

**Randomized comparison of  
intraaortic balloon counterpulsation  
versus  
optimal medical therapy in addition to early  
revascularization in acute myocardial infarction  
complicated by cardiogenic shock**

Holger Thiele, MD

Uwe Zeymer, MD; Franz-Josef Neumann, MD; Miroslaw Ferenc,  
MD; Hans-Georg Olbrich, MD; Jörg Hausleiter, MD; Gert Richardt, MD;  
Marcus Hennersdorf, MD; Klaus Empen, MD; Georg Fuernau, MD; Steffen Desch, MD;  
Ingo Eitel, MD; Rainer Hambrecht, MD; Jörg Fuhrmann, MD; Michael Böhm, MD;  
Henning Ebelt, MD; Steffen Schneider, PhD;  
Gerhard Schuler, MD; Karl Werdan, MD

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

University of Leipzig – Heart Center

# Disclosures

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University of Leipzig – Heart Center

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## Potential Conflict of Interest:

### Research Funding:

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### Consulting:

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### Speaker Honoraria:

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## History:

**1962** Animal studies  
Moulopoulos et al. Am Heart J 1962;63:669-675

**1968** First clinical description in shock  
Kantrowitz et al. JAMA 1968;203:135-140

**1973** Hemodynamic effects in shock,  
Mortality unchanged  
Scheidt et al. NEJM 1973;288:979-984

**> 40 years** > 1 Million patients treated, low complication rate,  
Benchmark registry  
Ferguson et al. JACC 2001;38:1456-1462



## IABP in AMI complicated by cardiogenic shock

ESC



Class IC

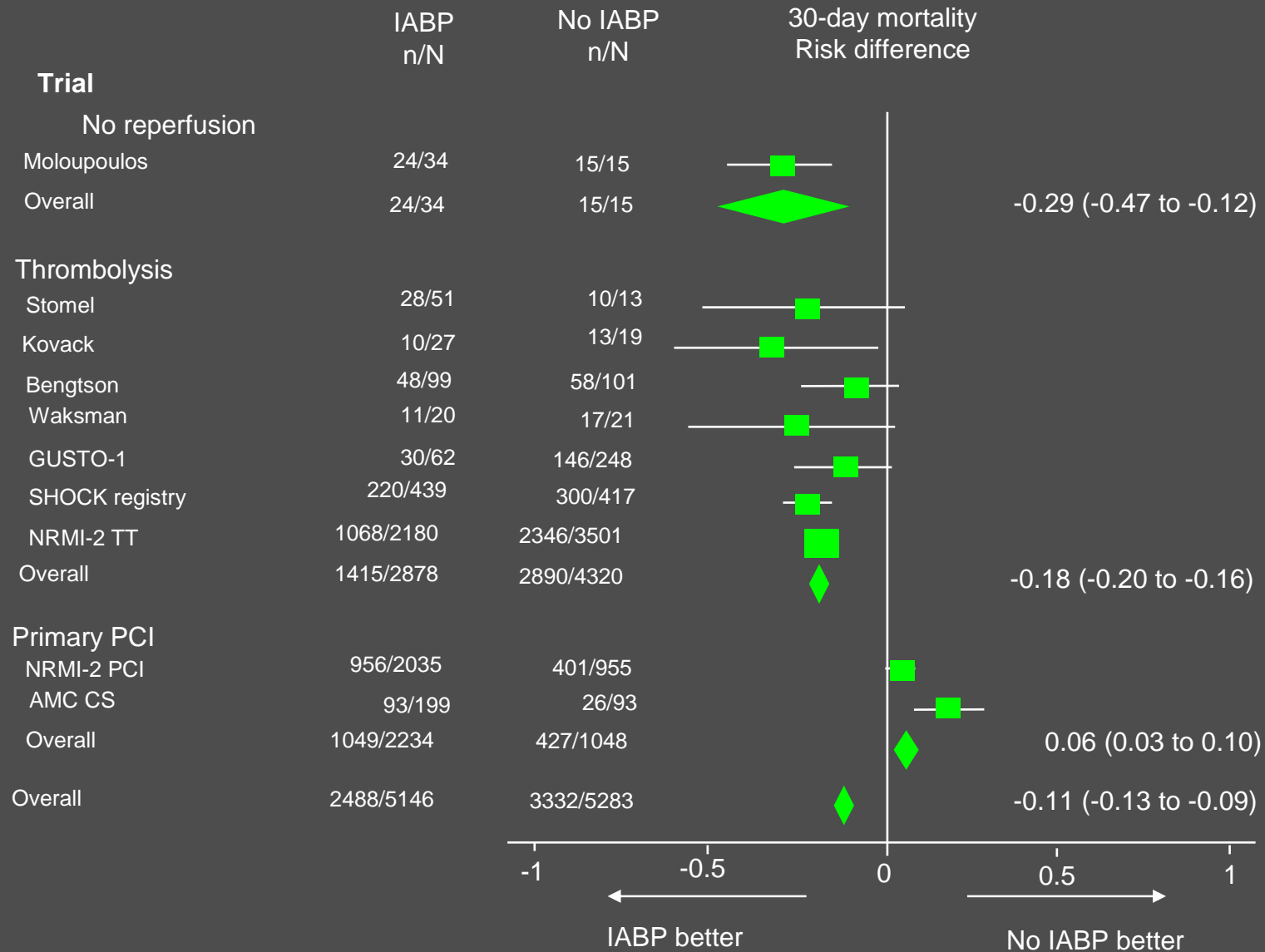
ACC/AHA



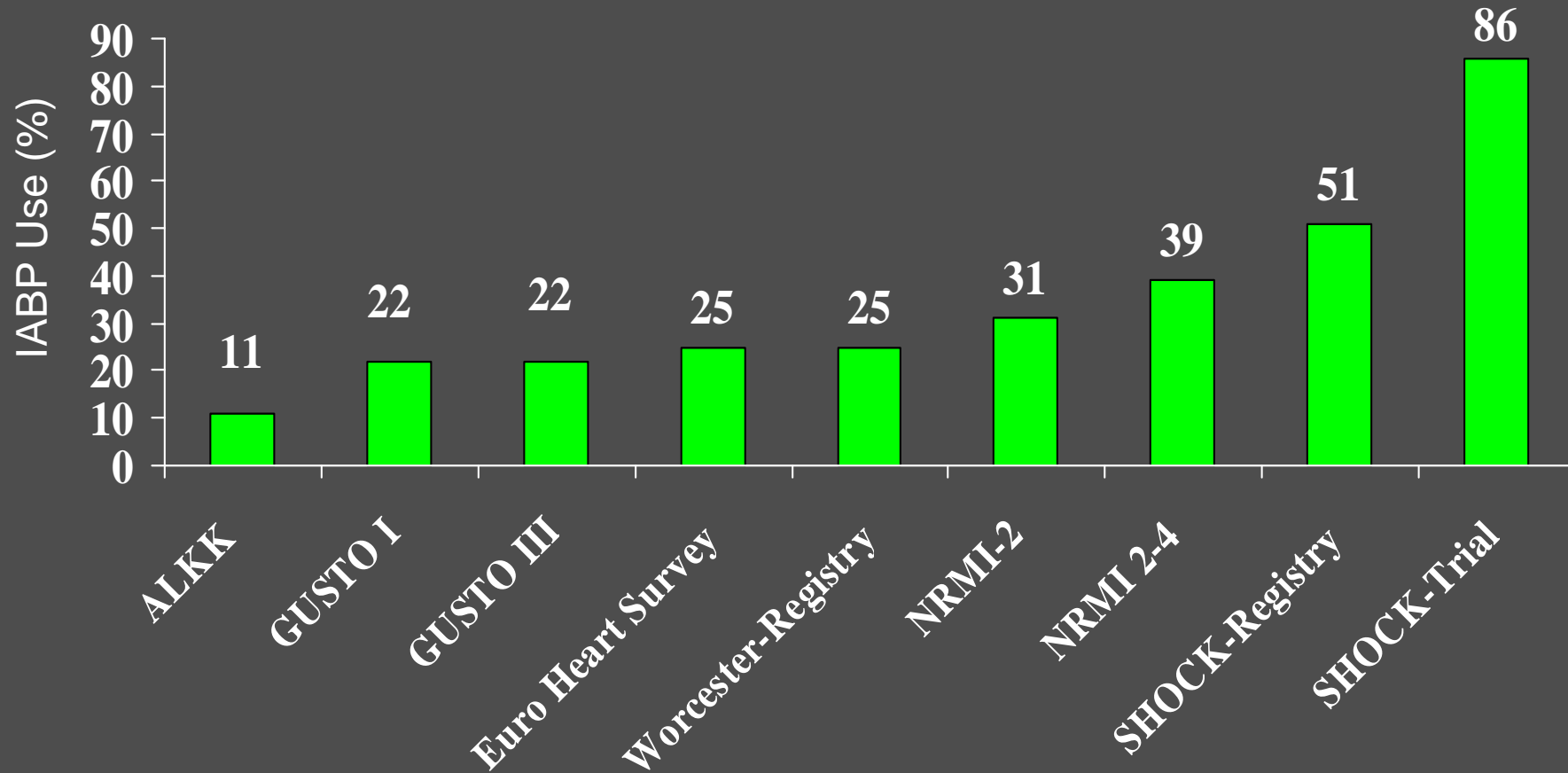
Class IB

Van de Werf et al. Eur Heart J 2008;29:2909-2945  
Wijns et al. Eur Heart J 2010;31:2501-2555  
Antman et al. Circulation 2004;110:82-292

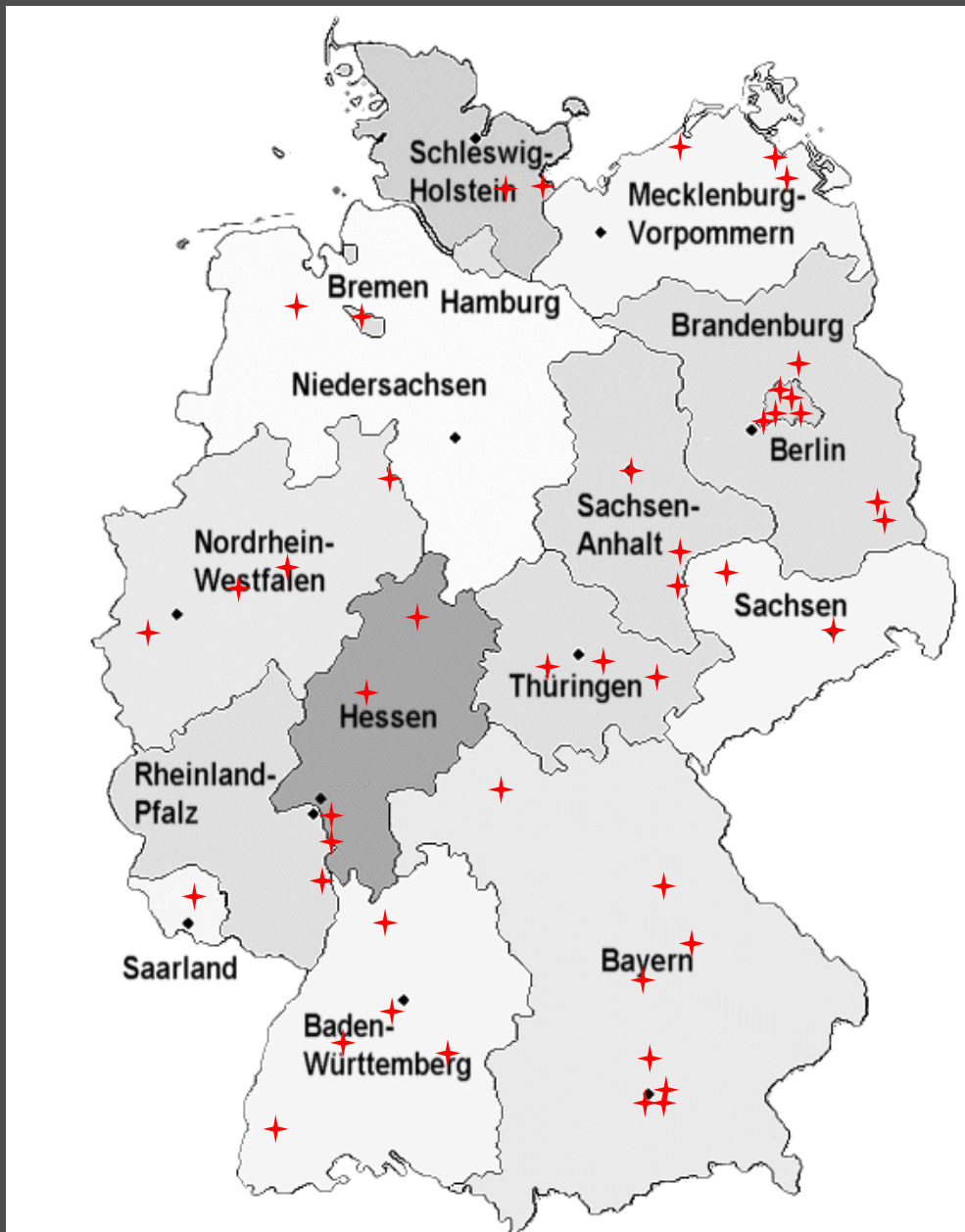
# Mortality IABP vs no IABP - Metaanalysis



# IABP-Use in Cardiogenic Shock



# Study Sites and Organisation



## DSMB:

Kurt Huber  
Ferenc Follath  
Bernhard Maisch  
Johannes Haerting

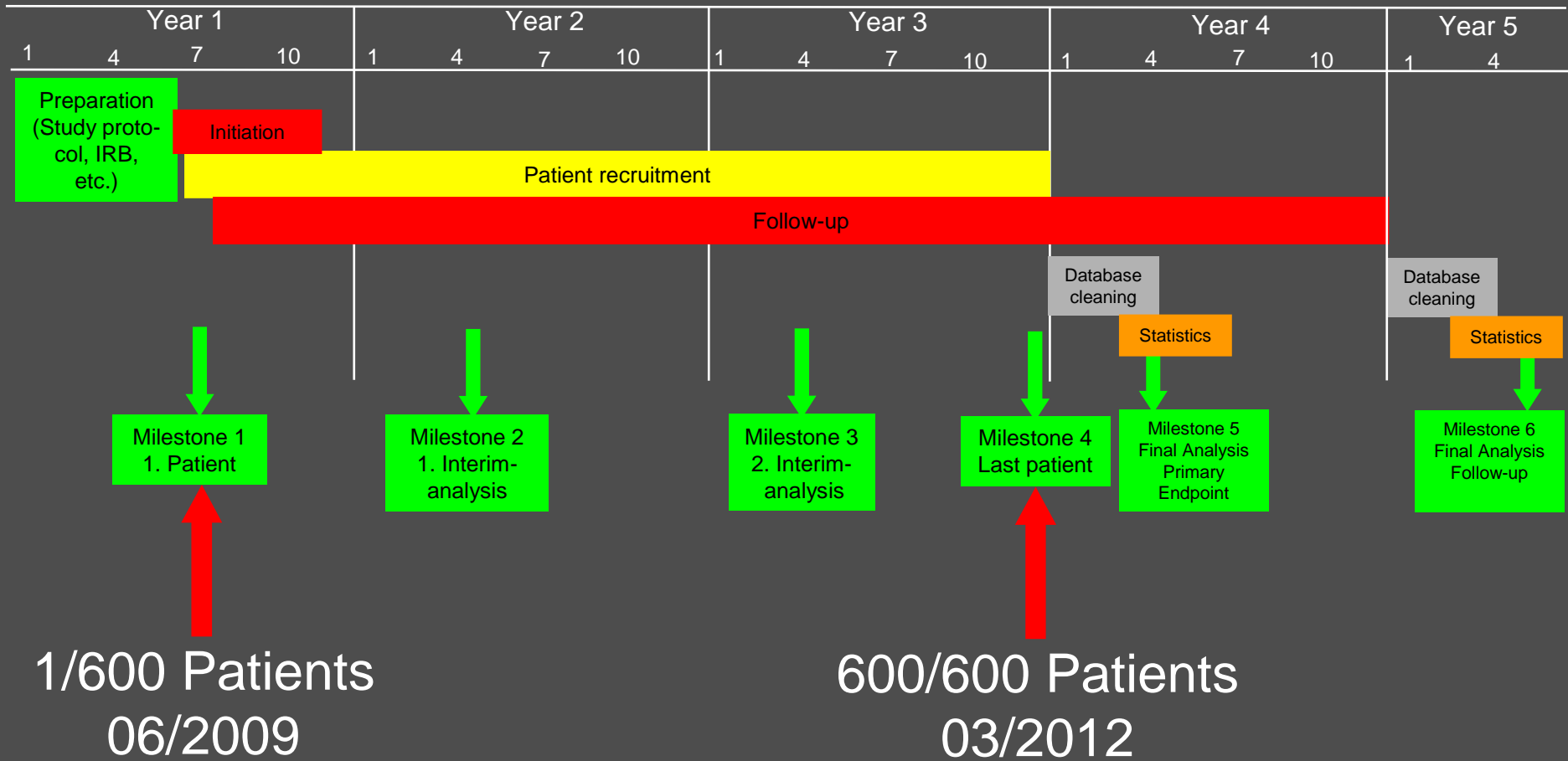
## Steering committee:

Holger Thiele  
Karl Werdan  
Uwe Zeymer  
Gerhard Schuler

## Support + Patronage:



# IABP-Shock-II Trial – Timelines





## Sample Size

- Estimated 12% absolute difference in survival rates
- Sequential statistical design with 2 interim analyses (33% and 66% of patients)
- Significance level 0.0005 at 1st or 0.014 at 2nd interim analysis.  
Final analysis at  $\alpha$ -level 0.044 → 564 patients
- To compensate losses in follow-up and putative center effect → 600 patients

## Primary Study Endpoint:

30-day all-cause mortality

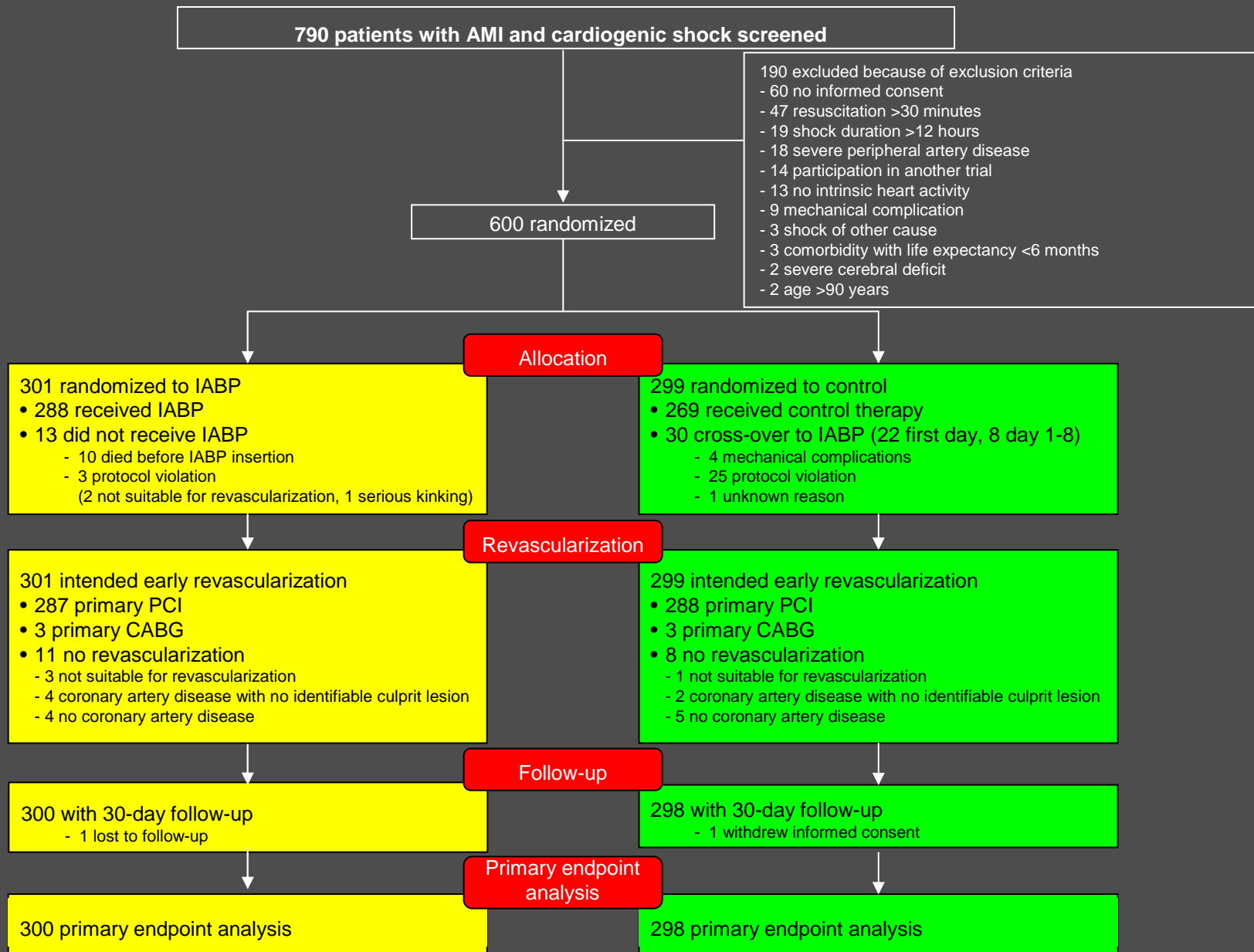
## Secondary Study Endpoints:

- Hemodynamic parameters (mean BP, heart rate pre and post revascularization)
- Serum-lactate (every 8 h for 48 h)
- SAPS-2 Score
- Serial creatinine-level and creatinine-clearance (Cockcroft-Gault-formula)
- Inflammatory reaction (CRP)

## Process of care

- Time until hemodynamic stabilization
- Catecholamine dose and duration
- Requirement for LVAD-implantation or HTx
- Requirement for renal replacement therapy
- Length of ICU-stay
- Length of mechanical ventilation
- Mortality after 6 and 12 months

# Trial Flow and Treatment



	IABP (n=301)	Control (n=299)
Age (years); median (IQR)	70 (58-78)	69 (58-76)
Male sex; n (%)	202 (67.1)	211 (70.6)
Current Smoking; n/total (%)	96/295 (32.5)	108/299 (36.1)
Hypertension; n/total (%)	213/296 (72.0)	199/299 (66.6)
Hypercholesterolemia; n/total (%)	122/295 (41.4)	105/299 (35.1)
Diabetes mellitus; n/total (%)	105/297 (35.4)	90/299 (30.1)
Body mass index (kg/m <sup>2</sup> ); median (IQR)	27.5 (24.7-30.1)	26.9 (24.7-29.4)
Prior myocardial infarction; n/total n (%)	71/300 (23.7)	61/299 (20.4)
Prior PCI; n/total n (%)	63/299 (21.1)	52/299 (17.4)
Prior CABG; n/total (%)	20/300 (6.7)	12/299 (4.0)
Fibrinolysis < 24 h before randomization; n/total (%)	28/301 (9.3)	20/299 (6.7)
STEMI/LBBB; n/total (%)	200/300 (66.7)	212/298 (71.1)
NSTEMI; n/total (%)	96/300 (32.0)	81/298 (27.2)
Resuscitation before randomization; n/total (%)	127/301 (42.2%)	143/299 (47.8)
Signs of impaired organ perfusion; n/total (%)		
Altered mental status	215/300 (71.7)	232/299 (77.6)
Cold, clammy skin and extremities	257/300 (85.7)	245/299 (81.9)
Oliguria	90/300 (30.0)	99/299 (33.1)
Serum lactate >2.0 mmol/l	226/300 (75.3)	218/298 (73.2)
Creatinine clearance (ml/min); median (IQR)	60.7 (43.4-86.6)	56.8 (39.7-78.1)
Infarct related artery; n/total (%)		
LAD	132/293 (45.1)	121/293 (41.3)
LCX	55/293 (18.8)	57/293 (19.5)
RCA	73/293 (24.9)	79/293 (27.0)
Left main	26/293 (8.9)	28/293 (9.6)
Bypass graft	7/293 (2.4)	8/293 (2.7)
Multivessel disease; n/total (%)	235/296 (79.4)	228/293 (77.9)
Left ventricular ejection fraction (%); median (IQR)	35 (25-45)	35 (25-45)

## Results

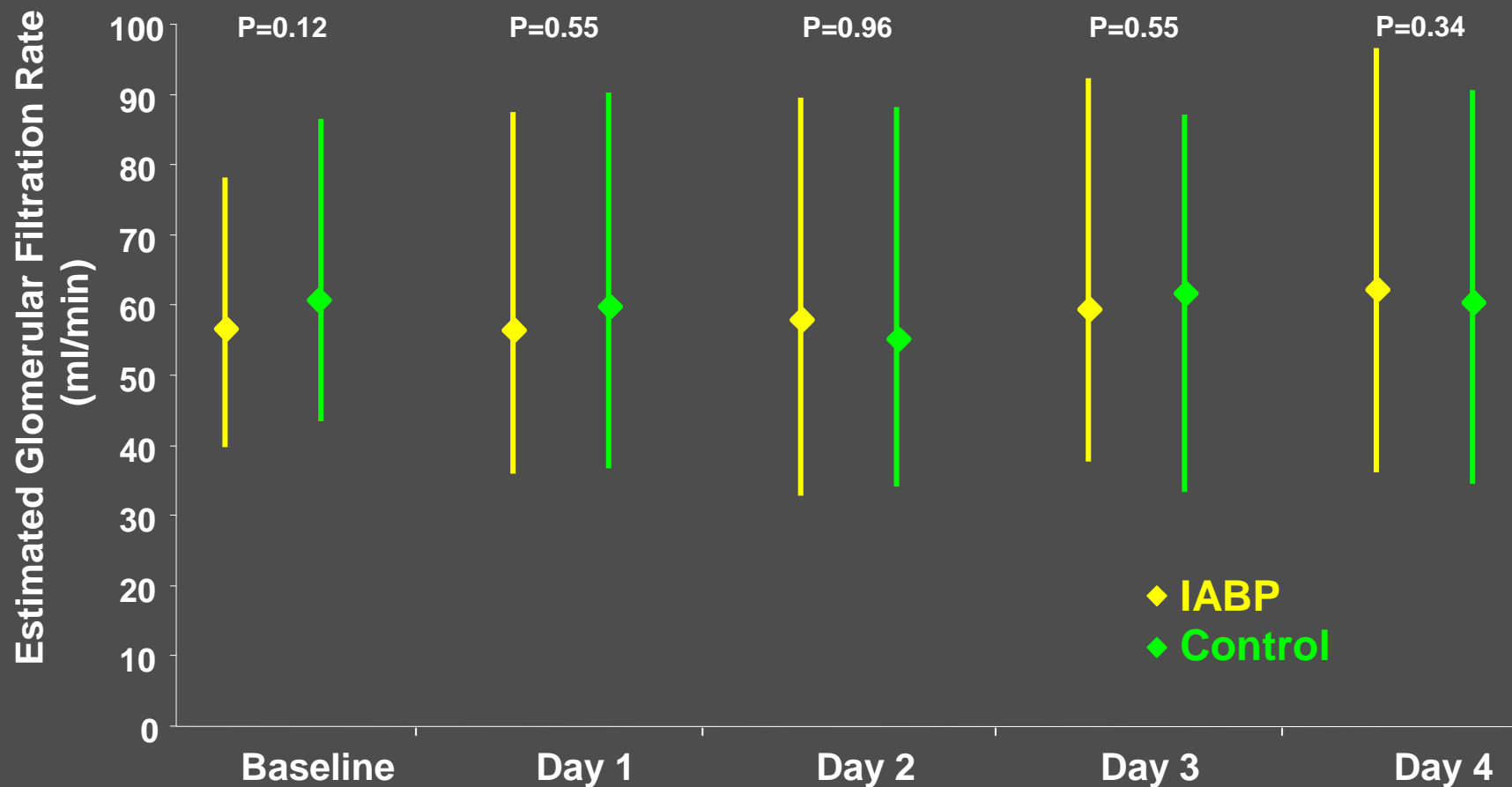
# Treatment + Process of Care Outcomes

Variable	IABP (n=301)	Control (n=299)	p
Primary PCI; n/total (%)	287/301 (95.3)	288/299 (96.3)	0.55
Stent implanted; n/total (%)	273/301 (90.7)	266/299 (89.0)	0.48
Drug-eluting stent; n/total (%)	126/301 (41.9)	123/299 (41.1)	0.86
Immediate PCI of non-culprit lesions; n/total (%)	90/301 (29.9)	81/299 (27.1)	0.45
Immediate bypass surgery; n/total (%)	8/301 (2.7)	10/299 (3.3)	0.62
Staged bypass surgery; n/total (%)	3/301 (1.0)	4/299 (1.3)	0.72
Active left ventricular assist device; n/total (%)	11/301 (3.7)	22/299 (7.4)	0.053
Mild hypothermia; n/total (%)	106/301 (35.2)	120/299 (40.1)	0.21
Mechanical ventilation; n/total (%)	240/301 (79.7)	252/299 (84.3)	0.15
Duration of mechanical ventilation (days); median (IQR)	3.0 (1.0-8.0)	3.0 (1.0-8.0)	0.44
Duration of intensive care treatment (days); median (IQR)	6.0 (3.0-12.0)	6.0 (3.0-13.0)	0.34
Renal replacement therapy; n/total (%)	62/301 (20.6)	47/299 (15.7)	0.12
Antiplatelets and anticoagulation; n/total (%)	293/299 (98.0)	284/298 (95.3)	0.07
Aspirin	216/299 (72.2)	206/298 (69.1)	0.40
Clopidogrel	80/299 (26.8)	76/298 (25.5)	0.73
Prasugrel	19/234 (8.1)	15/228 (6.6)	0.52
Ticagrelor*	138/299 (46.2)	143/298 (48.0)	0.63
Glycoprotein IIb/IIIa-inhibitors	288/299 (96.3)	275/298 (92.3)	0.03
Unfractionated heparin	60/299 (20.1)	59/298 (19.8)	0.94
Low molecular weight heparin	29/299 (9.7)	36/298 (12.1)	0.34
Bivalirudin			
Catecholamines (µg/kg per minute); median (IQR)			
Dopamine	4.1 (2.9-7.7)	4.2 (3.6-8.3)	0.76
Norepinephrine	0.3 (0.1-1.2)	0.4 (0.1-1.1)	0.73
Epinephrine	0.3 (0.1-1.3)	0.3 (0.2-1.4)	0.59
Dobutamine	10.2 (4.9-20.6)	9.0 (4.8-17.6)	0.25
Duration of catecholamines (days), median (IQR)	3.0 (1.0-5.0)	3.0 (1.0-6.0)	0.81
Time to hemodynamic stabilization (days); median (IQR)	3.0 (1.0-5.0)	3.0 (1.0-6.0)	0.50

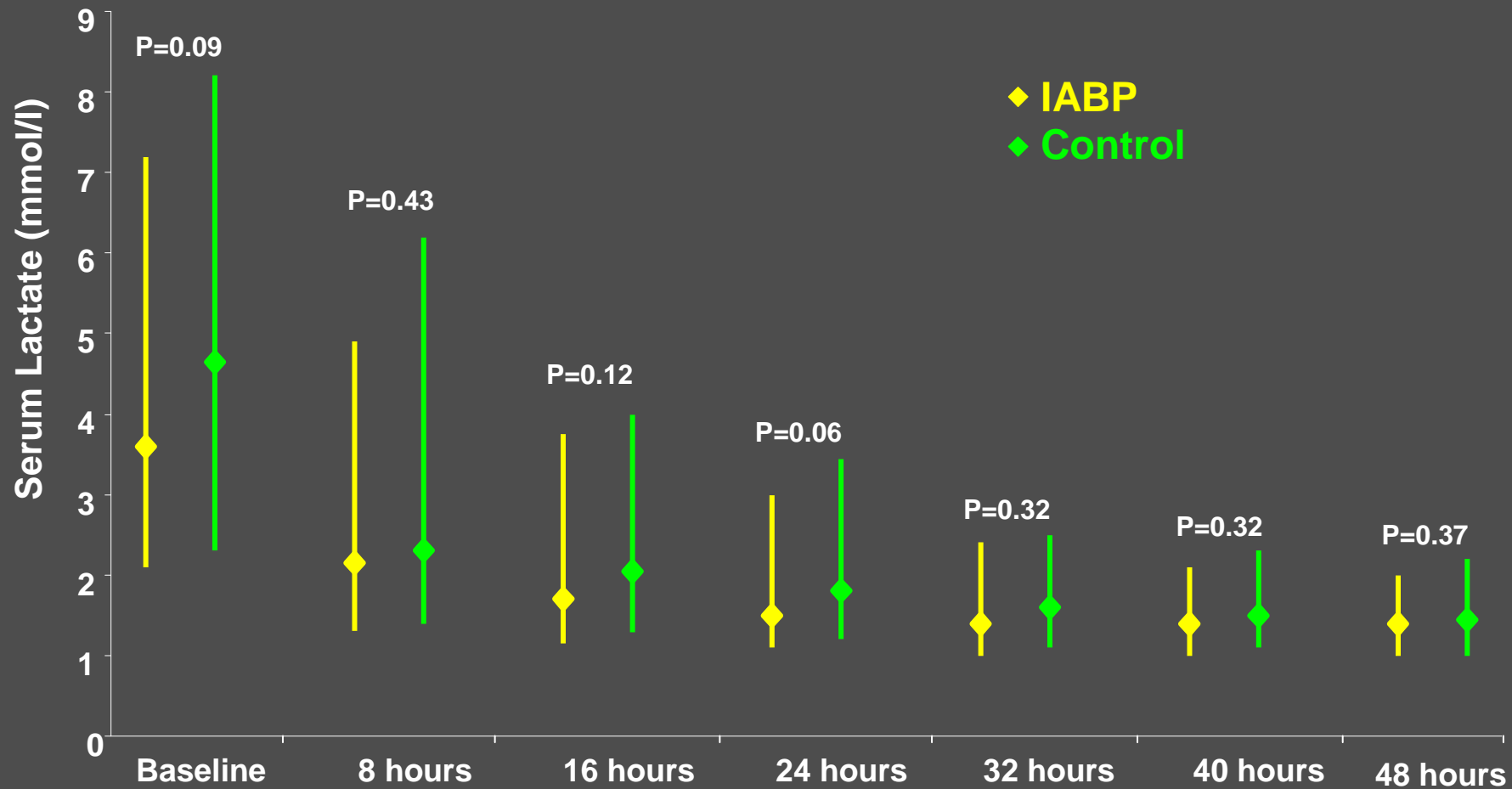
# Simplified Acute Physiology Score-II



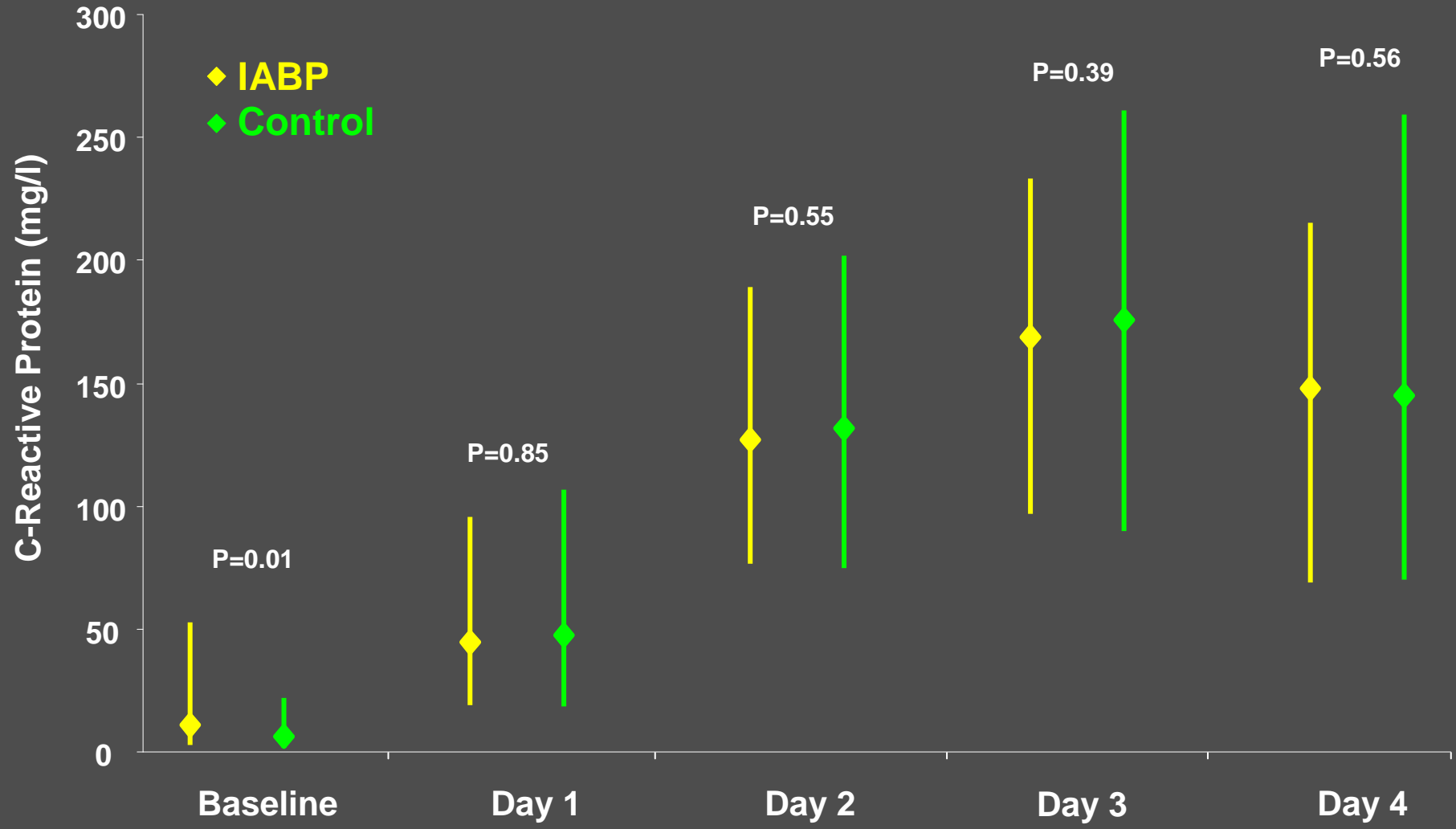
# Renal Function (eGFR)



# Serum Lactate

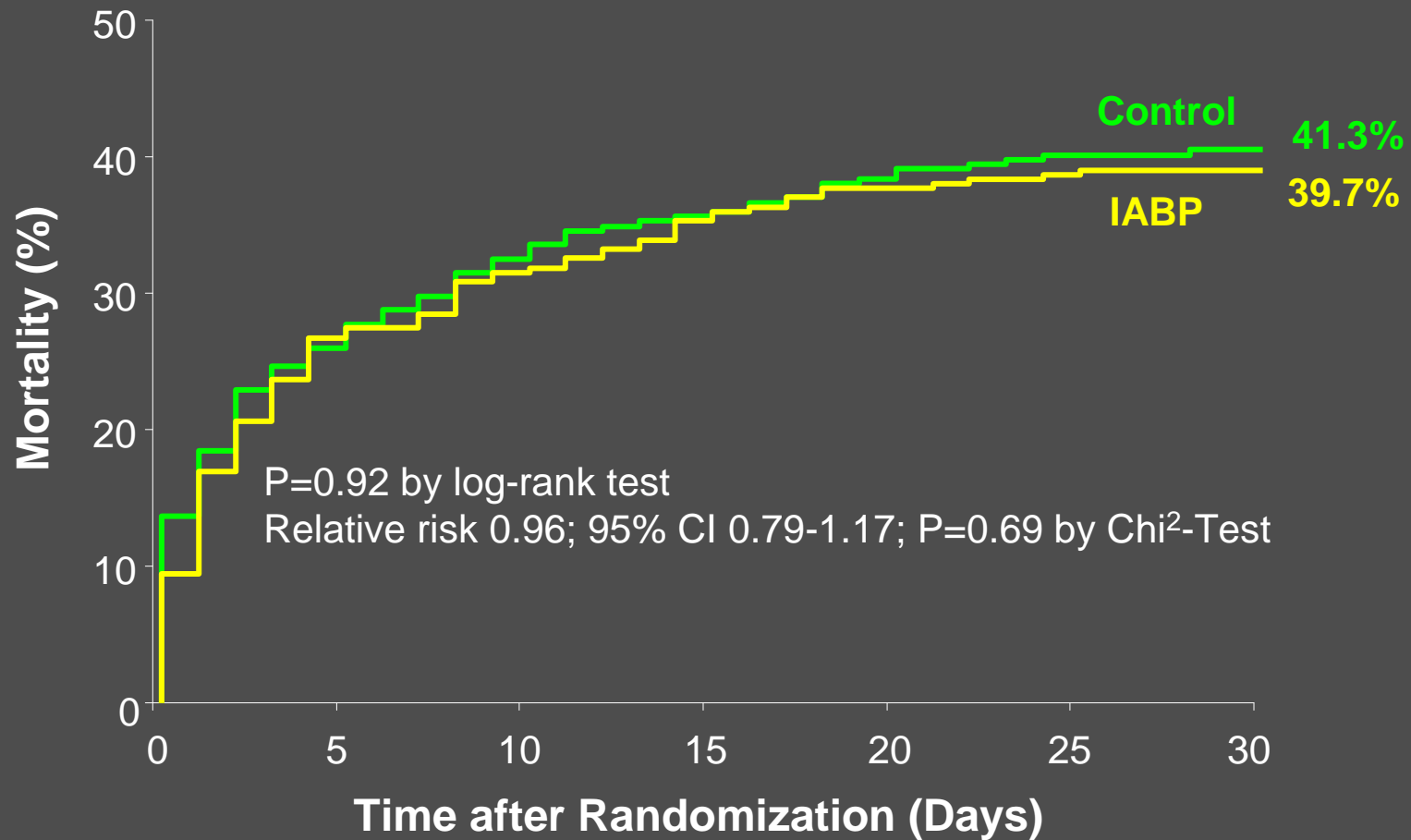


# Inflammatory Reaction (CRP)

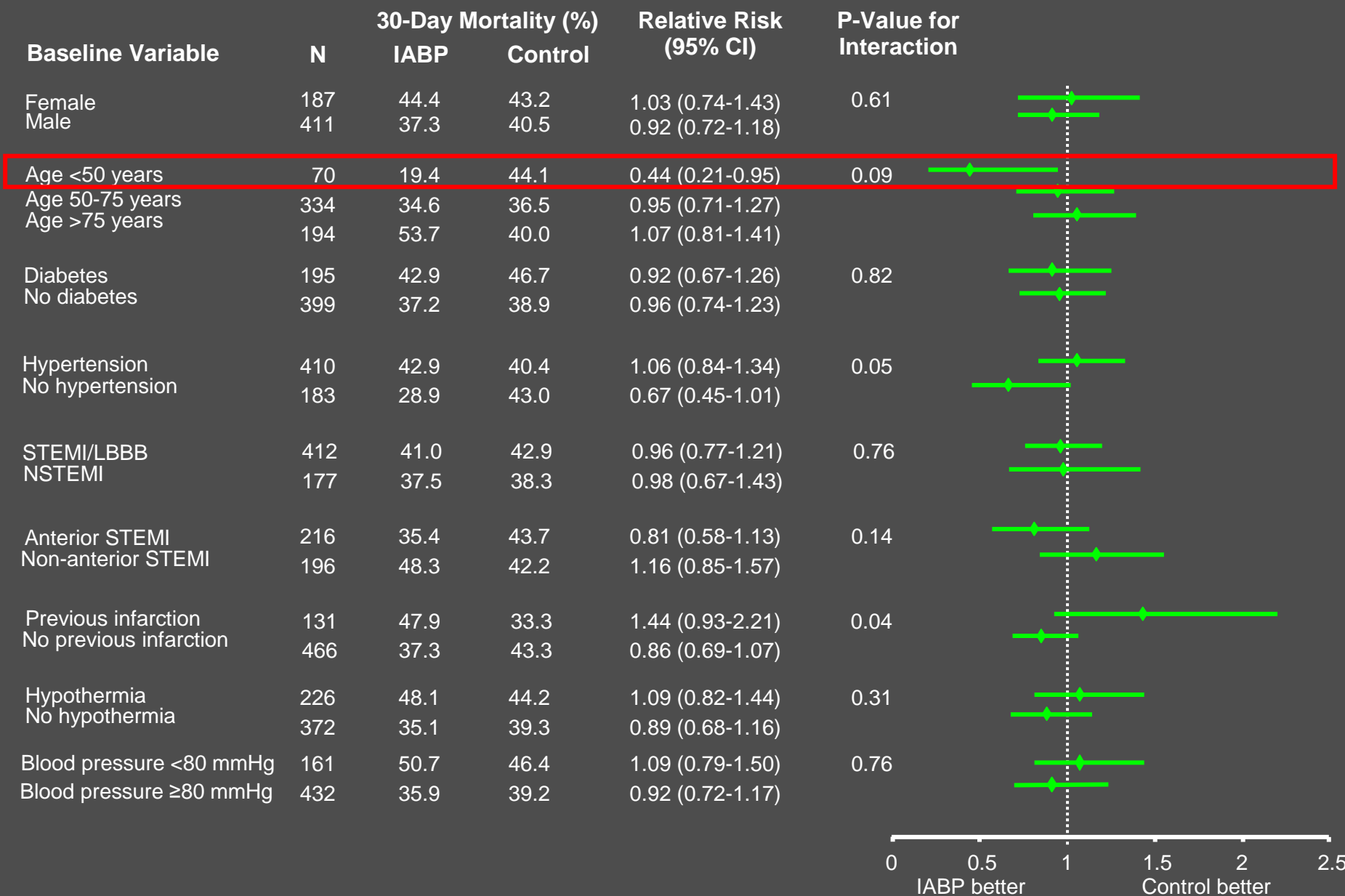




# Primary Study Endpoint (30-Day Mortality)

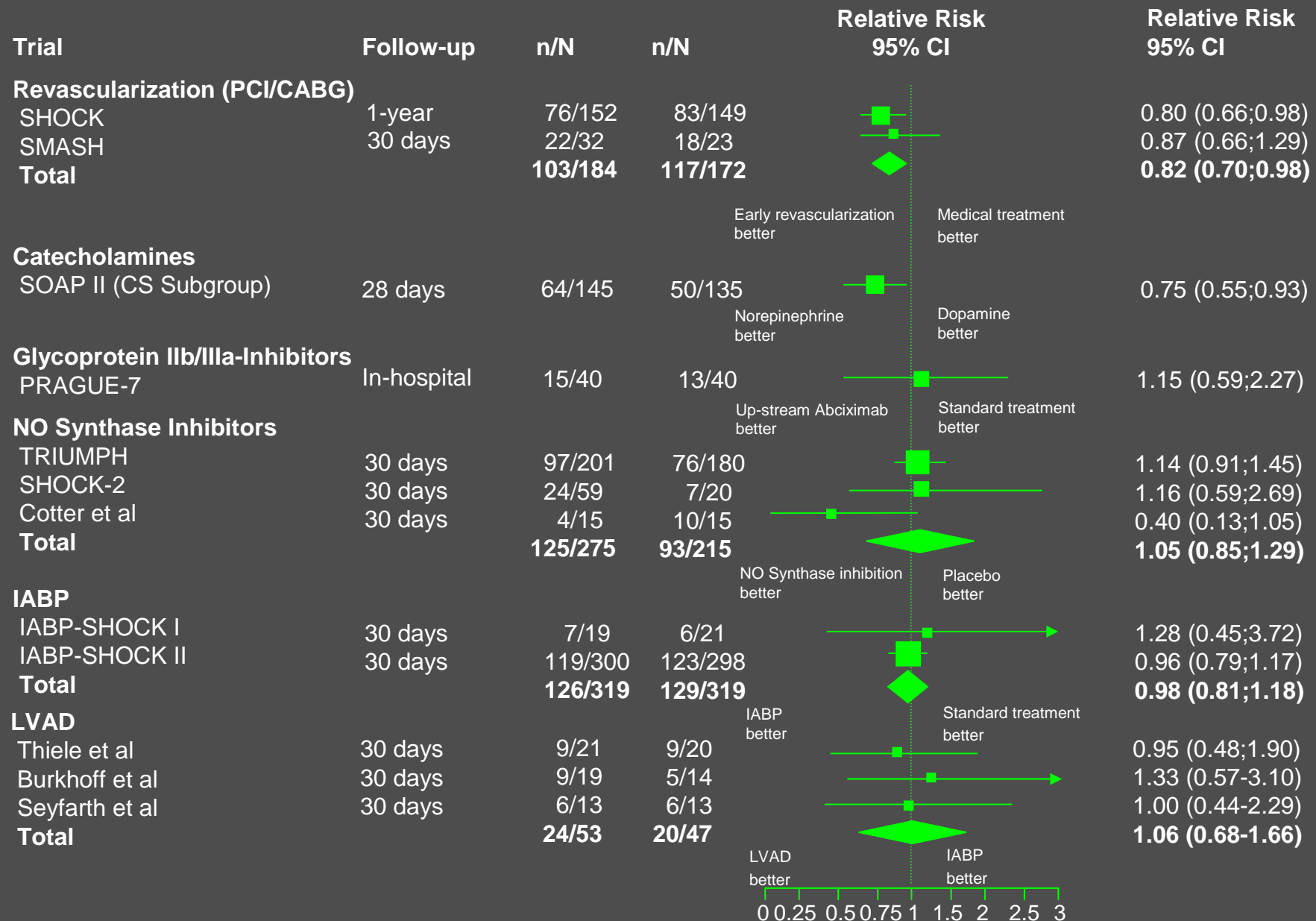


# Subgroups (30-Day Mortality)



	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

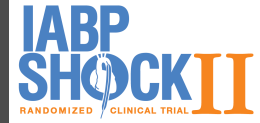
# Randomized Studies in Cardiogenic Shock



# Summary + Conclusions

- IABP support in cardiogenic shock is safe without significant inherent complications.
- However, IABP support did not reduce 30-day mortality in this large, randomized, multicenter trial in cardiogenic shock patients complicating myocardial infarction undergoing early revascularization.
- The primary study endpoint results are supported by a lack of benefit in secondary endpoints.

# Acknowledgement and Thank You



## IABP-SHOCK II Investigators from 37 German Sites

### Steering Committee

H. Thiele (Chair)  
G. Schuler  
K. Werdan  
U. Zeymer

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University of Leipzig –  
Heart Center  
Maquet Cardiovascular  
Teleflex Medical

### DSMB

J. Haerting (Chair)  
F. Follath  
K. Huber  
B. Maisch

### Study Sites

Leipzig: H. Thiele, G. Schuler, S. Desch, G. Fuernau, I. Eitel, S. de Waha, S. Wetzel, T. Pausewang, A. Leuschner  
Bad Krozingen: F.-J. Neumann, M. Ferenc  
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Munich German Heart Center: J. Hausleiter, A. de Waha, M. Orban, C. Lennerz, M. Seyfarth  
Bad Segeberg: G. Richardt, B. Schwarz, M. Abdel-Wahab, R. Toelg, V. Geist, M. Bahnsen-Maaß  
Heilbronn: M. Hennersdorf, U. Rieman, J. Graf, A. Kuhn, D. Scharpf  
Greifswald: K. Empen, S. Felix  
Halle (Saale): K. Werdan, H. Ebelt, A. Schlitt, M. Buerke  
Bremen: R. Hambrecht, E. Fiehn, A. Fach  
Ludwigshafen: U. Zeymer, A. K. Gitt, B. Mark, R. Winkler  
Bad Berka: B. Lauer, J. Fuhrmann  
Homburg/Saar: M. Böhm, A. Link  
Jena: H.R. Figulla, M. Ferrari, C. Jung, S. Utschig  
Lübeck: V. Kurowski, S. Wolfrum, P.W. Radke, H. Schunkert  
Hennigsdorf: H.-H. Minden  
Magdeburg: R. C. Braun-Dullaues, F. Walz, A. Schmeißer  
Cottbus – Heart Center: J. Krülls-Münch, K. Rochor  
Dresden: R. H. Strasser, G. Simonis  
Würzburg: S. Maier, G. Ertl  
Munich – Neuperlach: H. Mudra, M. Hug  
Regensburg: P. Bomba, P. Sick  
Berlin – Benjamin Franklin: C. Tschöpe, H.-P. Schutlheiss  
Berlin – Vivantes am Urban: H. Roth, D. Andresen  
Cottbus – Carl-Thiem-Klinikum: C. Kurek, J. Krülls-Münch  
Rostock: C. Nienaber, H. Ince, H. Schneider  
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Berlin – Charité Mitte: G. Baumann, F. Knebel  
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Merseburg: R. Prondzinsky  
Detmold: U. Tebbe  
Villingen-Schwenningen: R. Birkemeyer

### CEC

H. Thiele  
U. Zeymer

### CRO IHF Ludwigshafen

S. Schneider (Statistics chair)  
T. Oarrak (Statistics)  
U. Zeymer  
K. Vonderschmitt  
Z. Alkisoglu  
S. Frey  
B. Messemer