An approach to the removal of a leadless pacemaker with proximal and distal generator adherence to the myocardium

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Introduction

As Pinocchio eschewed his proverbial strings, the implanted cardiac pacemaker has also evolved the ability to provide therapy for brady-arrhythmias without the burden of being tethered to intravascular leads or a device pocket.

The small, completely intracardiac, leadless pacemakers provide a parsimonious alternative to the traditional single or dual chamber pacemaker, and they are of particular interest for patients who are expected to have a low burden of pacing or in whom long-term retention of intravascular hardware could result in adverse clinical outcomes.[1,2] While the Abbott/St. Jude Medical (St. Paul, MN) Nanostim pacemaker was recalled in 2016 owing to rare battery failures and potential dislodgement of the docking mechanism, it was implanted in many patients without issue.[3] The Medtronic (Minneapolis, MN) Micra device has been commercially available for several years with favorable acute and long-term outcomes as further support of this field of leadless technologies.[4,5] A more recent addition to the field of leadless pacemakers is the Abbott Medical (Abbott Park, IL) Aveir DR pacemaker system, which offers the possibility of true dual chamber pacing with the addition of a second leadless pacemaker that can be implanted in the right atrium and communicates wirelessly with a ventricular leadless pacemaker.[6]

The record for leadless pacemakers thus far shows that they can be safe and efficacious alternatives to transvenous pacemakers, and with continued refinement, it is likely that the volume of devices implanted will continue to grow over time. However, a proportion of these devices will likely need to be repositioned or removed.

KEY TEACHING POINTS

- The location of a right ventricular leadless pacemaker implant along interventricular septum has important implications for the feasibility of future device retrieval.
- Current retrieval tools for leadless pacemaker devices are limited, and they require access to the leadless pacemaker's proximal docking button. Creative problem solving may be required if the docking button is not readily accessible.
- As this technology is relatively novel, it is likely that we have yet to see the full range of experiences related to leadless pacemaker removal and long-term complications.

There has been some short-term experience with retrieval of these devices, including high procedural success during retrieval of the Nanostim device, with retrieval success in >90% of attempted cases.[7] In addition, successful removal of Micra devices using a variety of tools has been demonstrated in several cases.[8–11] However, despite high success rates, complications of attempted retrieval of leadless pacemakers can result in avulsion of myocardial tissue or tricuspid valve, and accordant surgical repair.[12,13] One purported benefit of the Aveir device is that it is designed with an integrated docking button intended to interface with a purpose-built tool specifically for its retrieval.[14,15] The relative novelty of the device limits our understanding of the real-world success of this approach, particularly in cases when the device has been in place for the entirety of its expected lifetime of ≥10 years.

Here, we present the case of a patient in whom an Aveir implantation resulted in suboptimal pacing parameters and subsequent need for complex removal of the leadless pacemaker device owing to distal and proximal myocardial adherence.

KEYWORDS Cardiovascular implantable electronic devices; Lead extraction; Leadless pacemaker; Aveir; Snare; Leadless pacemaker retrieval; Pacemaker complication

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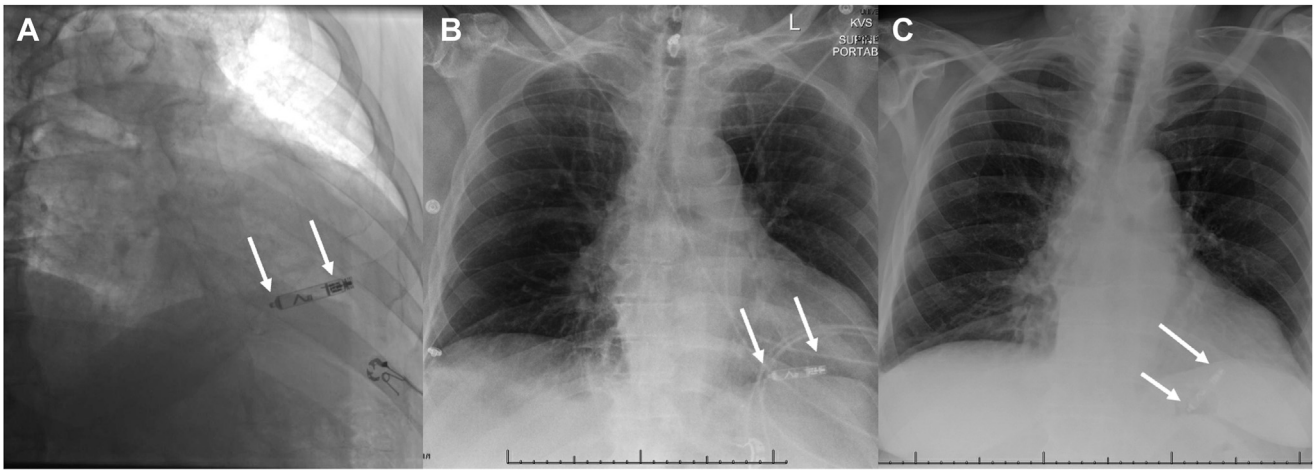

Figure 1 The figure shows the initial device (*arrow*) implant fluoroscopic imaging in an anterior-posterior projection (**A**) and the chest radiograph 1 day after implantation (**B**). **C:** The chest radiograph shows the device location approximately 6 months after implantation that was associated with a significant increase in pacing threshold.

Case report

An 82-year-old male patient with permanent rate-controlled atrial fibrillation, baseline conduction system disease with a bifascicular block, and several syncopal episodes underwent monitoring with 7 days of continuous mobile cardiac telemetry, which demonstrated long ventricular pauses during atrial fibrillation and waking periods of atrial fibrillation with slow ventricular response. Given his unexplained syncope and poor baseline conduction, he was referred for pacemaker implantation. The patient stated that he was active at baseline, and he attributed his overall good functional status to frequent aerobic physical activity. He therefore expressed some concern regarding arm restrictions and care of a pacemaker pocket wound. After an extensive and shared decision-making discussion, the patient elected to proceed with an Aveir VR leadless pacemaker implant in June 2023.

The initial parameters (R wave, 5.0 mV; threshold, 1.75 V @ 0.4 ms; impedance, 480 Ω) and position of the device were favorable (Figure 1A and 1B). A chest radiograph on the following day showed a stable position relative to the procedural fluoroscopic image with a proximal inferior tilt device location. The pacing parameters remained stable (R wave, 5.5 mV; threshold, 2.0 V @ 0.4 ms; impedance, 500 Ω), and the patient was discharged. At his 1-week follow-up appointment, his pacing parameters remained stable (threshold, 0.75 V @ 0.4 ms; impedance, 490 Ω). At follow-up in January 2024, it was noted that the RV capture threshold had increased (R wave, 4.5mV; threshold, 3.75 V @ 1.0 ms; impedance, 300 Ω), and the battery longevity was estimated at only 10 remaining months. A chest radiograph revealed significant inferior displacement of the proximal end of the device (Figure 1C). The patient was scheduled for removal of the leadless pacemaker with expectant implant of a new one in February 2024.

Under monitored anesthesia care, femoral access was obtained in the right femoral vein (RFV) and pre-closed with two Perclose devices. The venotomy was serially dilated to 24F, and the Abbott Aveir retrieval introducer sheath was placed in the RFV, through which an Aveir retrieval device was inserted and directed first to the right atrium and then to the right ventricle (RV) under fluoroscopic guidance.

Both a prior chest radiograph and initial cardiac fluoroscopy revealed that the leadless pacemaker was located in the RV apical septum, with the proximal button angled inferiorly (Figure 1) and limited proximal device movement during systole only. Initial attempts at maneuvering the Abbott LP retrieval catheter to the proximal button were impeded by what we suspected were RV trabeculations covering the proximal button, and although we seemed to be able to bump the body of the leadless pacemaker with the Abbott Medical tri-leaflet snare retrieval catheter system, the button could not engage with the snare (Figure 2A, Supplemental Video 1) and never displayed independence from the inferior ventricular wall.

A second venous access was obtained, with an 8F short sheath through which we introduced a deflectable quadripolar catheter directed toward the leadless pacemaker in an attempt to dissect free the septal aspect of the pacemaker and "lift" the proximal button enough to allow the retrieval catheter to access the button (Figure 2B). Although we were able to wiggle the device with the quadripolar catheter, the force needed to free the pacemaker was greater than that required maintain the curve around pacemaker (Supplemental Video 2). We did inadvertently snare the quadripolar catheter while it was wrapped around the leadless pacemaker (Figure 2C, Supplemental Videos 3, 4), and attempts at traction using this apparatus confirmed that the proximal button of the leadless pacemaker was indeed firmly stuck within RV trabeculation.

Given that we could not access the proximal button of the leadless pacemaker, we obtained a third venous access in the LFV with a long 16F Cook sheath, through which we made an attempt to secure the device with a Cook Needle's Eye Snare (Supplemental Figure 1A). Although we were able to

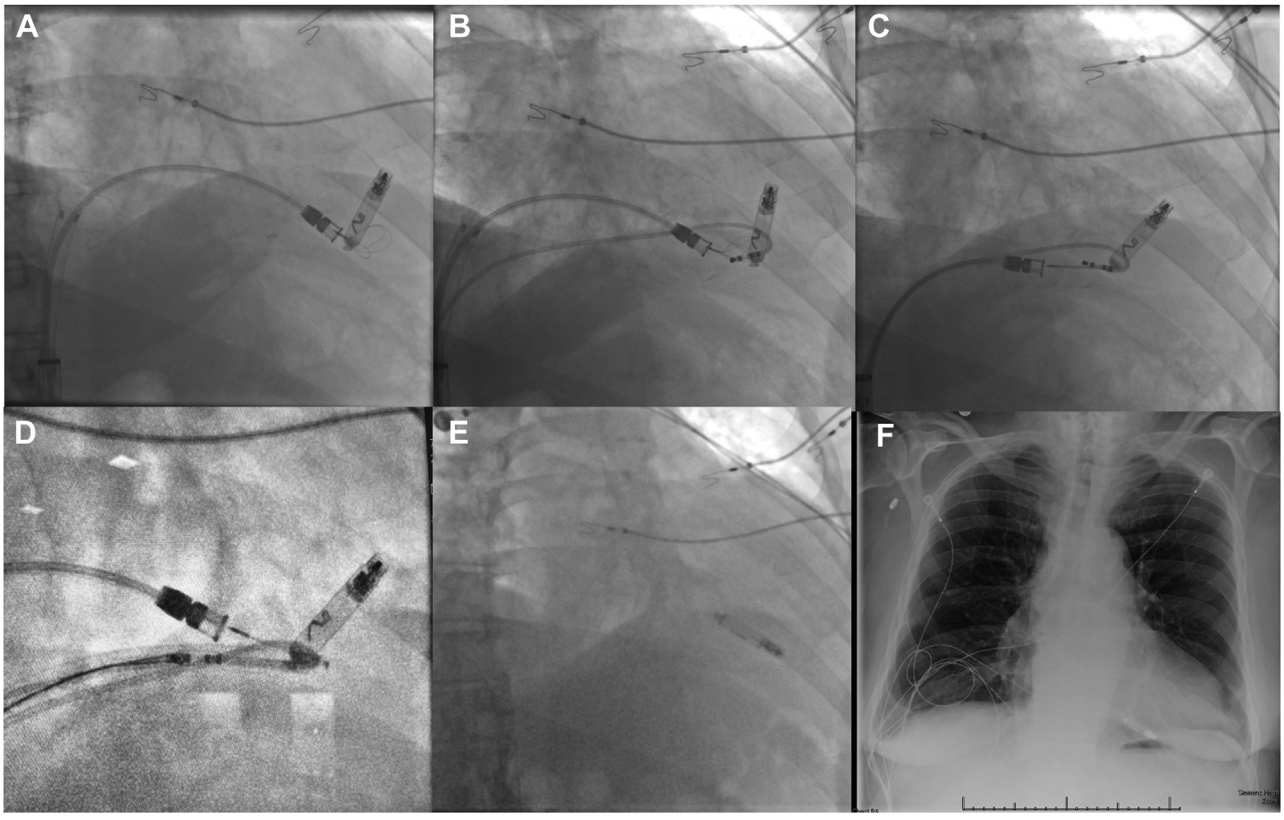

Figure 2 **A:** Initial fluoroscopic image of the device with an attempt to remove this with the Abbott Medical trileaflet snare and docking system (Supplemental Video 1). **B and C:** Navigation of a quadripolar catheter to free the septal aspect of the device and attempts to free the proximal end with additional traction and support from the trileaflet snare (Supplemental Videos 2 and 3). **D:** Magnified image of the quadripolar catheter held on the distal end by a gooseneck snare to lift the proximal end and hold it in place before snaring of the docking button. **E and F:** Final fluoroscopic and next-day radiographic imaging of the newly inserted pacemaker.

drape the snare over the body of the leadless pacemaker and navigate along the septal aspect of the device, were unable to adequately secure it. We made additional attempts at lifting, securing, or even moving the leadless pacemaker using a combination of the deflectable quadripolar catheter and aforementioned snares, as well as a gooseneck snare (Supplemental Figure 1B), all without success. We next engaged our colleagues in interventional radiology with the hope that their knowledge and expertise with a wider variety of snare tools would offer a novel solution.

In cooperation with the consulting interventional radiologist, a tandem approach was then used with a quadripolar catheter wrapped around the leadless pacemaker by one operator, while a gooseneck snare anchored by another operator was used to move the snare slightly more proximal along the catheter end. Both ends of this apparatus were held with gentle but steadily increasing traction, until the proximal button of the device 'popped' up from the inferior border of the cardiac silhouette and demonstrated more typical motion with the cardiac cycle. With this accomplished, a single operator was able to maneuver the Abbott retrieval catheter (Figure 2D) to the proximal docking button of the leadless pacemaker while the proximal aspect of the device was lifted and secured using the retrieval snare. We then advanced the protective sleeve over the device. The device was secured and unscrewed from the RV septum in the usual fashion and removed from the body. A bedside transthoracic echocardiogram revealed no evidence of pericardial effusion, nor worsening tricuspid regurgitation. A new Aveir device was implanted in the usual fashion and without notable difficulty, farther along the apical RV septum (Figure 2E and 2F), and it revealed favorable pacing parameters.

Discussion

With more leadless pacemaker devices being implanted, it stands to reason that a growing number of these devices will need to be removed. While cases have demonstrated the feasibility of removing these devices, our experience in this case highlights the relative uncertainty regarding the long-term ability to remove these devices. An important aspect of this case was the initial midseptal location with an inferior tilt towards the proximal region. The device progressively navigated inferiorly and became embedded in the inferior wall. This navigation affected pacemaker function (higher threshold) and the ability to engage the docking button. This effect highlights the need to consider device position at implant for stability, long-term device function, communication with an atrial device when applicable, and the potential need for future extraction. Prior work has shown

that fluoroscopic evidence of device motion at the time of implant portends a better prognosis for subsequent removal of the device, although our case demonstrates that this periprocedural or early finding can be confounded by subsequent migration of the proximal aspect of the device, resulting in decreased motion at the time of extraction.[11] We have shown a novel approach to free the proximal aspect of a leadless pacemaker to allow extraction through the docking mechanism.

Although certain leadless pacemaker devices feature a button to facilitate removal, this feature is of little use if the button is embedded or adherent to right ventricular trabeculations or portions of the tricuspid valve apparatus, as was the issue in the case presented here. Furthermore, it is documented that some devices eventually become encapsulated with a fibrous sheath the way traditional transvenous leads often do, limiting the ability to access or retrieve them.[13] For cases in which the Aveir retrieval catheter can easily access the proximal button of the leadless pacemaker, it does feature a protective sleeve which can be advanced over the leadless pacemaker to minimize tissue caught between the retrieval catheter and leadless pacemaker. Although this safety check is valuable for preventing damage to important structures such as tricuspid valve apparatus, the protective sleeve can be hindered by fibrous capsule or other structures overlying the body of the leadless pacemaker.

Alternative strategies might include abandonment of a prior chronic leadless pacemaker and implant of either an additional leadless pacemaker or a transvenous pacing system, although in our case, the angulation of the initial leadless pacemaker might have resulted in significant interaction with an additional device prompting the need to use often less favorable higher septal locations.

In our case, the saving grace was the ability to engage an on-call interventional radiology team, which afforded access to expertise and access to tools that are not traditionally used in the electrophysiology laboratory.

Conclusion

There are lingering questions regarding the long-term management of leadless pacemakers, particularly in relation to the retrieval of chronic devices. As the technology improves, we are likely to see growing numbers of leadless pacemaker implants, and it behooves us to closely study long-term complications, identify procedural difficulties with retrieval, and register outcomes of various strategies for management of the malfunctioning or depleted chronically implanted leadless pacemakers. As this case highlights, a multidisciplinary approach, which leverages different expertise and a variety of tools, may be required for more complex leadless pacemaker removals.

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Appendix

Supplementary data

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.hrcr.2024.10.007.

References

1. Reynolds D, Duray GZ, Omar R, et al. A leadless intracardiac transcatheter pacing system. N Engl J Med Mass Medical Soc 2016;374:533–541.
2. Reddy VY, Exner DV, Cantillon DJ, et al. Percutaneous implantation of an entirely intracardiac leadless pacemaker. N Engl J Med 2015;373:1125–1135.
3. Sperzel J, Hamm C, Hain A. Nanostim-leadless pacemaker. Herzschrittmachertherther Elektrophysiol 2018;29:327–333.
4. Ngo L, Nour D, Denman RA, et al. Safety and efficacy of leadless pacemakers: a systematic review and meta-analysis. J Am Heart Assoc 2021;10:e019212.
5. Sanchez R, Nadkarni A, Buck B, et al. Incidence of pacing-induced cardiomyopathy in pacemaker-dependent patients is lower with leadless pacemakers compared to transvenous pacemakers. J Cardiovasc Electrophysiol 2021;32:477–483.
6. Knops RE, Reddy VY, Ip JE, et al. A dual-chamber leadless pacemaker. N Engl J Med 2023;388:2360–2370.
7. Lakkireddy D, Knops R, Atwater B, et al. A worldwide experience of the management of battery failures and chronic device retrieval of the Nanostim leadless pacemaker. Heart Rhythm 2017;14:1756–1763.
8. Afzal MR, Jamal SM, Son JH, et al. Tips and tricks for safe retrieval of tine-based leadless pacemakers. J Innov Card Rhythm Manag 2021;12:4562–4568.
9. Hu Q, Chen K, Dai Y, Zhang S. Micra leadless pacemaker retrieval for broken tines: a case report. Clin Res Cardiol 2022;111:1295–1298.
10. Jain V, Shah AD, Lloyd MS. Need for a universal retrieval tool with countertraction for the removal of leadless pacemakers regardless of the manufacturer. Heart Rhythm 2023;20:1068–1069.
11. Minami K, Neužil P, Petrů J, et al. Retrieval of long-term implanted leadless pacemakers: a single-center experience. JACC Clin Electrophysiol 2020;6:1744–1751.
12. Wang Y, Ailawadi G, Brescia AA, Duggal NM. Surgical repair after leadless pacemaker–induced avulsion of tricuspid valve. Ann Thorac Surg Short Rep 2024;2:262–265.
13. Breeman KTN, du Long R, Beurskens NEG, et al. Tissues attached to retrieved leadless pacemakers: Histopathological evaluation of tissue composition in relation to implantation time and complications. Heart Rhythm 2021;18:2101–2109.
14. Banker RS, Rippy MK, Cooper N, et al. Retrieval of chronically implanted dual-chamber leadless pacemakers in an ovine model. Circ Arrhythm Electrophysiol 2023;16:e012232.
15. Neužil P, Petrů J, Chovanec M, Hála P, Šedivá L, Reddy VY. Retrieval and replacement of a helix-fixation leadless pacemaker at 9 years post-implant. HeartRhythm Case Rep 2023;9:258–262.