Propensity score-based analysis of 30-day survival in cardiogenic shock patients supported with different microaxial left ventricular assist devices

Journal Article

Author(s):

Nersesian, Gaik; Potapov, Evgenij V.; Nelki, Vivian; Stein, Julia; Starck, Christoph; [Falk, Volkmar](#) ; Schoenrath, Felix; Krackhardt, Florian; Tschöpe, Carsten; Spillmann, Frank

Publication date:

2021-11

Permanent link:

<https://doi.org/10.3929/ethz-b-000504183>

Rights / license:

[Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International](#)

Originally published in:

Journal of Cardiac Surgery 36(11), <https://doi.org/10.1111/jocs.15932>

ORIGINAL ARTICLE

Propensity score-based analysis of 30-day survival in cardiogenic shock patients supported with different microaxial left ventricular assist devices

Gaik Nersesian^{1,2} | Evgenij V. Potapov^{1,2} | Vivian Nelki³ | Julia Stein¹ |
Christoph Starck^{1,2} | Volkmar Falk^{1,2,4,5} | Felix Schoenrath^{1,2} |
Florian Krackhardt³ | Carsten Tschöpe^{2,3,6} | Frank Spillmann^{3,6}

¹Department of Cardiothoracic and Vascular Surgery, German Heart Center Berlin, Berlin, Germany

²DZHK (German Centre for Cardiovascular Research), Partner Site Berlin, Berlin, Germany

³Department of Internal Medicine and Cardiology, Charité-Universitätsmedizin, Berlin, Germany

⁴Department of Cardiothoracic Surgery, Charité-Universitätsmedizin Berlin, Corporate Member of Freie Universität Berlin, Humboldt-Universität zu Berlin, and Berlin Institute of Health, Berlin, Germany

⁵Department of Health Sciences and Technology, ETH Zürich, Zürich, Switzerland

⁶Berlin Institute of Health (BIH) Berlin-Brandenburg Center for Regenerative Therapy (BCRT), Charité-Universitätsmedizin Berlin, Campus Virchow Klinikum, Berlin, Germany

Correspondence

Gaik Nersesian, Deutsches Herzzentrum Berlin, Augustenburger Platz 1, 13353 Berlin, Germany.

Email: nersesian@dhzb.de

Abstract

Background and methods: Microaxial left ventricular assist devices are used increasingly for treating cardiogenic shock. We compared the short-term outcome of patients supported with different microaxial devices for cardiogenic shock. A retrospective propensity score-adjusted analysis was performed in cardiogenic shock patients treated with either the Impella CP ($n = 64$) or the Impella 5.0/5.5 ($n = 62$) at two tertiary cardiac care centers between 1/14 and 12/19.

Results: Patients in the Impella CP group were significantly older (69.6 ± 10.7 vs. 58.7 ± 11.9 years, $p = .001$), more likely in INTERMACS profile 1 (76.6% vs. 50%, $p = .003$) and post-C-reactive protein (CPR) (36% vs. 13%, $p = .006$). The median support time was 2.0 days [0.0, 5.3] in the CP group vs. 8.5 days [4.3, 15.8] in the 5.0/5.5 group ($p < .001$). The unadjusted 30-day survival was significantly higher in the Impella 5.0/5.5 group (58% vs. 36%, $p = .021$, odds ratio [OR] for 30-day survival on Impella 5.0/5.5 was 3.68 [95% confidence interval [CI]: [1.46–9.90]], $p = .0072$). After adjustment, the 30-day survival was similar for both devices (OR: 1.23, 95% CI: [0.34–4.18], $p = .744$). Lactate levels above 8 mmol/L and preoperative CPR were associated with a significant mortality increase in both cohorts (OR: 10.7, 95% CI: [3.45–47.34], $p < .001$; OR: 13.2, 95% CI: [4.28–57.89], $p < .001$, respectively).

Conclusion: Both Impella devices offer a similar effect with regard to survival in cardiogenic shock patients. Preoperative CPR or lactate levels exceeding 8 mmol/L immediately before implantation have a poor prognosis on Impella CP and Impella 5.0/5.5.

Abbreviations: ac-HF, acute on chronic heart failure; AHT, arterial hypertension; AMI, acute myocardial infarction; BMI, body mass index; CAD, coronary artery disease; CI, confidence interval; CS, cardiogenic shock; COPD, chronic obstructive pulmonary disease; CPR, cardiopulmonary resuscitation; CRP, C-reactive protein; DM, diabetes mellitus; ECLS, extracorporeal life support; GOT, glutamic-oxaloacetic transaminase; HFrEF, heart failure with reduced ejection fraction; IABP, intra-aortic balloon pump; ICU, intensive care unit; INR, international normalized ratio; INTERMACS, Interagency Registry of Mechanically Assisted Circulatory Support; IQR, interquartile range; LDH, lactate dehydrogenase; LVAD, left ventricular assist device; MAP, mean arterial pressure; MELD, model for end-stage liver disease; tempMCS, temporary mechanical circulatory support; OR, odds ratio; PCI, percutaneous coronary intervention; ROC, receiver operating characteristic; rpm, revolutions per minute; RV, right ventricle; RVAD, right ventricular assist device; RVF, right ventricular failure; SD, standard deviation; SHR, subdistribution hazard ratio; v-a ECLS, veno-arterial extracorporeal life support; WBC, white blood cell count.

Gaik Nersesian and Evgenij V. Potapov contributed equally to the study.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2021 The Authors. *Journal of Cardiac Surgery* Published by Wiley Periodicals LLC

KEYWORDS

cardiogenic shock, Impella, LVAD

1 | INTRODUCTION

The mortality in patients suffering from cardiogenic shock (CS) is high; the overall 30-day mortality for patients with CS associated with acute myocardial infarction (AMI) is approximately up to 50%.^{1,2} Medical treatment with high-dose inotropic support and vasoactive agents is essential for acute stabilization, but may lead to ventricular arrhythmias and further myocardial injury due to an increased afterload and myocardial workload.³ In this setting, the role of temporary mechanical circulatory support (tempMCS) is becoming increasingly important.¹

TempMCS can provide full haemodynamic support and improve organ perfusion, which may prevent or reverse multiorgan failure.⁴ Left ventricular unloading reduces myocardial oxygen consumption and may increase the chances of myocardial recovery or at least prevent further injury.⁵

Veno-arterial extracorporeal life support (v-a ECLS) is the most common temporary MCS device. V-a ECLS is available in most tertiary care centers, is relatively simple to implant and can be applied during cardiopulmonary resuscitation (CPR).⁶ Patients with biventricular or cardiorespiratory failure after CPR may benefit from ECLS therapy.⁷ However, v-a ECLS therapy cannot sufficiently unload the left ventricle and hence generates an extremely high afterload, which in turn increases left ventricular wall stress, myocardial oxygen demand and impairs coronary perfusion. In the absence of ventricular contractility, this can lead to pulmonary hypertension and subsequently to interstitial lung edema.⁸ Therefore, in case of isolated left ventricular failure, microaxial left ventricular assist devices such as the Impella (Abiomed Inc.) can be used as an alternative to or in combination with ECLS.⁹

The Impella devices are a family of microaxial pumps that can provide a flow of up to 5.5 L/min, achieving partial or full haemodynamic support, depending on the patient's needs. One of the most commonly used Impella devices is the Impella CP, which can generate up to 3.5 L/min of flow and is implanted percutaneously via femoral artery access. The Impella 5.0 and 5.5 LVADs are able to provide full haemodynamic support of up to 5.5 L/min. Due to their size, they require surgical implantation, usually via axillary artery access.

Despite the fact that both devices are used increasingly in CS patients, the optimal indication and correct patient selection for the type of support remain undefined. Therefore, we performed a retrospective analysis with the aim of comparing the effectiveness of both Impella CP and Impella 5.0/5.5 LVADs in CS patients.

2 | METHODS

The study is a retrospective analysis of 126 consecutive patients supported with the Impella CP or Impella 5.0/5.5 devices at two tertiary care centers. The study was approved by the institutional ethics committee (ES2/016/20).

2.1 | Patient selection

Patients ($n = 126$) underwent Impella CP, 5.0 or 5.5 implantation between January 2014 and December 2019. Patients supported with v-a-ECLS were not included in the analysis. The indication for Impella implantation was CS (INTERMACS profile 1, 2, 3 or SCAI level E, D, and C); all patients were over 18 years old.^{2,10} Patients were retrospectively divided into two groups according to the device type: an Impella CP group ($n = 64$) and an Impella 5.0/5.5 group ($n = 62$). Impella device selection depended on the medical institution: patients treated in the cardiological department of one centre received only Impella CP, while those in the cardiothoracic surgical department of another centre received Impella 5.0/5.5. Patients were admitted independently from the participating centers and were referred predominantly by a primary medical care centre on the basis of the clinical setting, therapeutic goals and capacities available.

The 30-day cut-off was chosen arbitrarily on the basis of several comparable shock studies.^{4,5}

2.2 | Data collection

Demographic, clinical and last available haemodynamic data and laboratory values before Impella implantation were retrospectively collected from the patients' charts and analysed. A 20% limit for missing data was set to exclude variables for which an excessive amount of data was missing. No relevant parameter had >10% missing data. The patients' follow-up data from at least 30 post-operative days were collected.

The MELD-XI score was calculated using the formula: $5.11 \times \ln(\text{bilirubin}) + 11.79 \times \ln(\text{creatinine}) + 9.44$.¹¹

2.3 | Statistical procedures

Continuous variables are summarized as mean and standard deviation (SD) or as median and interquartile range (IQR) in the case of skewed data. For categorical variables, numbers and percentages are presented. Patient groups were compared using Student's *t* test for normally distributed continuous data and the Mann-Whitney *U* test for non-normally distributed continuous data. For categorical data, χ^2 tests with Yates' continuity correction were used. To account for imbalances in preoperative data in the Impella CP, 5.0 and 5.5 groups, a propensity score was calculated with sex, age, etiology of CS, INTERMACS profile (The Interagency Registry of Mechanically Assisted Circulatory Support), CPR, CAD, IABP, AHT, DM, renal insufficiency, COPD, liver insufficiency, lactate, WBC, creatinine and INR. The influence of Impella CP, 5.0 and 5.5 on 30-day survival was calculated using logistic regression adjusting for the propensity score.

Due to the small patient number no propensity score matching was performed.

A receiver operating characteristic (ROC) curve was plotted for preoperative lactate. The area under the ROC curve was calculated as a measure for discrimination ability. Survival in different patient groups was analysed using Kaplan-Meier estimates with 95% confidence intervals (CIs). Log-rank testing was used to compare patient groups.

We assumed a $p < .05$ as the threshold for statistical significance. The analysis was exploratory in nature. R software version 4.0.2 was used for statistical analyses.

2.4 | Implantation technique

For 14 Fr size Impella CP placement, the right or left femoral artery was punctured and dilated, following which a 14 Fr introducer was placed. The 0.018 inch 260 cm placement guidewire was inserted and pushed through the aortic valve into the left ventricle (LV), after which the Impella CP pump was inserted under fluoroscopic guidance. The inlet cannula was placed approx. 3.5–4.5 cm below the level of the aortic valve. The Impella CP speed was initially set at level P8 (3.5 L/min; 44,000 rpm) if no suction occurred. Level P9 is the boost mode for Impella CP, which can be used to generate up to 3.7 L/min (46,000 rpm) for 5 min.

For Impella 5.0/5.5 placement, patients were intubated and operated under general anesthesia. The axillary artery was surgically exposed and a 10-mm Hemashield graft (MAQUET Ltd.) was anastomosed end-to-side and tunneled under the skin to allow primary wound closure. The 21 Fr Impella 5.0 (or 19 Fr Impella 5.5) pump was inserted through the graft under fluoroscopic and transesophageal echocardiographic guidance as described by Boll et al.¹² The inlet was positioned approx. 4.5 cm below the level of the aortic valve annulus. After optimal positioning the pump speed was increased stepwise to P9 (33,000 rpm) under a consistent reduction of inotropic support with a target mean arterial pressure (MAP) of 60–70 mmHg.

Impella 5.0 implantation was performed in 53 (42%) patients, nine (7%) were treated with Impella 5.5. For access, the left axillary artery was used in three (2%) cases, the right axillary artery in 59 (47%) cases.

2.5 | Anticoagulation

Anticoagulation was maintained by intravenous heparin and monitored by aPTT and anti-Xa levels (target: 70–90 s and 0.3–0.5 IU/ml, respectively).

2.6 | Device management

During the acute phase of CS, the maximum support level (P8 for Impella CP and P9 for Impella 5.0/5.5) was targeted in both groups,

TABLE 1 Patient demographics

Parameter	Total	Impella CP	Impella 5.0/5.5	p value
	n = 126	64 (51)	62 (49)	
Male sex (n, %)	95 (75)	43 (67)	52 (84)	.049
Age (years)	64 ± 12.5	69.6 ± 10.7	59 ± 11.8	<.001
BMI (kg/m ²)	27.2 [24–31]	26.8 [25–30]	27.7 [24–32]	.65
BMI > 30 kg/m ²	33 (26)	13 (22)	20 (34)	.21
Etiology of heart failure				
AMI (n, %)	64 (51)	50 (78)	14 (23)	.001
Acute on chronic HF	54 (43)	13 (20)	41 (66)	.001
Acute myocarditis (n, %)	8 (6)	1 (2)	7 (11)	.001
Risk factors				
Arterial hypertension (n, %)	65 (52)	31 (48)	34 (55)	.59
Diabetes mellitus (n, %)	52 (41)	28 (44)	24 (39)	.69
HLP (n, %)	38 (30)	18 (28)	20 (32)	.49
INTERMACS 1	80 (63)	49 (77)	31 (50)	.003
Previous open-heart surgery (n, %)	25 (20)	9 (14)	16 (26)	.15
PTCA (n, %)	73 (58)	44 (69)	29 (47)	.39
CPR (n, %)	31 (25)	23 (36)	8 (13)	.006
CPR duration (min)	48 ± 47	50 ± 53	43 ± 13	.8
CAD (n, %)	93 (74)	56 (88)	37 (60)	.001
Prior MI (n, %)	78 (62)	49 (77)	29 (47)	.001
Malignancy (n, %)	14 (11)	9 (14)	5 (8)	.49
Renal insufficiency (n, %)	50 (40)	16 (25)	34 (55)	.001
Renal replacement therapy (n, %)	16 (13)	7 (11)	9 (14.5)	.737
COPD (n, %)	52 (41)	20 (31)	32 (52)	.032
Liver insufficiency (n, %)	19 (15)	2 (3)	17 (27)	<.001
IABP (n, %)	11 (9)	3 (3)	9 (15)	.041

Note: Data are presented as median and interquartile range 25th–75th or as mean and standard deviation.

Abbreviations: AMI, acute myocardial infarction; BMI, body mass index; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; CPR, cardiopulmonary resuscitation; HLP, hypolipoproteinaemia; HF, heart failure; IABP, intra-aortic balloon counterpulsation; INTERMACS, Interagency Registry of Mechanically Assisted Circulatory Support; PTCA, percutaneous transluminal coronary angioplasty.

achieving up to 3.5 and 5.5 L/min for Impella CP and Impella 5.0/5.5, respectively. The support level was adapted to each patient's demand with the aim of achieving an inotropic support-free status with a target MAP of 60–70 mmHg.

3 | RESULTS

Demographic characteristics are presented in Table 1.

The last available preimplantation haemodynamic characteristics and laboratory data not older than 24 h before Impella implantation are presented in Table 2. Complications under Impella support are listed in Table 3.

While CS among Impella CP patients was predominantly caused by AMI ($n = 50$; 78%), the main cause of CS for Impella 5.0/5.5 was acute on chronic heart failure ($n = 41$, 66%). In the Impella CP cohort 19 patients were weaned from support, one patient was bridged to durable MCS and 44 died on support. In the Impella 5.0/5.5 group, the pump was removed for myocardial recovery in 16 cases, durable LVADs were implanted in 24 cases, and 22 patients died on support. The median support time was 2.0 [0.0, 5.3] days in the CP group versus 8.5 [4.3, 15.8] days in the 5.0/5.5 group ($p < .001$). The 30-day survival was 31% and 58%, while the survival to home discharge was estimated as 30% and 35% in the unadjusted cohorts, respectively. After propensity score adjustment the survival was similar between the groups (OR: 1.23, 95% CI: [0.34–4.18], $p = .74$).

Due to the fact that both devices showed a similar 30-day survival, Kaplan-Meier estimates for the risk of 30-day mortality for

lactate ≥ 8 mmol/L (OR: 10.7, 95% CI: [3.45–47.34], $p < .001$) and preoperative CPR (OR: 13.2, 95% CI: [4.28–57.89], $p < .001$) were calculated for the combined cohort (Figures 1 and 2).⁹ Figure 3 illustrates the ROC curve for preoperative lactate for the 30-day mortality: the specificity and sensitivity for the cut-off of 8 mmol/L were 94.8% and 36.9%, respectively.

The median lactate level in patients surviving 24 h after implantation was similar between the groups: 1.67 mmol/L [1.11, 3.83] for Impella CP and 1.72 mmol/L [1.16, 3.16] for Impella 5.0/5.5 (adjusted $p = .91$) (Figures 4 and 5).

TABLE 3 Complications on support

Complication	Impella CP	Impella 5.0/5.5
Major bleeding/hematoma (n, %)	6 (9)	8 (13)
Hemolysis/pump thrombosis (n, %)	4 (6)	7 (11)
Vascular complications ^a (n, %)	7 (11)	1 (1.6)
Access site infection (n, %)	0 (0)	5 (8)
Device dislodgement (n, %)	1 (1.5)	3 (5)
VT/VF (n, %)	2 (3)	6 (10)

Note: Data presented as number of patients.

Abbreviation: VT/VF, ventricular tachycardia/flutter.

^aVascular complications include: extremity ischemia, plexus injury, vascular thromboembolism, arteriovenous fistula, vessel dissection.

TABLE 2 Preoperative laboratory parameters

Parameter	Total	Impella CP	Impella 5.0/5.5	p value
WBC (K/ μ l)	13.8 [10.6–17.4]	13.7 [10.6–18]	13.8 [10.3–17]	.98
CRP (mg/dl)	26.8 [6.2, 108]	9.3 [3.7, 23.4]	27.7 [5.55, 80.8]	.013
Total bilirubin (mg/dl)	0.87 [0.54, 1.3]	1.13 [0.7, 1.8]	0.74 [0.46, 1.4]	.013
INR	1.4 [1.1, 1.75]	1.42 [1.3, 1.9]	1.25 [1.12, 1.7]	.009
Creatinine (mg/dl)	1.4 [1.1, 1.8]	1.64 [1.2, 2.2]	1.46 [1.00, 1.8]	.081
Urea (mg/dl)	56 [40–82.5]	49 [45–88]	62 [44–90]	.16
Arterial pH*	7.33 $\pm$ 0.1	7.3 $\pm$ 0.12	7.35 $\pm$ 0.08	.14
Lactate (mmol/L)	3.1 [1.56, 6.11]	4.33 [2.11, 8.56]	2.44 [1.33, 5.22]	.003
CK (U/L)	258 [93–854]	274 [115–881]	229 [80–767]	.34
CK-MB (U/L)	40.4 [25.4, 134]	35 [22.8, 100.5]	59.4 [35.4, 178.2]	.056
GOT (U/L)	118 [58–858]	198 [72–730]	86 [36–1070]	.23
GGT (U/L)	106 [46–167]	99 [36–137]	117 [51–181]	.87
LDH (U/L)	654 [362–1348]	701 [398–1125]	606 [329–1497]	.97
MELD-XI score	12.6 [10.8, 16.2]	16.25 [11, 21]	14.1 [7.7, 19.1]	.217

Note: Data are presented as median and interquartile range 25th–75th or as mean and standard deviation.

Abbreviations: CK, creatine kinase; CK-MB, myocardial specific creatine kinase isoenzyme; CRP, C-reactive protein; GGT, gamma-glutamyl transferase; GOT, glutamic-oxaloacetic transaminase; INR, international normalized ratio; LDH, lactate dehydrogenase; MELD, model for End-Stage Liver Disease; WBC, white blood cell count.

FIGURE 1 Cumulative survival for preoperative lactate level

A comparison of the effects of Impella CP and Impella 5.0/5.5 on postoperative lactate levels 24 h after implantation revealed no significant difference in paired patient samples: -0.94 mmol/L $[-2.89, 0]$ for Impella CP and -0.22 mmol/L $[-1.58, 0.36]$ for Impella 5.0/5.5 (adjusted $p = .65$) (Figure 5).

4 | DISCUSSION

Our study demonstrated a similar effect of mechanical circulatory support with Impella CP and Impella 5.0/5.5 in patients with profound CS after adjusting for significant confounders. Based on the presented analysis we developed a new algorithm for selecting the optimal mechanical circulatory support for patients in severe CS.

The Impella CP and 5.0/5.5 are widely used microaxial tempMCS devices. The Impella CP is frequently used in protected PCI (percutaneous coronary intervention) and may be a risk modifier if used in acute CS.^{13,14} The Impella 5.0/5.5 devices were developed as an alternative to v-a ECLS for patients with left ventricular failure. Arguments in favor of these devices include a reduced need for anticoagulation and effective LV unloading as well as the possibility of active patient mobilization.¹⁵

Despite the fact that tempMCS is considered an effective CS therapy and is recommended in the European Society of Cardiology (ESC) guidelines, the scientific evidence remains scarce.^{16,17}

Although the Impella CP provides only partial circulatory support, our study demonstrated no difference for full haemodynamic support with Impella 5.0/5.5. A number of aspects such

FIGURE 2 Cumulative survival for CPR during or immediately before Impella implantation. CPR, cardiopulmonary resuscitation

as differences in patient populations and implantation techniques need to be discussed. The main advantage of the Impella CP system is the rapid percutaneous implantation, which can be performed even during ongoing CPR. The surgical placement of the Impella 5.0/5.5 is more challenging and time-consuming, but the device enables a longer support duration as well as patient mobilization. The Impella CP cohort in our study predominantly included patients with acute myocardial infarction CS (AMICS) who underwent PCI; the system was implanted in the cath lab to stabilize the patient. Patients supported with an Impella 5.0/5.5 were more likely to suffer from acute on chronic heart failure (ac-HF). This is reflected by the support duration among our patients: the duration of tempMCS therapy was four times longer in the

Impella 5.0/5.5 cohort than in the Impella CP group, highlighting not only different device-specific features such as the possibility of allowing a patient's ambulation, but also the indication for therapy. The therapeutic goal in AMICS patients differs considerably from ac-HF: while revascularisation mostly restores myocardial perfusion and leads to partial myocardial recovery, ac-HF patients require long-term support and are more likely to be bridged to a durable LVAD or heart transplantation.^{10,18,19} The large discrepancy between the 30-day survival and the survival to discharge in the Impella 5.0/5.5 cohort (58% vs. 35%) is explained by a high percentage of patients undergoing durable LVAD implantation, which results in a longer in-hospital stay, as well as a non-Impella-related morbidity and mortality. Therefore, in the

FIGURE 3 Receiver operating characteristic curve for preoperative lactate

context of ac-HF with a dilated left ventricle, full and lasting support with Impella 5.0/5.5 might be more beneficial, while AMICS patients might be adequately treated with immediate Impella CP support.

A recently published study by Kerami et al. demonstrated no significant survival benefit in CS patients supported with v-a ECLS compared to those on Impella CP and 5.0 support. At the same time, v-a ECLS patients showed a significantly higher prevalence of vascular complications.²⁰ Due to the small cohort and significant differences in patient demographics, no statistical analysis of complications under support was performed (Table 3). The complications on Impella CP or Impella 5.0/5.5 support depend

predominantly on the implantation technique: while the Impella CP is usually inserted percutaneously through the femoral artery, the Impella 5.0/5.5 requires surgical implantation through a vascular prosthesis sewed to the axillary artery. Therefore, the Impella CP might be associated with a higher risk of leg ischemia and vessel dissection, while Impella 5.0/5.5 implantation may lead to brachial plexus injury and access site infection as well as bleeding due to the vascular prosthesis remaining in the wound.

Despite the fact that our study demonstrated no reduction in the 30-day mortality in CS patients compared with the results of the SHOCK II trial, an indirect comparison between previous trials and our analysis is not appropriate.²¹ The mortality rates in Impella CP

FIGURE 4 Box plot diagrams for preoperative and postoperative lactate. IQR, interquartile range

and Impella 5.0/5.5 cohorts are expected to be high due to a high percentage of patients in advanced CS correlating with SCAI stages D and E, which are associated with an in-hospital mortality of 40% and 67%, respectively.^{2,22} Moreover, around 25% of our patients underwent preoperative CPR. Resuscitated patients exhibit inferior outcomes with in-hospital mortality rates of around 90%.²³ In our study the 30-day survival among patients after CPR was below 10%, while resuscitated patients who underwent ECLS implantation

demonstrated survival rates of over 30%.²⁴ This finding demonstrates the lack of effectiveness of Impella support alone in patients suffering cardiac arrest.

Blood lactate is a well-known parameter for CS evaluation and mirrors the level of end-organ ischemia.^{4,5,9} A comparison of lactate levels 24 h after implantation demonstrated that both systems can lead to restoration of organ perfusion and fulfill metabolic demands. The median level of lactate reduction was compared between paired

FIGURE 5 Box plot diagrams for postoperative lactate reduction. IQR, interquartile range

samples using a propensity score-adjusted analysis and revealed no significant difference in effect between the devices. Based on previous publications we evaluated the impact of preoperative lactate on the patients' outcomes.⁹ In our study we demonstrated that lactate levels above 8 mmol/L are associated with a significantly higher mortality rate in CS patients supported with Impella CP and Impella 5.0/5.5. The high specificity of almost 95% allows us to use this

parameter as a cut-off for the preoperative identification of patients who may require more advanced support than Impella CP or 5.0/5.5 alone.

Still, patients with high preoperative lactate levels or after CPR, as well as patients with biventricular failure or cardiorespiratory failure represent a clinical challenge and are associated with poor outcomes on Impella CP or 5.0/5.5 support.⁹ In this setting, a

Algorithm for temporary mechanical circulatory device selection in cardiogenic shock

FIGURE 6 Algorithm for optimal temporary mechanical circulatory support selection in cardiogenic shock. AVR, aortic valve replacement; CPR, cardiopulmonary resuscitation; LV, left ventricle; LVEF, left ventricular ejection fraction; ROSC, return of spontaneous circulation; RV, right ventricle; RVAD, right ventricular assist device; TR, tricuspid regurgitation; VIS, vasoactive inotropic score; VT/VF, ventricular tachycardia/fibrillation; VSD, ventricular septal defect; (v) v-a ECLS, (veno) veno-arterial extracorporeal life support

combination with v-a ECLS as ECMELLA concept might be the best treatment providing both biventricular unloading and blood oxygenation.^{8,25} The multicentre study by Schrage et al. demonstrated a significant improvement in survival in ECMELLA patients compared to isolated v-a ECLS support if LV unloading with Impella is initiated within 2 h after v-a ECLS implantation.²⁶ Further, the novel ECMELLA 2.0 technique, using a single arterial access for v-a ECLS cannulation and Impella implantation, may potentially reduce the incidence of vascular complications associated with conventional femoral cannulation, simultaneously allowing mobilization and early bedside de-escalation.²⁷

Based on the presented analysis and recently published studies^{9,19,26,27} we developed a new algorithm for selecting the optimal mechanical circulatory support for patients in severe CS (Figure 6).

5 | CONCLUSION

After adjusting for significant confounders, our study found no differences in the effect of mechanical circulatory support with Impella CP and Impella 5.0/5.5 in patients with profound CS. Whether the use of Impella CP as treatment for ac-HF differs from Impella 5.0/5.5 support in the setting of acute MI and vice-versa warrants further investigation. A prospective randomized trial is required to compare partial and full haemodynamic support outcomes on Impella CP and 5.0/5.5 devices. Patients supported during or after CPR or with lactate levels ≥ 8 mmol/L immediately before implantation showed a poor survival on both devices. A standardized operational protocol including preoperative criteria and therapy targets based on internal results has been adopted in our clinic.

6 | LIMITATIONS

This was a retrospective, non-randomized study involving small patient cohorts with different patient populations. Both cohorts differed significantly in age, etiology of heart failure, resuscitation time, as well as renal and liver function, which are important determinants for survival and might influence the results of this study.

ACKNOWLEDGMENT

Open access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTERESTS

E. Potapov reports institutional grants, fees and nonfinancial support from Abbott and Medtronic during the conduct of the study, as well as institutional grants, fees and nonfinancial support from Berlin Heart and Abiomed outside the submitted work. C. Tschöpe has received speaker fees and/or contributions to congresses from Abbott, Abiomed, AstraZeneca, Bayer, Berlin Chemie, Pfizer and Servier outside the submitted work.

ORCID

Gaik Nersesian <http://orcid.org/0000-0002-9524-7705>

Evgenij V. Potapov <http://orcid.org/0000-0002-9720-3175>

REFERENCES

- Kormos RL, Cowger J, Pagani FD, et al. The Society of Thoracic Surgeons Intermacs database annual report: evolving indications, outcomes, and scientific partnerships. *J Heart Lung Transplant*. 2019; 38:114-126.
- Potapov EV, Weng Y, Hausmann H, Kopitz M, Pasic M, Hetzer R. New approach in treatment of acute cardiogenic shock requiring mechanical circulatory support. *Ann Thorac Surg*. 2003;76: 2112-2114.
- DeWitt ES, Black KJ, Thiagarajan RR, et al. Effects of commonly used inotropes on myocardial function and oxygen consumption under constant ventricular loading conditions. *J Appl Physiol*. 1985; 2016(121):7-14.
- Mastroianni C, Bouabdallaoui N, Leprince P, Lebreton G. Short-term mechanical circulatory support with the Impella 5.0 device for cardiogenic shock at La Pitie-Salpetriere. *Eur Heart J Acute Cardiovasc Care*. 2017;6:87-92.
- Gaudard P, Mourad M, Eliet J, et al. Management and outcome of patients supported with Impella 5.0 for refractory cardiogenic shock. *Crit Care*. 2015;19:363.
- Shishehbor MH, Moazami N, Tong MZ, Unai S, Tang WH, Soltesz EG. Cardiogenic shock: from ECMO to Impella and beyond. *Cleve Clin J Med*. 2017;84:287-295.
- Blumenstein J, Leick J, Liebetrau C, et al. Extracorporeal life support in cardiovascular patients with observed refractory in-hospital cardiac arrest is associated with favourable short and long-term outcomes: a propensity-matched analysis. *Eur Heart J Acute Cardiovasc Care*. 2016;5:13-22.
- Pappalardo F, Schulte C, Pieri M, et al. Concomitant implantation of Impella(R) on top of veno-arterial extracorporeal membrane oxygenation may improve survival of patients with cardiogenic shock. *Eur J Heart Fail*. 2017;19:404-412.
- Nersesian G, Tschöpe C, Spillmann F, et al. Prediction of survival of patients in cardiogenic shock treated by surgically implanted Impella 5+ short-term left ventricular assist device. *Interact Cardiovasc Thorac Surg*. 2020;31:475-482.
- Goldstein DJ, Meyns B, Xie R, et al. Third annual report from the ISHLT Mechanically Assisted Circulatory Support Registry: a comparison of centrifugal and axial continuous-flow left ventricular assist devices. *J Heart Lung Transplant*. 2019;38:352-363.
- Critsinelis A, Kurihara C, Volkovich N, et al. Model of End-Stage Liver Disease-eXcluding International Normalized Ratio (MELD-XI) scoring system to predict outcomes in patients who undergo left ventricular assist device implantation. *Ann Thorac Surg*. 2018;106: 513-519.
- Boll G, Fischer A, Kapur NK, Salehi P. Right axillary artery conduit is a safe and reliable access for implantation of Impella 5.0 microaxial pump. *Ann Vasc Surg*. 2019;54:54-59.
- Schrage B, Ibrahim K, Loehn T, et al. Impella support for acute myocardial infarction complicated by cardiogenic shock. *Circulation*. 2019;139:1249-1258.
- Johannsen L, Mahabadi AA, Totzeck M, et al. Access site complications following Impella-supported high-risk percutaneous coronary interventions. *Sci Rep*. 2019;9:17844.
- Patel SM, Lipinski J, Al-Kindi SG, et al. Simultaneous venoarterial extracorporeal membrane oxygenation and percutaneous left ventricular decompression therapy with impella is associated with improved outcomes in refractory cardiogenic shock. *ASAIO J*. 2019;65: 21-28.

16. Ibanez B, James S, Agewall S, et al. ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: the Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC). *Eur Heart J*. 2017;2018(39):119-177.
17. Leor J, Goldbourt U, Reicher-Reiss H, Kaplinsky E, Behar S. Cardiogenic shock complicating acute myocardial infarction in patients without heart failure on admission: incidence, risk factors, and outcome. SPRINT Study Group. *Am J Med*. 1993;94:265-273.
18. Kirklin JK, Pagani FD, Kormos RL, et al. Eighth annual INTERMACS report: Special focus on framing the impact of adverse events. *J Heart Lung Transplant*. 2017;36:1080-1086.
19. Potapov EV, Antonides C, Crespo-Leiro MG, et al. EACTS expert consensus on long-term mechanical circulatory support. *Eur J Cardiothorac Surg*. 2019;2019(56):230-270.
20. Karami M, den Uil CA, Ouweneel DM, et al. Mechanical circulatory support in cardiogenic shock from acute myocardial infarction: Impella CP/5.0 versus ECMO. *Eur Heart J Acute Cardiovasc Care*. 2020;9:164-172.
21. Thiele H, Zeymer U, Neumann FJ, et al. Intraaortic balloon support for myocardial infarction with cardiogenic shock. *N Engl J Med*. 2012;367:1287-1296.
22. Jentzer JC, van Diepen S, Barsness GW, et al. Cardiogenic shock classification to predict mortality in the cardiac intensive care unit. *J Am Coll Cardiol*. 2019;74:2117-2128.
23. Bossaert LL, Perkins GD, Askitopoulou H, et al. European Resuscitation Council Guidelines for Resuscitation 2015: Section 11. The ethics of resuscitation and end-of-life decisions. *Resuscitation*. 95, 2015:302-311.
24. Shin TG, Choi JH, Jo IJ, et al. Extracorporeal cardiopulmonary resuscitation in patients with in-hospital cardiac arrest: a comparison with conventional cardiopulmonary resuscitation. *Crit Care Med*. 2011;39:1-7.
25. Tschöpe C, Van Linthout S, Klein O, et al. Mechanical unloading by fulminant myocarditis: LV-IMPELLA, ECMELLA, BI-PELLA, and PROPELLA concepts. *J Cardiovasc Transl Res*. 2019;12:116-123.
26. Schrage B, Becher PM, Bernhardt A, et al. Left Ventricular unloading is associated with lower mortality in cardiogenic shock patients treated with veno-arterial extracorporeal membrane oxygenation: results from an international, multicenter cohort study. *Circulation*. 2020;142:2095-2106.
27. Eulert-Grehn JJ, Starck C, Kempfert J, Falk V, Potapov E. ECMELLA 2.0 - Single arterial access technique for a staged approach in cardiogenic shock. *Ann Thorac Surg*. 2020;111:135.

How to cite this article: Nersesian G, Potapov EV, Nelki V, et al. Propensity score-based analysis of 30-day survival in cardiogenic shock patients supported with different microaxial left ventricular assist devices. *J Card Surg*. 2021;36:4141-4152. <https://doi.org/10.1111/jocs.15932>