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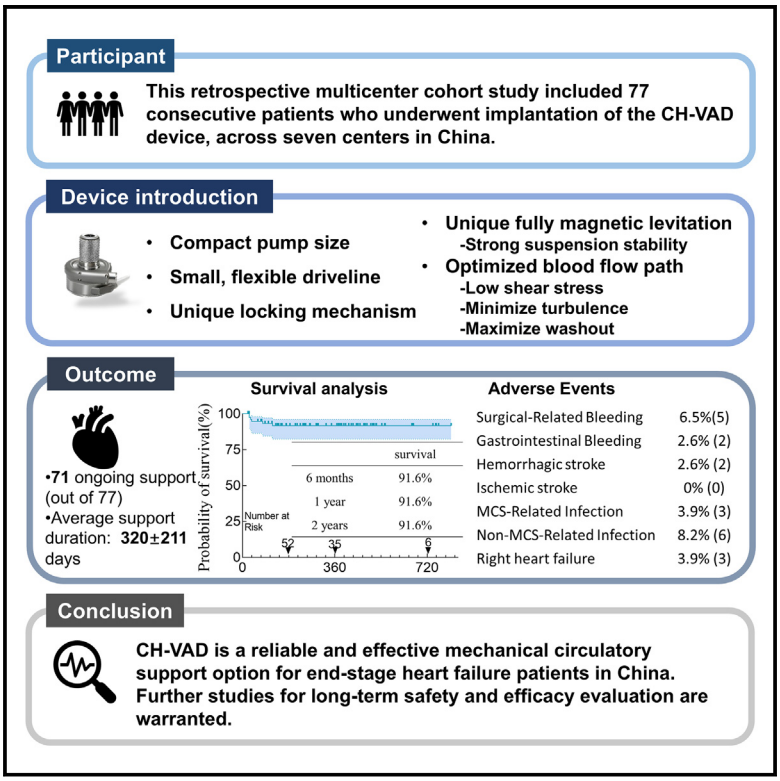
Multicenter study for CH-VAD as a fully magnetically levitated left ventricular assist device

Graphical abstract



Highlights

- CH-VAD showed a 91.6% survival rate at 6-month and 1-year follow-ups
- Low rates of adverse events; no pump thrombosis or device failure were reported
- CH-VAD provided reliable support for endstage heart failure patients in China

Authors

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In brief

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Multicenter study for CH-VAD as a fully magnetically levitated left ventricular assist device

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SUMMARY

The CH-VAD is a fully magnetically levitated left ventricular assist device (LVAD) designed for optimized hemocompatibility. This study evaluates the clinical outcomes of 77 patients implanted with the CH-VAD across seven centers in China from June 2022 to June 2024. Patients had a mean age of 57.5 years, primarily classified as INTERMACS 2 or 3, with dilated and ischemic cardiomyopathy as the main causes of heart failure (HF). The study reported a 91.6% survival rate at both 6-month and 1-year follow-ups, aligning with international LVAD outcomes. Key adverse events were infrequent, including low rates of right HF, reoperation for bleeding, and driveline infection. Importantly, no pump thrombosis or device failures were noted. The results suggest that the CH-VAD is a reliable and effective long-term mechanical circulatory support option for end-stage HF patients in China, warranting further studies for long-term efficacy evaluation.

INTRODUCTION

Heart failure (HF) represents a complex pathophysiological manifestation that emerges when cardiovascular diseases progress to their end stages, rendering the heart incapable of maintaining its function. The incidence of HF is continually rising globally, affecting over 60 million people worldwide, with approximately 6.4 million in the end-stage HF category.[1] In China, it is conservatively estimated that there are about 13 million HF patients, including around 1 million in the end-stage. End-stage HF is characterized by persistent symptoms of HF that interfere with daily activities despite maximal medical therapy, leading to repeated hospitalizations. The annual mortality rate for patients at this stage is as high as 50%.[2] Therefore, once end-stage HF occurs, it presents a prolonged and complex course, making treatment difficult and placing a significant burden on public health resources.

Currently, the main treatments for end-stage HF include heart transplantation (HTx) and mechanical circulatory support (MCS). HTx is considered the gold standard treatment for providing optimal survival and quality of life. However, the scarcity of donor hearts and the complexity of immunosuppressive therapy limit its application, with around 6,000 heart transplants performed globally each year, and only about 700 annually in China.[3] MCS devices, such as left ventricular assist devices (LVADs), offer an effective alternative. With continuous improvements in LVAD design, particularly the advent of fully magnetically levitated continuous-flow LVADs, the 2-year survival rate for patients has reached 81.2%,[4] achieving outcomes comparable to HTx.

LVADs have undergone significant evolution through three generations of blood pumps, including pulsatile, axial flow, and centrifugal pumps (hydrodynamic levitation, magneto-hydrodynamic levitation, and fully magnetically levitated). They have become a critical treatment option for end-stage HF. In the United States, approximately 3,000 patients receive LVADs annually, surpassing the number of heart transplants. The US Food and Drug Administration (FDA) has approved implantable LVADs for end-stage HF patients classified as INTERMACS levels 1–4, for use as long-term support (destination therapy [DT]), as a bridge to transplant (BTT), and as a bridge to recovery (BTR). Over the past five years, LVAD therapy has undergone significant transformation and development internationally. The largest clinical trial to date on LVAD therapy has shown that

Table 1. Baseline characteristics (*n* = 77)

Age, years	57.5 ± 11.9
Male sex, %	66(85.7%)
Body weight, kg	71.7 ± 14.8
Body mass index, kg/m^2	17.5 ± 4.2
Body surface area, m^2	1.92 ± 0.21
Primary heart failure etiology, %	
Ischemic etiology	26(33.8%)
Dilated cardiomyopathy	48(62.3%)
Valvular disease	2(2.6%)
Myocarditis	1(1.3%)
New York Heart Association class, %	
IIIb	15(19.5%)
IV	62(80.5%)
INTERMACS profile, %	
profile 1	4(5.2%)
profile 2	20(26.0%)
profile 3	46(59.7%)
profile 4	7(9.1%)
ECMO[a]	3(3.8%)
IABP[b]	7(9.1%)
Pre-operative risk factors, %	
Atrial fibrillation	22(28.6%)
Ventricular fibrillation/tachycardia	39(50.6%)
Stroke	6(7.8%)
Hypertension	29(37.7%)
Diabetes	29(37.7%)
Prior heart surgery	2(2.6%)
Prior cardiac interventions	29(37.7%)
Left ventricular ejection fraction, %	25.4 ± 6.2
Left ventricular end-diastolic dimension, mm	71.7 ± 10.9
Arterial blood pressure, mmHg	
Systolic	102.7 ± 17.1
Diastolic	63.1 ± 11.9
Pulmonary artery pressure, mmHg	
Systolic	36.8 ± 13.4
Diastolic	19.6 ± 8.8
Mean	26.6 ± 11.5
PCWP[c]	18.2 ± 10.8
Central venous pressure, mmHg	8.3 ± 4.9
Cardiac output, L/min	3.6 ± 1.2
Cardiac index, L/min/m^2	2.0 ± 0.7
Pulmonary vascular resistance, WU	3.1 ± 1.6
Laboratory values	
Total bilirubin, μmol/L	20.9 ± 13.5
Creatinine, μmol/L	106.4 ± 41.1
BUN[d], mmol/L	9.5 ± 4.7
Serum sodium, mmol/L	137.7 ± 4.8

[a]ECMO, extracorporeal membrane oxygenation.
[b]IABP, intra-aortic balloon pump.
[c]PCWP, pulmonary capillary wedge pressure.
[d]BUN, blood urea nitrogen.

compared to the HeartMate II, the latest generation centrifugal LVAD, the HeartMate 3, significantly reduces the incidence of device thrombosis, stroke, gastrointestinal (GI) bleeding, and mortality.[4,5] Compared to HTx, implantable LVADs have several advantages, such as the absence of the need for a donor heart and the lack of immune rejection, making them a life-saving device for an increasing number of end-stage HF patients.

The application of LVADs in China began relatively late but is currently experiencing rapid development. To date, there have been four officially approved LVADs in China. Among them, the CH-VAD (BrioHealth Technologies) is a centrifugal-flow device characterized by its fully magnetically levitated design and compact size. The first-in-man implantation of the CH-VAD took place in 2017 under compassionate use, marking a significant milestone in the application of durable LVADs in China.[6] Following this, a multi-center, single arm clinical trial was conducted, providing data that led to the approval of this device in China in 2021. Thus far, more than 300 patients have been implanted with the technology across China. A single-center study conducted at Fuwai Hospital with 50 consecutive patients revealed promising outcomes and a favorable adverse event profile; however, the findings are limited by the single-center nature of the study and the relatively small sample size.[7]

This multicenter observational study aims to evaluate the clinical efficacy and safety of the CH-VAD in end-stage HF patients when the device is used commercially, providing insights into its safety and effectiveness in real-world applications. This study includes all patients who received CH-VAD implants in a post-market approval setting between June 2022 and June 2024 across seven centers in China.

RESULTS

Baseline characteristics

A total of 77 patients were included in this study. The mean age was 57.5 ± 11.9 years, with 66 patients (85.7%) being male. The mean body weight was 71.7 ± 14.8 kg, and the mean body mass index (BMI) was 17.5 ± 4.2 kg/m^2. The primary etiology of HF was predominantly dilated cardiomyopathy for 48 patients (62.3%), followed by ischemic cardiomyopathy for 26 patients (33.8%), valvular disease for 2 patients (2.6%), and myocarditis for 1 patient (1.3%). Sixty-two patients (80.5%) were in New York Heart Association (NYHA) class IV, and 15 patients (19.5%) were in class IIIb. The INTERMACS profiles at baseline were 4 (5.2%) profile 1, 20 (26.0%) profile 2, 46 (59.7%) profile 3, and 7 (9.1%) profile 4. Additionally, 7 patients (9.1%) were supported by intra-aortic balloon pump (IABP) pre-operatively, and 3 patients (3.8%) had extracorporeal membrane oxygenation (ECMO) support. Detailed demographics and baseline data are provided in Table 1.

Operative and perioperative data

Of the 77 patients included in this study, several underwent concomitant surgical procedures. Coronary artery bypass graft surgery was performed in 13 patients (16.9%), mitral valve repair in 14 patients (18.2%), tricuspid valve repair in 22 patients (28.6%), and aortic valve replacement or repair in 11 patients (14.3%). Aortic root replacement was also performed in

Table 2. Operative data	
Concomitant surgical procedure	
Coronary artery bypass graft surgery	13(16.9%)
Mitral valve repair	14(18.2%)
Tricuspid valve repair	22(28.6%)
Aortic valve replacement/repair	11(14.3%)
Left atrial appendage exclusion	37(48.1%)
Patent foramen ovale closure	10(12.9%)
Ablation	7(9.1%)
Aortic root replacement	2(2.6%)
Cardiopulmonary bypass time, minutes	156.3 ± 47.5
Cross-clamp time, minutes	95.2 ± 41.6
Postoperative ICU[a] LOS[b], days	8(IQR[3] 5–13)
Postoperative Hospital LOS, days	27 (IQR 22–33)

[a]ICU: intensive care unit.
[b]LOS: length of stay.
[3]IQR: Interquartile Range

2 patients (2.6%). The mean cardiopulmonary bypass (CPB) time was 156.3 ± 47.5 min, and the mean aortic cross-clamp time was 95.2 ± 41.6 min. Postoperatively, the median length of stay (LOS) in the intensive care unit (ICU) was 8 (IQR 5–13) days, and the median postoperative hospital LOS was 27 (IQR 22–33) days. See Table 2 for more details.

Patient outcomes

The average CH-VAD duration of support was 320 ± 211 days (range 26 days–2.2 years). By the end of our study, a total of 71 patients were still supported by the device. 51 patients were over 6 months post-implantation, 34 patients had reached 1 year, and 5 patients had reached 2 years.

Six patients died after CH-VAD implantation, including 5 in-hospital deaths. The 6-month and 1-year survival rate was 91.6% (95% confidence interval [CI], 74–97) as shown in Figure 1. No BTT or explant. The adjudicated causes for death include infection (n = 3), cerebralvascular accident (CVA) event (n = 1), and multi-organ failure(n = 2).

Adverse events

The rates of adverse events observed in this study are reported in Table 3. During follow-up, 3 patients suffered from right HF, with an event rate per patient year (EPPY) of 0.04. One patient was treated with temporary right ventricular assist device (RVAD). 5 patients underwent re-operation due to surgical related bleeding, with an event rate of 0.07 EPPY. Only 2 patients experienced GI bleeding, with an event rate of 0.07 EPPY. One GI bleeding happened in the early phase after surgery, and the other happened during the long-term follow-up (Figure 2A). Driveline infection happened in 3 patients with a rate of 0.04 EPPY (Figure 2B). All patients were treated with enhanced wound care and antibiotics with successful healing. No surgical interventions were needed. There was no pump infection. Additionally, 6 patients (8.2%) experienced non-MCS-related infections, with an event rate of 0.09 EPPY. All neurological dysfunction occurred within six months after the surgery (Figure 2C).

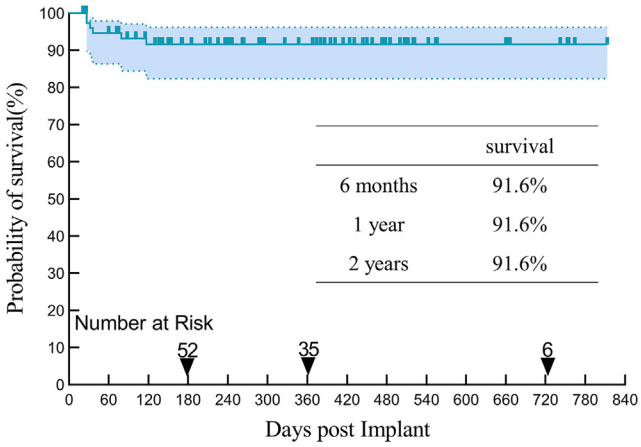

Figure 1. Kaplan-Meier analysis of survival after the CH-VAD implantation

The Kaplan-Meier survival curve demonstrates a 91.6% survival rate at 6 months and 1 year post-implantation (95% CI, 74–97). Six patients did not survive beyond the implantation period, with five of these cases being in-hospital mortalities.

Hemorrhagic stroke was observed in 2 patients (2.6%), with an event rate of 0.03 EPPY, while transient ischemic attack (TIA) occurred in 1 patient (1.3%), corresponding to an event rate of 0.01 EPPY. There was no pump thrombosis. Renal dysfunction affected 5 patients (6.5%), corresponding to an event rate of 0.07 EPPY. Aortic insufficiency was observed in 2 patients (2.6%), with an event rate of 0.03 EPPY.

Among 77 discharged patients, a total of 27 unplanned readmissions happened in 23 patients (42%). The overall readmission rate was 39.3 events per 100 patient-years (EPHPY). The most frequent primary causes of rehospitalization included HF-related events (10.2 EPHPY), followed by diagnostic/observation (5.8 EPHPY), neurological dysfunction (4.4 EPHPY) and wound dehiscence (4.4 EPHPY). (Table 4).

Follow-up management and functional status

During follow-up, the majority of patients (85%) were on a combination therapy of a vitamin K antagonist (VKA) and an antiplatelet agent, with 15% managed with VKA monotherapy. The anticoagulation protocol reflects a real-world approach to balancing the risks of thrombosis and bleeding in CH-VAD patients. By 6 months post-implantation, 100% of patients had improved to NYHA class I or II functional status, demonstrating significant recovery in HF symptoms. (Figure 3).

DISCUSSION

The present study offers valuable insights into the early clinical outcomes of the CH-VAD, a fully magnetically levitated LVAD, in Chinese patients with end-stage HF. As LVAD technology is still in its developmental stages in China, CH-VAD represents a significant advancement, providing a critical treatment option for HF patients who lack alternatives, such as HTx. This study, involving 77 patients from seven medical centers in China, aimed to evaluate the safety and efficacy of CH-VAD in a commercial

Table 3. Summary of adverse events

Events	Overall (PY[a] = 68.72)			0-90 days (PY = 6.90)			>90days (PY = 50.86)		
	Patients affected %(n)	Events (n)	Event rate (PPY[b])	Patients affected %(n)	Events (n)	Event rate (PPY)	Patients affected %(n)	Events (n)	Event rate (PPY)
Right heart failure	3.9%(3)	3	0.04	1.3% (1)	1	0.14	1.3% (1)	1	0.02
Major bleeding									
VAD[c] implantation-related bleeding	6.5%(5)	5	0.07	6.5%(5)	5	0.72	0%(0)	0	0.00
Gastrointestinal bleeding	2.6%(2)	2	0.03	1.3% (1)	1	0.14	1.3% (1)	1	0.02
Infections									
MCS[d]-related infection	3.9%(3)	3	0.04	0%(0)	0	0.00	3.9%(3)	3	0.06
Non-MCS-related infection	8.2%(6)	6	0.09	5.2%(4)	4	0.58	2.6%(2)	2	0.04
Ventricular arrhythmia	5.2%(4)	4	0.06	5.2%(4)	4	0.58	0%(0)	0	0.00
Supraventricular arrhythmia	1.3% (1)	1	0.01	0%(0)	0	0.00	1.3% (1)	1	0.02
Renal dysfunction	6.5%(5)	5	0.07	6.5%(5)	5	0.72	0%(0)	0	0.00
Respiratory failure	3.9%(3)	3	0.04	3.9%(3)	3	0.43	0%(0)	0	0.00
Pericardial effusion	5.2%(4)	4	0.06	3.9%(3)	3	0.43	1.3% (1)	1	0.02
Neurological dysfunction									
Hemorrhagic stroke	2.6%(2)	2	0.03	1.3% (1)	1	0.14	1.3% (1)	1	0.02
Ischemic stroke	0%(0)	0	0.00	0%(0)	0	0.00	0%(0)	0	0.00
TIA[e]	1.3% (1)	1	0.01	1.3% (1)	1	0.14	0%(0)	0	0.00
Aortic Insufficiency	2.6%(2)	2	0.03	0%(0)	0	0.00	2.6%(2)	2	0.04

[a]PY: patient-years.
[b]EPPY: event per patient year.
[c]VAD: ventricular assist device.
[d]MCS: mechanical circulatory support.
[e]TIA: transient ischemic attack.

setting, contributing to the growing body of evidence supporting its real-world clinical application.

In this study, the mean age of the patients was 57.5 years, with 85.7% being male. These demographic characteristics align closely with those reported in international studies of LVAD patients, where the average age typically falls between 55 and 60 years.[8–10] The relatively high proportion of male patients is also in line with global trends, as there tend to be more men than women with HF, especially those treated with LVADs.[11,12] Compared to a previous single-center study in China published last year,[7] the average age of LVAD recipients was only 47 years, significantly younger than the patients included in our

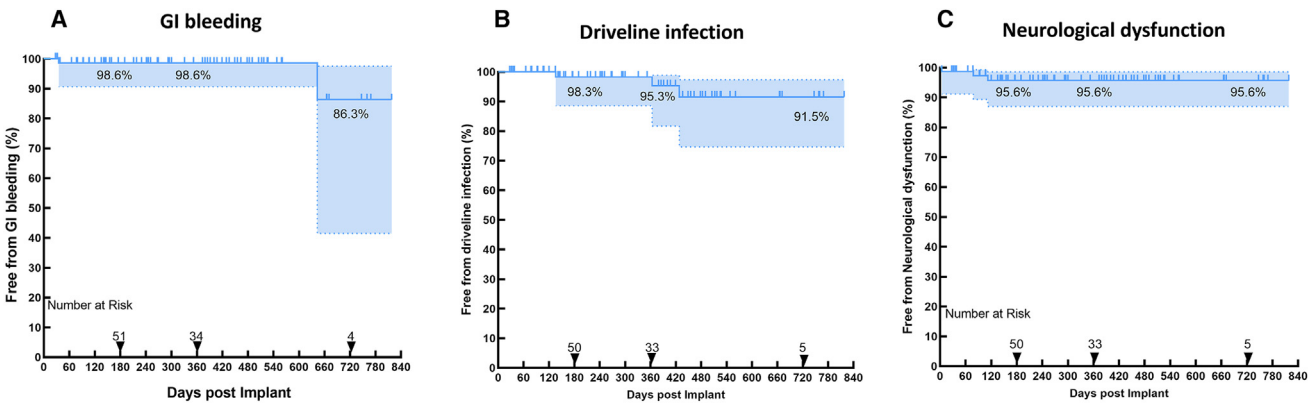

Figure 2. Kaplan-Meier analysis of adverse events (analyzed as freedom from first event)

Kaplan-Meier analysis of adverse events following CH-VAD implantation, presented as freedom from the first event.

(A) Two cases of gastrointestinal(GI) bleeding occurred: one in the early postoperative phase and the other during long-term follow-up.

(B) Driveline infection was observed in three patients.

(C) All instances of neurological dysfunction occurred within six months post-surgery.

Table 4. Rehospitalization (PY = 68.72)

	Patients affected %[a]	Events (n)	Event rate (PHPY[b])
Heart failure-related events	9.1%	7	10.2
Major infection	2.5%	2	2.9
Neurological dysfunction	3.9%	3	4.4
Wound dehiscence	3.9%	3	4.4
Major bleeding	2.6%	2	2.9
Ear, nose, and throat diseases	1.3%	1	1.5
Pericardial effusion	1.3%	1	1.5
Pleural effusion	1.3%	1	1.5
Diagnostic/observation	5.2%	4	5.8
Other events	3.9%	3	4.4

[a]PY: patient-years.
[b]EPHPY: events per 100 patient-years.

multicenter cohort. This discrepancy may be attributed to several factors. Firstly, earlier LVAD implementations in China were more likely to involve younger patients, as physicians were initially more cautious in selecting candidates for such an emerging and expensive therapy. Younger patients, with potentially fewer comorbidities, were perceived to have a better chance of survival and long-term benefit from the device. Additionally, as LVAD technology and surgical expertise have advanced in China, the indicated population has expanded to include older individuals, as seen in our study. This reflects a growing acceptance of LVAD therapy for a wider range of patients, including those who may not have been considered suitable candidates in the past.

The primary etiologies of HF in our cohort were dilated cardiomyopathy (62.3%) and ischemic cardiomyopathy (33.8%). This

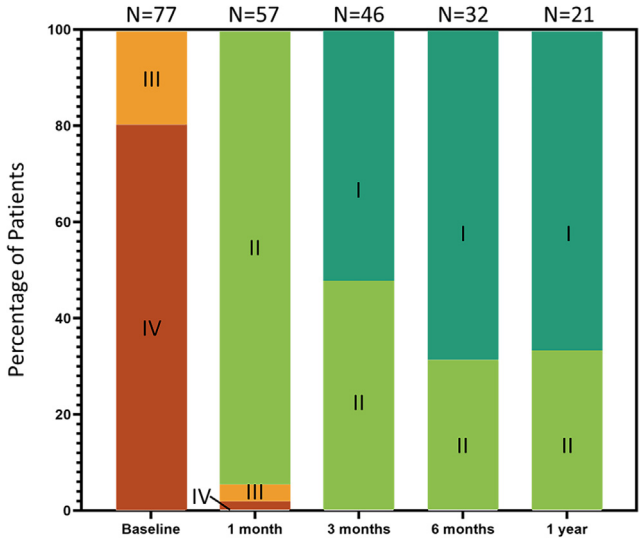

Figure 3. Improvement in NYHA functional class over time
Change in the New York Heart Association (NYHA) classification from baseline through 1 year follow-up shows marked improvement in functional capacity.

distribution is broadly consistent with international data, where these two conditions are also the most common causes of HF requiring LVAD implantation. However, the lower proportion of ischemic heart disease in our study is noteworthy. In western countries, ischemic cardiomyopathy often accounts for a higher percentage of cases due to the higher prevalence of coronary artery disease.[8–10] The relatively lower incidence of ischemic HF in our cohort may reflect regional differences in the underlying causes of HF, possibly due to variations in lifestyle, genetics, and healthcare access.

Regarding the severity of HF, most patients in our study were classified as INTERMACS profile 3 (59.7%) or INTERMACS profile 2 (26%), with only 5.2% in INTERMACS profile 1. When compared to the aforementioned earlier Chinese study,[7] where a larger proportion of patients were classified as INTERMACS profile 1 or profile 2, our cohort represents a shift toward treating patients in slightly less critical conditions. This evolution may be related to the growing availability of LVADs and improved familiarity with their use among Chinese clinicians. As the technology becomes more widespread and experience increases, it is likely that more patients with less acute presentations of HF (i.e., INTERMACS profile 3) are being considered for LVAD implantation, in contrast to earlier periods when the technology was reserved for patients in dire need (INTERMACS profiles 1–2).

Additionally, preoperative use of temporary mechanical support, such as ECMO (3.8%) and IABP (9.1%), was relatively low in our study compared to some international reports. This suggest that in China, top centers tend to be more selective in choosing patients for LVADs, often opting for earlier intervention in the disease trajectory or utilizing alternative management strategies before emergent mechanical support becomes necessary. Furthermore, the broader acceptance and understanding of LVAD therapy has likely led to an expansion in its indications, allowing clinicians to offer it as a proactive rather than purely reactive treatment option.

The survival outcomes in our study demonstrate the safety and efficacy of the CH-VAD in treating end-stage HF. Despite the severity of illness in this cohort, the 6-month and 1-year survival rate was 91.6%, which is comparable to or better than, international LVAD outcomes.[8,13] While six patients died during the study period, the overall survival is favorable. The five perioperative deaths are likely attributable to the learning curve in perioperative management. Importantly, no patients required a BTT or explant during the follow-up period, and there were no device malfunctions or pump replacements. This suggests that the CH-VAD is a reliable long-term support option, with a low rate of mechanical failure.

LVAD implantation remains a relatively recently developed procedure in China, which influenced surgical decisions, including the frequent use of cardiac arrest during implantation for enhanced safety. The average CPB time of 156 min and cross-clamp time of 95 min are longer than those reported in more experienced centers,[13] reflecting the early stage of LVAD implementation in China. Additionally, more than 70% of patients in this study underwent concomitant procedures, such as valve repairs or coronary artery bypass grafting, which may contribute to prolonged surgical times. These concomitant procedures were deemed necessary to optimize heart function and

improve the chances of long-term LVAD support.[14] Despite the complexity of the surgeries, the median ICU stay was 8 days, and the median total hospital stay was 27 days, which are reasonable given the surgical burden and the complexity of patient conditions.

The CH-VAD's design, intended to minimize hemocompatibility-related issues, was effective in this cohort, with a low incidence of blood-related adverse events. During follow-up, five patients required reoperation for surgical-related bleeding, which was managed successfully without further complications. GI bleeding occurred in two patients, with one early and one late event, but no other significant GI issues were noted. Neurological events, primarily hemorrhagic strokes, occurred in two patients, but there were no ischemic strokes or pump thrombosis, underscoring the device's effectiveness in reducing thromboembolic complications.

Infection, particularly driveline infection, is a known complication of LVAD therapy, but in this study, the infection rates were low. Driveline infections occurred in only three patients and were managed conservatively with antibiotics and wound care, without the need for surgical intervention. Notably, there were no cases of pump infection. This low infection rate can be attributed to strict adherence to infection prevention protocols across all centers, comprehensive patient education on wound care, and the development of a remote monitoring app for ongoing patient support. Additionally, the smaller and more flexible driveline design of the CH-VAD may have contributed to the reduced infection risk,[15,16] emphasizing the importance of both device design and proactive management in minimizing infection-related complications.

Despite the relatively long CPB times, the incidence of right HF in this cohort was low, with only three patients developing right HF. One of these patients required temporary RVAD support, but the overall rate of right HF was notably lower than expected. This can be attributed to careful preoperative patient selection and diligent intraoperative management. Moreover, the hemodynamically favorable design of the CH-VAD, which minimizes stress on the right heart, likely contributed to these positive outcomes. Maintaining right ventricular function is critical in LVAD patients, and the low rate of right HF in our cohort highlights the benefits of the CH-VAD's design and careful perioperative strategies.

In addition to clinical outcomes, it is important to acknowledge the ethical considerations surrounding LVAD therapy. Ensuring patient autonomy through a robust informed consent process is critical, particularly for a complex and resource-intensive treatment like CH-VAD implantation. Patients should be fully informed of the potential benefits, risks, and long-term implications of LVAD therapy. Furthermore, resource allocation presents a significant challenge in regions with limited healthcare resources. Expanding access to LVAD therapy should be approached with careful consideration to ensure equitable treatment opportunities for all eligible patients while maintaining the sustainability of the healthcare system.

Conclusion

In conclusion, the CH-VAD has demonstrated promising early outcomes in the treatment of end-stage HF in Chinese patients, with survival rates comparable to international standards and a low incidence of adverse events. The device has proven to be a reliable and effective option for patients who require long-term MCS, with no incidences of pump malfunction, thrombosis, or device-related mortality during the follow-up period. As LVAD technology continues to advance and become more widely available in China, further studies with larger patient cohorts and longer follow-up periods are needed to confirm the long-term efficacy and safety of the CH-VAD. These results suggest that the CH-VAD could play a crucial role in expanding treatment options for HF patients in China, offering an alternative to HTx and improving patient outcomes in a population with growing needs for MCS.

While this study demonstrates the promising outcomes of CH-VAD in the Chinese population, several key areas require further investigation. Future studies should explore the long-term cost-effectiveness of CH-VAD therapy, including its economic impact on both healthcare systems and patients. Additionally, more extensive quality-of-life assessments should be conducted to fully understand the broader impacts of CH-VAD implantation on patients' well-being. Comparative studies involving other LVAD devices currently available in China would also be valuable, as they would help identify the relative advantages and disadvantages of CH-VAD within the context of the Chinese healthcare system. These future directions will help optimize LVAD therapy and guide clinical decision-making in China.

Limitations of the study

This study has several limitations. First, the relatively small sample size of 77 patients limits the generalizability of our findings. Although this is one of the largest studies of CH-VAD patients in China, a larger multicenter cohort would provide more robust data, particularly regarding long-term outcomes and rare adverse events. Second, the follow-up period was relatively short, with only five patients reaching the two-year follow-up mark. Longer-term follow-up is essential to fully assess the durability of the CH-VAD, as well as its impact on survival, quality of life, and device-related complications over time. Third, this study is the lack of comparative data on other LVAD devices currently available in China, as research on alternative LVAD options is limited and requires further investigation in future studies. Additionally, this study was observational and retrospective in nature, which may introduce bias, particularly in terms of patient selection and data collection. Future studies could reduce the impact of selection bias by using a prospective study design and preset inclusion and exclusion criteria to provide more rigorous evidence in support of the safety and efficacy of CH-VAD. Finally, while the study included patients from seven centers across China, these hospitals represent some of the best in the country, and therefore the results may not be fully representative of all hospitals performing LVAD implantation, as surgical expertise and postoperative care can vary widely between centers.

RESOURCE AVAILABILITY

Lead contact

Further information and requests for resources should be directed to and will be fulfilled by the lead contact, Ming Gong (gongming@mail.ccmu.edu.cn).

Materials availability

This study did not generate new unique reagents.

Data and code availability

- All data reported in this paper will be shared by the lead contact upon request.
- This paper does not report original code.
- Any additional information required to reanalyze the data reported in this paper is available from the lead contact upon request.

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AUTHOR CONTRIBUTIONS

Y.L., conception and design, collection and assembly of data, data analysis and drafting article, critical revision of article, approval of article; S.Z., data analysis and drafting article, critical revision of article, approval of article; J.H., critical revision of article, approval of article; Q.L., critical revision of article, approval of article; X.D., critical revision of article, approval of article; Z.H., collection and assembly of data, critical revision of article, approval of article; K.H., collection and assembly of data, critical revision of article, approval of article; Z.G., collection and assembly of data, critical revision of article, approval of article; X.S., collection and assembly of data, critical revision of article, approval of article; D.Z., collection and assembly of data, critical revision of article, approval of article; Y.S., collection and assembly of data, critical revision of article, approval of article; H.Z., critical revision of article, approval of article; M.G., conception and design, critical revision of article, approval of article.

DECLARATION OF INTERESTS

The authors declare no competing interests.

STAR★METHODS

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STAR★METHODS

KEY RESOURCES TABLE

REAGENT or RESOURCE	SOURCE	IDENTIFIER
Deposited data		
CH-VAD cohort	This study	N/A
Software and algorithms		
STATA version 29	IBM Corp.	N/A
Prism version 9	GraphPad Software Inc.	N/A

EXPERIMENTAL MODEL AND STUDY PARTICIPANT DETAILS

Ethical committee approval

This study was approved by the Institutional Ethics Committee of Beijing Anzhen Hospital with a waiver of informed consent (KS2024086). The trial is registered in ClinicalTrials.gov under NCT06596499. The study adheres to the principles outlined in the Declaration of Helsinki and the ISHLT Ethics statement.

Study participant details

This multicenter, retrospective cohort study was conducted in seven hospitals across China, focusing on patients with end-stage heart failure who underwent CH-VAD implantation between June 2022 and June 2024. A total of 77 patients were enrolled. The indication for LVAD implantation followed established international guidelines. Besides, the selection of candidates for CH-VAD implantation was conducted by a multidisciplinary heart failure team, ensuring a comprehensive evaluation of patient suitability. Patients were all diagnosed with end-stage heart failure refractory to optimal medical therapy (NYHA Class IIIb or IV), and reduced left ventricular ejection fraction (LVEF < 30%). Furthermore, patients were also dependent on inotropic support or temporary mechanical circulatory assistance, or identified as high-risk for adverse outcomes without LVAD support. Patients with severe dysfunction of other vital organs, active infections, uncontrollable bleeding disorders, significant psychiatric or psychological conditions were not appropriate candidates as they could impair postoperative management and adherence and had a limited life expectancy to benefit from LVAD support.

METHOD DETAILS

Baseline measurements

Baseline measurements included demographic data such as age, gender, body weight, body mass index (BMI, calculated as weight in kilograms divided by height in meters squared), and body surface area (BSA, derived using the Du Bois formula). Primary heart failure etiologies were categorized as ischemic cardiomyopathy, dilated cardiomyopathy, valvular disease, or myocarditis. Functional and hemodynamic assessments included New York Heart Association (NYHA) classification and INTERMACS profiles, with additional documentation of pre-operative mechanical support using intra-aortic balloon pumps (IABP) or extracorporeal membrane oxygenation (ECMO). Pre-operative risk factors were evaluated, including atrial fibrillation, ventricular fibrillation or tachycardia, stroke, hypertension, diabetes, prior heart surgery, and previous cardiac interventions. Cardiac function parameters were measured, including left ventricular ejection fraction (LVEF), left ventricular end-diastolic dimension (LVEDD), arterial blood pressure, pulmonary artery pressure, central venous pressure, cardiac output, cardiac index, and pulmonary vascular resistance (PVR, calculated in Wood units). Laboratory evaluations included total bilirubin for liver function, creatinine and blood urea nitrogen (BUN) for renal function, and serum sodium for electrolyte status. All variables were systematically collected using standardized protocols to ensure data consistency and reliability.

Outcomes

The primary outcome was survival at 6 months and 1 year post-CH-VAD implantation. Secondary outcomes included device-related complications, such as bleeding, stroke, infection, and pump thrombosis. Data on adverse events were collected during follow-up visits or through hospital records and classified using standard criteria for ventricular assist device complications.

Device description

The CH-VAD pump is designed with a focus on superior hemocompatibility. Its separation of the magnetic levitation system from the motor allows for more efficient use of space within the pump while maintaining stable rotor suspension with high stiffness. This high

suspension stiffness ensures that the rotor remains stable, even during patient movement or physical activity, preventing contact with the pump housing. The optimized blood flow pathways minimize shear stress and promote thorough washing, reducing blood trauma and enhancing hemocompatibility. These features, demonstrated through computational fluid dynamics and in-vivo studies, enable smooth, high-volume blood flow (up to 10 L/min) with minimal impact on blood components.[17–19]

From a surgical perspective, the CH-VAD's compact design provides multiple advantages. Its small size reduces ventricular distortion during implantation, contributing to better post-operative outcomes. The 10-mm outflow graft can be anastomosed to alternative sites, offering greater surgical flexibility depending on the patient's anatomy. Additionally, the locking mechanism simplifies implantation, with two tabs and alignment symbols ensuring quick and precise orientation. This design not only reduces operating time but also enhances safety. The pump's narrow and flexible driveline (3.3 mm) further improves patient comfort, making long-term support more manageable and reducing the risk of driveline-related complications, such as exit site trauma or infection.

Study design

This retrospective multicenter cohort study included consecutive patients who underwent implantation of the CH-VAD device between June 1, 2022, and June 30, 2024, across seven centers in China. The study was initiated and led by Beijing Anzhen Hospital, with participation from six other medical centers. These centers were distributed across six provinces in China, including Sichuan Provincial People's Hospital of University of Electronic Science and Technology, Henan Chest Hospital, Shanghai Chest Hospital of Shanghai Jiao Tong University, Shanghai Zhongshan Hospital of Fudan University, Wuhan Asia Heart Hospital, and Jiangsu Provincial People's Hospital of Nanjing Medical University. The selection of participating centers was based on their comprehensive follow-up practices and willingness to contribute complete data. The study protocol was registered retrospectively at ClinicalTrials.gov (NCT06596499) and was approved by the Institutional Ethics Committee of Beijing Anzhen Hospital (KS2024086). The study adheres to the principles outlined in the Declaration of Helsinki and the ISHLT Ethics statement.

Study population

The inclusion criteria were all patients implanted with the CH-VAD as the primary device in a post-market approval setting, with no specific exclusion criteria. Based on these criteria, the study population consisted of all patients with end-stage HF who were implanted with the CH-VAD device across the seven participating centers, with no cases excluded. The decision to undergo surgery was made by a multidisciplinary heart failure team, including cardiac surgeons, cardiologists, echocardiography specialists, cardiovascular anesthesiologists, and other relevant specialists.

Data collection

Data were collected from the electronic medical record systems of the participating hospitals. This included demographic information, clinical characteristics, laboratory results, hemodynamic parameters, echocardiographic data, surgical details, clinical outcomes, adverse events, and readmission information. Adverse events were defined and classified according to the INTERMACS definitions.

Patient management

The indication for LVAD implantation followed established international guidelines.[20–22] Besides, the selection of candidates for CH-VAD implantation was conducted by a multidisciplinary heart failure team, ensuring a comprehensive evaluation of patient suitability. Patients were all diagnosed with end-stage heart failure refractory to optimal medical therapy (NYHA Class IIIb or IV), and reduced left ventricular ejection fraction (LVEF < 30%). Furthermore, patients were also dependent on inotropic support or temporary mechanical circulatory assistance, or identified as high-risk for adverse outcomes without LVAD support. Patients with severe dysfunction of other vital organs, active infections, uncontrollable bleeding disorders, significant psychiatric or psychological conditions were not appropriate candidates as they could impair postoperative management and adherence and had a limited life expectancy to benefit from LVAD support. In our clinical practice, informed consent is a thorough process where patients and their caregivers are well-informed about all available treatment options, including the potential benefits and risks associated with LVAD therapy. Surgeries were only performed with a signed informed consent.

Preoperative transesophageal echocardiography (TEE) was performed to assess valvular function, patent foramen ovale (PFO), ventricular structure, and the presence of thrombi. Necessary corrective procedures for concomitant valvular or coronary artery disease were performed prior to LVAD implantation. The surgical approach typically utilized a standard median sternotomy and cardiopulmonary bypass (CPB), though a minimally invasive sternotomy using femoral cannulation was also an option. The apical coring site was identified using a finger test under TEE guidance, to ensure the inflow cannula aligned parallel to the interventricular septum and pointing toward to the mitral valve. The apical ring was secured to the left ventricular apex using 8-10 interrupted mattress sutures, and the apex was cored using a rotational coring knife, with residual myocardial trabeculae removed as needed. The inflow cannula was inserted, and. the outflow graft was anastomosed to the ascending aorta. The driveline was tunneled through the rectus muscle, with the entire velour portion placed within the subcutaneous tunnel. After deairing, the CPB was gradually weaned as pump flow progressively increased under TEE monitoring.

Postoperative care focused on infection control, anticoagulation, and hemodynamic management. For infection prevention, empiric broad-spectrum antibiotic therapy was initiated, with adjustments made based on culture results if an infection was

suspected or confirmed. Anticoagulation therapy was initiated 12-24 hours after surgery once active bleeding was excluded and total chest tube output remained under 40 mL/hour over a four-hour period. Bridging therapy with continuous intravenous unfractionated heparin was used, titrating the activated partial thromboplastin time (APTT) to 45-60 seconds or the activated clotting time (ACT) to 175-200 seconds. Bivalirudin was substituted for patients who developed heparin-induced thrombocytopenia (HIT). Warfarin and aspirin at 100 mg/day were introduced on postoperative days 2-3, targeting an international normalized ratio (INR) of 2.0–2.5 for long-term management. Anticoagulation levels could be adjusted as needed to address specific clinical conditions. Hemodynamic management emphasized precise regulation of parameters such as mean arterial pressure, central venous pressure, pulmonary artery pressure and cardiac output. Echocardiographic assessments was used to guide LVAD pump speed adjustment, aiming to balance biventricular volume and ensure adequate organ perfusion. The typical pump speed range was 2400-3200 revolutions per minute, providing a flow of 3.0-6.0 L/min.

Statistical analysis

Data were represented as frequency distributions and percentages. Values of continuous variables were expressed as mean ± standard deviation and median with interquartile range, as necessary. Continuous variables were compared using independent samples t-tests or Wilcoxon rank-sum tests, where appropriate. Categorical variables were compared by means of $\chi 2$ tests or Fischer's exact test, where appropriate. To analyze changes in echocardiographic and hemodynamic parameters and laboratory values, McNemar matched-pairs tests were used to compare preoperative values to postoperative values after matching individual patient data. For all analyses, a $p < 0.05$ was considered statistically significant. Kaplan-Meier analysis was used to calculate survival and other time-to-event outcomes. All data were analyzed using STATA 29 software (IBM, Armonk, NY) and Prism version 9 (GraphPad Software, San Diego, Calif).

QUANTIFICATION AND STATISTICAL ANALYSIS

Quality assessment

A standardized case report form (CRF) was used to collect patient information consistently across all study centers. All collected data underwent routine quality checks, including cross-validation with original source documents, to ensure accuracy and completeness.

Statistical analysis

Data were represented as frequency distributions and percentages. Values of continuous variables were expressed as mean ± standard deviation and median with interquartile range, as necessary. Continuous variables were compared using independent samples t-tests or Wilcoxon rank-sum tests, where appropriate. Categorical variables were compared by means of $\chi 2$ tests or Fischer's exact test, where appropriate. To analyze changes in echocardiographic and hemodynamic parameters and laboratory values, McNemar matched-pairs tests were used to compare preoperative values to postoperative values after matching individual patient data. For all analyses, a $p < 0.05$ was considered statistically significant. Kaplan-Meier analysis was used to calculate survival and other time-to-event outcomes. All data were analyzed using STATA 29 software (IBM, Armonk, NY) and Prism version 9 (GraphPad Software, San Diego, Calif).

ADDITIONAL RESOURCES

The trial is registered in ClinicalTrials.gov under NCT06596499.