

Identifying the Right Mechanical Circulatory Support for the Right Patient

A primer on the common factors that impact MCS selection.

BY MIR BABAR BASIR, DO, FSCAI, AND WILLIAM W. O'NEILL, MD, MSCAI

Technologic advancements have changed the landscape of therapeutic options available in the cardiac catheterization lab. From complex cardiac interventions to pulmonary embolism response teams to cardiogenic shock teams, the cath lab has become the epicenter for cardiovascular care. This evolution has led to the increasing use of mechanical circulatory support (MCS) devices to provide temporary percutaneous hemodynamic support. Current technologies include intra-aortic balloon pump (IABP) counterpulsation, Impella (Abiomed, Inc.), TandemHeart (LivaNova), and venoarterial extracorporeal membrane oxygenation (VA-ECMO).

Choosing the right MCS device for the right patient can be a challenging decision for clinicians. MCS devices are used to treat a variety of conditions (Figure 1). Patients may require MCS as a bridge to definitive therapy, such as percutaneous coronary intervention (PCI)/coronary artery bypass grafting (CABG), durable left ventricular assist device (LVAD), or transplantation; whereas for others, temporary MCS is the definitive therapy with the hope of myocardial recovery.

Operators and institutions have diverse levels of expertise and experience with MCS. Unfortunately, there are few data from randomized controlled trials to help guide clinicians in making evidence-based decisions. Clinicians are left to objectively balance the benefits and risks of MCS (Figure 2). This article aims to provide readers with a practical approach for choosing the right MCS for the right patient by offering a road map using the following questions:

1. Who am I treating?
2. How much support do they need?
3. How much support can I provide?

4. How much experience and expertise do I have?
5. What do I do after the device has been implanted?

WHO AM I TREATING?

Choosing the right MCS for the right patient starts by identifying patient phenotypes. Common phenotypes of patients requiring MCS include those presenting with (1) acute-on-chronic decompensated heart failure (HF), (2) cardiogenic shock, or (3) hemodynamic compromise requiring complex intervention. MCS use for each of these unique phenotypes has a different therapeutic goal.

HOW MUCH SUPPORT DO THEY NEED?

Evaluating hemodynamics (using right heart catheterization) and tissue perfusion (using end-organ function and lactate) is crucial in assessing the hemodynamic requirements needed to restore normal tissue perfusion. Current studies evaluating the efficacy of MCS have unfortunately relied mostly on comparisons of one form of MCS versus

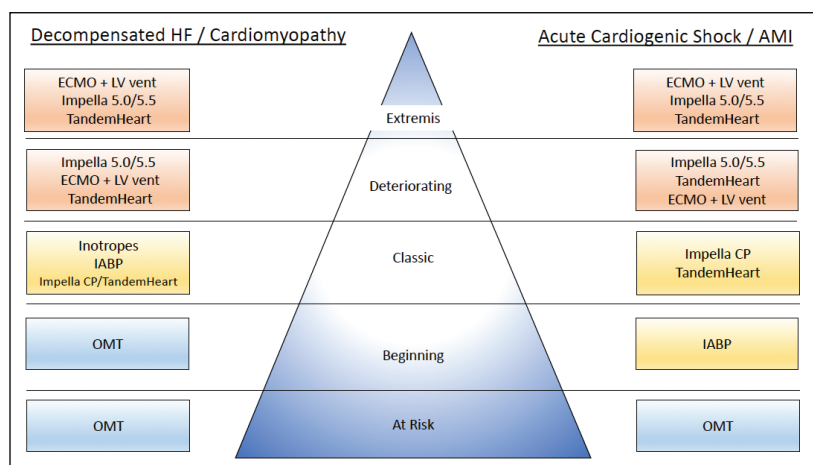


Figure 1. Suggested use of MCS devices based on the Society for Cardiovascular Angiography and Interventions stages of cardiogenic shock. AMI, acute myocardial infarction; OMT, optimal medical therapy.

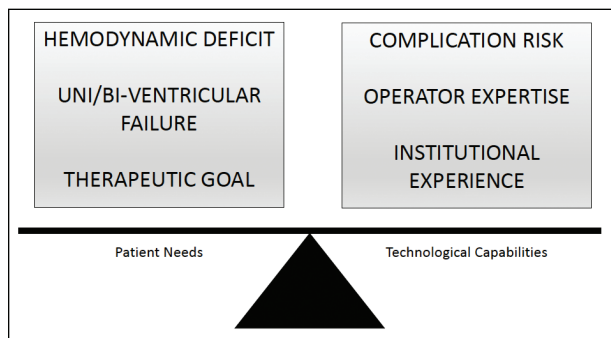


Figure 2. Clinicians must balance patient needs, risks and benefits of MCS, and operator and institutional experience and expertise when evaluating the need for MCS.

another in a given disease state. However, more important than grouping certain devices with certain diseases is to group MCS devices according to the hemodynamic deficit and therapeutic goals of a patient (Figure 3).

For example, a patient who presents with acute cardiogenic shock but is otherwise healthy is more likely to require a robust form of MCS to restore tissue perfusion. This patient's brain, kidneys, and other end organs have consistently seen a normal 5 to 6 L/min of cardiac output. But, after sustaining a large myocardial infarction, for example, such a patient may present with a cardiac output of 2.5 L/min, causing rapid hypoperfusion and concomitant

organ failure. Providing this type of patient with 3 to 5 L/min of support based on patient-specific hemodynamics is likely to restore end-organ perfusion and salvage.

A similar example would be a patient who presents with chronic HF and whose brain, kidneys, and other end organs have consistently seen a reduced cardiac output of 3.5 L/min. If such a patient presented in acute decompensated HF with a cardiac output of 2.5 L/min, providing 1 to 3 L/min of support based on patient-specific hemodynamics is also likely to restore end-organ perfusion.

HOW MUCH SUPPORT CAN I PROVIDE?

Each MCS device offers different levels of hemodynamic support, with a unique mechanism of action and device-specific risk/benefit profile.

IABP

IABPs have been available since the 1970s. Contemporary IABPs require a 7- to 8-F access and can be placed in the femoral, axillary, or brachial arteries. IABPs inflate during diastole and deflate during systole to provide increased coronary perfusion, reduce afterload and myocardial work, and deliver approximately 0.5 to 1 L/min of hemodynamic support. These devices are well suited for patients being bridged to other forms of therapy.

IABPs are commonly used in patients presenting with acute coronary syndrome who require CABG or complex

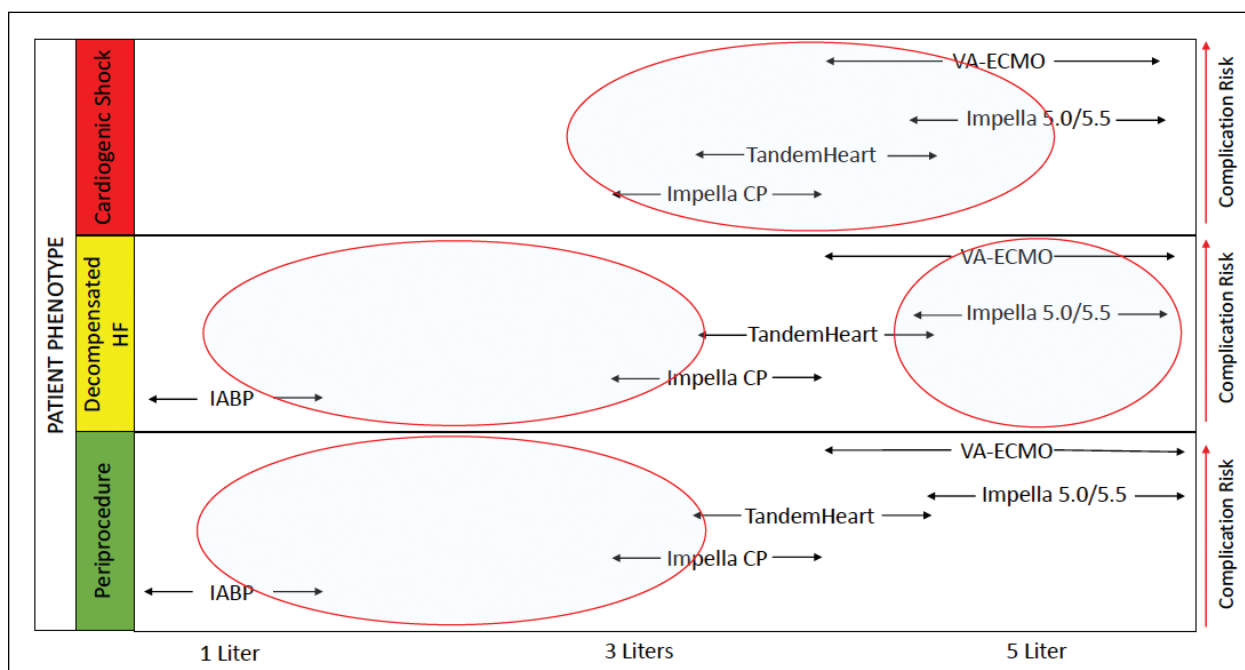


Figure 3. Choosing the right MCS should include evaluation of patient phenotype, hemodynamic needs, risk of complication, and MCS availability. Typical needs for patients based on phenotype are highlighted in red. Most patients requiring periprocedural MCS require 1–3 L/min of support, whereas patients presenting in cardiogenic shock typically require 3–5 L/min of support. MCS should be chosen accordingly. Patients with decompensated HF often can be treated quickly with medical therapy or an IABP; however, in those with significant end-organ hypoperfusion, complete hemodynamic support is often needed.

PCI, as well as in those with persistent ischemia after PCI. They are frequently used as a bridge to a durable LVAD and transplantation in patients with decompensated HF. By providing 0.5 to 1 L/min of hemodynamic support, IABPs can often restore end-organ function to allow for optimized conditions before definitive therapy. They are ideally suited for these scenarios because they do not interfere with surgical or percutaneous techniques and can be used to support patients postoperatively. IABPs require an access of only 7 to 8 F, are transferable between units and institutions, and can be easily removed at the bedside.

However, IABPs do not provide enough hemodynamic support for cases of cardiogenic shock. Multiple trials and large meta-analyses have demonstrated that routine use of IABPs in cardiogenic shock does not improve survival.

Impella

Impella devices have been available since 2006, with FDA approval for use in patients with cardiogenic shock since 2016. There are currently five available models of Impella: a dedicated right ventricular support device (Impella RP) and four left ventricular support devices, each with an incremental increase in hemodynamic support (Impella 2.5, CP 3.5, 5.0, and 5.5). Impella devices have been increasingly used to support complex interventions in patients with underlying hemodynamic compromise, as well as in those with cardiogenic shock.

Impella devices directly unload the left ventricle (LV) and decrease left ventricular wall stress, increase coronary artery perfusion, and support the mean arterial pressure and end-organ perfusion. Early use of Impella prior to PCI and before the use of escalating vasopressors has resulted in rapid hemodynamic improvements seen in the National Cardiogenic Shock Initiative (Table 1). No well-powered trials have been conducted to prove a mortality reduction

with the use of Impella in cardiogenic shock; however, the ongoing DANGER trial should answer this question once completed.

TandemLife

TandemLife pumps (LivaNova) have been available since 2004, and there are currently three available models: a dedicated right ventricular support device (Protek Duo), a left ventricular support device (TandemHeart) that can provide 4 L of support; and TandemLife, which is an ECMO circuit. The TandemHeart device requires a septostomy and indirectly unloads the LV by drainage of the left atria. Similar to Impella, it decreases left ventricular wall stress, increases coronary artery perfusion, and supports the mean arterial pressure and end-organ perfusion. The indications for use are also similar to those for Impella.

VA-ECMO

VA-ECMO has been available since the 1970s and provides cardiopulmonary bypass in patients with refractory cardiogenic shock. Unlike IABPs, Impella, or TandemHeart, ECMO provides biventricular support using a single circuit. Impella and TandemHeart devices can be combined to also provide biventricular support but require the use of two devices.

Widespread adoption of ECMO has been limited due to the need for dedicated perfusionists and an overall higher expertise of care. Historically, ECMO has been predominantly managed by surgeons. However, as shock management has migrated from the operating room to the cath lab, ECMO implantation and management has been increasingly delivered by cardiologists. VA-ECMO is ideally suited for patients with active cardiopulmonary resuscitation because it provides biventricular support with robust peripheral perfusion of the end organs. These benefits also make it well

TABLE 1. HEMODYNAMIC CHANGES OCCURRING WITHIN THE FIRST 24 HOURS OF MCS IMPLANTATION AND PCI IN AMICS

	Pre-MCS	Post-MCS	12 Hours	24 Hours
HR (bpm)	89	93	88	89
SBP (mm Hg)	79	114	106	107
DBP (mm Hg)	51	78	73	68
LVEDP (mm Hg)	29 (n = 76)	–	–	–
dPA (mm Hg)	25 (n = 52)	24 (n = 79)	20 (n = 91)	19 (n = 79)
Lactate (mg/dL)	5.3 (n = 99)	–	3.9 (n = 125)	2.9 (n = 93)
CPO (W)	0.67 (n = 57)	0.89 (n = 128)	0.85 (n = 117)	0.88 (n = 82)

Abbreviations: AMICS, acute myocardial infarction and cardiogenic shock; CPO, cardiac power output; DBP, diastolic blood pressure; dPA, diastolic pulmonary artery pressure; HR, heart rate; LVEDP, left ventricular end-diastolic pressure; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention; SBP, systolic blood pressure.

Note: MCS management only starts in the cath lab. Continuous assessment of perfusion and hemodynamics should be performed to ensure good outcomes. Patients with worsening hemodynamics should be considered for rapid escalation of MCS if current strategies are failing. This table demonstrates the rapid hemodynamic improvements seen in the National Cardiogenic Shock Initiative within 24 hours of MCS implantation and PCI.

suited as a bridge to LVAD and transplantation for patients with refractory cardiogenic shock in an attempt to perfuse and salvage end-organ function. However, physiologically, ECMO places an increased load against the LV and may increase infarct size and impede myocardial recovery, unlike Impella and Tandem Heart. Therefore, current strategies using ECMO in refractory cardiogenic shock emphasize the potential need for left ventricular venting. ECMO is associated with high rates of vascular access complications, bleeding, and stroke. There are currently two large trials (ECLS-SHOCK and ECMO-CS) in Europe evaluating the efficacy of ECMO in refractory cardiogenic shock that should guide patient care in the future.

HOW MUCH EXPERIENCE AND EXPERTISE DO I HAVE?

For most hospitals and interventional cardiologists, implanting and managing MCS devices is uncommon. Impella, for example, is used in approximately 6% of PCIs in the United States, whereas < 1% of cases require the use of TandemHeart or ECMO. Lack of experience can lead to complications during implantation and management. Similarly, most hospitals treat only 10 to 30 cases of acute myocardial infarction and cardiogenic shock (AMICS) per year.¹⁻⁴ Clinicians and cath lab staff may feel unprepared for these cases, which can quickly turn chaotic. Unfamiliarity with MCS devices can add to this stress and lead to complications. The combination of low-volume MCS operators and low institutional expertise with MCS has led to significant variability in treatment and outcomes.

To combat these obstacles in our community in Detroit, Michigan, we standardized shock care throughout five health systems across metro Detroit using a shock protocol known as the Detroit National Cardiogenic Shock Initiative. The protocol uses Impella as the standard MCS device in AMICS cases. Impella was readily available in the cath lab at all five hospitals (ECMO and TandemHeart were only available at one hospital), was FDA approved for use, and did not require a perfusionist or septostomy. We identified best practices associated with improved outcomes in AMICS, including (1) use of early MCS (ie, before escalating doses of vasopressors, prior to PCI, and, if possible, within 90 minutes of arrival to the hospital); (2) use of invasive hemodynamics to guide therapeutic decision-making, including weaning and escalating MCS; and (3) limiting device-associated complications.

With a protocol in place, clinicians and staff were not scrambling to make decisions to determine the next steps, and a more uniform process of care was developed. As comfort and experience grew with one form of MCS, institutions expanded their use of other forms of MCS, leading to greater experience, expertise, and patient care throughout the entire community. The protocol was then

shared across the United States, evolving into the National Cardiogenic Shock Initiative.

WHAT DO I DO AFTER THE DEVICE HAS BEEN IMPLANTED?

Choosing the right device for the right patient is only the beginning of MCS management. Continuous hemodynamic monitoring and assessment are vital to obtaining good patient outcomes. MCS devices are associated with vascular access complications, bleeding, hemolysis, device migration, and stroke, all of which increase with MCS duration. Continuous monitoring of end-organ perfusion and hemodynamics allows for rapid identification of worsening shock, which may require escalation of MCS or hemodynamic improvements that could lead to MCS explantation. Multidisciplinary teams are the foundation for optimizing MCS management and patient outcomes.

CONCLUSION

Choosing the right MCS for the right patient involves a thorough and balanced evaluation of the patient, including phenotype, history, physical examination, laboratory data, hemodynamic deficit, and goals of care, in addition to operator and institutional experience and expertise. ■

1. Shah M, Patnaik S, Patel B, et al. Trends in mechanical circulatory support use and hospital mortality among patients with acute myocardial infarction and non-infarction related cardiogenic shock in the United States. *Clin Res Cardiol*. 2018;107:287-303.
2. Strom JB, Zhao Y, Shen C, et al. National trends, predictors of use, and in-hospital outcomes in mechanical circulatory support for cardiogenic shock. *EuroIntervention*. 2018;13:e2152-e2159.
3. Vallabhajosula S, Prasad A, Bell MR, et al. Extracorporeal membrane oxygenation use in acute myocardial infarction in the United States, 2000 to 2014. *Circ Heart Fail*. 2019;12:e005929.
4. Stretch R, Sauer C, Yuh D, Bonde P. National trends in the utilization of short-term mechanical circulatory support incidence, outcomes, and cost analysis. *J Am Coll Cardiol*. 2014;64:1407-1415.

Mir Babar Basir, DO, FSCAI

Director of the Acute Mechanical Circulatory Support Program
Edith and Benson Ford Heart & Vascular Institute
Henry Ford Hospital
Detroit, Michigan
mbasir1@hfhs.org

Disclosures: Consultant to Abbott Vascular, Abiomed, Inc., Cardiovascular Systems, Inc., Chiesi, LivaNova, Procyon, and Zoll.

William W. O'Neill, MD, MScAI

Medical Director
Center for Structural Heart Disease
Edith and Benson Ford Heart & Vascular Institute
Henry Ford Hospital
Detroit, Michigan
woneill1@hfhs.org

Disclosures: Consultant to Abiomed, Inc., Boston Scientific Corporation, Edwards Lifesciences, and Medtronic.