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Influence of Preoperative Anatomical Characteristics on the Direction of Inflow Cannula in HeartMate 3

Shusuke Imaoka[1] | Daisuke Yoshioka[1] | Shunsuke Saito[1] | Takuji Kawamura[1] | Ai Kawamura[1] | Ryohei Matsuura[1] | Yusuke Misumi[1] | Koichi Toda[2] | Shigeru Miyagawa[1]

[1]Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, Osaka, Japan | [2]Department of Thoracic and Cardiovascular Surgery, Dokkyo Medical University Saitama Medical Center, Saitama, Japan

Correspondence: Shusuke Imaoka (s-imaoka@surg1.med.osaka-u.ac.jp) | Daisuke Yoshioka (djason55@gmail.com)

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ABSTRACT

Background: The influence of inflow cannula (IC) direction in HeartMate 3 (HM3) remains unclear. We investigated preoperative anatomical characteristics related to IC direction by analyzing computed tomography (CT) images and assessed the relationship between prognosis and IC direction in HM3.

Methods: We evaluated 48 patients who underwent HM3 implantation and categorized them based on the IC direction: anterior/lateral wall (group A, $n=18$), mitral/aortic valve (B, $n=21$), and posterior/inferior wall (C, $n=9$). In preoperative CT, the positional relationship between the mitral valve, left ventricle (LV) apex, chest wall, and diaphragm was evaluated. The survival rate and freedom rate from complications after HM3 implantation in each group were evaluated.

Results: On preoperative CT, group A had a higher mitral valve height from the LV apex than group B (68 ± 13 and 52 ± 14 mm, respectively; $p<0.01$). Group C had a longer distance between the LV apex and chest wall than group B (20 ± 9 and 9 ± 6 mm, $p<0.01$). Group C had a shorter thoracic depth from the LV apex than did group B (24 ± 9 and 39 ± 11 mm, $p<0.01$). The 3-year survival rates after HM3 implantation for groups A, B, and C were 88%, 90%, and 100%, respectively. The rates of freedom from complications after HM3 implantation at 3 years in groups A, B, and C were 50%, 43%, and 20%, respectively.

Conclusions: The IC direction in HM3 was influenced by the preoperative position of the mitral valve, LV apex, chest wall, and diaphragm. The IC direction in HM3 did not significantly affect survival rates.

1 | Background

The left ventricular assist device (LVAD) plays a crucial role in managing heart failure [1]. In most patients, the inflow cannula (IC) is inserted from the left ventricular (LV) apex toward the mitral valve. The direction of the IC in LVADs, such as HeartMate II and HeartWare, is critical in preventing complications such as device thrombosis, gastrointestinal bleeding, and heart failure [2–6]. A new fully magnetically levitated centrifugal continuous-flow circulatory pump, HeartMate 3 (HM3) (Abbott, IL, USA), has been developed, with a pump system, IC shape, and pump body significantly different from those of HeartMate II [7, 8]. However, the influence of the direction of the IC on the recurrence of complications in HM3 remains unclear.

Therefore, in this study, we reviewed data of patients who underwent HM3 implantation and computed tomography (CT) pre- and post-implantation. We investigated preoperative anatomical characteristics related to the IC direction and the relationship between the incidence of LVAD-related complications and the IC direction in HM3.

2 | Methods

2.1 | Patients

The HM3 was implanted in 54 patients aged >18 years at Osaka University Hospital between June 2019 and March 2024. Of these, a postoperative CT scan was performed in 50 patients. The mean follow-up duration in this study was 848 ± 582 days, and all follow-up examinations were completed on May 30, 2024. We investigated the IC direction in these 50 patients and categorized them based on the IC direction as follows: (i) anterior/lateral wall (group A, $n = 18$), (ii) mitral/aortic valve (group B, $n = 21$), (iii) posterior/inferior wall (group C, $n = 9$), and (iv) ventricular septum ($n = 2$). After excluding patients whose IC direction was toward the ventricular septum due to the limited number, we investigated the preoperative anatomical parameters among the three groups and the occurrence of complications after HM3 implantation. The mean follow-up duration in groups A, B, and C was 840 ± 558, 890 ± 573, and 767 ± 665 days, respectively (Figure 1a).

All patients and their families provided informed consent to participate in the related clinical studies before HM3 implantation.

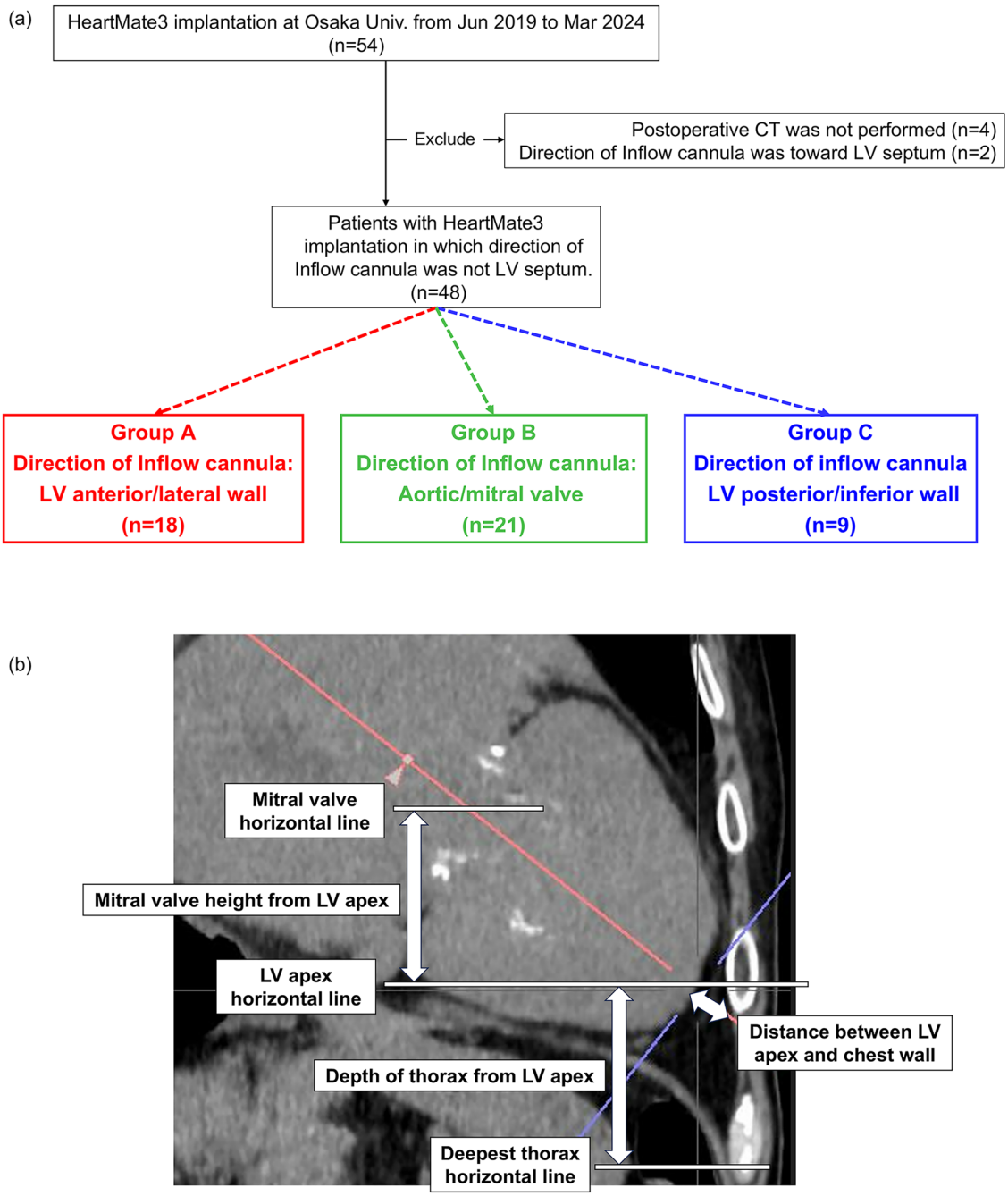

FIGURE 1 | Patient enrollment in this study and parameters measured on preoperative CT. (a) Patient enrollment, (b) Parameters measured on preoperative CT. CT, computed tomography; LV, left ventricle.

2.2 | Definition of Parameters Measured on Preoperative CT

Preoperative CT was evaluated using a thin slice image with a CT software, Aquarius iNtuition ver.4.4 (TERARECON, NC, USA). The center of the mitral valve and LV apex were identified on preoperative CT. The image containing the mitral valve and LV apex perpendicular to the axial image was drawn for preoperative evaluation. Mitral valve height from the LV apex was defined as the distance between the center of the mitral valve horizontal line and the LV apex horizontal line. Thoracic depth from the LV apex was defined as the distance between the LV apex horizontal line and the horizontal line of the deepest thorax. The distance between the LV apex and chest wall was defined as the distance from the LV apex to the chest wall as an extension of the center of the mitral valve and LV apex (Figure 1b).

2.3 | Surgical Procedure for LVAD Implantation

Generally, patients underwent LVAD implantation through a median sternotomy with systemic cardiopulmonary bypass, in which the IC is inserted into the left ventricular apex toward the mitral valve under transesophageal echocardiography guidance, and the outflow graft is anastomosed to the ascending aorta. The left pleura was incised longitudinally from the diaphragmatic surface, and the pump body was positioned across the pericardial sac and left thoracic cavity such that the IC was not directed toward the LV septum.

2.4 | Definition of Classification for IC Direction

IC direction was measured using postoperative CT after HM3 implantation. Postoperative CT was performed until initial discharge after HM3 implantation and evaluated using Aquarius iNtuition ver.4.4. The part of the LV that extended to the center of the IC face was assessed using the three-dimensional picture, and the patients were classified accordingly. Patients whose IC was directed toward the LV anterior/lateral wall, aortic/mitral valve, and posterior/inferior wall were defined as groups A, B, and C, respectively (Figure 1a).

2.5 | LVAD Hemodynamic Ramp Test

The LVAD hemodynamic ramp test was performed before hospital discharge. In this test, the rotational speed of HM3 was adjusted based on the hemodynamics using invasive arterial blood pressure monitoring, right heart catheterization, and echocardiographic findings. The rotational speed of HM3 resulted in an optimal hemodynamic profile, defined as achieving all three

TABLE 1 | Preoperative characteristics of patients in groups A, B, and C.

	All	Group A	Group B	Group C
	***n*=48**	***n*=18**	***n*=21**	***n*=9**
Age at LVAD implantation (years)	53 (44–59)	49 (41–54)	57 (46–59)	52 (48–59)
Female, *n* (%)	8 (17)	4 (22)	2 (10)	2 (22)
Body surface area (m^2)	1.7 (1.6–1.7)	1.7 (1.5–1.8)	1.7 (1.6–1.7)	1.7 (1.6–1.7)
Body mass index (kg/m^2)	21 (18–24)	21 (18–22)	21 (20–24)	18 (17–20)
Etiology				
ICM, *n* (%)	9 (19)	3 (17)	4 (19)	2 (22)
DCM, *n* (%)	24 (50)	11 (61)	10 (48)	3 (33)
HCM, *n* (%)	5 (10)	1 (6)	3 (14)	1 (11)
INTERMACS profile				
Profile I, *n* (%)	5 (10)	4 (22)	0 (0)	1 (11)
Profile II, *n* (%)	7 (15)	4 (22)	2 (10)	1 (11)
Profile III, *n* (%)	31 (65)	8 (44)	17 (81)	6 (67)
Profile IV, *n* (%)	4 (8)	2 (11)	2 (10)	0 (0)
Bridge-to-Bridge, *n* (%)	1 (2)	0 (0)	0 (0)	1 (11)
Preoperative comorbidity				
DM, *n* (%)	12 (25)	3 (17)	8 (38)	1 (11)
HT, *n* (%)	5 (10)	1 (6)	3 (14)	1 (11)
CVA, *n* (%)	5 (10)	3 (17)	2 (10)	0 (0)

Abbreviations: CVA, cerebrovascular accident; DCM, idiopathic dilated cardiomyopathy; DM, diabetes mellitus; HCM, hypertrophic cardio myopathy; HT; hypertension; ICM, ischemic cardiomyopathy; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; LVAD, left ventricle assist device.

of the following: central venous pressure < 12 mmHg, pulmonary artery wedge pressure (PAWP) < 18 mmHg, and cardiac index > 2.2 L/min/m^2. HM3 flow and PAWP were measured at 200 rotations per minute (rpm), which were lower and higher than the adjusted rotation speed, respectively.

2.6 | Definition of Complications After HM3 Implantation

Complications after HM3 implantation were defined as episodes that resulted in hospitalization for invasive procedures, intravenous treatment, transfusion of red blood cells, adjustment of anticoagulation therapy, or oral medication adjustment. Complications after HM3 implantation included cerebral infarction, cerebral hemorrhage, bleeding complications including gastrointestinal bleeding, heart failure, and arrhythmia. The IC direction was considered to have little influence on LVAD driveline infection. Thus, LVAD driveline infection was excluded from complications after HM3 implantation in this study.

2.7 | Anticoagulant Management

Antiplatelet therapy with aspirin (100 mg/day) was administered the day after implantation and was maintained throughout the LVAD support unless major bleeding occurred. No patient received dual antiplatelet therapy to prevent thrombosis. Furthermore, anticoagulation therapy with warfarin was initiated once adequate hemostasis was maintained, with a target international normalized ratio (INR) of 1.5–2.5. Systemic heparinization was performed until the target INR was achieved.

2.8 | Data Collection

Patient data included baseline characteristics; etiology; comorbidities; Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) profile; laboratory values; parameters of chest radiography, echocardiography, and CT; hemodynamics from the LVAD hemodynamic ramp test; and LVAD implantation duration. All patient data were collected from the electronic medical and operative records.

TABLE 2 | Preoperative and postoperative anatomical parameters of patients in groups A, B, and C.

	All	Group A	Group B	Group C	
	$n = 48$	$n = 18$	$n = 21$	$n = 9$	p
Preoperative chest X-ray					
Total cardiac dimension (mm)	168 ± 23	176 ± 23	165 ± 19	158 ± 25	0.13
Thoracic transverse diameter (mm)	295 ± 23	290 ± 24	300 ± 19	293 ± 27	0.23
CTR (%)	57 ± 8	61 ± 8*B	55 ± 7	54 ± 5	0.02*
Preoperative echocardiography					
LVDd (mm)	70 ± 13	70 ± 13	70 ± 13	67 ± 16	0.65
LVDs (mm)	64 ± 14	65 ± 15	66 ± 14	60 ± 16	0.62
EF (%)	22 ± 9	21 ± 10	20 ± 9	27 ± 8	0.17
RVDd (mm)	41 ± 10	45 ± 11	40 ± 8	35 ± 10	0.17
LAD (mm)	47 ± 12	48 ± 10	49 ± 13	42 ± 14	0.24
RAD (mm)	41 ± 11	44 ± 12	41 ± 10	35 ± 8	0.13
Preoperative CT					
Mitral valve height from LV apex	58 ± 15	68 ± 13*B	52 ± 14	49 ± 14	< 0.01*
Distance between Mitral valve and LV apex	103 ± 14	107 ± 13	99 ± 12	102 ± 17	0.39
Distance between LV apex and chest wall	11 ± 8	8 ± 5	9 ± 6	20 ± 9*B	< 0.01*
Depth of thorax from LV apex	35 ± 12	37 ± 11	39 ± 11	24 ± 9*B	< 0.01*
Postoperative echocardiography					
LVDd (mm)	54 ± 15	53 ± 15	61 ± 13	44 ± 15*B	0.02*
LVDs (mm)	49 ± 16	47 ± 16	56 ± 14	39 ± 16*B	0.02*
EF (%)	22 ± 15	24 ± 18	17 ± 11	29 ± 15	0.17
LAD (mm)	36 ± 11	36 ± 10	40 ± 11	28 ± 9*B	0.02*

Note: p values were obtained using Kruskal–Wallis test. When statistical significance was found in Kruskal–Wallis test, the Steel test was conducted with group B as the control group and *B showed a statistically significant difference from group B.
Abbreviations: CTR, cardio-thoracic ratio; LAD, left atrium dimension; LV, left ventricle; LVDd, left ventricular internal dimension in diastole; LVDs, left ventricular internal dimension in systole; LVEF, left ventricular ejection fraction; RAD, right atrium dimension; RVDd, right ventricular internal dimension in diastole.

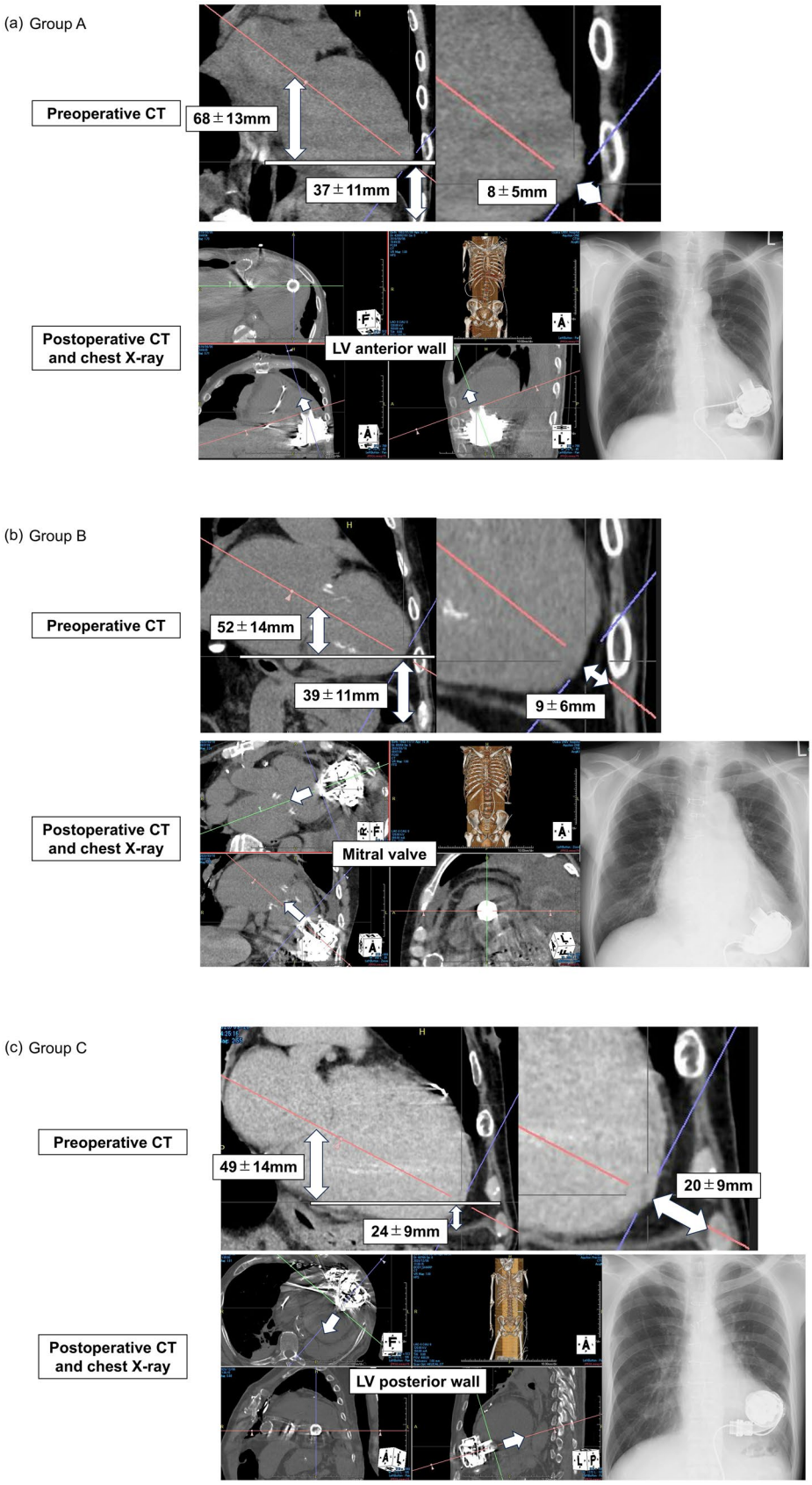

FIGURE 2 | Parameters measured on preoperative CT in terms of the direction of the IC. (a) Images of a patient with the IC directed toward the LV anterior wall, (b) images of a patient with the IC directed toward the mitral valve, and (c) images of a patient with the IC directed toward the LV posterior wall. CT, computer tomography; IC, inflow cannula; LV, left ventricle.

2.9 | Statistical Analyses

Continuous variables are presented as median (with interquartile range) or mean ± standard deviation. All statistical analyses were performed using JMP 17.0 (SAS Inc., Cary, NC, USA). Categorical variables are summarized as frequencies and percentages and were compared among the three groups using the Kruskal–Wallis test. When statistical significance was found in the Kruskal–Wallis test, the Steel test was conducted with group B as the control group. Statistical significance was set at $p < 0.05$. The Kaplan–Meier analysis was used to calculate the rates of freedom from complications and the survival rate after HM3 implantation. The Cox proportional hazards model was used to evaluate the influence of the direction of IC on the rates of freedom from complications and the survival rate after HM3 implantation.

3 | Results

3.1 | Patient Preoperative Characteristics and Direction of IC

The preoperative characteristics of the 48 enrolled patients are presented in Table 1. The mean age of the patients was 53 (44–59) years, and 40 (83%) were male. Postoperative CT scans showed that the IC was directed toward the LV anterior/lateral wall in 18 patients (group A), aortic/mitral valve in 21 patients (group B) and posterior/inferior wall in 8 patients (group C). No significant differences were observed in age, sex, body surface area, body mass index, etiology, INTERMACS profile, or preoperative comorbidities between the groups.

3.2 | Preoperative Anatomical Characteristics in Terms of IC Direction

The preoperative anatomical parameters measured using chest radiography, echocardiography, and CT are presented in Table 2, and a typical case from each group is shown in Figure 2. On chest radiography, patients in group A had a larger cardiothoracic ratio (CTR) than that of patients in group B (61% ± 8% and 55% ± 7%, respectively, $p = 0.02$). No significant differences were observed in the echocardiographic parameters of the left ventricle, right ventricle, left atrium, or right atrium between the groups. On preoperative CT, the patients in group A had a higher mitral valve height from the LV apex than that of patients in group B (68 ± 13 mm and 52 ± 14 mm, respectively, $p < 0.01$) (Figure 3a). Patients in group C had a longer distance between the LV apex and chest wall than those in group B (20 ± 9 mm and 9 ± 6 mm, respectively, $p < 0.01$) (Figure 3b). Furthermore, the patients in group C had a shorter thoracic depth from the LV apex than that of patients in group B (24 ± 9 mm and 39 ± 11 mm respectively, $p < 0.01$) (Figure 3c).

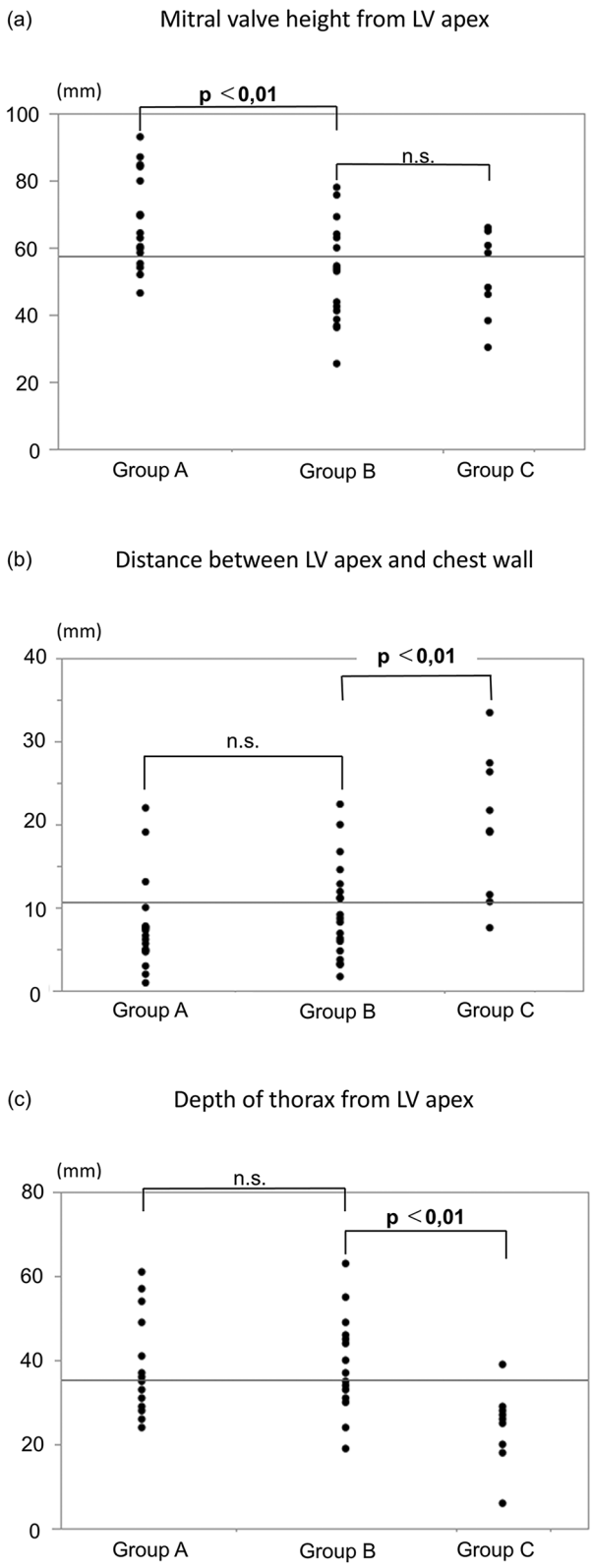

FIGURE 3 | Comparison of parameters measured on preoperative CT in each group. (a) Mitral valve height from the LV apex, (b) distance between the LV apex and chest wall, (c) depth of the thorax from the LV apex. CT, computed tomography; LV, left ventricle.

3.3 | Postoperative Echocardiographic Data in Terms of IC Direction

The postoperative echocardiographic data are presented in Table 2. Patients in group C had a smaller left ventricular internal dimension in diastole (LVDd), left ventricular internal dimension in systole (LVDs), and left atrium dimension (LAD) than those of patients in group B (LVDd: 44 ± 15 mm and 61 ± 13 mm, respectively, $p = 0.01$; LVDs: 39 ± 16 mm and 56 ± 14 mm, respectively, $p = 0.02$; LAD: 28 ± 9 mm and 40 ± 11 mm, respectively, $p = 0.03$).

TABLE 3 | Parameters during LVAD hemodynamic ramp test of patients in groups A, B, and C.

	All	Group A	Group B	Group C	
	n = 48	*n* = 18	*n* = 21	*n* = 9	*p*
HeartMate 3 flow (L/min)					
Adjusted rotation speed	3.8 ± 0.6	3.9 ± 0.8	3.8 ± 0.4	3.8 ± 0.7	0.97
200 rpm down from adjusted rotation speed	3.6 ± 0.6	3.6 ± 0.7	3.6 ± 0.3	3.5 ± 0.7	0.76
200 rpm up from adjusted rotation speed	4.1 ± 0.6	4.2 ± 0.7	4.1 ± 0.5	4.0 ± 0.7	0.81
Δ200rpm up-200 rpm down	0.5 ± 0.2	0.6 ± 0.2	0.5 ± 0.3	0.5 ± 0.2	0.53
PAWP (mmHg)					
Adjusted rotation speed	7 ± 4	8 ± 5	8 ± 4	6 ± 2	0.37
200 rpm down from adjusted rotation speed	8 ± 4	9 ± 5	9 ± 4	6 ± 2	0.28
200 rpm up from adjusted rotation speed	7 ± 4	7 ± 5	7 ± 4	6 ± 3	0.81
Δ200rpm up-200 rpm down	2 ± 2	2 ± 2	2 ± 2	1 ± 3	0.29

Note: p values were obtained using Kruskal–Wallis test.
Abbreviations: LVAD, left ventricle assist device; PAW, pulmonary artery wedge pressure; rpm, rotation per minute.

3.4 | HM3 Flow and PAWP During LVAD Hemodynamic Ramp Test

HM3 flow and PAWP at adjusted rotation speeds did not differ significantly between the groups. Furthermore, the differences in HM3 flow and PAWP between rotation speeds of 200 rpm lower and higher than the adjusted rotation speed were not significantly different among the groups (Table 3).

3.5 | Complication and Survival Rate After HM3 Implantation

The survival rates after HM3 implantation at 3 years in groups A, B, and C were 88%, 90%, and 100%, respectively ($p = 0.67$) (Figure 4a). The rates of freedom from complications after HM3 implantation at 3 years in groups A, B, and C were 50%, 43%, and 20%, respectively ($p = 0.70$) (Figure 4b). The survival rates and rates of freedom from complications after HM3 implantation were not significantly different between each group (Table 4).

The occurrence rate of heart failure in group B tended to be higher than that in groups A and C (group A: 11%; group B: 24%; group C: 11%). Furthermore, the occurrence rate of arrhythmia in group C tended to be higher than that in groups A and B (group A: 11%; group B: 10%; group C: 33%) (Table 5).

4 | Discussion

The primary findings of this study are as follows: (1) the IC in HM3 was influenced by the mitral valve height from the LV apex, the distance between the LV apex and chest wall, and the thoracic depth from the LV apex; (2) the IC direction in HM3 had little effect on the flow and PAWP; and (3) the IC direction may not significantly affect the survival rate in patients with HM3 implantation.

Previous research reported that the position of the mitral valve and LV apex influenced IC direction in patients with HeartMate II; however, the relationship between the actual direction of IC and the preoperative anatomical characteristics is unclear [9]. This study revealed that the preoperative positions of the LV apex, mitral valve, thorax, and diaphragm influenced the IC direction in HM3. It has been reported that the IC direction in HM3 varies [10]. In patients with a high CTR and increased mitral valve height from the LV apex, the LV apex was positioned near the thorax, and the mitral valve was located more at the cranial side. The IC tended to be oriented toward the cranial side, with the pump body positioned under the LV apex. Consequently, the IC may be directed toward the anterior/lateral wall. In patients with the LV apex located further from the thorax and close to the shallow part of the thorax, the pump body tended to be positioned next to the LV apex above the diaphragm. Consequently, the IC may be directed toward the LV posterior/inferior wall. Evaluating the preoperative anatomical features that influence the IC direction in HM3 may be valuable.

In this study, the IC direction in HM3 had little influence on flow and PAWP. A previous study reported that patients with an IC angle > 75° had a higher PAWP with HeartMate II [5]. In this study, the HM3 flow at the adjusted rotation speed was sufficient for LV unloading, regardless of the IC direction. The IC length in HM3 is shorter than that in other devices. The IC tip in HM3 may not easily touch the LV wall, even if the IC is directed toward the LV anterior/lateral or posterior/inferior wall, and the IC direction in HM3 does not significantly influence the flow and PAWP. However, the influence of the IC direction in HM3 on patients with a small LV was not examined, and further studies are needed.

In this study, the IC direction did not significantly influence the occurrence of complications or the survival rate after HM3 implantation. Previous studies reported that an IC directed toward the LV posterior wall was a risk factor for device thrombosis and gastrointestinal bleeding recurrence after HeartWare

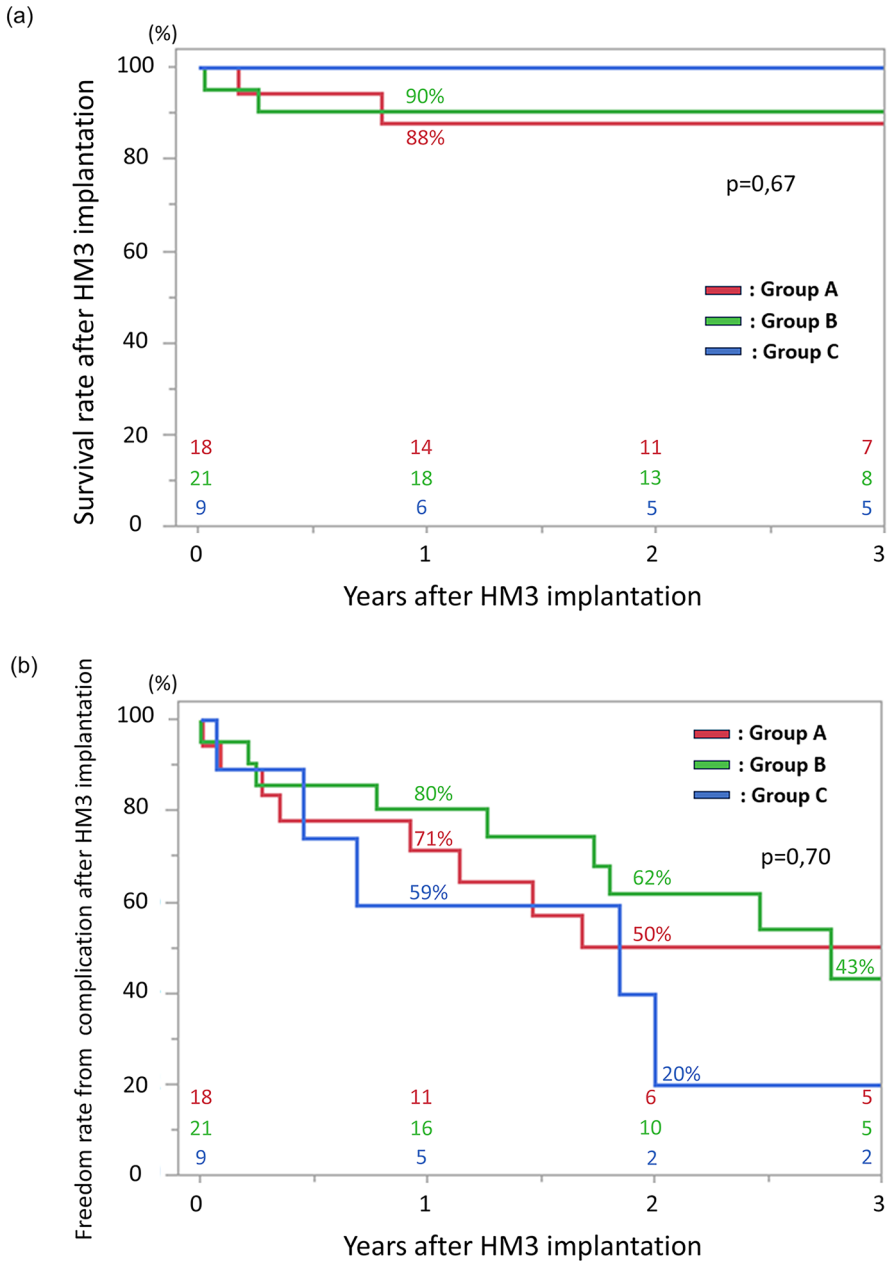

FIGURE 4 | Comparison of survival rate and rate of freedom from complications after HeartMate 3 implantation in each group. (a) Survival rate after HeartMate 3 implantation, (b) rate of freedom from complications after HeartMate 3 implantation. HM3, HeartMate3.

implantation [2, 3]. Another study reported that an IC directed toward the LV anterior wall was a risk factor for heart failure recurrence after HeartMate II implantation [5]. However, in the present study, the IC directed toward the anterior/lateral or posterior/inferior wall was not a risk factor for device thrombosis, gastrointestinal bleeding, or heart failure recurrence. Notably, HM3 is a new fully magnetically levitated centrifugal continuous-flow circulatory pump designed to reduce shear stress on blood elements and avert pump thrombosis [8, 11]. This advanced pump system might influence the occurrence of complications after HM3 implantation. Moreover, the INTRINSIC PULSALITY system in HM3, which adjusts rotor speed to produce changes in blood flow and arterial blood pressure [12], might also influence the occurrence of complications. However, patients with an IC directed toward the posterior/inferior wall tended to have arrhythmia that resulted in hospitalization. A previous study reported ventricular tachycardia caused by IC mechanical LV wall injury in a patient with HeartMate II [13]. In patients with an IC directed toward the posterior/inferior wall, the IC may cause LV wall injury. Furthermore, another study reported that IC angle $<10°$ indicated IC directed toward the posterior/inferior wall and was a risk factor for stroke occurrence in an HM3 patient [9]. It is important to ensure that the IC in HM3 is inserted in a direction that does not touch the LV wall, according to the morphological characteristics of each patient.

5 | Limitation

This study has some limitations, as it was a retrospective analysis conducted at a single center, and the number of patients included was relatively small.

TABLE 4 | Hazard ratio in the survival rate and freedom rate from complication after HM3 implantation.

	HR (95% CI)	*p*
Survival rate		
Group A vs. Group B	0.9 (0.1–6.1)	0.88
Group B vs. Group C	0.0 (0–)	1.00
Group A vs. Group C	0.0 (0–)	1.00
Freedom rate from complication		
Group A vs. Group B	1.0 (0.4–2.6)	0.92
Group B vs. Group C	1.6 (0.5–4.6)	0.40
Group A vs. Group C	1.5 (0.5–4.5)	0.51

Abbreviation: HR, hazard ratio.

TABLE 5 | Complications after HeartMate 3 implantation of patients in groups A, B, and C.

	All	Group A	Group B	Group C
	n = 48	*n* = 18	*n* = 21	*n* = 9
CVA, *n* (%)	3 (6)	1 (6)	1 (5)	1 (11)
HF, *n* (%)	8 (17)	2 (11)	5 (24)	1 (11)
Arrythmia, *n* (%)	7 (15)	2 (11)	2 (10)	3 (33)
Bleeding complication, *n* (%)	6 (13)	2 (11)	3 (14)	1 (11)
Low flow alarm, *n* (%)	4 (8)	1 (6)	2 (10)	1 (11)

Abbreviations: CVA, cerebrovascular attack; HF, heart failure.

6 | Conclusion

The IC direction in HM3 was influenced by the mitral valve height from the LV apex, the distance between the LV apex and chest wall, and the thoracic depth from the LV apex. Moreover, the IC direction in HM3 had little influence on the flow and PAWP and did not significantly affect the survival rate of patients with HM3.

Author Contributions

Shusuke Imaoka and Daisuke Yoshioka contributed to the study's conception and design. Shunsuke Saito and Takuji Kawamura contributed to the critical revision of the article. Ai Kawamura, Ryohei Matsuura, and Yusuke Misumi contributed to the data acquisition. Koichi Toda and Shigeru Miyagawa contributed to the approval of the article. Shusuke Imaoka drafted the manuscript, and all authors revised it.

Acknowledgments

The authors have nothing to report.

Ethics Statement

The present study was approved by Osaka University Graduate School of Medicine (Reference number: 21372(T1)-3).

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The deidentified participant data will not be shared.

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