individualize care. At present, we would not adhere strictly to a “for-cause” basis (as defined by the authors) for conversion, particularly for a near adult-sized stable patient with destination therapy. However, we need more data and will continue to scrutinize the data as they become available and adjust our viewpoint accordingly.

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Commentary: Guidance during uncertain times: Navigating the HeartWare HVAD recall

Alexis Shafii, MD,^{a,b} Kenneth Liao, MD, PhD,^{a,b} and Ravi K. Ghanta, MD^{a,b}

Ventricular assist device (VAD) technology is an established and essential option for patients with end-stage heart failure. In June 2021, Medtronic recalled the HeartWare HVAD system because it is associated with a high incidence of stroke, as well as a risk of device malfunction, specifically delay or failure of the pump to restart. According to the US Food and Drug Administration, these malfunctions led to more than 100 complaints, 14 deaths, and 13 pump removals.¹ This unfortunate outcome has left approximately 4000 patients worldwide in a vexing situation.

From the ^aMichael E. DeBakey Department of Surgery, Baylor College of Medicine; and ^bDepartment of Cardiovascular Surgery, Texas Heart Institute, Houston, Tex. Disclosures: Dr Shafii was the Institutional Principal Investigator for the HeartWare Destination Therapy study. All other authors reported no conflicts of interest.

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Address for reprints: Ravi K. Ghanta, MD, Michael E. DeBakey Department of Surgery, Baylor College of Medicine, One Baylor Plaza, MC-390, Houston, TX 77030 (E-mail: ravi.ghanta@bcm.edu).

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Alexis Shafii, MD, Kenneth Liao, MD, PhD, and Ravi K. Ghanta, MD

CENTRAL MESSAGE

HVAD to HeartMate 3 device exchange should only be performed “for cause” and in experienced centers. Prioritization for heart transplantation should be considered in HVAD patients.

For cardiac surgeons, the primary decisions are when and how these pumps should be replaced. Salerno and colleagues² present an Expert Opinion article on how to approach this question. The authors have a formidable cumulative experience in heart failure and mechanical circulatory support and represent a broad array of centers of excellence in the United States and Europe.

Given our experience at Baylor College of Medicine and Texas Heart Institute, we largely agree with the authors' principal points. First, patients currently supported by an HVAD should not undergo a prophylactic exchange to another device. Device failure rates are low (~0.4%), and an analysis of the Society of Thoracic Surgeons Intermacs registry associated HVAD-to-HM3 device exchange with 11% operative mortality and poorer 6-month survival compared with continued

HVAD support.³ Moreover, the HVAD differs from the HM3 in its functionality, having distinct head-capacity curves, which may affect right ventricular (RV) function. Certain types of patients who did well with the HVAD might not have had a similar RV response to an HVAD-to-HM3 exchange. Two of these groups would be patients with a small left ventricular (LV) cavity (LV internal diastolic diameter <5.5 cm)⁴ and those with marginal RV function.

Second, the authors describe reasonable surgical strategies for HVAD-to-HM3 exchange. Understanding the differences between the HVAD and HM3's apical sewing rings and inflow cannulas is paramount. Our practice for HVAD-to-HM3 exchange is to perform a sternotomy, excise the HVAD apical sewing ring, and place the larger HM3 sewing ring under cardiopulmonary bypass. For the outflow graft, we suggest replacing the graft in its entirety to the ascending aorta because this eliminates the risk of graft mismatch and flow limitation. While not mentioned in the article, there was a period of time in which it was en vogue to insert the HVAD into the diaphragmatic (inferior) wall rather than the LV apex.⁵ This implant technique became popular in our program because of the evolving understanding of the issues related to inflow cannula malalignment, which increases the risk of device thrombosis.⁶ When we encounter such patients requiring conversion to HM3, we have found it best to close the inferior wall coring site and relocate the HM3 to the traditional apical site. The main issue with the HM3 in the diaphragmatic position is that the intrapericardial space is too small to accommodate it.

Finally, given the morbidity and mortality associated with device exchange, a better option may be to increase prioritization of heart transplantation for these patients, which can be performed with far less mortality risk. Thus, the "solution" to this problem may be a policy change. The United Network for Organ Sharing status for these patients could be upgraded to Status 2 because of device malfunction. Although the donor pool remains limited, we suggest that it is both reasonable and ethical to prioritize patients who underwent implantation of approved VADs that are now under regulatory recall. Other VAD issues will continue to arise, and the precedent established with the current HVAD recall may be emulated in the future, which should spur the heart failure community to carefully consider how to manage patients affected by these issues.

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