

https://doi.org/10.5090/jcs.23.135 pISSN: 2765-1606 eISSN: 2765-1614 J Chest Surg. 2024;57(2):184-194

Surgical Outcomes of Centrifugal Continuous-Flow Implantable Left Ventricular Assist Devices: Heartmate 3 versus Heartware Ventricular Assist Device

Kinam Shin, M.D.¹, Won Chul Cho, M.D., Ph.D.², Nara Shin, M.Sc.³, Hong Rae Kim, M.D.¹, Min-Seok Kim, M.D., Ph.D.⁴, Cheol Hyun Chung, M.D., Ph.D.¹, Sung-Ho Jung, M.D., Ph.D.¹

¹Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul; ²Thoracic and Cardiovascular Surgery, Gangneung Asan Hospital, University of Ulsan College of Medicine, Gangneung; ³Heart Institute, Asan Medical Center, University of Ulsan College of Medicine; ⁴Heart Failure and Cardiac Transplantation Center, Asan Medical Center Heart Institute, University of Ulsan College of Medicine, Seoul, Korea

ARTICLE INFO

Received September 26, 2023 Revised November 26, 2023 Accepted December 7, 2023

Corresponding author

Sung-Ho Jung Tel 82-2-3010-5990 Fax 82-2-3010-6966 E-mail csjung@amc.seoul.kr ORCID https://orcid.org/0000-0002-3699-0312 **Background:** Left ventricular assist devices (LVADs) are widely employed as a therapeutic option for end-stage heart failure. We evaluated the outcomes associated with centrifugal-flow LVAD implantation, comparing 2 device models: the Heartmate 3 (HM3) and the Heartware Ventricular Assist Device (HVAD).

Methods: Data were collected from patients who underwent LVAD implantation between June 1, 2015 and December 31, 2022. We analyzed overall survival, first rehospitalization, and early, late, and LVAD-related complications.

Results: In total, 74 patients underwent LVAD implantation, with 42 receiving the HM3 and 32 the HVAD. A mild Interagency Registry for Mechanically Assisted Circulatory Support score was more common among HM3 than HVAD recipients (p=0.006), and patients receiving the HM3 exhibited lower rates of preoperative ventilator use (p=0.010) and extracorporeal membrane oxygenation (p=0.039). The overall early mortality rate was 5.4% (4 of 74 patients), with no significant difference between groups. Regarding early right ventricular (RV) failure, HM3 implantation was associated with a lower rate (13 of 42 [31.0%]) than HVAD implantation (18 of 32 [56.2%], p=0.051). The median rehospitalization-free period was longer for HM3 recipients (16.9 months) than HVAD recipients (5.3 months, p=0.013). Furthermore, HM3 recipients displayed a lower incidence of late hemorrhagic stroke (p=0.016). In the multivariable analysis, preoperative use of continuous renal replacement therapy (odds ratio, 22.31; p=0.002) was the only significant predictor of postoperative RV failure.

Conclusion: The LVAD models (HM3 and HVAD) demonstrated comparable overall survival rates. However, the HM3 was associated with a lower risk of late hemorrhagic stroke.

Keywords: Left ventricular assist device, Heartmate3

Introduction

The prevalence of end-stage heart failure (HF) is increasing in Korea, posing a major public health challenge and incurring substantial costs [1]. However, the scarcity of available organs means that heart transplantation, the goldstandard treatment for end-stage HF, is an option available to few patients. As an alternative, the implementation of a left ventricular assist device (LVAD), a durable mechanical circulatory support system, has become an established treatment for these cases. LVADs can serve as either a bridge to transplantation (BTT) or a destination therapy (DT) for those with end-stage HF. Several types of LVADs are available, with ongoing development and introduction of new models [2]. In the MOMENTUM3 trial, relative to an axial-flow LVAD, a fully magnetically levitated centrifugal-flow LVAD demonstrated a lower frequency of pump replacement or removal and a higher rate of survival free of disabling stroke [3]. Consequently, the use of the Heartmate 3 (HM3; Abbott Laboratories, Abbott Park, IL, USA),

Copyright © 2024, The Korean Society for Thoracic and Cardiovascular Surgery

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/ by-nc/4.0) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

a fully magnetically levitated centrifugal-flow LVAD, has seen an uptick. Two types of third-generation LVADs exist: the HM3 and the Heartware Ventricular Assist Device (HVAD; Medtronic, Minneapolis, MN, USA). Both the HM3 and the HVAD are centrifugal devices that are implanted within the pericardial space. Subsequent research has further highlighted the advantages of the HM3 over the HVAD, showing improvements in mean survival time and complication-free time along with fewer device malfunctions [4,5]. Moreover, as of July 2021, the distribution and sale of the HVAD had ceased [6]. Despite the adoption of the HM3 for patients with end-stage HF in Korea, no study has yet analyzed the outcomes associated with this device or compared it with other models used in the country. Therefore, our objective was to assess the outcomes of LVAD implantation at our center and to compare the results between the HM3 and HVAD models.

Methods

Patients

We consecutively enrolled 74 patients who underwent implantation of a centrifugal continuous-flow implantable LVAD at Asan Medical Center in Seoul, South Korea between June 2015 and December 2022. Until 2019, only the HVAD was utilized, while beginning in 2021, both HVAD and HM3 models were available. Initially, our preference was for the HM3 model. However, for patients with a smaller body size, we selected the HVAD due to its smaller dimensions. Beginning in June 2021, only HM3 models were used (Fig. 1). No patients were excluded from the

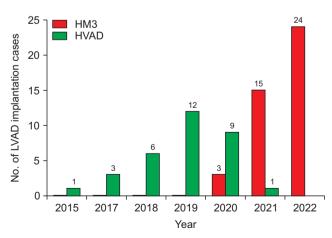


Fig. 1. Number of left ventricular assist device (LVAD) implantation cases by year. HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device.

present study. The patients were divided into 2 groups: 42 received the HM3, while 32 were implanted with the HVAD.

The study protocol received approval from the Institutional Ethics Committee/Review Board of Asan Medical Center (study number: 2023-0867; approval date: 2023-07-12). Given the retrospective nature of the study, the requirement for informed patient consent was waived.

Data acquisition and endpoints

All patients were followed until heart transplantation, death, or the end date of the study (December 31, 2022). Patients were censored at the time of transplantation or death. In the calculation of survival rates, cases involving heart transplantation were treated as censored data.

The primary outcome of interest was all-cause mortality following LVAD implantation. The secondary endpoints included first rehospitalization, early and late complications, and VAD-related complications. These endpoints were defined in accordance with the standards set by the International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support registry. For additional information on the definitions of these complications, refer to Supplementary Table 1.

Clinical data were collected through December 31, 2022, during routine visits to the outpatient clinic. To ascertain mortality status, details concerning the date and cause of death were obtained from the institutional electronic database of Asan Medical Center and the health claims database of the National Health Insurance Service. The latter institution represents a mandatory universal health insurance program covering all residents of the Republic of Korea. Early mortality was defined as death occurring within 30 days following surgery.

Surgical procedures

Overall, 69 cases involved full median sternotomy, while 5 patients underwent left thoracotomy with upper sternotomy or right anterior thoracotomy. The right atrial auricle was selected for venous cannulation. However, in cases requiring right atriotomy for combined surgery, bicaval venous cannulation was the preferred method. When combined procedures—for instance, aortic or mitral valve replacement—necessitated aortic cross-clamping, that step was completed first. Following declamping of the aorta, LVAD implantation was performed with the heart beating. Before administering heparin, a tunnel for the driveline was fashioned. The driveline exit site was positioned on the left side for right-handed patients and on the right side for left-handed patients. We employed the double-tunnel technique to establish a silicone-to-skin interface. The placement and orientation of the inflow cannula were verified using transesophageal echocardiography, ensuring it was directed from the true left ventricular apex towards the mitral valve. The outflow graft was connected using 5-0 Prolene sutures. For the next surgical procedure, a Gore-Tex membrane was utilized.

Following LVAD implantation surgery, we adhered to a standardized anticoagulation protocol. On postoperative day (POD) 1, barring any bleeding, heparin therapy was initiated with the goal of achieving an activated partial thromboplastin time (aPTT) of 50–75 seconds. In cases involving a bleeding tendency, the target aPTT was adjusted to a range of 40–60 seconds. From POD 3 onward, provided the chest tube drainage output was below 30 mL per hour, we introduced a regimen of 100 mg aspirin along with warfarin therapy. For the latter, the therapeutic objective was to achieve a target international normalized ratio of 2.0 to 3.0.

Statistical analysis

Continuous variables are presented as either the mean with standard deviation or the median with interquartile range (IQR, presented as 25th–75th percentile) following normality testing. Values were compared using the Student t-test or the Mann-Whitney U test. Categorical variables are presented as counts and percentages and were analyzed using either the chi-square test or the Fisher exact test. Survival and freedom-from-event outcomes were evaluated using Kaplan-Meier curves, with the log-rank test applied to assess differences between groups. Statistical analysis was performed using R ver. 4.3.0 (R Foundation for Statistical Computing, Vanderbilt University, Nashville, TN, USA).

Results

Baseline characteristics

This study included a total of 74 patients (mean age, 58.9 years), of whom 83.8% were male. The baseline characteristics of these patients are detailed in Table 1. No significant differences were observed in terms of sex, age, indication for surgery, or history of cardiac surgery between the groups. However, relative to those in the HVAD group, the HM3 group exhibited better Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) scores (p=0.006), a lower rate of preoperative ventilator use (1 patient [2.4%] versus 8 patients [25.0%], p=0.010), and a lower frequency of ECMO (4 patients [9.5%] versus 10 patients [31.2%], p=0.039). Additionally, ischemic cardiomyopathy was more prevalent in the HVAD group. Preoperative transthoracic echocardiography parameters showed no significant differences between groups (Table 2). The majority of procedures in both groups were performed through a median full sternotomy, and 31.1% of operations were performed in conjunction with other cardiac procedures (Table 3). The specific additional surgical procedures are detailed in Table 3.

Clinical outcomes

The early mortality rate was observed to be 5.4% (Table 4). No significant differences were found in the rates of early postoperative complications, including postoperative bleeding, gastrointestinal bleeding, pump failure, and stroke, between the groups. However, the HVAD recipients more frequently required the subsequent implantation of a right ventricular assist device (RVAD) following initial LVAD implantation (7 patients [21.9%] versus 1 patient [2.4%], p=0.022). Additionally, the HVAD group experienced longer intensive care unit (ICU) stays (13 days [IQR, 9–22 days] versus 8 days [IQR, 7–22 days], p=0.024) and greater overall hospitalization time (57 days [IQR, 38–84 days] versus 34 days [IQR, 27–45 days], p<0.001) following surgery.

The median follow-up duration was 200.5 days (IQR, 107-384 days). This value did not differ significantly between groups (HM3, 198 days; HVAD, 232 days; p=0.218). Over the follow-up period, 29 patients remained alive and LVAD-dependent, 29 patients underwent heart transplantation, and 16 patients died. The mean period from LVAD implantation to heart transplantation was 234.4±137.7 days. The overall survival rates at 6, 12, and 24 months were 84.8%, 79.7%, and 55.2%, respectively (Fig. 2A). The most common cause of death was sepsis due to pneumonia, followed by hemorrhagic stroke (Supplementary Table 2). In the HM3 group, the survival rates at 6 and 12 months were 85.6% and 75.6%, respectively, while in the HVAD group, survival rates were 83.7% at both 6 month and 12 month. No significant difference in survival was found between the groups (p=0.79) (Fig. 2B). The BTT group exhibited better survival rates than the participants receiving DT (p=0.029), with 6- and 12-month survival

Table 1. Baseline characteristics

Characteristic	Total (n=74)	HM3 (n=42)	HVAD (n=32)	p-value
Sex, male	62 (83.8)	38 (90.5)	24 (75)	0.141
Age (yr)	58.9±12.8	58.5±11.7	59.4±14.2	0.767
Height (cm)	167.2±8.3	168.1±8.8	165.9±7.6	0.273
Weight (kg)	64.1±14.7	67.7±17.3	60.3±9.3	0.033
Body mass index (kg/m ²)	22.8±4.3	23.6±5.1	21.8±2.7	0.060
Diabetes mellitus	22 (29.7)	12 (28.6)	10 (31.2)	1.000
Hypertension	13 (17.6)	8 (19.0)	5 (15.6)	0.940
Chronic kidney disease	30 (40.5)	15 (35.7)	15 (46.9)	0.466
Atrial fibrillation	20 (27.0)	11 (26.2)	9 (28.1)	1.000
History of cardiac surgery	19 (25.7)	10 (23.8)	9 (28.1)	0.879
Diagnosis				0.024
DCMP	40 (54.1)	26 (61.9)	14 (43.8)	
HCMP	5 (6.8)	5 (11.9)	0	
ICMP	27 (36.5)	10 (23.8)	17 (53.1)	
Mitral regurgitation	1 (1.4)	0	1 (3.1)	
Sarcoidosis	1 (1.4)	1 (2.4)	0	
Purpose of device implantation				0.624
Bridge to transplantation	63 (85.1)	37 (88.1)	26 (81.2)	
Destination therapy	11 (14.9)	5 (11.9)	6 (18.8)	
NTERMACS profile				0.006
1	4 (5.4)	1 (2.4)	3 (9.4)	
2	16 (21.6)	5 (11.9)	11 (34.4)	
3	41 (55.4)	24 (57.1)	17 (53.1)	
4	13 (17.6)	12 (28.6)	1 (3.1)	
Preoperative status				
Intensive care unit	20 (27.0)	8 (19.0)	12 (37.5)	0.132
Ventilator	9 (12.2)	1 (2.4)	8 (25.0)	0.010
ECMO	14 (18.9)	4 (9.5)	10 (31.2)	0.039
CRRT	8 (10.8)	3 (7.1)	5 (15.6)	0.432
Follow-up period (day)	201 (107–383)	198 (107-327)	232 (126-499)	0.218

Values are presented as number (%), mean±standard deviation, or median (quartile 1–quartile 3).

HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device; DCMP, dilated cardiomyopathy; HCMP, hypertrophic cardiomyopathy; ICMP, ischemic cardiomyopathy; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; ECMO, extracorporeal membrane oxygenation; CRRT, continuous renal replacement therapy.

rates of 87.1% and 82.9% for BTT and 72.7% and 63.6% for DT, respectively (Fig. 2C). Survival analysis stratified by INTERMACS profiles revealed 6-month survival rates of 75.0%, 65.0%, 91.6%, and 87.5% for INTERMACS profiles of 1, 2, 3, and 4, respectively. The 12-month survival rates were 75.0%, 65.0%, 83.3%, and 87.5%, respectively (Fig. 2D).

During the clinical follow-up period after discharge (median duration, 4.13 months; IQR, 1.53–6.63 months), a total of 31 patients (50.8%) required rehospitalization. Of these unplanned admissions, 12 patients had received HM3 implantation, while 19 patients were HVAD recipients. Rehospitalization was avoided more frequently in the HM3 group, with 73.1% of patients free of rehospitalization at 6 months and 53.3% at 12 months, compared to the HVAD group, which exhibited rates of 38.1% at 6 months and 12.7% at 12 months (Fig. 3A). Bleeding was identified as the leading cause of readmission, followed by infection (Supplementary Table 3). No significant differences were observed in the rates of late postoperative complications, including pneumonia, driveline infection, de novo aortic insufficiency, and pump thrombosis, between the groups (Table 5). Notably, the HM3 group had no reported cases of ischemic or hemorrhagic stroke. In contrast, within the HVAD group, 3 patients experienced ischemic stroke, while 6 had hemorrhagic strokes. The Kaplan-Meier analysis revealed a statistically significant difference in the incidence of stroke between the groups (p=0.007), as illustrated in Fig. 3B. The incidence of hemorrhagic stroke was higher in the HVAD group (p=0.013) (Fig. 3C). Although

Variable	Total (n=74)	HM3 (n=42)	HVAD (n=32)	p-value
LVEF	20.9±6.7	21.5±6.7	20.2±6.8	0.399
AR				0.429
None or trivial	59 (79.7)	34 (81.0)	25 (78.1)	
Mild	13 (17.6)	8 (19.0)	5 (15.6)	
Moderate	1 (1.4)	0	5 (15.6)	
Moderate to severe	0	0	0	
Severe	1 (1.4)	0	1 (1.4)	
MR				0.387
None or trivial	14 (18.9)	8 (19.0)	6 (18.8)	
Mild	25 (33.8)	15 (35.7)	10 (31.2)	
Moderate	12 (16.2)	9 (21.4)	3 (9.4)	
Moderate to severe	3 (4.1)	2 (4.8)	1 (3.1)	
Severe	20 (27.0)	8 (19.0)	12 (37.5)	
TR				0.826
None or trivial	13 (17.6)	8 (19.0)	5 (15.6)	
Mild	38 (51.4)	22 (52.4)	16 (50.0)	
Moderate	13 (17.6)	7 (16.7)	6 (18.8)	
Moderate to severe	1 (1.4)	0	1 (3.1)	
Severe	9 (12.2)	5 (11.9)	4 (12.5)	
Peak TR velocity	3.2±0.7	3.1±0.7	2.2±0.8	0.614

Table 2. Preoperative transthoracic echocardiography findings

Values are presented as mean±standard deviation or number (%).

HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device; LVEF, left ventricular ejection fraction; AR, aortic regurgitation; MR, mitral regurgitation; TR, tricuspid regurgitation.

Table 3. Surgical characteristics

Variable	Total (n=74)	HM3 (n=42)	HVAD (n=32)	p-value
Approach				0.536
Full sternotomy	69 (93.2)	38 (90.5)	31 (96.9)	
Thoracotomy	5 (6.8)	4 (9.5)	1 (3.1)	
CPB time (min)	109.5 (80–126)	110.7 (82–126)	107.8 (79–117)	0.796
ACC time (min)		150.4 (n=5)	114.1 (n=7)	
Combined surgery	23 (31.1)	13 (31.0)	10 (31.2)	1.000
None	51 (68.9)	29 (69.0)	22 (68.8)	
ASD closure	9 (12.2)	6 (14.3)	3 (9.4)	
AVP	4 (5.4)	3 (7.1)	1 (3.1)	
AVR	2 (2.7)	0	2 (6.2)	
MVP	1 (1.4)	0	1 (3.1)	
TVP	5 (6.8)	4 (9.5)	1 (3.1)	
TVR	1 (1.4)	0	1 (3.1)	
LV aneurysm resection	1 (1.4)	0	1 (3.1)	

Values are presented as number (%), median (quartile 1-quartile 3), or mean.

HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device; CPB, cardiopulmonary bypass; ACC, aortic cross-clamp; ASD, atrial septal defect; AVP, aortic valvuloplasty; AVR, aortic valve replacement; MVP, mitral valvuloplasty; TVP, tricuspid valvuloplasty; TVR, tricuspid valve replacement; LV, left ventricle.

the difference between HM3 and HVAD recipients was not statistically significant, the HM3 group displayed a lower incidence of ischemic stroke (p=0.063) (Fig. 3D).

Predictors of adverse clinical outcomes

In the multivariable analysis of risk factors for postoperative mortality, hypertension (hazard ratio [HR], 4.38; p= 0.012) and preoperative use of continuous renal replace-

Variable	Total (n=74)	HM3 (n=42)	HVAD (n=32)	p-value
Death (<30 day)	4 (5.4)	2 (4.8)	2 (6.2)	1.000
Bleeding control	15 (20.3)	6 (14.3)	9 (28.1)	0.240
GI bleeding	3 (4.1)	3 (7.1)	0	0.343
Pump malfunction	1 (1.4)	0	1 (3.1)	0.891
Pump failure	5 (6.8)	1 (2.4)	4 (12.5)	0.211
Driveline infection	1 (1.4)	0	1 (3.1)	0.891
Mediastinitis	2 (2.7)	0	2 (6.2)	0.358
Stroke	3 (4.1)	2 (4.8)	1 (3.1)	1.000
Pneumonia	11 (14.9)	7 (16.7)	4 (12.5)	0.866
RVAD	8 (10.8)	1 (2.4)	7 (21.9)	0.022
RV failure	31 (41.9)	13 (31.0)	18 (56.2)	0.051
Postoperative stay				
ICU stay (day)	12 (7–21)	8 (6–16)	13 (9–22)	0.024
Hospital stay (day)	42 (30–64)	34 (27–45)	57 (38-84)	< 0.001
Ventilation (hr)	20 (17-68)	20 (17-68)	21 (17-62)	0.772

Table 4. Early mortality and in-hospital complications

Values are presented as number (%) or median (quartile 1–quartile 3).

HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device; GI, gastrointestinal; RVAD, right ventricular assist device; RV, right ventricle; ICU, intensive care unit.

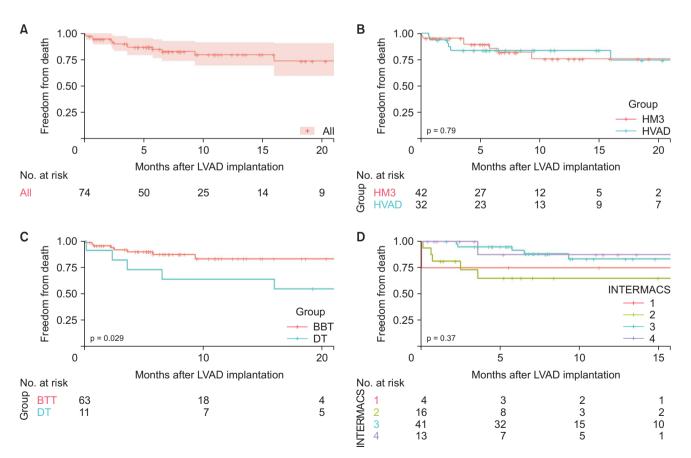


Fig. 2. Overall survival rate after left ventricular assist device (LVAD) implantation. (A) Survival across all patients. (B) Comparison between Heartmate 3 (HM3) and Heartware Ventricular Assist Device (HVAD). (C) Comparison between bridge to transplantation (BTT) and destination therapy (DT). (D) Stratification by Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).

JCS

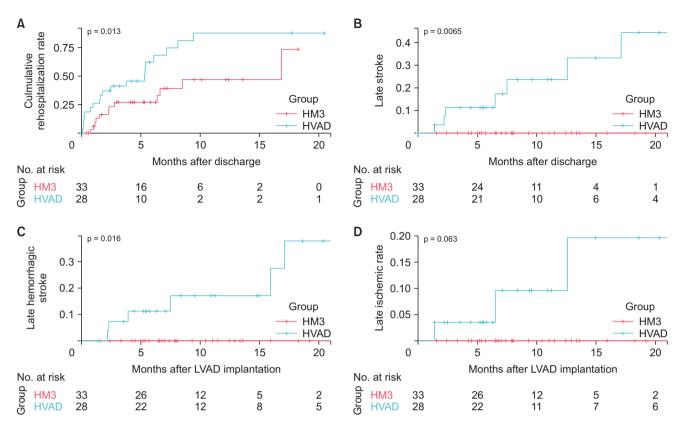


Fig. 3. Unexpected rehospitalization and late complications after discharge. (A) Cumulative rehospitalization rate after discharge. (B) Stroke. (C) Hemorrhagic stroke. (D) Ischemic stroke. HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device; LVAD, left ventricular assist device.

Tuble 51 Eate complications after als	enarge .			
Variable	Total (n=61)	HM3 (n=33)	HVAD (n=28)	p-value
Stroke	7 (11.5)	0	7 (25.0)	0.008
Hemorrhagic stroke	6 (9.8)	0	6 (21.4)	0.018
Ischemic stroke	3 (4.9)	0	3 (10.7)	0.182
Pneumonia	7 (11.5)	2 (6.1)	5 (17.9)	0.300
Driveline infection	4 (6.6)	1 (3.0)	3 (10.7)	0.491
De novo AR	3 (4.9)	1 (3.0)	2 (7.1)	0.884
GI bleeding	6 (9.8)	3 (9.1)	3 (10.7)	1.000
RV failure	7 (11.5)	2 (6.1)	5 (17.9)	0.300
Pump thrombosis	1 (1.6)	0	1 (3.6)	0.934

Table 5. Late complications after discharge

Values are presented as number (%).

HM3, Heartmate 3; HVAD, Heartware Ventricular Assist Device; AR, aortic regurgitation; GI, gastrointestinal; RV, right ventricle.

ment therapy (CRRT) (HR, 6.91; p=0.003) were identified as significant risk factors (Table 6). Regarding postoperative complications, the multivariable analysis did not reveal any statistically significant risk factors for early stroke (Supplementary Table 4A). In the univariable risk analysis for postoperative RV failure, male sex, HVAD implementation, preoperative CRRT, and preoperative ventilator use emerged as significant risk factors. However, in the final multivariable model, preoperative CRRT (OR, 22.31; p= 0.002) was identified as the sole significant predictor of postoperative RV failure in our cohort (Table 7). In the univariable risk analysis for late complications, no statistically significant predictors were found for ischemic stroke. HVAD emerged as the sole significant risk factor for hemorrhagic stroke (HR, 12.81; p=0.015) (Supplementary Table 4B, C).

Table 6. Risk factor analysis for mortality

Variable	Univariable and	Univariable analysis		Multivariable analysis	
	HR (95% CI)	p-value	HR (95% CI)	p-value	
HVAD	0.87 (0.31-2.46)	0.79			
Age	1.07 (1.00–1.15)	0.042	1.04 (0.98–1.11)	0.182	
Male sex	2.01 (0.44-9.20)	0.371			
Bbody mass index	0.95 (0.83-1.08)	0.425			
Hypertension	3.15 (1.11-8.89)	0.031	4.38 (1.38–13.89)	0.012	
Diabetes mellitus	2.54 (0.95-6.78)	0.062			
Chronic kidney disease	1.74 (0.65-4.68)	0.271			
Atrial fibrillation	1.09 (0.38-3.18)	0.867			
Preoperative status					
Ventilator	1.74 (0.49-6.19)	0.389			
ECMO	1.59 (0.51-4.96)	0.422			
CRRT	5.31 (1.8–15.7)	0.003	6.91 (1.96–24.42)	0.003	
CPB time	1.00 (0.99–1.01)	0.573			

HR, hazard ratio; CI, confidence interval; HVAD, Heartware Ventricular Assist Device; ECMO, extracorporeal membrane oxygenation; CRRT, continuous renal replacement therapy; CPB, cardiopulmonary bypass.

Table 7. Risk factor analysis for early complication: right ventricular failure

Variable -	Univariable analy	/sis	Multivariable analysis	
	OR (95% CI)	p-value	OR (95% CI)	p-value
HVAD	2.79 (1.10-7.31)	0.030	2.13 (0.76-6.27)	0.147
Age	1.00 (0.97-1.04)	0.953		
Male sex	0.29 (0.08-1.09)	0.067		
Body mass index	0.95 (0.85-1.07)	0.426		
Hypertension	1.05 (0.20-5.55)	0.954		
Diabetes mellitus	2.08 (0.76-5.73)	0.155		
Chronic kidney disease	1.39 (0.54–3.56)	0.492		
Atrial fibrillation	1.19 (0.42-3.35)	0.742		
Preoperative status				
Ventilator	5.08 (1.24-28.94)	0.023	2.08 (0.25-19.47)	0.499
ECMO	4.28 (1.32–16.02)	0.014	1.42 (0.22-8.01)	0.691
CRRT	31.47 (3.64-4135.65)	< 0.001	22.31 (2.38–2974.17)	0.002
CPB time	1.00 (0.99–1.01)	0.929		

OR, odds ratio; CI, confidence interval; HVAD, Heartware Ventricular Assist Device; ECMO, extracorporeal membrane oxygenation; CRRT, continuous renal replacement therapy; CPB, cardiopulmonary bypass.

Discussion

In this single-center study, we observed no significant difference in short-term survival following LVAD implantation based on the type of LVAD used. However, HVAD use was associated with the subsequent need for postoperative RVAD insertion and an elevated risk of postoperative stroke.

The short-term survival rates observed in this report align with findings from international studies. For the HM3 device, the MOMENTUM 3 trial demonstrated a 6-month survival rate of 87.3% and a 12-month survival rate of 84.4% [7]. In the present investigation, no statistically significant difference was found in overall survival based on the device type used, echoing results from other studies. In a separate article comparing the HM3 and HVAD, the 1-year survival rates were 83.2% for the HM3 and 86.0% for the HVAD [5]. Comparable survival rates for both devices have been reported in additional single-center studies [8,9]. Moreover, a multicenter study revealed no significant differences in overall survival rates, with 1-year rates of 73% for HM3 and 71% for HVAD [10]. In contrast, a separate study indicated that the HM3 may offer better overall survival than the HVAD, with 2-year sur-

vival rates of 77.4% for the HM3 and 53.2% for the HVAD [4]. However, that study focused on patients receiving DT at a single center. Unlike prior research, the HVAD group in the present investigation exhibited comparatively poor preoperative characteristics, but similar survival outcomes. This discrepancy may be due to the relatively low number of cases at our center. The difference in survival outcomes between these devices remains a topic of debate, underscoring the necessity for additional research in this field.

In the MOMENTUM3 trial, right HF emerged as the most common cause of death following LVAD implantation [7,11]. In a separate LVAD study conducted in Korea, the most prevalent cause of death was hemorrhagic stroke [12]. In contrast, our findings indicated that sepsis resulting from pneumonia was the primary cause of death. Additionally, the incidence of pneumonia exceeded 10% among our participants. In this study, high proportions of patients were preoperatively dependent on ECMO, received mechanical ventilation, and/or had stayed in the ICU prior to surgery. These preoperative conditions likely hindered postoperative ambulation and impeded effective lung care, thereby elevating the risk of developing pneumonia.

Numerous studies have documented the outcomes of ischemic and hemorrhagic strokes following LVAD implantation, highlighting the gravity of neurological complications. Research has indicated that fully magnetically levitated centrifugal-flow LVADs are superior to axial-flow LVADs in terms of survival free from disabling stroke [11]. Moreover, when comparing different centrifugal-flow LVADs, the HM3 has displayed better outcomes than the HVAD in terms of ischemic and hemorrhagic cerebrovascular accidents [13]. Another study revealed that the rate of severe neurological dysfunction was 13.9% in patients treated with the HM3, a better outcome than the 24.3% rate observed in HVAD recipients [5]. In the present study, HM3 implantation was also associated with favorable results regarding the incidence of stroke. Notably, no cases of late stroke were found in the HM3 group. Additionally, HVAD use was identified as a risk factor for hemorrhagic stroke. Future research may provide a deeper understanding of these differences, particularly considering the absence of late stroke cases in the HM3 group.

This study revealed varying outcomes regarding RV failure between the examined devices. Prior research has not definitively clarified the distinctions in RV failure following LVAD implantation [5,10]. In the present study, the disparate findings between groups may stem from high rates of RV failure after HVAD insertion at our institution. Early RV failure following HM3 implantation was observed in 31.0% of patients, with 2.4% requiring ECMO or RVAD insertion. These figures align with the MOMEN-TUM3 trial outcomes for HM3, which reported an RV failure rate of 31.7% with 3.2% of patients requiring mechanical support [7]. However, the early RV failure rate after HVAD implantation exceeded 50% in this study. We attribute this finding to the higher frequency of preoperative ECMO usage among participants. Over 30% of patients receiving HVAD were on ECMO preoperatively, indicating relatively compromised preoperative states. After accounting for variations in preoperative characteristics, multivariable analysis indicated that HVAD use was not statistically associated with an increased risk of RV failure. Instead, the preoperative use of CRRT emerged as a significant risk factor. This suggests that a patient's preoperative condition may exert a more substantial impact on RV failure than the specific device chosen. To elucidate these differences, additional data from HM3 implantations in severely ill conditions are required.

Both the duration of postoperative ICU stay and the length of hospitalization were shorter in the HM3 group than among the HVAD recipients. A separate study reported the median ICU stay as 12 days for the HM3 and 11 days for the HVAD group, without any significant difference [10]. However, our study identified a 5-day difference between the groups. This discrepancy may stem from differences in baseline characteristics and postoperative complications. Notably, the patients who received HVAD implantation displayed relatively poor INTERMACS scores, and comparatively high proportions required ventilator support and ECMO. Moreover, the HVAD recipients exhibited a higher incidence of postoperative RV failure, often necessitating RVAD implantation. We believe that these distinctions contributed to the prolonged postoperative ICU stays observed in the HVAD group. Consequently, our findings suggest that mitigating early complications could potentially decrease the duration of postoperative ICU stays, which may in turn lower the risk of pneumonia and improve overall survival.

This study had several limitations. First, the retrospective observational design is associated with inherent constraints. Second, the findings were based on a relatively small sample size from a single center, potentially restricting the generalizability of the results. The use of a small sample can also yield statistically unusual clinical findings. Third, differences were present in the preoperative characteristics, which could have influenced the results. It is conceivable that some of the variations in clinical outcomes were due to preoperative differences rather than the devices themselves. Finally, as this was a chronological study, changes may have occurred in the practitioners' skills and experience over time, potentially impacting the results. Nevertheless, despite these limitations, the findings are meaningful, particularly considering the infrequency of HVAD use. These results provide valuable information for subsequent research on the HM3 device and its effects.

In conclusion, in this study, the HM3 and the HVAD demonstrated comparable overall survival rates. Preoperative CRRT was identified as a risk factor for postoperative RV failure. Most notably, the HM3 was associated with superior outcomes regarding the incidence of hemorrhagic stroke compared to the HVAD.

Article information

ORCID

Kinam Shin: https://orcid.org/0009-0003-2098-1205 Won Chul Cho: https://orcid.org/0000-0002-3858-6516 Nara Shin: https://orcid.org/0009-0004-7829-1765 Hong Rae Kim: https://orcid.org/0000-0002-3305-6065 Min-Seok Kim: https://orcid.org/0000-0003-0860-3650 Cheol Hyun Chung: https://orcid.org/0000-0001-8981-6011 Sung-Ho Jung: https://orcid.org/0000-0002-3699-0312

Author contributions

Conceptualization: SHJ. Data curation: KS. Formal analysis: SHJ, CHC, HRK, NS, KS. Funding acquisition: none. Investigation: SHJ, WCC, KS. Methodology: SHJ, CHC, MSK. Project administration: SHJ. Visualization: SHJ, HRK, KS. Writing-original draft: KS. Writing-review & editing: SHJ, CHC, MSK, WCC, HRK, NS, KS.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-forprofit sectors.

Supplementary materials

Supplementary materials can be found via https://doi.

org/10.5090/jcs.23.135. **Supplementary Table 1**. Definitions of complications. **Supplementary Table 2**. Causes of death. **Supplementary Table 3**. Causes of unexpected rehospitalization. **Supplementary Table 4**. Risk factor analysis for early complication.

References

- Youn JC, Kim D, Cho JY, et al. Korean Society of Heart Failure Guidelines for the management of heart failure: treatment. Korean Circ J 2023;53:217-38. https://doi.org/10.4070/kcj.2023.0047
- Yuzefpolskaya M, Schroeder SE, Houston BA, et al. The Society of Thoracic Surgeons Intermacs 2022 Annual Report: focus on the 2018 heart transplant allocation system. Ann Thorac Surg 2023;115:311-27. https://doi.org/10.1016/j.athoracsur.2022.11.023
- Mehra MR, Uriel N, Naka Y, et al. A fully magnetically levitated left ventricular assist device: final report. N Engl J Med 2019;380:1618-27. https://doi.org/10.1056/NEJMoa1900486
- Wasilewski G, Kedziora A, Wisniowska-Smialek S, Tomsia P, Kaleta M, Wierzbicki K. Outcomes in patients with HeartMate3 versus HeartWare ventricular assist device implanted as destination therapy. Transplant Proc 2022;54:1049-53. https://doi.org/10.1016/j.transproceed.2022.02.020
- Mihalj M, Heinisch PP, Schober P, et al. Third-generation continuous-flow left ventricular assist devices: a comparative outcome analysis by device type. ESC Heart Fail 2022;9:3469-82. https://doi. org/10.1002/ehf2.13794
- Medtronic. Left ventricular assist device (LVAD) for advanced heart failure still walking beside you [Internet]. Medtronic; 2021 [cited 2023 Nov 2]. Available from: https://www.medtronic.com/us-en/patients/treatments-therapies/ventricular-assist-device.html
- Mehra MR, Goldstein DJ, Uriel N, et al. Two-year outcomes with a magnetically levitated cardiac pump in heart failure. N Engl J Med 2018;378:1386-95. https://doi.org/10.1056/NEJMoa1800866
- Itzhaki Ben Zadok O, Ben-Avraham B, Shaul A, et al. An 18-month comparison of clinical outcomes between continuous-flow left ventricular assist devices. Eur J Cardiothorac Surg 2019;56:1054-61. https://doi.org/10.1093/ejcts/ezz268
- Mueller M, Hoermandinger C, Richter G, et al. Retrospective 1-year outcome follow-up in 200 patients supported with HeartMate 3 and HeartWare left ventricular assist devices in a single centre. Eur J Cardiothorac Surg 2020;57:1160-5. https://doi.org/10.1093/ejcts/ ezaa017
- Potapov EV, Nersesian G, Lewin D, et al. Propensity score-based analysis of long-term follow-up in patients supported with durable centrifugal left ventricular assist devices: the EUROMACS analysis. Eur J Cardiothorac Surg 2021;60:579-87. https://doi.org/10.1093/ ejcts/ezab144
- 11. Mehra MR, Goldstein DJ, Cleveland JC, et al. Five-year outcomes in

patients with fully magnetically levitated vs axial-flow left ventricular assist devices in the MOMENTUM 3 randomized trial. JAMA 2022;328:1233-42. https://doi.org/10.1001/jama.2022.16197

12. Park Y, Kim D, Yang JH, Cho YH, Choi JO, Jeon ES. Clinical outcome in patients with end-stage heart failure who underwent continuous-flow left ventricular assist devices in a single center. Korean J Intern Med 2022;37:340-9. https://doi.org/10.3904/kjim.2021.088

 Cho SM, Mehaffey JH, Meyers SL, et al. Cerebrovascular events in patients with centrifugal-flow left ventricular assist devices: propensity score-matched analysis from the Intermacs Registry. Circulation 2021;144:763-72. https://doi.org/10.1161/CIRCULATIONAHA.121. 055716