# Hemodynamic Support for High-Risk PCI

Patient selection and procedural strategy are key in treating this evolving patient population.

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Percutaneous coronary intervention (PCI) for coronary artery disease (CAD) has become increasingly multifaceted as novel skill development and device innovation allow us to address increasingly complex disease.[1,2] Simultaneously, patients are presenting with higher rates of comorbidities and more complex CAD,[3,4] which may lead to a lower physiologic tolerance for complex revascularization techniques. In light of the shifting patient demographics in the cardiac catheterization lab, the concept of "protected PCI" has developed, in which mechanical circulatory support is increasingly utilized during percutaneous revascularization procedures of this higher-risk patient group (Figure 1). This article outlines strategies for patient selection and management of mechanical support to facilitate high-risk PCI.

## CARDIOGENIC SHOCK MANAGEMENT: SALVAGE PCI

The morbidity of cardiogenic shock (CS) complicating acute myocardial infarction (MI) remains extremely high, and its incidence may be increasing.[5] The National Cardiogenic Shock Initiative (CSI) defines CS by at least two of the following indications: (1) systolic blood pressure ≤ 90 mm Hg or requiring inotropes or vasopressors to maintain that pressure; (2) evidence of poor end-organ perfusion; and (3) cardiac index ≤ 2.2 L/min/$m^2$ and cardiac power ≤ 0.6 W.[6] These patients often present with complex physiology and coronary anatomy. To combat this, an increasing armamentarium of mechanical ventricular support devices has been developed. When patients present with initial CS, the management priority is to stabilize the patient hemodynamically with the least damage to myocardium. There is growing preclinical evidence that mechanical unloading of the ventricle may be the best way to facilitate this to provide end-organ perfusion while reducing the ischemic burden on the ventricle, as opposed to using vasopressors and inotropes, which increase myocardial oxygen demand.[7]

The choice of temporary mechanical circulatory support is dictated by institutional availability and patient hemodynamics. An intra-aortic balloon pump (IABP) is still the most widely used form of device support in overall CS presentations,[5] although there has been a shift toward temporary mechanical circulatory support systems and extracorporeal life support.[8] Extracorporeal life support is often required in cases of coinciding refractory respiratory or biventricular failure. Some centers move more quickly to peripheral extracorporeal life support, whereas others have higher utilization of the percutaneous microaxial devices, for which the Impella 2.5, CP, and 5.0 systems (Abiomed, Inc.) are the current mainstays of left ventricular support. The major advantage of Impella is its ability to reduce afterload while augmenting cardiac output. The TandemHeart device (TandemLife) can provide higher levels of systemic blood flow compared with the Impella 2.5 and CP devices (although similar to the Impella 5.0), with a largely neutral left ventricular afterload and reduction in preload, while also improving coronary perfusion pressure.[9] TandemHeart implantation requires transseptal puncture and large arterial cannulation, which many centers and operators are not set up to perform on an emergency basis.

Current evidence supporting the use of temporary mechanical circulatory support in acute coronary syndrome (ACS) presentations with CS is limited to substudies and registry trends. SHOCK II did not demonstrate a mortality benefit at 30 days from using IABP in MI patients with CS,[10] but it is not clear if IABPs provide sufficient augmentation of cardiac output or unloading to meet this benefit based on several hemodynamic studies.[11] In the interim, European guidelines have downgraded IABPs to a class III recommendation in overall CS,[12] except for cases of mechanical complications from MI,[13] whereas IABP remains a class IIa recommendation in the 2013 American College of Cardiology (ACC)/American Heart Association ST-segment elevation myocardial infarction (STEMI) guidelines.[14] The use of percutaneous microaxial left ventricular assist devices has dramatically increased in recent years[15] due to increasing data

supporting its hemodynamic and clinical benefit[16-18] and increased comfort in using these devices, despite a lack of proven benefit in randomized trials. Challenges in interpreting trial data for this group of patients include a heterogeneous population with high mortality rates in the primary shock presentations and difficulty enrolling a representative population in acute shock scenarios. The Detroit CSI demonstrated the feasibility of implementing a regional program, emphasizing early hemodynamic assessment and mechanical circulatory support in patients presenting with acute MI and CS.[19] The expanded National CSI is now underway to further evaluate outcomes using the strategy of early unloading of the left ventricle in acute MI (NCT03677180).

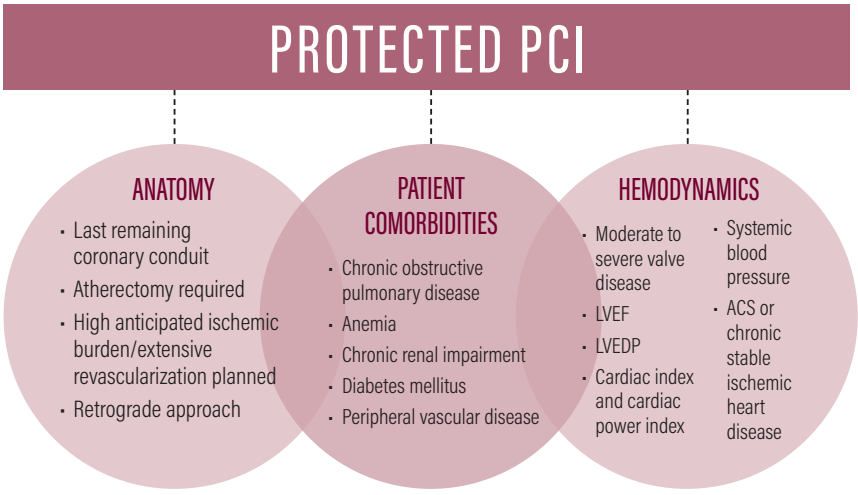



**Figure 1. The cross-section of patient and procedural factors to consider in protected PCI.**

With the current availability and relatively simple implantation of Impella devices as a means to unload the left ventricle, mechanical circulatory support as the first intervention in acute MI with CS and before PCI is an emerging concept.[20] Patient selection remains challenging, but the National CSI algorithm provides a tool to guide management in the ACS population presenting with shock, advocating for Impella placement if left ventricular end-diastolic pressure (LVEDP) is > 15 mm Hg or cardiac index is < 2.2 L/min/$m^2$ and then reassessment for right heart failure after PCI if cardiac power output is < 0.6 W while weaning vasoactive agents.[6] Although this approach outpaces the most recent level IIb guideline recommendations to consider left ventricular support devices beyond IABP,[21] it provides a logical protocol to aid in patient selection while accumulating additional data in this rapidly changing arena. The ongoing DTU STEMI trial will push this concept further, with a pilot trial recently demonstrating feasibility of left ventricular unloading followed by revascularization after 30 minutes of support in anterior STEMI patients presenting without CS.[22] Whether this concept improves long-term outcomes remains to be seen (NCT03000270).

## HIGH-RISK PCI WITHOUT CS

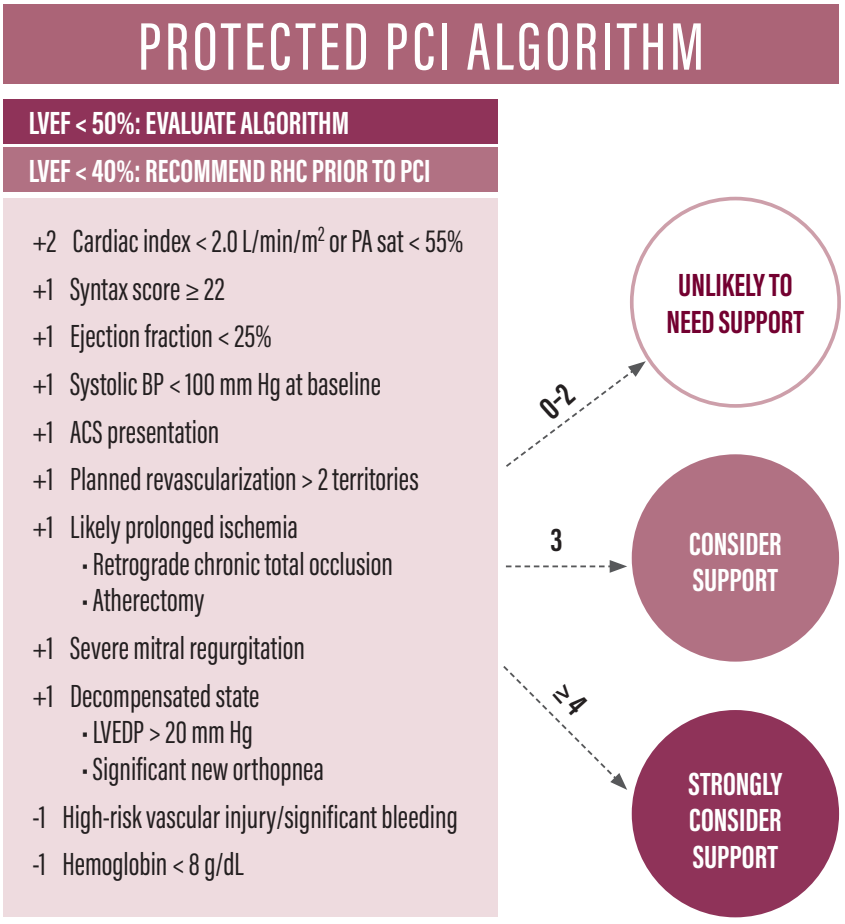
There has also been an increasing role for using mechanical circulatory support devices during planned PCI. Historical use of IABP in high-risk PCI was only 10.5% in the National Cardiovascular Data Registry, including patients with STEMI and CS as well as reduced left ventricular ejection fraction (LVEF) and unprotected left main intervention.[23] A randomized trial evaluating IABP for high-risk PCI did not demonstrate a reduction in short-term survival. Procedural hypotension and adverse events were reduced, but 12% of patients crossed over to IABP largely due to hypotension,[24] and a follow-up analysis suggested improved long-term outcomes in the IABP group.[25] Due to physiologic limitations of counterpulsation, which is dependent on cardiac reserve, IABPs are now used less frequently overall[15] and, anecdotally, have been replaced by other percutaneous mechanical circulatory pumps for device-assisted PCI at some centers. The more powerful percutaneous mechanical circulatory support devices are often selected due to their ability to provide higher levels of hemodynamic support independent of intrinsic cardiac work, although many operators continue to utilize IABPs based on institutional familiarity and availability.[26]

The ease of insertion and higher level of support with the Impella device has seen its use grow as part of an anticipatory or prophylactic strategy in patients undergoing high-risk PCI.[27] This concept of up-front support in high-risk procedures is growing in the context of these devices, which provide sufficient circulatory support during intervention such that physicians observe hemodynamic stability even with very diminished pulsatility during coronary intervention, as long as acceptable complication rates are observed at that institution. PROTECT-II randomized 452 patients to IABP versus Impella 2.5 for support during PCI in cases of unprotected left main or last remaining vessel intervention and LVEF ≤ 35% or complex three-vessel CAD and LVEF ≤ 30%, excluding patients with recent MI. There was no difference in the primary composite endpoint of adverse events at 30 days, although a trend suggested improved outcomes in the Impella 2.5 group at 90 days.[2] No randomized trials are available to compare with TandemHeart, but it is clearly preferential in special circumstances, including left ventricular thrombus and aortic valve disease or a need for higher rates of flow.[26,28] Despite current evidence, which is largely limited to a suggestion of benefit in subpopulations requir-

ing prolonged vessel preparation time and increased complexity,[26,27] anticipatory mechanical circulatory support implantation is increasingly utilized to prevent catastrophic cardiovascular collapse in high-risk cases, now termed *protected PCI*.

## PROTECTED PCI: PATIENT SELECTION FACTORS

Proper patient selection to avoid under- or overutilization of temporary mechanical circulatory support during planned PCI is paramount. In a growing experience of high-volume operators[28,29] and early registry findings,[30] the patient's cardiac physiology appears to be the primary consideration when considering protected PCI. Simply performing a complex technical case in a patient with reduced ejection fraction is not sufficient to require preprocedural implantation of mechanical circulatory support, although even an intervention on a technically simple lesion portends increased periprocedural risk in the setting of decompensated heart failure. Patients with intermediate- to high-risk predicted procedural risk warrant a pre-PCI right heart catheterization (RHC) to assess filling pressures and cardiac index/power.[31] Elevated LVEDP, especially in light of compromised cardiac index/power, leaves the patient at risk for an ischemic spiral of hypotension as a result of reduced coronary perfusion,[8] and patients fitting this profile are the most likely to benefit from the use of mechanical circulatory support during PCI. Once the patient has been optimized to the extent possible, clinically indicated revascularization should be pursued. Of note, no single threshold for cardiac output or filling pressures has been established for prophylactic mechanical circulatory support use. A single-center registry evaluating a proposed algorithm (Figure 2) to guide patient selection for protected PCI is ongoing, and findings regarding the adequacy of these characteristics to predict intraprocedural decompensation and benefit of up-front protected PCI are pending.[30]




Courtesy of James M. McCabe, MD (University of Washington).

**Figure 2. Proposed algorithm for screening patients for protected PCI. BP, blood pressure; PA sat, pulmonary artery saturation.**

## PROCEDURAL DETERMINANTS FOR PROTECTED PCI

Traditional trial definitions[2,24] and the Society for Cardiovascular Angiography and Interventions/ACC/Heart Failure Society of America/Society of Thoracic Surgeons 2015 expert consensus statement regarding use of mechanical circulatory support have defined high-risk PCI as intervention on the last remaining vessel, unprotected left main, or complex three-vessel disease, with an emphasis on the area of myocardium at risk during procedural ischemia. Other factors that may relate to ischemic burden of the case have also been described, including the use of atherectomy and retrograde crossing of collaterals in cases of PCI in chronic total occlusions. The 2015 expert consensus statement also emphasized the territory at risk and offers a simple algorithm to consider prophylactic support when both the technical aspects are complex and patient reserve is low; however, IABP/Impella use is reserved as a backup if the procedure is not complex in the setting of heart failure or if the case is complex but the patient has normal or only mildly reduced ventricular function.[26] It is important to stress that regardless of whether mechanical circulatory support is employed, good PCI practices to minimize ischemic time during the case remain crucial. If hemodynamic support is utilized, best practices for large-bore access are paramount for use of any of the devices. TandemHeart

arterial limb cannulas are available in 15- or 17-F sizes,[32] and Impella 2.5 and CP devices are delivered via a 14-F sheath.

Device removal after protected PCI is often dictated foremost by the clinical presentation. We would offer that baseline evaluation of cardiac status by RHC is the best practice, with serial evaluation while weaning down Impella support over 30 minutes with repeat assessment of filling pressures and cardiac index/power. In cases of ongoing pressor or inotrope requirement, additional time with mechanical support in the cardiac intensive care unit is typically warranted. If device support is utilized for high-risk or technically complex PCI when the patient has only mildly depressed cardiac function but appears well-compensated, then another strategy is to follow the LVEDP before intervention and reassess after completing PCI and prior to device removal.

## CONCLUSION

The concept of device-assisted, high-risk PCI is evolving as patients are presenting with greater morbidity and complexity, including patients who were previously not offered revascularization due to the risk of cardiovascular decompensation. There are a number of factors to consider (Figure 1) when incorporating planned or possible device-assisted PCI, and a full spectrum of cardiac care is required (Figure 2). Ongoing studies to guide proper patient selection for these procedures are needed. ■

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*Disclosures: Grant support and honoraria from Abiomed, Inc.*

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*Disclosures: Honoraria and consultant fees from Abbott Vascular, Boston Scientific Corporation, Teleflex, and Asahi.*