

Atrioventricular synchronous leadless pacemaker: state of art and broadened indications

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Leadless pacemakers (LLPMs) have become a major breakthrough in the management of bradyarrhythmia as an attractive alternative to the standard transvenous pacemakers (TV-PMs). Recently, the introduction of a second-generation LLPMs (Micra AV-MC1AVR1) has expanded pacing modes to obtain atrioventricular (AV) synchronous pacing, providing an interesting alternative in the actual scenario of leadless pacing. Nevertheless, actual reports have highlighted some concerns regarding those devices. In this review, we sought to provide an overview of this technology based on its approval studies and major reports.

Keywords

Leadless pacemakers; Atrioventricular synchrony; Micra-AV; Atrioventricular synchronous leadless pacemaker

1. Introduction

Since its inception, transvenous pacemaker (TV-PM) therapy evolved over time, providing significant benefits in terms of quality of life, thereby reducing mortality in high-risk patients with second-degree type II or third-degree atrioventricular block (AVB) [1]. Despite these positive effects, TV-PMs are still associated with a significant rate of combined short- and long-term system failure of up to 20% at 5 years. Leads and pocket-related complications are the most represented in the short-term (within 6 months from the implantation procedure), showing an incidence rate of 10% and mostly including lead dislodgements and pocket hematomas. Similarly, long-term complications as lead malfunctions, local and systemic infections, remain consistently represented in this population [2]. Unfortunately, infective complications are still associated with an elevated mortality risk-rate ranging from 12 to 31% [3, 4]. When compared to TV-PMs, leadless pacemakers (LLPMs) showed a high safety and efficacy profile, with a reduction of 51% of major complications in the early post-procedural period (within 6 months) and of 48–63% at one-year [5, 6]. However, first-generation LLPMs are only able to pace the ventricle (in VVI [R] mode), which largely limit their use to patients with atrial fibrillation (AF) with slow ventricular conduction and those considered to be at high-risk of TV-PMs related complications.

Recently, the introduction of a second-generation LLPMs (Micra AV-MC1AVR1) has expanded pacing modes to obtain AV synchronous pacing, providing an interesting alternative in the actual scenario of leadless pacing. Indeed, pacing modes that preserve atrioventricular synchrony (AVS) are recommended as a class I indication in patients who have high-degree AV block and sinus rhythm requiring permanent pacing, with dual-chamber pacemakers as the first choice and single-lead VDD pacing systems as a valid alternative [7]. Thus, several registries and randomized trials have shown an equivalent therapeutic efficacy of single-lead VDD pacing, when compared with DDD pacemakers [8–11]. To date, the only LLPM on the market, able to provide atrioventricular synchrony (VDD pacing mode), is the Micra AV-MC1AVR1 Transcatheter Pacing System (Medtronic, Inc., Minneapolis, MN, USA).

2. Micra AV-MC1AVR1 leadless pacemakers

The Micra-AV transcatheter Pacing System has a mass of 1.75 g and a volume of 0.8 cc, with the same external aspect of the previous VVI [R] mode (Micra MC1VR01) (Fig. 1A,B). Device fixation in the right ventricle is ensured through four nitinol tines (Fig. 1D). The implant procedure is the same for both devices: briefly, through a pre-dilatation of the femoral vein, Micra introducer/dilator (Fig. 1B) is inserted over a super stiff guidewire (0.035") in the right atrium. After removing the guidewire and the dilator, the delivery system (Fig. 1C) is advanced into the introducer up to the mid atrium. Subsequently, the Micra device is placed under fluoroscopy guidance in the septal portion of the right ventricle. Since Micra-VR and Micra-AV share the same implant technique, the substantial safety and efficacy profile of the implant procedure can be applied to both devices. In this regard, Micra-VR implant safety has been confirmed in the Micra post-approval registry, showing a 1% of adverse events in the acute setting, related to the implant procedure and a 96% freedom from major complications related to the implant procedure at 12-month follow-up [12].

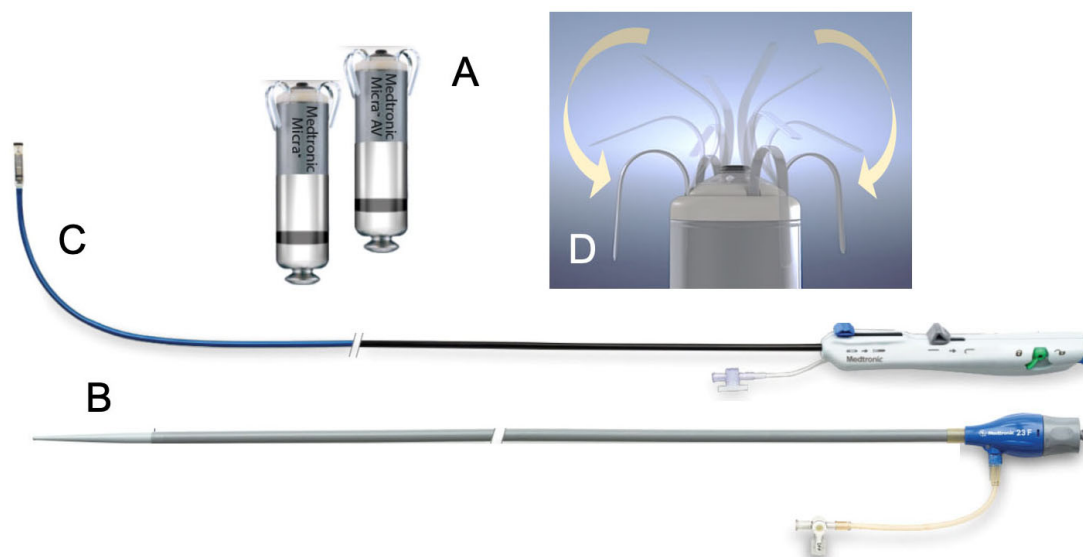


Fig. 1. Medtronic Micra transcatheter pacing system. (A) Micra AV-MC1AVR1 leadless pacemaker (left) and Micra MC1VR01 (right). (B) Micra 27Fr (outer diameter) introducer and dilator system. (C) Micra delivery system. (D) Micra fixation tines.

3. Micra AV-MC1AVR1 and atrioventricular synchrony

The AVS in Micra-AV LLPMs is provided by an accelerometer-based atrial sensing sensor, able to detect atrial contractions and provide rate-responsive ventricular pacing using the device's built-in 3-axis accelerometer (ACC) (Fig. 2).

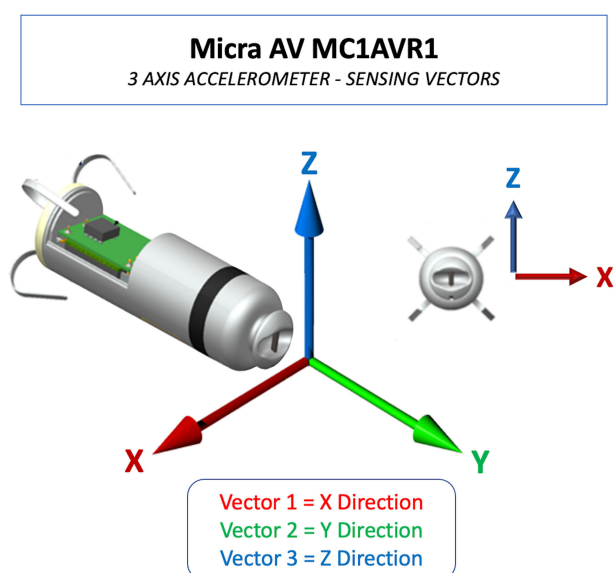


Fig. 2. Micra MC1AVR1 vectors and three-axis orientation.

The ACC is able to detect atrial components related to the various phases of the cardiac cycle:

- isovolumic contraction and mitral/tricuspid valve closure (A1),

- aortic/pulmonic valve closure (A2),
- passive ventricular filling (A3),
- atrial contraction (A4).

ACC segments A1 and A2, having ventricular origin, are rejected and identified in the blanking period. Conversely, A3 and A4 are of atrial origin and are associated with E- and A-waves across the mitral valve; A4 is therefore sensed as the atrial contraction (Fig. 3). The Micra-AV algorithm was tested in the *Micra Accelerometer Sensor Sub-Study (MASS)* and in the *MASS2* studies [13]. Those reports were prospective, non-randomized, multicenter clinical studies focused on the characteristics that may predict the association between the A4 amplitude and the atrial contraction during different postures, maneuvers, and vector combinations. The designed algorithm is able to synchronize the atrial marker (AM) with the detected A4, starting a programmable AV interval before the ventricular pacing. Since A3 and A4 signals may merge, potentially leading to inappropriate AVS, especially at higher cardiac rates, the algorithm included two different programmable thresholds. Specifically, a larger A3 threshold may be used to detect fused A3/A4 and a lower A4 threshold is able to detect the A4 signal later in diastole (Fig. 3). To avoid an electromechanical delay between the electrical P wave and the A4 signal on the ACC, the AM-VP was developed to be programmed with an appropriate delay (usually 20 ms), shorter than the atrial sensing-VP delay of conventional PMs (although a programmable range of 20 to 200 ms is allowed). In the Micra-AV, ventricular pacing is triggered on the basis of the A4 wave. In our experience, an AM-VP delay of 20 ms is able to provide a P-R interval of about 150 ms on the 12-lead electrocardiogram (ECG).

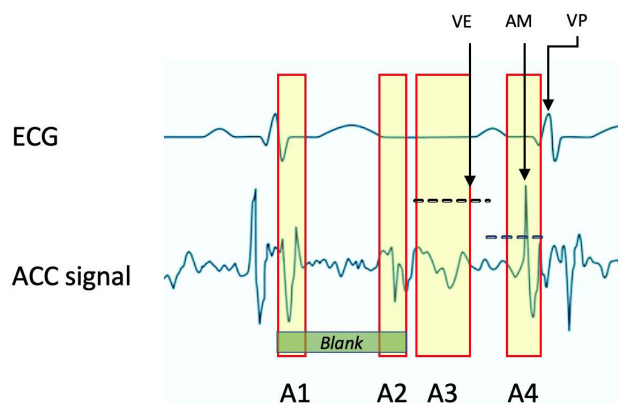


Fig. 3. Medtronic Micra-AV accelerometer signals. Top: electrocardiogram (ECG) signal. Down: accelerometer (ACC) signal. Yellow rectangles: A1, A2, A3, A4 signal windows. Green rectangle: A2 and A3 programmable blanking period. Dotted lines: programmable A3 and A4 threshold. First threshold is greater than the second allowing detection when the A3 and A4 signals fuse at higher heart rates. VE, end of A3 window; AM, atrial mechanical; VP, ventricular pacing.

The Micra-AV algorithm includes a rate smoothing feature able to maintain AVS during intermittent A4 undersensing. When an atrial contraction (A4) is not detected, ventricular pacing is delivered at a programmable rate smoothed interval (typically 100 ms) longer than the median R-R interval. Another interesting feature is the Conduction Mode Switch algorithm (also called “VVI+”), that is designed to trace intact conduction by periodically dropping into VVI-40 (VVI+ mode) to look for intrinsic conduction. When the spontaneous ventricular rate is above 40 bpm, the Micra-AV works in VVI+ mode; instead, when the intrinsic rate is <40 bpm, the device switches back to the VDD mode. The first conduction control is made up to one min after mode-switching to the VDD mode. Whenever the Micra-AV recognize AV block after switching to the VVI+ mode, the interval between these conduction checkpoints double (starting from 2 minutes and reaching up to a maximum of 8 hours). Of note, when working in the VVI+ mode, the Micra-AV deactivates the atrial sensing function, and the underlying rhythm detection is based on ventricular sensing only. This represents the main limitation of this algorithm, particularly evident in cases of junctional rhythm above 40 bpm, or in cases of second-degree AV block or 2 : 1 AV block, when the ventricular rate response is above 40 bpm.

Based on these summarized algorithms, AVS is provided through the VDD pacing mode. In MASS and MASS2 studies [13], the A4 sensing window was identified analyzing each cardiac cycle. Of note, the mean A4 amplitude varied across postures and vectors, generally showing larger amplitude with vector 2 (longitudinal to device body) when compared to vector 1 or vector 3, radial to device body (Fig. 2). Instead, the lowest A4 amplitude has been recorded in the standing and supine positions. With regard to the standing position, vector 2 resulted the best in detecting A4 signal.

Considering that the Micra-AV is not able to automatically choose the most appropriate vector, a selection of all the 3 vectors (1 + 2 + 3), when programming the device, seems the best choice to provide a proper AVS. However, the recruitment of all vectors negatively impacts battery longevity, thus, a selection of vector 1 and 2 (1 + 2), seems a valid alternative to 1 + 2 + 3 configuration.

4. Micra-AV programming: general considerations and pitfalls

A correct detection of intracardiac signals, particularly of the A4 wave, is crucial to provide AVS. A systematic approach should be aimed to identify a noise-free surface ECG with a clear P wave. Subsequently, it is important to line up the A1–A4 waves under the corresponding ECG signals (Fig. 4). In case of a small A4 signal, the ACC atrial-sensing vector can be changed, taking into account that vectors 1 and 3 are radial to the device body while vector 2 is longitudinal to the device body (Fig. 2). The manual atrial mechanical (MAM) test allows to get a clear view of the A1–A4 signals with respect to the surface ECG (Fig. 3). While running the MAM test, “auto” atrial mechanical features (auto A3 threshold, auto A3 window-end, and auto A4 threshold) should be turned off, in order to prevent the device from autocorrecting and changing the programmed intervals. First, the MAM test has to be run in the ventricular dual-inhibited (VDI) mode, which allows a clear distinction of the A1–A4 signals. Subsequently, the MAM test can be run in the ventricular dual response (VDD) mode. This second test is useful to make adjustments while observing the device attempting to track the atrium and identifying reasons for AVS failure (i.e., A4 undersensing), occurring when the device does not track the atrium as intended. The “auto” features can be turned on again when all tests have been run, and once appropriate baseline values are established. The MAM test and proper adjustments of the A4 threshold, A3 threshold, and A3 window, have always to be performed before discharge, particularly in patients with an underlying complete AVB. In those cases, reaching a high percentage of AVS is mandatory to increase the atrium-tracked ventricular stimulation and thereby to avoid the risk of pacemaker syndrome, occurring in cases of high burden of atrioventricular dyssynchrony.

5. Micra-AV in clinical trials

The *Micra Atrial TRacking Using A Ventricular AccELerometer (MARVEL)* study [13], designed on the basis of the algorithm developed in MASS and MASS2 studies, sought to test the feasibility of VDD pacing in patients with AVB. This prospective, non-randomized, multicenter clinical feasibility trial showed an average AVS of 87% (95% CI 81.8%–90.9%) in the enrolled population, ranging from 39.2%–100%, with the majority (83%) having an AVS average >70%. Among the 64 patients enrolled in this study, most of them (52%) had an underlying 2nd or 3rd-degree AVB. As expected VDD mode significantly improved AVS with respect to VVI mode

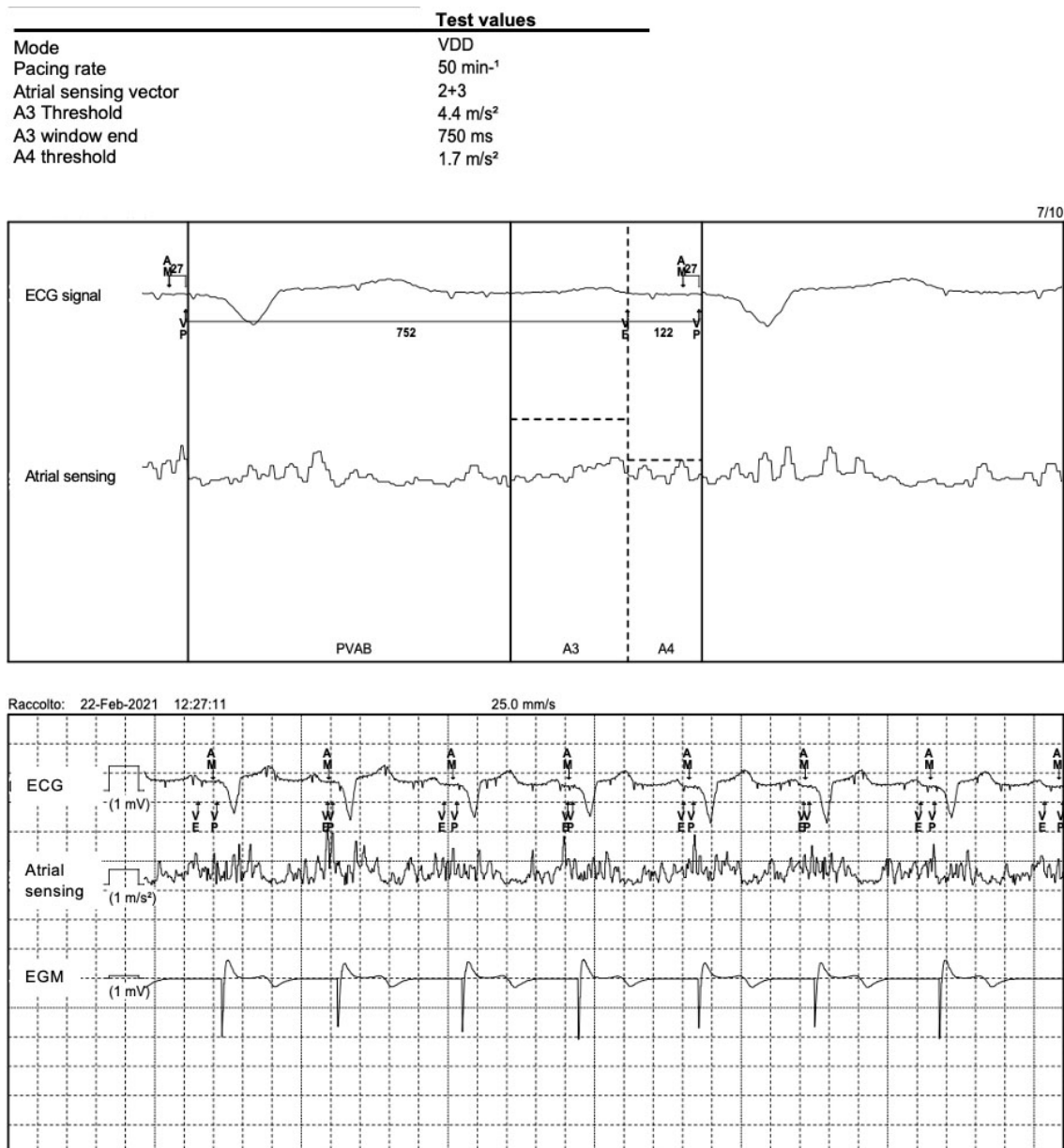


Fig. 4. Medtronic Micra-AV manual atrial mechanical (MAM) test. Top: manual atrial mechanic (MAM) test reporting A3 and A4 threshold, vector selected (2 + 3) and A3 window end. Middle: atrial mechanical sense test with signals (A3, A4 windows, and PVAB) adjustment providing a correct AVS. Down: Rhythm strip of the final programming after signals adjustment with atrioventricular sequential pacing (VE, end of A3 window; AM, atrial mechanical; VP, ventricular pacing). PVAB, post-ventricular atrial blanking period (used to blank the A1 and A2 signals); ECG, electrocardiogram; EGM, electrogram.

(89.9% vs 37.5%; $p < 0.001$). Interestingly, the rate smoothing algorithm provided a further increase of AVS, of about 8.7%. In a further analysis, Garweg C *et al.* [14] performed a short-term follow-up (6 months) in a subgroup of 9 patients enrolled in the MARVEL study. The authors demonstrated that the ACC-based sensing of mechanical activity (A4 signal) and the subsequent AVS remained stable over the time, except for two patients, both showing a high premature ventricular contraction (PVC) burden as the main cause of low AVS. Subsequently, further efforts have been made in order to identify the clinical predictors of a good A4 signal ampli-

tude, representing the major determinants of a high AVS percentage. The MARVEL 2 [15] study showed how the amplitude of the sensed mechanical atrial signal (A4) by the Micra accelerometer is related to the quality of AVS. In fact, among patients with AVS >90%, the mean A4 amplitude was higher than in patients with AVS ≤90% (3.1 ± 1.2 m/s² vs 2.4 ± 0.8 m/s²; $p = 0.030$). Moreover, the authors showed that the A4 amplitude was inversely related to the atrial function assessed by echocardiographic measurement of E/A and e'/a' ratio, and directly related to atrial contraction excursion (ACE) and atrial strain. Among all variables considered in

this study, coronary artery bypass graft history, high E/A ratio (>1.18), and low atrial strain (<10 mm), remained associated with a low A4 amplitude also after adjusting for confounders at multivariate analysis. Among the 40 patients with a persistent third-degree AV block and normal sinus rhythm (NSR), the median AVS was 94.3%. Of these patients, 25 (62.5%) had AVS $>90\%$ (median AVS 96.9%; IQR 95.3%–98.1%), while the remaining 15 patients had AVS $\leq 90\%$ (median AVS 79.6%; IQR 77.3%–81.6%). In patients with AVS $>90\%$, mean A4 amplitude was higher than in patients with AVS $\leq 90\%$. As a result of these findings, the new Micra-AV that incorporates the *MARVEL 2* algorithm, received the approval from the United States Food and Drug Administration and the CE mark in the European Economic Area in January 2020 and June 2020, respectively.

Despite Micra-AV valuable performances, the *MARVEL* and *MARVEL 2* trials have raised significant concerns. First, patients enrolled in both studies did not receive a Micra-AV implant, whereas a specific AVS algorithm was downloaded into the previous implanted Micra-VR devices, so that no patient could be considered as a “*de novo*” Micra-AV implant. Second, *MASS/MASS2* study enrolled only 75 patients, and the analysis of *MARVEL* and *MARVEL 2* was performed in a cohort of 64 patients each. Moreover, with regards to *MARVEL* study, the ultimate data were collected from a single outpatient visit, considering only 118,640 cardiac cycles, that overall represented an average of 30 min evaluation per patient. Similarly, the Micra-AV performance and related predictors of AVS in the *MARVEL 2* study were obtained approximately from 20 min observation for each patient. The small number of patients enrolled, and the limited number of the total cardiac cycles analyzed could be considered a significant weakness of those studies. Furthermore, among patients enrolled in *MARVEL* study, $n = 11$ (17%) had an AVS average of 51% during rest. Those data do not seem particularly encouraging, considering that 9 of these patients had an AVB, and probably required an elevate ventricular pacing burden, thereby potentially showing low rates of AVS. In addition, the most important conclusion of the *MARVEL 2* study is a double-edged sword. Indeed, if a low sinus rate variability (measured as the standard deviation of successive differences of P-P intervals <5 bpm) combined with an E/A ratio <0.94 can predict high AVS ($>90\%$) with $>90\%$ probability, on the other side having such strict predictors can lead to exclude a non-negligible number of patents from receiving LLPM.

6. Micra-AV in a real-life setting

At present, reported experiences with the Micra-AV are scarce, due to its recent introduction on the market, although these reports have shown how Micra-AV can be taken into account as a reasonable choice in peculiar clinical contexts. Specifically, the Micra-AV has been presented as a feasible choice in patients with a dual chamber transvenous PM programmed to AAI pacing, due to a RV lead malfunctioning [16–18]. This is particularly true for patients at high-risk for

lead extraction or for addition of further standard transvenous leads. Instead, Burkman *et al.* [19] reported a case of LLPM induced torsades de pointes, due to an acquired long-QT syndrome as result of the Medtronic “Tracking Check” algorithm, specifically designed to maintain AV synchronous pacing. In this case, the Micra-AV was initially implanted as a bridge therapy after biventricular pacemaker lead extraction, until a new transvenous biventricular system could be reimplanted after a complete resolution of the infectious process. Similarly, Halawa *et al.* [20] reported a case of a polymorphic ventricular tachycardia caused by atrial undersensing during VDD pacing, that led to “short-long-short” sequences or “R-on-T” phenomenon. As the authors suggested, this event may show a relationship with specific Micra-AV algorithms sought to minimize ventricular pacing. In a recent four-patients case series (2 with complete AVB) who underwent Micra-AV implant as a first choice, El-Chami *et al.* [21] showed how further adjustments of A3-A4 threshold, A3 length window, and disablement of “VVI+” algorithm were mandatory to provide correct AVS, underlining how tailored device programming has to be evaluated individually.

Until today, in our Center we successfully performed 7 Micra-AV LLPM implantations. In six out of seven cases this device represented a reasonable choice due to upper limb venous access issues, such as subclavian vein occlusion, with or without previous malfunctioning transvenous leads, due to particularly high infectious risks, and/or due to the presence of hemodialysis catheters (Fig. 5). In one case, Micra-AV was specifically chosen over a traditional TV-PM due to patient’s choice. All patients presented a consistent AVS during follow-up. Considering that this is a relatively young experience, as all other reported cases, a longer follow-up is needed to confirm Micra-AV clinical efficacy. Notably, we found that in some cases a proper choice of A3, A4 thresholds and A3 window end, is subject to a specific stepwise approach during follow-up, basing on specific patient’s characteristics and heart rate and often, the most appropriate programming could not be anticipated and fully predicted at discharge.

7. Micra-AV extraction/end of life management

One of the major challenges for a LLPM is its management after battery depletion or premature device malfunction. Due to its recent introduction, there are no experiences regarding Micra-AV late retrieval, but previous experiences with the Micra-VR showed that an early retrieval resulted feasible and safe [22], even if its success rate decreased to 78% when attempted six months after implantation, as described by Grubman *et al.* [23]. Nevertheless, extraction procedures have shown to be feasible also after a consistent time (up to 29 months) after implant [24], using a snare loop. Due their identical external structure, we think that these results could be exactly the same with the Micra-AV device. Retrieval solution can be taken into account in cases of young, pace-

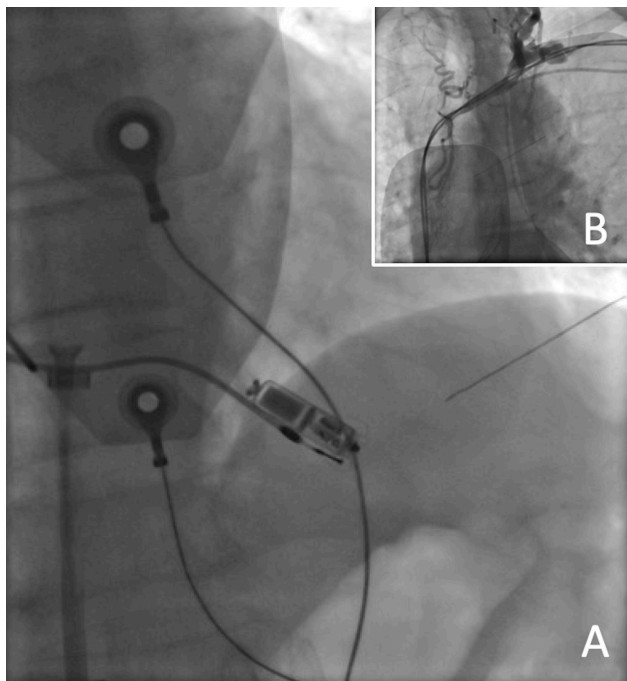


Fig. 5. Antero-posterior view of Micra-AV implant (A) in a patient with right ventricle transvenous lead malfunction and left subclavian vein occlusion (B).

maker dependent patients, in order to avoid an overload of implanted LLPMs, or in case of major infections, potentially leading to cardiac involvement (endocarditis). Alternatively, the leadless pacemaker can be abandoned, and a new system can be implanted at a different location in the right ventricle. Indeed, this is the recommended strategy from the Micra manufacturer in order to reduce the risk of procedural complications.

8. Conclusions

Micra-AV is a promising and interesting solution in the actual LLPMP scenario. Its newest AVS ability, associated with the excellent experiences derived from the previous Micra-VR device, make this new device an attractive alternative in different clinical settings. Notwithstanding, Micra-AV algorithms capable to provide AVS have notable limitations, so that their optimization require a stepwise process that should be followed over time. Patients selection is crucial to obtain good clinical outcomes, so that the choice to implant a Micra-AV should be tailored based on atrial electrical and mechanical characteristic, as well as on the underlying cardiac rhythm. Indeed, the impairment of the atrial function over time can lead a substantial reduction in AVS, that represents the major limitation for patients with NSR and high-degree AVB. Therefore, depending on the patient risk profile, a dual-chamber traditional pacing system should be still preferred in the presence of sinus node dysfunction and high-degree AVB. The Micra-AV does not seem the optimal choice for younger and physically active patients, as well as in cases of higher sinus rates. Conversely, the Micra-AV

has to be taken into account in patients with high infective risk and/or limited venous accesses. The overall benefits that the Micra-AV AVS algorithms may provide over time in the real-world population, have still to be validated in larger population studies with a long-term follow-up.

Author contributions

GM conceived and wrote the manuscript. MS, AG and MV revised the scientific literature. AC and GBF supervised the work in view of their expertise in the field. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Not applicable.

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Conflict of interest

The authors declare no conflict of interest.

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