Advances in Mechanical Circulatory Support

Percutaneous Circulatory Support in Cardiogenic Shock
Interventional Bridge to Recovery

Biswaajit Kar, MD; Sukhdeep S. Basra, MD, MPH; Nishant R. Shah, MD; Pranav Loyalka, MD

Over the past 2 decades, innovation in the realm of mechanical ventricular assist devices (VADs) has altered the management of cardiogenic shock (CS). Percutaneous VADs (PVADs) allow emergent and effective ventricular unloading while providing sufficient systemic perfusion pressure to reverse end-organ dysfunction. Despite relatively few randomized trials evaluating these devices, some cardiovascular society guidelines recommend the use of PVADs in patients not responding to standard treatments for CS, including intra-aortic balloon pump (IABP) counterpulsation (Class IIa, Level of Evidence C). The purpose of this review is to highlight the spectrum of CS, to review modern PVADs as an interventional bridge to recovery, to discuss unique clinical issues related to PVAD support, and finally to offer a perspective on the future directions of acute mechanical circulatory support research.

CS: Definition and Pathophysiology
CS is a state of end-organ hypoperfusion caused by left ventricular (LV), right ventricular (RV), or biventricular myocardial injury resulting in systolic and/or diastolic myocardial pump failure. Myocardial infarction (MI) with LV failure remains the most common cause of CS. In general, CS complicates 8.6% of ST-segment elevation MIs (STEMI) and 2.5% of non–ST-segment elevation MIs. Common causes of CS are listed in Table 1.

Clinically, CS is defined by both hemodynamic parameters (persistent hypotension [systolic blood pressure <80–90 mm Hg or mean arterial pressure 30 mm Hg lower than baseline], a cardiac index <1.8 L·min⁻¹·m⁻² without support or <2.0 to 2.2 L·min⁻¹·m⁻² with support, and elevated filling pressures [LV end-diastolic pressure >18 mm Hg or RV end-diastolic pressure >10–15 mm Hg]) and clinical signs/symptoms of hypoperfusion (cool extremities, decreased urine output, and/or altered mental status). Inadequate systemic perfusion results in secondary lactate acidosis, catecholamine and neurohormone release, and activation of systemic inflammatory and coagulation cascades. Together, these mechanisms contribute to further depression of myocardial function in a downward spiral.

It is increasingly clear that CS represents a wide clinical spectrum, including preshock (patients at significant risk of developing CS), mild CS (responsive to low-dose inotropes/vasopressors), profound CS (responsive to high-dose inotropes/vasopressors and IABP), and severe refractory CS (SRCS; unresponsive to high-dose inotropes/vasopressors and IABP). These definitions help define a general escalating treatment paradigm in the treatment of CS (Figure 1).

The general rationale for using mechanical VADs in patients with CS is to break the downward spiral by restoring adequate systemic perfusion pressure and allowing time to address the underlying cause of myocardial pump failure. These devices developed in 2 major directions: ventricular assist in series and ventricular assist in parallel with native LV function.

Short-Term VADs
IABP Counterpulsation
The original short-term VAD and currently the most frequently used mechanical assist device for CS, IABP counterpulsation improves coronary and peripheral perfusion via diastolic balloon inflation and augments LV performance via systolic balloon deflation (decrease in afterload). IABP counterpulsation is therefore dependent on a stable native cardiac rhythm. The first published clinical trial of IABPs in patients with CS demonstrated augmentation of cardiac output by 0.5 L/min. Subsequent data from the Should We Emergently Revascularize Occluded Coronaries for Cardiogenic Shock (SHOCK) Trial Registry demonstrated lower in-hospital mortality in patients with MI who received IABP in combination with thrombolytic therapy or early revascularization with percutaneous transluminal coronary angioplasty/coronary artery bypass graft surgery. Similarly, in the Global Utilization of Streptokinase and TPA for Occluded Coronary Arteries (GUSTO-I) trial, early institution of IABP and thrombolytic therapy in patients with acute MI (AMI) complicated by CS was associated with an increased risk of bleeding and adverse events but also a trend toward lower 30-day and 1-year all-cause mortality. Finally, results from the National Registry of Myocardial Infarction demonstrated that IABP in patients with AMI complicated by CS was associated with a significant reduction in mortality when used in conjunction with thrombolysis.

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Table 1. Common Causes of Cardiogenic Shock

<table>
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<th>Cause</th>
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<tr>
<td>MI without mechanical complications</td>
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<tr>
<td>MI with mechanical complications (ventricular septal rupture or papillary muscle/chordal rupture)</td>
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<tr>
<td>Acute decompensation of chronic heart failure</td>
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<tr>
<td>Acute myocarditis</td>
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<tr>
<td>Postcardiomyopathy</td>
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<tr>
<td>Takotsubo/stress-induced cardiomyopathy</td>
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<td>Peripartum cardiomyopathy</td>
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<tr>
<td>Refractory arrhythmias</td>
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<td>Cardiac tamponade</td>
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<tr>
<td>Massive pulmonary embolism</td>
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<tr>
<td>Acute rejection after orthotopic heart transplantation</td>
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<tr>
<td>Hypertrophic cardiomyopathy with severe outflow obstruction.</td>
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<tr>
<td>Aortic dissection complicated by acute severe aortic insufficiency and/or MI</td>
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MI indicates myocardial infarction.

with thrombolytic therapy but not in conjunction with primary angioplasty.10

Despite these initial results, a recent randomized controlled trial comparing IABPs and medical therapy in patients with AMI and CS undergoing percutaneous coronary intervention (PCI) demonstrated that the addition of IABPs did not result in a significant improvement in multiorgan dysfunction syndrome, cardiac index, or systemic inflammatory activation.11 Furthermore, a recent meta-analysis suggested that although IABPs may have a beneficial effect on hemodynamic parameters in infarct-related CS, the existing data do not support a mortality benefit.12 Finally, another recent meta-analysis evaluating the use of IABPs in patients with STEMI complicated by CS suggested no improvement in 30-day survival or LV ejection fraction and an increased risk of stroke and bleeding complications.13 Given these data, the role of IABPs in patients with CS is unclear, and further randomized trials are needed. Despite this ambiguity, the most current American College of Cardiology/American Heart Association14 and European Society of Cardiology1 guidelines for the management of STEMI state that initiation of IABP counterpulsation is a Class I (Level of Evidence B) indication for the management of CS not rapidly reversed by pharmacological therapy.

Surgically Implanted Temporary VADs

Given the minimal circulatory support afforded by IABPs, the next generation of external VADs was designed to be surgically implanted and powerful enough to provide full circulatory support. An early example was the Abiomed BVS System 5000 (Abiomed, Inc, Danvers, MA), an external, automated, gravity-filled, pneumatically driven device with blood inflow from the left atrium returned to the thoracic aorta (and/or inflow from the right atrium returned to the pulmonary artery) via transthoracic cannula insertion. It was first used to support patients with refractory heart failure in 1990,15 and a later 5-year retrospective review demonstrated successful weaning in 66% of the bridge-to-recovery group and successful transplantation in 66% of the bridge-to-transplantation group.16 Next-generation surgically implanted external VADs such as the CentriMag VAD (Levitronix, Waltham, MA) were designed to minimize blood trauma and mechanical failure. This magnetically levitated, centrifugal, continuous-flow rotary pump was first used for postcardiomyopathy CS and as a bridge to decision in 2006,17 has been demonstrated to have a low incidence of device-related complications in a multicenter trial,18 and has recently been demonstrated to be an effective bridge-to-recovery device in patients with severe graft rejection after heart transplantation (1-year survival of 32%).19 Additionally, the canulas of the device can be inserted percutaneously.20 The CentriMag VAD currently has 510k approval for up to 6 hours of circulatory support and has humanitarian use approval for up to 30 days of circulatory support in the setting of acute RV failure. Finally, the Impella Recover 5.0 VAD (Abiomed Inc), a catheter-mounted microaxial rotary pump inserted into the LV in a retrograde fashion via femoral artery access after surgical cut-down that is capable of augmenting cardiac output by 5.0 L/min, has been shown in single cases to be effective as a bridge-to-transplantation,21 a bridge-to-bridge,22 and a bridge-to-recovery device.23,24

Despite advances in surgically implanted external VAD technology and improvement in the morbidity and mortality attributable to these devices, important clinical problems remain, including the need for general anesthesia, systemic inflammation associated with an open surgical procedure, and the often prolonged delay associated with operating room activation. To address these issues while still maintaining the ability to provide adequate circulatory support, PVADs were developed.

PVADs: Principles and Devices

An ideal PVAD should have the following characteristics: the ability to be implanted rapidly and easily via a percutaneous approach; effective and reliable circulatory support (flow) to adequately unload the impaired ventricle(s), to maintain systemic perfusion pressure, and to reverse end-organ dysfunction (even in the setting of increased systemic vascular resistance); easy, uncomplicated operation after insertion; and
low complication rates (eg, limb ischemia, stroke, and hemolysis).

**Early PVADs**
Widely regarded as the first PVAD, the Hemopump Cardiac Assist System (Johnson & Johnson Interventional Systems, Rancho Cordova, CA) was a catheter-mounted, axial flow device positioned across the aortic valve and capable of providing up to 3.5 L/min of short-term (hours to days) cardiac support for patients with CS.25 Although the Hemopump is no longer used, its design served as the basis for future PVADs. A second early PVAD was the Bard cardiopulmonary support system (C.R. Bard, Inc, Billerica, MA), a battery-powered, portable, heart-lung machine implanted in a femoro-femoral bypass configuration. In a large series of 104 patients with CS who were emergently initiated on cardiopulmonary support, 32% survived to discharge.26 Similar to the Hemopump, this device served as the basis for future PVADs.

The current generation of PVADs includes the TandemHeart PVAD, the Impella Recover 2.5 PVAD, and percutaneous extracorporeal membrane oxygenation (ECMO; see Table 2 for a summary and comparison).

**TandemHeart PVAD**
The TandemHeart PVAD (CardiacAssist, Inc, Pittsburgh, PA) is a left atrial-femoral bypass centrifugal pump capable of providing up to 3.5 to 4.5 L/min of cardiac output when inserted percutaneously (Figure 2). It is currently Food and Drug Administration (FDA)–approved for up to 6 hours of circulatory support. An early trial to determine the efficacy and safety of the TandemHeart PVAD in patients with CS showed that it provided significantly better hemodynamic support than IABPs without any difference in 30-day mortality. Adverse events were similar between both groups.27 A later randomized trial in patients with CS after AMI undergoing PCI demonstrated similar results with significant improvement in hemodynamic parameters and no difference in 30-day mortality. However, severe bleeding and limb ischemia were encountered more frequently with TandemHeart PVAD support.28 A recent large retrospective study of 117 patients with SRCs initiated on TandemHeart PVAD support demonstrated a significant increase in cardiac index, systolic blood pressure, mixed venous oxygen saturation, and urine output concurrent with a significant decrease in pulmonary capillary wedge pressure. The 30- and 6-month mortality rates in this cohort were 40.2% and 45.3%, respectively.29 Additionally, the TandemHeart PVAD has been validated in smaller series as a successful bridge-to-transplantation,30 bridge-to-bridge,31 bridge-to-decision,32 and bridge-to-recovery33 device. Finally, case reports describe use of the TandemHeart PVAD for life-saving RV support in a number of clinical scenarios: for acute RV MI,34 in conjunction with IABP for biventricular MI,35 in conjunction with LV Impella Recover 2.5 PVAD support for severe cardiac allograft rejection,36 and for RV failure after surgical LV assist device implantation.37

**Impella Recover 2.5 PVAD**
The Impella Recover 2.5 PVAD (Abiomed Inc) is identical to the Impella Recover 5.0 device discussed above except that its 13F catheter size does not require surgical cut-down for insertion (Figure 2). It is capable of augmenting cardiac output by 2.5 L/min and is FDA approved for up to 6 hours of partial circulatory support. In the Impella LP2.5 vs. IABP in Cardiogenic SHOCK (ISAR-SHOCK) trial, patients with LV failure after AMI who received circulatory support with the Impella Recover 2.5 PVAD had significant improvement in cardiac index after 30 minutes of support compared with...
patients supported by IABP. However, overall 30-day mortality in both groups was 46%, and there was a higher incidence of hemolysis in patients treated with Impella PVAD support. More recent data suggest that the Impella Recover 5.0 device may be more appropriate than the Impella Recover 2.5 PVAD for patients with SRCS after STEMI. However, as mentioned above, the Impella Recover 2.5 PVAD has been used in combination with the TandemHeart PVAD as a bridge-to-recovery device, and case reports describe its use in combination with IABP for AMI complicated by CS and for CS after cardiac arrest.

**Percutaneous ECMO**

Although ECMO technology was developed in the 1960s, there has been a recent resurgence of this technology owing to better cannulation techniques, smaller cannulas, improved oxygenator machines, and device miniaturization. Together, these improvements have resulted in lightweight, portable, reliable, and rapidly implantable percutaneous ECMO systems in 2 possible configurations: veno-venous for pulmonary support and veno-arterial for cardiac and pulmonary support. The major advantage of these systems over other modern PVADs is the lack of need for transseptal puncture or transfer to a cardiac catheterization laboratory. Given its status as a relatively old technology, there is a wealth of published data regarding ECMO support in CS: It has been used with or without IABP for short-term cardiopulmonary support in patients with postcardiotomy CS; it has been used as a bridge-to-recovery device in patients with fulminant myocarditis; and it improves 30-day outcomes when used for hemodynamic support during primary PCI in patients presenting with STEMI and profound CS. More recent data demonstrate the increased portability of ECMO. In 38 patient with SRCS, percutaneous ECMO support was safely initiated in remote institutions with a mobile remote cardiac assist unit before transport to a tertiary care center. Similarly, an FDA-approved handheld mini-ECMO system, the CARDIOHELP system (Maquet AG, Hirrlingen, Germany), was im-
planted successfully and safely as a bridge-to-recovery device in out-of-hospital patients presenting with SRCS.46 Finally, the LIFEBRIDGE-B2T (Medizintechnik AG, Ampfing, Germany) is a portable cardiopulmonary bypass unit that can be implanted via the femoral vessels within 15 minutes and is capable of 3 to 4 L/min of circulatory support. It is FDA approved for support up to 6 hours. It has been used successfully to support high-risk PCI in a patient with CS47 and to support pulmonary emboleectomy in a patient with cardiovascular collapse secondary to a massive pulmonary embolism.48

Next-Generation PVADs
In addition to the devices discussed above, a number of novel PVADs have recently been developed. The Reitan Catheter Pump (Kiwimed, London, UK) consists of a catheter-mounted foldable propeller surrounded by a cage and is capable of circulatory support of up to 5 L/min. The device is deployed in the descending aorta, where it creates a negative pressure gradient (reduces afterload). A recent study demonstrated safety in 10 patients undergoing high-risk PCI,49 but a study demonstrating direct effects on hemodynamic parameters in humans has not yet been published. Additionally, the iVAC 3L PVAD (PulseCath BV, Amsterdam, the Netherlands) is a 17F or 21F catheter with an integrated 2-way valve system that pulls blood from the LV and delivers it to the ascending aorta and is driven by a standard IABP console. It is capable of generating pulsatile flow of 2 to 3 L/min. It has been used successfully in individual patients for cardiopulmonary bypass during coronary artery bypass grafting50 and for RV support for postcardiotomy RV failure.51 As with the Reitan Catheter, a study demonstrating direct effects on hemodynamic parameters in humans has not yet been published.

PVADs for Preshock: Support During High-Risk PCI and Ventricular Tachycardia Catheter Ablations
No universal guideline definition exists as to what constitutes a high-risk PCI. Although patients with severe 3-vessel disease, left main disease, single remaining patent vessel, and/or depressed LV function represent a high-risk population, the actual categorization of an individual PCI as high risk is up to the interventional cardiologist performing the procedure. IABPs are the most commonly used PVAD support during high-risk PCI. However, the recently published Balloon Pump-Assisted Coronary Intervention Study (BCIS) study demonstrated that elective initiation of IABP in patients undergoing high-risk PCI does not reduce the incidence of major adverse cardiac events. Furthermore, there were strong trends toward increased bleeding and access-site complications in the IABP group.52

Data on newer-generation PVAD support during high-risk PCI are encouraging. Both transseptal PVADs53 and catheter-based PVADs54 have been demonstrated to reduce infarct size in animal models of acute regional ischemia without hemodynamic compromise. The Prospective Feasibility Trial Investigating the Use of the Impella 2.5 System in Patients Undergoing High-Risk Percutaneous Coronary Intervention (PROTECT) I trial, which evaluated the safety and feasibility of the Impella Recover 2.5 PVAD for hemodynamic support during high-risk PCI in 20 patients, demonstrated successful device implantation in all patients, no cases of procedure-related hemodynamic compromise or limb ischemia, a 10% incidence of hemolysis, and a 30-day major adverse cardiac event rate of 20%.55 The follow-up PROTECT II trial was designed to compare prophylactic use of Impella Recover 2.5 PVAD support against IABP during high-risk PCI. The Data Safety Monitoring Board, after reviewing 50% of the enrollment data, determined that the trial would not meet its primary end point if outcome trends continued to be similar and recommended stopping the trial owing to futility.56 Subsequent analysis of the collected data revealed no difference between the 2 groups at 30 days but a trend of superiority of Impella 2.5 PVAD support over IABP at 90 days (Late Breaking Clinical Trial, William O’Neil, at the American College of Cardiology 60th Annual Scientific Session 2011; full results are expected to be published soon). Additional data from 144 patients in the Europella Registry, all of whom underwent Impella Recover 2.5 PVAD-assisted high-risk PCI, demonstrated 30-day mortality of 5.5% and a low incidence of adverse events.57 Correlative data from the USSpella Registry (Karim Benali, MD, personal communication, 2011) showed an 8% major adverse cardiac event rate and a 96% survival rate at 30 days after PCI in 175 patients who underwent Impella Recover 2.5 PVAD-assisted high-risk PCI. Finally, the currently enrolling Impella Versus IABP Reduces Infarct Size in STEMI Patients Treated With Primary PCI (IMPRESS in STEMI) trial will compare reduction of infarct size in patients with large anterior STEMI treated with primary PCI supported by the Impella Recover 2.5 PVAD versus IABP. Although there are no multicenter studies regarding use of the TandemHeart PVAD for circulatory support during high-risk PCI, recent single-center studies suggest that the device is effective in this clinical setting, with an acceptably low rate of device-related complications.58,59

In addition to the data for PVAD support during high-risk PCI, some data suggest that PVAD support may have a role in high-risk/unstable ventricular tachycardia catheter ablation procedures. The TandemHeart PVAD was used for circulatory support during successful ventricular tachycardia catheter ablation in a hypotensive patient.60 Similarly, the Impella Recover 2.5 PVAD was used for hemodynamic support in 3 patients during successful ablation of unstable ventricular tachycardia.61 Of important note, the transseptal configuration of the TandemHeart PVAD may potentially limit transseptal access for catheter ablation of ventricular tachycardia, and the presence of the Impella Recover 2.5 pump within the LV cavity may also limit catheter movement. Both devices also limit groin access.61 Despite these potential physical challenges, the initial results above suggest the possibility of PVAD use as a bridge-to-electric-recovery device.

PVADs: Important Clinical Considerations
Interhospital Transfer
The vast majority of patients with CS initially present at a “spoke” community hospital not equipped for primary PCI
and/or initiation of PVAD-mediated circulatory support. At those institutions, focused stabilization efforts should begin immediately, including securing the airway, starting vasopressor/inotrope support, and initiating IABP and primary PCI. If a patient’s clinical condition deteriorates, the patient should rapidly be transferred to a “hub” hospital capable of emergent initiation of PVAD-mediated circulatory support. A preexisting, seamless spoke-hub relationship between the transferring and receiving hospital is critical for optimal patient transport time and care. Furthermore, a well-defined PVAD team consisting of physicians, nurses, catheterization laboratory technicians, and circulatory support technicians should be activated before the patient’s arrival at the receiving hospital. Ideally, this team should have easy access to a prepackaged PVAD kit containing all the materials required for PVAD insertion.

**Principles for Patient Selection**

PVAD support should be reserved for highly selective cases in which its use is most likely to improve survival rather than prolong the process of dying. Therefore, PVAD-mediated circulatory support should be withheld in individual cases if, in the estimation of a multidisciplinary team that includes the patient’s family and the treating physician, there is no foreseeable exit strategy for PVAD removal (ie, bridge to revascularization, bridge to recovery, bridge to bridge [surgical VAD assist device], bridge to transplantation, or bridge to decision [additional time required to assess the likelihood of recovery]). In these cases, an open and honest discussion with family members regarding end-of-life issues and palliative care is more appropriate.

**Device Selection**

The specific type of PVAD chosen in an individual patient with CS depends on several factors; most important are the degree of mechanical support needed to adequately restore circulation and the presence of inadequate oxygenation. A critical component of determining the degree of mechanical support needed is assessment of RV function. The presence of RV dysfunction necessitates rapid correction of acidosis and consideration of pharmacologic support (ie, pulmonary vasodilators and/or inotropes) or mechanical support specifically targeted at assisting and/or unloading the RV (eg, percutaneous RV assist device, percutaneous biventricular assist device, or venoarterial ECMO). Other important considerations for PVAD selection include severity of end-organ dysfunction and underlying comorbidities (eg, peripheral vascular disease). In patients requiring long-term or biventricular circulatory support, patients with severe peripheral arterial disease, those with postcardiotomy CS, and patients who are hemodynamically stable enough to tolerate surgery, surgically implanted temporary VAD insertion, as opposed to PVAD insertion, may be considered. Furthermore, transitioning to a short-term surgical VAD may be considered in cases when PVAD support is used for acute hemodynamic stabilization. Figure 3 depicts a suggested approach to PVAD selection.

**Timing of Implantation**

Vasopressor/inotropic support in CS achieves short-term hemodynamic improvement at the expense of increasing oxygen demand and myocardial ATP consumption at a time when the myocardium is failing with supply-demand mismatch. For this reason, there is a narrow window of opportunity in which, rather than continued escalation of medical therapy, early institution of mechanical circulatory support via IABP and/or PVAD-mediated circulatory support should strongly be considered. For this reason, the concept of a door-to-unloading time for patients with SRCS, analogous to the well-established door-to-balloon time in patients with STEMI, has been proposed.

**Goals of Support and Weaning**

In the absence of definitive guidelines setting physiological parameter goals, efforts should be made to maintain mean arterial pressure >60 mm Hg and a mixed venous oxygen saturation of >70%. PVAD weaning, accomplished by gradually decreasing PVAD speed/flow, should be attempted in patients who demonstrate hemodynamic stability (including minimal/no pressor requirement) and improving end-organ function. Patients who do not meet the above criteria for recovery should be assessed for transition to a long-term surgical VAD or transplantation. Although there is no defined ideal duration of support for potentially recoverable patients because of the high variability in the underlying causes and severity of CS, the average duration of support in patients successfully weaned from TandemHeart PVAD support in a single center was 5.8±4.75 days.

**Complications**

Several serious complications are known to be associated with PVAD support. The first is limb ischemia, which is more likely in the setting of severe peripheral vascular disease and/or PVAD support requiring large-bore cannulation such as the 17F-cannula TandemHeart PVAD. For this reason, review of a patient’s arterial anatomy is critical during consideration of cannula size. If needed, an antegrade perfusion catheter may be used to prevent subclinical limb ischemia and/or reperfusion injury on device removal. Another complication associated with PVAD support is hemolysis,

Figure 3. Approach to percutaneous ventricular assist device (PVAD) selection in severe refractory cardiogenic shock. RV indicates right ventricular; LV, left ventricular; BIV, biventricular; V-V, veno-venous; ECMO, extracorporeal membrane oxygenation; RA, right atrial; LA, left atrial; V-A, veno-atrial; pRVAD, percutaneous RV assist device; and pLVAD, percutaneous LV assist device. Reprinted from Kar et al²⁹ with permission from the publisher. Copyright © 2011, Elsevier BV.
seen more frequently with microaxial devices like the Impella Recover 2.5 PVAD. Proper positioning of the inlet cannula with this device reduces the risk of hemolysis and of mechanical aortic valve injury. To reduce the risk of thrombotic events while on PVAD support, patients should be placed on a continuous intravenous heparin drip to maintain an activated clotting time >300 seconds (argatroban and bivalirudin are alternatives in patients with heparin-induced thrombocytopenia). Additionally, on the basis of several case reports in patients with surgical VADs, PVAD pump speed should be adjusted under echocardiography guidance to allow for at least intermittent opening of the aortic valve. If the VAD speed is too high and the aortic valve remains permanently closed, there is a high risk of aortic root thrombus formation and stroke. Another problem associated with excessive pump speed is overdecompression of the LV. This may result in suction of the interventricular septum toward the PVAD inlet cannula, obstructing inlet flow and potentially precipitating ventricular tachycardia or RV failure by septal shift. Finally, notation of systemic vascular resistance during PVAD support is crucial. Excessive systemic vascular resistance caused by comitant vasopressor use can cause submaximal pump flows at any speed, which can in turn result in inadequate end-organ perfusion.

Unique Challenges Associated With PVAD Research

Although PVADs have been shown to significantly improve hemodynamic parameters and end-organ function in patients with CS, it has been difficult to demonstrate a mortality benefit in randomized trials. One reason is the ethical dilemma created by randomizing patients with SIRS (sepsis) to not receive PVAD support even if randomized to receive such support in the context of randomized trials comparing PVADs and IABP. Other challenges associated with PVAD research include inappropriate patient and device selection and logistic barriers resulting in suboptimal timing of PVAD support initiation. To address these challenges, it may be beneficial to develop and validate predictive models to compare the efficacy of different PVADs.

Conclusions

Although the recent innovations in the field of mechanical circulatory support are impressive, there is a lack of randomized trial data evaluating the effectiveness and safety of these new devices. Undefined areas include appropriate patient selection, device selection, time of implantation, physiological goals of support, clinical outcomes, and cost-effectiveness. Randomization of patients with CS poses logistical and ethical challenges, but randomized clinical trials or acceptable alternative validation models are now necessary. A critical prerequisite for designing new studies/models is standardization of the definitions of the various stages of CS. In the meantime, the innovation of smaller, more powerful, and more versatile PVADs for use across the clinical spectrum of CS should continue.

Disclosures

Since 2009, Texas Heart Institute has been a training center for CardiacAssist. The authors report no other conflicts.

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