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Original Article

Impact of Impella Support on Clinical Outcomes in Patients with Postcardiotomy Cardiogenic Shock

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Purpose: This study aimed to elucidate the strategy of an effective Impella support for better clinical outcomes in patients with a postcardiotomy cardiogenic shock (PCCS).
Methods: This single-center retrospective observational study enrolled 31 patients with PCCS undergoing an elective open-heart surgery followed by Impella support between November 2018 and February 2022 for further analysis.
Results: The preoperative Euroscore II and left ventricular (LV) ejection fraction were 9.1 ± 10.4 and 35.7% ± 12.6%, respectively. The in-hospital mortality rate was 51.6% (n = 16). In survivors (n = 15), the mean Impella support time was 6.9 ± 3.5 days. Patients were discharged on the postoperative day 24.9 ± 16.4. Regarding LV remodeling, LV end-diastolic diameter was significantly decreased after Impella support (59.2 ± 6.0 mm vs. 54.4 ± 4.7 mm, $p = 0.01$, preoperative vs. postoperative). In-hospital mortality rates were comparable with small (CP, n = 6) or large (5.0, n = 25) Impella systems (33.3% [n = 2] vs. 56.0% [n = 14], $p = 0.39$). However, a lower in-hospital mortality rate was observed in the group with early initiation (i.e., intraoperative) of Impella support (n = 14) than that with delayed Impella initiation (i.e., in the postoperative course) (n = 11) (28.6% [n = 4] vs. 90.9% [n = 10], $p = 0.004$).
Conclusions: Impella support contributes to LV remodeling in PCCS patients. In-hospital mortality was comparable in different Impella sizes and lower in early Impella initiation.

Keywords: cardiogenic shock, Impella, extracorporeal membrane oxygenation, postcardiotomy

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Introduction

Postoperative low cardiac output syndrome (LCOS) is a serious complication that may occur after an open-heart surgery.[1)] Optimizing conventional therapies, such as correction of volume overload and adequate catecholamine support, is the first choice for recovery. However, these conservative therapies are not always sufficient for a successful stabilization, particularly in high-risk patients with significantly impaired left ventricular (LV) function or LV dilatation. A therapeutic strategy for a mechanical circulatory support (MCS) is often required. Historically, a venoarterial extracorporeal membrane oxygenation therapy (va-ECMO) has been administered

as the first choice of MCS for bridge-to-decision or recovery.[2] However, this trend has changed since the approval of LV micro-axial pump systems (Impella; Abiomed Inc., Danvers, MA, USA).[3] Impella support is advantageous as it obtains an antegrade blood flow and LV venting to decrease the LV load. Moreover, the omission of an oxygenator may reduce the risk of thrombotic adverse events compared to va-ECMO. However, reports on the postcardiotomy cardiogenic shock (PCCS), here defined as postoperative LCOS with a need for MCS, are scarce concerning the efficacy of Impella utilization.[4–7] Furthermore, the ideal setting of Impella, that is, the employed pump size, timing of initiation, and combination with other modes of MCS has not been fully discussed. Thus, we analyzed our cohort to elucidate an ideal strategy of an effective Impella support for better clinical outcomes in patients with PCCS.

Materials and Methods

Ethical statement

The study was conducted following the Declaration of Helsinki, and the Ethics Committee of the Medical Faculty of Heinrich Heine University, Düsseldorf, has approved this study (ref. 2020-1173). The authors have had full access to the data and take full responsibility for the integrity of this manuscript. All authors have read and agreed to the content of this manuscript. The informed consent was waived by the ethics committee due to a simple retrospective study without interventions to patients.

Study design and data collection

In the observation period between November 2018 and February 2022, 145 consecutive Impella (n = 26 for Impella CP; n = 119 for Impella 5.0 or 5.5) were administered in our department, of which 63 Impella were for patients with PCCS. Among them, 32 cases of Impella were initiated in patients undergoing an emergent open-heart surgery. To avoid various biases depending on the patient's circumstances and to evaluate the effective use of Impella, we enrolled only those patients who underwent an elective open-heart surgery and experienced PCCS followed by Impella support in this study (n = 31) (**Supplementary Fig. 1**; all supplementary files are available online.). The perioperative patient status, clinical outcomes, and parameters of LV remodeling after Impella support were analyzed. Furthermore, two subcohort analyses were conducted to analyze the employed pump size and timing of initiation to identify the effective utilization of Impella. The primary endpoint of this study was the in-hospital mortality rate. To assess the number of inotropes and vasopressors, postoperative inotrope score (IS) and vasoactive inotropic score (VIS) were calculated for each case according to the following definition:

IS = dopamine dose (μg/kg/min) + dobutamine dose (μg/kg/min) + 100 × epinephrine dose (μg/kg/min).
VIS = IS + 10 × milrinone dose (μg/kg/min) + 10000 × vasopressin dose (units/kg/min) + 100 × norepinephrine dose (μg/kg/min).

All data, including the preoperative features, perioperative clinical course information, and postoperative results, were retrospectively collected from the hospital's data management and quality assurance system.

Indication, surgical procedure, and standard anticoagulation of Impella

Regarding the intraoperative Impella insertion strategy, inotropic support and volume supplementation were initially adopted to the respective transesophageal echocardiography (TEE) findings in all cases. Pulmonary catheter-based hemodynamic monitoring was regularly achieved as a consensus between the surgical and anesthesiologic teams. Then, va-ECMO was primarily implanted if the patient had an acute biventricular failure. On the other hand, Impella was primarily inserted for isolated LV failure with or without mitral valve regurgitation. Also, Impella was implanted for LV distention and pulmonary edema under va-ECMO support.

Our standard Impella implantation procedure depends on the size of the Impella. In our center, the Impella 5.0 Implantation was selected as the first-line therapy. In one patient, the Impella 5.0 system could not be implanted due to size limitations of native supra-aortic branches after the preparation for the Impella 5.0 implantation. Thus, Impella CP was introduced via a 10-mm vascular graft anastomosed to the right subclavian artery. On the other hand, in five patients, Impella CP was implanted percutaneously via the femoral artery because the patients were transferred for coronary catheterization to a cardiac catheter laboratory. In an interdisciplinary discussion, a percutaneous approach was favored to avoid further surgical procedures. Large Impella systems (5.0) were mainly implanted via a 10-mm vascular graft anastomosed in an end-to-side manner to the subclavian

Table 1 Baseline clinical characteristics

	All patients (n = 31)		All patients (n = 31)
Age (y)	65.8 ± 10.7	Size of Impella, n (%)	
Male sex, n (%)	26 (83.9)	CP	6 (19.4)
		5.0 or 5.5	25 (80.6)
BMI (kg/m²)	27.3 ± 4.5	Access of Impella 5+, n (%)	
BSA (m²)	2.0 ± 0.2	Axillary	25 (80.6)
Euroscore II	9.1 ± 10.4	Femoral	5 (16.1)
NYHA classification ≥III, n (%)	16 (51.6)	Central	1 (3.2)
Arterial hypertension, n (%)	23 (74.2)	Preoperative TTE findings	
Hyperlipidemia, n (%)	11 (35.5)	LVEF (%)	35.7 ± 12.6
Diabetes, n (%)	11 (35.5)	LVEDD (mm)	57.4 ± 8.0
Peripheral vascular disease, n (%)	3 (9.7)	RVEF (%)	51.8 ± 9.7
Arrhythmia, n (%)	14 (45.2)	TAPSE (mm)	18.8 ± 3.3
COPD, n (%)	6 (19.4)	RVEDD (mm)	33.6 ± 5.8
Nicotine abuse, n (%)	10 (32.3)	PAP (without CVP) (mmHg)	36.1 ± 10.7
Drug abuse, n (%)	1 (3.2)	Operations	
Dialysis, n (%)	0 (0.0)	CABG ± ventricular plasty, n (%)	18 (58.1)
History of PCI, n (%)	4 (12.9)	Valve operations, n (%)	5 (16.1)
Biventricular failure, n (%)	10 (32.3)	Valve operations + CABG, n (%)	6 (19.4)
CAD, n (%)	24 (77.4)	Other, n (%)	2 (6.5)

Data documented as n (%) or mean ± standard deviation. BMI: body mass index; BSA: body surface area; CABG: coronary artery bypass grafting; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; CVP: central venous pressure; LVEDD: left ventricular end-diastolic diameter; RVEF: right ventricular ejection fraction; LVEF: left ventricular ejection fraction; PAP: pulmonary artery pressure; RVEDD: right ventricular end-diastolic diameter; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; TAPSE: tricuspid annular plane systolic excursion; TTE: transthoracic echocardiogram

artery, while Impella CP was implanted percutaneously via the femoral artery. As a deviation from this standard, in one case where a large Impella could not be inserted axillary, e.g., because of a small subclavian artery, Impella CP was inserted via the axillary artery as an alternative (n = 1 case). An intraoperative Impella implantation for PCCS was performed while the patient was under cardiopulmonary bypass (CPB) support. After starting Impella support at the lowest level (P2), gradual weaning of CPB and concomitant increase in Impella support were achieved under continuous TEE-monitoring and close direct vision observation of cardiac filling and contractility. Impella insertion was performed according to the manufacturer's recommendation using exclusively the material provided in the Impella kit and with the use of fluoroscopy as well as TEE. Impella support was started at a low level (P2) and gradually increased under TEE control of right ventricular function and intravascular volume status.

Our protocol for the Impella management, including the postoperative anticoagulation strategy, has been fully described in our previous series.[8,9]

Statistical analysis

Statistical analyses were performed using SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). Descriptive and comparative (χ^2 test, Mann–Whitney U test) statistics were calculated using this program. However, for a minimum expected value of less than five, the Fisher's exact test was used instead of the χ^2-test. The data of the interval-scaled variables were expressed as mean ± standard deviation. Statistical significance was set at $p < 0.05$.

Results

Baseline clinical characteristics

Patient characteristics are shown in **Table 1**. Most patients were male (83.9%) with a mean age of 65.8 ± 10.7 years. With respect to the preoperative risk assessment, the preoperative Euroscore II and left ventricular ejection fraction (LVEF) were 9.1 ± 10.4 and 35.7 ± 12.6%, respectively. Notably, 11 patients suffered from PCCS following perioperative complications, such as graft occlusion after coronary artery bypass grafting and prolonged CPB time, whose Euroscore II was 3.5 ± 5.2.

However, Euroscore II in the remaining 20 patients was 12.2 ± 11.2 (**Supplementary Table 1**). Over half of the patients (51.6%) suffered from severely impaired functional status (New York Heart Association [NYHA] classification ≥III). The most frequent underlying disease was coronary artery disease ± valve disease (77.4%), followed by valve disease (16.1%). Regarding 5 patients who underwent valve operations, mitral valve operations were performed in 4 patients. In 2 patients, CPB time was prolonged due to conversion from mitral valve repair (MVr) to mitral valve replacement (MVR). In one other patient, ECMELLA was inserted due to LV rupture after MVR. In the remaining patient, we performed MVr + tricuspid annuloplasty (TAP) in the setting of elevated preoperative risk (NYHA III, Euroscore II 29.0, LVEF 30%). In case of a fifth patient with cardiac decompensation in NYHA III (Euroscore II 13.0) and LVEF 26% (left ventricular end-diastolic diameter [LVEDD] 76 mm), we performed aortic valve replacement + MVR + TAP, and implanted Impella 5.0 through aortic valve biological prostheses via the right subclavian artery such as a usual Impella implantation under the support of TEE and fluoroscopy.

At the time of Impella implantation, an increased lactate level (4.4 ± 5.1 mmol/dL) and a relatively higher dose of catecholamines were observed. ECMELLA, termed as simultaneous utilization of va-ECMO and Impella, was applied in 16 patients (51.6%), and an isolated use of Impella was performed in 15 patients (48.4%). Additional details are provided in **Supplementary Table 2**.

Clinical outcomes in all cohorts

The in-hospital mortality rate was 51.6% (n = 16). The most common reason for death was multiple organ failure (n = 14, 87.5%), followed by cerebrovascular accident (n = 1, 7.1%) and septic shock (n = 1, 7.1%). In survivors (n = 15), the mean Impella support time was 6.88 ± 3.50 days, and patients were discharged on postoperative day 24.9 ± 16.4 (**Table 2**). Regarding LV remodeling, LVEDD was significantly decreased after Impella support (59.2 ± 6.0 vs. 54.4 ± 4.7 mm, $p = 0.01$, preoperative vs. postoperative), while there was no change in LVEF at discharge when compared to preoperative values (36.6% ± 13.3 % vs. 37.8% ± 10.5%, $p = 0.39$) (**Fig. 1**).

Subcohort analyses

Employed pump size

Table 3 shows the comparative analysis of clinical outcomes between patients receiving small (CP, n = 6) or large Impella (5.0, n = 25). We observed a comparable in-hospital mortality rate between groups (33.3% [n = 2] vs. 56.0% [n = 14], $p = 0.39$, CP vs. 5.0) in our limited cohort size.

Table 2 Clinical outcomes of Impella support

	All patients (n = 31)
In-hospital mortality, n (%)	16 (51.6)
MOF	14 (87.5)
CVA	1 (7.1)
SS/SIRS	1 (7.1)
Impella support duration among survivors (days)	6.9 ± 3.5
Time of discharge from hospital among survivors (postoperative day)	24.9 ± 16.4

Data documented as n (%) or mean ± standard deviation. CVA: cerebral vascular accident; MOF: multiple organ failure; SIRS: systemic inflammatory response syndrome; SS: septic shock

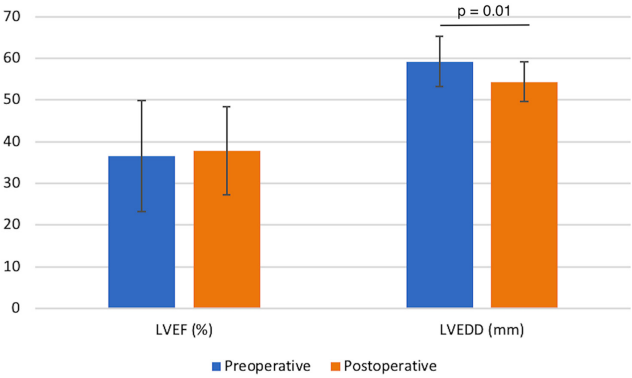

Fig. 1 The graphical explanation of LV remodeling after Impella support in survivors (n = 15). LV: left ventricular; EF: ejection fraction; LVEDD: left ventricular end-diastolic diameter

Timing of Impella initiation

Patients were allocated to two groups according to the timing of Impella initiation. There were 16 and 15 patients in the early (intraoperative; Impella supported OPCAB [n = 5].[10] Implantation before [n = 10] and after [n = 1] weaning from CPB) versus delayed Impella initiation (postoperative course) groups (2.0 ± 3.6 days after cardiac surgery), respectively. Further, we removed 6 patients who had early bypass failures after coronary artery bypass grafting to avoid selection bias. Then 25 patients (early [n = 14] vs. delayed [n = 11] Impella initiation) were analyzed. A lower in-hospital mortality rate was observed in the group of early initiation compared to that in the delayed Impella group (28.6% [n = 4] vs. 90.9% [n = 10], $p = 0.004$) (**Table 4**).

Table 3 Representative clinical features by comparative analysis between the Impella CP and 5.0

	CP (n = 6)	5.0 (n = 25)	*p*
Age (y)	64.1 ± 8.5	66.2 ± 11.3	0.48
Male sex, n (%)	5 (83.3)	21 (84.0)	1.00
BMI (kg/m²)	26.8 ± 4.5	27.4 ± 4.5	0.68
BSA (m²)	2.0 ± 0.2	2.0 ± 0.2	0.90
Lactate (mmol/dL)	4.8 ± 3.8	4.2 ± 5.4	0.54
IS	9.6 ± 5.3	10.6 ± 10.1	0.75
VIS	32.5 ± 27.8	37.3 ± 31.8	0.79
ECMELLA, n (%)	2 (33.3)	14 (56.0)	0.39
In-hospital mortality, n (%)	2 (33.3)	14 (56.0)	0.39

Data documented as n (%) or mean ± standard deviation. BMI: body mass index; BSA: body surface area; ECMELLA: venous-arterial extracorporeal membrane oxygenation + Impella; IS: inotrope score; VIS: vasoactive inotropic score

Table 4 Representative clinical features after comparative analysis according to the timing of Impella implantation

	Intraoperative (n = 14)	Postoperative (n = 11)	*p*
Age (y)	61.0 ± 6.2	70.2 ± 12.3	0.005
Male, n (%)	14 (100.0)	8 (72.7)	0.07
BMI (kg/m²)	27.9 ± 3.9	26.8 ± 5.2	0.69
BSA (m²)	2.1 ± 0.2	2.00 ± 0.2	0.32
Lactate (mmol/dL)	4.6 ± 6.7	4.1 ± 2.9	0.49
IS	9.6 ± 8.1	12.8 ± 12.0	0.64
VIS	32.5 ± 31.8	40.3 ± 33.3	0.51
ECMELLA, n (%)	5 (35.7)	8 (72.7)	0.12
In-hospital mortality, n (%)	4 (28.6)	10 (90.9)	0.004

Data documented as n (%) or mean ± standard deviation. BMI: body mass index; BSA: body surface area; ECMELLA: venous-arterial extracorporeal membrane oxygenation + Impella; IS: inotrope score; VIS: vasoactive inotropic score

Discussion

Our study describes clinical outcomes in patients with PCCS receiving LV venting by Impella with or without additional va-ECMO. This study's main findings suggest a favorable contribution of Impella support for LV remodeling with comparable in-hospital mortality rates between Impella CP and 5.0 and a lower in-hospital mortality rate by an early Impella initiation.

Refractory PCCS is clinically challenging to treat, and va-ECMO is often administered as the first choice MCS for respiratory and hemodynamic support. However, the clinical outcome of an isolated va-ECMO therapy in patients with PCCS remains unfavorable. Recently, Provaznik et al. reported that 39.1% of patients were dead on va-ECMO, and the overall survival rate was only 23.7% in the latter cohort.[11] Despite improved operative techniques and perioperative management, this outcome following isolated va-ECMO therapy for PCCS has not significantly improved over time as patients' backgrounds have also become more complicated.[12] Some studies have been conducted to overcome this issue to identify the risk factors for mortality in PCCS patients supported by va-ECMO. Ischemic heart disease and lactate levels before va-ECMO initiation have been suggested as independent risk factors for 90-day mortality.[13] Furthermore, reoperation and longer va-ECMO support duration were risk factors for weaning failure from va-ECMO. In contrast, older age, female sex, lower preoperative glomerular filtration rate, and longer va-ECMO support duration are predictors of in-hospital mortality after weaning from va-ECMO.[14,15] Regarding the timing of va-ECMO initiation for PCCS, Saha et al. concluded that early utilization of va-ECMO before

prolonged malperfusion contributes to improved clinical outcomes according to their risk analysis by a comparative study between two groups from different time periods.[16] This strategy may still be controversial because only some reports discuss this issue and their conclusions differ.[17,18] However, despite the early initiation of va-ECMO in the latest reports, mortality remains high at 43.3%.[16] Noteworthy, in-hospital survivors after va-ECMO support in the setting of PCCS may expect survival rates of 87% and 68.9% after 1 and 5 years, respectively, despite an in-hospital mortality of 51.7% in this group, suggesting that most patients will survive once they recover from initial PCCS.[19] Thus, developing a therapeutic strategy to improve the clinical outcome in the acute phase of PCCS is critical.[14]

For a long time, an intra-aortic balloon pump (IABP) was the premier device simultaneously inserted under va-ECMO support. A retrospective multicenter registry study has been conducted to determine whether simultaneous utilization of IABP would provide improved clinical outcomes with va-ECMO support. Similar to other single-center retrospective studies,[20] the latter study concluded that additional IABP support would not influence survival in patients with PCCS, although the rate of va-ECMO weaning may be improved.[21] Furthermore, LV distention worsened due to an increased afterload under va-ECMO support, which impaired LV recovery and clinical outcomes.[22] Therefore, the simultaneous use of LV venting, i.e., Impella support, has been expected to be an alternative to IABP since the early time point of its approval.

Previous studies have reported on clinical outcomes of solo Impella use in patients.[4–6] A multicenter prospective study of Impella 5.0/LD, termed RECOVER I, showed favorable clinical outcomes, with a 75% survival rate up to 1 year postoperatively in 16 patients.[5] Compared with the strict inclusion criteria of RECOVER I, David et al. performed a retrospective study of 29 all-comer patients with PCCS. Similarly, they found excellent clinical outcomes of solo Impella 5.0/LD for PCCS.[4] Regarding the analysis of employed pump size at solo Impella support, the choice of Impella size, CP or 5.0/5.5, showed no impact on the survival rate when a mixed cohort of CS patients was analyzed.[23] However, to date, the analysis of the clinical outcome of ECMELLA therapy in the setting of PCCS patients has not been well discussed. Hess et al. have reported on clinical outcomes of various temporary MCS modalities in the PCCS setting, analyzing 533 patients. However, no specific information regarding the clinical outcomes after ECMELLA support has been reported in detail in this study.[7]

The current study had some limitations. First, due to the limited cohort size and single-center retrospective study design, we were unable to perform subcohort analyses, e.g., comparative analysis with a focus on solo Impella vs. ECMELLA therapy. Further, long-term clinical outcomes should be analyzed to precisely interpret Impella efficacy in the PCCS setting. However, our retrospective observational study suggests that the early initiation of LV venting with Impella, even when a smaller system, such as CP, is utilized, will contribute to better clinical outcomes with or without the simultaneous use of va-ECMO for PCCS. In the future, this hypothesis should be analyzed in multicenter prospective comparative studies with larger cohorts.

Conclusion

The results herein suggest a good potential for an early initiation of LV venting with different sizes of Impella in combination with va-ECMO to improve clinical outcomes in patients with PCCS. We believe this study is the first step for further analyses of this issue.

Data Availability Statement

The data supporting this study's findings are available from the corresponding author upon reasonable request.

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Disclosure Statement

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