Gestion du choc cardiogénique

DanGer Shock

Nicolas Meneveau, CHU Besançon

CONFLITS D'INTÉRÊTS

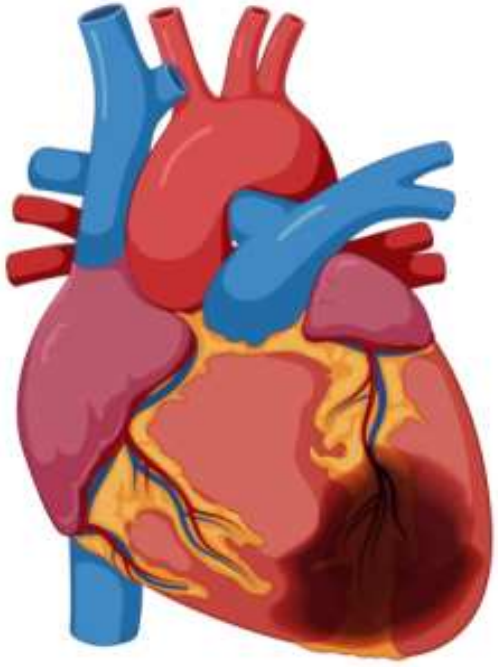
Speaker's name : Nicolas Meneveau

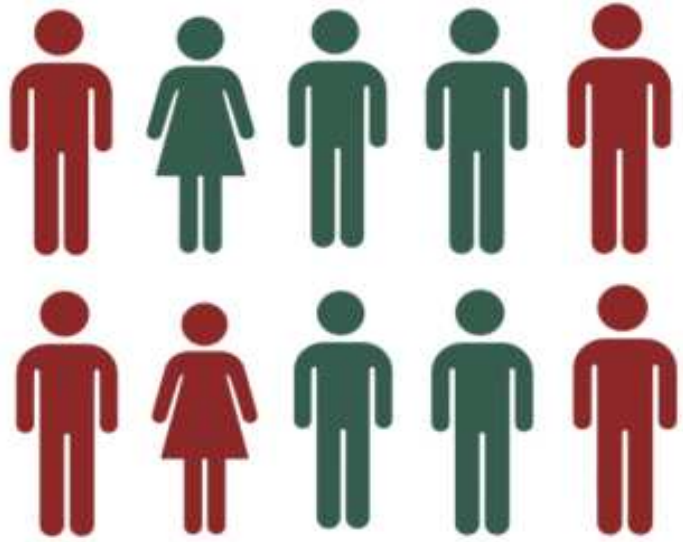
☑ I have the following potential conflicts of interest to report

Consulting fees - Abbott Medical
Consulting fees - INARI
Consulting fees - TERUMO
Honoraria - AstraZeneca
Consulting fees - Edwards Lifesciences
Consulting fees - Boston Scientific

HIGHTECH

Background





STEMI

One in ten will develop CS

½ will survive

Aissaoui N et al. Eur Heart J 2021. Goldberg RJ et al. Circulation 2009. Obling L et al. Eur Heart J Acute Cardiovasc Care 2018.

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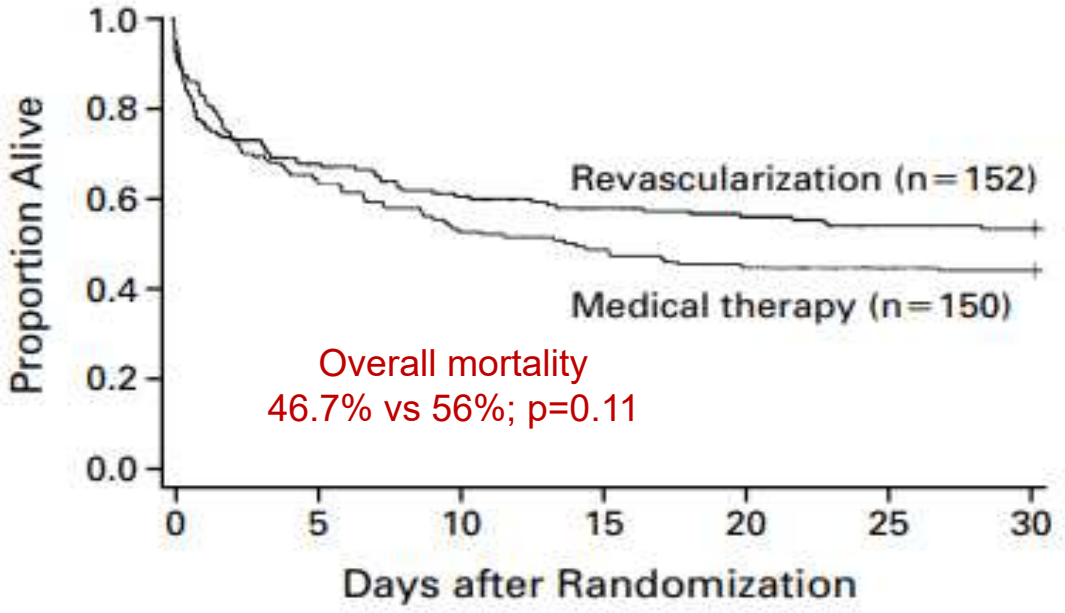
Acute MI complicated by cardiogenic shock : early revascularization

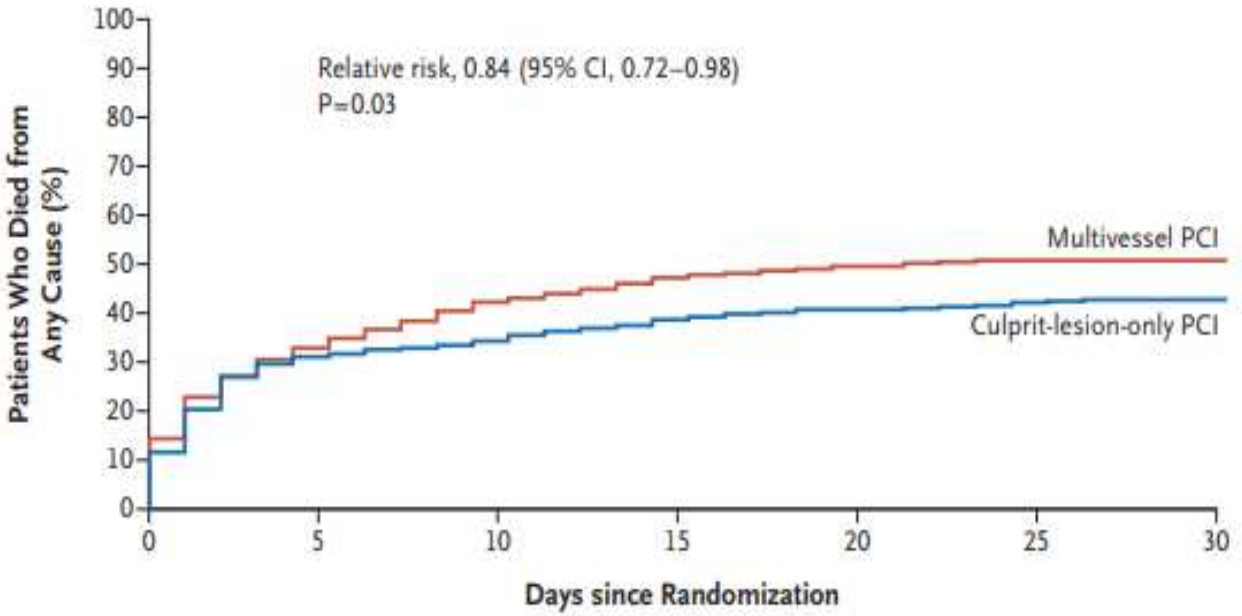
Early revascularization of IRA The SHOCK study



6-month mortality lower in the revascularization group than in the medical-therapy group (50.3% vs 63.1%, P=0.027)

Hochman JS et al. N Engl J Med 1999;341:625-34

PCI strategies in pts with AMI & shock The CULPRIT-SHOCK study



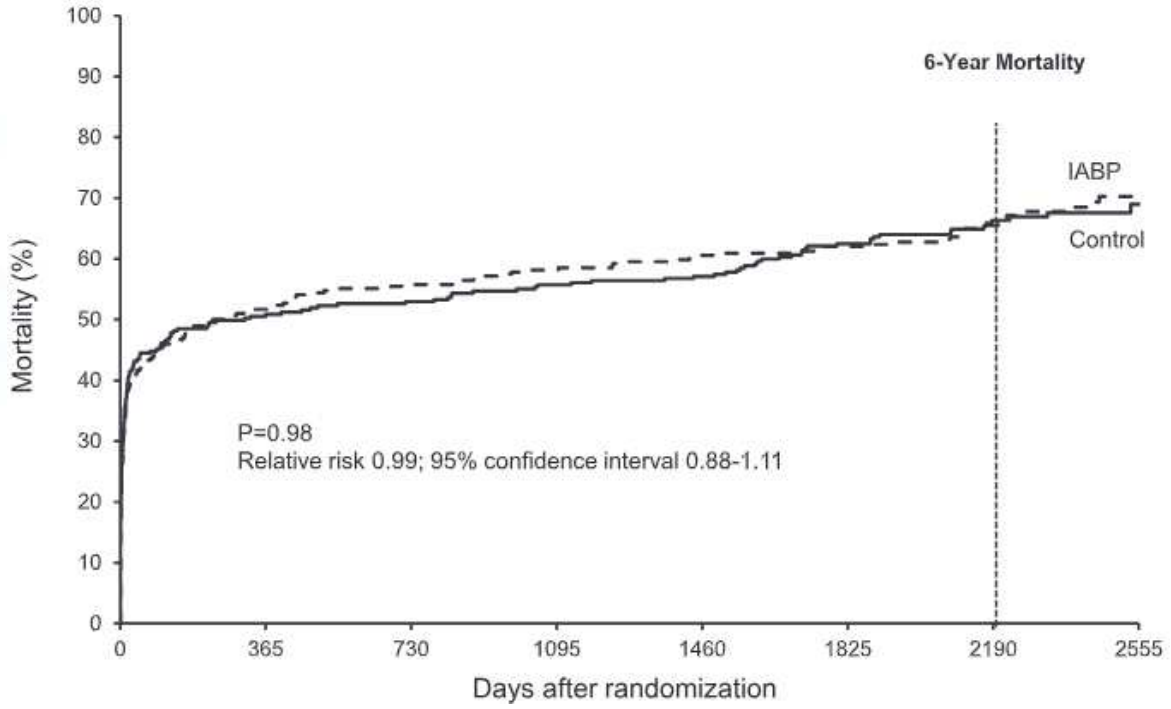
In Pts with multivessel disease, AMI & shock, the 30-day mortality was lower among those who underwent PCI of the culprit lesion only than among those who underwent immediate multivessel PCI.

Thiele H et al. N Engl J Med 2017;377:2419-32.

HIGHTECH

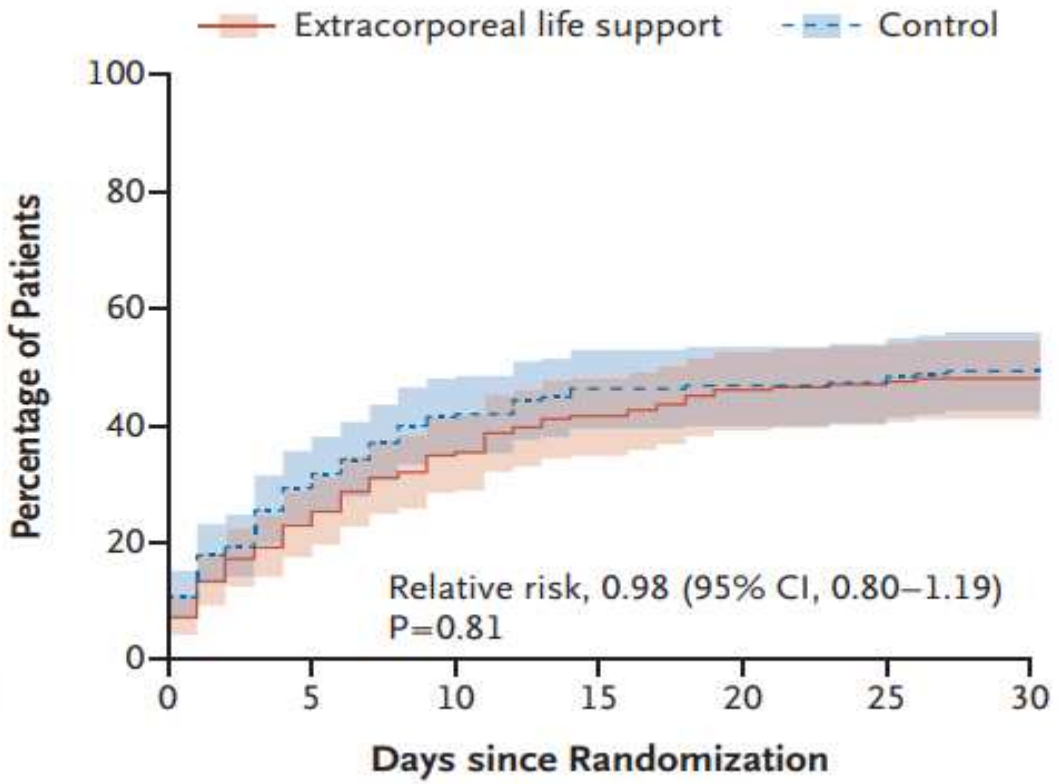
Acute MI complicated by cardiogenic shock : mechanical hemodynamic support

IABP for AMI with shock
The IABP-SHOCK II study



Thiele H et al. Lancet 2013;382:1638–45.

VA-ECMO for AMI with shock
The ECLS-SHOCK study



Thiele H et al. N Engl J Med 2023;389:1286-97.

HIGHTECH

DanGer Shock trial

Hypothesis : Routine use of the micro axial flow pump Impella CP on top of standard guideline directed care in patients with STEMI and cardiodiogenic shock result in a lower mortality compared with standard care alone

End-points :

Primary End-Point :

- Death from any cause at 180 D

Secondary End-Points :

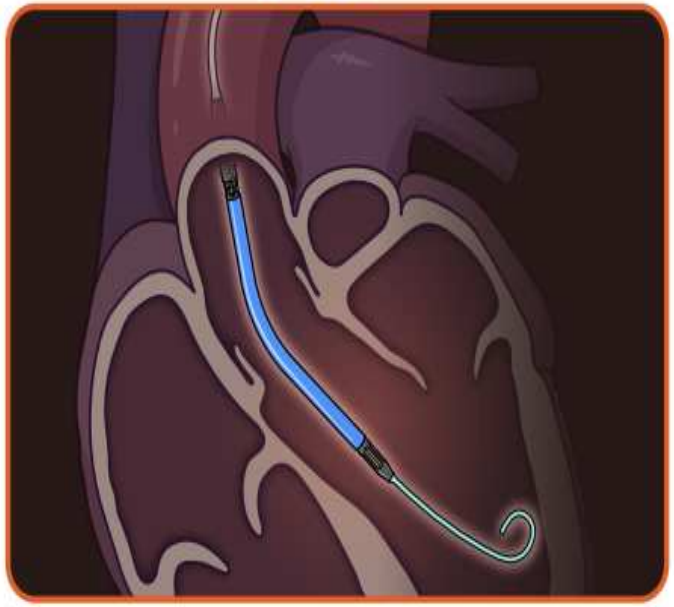
- Escalation of treatment to additional mechanical circulatory support, heart transplantation, or death from any cause at 180 D

- Days alive out of the hospital at 180 D

Sample size

- Assumed mortality 60% in SOC & 42% in mAFP grps (alpha à.05 & beta 0.80)

Microaxial Flow Pump
+ Standard Care
N=179



Standard
Care Alone
N=176

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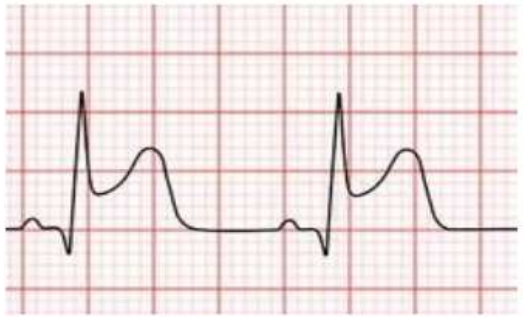
DanGer Shock trial

Inclusion criteria



STEMI

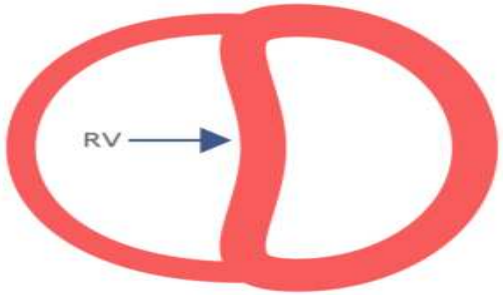
Hypotension
& hypoperfusion

FEVG < 45%

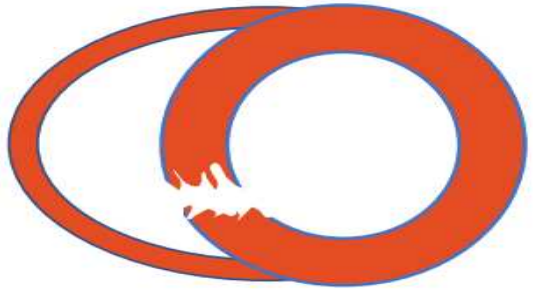
Randomization when shock diagnosed

Key exclusion criteria

Comatose OHCA
(Glasgow score ≤ 7)



RV failure



Mechanical complication

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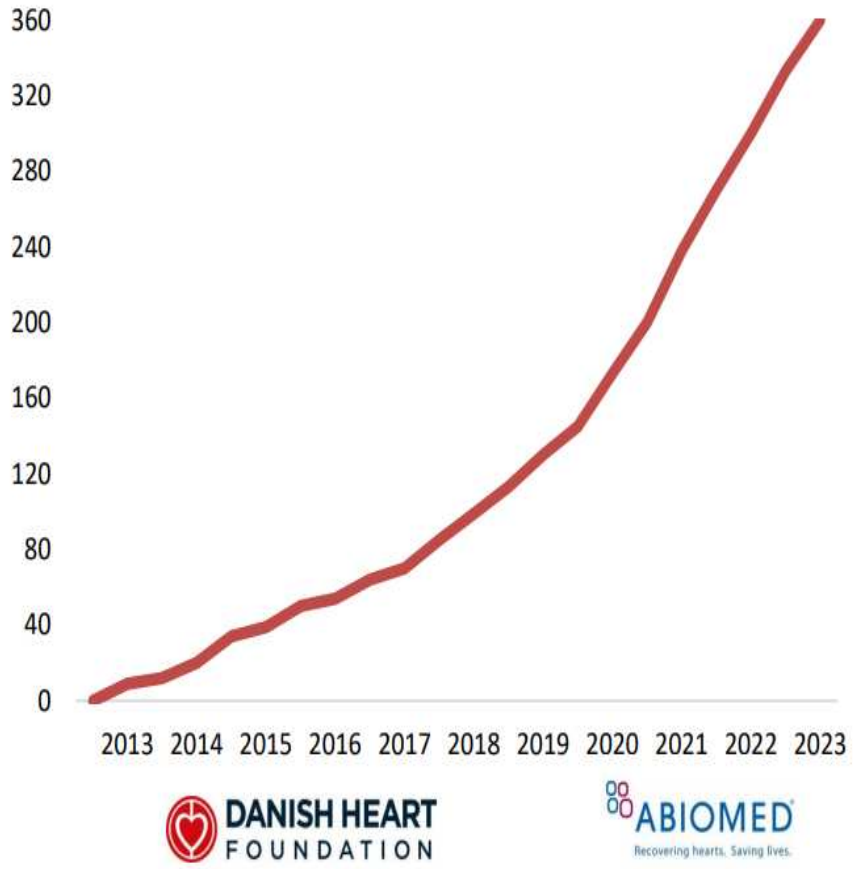
Trial Flow



DANISH HEART FOUNDATION

ABIOMED
Recovering hearts. Saving lives.

DanGer Shock
Danish German Cardiogenic Shock trial

Denmark 2013-2023
Copenhagen (117),
Odense (56),
Aarhus (41)
Aalborg (1)

Germany 2019 - 2023
Dresden (32)
Düsseldorf (25)
Jena (21)
Berlin (18)
Würzburg (14)
Hamburg (12)
Bonn (7)
Hannover (6)
Trier (0)

UK 2021-2023
London Harefield (10)

CRO: KCRI

STEMI & cardiogenic shock assessed for eligibility (N=1,211), Excluded (N=851), Randomized (N=360)

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Pts characteristics (N=355)

Median 67 yrs
79% male

Median 4 hrs from onset of
AMI Sptoms to randomization
84% randomized in cath lab

Median lactate 4.5 mmol/L

Median SBP 82 mmHg

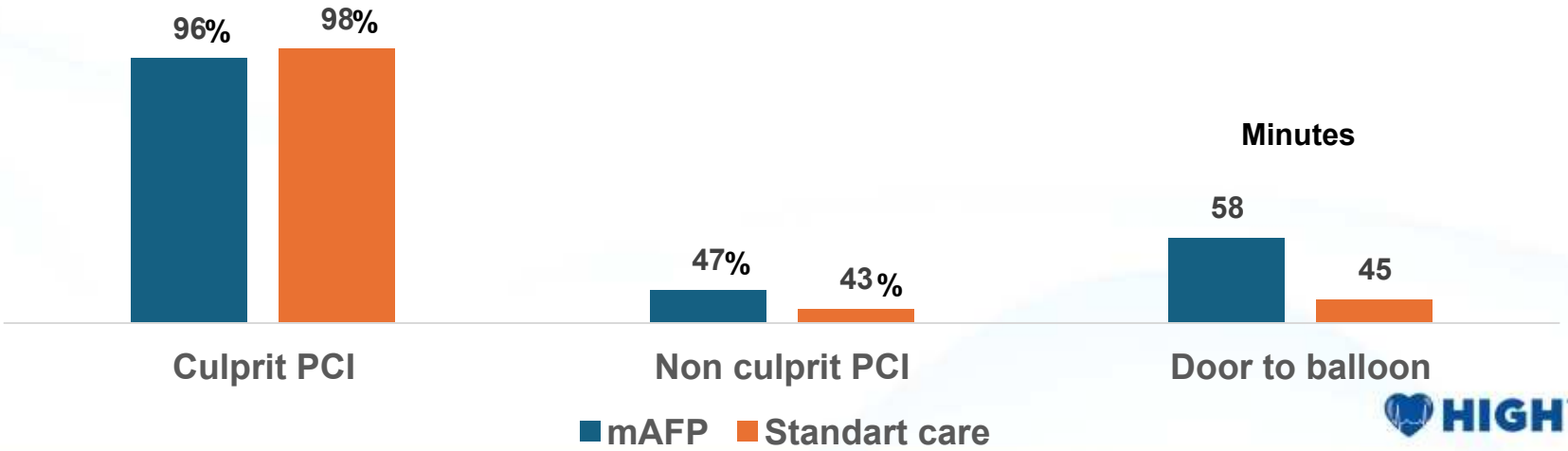
55% SCAI class C
45% SCAI class D or E

72% LAD or LM culprit
72% Multivessel disease

SCAI

Median LVEF 25%

Revascularisation



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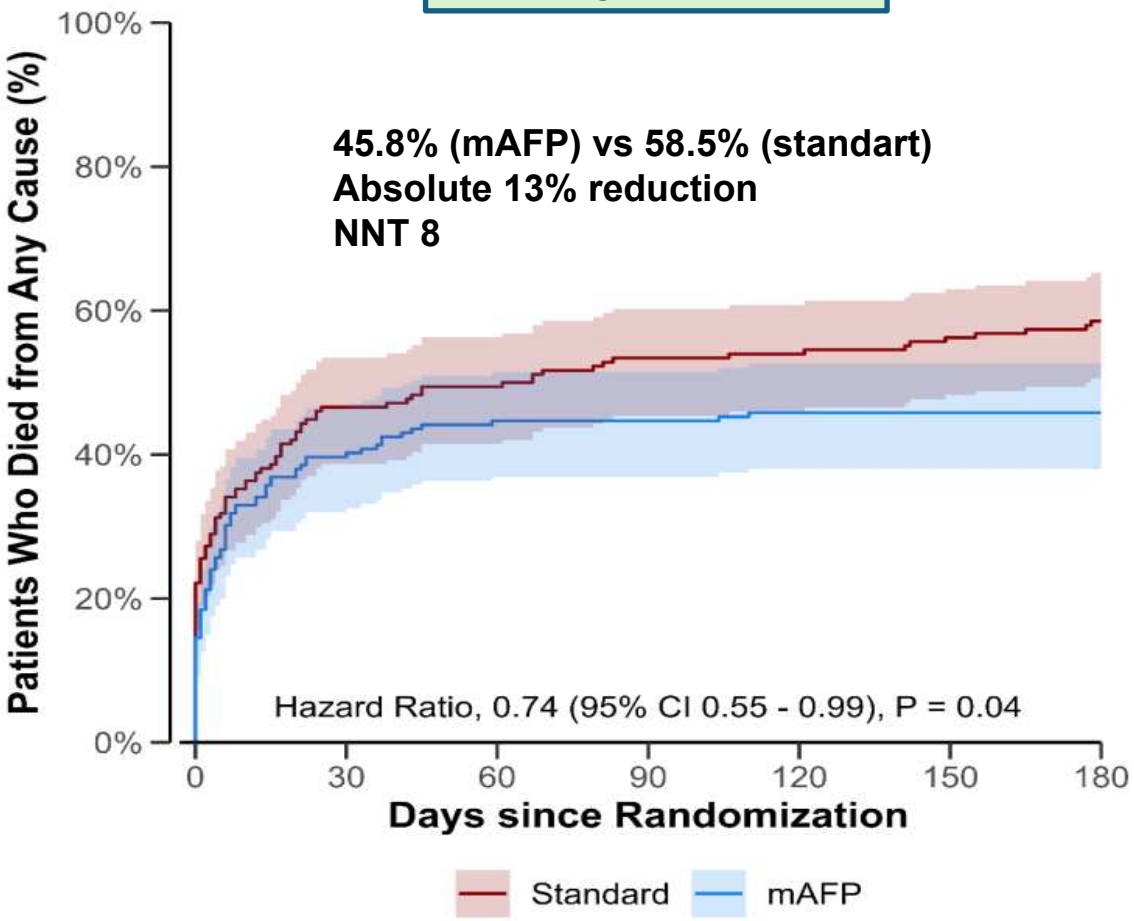
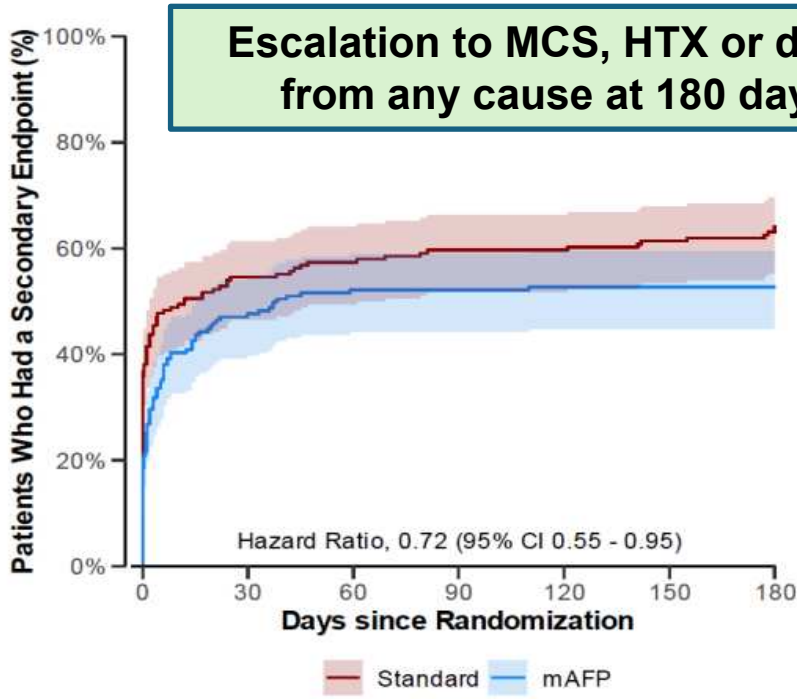
DanGer-Shock results

Primary End-Point

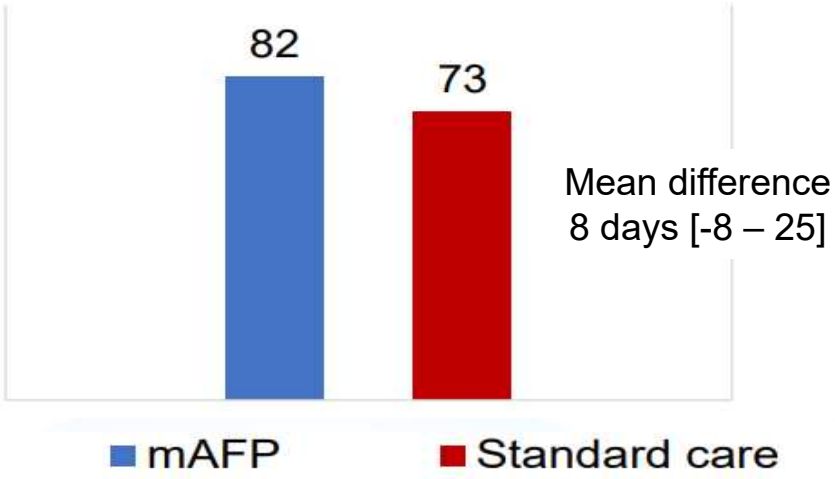
45.8% (mAFP) vs 58.5% (standart)
Absolute 13% reduction
NNT 8



Escalation to MCS, HTX or death from any cause at 180 days



Days alive out of the hospital



Mean difference
8 days [-8 – 25]

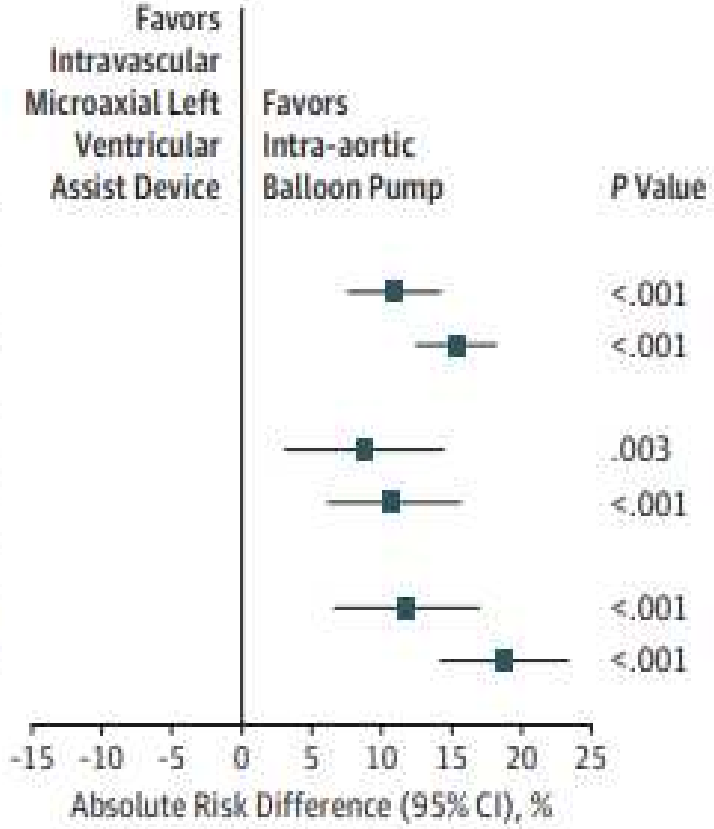
Adverse events

Event	Microaxial Flow Pump plus Standard Care (N=179)	Standard Care Alone (N=176)	Effect Size (95% CI)†
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)

Intravascular microaxial LV assist device vs IABP among Pts with AMI complicated by cardiogenic shock

A propensity-matched registry-based retrospective cohort study

	Intravascular Microaxial Left Ventricular Assist Device		Intra-aortic Balloon Pump		Absolute Risk Difference (95% CI), %	*P* Value
	No. of Patients	Patients, %	No. of Patients	Patients, %		
Overall (n = 1680 matched pairs)						
Mortality	756	45.0	573	34.1	10.9 (7.6-14.2)	<.001
Major bleeding	526	31.3	268	16.0	15.4 (12.5-18.2)	<.001
Device placement before initiation of percutaneous coronary intervention (n = 573 matched pairs)						
Mortality	261	45.5	211	36.8	8.7 (3.1-14.4)	.003
Major bleeding	157	27.4	95	16.6	10.8 (6.1-15.6)	<.001
Device placement after initiation of percutaneous coronary intervention (n = 662 matched pairs)						
Mortality	291	44.0	213	32.2	11.8 (6.6-17.0)	<.001
Major bleeding	228	34.4	104	15.7	18.7 (14.2-23.3)	<.001



Dhruva SS et al. JAMA 2020;323:734-745.

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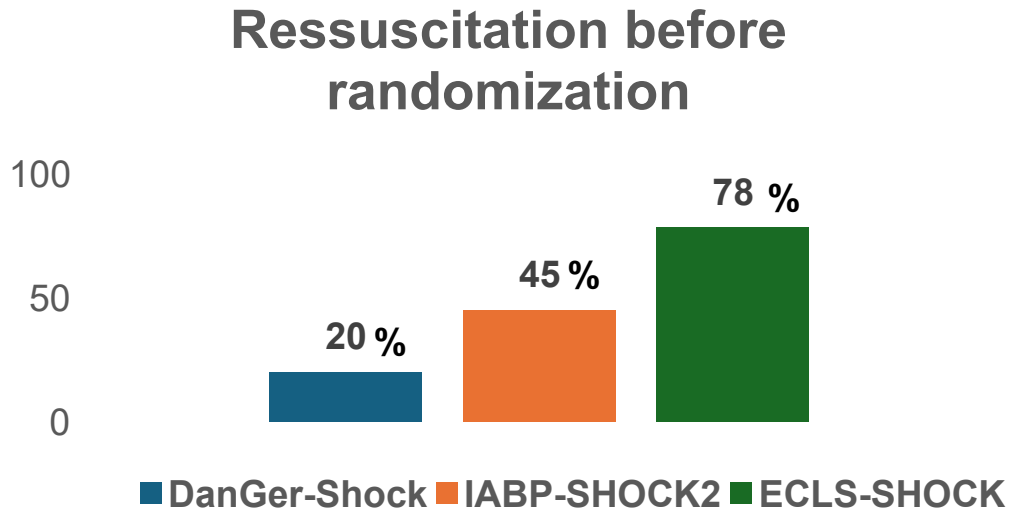
Why has Danger Shock succeeded where previous studies have failed?

DanGer-Shock vs IABP-Shock II & ECLS-Shock : Less severe pts ?



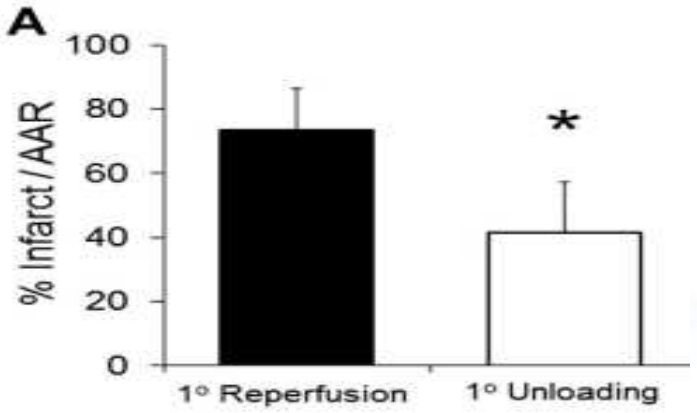
DanGer-Shock vs IMPELLA-STIC :

- Earlier management ?
  - Time from AMI to random. in DanGer-Shock : 4 hours
  - Time from AMI to random. in IMPELLA-STIC : > 70 hours

Unloading the LV in experimental studies :

⇒ decreases in wall stress & myocardial O^2 consumption

⇒ reduces myocardial injury and infarct size



Thiele H et al. Lancet 2013;382:1638–45. Thiele H et al. N Engl J Med 2023;389:1286-97. Kapur NV et al. J Am Coll Cardiol HF 2015;3:873–82.
Bochaton T et al. Arch Cardiovasc Dis 2020https://doi.org/10.1016/j.acvd.2019.10.005. Moller-Helgestad et al. Eurointervention 2019.

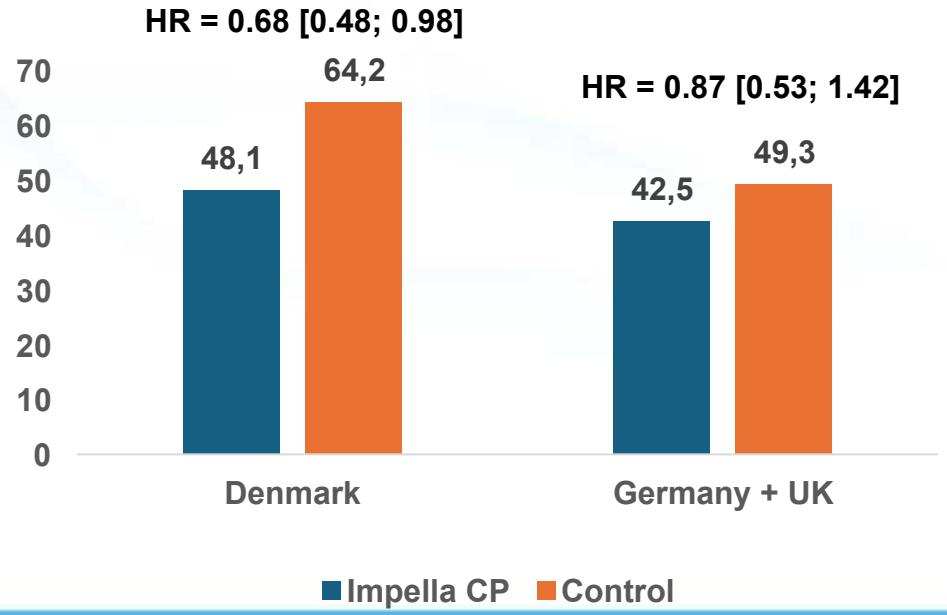
Limitations

Results cannot be extrapolated to :

- Pts with comatose OHCA
- NSTEMI pts
- SCAI C pts without elevated lactate levels
- Cardiogenic shock with biventricular failure

Trial conducted over a period of 10 yrs

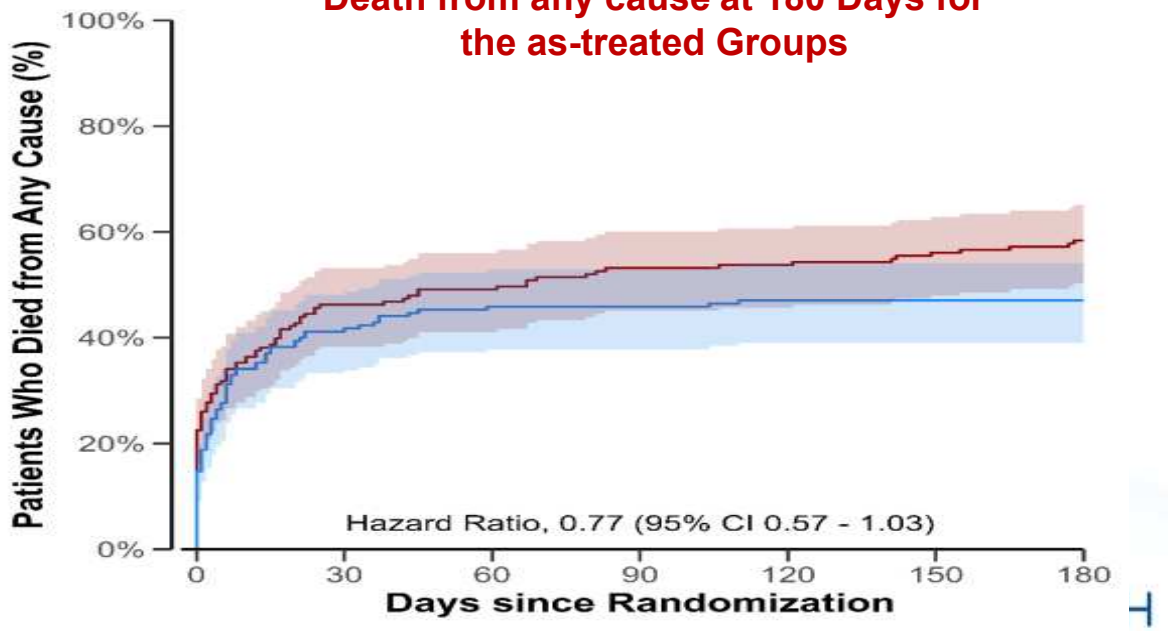
Results were heterogeneous from country to country (no apparent difference in Germany & UK)



Open-label trial :

- Despite the increased mortality rate observed in the control group, there was no increase in mechanical ventilation, use of inotropes or therapeutic escalation in this group
- Therapeutic escalation criteria were not pre-defined, and the decision was made by a heart team.
- More renal-replacement therapy in the mAFP group

Death from any cause at 180 Days for the as-treated Groups



Suggested management of acute STEMI with cardiogenic shock defined as
- SCAI C (+ lactates>2.5 mmol/L) & SCAI D or E
- Without refractory cardiac arrest, biventricular failure or PAD

Intensive care management if indicated (mechanical ventilation, vasopressor)

Pt presenting with initial cardiogenic shock

mAFP placed before PCI of the IRA

Pt presenting with secondary cardiogenic shock after PCI

mAFP placed within 12 hrs of PCI

mAFP for > 48 hours

Additional mechanical support if haemodynamic instability persists

2023 ACS Guidelines
- In pts with ACS & severe/refractory CS, short-term mechanical circulatory support may be considered **IIb C**
- The routine use of an IABP in ACS pts with CS & without mechanical complications is not recommended **III B**