Predictors of atrial mechanical sensing and atrioventricular synchrony with a leadless ventricular pacemaker: Results from the MARVEL 2 Study

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BACKGROUND The MARVEL (Micra Atrial TRacking Using a Venticular AccelErometer) 2 study assessed the efficacy of atrioventricular (AV) synchronous pacing with a Micra leadless pacemaker. Average atrioventricular synchrony (AVS) was 89.2%. Previously, low amplitude of the Micra-sensed atrial signal (A4) was observed to be a factor of low AVS.

OBJECTIVE The purpose of this study was to identify predictors of A4 amplitude and high AVS.

METHODS We analyzed 64 patients enrolled in MARVEL 2 who had visible P waves on electrocardiogram for assessing A4 amplitude and 40 patients with third-degree AV block for assessing AVS at rest. High AVS was defined as >90% correct atrial-triggered ventricular pacing. The association between clinical factors and echocardiographic parameters with A4 amplitude was investigated using a multivariable model with lasso variable selection. Variables associated with A4 amplitude together with premature ventricular contraction burden, sinus rate, and sinus rate variability (standard deviation of successive differences of P-P intervals [SDSD]) were assessed for association with AVS.

RESULTS In univariate analysis, low A4 amplitude was inversely related to atrial function assessed by E/A ratio and e’/a’ ratio, and was directly related to atrial contraction excursion (ACE) and atrial strain (Ea) on echocardiography (all P < .05). The multivariable lasso regression model found coronary artery bypass graft history, E/A ratio, ACE, and Ea were associated with low A4 amplitude.
E/A ratio and SDSD were multivariable predictors of high AVS, with >90% probability if E/A <0.94 and SDSD <5 bpm.

**CONCLUSION** Clinical parameters and echocardiographic markers of atrial function are associated with A4 signal amplitude. High AVS can be predicted by E/A ratio <0.94 and low sinus rate variability at rest.

### Background

In patients with normal sinus rhythm (NSR) and high-degree atrioventricular (AV) block, AV synchronous pacing mode improves stroke volume, cardiac output, and quality of life, and reduces the incidence of pacemaker syndrome and atrial fibrillation (AF). However, it does not reduce mortality or occurrence of stroke. Therefore, pacing modes that preserve atrioventricular synchrony (AVS) are recommended as a class I indication in patients who have high-degree AV block and NSR requiring permanent pacing, with dual-chamber pacemakers as the first choice and single-lead VDD pacing systems as an alternative. Leadless pacemakers were designed to reduce complications associated with transvenous pacemakers, particularly lead- and pocket-related complications, which historically have been reported to range as high as 2%–12%. Leadless pacemakers have demonstrated a high safety and efficacy profile. However, first-generation leadless pacemakers deliver only ventricular pacing (VVI[R] mode), which largely limits their use to patients with bradyarrhythmia and chronic AF and those considered to be at high risk for complications related to implantation of a leaded pacemaker. Recently, second-generation leadless pacemakers have expanded pacing modes to include AV synchronous pacing.

The MARVEL (Micra Atrial Tracking Using a Ventricular AccelErometer) and 2 studies demonstrated the feasibility of delivering AV synchronous pacing using a ventricular Micra leadless pacemaker (Medtronic, Inc, Minneapolis, MN, US). Specifically, the MARVEL 2 algorithm demonstrated a generally high proportion of AVS in patients with AV block, showing >95% of patients had >70% AVS at rest and increased left ventricular stroke volume. Notably, the optimal percentage of AVS required to maintain benefit while minimizing pacemaker syndrome has not been determined.

Two key factors influence high AVS with mechanical sensing–based VDD pacing: preoperative patient selection and postoperative management. Patient selection may be the more important of these 2 factors. The amplitude of the sensed mechanical atrial signal (A4) by the Micra accelerometer cannot be assessed before the implant procedure but is fundamental to ensure a high AVS percentage. Therefore, we sought to identify clinical predictors of A4 signal amplitude and determinants of a high AVS percentage.

### Methods

#### Study design

The MARVEL 2 study was a prospective, nonrandomized multicenter clinical trial. The primary aim of the MARVEL 2 study was to confirm the ability of an enhanced downloaded algorithm (MARVEL 2 algorithm) to provide AV synchronous pacing by mechanically sensing atrial contraction via the accelerometer signal from a ventricular Micra leadless pacemaker. The primary efficacy objective was to demonstrate the superiority of the MARVEL 2 algorithm to provide AV synchronous pacing relative to VVI pacing in subjects with persistent third-degree AV block and NSR at rest.

The protocol was approved by all local ethics committees and national regulatory agencies at each participating institution. All patients provided written informed consent.

#### Patients and procedures

All patients who were enrolled in the MARVEL 2 study and received the MARVEL 2 algorithm download were eligible for inclusion in this analysis. These patients were aged >18 years, had a history of AV block, and had previously undergone or were undergoing implant with a Micra.

The MARVEL 2 study procedures and algorithm (Supplemental Figure S1) have been previously described. In brief, custom software was temporarily downloaded into the Micra. A specialized Holter monitor was placed during study procedures to collect the electrocardiogram (ECG), electrogram (EGM), accelerometer waveform, and device markers. Performance was characterized with the patient at rest in a supine or sitting position (approximately 20 minutes).

#### Echocardiographic analysis

Echocardiograms were collected during VVI at a lower rate of 50 bpm. An echocardiography core laboratory (United Heart and Vascular, St. Paul, MN) measured parameters related to cardiac function in 2-, 3-, 4-, and 5-chamber and parasternal short-axis views. The laboratory was blinded to patient and study center. Previous studies have shown that atrial contraction can be seen in the right ventricular (RV) tricuspid annular plane systolic excursion view. To characterize atrial function in this view, we defined a parameter—atrial contraction excursion (ACE)—as the displacement during atrial contraction (Supplemental Figure S2).

#### ECG analysis

P waves were identified on surface ECG/Holter monitor by a technician blinded to the device and algorithm markers. An individual cardiac cycle was considered synchronous if a paced or sensed ventricular event occurred within 300 ms following a P wave. Sinus rate variability was calculated.
by the standard deviation of successive differences of P-P intervals (SDSD) method.12

In a subset of patients (n = 19) at 1 center (University Hospitals of Leuven, Leuven, Belgium), high-fidelity measurements of P-wave amplitude and duration were made from a 12-lead ECG using the MUSE Cardiology Information System (GE Medical Systems, Menomonie Falls, WI). These measurements were made by 2 observers who were blinded to AVS.

**Statistical analysis**

All patients with visible P waves on surface ECG were included in the analysis of A4 amplitude (n = 64), whereas only those with a predominant rhythm of persistent third-degree AV block and NSR (n = 40) were included in the analysis of AVS percentage, as patients with intact AV conduction would have high AVS regardless of A4 sensing. Based on previous reports using conventional VDD pacing systems, we defined high/satisfactory AVS as >90%.13–16 Demographics, medical history, and other baseline variables were compared among patients with >90% and ≤90% AVS using the Wilcoxon rank-sum test for continuous variables and the Fisher exact test for continuous variables. A4 amplitude was compared among patients with >90% and ≤90% AVS using the Student t test.

A 2-step modelling process was used to identify predictors of high AVS percentage (Supplemental Figure S3). First, to utilize the largest number of patients we identified predictors of A4 amplitude. Next we included any multivariable predictors of A4 amplitude together with measures of sinus rate, sinus rate variability, and premature ventricular complex (PVC) burden to identify predictors of high AVS.

Baseline medical history (n = 16 variables), cardiovascular medication use (n = 7 variables), echocardiographic measures (n = 26 variables), months since Micra implant, and device location in the RV were tested for univariate association with A4 amplitude using ordinary linear regression (Supplemental Table S1). After univariate regression, 9 echocardiographic variables were dropped from multivariable consideration because they were constructs of more clinically relevant variables (eg, left atrial ejection fraction was included, whereas left atrial end-diastolic volume and left atrial end-systolic volume were excluded). Due to the presence of missing data (primarily in echocardiographic parameters), 100 imputed datasets with complete data were created using multivariate imputation by chained equations (MICE). Due to the large number of candidate prognostic variables (n = 42) relative to the total sample size, lasso regression was used to identify multivariable predictors of A4 amplitude in each of the 100 imputed datasets. Lasso is a regression technique that selects variables maximizing prediction accuracy while penalizing overfitting rather than performing variable selection based on traditional measures of statistical significance. Candidate variables selected by lasso in at least 50% of imputed datasets were incorporated in the final model. The final model for A4 amplitude was fit to each of the imputed datasets using linear regression, with the results pooled across the repeated analyses using Rubin’s rules to account for the added variability due to the missing data.

In addition, the association between the absolute value of P-wave amplitude and P-wave duration with A4 amplitude was quantified using the Pearson correlation coefficient. Variables included in the final A4 amplitude model together with sinus rate, sinus rate variability (SDSD), and PVC burden were assessed for their univariate association with high AVS using univariate logistic regression. As none of these variables had missing values, multivariable analysis was performed on the original dataset. Multivariable predictors of high AVS were determined using lasso logistic regression, with the final model fit using ordinary logistic regression. In-sample discrimination ability of the final model was assessed by determining the area under the receiver operating characteristic curve (AUROC).

Analysis was conducted in SAS Version 9.4 (SAS Institute, Cary, NC) and R (R Core Team, 2017), utilizing the mice,17 glmnet,18 and ROCR19 packages to implement MICE, lasso variable selection, and ROC analyses, respectively.

**Results**

**Baseline characteristics**

Overall, 75 patients were enrolled in the MARVEL 2 study and received the software download. Mean age was 77.5 ± 11.8 years (range 21–94 years), and 30 patients (40%) were female (Table 1). Among the 75 patients, 40 (53%) had persistent third-degree AV block with NSR, 18 (24%) had 1:1 AV conduction, 6 (8%) had varying AV conduction to each of

Based on previous reports using conventional VDD pacing systems, we defined high/satisfactory AVS as >90%.13–16 Baseline medical history (n = 16 variables), cardiovascular medication use (n = 7 variables), echocardiographic measures (n = 26 variables), months since Micra implant, and device location in the RV were tested for univariate association with A4 amplitude using ordinary linear regression (Supplemental Table S1). After univariate regression, 9 echocardiographic variables were dropped from multivariable consideration because they were constructs of more clinically relevant variables (eg, left atrial ejection fraction was included, whereas left atrial end-diastolic volume and left atrial end-systolic volume were excluded). Due to the presence of missing data (primarily in echocardiographic parameters), 100 imputed datasets with complete data were created using multivariate imputation by chained equations (MICE). Due to the large number of candidate prognostic variables (n = 42) relative to the total sample size, lasso regression was used to identify multivariable predictors of A4 amplitude in each of the 100 imputed datasets. Lasso is a regression technique that selects variables maximizing prediction accuracy while penalizing overfitting rather than performing variable selection based on traditional measures of statistical significance. Candidate variables selected by lasso in at least 50% of imputed datasets were incorporated in the final model. The final model for A4 amplitude was fit to each of the imputed datasets using linear regression, with the results pooled across the repeated analyses using Rubin’s rules to account for the added variability due to the missing data.

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**Factors associated with A4 amplitude**

Of the 51 candidate predictor variables, 18 had a univariate association with A4 amplitude at the P < .1 level (Table 2 and Supplemental Table S1). Variables related to atrial function were associated with A4 amplitude, such as E/A ratio, ACE, e’/a’ ratio, and atrial strain (all P ≤.05). There was no significant association between device location and A4 amplitude. In addition, age, body mass index, and RV ejection fraction were not associated with A4 amplitude. There was no difference in
A4 amplitude among patients with third-degree AV block and NSR vs patients with intrinsic conduction.

The lasso regression model selected coronary artery bypass graft history, E/A ratio, ACE, and atrial strain for their multivariable association with A4 amplitude (Table 2). The final model for A4 amplitude accounted for 37.9% of the variability in the observed A4 amplitude.

In the subset of patients with high-fidelity measurements of P-wave amplitude and duration, the strongest association with A4 amplitude was P-wave amplitude in lead aVR (r = 0.52; P = .023). There was no association between A4 amplitude and P-wave duration (r = 0.13; P = .61).

Factors associated with AVS

The 4 multivariable predictors of A4 amplitude, plus average sinus rate, sinus rate variability (SDSD <5 bpm vs SDSD ≥5 bpm), and PVC burden (<2% vs ≥2%), were tested for their univariate and multivariable relationship with high AVS (Table 3).

None of the 40 patients with persistent third-degree AV block and NSR were missing data from the 7 candidate predictors. The lasso procedure identified SDSD and E/A ratio as multivariable predictors of high AVS. E/A ratio was negatively associated with high AVS (odds ratio 16.6; 95% CI 2.4–112.5; P = .004). The final model for high AVS discriminated well with AUROC of 0.89 (95% CI 0.75–0.98). The model predicts a >90% probability of high AVS if E/A >2.0 and SDSD <5 bpm or (2) E/A >1.3 and SDSD ≥5 bpm.
The relationship between E/A ratio, SDSD, and AVS percentage is shown in Figure 2B.

Discussion

The present study evaluated both the predictors of the A4 signal amplitude mechanically detected by the accelerometer contained in the Micra leadless pacemaker and the determinants of high AVS during VDD mode. Our findings based on the MARVEL 2 population provide insight into the selection of patients who could benefit from a leadless device that promotes AVS.

Quality of the A4 signal

Although it is possible to track a low-amplitude A4 signal with the MARVEL 2 algorithm, patients who exhibited high AVS (>90%) had a mean A4 signal amplitude higher than that of patients with a lower AVS (≤90%) (Figure 1). In multivariable analysis, the amplitude of the A4 signal correlated with the echocardiographic parameters E/A ratio, ACE, and atrial strain. ACE and atrial strain both are markers of atrial contraction strength.

Of interest, patient characteristics including age, body mass index, arterial blood pressure, and history of previous atrial arrhythmia were not multivariable predictors of A4 amplitude. Curiously, coronary artery bypass graft had a negative relationship with A4 amplitude. The reduction in A4 amplitude may be related to severity of ischemic disease\textsuperscript{20} and to right atrial cannulation during cardiopulmonary bypass surgery, both factors potentially leading to a reduction in atrial contraction. Device position was not associated with A4 amplitude. Therefore, no changes to the implant procedure of the Micra are currently recommended to optimize A4 sensing.

In our study, a low A4 amplitude was associated with low ACE and atrial strain, which are parameters of atrial function. Whether AV synchronous pacing would be beneficial in patients with impaired atrial function is not clear. An increased risk of stroke has been observed after the maze procedure in patients in sinus rhythm with a low P-wave amplitude and absence of left atrial mechanical activity.\textsuperscript{21} The lack of atrial contractile activity may explain the absence of reported benefit of DDD vs VVI pacing on mortality in patients with NSR and high-degree AV block.\textsuperscript{1,2,22} Impairment of atrial mechanical function over time also can lead to atrial undersensing. Its clinical significance will need to be evaluated in future clinical studies. Nevertheless, Marchandise et al\textsuperscript{23} previously showed that atrial undersensing had no clinical impact in patients with high-degree AV block treated by a conventional VDD system.

In a small group of patients (n = 19), A4 signal amplitude was correlated with the amplitude of the initial deflection of the P wave measured in aVR derivation on 12-lead ECG. To our knowledge, there is no clear evidence of a relationship between P-wave morphology and right atrial mechanical activity in healthy atria. Nevertheless, a low P-wave amplitude (≤0.05 mV) in the septal anterior leads has been associated with absence of left atrial mechanical contraction after modified Maze procedures.\textsuperscript{21}
<table>
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<th>Variable type</th>
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<td>Previous CABG</td>
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<td>–1.41 (–2.38 to –0.44)</td>
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<td>Previous valve surgery</td>
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<td>Echocardiography</td>
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<td>LV ejection fraction</td>
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<td>LA end-diastolic volume</td>
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<td>52 ± 19</td>
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<td>LA end-systolic volume</td>
<td>63</td>
<td>25 ± 10</td>
<td>–0.13 (–0.25 to 0.00)</td>
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<td>LA ejection fraction</td>
<td>63</td>
<td>53.2 ± 4</td>
<td>0.13 (–0.01 to 0.28)</td>
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<td>E/A (mitral valve)</td>
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<td>RV TAPSE</td>
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<td>E/e’</td>
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<td>e’/a’ average</td>
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<td>–0.24 (–0.41 to –0.08)</td>
<td>.005 0.12</td>
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<td>Atrial strain (Ea)</td>
<td>64</td>
<td>8.3 ± 4.4</td>
<td>0.16 (0.01 to 0.32)</td>
<td>.045 0.06</td>
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ACE = atrial contraction excursion; CABG = coronary artery bypass graft; CI = confidence interval; LA = left atrium; LV = left ventricle; RV = right ventricle; TAPSE = tricuspid annular plane systolic excursion; TR = tricuspid regurgitation.

*Summary values are given as mean ± SD, median, interquartile range, and range for continuous variables or percentage for categorical variables.

†Regression β values are standardized for continuous variables to represent an increase in 10% of the observed range.
High AVS
No preimplant measurement of A4 signal amplitude is available to identify patients who may have high (or low) AVS. Based on ECG and echocardiographic parameters, we showed that low sinus rate variability (SDSD < 5 bpm) combined with E/A ratio, 0.94 predicts high AVS (> 90%) with > 90% probability. Furthermore, high sinus rate variability and/or high E/A ratio can select patients unlikely to achieve high AVS most of the time. Patient age and average sinus rate had no influence on AVS.

Leadless pacemakers with a VDD pacing mode based on mechanical atrial sensing are intended to treat patients with high-degree AV block and NSR. Previously the cumulative incidence of sinus node dysfunction at 5 years was shown to be 2.6% in patients with no history of sinus dysfunction and 4.6% in patients having a preimplant sinus rate > 70 bpm when treated with single-lead VDD pacing. Therefore, depending on a patient’s risk profile and the potential advantage of the leadless pacing technology, dual-chamber pacing systems should be preferred in the presence of sinus node dysfunction and high-degree AV block.

Study limitations
Our study has several limitations related to the MARVEL 2 study design. First, AVS using a leadless pacing system was evaluated at rest in a small number of patients for a short duration (maximum 5 hours) during a single study visit. Second, predictors of AVS were not assessed before Micra implant, and chronic ventricular pacing may have altered the echocardiographic parameters. Third, echocardiographic analysis was performed in a core laboratory, whereas the variability of echocardiographic measurements among individual laboratories may be less consistent. Also, sinus variability is not frequently assessed, especially in patients with third-degree AV block, and quantification of P-P intervals in a clinical setting may be impractical. Therefore, the proposed predictors for A4 amplitude and high AVS over time should be validated in a larger population with longer follow-up.

Conclusion
The amplitude of the sensed mechanical atrial signal (A4) by the Micra accelerometer was related to atrial function assessed by echocardiography. We were able to predict, with high probability, high AVS > 90% in the presence of E/A ratio < 0.94 and low sinus rate variability at rest (assessed by SDSD). These findings, if appropriately validated in a future patient population, may be used to improve the selection of patients for leadless VDD pacing systems.

Acknowledgments
We thank Dedra Fagan of Medtronic for assistance in the preparation of this manuscript.

Appendix
Supplementary data
Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrthm.2020.07.024.
Figure 2  Atrioventricular synchrony (AVS) percentage by E/A ratio and sinus rate variability as measured by standard deviation of the successive differences of P-P intervals (SDSD) method. A: Model predicted probability AVS is >90% by E/A ratio and SDSD status. Dashed black lines indicate E/A ratio required for >10% and >90% chance of exceeding 90% AV synchrony. B: AVS percentage vs E/A ratio at screening by SDSD status. Red dashed line indicates 90% AVS.

References


