Mechanical circulatory support for patients with cardiogenic shock☆

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A R T I C L E   I N F O

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A B S T R A C T

Mortality from cardiogenic shock primarily in the setting of acute myocardial infarction is unchanged at approximately 50%, despite the availability of advanced ventricular assist devices. A description of currently available mechanical circulatory support (MCS) devices is provided with a suggested algorithm for therapy with different MCS devices in cardiogenic shock. In order to increase survival placement of these devices in cardiogenic shock prior to percutaneous coronary intervention of the infarct related artery is strongly recommended.

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Introduction

Acute myocardial infarction complicated by cardiogenic shock has a high mortality even with advances in mechanical circulatory support (MCS) and availability of these percutaneous left ventricular assist devices. Despite the advantages of these devices, usage is low [1]. A thorough knowledge of the indications, placement, and management of these devices is critical to improve outcomes.

Treatment goals

Cardiogenic Shock (CS) is a catastrophic event with a 50% mortality [2,3], despite current treatment strategies. Primary left ventricular (LV) pump failure reduces flow of oxygenated blood to vital organs and the reduced tissue perfusion results in metabolic acidosis, perpetuating the shock pathway [4].

The majority of cases of CS are due to acute myocardial infarction (AMICS) [5]. Hence goals of therapy should include:

1. Improved cardiac output and ventricular unloading utilizing mechanical circulatory support (MCS) [6].
2. Rapid reperfusion by restoring flow in the infarct related artery by primary percutaneous coronary intervention (PPCI).

MCS devices and their relationship to the pressure volume loop

Fundamental to the understanding of MCS is the pressure volume loop [7]. In Fig. 1, the pressure volume loop shifts to the right in CS with a drop in systemic pressures, reduction in stroke volume (the area under the curve, hence cardiac output) and increase in the LV volume and filling pressures.

In Fig. 2, [7] the effects of MCS devices are illustrated in grey against a backdrop of a normal pressure volume loop. Fig. 3 demonstrates the effect on continuous LV pressure volume loops when these devices are activated.

1. *Intraaortic balloon pump (IABP)* Fig. 4 [8] inflates during diastole and deflates during systole, increasing diastolic pressure (augmented pressure), improving coronary perfusion and decreasing impedance to systolic ejection with the net effect of increasing stroke volume and mean aortic pressure. As a result, there is a reduction in systolic pressure and ventricular afterload. The IABP is the most common LV support device used in most cardiac catheterization laboratories. It can be rapidly placed via femoral access and is contraindicated in severe peripheral vascular disease and aortic insufficiency. It provides insufficient support [9] between 0.5 and 1 l/min.

2. *Extracorporeal membrane oxygenators (ECMO)* such as the venoarterial ECMO (VA-ECMO) (Fig. 5) removes blood from the venous system to the arterial circulation via an oxygenator, increasing mean arterial pressures and afterload. Consequently, LV pressures are increased, and the LV frequently may require unloading or 'venting' due to an increased LV volume. Large bore arterial and venous cannulation is required. VA-ECMO does not unload the LV but can provide oxygenated blood flow up to 5 l/min [10]. There is increased risk of limb ischemia and there are options for both surgical and percutaneous access. Due to higher complication rates with use of this device, careful evaluation of the patient before device placement is mandatory [11].
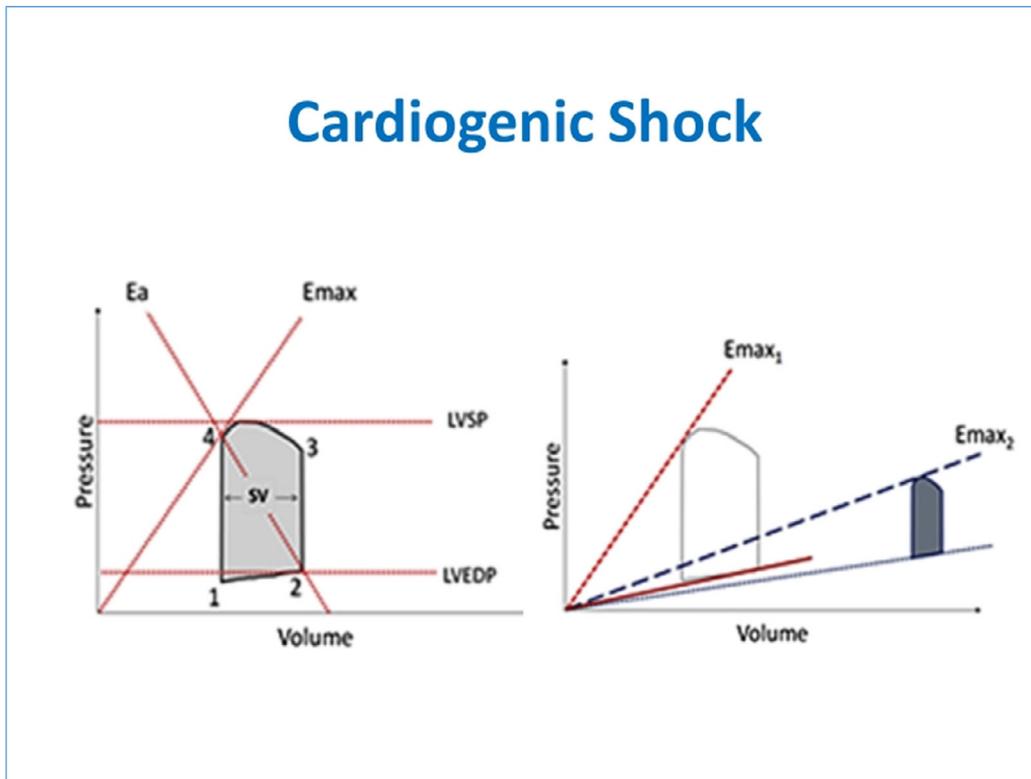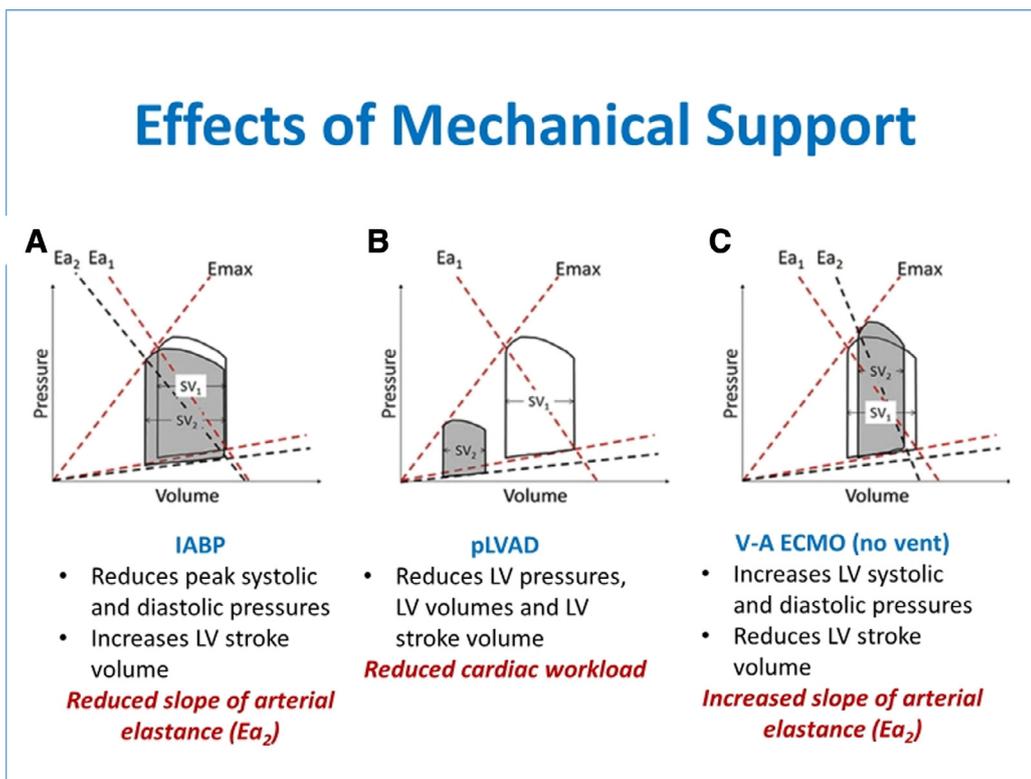
Fig. 1. The normal pressure volume loop and a shift to the right in cardiogenic shock with increase in left ventricular volumes and pressure and a decrease in systolic LV pressures. (From ref. no. [7].)

Fig. 2. Effects of different ventricular assist devices (VAD) on the pressure volume loop. Note that the Impella unloads the left ventricle and shifts the pressure volume loop to the left (B)
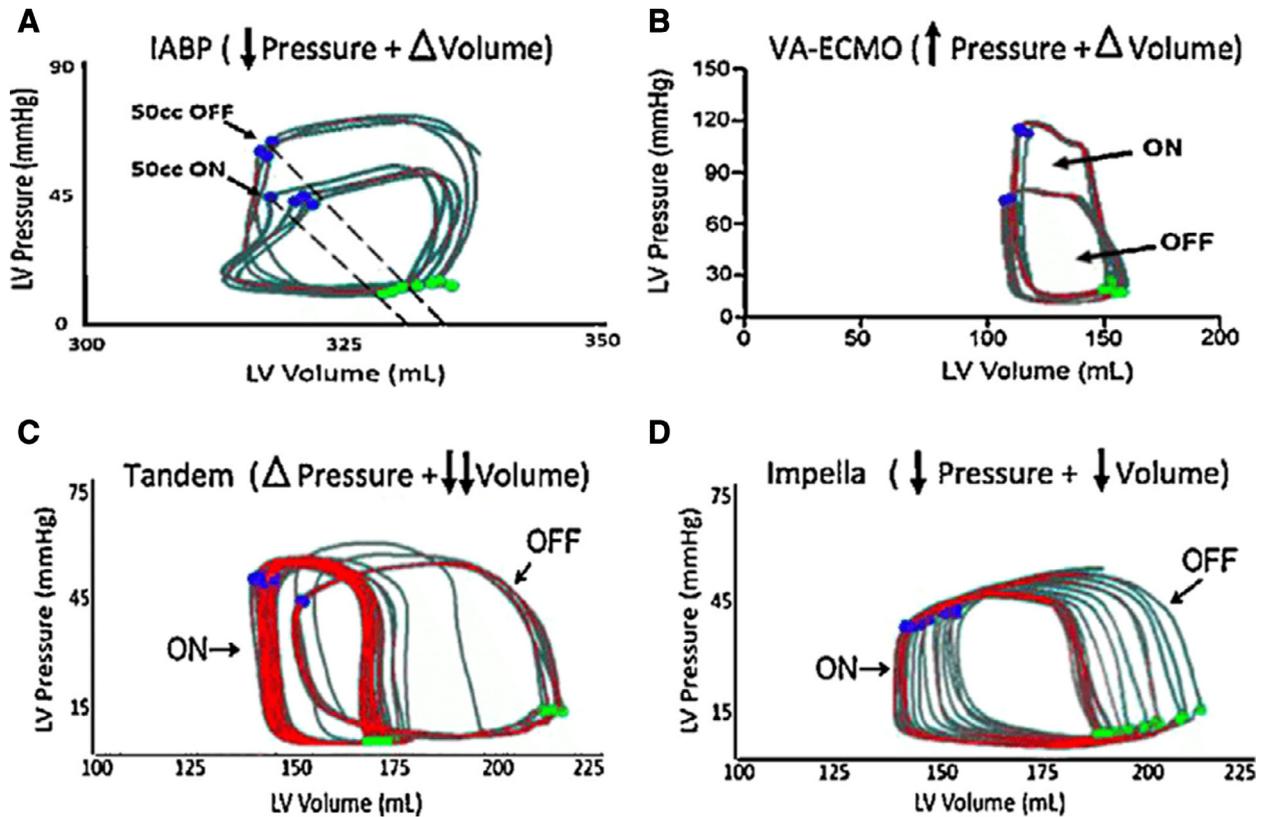
Fig. 3. Pressure volume loops demonstrating hemodynamic effects of acute mechanical circulatory support devices on the left ventricle. (A) IABP reduces LV afterload but does not unload the ventricle. (B) VA-ECMO increases the wall stress and afterload of the LV and does not unload without an LV vent (C) The LA-FA bypass, or TandemHeart device, unloads the left atrium, thereby decreasing LV end-diastolic volumes. (D) The Impella device unloads the LV by decreasing end-diastolic volume and pressure. (From M. Esposito, et al., The role of acute circulatory support in ST-segment elevation myocardial infarction complicated by cardiogenic shock, Indian Heart J (2017) (in Press).

3. *TandemHeart* (Fig. 6) is an extra-corporeal continuous flow centrifugal flow pump. A trans-septal canula removes oxygenated blood from the left atrium to an arterial outflow cannula in the femoral artery (FA). The device requires large bore cannulation and expertise in trans-septal puncture. LV volume is reduced and the increase in aortic pressures results in increased afterload that may affect LV unloading. Maximal support is 5 l/min. Hemorrhagic complications and risk of limb ischemia are similar to ECMO.

4. *Impella* (Fig. 7): (Abiomed, Danvers, Massachusetts) family of devices, are axial pumps that are placed in the left ventricle It is a miniaturized circulating impeller working on the Archimedes principle of removing blood continuously from the left ventricle across the aortic valve. LV pressures and volumes are reduced with decreased LV stroke work and myocardial oxygen demand. It can be rapidly deployed in the cardiac catheterization laboratory by the femoral access or alternatively via percutaneous axillary [12] or transcaval access [13]. It cannot be used in patients with aortic stenosis, mechanical aortic valve or in the presence of LV thrombus. It is the only device that directly unloads the left ventricle [14,15]. The Impella CP can provide maximal support of 3.5 l/min and the 5.0 Impella, 5 l/min. While sheath sizes are smaller than ECMO or TandemHeart, limb ischemia, hemorrhage or hemolysis can increase management complexity.

Right heart catheterization

Right heart catheterization is essential in managing these patients. It is generally performed after placement of MCS and reperfusion therapy with PPCI [16]. Recent data highlight the importance of calculating cardiac power output (CPO) [17] and pulmonary artery pulsatility index (PAPi) [18,19]. These two indices [20] may be superior to mixed venous oxygen saturation (MVO2) or cardiac index (CI) in the management of these critically ill patients and predicting mortality:

- CPO in watts:

$$\frac{\text{Mean arterial pressure (MAP) X cardiac output}}{451}$$

A CPO of <0.6 W suggests severe LV dysfunction
- PAPi:

$$\frac{\text{systolic pulmonary artery pressure} - \text{diastolic pulmonary artery pressure}}{\text{mean RA pressure}}$$

A PAPi of <1.0 suggests severe right ventricular dysfunction

Evidence for benefit of MCS

In general, MCS devices vary in their level of hemodynamic support. They reduce myocardial oxygen demand, unload the LV via reduced preload, reduce pulmonary capillary wedge pressure and augment coronary perfusion [6].

Intraortic Balloon Pump (IABP)

Mechanism	Pneumatic
Device Configuration	Descending aorta via femoral artery
Maximal Support	0.5 – 1 LPM
LV Unloading	+
Implant time, complexity	+
Management Complexity	+
Limb Ischemia Risk	+
Hemolysis Risk	0
Hemorrhage Risk	+
Contraindications	AI, severe PAD, Aortic disease

Fig. 4. Overview of the intaaortic balloon pump (IABP).

VENO ARTERIAL EXTRA CORPOREAL MEMBRANE OXYGENATOR (VA ECMO)

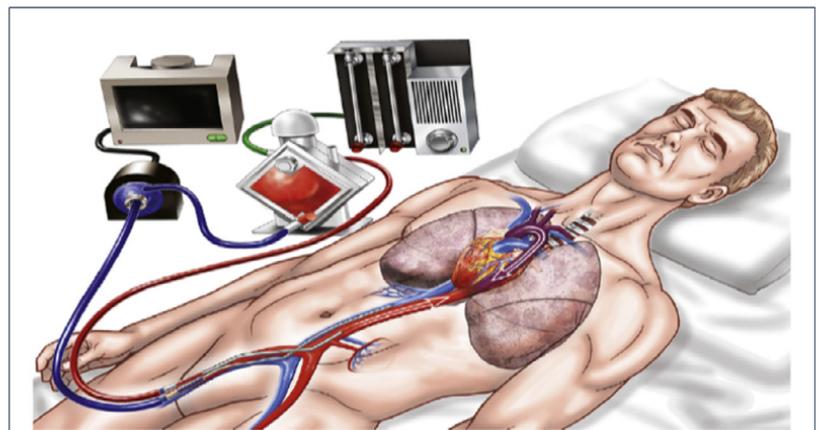| Mechanism	Centrifugal
Device Configuration	Inflow: Femoral vein/IVC Outflow: Femoral artery Pump: Extracorporeal
Maximal Support	>5 LPM
LV Unloading	0
Implant time, complexity	++
Management Complexity	+++
Limb Ischemia Risk	+++
Hemolysis Risk	++
Hemorrhage Risk	++++
Contraindications	AI, severe PAD, contraindication to AC

Fig. 5. Overview of veno arterial ECMO.

Tandem Heart

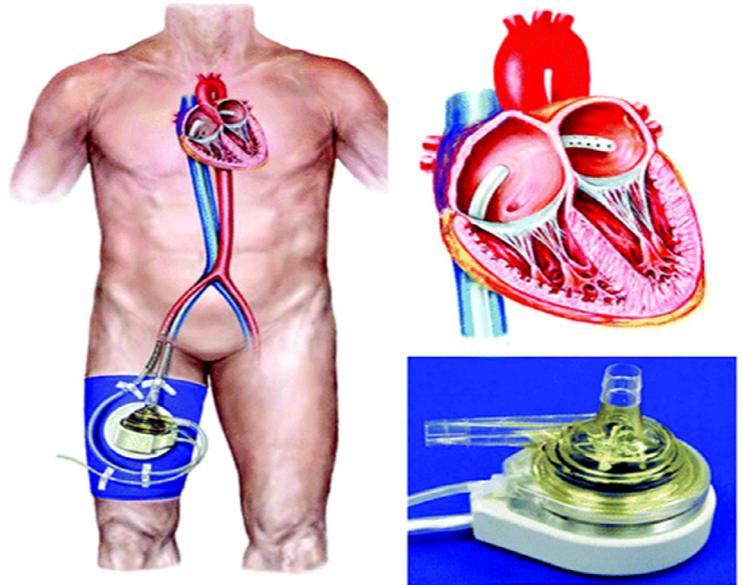| Mechanism	Centrifugal
Device Configuration	Inflow: LA via transeptal Outflow: Femoral artery Pump: Paracorporeal
Maximal Support	Up to 5 LPM
LV Unloading	++
Implant time, complexity	+++
Management Complexity	+++
Limb Ischemia Risk	+++
Hemolysis Risk	++
Hemorrhage Risk	+++
Contraindications	AI, severe PAD, contraindication to AC, LA thrombus

Fig. 6. Overview of TandemHeart.

IMPELLA

Mechanism	Axial
Device Configuration	Inflow: LV Outflow: Aorta Pump: Transaortic
Maximal Support	1-5 LPM (Impella 2.5, Impella CP, Impella 5)
LV Unloading	++ - +++
Implant time, complexity	++ - +++
Management Complexity	++
Limb Ischemia Risk	++
Hemolysis Risk	++
Hemorrhage Risk	++
Contraindications	LV thrombus, mechanical aortic valve, severe AS/AI, contraindication to AC
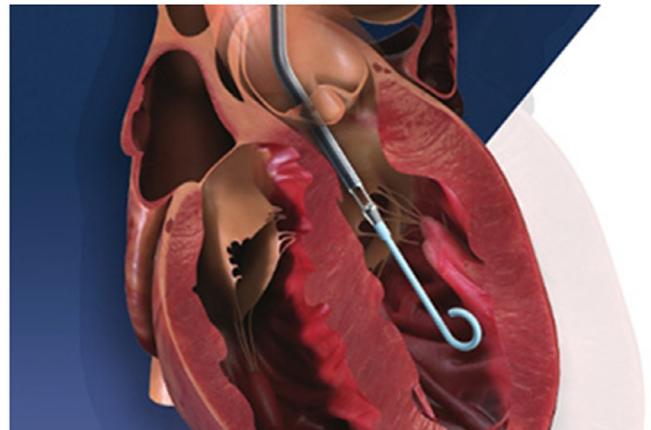
Fig. 7. Overview of impella.

The IABP provides minimal hemodynamic support, which may be insufficient in the more severe forms of CS [21,22]. Newer continuous flow devices such as Impella (LV- > Aorta) or TandemHeart (Left Atrium- > Femoral Artery) offer a greater level of LV support [23]. VA-ECMO has been used predominantly in profound CS and hypoxemia coupled with respiratory failure and those in cardiac arrest.

The use of MCS in high risk percutaneous coronary intervention (HR-PCI) and CS has been studied in several randomized clinical trials [21,24–26]. The IABP has not been shown to reduce mortality or major adverse events in patients with CS or HR-PCI except in

Fig. 8. An algorithmic approach to device use in cardiogenic shock.

the setting of ST segment elevation myocardial infarction (STEMI) in the SHOCK trial [27,28]. In the subsequent SHOCK-II trial [21], no benefit was seen with the IABP and in the European guidelines it carries a class III recommendation [29]. While randomized clinical trials have been too small [25] to demonstrate a mortality benefit with Impella compared to IABP in patients with HR-PCI

and CS, smaller studies and registries [15,20,30] have demonstrated superior hemodynamic support and improved cardiac power output (CPO). CPO (product of mean arterial blood pressure and cardiac output divided by 451) represents an independent predictor of mortality in the setting of AMICS [17]. Limited randomized clinical trials for TandemHeart have demonstrated superior hemodynamic

support compared to IABP in the setting of CS [23] with no difference in short term mortality. Finally, while ECMO provides excellent support of cardiopulmonary circulation, it has higher vascular complications compared to IABP. LV venting is frequently required with an IABP or Impella, to prevent increased myocardial oxygen demand secondary to increased afterload, which can precipitate further myocardial ischemia. For all these reasons, emergent use of ECMO for primary cardiovascular support had declined in the U.S, but is having a resurgence in patients with cardiac arrest despite no formal randomized trial data [31].

Which device to use?

MCS is generally used in the setting of AMICS. An algorithmic approach is suggested (Fig. 8). Timing of device placement is crucial. Ninety minutes after the onset of STEMI and CS is a key inflection point. In the FITT-STEMI trial [32], there was a significant decrease in survival after 90 minutes for patients in AMICS with 3.3% additional deaths for every 10 minute delay.

While the IABP is available in most cardiac catheterization laboratory and its use is likely to continue, a mortality benefit with this device has not been seen in cardiogenic shock [9,33]. Despite superior hemodynamic support, a survival advantage has not been seen with either VA-ECMO [31] or TandemHeart [23].

A ten-year (2004–2014) review of hospitalizations from CS [34] indicated an increase of MCS with pLVAD, predominantly the IABP (91% of cases with a decline in its use since 2008). Use of Impella and ECMO was still low at 5.4% and 3.2% respectively. In hospital mortality declined from 41.5% with no MCS to 32.7% with MCS. While rates of hospitalizations of AMICS has increased, tailoring the appropriate MCS device and timing of insertion remain unclear [35] since clinical trials in CS have been challenging with difficulty in enrollment. Registries [36] and the ongoing National Cardiogenic Shock initiative (NCSI) [14] have suggested that unloading the left ventricle with the Impella device followed by culprit vessel PCI may improve survival [16].

An algorithmic approach to cardiogenic shock

The suggested algorithm (Fig. 8) provides a pathway to appropriate device selection. Those with cardiac arrest who are in CS with no return of spontaneous circulation (ROSC) should proceed to VA-ECMO, if this resource is immediately available. Those who have ROSC but are comatose should be started on therapeutic hypothermia [37] and be stratified to MCS in the CS pathway, before PPCI. Hospitals that have IABP only, should insert this device and then proceed with PPCI. These patients should then be immediately transferred to a hospital with advanced MCS devices (Impella, ECMO, TandemHeart) and the CS pathway followed.

The CS pathway calls for evaluation for the presence of hypoxemia when VA-ECMO is the desired MCS or biventricular failure where choices include VA-ECMO, TandemHeart or Bipella (left sided Impella CP and right sided Impella RP). Due to large caliber of femoral arterial cannulas for both VA-ECMO and TandemHeart, an antegrade distal limb perfusion cannula may be required. With VA-ECMO, patients are at risk for cerebral hypoxemia due to shunting of blood away from the brain also known as the "North South syndrome" (venous blood is drawn from the inferior vena cava, oxygenated and delivered to the femoral arterial canula while pulmonary blood flow is not oxygenated in the lungs and delivers hypoxemic blood to the head and neck and upper extremeties). LV volumes are increased and may require decompression or 'venting' with an Impella (combination is known as ECPELLA). Isolated right ventricular (RV) failure and refractory shock may require the right sided Impella RP.

In the majority of AMICS, there is acute LV failure and as outlined by the algorithm, LV support provided by an Impella CP followed by PPCI to the culprit lesion only, is our favored approach.

Assessment of hemodynamics with right heart catheterization should follow and escalation of therapy to VA-ECMO is recommended in refractory shock. In approximately 50% of cases, RV dysfunction may be seen. In some cases, this may require escalation of therapy to biventricular support with Bipella.

Access

The femoral artery is the choice of access for placement pf Impella devices. Alternate access sites such as axillary [12,38] or transcaval route [13] can be considered in patients with femoral arteries <5 mm in diameter, severe lower extremity peripheral vascular disease including occluded aorta, prior vascular surgery or abdominal aortic aneurysms.

Post procedure management

After device placement, patients are managed in intensive care units with dedicated critical care specialists and nursing teams, well versed in escalation and de-escalation protocols for MCS While there is no standardization of management protocols, support should continue for at least 24 hours. Escalation to a permanent ventricular assist device and consideration of heart transplantation should be a team decision involving advanced heart failure specialists and the cardiac surgeon.

Conclusions

Several MCS devices are currently available for the management of patients with AMICS. However, despite their availability, mortality remains high, possibly due to low usage, timing of insertion of the device and the use of the IABP. While there are few randomized clinical trials and registries to support their use, data from smaller registries and the National Cardiogenic Shock initiative would suggest supporting the LV prior to culprit vessel PCI to improve survival. However, further evaluation is needed with a properly powered and designed randomized clinical trial. Escalation of therapy to VA-ECMO is generally reserved for patients with severe hypoxemia, salvage shock or biventricular failure. Developing an algorithmic approach with care pathways and protocols may improve survival in these critically ill patients.

Acknowledgment

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.tcm.2018.11.014.

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