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Role of Short-Term Percutaneous Mechanical Circulatory Support Devices as Bridge-to-Heart Transplantation

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Abstract

Cardiogenic shock is a life-threatening condition and mortality remains high if there is no response with medical therapy. Recently, short-term percutaneous mechanical circulatory support (pMCS) devices have increased in use for refractory cardiogenic shock. These devices can provide full treatment or bridging to long-term MCS devices if patients need long-term support. There are four types of well-known MCS devices including Impella (Abiomed, Danvers, MA), TandemHeart (CardiacAssist, Pittsburgh, PA), and extracorporeal membrane oxygenation (ECMO) and intra-aortic balloon pump for short-term and percutaneous application. In this chapter, we aim to discuss the physiologic concept, clinical evidences and applications, indications-contraindications, complications, and comparison of these most commonly used short-term pMCS devices for advanced heart failure.

Keywords: cardiogenic shock, mechanical circulatory support, intra-aortic balloon pump

1. Introduction

Orthotopic heart transplantation (OHT) still continues to be the gold standard treatment for advanced heart failure refractory in medical therapy [1]. However, limitations of organ donation cause rapid technological growth in the field of mechanical circulatory support. For patients who cannot have a heart transplant, another option may be a ventricular assist device (VAD). A ventricular assist device is a mechanical device implanted into the chest that helps in pumping blood from the ventricles to the body.

	IABP	Impella	TandemHeart	ECMO
Insertion time	6–22 min	11–41 min	15–45 min	15–60 min
Flow	None	2.5–5.0 L/min	4.5 L/min	5.0 L/min
MAP increase	Minimal	20–30 mmHg	36 mmHg	
PCWP reduction		–7 mmHg	–14 mmHg	
Duration of support	6 h to several weeks	6 h to several days	6 h to several days	6 h to several days
Leg ischemia	0.9%	3.9%	3.4–33%	18.8%
Bleeding	0.8%	13%	Up to 59.8%	18%

MAP: mean arterial pressure, PCWP: pulmonary capillary wedge pressure.

Table 1. The types and the characteristics of the pMCS devices.

VADs are commonly used as a temporary treatment for people waiting for a heart transplant. These devices are increasingly being used as a long-term treatment for people who have heart failure but are not eligible for a heart transplant.

The bridge-to-transplant strategy integrating with a long-term continuous-flow VAD has played a major role in providing circulatory support during the waiting period prior to transplantation.

Short-term mechanical circulatory support devices (MCS) provide good hemodynamic support for patients with cardiogenic shock and these devices are increasingly used as a bridge-to-decision in patients with refractory cardiogenic shock [2]. Short-term mechanical circulatory support devices acutely improve hemodynamic conditions.

When cardiogenic shock is refractory to medical therapy, percutaneous mechanical circulatory support (MCS) should be considered. Subsequently, these patients might be bridged to durable MCS either as a bridge-to-candidacy/transplantation or as a destination therapy.

There are three types (**Table 1**) of well-known MCS devices including Impella (Abiomed, Danvers, MA), TandemHeart (CardiacAssist, Pittsburgh, PA), and extracorporeal membrane oxygenation (ECMO), for short-term and percutaneous application. Intra-aortic balloon pump is also used for short-term support in cardiogenic shock with percutaneous way. These various devices can aid, restore, or maintain appropriate tissue perfusion before the development of irreversible end-organ damage.

Here, we discuss the patient selection, current state, ongoing advances, and implantation techniques of these percutaneous MCS.

2. IABP

IABPs are the most widely used MCS devices since its introduction in the 1960s. The IABP is a balloon catheter, which is generally inserted into the aorta through the femoral artery (**Figure 1**). At the beginning of diastole, the balloon inflates and the device increases the coronary perfusion.

By systole, the balloon deflates and left ventricular after-load reduces and increases the cardiac output. So the pump decreases the left ventricular stroke work, myocardial oxygen requirements, and increased cardiac output. In this manner, the balloon supports the heart indirectly. Since it is easy to insert, IABP is the most widely used form of mechanical circulatory support.

The indications for IABP usage are failure to wean from cardiopulmonary bypass, cardiogenic shock, heart failure, and acute heart attack. Although IABP is mainly used for surgical patients, the pump can be used during high-risk interventional cardiology procedures.

During acute-decompensated heart failure, IABP may help in supporting a patient who is awaiting a heart transplant in initial period, but if the patients need longer time, another p-MCS device can be replaced or long-term LVAD implantation may be required because of its limited length of use.

Before 2012, the American and European guidelines supported that implantation of IABP in cardiogenic shock recommended as a class I; but, in the IABP-SHOCK II trial study, IABP was not found to be associated with reduction in 30-day mortality in cardiogenic shock [3]. American guidelines have downgraded the recommendation for usage of the IABP from Class I to IIa, and European guidelines to Class III. Both American and European guidelines endorse the usage of other mechanical-assist devices that provide more hemodynamic support.

Absolute contraindications for IABP use are aortic insufficiency, aortic dissection-aneurysm, sepsis, and severe coagulopathy. Atherosclerosis and arterial tortuosity and left ventricular outflow tract obstruction are relative contraindications for IABP placement.

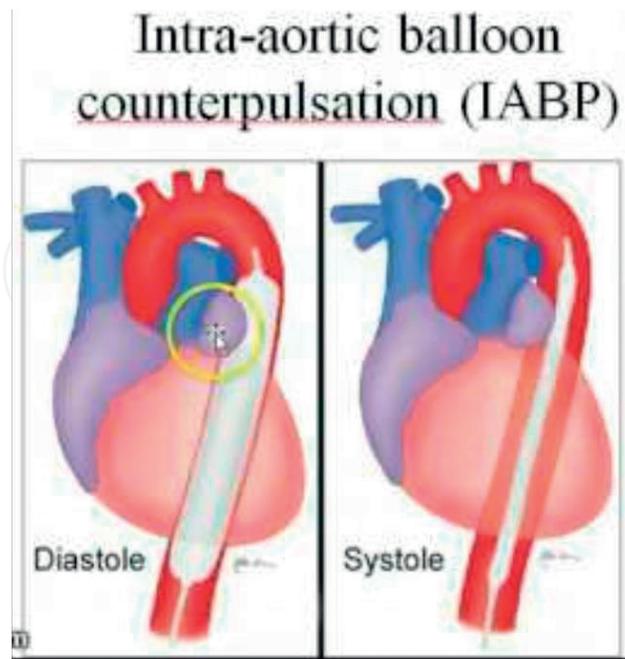


Figure 1. IABP.

3. Impella

Impella is a pump which pulls blood from the left ventricle and expels into the ascending aorta (**Figure 2**). The system has a continuous-flow microaxial pump located at the distal end of the catheter. The device can be inserted via a standard catheterization procedure through the femoral artery. It is inserted into the left ventricle via a femoral cut down or through the axillary artery, and goes through the ascending aorta, across the valve and into the left ventricle. This pump can produce a flow from 2.5 to 5.0 L/min. The principal feature mechanism of the device is to reduce the ventricular work, and to provide the circulatory support necessary to allow heart recovery.

Unlike the IABP, the Impella device uses continuous axial flow and consequently does not require pressure timing or electrocardiographic timing, allowing for stable output despite arrhythmias.

The device is mainly used during high-risk percutaneous coronary interventions (PCI) and in cardiogenic shock that is resistant to medical management. The device can also be used to hemodynamic support for the patient with severe left-ventricular dysfunction undergoing catheter ablation of hemodynamic condition [4].

In the setting of CS, two small trials have been performed with the Impella 2.5 pMCS, both using IABP therapy as the control therapy. The ISAR-SHOCK (efficacy study of LV assist device to treat patients with cardiogenic shock) trial randomized 26 patients between IABP and the Impella 2.5 in the setting of CS complicating AMI. The primary endpoint was the

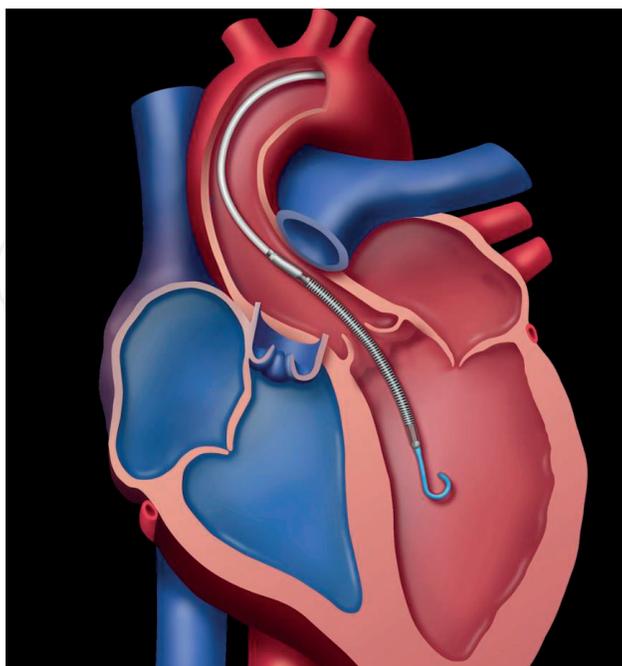


Figure 2. Impella.

difference in cardiac index after 30 min of support, and the trial showed a higher cardiac index in patients treated with Impella than with IABP. The overall mortality was 46% in both groups [5]. The IMPRESS in STEMI trial randomized between the IABP and Impella 2.5 in patients with cardiogenic pre-shock. This study was powered for a difference in left ventricular function. However, this trial was stopped prematurely due to a lack of enrollment after 21 patients had been enrolled [6].

The Impella pump can also be used for ventricular support in patients who develop heart failure after heart surgery. The device can provide immediate support and restore the hemodynamic stability for a period of up to 7 days, and this may allow time for creating a definitive treatment strategy [7]. Hence, patients who are waiting for a donor can be supported as a bridge-to-heart transplant with Impella device.

The Impella RP is a type of Impella pump designed for the treatment of right ventricular failure that can be inserted through the femoral vein. The prospective RECOVER RIGHT study showed that the safe, easily deployed, and reliable pump resulted in good hemodynamic benefit in patients with life-threatening right heart failure [8].

The Impella pump is not appropriate in patients with mural thrombus in the left ventricle, a mechanical aortic valve, severe aortic valve stenosis or insufficiency, severe peripheral arterial disease, significant right heart failure, combined cardiorespiratory failure, and atrial or ventricular septal defect (including post-infarct VSD).

4. TandemHeart

The TandemHeart is a continuous-flow centrifugal-assist device placed percutaneous way. Cannulas are inserted through the femoral vein and advanced across the intra-atrial septum into the left atrium (**Figure 3**). The pump withdraws oxygenated blood from the left atrium and returns to the femoral artery via arterial cannulas. The pump is capable of delivering blood flow up to 5.0 L/min.

The TandemHeart is creating a left atrial-to-femoral artery bypass that provides hemodynamic support during mainly high-risk coronary interventions and cardiogenic shock after cardiac surgery.

Among all other available percutaneous circulatory support options, only TandemHeart provides a steady supply of oxygenated blood to the body, while decompressing the left ventricle to reduce the work of the heart.

The device provides active hemodynamic support in patients who have little residual ventricular function and also can remain implanted for up to 3 weeks. For these reasons, if patients in advanced heart failure is too sick for immediate LVAD placement or transplantation, the TandemHeart may serve as a bridge-to-recovery, LVAD placement (as a bridge-to-bridge), or even transplantation.

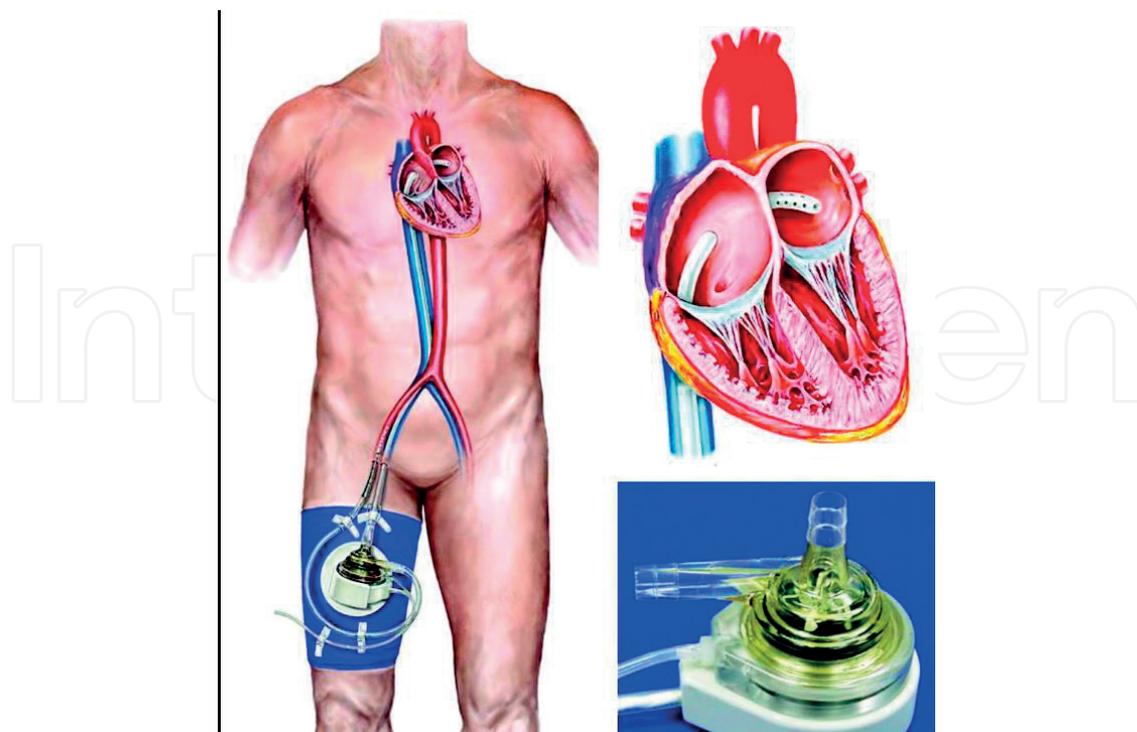


Figure 3. TandemHeart.

5. ECMO (extra corporeal membrane oxygenation)

ECMO provides a temporary support for heart and lungs. ECMO maintains gas exchange as well as cardiac support, and is used in patients suffering from respiratory failure, cardiac failure, or both. It is used for patients who have reversible cardiopulmonary failure such as advanced heart failure, acute respiratory distress syndrome (ARDS), pulmonary embolism, septic shock syndrome, and multiple organ system failure.

Blood is drained from the body with an external pump; then blood goes through a membrane gas exchanger for oxygenation and returns to the patient's circulation (**Figure 4**).

ECMO can be applied with three different ways such as veno-arterial, veno-venous, and central way. Venous-arterial (VA) ECMO drains blood from right atrium via a femoral venous or a right internal jugular venous catheter and blood returns to the aorta via femoral arterial catheter. VA-ECMO provides cardiac as well as pulmonary support. Venous-arterial ECMO (VA-ECMO) is considered in patients with cardiopulmonary collapse and is used to support patients in cardiogenic shock [9]. In non-post-cardiotomy failure patients requiring urgent cardiac support, peripheral VA-ECMO through the femoral artery and vein is the most common approach. Peripheral VA-ECMO has limitations, including retrograde blood flow leading to inadequate LV decompression. To solve this problem, some centers utilize concurrent IABP [10] or Impella [11] support to reduce the LV after-load, and hence pulmonary edema. Venous-venous (VV) ECMO drains blood from the right atrium and blood returns to the right atrium through the femoral or jugular venous catheter. VV-ECMO requires good

cardiac function and mainly uses in isolated severe respiratory failure. Veno-venous ECMO is reserved for patients in isolated respiratory failure with no significant cardiac dysfunction. Central ECMO can be applied after cardiac surgery if the heart cannot be weaned from the heart-lung machine due to post-cardiotomy syndrome. Cannulas, which are inserted for heart lung machine, can be connected to the ECMO circuit and the sternum leaves open and patient can transfer to the ICU with ECMO support for healing period.

With cardiac failure, VA-ECMO is the preferred method because it provides urgent circulatory support with oxygenation in the event of sudden heart failure, thus preventing organ damage. For this reason, it may help to support a patient who is awaiting a heart transplant.

Among other devices, one advantage of ECMO is providing hemofiltration and dialysis. The connectors have been incorporated between the oxygenator outlet and pump inlet so that a continuous renal replacement therapy (CRRT) device can be attached to the extracorporeal circuit.

In a VA-ECMO setting, when the heart has recovered, but if the lungs are still poorly functioning, the native cardiac output bounces against the pumped blood, usually in the aortic arch region. Accordingly, the coronary arteries, and to a variable degree the supra-aortic vessel as well, are provided with hypoxic blood, heart, and brain are harmed. Upper extremity cyanosis has brought up the term "Harlequin syndrome." Therapeutic options consist of a relocation of the arterial cannula in to right subclavian artery or aorta, or in converting the system into a VA-V-setting.

The healthcare team looking after patients on short-term percutaneous MCS aim to avoid any complications that may occur from being on these devices. Some of the more serious problems that may occur in these patients include: (1) bleeding especially from

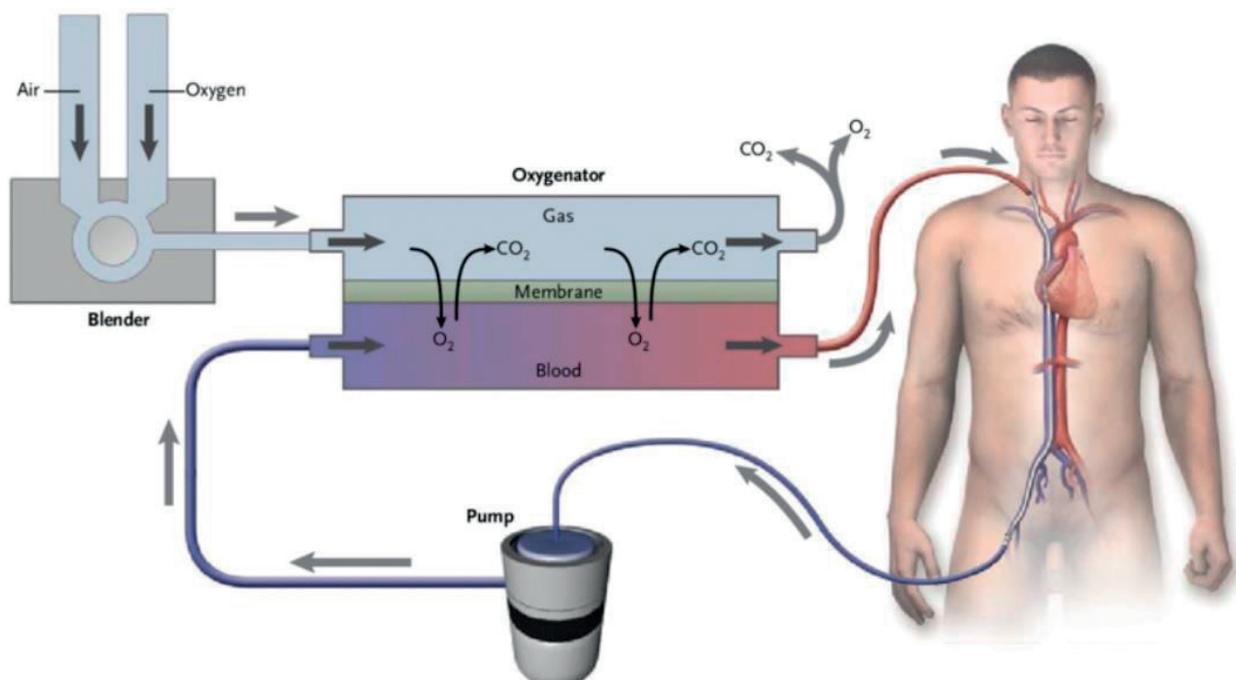


Figure 4. ECMO.

gastrointestinal system and brain. This can be a very serious problem if the bleeding happens in their brain, lungs, insertion sites of cannulae, or from gastrointestinal system. The patients should be monitored very carefully by frequent physical examinations and lab tests to make sure there is no bleeding. If there is bleeding, then medications can be given to help the blood to stop. Sometimes, surgery is needed to stop the bleeding. Blood and other blood products (such as platelets) may also need to be given if blood counts drop too low. (2) Acute renal failure may sometimes occur due to inadequate blood flow to their kidneys. With dialysis, the kidney damage may get better. However, in some cases, patients may need dialysis for the rest of their life. (3) Systemic or localized infection is another risk for these patients especially from the insertion site. Infections in these patients can usually be treated with antibiotics. However, some infections can cause to get sick and more organ damages. (4) Leg ischemia is usually the most common problem in these patients due to insertion of the catheter or cannulas through the femoral vessels. In some cases, blood flow may be affected in lower extremity due to occlusion of the vessels and ischemia may occur. Doctors should always be aware of leg ischemia. If this happens, surgery may be needed to get blood flowing back down the leg. (5) Stroke: in patients on short-term p-MCS, stroke is another life-threatening complication because of potential small blood clots. This can cause a stroke, and parts of the brain may be permanently damaged. Percutaneous MCS devices can also cause hemolysis and thrombocytopenia.

Mechanical circulatory support can prevent multi-organ failure and death in patients with advanced heart failure during waiting period. Long-term continuous-flow VAD has played a major role in providing circulatory support during the waiting period prior to transplantation, but long-term LVAD must be inserted through a thoracotomy or sternotomy, which can be hazardous and time consuming. For these reasons, patients in decompensated heart failure are best served by an initial period of stabilization with temporary devices.

Most series have combined a variety of temporary devices, but few long-term devices, and the evaluations have involved all patients with cardiogenic shock regardless of the indication for and the type of mechanical support and widely varying rates of recovery have been reported. There are four commonly used types of MCS available, which is temporary and percutaneous application. But the device choice and the implantation timing are not definitely established. Data regarding percutaneous MCS devices in cardiogenic shock are limited. A meta-analysis of three randomized trials comparing TandemHeart and Impella to IABP, TandemHeart and Impella were associated with higher cardiac index, higher mean arterial pressure, lower pulmonary capillary wedge pressure, but increased bleeding complications and no difference in 30-day mortality [12].

Another trial study showed that the Impella was not associated with decreased 30-day mortality in cardiogenic shock compared to IABP [13]. Each device should be applied according to the patient's condition and time for recovery, bridge-to-long-term devices, or bridge-to-transplantation. Another treatment strategy for percutaneous MCS is that we may consider to switch one device with other one depending on the indication. IABP can be opted for first option in patient with cardiogenic shock due to easy availability and rapid insertion. An IABP is simple and safe to insert, but provides little active hemodynamic support and depends on residual left ventricular function to be effective. If patients have worse left ventricular

function, Impella, TandemHeart, or VA-ECMO can be quickly and easily inserted percutaneously and provide active hemodynamic support. During acutely depressed left-ventricular function, IABP may be the first treatment option for clinician, but if patients need more time for recovery or patients need stronger hemodynamic support IABP can switch to Impella or TandemHeart. If patients have respiratory failure along with cardiogenic shock, VA-ECMO should be opted first because it provides oxygenation and good cardiac support.

There are only limited studies available for survival of transplanted patients after percutaneous MCS. Jasseron et al. reported that transplantation was associated with a lower risk of mortality, even if the overall survival rate and 1-year post-transplant survival rate were inferior in patient on VA-ECMO and they suggested that transplantation may be considered to be an acceptable primary therapy in selected patients on VA-ECMO [14].

Percutaneous MCS can also be used for the treatment of ventricular failure in the situation of acute allograft cardiac failure or post-transplant RV failure after cardiac transplantation.

Although each percutaneous MCS device has different working mechanisms, all of them can serve as a bridge-to-bridge or bridge-to-transplant strategy. Device selection or sequential application of percutaneous MCS should be managed according to the LV function, time for recovery, and patient's conditions.

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