# Assistance circulatoire mécanique temporaire : IMPELLA

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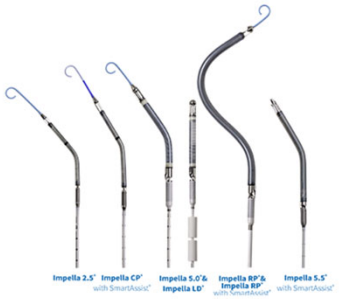
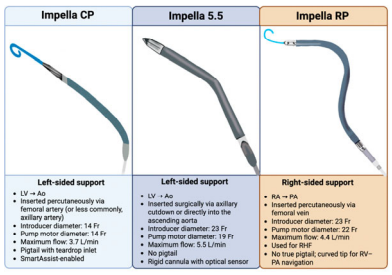
Conflit d'intêret pour cette présentation

Speaker pour les journées IMPELLA



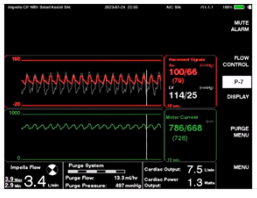




Farhat et al. Biomedicines 2025; 13 (9) : 2198.

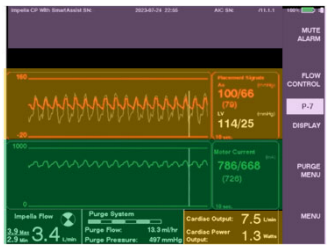
## CONSOLE ET FONCTIONNEMENT

## I. PARAMÈTRES HÉMODYNAMIQUES DE BASE

Surveillance intégré pompe–patient



## I. PARAMÈTRES HÉMODYNAMIQUES DE BASE



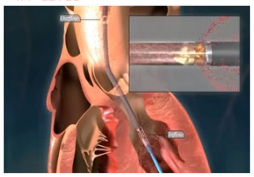

Signaux hémodynamiques **indirects**

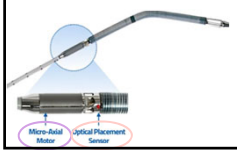
Signaux **mécaniques** moteurs

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.

Signaux **mécaniques** moteurs

## I. P-LEVEL

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

CP

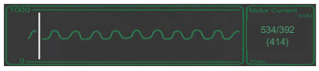
| Performance | *Débit (l/min) | Tours par minute (tr/min) |
|---|---|---|
| P-0 | 0,0 | 0 |
| P-1 | 0,0 - 0,9 | 23 000 |
| P-2 | 1,1 - 2,1 | 31 000 |
| P-3 | 1,6 - 2,3 | 33 000 |
| P-4 | 2,0 - 2,5 | 35 000 |
| P-5 | 2,3 - 2,7 | 37 000 |
| P-6 | 2,5 - 2,9 | 39 000 |
| P-7 | 2,9 - 3,3 | 42 000 |
| P-8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

Signaux **mécaniques** moteurs

## 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

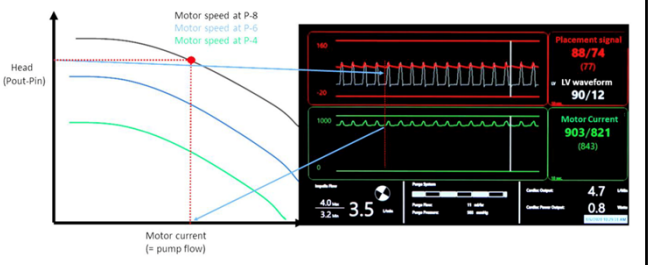
**3)** Ajustement du courant moteur

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

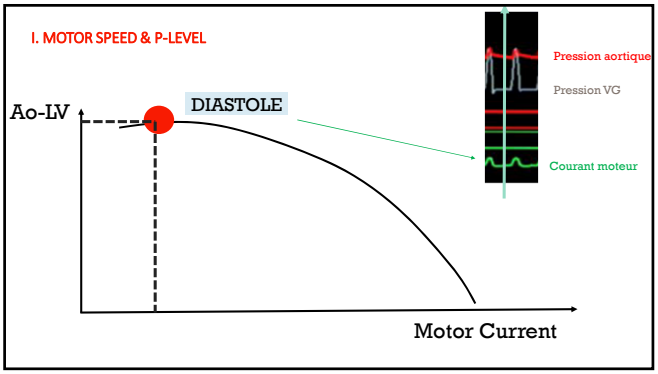
Signaux **mécaniques** moteurs

## I. MOTOR SPEED & P-LEVEL

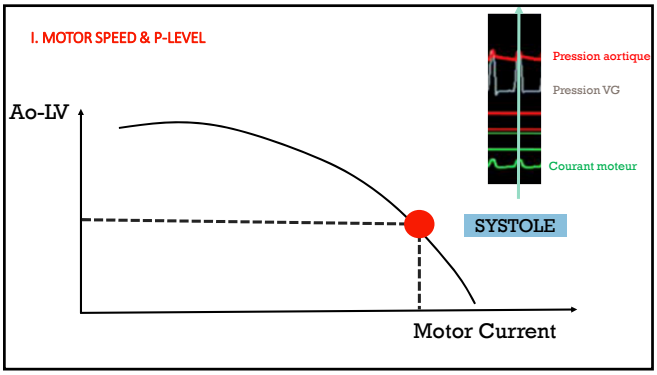
Signaux **mécaniques** moteurs




## I. MOTOR SPEED & P-LEVEL

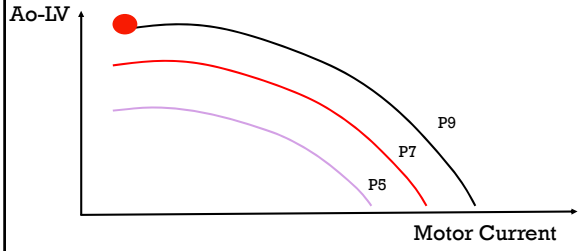


## I. MOTOR SPEED & P-LEVEL



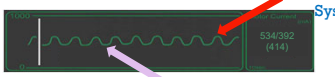



## I. MOTOR SPEED & P-LEVEL






## I. COURANT MOTEUR




Pic de consommation
Systole VG : gradient VG-Ao faible

Baisse de consommation
Diastole VG : gradient VG-Ao important

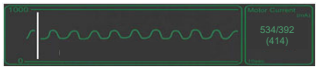
Pendant la systole, l'augmentation de la pression ventriculaire réduit le gradient trans-pompe.

**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

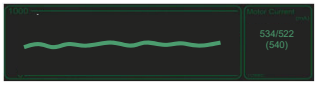



**Charge hydraulique**
- Gradient outlet-inlet (Ao-VG)
- Viscosité sanguine
- Résistance à l'écoulement

**Résistance mécanique**
- Thrombose
- Obstacle
- Kinking du cathéter



## I. COURANT MOTEUR

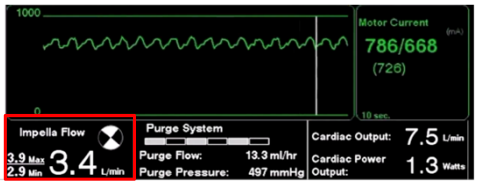



**Absence de gradient outflow-inflow :**
- Impella dans l'aorte
- Impella dans le ventricule
- faible systole ventriculaire :
  Faible inotropisme / Décharge trop intense / Défaillance VD

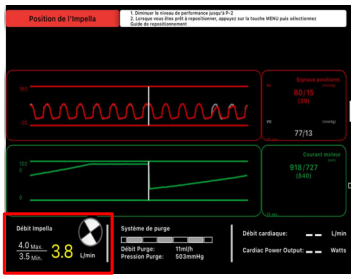


## I. IMPELLA FLOW

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



## I. IMPELLA FLOW

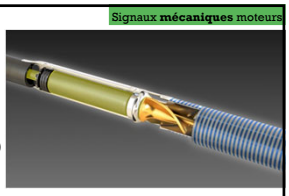



**Situations où l'estimation est fausse**

- 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)

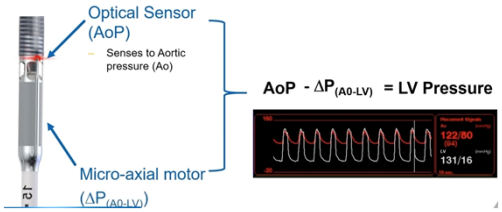


Le débit de purge est asservi à la pression de purge afin de maintenir une pression cible (300-1100 mmHg)

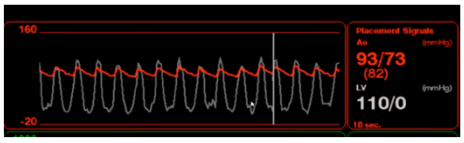

Débit de purge

Volume de liquide
+/- Héparine

## II. SIGNAUX HEMODYNAMIQUES INDIRECTS



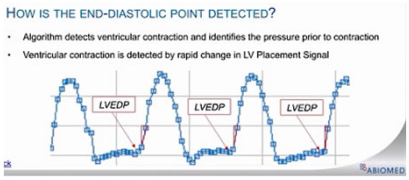



Le **signal LV est reconstruit indirectement** à partir de :

- RPM
- courant moteur
- variations instantanées de charge hydraulique

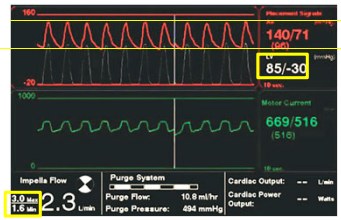




Signaux hémodynamiques **indirects**

## 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
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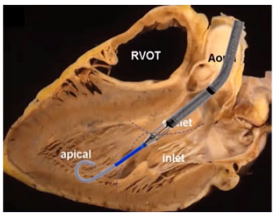
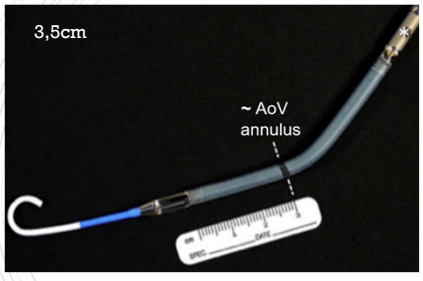
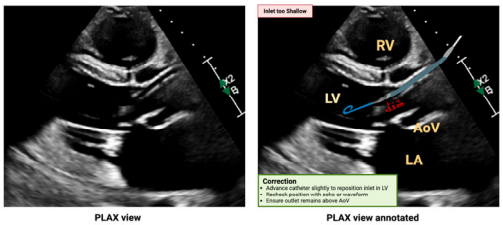
### 3) Capteur de pression (outlet)

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

## BONNE POSITION

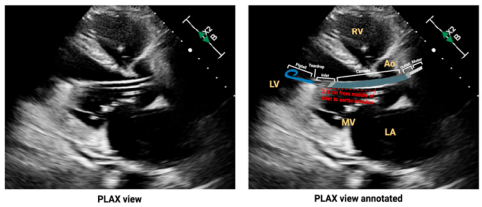


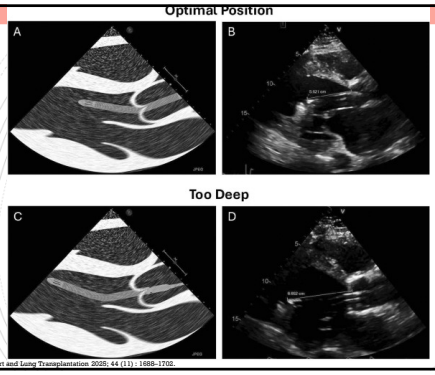




PLAX view

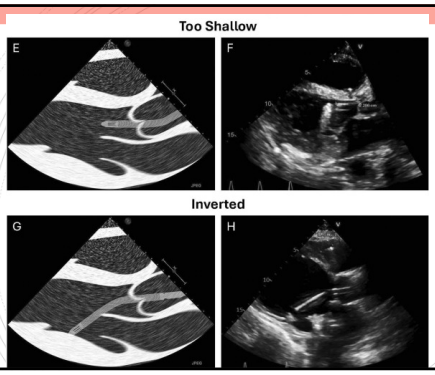
PLAX view annotated




PLAX view | PLAX view annotated




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

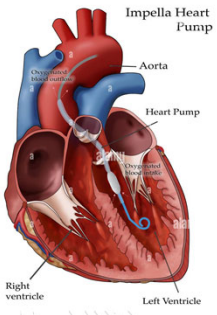



Recommandation ABIOMED

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

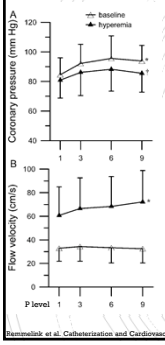
while the middle of the inlet of the Impella 5.5® with SmartAssist® should be approximately 5 cm from the aortic valve.

# RATIONNEL PHYSIOPATHOLOGIQUE




1. ↑ Perfusion coronarienne
   ↑ Délivrance O2 myocardique
2. Unloading : décharge ventriculaire active

## PERFUSION CORONARIENNE



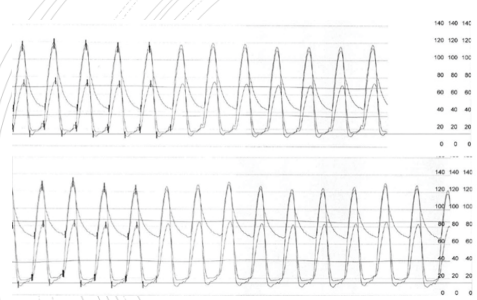

11 patients - High-risk PCI - FEVG 35 ± 10%

**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).

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

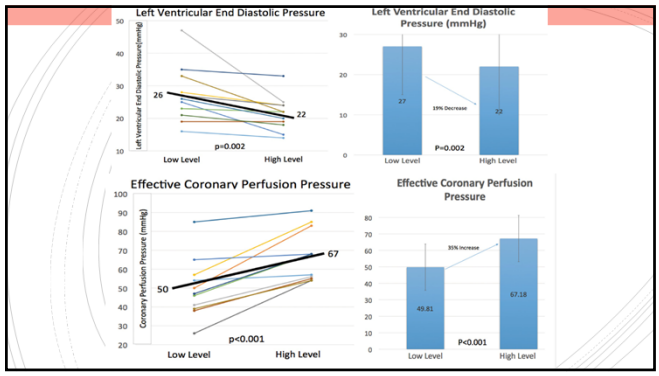


**Upper Tracing**
Impella CP at P2

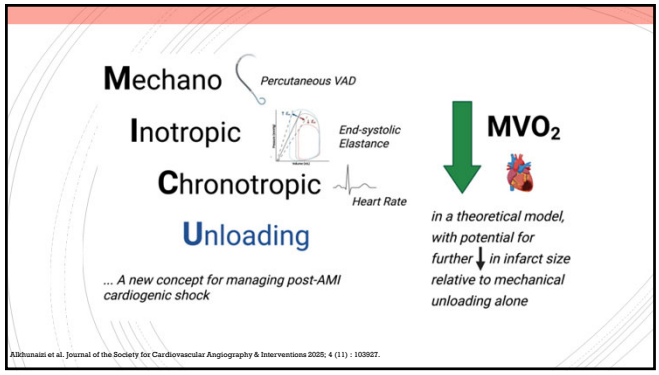
| | |
|---|---|
| LV | 116/12/21 mmHg |
| Ao | 112/43/68 mmHg |
| DCP | 72/19/35mmHg |
| ECPP | 47 mmHg |
| DPP | 22 mmHg |

**Lower Tracing**
Impella CP at P8

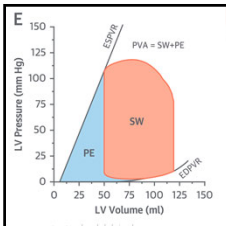
| | |
|---|---|
| LV | 126/12/18 mmHg |
| Ao | 122/68/86 mmHg |
| DCP | 81/20/41 mmHg |
| ECPP | 68 mmHg |
| DPP | 50 mmHg |




## PHYSIOLOGIE DE LA DÉCHARGE VENTRICULAIRE




Alkhunaizi et al. Journal of the Society for Cardiovascular Angiography & Interventions 2025; 4 (1) : 103927.




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

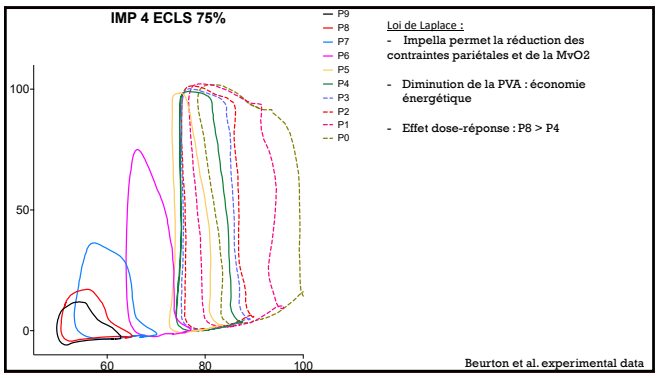
where α, β, and γ are constants that have been defined previously as follows:

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

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

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

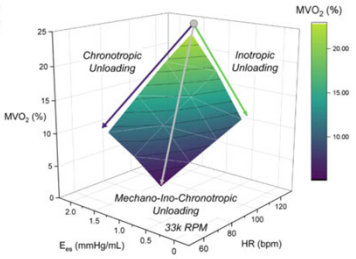
Alkhunaizi et al. Journal of the Society for Cardiovascular Angiography & Interventions 2025; 4 (1) : 103927.




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

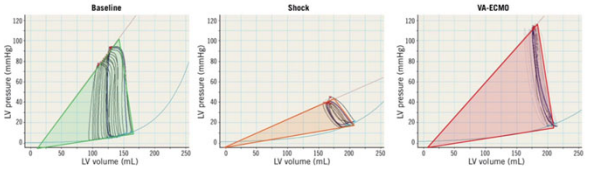
Beurton et al. experimental data




**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.**

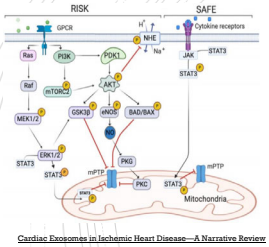
Alkhunaizi et al. Journal of the Society for Cardiovascular Angiography & Interventions 2025; 4 (1) : 103927.

- ↑↑ 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



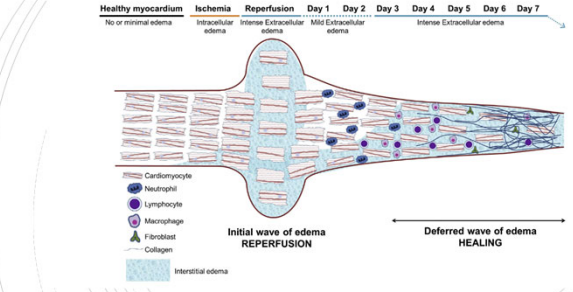

O. Moller-Helgestad et al. **EuroIntervention** 2019

Voies de signalisation




Cardiac Exosomes in Ischemic Heart Disease—A Narrative Review

Activation surtout en cas de décharge avant reperfusion

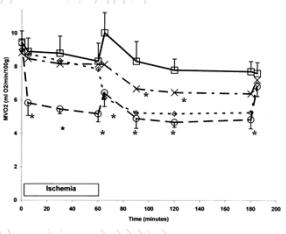


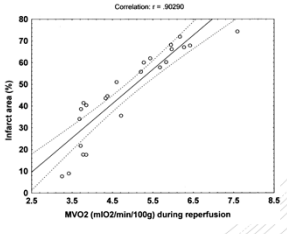

https://www.jacc.org/doi/epdf/10.1016/j.jacc.2019.05.024

## Le unloading réduit la taille de l'infarctus

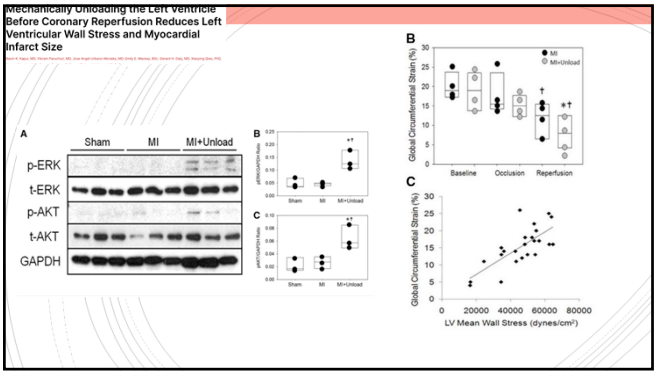
Left Ventricular Support by Catheter-Mounted Axial Flow Pump Reduces Infarct Size

Bart Meyns, MD, PhD, Jacek 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**



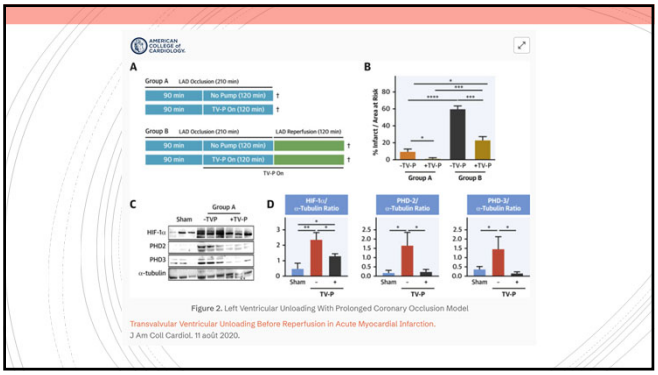
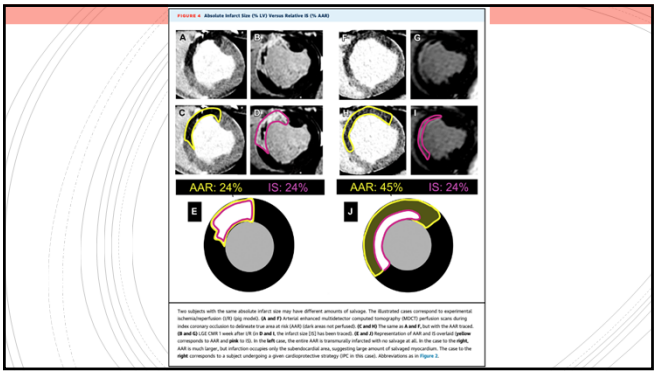



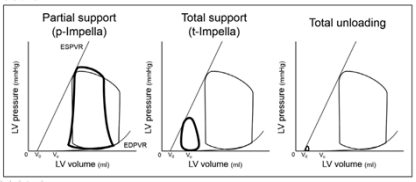

Figure 2. Left Ventricular Unloading With Prolonged Coronary Occlusion Model

Transvalvular Ventricular Unloading Before Reperfusion in Acute Myocardial Infarction.
J Am Coll Cardiol. 11 août 2020.

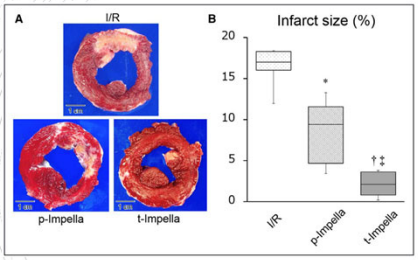



20 chiens
sham (thoracotomy only, no left anterior descending coronary artery occlusion or Impella support; n=5),
I/R (180 minutes ischemia followed by 60 minutes reperfusion, no Impella support; n=5),
p-Impella (p-Impella from 60 minutes after onset of ischemia to 60 minutes after reperfusion; n=5),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

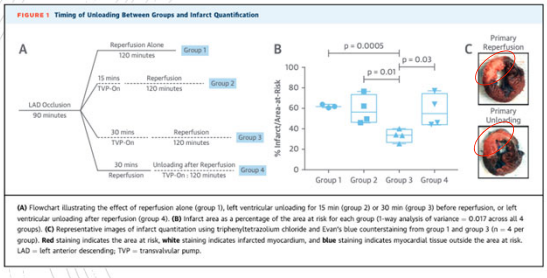
Evaluation J28



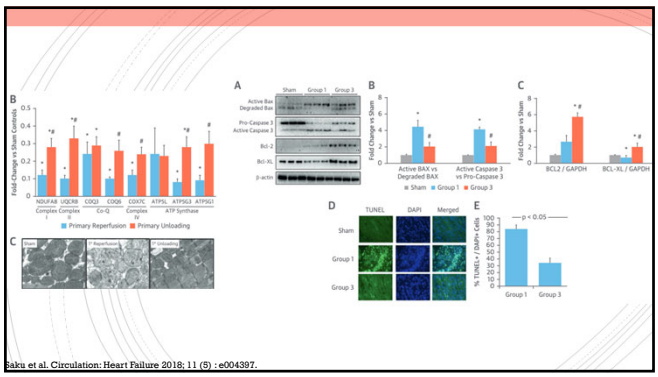

Saku et al. Circulation: Heart Failure 2018; 11 (5) : e004397.




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



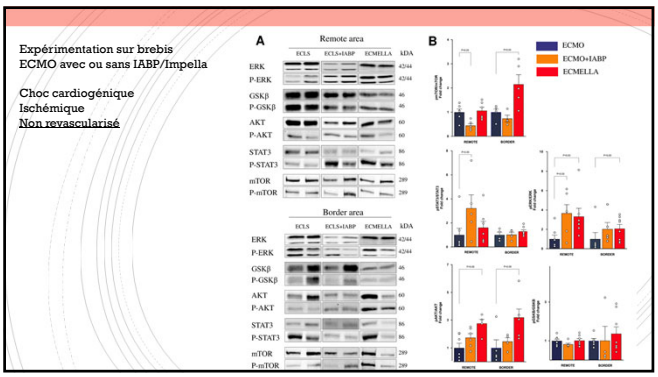

**(A)** Flowchart illustrating the effect of reperfusion alone (group 1), left ventricular unloading for 15 min (group 2) or 30 min (group 3) before reperfusion, or left ventricular unloading after reperfusion (group 4). **(B)** Infarct area as a percentage of the area at risk for each group (1-way analysis 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.

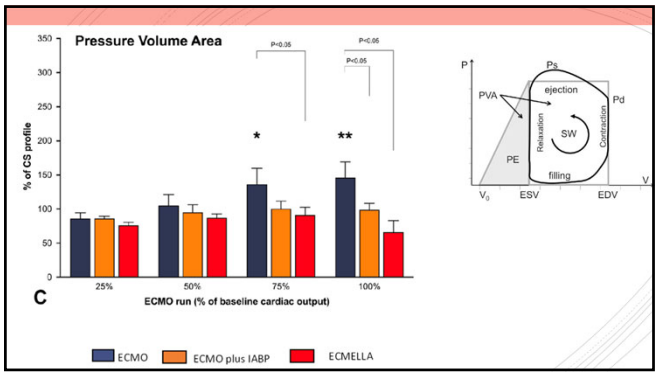


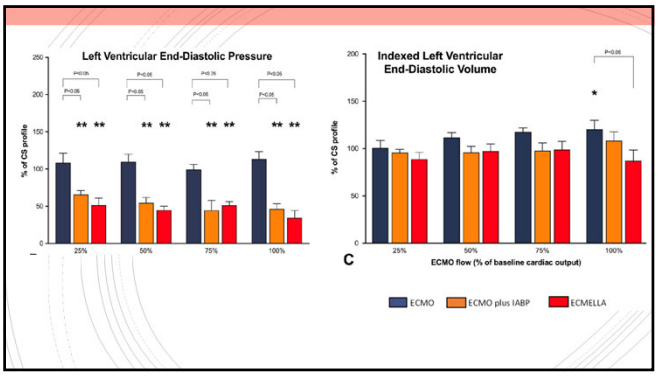
Saku et al. Circulation: Heart Failure 2018; 11 (5) : e004397.

Expérimentation sur brebis
ECMO avec ou sans IABP/Impella

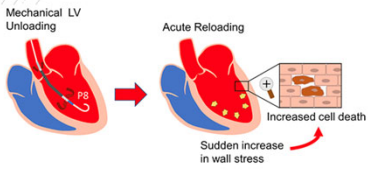
Choc cardiogénique
Ischémique
Non revascularisé





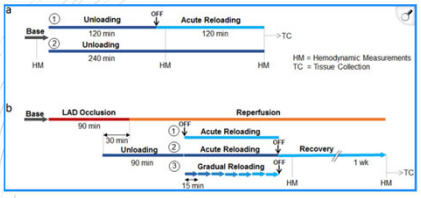




## Peut-être pire encore : le reloading après l'unloading




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

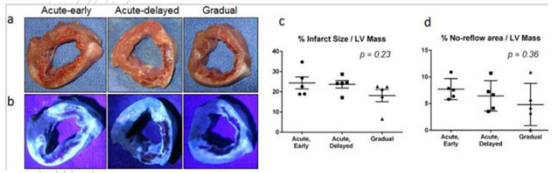
Mazurek et al. J Cardiovasc Transl Res 2024; 17 (2) : 233–241.




**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,[e] Christopher B. Granger, MD,[d] Paul L. Jenkins, PhD,[a] Melissa Nichols, MS,[a] Ori Ben-Yehuda, MD[a]

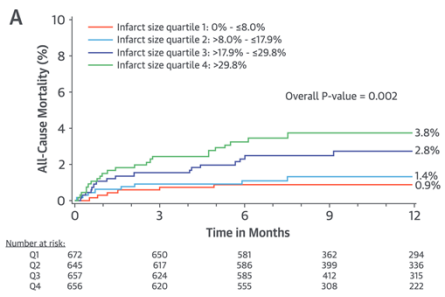
Pool de 10 RCT sur la PCI laire (2632 patients)
Taille de l'infarctus 1 mois après la randomisation par IRM ou SPECT
Suivi à 6 mois

**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

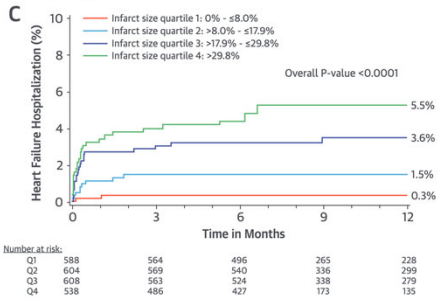
Augmentation de la mortalité tous les 5% de taille d'infarctus (Cox-adjusted hazard ratio: 1.19 [95% confidence interval: 1.18 to 1.20]; p < 0.0001)

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

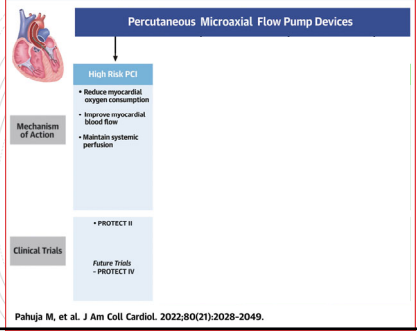



Stone et al. JACC 2016; 67 (14) : 1674–1683.




# LES ETUDES CLINIQUES SUR L'IMPELLA

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




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**

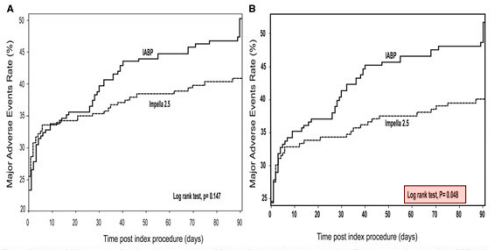
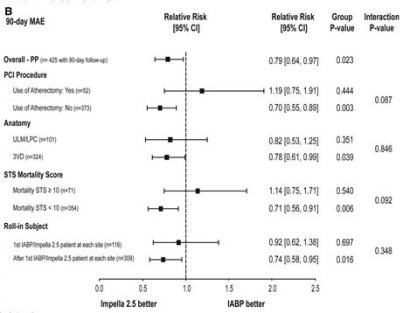



**Figure 2.** Kaplan–Meier curves of major adverse events to 90 days. **A**, intent-to-treat population. **B**, per protocol population. IABP indicates intra-aortic balloon pump.




**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** PROTECT III

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

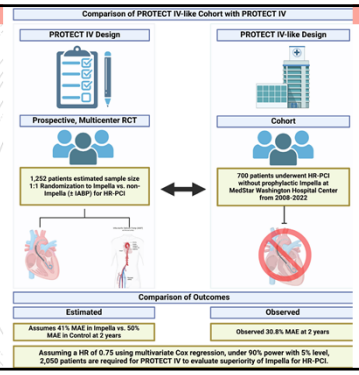
Registre prospective avec Impella 2.5 et CP dans la PCI à haut risque.
Mars 2017-2020 dans 4 centres américains

**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**

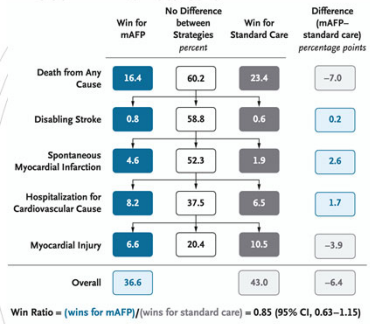



## Left Ventricular Unloading in High-Risk Percutaneous Coronary Intervention

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.,[1,3] Peter D. O'Kane, M.D.,[3] Roshan Weerackody, Ph.D.,[4] 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

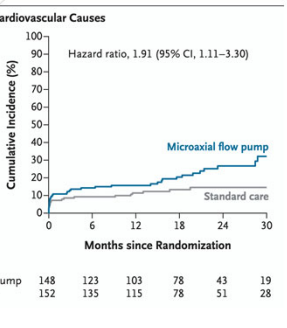
**Randomisation** : Impella CP vs soins standard
Exclusion des chocs cardiogéniques,




**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) |



**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)

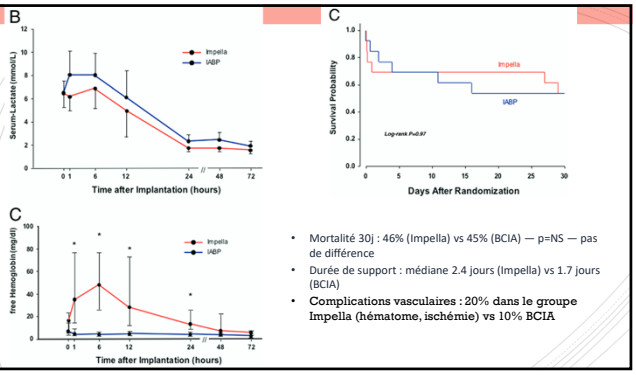
Ilaire: hémolyse, acidose et mortalité J30

**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/m²) | 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

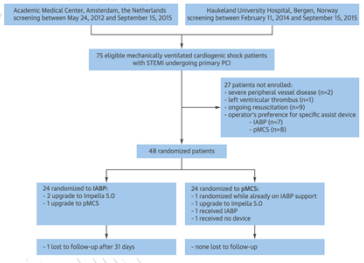
- 1ère RCT de supériorité
- Critère primaire objectif et mesurable (ΔIC à 30 min)
- Double aveugle

- 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**

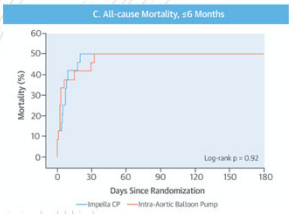
IMPRESS in Severe Shock trial

Ingmar M. Ouweneel, MSc,[1] Erlend Eriksen, MD,[1] Krishan D. Sjauw, MD, PhD,[1] Ivo M. van Dongen, MD,[1]




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

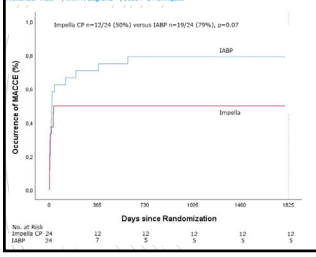
1er RCT avec la CP
CJP fort : mortalité J30
Suivi J90 et suivi 180J
Essai de faisabilité

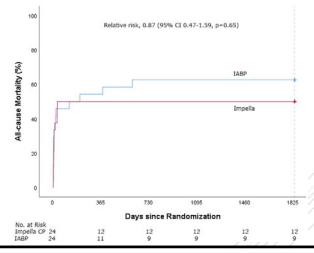
Sous dimensionné
Choc trop sévère : 90% d'ACR / SCAI D et E
Support de 2-3 jours
Groupe contrôle IABP ? (IABP-SHOCK II date de 2012)

**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)



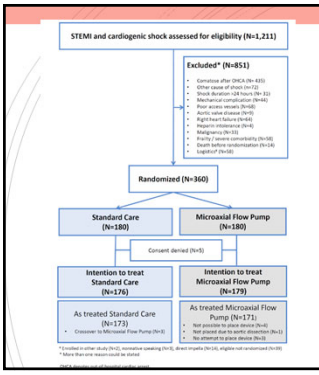




ORIGINAL ARTICLE

**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%



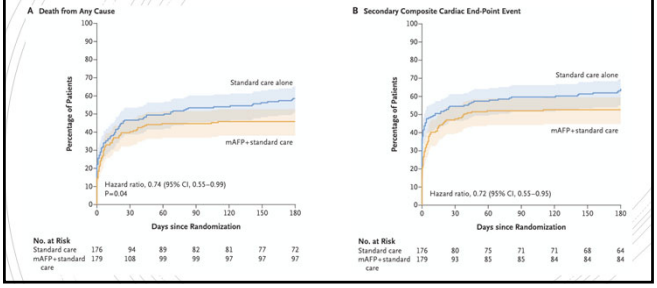

| Characteristic | Microaxial Flow Pump plus Standard Care (N = 179) | Standard Care Alone (N = 179) |
|---|---|---|
| Median age (IQR) — yr | 67 (58–76) | 69 (61–76) |
| Male sex — no. (%) | 142 (79.3) | 139 (79.0) |
| Median systolic blood pressure (IQR) — mm Hg | 84 (72–91) | 82 (72–91) |
| Median 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) | 170 (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 (8–19) | 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) | 3 (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¶) |

| Management | Microaxial Flow Pump plus Standard Care (N = 179) | Standard Care Alone (N = 176) |
|---|---|---|
| **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



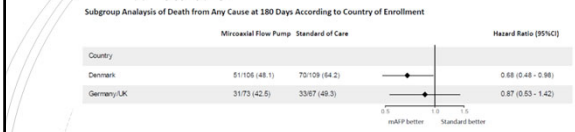
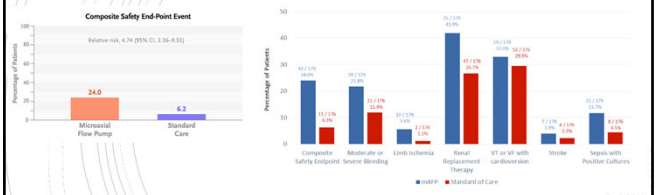



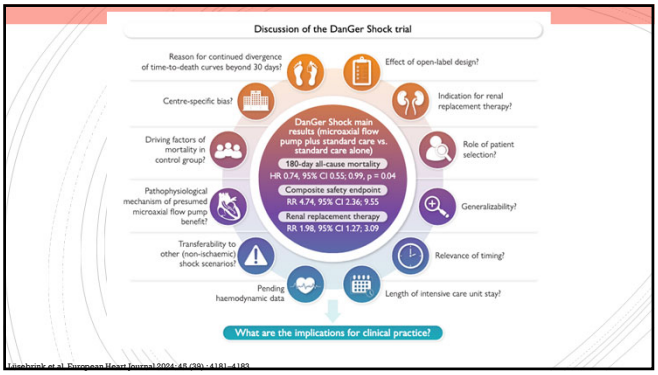

**Table S3 Cause of Death**

| | 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

HAS
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+*

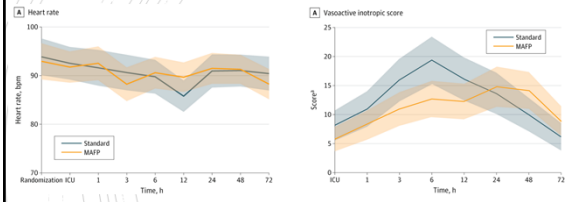
**R19B. The experts suggest considering Impella 5+ (5.0 or 5.5) support for CS patients due to predominant left ventricular failure.**

*Level of evidence: expert opinion*

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

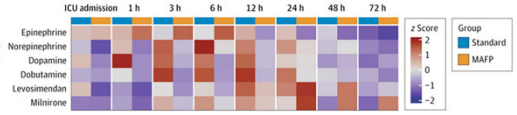
### A Substudy of the DanGer Shock Randomized Clinical Trial

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.

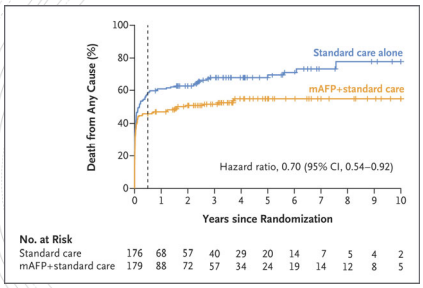
**Figure 3. Heatmap Depicting Dose of Vasoactive Drugs Used in the Microaxial Flow Pump (MAFP) and Standard-Care Groups at Different Time Points**

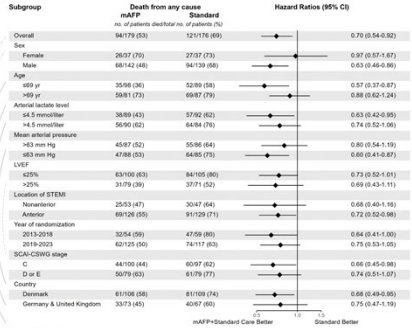



Doses were scaled to a *z* score to enable visual comparisons between groups and time points. The *z* score: gray depicts mean, red SD above mean, blue SD below mean. The colors can be compared between the 2 treatments (standard of care and MAFP) and between different times but not between the different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

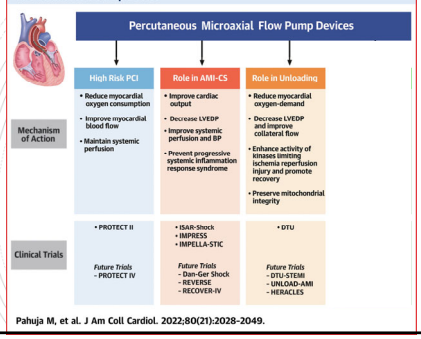
## Long-Term Outcomes of the DanGer Shock Trial

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


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



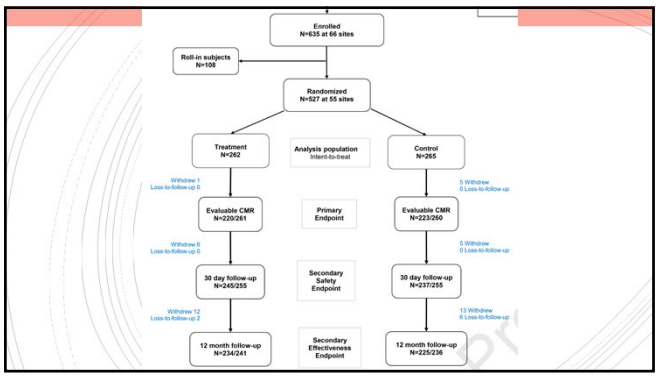

Pahuja M, et al. J Am Coll Cardiol. 2022;80(21):2028-2049.

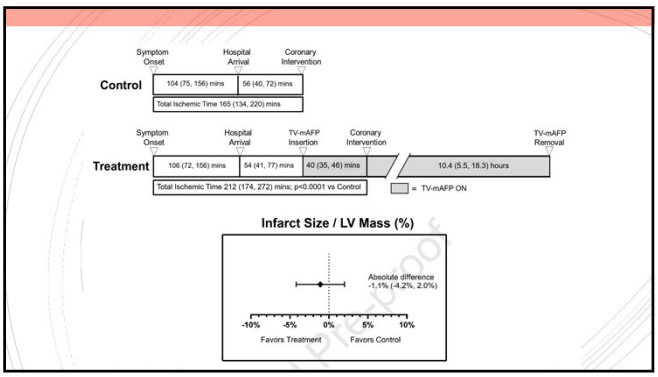
## Left Ventricular Unloading in Anterior STEMI without Shock: The STEMI Door to Unload (DTU) Randomized Controlled Trial

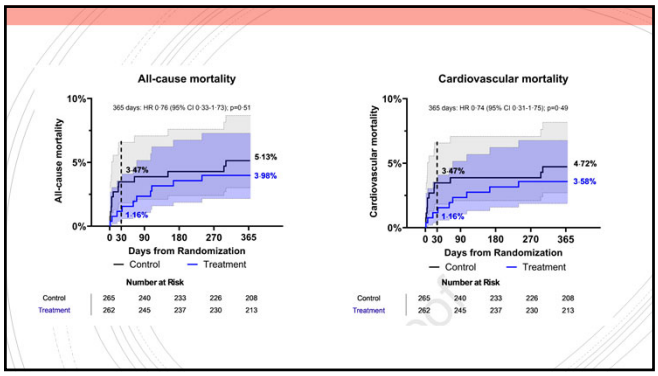
Navin K. Kapur MD [a b *], Norman Mangner MD [c], Nima Aghili MD [d], Haroon Faraz MD [e],

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




## Pourquoi cet échec ?

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

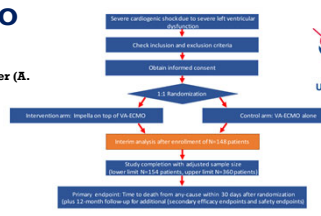
| | | | |
|---|---|---|---|
| Mean arterial pressure, mmHg | 106.5 ± 17.8 | 107.5 ± 17.9 | 105.5 ± 17.7 |

Et plus de complications hémorragiques

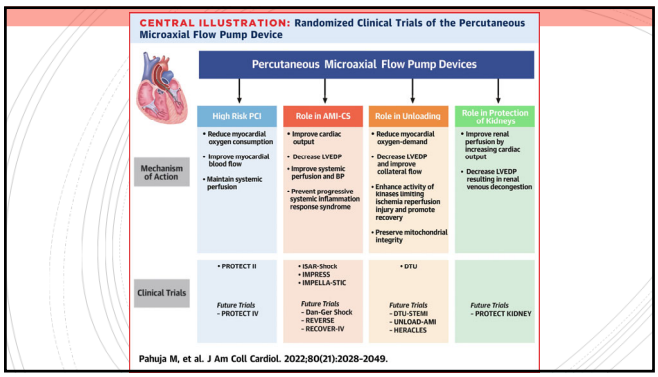
| | | | |
|---|---|---|---|
| Sécurité — Hémorragies majeures BARC 3-5 à 30j (traitement vs contrôle) | 89/262 = 34.0% | 16/265 = 6.0% | p < 0.01 |
| dont BARC 3a (↓Hb 3–5 g/dL) | 40/260 (15.4%) | — | |
| dont BARC 3b (↓Hb ≥5 g/dL) | 39/260 (15.4%) | — | |
| dont BARC 5 (fatal) | 1/260 (0.4%) | — | |

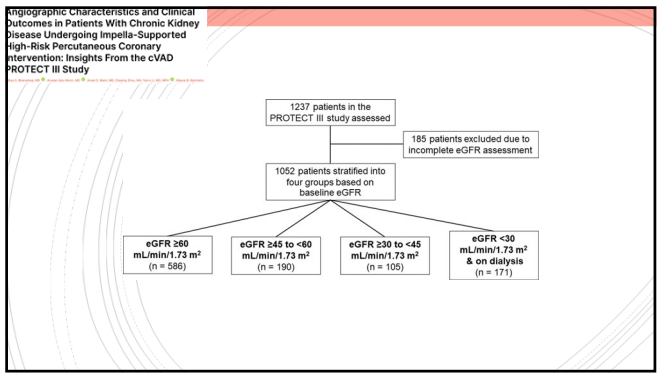
## UNLOAD ECMO

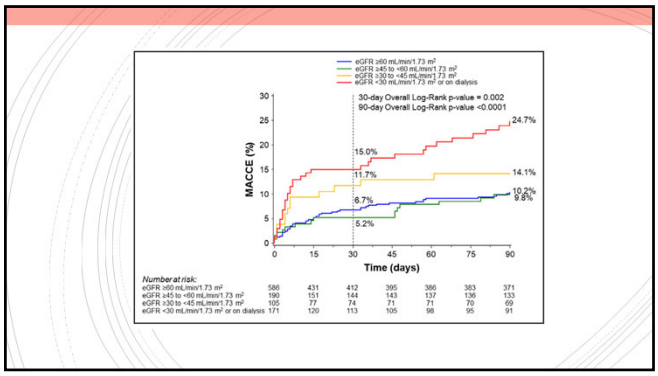
**PI: B. Schrage (Hamburg)**
**France: Montpellier Coordinator Center (A. Ughetto)**

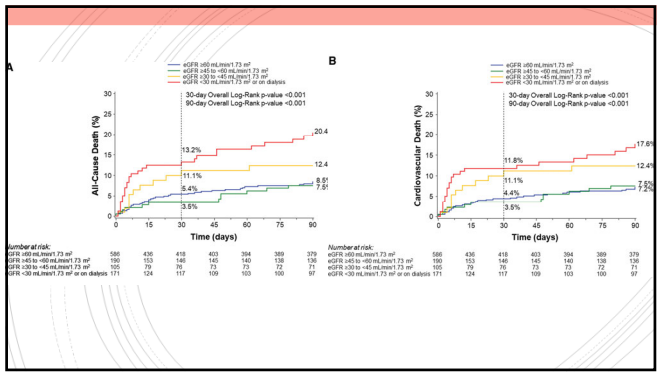



We hypothesize that left ventricular unloading by addition of an Impella on top of VA-ECMO for the treatment of patients with severe cardiogenic shock improves 30-day survival in comparison to VA-ECMO alone.

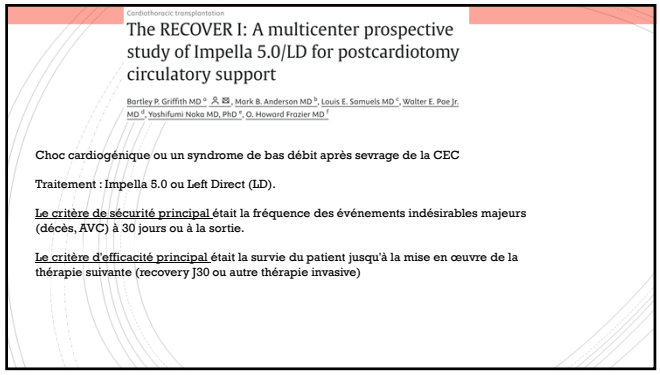



## IMPELLA en post-cardiotomie


Cardiothoracic transplantation

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

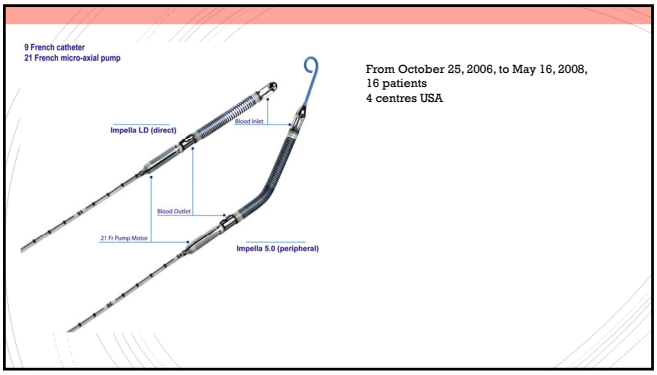
Bartley P. Griffith MD [a], Mark B. Anderson MD [b], Louis E. Samuels MD [c], Walter E. Pae Jr. MD [d], Yoshifumi Naka MD, PhD [e], O. Howard Frazier MD [f]

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

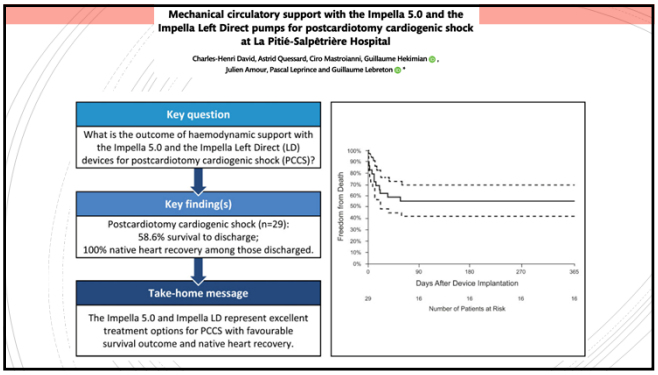
Traitement : Impella 5.0 ou Left Direct (LD).

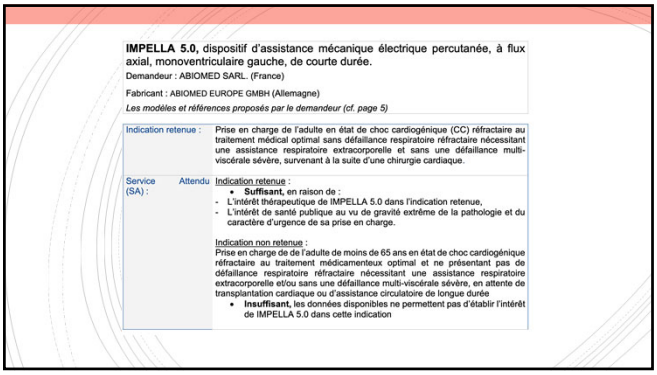
Le critère de sécurité principal était la fréquence des événements indésirables majeurs (décès, AVC) à 30 jours ou à la sortie.

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)




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



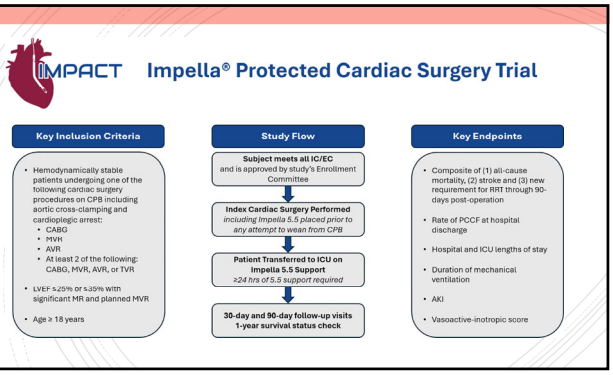
**IMPELLA 5.0,** dispositif d'assistance mécanique électrique percutanée, à flux axial, monoventriculaire gauche, de courte durée.

Demandeur : ABIOMED SARL. (France)

Fabricant : ABIOMED EUROPE GMBH (Allemagne)

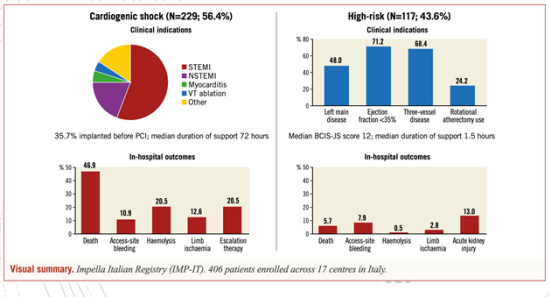
*Les modèles et références proposés par le demandeur (cf. page 5)*

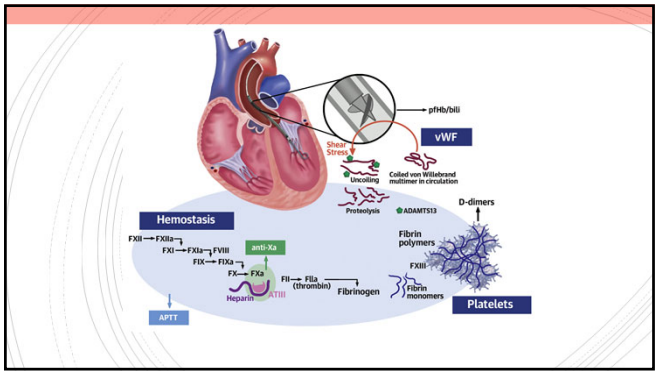
| | |
|---|---|
| Indication retenue : | Prise en charge de l'adulte en état de choc cardiogénique (CC) réfractaire au traitement médical optimal sans défaillance respiratoire réfractaire nécessitant une assistance respiratoire extracorporelle et sans une défaillance multi-viscérale sévère, survenant à la suite d'une chirurgie cardiaque. |
| Service Attendu (SA) : | Indication retenue :<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>Indication non retenue :<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 |




# COMPLICATIONS

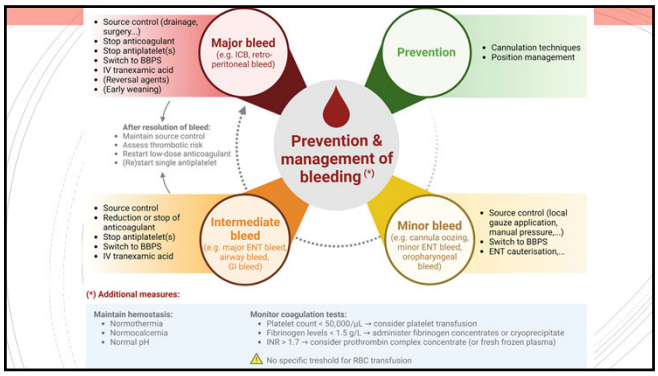
## Impella et complications



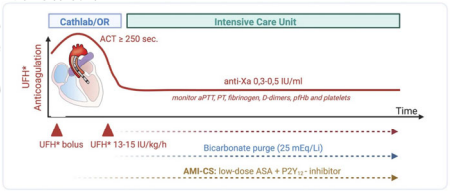




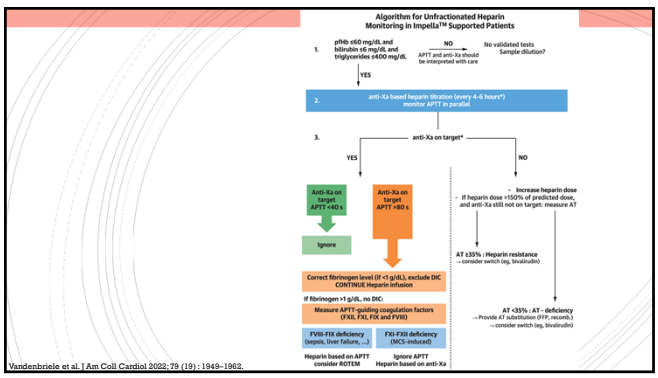
Vandenbriele et al. J Am Coll Cardiol 2022; 79 (19) : 1949–1962.



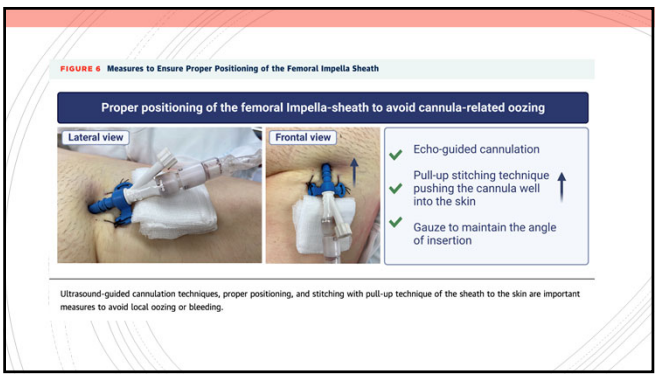

## Gestion de l'anticoagulation

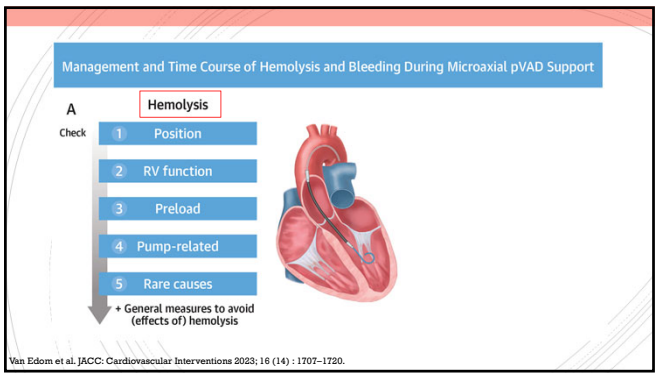


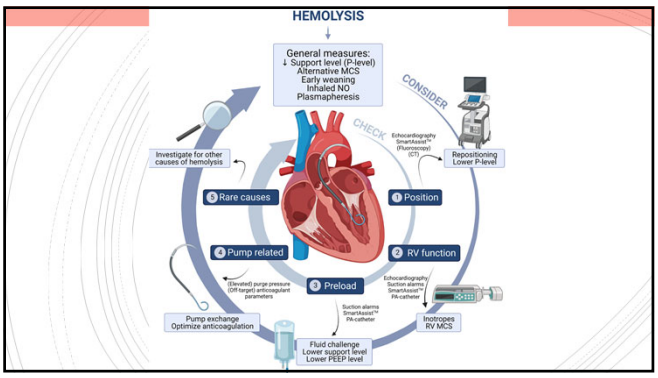

Bernhardt et al. The Journal of Heart and Lung Transplantation 2025; 44 (11) : 1688–1702.

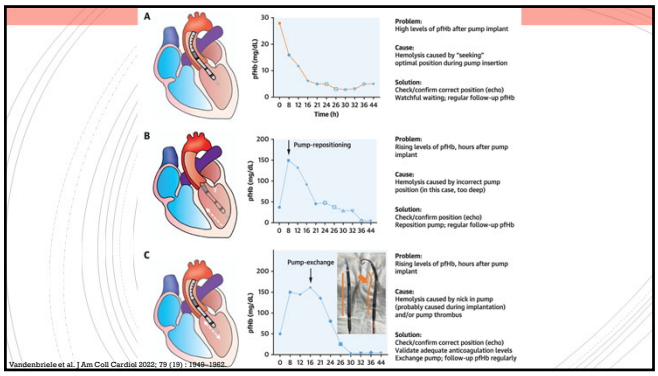


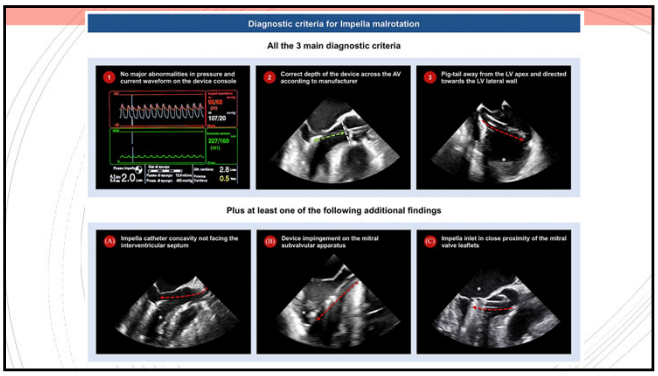

Vandenbriele et al. J Am Coll Cardiol 2022; 79 (19) : 1949–1962.




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
Investigate for other causes of hemolysis
Repositioning
Lower P-level
5 Rare causes
1 Position
4 Pump related
2 RV function
3 Preload
Pump exchange
Optimize anticoagulation
Fluid challenge
Lower support level
Lower PEEP level
Inotropes
RV MCS


A
B
C
Pump-repositioning
Pump-exchange
pfHb (mg/dL)
Time (h)
Problem:
High levels of pfHb after pump implant
Cause:
Hemolysis caused by "seeking" optimal position during pump insertion
Solution:
Check/confirm correct position (echo)
Watchful waiting; regular follow-up pfHb
Problem:
Rising levels of pfHb, hours after pump implant
Cause:
Hemolysis caused by incorrect pump position (in this case, too deep)
Solution:
Check/confirm position (echo)
Reposition pump; regular follow-up pfHb
Problem:
Rising levels of pfHb, hours after pump implant
Cause:
Hemolysis caused by nick in pump (probably caused during implantation) and/or pump thrombus
Solution:
Check/confirm correct position (echo)
Validate adequate anticoagulation levels
Exchange pump; follow-up pfHb regularly
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 Pigtail away from the LV apex and directed towards the LV lateral wall
Plus at least one of the following additional findings
A1 Impella catheter concavity not facing the interventricular septum
B1 Device impingement on the mitral subvalvular apparatus
C1 Impella inlet in close proximity of the mitral valve leaflets

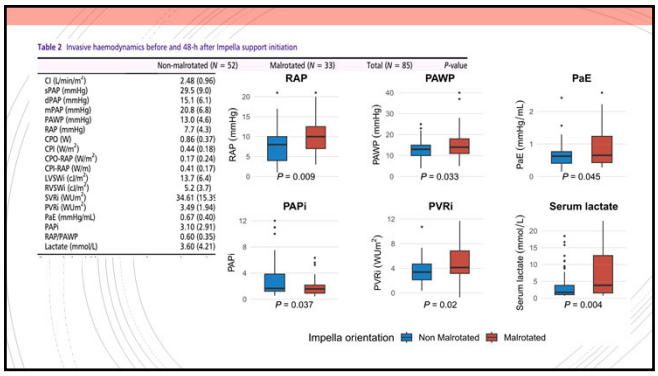
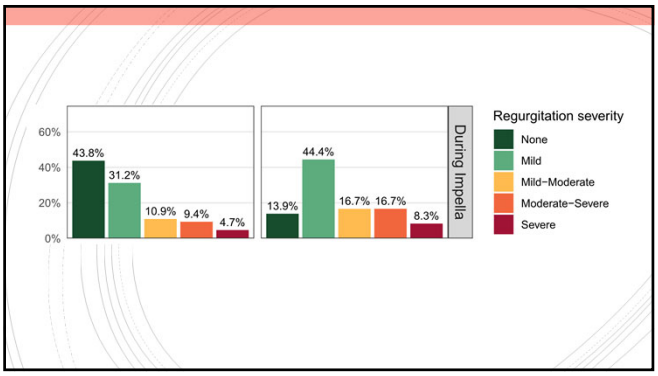
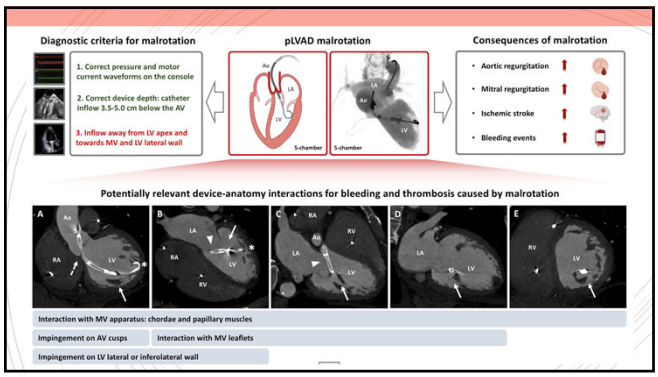
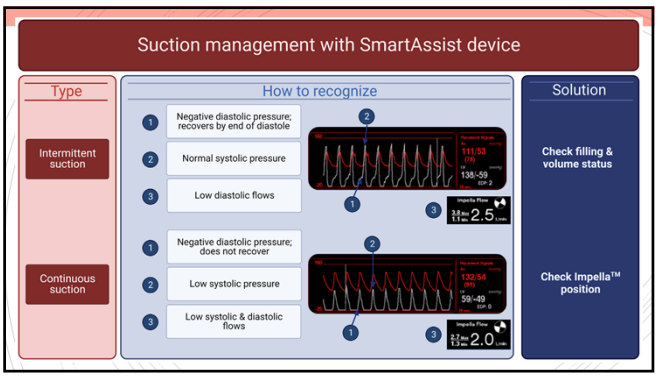


Table 2 Invasive haemodynamics before and 48-h after Impella support initiation
Non-malrotated (N = 52)
Malrotated (N = 33)
Total (N = 85)
P-value
CI (L/min/m²) 2.48 (0.96)
sPAP (mmHg) 29.5 (9.0)
dPAP (mmHg) 15.1 (6.1)
mPAP (mmHg) 20.8 (6.8)
PAWP (mmHg) 13.0 (4.6)
RAP (mmHg) 7.7 (4.3)
CPO (W) 0.86 (0.37)
CPI (W/m²) 0.44 (0.18)
CPO-RAP (W/m²) 0.17 (0.24)
CPI-RAP (W/m) 0.41 (0.17)
LVSWI (cJ/m²) 13.7 (6.4)
RVSWI (cJ/m²) 5.2 (3.7)
SVRi (WUm²) 34.61 (15.3
PVRi (WUm²) 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)
RAP
PAWP
PaE
PAPi
PVRi
Serum lactate
P = 0.009
P = 0.033
P = 0.045
P = 0.037
P = 0.02
P = 0.004
Impella orientation
Non Malrotated
Malrotated


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



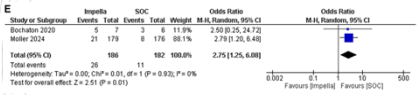




## SEPSIS

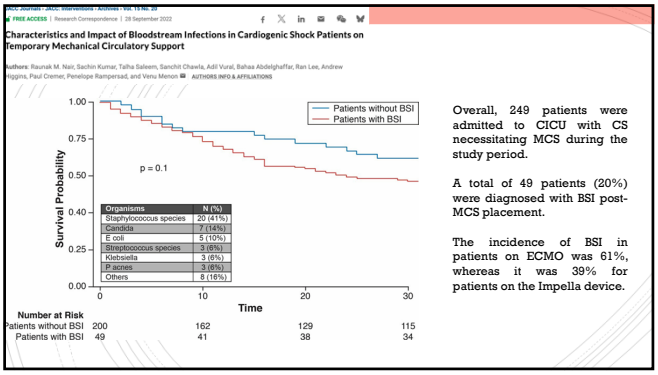
**OR de 2,75** (IC 95% : 1,25-6,08).

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) : e40598.



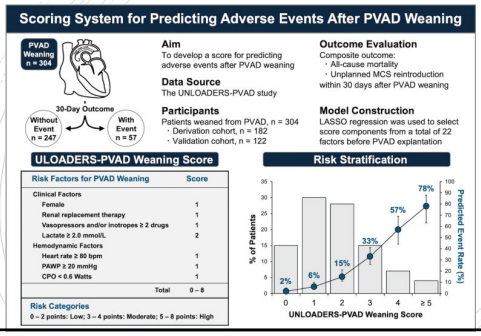

Overall, 249 patients were admitted to CICU with CS necessitating MCS during the study period.

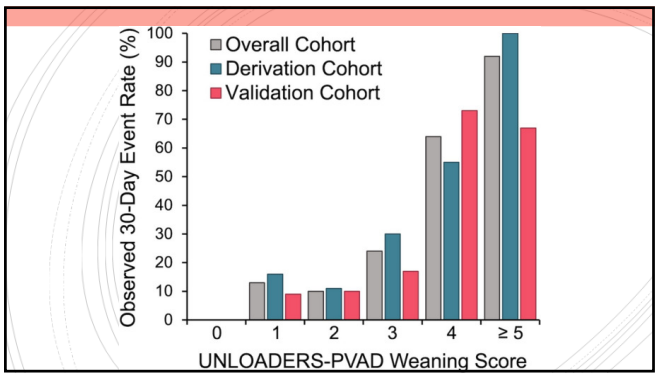
A total of 49 patients (20%) were diagnosed with BSI post-MCS placement.

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**



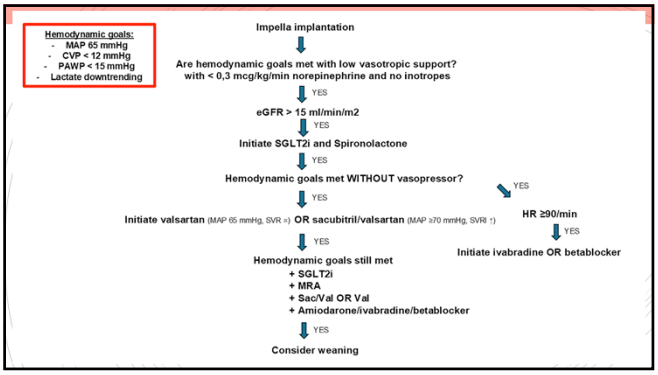


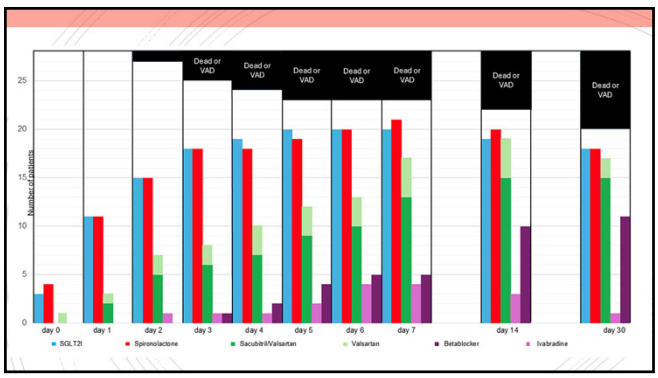

Aggressive Up-Titration of Heart Failure Guideline-Directed Medical Therapies in Cardiogenic Shock Supported by a Percutaneous Ventricular Assist Device

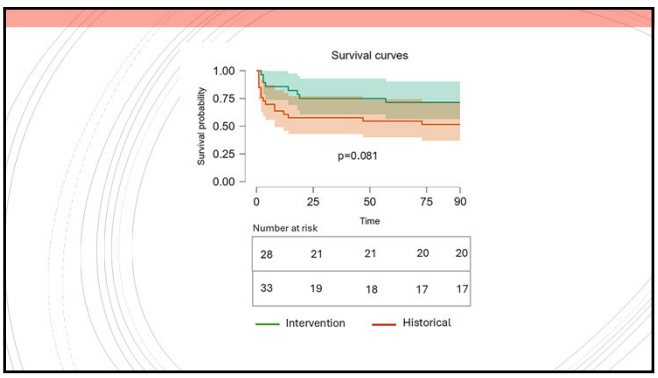
TIM BALTHAZAR, MD[1,2] MATTHIAS RAES, MD[2,3] TOM CARMELIET, MD[1,2] INES VAN LOO, MD[1] STIJN LOCHY, MD[1] JEAN-FRANÇOIS ARGACHA, MD, PhD[1,4] DANNY SCHOORS, MD, PhD[1,4] BERT VANDELOO, MD[1] MICHAEL MEKEIRELE, MD[2] JOOP JONCKHEER, MD, PhD[2] MARK LA MEIR, MD, PhD[1,4] and FREDERIK H. VERBRUGGE, MD,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

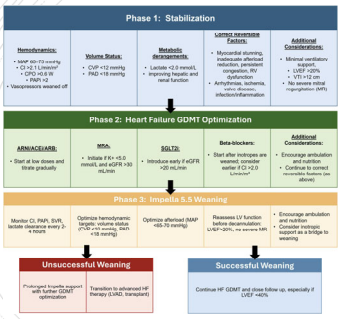
| | | | |
|---|---|---|---|
| pVAD | | | |
| Impella CP | 21 (75%) | NA | NA |
| Impella 5.5 | 7 (25%) | NA | NA |
| Veno-arterial ECMO | 9 (32%) | 11 (33%) | 1 |
| Venous-pulmonary arterial ECMO | 2 (7%) | 0 (0%) | |
| IABP | NA | 29 (88%) | NA |



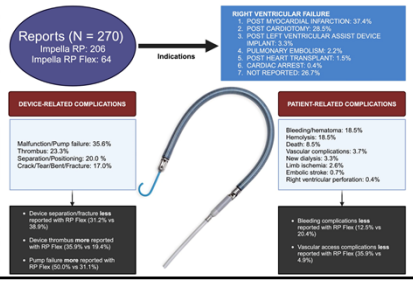
## En conclusion : l'impella doit etre sevrée




## 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[2] | Abhishek Chaturvedi[2] | Brian C. Case[1] | Hayder D. Hashim[1] | Itsik Ben-Dor[2] | Toby Rogers[3] | Ron Waksman[2]

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



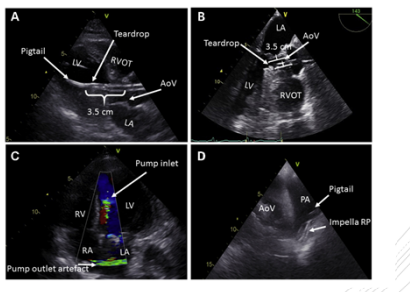

## Impella devices linked to a variety of safety concerns

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**

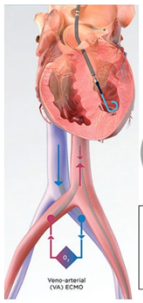
- Inflow: 3.5–4.5 cm below AV
- Outflow: above AV
- Orientation → LV apex
- Echo confirms proper alignment

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




Tim Balthazar et al. JACC Review Topic of the Week2021

## Initial management of the patient on ECPELLA




pVA ECMO → LV distension → Impella → ECPELLA

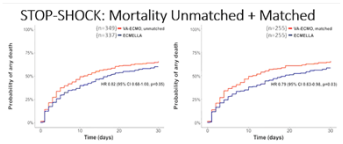
TTE/TOE + Data from PAC = Calculate flow balance

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

## mAFP

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

STOP-SHOCK: Mortality Unmatched + Matched

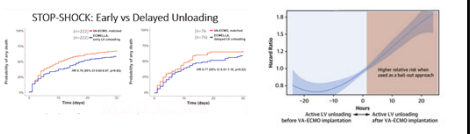


Mortality lower in patients with ECMELLA

Findings remain significant in propensity matched cohort

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

STOP-SHOCK: Early vs Delayed Unloading



*B.Schrage et al, Circulation 2020*

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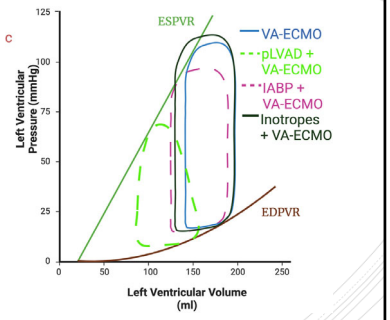
SO ...

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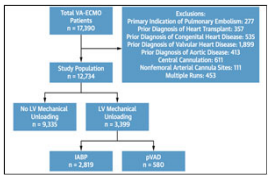
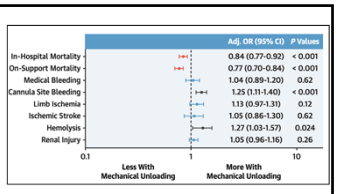
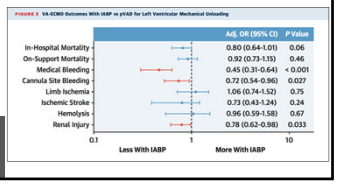
## Mechanical Left Ventricular Unloading in Patients Undergoing Venoarterial Extracorporeal Membrane Oxygenation



| | Adj. OR (95% CI) | P Values |
|---|---|---|
| In-Hospital Mortality | 0.84 (0.77-0.92) | < 0.001 |
| On-Support Mortality | 0.77 (0.70-0.84) | < 0.001 |
| Medical Bleeding | 1.04 (0.89-1.20) | 0.62 |
| Cannula Site Bleeding | 1.25 (1.11-1.40) | < 0.001 |
| Limb Ischemia | 1.13 (0.97-1.31) | 0.12 |
| Ischemic Stroke | 1.05 (0.86-1.30) | 0.62 |
| Hemolysis | 1.27 (1.03-1.57) | 0.024 |
| Renal Injury | 1.05 (0.96-1.16) | 0.26 |

Less With Mechanical Unloading — More With Mechanical Unloading



| | Adj. OR (95% CI) | P Value |
|---|---|---|
| In-Hospital Mortality | 0.80 (0.64-1.01) | 0.06 |
| On-Support Mortality | 0.92 (0.73-1.15) | 0.46 |
| Medical Bleeding | 0.45 (0.31-0.64) | < 0.001 |
| Cannula Site Bleeding | 0.72 (0.54-0.96) | 0.027 |
| Limb Ischemia | 1.06 (0.74-1.52) | 0.75 |
| Ischemic Stroke | 0.73 (0.43-1.24) | 0.24 |
| Hemolysis | 0.96 (0.59-1.58) | 0.67 |
| Renal Injury | 0.78 (0.62-0.98) | 0.033 |

Less With IABP — More With IABP

- **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**

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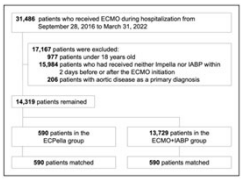
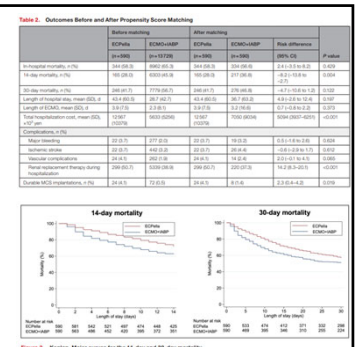
Journal of the American Heart Association

ORIGINAL RESEARCH

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

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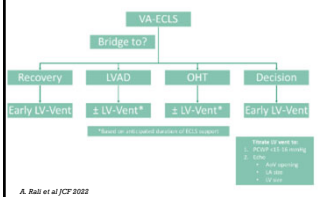
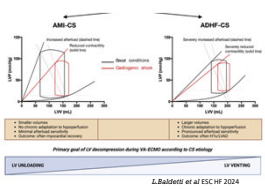
## Strategy Bases Approach to LV Unloading?




*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

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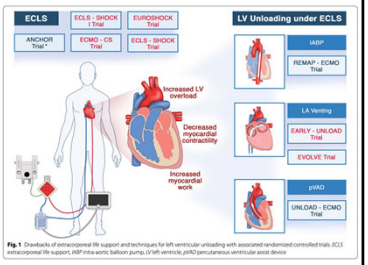
## Key Questions

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




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