CHAPTER 11

Overview, Indications, and Step-by-Step Techniques for Hemodynamic Support Devices

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Introduction

Hemodynamic support devices can be divided into either short term or long term. Short term devices are utilized for a wide range of clinical situations including high risk percutaneous coronary intervention and management of cardiogenic shock. Long term devices such as ventricular assist devices are utilized in advanced heart failure patients as either bridge to transplantation, bridge to recovery or destination therapy. In this chapter, we will review the short term hemodynamic support devices. Short term hemodynamic support devices include intraaortic balloon pump (IABP), left ventricle to aorta axial flow pump (Impella), Left atrium to aorta assist device (TandemHeart) and extracorporeal membrane oxygenation (ECMO) as shown in **Figure 1**.

Intraortic balloon counterpulsation

IABP is one of the most commonly used mechanical hemodynamic support devices. IABP consists of a balloon catheter which counterpulsates (inflates and deflates), as well as a mobile console which contains the parent controls and the helium transfer system.

Mechanism of action:

IABP results in two major direct hemodyamic consequences:

1. Reduction in afterload by reduced aortic volume during systole due to vacuum effect created by balloon deflation, thereby decreasing myocardial oxygen demand.[1]

2. Blood displacement into proximal aorta during diastole thereby improving coronary perfusion and myocardial oxygen supply.[2]

Indications:

IABP is very useful in stabilizing patients with significant hemodynamic compromise temporarily. The indications for IABP include: cardiogenic shock, acute myocardial infarction, high risk percutaneous coronary intervention (PCI), refractory unstable angina, bridge to coronary artery bypass surgery in patients with severe coronary artery stenosis, acute mitral regurgitation, intractable ventricular arrhythmias, refractory advanced heart failure patients awaiting definite therapy.

Contraindications:

Moderate to severe aortic regurgitation, aortic dissection, significant aortic aneurysm, uncontrolled sepsis, severe peripheral vascular disease, severe bleeding disorder, end stage refractory heart failure with no options for destination VAD or transplant.

Technique:

In most cases, IABP is placed through the common femoral artery approach, although alternate access sites such as the subclavian or axillary artery access can be used.[3, 4] Balloon pumps are manufactured in multiple sizes from 20cc to 50cc. Appropriate size of the balloon pump is chosen based on the patient's height, so that the balloon is positioned below the left subclavian artery and above the renal arteries.

Following cleaning and draping the femoral access site, the balloon pump femoral sheath (various sizes available, usually 7.5 French) is inserted using a modified Seldinger's technique. Next, the J tipped 0.018" guidewire is advanced up to the aortic arch under fluoroscopy. Then, the balloon catheter

is inserted over the guidewire under fluoroscopy to a position approximately 2cm below the origin of left subclavian artery. Next, the guidewire is removed and central lumen is flushed and connected to the transducer of the arterial pressure monitoring system. The position of the catheter is confirmed by fluoroscopy, chest X-Ray or transesophageal echocardiogram.

There are several options for triggering balloon inflation and deflation including EKG, arterial pressure waveform and internal trigger mode for patients with cardiac arrest. The inflation and deflation timings can be manually adjusted to maximize augmentation. Low dose heparin is often routinely prescribed to maintain aPTT of 50-70 seconds although the need for anticoagulation with IABP is controversial. Patient with IABP should get daily chest X-Rays to confirm position, daily labs (monitor hemoglobin, platelets and renal function), frequent lower extremity pulse checks, and restricted hip flexion.

Possible complications from IABP include limb ischemia, bleeding at the insertion site, groin hematoma, aortic dissection, renal failure, bowel ischemia, stroke, and infection. Patients should be routinely assessed for candidacy for weaning.

Limitations of IABP must be noted. It only minimally increases cardiac output (estimated ~0.5L/min). The Shock trial showed no benefit of IABP in the setting of acute MI/shock; however, it currently has a class IIb recommendation in this patient population.

Left ventricle to aorta axial flow pump (Impella)

The Impella device is available in different sizes – Impella 2.5, Impella CP, Impella 5.0. There is also a right ventricular assist device, Impella RP. The Impella is designed to be placed percutaneously via the femoral artery, axillary artery or surgically via a graft placed in the subclavian or axillary artery (**Table 1**).

Mechanism of action:

Impella is an axial flow pump with inflow placed retrograde across the aortic valve into the left ventricle (LV). The outflow is located in the ascending aorta and a pump rotating at high speeds accelerates blood from LV into the aorta. It decreases LV end diastolic pressure and oxygen demand and increases cardiac power output.

Indications:

There are two clinical scenarios where this may be helpful: 1. High risk PCI: Impella 2.5 and Impella CP may be considered for short term (<6 hours) support for high risk PCI (e.g. unprotected left main, low ejection fraction) to prevent hemodynamic instability. 2. Cardiogenic shock: Impella devices can be used for temporary ventricular support in patients with cardiogenic shock for short term (<4 days for Impella 2.5 and Impella CP and <6 days for Impella 5.0).

Contraindications:

LV mural thrombus, presence of mechanical aortic valve, severe aortic stenosis (relative), severe peripheral artery disease (relative)

Technique:[5]

Percutaneous femoral insertion: Using modified Seldinger's technique, under standard precautions, right or left common femoral artery access is obtained. Heparin is administered to maintain therapeutic anticoagulation (ACT >250 seconds). A stiff wire is placed in the aorta and serial dilations of the femoral arteriotomy site is performed and Impella peel-away insertion sheath is placed (13Fr for Impella 2.5 and 14Fr for Impella CP). The device is purged and kept ready on the table. Next, insert a

pigtail catheter or a multipurpose catheter over a 0.035” guidewire and advance into the left ventricle. Remove the 0.035” guidewire leaving the diagnostic catheter in the LV.

Next, make a gentle curve on the 0.018-inch guidewire provided with the kit and advance into the diagnostic catheter and place in the apex of the LV. Remove the diagnostic catheter and back load the Impella catheter over the 0.018” guidewire. Under fluoroscopy, the Impella catheter is advanced along the placement guidewire and across the aortic valve into the LV. Remove the placement guidewire and confirm position with fluoroscopy and aortic waveform located on the automated Impella controller. The device can be initiated at this point. Pull the introducer sheath over the Impella catheter, peel away the sheath, and advance the repositioning sheath to achieve hemostasis. 5% Dextrose solution is used for purge with heparin to maintain ACT between 160-180 seconds.

Surgical placement of Impella: Impella 5.0 typically requires axillary artery access. An axillary insertion kit comes with a short 23Fr peel away sheath. The axillary artery is isolated and exposed with surgical cutdown. Subsequently, a 10mm x 20cm long vascular graft is attached to the axillary artery using end to side anastomosis. After checking hemostasis, insert the introducer into the graft and secure it with a graft lock. Next, insert a 0.035” guidewire with 4-6Fr diagnostic catheter and advance the catheter into LV. Next, remove the guidewire and exchange it for a 0.018” stiff placement guidewire. Remove the diagnostic catheter. Next, remove the protective sleeve on the 8Fr silicone coated lubrication dilator and insert the dilator into the introducer over the placement guidewire to coat the hemostatic valve with silicone oil. The dilator is then removed and the Impella 5.0 is advanced over the placement guidewire and placed in the LV. Remove the guidewire and initiate the Impella device. Next, remove the introducer sheath out the graft and peel away. Trim any excess graft and advance the repositioning sheath. Suture and secure the graft around the repositioning sheath.

Echocardiogram is done post Impella placement to confirm appropriate device and to guide repositioning if needed (**Figure 2**).

Left atrial to aorta assist device (TandemHeart)

The TandemHeart is a percutaneous left atrial to femoral artery bypass centrifugal flow pump system. A trans-septal puncture enables a 24 French ProtekSolo inflow cannula to be placed in the left atrium that drains oxygenated blood that is then pumped by a continuous flow centrifugal pump through a 15 or 17 French ProtekSolo arterial cannula in the common femoral artery. The continuous centrifugal flow pump can run at 7500 rpm delivering up to 5 liters per minute of flow.

Mechanism of Action:

Left ventricular unloading and reduction of preload is achieved by draining oxygenated blood from the left atrium. It reduces both left ventricular volume and pressure. Circulatory support is augmented due to increasing the aortic systolic, diastolic and mean arterial pressure, which then maintains organ perfusion. Myocardial perfusion is improved by decreasing the left ventricular end diastolic pressure and increasing the aortic diastolic pressure, thereby increasing the trans-myocardial perfusion gradient.

Indications:

Temporary cardiopulmonary bypass, high risk PCI,[6] cardiogenic shock complicating acute myocardial infarction,[7] decompensated heart failure.

Contraindications:

Predominantly right heart failure, ventricular septal defect, moderate to severe aortic insufficiency, severe peripheral vascular disease, left atrial (appendage) thrombus.

Technique:

Access is obtained using modified Seldinger technique in the femoral vein and femoral artery. An iliofemoral angiogram is first obtained to ensure patency of the iliofemoral arterial vessel prior to implantation.

Using a trans-septal introducer sheath and specialty needle, a standard trans-septal puncture is obtained under fluoroscopy and intra-cardiac echocardiogram (ICE) or trans-esophageal echocardiogram (TEE) guidance through the femoral vein. An 0.025" guidewire is then inserted into the left atrium. 100 units/kg of unfractionated heparin is then administered intravenously to obtain an activated clotting time of > 400 seconds. The sheath and needle are removed. The trans-septal puncture is then serially dilated with a 14Fr followed by a 21Fr dilator. The 24Fr ProtekSolo inflow venous cannula and introducer assembly are then advanced over the 0.025" guidewire into the left atrium. Position of the inflow cannula is confirmed by pressure transduction, blood gas analysis and echocardiographic assistance. The inflow cannula has an end hole and 14 side holes at the distal end. Using echocardiographic and fluoroscopic guidance, care must be taken to ensure that all the side holes in the distal end of the inflow cannula are completely in the left atrium to prevent left to right shunting. The obturator and guidewire are then removed. The inflow cannula is then cross-clamped.

After serial dilatations, the ProtekSolo 15 or 17Fr outflow arterial cannula is then inserted into the femoral artery and advanced over the 0.035" guidewire up to the aortic bifurcation. The wire and introducer are removed, and the arterial cannula is clamped. If the femoral and/or iliac arteries are small, bilateral common femoral arterial access is obtained and two 12Fr arterial cannulas are placed in the bilateral femoral arteries.

The air is then purged from the extracorporeal circuit. The trans-septal inflow cannula is then attached to the inflow portion of the centrifugal pump using a wet-to-wet technique and the clamp is removed. The pump is turned on at 5500 rpm. After confirming absence of air in the pump and inflow

cannula, the clamp across the outflow cannula is removed. The pump is ramped up until desired flow rate is achieved. Unfractionated heparin is administered intravenously to maintain an activated clotting time of about 200 seconds throughout the hemodynamic support time to prevent thromboembolic complications. The cannulas and pump are sutured to the patient's skin and the patient is kept immobile to prevent dislodgement or kinking of the cannulas.

TandemHeart is approved for 6 hours of support by the US FDA and up to 30 days by the European Commission.

Potential complications of the TandemHeart include puncture of the aortic root, coronary sinus or right atrial posterior free wall during trans-septal puncture; thromboembolism; systemic hypothermia; cannula dislodgement; bleeding; limb ischemia; and sepsis.

Extracorporeal Membrane Oxygenation (ECMO)

ECMO is a form of extracorporeal cardiopulmonary support system that is used for patients with respiratory and/or circulatory collapse. VV ECMO is venovenous ECMO that is used for severe respiratory failure that involves draining deoxygenated blood from the right atrium that is then oxygenated using an artificial membrane lung and then returned to the right atrium. VA ECMO is venoarterial ECMO that can provide hemodynamic support that involves draining blood from the right atrium into an oxygenator and then pumped back using a centrifugal flow pump to the arterial system.[8] ECMO can be done percutaneously (peripheral ECMO) at bedside or surgically (central ECMO) in the operating room. Flows of 4 to 8 liters per minute are achieved using the centrifugal flow pump up to 4000 rpm. Peripherally inserted VA ECMO is described here.

Mechanism of Action:

ECMO maintains circulatory support by increasing systolic, diastolic and mean arterial pressures to maintain end organ perfusion. It also maintains respiratory support by oxygenating venous blood that is returned to the arterial system, thereby bypassing the lung. Trans-myocardial perfusion may improve by increasing the aortic diastolic pressure. However, ECMO does not unload the left ventricle, and increased left ventricular end diastolic pressures may adversely affect the coronary perfusion.

Indications:

Cardiogenic shock or cardiopulmonary arrest with severe pulmonary congestion, high risk PCI, fulminant myocarditis, post cardiotomy circulatory failure, massive pulmonary embolism, support as a bridge to heart transplant or ventricular assist device or decision.

Contraindications:

Pre-existing condition incompatible with recovery including severe neurological injury, end stage malignancy, severe aortic regurgitation, severe peripheral arterial disease, uncontrollable bleeding, recent stroke, or sepsis.

Technique:

Peripheral VA ECMO involves draining blood from the right atrium using an inflow cannula and returning the blood after it has passed through the oxygenator and heat exchanger into the femoral, axillary or common carotid artery.

Venous and arterial access is obtained in the femoral vein and artery either by percutaneous Seldinger technique, open cut down, open cut down Seldinger technique (Semi-Seldinger), or open cut down with end to side graft anastomosis (Dacron). A venous cannula (19 to 25Fr sizes) is inserted with

the tip of the cannula at the level of the right atrium either through the femoral vein or the internal jugular vein. Flow rates are determined by the size of the inflow venous cannulas.

A 15 to 23Fr short arterial cannula is inserted in to the common femoral artery directed towards the descending aorta. Axillary arterial cannula insertion requires surgical cut down but enables early ambulation. Common carotid artery cannulation is associated with high risk of watershed cerebral infarction. The venous and arterial cannulas are connected to the centrifugal flow pump using a wet to wet technique and the ECMO circuit is completed. Blood flow is increased until arterial oxyhemoglobin saturation is > 90%, venous oxyhemoglobin saturation is 20-25% less than the arterial oxyhemoglobin saturation, and adequate tissue perfusion is obtained.

Systemic anticoagulation using intravenous heparin to maintain an activated clotting time of 180 – 210 seconds is used. Platelet levels are maintained over 50,000 /microliter and hemoglobin is kept above 12 gram/deciliter.

To maintain ipsilateral antegrade limb arterial circulation, a reperfusion circuit is used where a catheter is inserted distal to the main femoral arterial cannula and a portion of the oxygenated blood is redirected through this catheter to prevent limb ischemia.

In peripherally cannulated VA ECMO, North-South Syndrome can occur due to the differential hypoxemia between the upper body and lower body in patients with poor respiratory function and marked pulsatility. This watershed can lead to persistent dual circuit perfusion where the heart, brain and upper extremities are perfused by the poorly oxygenated blood that cycles from the left ventricle to the upper body that then drains into the superior vena cava. The oxygenated blood from the VA ECMO system perfuses the lower body and abdominal viscera and drains into the inferior vena cava and reenters the ECMO circuit. To diagnose this condition, frequent blood gas analysis is required from the right upper extremity via an arterial line. This can be corrected by infusing arterial blood into the right atrium (referred to as VA-V access).[9]

Other complications include life threatening bleeding, thromboembolism, neurological injury, and cardiac thrombosis.

One of the limitations of ECMO is left ventricular distension and pulmonary edema, since the arterial flow is retrograde towards the ascending aorta. The left ventricle may need “venting” using inotropes, diuresis, intra-aortic balloon counterpulsation pump, left ventricle to aorta axial flow pump (Impella), or by percutaneous left ventricular drainage (via trans-atrial balloon septostomy or insertion of left atrial or ventricular drainage catheter). In refractory cardiogenic shock patients, adding Impella to ECMO (ECPELLA) resulted in lower all-cause mortality at 30 days and lower inotrope use, compared with ECMO alone.[10]

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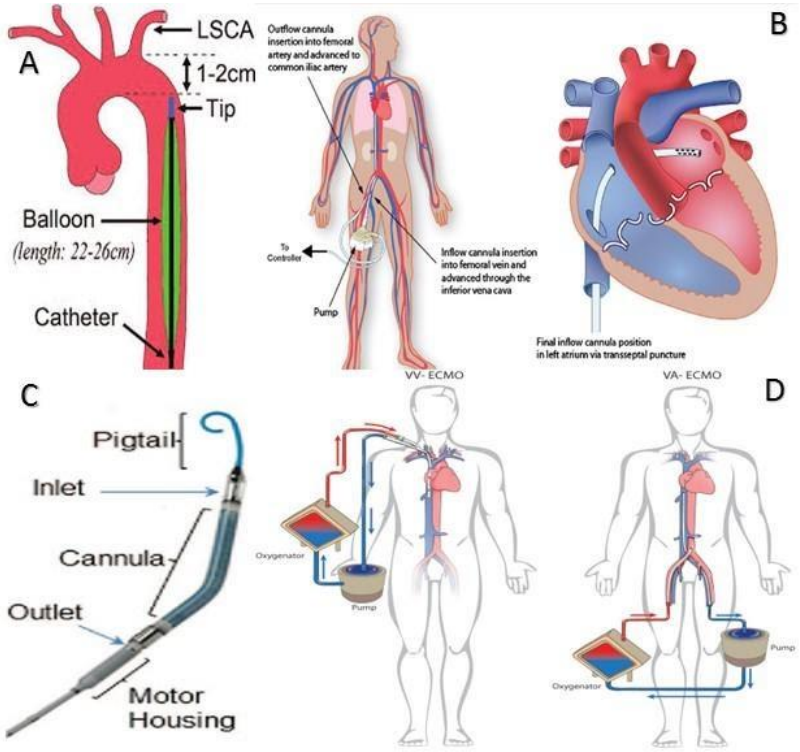
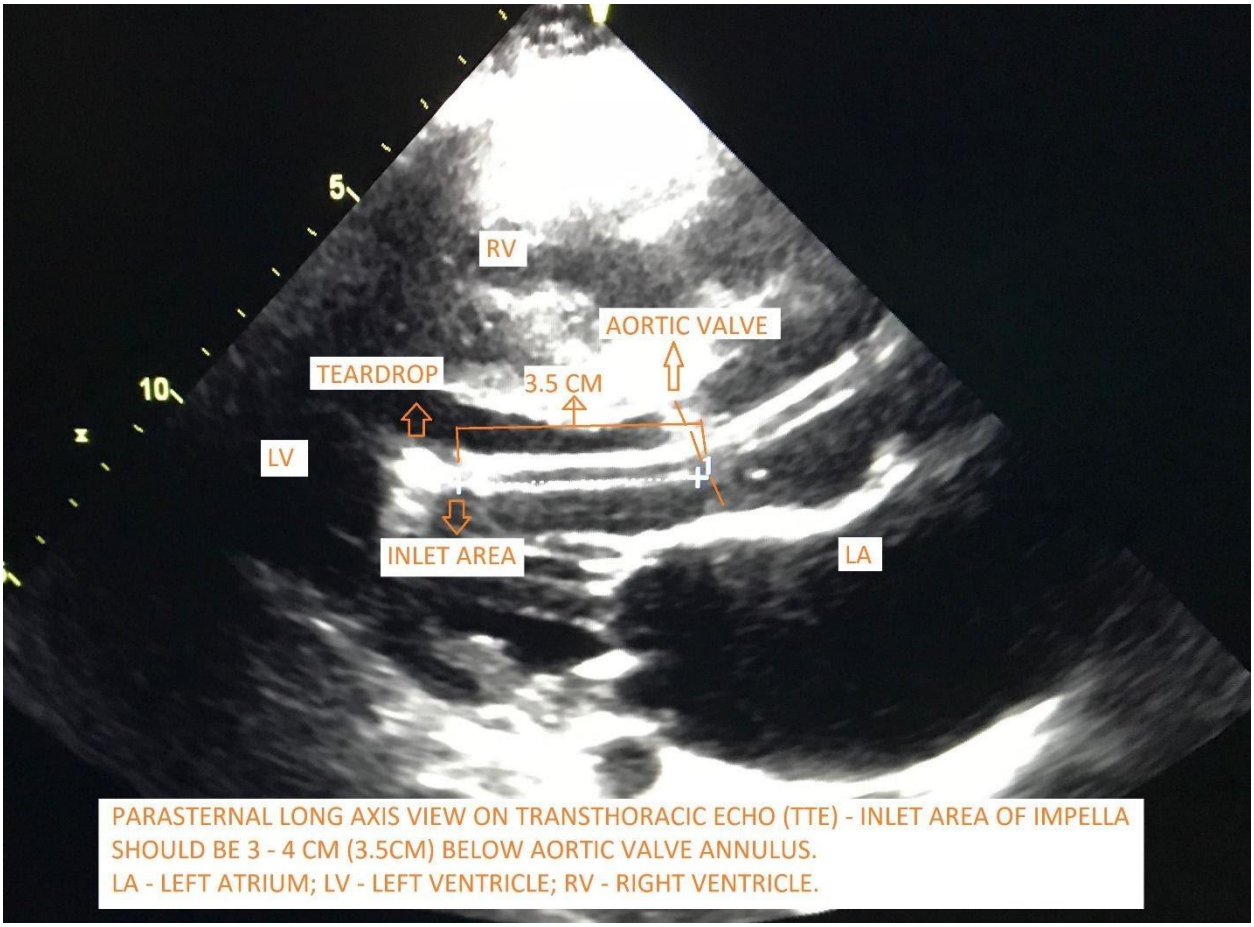
Figures

Figure 1: Schematic diagram showing the various mechanical support devices



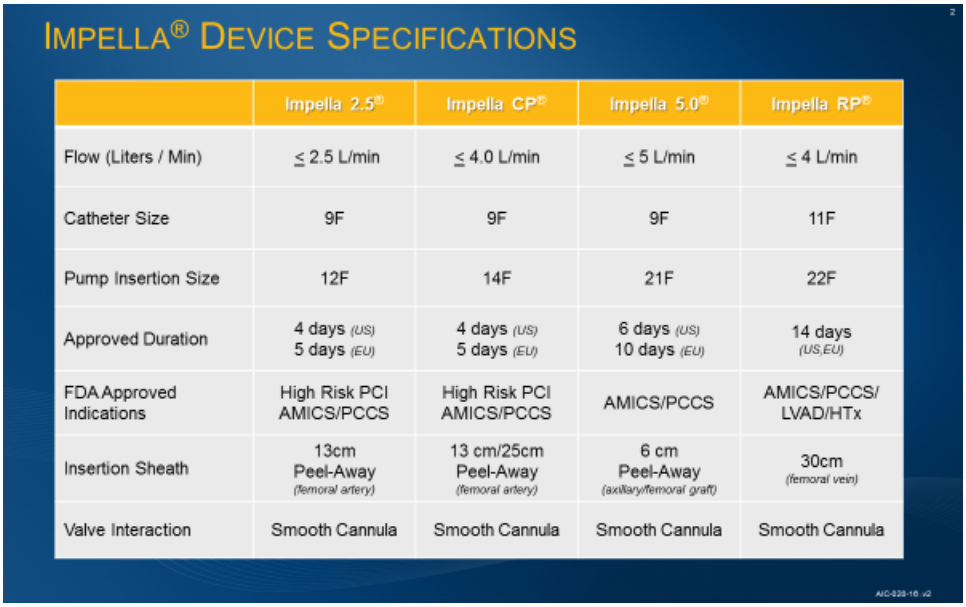
A: Intraaortic balloon pump (IABP); B: TandemHeart; C: Impella; D: Extracorporeal Membrane Oxygenation (ECMO).

Figure 2: Parasternal long axis view on transthoracic echocardiogram showing the inlet area is 3.5 cm (3 – 4 cm ideal) below the aortic valve annulus



Tables

Table 1: Characteristics of various Impella devices currently used in a variety of clinical settings



IMPELLA® DEVICE SPECIFICATIONS

	Impella 2.5®	Impella CP®	Impella 5.0®	Impella RP®
Flow (Liters / Min)	≤ 2.5 L/min	≤ 4.0 L/min	≤ 5 L/min	≤ 4 L/min
Catheter Size	9F	9F	9F	11F
Pump Insertion Size	12F	14F	21F	22F
Approved Duration	4 days (US) 5 days (EU)	4 days (US) 5 days (EU)	6 days (US) 10 days (EU)	14 days (US,EU)
FDA Approved Indications	High Risk PCI AMICS/PCCS	High Risk PCI AMICS/PCCS	AMICS/PCCS	AMICS/PCCS/ LVAD/HTx
Insertion Sheath	13cm Peel-Away (femoral artery)	13 cm/25cm Peel-Away (femoral artery)	6 cm Peel-Away (axillary/femoral graft)	30cm (femoral vein)
Valve Interaction	Smooth Cannula	Smooth Cannula	Smooth Cannula	Smooth Cannula

References

1. Santa-Cruz RA, Cohen MG, Ohman EM. Aortic counterpulsation: a review of the hemodynamic effects and indications for use. Catheter Cardiovasc Interv 2006;67:68-77.
2. Kern MJ, Aguirre FV, Tatineni S, et al. Enhanced coronary blood flow velocity during intraaortic balloon counterpulsation in critically ill patients. J Am Coll Cardiol 1993;21:359-68.
3. Raman J, Loor G, London M, et al. Subclavian artery access for ambulatory balloon pump insertion. Ann Thorac Surg 2010;90:1032-4.
4. Estep JD, Cordero-Reyes AM, Bhimaraj A, et al. Percutaneous placement of an intra-aortic balloon pump in the left axillary/subclavian position provides safe, ambulatory long-term support as bridge to heart transplantation. J Am Coll Cardiol HF 2013;1:382-8.
5. "Education." Protected PCI Community, www.protectedpci.com/education. Accessed 12/2018.
6. Aragon J, Lee MS, Kar S, et al. Percutaneous left ventricular assist device: "TandemHeart" for high-risk coronary intervention. Catheter Cardiovasc Interv 2005;65:346-52.

7. Thiele H, Lauer B, Hambrecht R, et al. Reversal of Cardiogenic Shock by Percutaneous Left Atrial-to-Femoral Arterial Bypass Assistance. Circulation 2001;104:2917-22.
8. Makdisi G, Wang IW. Extra Corporeal Membrane Oxygenation (ECMO) review of a lifesaving technology. J Thorac Dis 2015;7:e166-76.
9. Pavlushkov E, Berman M, Valchanov K. Cannulation techniques for extracorporeal life support. Ann Transl Med 2017;5:70.
10. Patel SM, Lipinski J, Al-Kindi SG, et al. Simultaneous Venoarterial Extracorporeal Membrane Oxygenation and Percutaneous Left Ventricular Decompression Therapy with Impella Is Associated with Improved Outcomes in Refractory Cardiogenic Shock. ASAIO J 2019;65:21-28.