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Escalation and de-escalation of mechanical circulatory support in cardiogenic shock

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KEYWORDS

Mechanical circulatory support; Cardiogenic shock; Ventricular dysfunction; Unloading

Cardiogenic shock (CS) is a clinical entity that includes a wide spectrum of different scenarios. Mechanical circulatory support (MCS) plays a fundamental role in the contemporary treatment of CS, and *device selection* is a key element in determining optimal treatment in this complex population. Cardiac support with mechanical devices should allow reduction and complete weaning from inotropes. Persistence of elevated left ventricular (LV) filling pressures, pulmonary congestion, metabolic decompensation, and end-organ damage during current MCS are criteria for MCS escalation. Precise diagnosis of the underlying cause of right ventricular (RV) failure is fundamental for undertaking the correct escalation strategy. In the setting of both MCS escalation and de-escalation, it is important to select a strategy in relation to longterm perspectives (bridge-to-recovery, bridge-to-LV assist device, or bridge-to-heart transplantation). Small retrospective studies have demonstrated that the BiPella approach is feasible, reduces cardiac filling pressures and improves cardiac output across a range of causes of CS. Simultaneous LV and RV device implantation and lower RV afterload may be associated with better outcomes in biventricular CS, but prospective studies are still required.

Introduction

Cardiogenic shock (CS) is a clinical entity that includes a wide spectrum of different scenarios. Each patient presents with peculiar characteristics; the haemodynamic status rapidly changes, and survival in this complex population suffers from many variables. In this context, physicians should move towards *patient-centred care* with a specific patient-tailored approach.

Mechanical circulatory support (MCS) plays a fundamental role in the contemporary treatment of CS, and *device selection* is a key element in determining optimal treatment in this complex population. Contemporary critical care cardiology is moving towards the strategic use of different MCS devices, each characterized by specific nominal flow, potential complications, and expected durations. A simultaneous or consecutive combination of MCS, with correct timing and indications for implantation, escalation and de-escalation, customized for each patient and clinical scenario, can improve outcomes. *Table 1* summarizes haemodynamic effects of different MCS devices. Previous studies demonstrated a temporal relationship between the early use of percutaneous MCS and improved clinical outcomes in CS patients.¹⁻³

Likewise, a *multidisciplinary shock team* that merges different profiles of physicians provides a timely diagnosis and delivers the most appropriate care, reducing mortality

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	IABP	Impella		VA-ECMO
		2.5/CP	5.0/5.5	
LV flow	Ť	Ļ	\downarrow	Ļ
CO	Î	$\uparrow\uparrow$	$\uparrow\uparrow\uparrow$	$\uparrow\uparrow\uparrow$
MAP	Î	<u> </u>	<u> </u>	$\uparrow\uparrow$
PCWP	$= or \downarrow$	\downarrow	$\downarrow\downarrow$	$=$ or \uparrow
LV afterload	\downarrow	\downarrow	\downarrow	$\uparrow\uparrow\uparrow$
CVP	$= or \downarrow$	$=$ or \downarrow	$=$ or \downarrow	\downarrow
MVO ₂	\downarrow	$\downarrow\downarrow$	$\downarrow\downarrow$	$=$ or \uparrow
Coronary perfusion	Î	Î	Î	=
Peripheral tissue perfusion	Î	$\uparrow\uparrow$	$\uparrow\uparrow\uparrow$	$\uparrow\uparrow\uparrow$

 Table 1
 Haemodynamic effects of different mechanical circulatory support devices

↑, increased; ↓, reduced; CO, cardiac output; CVP, central venous pressure; IABP, intra-aortic balloon pump; LV, left ventricle; MAP, mean arterial pressure; MVO₂, myocardial oxygen consumption; PCWP, pulmonary capillary wedge pressure; VA-ECMO, venoarterial extracorporeal membrane oxygenation.

in CS.⁴ All patients with CS should be cared for in an intensive care unit with the availability of comprehensive haemodynamic invasive and non-invasive monitoring. The use of pulmonary artery catheters is strongly advised, not to support diagnosis but rather for advanced and comprehensive management. Continuous monitoring should focus on pump performance, cardiac output, blood pressure, cardiac filling pressures, and residual ejection of the left ventricle; these, together with shock parameters (lactates, metabolic acidosis, mixed venous oxygen saturation), should drive pump speed settings and detect haemodynamic status changes to guide prompt therapeutic action by physicians.

Escalation

Criteria and timing

As the dynamics of myocardial dysfunction is extremely complex in CS due to the interplay between primary and secondary myocardial dysfunction and, eventually, the occurrence of right ventricular (RV) failure, clinical sensitivity should trigger the need for escalation of MCS and selection of the most appropriate configuration (ECpella, BiPella, Impella 5.0/5.5, intrathoracic ventricular assist device). Aortic regurgitation should be approached at this stage.

First, adequate cardiac support with mechanical devices should allow reduction and complete weaning from inotropes. Despite the positive effect on myocardial contractility and temporary improvements in haemodynamics, administration of inotropes is burdened by increased myocardial oxygen consumption and arrhythmic risk, which might be associated with increased mortality.^{5,6} The current European Society of Cardiology (ESC) Guidelines on Acute and Chronic Heart Failure state that inotropes may be considered as initial therapy if there is a need to maintain systolic blood pressure in the presence of persistent hypoperfusion (Class IIb); however, rather than combining several inotropes, device therapy has to be considered when there is an inadequate response. 7

In the setting of CS with MCS, inotrope cut-off values are extremely valuable for clinical purposes: an inotropic score >20 on MCS should warrant evaluation for escalation.⁸ Similarly, the requirement of inotropes for more than 48 h should trigger a full haemodynamic re-evaluation.

Moreover, persistence of elevated left ventricular (LV) filling pressures, pulmonary congestion, metabolic decompensation, and end-organ damage during current MCS are criteria for MCS escalation.

Complete clinical, haemodynamic, and echocardiographic evaluations should be repeated at least every 24 h, and prompt MCS escalation should be considered when previous criteria are matched, given the evidence that the early use of appropriate MCS correlates with better clinical outcomes.¹⁻³

Uni/biventricular escalation

Multiparametric evaluation is fundamental to make the correct diagnosis of persistent CS (uni- or biventricular dys-function) and, consequently, to select the appropriate timing and MCS escalation strategy.

Univentricular dysfunction (LV dysfunction with preserved RV contractility) allows delayed or elective MCS escalation (a few to 24 h). Usually, first-line MCS in patients with residual LV function is represented by femoral percutaneous devices [Impella 2.5/CP or intra-aortic balloon pump (IABP)] due to their easier and faster implantation. When MCS escalation is needed, the transition from femoral percutaneous MCS (Impella 2.5/CP or IABP) to an upper body approach with a more powerful pump (Impella 5.0/ 5.5) is advised.

The Impella 5.0 device is designed for surgical transaxillary insertion (21-F pump motor with a 9-F catheter) and requires time to assess the technical feasibility (first, the sizing of axillary arteries) and to organize the availability of an operating room and vascular surgeons. The following items are considered absolute contraindications for performing the procedure: a vessel artery diameter <6 mm, the presence of heavy calcifications, obstruction or dissection, pre-existing upper extremity ischaemia, previous arterial axillary open cannulations or surgical access/scars, infraclavicular infections, arteriovenous fistulae for dialysis, and a patent internal mammary artery graft; the right axillary artery is preferably used, unless contraindicated due to anatomical, clinical, or pathological reasons.⁹

To date, there is no robust evidence regarding the Impella 5.0 device in randomized clinical trials. However, observational studies have demonstrated the efficacy and safety of this device in the context of CS. The main advantages of the Impella 5.0 device with respect to other percutaneous LV assist devices (LVADs) are as follows:

- Impella 5.5/5.0 provide full cardiac support, even in the absence of residual LV function, due to the nominal flow of 5.5 or 5 L/min respectively.
- Impella 5.0 is associated with a lower rate of vascular complications than other types of MCS such as venoarterial extracorporeal membrane oxygenation (VA-ECMO)¹⁰ and is characterized by greater stability of

the device position due to surgical insertion and fixation⁹; the patient can be safely mobilized out of bed, favouring the recovery of his or her general physical status.

 The longer duration of support allows time to evaluate myocardial recovery, and if not present, Impella 5.5 and 5.0 represent a valuable bridge-to-decision device towards long-term therapies such as LVAD implantation or heart transplantation (discussed in the next section long-term strategies).

Biventricular dysfunction with concomitant right heart failure development, on the contrary, requires urgent decision-making and MCS escalation (hours).

Precise diagnosis of the underlying cause of *RV failure* is fundamental for undertaking the correct escalation strategy. RV failure should be detected with both haemodynamic and echocardiographic monitoring, as increased central venous pressure [right atrial pressure (RAP) > 16 mmHg] and reduced RV function echocardiographic (tricuspid annular plane systolic excursion and tissue Doppler S' wave) and/or invasive (low pulmonary artery pulsatility index < 1.85 or high RAP/pulmonary capillary wedge pressure ratio > 0.59) parameters.¹¹

First, the most common differential diagnosis of RV failure must be ruled out: pulmonary complications (pneumothorax, pleural effusion, atelectasis), pulmonary embolism, RV outflow tamponade, LV pump displacement or suction, and the persistence of metabolic decompensation (acidosis, hypercapnia).

Once these mechanisms are excluded, to select the correct MCS escalation strategy, the definition of the underlying cause of RV failure is mandatory: haemodynamic monitoring is necessary for differential diagnosis between primary and secondary RV failure.

Secondary RV failure is characterized by increased LV filling pressure and requires LV MCS escalation with upgrade of LV unloading by increasing pump flow or with a more powerful pump (see univentricular dysfunction). Instead, *primary RV failure* is characterized by normal LV filling pressure values and requires escalation with RV MCS support. The biventricular MCS strategies are VA-ECMO support, the addition of an RV assist device with ProtekDuo cannula and BiPELLA support.¹²

When upgrading with VA-ECMO, concomitant LV unloading with a transaortic pump (ECpella strategy) is strongly recommended. Previous studies demonstrated a reduction in mortality with LV unloading with Impella while on VA-ECMO support.^{3,13,14}

A second more recent approach for biventricular dysfunction is represented by the concomitant use of LV Impella (CP/5.0/5.5) and RV Impella (RP).¹⁵ Small retrospective studies have demonstrated that the BiPella approach is feasible, reduces cardiac filling pressures and improves cardiac output across a range of causes of CS. Simultaneous LV and RV device implantation and lower RV afterload may be associated with better outcomes in biventricular CS, but prospective studies are still required¹⁶⁻¹⁸ (*Figure 1*).

De-escalation

VA-ECMO is still considered the standard of MCS in patients with profound CS (INTERMACS 1 patient) or refractory cardiac arrest (eCPR).

Despite its efficacy as rescue therapy in refractory CS patients, VA-ECMO support is associated with a substantial burden of complications, and these patients often require definitive heart replacement therapy after resuscitation due to the lack of myocardial recovery. This is further evidenced by the fact that ECMO provides full haemodynamic support for patients but increases the afterload to the left ventricle with end-diastolic pressure and volume augmentation, jeopardizing myocardial recovery.¹⁹ Furthermore, previous studies have reported that in the setting of acute de novo CS treated with VA-ECMO, the duration of VA-ECMO is strongly correlated with the risk of hospital mortality.²⁰

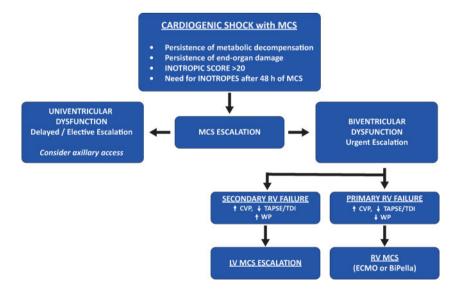


Figure 1 Mechanical circulatory support escalation. CVP, central venous pressure; ECMO, extracorporeal membrane oxygenation; LV, left ventricular; RV, right ventricular; TAPSE, tricuspid annular plane systolic excursion; WP, wedge pressure.

From this perspective, the need for a device that allows for rapid weaning from ECMO and a longer period of support as a bridge to recovery or heart replacement therapies should be acknowledged.

Minimally invasive LVAD therapy using the Impella 5.0 or 5.5 device via axillary surgical access has been demonstrated to be the most attractive strategy for MCS deescalation in this population. The rationale of this two-step strategy is to overcome the resuscitation phase and optimize the haemodynamic status with a short VA-ECMO support period and then to implant the Impella 5.0 device for ECMO weaning and mid-term support.

Criteria and timing

At the time of implantation, VA-ECMO flow parameters must be set with the primary goal of reverting circulatory and metabolic alterations as measured by clinical and haemodynamic parameters, and LV unloading with percutaneous MCS must be strategically pursued to prevent the complications associated with LV stagnation in akinetic LV ventricles and to facilitate myocardial salvage.

Once haemodynamic and metabolic stabilization is achieved (significant reduction in serum lactates and end-organ damage), due to the lack of consistent myocardial recovery, Impella 5.0 should be implanted and set at maximum flow. In the next hours, VA-ECMO flow must be progressively decreased. Invasive haemodynamic monitoring and echocardiographic parameters must drive ECMO de-escalation and appropriate ECMO removal timing.

In a recent case series, we first showed that all nine enrolled patients could be effectively weaned from VA-ECMO with axillary Impella 5.0 after a median time of 22 h after implantation²¹ (*Figure 2*).

Special scenarios

Special scenarios occur when the patient presents contraindications to Impella device, like intraventricular thrombus, severe aortic disease or mechanical aortic prosthesis. Alternative therapeutic strategies with different devices must be considered:

- TandemHeart (CardiacAssist, Inc., Pittsburgh, USA). In the presence of intraventricular thrombus or mechanical aortic prosthesis, the TandemHeart device should be considered for both escalation therapy and weaning from VA-ECMO support. TandemHeart requires a venous cannula to be advanced in the left atrium after transeptal puncture and provides left chambers unloading; oxygenated blood is drawn from the left atrium and returned via an external centrifugal pump and an arterial cannula in the femoral artery to the lower abdominal aorta. However, TandemHeart requires fluoroscopic guidance for transseptal puncture, making it less adequate for the urgent setting.²²
- Paracorporeal LVAD/biventricular assist device (BiVAD). In VA-ECMO supported patients with persistent CS and concomitant severe aortic valve regurgitation, aortic valve replacement with a tissue valve combined with paracorporeal LVAD/BiVAD positionement should be considered in order to effectively wean the patient from VA-ECMO support.

Long-term strategies

In the setting of both MCS escalation and de-escalation, it is important to select a strategy in relation to longterm perspectives (bridge-to-recovery, bridge-to-LVAD, or bridge-to-heart transplantation).

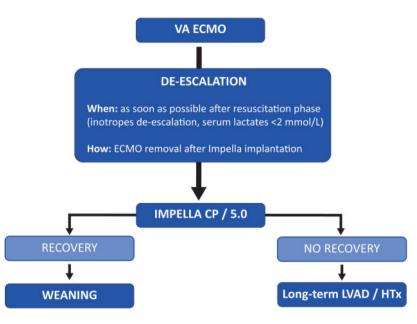


Figure 2. Mechanical circulatory support de-escalation. HTx, heart transplantation; LVAD, left ventricular assist device; VA-ECMO, venoarterial extracorporeal membrane oxygenation.

Axillary Impe	ella 5.0/5.5
Strategies	 Bridge-to-recovery Bridge-to-LVAD Bridge-to-heart transplantation
Advantages	 Resolution of intercurrent clinical conditions (infection, end-organ damage) Early extubation and oral feeding Early mobilization Neurological evaluation and recovery Patient consent Longer mechanical support (bridge-to- recovery) Evaluation and optimization of the right ven- tricle (bridge-to-LVAD) Healing of myocardial tissue at the apical site (bridge-to-LVAD) Evaluation of pulmonary artery pressure and PVR (bridge-to-heart transplantation)

In this setting, MCS with the most powerful pump, Impella 5.0/5.5, with an upper body approach is advised. The main therapeutic advantages of the Impella 5.0/5.5device with respect to other percutaneous LVADs are as follows (*Table 2*):

- Resolution of intercurrent clinical conditions. In the complex and frail population affected by CS, the longer duration of MCS allows the resolution of intercurrent clinical conditions such as infection and organ damage.
- Early extubation and mobilization. Axillary support allows patient extubation, oral feeding and mobilization with physical therapy while receiving maximal haemodynamic support, which has been demonstrated to aid weaning from temporary MCS and bridge-to-LVAD and is associated with a better prognosis at discharge.²³
- Bridge-to-long-term therapies. The implantation of a full support midterm LVAD (Impella 5.0/5.5) allows the evaluation of RV function and pulmonary vascular resistance; this is particularly valuable in light of the dismal results of direct INTERMACS 1 implantation of LVAD or heart transplantation. Previous studies have shown that VA-ECMO support before LVAD implantation is a strong independent predictor of post-LVAD RV failure^{24,25}; bridging with IMPELLA 5.0 allows, thorough evaluation and optimization of the right ventricle, a real 'LVAD test' in terms of haemodynamics, thus improving outcomes after long-term LVAD implantation.²¹
- Neurological evaluation and patient consent: an important percentage of these subjects experience cardiac arrest and subsequent anoxic brain injury. Indeed, Bernhardt *et al.*²⁶ demonstrated that Impella

5.0 support represented a valuable bridge-to-decision option in patients treated with ECMO, allowing neurological recovery in approximately two-thirds of patients. Furthermore, during this period, given the abrupt onset of the disease, patients and relatives can be adequately informed about the therapeutic program and provide their consent, and they have time to realize and accept the new condition.

Outlook

For historical reasons, escalating therapy by adding mechanical devices in CS for the condition of insufficient response to inotropic and vasopressor support is a frequent approach chosen.

The absence of randomized or cohort-based evidence that any (beta-adrenergic or phosphodiesterase inhibiting) inotrope saves lives in CS after half a century of their use raised concerns regarding this approach. Potentially, such a stepwise approach only prolongs the duration of cardiac and multiorgan damage in CS.

As the core of CS is severe organ damage to the heart and as heart recovery is the key to long-term survival, the more rational approach of avoiding any pharmacological or mechanical stress to the diseased heart by primary implantation of a mechanical support device and full resting of the heart pharmacologically and mechanical unloading merits strong scrutiny in the future and is the objective of ongoing clinical trials. While IABP is only marginally effective haemodynamically and ECMO is haemodynamically powerful but has a large complication rate and a limited cardiac recovery rate in CS for reasons discussed in a companion paper in this supplement, the Impella family, characterized by being haemodynamically powerful but associated with a low rate of complications, has opened the door to a potentially new era in CS therapy.

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