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Defining the Role for Percutaneous Mechanical Circulatory Support Devices for Medically Refractory Heart Failure

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Abstract

Despite significant advances in the management of heart failure, short-term mortality due to advanced heart failure and cardiogenic shock remains unacceptably high. Developed over the past few decades, percutaneous circulatory support devices offer a rapid and effective approach to slow the downward spiral of hemodynamic instability in patients presenting with decompensated heart failure until a more definitive strategy is pursued or patients recover. This review will discuss the goals of percutaneous circulatory support, the types of devices currently available, and the most recent clinical datasets examining the utility of these devices.

Keywords

Percutaneous mechanical support; Impella; TandemHeart; ECMO; cardiogenic shock; refractory heart failure; assist device

Introduction

Over the past 50 years, innovations in the fields of cardiac surgery, interventional cardiology, and heart failure/transplant medicine have redefined the term ‘advanced heart failure’. Each year, nearly 500,000 new patients are diagnosed with heart failure, leading to a massive cumulative increase in the heart failure population that now includes nearly 2.6 % of the population in the United States [1, 2]. Consistent with this observation, advances in coronary intervention have significantly reduced in-hospital mortality due to acute myocardial infarction (AMI) and, as a result, nearly 25 % of patients surviving an AMI ultimately develop systolic heart failure [3]. Furthermore, advances in surgical ventricular assist device (VAD) technology have redefined the term medical futility in heart failure and opened the door for more supportive therapies for patients with New York Heart Association Class III and IV symptoms. As a result, the number of VAD recipients has also grown over the past decade. This increasing population of heart failure patients has led to a growing demand for mechanical support options to manage medically refractory heart failure. Percutaneously delivered circulatory support devices have evolved over the past 30 years to now include pulsatile, axial-flow, and centrifugal-flow options that can be rapidly deployed in patients

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with advanced heart failure and cardiogenic shock (Fig. 1). Since these devices are commonly deployed by interventional cardiologists, the approach to the advanced heart failure patient now requires a multi-disciplinary understanding of an individual's hemodynamic condition and candidacy for revascularization, surgical VAD or cardiac transplantation.

Goals of Percutaneous Mechanical Support and Device Options

In the advanced heart failure patient, the left ventricular pressure-volume loop shows an increase in end-diastolic and systolic volume and an increase in load-independent contractility or end-systolic elastance. With medical therapy to optimize preload and afterload, the majority of heart failure patients will generate a normal stroke volume and can sustain systemic perfusion despite a low left ventricular ejection fraction. However, when a patient develops acutely decompensated heart failure or cardiogenic shock, left ventricular volumes may increase, and end-systolic elastance progressively decline. In these cases, inotropic and vasopressor support are often required to maintain systemic perfusion. In medically refractory heart failure, mechanical support may be required (Fig. 2a).

The overall goals of percutaneous circulatory support systems are to: (1) improve native cardiac output, (2) augment coronary perfusion, (3) reduce ventricular volume and filling pressures, thereby reducing wall stress, stroke work, and myocardial oxygen consumption, and (4) maintain vital organ perfusion. Clinical scenarios where these devices are commonly deployed include: moderate to severe cardiogenic shock; mechanical complications following AMI; high risk coronary and non-coronary intervention; and for high-risk electrophysiologic ablations (Table 1).

Percutaneous circulatory support devices can be categorized by the type of pump used to generate either pulsatile or continuous blood flow. Each device impacts native ventricular function in a unique way and requires adequate preload for optimal use. The intra-aortic balloon pump (IABP) is a catheter-mounted balloon that augments pulsatile blood flow by inflating during diastole, which displaces blood volume in the descending aorta and increases mean aortic pressure, thereby potentially augmenting coronary perfusion [4]. Upon deflation, during systole, the IABP generates a pressure sink, which is filled by ejecting blood from the heart. As a result, the net effect of an IABP reduces ventricular afterload leading to an increase in mean arterial pressure and an augmentation in ventricular stroke volume (Fig. 2b). More recently, larger capacity IABPs, known as the Mega Series (Maquet Inc), have been introduced into clinical practice. Advantages of IABPs include: ease of insertion, global familiarity with the technology, and relative cost.

Both the Impella (Abiomed Inc) and TandemHeart (CardiacAssist Inc) devices are rotodynamic pumps that generate continuous, minimally pulsatile blood flow when functioning optimally. The Impella devices are catheter-mounted axial-flow pumps that are placed into the left ventricle in retrograde fashion across the aortic valve [5, 6]. The pump transfers kinetic energy from a circulating impeller to the blood stream, which results in continuous blood flow from the left ventricle to ascending aorta. The Impella 2.5 LP and CP devices can be deployed without the need for surgery, while the Impella 5.0 device requires

surgical vascular access. There is limited experience with the CP device in the United States. More recently, preclinical data for another axial-flow catheter design, the percutaneous heart pump (PHP; Thoratec Inc) was reported [7]. In contrast to axial-flow catheters, the TandemHeart device [8] is an extra-corporeal centrifugal flow pump that reduces left ventricular *preload* by transferring oxygenated blood from the left atrium to the descending aorta via two cannulas: a trans-septal inflow cannula in the left atrium and an arterial outflow cannula in the femoral artery. The net effect of both devices is to reduce native left ventricular volume and pressure, while increasing mean arterial pressure without greatly influencing ventricular afterload (Figure 2B). Advantages of the Impella 2.5 and CP devices is ease of insertion via a single arterial access, while an advantage of the TandemHeart device is the magnitude of support provided without the need for surgical vascular access. No studies comparing these continuous flow devices head-to-head exist.

Other centrifugal pumps include the Centrimag (Thoratec), Rotaflow (Maquet), and Biomedicus (Medtronic) pumps, which are more commonly implanted surgically or used to provide flow for veno-arterial extra-corporeal membrane oxygenation (VA-ECMO). VA-ECMO is more commonly used to enhance systemic oxygenation during cardio-respiratory collapse or biventricular failure [9]. The major effect of VA-ECMO is to displace blood volume from the venous to the arterial circulation. As a result, a reduction in both right and left ventricular volumes can be observed with a concomitant increase in left ventricular afterload (Fig. 2b). This increase in afterload contrasts with left atrial to femoral artery bypass pumps since there is no direct venting of the left ventricle with VA-ECMO. For this reason, some operators have combined VA-ECMO with use of the Impella 2.5 to reduce any negative effects of increased left ventricular afterload during VA-ECMO use [10]. Advantages of VA-ECMO include the relative ease of insertion and ability to support systemic oxygenation.

Clinical Trials

Clinical trials examining the utility of percutaneous circulatory support devices have failed to identify reduced in-hospital mortality associated with device use in the setting of high-risk PCI or cardiogenic shock. Perhaps the most aggressively studied of these devices is the IABP with decades of clinical experience and registry data supporting its use since its first application in clinical practice in 1968 [11]. However, recent studies attempting to identify optimal candidates for IABP support in high risk PCI, acute MI, or cardiogenic shock have shown no significant benefit to elective IABP insertion. The CRISP-AMI trial [12] showed that IABP implantation immediately prior to revascularization for an anterior ST-elevation myocardial infarction did not reduce infarct size or improve short-term survival. Interestingly, 6-month follow up data did show a trend towards benefit with pre-reperfusion IABP use. This early observation of a trend towards decreased mortality with IABP support in AMI was recently supported by a follow up analysis of the Balloon-pump assisted Coronary Intervention Study (BCIS-1), which showed a 34 % relative reduction in all cause mortality with elective IABP use in patients with severe ischemic cardiomyopathy undergoing high risk PCI [13]. The IABP-SHOCK II study [14] was another important and large trial that effectively showed that not all patients presenting with an acute coronary syndrome (ACS) with marginal blood pressures and clinical evidence of hypoperfusion

should receive an IABP. In this study, trends towards benefit with IABP use were observed in younger patients with anterior myocardial infarction, no hypertension, and no prior infarction. The importance of this trial is that it confirms what most catheterization laboratories already practice, namely, to avoid non-discretionary use of an IABP in ACS. Taken together, these trials suggest that the maximal benefit of IABP support is likely to be observed in patients with acute or chronic heart failure who present with decompensated hemodynamic status.

For the Impella device, two large registries have also confirmed the safety of the Impella 2.5 LP device [15–16]. The ISAR-SHOCK trial was a small randomized clinical trial of Impella 2.5 compared to IABP in patients with cardiogenic shock [17]. It demonstrated a significantly improved hemodynamic profile after 30 minutes of deployment, with a change in cardiac index of 0.49 ± 0.46 l/min/m² compared to a change of 0.11 ± 0.31 l/min/m² in the IABP group following device deployment. There was no change in mortality rate at 30 days, reported at 46 % in both groups [17]. Similarly, the recently published PROTECT II study [18] was terminated early due to a determination of futility. No difference in major adverse cardiovascular events (MACE) was observed between IABP and Impella 2.5 for patients undergoing high risk PCI. The RECOVER I multicenter trial [19] yielded promising results with the use of surgically deployed Impella 5.0 device for postcardiotomy circulatory support, with a 30-day survival rate of 94 %.

The safety and efficacy of the TandemHeart assist device over IABP was clinically assessed in a small number of cardiogenic shock patients, mostly due to AMI, in a multicenter randomized clinical trial in which the TandemHeart device significantly improved hemodynamic parameters [20]. Similar favorable hemodynamic profiles with no mortality benefit over IABP were noted in an earlier trial by Thiele et al. [21]. Kar et al. recently published their experience with the use of TandemHeart in 117 patients with severe cardiogenic shock refractory to IABP and pressor support [22]. Patients had significant improvement in their hemodynamic profiles including mean arterial pressure, pulmonary capillary wedge pressure, and mixed venous oxygen saturation; along with improvement in end-organ perfusion evident by decreasing lactate levels and increasing urine outputs. In this study 40.2% of patients died within 30 days after device implantation [22], which is lower than previously reported mortality rates in the SHOCK trial [23]. An important meta-analysis of smaller studies evaluating these continuous flow devices for cardiogenic shock showed improved hemodynamic profiles associated with the Impella and TandemHeart devices compared to IABP; however showed no difference in short-term mortality (24). These data leave open many questions about the optimal magnitude, timing, and type of percutaneous mechanical support for patients with cardiogenic shock. In addition to their use as a bridge to recovery, several recent case reports and series report increasing utilization in clinical practice of Impella and TandemHeart devices as a part of a ‘bridge-to-decision’ strategy to allow time for full assessment of end-organ recovery, and VAD or transplant candidacy. No studies have specifically addressed the role of percutaneous circulatory support devices in the advanced heart failure patient being considered for surgical VAD or cardiac transplantation.

No large randomized clinical trials have assessed the use of ECMO in cardiogenic shock. Several observational studies reported favorable hemodynamic profiles. In a rare study, Combes et al. [25] studied the use of ECMO in refractory cardiogenic shock and demonstrated a long term survival rate of 36 %.

The findings of previously published studies suggest the need for a more comprehensive examination of how these devices impact native ventricular function and based on this information, how best to match patients with the appropriate device. For example, a common thread missing from all of these trials is an assessment of the patient's hemodynamic status prior to device deployment. Since these devices effectively 'unload' the heart of excess volume congestion and pressure overload, it would seem that measuring these variables prior to device deployment may help identify 'responders' versus 'non-responders'. As is commonly appreciated in the catheterization lab, hypotension and low systemic perfusion does not always equal massively elevated cardiac filling pressures. As a result, deploying any of these devices in patients with normal or low cardiac filling pressures would potentially have minimal impact on systemic perfusion. Similar to their surgical counterparts, percutaneously delivered circulatory support devices are sensitive to preload and afterload. For these reasons, trial design specialists and clinicians may consider including measures of baseline hemodynamics as part of their enrollment criteria to identify the 'hemodynamically-loaded' patient who might best respond to a mechanical 'unloading' therapy.

Right Heart Failure

The critical importance of right ventricular (RV) function in the advanced heart failure populations has become more apparent over the past few decades. In the setting of LV failure, acute myocardial infarction (AMI), pulmonary hypertension, congenital heart disease, or acute pulmonary embolus, concomitant RV dysfunction is associated with higher morbidity and short-term mortality [26–33]. Furthermore, despite advances in left sided therapeutic options, the presence of RV dysfunction remains a major cause of mortality after heart transplantation and LVAD placement. Among heart transplant recipients, 2–3 % of patients will develop some degree of RV dysfunction in the perioperative setting, which is associated with a 4 to 5 fold increase in short-term mortality [34]. Among LVAD recipients, the incidence of RV failure ranges from 5 % to 44 % and depends on the criteria used to define RV failure. Among patients with RV failure after LVAD placement, a RV support device was required in 16 % to 100 % of subjects and in-hospital mortality ranged between 24 % to 83 % [35]. These findings highlight the importance of RV failure in the advanced heart failure population.

Contemporary management of RV failure includes reversal of the primary cause, volume resuscitation, inotropic support, and pulmonary vasodilation which serve to maintain RV preload, enhance RV contractility, and reduce RV afterload respectively [36]. In refractory RV failure, treatment options are limited to surgical RV assist devices (RVAD), extracorporeal membrane oxygenation (ECMO), atrial septostomy, and cardiac transplantation. Percutaneously delivered circulatory support for RV failure is an emerging field with several device options available including the intra-aortic balloon pump (IABP),

[37] the TandemHeart RVAD (TH-RVAD) [38], and veno-arterial ECMO (VA-ECMO). More recently the Impella RP axial flow catheter was introduced in Europe for RV failure, however no published studies on this device exist at this time.

At present, minimal data exploring the clinical utility of percutaneous RV support devices exists. Several studies have shown the potential benefits of centrifugal flow pumps in RV failure using surgical and hybridized surgical-percutaneous deployment with the Centrimag (Thoratec Inc) [39] and the Rotaflow (Maquet Inc) [40] pumps, respectively. A single-center experience with percutaneous deployment of the TH-RVAD in nine patients with medically refractory RV failure identified that compared to pre-procedural values, mean arterial pressure (57 ± 7 vs. 75 ± 19 , $p<0.05$), right atrial pressure (22 ± 3 vs 15 ± 6 , $p<0.05$), cardiac index (1.5 ± 0.4 vs. 2.3 ± 0.5 , $p<0.05$), mixed venous oxygen saturation (40 ± 14 vs. 58 ± 4 , $p<0.05$) and right ventricular stroke work (3.4 ± 3.9 vs. 9.7 ± 6.8 , $p<0.05$) improved significantly within 24 hours of TH-RVAD implantation. In-hospital mortality among nine patients was 44% ($n=4$). Time from admission to TH-RVAD placement was lower in subjects who survived to hospital discharge (0.9 ± 0.8 vs. 4.8 ± 3.5 days, $p=0.04$, survivors vs. non-survivors) [41]. More recently, the TandemHeart in Right VEntricular support (THRIVE) study was a retrospective, observational registry of 46 patients receiving a TH-RVAD for RV failure in eight tertiary care centers in the United States [42]. The central finding of this report was that implantation of the TH-RVAD is clinically feasible via both surgical and percutaneous routes and is associated with acute hemodynamic improvement in RV failure across a broad variety of clinical presentations. In-hospital mortality varied widely amongst different indications for mechanical RV support and was lowest among patients with RV failure in the setting of AMI or after LVAD implantation. Increased age, biventricular failure, and TIMI major bleeding were more commonly observed in patients not surviving to hospital discharge. As experience with percutaneous RV support devices grows, their role in the armamentarium of the mechanical therapies for RV failure will depend less on the technical ability to place the device, but rather on improved algorithms for patient selection, patient and device monitoring, and weaning protocols.

Defining the Role of Percutaneous Mechanical Support Devices

No algorithms to specifically address the role of circulatory support devices in advanced heart failure or cardiogenic shock exist. Irrespective of the etiology, the use of percutaneous assist devices is intended to provide short term hemodynamic biventricular support for left and/or right heart failure. These devices can play an instrumental role in stabilizing the advanced heart failure patient so that an appropriate 'exit strategy' is identified. These 'exit strategies' may include recovery of the patient, implantation of a more durable, surgically-implanted VAD, or cardiac transplantation. By slowing the downward spiral from decompensated heart failure to cardiogenic shock and death, the role of percutaneous circulatory support will likely become more important over time. At this time, these devices should be considered for patients with New York Heart Association Class III or IV heart failure symptoms who are currently failing medical therapy alone. Consistent with this approach, the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) has defined seven clinical profiles before implantation of a surgical VAD [43]. Cardiogenic shock is identified by INTERMACS profiles 1 and 2. INTERMACS

profile 1 “Crash and burn” includes patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels. INTERMACS profile 2 “Sliding on inotropes” includes patient with declining function despite intravenous inotropic support, manifested by worsening renal function, nutritional depletion, and an inability to restore volume balance. For INTERMACS I and 2 profiles, percutaneous circulatory support should be considered. Several key principles should guide decision making and include: (1) a careful assessment of a patient’s hemodynamic status including biventricular filling pressures, cardiac index, and systemic perfusion, (2) rapid initiation of medical therapy including inotropes and vasopressors, (3) close monitoring for evidence of medically refractory heart failure, thereby leading to early escalation to a mechanical support strategy, which may include an IABP or going directly to a percutaneously deployed continuous flow device, and (4) continuous hemodynamic monitoring after device deployment to identify patients who may require more aggressive support options including surgical VAD deployment. Given the complexity of patients with advanced heart failure, a multidisciplinary discussion should be held in advance of device deployment with a consensus opinion from physicians representing heart failure/transplant, cardiac surgery, and interventional cardiology.

Conclusions and Future Directions

As device innovation in the domain of circulatory support continues to expand to include options for the failing right ventricle, interventionalists are now being asked to return to their roots in invasive hemodynamics and think more like heart failure specialists. This potent hybridization of interventional cardiology and heart failure may ultimately yield the best approach to managing patients with advanced heart failure and cardiogenic shock.

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Figure 1. Schematic representation of commonly used percutaneous mechanical circulatory support devices used in medically refractory heart failure. A: Intra-aortic balloon pump, B: Impella®, C: TandemHeart™. From Desai NR and Bhatt DL, “Evaluating percutaneous support for cardiogenic shock: data shock and sticker shock,” *European Heart Journal* (2009) 30, 2073–2075, by permission of Oxford University Press.

Figure 2.**Hemodynamics of Mechanical Circulatory Support**

A) Hemodynamics of Percutaneous Circulatory Support Devices in the Pressure Volume (PV) Domain. Each PV loop represents one cardiac cycle (Point 1: end-systolic isovolumic relaxation; Point 2: end-diastolic filling; Point 3: peak of isovolumic contraction; Point 4: end-systolic ejection). Stroke volume (SV) is represented by the width of the PV loop as the difference between end-systolic and end-diastolic volumes (Point 1 – Point 2). Load-independent contractility also known as end-systolic elastance (Ees), is defined as the maximal slope of the end-systolic pressure-volume relationship. Effective arterial elastance (Ea) is a measure of afterload and is defined as the ratio of end-systolic pressure and stroke volume. In Compensated Heart Failure, Ees is reduced and LV volumes are increased, however SV and LV end-diastolic pressure (LVEDP) may be normal. In Decompensated HF/ Shock, Ees and SV are significantly reduced, while LV volumes and LVEDP are increased.

B) Illustrations of PV loops showing the primary hemodynamic impact of each percutaneous circulatory support devices. Intra-aortic balloon pump (IABP) counterpulsation reduces Ea and increases SV. The Impella and TandemHeart devices reduce native LV volumes and SV. Veno-arterial Extra-corporeal Membrane Oxygenation (ECMO) reduces native SV and increases Ea.

Table 1

Indications and Contraindications of Percutaneous Mechanical Circulatory Support

Indications of Mechanical Circulatory Support	
Moderate to severe cardiogenic shock	
<ul style="list-style-type: none"> • Acute myocardial infarction • Acute myocarditis • Post-cardiotomy • Postpartum cardiomyopathy • Decompensated chronic heart failure • Acute rejection following cardiac transplantation 	
Mechanical complications of acute myocardial infarction	
<ul style="list-style-type: none"> • Ventricular septal defects • Ischemic mitral regurgitation 	
High- risk percutaneous coronary intervention	
High- risk non-coronary interventions	
<ul style="list-style-type: none"> • Aortic valve replacement 	
High- risk electrophysiologic conditions	
<ul style="list-style-type: none"> • Refractory or recurrent ventricular tachycardia • High- risk ventricular tachycardia ablation 	
Contraindications of Mechanical Circulatory Support	
Prolonged cardiopulmonary resuscitation with inadequate perfusion	
<ul style="list-style-type: none"> • Advanced age • Advance malignancy • Existing organ dysfunction (advanced chronic obstructive pulmonary disease, interstitial lung disease, liver cirrhosis, dementia, and prior stroke with significant disability) 	
Relative Contraindications	
<ul style="list-style-type: none"> • Contraindication to anticoagulation • Severe peripheral vascular disease 	
Device Specific Contraindications	
IABP	
<ul style="list-style-type: none"> • Severe aortic regurgitation • Large abdominal aortic aneurysm • Aortic dissection 	
Impella	
<ul style="list-style-type: none"> • LV mural thrombus • Moderate to severe aortic stenosis • Moderate to severe aortic regurgitation • The presence of a mechanical aortic valve 	

Indications of Mechanical Circulatory Support	
<ul style="list-style-type: none">• Abnormalities of the aorta: Aneurysm, heavy calcification, or extreme tortuosity• Recent stroke or TIA in the past 3 months	
TandemHeart	
<ul style="list-style-type: none">• Right-sided heart failure• Moderate to severe aortic regurgitation	
ECMO	
<ul style="list-style-type: none">• Mechanically ventilated patients for longer than 7 days	

Table 2

Complications of Percutaneous Mechanical Circulatory Support:

General Complications of Mechanical Circulatory Support	
•	Bleeding
•	Infection and sepsis
•	Limb ischemia
•	Neurologic insult
Device Specific Complications	
IABP	
•	Malposition: Risk of obstructing subclavian, renal, or mesenteric arterial blood flow
•	Aortic rupture or dissection
•	Air or plaque embolism
•	IABP rupture
Impella	
•	Aortic valve injury
•	Aortic valve insufficiency
•	LV puncture causing tamponade/rupture
•	Ventricular arrhythmias
TandemHeart	
•	Antegrade or retrograde cannula migration
•	LA puncture causing tamponade
•	Mechanical injury to the IVC
•	Potential of inter-atrial shunt after device removal
ECMO	
•	Thrombosis of the ECMO circuit
•	Systemic gas embolism
•	Potential for circuit rupture and hemorrhage
•	Upper body hypoxia due to incomplete retrograde oxygenation
•	Progressive LV dilation
•	Failure of oxygenator