Response to atrial arrhythmias in an atrioventricular synchronous ventricular leadless pacemaker: A case report in a paroxysmal atrial fibrillation patient

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Introduction

The recent introduction of leadless pacing technologies in real-world practice has been successful, demonstrating a high procedural success rate (99.6%) with a low rate of major complications (1.51%) through 30 days postimplant, and reaffirming the positive results observed in the investigational trial.[1,2] Existing leadless pacing systems, however, are designed as single-chamber pacemakers, limiting their potential use to 14%–32% of all pacemaker implantations.[3,4] Among patients with complete atrioventricular (AV) block and preserved sinus node function, maintenance of AV synchrony has been shown to improve stroke volume and quality of life and to decrease the risk of development of pacemaker syndrome.[5–7]

Micra TPS (Medtronic, Minneapolis, MN) is a transcatheter pacing system that is directly implanted in the right ventricle and provides rate response via a 3-axis accelerometer (ACC). Custom software was developed to detect atrial contraction using the ACC, enabling AV synchronous pacing in this single-chamber ventricular leadless pacemaker. AV synchronous pacemakers should not track atrial arrhythmias in order to minimize patient symptoms.

KEYWORDS Accelerometer; Atrial contraction; AV block; AV synchronous pacing; Leadless pacemaker; Paroxysmal atrial fibrillation
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Case report

The Micra Atrial TRacking Using a Ventricular AccELerometer (MARVEL) study was a prospective nonrandomized, multicenter clinical research study designed to characterize the performance of an AV synchronous algorithm temporarily downloaded into the Micra leadless pacemaker. Four distinct segments of the ACC signal that correspond to isovolumetric contraction and mitral/tricuspid valve closure (A1), aortic/pulmonary valve closure (A2), passive ventricular filling (A3), and atrial contraction (A4) (Figure 1A) can be observed during sinus rhythm (SR). The algorithm supports a VDD mode, where all detected signals are tracked with ventricular demand pacing, and a VDI mode, where the signals are detected but not tracked. The study protocol was approved by the Ethics Committee at University Hospitals Leuven and the patient provided written informed consent. The detailed study design and primary results have been previously reported.[8]

We report the case of an 86-year-old man who was implanted with a Micra TPS after repeated episodes of complete heart block and who was included in the MARVEL study. The patient had no relevant medical history except frequent episodes of paroxysmal atrial fibrillation (PAF). A baseline 12-lead electrocardiogram immediately prior to AV algorithm software download showed SR at 38 beats/min with first-degree AV block and complete right bundle branch block. During data collection, the patient developed an episode of PAF. We report the behavior of the VDD pacing system during SR and PAF.

In SR, all the ACC signals were recognized, and the algorithm appropriately tracked the atrial contraction (Figure 1A). The investigational protocol included a 30-minute resting period where AV synchrony was assessed. During this period, the percentage of AV synchronous beats was 98.4%. For protocol reasons, the patient had been programmed to VDI mode prior to the initiation of the atrial arrhythmia, so pacing at the lower rate occurred both at the onset and after the initiation of the arrhythmia. After programming to VDD mode, the A1,

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KEY TEACHING POINTS

- Current pacing guidelines recognize VDD pacing systems as an alternative to DDD pacemakers among patients with high-degree atrioventricular (AV) block.
- The Micra Atrial TRacking Using a Ventricular AccELerometer (MARVEL) study has recently shown that an AV synchronous pacing mode is feasible using a single-chamber ventricular leadless pacemaker.
- We present a first-in-human description of an episode of paroxysmal atrial fibrillation in an "AV synchronous ventricular leadless pacemaker."

A2, and A3 signals were observable, but the A4 signal was no longer present as there was diminished atrial contraction during atrial fibrillation (AF). The MARVEL algorithm is programmed to rate smooth when there is occasional absence of detected A4 signal. In the continued absence of A4 signal, the rate smoothing gradually decreases the ventricular rate to the lower rate. In our patient, we observed ventricular pacing at the preprogrammed lower rate of 50 beats/min while programmed in VDD mode, avoiding any undesired atrial tracking during PAF (Figure 1B).

Discussion

The MARVEL study was recently published and showed that an ACC-based atrial sensing (VDD pacing mode) algorithm in previously implanted Micra TPS devices provided an average AV synchrony percentage at rest of 87% across all patients.[8] In patients presenting with high-degree AV block (second or third degree), the algorithm improved AV synchrony from 37.5% to 80% when comparing VVI vs VDD pacing mode. Presence of sinus node dysfunction, premature ventricular contractions, and low-amplitude A4 were factors limiting AV synchrony.

The current ACC/AHA/NASPE/ESC pacing guidelines recognize conventional VDD pacing systems as a potential alternative to DDD pacemakers within patients with high-degree AV block and preserved sinus node function.[3,9] Nevertheless, VDD pacing is rarely used owing to the risk of atrial undersensing or the future need for atrial pacing. Recently, Schaer and colleagues showed that 2% of implanted VDD systems will need an upgrade to DDD systems owing to failure of the system or development of sinus node dysfunction.[10]

The Micra IDE trial and the postmarket registry have shown major complication rates of 4.0% at 1 year and 1.56% at 30 days follow-up, respectively, reducing the risk of major complications by 50% compared to the historical control of traditional pacing system.[1,2,11] Leadless pacing technology that provides an improvement in AV synchrony seems a promising safe alternative to conventional dual-chamber pacing systems for patients without sinus node dysfunction.

While developing new technology, patient safety must remain our priority and a pacemaker that tracks atrial activity must respond appropriately during atrial arrhythmias. Although the algorithm would not be of benefit to patients with persistent or permanent atrial arrhythmias owing to the A4 signal during AF likely being low and not detected, many patients, with or without AF history, will experience

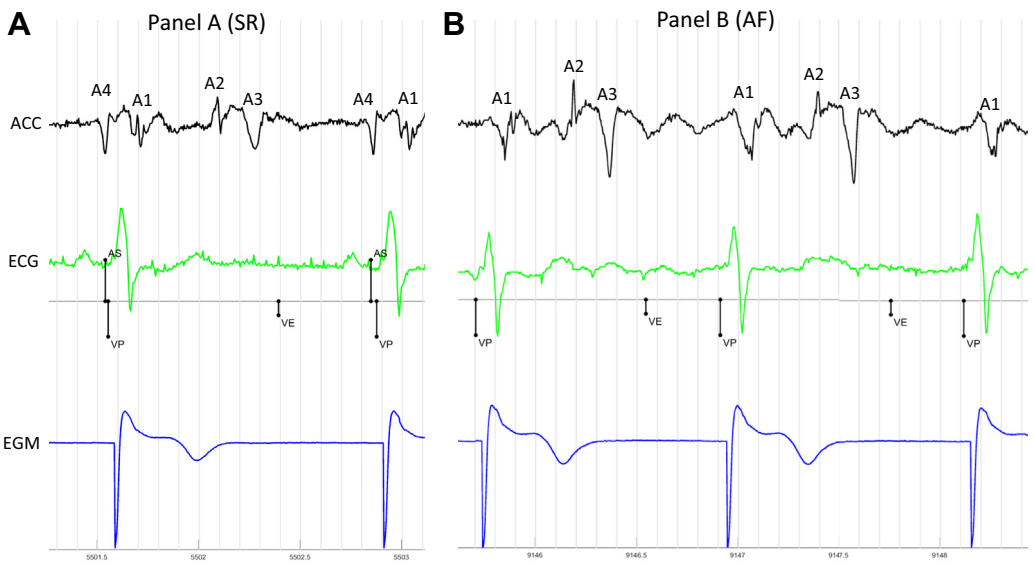

Figure 1 From top to bottom: Accelerometer (ACC), surface electrocardiogram (ECG), and ventricular electrogram (EGM). VE indicates the end of the programmed A3 window. **A:** Appropriate detection and tracking of the different ACC signals—isovolumetric contraction and mitral/tricuspid valve closure (A1), aortic/pulmonary valve closure (A2), passive ventricular filling (A3), and atrial contraction (A4)—during sinus rhythm (SR) are shown; atrial sense (AS) marker confirms the detection of the atrial contraction, followed by a ventricular paced event (VP marker). **B:** The ACC signal during atrial fibrillation (AF) and lower rate pacing. A1, A2, and A3 are identifiable and have the same amplitude, but a distinct A4 signal is no longer present.

episodes of PAF during their follow-up. A recent publication reported that 39.9% of patients without AF history at the time of pacemaker implant experienced at least 1 episode of AF during a median follow-up of 2.4 ± 1.7 years.[12] We report a first-in-human experience with an ACC-based VDD pacing algorithm in a Micra single-chamber leadless pacemaker during an episode of PAF. This algorithm demonstrated tracking of the atrium during SR and lower rate pacing during PAF.

References

1. Roberts PR, Clementy N, Al Samadi F, et al. A leadless pacemaker in the real-world setting: The Micra Transcatheter Pacing System Post-Approval Registry. Heart Rhythm 2017;14:1375–1379.
2. Duray GZ, Ritter P, El-Chami M, et al. Long-term performance of a transcatheter pacing system: 12-month results from the Micra Transcatheter Pacing Study. Heart Rhythm 2017;14:702–709.
3. European Society of Cardiology (ESC), European Heart Rhythm Association (EHRA), Brignole M, et al. 2013 ESC guidelines on cardiac pacing and cardiac resynchronization therapy: the task force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA). Europace 2013;15:1070–1118.
4. Greenspon AJ, Patel JD, Lau E, Ochoa JA, Frisch DR, Ho RT, Pavri BB, Kurtz SM. Trends in permanent pacemaker implantation in the United States from 1993 to 2009: increasing complexity of patients and procedures. J Am Coll Cardiol 2012;60:1540–1545.
5. Lamas GA, Ellenbogen KA. Evidence base for pacemaker mode selection: from physiology to randomized trials. Circulation 2004;109:443–451.
6. Lamas GA, Orav EJ, Stambler BS, Ellenbogen KA, Sgarbossa EB, Huang SK, Marinchak RA, Estes NA 3rd, Mitchell GF, Lieberman EH, Mangione CM, Goldman L. Quality of life and clinical outcomes in elderly patients treated with ventricular pacing as compared with dual-chamber pacing. Pacemaker Selection in the Elderly Investigators. N Engl J Med 1998;338:1097–1104.
7. Nielsen JC, Andersen HR, Thomsen PE, Thuesen L, Mortensen PT, Vesterlund T, Pedersen AK. Heart failure and echocardiographic changes during long-term follow-up of patients with sick sinus syndrome randomized to single-chamber atrial or ventricular pacing. Circulation 1998;97:987–995.
8. Chinitz L, Ritter P, Khelae SK, Iacopino S, Garweg C, Grazia-Bongiorni M, Neuzil P, Johansen JB, Mont L, Gonzalez E. Accelerometer based AV synchronous pacing with a ventricular leadless pacemaker: results from the Micra AV feasibility studies. Heart Rhythm 2018;15:1363–1371.
9. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices) developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. J Am Coll Cardiol 2008;51:e1–e62.
10. Schaer BA, Weinbacher M, Zellweger MJ, Sticherling C, Osswald S. Value of VDD-pacing systems in patients with atrioventricular block: experience over a decade. Int J Cardiol 2007;122:239–243.
11. Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. N Engl J Med 2016;374:533–541.
12. Boriani G, Glotzer TV, Ziegler PD, De Melis M, Mangoni di S Stephano L, Sepsi M, Landolina M, Lunati M, Lewalter T, Camm AJ. Detection of new atrial fibrillation in patients with cardiac implanted electronic devices and factors associated with transition to higher device-detected atrial fibrillation burden. Heart Rhythm 2018;15:376–383.