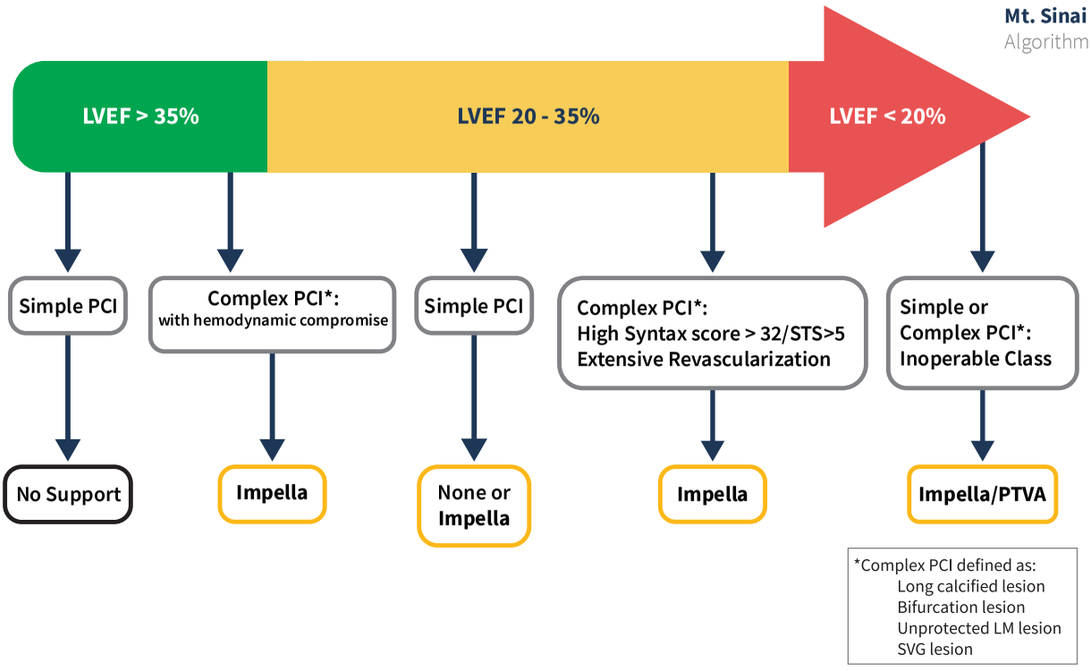
Protected PCI with Impella® Guidance Protocol Example

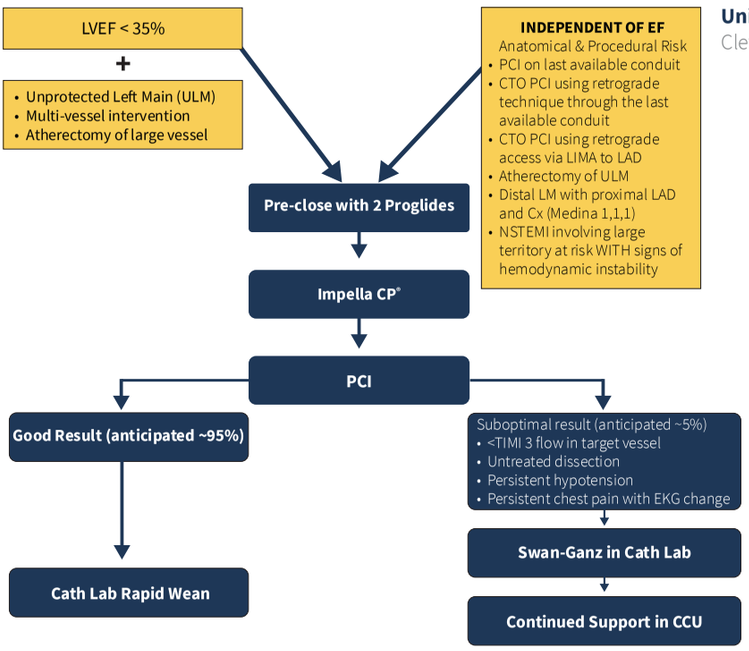
Mt. Sinai
Algorithm



*Complex PCI defined as:
- Long calcified lesion
- Bifurcation lesion
- Unprotected LM lesion
- SVG lesion

Protected PCI with Impella Guidance Protocol Example

University Hospitals
Cleveland Medical Center



Protected PCI with Impella Guidance Protocol Example

Inova Heart & Vascular Institute

Clinical Goals
- Increase ventricular function
- Decrease angina/heart failure
- Reduce rehospitalization
- Improve quality of life

High Risk PCI Criteria

Hemodynamic Compromise
- Decreased EF
- Heart Failure
- Abnormal cardiac pressures

Complex Anatomy
- Left main disease
- Multivessel disease
- Last remaining conduit
- Complex CTO
- Heavy calcification
- Complex bifurcation
- Large area of myocardium at risk

Comorbidities
- LV dysfunction
- Acute coronary syndrome
- Advanced age
- Valvular heart disease
- Surgical turn-down

Heart Team Evaluation
- Assess for appropriateness of medical therapy vs. CABG vs. PCI
- See "High Risk PCI Criteria"

Protected PCI

Percutaneous MCS (PMCS) pre-PCI
Right heart catheterization
Coronary revascularization

Conventional PCI

Hemodynamic compromise
Myocardial stunning
No reflow
Consider Bail-Out PMCS

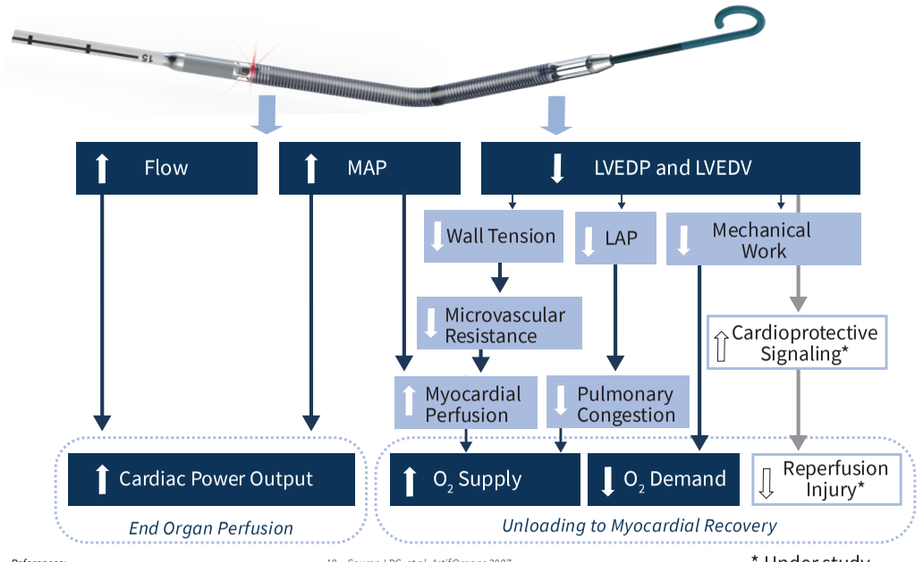
Assess for PMCS Weaning Post-PCI

Stable hemodynamics → **Explant PMCS In Cath Lab**

Low-dose pharmacologic support → **PMCS < 24 hours In CCU**

High-dose pharmacologic support
Inability to wean PMCS → **Assess for PMCS Escalation**

Hemodynamic Effects of Impella® Devices



* Under study

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INDICATIONS

High-Risk PCI

The Impella 2.5®, Impella CP® and Impella CP® with SmartAssist® Systems are temporary (≤ 6 hours) ventricular support devices indicated for use during high-risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease, when a heart team, including a cardiac surgeon, has determined high-risk PCI is the appropriate therapeutic option. Use of the Impella 2.5, Impella CP, and Impella CP with SmartAssist Systems in these patients may prevent hemodynamic instability, which can result from repeat episodes of reversible myocardial ischemia that occur during planned temporary coronary occlusions and may reduce peri- and post-procedural adverse events.

Cardiogenic Shock

The Impella 2.5®, Impella CP®, Impella CP® with SmartAssist®, Impella 5.0®, Impella 5.5® with SmartAssist® and Impella LD® Catheters, in conjunction with the Automated Impella Controller™ (collectively, "Impella® System Therapy"), are temporary ventricular support devices intended for short term use (≤ 4 days for the Impella 2.5, Impella CP, and the Impella CP with SmartAssist, and ≤ 14 days for the Impella 5.0, Impella 5.5 with SmartAssist and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction or open heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures (including volume loading and use of pressors and inotropes, with or without IABP). The intent of Impella System Therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.

Important Risk Information for Impella devices

CONTRAINDICATIONS

The Impella 2.5, Impella CP, Impella CP with SmartAssist, Impella 5.0, Impella 5.5 with SmartAssist and Impella LD are contraindicated for use with patients experiencing any of the following conditions: Mural thrombus in the left ventricle; Presence of a mechanical aortic valve or heart constrictive device; Aortic valve stenosis/calcification (equivalent to an orifice area of 0.6 cm^2 or less); Moderate to severe aortic insufficiency (echocardiographic assessment graded as ≥ +2); Severe peripheral arterial disease precluding placement of the Impella System; Significant right heart failure*; Combined cardiorespiratory failure*; Presence of an Atrial or Ventricular Septal Defect (including post-infarct VSD)*; Left ventricular rupture*; Cardiac tamponade*

*** This condition is a contraindication for the cardiogenic shock indication only.**

POTENTIAL ADVERSE EVENTS

Acute renal dysfunction, Aortic valve injury, Bleeding, Cardiogenic shock, Cerebral vascular accident/Stroke, Death, Hemolysis, Limb ischemia, Myocardial infarction, Renal failure, Thrombocytopenia and Vascular injury

Right-Side Support

The Impella RP® System is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery.

Important Risk Information for Impella devices

CONTRAINDICATIONS

The Impella RP System is contraindicated for patients with the following conditions: Disorders of the pulmonary artery wall that would preclude placement or correct positioning of the Impella RP device. Mechanical valves, severe valvular stenosis or valvular regurgitation of the tricuspid or pulmonary valve. Mural thrombus of the right atrium or vena cava. Anatomic conditions precluding insertion of the pump. Presence of a vena cava filter or caval interruption device, unless there is clear access from the femoral vein to the right atrium that is large enough to accommodate a 22 Fr catheter.

CONTRAINDICATIONS

The potential adverse effects (eg, complications) associated with the use of the Impella RP System: Arrhythmia, Atrial fibrillation, Bleeding, Cardiac tamponade, Cardiogenic shock, Death, Device malfunction, Hemolysis, Hepatic failure, Insertion site infection, Perforation, Phlegmasia cerulea dolens (a severe form of deep venous thrombosis), Pulmonary valve insufficiency, Respiratory dysfunction, Sepsis, Thrombocytopenia, Thrombotic vascular (non-central nervous system) complication, Tricuspid valve injury, Vascular injury, Venous thrombosis, Ventricular fibrillation and/or tachycardia.

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.

Visit ***www.abiomed.com/important-safety-information*** to learn more

Impella® CLINICAL SUPPORT CENTER 24/7

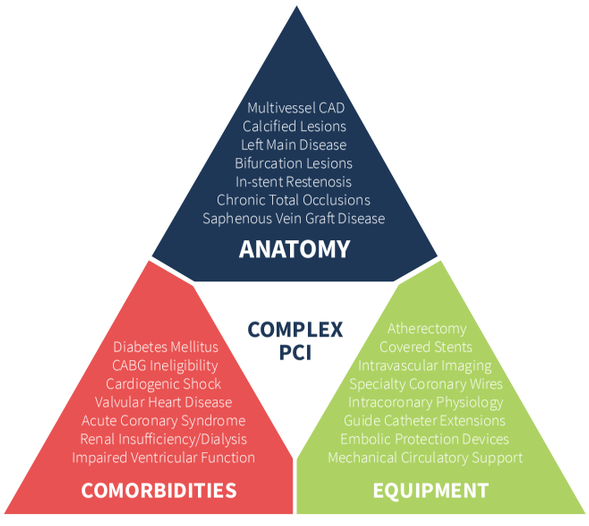
24/7 Impella Clinical Support and Technical Expertise

1-800-422-8666 (US)

ABIOMED

Careful Risks Assessment to Optimize Patient Safety

High-Risk Factors Include Anatomy, Comorbidities and Procedural Complexity



Riley et al. SCAI Position Statement, May 2020 doi: 10.1002/ccd.28994

In-hospital Mortality Risks*

Surgical Ineligibility: 6-7x increase in mortality[2,3]

Chronic Kidney Disease: 2-3x increase in mortality[5]

Impaired LV (<50% EF): 15% increase in mortality[4]

Long-Term Mortality Risks*

Incomplete Revasc: 3x increase in 5-year mortality[1]

Severe Calcification: 72% increase in 5-year mortality[6]

Valvular Heart Disease: increase in 1-year mortality[7]

**As referenced in SCAI Statement*

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