

# Leadless Pacing with Mechanical Atrial Sensing and Variable AV Conduction

Jason Cook<sup>1</sup> and Travis Richardson<sup>1</sup>

<sup>1</sup>Vanderbilt University Medical Center

April 19, 2021

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Jason Cook, MD

Travis D. Richardson, MD

From Vanderbilt University Medical Center. Nashville, Tennessee

Corresponding author:

Travis D. Richardson, MD

Assistant Professor Cardiac Electrophysiology

Vanderbilt Heart and Vascular Institute

1215 21st Ave S. Nashville, TN

Medical Center East, South Tower, Suite 5209

ph (615) 936-7537

fax (615) 936-5064

travis.d.richardson@vanderbilt.edu

Word Count:1331

Disclosures: The authors report no relevant financial disclosures.

Funding: None

The Micra<sup>TM</sup> leadless transcatheter pacing system (Medtronic Inc., Mounds View, MN) has been shown to be an effective alternative to transvenous pacing with excellent implantation success rates and durable long-term performance.<sup>1-3</sup> The first generation device provided single chamber right ventricular pacing with rate responsiveness enabled by a 3-axis accelerometer.

Recently, the MARVEL 2 study (Micra Atrial tRacking using a Ventricular accELerometer 2) reported the ability of software enhancements to allow a leadless pacemaker to deliver single chamber atrioventricular (AV) synchronized pacing.<sup>4</sup> In contrast to dual-chamber transvenous pacemakers which sense atrial electrograms, the MARVEL 2 algorithm adjudicates atrial events using mechanically sensed atrial activity from the 3-axis accelerometer. During initial programming, the relative timing of mechanical events to the ventricular electrogram allows for identification of A3 (passive ventricular filling) and A4 (atrial contraction). Atrial-sensed events are then defined by the A4 signal, and tracking may occur. MARVEL 2 reported VDD pacing was achieved at rest in an impressive 89.2% of patients.

The Micra AV<sup>TM</sup> system's unique programming includes three basic pacing modes: VDD, VVI and VDIR (Figure 1). Additionally, two mode switch algorithms are available and by default programmed on: the AV conduction mode switch and the activity mode switch. Unlike mode switch algorithms in dual chamber pacing systems, which are intended to avoid inappropriate tracking of atrial arrhythmias, these algorithms are intended to 1) minimize ventricular pacing, and 2) to improve rate support during patient activity respectively.

When the AV conduction mode switch algorithm is enabled, the device periodically switches from VDD to VVI at 40 bpm to allow for intrinsic AV conduction. If ventricular sensing occurs above a rate of 40 bpm, in order to reduce right ventricular pacing, VVI 40 programming will continue regardless of the programmed lower rate limit. However, if two of any window of four beats are paced at VVI 40, the device reverts to VDD. Thereafter, reassessments of AV conduction are performed at increasing intervals starting at 2 minutes until either AV conduction is detected or 8 hours is reached at which point subsequent testing occurs at regular 8 hour intervals.

The activity mode switch algorithm utilizes the sensor indicated rate in an attempt to ensure adequate ventricular rate support during patient activity regardless of AV conduction. The sensor in the Micra<sup>TM</sup> is always running. If at any time 1) the sensor indicated rate is above the device programmed ADL rate, and 2) the current ventricular rate is >20 BPM below the sensor rate, the activity mode switch will change the device to VDIR mode with heart rates determined by the sensor. This switch may occur from either the VDD mode or VVI in the setting of AV conduction. The device will revert to VDD mode when the sensor rate drops below the ADL rate.

With the added functionality of atrial sensing and the incorporation of the MARVEL 2 algorithms described above, in this issue of the Journal of Cardiovascular Electrophysiology, Garweg et al. examined the pacing behavior of the Micra AV<sup>TM</sup> in the presence of variable AV conduction, atrial arrhythmias, sinus bradycardia (< 40 bpm), sinus arrhythmia, and periods of atrial and ventricular ectopy (Reference). During the data collection period in MARVEL 2, ECG, electrogram, accelerometer waveforms, and device marker data were obtained; this was collected either after initial implant and follow-up or, for patients with previously placed devices, during a single encounter. The average monitoring period was 153 minutes. The study included 73 patients with normal sinus node function and varying degrees of AV block.

While the number of patients with variable AV conduction was small (5), the investigators found that the rhythm checks allowed for appropriate mode adjustments during the study period. During periods of AV block, as expected, 99.9% ventricular pacing was observed while during 1:1 AV conduction only 0.2% pacing was observed. Ventricular pacing was monitored in patients with 1:1 AV conduction using conventional VVI pacing and MARVEL 2 programming. MARVEL 2 programming using the AV conduction mode switch algorithm resulted in a reduction in ventricular pacing from 22.8% to 0.2% (n=18). Reducing the burden of ventricular pacing is an important enhancement to the system with the potential to minimize pacing-induced cardiomyopathy.<sup>5</sup>

One potential pitfall of atrial sensing addressed by this study is tracking of atrial arrhythmias. While the sample size was small (n=7), tracking of atrial fibrillation resulting in pacing at the upper tracking rate was not observed in any of the patients. In one patient with atrial flutter, intermittent atrial tracking did occur but did not result in tachycardia. In contrast to atrial rate based mode switching used in conventional dual-chamber pacemakers, the behavior of the MARVEL 2 algorithm during atrial fibrillation is dictated by the sensed ventricular rate. With the AV conduction mode switch enabled, if the ventricular rate is above 40 bpm, the pacing mode will be VVI at 40 bpm. If rates are less than 40 bpm, the pacing mode will be VDD. In the context of atrial fibrillation, reduced atrial contractility results in lack of mechanical sensing, and pacing at the lower rate is observed. In this small sample size, atrial arrhythmias did not result in device tracking resulting in tachycardia. Further investigation in a larger number of patients is warranted to better characterize these findings and to assess pacing behavior during more organized atrial arrhythmias which could result in mechanical sensing (atrial tachycardia and atrial flutter, for example).

While the MARVEL 2 programming seems to perform well in the setting of atrial fibrillation or intermittent complete AV block, there are some potential pitfalls. AV conduction mode switch behavior is based on sensed ventricular rates with a threshold of 40 bpm; this cutoff is not currently programmable. Any ventricular sensed rhythm with a rate greater than 40 bpm will result in the device continuing at VVI 40. For example, in a patient with sinus rhythm at 90 bpm and 2:1 AV conduction, the device would not track the atrium and pace at 90 bpm, but rather remain VVI 40 because the ventricular sensed rate is above 40 bpm. The same would be observed in patients with junctional or ventricular escape rhythms >40 bpm. In this sense, pacing could be inappropriately inhibited during a potentially hemodynamically significant rhythm. For this reason, in our opinion, the AV conduction mode switch algorithm should be disabled in the majority of patients with AV block as this physiology is dynamic and sudden loss of rate support can have deleterious consequences. While the activity mode switch algorithm may address some of these concerns real world data are needed for validation.

There is no question that the functionality and indications for leadless pacemakers will continue to expand. In current guidelines, which predate the development of the Micra AV<sup>TM</sup>, single chamber ventricular pacing is only recommended in patients with AV block and permanent atrial fibrillation, a low burden of anticipated pacing, or substantial comorbidities.<sup>6</sup> Given the potential for lower complication rates compared with transvenous systems, Micra AV may be a superior option in some patients with complete heart block and preserved ventricular function. However, with the advent of conduction system pacing, the decreased risks of a leadless system have to be balanced with the relative risk of long term right ventricular pacing. Although the results will need to be validated with larger, longer-term studies, which are underway (Clinical trials.gov NCT04245345), these data indicate that Micra AV<sup>TM</sup> is likely to perform well in the setting of atrial arrhythmias. In patients with variable AV conduction, there are certainly pitfalls to the AV conduction mode switch algorithm, many of which could be avoided by the ability to program the mode switch VVI rate. While leadless pacing is often considered in patients with multiple comorbidities at high risk of complications from a transvenous system, we may be on the cusp of a dramatic paradigm shift. The technological developments and success of leadless pacing to date prompt the question of when, and not if, leadless dual chamber pacing and potentially even cardiac resynchronization will be available.

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