Retrieval of an infected leadless pacemaker

Kristin Ellison, MD, FHRS, Aaron Hesselson, MD, FHRS, Karam Ayoub, MD, Steve Leung, MD, John Gurley, MD

From the Division of Cardiovascular Medicine, Gill Heart & Vascular Institute, University of Kentucky, Lexington, Kentucky.

Introduction

Leadless pacing systems are a viable alternative when extraction of an infected conventional pacing system is required. Leadless pacemakers have also shown resistance to infection even when inserted at the time of or shortly after conventional system extraction.[1,2] Our case documents the rare occurrence of Micra Transcatheter Pacemaker System (Medtronic, Minneapolis, MN) infection in a patient with chronic recurrent transvenous device infection and the successful retrieval of this infected device 4 months after implantation.

Case report

A 37-year-old woman with past medical history of Crohn disease and neurocardiogenic syncope status post leadless pacemaker implantation was admitted with sepsis. Three years prior to presentation, she underwent dual-chamber pacemaker implantation for neurocardiogenic syncope. A year later, she underwent atrial lead revision, which was complicated by sepsis from pocket infection, leading to complete device extraction. Another dual-chamber pacemaker was subsequently implanted on the contralateral chest position. This system required a ventricular lead revision that was again complicated by pocket infection and bacteremia secondary to methicillin-resistant *Staphylococcus aureus* and *Acinetobacter*. As a result, that system was also extracted, and a leadless pacemaker (LP) system (Micra; Medtronic) was implanted. A month after implantation, the patient presented to an outside facility with fever, and was treated with several regimens of oral and intravenous antibiotics for a total of 4 weeks. This included vancomycin, meropenem, ceftriaxone, cefdinir, and doxycycline. The hospital course was complicated by pancytopenia, central venous catheter–associated deep vein thrombosis requiring systemic anticoagulation, and *Candida albicans* fungemia requiring antifungal therapy with micafungin.

Owing to recurrent fevers of unknown origin, the patient was transferred to our hospital for further management. After arrival, extensive evaluation was performed to identify the source of infection. We decided to further evaluate the LP as a potential source of infection, and intracardiac echocardiographic (ICE) imaging of the device was obtained. ICE images showed frond-like material on the surface of the LP measuring 1.3 cm by 0.5 cm (Figure 1). Differential diagnosis of the frond-like material was thrombus vs vegetation. A chest computed tomographic scan localized the device in the right ventricular outflow tract (RVOT) (Figure 2). Based on this clinical scenario, we had high suspicion of LP infection. Therefore, the patient was taken to the catheterization lab for LP extraction under conscious sedation.

A 4F left femoral artery sheath was placed for blood pressure monitoring and a 9F sheath was placed in the left femoral vein for an 8F AcuNav (Biosense Webster, Irvine, CA) ICE catheter. Using the ICE catheter, the atrial septum was evaluated and showed no evidence of patent foramen ovale or atrial septal defect. A 6F sheath was placed in the right femoral vein for venous access. The 6F sheath was removed over a guide wire, and the puncture site was dilated with a 10 × 40 mm DORADO balloon (Bard, Temple AZ) and a purse-string rubber tourniquet was applied for

KEY TEACHING POINTS

- The incidence of infection of leadless pacemaker is rare.
- Leadless devices can be implanted at the time of or shortly after extraction of an infected conventional device without risk of seeding a new device.
- Intracardiac echocardiography catheter is helpful to diagnose device infection and facilitate device retrieval.
- Extracorporeal membrane oxygenation cannula can be modified to explant the Micra device (Medtronic, Minneapolis, MN).

KEYWORDS Cannula; Device infection; Device retrieval; Intracardiac echocardiogram; Leadless pacemaker
(Heart Rhythm Case Reports 2020;6:863–866)

Funding Sources: The authors have no funding sources to disclose. Disclosures: The authors have no conflicts of interest to disclose. **Address reprint requests and correspondence:** Dr Kristin Ellison, Division of Cardiovascular Medicine, The Gill Heart & Vascular Institute, 900 South Limestone St, CTW 326, Lexington, KY 40536. E-mail address: keel233@uky.edu.

https://doi.org/10.1016/j.hrcr.2020.08.022

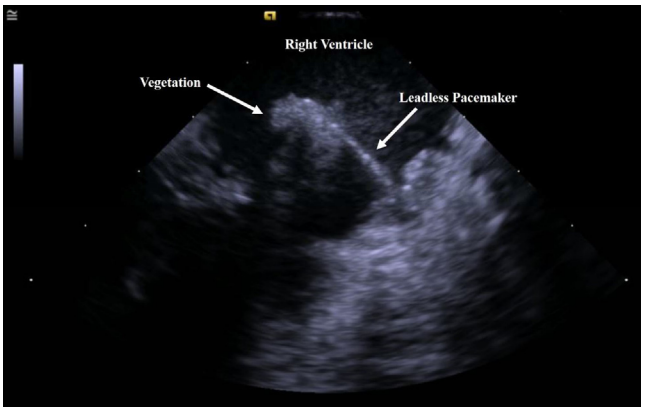

Figure 1 Intracardiac echocardiogram (ICE) image. The ICE catheter is positioned in the right ventricle, and it showed a large mobile vegetation attached to the pacemaker.

hemostasis. The balloon was removed, and a modified 28F Edwards venous cannula (28F × 68 cm) was inserted under fluoroscopy and advanced to the inferior vena cava/right atrial junction. This catheter is commonly available and of adequate size to retrieve a Micra device without the need to use a new Micra system. The cannula was punctured and accessed with a standard 7F sheath delivered directly into the cannula to enable continuous flush through the system to prevent catheter-related thrombosis. A balloon wedge catheter was used to deliver an 0.035-inch Amplatz super stiff guide wire into the left pulmonary artery. The venous cannula with a dilator over the guide wire was then advanced to the RVOT. The dilator and guide wire were then removed. The cannula could then be withdrawn (not pushed) to the proximity of the LP. A 6F Goose Neck snare (25 mm loop diameter × 120 cm) was delivered beyond the LP and was then able to loop around the device with pull-back.

Under fluoroscopic and ICE imaging, the LP appeared fixated at the boundary of the septum and the lateral wall, with the button retrieval feature end directed toward the RVOT. This correlated with the computed tomographic images. Initially, the LP body was snared and mobilized from the RVOT into the body of the right ventricle. The proximal button end became more amenable for retrieval. The button was successfully grasped with the snare (Figure 3). The device was slowly retracted across the tricuspid valve, avoiding any pulling on the TV apparatus. The LP was guided into the 28F cannula under ICE guidance. It was completely removed from the body and the tip was sent for culture and surgical pathology analysis. The patient tolerated the procedure without any hemodynamic compromise. There was no pericardial effusion documented by ICE.

Pathologic analysis showed soft tissue fragments wrapped around the device. Cultures and Gram stain from the device were negative. An additional set of blood cultures obtained the day after removal were positive for *C. albicans*. She continued treatment of her fungemia. All subsequent blood cultures over the following 2 weeks prior to discharge were negative. The patient remained clinically stable and was discharged home without the need to reimplant a pacemaker.

Discussion

There are 2 leadless pacing systems currently in use: the Micra transcatheter pacing system and the Nanostim Leadless Cardiac Pacemaker (Abbott, Lake Bluff, IL). The Nanostim is not currently FDA approved and has had 2 major recalls related to premature battery depletion and detachment of the docking button, which facilitates retrieval. Micra was FDA approved in 2016. The fixation mechanisms differ between these devices. Micra has nitinol tines that requires a larger sheath to implant and Nanostim has a screw-in helix

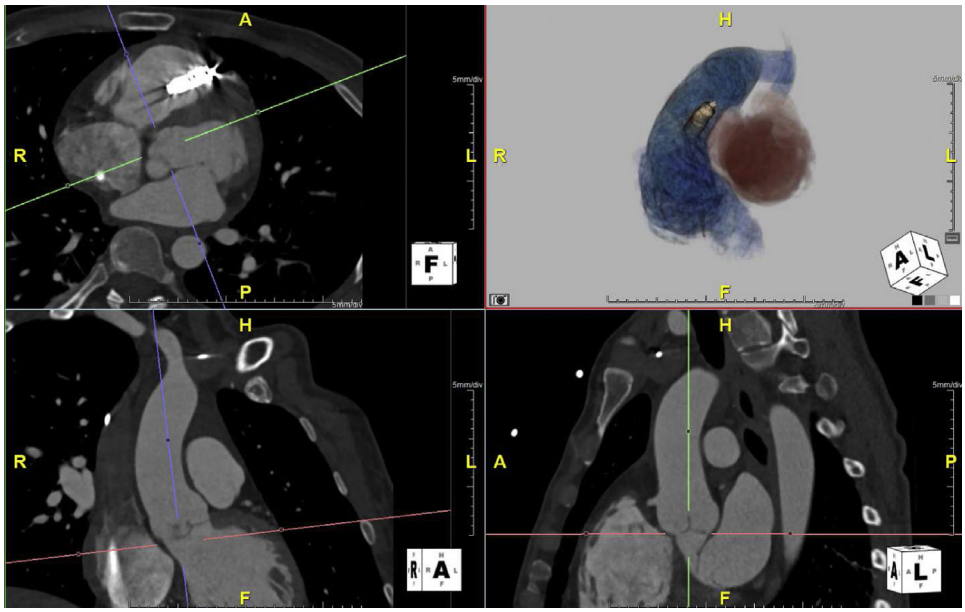

Figure 2 Pre-extraction chest computed tomographic scan. Three-dimensional reconstruction of the leadless pacemaker confirms its position in the right ventricular outflow tract.

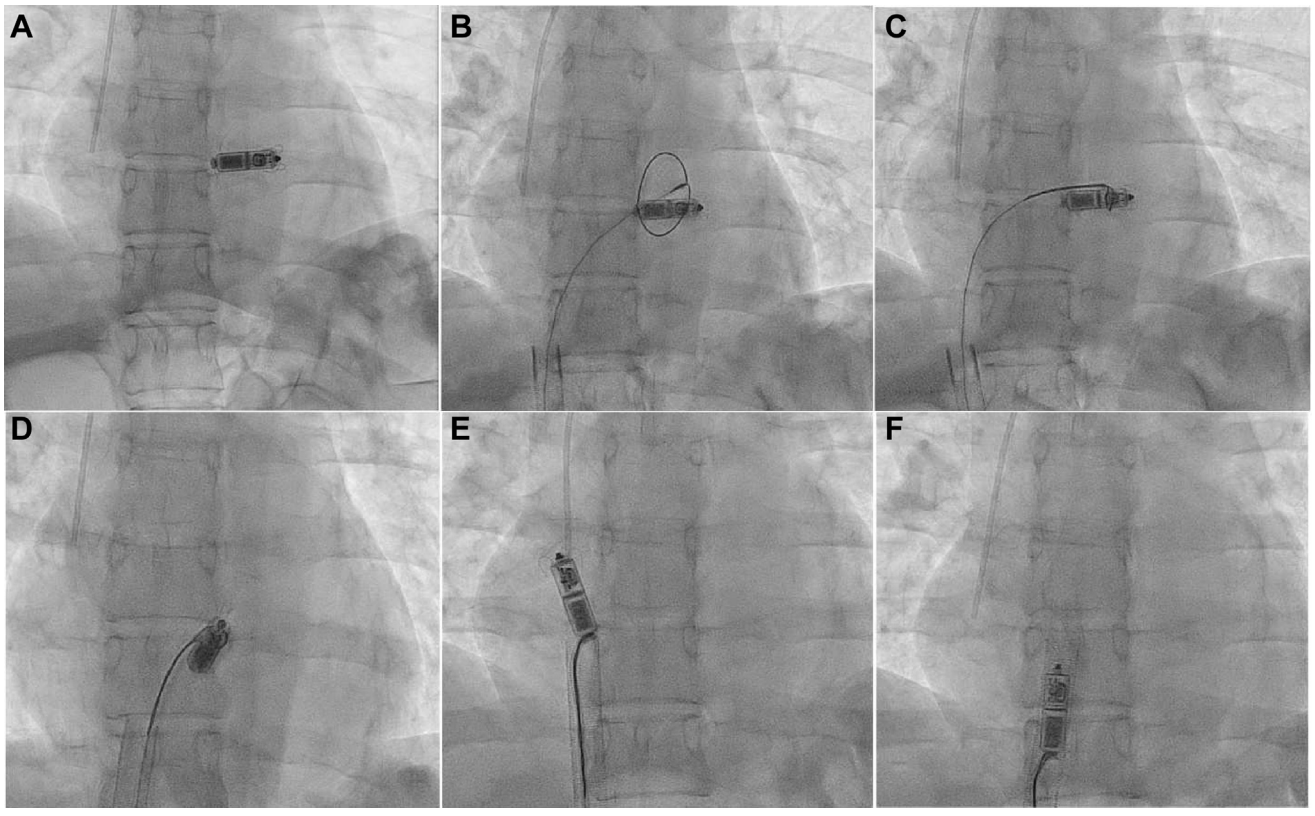

Figure 3 Device retrieval process under fluoroscopy. **A:** At the beginning of the procedure, the device was visualized on fluoroscopy. **B:** Under ultrasound guidance, a 28F Edwards venous cannula was inserted and advanced to the junction between the inferior vena cava and the right atrium. The system was advanced to the right ventricular outflow tract to deliver the snare and then pulled back as described in text. **C:** A snaring tool was advanced through the 28F cannula and grasped the leadless pacemaker. **D–F:** The device was then slowly retracted and pulled back into the cannula.

fixation mechanism. Nanostim is a longer device at 41.4 mm while Micra is 25.9 mm. The sensor for the Micra is an accelerometer and Nanostim has a temperature-driven sensor.[3] Several trials have documented negligible infection rates after implantation of both LPs.[2,4,5] As of 2019, the Micra clinical trials have enrolled more than 2500 study participants without any reported device-related infections.[5] A 2019 e-mail advertisement from Medtronic reports that a total of 50,000 Micras have been implanted worldwide. To date there has been only 1 other case report of documented Micra infection.[6] LPs are felt to be resistant to infection owing to the lower surface area, no device pocket, turbulent right ventricular flow, and subsequent device encapsulation. The Micra transcatheter pacemaker is largely encased titanium with a parylene coating. A recent study by El-Chami and colleagues[1] documented that the perylene coating on titanium provided bacterial resistance to *S. aureus* and *Pseudomonas aeruginosa* compared to bare titanium and postulated this to be a potential mechanism of the device's bacterial resistance. A substudy of the Micra Transcatheter Pacing study reviewed the incidence and outcomes of patients who developed serious infectious events (bacteremia or endocarditis) after Micra implantation.[2] Among the 720 patients implanted in the investigational trial, 15 patients had 21 serious infectious events. These occurred at a mean of 4.8 ± 4.5 months after implant. Patients were followed for an additional 13 ± 9.5 months. All events were adjudicated and determined to be unrelated to Micra device or implant procedure, and no persistent bacteremia was seen after antibiotic treatment. Beurskens and colleagues[4] reported on 17 patients with early and late implant of leadless devices after extraction of an infected conventional pacing system. Eleven patients were implanted with Nanostim and 6 with Micra. Six patients had early implantation of less than 1 week after extraction and 11 patients were implanted greater than 1 week after extraction. There were no LP infections during the mean follow-up of 20 ± 14 months. Kypta and colleagues[7] demonstrated similar findings in 6 patients who were pacer dependent and had infected conventional pacemakers removed. Two of these patients had the LP device implanted at the time of extraction. The remaining 4 patients had temporary wires placed and had the LP placed 2 hours to 2 days after extraction. All patients stayed free of infection during a 12-week follow-up. Positron emission tomography was done on all patients, and there were no signs of infection around the leadless device. In 2016, Koay and colleagues[6] published a case study of an infected transcatheter pacemaker treated with percutaneous extraction. The patient was an 80-year-old woman with recurrent urinary tract infections and atrial fibrillation with rapid ventricular

response and bradycardia. A Micra LP was implanted to facilitate rate control. The patient had an uneventful implant and received perioperative cefazolin. One month later, she developed fever and chills and had blood cultures positive for methicillin-resistant *S. aureus*. Transesophageal echo demonstrated a 1.2 × 0.9 cm vegetation. Blood cultures remained positive despite directed antibiotic therapy, and the decision was made to extract the device.

This device was successfully extracted using the Micra delivery sheath, an 8.5F Agilis steerable sheath, and a 6F Amplatz Goose Neck Snare (Medtronic). The proximal button retrieval feature was captured, and the device was pulled into the sheath. With counter-traction, the entire system was removed. The patient received antibiotics for 6 weeks, and blood cultures became negative. In our case, there was no echocardiographic evidence of atrial septal defect. In situations where patent foramen ovale or atrial septal defect are present, one can consider using distal embolic protection devices to prevent cerebrovascular accidents secondary to right-to-left paradoxical embolization.[8]

In 2016 Reddy and colleagues[9] reviewed the retrieval experience of 9 centers and 16 patients with leadless devices and showed a 94% retrieval success rate with no 30-day complications. All 5 patients with implant duration <6 weeks were successful at removal. Ten of the 11 (91%) of the chronic retrievals ≥6 weeks (range 88–1188 days) had successful explant. None of these devices were removed on account of infection.

The Micra delivery sheath is not separately available from the pacing generator. Our methodology for removal was devised so as to not "waste" the cost of an unused generator. Because the sheath used for our extraction is generally available, this would seem a more cost-efficient process than those described using a Micra delivery sheath for subsequent removal.

Conclusion

Our case documents the rare finding of LP infection and successful retrieval of the device at 120 days. The device was initially repositioned into the RV cavity from the outflow tract with the snare and ICE guidance. This enabled the retrieval button to be snared and careful retraction of the device through the tricuspid apparatus. A novel catheter system was constructed utilizing an extracorporeal membrane oxygenation sheath cannulated with a 7F sheath to allow continuous irrigation through the system.

Our patient was immunocompromised with indwelling lines and 2 prior device extractions. She received several rounds of high-dose antibiotic therapy and in that setting developed fungal sepsis. Her ICE images demonstrated impressive frond-like material attached to the device. The differential of thrombus vs vegetation favored vegetation based on persistent blood cultures being positive for *C. albicans* and the material developed in the setting of therapeutic rivaroxaban. Cultures from her system were negative, but her blood cultures cleared after device explant and antifungal therapy. This is a very unusual clinical scenario, and in general Micra implantation after infected conventional device removal is a viable strategy. An LP implant can not only avoid need for temporary pacing systems and their inherent risks, but also decrease the risk of future device infections. In our patient, the initial indication for implanting a pacemaker in neurocardiogenic syncope is controversial and she had no immediate pacing indication; as such, we were fortunately able to defer reimplantation.

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