Impella in the Real World: is it the Best Alternative?

Prof Alaide Chieffo
EAPCI President, FESC, FSCAI

Interventional Cardiology Unit, IRCCS Ospedale San Raffaele
Vita Salute San Raffaele University,
Milan, Italy

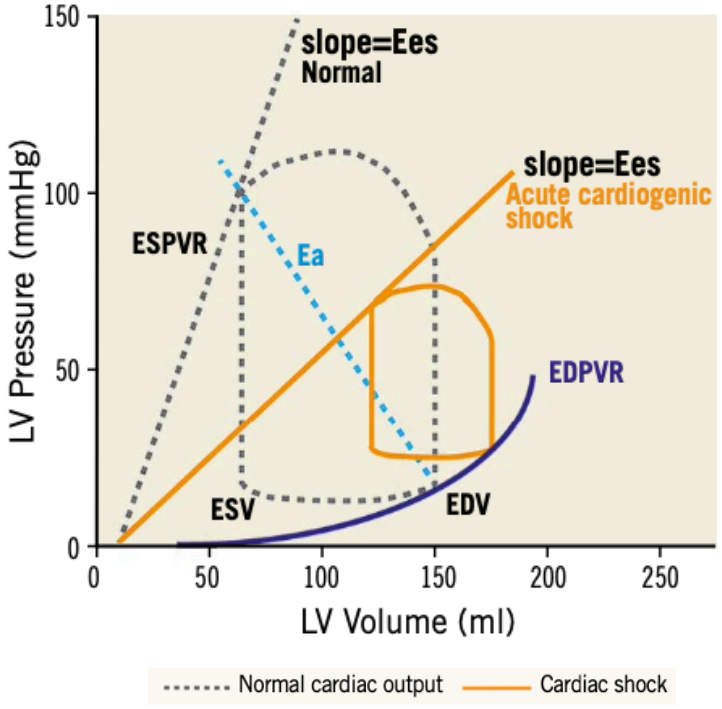
The Impella Device

- The Impella devices are catheter-based microaxial flow pumps
- The devices for left ventricular support (Impella CP and Impella 5.5) are deployed in a retrograde fashion across the aortic valve, with an inflow tract positioned in the LV and an outflow tract in the ascending aorta
- The Impella device pumps blood from the LV to the aorta augmenting CO and MAP, as well as unloading the LV.

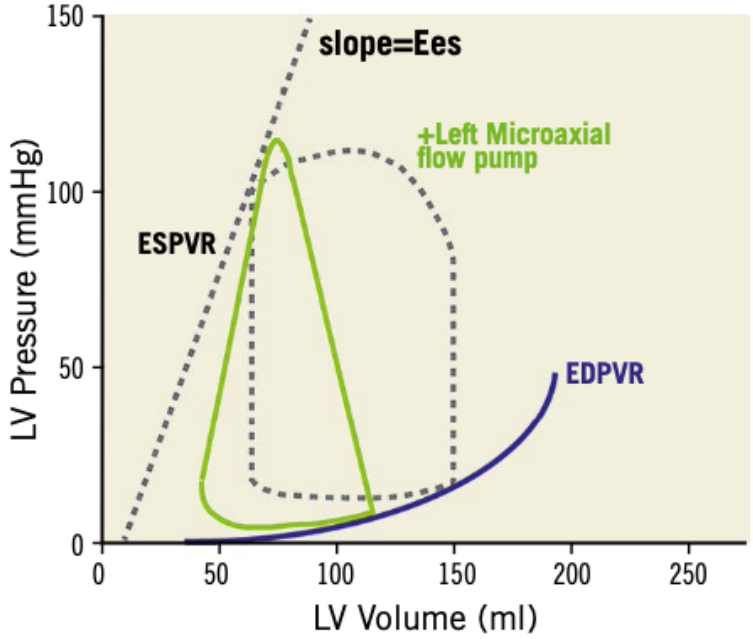
Figure: www.abiomed.com

Haemodynamic Effects of Impella

Cardiogenic Shock



Impella Support



- Loss of normal isovolumetric periods
- Reduced EDPVR
- Conversion of the typical PV-loop to a triangular shape

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Chieffo et al. EuroIntervention (2021) and
EHJ: Acute Cardiovascular Care (2021)

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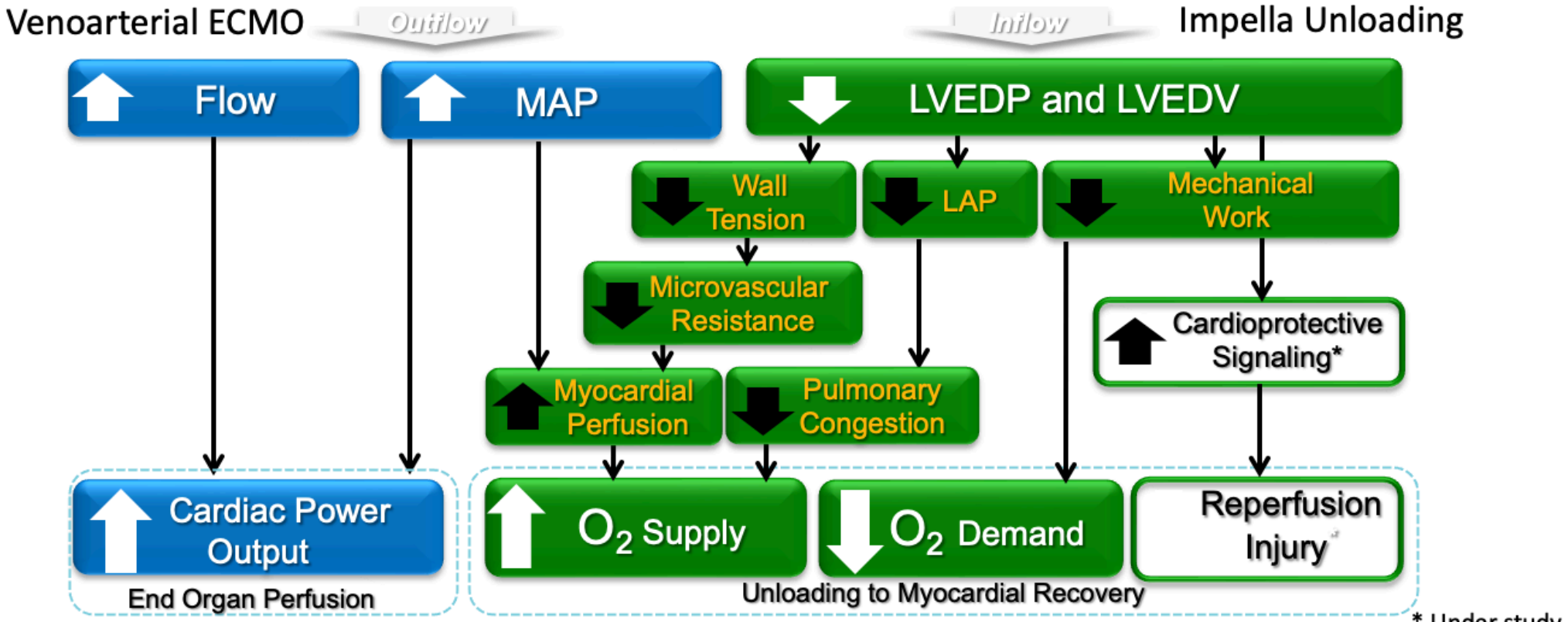
Impella Unloads the LV



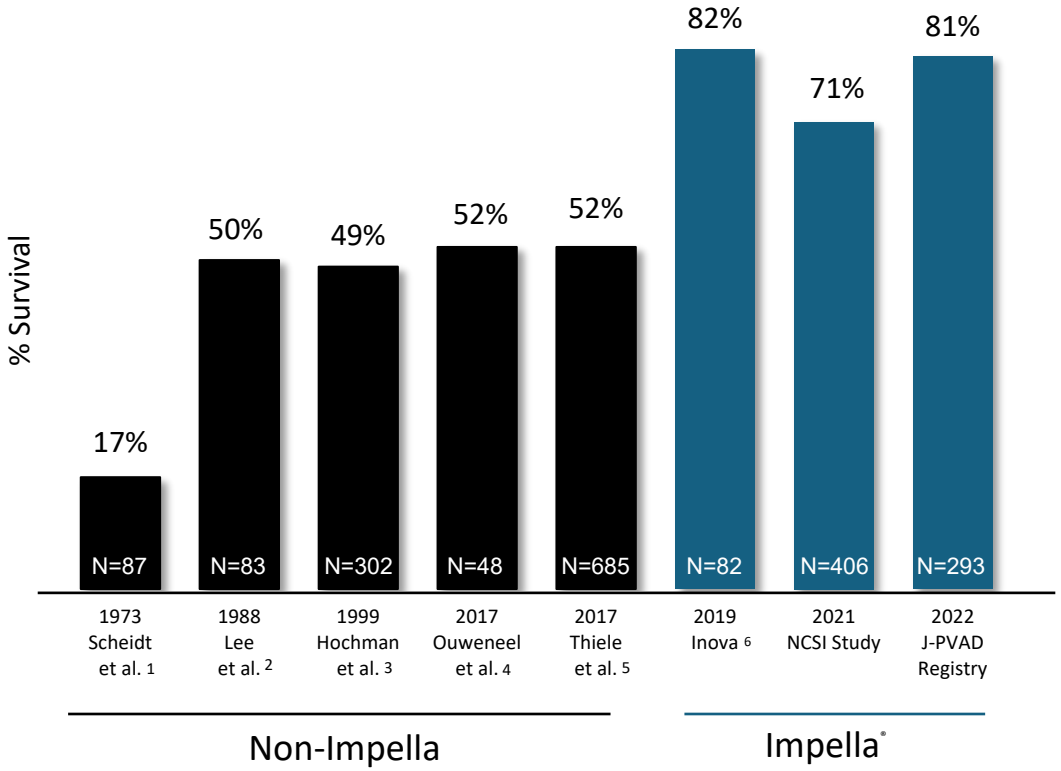
Fincke R, et al. J Am Coll Cardiol 2004
den Uil CA, et al. Eur Heart J 2010
Mendoza DD, et al. Am Heart J 2007
Torgersen C, et al. Crit Care 2009
Torre-Amione G, et al. J Card Fail 2009

Suga H. Am J Physiol 1979
Suga H, et al. Am J Physiol 1981
Burkhoff D, et al. Am J Physiol Heart Circ Physiol 2005
Burkhoff D. Mechanical Properties Of The Heart And Its Interaction With The Vascular System. (White Paper) 2011

Sauren LDC, et al. Artif Organs 2007
Meyns B, et al. J Am Coll Cardiol 2003
Remmelink M, et al. Catheter Cardiovasc Interv 2007
Aqel RA, et al. J Nucl Cardiol 2009
Lam K, et al. Clin Res Cardiol 2009

Reesink KD, et al. Chest 2004
Esposito M, et al. J Am Coll Cardiol 2018
Remmelink M, et al. Catheter Cardiovasc Interv 2010
Naidu SS. Circulation 2011
Weber DM, et al. Cardiac Interventions Today Supplement Aug/Sep 2009

Outcomes of Investigator Led Studies



Best Practice Protocols Include[6-9]

- Identify CS early and Impella® pre-PCI < 90 mins
- Aggressive down-titration of inotropes
- Identify RV dysfunction early and support
- Identify inadequate LV support and escalate
- Systematic use of RHC to guide therapy

The J-PVAD Registry is a registry of ALL Impella patients in Japan, conducted by 10 Japanese professional societies, including the Japanese Circulation Society (JCS).

1. Scheidt, S. et al. (1973). N Engl J Med,
2. Lee, L. et al. (1988). Circulation,
3. Hochman, J. et al. (1999). N Engl J Med,
4. Ouweneel, D. et al. (2017). J Am Coll Cardiol,
5. IMPRESS in Severe Shock/Cardiac Arrest. ~10% Impella pre-PCI.
5. Thiele, H. et al. (2017). N Engl J Med,. ~5% with Impella
6. Tehrani, B. et al. (2019). J Am Coll Cardiol,
7. O'Neill, W. et al. (2020). TCT Connect
8. Basir,B. et al. (2021). SCAI Scientific Sessions
9. Ako, J. (2022). TCT. AMICS with Impella-only Support

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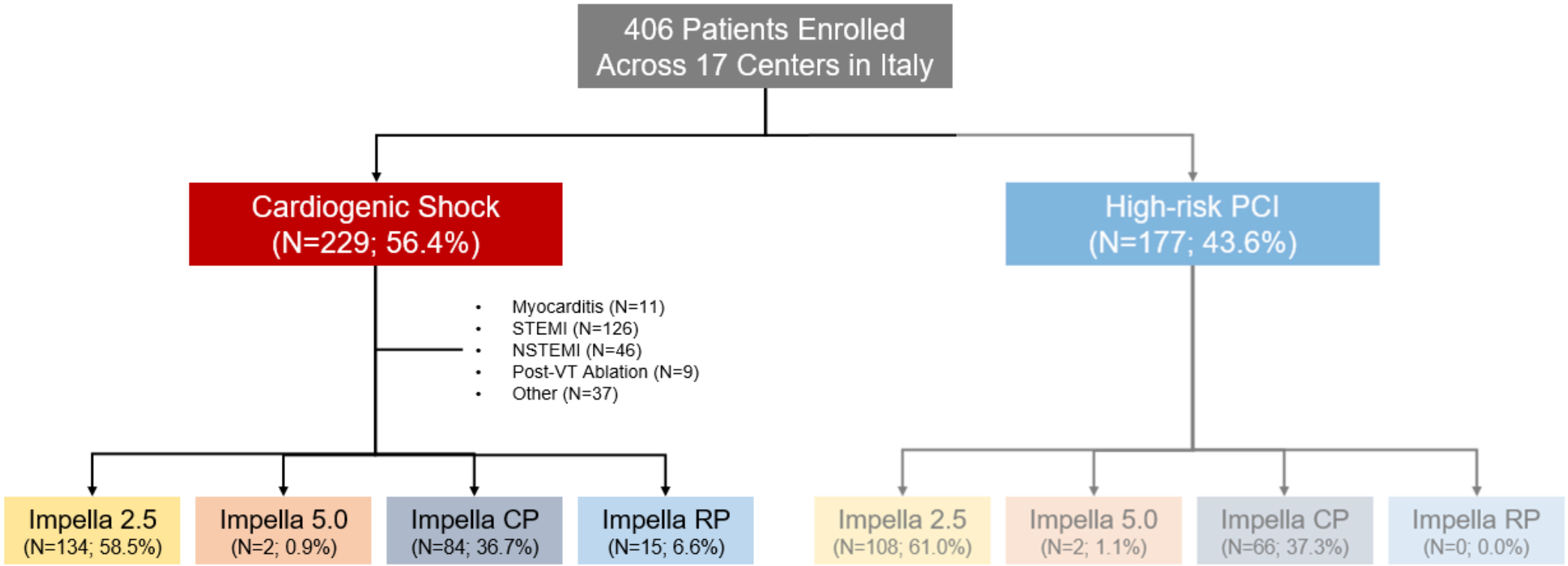
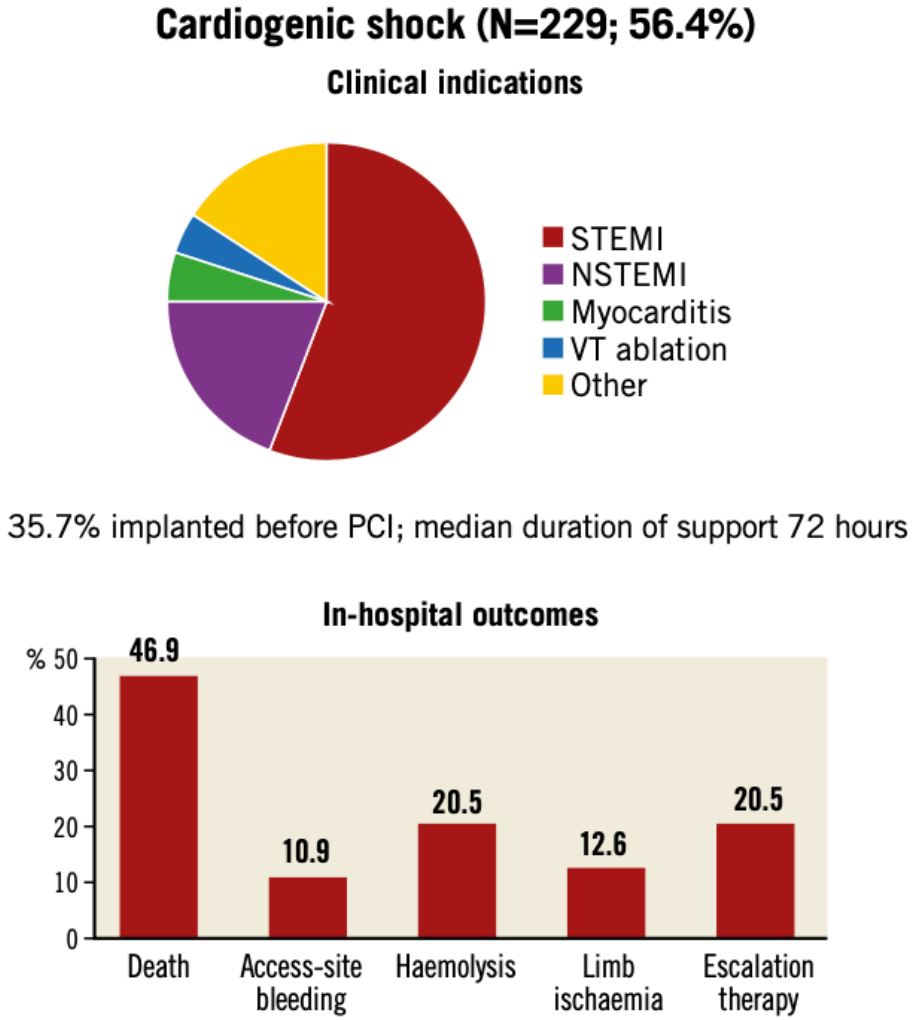
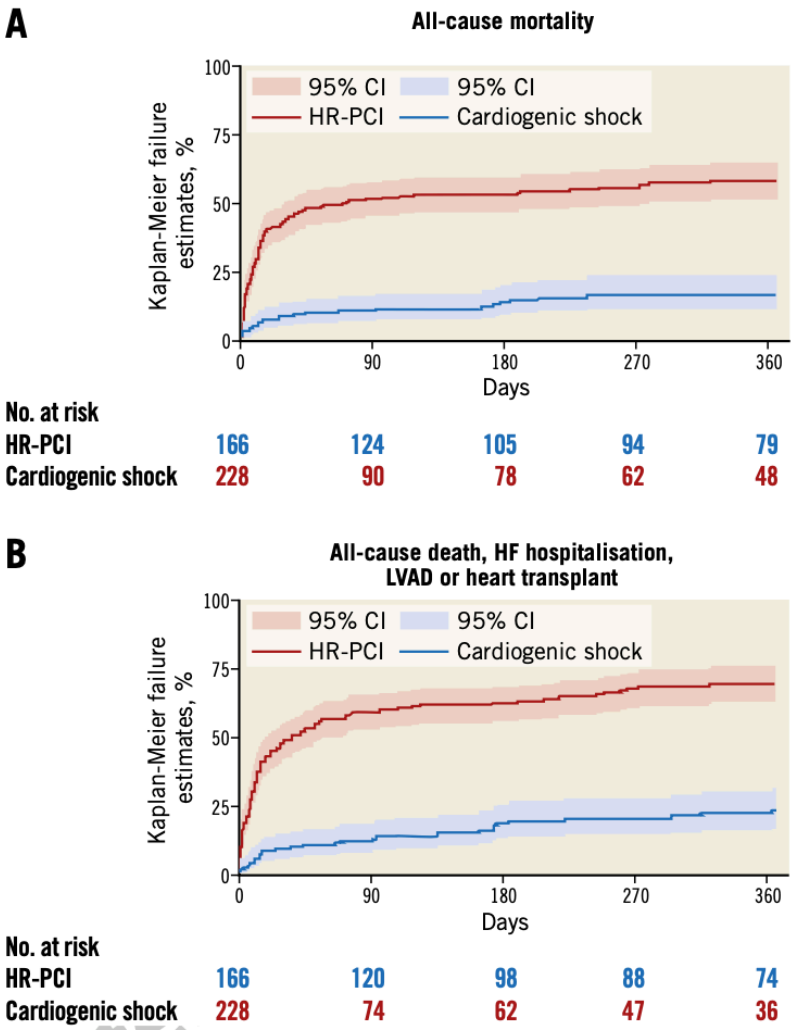
Impella Use in a Real-World Population: the IMP-IT Registry



Chieffo et al . Eurointervention 2020

Impella Use in a Real-World Population: the IMP-IT Registry





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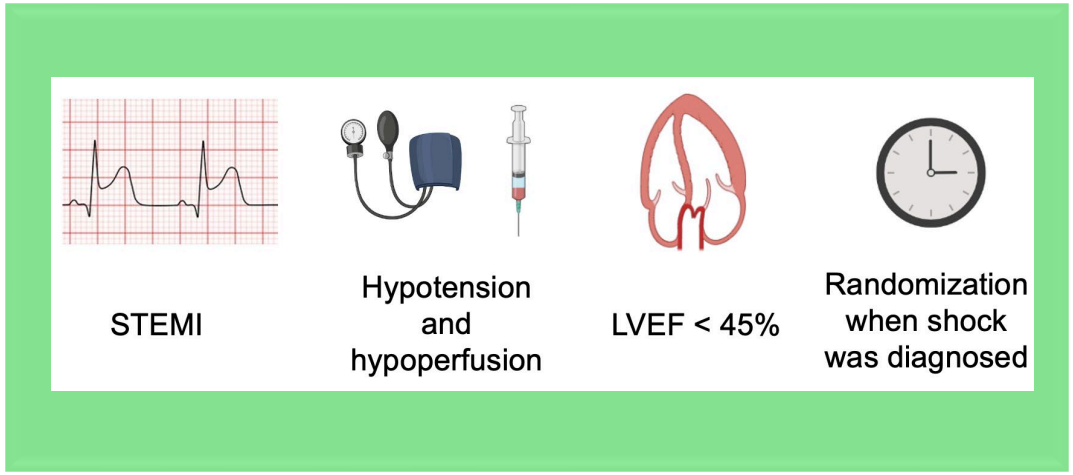
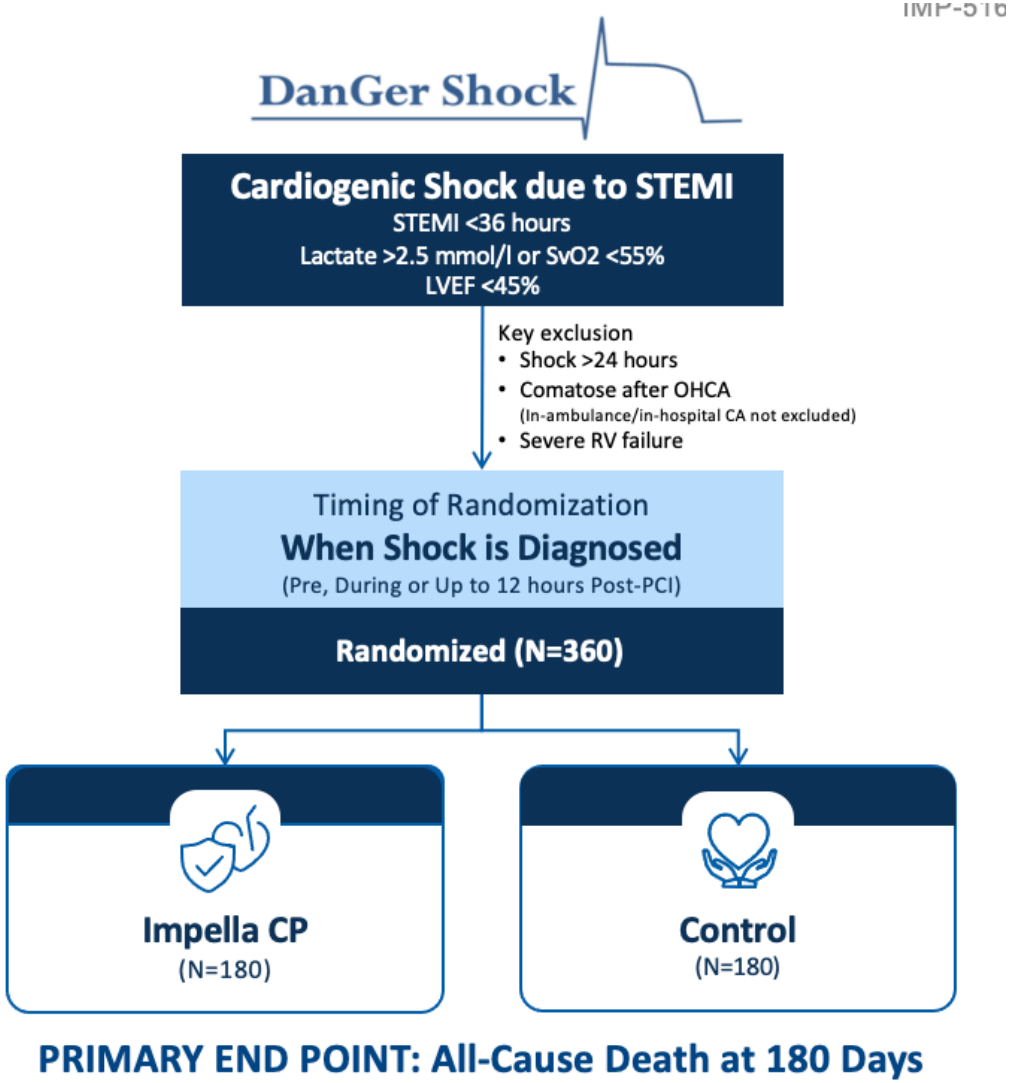
Latest Evidence: The DanGer Shock Trial





Moller et al. NEJM 2024

Latest Evidence: The DanGer Shock Trial

Median 67 years
79% male

Median 4 hrs from onset of STEMI symptoms to randomization

84% randomized in cath lab

Median lactate 4.5 mmol/L

Median LVEF 25%

Median systolic BP
82 mmHg

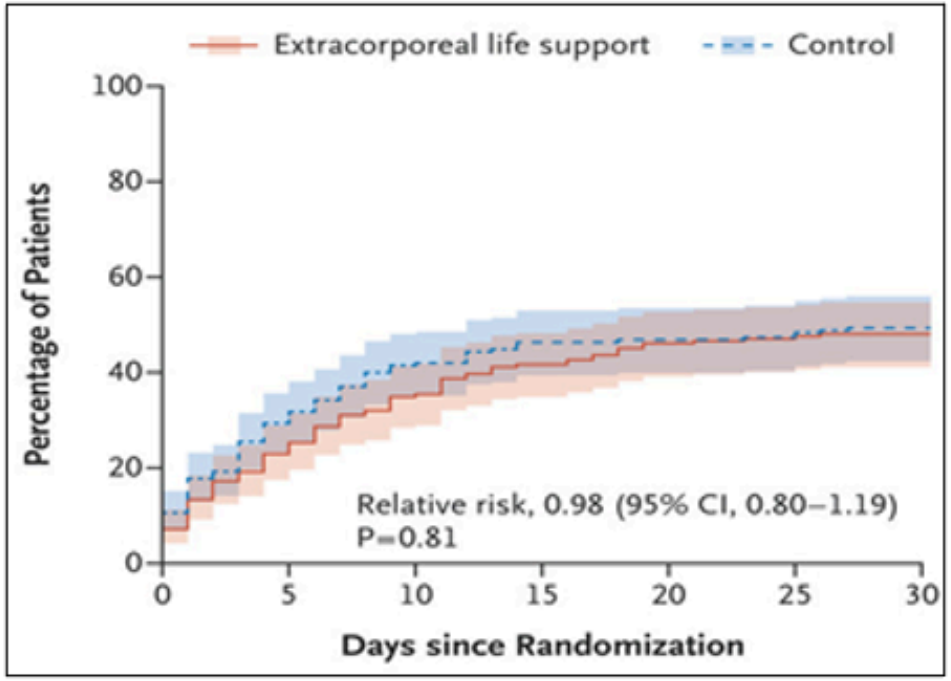
72% LAD or LM culprit
72% Multi vessel disease

55% SCAI class C
45% SCAI class D or E

Moller et al. NEJM 2024

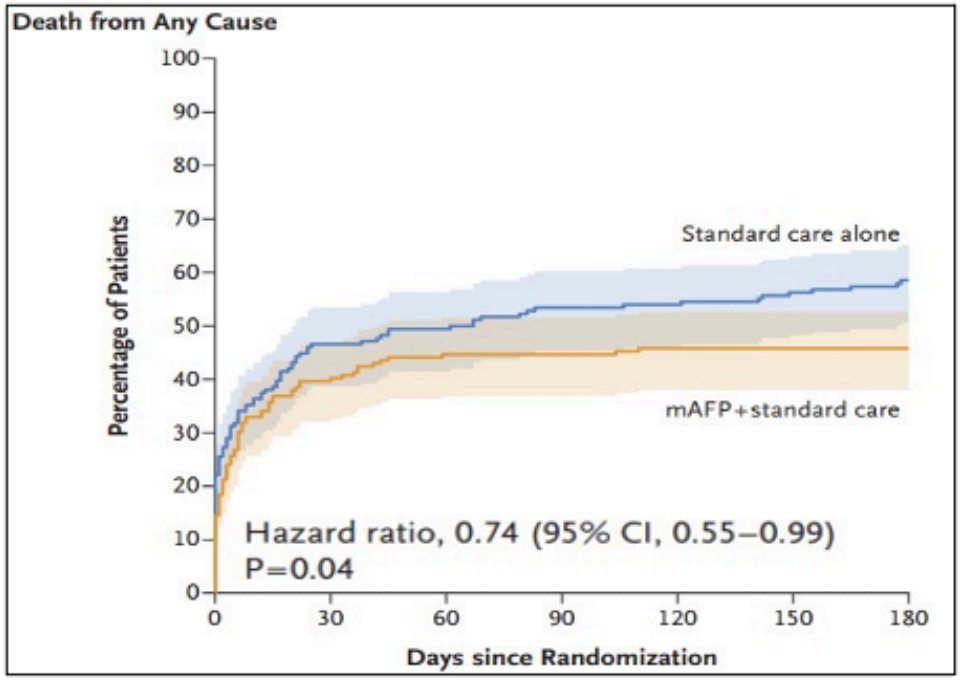
Latest Evidence: ECMO vs Impella in CS

ECLS Shock (ECMO)[2]



No Difference in 30-Day Mortality (p=0.81)

DanGer Shock (Impella)[3]



12.7% Absolute Reduction in 180-Day Mortality (p=0.04)

Thiele et al. NEJM 2023

Moller et al. NEJM 2024

What Should We Learn From DanGer Shock?

To target patients that can benefit from invasive support

ECLS Shock

Characteristic	ECLS (N=209)	Control (N=208)
SCAI shock stage — no. (%)‡		
C	104 (49.8)	111 (53.4)
D	38 (18.2)	18 (8.7)
E	67 (32.1)	79 (38.0)

DanGer Shock

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)

To confirm the importance of appropriate timing for device insertion

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)

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What Should We Learn From DanGer Shock?

Event	Microaxial Flow Pump plus Standard Care (N=179)	Standard Care Alone (N=176)	Effect Size (95% CI)†
Primary end point: death from any cause at 180 days — no. (%)	82 (45.8)	103 (58.5)	0.74 (0.55 to 0.99)‡
Secondary end point			
Composite cardiac end point — no. (%)§	94 (52.5)	112 (63.6)	0.72 (0.55 to 0.95)
No. of days alive and out of the hospital (range)¶	82 (0 to 177)	73 (0 to 179)	8 (−8 to 25)
Adverse events			
Composite safety end point — no. (%)‖	43 (24.0)	11 (6.2)	4.74 (2.36 to 9.55)
Moderate or severe bleeding — no. (%)**	39 (21.8)	21 (11.9)	2.06 (1.15 to 3.66)
Limb ischemia — no. (%)	10 (5.6)	2 (1.1)	5.15 (1.11 to 23.84)
Renal-replacement therapy — no. (%)	75 (41.9)	47 (26.7)	1.98 (1.27 to 3.09)
Stroke — no. (%)	7 (3.9)	4 (2.3)	1.75 (0.50 to 6.01)
Cardioversion after ventricular tachycardia or fibrillation — no. (%)	59 (33.0)	52 (29.5)	1.17 (0.75 to 1.83)
Sepsis with positive blood culture†† — no. (%)	21 (11.7)	8 (4.5)	2.79 (1.20 to 6.48)

Adverse events remain a major limitation for the use of Impella devices

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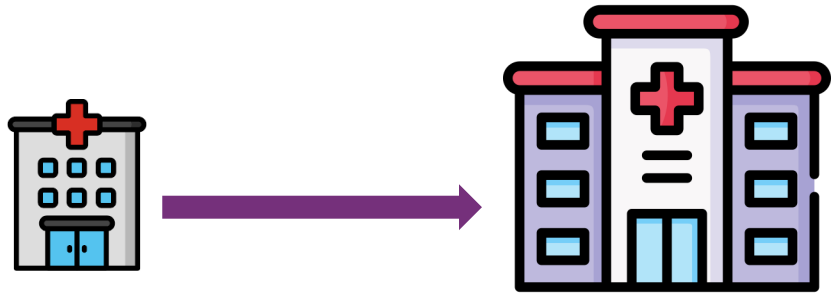
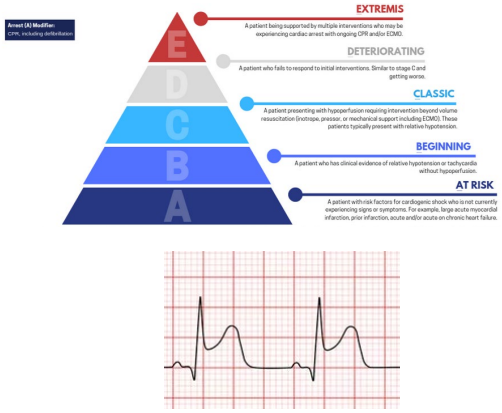
Role of Impella in the Comprehensive Management of CS



Multidisciplinary management



Appropriate patient selection and stratification

Optimal combination of medical therapy and MCS

How Effectively are We Investigating the Efficacy of Impella?

Is short term all-cause mortality a good endpoint to evaluate the efficacy of a device which is not a cure, but a bridge to opportunity?

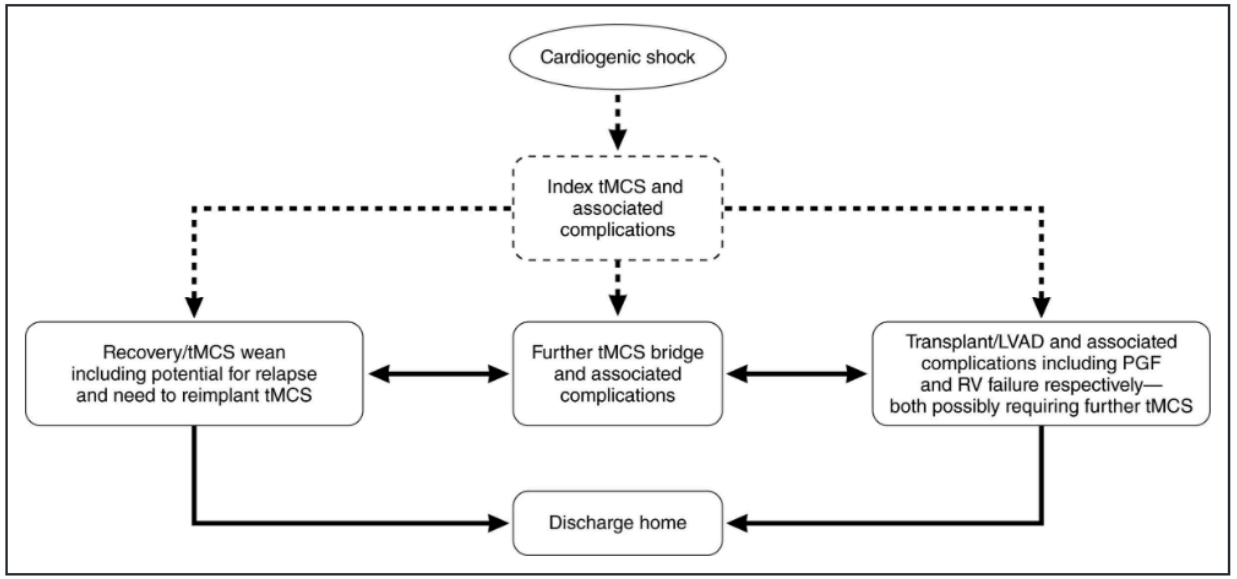
Circulation
Volume 147, Issue 20, 16 May 2023; Pages 1489-1491
https://doi-org.sanraffaele.idm.oclc.org/10.1161/CIRCULATIONAHA.122.063616

American Heart Association.

ON MY MIND

Issues With the Design of Randomized Trials of Temporary Mechanical Circulatory Support for Cardiogenic Shock

Jonathan R. Dalzell, MBChB, MD



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Take Home Message

- The Impella device is a promising technology for support during CS, which also provides significant haemodynamic advantages. However, the rate of adverse events highlights the importance of optimal patient selection

- Real-world, investigator driven studies performed according to best clinical practice have demonstrated safe and effective outcomes using the Impella device. Strong positive results have also been confirmed by the DanGer Trial

- The approach to CS is multistrategic and multidisciplinary, and Impella should be considered as part of a comprehensive management. Similarly, studies investigating the efficacy of Impella should not solely investigate mortality-related outcomes

chieffo.alaide@hsr.it
@alaide_chief
Dra_chieffo
Linkedin.com/in/alaide-chieffo-922ba831

@EAPCIPresident

@EAPCICommunity

Thanks for your attention