Check for updates

15408167, ja, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jce.15723 by Universität Bern, Wiley Online Library on [02/11/2022]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Accepted Article

source: https://doi.org/10.48350/174414 | downloaded: 23.4.2024

Andreas Haeberlin ORCID iD: 0000-0002-9283-0110

Real-life ambulatory performance of leadless AV synchronous pacemakers – are all questions answered?

Andreas Haeberlin, MD, PhD[1,2]

[1]Dept. of Cardiology, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland

2Artorg Center for Biomedical Engineering, University of Bern, Bern, Switzerland

Short title: Ambulatory performance of leadless pacemakers

Key words: leadless pacemakers, AV synchrony, Micra, atrio-ventricular synchrony, leadless

Funding: None.

Conflicts of interest statement: Dr. Haeberlin has received travel/educational grants from Medtronic and Philips/Spectranetics. He is consultant/advisor for DiNAQOR and Biotronik and proctor for Medtronic without impact on his personal remuneration. He is co-founder/head of Act-Inno, a cardiovascular device testing company.

Corresponding author:

Andreas Haeberlin, MD, PhD

Dept. of Cardiology, Bern University Hospital

Freiburgstrasse 3

3005 Bern

SWITZERLAND

Phone: +41316640674

E-mail: andreas.haeberlin@insel.ch

Invited editorial

Leadless pacemakers (LLPMs) have revolutionized the world of cardiac pacing since they allow overcoming the Achilles' heel of conventional transvenous systems, the pacing lead. The latest generation of the most widely used LLPM, the Micra AV TPS (Medtronic, United States), is able to

This article has been accepted for publication and undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1111/jce.15723.

This article is protected by copyright. All rights reserved.

provide atrio-ventricular (AV) synchronous pacing. These devices provide atrial sensing by contactless mechanical detection of the atrial contraction via an integrated accelerometer that is also used to provide the device's rate response. Early short-term feasibility studies showed improved AV synchrony compared to LLPMs programmed in VVI mode [1, 2]. Moreover, atrial sensing and device function appeared stable over time and was only rarely disturbed by intermittent arrhythmias [3]. Thus, these LLPMs significantly widen the device portfolio and more patients may now potentially qualify for a LLPM.

Due to the novel concept for atrial sensing, the true rate of AV synchrony (AVS) in these devices has been a matter of controversy. Overall AVS in the initial feasibility studies was in the range of 60-90% and seemed to be heavily dependent on patient activities and – by nature – intrinsic AV conduction [1, 2]. In order to program LLPMs optimally, device specialists require accurate information about ambulant device performance since it may enable them to adjust atrial sensing parameters and further improve AVS [4].

In this issue of the Journal of Cardiovascular Electrophysiology, Dr. Garweg and co-workers present an interesting analysis on the reliability of the AM-VP marker to predict true AVS. This analysis bases predominantly on the 40 MARVEL 2 patients that underwent monitoring with a special Holter ECG, which registered surface ECG and LLPM device markers simultaneously. In a second step, the authors extrapolated the findings of the 40 patients to an outpatient cohort of >4'000 patients, who were surveilled via remote monitoring. The authors conclude that AM-VP is a reliable marker for true AVS and median AVS in an outpatient cohort is in the range of 75%. Reassuringly, the device-based atrial signal amplitude measurement remained stable over time and the device's projected battery longevity was 10.5 years.

First, the authors have to be congratulated on their study, which is providing novel evidence concerning the reliability of the LLPM device statistics. However, it is important to underline some key limitations of this analysis. In MARVEL 2, the 40 LLPMs were programmed by experts that analyzed all two-vector combinations of the accelerometer and optimized the device for atrial sensing in supine position. The marker validation using the Holter ECG was subsequently also performed mostly at rest and while patients were laying. Moreover, the extensive optimization procedure does not necessarily reflect clinical routine and may have helped to improve the diagnostic accuracy of the device markers. Therefore, caution should be exercised when concluding that AM-VP is in general a reliable marker for

This article is protected by copyright. All rights reserved.

Accepted Article

15408167, ja, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jce.15723 by Universität Bern, Wiley Online Library on [02/11/2022]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

AVS in the outpatient setting. These markers/counters are exclusively device-collected based on presumed atrial mechanical activity. Intermittent oversensing of mechanical signals that are unrelated to the atrial mechanical contraction (e.g. induced by physical activity or A3 oversensing) would also result in AM-VP sequences and imply AV synchrony. Indeed, Briongos-Figuero et al. also found a positive correlation between AVS determined by Holter-ECG and the LLPM device counters, but the correlation coefficient was only moderate (ICC 0.52) [5]. Thus, important questions remain and further studies are required, which validate the reliability of the device counters in a real-life outpatient setting against long-term surface ECG data.

Based on the CareLink analysis of >4'000 mostly paced patients, Garweg et al. further conclude that median ambulatory AVS was in the range of 75% in their cohort. While this conclusion bases on the analysis and extrapolation of exclusively device-collected data, recently published primary results of the AccelAV study support these findings [6]. Ambulatory AVS in AccelAV was assessed using 24h-Holter ECGs in patients with complete AV block and found to be in a very similar range (~75%). In consecutively included LLPM patients showing a higher rate of intact AV conduction, outpatient AVS even reached almost 90% [5]. Atrial tracking at lower sinus rates at rest seems to be relatively robust in particular. However, the results provided in the study by Garweg et al., Neugebauer et al., and in AccelAV have a crucial finding in common: appropriate atrial tracking at sinus rates ≥80-100 beats per minute is often challenging to achieve [4, 6]. Device optimization after a run-in phase is paramount and significantly improves AVS [4-6]. The A3 window end (time and maximum) and A4 threshold (threshold and minimum) have a significant impact on AVS when analyzed in multivariate models [4, 5]. Unsurprisingly, the general programming recommendations for an appropriate A3 threshold have changed recently as well [4, 6]. Cardiac device specialists should consider these novel findings and implement the latest recommendations in their LLPM follow-up optimization practice.

In summary, there is increasing evidence that (1) LLPMs with mechanical sensing provide an adequate degree of AVS in the outpatient setting when optimized properly and (2) analysis of the device statistics may reveal potential programming-associated problems and, therefore, help improving the device programming. While LLPMs with mechanical atrial sensing may still be considered an interim solution on the way towards future LLPMs with electrical atrial sensing and true DDD capabilities [7-9], it seems that the innovative mechanical sensing concept of contemporary systems works reasonably well.

This article is protected by copyright. All rights reserved.

Accepted Article

15408167, ja, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jce.15723 by Universität Bern, Wiley Online Library on [02/11/2022]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Accepted Article

References

1. Chinitz L, Ritter P, Khelae SK, Iacopino S, Garweg C, Grazia-Bongiorni M, Neuzil P, Johansen JB, Mont L, Gonzalez E, Sagi V, Duray GZ, Clementy N, Sheldon T, Splett V, Stromberg K, Wood N and Steinwender C. Accelerometer-based atrioventricular synchronous pacing with a ventricular leadless pacemaker: Results from the Micra atrioventricular feasibility studies. *Heart Rhythm*. 2018;15:1363-1371.
2. Steinwender C, Khelae SK, Garweg C, Chan JYS, Ritter P, Johansen JB, Sagi V, Epstein LM, Piccini JP, Pascual M, Mont L, Sheldon T, Splett V, Stromberg K, Wood N and Chinitz L. Atrioventricular Synchronous Pacing Using a Leadless Ventricular Pacemaker: Results From the MARVEL 2 Study. *JACC Clinical electrophysiology*. 2020;6:94-106.
3. Garweg C, Splett V, Sheldon TJ, Chinitz L, Ritter P, Steinwender C, Lemme F and Willems R. Behavior of leadless AV synchronous pacing during atrial arrhythmias and stability of the atrial signals over time-Results of the MARVEL Evolve subanalysis. *Pacing Clin Electrophysiol*. 2019;42:381-387.
4. Neugebauer F, Noti F, van Gool S, Roten L, Baldinger SH, Seiler J, Madaffari A, Servatius H, Ryser A, Tanner H, Reichlin T and Haeberlin A. Leadless atrioventricular synchronous pacing in an outpatient setting: Early lessons learned on factors affecting atrioventricular synchrony. *Heart Rhythm*. 2022;19:748-756.
5. Briongos-Figuero S, Estévez-Paniagua Á, Sánchez Hernández A, Jiménez S, Gómez-Mariscal E, Abad Motos A and Muñoz-Aguilera R. Optimizing atrial sensing parameters in leadless pacemakers: Atrioventricular synchrony achievement in the real world. *Heart Rhythm*. 2022.
6. Chinitz LA, El-Chami MF, Sagi V, Garcia H, Hackett FK, Leal M, Whalen P, Henrikson CA, Greenspon AJ, Sheldon T, Stromberg K, Wood N, Fagan DH and Sun Chan JY. Ambulatory atrioventricular synchronous pacing over time using a leadless ventricular pacemaker: Primary results from the AccelAV study. *Heart Rhythm.* 2022.
7. Rashtian M, Banker RS, Neuzil P, Breeman K, Nee P, Badie N, Victorine K, Ligon D, Rippy MK, Eldadah Z, Doshi R, Cantillon DJ and Knops RE. Preclinical safety and electrical performance of novel atrial leadless pacemaker with dual-helix fixation. *Heart Rhythm*. 2022;19:776-781.
8. Bereuter L, Niederhauser T, Kucera M, Loosli D, Steib I, Schildknecht M, Zurbuchen A, Noti F, Tanner H, Reichlin T and Haeberlin A. Leadless cardiac resynchronization therapy: An in vivo proof-of-concept study of wireless pacemaker synchronization. *Heart Rhythm*. 2019;16:936-942.
9. Bereuter L, Kuenzle T, Niederhauser T, Kucera M, Obrist D, Reichlin T, Tanner H and Haeberlin A. Fundamental Characterization of Conductive Intracardiac Communication for Leadless Multisite Pacemaker Systems. *IEEE Trans Biomed Circuits Syst*. 2019;13:237-247.

This article is protected by copyright. All rights reserved.

15408167, ja, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jce.15723 by Universität Bern, Wiley Online Library on [02/11/2022]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License