Mechanical Circulatory Support for the Failing Heart: Which Device to Choose

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Abstract
Critical cardiogenic shock remains a problem with staggering mortality, with the best hope of survival depending on timely and aggressive intervention. This often requires the use of extracorporeal mechanical support in addition to vasoactive medications to manage patients through their initial insult. The decision to use such support must be made early in the clinical presentation, and is best done in a multidisciplinary fashion. In this article, we review the literature and provide an algorithm for the treatment of cardiogenic shock.

Keywords: cardiogenic shock; extracorporeal support; temporary mechanical circulatory assist

Introduction
The spectrum of acute heart failure syndromes (AHFS) continues to broaden and frequently includes those with cardiogenic shock (CS). Despite advances in pharmacotherapy and revascularization techniques, these syndromes exert a tremendous mortality risk. Traditionally, support has been focused on the use of intra-aortic balloon pump (IABP) insertion along with vasoactive medication to improve hemodynamics in this population in an effort to improve outcomes. More recently, however, a number of percutaneous devices with greater hemodynamic support profiles have been introduced, providing the clinician with more options to treat those with AHFS complicated by CS. In this new landscape, effectively and efficiently selecting the appropriate device for mechanical circulatory support (MCS) can be challenging, requiring the publication of updated consensus statements [1]. In this article, we aim to provide guidance on the appropriate use of these devices and how best to incorporate their implantation into a multidisciplinary care team approach.

Acute Heart Failure Syndromes and Medical Therapy
Historically, patients with AHFS have had a wide ranging risk of mortality, largely based on initial presentation. Data from the Acute Decompensated Heart Failure National Registry (ADHERE) registry show inpatient mortality as high as 21.9% in those who have elevated blood urea nitrogen and creatinine levels in the setting of hypotension [2]. Those who present with an AHFS complicated by frank CS have a dismal prognosis, with more contemporary registry data suggesting that two of every three such patients will fail to survive to discharge [3]. The need for, and the timing of, vasoactive medication...
administration can further refine one’s risk of inhospital death. Data from ADHERE suggest that early vasoactive medication administration, within 6 h of presentation, reduces the risk of mortality, with the adjusted odds of death increasing by 6.8% with each 6-h incremental delay in treatment [4]. Additionally, the type of vasoactive medication required, vasodilators versus inotropic support, has also been demonstrated to predict outcomes in a hospitalized group of patients, with those requiring inotropic support noted to have worse survival [5]. The dose and number of inotropic agents required to maintain relative stability also correlates with outcomes, with a mortality rate of 80% in patients requiring three agents at a high dose [6].

Although these data paint a bleak picture for the management of AHFS, they do indicate that earlier recognition of shock syndromes and rapid initiation of therapies, as well as the magnitude of medical intervention, profoundly impact outcomes in this population. Therefore, the clinician is provided with an opportunity to quickly risk-stratify patients and identify those who may benefit from escalation of care with the addition of MCS and transfer to an advanced heart failure center.

**Acute Heart Failure Syndromes and Mechanical Circulatory Support**

Although first described nearly 50 years ago [7], the IABP continues to be the mainstay of temporary MCS in clinical practice. The IABP system consists of a dual-lumen catheter and balloon connected to a pump. One lumen is connected directly to the pump and fills with helium with each inflation. The other lumen allows aortic pressure transduction and access for guidewire insertion. Balloon inflation occurs with the start of diastole, followed by rapid deflation with the start of systole. Timing has traditionally been based on electrocardiogram or pressure triggers, with the former using the midpoint of the T wave for inflation and the start of the R wave for deflation. Arrhythmias and tachycardia can perturb this method of counterpulsation timing. However, newer fiber-optic catheters, which can improve timing algorithms, are now available in sites of 7F to 9F, with displacement capacities of 30–50 mL [8, 9].

IABP counterpulsation has a number of hemodynamic effects, including decreased afterload, diastolic blood pressure augmentation which improves coronary arterial perfusion, and a direct unloading of the left ventricle [10]. Despite these potential benefits, clinical trial data have been less than robust in regard to the hemodynamic impact of IABP placement in CS. The IABP Cardiogenic Shock Trial found no difference with IABP use in comparison with medical therapy in a small group of patients with acute myocardial infarction complicated by CS [11]. Serial hemodynamic measurements over a 96-h period demonstrated no significant change in various parameters, including mean arterial pressure, cardiac output, left ventricular (LV) stroke work index, or cardiac power output. Although not used extensively in the clinical setting, cardiac power output, defined as mean arterial pressure × cardiac output/451 and reported in watts, has been demonstrated to hold prognostic value in CS patients as the strongest independent hemodynamic predictor of inpatient death [12]. These disappointing results were followed by the results of the IABP-SHOCK II trial, a prospective and randomized study of 600 patients, which demonstrated no mortality benefit with IABP placement in a similar patient population [13]. In this analysis, there was no difference in serum lactate levels with the use of an IABP, suggesting no change in end-organ perfusion, confirming the hemodynamic results seen in its predecessor. Longer 12-month results also revealed no difference with IABP use [14].

These data suggest that the IABP may have limited utility in those individuals who have critical CS. There is, however, evidence that its use may be of benefit in high-risk percutaneous coronary intervention as it pertains to the prevention of intraprocedural hypotension and improvement in long-term mortality in select patients [15, 16].

More robust percutaneous MCS is available in the form of the TandemHeart (CardiacAssist, Pittsburgh, PA, USA) and Impella (Abiomed, Danvers, MA, USA) devices, best thought of as percutaneous ventricular assist devices (pVADs) (Table 1). The TandemHeart (Figure 1) is a left atrial to femoral artery bypass system. Venous access is obtained via a 21F cannula, which is then placed transseptally in the left atrium. This cannula is attached to
Table 1 Percutaneous Mechanical Circulatory Support Options.

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>IABP</th>
<th>Impella</th>
<th>TandemHeart</th>
<th>ECMO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion</td>
<td>Pneumatic counterpulsation</td>
<td>Microaxial, continuous flow</td>
<td>Centrifugal, continuous flow</td>
<td>Centrifugal, continuous flow</td>
</tr>
<tr>
<td>7F to 9F femoral artery</td>
<td>12F to 15F femoral artery</td>
<td>21F inflow femoral vein, 15F to 17F outflow femoral artery</td>
<td>18F to 31F inflow femoral vein, 15F to 22F outflow femoral artery</td>
<td></td>
</tr>
<tr>
<td>Benefits</td>
<td>Ease of insertion, rapid, universal</td>
<td>Multiple platforms, greater degree of hemodynamic support</td>
<td>Greater degree of hemodynamic support</td>
<td>Greater degree of hemodynamic support, can be placed at the bedside</td>
</tr>
<tr>
<td>Special considerations</td>
<td>Contraindicated with AI</td>
<td>Small changes in position can affect flow. Monitor for hemolysis. Greater degree of support requires surgical cutdown</td>
<td>Monitor for hemolysis. May require antegrade perfusion sheath to avoid limb ischemia</td>
<td>Requires surgical support and perfusionist. May require antegrade perfusion sheath to avoid limb ischemia</td>
</tr>
</tbody>
</table>

AI, aortic insufficiency; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump.

Figure 1 The TandemHeart System. Illustration of the centrifugal pump, inflow and outflow cannulation (left), and the transeptal position of the inflow cannula. Courtesy of CardiacAssist.

A centrifugal pump, controlled by an external console, which removes oxygenated blood from the left atrium and returns it to the arterial circulation via a 15F or 17F arterial return cannula which is capable of delivering a flow rate of up to 5 L/min.

The TandemHeart system effectively reduces LV preload, wall stress, and myocardial oxygen demand [17, 18]. In a comparison of the IABP and the TandemHeart in 41 patients with CS following acute myocardial infarction, the TandemHeart system provided better hemodynamic improvements as assessed by changes in cardiac output, systemic vascular resistance, and cardiac power index [19]. Serum lactate levels were also significantly improved, suggesting greater end-organ perfusion and an initial reversal of CS in the TandemHeart group as compared with support with an IABP. This was at the expense of increased bleeding and limb ischemia, owing to its larger profile, but did not provide a mortality advantage in this small study. A larger, albeit retrospective, single-center analysis further demonstrated the hemodynamic superiority of the TandemHeart in 117 patients with CS refractory to vasopressor and IABP support [20]. Over an average duration of support of nearly 1 week, cardiac index, systolic blood pressure, and urine output all increased. More precise markers of end-organ perfusion, such as mixed venous oxygenation and lactate levels, were also significantly improved. Although 6-month mortality remained high at 45.3%, nearly half of these patients were undergoing active cardiopulmonary resuscitation immediately before or during implantation of the TandemHeart, demonstrating the severity of illness in this population. This helps to establish the utility of more robust percutaneous MCS in those patients who do not respond to initial, more conservative measures. In particular, this can be an invaluable method of bridging patients to a more definitive treatment – namely, durable LV assist device (LVAD) implantation.
The Impella is also a commercially available pVAD which provides axial flow from the left ventricle into the ascending aorta (Figure 2). There are three versions available, with the 2.5 and CP devices, 12F and 15F, respectively, placed percutaneously via the femoral artery. The Impella 2.5 can provide a flow rate of up to 2.5 L/min, with the Impella CP capable of providing up to 4 L/min. A larger device (Impella 5.0) is also available, which requires a surgical cutdown and can alternatively be placed into the subclavian artery for more stable positioning and longer-term support [21]. As the name suggests, this device can provide a flow rate of up to 5 L/min. When it is placed from the femoral artery, insertion is similar to the placement of an IABP, over a wire into the aorta and across the aortic valve, with the distal end of the Impella having a pigtail loop which is taken into the left ventricle. Connected to this is the blood inlet area, followed by the outlet area and the motor housing. Via axial flow, blood is withdrawn from the left ventricle and propelled into the ascending aorta, thereby directly unloading the left ventricle. This provides decreased wall stress in addition to other beneficial hemodynamic effects such as a decrease in pulmonary capillary wedge pressure and increased coronary perfusion pressure and flow, and a resultant decrease in myocardial oxygen demand [22, 23]. Although these data, and much of the available literature on the Impella system, are taken from the Impella 2.5 and its use in high-risk percutaneous coronary intervention, there are emerging data regarding the more powerful platforms. A small single-center study of 34 patients with profound CS in the setting of acute myocardial infarction suggested improved survival with the Impella 5.0 compared with the Impella 2.5, in both those in whom the larger device was initially implanted and those who received an upgrade [24]. The Impella 5.0 has also been demonstrated to provide equivalent, if not superior, outcomes in critical CS when compared retrospectively with extracorporeal membrane oxygenation (ECMO) [25]. In general, for the management of critical CS, the Impella CP and Impella 5.0 should be considered as the Impella 2.5 is unlikely to provide the needed hemodynamic support to improve outcomes.

Although there are promising data regarding the role of pVADs in critical CS as it pertains to hemodynamic and metabolic improvements, there has yet to be demonstrated a mortality benefit with these devices. A meta-analysis of three prospective trials comparing pVADs with IABPs confirmed superiority of the former in regard to hemodynamic parameters, without a resultant improvement in 30-day mortality [26]. However, this was an analysis of 100 patients, and larger trials, with improved power, are likely necessary to adequately address the issue of mortality.

Figure 2 Impella Devices.
The Impella CP (left) and Impella 5.0 (right) catheters. Courtesy of Abiomed.
ECMO, and the large class of extracorporeal life support, provides full life support and devices can be placed at the bedside without the aid of fluoroscopy. Venovenous ECMO provides gas exchange with circulatory support and is not of utility in CS. Venoarterial ECMO, however, offers full cardiopulmonary support and can be life-saving in critical CS. The venoarterial ECMO circuit is made up of a venous cannula and an arterial cannula connected to a centrifugal pump which has a membrane oxygenator. The venous cannula drains deoxygenated blood into the membrane oxygenator for gas exchange, and this is then propelled back to the patient through the arterial cannula. The cannulae are similar in size to those used with the TandemHeart, and venoarterial ECMO is able to provide a flow rate of up to 6 L/min. As there is no direct unloading of the left ventricle, and blood is returned into the arterial system resulting in an increase in afterload, this type of support can be combined with an IABP or Impella for optimal hemodynamic and metabolic effects [27]. Venoarterial ECMO has been demonstrated to be a viable, rapid, and transportable method of providing urgent MCS to patients as a method to bridge them to more durable support or transplantation [28].

**The Special Case of Right Ventricular Heart Failure**

Medical management of acute right ventricular failure focuses on reducing right ventricular afterload and improving the contractile function of the right side of the heart. MCS has largely been limited to surgical intervention with right ventricular assist devices, with an IABP providing indirect benefit to the right ventricle by unloading the left ventricle. More recently, however, percutaneous support specific to the right side of the heart has been developed and approved for limited use. This can be provided in the form of continuous-flow right ventricular support devices – namely, the PROTEK Duo (CardiacAssist, Pittsburgh, PA, USA) and the Impella RP. The PROTEK Duo is a coaxial dual-lumen cannula, with a 29F outer cannula and a 16F inner cannula (Figure 3). The cannulae have inflow and outflow ports, and are connected to the TandemHeart centrifugal pump. This allows blood to be withdrawn from the right atrium and returned to the pulmonary artery. The Impella RP is a microaxial pump consisting of a 23F pump head and outflow cannula mounted on an 11F catheter (Figure 4). It can be implanted via the femoral vein and advanced across the pulmonic valve. The inflow portion of

![Figure 3 PROTEK Duo Right Ventricular Support Device with TandemHeart. Courtesy of CardiacAssist.](image)

![Figure 4 Impella RP Catheter. Courtesy of Abiomed.](image)
the catheter remains in the inferior vena cava, with the outflow in the pulmonary artery. Both devices have been demonstrated to improve hemodynamic status in patients with acute right ventricular failure [29, 30].

**Treating the Cardiogenic Shock Patient**

Regardless of the method used to initially treat patients with CS, rapid identification and early initiation of therapy is of paramount importance if one hopes to have any meaningful chance of survival. Patients with an acute coronary syndrome should first be taken to the cardiac catheterization laboratory. Inotropic support is a reasonable first-line choice for support; however, its use must be weighed against the spectrum of illness and degree of CS. As discussed earlier, as inotrope requirements increase, so too does mortality [6]. Therefore, inotropic support is likely to provide benefit in more milder-shock syndromes. Its use in high doses, or in combination with other vasoactive medications, should trigger further evaluation with invasive hemodynamics and real-time consultation with a multidisciplinary team.

This realization of the spectrum of CS and the need to tailor therapy to the degree of hemodynamic support needed, with the goals of the patient in mind, has led to the concept of the “Shock Team.” Although it has been described in multiple formats and with different constituents, the premise is that real-time, early consultation between heart failure, interventional cardiology, critical care, and cardiac surgery specialists takes place to share decision making and devise an initial strategy for hemodynamic support. Depending on the degree of CS, this may include placement of a pVAD or ECMO if patients are felt to be acceptable candidates for more durable therapy such as an LVAD or transplantation.

We suggest that patients with an identified shock syndrome be evaluated in the following, multidisciplinary team fashion (Figure 5). Following activation of the Shock Team, the patient should be taken to the cardiac catheterization laboratory for invasive hemodynamic measurements. In cases of mild-to-moderate CS, inotropic support and IABP placement is reasonable. More severe shock

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**Figure 5** Critical Cardiogenic Shock Algorithm.

CCU, coronary care unit; ECMO, extracorporeal membrane oxygenation; HF, heart failure; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; PA Sat, pulmonary arterial saturation; pVAD, percutaneous ventricular assist device; VAD, ventricular assist device.
syndromes should be treated with a pVAD, again if, in the estimation of the team, the patient is an appropriate candidate for advanced therapies for heart failure. In the case of IABP placement and inotropic support, the patient and the team should remain in the cardiac catheterization laboratory. If no improvement in hemodynamics parameters is noted, such as pulmonary arterial saturation, the IABP should be exchanged for a pVAD. In the case of improvement in hemodynamic parameters, the patient’s lactate levels and pulmonary arterial saturation should be monitored every 6 h. If there is no sustained improvement, or if evidence of poor end-organ perfusion remains, therapy should be escalated either to a pVAD or ECMO, with the goal being to transition the patient to a durable LVAD within days.

This type of graded approach with a multidisciplinary team has been successful in improving outcomes with CS, with those who survived the period of initial temporary MCS having a survival rate of 80% at 1 year [31]. A modified “team and network” approach has also been described, which incorporates early referral to advanced heart failure centers, and holds promise for improving outcomes in appropriately selected patients [32]. It remains unclear, however, what financial burden this would place on the health care system, with initial analyses suggesting a cost benefit for a pVAD over an IABP and ECMO; however, additional study is required [33, 34].

Conclusion and Take-Home Message

CS remains a problem with significant impact on the health care system, and although outcomes remain poor, early identification and aggressive therapy may provide benefit. The key to such an approach is ongoing evaluation by a multidisciplinary team, and rapid escalation of care when appropriate. The heterogeneity of patients with CS and the wide spectrum of the severity of illness encountered with this clinical syndrome are likely to confound trial design and preclude definitive data to guide therapies. Therefore, care should be tailored to the findings in specific patients, with an understanding of patient and family goals, while next utilizing individual and facility expertise. Early referral to an advanced heart failure center should be considered in all patients with a high-risk CS syndrome, where more robust MCS can be delivered. Cost considerations will need to be evaluated further to help define the optimal delivery method for these strategies.

Conflict of Interest

The authors declare no conflict of interest.

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