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# Mechanical Circulatory Support in High-Risk Percutaneous Coronary Intervention



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## KEYWORDS

- High-risk percutaneous coronary intervention • Mechanical circulatory support
- Coronary artery disease • Risk assessment • Hemodynamics
- Percutaneous coronary intervention • Heart-assist devices

## KEY POINTS

- Identifying patients at high risk for percutaneous coronary intervention (PCI) involves a synthesis of a patient comorbidities, hemodynamic status, and lesion characteristics.
- Mechanical circulatory support devices are used in high-risk PCI to augment cardiac output and reduce myocardial oxygen demand during coronary intervention.
- The use of mechanical circulatory support devices allows more complete revascularization and facilitates procedures that previously may not have been technically feasible.
- Prospective randomized trials to date have not shown a benefit for the routine use of mechanical circulatory support in patients with low ejection fraction and a high burden of coronary disease.
- Further research is required to identify groups that will receive the maximal benefit of mechanical circulatory support in high-risk PCI.

## INTRODUCTION

Coronary artery disease remains a leading worldwide cause of morbidity and mortality.<sup>1</sup> As medical and interventional therapies available to patients with atherosclerotic heart disease have improved, the number of patients surviving index coronary events has increased considerably.<sup>2</sup> The care of this older, more medically and anatomically complex group of patients has resulted in an increasing number of patients with indications for coronary revascularization who are at high risk of periprocedural hemodynamic collapse and increased morbidity and mortality.<sup>3</sup>

Concurrently, the technology available to perform complex percutaneous coronary interventions (PCIs) has dramatically improved with the advent of coronary guides and guide extensions, specialized coronary wires, atherectomy devices, lower profile balloons and stents, intravascular imaging, specialized equipment for chronic total occlusions (CTOs), and percutaneous mechanical circulatory support (MCS) devices.<sup>4</sup> Patients who previously may not have been offered coronary revascularization because of technical factors or risk associated with cardiac surgery can now be considered for percutaneous revascularization. A clinical case that exemplifies this patient population is

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a 66-year-old man with a history of alcohol abuse who presented to an outside facility with 1 hour of chest pain. He rapidly developed hypoxic respiratory failure, and intubation was complicated by polymorphic ventricular tachycardia and cardiac arrest. Urgent cardiac catheterization was notable for cardiogenic shock with a cardiac index of 0.9 L/min/m<sup>2</sup> and severe 3-vessel coronary artery disease, with CTOs of the right and left circumflex coronary arteries and a highly calcific 95% stenosis of the proximal left anterior descending coronary artery (Fig. 1). The patient was urgently transferred to a tertiary referral center where, given severe peripheral arterial disease and cardiogenic shock, a transcaval Impella 5.0 was placed (Fig. 2). After stabilization of end-organ function, the patient underwent successful atherectomy and PCI of the left main to left anterior descending (LAD) artery (Fig. 3). The patient ultimately was successfully weaned from MCS and discharged to rehabilitation in good condition. In patients such as this and many others with high-risk lesions and clinical risk, a key element that has facilitated PCI is the advent of percutaneous MCS.

Percutaneous MCS in PCI is generally used in one of 2 clinical settings: patients with acute myocardial infarctions (MIs) presenting with

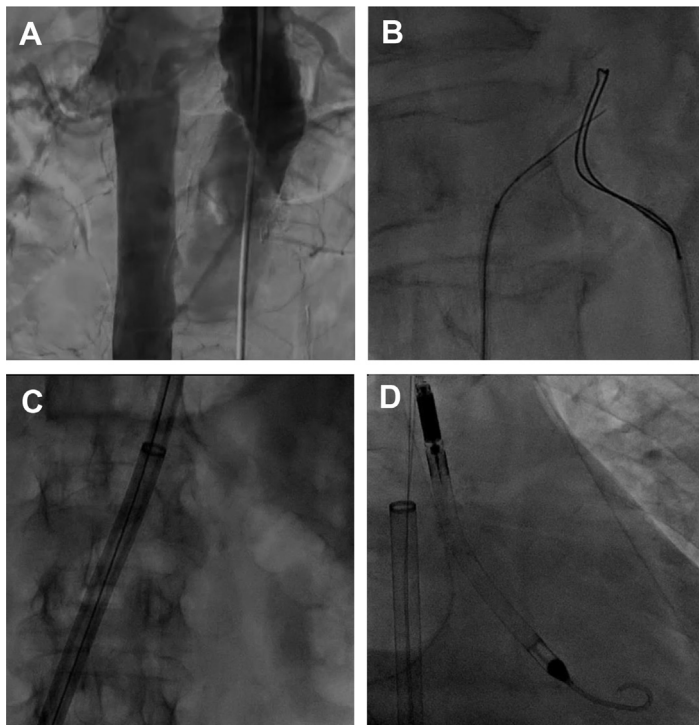
cardiogenic shock, and patients electively undergoing planned high-risk PCI.<sup>5</sup> In this article, the use of MCS in elective high-risk PCI is discussed.

Although the use of MCS in high-risk PCI has been theorized to allow safer, more complete coronary interventions, MCS in high-risk PCI has not conclusively been shown to be associated with improved clinical outcomes in prospective randomized clinical trials.<sup>6,7</sup> This article discusses the elements of decision making in the use of hemodynamic support in high-risk PCI, the current state of the evidence base for the use of MCS in high-risk PCI, and a practical approach to clinical decision making.

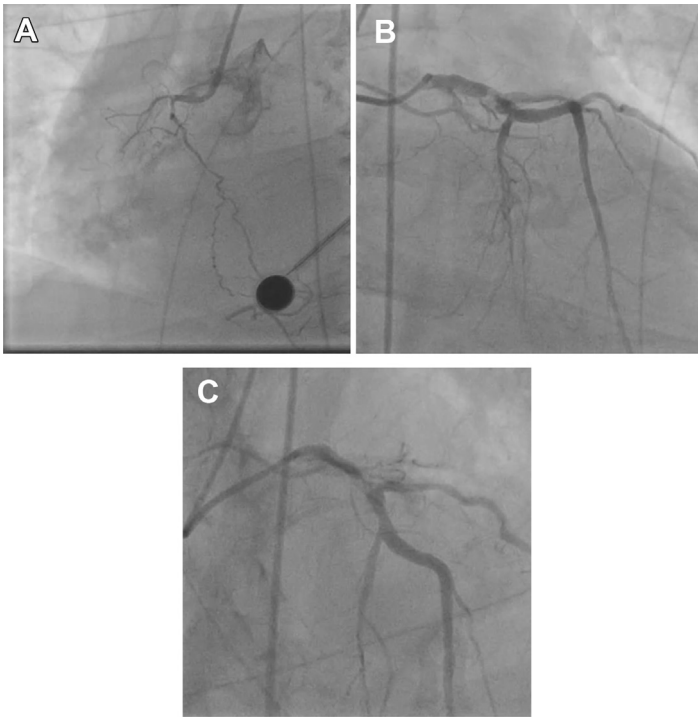
### DEFINING HIGH-RISK PERCUTANEOUS CORONARY INTERVENTION

At present, there is no standardized definition of high-risk PCI. Although risk calculators exist for both coronary artery bypass grafting (CABG) and PCI,<sup>8,9</sup> experts believe that these calculators do not adequately capture the complexity of this patient group.<sup>10,11</sup>

All proposed definitions of high-risk PCI incorporate 3 general categories of factors that, in combination, designate a procedure as high risk and can justify the use of periprocedural MCS: patient-specific comorbidities,

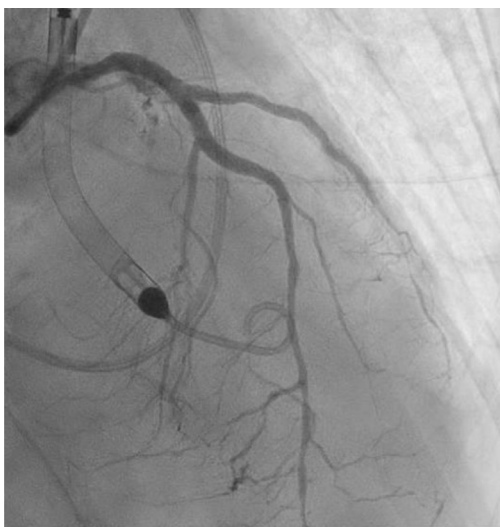


**Fig. 1.** Transcaval insertion of an intravascular micro-axial pump delivering up to 5.0 L/min with (A) simultaneous IVC and aorta angiography, (B) transcaval puncture, (C) 24 French sheath advancement, and (D) device positioning.



**Fig. 2.** Diagnostic angiography showing (A) a CTO of the right coronary artery as well as a CTO of the left circumflex and an eccentric, calcific stenosis of the proximal left anterior descending coronary artery (B, C).

hemodynamic factors, and factors specific to lesion and procedural technique (Fig. 4).<sup>5,12</sup> The relative importance of each of these factors in this qualitative assessment of procedural risk



**Fig. 3.** Completion angiogram following intravascular micro-axial pump supported atherectomy of the proximal left anterior descending coronary artery and bifurcation stenting with the first diagonal branch.

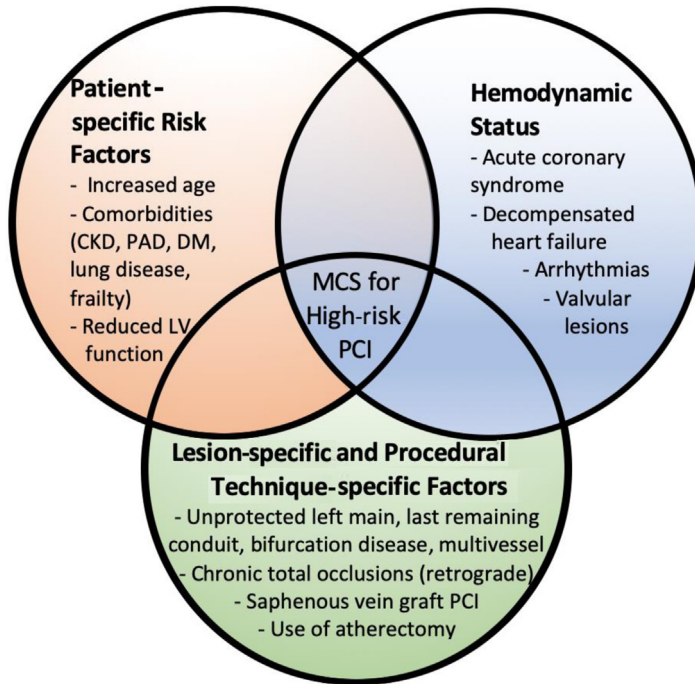
is unknown and remains a future direction for research.

#### Patient-Specific Factors

Comorbid diabetes mellitus, chronic lung disease, chronic kidney disease, prior MI, reduced left ventricular ejection fraction (LVEF), and peripheral arterial disease have all been associated with worse outcomes in PCI.<sup>13–17</sup> Advanced age and frailty are also associated with higher morbidity and mortality in patients undergoing PCI.<sup>18</sup> The aggregate of the patient's underlying health status is an important factor in determining the patient's ability to tolerate the stresses of transient ischemia, bleeding, arrhythmias, and hypotension often encountered in high-risk PCI. Patients with a lower physiologic reserve are more likely to incur end-organ dysfunction and ultimately mortality as a result of the hemodynamic stress of PCI and should be more strongly considered for the use of MCS.

#### Hemodynamic Status

The acuity of the clinical presentation before PCI remains the strongest predictor of procedural major adverse events.<sup>19</sup> PCI in the setting of acute coronary syndrome confers a higher risk of adverse events than elective PCI. Symptomatic heart failure with increased filling pressures



**Fig. 4.** Contributing factors in defining the high-risk PCI patient group most likely to benefit from invasive hemodynamic assessment and the use of MCS. CKD, chronic kidney disease; DM, diabetes mellitus; LV, left ventricle; PAD, peripheral arterial disease.

reduces the patient's ability to tolerate prolonged supine positioning and increases the patient's likelihood of developing further heart failure decompensation with contrast administration and ischemic insults during PCI. This condition can result in both hemodynamic and respiratory decompensation.<sup>20</sup> Arrhythmias, including atrial fibrillation and ventricular tachycardia, as well as underlying valvular lesions affect the patient's hemodynamic status and can be exacerbated during PCI.<sup>21,22</sup> Of particular note is severe aortic stenosis; patients with ischemia (caused in PCI during balloon inflations, atherectomy, and so forth) develop worsening hypotension because of ventricular stunning in the face of a high fixed afterload.

To most accurately evaluate a patient's current hemodynamic status, right heart catheterization is performed at the beginning of a high-risk PCI to characterize the patient's current filling pressures and hemodynamics. Operators are encouraged to begin all high-risk PCIs with a right heart catheterization to reevaluate the patient's filling pressures and biventricular function because the patient's hemodynamic status may have changed since the last interrogation because of ongoing medication titration. In addition, when evaluating the patient's status at the conclusion of a PCI, it can be useful to have preprocedural hemodynamics for comparison.

#### Factors Specific to Lesion and Procedural Technique

Lesion complexity and anticipated procedural techniques confer important prognostic information when evaluating the risk and anticipated benefits of a coronary intervention. Lesions defined empirically as high complexity include unprotected left main stenosis, heavy calcified or diffuse disease, true bifurcation lesions (Medina 1/1/1, 1/0/1, and 0/1/1), saphenous vein graft lesions, and CTOs.<sup>23,24</sup> Several risk scores have been validated to quantify the anatomic complexity and significance of a patient's coronary artery disease, including the Duke Jeopardy score and the Synergy Between PCI with Taxus and CABG (SYNTAX) score.<sup>25,26</sup>

The Duke Jeopardy score was first described by Califf and colleagues<sup>25</sup> in an effort to predict survival based on the distribution and degree of coronary artery disease. The Duke Jeopardy score estimates the amount of myocardium at risk by dividing the coronary tree into 6 anatomic segments (left anterior descending, first diagonal branch, first septal, left circumflex, first obtuse marginal, and posterior descending artery). Two points are assigned for each segment that has a stenosis 70% or greater, with the addition of 2 points for each downstream segment from a lesion. For example, a significant

proximal LAD lesion would have a Jeopardy score of 6 (2 for LAD, 2 for first septal, 2 for diagonal). Jeopardy scores range from 0 to 12, with a score of 2 conferring a 97% 5-year survival and a score of 12 conferring a 55% 5 year survival.

The SYNTAX score was developed to stratify the anatomic complexity of coronary lesions in patients with 3-vessel or left main coronary artery disease to guide surgical versus percutaneous revascularization strategy in a clinical trial.<sup>26</sup> Unlike the Duke Jeopardy score, the SYNTAX score includes lesion characteristics such as calcification, length, ostial location, and bifurcation involvement. In the SYNTAX trial, patients were divided into tertiles of SYNTAX scores, with a score of 22 or lower considered low complexity, 23 to 32 intermediate, and 33 or greater high complexity. The SYNTAX score was further refined with the SYNTAX II score, which combines both anatomic and clinical factors to aid heart team decision making.

Defining high-risk coronary interventions includes an evaluation of anatomic complexity, as exemplified by the Duke Jeopardy score or SYNTAX score. In addition, planned procedural techniques are an important factor in lesion evaluation.<sup>27</sup> Use of atherectomy and prolonged kissing balloon inflations are more likely to induce significant ischemia and hypotension.<sup>28</sup> Use of the retrograde approach in CTO PCI is also associated with higher hemodynamic stress than antegrade CTO PCI because of ischemia to collaterals perfusing the CTO territory and ischemia in the territory of the donor vessel.<sup>29,30</sup> Any lesion involving the last remaining vessel carries high risk of hemodynamic decompensation when ischemia is induced during angioplasty and in the event of any complication involving the last remaining vessel.

## HEMODYNAMIC EFFECTS OF MECHANICAL CIRCULATORY SUPPORT IN HIGH-RISK PERCUTANEOUS CORONARY INTERVENTION

The goal of MCS in high-risk PCI is to reduce myocardial oxygen consumption, improve myocardial blood flow, and maintain systemic perfusion during the procedure.<sup>31</sup> Reduced myocardial oxygen consumption and improved myocardial blood flow increase the threshold at which the ventricle becomes ischemic.<sup>32</sup> This condition reduces the adverse effects of myocardial ischemia, including arrhythmias, increased filling pressures caused by diastolic dysfunction, and ultimately systemic hypotension.

Maintaining systemic perfusion with a stable cardiac output and mean arterial pressure prevents the adverse metabolic effects of tissue hypoperfusion that lead to end-organ dysfunction, morbidity, and mortality.

Myocardial oxygen extraction is an efficient process with 70% to 80% of oxygen extracted by myocardial tissue in resting conditions.<sup>33</sup> Because myocardial oxygen extraction is unable to be significantly augmented, changes in myocardial oxygen delivery are primarily driven by coronary blood flow. Coronary blood flow is determined by the systemic pressure, left ventricular end-diastolic pressure, and wall tension. These factors are controlled by the preload, afterload, heart rate, contractility, and wall stress of the ventricle. Imbalance between oxygen supply, as determined by coronary blood flow, and demand results in myocardial ischemia.<sup>34</sup> In general, therapies that reduce afterload or preload, decrease wall stress, or reduce heart rate decrease the myocardial oxygen demand of the ventricle and improve myocardial blood flow, thus reducing the ischemic burden on the heart. The abilities of MCS devices to reduce myocardial oxygen demand and augment coronary blood flow are variable based on the design of each device.<sup>34</sup>

The current MCS devices used in high-risk PCI include the intra-aortic balloon pump (IABP), left ventricle (LV) to aorta assist devices (Impella 2.5, Impella CP, Impella 5.0), left atrium to aorta assist devices (TandemHeart), and venoarterial extracorporeal membrane oxygenation (VA-ECMO).

The variable effect on hemodynamics, myocardial oxygen consumption, and cardiac output augmentation of these MCS devices is summarized in [Table 1](#).

## CURRENT EVIDENCE

### Intra-aortic Balloon Pump

As the first widely used percutaneous MCS device, the IABP has enjoyed high rates of use because of widespread availability and ease of use. The IABP has been studied extensively in acute MI with cardiogenic shock (AMICS). Despite its continued use in patients presenting with AMICS, the pivotal IABP-SHOCK II (Intra-aortic Balloon Support for Myocardial Infarction with Cardiogenic Shock) trial found the IABP to not be superior to medical management for the management of cardiogenic shock in patients presenting with acute coronary syndrome.<sup>35</sup>

Within the realm of elective high-risk PCI, several observational trials suggested reduced rates of major adverse cardiac events with upfront IABP insertion compared with ad hoc

**Table 1**  
Hemodynamic effects of commonly used mechanical circulatory support platforms

	Afterload	LVEDP	MAP	CO	Left Ventricular Unloading	Myocardial Oxygen Demand	Maximal Flow (L/min)
IABP	↓	↓	↑	↑	↑	↓	0.5
Impella CP	Variable	↓	↑	↑	↑	↓	4.0
Tandem Heart	↔	↓	↑	↑	↑	↓	5.0
VA-ECMO	↑	↑ to ↔	↑	↑	↓	↔	7.0

Abbreviations: CO, cardiac output; LVEDP, left ventricular end-diastolic pressure; MAP, mean arterial pressure.

IABP insertion. This hypothesis was tested in the Elective Intra-aortic Balloon Counterpulsation During High-risk Percutaneous Coronary Intervention (BCIS-1) trial.<sup>6</sup> The BCIS-1 trial was the first clinical trial to prospectively study MCS in elective high-risk PCI in a randomized fashion. Ultimately, 300 patients were randomized to IABP insertion before high-risk PCI with balloon pump in place for 4 to 24 hours versus standard PCI. The composite end point of MI, death, stroke, or further revascularization at hospital discharge was not significantly different between the groups. Routine IABP use was associated with fewer procedural complications, including periprocedural hypotension and pulmonary edema. However, the routine IABP group had more minor bleeding and access site complications than standard PCI.

Although not powered to examine all-cause mortality, the BCIS-1 cohort was followed for long-term all-cause mortality.<sup>36</sup> The investigators reported a statistically significant reduction in all-cause mortality in the routine IABP group at a median of 51 months after the index procedure. The overall mortality for the cohort was high (33%), reflecting the high-risk patient population enrolled in the BCIS-1 trial. The hazard ratio for all-cause mortality in patients with routine IABP placement before PCI was 0.66, conferring a 34% reduction in all-cause mortality compared with the unsupported PCI group.

Overall, elective IABP insertion in high-risk PCI has a limited role in modern practice. Upfront IABP may be a reasonable option in patients at particularly high risk of hemodynamic decompensation with poor vascular access prohibiting larger device insertion.

### Impella

The Impella was first introduced in Europe in 2004. In 2008, the Impella 2.5 became available

in the United States, receiving US Food and Drug Administration (FDA) approval for partial hemodynamic support in cardiac procedures not requiring cardiopulmonary bypass.<sup>37</sup> Since its approval, the Impella has been used in a variety of clinical settings, including cardiogenic shock, acute MI, postcardiotomy syndrome, and high-risk PCI.<sup>38–40</sup> In the subsequent decade, the device has been iterated, with the Impella CP and the Impella 5.0 offering superior cardiac output augmentation and ventricular unloading. The Impella 2.5, CP, and 5.0 have now received FDA approval for procedural use in high-risk PCI as well as in the setting of acute MI and cardiogenic shock.<sup>41</sup>

The Impella system was hypothesized to be superior to IABP in high-risk PCI because of its greater ability to directly unload the ventricle and provide continuous cardiac output, with the Impella 5.0 providing up to 5 L/min compared with the modest contribution of 0.5 L/min with the IABP. The feasibility of Impella-supported high-risk PCI was first prospectively evaluated in the the PROTECT I trial (A prospective feasibility trial investigating the use of the Impella 2.5 system in patients undergoing high-risk percutaneous coronary intervention).<sup>42</sup> Twenty patients undergoing high-risk PCI, defined as unprotected left main or last remaining conduit PCI with an LVEF less than or equal to 35%, underwent Impella 2.5 insertion before PCI. The primary safety end point of major adverse cardiac events, defined as death, MI, target vessel revascularization, urgent CABG, or stroke at 30 days, occurred in 20% of patients. Two patients had increased periprocedural cardiac enzyme levels meeting the definition of MI, and 2 patients expired during the 30 days following the procedure (1 of renal failure leading to cardiac arrest, 1 of sudden cardiac death). Safety end points were reassuring, with the most common complication being access site hematomas in 8 out of 20 patients (although, notably,

hemostasis in this trial was achieved with manual compression on the 13-Fr arterial access sites). From an efficacy perspective, all patients were free from hemodynamic compromise during their procedures, and angiographic success was achieved in all patients.

The USpella registry was a multicenter registry designed to evaluate the safety and clinical outcomes of Impella 2.5 in real-world use.<sup>43</sup> In the USpella registry, high-risk PCI was defined at the discretion of the operator and included patients with reduced LV function, complex coronary anatomy, or a high burden of comorbidities. Among the patients who had prophylactic Impella insertion before high-risk PCI to prevent hemodynamic compromise, the rate of overall major adverse cardiac events was 8% with a 96% 30-day survival. The low overall rate of adverse events was notable in light of the anatomic complexity and high-risk nature of the cohort, with an average SYNTAX score of 37%, 56% of patients being surgical turndowns, 66% of patients with New York Heart Association (NYHA) class III or IV symptoms, and 69% of patients with an ejection fraction less than 35%. Secondary safety outcomes were most notable for access site complications (3.4% with access site bleeding requiring transfusion, 3.4% with vascular complications such as dissection or arteriovenous fistula, and 8.6% with hematomas) despite use of endovascular suture-based closure devices. The findings of the USpella registry were encouraging, with clinical outcomes showing 90% success rates in multivessel revascularization, improvement in LVEF, and improvement in NYHA class at discharge. Overall, these results supported the safety and feasibility of the use of Impella 2.5 in high-risk single-vessel and multivessel PCI.

In light of the safety and feasibility of Impella-supported high-risk PCI in PROTECT I and findings suggesting benefit in the USpella registry, the use of the Impella 2.5 versus IABP was studied in patients undergoing high-risk PCI in the prospective, randomized controlled PROTECT II study (A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus Intra-Aortic Balloon Pump in patients undergoing high-risk percutaneous coronary intervention).<sup>7</sup> In PROTECT II, patients were eligible for enrollment if they were undergoing elective PCI for unprotected left main, last remaining conduit, or 3-vessel coronary disease with an LVEF less than or equal to 35%. Following iliofemoral angiography to verify anatomic appropriateness for randomization, patients were randomized to

IABP or Impella 2.5 insertion before PCI. The study was concluded early because of futility with a total of 452 patients enrolled in the trial. The patients included in PROTECT II were a high-risk cohort, with 66% of patients with NYHA class III or IV symptoms, an average LVEF of 24%, an average SYNTAX score of 30, and a mean Society of Thoracic Surgeons (STS) mortality of 6%. Notably, there were significant differences in the procedural characteristics between the groups randomized to Impella versus IABP. In procedures among patients randomized to Impella, more contrast was used, more stents were placed, and atherectomy was used more frequently, with a greater duration of use and number of runs. In total, this suggests more extensive and complete coronary revascularization undertaken in the Impella group than in the IABP group.

PROTECT II did not find significant difference in the rate of major adverse events, defined as a composite of all-cause death, MI, stroke, TIA, revascularization procedure, cardiac or vascular operation, acute renal insufficiency, severe intra-procedural hypotension requiring therapy, cardiopulmonary resuscitation, ventricular tachycardia requiring cardioversion, new aortic insufficiency, or angiographic failure of PCI. In the intention-to-treat analysis, there was a 35.1% major adverse event rate in the Impella 2.5 group versus 40.1% in the IABP group ( $P = .277$ ). At 90 days, a trend toward lower major adverse events in the Impella group was noted, although this did not reach statistical significance ( $P = .066$ ). In the per-protocol population, although the 30-day outcomes did not show a significant difference in major adverse events, the 90-day major adverse event rate was significantly lower in the Impella arm (40% vs 51%;  $P = .023$ ). Patients in the Impella group were significantly less likely to undergo repeat revascularization at 90 days compared with the IABP group. Patients in the study showed significant improvements in LVEF and NYHA class, although this did not differ between the Impella and IABP groups.

Overall, the PROTECT II trial was a negative trial. The investigators were not able to show a difference in the primary outcome of major adverse events at 30 days between the patients randomized to Impella versus IABP. However, these findings must be interpreted in the context of variation in procedural techniques used by operators, with more extensive rotational atherectomy and stenting used in the Impella group, likely because of the patients' hemodynamic



stability and perceived ability to tolerate more aggressive techniques. This hypothesis fits with the Impella group having higher rates of periprocedural MI at 30 days and lower rates of repeat revascularization at 90 days. In addition, it is unclear whether the high-risk patients in PROTECT II would have been considered candidates for revascularization in the absence of MCS.

### TandemHeart

The TandemHeart is a left ventricular assist device that is inserted percutaneously and diverts blood from the left atrium to the femoral artery at up to 5 L/min. Although the need for left atrial access via trans-septal puncture has limited widespread use of this device, several specific clinical settings make the use of TandemHeart attractive, including patients with significant aortic valve disorder or the presence of a left ventricular thrombus. To date, no randomized data has been collected regarding the use of TandemHeart in high-risk PCI.

A prospectively collected single-center registry is the largest published experience describing the use of TandemHeart in high-risk PCI.<sup>44</sup> In this registry from the Mayo clinic, 64 patients underwent high-risk PCI (LVEF < 30% and a Duke Jeopardy score of 8 or greater) with TandemHeart over a 5-year period. All of the patients were deemed inoperable because of comorbidities, severity of cardiovascular disease, or both. They were also thought to have a burden of disease and underlying cardiac dysfunction to such a degree that an Impella was considered inadequate periprocedural hemodynamic support. This opinion is reflected in the baseline characteristics of the patient cohort, with an average LVEF of 20%, median SYNTAX score of 33, and median Jeopardy score of 10. Many of these patients had a recent MI (52%) complicated by periprocedural cardiogenic shock (29%), with 45% of patients already having an IABP in place before intervention.

Despite the high coronary complexity and high risk of this group, there was a 97% procedural success rate, with left main intervention in 62% of patients and rotational atherectomy in 48% of patients. The 30-day survival in this high-risk group was 90%. The most common adverse event was vascular complications (13% of patients), which largely occurred in the early experience. The rates of access site complications decreased markedly with the routine assessment of iliofemoral access as a component of case selection and procedure planning.

A meta-analysis by Briasoulis and colleagues<sup>45</sup> included 8 cohort studies with a total of 205 patients that received TandemHeart for high-risk PCI. Short-term mortality was 8%, with major bleeding rates of 3.6%. These outcomes are in line with prior studies given the high-risk nature of the group being studied.

Overall, the limited data available supports the use of TandemHeart for MCS in select high-risk PCI. The high rates of 30-day mortality and vascular complications may at least in part be explained by the selection bias among these observational studies; patients with TandemHeart placement were considered to need more hemodynamic support than could be provided by an Impella and were likely sicker at baseline. Despite this, observational data have shown acceptable safety and feasibility in TandemHeart placement for high-risk PCI in this inoperable cohort of patients.

### Venoarterial Extracorporeal Membrane Oxygenation

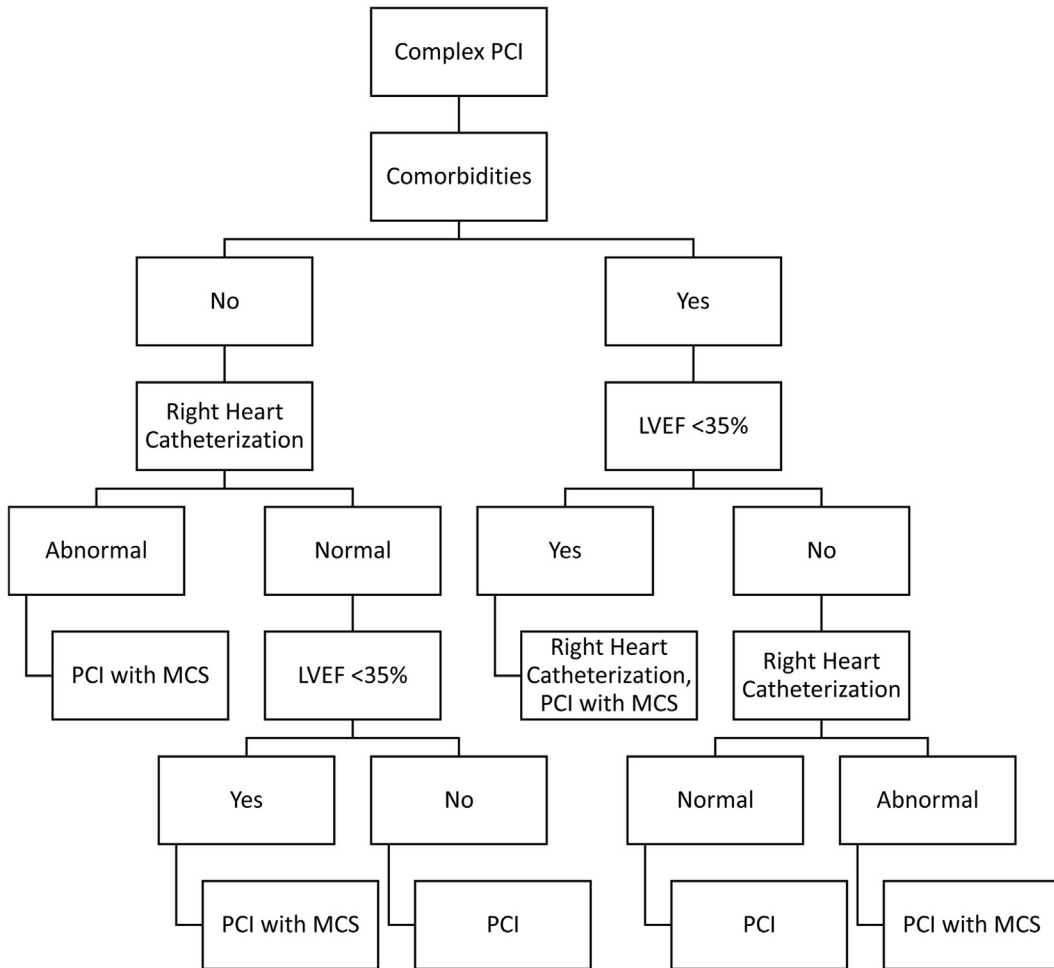
Data for elective high-risk PCI on ECMO are limited to small single-center experiences. Brilakis and colleagues<sup>46</sup> describe their experience with 5 patients over the course of 5 years who underwent high-risk PCI with ECMO support. The patients underwent PCI for LV systolic dysfunction (4 patients) or non-ST elevation MI (1 patient). All interventions were technically successful. The most common adverse event was vascular access complications, with 1 pseudoaneurysm requiring surgical repair and 2 femoral hematomas. All of their patients lived through 1-year follow-up with a mean increase in LVEF of 24%.

Similar findings were reported by Barbarash and colleagues,<sup>47</sup> whose experience with elective high-risk PCI with ECMO support included 12 inoperable patients in 1 year. In this group, all PCI procedures were technically successful and no in-hospital major adverse events were observed. There were minimal vascular complications in this case series, with only 1 femoral hematoma reported. Six-month follow-up was notable for 100% survival, with 2 patients requiring repeat revascularization.

These single-center reports suggest that ECMO-supported PCI is feasible and can be performed safely in a highly selected group of patients in experienced centers.

## CLINICAL DECISION MAKING

Clinical decision making for patients undergoing high-risk PCI requires a nuanced understanding of the complex interplay between patient,



**Fig. 5.** Algorithm for decision making in the use of MCS for patients undergoing elective high-risk PCI. Patients entering the algorithm are those undergoing complex PCI, defined as procedures with high potential for ischemia, including Duke Jeopardy score greater than 8, last remaining conduit, multivessel obstructive disease, left main bifurcation with planned atherectomy, retrograde CTO, and those in which an unanticipated complication such as no reflow or dissection would likely result in hemodynamic collapse. Comorbidities include significant valvular lesions, prior diagnosis of heart failure, chronic kidney disease, advanced age, and frailty.

lesion, and hemodynamic characteristics as well as the unique assets and liabilities of the available MCS modalities. Although general conclusions can be drawn from the available randomized and observational data, these must be weighed carefully against patient-specific and procedure-specific considerations. Although several decision-making algorithms have been proposed (Fig. 5), none have been prospectively validated.

### Heart Team Approach

The heart team, a multidisciplinary group convened to discuss complex patient care

decisions, was initially established in clinical trials as a way to select appropriate patients for interventional versus surgical revascularization. The heart team is composed at a minimum of the patient's primary cardiologist, consulting interventional cardiologist, and consulting cardiac surgeon. Similar to the manner in which the heart team has become the standard of care in aortic valve disease, a heart team for coronary artery disease has been proposed as the standard of care for patients being evaluated for high-risk revascularization.<sup>12</sup> These teams use a comprehensive patient assessment to weigh the relative risks and benefits of

medical, interventional, or surgical treatment in a balanced manner and provide unified, clear recommendations to team members, patients, and families. In addition to gaining multiple perspectives on patient management, this collaborative approach has been shown to be feasible and promote the application of evidence-based guidelines to patient care.<sup>48</sup>

### Device Selection

When selecting an MCS modality for high-risk PCI, it is important to consider the amount of support needed, adequacy of vascular access, and device-specific contraindications.

As detailed previously in this article, the available MCS devices provide different levels of hemodynamic support, from 0.5 L/min with IABP to 5 to 6 L/min with VA-ECMO. The cardiac output deficit is one method to determine the amount of hemodynamic support needed. In this paradigm, the target cardiac index is 2.2 L/min. The cardiac output deficit is the difference between the target cardiac output and the cardiac output nadir during the procedure. Although the cardiac output nadir is only possible to estimate in advance, it can be approximated based on the patient's preprocedure hemodynamics as well as an estimate of the amount of myocardium susceptible to stunning during intervention.

Limitations in vascular access are also an important consideration when choosing MCS devices. When femoral arterial access is prohibitive because of peripheral arterial disease, excessive tortuosity, or small patient habitus, alternative access (subclavian cutdown or percutaneous axillary access) has been shown to be feasible and safe for both IABP and Impella CP.<sup>49–51</sup> Severe peripheral arterial disease can be prohibitive when considering larger sheaths for blood return for TandemHeart or VA-ECMO. A novel approach in patients requiring large-bore access for ECMO, TandemHeart, or Impella 5.0 with inadequate transfemoral access is transcaval access, which allows venous transfemoral access with the sheath traversing the inferior vena cava to the abdominal aorta by means of percutaneous access.<sup>52,53</sup> Although this novel approach has allowed a class of patients who previously would have been ineligible for MCS to undergo these procedures, its use is limited by the small number of operators with adequate skills for percutaneous transcaval access, management, and removal.

In addition, device-specific contraindications must be considered when choosing an appropriate MCS platform. With the exception of the

IABP, all MCS platforms require patients to be able to tolerate systemic anticoagulation.<sup>5</sup> Patients with IABP must have a stable rhythm and a competent aortic valve. The Impella is contraindicated in patients with a mechanical aortic valve and in the presence of left ventricular thrombus. It can be difficult to deliver in challenging aortic anatomy, and severe aortic valve disorder is a relative contraindication. Impella and TandemHeart require an adequately functioning right ventricle and stable rhythm. The TandemHeart requires interatrial septum anatomy appropriate for a transseptal puncture. In addition, VA-ECMO can result in ventricular distention if the underlying pulsatility of the ventricle is unable to adequately compete with the flow from the ECMO circuit.<sup>5</sup>

With all MCS devices, appropriate patient selection is a prerequisite, and a plan for inability to separate from the device should be discussed before MCS insertion with the input of advanced heart failure and palliative care team members. It is critical to monitor for complications including limb ischemia, stroke, and bleeding as long as the MCS device is in place.

### FUTURE DIRECTIONS

As procedural techniques continue to evolve, the importance of appropriate patient selection will remain a focus in high-risk PCI. At present, there are limited data guiding the use and selection of MCS devices. Identifying patients in a systematic fashion that incorporates patient, lesion, and hemodynamic factors is critical to advancing clinical research. Clinically, more sophisticated methods for patient selection will allow identification of the patients who are the most likely to benefit from intervention as well as those in whom high-risk PCI is futile.

### SUMMARY

Overall, the growing technical complexity of modern PCI combined with the increasingly comorbid elderly population has resulted in an expanding group of patients who are considered inoperable or high risk for CABG. These patients, identified based on their comorbidities, lesion characteristics, and hemodynamic state, represent a cohort who now are offered high-risk PCI with the use of MCS. To date, clinical research has not conclusively shown benefit to the routine use of MCS in prospective randomized controlled trials. Ongoing research focusing on identifying the appropriate patient/lesion to derive the greatest benefit with MCS-facilitated

high-risk PCI is critical to the growth of this field. In addition, lower-profile, more powerful devices that maximize hemodynamic benefits while minimizing vascular complications will be critical to making MCS more efficacious in this group of patients and interventions.

## CLINICS CARE POINTS

- Identifying patients who are high risk for hemodynamic collapse during elective high-risk PCI requires understanding of patient-specific risk factors, hemodynamics, and lesion/procedural technique factors. Patients with multiple comorbidities and decompensated hemodynamics who require advanced interventional techniques, including kissing balloons, atherectomy, or use of last remaining conduit, should be strongly considered for MCS.
- The most widely used device in the United States for high-risk PCI is the IABP. The IABP has a low risk of vascular complications, but provides minimal augmentation in forward systemic flow.
- The LV to aortic assist device (Impella) has grown in use given the ease of use, effectiveness of ventricular unloading, and stable increases in cardiac output with this device. Vascular complications remain an important complication limiting the clinical benefit of these devices.
- The use of TandemHeart and VA-ECMO to support high-risk PCI has been shown to be safe and feasible in limited observational data.
- Future directions for research in high-risk PCI will likely focus on identifying the group of patients most likely to benefit from MCS-supported PCI.

## DISCLOSURES

The authors have no relevant disclosures to report.

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