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Review Article,

Percutaneous Mechanical Circulatory Support Use in Cardiogenic Shock and High-Risk Percutaneous Intervention

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Abstrect:
Mechanical circulatory support devices use has been increased significantly in last few years. These devices can provide additional hemodynamic support in patients with cardiogenic shock refractory to pharmacological therapy. Percutaneous mechanical circulatory support devices can also provide reliable hemodynamic support during percutaneous coronary intervention (PCI) in patients with complex lesions and comorbidities like heart failure with reduced ejection fraction. In this article, we reviewed the different types of percutaneous mechanical circulatory support devices available for use in cardiogenic shock and high-risk PCI, along with an insight into the technical aspects of each device.

Keywords: Mechanical Circulatory Support, Extracorporeal membrane oxygenation, Intra-aortic balloon pump, Percutaneous coronary intervention

Introduction:

Statistical data has shown that patients now treated in cardiac catheterization laboratories are older with several comorbidities, including renal failure, diabetes, and heart failure [1]. In past patients who were not suitable candidates for percutaneous coronary intervention due to their numerous comorbidities now seems to be a suitable candidate due to tremendous advancements in the field of interventional cardiology like new stent design and availability of advance mechanical circulatory support devices, i.e., Impella, performing PCI on these high-risk patients become a viable option. There are two areas of cardiology in which mechanical circulatory support devices keep evolving: one is high-risk PCI (percutaneous coronary intervention), and the other is a cardiogenic shock that is refractory to initial pressor support.

Mechanical circulatory support in cardiogenic shock:

Cardiogenic shock is a life-threatening condition and is defined as end-organ dysfunction due to decreased cardiac output. In most trials, cardiogenic shock was defined as mean arterial pressure (MAP) of less than 90 mm Hg for > 30 minutes, along with signs of hypoperfusion, i.e., increased lactate and decreased urine output [2]. There are many etiologies of cardiogenic shock. Cardiogenic shock can develop in 5 to 10% of acute myocardial infarction cases [3]. Left ventricular failure, followed by severe mitral regurgitation (MR), ventricular septal defect, and acute right ventricle (RV) failure, are the most common causes of cardiogenic shock in acute myocardial infarction. Besides acute myocardial infarction, other causes of cardiogenic shock include fulminant myocarditis and end-stage acute on chronic heart failure. Mechanical circulatory support devices can provide potential benefits of organ perfusion, reducing intracardiac filling pressure, decreasing left ventricular volume, and increasing coronary perfusion in the state of shock [4].

Although primarily inotropes use as an initial intervention in hemodynamically unstable patients with cardiogenic shock, the use of multiple

pharmacological therapies is associated with increased mortality; the probable mechanism includes an increase in myocardial oxygen demand and risks of significant arrhythmia [5].

Management of cardiogenic shock has been changed dramatically due to advancements in mechanical circulatory support devices. Now tertiary care centers started approaching cardiogenic shock by use of shock team in which patients are initially assessed in the emergency room and then directly assessed by an acute mechanical circulatory specialist with the team consists of advanced heart failure specialist, interventional cardiology, cardiac surgeon, and the critical care team specialist.

Mechanical circulatory support in high-risk percutaneous intervention:

Since the first percutaneous intervention performed in 1977 by Andrea Gruntzig, this field has seen a tremendous transformation due to new stent design, advanced guidewires, use of atherectomy devices, and clinicians' tireless efforts of analyzing research data to improve intervention procedures outcomes.[5]

There is no set definition for high-risk percutaneous coronary intervention, but usually, many parameters can make the percutaneous intervention higher risk. These parameters can be divided into anatomical factors, the presence of comorbidities, and clinical status. Anatomical factors for high-risk PCI (percutaneous intervention) include unprotected left main, a triple-vessel disease with a high Syntax score, and the last remaining patent vessel. In addition, ejection fraction (EF) less than 35% or decompensated heart failure, valvular conditions like severe aortic stenosis, and multiple comorbidities like advanced COPD and chronic kidney disease are also high-risk PCI features [6].

Types of percutaneous Mechanical Circulatory Support Devices:

Mechanical circulatory support devices can be classified into distinct categories depending upon the location, intracorporeal versus extracorporeal, and type of flow, pulsatile versus axial.

To understand the fundamentals of acute mechanical circulatory support, it is imperative to understand the effects of mechanical circulatory support on the pressure-volume loop curve. A mechanical circulatory support device benefits the cardiovascular system by taking over the heart's mechanical work, leading to a decrease in oxygen consumption. As left ventricular pressure and left ventricular volume are decreased by mechanical circulatory support, this leads to a decrease in myocardial oxygen demand.

Intra-aortic balloon pump (IABP):

Intra-aortic balloon pump is one of the oldest percutaneous mechanical circulatory devices in use. It was first implanted clinically in 1967 at Maimonides Medical Center by Dr.Adrian Kantrowitz and Dr. Stephen Phillips. Intra-aortic balloon pump work on the principle of counter pulsation [7]. The efficacy of an intra-aortic balloon pump depends upon the quality of native LV pulsation; therefore, in advanced LV failure, an intra-aortic balloon pump becomes less effective. Intra-aortic balloon pump beneficial effects include decreased oxygen demand of myocardium, increased coronary perfusion during diastole, decreased afterload, and increased cardiac output.

BCIS 1 trial was one of the initial trials that were done between 2005-2009. It includes 300 patients with severely reduced ejection fraction and significant CAD. One group had intra-aortic balloon pump placement before PCI, versus the other group does not have any support device. The primary outcome was measured in terms of major adverse cardiovascular events (MACE). This trial did not show any difference in MACE (major adverse cardiovascular events) (15.2% vs. 16.0%) between the two groups.

Balloon pump has its advantages and disadvantages. The significant advantage of the balloon pump is its wide availability and relatively easy deployment compared to other mechanical circulatory devices. Contraindications to use a balloon pump are aortic regurgitation and severe peripheral arterial disease. Potential complications are limb ischemia, vascular trauma, risk of bowel ischemia, and balloon rupture.

Impella:

Impella is an advanced mechanical circulatory support device with properties closer to the ideal circulatory device. Impella is an axial flow device with a non-pulsatile flow that works on the principle of differential pressure. The device flow depends directly upon revolution per minute (RPM) and inversely on the pressure gradient between the aorta and left ventricular. As in cardiogenic shock, there is less difference between

diastolic aortic pressure and left ventricular end-diastolic pressure; this provides an Impella advantage over intra-aortic balloon pump, especially in advance left ventricular failure. Impella device has three device versions. Impella 2.5, Impella CP, and Impella 5.0. Impella 2.5 gives a cardiac output of 2.5 L, Impella CP gives a cardiac output of 4 L /min, and Impella 5.0 provides a cardiac output of 5 L/min. [9].

ISAR-SHOCK trial was one of earlier trials in which Impella 2.5 was used. In this trial, 25 patients with cardiogenic shock with acute MI (Myocardial Infarction) were randomized into Impella 2.5 versus intra-aortic balloon pump. The primary outcome was measured in change in the cardiac index compared to baseline after 30 minutes of deployment. Secondary outcomes were measured in terms of lactic acid level, hemolysis, and mortality at 30 days. This study did not find a difference regarding the improvement of a cardiac index between the two groups [10].

In Protect II trial, 448 patients with high-risk PCI were randomized into two groups. In one group balloon pump was used as a mechanical circulatory support device, and in another group, Impella 2.5 was used. The primary outcome was measured in terms of MACE at 30 days. There was no difference found in 30 days regarding MACE (Major Adverse Cardiovascular Endpoints), but at 90 days, the Impella group has fewer adverse events that can be attributed to the lesser need for repeat revascularization as compared to the IABP group [11]. In addition, cardiac power output was measured as a secondary endpoint, and the Impella group has a maximal decrease in cardiac power output (CPO) support.

Regarding technical consideration, Impella needs a larger sheath size as compared to a balloon pump. In addition, a left femoral angiogram should be done to ensure no excessive tortuosity or stenosis of the femoral artery that can make the device implantation difficult. The one downside of Impella is, due to its small pump size, it can cause hemolysis; therefore, in patients on Impella, LDH and free plasma hemoglobin should be checked periodically.

Contraindications to the deployment of Impella are LV thrombus, severe aortic stenosis with AVA less than 0.6 cm2, moderate to severe AR, severe peripheral vascular disease, mechanical aortic valve, and contraindication to use of anticoagulation.

Tandem Heart:

TandemHeart is left atrium (LA) to femoral artery (FA) bypass, although it improves cardiac index to a greater extent as compared to intra-aortic balloon pump, it is not very widely used because its deployment is more complex due to requirement of transseptal puncture with a large-bore cannula to place canula in left atrium [12].

Extracorporeal membrane oxygenation (ECMO):

ECMO is a percutaneously placed advanced circulatory support device. Its works more on the principle of a heart-lung bypass machine. It takes blood from the right atrium and returns it to descending aorta after oxygenation, providing cardiac output from 5 L/min up to 7 L/min. There are many benefits of ECMO as compared to other devices. One advantage is it can provide biventricular support; the additional benefit is its establishment of complete cardiopulmonary support; therefore, it is beneficial in cardiac arrest patients currently undergoing cardiopulmonary resuscitation.

The study by Sheu showed increased survival in individuals with profound shock with the use of ECMO 39% vs. 72% [13].

The downside of ECMO is it increases afterload; therefore, if LV function is poor, it can cause LV dilation, and resulted back pressure leads to increased pulmonary capillary wedge pressure and pulmonary edema. Therefore, after initiation of ECMO, close monitoring of respiratory status and hemodynamic parameters is needed, and if LV overload is observed, LV venting could be done with the use of inotropes, intra-aortic balloon pump, or with the help of Impella.

Table1: Summary of characteristics of different Mechanical Circulatory Support Devices

	IAPB	IMPELLA	Tandem Heart	VA-ECMO
Mechanism	Aorta	LV-->Aorta	LA--> Aorta	RA--> Aorta

Main hemodynamic effects	LV volume and Pressure unloading	LV volume and Pressure unloading	LV volume unloading	Right and left ventricle pressure and volume unloading
Pump Mechanism	Pneumatic	Axial	Centrifugal	Centrifugal
Sheath Size	8 F	13-22F (depending upon Impella type)	21 Fr inflow and 15, -17 Fr outflow	18-21 Fr inflow,15-22 Fr. outflow
Size of Femoral artery	>4mm	>5-5.5mm	8.0 mm	8.0mm
Flow, L/MIN	0.5-1	2.5-5.0 L/min	4-6	4-6
Level of hemodynamic support	low	Moderate in Impella 2.5 and high in 5.0	high	high
Risk of Vascular Complications	+	++	+++	++++
Risk of hemolysis	Very low	low	low	low
Implantation time	Very less	Moderate in Impella 2.5, high in 5.0	high	moderate
Maximum implants Days	weeks	7 days	14 days	weeks
Ventricle Supported	LV	LV separate R sided Impella require for RV support	LV or RV	LV and RV
Afterload	↓	↓	↑	↑↑
MAP	↑	↑↑	↑↑	↑↑
LVEDP	↓	↓↓	↓↓	<-->
LV Preload	--	↓↓	↓	↓
Effect on coronary perfusion	↑	↑	<-->	<-->
Advantages	Easy deployment Less vascular complications	Multiple device availability with different flow rate.	High cardiac output, less increase in afterload as compared to VA-ECMO	Highest cardiac output, complete cardiopulmonary support
Disadvantages	Less support, not very helpful in advance LV failure and in cases of arrhythmia.	Need larger sheath size, frequent repositioning of device can be needed	Need more skilled operator because requirement of intraarterial puncture	Need large team for post device care, increase afterload leads to LV distension
Contraindications	Moderate to severe aortic regurgitation, Severe PAD	Moderate to severe aortic regurgitation, Severe PAD Mechanical aortic valve Left ventricle thrombus Severe aortic stenosis <0.6 m2 Contraindication to use anticoagulation.	Moderate to severe aortic regurgitation, Severe PAD Contraindication to use anticoagulation LA thrombus	Moderate to severe aortic regurgitation, Severe PAD Contraindication to use anticoagulation

Right ventricular mechanical circulatory support

Right ventricular support is needed in cases of right ventricular infarction or acute right ventricle failure after placement of left ventricular assist device. As compared to the left ventricle, there is less options for right ventricular support. Available options for right ventricular mechanical circulatory support are right-sided Impella, double cannula Tandem heart and ECMO.

Timing of initiation of MCS (Mechanical Circulatory Support) in cardiogenic shock patients with acute myocardial infarction

In the above-mentioned trials, the main question that was not answered is the timing of initiation of mechanical circulatory support (pre-PCI versus post PCI) will change the outcomes or not.

US (United States) Pella registry categorize outcome in view of the timing of initiation of mechanical circulatory device. In this trial, 154 patients were randomized into two groups. In one group, Impella was initiated pre-PCI versus another group in which Impella was initiated post PCI. The primary outcome was measured in terms of survival to discharge. The secondary outcomes were measured as incidence of MI, stroke, repeat need of revascularization, and vascular complications. The result of the study favors Impella in the pre-PCI group [5].

Another important study Detroit cardiogenic shock initiative (DCSI), in which 41 patients with cardiogenic shock after acute MI received Impella before PCI. Study participants were compared with historical controls from the previous years. The study showed survival to explant was 85% in Impella pre-PCI group versus 51% in historical controls.

Conclusion:

In conclusion, mechanical circulatory support devices are changing the landscape of cardiogenic shock and high-risk PCI interventions. Choice of mechanical circulatory support device should be individualized, keeping in view specific indications and contraindications for each device.

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