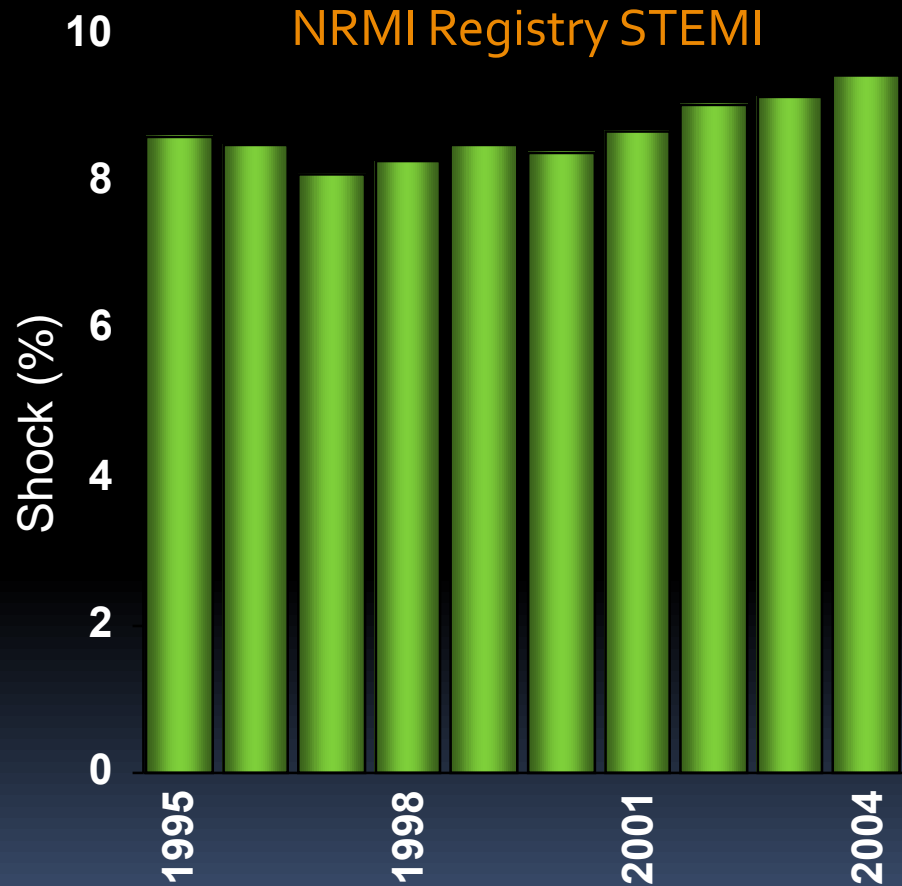


THE ROLE OF HEMODYNAMIC SUPPORT IN EMERGENT PERCUTANEOUS REVASCULARIZATION

HM Thai, MD, FACC, FSCAI
Associate Professor of Medicine
Associate Director,
Interventional Cardiology
Fellowship
University of Arizona

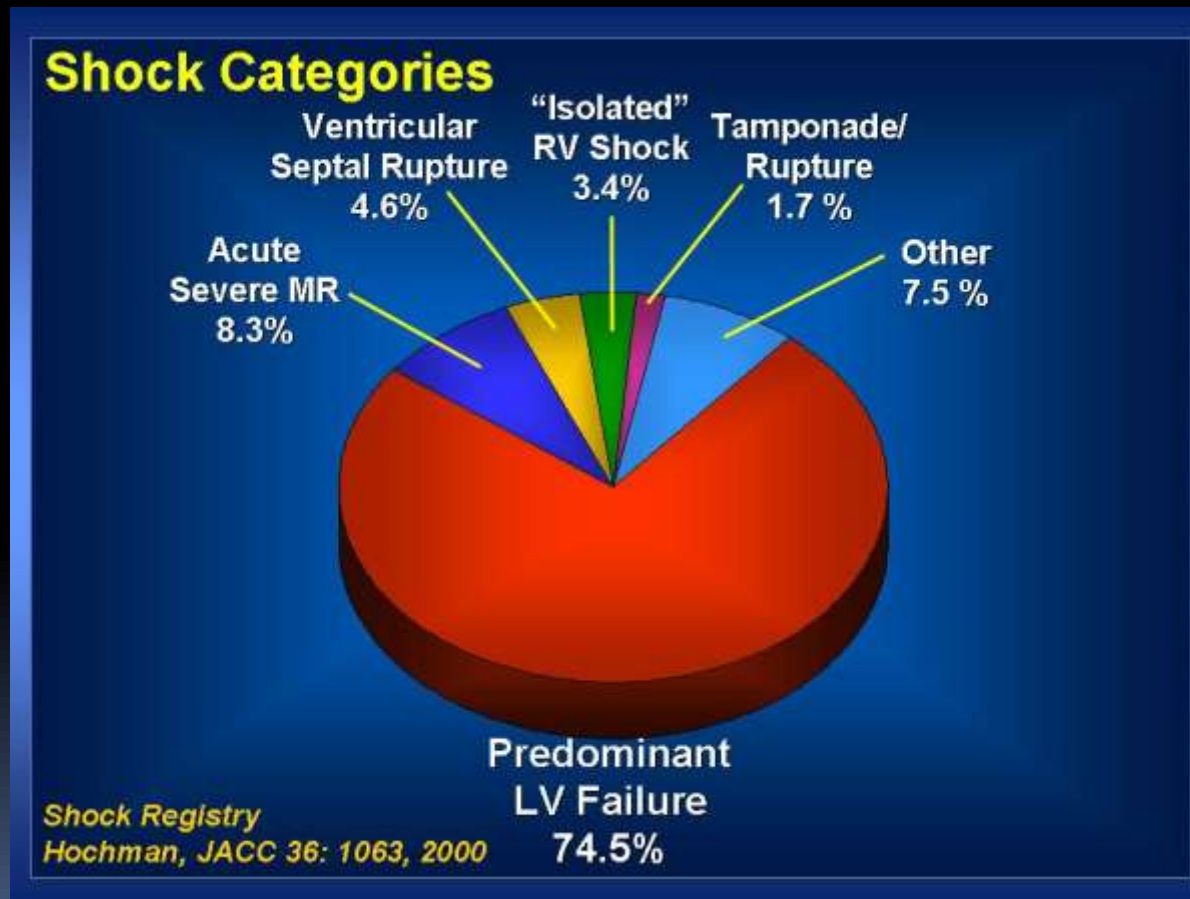


Cardiogenic Shock Incidence

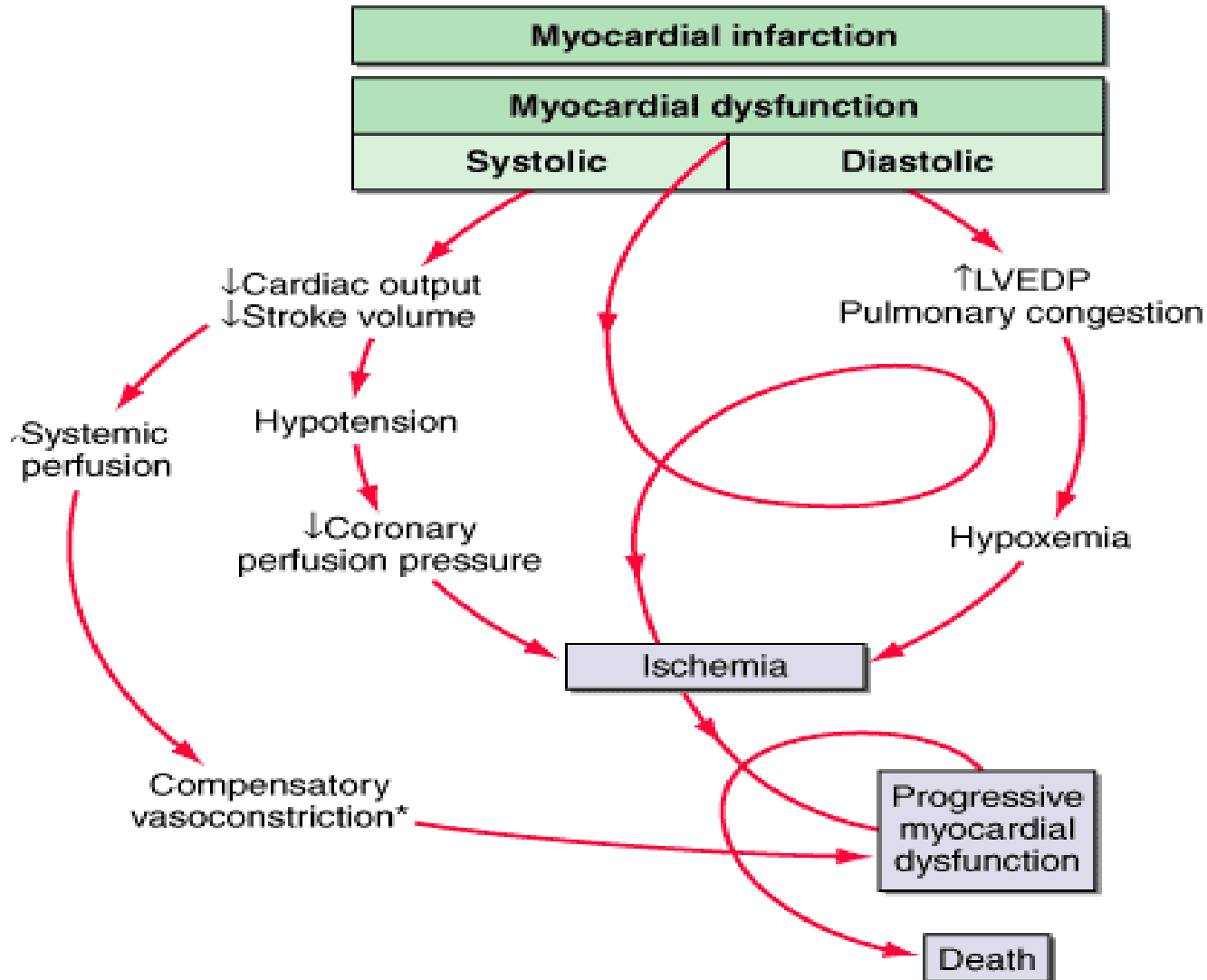


- ~8% of STEMI in NRMI
- 2% of NSTEMI
- ~50,000 patients per year
- 11% 2014

Cardiogenic Shock Etiology Shock Trial and Registry

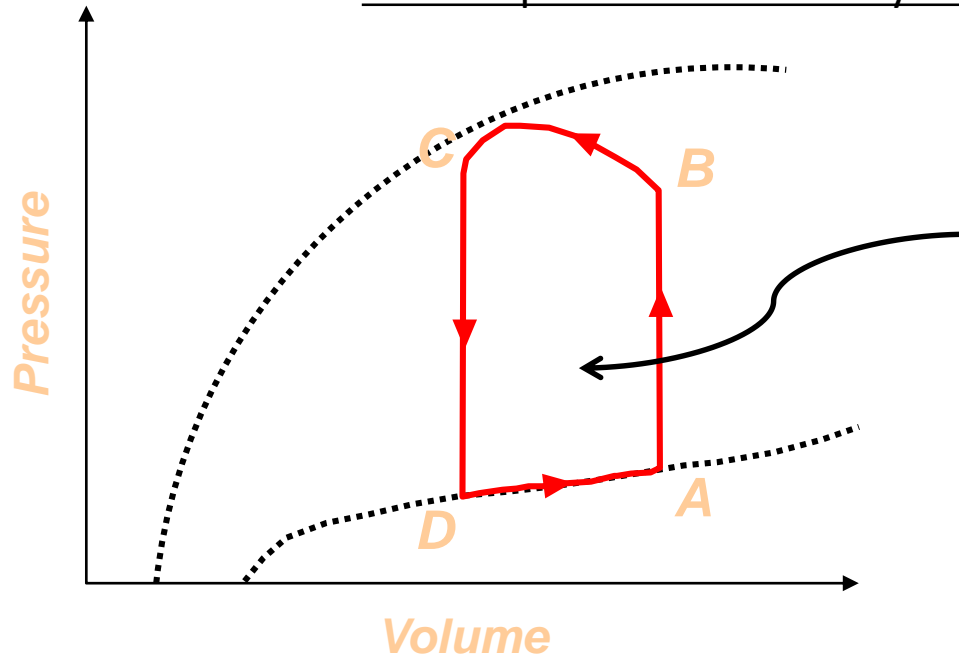


Pathophysiology



“Unloading” ... Reducing Work (O_2 demand) of the Myocardium

“PV Loop” of the Cardiac Cycle

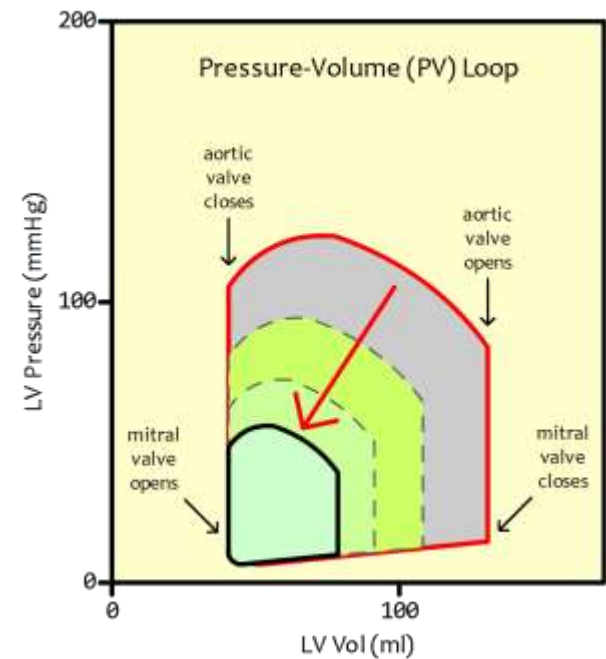
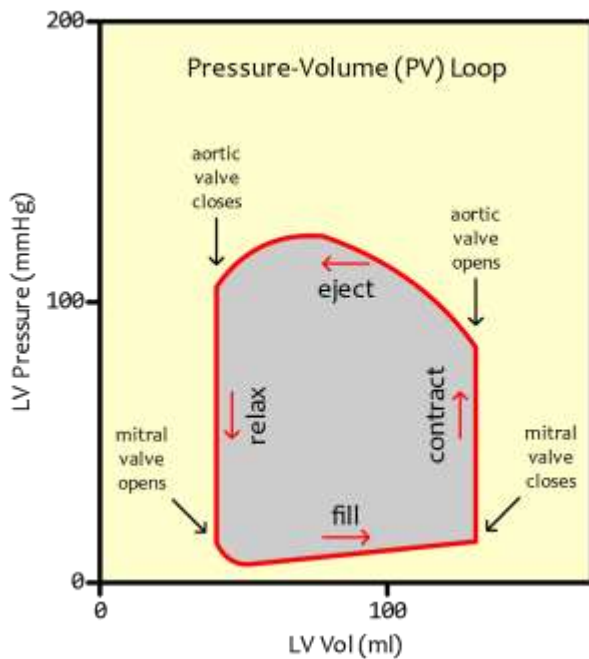


- A. End Diastole – Mitral Valve Closure
- B. Aortic Valve Opening
- C. End Systole - Aortic Valve Closure
- D. Mitral Valve Opening

- $Work = Pressure \times Volume$
- Ventricular “Work” = Area of PV Loop; proportional to O_2 demand
- Unloading Work = Reducing Area of PV Loop

Measuring Performance in Circulatory Support

The area inside the resulting PV loop is equal to the work being done by the heart in a single cardiac cycle



Smaller area inside the PV loop means less work being done by the LV

The Evidence for Pressors in Shock

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

MARCH 4, 2010

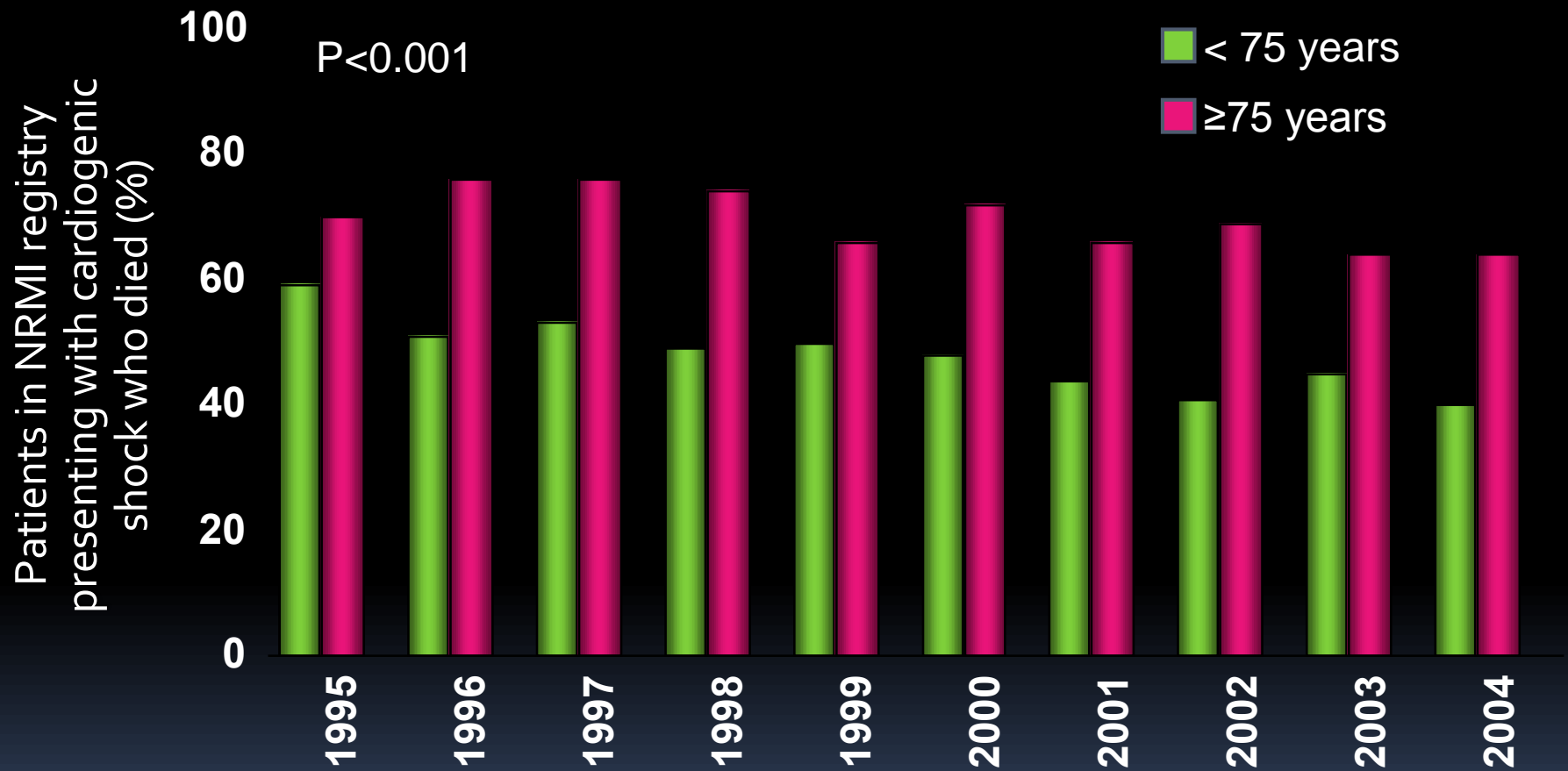
VOL. 362 NO. 9

Comparison of Dopamine and Norepinephrine in the Treatment of Shock

Daniel De Backer, M.D., Ph.D., Patrick Biston, M.D., Jacques Devriendt, M.D., Christian Madl, M.D.,
Didier Chochrad, M.D., Cesar Aldecoa, M.D., Alexandre Brasseur, M.D., Pierre Defrance, M.D.,
Philippe Gottignies, M.D., and Jean-Louis Vincent, M.D., Ph.D., for the SOAP II Investigators*

A subgroup analysis showed that dopamine, as compared with norepinephrine, was associated with an increased rate of death at 28 days among the 280 patients with cardiogenic shock but not among the 1044 patients with septic shock or the 263 with hypovolemic shock ($P=0.03$ for cardiogenic shock, $P=0.19$ for septic shock, and $P=0.84$ for hypovolemic shock, in Kaplan–Meier analyses).

Cardiogenic Shock Prognosis

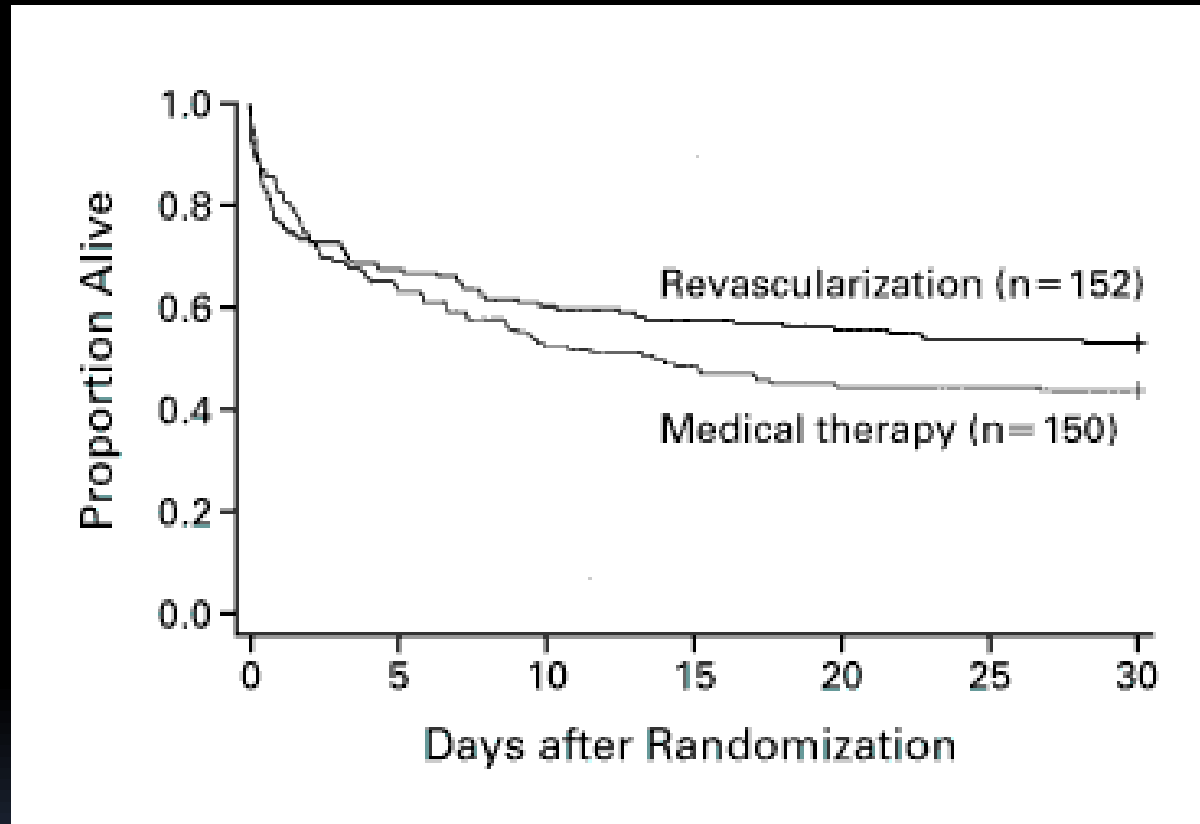


Clinical Goals of Emergent Support

- Revascularization
- Restore Stable Hemodynamics
 - reversing decline of end-organ perfusion, reducing risk of end-organ failure, breaking cycle of cardiogenic shock
- Minimize Infarct Size
 - reducing myocardial ischemia, halting cell damage, maximizing residual cardiac function
- Ease-of-Use & Safety
 - consistent with critical treatment time scenarios and risk-benefit considerations of emergency care

SHOCK Trial

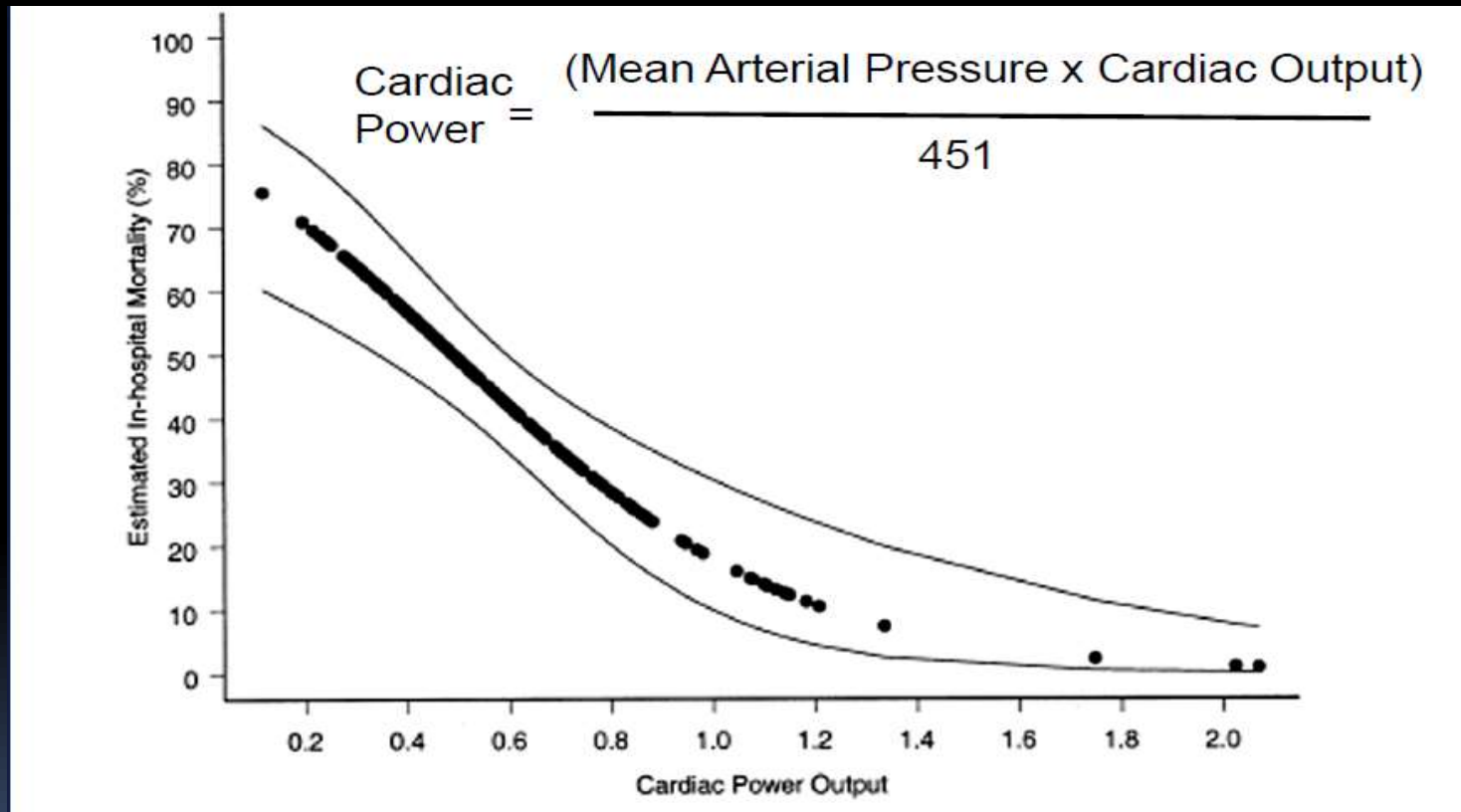
Early intervention vs. Conservative medical management



30-day Mortality – 44.0% vs 53.3%

Cardiac Power

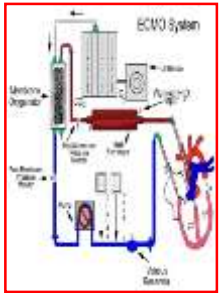
The Most Important Predictor of Mortality in the SHOCK Trial



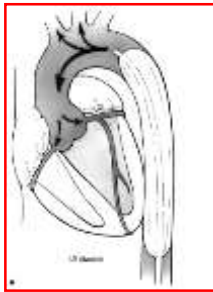
2011 ACCF/AHA/SCAI PCI Guidelines

- Class I: Section 5.2.3 Cardiogenic Shock:
Recommendation: "A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (384,424–427)." This classification includes the statement: "Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients."
- Class II b: Section 5.6 Percutaneous Hemodynamic Support Devices:
Recommendation: "Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients."

Mechanical Assist: Historical Perspectives



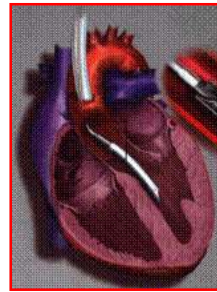
ECMO



IABP



CPS



Hemopump



TandemHeart



Impella



70's

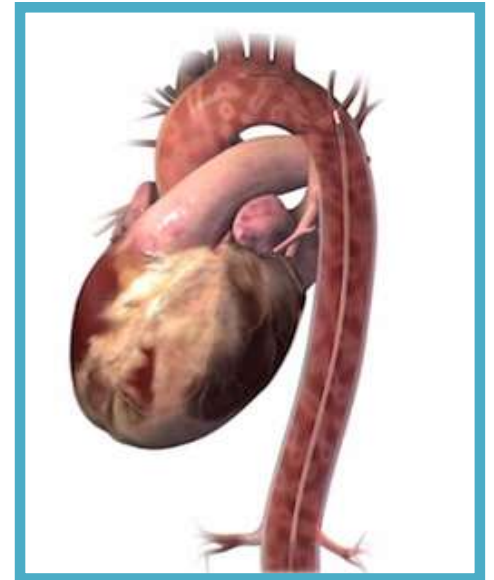
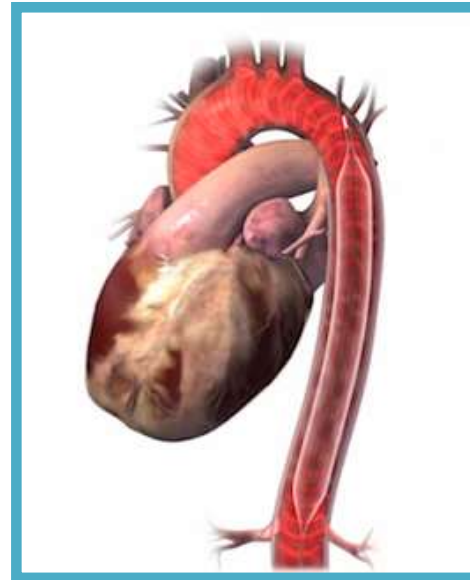
80's

90's

00's

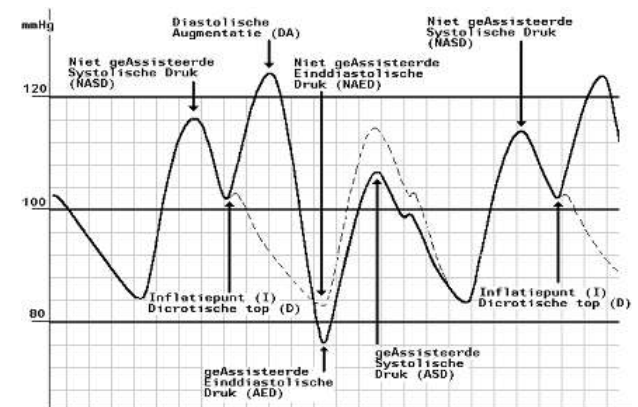
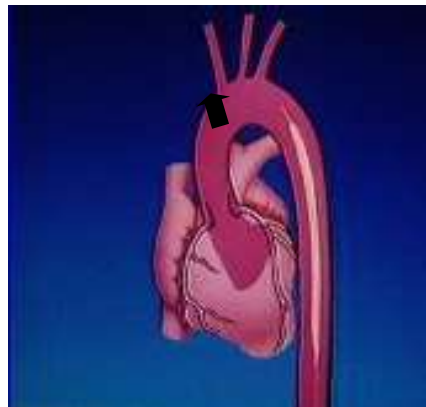
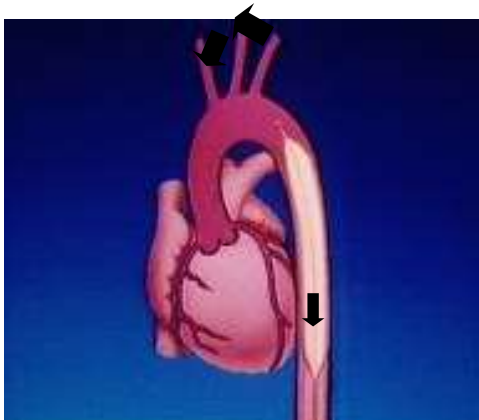
PRIMARY GOAL OF IABP THERAPY

- Increase blood flow to the coronary arteries by augmenting diastole
- Decrease left ventricular end diastolic pressure and systolic pressure to improve pumping efficiency and improve cardiac output



Intra Aortic Balloon Counterpulsation

- Hemodynamic stabilization:
 - cardiac index \uparrow and early diastolic pressure \uparrow
 - diastolic blood flow augmentation in the coronary and systemic circulation
 - systolic reduction in afterload and aortic impedance
- LV recovery / infarct size reduction
 - peak left ventricular wall stress \downarrow
 - myocardial oxygen consumption \downarrow



IABP in daily clinical practice

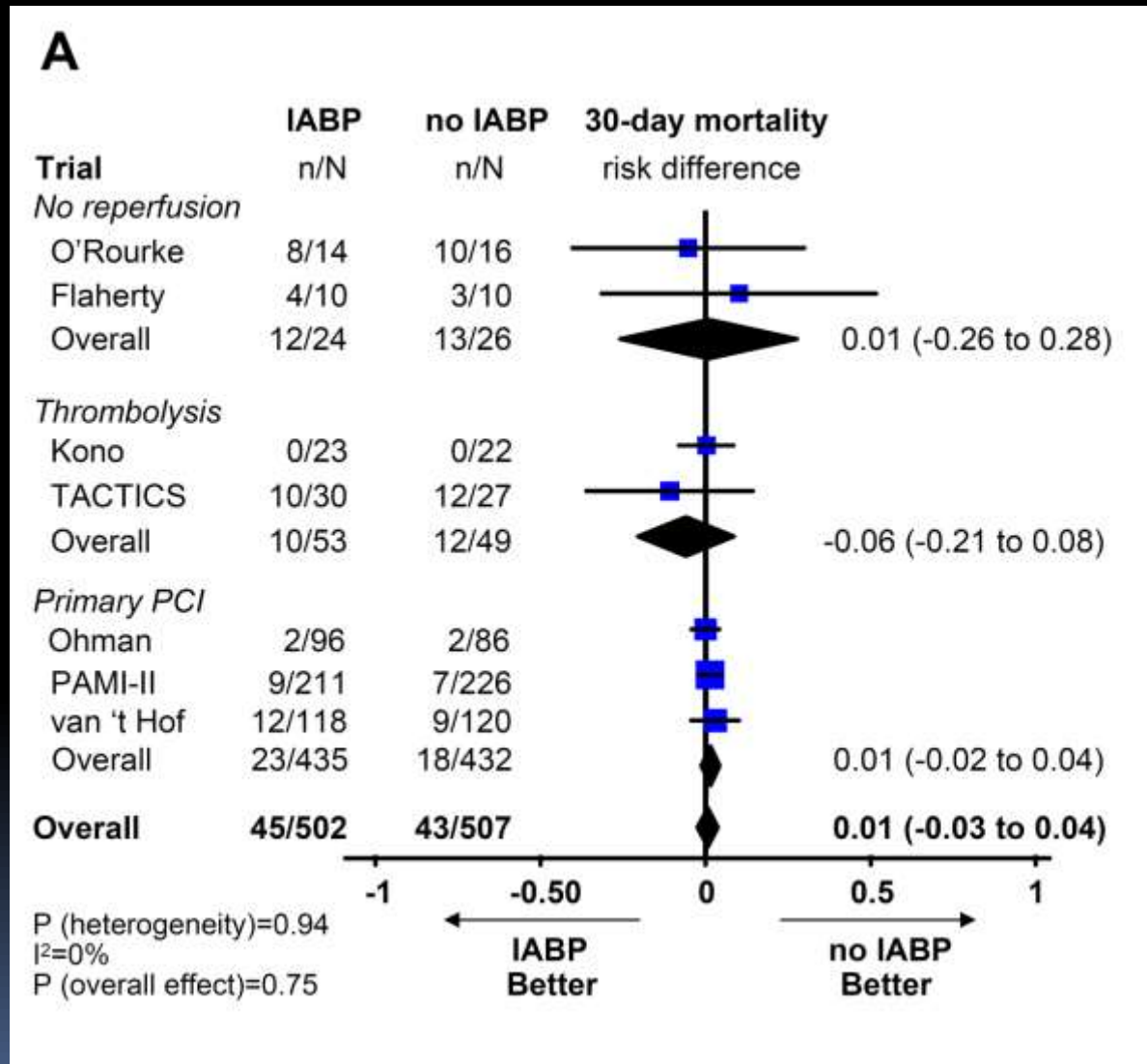
Table 1. Principal Indications for Intra-Aortic Balloon Pump Use in 5,495 Patients With AMI

Cardiogenic shock	27.3%
Support for high-risk catheterization and angioplasty	27.2%
Mechanical complications of AMI (VSD and PMR)	11.7%
Pre-operative support for high-risk cardiac surgery	11.2%
Refractory post-MI unstable angina	10.0%
Weaning from cardiopulmonary bypass	4.8%
Refractory left ventricular failure	4.5%
Refractory ventricular arrhythmias	1.3%
Intra-operative support during surgery	0.5%
Other or indication not recorded	1.5%

AMI = acute myocardial infarction; MI = myocardial infarction; PMR = papillary muscle rupture; VSD = ventricular septal defect.

IABP vs Control in HR-STEMI – 30-day mortality

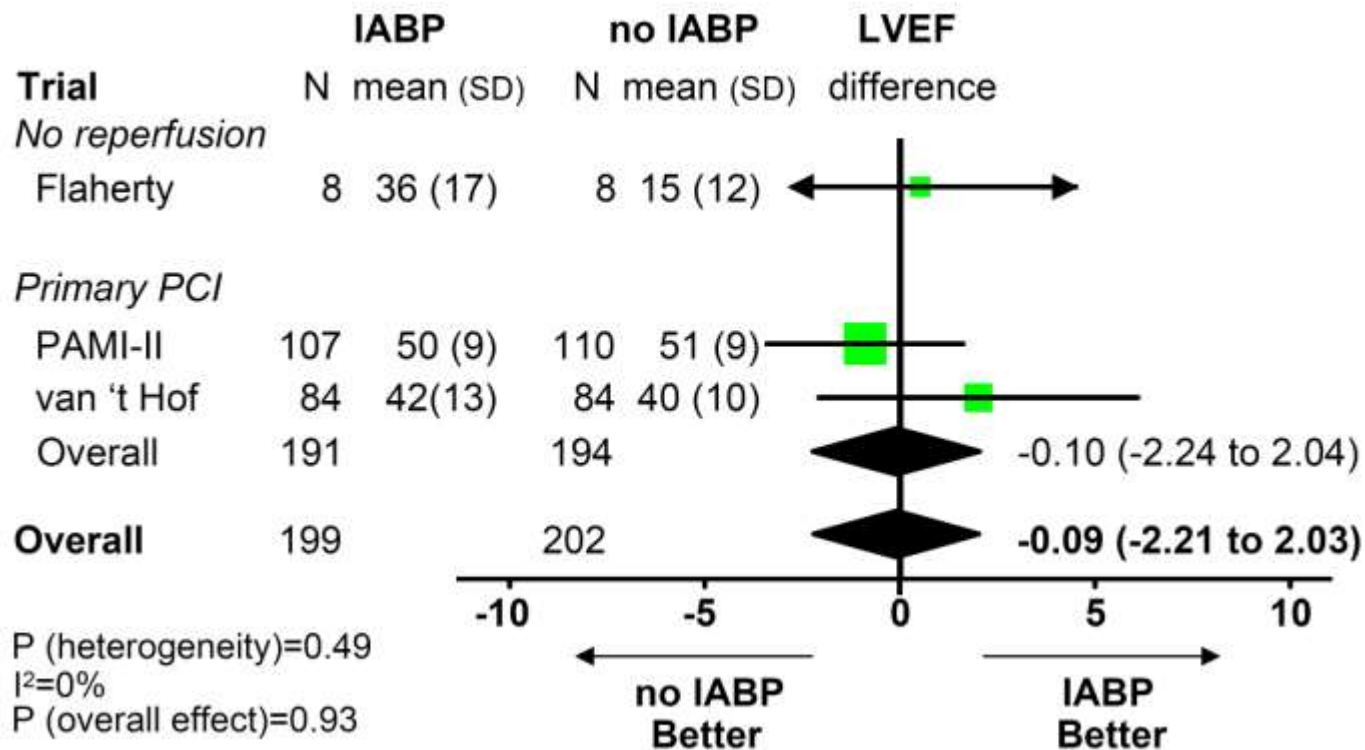
Randomized controlled trials



IABP vs Control in HR-STEMI – LVEF

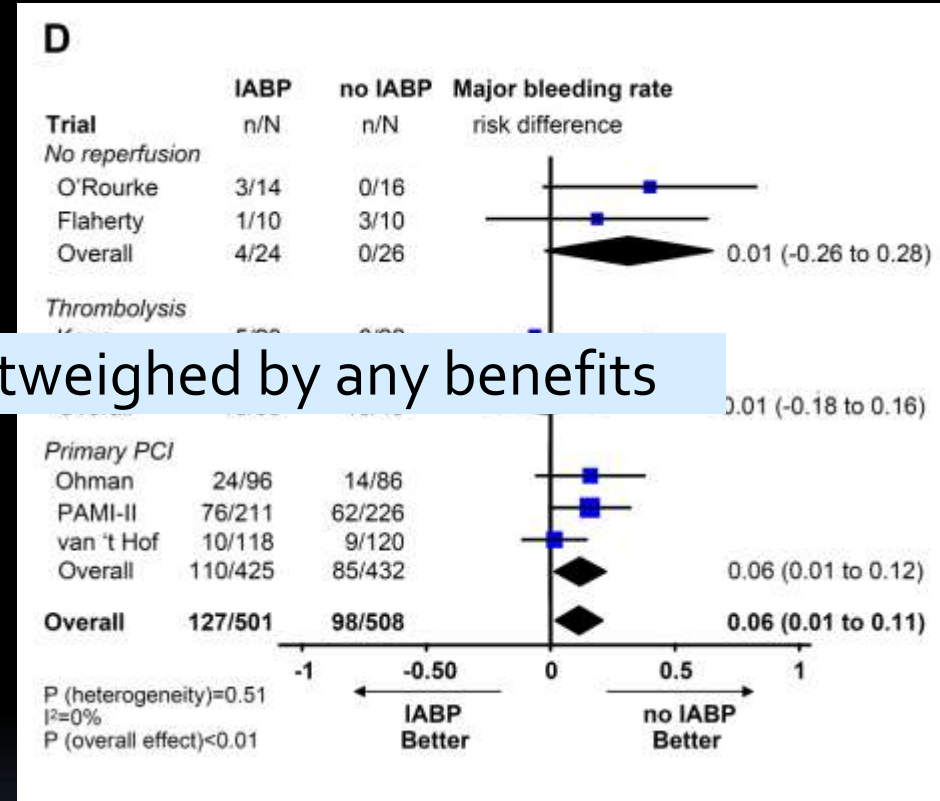
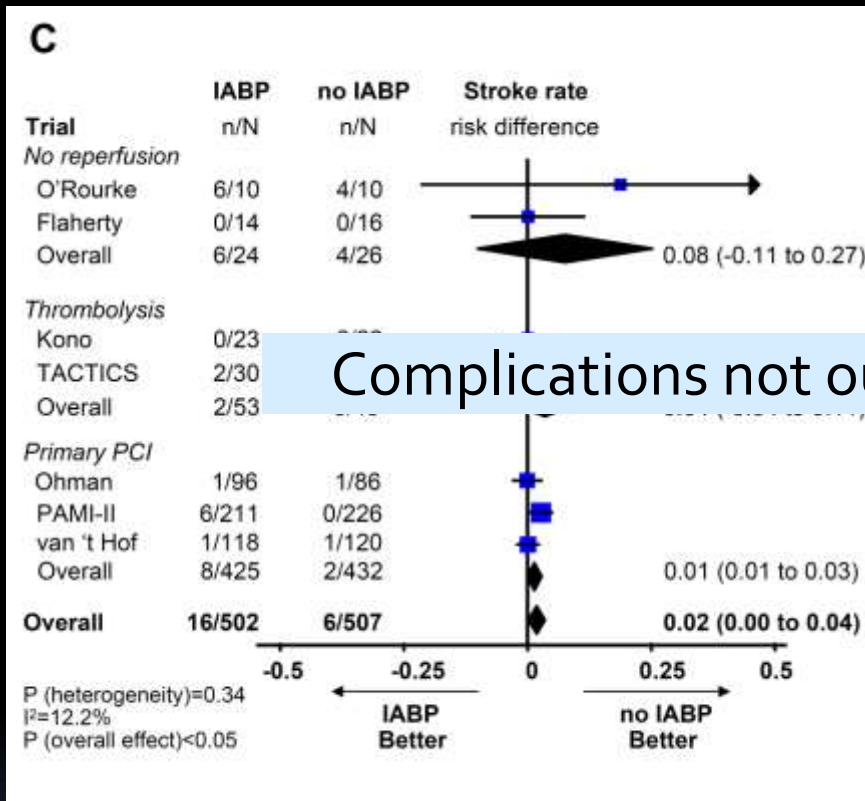
Randomized controlled trials

B



IABP vs Control in HR-STEMI – Stroke / Bleeding

Randomized controlled trials



Complications not outweighed by any benefits

IABP 2% increase in Stroke

IABP 6% increase in Bleeding

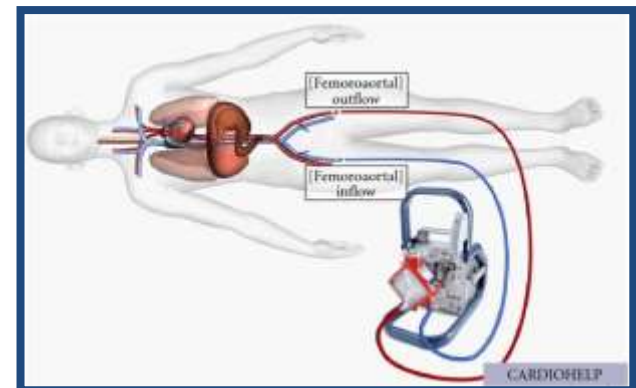
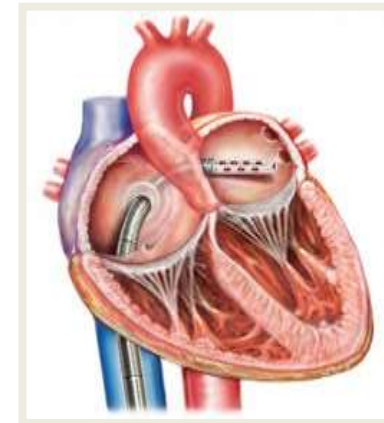
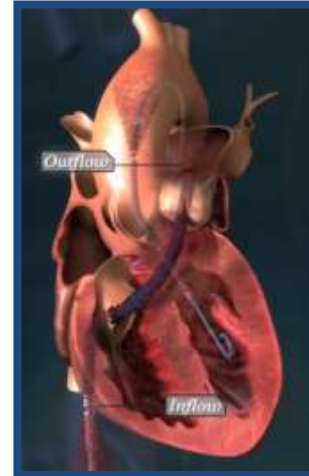
PRIMARY GOAL OF pVADS & ECLS

Primary Goal of pVADs

- Actively unload the left ventricle
- Removes blood from the left ventricle and places in the ascending aorta

Primary Goal of ECLS

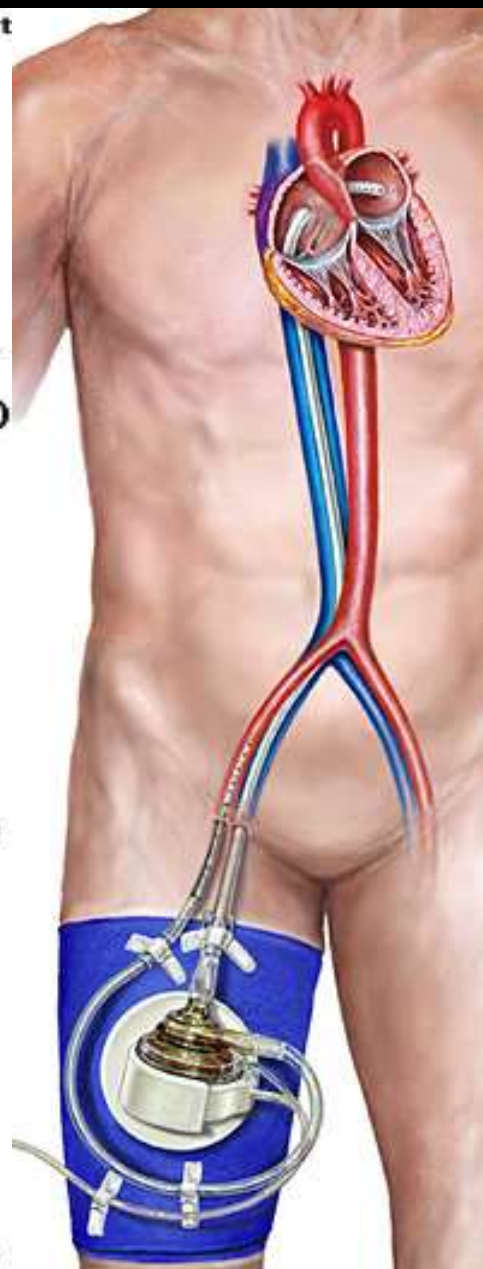
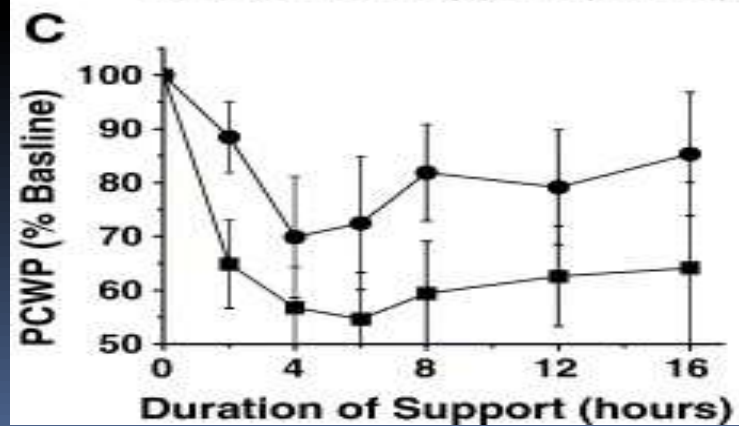
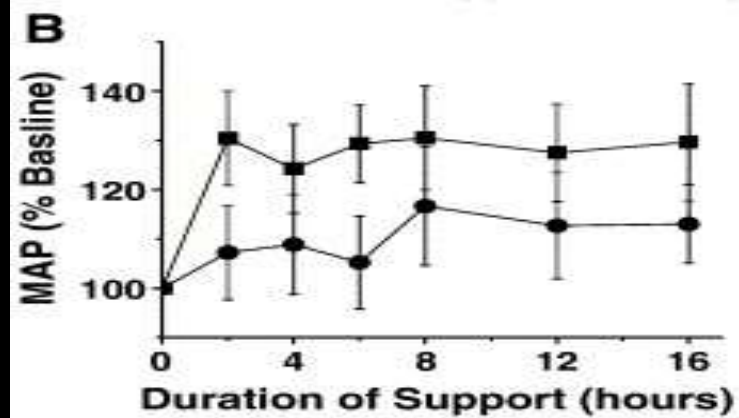
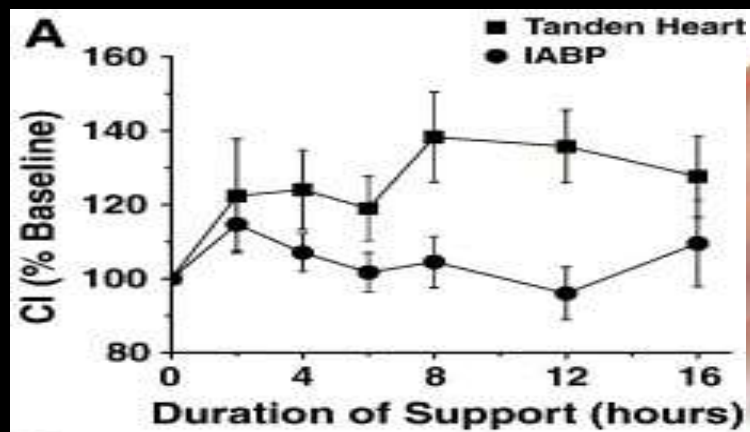
- Removes blood from the left atrium and returns to the circulation
- Provides extracorporeal support to replace or support cardiac circulation
- Provides oxygenation and CO2 removal



Percutaneous Devices for Hemodynamic Support: Technical Features

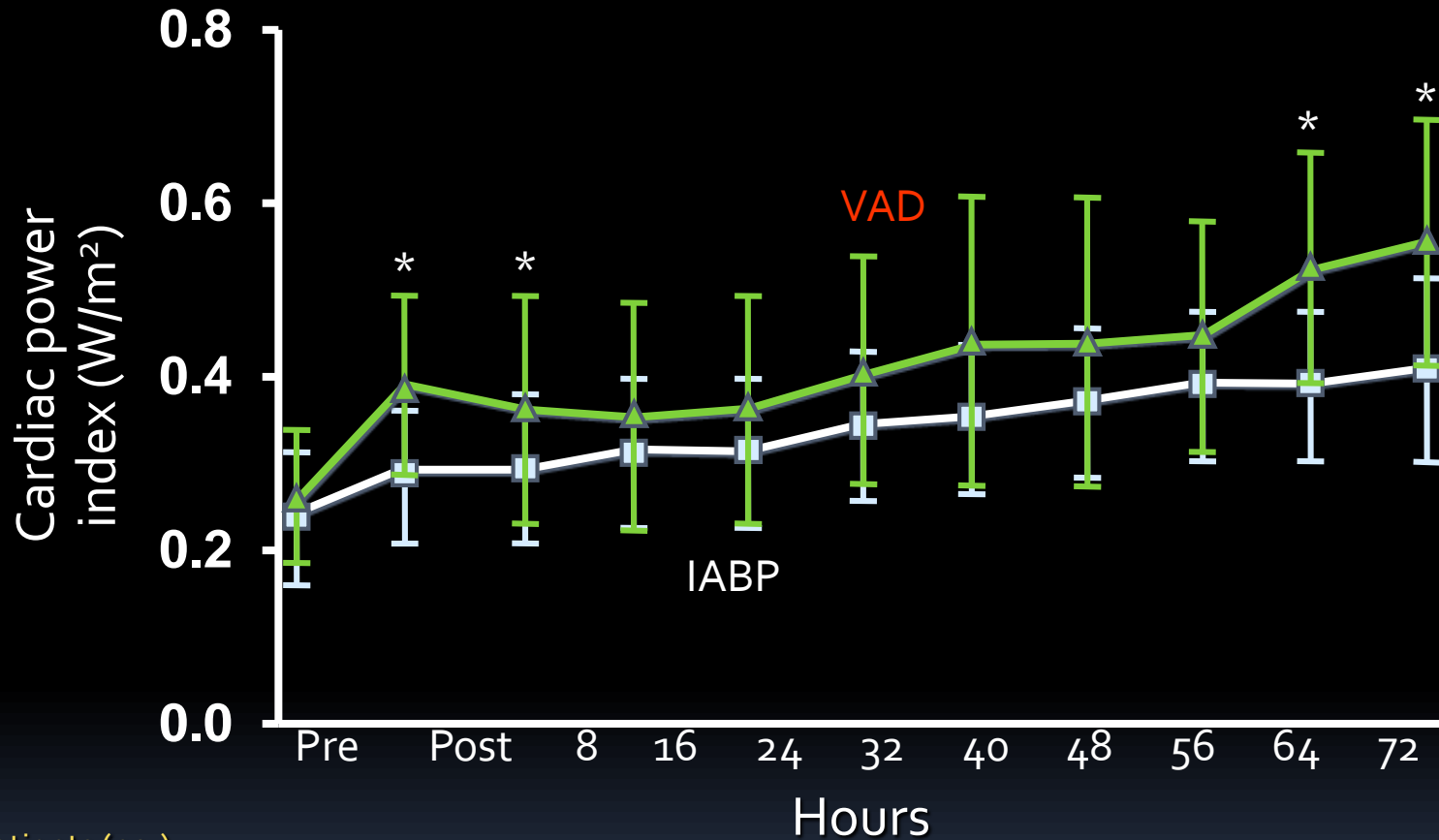
	TandemHeart	Impella LP 5.0	Impella 2.5
Cannula size	21 Vein ,15-17 Arterial (12 Fr arterial x 2)	21 Fr	13 Fr
Flow (L/min)	4	5	2.5
Pump speed (rpm)	7500 (Centrifugal)	33,000 (axial)	33,000 (axial)
Insertion	FA + LA	FA cutdown	FA perc.
Anticoagulation	Yes	Yes	Yes
Cost (relative to IABP)	+++++	++++	+++

Modified from Thiele,
Eur Heart J 28: 2057, 2007



Randomized Trial of Tandem Heart vs IABP

n=41



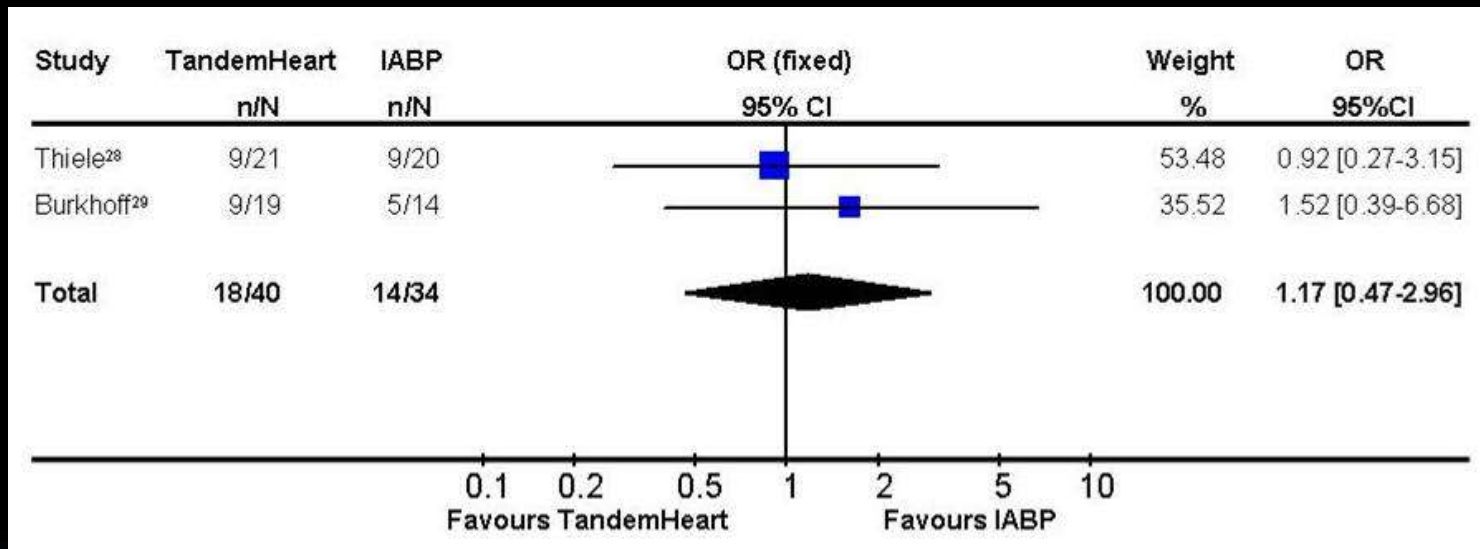
Patients (no.)

IABP	20	20	17	17	16	16	16	16	16	16	16
VAD	21	21	21	21	21	19	19	18	18	17	17

Primary endpoint: cardiac power index = CI x mean arterial pressure x 0.0022

Tandem Heart

Randomized Trials TandemHeart vs. IABP in STEMI + CS Meta-analysis



Venous sheath 21F
Transseptal puncture - inflow left atrium.
15F or 17F arterial cannulae.

average insertion time > 30 45–60 min
ACT > 200 seconds during support

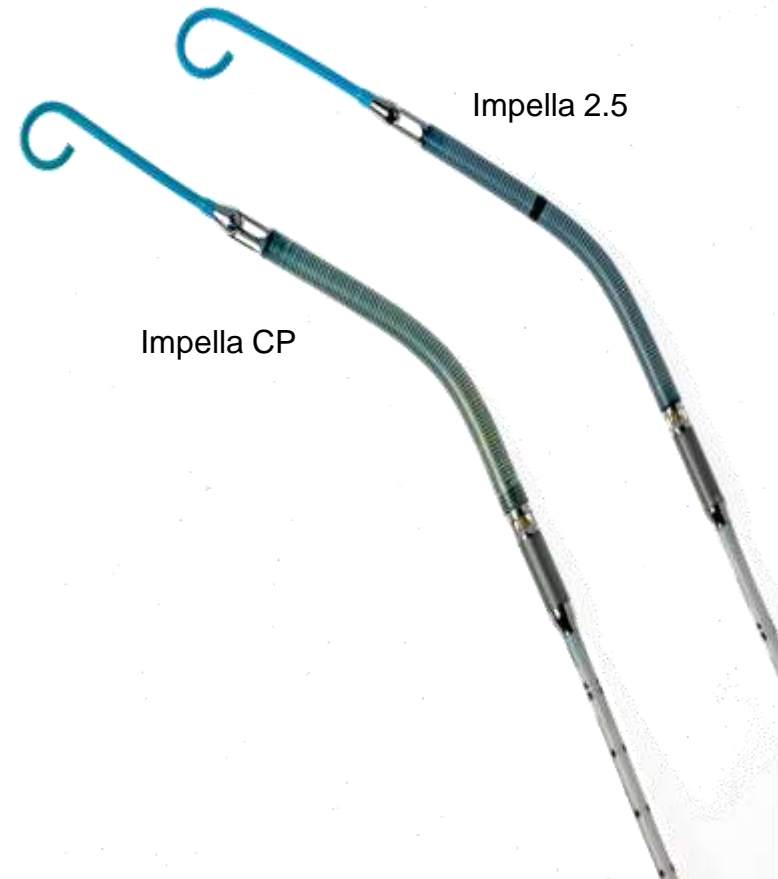
Not easy
Time consuming
Learning curve
Limb ischemia
Bleeding


Impella



Impella CP™ – Impella® 2.5 Comparison

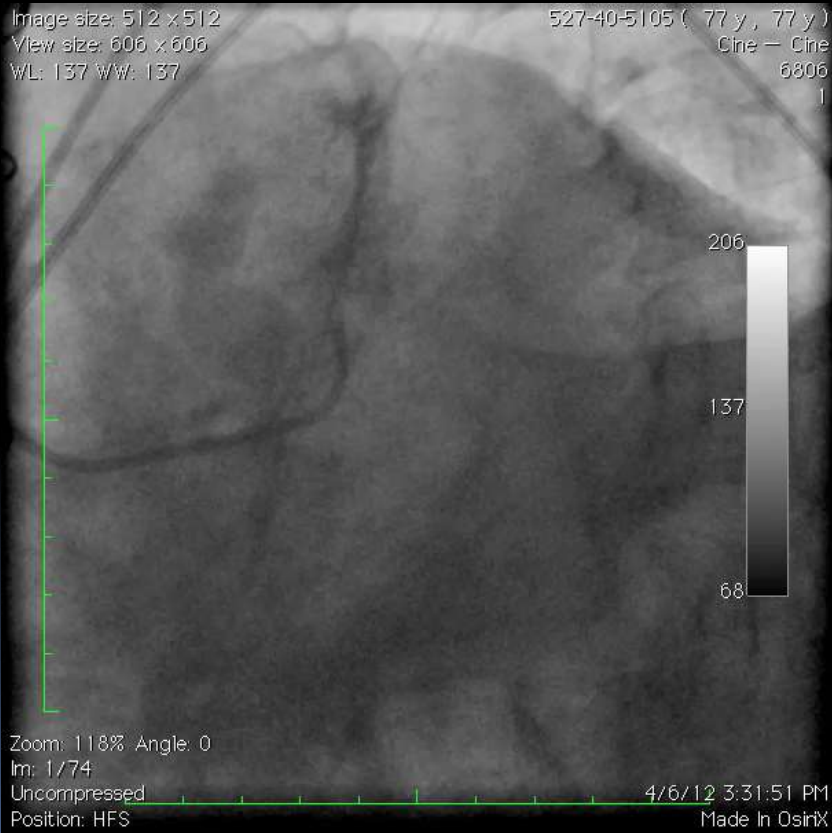
	Impella 2.5	Impella CP
Mean Flow Rate (L/min, max)	2.3 to 2.5	3.3. to 3.5 (at P9)
Catheter Size	9 Fr	9 Fr
Pump Size	12 Fr	14 Fr
Insertion Method	Percutaneous via 13 Fr Introducer Sheath	Percutaneous via 14 Fr Introducer Sheath
Guidewire	0.018" Silicone Wire	0.018" PTFE Wire
Placement Measurement	Fluid-filled Pressure Lumen	Fluid-filled Pressure Lumen
Cannula Geometry	Curved, Pigtail	Curved, Pigtail
RPM	51,000	46,000
P-level	P1-P9 (Boost Mode)	P1-P9



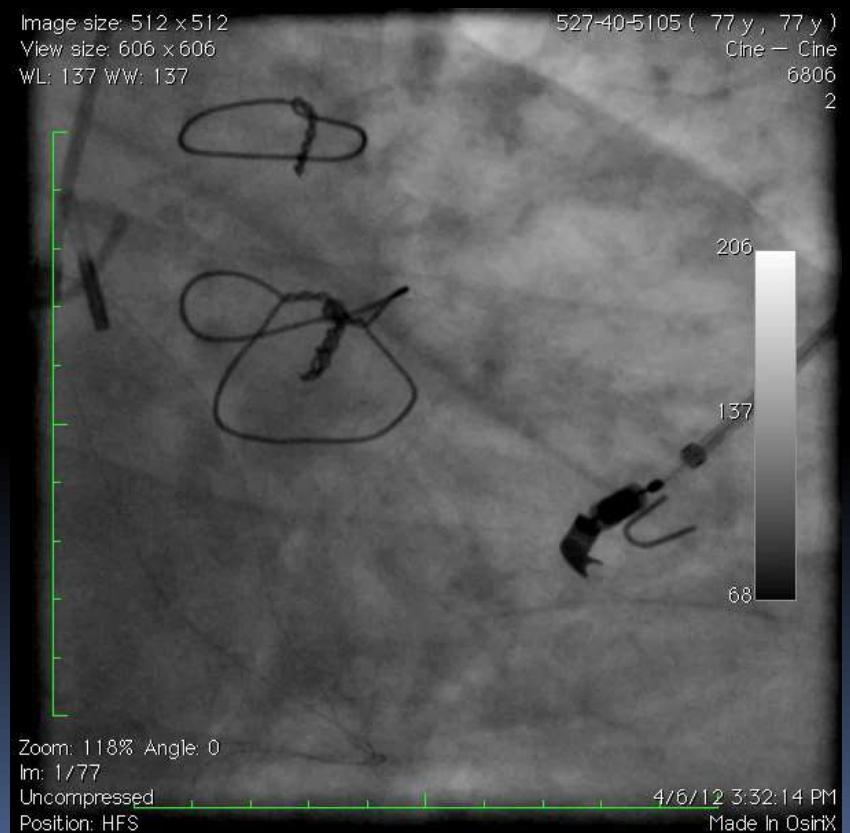
- 
- 89 yo male with admitted with NSTEMI
 - PMH:
 - MVR (bioprosthetic) – No CABG
 - DM
 - Treated conservatively with heparin/integrilin/ASA/plavix
 - In the next 24 hours: Developed pulmonary edema and early shock
 - Taken to the cath lab


89 yo male with multi-vessel CAD, NSTEMI LVEF 20% in early cardiogenic shock

89 yo male with multivessel CAD




LVEF 20%, turned down by CT surgery





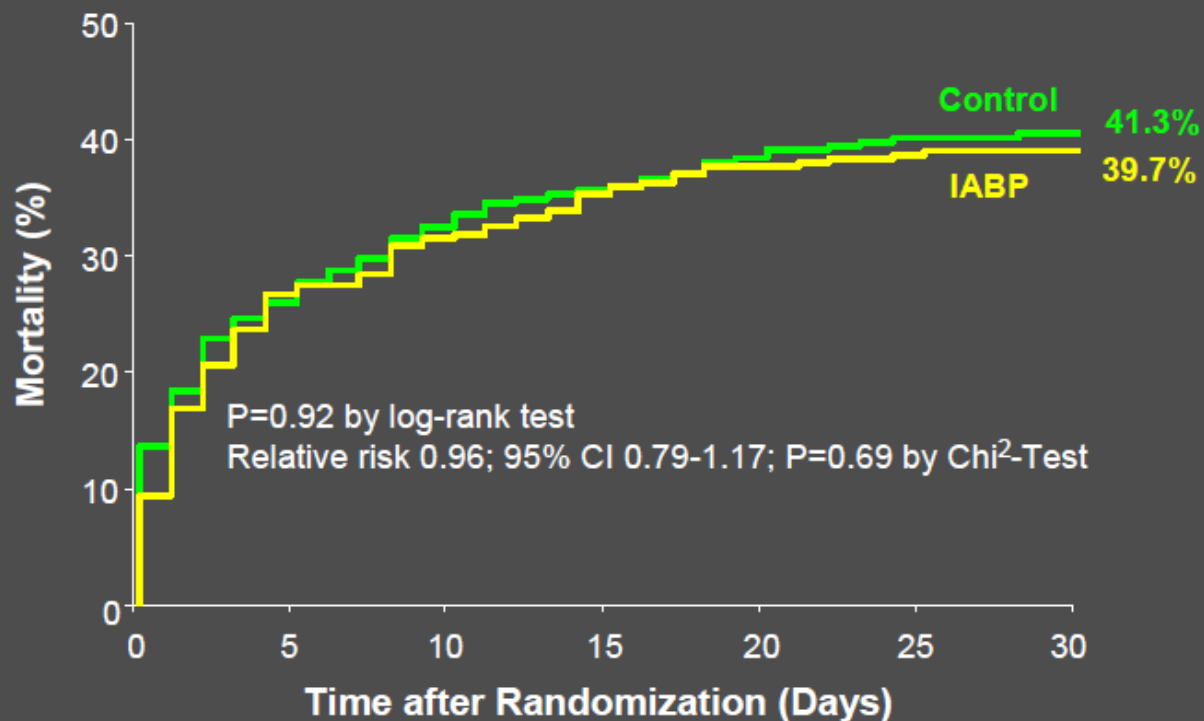
What is the contemporary clinical evidence in emergent cases?

- Hemodynamic support in clinical trials
 - IABP vs Impella
 - Cardiogenic shock
- 

SHOCK II

Results

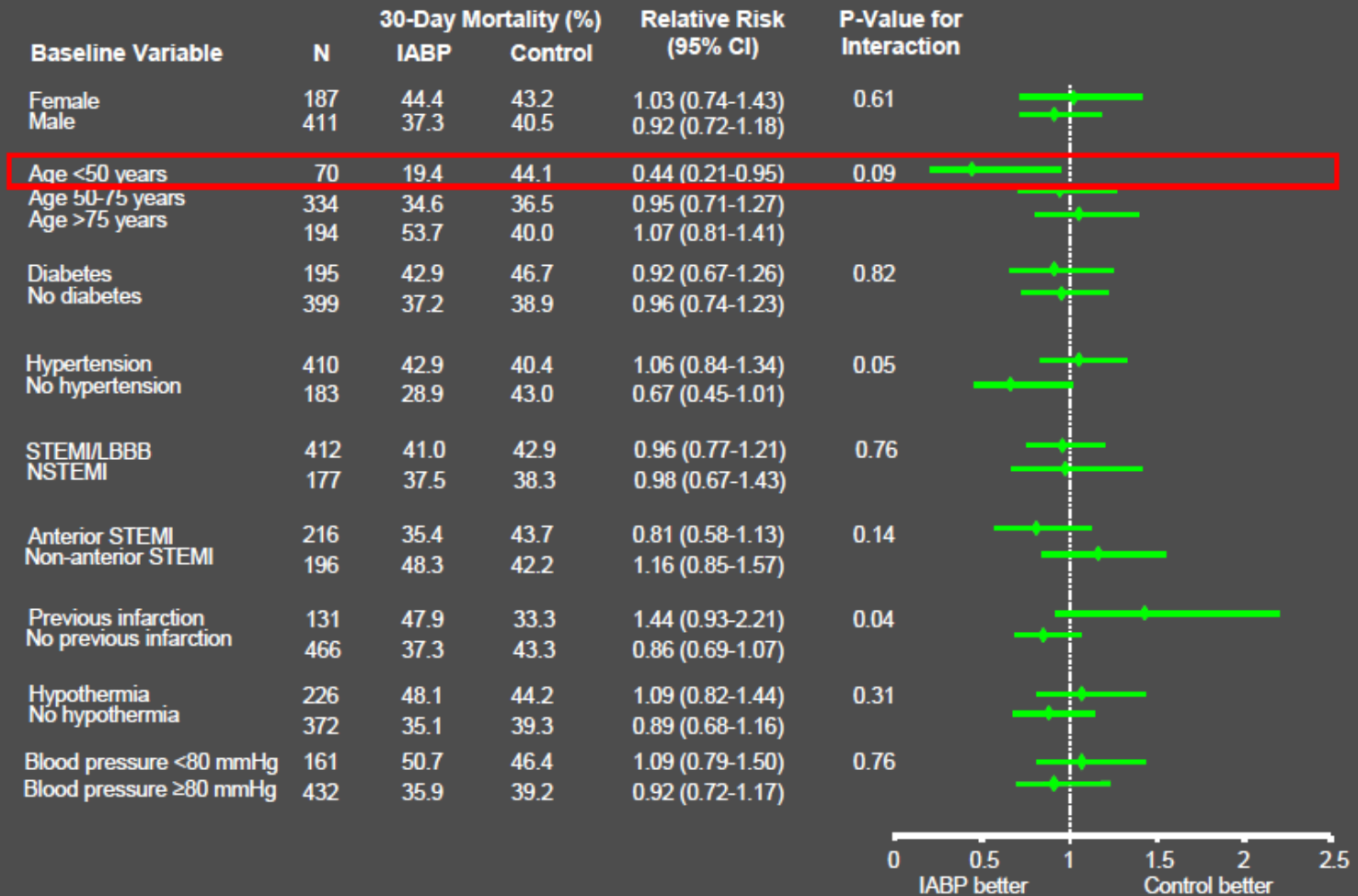
Primary Study Endpoint (30-Day Mortality)



SHOCK II

Results

Subgroups (30-Day Mortality)



SHOCK II

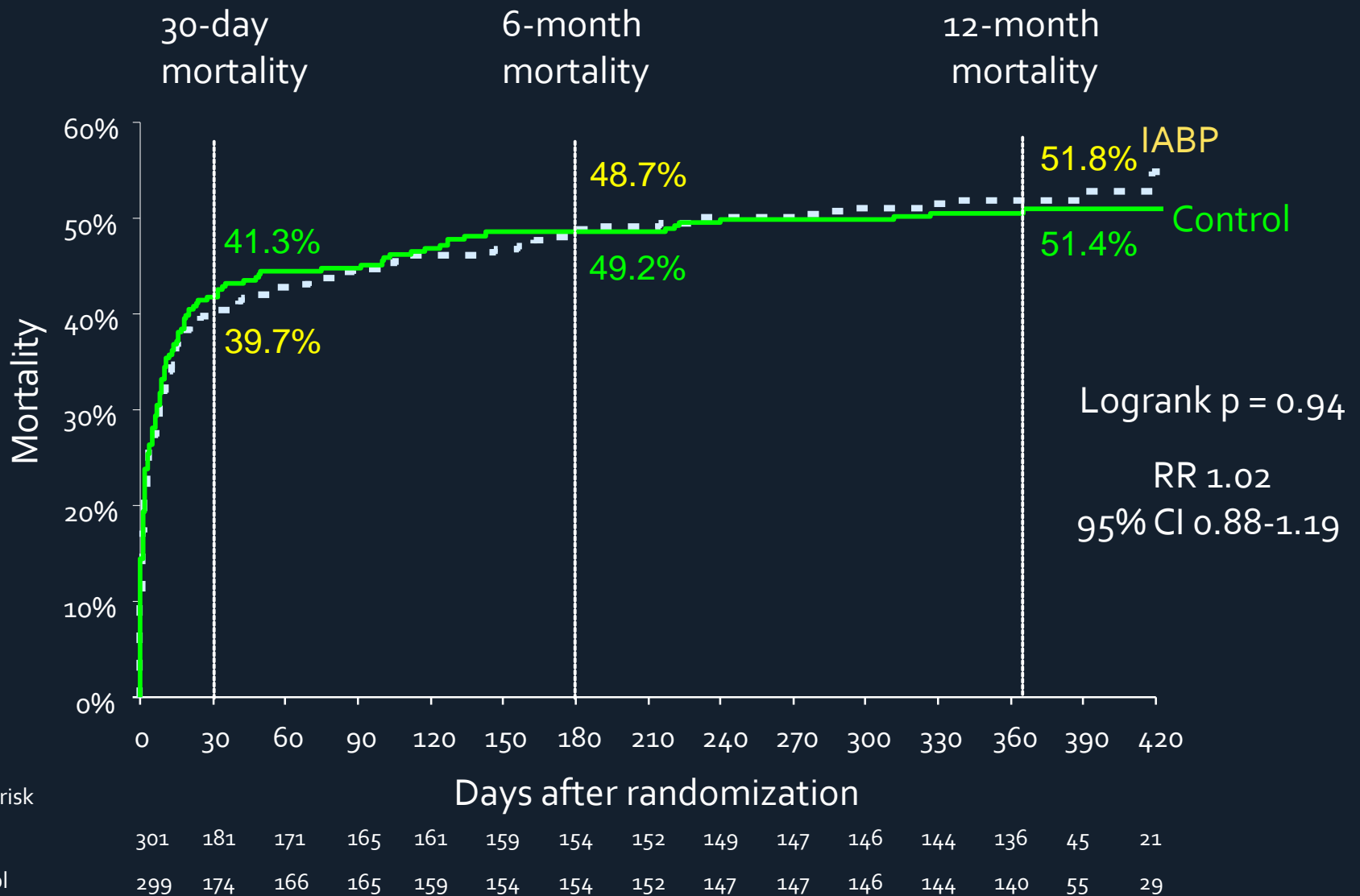
Results

Safety



	IABP (n=300)	Control (n=298)	P
Stroke in-hospital n/total (%)	2/300 (0.7)	5/298 (1.7)	0.28
GUSTO bleeding; n/total n (%)			
Life-threatening/severe	10/300 (3.3)	13/298 (4.4)	0.51
Moderate	52/300 (17.3)	49/298 (16.4)	0.77
Peripheral ischemic complication requiring intervention; n/total n (%)	13/300 (4.3)	10/298 (3.4)	0.53
Sepsis; n/total n (%)	47/300 (15.7)	61/298 (20.5)	0.15

IABP SHOCK II: 1 year Mortality



The Current Use of Impella 2.5 in Acute Myocardial Infarction Complicated by Cardiogenic Shock: Results from the USpella Registry

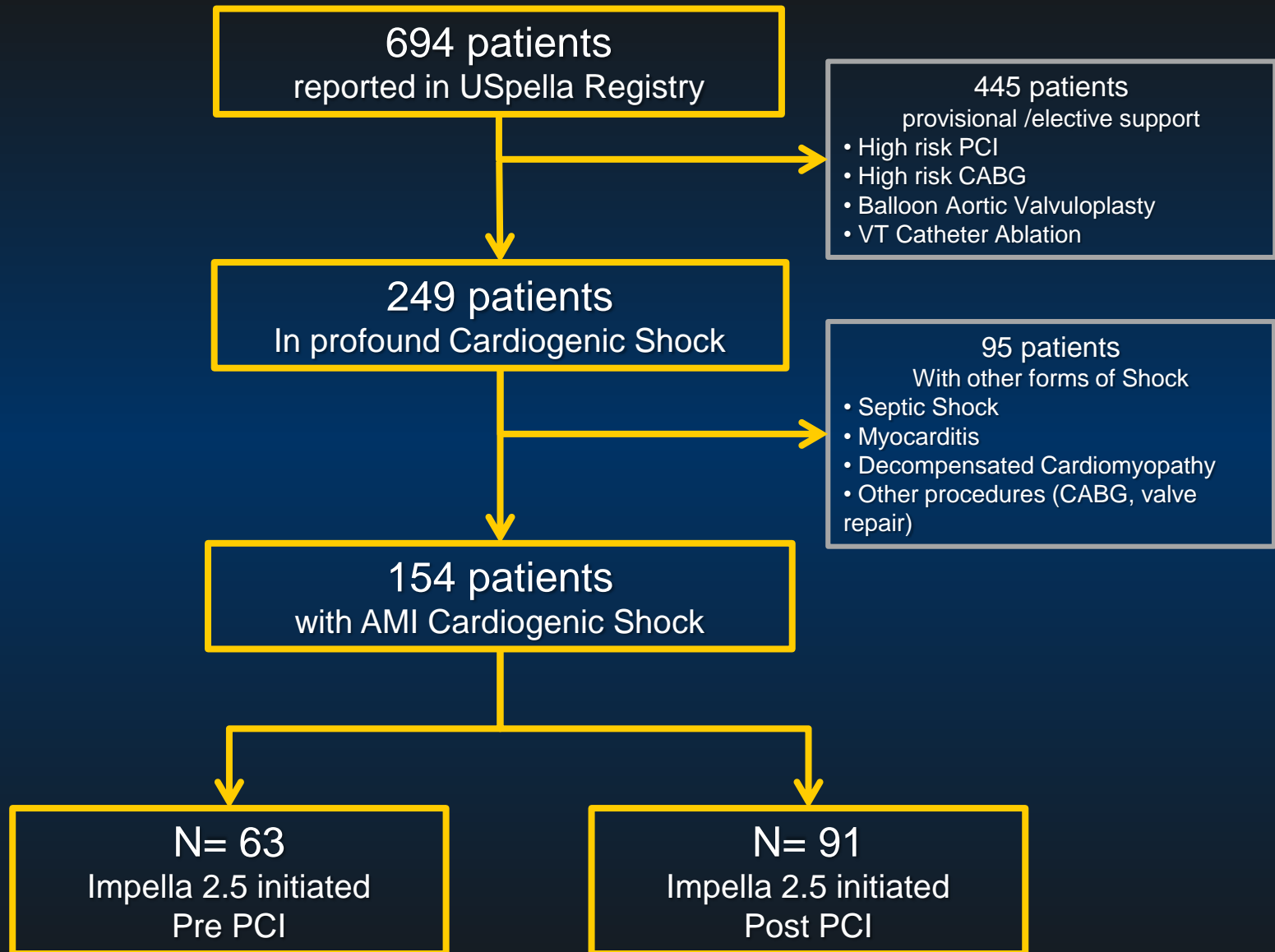
William W. O'Neill, MD^{*}; Theodore Schreiber, MD[‡]; David H. W. Wohns, MD[±]; Charanjit Rihal, MD[¶]; Srihari S. Naidu, MD[#]; Andrew B. Civitello, MD[†]; Simon R. Dixon, MBChB^{**}; Joseph M. Massaro, PhD^{||}; Brijeshwar Maini, MD^{††}; E. Magnus Ohman, MD^{¶¶}.

From the ^{*}Henry Ford Hospital, Detroit, MI, USA; [‡]Detroit Medical Center, Detroit, MI, USA; [±]Spectrum Health, Grand Rapids, MI, USA; [¶]Mayo Clinic, Rochester, MN, USA; [#]Winthrop University Hospital, Mineola, NY, USA; [†]Texas Heart Institute, Houston, TX, USA;

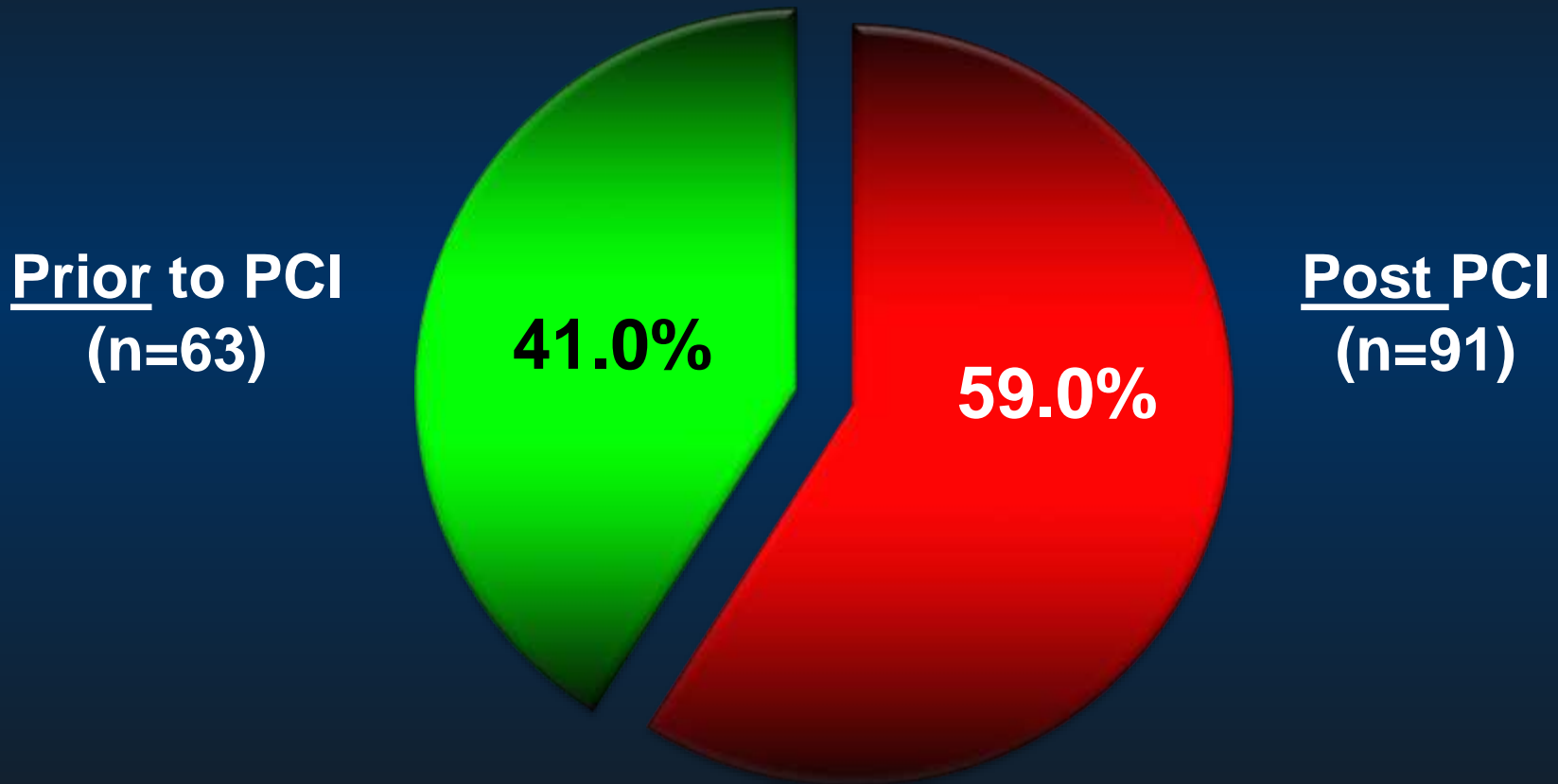
^{**}Beaumont Hospital, Royal Oak, MI, USA; ^{||}Harvard Research Institute, Boston, MA, USA; ^{††}Pinnacle Health Medical Center, Wormleysburg, PA, USA; ^{¶¶}Duke University Medical Center, Durham, NC, USA.

Study Flow Chart

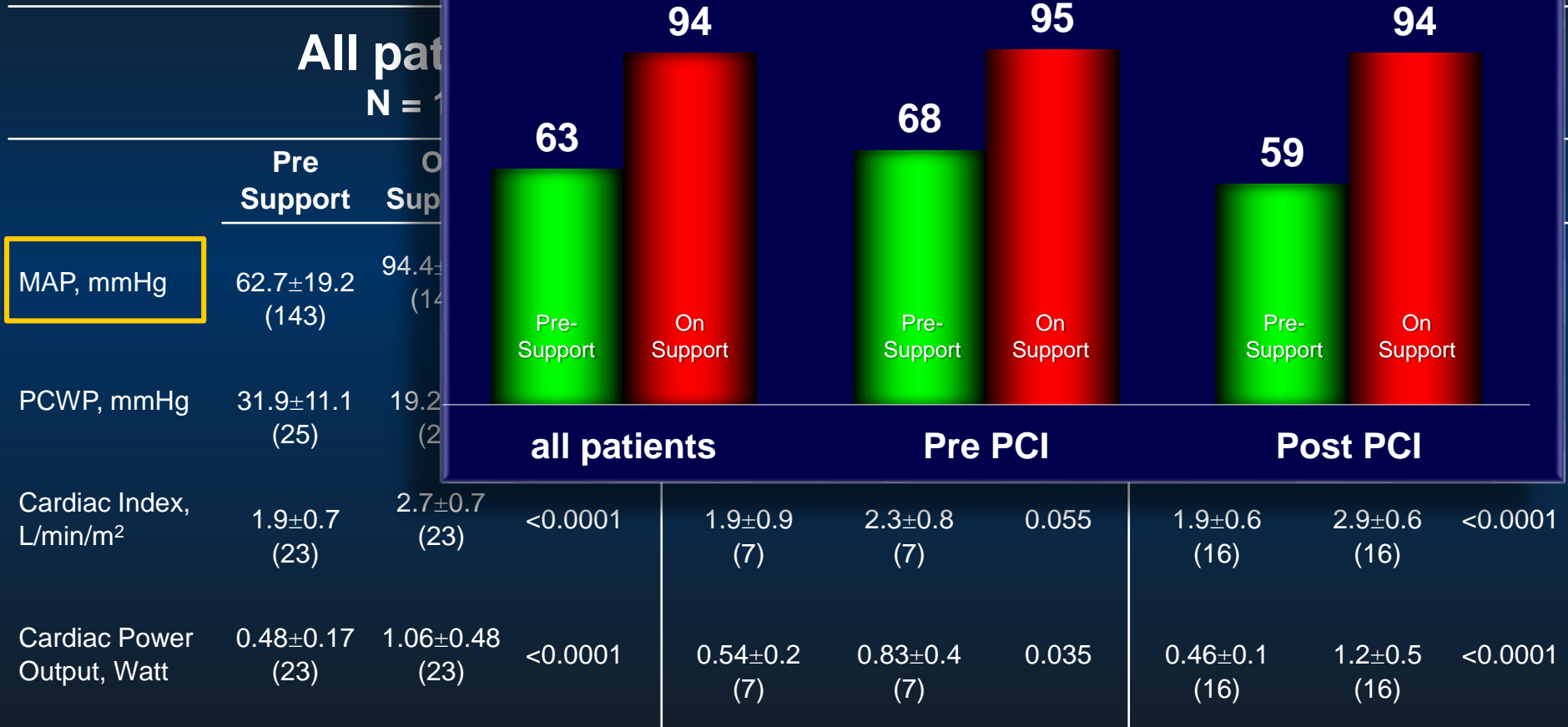
(06/08-05/12)



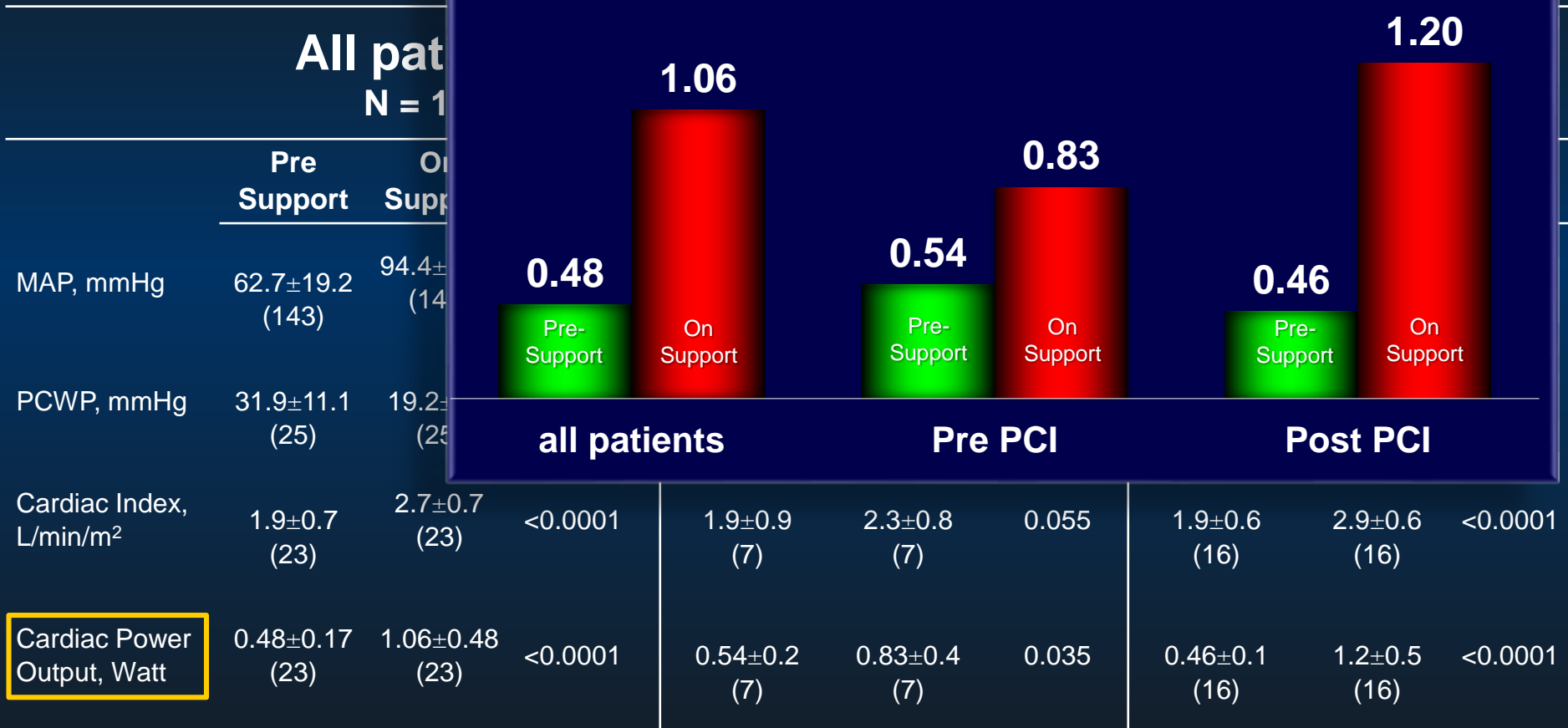
Impella[®] Insertion Timing (N= 154)



Hemodynamics

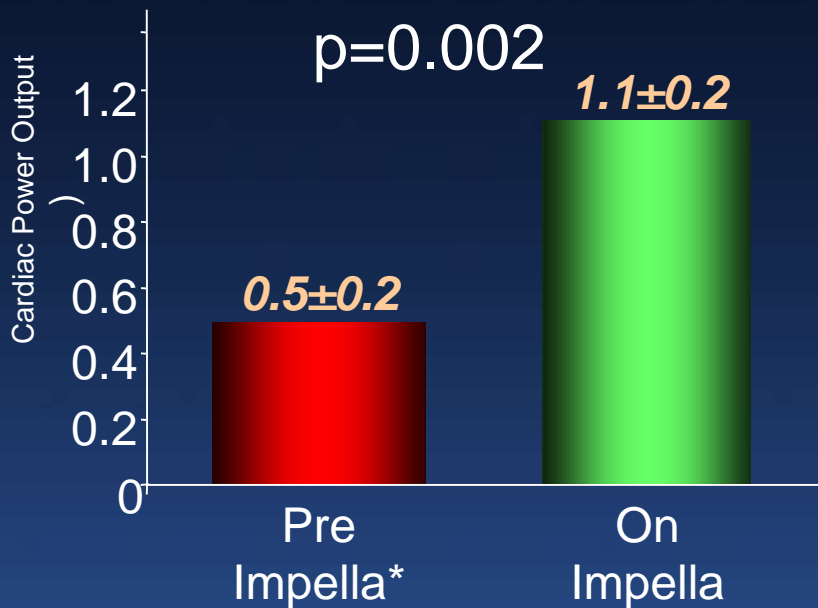


Hemodynamics

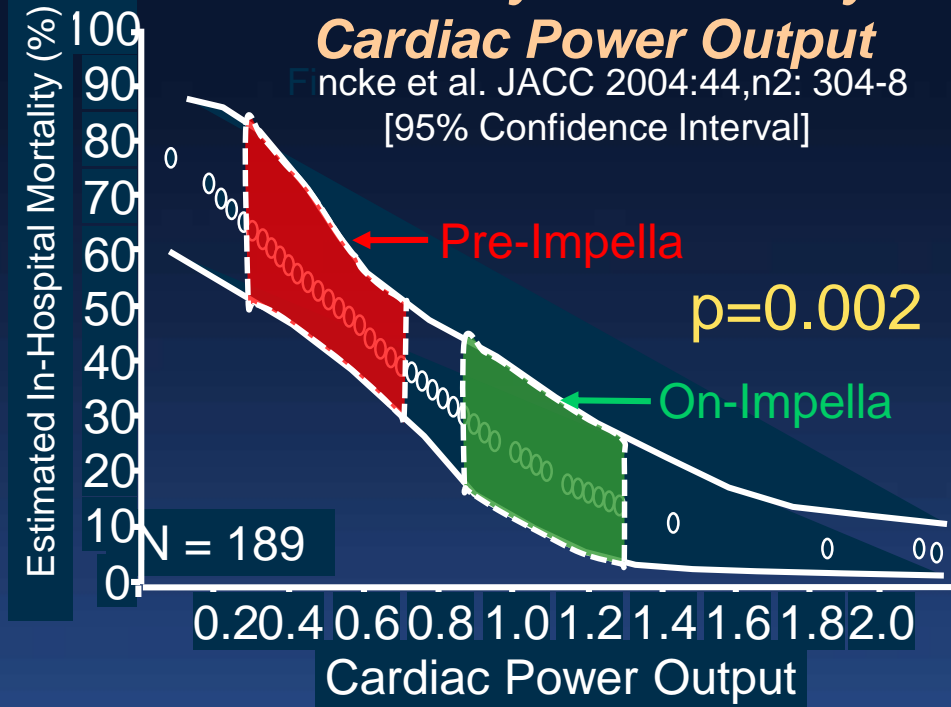


Impella Improves Cardiac Power Output, the Strongest Correlate of in-hospital Mortality

Cardiac Power Output in USpella AMI Shock

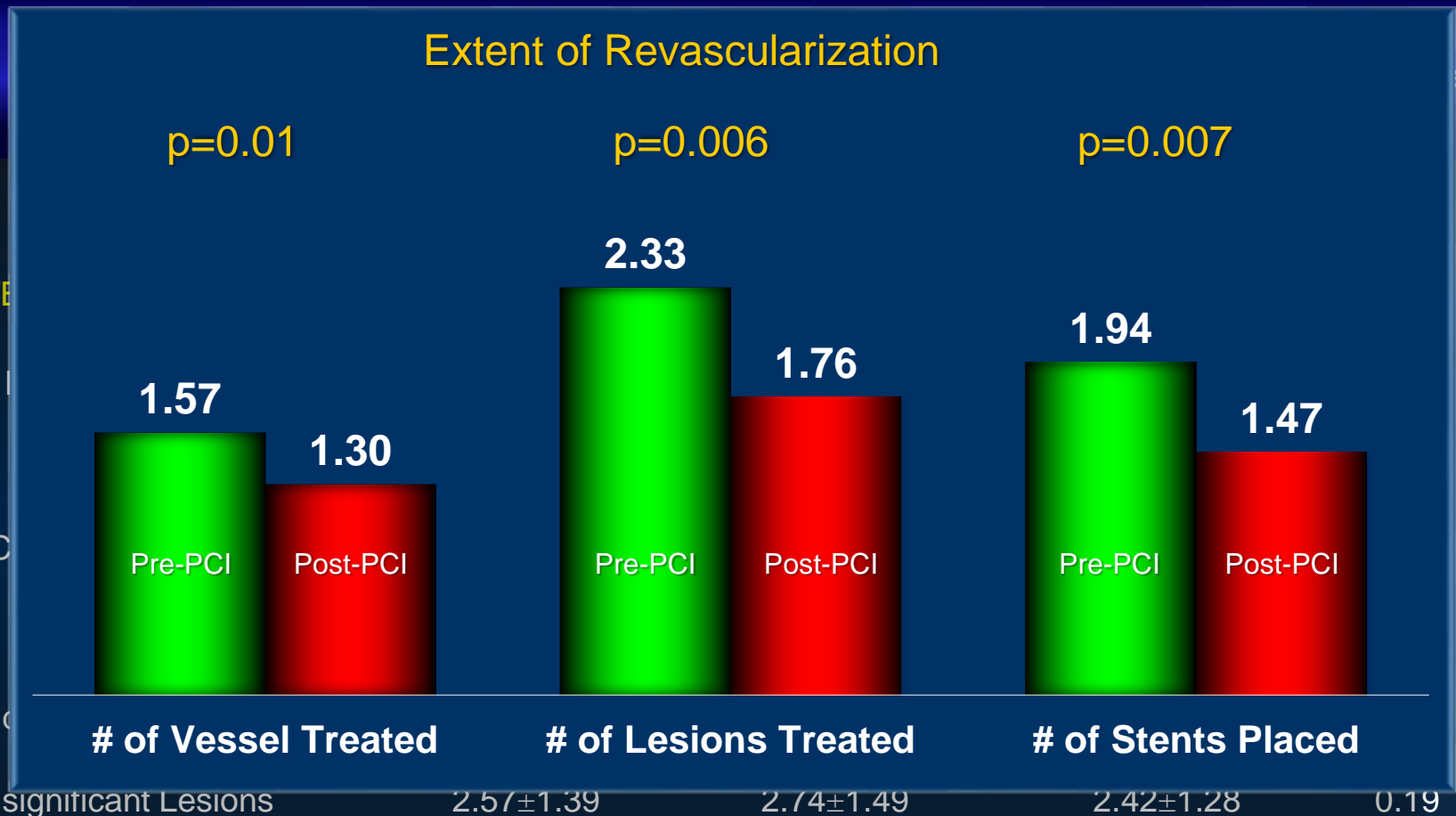


Mortality Predicted by Cardiac Power Output



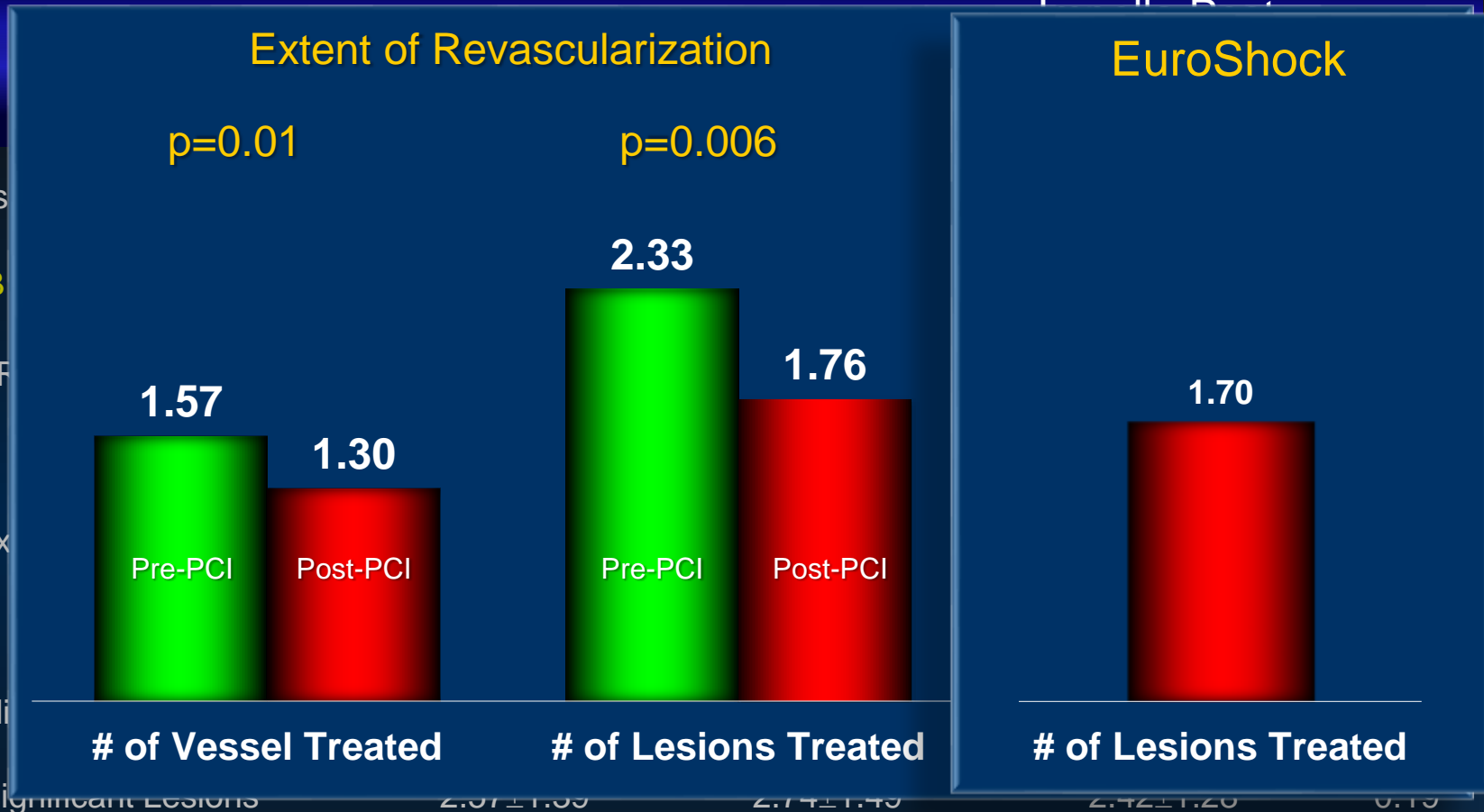
*Pre-Impella measurements were recorded under clinical conditions (i.e, with inotropes + IABP)

Procedural Characteristics



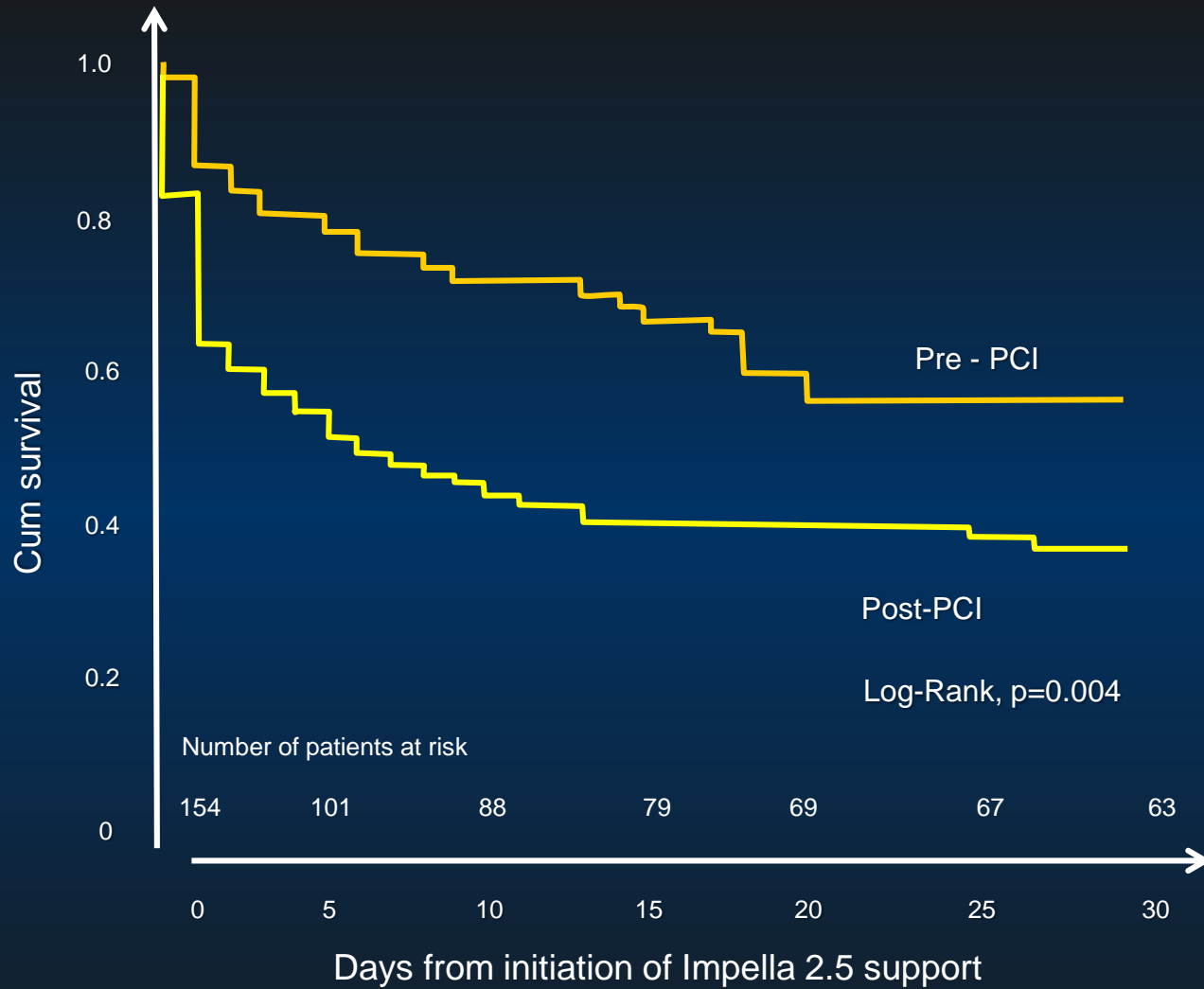
Number of vessel treated	1.42±0.63	1.57±0.67	1.30±0.57	0.01
TIMI Flow [0-1] Prior to PCI	80.2%	71.9%	84.8%	0.14
TIMI Flow [0-1] Post PCI	8.7%	4.6%	11.9%	0.19

Procedural Characteristics



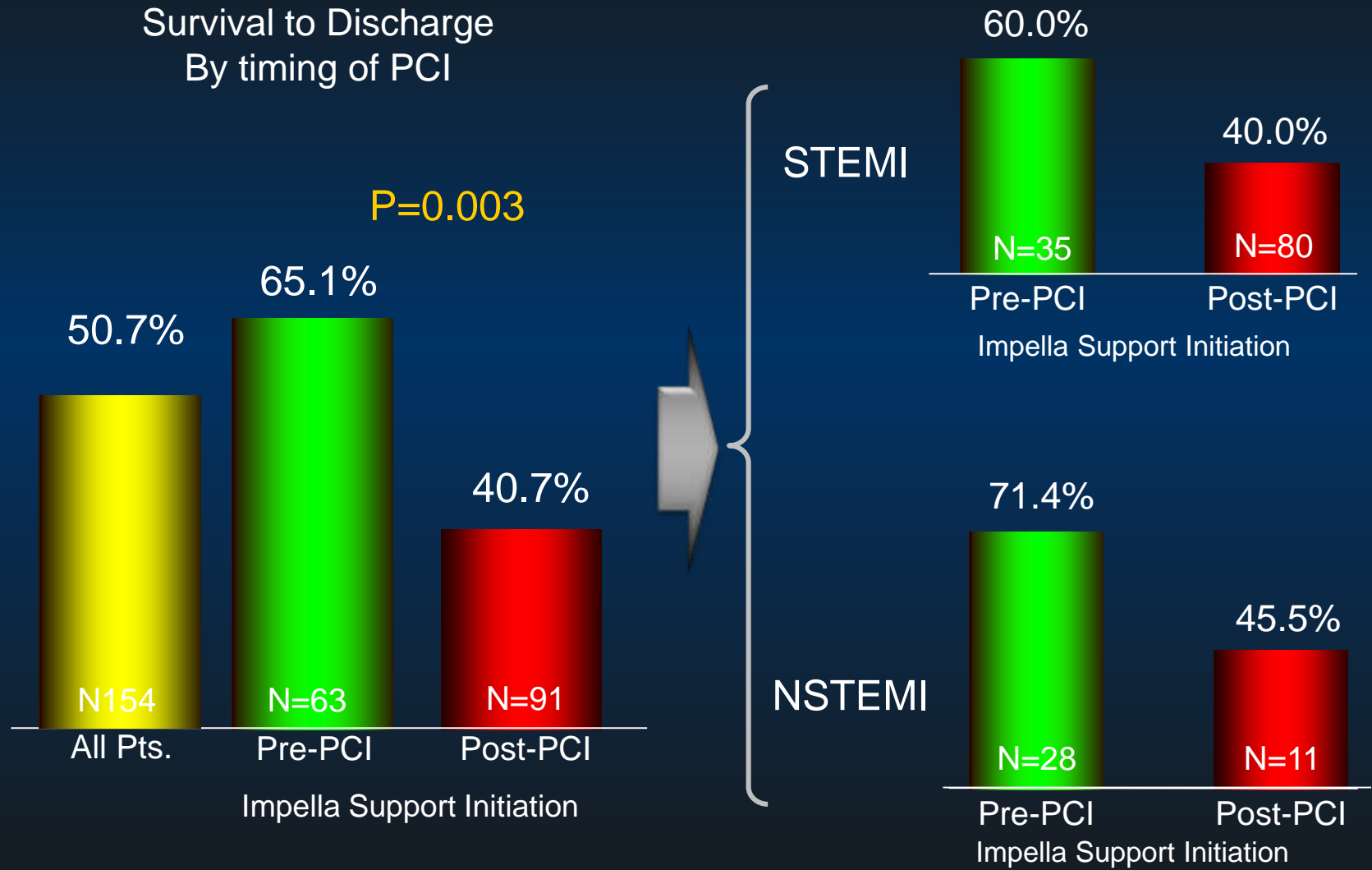
Number of vessel treated	1.42±0.63	1.57±0.67	1.30±0.57	0.01
TIMI Flow [0-1] Prior to PCI	80.2%	71.9%	84.8%	0.14
TIMI Flow [0-1] Post PCI	8.7%	4.6%	11.9%	0.19

Outcome



Survival to Discharge by Timing of PCI

Timing of Support Initiation (154)

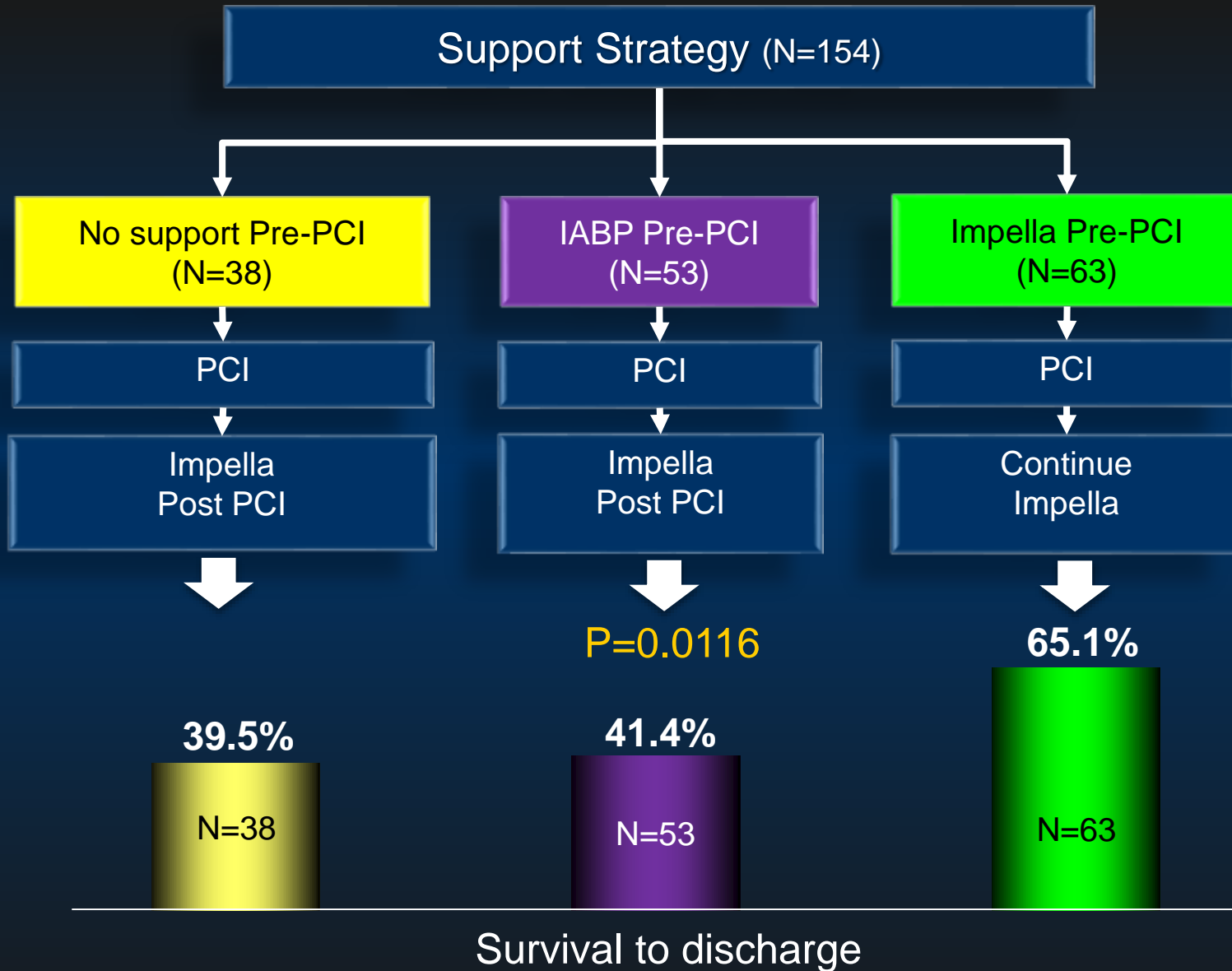


Independent Predictors of In-Hospital Mortality Using a Multivariate Analysis*

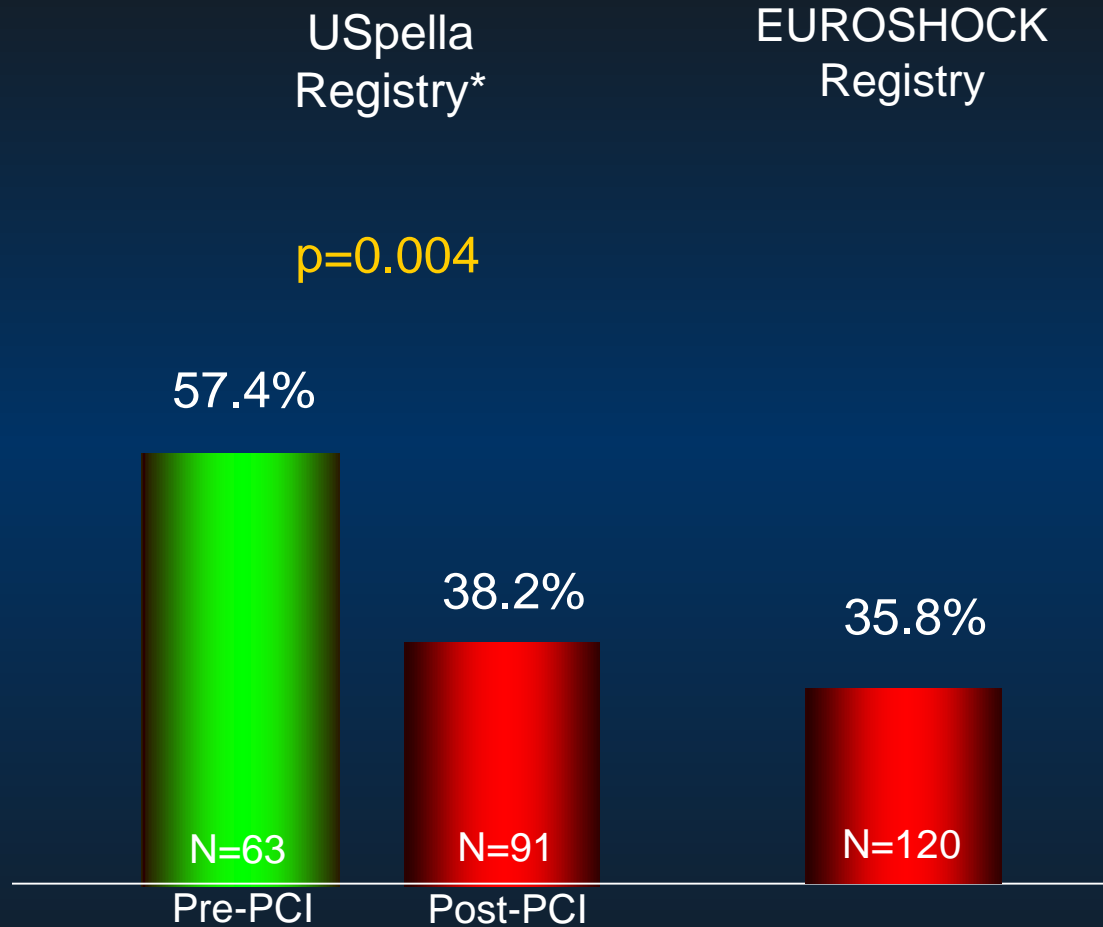
Parameter Tested*	Odds-ratio	[CI 95%]	<i>p</i> -value
Initiation of Impella support prior to PCI	0.37	0.17 - 0.79	0.01
Age	1.05	1.02 - 1.08	0.003
Number of inotropes	1.56	1.1 - 2.18	0.01
Cardiogenic shock onset prior to admission	2.42	1.12 - 5.24	0.03
Mechanical ventilation	4.59	2.02 - 10.42	0.0003

* The multivariate analysis logistic model included the following as candidates for entry age, gender, history of chronic obstructive pulmonary disease, diabetes, peripheral vascular disease or prior stroke, STEMI vs. NSTEMI, cardiac arrest prior to admission, onset and duration of CS, patient transfer from outlying facility, evidence of anoxic brain injury pre-Impella support, need for mechanical ventilation, systolic and diastolic blood pressure, level of inotropic support pre-Impella support and potential use of IABP prior to Impella support, and baseline serum creatinine levels.

Outcome By Support Strategy



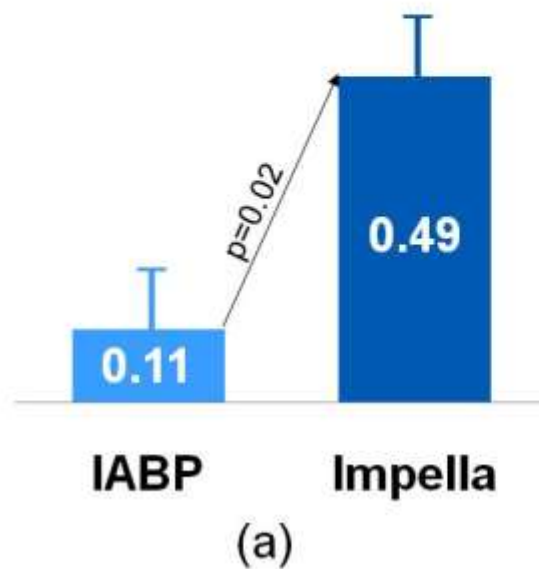
30 Day Survival



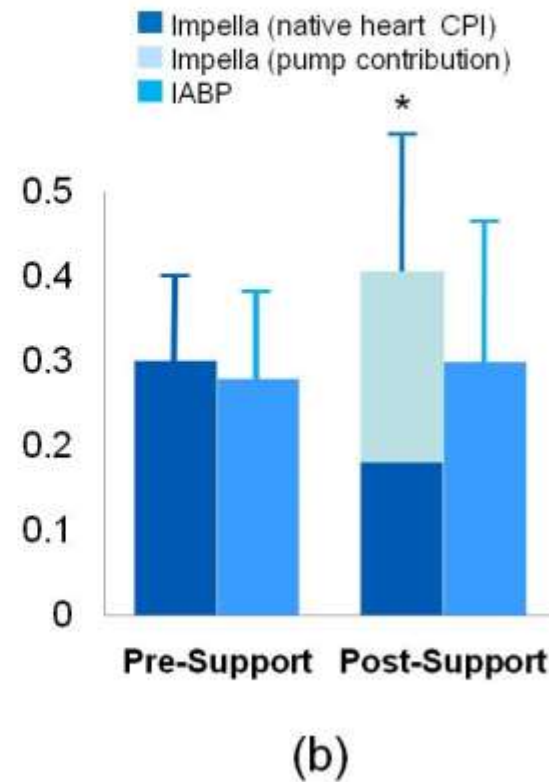
*: Kaplan Meier analysis estimated 30 day survival

Impella vs. IABP for STEMI+CS ISAR-SHOCK (n=26)

Change in Cardiac Index
IABP vs. Impella 2.5



Cardiac Power Index (CPI)
IABP vs. Impella 2.5



*Adapted from Seyfarth, et al., J Am Coll Cardiol. 2008 Nov 4;52(19):1584-8

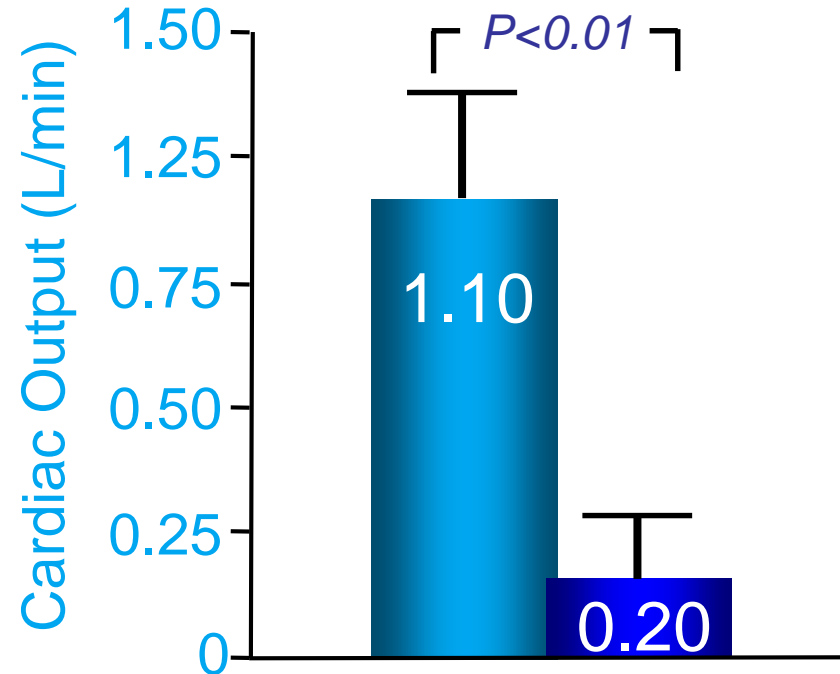
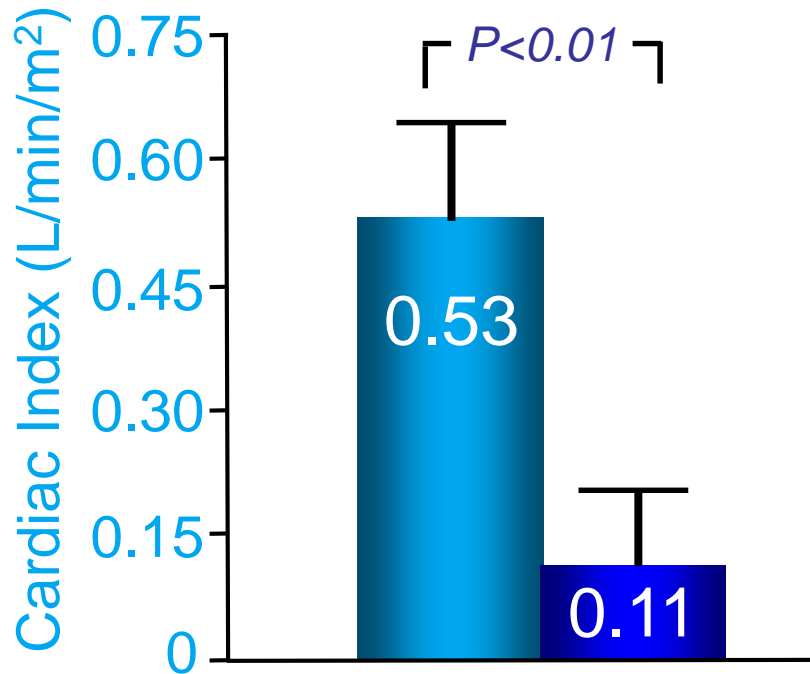
ISAR-SHOCK Randomized Trial: IMPELLA 2.5 Provides a Better Hemodynamic Support Than IABP in AMI Cardiogenic Shock

Primary Endpoint:

Increase in Cardiac Index From Baseline

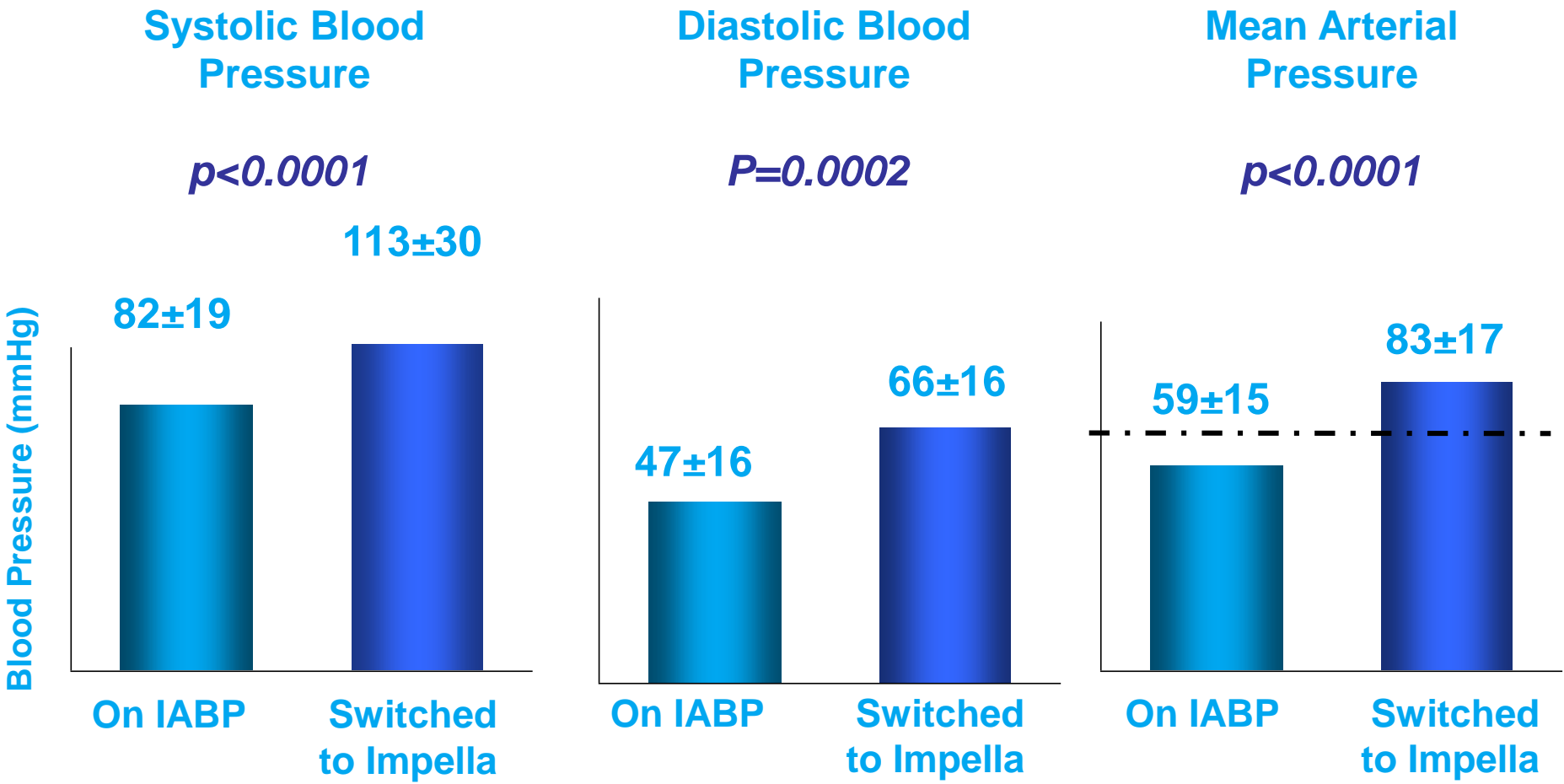
(measured after 20 min of support)

■ Impella ■ IABP

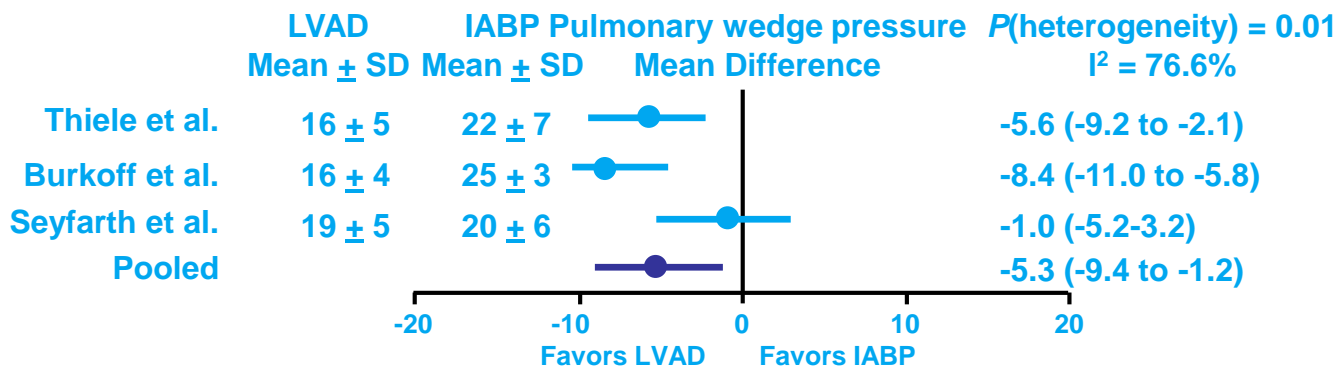
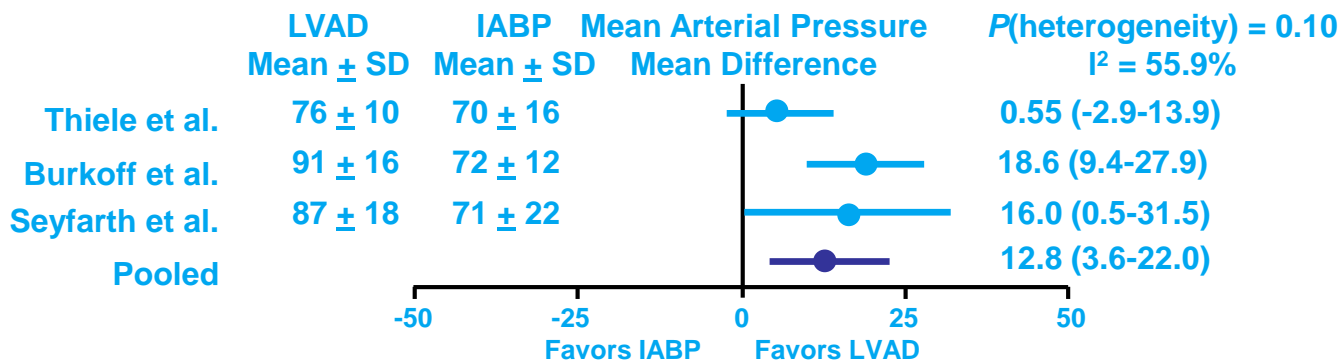
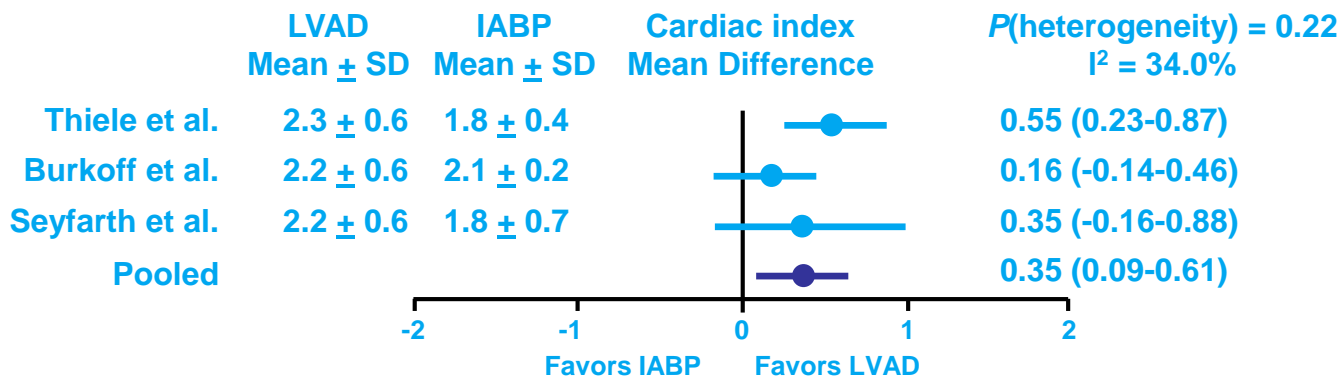


Gain on Hemodynamics When Switching from IABP to Impella in AMI Shock

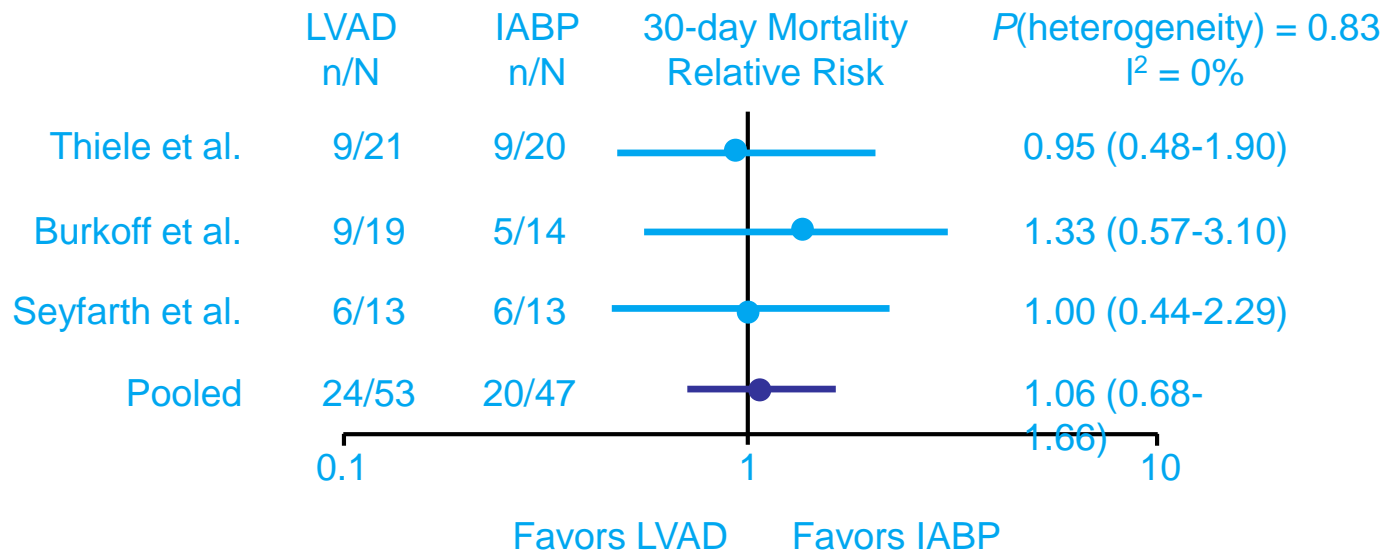
Patient serves as his/her own control (N=20)



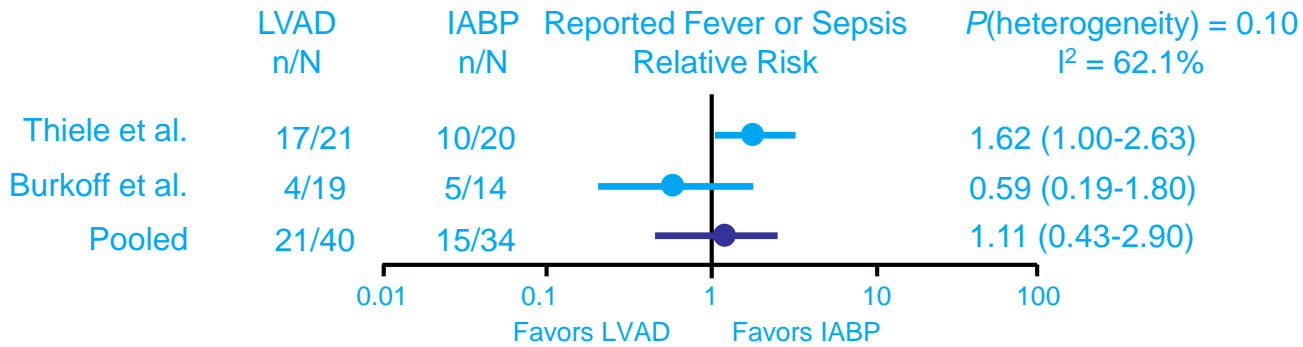
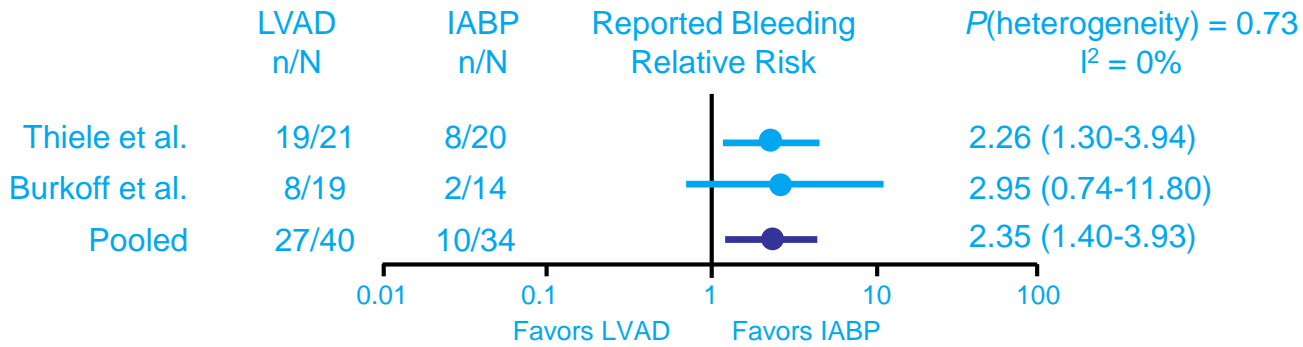
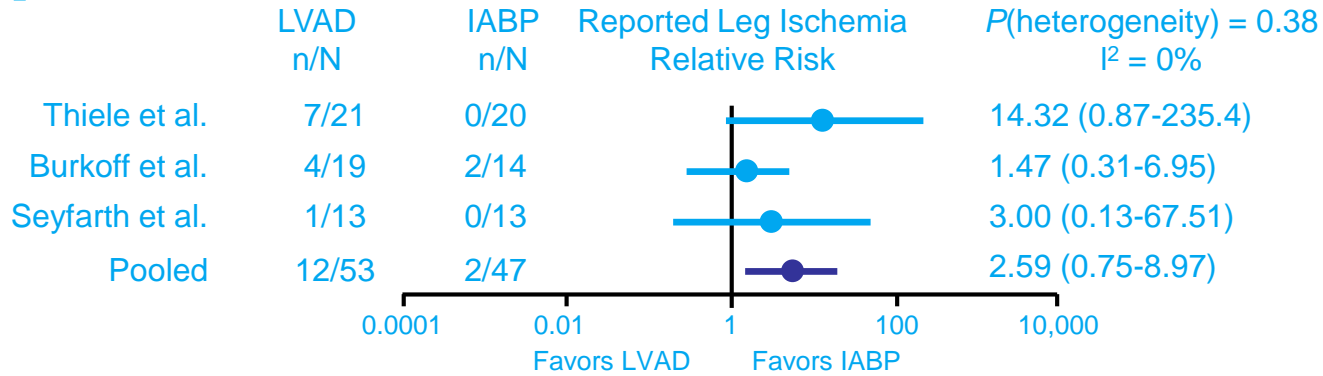
Hemodynamics



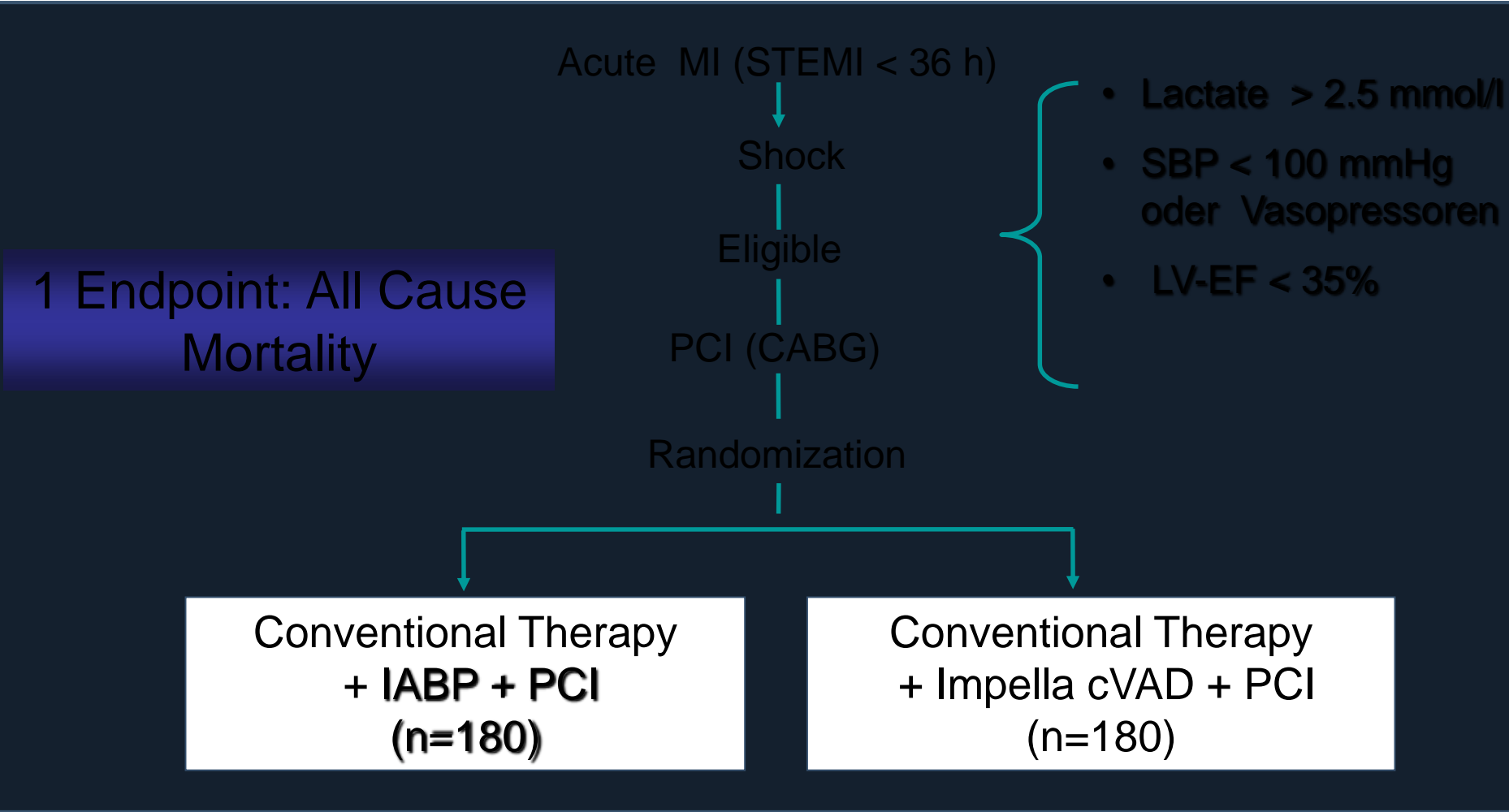
30 Day Mortality



Complications



DanShock Trial – Enrolling

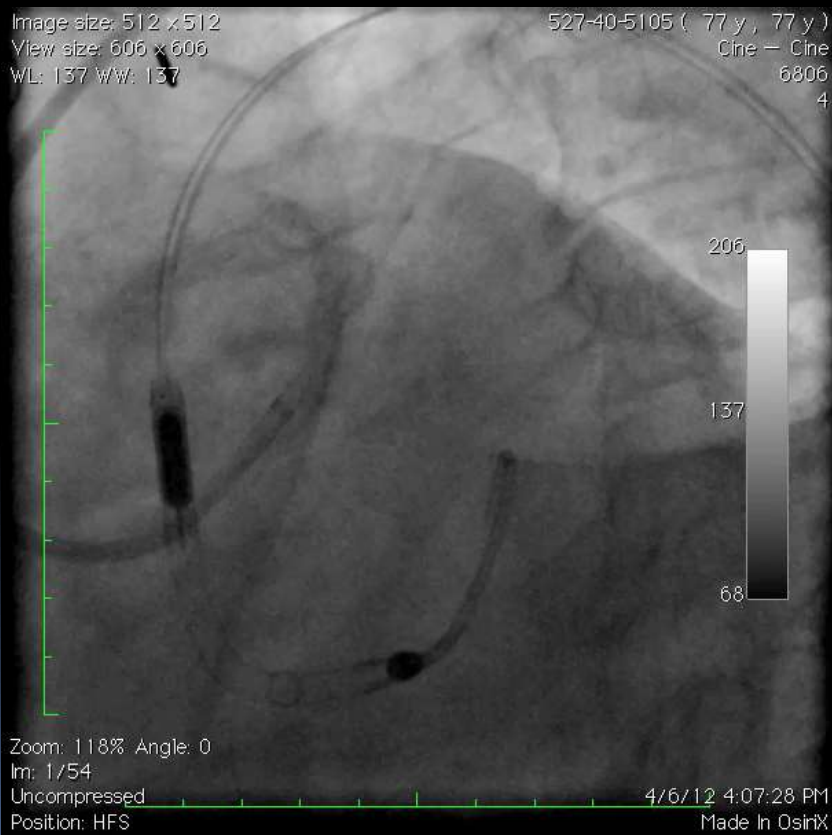


2011 ACCF/AHA/SCAI PCI Guidelines

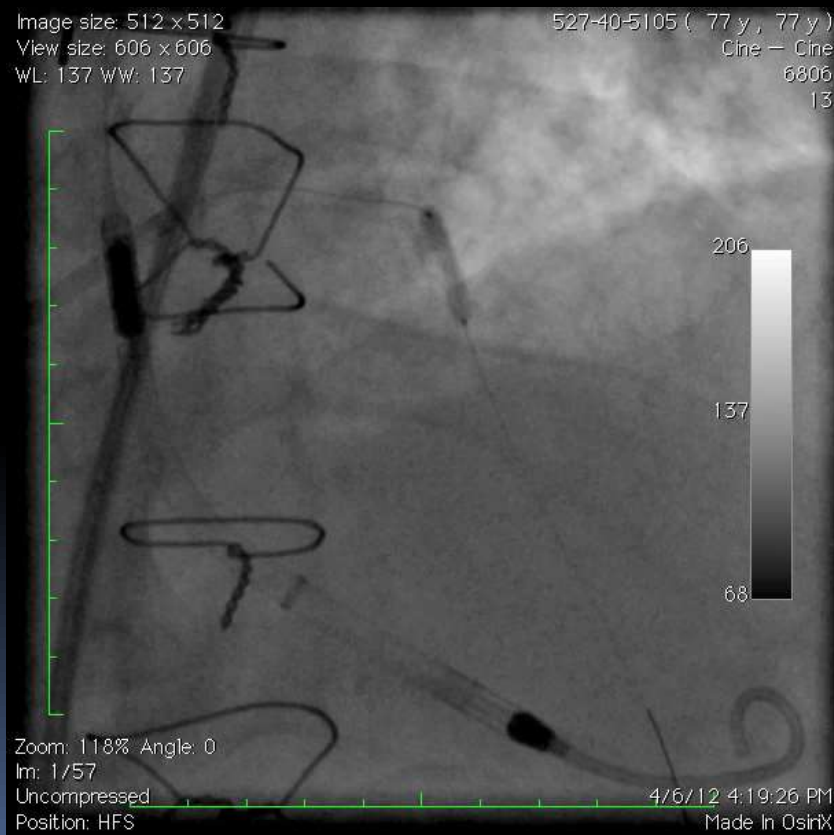
- Class I: Section 5.2.3 Cardiogenic Shock:
Recommendation: "A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy (384,424–427)." This classification includes the statement: "Refractory cardiogenic shock unresponsive to revascularization may necessitate institution of more intensive cardiac support with a ventricular assist device or other hemodynamic support devices to allow for myocardial recovery or subsequent cardiac transplantation in suitable patients."
- Class II b: Section 5.6 Percutaneous Hemodynamic Support Devices:
Recommendation: "Elective insertion of an appropriate hemodynamic support device as an adjunct to PCI may be reasonable in carefully selected high-risk patients."



Impella deployed in LV



ASC balloon LAD





LAD completely revascularized with Resolute DES

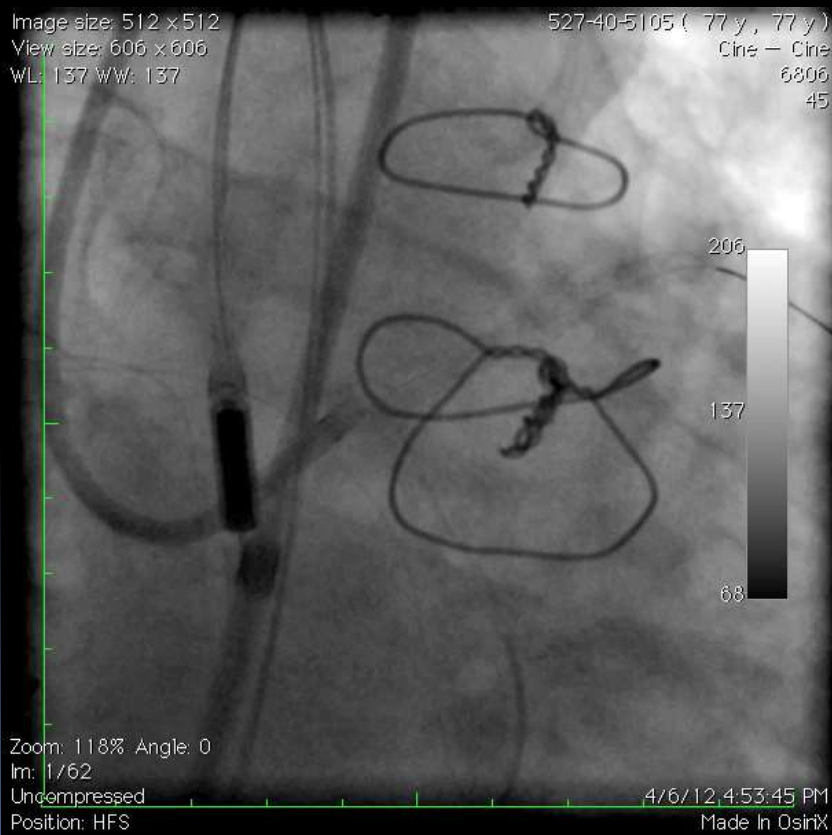


ASC balloon in Circ/OM

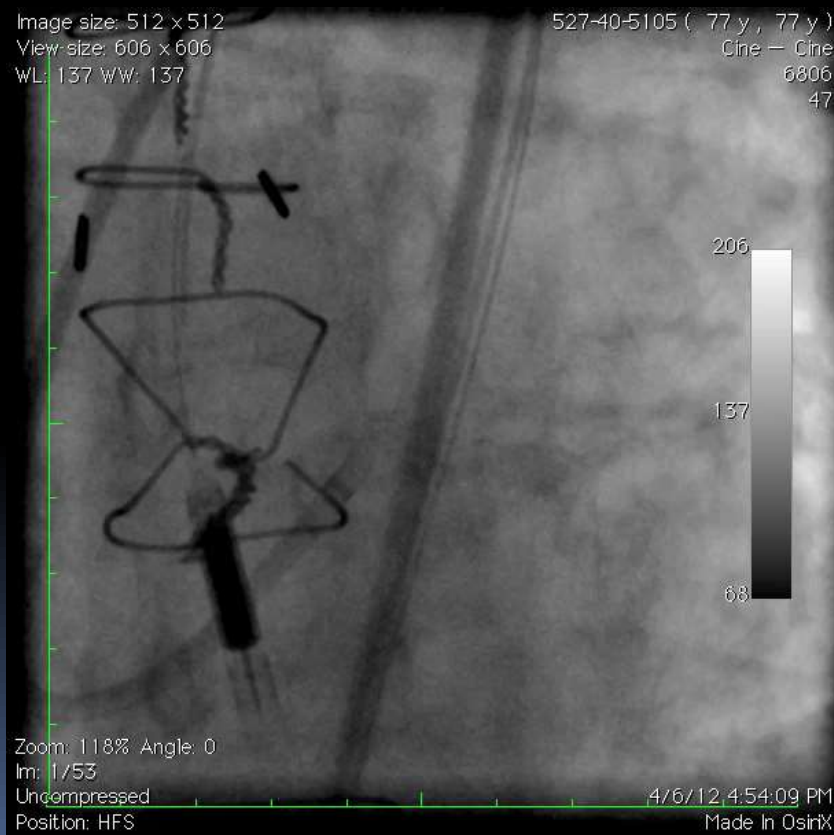






Circ/OM treated with Resolute post ASC balloon



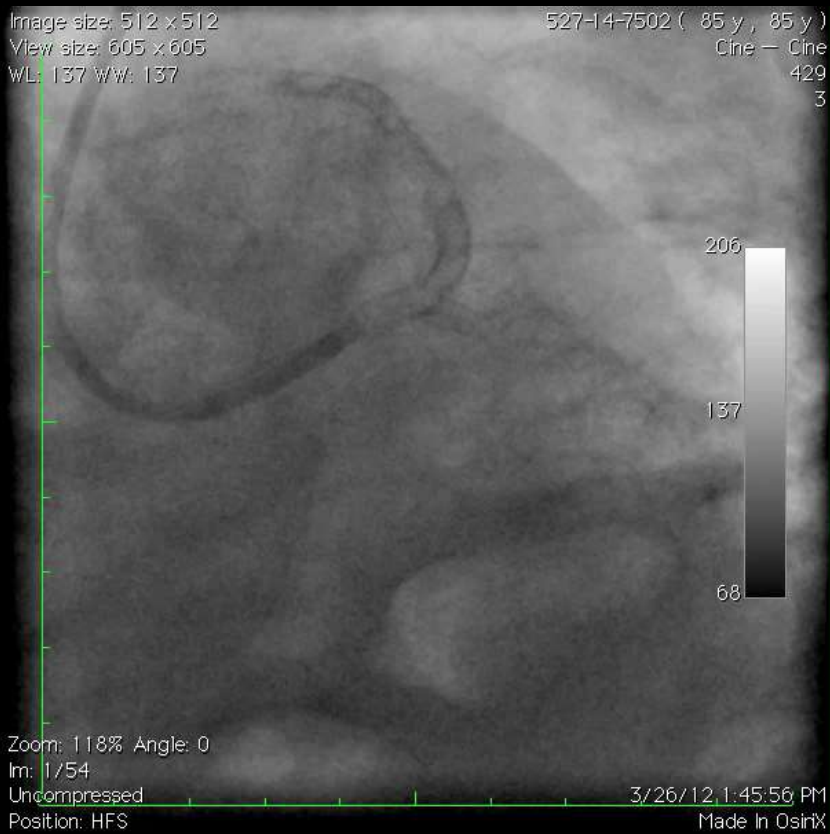
Final results



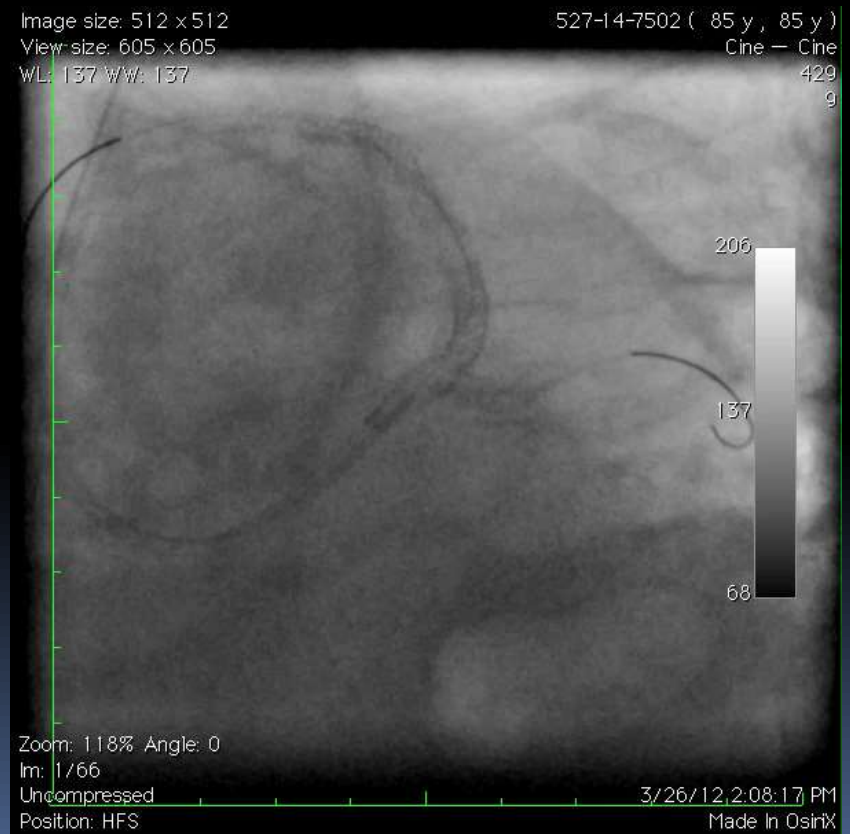
- 
- 75 yo male with DM, ESRD on dialysis, LVEF 25%, left main disease previously turned down by CT surgery
 - Received left main PCI in 2010
 - Readmitted with NSTEMI
- 

75 yo male with LM disease and ISR of DES placed in 2010

DES ISR in LM and Circ ostium



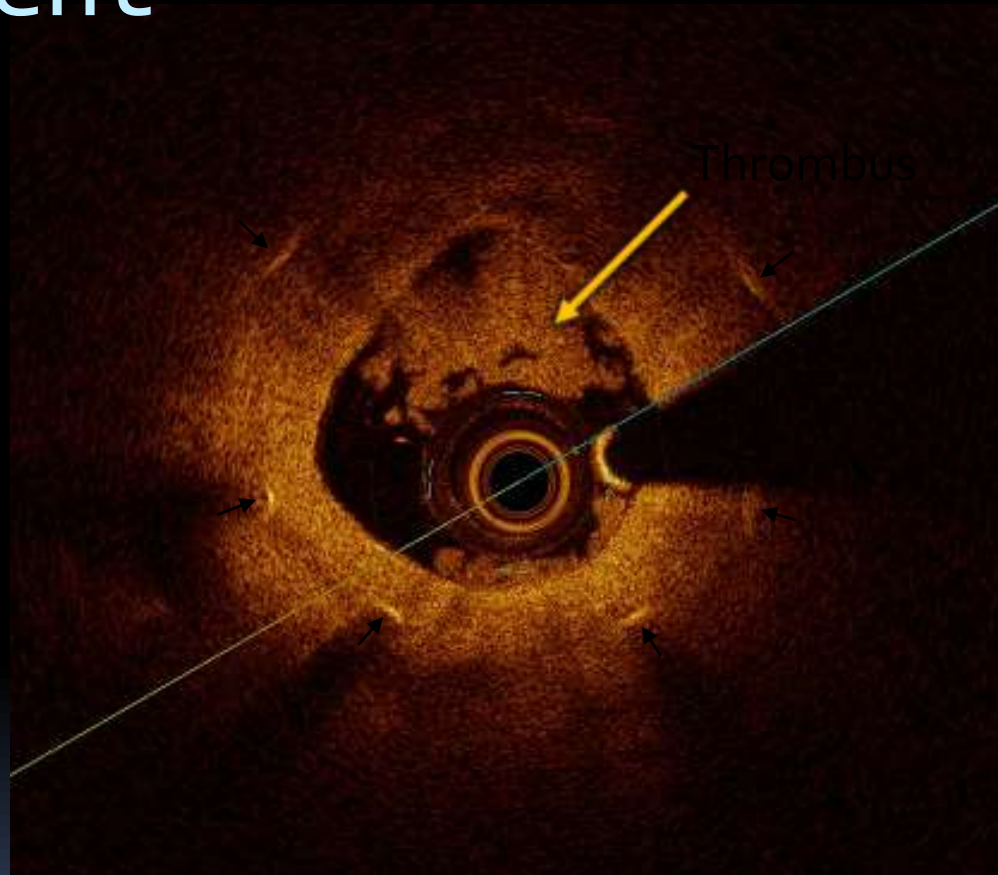
Balloon of L Circ ostium





Severe In-Stent Restenosis



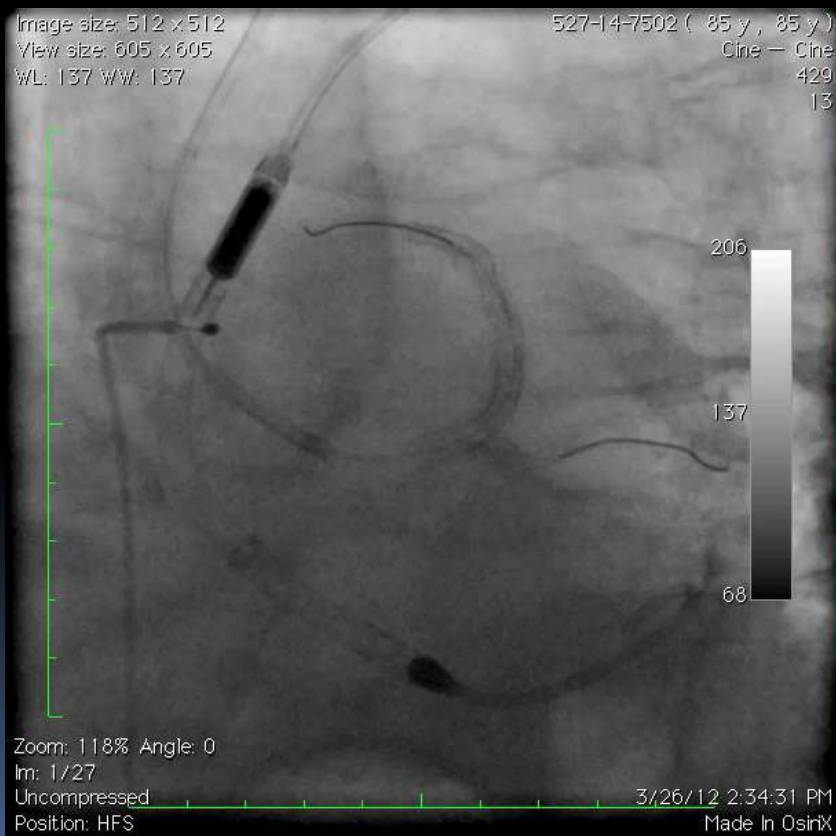
Ruptured plaque inside ISR segment



- 
- Patient developed ventricular fibrillation
 - Converted with 1 shock
 - Became hypotensive and bradycardic
 - Impella placed emergently
- 



Patient went into cardiogenic shock

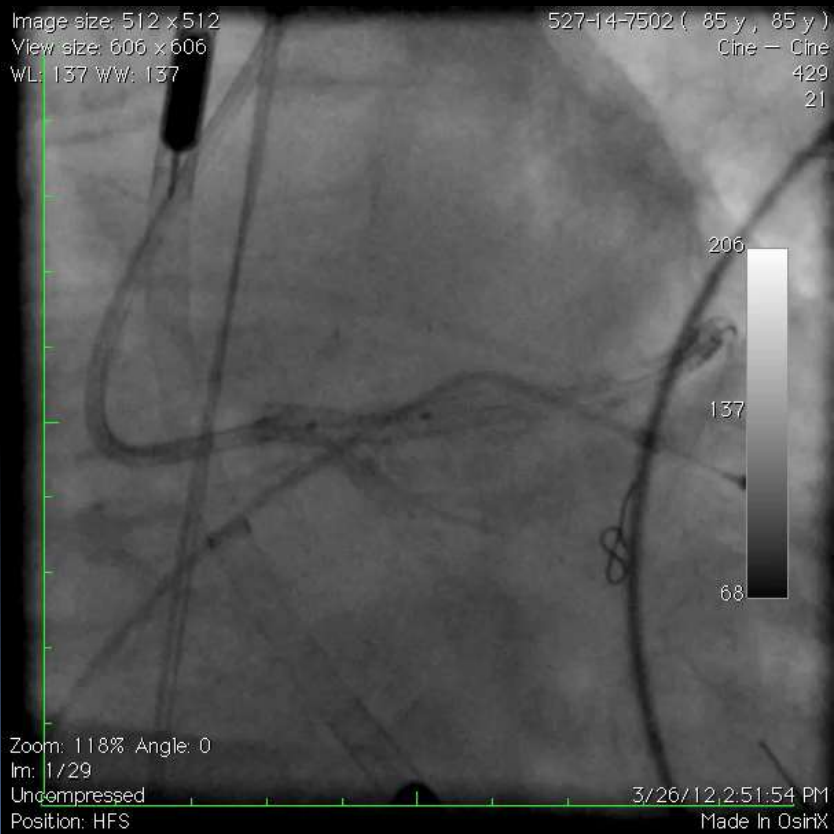


Stabilized after Impella placed





ASC balloon and DES in left main

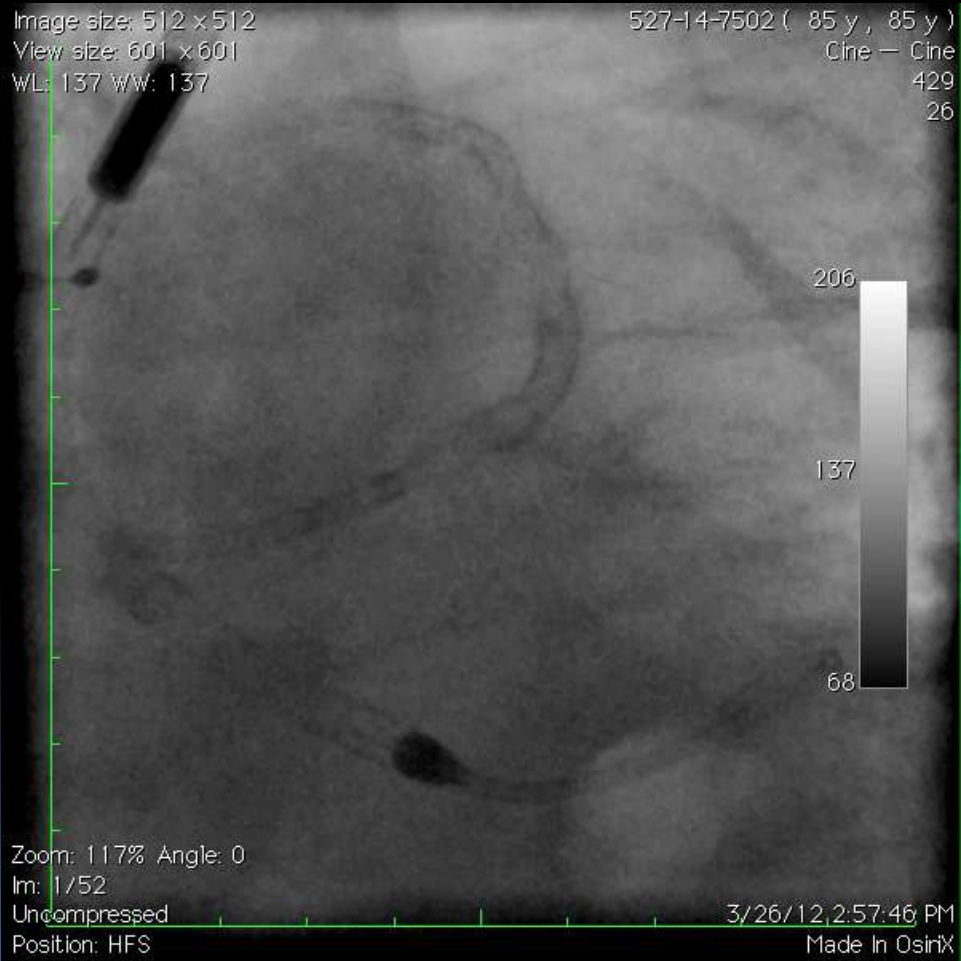


ASC balloon 'grooves'




Image size: 512 x 512
View size: 601 x 601
WL: 137 WW: 137

527-14-7502 (85 y , 85 y)
Cine - Cine
429
26



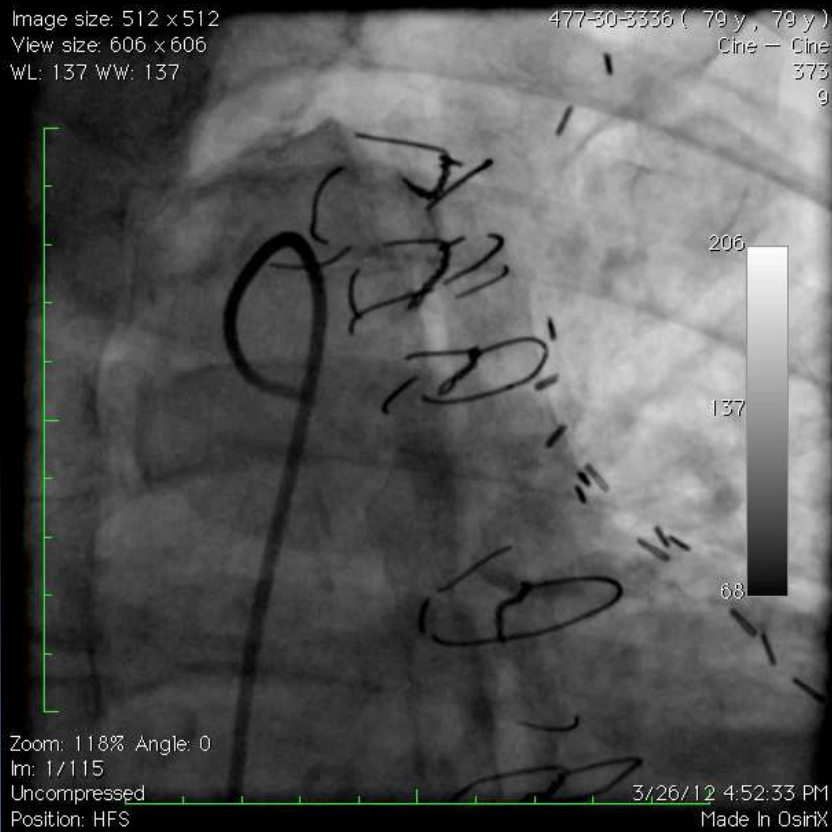
Zoom: 117% Angle: 0
Im: 1/52
Uncompressed
Position: HFS

3/26/12 2:57:46 PM
Made In OsiriX

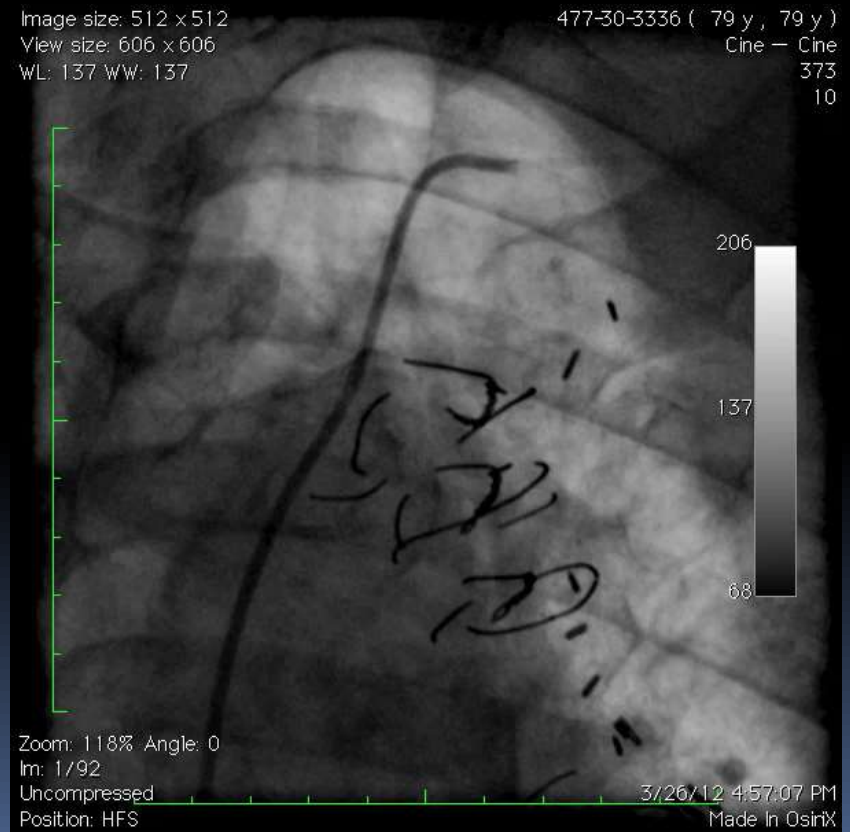
- 
- 89 yo male with prior CABG and severe PVD
 - Admitted with NSTEMI
 - Single remaining SVG supplies lateral wall
 - LIMA is down
 - LAD supplied by collaterals from RCA
 - LVEF 15%
 - Hypotensive on 3 pressors

89 yo male with prior CABG and single remaining graft

SVG with severe disease



LIMA occluded



Diffuse white (platelet rich) thrombus in distal SVG

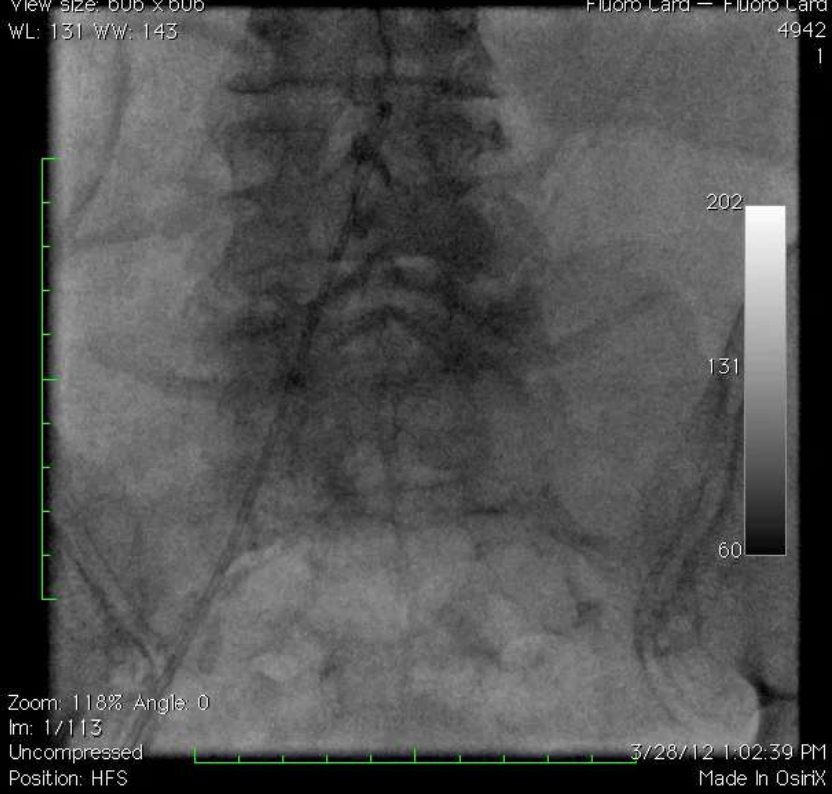




Severe PVD

Image size: 512 x 512
View size: 606 x 606
WL: 131 WW: 143

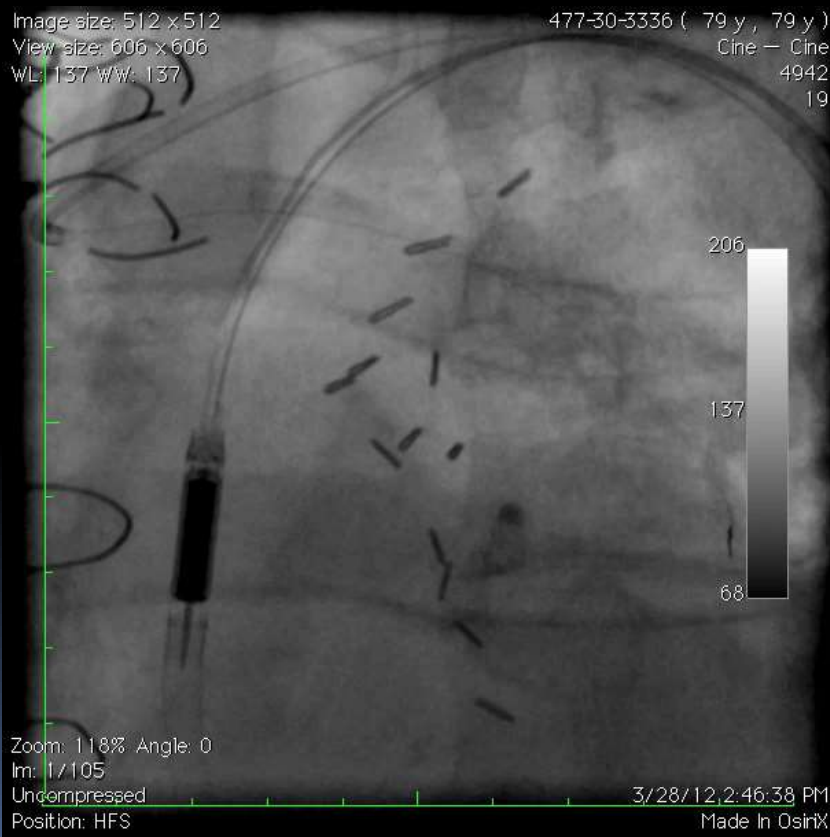
477-30-3336 (79 y , 79 y)
Fluoro Card — Fluoro Card
4942
1




Impella 2.5 placed via long 14F sheath

Image size: 512 x 512
View size: 606 x 606
WL: 137 WW: 137

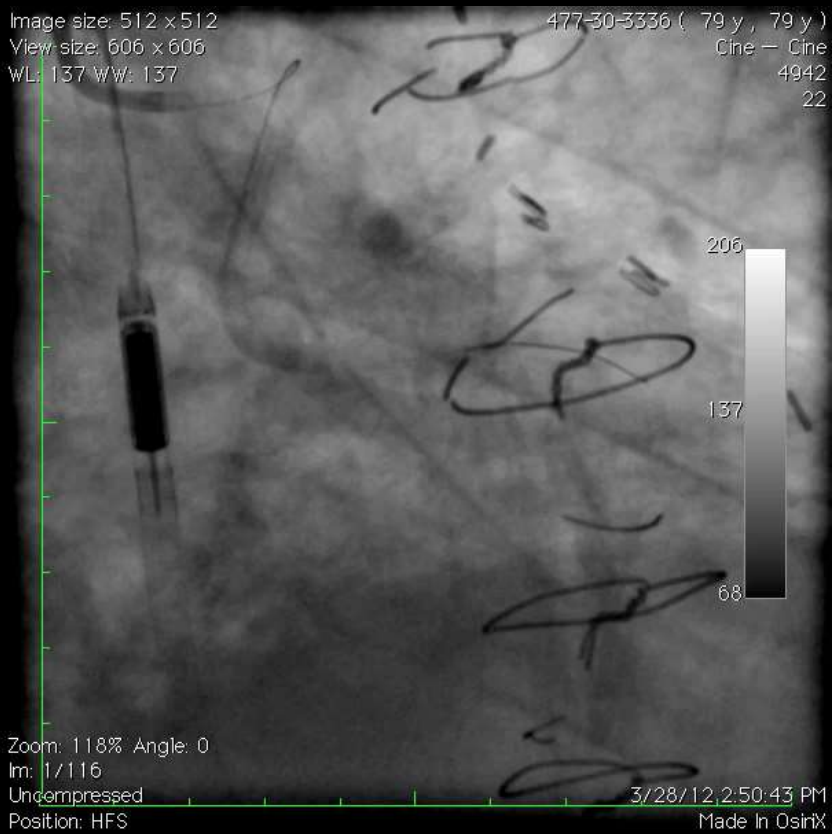
477-30-3336 (79 y , 79 y)
Cine — Cine
4942
19



- 
- A vertical bar on the left side of the slide, consisting of a white top section with a barcode-like pattern, a dark grey middle section, a yellow segment, and a long pink bottom section.
- Main concern is that PCI attempt will shut down SVG, since no place to land filter device
 - Not a lot of safety margin



Severe disease in SVG



No reflow in SVG

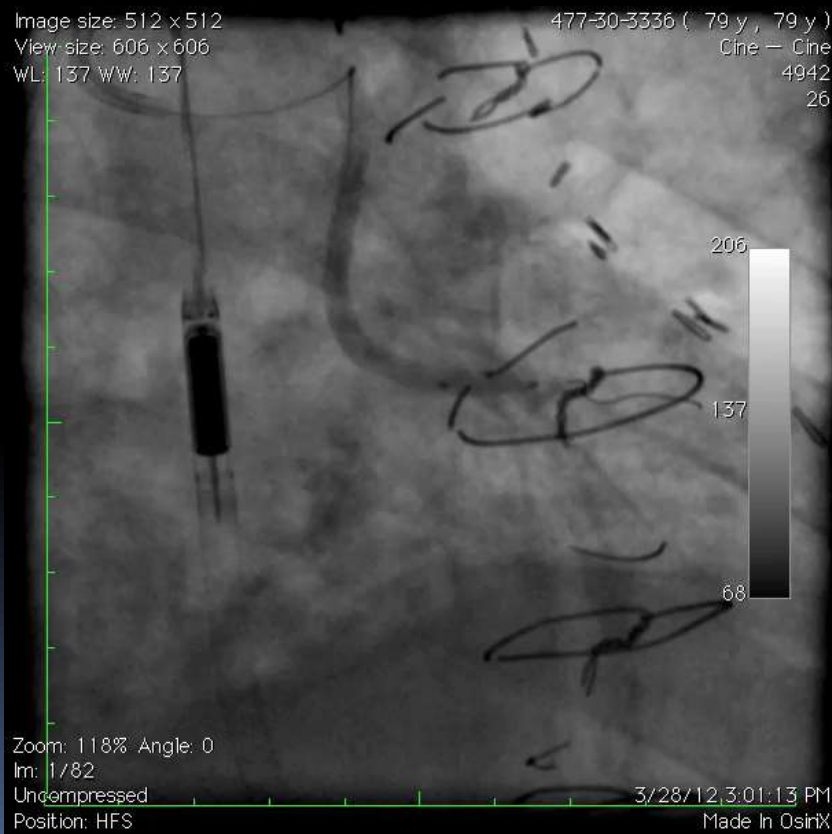
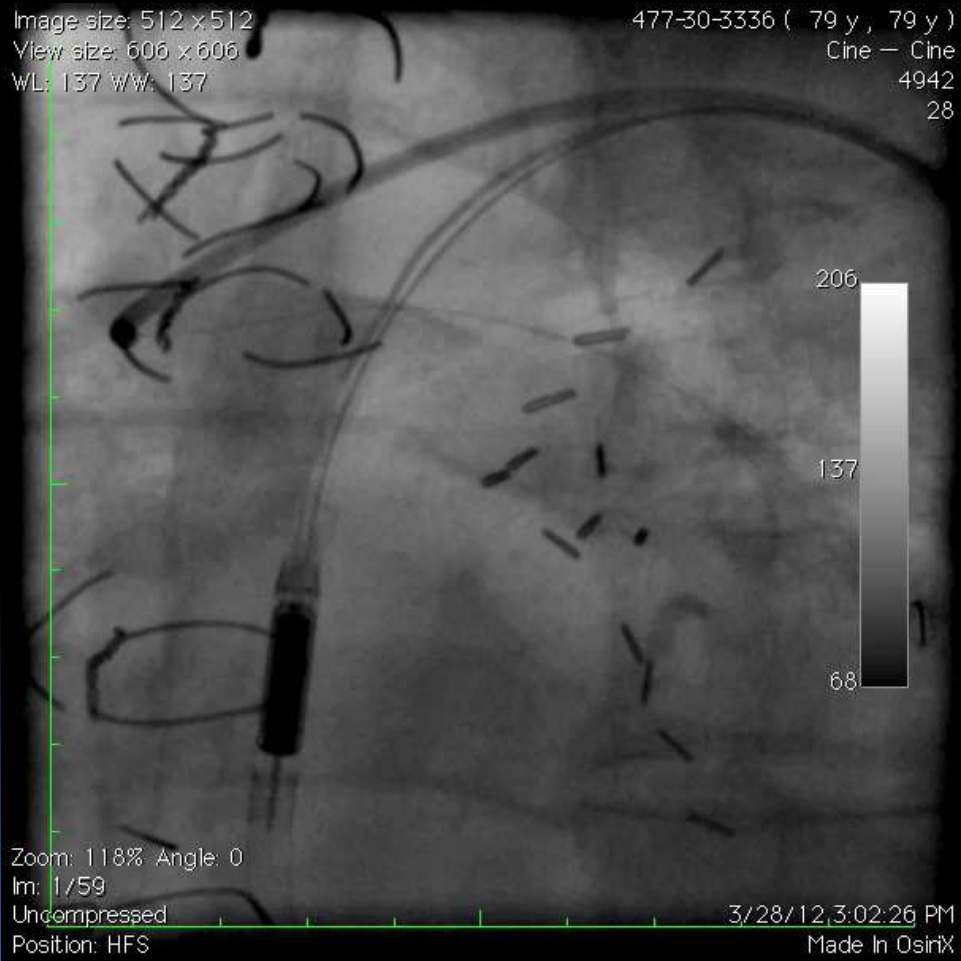



Image size: 512 x 512
View size: 606 x 606
WL: 137 WW: 137

477-30-3336 (79 y , 79 y)
Cine - Cine
4942
28



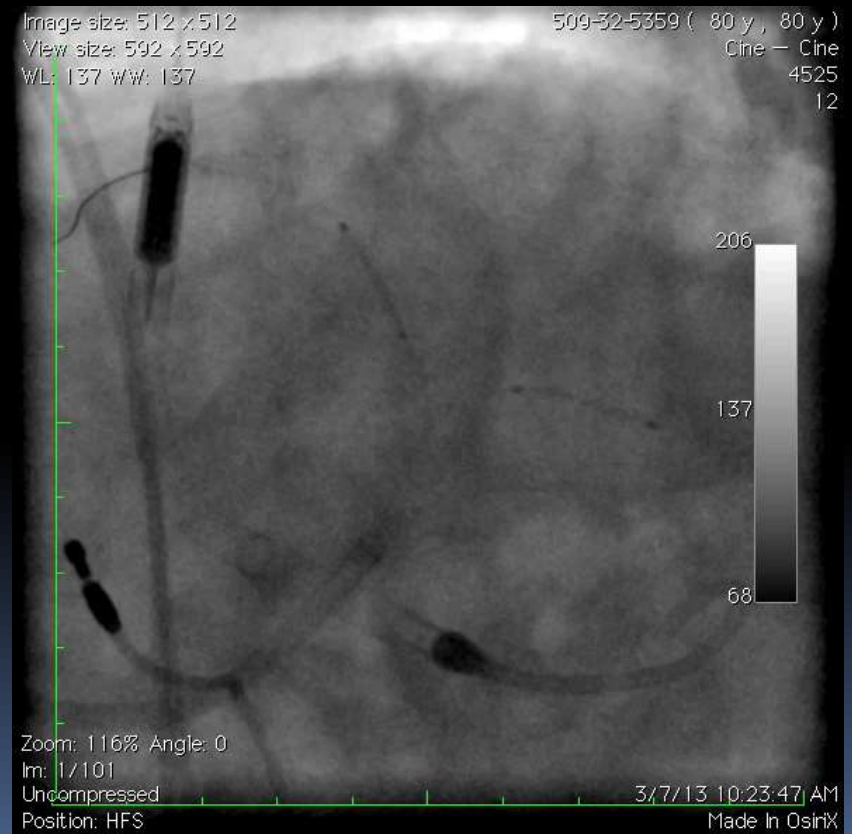
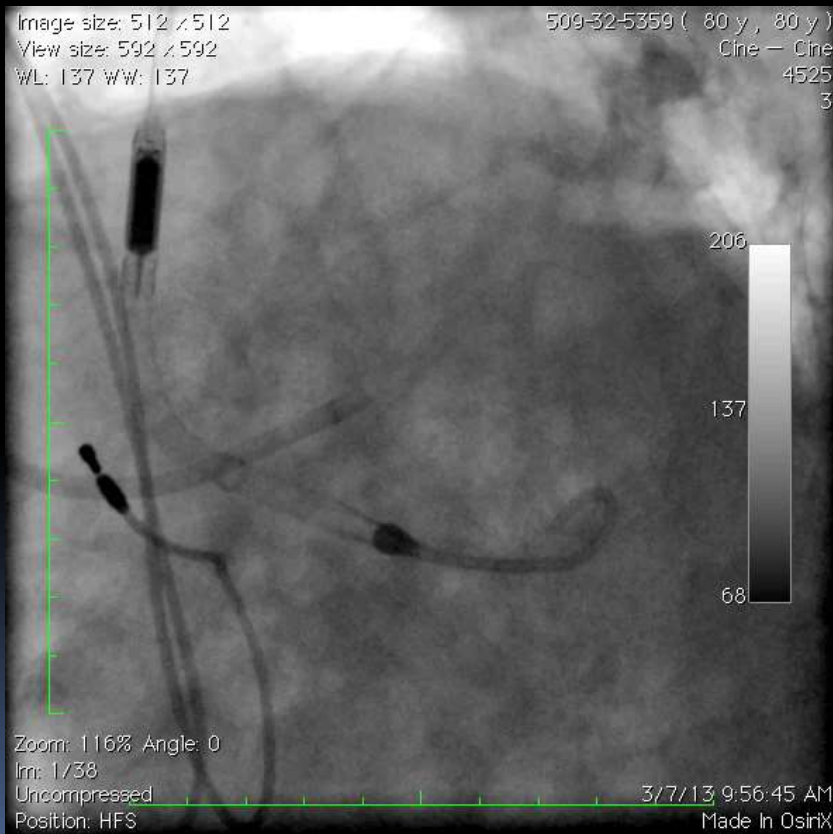
Zoom: 118% Angle: 0
Im: 1/59
Uncompressed
Position: HFS

3/28/12, 3:02:26 PM
Made In OsiriX

- 
- 79 yo male with 6.5 cm AAA, referred for cath after admitted with NSTEMI
 - Severe left main and multivessel disease
 - LVEF 25%
 - In cardiogenic shock on 2 pressors
 - CT surgery deemed too high risk for CABG
 - Referred for Impella supported PCI

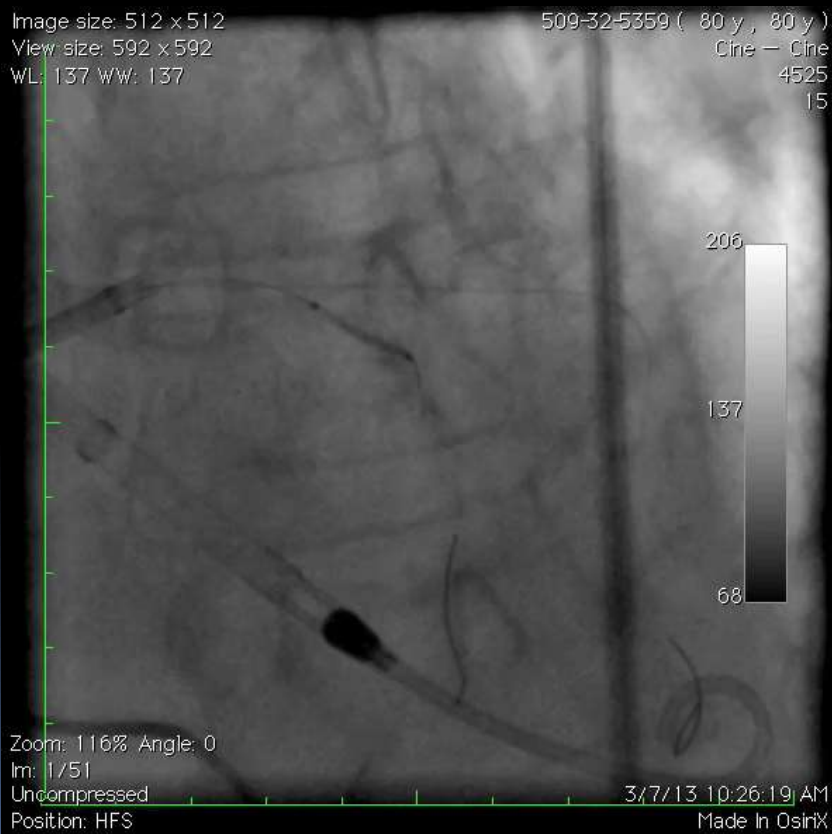
79 yo male with LM disease, severe 6.5 cm AAA

DES post ASC Ballooning

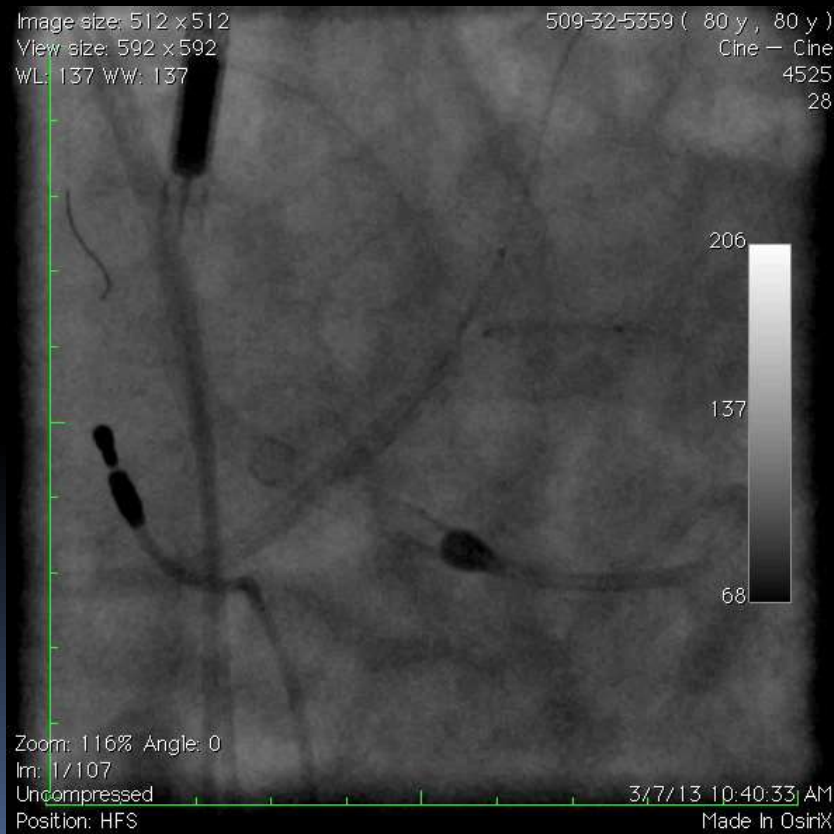




ASC Ballooning of LAD

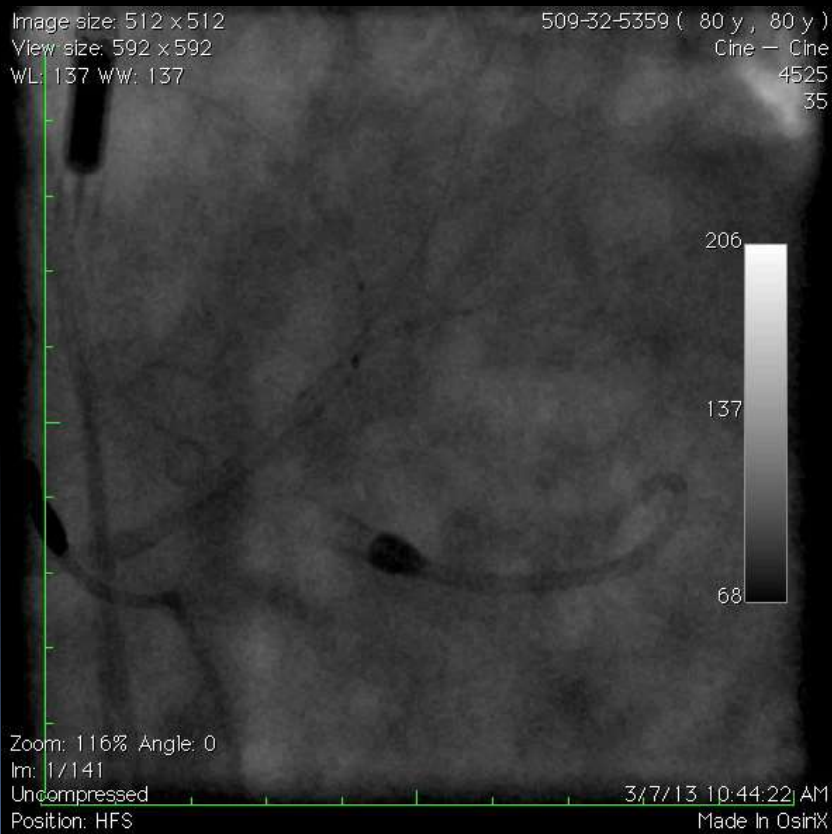


Sequential DES deployment





SKS Strategy



Impella from L subclavian access

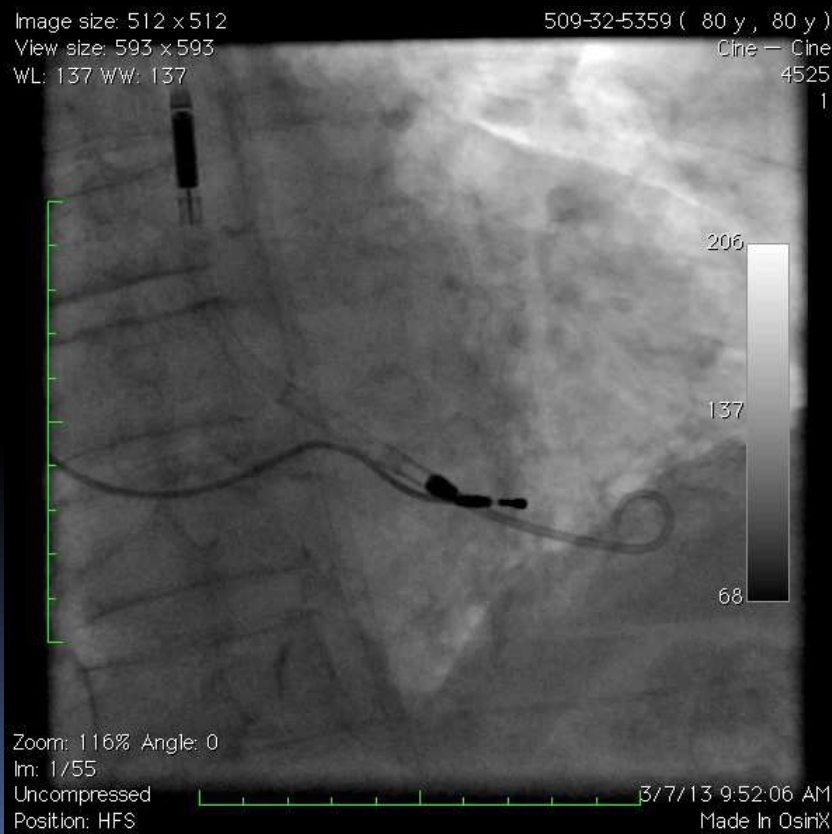
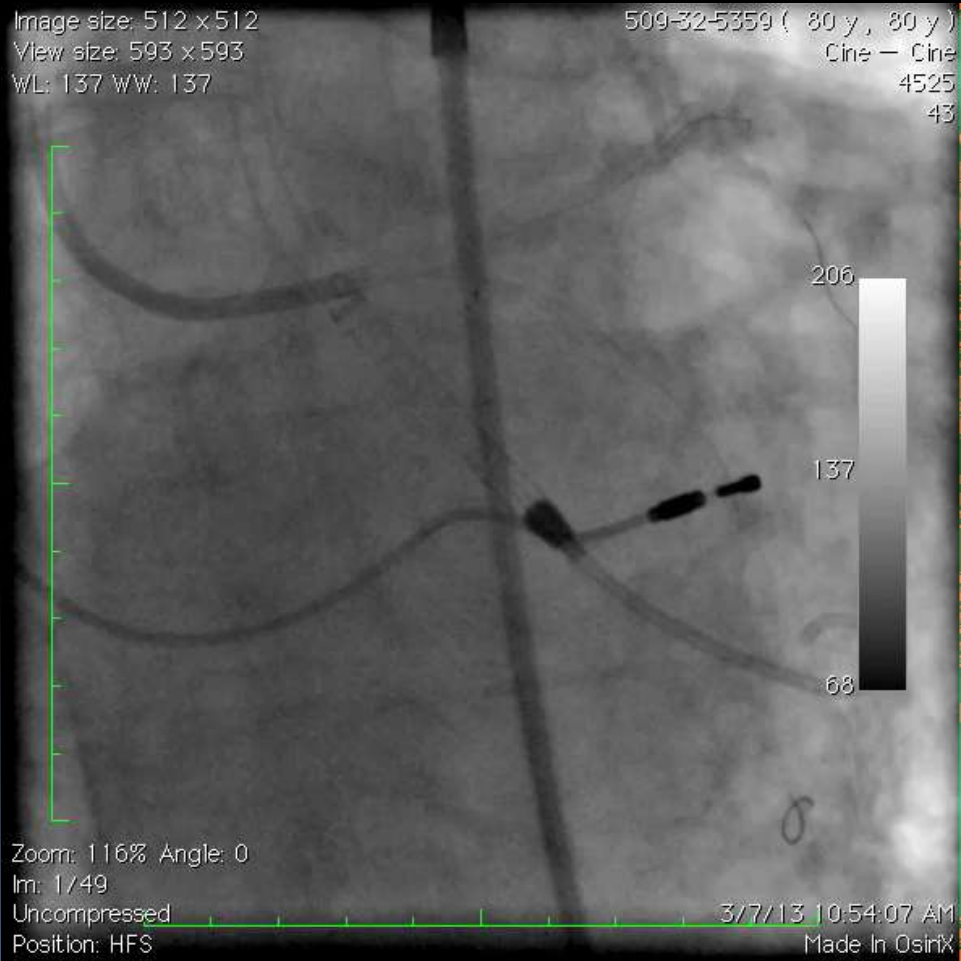



Image size: 512 x 512
View size: 593 x 593
WL: 137 WW: 137

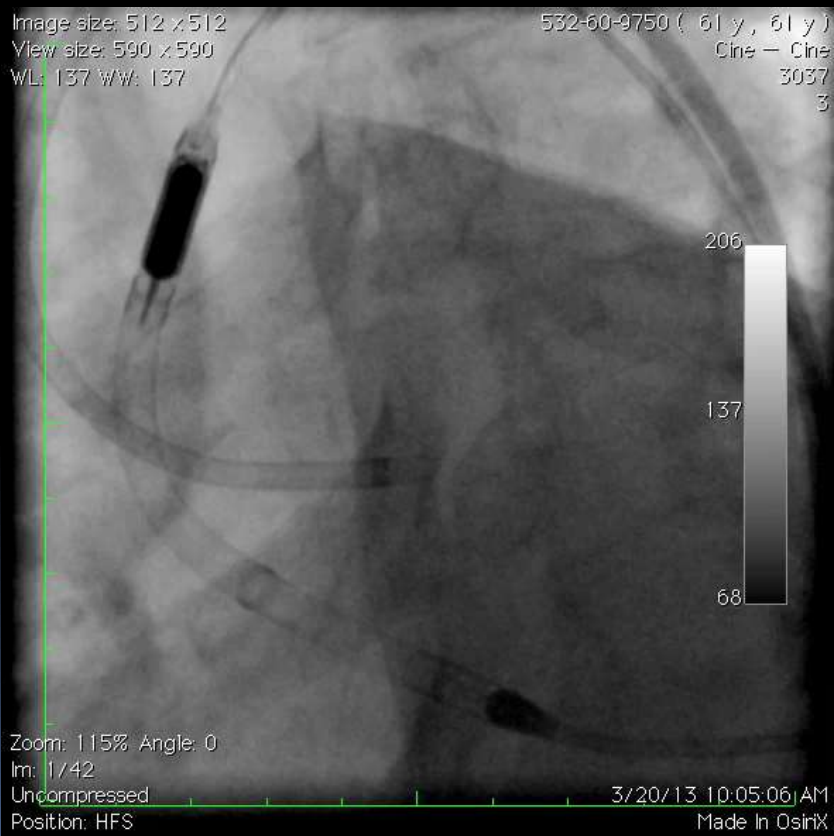
509-32-5359 (80 y , 80 y)
Cine - Cine
4525
43



Zoom: 116% Angle: 0
Im: 1/49
Uncompressed
Position: HFS

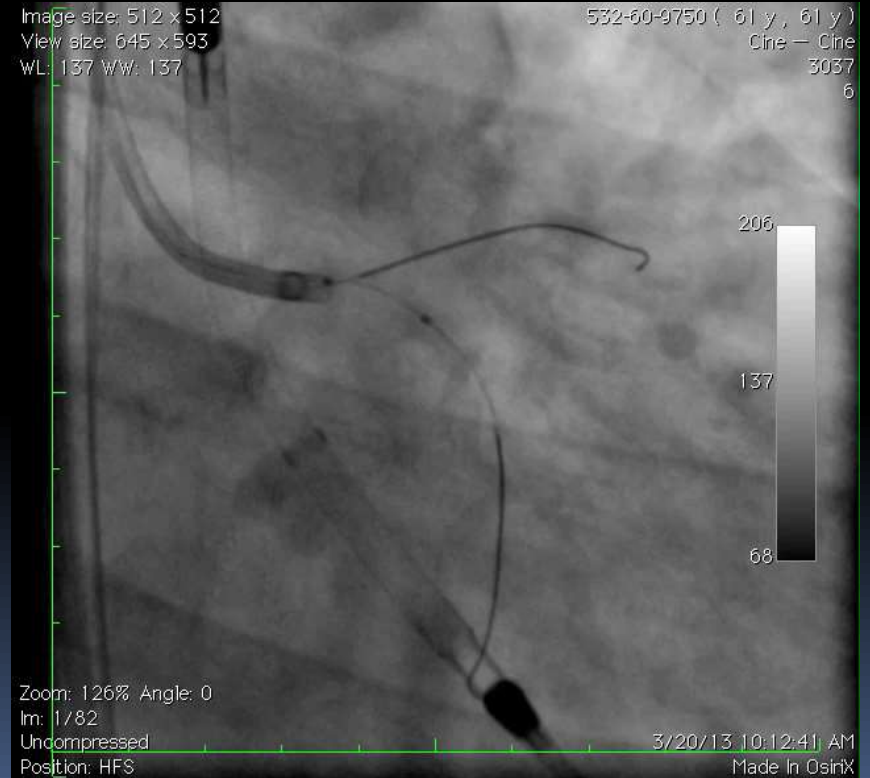
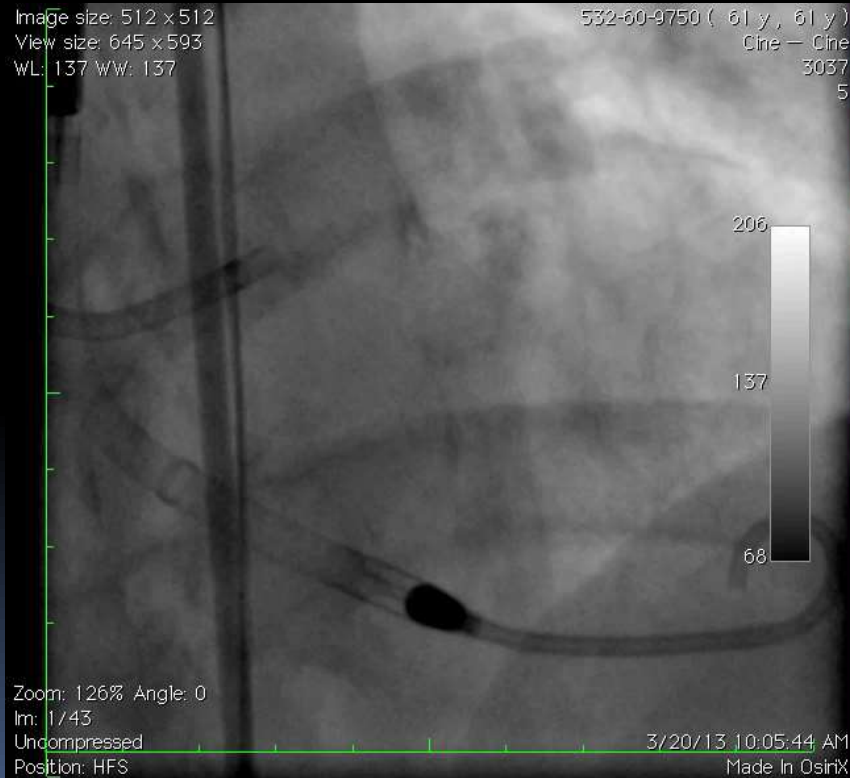
3/7/13 10:54:07 AM
Made In OsiriX

- 
- 77 yo male with left main, multivessel CAD
 - LVEF 20%
 - COPD, ESRD
 - Presented with STEMI and CS





ASC Balloon of Circumflex

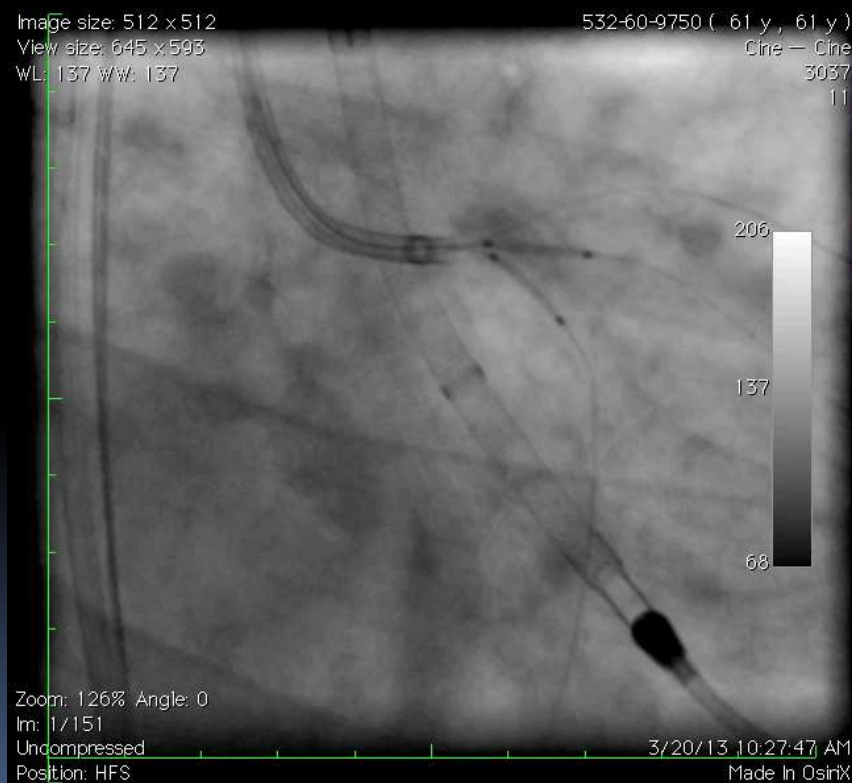




SKS ASC balloons

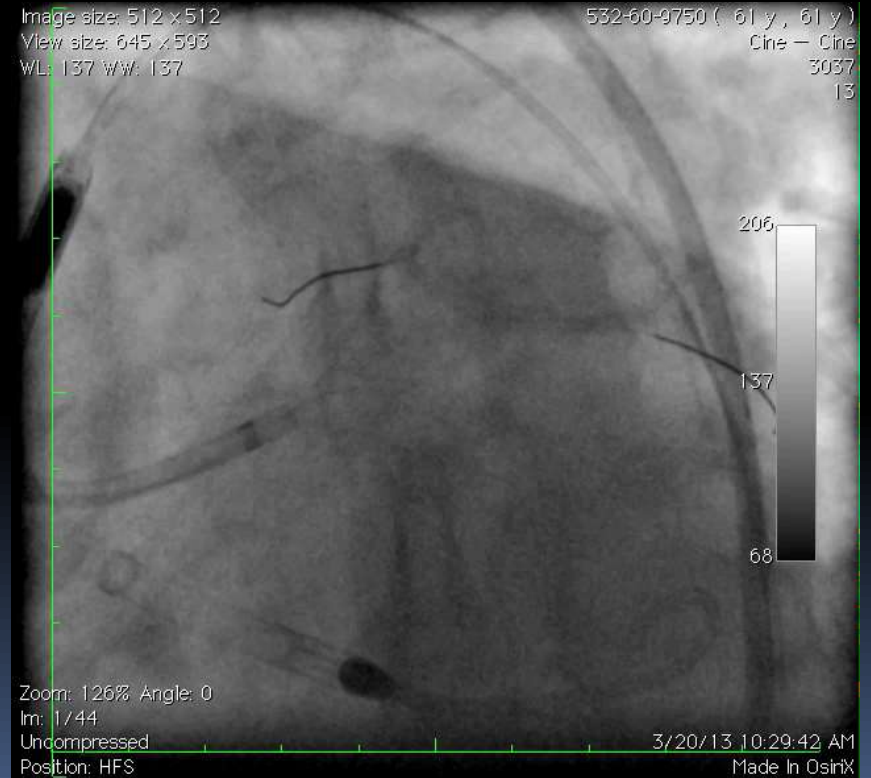
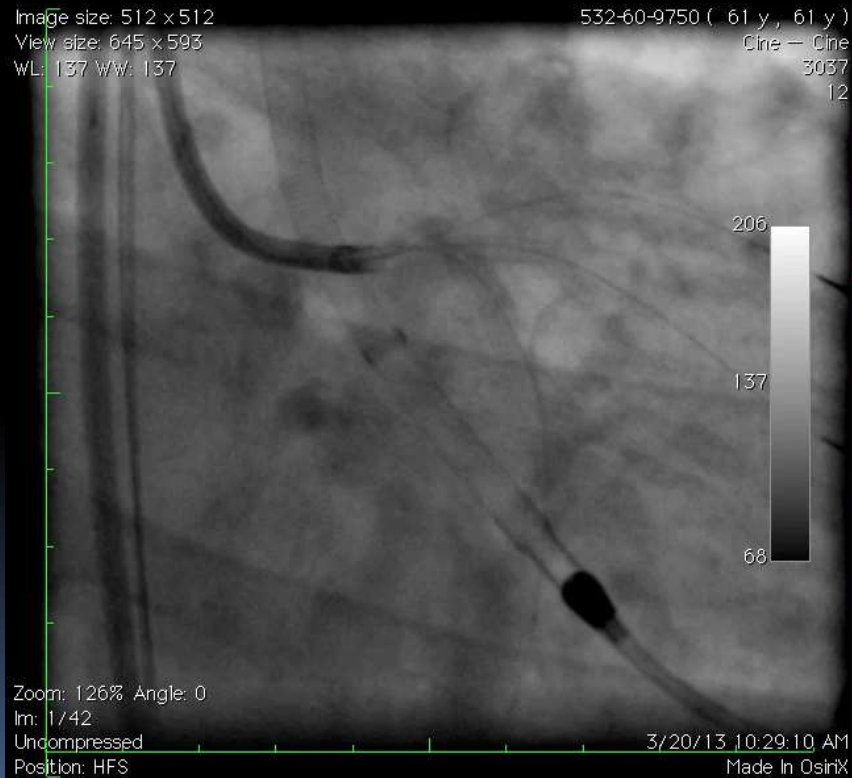


SKS Resolute



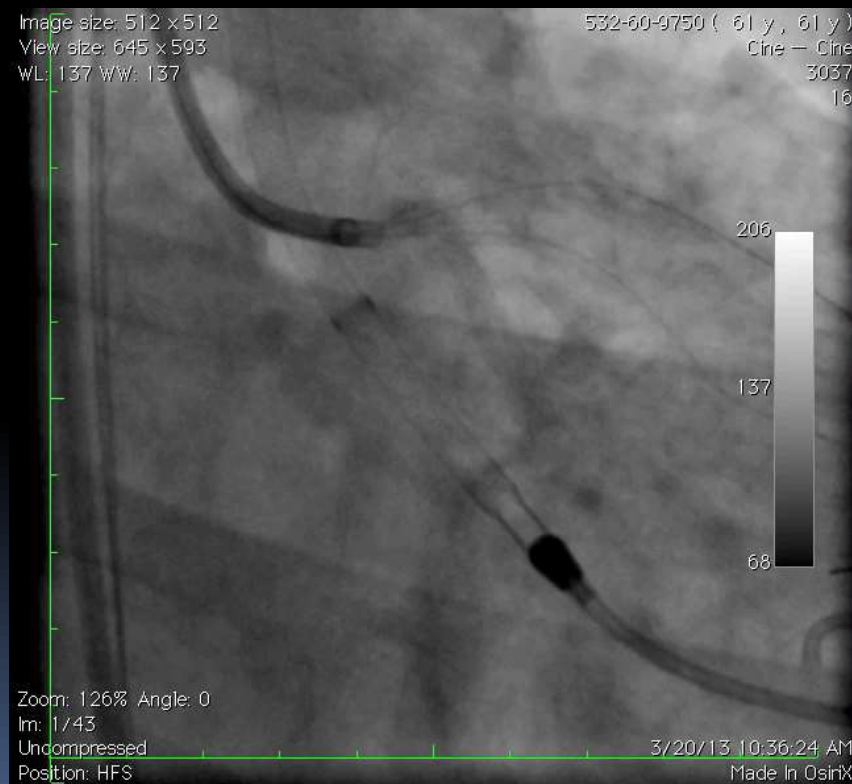
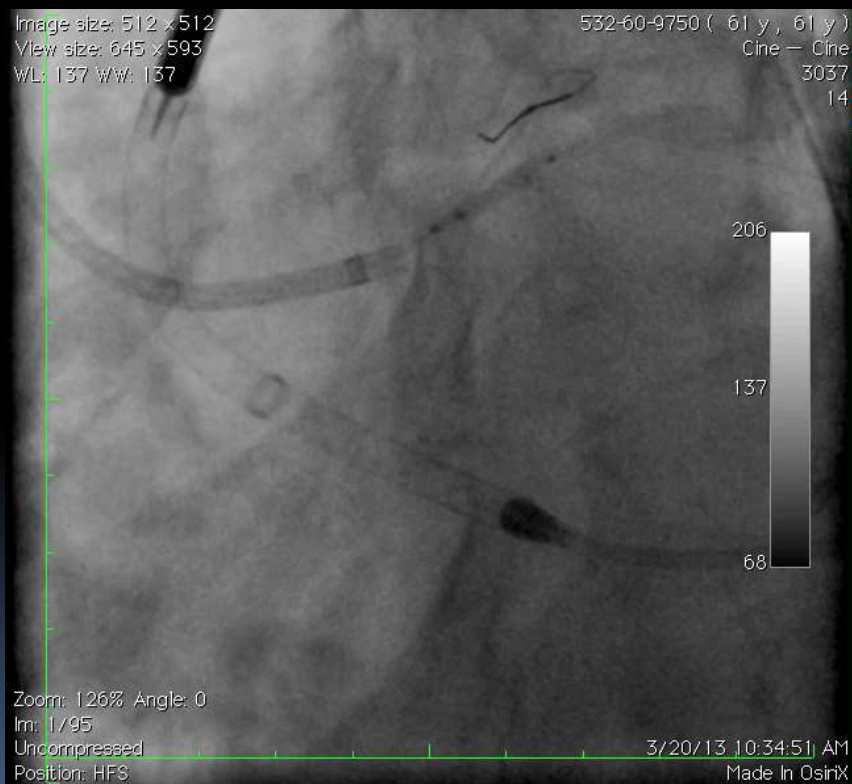


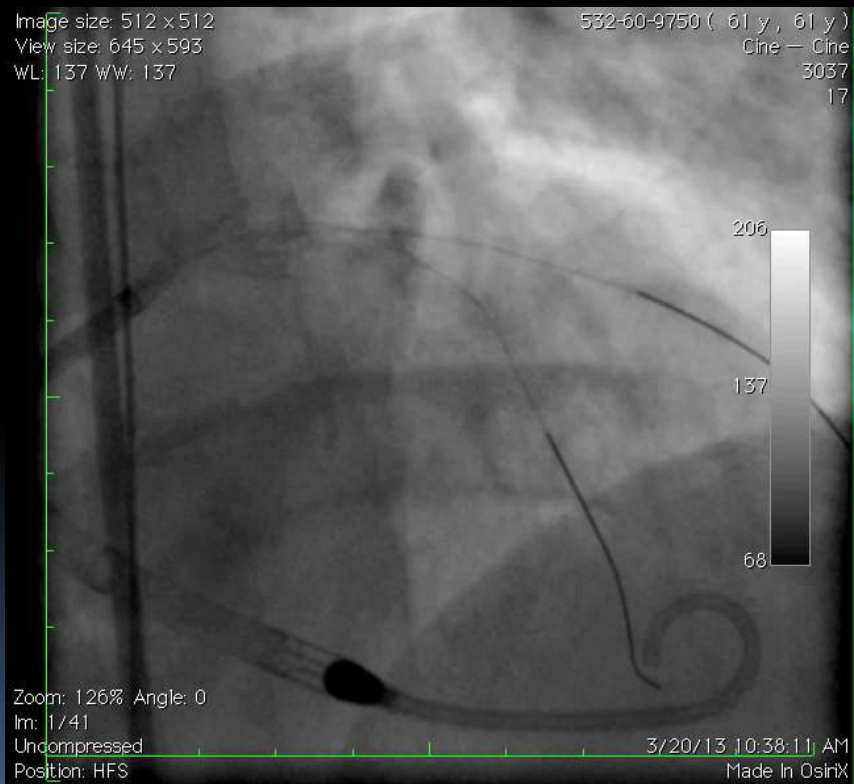
Residual left main lesion





ASC to protect Ramus while Resolute to Left Main

























Be Persistent!