

# ACC.24

## **Percutaneous Transvalvular Micro-axial Flow Pump in Infarct Related Cardiogenic Shock.**

### **Results of The DanGer-Shock Trial**

**Jacob Eifer Møller**

Professor MD PhD DMSc

Odense University Hospital and Rigshospitalet, Denmark

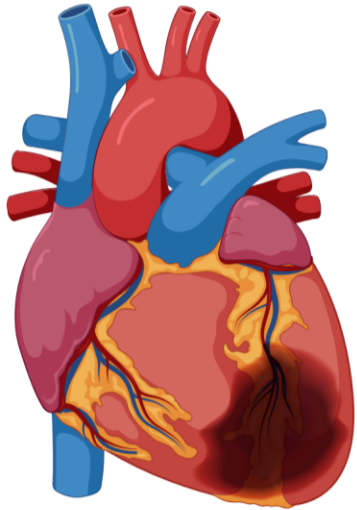
Jacob.moeller1@rsyd.dk



# Disclosure

- Institutional research grants Abiomed, Novo Nordic Foundation
- Speakers fee Abbott, Boehringer Ingelheim
- Steering committee Recover IV

# Background



STEMI

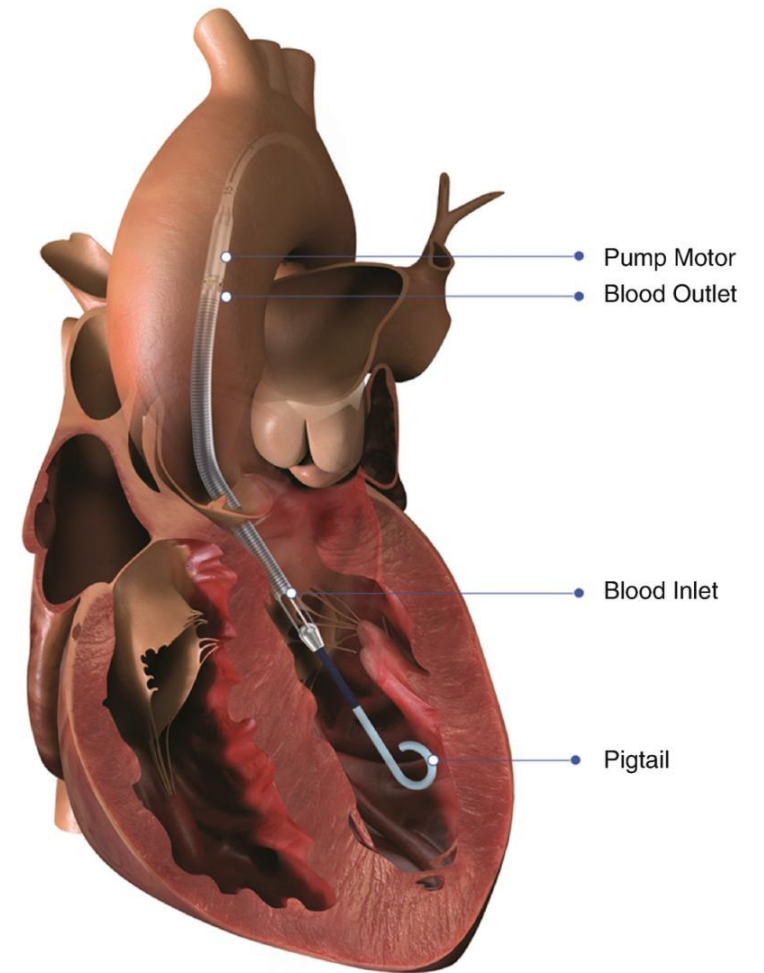
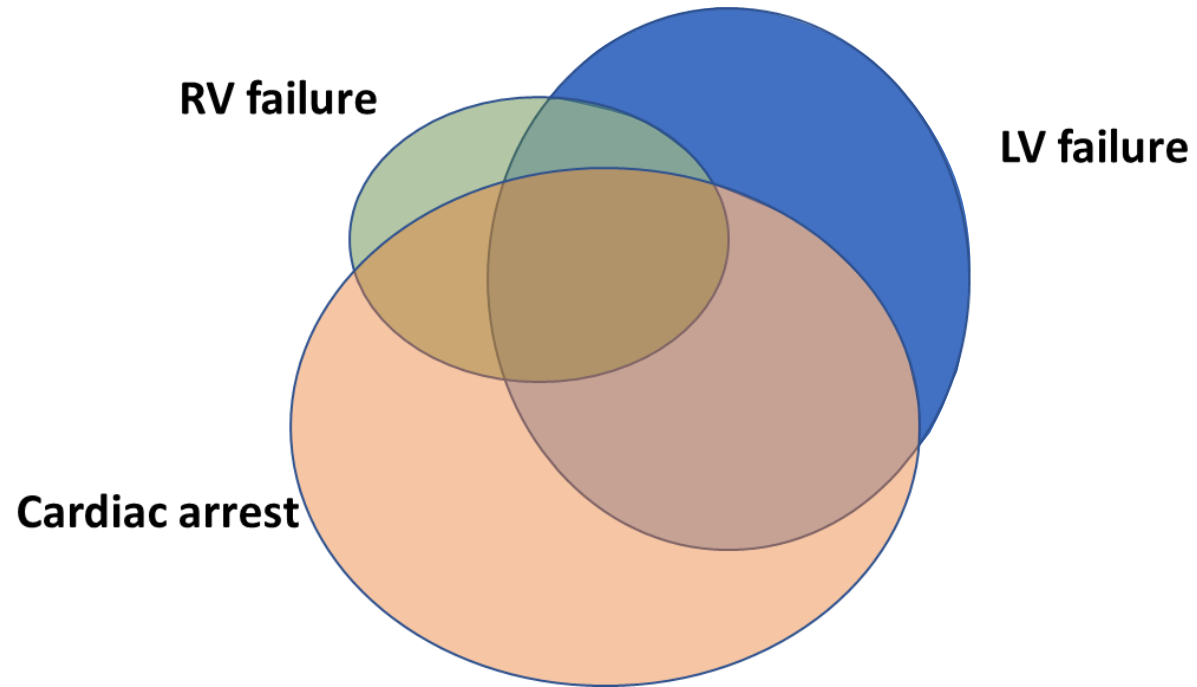


One in ten will develop CS



$\frac{1}{2}$  will survive

# AMI – Cardiogenic Shock

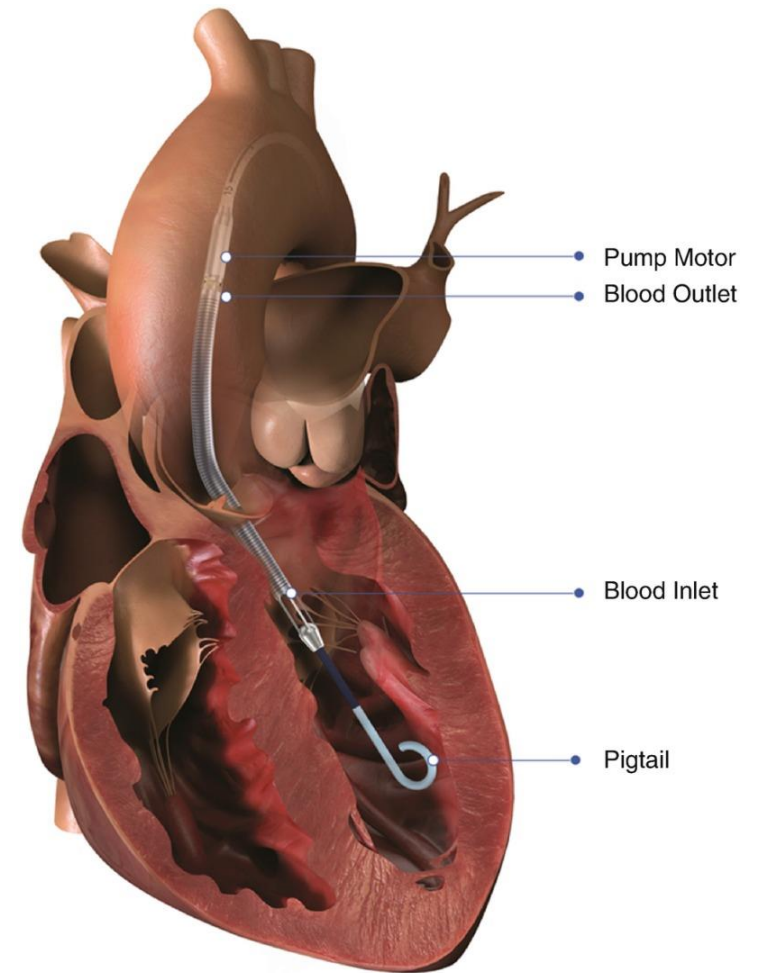


Micro Axial Flow Pump



# Hypothesis

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



Micro Axial Flow Pump

# End points and Sample Size

- Primary end point
  - Death from any cause at 180 days
- Secondary end points
  - Escalation to short or longterm MCS, HTX or Death from any cause at 180 days
  - Days alive out of the hospital at 180 days
- Sample size
  - Alpha 0.05, beta 0.8
  - Assumed mortality in standard care 60%
  - Assumed mortality in mAFP group 42%
  - N=360 and at least 165 deaths

# Inclusion criteria



STEMI



Hypotension  
and  
hypoperfusion



LVEF < 45%

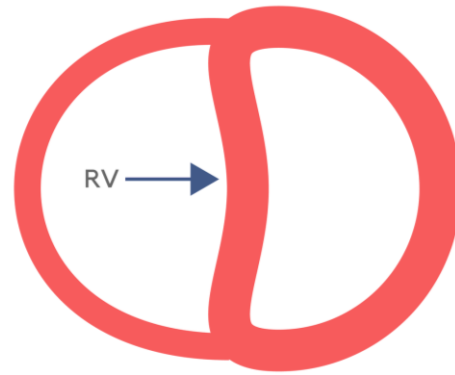


Randomization  
when shock  
was diagnosed

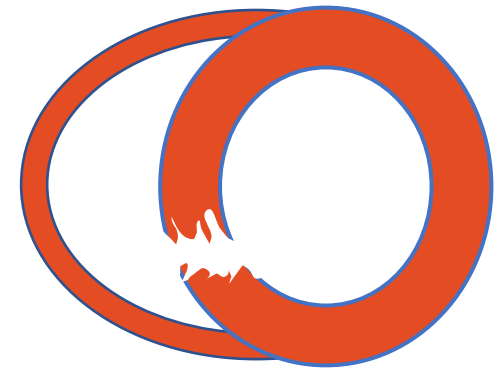
# Key exclusion criteria



Comatose  
OHCA



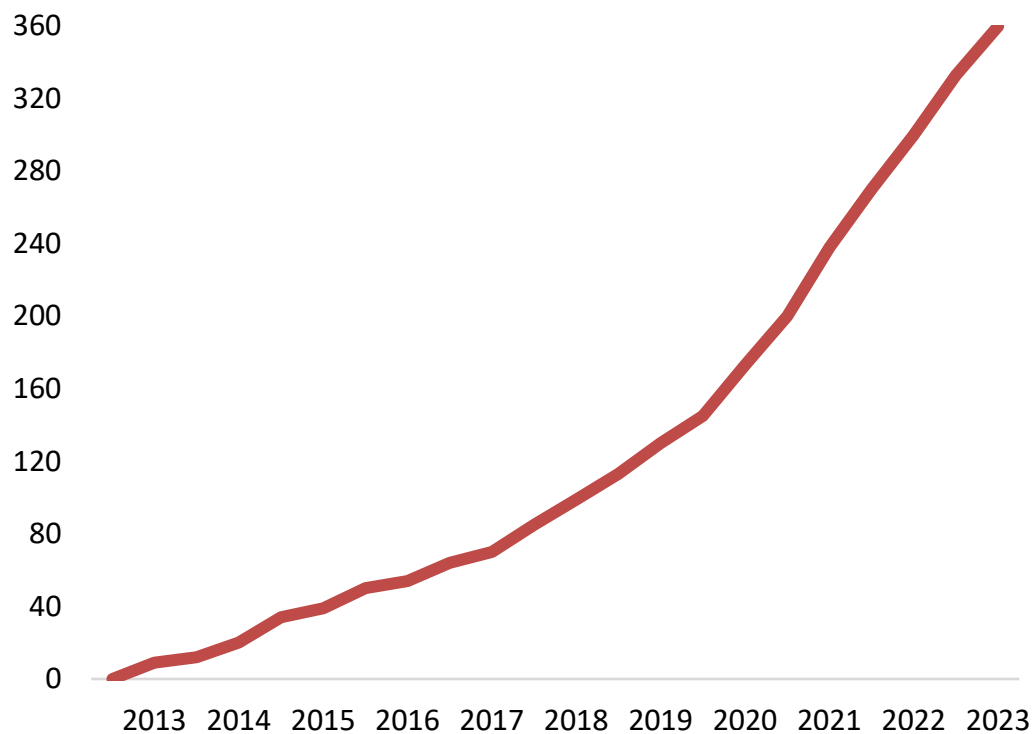
RV failure



Mechanical  
complication

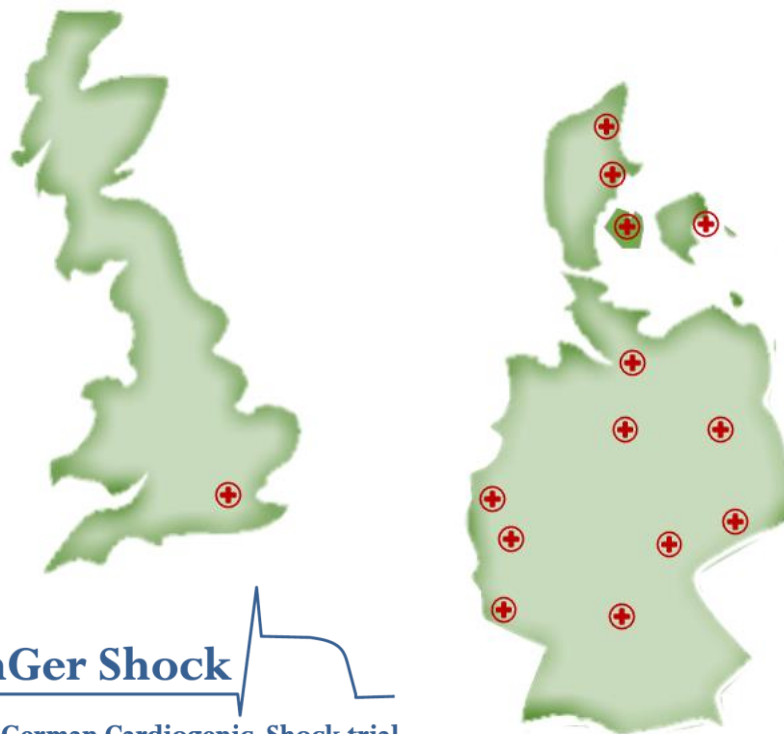


# Trial Flow



## DanGer Shock

Danish German Cardiogenic Shock trial



### Denmark 2013-2023

Copenhagen (117),  
Odense (56),  
Aarhus (41)  
Aalborg (1)

### Germany 2019 - 2023

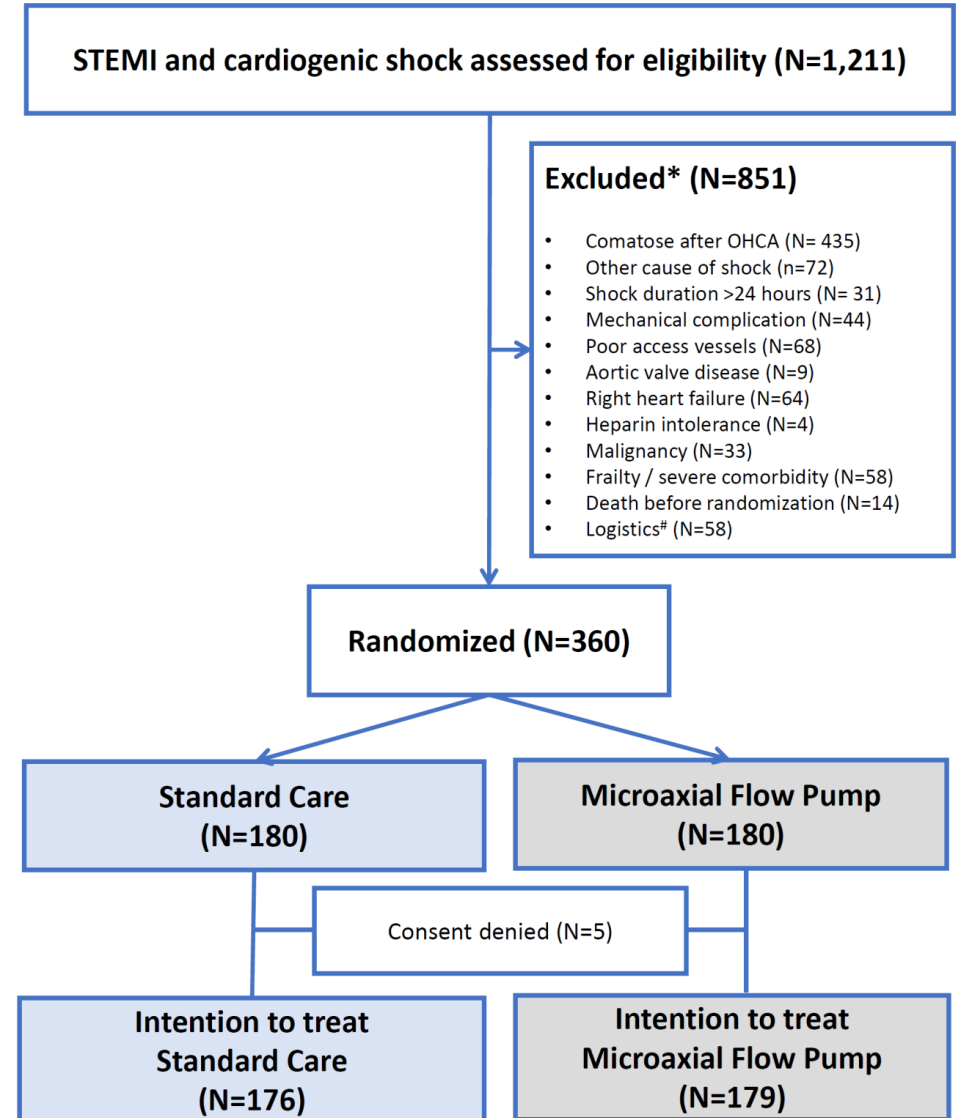
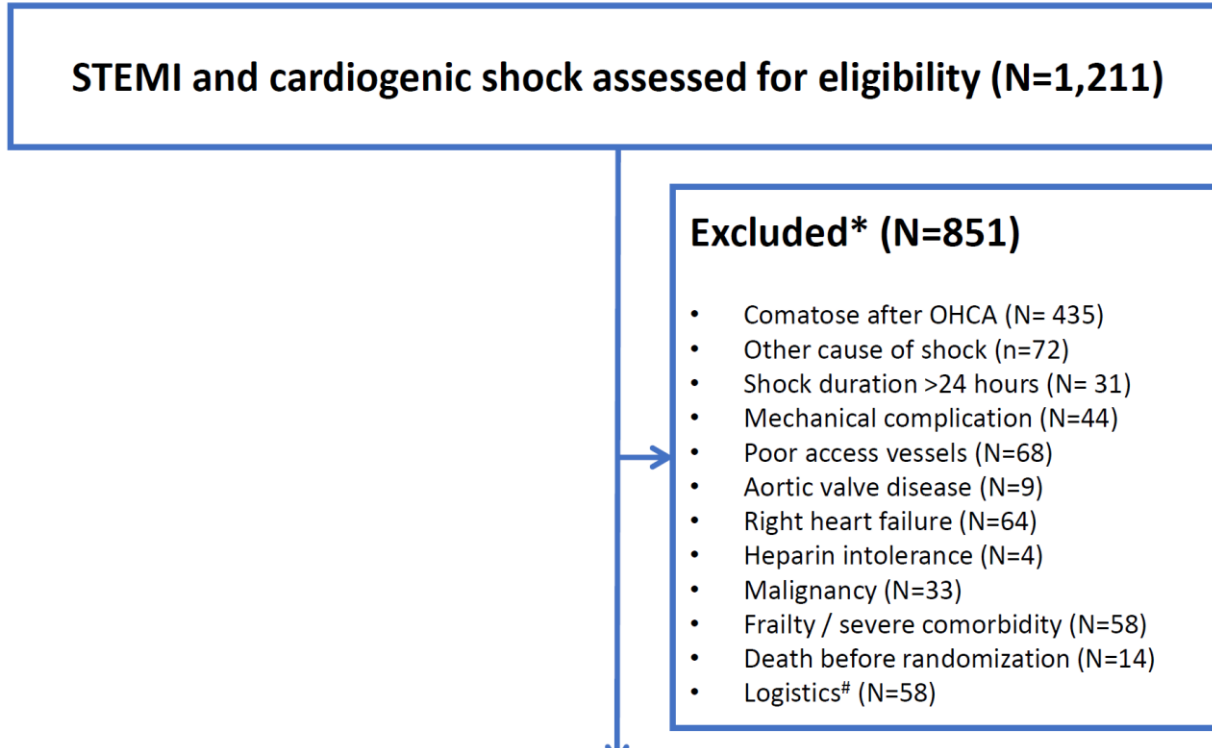
Dresden (32)  
Düsseldorf (25)  
Jena (21)  
Berlin (18)  
Würzburg (14)  
Hamburg (12)  
Bonn (7)  
Hannover (6)  
Trier (0)

### UK 2021-2023

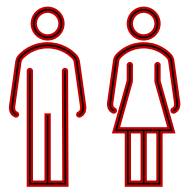
London Harefield (10)

CRO: ! **KCRI**

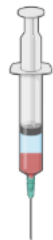
# Trial Flow



# Patients characteristics – N=355



Median 67 years  
79% male



Median lactate 4.5 mmol/L



72% LAD or LM culprit  
72% Multi vessel disease



Median 4 hrs from onset of STEMI  
symptoms to randomization

84% randomized in cath lab



Median LVEF 25%



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



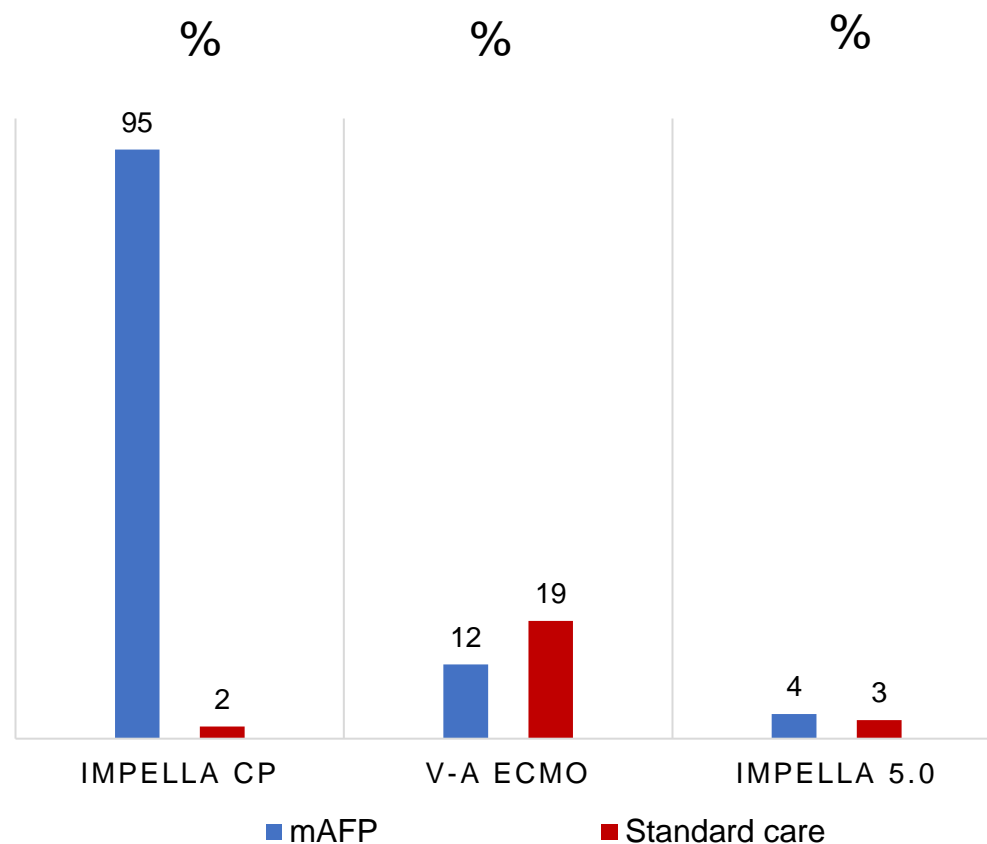
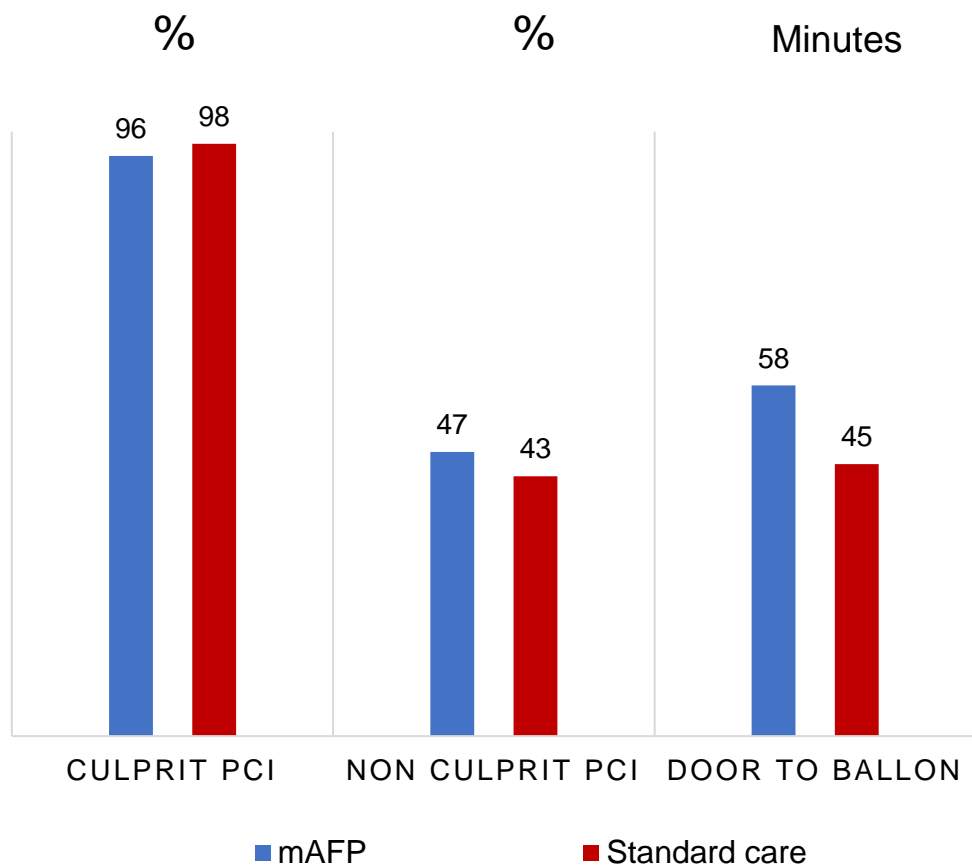
Median systolic BP  
82 mmHg



# Revascularization

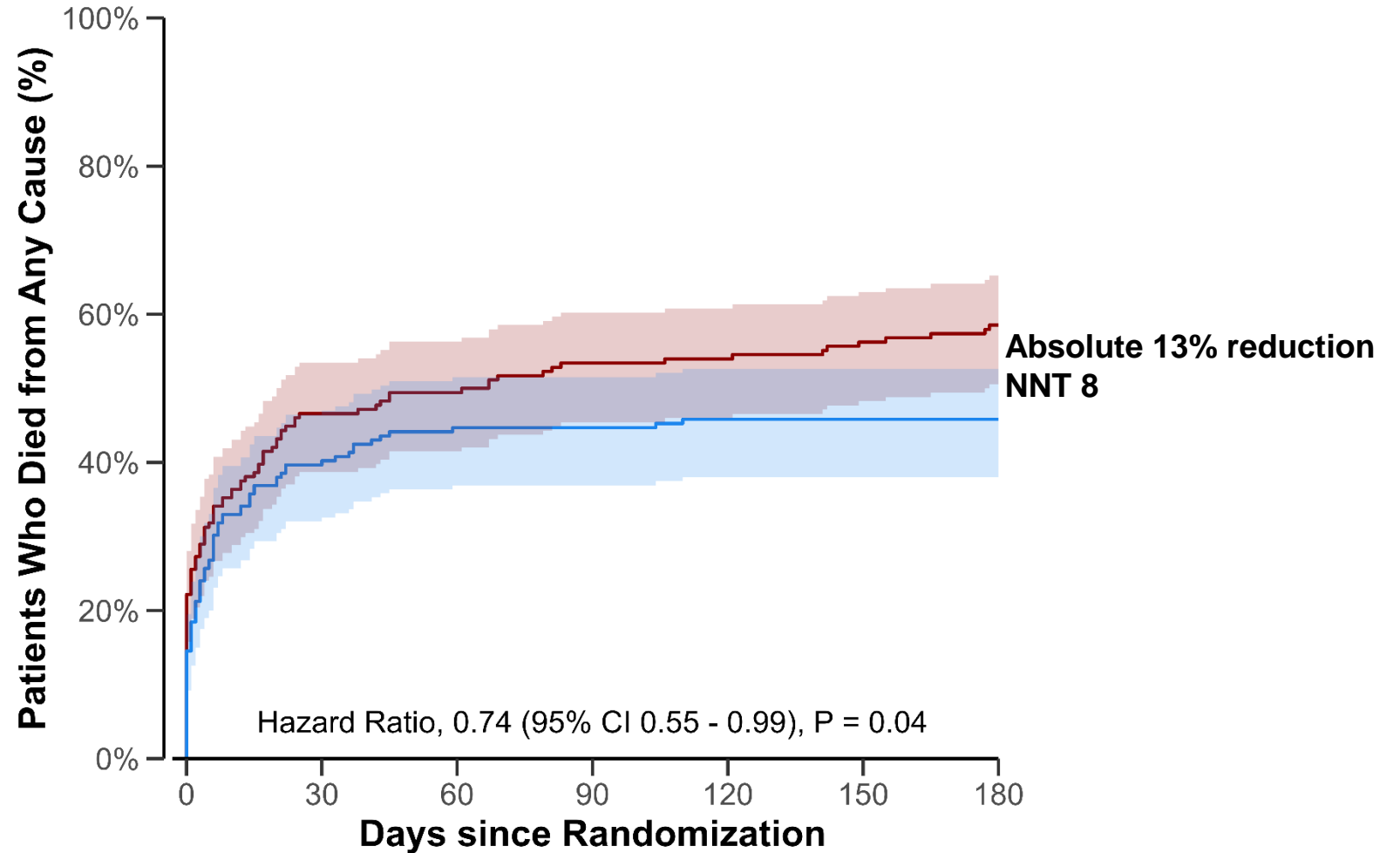


# Temporary MCS





# Primary end point

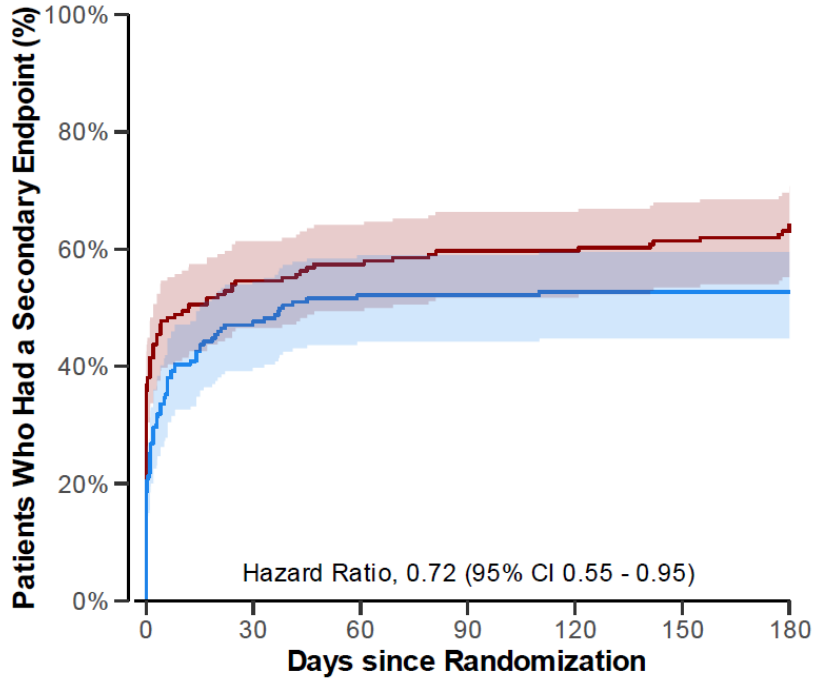


No. at Risk

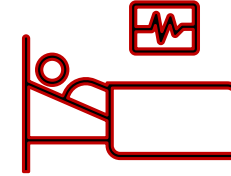
Standard	176	94	89	82	81	77	72
mAFP	179	108	99	99	97	97	97

# Secondary end points

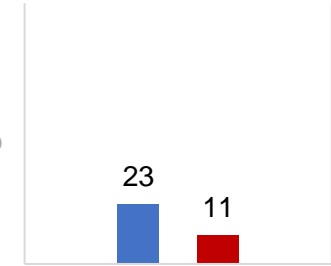
Escalation to short or longterm MCS, HTX or Death from any cause at 180 days



	No. at Risk						
	0	30	60	90	120	150	180
Standard	176	80	75	71	71	68	64
mAFP	179	93	85	85	84	84	84

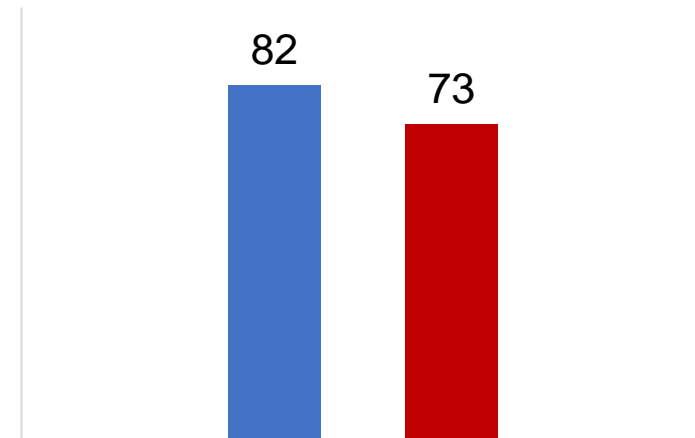


%



STILL IN HOSPITAL DAY 30

Mean difference 8 days (95%CI -8 to 25)

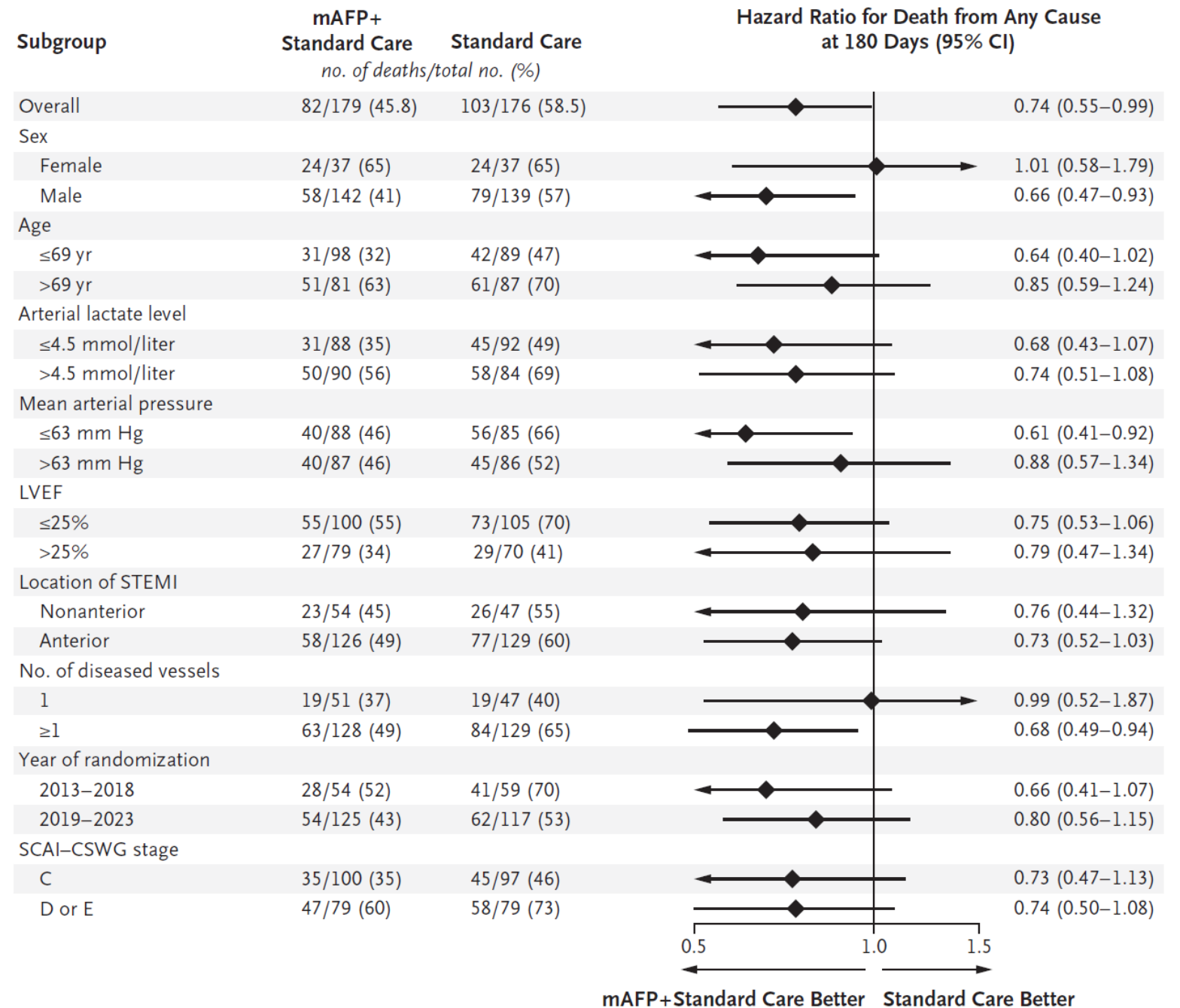


DAYS ALIVE OUT OF THE HOSPITAL

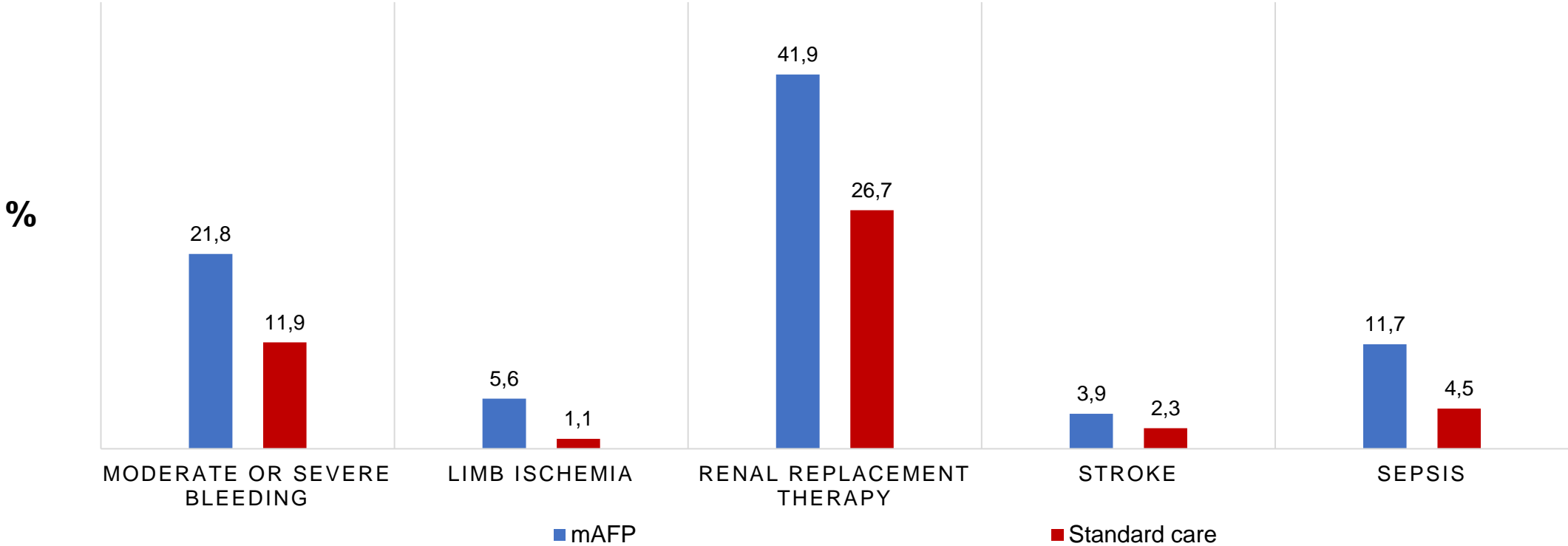
■ mAFP

■ Standard care

# Prespecified Subgroups



# Adverse events





# Conclusion

- The routine use of a mAFP on top of standard care reduced death from any cause in patients with STEMI and cardiogenic shock.
- This was associated with an increased risk of adverse events.
- The study results cannot be extrapolated to other causes of cardiogenic shock including comatose OHCA, NonSTEMI and nonischemic cardiogenic shock



The NEW ENGLAND  
JOURNAL of MEDICINE

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, A. Schäfer, N. Werner, M. Frydland, L. Holmvang, J. Kjærgaard, R. Sørensen, J. Lønborg, M.G. Lindholm, N.L.J. Udesen, A. Junker, H. Schmidt, C.J. Terkelsen, S. Christensen, E.H. Christiansen, A. Linke, F.J. Woitek, R. Westenfeld, S. Möbius-Winkler, K. Wachtell, H.B. Ravn, J.F. Lassen, S. Boesgaard, O. Gerke, and C. Hassager, for the DanGer Shock Investigators\*

