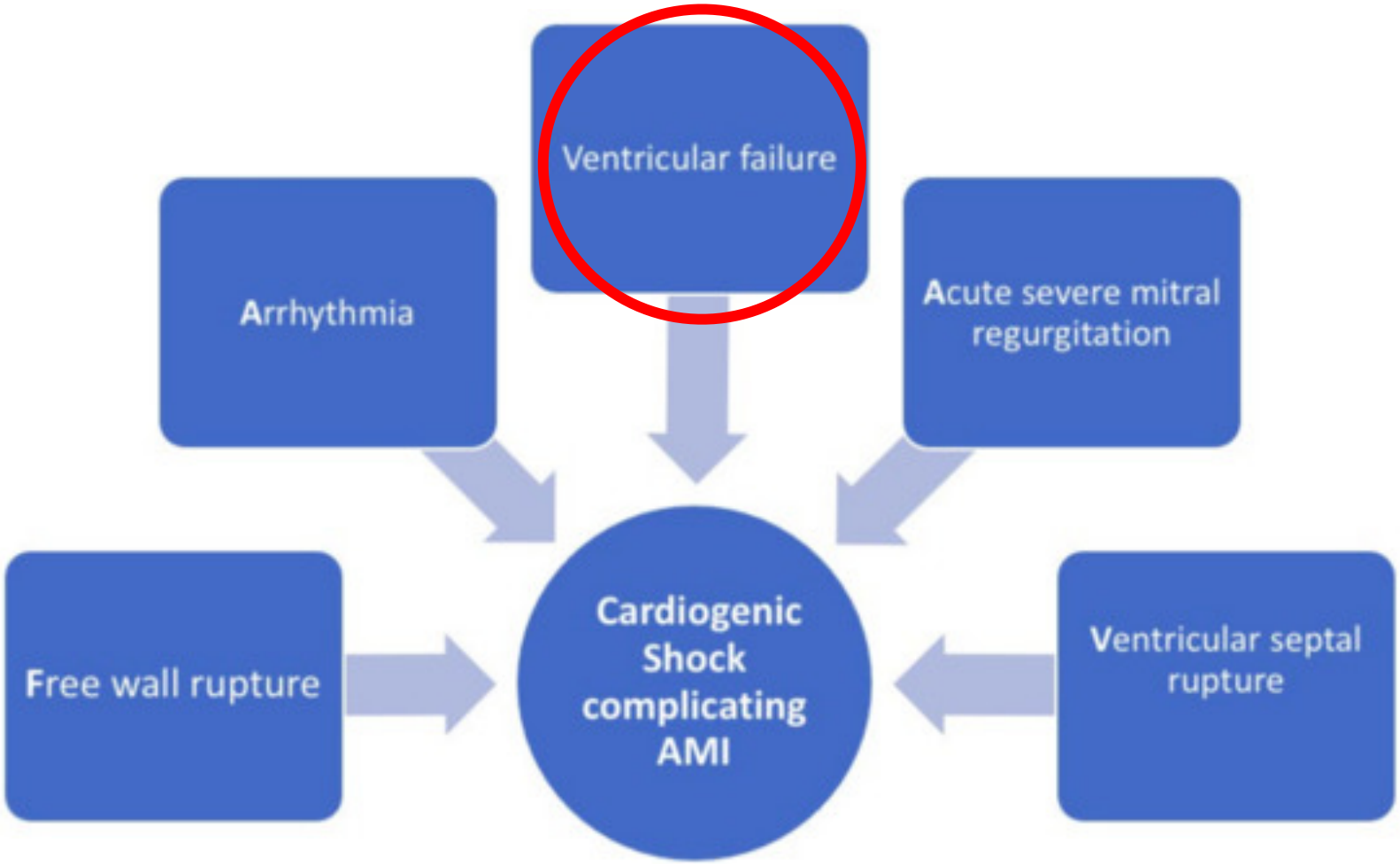
Mechanical support in cardiogenic shock complicating acute myocardial infarction

Giuseppe De Luca, MD, PhD
Full Professor of Cardiology
University of Messina

Causes of CS complicating AMI



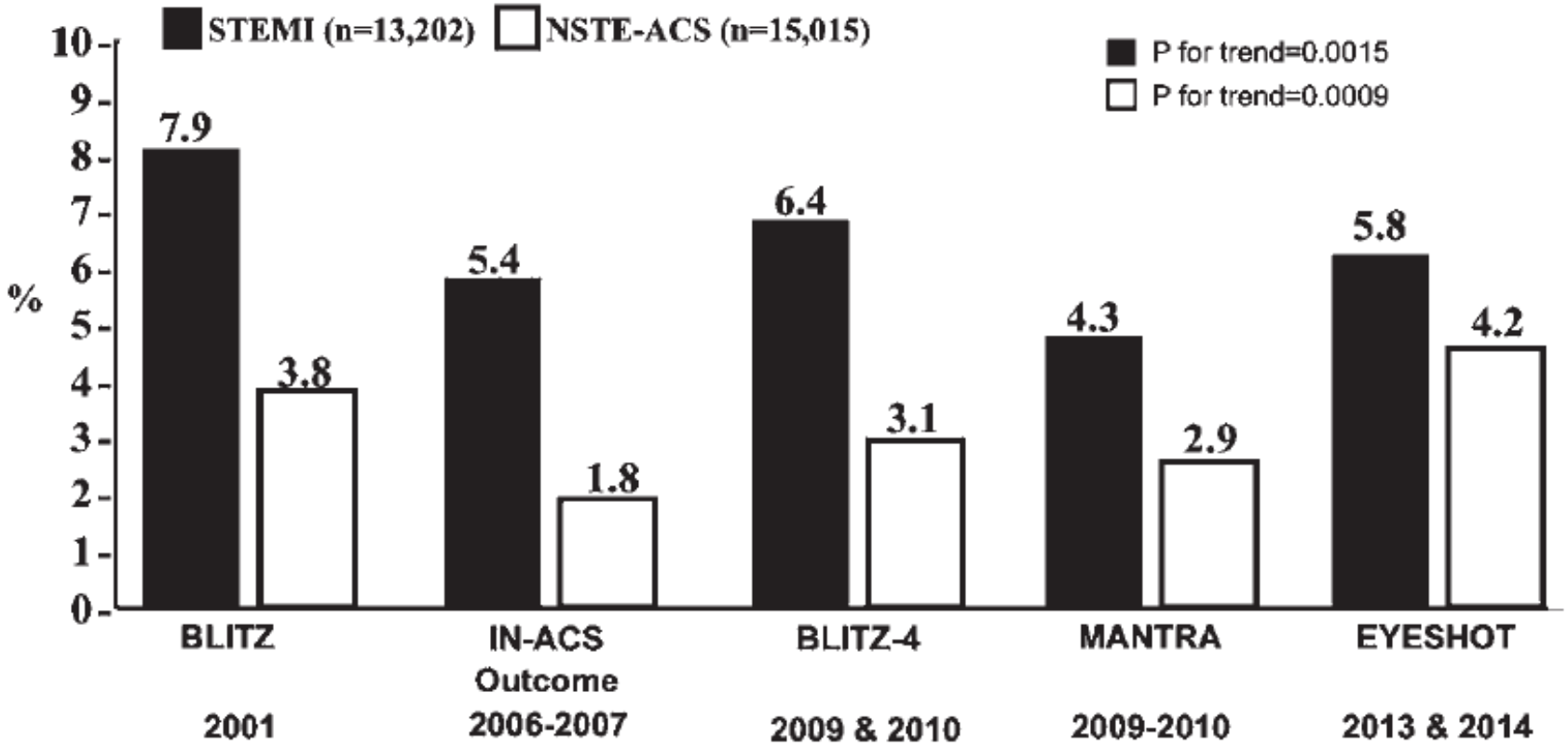


Figure 1 Incidence of cardiogenic shock among patients with an initial diagnosis of ST-elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTE-ACS) enrolled in different registries.

Massimo Gulizia[1], and Stefano Savonitto[3]*

cardiogenic shock at admission increased from 1.9% in 2001 to 2.7% in 2014 (*P* for trend=0.01),

while the number of patients developing shock during hospitalization declined from 4.8% in 2001 to 2.1% in 2014 (*P* for trend <0.0001).

at the time of admission

later or during hospitalization.

MECHANICAL SUPPORT IN CARDIOGENIC SHOCK

1) RATIONALE

2) CLINICAL EVIDENCE

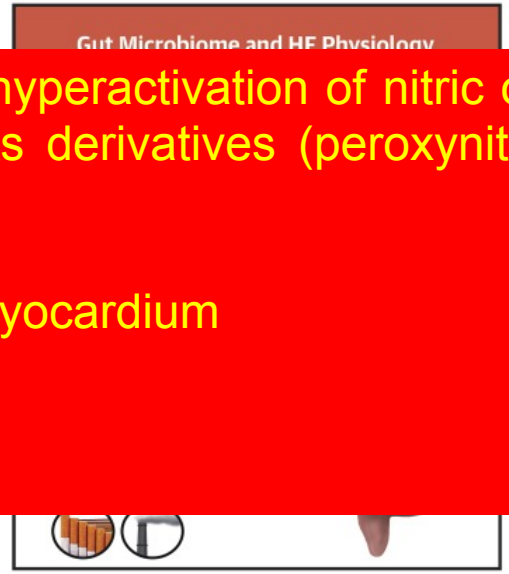
3) PREPROCEDURAL OR POSTPROCEDURAL?

Treatment strategies in cardiogenic shock

Early diagnosis and prevention

The activation of the inflammatory cascade results in the hyperactivation of nitric oxide synthase. The increased production of nitric oxide and its derivatives (peroxynitrites) results in negative effects at various levels:

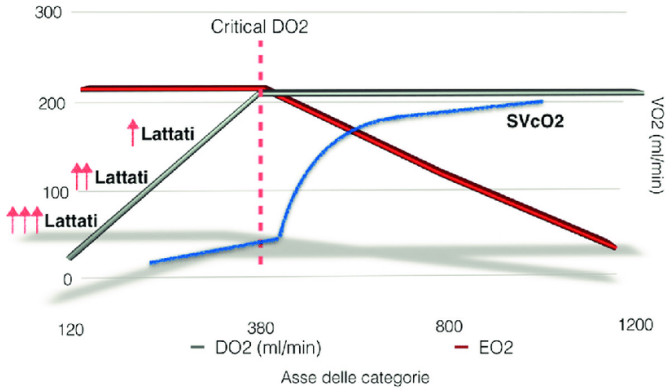
1) inhibition of myocardial contractility
2) Inhibition of mitochondrial respiration in non-ischemic myocardium
3) Alteration of carbohydrate metabolism
4) Reduced responsiveness to catecholamines
5) Induction of systemic vasodilation



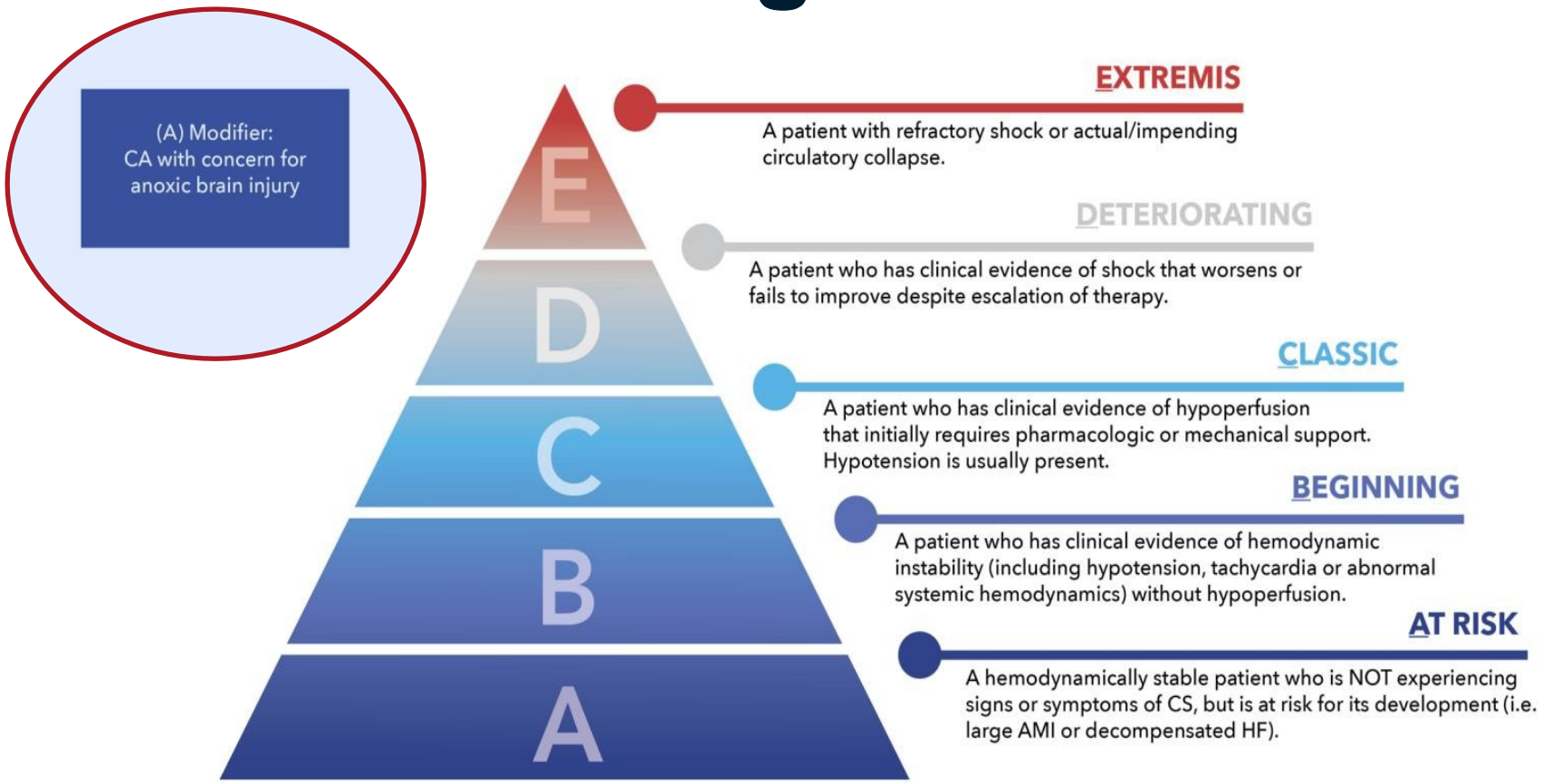
ScvO2

Pv-aCO2

2) Lactates increase in a later phase. Therefore, we need very sensitive markers useful in the early phase for an early diagnosis of initial haemodinamic compromise



SCAI SHOCK II Definition – Cardiogenic Shock



Naidu et al. JACC 2022;79:933-946

MECHANICAL SUPPORT IN CARDIOGENIC SHOCK

1) RATIONALE

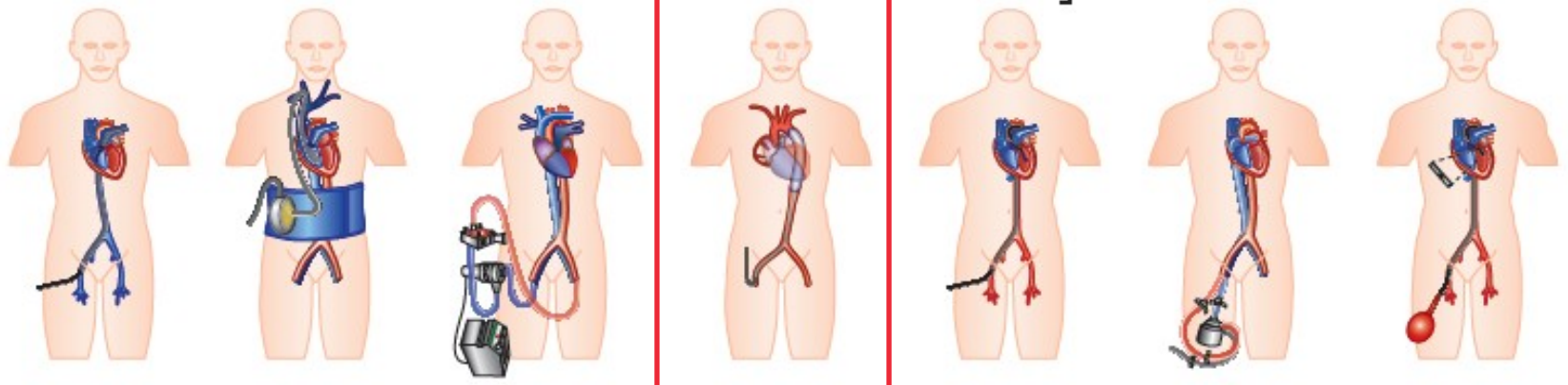
2) CLINICAL EVIDENCE

3) PREPROCEDURAL OR POSTPROCEDURAL?

Currently Available MCS

Right ventricular support

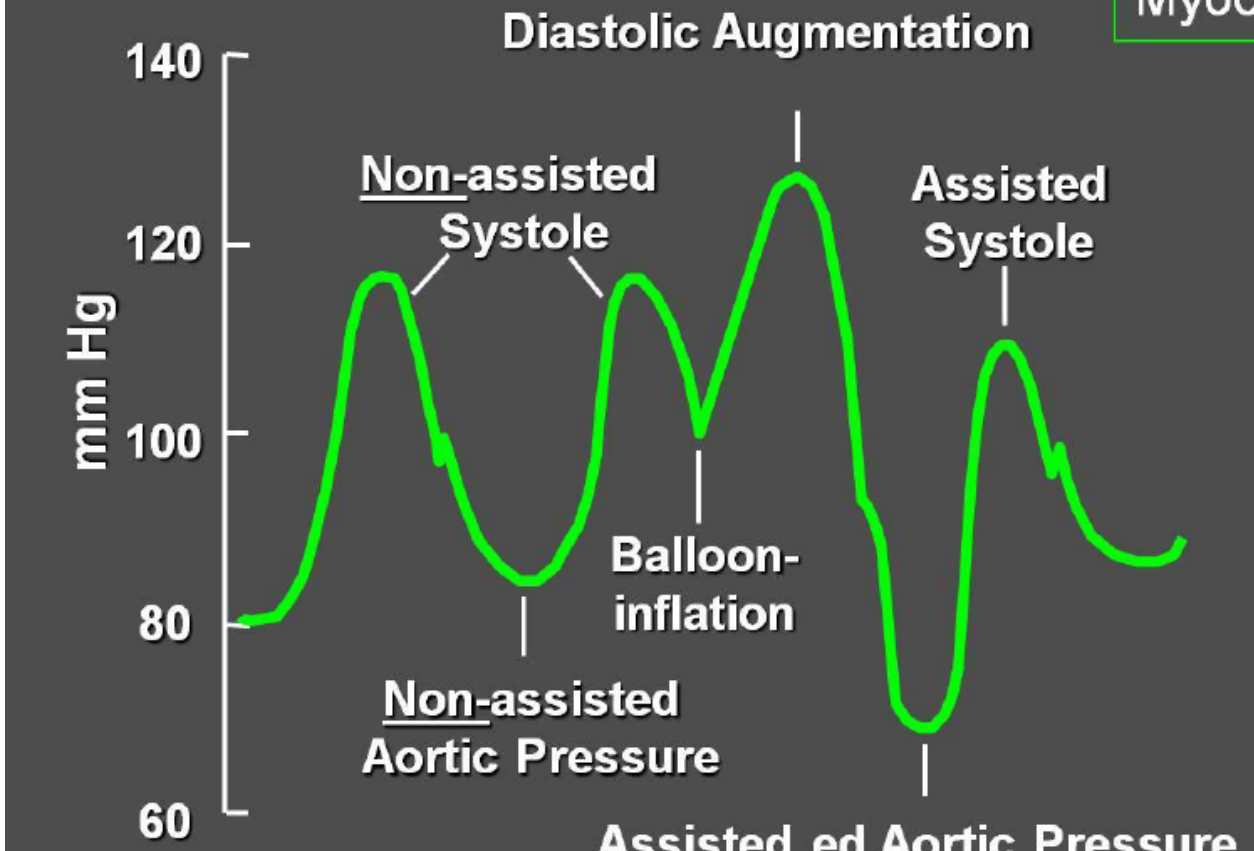
Left ventricular support

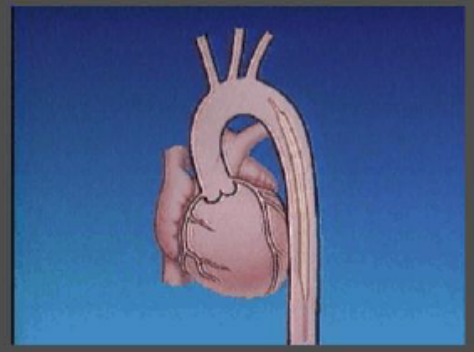


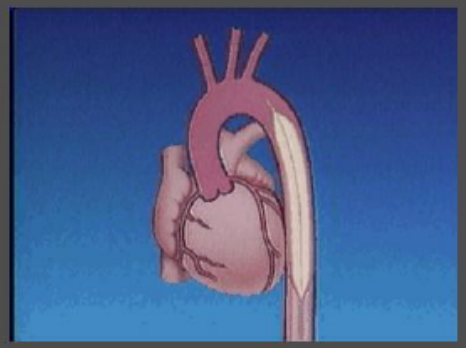
	a) Impella RP	b) TandemHeart RA-PA	c) VA-ECMO	d) IABP	e) Impella 2.5 CP 5.0 5.5	f) TandemHeart	g) iVAC 2L
Flow:	max. 4.0 L	max. 4.0 L	max. 7.0 L		2.5-5.5 L	max. 4.0 L	max. 2.8 L
Pump speed:	33.000 rpm	max. 7.500 rpm	max. 5000 rpm		max. 51.000 rpm	max. 7.500 rpm	40 ml/beat
Cannula size:	22 F	29 F	14-19 F arterial 17-21F venous	7-8 F	12-14 F	12-19 F arterial 21F venous	17 F
Insertion/ Placement	Femoral vein	Internal jugular vein	Femoral artery Femoral vein	Femoral artery	Femoral artery	Femoral artery Femoral vein for LA access	Femoral artery
LV Unloading	-	-	-	(+)	+ - ++	++	+
RV Unloading	+	+	++	-	-	-	-

IABP – Arterial Pressure Curves

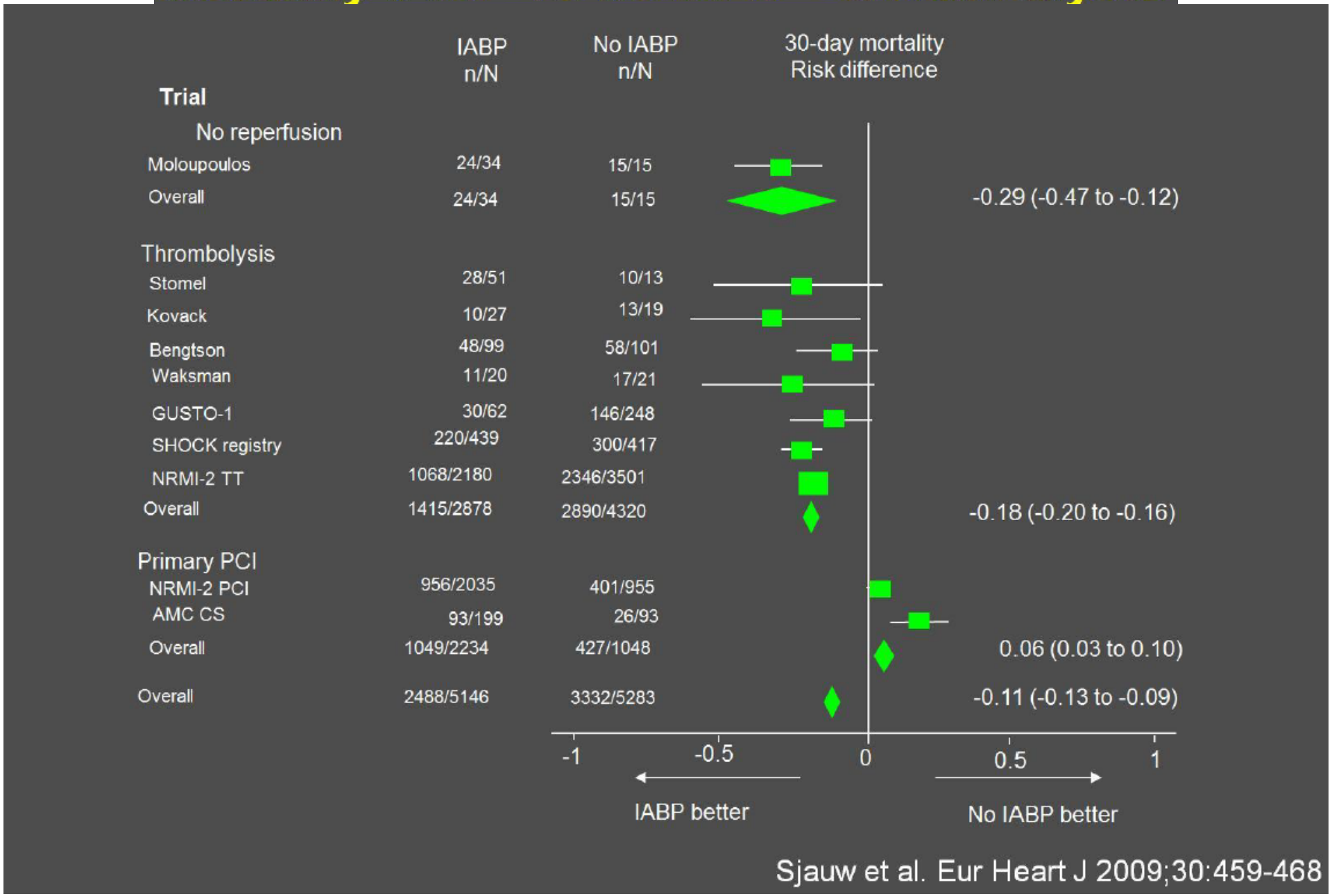
Improvement of coronary perfusic
Reduction afterload
Myocardial O_2-consumption ↓







Mortality IABP vs no IABP - Metaanalysis



Sjauw et al. Eur Heart J 2009;30:459-468

Is Intraaortic Balloon Counterpulsation Really Useful in Cardiogenic Shock? Results of the IABP-SHOCK II Trial

Gerhard Schuler and Holger Thiele

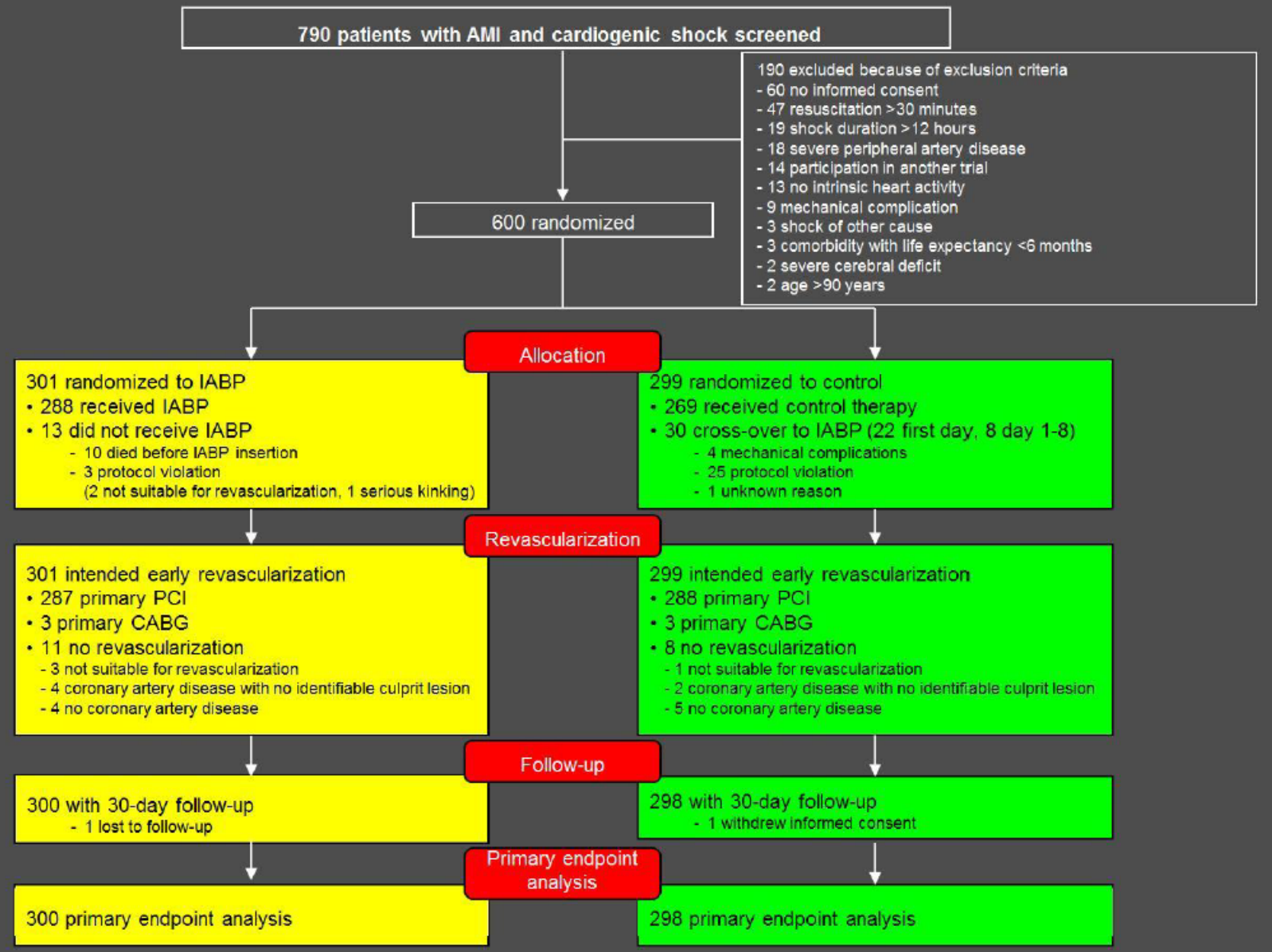
on behalf of the **IABP-SHOCK II Trial** Investigators

University of Leipzig – Heart Center

Results

Trial Flow and Treatment

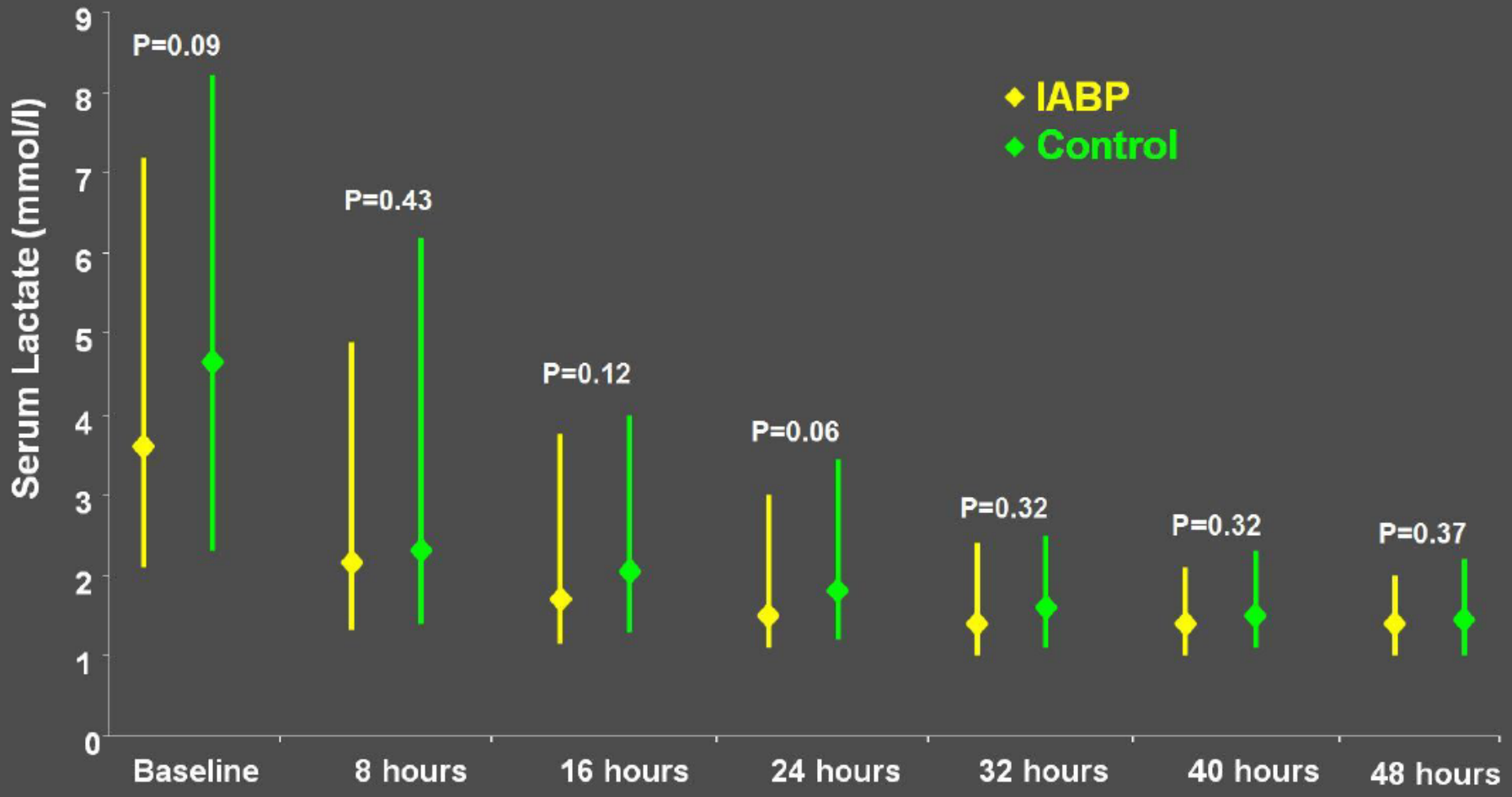
IABP SHOCK II RANDOMIZED CLINICAL TRIAL



Results

Serum Lactate

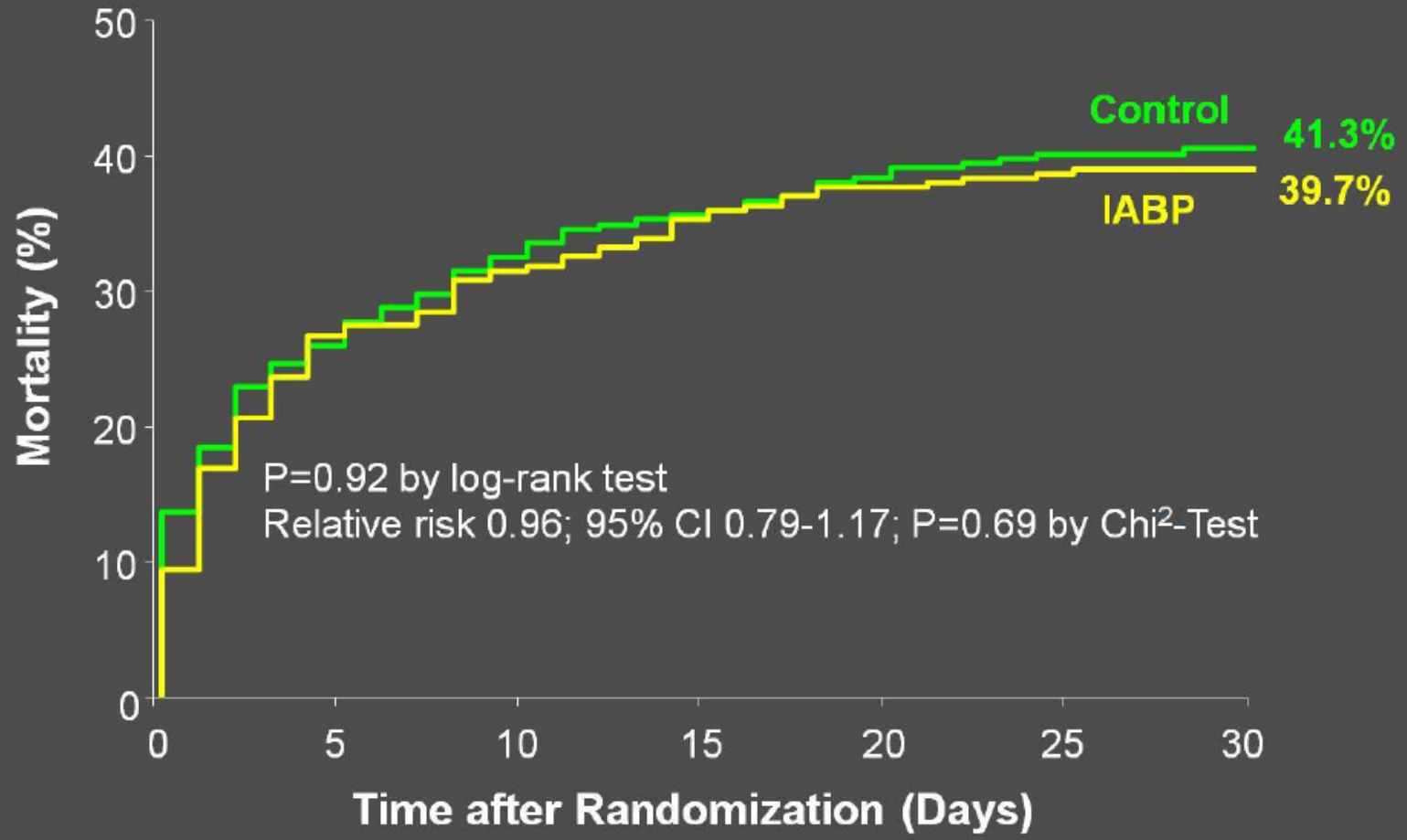
IABP SHOCK II
RANDOMIZED CLINICAL TRIAL



Results

Primary Study Endpoint (30-Day Mortality)

IABP SHOCK II
RANDOMIZED CLINICAL TRIAL

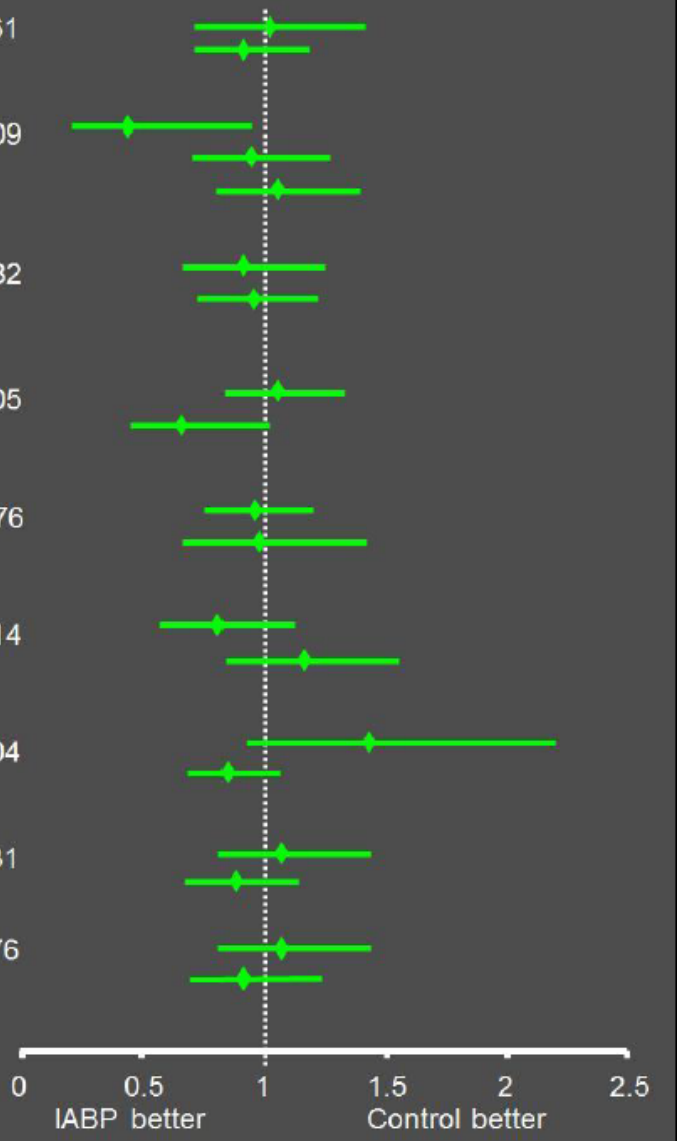


Results

Subgroups (30-Day Mortality)

IABP SHOCK II RANDOMIZED CLINICAL TRIAL

Baseline Variable	N	30-Day Mortality (%) IABP	30-Day Mortality (%) Control	Relative Risk (95% CI)	P-Value for Interaction
Female	187	44.4	43.2	1.03 (0.74-1.43)	0.61
Male	411	37.3	40.5	0.92 (0.72-1.18)	
Age <50 years	70	19.4	44.1	0.44 (0.21-0.95)	0.09
Age 50-75 years	334	34.6	36.5	0.95 (0.71-1.27)	
Age >75 years	194	53.7	40.0	1.07 (0.81-1.41)	
Diabetes	195	42.9	46.7	0.92 (0.67-1.26)	0.82
No diabetes	399	37.2	38.9	0.96 (0.74-1.23)	
Hypertension	410	42.9	40.4	1.06 (0.84-1.34)	0.05
No hypertension	183	28.9	43.0	0.67 (0.45-1.01)	
STEMI/LBBB	412	41.0	42.9	0.96 (0.77-1.21)	0.76
NSTEMI	177	37.5	38.3	0.98 (0.67-1.43)	
Anterior STEMI	216	35.4	43.7	0.81 (0.58-1.13)	0.14
Non-anterior STEMI	196	48.3	42.2	1.16 (0.85-1.57)	
Previous infarction	131	47.9	33.3	1.44 (0.93-2.21)	0.04
No previous infarction	466	37.3	43.3	0.86 (0.69-1.07)	
Hypothermia	226	48.1	44.2	1.09 (0.82-1.44)	0.31
No hypothermia	372	35.1	39.3	0.89 (0.68-1.16)	
Blood pressure <80 mmHg	161	50.7	46.4	1.09 (0.79-1.50)	0.76
Blood pressure ≥80 mmHg	432	35.9	39.2	0.92 (0.72-1.17)	



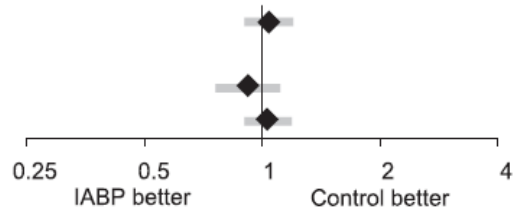
Safety

IABP SHOCK II RANDOMIZED CLINICAL TRIAL

	IABP (n=300)	Control (n=298)	P
Stroke in-hospital n/total (%)	2/300 (0.7)	5/298 (1.7)	0.28
GUSTO bleeding; n/total n (%)			
Life-threatening/severe	10/300 (3.3)	13/298 (4.4)	0.51
Moderate	52/300 (17.3)	49/298 (16.4)	0.77
Peripheral ischemic complication requiring intervention; n/total n (%)	13/300 (4.3)	10/298 (3.4)	0.53
Sepsis; n/total n (%)	47/300 (15.7)	61/298 (20.5)	0.15

ORIGINAL RESEARCH ARTICLE

Baseline Variable	N	6-Year Mortality n (%) IABP	Control	Relative Risk (95% CI)	P-Value for Interaction	Relative Risk (95% CI)
No hypothermia	369	132 (68.4)	116 (65.9)	1.04 (0.90-1.20)		
Blood pressure <80 mmHg	160	54 (70.1)	63 (75.9)	0.92 (0.76-1.11)	0.35	
Blood pressure ≥80 mmHg	425	142 (65.4)	132 (63.5)	1.03 (0.90-1.19)		



Forest plot subgroup analyses for all patients with 6-year follow-up

Table 1. Clinical Outcomes at 6 Years

Variable	Intraaortic Balloon Pump (n=297)	Control (n=294)	Relative Risk (95% CI)	*P* Value
All-cause mortality	197/297 (66.3)	197/294 (67.0)	0.99 (0.88–1.11)	0.98
Events in 6-year survivors				
Reinfarction	9/100 (9.0)	7/97 (7.2)	1.25 (0.48–3.22)	0.65
Stroke	1/100 (1.0)	6/97 (6.2)	0.16 (0.02–1.32)	0.06
Recurrent revascularization	26/100 (26.0)	31/97 (32.0)	0.81 (0.52–1.26)	0.36
Repeat percutaneous coronary intervention	18/100 (18.0)	26/97 (26.8)	0.67 (0.39–1.14)	0.14
Additional coronary artery bypass grafting	8/100 (8.0)	7/97 (7.2)	1.11 (0.42–2.94)	0.84
Implantable cardioverter defibrillator implantation	13/100 (13.0)	15/97 (15.5)	0.84 (0.42–1.67)	0.62

Values indicate n/total (%).

HERZZENTRUM LEIPZIG

Leipzig Heart Science LHS

UNIVERSITÄT LEIPZIG
Medizinische Fakultät

ECLS-SHOCK

Extracorporeal life support for acute myocardial infarction complicated by cardiogenic shock

ECLS-SHOCK

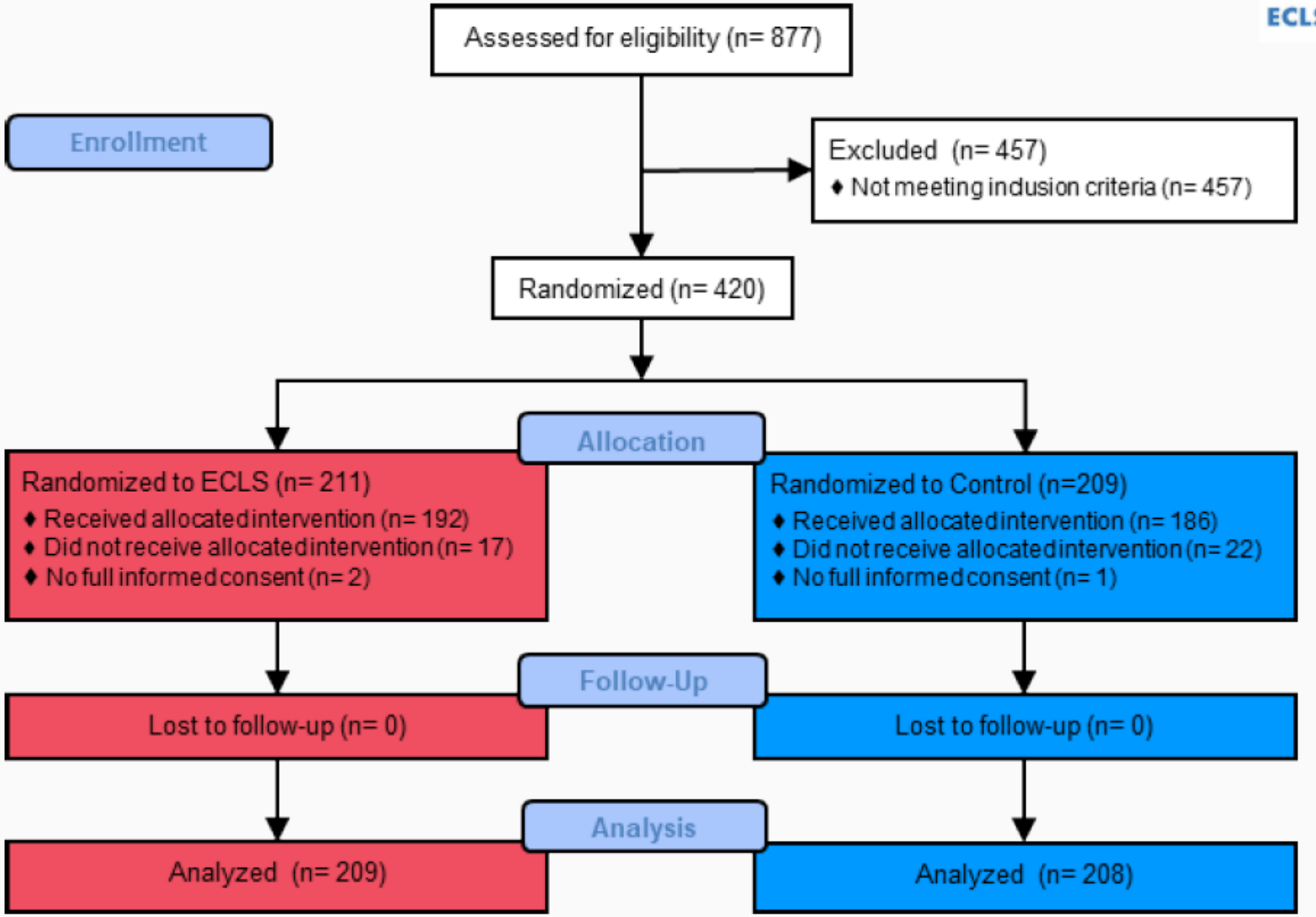
Holger Thiele on behalf of the ECLS-SHOCK Investigators

26th of August 2023

Results

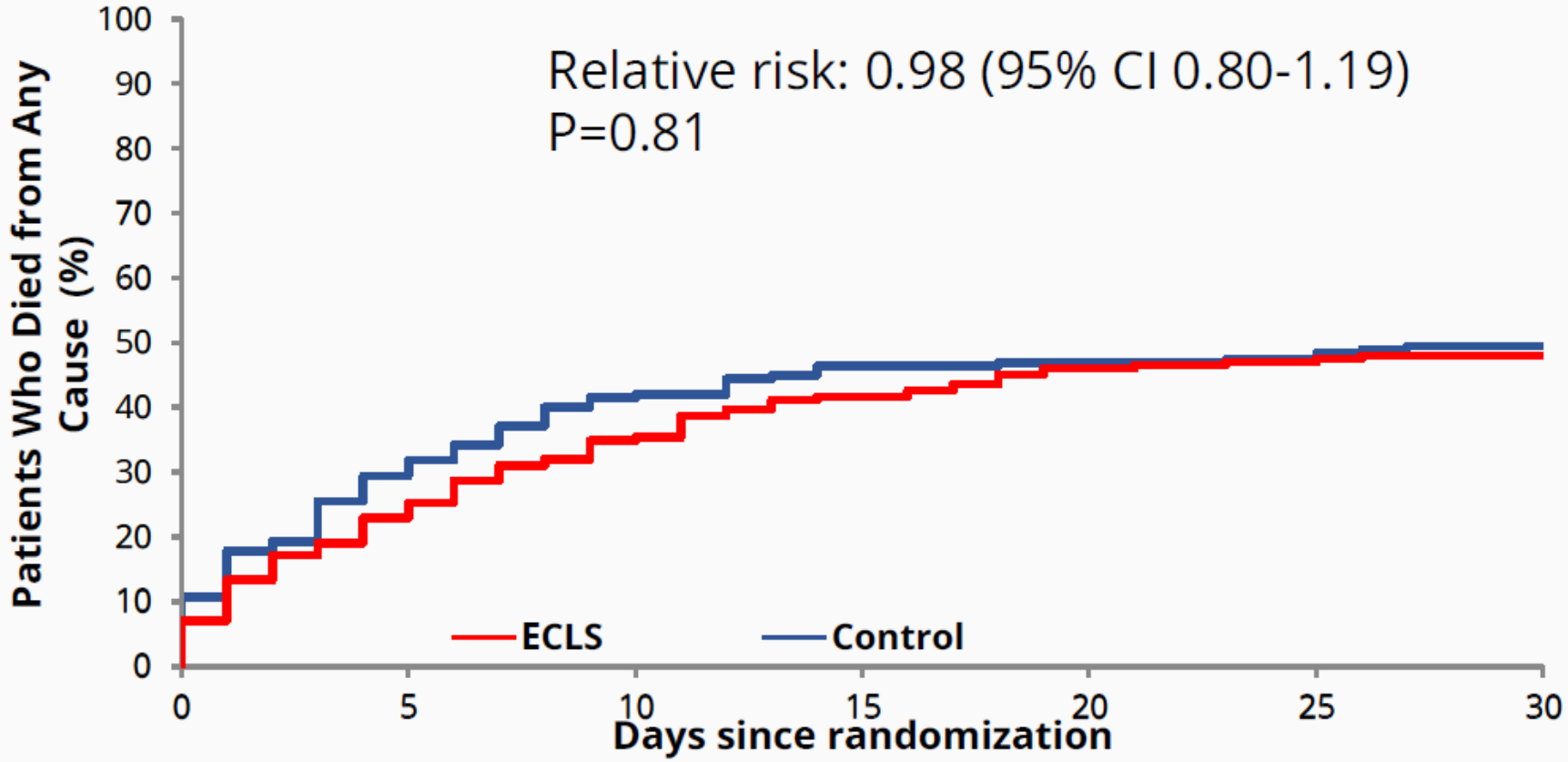
44 study sites

Trial Flow



Thiele et al. Am Heart J 2021;234:

Primary Endpoint – 30-Day All-Cause Mortality



No. at							
Control	208	146	120	109	105	104	100

Resul
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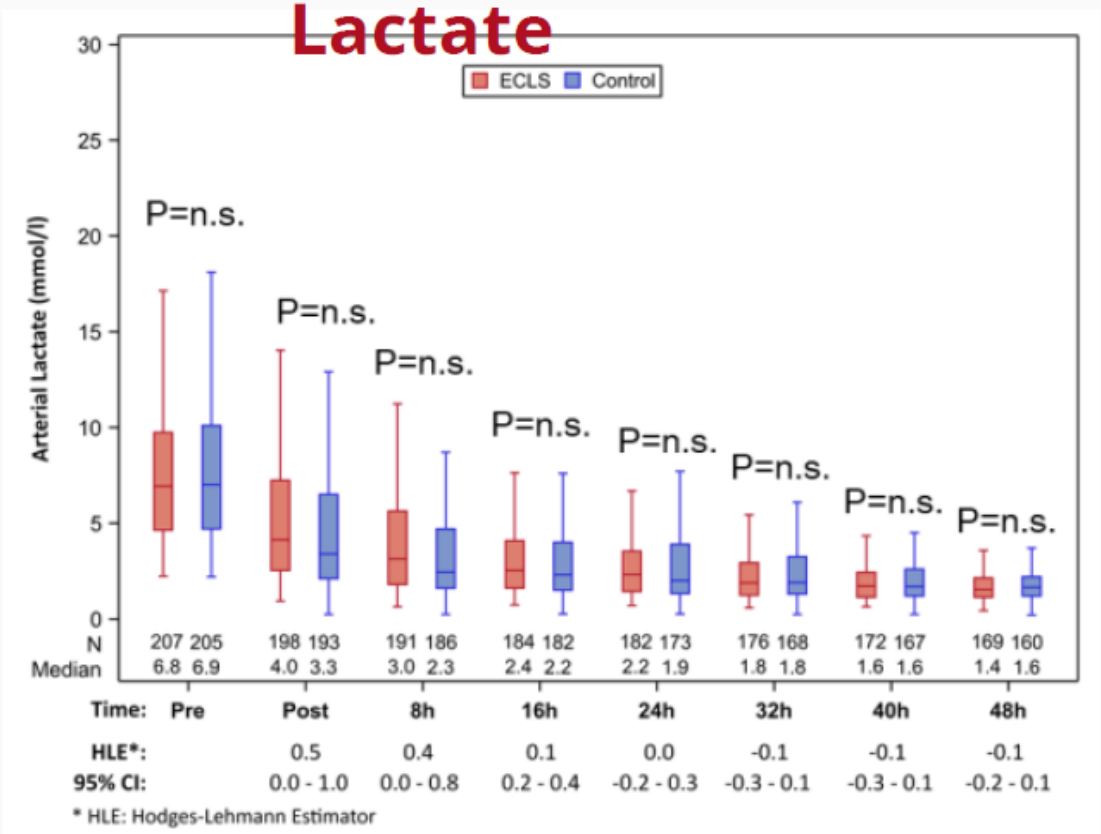
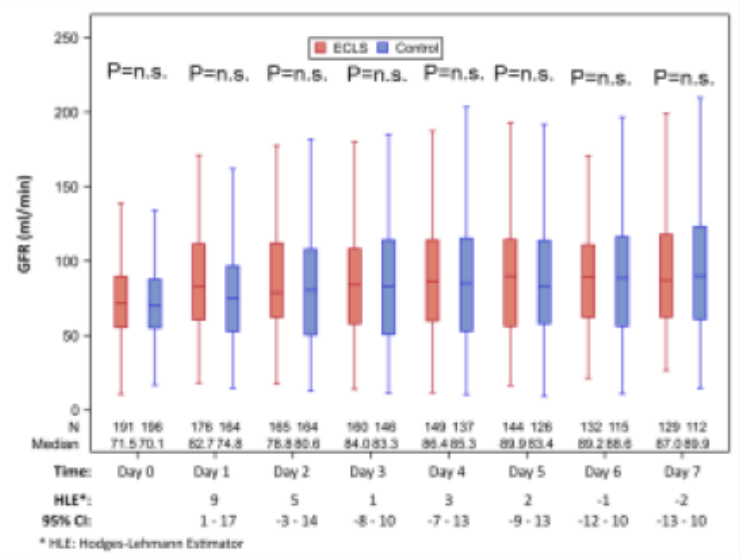
Key Secondary Endpoints

ECLS-SHOCK

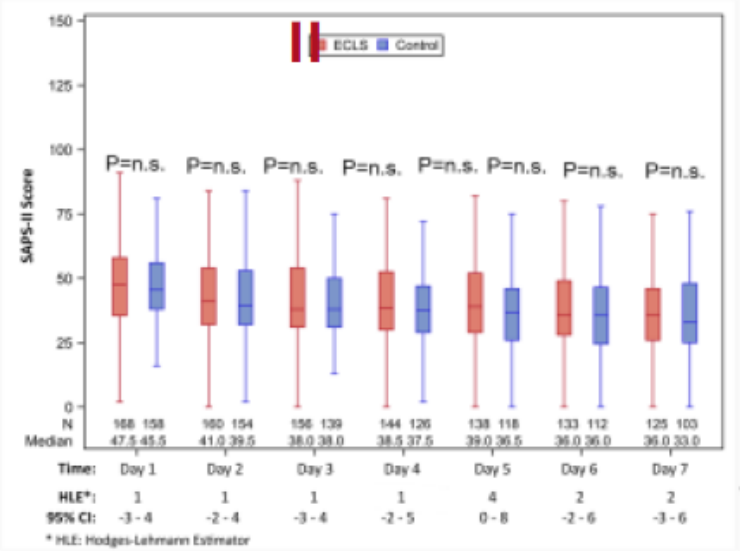
Arterial Lactate



Renal Function -



SAPS-II



Resul
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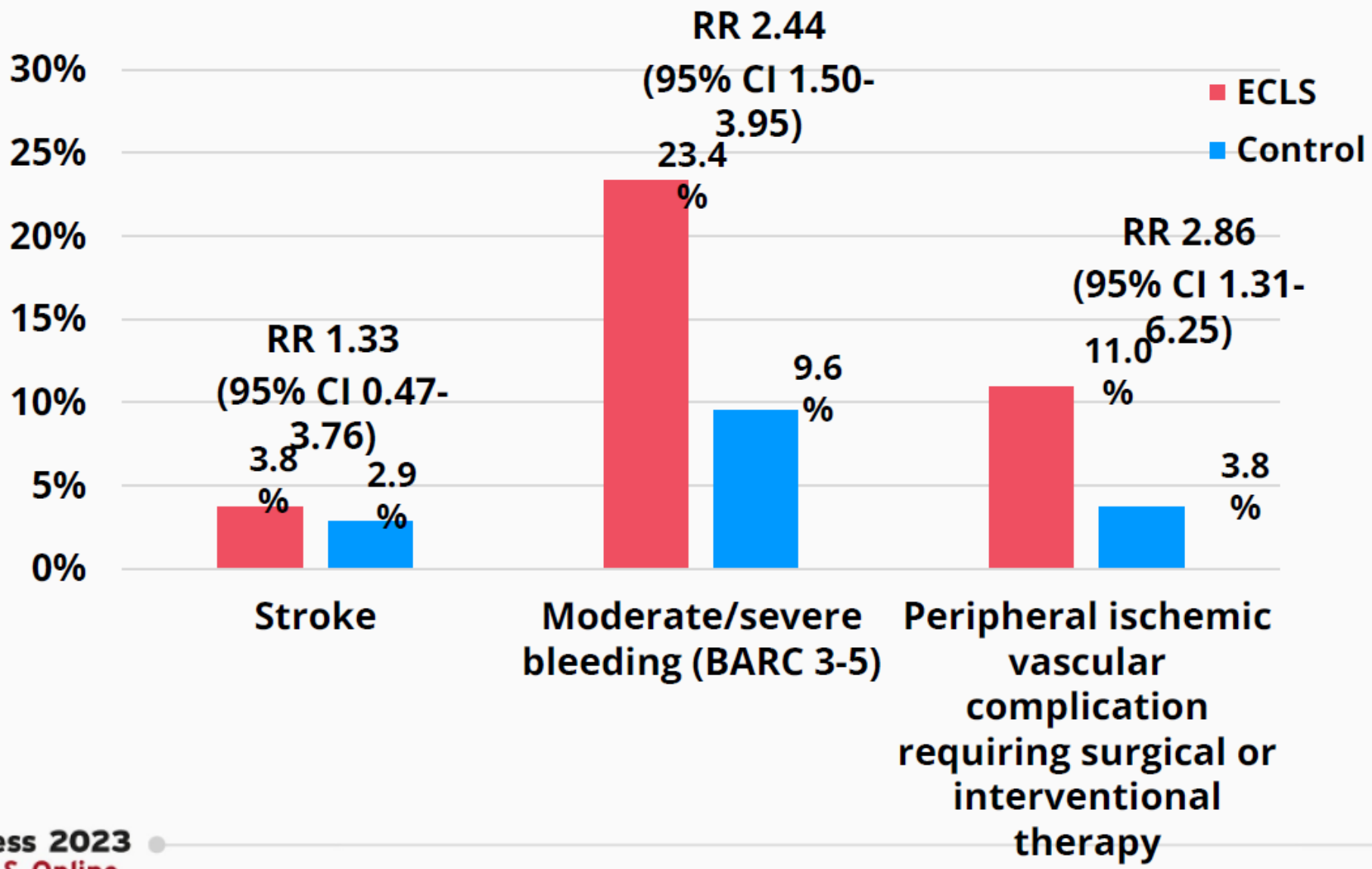
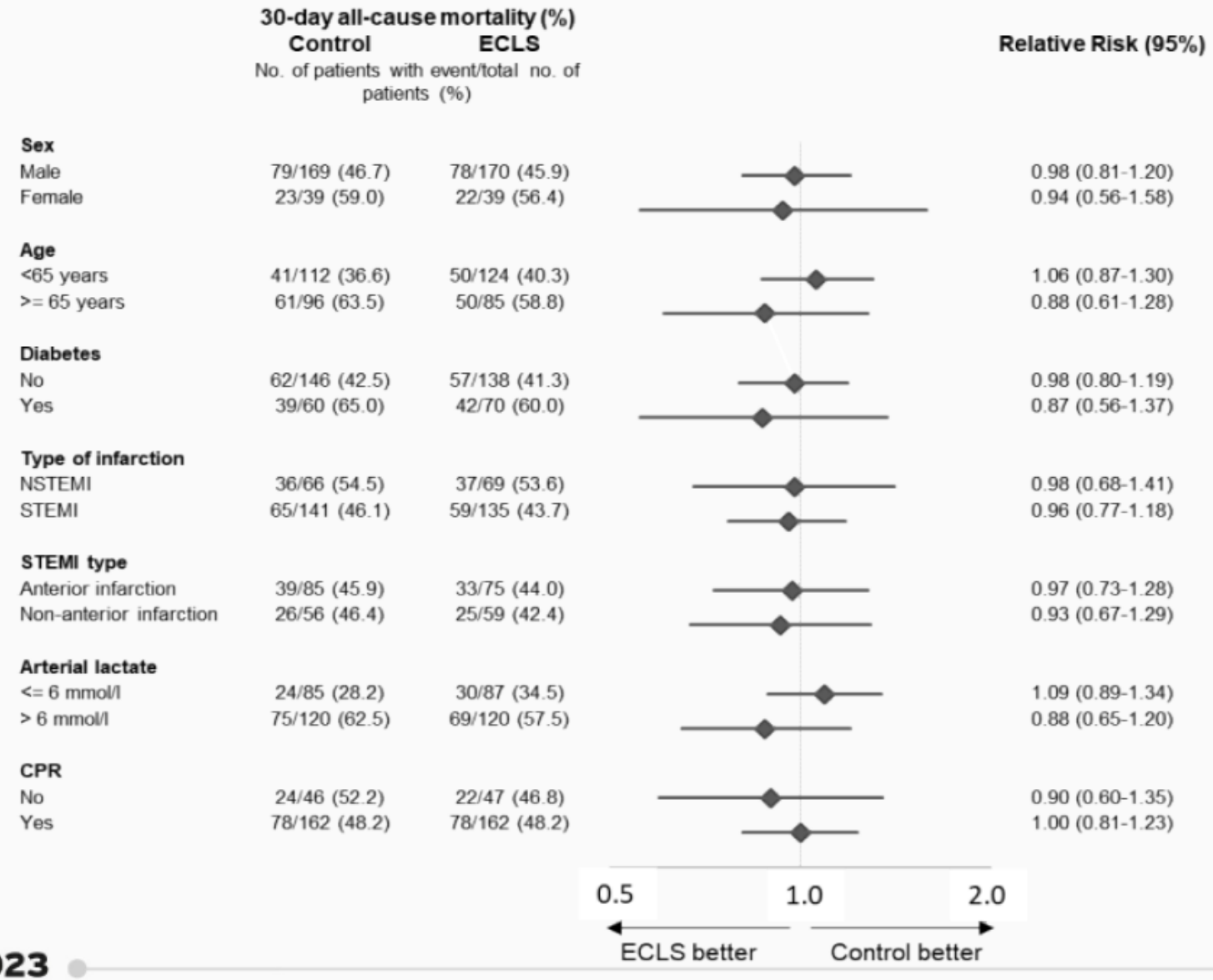
Safety



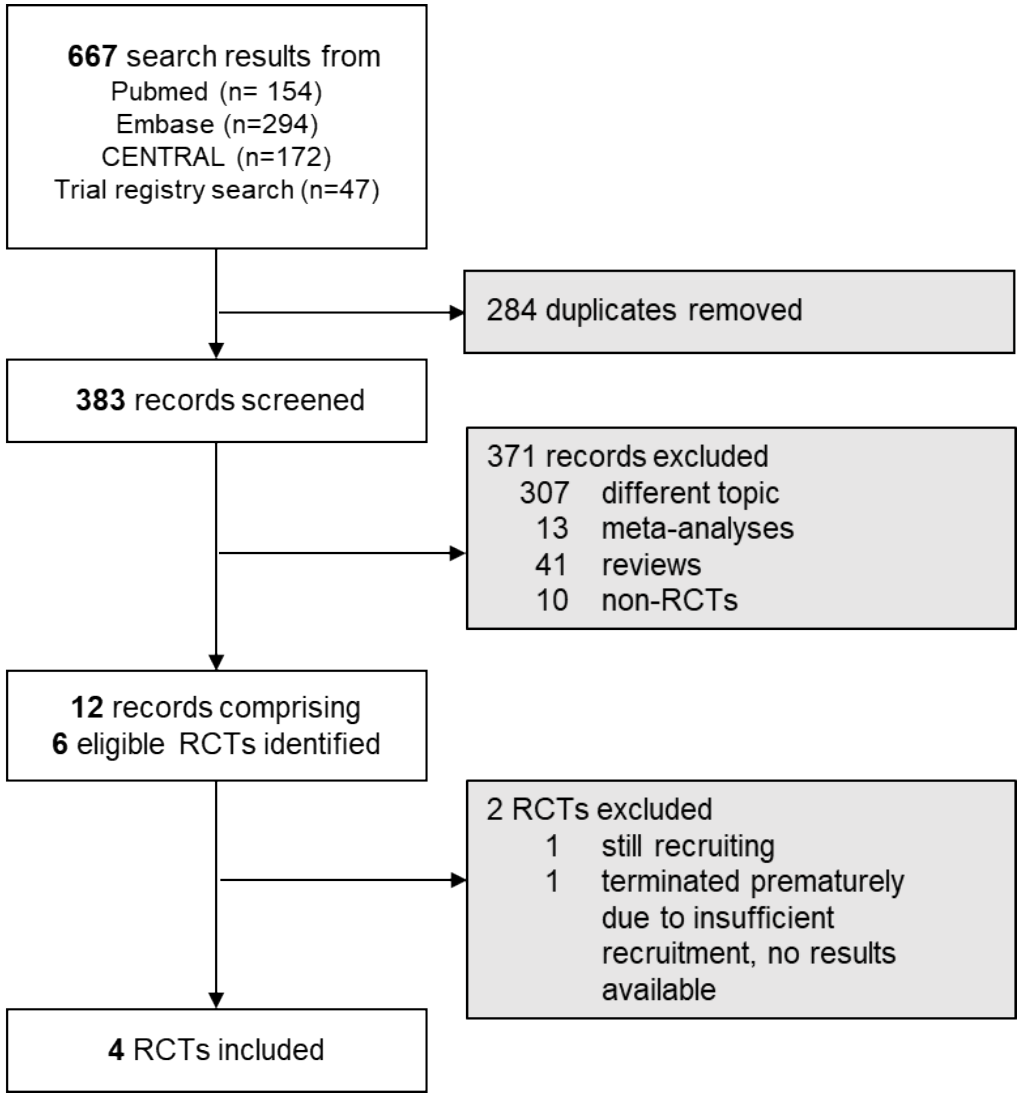
Results

30-Day All-Cause Mortality - Subgroups

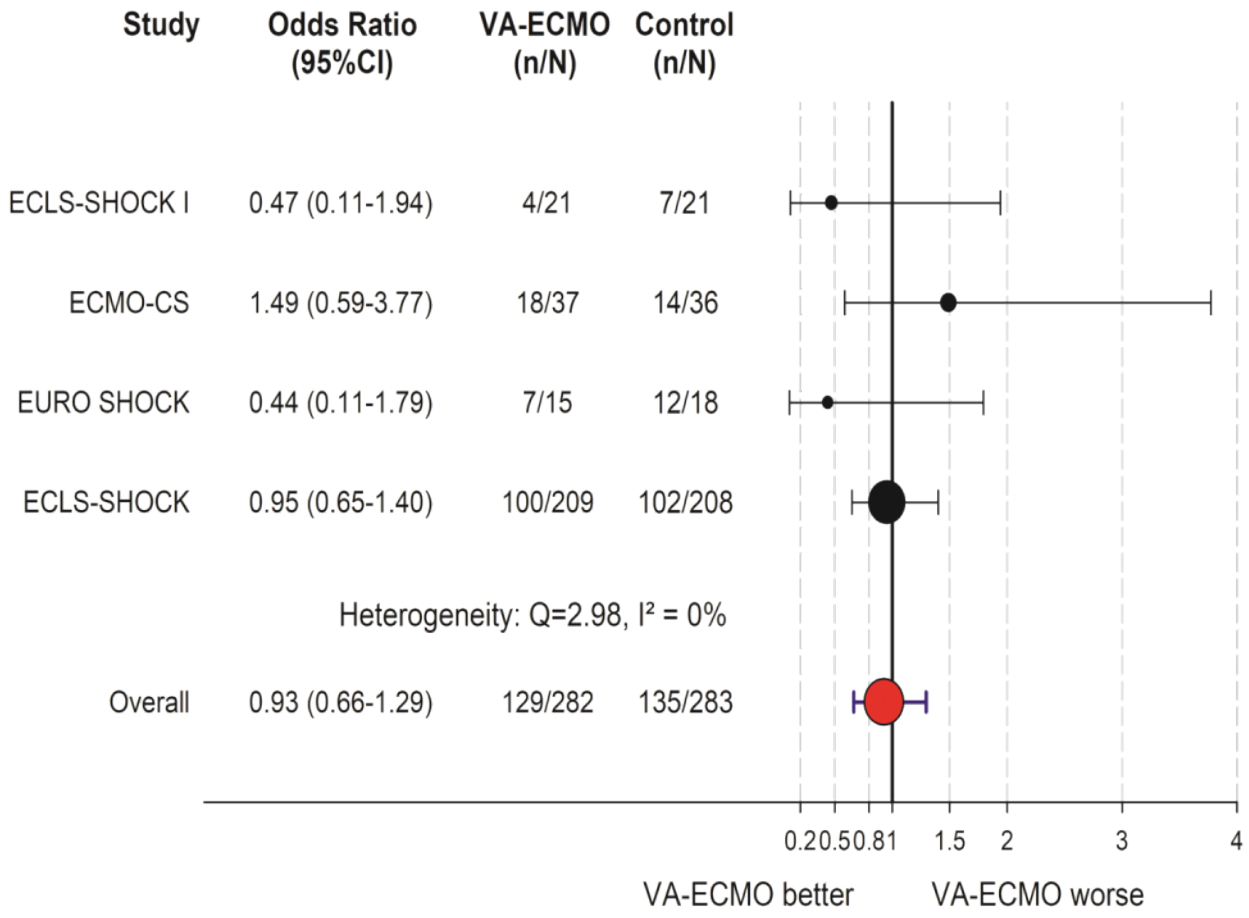
ECLS-SHOCK

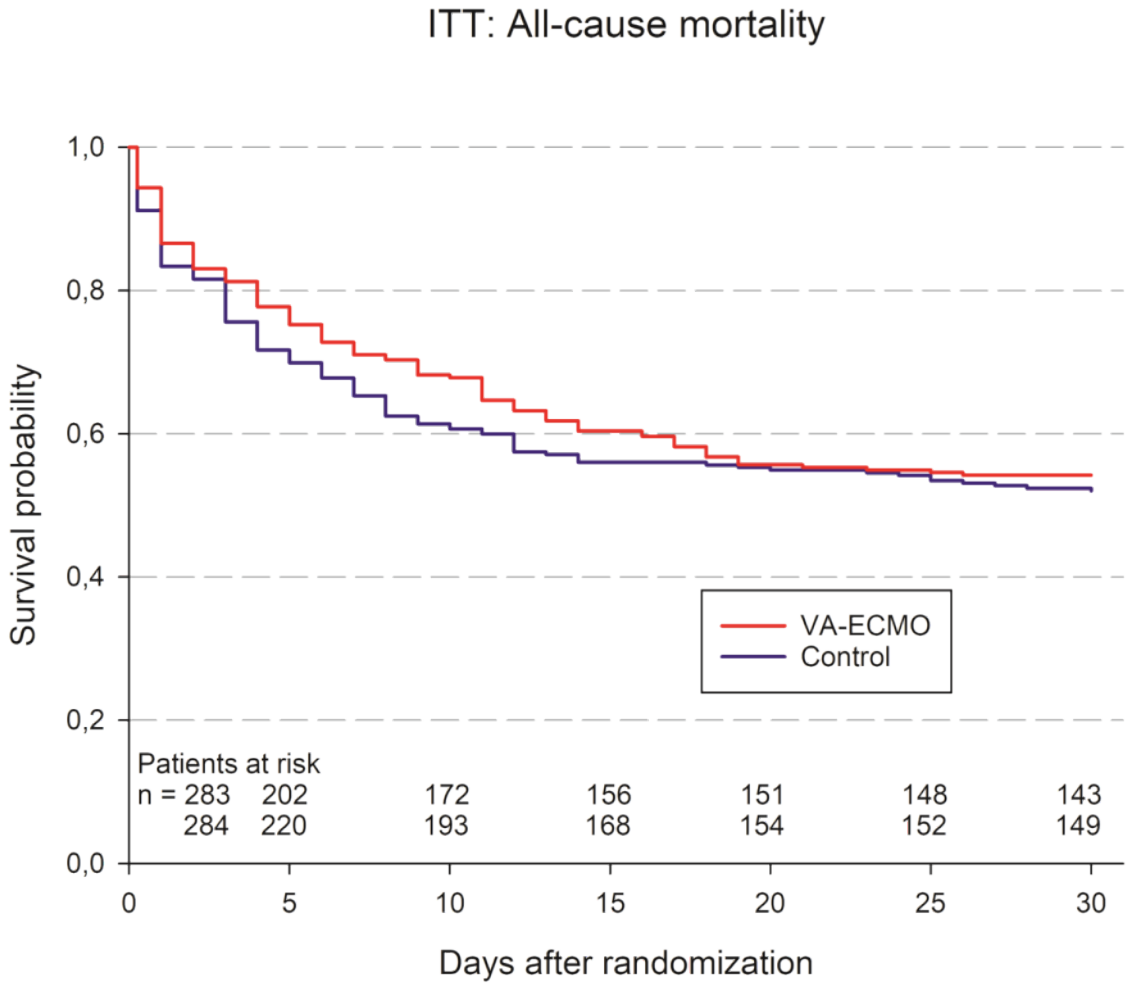


IPD Metaanalysis – VA-ECMO vs Control



IPD Metaanalysis – 30-Day All-Cause Mortality





Zeymer et al. Lancet 2023;epub

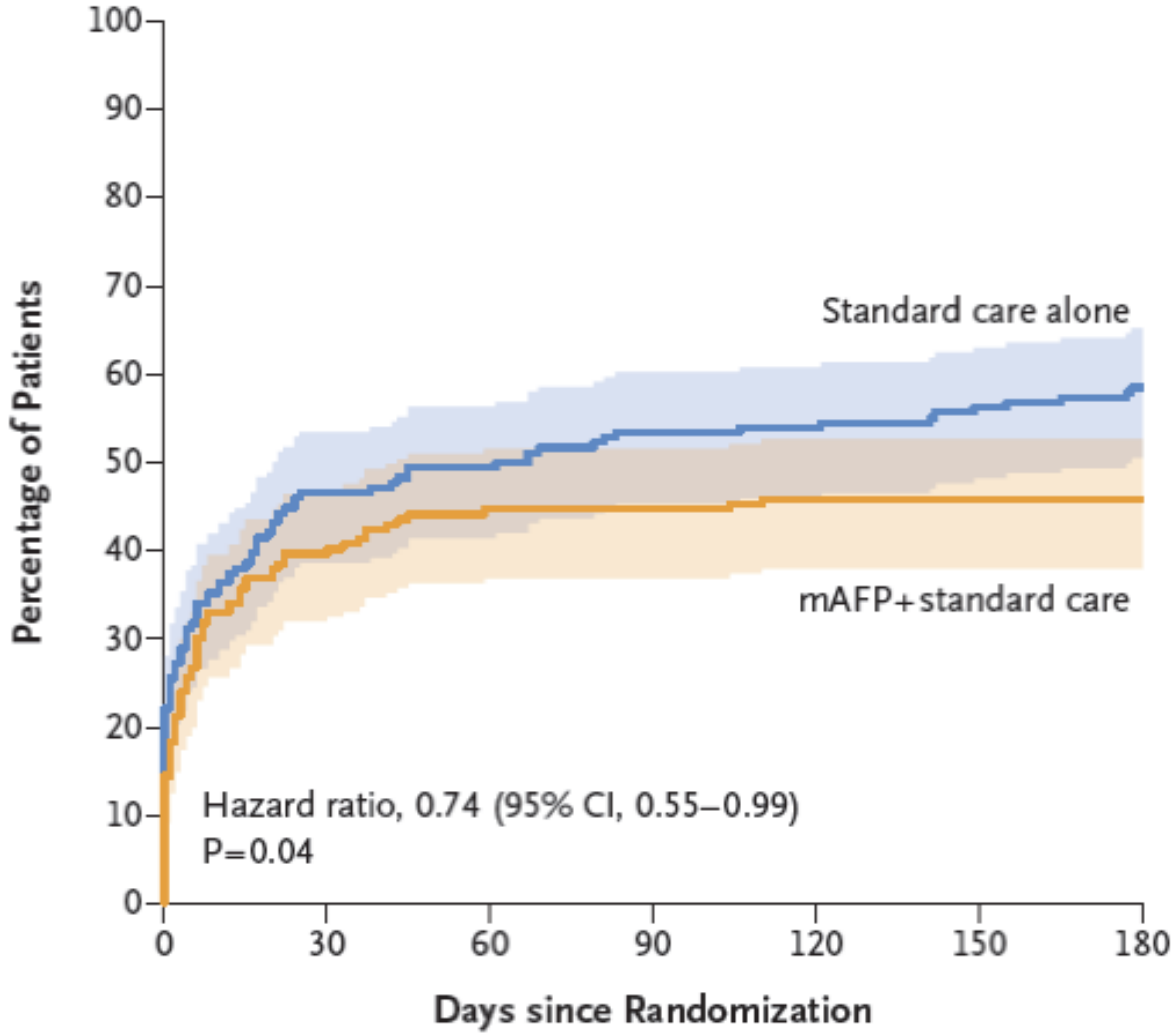
The NEW ENGLAND JOURNAL of MEDICINE

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*

A Death from Any Cause



No. at Risk							
Standard care	176	94	89	82	81	77	72
mAFP+standard care	179	108	99	99	97	97	97

SELECTION BIAS

Study organization

This study is an investigator-initiated trial with a lead principal investigator, JEM and a steering committee responsible for the scientific content of the protocol and the conduct of the study. The trial was initially approved by the Danish National Ethical Committee in November 2012 (H-2-2012-034) and registered at ClinicalTrials.gov (NCT01633502). In January 2013, the first patient was enrolled and the study was initially planned to end in 2018 including only Danish patients (DANSHOCK). The clinical landscape in Denmark is unique as 4 specialized invasive centers (Rigshospitalet Copenhagen, Odense, Skejby, and Aalborg) provide primary PCI service for the entire country. Hence, almost 3000 patients are annually triaged by wireless transmission of ECG recording and a short history from the ambulance and referred to acute angiography for suspected STEMI with minimal time delay. However, despite this, enrollment rate has been prolonged with only 100 patients randomized until end of June 2018. Slow enrollment is mainly due to lower than the anticipated incidence rate of shock, according to the inclusion criteria and a higher rate of exclusion (described in detail in the discussion section). This led to a change in study composition in 2018. To increase the enrollment rate, additional German sites with high volume of PCI procedures and experience with mechan-

4 danish high-volume centers (3000 STEMI/year)

1/2013 to 6/2018

5.5 years → 16/17000 STEMI

↓

100 CS STEMI (0.6%)

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

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

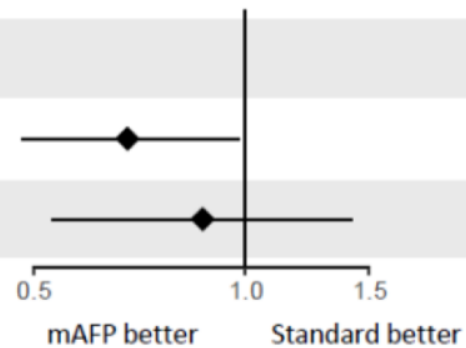
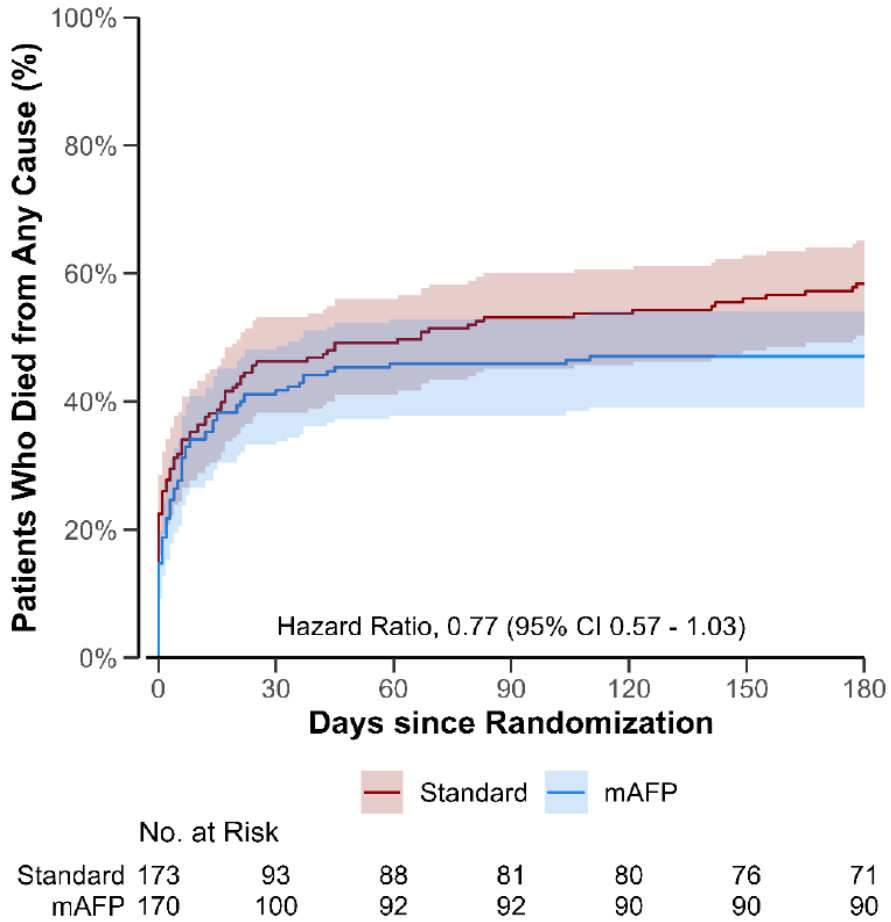


Figure S4. Death from Any Cause at 180 Days for the As-treated Groups.



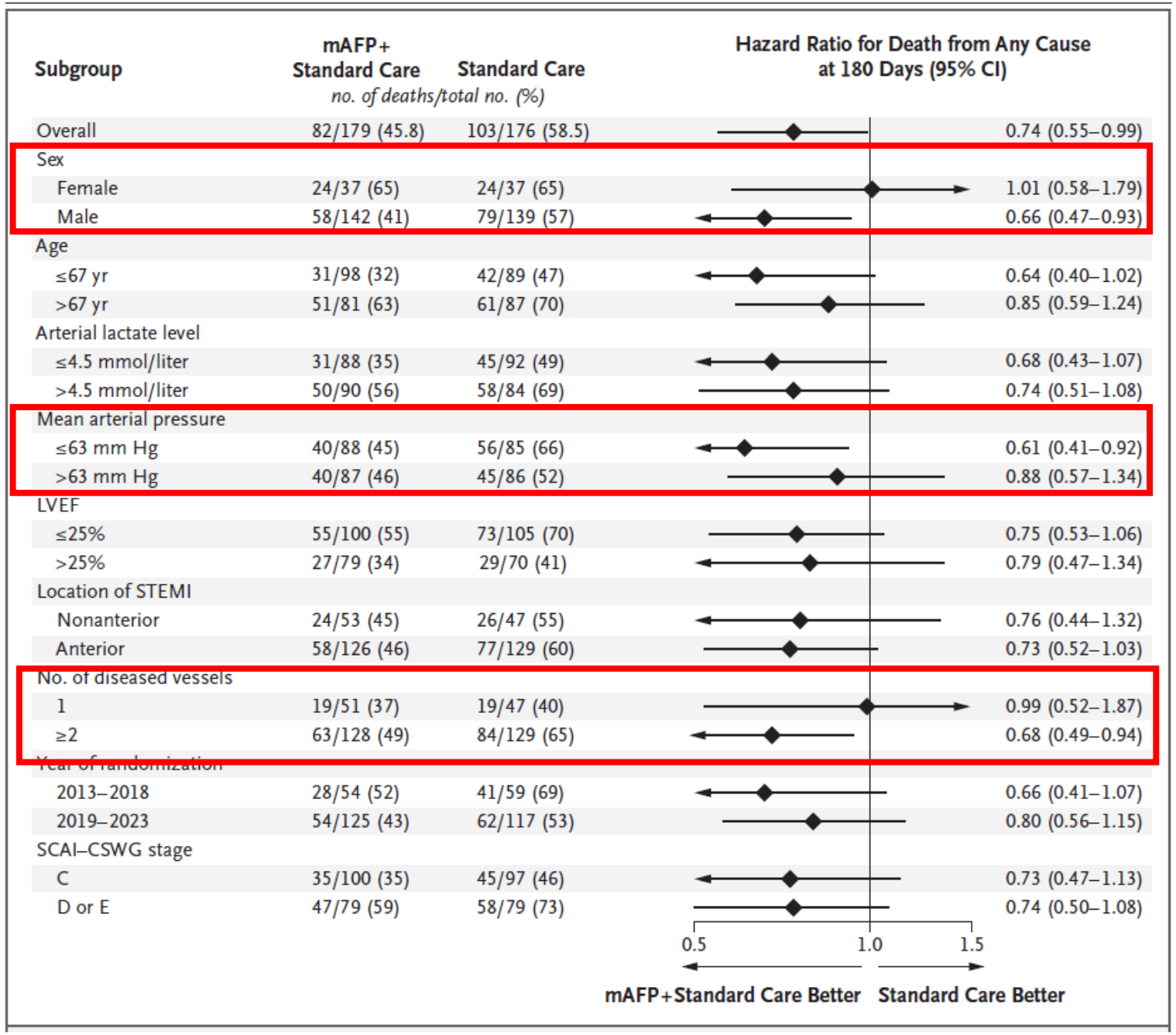
The figure shows the time-to-event curves for the primary endpoint (death from any cause at 180 days). The patients assigned to the microaxial flow pump group compared with those who received only standard care. The hazard ratio presented is from an unadjusted analysis. Patients who did not receive the microaxial flow pump in the microaxial flow pump group (N=9) and patients receiving the microaxial flow pump for hemodynamic instability in the standard care group (N=3) were excluded. The shaded areas indicate the 95% confidence intervals. The widths of the confidence intervals have not been adjusted for multiplicity and may not be used in place of hypothesis testing.

Table 3. End Points and Adverse Events in the Intention-to-Treat Population.*

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)

Table 2. Ongoing (Still Recruiting or Completed but Not Published) Randomized Trials in Cardiogenic Shock.*

Trial and ClincalTrials.gov No.	Type of Cardiogenic Shock	Experimental Intervention	Control	Sample Size	Primary End Point	Remarks
Mechanical circulatory support						
ECMO-RRT (NCT02870946)	AMI and HF	VA-ECMO plus RRT	VA-ECMO only	362	Mortality at 30 days	
HEMO-ECMO (NCT03729765)	AMI and HF	VA-ECMO plus hemo-perfusion	VA-ECMO	60	Change in IL-6 level at 3 days	
ANCHOR (NCT04184635)	AMI	VA-ECMO plus IABP	Best medical therapy	400	Mortality or VA-ECMO at 30 days	
UNLOAD-ECMO (NCT05577195)	AMI and HF	VA-ECMO plus Impella CP	VA-ECMO	198	Mortality at 30 days	Lactate level >5 mmol/liter for inclusion
ULYSS (NCT05366452)	AMI	Impella CP	Best medical therapy	204	Either composite of all-cause death, ECMO, LVAD, or heart transplantation at 30 days	
RECOVER IV (NCT05506449)	AMI	Impella CP	Best medical therapy including IABP	558	Mortality at 30 days	Stopped early for safety
ICONE (NCT05699005)	AMI and HF	Individualized transfusion during VA-ECMO	Conventional transfusion during VA-ECMO	138	Total number of PRBCs transfused during support, adjusted for VA- ECMO duration	
REMAP ECMO (NCT05913622)	AMI and HF	VA-ECMO plus IABP	VA-ECMO	430	Successful weaning from VA-ECMO at 30 days	Bayesian analysis, adaptive design


Subgroup
mAFP+ Standard Care
Standard Care
no. of deaths/total no. (%)
Hazard Ratio for Death from Any Cause at 180 Days (95% CI)
Overall 82/179 (45.8) 103/176 (58.5) 0.74 (0.55–0.99)
Sex
Female 24/37 (65) 24/37 (65) 1.01 (0.58–1.79)
Male 58/142 (41) 79/139 (57) 0.66 (0.47–0.93)
Age
≤67 yr 31/98 (32) 42/89 (47) 0.64 (0.40–1.02)
>67 yr 51/81 (63) 61/87 (70) 0.85 (0.59–1.24)
Arterial lactate level
≤4.5 mmol/liter 31/88 (35) 45/92 (49) 0.68 (0.43–1.07)
>4.5 mmol/liter 50/90 (56) 58/84 (69) 0.74 (0.51–1.08)
Mean arterial pressure
≤63 mm Hg 40/88 (45) 56/85 (66) 0.61 (0.41–0.92)
>63 mm Hg 40/87 (46) 45/86 (52) 0.88 (0.57–1.34)
LVEF
≤25% 55/100 (55) 73/105 (70) 0.75 (0.53–1.06)
>25% 27/79 (34) 29/70 (41) 0.79 (0.47–1.34)
Location of STEMI
Nonanterior 24/53 (45) 26/47 (55) 0.76 (0.44–1.32)
Anterior 58/126 (46) 77/129 (60) 0.73 (0.52–1.03)
No. of diseased vessels
1 19/51 (37) 19/47 (40) 0.99 (0.52–1.87)
≥2 63/128 (49) 84/129 (65) 0.68 (0.49–0.94)
Year of randomization
2013–2018 28/54 (52) 41/59 (69) 0.66 (0.41–1.07)
2019–2023 54/125 (43) 62/117 (53) 0.80 (0.56–1.15)
SCAI–CSWG stage
C 35/100 (35) 45/97 (46) 0.73 (0.47–1.13)
D or E 47/79 (59) 58/79 (73) 0.74 (0.50–1.08)
0.5
1.0
1.5
mAFP+Standard Care Better
Standard Care Better

MECHANICAL SUPPORT IN CARDIOGENIC SHOCK

1) RATIONALE

2) CLINICAL EVIDENCE

3) PREPROCEDURAL OR POSTPROCEDURAL?

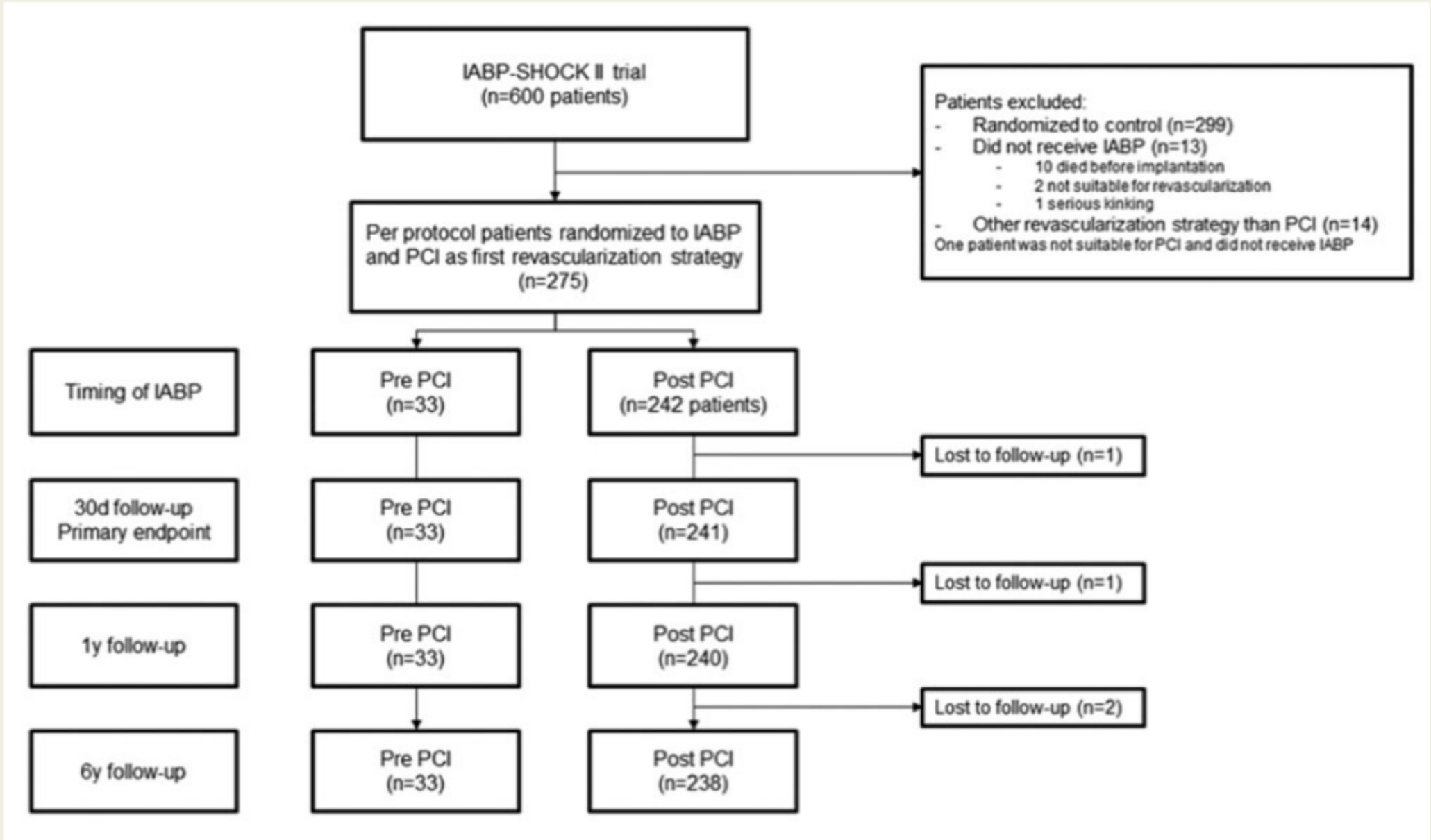


Figure 1 Study flow. IABP: intraaortic balloon pump; PCI: percutaneous coronary intervention.

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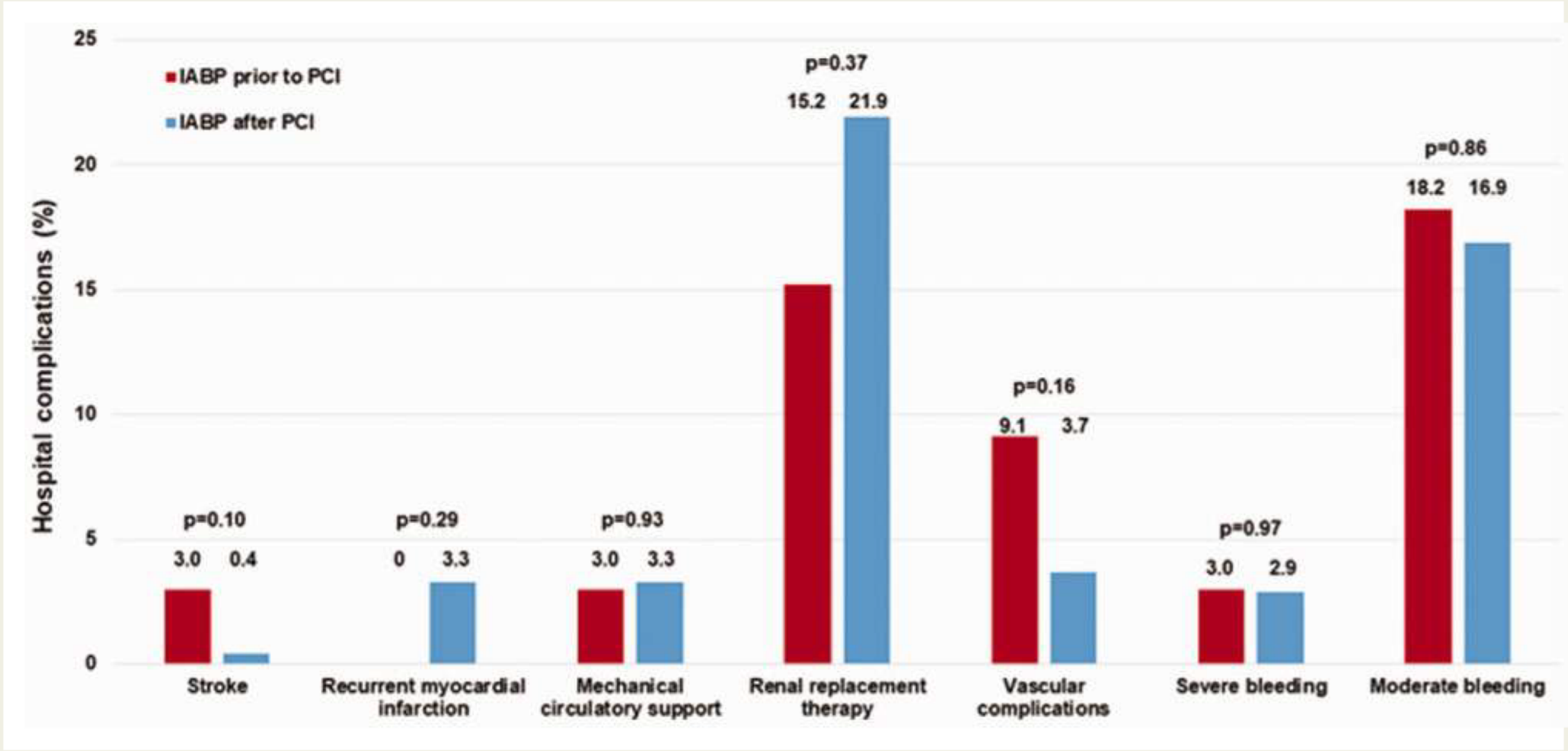
Table 1 Baseline characteristics

Haemoglobin, mmol/l	8.7 (7.7–9.1)	8.1 (7.1–9.0)	0.16
Leukocytes, 10^9/l	12.2 (9.7–16.1)	13.4 (10.3–18.3)	0.35
SAPS-II score at baseline	55 (38–67)	51 (37–66)	0.60

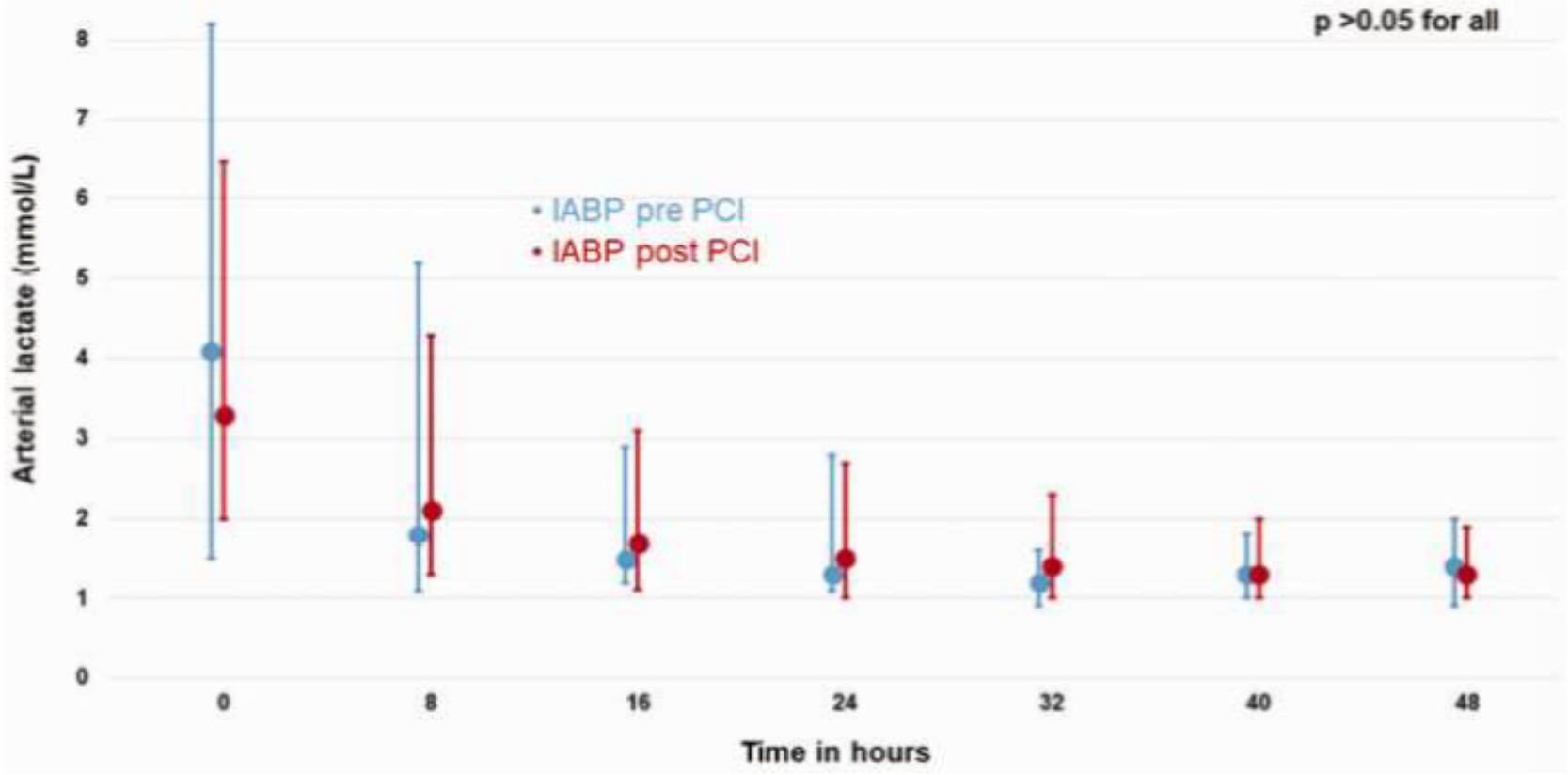
Table 2 Procedural data

	IABP prior to PCI 33 (12%)	IABP after PCI 242 (88%)	*p*-value
Number of diseased vessels			0.99
One	21% (7/33)	21% (50/242)	
Two	27% (9/33)	29% (69/242)	
Three	52% (17/33)	51% (123/242)	
Infarct related artery			0.46
Left main coronary artery	9% (3/33)	9% (21/242)	
LAD	46% (15/33)	47% (113/242)	
LCX	12% (4/33)	19% (47/242)	
RCA	27% (9/33)	24% (57/242)	
Bypass graft	6% (2/33)	2% (4/242)	
Revascularization technique			
Drug eluting stent	76% (25/33)	43% (98/230)	<0.001
Bare metal stent	24% (8/33)	59% (136/230)	<0.001
Angioplasty only	0% (0/33)	5% (12/242)	0.19
Thrombus aspiration	45% (15/33)	24% (59/242)	0.01
Glycoprotein IIb/IIIa inhibitor use	49% (16/33)	49% (118/242)	0.98
TIMI flow 0 before PCI	67% (22/33)	60% (145/242)	0.46
TIMI flow 3 after PCI	94% (31/33)	82% (199/242)	0.08

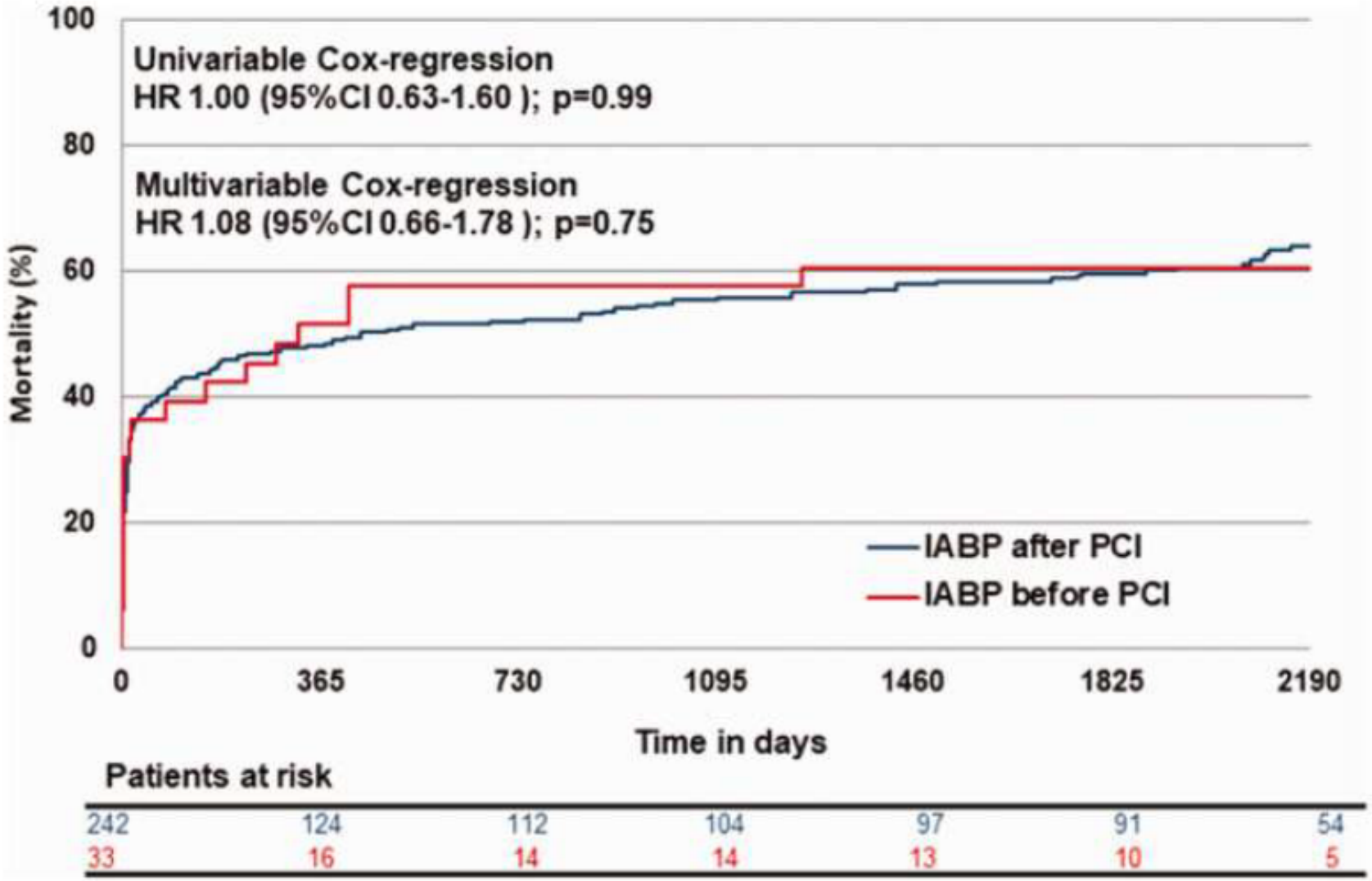
HOSPITAL COMPLICATIONS



TIMING OF IABP AND LACTATE LEVELS



LONG-TERM ALL CAUSE MORTALITY



DANGER SHOCK Trial: Timing of randomization

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)

DANGER SHOCK Trial: Adjusted outcome analysis

Adjusted Cox Proportional Hazards Analyses*

A multiple Cox proportional hazards analysis was performed for primary and composite secondary end point with adjustment for the timing of randomization relative to percutaneous coronary intervention, localization of the myocardial infarction (anterior versus non-anterior), and country of randomization (Denmark versus Germany and the United Kingdom).

	Microaxial Flow Pump (N=179)	Standard Care (N=176)	Adjusted Hazard Ratio (95%CI)
Primary Outcome			
Death from any cause at 180 days – no. (%)	82 (45.8)	103 (58.5)	HR 0.74 (0.55 to 0.99)
Secondary Outcome			
Composite Cardiac Event – no. (%)	94 (52.5)	112 (63.6)	HR 0.73 (0.55 to 0.96)

CONCLUSIONI

Lo shock cardiogeno rappresenta tuttora il tallone d'achille della cardiologia (mortalità circa 50%)

Incidenza stabile negli anni (circa 4%), con una riduzione dell'incidenza di shock che si sviluppa durante l'ospedalizzazione

Nonostante i presupposti fisiopatologici, manca una forte evidenza di benefici dall'utilizzo routinario di sistemi di supporto meccanico nei pazienti con shock cardiogeno in corso di IMA

Studi randomizzati sono certamente necessari per identificare la migliore popolazione che può ottenere benefici da un supporto meccanico, soprattutto con l'Impella CP e nelle fasi molto precoci dello shock

Back-up slides

Between December 12, 2019 and September 3, 2024, 527 patients were randomized; 262 patients were assigned to the treatment group and 265 to the control group.

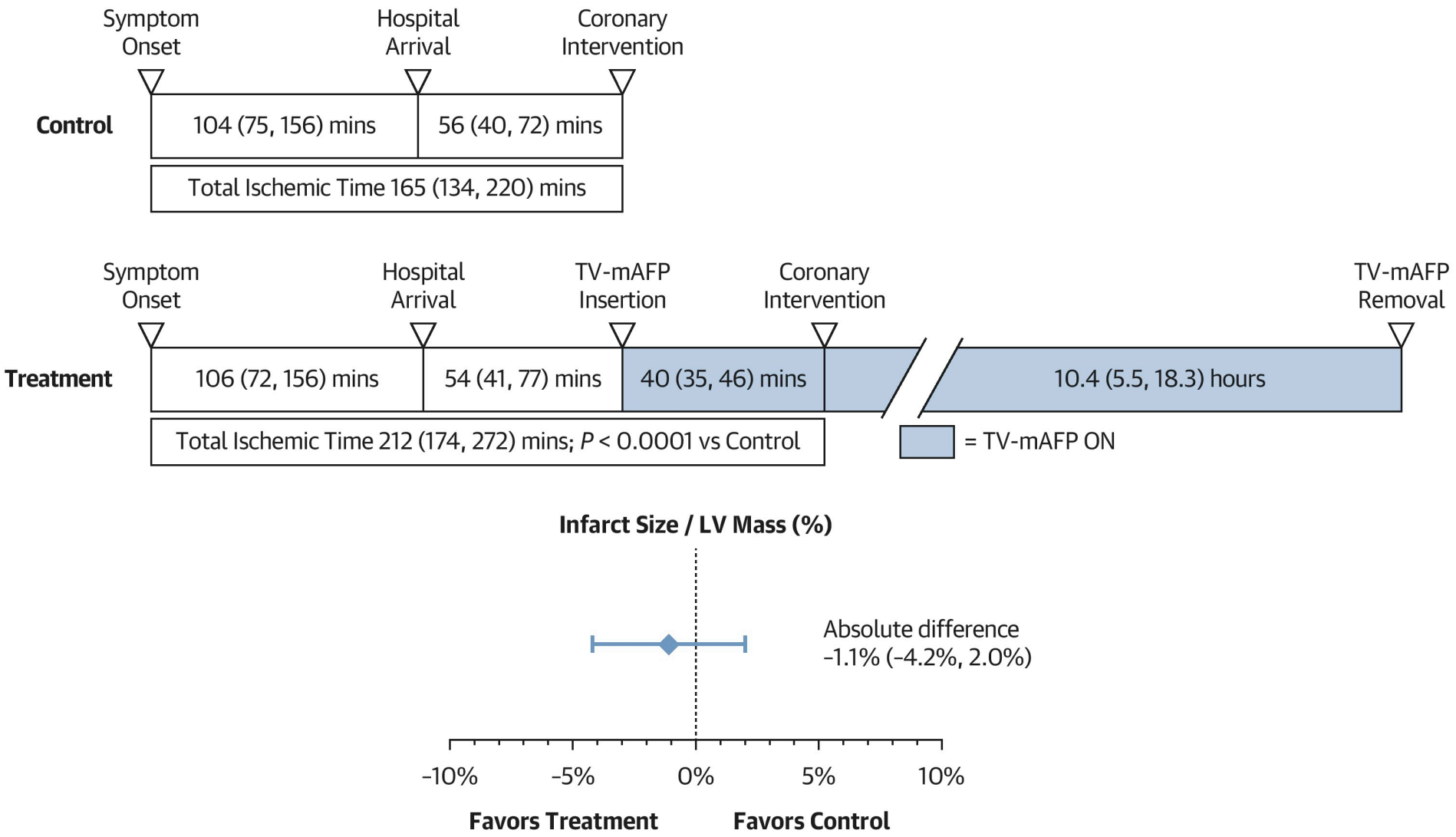
Total ischemic time was longer in the treatment arm.

IS/LVM was 30.8% ± 16.2% in the treatment group and 31.9% ± 16.9% in the control group (mean difference: –1.1%; 95% CI: –4.2 to 2.0; P = 0.50).

Major bleeding or vascular complications at 30-day follow-up occurred more frequently in the treatment group when compared with either a prespecified performance goal or the control group.

Kapur NK et al. JACC 2026

CENTRAL ILLUSTRATION: Ischemic Time and Infarct Size in the STEMI-DTU Trial



Kapur NK, et al. JACC. 2026;10.1016/j.jacc.2026.03.071

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Major bleeding or vascular complications at 30-day follow-up occurred more frequently in the treatment group when compared with either a prespecified performance goal or the control group.

Combination of a TV-mAFP plus delayed PCI did not reduce infarct size in patients with anterior STEMI without cardiogenic shock compared with PCI alone.

Kapur NK et al. JACC 2026