

Hemodynamic Support for PCI

An in-depth look at who, when, and how.

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Prior to considering the profile of patients with comorbidities and anatomic lesion complexity who stand to benefit from hemodynamic support (HDS) during percutaneous coronary intervention (PCI), it is important to understand why HDS is becoming a necessary tool for cardiac catheterization laboratories and hospitals.

Primarily, the risk profile of patients referred for PCI is changing. Since the advent of drug-eluting stents and appropriate use criteria, PCI volume has declined nationally.¹ The increasing number of patients with severe comorbidities and anatomic lesion complexity alone has been increasing. The ongoing emphasis on outcomes seen with coronary artery bypass graft (CABG) surgery has led to some patients at high surgical risk being turned down by surgeons and referred for PCI. At the same time, the field of interventional cardiology and its ability to provide complete revascularization has been evolving. Many techniques and tools have been developed to percutaneously address complex anatomic lesions that were traditionally referred for surgery (eg, left main disease or chronic total occlusions). Therefore, the number of high-risk patients undergoing PCI is continuing to grow.² As we perform PCI in these patients, we need to be able to completely revascularize them in a safe and standardized manner to ensure good outcomes across the spectrum of disease.

When treating patients with high-risk ischemic heart disease, it is important to understand the need for complete revascularization. In the SYNTAX trial, 43% of patients in the PCI arm and 37% of patients in the CABG arm were incompletely revascularized, and major adverse cardiovascular events (MACE) were higher in patients with incomplete versus complete revascularization (41.9% vs 29.6%; $P < .001$).³ Additionally, a meta-analysis of 89,883 patients with multivessel coronary artery disease undergoing revascularization with either PCI or CABG showed that complete revascularization

was associated with a significant decrease in morbidity and mortality.⁴ Therefore, complete revascularization (minimizing residual ischemia) in complex PCI is associated with improved outcomes and should be a key objective in multivessel coronary artery disease. This can be done in a staged format or single setting. When using HDS for PCI, it is often preferable to perform complete revascularization in a single setting.

WHO?

SYNTAX and other studies have led to established guidelines on PCI versus CABG for a range of anatomic complexities, whereas the Society of Thoracic Surgeons' (STS) and European System for Cardiac Operative Risk Evaluation (EuroSCORE) risk scores estimate surgical risk based on the patient's comorbidities. Guidelines for revascularization in patients with moderate to high anatomic complexity and high surgical risk are less clear.

A growing patient population has a convergence of multiple high-risk factors including complex coronary artery disease (such as left main) or multivessel disease (including chronically occluded coronary arteries). These patients also often have depressed left ventricular function, as well as additional clinical comorbidities such as advancing age, diabetes, peripheral vascular disease, and chronic kidney disease that increase the risk of a PCI procedure as well as surgical treatment. Although these patients are at higher risk, they also have the most to gain from successful revascularization.

The BCIS trial⁵ randomized 301 patients with a left ventricular ejection fraction (LVEF) $\leq 30\%$ and extensive coronary disease to planned intra-aortic balloon pump (IABP) placement prior to PCI or not. There was no significant difference in major adverse events noted between the groups at 28 days. Procedural complications were noted more frequently in patients not receiving planned IABP.

In the PROTECT II trial,⁶ 452 symptomatic patients undergoing nonemergent PCI of an unprotected left main or last patent coronary vessel with LVEF $\leq 35\%$ or three-vessel disease with LVEF $\leq 30\%$ were randomized to HDS with either the Impella 2.5 (Abiomed, Inc.) or IABP. Patients enrolled in the study had a EuroSCORE that was more than double that of patients in the SYNTAX trial (9 vs 4), with 64% deemed not to be surgical candidates. The primary endpoint of MACE at

30 days was not significantly different between the groups (35.1% for Impella vs 40.1% for IABP; $P = .227$ in the intent-to-treat population). However, at 90 days, MACE occurred in 40% versus 51% ($P = .023$) in the Impella versus IABP per-protocol analysis. This was driven by the higher need for repeat revascularization in the IABP arm. Overall, there was an improvement in LVEF (27% to 33%; $P < .01$) with a 58% reduction in New York Heart Association class III/IV symptoms in patients enrolled in the trial. Complete revascularization with three vessels treated as opposed to one vessel resulted in fewer adverse events at 90 days (17% vs 33.8%; $P = .019$).

The authors noted a high frequency of angiographic success, low incidence of renal failure, and acceptable mortality rate. These results demonstrated that high-risk symptomatic patients who did not undergo CABG could be revascularized successfully using HDS and contemporary PCI techniques, leading to US Food and Drug Administration (FDA) approval of the Impella 2.5 device for elective high-risk PCI.

WHEN?

“When should hemodynamic support be used” is perhaps the most challenging clinical question to answer because complex PCI varies widely based on operator experience, anatomic considerations, and patient comorbidities.

Per the PROTECT II trial criteria and FDA label,⁷ at our institution, we assess the need for HDS during pre-procedure planning with attention paid to anticipated

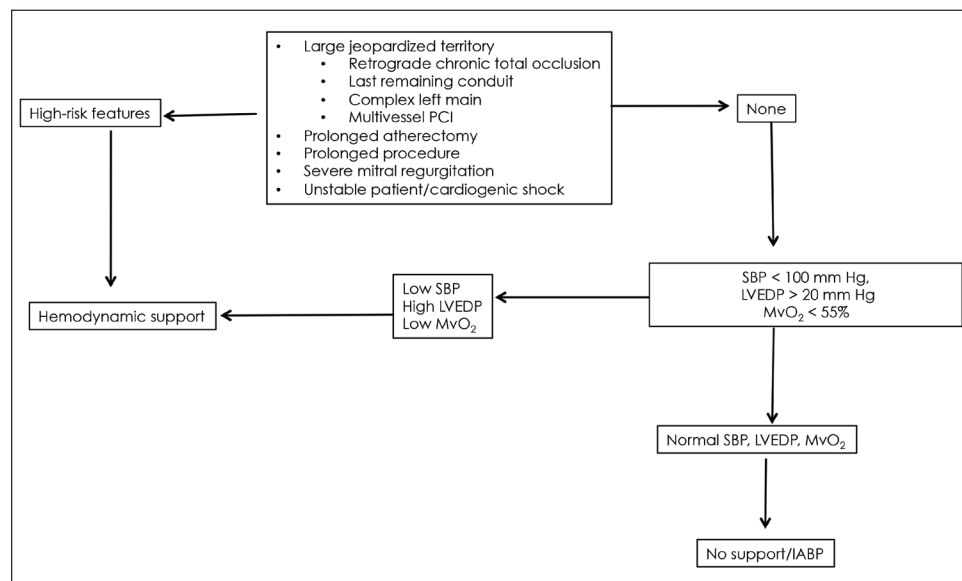


Figure 1. Algorithm for patient selection for HDS (LVEDP, left ventricular end-diastolic pressure; MvO₂, mixed venous oxygen saturation; SBP, systolic blood pressure).

case duration, lesion complexity including the need for atherectomy or the potential for prolonged ischemia (in cases such as retrograde chronic total occlusion PCI), clinical status of the patient, and LVEF. Other factors that may need to be considered include left ventricular end-diastolic pressure > 20 mm Hg, systolic blood pressure < 100 mm Hg, and mixed venous oxygen saturation $< 55\%$, which provides further data to inform the operator that the patient is at a higher risk for intraprocedural events. The data on left ventricular end-diastolic pressure, MvO₂, and systolic blood pressure enable us to obtain a clearer picture of who will benefit from HDS prior to beginning the procedure. Figure 1 can be used as a guide in the assessment for HDS.

HDS should be initiated electively, prior to PCI, rather than placed emergently after hemodynamic compromise. In our experience with high-risk PCI, it is not uncommon to see the mean arterial pressure (MAP) tracing flatten with loss of pulsatility with balloon inflations or prolonged atherectomy. Cardiac output is maintained only due to HDS (Figure 2). We are able to perform adequate lesion preparation as necessary with atherectomy and balloon predilatation, as well as perform image-guided stent optimization with no significant hypotension or hemodynamic compromise. It is in these scenarios, where a patient's poor hemodynamic reserve may compromise patient safety or procedure success, which HDS proves most valuable.

This value is corroborated by results from the US Impella registry,⁸ which showed moderate increases in

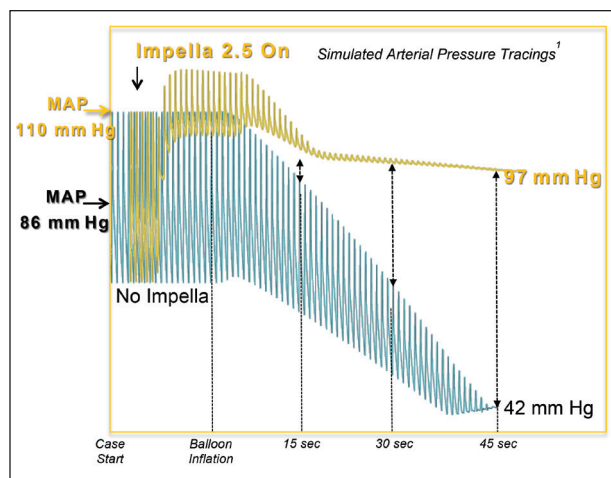


Figure 2. Simulated arterial pressure tracing in a patient with left main disease undergoing PCI without HDS (blue line) and with the Impella 2.5 for HDS (yellow line). Without HDS, we see declining arterial pressure the longer the coronary blood flow is disrupted. In contrast, if Impella support is instituted prior to the intervention, the MAP is increased when the device is activated and, although there is a decline in systolic pressure and native contractility, the MAP is maintained during balloon inflation. Reprinted with permission from Carr JA, Nemoto N, Schwartz RS, Shadden SC. Physiologic computational modeling. *Am J Physiol.* 1991;260:H146–H157.

systolic blood pressure, diastolic blood pressure, and MAP in 175 consecutive patients undergoing PCI with the Impella 2.5 for HDS. The overall angiographic revascularization success was 99% with a reduction in mean SYNTAX score after PCI from 36 to 18 and an improvement in LVEF from 31% to 36% ($P < .0001$). In PROTECT II, a significant reduction in severe hypotension was seen with use of the Impella 2.5 compared to IABP, with patients undergoing treatment of three vessels deriving the most benefit (procedural decrease in MAP from baseline -7.6% vs -18.8% ; $P = .026$).⁹

HOW?

Considerations for choosing levels of HDS include both hemodynamic burden and compromise. Although the IABP and Impella 2.5 are the only devices with FDA approval for use in elective high-risk PCI, other devices including the Impella CP, Impella 5.0, and TandemHeart (Cardiac Assist, Inc.)¹⁰ have also been used and may be necessary for HDS in patients with cardiogenic shock undergoing PCI.¹¹ Despite the use of extracorporeal membrane oxygenation for protected PCI, it has not been well studied, and an increase in afterload and left ventricular wall tension may negatively affect hemodynamics during protected PCI.

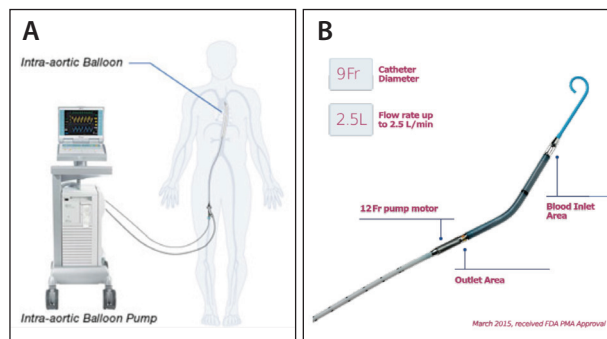


Figure 3. Devices available for HDS. IABP: a percutaneously placed inflatable balloon catheter that inflates during diastole and deflates with systole. Pneumatic flow of helium from the console is used to inflate and deflate the balloon. It augments left ventricular output by up to 0.5 L/min (A). Impella 2.5: a percutaneously placed catheter-mounted microaxial rotary pump inserted into the left ventricle in a retrograde fashion. Blood enters the device through the inlet in the left ventricle and exits the device through the exit port in the ascending aorta (B).

The IABP (Figure 3A) consists of an inflatable balloon catheter that inflates during diastole and deflates with systole. Pneumatic flow of helium from the console is used to inflate and deflate the balloon. Left ventricular output is augmented by up to 0.5 to 1 L/min.¹² IABP should be considered in patients at high risk with relatively less concern for hemodynamic compromise or anticipated shorter procedure duration. Complications include bleeding and vascular access complications; however, these are less likely compared to Impella.

The Impella (Figure 3B) is a catheter-mounted microaxial rotary pump inserted into the left ventricle in a retrograde fashion. Blood enters the device through the inlet in the left ventricle and leaves the device through the exit port in the ascending aorta, which leads to a decrease in left ventricular preload and end diastolic pressure. There is also a decrease in microvascular resistance and an increase in aortic pressure, leading to increased myocardial oxygen supply and decreased demand. The Impella 2.5, CP, and 5.0 provide up to 2.5, 4, and 5 L/min of circulatory support, respectively.¹³ As previously described, the Impella device should be considered in high-risk patients with anatomically complex lesions requiring prolonged procedures and atherectomy where the concern for hemodynamic instability is high. Complications include large-bore access vascular, bleeding complications, and hemolysis.

SUMMARY

Many centers will want to be able to offer this type of therapy to more patients. A note of caution to be made
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is that these patients will have higher complication rates, including mortality. It is essential that those wishing to pursue this type of therapy clearly see it as a program. Also necessary are the presence of on-site surgery to discuss options and manage potential complications, as well as a strong cath lab staff with experience in HDS, atherectomy, and critically ill patient management. The staff members of the intensive care unit and recovery areas need to be trained and prepared to handle a more complicated and ill patient population. We have learned through the development of the structural heart disease program that HDS/complete revascularization needs a similar heart team/program to provide the necessary care to achieve better outcomes.

In conclusion, surgery may indeed be the best option for patients with a high burden of ischemia and complex disease. However, patients who are poor candidates for surgery are increasingly being referred for PCI. The goal in these patients should be complete revascularization. HDS enables us to safely perform high-risk interventions and complete revascularization, thereby allowing interventional cardiologists to help patients without surgical options. ■

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