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EXPERT CONSENSUS DOCUMENT

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care

Endorsed by the American Heart Assocation, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology-Association Canadienne de Cardiologie d'intervention*

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ABSTRACT

Although historically the intra-aortic balloon pump has been the only mechanical circulatory support device available to clinicians, a number of new devices have become commercially available and have entered clinical practice. These include axial flow pumps, such as Impella®; left atrial to femoral artery bypass pumps, specifically the TandemHeart; and new devices for institution of extracorporeal membrane oxygenation. These devices differ significantly in their hemodynamic effects, insertion, monitoring, and clinical applicability. This document reviews the physiologic impact on the circulation of these devices and their use in specific clinical situations. These situations include patients undergoing high-risk percutaneous coronary intervention, those presenting with cardiogenic shock, and acute decompensated heart failure. Specialized uses for right-sided support and in pediatric populations are discussed and the clinical utility of mechanical circulatory support devices is reviewed, as are the American College of Cardiology/American Heart Association clinical practice guidelines.

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*The Canadian Association of Interventional Cardiology (CAIC) is approached by other guideline developers and asked to review and consider guidelines for endorsement. Guidelines developed by external organizations will be considered for affirmation of value. The CAIC may not agree with every recommendation in such a document, but overall considers the document to be of educational value to its members.

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INTRODUCTION

Percutaneous hemodynamic support has historically been limited to the intra-aortic balloon pump (IABP) or extracorporeal bypass with membrane oxygenator (ECMO) (1–3). Although the IABP is widely available, limitations include modest hemodynamic support or myocardial protection; ECMO can provide full hemodynamic support but is limited by complexity and need for perfusion expertise and is rarely used in the catheterization laboratory environment. These limitations have spurred development of alternative percutaneous mechanical circulatory support (MCS) devices with the potential to provide greater cardiac and systemic support and reduce morbidity and mortality among high-risk patient subsets (1).

In parallel, cardiovascular practice has seen rapid growth in cohorts that may benefit from the use of such devices (4). These include patients with chronic systolic dysfunction and acute decompensated heart failure (ADHF), those in whom high-risk multivessel percutaneous coronary intervention (PCI) or other procedures may be required, those with acute cardiogenic shock, and those with residual or concomitant cardiac dysfunction from myocardial infarction despite reperfusion. Among patients with cardiogenic shock, in particular, acute implantation of surgical MCS remains associated with relatively poor outcomes. Accordingly, there has been a rise in the development and use of percutaneous devices over the past decade for both acute (e.g., acute myocardial infarction (MI) complicated by cardiogenic shock or mechanical complications) and acute on chronic (e.g., high risk (HR) PCI) indications.

Percutaneous MCS devices have become an integral component of the cardiovascular therapeutic armamentarium. The 2011 American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) Guideline for Percutaneous Coronary Intervention recommends consideration of percutaneous MCS in two clinical settings: a) as an adjunct to HR PCI (Class IIb) and b) for cardiogenic shock in patients presenting with ST-elevation myocardial infarction (Class Ib) (5). However, no additional guidance is provided. The goal of this document is to provide such guidance on the appropriate clinical settings for MCS utilization and to review the available devices, treatment strategies, practical recommendations for use, gaps in knowledge, and evolving practice.

CLINICAL SETTINGS AND HEMODYNAMIC SUBSTRATES

Potential benefits of MCS include the ability to: 1) maintain vital organ perfusion, thereby preventing systemic shock syndrome, 2) reduce intracardiac filling pressures, thereby reducing congestion and/or pulmonary edema, 3) reduce left ventricular volumes, wall stress, and myocardial oxygen consumption, 4) augment coronary perfusion, 5) support the circulation during complex interventional and electrophysiologic procedures, and, theoretically, 6) limit infarct size. As new MCS devices become available, several specific patient populations likely to benefit from this therapy can be identified. These include patients undergoing high-risk PCI (HR-PCI), and those with large acute myocardial infarctions (AMI), acute decompensated heart failure (ADHF), and cardiogenic shock.

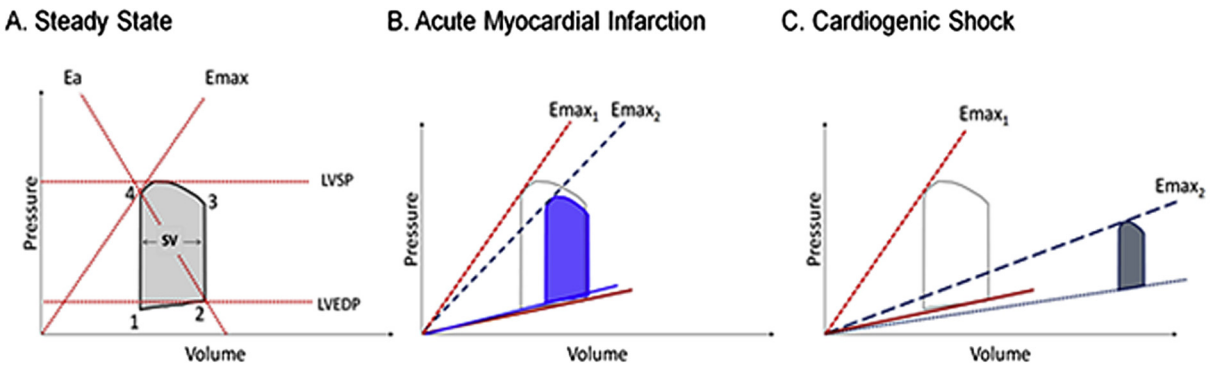
The hemodynamic condition of the left ventricle (LV) in these populations is illustrated by the pressure-volume (PV) loop (**Figure 1**), which provides information about contractile function, relaxation properties, stroke volume, cardiac work, and myocardial oxygen consumption (6–10). The anticipated effect with available support devices is shown in **Figure 2**. Each clinical syndrome presents a unique set of hemodynamic variables where cardiac function and myocardial oxygen supply or demand is compromised. For example, in AMI, patients may present with reduced LV contractile function, acute diastolic dysfunction, elevated LV end-diastolic volume (LVEDV) and pressure (LVEDP), and increased LV work (oxygen demand) in addition to diminished coronary blood flow. In cardiogenic shock LV contractile function is severely reduced with significantly increased LVEDV and LVEDP, markedly reduced stroke volume, but increased myocardial oxygen demand; coronary blood flow may also be impaired by hypotension and elevated wall stress. These pressure-volume loops provide hemodynamic characterization only of the LV and do not provide information on right ventricular function or extra-cardiac problems that may be impacted by MCS such as systemic hypoperfusion of the cerebral, visceral, renal, and peripheral arteries.

HR PCI

Each aspect of PCI from guide catheter engagement to coronary wiring, balloon inflation, and stent deployment incurs a potential risk of damage to the coronary vasculature with impairment of myocardial perfusion, either transient or persistent. At present, no single, unifying definition for HR-PCI exists but variables that contribute to elevated risk during PCI have been well defined and can be categorized into three major groups: 1) patient specific, 2) lesion specific, and 3) clinical presentation specific.

Patient-specific variables include increased age, impaired left ventricular function, symptoms of heart failure, diabetes mellitus, chronic kidney disease, prior myocardial infarction, multivessel or left main disease,

FIGURE 1 Normal and Abnormal Pressure Volume Loops



Each pressure volume (PV) loop represents one cardiac cycle **(A)**. Beginning at the end of isovolumic relaxation (Point 1), LV volume increases during diastole (Phase 1 to 2). At end-diastole (Point 2), LV volume is maximal and isovolumic contraction (Phase 2 to 3) begins. At the peak of isovolume contraction, LV pressure exceeds aortic pressure and blood begins to eject from the LV into the aorta (Point 3). During this systolic ejection phase, LV volume decreases until aortic pressure exceeds LV pressure and the aortic valve closes, which is known as the end-systolic pressure-volume point (ESPV) (Point 4). Stroke volume (SV) is represented by the width of the PV loop as the volume difference between end-systolic and end-diastolic volumes (Points 1 and 2). The shaded area within the loop represents stroke work. Load-independent LV contractility, also known as E_{max}, is defined as the maximal slope of the ESPV point under various loading conditions, known as the ESPV relationship (ESPVR). Effective arterial elastance (E_a) is a component of LV after- load and is defined as the ratio of end-systolic pressure and stroke volume. Under steady state conditions, optimal LV pump efficiency occurs when the ratio of E_a:E_{max} approaches 1. **(B)** Representative PV loop in AMI (blue loop). LV contractility (E_{max}) is reduced; LV pressure, SV, and LV stroke work may be unchanged or reduced; and LVEDP is increased. **(C)** Representative PV loop in cardiogenic shock (gray loop). E_{max} is severely reduced; LVEDV and LVEDP are increased; and SV is reduced.

and peripheral arterial disease (11-18). Lesion-specific variables encompass anatomic characteristics such as left main stenosis, bifurcation disease, saphenous vein grafts, ostial stenoses, heavily calcified lesions, and chronic total occlusions (19-23). Lesions that supply a large territory (including a last patent conduit, left main disease, or critical 3-vessel disease) also increase risk should dissection or occlusion occur during PCI—particularly in combination with poor ventricular function. Finally, the clinical setting, such as acute coronary syndrome or cardiogenic shock, can increase the risk of an adverse event with PCI. The combination of severe left ventricular dysfunction, particularly ADHF, with a lesion(s) that is difficult to treat is an example of HR-PCI.

Need for an MCS device for HR-PCI depends upon the hemodynamic condition of the patient at the time of PCI, the anticipated risk of hemodynamic compromise during the procedure, and the need for hemodynamic support after revascularization. Risk calculators specifically designed to assess the real-time need for MCS during PCI do not exist and require further investigation.

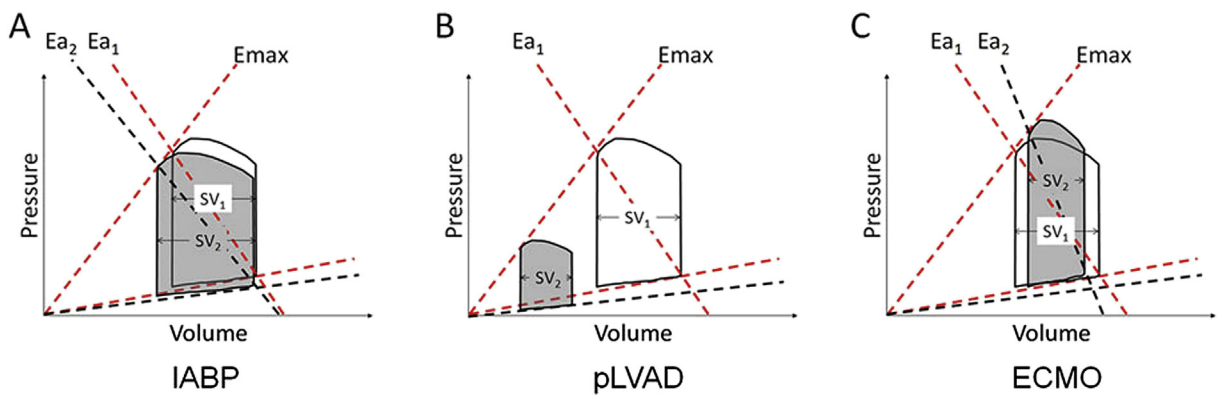
Acute Myocardial Infarction

Although the vast majority of non-ST- and ST-segment elevation myocardial infarction (NSTEMI and STEMI) patients can be safely and effectively treated using standard techniques, selected patients may benefit from the unloading and hemodynamic effects of MCS, which may serve to reduce myocardial oxygen consumption and ischemia, and improve coronary perfusion through effects on coronary blood flow. Due to the presence of active and ongoing myocardial ischemia, NSTEMI and STEMI are among the high-risk clinical scenarios for PCI. Several factors make these patients high risk. Due to myocardial ischemia, left ventricular (LV) diastolic and systolic function is impaired and contributes to elevated in- tracardiac filling pressures. Furthermore, PCI is associated with the risk of thrombotic embolization and infarct extension, which can lead to hemodynamic decompensation. Finally, although standard therapy for STEMI is rapid myocardial reperfusion, up to one-third of STEMI patients do not experience effective reperfusion as assessed by resolution of ST-segment elevation, and reperfusion itself may cause myocardial damage (reperfusion injury) and life- threatening ventricular arrhythmias (24). Whether MCS can reduce myocardial injury in the setting of acute occlusion and subsequent reperfusion for myocardial infarction is unknown.

Advanced Heart Failure and Cardiogenic Shock

Heart failure is a major cause of morbidity and mortality worldwide. In the United States alone, an estimated 5.7 million adults 20 years or older have heart failure, of whom nearly 50% have reduced LV ejection fraction (25).

FIGURE 2 Cardiac Effects of Mechanical Support



Illustrations of PV loops after activation of device therapy (gray loops). **(A)** Intra-aortic balloon pump (IABP) counterpulsation reduces both peak LV systolic and diastolic pressures and increases LV stroke volume. The net effect is a reduced slope of arterial elastance (E_{a2}), **(B)** Percutaneous LV assist devices (pLVAD: Impella and TandemHeart) significantly reduce LV pressures, LV volumes, and LV stroke volume. The net effect is a significant reduction in cardiac workload. **(C)** Veno-arterial extra-corporeal membrane oxygenation (VA-ECMO) without a LV venting strategy increases LV systolic and diastolic pressure, while reducing LV stroke volume. The net effect is an increase in arterial elastance (E_a).

Cardiogenic shock is defined as systemic tissue hypoperfusion secondary to inadequate cardiac output despite adequate circulatory volume and LV filling pressure. Diagnostic hemodynamic criteria include: a systolic blood pressure <90 mm Hg for >30 min; a drop in mean arterial blood pressure >30 mm Hg below baseline, with a cardiac index (CI) <1.8 L/min/m^2 without hemodynamic support or <2.2 L/min/m^2 with support; and a pulmonary capillary wedge pressure (PCWP) >15 mm Hg (26-28).

Among patients with advanced heart failure, technologic advances have facilitated the use of surgically implanted left ventricular assist devices (LVADs) as a bridge to recovery, bridge to transplant, or for use as permanent (destination) therapy (29). Biventricular assist devices and the total artificial heart are also available as a bridge to transplant for patients with biventricular heart failure. As a result, the use of MCS devices as a treatment strategy for patients presenting with advanced heart failure or cardiogenic shock may be considered. The primary goal of such a strategy is stabilizing a critically ill patient before making a decision regarding durable therapy. Moreover, MCSs may allow for myocardial recovery, possibly obviating the need for destination therapy.

The optimal timing of MCS insertion in ADHF and cardiogenic shock remains unknown and significant practice variability exists. For patients with advanced HF, the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) has defined seven clinical profiles before implantation of a surgical VAD. Cardiogenic shock is identified by INTERMACS profiles 1 and 2 patients, who either have acutely decompensated or are failing to respond to aggressive inotrope therapy, respectively (30). Both INTERMACS 1 and 2 patients may be considered for temporary MCS support as a bridge to recovery, surgical MCS, or cardiac transplantation.

Emerging Populations

Given the growing numbers of patients with compromised cardiac function undergoing percutaneous coronary and valve therapies new applications for this technology are emerging. In the adult population, patients with severe, nonoperable valve disease represent a rapidly growing population; carefully selected patients may benefit from cardiac support during percutaneous aortic valvuloplasty or aortic valve replacement (31,32). Similarly, patients referred for electrophysiologic procedures with severe underling LV dysfunction may not tolerate sustained arrhythmias during prolonged electrophysiological mapping and ablation procedures (33,34). Finally, patients with right ventricular (RV) failure are at considerably higher risk for morbidity and mortality when presenting with AMI, ADHF, or CS. Use of MCS for RV or biventricular support has been reported (35-37) and represents an important new use for this technology. Although not yet available in the United States, a dedicated RV support device is under clinical evaluation (35,38).

Many children have or will develop disorders involving the myocardium. The current therapeutic options for circulatory support in the pediatric population are quite limited. Primary indications for circulatory support in pediatrics include heart failure related to congenital heart

disease, cardiomyopathy and myocarditis, and cardiac allograft failure. The most commonly used method of circulatory support in children is ECMO. According to the most recent Extracorporeal Life Support Organization (ELSO) Registry Report from January 2013, a total of 6,225 pediatric patients (>31 days to 18 years) have been supported on ECMO since 1990 due to cardiac failure with a 65% survival from ECMO but only a 49% survival to discharge (39). ECMO is able to provide complete circulatory support in a wide range of patients from newborns to adults both with and without congenital heart disease but is highly invasive and survival rates remain low at 40 to 50% (39). At this time, the only percutaneous device approved in the United States for short-term cardiac support in children is the IABP, with all other modalities requiring surgical implantation. MCSs have been utilized for circulatory support in older children successfully in their current configuration (40,41). An important limitation in this patient population is femoral vessel size. Further device iterations may allow broader application.

AVAILABLE DEVICES AND/OR STRATEGIES

Intra-Aortic Balloon Pump

The IABP remains the most commonly used form of circulatory support. The IABP has two major components, a balloon catheter and a pump console to control the balloon. The catheter itself is a double-lumen 7.5-8.0 Fr catheter with a polyethylene balloon attached at its distal end. One lumen is attached to the pump and is used to inflate the balloon with gas. Helium is used because its low viscosity facilitates rapid transfer in and out of the balloon, and because it absorbs very rapidly in blood in the case of balloon rupture. The second lumen of the IABP is used for guidewire insertion and to transduce aortic pressure.

Timing of balloon inflation and deflation is based on electrocardiogram (ECG) or pressure triggers. The balloon inflates with the onset of diastole, which roughly corresponds with electrophysiologic repolarization or the middle of the T-wave on the surface ECG. Following diastole, the balloon rapidly deflates at the onset of LV systole, which is timed to the peak of the R-wave on the surface ECG. Poor ECG quality, electrical interference, and cardiac arrhythmias can result in erratic balloon inflation/deflation and make pumping inadequate or impossible. Excessive tachycardia also mitigates the usefulness for diastolic pressure augmentation, due to a reduction of the time spent in diastole. Modern timing algorithms utilizing fiberoptics can somewhat improve device performance even in the setting of tachycardia or irregular pulse (42), while larger volume balloons (i.e., 50 ml) have recently been developed (43).

Hemodynamic Effects

The IABP increases diastolic blood pressure, decreases afterload, decreases myocardial oxygen consumption, increases coronary artery perfusion, and modestly enhances cardiac output. The IABP provides modest ventricular unloading but does increase mean arterial pressure and coronary blood flow. Patients must have some level of left ventricular function and electrical stability for an IABP to be effective, as any increase in cardiac output is dependent on the work of the heart itself. Optimal hemodynamic effect from the IABP is dependent on several factors, including the balloon's position in the aorta, the blood displacement volume, the balloon diameter in relation to aortic diameter, the timing of balloon inflation in diastole and deflation in systole, and the patient's own heart rate, blood pressure and vascular resistance (44).

Contraindications and Complications

Aortic valve regurgitation of greater than a mild degree has traditionally been considered a contraindication to the IABP as diastolic balloon inflation may worsen the degree of regurgitation. Severe peripheral arterial or aortic disease increases the risk of vascular complications such as thromboembolism to the lower extremities or visceral arteries (45).

The majority of complications from IABP use are vascular and may include stroke (46), limb ischemia, or vascular trauma. Thrombocytopenia from platelet deposition on the IABP membrane (or use of heparin), infection, and complications of immobility can occur in patients who remain on prolonged IABP therapy. Trauma to the aorta or ostia of visceral arteries, including the renal arteries, can occur and result in severe life-threatening complications such as bowel ischemia, atheroembolism, and acute kidney injury.

There is variability in use of anticoagulation for IABP. Many centers do routinely use anticoagulation, but others do not, particularly with 1:1 pumping. No definitive data exist to provide guidance. Each institution should establish its protocol, with monitoring of bleeding and ischemic complications.

Left Atrial to Aorta Assist Devices

Currently, only one left atrial–aorta assist device is commercially available, TandemHeart. This is a percutaneously inserted circulatory assist device that pumps blood extracorporeally from the left atrium (LA) to the iliofemoral arterial system via a transseptally placed left atrial cannula, thereby bypassing the LV (47). The TandemHeart has four components: a 21-F transseptal cannula, a centrifugal pump, a femoral arterial cannula, and a control console. Regulatory status includes U.S.

Food and Drug Administration (FDA) approval to provide extracorporeal circulatory support for up to 6 h and CE mark for use up to 30 days. It also has FDA approval to add an oxygenator to the circuit allowing for concomitant LV unloading and oxygenation.

The transseptal cannula is made of wire-reinforced polyurethane with a large end-hole and 14-side holes that allow for aspiration of left atrial blood. The arterial perfusion cannula is available in sizes ranging from 15- to 19-F and is the main determinant of maximal flow. The centrifugal blood pump contains a hydrodynamic bearing that supports a spinning impeller. The pump has a motor chamber and a blood chamber that are separated by a polymeric membrane. The impeller is powered by a brushless DC electromagnetic motor, rotating between 3,000 and 7,500 rpm. The external console controls the pump and provides battery backup in case of power failure. A continuous infusion of heparinized saline flows into the lower chamber of the pump, which provides lubrication and cooling, and prevents thrombus formation.

Hemodynamic Effects

During MCS with TandemHeart, both the LV and the pump contribute flow to the aorta simultaneously (thereby working in parallel, or tandem, rather than in series). The redirection of blood from the LA reduces LV preload, LV workload, filling pressures, wall stress, and myocardial oxygen demand (47,48). The increase in arterial blood pressure and cardiac output supports systemic perfusion. The 19-F arterial cannula allows up to 5 L/min of flow whereas the 15-F cannula will allow up to 3.5 L/min. These values are additive to left ventricular output through the aortic valve, although the contribution of the heart is typically reduced as MCS support is increased due to changes in LV loading conditions (i.e., decrease in preload and increase in afterload). Coronary flow is driven by the perfusion pressure (diastolic pressure−right atrial pressure). With two pumps in parallel, the aorta is perfused and pressured by both LV and the TandemHeart, with the relative contribution of each varying and dependent upon LV response to the pump. Not infrequently LV contraction virtually ceases and perfusion is pump-dependent with a flat mean arterial pressure curve. Ventricular tachycardia or fibrillation usually but not always renders LVADs ineffective due to right ventricular failure (RVF) (49).

Contraindications and Complications

Adequate RV function or a concomitant RVAD is usually necessary to maintain left atrial volume. There is limited experience with the use of the TandemHeart device in the setting of a ventricular septal defect or severe aortic regurgitation (50,51). Severe peripheral arterial disease, which is commonly present in elderly patients, may preclude placement of the arterial cannula, or result in peripheral ischemia. In select cases with peripheral arterial disease, a 5- or 6-F sheath can be placed antegrade into the superficial femoral artery and spliced into the arterial outflow cannula to provide limb perfusion. Profound coagulopathies and bleeding diatheses such as heparin induced thrombocytopenia or disseminated intravascular coagulation are contraindications to use of TandemHeart as are the presence of a right or left atrial thrombus. Anticoagulation is important to prevent thromboembolism or in situ thrombosis and few data with anticoagulants other than unfractionated heparin are available although anecdotal reports exist. Activated clotting times about 300 are typically required. Alternative agents such as bivalirudin or argatroban may be required in case of heparin contraindications and their use is empiric.

Complications from the device are similar to other percutaneous support devices and include vascular trauma and limb ischemia (47). Expertise with transseptal puncture is required, particularly given the caliber of the venous cannula. The relatively low numbers of interventional cardiologists regularly performing transseptal puncture in their practice is an important barrier to clinical application in many labs. Collaboration with colleagues with transseptal experience and imaging guidance using intracardiac or transesophageal echocardiography can facilitate training and safety of the transseptal puncture. Complications unique to transseptal puncture, such as cardiac tamponade can occur; and these risks are increased among anticoagulated patients. Other possible complications include thrombo-or air-embolism and hemolysis. Care must be taken to prevent dislodgement of the left atrial cannula, particularly during patient transport, or if the patient moves their leg, as dislodgement into the right atrium will result in massive right to left shunt and severe systemic desaturation. The cannula may also migrate into a pulmonary vein leading to device malfunction.

LV to Aorta-Assist Devices

The Impella is a nonpulsatile axial flow Archimedes-screw pump designed to propel blood from the LV into the ascending aorta, in series with the LV (47). Three versions are now available. The 12-F (Impella 2.5) and 21-F (Impella 5.0) devices which provide maximal flow rates of 2.5 and 5.0 L/min, respectively, and a new 14-F device (Impella CP) with an intermediate level of support of 3.0 to 4.0 L/min. These devices are designed to be placed via the femoral artery, either percutaneously (2.5 and CP) or with a surgical cutdown (5.0). Alternate access sites such as the subclavian artery have been described but are not routinely used. The tip of the catheter is a flexible pigtail loop that stabilizes the device in the LV with a low

likelihood of perforation. The pigtail connects to a 12-F (2.5 device), 14-F (CP device), or 21-F cannula (5.0 device) that contains the pump inlet and outlet areas, motor housing, and pump pressure monitor. Due to its size, the Impella 5.0 requires a surgical cutdown for deployment via the axillary or femoral artery. A possible advantage of the axillary approach is the potential for long-term support (52).

The proximal 9-F catheter shaft houses the motor power leads and purge and pressure measurement lumens. The catheter's proximal end consists of a hub for attachment of a console cable and side arms for attachment of purge solution and pressure-measurement tubing. As the Impella CP device has just recently become available in the United States, the greatest experience to date has been with the Impella 2.5 device.

Unlike the IABP, and comparable to the TandemHeart, the Impella does not require timing, nor is a trigger from an electrocardiographic rhythm or arterial pressure needed. Similar to the TandemHeart, the device allows for stability despite transient arrhythmias, but asystole and ventricular fibrillation are poorly tolerated. The device has received FDA approval for providing up to 6 h of partial circulatory support whereas in Europe, the Impella 2.5 is approved for use of up to 5 days.

Hemodynamic Effects

The Impella pumps blood from the LV into the ascending aorta, thereby unloading the LV and increasing forward flow. It reduces myocardial oxygen consumption, improves mean arterial pressure, and reduces pulmonary capillary wedge pressure (53). The Impella 2.5 provides a greater increase in cardiac output than the IABP but less than the TandemHeart device. The more powerful Impella CP and 5.0 devices are comparable to the TandemHeart device in terms of support. Whether the Impella CP further reduces native left ventricular stroke work and wall stress at comparable flow rates to the TandemHeart based on device inflow location is unknown. Similar to the TandemHeart, adequate RV function or concomitant RVAD is necessary to maintain LV preload and hemodynamic support during biventricular failure or unstable ventricular arrhythmias (49).

Contraindications and Complications

Use of the Impella is contraindicated in patients with a mechanical aortic valve or left ventricular thrombus. Aortic stenosis and regurgitation are relative contraindications, although reports of use in critical aortic stenosis for hemodynamic rescue or to facilitate valvuloplasty exist (54). The device should not be placed in patients with severe peripheral arterial disease or who cannot tolerate systemic anticoagulation. Theoretically, use of Impella may worsen right-to-left shunting and hypoxemia in patients with a preexisting ventricular septal defect.

The most commonly reported complications of Impella placement are limb ischemia, vascular injury, and bleeding requiring blood transfusion (55). Vascular complications common to all transfemoral procedures such as hematoma, pseudoaneurysm, and arterial- venous fistula, and retroperitoneal hemorrhage can occur with any mechanical support device.

Hemolysis due to mechanical erythrocyte shearing has been reported within the first 24 h of use in 5% to 10% of patients, and may respond to repositioning the device (55). Persistent hemolysis associated with acute kidney injury is an indication for device removal.

Extracorporeal Membrane Oxygenation

ECMO provides cardiopulmonary support for patients whose heart and lungs can no longer provide adequate physiologic support. ECMO can be either veno-veno (V-V) for oxygenation only or veno-arterial (V-A) for oxygenation and circulatory support. In cases of biventricular failure, V-A ECMO is the MCS of choice for patients in cardiogenic shock and impaired oxygenation, as it provides full cardiopulmonary support. ECMO may be placed at the bedside without fluoroscopic guidance.

Similar to a cardiopulmonary bypass circuit used in cardiac surgery, V-A ECMO involves a circuit composed of a centrifugal, nonpulsatile pump for blood propulsion, and a membrane oxygenator for gas exchange. A venous cannula drains deoxygenated blood into a membrane oxygenator for gas exchange, and oxygenated blood is subsequently infused into the patient via an arterial cannula. Anticoagulation is required and unfractionated heparin is the most commonly used agent. The degree of anticoagulation is dependent on the type of membrane oxygenator used, with ACTs ranging between 180 and 250. Venous and arterial cannulae can vary in size but typically will be similar to TandemHeart (20-F venous, 17-F arterial). An experienced cardiac perfusionist is required for management of the ECMO system, whereas they are not required for the other devices.

While any standard ECMO or perfusion system available in the hospital may be used, new portable ECMO systems such as CardioHelp (Maquet) have now attained FDA approval and may find a useful role in catheterization laboratories due to the relative ease of implantation and initiation.

Hemodynamic Effects

V-V ECMO offers gas exchange without hemodynamic support and is useful for conditions associated with severe impairment of gas exchange with stable hemodynamics such as ARDS, or rarely, pulmonary embolism.

On the other hand, V-A ECMO provides systemic circulatory support with flows sometimes exceeding 6 L/min depending on cannula sizes. However, due to high myocardial oxygen demand (secondary to high filling pressures and volume), V-A ECMO alone may not significantly reduce ventricular wall stress (56). This has theoretic negative consequences on myocardial protection unless the LV is vented or unloaded by concomitant IABP or Impella (57). Metabolic derangement and deleterious systemic effects of cardiogenic shock can often be corrected within hours of initiation of ECMO.

Contraindications and Complications

Perfusionists familiar with device function and maintenance should be readily available. Significant aortic insufficiency may worsen with ECMO and promote increased ventricular wall stress without a venting strategy. Patients with severe peripheral arterial disease should not undergo peripheral cannulation and central cannulation should be considered. Anticoagulation is necessary to prevent thrombosis of the membrane oxygenator and varies dependent upon type. Typical activated clotting times (ACTs) are between 180 and 250. Each laboratory and hospital with a mechanical support program should have target ACTs and regular monitoring as part of its protocol. Alternative antithrombin agents may be required if contraindications to unfractionated heparin exist (58).

Complications of ECMO relate to bleeding and thromboembolic events, as well as hemolysis. Thromboembolic events may occur both in the circuit or the patient if adequate anticoagulation is not achieved. Cannulation complications, common to all large cannulae, may include venous thrombosis or distal arterial ischemia. Similar to TandemHeart, a second, antegrade, arterial sheath inserted into the superficial femoral artery can provide antegrade limb perfusion when needed. Stroke, either embolic or hemorrhagic, can occur and care must be taken to assure adequate but not excessive anticoagulation.

Right-Sided Support

RVF is associated with increased morbidity and mortality (59–67). Management of RVF focuses on reversing the underlying cause, maintaining adequate preload, reducing RV afterload, and enhancing RV contractility. In RVF refractory to medical therapy, options include surgical RVAD implantation, veno-arterial ECMO, cardiac transplantation, or a total artificial heart (67). Historically, percutaneous mechanical support for RVF has been limited to the IABP, which only indirectly benefits RV function by reducing LV afterload and enhancing coronary perfusion. Since RV stroke work requires one-sixth the energy expenditure of the LV (68), pumps that generate continuous flow with a minimal, low-amplitude pulsatile component, may more closely approximate native RV function.

Right ventricular support using two venous cannulas and ECMO or a TandemHeart centrifugal pump providing flow from the right atrium to main pulmonary artery has been reported (69). Since the earliest reports, the TandemHeart RV support device has been implanted for RVF in the setting of AMI (70,71), post-LVAD implant (72), severe pulmonary hypertension (73), and acute cardiac allograft failure (74). Right internal jugular venous cannulation can be used and is particularly useful when the distance from the femoral vein to the fifth intercostal space exceeds 58 cm or if femoral venous access is limited by infection, thrombosis, or an inferior vena caval filter (75). Close monitoring for antegrade cannula migration is essential and may present as hypoxic respiratory failure, hemothorax, hemoptysis, decreased cardiac output, and an acute decrease in device flow. TandemHeart is not FDA-approved for use as an RVAD (36). The Impella RP, a catheter-mounted axial flow pump is undergoing evaluation for management of RVF (38). A potential advantage of the Impella RP device is the need for only a single venous access site. As experience with percutaneous RV support devices grows, their role in the interventional armamentarium of mechanical therapies for heart failure will evolve and will require algorithms for risk stratification, patient and device monitoring, and weaning protocols.

Theoretical Comparison of Hemodynamic and Myocardial Effects

The primary mechanism of benefit of MCS is to reduce native LV stroke work and myocardial oxygen demand while maintaining systemic and coronary perfusion. Myocardial effects of reducing LV volume and pressure, known as “LV unloading” have been well described (76). Device options can be classified according to pump type and include: volume-displacement pumps (IABP) and continuous-flow pumps, which can be further grouped as axial-flow (Impella) or centrifugal-flow (TandemHeart; CentriMag; Rotaflow) MCSs.

By displacing blood volume in the descending aorta during systole, the IABP generates a vacuum that is replaced by blood from the LV. The net result is reduced LV afterload, increased stroke volume, and a small reduction in LV stroke work (77). However, the IABP is functionally limited by balloon capacity, accurate timing, and a dependence on native LV function. Whether newer generation, larger capacity IABPs will provide more cardiac support remains unknown.

With minimal native LV function continuous flow devices actively reduce LV stroke work and myocardial oxygen demand, and can maintain systemic perfusion.

Output of these devices is determined by rotor speed and is influenced by preload and afterload. Whether axial or centrifugal flow pumps have different effects on LV unloading has not been clearly established (78,79). Differences between these two device types that impact hemodynamic effects are the rotor sizes and the caliber of the inflow and outflow segments.

Technical differences between axial and centrifugal devices exist and relate to the location of device inflow and outflow. The Impella is placed across the aortic valve into the LV for direct unloading, while the TandemHeart inflow cannula is placed across the interatrial septum into the LA, thereby reducing LV stroke work indirectly by reducing LV preload. No patient-level data exist currently to suggest that any meaningful difference is observed between unloading via the LA or the LV. In contrast, ECMO, which displaces venous volume into the arterial circulation, can significantly increase after-load on the LV, thereby potentially reducing LV stroke volume, increasing myocardial oxygen demand, and necessitating "venting" of the LV (80). The major technical difference is that to achieve device flow rates of 5 L/min, the TandemHeart device requires venous and arterial cannulation with trans-septal puncture, while the Impella 5.0 pump requires surgical vascular access.

CLINICAL DATA AND GUIDELINES

The American College of Cardiology, the American Heart Association, and the Society for Cardiovascular Angiography and Intervention have published expert consensus documents and clinical practice guidelines referencing the use of left ventricular assist devices. The most recent guidelines relating to percutaneous coronary intervention and management of acute coronary syndromes recommend consideration of hemodynamic support devices in the settings of HR-PCI and STEMI with cardiogenic shock and for use in unstable patients being transported from one hospital center to another (5,81).

Intra-Aortic Balloon Pump

In a retrospective study of 48 patients who underwent primary PCI for acute myocardial infarction complicated by cardiogenic shock, those that had an IABP placed before PCI had a lower peak creatine kinase (CK), lower in-hospital mortality and fewer major adverse cardiac events than those with IABP inserted after PCI (82). However, a nonrandomized study examined the use of IABP in HR-PCI using the National Cardiovascular Data Registry database and found no differences in overall mortality and wide regional variation in the use of IABP in this setting (83). Similarly, a meta-analysis of IABP use in AMI found no benefit and potential harm, including a higher risk of stroke (46). Finally, prospective randomized, controlled trials have failed to demonstrate conclusive proof of IABP benefit. The IABP-SHOCK II Trial (84) randomized 600 patients with cardiogenic shock complicating AMI to IABP or no IABP, with all patients expected to undergo early revascularization and to receive optimal medical therapy. The vast majority (83%) of IABP were inserted after the primary PCI procedure; at 30 days, there were 119 deaths (39.7%) in the IABP group and 123 deaths (41.3%) in the control group ($p = 0.69$), and no significant differences in secondary clinical, laboratory, and resource utilization endpoints. Rates of major bleeding, sepsis, and stroke were also similar between the two groups (84).

Despite limited evidence of meaningful benefit, IABP has received a Class IIa indication for use during STEMI complicated by cardiogenic shock in the 2013 ACCF/AHA guideline statement pertaining to STEMI management (81). IABP use in STEMI without shock was not addressed except to note that it may be useful for mechanical complications of STEMI. Additionally, the current ACCF/AHA guideline statement (5) and the most recent SCAI expert consensus document (85) on PCI without on-site cardiac surgery agree that the ability to provide IABP support during transport of unstable patients is a requirement for such centers.

The CRISP AMI (Counterpulsation to Reduce Infarct Size Pre-PCI Acute Myocardial Infarction) trial was a 30-center randomized controlled trial that investigated whether routine IABP placement immediately before reperfusion reduced myocardial infarct size in patients presenting with an anterior STEMI. The trial enrolled 337 patients in nine countries. No reduction in infarct size as assessed by cardiac magnetic resonance imaging was found 3 to 5 days following coronary intervention, and no significant difference in survival was observed at 6-month follow-up between groups (86).

In a large study from the National Cardiovascular Data Registry, IABP was used in only 10.5% of 181,599 high-risk interventions (defined unprotected left main intervention, reduced left ventricular ejection fraction, STEMI and cardiogenic shock) (83). IABP use in this analysis was not associated with lower mortality and varied widely between centers. Since all retrospective nonrandomized studies are subject to significant selection and referral bias it remains unknown what the outcomes of the 18,990 patients would have been had an IABP not been used.

Finally, a prospective randomized clinical trial, BCIS-1, enrolled 301 patients across 17 centers in the UK and failed to show a mortality benefit of routine IABP over provisional IABP use among those referred for HR-PCI (87). On the other hand, routine IABP use significantly reduced major procedural complications (1.3% vs. 10.7%, $p < 0.001$), particularly procedural hypotension.

Procedural hypotension in the group randomized to no IABP necessitated crossing over to IABP in 12% of patients. A long-term follow-up analysis of BCIS-1 out to 51 months showed a 34% relative reduction in all-cause mortality with routine IABP use in patients with severe ischemic cardiomyopathy undergoing HR-PCI (88).

Percutaneous Mechanical Circulatory Support

The opportunity for these systems to provide greater hemodynamic support than IABP has been demonstrated (89); however, there have been few randomized clinical trials. In an analysis of 117 patients with severe cardiogenic shock refractory to IABP and/or vasopressor therapy, Kar et al. (89) observed significant improvements in cardiac index, systolic blood pressure, and urine output with TandemHeart support over an average implant time of 6 days. In addition, pulmonary capillary wedge pressure and serum creatinine levels decreased. Despite these clinical and laboratory improvements, 30-day mortality remained high at 40% with significant bleeding complications. Whether observed mortality would have been higher without circulatory support cannot be determined; however, it bears emphasis that these were the sickest subgroup with true refractory shock with almost one-half undergoing CPR during their course. In a small open-labeled study, Burkhoff et al. (90) randomized 33 patients within 24 h of developing cardiogenic shock to treatment with an IABP or TandemHeart. Compared with IABP, the TandemHeart device resulted in a greater increase in cardiac index and decrease in pulmonary capillary wedge pressure, but no difference in severe adverse events or 30-day mortality. Low statistical power due to small numbers precluded definitive conclusions.

Similar hemodynamic improvements have been demonstrated with the Impella 2.5 system in CS. Seyfarth et al. (91) randomly allocated 25 patients with AMI and cardiogenic shock to receive percutaneous support with an IABP or Impella 2.5 device. Early increases in cardiac index were greater with Impella (+0.49 L/(min m^2) vs. +0.11 L/min/m^2; $p = 0.02$). Similar to the TandemHeart data, 30-day mortality was high 46%) and not different between the two groups. Elective use of the Impella 2.5 system has been demonstrated to be safe in HR-PCI (92) although an earlier study raised some concerns about hemolysis and increased left ventricular volume after device activation (93).

A large observational study of the Impella 2.5 device in HR-PCI has been published (94). Most patients were extremely high risk, including inoperable patients with a high prevalence of chronic kidney disease, prior coronary artery bypass grafting, and severe LV dysfunction, as well as a high prevalence of NYHA class III to IV heart failure. Despite these risk factors, procedural success was high with a 90% success rate with multi-vessel revascularization and 8% rate of 30-day major adverse cardiac events. Survival was 91% and 88% at 6 and 12 months, respectively.

The PROTECT 2 trial is the largest single randomized clinical trial of HR-PCI using MCS ever performed and enrolled 452 symptomatic patients with complex three-vessel disease or unprotected left main coronary artery disease and severely depressed left ventricular function to IABP ($n = 226$) or Impella 2.5 ($n = 226$) support for HR PCI (95). The primary end point was a 30-day composite of 11 adverse events and was not significantly different between groups (Impella 35.1% vs. 40.1% IABP, $p = 0.227$) in the intent-to-treat population. The trial was stopped early for futility. Primary endpoint differences were greater in the per protocol population (34.3% Impella vs. 42.2% IABP, $p = 0.092$). Impella provided superior hemodynamic support in comparison with IABP, and at 90 days a trend toward decreased events was observed in the intent-to-treat population (40.6% Impella vs. 49.3% IABP, $p = 0.066$). Differences were magnified in the per protocol population (40.0% Impella vs. 51.0% IABP, $p = 0.023$) (90). A subsequent analysis redefining myocardial infarction as the development of new Q waves or CKMB more than eight times the upper limit of normal demonstrated lower rates of events in patients treated with Impella (composite event rate 37% vs. 49%, $p = 0.014$), respectively; and major adverse cardiac and cerebrovascular events 22% vs. 31%, $p = 0.034$) (96). Interestingly, this is consistent with the late mortality reduction demonstrated in BCIS-1 and has been the cause of intense speculation. The potential mechanism for late benefit may relate to more stable procedural hemodynamics allowing for greater and more complete revascularization, including allowing for more complex PCI procedures such as rotational atherectomy (97).

No comparable randomized trial of HR-PCI with the TandemHeart device exists. Alli et al. (98) reported a series of 54 patients using the TandemHeart for HR-PCI. All patients were deemed high risk for surgery and underwent complex PCI, with left main and multivessel stenting performed in 64%. Procedural success was high at 97%, and 6-month survival was 87%. Besides demonstrating the safety and feasibility of this device to allow complex intervention in a very high-risk, non-surgical group, hemodynamics improved during support, with a decrease in cardiac filling pressures and increase in cardiac output. No patient required hemodialysis but vascular complications occurred in 13%. Other small series of patients undergoing HR-PCI with TandemHeart support have also been reported (99,100).

It is important to note that the sickest patients with most significant hemodynamic compromise are clearly not readily enrolled in large clinical trials. Clinical

operators frequently empirically use commercially available MCS for hemodynamic support. Exclusion from enrollment of those candidates who would have been the most likely to benefit from enhanced MCS will decrease the power of clinical trials to detect outcome differences.

Extra-Corporeal Membrane Oxygenation (ECMO)

ECMO is part of a broader category termed extracorporeal life support (ECLS) (101). This term includes cardiopulmonary support, extracorporeal CO_2 removal, and ECMO. A common cardiac indication for ECMO is in patients with postcardiotomy syndrome and an inability to wean from cardiopulmonary bypass. ECMO has also been used to support patients with allograft failure following cardiac transplantation, fulminant myocarditis, and severe decompensated heart failure refractory to standard therapies. As a bridge to definitive therapy, ECMO has also been used in patients with cardiogenic shock from acute coronary syndromes and as a bridge to transplant with or without the use of other ventricular assist devices. Multiple reports of ECMO being instituted for cardiac arrest (102,103) exist, and the institution of ECMO for cardiovascular collapse and cardiac arrest is rapidly growing in popularity (104). A major advantage is the relative ease of implementation, but a disadvantage is the need for specialized perfusion expertise and nursing. Nichol et al. reviewed 84 studies of ECMO instituted for cardiogenic shock or cardiac arrest and showed an overall survival of 50% (105).

Analysis of the ELSO (Extracorporeal Life Support Organization) registry for ECMO used in the setting of adult cardiac arrest demonstrated a 27% survival to hospital discharge with the need for renal replacement therapy increasing odds of mortality (106). A more recent experience similarly found 49% survival with use of either MCS or ECMO in cardiogenic shock, with ongoing cardiopulmonary resuscitation a risk factor for increased mortality (107). There are no large randomized controlled trials with use of ECMO.

RECOMMENDATIONS FOR USE

When to Consider Mechanical Circulatory Support

For historic reasons, positive inotropes and vasopressors have been first-line therapy for hemodynamic instability and cardiogenic shock. Given the lack of data showing benefit with these agents, and the potential for harm with coronary and peripheral vasoconstriction, MCS may be considered in carefully selected patients with severe hemodynamically unstable cardiovascular presentations. **Table 1** lists the most common scenarios in which MCS may be used to provide hemodynamic support and bridge to recovery or definitive therapy. **Table 2** provides a guide for clinical use for HR PCI.

Timing of MCS insertion depends on the indication for use. For cardiogenic shock, a support device should be inserted as soon as possible, particularly if initial attempts with fluid resuscitation and pharmacologic support fail to show any significant hemodynamic benefit, and before PCI (110). Early initiation of MCS support can mitigate the consequences of systemic hypoperfusion, worsening ischemia, and declining cardiac function. Hemodynamic evaluation and monitoring with right heart catheterization is helpful in most cases.

For prophylactic support during elective, high-risk procedures, the device should be placed before the start of the intervention. If a patient is hemodynamically stable post-procedure, the device can usually be removed immediately. Patients who remain hemodynamically unstable post-procedure or those with cardiogenic shock may remain on percutaneous support until their hemodynamic status improves. Although these devices are labeled for as little as 6 h of use, they have been successfully employed for days or even weeks in selected cases of prolonged shock. A team approach with input from advanced heart failure specialists and VAD/transplant surgeons can facilitate decision making.

MCS Device Selection

Multiple factors must be considered when choosing MCS including: the hemodynamic condition of the patient, hemodynamic impact of the device, technical considerations including ease and rapidity of insertion, and the ultimate goals of support. In emergent situations (e.g. STEMI), IABP is often selected as the quickest and most familiar way to obtain some degree of hemodynamic stabilization, especially in the setting of AMI with pump failure. The initial effects of the IABP on coronary blood flow may be particularly desirable in this setting as well. However, the IABP often requires concomitant pharmacologic support to maintain hemodynamics in those with pump failure, and recent data raise questions about the efficacy and safety of IABP support in this setting (46,86,111,112). Operators familiar with the Impella may elect to insert this device instead in such patients, in order to minimize or obviate pressor use, reduce myocardial oxygen demand and improve systemic perfusion, thereby avoiding systemic shock. In experienced centers, insertion of an Impella 2.5 or CP device may be as rapid as an IABP.

If hemodynamic compromise occurs despite appropriate medical management and/or IABP, one may consider more powerful hemodynamic support devices such as an axial or centrifugal flow pump. Use of these devices requires an experienced team and may not be possible under all circumstances, particularly with adverse conditions. With experience the Impella 2.5 or CP can be inserted rapidly and provide a higher magnitude of support compared to

TABLE 1 Suggested Indications for Percutaneous MCS

Indication	Comments
Complications of AMI	Ischemic mitral regurgitation is particularly well-suited to these devices as the hemodynamic disturbance is usually acute and substantial. Acutely depressed LV function from large AMI during and after primary PCI is an increasing indication for temporary MCS use. Cardiogenic shock from RV infarction can be treated with percutaneous right ventricular support.
Severe heart failure in the setting of nonischemic cardiomyopathy	Examples include severe exacerbations of chronic systolic heart failure as well as acutely reversible cardiomyopathies such as fulminant myocarditis, stress cardiomyopathy, or peripartum cardiomyopathy. In patients presenting in INTERMACS profiles 1 or 2, MCS can be used as a bridge to destination VAD placement or as a bridge to recovery if the ejection fraction rapidly improves (108).
Acute cardiac allograft failure	Primary allograft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection, prolonged ischemic time, or inadequate organ preservation.
Post-transplant RV failure	Acute RV failure has several potential causes, including recipient pulmonary hypertension, intraoperative injury/ischemia, and excess volume/blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of inotropic and pulmonary vasodilator therapy (109).
Patients slow to wean from cardiopulmonary bypass following heart surgery	Although selected patients may be transitioned to a percutaneous system for additional weaning, this is rarely done.
Refractory arrhythmias	Patients can be treated with a percutaneous system that is somewhat independent of the cardiac rhythm. For recurrent, refractory, ventricular arrhythmias, ECMO may be required for biventricular failure.
Prophylactic use for high risk PCI	Particularly in patients with severe LV dysfunction (EF <20% to 30%) and complex coronary artery disease involving a large territory (sole-remaining vessel, left main or three vessel disease) (94,95,98).
High-risk or complex ablation of ventricular tachycardia	Similar to HR-PCI, complex VT ablation can be made feasible with percutaneous support. MCS use allows the patient to remain in VT longer during arrhythmia mapping without as much concern about systemic hypoperfusion.
High-risk percutaneous valve interventions	These evolving procedures may be aided with the use of MCSs.

an IABP. For patients who continue to deteriorate despite such support, TandemHeart using the larger arterial outflow cannula, ECMO, or surgical cutdown for delivery of an Impella 5.0 should be considered.

Operators must consider the advantages and disadvantages of initially selecting a device to achieve higher cardiac output by inserting it at the beginning of a high-risk procedure or at the early stages of ADHF or shock, and perhaps obviating peripheral and coronary vasoconstriction that accompany vasopressor therapy. In patients with cardiogenic shock and mechanical complications, the TandemHeart or Impella 5.0 offers the greatest cardiac output and hemodynamic support while the individual is evaluated for surgery. Inotropes may still be required to support RV function after placement of a left-sided support device. Patients with biventricular failure and/or impaired oxygenation may require ECMO support. Biventricular support with two different devices (e.g., TandemHeart for RV support and Impella or IABP for LV support) has also been reported.

Early MCS implantation before the patient requires multiple vasopressors is theoretically attractive but requires testing in controlled trials. Insertion of an Impella or TandemHeart device should permit completion of a revascularization procedure without hypotension and systemic hypoperfusion, reduce vasoconstriction more quickly, and achieve a greater likelihood of improved late survival. Such an approach is supported by recent guidelines (5).

Gaps in Knowledge

Given the limited prospective, randomized, multicenter data with MCS use, these recommendations must be tempered with understanding of knowledge gaps. The effects of percutaneous MCS on reducing LV stroke work and myocardial oxygen demand in acute myocardial infarction are poorly understood. MCSs may reduce infarct size and/or ischemic complications, but available clinical data so far does not support this indication.

In patients undergoing HR-PCI, more data are needed on subgroups of patients that may benefit from support (e.g., based on clinical or angiographic characteristics). Likewise, for patients with AMI complicated by cardiogenic shock, the limitations of IABP use are apparent. A phase III, multicenter, three-arm study comparing outcomes with IABP, MCS or neither, with power to

TABLE 2 Suggested Schema for Support Device in High-Risk PCI

Patient With Left Main, Last Remaining Conduit, or Severe Multivessel Disease	Anticipated Noncomplex PCI	Anticipated Technically Challenging or Prolonged PCI
Normal or mildly reduced left ventricular function	None	IABP/Impella as back up
Severe left ventricular dysfunction (EF <35%) or recent decompensated heart failure	IABP/Impella as back up	Impella or TandemHeart, choice dependent upon vascular anatomy, local expertise, and availability. ECMO for concomitant hypoxemia or RV failure.

A suggested schema for use of support devices for high-risk PCI based upon clinical and anatomic circumstances. The greater the likelihood of hemodynamic compromise or collapse the greater the potential benefit of MCS.

determine clinical outcome differences not only in short-term hemodynamics but also long-term survival, is needed. With the re-emergence of ECMO at many centers, the trade-offs between complete cardiopulmonary support versus complexity of intervention and monitoring and potential for complications and impaired myocardial protection need to be defined. On the other hand, partial LV support may offer benefits over current MCS technology in terms of ease of application and patient acceptability.

The potential advantages of these devices over pharmacologic therapy such as inotropes, with known adverse effects on myocardial oxygen consumption and cardiac rhythm, need to be determined in controlled studies. Finally, more development and clinical data are needed on RV support devices.

Cost Effectiveness

The support devices discussed in this document are expensive, with acquisition, disposable, and operating costs greatly exceeding that of the IABP. Costs incurred during both the initial hospitalization and any subsequent readmissions need to be considered. This is particularly true as most patients are older, have multiple comorbidities, and may experience prolonged hospital length of stays and high readmission rates. A recent European study modeled cost-effectiveness of an Impella in comparison with IABP using decision trees bases upon rates of endpoints reported in the literature. The Impella was associated with an incremental quality-adjusted life-year (QALY) between 0.22 (with Euro registry data) and 0.27 (with U.S. registry data). The incremental cost-effectiveness ratio (ICER) of the device varied between €38,069/$52,063 (with Euroregistry data) and €31,727/$43,390 (with U.S. registry data) per QALY compared with IABP, which is within conventionally accepted parameters of cost effectiveness (113).

A second study utilizing 2010–2011 MedPAR data evaluated the cost-effectiveness of emergency MCS for cardiogenic shock (N = 883) compared with surgical ECMO or VAD therapy (N = 305). MCS was associated with better survival to hospital discharge (56% vs. 42%, $p < 0.001$), reduced LOS (13.2 and 17.9 days, respectively, $p = 0.055$) and significantly lower inpatient costs ($90,929 and $144,257, respectively, $p < 0.001$) (114).

Future Directions: Myocyte Protection and Recovery

Another potential use of ventricular support is myocyte preservation during acute ischemic insult (115). Ventricular unloading may reduce myocardial infarct size through enhanced hemodynamics, preserved energetics, and activation of cardioprotective mechanisms (48,116). Despite limited unloading potency, some animal infarct model studies found improved myocyte recovery with IABP use (117,118). However, as described above, the CRISP-AMI study (101) found no difference in mean final infarct size between STEMI patients (not complicated by cardiogenic shock) who received routine IABP compared with those who did not. Animal studies of LV unloading with Impella appeared more favorable (56,119–121) and a preliminary clinical report of Impella for infarct size reduction in the STEMI setting was encouraging (122). The MINI-AMI (Minimizing Infarct Size with Impella 2.5 Following PCI for Acute Myocardial Infarction) trial sought to measure this benefit, but this study was terminated before completion (123). The TandemHeart device will be studied in a trial of similar design entitled TRIS (TandemHeart To Reduce Infarct Size) (Howard C, personal communication). This trial will test the hypothesis that left ventricular unloading before primary PCI will reduce infarct size. No human subject studies of ECMO have been announced to test efficacy in myocardial salvage but portable ECMO devices that have recently become available may have an important role to play in the future.

CONCLUSIONS AND SUMMARY

The availability of percutaneous MCS has broadened therapeutic options for patients that require hemodynamic support. A variety of devices are now available, each with specific technical and clinical nuances.

Unfortunately, definitive clinical evidence is in many cases either unavailable or controversial. We provide the following consensus-based summary statements based upon the anticipated hemodynamic effects and risks, clinical outcomes data as well as knowledge gaps.

1. Percutaneous MCS provides superior hemodynamic support compared to pharmacologic therapy. This is particularly apparent for the Impella and TandemHeart devices. These devices should remain available clinically and be appropriately reimbursed.
2. Patients in cardiogenic shock represent an extremely high risk group in whom mortality has remained high despite revascularization and pharmacologic therapies. Early placement of an appropriate MCS may be considered in those who fail to stabilize or show signs of improvement quickly after initial interventions.
3. MCS may be considered for patients undergoing high-risk PCI, such as those requiring multivessel, left main, or last patent conduit interventions, particularly if the patient is inoperable or has severely decreased ejection fraction or elevated cardiac filling pressures.
4. In the setting of profound cardiogenic shock, IABP is less likely to provide benefit than continuous flow

pumps including the Impella CP and TandemHeart. ECMO may also provide benefit, particularly for patients with impaired respiratory gas exchange.

5. Patients with acute decompensated heart failure may benefit from early use of percutaneous MCS when they continue to deteriorate despite initial interventions. MCS may be considered if patients are candidates for surgically implanted VADs or if rapid recovery is expected (e.g., fulminant myocarditis or stress-induced cardiomyopathy).
6. When oxygenation remains impaired, adding an oxygenator to a TandemHeart circuit or use of ECMO should be considered based upon local availability.
7. There are insufficient data to support or refute the notion that routine use of MCSs as an adjunct to primary revascularization in the setting of large acute myocardial infarction is useful in reducing reperfusion injury or infarct size. Exploratory studies are underway.
8. MCSs may be used for failure to wean off cardiopulmonary bypass, considered as an adjunct to high-risk electrophysiologic procedures when prolonged hypotension is anticipated, or rarely, for valvular interventions.
9. Severe biventricular failure may require use of both right- and left-sided percutaneous MCS or veno-arterial ECMO. Certain patients may respond to LVAD implantation with inotropes and/or pulmonary vasodilators to support the right heart. MCS may also be considered for isolated acute RVF complicated by cardiogenic shock.
10. Registries and randomized controlled trials comparing different strategies in different clinical scenarios are critically needed.
11. Early analyses suggest cost-effectiveness of MCS for emergent use in comparison to surgical ECMO or VAD support, and for elective use in comparison to IABP. Further data are necessary.

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KEY WORDS ACC Expert Consensus Document, cardiogenic, percutaneous coronary intervention, shock, ventricular assist device

APPENDIX A. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)–SCAI/ACC/HFSA/STS CLINICAL EXPERT CONSENSUS STATEMENT ON THE USE OF PERCUTANEOUS VENTRICULAR ASSIST DEVICES IN CARDIOVASCULAR CARE

Committee Member	Consultant	Speakers Bureau	Ownership/Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Srihari Naidu, MD	None	None	None	None	None	None
Charanjit Rihal, MD	None	None	None	None	None	None
James Burke, MD	None	None	None	None	None	None
James Goldstein, MD	None	None	None	None	None	None
Kirk Garratt, MD	None	None	None	None	None	None
Michael Givertz, MD	None	None	None	None	None	None
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Vivian Dimas, MD	None	None	None	None	None	None
Wilson Szeto, MD	None	None	None	None	None	None

This table represents relevant healthcare relationships of committee members with industry and other entities that were reported by authors at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10, 000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.acc.org/guidelines/about-guidelines-and-clinical-documents for definitions of disclosure categories or additional information about the ACC Disclosure Policy for Writing Committees.

[a]Significant relationship.

APPENDIX B. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (COMPREHENSIVE)–SCAI/ACC/HFSA/STS CLINICAL EXPERT CONSENSUS STATEMENT ON THE USE OF PERCUTANEOUS VENTRICULAR ASSIST DEVICES IN CARDIOVASCULAR CARE

Committee Member	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
Srihari Naidu, MD	None	None	None	None	None	None
Charanjit Rihal, MD	None	None	None	None	None	None
James Burke, MD	None	None	None	None	None	None
James Goldstein, MD	InfraReDx, Inc.[a]	None	None	None	None	None
Kirk Garratt, MD	Abbott Vascular Daiichi- Sankyo/Eli Lilly[a] MedLogics[a] Guided Delivery Systems[a] The Medicines Company Boston Scientific	Abbott Vascular Medtronic The Medicines Company Boston Scientific	None	None	None	None
Michael Givertz, MD	None	None	None	None	Biocontrol—Data Safety Monitoring Board	None
Morton Kern, MD	Merit Medical[a]	Volcano[a] St. Jude[a]			Chief Cardiology, LBVAH[b]	None Plaintiff 2010 Defendant
Navin Kapur, MD	Thoratec	None	None	CardiacAssist[a]	None	None
Thomas Tu, MD	None	None	None	None	None	None
Vivian Dimas, MD	None	None	None	None	None	None
Wilson Szeto, MD	MicroInterventional Device	None	None	Edwards Life Sciences	None	None

This table represents all healthcare relationships of committee members with industry and other entities that were reported by authors, including those not deemed to be relevant to this document, at the time this document was under development. The table does not necessarily reflect relationships with industry at the time of publication. A person is deemed to have a significant interest in a business if the interest represents ownership of ≥5% of the voting stock or share of the business entity, or ownership of ≥$10,000 of the fair market value of the business entity; or if funds received by the person from the business entity exceed 5% of the person's gross income for the previous year. Relationships that exist with no financial benefit are also included for the purpose of transparency. Relationships in this table are modest unless otherwise noted. Please refer to http://www.acc.org/guidelines/about-guidelines-and-clinical-documents for definitions of disclosure categories or additional information about the ACC Disclosure Policy for Writing Committees.
[a]Significant relationship. [b]No financial benefit.

APPENDIX C. PEER REVIEWER RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT)–SCAI/ACC/HFSA/STS CLINICAL EXPERT CONSENSUS STATEMENT ON THE USE OF PERCUTANEOUS MECHANICAL CIRCULATORY SUPPORT DEVICES IN CARDIOVASCULAR CARE

Committee Member	Representation	Consultant	Speakers Bureau	Ownership/ Partnership/ Principal	Personal Research	Institutional, Organizational, or Other Financial Benefit	Expert Witness
E. Murat Tuzcu, MD	ACC	None	None	None	None	None	None
Hector O. Ventura, MD	ACC	None	None	None	None	None	None
Anthony A. Bavry, MD	ACC	None	None	None	None	None	None
Hani Jneid, MD	ACC	None	None	None	None	None	None
Gurusher S. Panjrath, MD	ACC	None	None	None	None	None	None
Peter Eckman, MD	ACC	None	None	None	None	None	None
Sean Patrick Pinney, MD	ACC	None	None	None	None	None	None
Joaquin E. Cigarroa, MD	ACC	None	None	None	None	None	None
Robert N. Piana, MD	ACC	None	None	None	None	None	None
Ehtisham Mahmud, MD	ACC	Abiomed	None	None	None	None	None
Robert N. Vincent, MD	ACC	None	None	None	None	None	None
James B. McClurken, MD	ACC	None	None	None	None	None	None
Pasala S. Ravichandran, MBBS	ACC	None	None	None	None	None	None
George H. Crossley, III, MD	ACC	None	None	None	None	None	None
Marwan Refaat, MD	ACC	None	None	None	None	None	None
Glenn N. Levine, MD	ACC	None	None	None	None	None	None
Mariell Jessup, MD	ACC	None	None	None	None	None	None
Dmitriy N. Feldman, MD	SCAI	Maquet	None	None	None	None	None
Jeffrey Schussler, MD	SCAI	None	None	None	None	None	None
Jennifer Peura, MD	AHA	Abiomed	None	None	None	None	None
Scott Silvestry, MD	AHA	None	None	None	None	None	None
Robert Kormos, MD	STS	None	None	None	None	None	None
Joseph Cleveland, Jr., MD	STS	None	None	None	None	None	None
James C. Fang, MD	HFSA	Maquet	None	None	None	None	None
Gregory A. Ewald, MD	HFSA	None	None	None	None	None	None

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