# Assistance circulatoire mécanique temporaire : IMPELLA

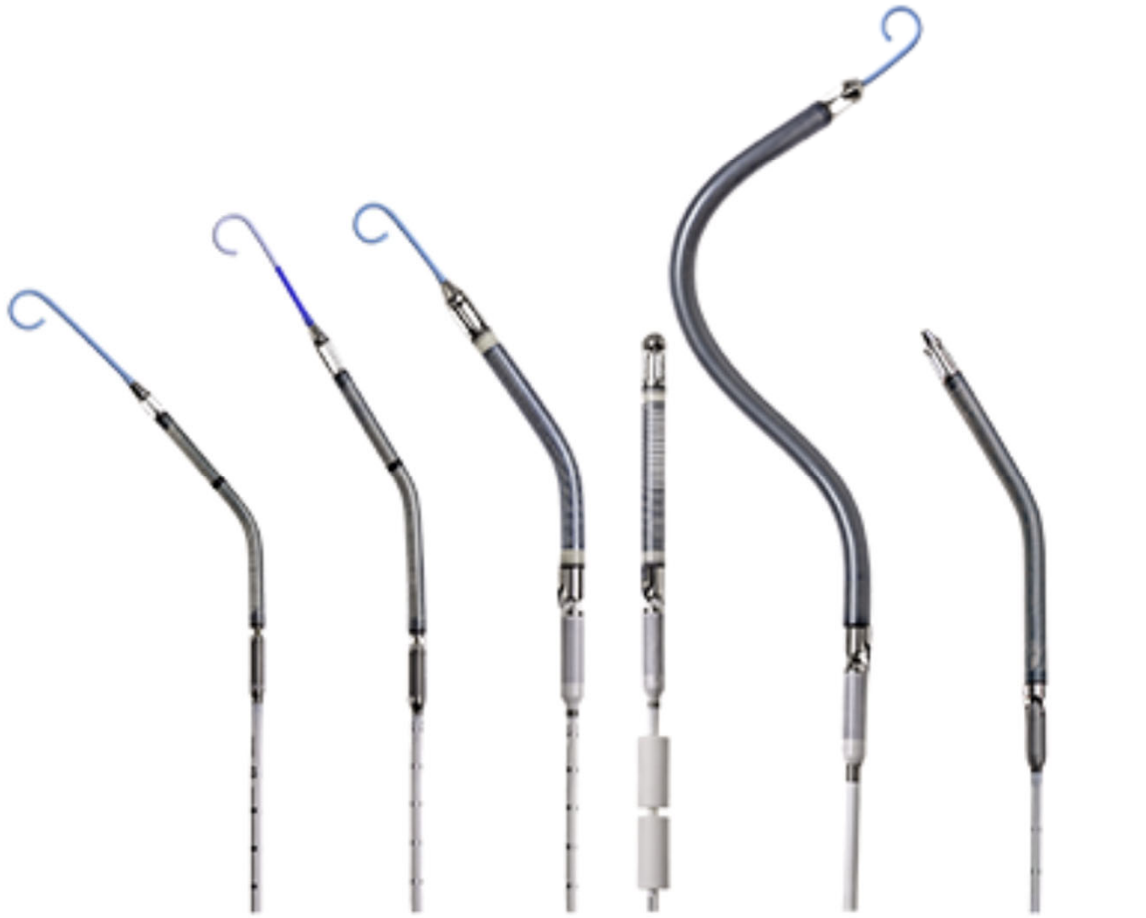
Dr Antoine BEURTON

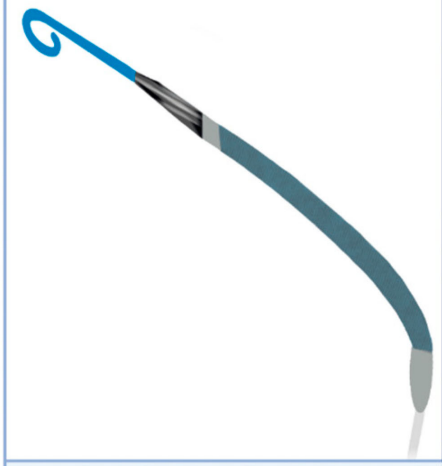
Praticien hospitalier

Service d'anesthésie-réanimation cardiovasculaire, CHU Bordeaux

Conflit d'intêret pour cette présentation

Speaker pour les journées IMPELLA


Impella 2.5®
Impella CP®
with SmartAssist®
Impella 5.0®&
Impella LD®
Impella RP®&
Impella RP®
with SmartAssist®
Impella 5.5®
with SmartAssist®

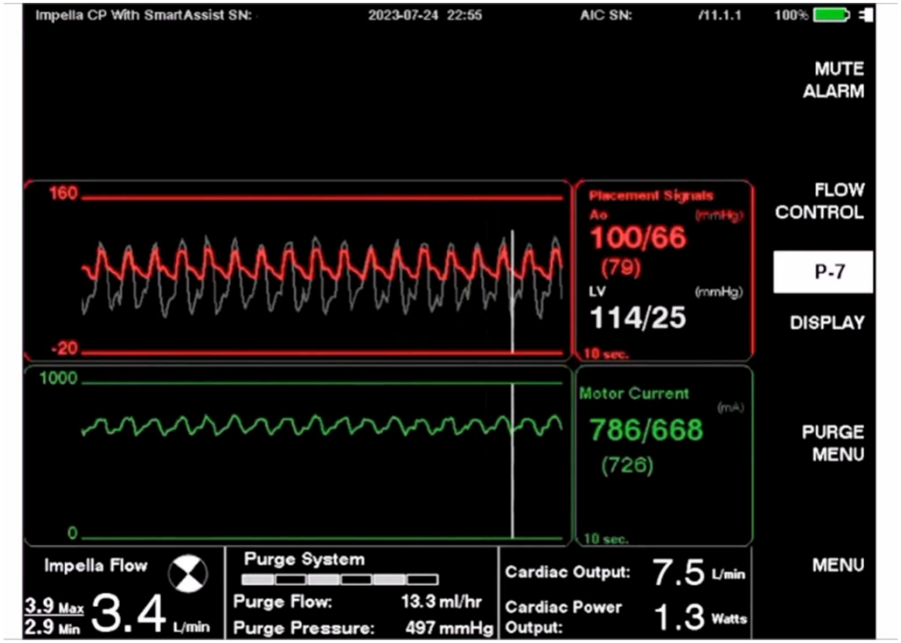
| Impella CP | Impella 5.5 | Impella RP |
|---|---|---|
|  |  |  |
| **Left-sided support**<br>• LV → Ao<br>• Inserted percutaneously via femoral artery (or less commonly, axillary artery)<br>• Introducer diameter: 14 Fr<br>• Pump motor diameter: 14 Fr<br>• Maximum flow: 3.7 L/min<br>• Pigtail with teardrop inlet<br>• SmartAssist-enabled | **Left-sided support**<br>• LV → Ao<br>• Inserted surgically via axillary cutdown or directly into the ascending aorta<br>• Introducer diameter: 23 Fr<br>• Pump motor diameter: 19 Fr<br>• Maximum flow: 5.5 L/min<br>• No pigtail<br>• Rigid cannula with optical sensor | **Right-sided support**<br>• RA → PA<br>• Inserted percutaneously via femoral vein<br>• Introducer diameter: 23 Fr<br>• Pump motor diameter: 22 Fr<br>• Maximum flow: 4.4 L/min<br>• Used for RHF<br>• No true pigtail; curved tip for RV–PA navigation |

Farhat et al. Biomedicines 2025; 13 (9) : 2198.

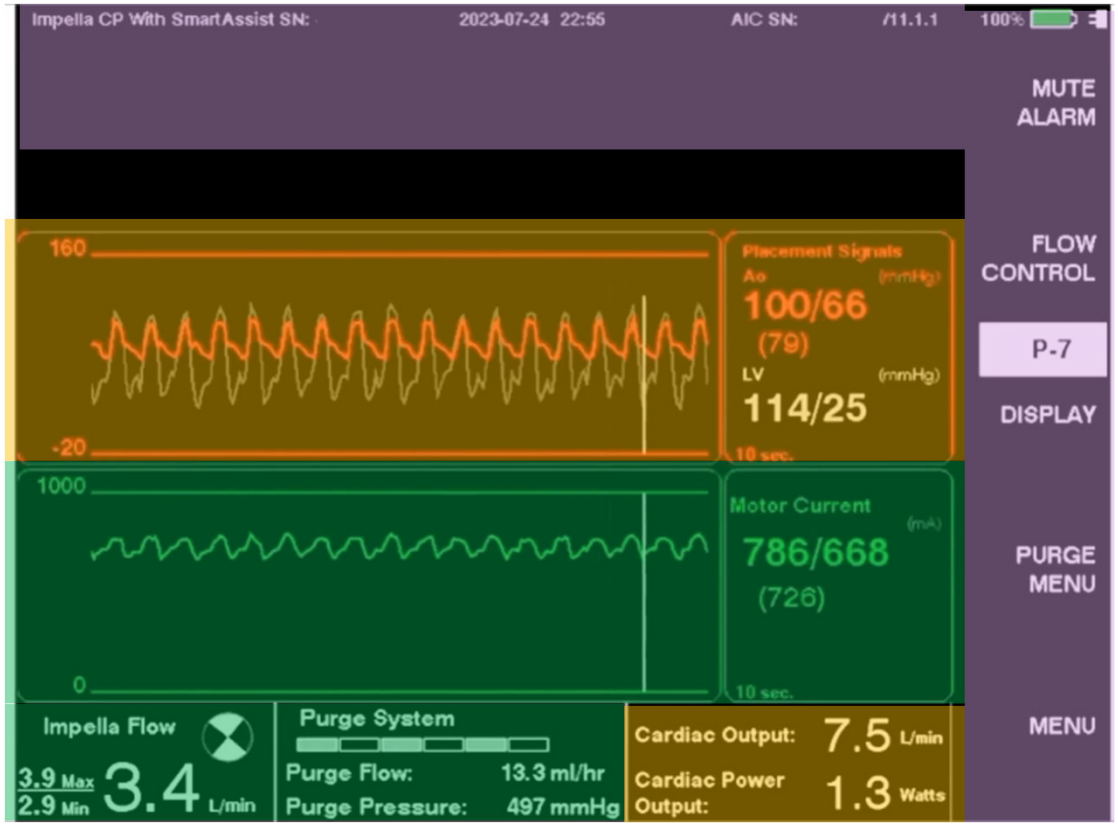
# CONSOLE ET FONCTIONNEMENT

# I. PARAMÈTRES HÉMODYNAMIQUES DE BASE

Surveillance intégré pompe–patient



# I. PARAMÈTRES HÉMODYNAMIQUES DE BASE



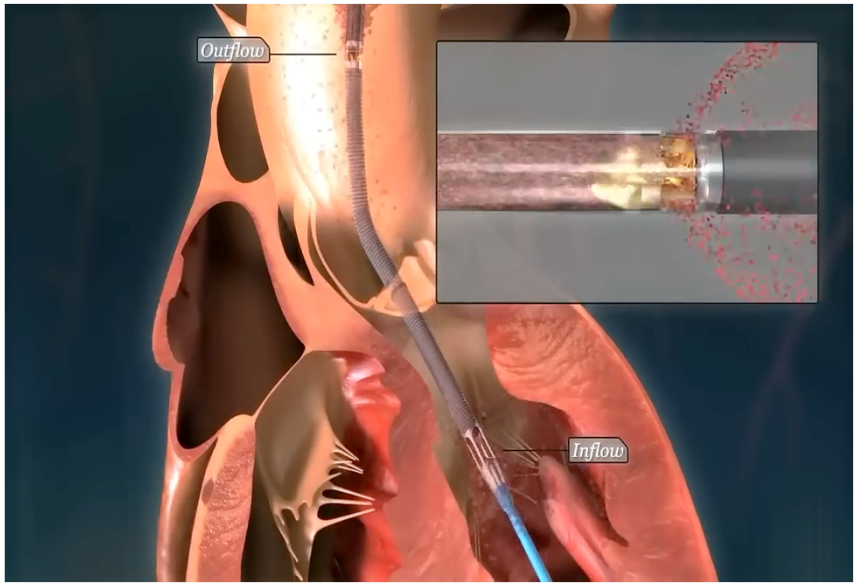

Signaux hémodynamiques **indirects**

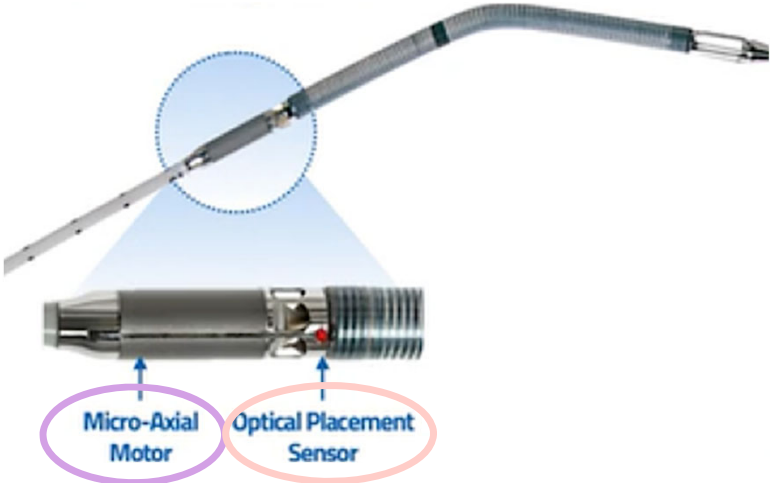
Signaux **mécaniques** moteurs

Signaux **techniques**

Signaux **mécaniques** moteurs

# I. P-LEVEL




## 1) P-Level => RPM

Signal **fiable, déterministe**, indépendant de l'hémodynamique

## 2) Courant moteur

**Signal mécanique continu** du travail du rotor
Dépend de la charge hydraulique, viscosité, résistances mécaniques.

## 3) Capteur de pression (outlet)

Capteur optique de pression – normalement dans l'aorte
C'est **la seule pression vraie** sur la console.

## I. P-LEVEL

On prescrit et on règle une Performance / P-level qui correspond à un **TPM ou RPM**

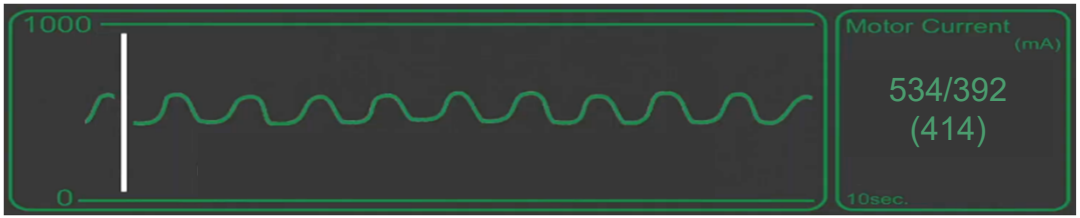
### CP

| Performance | *Débit (l/min) | Tours par minute (tr/min) |
|---|---|---|
| P-0 | 0,0 | 0 |
| P-1 | 0,0 - 0,9 | 23 000 |
| P-2 | 1,1 - 2,1 | 31 000 |
| P-3 | 1,6 - 2,3 | 33 000 |
| P-4 | 2,0 - 2,5 | 35 000 |
| P-5 | 2,3 - 2,7 | 37 000 |
| P-6 | 2,5 - 2,9 | 39 000 |
| P-7 | 2,9 - 3,3 | 42 000 |
| P-8 | 3,1 - 3,4 | 44 000 |
| P-9** | 3,3 - 3,7 | 46 000 |

### 5.5

| P-level | Mean Flow (L/min) 30 - 60 mmHg | Revolutions Per Minute (rpm) |
|---|---|---|
| P-0 | 0 | 0 |
| P-1 | 0 | 12,000 |
| P-2 | 0.0 - 1.9 | 17,000 |
| P-3 | 1.1 - 2.7 | 20,000 |
| P-4 | 1.9 - 3.3 | 22,000 |
| P-5 | 2.8 - 3.7 | 24,000 |
| P-6 | 3.4 - 4.1 | 26,000 |
| P-7 | 3.9 - 4.5 | 28,000 |
| P-8 | 4.3 - 4.9 | 30,000 |
| P-9 | 5.0 - 5.5 | 33,000 |

# I. COURANT MOTEUR




## Boucle de régulation de la vitesse du rotor

**1)** La prescription du P-level (correspond à un RPM)

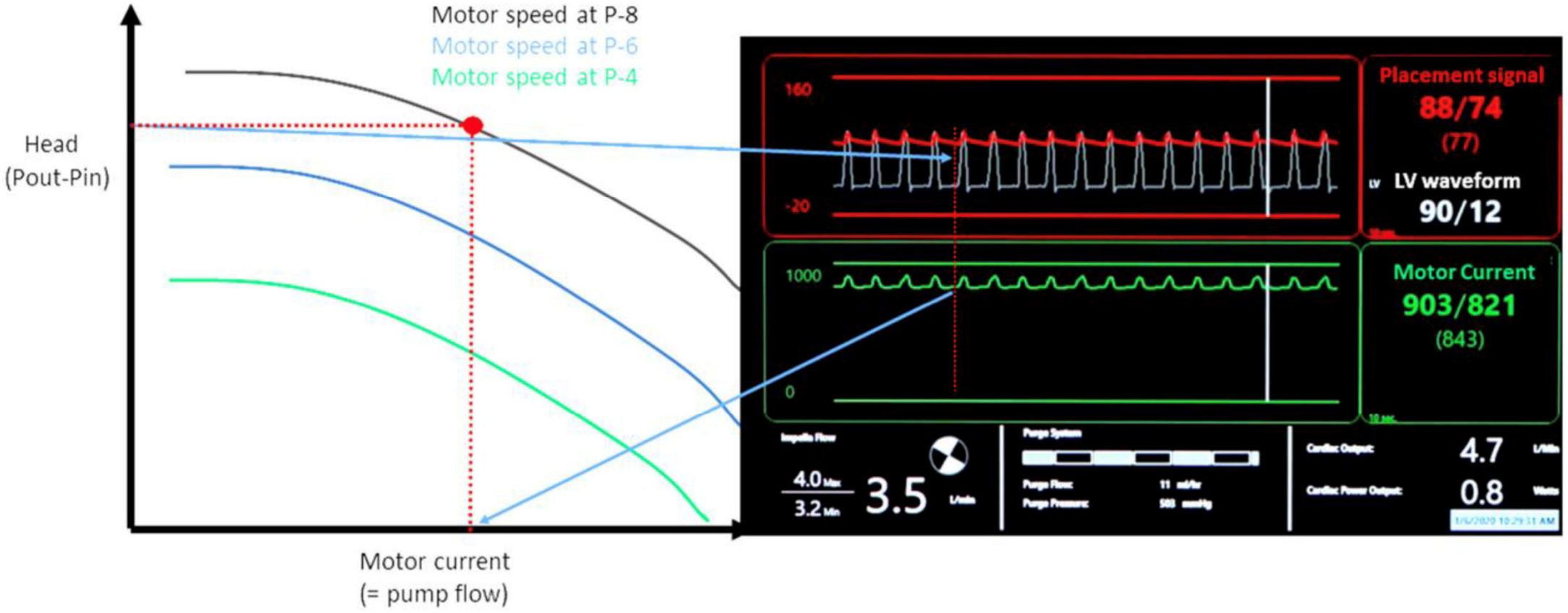
**2)** La vitesse réelle du rotor est mesurée en continu par le contrôleur

**3)** Ajustement du courant moteur

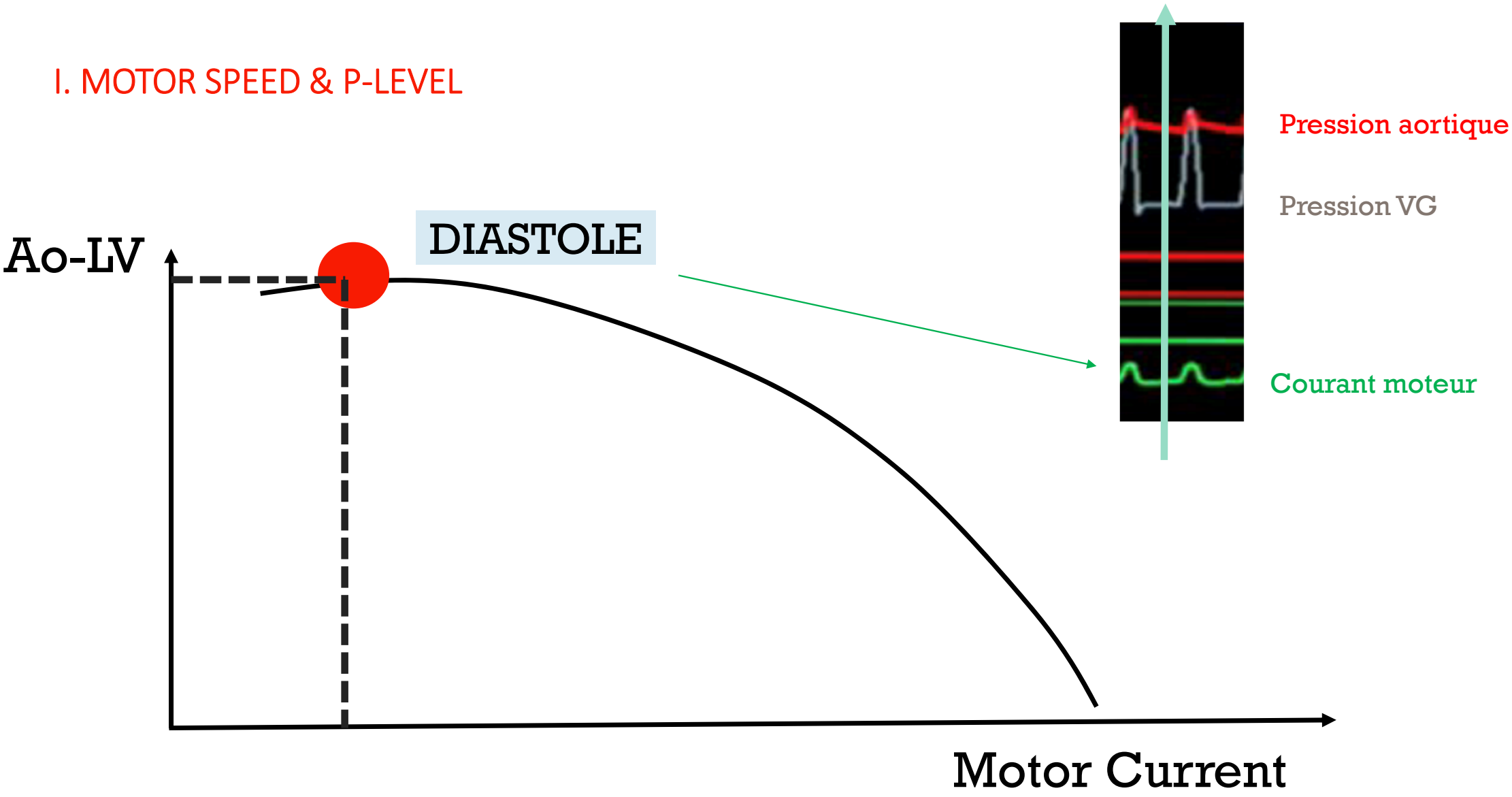
**4)** Le courant génère le couple moteur nécessaire pour maintenir une vitesse constante

# I. MOTOR SPEED & P-LEVEL

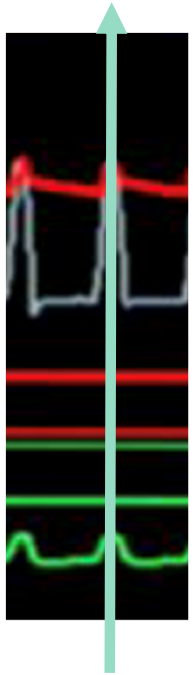
Signaux **mécaniques** moteurs



# I. MOTOR SPEED & P-LEVEL



# I. MOTOR SPEED & P-LEVEL

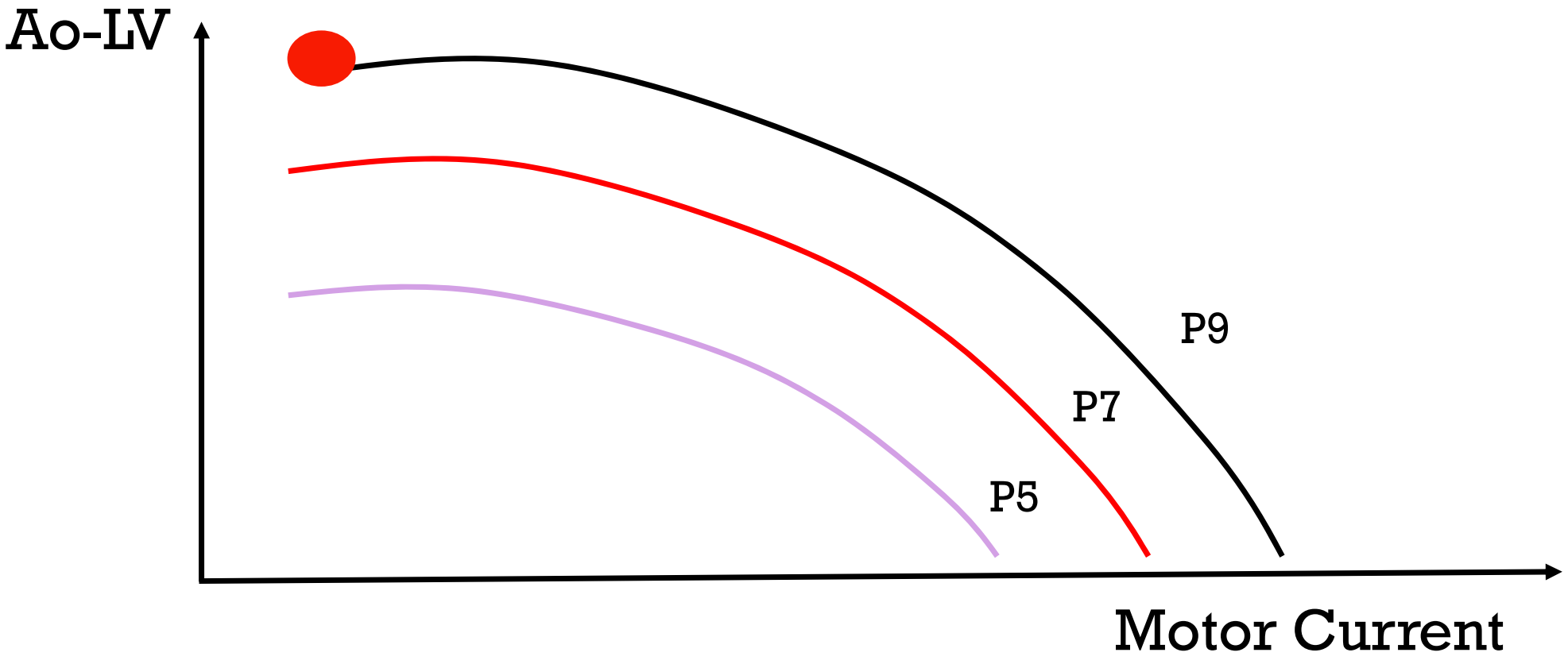


Pression aortique

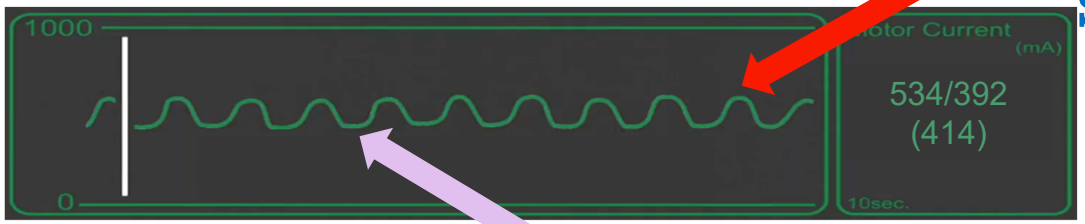
Pression VG

Courant moteur

# I. MOTOR SPEED & P-LEVEL



# I. COURANT MOTEUR




Pic de consommation

Systole VG : gradient VG-Ao faible

Baisse de consommation

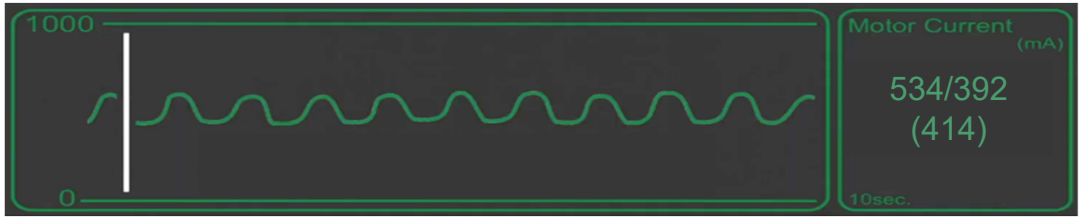
Diastole VG : gradient VG-Ao important

Pendant la systole, l'augmentation de la pression ventriculaire réduit le gradient trans-pompe.

**Un débit plus élevé à travers le rotor génère des forces hydrauliques plus importantes sur les pales**, ce qui nécessite un **couple moteur plus élevé** pour maintenir la même vitesse de rotation → donc **plus de courant**.

**L'Impella ne pousse pas contre la systole, elle est entraînée par elle.**

# I. COURANT MOTEUR



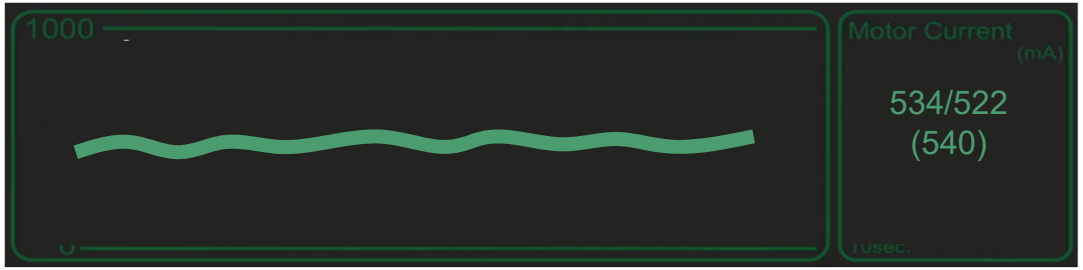

## Charge hydraulique

- Gradient outlet-inlet (Ao-VG)
- Viscosité sanguine
- Résistance à l'écoulement

## Résistance mécanique

- Thrombose
- Obstacle
- Kinking du cathéter

# I. COURANT MOTEUR



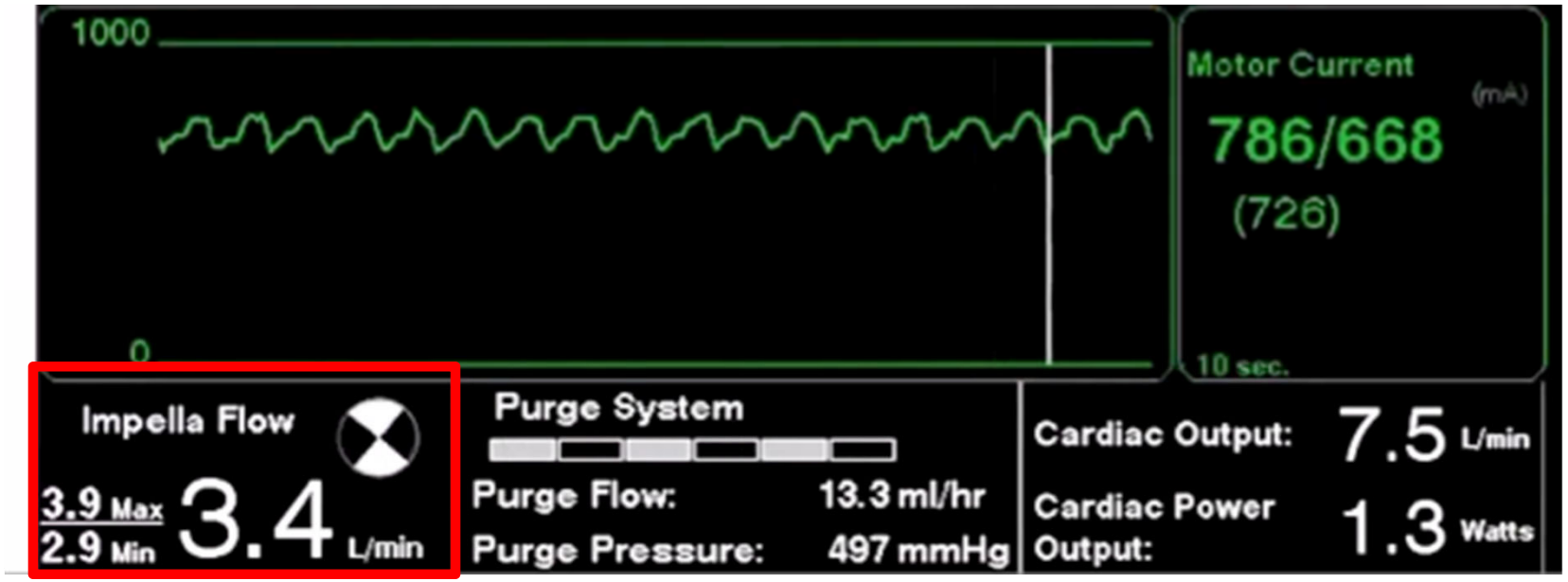

**Absence de gradient outflow-inflow :**

- Impella dans l'aorte
- Impella dans le ventricule
- faible systole ventriculaire :

  Faible inotropisme / Décharge trop intense / Défaillance VD

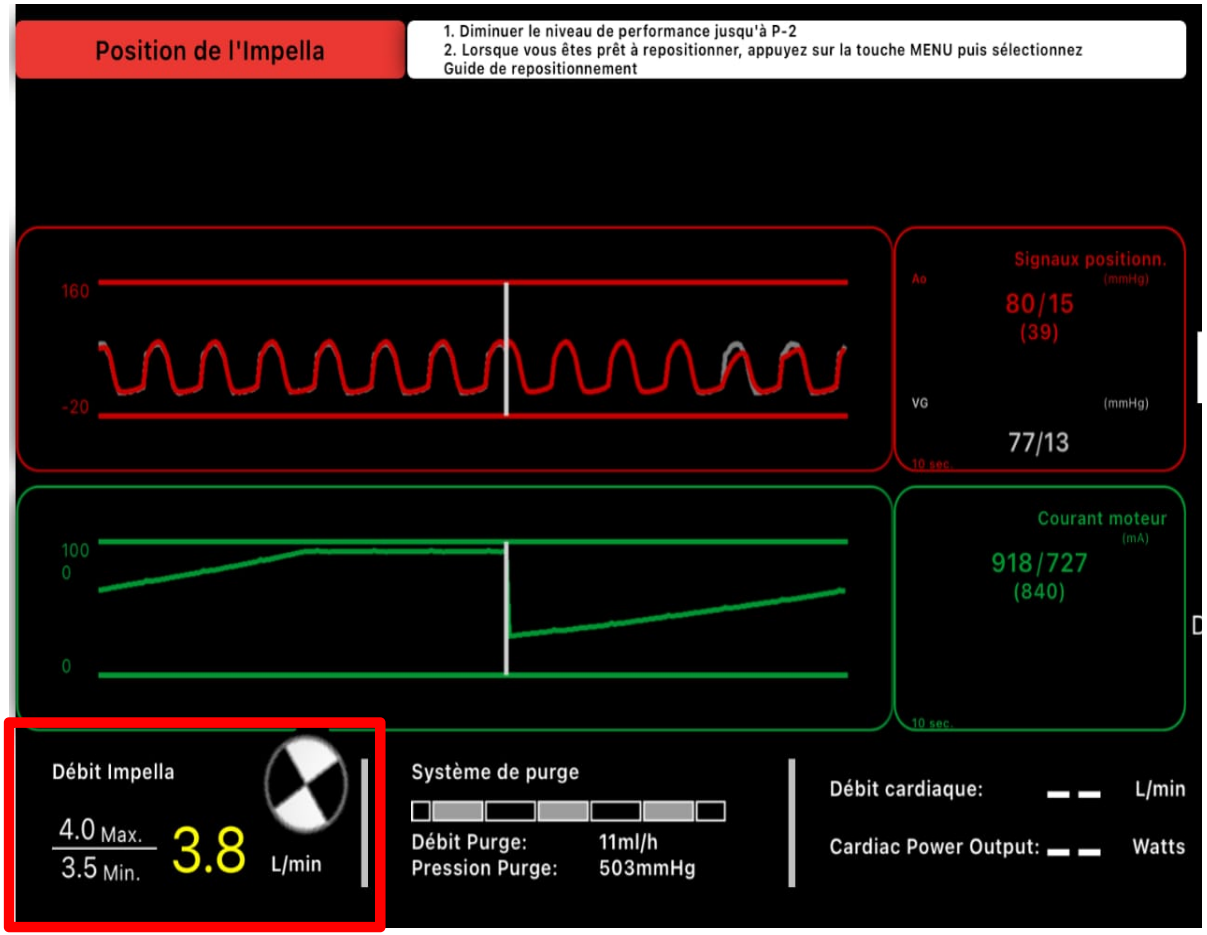
# I. IMPELLA FLOW

Le débit est un indicateur de fonctionnement de la pompe, **pas un débit mesuré.**



Signaux **mécaniques** moteurs

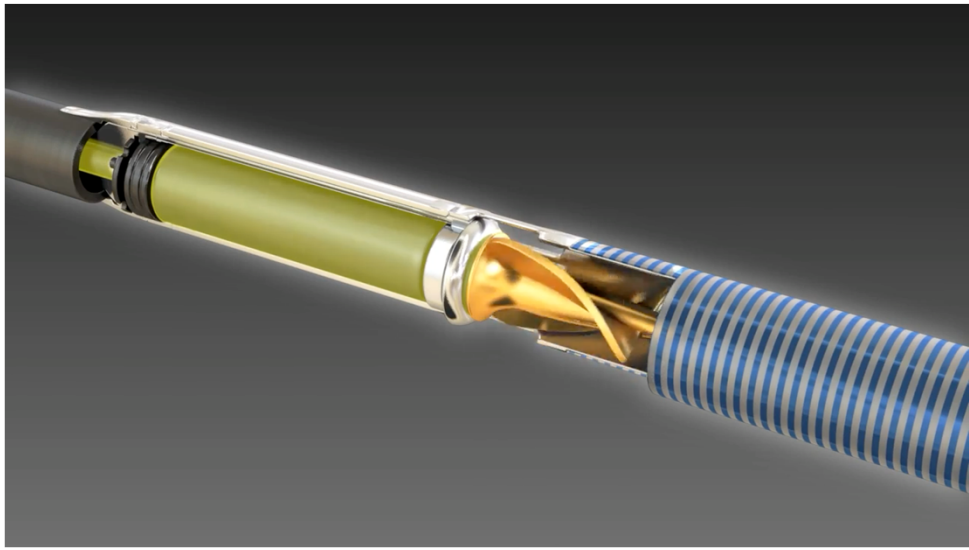
# I. IMPELLA FLOW




## Situations où l'estimation est fausse

- Aspiration
- Malposition de la pompe
- Thrombose
- Viscosité anormale
- Sténose de valve aortique

# PURGE



**Facteurs déterminant :**

1. Résistance ligne purge (longueur, diamètre)
2. Résistance cathéter (calibre lumière purge)
3. Pression aortique
4. Viscosité de la solution de purge
5. Obstructions partielles (thrombus, kinks)

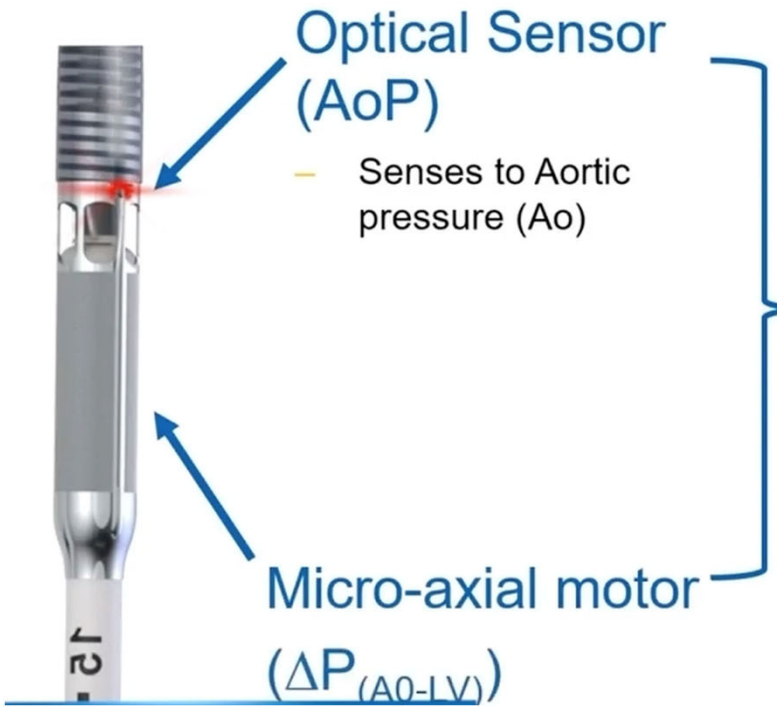
Le débit de purge est asservi à la pression de purge afin de maintenir une pression cible (300-1100 mmHg)

300 mmHg

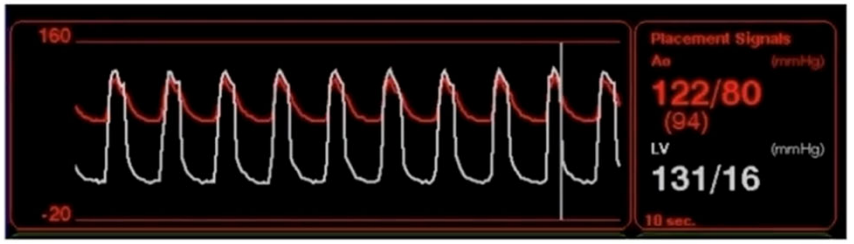
**Débit de purge**

Volume de liquide
+/- Héparine

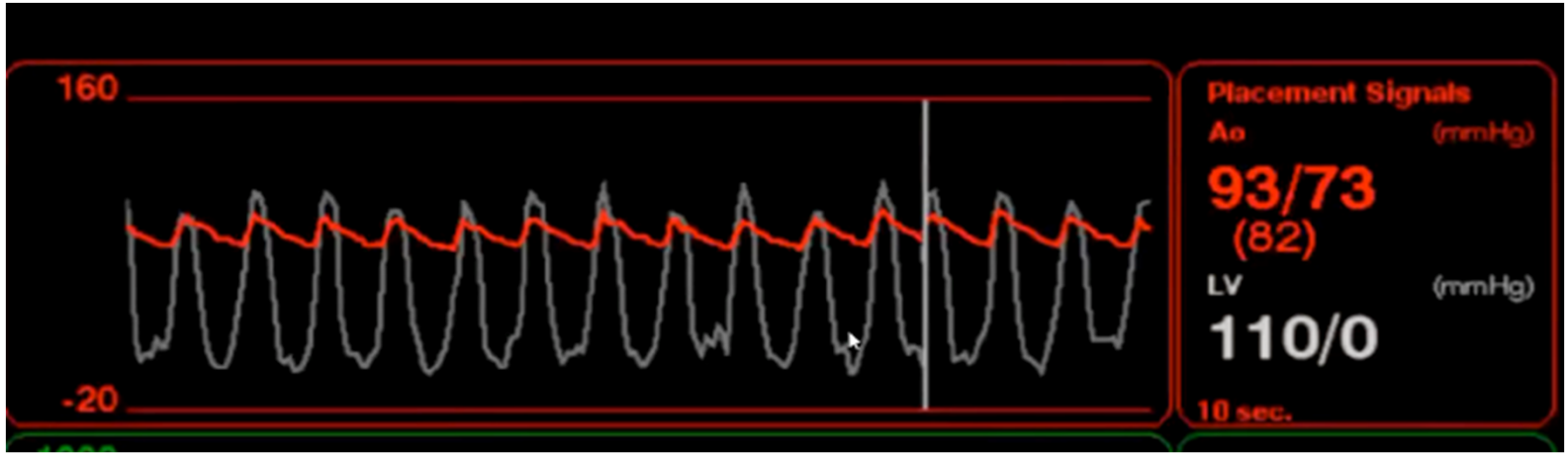
# II. SIGNAUX HEMODYNAMIQUES INDIRECTS




**AoP - $\Delta P_{(A0-LV)}$ = LV Pressure**



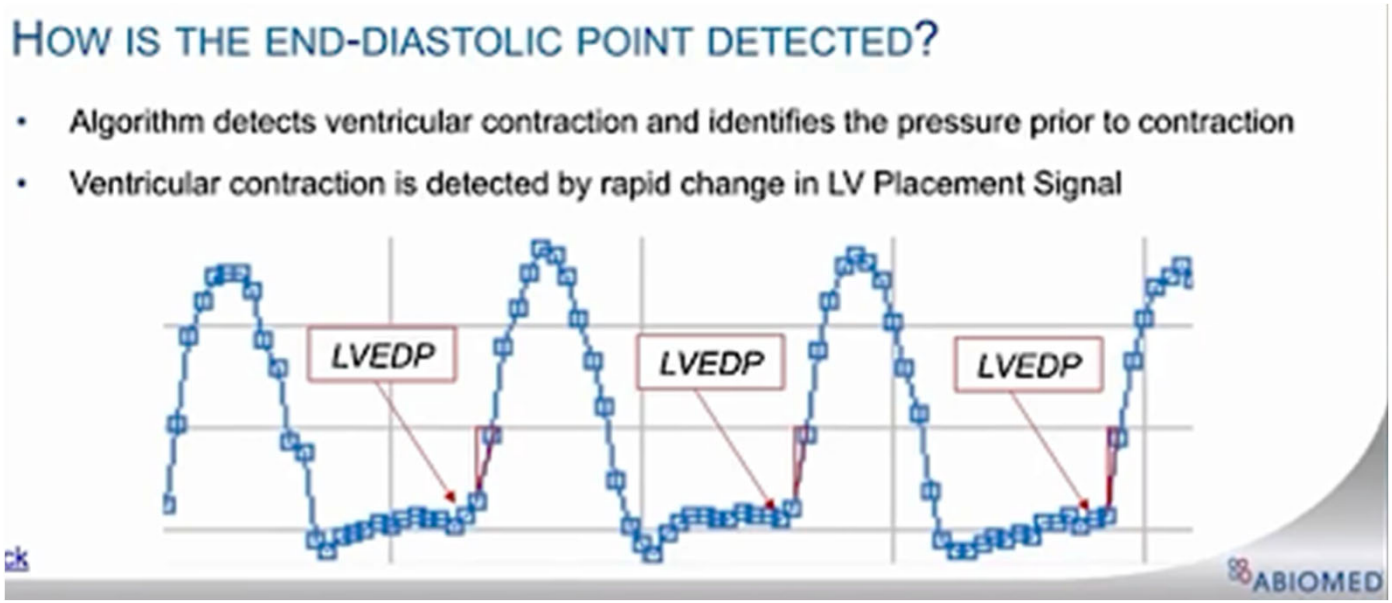
Signaux hémodynamiques **indirects**




Le **signal LV est reconstruit indirectement** à partir de :

- RPM
- courant moteur
- variations instantanées de charge hydraulique

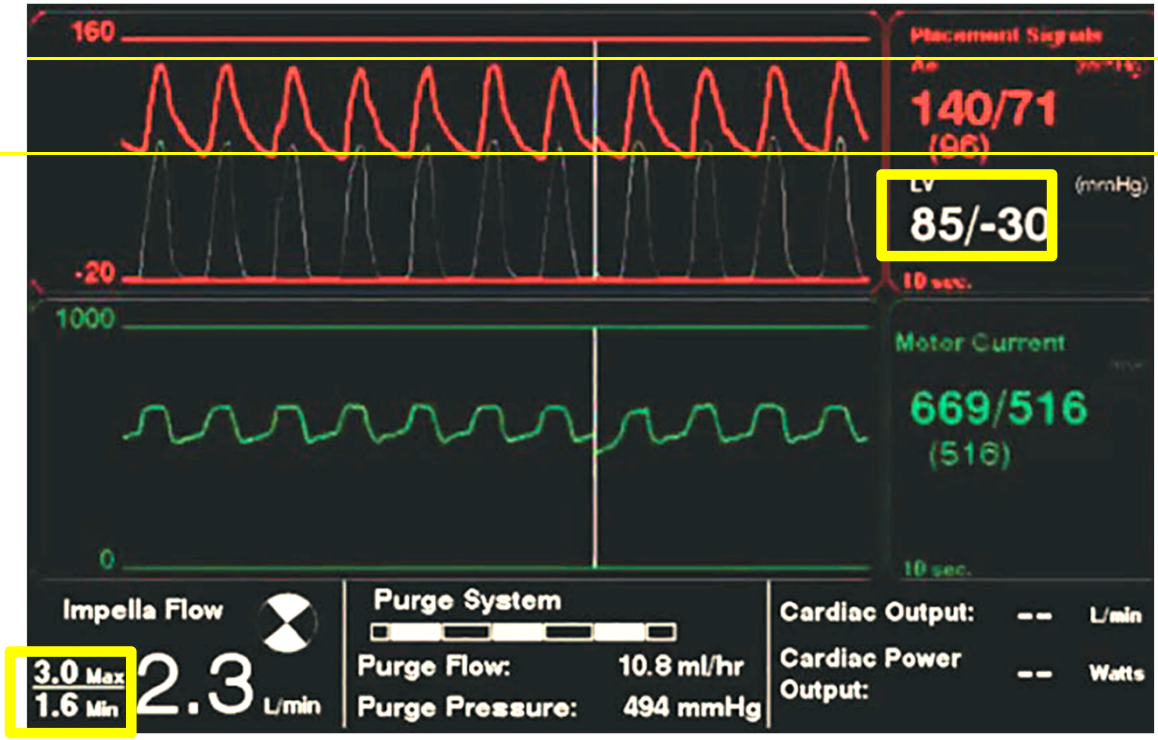
Signaux hémodynamiques **indirects**



Signaux hémodynamiques **indirects**

## II. ASPIRATION

Débit Impella ↓ + pression diastolique négative persistante + pression systolique VG ↓ → **malposition du dispositif**



# 3 valeurs importantes

## 1) P-Level => RPM

Signal **fiable, déterministe**, indépendant de l'hémodynamique

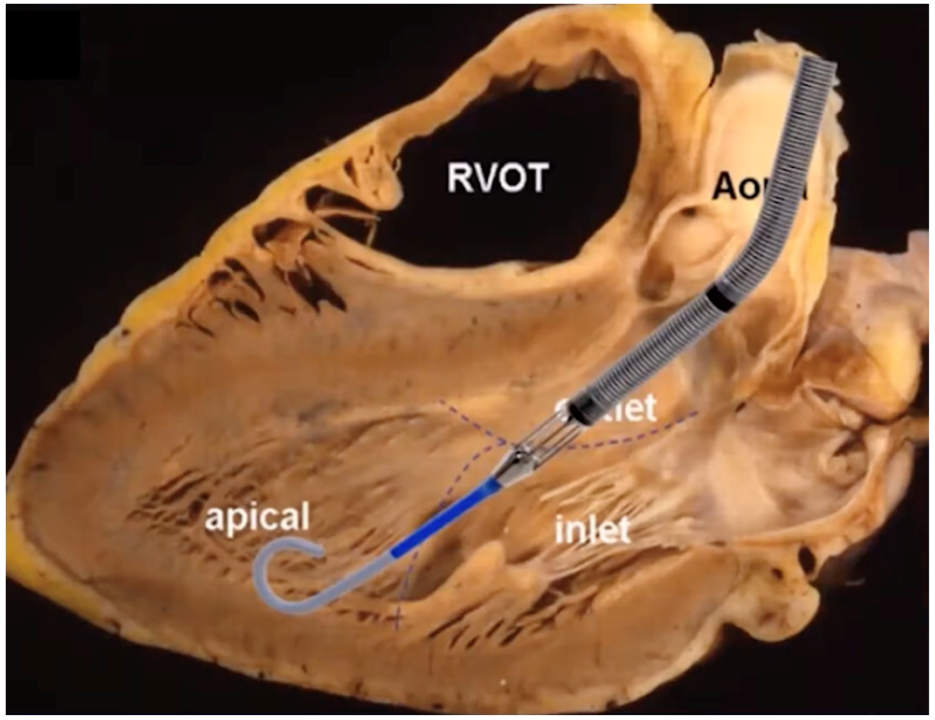
## 2) Courant moteur

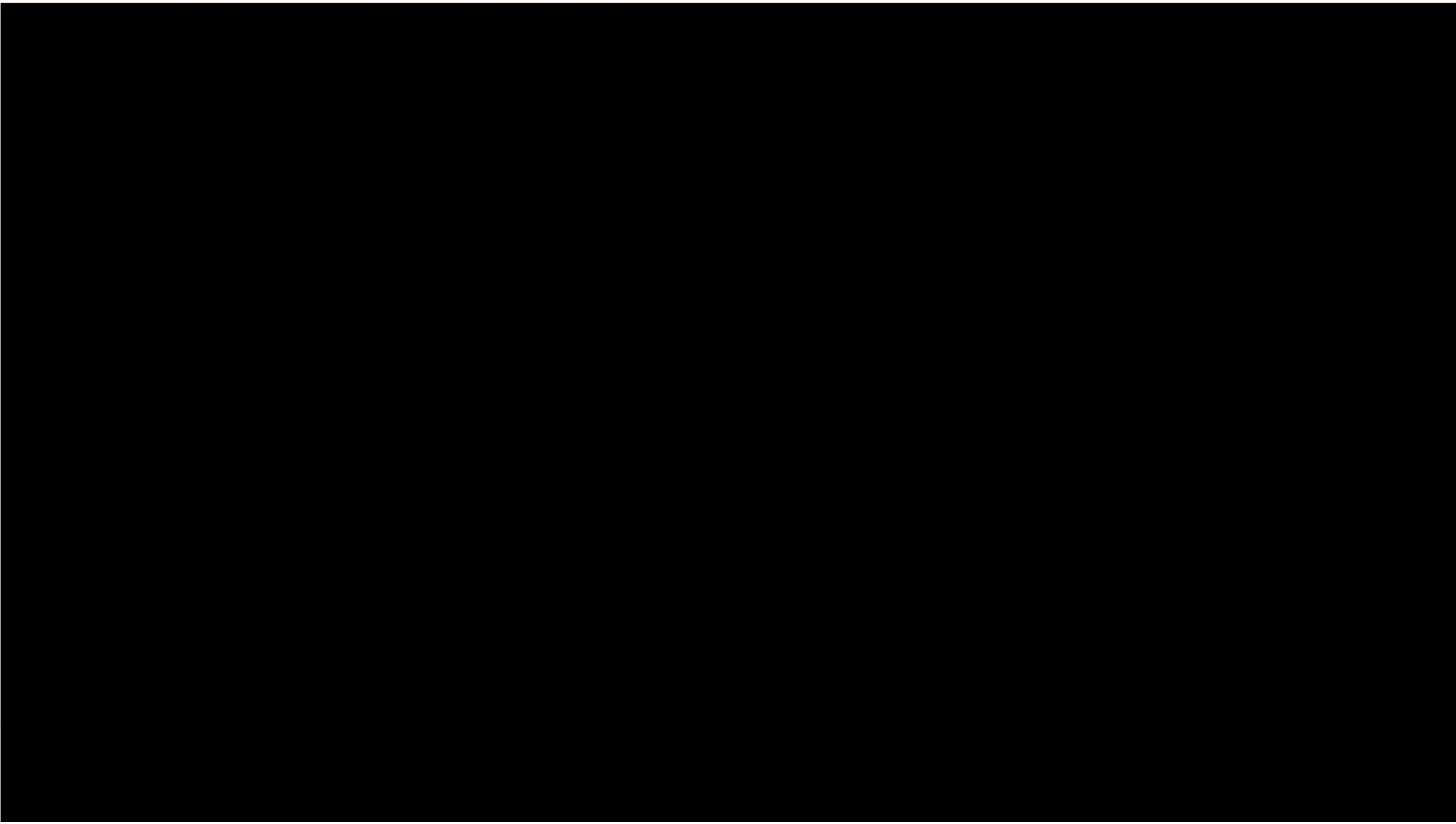
**Signal mécanique continu** du travail du rotor
Dépend de la charge hydraulique, viscosité, résistances mécaniques.

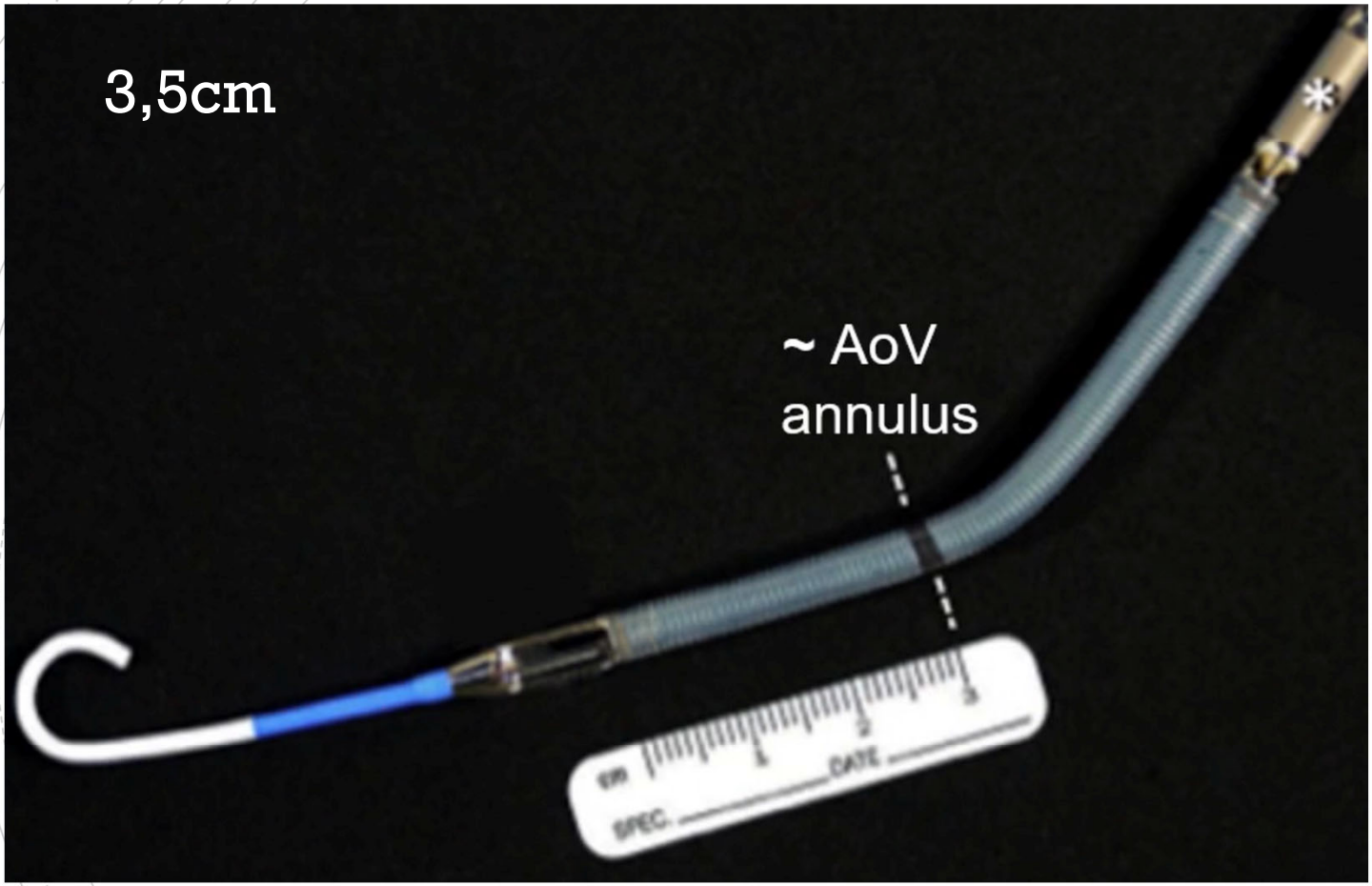
## 3) Capteur de pression (outlet)

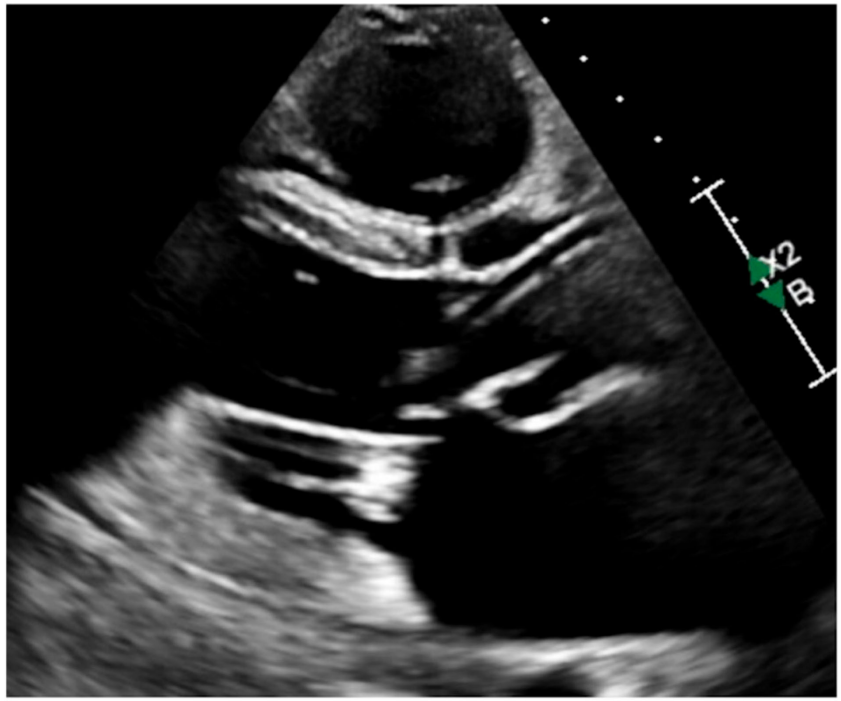
Capteur optique de pression – normalement dans l'aorte
C'est **la seule pression vraie** sur la console.

# BONNE POSITION

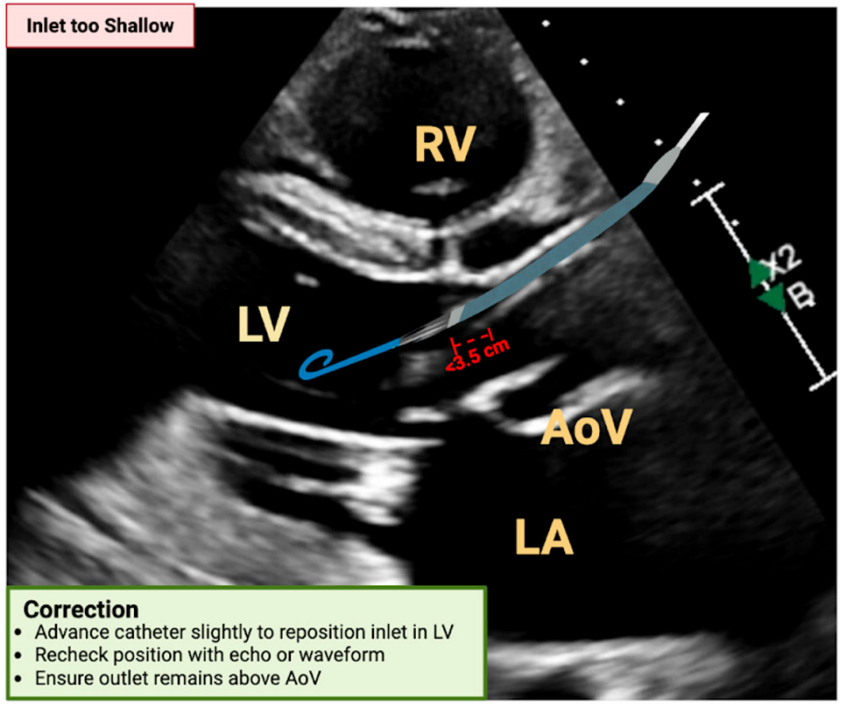




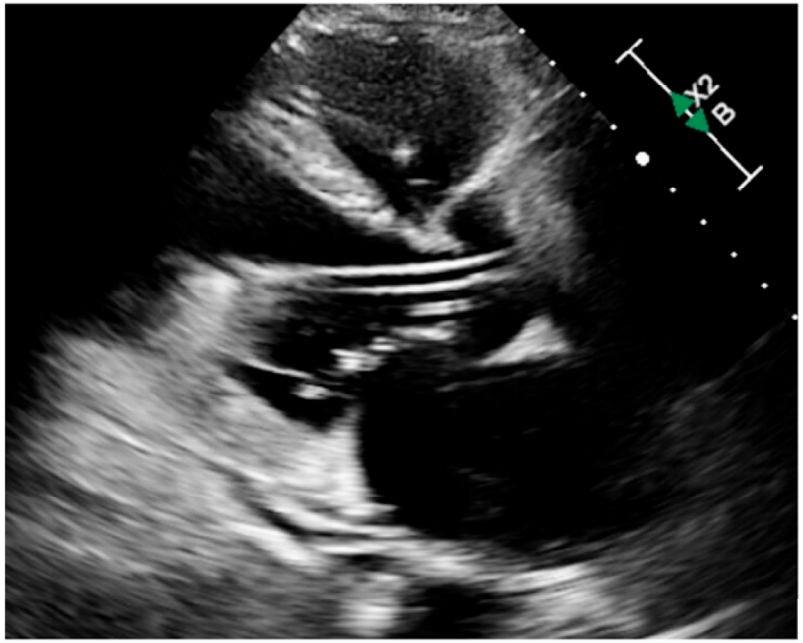

3,5cm
~ AoV
annulus
*
SPEC.
DATE



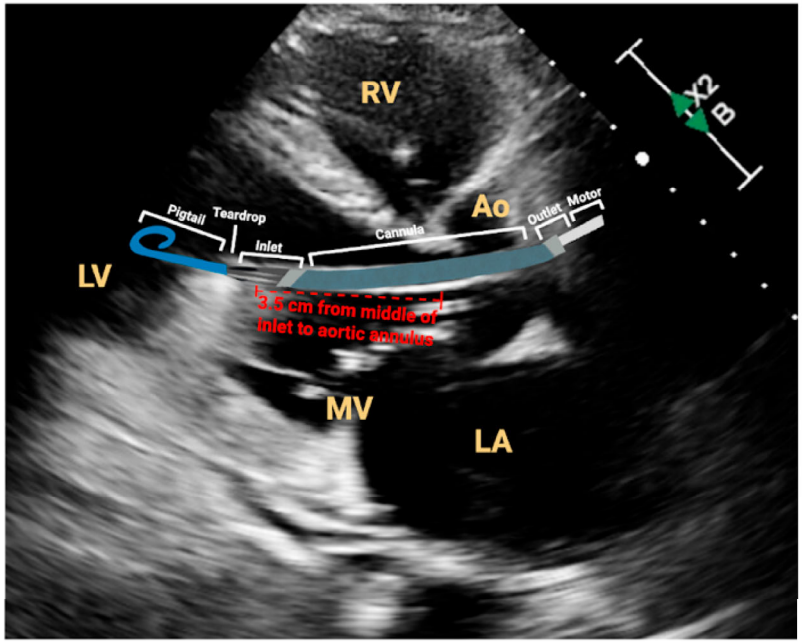
PLAX view




PLAX view annotated

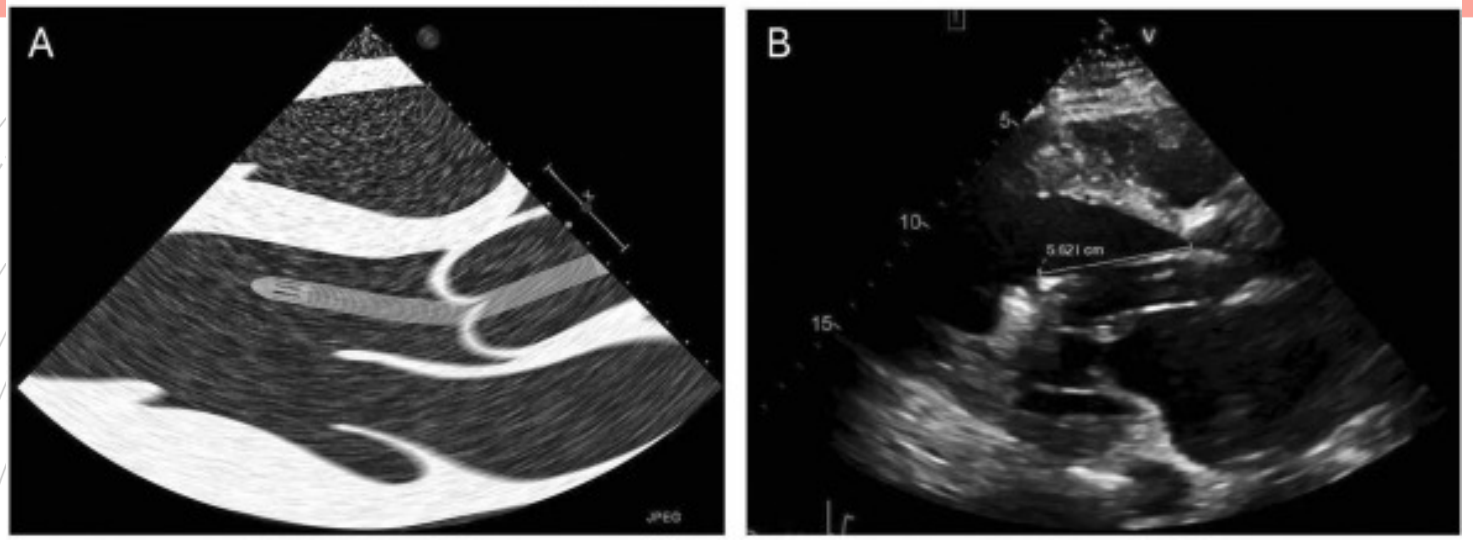



PLAX view

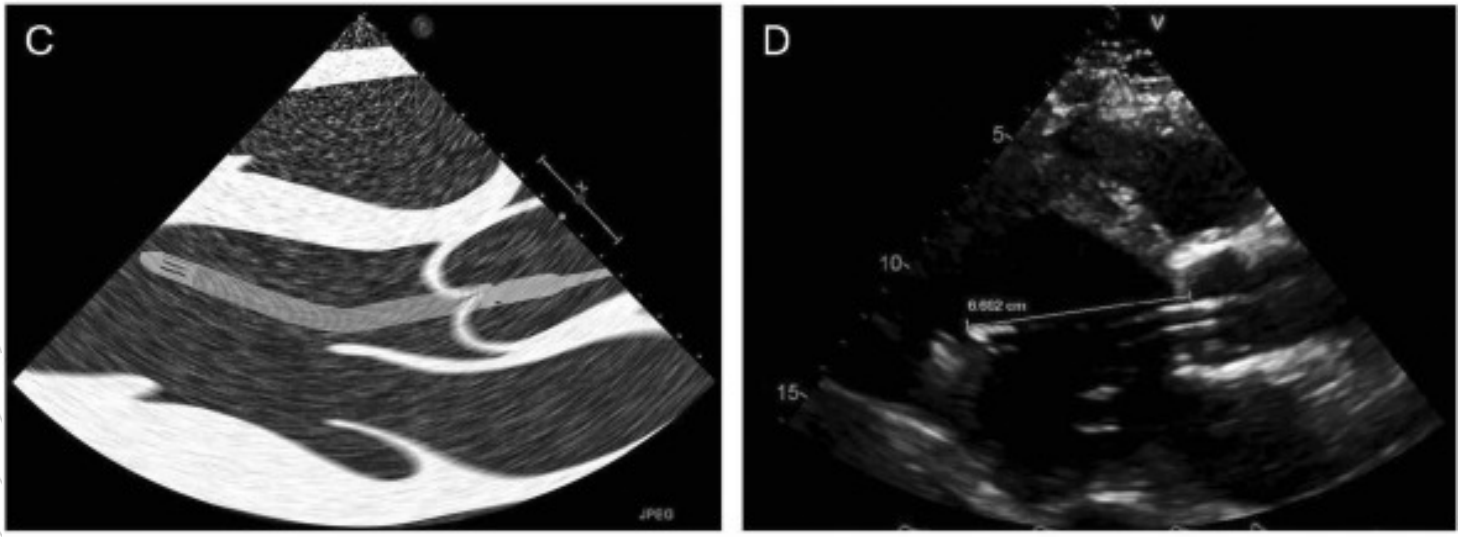



PLAX view annotated

## Optimal Position

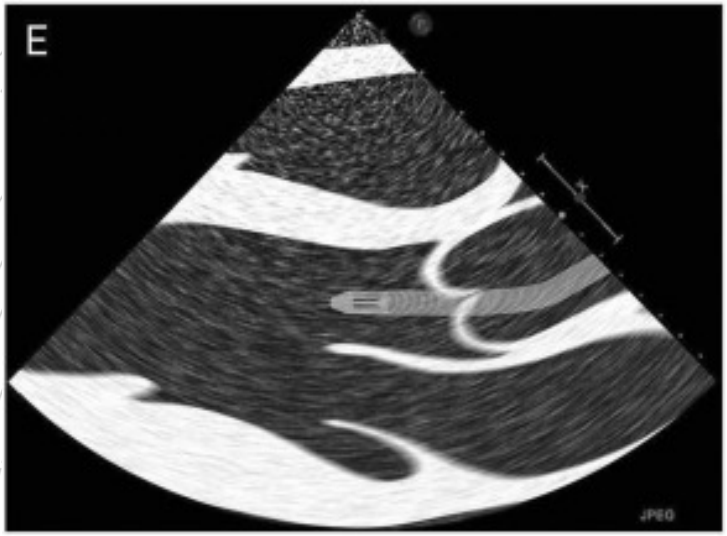


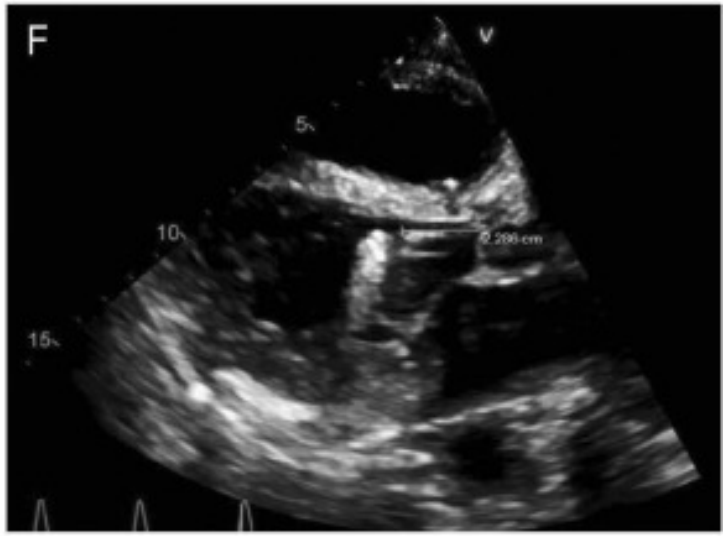

## Too Deep



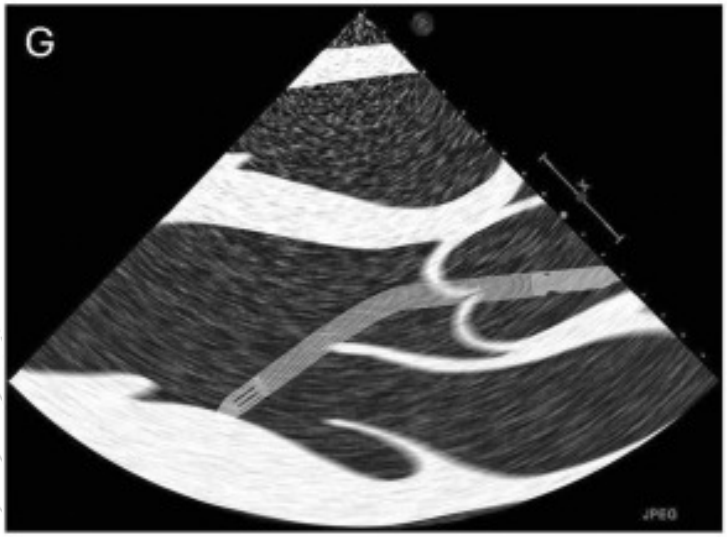

Bernhardt et al. The Journal of Heart and Lung Transplantation 2025; 44 (11) : 1688–1702.

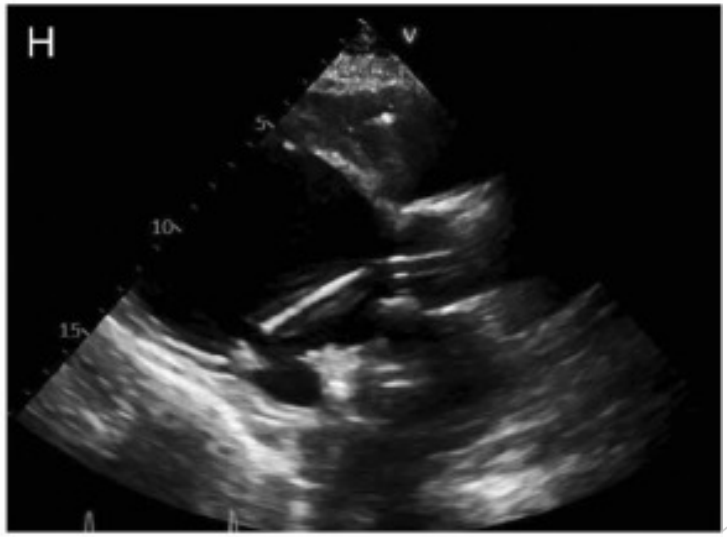
## Too Shallow




## Inverted

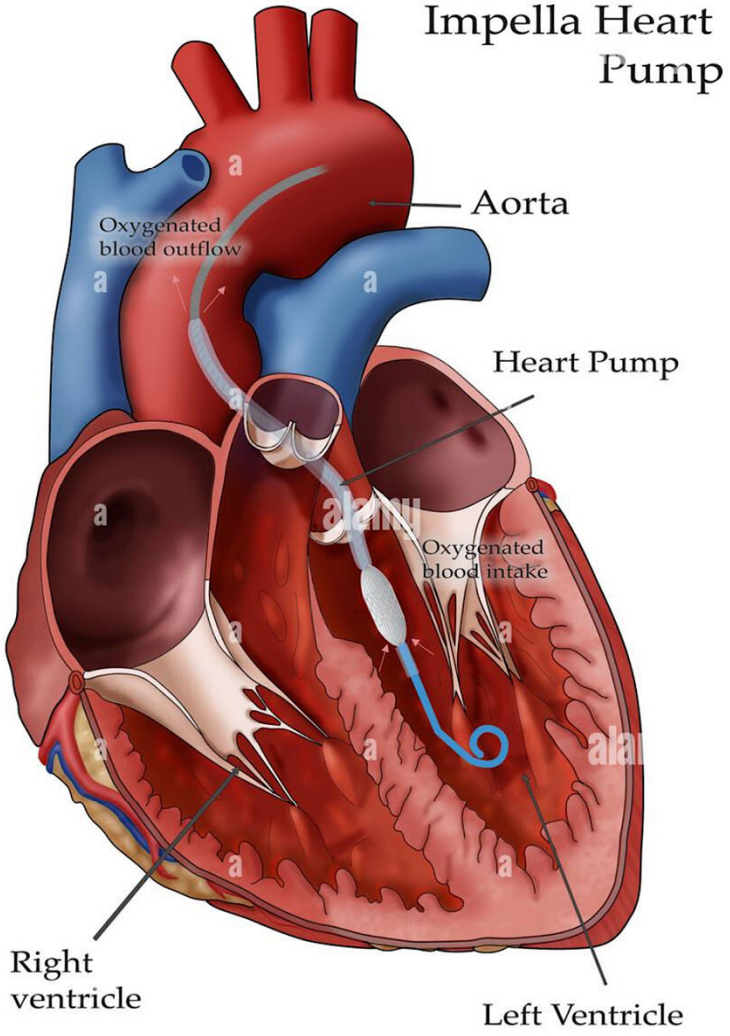


The middle of the inlet of the Impella CP® should be approximately 3.5 cm from the aortic valve

while the middle of the inlet of the Impella 5.5® with SmartAssist® should be approximately 5 cm from the aortic valve.

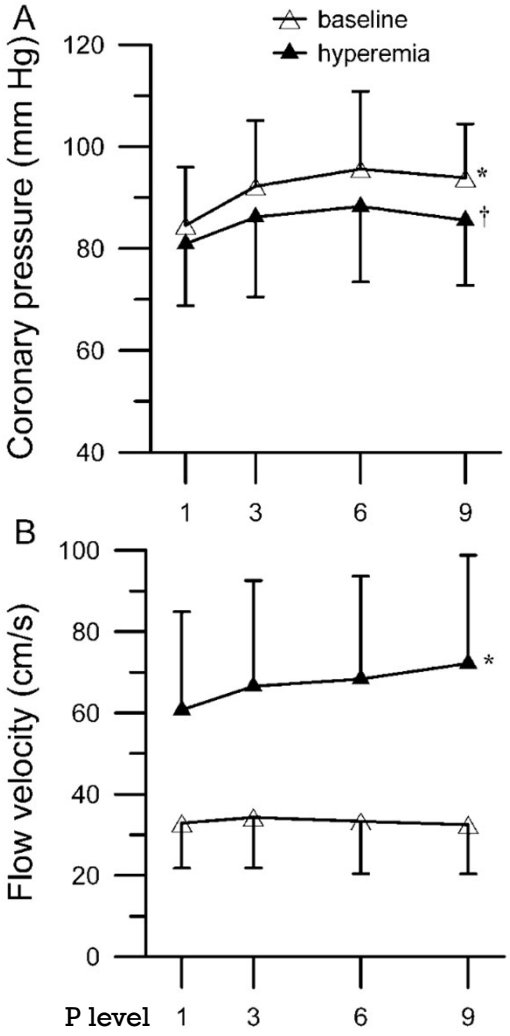
# RATIONNEL PHYSIOPATHOLOGIQUE




1. ↑ Perfusion coronarienne
   ↑ Délivrance O2 myocardique

2. Unloading : décharge ventriculaire active

# PERFUSION CORONARIENNE



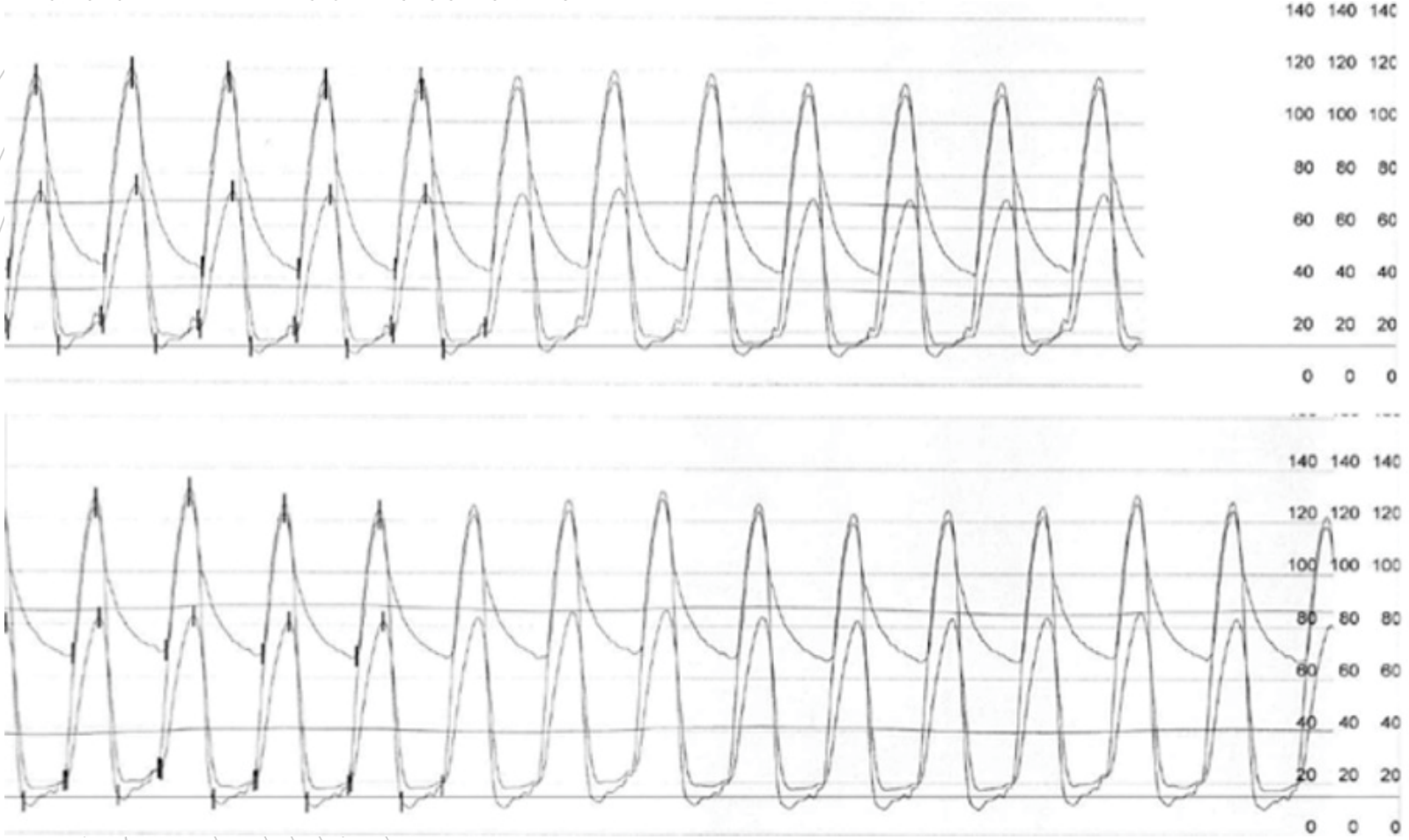

11 patients - High-risk PCI - FEVG 35 ± 10%

**TABLE II. Hemodynamic Characteristics**

| | Impella® support level | | | | |
|---|---|---|---|---|---|
| | 1 | 3 | 6 | 9 | *P* |
| Baseline $P_a$ | 85 ± 11 | 93 ± 13 | 96 ± 15 | 96 ± 10 | 0.001 |
| Baseline $P_d$ | 85 ± 11 | 92 ± 13 | 96 ± 15 | 94 ± 11 | 0.001 |
| Hyperemic $P_a$ | 85 ± 12 | 91 ± 15 | 94 ± 14 | 92 ± 12 | 0.006 |
| Hyperemic $P_d$ | 81 ± 12 | 86 ± 16 | 88 ± 15 | 86 ± 13 | 0.02 |
| FFR | 0.97 ± 0.03 | 0.96 ± 0.04 | 0.96 ± 0.04 | 0.95 ± 0.06 | 0.2 |
| Baseline APV | 33 ± 11 | 34 ± 12 | 33 ± 13 | 32 ± 12 | 0.9 |
| Hyperemic APV | 61 ± 24 | 67 ± 26 | 68 ± 25 | 72 ± 27 | 0.001 |
| CFVR | 1.88 ± 0.52 | 2.10 ± 0.62 | 2.19 ± 0.67 | 2.34 ± 0.63 | <0.001 |
| Baseline MR | 2.99 ± 1.79 | 3.23 ± 1.96 | 3.31 ± 2.08 | 3.25 ± 1.87 | 0.2 |
| Hyperemic MR | 1.71 ± 0.93 | 1.64 ± 0.82 | 1.55 ± 0.71 | 1.36 ± 0.58 | 0.1 |
| ΔMR | 1.28 ± 1.32 | 1.58 ± 1.52 | 1.76 ± 1.70 | 1.89 ± 1.43 | 0.005 |

Values are mean ± SD. $P_a$, mean aortic pressure (mm Hg); $P_d$, mean distal coronary pressure (mm Hg); FFR, fractional flow reserve; CFVR, coronary flow velocity reserve; APV, average peak flow velocity (cm/sec); MR, coronary microvascular resistance index (mm Hg $cm^{-1}$ sec); ΔMR, variable arteriolar resistance index (mm Hg $cm^{-1}$ sec).

Remmelink et al. Catheterization and Cardiovascular Interventions 2007; 70 (4) : 532–537.




**Upper Tracing**

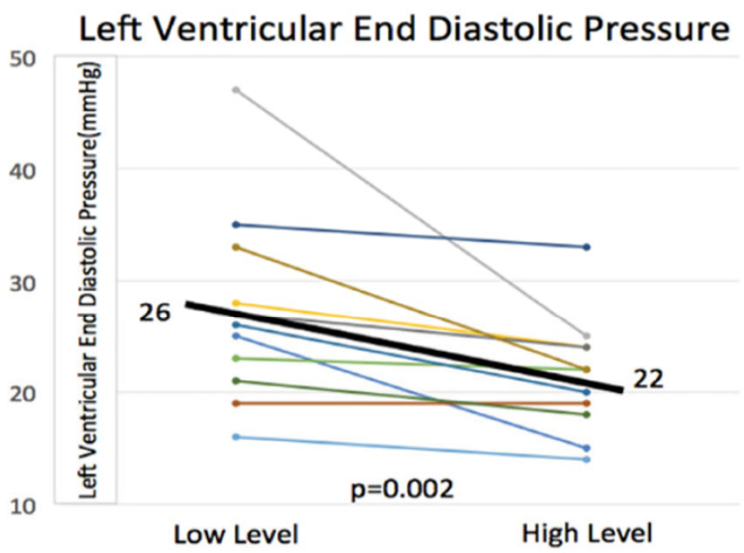
Impella CP at P2

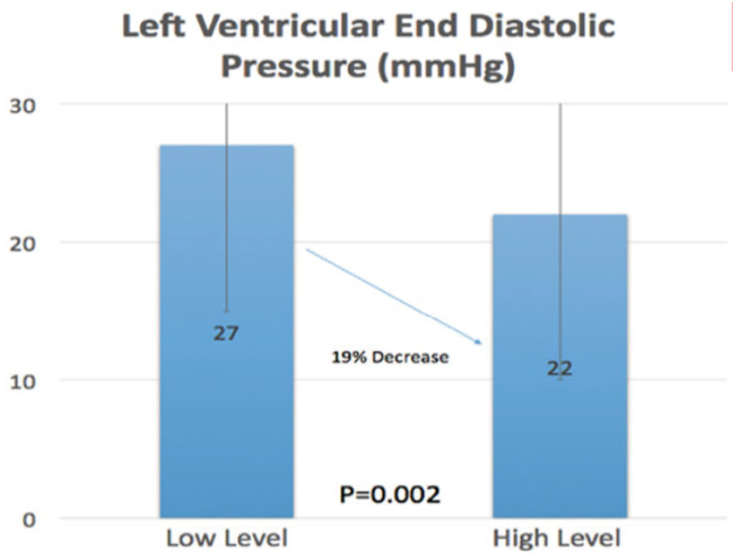
| | |
|---|---|
| LV | 116/12/21 mmHg |
| Ao | 112/43/68 mmHg |
| DCP | 72/19/35mmHg |
| ECPP | 47 mmHg |
| DPP | 22 mmHg |

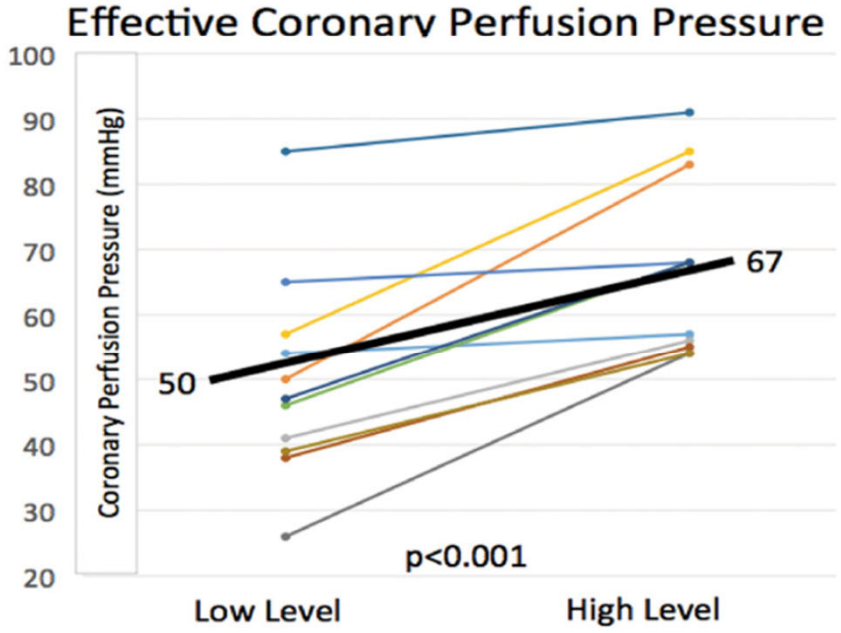
**Lower Tracing**

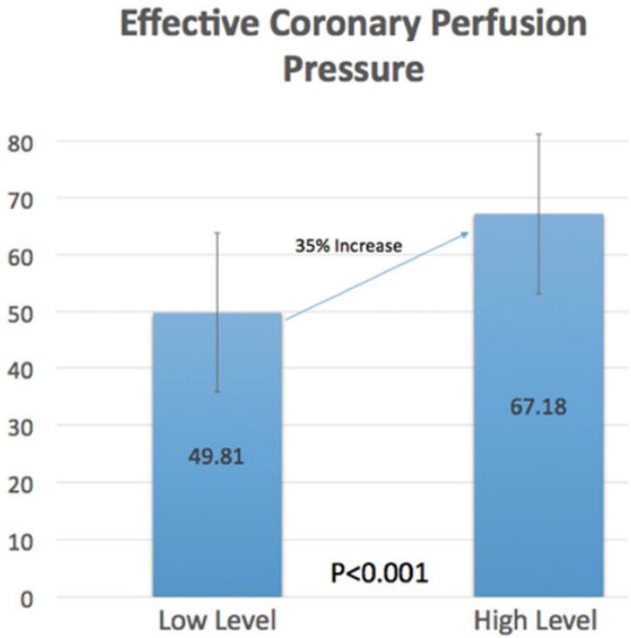
Impella CP at P8

| | |
|---|---|
| LV | 126/12/18 mmHg |
| Ao | 122/68/86 mmHg |
| DCP | 81/20/41 mmHg |
| ECPP | 68 mmHg |
| DPP | 50 mmHg |


Left Ventricular End Diastolic Pressure
Left Ventricular End Diastolic Pressure(mmHg)
50
40
30
20
10
26
22
p=0.002
Low Level
High Level


Left Ventricular End Diastolic Pressure (mmHg)
30
20
10
0
27
19% Decrease
22
P=0.002
Low Level
High Level


Effective Coronary Perfusion Pressure
Coronary Perfusion Pressure (mmHg)
100
90
80
70
60
50
40
30
20
50
67
p<0.001
Low Level
High Level

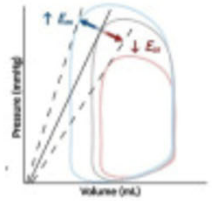

Effective Coronary Perfusion Pressure
80
70
60
50
40
30
20
10
0
35% Increase
49.81
67.18
P<0.001
Low Level
High Level

# PHYSIOLOGIE DE LA DÉCHARGE VENTRICULAIRE

**M**echano

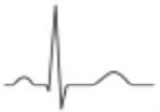
*Percutaneous VAD*

**I**notropic



*End-systolic Elastance*

**C**hronotropic

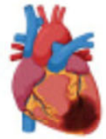


*Heart Rate*

**U**nloading

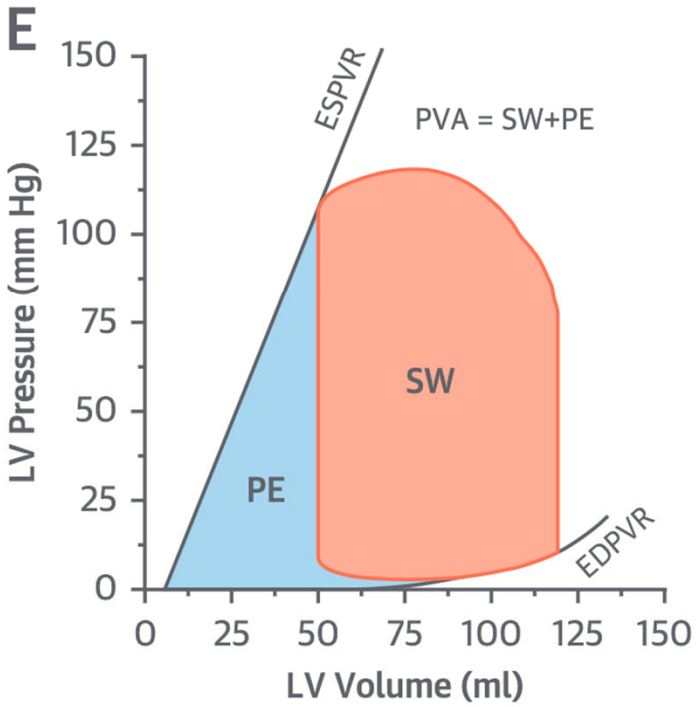
*... A new concept for managing post-AMI cardiogenic shock*

**$MVO_2$**



*in a theoretical model, with potential for further ↓ in infarct size relative to mechanical unloading alone*

Alkhunaizi et al. Journal of the Society for Cardiovascular Angiography & Interventions 2025; 4 (11) : 103927.




$$\mathrm{MVO_2} = \alpha \times (\mathrm{PVA} \times \mathrm{HR}) + \beta \times (\mathrm{E_{es}} \times \mathrm{HR}) + \gamma \times (\mathrm{HR})$$

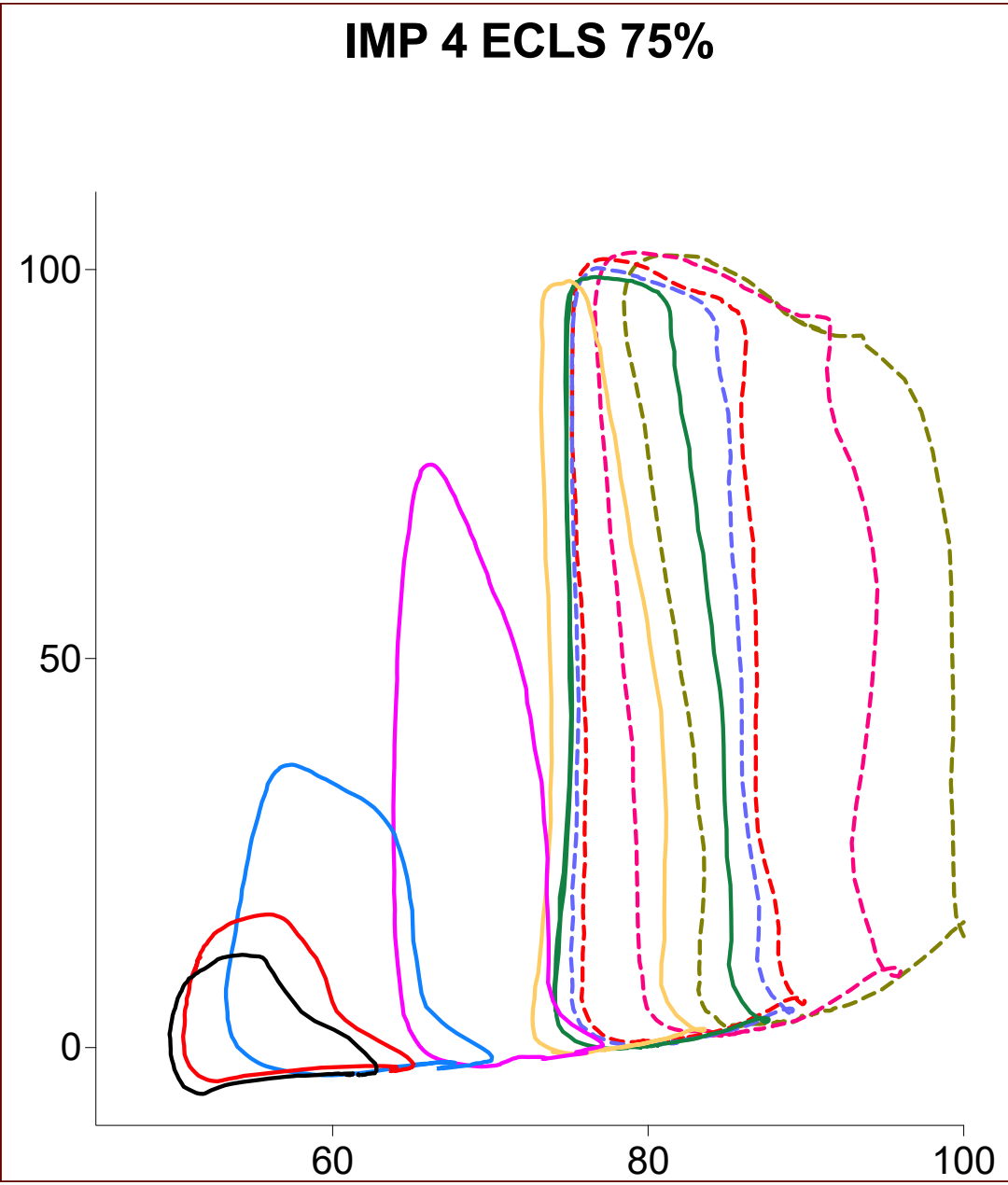
where α, β, and γ are constants that have been defined previously as follows:

$$\alpha = 1.8 \times 10^{-5}\ \mathrm{mL\ O_2 \cdot mmHg^{-1} \cdot mL^{-1}}$$

$$\beta = 2.4 \times 10^{-3}\ \mathrm{mL\ O_2 \cdot beats^{-1} \cdot mmHg^{-1} \cdot mL \cdot g \cdot 100^{-1}}$$

$$\gamma = 1.4 \times 10^{-2}\ \mathrm{mL\ O_2 \cdot beats^{-1} \cdot g \cdot 100^{-1}}$$

Alkhunaizi et al. Journal of the Society for Cardiovascular Angiography & Interventions 2025; 4 (11) : 103927.



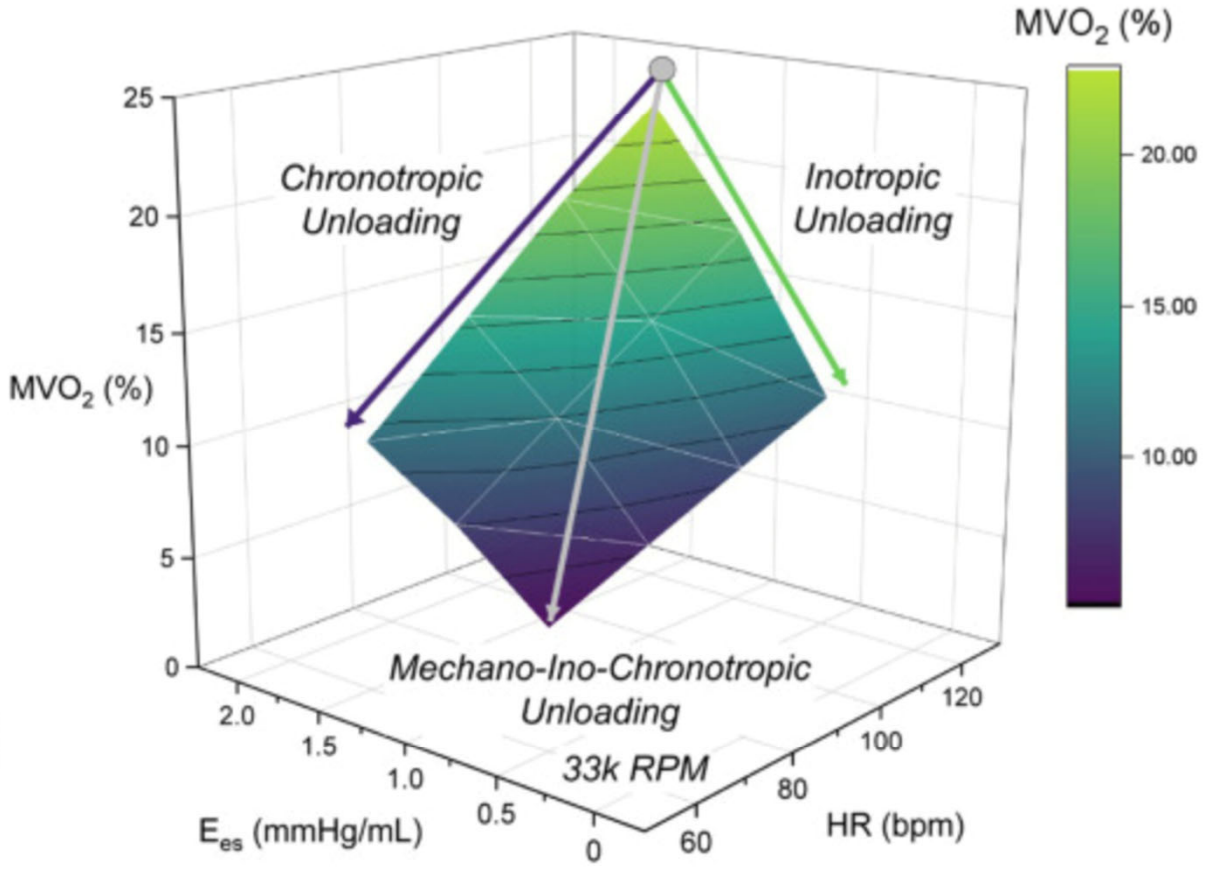

Loi de Laplace :

- Impella permet la réduction des contraintes pariétales et de la MvO2

- Diminution de la PVA : économie énergétique

- Effet dose-réponse : P8 > P4

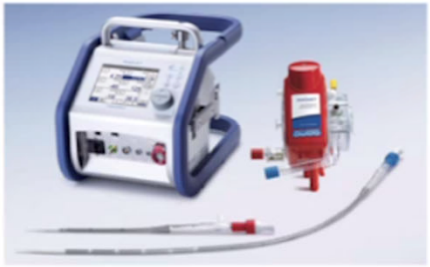
Beurton et al. experimental data

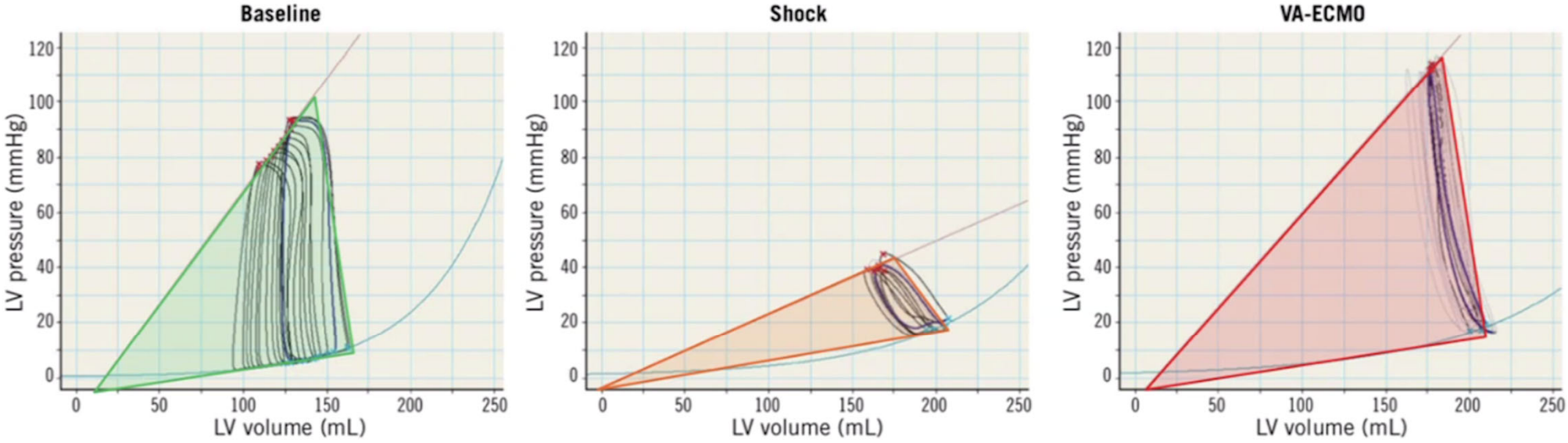



**In a simulation with full mechanical unloading with a pVAD operating at 33000 RPM, $MVO_2$ is most reduced when $E_{es}$—reflecting inotropy—and HR—reflecting chronotropy—are reduced.**

Alkhunaizi et al. Journal of the Society for Cardiovascular Angiography & Interventions 2025; 4 (11) : 103927.

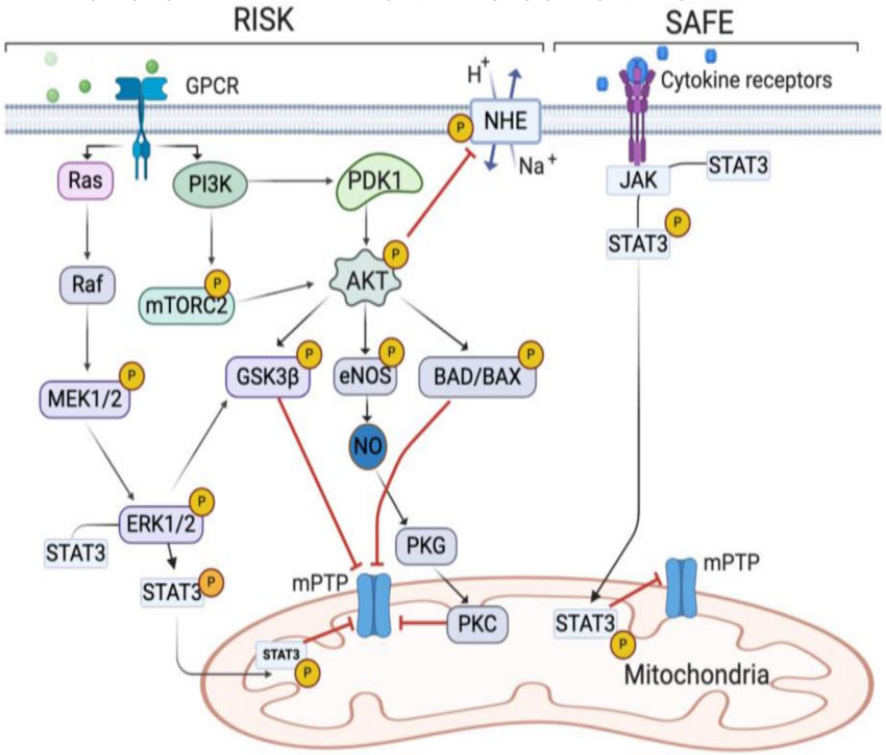
- **↑↑ LV Afterload - ↑ LV Congestion - ↑↑ LV $MVO_2$**
  - Swine CS model *(microspheres embolization)*
    - **Baseline CO : 5,2** [4,5-5,8] → **CS : 2,3** [2,0-2,6] L/min
    - **pVA-ECMO flow : 3,0** L/min + **residual CO : 2,9** [1,9-3,8] L/min






O. Moller-Helgestad et al. **EuroIntervention** 2019

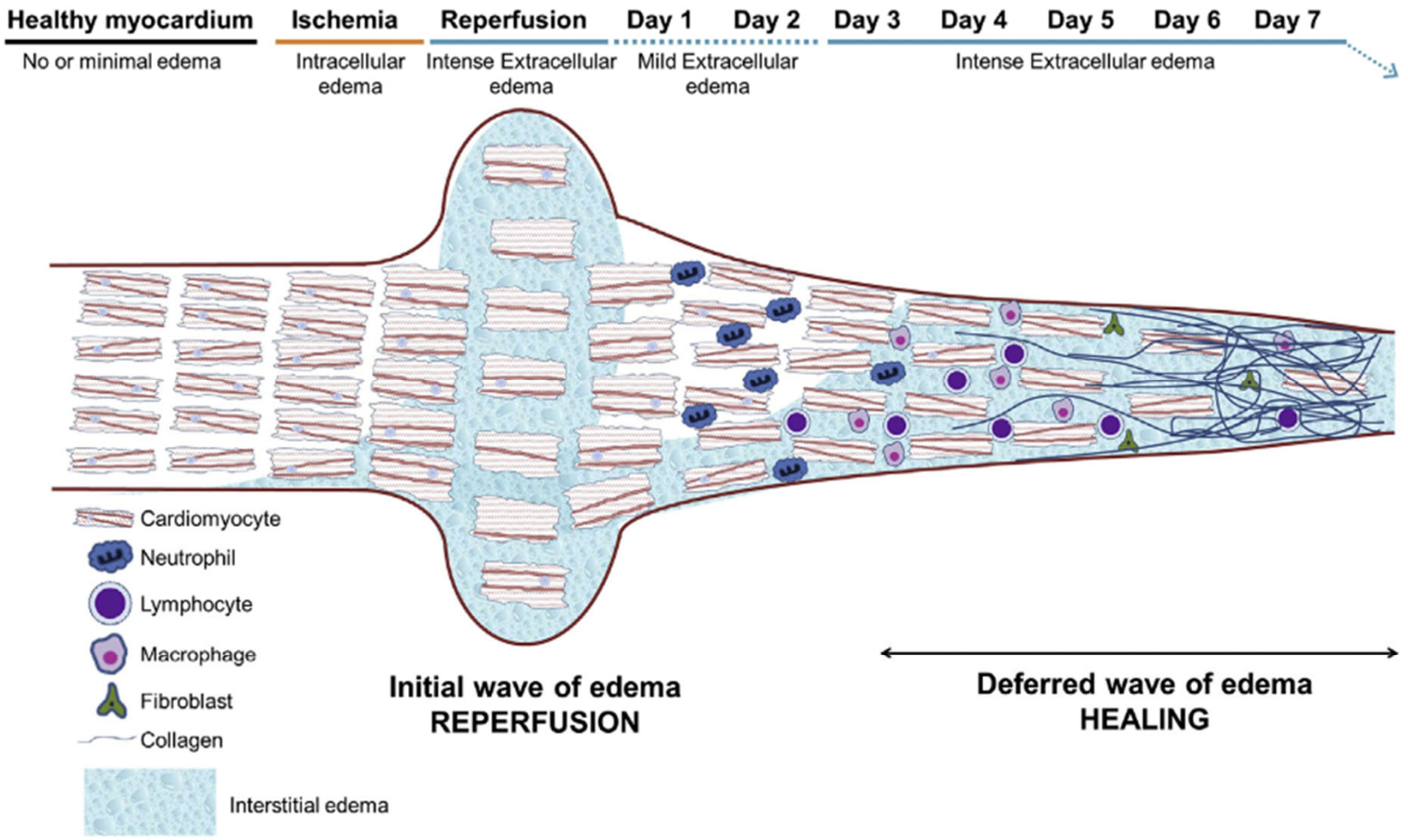
# Voies de signalisation




Cardiac Exosomes in Ischemic Heart Disease—A Narrative Review

Activation surtout en cas de décharge avant reperfusion

**FIGURE 1** Dynamic Tissue Composition Changes Occurring After Ischemia/Reperfusion

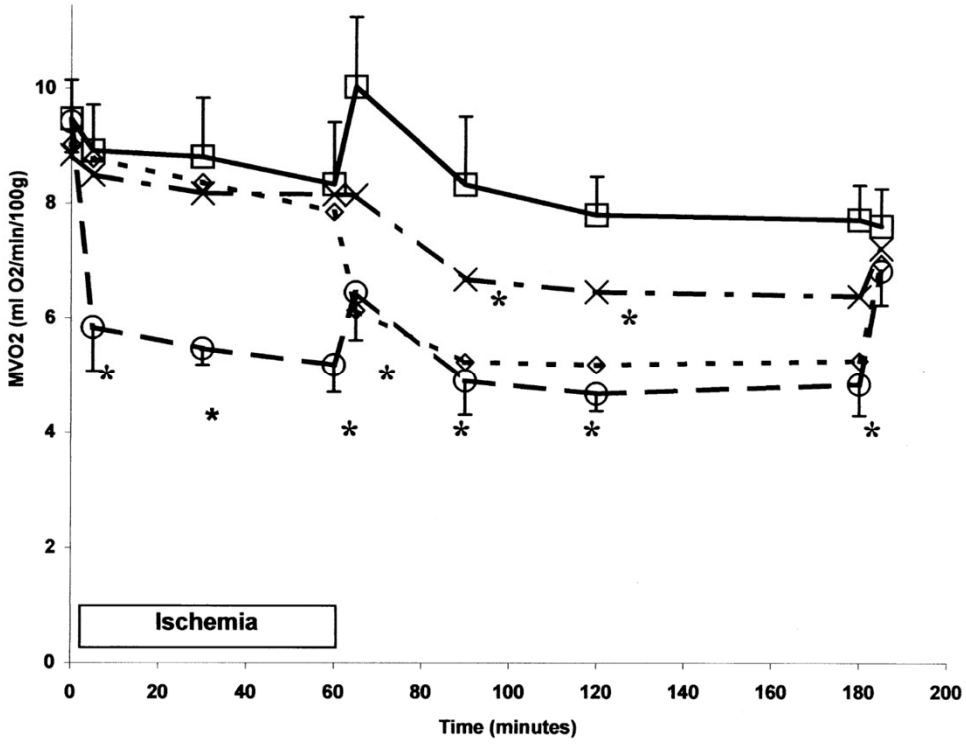


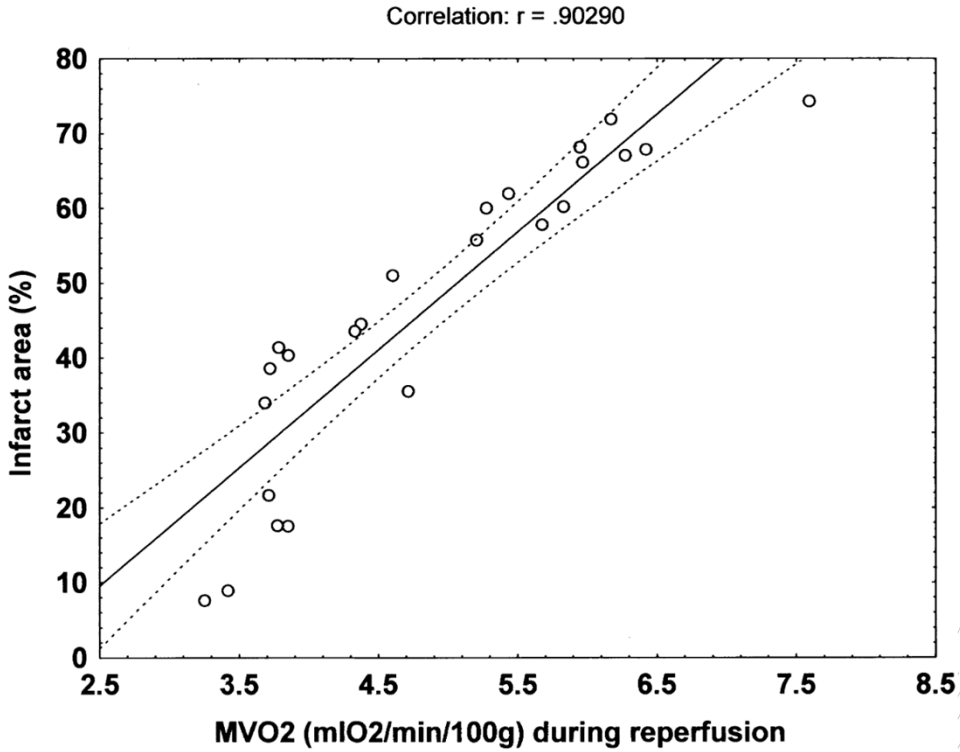

https://www.jacc.org/doi/epdf/10.1016/j.jacc.2019.05.024

# Le unloading réduit la taille de l'infarctus

## Left Ventricular Support by Catheter-Mounted Axial Flow Pump Reduces Infarct Size

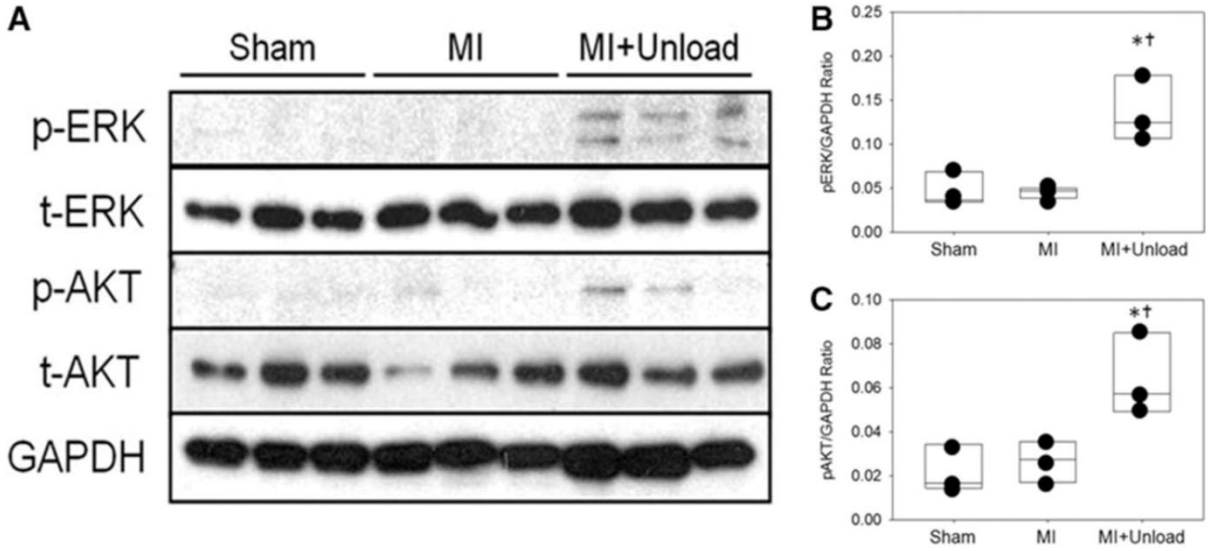
Bart Meyns, MD, PHD, Jarek Stolinski, MD, Veerle Leunens, Erik Verbeken, MD, PHD, Willem Flameng, MD, PHD
*Leuven, Belgium*

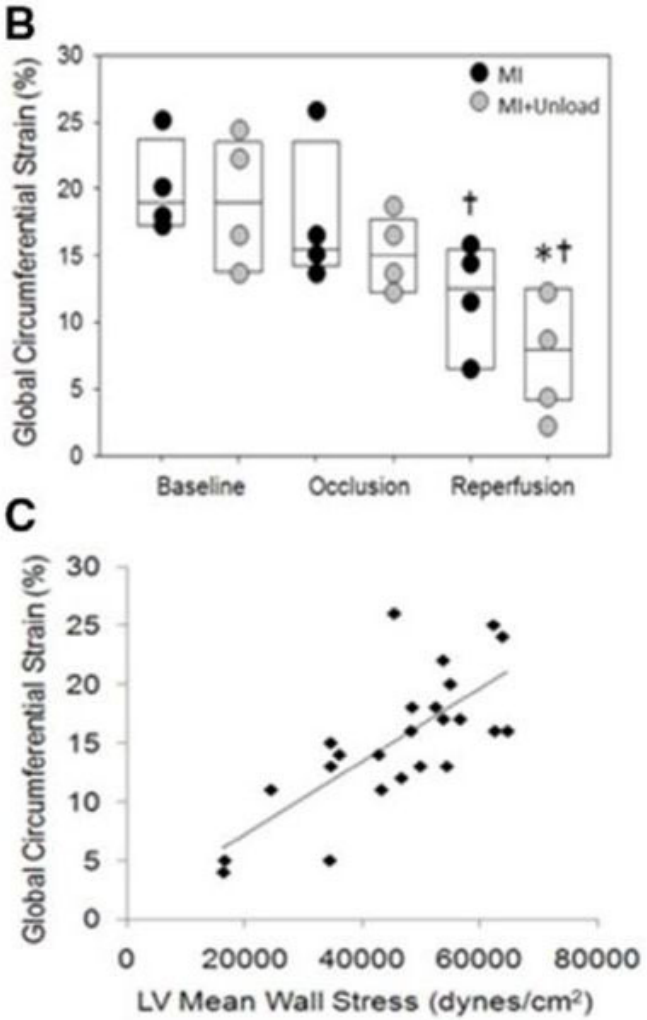


# Mechanically Unloading the Left Ventricle Before Coronary Reperfusion Reduces Left Ventricular Wall Stress and Myocardial Infarct Size

Navin K. Kapur, MD, Vikram Paruchuri, MD, Jose Angel Urbano-Morales, MD, Emily E. Mackey, BSc, Gerard H. Daly, MD, Xiaoying Qiao, PhD,



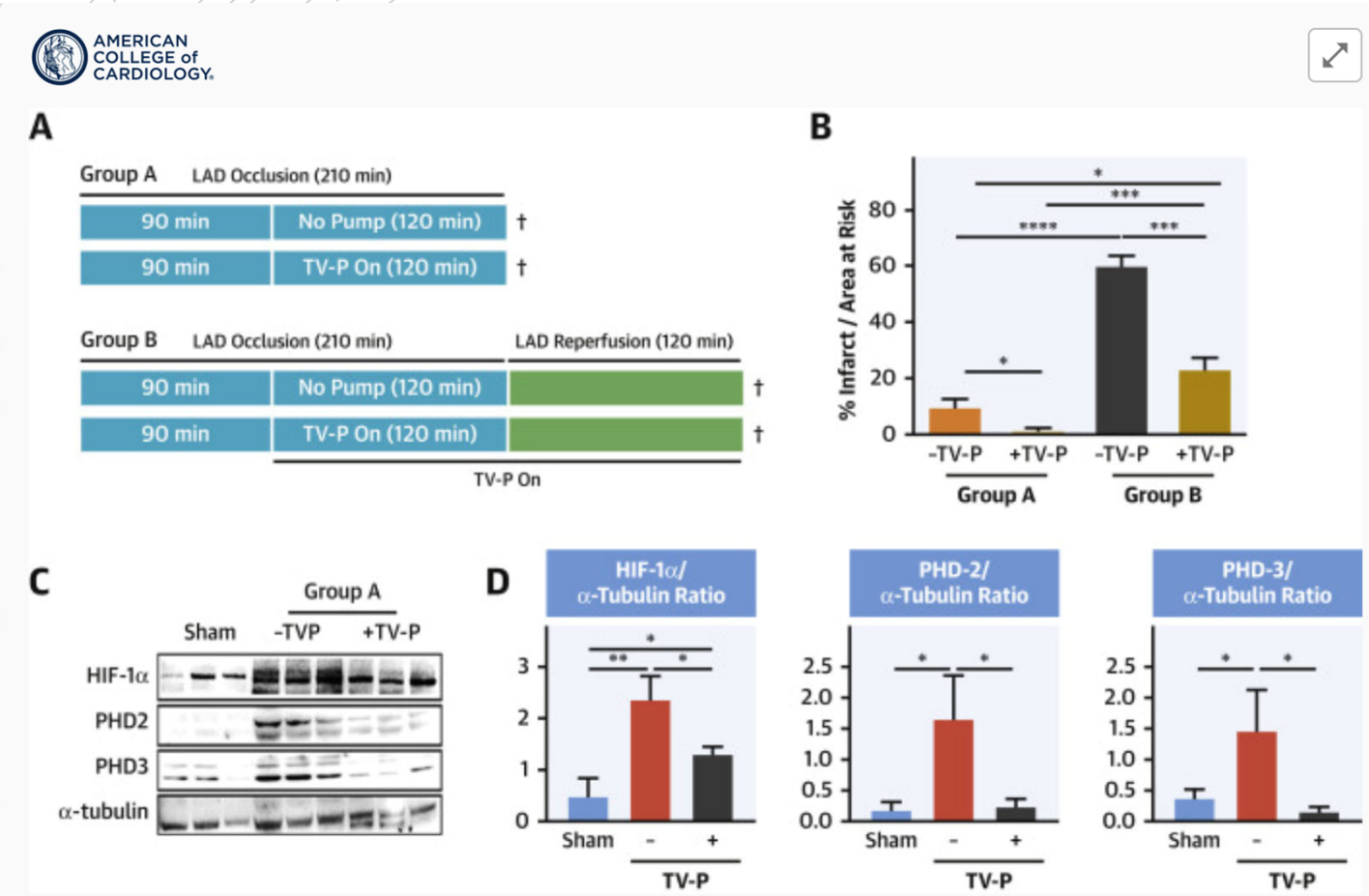
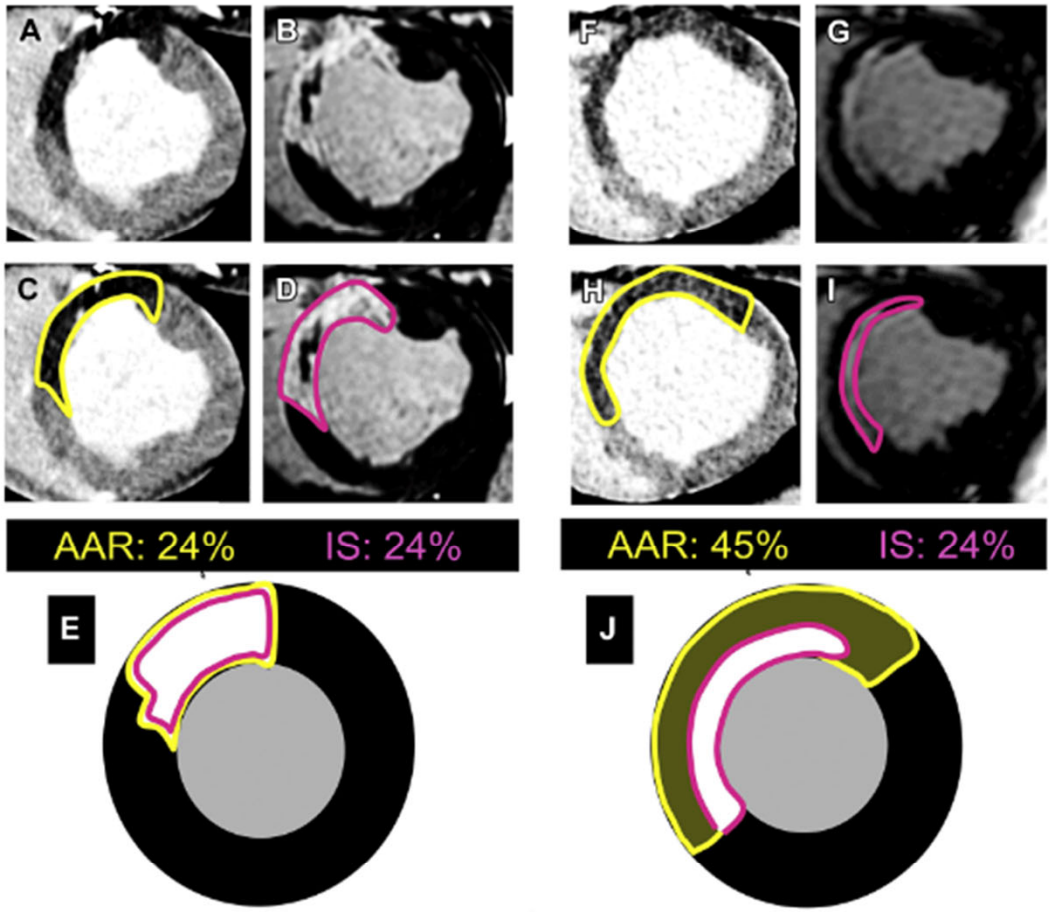



**Figure 2.** Left Ventricular Unloading With Prolonged Coronary Occlusion Model

Transvalvular Ventricular Unloading Before Reperfusion in Acute Myocardial Infarction.

J Am Coll Cardiol. 11 août 2020.

**FIGURE 4** Absolute Infarct Size (% LV) Versus Relative IS (% AAR)

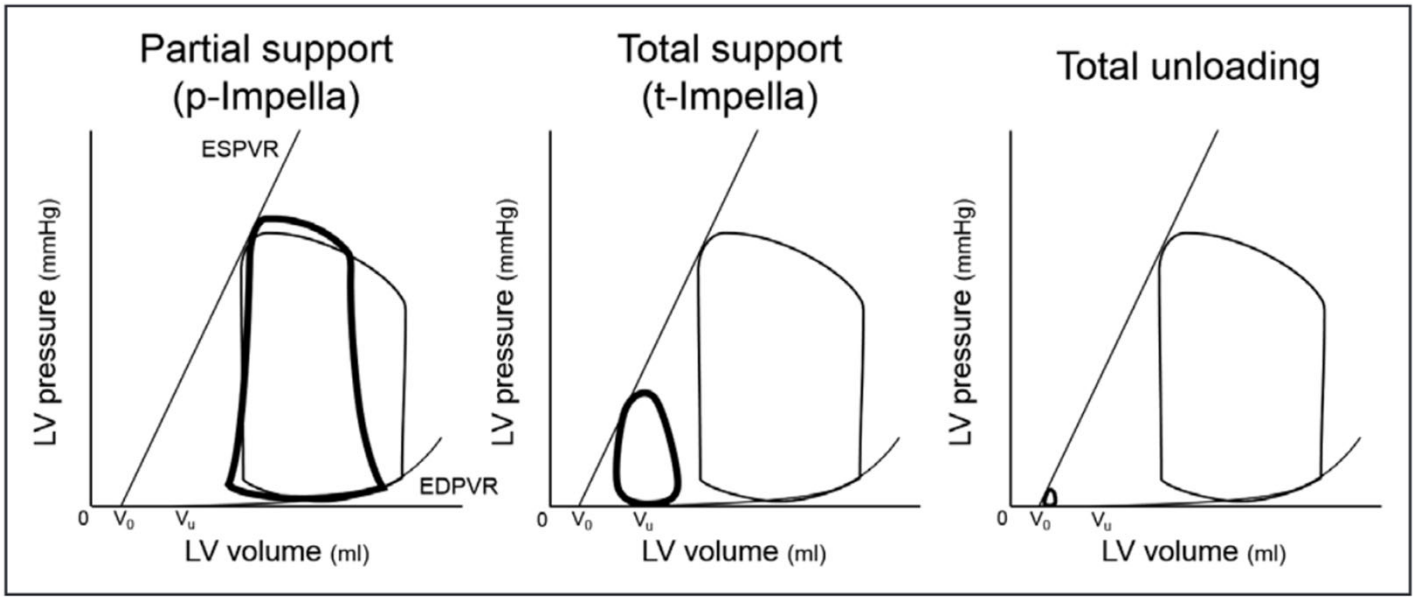



Two subjects with the same absolute infarct size may have different amounts of salvage. The illustrated cases correspond to experimental ischemia/reperfusion (I/R) (pig model). **(A and F)** Arterial enhanced multidetector computed tomography (MDCT) perfusion scans during index coronary occlusion to delineate true area at risk (AAR) (dark areas not perfused). **(C and H)** The same as **A and F,** but with the AAR traced. **(B and G)** LGE CMR 1 week after I/R (in **D and I**, the infarct size [IS] has been traced). **(E and J)** Representation of AAR and IS overlaid (**yellow** corresponds to AAR and **pink** to IS). In the **left** case, the entire AAR is transmurally infarcted with no salvage at all. In the case to the **right,** AAR is much larger, but infarction occupies only the subendocardial area, suggesting large amount of salvaged myocardium. The case to the **right** corresponds to a subject undergoing a given cardioprotective strategy (IPC in this case). Abbreviations as in Figure 2.

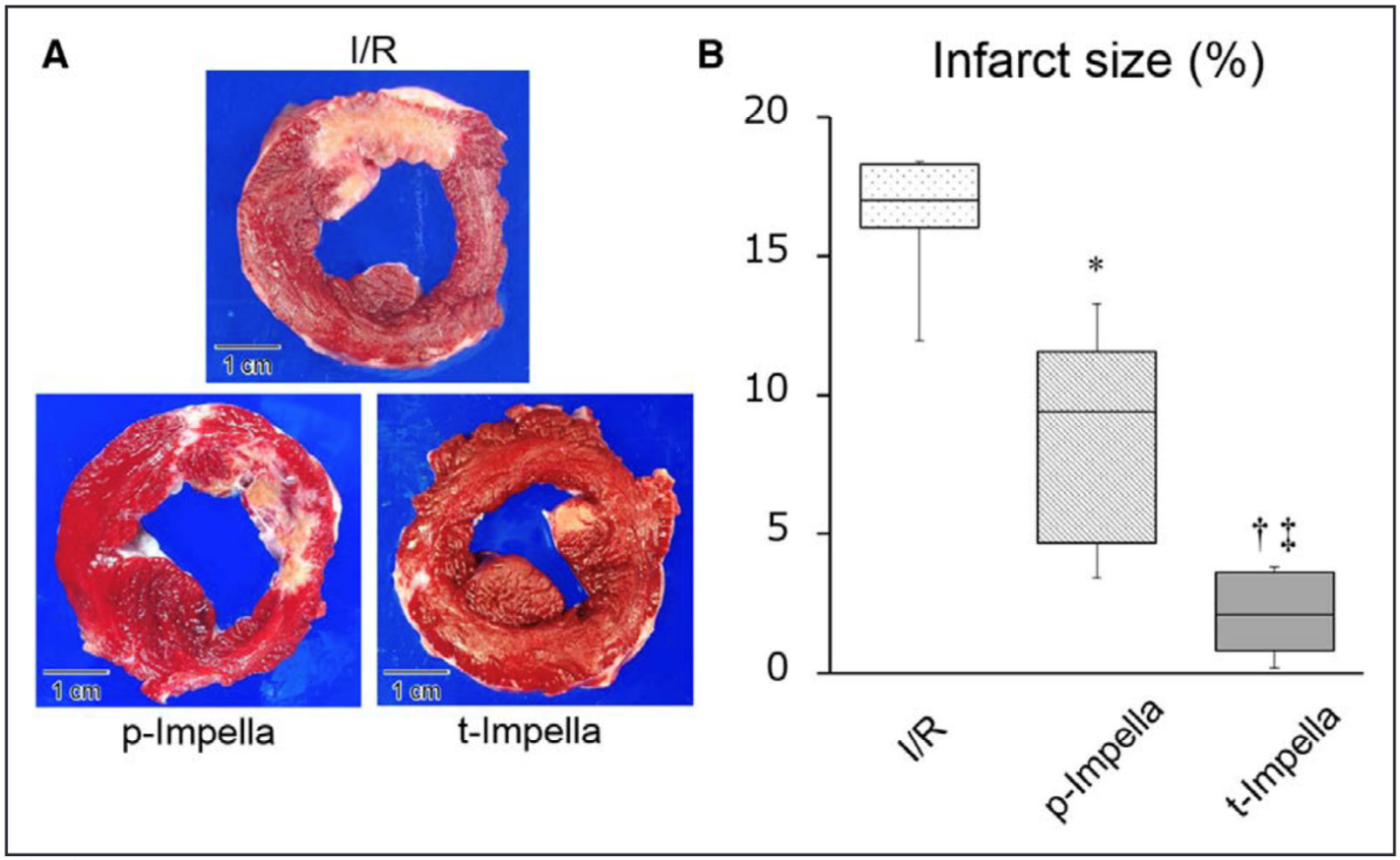
20 chiens

sham (thoracotomy only, no left anterior descending coronary artery occlusion or Impella support; n=5),
I/R (180 minutes ischemia followed by 60 minutes reperfusion, no Impella support; n=5),
p-Impella (p-Impella from 60 minutes after onset of ischemia to 60 minutes after reperfusion; n=5),
t-Impella (t-Impella from 60 minutes after onset of ischemia to 60 minutes after reperfusion; n=5).

Evaluation J28

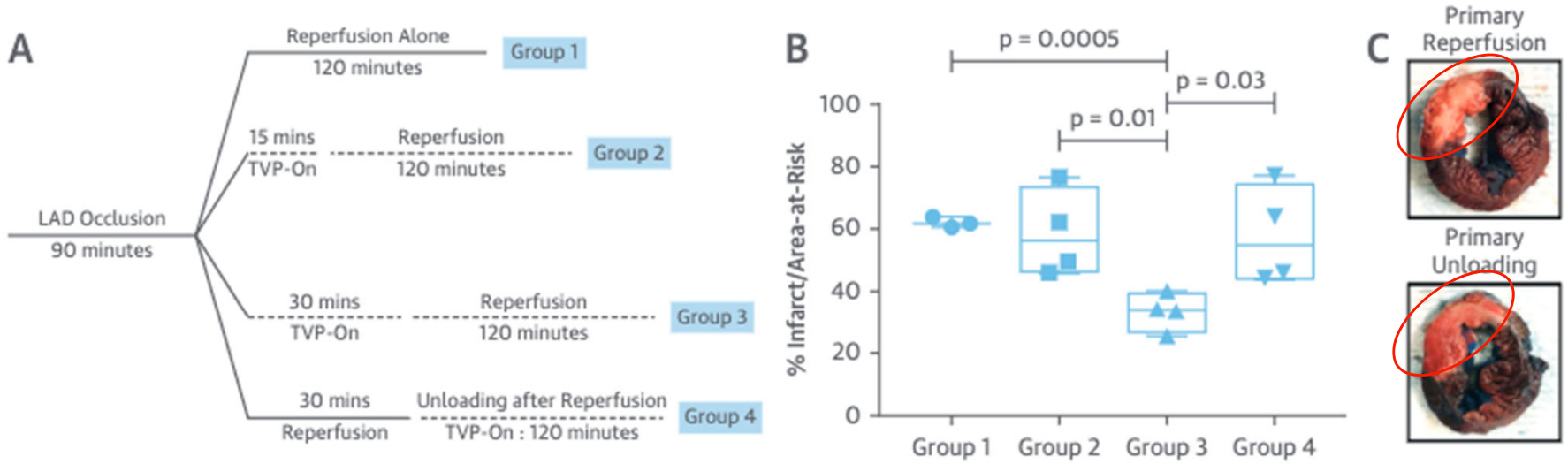



Saku et al. Circulation: Heart Failure 2018; 11 (5) : e004397.

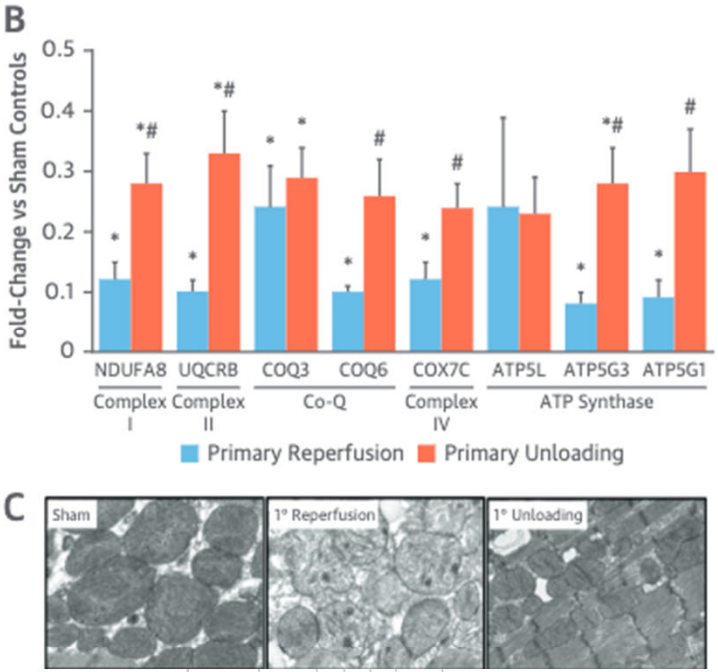


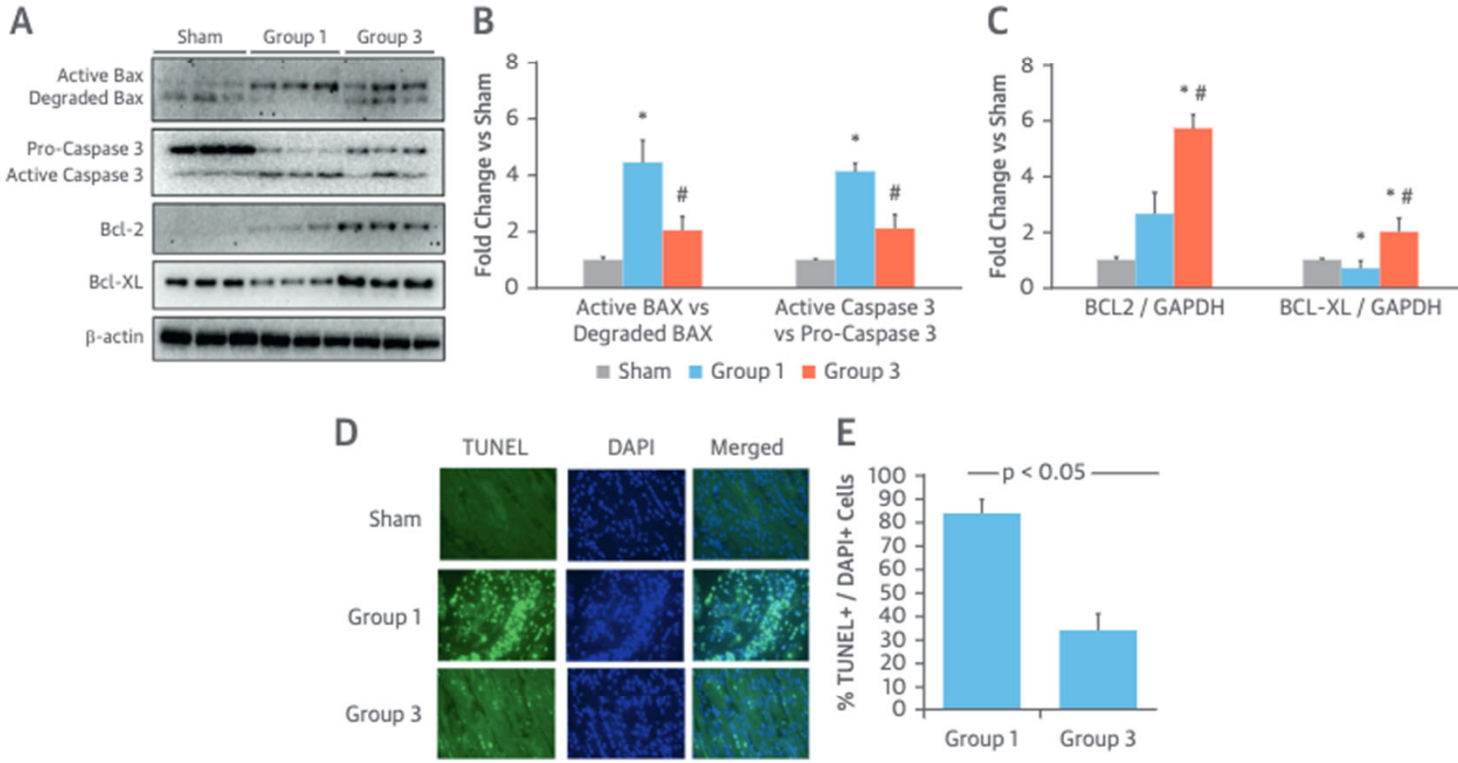

Saku et al. Circulation: Heart Failure 2018; 11 (5) : e004397.

**FIGURE 1** **Timing of Unloading Between Groups and Infarct Quantification**




**(A)** Flowchart illustrating the effect of reperfusion alone (group 1), left ventricular unloading for 15 min (group 2) or 30 min (group 3) before reperfusion, or left ventricular unloading after reperfusion (group 4). **(B)** Infarct area as a percentage of the area at risk for each group (1-way analysis of variance = 0.017 across all 4 groups). **(C)** Representative images of infarct quantitation using triphenyltetrazolium chloride and Evan's blue counterstaining from group 1 and group 3 (n = 4 per group). **Red** staining indicates the area at risk, **white** staining indicates infarcted myocardium, and **blue** staining indicates myocardial tissue outside the area at risk. LAD = left anterior descending; TVP = transvalvular pump.

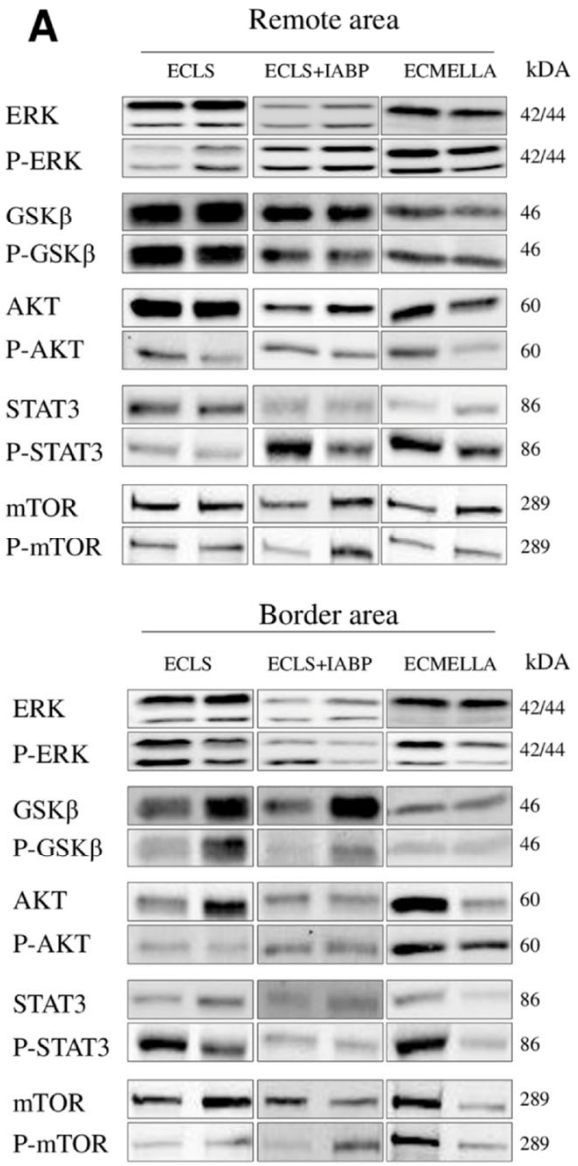


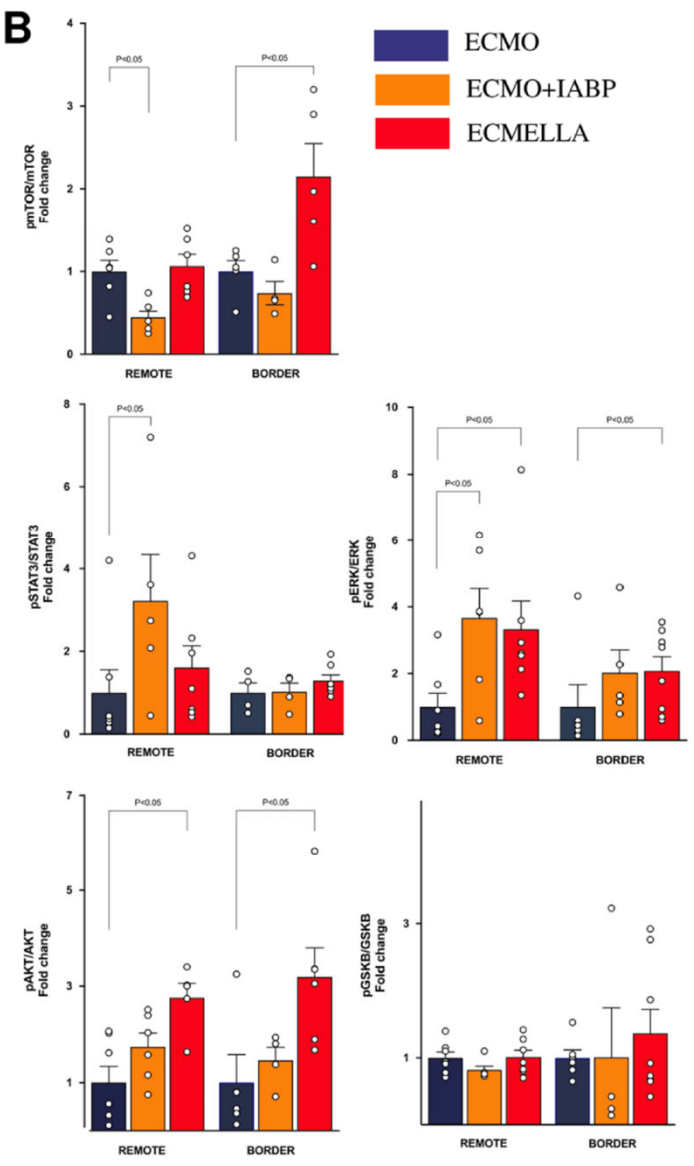



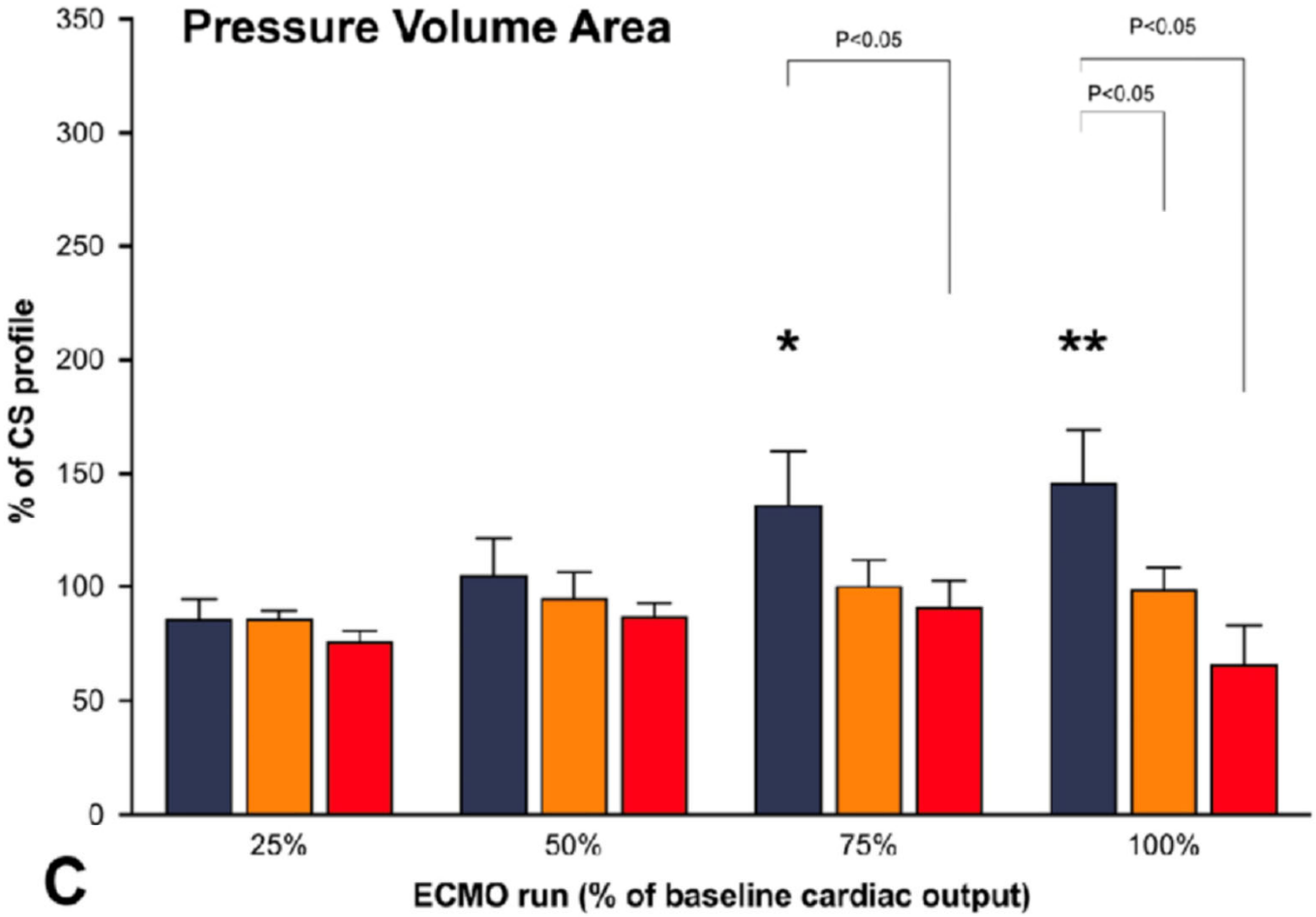

Saku et al. Circulation: Heart Failure 2018; 11 (5) : e004397.

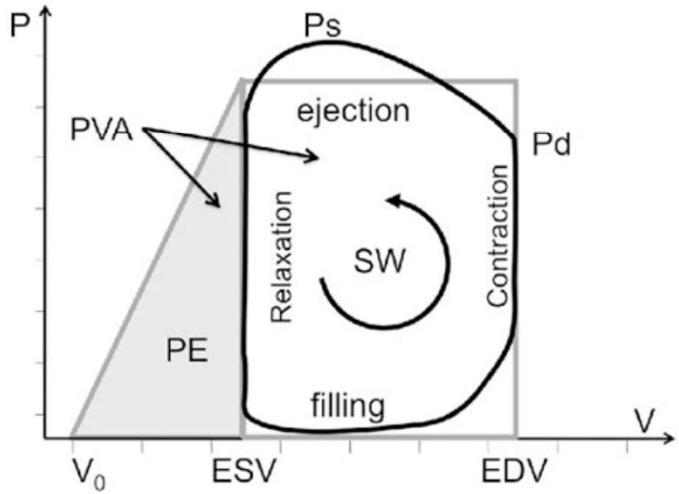
Expérimentation sur brebis
ECMO avec ou sans IABP/Impella

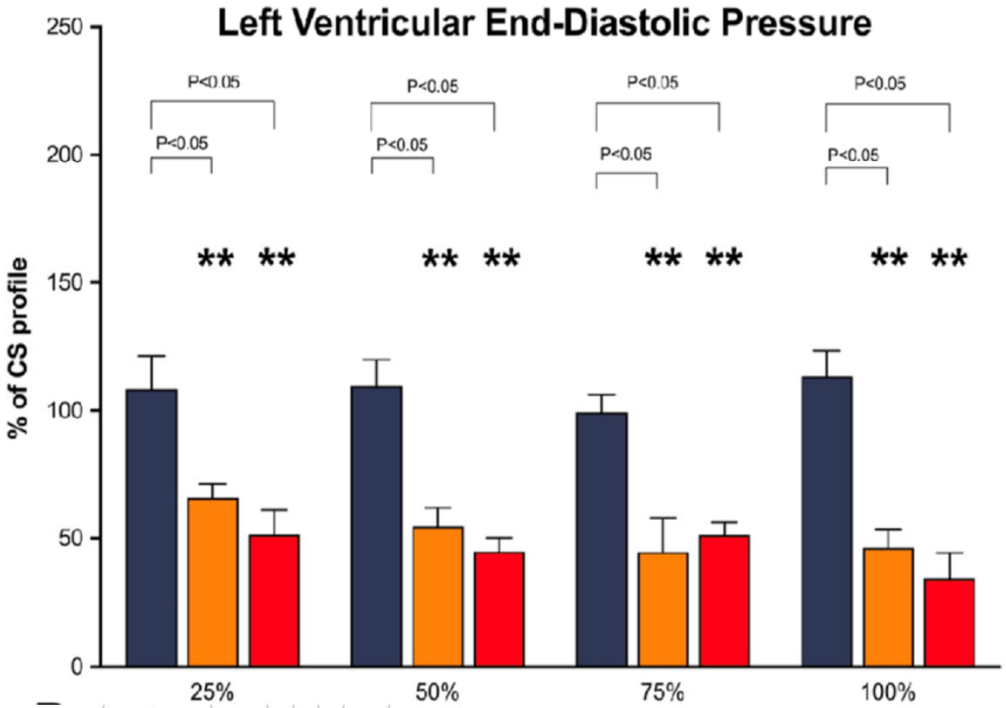
Choc cardiogénique
Ischémique
<u>Non revascularisé</u>

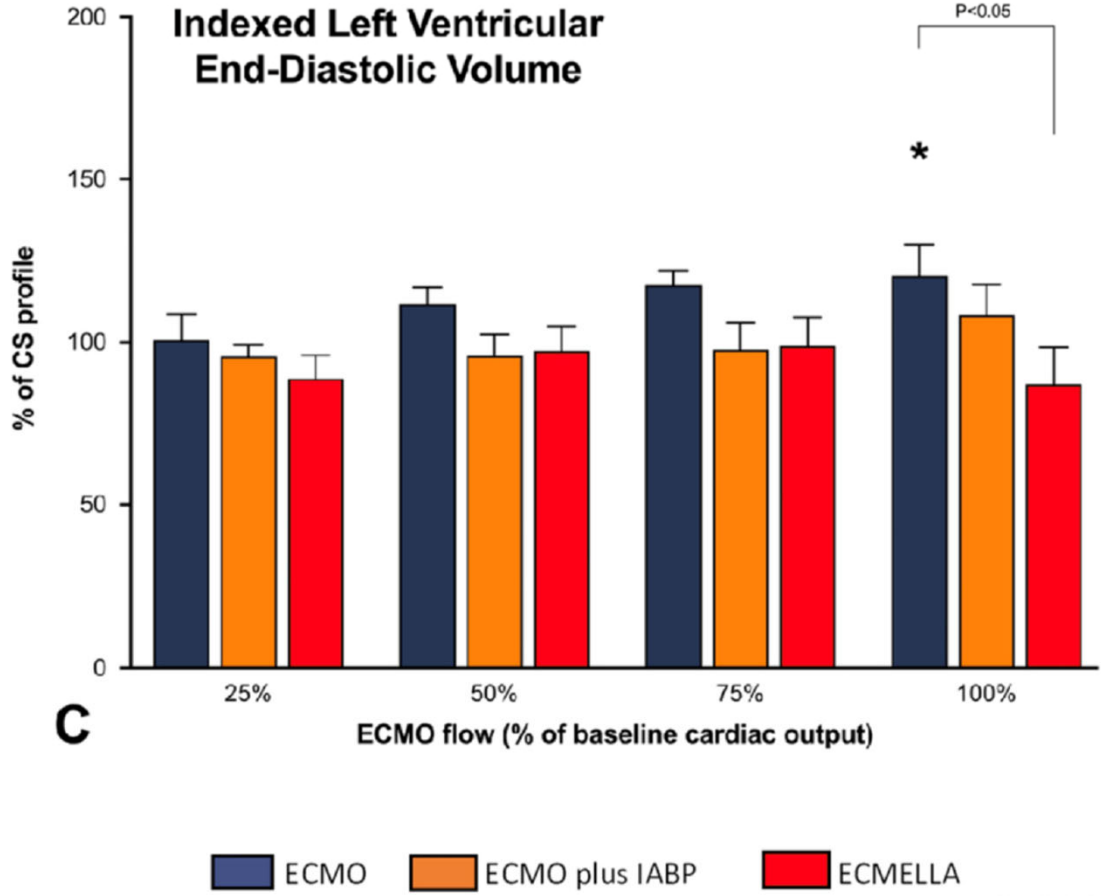


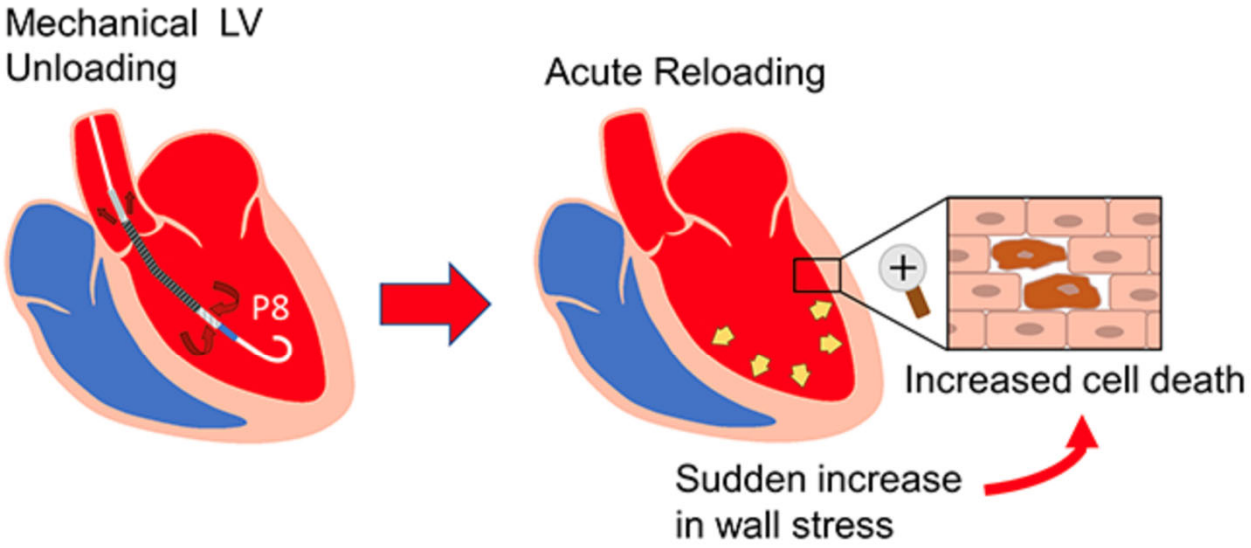

Pressure Volume Area
P<0.05
P<0.05
P<0.05
*
**
% of CS profile
350
300
250
200
150
100
50
0
25%
50%
75%
100%
ECMO run (% of baseline cardiac output)
C
ECMO
ECMO plus IABP
ECMELLA


P
Ps
ejection
PVA
Pd
Relaxation
SW
Contraction
PE
filling
V
V0
ESV
EDV


Left Ventricular End-Diastolic Pressure
% of CS profile
250
200
150
100
50
0
P<0.05
P<0.05
P<0.05
P<0.05
P<0.05
P<0.05
P<0.05
P<0.05
** **
** **
** **
** **
25%
50%
75%
100%

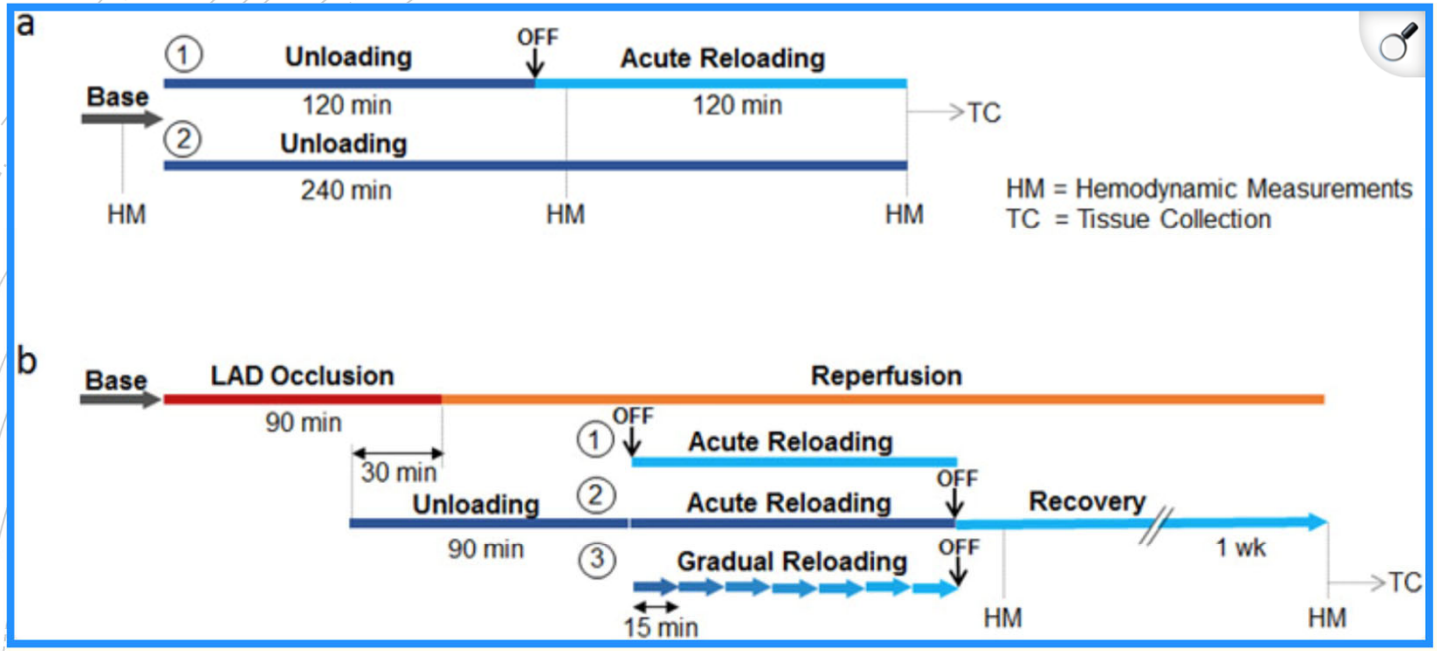

Indexed Left Ventricular End-Diastolic Volume
% of CS profile
200
150
100
50
0
P<0.05
*
25%
50%
75%
100%
ECMO flow (% of baseline cardiac output)
C
ECMO
ECMO plus IABP
ECMELLA

# Peut-être pire encore : le reloading après l'unloading




Acute reloading after mechanical left ventricular unloading causes rapid elevation in end-diastolic wall stress and induces cell death.

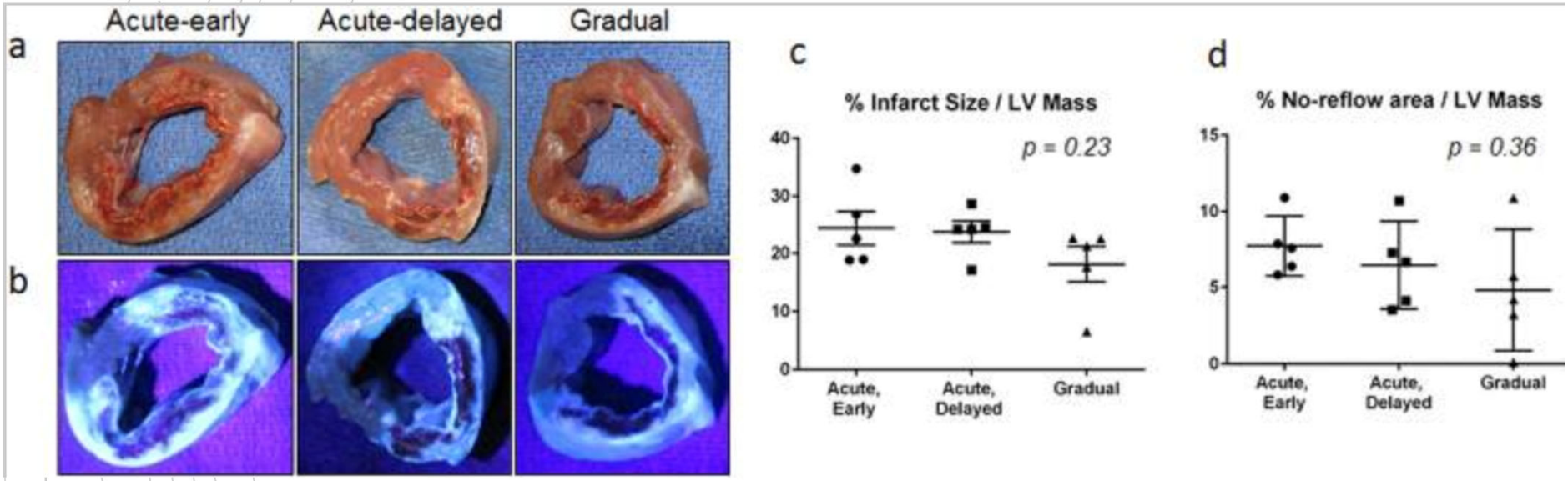
Mazurek et al. J Cardiovasc Transl Res 2024; 17 (2) : 233–241.




**Normal heart study:** After baseline hemodynamic and functional measurements, healthy hearts were unloaded at the P8 flow setting of the Impella CP. After 2 hours, the LV was acutely reloaded by removing the pump (1) or continued for another 2 hours (2). Hemodynamic measurements were recorded at 5 minutes and 2 hours of reloading or 4 hours of unloading, and LV tissue was collected.

**b, MI study:** Following baseline measurements, an anterior MI was created by 90 minutes of LAD occlusion. LV unloading was started with Impella CP at P8 after 60 minutes of balloon occlusion, with reperfusion 30 minutes later. LV unloading continued for another 60 minutes after which animals were reloaded by either early acute (1), delayed acute (2), or gradual (3); adjusting the flow rate down by one setting every 15 minutes) reloading. Animals were recovered after acquiring hemodynamic and functional measurements, which were repeated at 1 week before the termination of the study with tissue collection for downstream analysis.

Taille d'infarctus réduit en diminuant progressivement l'unloading



# Relationship Between Infarct Size and Outcomes Following Primary PCI

## Patient-Level Analysis From 10 Randomized Trials

Gregg W. Stone, MD,[a] Harry P. Selker, MD,[b] Holger Thiele, MD,[c] Manesh R. Patel, MD,[d] James E. Udelson, MD,[b] E. Magnus Ohman, MD,[d] Akiko Maehara, MD,[a] Ingo Eitel, MD,[c] Christopher B. Granger, MD,[d] Paul L. Jenkins, PhD,[e] Melissa Nichols, MS,[a] Ori Ben-Yehuda, MD[a]

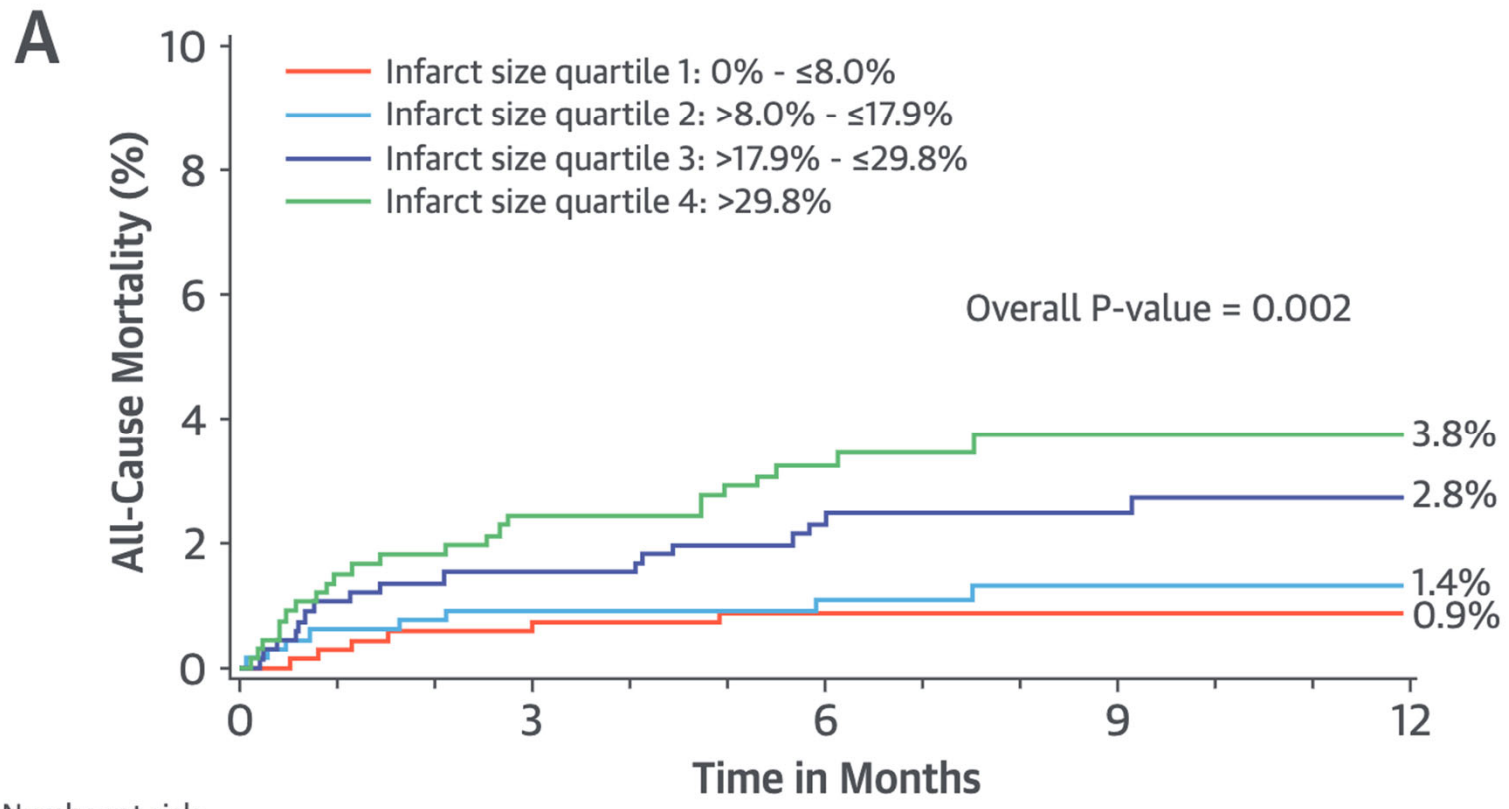
Pool de 10 RCT sur la PCI laire (2632 patients)
Taille de l'infarctus 1 mois après la randomisation par IRM ou SPECT
Suivi à 6 mois

**Résultats :**
Taille d'infarctus par IRM dans 1889 patients (71.8%) et par SPECT chez 743 patients (28.2%).
17.9% (8.0%, 29.8%) en masse VG

Augmentation de la mortalité tous les 5% de taille d'infarctus (Cox-adjusted hazard ratio: 1.19 [95% confidence interval: 1.18 to 1.20]; p < 0.0001)

Indépendant de l'âge, sexe, diabète, HTA, hyperlipidémie, tabac, type d'infarctus.

**FIGURE 2** **Time to First Event Analysis (From Time of Study Entry) According to Quartiles of IS**

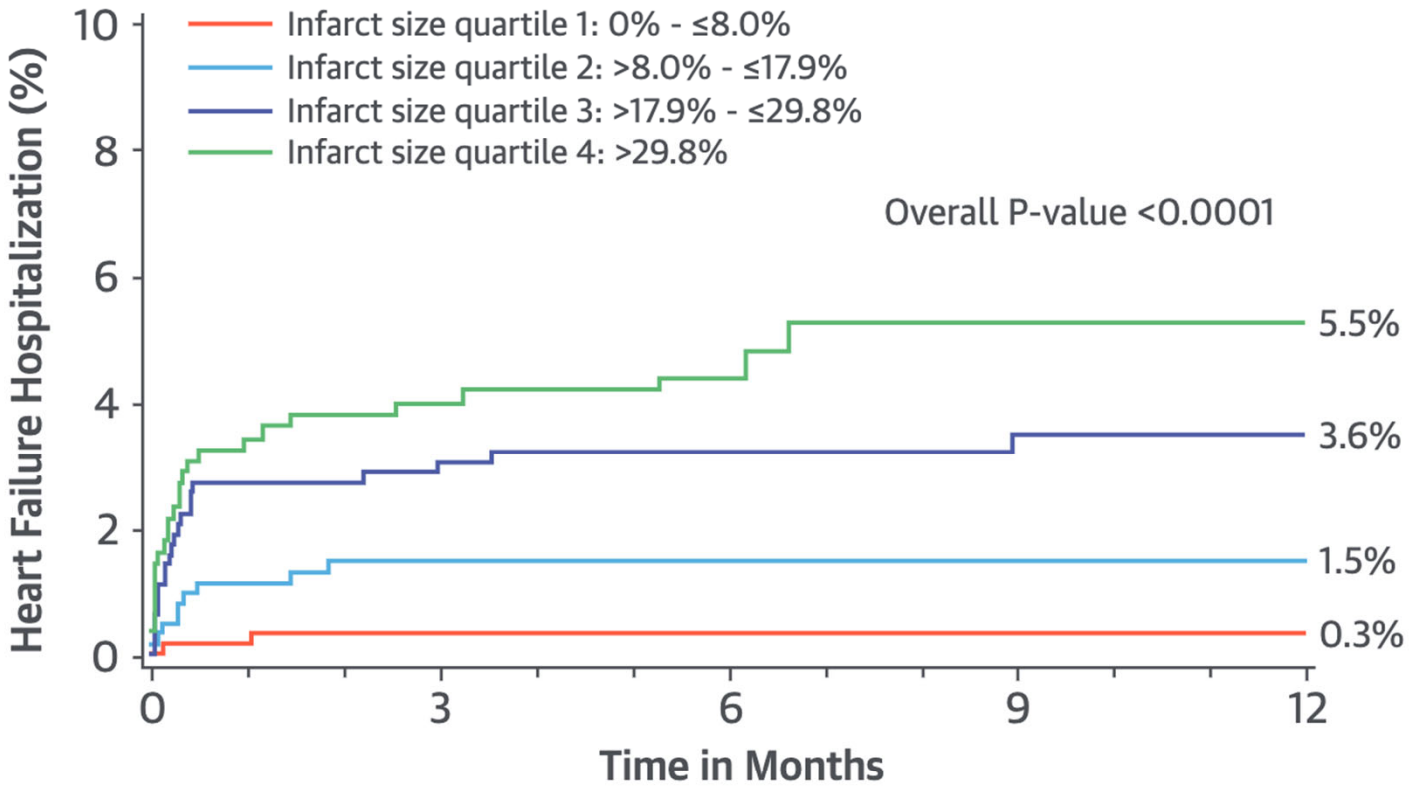



Number at risk:

| | | | | | |
|---|---|---|---|---|---|
| Q1 | 672 | 650 | 581 | 362 | 294 |
| Q2 | 645 | 617 | 586 | 399 | 336 |
| Q3 | 657 | 624 | 585 | 412 | 315 |
| Q4 | 656 | 620 | 555 | 308 | 222 |

Stone et al. JACC 2016; 67 (14) : 1674–1683.

C

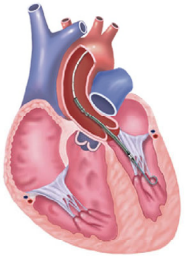



Number at risk:

| | | | | | |
|---|---|---|---|---|---|
| Q1 | 588 | 564 | 496 | 265 | 228 |
| Q2 | 604 | 569 | 540 | 336 | 299 |
| Q3 | 608 | 563 | 524 | 338 | 279 |
| Q4 | 538 | 486 | 427 | 173 | 135 |

# LES ETUDES CLINIQUES SUR L'IMPELLA

## CENTRAL ILLUSTRATION: Randomized Clinical Trials of the Percutaneous Microaxial Flow Pump Device



**Percutaneous Microaxial Flow Pump Devices**

**High Risk PCI**

**Mechanism of Action**

- Reduce myocardial oxygen consumption
- Improve myocardial blood flow
- Maintain systemic perfusion

**Clinical Trials**

- PROTECT II

*Future Trials*
- PROTECT IV

Pahuja M, et al. J Am Coll Cardiol. 2022;80(21):2028-2049.

# **The Value of Left Ventricular Support in Patients With Reduced Left Ventricular Function Undergoing Extensive Revascularization:** An Analysis From the PROTECT-II Randomized Trial

**Authors**: David A. Burke, MD, Harun Kundi, MD, Alexandra Almonacid, MD, William O'Neill, MD, Jeffrey Moses, MD, Neal Kleiman, MD, Simon Dixon, MD, Igor Palacios, MD, Luis A. Guzman, MD, E. Magnus Ohman, MD, Jeffrey J. Popma, MD, and Duane S. Pinto, MD, MPH | AUTHORS INFO & AFFILIATIONS

448 patients (225 Impella vs 223 BCIA)
Multicentrique, 112 centres

PCI haut risque +++

FEVG ≤ 35% + lésion tronc commun non protégé
Ou FEVG ≤ 30% + maladie tritronculaire
Ou dernier vaisseau perméable

Exclusions : choc cardiogénique, STEMI < 48h, IA ≥ 2, IRM < 30 mL/min

MACE à J30

35.1% for Impella 2.5 versus 40.1% for IABP, *P*=0.227 in the intent-to-treat population
34.3% versus 42.2%, *P*=0.092 in the per protocol population.

**A J90**

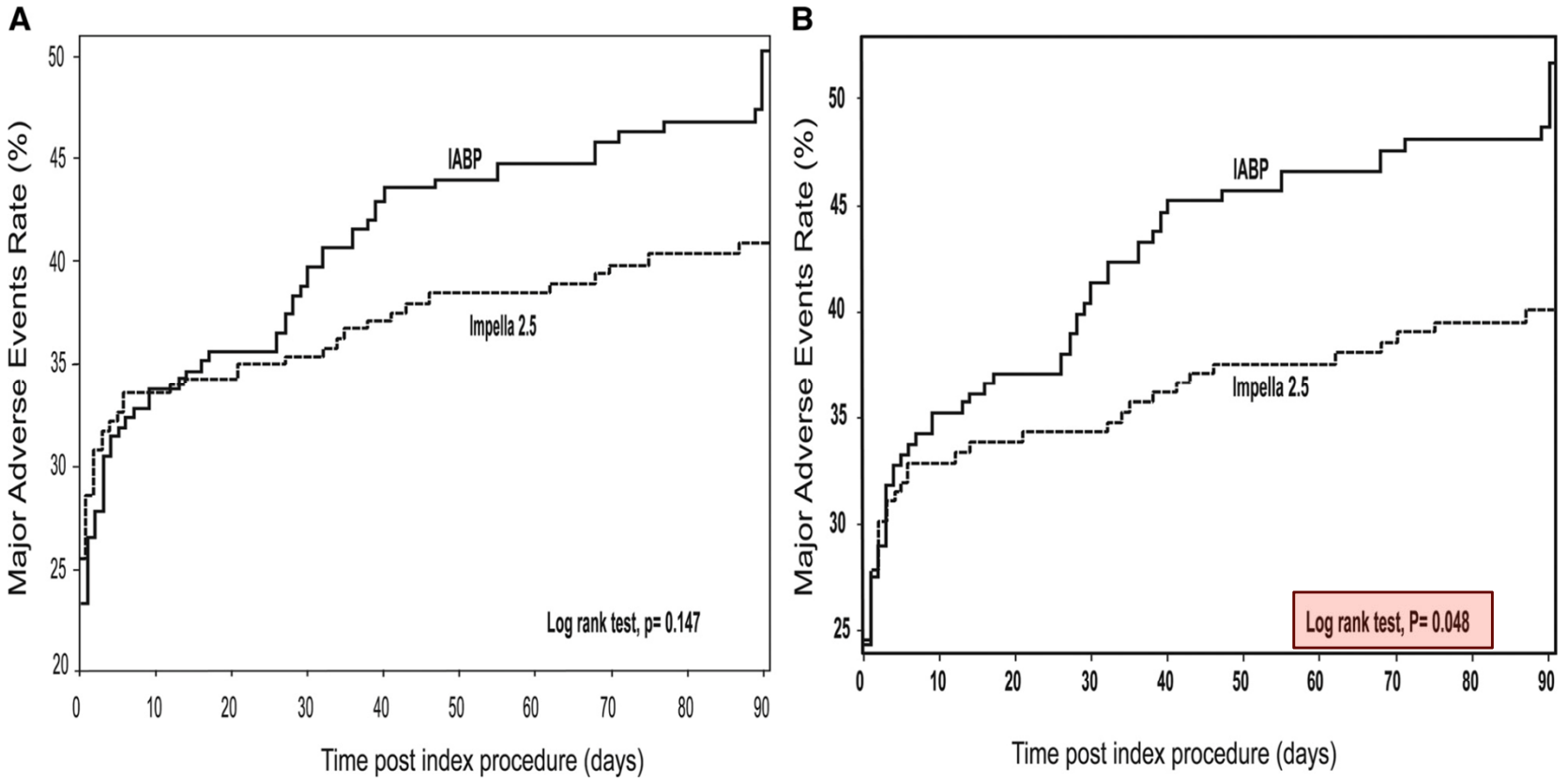
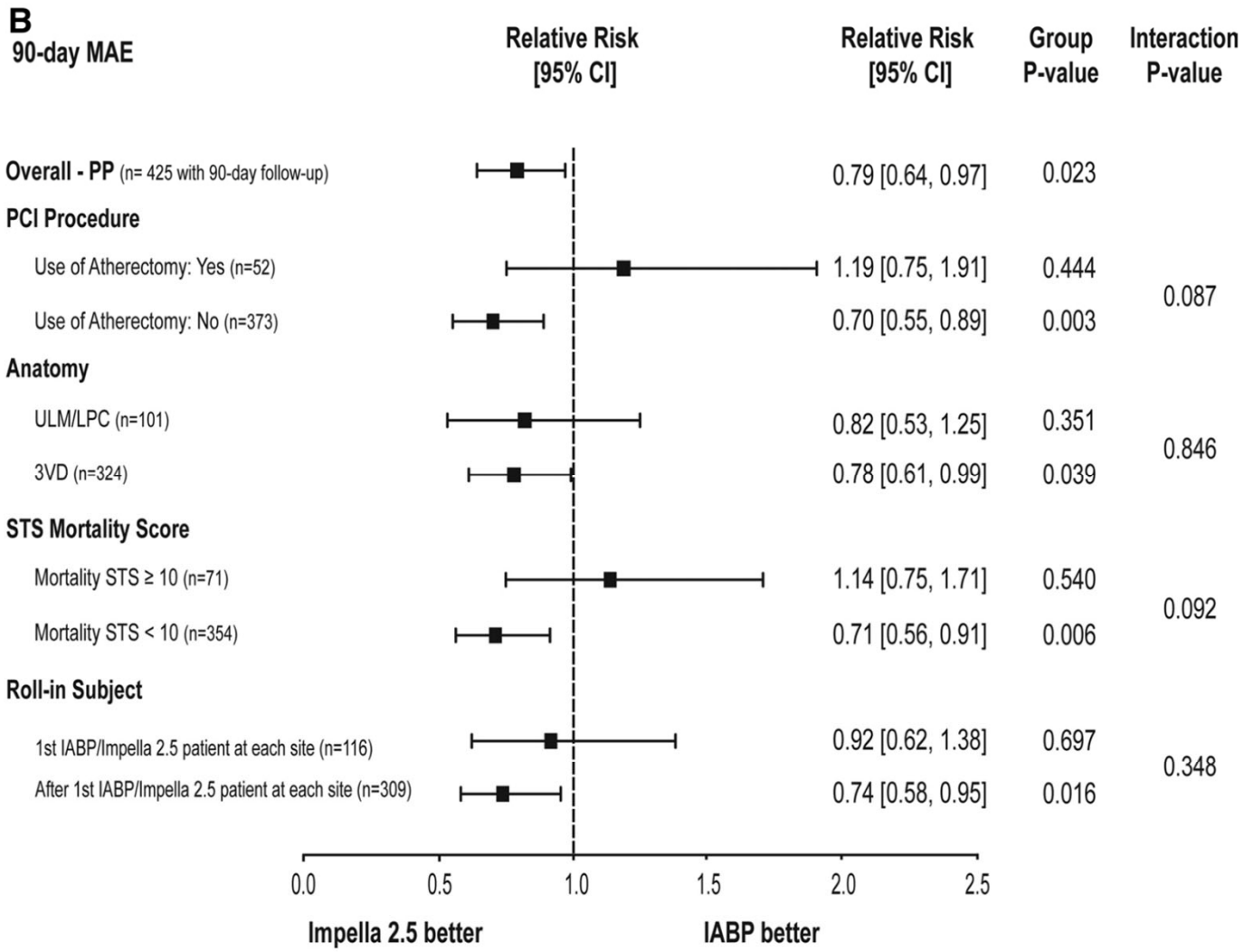


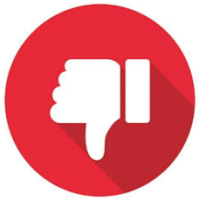

**Figure 2.** Kaplan–Meier curves of major adverse events to 90 days. **A**, intent-to-treat population. **B**, per protocol population. IABP indicates intra-aortic balloon pump.


B
90-day MAE
Relative Risk [95% CI]
Relative Risk [95% CI]
Group P-value
Interaction P-value
Overall - PP (n= 425 with 90-day follow-up)
0.79 [0.64, 0.97]
0.023
PCI Procedure
Use of Atherectomy: Yes (n=52)
1.19 [0.75, 1.91]
0.444
0.087
Use of Atherectomy: No (n=373)
0.70 [0.55, 0.89]
0.003
Anatomy
ULM/LPC (n=101)
0.82 [0.53, 1.25]
0.351
0.846
3VD (n=324)
0.78 [0.61, 0.99]
0.039
STS Mortality Score
Mortality STS ≥ 10 (n=71)
1.14 [0.75, 1.71]
0.540
0.092
Mortality STS < 10 (n=354)
0.71 [0.56, 0.91]
0.006
Roll-in Subject
1st IABP/Impella 2.5 patient at each site (n=116)
0.92 [0.62, 1.38]
0.697
0.348
After 1st IABP/Impella 2.5 patient at each site (n=309)
0.74 [0.58, 0.95]
0.016
0.0
0.5
1.0
1.5
2.0
2.5
Impella 2.5 better
IABP better

## Les résultats selon les deux analyses

| Temps | **Analyse ITT** | **Analyse Per Protocole** |
|---|---|---|
| **30 jours** | 35.1% vs 40.1% — **NS** (p=0.227) | 34.3% vs 42.2% — **NS** (p=0.092) |
| **90 jours** | 40.6% vs 49.3% — **tendance** (p=0.066) | 40.0% vs 51.0% — **SIGNIFICATIF** (p=0.023) |

RCT multicentrique
Critères d’inclusion bien défini – hors choc
Suivi J90



Durée de support courte
Critère composite
Arret précoce pour futilité

# Improved outcomes in patients with severely depressed LVEF undergoing percutaneous coronary intervention with contemporary practices

William W O'Neill [1], Mark Anderson [2], Daniel Burkhoff [3], Cindy L Grines [4], Navin K Kapur [5],

PROTECT III

Registre prospective avec Impella 2.5 et CP dans la PCI à haut risque.
Mars 2017-2020 dans 4 centres américains

**1 134 patients**
Comparison des patients PROTECT II versus PROTECT III (**504 patients "PROTECT II-like »)**

**MACCE à 90 jours** : **15,1% vs 21,9%** (p = 0,037) — en faveur de PROTECT III

Après appariement par score de propension : **10,4% vs 16,9%** (p = 0,048)

**Saignements nécessitant transfusion** : 1,8% vs 9,3% (p < 0,001)

**Hypotension procédurale** : 2,2% vs 10,1% (p < 0,001)

**RCP ou arythmie ventriculaire** : 1,6% vs 6,9% (p < 0,001)

Registre prospectif post commercialisation

**la comparaison se fait avec des données historiques de PROTECT II (2009-2010)**

Pas de randomisation : registre prospectif

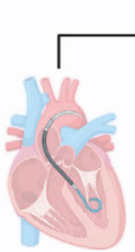
Biais de selection: **moins d'IDM antérieur dans PROTECT III**

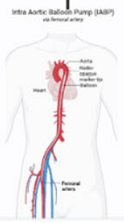
## Comparison of PROTECT IV-like Cohort with PROTECT IV

### PROTECT IV Design

**Prospective, Multicenter RCT**

1,252 patients estimated sample size
1:1 Randomization to Impella vs. non-Impella (± IABP) for HR-PCI

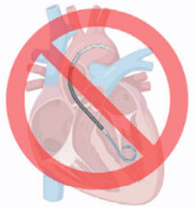




### PROTECT IV-like Design

**Cohort**

700 patients underwent HR-PCI without prophylactic Impella at MedStar Washington Hospital Center from 2008-2022



## Comparison of Outcomes

### Estimated

Assumes 41% MAE in Impella vs. 50% MAE in Control at 2 years

### Observed

Observed 30.8% MAE at 2 years

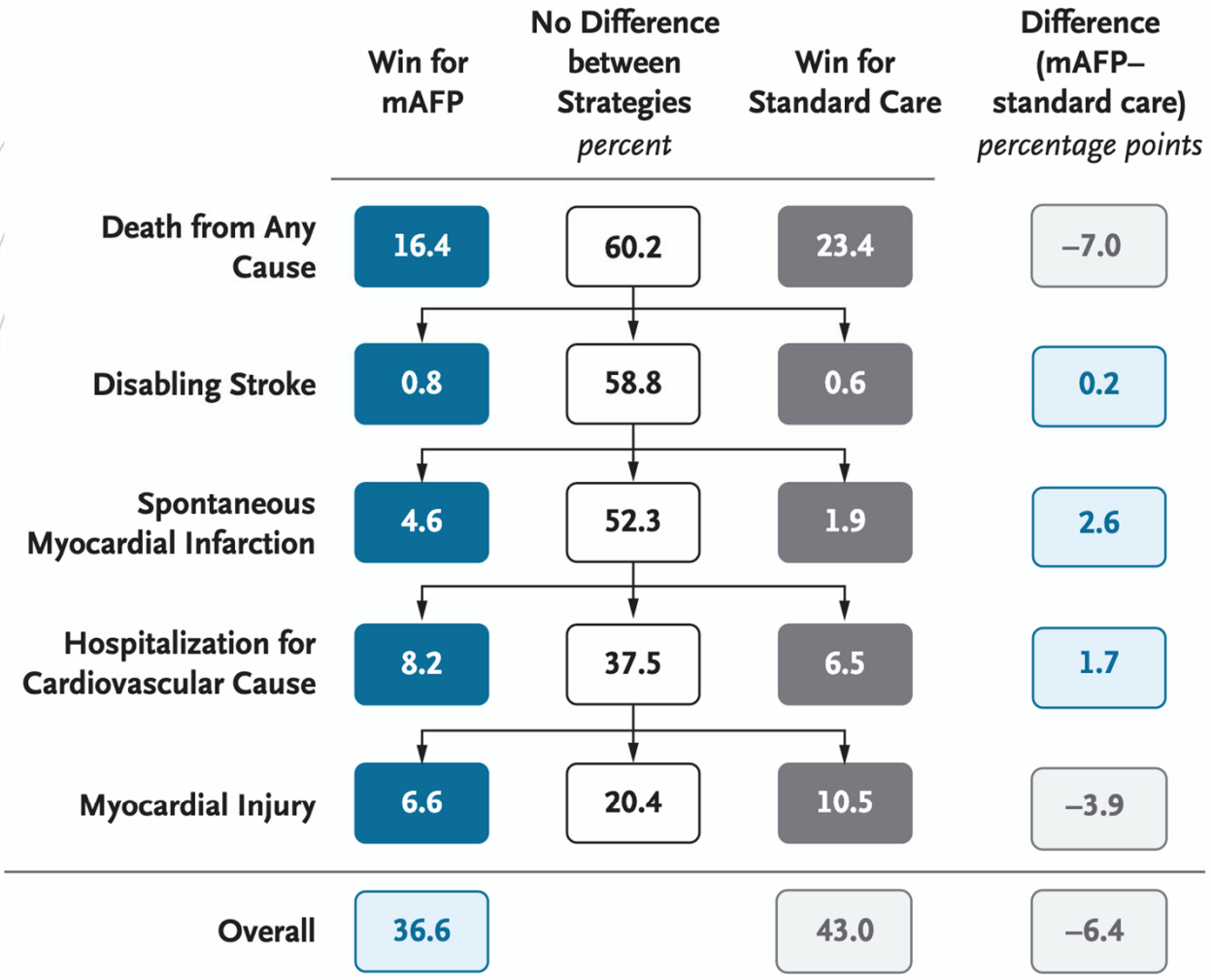
Assuming a HR of 0.75 using multivariate Cox regression, under 90% power with 5% level, 2,050 patients are required for PROTECT IV to evaluate superiority of Impella for HR-PCI.

# Left Ventricular Unloading in High-Risk Percutaneous Coronary Intervention

Divaka Perera, M.D.,[1,2] Matthew Ryan, Ph.D.,[1,2] Saad M. Ezad, Ph.D.,[1,3]
Sohail Q. Khan, M.D.,[4] Ian Webb, Ph.D.,[1,5] Peter D. O'Kane, M.D.,[3]
Roshan Weerackody, Ph.D.,[6] Matthew Dodd, Ph.D.,[7] Matthew Kwok, M.Sc.,[7]
Lynn Laidlaw, B.A.,[7] Laura Van Dyck, B.Sc.,[7] Benjamin Wrigley, M.D.,[8]

RCT **21 centres au Royaume-Uni**.
**300 patients**
PCI programmée avec :
dysfonction VG sévère (FEVG ≤ 35% ou 45% avec IM)
et coronaropathie étendue

**Randomisation** : Impella CP vs soins standard
Exclusion des chocs cardiogéniques,



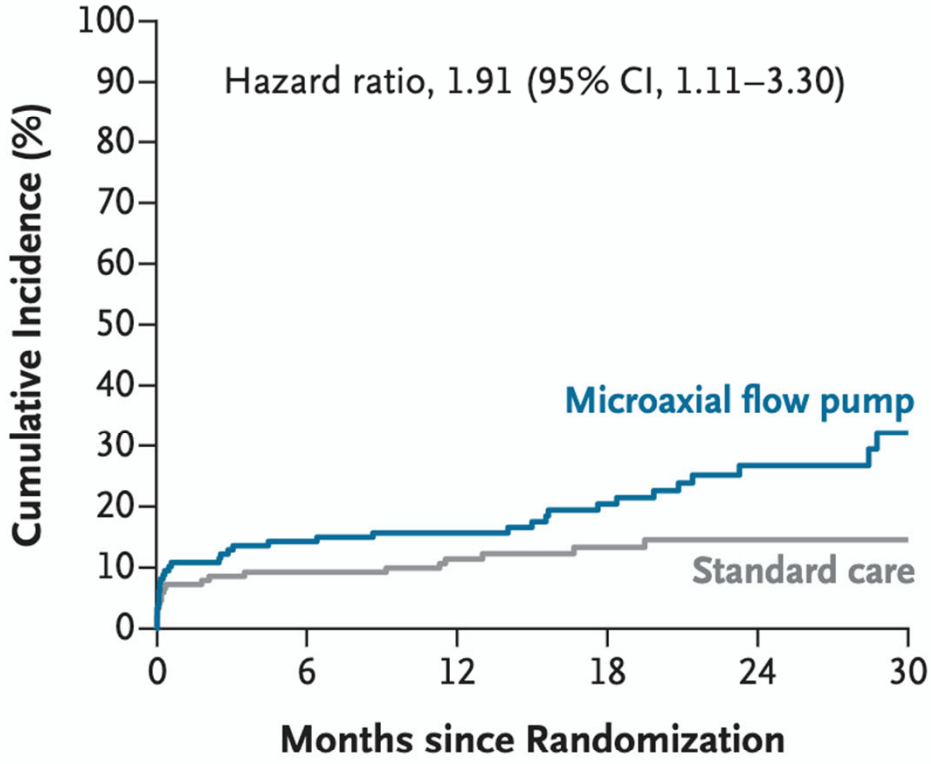

Win Ratio = (wins for mAFP)/(wins for standard care) = 0.85 (95% CI, 0.63–1.15)

**En gris = en faveur du groupe CONTROLE**

**Table 2. Secondary Outcomes.***

| Outcome | Microaxial Flow Pump (N=148) | Standard Care (N=152) | Hazard or Risk Ratio (95% CI)† |
|---|---|---|---|
| | *number of patients (total number)* | | |
| **Major secondary outcomes** | | | |
| Death | | | |
| From any cause | 47/148 (32.6) | 33/152 (23.4) | 1.54 (0.99–2.41) |
| From cardiovascular cause‡ | 36/148 (26.7) | 20/152 (14.5) | 1.91 (1.11–3.30) |
| Disabling stroke‡ | 3/148 (3.5) | 6/152 (4.5) | 0.53 (0.13–2.11) |
| Spontaneous myocardial infarction‡ | 9/148 (6.8) | 15/152 (12.4) | 0.64 (0.28–1.47) |
| Hospitalization for cardiovascular cause‡ | 32/148 (24.5) | 29/152 (21.0) | 1.20 (0.72–1.98) |
| Periprocedural myocardial injury§ | 82/133 (61.7) | 62/124 (50.0) | 1.23 (0.99–1.54) |
| **Sensitivity analyses** | | | |
| Nonhierarchical composite outcome | | | |
| Including periprocedural myocardial injury ¶ | 111/140 (79.3) | 100/139 (73.6) | 1.24 (0.94–1.62) |
| Excluding periprocedural myocardial injury | 64/148 (45.3) | 65/152 (45.4) | 1.06 (0.75–1.49) |

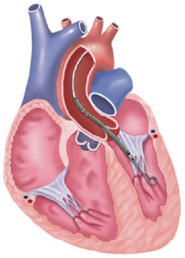
**B** **Death from Cardiovascular Causes**




**No. at Risk**

| | | | | | | |
|---|---|---|---|---|---|---|
| Microaxial flow pump | 148 | 123 | 103 | 78 | 43 | 19 |
| Standard care | 152 | 135 | 115 | 78 | 51 | 28 |

## CENTRAL ILLUSTRATION: Randomized Clinical Trials of the Percutaneous Microaxial Flow Pump Device



**Percutaneous Microaxial Flow Pump Devices**

| | High Risk PCI | Role in AMI-CS |
|---|---|---|
| Mechanism of Action | • Reduce myocardial oxygen consumption<br>• Improve myocardial blood flow<br>• Maintain systemic perfusion | • Improve cardiac output<br>• Decrease LVEDP<br>• Improve systemic perfusion and BP<br>• Prevent progressive systemic inflammation response syndrome |
| Clinical Trials | • PROTECT II<br>*Future Trials*<br>- PROTECT IV | • ISAR-Shock<br>• IMPRESS<br>• IMPELLA-STIC<br>*Future Trials*<br>- Dan-Ger Shock<br>- REVERSE<br>- RECOVER-IV |

Pahuja M, et al. J Am Coll Cardiol. 2022;80(21):2028-2049.

# A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

**Authors**: Melchior Seyfarth, MD ✉, Dirk Sibbing, MD, Iris Bauer, MS, Georg Fröhlich, MD, Lorenz Bott-Flügel, MD, Robert Byrne, MB, MRCPI, Josef Dirschinger, MD, Adnan Kastrati, MD, and Albert Schömig, MD | AUTHORS INFO & AFFILIATIONS

2012
Randomisée - 2 centres
26 patients
IABP vs. 2.5

STEMI ou NSTEMI revascularisés (≈4,5h)
Choc cardiogénique

ΔIC à 30 min (Swan ganz)

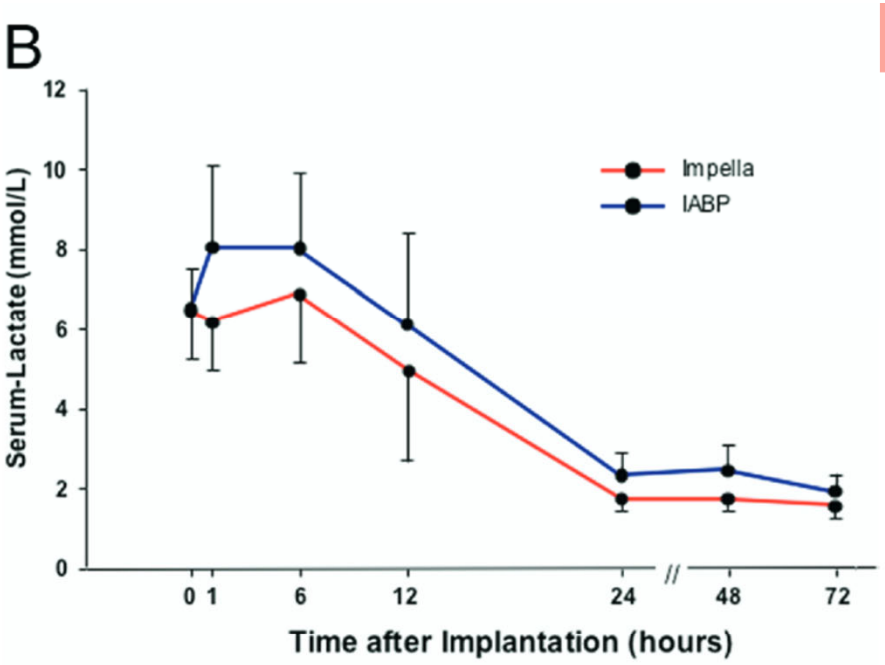
IIaire: hémolyse, acidose et mortalité J30

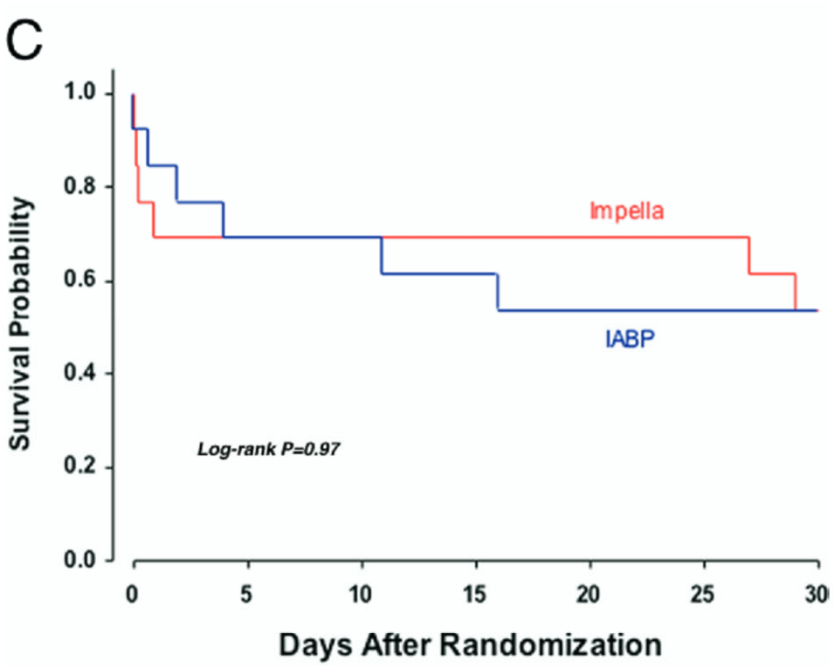
# A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

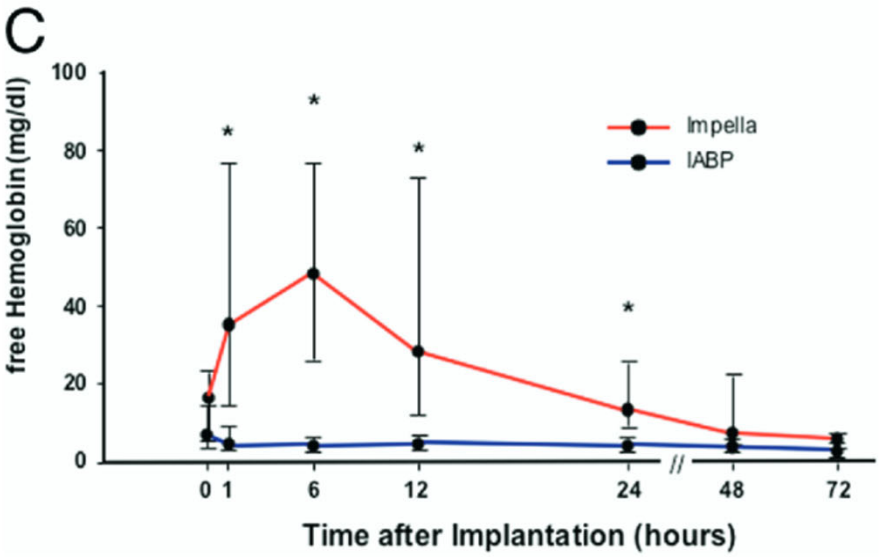
**Authors**: Melchior Seyfarth, MD ✉, Dirk Sibbing, MD, Iris Bauer, MS, Georg Fröhlich, MD, Lorenz Bott-Flügel, MD, Robert Byrne, MB, MRCPI, Josef Dirschinger, MD, Adnan Kastrati, MD, and Albert Schömig, MD | AUTHORS INFO & AFFILIATIONS

**Table 2** Hemodynamic Values Before and After Device Implantation

| | Impella Before (n = 13) | IABP Before (n = 13) | Impella After (n = 13) | IABP After (n = 13) | p Value |
|---|---|---|---|---|---|
| CI (l/min/m$^2$) | 1.71 ± 0.45 | 1.73 ± 0.59 | 2.20 ± 0.64 | 1.84 ± 0.71 | 0.18 |
| CO (l/min) | 3.16 ± 0.77 | 3.46 ± 1.46 | 4.12 ± 1.21 | 3.67 ± 1.76 | 0.48 |
| Mean AP (mm Hg) | 78 ± 16 | 72 ± 17 | 87 ± 18 | 71 ± 22 | 0.062 |
| Systolic AP (mm Hg) | 106 ± 22 | 101 ± 23 | 110 ± 24 | 97 ± 29 | 0.20 |
| Diastolic AP (mm Hg) | 64 ± 15 | 58 ± 14 | 74 ± 17 | 50 ± 16 | 0.001 |
| Heart rate (beats/min) | 95 ± 24 | 97 ± 24 | 103 ± 21 | 99 ± 22 | 0.68 |
| PCWP (mm Hg) | 22 ± 8 | 22 ± 7 | 19 ± 5 | 20 ± 6 | 0.67 |
| RAP (mm Hg) | 13 ± 7 | 12 ± 6 | 13 ± 3 | 12 ± 5 | 0.82 |
| Mean PAP (mm Hg) | 28 ± 8 | 28 ± 9 | 28 ± 8 | 30 ± 11 | 0.73 |
| SVR (dyn·s·cm$^{-5}$) | 1,617 ± 385 | 1,546 ± 763 | 1,457 ± 467 | 1,333 ± 784 | 0.63 |



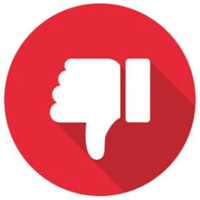




- Mortalité 30j : 46% (Impella) vs 45% (BCIA) — p=NS — pas de différence
- Durée de support : médiane 2.4 jours (Impella) vs 1.7 jours (BCIA)
- **Complications vasculaires : 20% dans le groupe Impella (hématome, ischémie) vs 10% BCIA**

# A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

**Authors**: Melchior Seyfarth, MD ✉, Dirk Sibbing, MD, Iris Bauer, MS, Georg Fröhlich, MD, Lorenz Bott-Flügel, MD, Robert Byrne, MB, MRCPI, Josef Dirschinger, MD, Adnan Kastrati, MD, and Albert Schömig, MD | AUTHORS INFO & AFFILIATIONS

- 1er RCT de supériorité
- Critère primaire objectif et mesurable (ΔIC à 30 min)
- Double aveugle

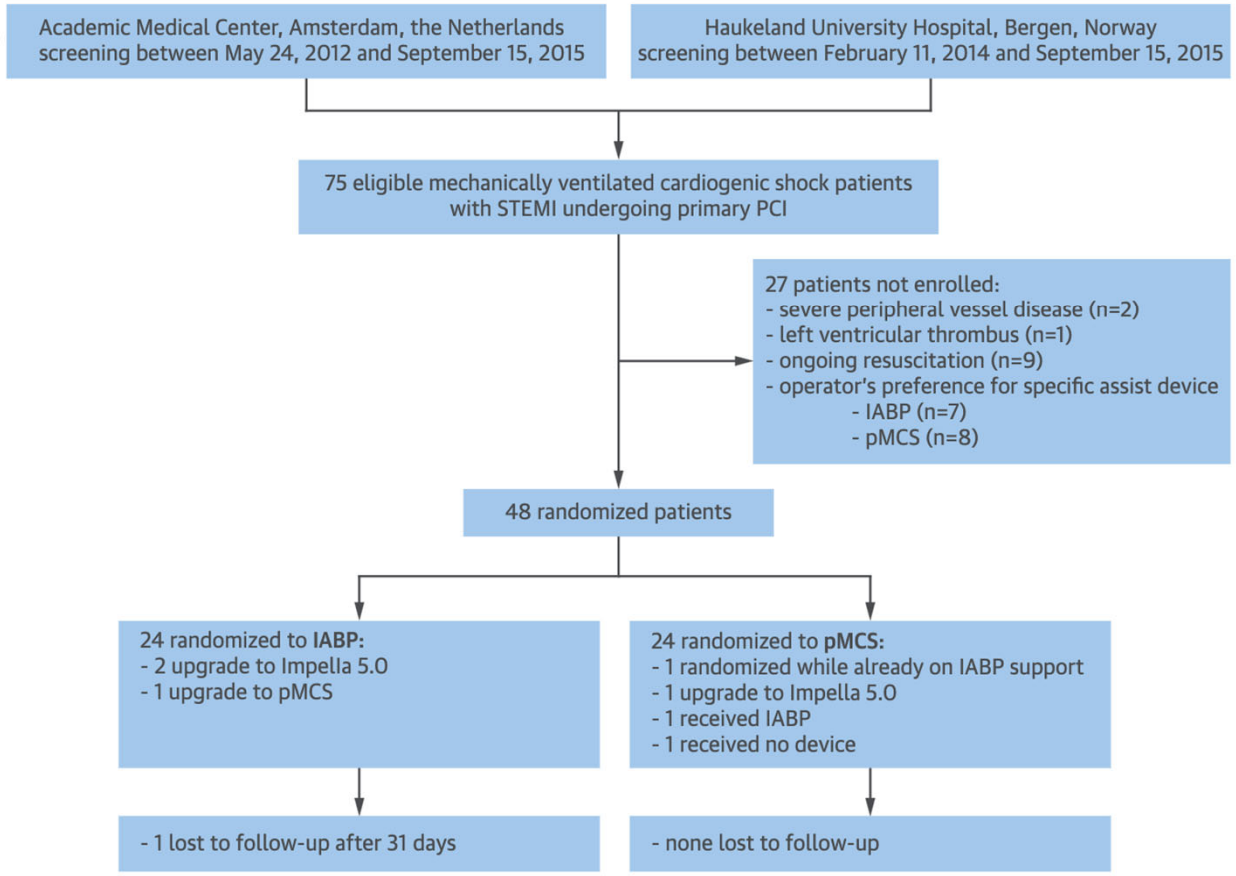


- N=26
- Modèle et groupe contrôle obsolètes
- CJP purement hémodynamique

# Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction

Dagmar M. Ouweneel, MSc,[a] Erlend Eriksen, MD,[b] Krischan D. Sjauw, MD, PhD,[a] Ivo M. van Dongen, MD,[a]

## IMPRESS in Severe Shock trial

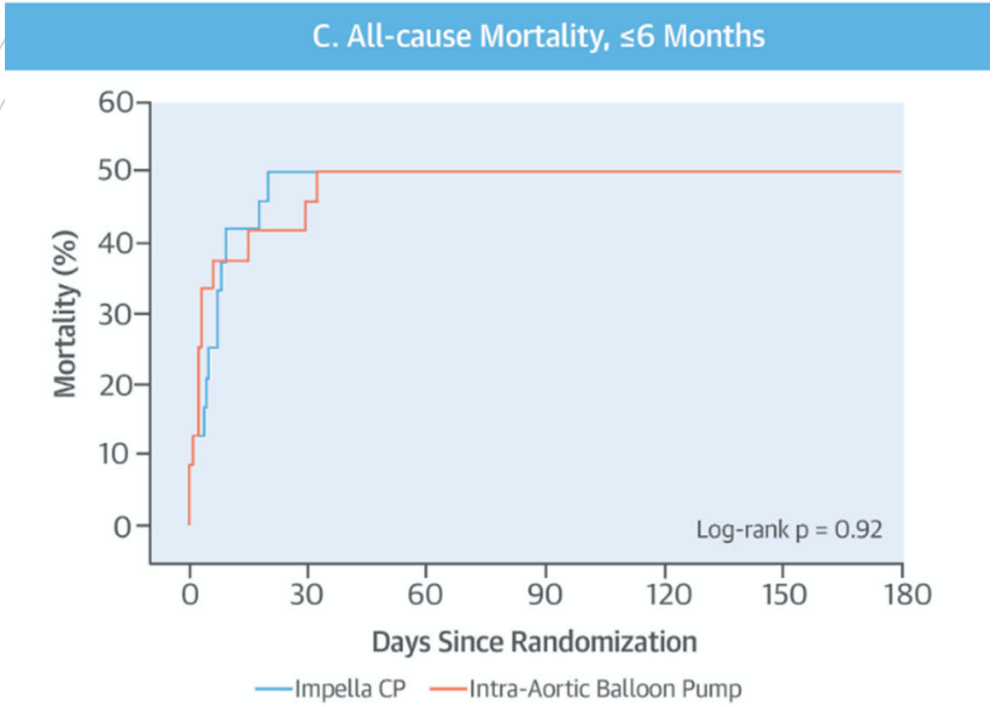



**Choc cardiogénique**

Lactate : 7.5 ± 3.2 vs. 8.9 ± 6.6

> 90 % ACR préhospitalier

> 90 % VM



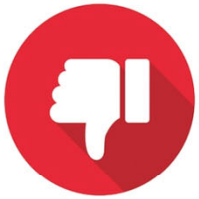

Transfusion (IMP vs. IABP) : 46% vs. 33%

Durée de séjour hospitalier : 16 vs 10 jours

Hémorragie sévère : 33% vs 8%

## IMPRESS in Severe Shock trial

- 1er RCT avec la CP
- CJP fort : mortalité J30
- Suivi J90 et suivi 180J
- Essai de faisabilité

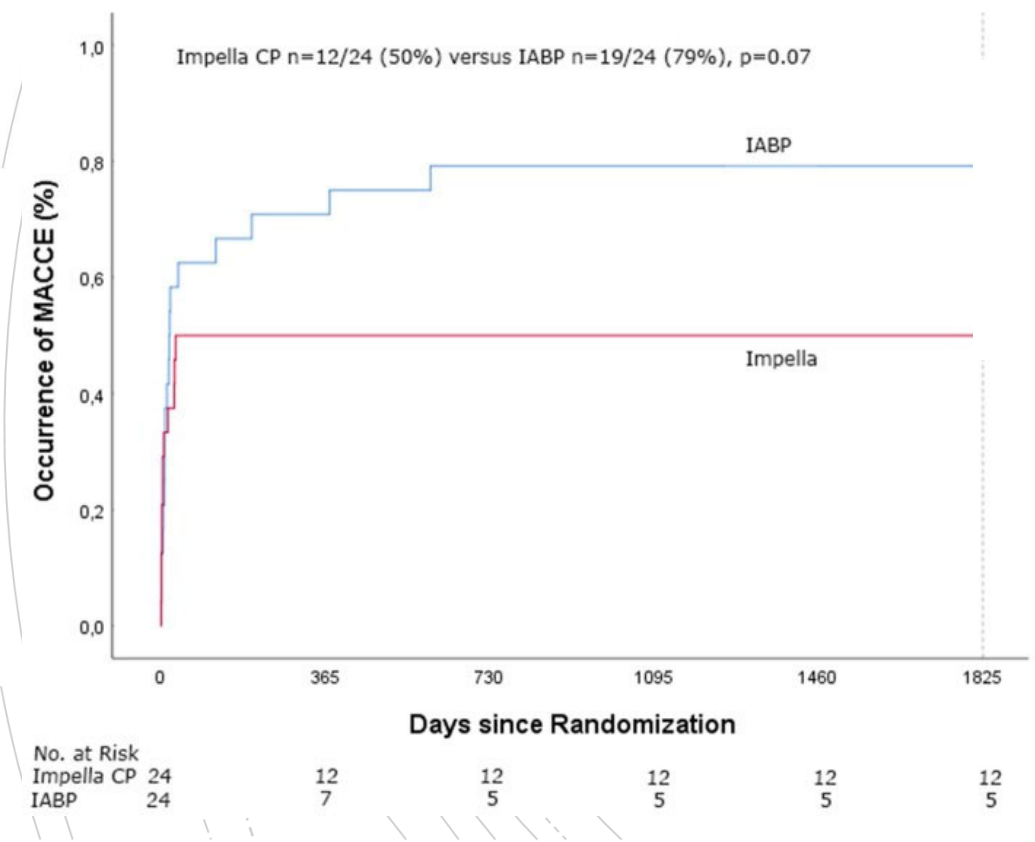


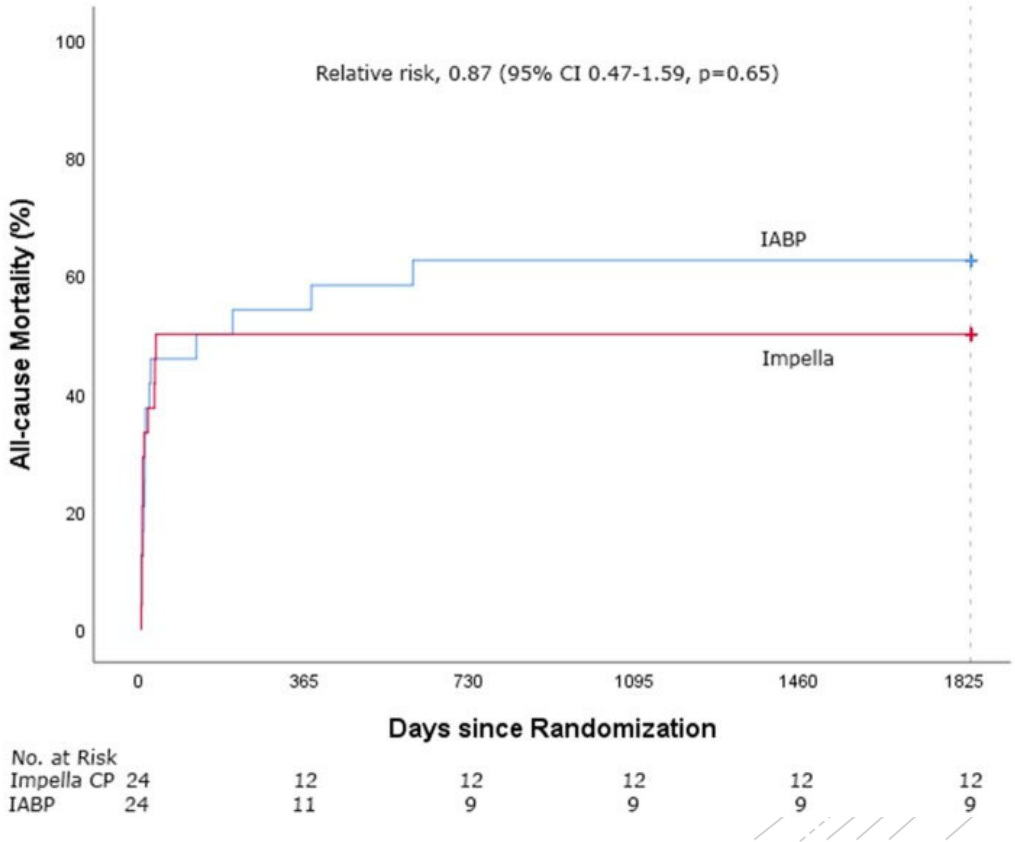
- Sous dimensionné
- Choc trop sévère : 90% d'ACR / SCAI D et E
- Support de 2-3 jours
- Groupe contrôle IABP ? (IABP-SHOCK II date de 2012)

# Long-term 5-year outcome of the randomized IMPRESS in severe shock trial: percutaneous mechanical circulatory support vs. intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction

Mina Karami [1], Erlend Eriksen [2], Dagmar M Ouweneel [1], Bimmer E Claessen [1 3], M Marije Vis [1], Jan Baan [1], Marcel Beijk [1], Erik J S Packer [2], Krischan D Sjauw [4], Annemarie Engstrom [1 5], Alexander Vlaar [6], Wim K Lagrand [6], Jose P S Henriques [1]

2012-2015
48 patients Impella CP ($n = 24$) or IABP ($n = 24$)



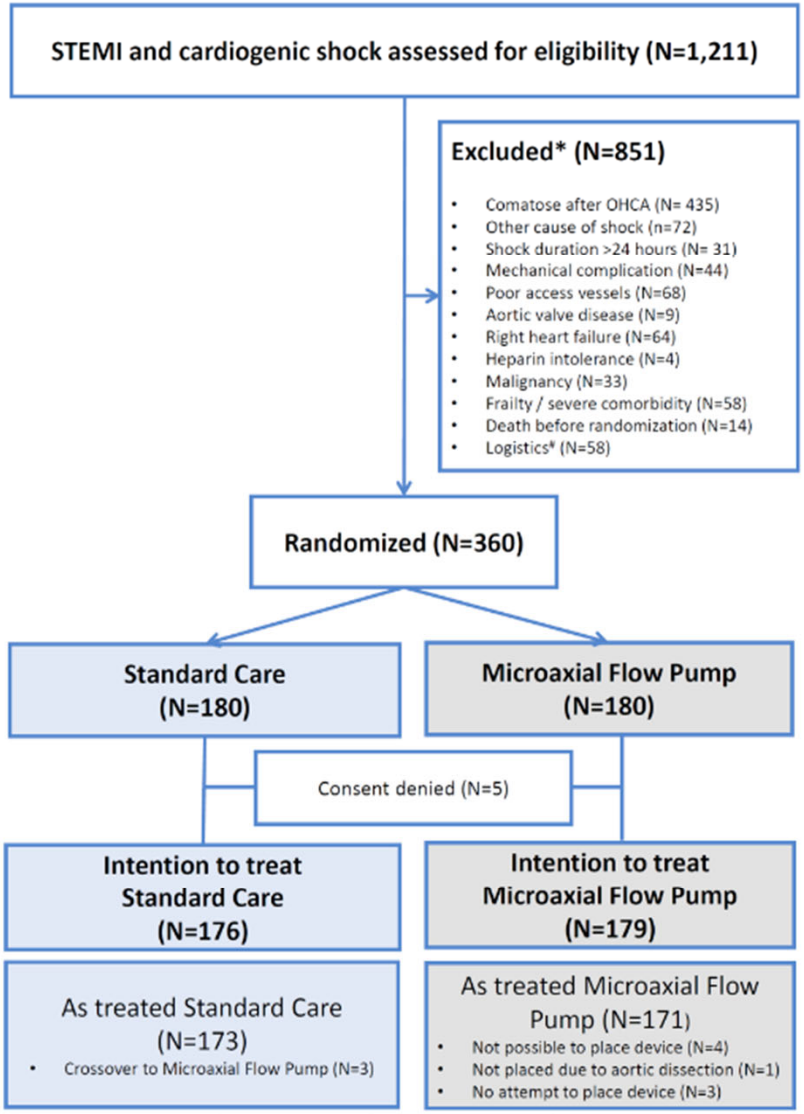



ORIGINAL ARTICLE

# Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock

J.E. Møller, T. Engstrøm, L.O. Jensen, H. Eiskjær, N. Mangner, A. Polzin, P.C. Schulze, C. Skurk, P. Nordbeck, P. Clemmensen, V. Panoulas, S. Zimmer,

1. **ST-segment elevation myocardial infarction** <36 h duration
   (**or** new onset ST segment depression **or** LBBB **and** acute proximal coronary artery occlusion)
2. **Cardiogenic shock** <24 h duration, confirmed by:
   - ✓ tissue hypoperfusion (lactate ≥2.5 mmol/L and/or SvO2 <55%)
   - ✓ **and** systolic blood pressure <100mmHg **and/or** need for vasopressor
   - ✓ **and** LV EF < 45%




* Enrolled in other study (N=2), nonnative speaking (N=3), direct Impella (N=14), eligible not randomized (N=39)
* More than one reason could be stated

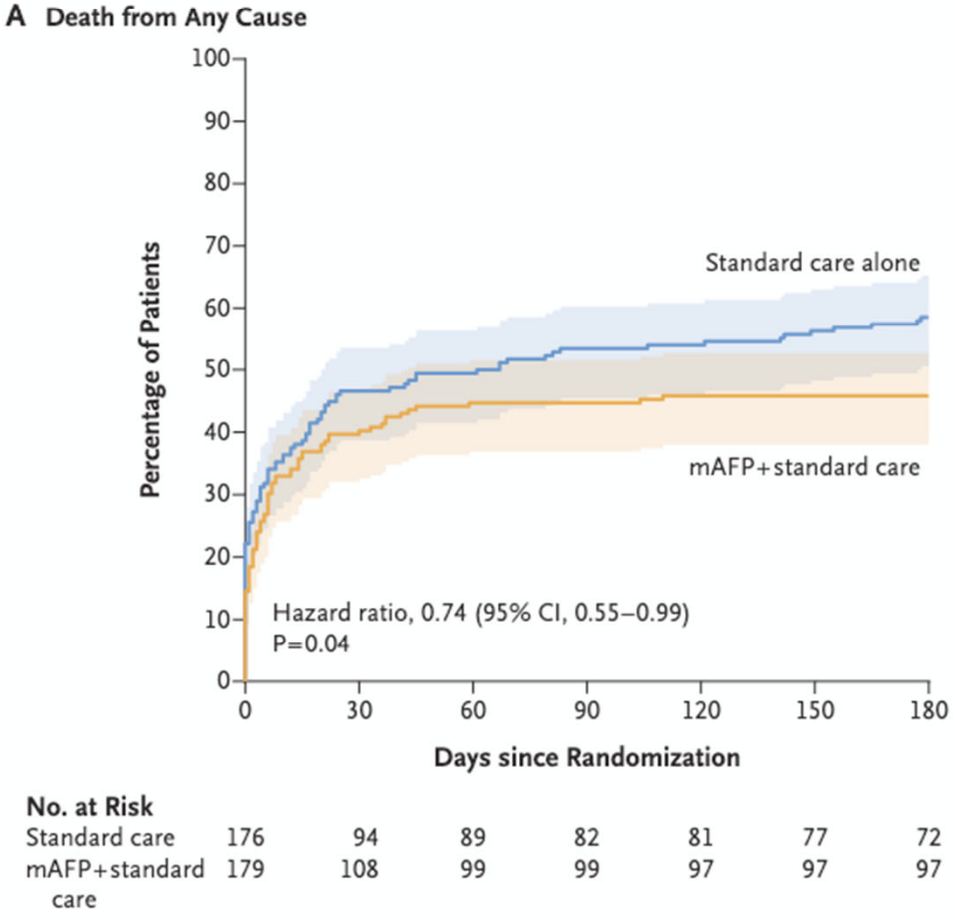
OHCA denotes out-of-hospital cardiac arrest.

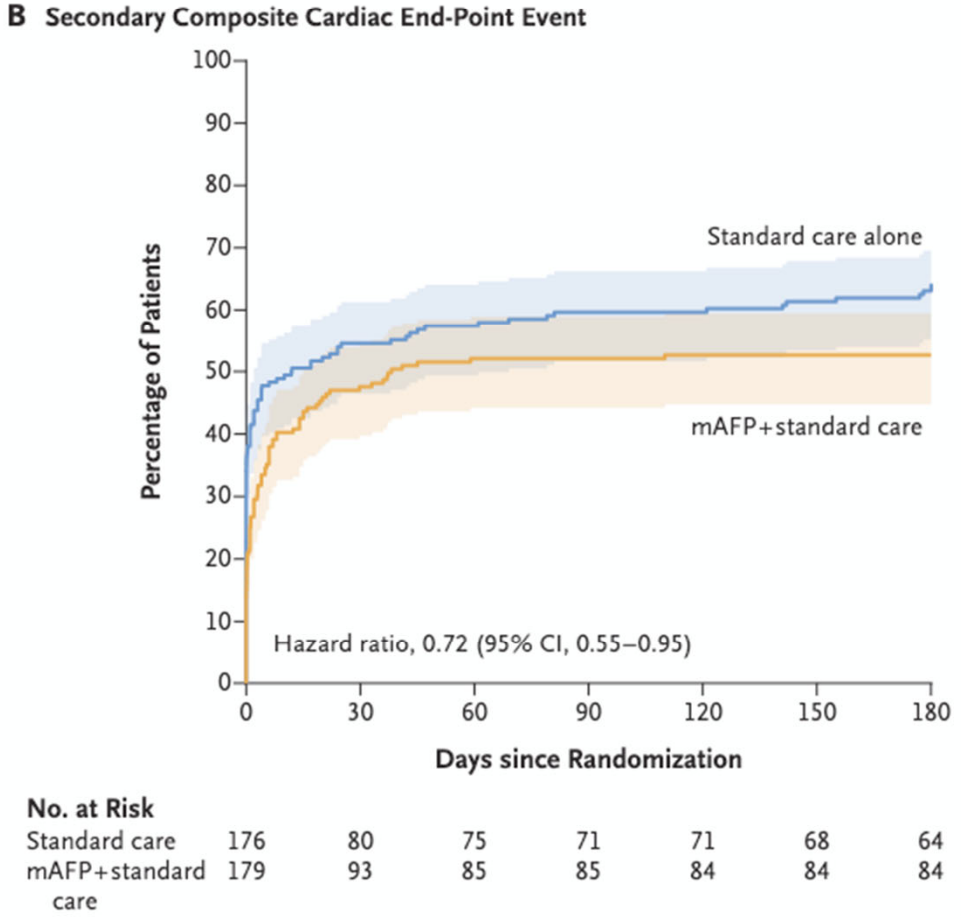
| Characteristic | Microaxial Flow Pump plus Standard Care (N=179) | Standard Care Alone (N=176) |
|---|---|---|
| Median age (IQR) — yr | 67 (58–76) | 69 (61–76) |
| Male sex — no. (%) | 142 (79.3) | 139 (79.0) |
| Median systolic blood pressure (IQR) — mm Hg | 84 (72–91) | 82 (72–91) |
| Median of the mean arterial blood pressure (IQR) — mm Hg | 63 (55–72) | 64 (55–73) |
| Median heart rate (IQR) — beats/min | 94 (77–110) | 95 (76–111) |
| Median arterial lactate level (IQR) — mmol/liter | 4.6 (3.4–7.1) | 4.5 (3.2–6.9) |
| Median left ventricular ejection fraction (IQR) — % | 25 (20–31) | 25 (15–30) |
| Resuscitation before randomization — no. (%) | 39 (21.8) | 33 (18.8) |
| Intubation before randomization — no. (%) | 35 (19.6) | 28 (15.9) |
| Transfer from outside hospital — no. (%) | 51 (28.5) | 48 (27.3) |
| Anterior myocardial infarction — no. (%) | 126 (70.4) | 129 (73.3) |
| SCAI–CSWG stage at admission — no. (%)† | | |
| C | 100 (55.9) | 97 (55.1) |
| D | 51 (28.5) | 50 (28.4) |
| E | 28 (15.6) | 29 (16.5) |
| No. of diseased vessels on coronary angiography — no. (%) | | |
| 0 | 1 (0.6) | 0 |
| 1 | 52 (29.1) | 47 (26.7) |
| 2 | 70 (39.1) | 64 (36.4) |
| 3 | 56 (31.3) | 65 (36.9) |
| Timing of randomization | | |
| Median time from symptom onset to randomization (IQR) — hr | 4.8 (2.4–12.8) | 3.8 (2.2–9.4) |
| Randomization performed before revascularization — no. (%) | 99 (55.3) | 102 (58.0) |
| Randomization performed in the catheterization laboratory but after revascularization — no. (%) | 48 (26.8) | 48 (27.3) |
| Randomization performed ≤12 hr after departure from the catheterization laboratory — no. (%) | 32 (17.9) | 26 (14.8) |

**Table 2.** In-Hospital Management of Cardiogenic Shock.*

| Management | Microaxial Flow Pump plus Standard Care (N=179) | Standard Care Alone (N=176) |
|---|---|---|
| **Revascularization** | | |
| PCI — no. (%) | 171 (95.5) | 172 (97.7) |
| Non–culprit vessel PCI — no./no. of patients with multivessel disease (%) | 59/127 (46.5) | 55/129 (42.6) |
| Immediate CABG — no. (%) | 1 (0.6) | 4 (2.3) |
| Median time from admission to balloon inflation (IQR) — min | 58 (36–114) | 45 (31–81) |
| **Mechanical circulatory support** | | |
| Placement of Impella CP device — no. (%)† | 170 (95.0) | 3 (1.7) |
| Randomization occurred before PCI and microaxial flow pump placed before PCI — no./total no. (%) | 84/99 (84.8) | 3/3 (100) |
| Median time from randomization to placement of microaxial flow pump (IQR) — min | 14 (8–29) | 15 (8–31) |
| Median duration of microaxial flow pump support (IQR) — hr | 59 (30–87) | 60 (31–92) |
| Mechanical hemolysis — no./total no. (%) | 21/170 (12.4) | 1/3 (33.3) |
| Device malfunction — no./total no. (%)‡ | 2/170 (1.2) | 1/3 (33.3) |
| Successful weaning from microaxial flow pump — no./total no. (%) | 138/170 (81.2) | 1/3 (33.3) |
| **Escalation to additional mechanical circulatory support** | | |
| Placement of Impella 5.0 device — no. (%) | 7 (3.9) | 5 (2.8) |
| Placement of Impella CP for venting during venoarterial ECMO therapy — no. (%) | 0 | 4 (2.3) |
| Placement of Impella 2.5 device — no. (%) | 0 | 1 (0.6) |
| Placement of Impella RP device — no. (%) | 0 | 0 |
| Venoarterial ECMO — no. (%) | 21 (11.7) | 33 (18.8) |
| Median time from randomization to placement of venoarterial ECMO (IQR) — hr | 14 (4–54) | 2 (1–5) |
| Placement of permanent LVAD — no. (%) | 10 (5.6) | 4 (2.3) |
| Any escalation to additional mechanical circulatory support — no. (%) | 28 (15.6)§ | 37 (21.0)¶ |
| **Staged in-hospital revascularization procedures** | | |
| PCI — no. (%) | 7 (3.9) | 10 (5.7) |
| CABG — no. (%) | 0 | 3 (1.7) |
| Median duration of ICU admission (IQR) — days | 6 (2–15) | 3 (0–10) |
| Still in ICU at day 30 — no. (%) | 22 (12.3) | 11 (6.2) |
| Median duration of hospitalization (IQR) — days | 12 (4–27) | 7 (1–19) |
| Still in hospital at day 30 — no. (%) | 41 (22.9) | 19 (10.8) |
| **Intensive care management** | | |
| Mechanical ventilation — no. (%) | 133 (74.3) | 116 (65.9) |
| Median duration of mechanical ventilation (IQR) — days | 5 (2–10) | 3 (1–10) |
| Medication use — no. (%) | | |
| Any vasopressor | 159 (88.8) | 146 (83.0) |
| Norepinephrine | 156 (87.2) | 142 (80.7) |
| Dopamine | 51 (28.5) | 41 (23.3) |
| Epinephrine | 67 (37.4) | 66 (37.5) |
| Any inotrope | 124 (69.3) | 109 (61.9) |
| Dobutamine | 62 (34.6) | 59 (33.5) |
| Milrinone | 63 (35.2) | 58 (33.0) |
| Levosimendan | 40 (22.3) | 39 (22.2) |

Décès J180 : 45,8% vs 58,5%
HR 0.74; 95% CI, 0.55 to 0.99; P = 0.04



**Subgroup Analaysis of Death from Any Cause at 180 Days According to Country of Enrollment**

| | Mircoaxial Flow Pump | Standard of Care | Hazard Ratio (95%CI) |
|---|---|---|---|
| Country | | | |
| Denmark | 51/106 (48.1) | 70/109 (64.2) | 0.68 (0.48 - 0.98) |
| Germany/UK | 31/73 (42.5) | 33/67 (49.3) | 0.87 (0.53 - 1.42) |

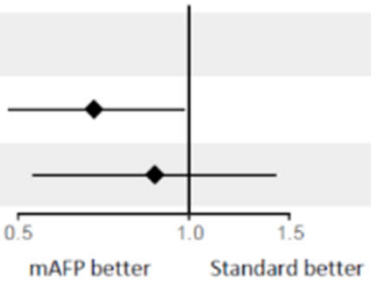



**Table S3 Cause of Death**

| | Microaxial Flow Pump | Standard Care |
|---|---|---|
| Death occurring from randomization to 30 days | | |
| Cardiac * — no./total (%) | 40 / 72 (55.6) | 58 / 82 (70.7) |
| Multiorgan failure — no. (%)/total | 20 / 72 (27.8) | 19 / 82 (23.2) |
| Neurological — no. (%)/total | 4 / 72 (5.6) | 1 / 82 (1.2) |
| Respiratory — no. (%)/total | 2 / 72 (2.8) | 0 / 82 (0.0) |
| Other — no. (%)/total | 6 / 72 (8.3) | 4 / 82 (4.9) |

# DANGER SHOCK : ADVERSE EVENTS

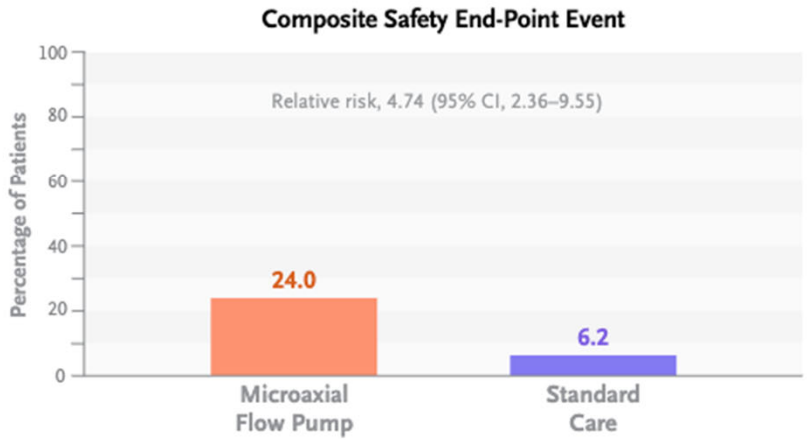
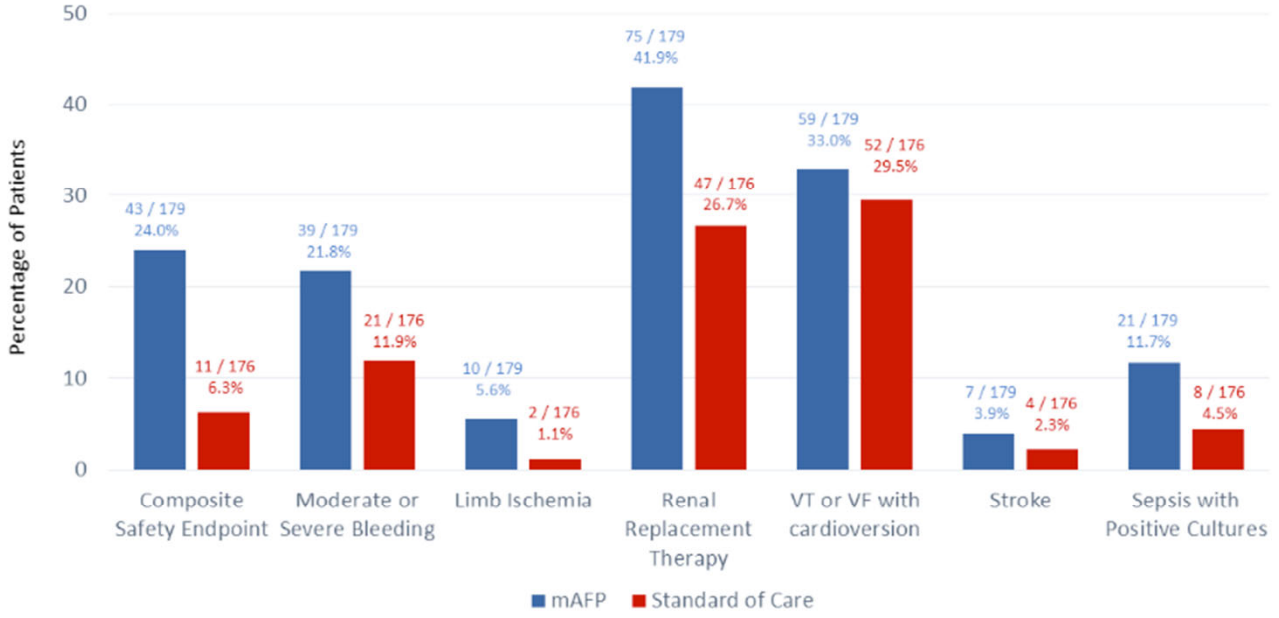



**Figure S7. Adverse Events during Hospitalization.**




Lüsebrink et al. European Heart Journal 2024; 45 (39) : 4181–4183.

HAUTE AUTORITÉ DE SANTÉ

**ÉVALUER** LES TECHNOLOGIES DE SANTÉ

**AVIS SUR LES DISPOSITIFS MEDICAUX**

# IMPELLA CP avec SMARTASSIST

## Dispositif d'assistance mécanique électrique percutanée, à flux axillaire, monoventriculaire gauche, de courte durée

Inscription

**Adopté par la Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé le 14 janvier 2025**

| | |
|---|---|
| **Indication retenue** | Prise en charge des patients présentant une réduction de la fonction ventriculaire gauche en raison d'un choc cardiogénique post-infarctus du myocarde avec élévation du segment ST (STEMI) avant ou après une intervention coronaire percutanée. Sont exclus, les patients qui ont eu un arrêt cardiaque avant le transfert à l'hôpital et qui ont un score ≤ 7 sur l'échelle de coma de Glasgow persistant après le retour de la circulation spontanée ainsi que les patients ayant une défaillance sévère du ventricule droit |

Practice Guideline > Arch Cardiovasc Dis. 2026 Mar 31:S1875-2136(26)00051-3.
doi: 10.1016/j.acvd.2026.02.001. Online ahead of print.

# Experts' recommendations for the management of adult patients with cardiogenic shock

Nadia Aissaoui [1], Clement Delmas [2], Hamid Merdji [3], Guillaume Schurtz [4], Guillaume Baudry [5], Antoine Beurton [6], Florence Boissier [7], Laurent Bonello [8], Bernard Cholley [9], Nicolas Combaret [5], Alain Combes [10], Charles-Henri David [11], Daniel De Backer [12], Pierre Grégoire Guinot [13], Olfa Hamzaoui [14], Brahim Harbaoui [15], Julien Imbault [6], Nicolas Nesseler [16], Antoine Kimmoun [17], Michel Kindo [18], Guillaume Lebreton [19], Guillaume Leurent [20], Bruno Levy [21], Stéphane Manzo-Silberman [22], Anne-Céline Martin [23], Armand Mekontso-Dessap [24], Imane Adda [25], Joy Mootien [26], Alexandre Ouattara [27], Matteo Pozzi [28], Etienne Puymirat [29], Francois Roubille [30], Antonin Trimaille [31], Aurore Ughetto [32], Eric Van Belle [4], Eric Bonnefoy [33], Khaldoun Kuteifan [34]

*5.5.2. Impella*

**R19A. An Impella CP should probably be considered in AMI-CS patients after discussion with CS expert team.**

*Level of evidence: grade 2+*

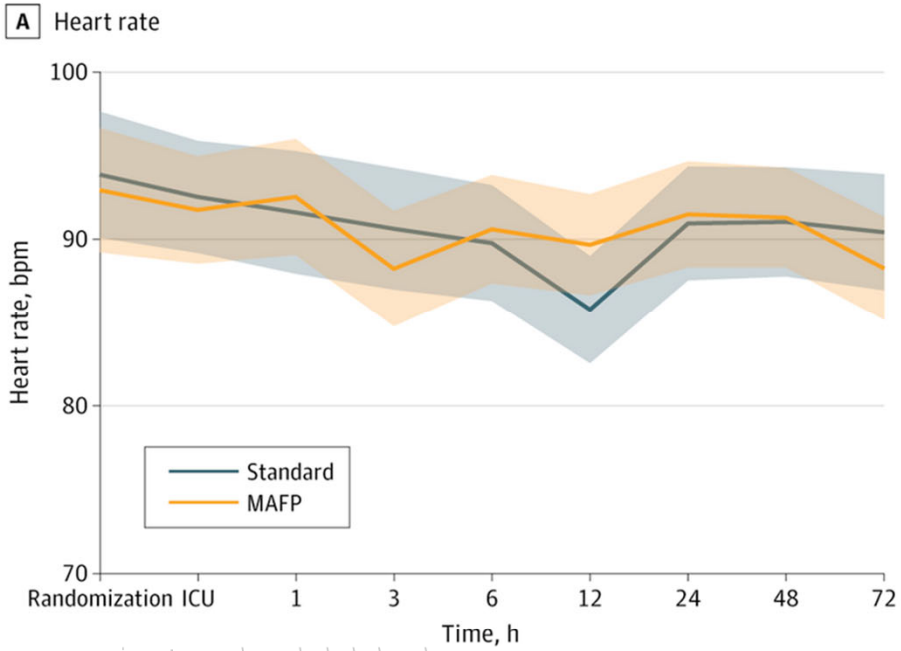
**R19B. The experts suggest considering Impella 5+ (5.0 or 5.5) support for CS patients due to predominant left ventricular failure.**

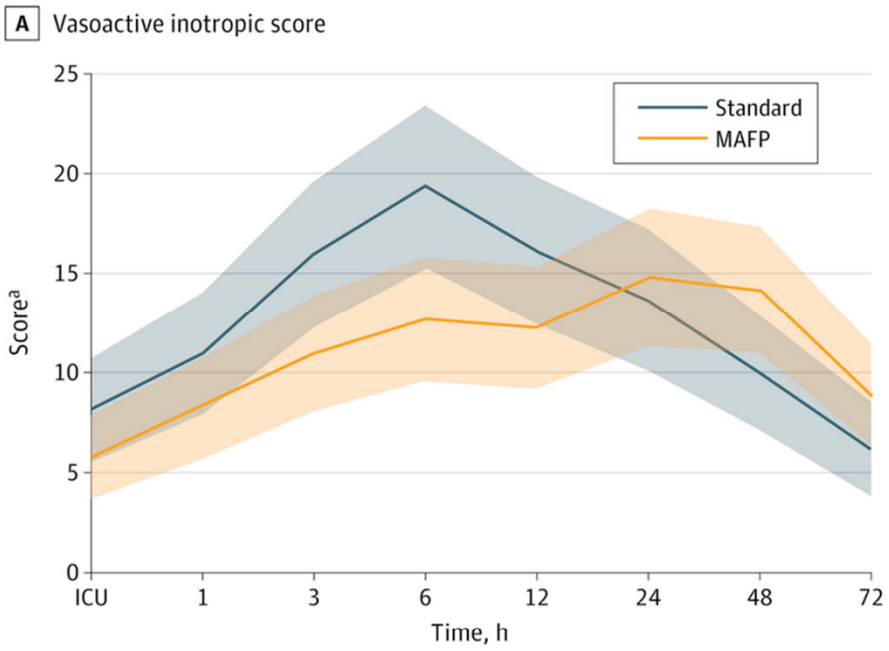
*Level of evidence: expert opinion*

# Microaxial Flow Pump Hemodynamic and Metabolic Effects in Infarct-Related Cardiogenic Shock

## A Substudy of the DanGer Shock Randomized Clinical Trial

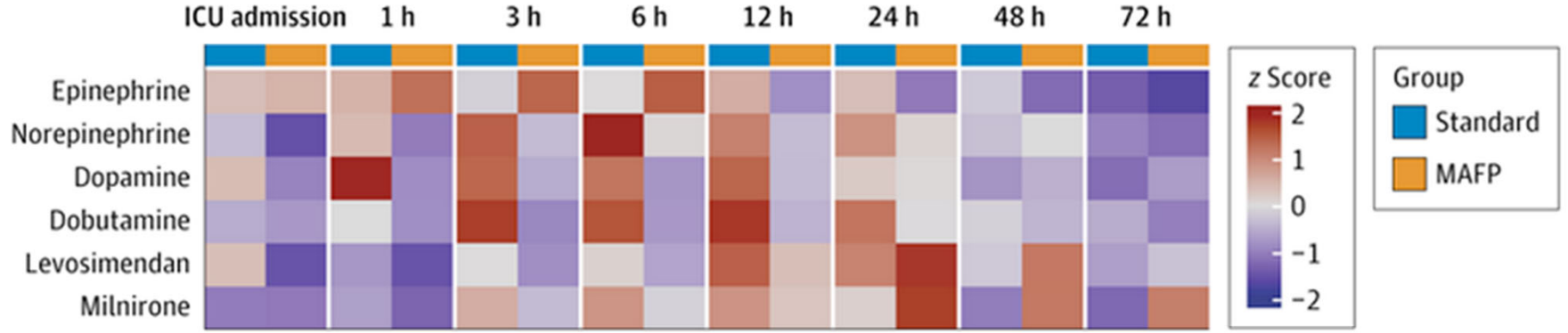
Nanna Louise Junker Udesen, MD, PhD[1]; Rasmus Paulin Beske, MD[2]; Christian Hassager, MD, DMSc[2,3]; et al



Clinical stability allowing discharge from the ICU within 72 hours was achieved in 51 patients (29%) in the standard-care group and 26 patients (15%) in the MAFP group.
Mortality at 30 days in patients discharged alive within 72 hours was 4% in both groups.

**Figure 3. Heatmap Depicting Dose of Vasoactive Drugs Used in the Microaxial Flow Pump (MAFP) and Standard-Care Groups at Different Time Points**

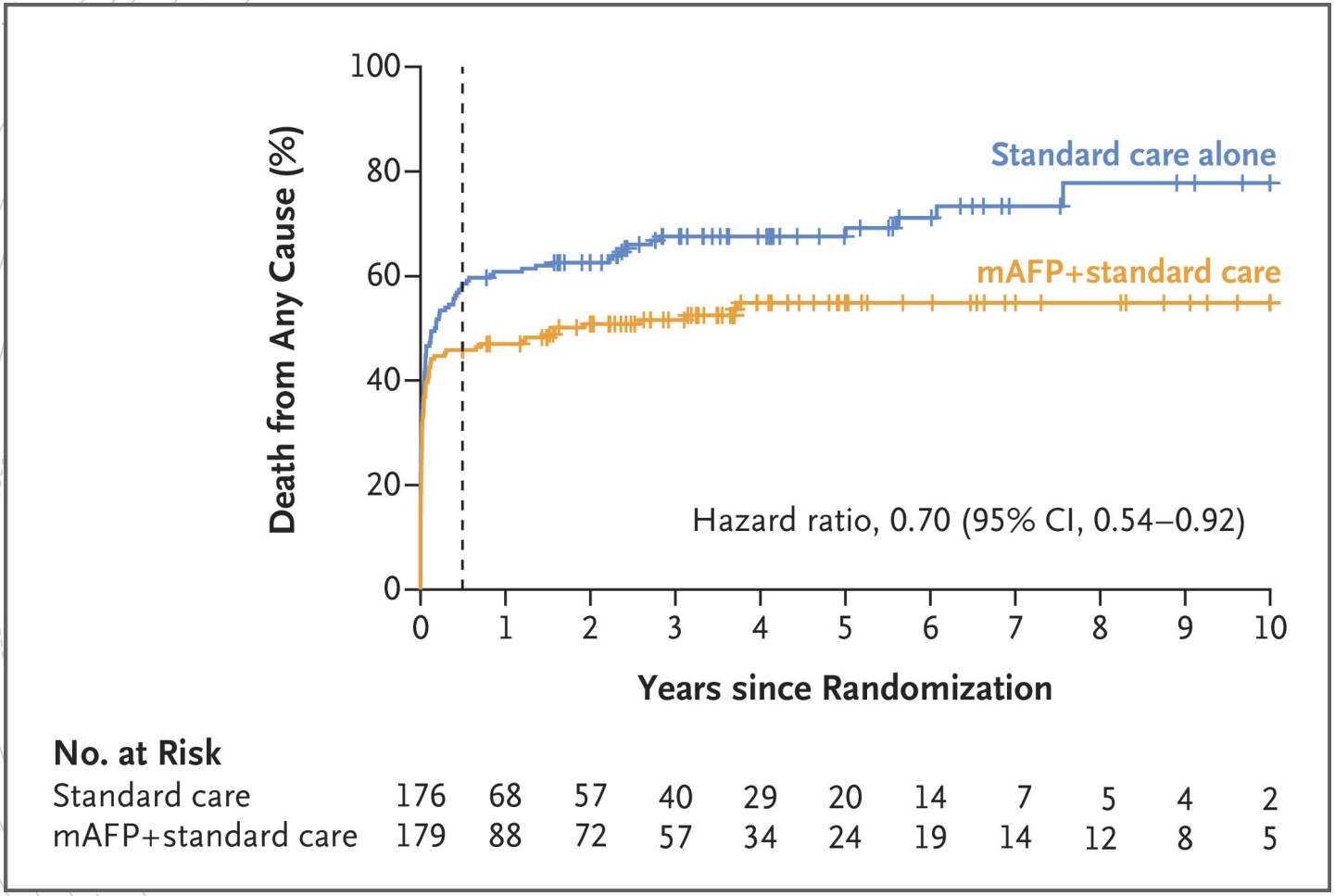


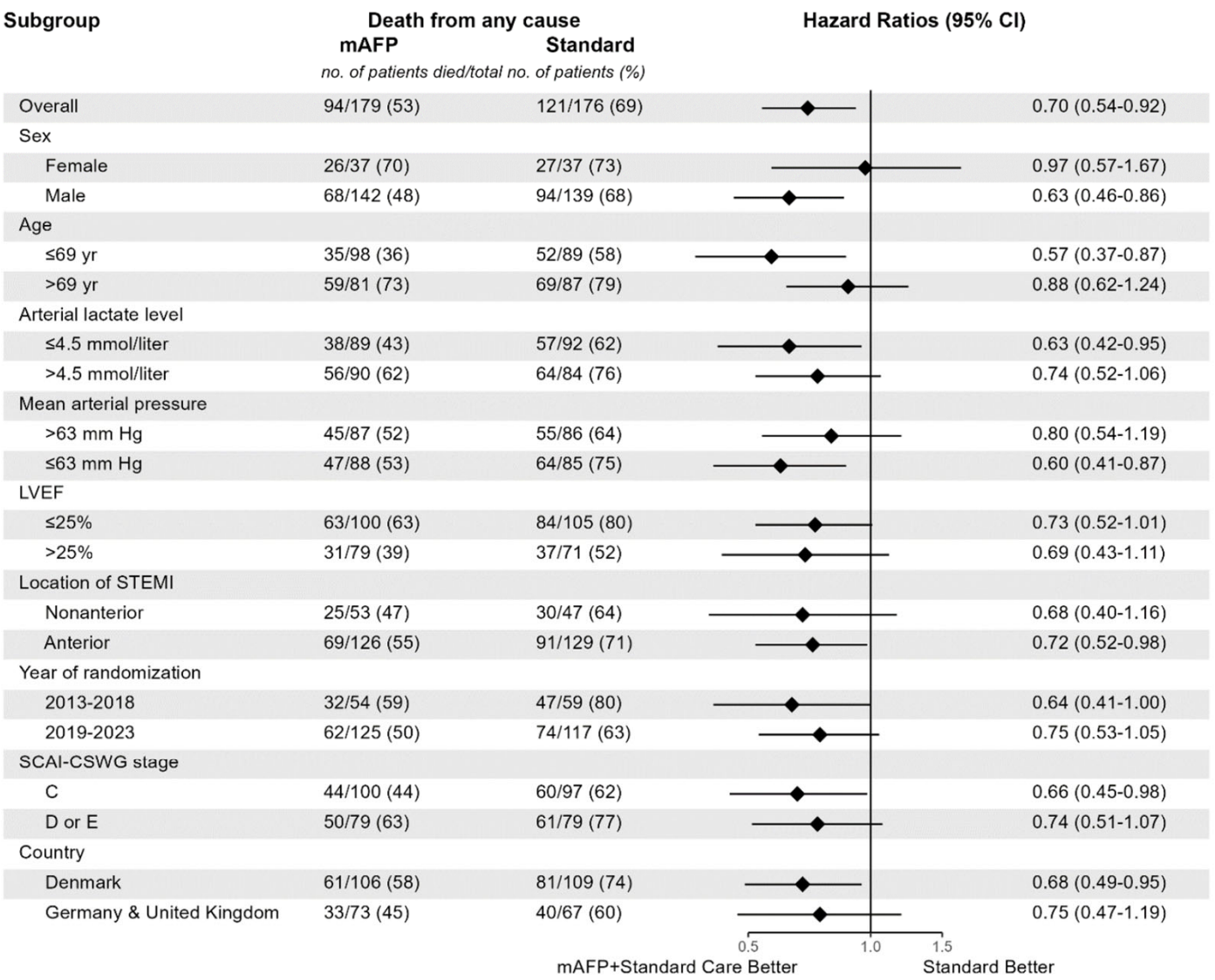

Doses were scaled to a *z* score to enable visual comparisons between groups and time points. The *z* score: gray depicts mean, red SD above mean, blue SD below mean. The colors can be compared between the 2 treatments (standard of care and MAFP) and between different times but not between the different groups of vasoactive drugs. ICU indicates intensive care unit.

# Long-Term Outcomes of the DanGer Shock Trial

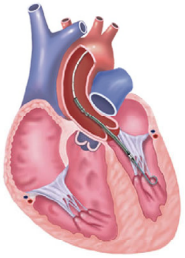
Published August 31, 2025 | N Engl J Med 2025;393:1037-1038 | DOI: 10.1056/NEJMc2508284 | VOL. 393 NO. 10






Subgroup
Death from any cause
mAFP
Standard
no. of patients died/total no. of patients (%)
Hazard Ratios (95% CI)
Overall 94/179 (53) 121/176 (69) 0.70 (0.54-0.92)
Sex
Female 26/37 (70) 27/37 (73) 0.97 (0.57-1.67)
Male 68/142 (48) 94/139 (68) 0.63 (0.46-0.86)
Age
≤69 yr 35/98 (36) 52/89 (58) 0.57 (0.37-0.87)
>69 yr 59/81 (73) 69/87 (79) 0.88 (0.62-1.24)
Arterial lactate level
≤4.5 mmol/liter 38/89 (43) 57/92 (62) 0.63 (0.42-0.95)
>4.5 mmol/liter 56/90 (62) 64/84 (76) 0.74 (0.52-1.06)
Mean arterial pressure
>63 mm Hg 45/87 (52) 55/86 (64) 0.80 (0.54-1.19)
≤63 mm Hg 47/88 (53) 64/85 (75) 0.60 (0.41-0.87)
LVEF
≤25% 63/100 (63) 84/105 (80) 0.73 (0.52-1.01)
>25% 31/79 (39) 37/71 (52) 0.69 (0.43-1.11)
Location of STEMI
Nonanterior 25/53 (47) 30/47 (64) 0.68 (0.40-1.16)
Anterior 69/126 (55) 91/129 (71) 0.72 (0.52-0.98)
Year of randomization
2013-2018 32/54 (59) 47/59 (80) 0.64 (0.41-1.00)
2019-2023 62/125 (50) 74/117 (63) 0.75 (0.53-1.05)
SCAI-CSWG stage
C 44/100 (44) 60/97 (62) 0.66 (0.45-0.98)
D or E 50/79 (63) 61/79 (77) 0.74 (0.51-1.07)
Country
Denmark 61/106 (58) 81/109 (74) 0.68 (0.49-0.95)
Germany & United Kingdom 33/73 (45) 40/67 (60) 0.75 (0.47-1.19)
0.5
1.0
1.5
mAFP+Standard Care Better
Standard Better

## CENTRAL ILLUSTRATION: Randomized Clinical Trials of the Percutaneous Microaxial Flow Pump Device



**Percutaneous Microaxial Flow Pump Devices**

| | High Risk PCI | Role in AMI-CS | Role in Unloading |
|---|---|---|---|
| Mechanism of Action | • Reduce myocardial oxygen consumption<br>• Improve myocardial blood flow<br>• Maintain systemic perfusion | • Improve cardiac output<br>• Decrease LVEDP<br>• Improve systemic perfusion and BP<br>• Prevent progressive systemic inflammation response syndrome | • Reduce myocardial oxygen-demand<br>• Decrease LVEDP and improve collateral flow<br>• Enhance activity of kinases limiting ischemia reperfusion injury and promote recovery<br>• Preserve mitochondrial integrity |
| Clinical Trials | • PROTECT II<br>*Future Trials*<br>- PROTECT IV | • ISAR-Shock<br>• IMPRESS<br>• IMPELLA-STIC<br>*Future Trials*<br>- Dan-Ger Shock<br>- REVERSE<br>- RECOVER-IV | • DTU<br>*Future Trials*<br>- DTU-STEMI<br>- UNLOAD-AMI<br>- HERACLES |

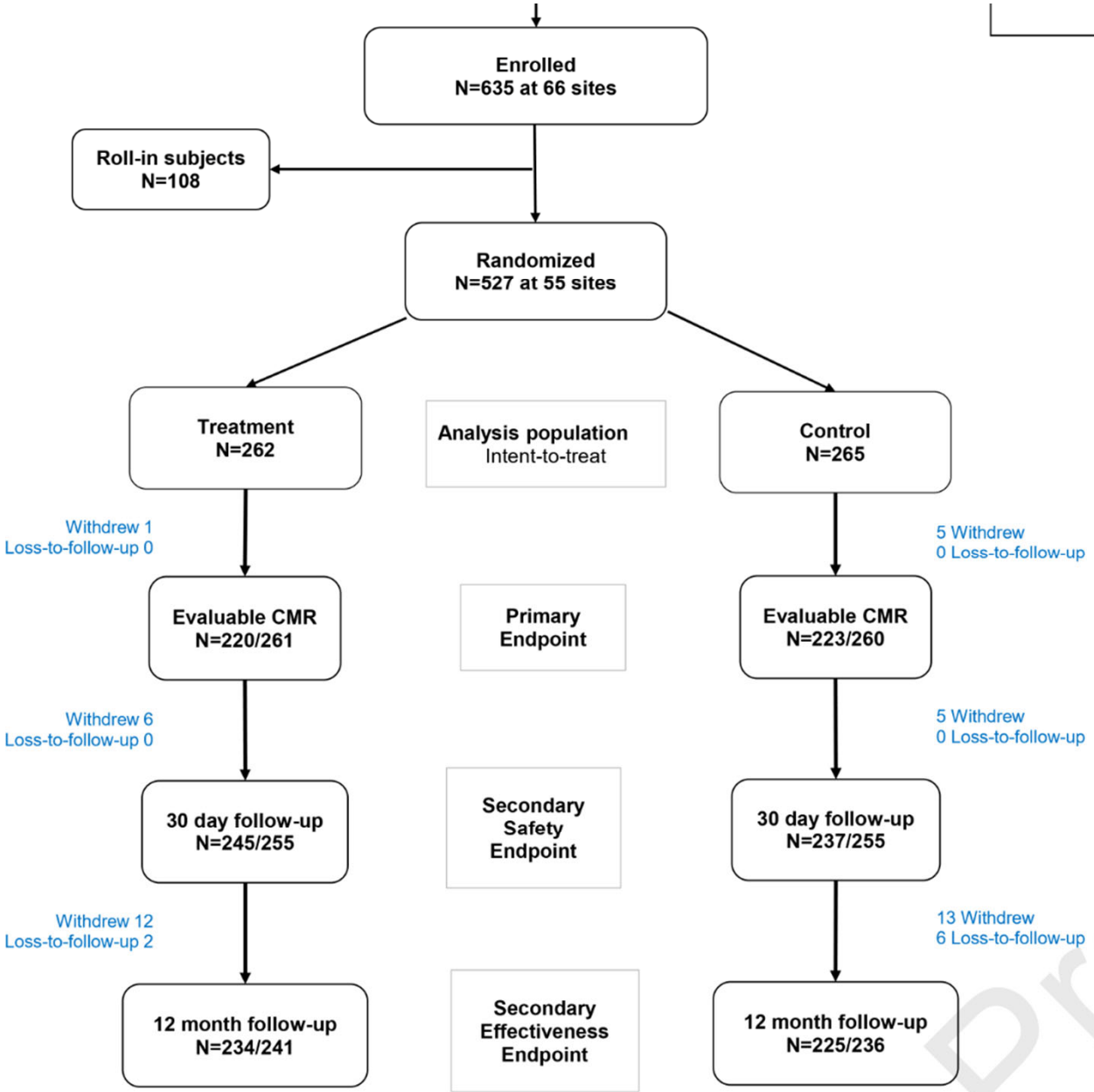
Pahuja M, et al. J Am Coll Cardiol. 2022;80(21):2028-2049.

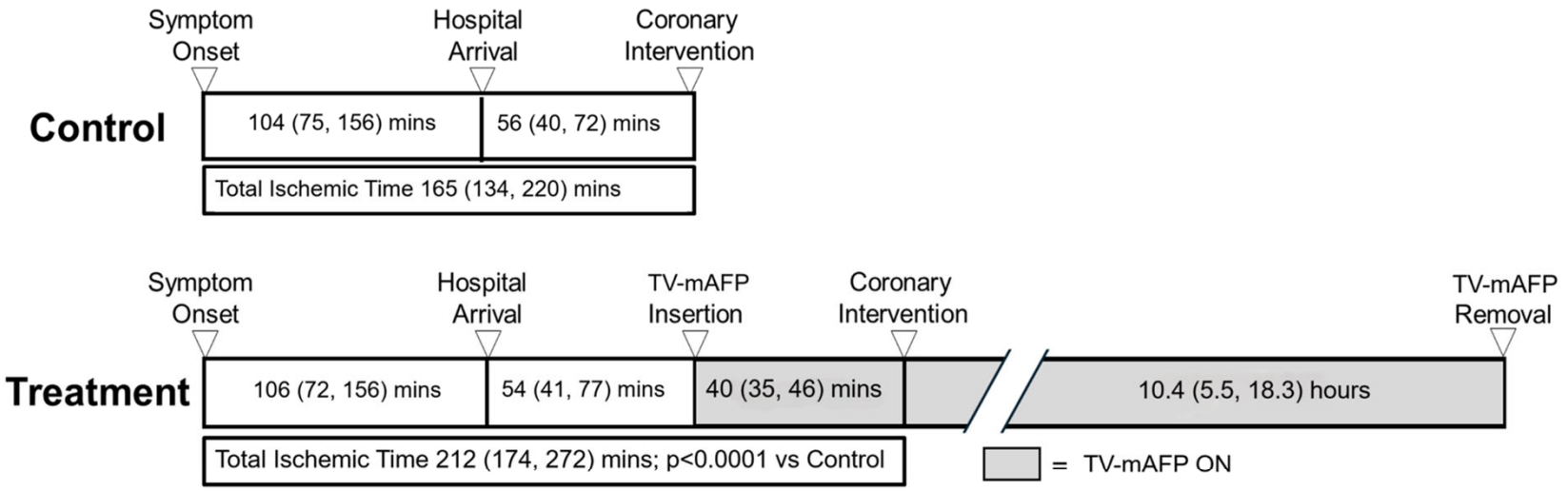
# Left Ventricular Unloading in Anterior STEMI without Shock: The STEMI Door to Unload (DTU) Randomized Controlled Trial

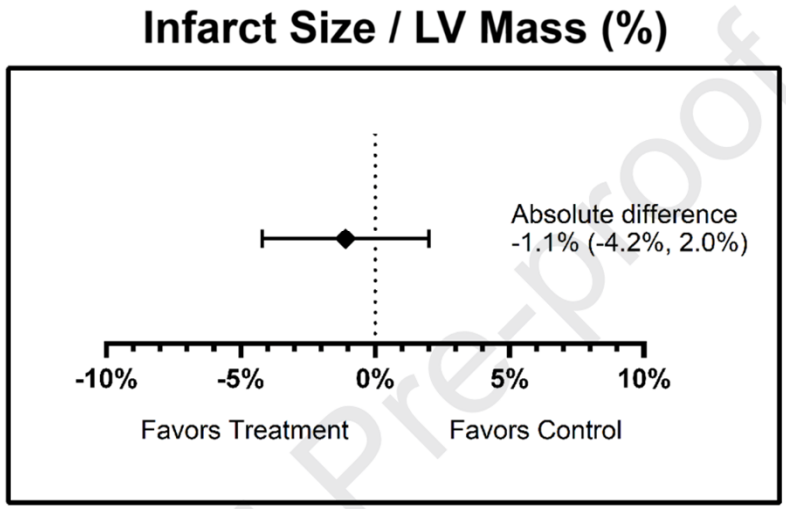
Navin K. Kapur MD [a b *], Norman Mangner MD [c], Nima Aghili MD [d], Haroon Faraz MD [e],

Adultes 18–85 ans · STEMI antérieur sans choc cardiogénique · délai 1–6h · premier IDM
RCT : Impella CP 30 min avant PCI vs Contrôle (PCI seule)

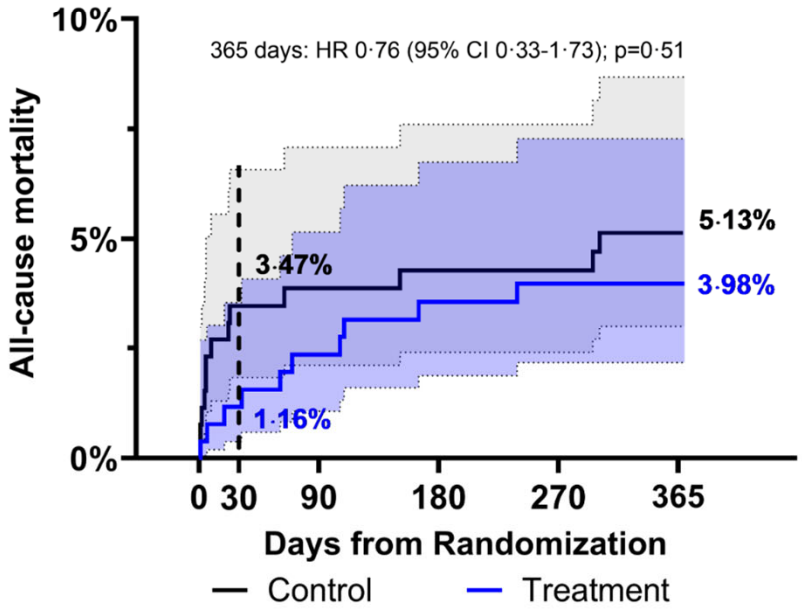
Objectif : Taille IDM / masse VG (IS/LVM, %) par CMR gadolinium à J3–5


Enrolled
N=635 at 66 sites
Roll-in subjects
N=108
Randomized
N=527 at 55 sites
Treatment
N=262
Analysis population
Intent-to-treat
Control
N=265
Withdrew 1
Loss-to-follow-up 0
5 Withdrew
0 Loss-to-follow-up
Evaluable CMR
N=220/261
Primary
Endpoint
Evaluable CMR
N=223/260
Withdrew 6
Loss-to-follow-up 0
5 Withdrew
0 Loss-to-follow-up
30 day follow-up
N=245/255
Secondary
Safety
Endpoint
30 day follow-up
N=237/255
Withdrew 12
Loss-to-follow-up 2
13 Withdrew
6 Loss-to-follow-up
12 month follow-up
N=234/241
Secondary
Effectiveness
Endpoint
12 month follow-up
N=225/236


Symptom Onset
Hospital Arrival
Coronary Intervention
Control
104 (75, 156) mins
56 (40, 72) mins
Total Ischemic Time 165 (134, 220) mins
Symptom Onset
Hospital Arrival
TV-mAFP Insertion
Coronary Intervention
TV-mAFP Removal
Treatment
106 (72, 156) mins
54 (41, 77) mins
40 (35, 46) mins
10.4 (5.5, 18.3) hours
Total Ischemic Time 212 (174, 272) mins; p<0.0001 vs Control
= TV-mAFP ON


Infarct Size / LV Mass (%)
Absolute difference
-1.1% (-4.2%, 2.0%)
-10%
-5%
0%
5%
10%
Favors Treatment
Favors Control

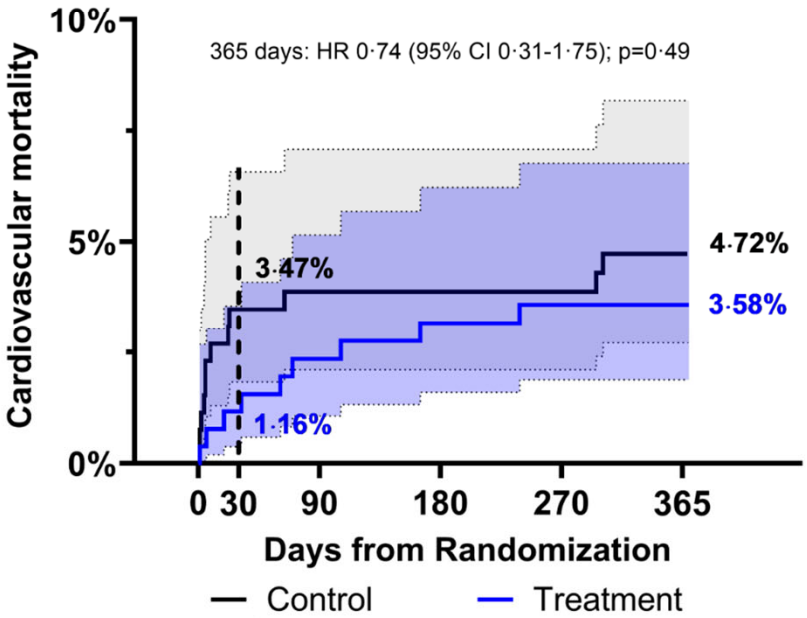
## All-cause mortality




**Number at Risk**

| | | | | | |
|---|---|---|---|---|---|
| Control | 265 | 240 | 233 | 226 | 208 |
| Treatment | 262 | 245 | 237 | 230 | 213 |

## Cardiovascular mortality




**Number at Risk**

| | | | | | |
|---|---|---|---|---|---|
| Control | 265 | 240 | 233 | 226 | 208 |
| Treatment | 262 | 245 | 237 | 230 | 213 |

# Pourquoi cet échec ?

1. Allongement du temps d'ischémie (+47 min)
2. Hypertension des patients (par rapport à l'hypotension sur modèles animaux)

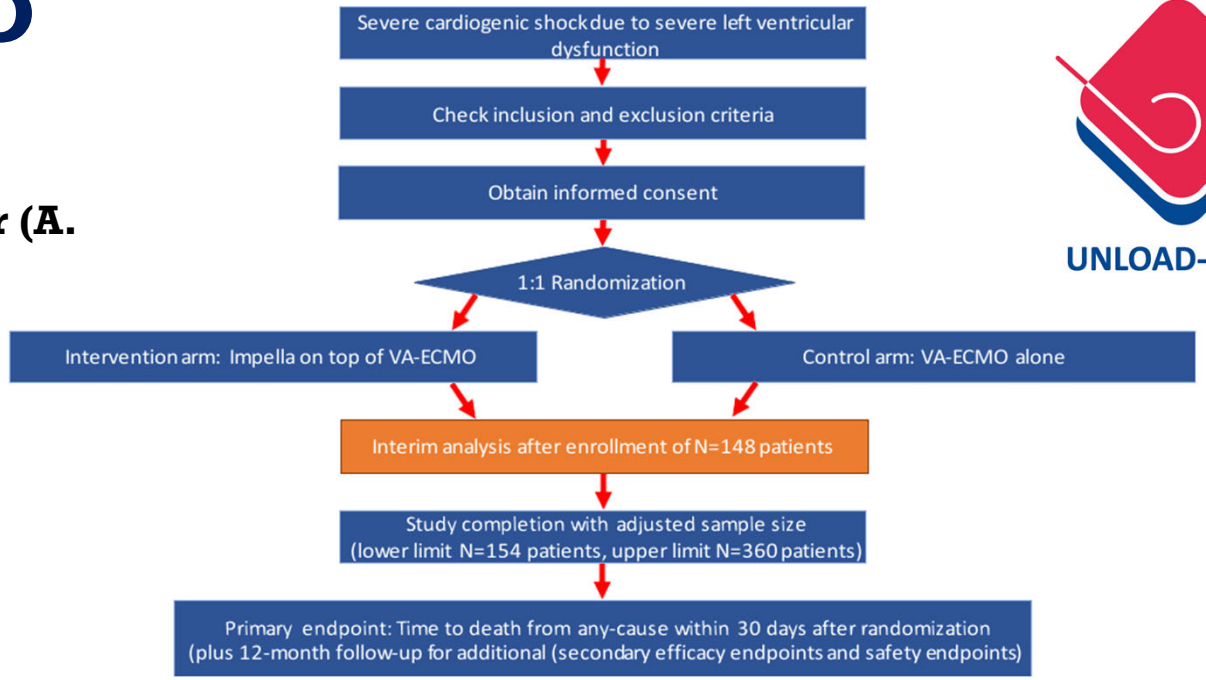
| | | | |
|---|---|---|---|
| Mean arterial pressure, mmHg | 106.5 ± 17.8 | 107.5 ± 17.9 | 105.5 ± 17.7 |

Et plus de complications hémorragiques

| | | | |
|---|---|---|---|
| Sécurité — Hémorragies majeures BARC 3-5 à 30j (traitement vs contrôle) | 89/262 = 34.0% | 16/265 = 6.0% | p < 0.01 |
| dont BARC 3a (↓Hb 3–5 g/dL) | 40/260 (15.4%) | — | |
| dont BARC 3b (↓Hb ≥5 g/dL) | 39/260 (15.4%) | — | |
| dont BARC 5 (fatal) | 1/260 (0.4%) | — | |

# UNLOAD ECMO

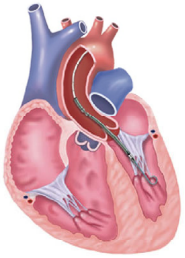
**PI: B. Schrage (Hamburg)**
**France: Montpellier Coordinator Center (A. Ughetto)**


UNLOAD-ECMO

**We hypothesize that left ventricular unloading by addition of an Impella on top of VA-ECMO for the treatment of patients with severe cardiogenic shock improves 30-day survival in comparison to VA-ECMO alone.**

## CENTRAL ILLUSTRATION: Randomized Clinical Trials of the Percutaneous Microaxial Flow Pump Device



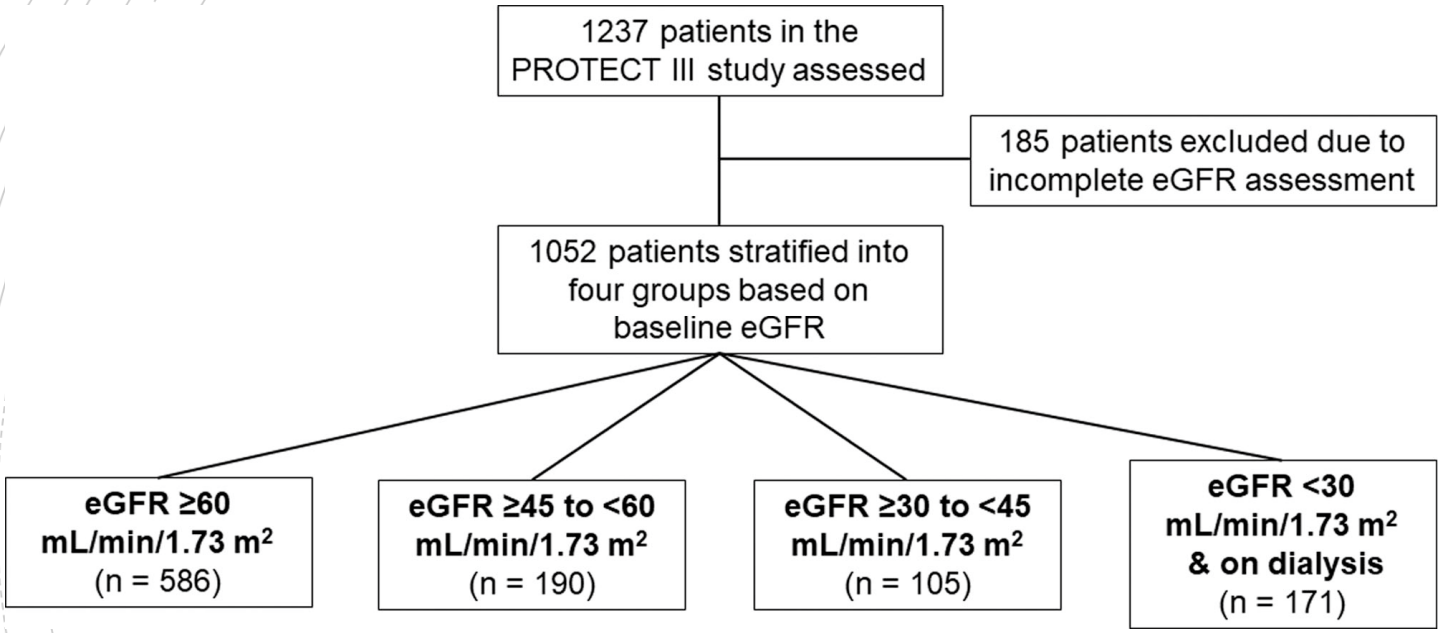
**Percutaneous Microaxial Flow Pump Devices**

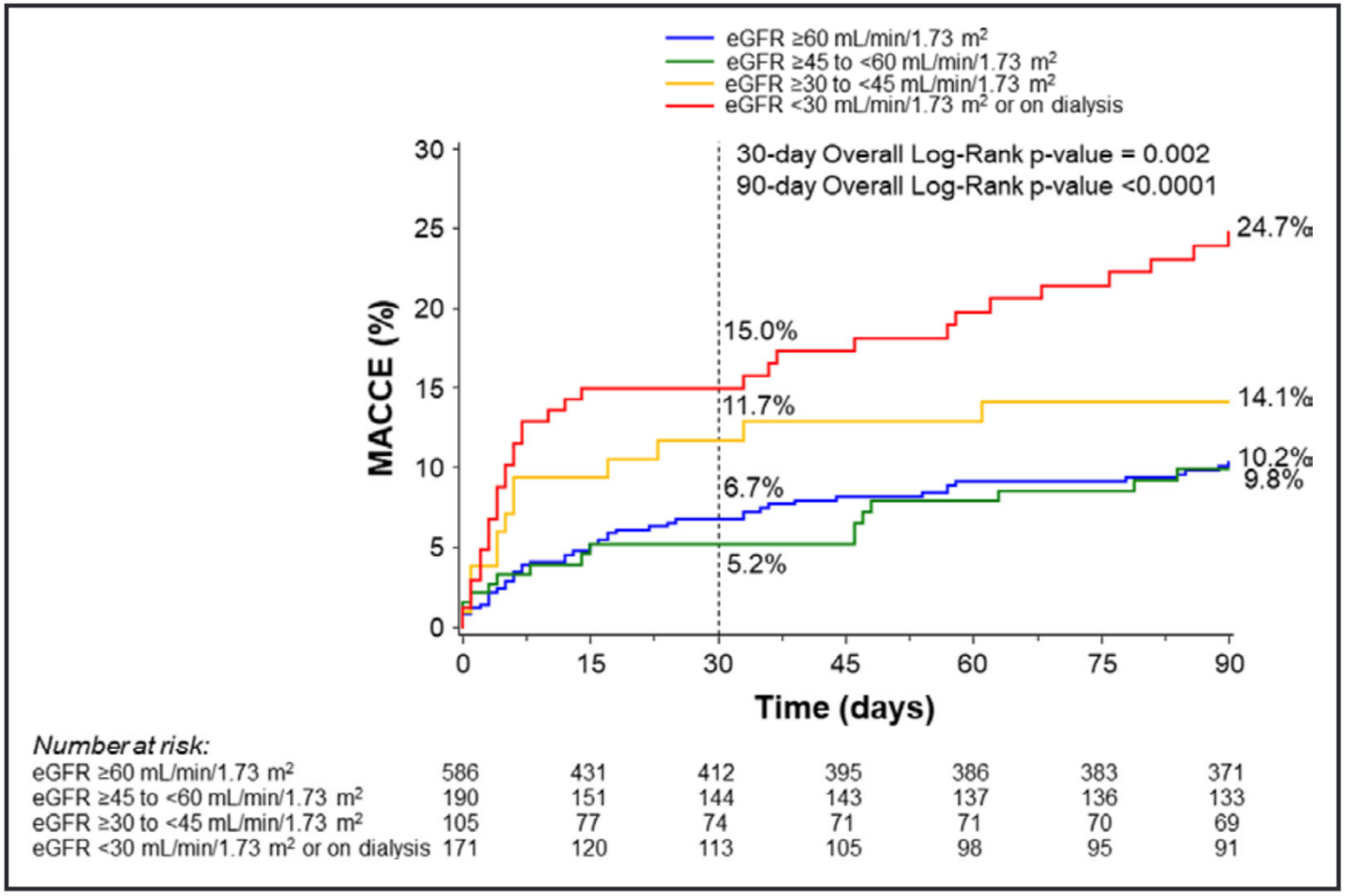
| | High Risk PCI | Role in AMI-CS | Role in Unloading | Role in Protection of Kidneys |
|---|---|---|---|---|
| Mechanism of Action | • Reduce myocardial oxygen consumption<br>• Improve myocardial blood flow<br>• Maintain systemic perfusion | • Improve cardiac output<br>• Decrease LVEDP<br>• Improve systemic perfusion and BP<br>• Prevent progressive systemic inflammation response syndrome | • Reduce myocardial oxygen-demand<br>• Decrease LVEDP and improve collateral flow<br>• Enhance activity of kinases limiting ischemia reperfusion injury and promote recovery<br>• Preserve mitochondrial integrity | • Improve renal perfusion by increasing cardiac output<br>• Decrease LVEDP resulting in renal venous decongestion |
| Clinical Trials | • PROTECT II<br>*Future Trials*<br>- PROTECT IV | • ISAR-Shock<br>• IMPRESS<br>• IMPELLA-STIC<br>*Future Trials*<br>- Dan-Ger Shock<br>- REVERSE<br>- RECOVER-IV | • DTU<br>*Future Trials*<br>- DTU-STEMI<br>- UNLOAD-AMI<br>- HERACLES | *Future Trials*<br>- PROTECT KIDNEY |

Pahuja M, et al. J Am Coll Cardiol. 2022;80(21):2028-2049.

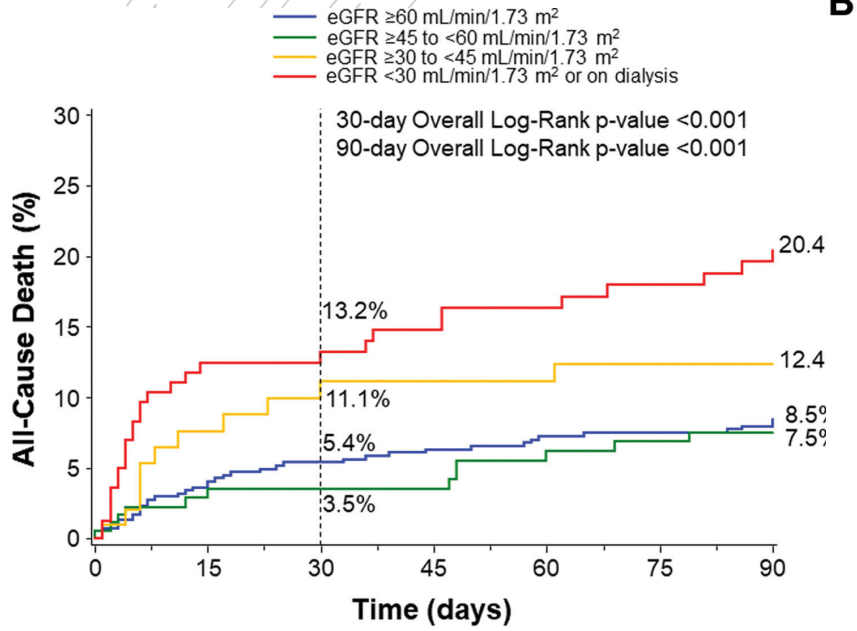
# Angiographic Characteristics and Clinical Outcomes in Patients With Chronic Kidney Disease Undergoing Impella-Supported High-Risk Percutaneous Coronary Intervention: Insights From the cVAD PROTECT III Study

Aditya S. Bharadwaj, MD, Arsalan Abu-Much, MD, Aneel S. Maini, MD, Zhipeng Zhou, MA, Yanru Li, MS, MPH, Wayne B. Batchelor,




eGFR ≥60 mL/min/1.73 m²
eGFR ≥45 to <60 mL/min/1.73 m²
eGFR ≥30 to <45 mL/min/1.73 m²
eGFR <30 mL/min/1.73 m² or on dialysis
30-day Overall Log-Rank p-value = 0.002
90-day Overall Log-Rank p-value <0.0001
MACCE (%)
Time (days)
24.7%a
15.0%
14.1%a
11.7%
10.2%a
9.8%
6.7%
5.2%
Number at risk:
eGFR ≥60 mL/min/1.73 m² 586 431 412 395 386 383 371
eGFR ≥45 to <60 mL/min/1.73 m² 190 151 144 143 137 136 133
eGFR ≥30 to <45 mL/min/1.73 m² 105 77 74 71 71 70 69
eGFR <30 mL/min/1.73 m² or on dialysis 171 120 113 105 98 95 91

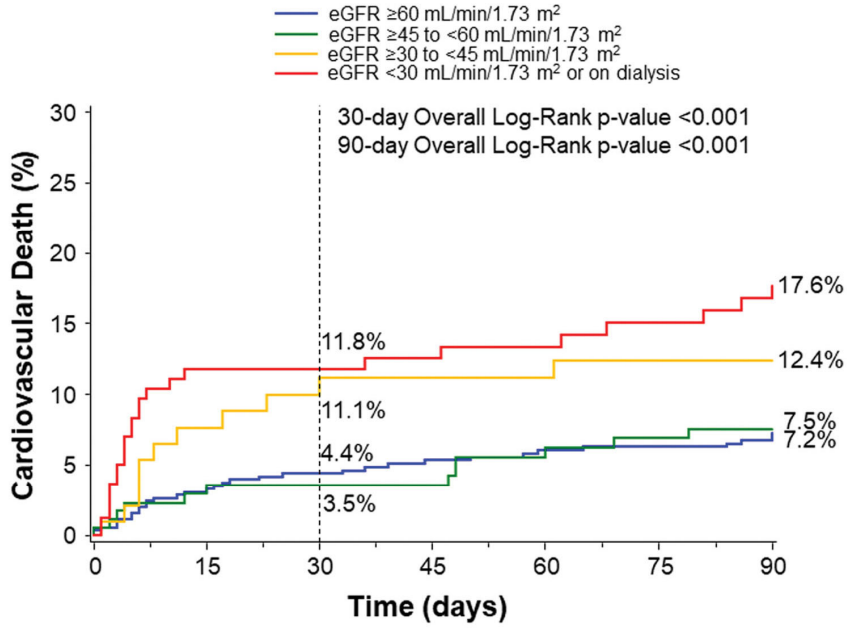
**A**




*Number at risk:*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| eGFR ≥60 mL/min/1.73 m² | 586 | 436 | 418 | 403 | 394 | 389 | 379 |
| eGFR ≥45 to <60 mL/min/1.73 m² | 190 | 153 | 146 | 145 | 140 | 138 | 136 |
| eGFR ≥30 to <45 mL/min/1.73 m² | 105 | 79 | 76 | 73 | 73 | 72 | 71 |
| eGFR <30 mL/min/1.73 m² or on dialysis | 171 | 124 | 117 | 109 | 103 | 100 | 97 |

**B**




*Number at risk:*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| eGFR ≥60 mL/min/1.73 m² | 586 | 436 | 418 | 403 | 394 | 389 | 379 |
| eGFR ≥45 to <60 mL/min/1.73 m² | 190 | 153 | 146 | 145 | 140 | 138 | 136 |
| eGFR ≥30 to <45 mL/min/1.73 m² | 105 | 79 | 76 | 73 | 73 | 72 | 71 |
| eGFR <30 mL/min/1.73 m² or on dialysis | 171 | 124 | 117 | 109 | 103 | 100 | 97 |

# IMPELLA en post-cardiotomie

Cardiothoracic transplantation

# The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support

Bartley P. Griffith MD [a], Mark B. Anderson MD [b], Louis E. Samuels MD [c], Walter E. Pae Jr. MD [d], Yoshifumi Naka MD, PhD [e], O. Howard Frazier MD [f]

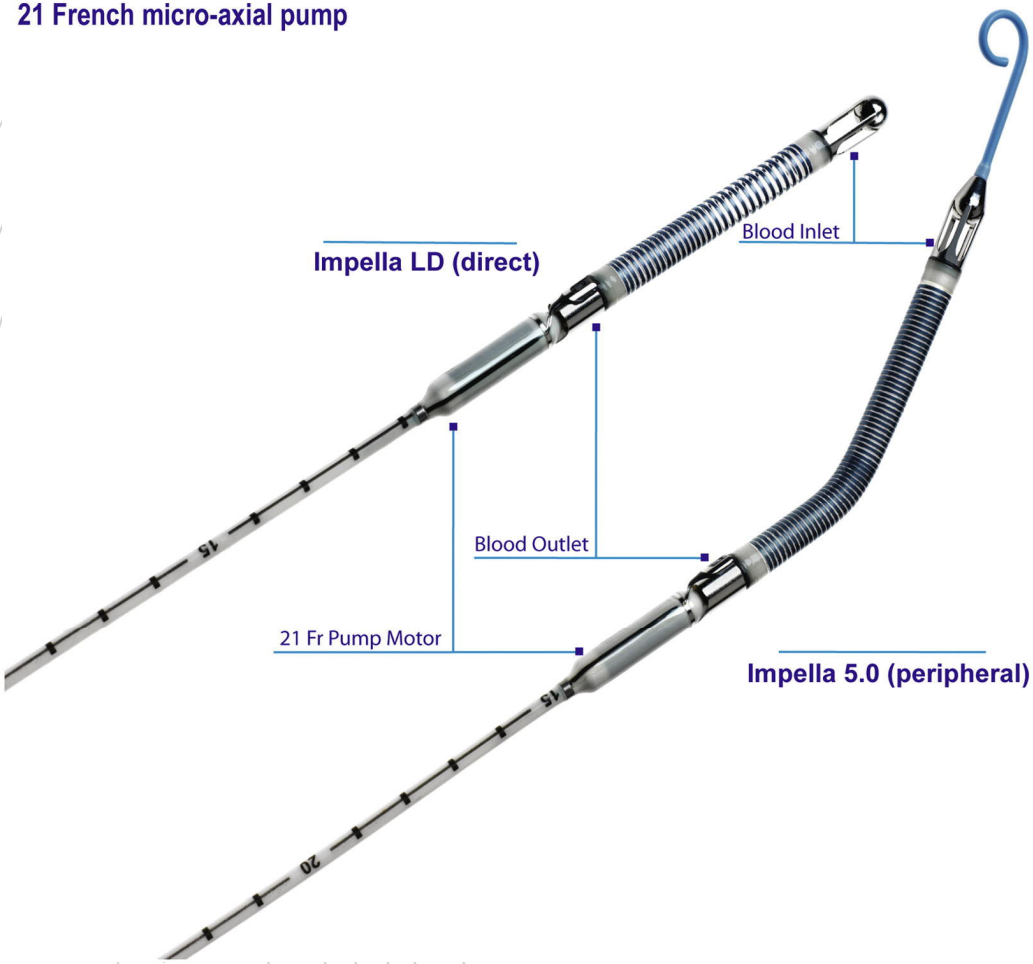
Choc cardiogénique ou un syndrome de bas débit après sevrage de la CEC

Traitement : Impella 5.0 ou Left Direct (LD).

Le critère de sécurité principal était la fréquence des événements indésirables majeurs (décès, AVC) à 30 jours ou à la sortie.

Le critère d'efficacité principal était la survie du patient jusqu'à la mise en œuvre de la thérapie suivante (recovery J30 ou autre thérapie invasive)

9 French catheter
21 French micro-axial pump




From October 25, 2006, to May 16, 2008,
16 patients
4 centres USA

# Mechanical circulatory support with the Impella 5.0 and the Impella Left Direct pumps for postcardiotomy cardiogenic shock at La Pitié-Salpêtrière Hospital

Charles-Henri David, Astrid Quessard, Ciro Mastroianni, Guillaume Hekimian ,
Julien Amour, Pascal Leprince and Guillaume Lebreton *

## Key question

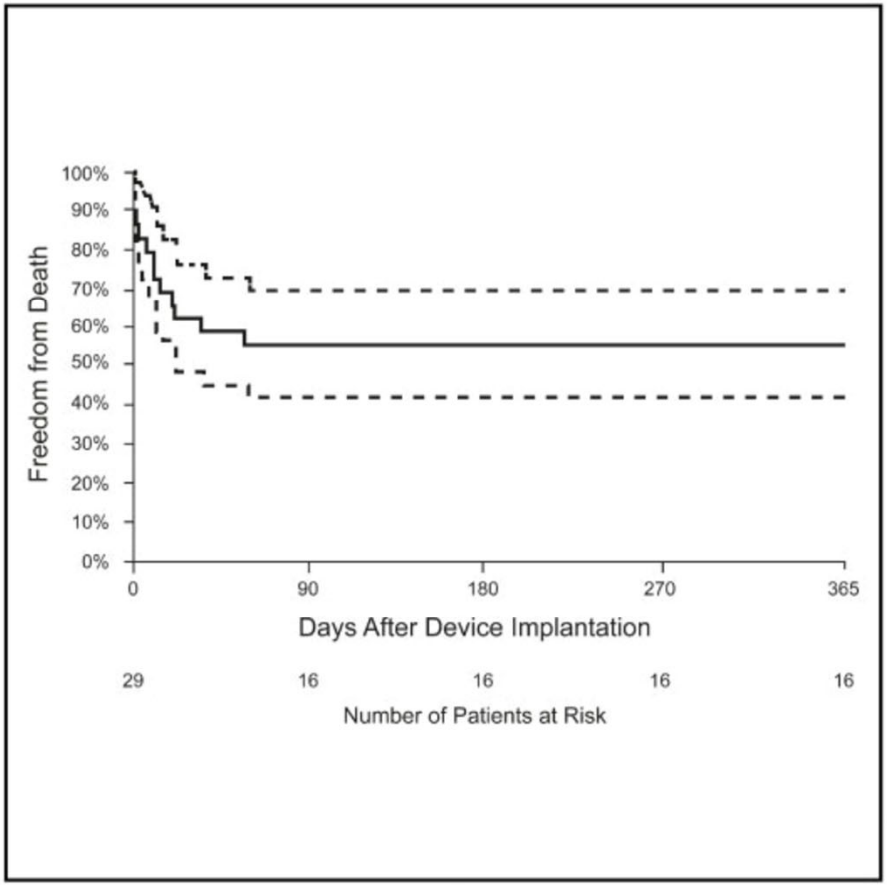
What is the outcome of haemodynamic support with the Impella 5.0 and the Impella Left Direct (LD) devices for postcardiotomy cardiogenic shock (PCCS)?

## Key finding(s)

Postcardiotomy cardiogenic shock (n=29):
58.6% survival to discharge;
100% native heart recovery among those discharged.

## Take-home message

The Impella 5.0 and Impella LD represent excellent treatment options for PCCS with favourable survival outcome and native heart recovery.



**IMPELLA 5.0,** dispositif d'assistance mécanique électrique percutanée, à flux axial, monoventriculaire gauche, de courte durée.

Demandeur : ABIOMED SARL. (France)

Fabricant : ABIOMED EUROPE GMBH (Allemagne)

*Les modèles et références proposés par le demandeur (cf. page 5)*

| | |
|---|---|
| Indication retenue : | Prise en charge de l'adulte en état de choc cardiogénique (CC) réfractaire au traitement médical optimal sans défaillance respiratoire réfractaire nécessitant une assistance respiratoire extracorporelle et sans une défaillance multi-viscérale sévère, survenant à la suite d'une chirurgie cardiaque. |
| Service Attendu (SA) : | <u>Indication retenue</u> :<br>• **Suffisant,** en raison de :<br>- L'intérêt thérapeutique de IMPELLA 5.0 dans l'indication retenue,<br>- L'intérêt de santé publique au vu de gravité extrême de la pathologie et du caractère d'urgence de sa prise en charge.<br><br><u>Indication non retenue</u> :<br>Prise en charge de de l'adulte de moins de 65 ans en état de choc cardiogénique réfractaire au traitement médicamenteux optimal et ne présentant pas de défaillance respiratoire réfractaire nécessitant une assistance respiratoire extracorporelle et/ou sans une défaillance multi-viscérale sévère, en attente de transplantation cardiaque ou d'assistance circulatoire de longue durée<br>• **Insuffisant,** les données disponibles ne permettent pas d'établir l'intérêt de IMPELLA 5.0 dans cette indication |

# IMPACT Impella® Protected Cardiac Surgery Trial

## Key Inclusion Criteria

- Hemodynamically stable patients undergoing one of the following cardiac surgery procedures on CPB including aortic cross-clamping and cardioplegic arrest:
  - CABG
  - MVR
  - AVR
  - At least 2 of the following: CABG, MVR, AVR, or TVR
- LVEF ≤25% or ≤35% with significant MR and planned MVR
- Age ≥ 18 years

## Study Flow

**Subject meets all IC/EC**
and is approved by study's Enrollment Committee

↓

**Index Cardiac Surgery Performed**
*including Impella 5.5 placed prior to any attempt to wean from CPB*

↓

**Patient Transferred to ICU on Impella 5.5 Support**
*≥24 hrs of 5.5 support required*

↓

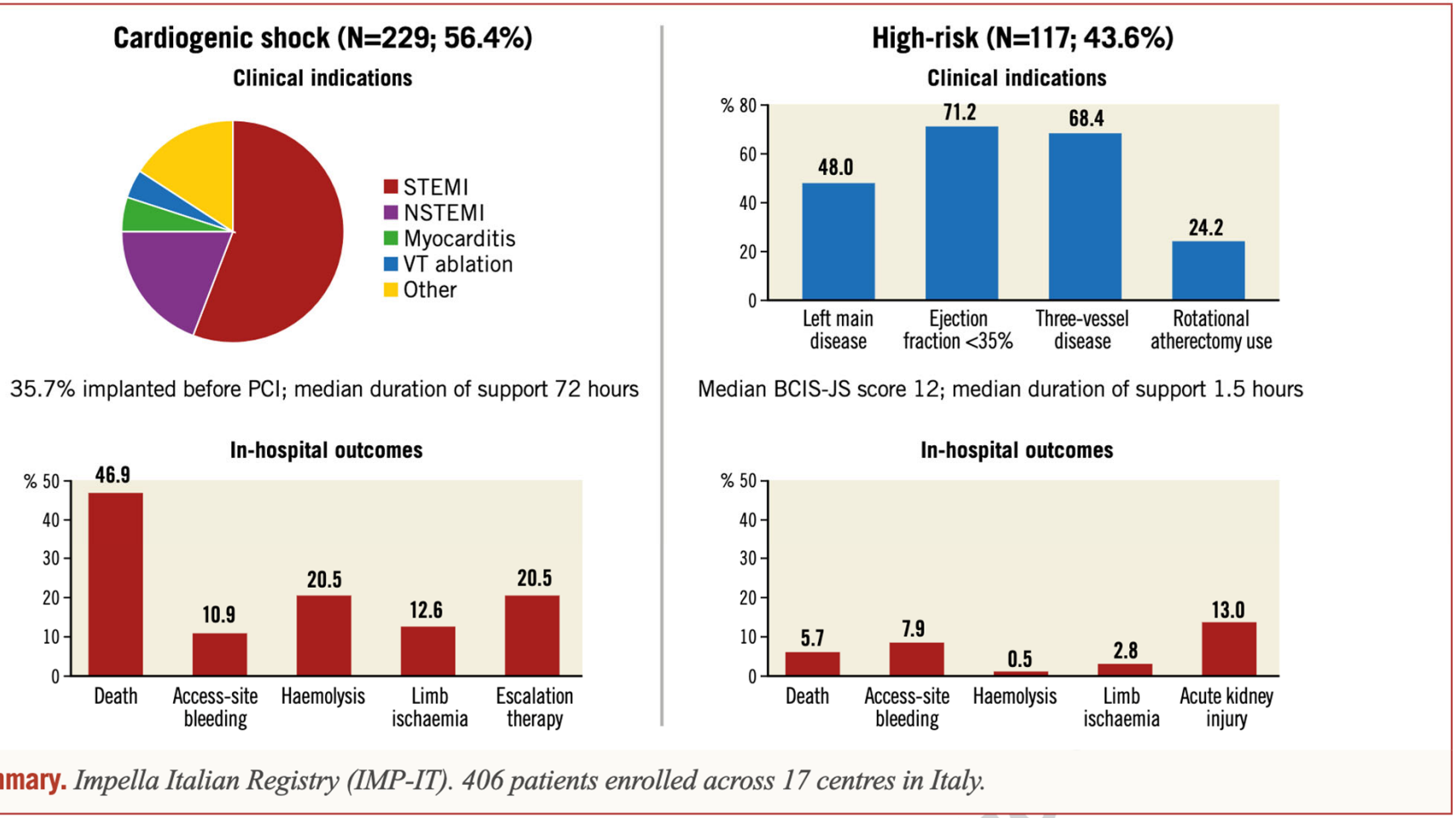
**30-day and 90-day follow-up visits**
**1-year survival status check**

## Key Endpoints

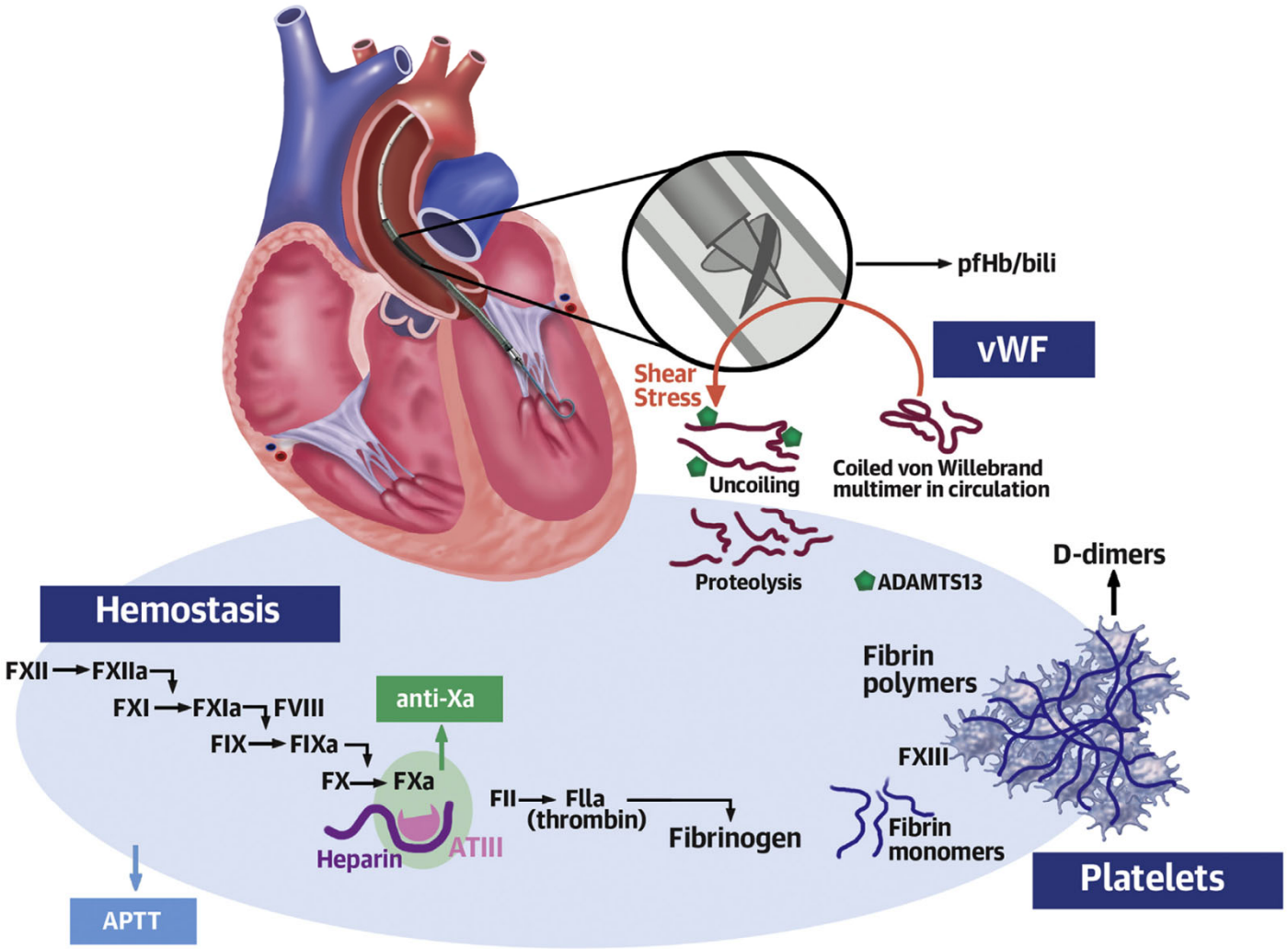
- Composite of (1) all-cause mortality, (2) stroke and (3) new requirement for RRT through 90-days post-operation
- Rate of PCCF at hospital discharge
- Hospital and ICU lengths of stay
- Duration of mechanical ventilation
- AKI
- Vasoactive-inotropic score

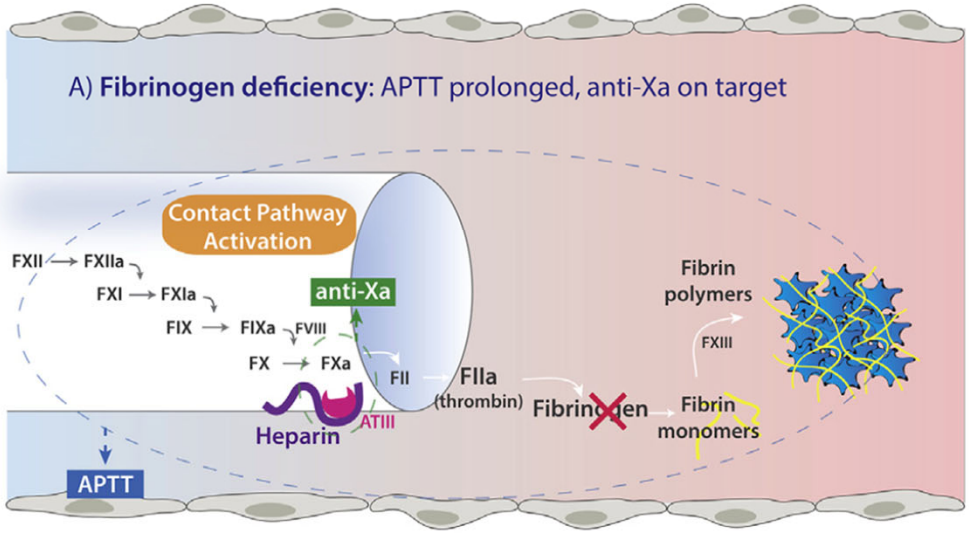
# COMPLICATIONS

# Impella et complications

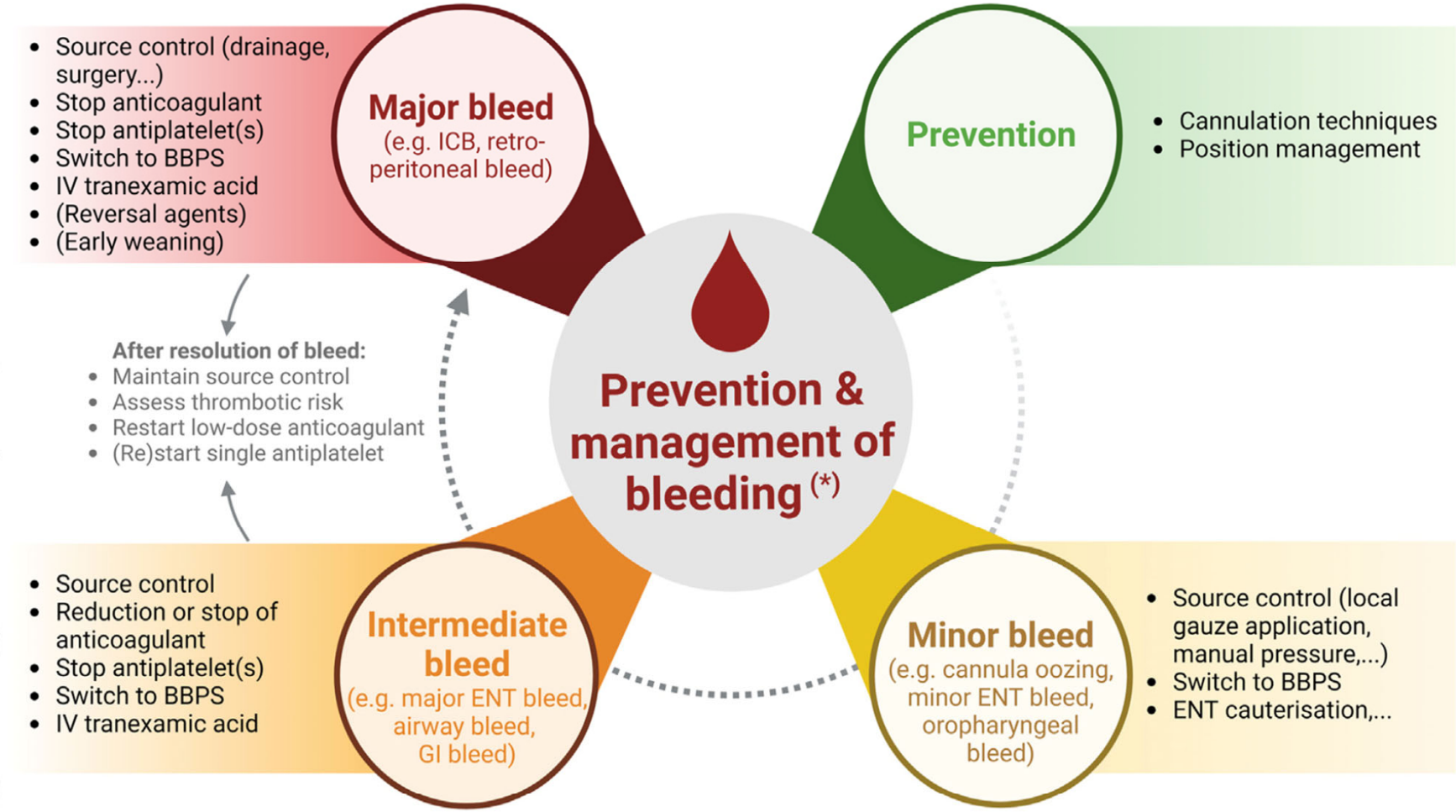



**Visual summary.** *Impella Italian Registry (IMP-IT). 406 patients enrolled across 17 centres in Italy.*


pfHb/bili
vWF
Shear Stress
Uncoiling
Coiled von Willebrand multimer in circulation
Proteolysis
ADAMTS13
D-dimers
Hemostasis
FXII → FXIIa
FXI → FXIa
FVIII
FIX → FIXa
FX → FXa
anti-Xa
Heparin
ATIII
FII → FIIa (thrombin)
Fibrinogen
Fibrin polymers
FXIII
Fibrin monomers
Platelets
APTT




Vandenbriele et al. J Am Coll Cardiol 2022; 79 (19) : 1949–1962.



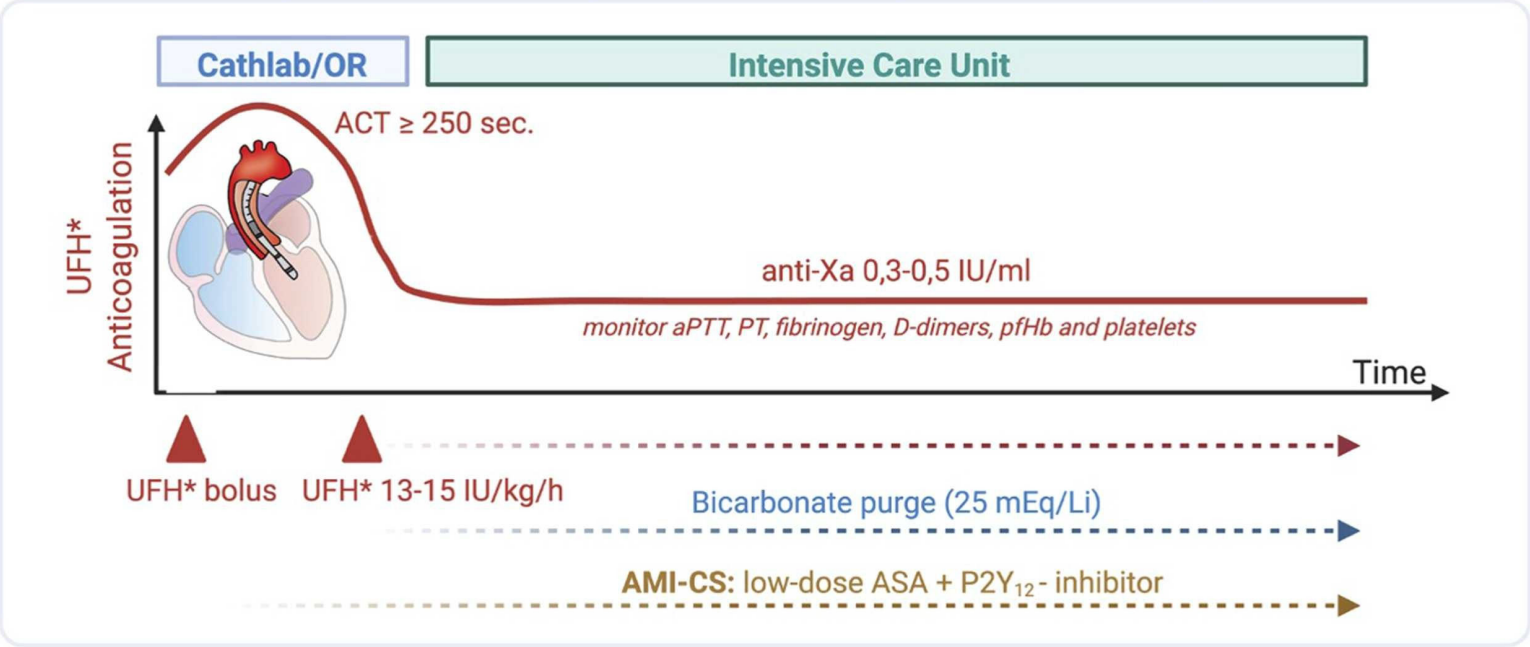

**(*) Additional measures:**

**Maintain hemostasis:**
- Normothermia
- Normocalcemia
- Normal pH

**Monitor coagulation tests:**
- Platelet count < 50,000/µL → consider platelet transfusion
- Fibrinogen levels < 1.5 g/L → administer fibrinogen concentrates or cryoprecipitate
- INR > 1.7 → consider prothrombin complex concentrate (or fresh frozen plasma)

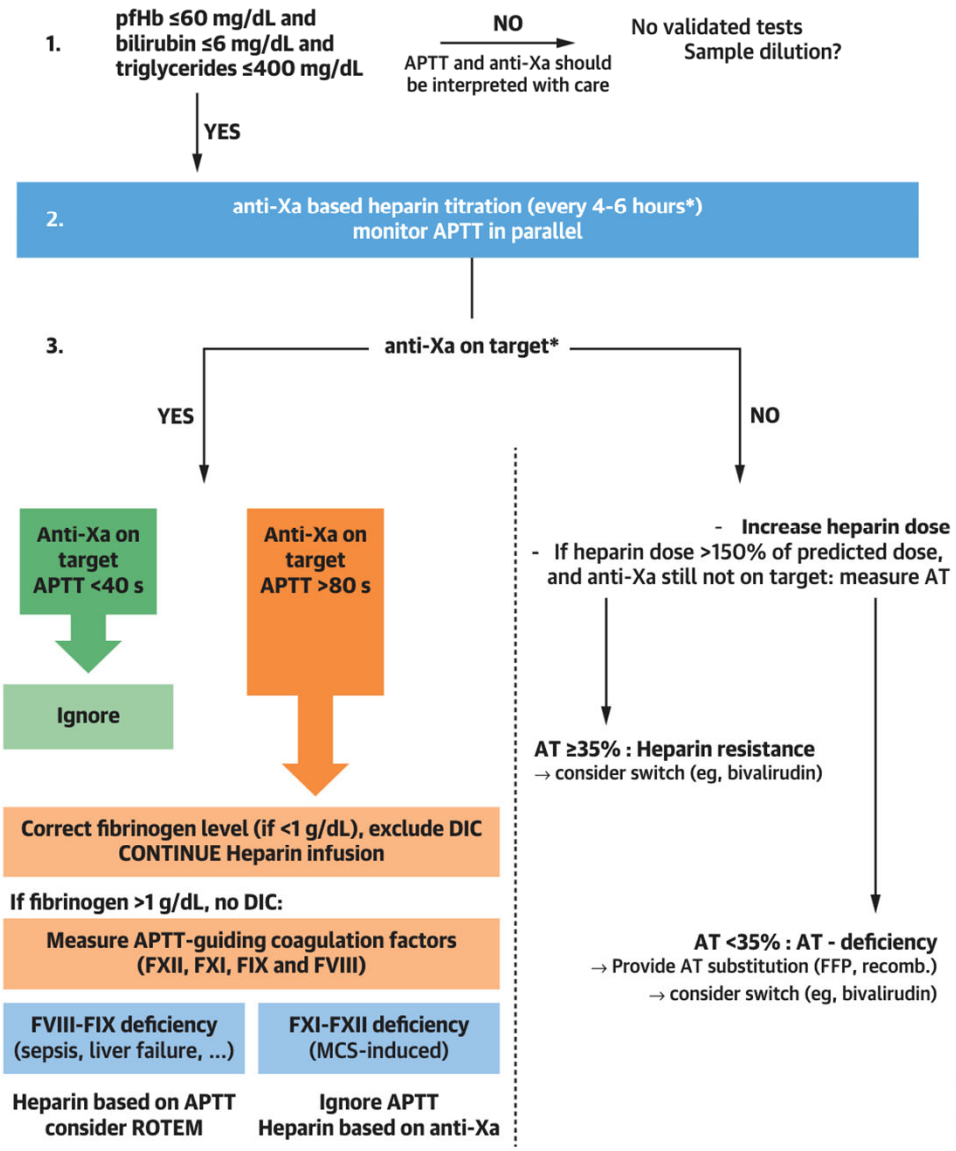
⚠ No specific treshold for RBC transfusion

# Gestion de l'anticoagulation



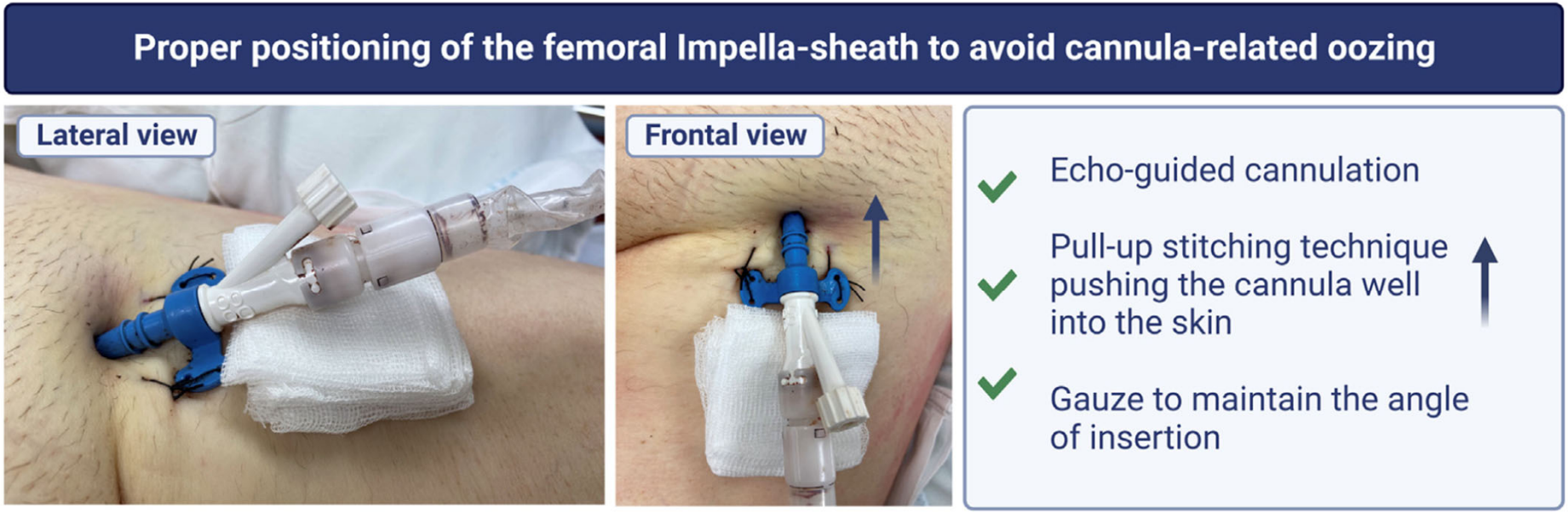

Bernhardt et al. The Journal of Heart and Lung Transplantation 2025; 44 (11) : 1688–1702.

## Algorithm for Unfractionated Heparin Monitoring in Impella™ Supported Patients




Vandenbriele et al. J Am Coll Cardiol 2022; 79 (19) : 1949–1962.

**FIGURE 6** **Measures to Ensure Proper Positioning of the Femoral Impella Sheath**




Ultrasound-guided cannulation techniques, proper positioning, and stitching with pull-up technique of the sheath to the skin are important measures to avoid local oozing or bleeding.

## Management and Time Course of Hemolysis and Bleeding During Microaxial pVAD Support

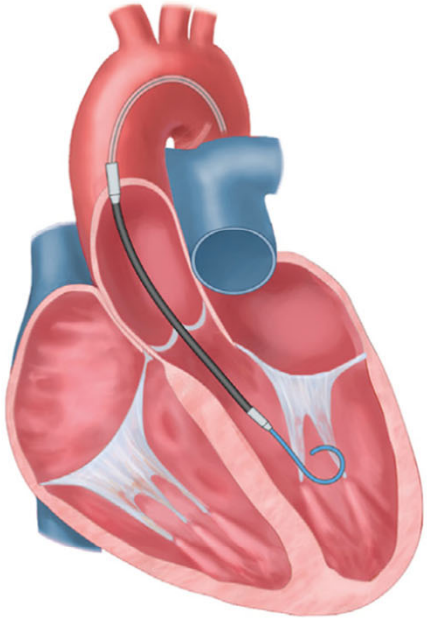
**A**

**Hemolysis**

Check

1. Position
2. RV function
3. Preload
4. Pump-related
5. Rare causes

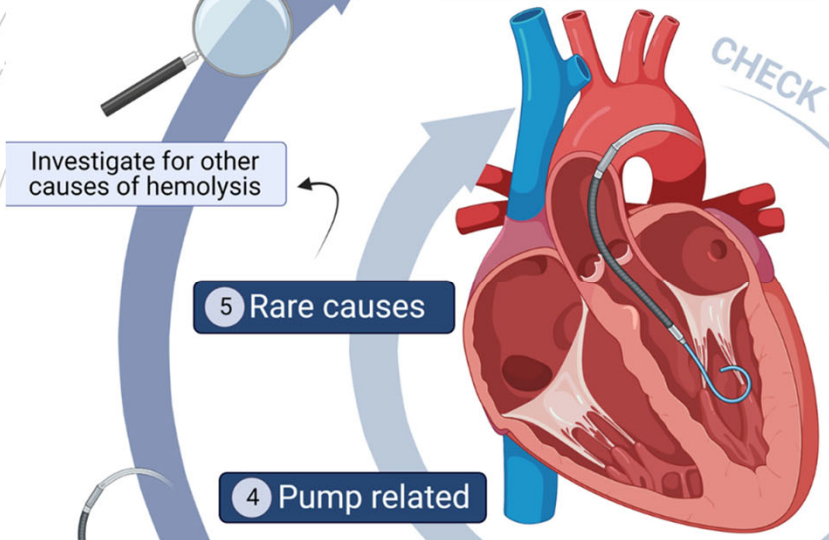
+ General measures to avoid (effects of) hemolysis



Van Edom et al. JACC: Cardiovascular Interventions 2023; 16 (14) : 1707–1720.

# HEMOLYSIS

General measures:
↓ Support level (P-level)
Alternative MCS
Early weaning
Inhaled NO
Plasmapheresis



CONSIDER

CHECK

Echocardiography
SmartAssist™
(Fluoroscopy)
(CT)

Repositioning
Lower P-level

1 Position

2 RV function

Echocardiography
Suction alarms
SmartAssist™
PA-catheter

Inotropes
RV MCS

Suction alarms
SmartAssist™
PA-catheter

Fluid challenge
Lower support level
Lower PEEP level

3 Preload

(Elevated) purge pressure
(Off-target) anticoagulant
parameters

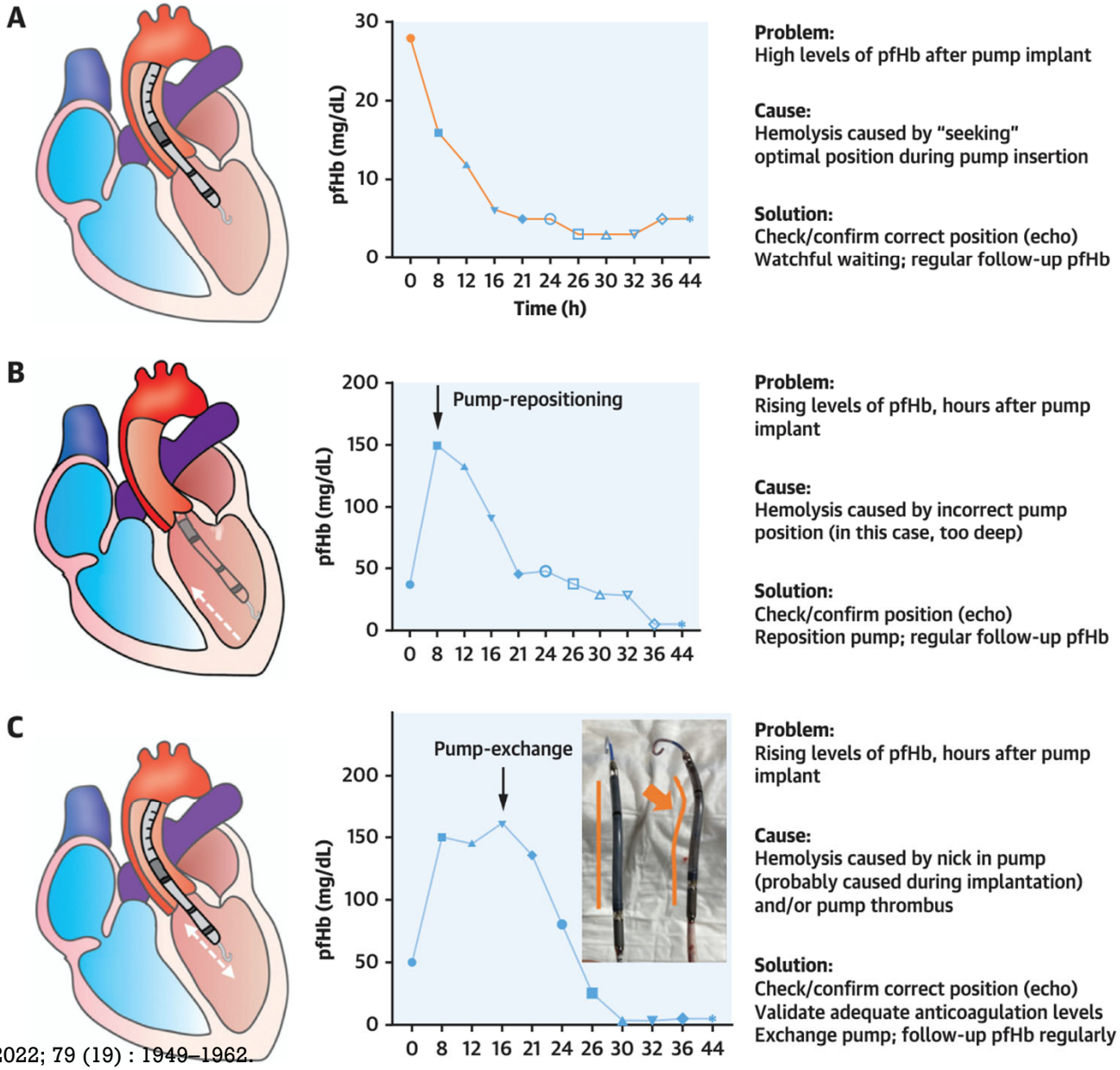
4 Pump related

Pump exchange
Optimize anticoagulation

5 Rare causes



Investigate for other
causes of hemolysis

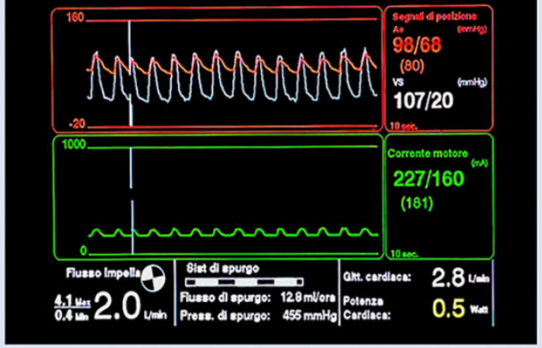



Vandenbriele et al. J Am Coll Cardiol 2022; 79 (19) : 1949–1962.

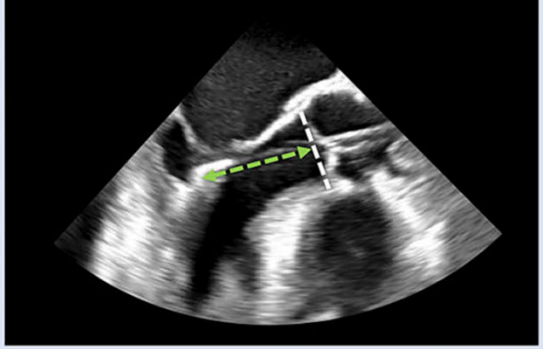
# Diagnostic criteria for Impella malrotation

## All the 3 main diagnostic criteria

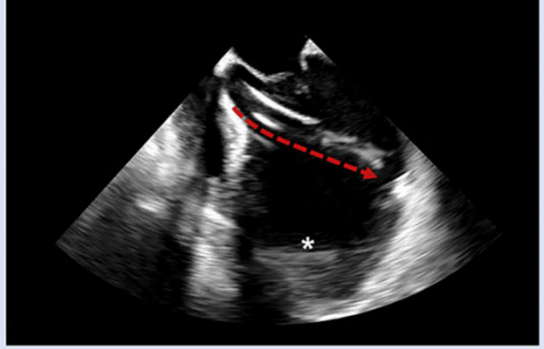
**1** No major abnormalities in pressure and current waveform on the device console




**2** Correct depth of the device across the AV according to manufacturer

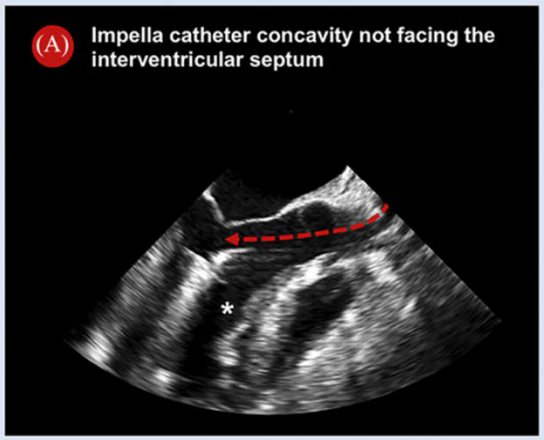


**3** Pig-tail away from the LV apex and directed towards the LV lateral wall

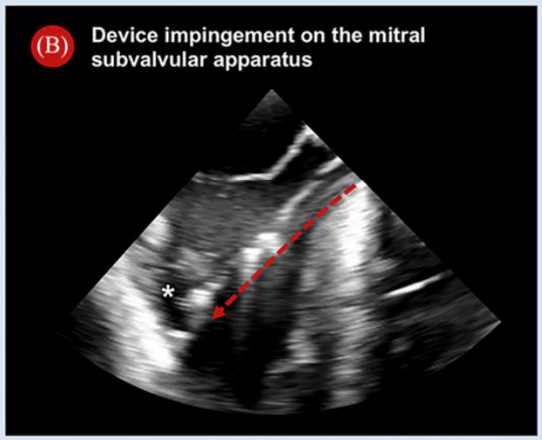


## Plus at least one of the following additional findings

**(A)** Impella catheter concavity not facing the interventricular septum



**(B)** Device impingement on the mitral subvalvular apparatus



**(C)** Impella inlet in close proximity of the mitral valve leaflets

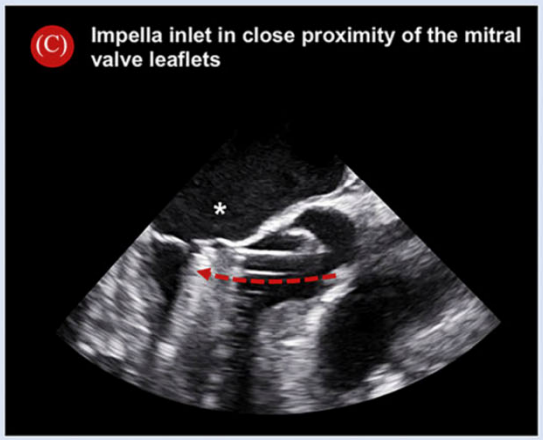
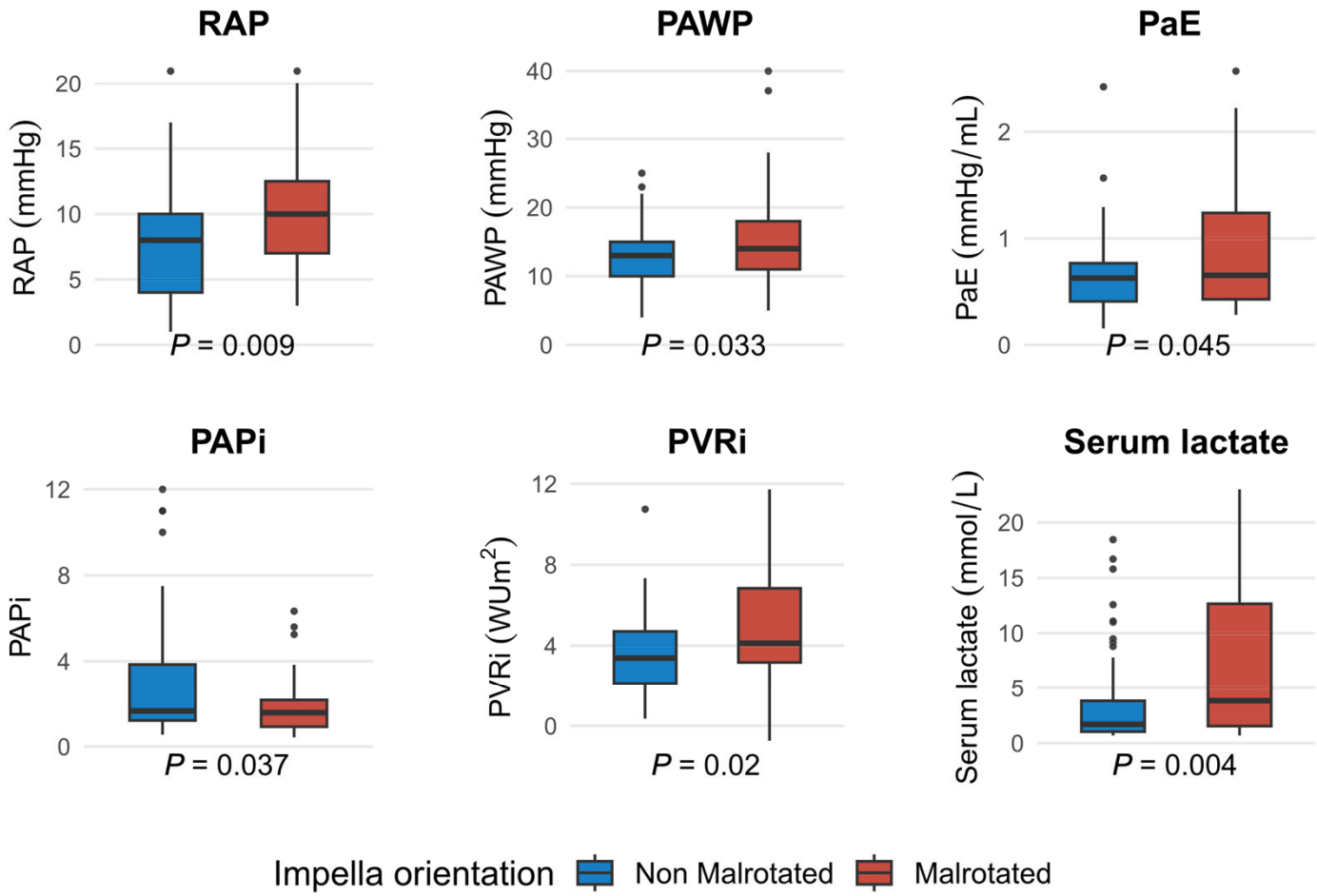
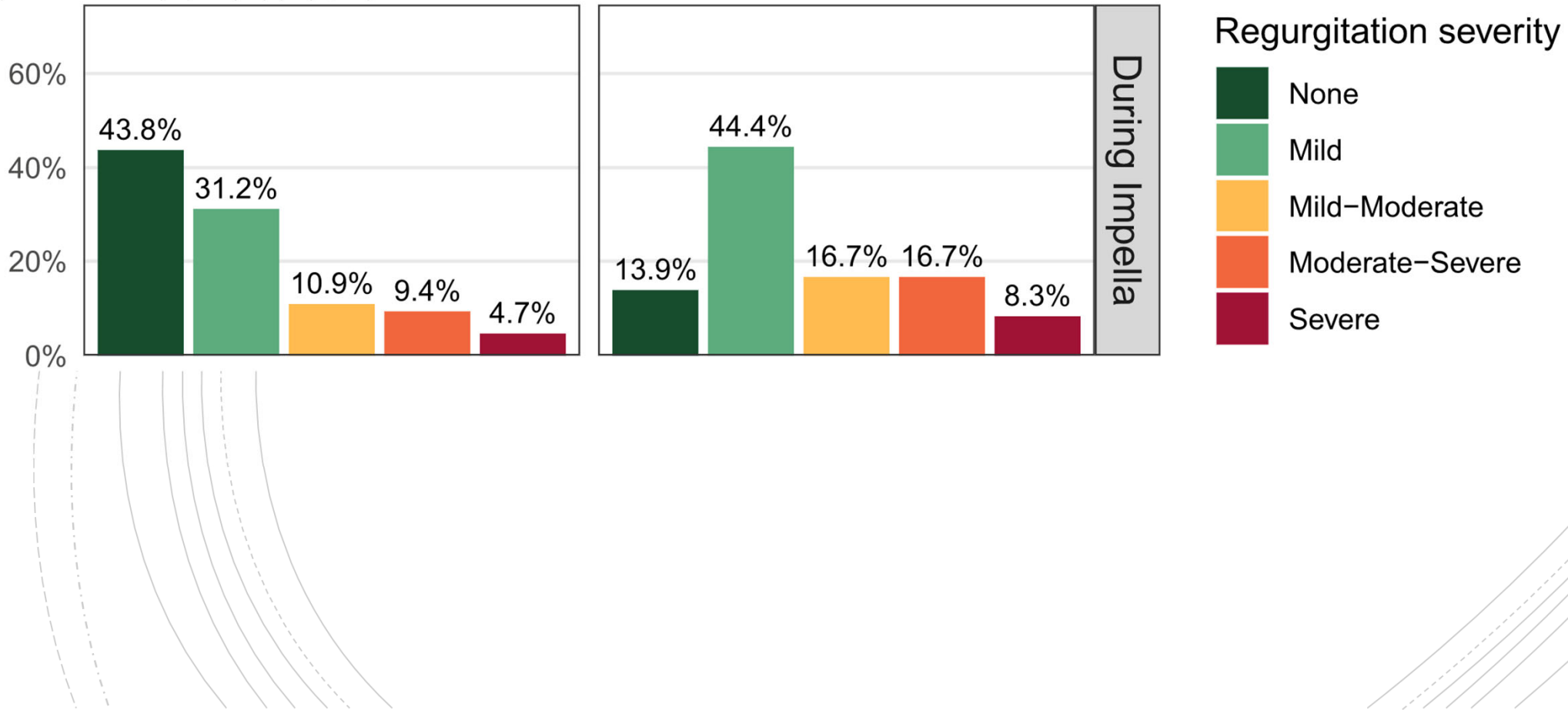


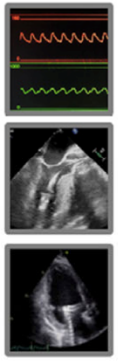
**Table 2** Invasive haemodynamics before and 48-h after Impella support initiation

| | Non-malrotated ($N$ = 52) | Malrotated ($N$ = 33) | Total ($N$ = 85) | $P$-value |
|---|---|---|---|---|
| CI (L/min/m$^2$) | 2.48 (0.96) | | | |
| sPAP (mmHg) | 29.5 (9.0) | | | |
| dPAP (mmHg) | 15.1 (6.1) | | | |
| mPAP (mmHg) | 20.8 (6.8) | | | |
| PAWP (mmHg) | 13.0 (4.6) | | | |
| RAP (mmHg) | 7.7 (4.3) | | | |
| CPO (W) | 0.86 (0.37) | | | |
| CPI (W/m$^2$) | 0.44 (0.18) | | | |
| CPO-RAP (W/m$^2$) | 0.17 (0.24) | | | |
| CPI-RAP (W/m) | 0.41 (0.17) | | | |
| LVSWi (cJ/m$^2$) | 13.7 (6.4) | | | |
| RVSWi (cJ/m$^2$) | 5.2 (3.7) | | | |
| SVRi (WUm$^2$) | 34.61 (15.3 | | | |
| PVRi (WUm$^2$) | 3.49 (1.94) | | | |
| PaE (mmHg/mL) | 0.67 (0.40) | | | |
| PAPi | 3.10 (2.91) | | | |
| RAP/PAWP | 0.60 (0.35) | | | |
| Lactate (mmol/L) | 3.60 (4.21) | | | |



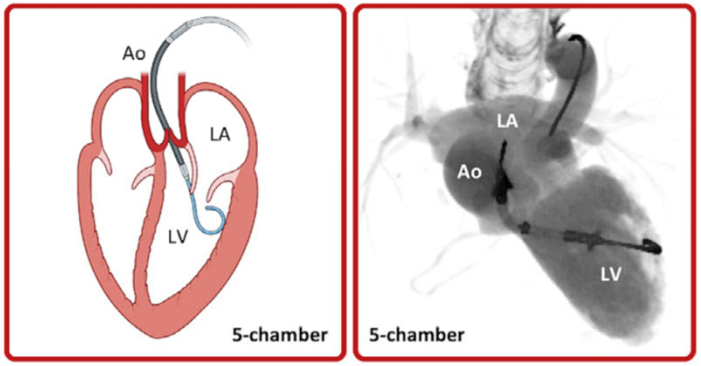

60%
40%
20%
0%
43.8%
31.2%
10.9%
9.4%
4.7%
13.9%
44.4%
16.7%
16.7%
8.3%
During Impella
Regurgitation severity
None
Mild
Mild−Moderate
Moderate−Severe
Severe

## Diagnostic criteria for malrotation



1. Correct pressure and motor current waveforms on the console
2. Correct device depth: catheter inflow 3.5-5.0 cm below the AV
3. Inflow away from LV apex and towards MV and LV lateral wall

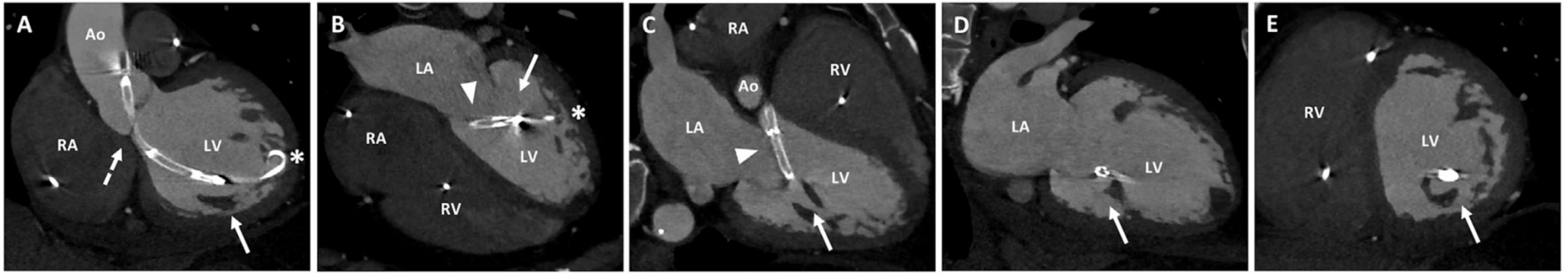
## pLVAD malrotation




## Consequences of malrotation

- Aortic regurgitation ↑
- Mitral regurgitation ↑
- Ischemic stroke ↑
- Bleeding events ↑

## Potentially relevant device-anatomy interactions for bleeding and thrombosis caused by malrotation




Interaction with MV apparatus: chordae and papillary muscles

Impingement on AV cusps

Interaction with MV leaflets

Impingement on LV lateral or inferolateral wall

# Suction management with SmartAssist device

## Type

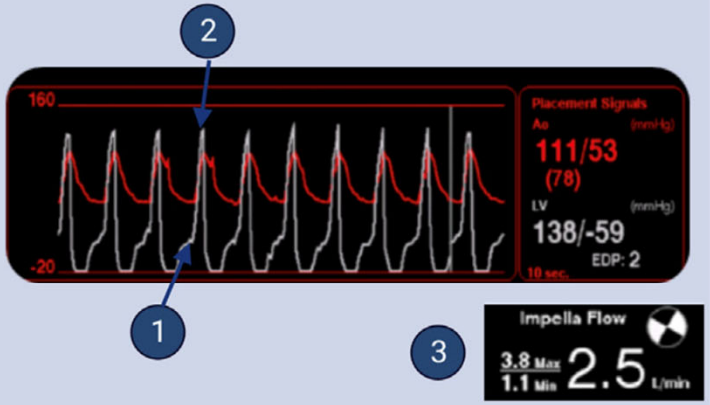
**Intermittent suction**

**Continuous suction**

## How to recognize

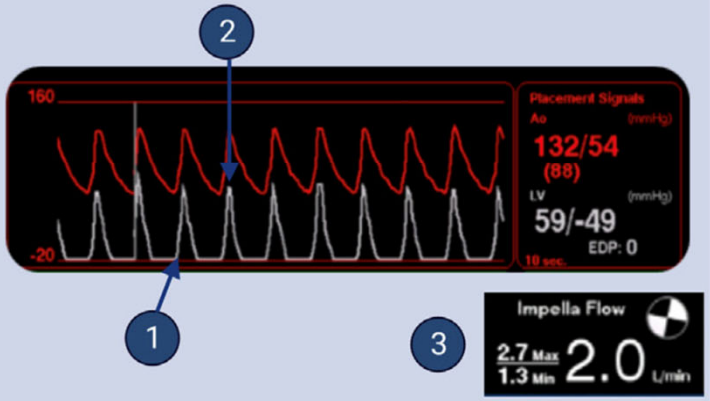
**Intermittent suction**

1. Negative diastolic pressure; recovers by end of diastole
2. Normal systolic pressure
3. Low diastolic flows




**Continuous suction**

1. Negative diastolic pressure; does not recover
2. Low systolic pressure
3. Low systolic & diastolic flows




## Solution

**Check filling & volume status**

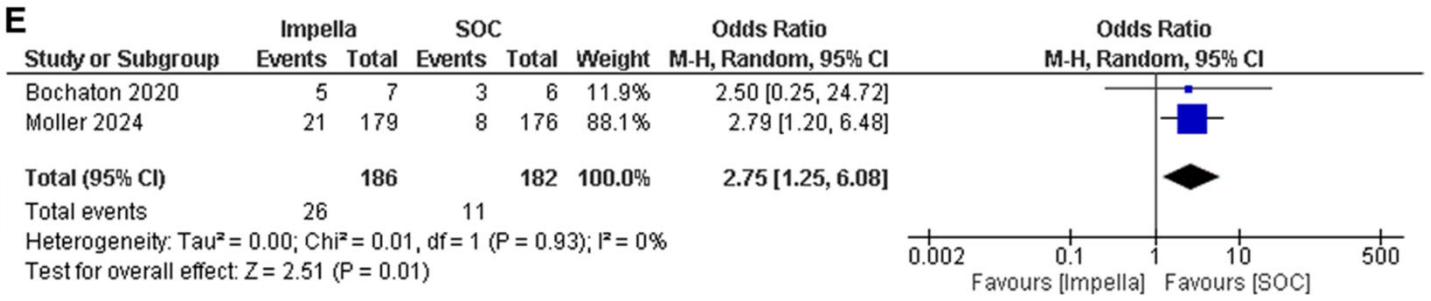
**Check Impella™ position**

# SEPSIS

**OR de 2,75** (IC 95% : 1,25-6,08).

Par rapport à IABP : Impella ont 2 fois plus de sepsis (12.69% vs 6.44%; P = .01).

DanGer-Shock, hémocultures positives chez **11,7% vs 4,5%** (RR 2,79).



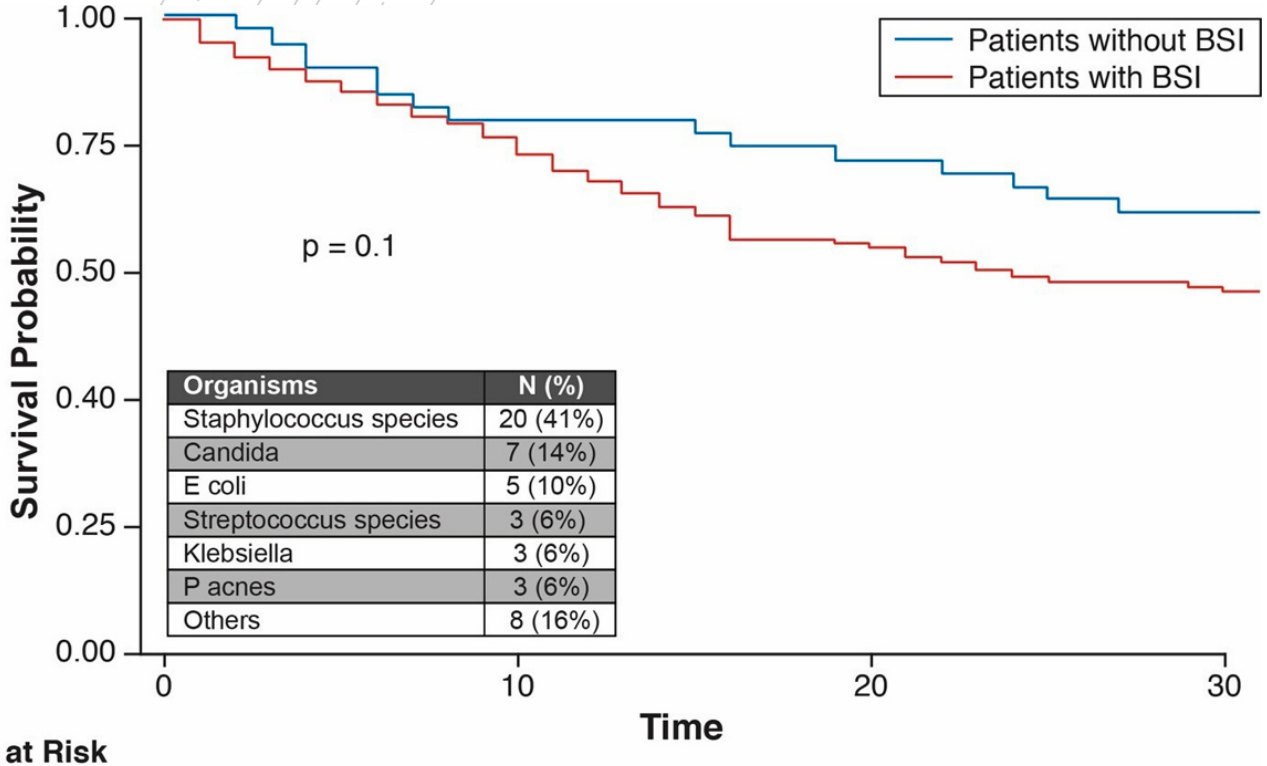

Tariq et al. Medicine (Baltimore) 2024; 103 (46) : e40595.

JACC Journals › JACC: Interventions › Archives › Vol. 15 No. 20

FREE ACCESS | Research Correspondence | 28 September 2022

# Characteristics and Impact of Bloodstream Infections in Cardiogenic Shock Patients on Temporary Mechanical Circulatory Support

**Authors**: Raunak M. Nair, Sachin Kumar, Talha Saleem, Sanchit Chawla, Adil Vural, Bahaa Abdelghaffar, Ran Lee, Andrew Higgins, Paul Cremer, Penelope Rampersad, and Venu Menon | AUTHORS INFO & AFFILIATIONS




| Organisms | N (%) |
|---|---|
| Staphylococcus species | 20 (41%) |
| Candida | 7 (14%) |
| E coli | 5 (10%) |
| Streptococcus species | 3 (6%) |
| Klebsiella | 3 (6%) |
| P acnes | 3 (6%) |
| Others | 8 (16%) |

**Number at Risk**

| | | | | |
|---|---|---|---|---|
| Patients without BSI | 200 | 162 | 129 | 115 |
| Patients with BSI | 49 | 41 | 38 | 34 |

Overall, 249 patients were admitted to CICU with CS necessitating MCS during the study period.

A total of 49 patients (20%) were diagnosed with BSI post-MCS placement.

The incidence of BSI in patients on ECMO was 61%, whereas it was 39% for patients on the Impella device.

# SEVRAGE

# UNLOADERS-PVAD Weaning Score: predicting post-weaning adverse events in cardiogenic shock patients supported by microaxial flow pump

## Scoring System for Predicting Adverse Events After PVAD Weaning

PVAD Weaning n = 304

30-Day Outcome

Without Event n = 247

With Event n = 57

### Aim
To develop a score for predicting adverse events after PVAD weaning

### Data Source
The UNLOADERS-PVAD study

### Participants
Patients weaned from PVAD, n = 304
- Derivation cohort, n = 182
- Validation cohort, n = 122

### Outcome Evaluation
Composite outcome:
- All-cause mortality
- Unplanned MCS reintroduction

within 30 days after PVAD weaning

### Model Construction
LASSO regression was used to select score components from a total of 22 factors before PVAD explantation

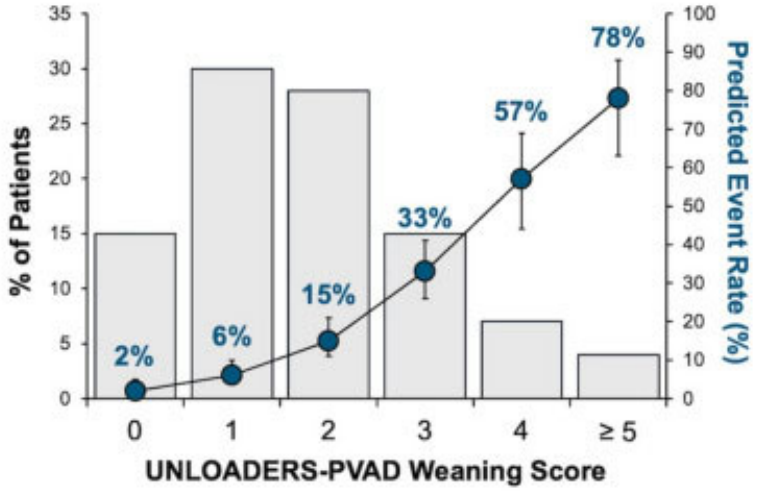
### ULOADERS-PVAD Weaning Score

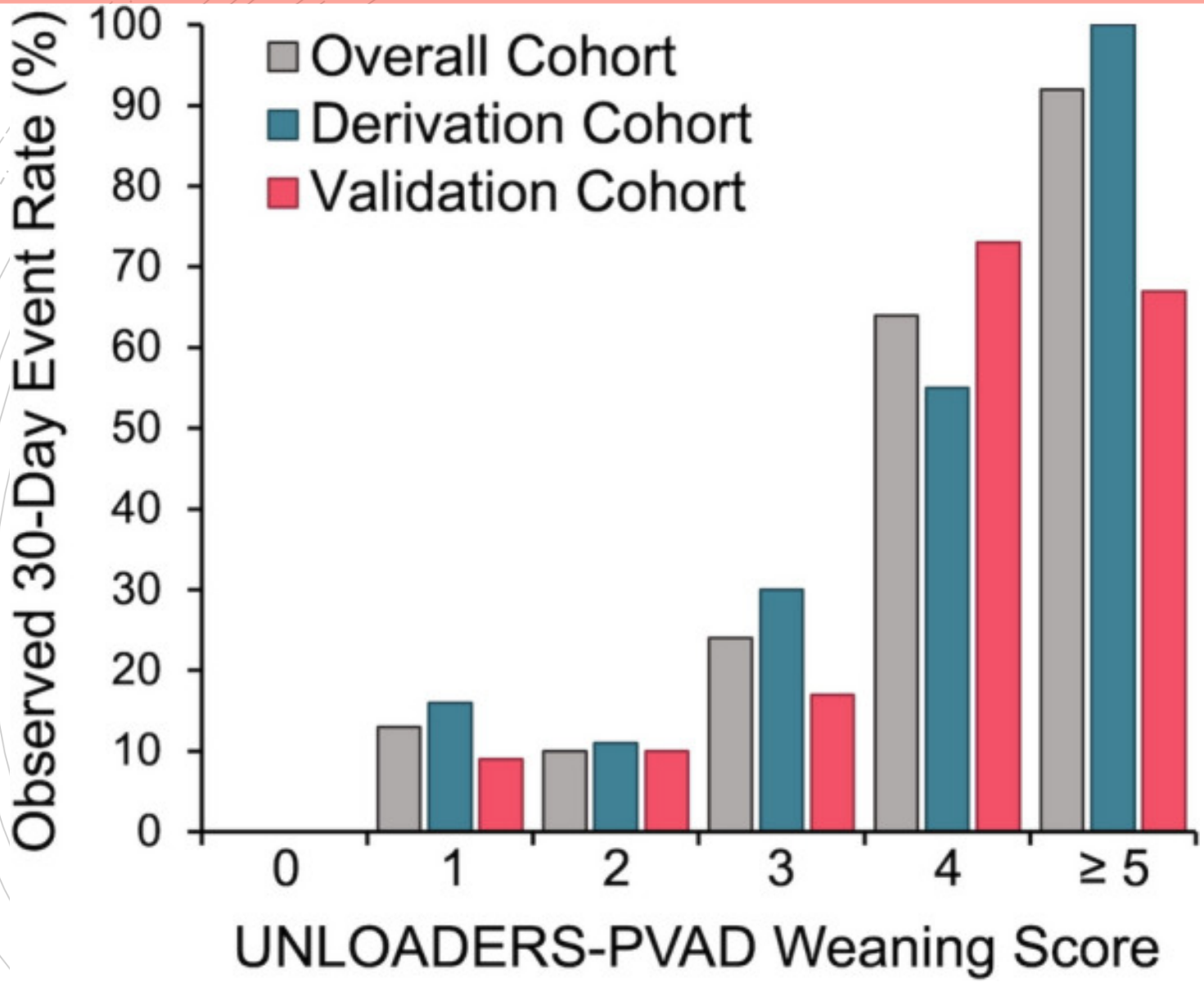
| Risk Factors for PVAD Weaning | Score |
|---|---|
| **Clinical Factors** | |
| Female | 1 |
| Renal replacement therapy | 1 |
| Vasopressors and/or inotropes ≥ 2 drugs | 1 |
| Lactate ≥ 2.0 mmol/L | 2 |
| **Hemodynamic Factors** | |
| Heart rate ≥ 80 bpm | 1 |
| PAWP ≥ 20 mmHg | 1 |
| CPO < 0.6 Watts | 1 |
| Total | 0 – 8 |

**Risk Categories**

0 – 2 points: Low; 3 – 4 points: Moderate; 5 – 8 points: High

### Risk Stratification




Observed 30-Day Event Rate (%)
100
90
80
70
60
50
40
30
20
10
0
Overall Cohort
Derivation Cohort
Validation Cohort
0
1
2
3
4
≥ 5
UNLOADERS-PVAD Weaning Score

# Aggressive Up-Titration of Heart Failure Guideline-Directed Medical Therapies in Cardiogenic Shock Supported by a Percutaneous Ventricular Assist Device

TIM BALTHAZAR, MD[1,2] MATTHIAS RAES, MD[2,3] TOM CARMELIET, MD[1,2] INES VAN LOO, MD[1]
STIJN LOCHY, MD[1] JEAN-FRANÇOIS ARGACHA, MD, PhD[1,4] DANNY SCHOORS, MD, PhD[1,4]
BERT VANDELOO, MD[1] MICHAEL MEKEIRELE, MD[2] JOOP JONCKHEER, MD, PhD[2]
MARK LA MEIR, MD, PhD[1,4] and FREDERIK H. VERBRUGGE, MD, PhD, MSc[1,2,4]

| | Intervention N = 28 | Historical N = 33 | *P* Value |
|---|---|---|---|
| Age (years) | 61 (50–71) | 68 (60–75) | 0.080 |
| Male sex | 23 (82%) | 21 (64%) | 0.154 |
| Cardiogenic Shock Etiology | | | |
| Acute myocardial infarction | 17 (61%) | 23 (70%) | 0.759 |
| Acute decompensated heart failure | 5 (18%) | 1 (3%) | 0.085 |
| Myocarditis | 1 (3%) | 1 (3%) | 1 |
| Post-cardiotomy failure | 5 (18%) | 8 (24%) | 0.755 |
| Left ventricular ejection fraction (%) | 15 (10–20) | 25 (20–34) | <**0.001** |
| SCAI Stage at pVAD Insertion | | | 0.449 |
| C | 5 (18%) | 10 (30%) | |
| D | 11 (39%) | 13 (39%) | |
| E | 12 (43%) | 10 (30%) | |
| Arterial blood lactate (mmol/L) | 6.2 (3–10) | 6.6 (2–12) | 0.341 |
| Post-cardiac arrest status | 8 (29%) | 15 (45%) | 0.197 |
| Mechanical ventilation | 24 (86%) | 24 (73%) | 0.347 |
| Vasotropic inotropic score | 30 (8–91) | 28 (18–57) | 0.849 |

| | | | |
|---|---|---|---|
| pVAD | | | |
| Impella CP | 21 (75%) | NA | NA |
| Impella 5.5 | 7 (25%) | NA | NA |
| Veno-arterial ECMO | 9 (32%) | 11 (33%) | 1 |
| Venous-pulmonary arterial ECMO | 2 (7%) | 0 (0%) | |
| IABP | NA | 29 (88%) | NA |

**Hemodynamic goals:**
- MAP 65 mmHg
- CVP < 12 mmHg
- PAWP < 15 mmHg
- Lactate downtrending

**Impella implantation**

↓

**Are hemodynamic goals met with low vasotropic support?**
**with < 0,3 mcg/kg/min norepinephrine and no inotropes**

↓ YES

**eGFR > 15 ml/min/m2**

↓ YES

**Initiate SGLT2i and Spironolactone**

↓ YES

**Hemodynamic goals met WITHOUT vasopressor?**

↓ YES

**Initiate valsartan** (MAP 65 mmHg, SVR =) **OR sacubitril/valsartan** (MAP ≥70 mmHg, SVRI ↑)

↓ YES

**Hemodynamic goals still met**
**+ SGLT2i**
**+ MRA**
**+ Sac/Val OR Val**
**+ Amiodarone/ivabradine/betablocker**

↓ YES

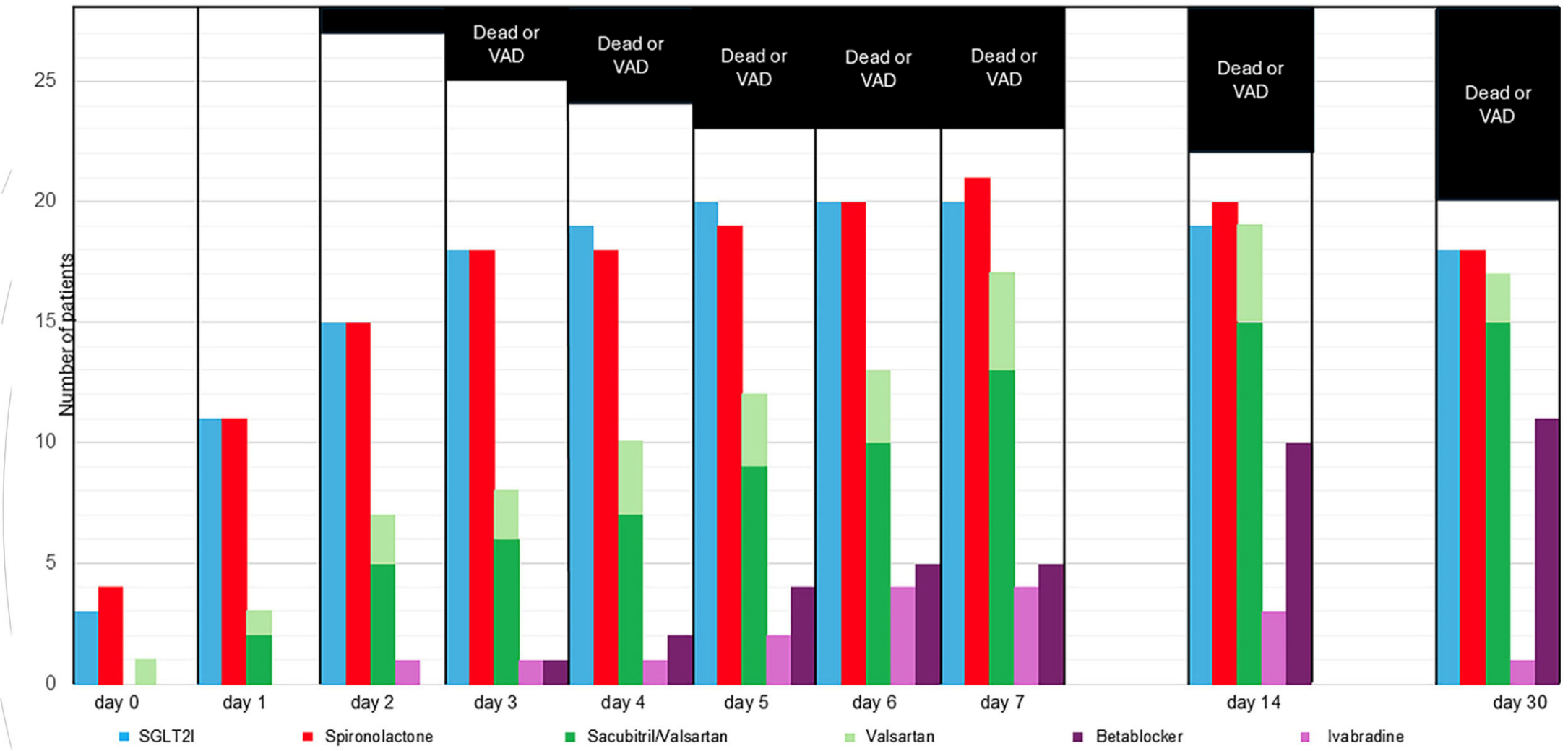
**Consider weaning**

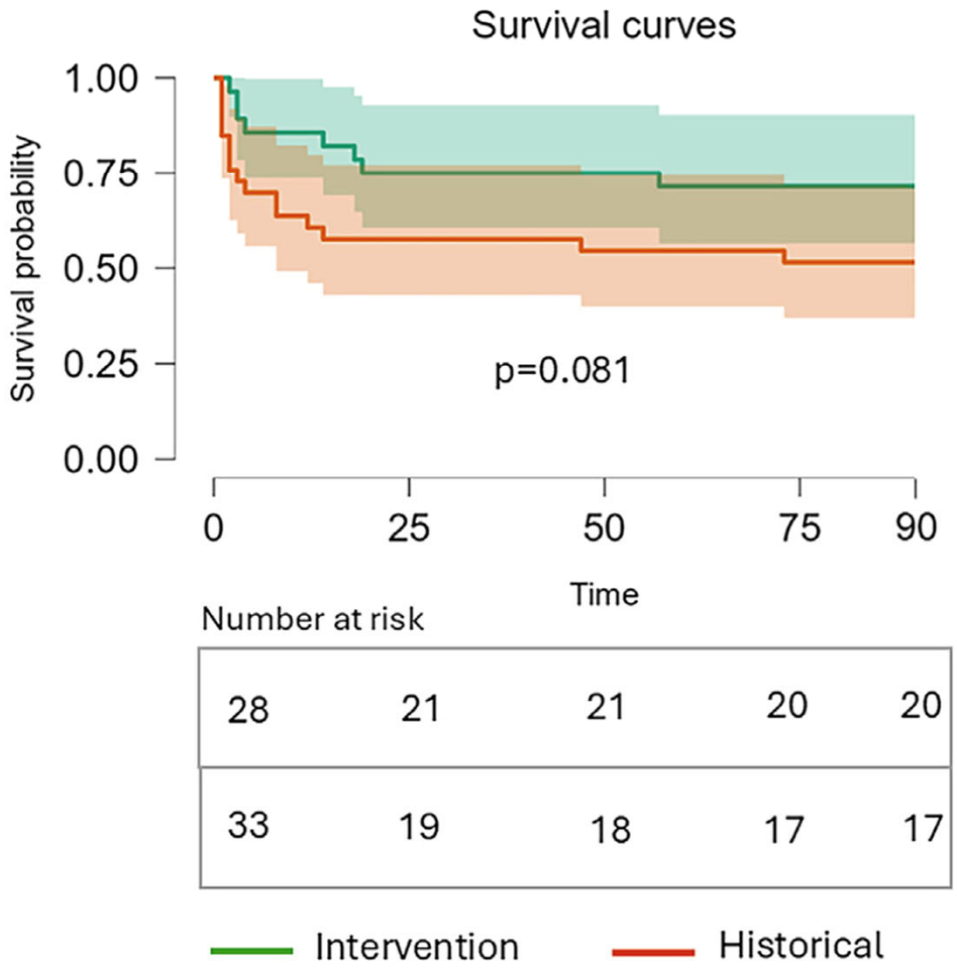
↘ YES

**HR ≥90/min**

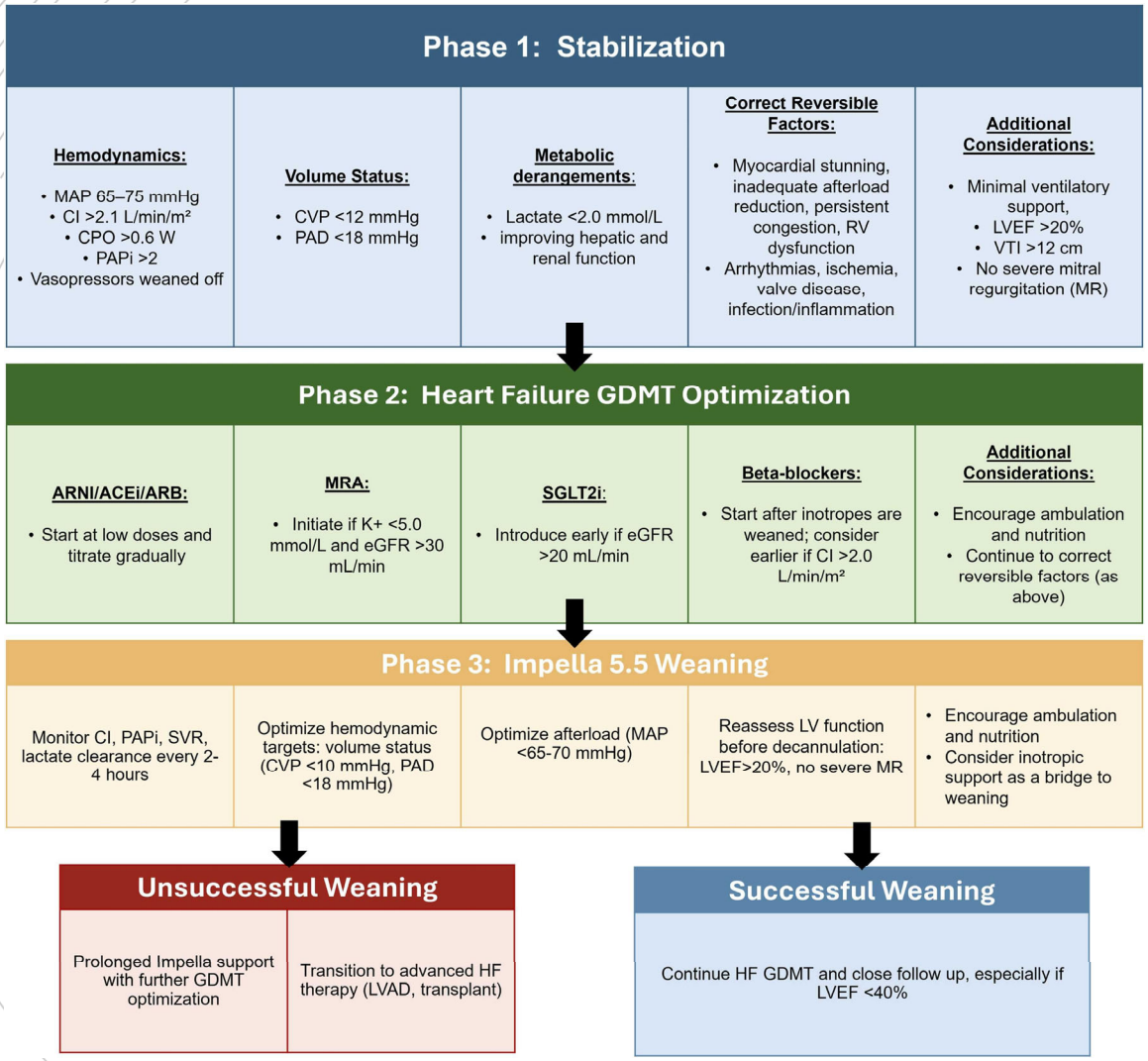
↓ YES

**Initiate ivabradine OR betablocker**


Dead or VAD
Dead or VAD
Dead or VAD
Dead or VAD
Dead or VAD
Dead or VAD
Dead or VAD
Number of patients
0
5
10
15
20
25
day 0
day 1
day 2
day 3
day 4
day 5
day 6
day 7
day 14
day 30
SGLT2I
Spironolactone
Sacubitril/Valsartan
Valsartan
Betablocker
Ivabradine


Survival curves
Survival probability
1.00
0.75
0.50
0.25
0.00
p=0.081
0
25
50
75
90
Time
Number at risk
28
21
21
20
20
33
19
18
17
17
Intervention
Historical

# En conclusion : l'impella doit etre sevrée



# Adverse Events and Failure Modes Related to Impella RP/ RP Flex: Insights From FDA MAUDE Database

Kalyan R. Chitturi[1] | Ryan Wallace[2] | Marta Lorente-Ros[2] | Ilan Merdler[1] | Abhishek Chaturvedi[1] | Brian C. Case[1] | Hayder D. Hashim[1] | Itsik Ben-Dor[1] | Toby Rogers[1] | Ron Waksman[1]

## FDA MAUDE Database: Impella RP and RP Flex Reported Complications

Reports (N = 270)
Impella RP: 206
Impella RP Flex: 64

Indications

**RIGHT VENTRICULAR FAILURE**
1. POST MYOCARDIAL INFARCTION: 37.4%
2. POST CARDIOTOMY: 28.5%
3. POST LEFT VENTRICULAR ASSIST DEVICE IMPLANT: 3.3%
4. PULMONARY EMBOLISM: 2.2%
5. POST HEART TRANSPLANT: 1.5%
6. CARDIAC ARREST: 0.4%
7. NOT REPORTED: 26.7%

**DEVICE-RELATED COMPLICATIONS**

Malfunction/Pump failure: 35.6%
Thrombus: 23.3%
Separation/Positioning: 20.0 %
Crack/Tear/Bent/Fracture: 17.0%

- Device separation/fracture **less** reported with RP Flex (31.2% vs 38.9%)
- Device thrombus **more** reported with RP Flex (35.9% vs 19.4%)
- Pump failure **more** reported with RP Flex (50.0% vs 31.1%)

**PATIENT-RELATED COMPLICATIONS**

Bleeding/hematoma: 18.5%
Hemolysis: 18.5%
Death: 8.5%
Vascular complications: 3.7%
New dialysis: 3.3%
Limb ischemia: 2.6%
Embolic stroke: 0.7%
Right ventricular perforation: 0.4%

- Bleeding complications **less** reported with RP Flex (12.5% vs 20.4%)
- Vascular access complications **less** reported with RP Flex (35.9% vs 4.9%)

## Impella devices linked to a variety of safety concerns

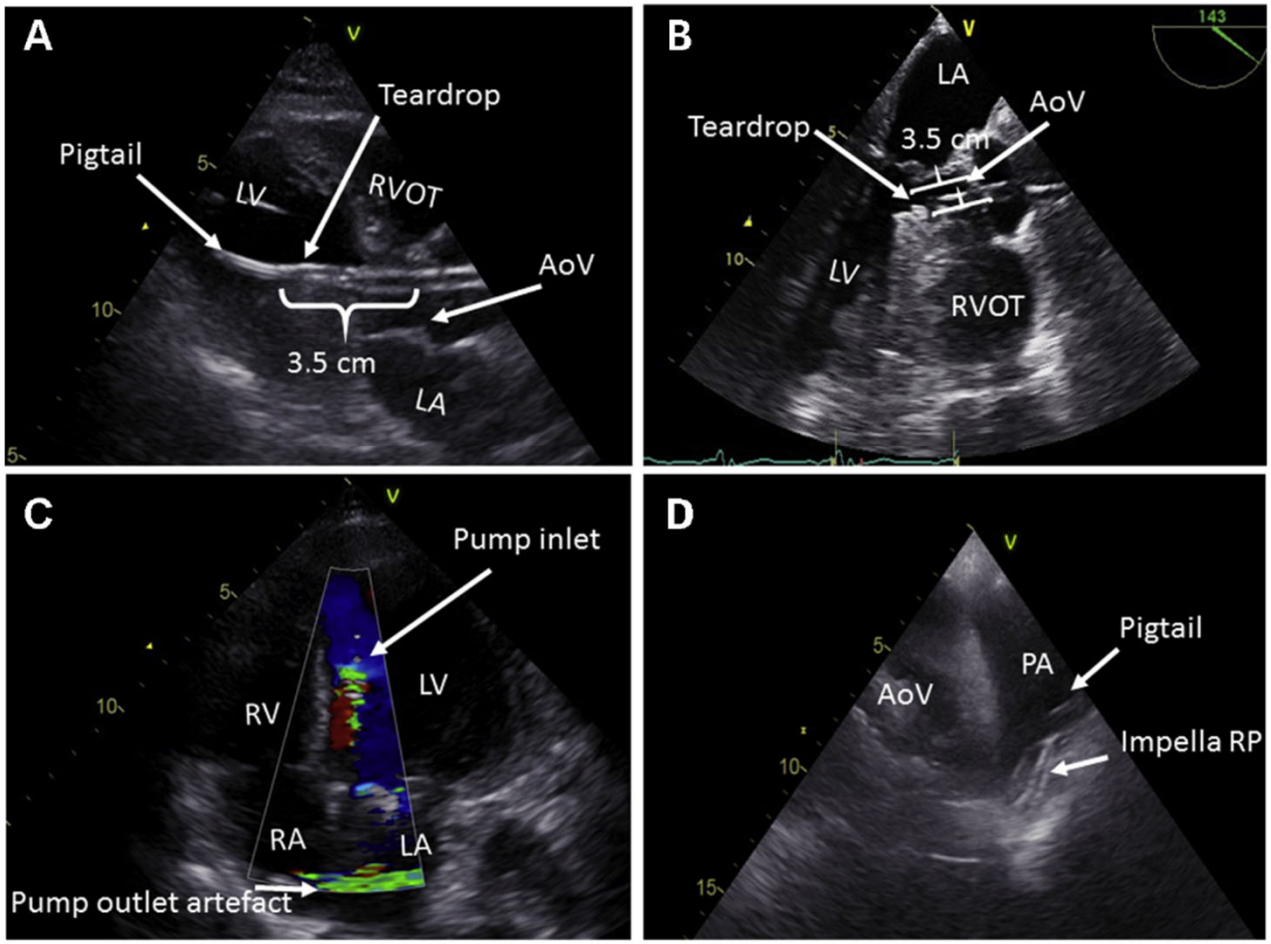
Johnson & Johnson MedTech's Impella platform has been associated with a significant number of recalls and safety alerts. In the last several months alone, AIC issues were linked to one recall in July 2025, a second recall in September 2025, a third and fourth recall in October 2025 and then a fifth recall in December 2025. A separate recall related to these devices was announced in March.

## Correct Impella position

- Inflow: 3.5–4.5 cm below AV
- Outflow: above AV
- Orientation → LV apex
- Echo confirms proper alignment

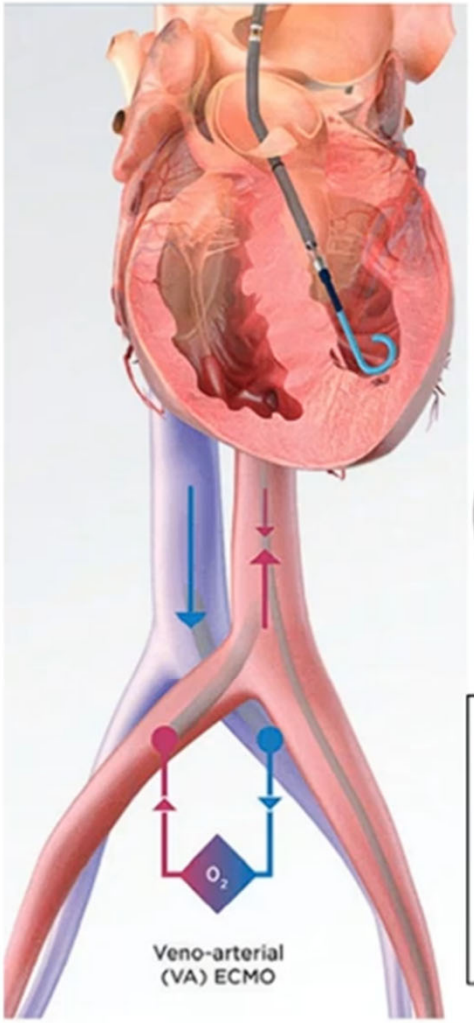
- ❑ PLAX TTE → "teardrop" 3.5 cm below AV
- ❑ TOE 140° → confirm position
- ❑ Apical 4-chamber + Doppler → inflow (flow convergence) / outlet (mosaic artifact)

**FIGURE 4 Optimal Device Position on Echocardiography**




*Tim Balthazar et al, JACC Review Topic of the Week2021*

# Initial management of the patient on ECPELLA



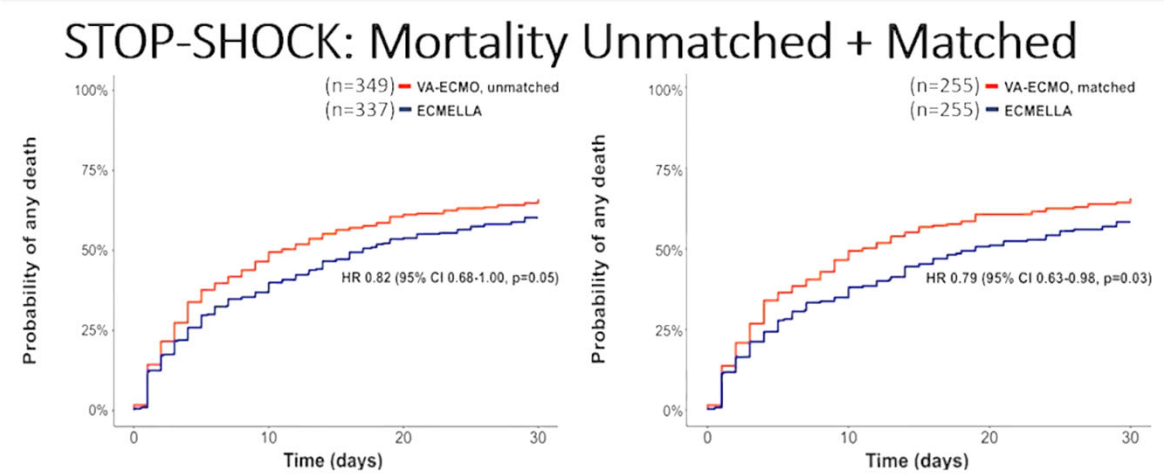

pVA ECMO → LV distension → Impella → ECPELLA

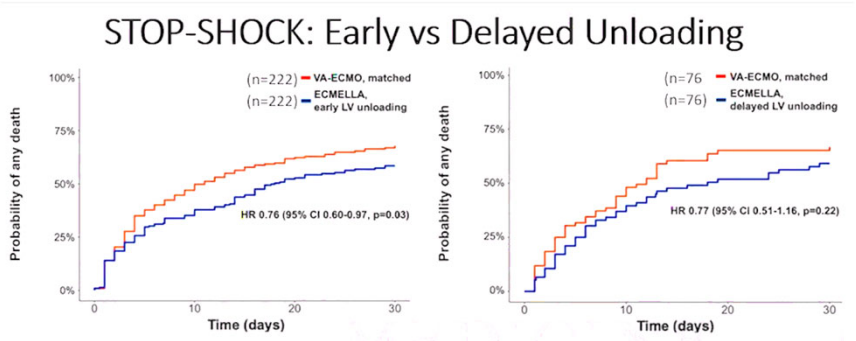
TTE/TOE + Data from PAC = Calculate flow balance

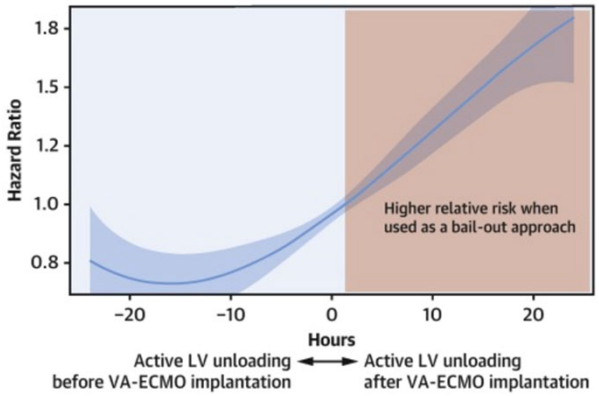
| | |
|---|---|
| LVEDD/LVEDV<br>Impella position<br>Suction events<br>Diastolic function<br>TAPSE/RV FAC | PCWP<br>SvO2<br>PAPi<br>CVP/PCWP |

# mAFP

**When and Which Strategies should we consider to unload the LV ?**



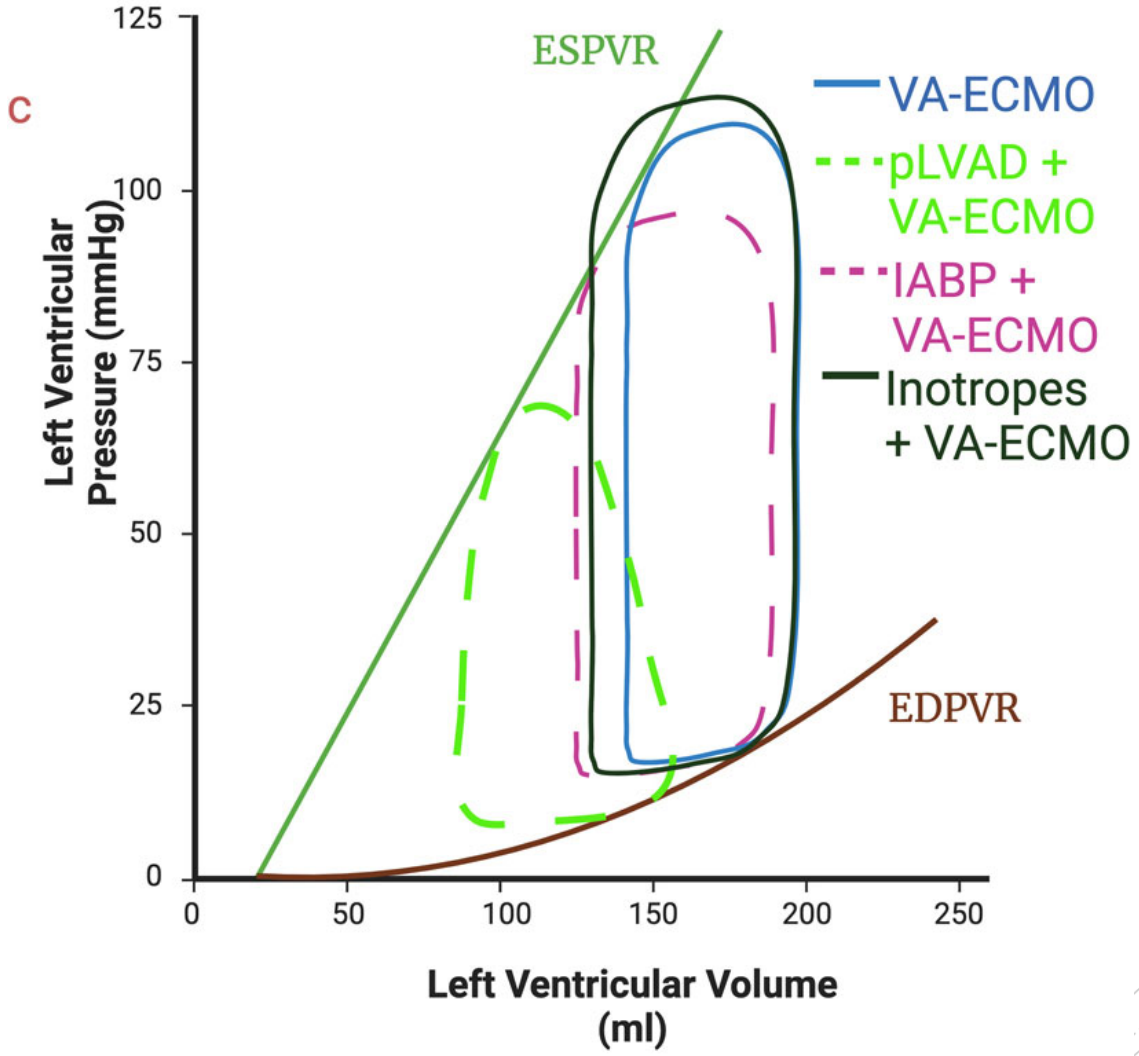

Mortality lower in patients with ECMELLA

Findings remain significant in propensity matched cohort

Mortality benefit present in early ECMELLA (<2h post ECMO)

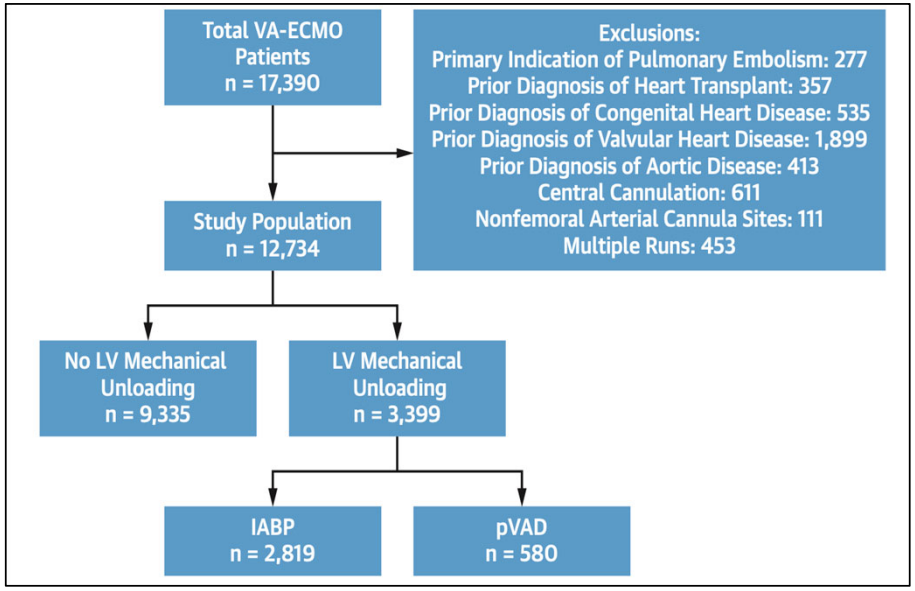
*B. Schrage et al, Circulation 2020*

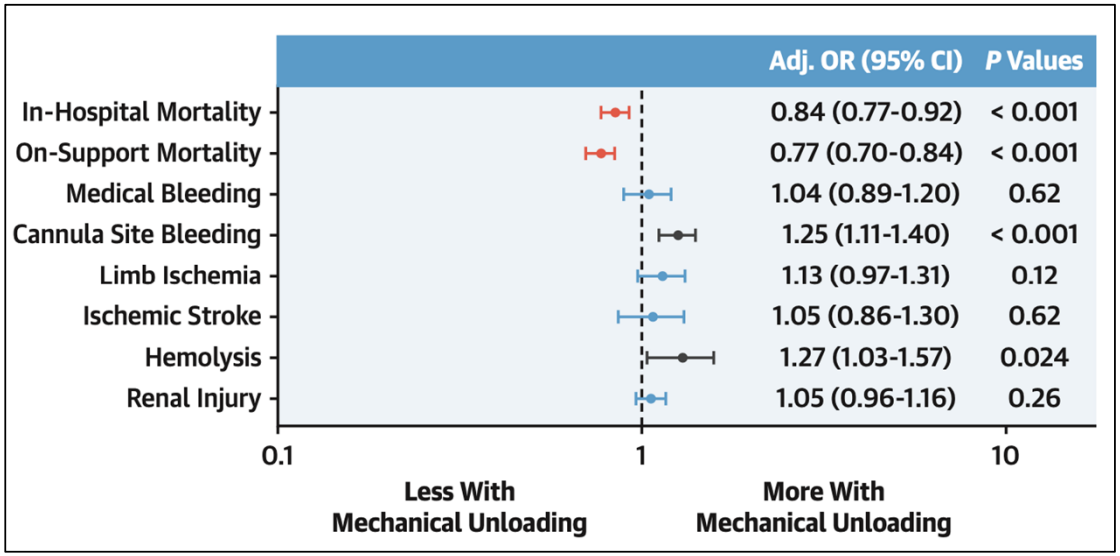
SO …

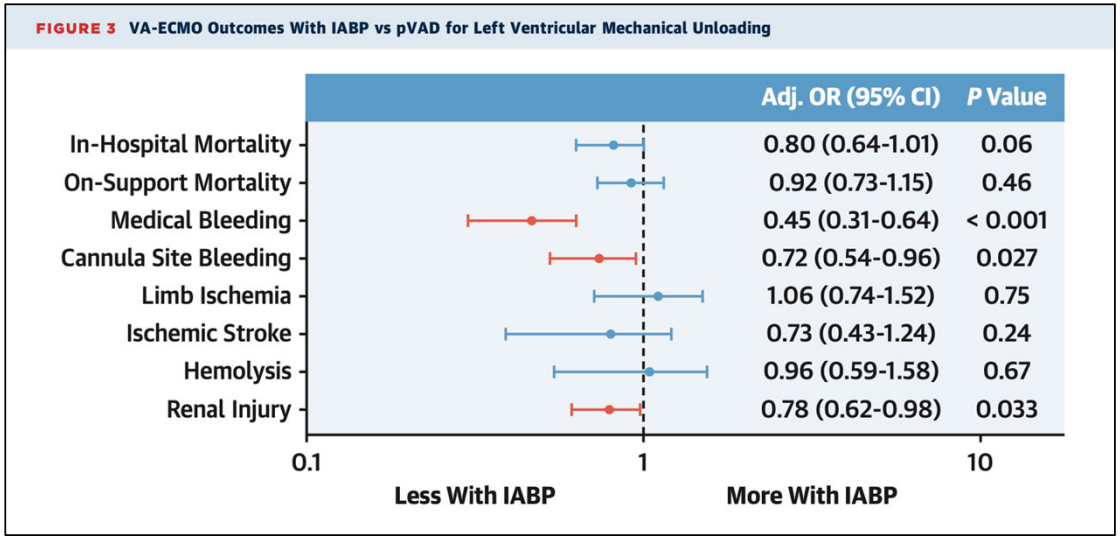

c
ESPVR
VA-ECMO
pLVAD + VA-ECMO
IABP + VA-ECMO
Inotropes + VA-ECMO
EDPVR
Left Ventricular Pressure (mmHg)
125
100
75
50
25
0
0
50
100
150
200
250
Left Ventricular Volume (ml)

# Mechanical Left Ventricular Unloading in Patients Undergoing Venoarterial Extracorporeal Membrane Oxygenation

E. Wilson Grandin, MD, MPH, MED,[a,b] Jose I. Nunez, MD,[c] Brooks Willar, MD,[d] Kevin Kennedy, MS,[b] Peter Rycus, MPH,[e] Joseph E. Tonna, MD, MS,[e,f] Navin K. Kapur, MD,[g] Shahzad Shaefi, MD, MPH,[h] A. Reshad Garan, MD, MS[a]




- 86,4% of patients with mechanical unloading had IABP or pVAD in place PRIOR to VA-ECMO
  → VA-ECMO used as « Therapy Intensification »

- In Hospital Mortality lower with LVU
- In Hospital Mortality lower with IABP with lower bleeding and renal

Journal of the American Heart Association

ORIGINAL RESEARCH

# Effectiveness of an Impella Versus Intra-Aortic Balloon Pump in Patients Who Received Extracorporeal Membrane Oxygenation

Yuji Nishimoto, MD; Hiroyuki Ohbe, MD, MPH, PhD; Jun Nakata, MD; Toru Takiguchi, MD, PhD; Mikio Nakajima, MD, MPH, PhD; Yusuke Sasabuchi, MD, MPH, PhD; Toshiaki Isogai, MD, MPH; Hiroki Matsui, MPH, PhD; Yukihito Sato, MD, PhD; Tetsuya Watanabe, MD, PhD; Takahisa Yamada, MD, PhD; Masatake Fukunami, MD, PhD; Hideo Yasunaga, MD, PhD

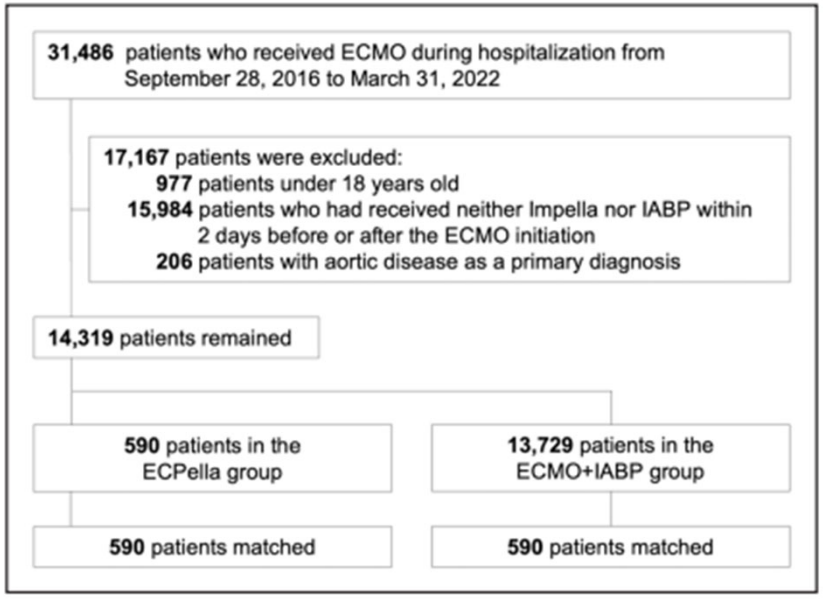



**Table 2. Outcomes Before and After Propensity Score Matching**

| | Before matching | | After matching | | | |
|---|---|---|---|---|---|---|
| | ECPella | ECMO+IABP | ECPella | ECMO+IABP | Risk difference | |
| | (*n* = 590) | (*n* = 13729) | (*n* = 590) | (*n* = 590) | (95% CI) | *P* value |
| In-hospital mortality, *n* (%) | 344 (58.3) | 8962 (65.3) | 344 (58.3) | 334 (56.6) | 2.4 (−3.5 to 8.2) | 0.429 |
| 14-day mortality, *n* (%) | 165 (28.0) | 6303 (45.9) | 165 (28.0) | 217 (36.8) | −8.2 (−13.8 to −2.7) | 0.004 |
| 30-day mortality, *n* (%) | 246 (41.7) | 7779 (56.7) | 246 (41.7) | 276 (46.8) | −4.7 (−10.6 to 1.2) | 0.122 |
| Length of hospital stay, mean (SD), d | 43.4 (60.5) | 28.7 (42.7) | 43.4 (60.5) | 36.7 (63.2) | 4.9 (−2.6 to 12.4) | 0.197 |
| Length of ECMO, mean (SD), d | 3.9 (7.5) | 2.3 (8.1) | 3.9 (7.5) | 3.2 (16.6) | 0.7 (−0.8 to 2.2) | 0.373 |
| Total hospitalization cost, mean (SD), $\times 10^3$ yen | 12567 (10379) | 5633 (5256) | 12567 (10379) | 7050 (9034) | 5094 (3937–6251) | <0.001 |
| Complications, *n* (%) | | | | | | |
| Major bleeding | 22 (3.7) | 277 (2.0) | 22 (3.7) | 19 (3.2) | 0.5 (−1.6 to 2.6) | 0.624 |
| Ischemic stroke | 22 (3.7) | 442 (3.2) | 22 (3.7) | 26 (4.4) | −0.6 (−2.9 to 1.7) | 0.612 |
| Vascular complications | 24 (4.1) | 262 (1.9) | 24 (4.1) | 14 (2.4) | 2.0 (−0.1 to 4.1) | 0.065 |
| Renal replacement therapy during hospitalization | 299 (50.7) | 5339 (38.9) | 299 (50.7) | 220 (37.3) | 14.2 (8.3–20.1) | <0.001 |
| Durable MCS implantations, *n* (%) | 24 (4.1) | 72 (0.5) | 24 (4.1) | 8 (1.4) | 2.3 (0.4–4.2) | 0.019 |

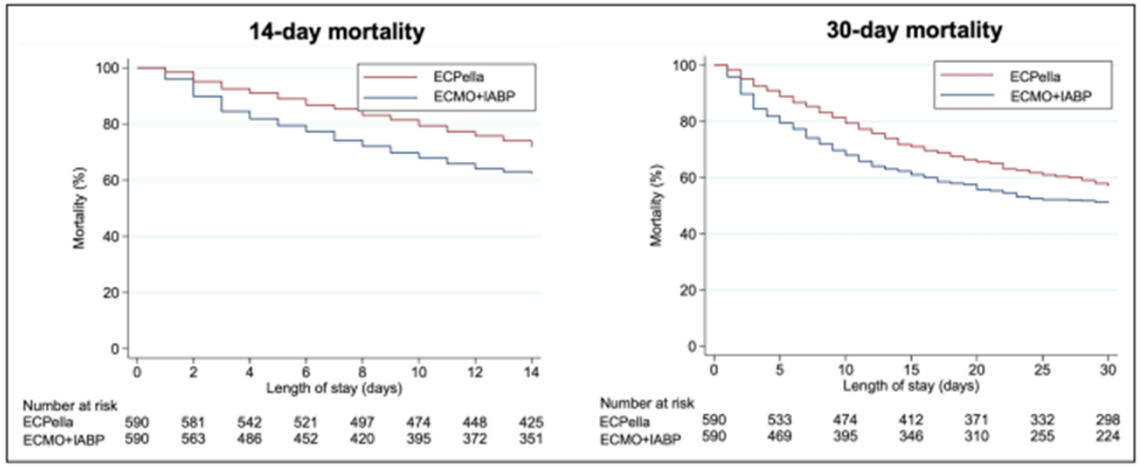
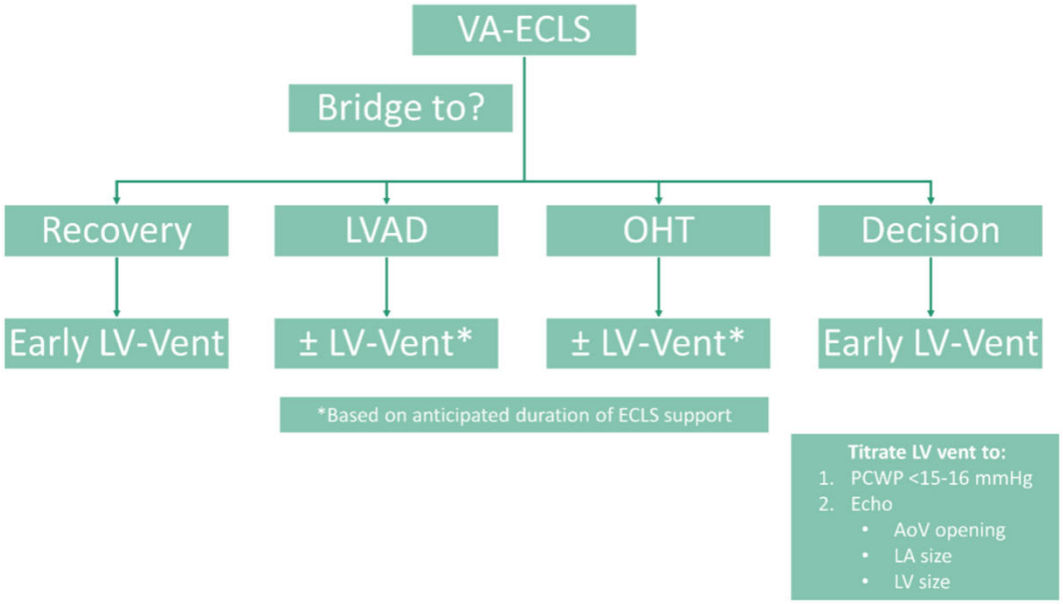
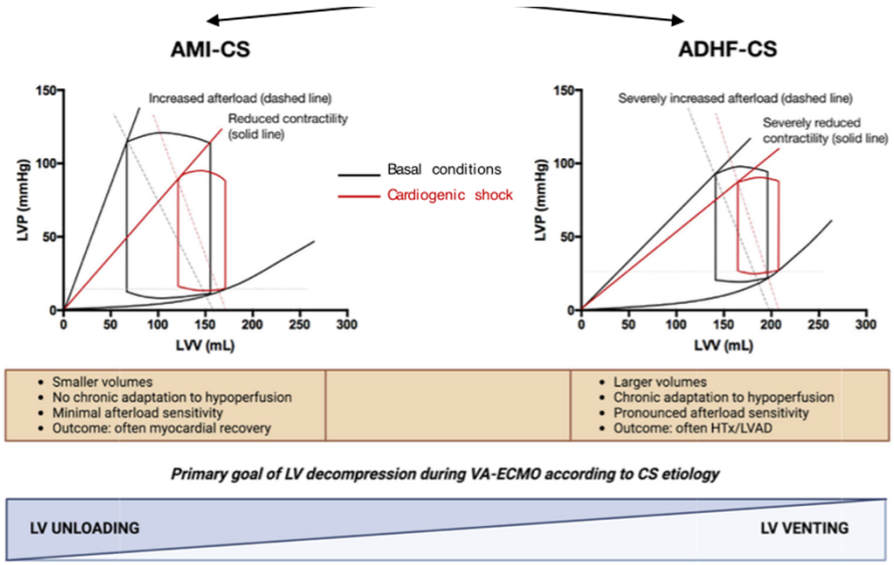



**Figure 2. Kaplan–Meier curves for the 14-day and 30-day mortality.**
ECMO indicates extracorporeal membrane oxygenation; ECPella, combination of extracorporeal membrane oxygenation and Impella; and IABP, intra-aortic balloon pump.

# Strategy Bases Approach to LV Unloading?




*A. Rali et al JCF 2022*




*L.Baldetti et al* ESC HF 2024

**Bridge to Recovery /Decision: AMI-CS +++**

Early LV Unload to allow for maximal recovery

**Bridge to HT/LVAD : HF-CS +++**

« Wait and see » goal is to prevent MSOF

# Key Questions

1. Why should we consider LV Unloading ?

To avoid complication due to increased LV afterload

2. Which patient population should we consider for LV unloading

All Cardiogenic Shock on VA-ECMO

3. When should we consider LV unloading? (Early vs Delayed)

Early and comprehensive is likely better than late and partial

4. Which Strategies should we use to unload the LV ?

IABP vs pVAD : no quality data exists

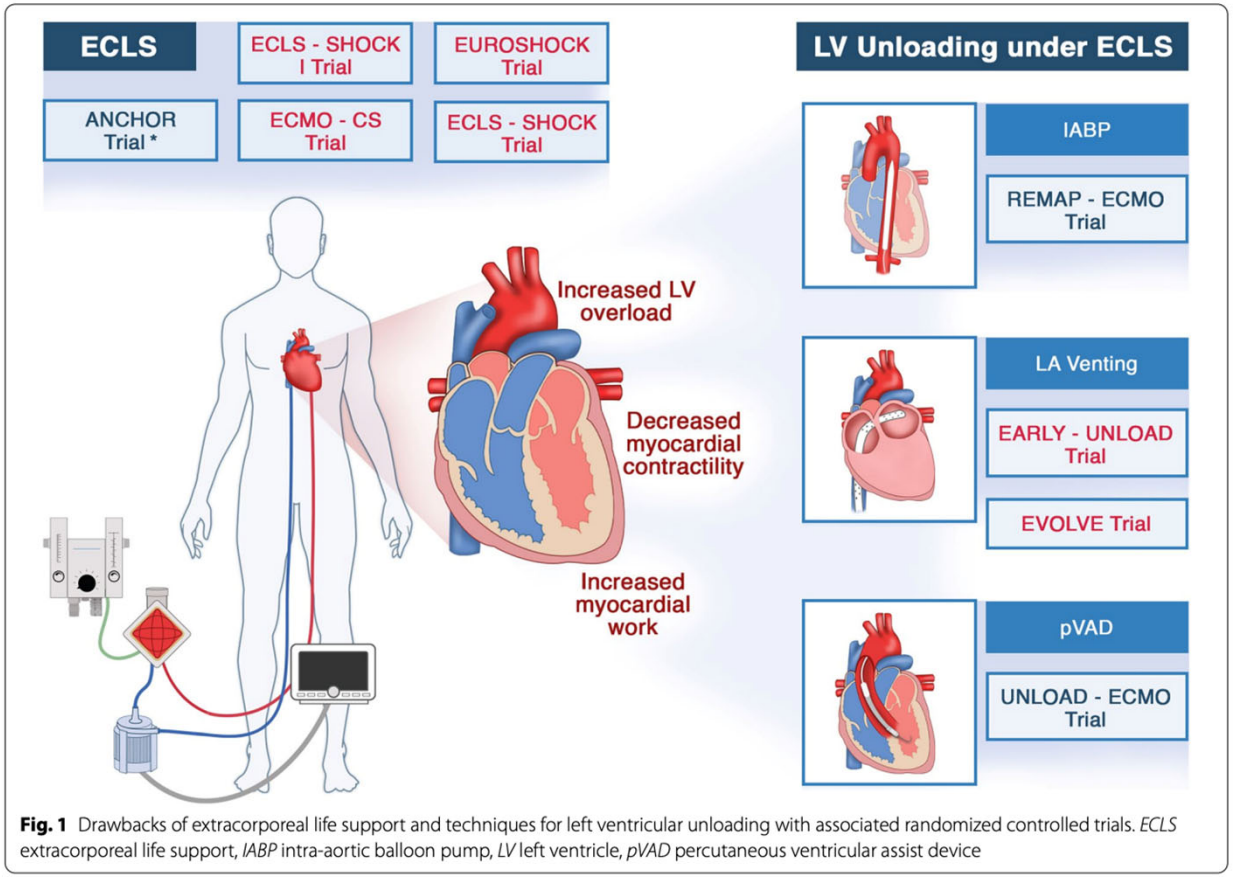



**Fig. 1** Drawbacks of extracorporeal life support and techniques for left ventricular unloading with associated randomized controlled trials. *ECLS* extracorporeal life support, *IABP* intra-aortic balloon pump, *LV* left ventricle, *pVAD* percutaneous ventricular assist device

*A. Ughetto, B.Schrage, C.Delmas ICM 2024*