

Successful removal of a leadless pacemaker from the pulmonary artery via a novel basket retrieval system

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Introduction

Leadless pacemakers present an alternative to traditional transvenous lead-based systems with the advantage of reduced risk of infection, vascular stenosis, pneumothorax, and tricuspid valve leaflet impingement.^{1,2} The Micra AV (Micra; Medtronic PLC, Dublin, Ireland) (Supplemental Figure 1) is a recently FDA-approved device that has a broadened use for patients with symptomatic heart block by adding the ability to track atrial activity. The Micra is implanted with a 23F deflectable delivery sheath that is advanced through a 27F outer sheath placed in the common femoral vein. The leadless pacemaker is delivered to a septal location within the right ventricle (RV) and is held in place by 4 nitinol tines, which secure into the trabeculated RV myocardium.

Micra devices have a flange on the proximal end of the device that enables retrieval via a snare.³ While most dislodged leadless pacing devices remain within the RV, there are several reported cases of dislodged leadless pacemakers that have embolized to the pulmonary arteries, requiring complex retrievals.^{3,4} Special considerations during the retrieval of a Micra device include avoiding injury to the pulmonary and tricuspid valves, adjacent vasculature, and cardiac chambers. In this case, the 3-month dwell time of the device is also a consideration.

Here, we describe a case highlighting techniques to facilitate a safe retrieval of a nonacute embolized leadless Micra pacemaker to the right pulmonary artery (PA) using the ONO endovascular retrieval system (ONOCOR

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KEY TEACHING POINTS

- Leadless pacemakers are an alternative to traditional pacemakers, with fewer complications related to venous stenosis, infection, or valve impingement. These pacemakers carry a risk of dislodgement and embolization into the pulmonary arteries. It may be necessary to remove these devices endovascularly.
- It is preferable to capture these devices into a sheath in the pulmonary artery in order to protect the pulmonary and tricuspid valves from the nitinol tines used to secure the device in the right ventricle. Traditional strategies use snaring techniques and a large sheath for safe retrieval. Snaring via the distal flange and/or nitinol tines is effective but not always possible, and alternatives to this strategy must be considered for complex retrieval cases or difficult anatomic positioning of the embolized device.
- Retrieval of dislodged leadless pacemakers should be performed as soon as possible after recognition of dislodgement. Facilities that place leadless pacemakers should have the necessary personnel and equipment for retrieval at the time of placement.
- A tug test should be performed during placement of Micra leadless pacemakers prior to deployment to reduce the risk of dislodgement and embolization.
- A multidisciplinary approach between specialties is important for difficult pacemaker retrieval cases. Multiple strategies from each discipline were employed that ultimately resulted in successful retrieval of the Micra via the use of a novel basket retrieval catheter.

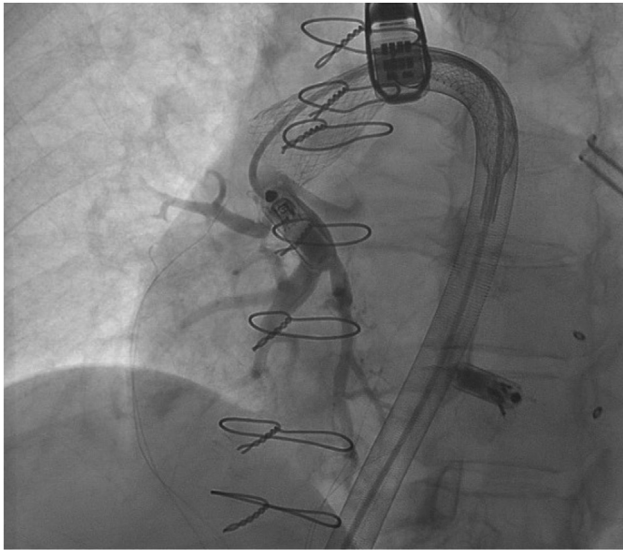


Figure 1 Pulmonary artery angiogram after deployment of the ONO retrieval catheter (ONOCOR LLC) demonstrating the Micra lodged in the right posterolateral branch.

LLC, Philadelphia, PA). This is the first reported case using the ONO device to retrieve a leadless pacemaker in humans.

Case report

A 52-year-old woman with severe mitral regurgitation status post mitral valve replacement and left atrial appendage ligation recently developed tachy-brady syndrome and was treated with leadless pacemaker implantation at an outside institution. One day after Micra placement, she was found to have embolization of the device to the right PA. A second Micra device was subsequently implanted, and she was then discharged home with the first device remaining in the PA. Three months after initial implantation, she was referred to our center for retrieval of the embolized leadless pacemaker.

A Computed Tomography Angiography of the chest was obtained, and 3-dimensional reconstruction was performed for preprocedure planning (Supplemental Figure 2). The tines of the device were oriented toward the proximal vessel.

Under general anesthesia, femoral vein access was obtained and a 26F Gore DrySeal sheath (Gore Medical, Flagstaff, AZ) was advanced into the right PA over a Lunderquist wire (Cook Medical, Bloomington, IN). Left common femoral vein access was also obtained to allow for temporary cardiac pacing if needed during the procedure. Heparin was given to maintain an activated clotting time >220 seconds. Pulmonary angiography was then performed, which confirmed location of the device seated snugly in the right posterolateral trunk. Through the DrySeal sheath, an ONO vascular retrieval system (ONOCOR LLC) was advanced beyond the sheath to ensure coaxial orientation of the pacemaker with respect to the sheath for recapture in order to prevent the need for an uncovered Micra to be retracted through the pulmonary and tricuspid valves.

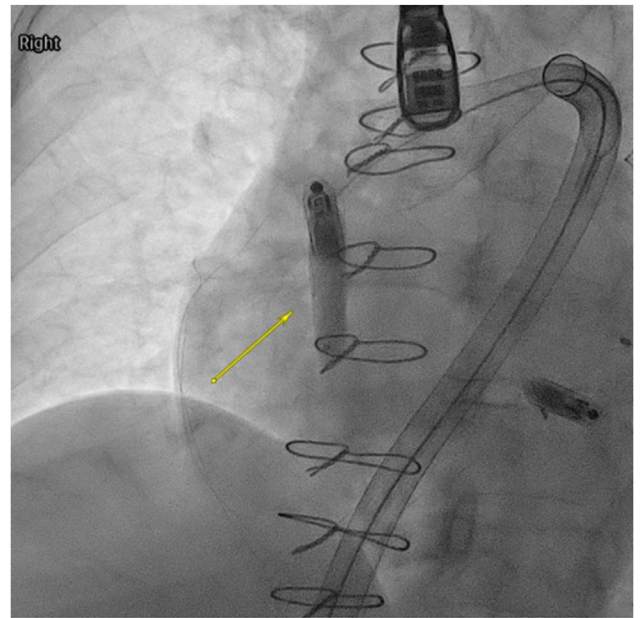


Figure 2 Spot fluoroscopic image with balloon deployment distal to the Micra during a successful attempt to dislodge the device into the larger proximal portion of the vessel.

Cannulation of the posterolateral trunk containing the Micra was obtained with an 0.035 Glidewire and a 5F JR 4 catheter that were advanced through the central lumen of the ONO (Figure 1). Multiple attempts were then made to retrieve the device with a Gooseneck snare (Microvena, St. Paul, MN); however, the Micra device had started to heal into the distal PA and there was inadequate luminal space surrounding the device to allow for snaring. Thus, a 10 × 20 mm noncompliant balloon (Armada; Abbott, Abbott Park, IL) was advanced distal to the device, inflated, and then retracted proximally. This maneuver successfully dislodged the pacemaker and reoriented it into the larger, more proximal right PA to facilitate retrieval with a snare (Figure 2).

The distal flange of the device was snared, and the pacemaker was retracted to the edge of the ONO retrieval device. The Micra device was sitting perpendicular because of the angulation of takeoff between the right PA and the branch containing the device (Figure 3A and 3B). Therefore, the ONO was redeployed in a more proximal location to allow for deployment in a portion of the vessel with a larger diameter (Figure 3C). The device was then able to be retracted into the nitinol ONO basket and was easily recaptured by the ONO retrieval device in a more coaxial orientation. This allowed the pacemaker to be pulled easily into the DrySeal sheath in a coaxial orientation (Figure 3C). The Micra was easily removed from the body (Figure 3D; Supplemental Figure 3).

Intraoperative transesophageal echocardiogram was performed intermittently throughout the procedure and demonstrated the absence of pericardial or pleural effusion as well as normal pulmonic and tricuspid valve structure and function. No acute complications were noted in the postprocedural period.

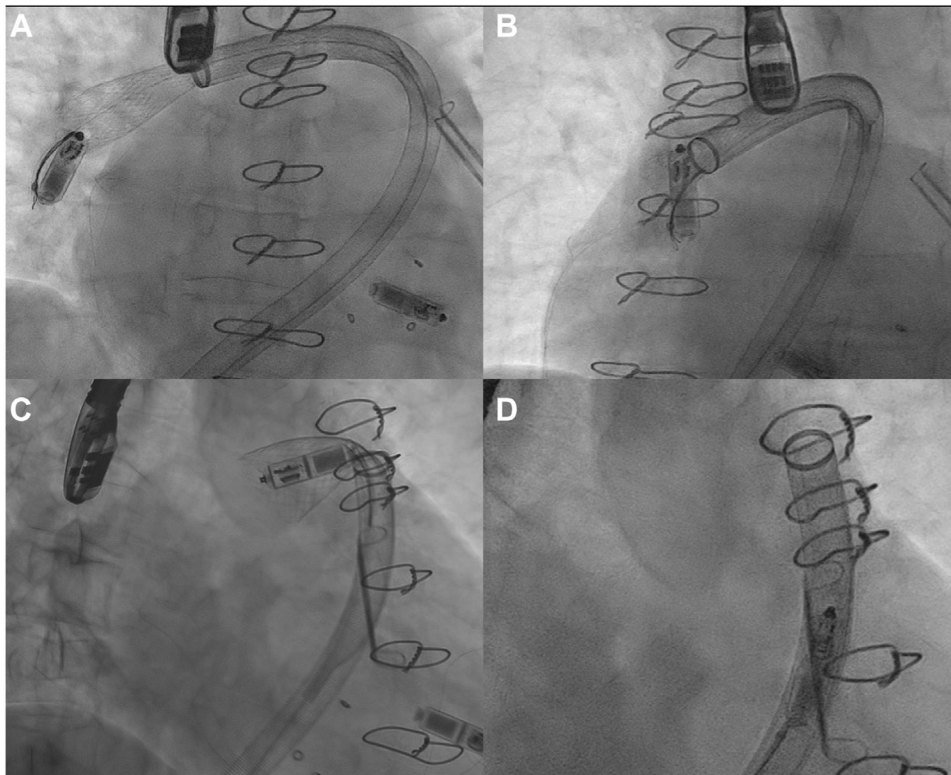


Figure 3 Spot fluoroscopic images. **A:** Successful snaring of the distal flange of the Micra. **B:** Perpendicular orientation of the branch vessel preventing coaxial orientation with the sheath. **C:** Successful capture within the ONO (ONOCOR LLC) after repositioning the outer sheath and ONO within the larger lumen of the proximal right pulmonary artery. **D:** Retrieval of Micra with the ONO into Gore DrySeal Sheath, distal to the pulmonary valve.

Discussion

The retrieval of leadless pacemakers from the pulmonary arterial system presents the unique challenge of protecting both the tricuspid and pulmonic valves. Snaring directly from the PA with device retraction through both the pulmonary and tricuspid valves has been reported. However, this method risks device entanglement in the tricuspid apparatus, particularly if the device is retracted via its retrieval flange, as this orients the nitinol tines opposite to the direction of transit.^{3–5} Previous reports have described successful retrieval of a Micra device in the PA with a Gore DrySeal sheath and the INARI T24 Flowtriever (Inari Medical, Irvine, CA). The Flowtriever sheath is an attractive alternative to the Gore DrySeal because it was designed specifically for use in the PA and can perform aspiration if inadvertent clot forms during the procedure. Previous reports describe the use of single snares, tri-looped snares, or a double snare technique in combination with a large sheath to facilitate capture of the device and protection of the pulmonic valves.^{4–6}

This is the first reported use of the ONO retrieval device for a leadless pacemaker in humans. The device is a 12F system using a series of braided nitinol loops forming a basket, fused to a 7.5F inner diameter catheter. Tension on the catheter translates into radial compression forces at the basket like a 1-sided finger trap (Supplemental Figure 4). This device

received FDA approval in May of 2022. The device can be snared just enough to pull it into the basket of the ONO. Once in the nitinol basket, compression of the basket orients the device in a coaxial fashion and “swallows” it into the DrySeal sheath.

The Micra leadless pacemaker has a distal flange designed to be used for repositioning and return into the introducer sheath during placement. Retrieval is typically easiest at the time of placement when a tether suture is secured to the distal end of the device and allows direct tension on the device without the need for snaring. Following implantation and release of the tether suture, retrieval becomes more difficult, especially if these efforts are delayed. In this case, the device had become lodged in the distal PA branch and maneuvers were required to free it prior to snaring.

To internalize the device into a sheath, coaxial orientation must be maintained. The Micra is 6.7 mm in diameter, leaving little margin for off-axis internalization into a sheath. While the Micra has a retrieval flange on the back end of the device, the orientation within the PA in our case, with flange oriented distally, limited direct snaring and tension from the back of the device. Sometimes, distal branches of the PA are not large enough to allow flipping of a Micra on its long axis. The first retraction resulted in the device being flipped perpendicular to the sheath (Figure 3B). To troubleshoot this, previous reports describe the use of a double snare

technique and utilization of the tines to control both sides of the device.⁴ The nitinol tines are unfolded when delivered and are designed to be flexible, so snaring the tines directly will often not lead to a successful retrieval, as the tines will deform once traction is applied. The basket retrieval device allowed for easy repositioning without the risk of unfolding the tines and was also easily redeployed and retracted to optimize basket size and engagement angle with the device for retrieval into the sheath. After the device was brought to the edge of the sheath, tension was placed on both the snare and the basket retrieval device to maintain correct orientation during retraction into the sheath.

Conclusion

This is the first described use of a novel basket retrieval device for foreign body retrieval in humans. This device may represent a promising alternative to the double snare technique and allow for protection of high-risk structures, such as cardiac valves, during complex foreign body retrievals, especially in the case of embolized leadless pacemakers.

Appendix Supplementary Data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hrcr.2022.12.015>

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