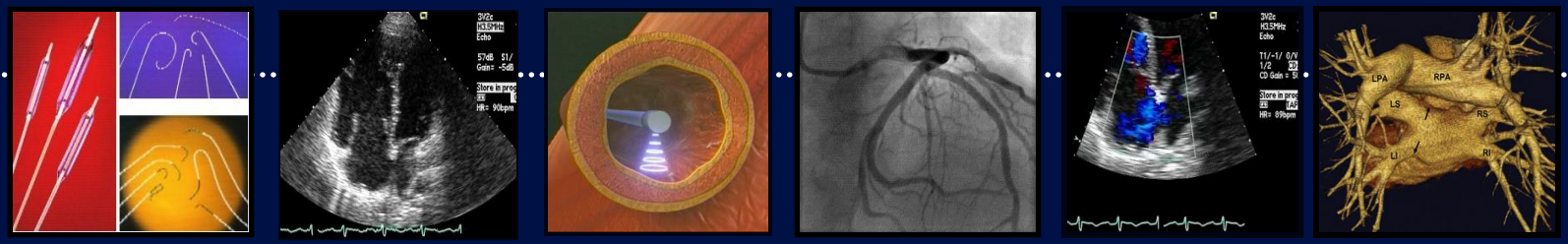
Cath Lab Essentials : LV Assist Devices for Hemodynamic Support (IABP, Impella, Tandem Heart)



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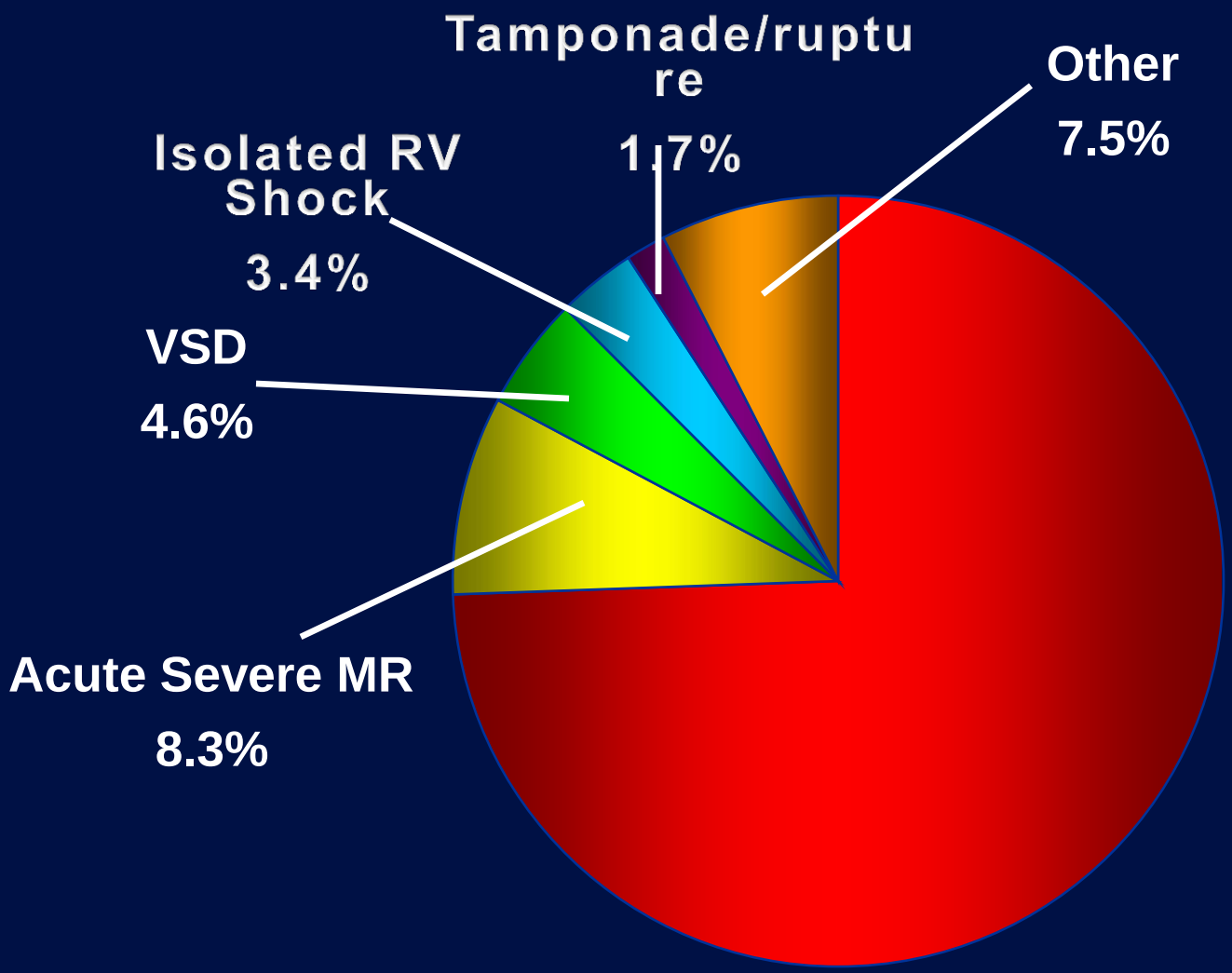
Goals

- To compare and contrast mechanical LV assistance and percutaneous support devices in terms of their designs and ideal applications
- Review current indications for commonly used devices
- Describe the factors that should be considered when choosing the most appropriate devices

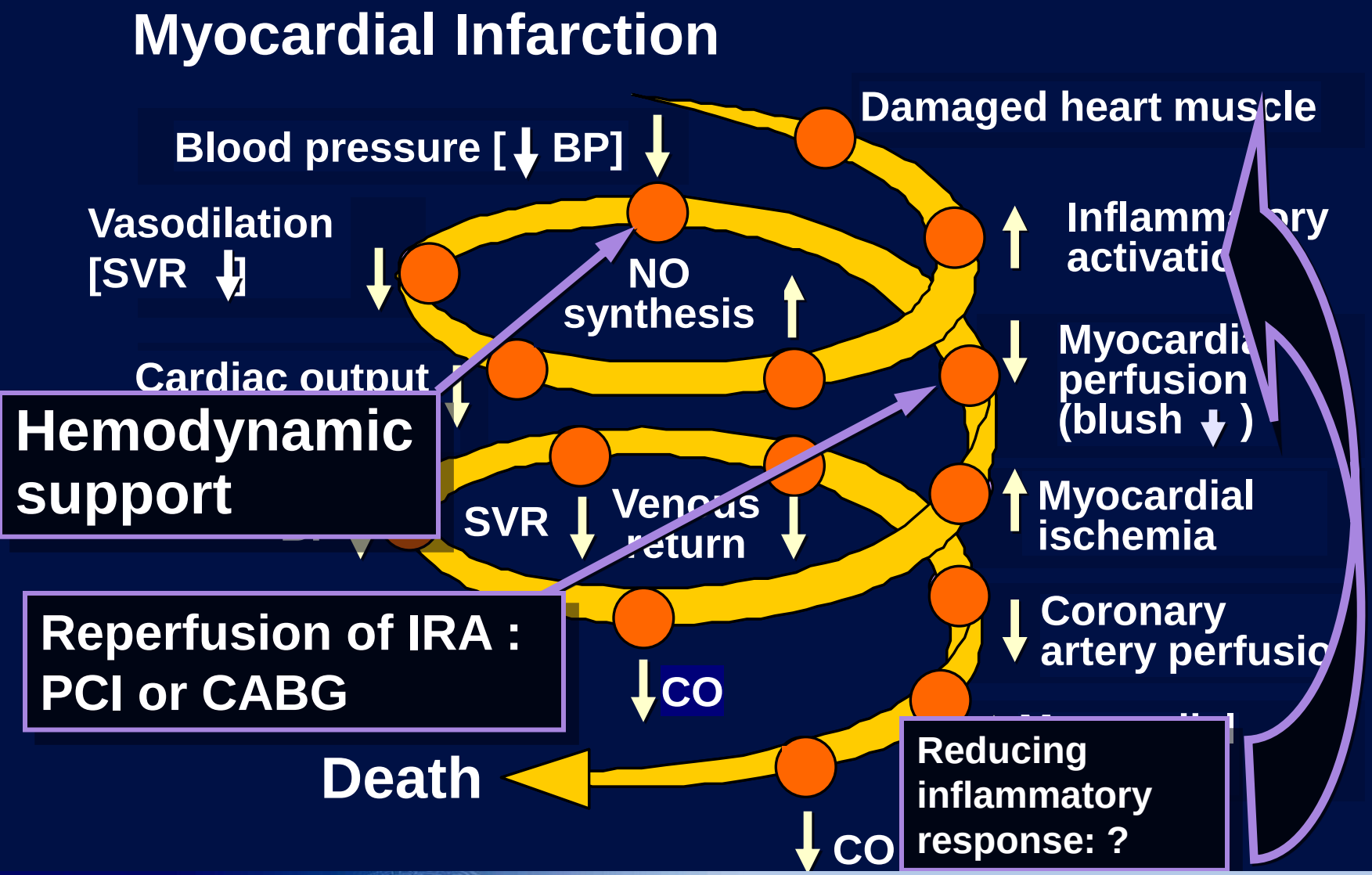
Causes of Cardiogenic Shock



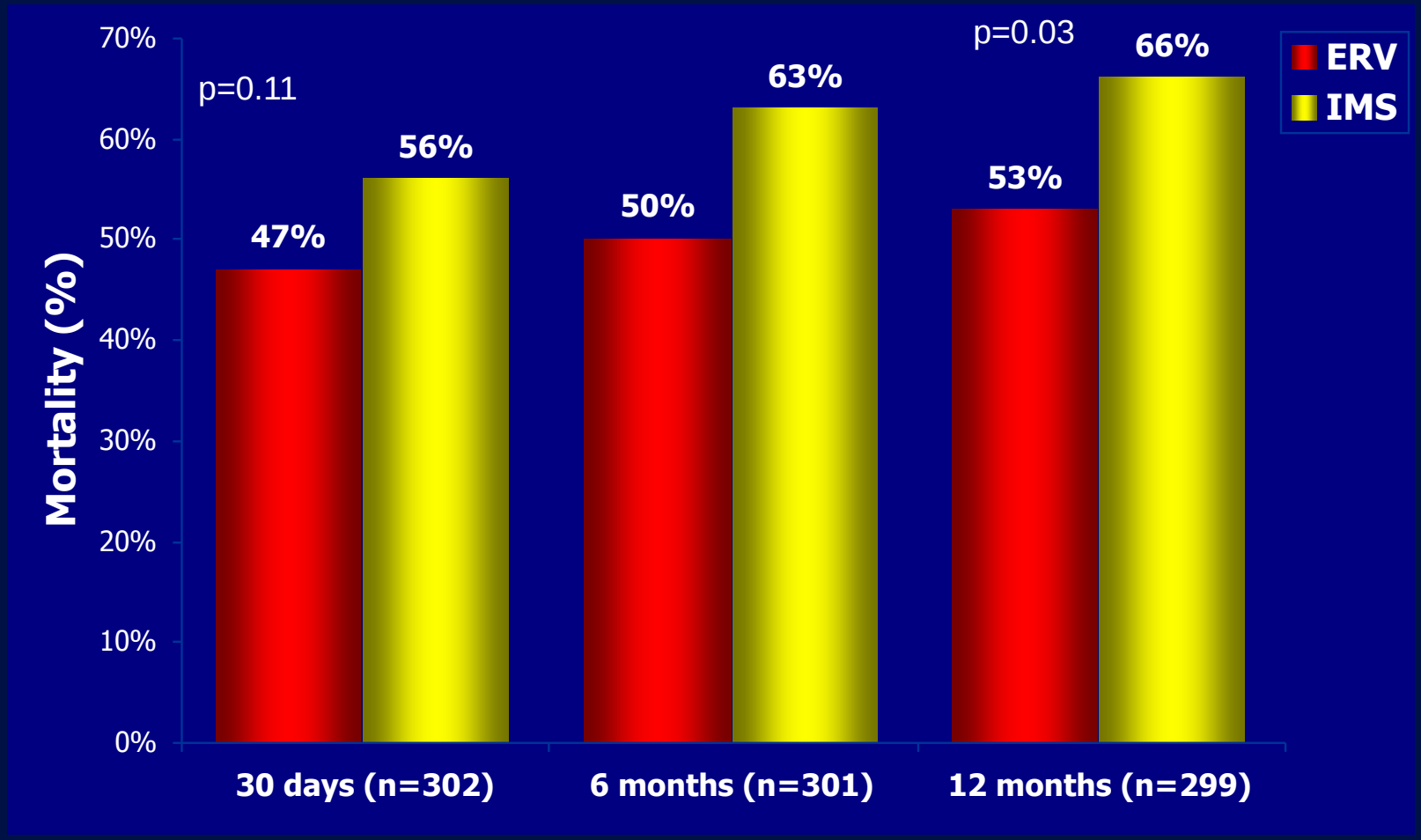
Shock Registry

JACC 2000 35:1063

Physiology of Cardiogenic Shock: A Downward Spiral



Emergency revascularisation - SHOCK Trial

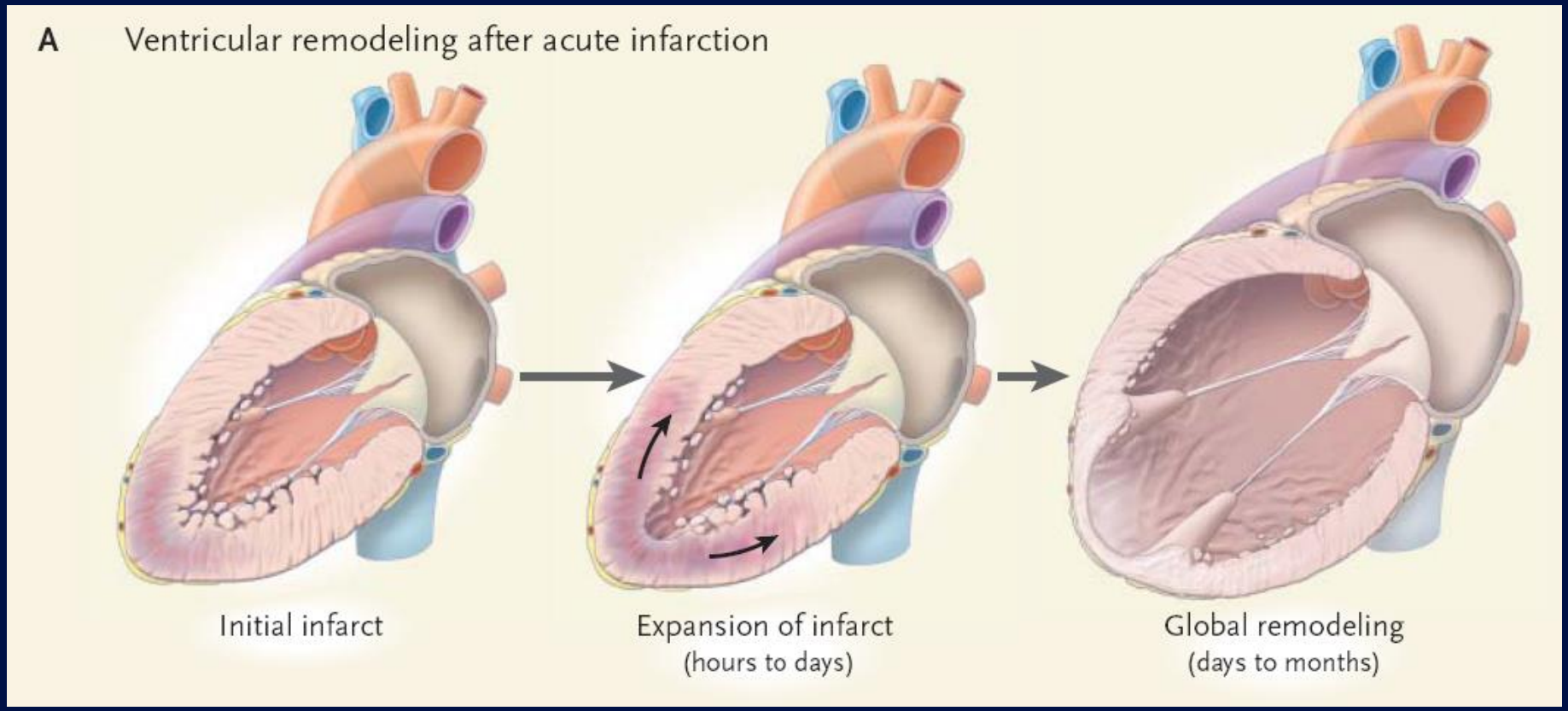


85% of survivors NYHA Class I/II at 12 months after early revascularization or initial medical stabilization

Hochman JAMA 2000;285:190

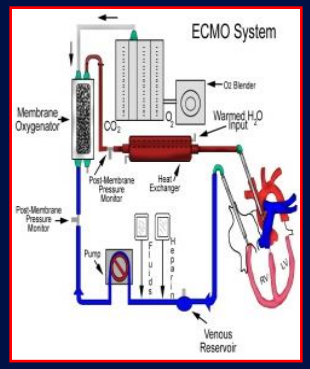
Heart muscle can recover with support

High Potential of heart muscle recovery, Gain in Ejection Fraction → **Low Potential of heart muscle recovery, Loss in Ejection Fraction**

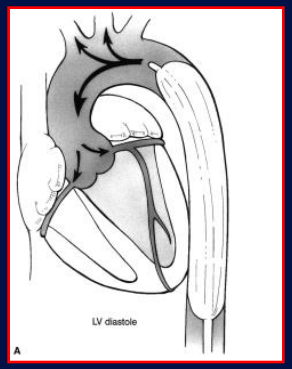


New England Journal of Medicine: 2003; 348:2007-18

Cardiac Support in Cath lab
Hemodynamic Principles

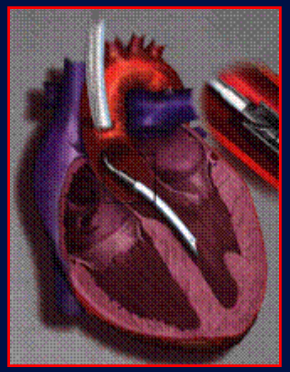


ECMO

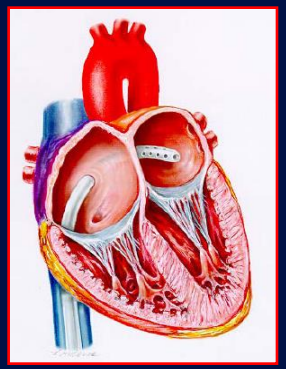


IABP

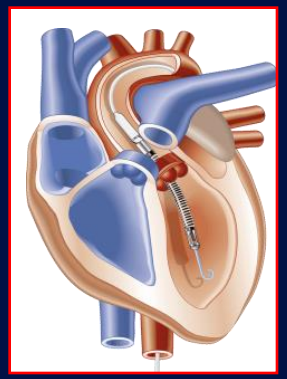
CPS



Hemopump



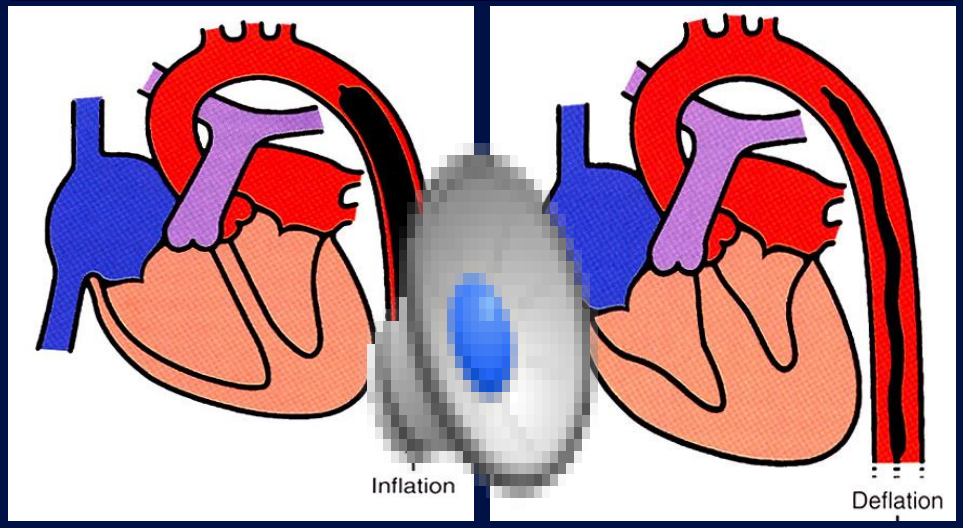
TandemHeart



Impella

Intra-Aortic Balloon Pump

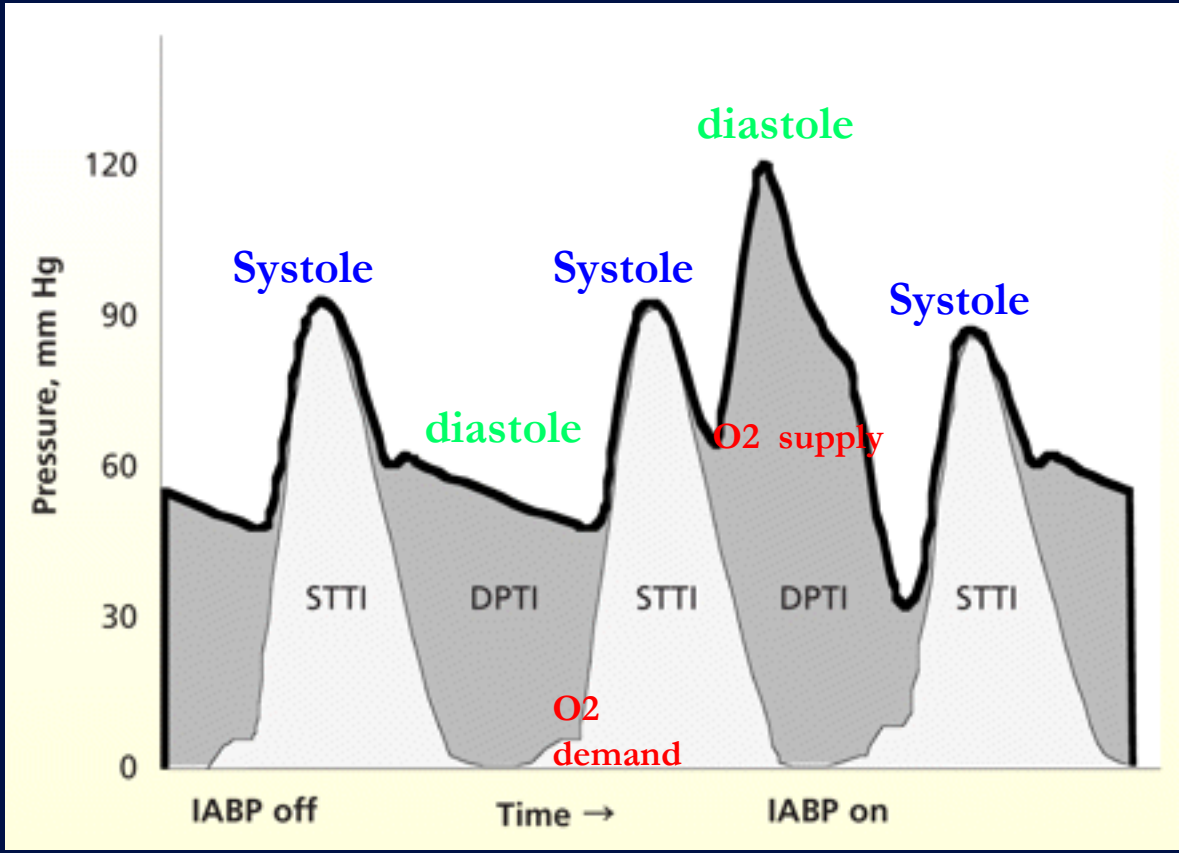
- Introduced in 1968 (Kantrowitz)
- First "true percutaneous" support device
- Cheapest, commonest (20% of all cardiogenic shock cases), CO 0.5L/min
- Stabilize pt, but not full support
- No outcome benefit



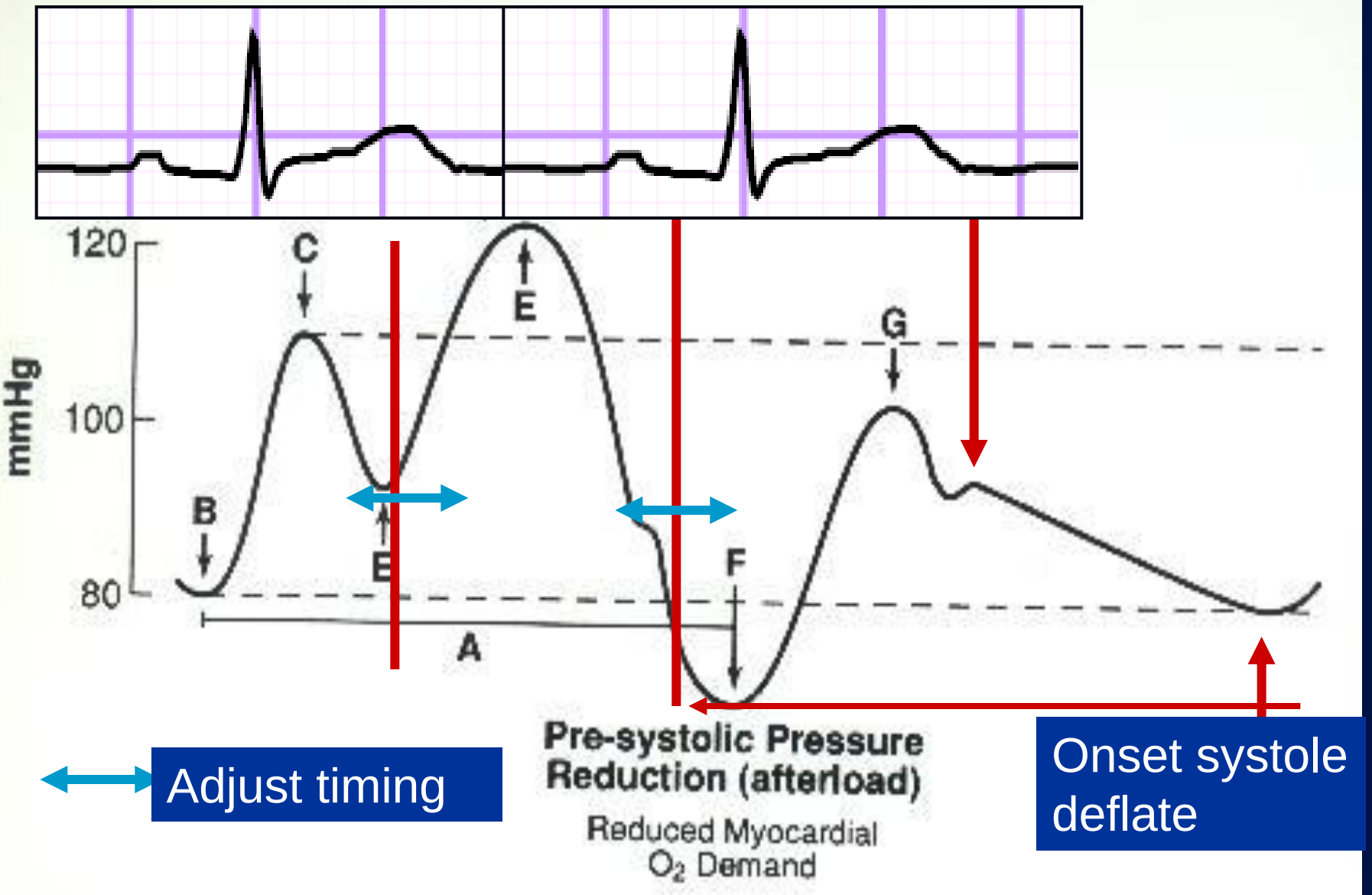
Hemodynamic Effects:

Diastolic pressure	↑↑
CO	↑
MAP	↑
LV Wall Tension	↓↓
PCWP	↓↓
Oxygen Demand	↓
LV Volume	↓
Coronary Blood Flow	←→

IABP improves myocardial Oxygen supply



STTI represents oxygen demand, and the diastolic pressure time index (DPTI) represents oxygen supply. IABP counterpulsation increases DPTI during IABP inflation and decreases STTI on the beat following IABP deflation. Intra-aortic balloon counterpulsation improves the ratio of myocardial oxygen supply and demand, reducing the risk of further ischemia or reductions in contractility.


120
100
80
mmHg
C
E
G
B
E
F
A
Pre-systolic Pressure Reduction (afterload)
Reduced Myocardial O2 Demand
Adjust timing
Onset systole deflate

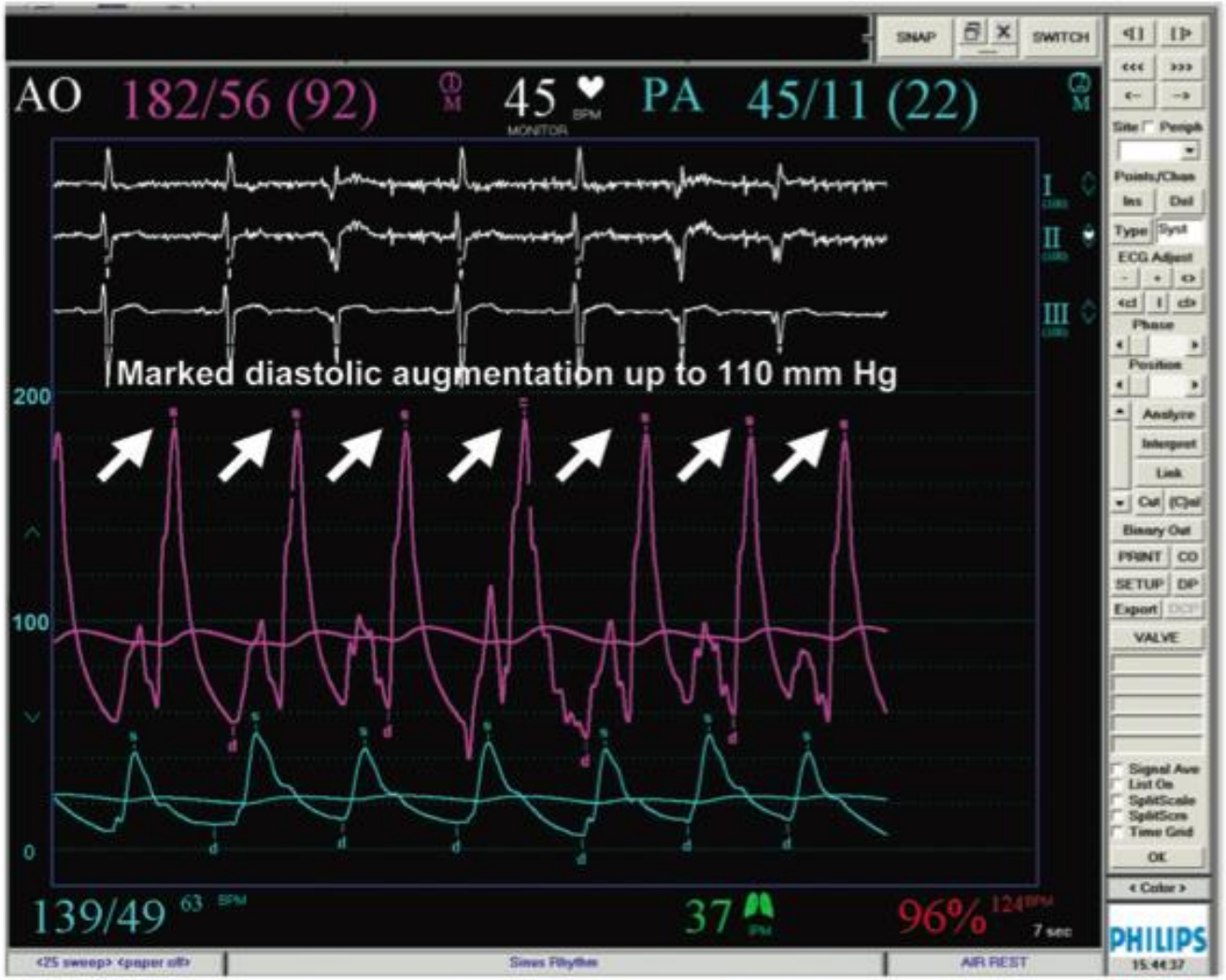


Figure 5. *Marked diastolic augmentation of aortic pressures observed with intra-aortic balloon pump use.*

Nair et al Journal of Invasive Cardiology 2011

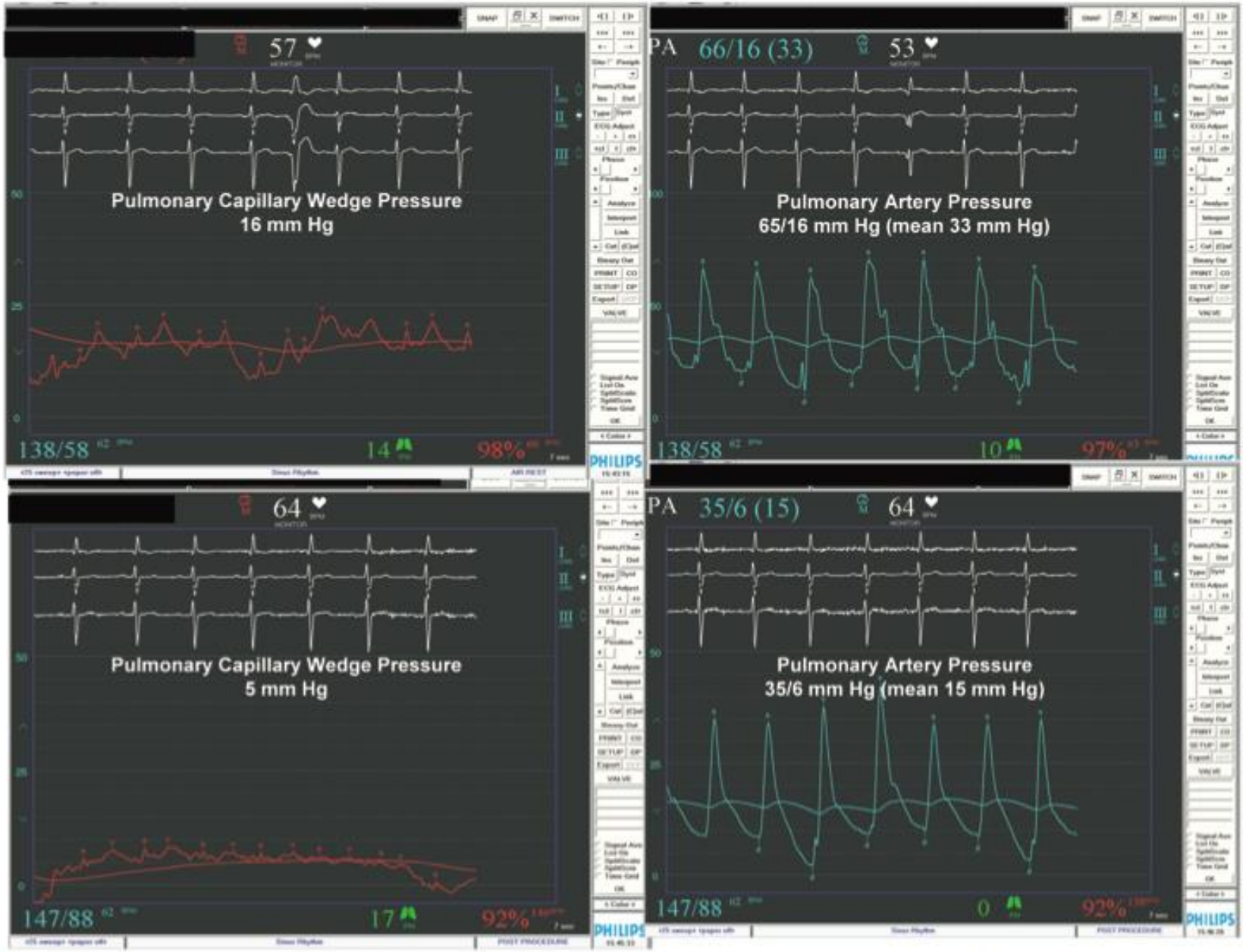
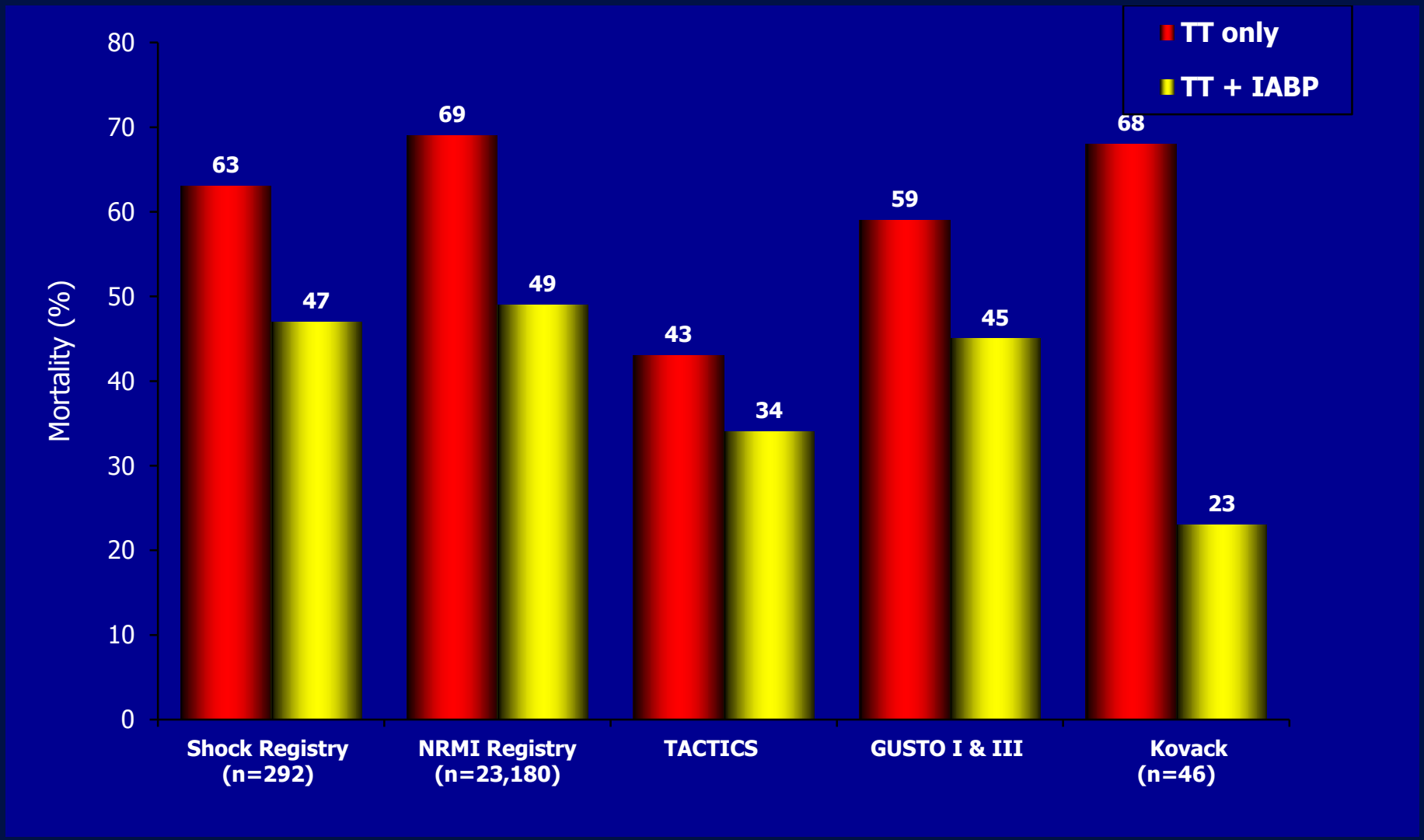


Figure 4. *Pulmonary capillary wedge pressure (left) and pulmonary artery pressure (right) before (top) and after (bottom) insertion of the intra-aortic balloon pump.*

Nair et al Journal of Invasive Cardiology 2011

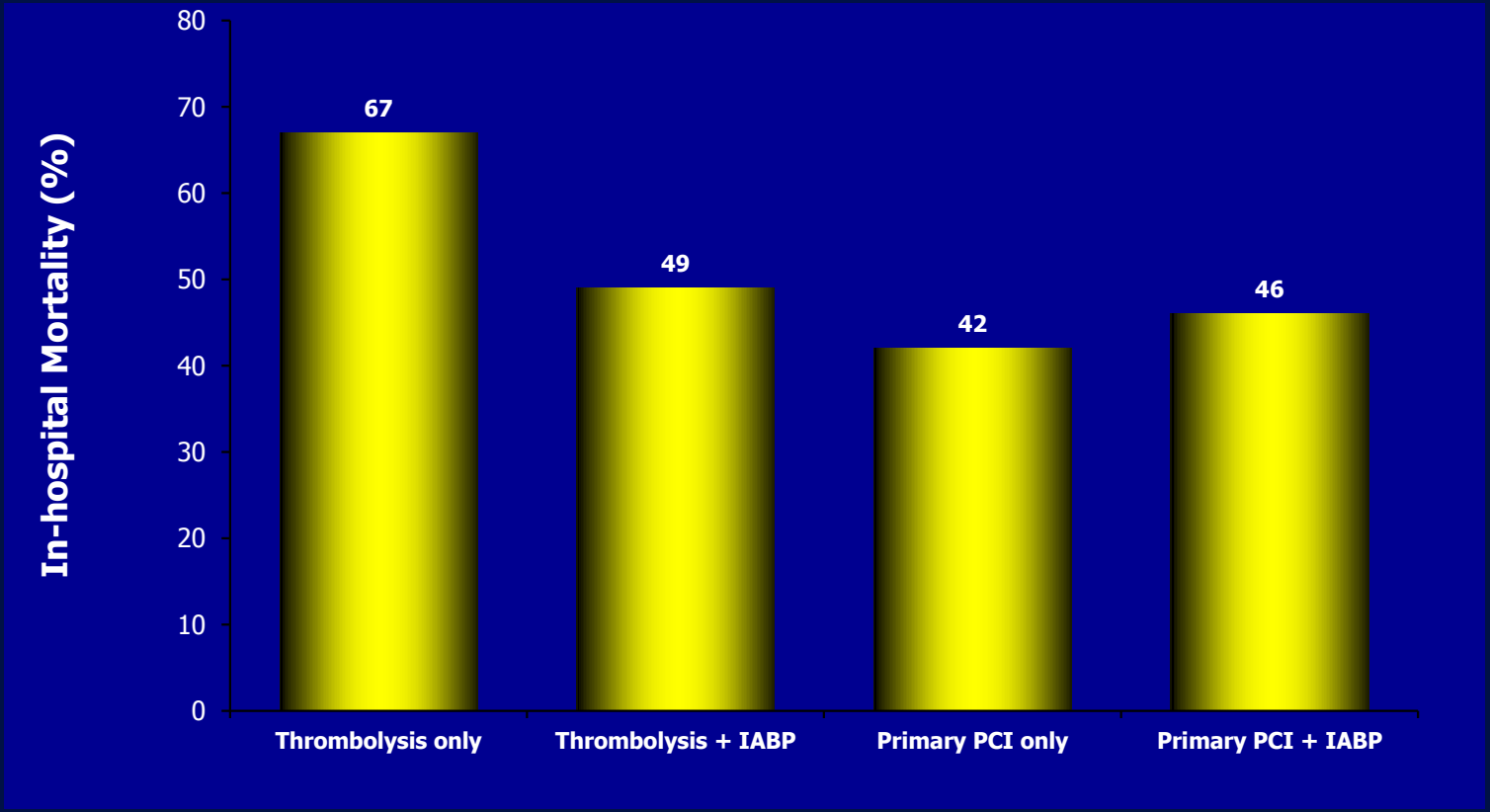
Early Trials and Registry Data for IABP



IABP in Cardiogenic Shock Primary PCI

Retrospective analysis of 23,180 patients from NRMI database

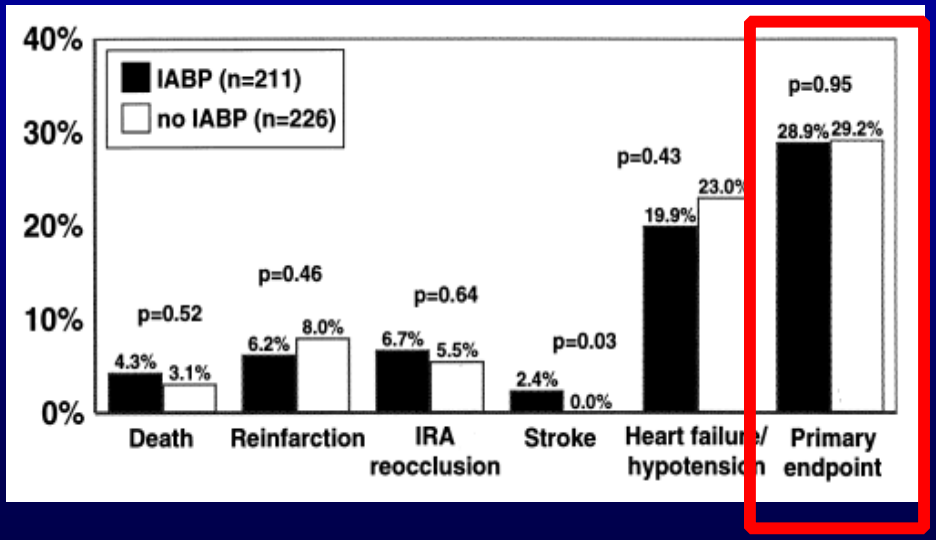
7268 treated by IABP (trend towards improved mortality)

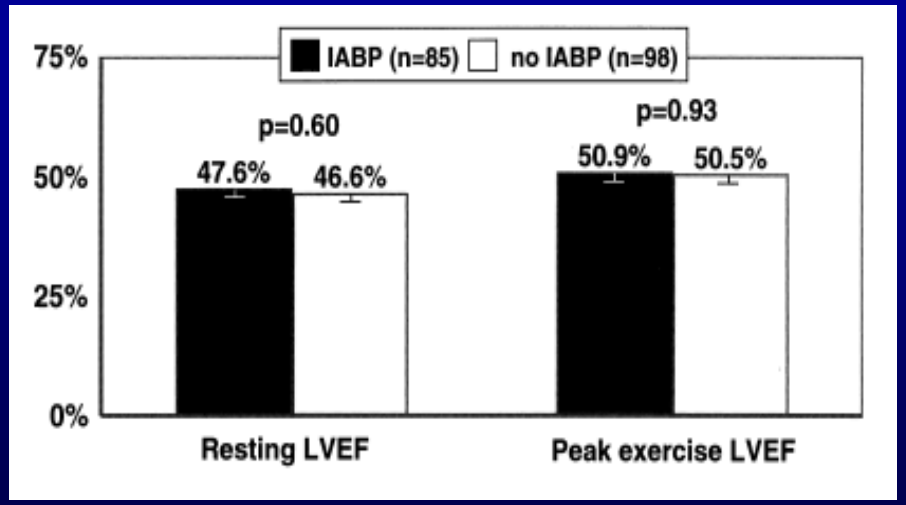


PAMI-II

Stone et al, J Am Coll Cardiol 29:1459, 1997

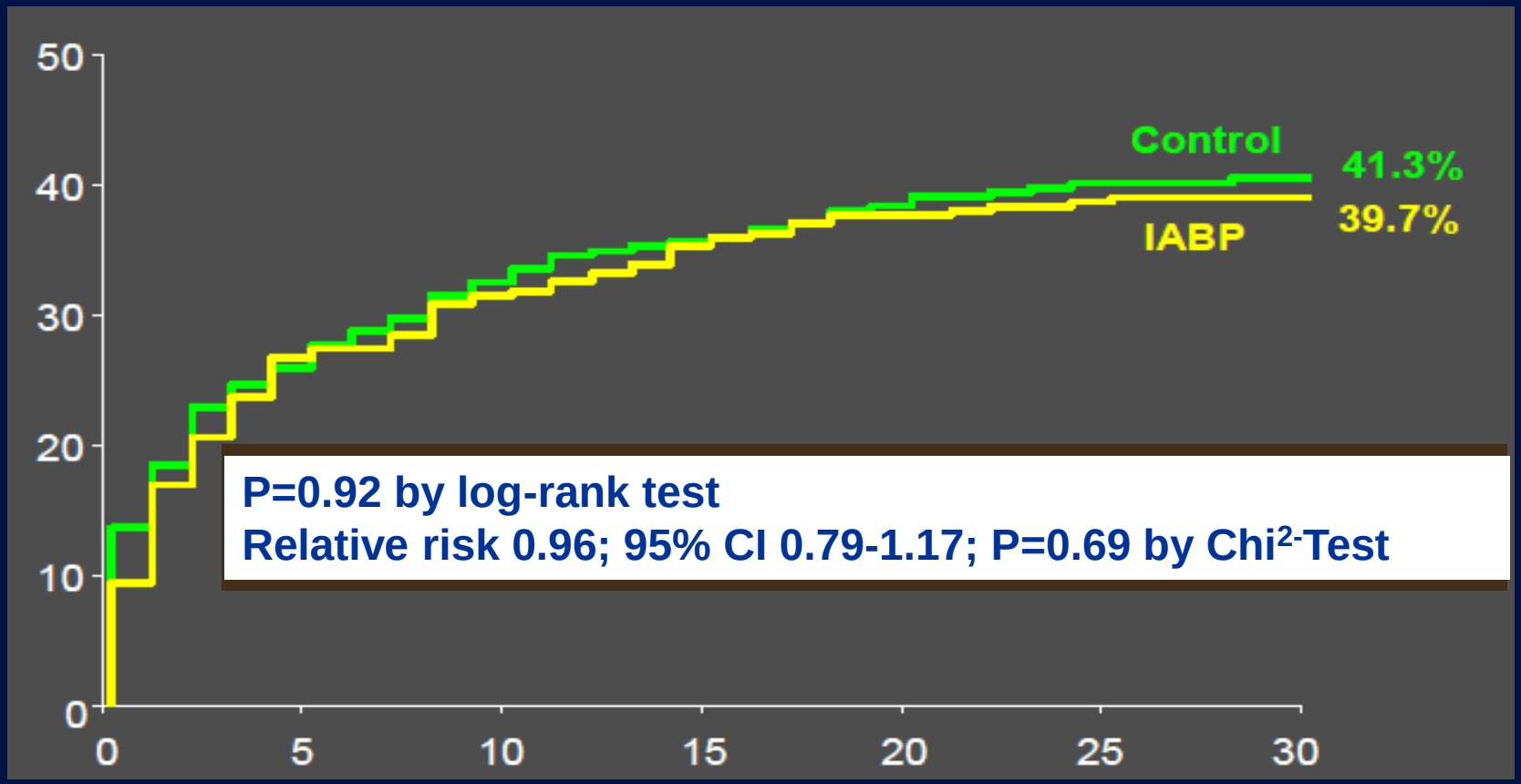
- High risk patients (age > 70, EF < 45%, etc) in PPCI in AMI
- Randomized to 26-48 hrs IABP (n=211) or conventional Rx after PCI (n=226)
- No benefit in mortality or LV function, at discharge or 6 weeks





IABP-Shock II Trial: Results Primary Study Endpoint: 30-day Mortality

(IABP in Cardiogenic Shock and Primary PCI)



Thiele H et al. NEJM 2012;367:1287.

Indications for IABP

- High Risk PCI
- Cardiogenic Shock
- Refractory Ischemia
  - Left Main
  - 3 Vessel CAD
  - VT/VFib
- MR or VSD after MI
- Severe CHF--? Bridge to Transplant
- Pre-operative stablization
- Weaning therapy after CABG

Contraindication to IABP

- Peripheral vascular disease
- Aortic regurgitation
- Aortic Dissection
- PDA
- HOCM
- Heparin intolerance
- Bleeding Diathesis
- Sepsis

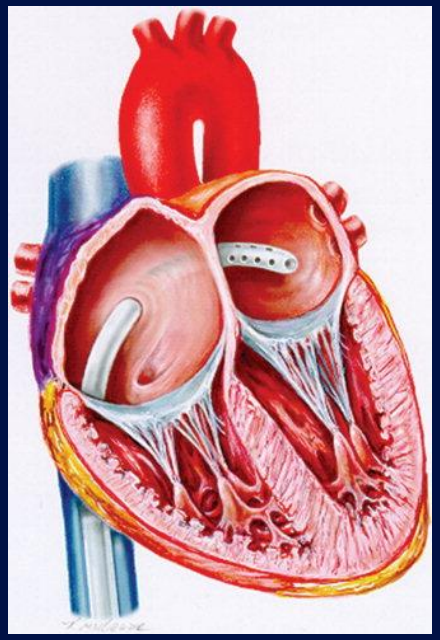
Complications of IABP

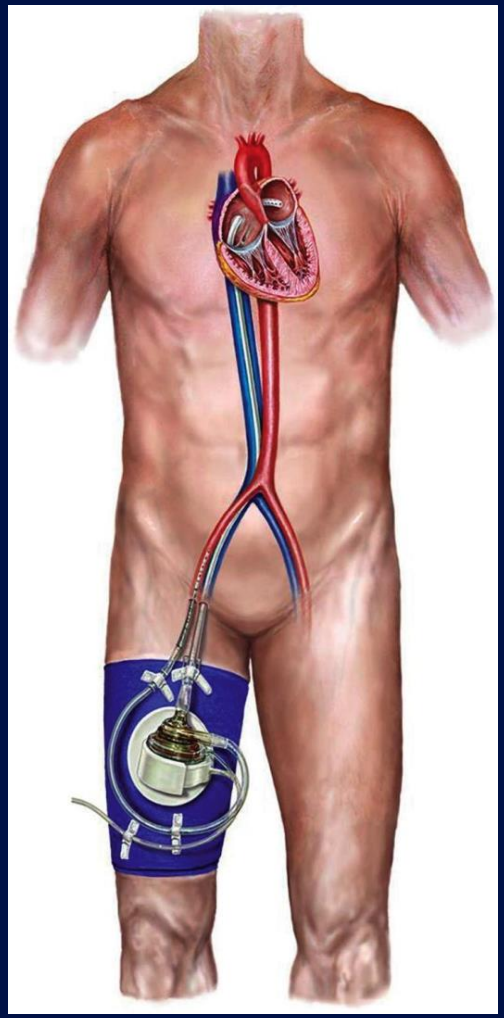
- Vascular Access bleeding/complications
- Limb Ischemia
- Infection
- Thrombocytopenia
- Migration and aortic arch trauma
- Other non-vascular (CVA, embolization of cholesterol, balloon rupture)
- Air embolism risk (reduced by using helium gas)

Hemodynamic Advantage of pVAD vs. IABP

	pVAD	IABP
Directly unload the left ventricle	+++	-
Reduce myocardial workload and oxygen consumption	+++	++
Increase cardiac output and coronary and end-organ perfusion	+++	+

Tandem Heart

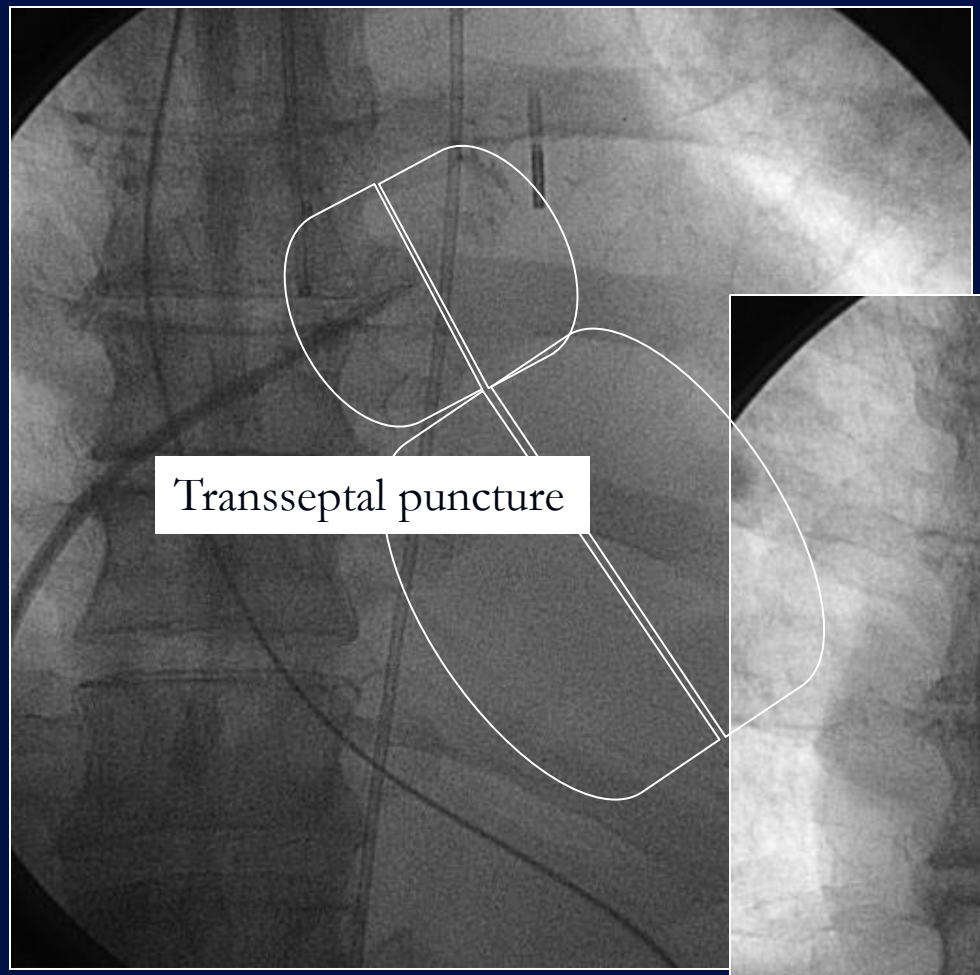


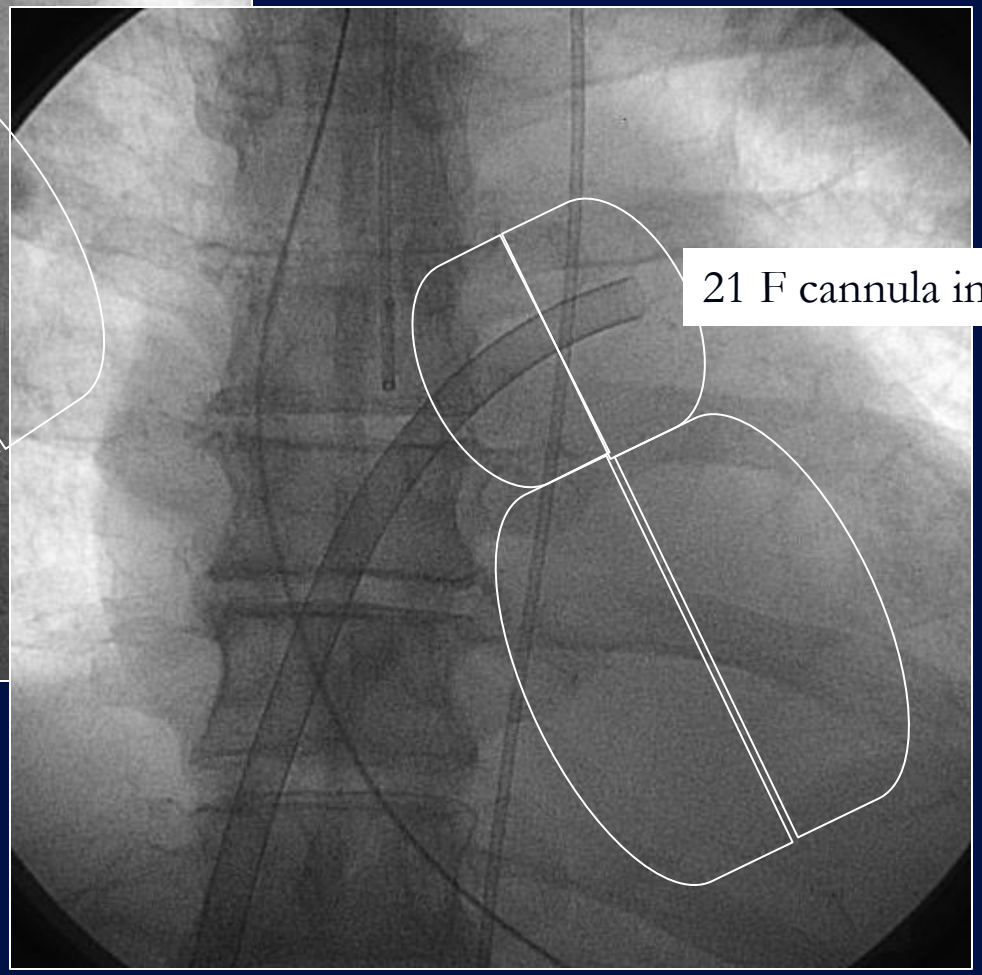


- Left atrial-to-femoral arterial LVAD
- 21F venous transeptal cannula
- 17F arterial cannula
- Maximum flow 4-5L/min

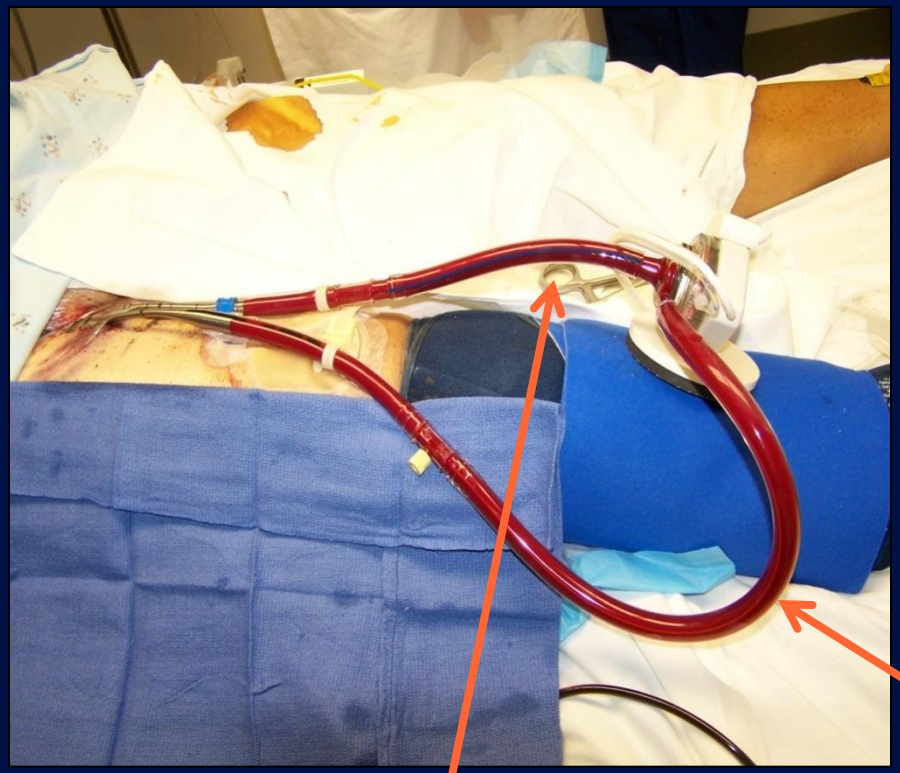
Hemodynamic Effects

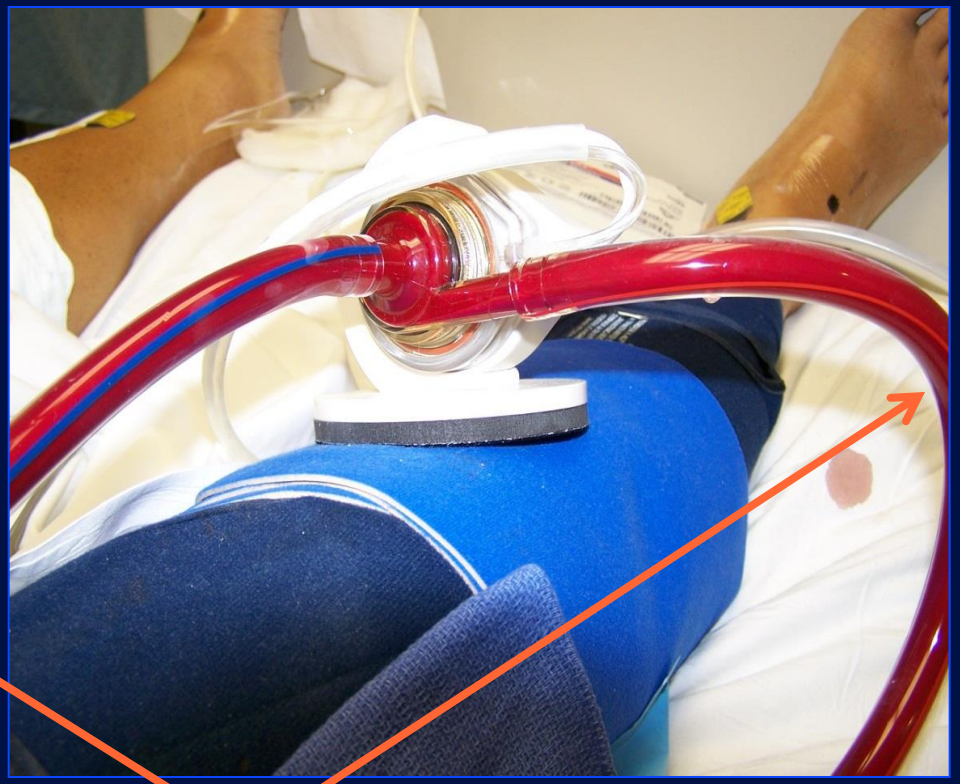
CO	↑↑
MAP	↑
PCWP	↓↓


Transseptal puncture


21 F cannula in LA

Tandem Heart and cannulae



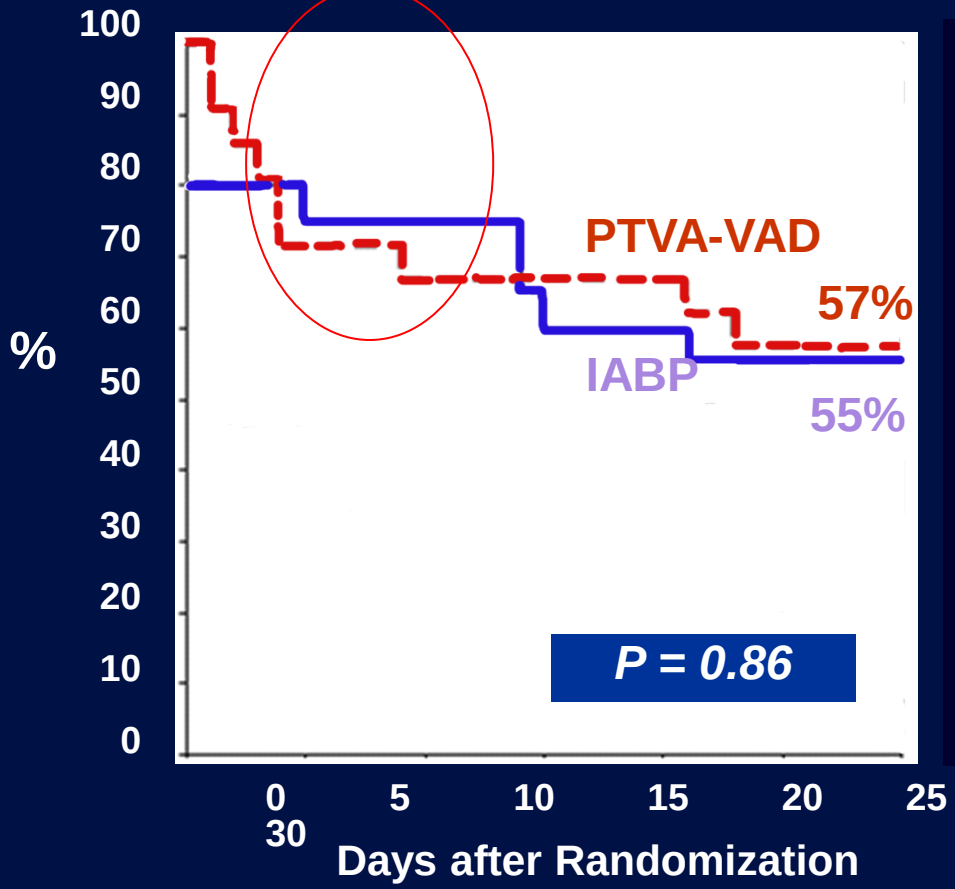


Venous cannula

arterial return cannula

TandemHeart Shock study:Randomized Comparison of IABP with PTVA (VAD) Device in Patients with Cardiogenic Shock

Kaplan–Meier Survival Estimates for 30 Day Survival

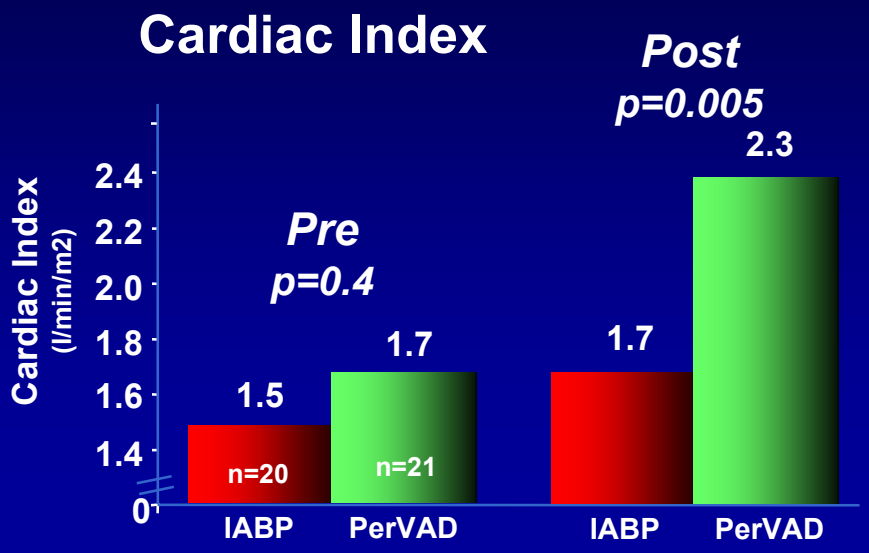


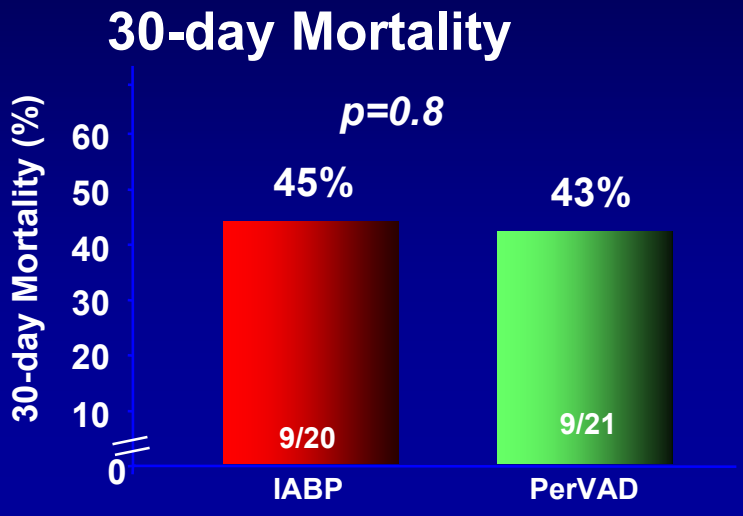
PTVA-VAD:

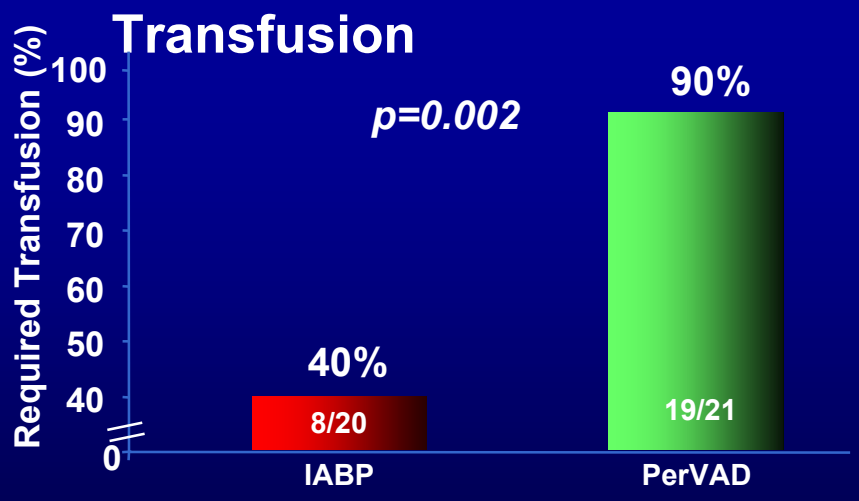
- Cardiac Power Index (CO x MBP)
- Hemodynamic parameters
- Metabolic parameters
- Vascular complications

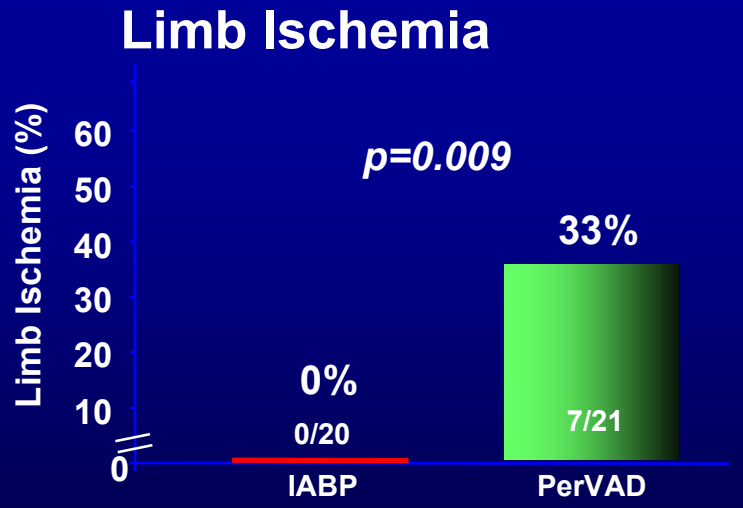
Thiele et al, Eur Heart J 2005;26:1276

TandemHeart Shock Study





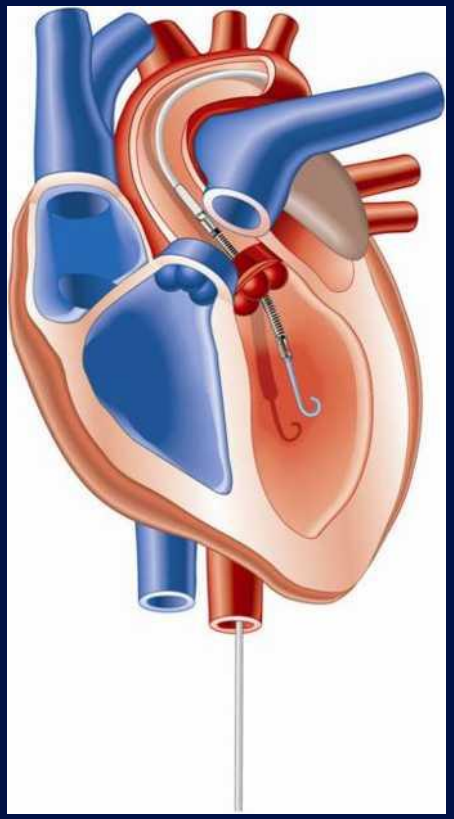


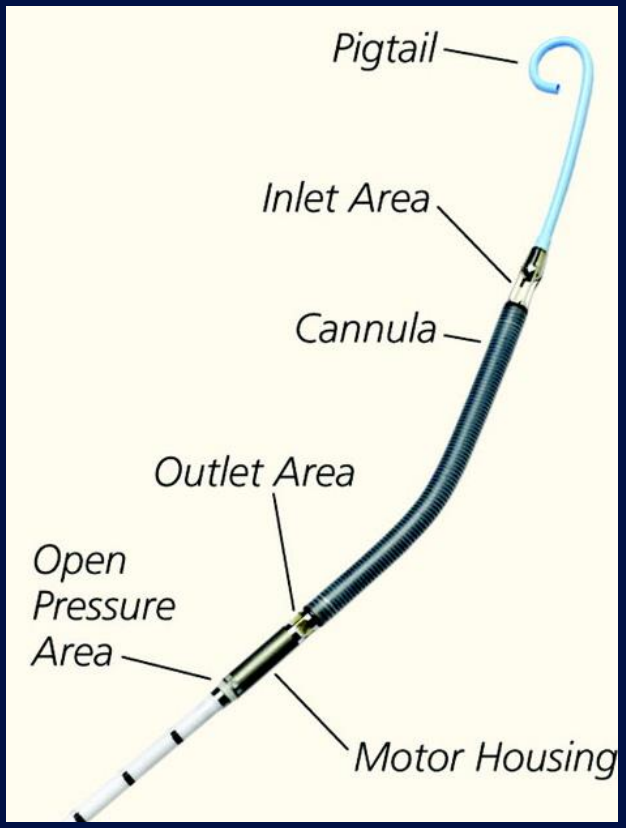


Thiele and al. Eur. Heart Journal 2005 Jul;26(13):1276-83

Impella

- Axial flow pump
- Much simpler to use
- Increases cardiac output & unloads LV
- LP 2.5 – CO 2.5 L/min
- CP
  - 14 F percutaneous approach; Maximum 4 L flow
- LP 5.0
  - 21 F surgical cutdown; Maximum 5L flow



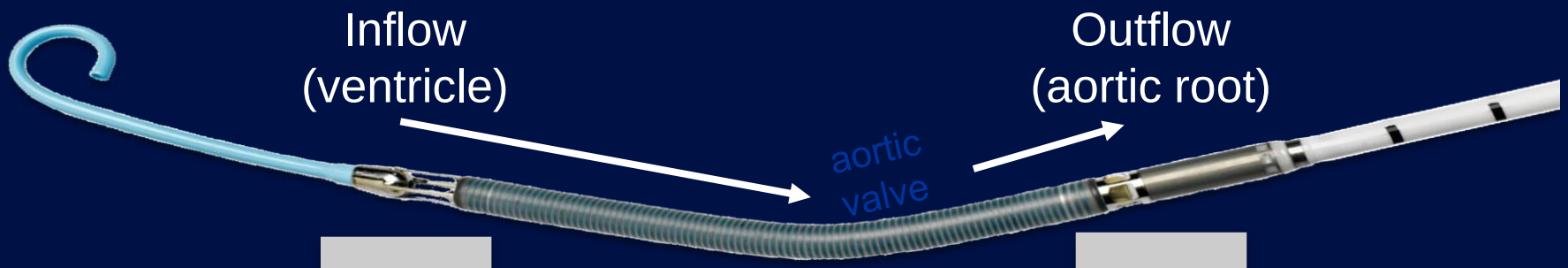


Impella insertion

The Impella CP is built on the same foundation as the Impella 2.5, but provides more than a 50% increase in pumped blood volume (approx. 4L/min)

Principles of Impella Design

Mimic Heart´s Natural Function



EDV, EDP

AOP

Flow

O_2 Demand

O_2 Supply

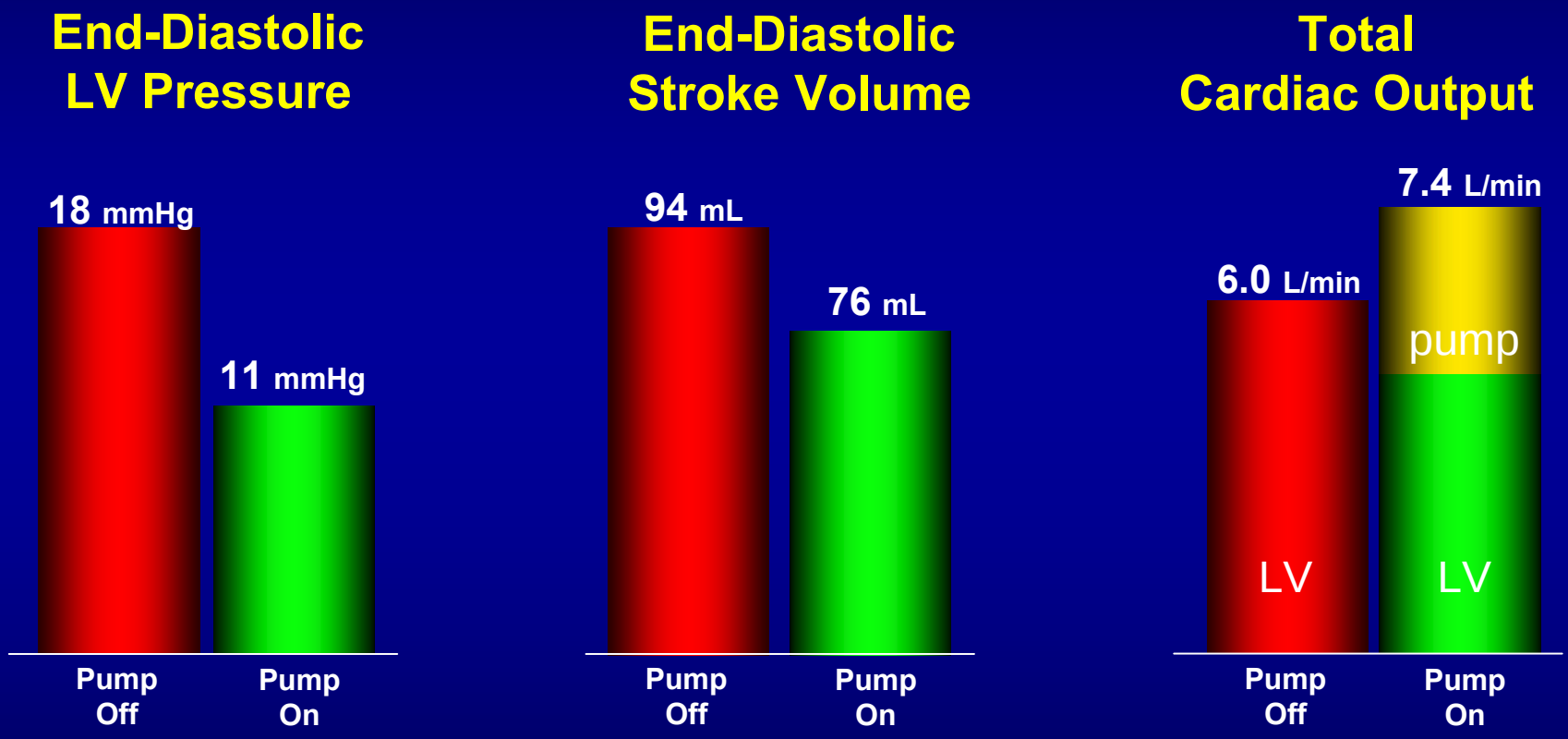
Cardiac Power Output

Myocardial Protection

Systemic Hemodynamic Support

Naidu S S Circulation 2011;123:533-543

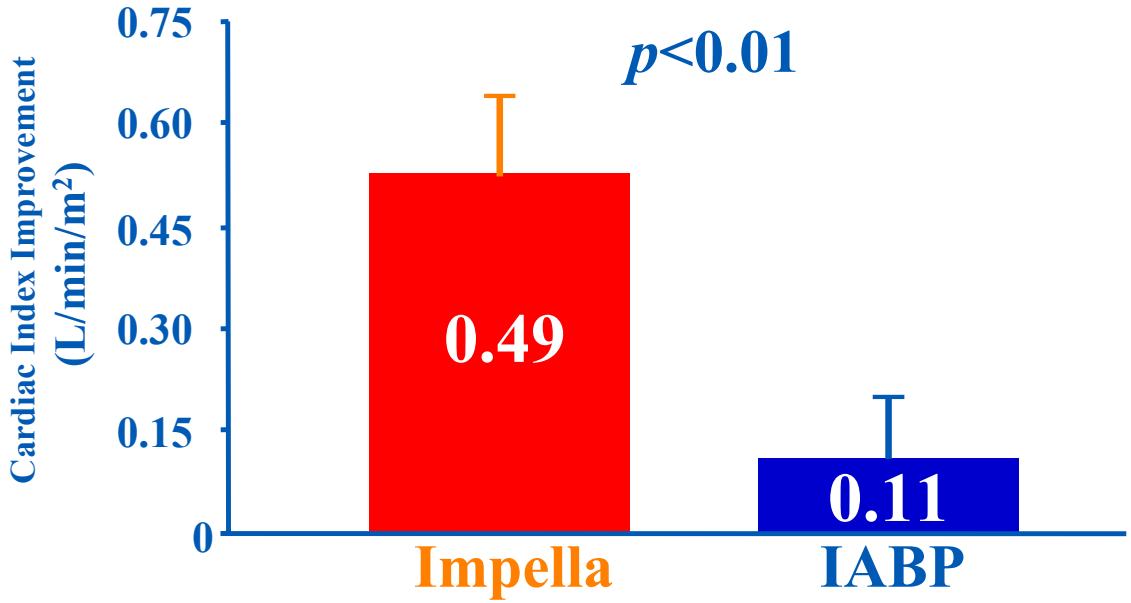
IMPELLA Unloads Actively the Ventricle, Reduces Work Loads and Increases Cardiac Output



M.Valgimigli et al.,Catheterization & Cardiovascular Interventions 65:263–267 (2005)

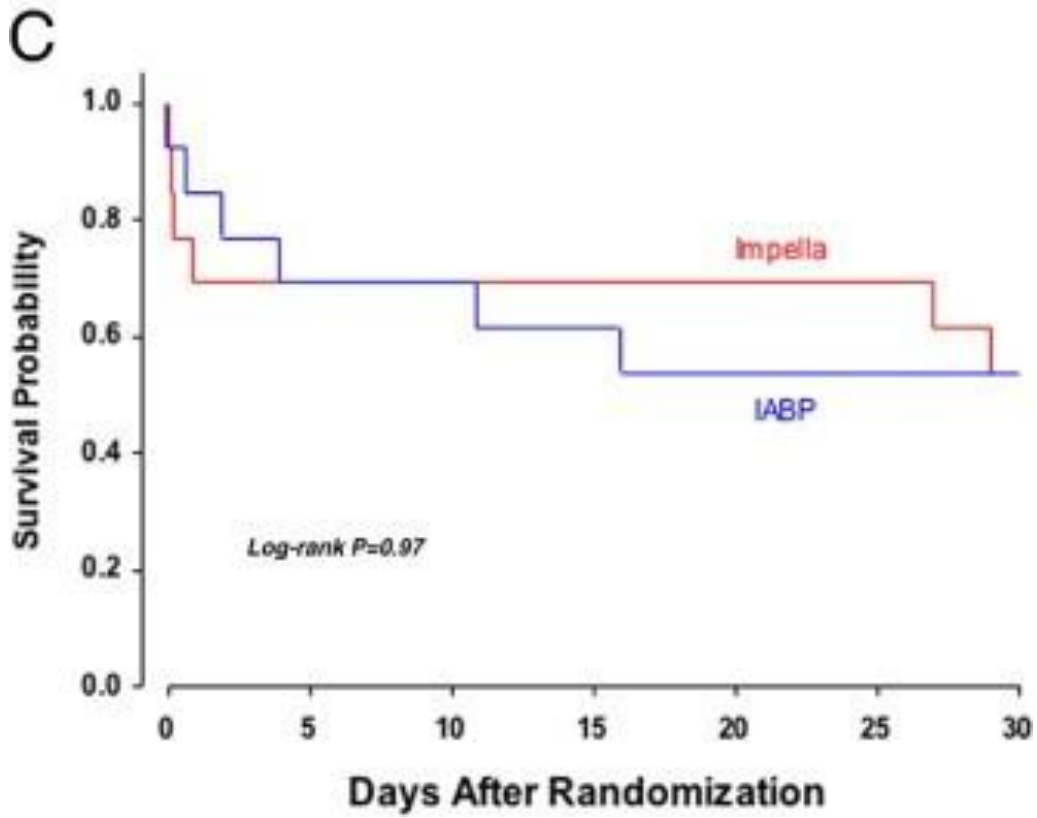
ISAR-SHOCK RANDOMIZED TRIAL:
IMPELLA 2.5 Provides Better Hemodynamic Support Than IABP in AMI Cardiogenic Shock*

Primary Endpoint:
Increase in Cardiac Index From Baseline
(measured after 30 min of support)



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

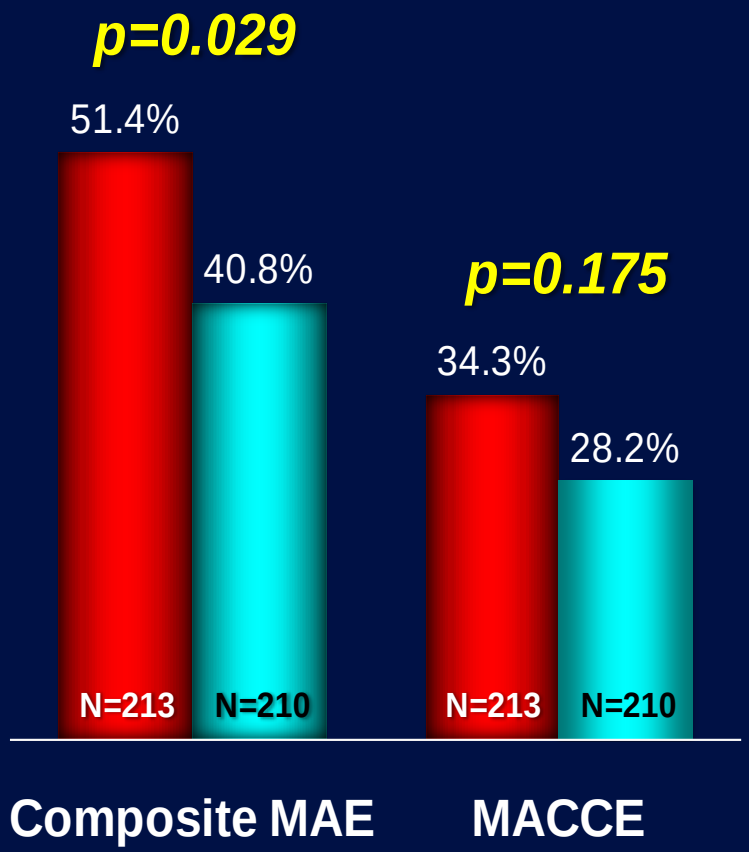
ISAR Shock: A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous LV Assist Device Versus IABP in Cardiogenic Shock

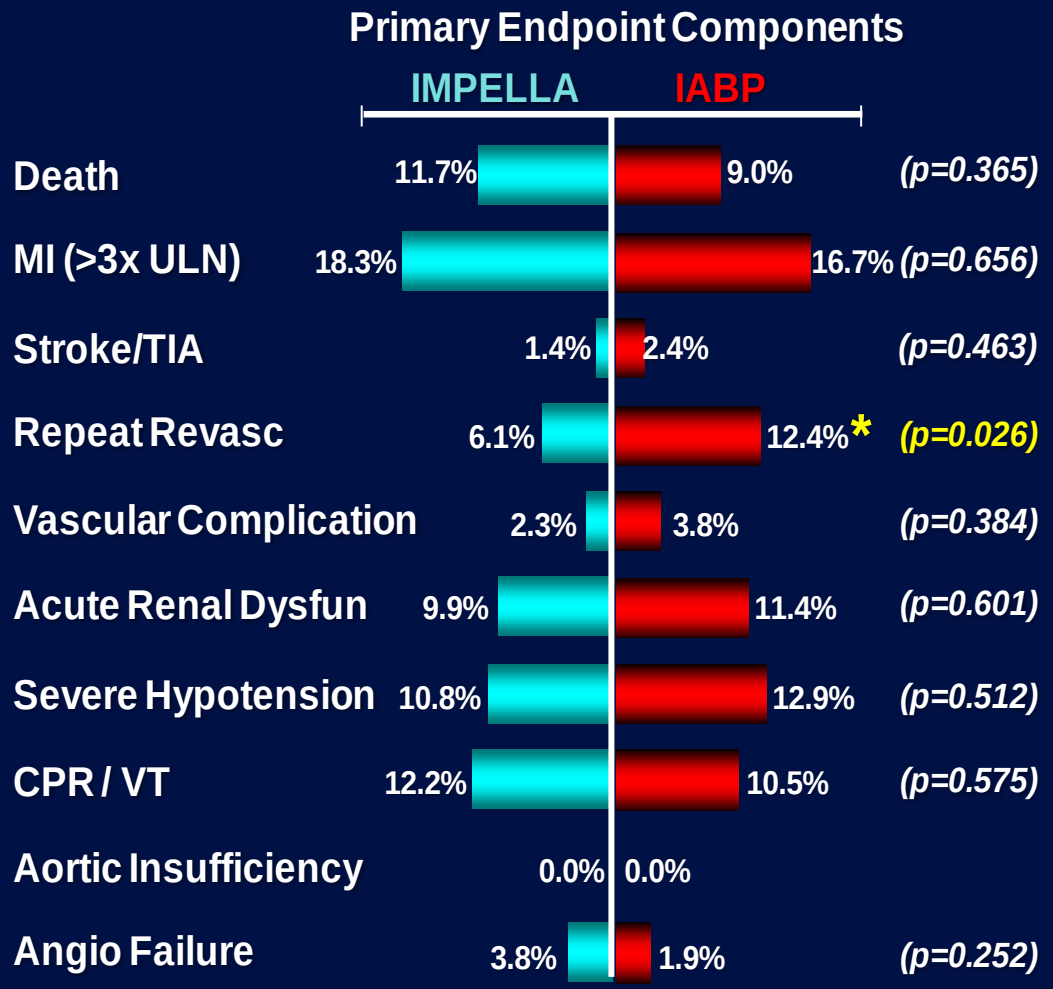


Overall 30 day mortality was 46% in both groups

PROTECT II 90-day Outcome (PP)

Hemodynamic support during high-risk, non-emergent PCI, N=654 Unprotected LM or last patent conduit & EF≤35% *or* 3VD & EF ≥30%.





** Designates statistically significant difference (p<0.05). All other differences are non-significant*

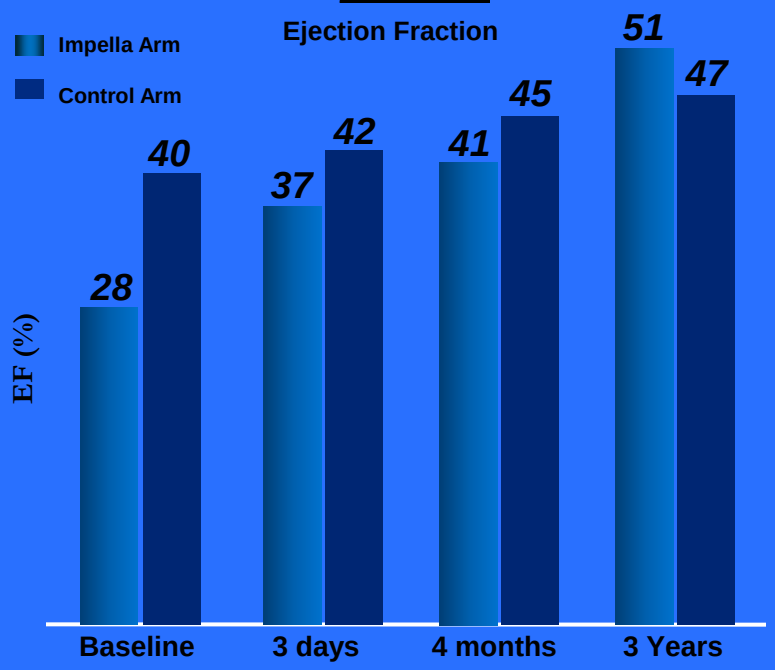
Per Protocol (PP)= Patients that met all incl./ excl. criteria.

The Impella device provided a higher level of support with an equal or lower adverse cardiac event rate

O'Neill et al, Circulation. 2012;126:1717

Impella demonstrates EF improvemen

MACH II [1] Study-Impella support post MI

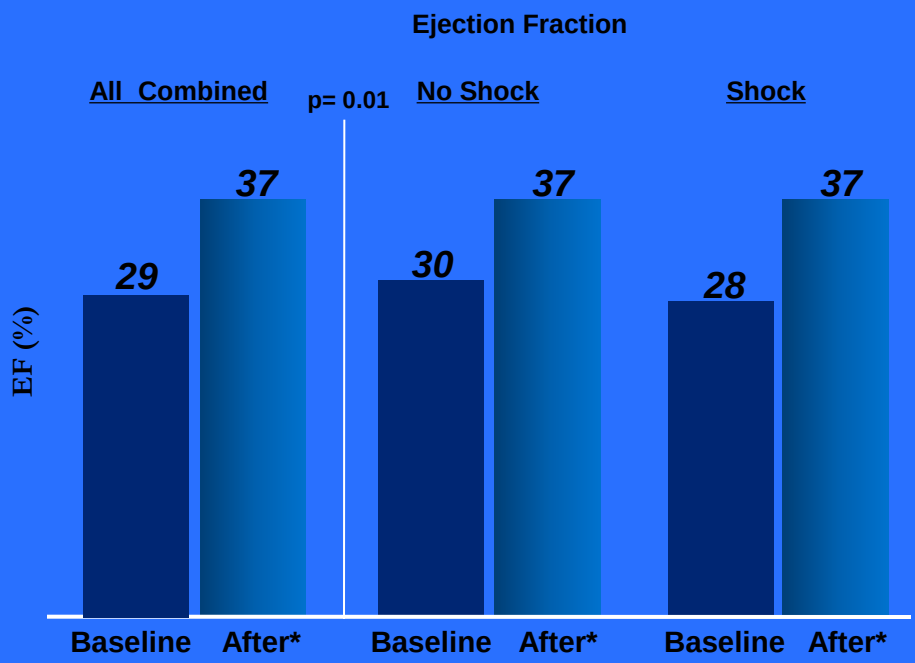


Journal of American College of Cardiology, March 11, 2008

MACH II (N=20)

- Impella arm sicker at Baseline
- Impella arm increased EF by 23 points
- Control arm increased EF by 7
- Impella arm had better QOL/activity[1] at 3 years

LVEF Improvement w/Impella Support



USpella[2] Registry 9/2009

- Patients increased EF 7-9 points
- 68% failing on IAB in cardiogenic shock
- Age at 64 ± 16

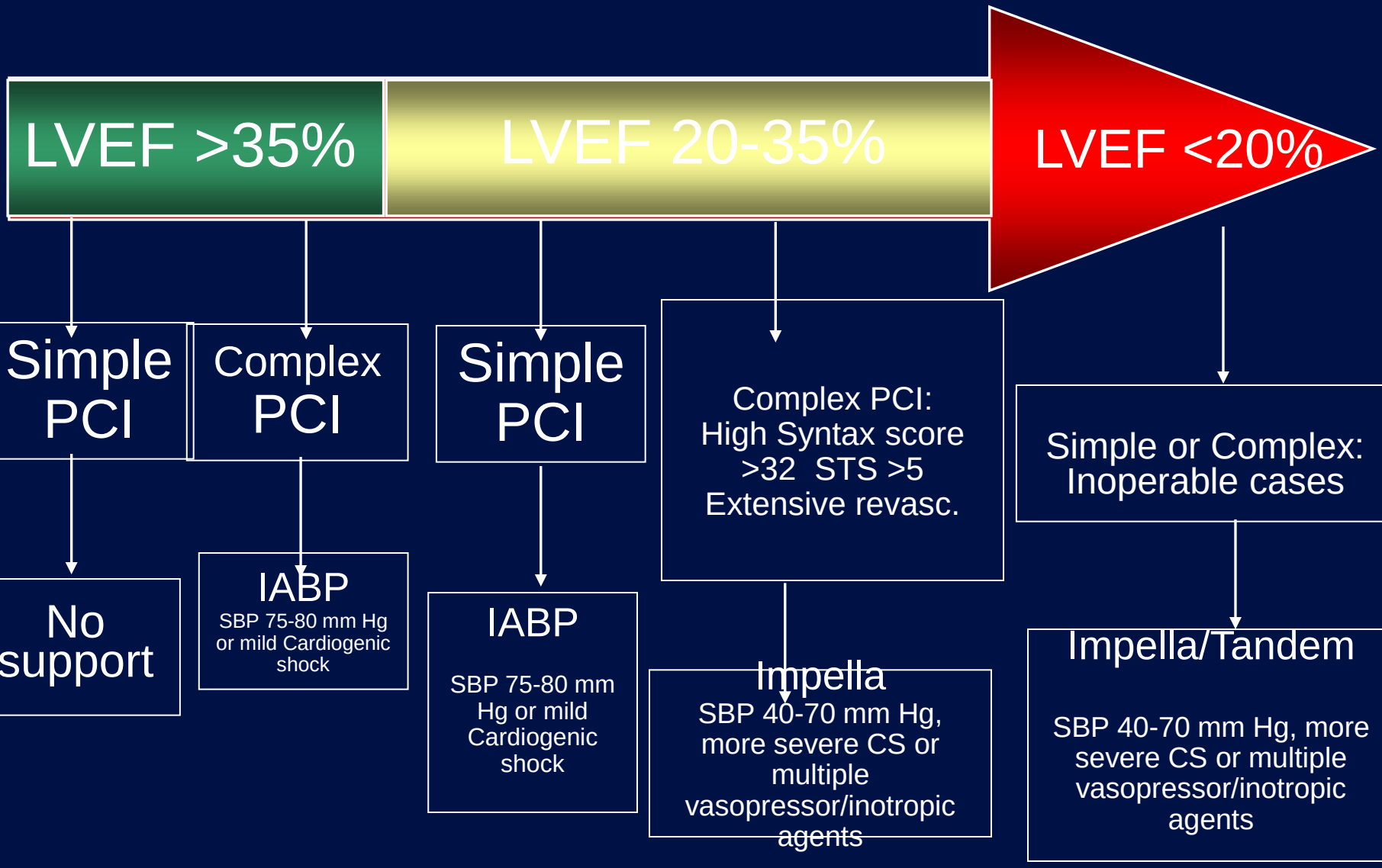
1. MACH II Trial – Academic Medical Center, Netherlands, Mechanical Assistance for Acute Congestive Heart Failure, published in Journal of American College of Cardiology, March 11, 2008; 51: 1044-1046., 3-Year follow-up presented at TCT 2009

2. USpella, N=25 subjects have LVEF measurements
   * Longest available follow-up from PCI

Approach to cardiogenic shock

- Systolic BP > 70-85 mm Hg and good mentation: consider IABP to help prevent shock.
- Consider IABP in:
  - Bridge to surgery
  - Severe HF
  - Cardiogenic shock (mild to severe)
- BP < 70, or on inotropes and vasopressors: consider Impella (2.5-5L CO) or Tandem heart (4-5L)
- Complete Cardiogenic arrest: Extracorporeal membrane oxygenation and complete bypass

LV Support during High-Risk PCI: LVEF + Lesion Complexity



Questions

- What are the complications of IABP?
  A. vascular complications
  B. CVA
  C. embolization of cholesterol
  D. balloon rupture
  E. All of the above

Questions

- The following statement is true/false
- An IABP achieve its action through a counter pulsation: Deflates during systole
  Inflates during Diastole
- What is used to inflate and deflate the balloon?