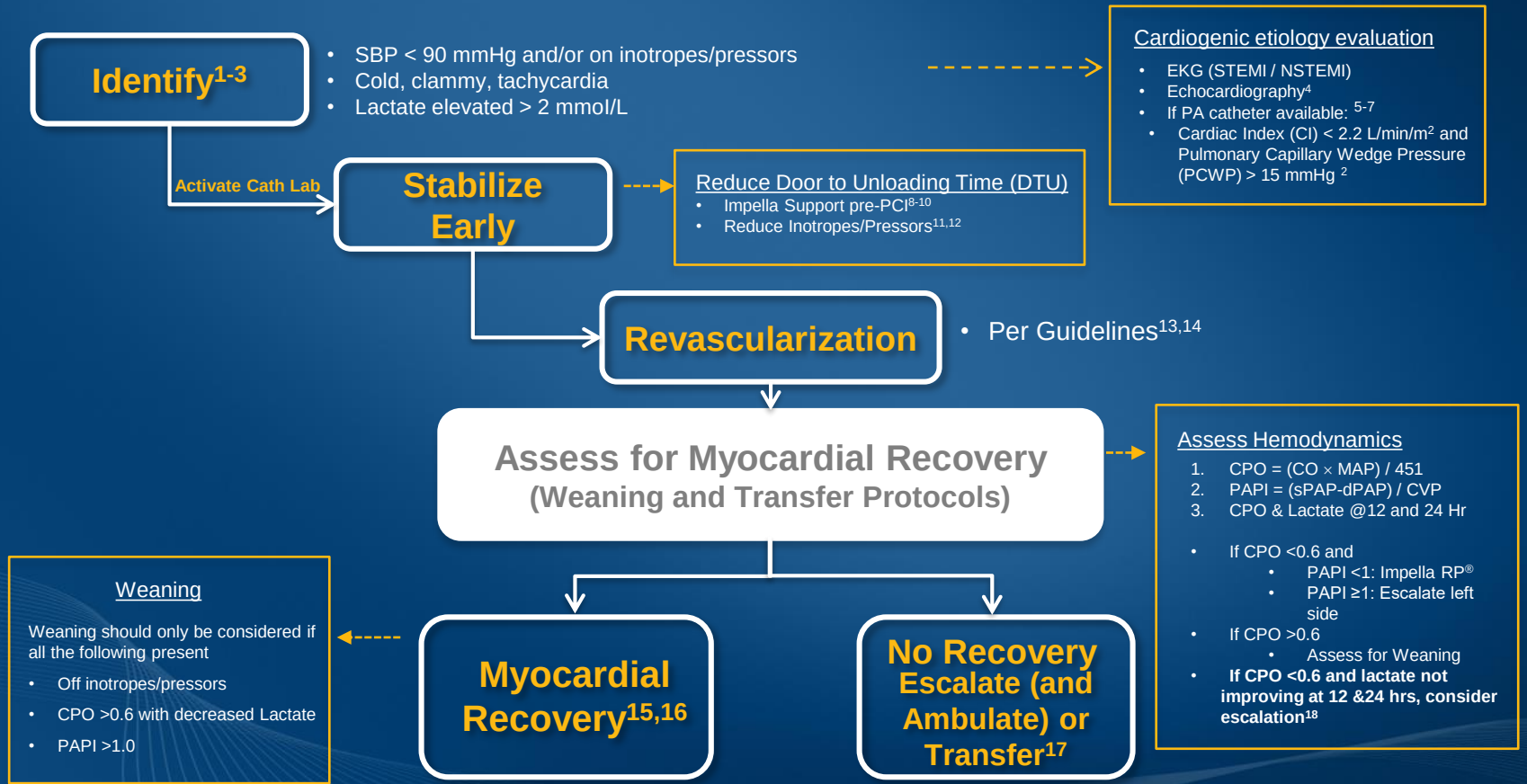
Cardiogenic Shock Protocol

IMPELLA® BEST PRACTICES IN AMI CARDIOGENIC SHOCK



1. Reyentovich A, et al. Nat Rev Cardiol. 2016;13(8):481-492.
2. Hochman JS, et al. N Engl J Med. 1999;341(9):625-634.
3. Rihal CS, et.al. J Am Coll Cardiol. 2015;65(19):e7-e26.
4. Picard MH, et al. Circulation. 2003;107(2):279-284.
5. Cohen MG, et al. Am J Med. 2005;118(5):482-488.
6. Kahwash R, et al. Cardiol Clin. 2011;29(2):281-288.
7. Chatterjee K. Circulation 2009;119(1):147-152.
8. O'Neill WW, et al. J Interv Cardiol. 2014;27(1):1-11.
9. Joseph SM, et al. J Interv Cardiol. 2016 Jun;29(3):248-56.
10. Schroeter MR, et al. J Invasive Cardiol. 2016 Aug 15. [Epub ahead of print]
11. Samuels LE, et al. J Card Surg. 1999;14(4):288-293.
12. De Backer D, et al. N Engl J Med. 2010;362(9):779-789.
13. O'Gara PT, et al. J Am Coll Cardiol. 2013;61(4):e78-e140.
14. Steg PG, et al. Eur Heart J. 2012;33(20):2569-2619.
15. Casassus F, et al. J Interv Cardiol. 2015;28(1):41-50.
16. Lemaire A, et al. Ann Thorac Surg. 2014;97(1):133-138.
17. Anderson MB, et al. J Heart Lung Transplant. 2015;34(12):1549-1560
18. Basir, B, et al. Lactate and CPO reliably Predict. TCT 2018

Identify: Minimize Duration of Shock

Suspect
Cardiogenic Shock
See A

Confirm
CGS Diagnosis
reassess every 1-2 hours if criteria not initially met
See B

Activate
Heart Recovery Team/
Cardiac Cath Lab

Suspect Shock A

Consider any of these criteria:

- Cool, clammy, pale skin
- Confusion/anxiety
- Rapid, shallow breathing
- SBP < 90 mmHg > 30 min
- Inotrope/vasopressor and/or IABP to maintain SBP > 90 mmHg
- Decrease in urine output (<0.5 cc/kg/h)
- Serum lactate level > 2 mmol/L

Diagnose CGS B

- STEMI/Non-STEMI
- ECG ST segment abnormalities
- Troponin
- ECHO (assess cardiac function)

If PA Catheter (PAC) available:

- Cardiac Index (CI) < 2.2 L/min/m^2 AND Pulmonary Capillary Wedge Pressure (PCWP) > 15 mmHg

Stabilize Early and Complete Revascularization

BEST PRACTICE

Assess Hemodynamics: LVEDP or PAC

- If sustained hypotension (SBP < 90 mmHg) for > 30 min

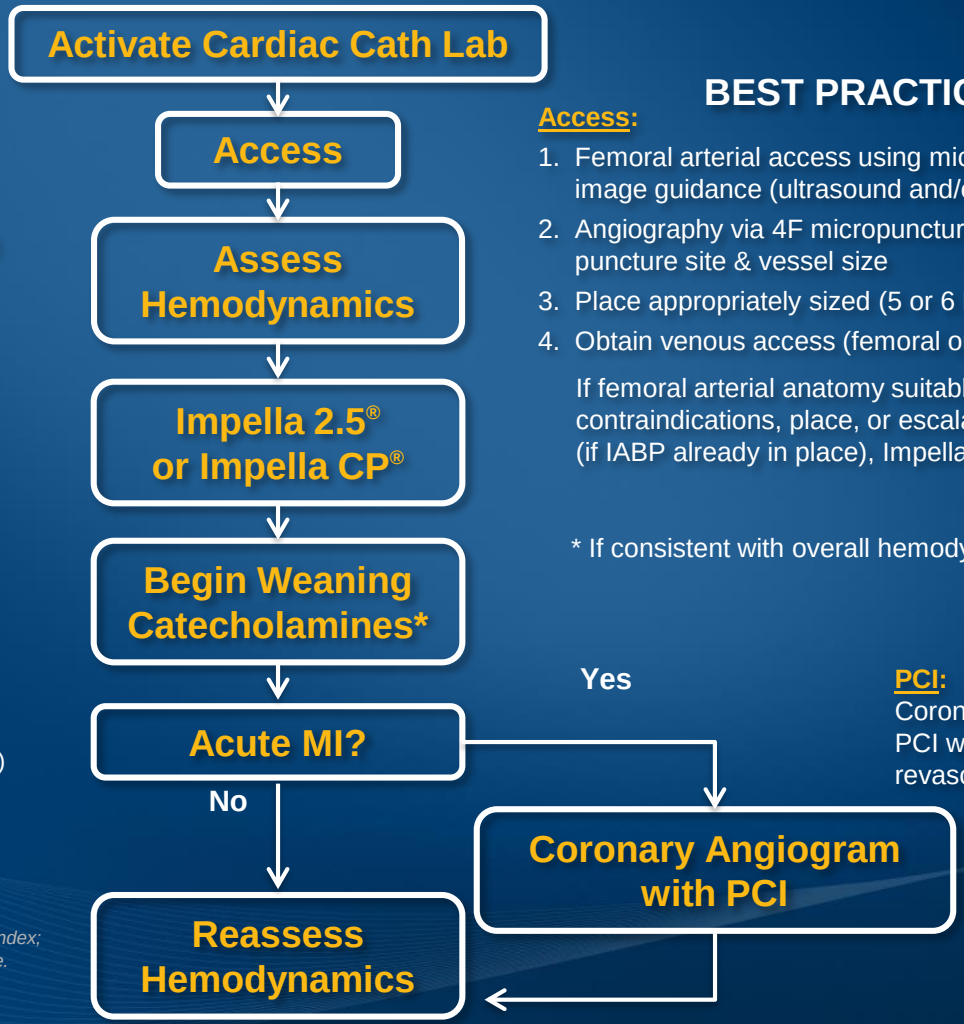
  Or

- CI < 2.2 with LVEDP or PCWP >18 mmHg, consider mechanical circulatory support

Reassess Hemodynamics: PAC (if not done initially)

1. CPO = MAP × CO/451 W
2. PAPI = sPAP-dPAP/RA

CO, cardiac output; CPO, cardiac power output; dPAP, diastolic pulmonary arterial pressure; MAP, mean arterial pressure; PAC, pulmonary arterial catheter; PAPI, pulmonary artery pulsatility index; RA, right arterial pressure; sPAP, systolic pulmonary arterial pressure.



BEST PRACTICE

Access:

1. Femoral arterial access using micropuncture with image guidance (ultrasound and/or fluoroscopy)[1]
2. Angiography via 4F micropuncture dilator to confirm puncture site & vessel size
3. Place appropriately sized (5 or 6 Fr) arterial sheath
4. Obtain venous access (femoral or internal jugular)

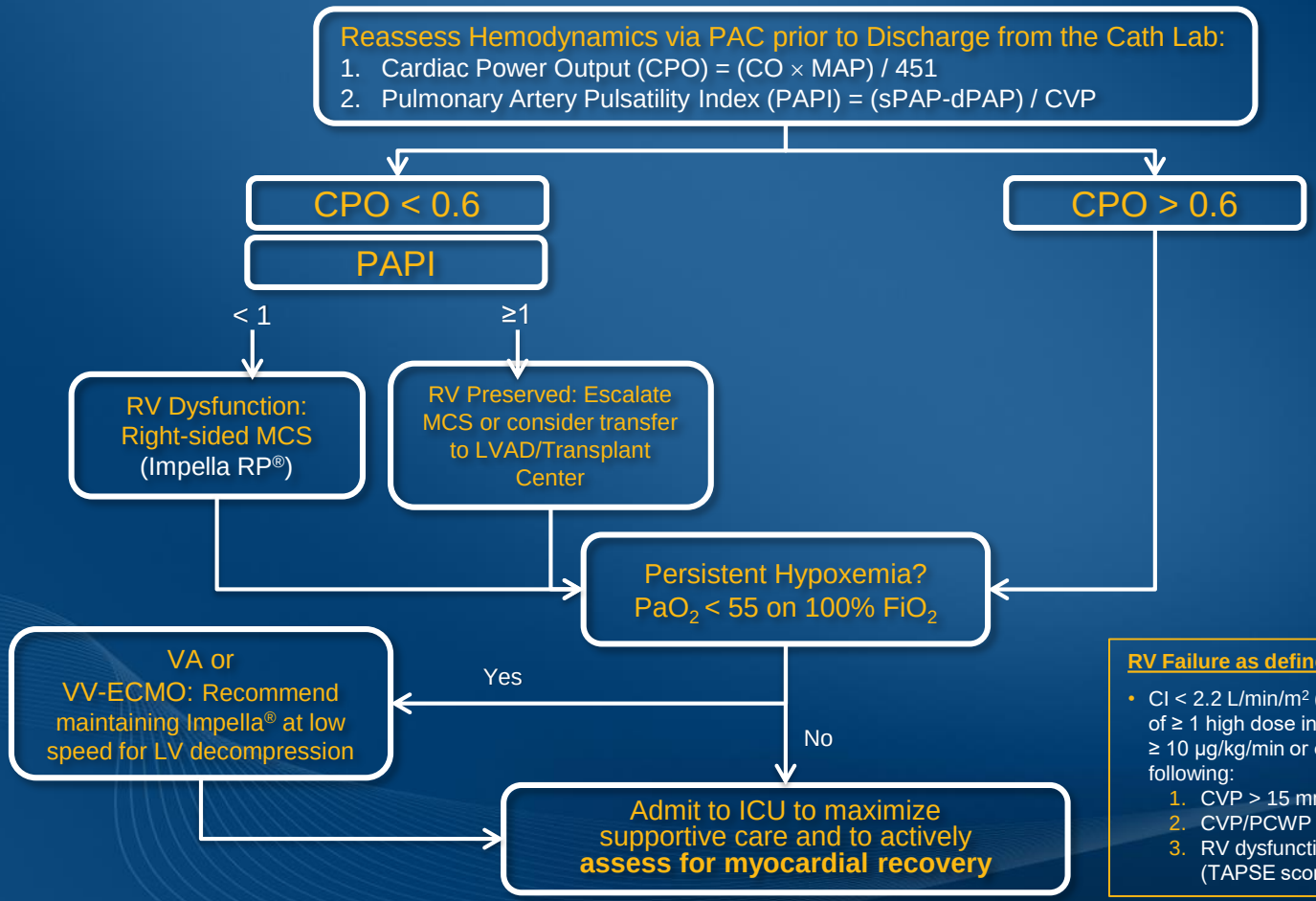
If femoral arterial anatomy suitable and no contraindications, place, or escalate to (if IABP already in place), Impella 2.5 or Impella CP

* If consistent with overall hemodynamic management

PCI:
Coronary angiography and PCI with goal of complete revascularization

Soverow J, Lee MS. J Invasive Cardiol. 2014;26(12):659-667.

Reassess Prior to Discharge From Cath Lab

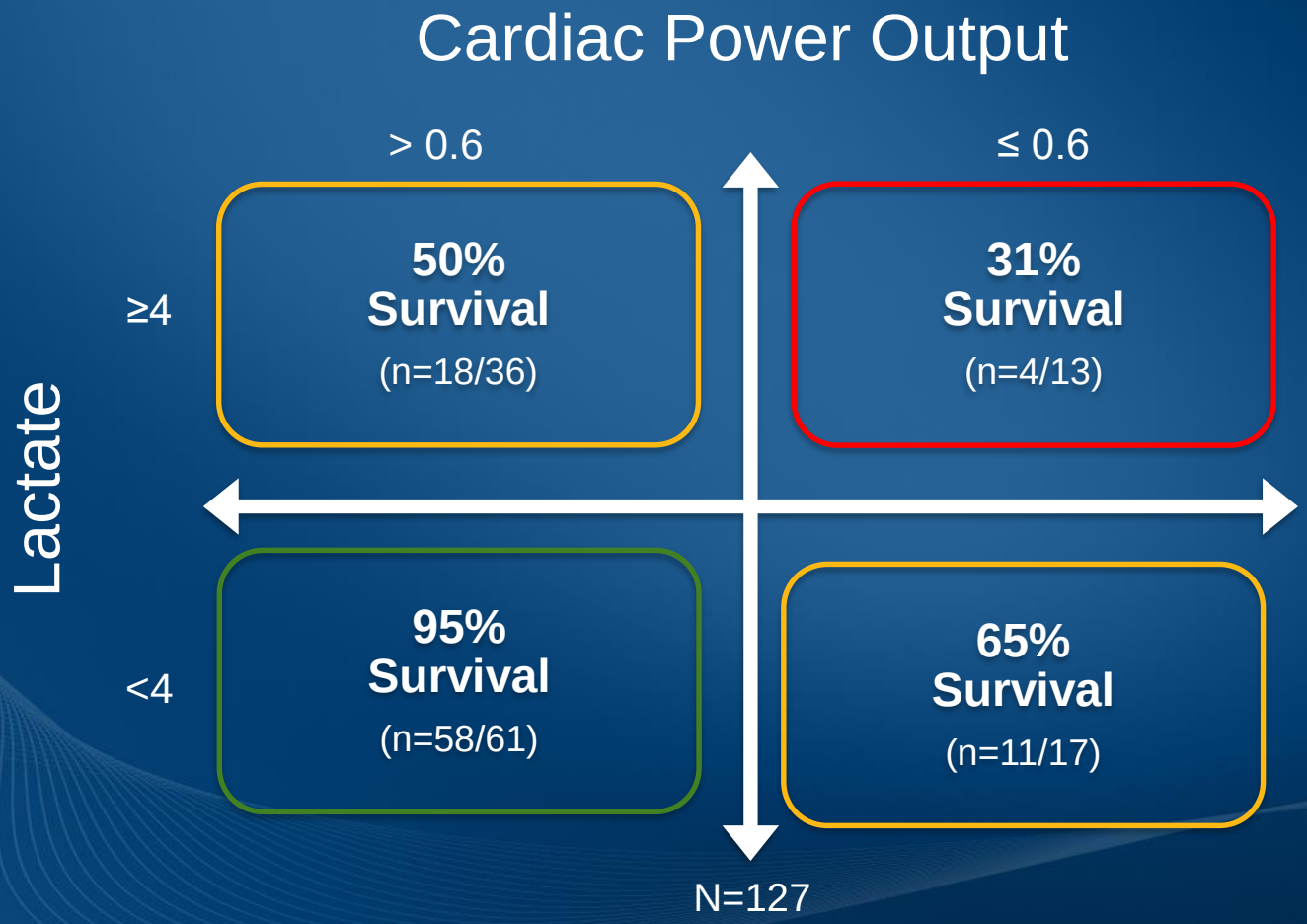


RV Failure as defined by Recover Right[1]:

- CI < 2.2 L/min/m² (despite continuous infusion of ≥ 1 high dose inotrope, ie, da/dobutamine ≥ 10 µg/kg/min or equivalent) and any of the following:
  1. CVP > 15 mmHg, *or*
  2. CVP/PCWP or LAP ratio >0.63, *or*
  3. RV dysfunction on TTE (TAPSE score ≤14 mm)

Anderson MB, et al. J Heart Lung Transplant. 2015;34(12):1549-1560.

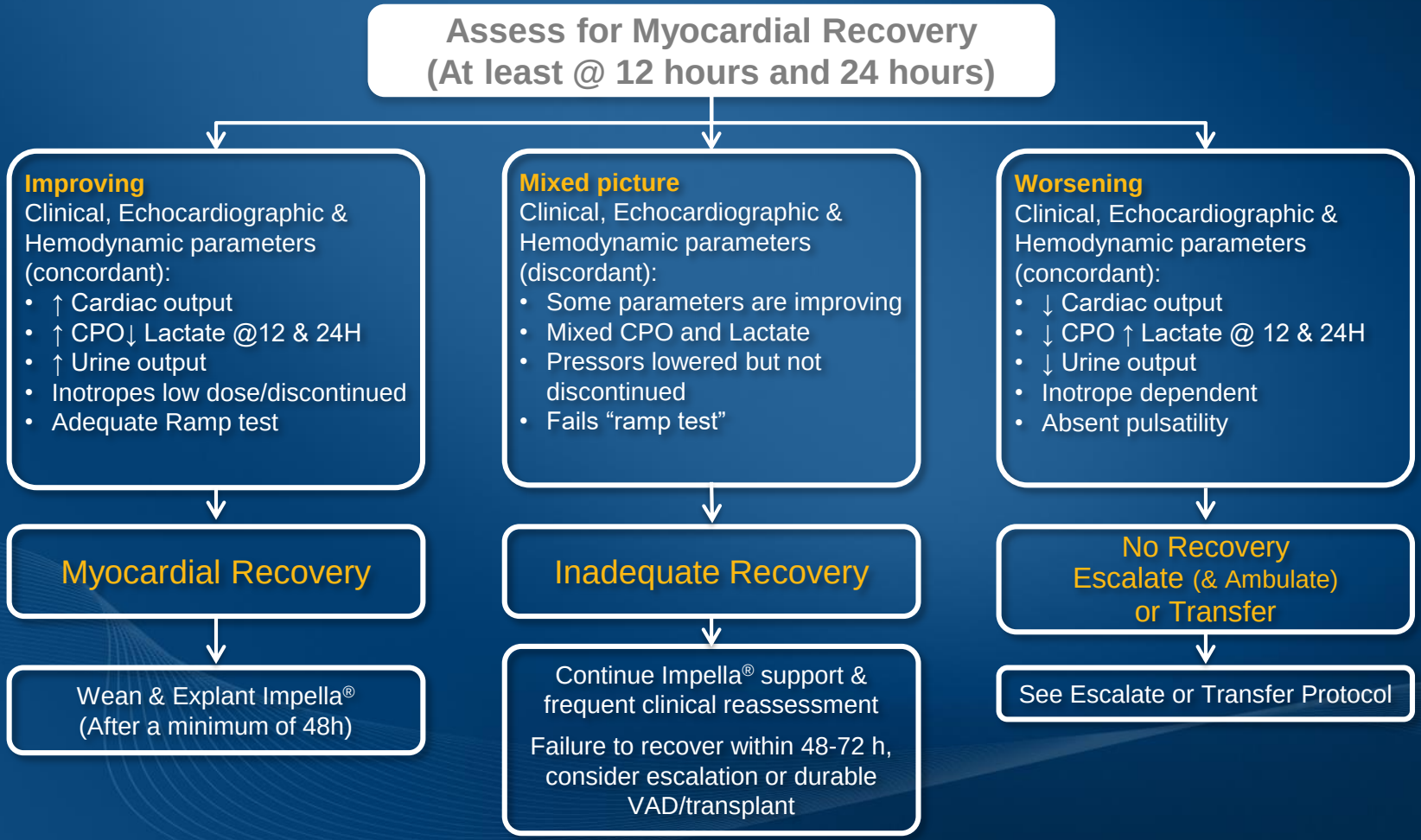
Predictors of Survival at 12-24 Hours on Impella®[1]



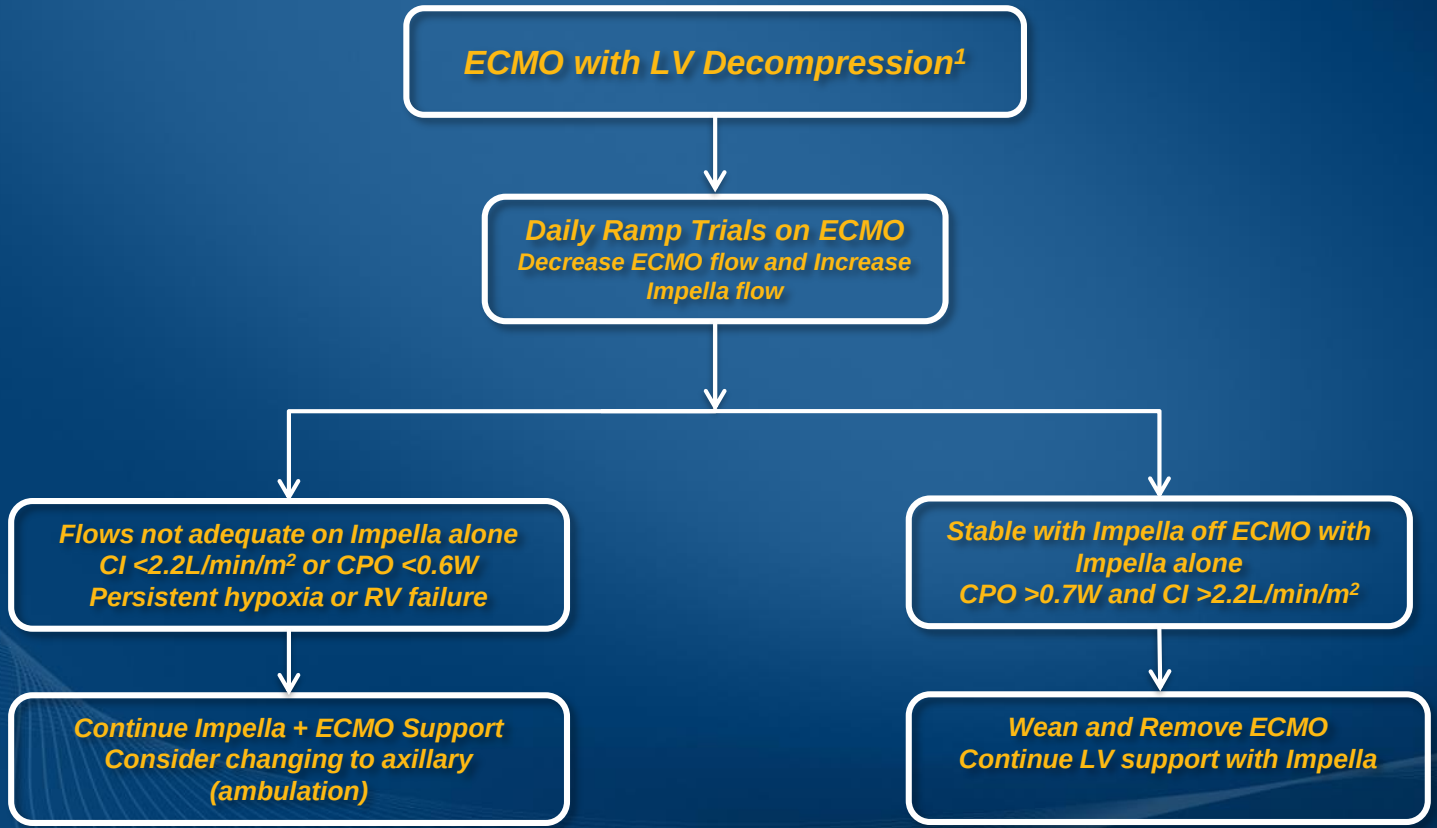
Data from the National Cardiogenic Shock Initiative (NCSI) AMI/CGS Study

1. Presented at SCAI 2019 by William O'Neill, MD

Escalation, Weaning, and Transfer



IMPELLA® WITH ECMO STRATEGY



1. Pappalardo F, Schulte C, Pieri M, et al. Concomitant implantation of Impella® on top of veno-arterial extracorporeal membrane oxygenation may improve survival of patients with cardiogenic shock. Eur J Heart Fail. 2016 Oct 6

2. ELSO Guidelines for Cardiopulmonary Extracorporeal Life Support Extracorporeal Life Support Organization, Version 1.3, Ann Arbor MI, US

No Recovery: Escalate (& Ambulate) or Transfer

RV Failure as defined by Recover Right[1]:

- CI < 2.2 L/min/m² (despite continuous infusion of ≥ 1 high dose inotrope, ie, da/dobutamine ≥ 10 µg/kg/min or equivalent) and any of the following:
  1. CVP > 15 mmHg, *or*
  2. CVP/PCWP or LAP ratio >0.63, *or*
  3. RV dysfunction on TTE (TAPSE score ≤14 mm)

No Recovery
Escalate (& Ambulate) or Transfer
Guidance by RHC Is Critical

CPO remains < 0.6, Lactate non-responder @ 12 and 24 hours

Worsening / not improving clinical, echocardiographic & hemodynamic parameters (concordant):

- ↓ Cardiac output
- ↓ CPO
- ↓ Urine output
- ↑ Lactate
- Inotrope dependent
- Absent pulsatility

PAPI < 1 (RV Failure)

Biventricular support with Impella RP® on the right side (transfer if not available)

PAPI ≥ 1 (acceptable RV function)

Consider left-side escalation with Impella 5.0® (transfer if not available)

CPO = (CO × MAP) / 451.
PAPI = (sPAP – dPAP) / RA.

Anderson MB, et al. J Heart Lung Transplant. 2015;34(12):1549-1560.

IMPELLA® DEVICE INDICATION & SAFETY INFO.

INDICATIONS FOR USE

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® 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, 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 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 cm2 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

In addition to the risks above, there are other **WARNINGS** and **PRECAUTIONS** associated with Impella devices.
Visit ***http://www.abiomed.com/important-safety-information*** to learn more.

RIGHT-SIDE SUPPORT – INDICATION & SAFETY INFO.

INDICATIONS FOR USE

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 RP System

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.

POTENTIAL ADVERSE EVENTS

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 RP.

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