Extraction of a 5-year-old leadless pacemaker using a competing manufacturer's removal tool

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Introduction

Leadless cardiac pacemakers (LCP) became commercially available in Europe in 2012. Since that time, implant volumes have steadily grown as the capabilities of these devices have improved beyond simple VVI pacing. Additional advances to these devices, including dual-chamber leadless pacing, conduction system pacing, and the ability to pair with extravascular or subcutaneous defibrillators, are among the advances already in development. These will almost certainly further expand the role and implant volumes for LCPs. Growing numbers of implanted LCPs will likely be accompanied by growing numbers of devices that need to be extracted.

While the Medtronic Micra Transcatheter Pacing System (TPS) (Medtronic, Minneapolis, MN) includes a design feature or knob on the proximal end to allow snaring and removal, there are reports of complete encapsulation over time, and the manufacturer generally recommends abandoning these devices at end of life.[1,2] Several reports describe successful removal of Micra LCPs, although most describe removal of devices relatively soon after implant. Dar and colleagues[3] reported a single-center experience of the removal of 40 Micra LCPs with a mean implant time of 46 days, with the oldest device removed at 95 days. Grubman and colleagues[4] describe a cohort of patients with Micra TPS retrieval out to 406 days post implant, and El-Chami and colleagues[5] have described a single case of Micra TPS extraction at approximately 4 years. In this case, we describe the successful extraction of a 5.5-year-old (67 months) Micra TPS using the Aveir (Abbott, Abbott Park, IL) retrieval catheter. To our knowledge, this case is notable, as it represents the longest published Micra dwell time to be removed and the first published description of the use of the Abbott Aveir removal tool to extract a Micra LCP.

KEY TEACHING POINTS

- Leadless cardiac pacemaker volumes are expanding and may continue to grow as capabilities grow. With expanding implant volumes, more of these devices may require extraction.
- Little is known about the safety and feasibility of extraction of the Micra LCP with dwell times greater than 1 year.
- Currently available extraction tools are limited, but use of tools across competing manufacturers, where able, may help expand options.

Case report

A 38-year-old male patient with a nonischemic cardiomyopathy, a history of intravenous drug use complicated by recurrent endocarditis, and multiple open heart surgeries presented with bioprosthetic aortic valve stenosis and worsening heart failure symptoms in the setting of chronic right ventricular (RV) pacing. He first developed infective endocarditis in 2015 and underwent aortic valve replacement and debridement of an aortic root abscess. He developed tricuspid and prosthetic aortic valve endocarditis in 2017 and underwent redo sternotomy with mitral valve replacement and redo aortic valve replacement. He developed high-degree atrioventricular block and had a Micra VR TPS implanted in March 2017. At the time, the LCP was chosen in hopes it would minimize the risk of recurrent infection. (Although there are no guidelines addressing the treatment of cardiac implantable device infection with LCPs, existing data support a lower risk of infection with LCP compared to transvenous leads.) This was later turned off and a biventricular implantable cardioverter-defibrillator (ICD) was implanted in August 2017. In October 2019, the biventricular ICD was extracted and the Micra TPS turned back on after the patient developed methicillin-sensitive Staphylococcus aureus bacteremia. The patient abstained from further intravenous drug use and had no further infection; however, he developed severe bioprosthetic aortic valve stenosis and worsening heart failure symptoms with a left ventricular ejection fraction of 15% and recurrent admissions for decompensation. He was admitted in October 2022 and underwent

KEYWORDS Leadless pacemaker; Extraction; Femoral extraction; Micra; Aveir

(Heart Rhythm Case Reports 2023;9:441–444)

Funding Sources: None. Disclosures: Thomas Callahan: Consultant: Biotronik, Philips (modest); Bruce L. Wilkoff: Consultant, Research and Speaker: Medtronic, Boston Scientific, Abbott, Biotronik, Philips, Cook, Xcardia (modest). **Address reprint requests and correspondence:** Dr Thomas D. Callahan, IV, Dept of Cardiology, J2-2, Cleveland Clinic, 9500 Euclid Ave, Cleveland, OH 44195. E-mail address: callaht@ccf.org.

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https://doi.org/10.1016/j.hrcr.2023.04.004

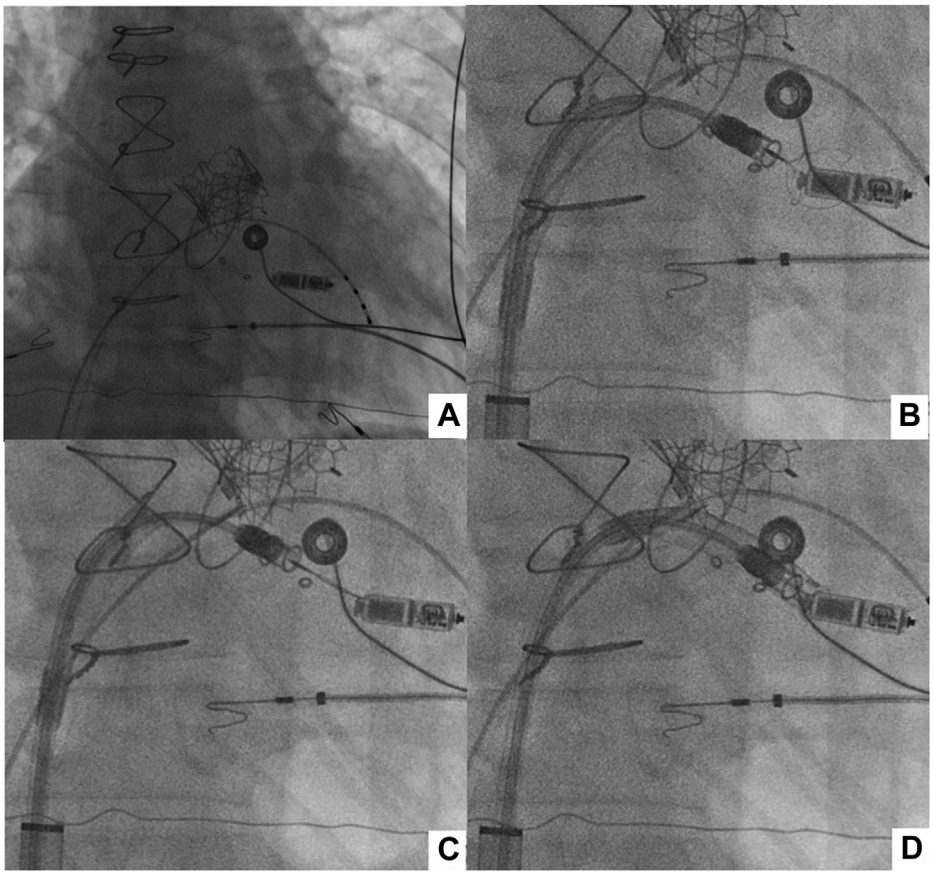

Figure 1 The Micra Transcatheter Pacing System (Medtronic). **A:** In position; **B, C:** being snared; **D:** with protective sleeve over proximal portion.

transcatheter aortic valve replacement. A device interrogation confirmed sinus rhythm and complete heart block with >99% asynchronous RV pacing. An electrophysiology consult was called to consider implantation of a new biventricular device. After a careful shared decision-making discussion with the patient, he expressed his desire to have all nonessential hardware removed if possible. While multiple reports describe the safe removal of LCPs, including extraction of Micra devices with dwell times of up to 4 years, a paucity of existing data makes complication rates difficult to estimate. In accordance with the patient's wishes, we planned to attempt extraction of the LCP at the time of the biventricular ICD implantation with the understanding that attempts at extraction would be abandoned if intraoperative features or technical challenges suggested escalating risk.

Under general anesthesia, femoral venous access was obtained for intracardiac echo to facilitate imaging of the device and assist in guiding the snare. A temporary pacing wire was also placed via a second venous access and a third femoral venous access was obtained for a 26F sheath.

Fluoroscopy revealed the LCP positioned in the RV apical septum (Figure 1A). Intracardiac echocardiography imaging demonstrated the LCP in the right ventricle with the button standing in the RV cavity, unimpeded by trabeculations or the tricuspid valve apparatus. The Abbott Aveir steerable retrieval sheath was advanced to the right atrium and then across the tricuspid valve. Using intracardiac ultrasound and fluoroscopy, the snare was advanced over the LCP, and the button was secured (Figure 1B and 1C). The LCP was docked with the extraction tool, and the protective sleeve was advanced over the device (Figure 1D). With application of traction to the snare and countertraction with the sleeve against the endocardial tissue, the LCP was freed from the myocardium and removed via the 26F sheath (Figure 2A–2D). Intracardiac echocardiography imaging after removal seemed to show a tissue cast. Examination of the extracted LCP revealed no adherent encapsulation or myocardial tissue (Figure 3). The patient remained hemodynamically stable, and the case proceeded to successful placement of the biventricular device.

Discussion

With growing implant volumes, it is likely the number of patients requiring removal of LCPs will also expand. While some LCPs are designed for removal at end of life, others, such as the Micra TPS, are not, and dedicated tools for late extraction are limited. The Medtronic Micra fixates to the RV endocardium with 4 tines, which secure the device within the RV trabeculations. Device design includes a knob on the proximal end of the device to facilitate capture with a snare. However, over time the device may become encapsulated,

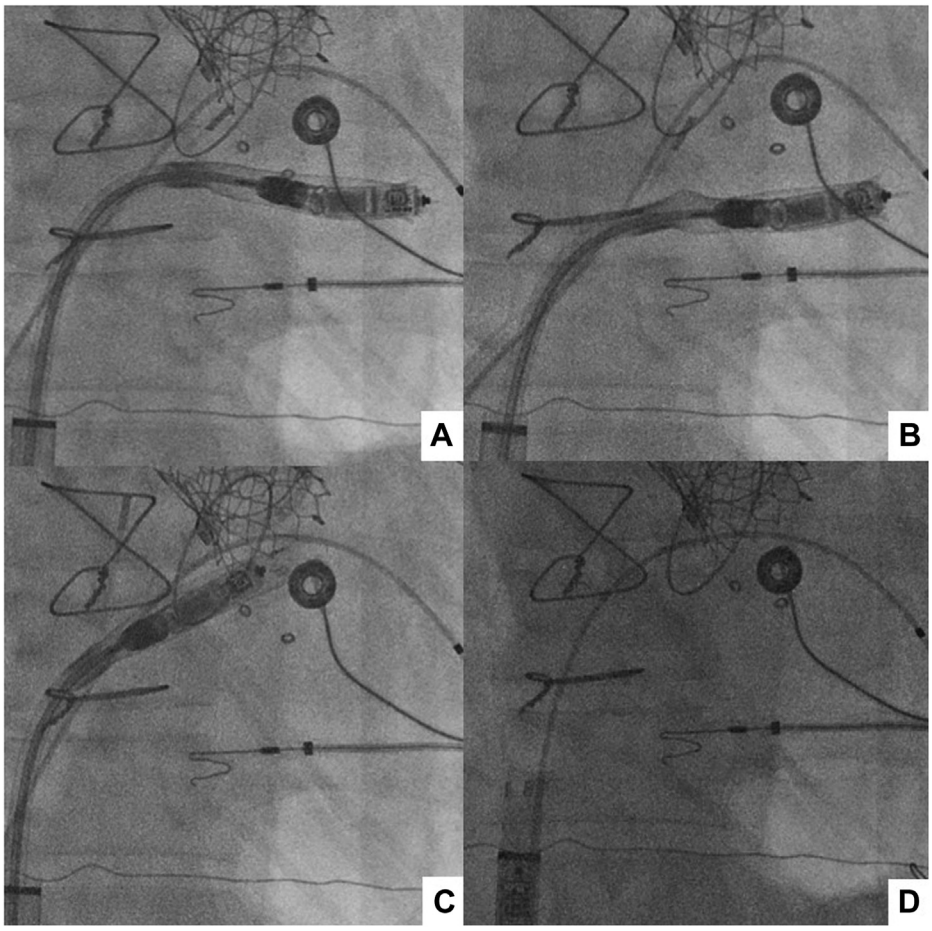

Figure 2 Micra Transcatheter Pacing System (Medtronic): **A:** with protective sleeve advanced to distal edge; **B:** applying traction and countertraction; **C:** released from myocardium; **D:** removed into 26F sheath.

making it more difficult to remove. Published techniques for extraction include use of a snare through a Micra delivery sheath and use of a snare through a steerable sheath. However, the Micra delivery sheath currently is only available with a new device and most steerable sheaths are too small to slide over the Micra TPS. Although capturing the proximal knob with a snare through a steerable sheath allows traction to be applied to remove the device, since the sheath cannot be advanced over the TPS, this technique does not allow application of countertraction.

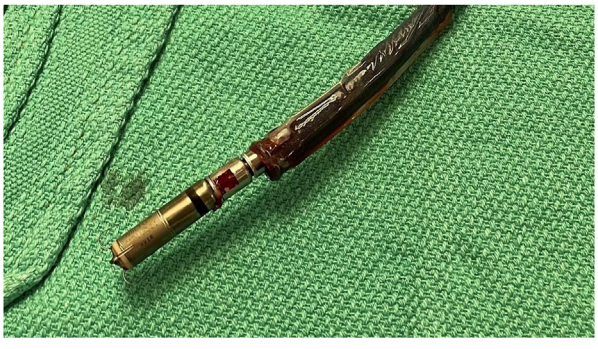

Figure 3 Micra Transcatheter Pacing System (Medtronic) ex vivo after extraction.

The Abbott Aveir LCP fixes to the myocardium with a helix and is designed to be removed using a dedicated retrieval tool. The tool includes a multi-loop snare and a protective sheath that can be advanced over the LCP once it has been snared. While the outer diameter of the Aveir LCP is smaller than that of the Micra (6.44 mm vs 6.7 mm), the protective sleeve is flexible and designed with additional tolerance, meaning it can be advanced over a Micra TPS. In addition to providing countertraction to the myocardium and encapsulated tissue, advancing the protective sleeve over the Micra TPS before applying traction may help ensure that components of the subvalvular apparatus are not trapped in the snare, as these would likely prevent the sleeve from advancing to the distal end of the device.

Much remains to be done to better understand the safety and efficacy of late LCP extraction. Extraction of these devices comes with some risk of serious complications, such as myocardial perforation, tamponade, and injury to the tricuspid valve. Further studies are warranted to guide decisions about when to extract and which patients present the highest risk. Additionally, improvements in preoperative testing, imaging, and dedicated tools are needed. We describe a case of successful Micra LCP extraction at 5.5 years (67 months) using the Aveir extraction tool.

Conclusion

This case reports the removal of a Micra TPS with a dwell time greater than 5 years using the Aveir removal catheter. This report may help guide advances in late LCP extraction.

Appendix

Supplementary Data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrcr.2023.04.004.

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