

An Early Look at a New Leadless Pacemaker

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Abstract

Early product performance issues involving a new leadless pacemaker result in potentially harmful exchanges during device implantation.

Editorial

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The Aveir[®] leadless pacemaker (LP) (Abbott, USA) received Food and Drug Administration (FDA) approval in April 2022 after a successful LEADLESS II-Phase 2 clinical trial.¹ A month later, in early May 2022, the manufacturer submitted its first Aveir medical device report (MDR) to the FDA describing an adverse clinical event. Such reporting is mandatory when a marketed device may have caused or contributed to a death or serious injury or malfunctioned. The reports are stored in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, and they are freely available and searchable online at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>.

Physicians and researchers often query MAUDE to assess medical device performance issues that have not been announced or published and yet are important because they may impact patient safety. A MAUDE report lists the device and patient problems, the date of the event, and a narrative description of the event. If available, the results of returned product analyses are also detailed. The denominator (number of devices exposed) is not provided, and thus the incidence of a given problem cannot be calculated unless the number is available from the manufacturer or another credible source such as a device registry. MAUDE does not provide patient demographic or clinical information, and not all adverse events are reported to the FDA, especially those occurring outside the United States. Despite these limitations, MAUDE is a useful surveillance tool for identifying serious product problems that may be unappreciated or otherwise unrecognized by the medical community. Importantly, MAUDE often reflects product deficiencies that are emerge only after a device is introduced into the "real-world" of widespread clinical use.²

In this issue of the *Journal*, Garg et al³ describe the results of their analysis of 64 Aveir LP MDRs they found in MAUDE in January 2023. These included reports received by the FDA during the 8 months from May-December 2022; excluded were 34 MDRs that were duplicate reports or related to the programmer or introducer. They found 8 major adverse events, including 2 perforation-related deaths, 3 pericardial effusions requiring pericardiocentesis, and 3 patients who had sustained ventricular tachycardia. Ostensibly these events were procedural complications rather than device-specific issues.

The device-specific problems included 9 device separation failures, whereby the pacemaker could not be released from the delivery system; all of them were removed and a new system reintroduced. Some of the removed devices exhibited tether fragmentation; the tethers maintain contact with the Aveir LP when it is undocked from the delivery catheter during threshold testing. In 5 cases, the active fixation helix became distorted and required LP replacement. Altogether, of 64 initial implant attempts, 27 Aveir LPs (42.2%) were not implanted and required replacement with another pacemaker. In addition, there were a number of electrode-tissue deficiencies manifested by high threshold, low sensing, or abnormal impedance.

This brief report highlights several product performance issues that will require close monitoring. Perforation and pericardial effusion are complications shared by all implantable intracardiac electrophysiology devices, and they occur more frequently when a device has to be repositioned or exchanged. Why the Aveir LPs suffered separation failures and damaged helices are important questions for the manufacturer to answer and resolve. Otherwise, potentially harmful LP exchanges will continue to occur. \

References

- 1-Reddy VY, Exner DV, Doshi R, et al. Primary results on safety and efficacy from the LEADLESS II-Phase 2 worldwide clinical trial. *J Am Coll Cardiol EP* 2022; 8: 115-119.
- 2- Hauser RG, Gornick CC, Abdelhadi RH, Tang CT, Casey SA, Sengupta JD. Major adverse clinical events associated with implantation of a leadless intracardiac pacemaker. *Heart Rhythm* 2021; 18: 1132-1139.
- 3-Garg J, Shah K, Bhardwaj R, et al. Adverse events associated with Aveir VR leadless pacemaker: A Food and Drug Administration MAUDE database study. *J Cardiovasc Electrophysiol* 2023; -----.