Ventricular counterpulsation for percutaneous ventricular support - Pulsecath

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Saturday Sep 22nd, 2018

Room 6D, upper level, 17:37 – 17:47am

Disclosures

Erasmus MC
University Medical Center Rotterdam

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Disclosures

Institutional research support:	Boston Scientific; Acist; Abott Vascular; Medtronic; Pie Medical, PulseCath
Consultancy fees:	Pythagoras Medical; Acist; Medtronic; ReCor Medical; PulseCath

Consensus Statement

2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care (Endorsed by the

MCS may complement PCIs in elective high-risk interventions and in cardiogenic shock

Decision based on anatomical, clinical and hemodynamic criteria:

- disease extension
- complex coronary lesions including left main stem disease, heavy calcification, bifurcations and chronic total occlusions amenable to PCI.
- Age
- co-morbidities
- low contractile reserve

Rihal C.S. et al. J Card Fail. 2015;21(6):499-518.

The struggle for evidence

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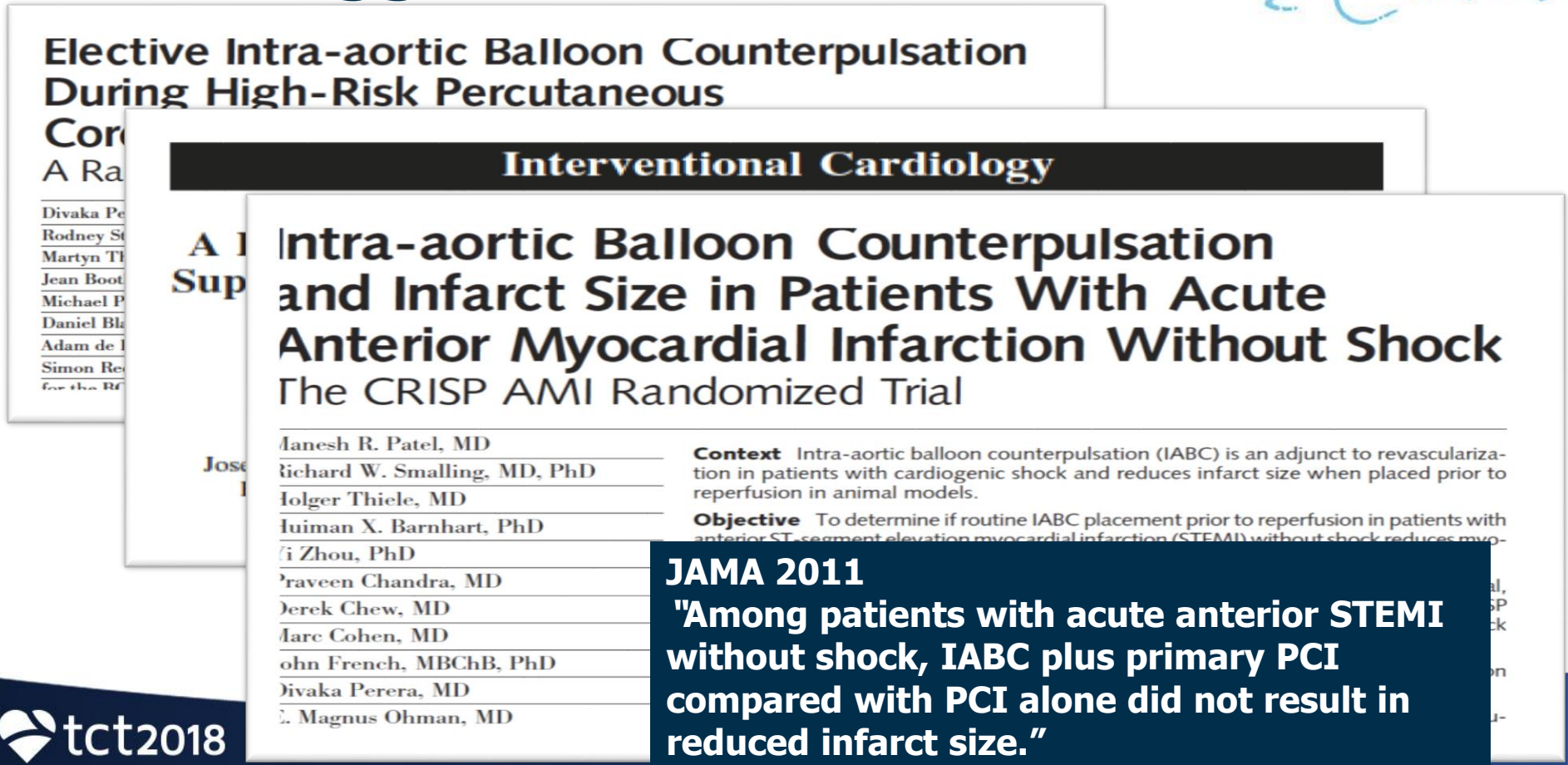


Elective Intra-aortic Balloon Counterpulsation During High-Risk Percutaneous Cor
A Ra

Interventional Cardiology

Intra-aortic Balloon Counterpulsation and Infarct Size in Patients With Acute Anterior Myocardial Infarction Without Shock
The CRISP AMI Randomized Trial

Manesh R. Patel, MD
Richard W. Smalling, MD, PhD
Holger Thiele, MD
Huiman X. Barnhart, PhD
Yi Zhou, PhD
Praveen Chandra, MD
Derek Chew, MD
Marc Cohen, MD
John French, MBChB, PhD
Divaka Perera, MD
C. Magnus Ohman, MD

Context Intra-aortic balloon counterpulsation (IABC) is an adjunct to revascularization in patients with cardiogenic shock and reduces infarct size when placed prior to reperfusion in animal models.

Objective To determine if routine IABC placement prior to reperfusion in patients with

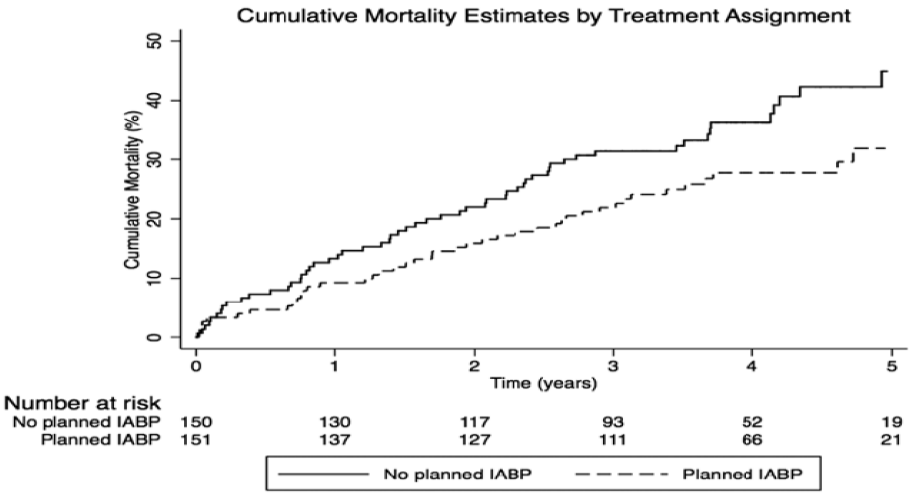
JAMA 2011
"Among patients with acute anterior STEMI without shock, IABC plus primary PCI compared with PCI alone did not result in reduced infarct size."

Longer-term outcome favor MCS

IABP and Impella 2.5

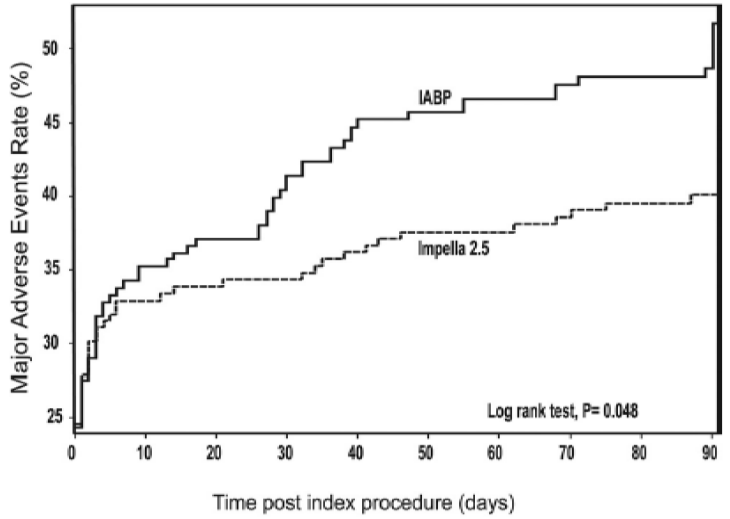
Long-term data of BCIS-I trial

Perera et al. Circulation 2013



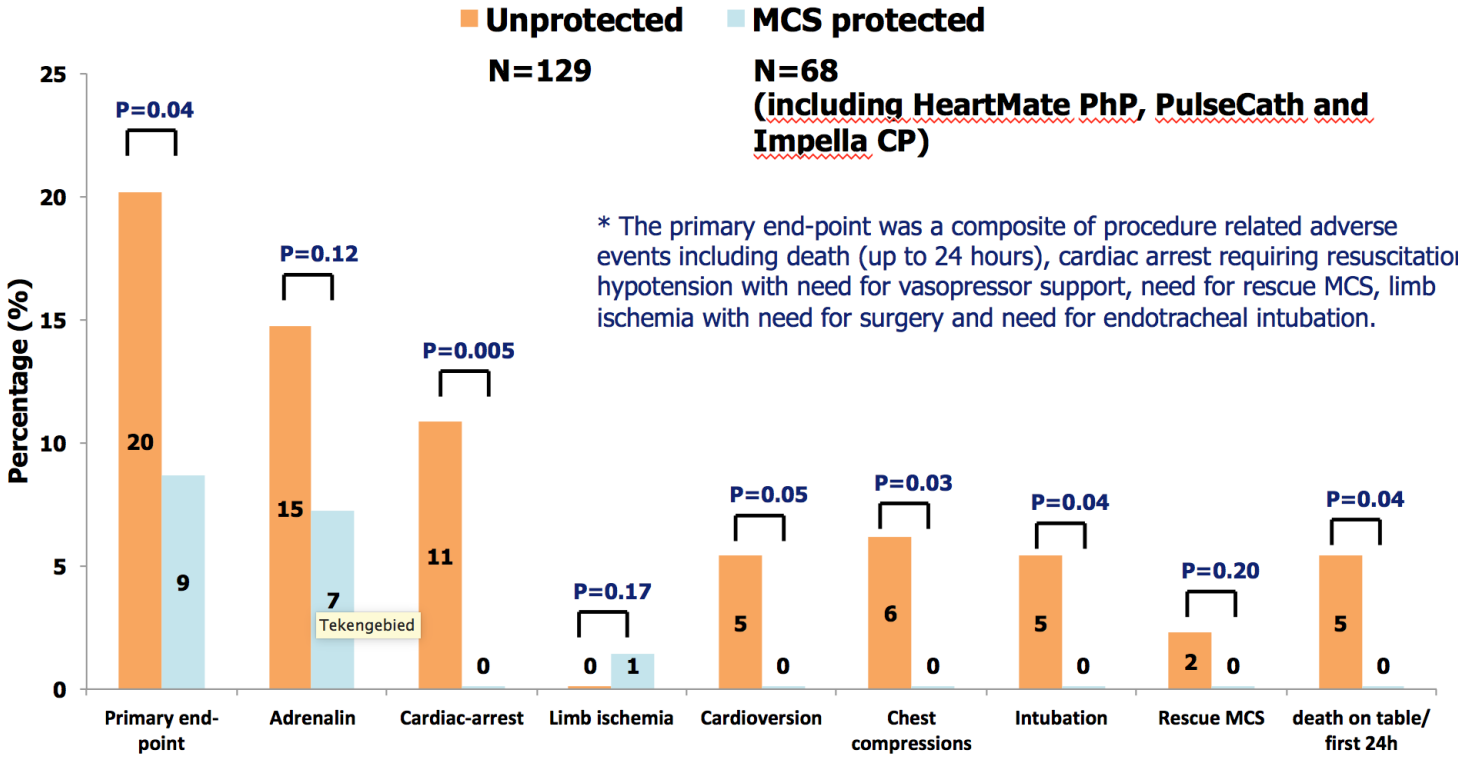
Per protocol analysis of PROTECT-II

O'Neill et al. Circulation 2012



High Risk PCI in Erasmus MC

198 elective cases



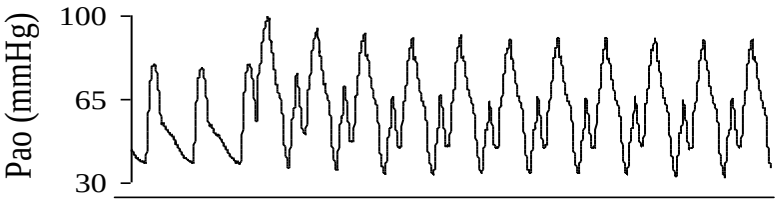
* The primary end-point was a composite of procedure related adverse events including death (up to 24 hours), cardiac arrest requiring resuscitation, hypotension with need for vasopressor support, need for rescue MCS, limb ischemia with need for surgery and need for endotracheal intubation.

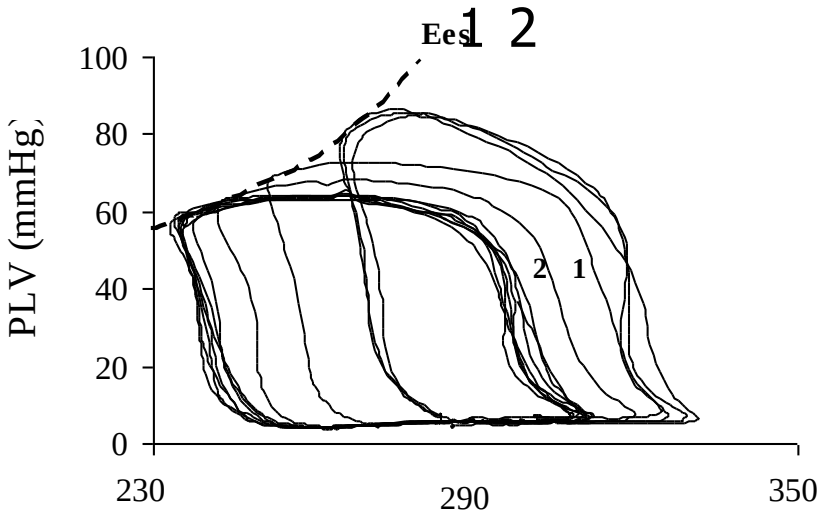
Multiple options for MCS

	IABP	iVAC2L*	Impella
Size(F)	7-8	17	13(2.5), 14 (CP), 21 (5.0)
Pump	Pneumatic	Pneumatic	Axial flow
Support	Counterpulsation	LV to aorta	LV to aorta
Max. flow (L/min)	0.3-1.0	2.0	2.5, 3.7, 5.0
Insertion site	Femoral artery	Femoral artery	Femoral artery
CE mark	Weeks	24h	10 days
FDA	Weeks	No	7 days
Requires stable rhythm	yes	no	no
Implantation time (min)	10	16	11-25
Afterload	↓	↓	↓
MAP	↓	↑	↑↑
Cardiac output	↑	↑↑	↑↑↑
EDP	↓	↓	↓↓
PCWP	↓	↔	↓↓
Preload	↔	unknown	↓↓
Coronary perfusion	↑	unknown	↑
MVO_2	↓	↓↓	↓↓
Hemolysis	0	0	+++++

IABP

SINCE 1968



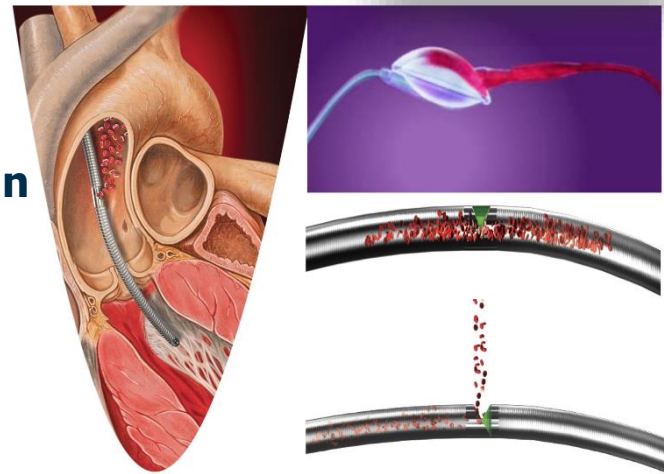


- Decreases afterload
- Decreases LVEDV, Wall Stress and stroke work
- Increases stroke volume and MAP
- Increase in mean coronary pressure to lower intra-myocardial pressure
- Reduces myocardial microvascular Resistance
- Decreases MVO2
- Improves coronary blood flow, myocardial perfusion, and oxygen supply improve
- Limited increase in CO (<0.5L)

Schreuder J. Et al. Ann Thorac Surg. 2005;79(3):872-880.

PulseCath iVAC2L

- 17F catheter across aortic valve is connected to an extracorporeal membrane pump
- iVAC2L actively aspirates blood from the left ventricle in systole and ejects this blood into the ascending aorta during diastole
- Pump is compatible with standard IABP console as a driver

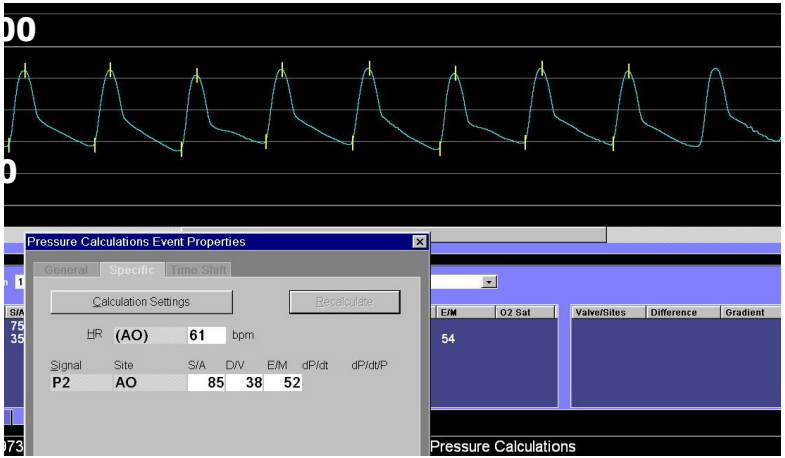


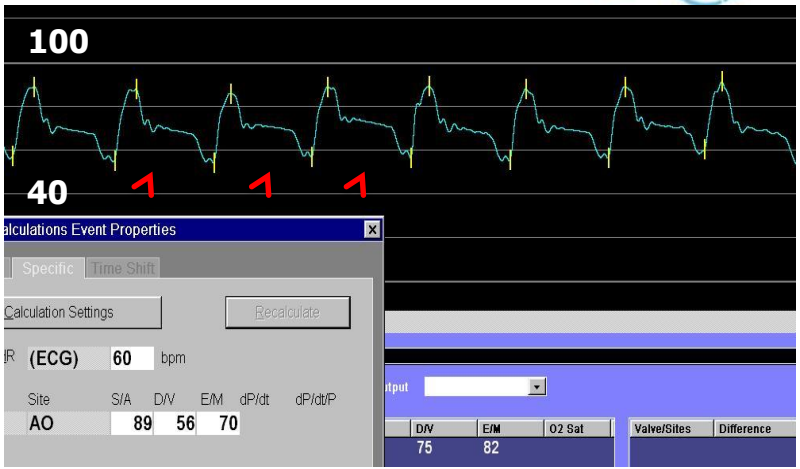
Van Mieghem N. et al. EuroIntervention 2015;11:835-9

iVAC2L Procedure overview

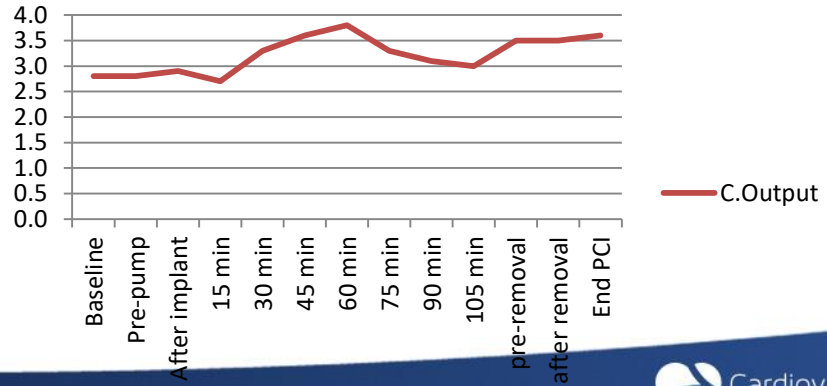
Van Mieghem N. et al. EuroIntervention 2015;11:835-9

Hemodynamics with PulseCath





- Counterpulsation
- Diastolic Pressure increases
- MAP increases
- C.O. varies*



Van Mieghem N. et al. EuroIntervention 2015;11:835-9

Rotterdam PulseCath Feasibility Study

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University Medical Center Rotterdam

- Prospective observational Study
- N = 14 patients
- High-risk PCI
- Angiographic success 100%
- 1 major vascular complication

Pulsatile iVAC 2L circulatory support in high-risk percutaneous coronary intervention

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KEYWORDS

- haemodynamics
- high-risk procedure
- intra-aortic balloon pump
- mechanical circulatory support
- percutaneous coronary intervention

Abstract

Aims: Our aim was to test the feasibility and safety of the transfemoral PulseCath iVAC 2L (PulseCath, Amsterdam, The Netherlands).

Methods and results: Circulatory support devices are helpful adjunctive tools to perform high-risk percutaneous coronary interventions (PCI). The PulseCath iVAC 2L is a novel pulsatile circulatory support system capable of generating output of up to 2 L/min. We performed a prospective clinical pilot study enrolling 14 patients who underwent high-risk PCI under protection with the iVAC 2L. Median age was 74 (56-84) years. Implantation of the iVAC 2L was successful in 13 (93%) patients. Median device flow was 1.4 (1.1-2.0) L/min. Total support time was 67 (23-149) minutes. The use of iVAC 2L support was associated with a better mean arterial pressure and cardiac output during the procedure. Angiographic success was 100%. There was one major procedural complication related to the 19 Fr access sheath. There were no major adverse events at three-month follow-up.

Conclusions: Circulatory support with the iVAC 2L device is feasible and safe in patients undergoing high-risk PCI.

Patient selection

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Inclusion

- Indicated for high-risk PCI and/or MCS support
- Expected MCS support up to 24 hr
- Patient is older than 18 years
- Signed Informed Consent

Exclusion

- Significant ascending aorta disease
- Significant degenerative AV disease or AoV prosthesis
- LV thrombus
- Severe peripheral arterial disease
- Bleeding disorders
- Recent stroke (< 6 months) and/or residual mRS > 2

Den Uil et al. EuroIntervention 2017;12:1689-96

Baseline characteristics

AGE, Y	74 [56-84]
GENDER, M	64%
MYOCARDIAL INFARCTION <30 DAYS	57%
CONGESTIVE HEART FAILURE	79%
CURRENT NYHA CLASS III/IV	64%
DIABETES MELLITUS	21%
RENAL INSUFFICIENCY	36%
PERIPHERAL ARTERIAL DISEASE	21%
IMPLANTABLE CARDIAC DEFIBRILLATOR	7%
PREVIOUS CABG	7%
LVEF, %	30 [16-35]
STS MORTALITY SCORE, %	5 [1-11]
SYNTAX SCORE	28.3 [16.5-58.5]
NOT SURGICAL CANDIDATE	57%

Den Uil et al. EuroIntervention 2017;12:1689-96

Procedural characteristics

NO. OF LESIONS ATTEMPTED	3 [2-5]
LEFT MAIN STEM PCI	69%
USE OF HEPARIN, %	100%
TOTAL CONTRAST MEDIA, ML	200 [60-300]
ROTATIONAL ATHERECTOMY, %	8%
TOTAL SUPPORT TIME, MIN	67 [23-149]

Den Uil et al. EuroIntervention 2017;12:1689-96

Biochemical characteristics

	Reference	Baseline	2 hours	24 hours
HAEMOGLOBIN (MMOL/L)	M: 8.6-10.5 mmol/L F: 7.5-9.5 mmol/L	7.2 [5.3-8.9]	6.5 [5.5-8.3]	6.3 [5.5-8.4]
FREE HAEMOGLOBIN (MMOL/L)	0-6 µmol/L	4 [1-10]	6 [1-10]	4 [3-8]
HAPTOGLOBIN (G/L)	>0.27 g/L	2.0 [1.2-3.3]	1.5 [0.8-2.9]	2.3 [1.6-2.8]
TOTAL BILIRUBIN (MMOL/L)	<17 µmol/L	7 [3-19]	8 [4-16]	7 [4-20]
LDH (U/L)	<247 U/L	189 [122-573]	206 [122-686]	231 [129-442]
CREATININE (MMOL/L)	65-115 µmol/L	95 [57-227]	97 [54-205]	99 [54-196]

No hemolysis

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iVAC2L Hemodynamic effects

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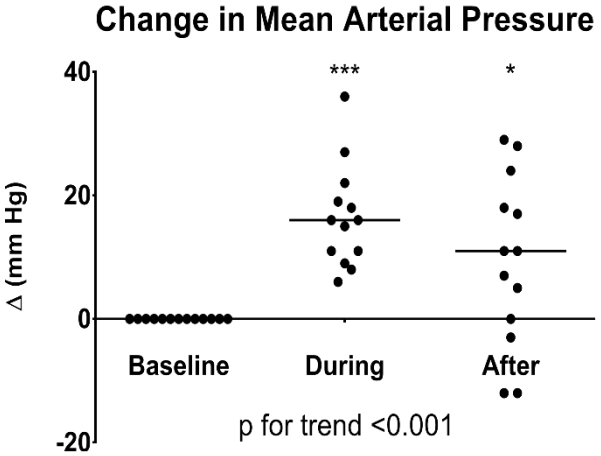
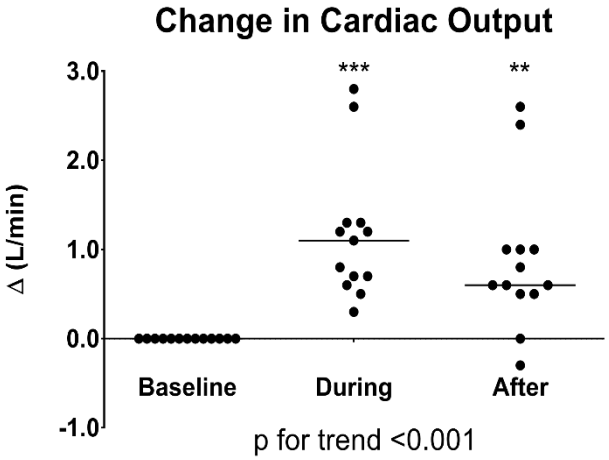
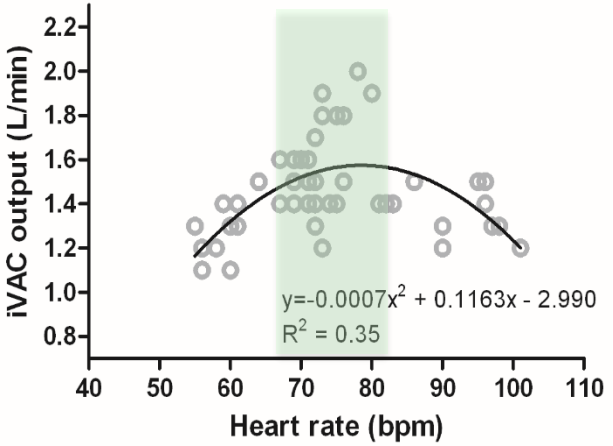




Max iVAC2L support @ 78 bpm



Den Uil et al. EuroIntervention 2017;12:1689-96

Pulsatile vs. Continuous flow

Pulsatile Left Ventricular Assist Devices: What Is the Role in the Modern Era?

Pavan Atluri, MD, and Michael A. Acker, MD

With the widespread use of continuous-flow ventricular assist devices (VADs), the role of pulsatile VADs remain in question. In acute cardiogenic shock, pulsatile VADs maximize perfusion pressure, restore end organ perfusion, and maximally unload the pulmonary circulation and right heart. In addition, pulsatile left VADs allow for easy conversion to biventricular support using one platform, in the case of acute right ventricular failure. Pulsatile VADs still have a major role in the treatment of acute cardiogenic shock.

Semin Thoracic Surg 22:106-108

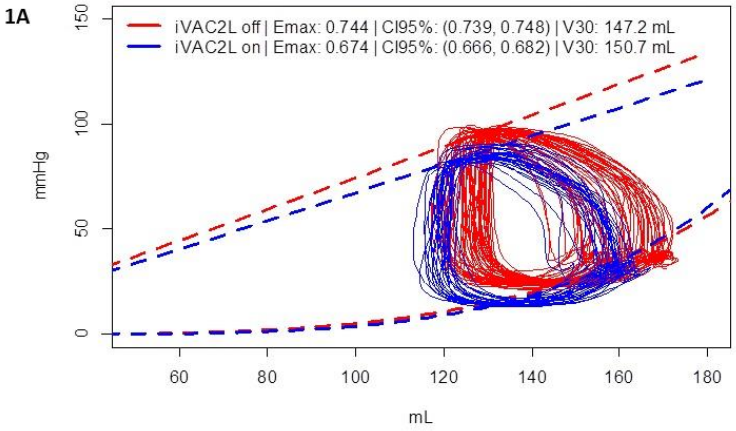
Keywords: cardiogenic shock, LVADs, BVADS

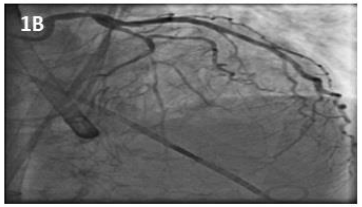
Difference in long-term support v.s. salvage intervention (shock)

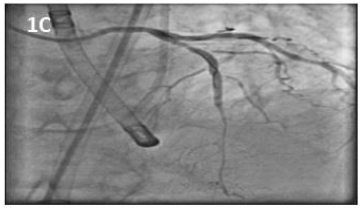
Pulsatile LV support results in superior LV unloading, higher systemic perfusion pressure, theoretically augmented coronary perfusion and more unloading of the right heart and pulmonary circulatory system (SynCardia Total Artificial Heart experience)

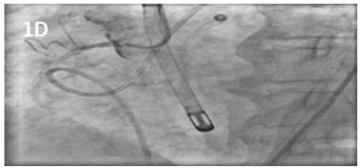
Atluri P et al. Semin Thorac Cardiovasc Surg. 2010;22:106-8.

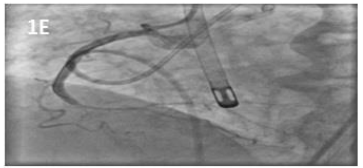
iVAC2L as assessed by PV Loop

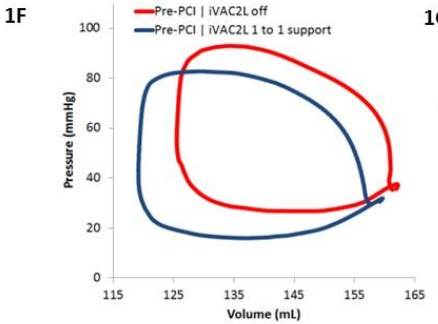


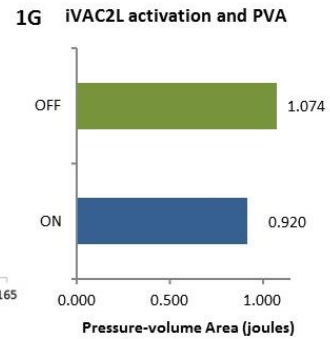


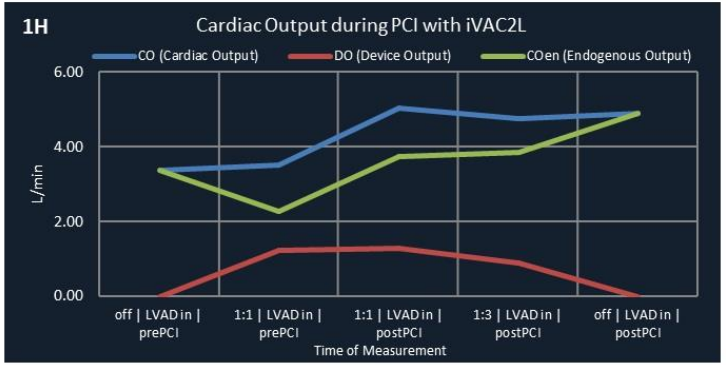






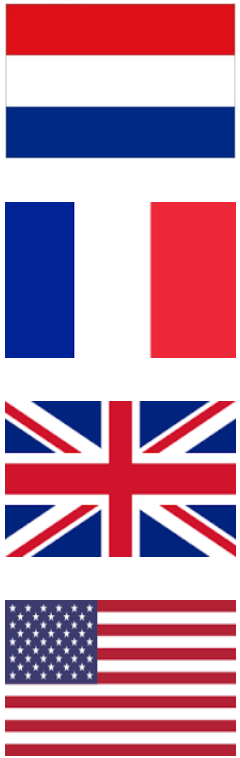






Pulse trial

- **Prospective observational study**
- **4 Centers**
- **N = 40 patients**
- **High-risk PCI**
- **iVAC2L (or Impella CP) & PV Loops with conductance catheter**
- **Assess hemodynamic unloading of LV**



Conclusions

- **Percutaneous MCS unloads the left ventricle**
- **MCS is feasible in high-risk PCI and might improve (long-term) patient outcomes**
- **iVAC2L is a promising new technology**
- **From HD perspective more performant than IABP**
- **PULSE TRIAL will further address LV unloading mechanism**