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Cardiac ECMO: changing role in times of Impella and ventricular assist devices?

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Abstract

Mortality in infarct-related as well as heart failure-associated cardiogenic shock remains high, reaching 40–50% depending on the etiology and severity of cardiogenic shock. Percutaneous active mechanical circulatory support devices including veno-arterial extracorporeal membrane oxygenation (VA-ECMO) and microaxial left ventricular mechanical circulatory support devices are rapidly evolving in their use. However, evidence of VA-ECMO therapy has only recently emerged and showed no benefit for mortality, with an associated higher complication rate. Evidence for microaxial left ventricular mechanical circulatory support devices such as the Impella pump (Abiomed, Danvers/MA, USA) is limited. The current article aims to give an overview of the basics of VA-ECMO therapy and microaxial left ventricular mechanical circulatory support devices, the current evidence, ongoing trials, patient selection, and potential complications. This article is freely available.

Keywords
Acute myocardial infarction · Cardiogenic shock · Extracorporeal membrane oxygenation · Extracorporeal life support · Mechanical circulatory support

Introduction

Cardiogenic shock (CS) remains the leading cause of death in hospitalized patients with acute myocardial infarction (AMI; [1]). Up to 10% of AMI patients develop CS, with left ventricular (LV) failure being the leading cause, followed by more rare causes such as right ventricular failure and mechanical complications of AMI [1]. Furthermore, there is increasing evidence of heart-failure-related CS [2]. Given the relatively heterogeneous nature of the causes of non-AMI-CS in comparison with AMI-CS—such as decompensated acute-on-chronic heart failure, valvular heart disease, acute myocarditis, Takotsubo syndrome, and arrhythmias—mortality rates are hardly comparable. Despite major advances in acute cardiac care, mortality remains particularly high for AMI-CS, reaching 40–50% during the first 30 days [1]. To date, revascularization of the culprit lesion is the only causal and effective evidence-based treatment for AMI-CS [1, 3]. The quest for further improvement of the treatment situation therefore continues, and especially the use of active mechanical circulatory support (MCS) devices is rapidly evolving.

Next to percutaneous LV assist devices such as microaxial MCS like Impella (Abiomed, Danvers, MA, USA), veno-arterial extracorporeal membrane oxygenation (VA-ECMO), also called "extracorporeal life support" (ECLS), is the major representative of MCS devices. Particularly since 2012, following the publication of

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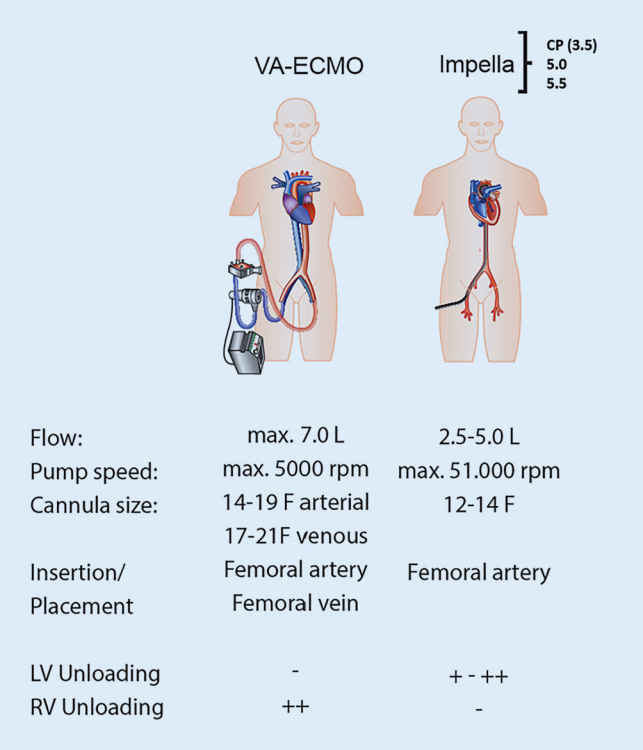

Fig. 1 ◀ Basic overview of veno-arterial extra-corporeal membrane oxygenation (*VA-ECMO*) and Impella.. *LV* left ventricular, *RV* right ventricular, *F* French, *L* liter, *rpm* rotation per minute. (Adapted from [1], reprint with permission, H. Thiele et al., all rights reserved)

the IABP-SHOCK II trial [4] results, the use of MCS devices of all forms has increased exponentially [5].

This increase in MCS use may also be associated with the upgrade in the recommendations for short-term percutaneous MCS in patients with CS from the previous class IIb–IIa recommendation with a level of evidence C in the recent European heart failure guidelines [6, 7].

Veno-arterial extracorporeal membrane oxygenation

Compared to other MCS, VA-ECMO is able to give full hemodynamic and respiratory support.

There has been an increase in VA-ECMO use by up to 30-fold since 2012 [8, 9], which has been accompanied by the facilitated availability, the new percutaneous techniques for insertion, and the development of smaller and easier-to-use systems.

Basic operating principle of VA-ECMO

The detailed structure of ECMO devices varies between manufacturers. Basically, the VA-ECMO system contains (1) an inflow cannula transporting blood from a central vein to the pump, (2) a centrifugal pump, (3) a membrane oxygenator capable of fully undertaking blood oxygenation and decarboxylation, (4) a blood warmer, and (5) an outflow cannula leading to a central artery (**Fig. 1**). The device is thus able to give hemodynamic support to both ventricles. Cannulation can be performed either centrally (via the right atrium and aorta or subclavian artery) or peripherally, which is today most frequently chosen in interventional cardiology. A major advantage of the peripheral access is the less invasive approach. This way, experienced centers without on-site cardiac surgery can now also perform VA-ECMO.

Evidence of VA-ECMO in CS

Despite the steadily increasing use, the available evidence for VA-ECMO in AMI-CS has been scant to date.

In the meantime, the results of several randomized controlled trials (RCTs) have been published. Among the larger trials, Ostadal et al. performed an RCT investigating early VA-ECMO implantation in 117 patients with multiple causes of CS, finding no difference in the primary composite endpoint of all-cause mortality, resuscitated cardiac arrest, or implementation of another circulatory assist device at 30 days (63.8% vs. 71.2%; hazard ratio: 0.72; 95% confidence interval [CI]: 0.46–1.12) or benefit in all-cause mortality between the VA-ECMO group and the control group [10]. Limitations of this ECMO-CS trial include a relevant rate of cross-over of 39%, making any interpretation difficult [10]. Our group recently provided the largest RCT to date comparing VA-ECMO against optimal medical therapy in 420 patients with AMI-CS and with planned early revascularization [11]. There was no significant difference in the 30-day mortality rate between the VA-ECMO group (47.8%) and the control group (49.0%; relative risk: 0.98; 95% CI: 0.80–1.19; $p = 0.81$; [11]).

Lastly, a recent individual patient-data meta-analysis incorporating results from the available four RCTs, including 567 patients with AMI-CS, showed no significant 30-day mortality benefit for patients receiving VA-ECMO (45.7%) in comparison with those receiving medical therapy alone (47.7%; odds ratio: 0.92; 95% CI: 0.66–1.29; [12]).

The question remains whether specific subgroups of patients in CS benefit from the VA-ECMO therapy provided more than others, as current guidelines do not reflect the patient selection to help guide VA-ECMO or other MCS initiation. Results from a subgroup analysis provided by the aforementioned individual patient-data meta-analysis, looking at age (> 65 vs. ≤ 65 years), sex (male vs. female), lactate levels (< vs. ≥ 5 mmol/L), prior cardiac arrest (yes vs. no), type, and location of infarction (ST-elevation myocardial infarction [STEMI] vs. non-STMI, anterior vs. other location) as well as post-percutaneous coronary intervention results (Thrombolysis in Myocardial Infarction flow of 0/1 vs. 2/3), provided no survival benefit in any of the subgroups analyzed [12]. Furthermore, whether clinical benefit might outweigh complications in certain subgroups not represented here remains to be addressed.

The timing of VA-ECMO therapy initiation may alter outcomes. Results stemming from an observational meta-analysis including 1352 patients undergoing MCS for AMI-CS (intra-aortic balloon pump [IABP]: $n = 956$; Impella: $n = 203$; VA-ECMO: $n = 193$), showed that initiation

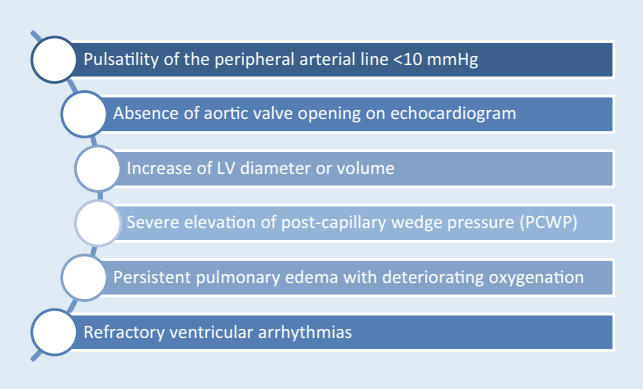

Fig. 2 ◀ Potential indications for left ventricular (*LV*) venting during veno-arterial extracorporeal membrane oxygenation therapy

of VA-ECMO prior to PCI significantly reduced the risk of mortality [13]. However, this hypothesis was refuted in the most recent ECLS-SHOCK trial: Despite an implementation rate for VA-ECMO of roughly 50% before or during revascularization, no clinical benefit of early VA-ECMO was observed [11]. This may call for future exploration of whether the timing of VA-ECMO initiation has an impact on clinical outcomes.

Complications of VA-ECMO

Another important aspect that must be reflected upon in the application of VA-ECMO in CS is safety. The most frequent complications include (1) bleeding, (2) clotting, (3) hemolysis, (4) limb ischemia, (5) afterload increase, and (6) harlequin syndrome, and (7) infections.

Bleeding

In the ECLS-SHOCK trial, the safety outcome comprised moderate or severe bleeding, which occurred with higher frequency in the VA-ECMO group (23.4%) versus the control group (9.6%; relative risk: 2.44; 95% CI: 1.50–3.95; [11]). Additionally, results from the recent meta-analysis have shown that moderate or severe bleeding occurred more often in the VA-ECMO group compared to the control group across all RCTs (odds ratio: 2.44; 95% CI: 1.56–3.84; [12]). Given that bleeding in patients with AMI-CS is known to be associated with worse outcomes [14], these results indicate that VA-ECMO may even be harming patients.

Peripheral ischemic complications

Furthermore, peripheral ischemic complications were observed more frequently in the VA-ECMO group than in the control group, despite a high rate of antegrade perfusion cannulae applied (95%; odds ratio: 3.53; 95% CI: 1.70–7.34; [11, 12]).

Afterload increase

It is known that VA-ECMO increases LV afterload, which may worsen the LV function, increase myocardial workload, and worsen lung edema. Eventual modifications to VA-ECMO therapy in order to enable LV unloading, for example, VA-ECMO + Impella (ECMELLA) or VA-ECMO + IABP, have been applied based on pathophysiological considerations.

Retrospective studies showed a survival benefit in patients with the Impella venting strategy compared to patients with VA-ECMO only. The largest propensity-matched study analyzed a total of 510 patients from four multinational tertiary care centers and showed an association with lower 30-day mortality for ECMELLA compared to VA-ECMO alone (hazard ratio: 0.79; 95% CI: 0.63–0.98; $p = 0.03$), despite a higher rate of severe bleeding (38.4% ECMELLA vs. 17.9% VA-ECMO alone), hemolysis (33.6% vs. 22.4%), interventions due to access-site-related ischemia (21.6% vs. 12.3%), and the need for renal replacement therapy (58.5% vs. 39.1%; [15]).

Unloading with Impella was rarely applied (6%) in the ECLS-SHOCK trial, which had predefined criteria for LV unloading [11]. Rates were slightly higher in the individual patient-data meta-analysis [12], however, leaving open questions regarding possible benefits of VA-ECMO plus routine LV unloading.

Animal and human in vivo studies showed a significantly decreased LV afterload of IABP in conjunction with VA-ECMO [16]. A meta-analysis including 14 previous retrospective studies with IABP as unloading strategy during VA-ECMO therapy showed a reduction of in-hospital mortality for patients with concomitant IABP treatment (odds ratio: 0.61; 95% CI: 0.46–0.81; $p < 0.001$), although a higher reduction in mortality for preload targeting venting strategies was displayed [17].

Further strategies to enhance LV unloading include a pigtail catheter from the LV to the venous ECMO cannula, surgical cannulation of the LV through the apex, or percutaneous balloon atrial septostomy and also transseptal cannula to the venous system. To date, only one RCT of LV unloading in VA-ECMO with a transseptal cannula has been published [18]. At 30 days, all-cause death had occurred in 27 (46.6%) patients in the early unloading group and 26 (44.8%) patients in the conventional group (hazard ratio: 1.02; 95% CI: 0.59–1.74; $p = 0.942$). However, crossover to rescue transseptal left atrial cannulation occurred in 29 patients (50%) in the conventional group.

Currently, it remains unclear whether a routine unloading strategy is superior to a selective unloading strategy based on typical criteria (see **Fig. 2**).

An RCT is currently being conducted on VA-ECMO plus Impella versus VA-ECMO alone: UNLOAD ECMO [NCT05577195].

VA-ECMO in mechanical complications of AMI

Patients with CS due to mechanical complications of AMI play a special role in VA-ECMO therapy and have been excluded from the ECLS-SHOCK trial and also from the individual patient data meta-analysis. In these patients, VA-ECMO might be used as an option for bridging to surgical or interventional therapy, which is often performed after an interval of 1 week or longer. Again, there is little evidence. In contrast to the European heart failure guidelines, guidelines in acute coronary syndromes

Table 1 Overview of propensity-matched studies (including > 100 patients) comparing Impella against control in cardiogenic shock[a]

Schrage et al. Circulation 2019; 139:1249–1258 [24]	
Dhruva et al. JAMA 2020; 323:734–745 [26]	
Amin et al. Circulation 2020; 141:273–284 [27]	
Kim et al. Cath Cardiovasc Interv 2022; 99:658–663 [25]	
Almarzooq et al. JAMA Cardiol 2023; epub [29]	
Miller et al. JAMA Intern Med 2022; 182:926–933 [28]	

[a]Icons indicate higher mortality, more bleeding, and/or costs with Impella versus control

recommend short-term mechanical circulatory support with a class IIb recommendation, level of evidence C for ventricular septal rupture and refractory CS [19]. A recent review addressed the use of active MCS in the setting of ventricular septal defects, which, however, is limited by a lack of any RCT [20].

Evidence for Impella

Since the decline in the use of IABP in CS following the downgrade of the guideline recommendation level [7], the use of Impella—similar to VA-ECMO—has steadily increased [5].

Basic operating principle of Impella

The Impella device is a percutaneous transvalvular microaxial flow pump based on the principle of a rotating Archimedes screw within a hollow pipe. It pumps blood from the LV to the ascending aorta by traversing the aortic valve. It is available as Impella CP®, which in contrast to the Impella Recover® LP 5.0 and 5.5 LD does not need a surgical cut down (**Fig. 1**).

RCT evidence

Despite this spike in implementation, data from RCTs on its benefit in clinical practice are limited to only two small RCTs. In an individual patient-data-based meta-analysis published in 2017 including four randomized studies comparing MCS (two Tandem Heart and two Impella) against IABP as a control [21], the ISAR-SHOCK and IMPRESS in Severe Shock trials compared clinical efficacy and safety endpoints of Impella versus IABP support [22, 23]. There was no difference in short-term mortality between the groups, although there was an increase in bleeding as well as a numerically higher incidence of limb ischemia following percutaneous MCS [21]. Failure to provide any mortality benefit across all randomized studies (relative risk: 1.01; 95% CI: 0.70–1.44; $p = 0.98$; $I^2 = 0\%$), while simultaneously showing increasing complications, introduces the question of whether increasing application of LV-MCS has the same negative impact as VA-ECMO.

Propensity-matched evidence

In general, propensity-matched analyses are considered the second-best evidence-generation if evidence from RCTs is limited. Although there are limitations to propensity-matched analyses, further evidence from mainly six larger (> 100 patients) studies has been published also scrutinizing the clinical benefit and associated adverse events of MCS by Impella, currently including > 100,000 patients [24–29]. In summary, again the results showed that Impella was associated with a similar or even higher in-hospital mortality compared to IABP and concomitantly increased the risk of major bleeding. The results of these propensity-matched analyses are displayed in **Table 1**.

With the limitations of propensity-matched analyses in mind, a recently published large observational study comparing 23,478 patients receiving Impella support versus alternative treatments (IABP and conservative therapy) in AMI-CS applied sophisticated statistical analysis. The aim was to assess the effectiveness of different baseline treatments, to determine the efficacy of Impella in treatments, and to analyze the impact of timing of implantation on outcomes; again, the findings were a higher or only neutral 30-day mortality rate associated with Impella support across multiple analyses [29].

Upcoming evidence

The aforementioned trials and propensity-matched analyses did not perform meaningful subgroup analyses, and it remains to be seen which patient in CS (if any) will prove to be the "optimal candidate" for Impella support. Evidence from larger RCTs such as the DanGer Shock trial (NCT01633502) is eagerly anticipated for presentation in spring 2024, but until then, evidence supporting a clear advantage of Impella support in CS remains non-existent. Another trial is still in the planning phase (RECOVER IV: NCT05506449) and results will unlikely be available within the next 5 years.

Future application of MCS in CS

There is no doubt that the management of CS patients beyond initial implantation of VA-ECMO or microaxial flow devices is demanding, binding a large number of intensive care unit resources and requiring experienced multidisciplinary teams. Considering the evidence on both the efficacy and safety, any intensivist or interventional cardiologist is forced not only to scrutinize whether MCS in CS provides clinical benefit, but to fundamentally reassess whether there is an overuse, potentially harming patients. The results from the most recent RCTs on VA-ECMO and also from the RCTs as well as propensity-matched Impella analyses clearly challenge a routine application of VA-ECMO or other MCS in AMI-CS. Historically, implementation of IABP support was a common approach for the stabilization of hemodynamics until RCTs assessing the efficacy of IABP implementation in patients with AMI-CS proved a lack of mortality benefit, necessitating a recommendation downgrade for routine use (class III, level of evidence B) [7].

Based on the current evidence, such a routine use of VA-ECMO or Impella is surely also not justified in AMI-CS. Considering the associated complications of these devices, even a recommendation for selected use as in the current guidelines probably needs to be reassessed. In the

end, two major questions remain: (1) Is there a subgroup of patients benefiting from MCS, considering that if existent, this subgroup probably will likely be very small (< 5–10% of all CS patients); and (2) Is there a mortality benefit at all for MCS?

To question the role of MCS in other clinical scenarios would be premature, yet for patients in AMI-CS, the existing evidence calls for revision. With in-hospital mortality rates stagnating in CS, resource requirements remaining high, and with the number of patients requiring hemodynamic stabilization growing steadily, finding the right therapy for the right patient to improve outcomes will become increasingly difficult. Until a better understanding of the clinical benefits, complications, and management of MCS in the setting of CS is provided by further RCTs in different CS scenarios such as heart-failure-related CS or post-cardiotomy CS [30], this resource-intensive therapy should probably by restricted to a very small group of patients at dedicated centers with foreseeable survival and reasonable long-term prognosis.

Practical conclusion

- **Based on the available evidence, mechanical circulatory support (MCS) did not show a mortality benefit in cardiogenic shock (CS).**
- **Furthermore, MCS increases complications such as bleeding or limb ischemia.**
- **This challenges current guideline recommendations with a class IIa, level of evidence C, in the European Society of Cardiology (ESC) heart failure guidelines and a class IIb, level of evidence C, in the ESC acute coronary syndrome guidelines.**
- **Based on evidence, MCS is probably overused.**
- **The selection of patients possibly having a benefit from MCS is most likely very small and future trials will have to define optimal patient selection.**

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Declarations

Conflict of interest. H. Thiele declares that he has no competing interests.

For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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Zusammenfassung

Kardiale ECMO: Bedeutungswechsel in Zeiten von Impella und ventrikulären Assistenzsystemen?

Die Mortalität sowohl bei infarktbedingtem als auch bei herzinsuffizienzbedingtem kardiogenem Schock bleibt mit 40–50 % hoch, je nach der Ätiologie und dem Schweregrad des kardiogenen Schocks. Zunehmend werden perkutane aktive mechanische Kreislaufunterstützungssysteme wie die venoarterielle extrakorporale Membranoxygenation (VA-ECMO) und mikroaxiale linksventrikuläre Unterstützungssysteme eingesetzt. Kürzlich publizierte Studien zur VA-ECMO haben allerdings keinen Vorteil in Bezug auf die Mortalität zeigen können bei gleichzeitig höherer Rate an auftretenden Komplikationen durch die VA-ECMO. Die Evidenz für mikroaxiale linksventrikuläre mechanische Unterstützungssysteme wie die Pumpe Impella (Fa. Abiomed, Danvers/MA, USA) ist sehr limitiert. Dieses aktuelle Review gibt einen Überblick über die Grundlagen der VA-ECMO-Therapie und mikroaxiale linksventrikuläre Unterstützungssysteme, aktuelle Evidenz, laufende Studien, Patientenselektion und potenzielle Komplikationen.

Schlüsselwörter
Akuter Myokardinfarkt · Kardiogener Schock · Extrakorporale Membranoxygenation · Extrakorporale lebenserhaltende Maßnahmen · Mechanische Kreislaufunterstützung