Commentary: Beyond Data: Transparency and Trust

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Commentary: Beyond Data: Transparency and Trust

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Central Message: 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.

Central Picture Legend: Scott C Silvestry MD

In this month’s Journal, Drs. Balachandran, Frazier and Rogers convey their perspective in their Expert Invited Opinion in “Doing the Wrong Thing for the Right Reasons: The Demise of the HVAD” outlining the trials and tribulations of the Medtronic Heartware HVAD left ventricular assist device and its removal from the world market earlier last year. Their perspective is insightful and enlightening, coming from one of the storied founding fathers of mechanical circulatory support 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 trial and the tiered Destination Therapy ENDURANCE trial as well the and post-approval data and regulatory challenges. This story clearly demonstrated increased neurological adverse events, and a high number of FDA recalls before evidence of sudden pump stoppage delivered the coup de grace prompting HVAD’s market removal. While 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 of the HVAD device.
and in the management strategies of the MCS teams in the patients that had them.

3. All outcomes in the MCS domain are the result of the interaction between the LVAD, the patient, and the surgical and medical management by clinical teams – with outcomes often difficult to definitively attribute to one category or another without overlap.

As the authors note, the Heartware HVAD is a cautionary tale for all. When is a pump ready for approval and widespread use? When are the signals seen in a clinical trial enough to warrant a pause? And when does a device which is generally life-saving, warrant removal from the market for black swan events of such a low frequency that they may escape detection in a tiny subpopulation of patients?

The answers are unknowable, but the data suggest that Medtronic acted in the best interests of our patients, despite the wake of orphaned patients and disenfranchised medical professionals who invested in this device and believed in the apparent benefit it offered our patients. The authors remind us of the data on the Heartware HVAD LVAD and its implications: Higher adverse neurological event rates from the clinical trials, as well as troubling numbers of FDA recalls, culminating in sudden stoppage events associated with the deaths of at least 26 patients over 13 years- data which Medtronic who acquired Heartware and the HVAD LVAD in 2016 (2) grew increasingly concerned about. These data cannot and should not be ignored.

Yet many patients received lifesaving benefits from their HVAD LVAD. In total, more than 19,000 HVADs were implanted over the now defined lifecycle of the HVAD with its clinical utility defined by its smaller size and magnetically levitated centrifugal flow pump with a hydrodynamic bearing, featuring enhanced monitoring offering unique advantages. HVAD’s smaller size allowed positioning in the pericardium without a “pump pocket” and made it a surgeon friendly pump with rapid innovation in minimally invasive techniques- with best in class survival results (3), off pump implantation, and application to populations without prior durable MCS options such as older children, small adults, and the anatomically disadvantaged adults with congenital heart disease as well as off-label use to support the neglected failing right ventricle (4-6).
The authors remind us that the field of assisted circulation has a colorful history of collaborative development. Dr Frazier has recounted, to those of us fortunate enough to hear, how the crucible of collaboration formed the HVAD from an innovative idea and how the device moved from the bench to the clinical laboratory to the hospital. The lifeblood of this device was not solely engineers, nor was it only spilled at the time of inception. Many engaged medical professionals, and I count myself as one, invested intellectual energy and effort in this device and others, to advance our field and worked to offer the best devices to our patients as well as obtain the necessary data to assess benefit and safety. Through competition, innovation, and analysis, we made observations about one pump against the background of another and vice versa.

The authors underscore the need to pause the marketing of HVAD but ask the important question whether Medtronic’s decision to abandon the device was correct- citing the casualty of the collaborative process as well as damage to the process of innovation – invent, study, refine, study. With one pump left standing, we are warned that without competition added to this cycle, the imperative for device companies to maintain pace during the research and development timeline and to invest resources to keep market share is lessened. This competitive cycle made our pumps better, more quickly, and fueled our drive to become better at managing our patients with pumps. Competition drove the urgency for ongoing technology development, keeping complacency at bay. With one FDA approved LVAD left standing currently, where is the urgency for a fully implantable LVAD system? And the urgency for the next, smaller, better pump when the market share is assured by monopoly.

The last casualty of this process is physician’s trust: trust in the devices, and trust in their value in partnering with the companies developing and marketing MCS devices. In the end, the physician conveys to a patient that a device-based therapy is appropriate-and that the device itself is to be trusted. This trust goes beyond the device and data, but to the people and the company offering the device with a promise of transparency, value, and future support. The authors suggest that Medtronic, in their withdrawal of the Heartware HVAD acted in a unilateral and with less than perfect collaboration towards their physician partners. Along with Drs. Balachandran, Frazier and Rogers, I wonder about future trust and collaboration between clinicians and medical device companies, as well as our patients who depend on that relationship.
References


2. Medtronic buys HeartWare in $1.1 billion deal (usatoday.com) (Accessed December 1, 2021)


