55%) requiring decreased minimal A4 threshold.

Five patients (10%) were reprogrammed to a new mode at first follow-up (4 VDD [8%], 1 VDI [2%]). All 3 patients (2 in the complete heart block group) who were transitioned to a nontracking mode during the index admission owing to difficulty with AV conduction mode switch had successful transition back to VDD mode at outpatient follow-up. One patient was transitioned from VDD to VDI at follow-up owing to pacemaker syndrome with poor P-wave tracking despite significant troubleshooting.

Second outpatient follow-up

Thirty-six patients in our cohort (72%) completed 2 outpatient visits during the follow-up period with a mean follow-up time of 5.3 ± 2.7 months (Table 4, Supplemental Table 2). Of these, 15 had complete heart block, 29 had remained in VDD mode throughout the follow-up period, and 22 had their device reprogrammed at their first visit. In all patients with 2 follow-up visits, the mean tracking index was $45\% \pm 34\%$ at the first visit and $54\% \pm 30\%$ at the second visit (P value for improvement from first to second visit = .09). In patients with complete heart block, the mean tracking index improved from $44\% \pm 30\%$ to $62\% \pm 25\%$ ($P = .02$) (Figures 3 and 4). In all patients, the median total AV synchrony was 89% [67%, 99%] at the first visit and 93% [78%, 100%] at the second visit ($P = .10$). In the complete heart block subgroup, median total AV synchrony was 86% [52%, 98%] at the first visit and 97% [82%, 99%] at the second visit ($P = .04$). Among 8 patients with $\geq 50\%$ pacing, median total AV synchrony was 73% [52%, 80%] at the first visit and 78% [70%, 85%] at the second visit ($P = .09$). The number of patients with greater than 70% total AV synchrony was 26 (72%) at first visit and 30 (83%) at second visit

Table 4 Pacing and atrioventricular synchrony metrics in patients who completed 2 visits

	Number	Tracking index (mean)		P	Total AV synchrony (median)		P	AV synchrony >70% (number)		P
		Visit 1	Visit 2		Visit 1	Visit 2		Visit 1	Visit 2	
Full cohort	36	$45\% \pm 34\%$	$54\% \pm 30\%$	$P = .09$	89% [67%, 99%]	93% [78%, 100%]	$P = .10$	26 (72%)	30 (83%)	$P = .22$
<50% pacing	25 (69%)	$36\% \pm 33\%$	$43\% \pm 27\%$	$P = .49$	97% [81%, 99%]	99% [93%, 100%]	$P = .31$	19 (76%)	22 (88%)	$P = .38$
$\geq 50\%$ pacing	11 (31%)	$59\% \pm 31\%$	$70\% \pm 26\%$	$P = .04$	73% [52%, 80%]	78% [70%, 85%]	$P = .09$	7 (64%)	8 (73%)	$P = 1.0$
VDD	29	$58\% \pm 27\%$	$64\% \pm 22\%$	$P = .23$	96% [74%, 99%]	95% [85%, 100%]	$P = .21$	25 (86%)	28 (97%)	$P = .25$
<50% pacing	20 (69%)	$48\% \pm 30\%$	$51\% \pm 21\%$	$P = .81$	99% [95%, 99%]	99% [94%, 100%]	$P = .46$	18 (90%)	20 (100%)	$P = .50$
$\geq 50\%$ pacing	9 (31%)	$73\% \pm 12\%$	$81\% \pm 7\%$	$P = .03$	74% [73%, 86%]	79% [76%, 85%]	$P = .17$	7 (78%)	8 (89%)	$P = 1.0$
CHB	15	$44\% \pm 30\%$	$62\% \pm 25\%$	$P = .02$	86% [52%, 98%]	97% [82%, 99%]	$P = .04$	10 (67%)	13 (87%)	$P = .25$
<50% pacing	9 (60%)	$31\% \pm 30\%$	$48\% \pm 29\%$	$P = .23$	97% [96%, 100%]	99% [98%, 100%]	$P = .12$	7 (78%)	9 (100%)	$P = .50$
$\geq 50\%$ pacing	6 (40%)	$54\% \pm 29\%$	$73\% \pm 15\%$	$P = .04$	66% [49%, 74%]	75% [69%, 83%]	$P = .12$	3 (50%)	4 (67%)	$P = 1.0$

CHB = complete heart block.

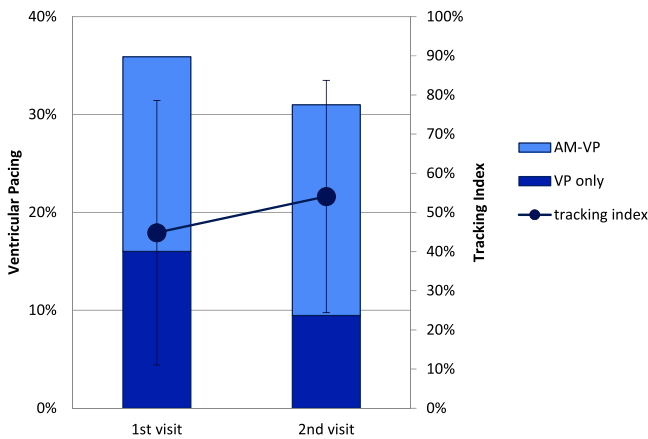


Figure 3 Change in pacing burden and tracking index after optimization. Average tracking efficiency metrics at first visit and second visit for patients who completed 2 visits. Abbreviations as in Figure 1.

($P = .22$). In patients with complete heart block, >70% AV synchrony was achieved in 10 (67%) at first visit and 13 (87%) at second visit ($P = .25$). In patients with $\geq 50\%$ pacing, >70% AV synchrony was achieved in 7 (64%) at first visit and 8 (73%) at second visit ($P = 1.0$). At last follow-up, no patients required transition to a transvenous device.

Discussion

AV-synchronous leadless pacemakers have the potential to offer the benefits of a single-chamber leadless device and avoid the risks associated with transvenous devices without sacrificing AV synchrony. In our early experience with 50

consecutive patients who received an AV-synchronous leadless pacemaker, we report 3 major findings. First, despite programming optimization at the time of implant, 70% of patients received further adjustment of atrial sensing parameters during outpatient follow-up. Second, in the majority of individuals, atrial sensing was maximized during follow-up with a lower A4 threshold than that selected during the implanting procedure. Third, programming changes improved atrial tracking and average total AV synchrony in patients with complete heart block. Of note, there was lower total AV synchrony in patients with $\geq 50\%$ pacing burden compared with those who had lower pacing needs.

Overall, 70% of patients in our cohort, and nearly 80% of those with complete heart block as pacing indication, received adjustment in programmed parameters at first post-implant outpatient visit, highlighting the importance of in-person follow-up during the early surveillance period. For comparison, the FOLLOWPACE study reported a 54% incidence of programming changes for transvenous pacemakers at first follow-up.¹⁰ It is possible that the high rate of reprogramming reflects the learning curve associated with optimizing the novel programming parameters of the Micra AV for individual patients. However, there may additionally be a subset of patients who have poor atrial tracking regardless of programmed parameters, as some patients had only marginal improvement in AV synchrony after repeat MAM testing-guided optimization. Refining patient selection and the AV synchrony algorithm may reduce the number of cases requiring frequent troubleshooting.

The most common programming adjustment for the leadless pacemaker in our cohort was lowering of the minimal A4

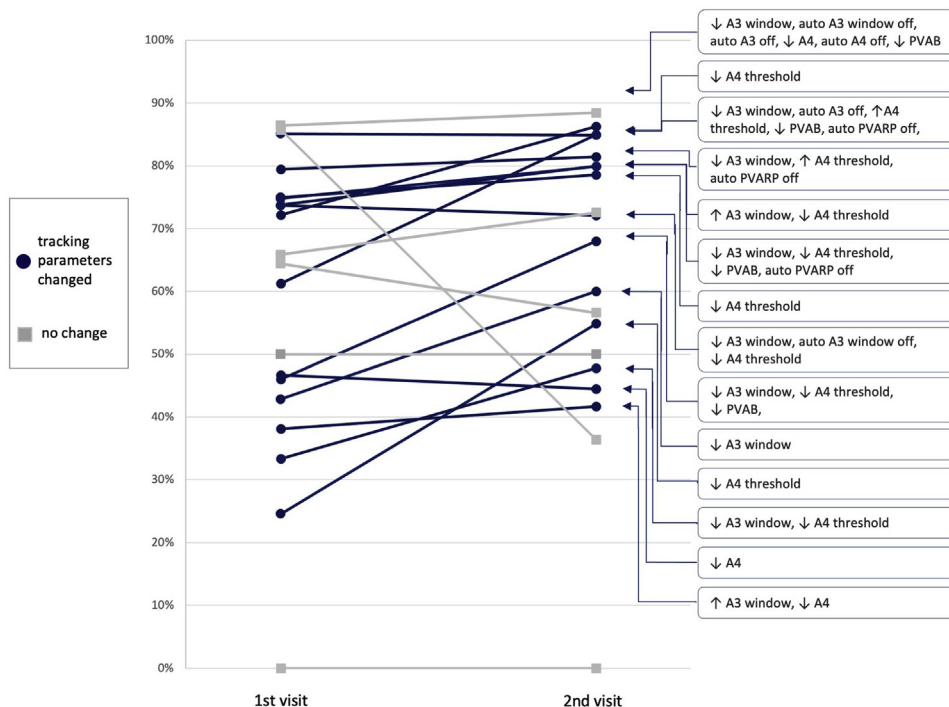


Figure 4 Programming optimization and improvement in tracking index. Tracking index at each visit along with parameter changes performed at first visit are displayed. Patients with 2 visits and at least 0.1% pacing were included. Those who were in a nontracking mode at either visit were excluded. PVAB = post-ventricular atrial blanking; PVARP = postventricular atrial refractory period.

threshold, the most direct atrial sensing metric. In most cases, the auto-sensing algorithm was left on, and it remains to be seen whether patients with low A4 signal have better tracking with fully manual A4 threshold selection. Low intrinsic A4 signal has historically been the most common reason cited for low tracking rates with Micra AV, encompassing more than half of the participants with low AV synchrony in MASS 2¹¹ and all participants with this issue in MARVEL 2.⁸ Low amplitude and poor differentiation of A4 signal correlate with impaired atrial kick.¹² In a secondary analysis of MARVEL 2, individuals with electrocardiographic and echocardiographic markers of diastolic dysfunction and/or atrial myopathy were found to be at higher risk of reduced compatibility with the mechanical atrial sensing algorithm.¹² Future investigations refining predictors of A4 sensing in clinical practice may offer further guidance for clinicians regarding device selection for patients with AV block, particularly in cases without an absolute contraindication to transvenous systems. Whether loss of AV synchrony impacts clinical outcomes, such as atrial arrhythmia burden or heart failure hospitalizations, in those with poor atrial contractile function remains an important area of ongoing study.

To evaluate the degree of AV-synchronous pacing across a spectrum of total pacing needs, we calculated the fraction of paced beats that represent successful atrial tracking, termed *tracking index*. Adjustment in Micra AV atrial sensing parameters resulted in improved tracking index in patients with complete heart block. The MARVEL 1 and 2 trials used a benchmark of 70% AV synchrony at rest, with nearly 90% of patients meeting this standard during study Holter monitoring procedures. For comparison, incidence of atrial dyssynchrony was reported to be between 2% and 23% in historic cohorts with single-lead transvenous VDD pacemakers; a meta-analysis reported significant atrial undersensing in 10.6% of patients, compared to 3.6% among matched cohorts with DDD pacemakers.¹³ Average total AV synchrony in our cohort remained relatively high across extended follow-up; however, only 63% of our patients achieved the benchmark of greater than 70% AV synchrony in the first follow-up period with settings selected via MAM testing following implant. In our subgroup of patients who completed 2 outpatient visits, 40% of those who did not reach 70% AV synchrony at first visit crossed this threshold after programming changes, suggesting a benefit to outpatient optimization that may be further elucidated with a larger cohort.

Lower AV synchrony remained more prevalent in those with high pacing burden, in whom total AV synchrony is more dependent on device-driven atrial tracking compared to those with high intrinsic AV synchrony. Only 35% of patients with $\geq 50\%$ pacing requirements (most of whom had $>90\%$ pacing) achieved $>70\%$ total AV synchrony at first visit. While the proportion of patients achieving $>70\%$ total AV synchrony improved after outpatient programming optimization, comparatively lower AV synchrony in those with $\geq 50\%$ pacing persisted. Notably, the amount of AV synchrony needed to derive benefit,

particularly symptomatic benefit, over asynchronous pacing is not well established. Studies using single-lead transvenous VDD systems suggest decreased exercise duration and worse subjective physical function score when AV synchrony is lower than 90%.¹⁴ It is unclear whether exercise intolerance in this population is more attributable to AV dyssynchrony or inadequate heart rate response—an important distinction, as the activity mode switch feature in Micra AV is designed to provide physiologic exertional heart rate increase, even at the expense of AV synchrony. The tracking efficiency observed in our cohort represents a clear benefit of mechanical atrial sensing over purely asynchronous pacing, but also leaves room for further improvement in patient selection and device programming for those with high pacing needs.

Limitations

This was a single-center observational retrospective study, limited by modest sample size and by data readily available in the medical record. Specifically, quantification of AV synchrony was extrapolated from device interrogation data and could not be further validated with continuous ambulatory telemetry. The potential exists for occult paroxysmal AF as a cause of lower AV synchrony or for AV block with junctional escape rhythm above the programmed rate, prompting maintenance of AV conduction mode switch in the absence of true AV synchrony. There was no structured mechanism for reporting symptom burden or quality of life, which will be important metrics in future prospective studies aimed at refining patient selection. Patient selection for leadless TPS was based on clinician judgment, and therefore our experience in this selected population may differ from that of other institutions. Similarly, mode changes and adjustment in pacing parameters were performed at each clinician's discretion using MAM testing for guidance. While this validates our description of the clinical practice experience, it limits the generalizability of our data.

Conclusion

In patients with AV-synchronous leadless pacemakers, programming changes to atrial sensing parameters are often needed to optimize device function. After outpatient optimization of programmed parameters in patients with complete heart block, tracking index and total AV synchrony increased. Median total AV synchrony was maintained over 80% across the follow-up period. Patients with higher pacing burden had lower average AV synchrony than those with low pacing burden. These findings support ongoing enhancement of the AV-synchronous leadless pacing algorithm and further investigation regarding patient selection for mechanical atrial sensing devices.

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Authorship

All authors attest they meet the current ICMJE criteria for authorship.

Patient Consent

Patient consent was waived in accordance with the retrospective nature of the study.

Ethics Statement

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Duke University Hospital Institutional Review Board.

Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hroo.2021.08.003>.

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