

Pulsatile mechanical Circulatory Support

When & How

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My Conflict of Interest

- Research Grant Support: Abbott, Boston Scientific, Edwards Lifesciences, Medtronic, PulseCath BV, Daiichi Sankyo , Teleflex, Astra Zeneca, HeartFlow
- Advisory board: Abbott, Ancora, Boston Scientific, Medtronic, PulseCath BV, Daiichi Sankyo, Abiomed, JenaValve, Anteris, Bolt Medical, Siemens, Pie Medical, Luma Vision, FEops, Materialise

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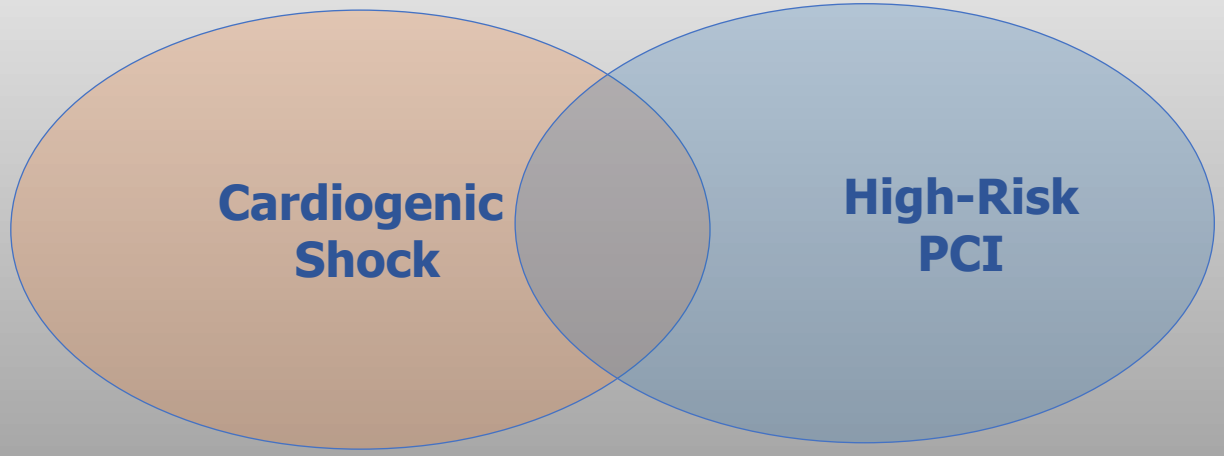
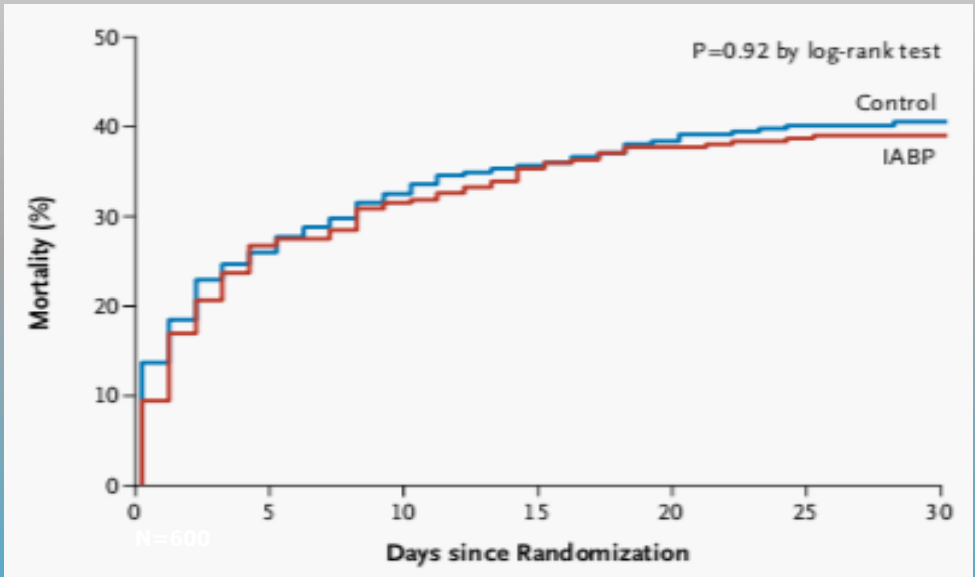
MCS is about Timing



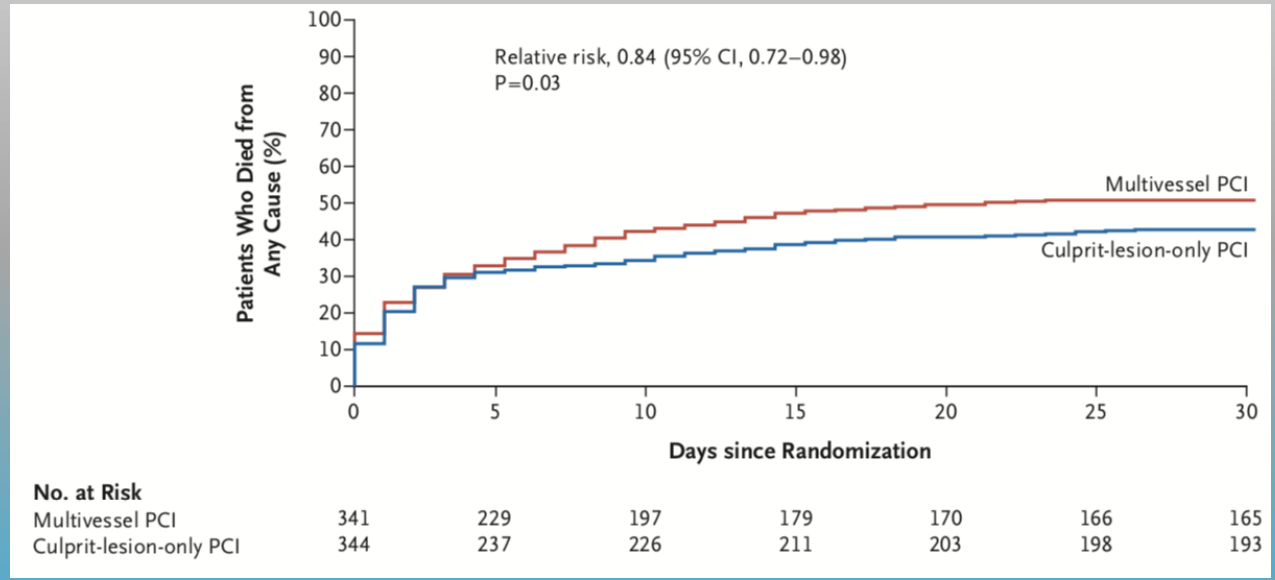
- Anticipate
- Escalate
- Choose wisely
- Minimize inotropics/vasopressors

When IABP doesn't work…

IABP SHOCK II Trial



CULPRIT SHOCK Trial



Thiele et al. NEJM 2012;367:1287-96
Thiele et al. NEJM 2017;377:2419-32

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When IABP doesn't work…

IABP SHOCK II Trial

- OHCA > 40%
- Catecholamines prior to randomization 90%
- Only 30cc IABP device

CULPRIT SHOCK Trial

- OHCA > 50%
- Catecholamines in 90%
- Any MCS in 28%
  - ✓ 27% IABP
  - ✓ 38% Impella
  - ✓ ECLS (ECMO) 38%

Thiele et al. NEJM 2012;367:1287-96
Thiele et al. NEJM 2017;377:2419-32

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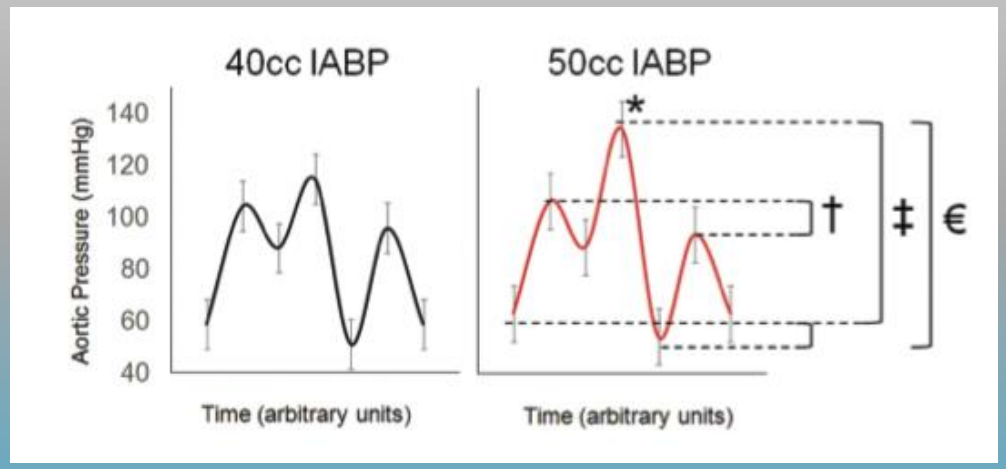
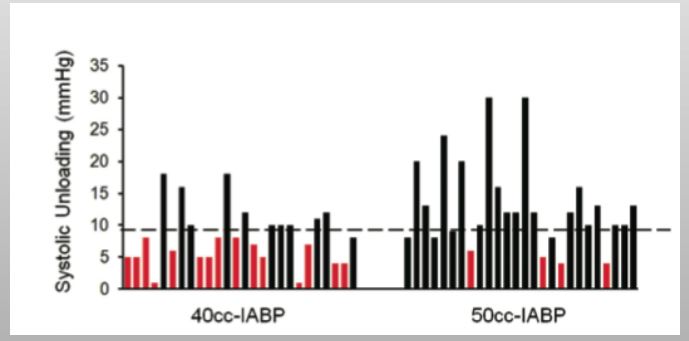
IABP Size Matters

Real world Practice Study with 40cc vs 50cc IABP (n = 52)

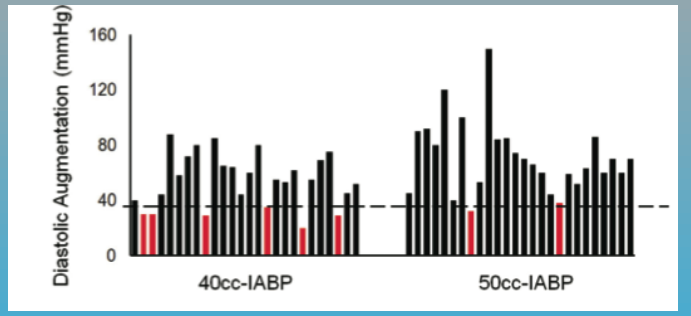


IABP Hemodynamic Variables	40 cc IABP	50 cc IABP	*P*-Value
Systolic unloading (B-F)	9 ± 4	13 ± 7	.01
Diastolic augmentation (D-A)	56 ± 18	71 ± 26	.02

Responders = Systolic pressure ⇩ > 10 mmHg



Responders = Diastolic pressure augmentation ⇧ > 40 mmHg



Non-responder

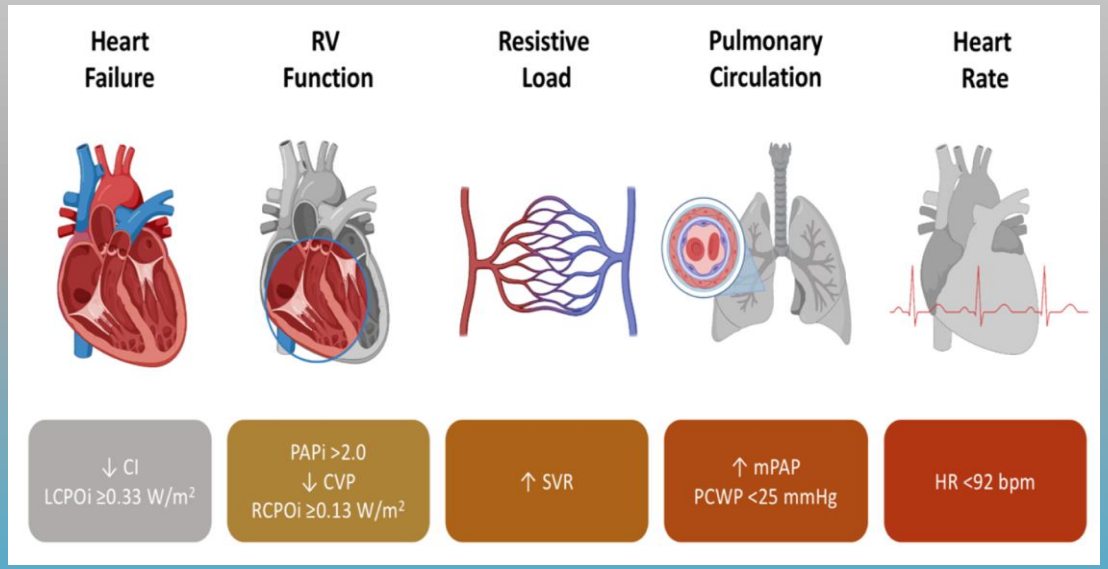
Responder

Kapur et al. J Invas Cardiol 2015;27:182-8

When IABP does work…

	Univariate Analysis		Multivariate Analysis		VIF
	P-Value	Odds Ratio (95% CI)	*P*-Value	Odds Ratio (95% CI)	
Dichotomous variables					
Heart rate <92 beats/min	<.02*	4.38 (1.69-11.4)	.02*	4.08 (1.25-13.3)	1.23
CVP <9 mm Hg	<.001*	7.27 (2.76-19.2)	.18	3.27 (0.59-18.2)	2.79
Mean pulmonary artery pressure <37 mm Hg	<.001*	6.38 (2.44-16.7)	.26	2.09 (0.59-7.47)	1.81
Pulmonary capillary wedge pressure <25 mm Hg	<.001*	10.5 (3.52-31.5)	.02*	4.66 (1.29-16.9)	2.71
Cardiac index >1.85 L/min/m²	<.01*	4.48 (1.61-12.5)	.09	2.98 (0.83-10.7)	1.18
Pulmonary artery pulsatility index >2.45	.03*	2.71 (1.12-6.57)	.64	0.677 (0.13-3.52)	1.87

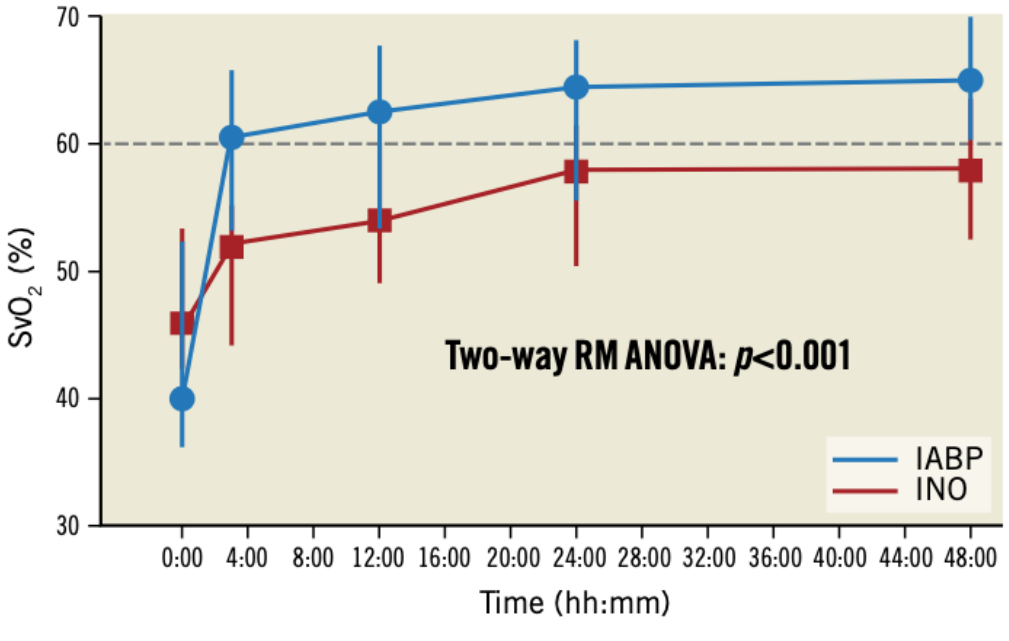
VIF = variance inflation factor; CI = confidence interval. *P<.05 by logistic regression analyses.



Baldetti et al. Circulation Heart Failure 2021;14:1263-77

When IABP does work…

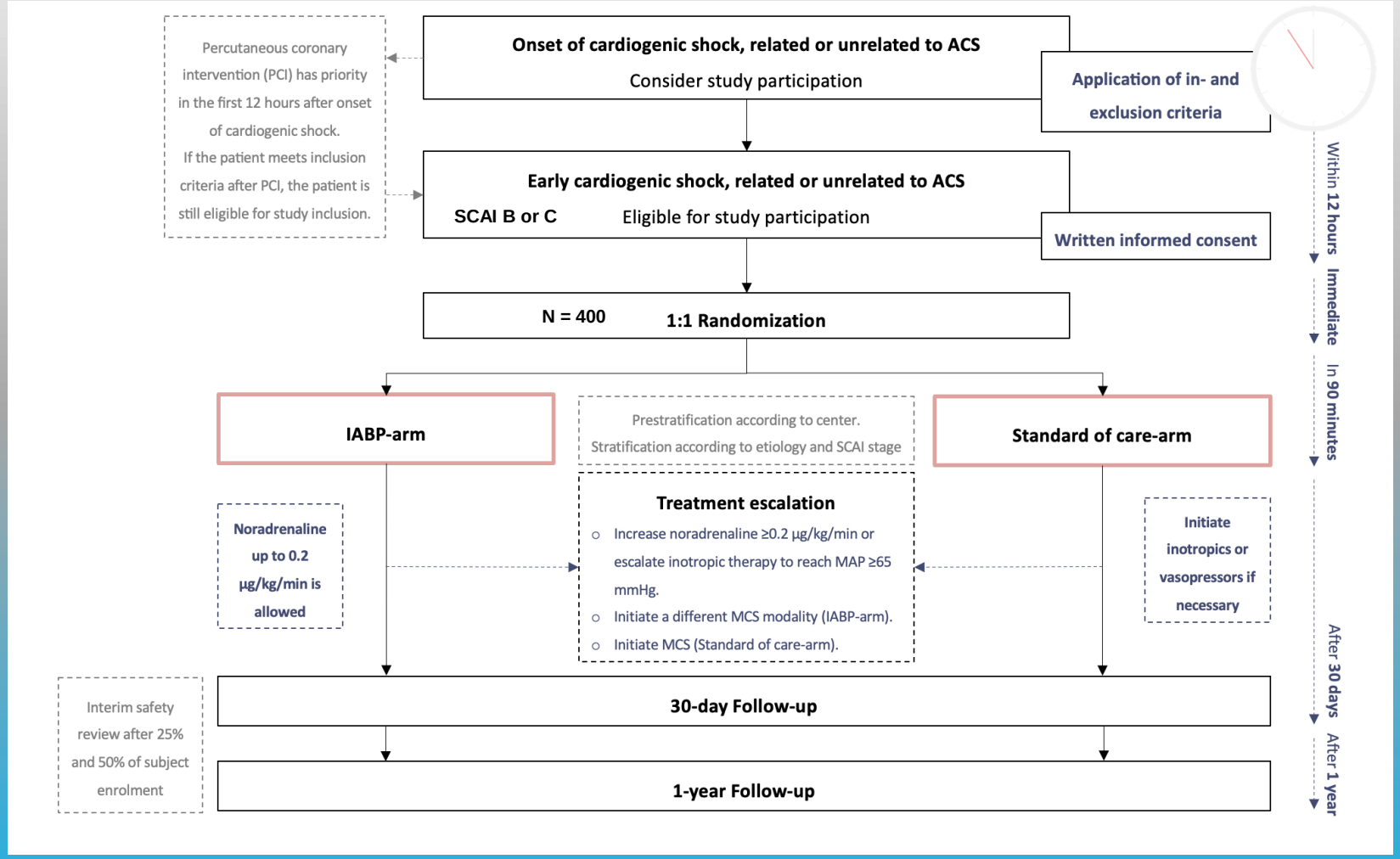
- Randomized Trial in decompensated heart failure & Low output n= 32
- 50mL IABP bedside implant vs. Inotropes
- Primary Endpoint SvO_2 @ 3 hours



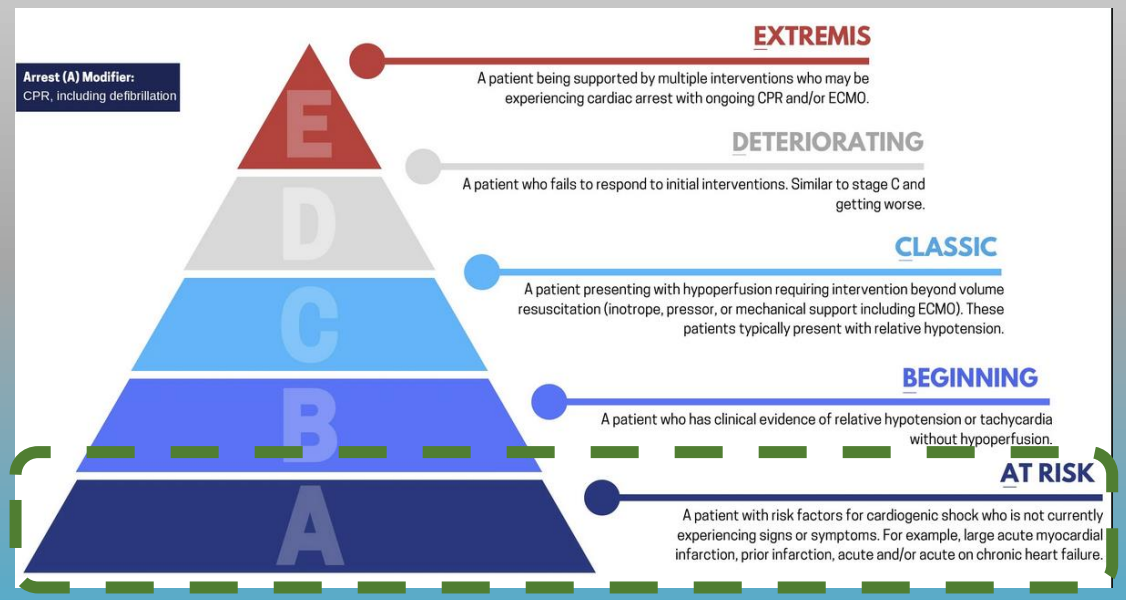
		IABP (n=16)	Inotropes (n=16)	*p*-value
Primary endpoint				
ΔSvO_2 (3h-0h), %		+17 [+9; +24]	+5 [+2; +9]	<0.001
Secondary endpoints				
CPO at T48h, W		0.73 [0.62-0.96]	0.59 [0.48-0.80]	0.17
ΔCPO (48h-0h), W		+0.27 [+0.17; +0.45]	+0.09 [–0.04; +0.21]	0.004
NT-proBNP level at T48h, ng/L		4,907 [3,254-7,628]	8,772 [5,957-16,712]	0.01
ΔNT-proBNP (48h-0h), % change		–59.3 [–78.5; –46.7]	–16.0 [–40.4; +3.3]	<0.001
Cumulative fluid balance at T48h, mL		–3,066 [–3,876; –2,205]	–1,198 [–2,251; –70]	0.006
ΔDyspnoea severity score at T48h*		–4 [–6; –3]	–2 [–3; 0]	0.02
Crossover or other escalation of therapy		3 (19%)	7 (44%)	0.25
Crossover		2 (13%)	3 (19%)	
Other escalation of therapy¶		1 (6%)	6 (38%)	
Length of stay in the hospital‡		29 [23-57]	15 [10-18]	0.02
MACE§	30 days	5 (31%)	10 (63%)	0.16
	90 days	6 (38%)	11 (69%)	0.16

C den Uil, NM Van Mieghem et al. EuroIntervention 2019;15:586-93

IABP On Time RCT



Pulsatile MCS in High-Risk PCI



SCAI SHOCK STAGE	PHYSICAL EXAM	BIOCHEMICAL MARKERS	HEMODYNAMICS
A	Normal JVP Lung sounds clear Strong distal pulses Normal mentation	Normal renal function Normal lactic acid	Normotensive (SBP≥100 or normal for pt.) If hemodynamics done: ▪ Cardiac index ≥2.5 ▪ CVP <10 ▪ PA Sat ≥65%
B	Elevated JVP Rales in lung fields Strong distal pulses Normal mentation	Normal lactate Minimal renal function impairment Elevated BNP	SBP <90 OR MAP <60 OR >30mmHg drop Pulse ≥100 If hemodynamics done: ▪ Cardiac Index ≥2.2 ▪ PA Sat ≥65%
C	Ashen, mottled, dusky Volume overload Extensive Rales Killip class 3 or 4 BiPap or mechanical ventilation Acute alteration in mental status	Lactate ≥2 Creatinine doubling OR >50% drop in GFR Increased LFTs Elevated BNP Urine Output <30mL/h	Drugs/device used to maintain BP above stage B values. ▪ Cardiac Index <2.2 ▪ PCWP >15 ▪ RAP/PCWP ≥0.8 ▪ PAPI <1.85 ▪ Cardiac Power Output ≤0.6
D	Any of stage C	Any of stage C AND deteriorating	Any of stage C AND Requiring multiple pressors OR addition of mechanical circulatory support devices to maintain perfusion
E	Near pulselessness Cardiac collapse Mechanical ventilation Defibrillator used	Lactate ≥5 pH ≤ 7.2	No SBP without resuscitation PEA or Refractory VT/VF Hypotension despite maximal support

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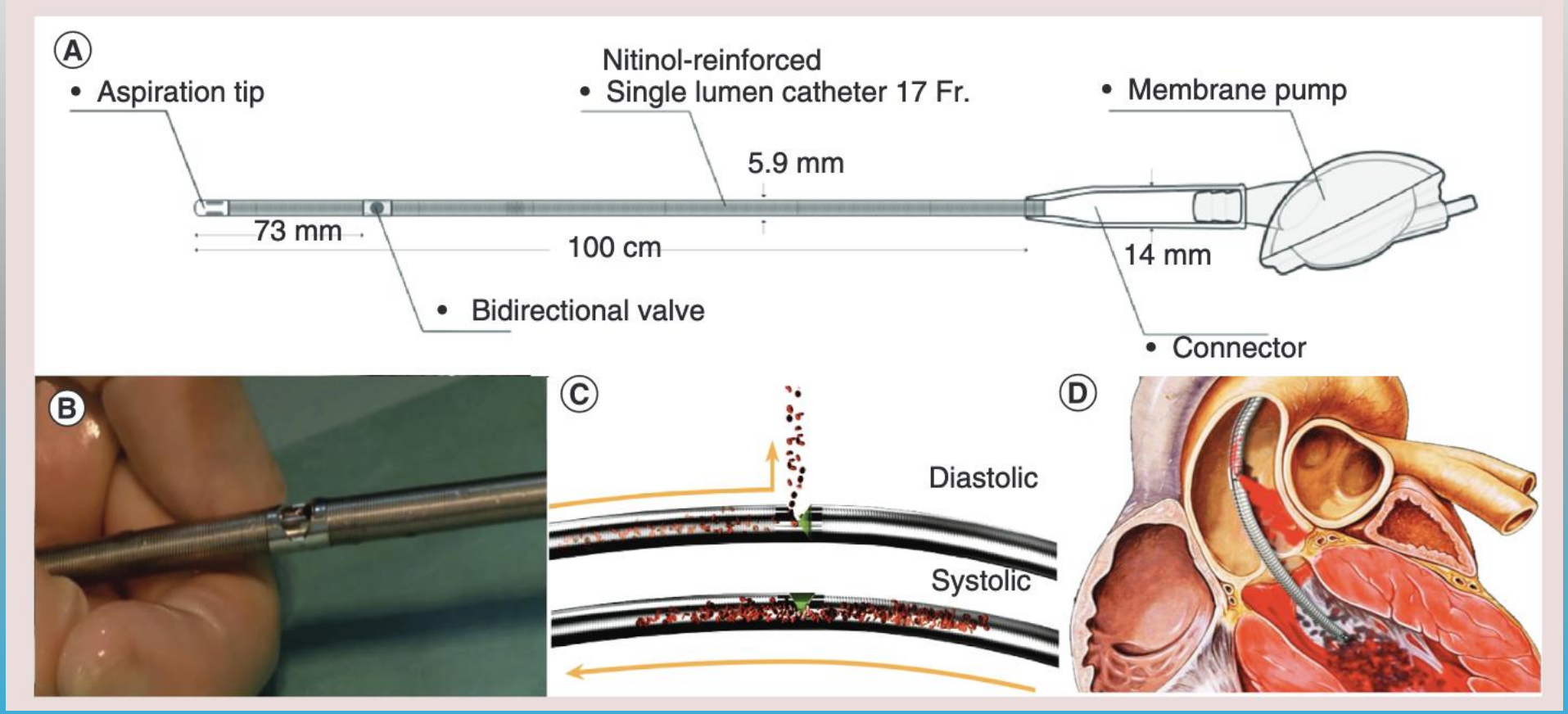
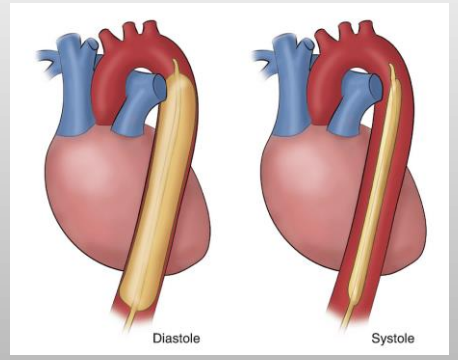
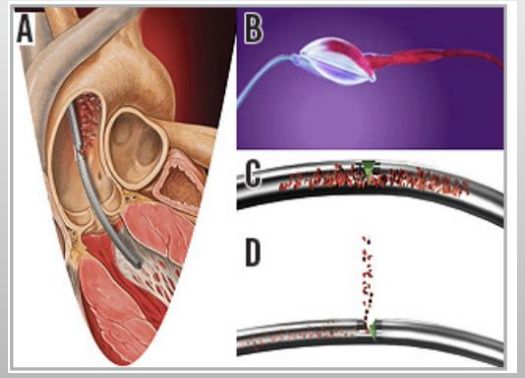
IVAC2L Principle



Pulsatile MCS





	IABP	iVAC2L
Profile	7F	17F
Pulsatile cardiac support	+ 0.5 L/min	+ 1.4 – 2.0 L/min
Stroke Volume	↔	↑
Stroke Work	↗	↑
LV end diastolic pressure	↔	↓
LV end systolic pressure	↓	↓
LV end diastolic volume	↔	↓
LV end systolic volume	↘	↓
Diastolic aortic pressure	↑	↑
Systolic aortic pressure	↓	↓
MAP	↗	↑
Cardiac output	↗	↑

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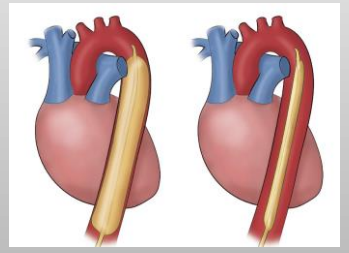
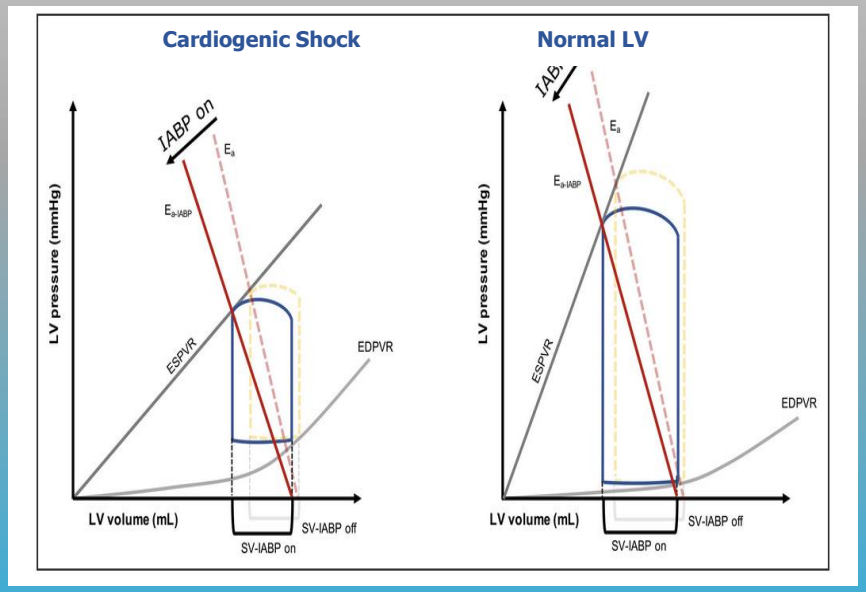
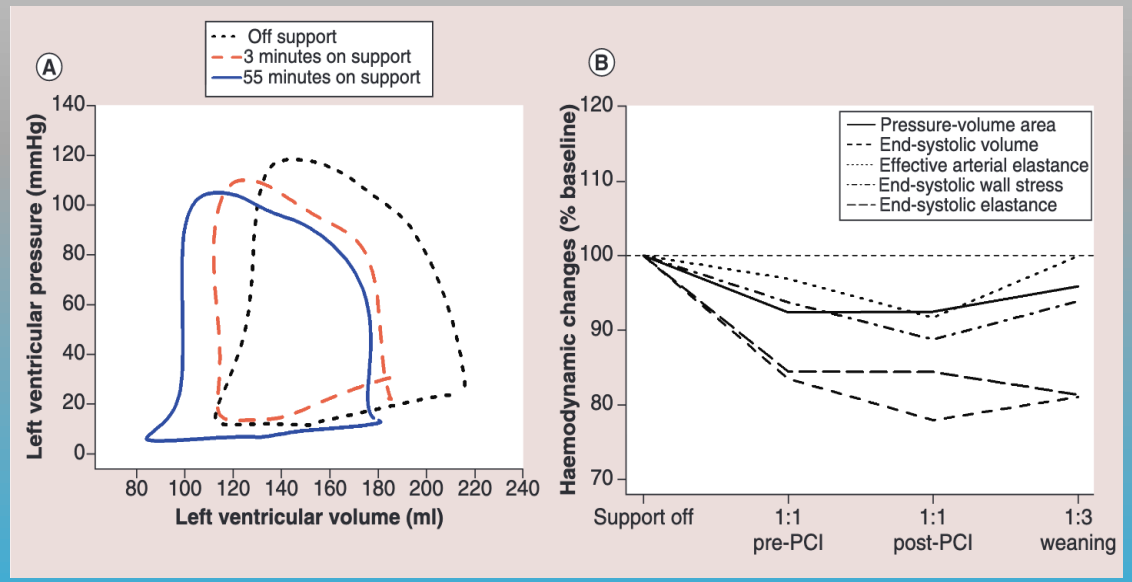
Pulsatile MCS & Cardiac Mechanics







Baldetti et al. Circulation Heart Failure 2021;14
Bastos et al. Future Cardiology 2020;16:103-12

PULSE TRIAL

- **DESIGN: Multi-centric open-label trial, with patients undergoing high-risk PCI under mechanical circulatory support.**

- **OBJECTIVE: To understand by PV loops the hemodynamics of pulsatile LV-to-aorta support in high-risk PCIs**

- **PRINCIPAL INVESTIGATORS:**

  M. Bastos & NM Van Mieghem

  Erasmus University Medical Center, Rotterdam, The Netherlands.

- **Age > 18 years**

- **Heart team consensus for high-risk PCI**

- **Exclusion**

  - **signs of cardiogenic shock**
  - **Significant aortic valve disease**
  - **Peripheral artery disease and/or size**

    < 6mm in diameter

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Bastos et al. Cardiovasc Revasc Med 2022 Online ahead of print

PULSE TRIAL

n	29
Age (years)	74 (70-81)
Gender (M) (%)	65.5 (19)
Diabetes Mellitus (%)	31 (9)
Hypertension (%)	72.4 (21)
Stable angina (%)	55.2 (16)
Unstable angina (%)	20.7 (6)
ACS (%)	37.9 (11)
Chronic kidney disease (%)	44.8 (13)
COPD (%)	24.1 (7)
Mitral regurgitation (%)	34.5 (10)
Atrial fibrillation (%)	20.7 (6)
EF < 40% (%)	37.9 (11)
SYNTAX SCORE	31 ± 8
Euroscore II	3.9 (1.9-5.2)

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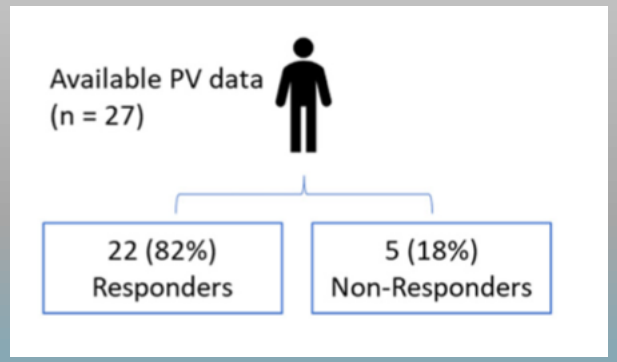
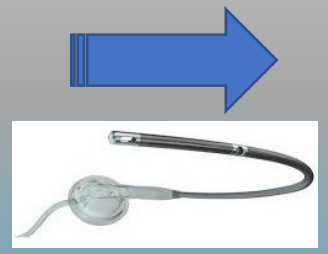
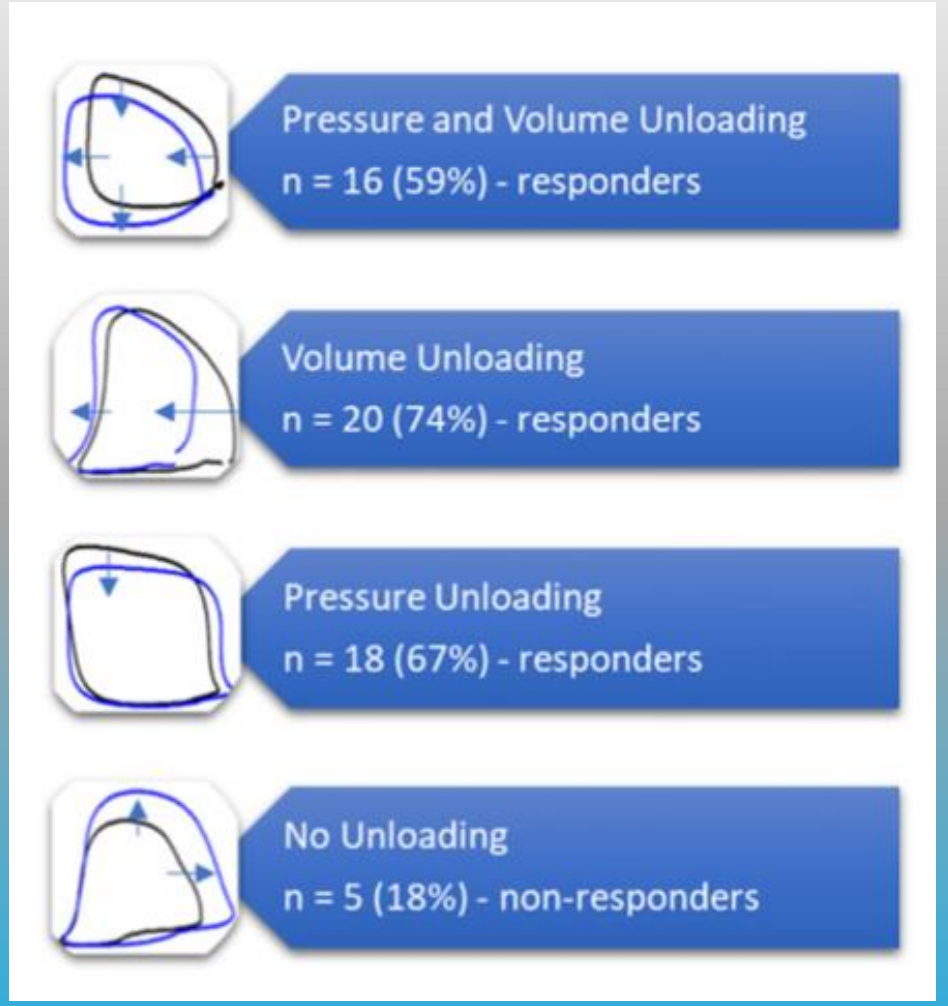
Bastos et al. Cardiovasc Revasc Med 2022 Online ahead of print
Bastos et al. Cardiovasc Revasc Med 2022;42:139–42

PULSE TRIAL – IVAC2L LV UNLOADING







PULSE II TRIAL

Pulsatile versus Axial flow MCS in high-risk PCI

Clinically stable patient; unprotected left main, multivessel disease or single remaining vessel

Heart Team consensus for HR-PCI with MCS

156 patients randomization 1:1

Main EXCLUSION criteria
- LV thrombus
- > Moderate AS/AR
- Significant PAD; CFA < 6 mm
- Stroke < 3 months
- Major bleeding < 3 months

PULSATILE iVAC2L ⟷ Axial Flow Impella CP

Primary Clinical Endpoint @ 3 months

All-cause mortality, myocardial infarction, unplanned revascularization, stroke/TIA, acute kidney injury, escalation to other MCS device, cardiopulmonary resuscitation or VT requiring cardioversion, major bleeding

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In conclusion

- MCS = valuable tool in high-risk PCI yet difficult to prove as it most often will only run in the background
- ✓ Timing and LV filling = key to demonstrate LV unloading
- IABP may still be effective in selected patients with (early) HD compromise
- In terms of pulsatile MCS
  - ✓ IABP may not be potent enough in severe hemodynamic compromise
  - ✓ PulseCath iVAC2L = more potent & may be effective in high-risk PCI
  - ✓ New RCTs are kicking off in 2024

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