Impella for cardiogenic shock

Nijmegen, 10 Februari , 2015

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Potential conflicts of interest

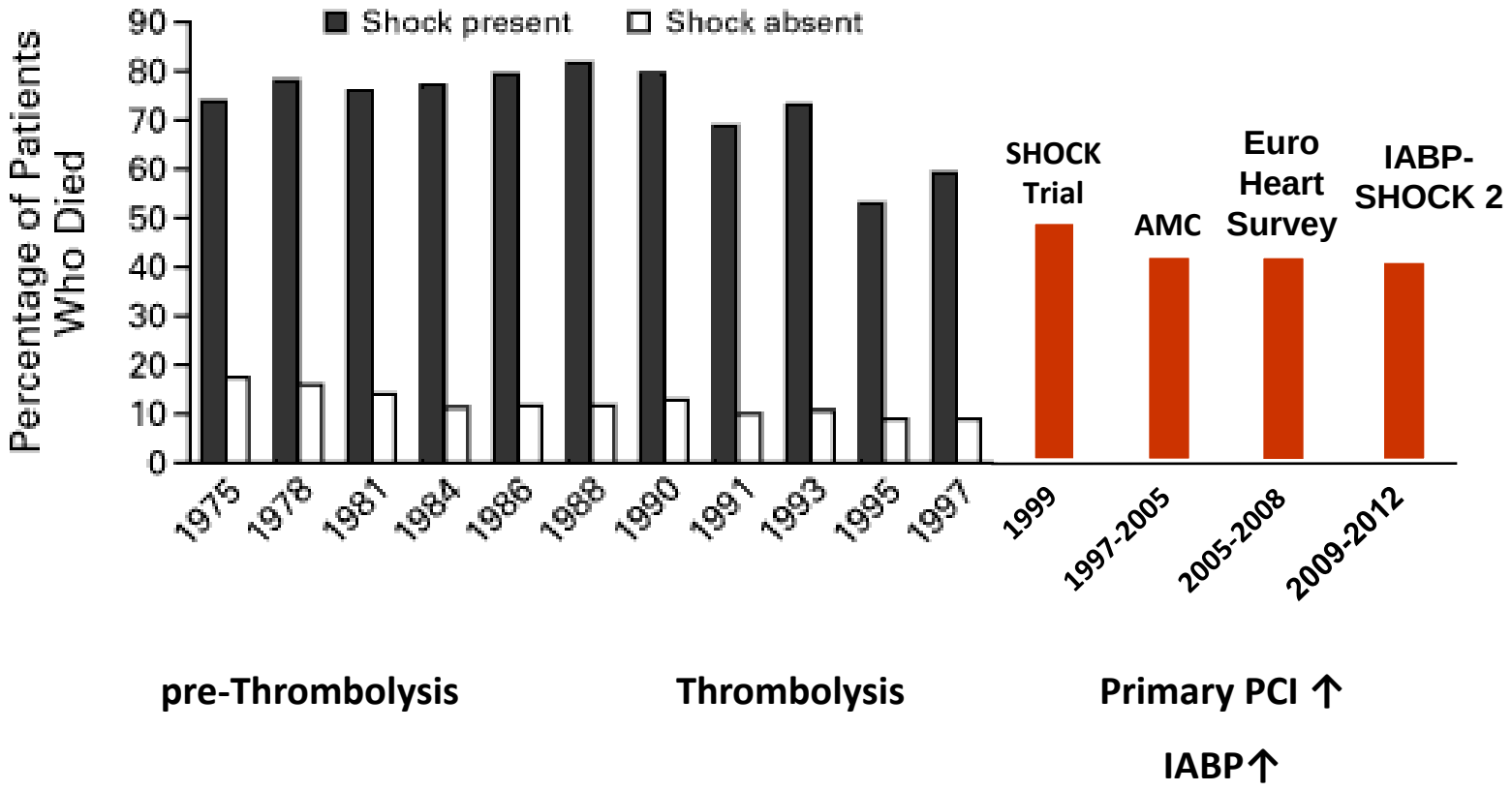
Research grant Abbott Vascular	(>10.000 euro)
Research grant Abiomed Inc.	(>10.000 euro)
Research grant BBraun	(>10.000 euro)
Research grant Biotronik	(>10.000 euro)
Research grant InspireMD	(>10.000 euro)

Global Impella Advisory board member
European working group on the use of Impella

Cardiogenic shock - Agenda

1. Acute Myocardial infarction setting
2. Brief overview various target therapies
3. The role for mechanical support

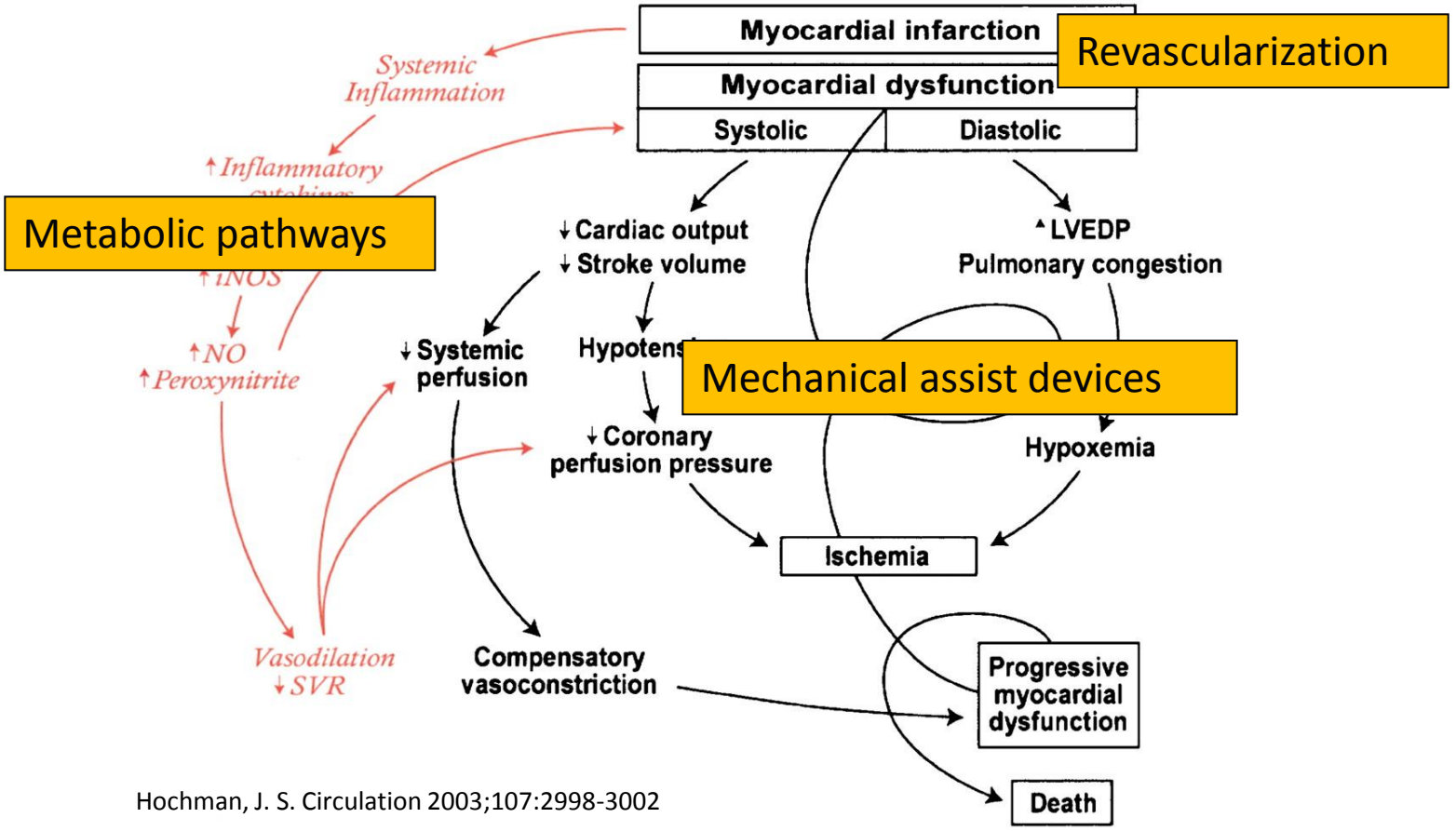
Mortality in CS



Goldberg et al. NEJM 1999;
Hochman et al. NEJM 1999;
Sjauw, Henriques et al. NHJ 2012
Zeymer et al. Eurointervention 2011;
Thiele et al. ESC 2012

STEMI + CS - DEATH

<10% of all STEMI but accounts for 90% of mortality



Hochman, J. S. Circulation 2003;107:2998-3002

Inotropic and vasopressor agents

The good…

- Improve haemodynamic parameters rapidly in CS.
- The haemodynamic benefits are perceived to outweigh the risks because hypotension itself compromises myocardial perfusion.
- Pharmacological circulatory support is recommended in CS

Inotropic and vasopressor agents

The bad…

- Increase myocardial oxygen consumption
- Can cause myocardial ischaemia
- Can cause ventricular arrhythmias,
- Can cause contraction band necrosis
- Can cause infarct expansion

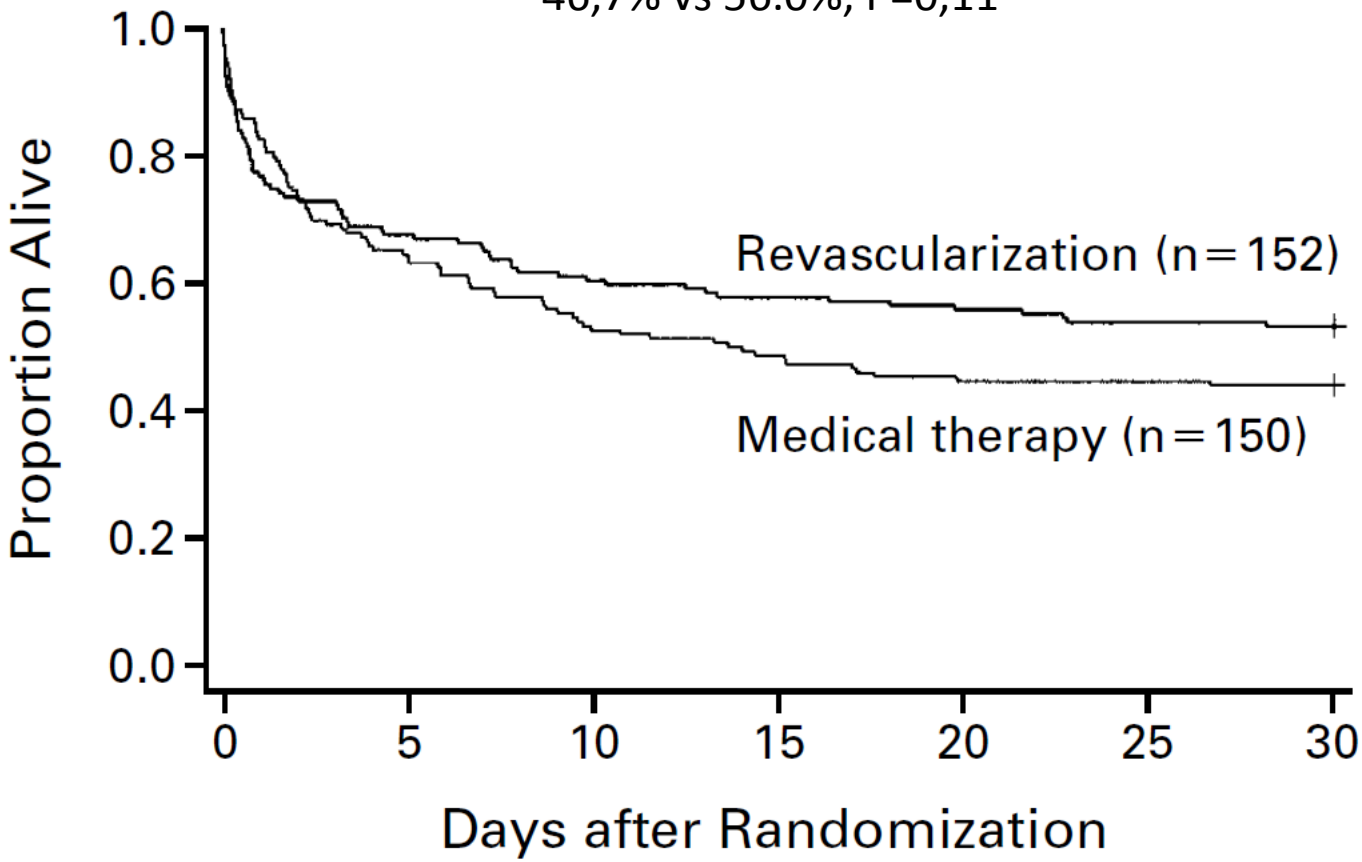
- Pharmacological circulatory support is recommended in CS….

…….Although these drugs have not shown to improve patient outcomes in RCT's.

Revascularization

SHOCK TRIAL @ 30 days

46,7% vs 56.0%, P=0,11



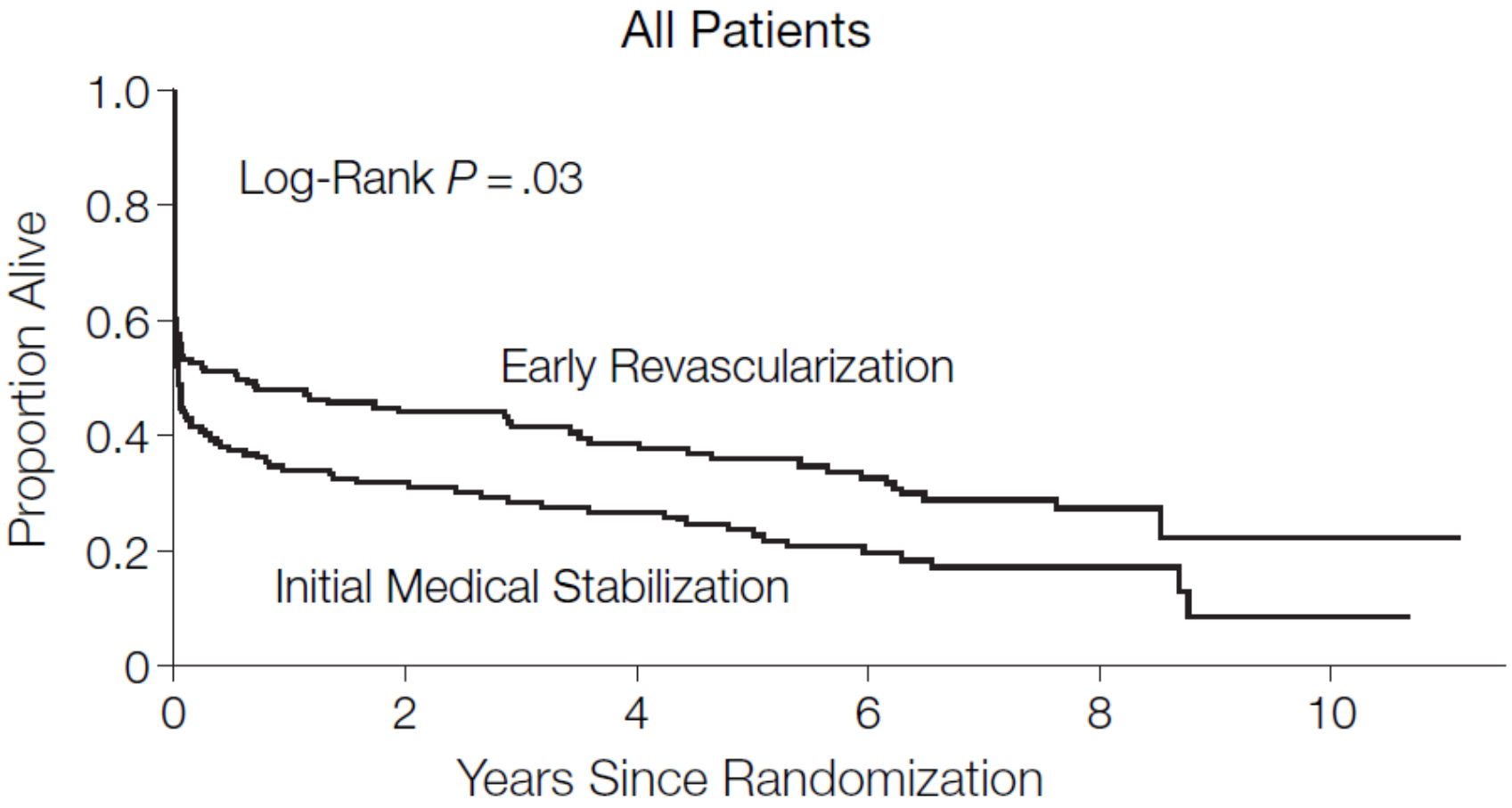
80% IABP

80% IABP

Hochmann, NEJM 1999

Revascularization

SHOCK TRIAL @ long term



Hochmann, NEJM 1999, JAMA 2006

@ 6 months mortality 50.3% vs 63.1%, p=0.03, NNT 8

Mechanical Circulatory Support

STEMI

- Myocardial recovery

STEMI + CS

- Myocardial recovery
- Organ recovery

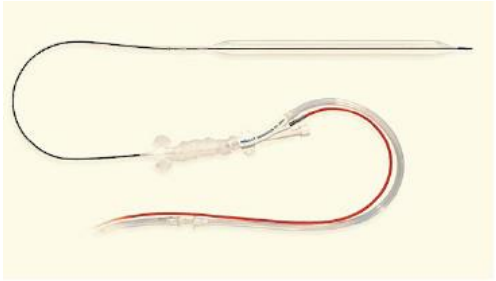
Mechanisms

- acceleration recovery of contractility in stunned myocardium by increasing postischemic myocardial (microvascular) blood flow.

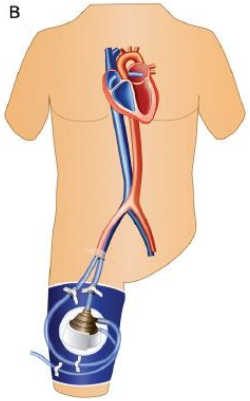
- unloading effect:
  peak left ventricular wall stress↓
  myocardial workload↓
  → reduced myocardial oxygen consumption.

Sjauw KD, Engström AE, Henriques JPS; Percutaneous Mechanical Cardiac Assist In Myocardial Infarction. Where Are we Now, Where Are We Going? Acute Card Care 2007;9(4):222-30

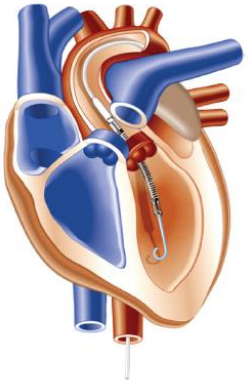
Currently available devices



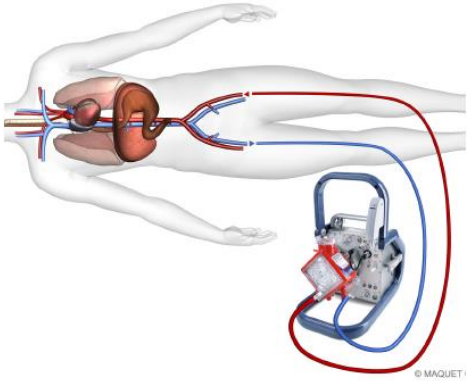
IABP



TandemHeart



Impella 2.5
Impella 3.7 (CP)
Impella 5.0 (surgical insertion)



Minituarized ECMO

IABP - The guidelines in 2010

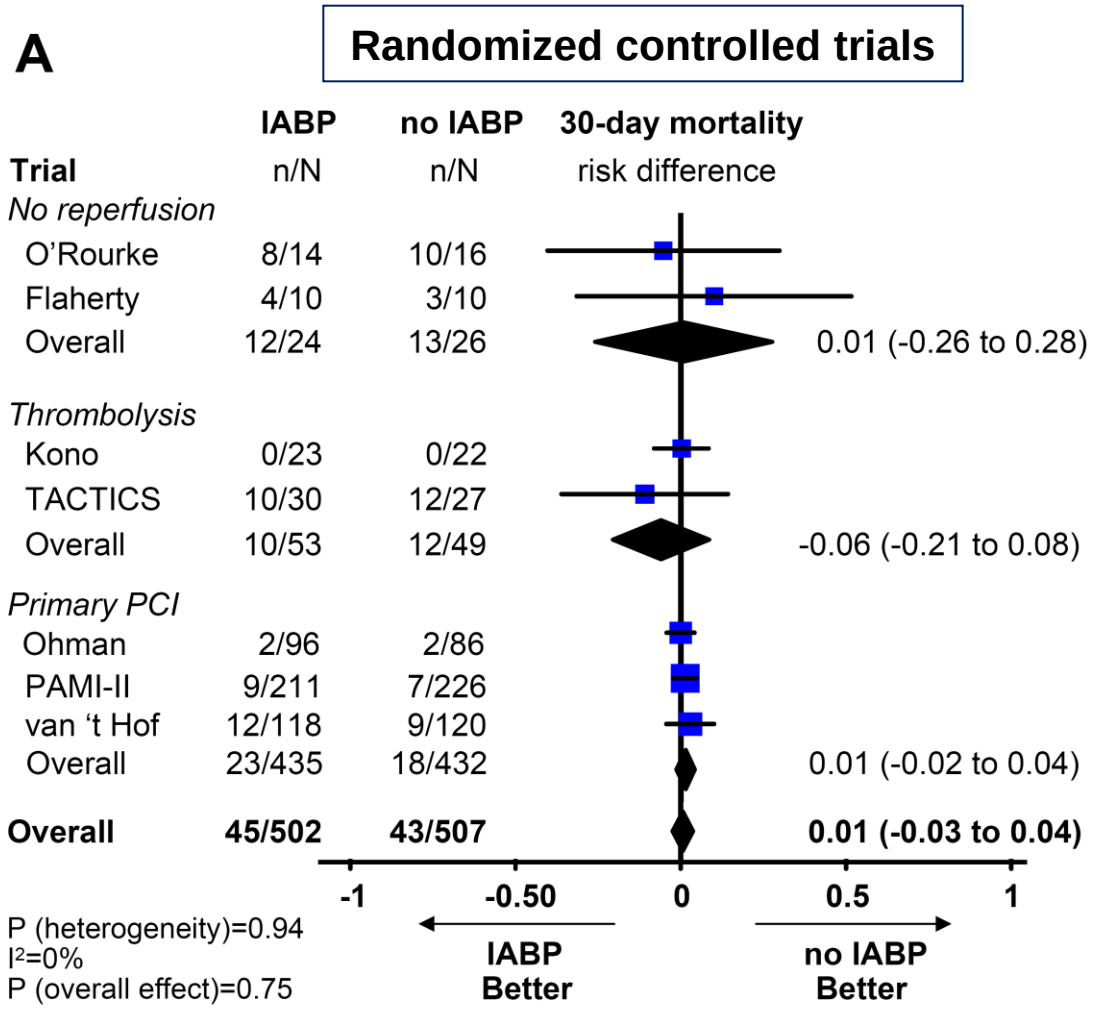
ACC/AHA

Class 1a

ESC

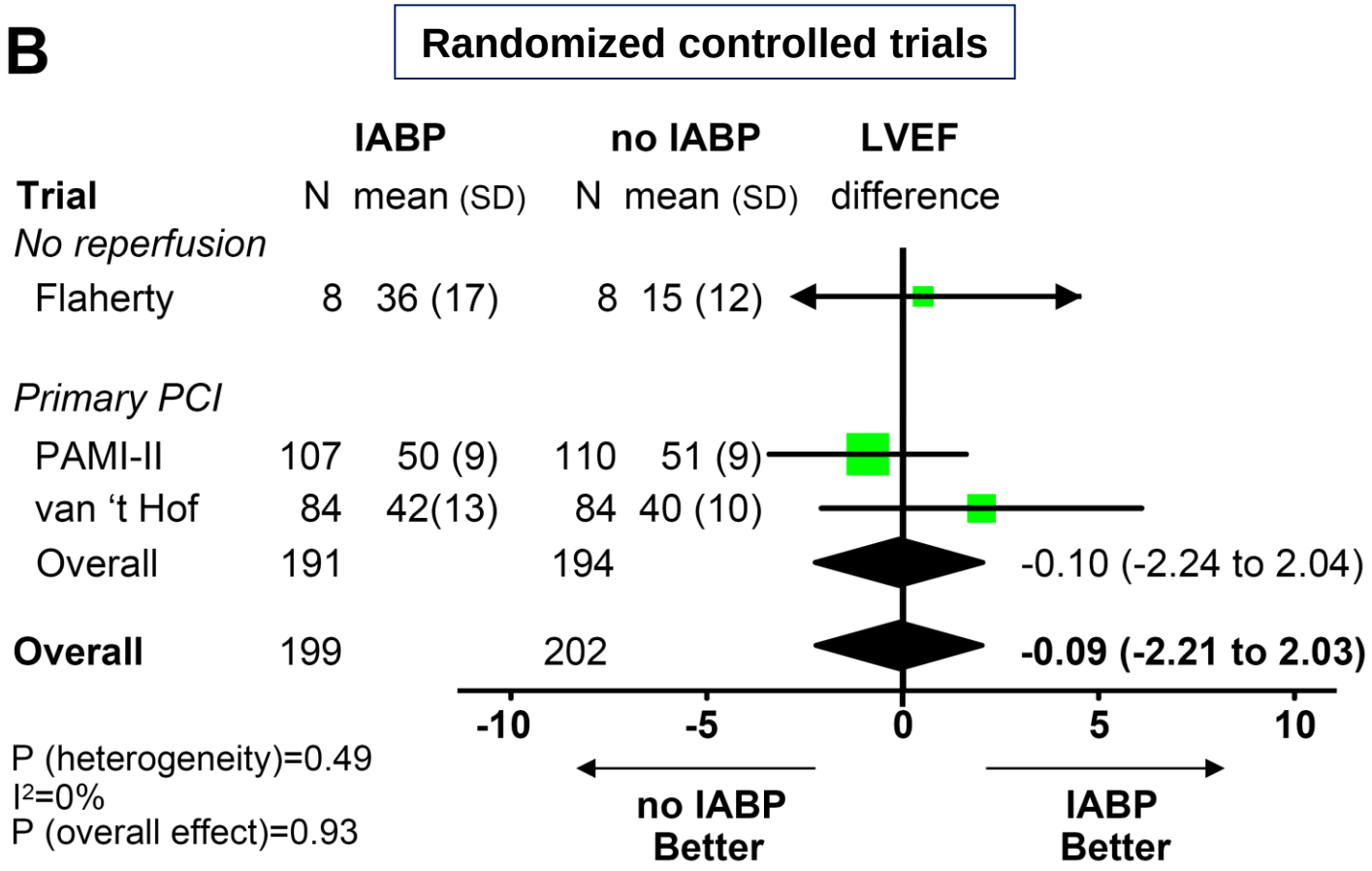
Class 1b

IABP in STEMI



Sjauw KD, et al. Eur Heart Journal, 2009

IABP in STEMI



Sjauw KD, et al. Eur Heart Journal, 2009

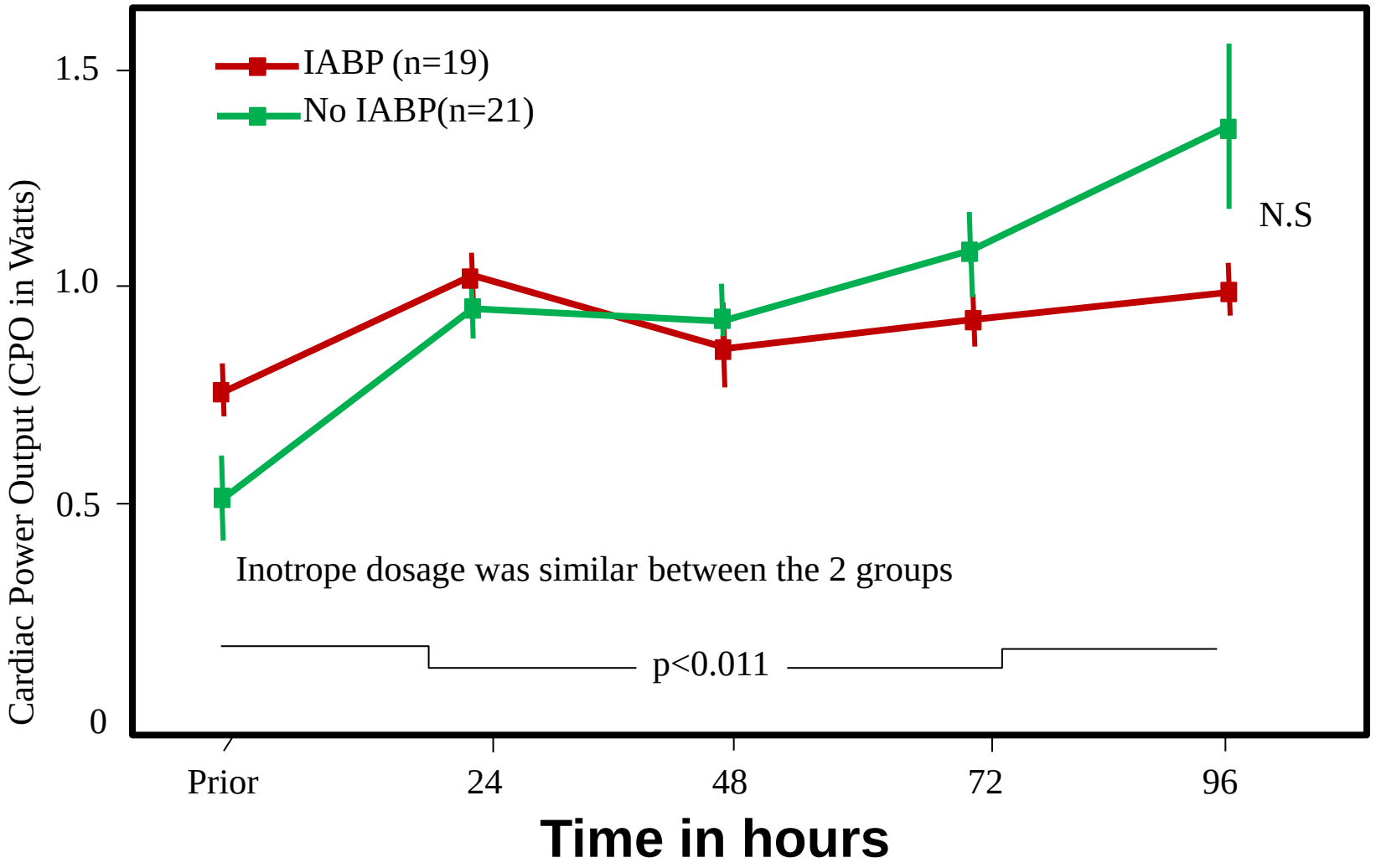
The CRISP AMI Trial

N=337

	IABC Plus PCI (n = 161)	PCI Alone (n = 176)	*P* Value
	4.0 (3.0-5.0)	4.0 (3.0-4.0)	.20
Infarct size, % of left ventricular mass			
Per-protocol analysis, No. (%)	133 (82.6)	142 (80.7)	
Mean (95% CI)	42.1 (38.7-45.6)	37.5 (34.3-40.8)	.06
Median (IQR)	42.8 (27.2-54.7)	36.2 (25.9-49.4)	
Multiple imputation analysis			
Mean (95% CI)	42.1 (38.6-45.6)	37.6 (34.3-40.9)	.07
Median (IQR)	42.5 (27.1-55.9)	36.4 (24.9-49.9)	

Patel MRet al, JAMA, 2011

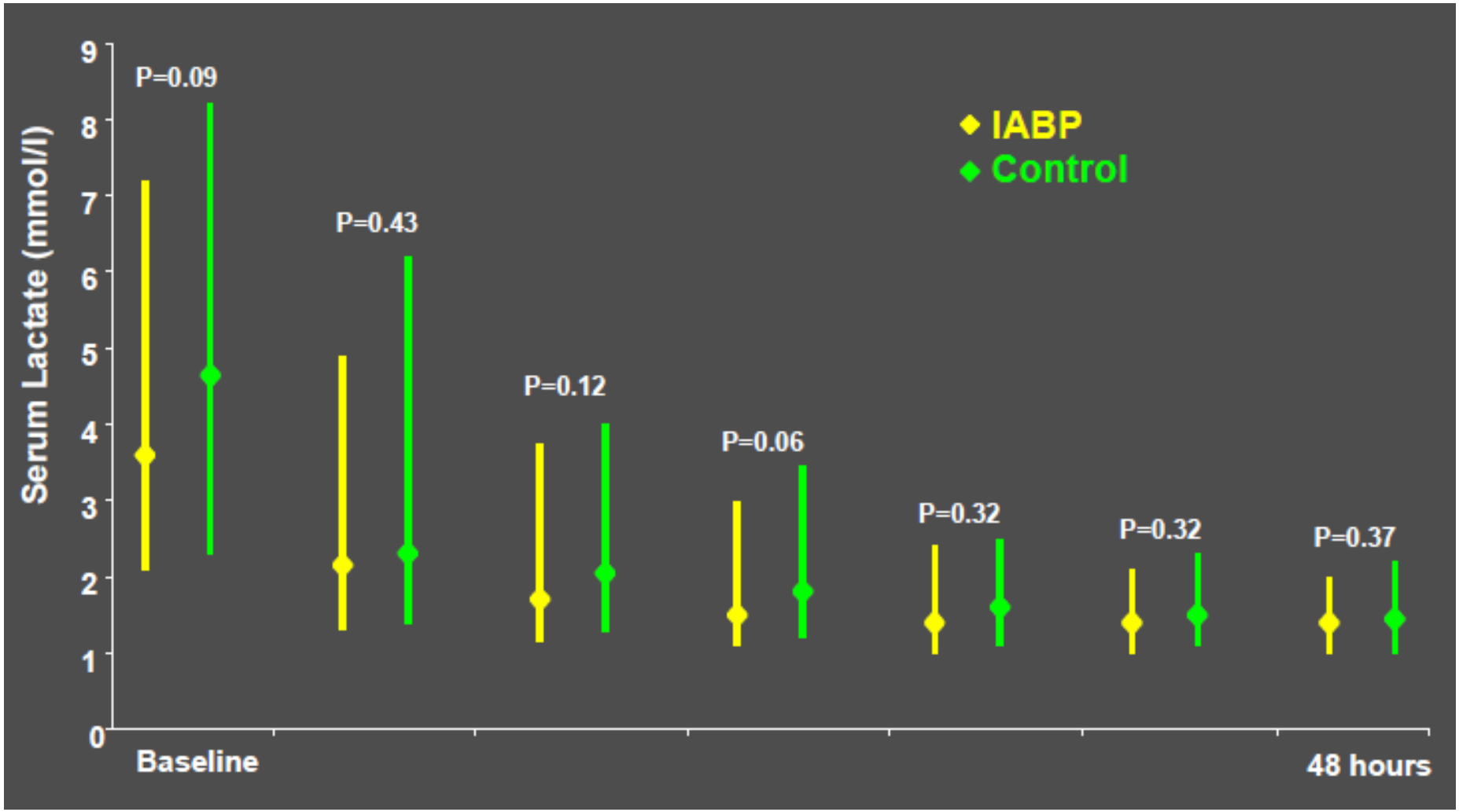
No Hemodynamic Benefit IABP



Prondzinsky et al. SHOCK 2012;37:378-384

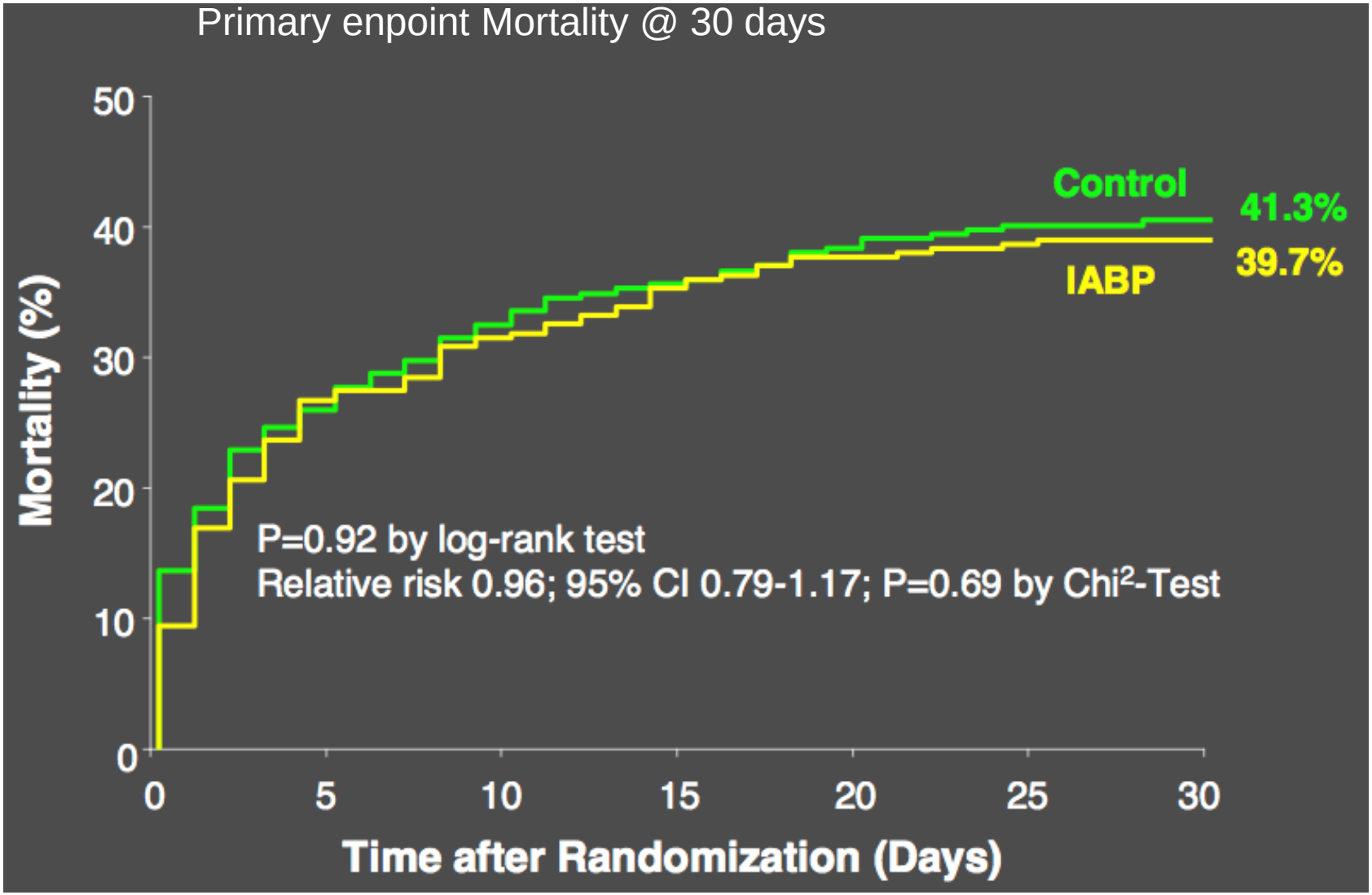
(Clinical Trials.gov ID NCT 00469248)

IABP-SHOCK 2 - Lactate



Thiele et al. Presented ESC Congress Munchen 2012

IABP-SHOCK 2



Thiele et al. Presented ESC Congress Munchen 2012

?

GETINGE GROUP

IABP endures as the go-to standard for hemodynamic support

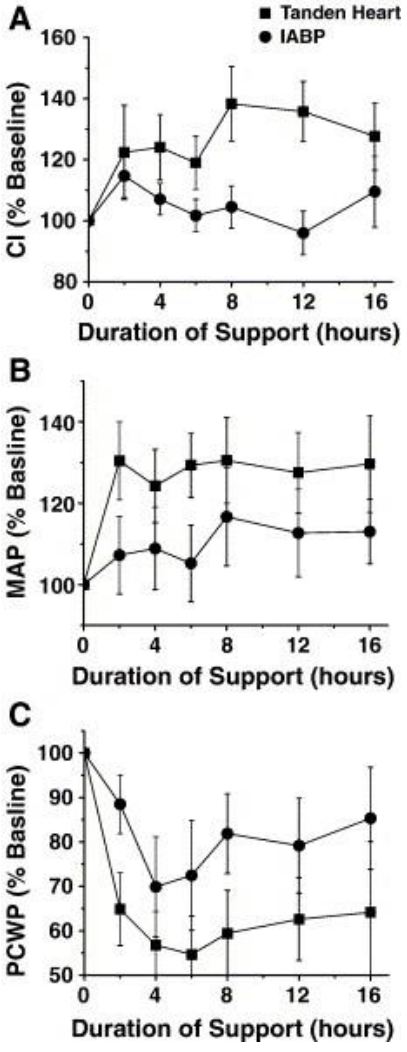
Other more costly and more invasive procedures may attract attention, but IABP therapy is the one that has earned your trust and loyalty.

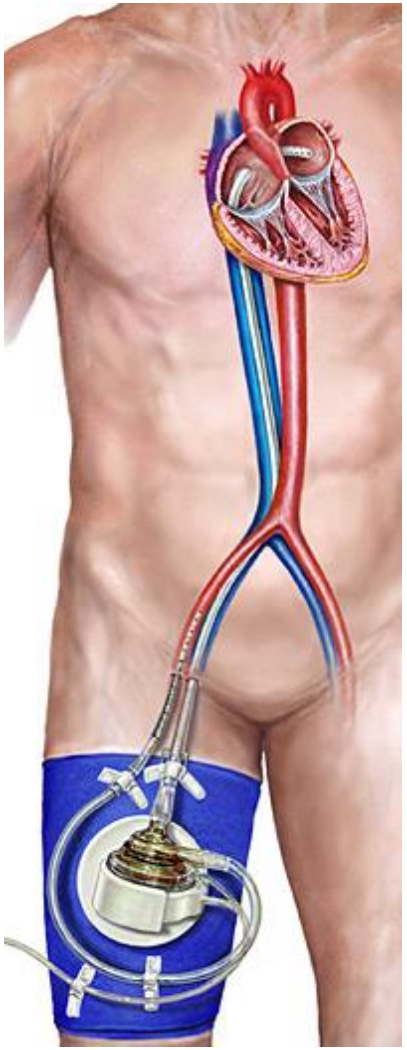
For years, it's offered minimal complications, superior ease of use, and positive results. No wonder it's the most-used, most-studied, and most-published cardiac assist device. Recent clinical guidelines have reaffirmed your clinical observations: it's the first-line device for acute hemodynamic support.

MAQUET has been a driving force in IABP since its beginnings, and is pleased to lead the way in its future.

Safe, effective, and easy to use
—it's the choice that's easy to love.

New devices provide more support

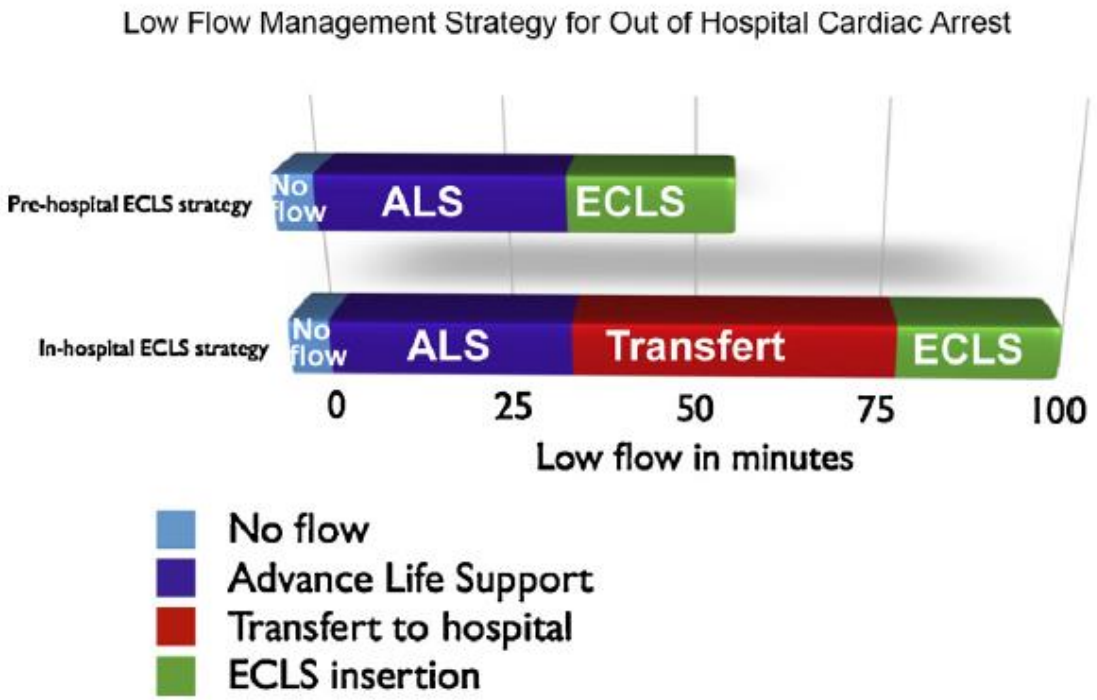




Thiele Eur Heart J 2005
Burkhoff Am Heart J 2006

Feasibility of EMCO by nonsurgeons

7 patients included in 1 year
6 patients died
Death rate 86%



Lamhaut L et al. Resuscitation 2013 July

Regional Cardiogenic Shock Centers

5 years 93 pts

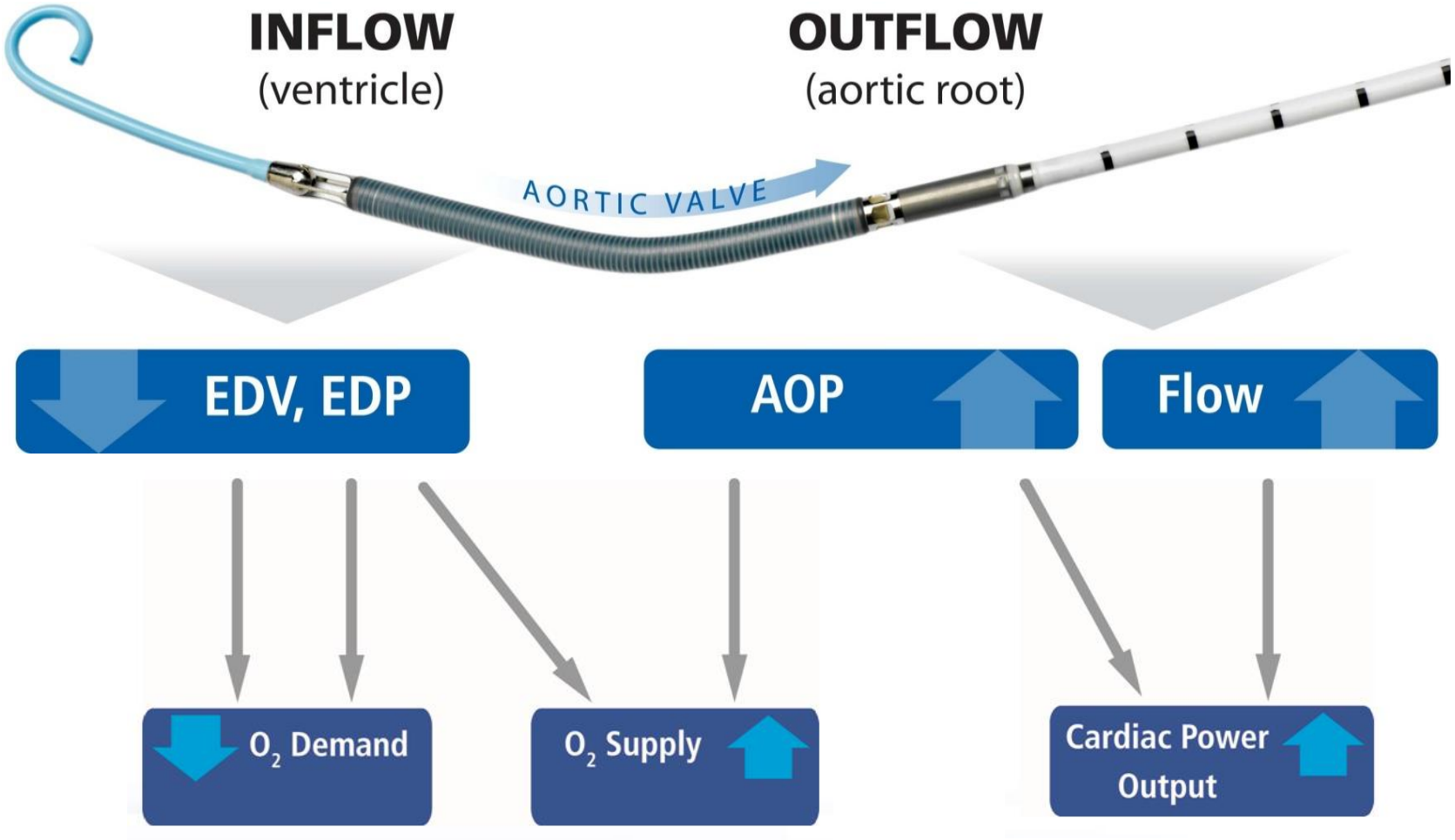
1. Go out to the patient
2. Start support @ local facility
3. Transfer to expert shock center

In hospital survival rate 36.8% Not statistically different from that of 123 consecutive patients who received ECMO at our institution during the same period

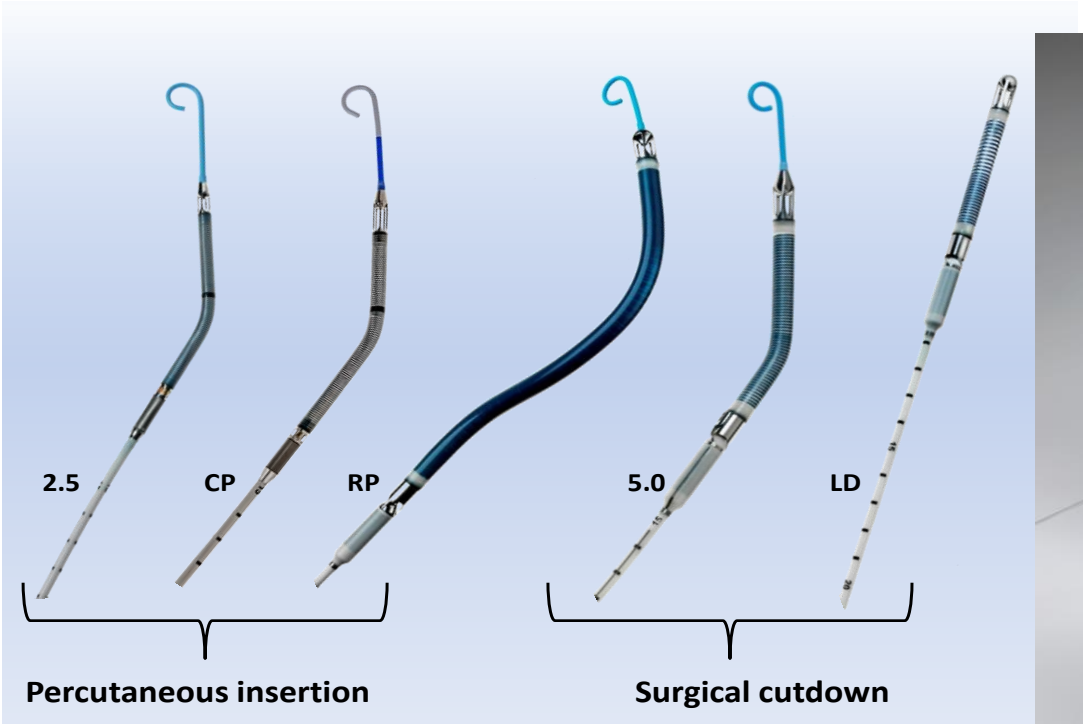
Beurtheret S et al. Eur Heart J, 2012

Impella LV-Support

Physiological Results of Impella® Support



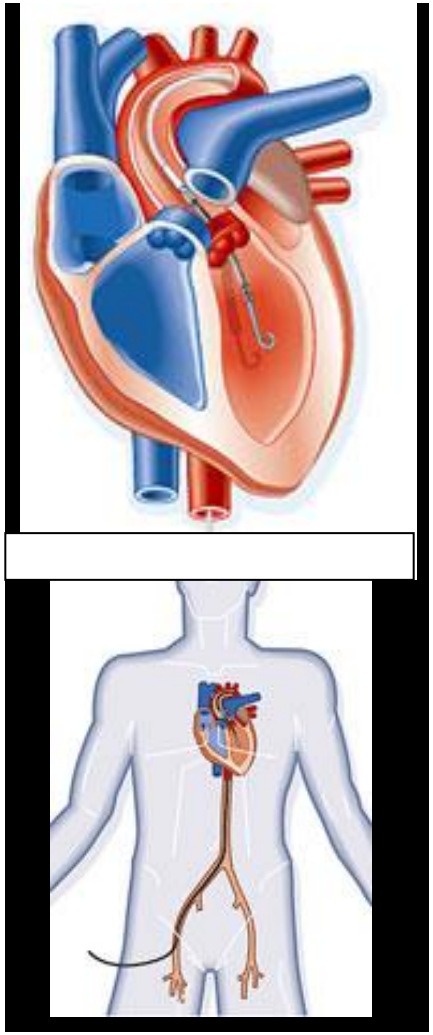
Impella family

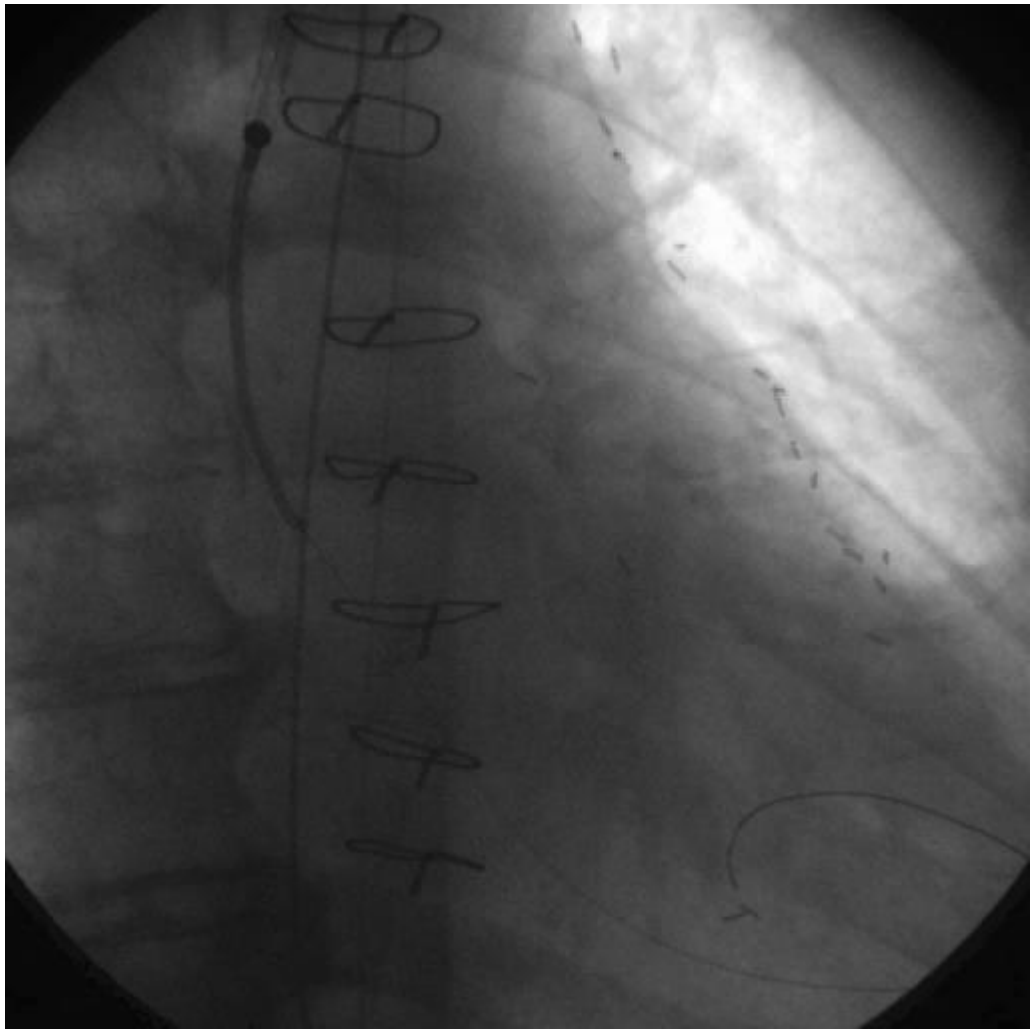


Impella family

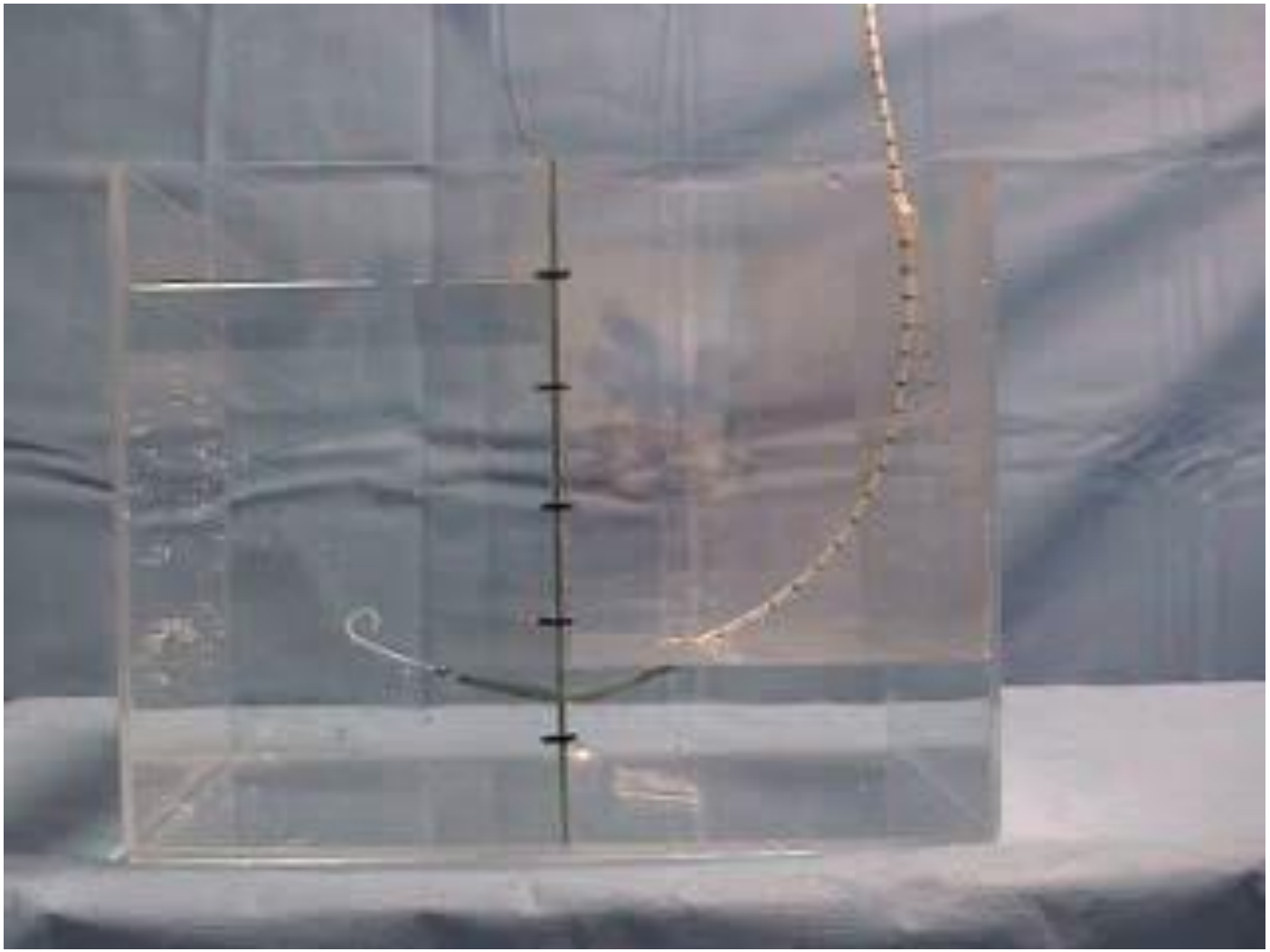
	Impella 2.5	Impella CP	Impella 5.0/LD	Impella RP
Access	Percutaneous, Femoral	Percutaneous, Femoral	Surgical, Axillary/ Fem or Ascend aorta	Percutaneous, Femoral Vein
Output (max)	2.5 L/min	3,7-4.0 L/ min	5.0 L/ min	4.6 L/ min
Guiding catheter size	9F	9F	9F	11F
Motor Size	12F	14F	21F	22F
Introducer Size	13F Peel away	14F Peel away	Dacron graft 10mm	23F Peel away
RPM (max)	51,000	46,000	33,000	33,000
EU approval	5 days CE Mark	5 days CE Mark	10 days CE Mark	14 days CE Mark

Impella





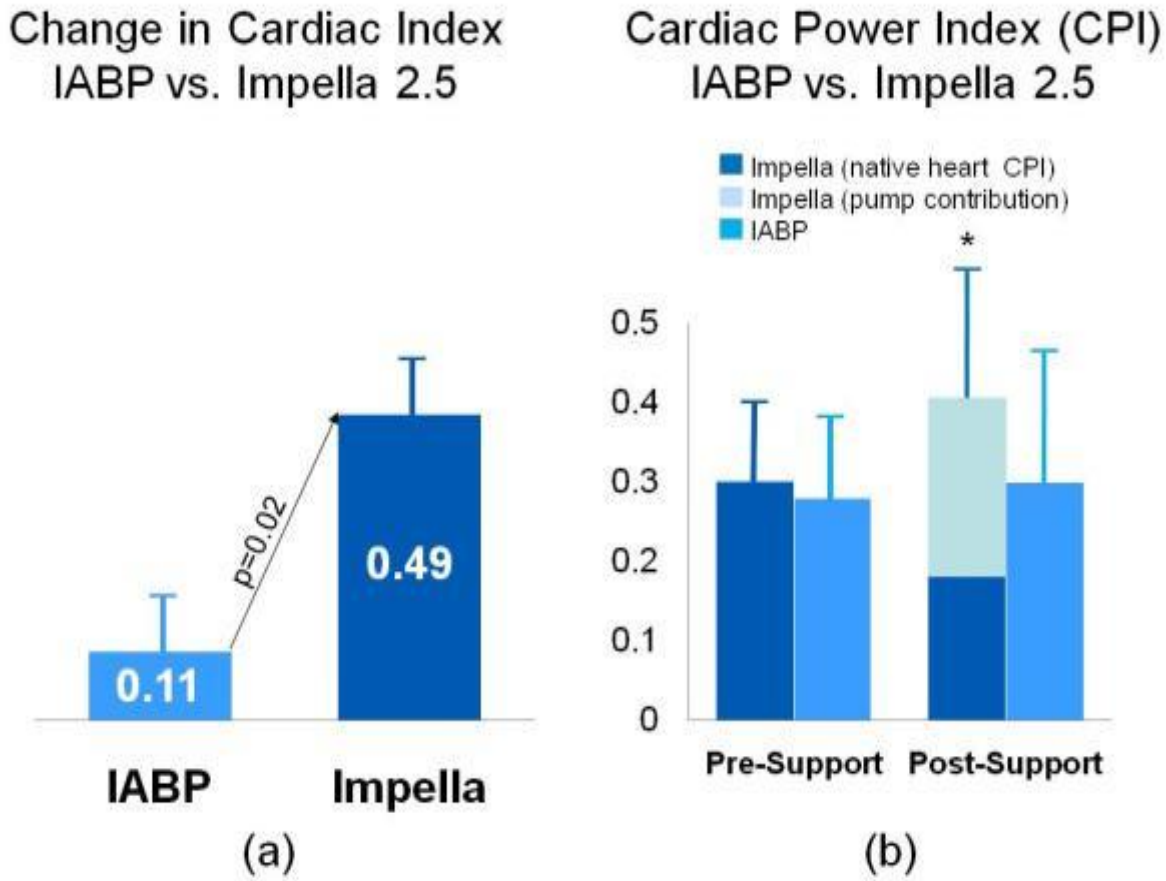
Impella

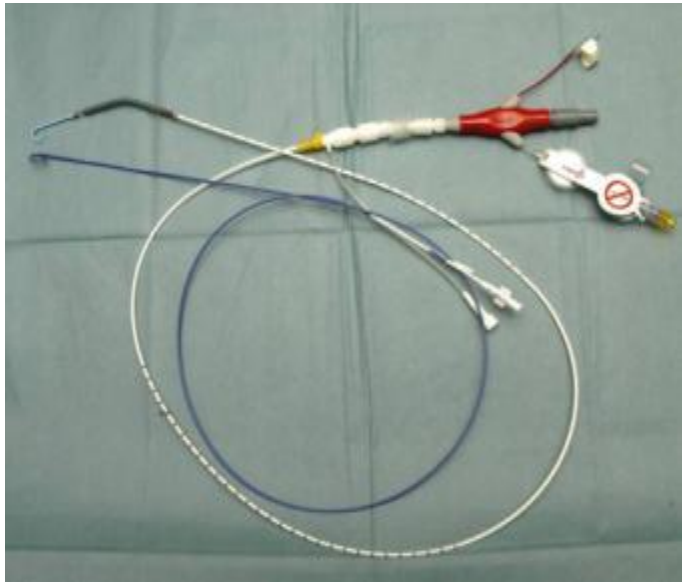


Sjauw KD, Acute Cardiac Care 2007

Impella

Better unloading + more support





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

The AMC MACH/Impella program

1: Elective high-risk PCI procedures[1,2]

1a: Safety and feasibility of elective high-risk PCI with Impella 2.5 support*

1b: Intracoronary flow measurements high-risk PCI Procedures Impella 2.5 support §

1c: Europella short term FUP

1d: Europella long term FUP

1e: Protect 1

1f: Protect 2

2: Acute myocardial infarction

2a: Safety and Feasibility in STEMI patients[3]

2b: STEMI patients in cardiogenic pre-shock

2c: STEMI patients in severe cardiogenic shock

2d: P/V loop measurements and/or intracoronary flow measurements[4]

Phase 3: End-stage heart failure

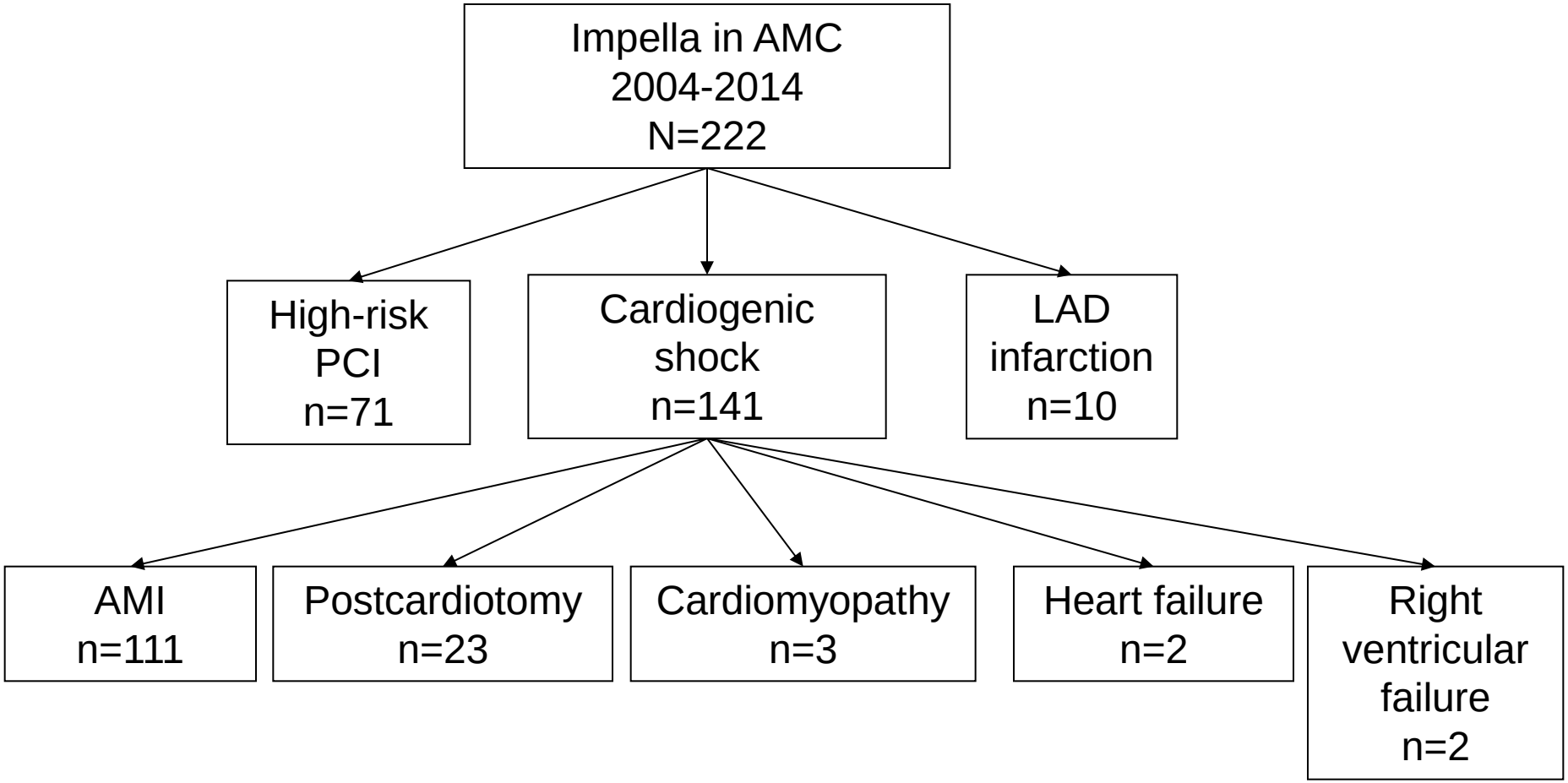
Phase 4: Left ventricular assistance after cardiac surgery

Phase 5: All other patients

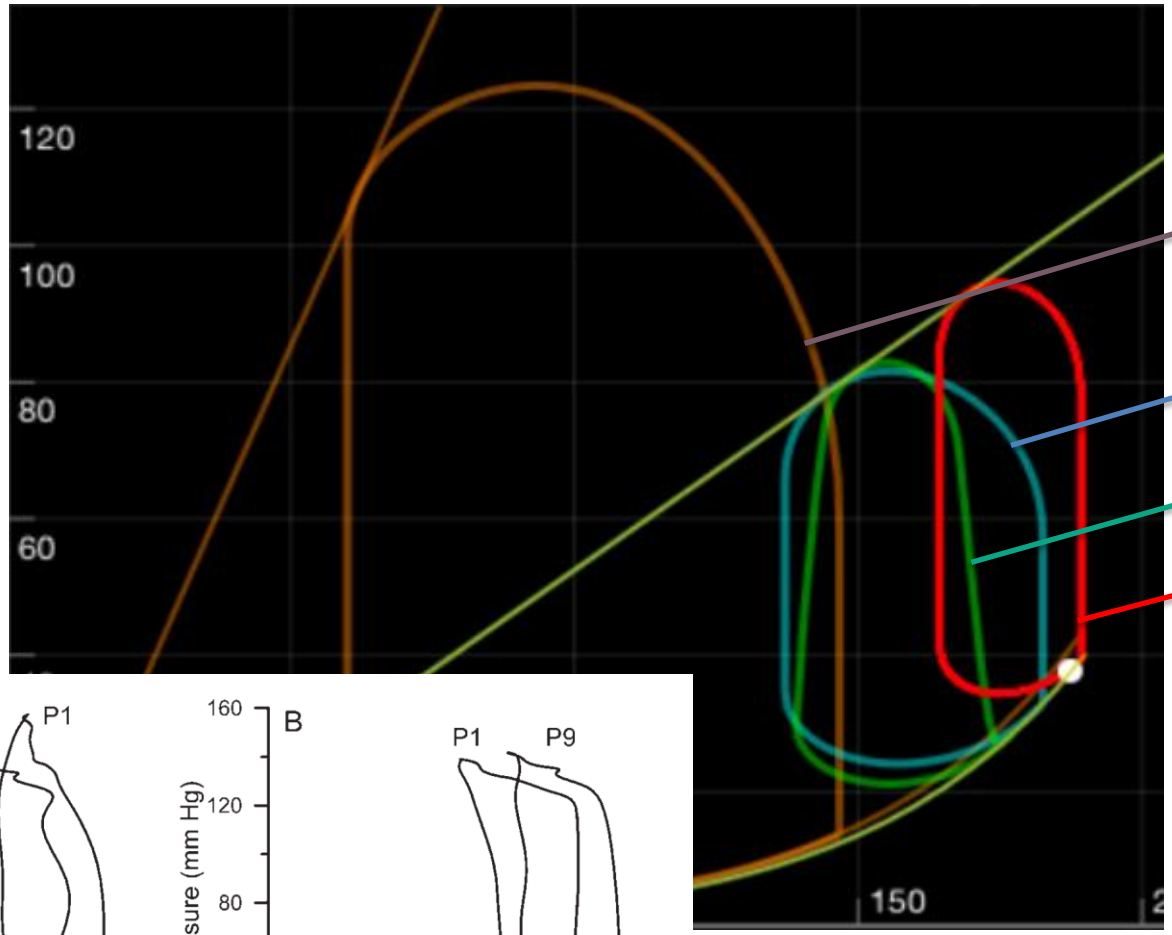
1. Henriques JP, Remmelink M; Am J Cardiol. 2006
2. Remmelink M, Sjauw KD, Henriques JP, Baan jr. J; CCI 2007
3. Sjauw KD, Remmelink M, Baan jr. J, Henriques JP; JACC 2008

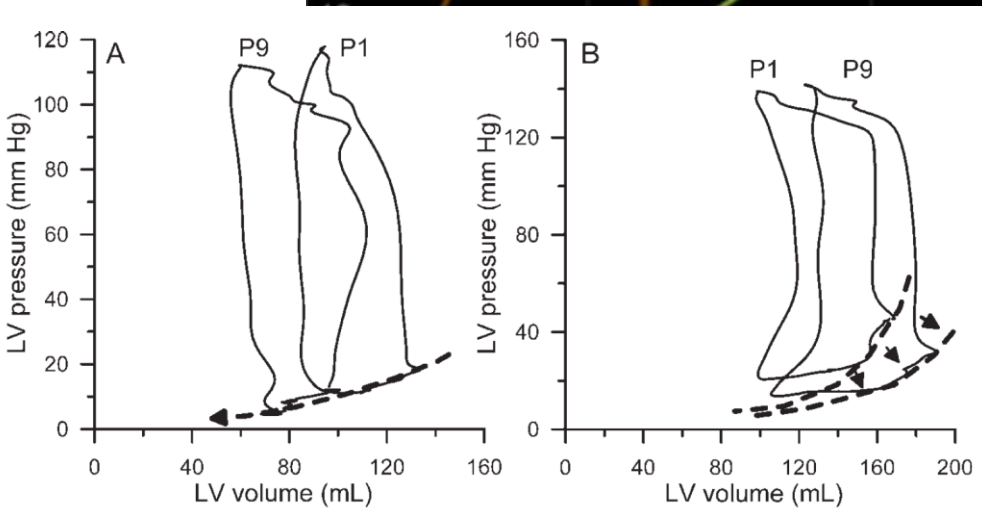
Cardiogenic shock

Impella - AMC



PV-loops



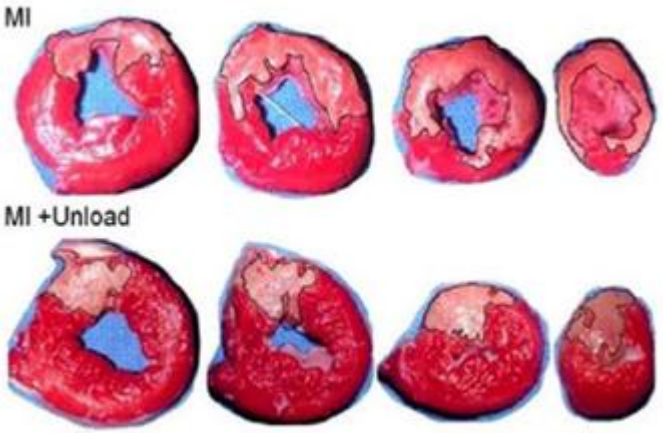


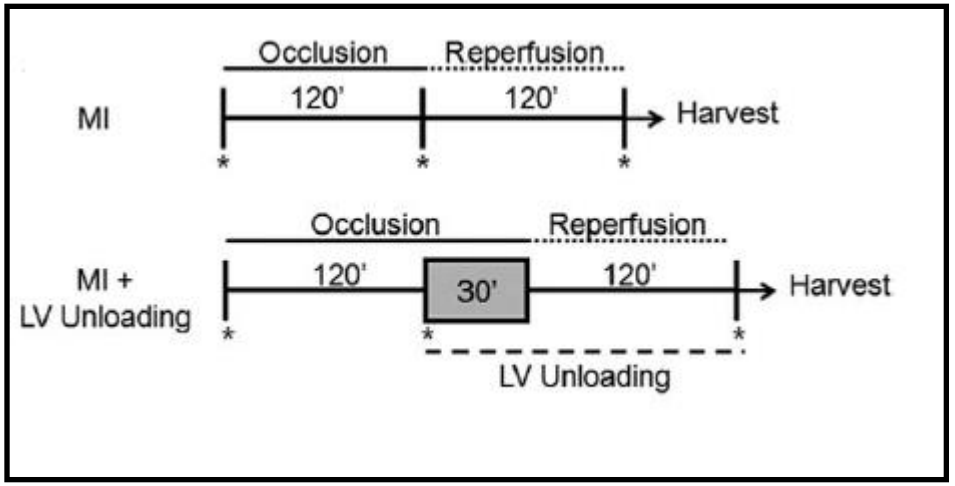
European working group on the clinical use of Impella. Submitted

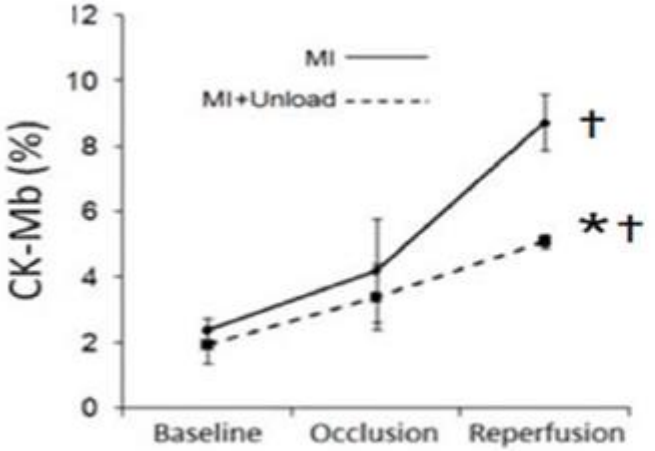
Unloading even prior to reperfusion

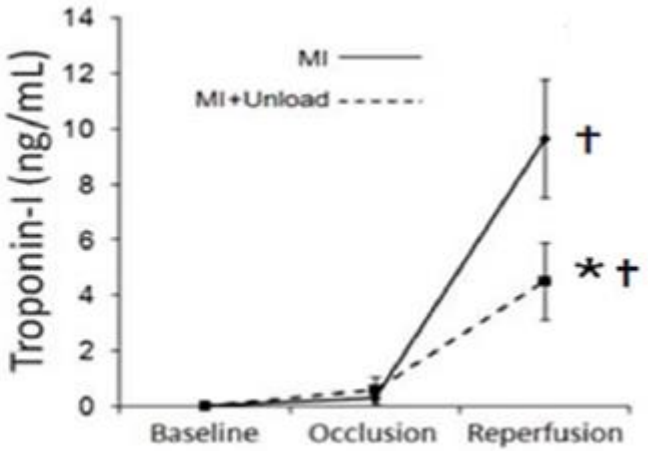
N=4

N=4



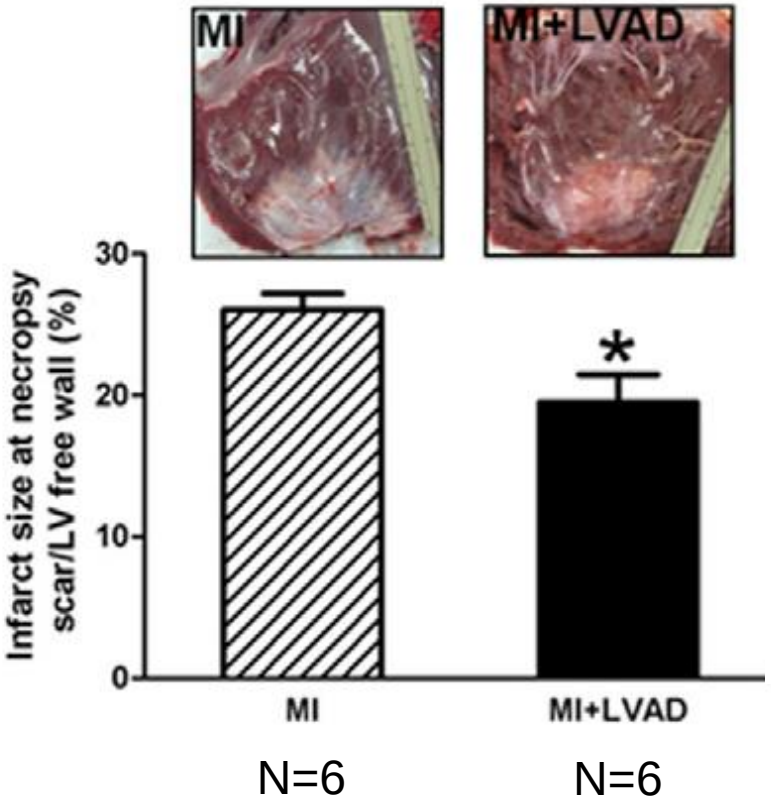


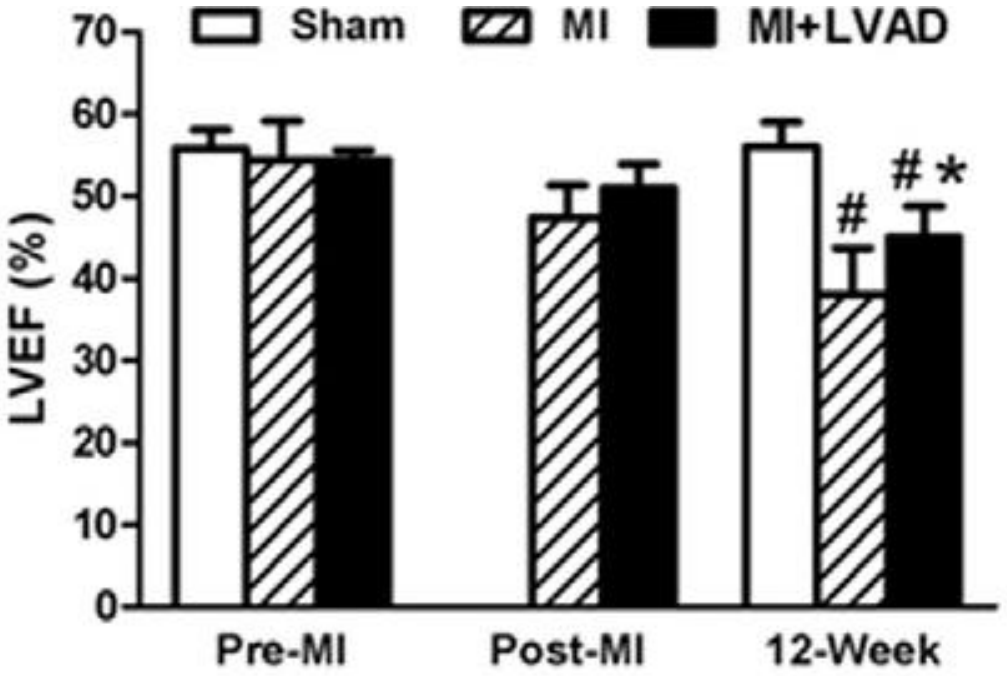




Kapur NK et al. Circulation 2013

Unloading after MI without reperfusion





Wei X al. JACC Cardiovasc Interv 2013

Myocardial recovery – IMPELLA 2,5

Unloading in STEMI

Non randomized pilot study

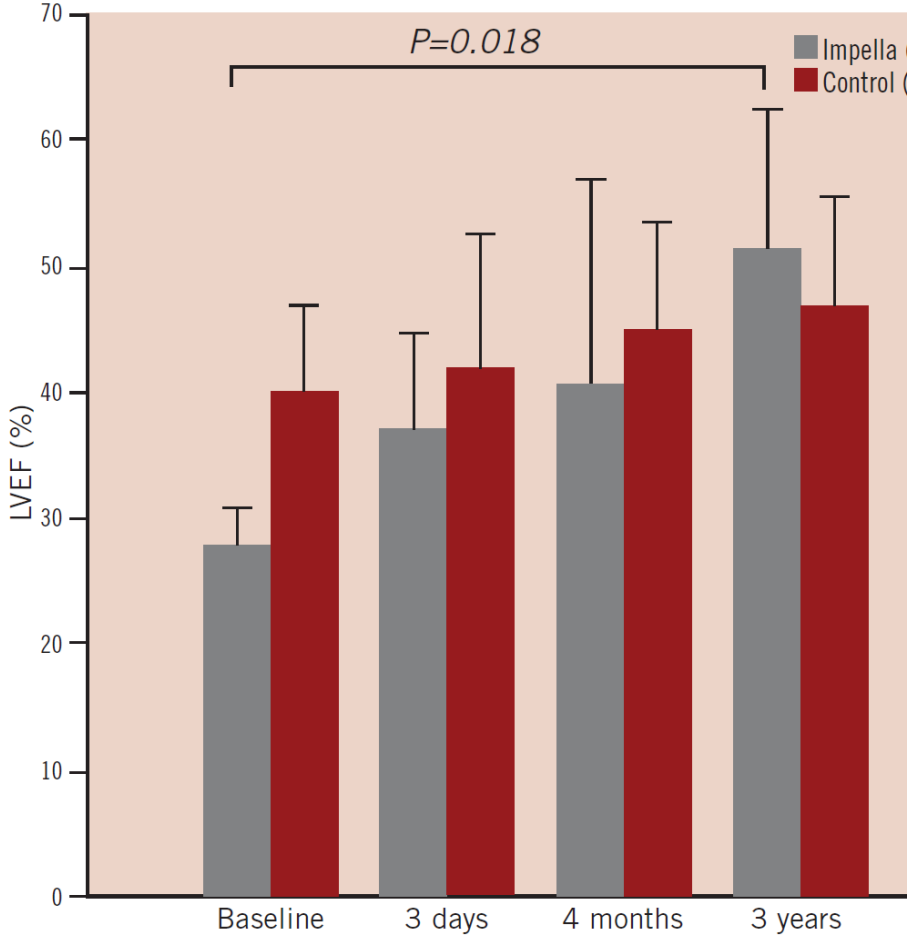
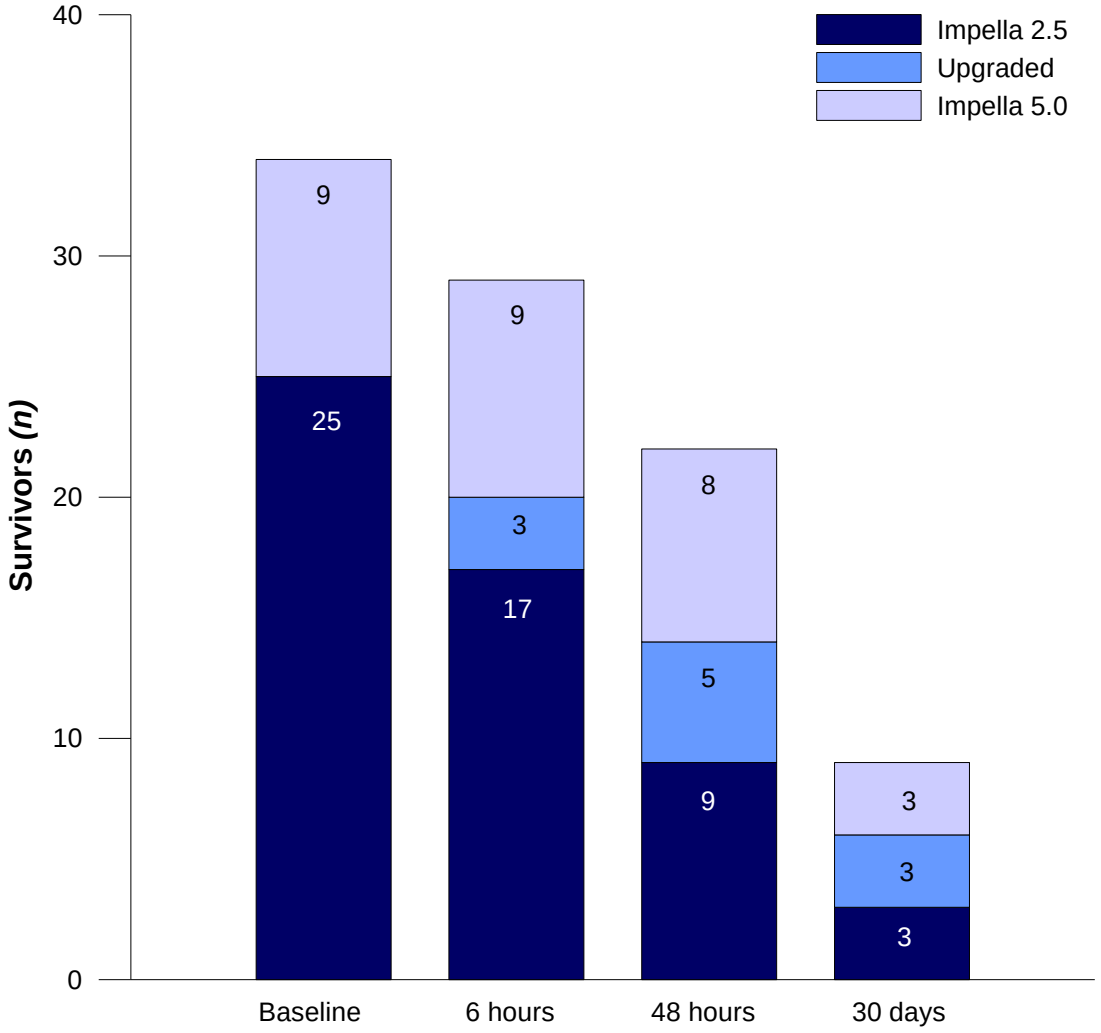


Figure 2. Serial evaluation of left ventricular ejection fraction (L

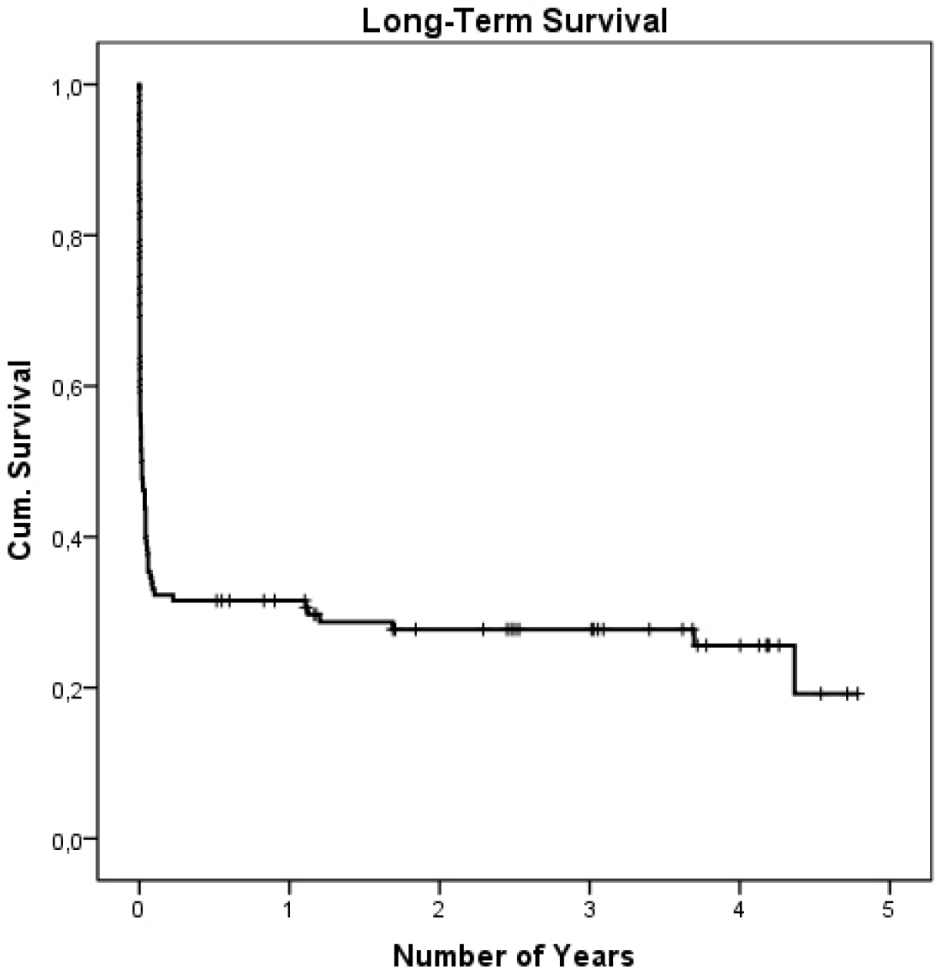
Engstrom AE, et al. EuroIntervention, feb. 2011

Are all devices equal? – Upgrade?



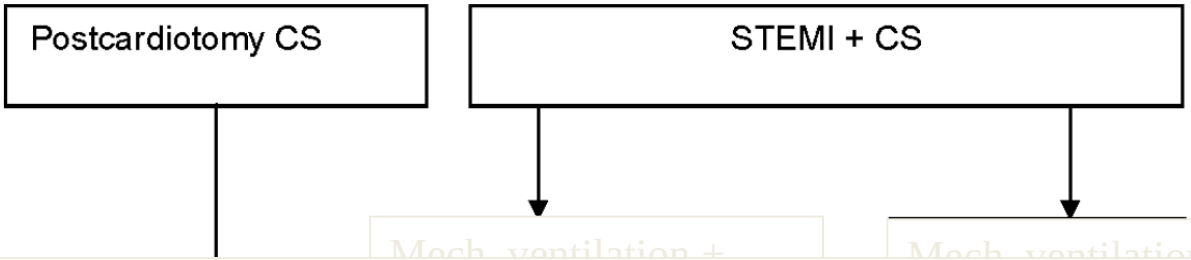
Engstrom AE, et al. Critical Care Medicine,2012

Impella 2,5 Euroshock registry

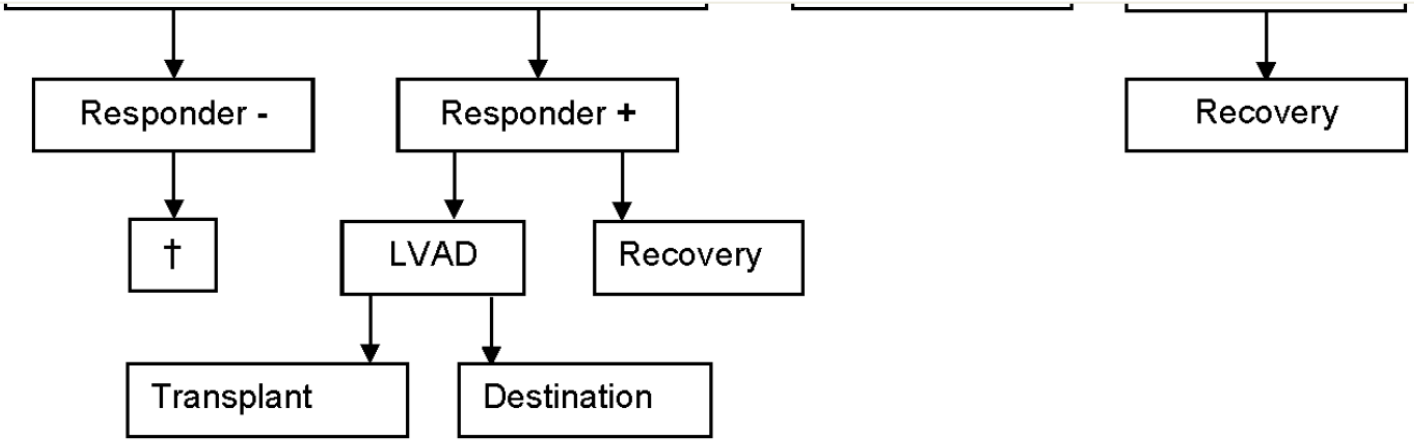


Lauten A, Engstrom AE, et al. Circulation Heart Failure, 2013

Implemented AMC strategy

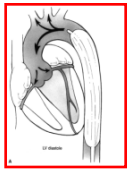


Impella CP 14 Fr providing >3,7 L/min

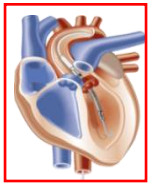


Ongoing trials with LV assist devices

IMPRESS Severe Shock
(= postarrest SHOCK)



IABP



Impella CP

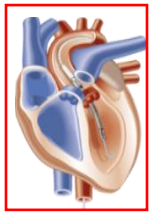
42 patients in
24 months
Two sites

48 patients planned

AMC, Amsterdam, NL
Haukeland, Bergen, N

Danish National Shock
routine care vs CP

Standard care



Impella CP

32 patients in
24 months

360 patients planned

Percutaneous circulatory support

	IABP	ECMO	TandemHeart	Impella 2.5	Impella CP	Impella 5.0	Impella RP
Pump mechanism	Pneumatic	Centrifugal	Centrifugal	Axial flow	Axial flow	Axial flow	Axial flow
Cannula size	7-9 F	18-21 F inflow; 15-22 F outflow	21 F inflow 15-17 F outflow	13 F	14 F	22 F Surgical cut-down	23 F
Insertion technique	descending aorta via the femoral artery	Inflow in RA via femoral vein, outflow in desc aorta via femoral artery	inflow in LA via femoral vein and trans-septal puncture outflow 15-17 F femoral artery	Across aortic valve via femoral artery	Across aortic valve via femoral artery	Across aortic valve via surgical cut-down of femoral artery	Via femoral vein accross tricuspid and pulmonary valve
Haemodynamic support	0.5 -1.0 L/min	> 4.5 L/min	4 L/min	2.5 L/min	3.7 – 4.0 L/min	5.0 L/min	4.0 L/min
Implantation time	+	++	++++	++	++	++++	++
Risk of limb ischaemia	+	+++	+++	++	++	++	+
Anticoagulation	+	+++	+++	+	+	+	+
Haemolysis	+	++	++	++	++	++	++
Requires stable rhythm	Yes	No	No	No	No	No	No
management complexity	+	+++	++++	++	++	++	++

Adapted from Ouweneel and Henriques. Heart 2012

ACC/AHA guidelines over the years

Year	Device	Recommendation	
2011	IABP	I/B	A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy
	Left ventricular assist devices	I/B	A hemodynamic support device is recommended for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy
2013	IABP	IIa/B	The use of intra-aortic balloon pump (IABP) counterpulsation can be useful for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy
	Left ventricular assist devices	IIb/C	Alternative LV assist devices for circulatory support may be considered in patients with refractory cardiogenic shock

Ouweneel DM, et al. Submiited

ESC guidelines over the years

Year	Device	Recommendation	
2010	IABP	I/C	IABP insertion is recommended in patients with haemodynamic instability (particularly those in cardiogenic shock and with mechanical complications
	Left ventricular assist devices	III/B	Routine use of percutaneous centrifugal pumps is not recommended
2012	IABP	IIb/B	Intra-aortic balloon pumping may be considered (in patients with cardiogenic shock (Killip class IV)
	Left ventricular assist devices	IIb/C	LV assist devices may be considered for circulatory support in patients in refractory shock
2014	IABP	III/A	Routine use of IABP in patients with cardiogenic shock is not recommended
	Left ventricular assist devices	IIb/C	Short-term mechanical circulatory support in ACS patients with cardiogenic shock may be considered

Ouweneel DM, et al. Submiited

SHOCK CASE

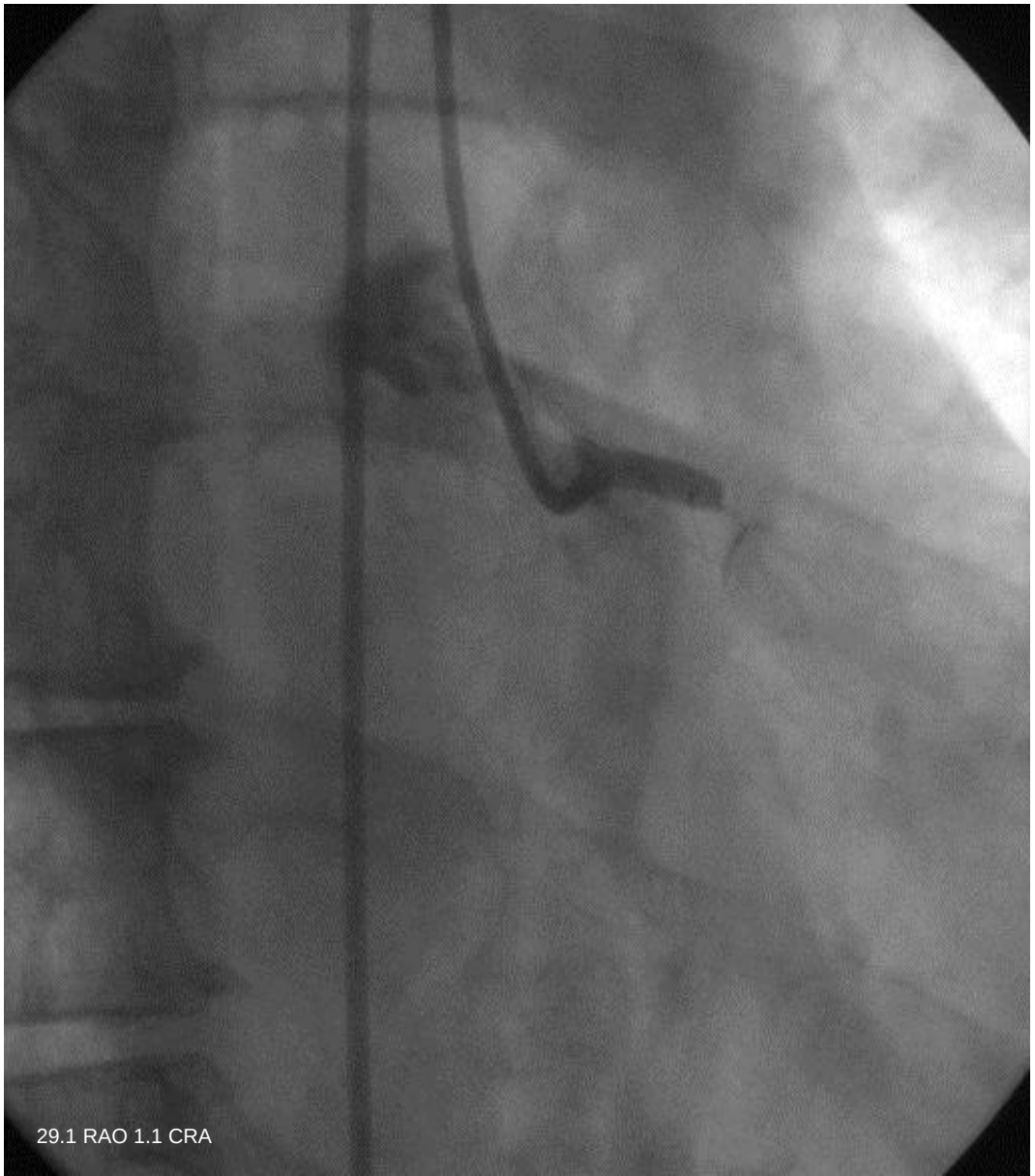
- 51 yr old male
- Wakes up with chestpain and shortness of breath
- Calls 112 (prehospitale triage system - EMS)
- EMS calls+sends EKG: abnormal but poor clinical condition
- Immediate transfer to our hospital and cath-lab notified
- Initiate treatment: Aspirin, Clopidogrel, Heparin and Oxygen

Patient Clinical Condition on Arrival

- Severely distressed/restless on arrival @ hospital
- Pale with cold and discolored extremities
- BP 60/40
- HR 104/min
- Saturation 81 with O2
- Breathing >30/min

NOT INTUBATED YET

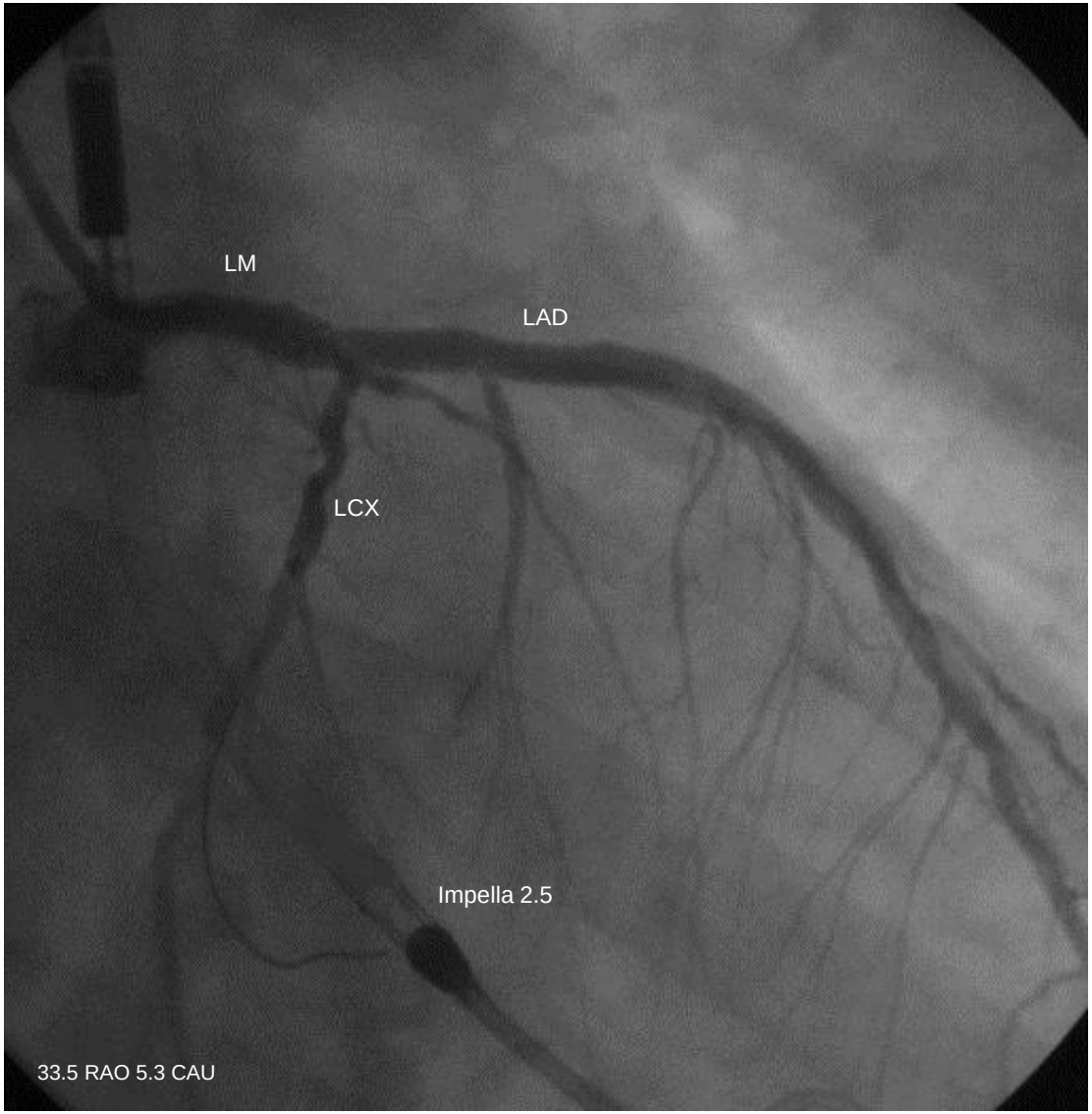
Just one shot….what next?



Initiate Organ and Myocardial Recovery

- Immediate Impella 2,5 placement left groin
- Immediate patient relief – less short of breath
- BP 80/70 (initial BP 60/40)
- Heart rate 105/min

PCI final result – TIMI 2-3



Clinical course - Immediately after PCI

- BP 95/85 (pulsepressure),
- heartrate 100/min
- Saturation 90% with O2
- Some ECG resolution
- No inotropes
- No vasopressors
- Not to ICU but to CCU
- Echo: LVEF 15-20% (only inferior wall contractions)

Clinical course until discharge

- CK MB 700 U/L
- Initial rise in creatinine levels and low urine production but restoration after 2-3 days
- Total Impella 2,5 support for 8 days
- Weaned well and was discharged to local hospital and home a week later – total admission time: 19 days

Post discharge FUP

- LVEF 46% @ 4 months, no residual ischemia
- Reangio after 9 months for LM PCI : good result
- Has resumed all his former activities without apparent limitations

A recovered heart and patient

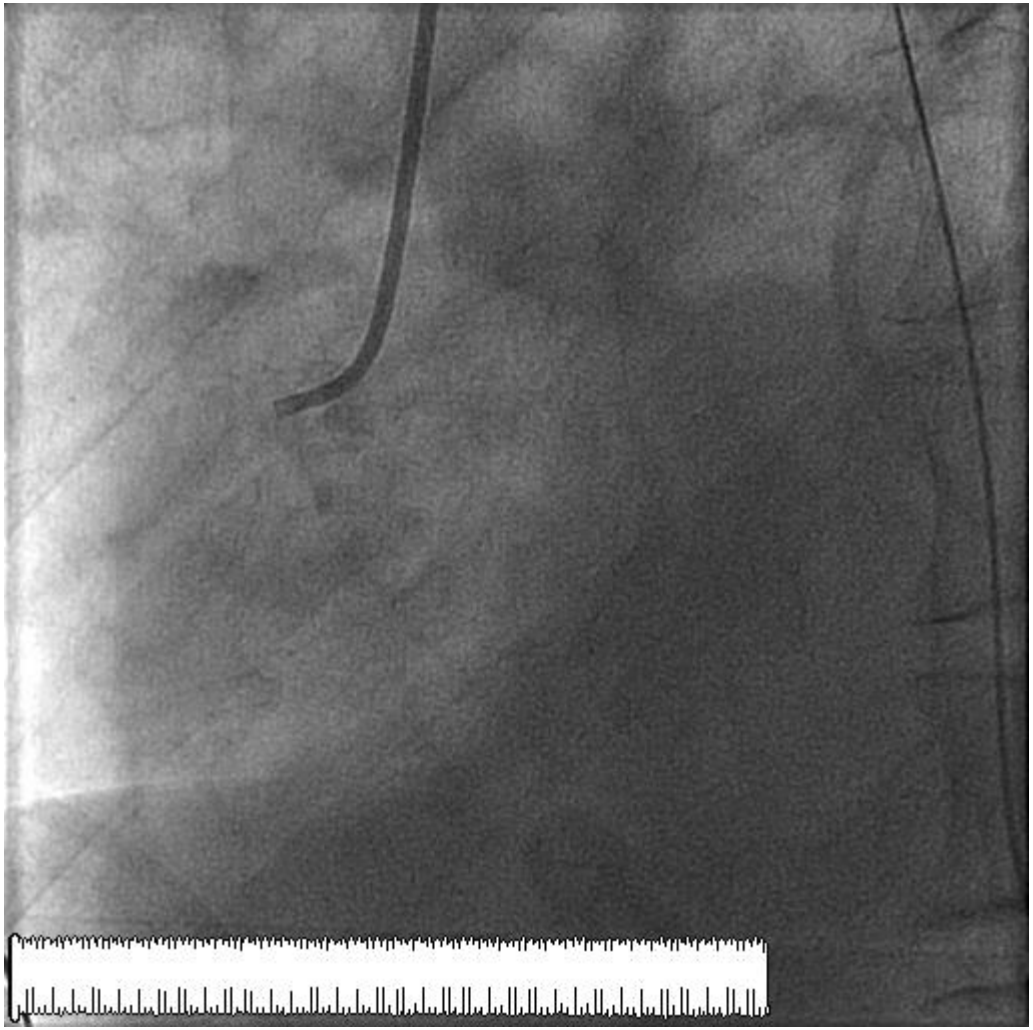
SEVERE SHOCK CASE

- 46 yr old male
- No previous medical history
- Out-of-hospital-arrest and immediate BLS by friends
- Arrival of Ambulance and multiple times defibrillated
- After 20 minutes some degree of pulsatility
- ECG: large anterior STEMI

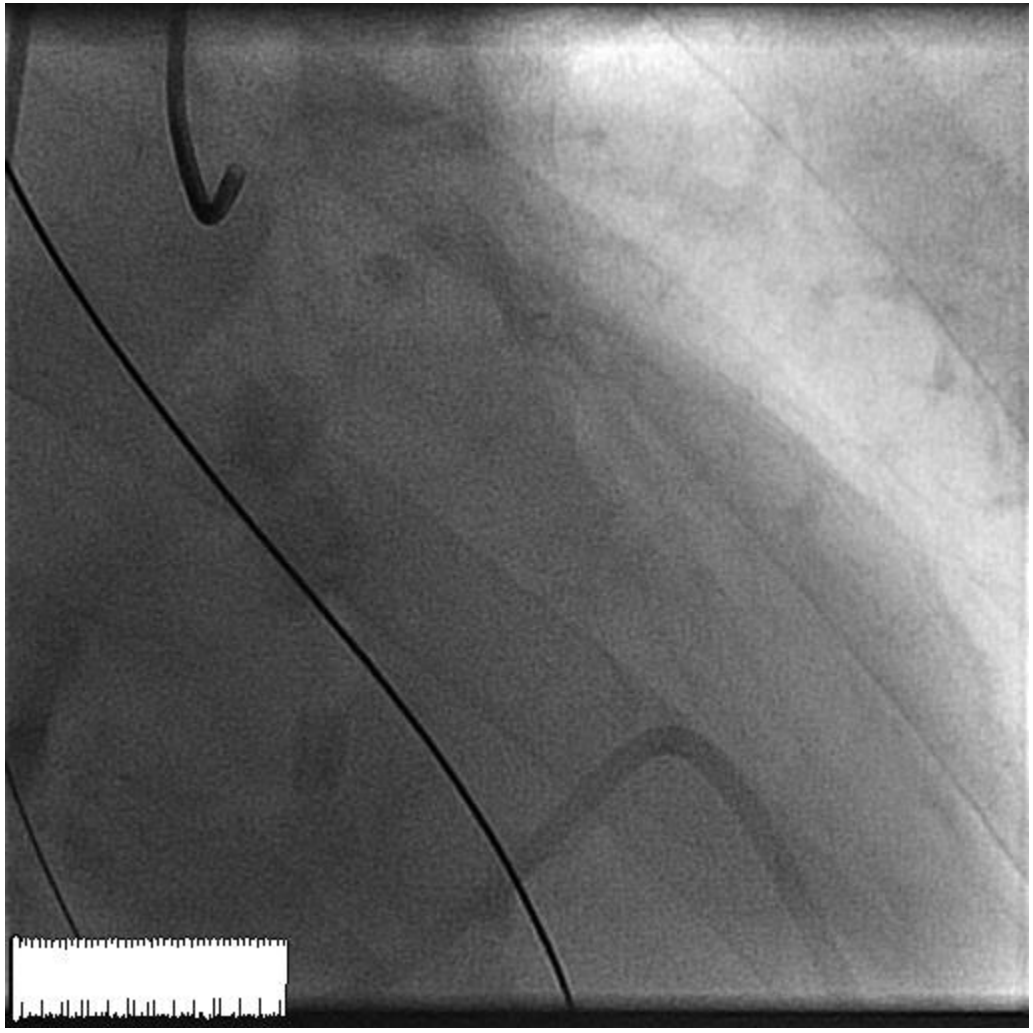
Arrival @ cathlab

- Intubated and blood through endotracheal tube
- Cold extremities
- BP 75/60
- HR 110/min
- On inotropes:
  - adrenaline high dose
  - dobutamine medium dose
  - Norepinephrine medium dose

RCA

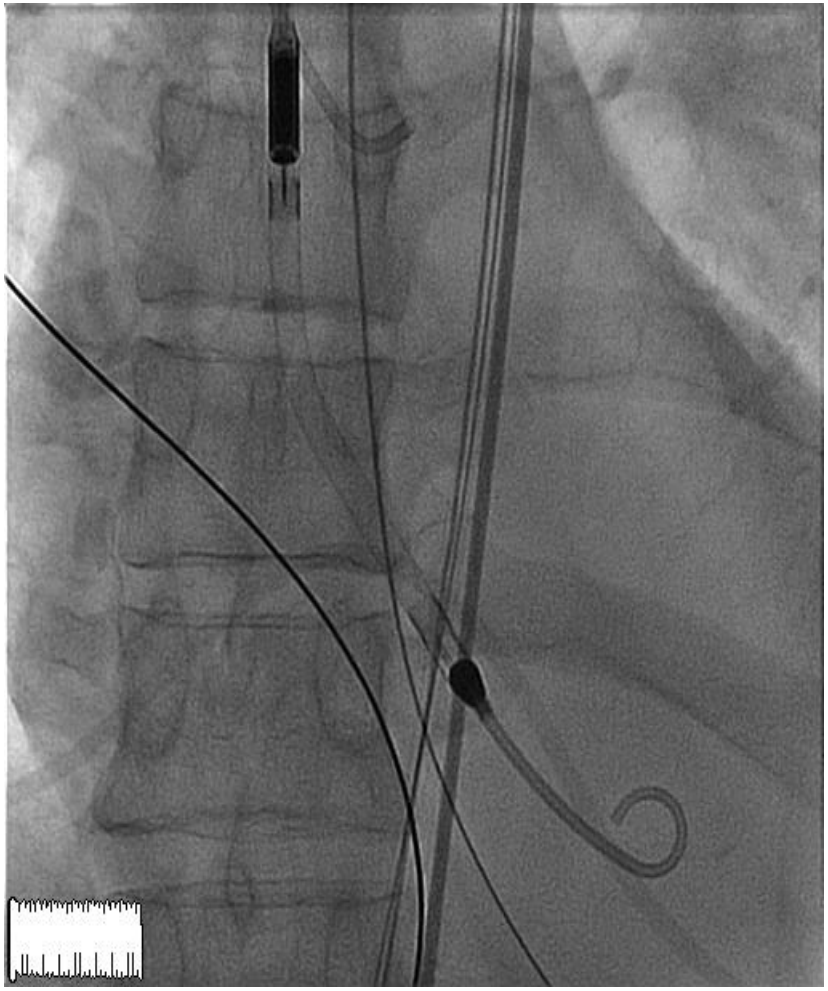


LCA



Femoral artery

Circulatory support first



IMPELLA CP >3,7 L/min

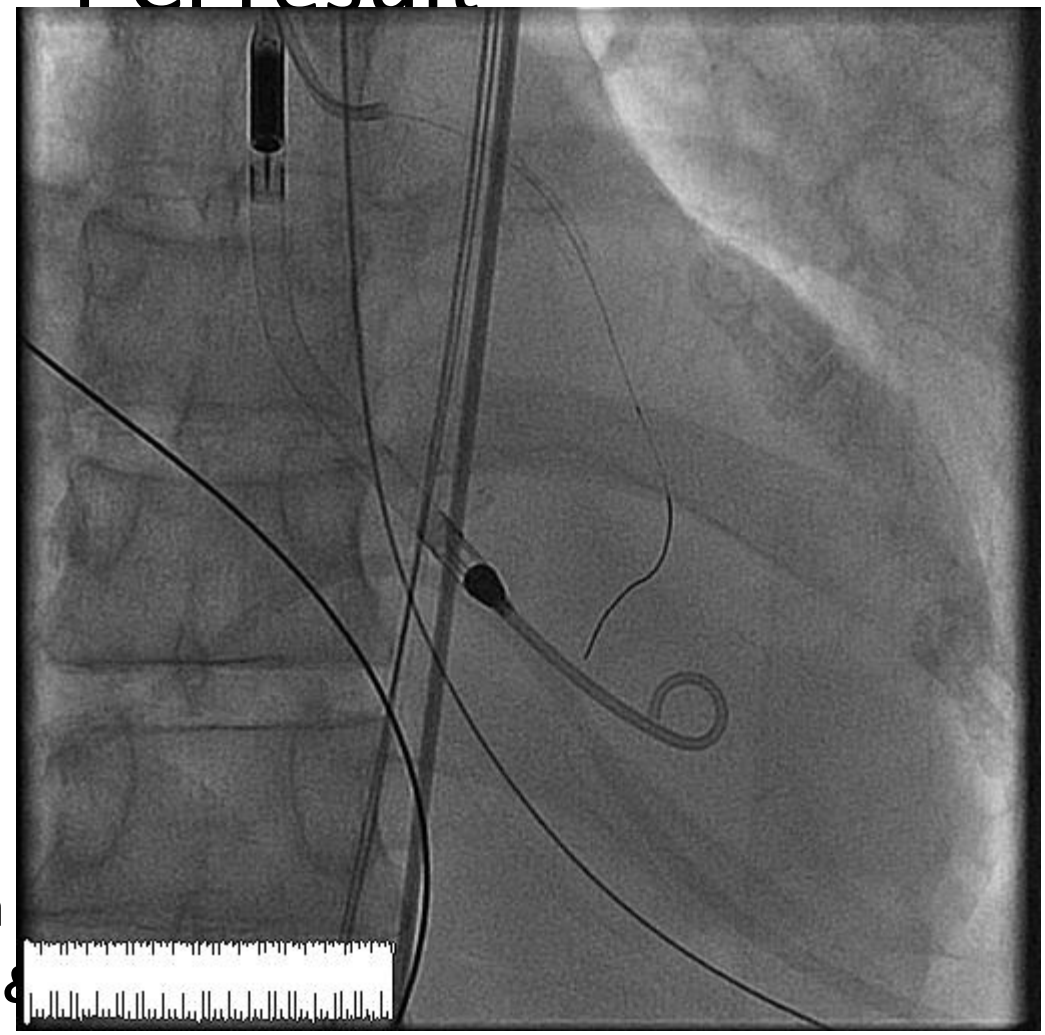
PCI

- Wire
- Thrombusaspiration

- Complete collapse of circulation
- No pulsatility on arterial line during 10 min.
  ~60 mm Hg

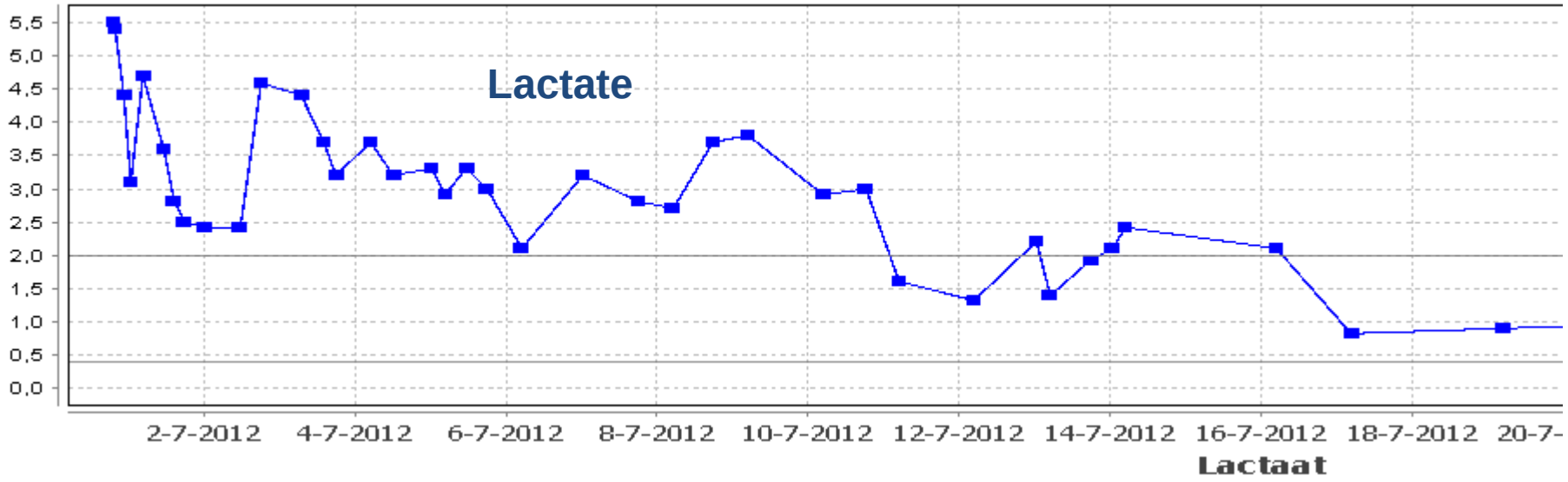
- Stentys stent

PCI result



- **Leaving the cath-lab**
- **BP 90/70**
- **HR 100/min**
- **Impella CP on 3.7 L/min**
- **Still on norepinephrine &**
- **No longer adrenaline**

ICU


Lactate
5,5
5,0
4,5
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3,5
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2,5
2,0
1,5
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0,5
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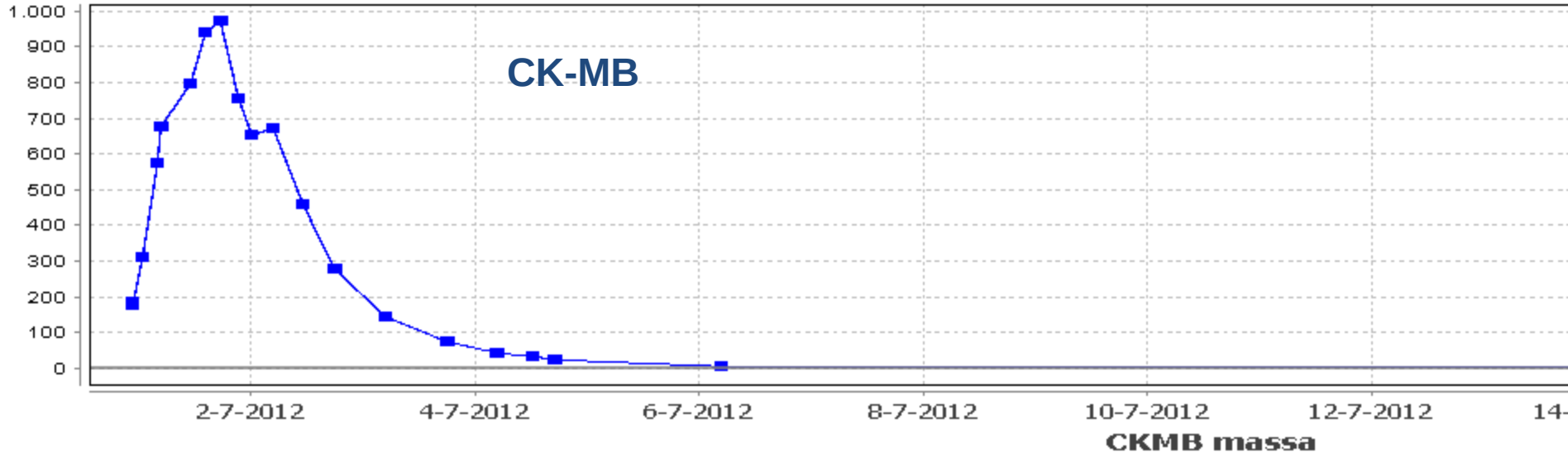
2-7-2012
4-7-2012
6-7-2012
8-7-2012
10-7-2012
12-7-2012
14-7-2012
16-7-2012
18-7-2012
20-7-
Lactaat


CK-MB
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700
600
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400
300
200
100
0
2-7-2012
4-7-2012
6-7-2012
8-7-2012
10-7-2012
12-7-2012
14-
CKMB massa

Clinical course

- ICU stay – 22 days
- Polyneuropathy
- 13 days on Impella CP support of which 10 days full support
- 3 days CCU/medium care
- Predischarge LVEF on echo and MIBI 33%
- ICD decision (?)
- Total hospital stay 43 days

- Has resumed all his former activities @ 3 months after discharge

Conclusions

Cardiogenic shock is still a condition with 50% mortality

IABP should not be used for cardiogenic shock

More potent percutaneous devices enter the cath-lab

What device for what condition?

ECMO best cards for ongoing resuscitation

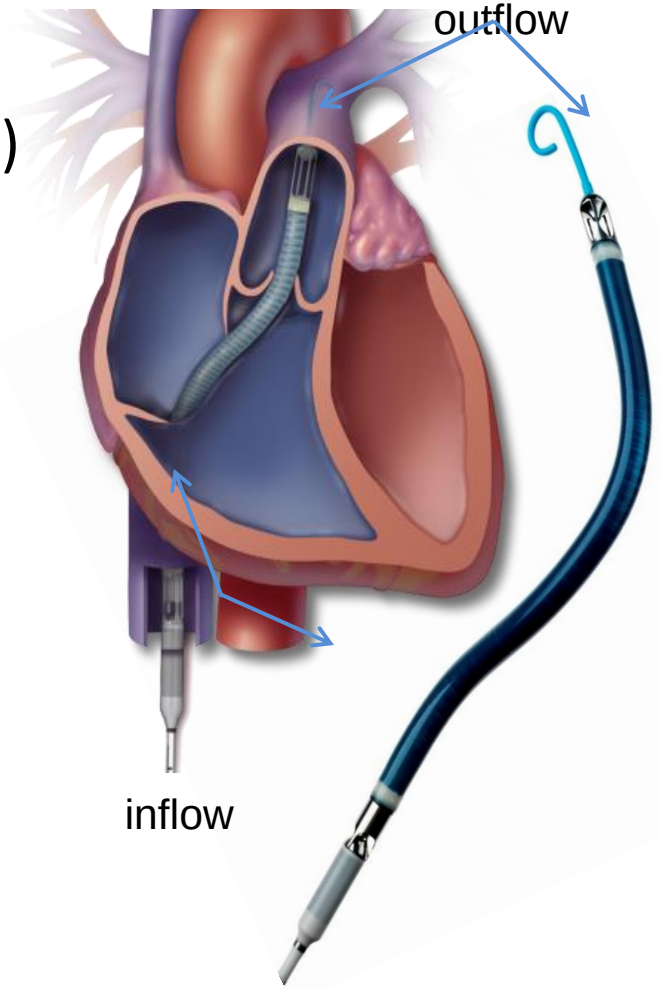
Impella has best cards for cardiogenic shock

My guess for the future : Circulatory support before PCI !

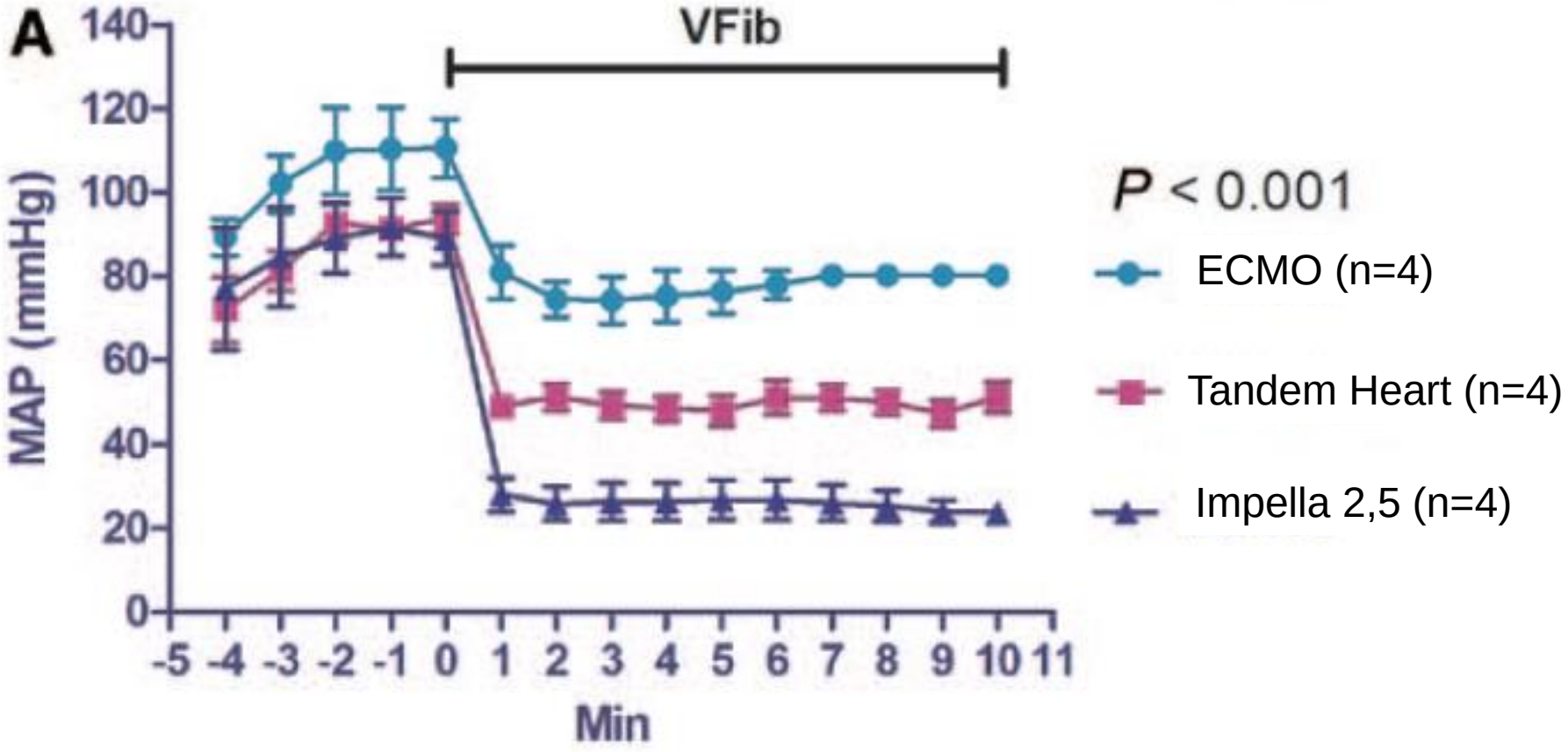
Greetings from Amsterdam!

Impella® RP

- Temporary circulatory support for RV failure
- Single vascular access (femoral vein)
- Placed under fluoroscopic guidance
- No sternotomy required
- No extracorporeal circulation
- 22 Fr pump on an 11 Fr catheter
- Maximum flows > 4 L/min



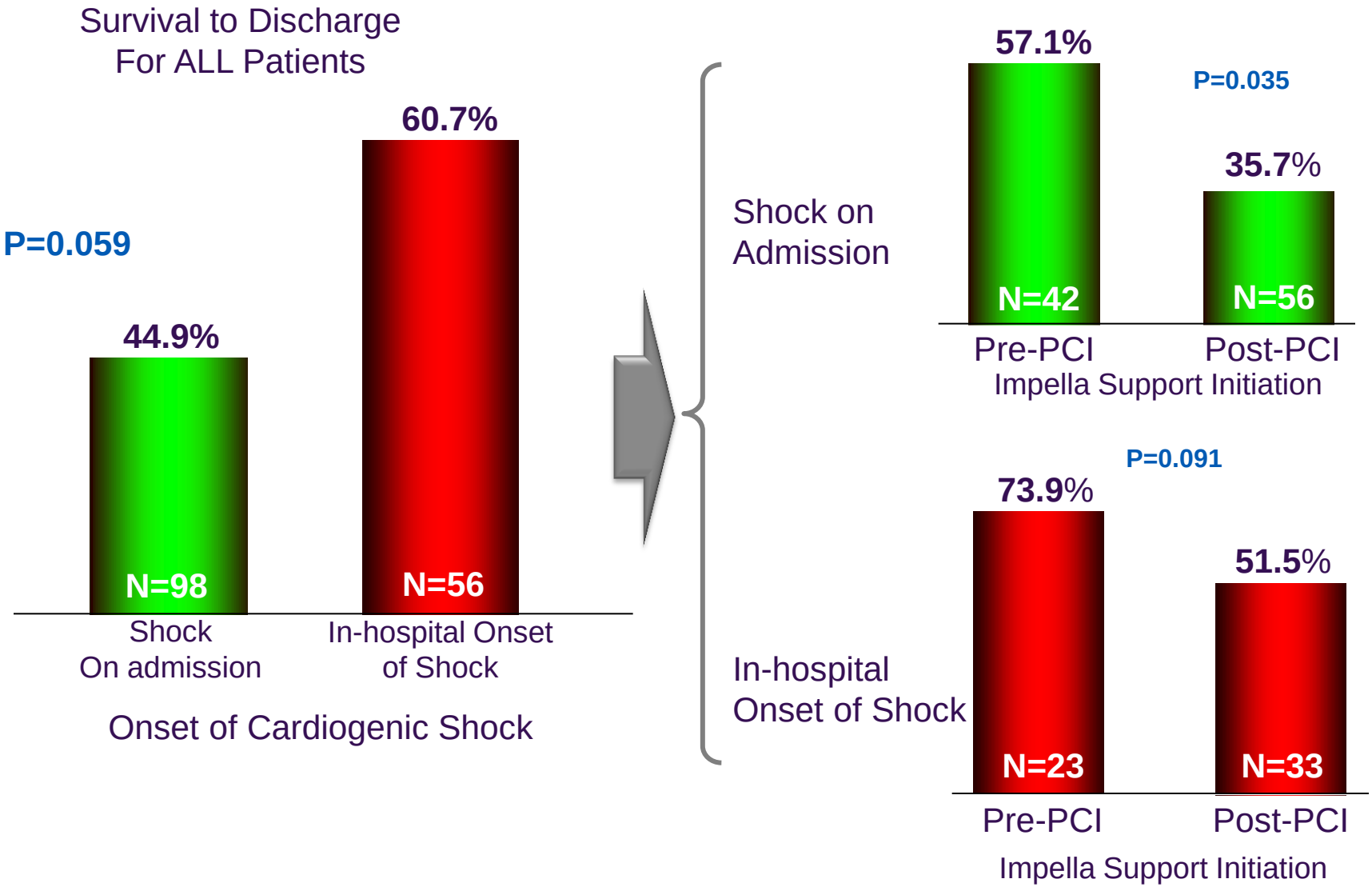
Direct comparison in VF



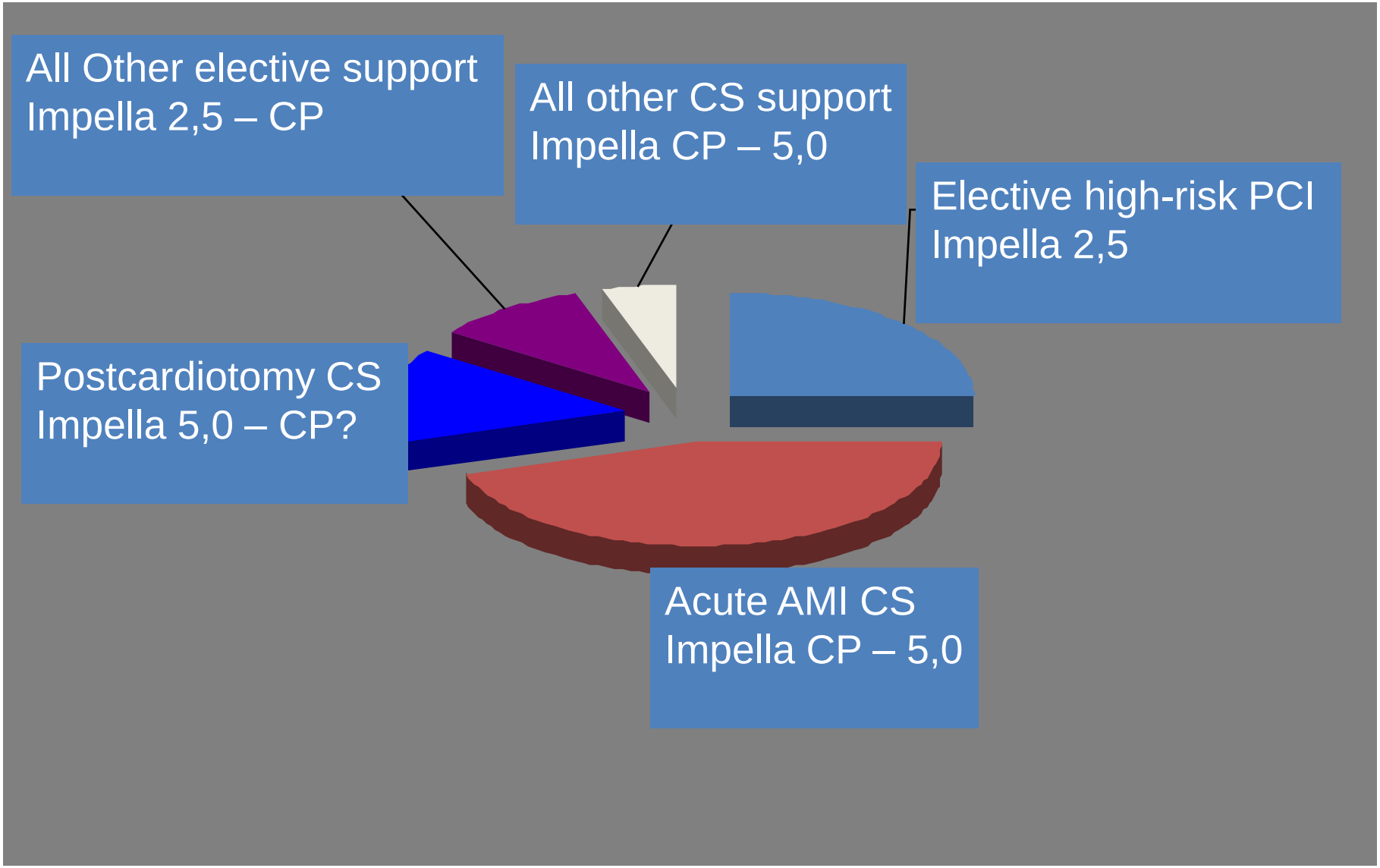
Ostadal P et al. Circ Arrhythm Electrophysiol. 2012

Impella 2,5

US-Pella SHOCK registry



My personal recommendation for Impella usage



Geographic distribution of Impella per indication

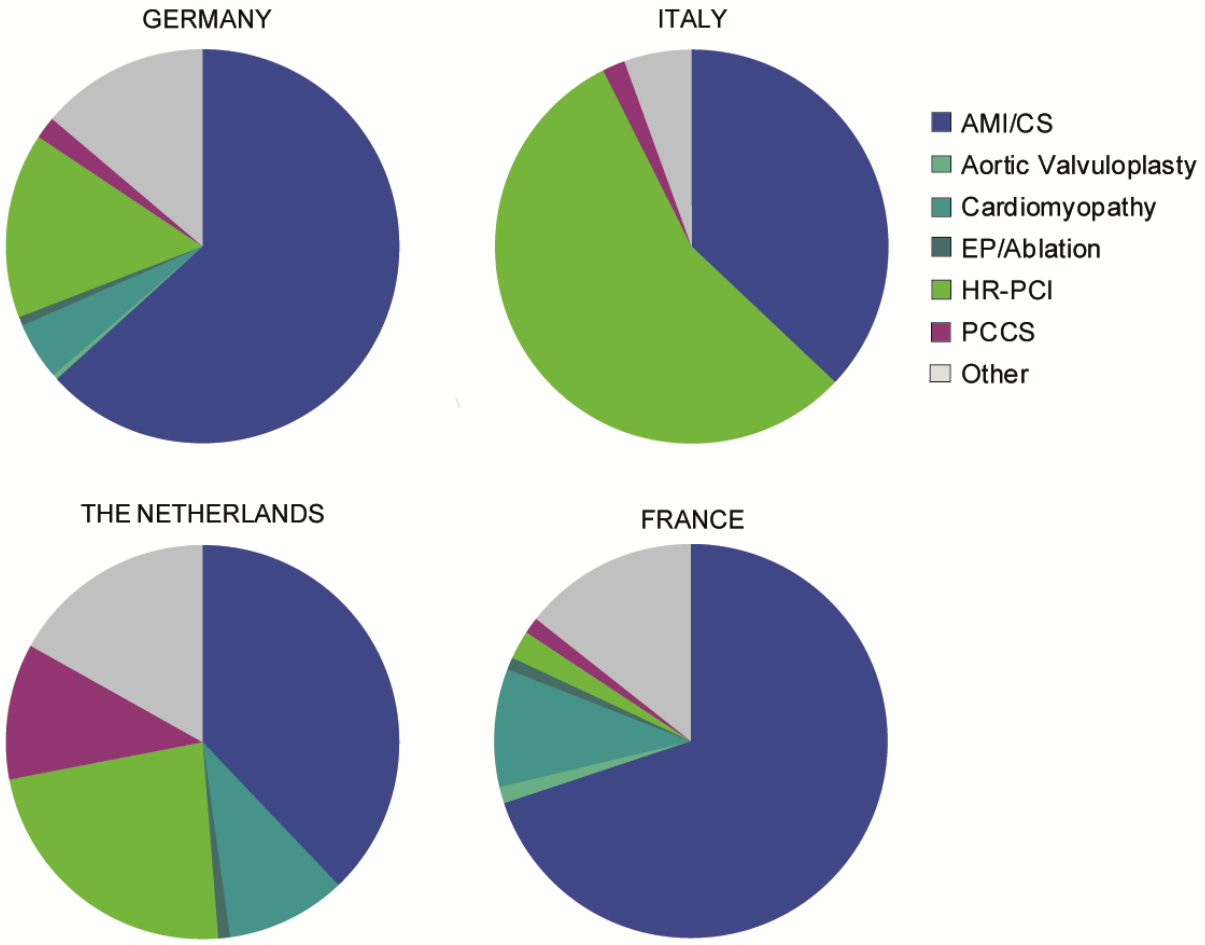
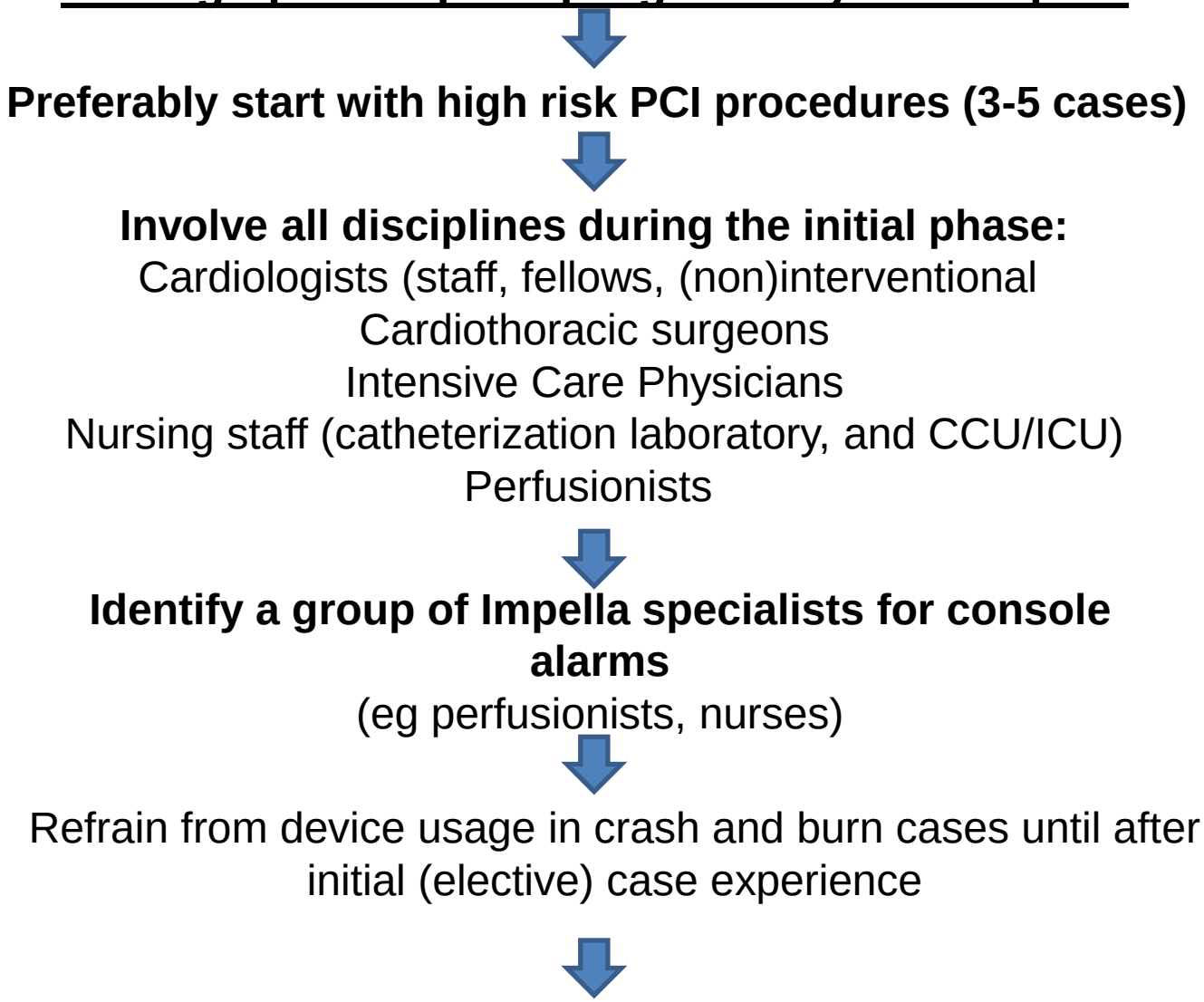


Figure 7


Setting up an Impella program in your hospital
Preferably start with high risk PCI procedures (3-5 cases)
Involve all disciplines during the initial phase:
Cardiologists (staff, fellows, (non)interventional
Cardiothoracic surgeons
Intensive Care Physicians
Nursing staff (catheterization laboratory, and CCU/ICU)
Perfusionists
Identify a group of Impella specialists for console alarms
(eg perfusionists, nurses)
Refrain from device usage in crash and burn cases until after initial (elective) case experience
Evaluate every case during first 10 cases

Impella CP™

- Increased Cardiac Power
  - Up to 3,7 L/Min Peak Flow
- Speed of the Cath Lab
  - Percutaneous implant of a 9 Fr catheter / 14 Fr pump
- Compatible with 14 Fr sheath
  - Abiomed peel-away (Oscor)
  - Cook 30cm, 14Fr