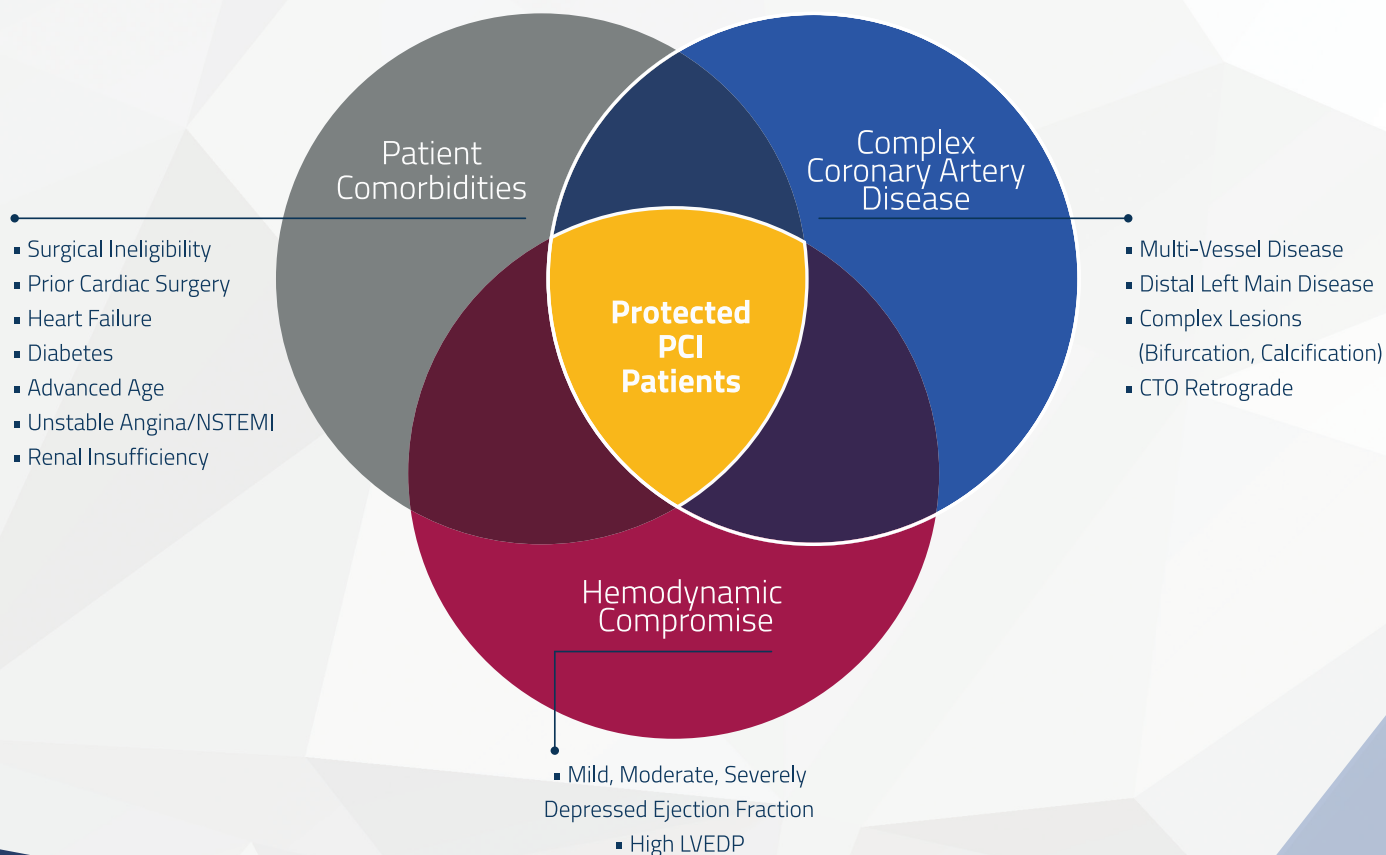


Cardiac Interventions TODAY

May/June 2018



HIGH-RISK, COMPLEX CORONARY ARTERY DISEASE

Treating a
Growing Patient
Population Using
Protected PCI
With Impella®

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Treating the Growing Population of Patients With High-Risk, Complex Coronary Artery Disease: Protected PCI With Impella®

BY SETH BILAZARIAN, MD, FACC, FSCAI

The number of patients in the United States with high-risk complex coronary artery disease (CAD) continues to grow and is projected to increase by almost 50% over the next 25 years.¹ This trend is also supported by a recent report showing that the proportion of percutaneous coronary interventions (PCI) involving greater complexity has grown to 30% in 2016 compared to 23% in 2012.²

Patients with high-risk CAD pose two unique challenges. First, it is particularly challenging to effectively revascularize these patients, as they present with complex disease, including left main disease, prior coronary artery bypass grafting (CABG), heavy calcification, multivessel disease, and/or chronic total occlusions (CTOs). Treatment of complex coronary lesions and anatomy requires interventional cardiologists with advanced skills and expertise in a broad range of techniques. This involves keeping abreast of new technologies and being able to adopt and gain experience for maximum patient benefit. Second, these patients have limited ability to tolerate interventions required to achieve durable and complete revascularization. Many high-risk patients are not eligible for CABG, thus limiting their treatment options. These patients often have concomitant presence of comorbid conditions, such as congestive heart failure, diabetes, renal failure, and compromised hemodynamics, which may complicate their intraprocedural stability and postprocedural recovery. Additionally, higher risk of complications and unplanned procedural hazards may impact the interventional procedure and affect the completeness of revascularization.³

Complete revascularization is important because it has been shown to be associated with a significantly lower rate of major adverse cardiovascular events (MACE; $P < .001$),

myocardial infarction ($P = .0007$), and revascularization ($P < .001$).^{4,5} In addition, revascularization procedures conducted in a single session result in significantly fewer major adverse cerebral and cardiovascular events (MACCE; $P = .004$) and deaths ($P = .006$) compared to staged PCI procedures.⁶ The use of hemodynamic support during PCI in patients with high-risk complex CAD helps maintain hemodynamic stability, which enables more complete revascularization in the safest manner possible.⁷

ABOUT PROTECTED PCI

A Protected PCI is an Impella® Heart Pump–supported PCI that helps maintain hemodynamic stability during revascularization and is indicated for high-risk, complicated CAD in patients with or without depressed left ventricular (LV) systolic function. The US Food and Drug Administration (FDA) has recently expanded the indication for use in patients with high-risk PCI.⁸

The Impella Heart Pump directly unloads the left ventricle and propels blood forward, from the left ventricle into the aorta, in a manner consistent with normal physiology. Providing both active forward flow (up to 3.7 L/min) and maintenance of the systemic aortic pressure (Figure 1) contributes to maintenance of overall cardiac power output.^{3,9-14} Cardiac power output has become more commonly used as an objective measure of cardiac performance and is easily calculated as the product of cardiac output (L/min), mean arterial pressure (mm Hg), and a constant.

In addition, Impella provides left ventricle unloading. Protected PCI with Impella reduces end-diastolic volume and pressure¹⁵⁻¹⁹ and augments peak coronary flow,^{9,12,15,16} leading to a favorable alteration of the balance of myocardial oxygen supply and demand. This cascade of

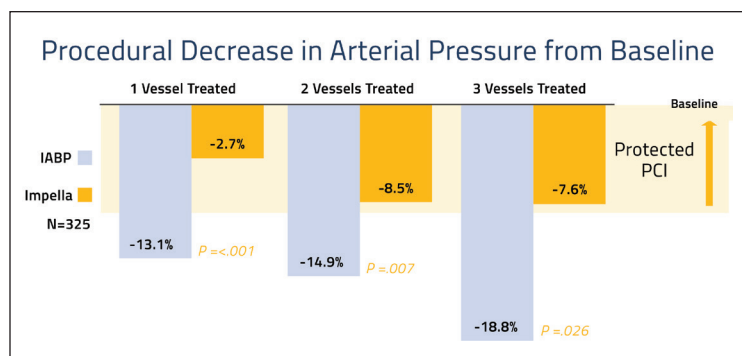


Figure 1. The decrease in arterial pressure during the procedure is significantly less on Impella 2.5 than on intra-aortic balloon pump (IABP).⁷

hemodynamic effects has been described in the literature^{9,20} and validated in computational modeling, as well as a variety of preclinical and clinical studies, including the PROTECT II randomized controlled trial and the catheter-based Ventricular Assist Device (cVAD) Registry.^{3,9-21}

cVAD REGISTRY™ SUPPORTS SAFETY AND EFFECTIVENESS

The cVAD Registry is an FDA-audited, institutional review board (IRB)-approved, ongoing, multicenter, prospective study being conducted at sites in the United States, Europe, and Canada, with data collected on more than 3,000 Impella patients. The cVAD Registry data have demonstrated:

- Patients undergoing high-risk PCI in clinical practice are similar to PROTECT II patients with high-risk features, including a depressed LV function (mean LV ejection fraction [LVEF], $30\% \pm 16\%$) and complex coronary anatomy and high risk for surgical revascularization (mean Society of Thoracic Surgeons score, $6\% \pm 6\%$)
- The use of Impella during high-risk PCI provides hemodynamic support during these interventions with a significant increase in mean arterial pressure from baseline ($P < .001$)²²
- Patients treated with Protected PCI have a post-PCI increase in LVEF (LVEF, $31\% \pm 15\%$ vs $36\% \pm 14\%$; $P < .0001$) and a 52% reduction of New York Heart Association (NYHA) class III/IV symptoms after discharge²²
- Protected PCI with Impella is safe in high-risk patients and adverse events were low and consistent with the PROTECT II results²²

In 2017, the cVAD steering committee directed a study revision at 37 United States sites with plans to expand this version globally. This update included a prospective study design with nested data collection by indication and includes angiographic and echocardiographic core lab data collection. Patients providing consent will be

followed for 1 year. In 2017, the FDA permitted the cVAD Registry as a vehicle for four Impella post-approval studies.

NEW EXPANDED INDICATIONS FOR PROTECTED PCI

The initial FDA approval for the Impella system was based on several clinical studies, including PROTECT I and PROTECT II, which enrolled patients undergoing elective and urgent PCI who had advanced comorbidities and the most severe LV dysfunction of any population studied in interventional cardiology. Patients were symptomatic and presented with high-risk features, including complex coronary anatomy (mean

SYNTAX score, 30 ± 13), depressed LVEF (mean LVEF, $24\% \pm 6\%$), and other comorbidities, including previous procedures, with 64% of the patients deemed ineligible for CABG.

Based on these studies, low ejection fraction (EF) was initially a requirement to be considered high risk. However, through the cVAD clinical experience, it has been shown that depressed EF is only one of many factors that define a patient as high risk. Patients with complex coronary anatomy or in whom complex procedures are planned (eg, use of ablative technologies such as rotational, orbital, or laser atherectomy), extensive comorbidities including surgical ineligibility, or those at risk for hemodynamic collapse can also be considered high risk and may benefit from a Protected PCI procedure.

Based on data from the cVAD Registry, the FDA recently granted approval to expand the indications for the Impella Heart Pump, eliminating depressed EF as a requirement for on-label use of Impella in Protected PCI. With this postmarket approval, patients with or without depressed LV systolic function in the presence of severe CAD or complex anatomy (eg, left main, multivessel, or requiring rotational atherectomy) may be appropriate when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option.

The data supporting this expanded indication included an analysis of 229 consecutive patients with mild to moderately reduced EF. In this cohort, a majority of the patients were not eligible for CABG due to surgical risk factors. On average, these patients were older, more often female, had more hypertension, and had significantly more lesions treated and left main intervention than patients in the cVAD Registry cohort with $EF < 35\%$ ($n = 464$). This comparison demonstrated that high-risk PCI with Impella support was feasible, safe, and achieved favorable outcomes in patients with mild to moderately reduced EF. The data collection from the cVAD Registry submitted to the FDA for this postmarket approval includes IRB approval, data monitoring, and clinical events committee adjudication.

PROTECTED PCI REDUCES RATE OF ACUTE KIDNEY INJURY

A retrospective, single-center study found that the use of hemodynamic support with Impella during high-risk PCI reduced the risk of acute kidney injury (AKI), even in the presence of preexisting kidney disease and low EF.²³ This study builds upon a growing body of evidence of the benefits of hemodynamic support with Impella during high-risk PCI.

For this retrospective study, investigators analyzed procedural and clinical outcomes of 230 patients with an EF $\leq$ 35% before undergoing high-risk PCI.²³ Patients undergoing high-risk PCI supported with Impella 2.5 (n = 115) were compared with a matched-control cohort of 115 patients undergoing PCI without hemodynamic support. In the study, Impella-supported patients had more preprocedural presentation of acute coronary syndromes and heart failure, more left main involvement and multivessel disease, lower EF, longer procedures, and greater median volume of contrast used.

Despite these increased risk factors for kidney injury in the Impella arm, the authors found that only 5.2% of the Impella-supported patients developed AKI postprocedure compared to 27.8% in the unsupported patient cohort ($P < .001$).²³ Patients who did not receive Impella were six times more likely to need dialysis. Based on this study, Protected PCI with Impella may improve outcomes, health care costs, and quality of life through lower rates of AKI, reduced need for dialysis, and shorter length of hospital stay.

PROTECT II CLINICAL STUDY

PROTECT II was a prospective, multicenter, randomized trial comparing outcomes between Impella 2.5 and the IABP in patients requiring hemodynamic support during elective or urgent high-risk PCI. The study enrolled 452 patients at 112 sites.

The primary efficacy endpoint was a composite of ten major adverse events: death, stroke/transient ischemic attack, myocardial infarction, repeat revascularization, need for cardiac or vascular operation, acute renal dysfunction, cardiopulmonary resuscitation or ventricular arrhythmia requiring cardioversion, increase in aortic insufficiency by more than one grade, severe hypotension, and failure to achieve angiographic success. The multiple safety endpoints including this primary endpoint allowed for a comprehensive evaluation of Impella's safety profile at 30 days with a follow-up analysis at 90 days (both prespecified).

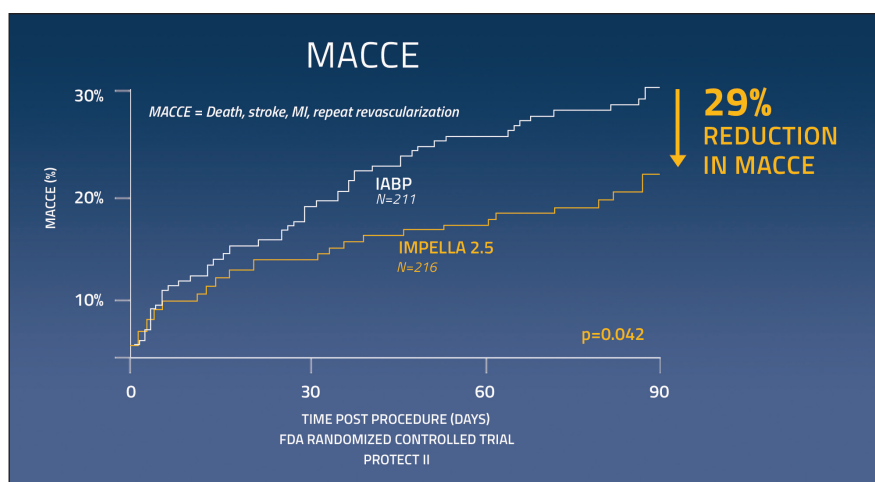


Figure 2. The Impella 2.5 produced fewer MACCE than IABP.²⁴

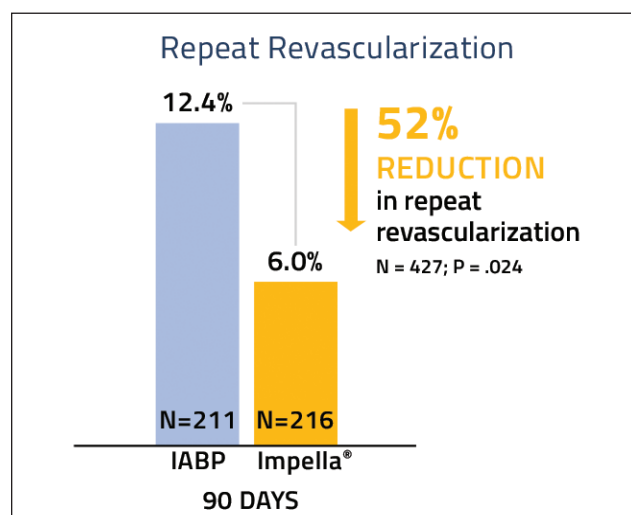


Figure 3. The patients treated with Impella 2.5 had 52% fewer readmissions due to revascularization.²⁵

The enrolled population consisted of patients undergoing elective or urgent hemodynamically supported high-risk PCI on an unprotected left main or last patent conduit with an LVEF $\leq$ 35% or patients who had three-vessel disease and an LVEF $\leq$ 30%. Investigators identified target lesions prior to randomization and then aimed for the most complete revascularization of the myocardium at jeopardy in the index procedure. The study showed the use of Impella was associated with improved clinical outcomes compared to IABP:

- Significant reduction in MACCE events (Figure 2) at 90 days postprocedure (15.9% vs 28.5%; $P = .013$)²⁴
- Significant reduction in major adverse events at 90 days (40% vs 51%; $P = .023$)³
- Fewer readmissions (Figure 3) and fewer days in the hospital (Figure 4)^{25,26}

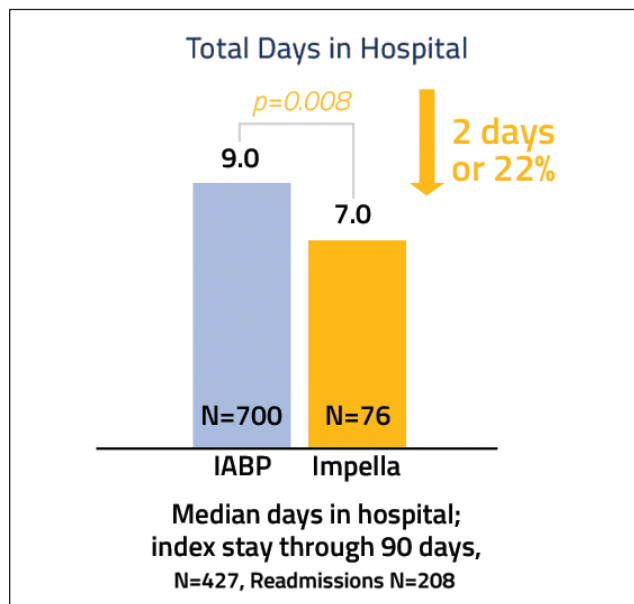


Figure 4. Patients treated with Impella 2.5 stayed in the hospital 2 fewer days than IABP patients on average.²⁶

- 58% reduction in NYHA class III and IV heart failure symptoms (Figure 5)³

The benefit of hemodynamic support was also evaluated as a function of the extent of revascularization. In aggregate, more extensive revascularization was associated with improved 90-day outcomes in terms of MACCE events compared to a limited revascularization ($P < .01$).²⁷ Moreover, the use of Impella was associated with improved clinical outcomes compared to the IABP when extensive revascularization was performed.²⁸

COST-EFFECTIVENESS

According to the American Heart Association, cardiovascular disease is one of the most prevalent and costly disease categories, with over \$300 billion in direct and indirect costs. In the United States, heart failure is the leading cause for medical readmissions among the Medicare population, and approximately one of every four patients with acute heart failure is readmitted within 90 days of initial admission.

In multiple studies and economic models, Protected PCI with Impella has demonstrated significant cost savings and cost-effectiveness with reduced length of stay and reduced readmissions from repeat procedures.^{25,27,29} By providing support to the failing heart sooner, clinicians may improve patients' outcomes and avoid longer-term cost outlays associated with alternative resource-intensive therapies and open heart procedures.²⁵

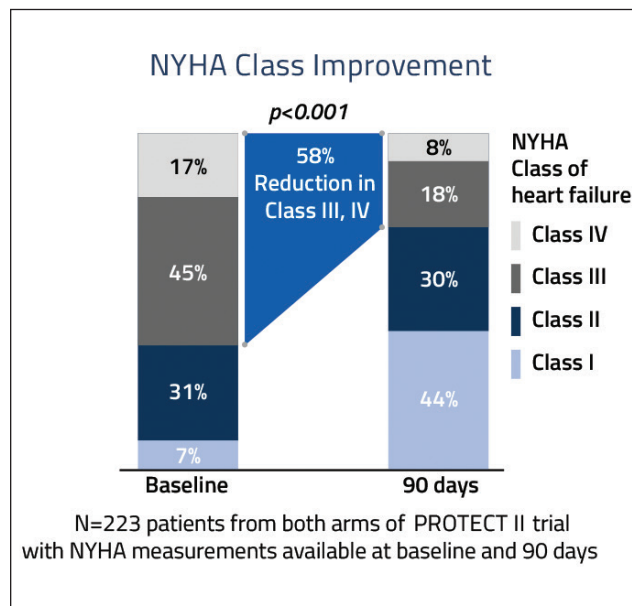


Figure 5. Patients treated with the Impella 2.5 showed a significant improvement in NYHA classification after Protected PCI.³

The PROTECT II economic study concluded that for patients with severe LV dysfunction and complex anatomy, Impella-assisted PCI significantly reduced major adverse events at an incremental cost per quality-adjusted life-year (QALY) considered to be cost-effective for advanced cardiovascular technologies (\$39,000/QALY).²⁵ In the 90 days after initial hospitalization, Impella patients experienced:

- Two fewer days in the hospital ($P = .001$)²⁵
- A 52% reduction in hospitalizations due to repeat revascularization ($P = .024$)²⁵
- 50% lower rehospitalization costs compared to the IABP ($P = .023$)²⁵

The cost-effectiveness demonstrated with the use of Impella is in agreement with the use of other percutaneous ventricular assist devices (pVADs) as well. A study of national trends in the utilization of pVADs and other short-term mechanical support by Stretch et al observed a correlation between increased utilization of pVADs and decreased costs.²⁹ A systematic review by Maini et al appraised the findings of six cost-effectiveness studies of pVADs.²⁷ Length of stay reductions were observed in all studies, with a clinically relevant observation of fewer days in the intensive care unit, fewer days from readmissions, and two fewer days in the hospital over 90 days.

SOCIETY GUIDELINES SUPPORT IMPELLA IN HIGH-RISK PCI

Intersocietal clinical guidelines (American College of Cardiology, Heart Failure Society of America, Society

for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons) agree that Impella Heart Pump may be beneficial for technically challenging lesions or for prolonged PCI in patients with reduced or normal LV function and severe CAD.³⁰ The Interventional Scientific Council of the American College of Cardiology has also published a consensus document detailing the recommended practice approach to percutaneous mechanical circulatory support in patients undergoing high-risk PCI.³¹

CONCLUSION

Heart failure patients are growing in number, and identification of an ischemic substrate in patients with LV systolic dysfunction identifies patients that may benefit by revascularization. Underevaluation is rampant, and complete revascularization improves outcomes, including quality of life, readmission, and cost of care. Procedural and baseline patient complexity has increased, and these risks can be mitigated with a Protected PCI approach using Impella for hemodynamic support in high-risk PCI patients. ■

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CASE REPORT

A Case of Complex, High-Risk, and Indicated PCI

BY BEHNAM TEHRANI, MD, FSCAI

CASE INTRODUCTION

- A 75-year-old man with coronary calcification and comorbidities underwent a successful Protected percutaneous coronary intervention (PCI) with Impella CP® (Abiomed, Inc.) support
- The patient had preserved left ventricular ejection fraction, but had complex coronary anatomy and multiple comorbidities, including advanced lung disease

CLINICAL PRESENTATION

A 75-year-old man with multiple medical comorbidities (ie, atrial fibrillation, diabetes, advanced chronic obstructive pulmonary disease, diastolic heart failure, and muscular dystrophy) presented with acute pulmonary edema and approximately 1 week of chest pain and shortness of breath that had progressed over several weeks.

Coronary angiography showed extensive calcification in the coronary arteries. The angiogram also showed a large but heavily diseased and calcified left anterior descending (LAD) artery subtotally in the mid-segment (Figures 1A and 1B). The disease extended into the distal left main coronary artery, and high-grade disease was present in the proximal obtuse marginal branch and also included a medium but dominant right coronary artery with a 70% to 80% lesion distally.

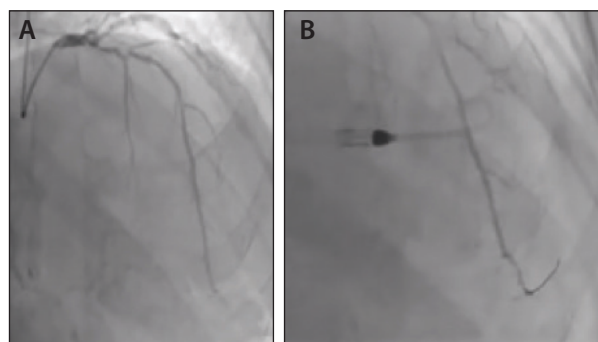


Figure 1. Diagnostic angiogram showing the extent of disease (A). Anteroposterior cranial projection depicting long segment of heavily calcified subtotally occluded mid LAD (B).

The INOVA Heart and Vascular Institute Protected PCI algorithm was used (Figure 2), and with the patient's preserved left ventricular function, a multidisciplinary

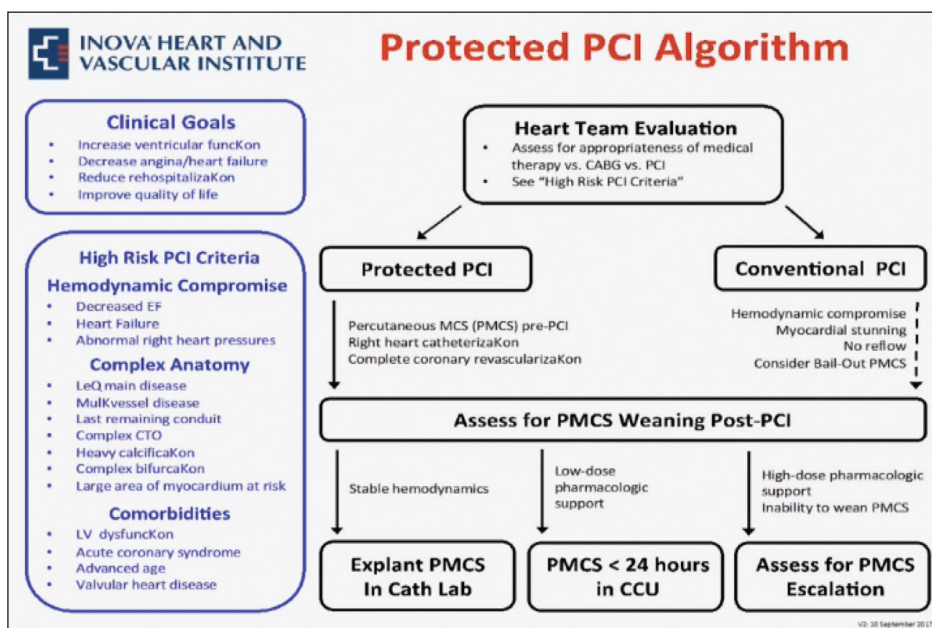


Figure 2. INOVA Heart and Vascular Institute Protected PCI algorithm.

heart team reviewed the case for consideration of the best revascularization option.

Anatomically, the patient had good targets for coronary artery bypass grafting, but due to comorbidities, particularly the patient's advanced lung disease, it was determined that the patient would be difficult to wean from the ventilator postoperatively. Given the large amount of myocardium at risk and the severe degree of calcification requiring rotational atherectomy of the left main, the heart team agreed that the patient was a candidate for Protected PCI with the Impella CP device.

PROCEDURE

Interventionalists proceeded with femoral access using ultrasound guidance and a micropuncture technique. Rotational atherectomy was used on the LAD with a satisfactory result. The patient's mean arterial pressure declined during the procedure, confirming that hemodynamic support was necessary.

A 3.0-mm stent was placed in the proximal and mid LAD, and a modified culotte technique was used to place a stent in the circumflex. Finally, the team stented into the left main coronary artery with a 4.0-mm stent and confirmed placement with intravascular ultrasound (Figure 3).

CASE SUMMARY

The patient was discharged home 24 hours after the procedure with optimization of guideline-directed

medical therapy and was seen at the office with no refractory angina.

In this case, a heart team approach was employed for decision-making, and because of the patient's severe disease and comorbidities, he was not referred for surgery. Protected PCI with percutaneous hemodynamic support was performed, and the patient was successfully revascularized. ■

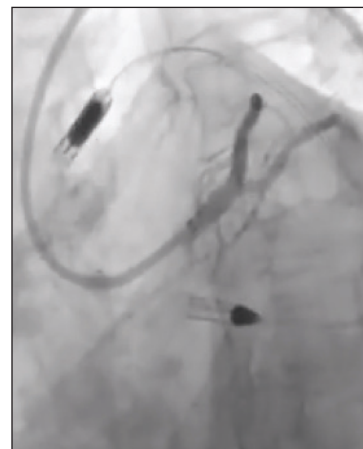


Figure 3. Final left anterior oblique caudal projection following Protected PCI of the left main, LAD, and circumflex.

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Disclosures: None.

Developing a Protected PCI Program: Heart Team Approach at Spectrum Health

BY DAVID WOHN, MD, MBA, FACC, FSCAI

The Spectrum Health Heart Team, formed in 2015, represents a true collaboration between cardiothoracic surgeons, interventional cardiologists, heart failure specialists, cardiac anesthesiologists, advanced imaging specialists, and intensivists. Each week, the team of 20 to 25 physicians, along with nurses and physician assistants, meets to review challenging cases with the goal of determining the best treatment course for each patient. By reviewing patients from a multidisciplinary perspective, we have a thorough discussion of the risks and benefits of each proposed treatment and communicate the best alternatives to our patients for an optimal outcome that meets their personal goals. Our heart team coordinator continues to oversee and coordinate care throughout their course.

When patients are referred for Protected percutaneous coronary intervention (PCI), our dedicated coordinator helps to navigate their treatment, similar to the role of a transcatheter aortic valve replacement coordinator. Our Protected PCI coordinator's responsibilities include managing the relationship with the referring physician, coordinating the procedure and follow-up appointments, and answering patient questions.

MULTIDISCIPLINARY HEART TEAM: CHANGING THE CARE PARADIGM

The multidisciplinary team came together at Spectrum Health to address the challenges of treating complex patients and streamlining the treatment paths they may follow. We routinely evaluate patients presenting with cardiogenic shock, congestive heart failure, left ventricular dysfunction, and those with chronic total occlusions or other patients who would be considered high-risk for revascularization. Our mission is to connect patients with the right providers and procedures. This approach is changing the paradigm given that a large group weighs in on the individual patient, with a goal of achieving the optimum care that meets patient goals. Patient-centered, shared decision-making that respects and understands patient goals and expectations is central to our process.

Approach to Clinical Decision-Making

In addition to the heart team meetings, the team employs an algorithm for clinical decision-making, which has become more granular and includes the use of a scoring system. This decision-making guide has resulted in a greater standardization of care. Over the years, our rigorous multidisciplinary approach has benefited patients; the heart team has evaluated close to 1,000 patients. We have created a database that allows us to review recommendations and outcomes in this complex patient population.

Patient Referrals

Heart team evaluations are a significant source for referral of patients for Protected PCI and other higher-risk procedures such as chronic total occlusion PCI. Both inpatients and outpatients are referred to the heart team and include patients beyond those with coronary artery disease. To ensure all eligible patients in the community have the option of a Protected PCI, our Protected PCI coordinator is now initiating a community outreach program to build awareness of these potentially life-changing procedures.

SUMMARY

The heart team at Spectrum Health is singularly focused on providing the best available care to our patients. We are proud to meet the needs of the growing population of high-risk patients who may have been told that they have no other treatment options. We rely on the skills and expertise of the heart team and have a rigorous approach to achieve consensus on treatment decisions, while recognizing individual perspectives. This true team approach is positively impacting patient outcomes in our community, and we believe it is a model that other facilities can adopt with similar success. ■

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Disclosures: None.

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To learn more about the Impella platform of heart pumps, including important risk and safety information associated with the use of the devices, please visit: www.abiomed.com/important-safety-information