



**I would ask for Impella, I trust it**

**Dott. Matteo Attisani**

**Cardiac Surgery**

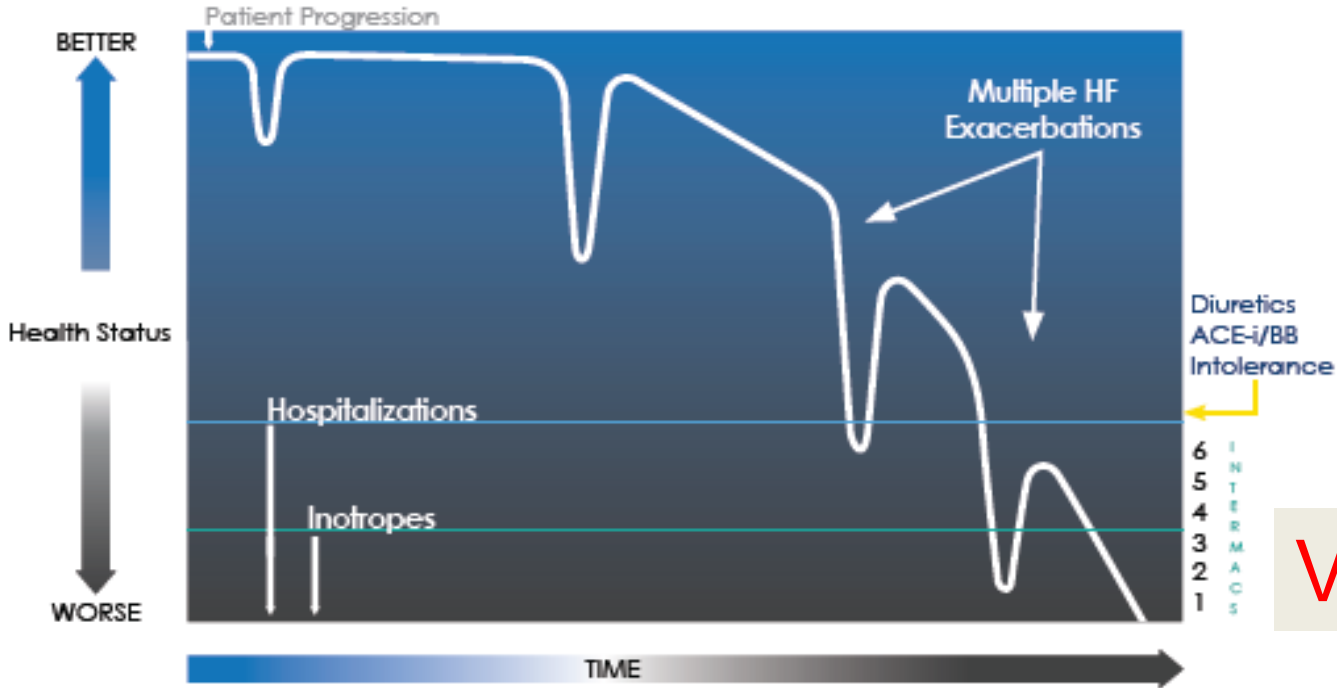
**Department of Cardiovascular and Thoracic surgery**

**Heart and Lung Transplantation Programme**

**University of Turin – Italy**

**Prof Mauro Rinaldi**

# PROGRESSIVE NATURE OF HEART FAILURE



- Overall, 50% of heart failure patients do not survive beyond four years.<sup>1</sup>
- 40% of patients hospitalized with HF do not survive or are readmitted within one year.<sup>1</sup>

VAD program

<sup>1</sup> Dickstein K, et al. *Eur Heart J.* 2008;20:2388-2442.

## Cardiogenic Shock: clinical definition

### Unresponsive Hypotension

Prolonged MAP < 60 mmhg for > 30 min (or decrease in SBP more than 40 mmhg)

CI < 1,8 l/min/m<sup>2</sup> or < 2,2 l/min/m<sup>2</sup> with **inotropic support**

### High filling pressures

CVP > 14 mmhg

Wedge pressure > 16 mmhg

### Inadequate tissue perfusion

SVO<sub>2</sub> < 55; Lactate continuously increase (or > 3)

Alteration in consciousness

Urine output < 30 cc/h

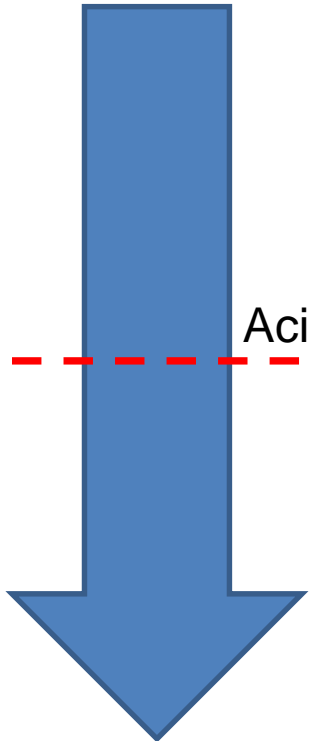
## SCAI clinical expert consensus statement on the classification of cardiogenic shock

This document was endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), the Society of Critical Care Medicine (SCCM), and the Society of Thoracic Surgeons (STS) in April 2019

		Volume Status	
		Dry	Wet
Peripheral Perfusion	Warm	<b>Vasodilatory shock</b> (not CS) Increased cardiac index, low SVRI, low/ normal PCWP	<b>Mixed CS</b> Low cardiac index, low / normal SVRI, Elevated PCWP
	Cold	<b>Euvolemic CS</b> Low Cardiac index, high SVRI, low / normal PCWP	<b>Classic CS</b> Low cardiac index, High SVRI, Elevated PCWP

**FIGURE 2** Different hemodynamic presentations of CS [Color figure can be viewed at [wileyonlinelibrary.com](http://wileyonlinelibrary.com)]

# Low cardiac Output



Acidosis

Cardiac Arrest

**TABLE 1** Descriptors of shock stages: physical exam, biochemical markers and hemodynamics

Stage	Description	Physical exam/bedside findings	Biochemical markers	Hemodynamics
<b>A</b> At risk	A patient who is not currently experiencing signs or symptoms of CS, but is at risk for its development. These patients may include those with large acute myocardial infarction or prior infarction acute and/or acute on chronic heart failure symptoms.	Normal JVP Lung sounds clear Warm and well perfused • Strong distal pulses • Normal mentation	Normal labs • 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>B</b> Beginning CS	A patient who has clinical evidence of relative hypotension or tachycardia without hypoperfusion.	Elevated JVP Rales in lung fields Warm and well perfused • Strong distal pulses • Normal mentation	Normal lactate Minimal renal function impairment Elevated BNP	SBP < 90 OR MAP < 60 OR > 30 mmHg drop from baseline Pulse ≥ 100 If hemodynamics done • cardiac index ≥ 2.2 • PA sat ≥ 65%
<b>C</b> Classic CS	A patient that manifests with hypoperfusion that requires intervention (inotrope, pressor or mechanical support, including ECMO) beyond volume resuscitation to restore perfusion. These patients typically present with relative hypotension.	<b>May Include Any of:</b> Looks unwell Panicked Ashen, mottled, dusky Volume overload Extensive rales Killip class 3 or 4 BiPap or mechanical ventilation Cold, clammy Acute alteration in mental status Urine output < 30 mL/h	<b>May Include Any of:</b> Lactate ≥ 2 Creatinine doubling OR > 50% drop in GFR Increased LFTs Elevated BNP	<b>May Include Any of:</b> SBP < 90 OR MAP < 60 OR > 30 mmHg drop from baseline AND drugs/device used to maintain BP above these targets Hemodynamics • cardiac index < 2.2 • PCWP > 15 • RAP/PCWP ≥ 0.8 • PAPI < 1.85 • cardiac power output ≤ 0.6
<b>D</b> Deteriorating/ doom	A patient that is similar to category C but are getting worse. They have failure to respond to initial interventions.	<b>Any of stage C</b>	<b>Any of Stage C AND:</b> Deteriorating	<b>Any of Stage C AND:</b> Requiring multiple pressors OR addition of mechanical circulatory support devices to maintain perfusion
<b>E</b> Extremis	A patient that is experiencing cardiac arrest with ongoing CPR and/or ECMO, being supported by multiple interventions.	Near Pulselessness Cardiac collapse Mechanical ventilation Defibrillator or used	<b>"Trying to die"</b> CPR (A-modifier) pH ≤ 7.2 Lactate ≥ 5	No SBP without resuscitation PEA or refractory VT/VF Hypotension despite maximal support

MCS

Acidosis

Conventional therapy  
IABP Inotropes

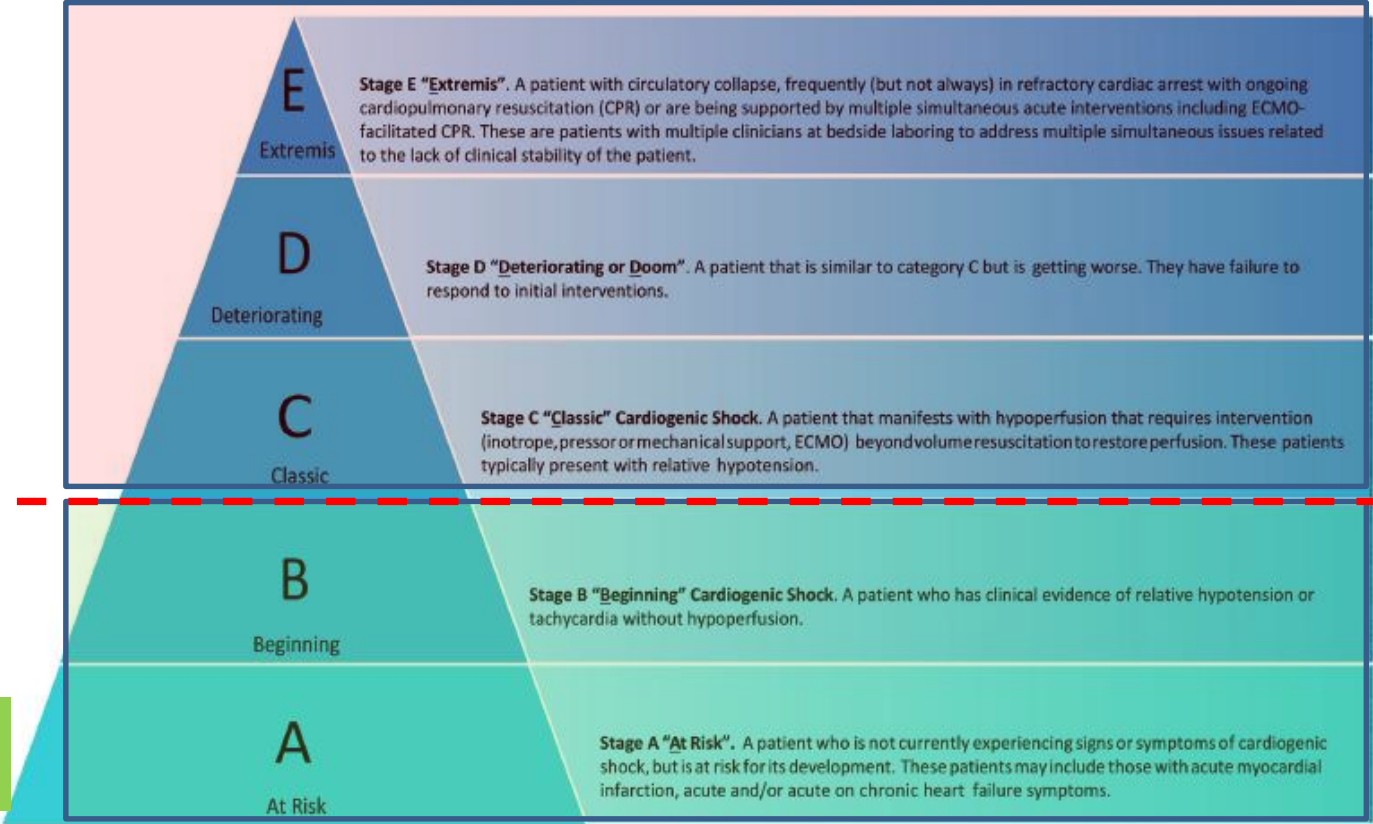


FIGURE 1 The pyramid of CS classification [Color figure can be viewed at wileyonlinelibrary.com]

## *AMI and Cardiogenic Shock*

**Early Assistance or Early Reperfusion?**

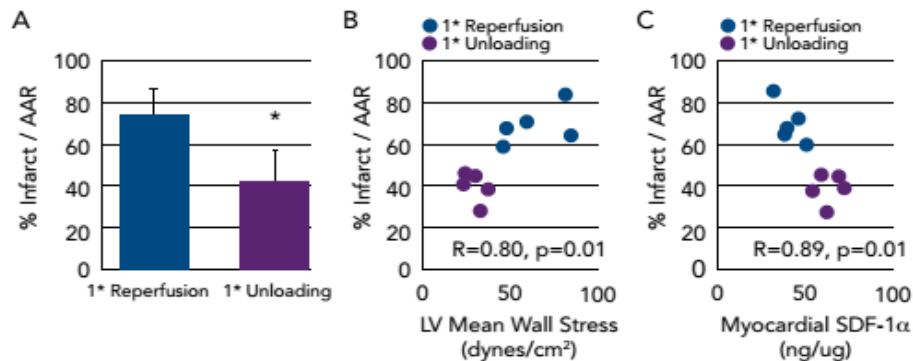
# Primary Left Ventricular Unloading

JACC

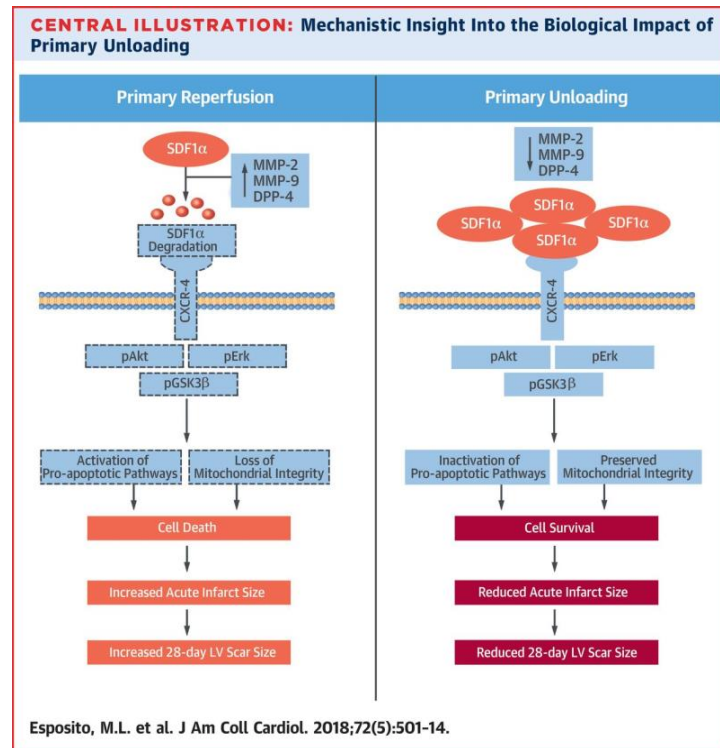
## Left Ventricular Unloading Before Reperfusion Promotes Functional Recovery After Acute Myocardial Infarction

Michele L. Esposito, Yali Zhang, Xiaoying Qiao et al.

Figure 2: Effect of Mechanical Circulatory Support Before Reperfusion in Acute Myocardial Infarction



Source: Kapur et al, 2015.<sup>9</sup> AAR = assessment of the area at risk; LV = left ventricular; SDF-1 = stromal cell-derived factor 1





# Unloading of the Left Ventricle

## **Immediate Mechanical Effects (minutes...)**

*Less myocardial oxygen demand*

*More myocardial Oxygen supply (subendocardial reperfusion)*

## **Long-term Biochemical Effects (hours-days...)**

*Inactivation of pro-apoptotic pathways*

*Preserve mitochondrial integrity*

*Reduce AMI area and size*

## *AMI and Cardiogenic Shock*

**Early Assistance or Early Reperfusion?**

**Early Assistance and Reperfusion!**

# Currently available percutaneous MCS



	iVAC 2L <sup>®</sup>	TandemHeart <sup>™</sup>	Impella <sup>®</sup> 5.0	Impella <sup>®</sup> 2.5	Impella <sup>®</sup> CP	ECLS (multiple systems)
Catheter size (F)	11 (expandable)	–	9	9	9	–
Cannula size (F)	17	21 venous 12–19 arterial	21	12	–	17–21 venous 16–19 arterial
Flow (L/min)	Max 2.8	Max. 4.0	Max. 5.0	Max. 2.5	3.7–4.0	Max. 7.0
Pump speed (rpm)	Pulsatile, 40 mL/beat	Max. 7500	Max. 33 000	Max. 51 000	Max. 51 000	Max. 5000
Insertion/placement	Percutaneous (femoral artery)	Percutaneous (femoral artery + vein for left atrium)	Peripheral surgical (femoral artery)	Percutaneous (femoral artery)	Percutaneous (femoral artery)	Percutaneous (femoral artery + vein)
LV unloading	+	++	++	+	+	–
Anticoagulation	+	+	+	+	+	+
Recommended duration of use	–21 days	–14 days	10 days	10 days	10 days	–7 days
CE-certification	+	+	+	+	+	+
FDA	–	+	+	+	+	+
Relative costs	++	+++++	+++++	+++	+++++	+(+)

Reproduced from Ref. [57] with permission



Impella®  
World's Smallest Heart Pump

## VA ECMO

Low cost

Biventricular support

Oxygenator

Feasible implantation on CPR

No Cath Lab

LV overload

Subendocardial malperfusion

Risk of Bleeding

Limb perfusion

Cardiac surgeon?

## Impella

Less invasive

LV unloading

Subendocardial reperfusion

Small catheters

Easy to implant

Harlequin syndrome

Limb malperfusion

Partial support ?

Hemolysis

Cath Lab

High costs

## Advantages

## Disadvantages

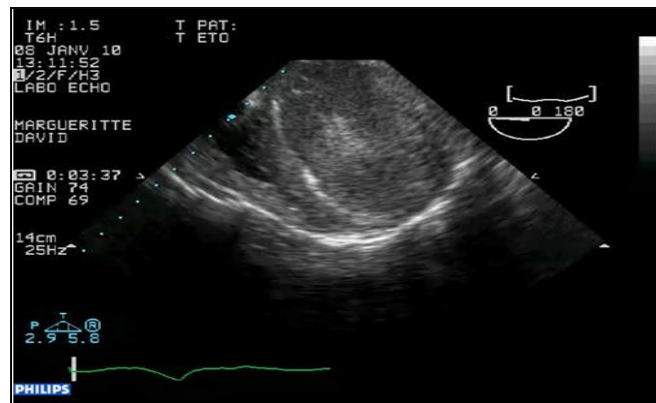
# Rationale for UNLOAD the LV on VA ECMO

LV overload

Pulmonary edema

Harlequin syndrome

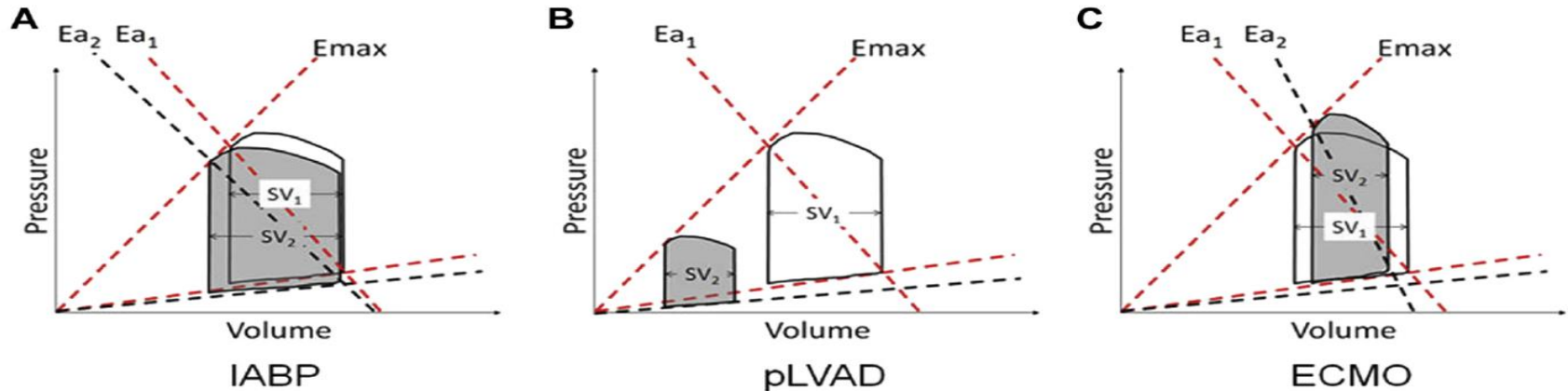
MOF



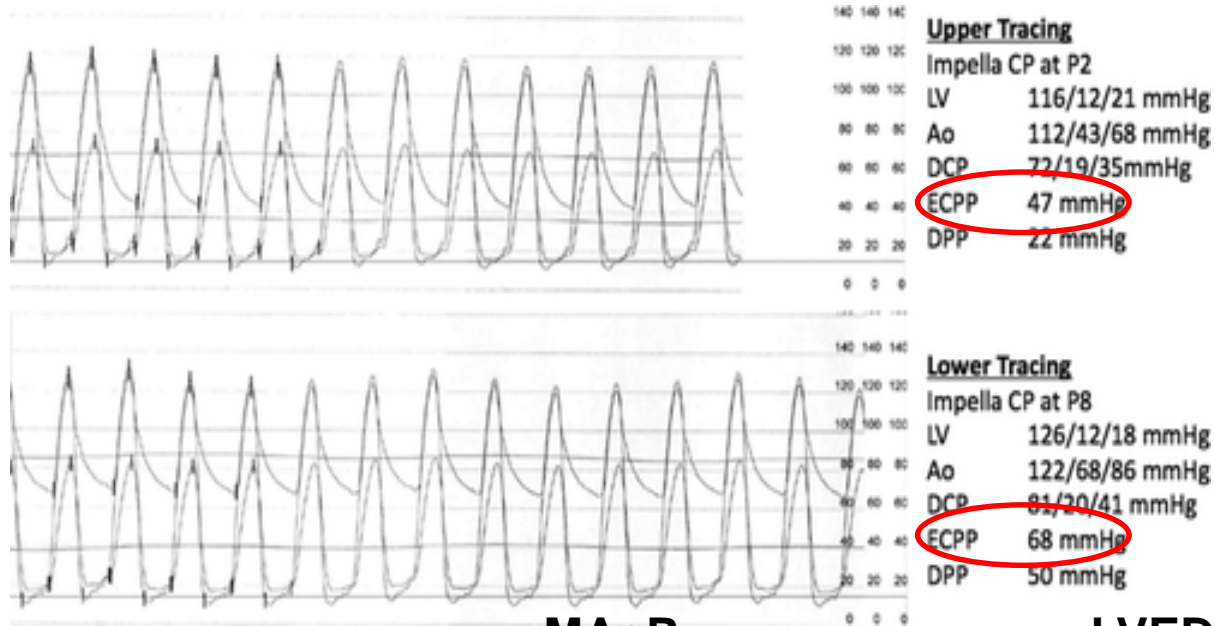
**2015 SCAI/ACC/HFSA/STS Clinical Expert Consensus Statement on the Use of Percutaneous Mechanical Circulatory Support Devices in Cardiovascular Care (Endorsed by the American Heart Association, the Cardiological Society of India, and Sociedad Latino Americana de Cardiologia Intervencion; Affirmation of Value by the Canadian Association of Interventional Cardiology—Association Canadienne de Cardiologie d'intervention)\***

Journal of Cardiac Failure Vol. 21 No. 6 2015

**Left ventricular overload on ECMO**



# Unloading and Coronary perfusion



**ECPP**  
(Effective Coronary Perfusion Pressure)

**MAoP**  
(Mean  
Ao Pressure)

—

**LVEDP**  
(LV end-diastolic  
pressure)

Mohammad Alqarqaz. **Circulation:**

**Cardiovascular Interventions. Effects of Impella on Coronary Perfusion in Patients With Critical Coronary Artery Stenosis**



## Turin Experience 2011- 2019

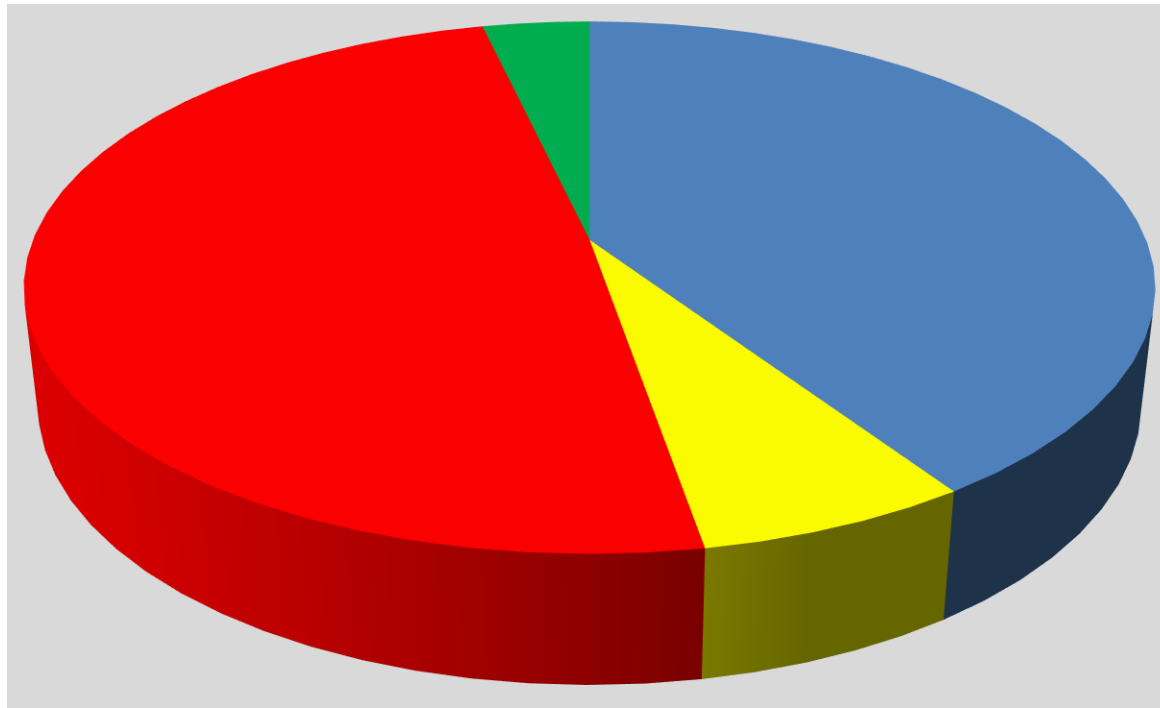
**VA ECMO number of implants = 171**

Intermacs 1 level

Mean age of 50,4 years

20% previous cardiac arrest

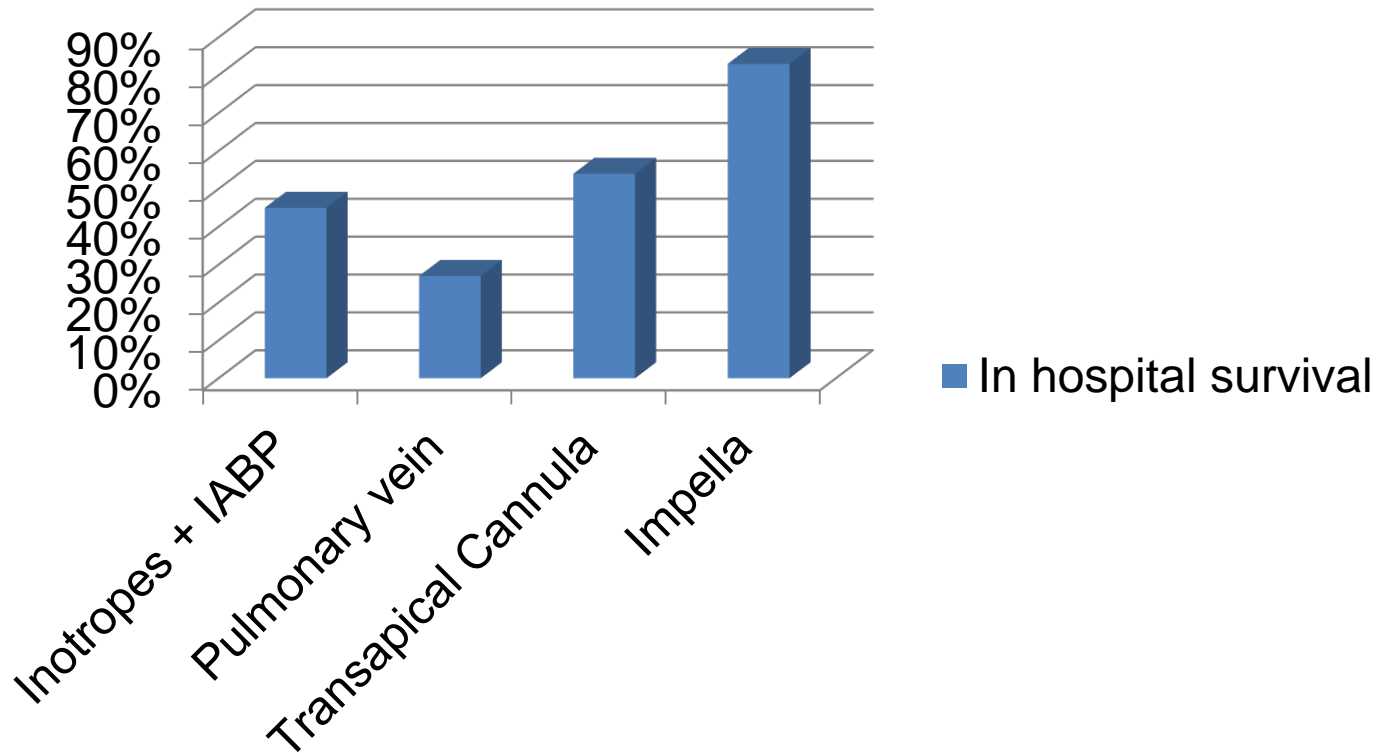
### Unloading Strategy



■ Inotropes+ IABP	67
■ Pulmonary vein	11
■ Transapical Cannula	81
■ Impella	6

# Turin Experience 2011- 2019


## In hospital survival



**Turin experience 2011-2019**  
**VA ECMO+ LV vent N= 81 patients**

**Mean time of recovery**

**In hospital mortality rate**

Fulminant myocarditis	3,9 days		0/12	0%
Acute Myocardial Infarction	5,7 days		13/32	40%
Hydiopathic CMP	6,5 days		7/14	50%
Post HTX	8,4 days		4/6	66%
Postcardiotomy	10,1 days		13/17	76%

## **Veno Arterial (VA) ECMO in Fulminant Myocarditis:**

**which is the best strategy to unload the Left Ventricle?**

**M. Attisani MD, D. Brenna MD, G. Maraschioni MD, M. Rinaldi MD PhD**  
Division of Cardiac Surgery - Città della Salute e della Scienza - Molinette,  
Turin, Italy

# CLINICAL CASE

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44 years old patient presenting with life - threatening cardiogenic shock and strong suspect of fulminant myocarditis:

- EF 10%
- Elevated cardiac enzymes (Tn-I 2856 ng/L)
- Very thick oedematous cardiac walls (IVS 20 mm)
- Undamage coronary arteries

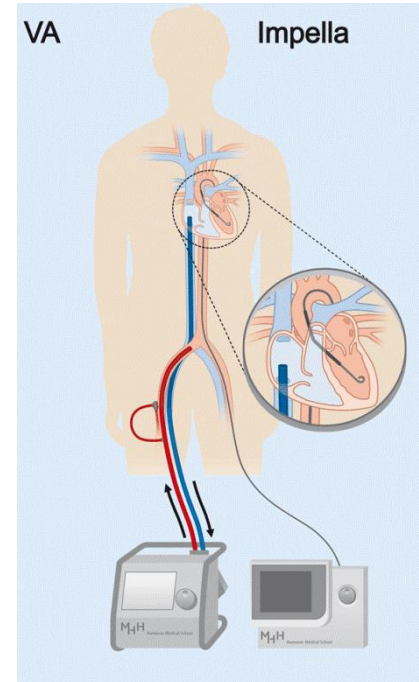
In these cases **LV venting by transapical cannulation (TLVV)** can be less effective, burdened by increased risks of **hemolysis, bleeding and suction events**.  
We decide to position **Impella® CP**.

# CLINICAL CASE

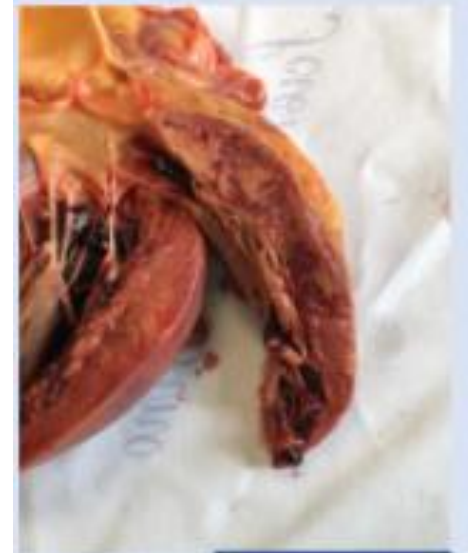
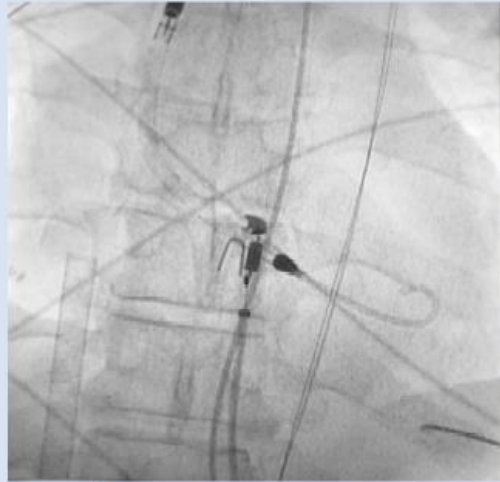
We combine extracorporeal life support (ECLS) with veno-arterial extracorporeal membrane oxygenation (VA-ECMO) with endovascular unloading systems, like Impella®



ECMO+ Impella  
**“ECPELLA Approach”**



# ECPELLA in Fulminant Myocarditis



# RESULTS

## Weaning from ECMO in 5 days

## Weaning from Impella 10 days

- Complete recovery of right ventricle function
- Complete recovery of the lung
- LV EF 35%
- No clinic or laboratory signs of low cardiac output

Death for sepsis 1 month after hospitalization

Post-mortem tissue examination was compatible with **healed Giant-Cell myocarditis**.





# Impella RVAD Indications

**Post Heart Transplant PGD**

**Post LVAD**

Post cardiectomy

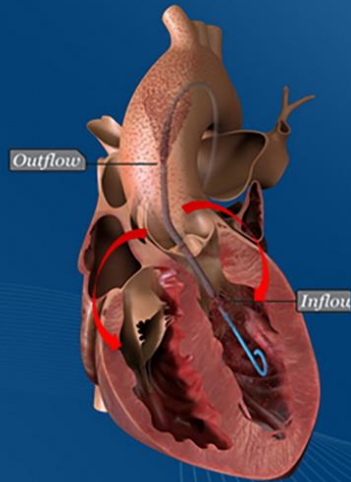
RV Acute Myocardial Infarction

Pulmonary Thromboembolism

# Bipella (BiVAD) Concept

## HEMODYNAMIC STABILIZATION WITH IMPELLA<sup>®</sup>

Unloads Left Ventricle  
& Coronary Perfusion



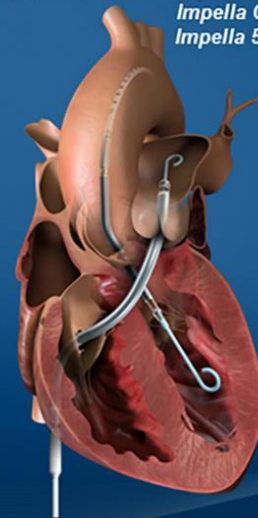
End Organ  
Perfusion



Right Side  
Support

Right Side  
Impella RP<sup>®</sup>

Left Side  
Impella 2.5<sup>®</sup>  
Impella CP<sup>®</sup>  
Impella 5.0<sup>®</sup>



Seyfarth et al., JACC, 2008  
Remmelink M et al., Cath Card Interv. 2007

IMP-581 v5

Lam K et al., Clin Res Cardiol, 2009  
Casassus et al., JOIC, 2015

Anderson MB et al., J Ht Lg Transplant. 2015

**Take home message**

**IABP or Impella or VA ECMO ?**

# MCS alghorytm

LM disease/CTO+  
EF < 25 %

**Elective**

Heart Team

LV  
LV-RV

*Prophylactic*  
Impella + PTCA  
VAECMO+ IABP+ PTCA

CABG (*after downloading*)

# Cardiogenic Shock

**Emergency**

**A- At Risk**

Wait and Watch or Inotropes

**B- Beginning**

IABP or Impella

**C-Classic**

LV  
LV-RV  
RV

Impella

+IABP

VA ECMO

+Ecpella

**D-Deterioration**

*Bipella?*

+TLV

Rimpella-RVAD

+IABP

**E-Extreme**

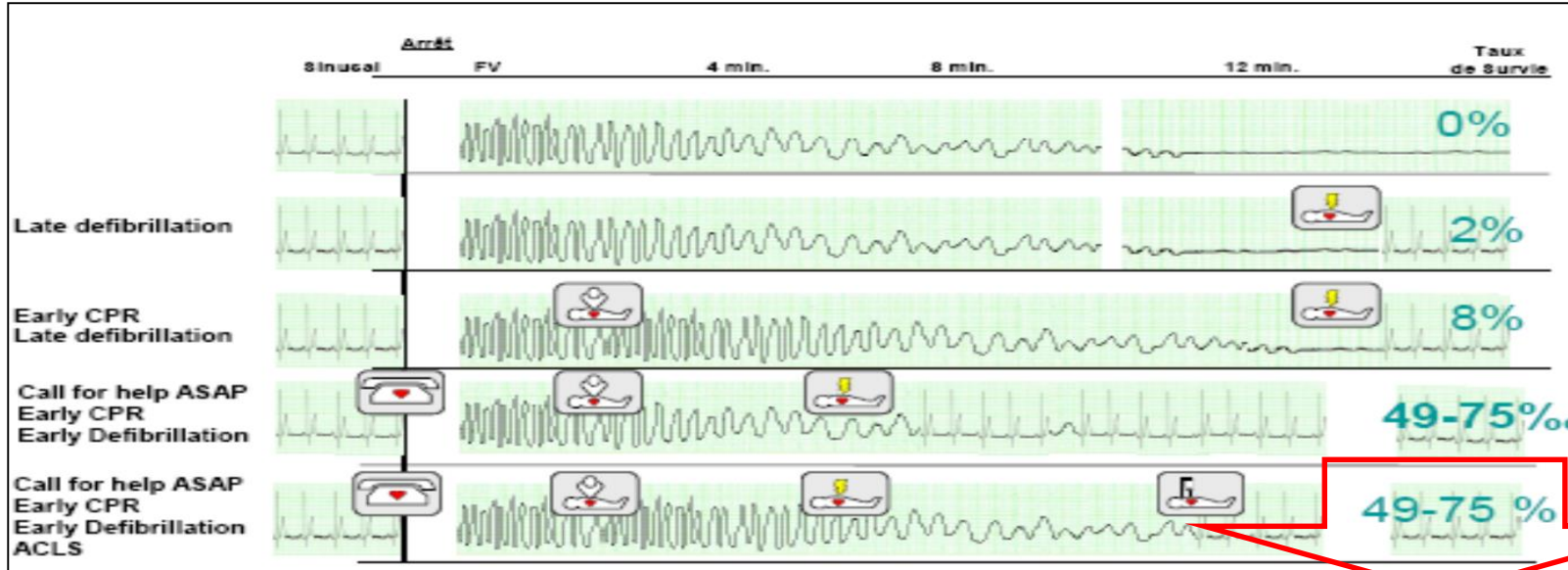
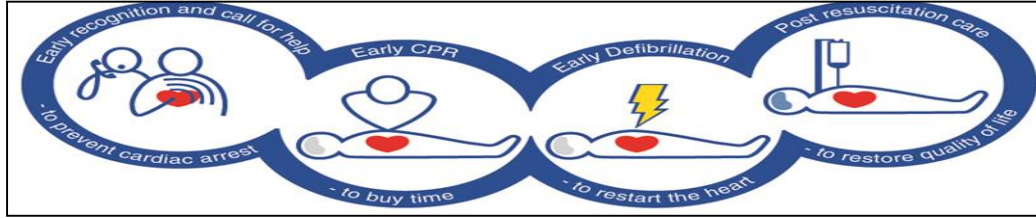
*CPR*

VA ECMO

+Ecpella

+TLV

# Survival Chain



L.Becker, A.H.A. datas

**V-A ECMO**