

# Impact of Ischaemic and Dilated Cardiomyopathy on Short-Term and Long-Term Survival After Ventricular Assist Device Implantation: A Single-Centre Experience



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## Background

Prognosis of patients with end-stage heart failure is known to be impacted by the aetiology of heart failure (HF). Ischaemic cardiomyopathy (ICM) and dilated cardiomyopathy (DCM) are the most frequent pathologies necessitating ventricular assist device (VAD) support in these patients. However, the specific impact of ICM and DCM in clinical outcomes after VAD implantation remains unclear. Therefore, this study aimed to analyse clinical differences in ICM and DCM patients after LVAD surgery from the current institution.

## Methods

All consecutive patients from the LVAD centre were included in this retrospective study. To analyse specific differences in in-hospital outcomes, patients were divided into two groups: ICM and DCM. Long-term follow-up was calculated by Kaplan-Meier estimation of survival.

## Results

Between January 2010 and July 2020, 60 consecutive patients underwent LVAD implantation at the institution: 36 patients (60%) were supported due to end-stage ICM and 24 patients (40%) in regard of therapy-refractory DCM. Baseline characteristics showed no between-group differences. The ICM patients showed a clear trend to higher amount of additional cardiac procedures during VAD surgery (36% ICM vs 12% DCM;  $p=0.052$ ). In-hospital mortality was comparable between ICM and DCM patients (36% ICM vs 21% DCM;  $p=0.206$ ). A trend towards higher frequency of pump thrombosis was seen in DCM patients ( $p=0.080$ ). Long-term survival was comparable between the groups.

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**Conclusion**

The aetiology of heart failure did not impact short-term or long-term clinical outcomes after VAD surgery. Multicentre registry data are necessary to substantiate these findings.

**Keywords**

Left ventricular assist device • Ischaemic cardiomyopathy • Dilated cardiomyopathy • Cardiogenic shock

**Introduction**

A decrease in organ donors has led in an increase in waiting times for heart transplantation, and left ventricular assist device (LVAD) therapy has switched from bridge to transplant to bridge to destination in the majority of implantations performed over the last few years [1]. Meanwhile, LVAD surgery is an established treatment option for patients with advanced cardiomyopathy [2–4]. Depending on the form of heart failure (HF), prognosis is influenced by aetiology, age, comorbidities, and individual progression of HF [5]. Among the variety of HF forms, ischaemic cardiomyopathy (ICM) and dilated cardiomyopathy (DCM) are the main causes of chronic HF [6]. Congruent with epidemiological data, ICM and DCM patients present the largest group of patients treated with LVAD [7]. In 2002, Heerdt *et al.* demonstrated LVAD-induced reverse ventricular remodelling in ICM patients, but not in DCM patients [8]. Symons *et al.* showed in their multicentre trial that coronary artery endothelial function was significantly more improved in LVAD-supported ICM patients compared with DCM patients [9]. Translation of these findings into clinical outcomes is necessary to identify the impact of the underlying HF after LVAD implantation. In this context, data comparing clinical outcomes of ICM and DCM patients after LVAD surgery are scarce and lacking in current literature.

Therefore, this study aimed to analyse clinical differences in ICM and DCM patients after LVAD surgery, from the current institution, with respect to in-hospital and long-term outcomes.

**Methods**

The Institutional Review Board approved this study. Informed written consent was waived due to the retrospective design. It included 60 consecutive patients who received continuous-flow, centrifugal pump LVAD for either destination or bridge to transplant therapy between February 2010 and December 2020. All patients met the medical policy guideline of New York Heart Association (NYHA) class IV HF. Patients were divided into two groups depending on type of HF: ICM,  $n=36$  and DCM,  $n=24$ .

**Endpoints and Definitions**

The primary endpoint was in-hospital mortality. Long-term survival was assessed by Kaplan-Meier-survival curve. In-hospital mortality was defined as death from any cause within the in-patient stay. Acute kidney injury was defined by increases in serum creatinine and/or the need for dialysis. The

current Kidney Disease: Improving Global Outcomes (KDIGO) guidelines modified the RIFLE criteria<sup>1</sup> to include changes in creatinine as small as 0.3 mg/dL. In general, INTERMACS<sup>2</sup> profiles I–III present inotrope-dependent patients from ‘crash and burn’ (INTERMACS class I) to those who are haemodynamically stable on inotrope medication (INTERMACS class III), and profiles IV–VII demonstrate non-inotrope-dependent patients with diverse forms of severe HF symptoms. According to the INTERMACS registry, right ventricular failure is defined as symptoms and signs of sustained right ventricular (RV) dysfunction (defined as central venous pressure >18 mmHg with a cardiac index <2.0 L/min/m<sup>2</sup> in the absence of pulmonary capillary wedge pressure >18 mmHg, malignant arrhythmias or pneumothorax), necessitating right ventricular assist device (RVAD) or inotropic therapy for >7 days any time after LVAD implantation.

**Follow-Up**

Patients were followed up systematically at the University Hospital of Cologne during their regular outpatient care. Mean follow-up among survivors was 50.4 months (range, 36–64.8 months).

**Statistical Analysis**

Statistical analysis was performed using Statistical Package for Social Sciences, version 23.0 (SPSS IBM., Armonk, NY, USA). Baseline, intraprocedural, and follow-up data up to 30 days were retrospectively collected and entered into a standardised database and analysed. Data are presented as absolute numbers and percentages for categorical variables. Continuous data were evaluated for normality using one sample Kolmogorov-Smirnov test and were expressed as the mean  $\pm$  standard deviation (SD) in cases of normally distributed or median (interquartile range) in cases of non-normally distributed continuous variables. Univariate analysis was performed using either Student *t*-test or Mann-Whitney U test for normally and non-normally distributed continuous variables, respectively. Pearson’s  $\chi^2$  or Fisher exact tests were used for comparison of categorical data, depending on the minimum expected count in each cross-tab. Long-term data were estimated by Kaplan-Meier-survival curve and Log-rank-test. A level of significance was set at two-tailed  $p<0.05$ .

**Results**

Between January 2010 and July 2020, 60 consecutive patients underwent LVAD implantation at the current institution.

<sup>1</sup> Risk, Injury, Failure, Loss of kidney function, and End-stage kidney disease.

<sup>2</sup> Interagency Registry for Mechanically Assisted Circulatory support.

**Table 1** Baseline characteristics of patients supported with LVAD.

	ICM (n=36)	DCM (n=24)	P-value
Age (yr)	58±11	58±10	0.976
Male	33 (92)	21 (87)	0.598
Height (m)	176 (170;180)	176 (175;180)	0.989
Weight (kg)	79 (73;89)	81 (75;90)	0.917
BMI (kg/m <sup>2</sup> )	26 (24;29)	26 (23;31)	0.200
Aim of surgery			
Bridge to transplant	8 (22)	7 (29)	0.543
Destination therapy	18 (50)	13 (54)	0.752
Ultima ratio	10 (28)	4 (17)	0.319
Comorbidities			
NYHA IV	34 (100)	26 (100)	0.688
COPD	8 (22)	8 (33)	0.290
Pulmonary hypertension	16 (44)	5 (21)	0.076
Peripheral vascular disease	13 (36)	6 (25)	0.203
Coronary artery disease	23 (67)	13 (54)	0.571
Chronic kidney disease	18 (50)	18 (75)	0.085
Atrial fibrillation	16 (44)	10 (42)	0.942
Diabetes mellitus II	10 (28)	9 (37)	0.507
Cerebral vascular disease	11 (31)	6 (25)	0.427
Prior myocardial infarction	24 (67)	10 (42)	0.079
Previous cardiac surgery			
Re-do surgery	9 (25)	6 (25)	0.611
Single CABG	6 (17)	6 (25)	0.309
Tricuspid valve repair/replacement	1 (3)	0 (0)	0.174
Aortic valve replacement	4 (11)	3 (12)	0.775
Mitral valve replacement	2 (6)	1 (4)	0.208

Abbreviations: ICM, ischaemic cardiomyopathy; DCM, dilated cardiomyopathy; BMI, body mass index; NYHA, New York Heart Association class; COPD, chronic obstructive pulmonary disease; LVAD, left ventricular assist device; CABG, coronary artery bypass graft.

Thirty-six (36) patients (60%) were supported due to end-stage ICM and 24 patients (40%) due to therapy-refractory DCM. Baseline characteristics are presented in Table 1. Age did not differ between the groups (58±11 ICM vs 58±10 DCM;  $p=0.976$ ). Furthermore, ICM (92%) and DCM (87%) were more frequent in men than in women. The aim of surgery showed no difference regarding HF. Comorbidities were generally comparable between the groups. Previous myocardial infarction ( $p=0.079$ ) and pulmonary hypertension ( $p=0.076$ ) showed a trend towards a higher incidence in ICM patients and chronic kidney disease ( $p=0.085$ ) in DCM patients. Previous cardiac surgery procedures showed no between-group difference.

Laboratory parameters (creatinine, albumin, bilirubin) prior to LVAD surgery did not differ (Table 2). Echocardiographic data were comparable, resulting in 19±7% left

**Table 2** Laboratory parameter, echocardiographic data, and INTERMACS profile prior to surgery.

	ICM (n=36)	DCM (n=24)	P-value
Laboratory parameter			
Serum creatinine (mg/dL)	1.6 (1.1;2.1)	1.5 (1.2;2)	0.784
Albumin (g/L)	30±10	32±14	0.693
Total bilirubin (mg/dL)	1.2 (0.5;2.1)	1.3 (0.7;3.9)	0.956
Echocardiographic data			
LVEDD (mm)	67±10	71±9	0.342
TAPSE (mm)	14±4	13±4	0.811
sPAP (mmHg)	53±8	55±12	0.435
Cardiac index (L/min/m <sup>2</sup> )	1.25 (1.2;1.3)	1.4 (1.2;1.7)	0.062
LVEF (%)	19±7	17±7	0.435
INTERMACS profile			
Profile 1–3	17 (47)	10 (42)	0.778
Profile 4	7 (19)	4 (17)	0.843
Profile 5	6 (17)	6 (25)	0.381
Profile 6	6 (17)	4 (17)	0.942
Profile 7	0 (0)	0 (0)	-

Abbreviations: LVEDD, left ventricular end diastolic diameter; TAPSE, tricuspid annular plane systolic excursion; sPAP, systolic pulmonary artery pressure; LVEF, left ventricular ejection fraction; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory support.

ventricular ejection fraction in ICM patients, and 17±7% in DCM patients. DCM patients showed a trend towards a higher cardiac index ( $p=0.062$ ). INTERMACS profile distribution was comparable between the groups. Most patients were in INTERMACS profile 1–3 (47% ICM vs 42% DCM;  $p=0.778$ ).

Intraoperative data are summarised in Table 3. The majority of patients were supported with Heart Ware HVAD (Heart Ware International Inc., Framingham, MA, USA) (81% ICM vs 75% DCM;  $p=0.542$ ). DCM patients significantly more often received HeartMate III (Abbott, Chicago, IL, USA) ( $p<0.001$ ). ICM patients showed a clear trend to higher amounts of additional cardiac procedures during LVAD surgery (36% ICM vs 12% DCM;  $p=0.052$ ). Incidences of temporary RVAD due to right ventricular failure and concomitant ECMO support were comparable.

Postoperative inotropic therapy with milrinone significantly differed between the groups (0.2 (0.05;0.2) µg/kg/min ICM vs. 0.25 (0.2;0.3) µg/kg/min DCM;  $p<0.001$ ). Laboratory parameters showed no difference postoperatively (Table 4).

Outcomes are presented in Table 5. In-hospital mortality was comparable between ICM and DCM patients (36% ICM vs 21% DCM;  $p=0.206$ ). Median hospital stay was 28 (6;53) days in ICM patients and 38 (24;83) days in DCM patients ( $p=0.349$ ). Moreover, there was a trend towards more frequent pump thrombosis in DCM patients ( $p=0.080$ ). Other

**Table 3** Intraoperative data.

	ICM (n=36)	DCM (n=24)	P-value
Heart Ware HVAD	29 (81)	18 (75)	0.542
Heart Mate III	1 (3)	6 (25)	<0.001
BiVAD (Berlin Heart)	1 (3)	0 (0)	0.174
CPB time (min)	86 (64;126)	89 (71;121)	0.787
Cross-clamp time (min)	0 (0)	0 (0)	-
Procedure time (min)	182 (143;227)	187 (148;211)	0.787
Combined surgery	13 (36)	3 (12)	0.052
Chest packing	6 (17)	6 (25)	0.391
IABP	6 (17)	2 (8)	0.417
Temporary RVAD	4 (11)	1 (4)	0.340
ECMO	11 (31)	4 (17)	0.296

Abbreviations: BiVAD, bi-ventricular assist device; CPB, cardiopulmonary bypass; IABP, intra-aortic balloon pump; RVAD, right ventricular assist device; ECMO, extracorporeal membrane oxygenation.

adverse in-patient outcomes did not differ between the groups. No other differences were noted between ICM and DCM patients in terms of adverse events.

## Overall Long-Term Survival and Survival for ICM and DCM Patients After LVAD Implantation

Kaplan-Meier analysis (Figure 1) from day 90 showed no difference in survival between patients with ICM compared with those with DCM (log-rank test,  $p=0.197$ ). Kaplan-Meier estimation for long term-survival showed no significant difference between patients suffering from ischaemic and dilated cardiomyopathy (Figure 2) (log-rank test;  $p=0.105$ ).

## Discussion

This study was performed to investigate whether aetiology of HF impacts either short-term or long-term outcomes in LVAD patients. From observation, no significant differences were obvious, indicating comparable results for both group of patients in mid-volume centres. Additionally, long-term survival up to 5 years was comparable.

Diverse studies have shown that patients with ischaemic cardiomyopathy have reduced survival compared with patients with dilated cardiomyopathy [7]. Both cardiomyopathies are characterised by some degree of fibrosis, remodelling, and a variable amount of viable myocardium, with a higher risk of sudden cardiac death in ICM patients [10]. The observed survival in the current cohort was similar, despite a trend towards a higher amount of pulmonary hypertension and prior myocardial infarction in ICM patients.

In contrast to the current findings, some studies have shown that ICM patients have diminished survival

**Table 4** Postoperative catecholamine therapy and laboratory parameters.

	ICM (n=36)	DCM (n=24)	P-value
Inotropic and vasoactive supports			
Adrenalin ( $\mu\text{g}/\text{kg}/\text{min}$ )	0.1 (0.1;0.2)	0.2 (0.1;0.2)	0.280
Milrinone ( $\mu\text{g}/\text{kg}/\text{min}$ )	0.2 (0.05;0.2)	0.25 (0.2;0.3)	<0.001
Noradrenalin ( $\mu\text{g}/\text{kg}/\text{min}$ )	0.25 (0.18;0.37)	0.25 (0.19;0.4)	0.979
Laboratory parameter			
Creatinine (mg/dL)	2.1 (1.5;2.5)	1.6 (1.2;2.2)	0.053
ASAT (U/L)	126 (59;582)	91 (44;158)	0.406
ALAT (U/L)	67 (29;372)	39 (24;119)	0.782
Albumin (g/L)	23 (16;29)	24 (20;29)	0.904
Platelets (g/L)	123 $\pm$ 67	126 $\pm$ 74	0.894
Haematocrit (%)	28 (26;32)	28 (26;31)	0.861
Transfusions			
RBC (units)	13 (6;26)	10 (2;33)	0.791
Platelets (units)	2 (0;4)	1 (0;4)	0.346
FFP (units)	4 (1;9)	4 (0.25;12)	0.878

Abbreviations: ASAT, aspartate aminotransferase; ALAT, alanine aminotransferase; RBC, red blood cells; FFP, fresh frozen plasma.

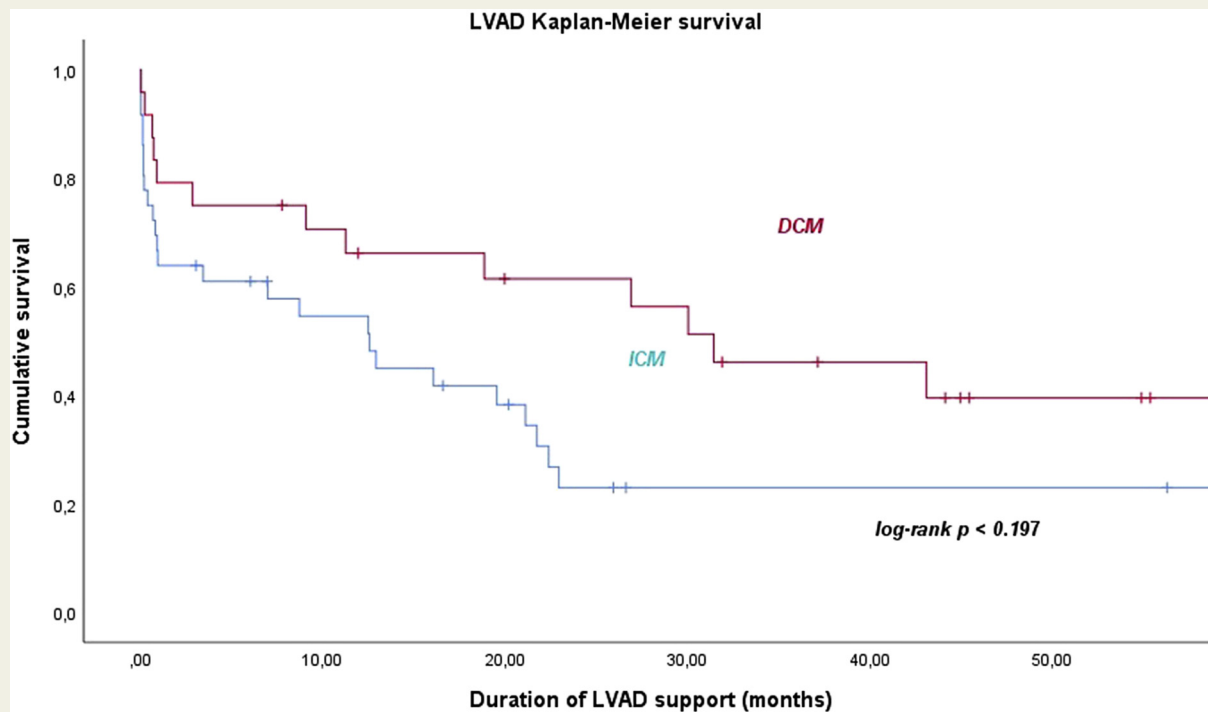
compared with DCM patients. Likoff et al. reported significantly higher mortality at 12 months for patients with ICM compared with DCM (36% vs 24%, respectively;  $p<0.001$ ) [11]. Another study showed that an ischaemic aetiology for HF was an independent predictor of mortality [12]. However, Chou et al. reported, concomitant with the current analysis, similar survival between both groups, with a 1-year survival of 72% for ICM patients versus 74% for DCM patients [13]. Moreover, the aetiology of HF in the Studies of Left Ventricular Dysfunction (SOLVD) registry also did not affect mortality [14]; this is a registry of 6,336 patients with congestive HF or LV dysfunction that is designed to describe the clinical course of an unselected group of patients.

In addition, Tsiouris et al. presented data from their LVAD program, comparing results of patients regarding the aetiology of HF [15]. Survival was similar in both groups within 30 days, 6 months, and 1 year after LVAD surgery ( $p=0.743$ ) [15]. Moreover, the type of cardiomyopathy was not an independent predictor of survival in multivariate logistic regression analysis. Therefore, the authors corroborated the current findings and stated that aetiology of cardiomyopathy does not influence outcomes after LVAD surgery. It is believed that the current study is the first to describe these results and also for a follow-up period of 5 years. Additionally, clinical parameters and short-term outcomes in this analysis were comparable and did not indicate a difference between the analysed cohorts. In this context, several questions arise about why outcomes appear similar, despite

**Table 5** In-hospital outcomes after LVAD surgery.

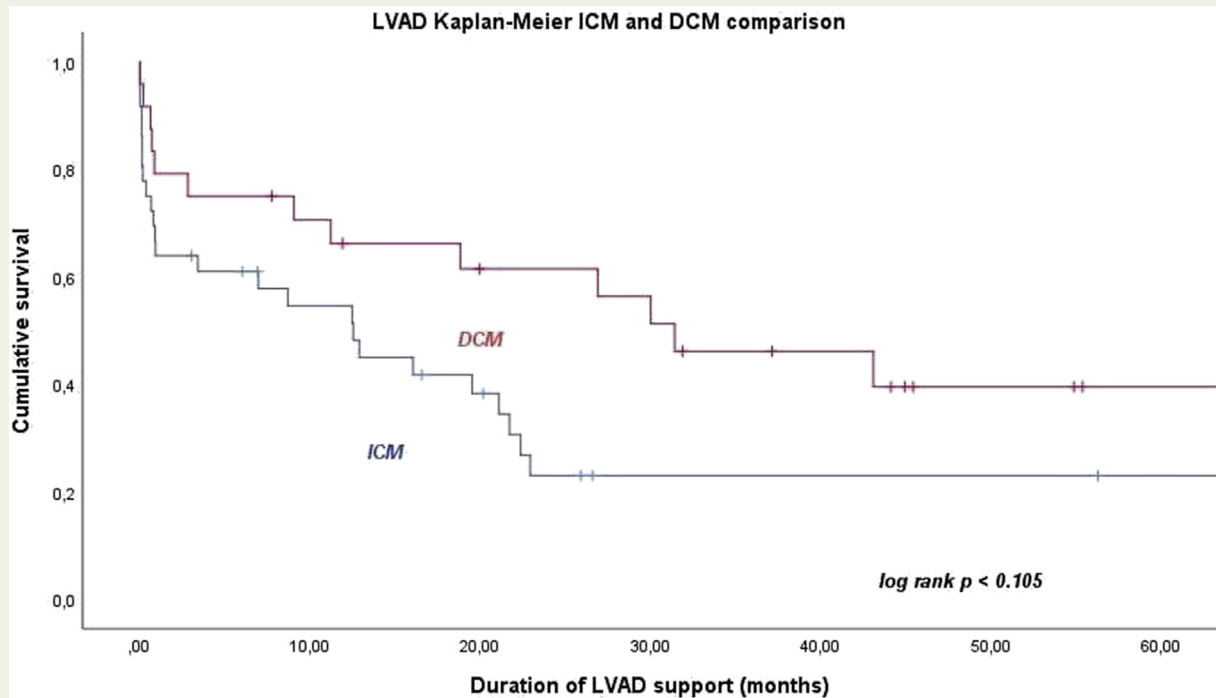
	ICM (n=36)	DCM (n=24)	P-value
In-hospital mortality	13 (36)	5 (21)	0.206
ICU stay (d)	12 (5;30)	20 (9;57)	0.349
Hospital stay (d)	28 (6;53)	38 (24;83)	0.349
Adverse outcomes			
Bleeding volume in 24 hr (mL)	1,300 (1,020;2,140)	1,200 (1,100;1,250)	0.350
Re-thoracotomy	7 (19)	5 (21)	0.807
Pump thrombosis	2 (6)	2 (8)	0.080
RVAD thrombosis	1 (3)	0 (0)	0.410
Right heart failure	12 (33)	5 (21)	0.448
RI requiring dialysis	17 (42)	8 (33)	0.503
Stroke	3 (8)	3 (12)	0.174
Hepatic dysfunction	6 (17)	4 (17)	0.820
Cardiac arrhythmias	13 (36)	9 (37)	0.614
Worsening HF	7 (19)	1 (4)	0.124
Haemolysis	7 (19)	3 (12)	0.621
Driveline infection	6 (17)	3 (12)	0.812
Sepsis	8 (22)	6 (25)	0.591

Abbreviations: ICU, intensive care unit; RVAD, right ventricular assist device; RI, renal insufficiency; HF, heart failure; ICM, ischaemic cardiomyopathy; DCM, dilated cardiomyopathy.



**Figure 1** Kaplan-Meier analysis from day 90 showed no difference in survival between patients with ischaemic cardiomyopathy (ICM) compared with those with dilated cardiomyopathy (DCM) (log-rank test,  $p=0.197$ ).

Abbreviation: LVAD, left ventricular assist device.



**Figure 2** Kaplan-Meier estimation for long term-survival showed no significant difference between patients suffering from ischaemic cardiomyopathy and dilated cardiomyopathy (log-rank test;  $p=0.105$ ). Abbreviations: DCM, dilated cardiomyopathy; ICM, ischaemic cardiomyopathy; LVAD, left ventricular assist device.

known differences in structural myocardial remodelling following LVAD surgery regarding underlying cardiomyopathy [16]. There is evidence for specific downregulation and upregulation of extracellular matrix-associated proteins during VAD circulation, depending on the aetiology of HF [17]. However, available data suggest that sequential beneficial effects diminish regarding in-hospital outcomes.

### Limitations

This study had several limitations. First, it was an observational, non-randomised study and subject to limitations inherent to any retrospective study. Second, statistical tests may have been insufficiently powered due to the relatively small sample size. Third, the potential inaccuracy of data retrieved from medical records reduced the power of the study. Finally, it was a single institutional study and selection bias may have been introduced.

### Conclusion

Aetiology of heart failure did not impact short-term or long-term clinical outcomes in mid-volume assist device centres after VAD surgery. To translate known pathophysiologic differences into clinical outcomes, experimental data might be necessary. Moreover, multicentre registry data could substantiate these findings, which are congruent with the majority of current studies.

### Disclosures

The authors have nothing to disclose.

### Conflicts of Interest

The authors declare no conflicts of interest.

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