High Risk Percutaneous Coronary Intervention

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Disclosure

I have no financial conflicts of interest to disclose

Objectives

Understand the difference between high risk patients and high risk anatomy as it pertains to supported PCI

Explore algorithms to determine use of MCS during PCI

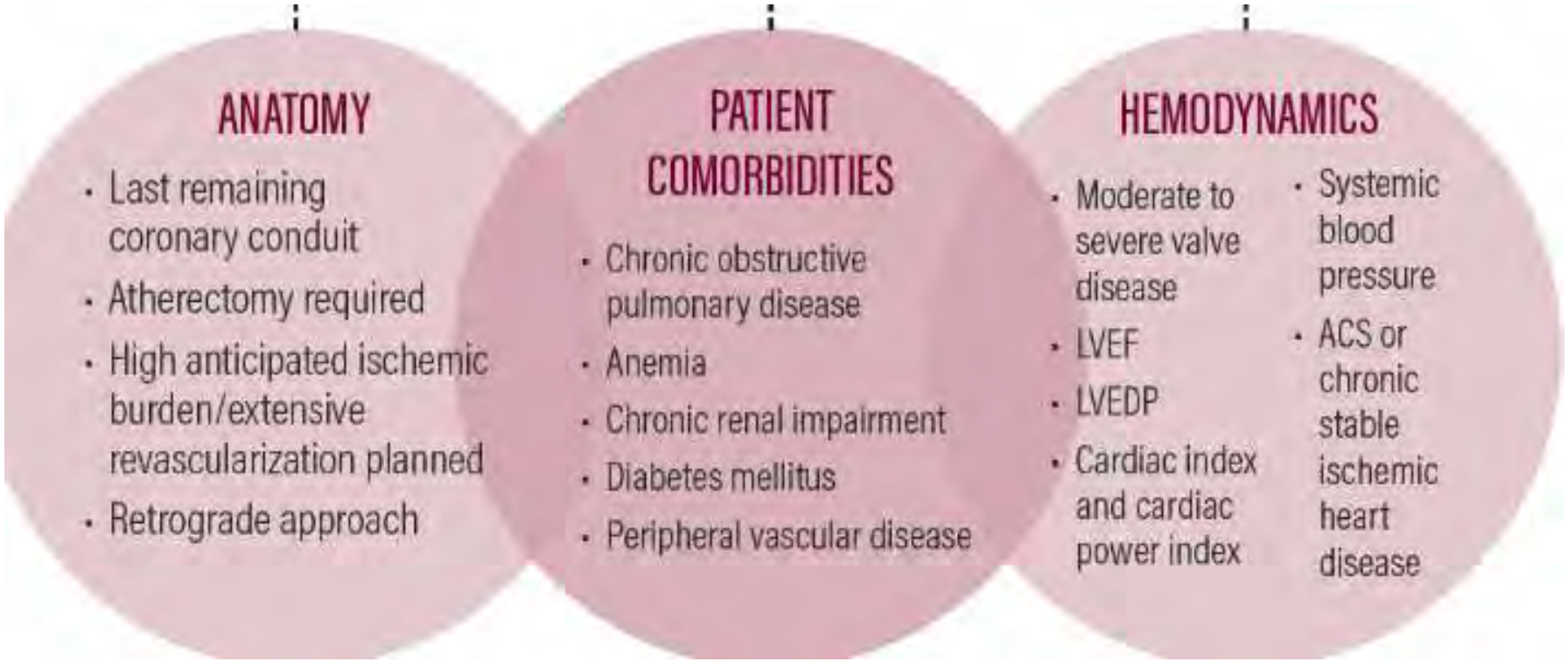
Steps for large bore access and closure

Dealing with an occlusive large bore sheath

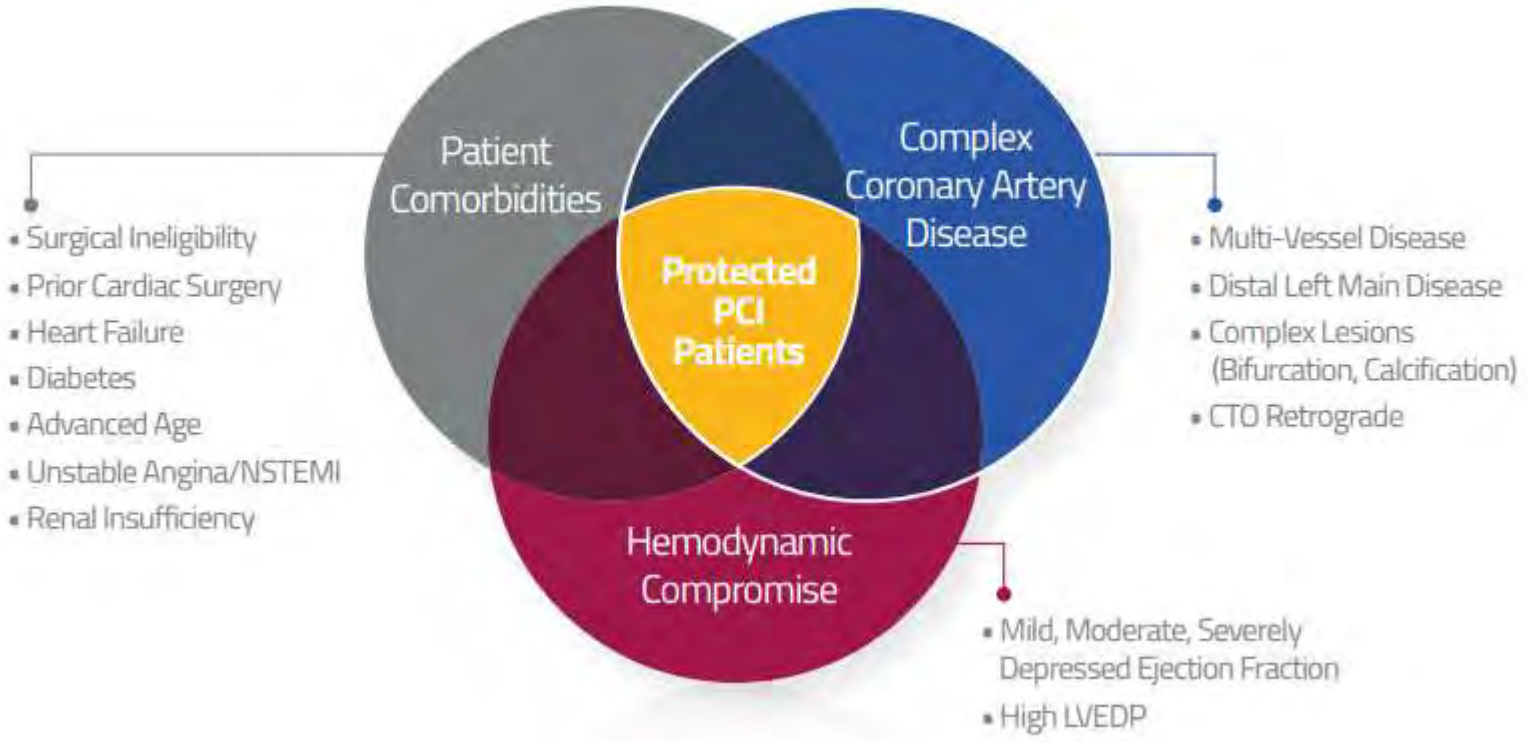
The “Single Access” approach

High Risk Patient vs High Risk Anatomy

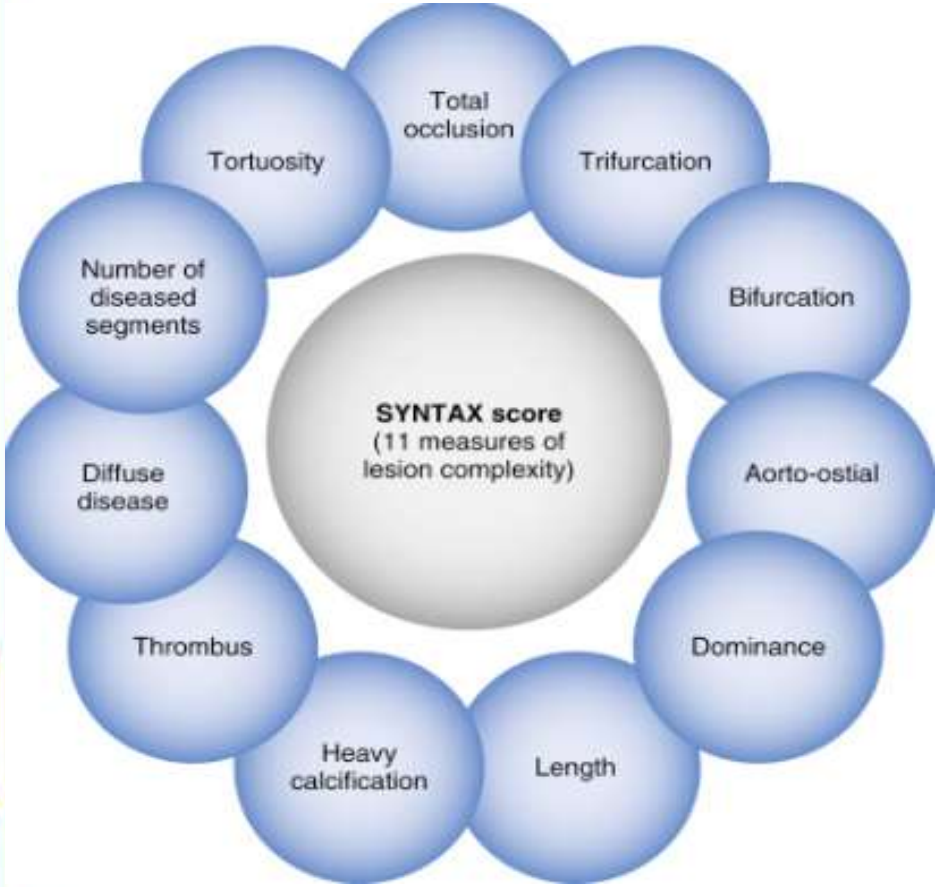
Patient and Lesion Risk Factors

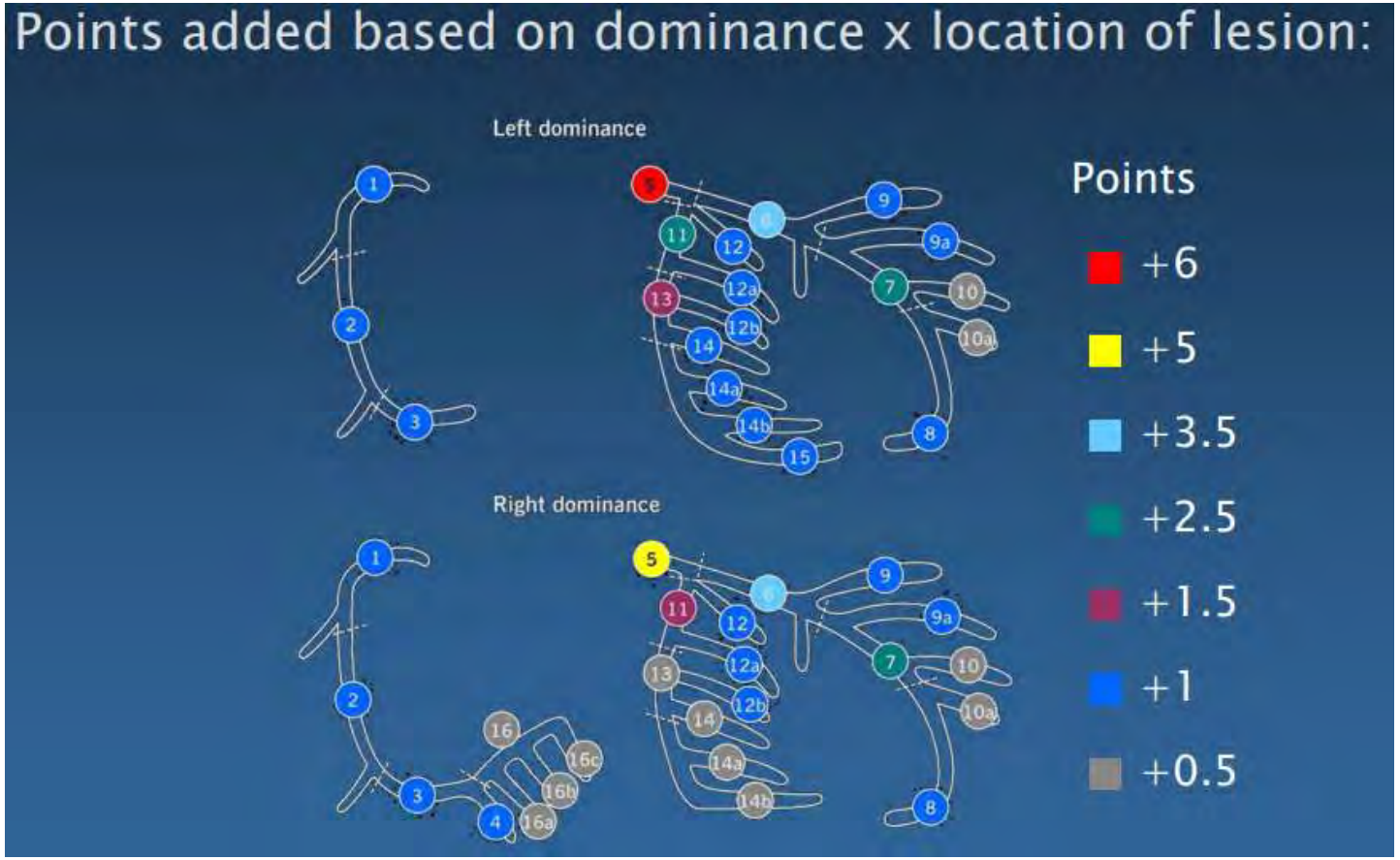


Patient Identification



Anatomical Assessment





Components of a Syntax Score

PCI Risk

SCAI
Society for Cardiovascular Angiography & Interventions

PCI Risk Calculator

Age

Age of patient at the time of care.

Height

Indicate the patient's height in centimeters.

Weight

Indicate the patient's weight in kilograms.

Diabetes Mellitus?

No

Diabetes Therapy?

None

Chronic Lung Disease?

No

PCI Status

Elective

PCI Indication

Other

Back

Continue

Evidence

PROTECT I

Abstract

Objectives: We sought to evaluate the safety and feasibility of the Impella 2.5 system (Abiomed Inc., Danvers, Massachusetts) in patients undergoing high-risk percutaneous coronary intervention (PCI).

Background: The Impella 2.5 is a miniaturized percutaneous cardiac assist device, which provides up to 2.5 l/min forward flow from the left ventricle into the systemic circulation.

Methods: In a prospective, multicenter study, 20 patients underwent high-risk PCI with minimally invasive circulatory support employing the Impella 2.5 system. All patients had poor left ventricular function (ejection fraction <or=35%) and underwent PCI on an unprotected left main coronary artery or last patent coronary conduit. Patients with recent ST-segment elevation myocardial infarction or cardiogenic shock were excluded. The primary safety end point was the incidence of major adverse cardiac events at 30 days. The primary efficacy end point was freedom from hemodynamic compromise during PCI (defined as a decrease in mean arterial pressure below 60 mm Hg for >10 min).

Results: The Impella 2.5 device was implanted successfully in all patients. The mean duration of circulatory support was 1.7 +/- 0.6 h (range: 0.4 to 2.5 h). Mean pump flow during PCI was 2.2 +/- 0.3 l/min. At 30 days, the incidence of major adverse cardiac events was 20% (2 patients had a 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. None of the patients developed hemodynamic compromise during PCI.

Conclusions: The Impella 2.5 system is safe, easy to implant, and provides excellent hemodynamic support during high-risk PCI. (The PROTECT I Trial; NCT00534859).

Simon R Dixon, JACC CV Interventions, 2009

PROTECT II

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

The PROTECT II Study

William W. O'Neill, Neal S. Kleiman, Jeffrey Moses, Jose P.S. Henriques, Simon Dixon, Joseph Massaro, Igor Palacios, Brijeshwar Maini, Suresh Mulukutla, Vladimir Dzavik, Jeffrey Popma, Pamela S. Douglas and Magnus Ohman

Originally published 30 Aug 2012 | https://doi.org/10.1161/CIRCULATIONAHA.112.098194 | Circulation. 2012;126:1717–1727

Other version(s) of this article

Abstract

Background—

Although coronary artery bypass grafting is generally preferred in symptomatic patients with severe, complex multivessel, or left main disease, some patients present with clinical features that make coronary artery bypass grafting clinically unattractive. Percutaneous coronary intervention with hemodynamic support may be feasible for these patients. Currently, there is no systematic comparative evaluation of hemodynamic support devices for this indication.

Methods and Results—

We randomly assigned 452 symptomatic patients with complex 3-vessel disease or unprotected left main coronary artery disease and severely depressed left ventricular function to intra-aortic balloon pump (IABP) (n=226) or Impella 2 (n=226) support during nonemergent high-risk percutaneous coronary intervention. The primary end point was the 30-day incidence of major adverse events. A 90-day follow-up was required, as well, by protocol. Impella 2.5 provided superior hemodynamic support in comparison with IABP, with maximal decrease in cardiac power output from baseline of −0.04±0.24 W in comparison with −0.14±0.27 W for IABP (P=0.001). The primary end point (30-day major adverse events) was not statistically different between groups: 35.1% for Impella 2.5 versus 40.1% for IABP, P=0.227 in the intent-to-treat population and 34.3% versus 42.2%, P=0.092 in the per protocol population. At 90 days, a strong trend toward decreased major adverse events was observed in Impella 2.5–supported patients in comparison with IABP: 40.6% versus 49.3%, P=0.066 in the intent-to-treat population and 40.0% versus 51.0%, P=0.023 in the per protocol population, respectively.

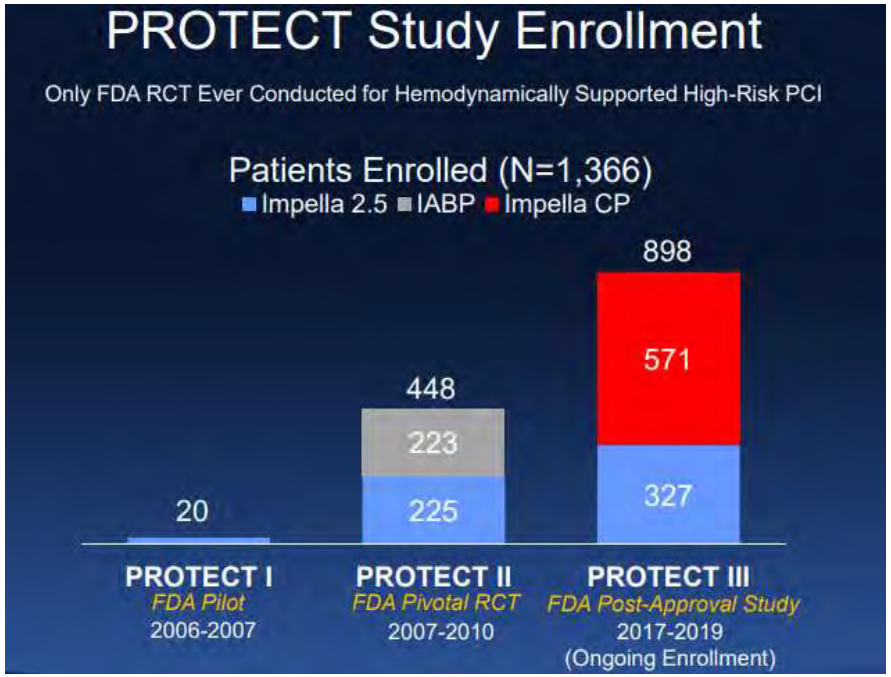
Conclusions—

The 30-day incidence of major adverse events was not different for patients with IABP or Impella 2.5 hemodynamic support. However, trends for improved outcomes were observed for Impella 2.5–supported patients at 90 days.

William W. O'Neill, Circulation, 2012

- Though the primary endpoint of 30-day major adverse event (MAE) rate in the ITT population was narrowly missed and the trial was halted for futility, the pre-specified analysis of 90-day MAE rate in patients treated per protocol with the Impella 2.5 was significantly lower than the rate observed with IABP.
- This lead to FDA approval of Impella for the above indication.

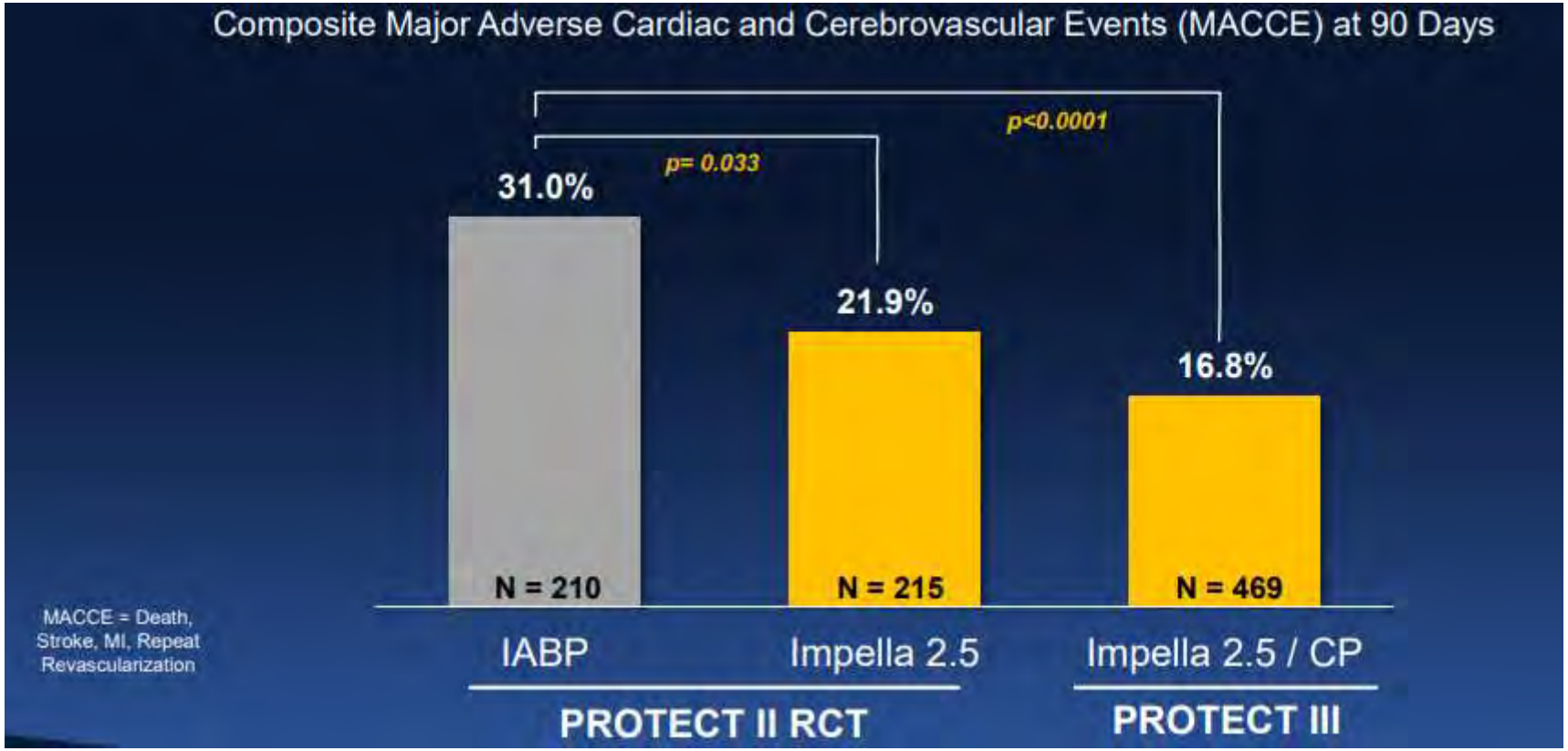
PROTECT III



	PROTECT III		
	All N=898	Impella CP N=571	Impella 2.5 N=327
# Vessels Treated	2.00±0.77	2.00±0.75	2.02±0.80
3 Vessels Treated	29.9%	28.2%	32.7%
LAD	37.7%	37.6%	37.9%
Left Main	15.7%	16.8%	13.5%
LCx	27.7%	27.1%	28.9%
RCA	15.7%	15.3%	16.4%
Pre-PCI TIMI 0/1	14.7%	15.7%	12.5%
Atherectomy Use	43.3%	45.2%	40.0%
# Vessels w/ Atherectomy	2.01±0.75	2.03±0.74	1.96±0.77
Contrast Volume (mL)	204.2±105.6	206.9±105.4	199.4±106.0
Length of Support (hrs)	6.79±21.1	7.78±22.3	4.83±18.2

William W. O'Neill, Mark Anderson, Daniel Burkhoff, Cindy L. Grines, Navin K. Kapur, Alexandra J. Lansky, Salvatore Mannino, James M. McCabe, Khaldoon Alaswad, Ramesh Daggubati, David Wohns, Perwaiz M. Meraj, Duane S. Pinto, Jeffrey J. Popma, Jeffrey W. Moses, Theodore L. Schreiber, E. Magnus Ohman,
Improved outcomes in patients with severely depressed LVEF undergoing percutaneous coronary intervention with contemporary practices,
American Heart Journal,
Volume 248,
2022,
Pages 139-149,

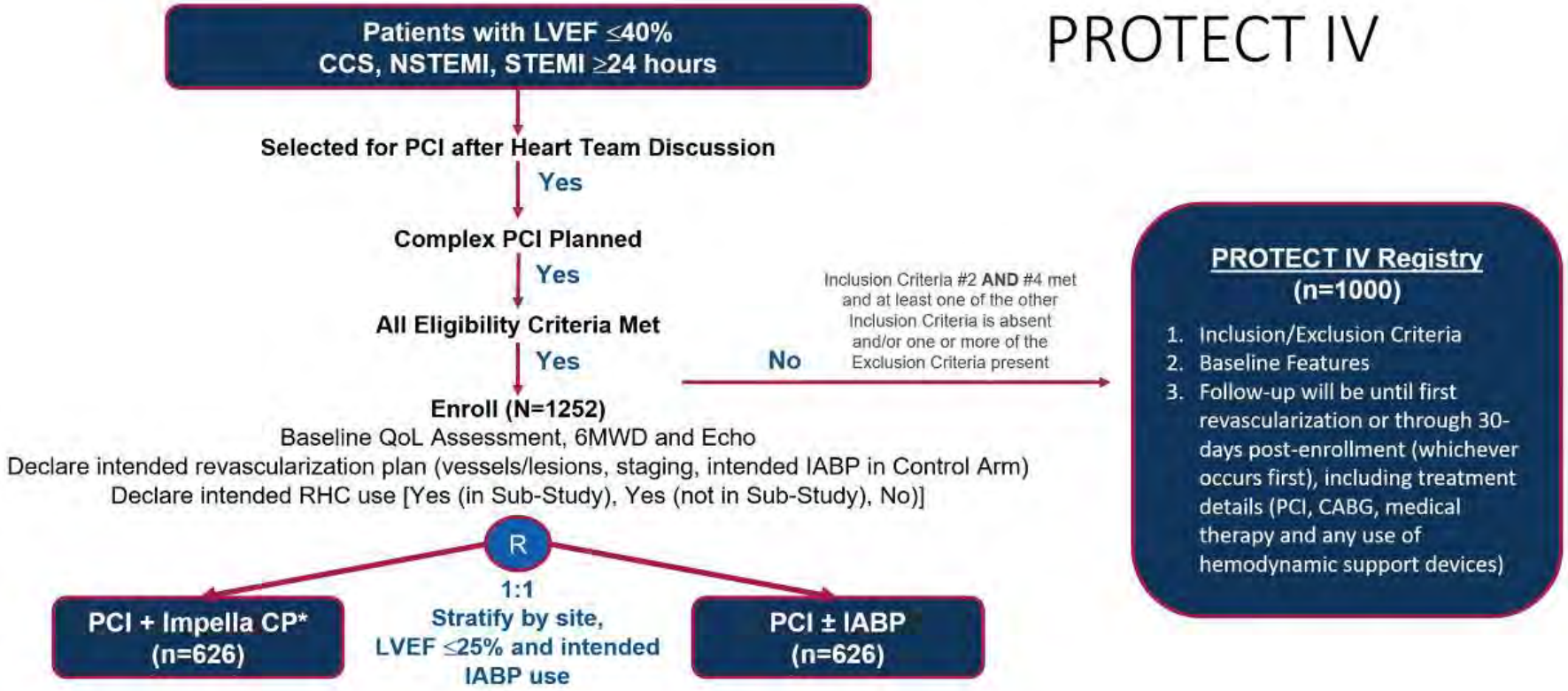
PROTECT III



PROTECT III study demonstrated

- Improved completeness of revascularization
- Less bleeding,
- Improved 90-day clinical outcomes compared to PROTECT II for Impella-supported high-risk percutaneous coronary intervention among patients with severely depressed LVEF.

PROTECT IV



Clinical Follow-Up: 1-month post-discharge and 6-months, 1-year, annually through 3-years post-RND (+sweep visit when last patient enrolled reaches 1-year follow-up post-RND); Echocardiography at 6-months, 1-year and 3-years post-RND; QOL, 6MWD and cost assessment at 30-day post-discharge and 1- and 3-years post-RND

Primary Endpoint: All-cause death, stroke, MI or hospitalization for cardiovascular causes measured through 3-year follow-up, min. 1-year follow-up in all patients

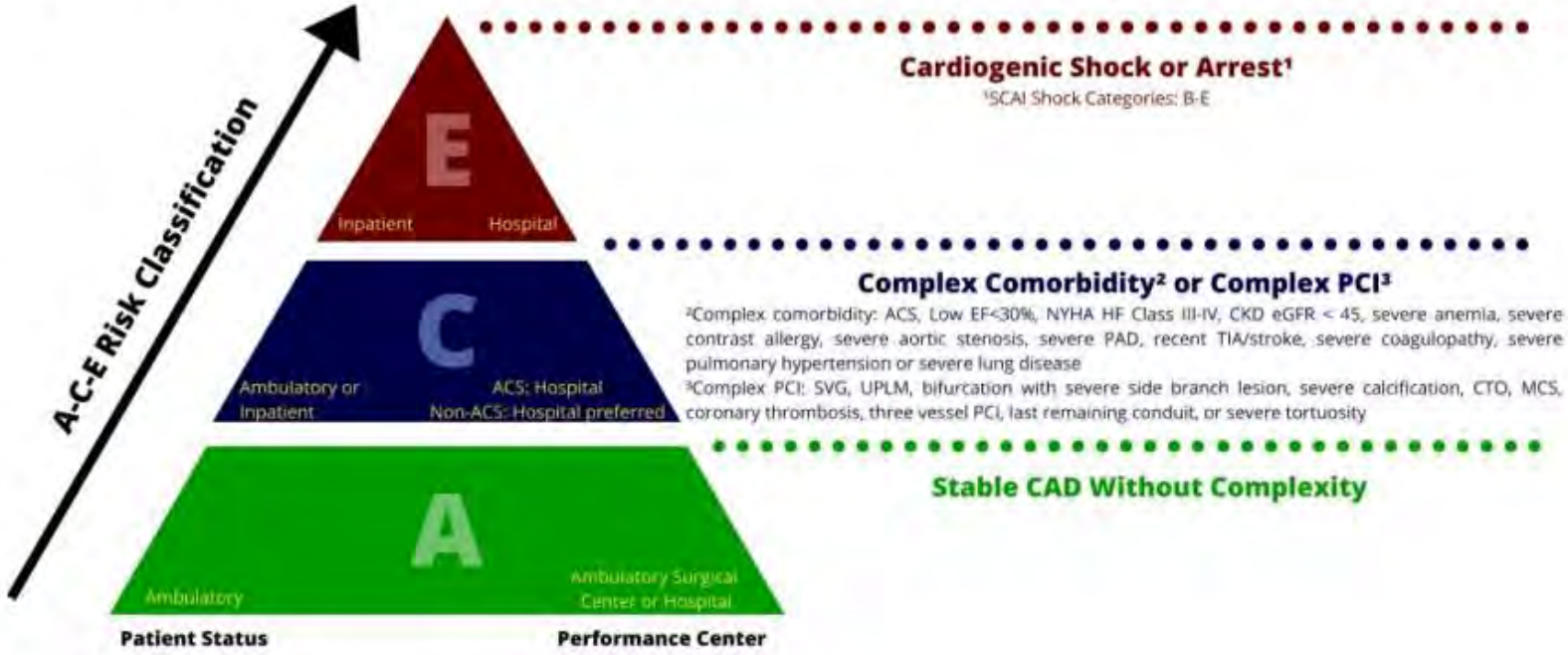
https://clinicaltrials.gov/ct2/show/NCT04763200

When, Who, What & How

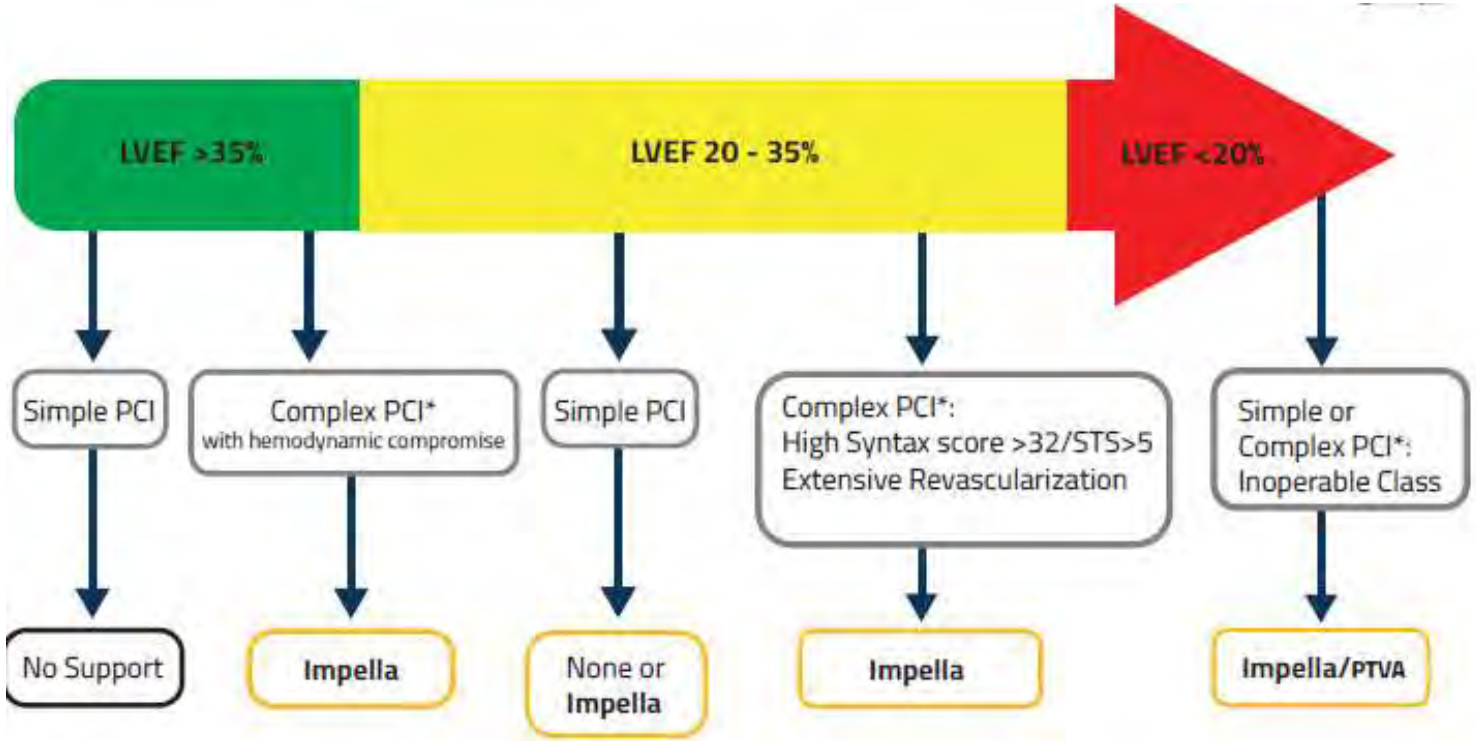
SCAI Consensus on PCI in Complex CAD (2020)

Figure 1. PCI Risk Stratification

SCAI Expert Consensus Opinion Regarding PCI Risk Stratification pyramid integrating PCI complexity, clinical comorbidities, and site where procedure is to be performed. PCI, percutaneous coronary intervention; ACS, acute coronary syndrome, SVG, saphenous vein graft; UPLM, unprotected left main; CTO, chronic total occlusion; MCS, mechanical circulatory support; EF, ejection fraction; HF, heart failure; CKD, chronic kidney disease; PAD peripheral arterial disease, NYHA, New York Heart Association; eGFR, estimated glomerular filtration rate, TIA, transient ischemic attack.



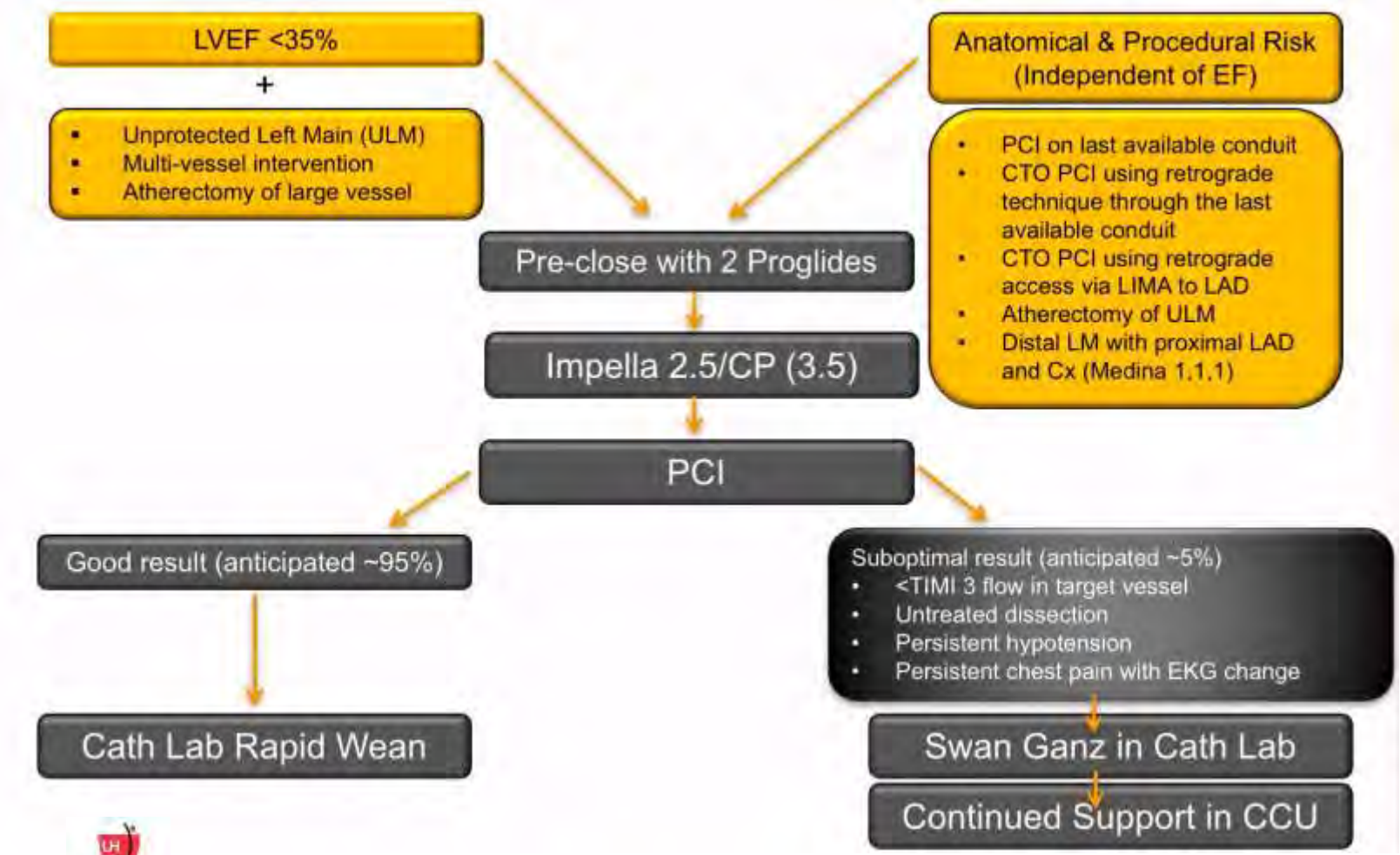
The When and The Who



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

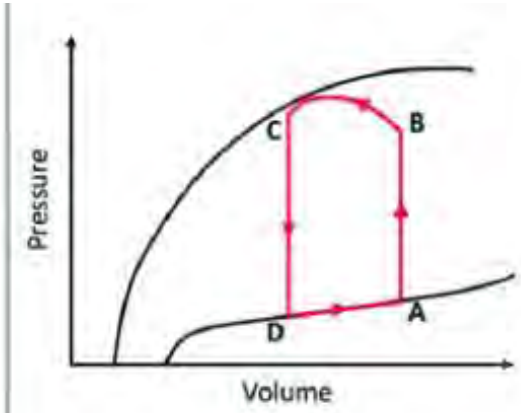
Mount Sinai

The When and The Who



University Hospitals

What

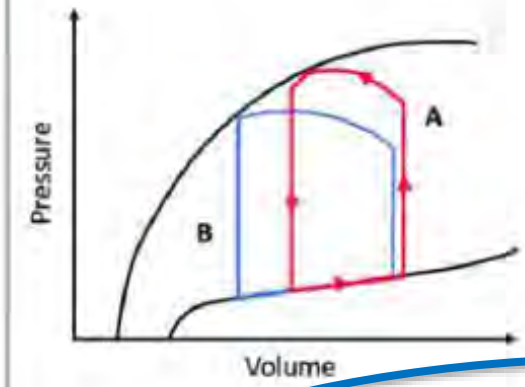


Work = Pressure x Volume

Ventricular "Work" = Area of PV Loop; proportional to O2 demand

Unloading Work = Reducing Area of PV Loop

A = End diastole (mitral valve closure)
B = Aortic valve opening
C = End systole (aortic valve closure)
D = Mitral valve opening

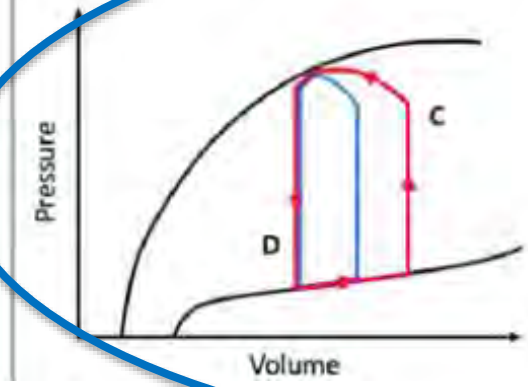


IABP

- Reduces systolic aortic pressure
- Increases stroke volume

Effect on Cardiac Work = Stroke Volume increase offsets pressure reduction

A = Baseline PV loop
B = After IABP



Impella

- Unloads left ventricle
- Reduces diastolic volume

Effect on Cardiac Work = Volume reduction reduces PV loop area and cardiac work

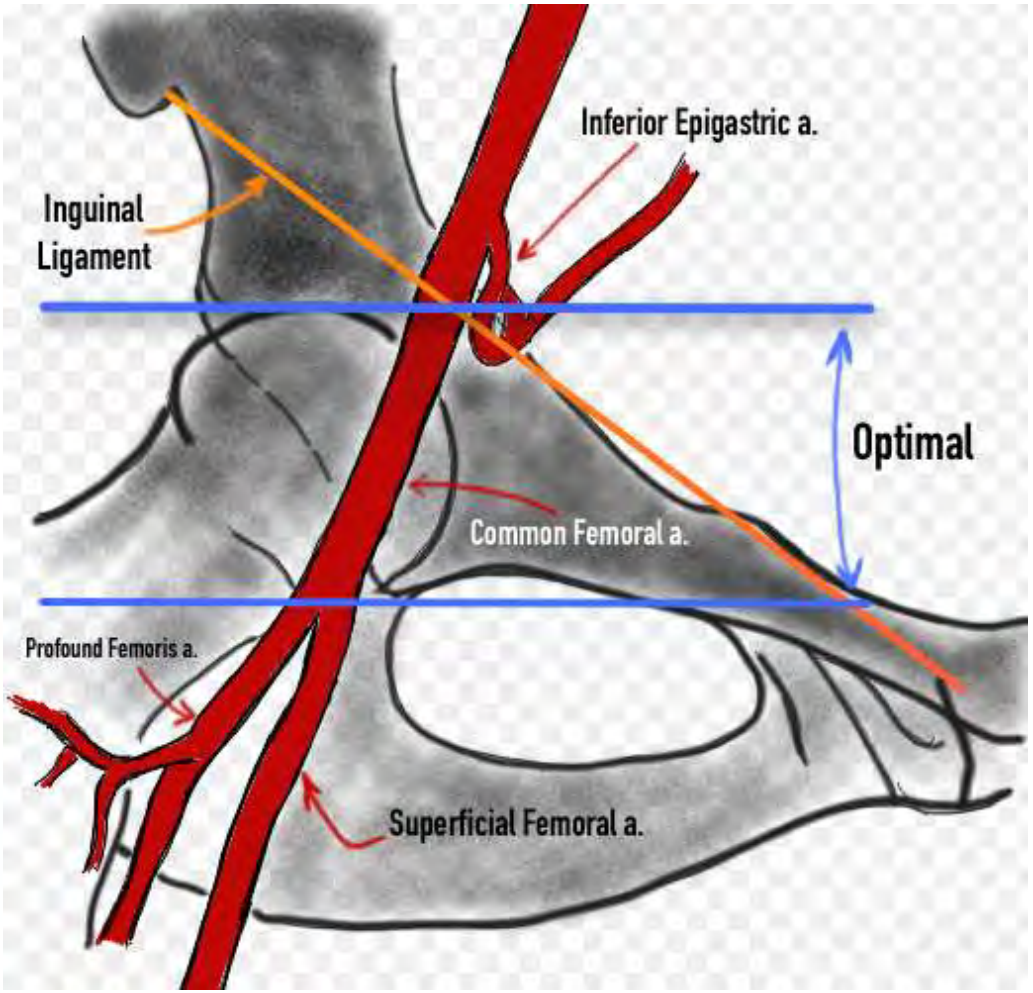
C = Baseline PV loop
D = After Impella

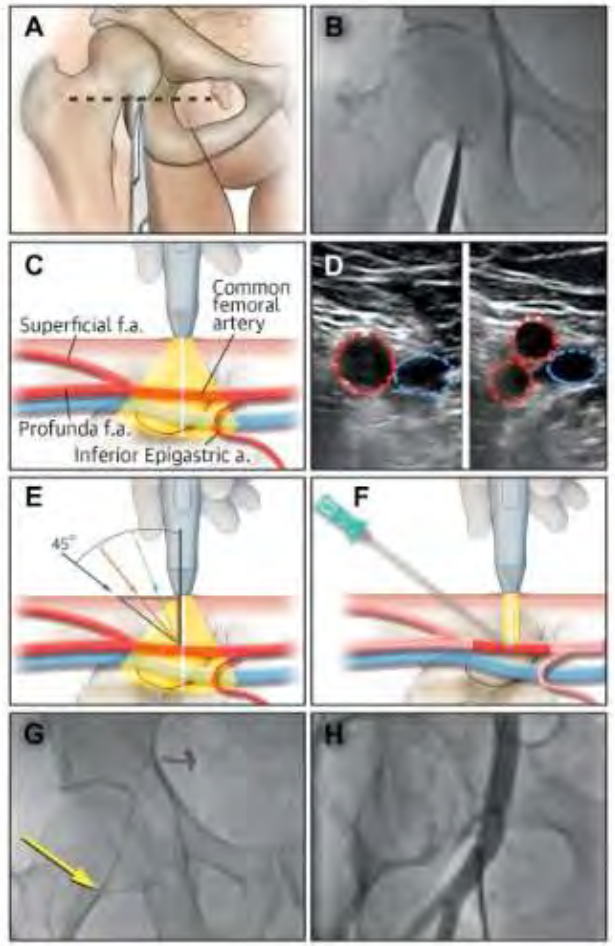
How - Large Bore Access

Routine: Sheath size <8 Fr

Large Bore: Sheath size ≥ 8 Fr (some places consider ≥ 12 Fr)

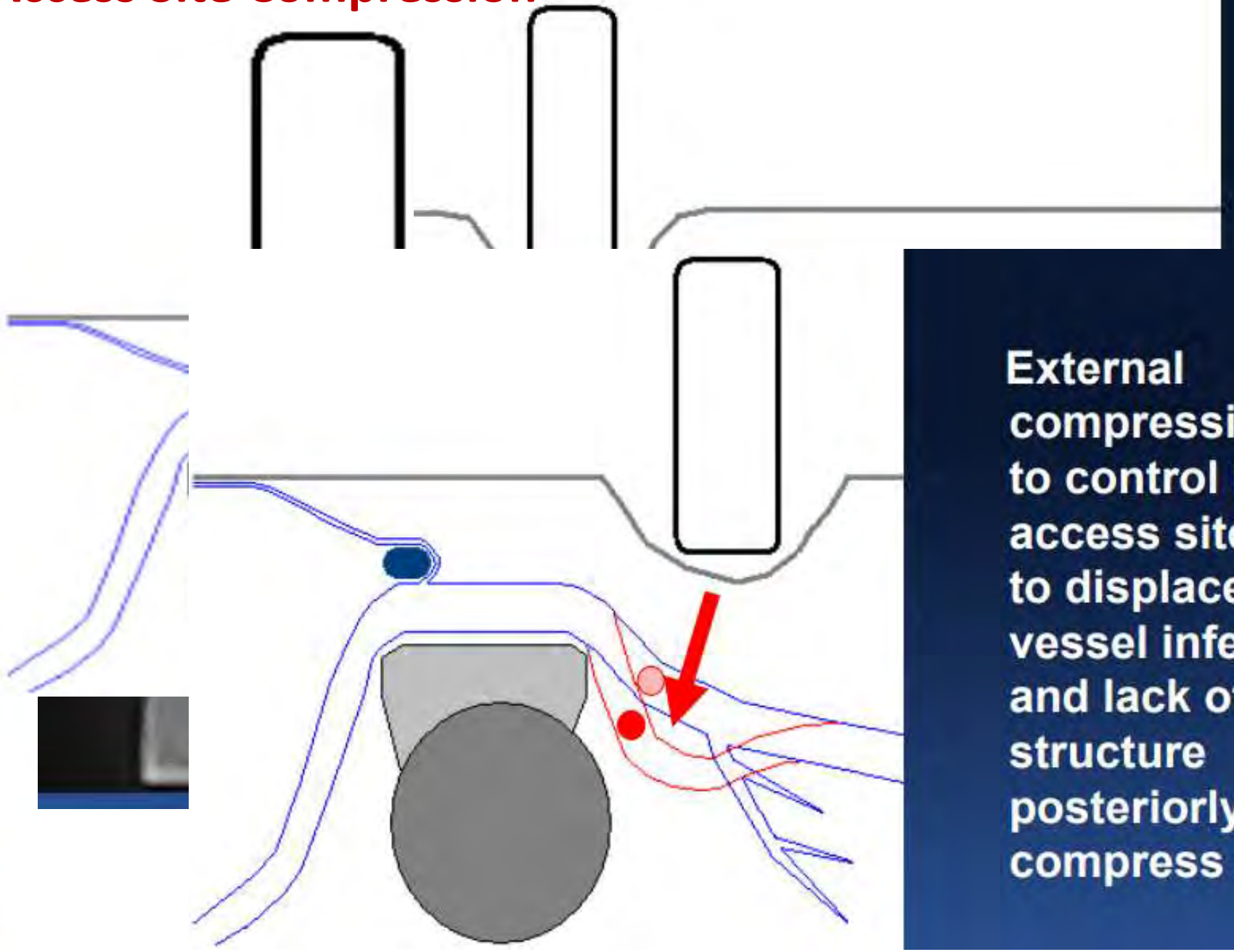
Femoral Artery





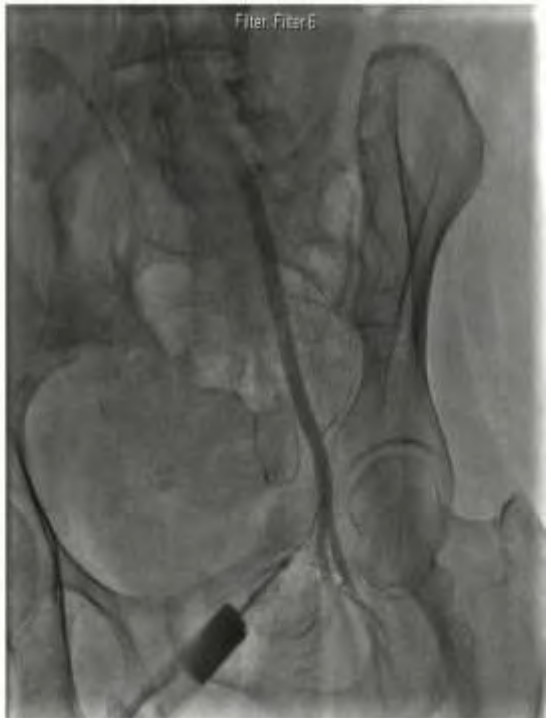
Sandoval, Y. et al. J Am Coll Cardiol Intv. 2017;10(22):2233-41.

Access Site Compression



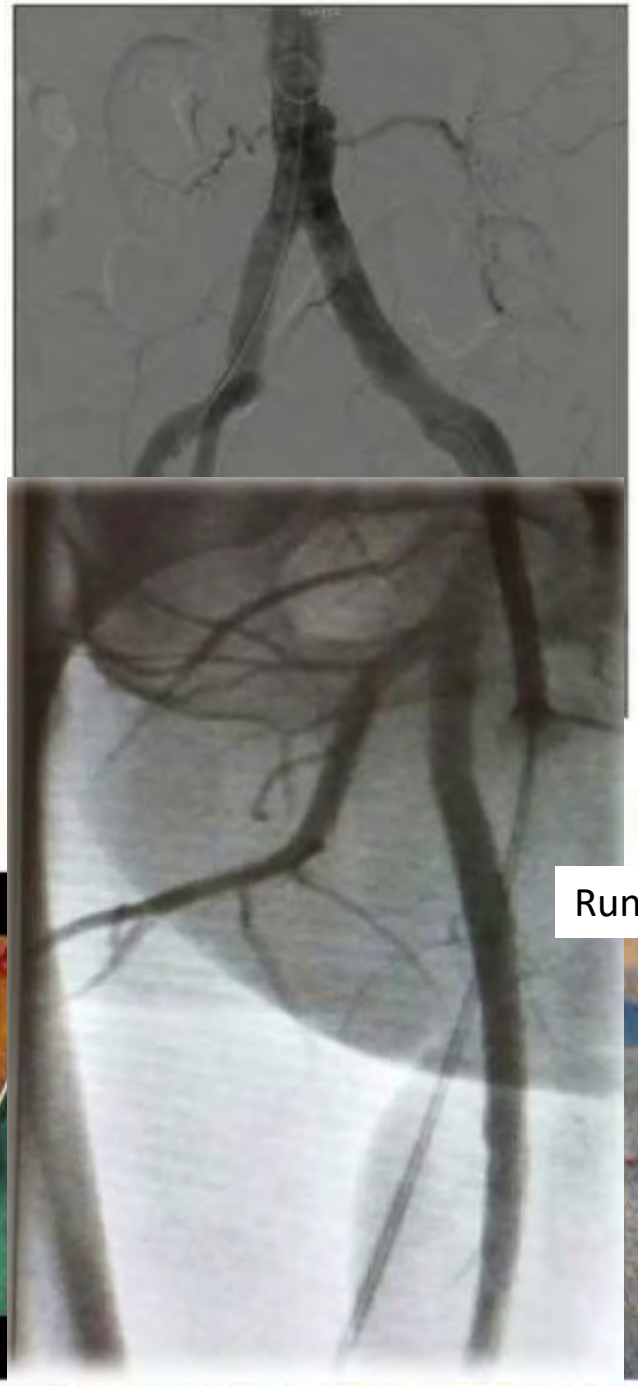
External compression fails to control low access sites due to displacement of vessel inferiorly and lack of bony structure posteriorly to compress against

Steps

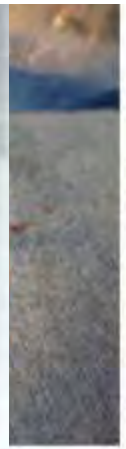


Ipsilateral Femoral Angiography

- Deployment at 10'o clock



Runoff Angiography



- Angiography via micro-puncture sheath or standard 6 F sheath
- Upsize sheath.
- Distal abdominal aortic angiogram with a 5 F IMA or Pigtail

(to evaluate size and tortuosity of external iliac and common femoral arteries on both sides)

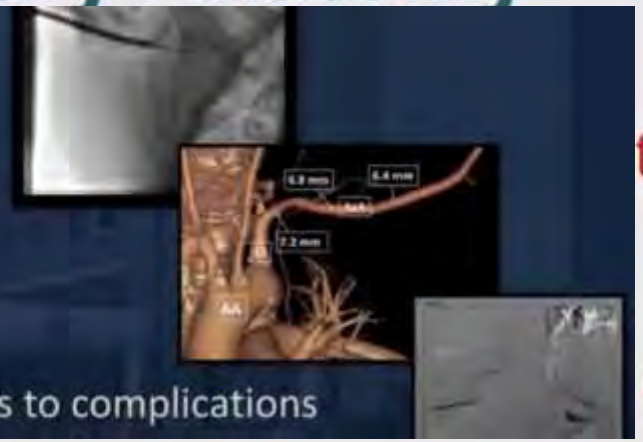
- Use larger and less tortuous side of the two for the large bore sheath (preferably > 5 mm)
- Preclose large bore sheath side prior to insertion of dilators or large bore sheath.
- Use a heavy guidewire (AES, ASS, Lunderquist) to place large bore sheath.
- Take runoff angiogram via large bore sheath if thinking of leaving it in after case.

Axillary Artery Access for MCS

Axillary Anatomy

Pros

- 6mm diameter
- Easy to insert
- Faster insertion time
- Lower bleeding risk
- Ambulation
- Emergent procedure
- Percutaneous solutions to complications

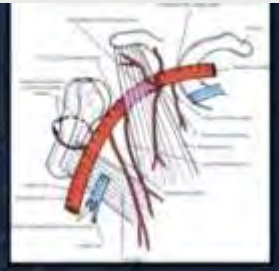


to Axillary

ultrasound

Cons

- Lack of dedicated equipment
- Lack of familiarity of the anatomy for most ICs
- Difficult room set up
- Cannot use Impella 5.0 L without surgical cutdown

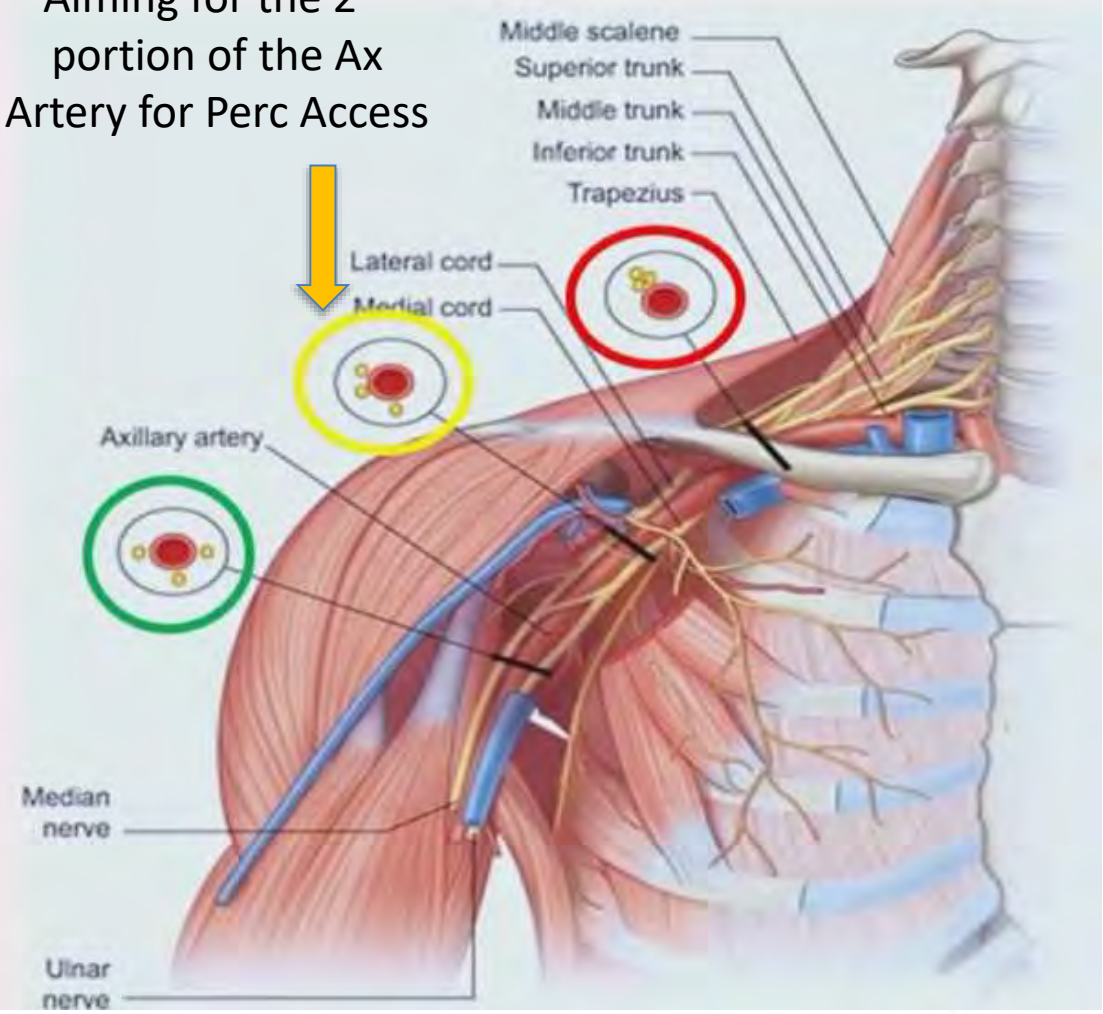


6.0mm-6.2mm

d 2% vs 20%

also be avoided due to increased risk of compartment syndrome

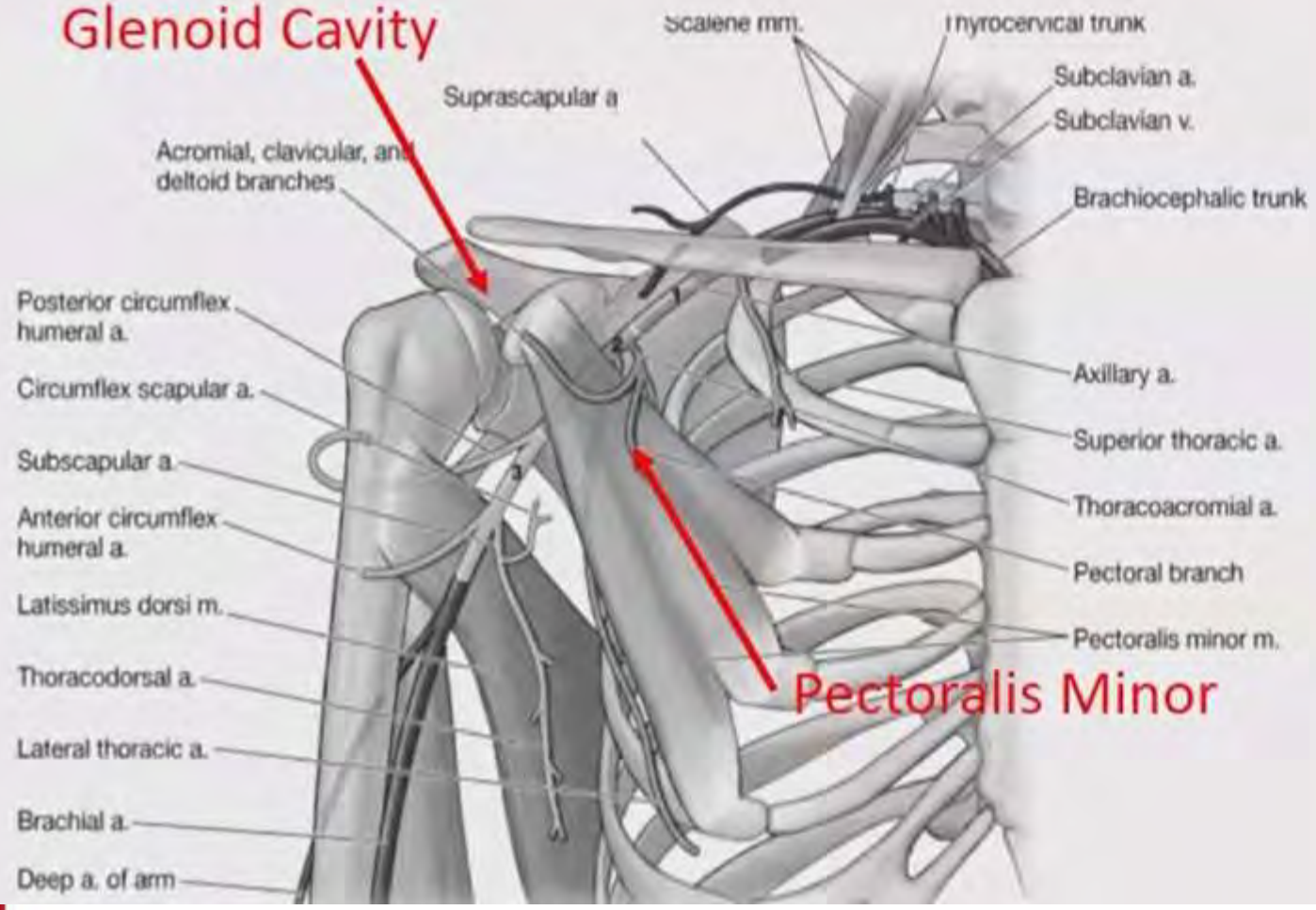
Aiming for the 2nd portion of the Ax Artery for Perc Access



Axillary Artery Access for MCS

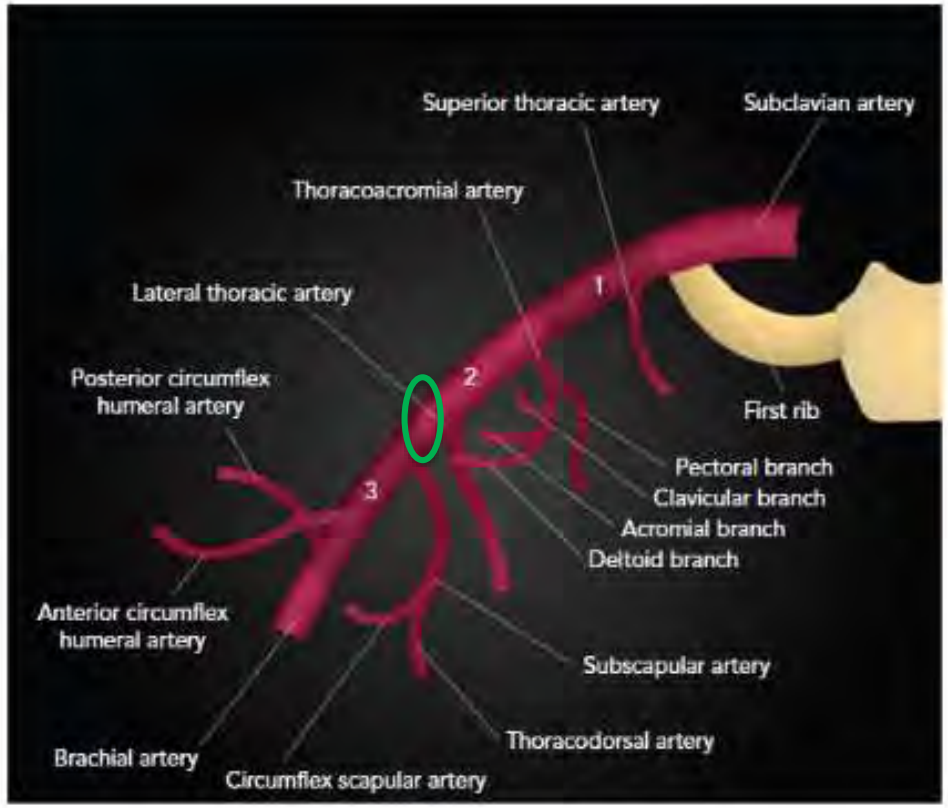
Anatomy

Mark the Head of the Humerus on Fluoro (as you would Femoral Head on TF Access)



Branches from AA segments:

- 1st: Superior thoracic artery
- 2nd: thoracoacromial and lateral thoracic artery
- 3rd: subscapular, anterior humeral circumflex and posterior humeral circumflex.

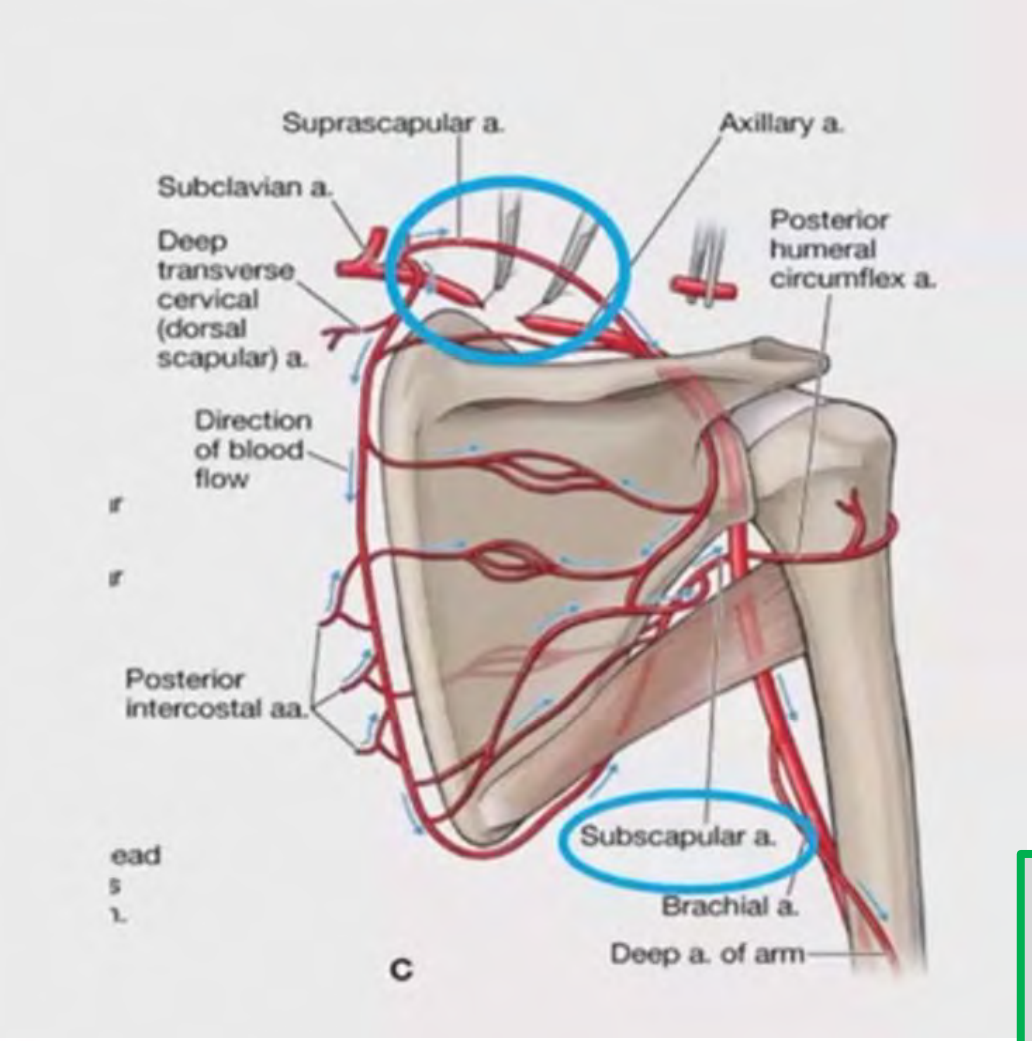


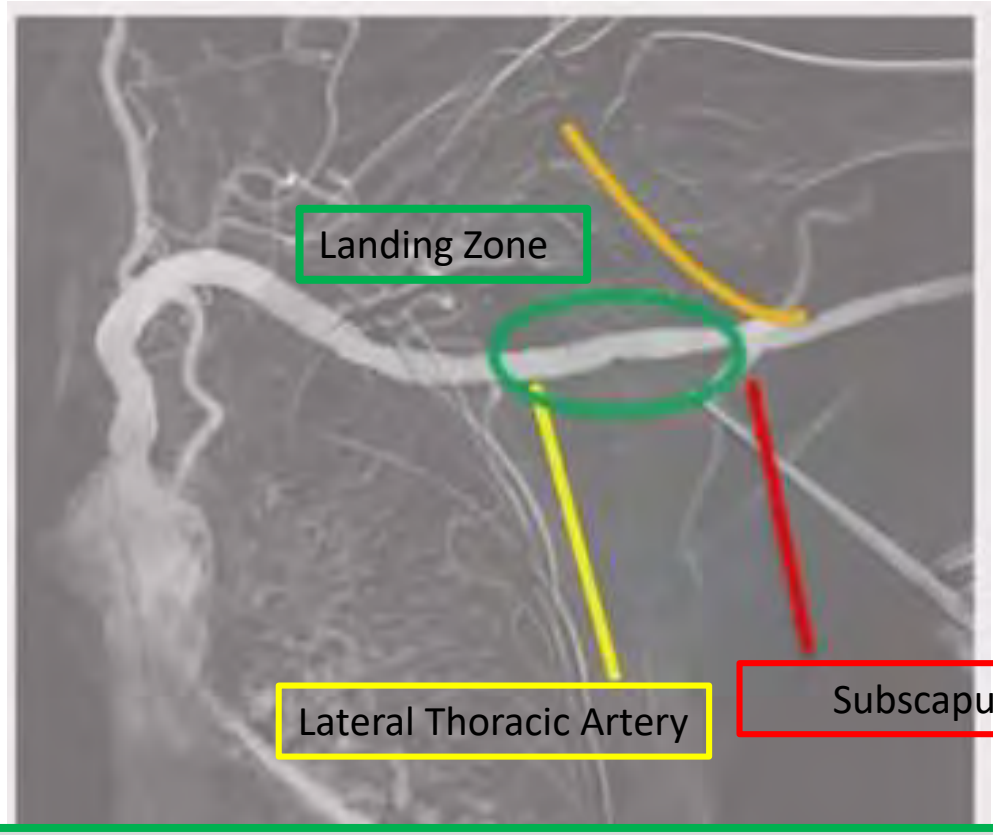
Source: Hapugoda 2019.[17] Reproduced with permission from Radiopaedia.

The branches can be remembered ***"Screw The Lawyers Save A Patient"***

Axillary Artery Access for MCS

Access Should Be Proximal to the Subscapular Artery





- So, you want to be:

In 2nd portion of Axa.
Lateral to Thoracoacromial or Lateral Thoracic artery
Medial to Subscapular or Circumflex Humeral arteries

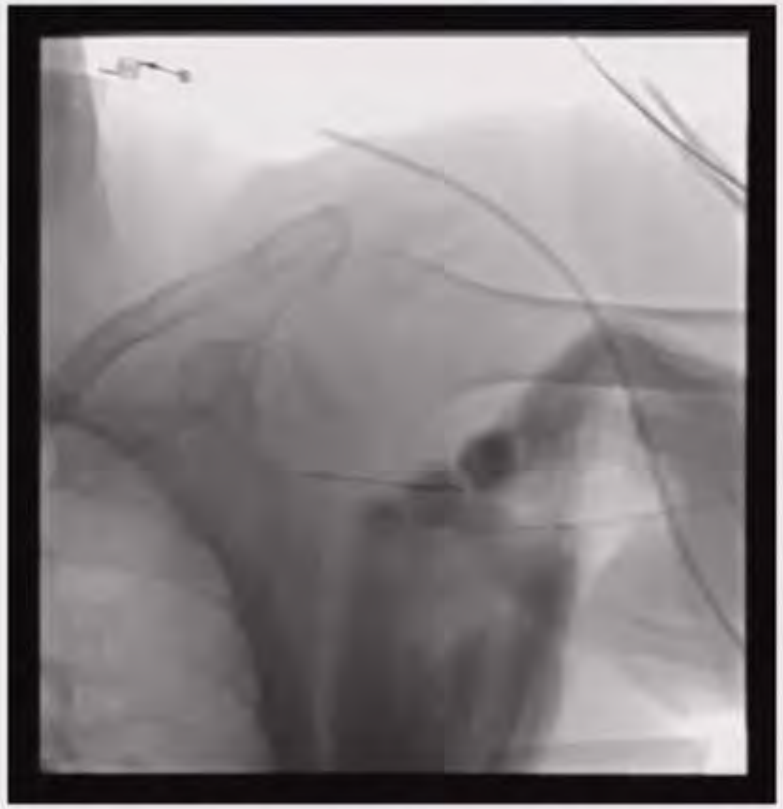
Axillary Artery Access for MCS

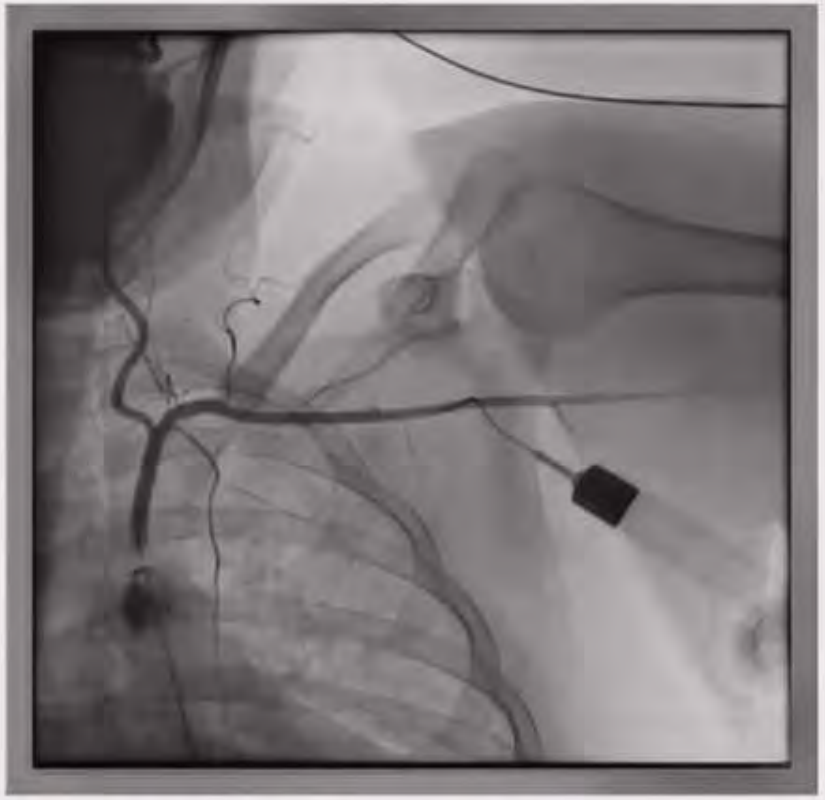
Access Should Be Proximal to the Subscapular Artery

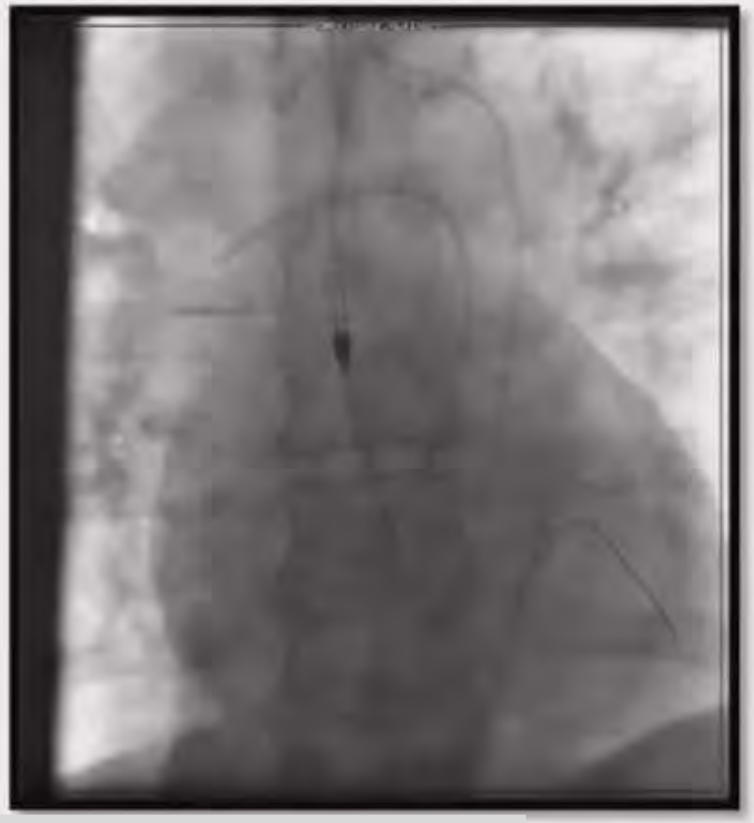
- Access in 1st segment is in the chest and compressibility of Axa is challenging and bleeding into chest is hard to identify.

- Access in the 3rd segment can cause avascular necrosis of humeral head if the circumflex humeral arteries are injured or if a covered stent is needed and placed across the circumflex humeral arteries. Also, injury to brachial plexus is more likely.

Axillary Artery Access for MCS







4. Micropuncture access **SHALLOW AND PARALLEL TO VESSEL** (through pectoralis minor muscle)
5. Verify access point through micropuncture (if suboptimal trajectory or location, okay to restick)
6. Upsize with 8Fr dilator, double Pre-close technique most commonly used

(since access is always through pectoralis minor muscle, after placing 5 or 6 Fr sheath, it's important to dilate tract with 7 F or 8 Fr dilator before Percloses to make room for Perclose device).

Axillary Artery Access for MCS

7. After Percloses place a 9 Fr sheath.
8. Exchange the standard 0.035 inch J wire for a heavy wire (AES, ASS, Lunderquist) via a MP catheter.
9. Remove 9 Fr sheath
10. Dilate tract with dilators in Impella kit over the heavy wire.
11. Place the Impella sheath over the heavy wire.
12. Exchange the heavy wire using an AL-1 catheter (through the Impella sheath).
13. Use the AL-1 catheter to cross the Ao valve using an 0.035 inch GW (J or straight tip).
14. Advance AL-1 into the LV and place a J wire in the LV and remove the AL-1.
15. Place a Pigtail catheter (angled) and remove the 0.035 inch GW.
16. Place the Impella 0.018 inch GW into the LV via the angled Pigtail catheter, remove the latter.
17. Place the Impella MCS device over the 0.018 inch GW.

Device:	Impella 2.5
Peel-away Introducer Sheath:	13 Fr x 13 cm
Insertion:	Femoral

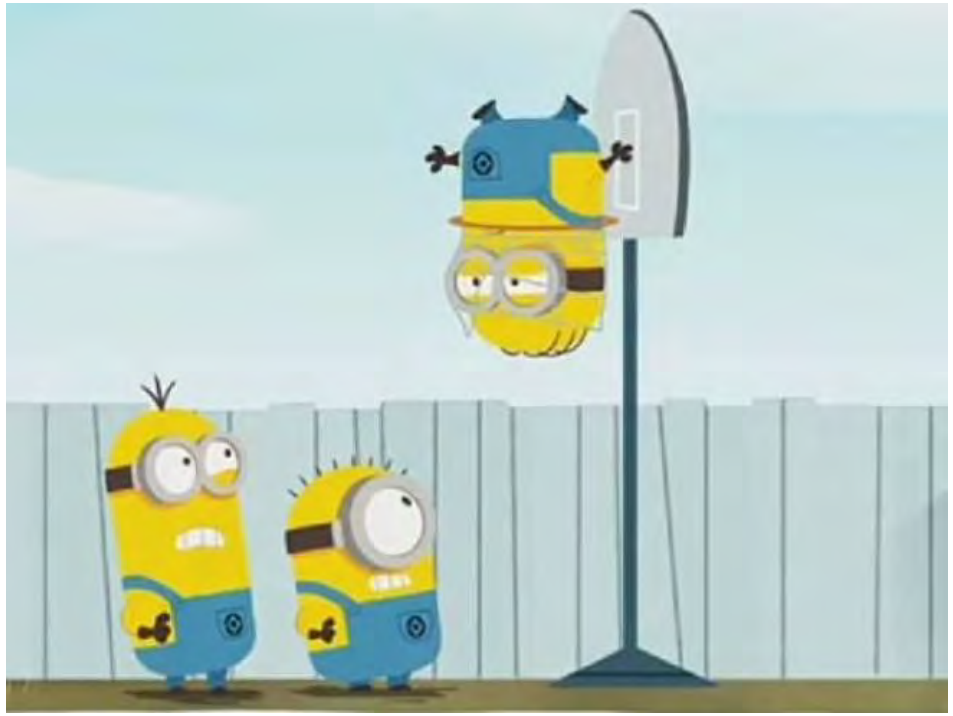
Device:	Impella CP
Peel-away Introducer Sheath:	14 Fr x 13 cm, 14 Fr x 25 cm
Insertion:	Femoral

Device:	Impella 5.0
Peel-away Introducer Sheath:	23 Fr
Insertion:	Femoral

Device:	Impella 2.5/ Impella CP/ Impella 5.0
Peel-away Introducer Sheath:	23 Fr x 6 cm
Insertion:	Axillary

Device:	Impella RP
Peel-away Introducer Sheath:	23 Fr
Insertion:	Femoral

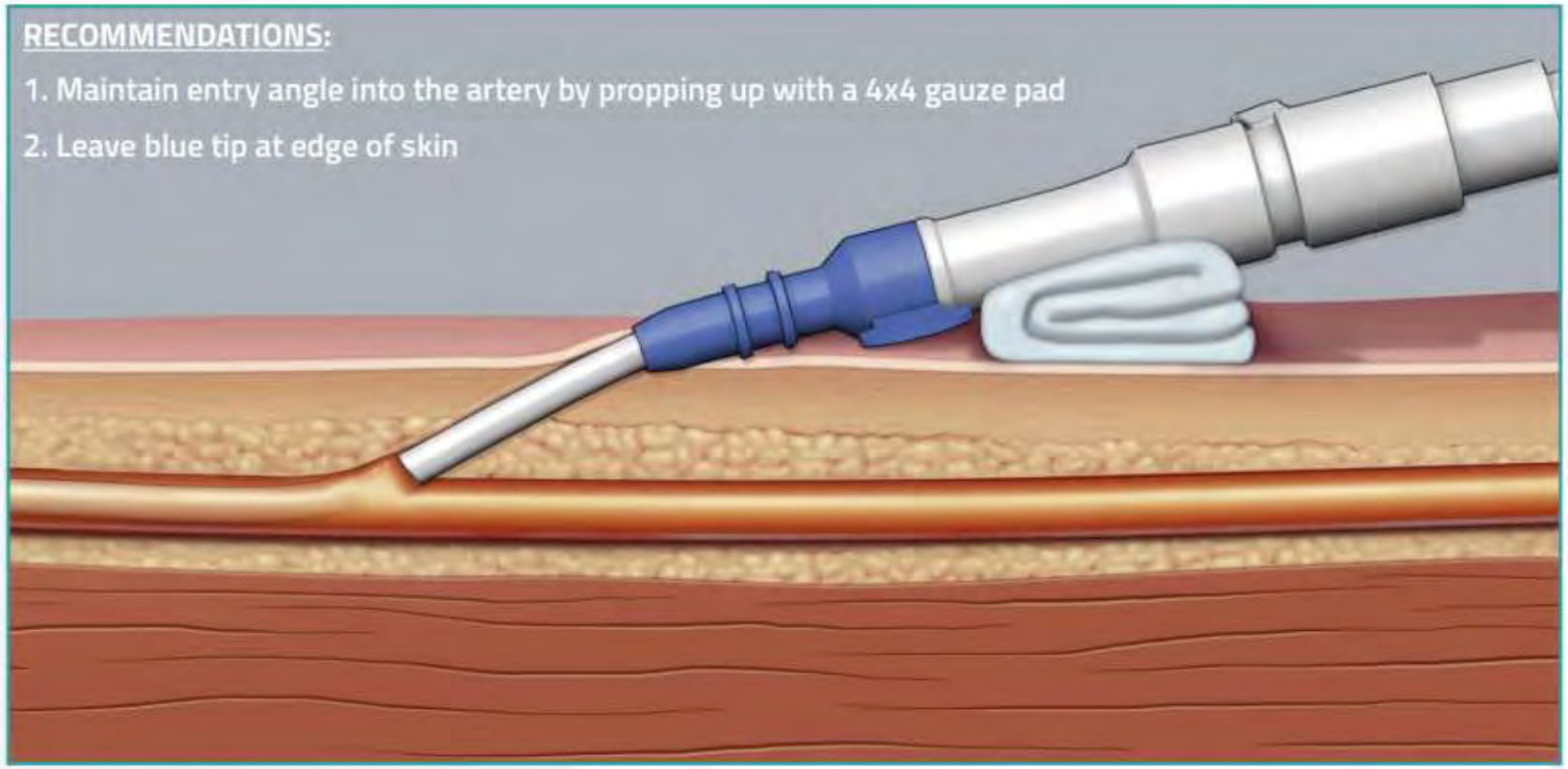
Occlusive Sheath



Steps to Deal with an Occlusive Sheath

- Peel away sheath removal and advancement of repositioning / reaccess sheath.
- Fem-fem bypass techniques

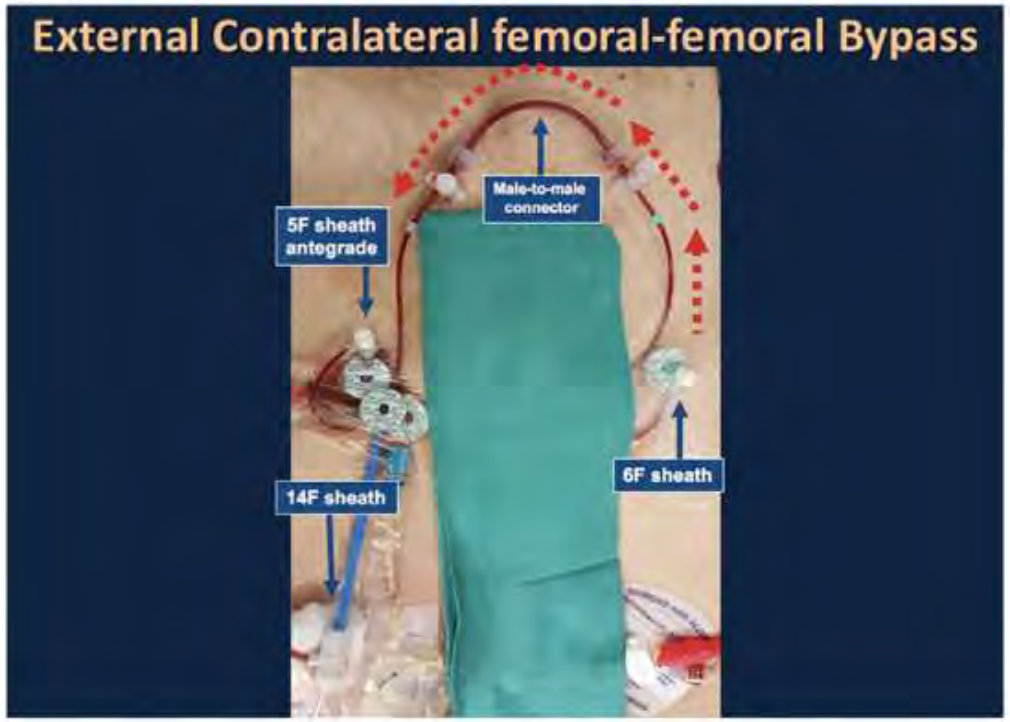
Reaccess Sheath



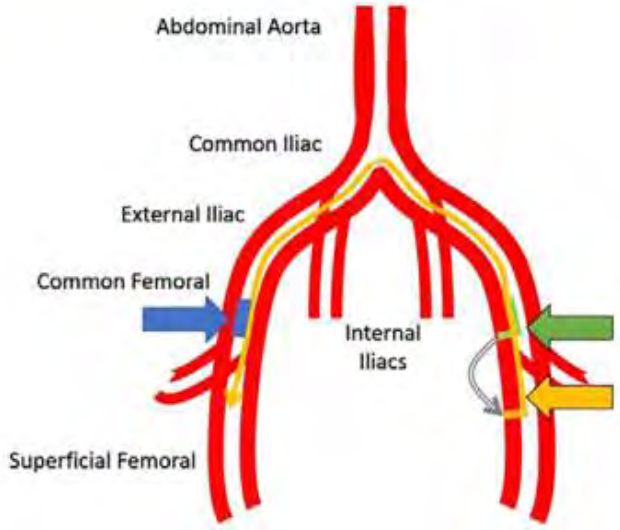
Peel away sheath: 14 Fr ID
Reaccess sheath: 13 Fr OD (so more like a guide catheter)
Replace a sheath in place of the reaccess sheath: 11 or 12 Fr sheath are size options

Fem-Fem Bypass (External)

(A)



(B)



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VASCULAR ACCESS

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Access and closure management of large bore femoral arterial access

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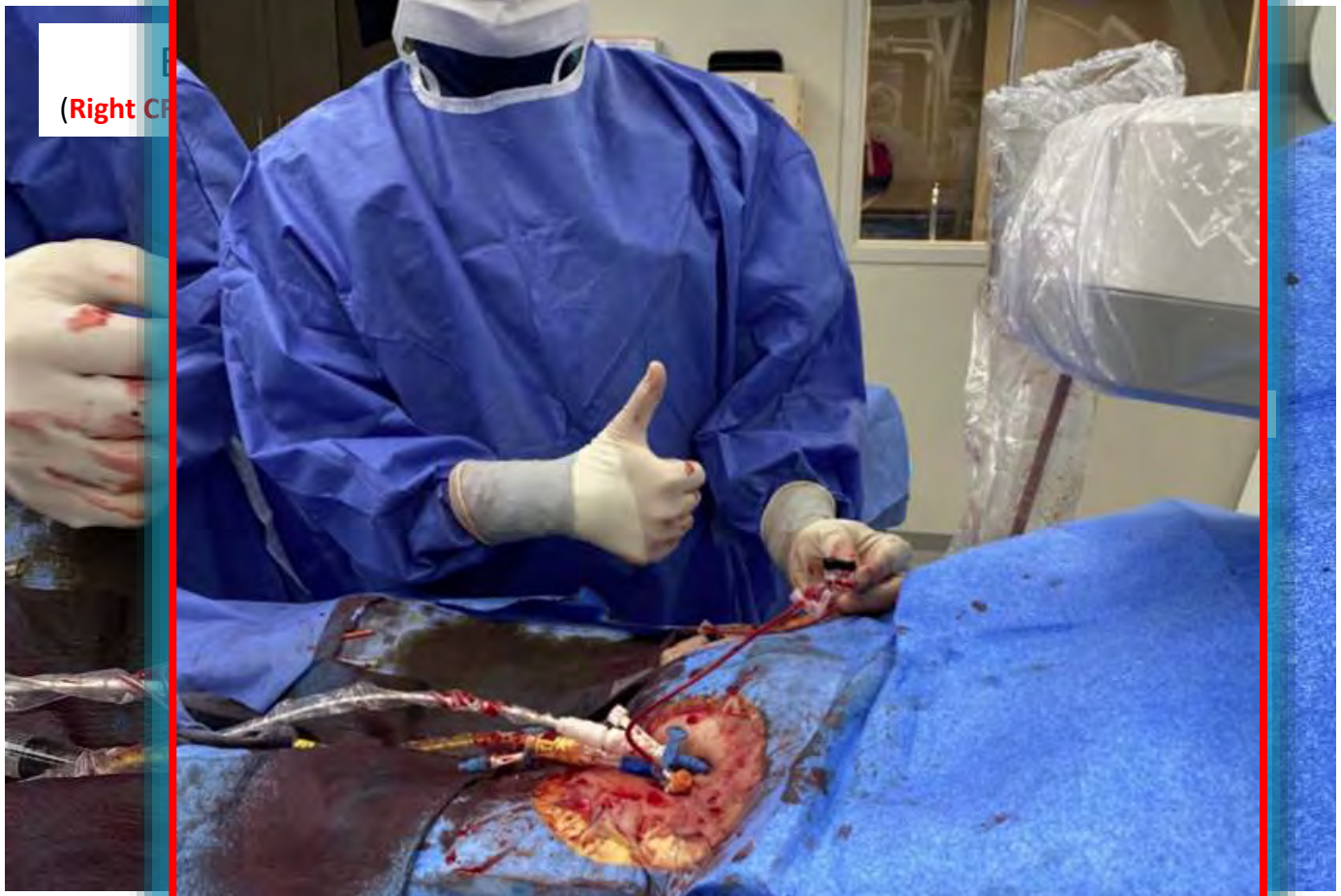
(Right CF



Single Access

Use of the Impella CP® Introducer with the Single-Access Approach for Interventional Procedures

What's New

Best Practices: Abiomed has completed testing, which has shown its Impella CP Introducer is compatible with the single-access approach. Specifically, tests were completed to qualify the 7 F x 45 cm Terumo Pinnacle® Destination® Guiding sheath with 35 cm of hydrophilic coating. During the tests, it was noted that some resistance may be experienced when passing 7 F sheaths through the puncture, and manipulation of some interventional catheters (within the 7 F sheath) may be restricted. Hydrophilic coated sheaths significantly reduce the resistance experienced, and, therefore, are recommended when using a 7 F sheath. Both coated and uncoated 6 F sheaths are compatible with the single-access approach. Use of longer additional sheaths will result in less potential for interaction with the 9 F catheter shaft (when later manipulating interventional catheters). Once the additional sheath is inserted, the 9 F catheter shaft is fixed. In addition, when initially inserting the additional sheath, it is important to fix the 9 F catheter shaft to avoid antegrade migration of the Impella pump within the left ventricle. At the conclusion of the procedure, the additional sheath can be removed, and the Impella CP pump and the Impella CP Introducer can be removed using standard techniques.

is not required to place sheaths up to 7 F. The Impella CP Introducer's instructions for use, including details on use of the single-access approach can be found here.

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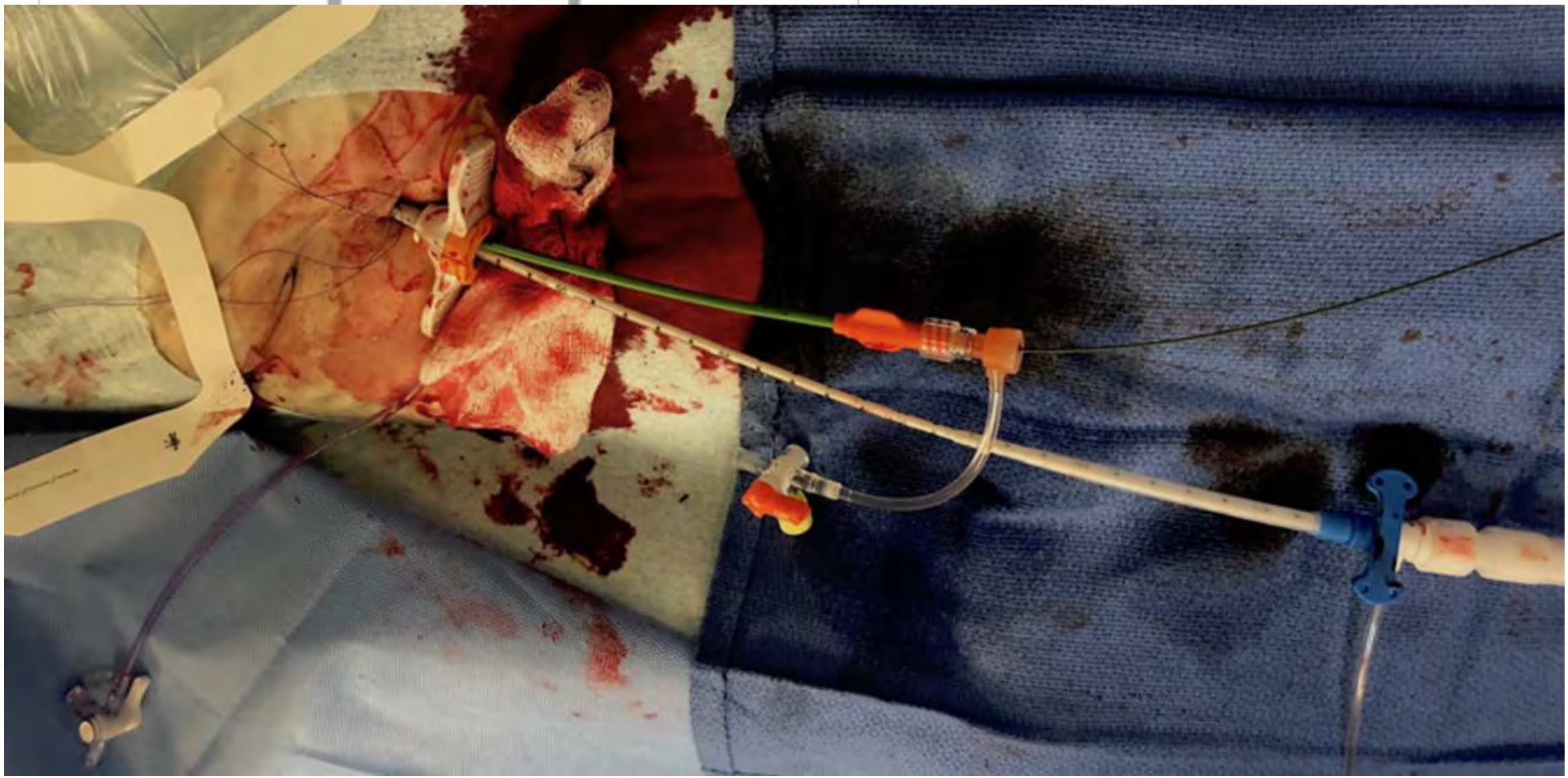

Puncture Sites

Complication Management

Complications and Management

Perforation - Covered stent

Thrombosis (fortunately rare) - Thrombolytics, aspiration thrombectomy, ballooning (can all be counterproductive due to distal embolization)

TABLE 2. SHEATH SIZE NEEDED TO DELIVER AN ePTFE-COVERED NITINOL SELF-EXPANDING STENT

Device Name	Expanded Stent Graft Diameter (mm)	Expanded Stent Graft Length (mm)	Sheath Diameter Needed to Deliver Device (F)
Fluency Plus	6	40, 60, 80, 100, 120	8
	7	40, 60	8
	7	80, 100, 120	9
	8–10	40, 60, 80, 100, 120	9
	12, 13.5	40, 60, 80, 100, 120	10
Viabahn	5	25, 50, 75,* 100, 150, 250	6,*7
	6	25, 50, 75,* 100, 150, 250	6,*7
	7	25, 50, 75,* 100, 150, 250	7
	8	25, 50, 75,* 100, 150, 250	7
	9	50, 75,* 100, 150	9
	10	25, 50, 100, 150	11
	11	25, 50, 100	11
	13	25, 50, 100	12

Abbreviation: ePTFE, expanded polytetrafluoroethylene.
*Only in the 0.018-inch guidewire delivery system.

Guidelines

Guidelines for Mechanical Circulatory Support

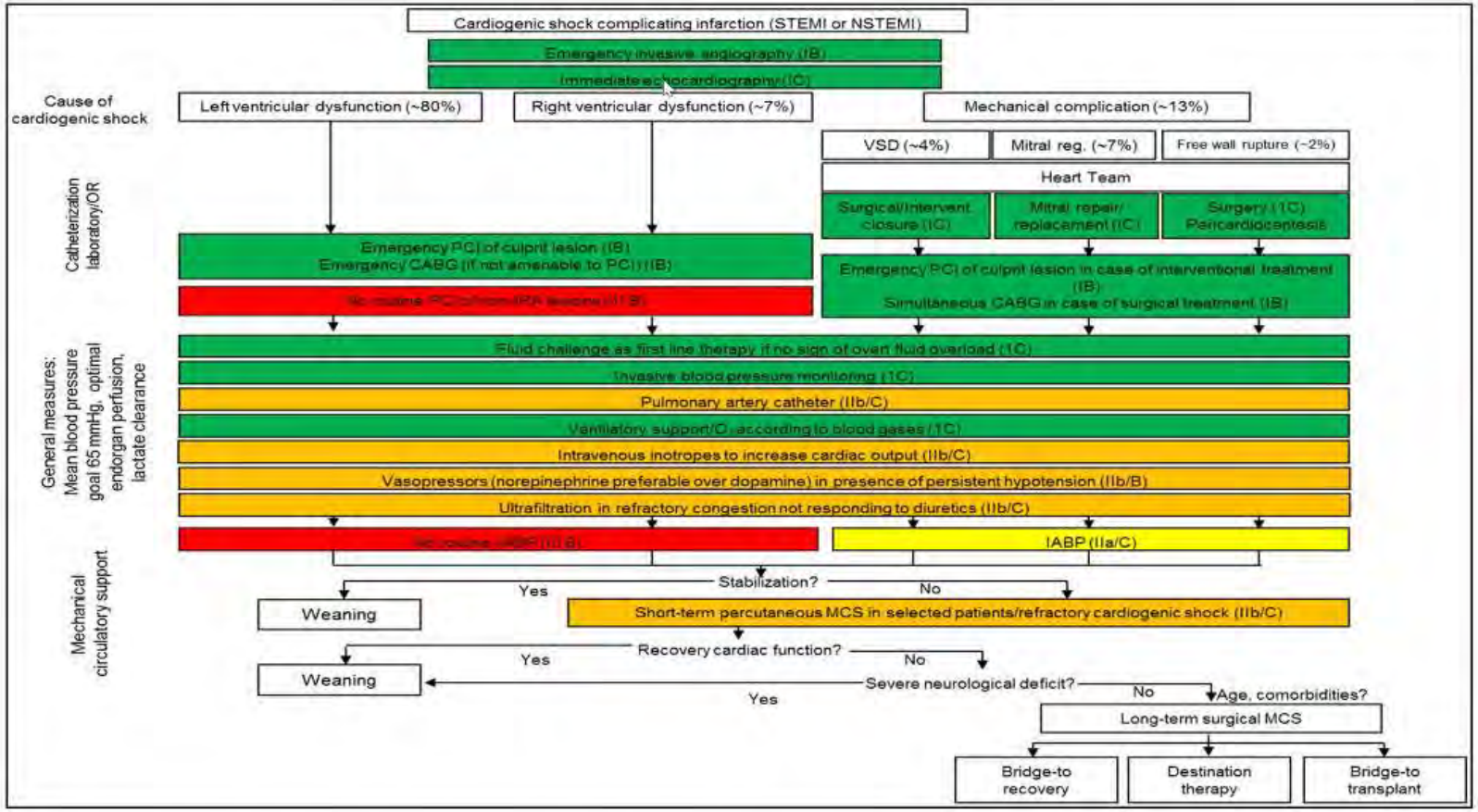
- **High-Risk PCI:**
  2015 SCAI/ACC/AHA Expert Consensus Statement
  →Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients, and alternative LV assist devices for circulatory support may be considered in patients with refractory cardiogenic shock (Class IIb, Level C)

- **Acute Myocardial Infraction:**
  2011 ACC/AHA/ESC Guidelines
  →MCS for cardiogenic shock in STEMI (Class IB, IC)

  2013 ACC/AHA Guidelines for the management of STEMI
  →IABP for cardiogenic shock (Class IIa, level of evidence B)
  →Alternative MCS devices can be considered in refractory cardiogenic shock (class IIb, level of evidence C)

  2017 ESC Guidelines
  →IABP use should be considered in patients with cardiogenic shock due to mechanical complications (class IIa, level of evidence C)
  →Routine IABP use is not indicated in patients with CS and acute MI or acute or chronic HF complicated by CS (class III, level of evidence B)

Treatment algorithm for patients with cardiogenic shock complicating myocardial infarction



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Thank You

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