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CASE REPORT

Percutaneous extraction of a Micra AV transcatheter pacing system due to a rare sudden battery failure after 19 months from implantation: A first experience worldwide

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Abstract

Introduction: Micra AV Transcatheter Pacing System (TPS) represents an innovative second-generation leadless pacemaker which represents an effective alternative to conventional devices in selected cases. Intrinsic malfunctions of these devices are rare, requiring sometimes their retrieval. When performed in experienced centers, this procedure is safe.

Case Presentation: We describe a case of sudden battery malfunction of a Micra AV TPS, which required the extraction and the placement of a new pacing system in the right ventricle.

Discussion: This case, which has never been reported, highlights the need to a careful fluoroscopic evaluation and the usefulness of remote monitoring.

KEYWORDS
battery malfunction, cardiac pacing, extraction, fluoroscopy, leadless pacemaker, Micra AV, remote monitoring

1 | INTRODUCTION

Micra AV Transcatheter Pacing System (TPS) (Medtronic Micra AV Model MC1AVR1 Medtronic Inc, Minneapolis, MN, USA) represents an innovative second-generation leadless pacemaker (LP) implanted in the right ventricle via femoral venous approach, able to provide atrio-ventricular (AV) effective synchronous pacing, through the detection of atrial contractions by an accelerometer-based atrial sensing sensor.[1] Therefore, recent European guidelines recommend LPs in patients requiring a single chamber ventricular pacing system as an alternative to conventional pacemakers in case of difficult upper venous access, pocket issues or high risk of infection, taking into consideration the patient's preference and life expectancy.[2] Observational data demonstrated the safety and efficacy of Micra TPS, with an excellent implant success rate, stable pacing parameters, and no battery concerns in the short and mid-term follow up. In contrast, data regarding long-term outcomes are limited. Moreover, the management of non-functioning or End-of-Life (EoL) devices needs to be further investigated. To the best of our knowledge, this is the first case of sudden battery malfunction after 19 months from implantation of a Micra AV TPS, which required the placement of a new pacing system in the right ventricle and the subsequent extraction of the old device.

ABBREVIATIONS: AV, atrio-ventricular; AVB, atrio-ventricular block; ECG, electrocardiogram; EoL, End-of-Life; LP, leadless pacemaker; TPS, transcatheter pacing system.

Vincenzo Ezio Santobuono and Paolo Basile contributed equally to this study.

2 | CASE PRESENTATION

An 85-year-old man, affected by arterial hypertension, chronic obstructive pulmonary disease and chronic renal disease, was

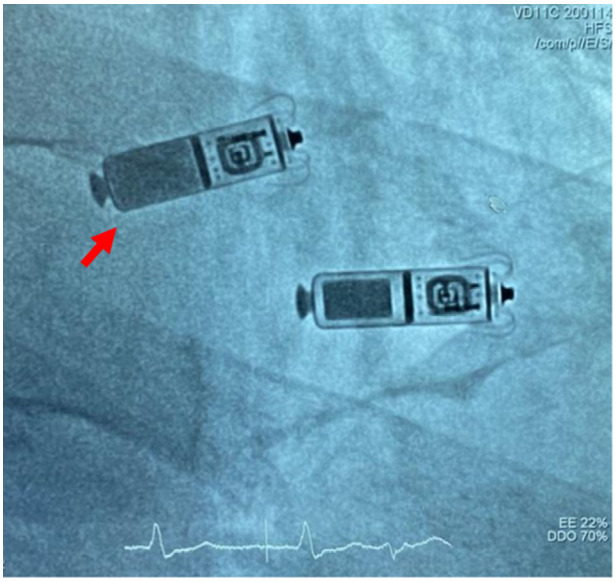

FIGURE 1 Fluoroscopic evaluation. During the procedure, by fluoroscopic evaluation, after the implantation of a new Micra AV TPS, a deeper side-by-side morphological examination of the two devices revealed a significant alteration (red arrow) of the separatory bag in the old device. Micra AV TPS, Micra AV transcatheter pacing system. [Color figure can be viewed at wileyonlinelibrary.com]

admitted in our tertiary referral hospital in August 2020 after the diagnosis of paroxysmal complete AVB during ECG ambulatory monitoring. The systolic function of left ventricle, assessed by transthoracic echocardiogram, was normal. A Micra AV TPS was implanted in the right ventricular septum under local anesthesia via right femoral vein by an experienced physician at our electrophysiology laboratory. Nor intraprocedural neither postoperative complication occurred and stable device parameters was maintained throughout the hospitalization (P wave at 14.3 mV, impedance of 1080 ohms and pacing threshold of 0.13 V at 0.24 ms). The Micra AV TPS was set at 50 bpm as its lower rate with AV conduction mode switch (VVI+) activated.

During the 7-month follow-up at our outpatient clinic of electrophysiology the pacemaker interrogation displayed optimal pacing and sensing parameters (P wave at 13,9 mV, impedance of 987 ohms, and pacing threshold of 0.38 V at 0.24 ms) with an estimated battery longevity of about 8 years. Moreover, the benefits of remote monitoring were offered to the patient, who declined this service.

In March 2022, during a routine pacemaker electronical follow-up, the device was unable to be interrogated by two different programmers. The 24-hour ECG monitoring showed further intermittent complete AVB episodes without pacing activity. Thus, the patient was immediately admitted to our ward to further diagnostic investigations. A subsequent bi-plane fluoroscopic examination demonstrated that the device was in the appropriate position. Therefore, by local anesthesia and with a surgeon as a bystander, via femoral vein access a new Micra AV TPS was placed in the right ventricle. During fluoroscopy, a deeper side-by-side morphological examination of the two devices revealed a significant alteration of the battery housing in the old Micra AV TPS battery (Figure 1). Thus, the old device was extracted and the cause of its malfunction was investigated. The Micra AV TPS retrieval

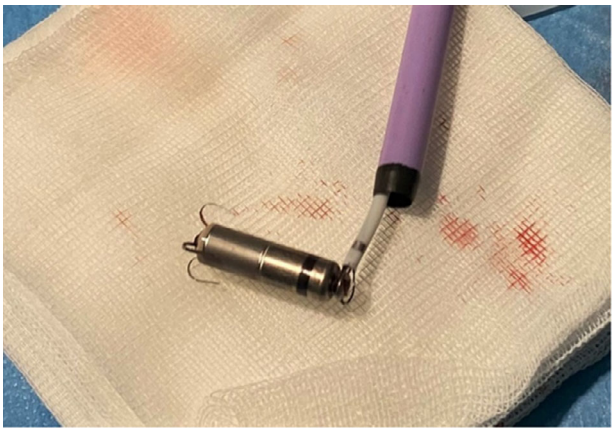

FIGURE 2 Visual inspection of Micra AV TPS after extraction. In the picture it can be observed the external structural integrity and the absence of adhesions or fibrocellular encapsulation. Micra AV TPS, Micra AV transcatheter pacing system. [Color figure can be viewed at wileyonlinelibrary.com]

was performed using a percutaneous tool, according to a specific approach described by Afzal et al.[3] More precisely, an 8.5-French Agilis NxT med-curl steerable introducer (St. Jude Medical) within the 23-French Micra introducer (Medtronic) was advanced in the right atrium and then curved into the right ventricle across the tricuspid valve. Subsequently, the deflectable Agilis introducer was used to advance a 7-French Atrieve Vascular Snare (Argon Medical Devices) into the right ventricle. Through bi-plane fluoroscopy, was achieved a coaxial position between the Atrieve Vascular Snare and the exhaust Micra AV TPS. The Atrieve Vascular Snare was maneuvered around the device and slowly pulled back to entrap the retrieval feature on the surface of the Micra TPS. Micra AV TPS was successfully retracted from the myocardium operating a cautious traction availing of systo-diastolic beat-by-beat chamber movements. After that, it was removed from the heart with the use of the Micra introducer. The inspection at the end of the procedure, did not reveal structural anomalies, adhesions, or capsules around the retrieved Micra TPS (Figure 2). No complications occurred in the peri and post-procedural period. Thus, after 3 days of monitoring, the patient was discharged at home in good clinical conditions. Further interrogations of the new device revealed a proper functioning throughout the follow up. An extensive technical investigation of the retrieved device was performed by the manufacturer. At visual inspection no anomalies were noted. A loss of electrical output and telemetry was exhibited during initial testing. Further analysis determined the loss of output resulted from substantial depletion of the battery and the destructive analysis indicated shorting/low impedance in the battery. A breach in the cathode separator bag was revealed, which caused an internal short circuit and, consequently, a sudden depletion of the battery.

3 | DISCUSSION

Leadless cardiac pacing is a great advancement in bradycardia therapy and, in selected cases, a valuable alternative to conventional pacing

systems.[4] Safety and efficacy of LPs was pointed out by several studies, even in older patients.[5,6] Indeed, in this case was considered the best option among pacing systems, due to old age and comorbidity of the patient, conditions that increase the risk of severe device-related complications. Furthermore, a duration of the battery was expected to be beyond the life-expectancy of the patient, due to the intermittent nature of AVB.

Initially, two LPs systems were commercially available: Nanostim LCP from St. Jude Medical and Micra TPS from Medtronic. However, actually the Micra TPS is the only approved by US Food and Drug Administration and it has obtained CE mark, due to a safety recall of the Nanostim device in 2016 related to concerns on abrupt battery failure.[7] Similar battery issues have not been described for the Micra TPS. Bhatia et al. reported their experience in a large volume center during the follow-up of 302 patients with implanted Micra TPS. Among these, two cases of premature battery depletion are described, but related to elevated pacing thresholds.[8] In 2019, another Micra TPS extraction has been reported 23 months after implantation due to a stable increase in the pacing threshold over time, leading to battery depletion.[9] Also, Grubman and colleagues reported in their study three cases of expected battery depletion due to elevated pacing thresholds.[10] To best of our knowledge, this is the first case of a Micra AV TPS extraction due to an unexpected battery failure not related to elevated pacing thresholds.

The Micra AV TPS estimated cycle of live ranges from 5 to 15 years, according to the rate of pacing. The management of EoL of these devices is still debated. The preferred option is turning off and leaving the device in situ, since it was observed that the right ventricle can accommodate at least three Micra TPS without interactions in most patients.[11] In rare cases, such us infection, device embolization, the necessity of a dual chamber device or a cardiac resynchronization therapy, the operator may choose to attempt an extraction.[12] The Micra TPS retrieval is a safe procedure when performed by experienced operators. Afzal et al. did not report serious adverse complications in a worldwide registry of 40 Micra TPS recovery.[13] However, retrieval in some circumstances can be challenging due to the presence of myofibrocellular tissue on the surface of the device.[14] In our case, no encapsulation was observed.

We decided to proceed with the retrieval of the device for safety issues, in order to be reassured of the external shell integrity and avoid the possibility of blood contamination by the internal components of the device. Furthermore, this may allow a thorough analysis of the device by the manufacturer leading to a precise definition of the cause of this unexpected device failure.

The importance of implantable cardiac device remote monitoring needs to be highlighted. Indeed, it may provide a closer control of the device's parameters. This may allow an early recognition of potential malfunctioning and worrisome clinical events, improving the safety and reducing the patient risk of major adverse events.[15] Hence, more efforts should be made to intensify the use of this service in clinical practice. On the other hand, it is of interest underlying the appropriateness of fluoroscopic approach as compared to chest radiography in case of suspected device failure. It may help clinicians in the identification of LP dislodgment and the evaluation of its integrity by a comprehensive visual inspection.

4 | CONCLUSIONS

We report a first case of a rare Micra AV TPS sudden battery failure not related to increased thresholds followed by its extraction and re-implantation of a new device.

The implantation of a new LP and the subsequent extraction of this second-generation LP is a safe procedure in experienced centers. Increased surveillance, especially with the aid of remote monitoring, should be addressed to guarantee the safety and efficacy of these new devices. In case of suspected malfunction, a thorough and urgent diagnostic evaluation, including fluoroscopy, is mandatory.

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CONFLICT OF INTEREST STATEMENT

Authors have no conflicts to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

PATIENT CONSENT

Informed consent to publish these data was obtained from the patient.

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