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Early Dislodgement and Iliac Vein Embolization of a Ventricular Leadless Pacemaker: A Case Report

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Abstract

Although leadless pacemakers (LP) eliminate the risk of pocket and lead complications associated with transvenous pacemakers, groin site complications, tamponade, and dislodgement remain possible. A distal retrograde venous embolization is possible but rare; it should raise attention to a potential accidental left implantation using a patent foramen ovale, with arterial embolization. Thanks to his retrievable design and specialty designed catheter, successful AVEIR LP retrieval happened in most cases. This case highlights an ingenious approach when access to the embolization site is difficult: the use of a electrophysiology steerable catheter to guide the retrieval catheter.

Keywords: Leadless pacemaker; Dislodgment; Embolization; Retrieval; AVEIR VR

Introduction

Leadless pacemakers (LP) are small self-contained units implanted directly into the heart and were initially developed to avoid limitations and complications related to traditional transvenous pacemakers. This includes mainly pocket complications, lead complications and infections [1]. However, other procedural complications persist and include vascular access complications, pericardial effusion/tamponade, and device dislodgement. While recent meta-analysis confirmed significant lower association of overall complication, dislodgement and pneumothorax with LP compared to transvenous pacemakers, higher risk of pericardial effusion and tamponade were observed [2].

In this clinical case, we report an unusual distal retrograde venous embolization of LP. We discuss the differential diagnosis and the associated diagnostic approach.

Finally, we describe the retrieval procedure and strategies required for the sometimes tedious recovery of these distal venous embolizations.

Case Presentation

A 90 years-old patient with a history of permanent atrial fibrillation (AF) presented spontaneous symptomatic AF-related bradycardia with indication for single chamber pacemaker implantation. Due to advanced age, frailty and associated comorbidities, decision was made to implant a leadless pacemaker (AVEIR VR, Abbott).

The procedure was performed under general anesthesia. Puncture of the right femoral vein was performed under ultrasound guidance and a dedicated 27 F delivery-sheat was introduced into the inferior vena cava. The AVEIR VR was brought into the right ventricle using dedicated deflectable delivery catheter. Septal position of the device was assessed using fluoroscopic guidance (including right anterior oblique (RAO) and left anterior oblique (LAO) views) and contrast injections (Figure 1). Three different septal sites were studied through the AVEIR electrical mapping, with unsatisfactory measurements (namely high pacing threshold and low/no current of injury). Finally, a fourth position with acceptable measurements was found at the apical segment of the interventricular septum. After deployment, the device showed a good current of injury, stable impedance and sensitivity (respectively 430 Ohms and 5,2 mV), and an improved but sub-normal capture threshold (2,25V x 0,8 ms). To confirm secure fixation, a deflection test was performed, and the device was deemed stable and was released in this position. The patient was then discharged to the cardiology department for observation and quickly complained of rhythmic contraction of his adductors. Undersensing and loss of capture were identified on the telemetry monitoring and device interrogation was unsuccessful at the patient's chest level. A chest radiograph confirmed the dislodgment and the embolization in the pelvic area was seen by abdomino-pelvic radiograph (Figure 2).

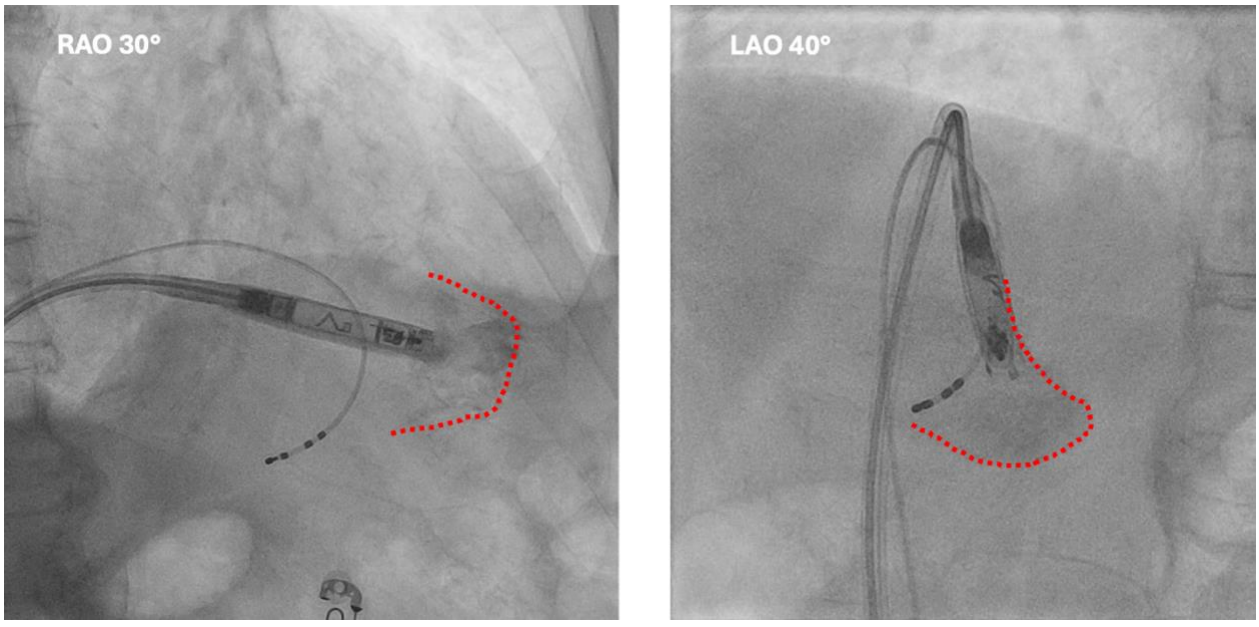

Figure 1: Peri-implant fluoroscopy with contrast injection showing the position of device implantation.
The quadripolar catheter was used for eventual backup pacing.
The RAO 30° view shows apicoseptal positioning of the device and LAO 40° confirms right-sided septal position of the device. Red dotted lines delineate the right ventricle endocardium.

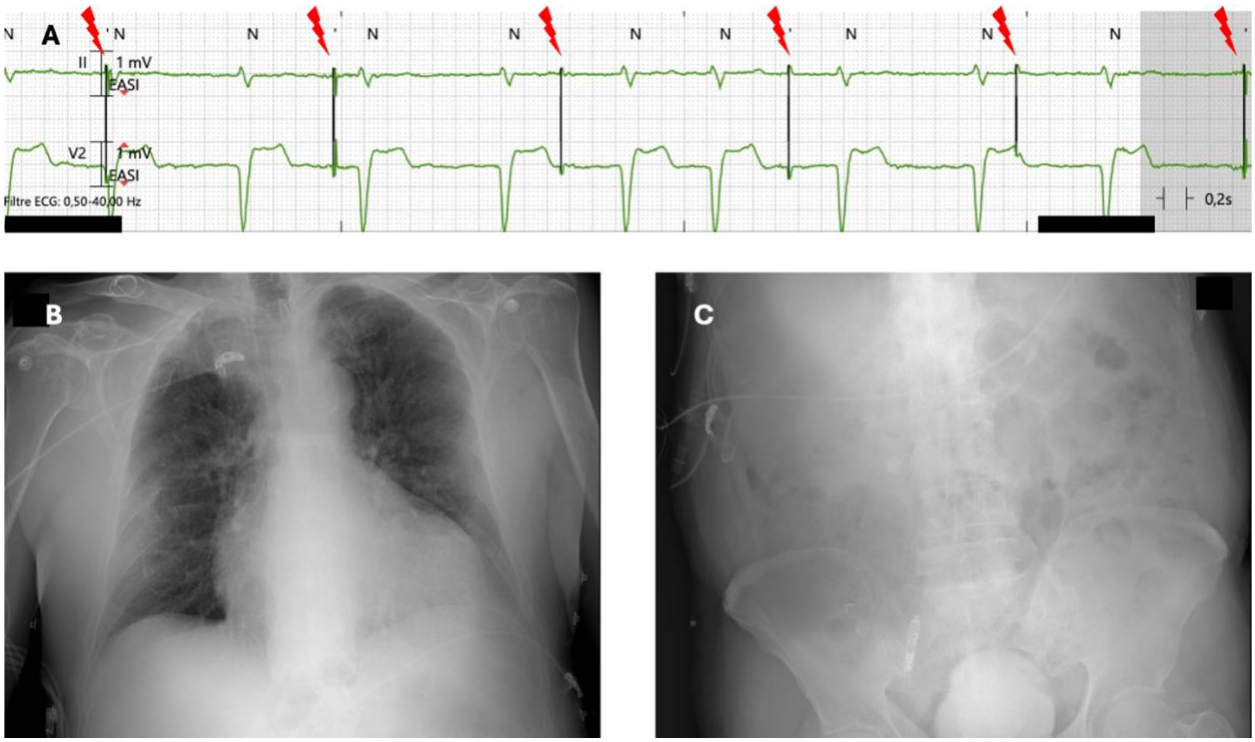

Figure 2: Suspicion and confirmation of the dislodgement of the LP in the pelvic area.

(A): Shows telemetry monitoring. Red flash shows the pacing spikes of the device, demonstrating both undersensing of intrinsic QRS and loss of ventricular capture (exit block).

(B): Shows a chest X-Ray demonstrating the absence of the device where it was earlier implanted in the right ventricle.

(C): Shows the iliac embolization site, suspected based on lower limb regular muscular contractions.

Lower limb fluoroscopy and phlebography was performed the next day and confirmed venous embolization of the device in a side branch of the right internal iliac vein. Consecutively, a contralateral left femoral venous access was used to introduce the retrieval system (AVEIR retrieval catheter LSCR111, sheath size 27F). Due to difficulty in cannulating the side venous branch in which the device was embolized, a deflectable quadripolar catheter was used for selective cannulation of this branch. A snare of the retrieval system was previously attached to the quadripolar catheter to use it as a guide for cannulating the venous branch, which was successful. The docking button was then captured using the three snares, the protective sleeve was advanced, and the device docked into the docking cap. The device was finally successfully retrieved by withdrawing into the AVEIR introducer sheath (Figure 3). A new AVEIR VR LP was implanted in the apical segment of the interventricular septum during the same procedure. The total procedure (embolized device withdrawing and implantation of a new one) was 85 minutes with total fluoroscopy time of 19 minutes. Chest radiography on post-procedural day confirmed appropriate device positioning. LP interrogation demonstrated normal device function and stable pacing parameters compared with immediate post-implant values (capture threshold 0,5V x 0,4ms, impedance 530 Ohms and sensitivity 9 mV, compared with respectively 0,75V x 0,4ms, 550 Ohms and 7,2 mV in immediate post-implantation). At 8-week follow up, the device interrogation showed stable values (respectively 0,5V x 0,4ms, 750 Ohms and 11mV).

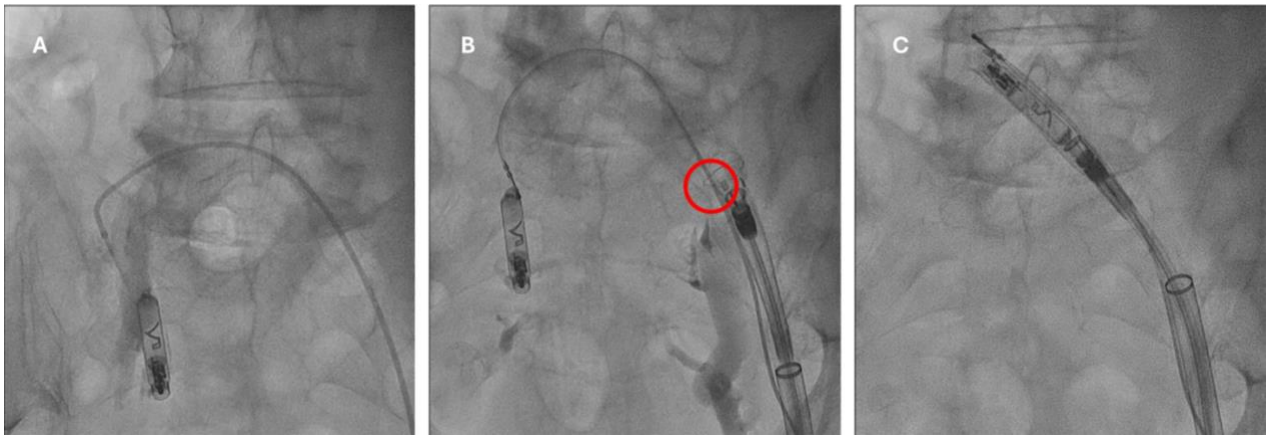

Figure 3: Steps of the retrieval procedure.

(A): Shows contrast injection using a left femoral access confirming the venous embolization in a side branch of the internal iliac vein.

(B): Highlights the use of an electrophysiology deflectable catheter to canulate the side branch. The catheter was passed in one snare to allow guidance of the retrieval catheter in the side branch, facilitating capture of the docking button.

(C): Shows final capture and retraction of the device and retrieval system in the delivery sheath.

Discussion

This case illustrates a complex implantation with mapping of different implant sites with unsatisfactory values. An acceptable position ultimately had to be accepted, despite slightly elevated stimulation thresholds. Notably, current of injury and pull test performed at the end of the procedure demonstrated good device stability, unpredictive of further embolization.

Currently, two single chamber leadless pacemakers have been approved by the Food and Drug Administration: Micra VR/DR (Medtronic), since 2016, and AVEIR AR/VR (Abbott) since 2022. Even if there is no randomized head-to-head comparative study, there appears to be a significant difference in dislodgment et embolization rates between Micra VR et AVEIR VR. The Micra transcatheter pacing system has seen a recently published registry of five-year follow-up, that reported only one Micra embolization (0.06%) and two dislocations without embolization (0.11%) including 1809 implants [3]. To compare, 53 of 5990 (0.88%) AVEIR VR implants exhibited dislocation and embolization during a period of 21 months. Most cases (32 events, 60.4%) happened during the procedure itself, whereas 21 cases (39,1%) took place after implantation: five within a few hours following the procedure, three the next day, two before discharge, and 11 cases the precise timing post-implantation was not reported. One explanation of this difference between the risk of dislodgment and embolization between Micra and AVEIR systems is their different fixation mechanisms: Micra VR uses active fixation nitinol tines while the AVEIR VR uses an active fixation helical screw. Delivery tools are also different between systems and separation problems could contribute to this dislocation rate. Further studies are needed to determine whether impedance or other metrics are associated with adequate AVEIR fixation [4]. Some case reports suggest that a decrease in impedance may be an early sign of late dislodgment [5].

Usually described embolization sites include the pulmonary arteries, right atrium and vena cava [4]. This case highlights an unusual dislodgement and embolization of LP in a side branch of the internal iliac vein. Early embolization was suspected based on leg muscle contractions at a rate of 30 per minute, due to pelvic nerve stimulation induced by the LP. The diagnosis of embolization was then confirmed by the detection of undersensing with exit block on telemetry monitoring. The absence of LP detection by the interrogator at the thoracic level and radiography ultimately confirmed its peripheral embolization at the iliac level. This unusual location implies a long retrograde venous path taken by the device, probably under the effect of gravity. A crucial differential diagnosis for this clinical scenario is accidental implantation in the LV through a patent foramen ovale (or interatrial or ventricular defect) with arterial embolization of the LP. Making the difference is essential because of the specific complications that may be associated with arterial embolization, on the one hand, and in order to plan the retrieval procedure correctly, on the other. In this case, conscientious review of peri-implant fluoroscopy images using multiple views (including LAO with contrast enabling identification of the interventricular septum on Figure 1) and phlebography of the lower limbs formally confirmed the venous nature of the embolization and enabled the retrieval procedure to be planned appropriately.

Due to the risk of device dislodgement and embolization, dedicated retrieval catheters and snare systems have been developed to facilitate safe percutaneous extraction when necessary.

The AVEIR VR LP incorporates a helix-fixation designed to permit retrieval during both acute and long-term situations. Most common indications for device retrieval are battery depletion, dislodgement/embolization, inadequate thresholds secondary from micro-dislodgment, the requirement of device upgrading and, more rarely, or mechanical factors (eg, inadequate fixation or ventricular ectopy). Due to the recent nature of the technology and a lack of long-term perspective, data on the retrievability of LP in these various situations is sparse. Techniques for free-floating capture and retrieval have also been developed in case of dislodgement and embolization [6]. When attempted, successful AVEIR LP retrieval happened in 92% [4].

The orientation of the docking button plays a critical role in the retrieval strategy. If this docking button is not accessible without repositioning the device, the distal/helix end may be snared with the retrieval catheter. In the case of a free-floating or upside-down LP, any part of the LP can be grabbed and the snares are locked in a closed position around the LP. The protective sleeve is advanced around the device without docking the device into the docking cap, and this allows the LP to be withdrawn into the introducer sheath. If the protective sleeve cannot be advanced over the LP, withdrawing the LP into the introducer sheath can be difficult but still achievable without releasing the device. A first approach consists of a gradual rotation and retraction of the device: that guides the end of the device that is closer to the snared end of the LP into the introducer sheath. A second approach consists in a second snare through a separate venous access sheath [6].

In our case, the docking system was well oriented, and the main difficulty was accessing the side branch of the right internal iliac vein via a left femoral veinous access. To do so, we used a deflectable quadripolar catheter to canulate the vein, on which we hung a snare of the retrieval system to guide the three snares catheter through the femoral and then the right iliac venous junctions. Once the docking button captured by the snares, the protective sleeved was advanced and the device docked into the docking cap. Then, the LP was quite easily withdrawn into the introducer sheath.

Conclusion

LPs and in particular AVEIR LP system have a high level of safety and efficacy and avoid some complications of transvenous pacemakers. However, early or late dislodgement and embolization may happen. A thorough diagnostic approach allows for proper planning of the retrieval procedure. Thanks to his retrievable design and specialty designed catheter, successful AVEIR LP retrieval happened in most cases but may require ingenious approaches on a case-by-case basis in complex situations.

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