

The Use of Percutaneous Left Ventricular Assist Device in High-risk Percutaneous Coronary Intervention and Cardiogenic Shock

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Patients with high-risk coronary lesions may be denied coronary artery bypass grafting due to excessive comorbidities. Percutaneous coronary intervention (PCI) may be a feasible revascularization strategy in high-risk patients who present with ST-elevation myocardial infarction and cardiogenic shock. Historically, the use of intra-aortic balloon pump (IABP) has been used in high-risk PCI and cardiogenic shock. However, recent data has shown that elective IABP insertion did not reduce the incidence of major cardiovascular events following PCI. The use of a left ventricular assist device is a reasonable and safe alternative compared with IABP counterpulsation, giving greater cardiac output and hemodynamic support in patients undergoing high-risk PCI and in those with severe cardiogenic shock. This review outlines a case of severe cardiogenic shock and hemodynamic instability where high-risk PCI is a reasonable option.

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KEY WORDS

Percutaneous coronary intervention • Left ventricular assist device • Cardiogenic shock
• Intra-aortic balloon pump

Technical advances in percutaneous coronary intervention (PCI) have allowed for the treatment of complex, high-risk coronary lesions. Those with severe three-vessel disease, left main disease, a single remaining patent vessel, or depressed left ventricular (LV) systolic function represent a high-risk population, especially if they

are denied coronary artery bypass grafting (CABG) due to excessive comorbidities, including hypertension, hyperlipidemia, diabetes, chronic obstructive pulmonary disease, tobacco use, and renal failure.^{1,2}

Even though CABG remains the recommended revascularization strategy for symptomatic patients with severe three-vessel or left main disease, in

patients with excessive comorbidities and mortality risks, PCI may be a feasible revascularization strategy in high-risk patients presenting with ST-elevation myocardial

or more. The Impella 2.5 catheter is connected distally to a portable mobile console that displays invasive pressure with the actual revolutions per minute of the pump as

subendocardial flow.⁸ In addition, with the release of the new Impella 5.0 L/min LVAD, more hemodynamic support can be provided for patients undergoing high-risk PCI and in those with severe cardiogenic shock.

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infarction (STEMI) and cardiogenic shock. In these patients, more attention has been placed on the possibility of utilizing circulatory assistance for high-risk PCI procedures to facilitate procedural safety and for improved outcomes.³⁻⁵ Historical standard of care in high-risk PCI and cardiogenic shock has been use of intra-aortic balloon pumps (IABPs) and inotropes; current American Heart Association/American College of Cardiology guidelines have recently been challenged by the Balloon Pump Accessed Coronary Intervention Study (BCIS) randomized, controlled trial,⁶ which showed that elective IABP insertion did not reduce the incidence of major cardiovascular events following PCI. These results do not support a strategy of routine IABP placement before PCI in all patients with severe LV dysfunction and extensive coronary artery disease.

The Impella® 2.5 (Abiomed, Danvers, MA) device is a 12-F rotary blood pump that is placed across the aortic valve; it aspirates blood from the LV cavity and expels it into the ascending aorta. The pump provides up to 2.5 L/min at its maximal rotation speed of 51,000 revolutions per minute. The device is inserted percutaneously through a 13-F femoral sheath and is mounted on a 9-F pigtail catheter, allowing it to be easily placed across the aortic valve and left in place for up to 5 days

well as motor current, thus guiding the correct positioning and functioning of the device.³

Studies have demonstrated that the Impella provides superior hemodynamic support compared with IABP.⁷ Seyfarth and colleagues⁷ concluded that, in patients who presented with anterior myocardial infarction and cardiogenic shock, the use of the Impella 2.5 LV assist device (LVAD) is a reasonable and safe alternative compared with IABP counterpulsation, giving greater cardiac output and hemodynamic support.

In their study, the cardiac index in the Impella arm was 1.71 L/min/m² at baseline and 2.20 L/min/m² at 30 minutes (change, 0.49 L/min/m²). In the IABP arm, after 30 hours, cardiac index was 2.51 L/min/m² in the Impella group versus 2.40 L/min/m² in the IABP group. Thus, there was a greater increase of cardiac index 30 minutes after onset of support in patients supported with the Impella 2.5 as compared with patients supported with IABP. In patients with STEMI and cardiogenic shock who are not amenable to CABG and high-risk PCI is not an option, the Impella 2.5 is a reasonable option for improving cardiac output and providing optimal hemodynamic support, in addition to improving regional myocardial blood flow through reduction in wall tension and resistance to

Case Review

A 66-year-old man with a history of hypertension, an extensive smoking history, and chronic obstructive pulmonary disease underwent emergent cardiac catheterization for anterior STEMI and cardiogenic shock requiring dopamine and norepinephrine. An echocardiogram showed an LV ejection fraction (EF) of < 20% with depressed right ventricular EF. Coronary angiography revealed a completely occluded left anterior descending artery (LAD) after the takeoff of a small first diagonal branch, 99% subtotal stenosis of the proximal right coronary artery (RCA), and 60% to 70% stenosis of the proximal segment of the left circumflex artery (Figure 1). During the procedure, the patient developed pulseless ventricular tachycardia that required cardiopulmonary resuscitation and defibrillation. Given the hemodynamic and

Figure 1. Coronary angiography demonstrating a thrombotic occlusion of the mid left anterior descending artery.

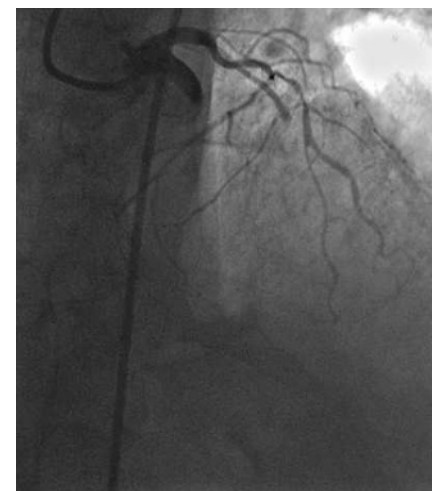




Figure 2. Coronary angiography after stenting of the left anterior descending artery. The Impella® device (Abiomed, Danvers, MA) is in the left ventricle.

arrhythmic instability, the Impella 2.5 was inserted into the left femoral artery. The patient then underwent an uneventful PCI with serial thrombectomy runs in the mid LAD followed by the placement of a 2.5×23 mm everolimus-eluting stent in the LAD (Figure 2). Given the depressed right ventricular EF and hemodynamic and electrical instability, it was decided to perform PCI on the RCA lesion as well. Thus, this was followed by placement of a 2.25×28 mm and a 2.5×12 mm everolimus-eluting stent in an overlapping fashion in the proximal RCA. The patient was then transferred to the cardiac care unit with the Impella in place; a pulmonary catheter line was placed immediately after PCI, and vasopressin and dopamine were continued for hemodynamic support. Initial post-PCI hemodynamic measurements included the following: central venous pressure, 16 mm Hg (3-8 mm Hg); right ventricular pressure, 49/17 mm Hg (15-30/3-8 mm Hg); pulmonary artery pressure, 46/32 mm Hg (15-30/4-12 mm Hg); pulmonary capillary wedge pressure, 20 mm Hg (4-15 mm Hg); cardiac output, 4.3 L/min (4-6 L/min); cardiac index, 1.98 L/min/m² (2.5-3.5 L/min/m²); systemic vascular resistance,

1032 dyn-s-cm⁻⁵ (800-1200 dyn-s-cm⁻⁵); and pulmonary vascular resistance 310 dyn-s-cm⁻⁵ (150-250 dyn-s-cm⁻⁵). Given the elevated right- and left-sided filling pressures, gentle diuresis was initiated. The following morning, repeat echocardiogram showed the LVEF improved to 30% to 35%. On day 2, the Impella was removed. Seven days postprocedure, the patient was off all pressor support and LVEF continued to increase to 40%. He was discharged 10 days after STEMI admission and PCI.

Discussion

The Impella 2.5 has more recently become an alternative option in providing circulatory support in patients with cardiogenic shock undergoing high-risk PCI. Its ability to directly unload the left ventricle, and reduce LV diastolic pressure, myocardial workload, and oxygen consumption, and improve coronary perfusion and cardiac output can be pivotal during hemodynamic compromise. It has also been shown to have a favorable effect on coronary flow hemodynamics in humans, including increased aortic and intracoronary pressure, hyperemic flow velocity and coronary flow velocity reserve, and decreased coronary microvascular resistance.⁹ In a study by Reesink and associates,¹⁰ the Impella was compared with the IABP in an animal model. The animals were subjected to

LV pressure, and external LV work. The Impella also reduced both LV end-diastolic and systolic volume significantly as compared with the IABP. The IABP significantly increased coronary flow compared with the Impella. However, the Impella was more effective at unloading the left ventricle than the IABP. In an elegant animal study, Sauren and colleagues¹¹ characterized the much higher coronary blood flow augmentation seen with Impella compared with IABP due to the much more effective unloading of the left ventricle and reduction of microvascular resistance. There are several important trials that have looked at the clinical outcomes of Impella and high-risk PCI (Table 1).

The Europella registry was the first large-scale study that demonstrated the safety, efficacy, and clinical outcomes of Impella.⁵ This registry included 144 consecutive patients who underwent a high-risk PCI, which was defined as left main disease, last remaining vessel disease, multivessel coronary artery disease, and LV dysfunction. Mortality at 30 days was 5.5%. Rates of myocardial infarction, stroke, bleeding requiring transfusion/surgery, and vascular complications at 30 days were 0%, 0.7%, 6.2%, and 4.0%, respectively.

The Prospective Feasibility Trial Investigating the Use of the IMPELLA RECOVER LP 2.5

PROTECT I demonstrated that Impella is an easily implantable, safe device that provides adequate hemodynamic support in high-risk PCI.

inducible acute mitral regurgitation by stenting of the mitral valve via an inferior vena cava filter. Next, the IABP or the Impella was inserted and hemodynamic parameters were compared. Both devices increased cardiac output, mean aortic pressure, and carotid artery flow, and reduced left atrial pressure, peak

System in Patients Undergoing High-Risk PCI (PROTECT I) demonstrated that Impella is an easily implantable, safe device that provides adequate hemodynamic support in high-risk PCI. Of the 20 patients, the 30-day incidence of major adverse cardiac events (MACE) was 20% (2 patients had a

TABLE 1**Studies Comparing the Impella® 2.5 and High-risk PCI, Including Survival, Major Complications, and Coronary Hemodynamics**

Study	N	Device Used	Procedure Type	Comments	Survival
Anderson MB et al ¹⁵	50	Impella 2.5	High-risk PCI	Complications: limb ischemia 2%, bleeding 4%, infection 2%	47/50
Dixon SR et al ³	20	Impella 2.5	High-risk PCI	Hemolysis 10%	18/20
Henriques JP et al ¹⁶	19	Impella 2.5	High-risk PCI	No device-related events; all survived	19/19
Rummelink M et al ⁹	11	Impella 2.5	High-risk PCI	Increased aortic and intracoronary pressure; decreased coronary resistance and hyperemic flow velocity	11/11

PCI, percutaneous coronary intervention.

periprocedural myocardial infarction; 2 patients died at days 12 and 14). There was no evidence of aortic valve injury, cardiac perforation, or limb ischemia. Two patients (10%) developed mild, transient hemolysis without clinical sequelae. The PROTECT I trial showed that Impella is a reasonable alternative in high-risk PCI and cardiogenic shock with low MACE rates.³ Even though the PROTECT I trial showed good clinical outcomes for Impella, one key comparison that was not addressed is whether Impella has better clinical outcomes in comparison with IABP.

The PROTECT II sought to look at in-hospital event rates and 30-day event rates between Impella and IABP. The 30-day MACE rates were higher than anticipated for IABP (40.1%) and were 35.1% for Impella. Thus, outcomes in the Impella group demonstrated a trend toward a reduction of MACE at 30 days and a significant reduction of the MACE rate at 90-day follow-up in the per-protocol population ($n = 427$), with an IABP MACE rate of 49.3% and an Impella MACE rate of 40.6%. However, PROTECT II was halted because the assumptions of MACE rates used at interim

analysis did not predict that the primary endpoint would be reached. The secondary endpoint of 90-day MACE in the per-protocol population did indeed suggest that that Impella was superior to IABP.¹² Table 2 demonstrates the only randomized control trials between Impella and IABP. Rotational atherectomy was used twice as often in the Impella group as in the IABP group (25% vs 13%; $P = .04$). In the Impella group, atherectomy was linked to twice the rate of adverse events as treatment with no atherectomy, driven by a higher rate of postprocedural myocardial

TABLE 2**Randomized, Controlled Trials Comparing the Impella® 2.5 With IABP, Including Survival**

Study	N	Device Used	Patient Type	Comments	Survival
O'Neill WW et al ¹²	<u>30 days</u>	Impella 2.5	Complex 3-vessel disease or unprotected left main coronary artery disease and severely depressed LV function	No difference of MACE at 30 days between IABP or Impella 2.5; however, trends for improved outcomes at 90 days	<u>30 days</u>
	225	IABP			208/225
	222				209/222
	<u>90 days</u>				<u>90 days</u>
Seyfarth M et al ⁷	224		Ischemic cardiogenic shock	Greater increase in cardiac index and BP with Impella	198/224
	219				200/219
	11	Impella 2.5			6/11
	13	IABP			4/13

BP, blood pressure; IABP, intra-aortic balloon pump; LV, left ventricular; MACE, major adverse cardiac events.

TABLE 3**Comparison of Hemodynamic Parameters Comparing LVAD (Impella® 2.5 and TandemHeart™ Percutaneous Ventricular Assist Device Versus IABP**

	Thiele H et al ¹⁷		Burkhoff D et al ¹⁸		Seyfarth M et al ⁷	
	LVAD: TandemHeart (n = 21)	IABP (n = 20)	LVAD: TandemHeart (n = 19)	IABP (n = 14)	LVAD: Impella 2.5 (n = 12)	IABP (n = 13)
CI ± SD (L/min/m ²)	2.3 ± 0.6	1.8 ± 0.4	2.2 ± 0.6	2.1 ± 0.2	2.2 ± 0.6	1.8 ± 0.7
MAP ± SD (mm Hg)	76 ± 10	70 ± 16	91 ± 16	72 ± 12	87 ± 18	71 ± 22
PCWP ± SD (mm Hg)	16 ± 5	22 ± 7	16 ± 4	20 ± 6	19 ± 5	20 ± 6

CI, cardiac index; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MAP, mean arterial pressure; PCWP, pulmonary capillary wedge pressure; SD, standard deviation.

infarction as evidenced by cardiac biomarkers of infarction at three times the normal limit.¹³

A meta-analysis of controlled trials comparing percutaneous LVAD (which included Impella and the TandemHeart (CardiacAssist, Pittsburgh, PA) with IABP reported that, although use of percutaneous LVAD resulted in a better hemo-

dynamic profile compared with IABP counterpulsation (Table 3), it did not translate into improved 30-day survival. However, the single paper referenced for Impella consisted of 13 patients and was not powered to show a difference in mortality.^{7,14}

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Conclusions

The question of whether Impella is superior to IABP is difficult to answer. Major adverse events were higher than expected for both devices but particularly impressive when comparing IABP and Impella; adverse event rates for the Impella

decreased over the 3 years of the PROTECT II study to 36%, whereas adverse event rates for the IABP remained at approximately 50% (n = 425). This is consistent with a mature technology (IABP) and a technology that has been recently introduced. Impella support maybe a more reasonable alternative to IABP for hemodynamic support,

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MAIN POINTS

- Patients with high-risk coronary lesions may be denied coronary artery bypass grafting (CABG) due to excessive comorbidities, including hypertension, hyperlipidemia, diabetes, chronic obstructive pulmonary disease, tobacco use, and renal failure.
- Technical advances in percutaneous coronary intervention (PCI) have allowed for the treatment of complex, coronary lesions in high-risk populations, such as those with severe three-vessel disease, left main disease, a single remaining patent vessel, or depressed left ventricular (LV) systolic function, especially if they are denied CABG.
- The standard of care in high-risk PCI and cardiogenic shock has been use of intra-aortic balloon pumps (IABPs) and inotropes; however, recent data have challenged this assumption, showing that elective IABP insertion did not reduce the incidence of major cardiovascular events following PCI. These results do not support a strategy of routine IABP placement before PCI in all patients with severe LV dysfunction and extensive coronary artery disease.
- The use of a LV assist device is a reasonable and safe alternative compared with IABP counterpulsation, giving greater cardiac output and hemodynamic support in patients undergoing high-risk PCI and in those with severe cardiogenic shock.

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