



# HOT TOPICS IN CARDIOLOGIA 2023

13 e 14 Novembre 2023

Villa Doria D'Angri - Via F. Petrarca 80,  
Napoli

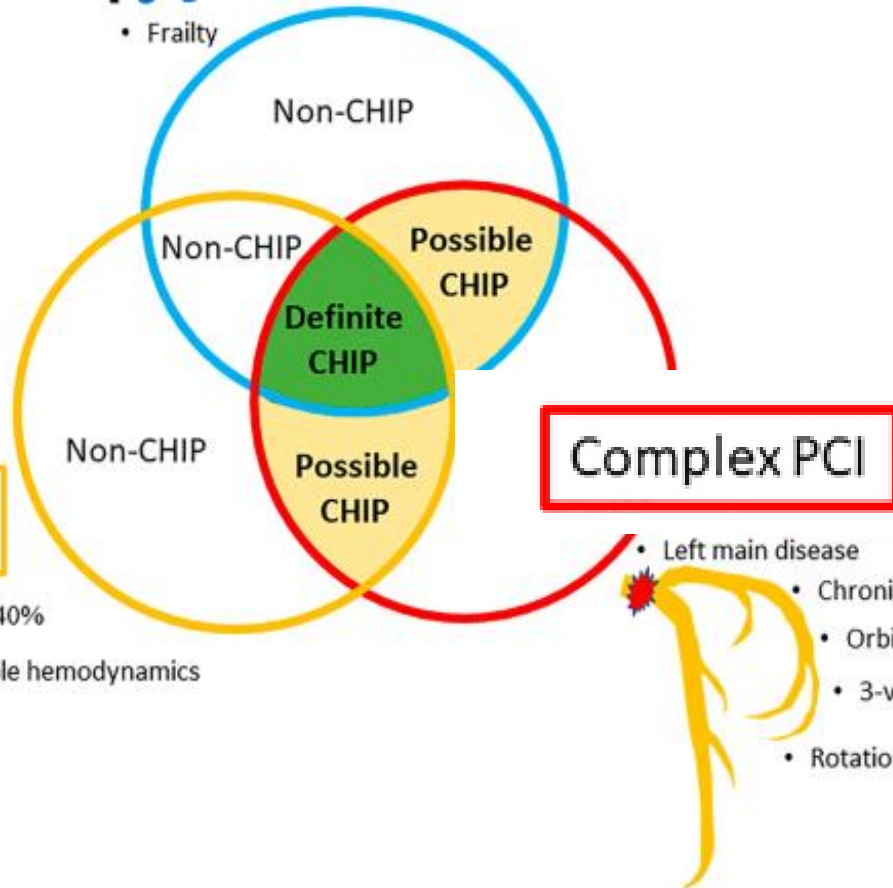
PCI COMPLESSA NEL  
PAZIENTE CHIP

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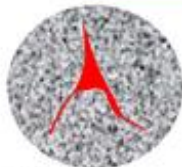


### Patient factors

- Active malignancy
- Liver cirrhosis
- Hemodialysis
- Frailty
- Pulmonary disease
- Past cerebral infarction
- Immunosuppressive drugs



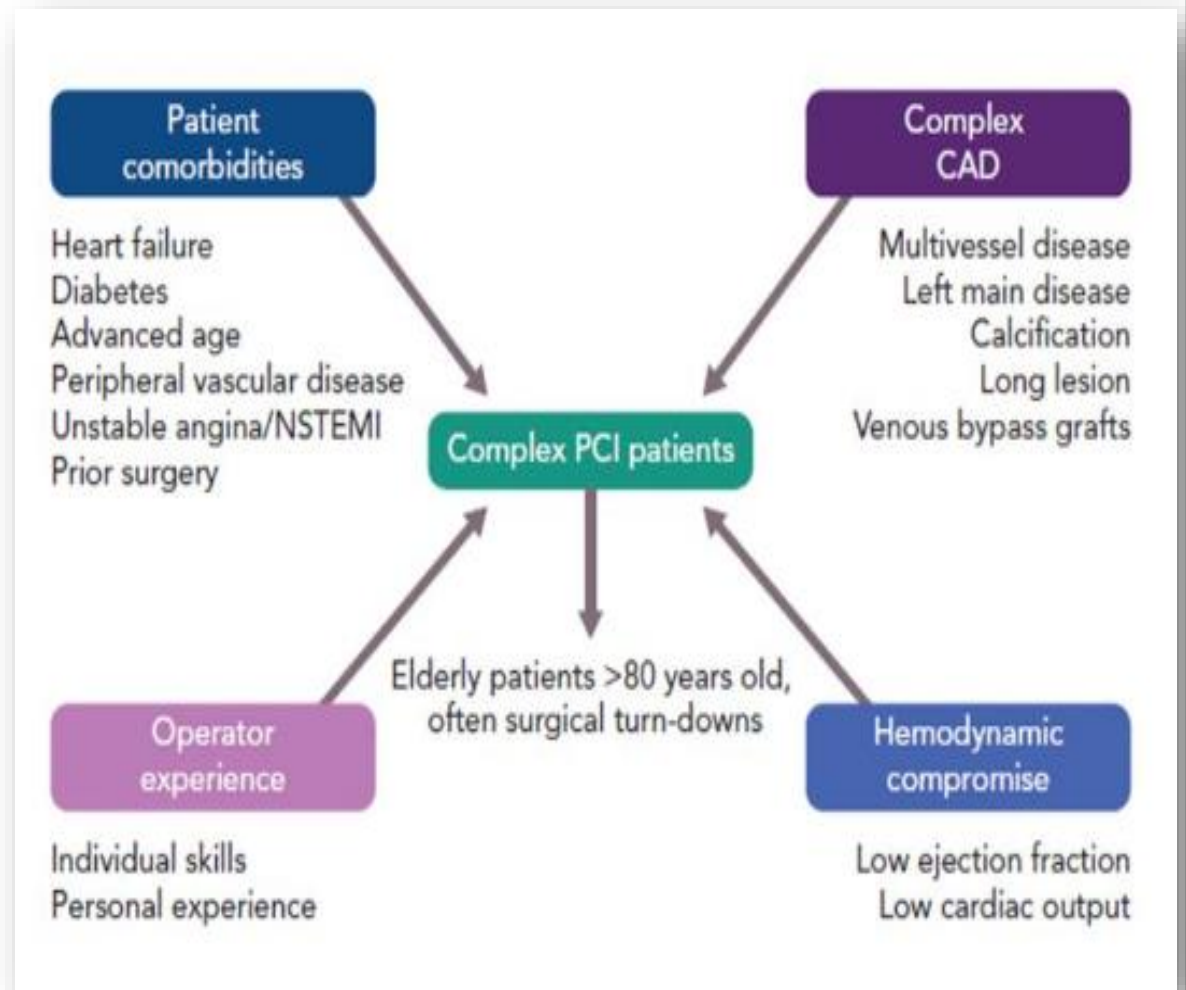
### Complicated heart disease



- LVEF <40%
- Unstable hemodynamics
- Valvular disease (ex. aortic stenosis)

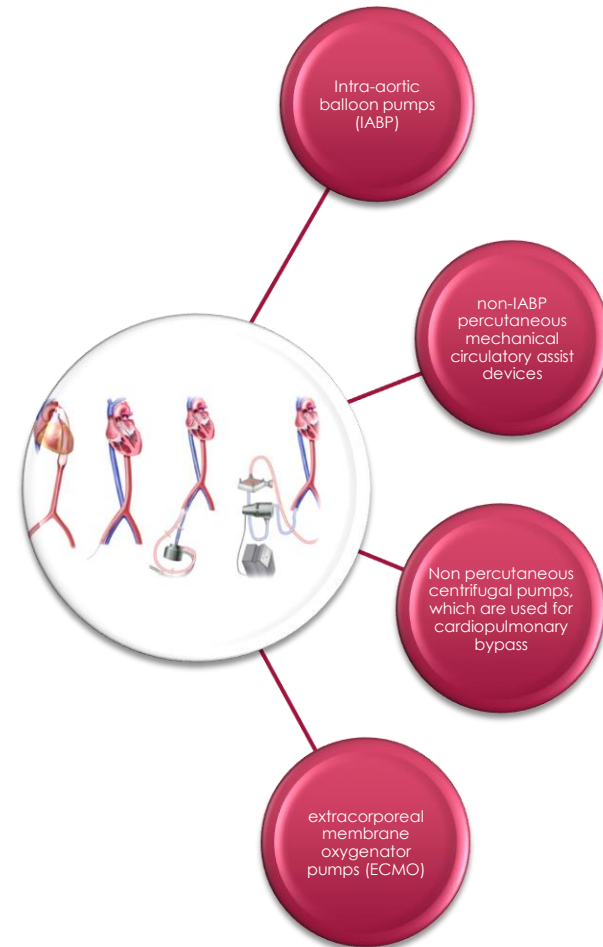
# Types of PCI and what constitutes high-risk PCI?

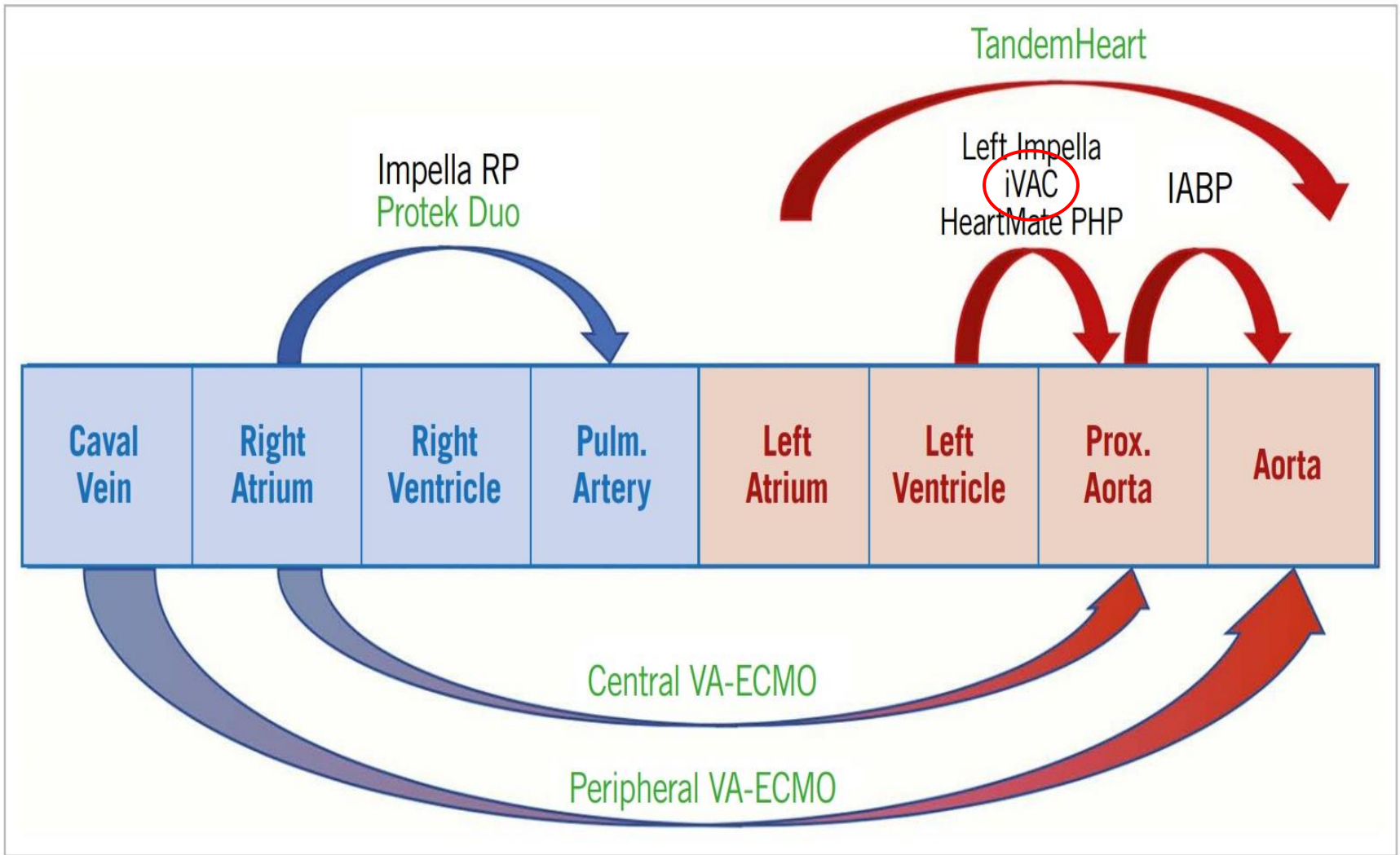
- ✓ CTO angioplasty
- ✓ Laser angioplasty
- ✓ Rotational atherectomy
- ✓ LM angioplasty
- ✓ MCS-supported PCI



# Background to Short Term Mechanical Circulatory Devices

- Short-term mechanical circulatory assist devices are designed to provide hemodynamic support for a wide range of clinical conditions
- These devices provides circulatory support by performing work for a failing left or right ventricle or both
- There has been a significant increase in the use of short-term percutaneous ventricular assist devices (pVADs) as acute circulatory support in cardiogenic shock and to provide hemodynamic support during interventional procedures, including high-risk PCI





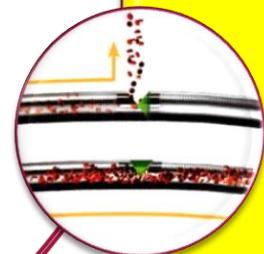
# iVAC 2L



**iVAC 2L is a short term Pulsatile Mechanical Circulatory Support System in the form of a pVAD (Percutaneous Ventricular Assist Device) that effectively generates blood flow of up to 2 liters per minute**

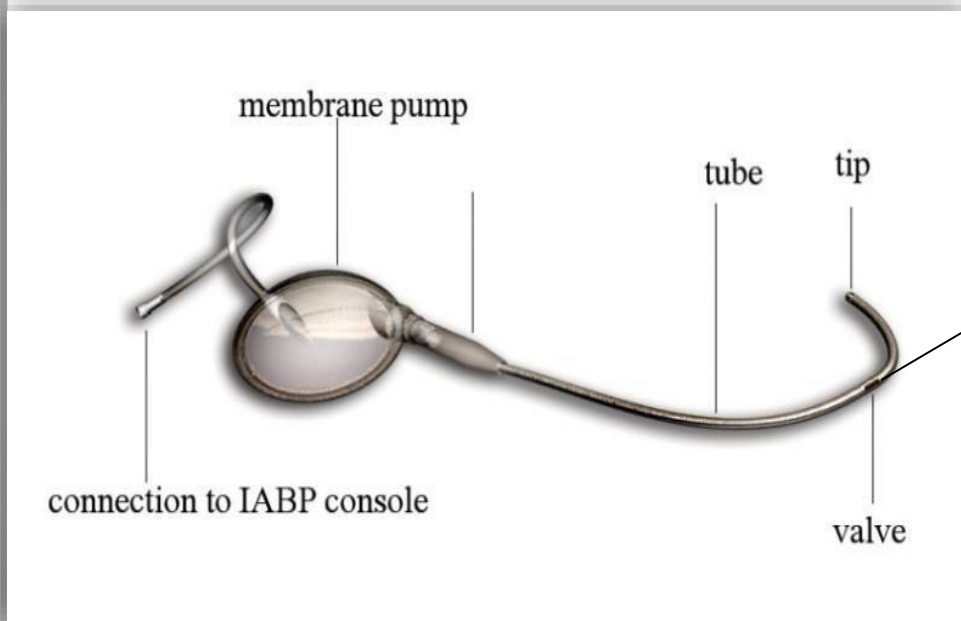


**It works by actively unloading the left ventricle to provide critical hemodynamic support for patients being treated for acute myocardial infarction and cardiogenic shock**



**Its application as hemodynamical backup may also result in more extensive treatment of the coronary lesions and improved long-term clinical outcomes and improve myocardial perfusion and optimize the cardiac workload, thus reducing the likelihood of peri- and post-procedural adverse events**

# Characteristics



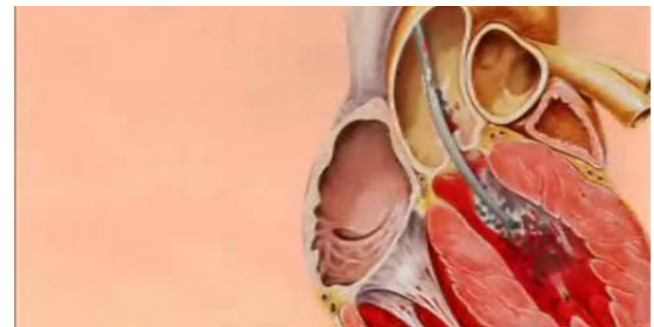
- **17Fr flexible thin-walled catheter**
- **Bi directional valve**
- **Single port 40cc membrane pump**
- **Run by an IABP console**

## Indications

- ✓ Protected high-risk PCI
- ✓ Cardiogenic shock

## Contra indications

- ✓ Femoral artery diameter  $< 6$  mm
- ✓ Severe Aortic stenosis
- ✓ Thrombus in LV
- ✓ Presence of mechanical aortic valve





# IVAC 2L

## BENEFITS – ADVANTAGES

### BENEFITS

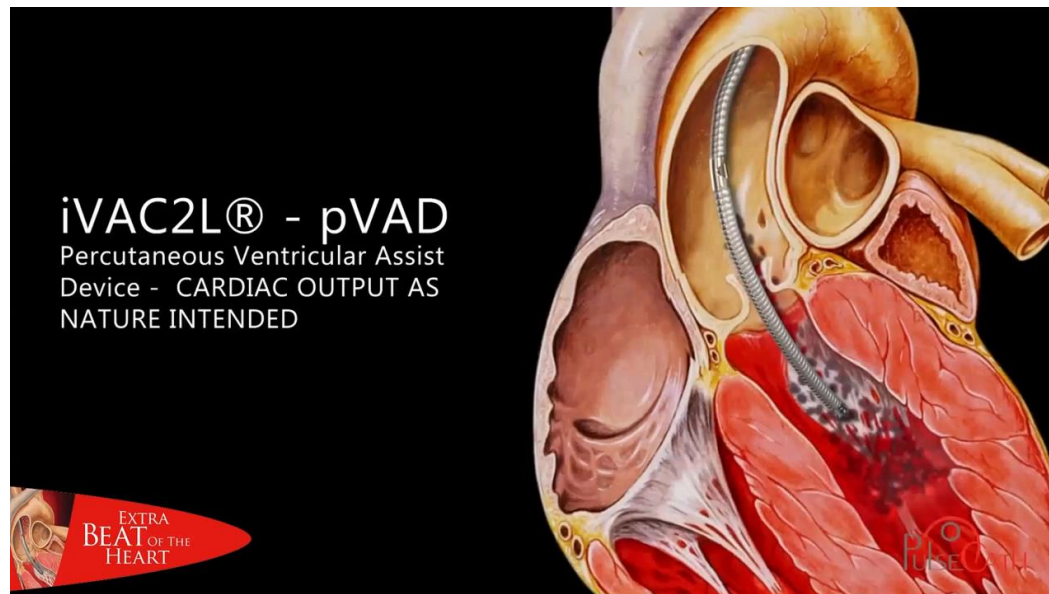
- Ease of use, short learning curve**
- Reduced strain on heart muscle**
- Improvement in hemodynamic parameters that effect the organs**
- Unloading of the LV reducing afterload aortic pressure**
- Improves cardiac output**

### ADVANTAGES

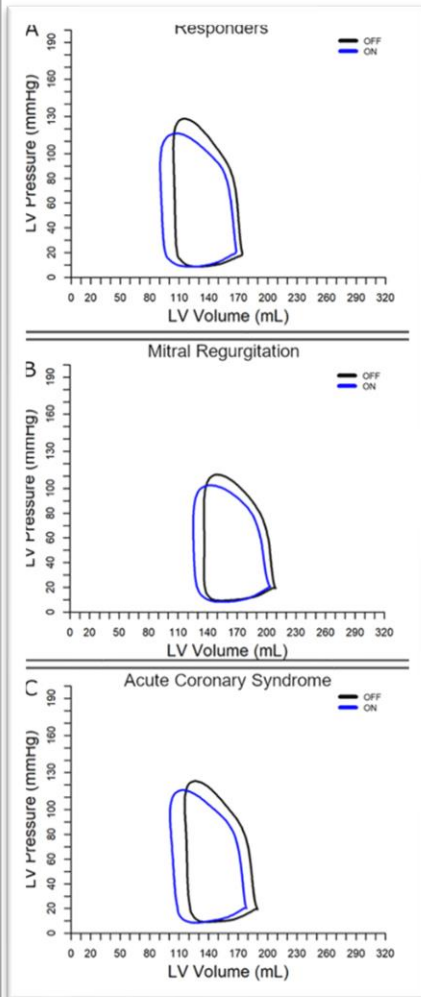
- Swift percutaneous approach, also in emergency situations**
- Reduce ventricular volume and pressure**
- Non-significant hemolysis**
- Standard transfemoral, percutaneous approach that follows routine procedure**
- Improves coronary artery and end-organ perfusion**

# How does it work?

- The iVAC 2L is activated by standard IABP console that is triggered by ECG /AP
- The helium from IABP console is “pushing and pulling” the iVAC 2L membrane pump synchronized with heart beats
- During aspiration, blood enters the catheter through its tip located at the left ventricular and is aspirated into the membrane pump
- The membrane pump pushes the blood back in the catheter, the valve at the side hole opens, and ejects the blood out sideways to aorta during diastole



# Effect of next generation pulsatile mechanical circulatory support on cardiac mechanics – The PULSE trial



- ✓ Mechanical circulatory support with PulseCath iVAC 2L in high-risk percutaneous coronary interventions offers LV unloading and reduces myocardial oxygen consumption particularly in patients with acute coronary syndrome or concomitant mitral regurgitation
- ✓ The mean age was 74 (IQR: 70–81) years and the mean SYNTAX score was  $31 \pm 8.3$
- ✓ Left ventricular unloading with iVAC 2L MCS was demonstrated in 82% of patients with complete PV studies
- ✓ 90% of Patients with moderate or severe mitral regurgitation or presenting with acute coronary syndrome (ACS) were most responsive to iVAC 2L unloading
- ✓ In 81% of patients significant reductions in afterload (Ea:  $-19\%$ ) with increases in stroke volume ( $+11\%$ ) and cardiac output ( $+11\%$ )

# CLINICAL OUTCOME PULSE TRIAL

- ✓ PCI was feasible with iVAC 2L MCS in patients with advanced coronary artery disease and very high to prohibitive operative risks
- ✓ Procedural success in 91% of cases
- ✓ 30-day mortality 6.9%; comparable to PROTECT II outcomes: IABP 6.2% and Impella 6.9%
- ✓ PULSE patients were at higher risk than in PROTECT II

# COMPARISON OF IVAC 2L TO IMPELLA CP

- ✓ Different functions – Pulsatile support Vs Continuous flow
- ✓ iVAC 2L although a smaller pump generates equivalent results to Impella CP
- ✓ Works with the heart
- ✓ No significant hemolysis in comparison to Impella CP
- ✓ Easy to operate and time efficient
- ✓ Cost effective

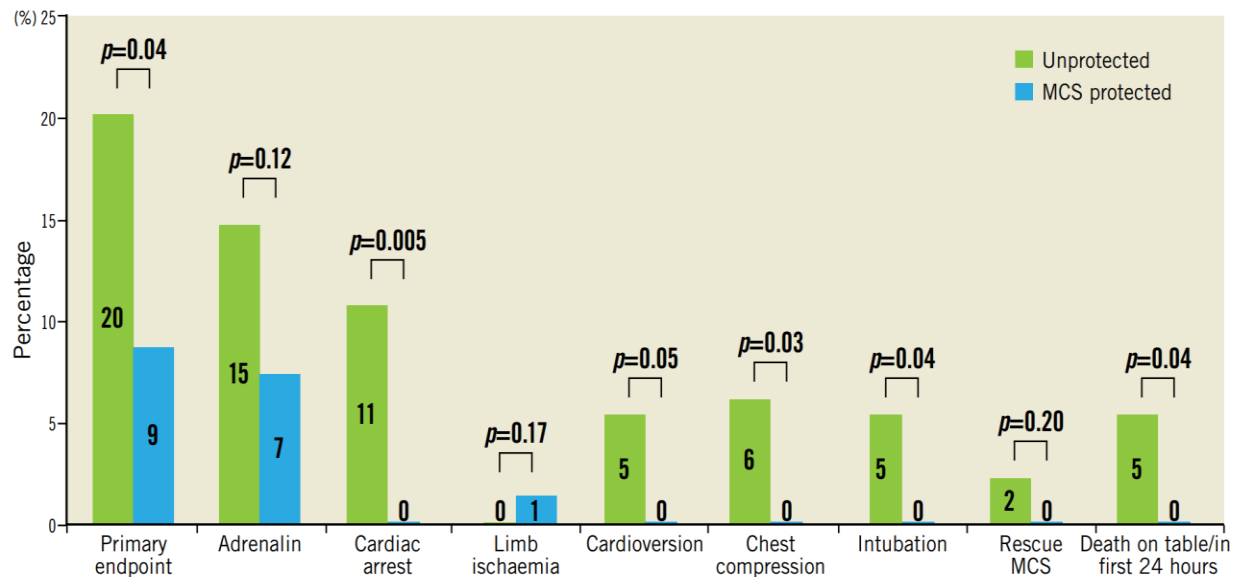
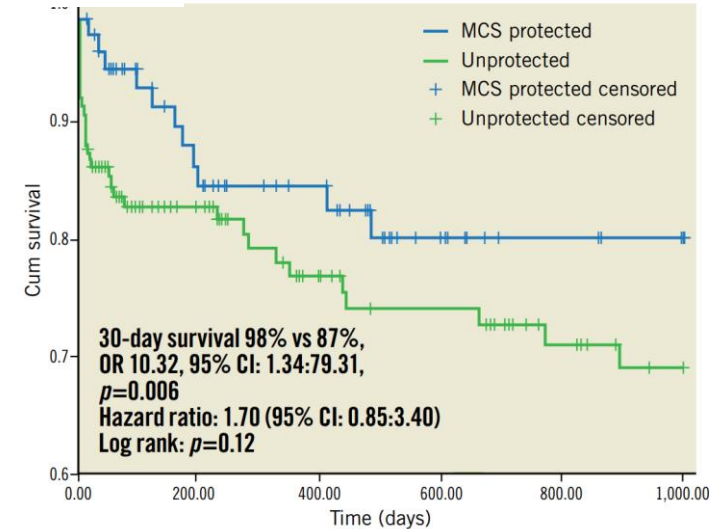
# iVAC 2L vs Impella 2.5



- ✓ **40 patients iVAC 2L vs Impella 2.5 during protected high-risk PCI (LVEF 33%)**
- ✓ **PCI Success in 98% of cases**
- ✓ **Both devices led to a significant increase in aortic pressure**
- ✓ **Both devices ensured stable hemodynamic conditions for performing successful high-risk PCI**
- ✓ **Complication rates by use of both devices seem acceptable**
- ✓ **Signs of potential hemolysis were only present under Impella 2.5**
- ✓ **High-risk PCI's under mechanical circulatory support by the pulsatile iVAC 2L or the continuous flow Impella 2.5 device are feasible and safe**

## New-generation mechanical circulatory support during high-risk PCI: a cross-sectional analysis

“In a consecutive real-world cohort of high-risk PCI patients, protection with new-generation MCS resulted in better procedural outcomes despite worse EF and more complex coronary artery disease at baseline”

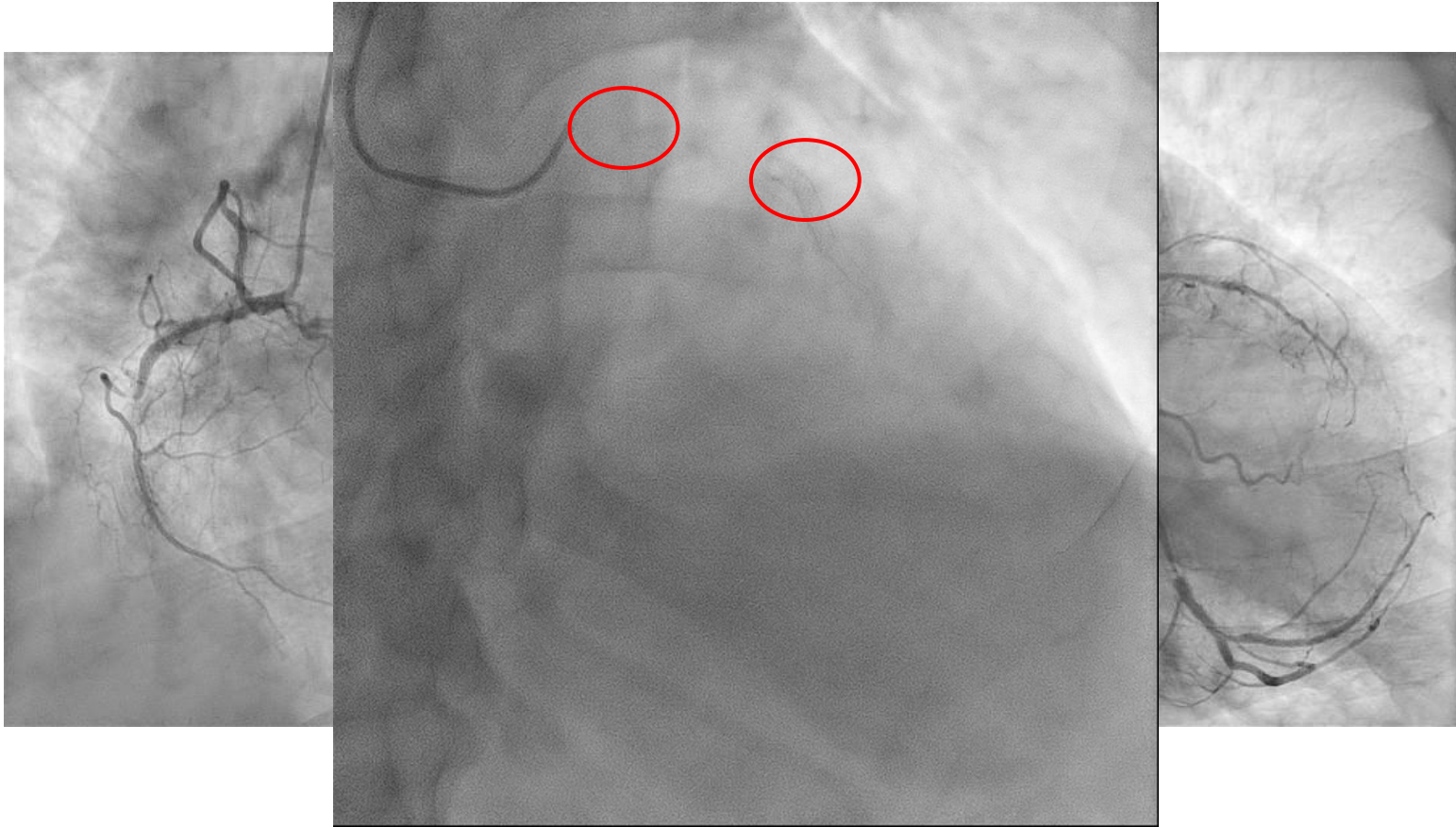


# CASO CLINICO

- ✓ Uomo, anni 65
- ✓ DM 2 in terapia mista, dislipidemia, ipertensione arteriosa, IRC
- ✓ CAD – nota CTO IVA, pregressa PCI + DES su coronaria dx e ramo circonflesso nel 2021 per STEMI IPL
- ✓ Ricovero in Luglio 2023 per NSTEMI con associato stato settico
- ✓ Ecocardio: FE 30%, IM moderato-severa, acinesia e fibrosi di apice e parete inferiore
- ✓ Impianto di ICD bicamerale alla risoluzione della sepsi



# CORONAROGRAFIA



# PCI



