Left Ventricular Support During High Risk PCI: Expanded Indications, Technique and Outcomes

Cardiovascular Interventions 2018

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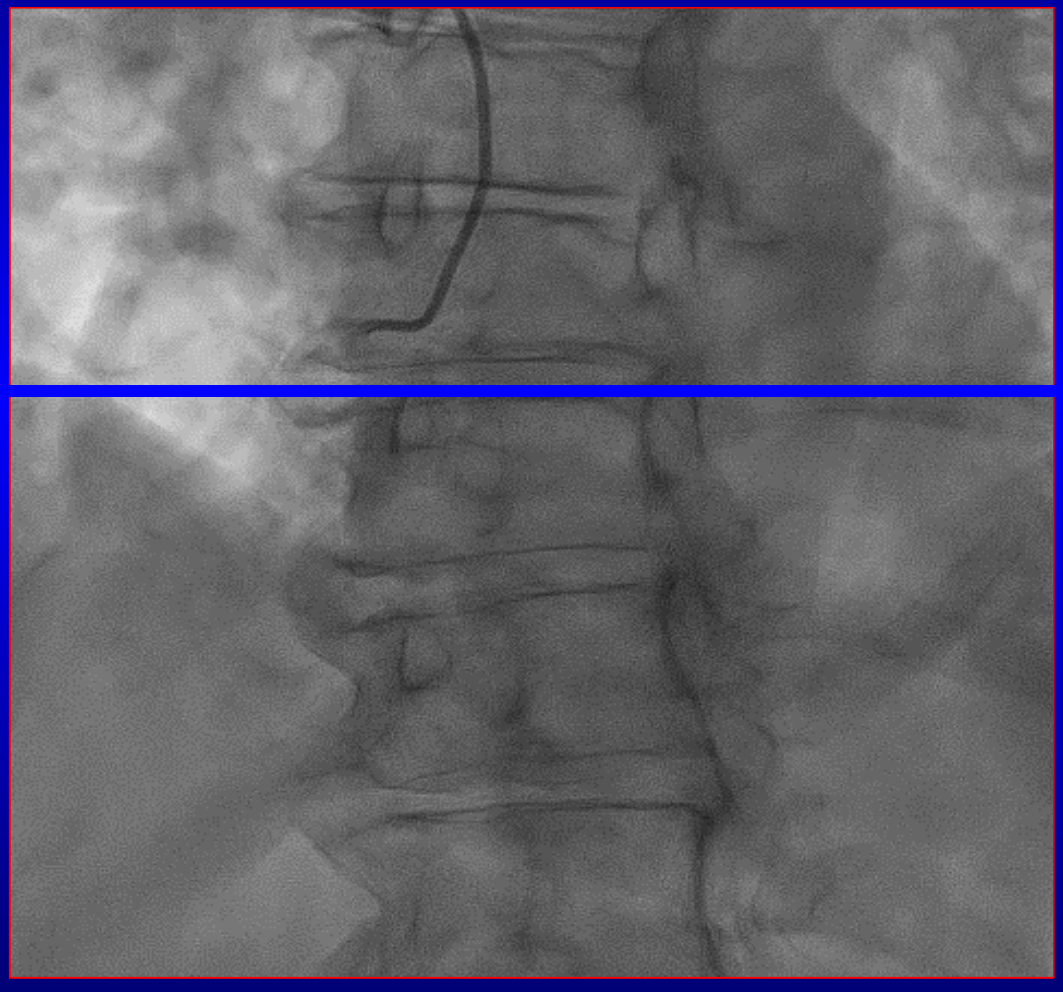
High Risk Elective PCI

Case Presentation

- 81 year old frail female with hypertension, hypercholesterolemia and hypothyroidism.
- Advanced obstructive & restrictive lung disease
- Presented with shortness of breath and protracted angina with minimal effort.
- Echocardiography: 45% EF with mild global hypokinesis.
- Relevant laboratory data: Creatinine 1.3 (GFR 43 ml/min/1.73m2).

Coronary Angiography



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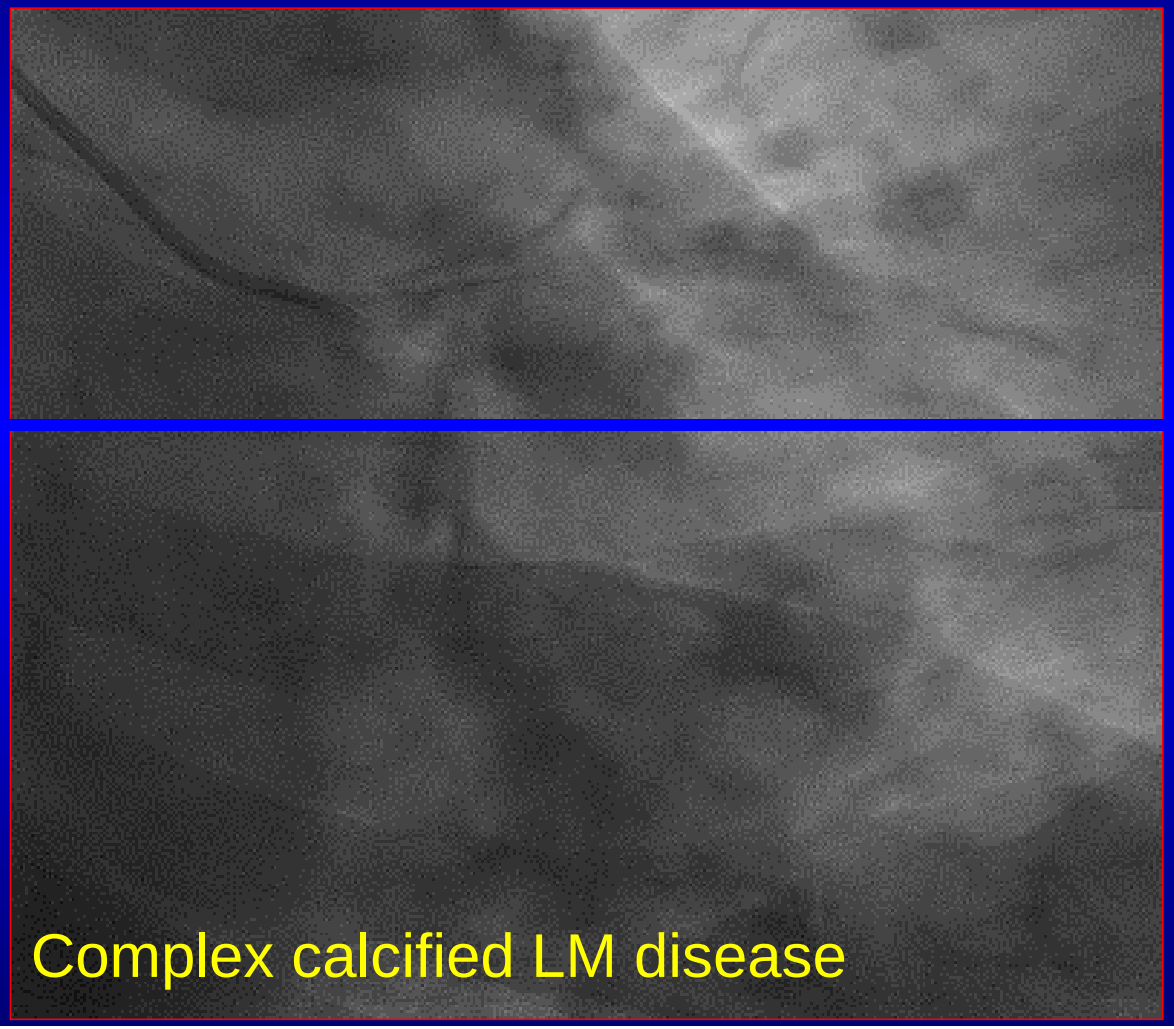
Coronary Angiography



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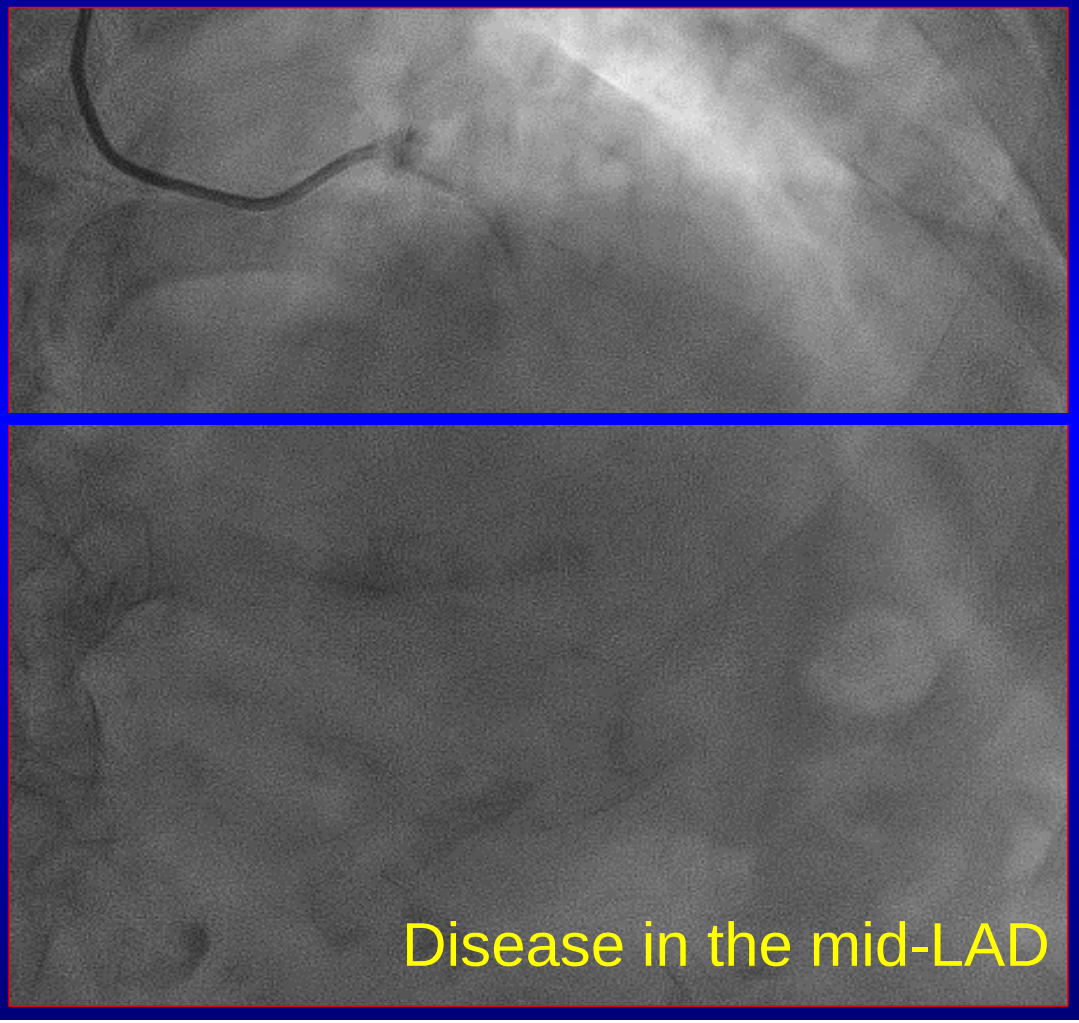
Coronary Angiography



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Evaluated by Our Institution's Heart Team

Declined Bypass Surgery Based on the Following:

- Advanced age.
- Overall frailty.
- Lung disease: Seen by pulmonary medicine and considered to have advanced obstructive & restrictive airway disease.
- She was considered for complex PCI.
- Syntax Score 21
- Syntax II Score:
  - PCI 51.1 with 4 year mortality of 34.0%
  - CABG 53.1 with 4 year mortality of 38.8%
- STS score : 6.8

Procedural Considerations

- She was considered for complex coronary intervention:
  a. Transradial vs transfemoral approach.
  b. Lesion pretreatment strategy (POBA vs RA).
  c. With or without mechanical circulatory support?

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What Next ?

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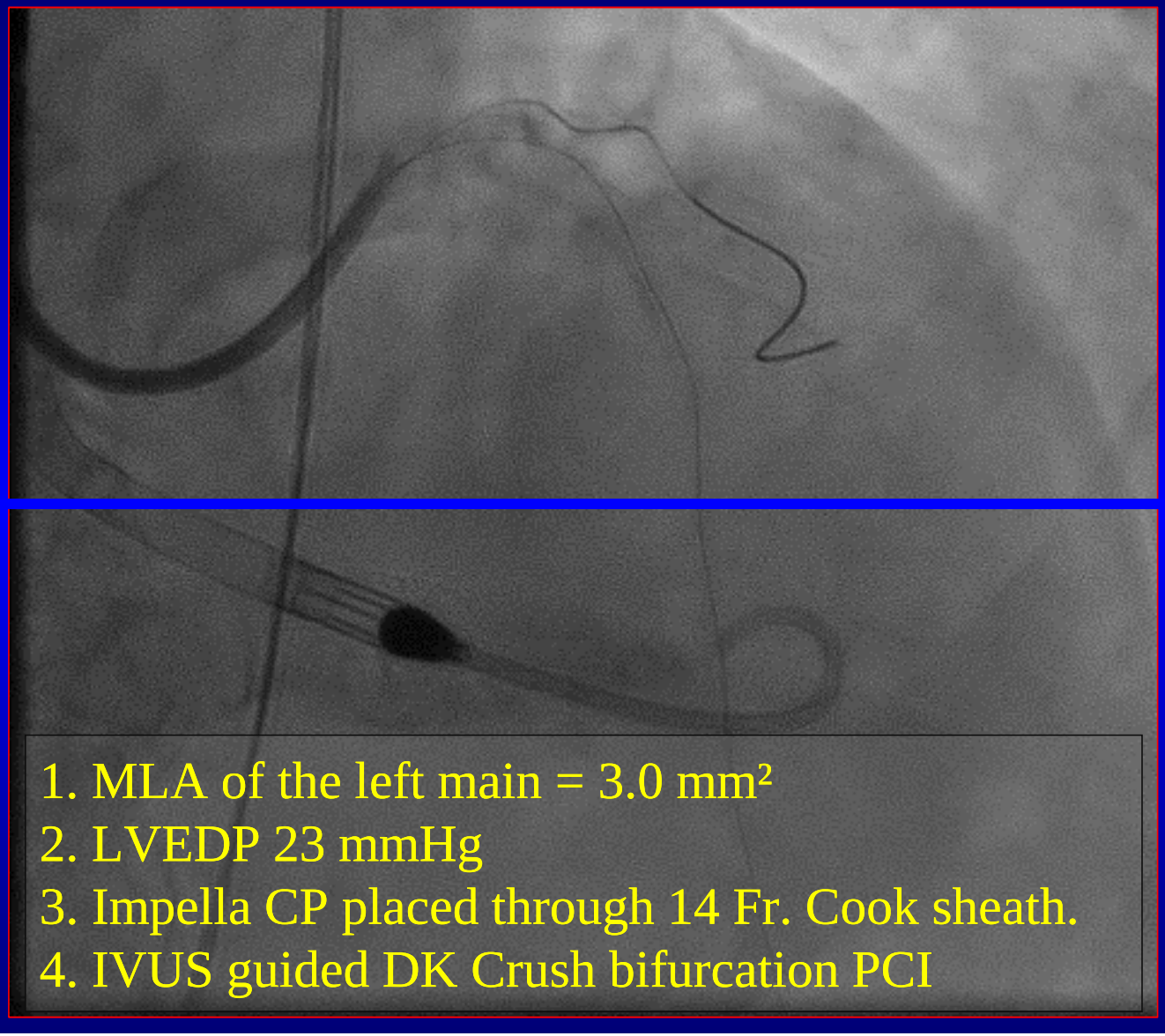

1. MLA of the left main = 3.0 mm^2
2. LVEDP 23 mmHg
3. Impella CP placed through 14 Fr. Cook sheath.
4. IVUS guided DK Crush bifurcation PCI

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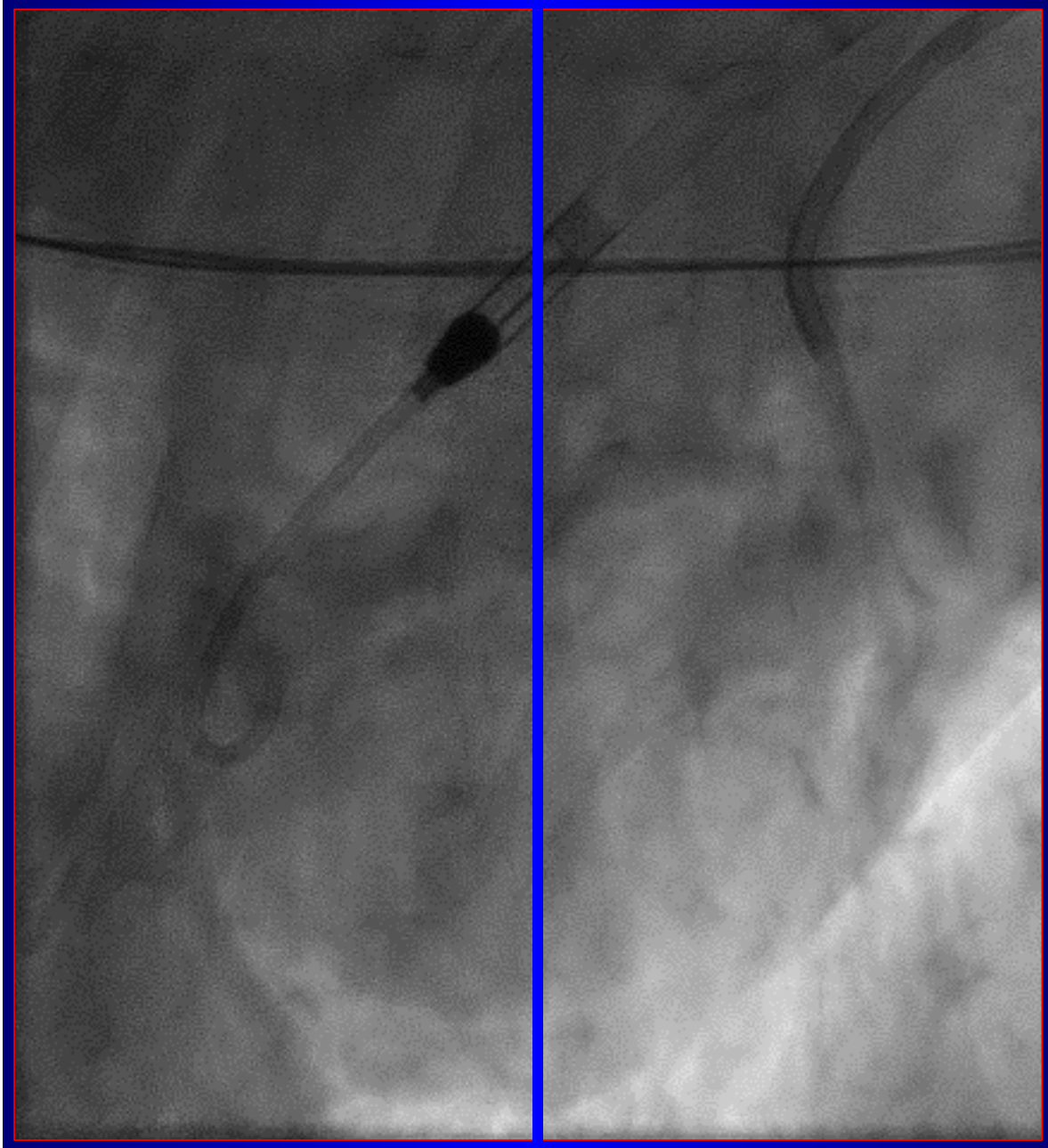

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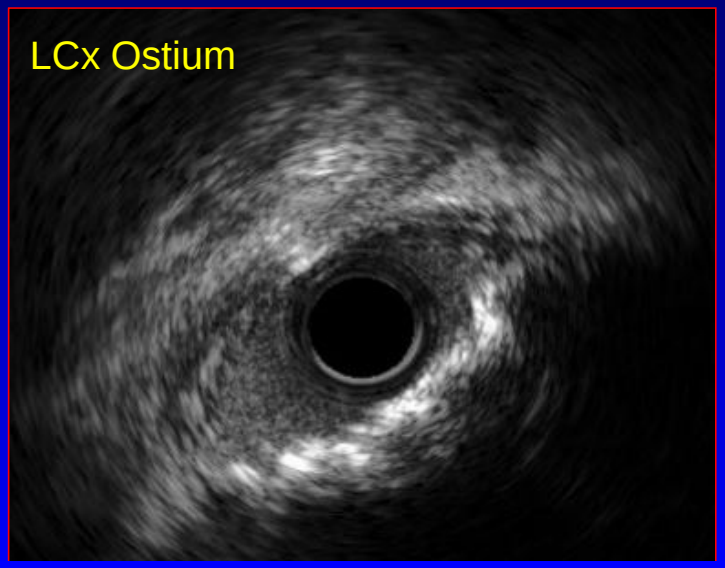
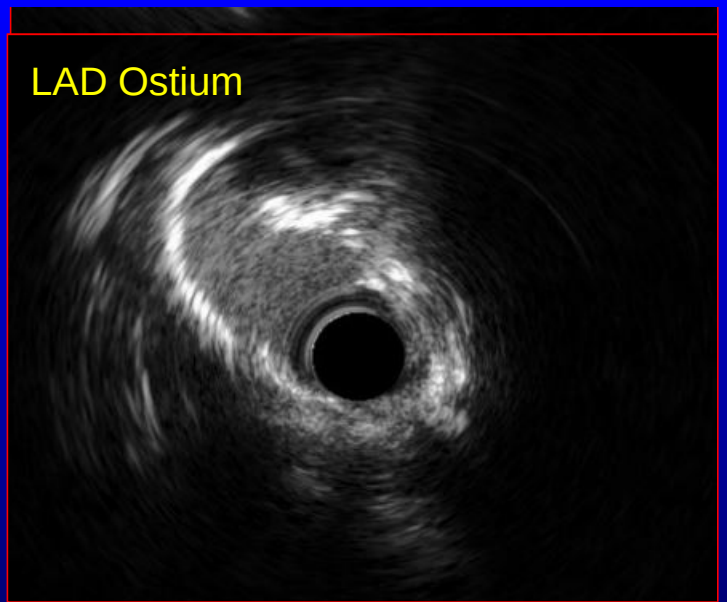
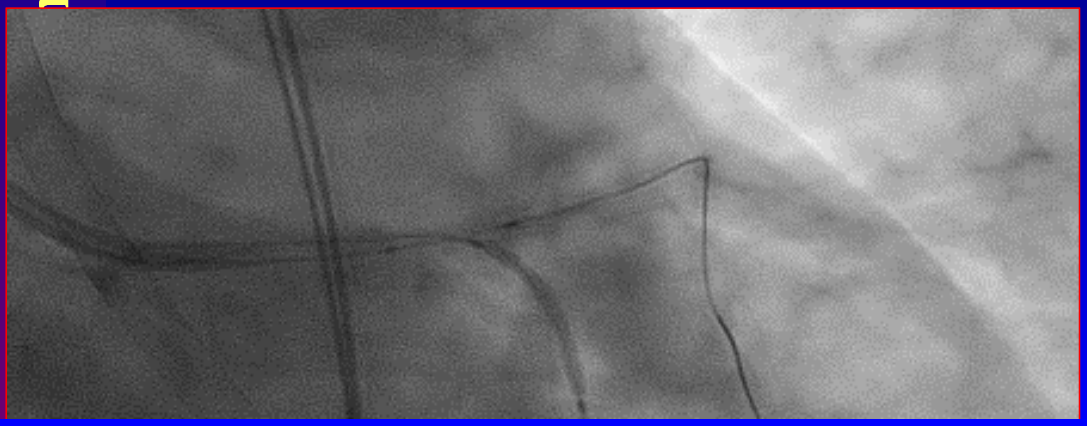
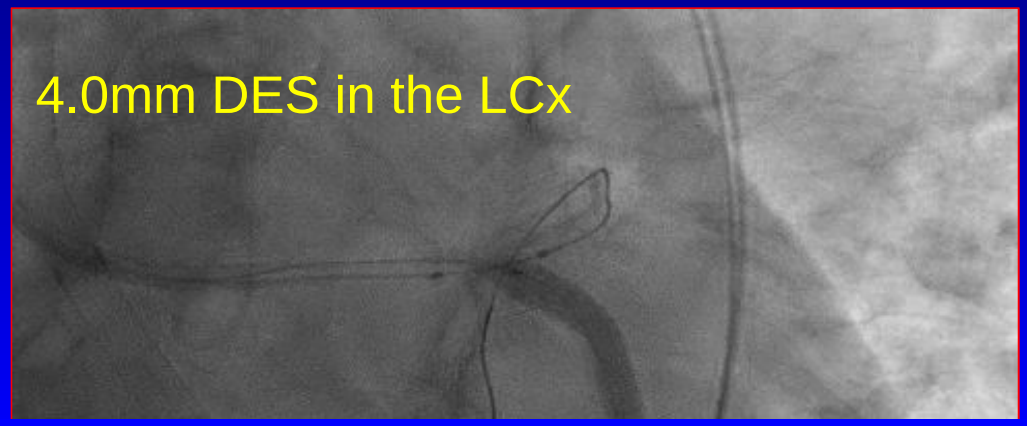


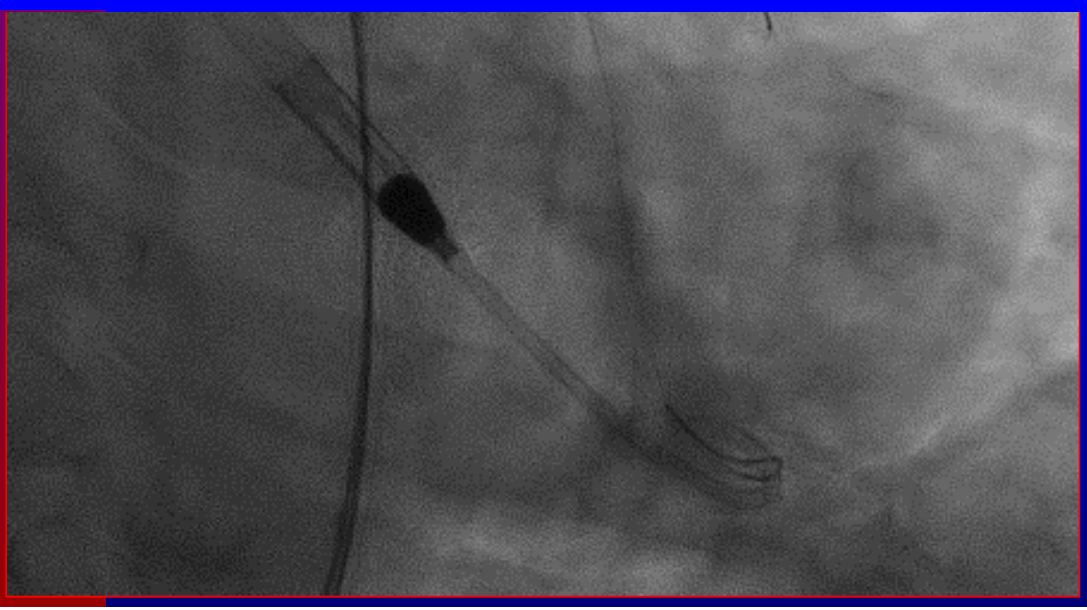
Lesion pretreatment with rotational atherectomy:
Heavy calcium burden in the LM and LAD/LCx ostia

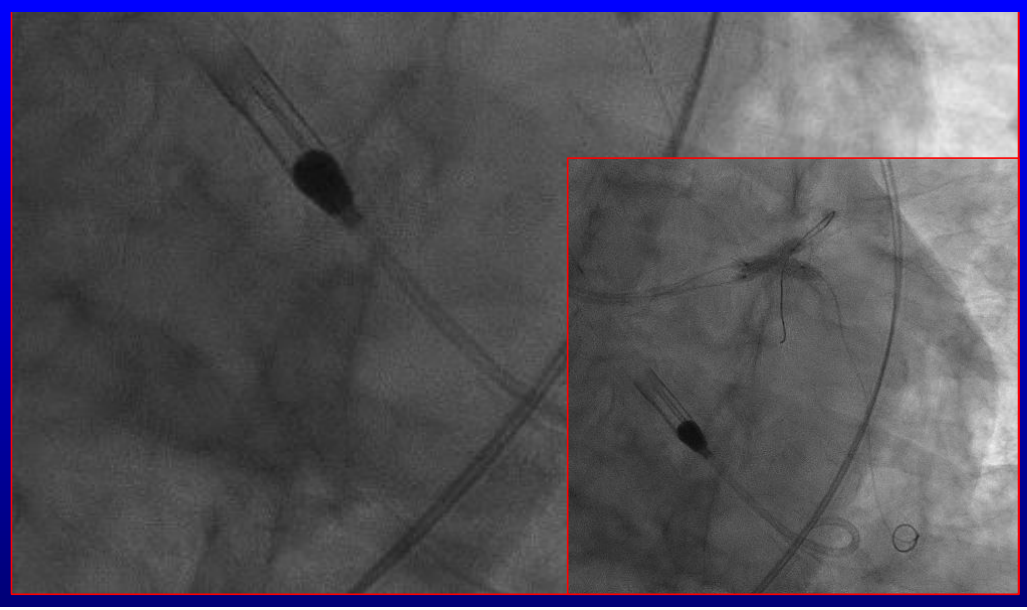


Planned DK Crush Technique

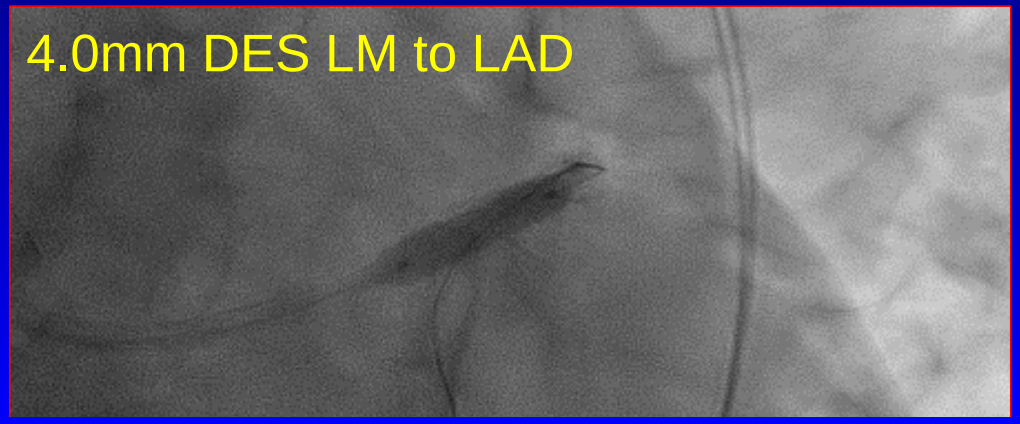


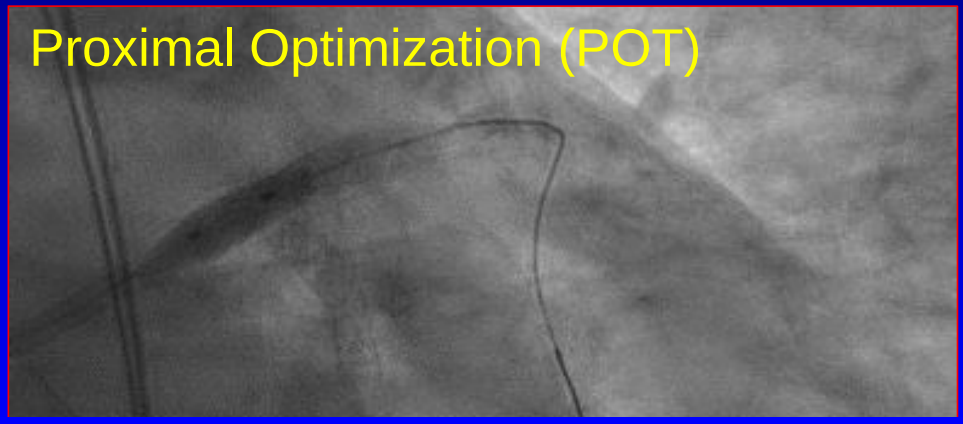


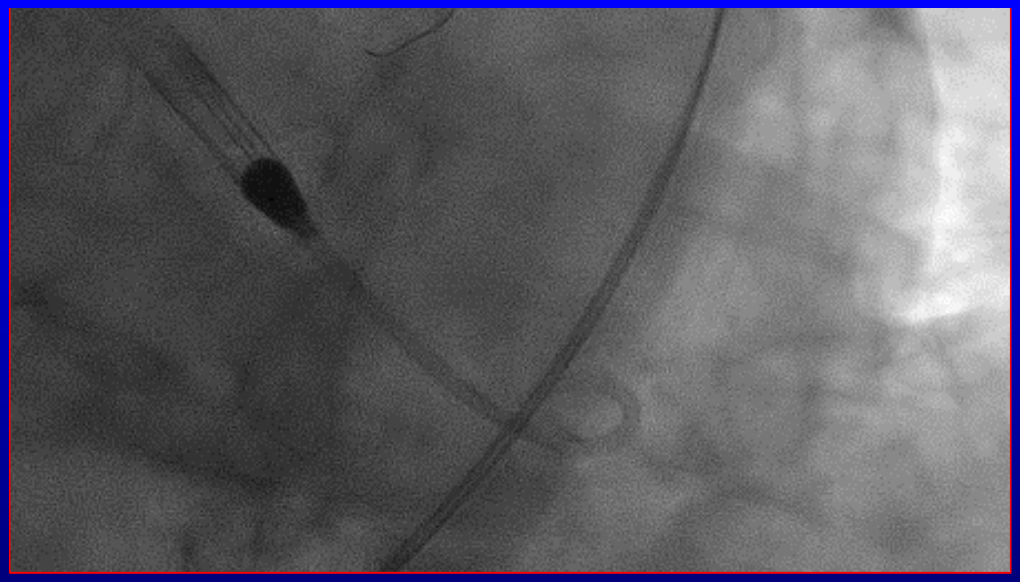


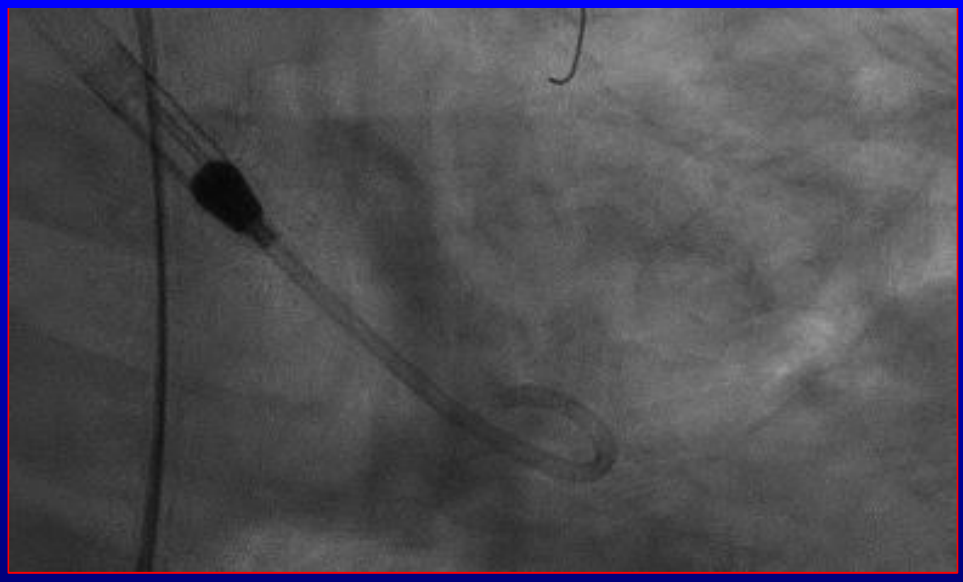


Left Main-LAD Stent









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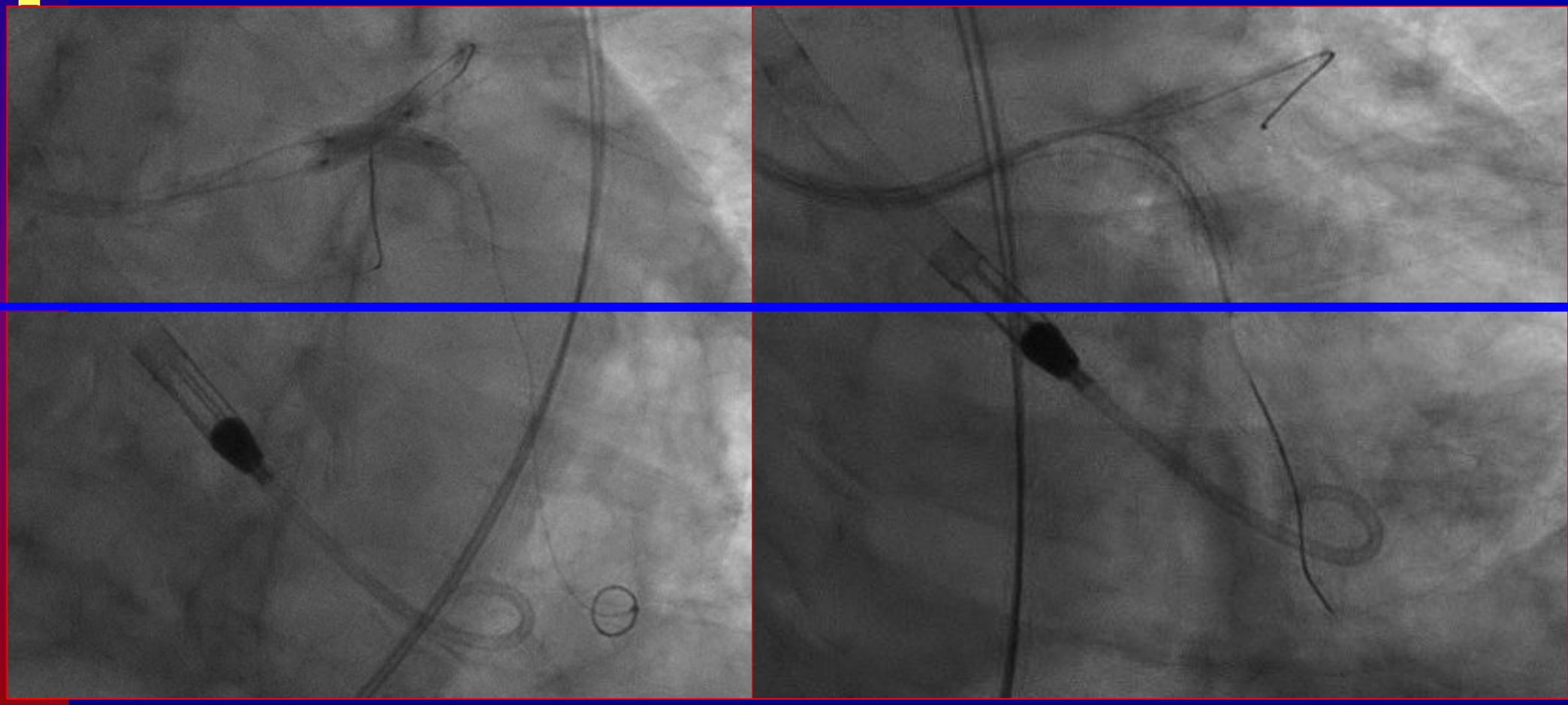
FKB + Final IVUS Run



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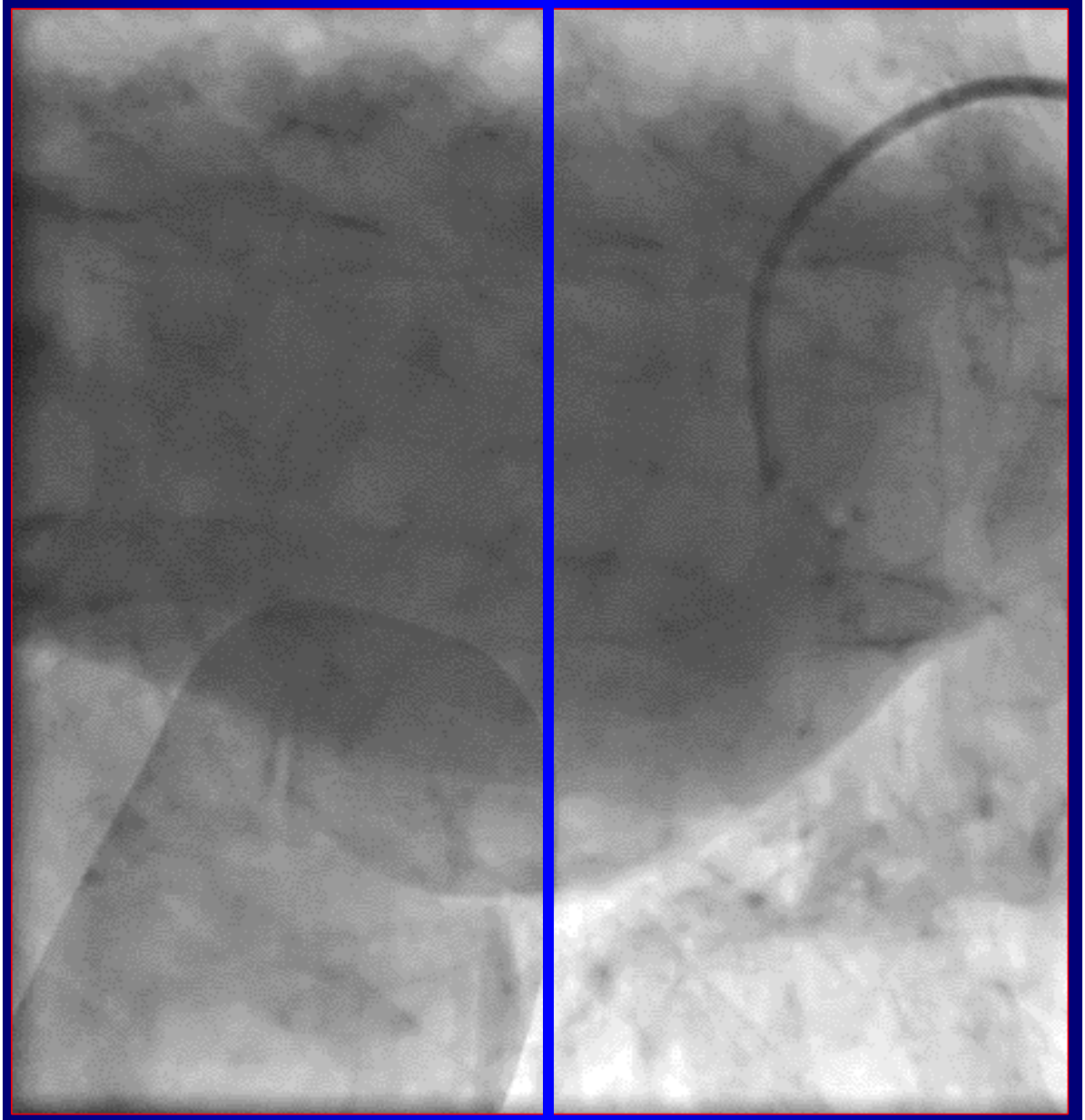

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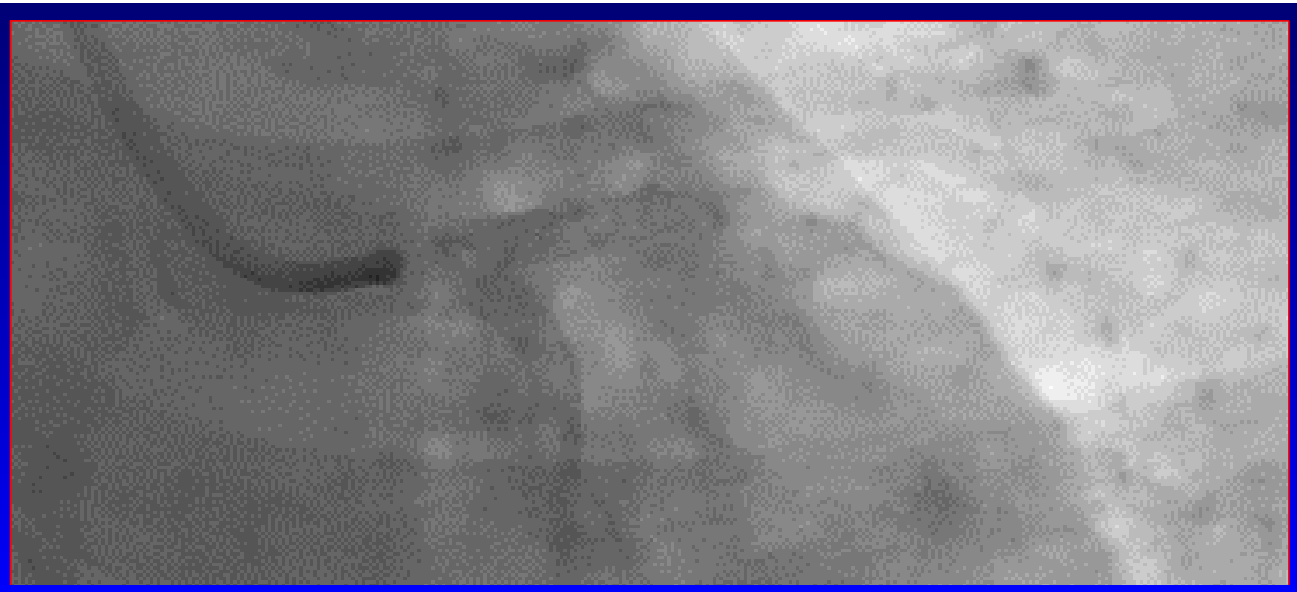

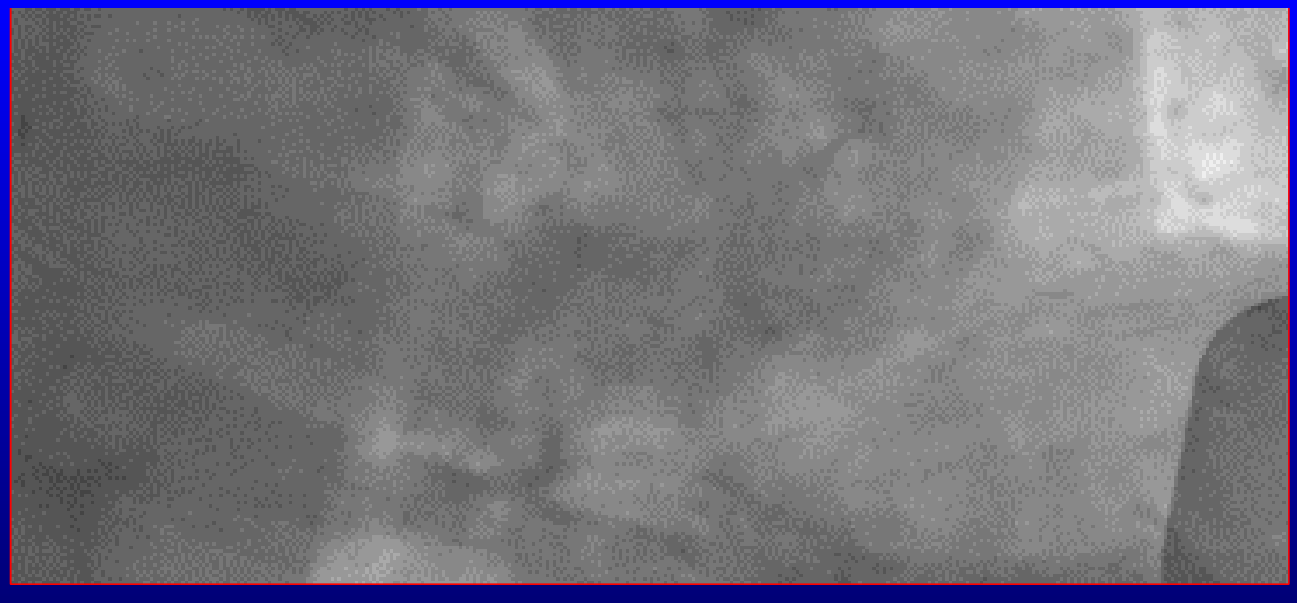

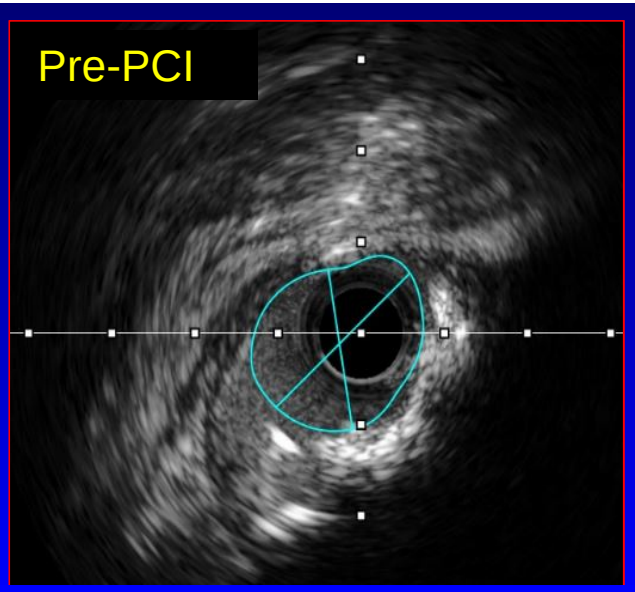

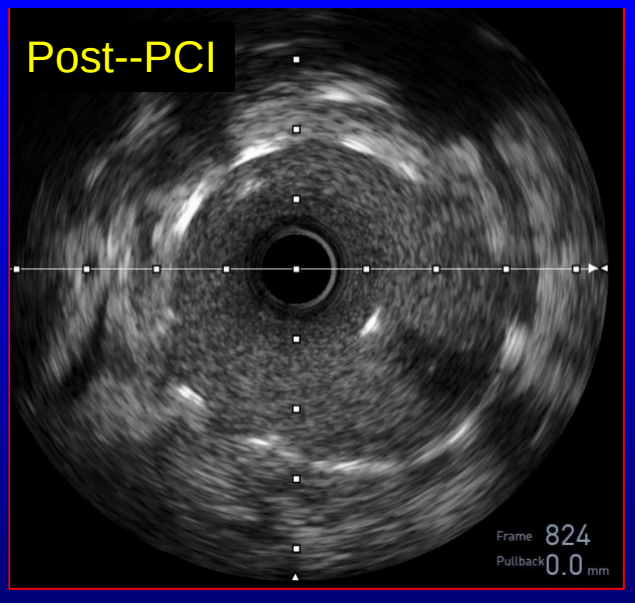

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Following Perclose

1. Our group's experience is that complex PCI can be more safely performed with MCS.
2. This expands the "possibility" of performing PCI.
3. Need to mindful of vascular complications (though in experienced hands complications are low).
4. Our general strategy is a hybrid of TF and TR approach.
5. If you do not have a robust MCS practice, recommend you pursue starting one.

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The Evolution of Mechanical Circulatory Support

- Management of patients requiring temporary, MCS during high-risk percutaneous coronary intervention (PCI) is rapidly evolving and increasing.

- With the availability of the Impella 2.5, CP, 5.0, LD, and RP percutaneous MCS devices, there is a need for continued surveillance of outcomes (in the form of registry publications).

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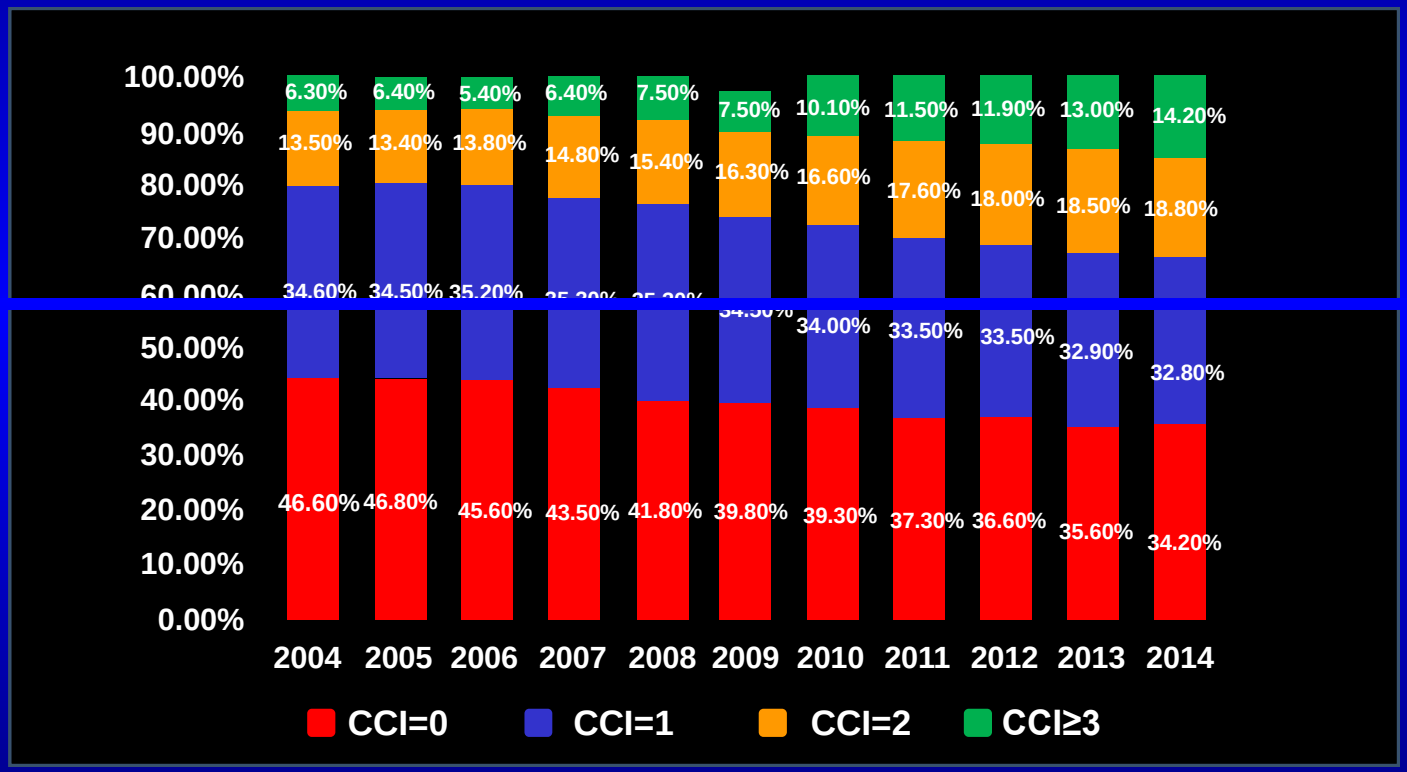
Increasing Co-morbidity in Cath Lab 2004-2014 n=6,601, 526 PCI



Rios et al,
DOI:10.1016/j.amjcard.2018.07.011

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Comorbidity and Risk of Complications

	Charlson Comorbidity Index Score		
	1 v 0	2 v 0	≥3 v 0
In-hospital mortality	1.19 (1.15, 1.25)	1.41 (1.34, 1.48)	1.96 (1.86, 2.07)
Any complication	1.23 (1.21, 1.27)	1.66 (1.61, 1.70)	2.47 (2.38, 2.56)
Bleeding complication	1.57 (1.52, 1.61)	2.47 (2.39, 2.56)	4.26 (4.09, 4.42)
Vascular complication	1.06 (1.02, 1.10)	1.09 (1.03, 1.15)	1.12 (1.05, 1.20)
Cardiac complication	0.94 (0.91, 0.97)	0.94 (0.90, 0.99)	1.00 (0.95, 1.04)
Stroke	1.30 (1.26, 1.34)	1.72 (1.67, 1.79)	2.40 (2.30, 2.51)

Rios et al,
DOI:10.1016/j.amjcard.2018.07.011

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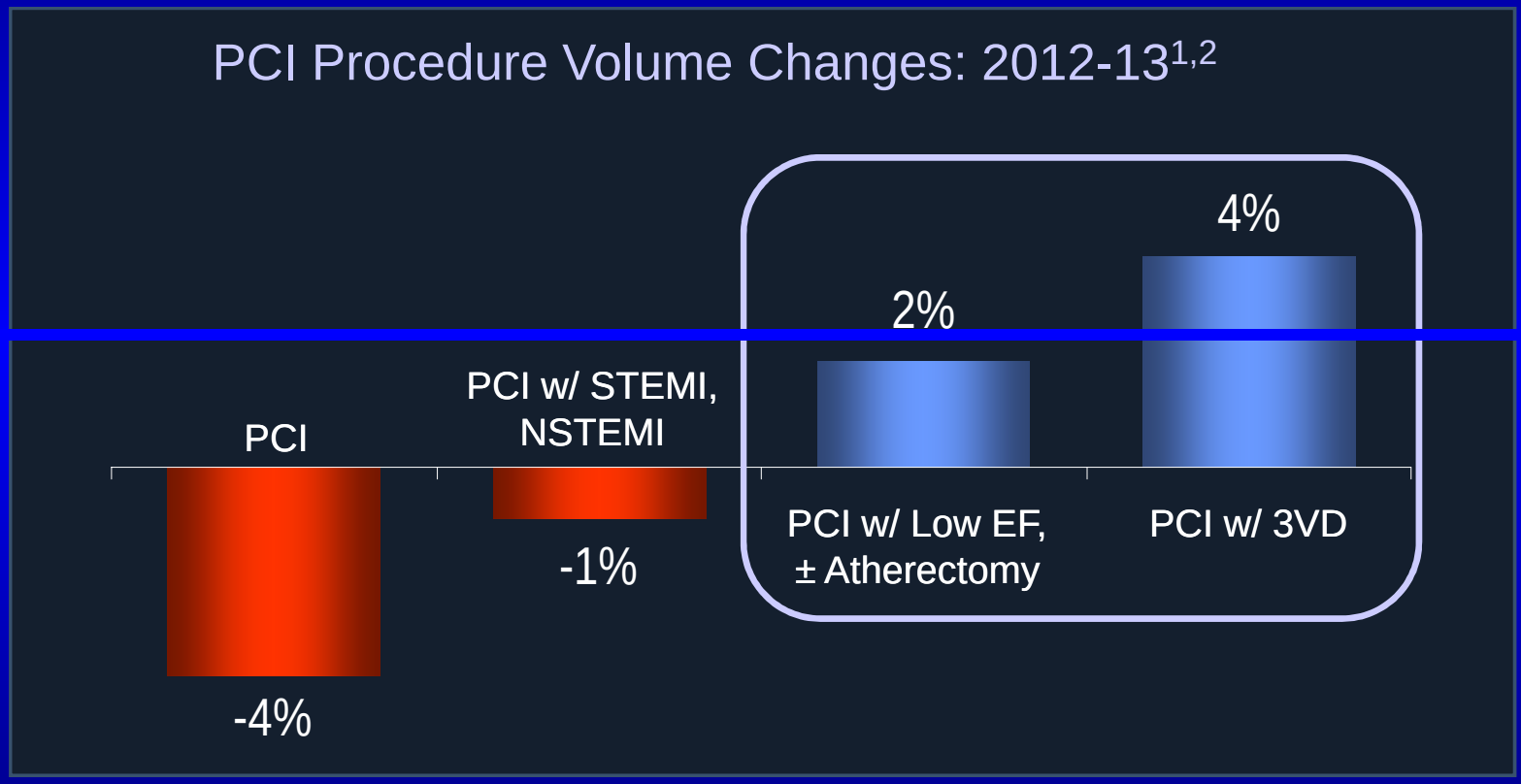
Increasing High Risk Population in the Cath Lab



1. IMS PTCA Report, 2013
2. Based on ICD-9 Diagnosis/Procedure and AMA CPT coding

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Clinical Goals of Prophylactic Support

- Maintain Hemodynamics
  - Prevent hemodynamic instability
  - Reduce peri and post procedural adverse events.
- Facilitate Complete revascularization
  - Raising the patient's ischemic threshold to minimize functional disruption from balloon inflation or coronary dissection
- Prophylactic Safety Profile and Ease-of-Use
  - Address complications such as bleeding, or embolization to end organs, such as stroke or limb ischemia

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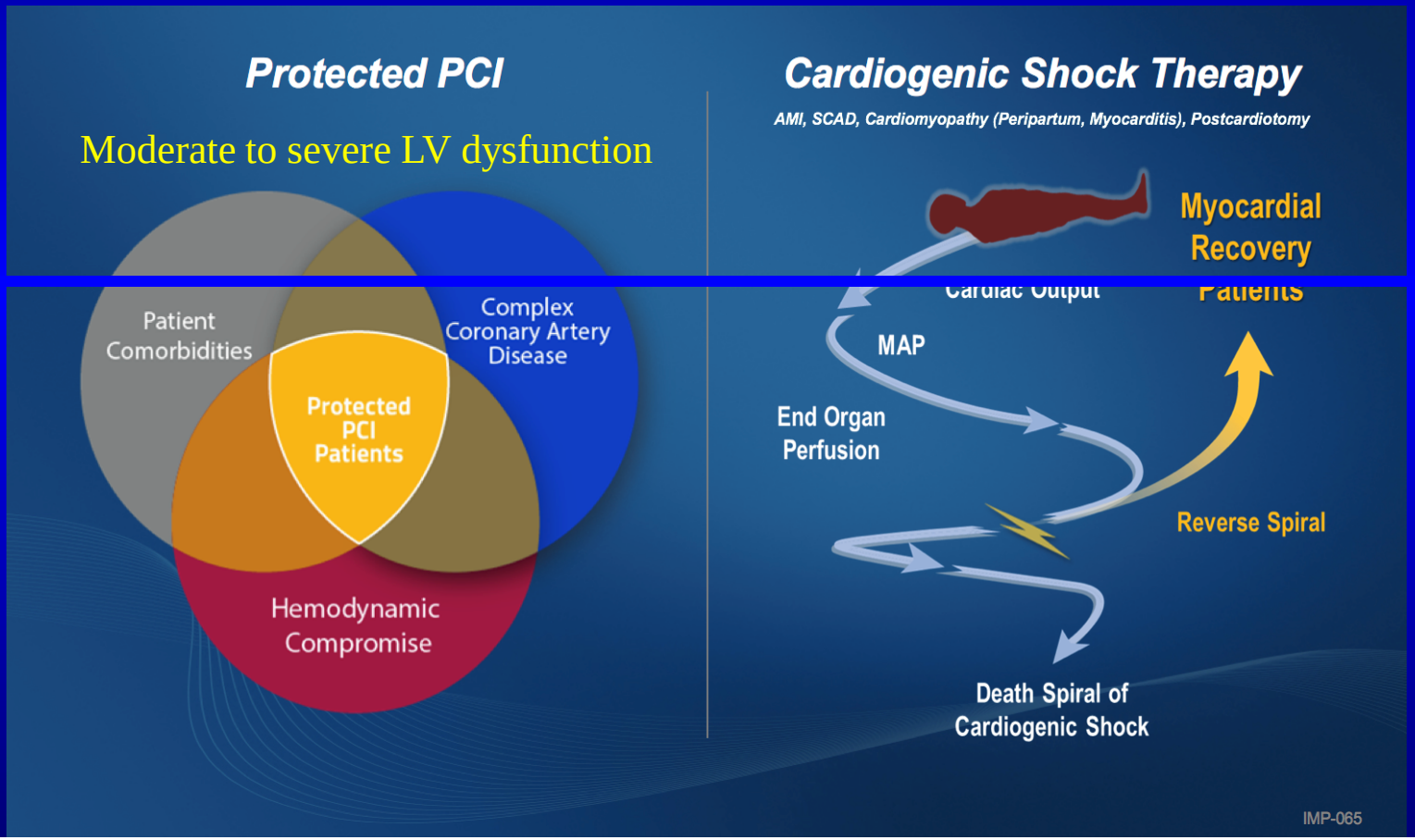
Mechanical Circulatory Support

Patients That Historically Benefit from Impella ®



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Growing Body of Literature to Support protected PCI

Scientific Evidence to Support PMA Applications*	Total Number of Patients in the Cohort	Number of Impella Protected PCI Patients
Severely Reduced LVEF ≤35%		
Protect I	20	20
Protect II	452	225
U.S. Impella Registry	1,322	709
Literature review	2,537	756
Mild, Moderately Reduced LVEF >35%		
cVAD Registry Study	→ 693	464 with LVEF≤ 35% 229 with LVEF≥ 35%
Total	5,024	2,403

** Patient data may be provided in multiple PMA applications*

cVAI Registry

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The cVAD registry for percutaneous temporary hemodynamic support: A prospective registry of Impella mechanical circulatory support use in high-risk PCI, cardiogenic shock, and decompensated heart failure

George W. Vetrovec, MD, Mark Anderson, MD, Theodore Schreiber, MD, Jeffrey Popma, MD, William Lombardi, MD, Brijeshwar Maini, MD, Jacob Eifer Moller, MD, Andreas Schäfer, MD, Simon R. Dixon, MBChB, Shelley Hall, MD, E. Magnus Ohman, MD, Catalin Mindrescu, MD, Jeffrey Moses, MD, William O'Neill, MD

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Favorable MACCE in Both Patient Cohorts

Adverse Events	LVEF <=35% (N=661 Patients)	LVEF >35% (N=230 Patients)	P-Value
MACCE	4.54%	3.48%	0.574
Death	3.78%	1.74%	0.193
Myocardial Infarction	0.30%	1.30%	0.112
CVA/Stroke	0.00%	0.00%	--
Revascularization	0.61%	1.30%	0.383
Acute Renal Dysfunction	6.05%	2.61%	0.055
Bleeding requiring Surgery	0.76%	0.43%	1.000
Vascular Complication requiring Surgery	1.06%	2.17%	0.201
Device Malfunction	0.15%	0.00%	1.000
Failure to Achieve Angiographic Success (Residual Stenosis <30% after stent implant)	0.30%	0.87%	0.275

MACCE and adverse event rates favorable and consistent between two patient cohorts

Alaswad, O'Neill, et al. American Journal of Cardiology 2018

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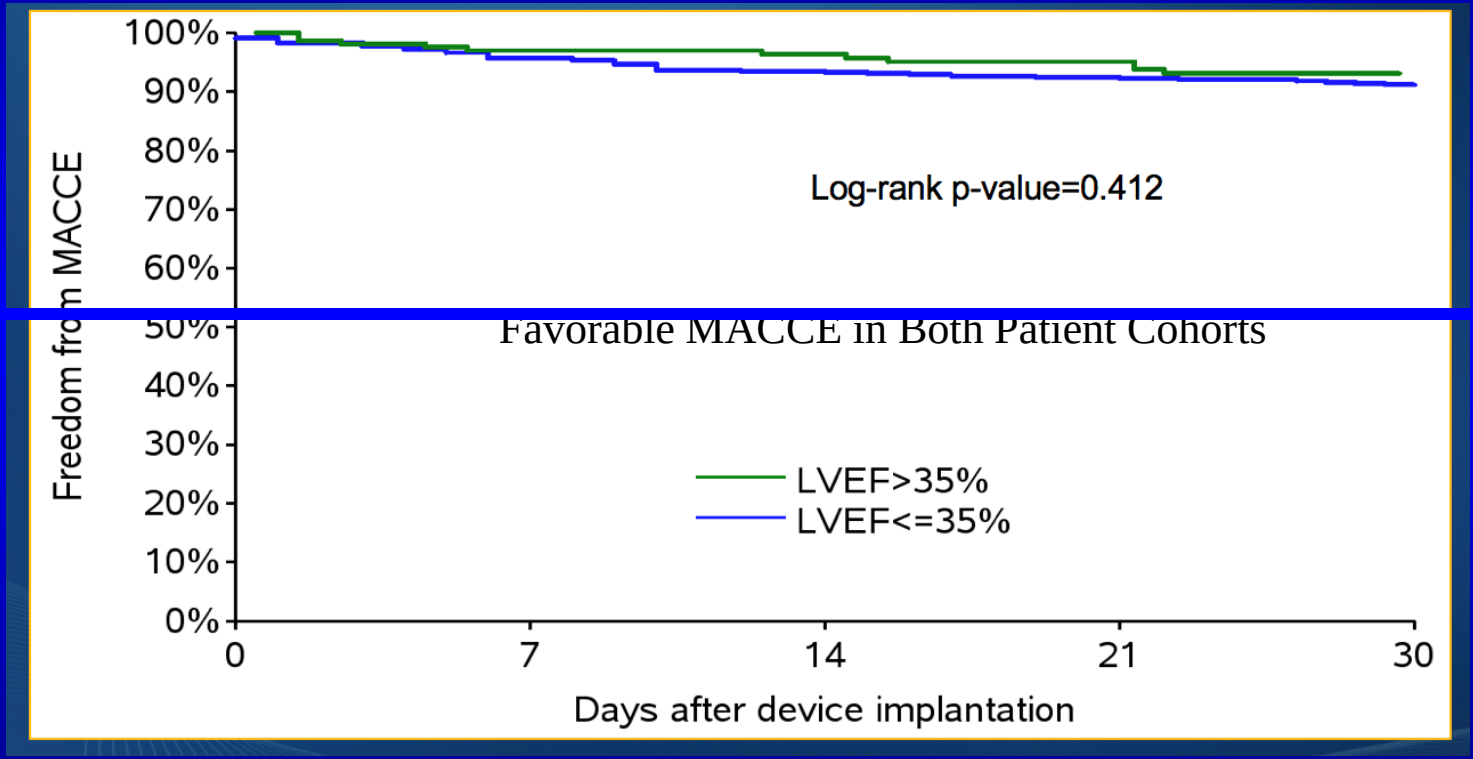
- Actual mortality rate in the >35% EF group was 1.74%, whereas there STS score 4.87%
- Are these high risk patients treated better with PCI?



Very sick patients, advanced disease with favorable outcomes.

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Expanded Indication For High Risk PCI

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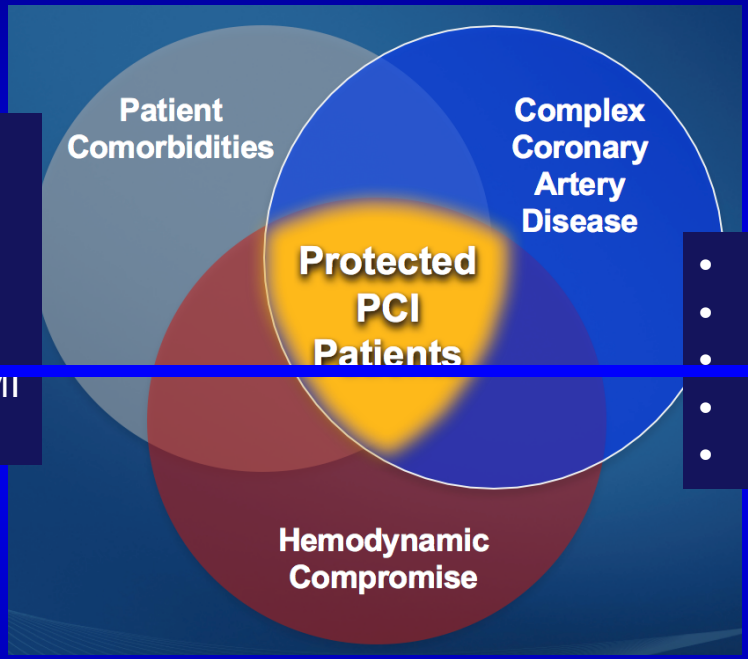
Growing Population of Patients Appropriate for PCI

- Surgical ineligibility
- Previous heart surgery
- Advanced CHF
- Diabetes
- Advanced age
- Unstable angina/NSTEMI
- ARF/CKD



- Multivessel CAD
- UPLM-CAD
- Complex lesion
- Bifurcations,
- CTOs, Ca++

- Mild, moderate or severely depressed LV function
- High LVEDP

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High Risk PCI Expanded FDA Indication

Expanded to Include Mild and Moderately Reduced Ejection Faction

The Impella 2.5 and Impella CP are indicated for providing temporary (< 6 hours) ventricular support during elective or urgent high risk percutaneous coronary interventions (PCI) performed in hemodynamically stable patients with severe coronary artery disease, [~~and depressed left ventricular ejection fraction~~] when a heart team, including a cardiac surgeon, has determined high risk PCI is the appropriate therapeutic option.

Use of the Impella 2.5 and the Impella CP 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.

The Impella ® platform is the only percutaneous temporary ventricular support devices that are FDA-approved as safe and effective for High Risk PCI

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Why Registry Data is Needed?

- Large randomized trials of hemodynamic support, involving cardiogenic shock, are challenging to conduct.
- There is increasing interest in the use of registries to provide "real world" experience and to allow the flexibility to evaluate individual patient uses and outcomes.
- Current, large databases have not captured the specific impact of mechanical support in the treatment of cardiogenic shock.

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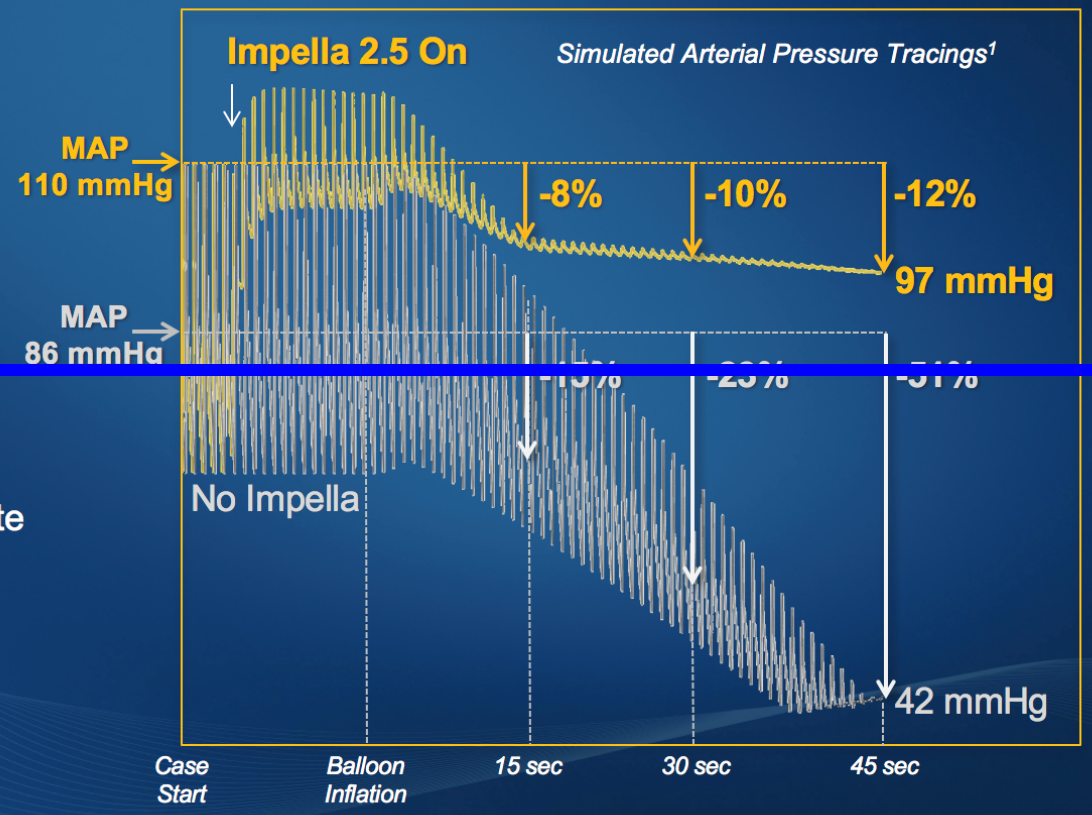
Hemodynamics of Protected PCI

High Risk "Last Conduit" Patient

Case Example

- 66 yo male
- 85% SVG
- Last patent conduit
- NYHA Class IV
- Prior CABG
- Prior PCI
- Not Surgical Candidate
- *EF = 30%*



1. Physiologic computational modeling, Am J Physiol 1991;260 (HCP 29): H146-H157

IMP-065

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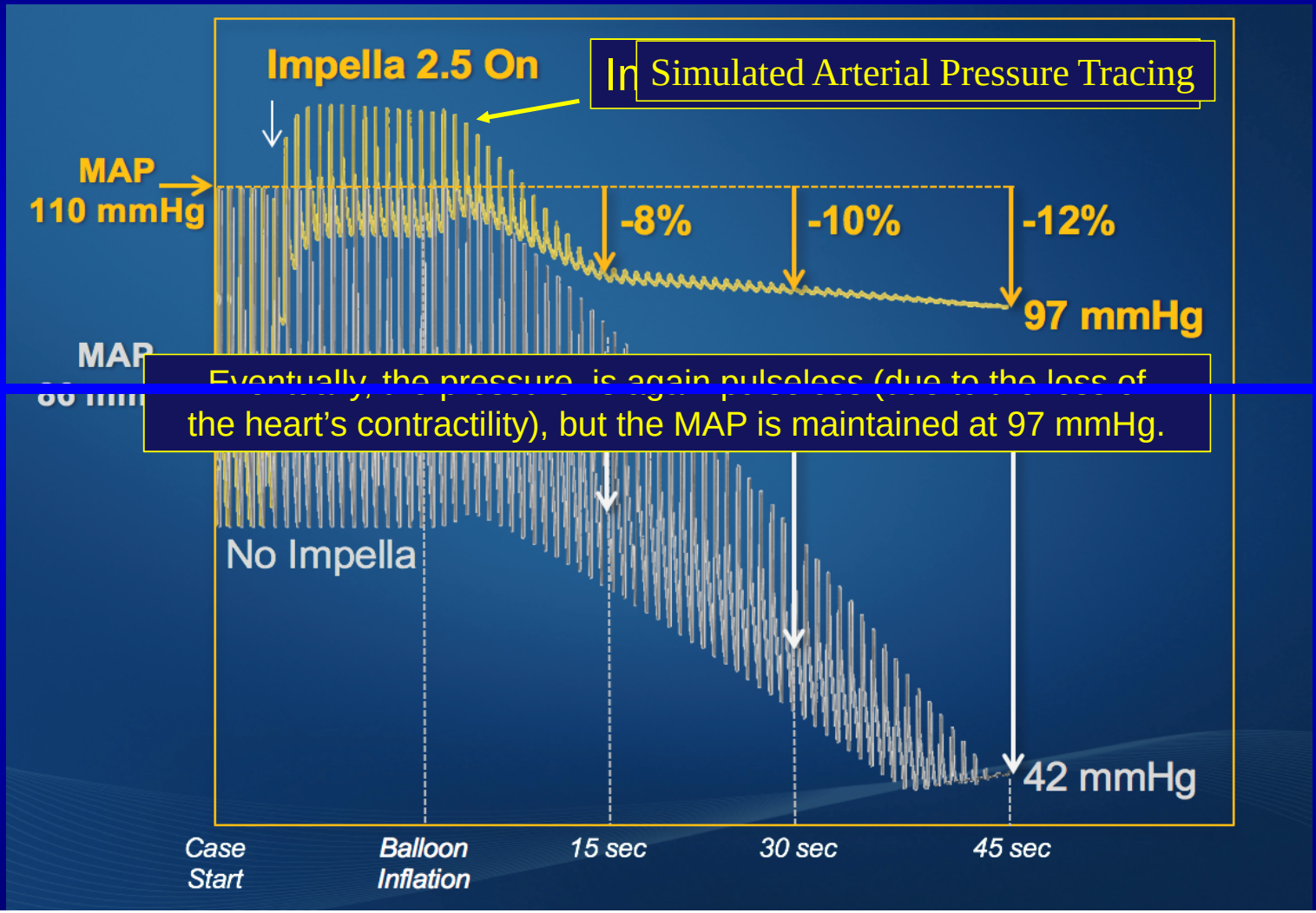
Balloon Inflation: the pressure initially declines as the contractility of the heart collapses, but **MCS** stabilizes the arterial pressure though the heart continues to lose contractility.



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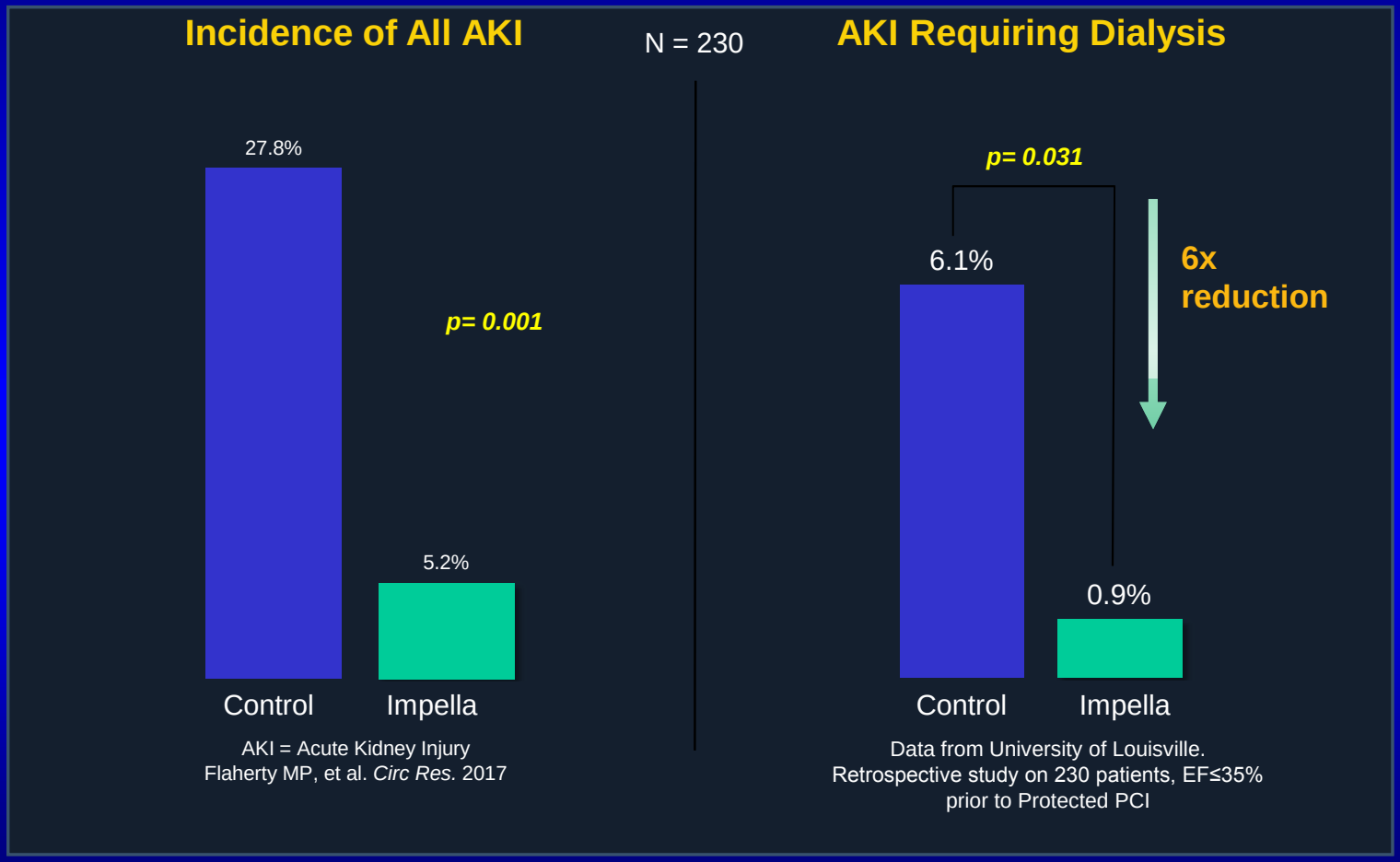
Use of Impella® is Associated with Reduced Kidney Injury



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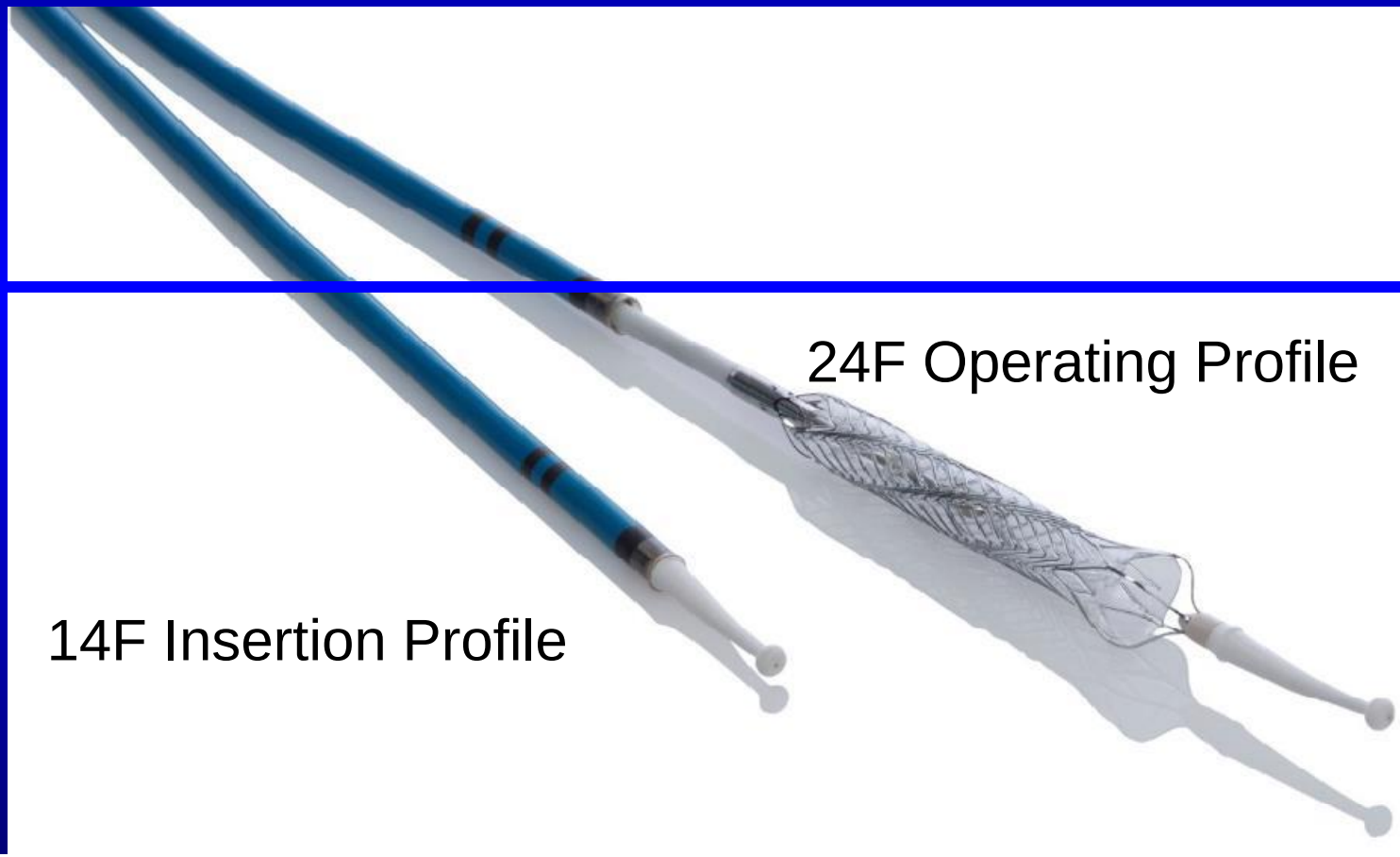
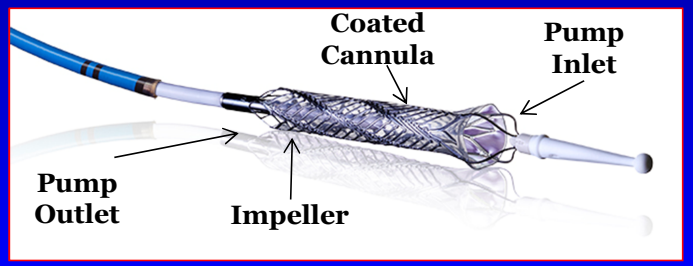
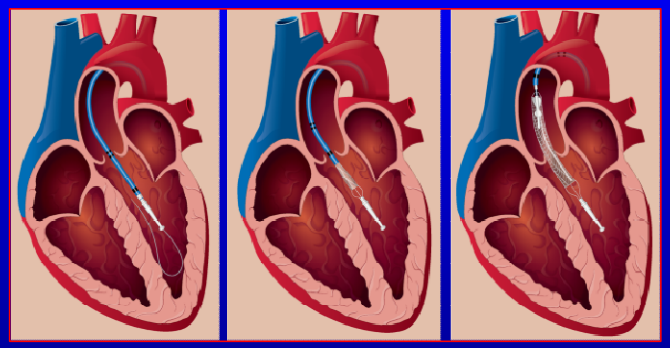
HeartMate PHP™ Catheter Pump



HeartMate PHP (Percutaneous Heart Pump)

- Low-profile, rapid-insertion, catheter-based percutaneous heart pump.
- Collapsible elastomeric impeller and nitinol cannula.
- 14F profile expanding to 24F when unsheathed across aortic valve
- Designed to provide high forward flow at low RPMs.
- Provides for unloading of the the LV and perfusion of end organs.
- Delivers over 4 lpm average flow.
- Might this reduce hemolysis?





Insertion Sequence

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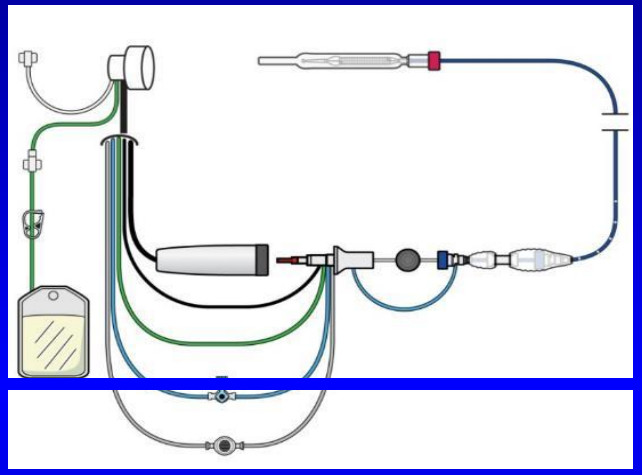
HeartMate PHP System Components

- **PHP Console**
  - Intuitive touch screen
  - 1 hour battery back-up
  - Lightweight (6.0 kg)
  - Pole-mounted



- **PHP Catheter**
  - 14F over-the-wire
  - Quick set-up
  - Integrated motor
  - .018” guidewire compatible

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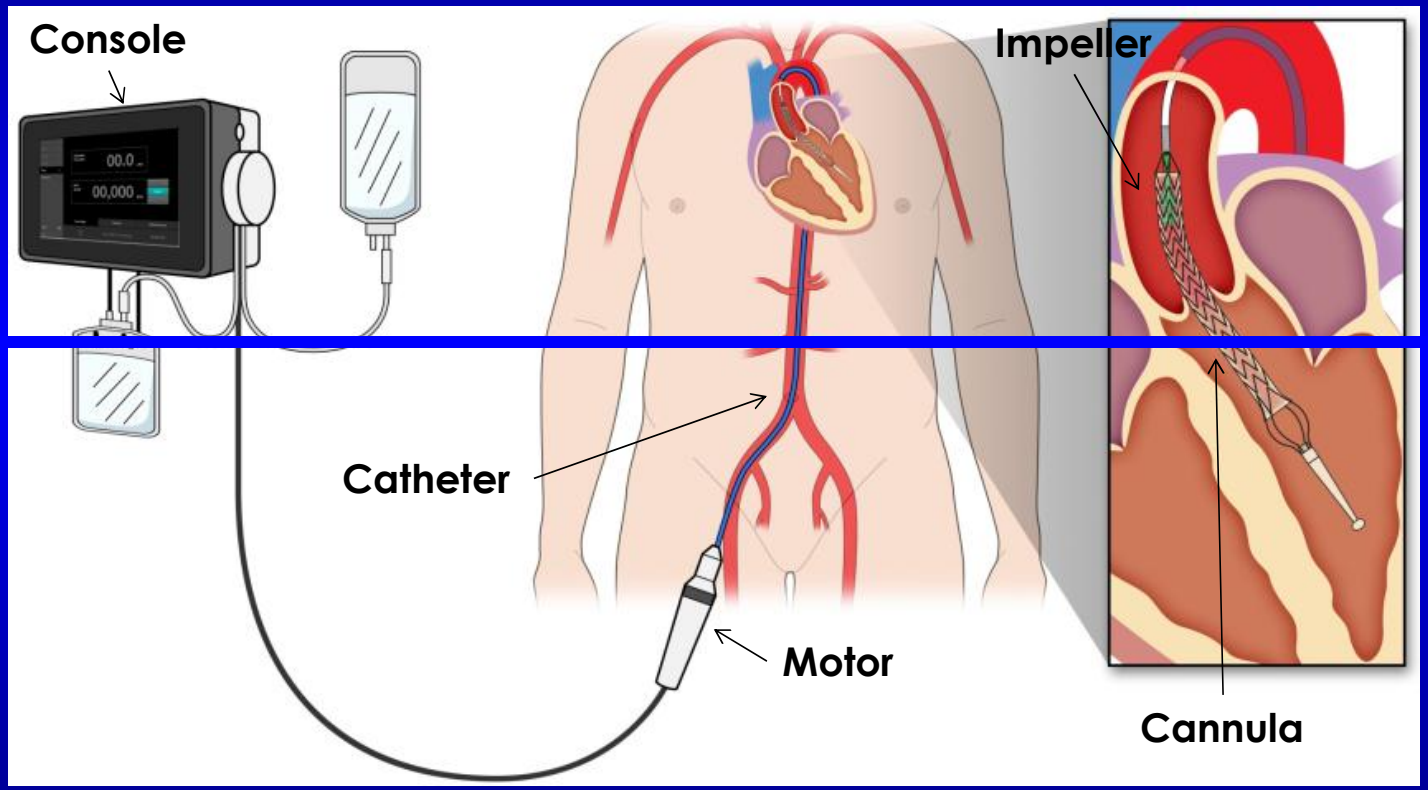
HeartMate PHP System



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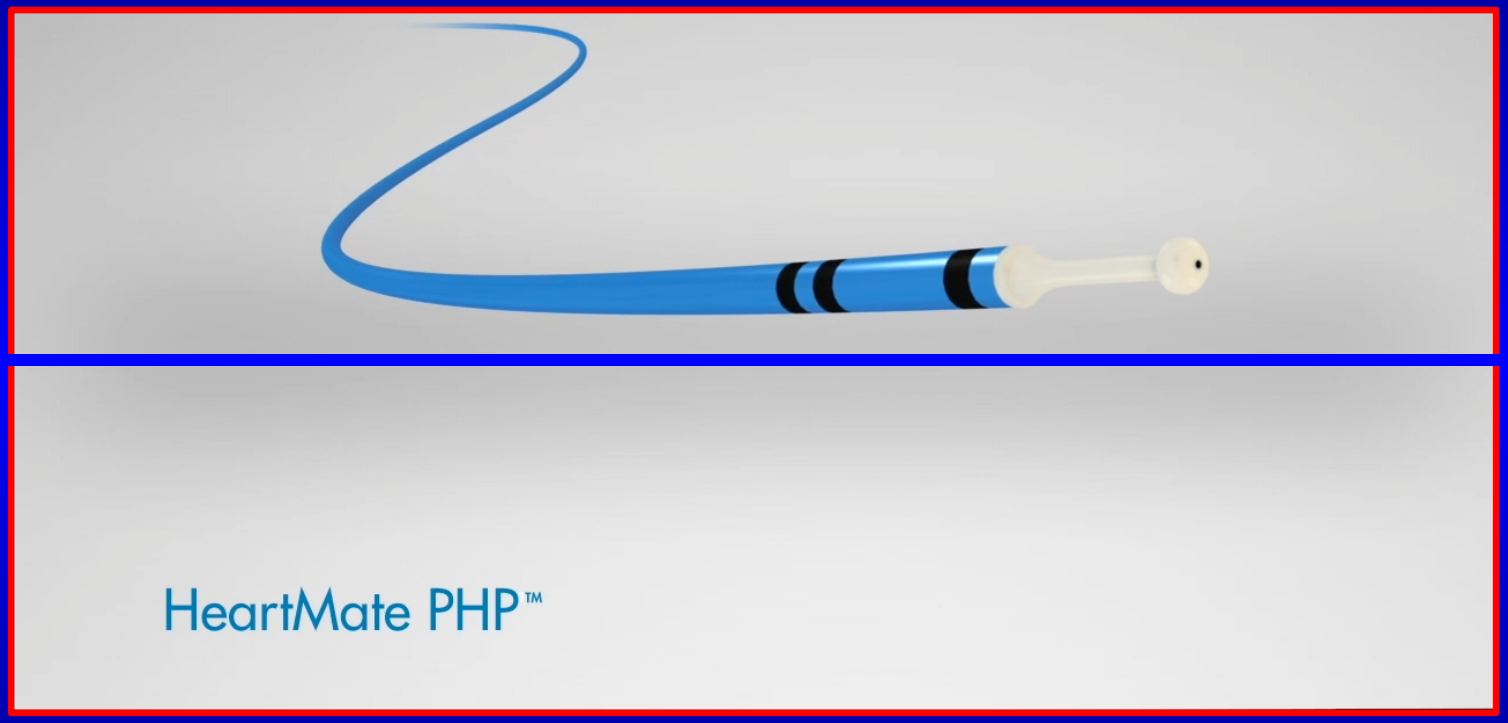
Impl[illegible] Flow



Device Can Be Retracted & Re-Sheathed

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HeartMate PHP Flow Principles

HeartMate PHP flow is a function of:

1. **The speed of the impeller**

   ↑Speed → ↑Flow

   ↓Speed → ↓ Flow

AND

2. **The difference in pressure across the pump**

   ↑ Pressure gradient → ↓ Flow

   ↓ Pressure gradient → ↑ Flow

At any given speed, decreased pressure gradient across the aortic valve will *increase* flow

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SHIELD II U.S. IDE Trial

Supporting patients undergoing HIgh-risk PCI using a high-flow pErcutaneous Left ventricular support Device

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IDE Clinical Study Summary

Primary Objective	Assess the safety and efficacy of the HeartMate PHP in supporting patients with severe symptomatic coronary artery disease with diminished but stable cardiovascular function, who are undergoing elective or urgent **high risk percutaneous coronary interventions (PCI)** but are not candidates for coronary artery bypass graft (CABG) surgery.
Study Design	Prospective, **randomized**, multi-center, open-label trial of the HeartMate PHP at up to **100 sites** in the US. Control device will be the **Abiomed Impella® 2.5 or CP.**
Patient Population	1. Nonrandomized Roll-In Phase: Up to 300 patients undergoing PCI per the Inclusion/Exclusion criteria; up to 3 roll-in patients per site. 2. Randomized Phase: Up to **425 patients** undergoing PCI per the Inclusion/Exclusion criteria.
Study Duration and Follow-up	Data will be collected at baseline, during the PCI procedure, post-procedure, discharge, and **90 days** post device removal. All patients will have a follow-up visit at 90 days post-device removal.

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HeartMate PHP SHIELD I Trial

Design: Prospective, nonrandomized, open-label, multicenter trial

Primary Performance Endpoint:

Freedom from hemodynamic compromise during PCI procedure defined as: Mean Arterial Pressure (MAP) not falling below 60mm Hg for more than 10 minutes during the PCI procedure and additional pressor medication is not required.

Primary Safety Endpoint:

Composite of Major Adverse Events (MAE):

- device-related cardiac death,
- new Q wave myocardial infarction,
- surgical intervention due to device complication or malfunction,
- device-related access site complication requiring intervention or device related limb ischemia,
- cerebral vascular accident (CVA),
- new or worsening aortic valve insufficiency,
- major bleeding complication (BARC ≥ 3),
- severe hypotension

CAUTION: Investigational Device. Limited by Federal (United States) law to investigational use only.

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Percutaneous Heart Pump™

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HeartMate PHP SHIELD I Trial

Key Entrance Criteria

Elective PCI trial

Major Inclusion

- Patient presents with a non-emergent need for complex PCI with an ejection fraction of ≤ 35% requiring hemodynamic support during the procedure and heart team determination that patient is not an optimal surgical candidate.

Major Exclusions

- Emergency PCI
- STEMI within 7 days of procedure
- Cardiac arrest within 7 days of procedure requiring CPR or defibrillation
- Hemodynamic support with the HeartMate PHP post-PCI is anticipated
- Cardiogenic shock
- Aortic valve insufficiency, stenosis, or replacement
- CVA/TIA within 3 months of procedure
- Severe peripheral vascular disease

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HeartMate PHP SHIELD I Baseline Parameters

Number of Patients	46		
Number of Females	7		
	Median	Min	Max
Age (years)	67.5	36	88
MAP (mmHg)	94	70	120
Baseline LVEF*	30		
LM disease	10 (22%)		
Multivessel disease	22 (48%)		
Diabetes Mellitus	22 (48%)		

*as determined by core laboratory. Patient enrollment was based on site-reported EF determination.

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Heart… …oints

No clinically relevant signs of hemolysis

Stable hemodynamics without adjunctive pressors

Successful insertion & removal in all patients

No change in aortic valve function

No procedural MI's

Primary Safety Endpoint*:

Devi…	
New …	…
Surgical intervention due to device c… malfunction	…
Device-related access site complication requiring intervention or device-related limb ischemia	…
CVA	1 (2.2)
New or worsening aortic valve insufficiency	1 (2.2)
Major bleeding complication (BARC ≥ 3)	1 (2.2)
Severe intraprocedural hypotension	0
TOTAL	**4 (8.8)**

There was no clinically significant hemolysis (gross hematuria and or end organ dysfunction).

*CEC adjudicated

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Summary

- HeartMate PHP is a 12 Fr profile catheter based circulatory support device designed to deliver 4-5 L/min forward flow
- A preliminary FIH study and CE Mark trial have demonstrated:
  - Successful insertion, deployment, and removal of HeartMate PHP in all subjects
  - Maintenance of hemodynamic stability during PHP therapy without the need for adjunctive pharmacological or mechanical support
  - No observed device-related adverse events
    - No clinically relevant hemolysis
    - No significant access site complications or bleeding during device use or through 30-day follow-up
    - No significant changes in aortic valve structure or function post procedure, discharge or 30 days
- US Pivotal Trial in high-risk PCI ongoing, first patient enrolled Sept 1, 2015

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SHIELD II

HeartMate PHP US Pivotal IDE Trial

Patient Population	Approximately 425 pts undergoing elective, high-risk PCI
Study Design	2 PHP :1 Impella 2.5 RCT, multicenter Up to 180 pts non-randomized roll-in phase
Primary Efficacy Endpoint	90-day composite of cardiac death, MI, stroke, repeat revascularization (PCI or CABG), BARC 3 or 5 bleeding, aortic regurgitation >2 grades from baseline, severe hypotension requiring vasopressor support
Key Secondary Endpoints	◦ Periprocedural hemodynamics: CO/CI, CP, MAP, PCW, CI ◦ Completeness of revascularization ◦ Device-related access site complications ◦ Duration of hospital stay and economics
Enrollment Criteria	◦ LVEF ≤35%, and ▫ UPLM or last remaining conduit PCI, or ▫ PCI with 3 vessel CAD ◦ NO shock, mod/sev AI/AS, AVR, recent MI

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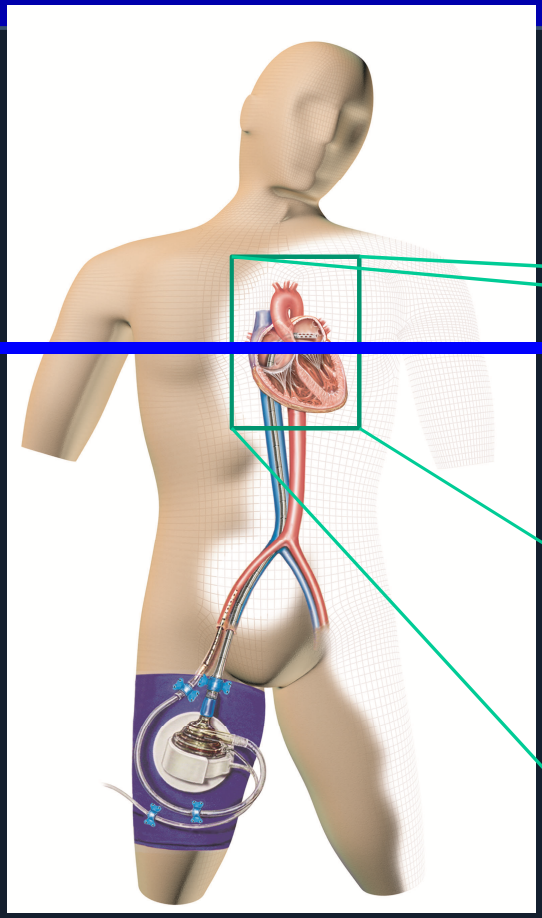
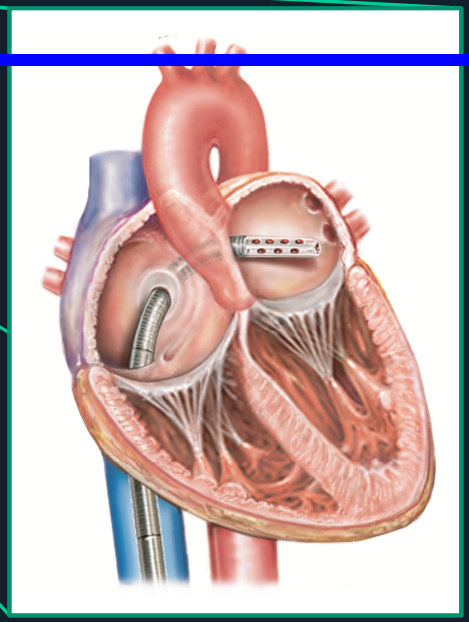
The TandemHeart Transseptal Cannula



Withdraws oxygenated blood from the left atrium via a transseptal cannula; returns to the femoral artery.

Creates an extracorporeal circuit that completely bypasses the left ventricle, our target for work reduction.



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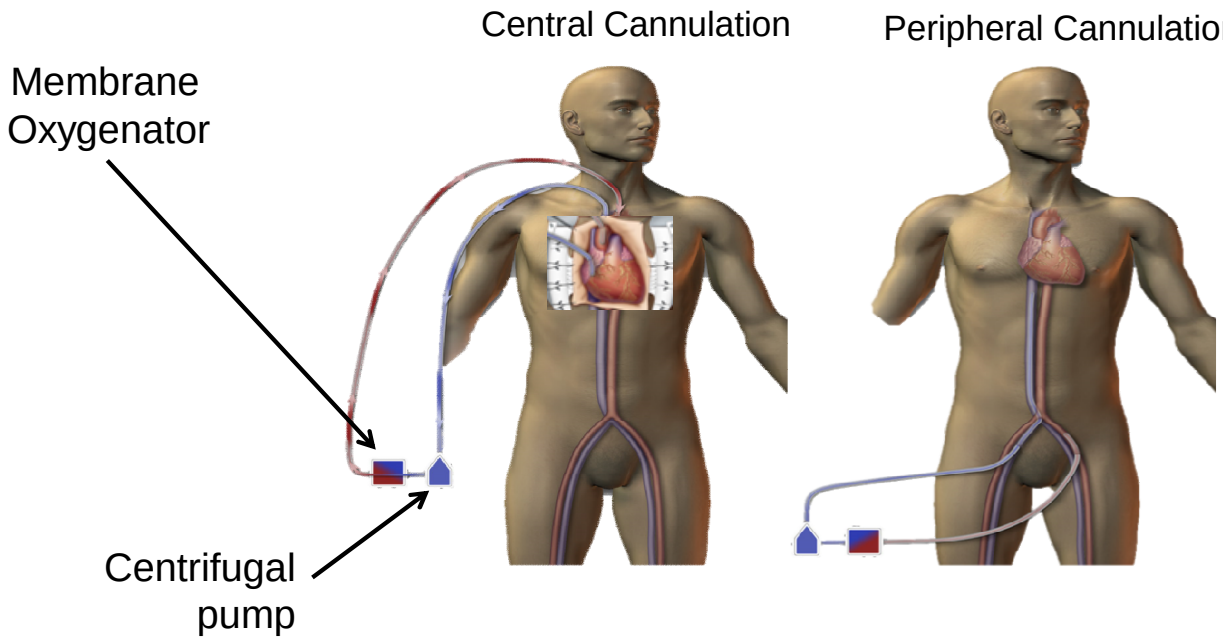
Contemporary ECMO System Components



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Conclusions

- High risk PCI is increasing as patient and lesion complexity increase.
- Complex patients have higher mortality and morbidity.
- Prophylactic use of mechanical circulatory support should be considered when a high risk of hemodynamic compromise exists based on anatomical and clinical variables.