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Commentary: Collateral impact of the HVAD decision and the path forward

James K. Kirklin, MD

Balachandran and colleagues¹ have provided an elegant presentation of the circumstances, immediate impact, and potential future implications of the Medtronic decision to remove the HVAD left ventricular assist device (LVAD) from the market in June, 2021. The authors have provided historical context and their unique perspective, making this piece a “must-read” for all practitioners in this field.

Going forward, it is vital to reflect on the real limitations of these modern continuous-flow devices, which function with a small fraction of physiologic pulsatility. The current issue is not durability or effective performance; it is rather the associated adverse event profile that hinders widespread application of these devices for anything but spiraling circulatory failure. As recently as 2020, application of these devices in severe but stable (ambulatory) heart failure accounted for <13% of implants.² The major adverse events of stroke, device-related infection, gastrointestinal bleeding, renal dysfunction, and respiratory failure are major predictors of subsequent mortality, and, with rare exceptions, are equally as likely among patients with ambulatory heart failure as among those with inotrope dependence and/or impending circulatory collapse.³ The Society of Thoracic Surgeons INTERMACS national mechanical circulatory support registry has provided unique insights into the powerful impact of these adverse events on not only survival but also health-related quality of life during support.⁴

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CENTRAL MESSAGE

The industry decision to remove the HVAD LVAD from the market, driven by recalls and adverse events, leaves remaining challenges in reducing adverse events and a potential gap in circulatory support for children.

No LVAD will gain widespread application across a broader spectrum of advanced heart failure until the adverse event rates demonstrate major improvement over those recorded in the past 5 years.

An area of real concern is the pediatric population. The HVAD was not designed for small children, but the pediatric community rapidly embraced this device for adolescents and older children because of its relatively small size and the convenience of hospital discharge.⁵ The HeartMate3 device is increasingly being applied in the pediatric population, but its larger size compared with the HVAD will become an immutable barrier in small children. The pediatric community has greatly benefitted from the availability of the pediatric Berlin Heart EXCOR for infants and small children, saving countless lives for >2 decades,⁶ but the extracorporeal nature of this device limits safe mobility, particularly if hospital discharge is realized in the future. Clearly, ongoing innovations are necessary in the pediatric population, but the potential looms for a domino effect of this industry decision that could impede progress in the development of smaller devices.

The authors put forth an optimistic view of the stakeholder response to this unfortunate chain of events—let's hope that young engineers and start-up device companies will receive the needed enthusiastic support from the advanced heart failure medical and surgical communities.

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Commentary: Beyond data: Transparency and trust

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In this month's issue, Drs Balachandran and colleagues¹ convey their perspective in their Expert Invited Opinion in "Doing the wrong thing for the right reasons: the demise of the HVAD," and outline the trials and tribulations of the Medtronic HeartWare HVAD left ventricular assist device (LVAD) and its removal from the world market earlier last year (August 12, 2021). Their perspective is insightful and enlightening, coming from one of the storied founding fathers of mechanical circulatory support (MCS) as well as a foundational thought leader.

In this piece, the authors describe the development of the HVAD and its progress through the bridge to transplant ADVANCE (Evaluation of the HeartWare Left Ventricular Assist Device for the Treatment of Advanced Heart Failure) trial and the tiered destination therapy ENDURANCE (A Prospective, Randomized, Controlled, Un-blinded, Multi-Center Clinical Trial to Evaluate the HeartWare Ventricular Assist System (VAS) for Destination Therapy of Advanced Heart Failure) trial and the and post-approval data and regulatory challenges.¹ This story clearly showed increased

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Developing MCS devices requires collaboration to achieve clinical use while assessing risk-benefit as data accrue. The decision to withdraw a device has important implications beyond clinical use.

neurological adverse events, and a high number of Food and Drug Administration (FDA) recalls before evidence of sudden pump stoppage delivered the coup de grace prompting HVAD's market removal. Although this story and these data belong to the HeartWare LVAD, a similar arc could have occurred with any LVAD, or even general cardiac surgical device, and our community should take note of this narrative. In their article, Balachandran and coauthors weave several important lesson and themes:

1. This pump and others of its era were developed in collaboration with surgeons, cardiologists, engineers, and the origin company, HeartWare.
2. The clinical trials that delivered the pumps into wider clinical use had signals for adverse events that evolved over time and were potentially mitigated by iterations

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