



Choosing the appropriate left ventricular assist device for your patient

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Abstract

The increasing incidence of advanced heart failure and severe donor organ shortage for cardiac transplant has led to the development of implantable left ventricular assist devices (LVAD) for long-term mechanical circulatory support. There has been tremendous improvement in the device technology of LVADs, and there are a number of devices in use throughout the world. This article reviews the evidence behind each device and their unique features that can help when choosing a durable LVAD for an individual patient.

Keywords Left ventricular assist device · Mechanical circulatory support · Advanced congestive heart failure · Patient selection

Introduction

Advanced congestive heart failure (aCHF) is a debilitating disease with a profound effect on a patient's functional status, quality of life (QOL), and their survival. Despite advancements in the medical management of CHF, for patients with aCHF, only surgical interventions have had a significant impact on functional status, QOL, and survival [1]. The most effective surgical treatment remains heart transplantation, with a median survival of 10.7 years and marked improvement in functional status and QOL [2]. However, heart transplantation is limited by the number of available donor organs. In the USA, between 1987 and 2012, 40,253 patients were listed for heart transplant, but only 26,943 transplants were performed [3]. Mechanical circulatory support (MCS) devices have been developed both as an adjunct and an alternative to heart transplantation. Implantable LVADs are the only MCS devices available for durable, long-term support and can be used either as a bridge to transplant (BTT) or as destination therapy (DT). This article will review the durable LVAD models that are available and discuss factors that contribute to choosing a specific model for an individual patient.

Development of MCS devices originated with the artificial heart program at the US National Institute of Health in 1964. The first-generation LVADs were designed to provide pulsatile flow and were pneumatically driven. A significant drawback of these devices was their large size, which required a larger body habitus for implantation to be feasible. In addition, the pump was often implanted into the abdominal cavity, though it could be placed pre-peritoneal. The pneumatic drivers were very loud and decreased patients' QOL. Subsequent devices were electrically driven. The first self-contained LVAD was approved by the US Food and Drug Administration (FDA) in 1998 as a bridge to transplant [4]. The REMATCH trial, a randomized controlled trial (RCT) of 129 patients, showed improved long-term survival and QOL with LVAD use compared to optimal medical therapy and led to the FDA approval of the HeartMate XVE (Thoratec, Pleasanton, CA) (Fig. 1) for DT [1]. There were high rates of infections and hemocompatibility-related adverse events (non-surgical bleeding, thromboembolic events, pump thrombosis, neurologic events). In addition, the devices had multiple moving parts that were not designed for long-term use and required frequent device replacement [5]. The 2-year survival after device implantation was only 23% and, while superior to the 8% survival in the medical group, was still far from optimal.

The second-generation LVADs were axial flow devices that provided continuous flow and were designed to improve on the durability of the device, hemocompatibility, and overall outcomes. The most widely used second-generation LVAD is the HeartMate II (HMII) (Thoratec, Pleasanton, CA)

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Fig. 1 HeartMate XVE (left) and HeartMate II (right)

(Fig.1). Rather than pneumatic compression, the pump contains a single moving piece, the internal rotor (Fig.2), that is suspended by a mechanical bearing and powered by an external driver connected by a percutaneous driveline (Fig. 3). The HMII is much smaller than the first-generation LVADs with a displacement volume of 63 mL and weight of 390 g. In comparison, the HeartMate XVE has a 450 mL displacement volume and weight of 1250 g. Another significant difference is that the HMII pump is placed in a pre-peritoneal pocket in the abdominal wall, as opposed to the intraperitoneal location that was often used for first-generation LVADs. Since the pump is located outside the thoracic cavity, the HMII can be used for patients with very little pericardial/thoracic space.

Initial evaluation of the HMII was conducted in an FDA-approved, prospective, pivotal trial of 133 patients as a BTT device. This trial demonstrated that the HMII was an effective device for BTT with excellent hemodynamic support, an acceptable safety profile, and improved end-organ function, functional status, and QOL. As a BTT trial, however, the

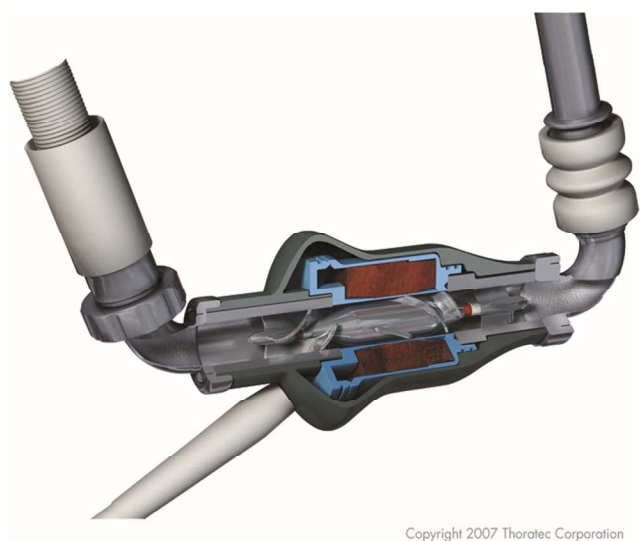


Fig. 2 HeartMate II internal rotor

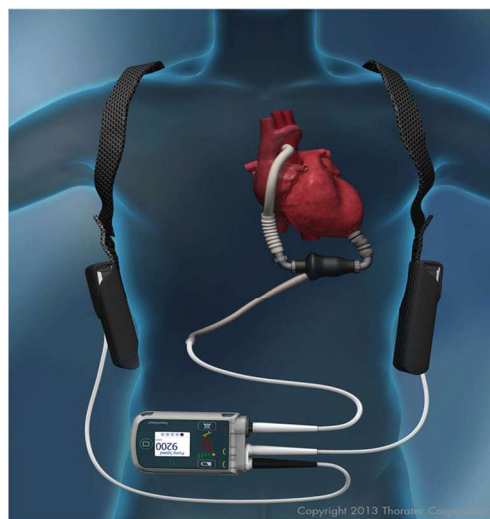


Fig. 3 HeartMate II

mean duration of support was only 168 days and provided limited insight into long-term outcomes and device durability [6]. The HMII became the first FDA-approved continuous flow LVAD as BTT device in 2008. Enrolment in the pivotal trial continued after initial publication and included 281 patients in total. The final results were consistent with the original analysis [7]. The HMII was then evaluated in a pivotal trial for use as DT. This pivotal trial was an RCT that randomized patients in a 2:1 ratio to receive the HMII versus a pulsatile LVAD (HeartMate XVE) with the primary endpoint of 2-year survival without a disabling stroke or reoperation to repair or replace the LVAD. The multicenter trial enrolled 200 patients and randomized 134 patients to receive the HMII and 66 to receive the HM XVE. The mean follow-up period was much longer than the BTT pivotal trial: 1.7 year follow-up for the HMII group and 0.6 years for the HM XVE group. A statistically significant number of patients in HMII group met the primary endpoint compared to the HM XVE group (46% vs 11%). The HMII showed significant improvement in long-term survival with 1- and 2-year survival rates of 68% and 58%, respectively, compared to 55% and 24% in the HM XVE group. The HMII showed similar improvements in functional status as the HM XVE and greater improvement in QOL. The devices did not differ in the incidence of stroke, but the HMII had significantly less LVAD and non-LVAD-related infections, right heart failure, arrhythmias, and end-organ dysfunction [8]. This trial led to FDA approval of the HMII for DT in 2010. Given the improved durability, survival, and adverse event profile, the second-generation devices replaced the first-generation LVADs in clinical use.

As the use of axial flow LVADs increased, much higher rates of pump thrombosis were observed. A retrospective review of three high-volume centers was conducted to evaluate rates of pump thrombosis and included 837 patients and 895 devices between 2004 and 2013. The study found 72 events of pump

thrombosis in a total of 66 patients (7.9%). The highest risk of pump thrombosis was shortly after implantation but continued to accumulate, with a 12.3% risk of pump thrombosis after 24 months of support. The management of the pump thrombosis is varied and includes rescue transplant [11], device exchange [21], explantation [2], and medical management (32). Pump thrombosis had a significant impact on mortality, 16.8% versus 35.6%, at 18 months. Patients who were treated with transplant or device exchange had much better outcomes than those treated medically [9]. It was hypothesized that pump thrombus is caused by mechanical and thermal stresses to the circulating blood components as they pass through the pump [10].

A third generation of LVADs was created with centrifugal flow. Like the second-generation devices, they provide continuous flow. The first third-generation LVAD to be extensively studied was the HeartWare HVAD (HeartWare International Inc., Framingham, MA) (Fig. 4). The HVAD was initially evaluated as a BTT device in a European pivotal trial and a US trial, the ADVANCE trial. The HVAD is much smaller (Fig. 5), with a 50-mL displacement volume and a weight of 140 g, compared to prior models, and sits within the pericardial space. The HVAD does not require a pre-peritoneal pocket. There is a single moving component, the impeller, within the pump, and it is suspended by magnetic and hydrodynamic forces that create frictionless rotation to limit stress to the blood components (Fig. 6). It is the only LVAD that has an FDA-approved minimally invasive approach for insertion. The results of the LATERAL trial, which included 145 patients, demonstrated the safety and efficacy of inserting the HVAD through two mini-thoracotomy incisions [11]. Another unique feature of the HVAD is a pressure-flow waveform displayed on the controller. This can be used to detect



Fig. 4 HVAD



Fig. 5 HVAD

changes in the patient's clinical status and guide earlier intervention [12]. The European pivotal trial was a multicenter, prospective trial that enrolled 50 patients who received an HVAD as a BTT. The primary objective was based on 180-day outcomes, but patients were followed for 2 years if the HVAD remained in place. The mean duration of support was 348 days. The trial showed excellent survival of 84% and 79% at 1 and 2 years, respectively. There was also significant improvement in QOL and a favorable adverse event profile [13]. In the ADVANCE trial, 140 patients received an HVAD as BTT and were compared to controls from the Interagency Registry for Mechanical-Assisted Circulatory Support (INTERMACS) database. The results corroborated the findings in the European trial and showed non-inferiority compared to the INTERMACS controls. There was an 86% 1-year survival in the ADVANCE trial [14]. An important finding in the HVAD trial was the decreased incidence of pump thrombosis. The HVAD received the European CE Mark for BTT in 2009 and FDA approval for BTT in 2012.

With the introduction of the third-generation LVAD, the ENDURANCE trial was conducted to compare the safety and efficacy of the second- and third-generation LVADs. ENDURANCE was a multicenter RCT in the USA that



Fig. 6 HVAD internal impeller

randomized aCHF patients not eligible for transplant in a 2:1 ratio to a centrifugal flow (HVAD) or axial flow (HMII) LVAD. The primary outcome was a 2-year survival free of a debilitating stroke with the original device in place, elective transplantation, or device explant after LV recovery. The HVAD intention to treat a group consisted of 297 patients and 148 patients was randomized to receive the HMII. Non-inferiority was found based on the primary outcome, with 55.0% of patients meeting the primary outcome with the HVAD and 57.4% with the HMII. There was no significant difference between groups for the number of deaths or disabling strokes. The HMII did have significantly more events related to device malfunction requiring device exchange, explant, or urgent transplant. Adverse events that were more prevalent with the HVAD than the HMII included stroke of any severity (29.7% vs 12.1%), incidence of right ventricular (RV) failure (38.5% vs 26.8%), and a higher incidence of sepsis (23.6% vs 15.4%). Notably, the HVAD group did not have a higher incidence of RVAD placement despite the higher rate of RV failure. The increased incidence of stroke, especially hemorrhagic, was correlated with elevated blood pressures. Notable adverse outcomes that did not differ included reoperations for bleeding, GI bleeding, and driveline infections. Both groups had similar degrees of improvement in functional status and QOL [15].

The ENDURANCE Supplemental trial was conducted to further investigate the higher incidence of stroke with the HVAD. The primary endpoint was changed to neurologic injury within the first 12 months. An additional 308 patients received an HVAD, and 157 received a HMII. Patients who received an HVAD had to adhere to a strict blood pressure management protocol. The goal of the study was to see if neurologic events could be reduced in the HVAD group with improved blood pressure management. The study showed no significant difference in the rate of neurologic injury between the groups. There was a higher incidence of transient ischemia attacks (TIA) in the HVAD group versus the HMII group (4.2% vs 0.6%) but a higher incidence of disabling strokes (1.6% vs 3.2%) in the HMII group. The post-stroke level of disability was higher in the HMII group. When compared to the ENDURANCE trial, the ENDURANCE Supplemental trial showed significantly less hemorrhagic strokes after HVAD implantation. Based on pre-specified criteria, non-inferiority of the HVAD was demonstrated. It was felt, however, that after looking at all the data from the trial, there was significant improvement in the rate of stroke with the blood pressure management strategy. The supplemental trial again demonstrated a significantly higher rate of hemolysis, pump thrombosis, and device exchange in the HMII group compared to the HVAD group. The rates of other adverse events, the change in QOL, and functional improvements remained similar between the two groups as they had in the ENDURANCE trial [16]. The ENDURANCE trial and

ENDURANCE Supplemental trial led to FDA approval for the HVAD as DT in 2017.

Another third-generation LVAD, the HeartMate 3 (HM3) (Thoratec, Pleasanton, Calif.) (Figs. 7 and 8), was also developed with the goal of decreasing pump thrombosis. It is a centrifugal pump that sits in the pericardial space. The internal rotor is magnetically levitated, avoiding the need for a mechanical bearing that causes shear stress to the circulating blood elements and reduces the risk of mechanical failure. The device is programmed to rapidly fluctuate the rotor speed to create an intrinsic pulse that limits stasis [17]. The HM3 was originally evaluated in a single-arm, prospective trial in Europe. The trial enrolled 50 patients that were both BTT (54%) and DT (46%). There was 92% survival at 6 months with no pump thrombosis or device malfunction. The rates of other adverse events were similar or lower to those of other devices [18]. The HM3 received CE mark approval in 2015 as both a BTT and DT device.

The HM3 was further evaluated in the MOMENTUM 3 trial, a multicenter RCT that randomized patients in a 1:1 fashion to receive a HMII or HM3. Patients with a therapeutic goal of BTT and DT were included in the study. The study was a non-inferiority and superiority trial with the primary outcome of survival free of a disabling stroke or reoperation to exchange or remove the device. Transplant, other than urgent transplant for device thrombosis/malfunction, was considered a treatment success. The data from the study was published at the 6-month and 2-year marks. The initial 6-month trial randomized 152 patients to the HM3 group and 142 patients to the HMII group. The primary endpoint was met in 86.2% of HM3 patients vs. 76.8% of HMII patients, and this showed superiority of the HM3. This difference was due primarily to a much lower rate of reoperations for device malfunction in the HM3 group (0.7% vs. 7.7%). There were no cases of pump thrombosis in the HM3 group, and 10.1% of patients in the HMII group had pump thrombosis. There was no difference between groups in other adverse events. Both devices showed



Fig. 7 HeartMate 3

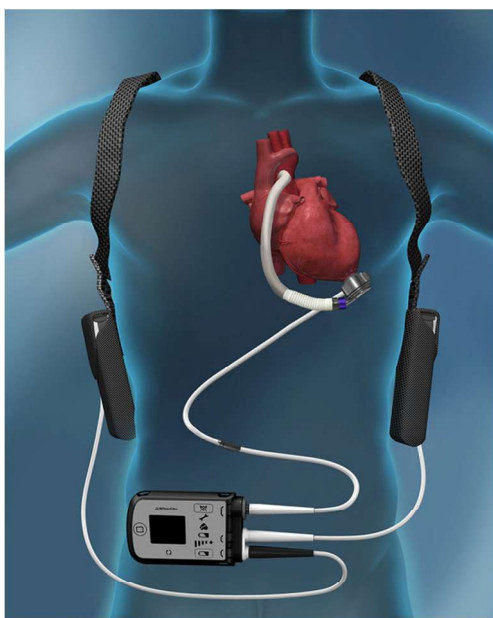


Fig. 8 HeartMate 3

improvement in functional status and QOL, but there was no difference between groups [17].

The second analysis of the MOMENTUM 3 trial with 2-year outcomes included 190 patients in the HM3 group and 176 in the HMII group. The primary endpoint was met in 79.5% and 60.2% of patients, respectively. Based on these results, the HM3 was found to have superiority compared to the HMII. This difference was again driven by reoperations for device malfunction, which occurred in 1.6% of patients in the HM3 group and in 17% of patients in the HMII group. Pump thrombosis only occurred in 1.1% of cases in the HM3 group, and there were no reoperations for pump thrombosis.

In the HMII group, 15.7% of patients had pump thrombosis with 12.2% requiring reoperation. As in the 6-month analysis, there was not a significant difference between groups for other adverse events, including stroke, surgical bleeding, non-surgical bleeding, or driveline infection. In addition, there was not a significant difference in the degree of improvement for functional status or QOL [19]. A more in depth study of the hemocompatibility-related adverse events (non-surgical bleeding, thromboembolic event, pump thrombosis, or neurological events) in the MOMENTUM 3 trial at the 6-month point showed that the HM3 had superior hemocompatibility compared to the HMII. This was due to the higher incidence of non-disabling strokes and pump thrombosis in the HMII group [20]. The HM3 received FDA approval as a BTT device in 2017 and for DT in 2018. While there is not a trial comparing the HVAD and the HM3, comparisons between the two devices can be made because the ENDURANCE trial, ENDURANCE Supplemental trial, and MOMENTUM 3 trial all used the HMII as the control group. (Table 1) compares the three devices and summarizes the results of the three trials.

The HMII, HVAD, and HM3 are the most widely used LVADs but there are a number of other second- and third-generation devices that are available for clinical use around the world.

The aVAD (Reliant Heart Inc., Houston, TX) is an axial flow LVAD that was developed from the HeartAssist 5 (Reliant Heart Inc.). The aVAD has a miniaturized pump housing that allows it to sit within the pericardium. The aVAD also uses a novel feature, the FastConnect system (Reliant Heart Inc.), which allows the pump depth to be adjusted during insertion to accommodate different ventricular cavity sizes and potentially prevent suction events. Another unique feature of the aVAD is its capability for remote

Table 1 Pooled data from the ENDURANCE trial, ENDURANCE Supplemental trial, and MOMENTUM 3 trial

	HeartMate II	HVAD	HeartMate 3
Outcomes			
1-year survival	73.2–84.7%	72.0%	88%
2-year survival	60.2–76.2%	67.6%	82.6%
Adverse events			
Pump thrombosis	10.2–15.7%	4.5–6.4%	1.1%
Device Exchange	10.2–24.5%	3.2–7.7%	2.8%
Neurologic events			
- Ischemic stroke	7.6–13.4%	13–17.6%	6.3%
- Hemorrhagic stroke	4.0–9.3%	5.2–14.9%	4.2%
Postoperative bleeding requiring re-operation	17.4–18.1%	15.2%	12.2%
Gastrointestinal Bleed	27.3–34.2%	35.1%	27%
Driveline infection	12.1–19.8%	19.6–24%	23.8%
RV failure	26.8–38.2%	35.4–38.5%	31.7%
- RVAD	3.4–4.7%	2.7%	3.2%

monitoring. Within the controller, there is a system called the VAD link (Reliant Heart Inc.) that can connect to the Internet and provide real-time data for the device flow, speed, and power consumption. The data from VAD link can be viewed by the patient's clinical team on a mobile application or through a web browser [21]. The goal of remote monitoring is to detect changes in clinical status earlier to prevent complications and the need for hospital readmissions and to increase patient satisfaction. Presumably, the physician's ability to manage LVAD patients in the outpatient setting would significantly improve with this technology [22]. The aVAD is still being evaluated in initial trials, and data on clinical outcome and adverse events is not available. It is currently approved in Europe but has not been approved in the USA.

The Jarvik 2000 (Jarvik Heart Inc., New York, NY) is an axial flow, intraventricular LVAD. The small size of the pump allows it to sit within the ventricle and is a good option for patients with small thoracic cavities. An additional advantage of the Jarvik 2000 is that it can be inserted through alternative approaches, including a thoracotomy or a subcostal incision, and it can be done without cardiopulmonary bypass in select patients [23, 24]. The advantage of an alternative insertion is that it does not complicate a future heart transplant. A unique feature of the Jarvik 2000 is that the speed controller can be adjusted by the patient to accommodate increased activity [25]. There have been small studies evaluating the Jarvik 2000, but there has not been a large trial to clearly demonstrate its outcomes or adverse event profile. The Jarvik 2000 is still in the stage of FDA-approved clinical trials in the USA but is approved for use in Europe and Japan.

EVAHEART (Sun Medical, Nagano, Japan) (Fig. 9) is a centrifugal flow LVAD that is clinically available in Japan and is undergoing a FDA pivotal trial in the USA. The data available is limited primarily to a Japanese post-approval study of 96 patients. The trial showed excellent results in terms of hemolysis, pump thrombosis, and GI bleeds but had high rates of driveline infections (14.6%) and neurologic events (17.7% ischemic stroke, 13.5% hemorrhagic stroke, and 3.1% (TIA)) [26]. A small, retrospective study comparing EVAHEART to HMII collaborated these results showing much higher rates of driveline infection (72% vs 15%) and neurologic events (79% vs 11%) in the EVAHEART cohort [27]. The advantage of the EVAHEART is a unique pressure-flow system that leads to variation in flow between systole and diastole that provides pulsatile flow with a pulse pressure of 15–30 mmHg [26]. It is postulated that the pulsatility may explain the absence of GI bleeds in the post-approval trial. A new model, the EVAHEART 2, is currently in clinical trials (Fig. 9).

The DuraHeart (Terumo Heart Inc., MI, USA) is a magnetically levitated centrifugal flow LVAD approved for clinical use in Europe and Japan. The device is inserted through a median sternotomy and sits in a pre-peritoneal abdominal

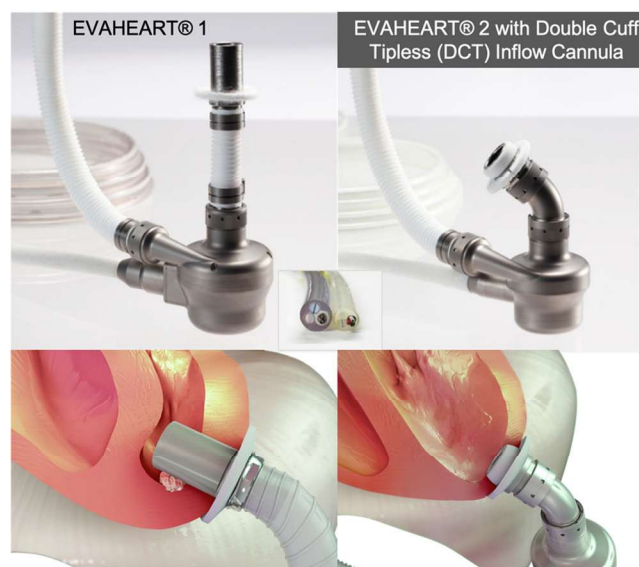


Fig. 9 EVAHEART and EVAHEART 2

pocket. The data for the DuraHeart comes primarily from a European clinical trial of 68 patients. Survival was comparable to INTERMACS data and was 77% at 1 year and 61% at 2 years. Adverse outcomes were also similar to INTERMACS data with a higher incidence of neurologic dysfunction (27%) [28]. These results were reproduced in the US SUSTAIN trial that accrued 63 patients prior to closing prematurely due to slow enrollment.

The INCOR (Berlin Heart AG, Germany) (Fig. 10) is an intrapericardial, magnetically accentuated axial flow LVAD. It is approved for clinical use in Europe. There is very little data available for the INCOR. There is an initial European trial that demonstrated safety in 15 patients [29]. There is also a retrospective review of 42 patients in Italy who received the INCOR between 2006 and 2012. This study showed survival consistent with INTERMACS data. The adverse events profile showed a high rate of stroke (32%), but there were no cases of GI bleed or pump thrombosis [30].



Fig. 10 Berlin Heart INCOR® ventricular assist device

The benefits of using LVADs for the treatment of aCHF have been well established, and there have been many devices developed to fill this treatment need. Of the devices available, the HeartMate II, HVAD, and HeartMate 3 are the most widely utilized and have the highest-quality data to support their use. The HMII has high rates of pump thrombosis and reoperations for device malfunction, and there are few clear indications for the use of a HMII over the other two devices. One indication would be patients who already have a HMII but require a device exchange. This exchange can be

performed through a subcostal approach and avoid a re-operative sternotomy. The MOMENTUM 3 trial makes a very strong argument for the use of HM3 as the standard choice of LVAD. While the HM3 has not been compared in a randomized trial to the HVAD, comparing the results of the ENDURANCE and MOMENTUM 3 trials suggests that the HM3 has the best hemocompatibility of all three devices. The choice between these two devices can be segregated by several parameters, including surgical and patient factors, wearability, driveline, and the user interface (Table 2). To

Table 2 Comparison of HVAD and HM3

	HVAD	HeartMate 3
Device specifications		
Flow type	Centrifugal	Centrifugal
Weight	140 g	200 g
Displaced volume	50 mL	80 mL
Implant approach	Sternotomy or mini-thoracotomy	Sternotomy
Patient and surgical considerations	Small size, small outflow graft (10 mm), and an easy to affix apical cuff makes it ideal for: • Small adults • Pediatric patients • Bloodless implants (such as Jehovah Witness patients) • Biventricular support • Thoracotomy approach	Stronger pump ideal for larger patients
Wearability		
Peripherals (batteries, controllers)	Bulky, worn in a pack similar to a purse	Can be distributed allowing for more activity (e.g., golf) and concealment with clothing
Battery	6 h per charge	10–17 h per charge Backup battery: Prevents loss of support if there is a double disconnect, particularly important with closed aortic valve
Driveline	Smaller size, appears to have less infections, and they are easier to manage	Stiff driveline, requires double anchoring Pump driveline connects to a replaceable modular line a short distance out of the skin exit site
User interface	Has high-power alarms and a flow waveform. Alarms can be adjusted for each patient to prevent unnecessary alarms	Flow alarm set at 2.5 L/min, frequently alarms in smaller patients, can require admission for fluids and BP management to stop alarms

summarize the comparisons, the HVAD is less expensive and is preferred in smaller patients, especially females and children. The HM3 is preferred in larger patients and for patients whom an active lifestyle is important.

The other devices described all have unique features that make them appealing, but they all lack high-quality data at this time. There may be situations, however, in which one of the unique features of these devices makes it the best LVAD for a certain patient. Further studies need to be performed before these devices are more widely utilized.

There are many other important factors that play a role in selecting a LVAD for your patient: which devices are available and their approved indications in your practice location, what device is covered by a patient's insurance, and what device your hospital and care team has experience with. All the devices that have received the CE mark or FDA approval have demonstrated an acceptable safety profile and can be used successfully.

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Compliance with ethical standards

Ethical This article is a review of previously published work and of clinical experience and is not the publication of primary data. The article provides opinions based on this experience. The article complies with the ethical responsibilities outlined by the journal.

Human and animal rights This article is a review article and not a publication of primary data.

Informed consent This article is a review article and not a publication of primary data.

Conflicts of interest Trever Symalla has no conflict(s) of interest. Valluvan Jeevanadam is a consultant for Abbott.

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