

Intracoronary Compared with Intravenous Bolus Abciximab Application During Primary Percutaneous Coronary Intervention

The Abciximab Intracoronary versus intravenously Drug
Application in ST-Elevation Myocardial Infarction
(AIDA STEMI) trial

Holger Thiele, MD;

Jochen Wöhrle, MD; Rainer Hambrecht, MD; Harald Rittger, MD; Ralf Birkemeyer, MD;
Bernward Lauer, MD; Petra Neuhaus, PhD; Oana Brosteanu, PhD; Peter Sick, MD; Marcus Wiemer, MD;
Sebastian Kerber, MD; Ingo Eitel, MD; Klaus Kleinertz, MD; Gerhard Schuler, MD
on behalf of the AIDA STEMI Investigators

Disclosures

Off-label use of IC abciximab

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University of Leipzig – Heart Center

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Potential Conflict of Interest:

Research Funding:

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Consulting:

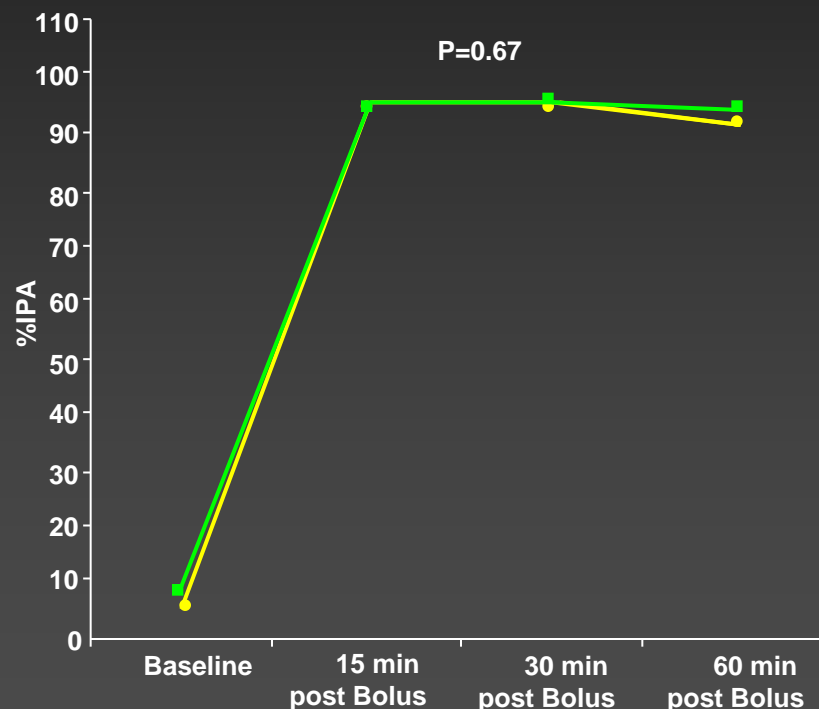
Maquet Cardiovascular, Avidal

Speaker Honoraria:

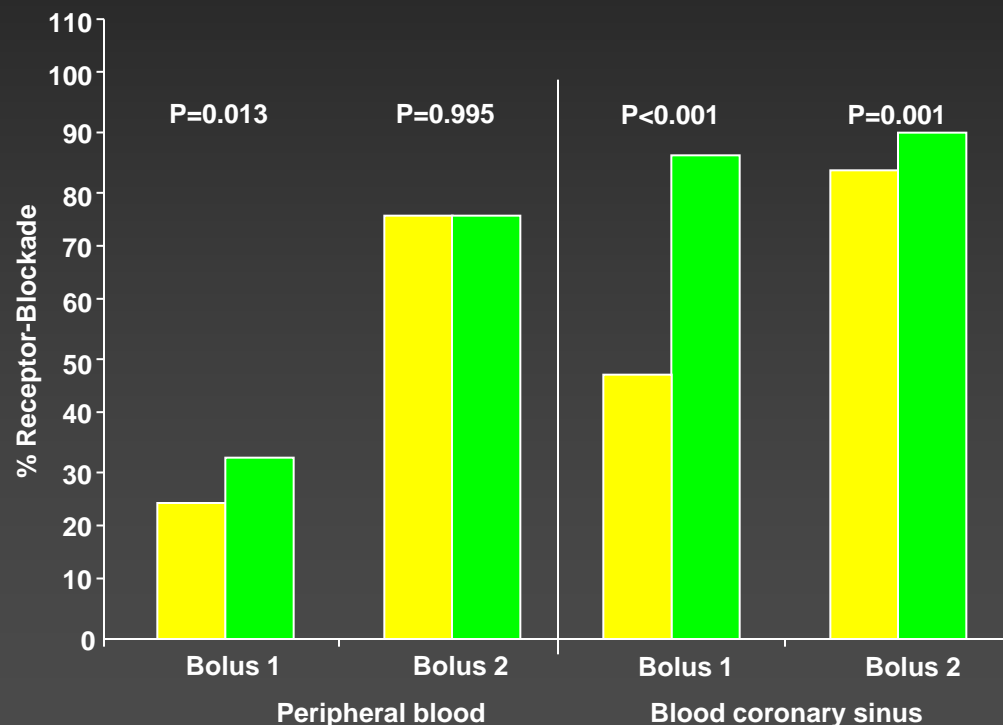
Lilly, Astra Zeneca, Daiichi Sankyo, Boehringer Ingelheim, Maquet Cardiovascular, Medicines Company

2 x Bolus within 10 min. 180 µg/kg eptifibatide IC versus IV, subsequently 2 µg/kg⁻¹ .min⁻¹ continuous infusion i.v. for 18 h

IPA Periphery (20 µmol/L ADP)



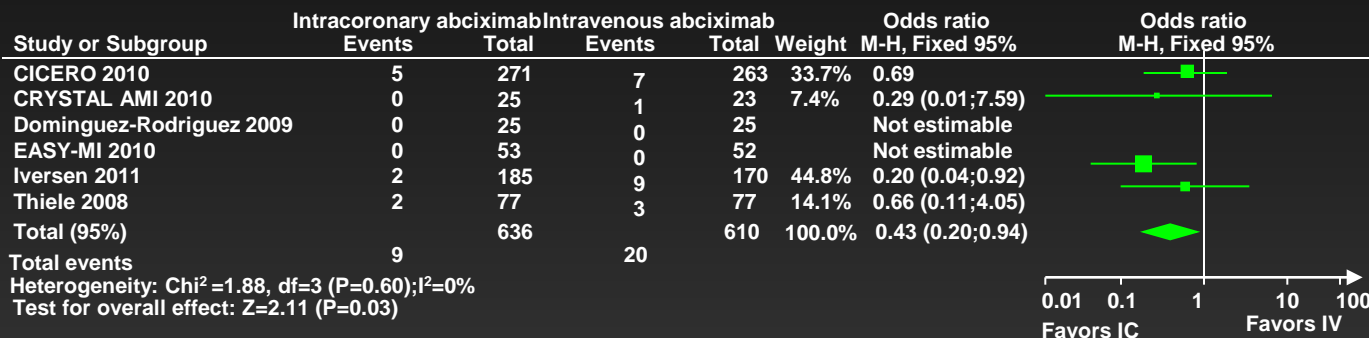
GpIIb/IIIa Receptor-Blockade



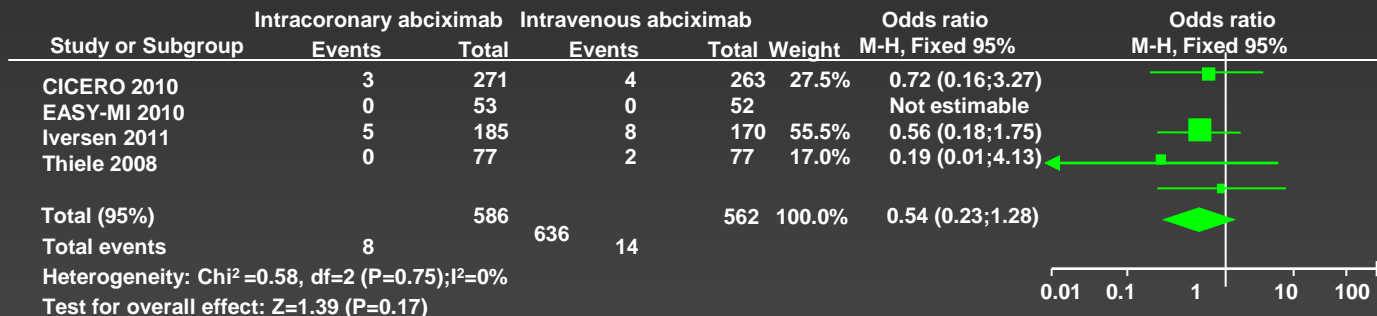
■ IC Eptifibatide n=21

■ IV Eptifibatide n=19

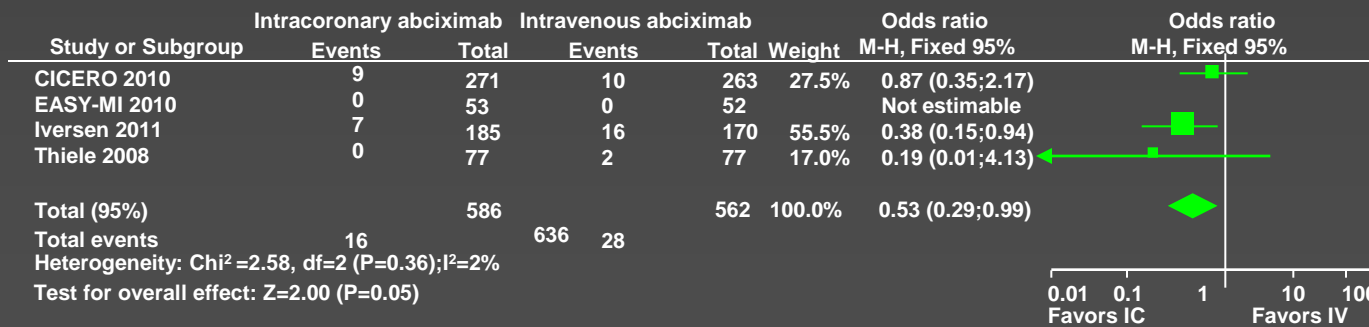
30-day Mortality

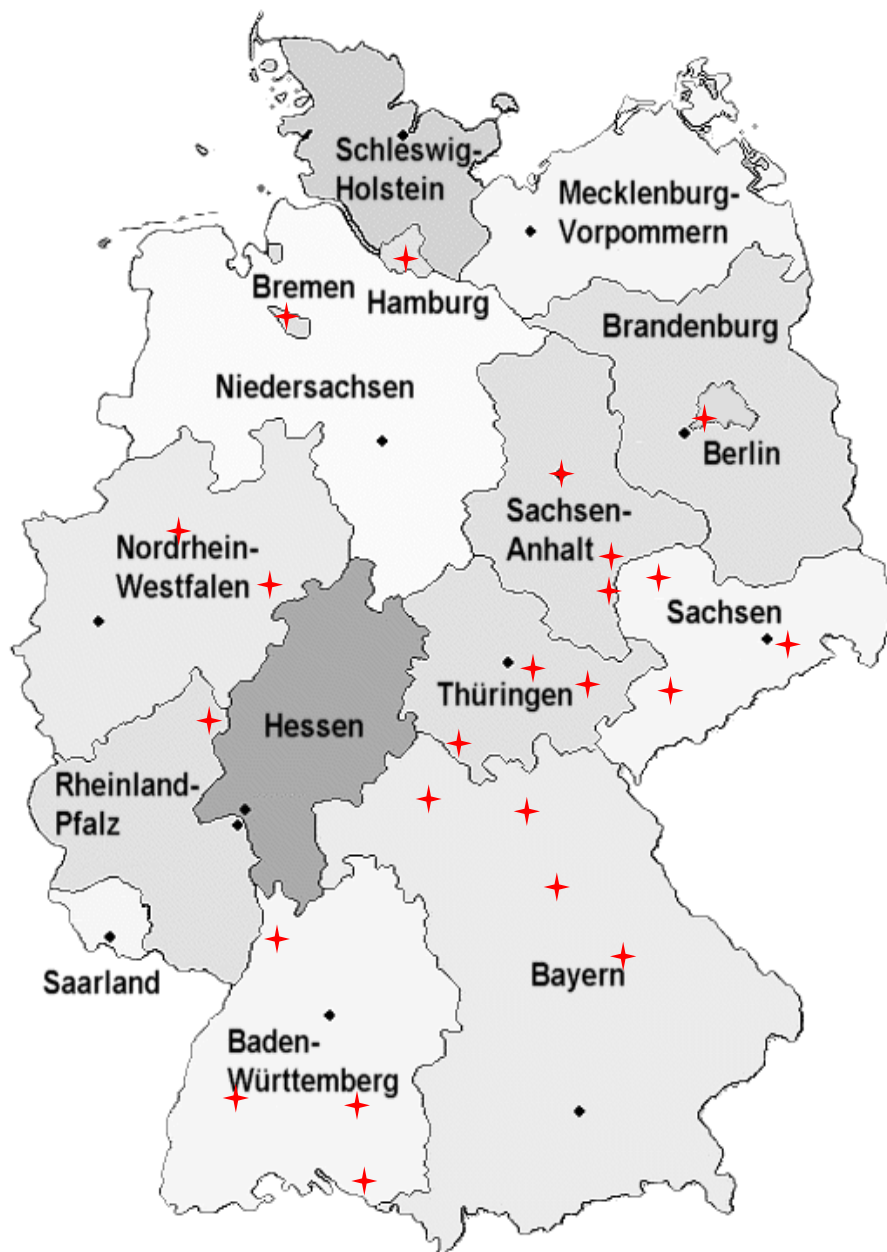


30-day Myocardial Infarction



30-day Target Vessel Revascularization





Investigator Initiated Trial

DSMB:

Uwe Zeymer
Hans-Richard Arntz
Christoph Bode
Karl Wegscheider

Steering Committee:

Holger Thiele
Jochen Wöhrle
Oana Brosteanu
Gerhard Schuler

CRO:

Clinical Trial Center Leipzig

- **Sample Size**

- Estimated event rate within 90 days 12% in IV arm
- 4% absolute reduction by IC abciximab injection
- 80% power at 2-sided α -level \rightarrow 1864 patients
- To compensate losses in follow-up \rightarrow 2065 patients

- **Primary Study Endpoint:**

Composite of all-cause death, reinfarction, new congestive heart failure at 90 days after randomization

- **Secondary Study Endpoints:**

- Time to occurrence of combined clinical endpoint
- TIMI-flow post PCI
- ST-segment resolution
- Infarct size by AUC of CK-release

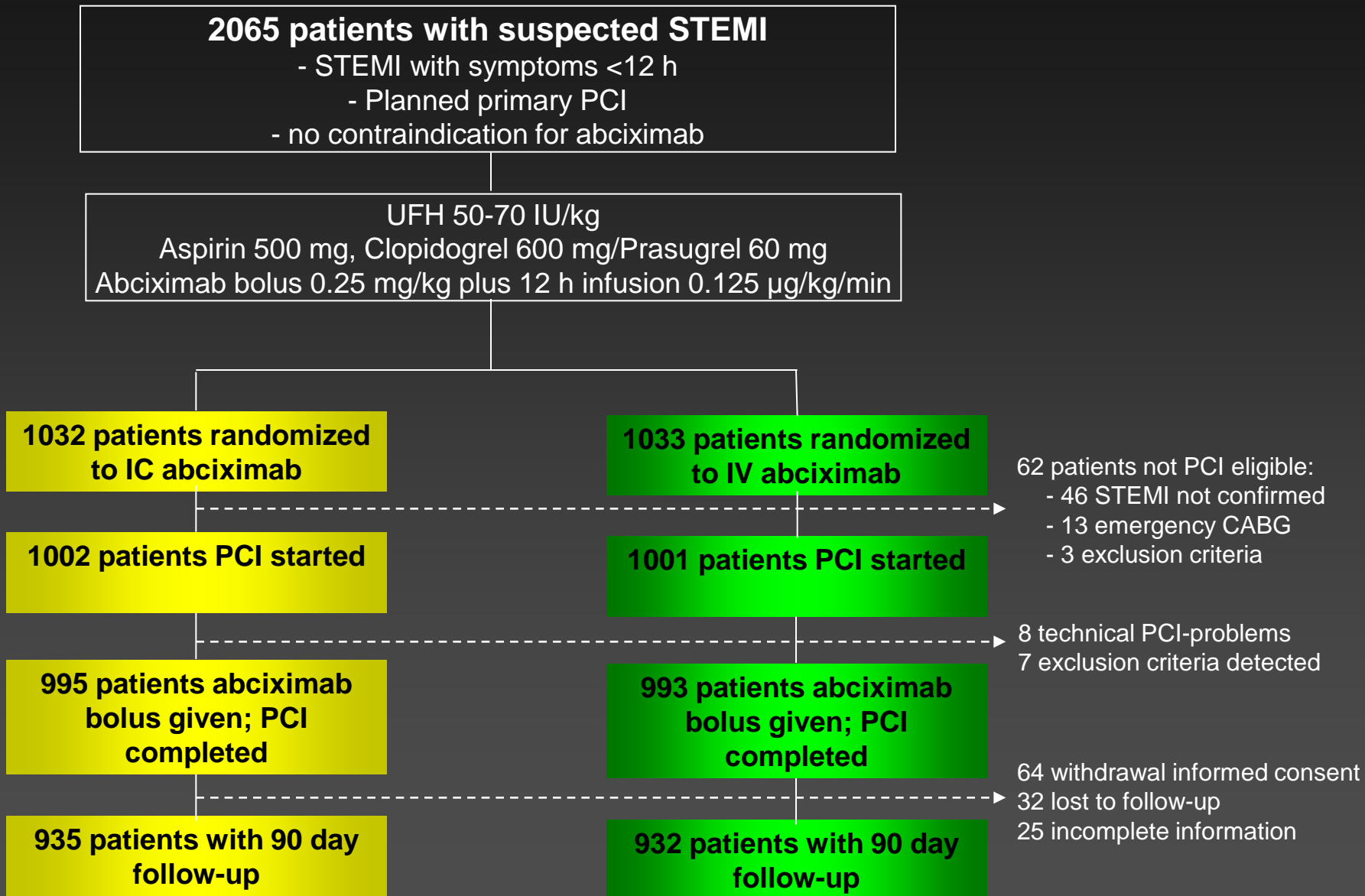
- **Safety:**

- GUSTO bleeding
- life-threatening arrhythmia/hemodynamic compromise during abciximab injection

Thiele et al. Circulation 2008;118:49-57

Thiele et al. Am Heart J 2010;159:547-554

Study Design, Flow, and Compliance

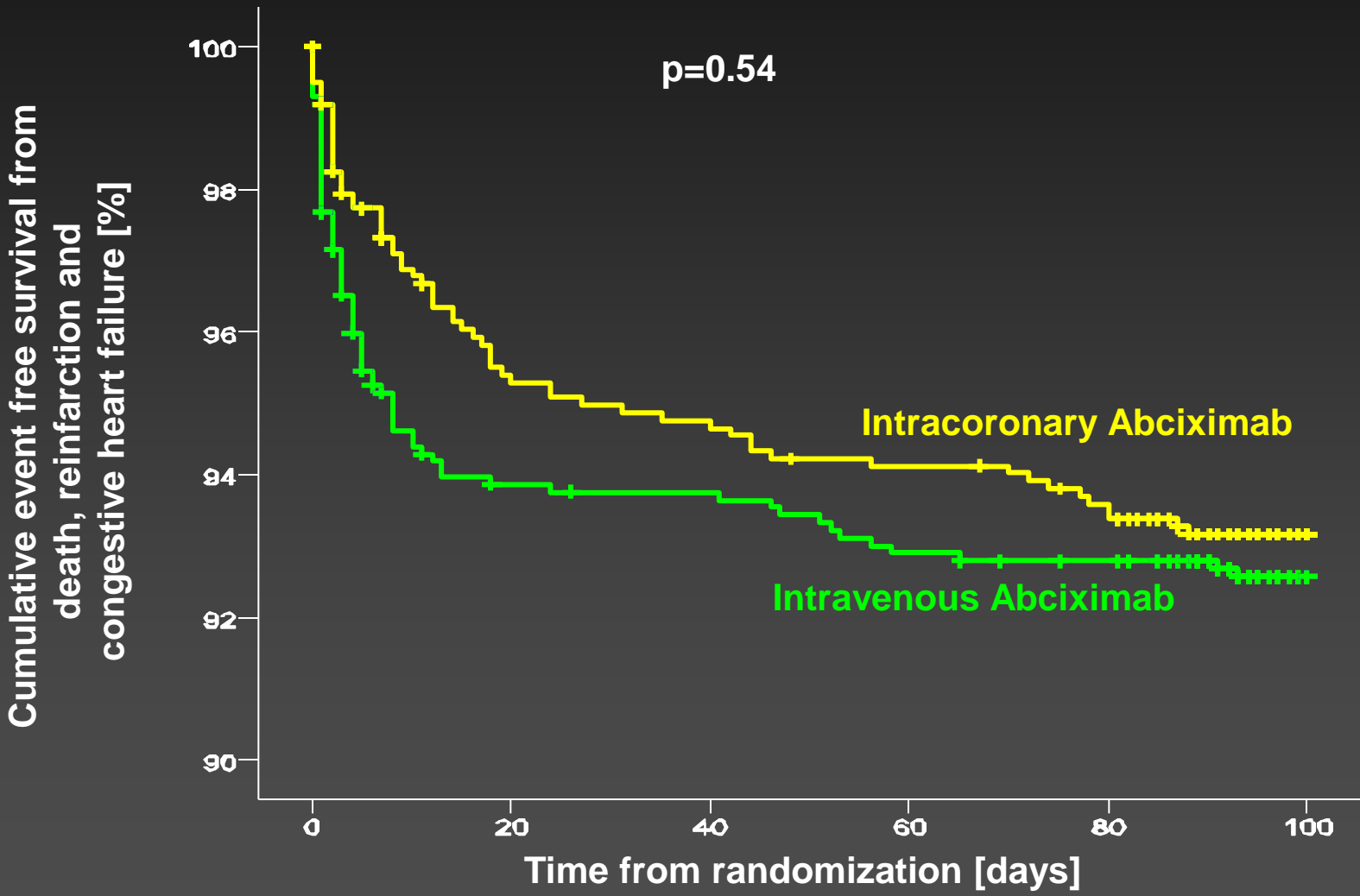


	IC Abciximab (n=1032)	IV Abciximab (n=1033)
Age (years); median (IQR)	63 (52-72)	62 (52-72)
Male sex; n (%)	776 (75.2)	778 (75.3)
Current Smoking; n/total n (%)	400/928 (43.1)	426/918 (46.4)
Hypertension; n/total n (%)	707/983 (71.9)	684/991 (69.0)
Hypercholesterolemia; n/total n (%)	382/970 (39.4)	413/962 (42.9)
Diabetes mellitus; n/total n (%)	202/992 (20.4)	199/990 (20.1)
Body mass index (kg/m ²); median (IQR)	27.5 (25.0-30.4)	27.4 (24.8-30.4)
Prior myocardial infarction; n/total n (%)	87/988 (8.8)	91/988 (9.2)
Prior PCI; n/total n (%)	94/990 (9.5)	104/983 (10.6)
Prior CABG; n/total n (%)	19/993 (1.9)	22/989 (2.2)
Anterior myocardial infarction; n/total n (%)	473/953 (49.6)	442/931 (47.5)
Creatinine clearance (ml/min); median (IQR)	91.6 (68.7-118.5)	91.3 (68.5-116.9)
Symptom-onset - PCI hospital, median (IQR)	160 (100-285)	166 (101-287)
Door-to-balloon-time; median (IQR)	32 (22-50)	32 (22-49)
Killip class on admission; n/total n (%)		
1	854/995 (85.8)	869/997 (87.2)
2	95/995 (9.5)	76/997 (7.6)
3	29/995 (2.9)	26/997 (2.6)
4	17/995 (1.7)	26/997 (2.6)
Left ventricular ejection fraction (%); median (IQR)	50 (45-60)	50 (45-60)

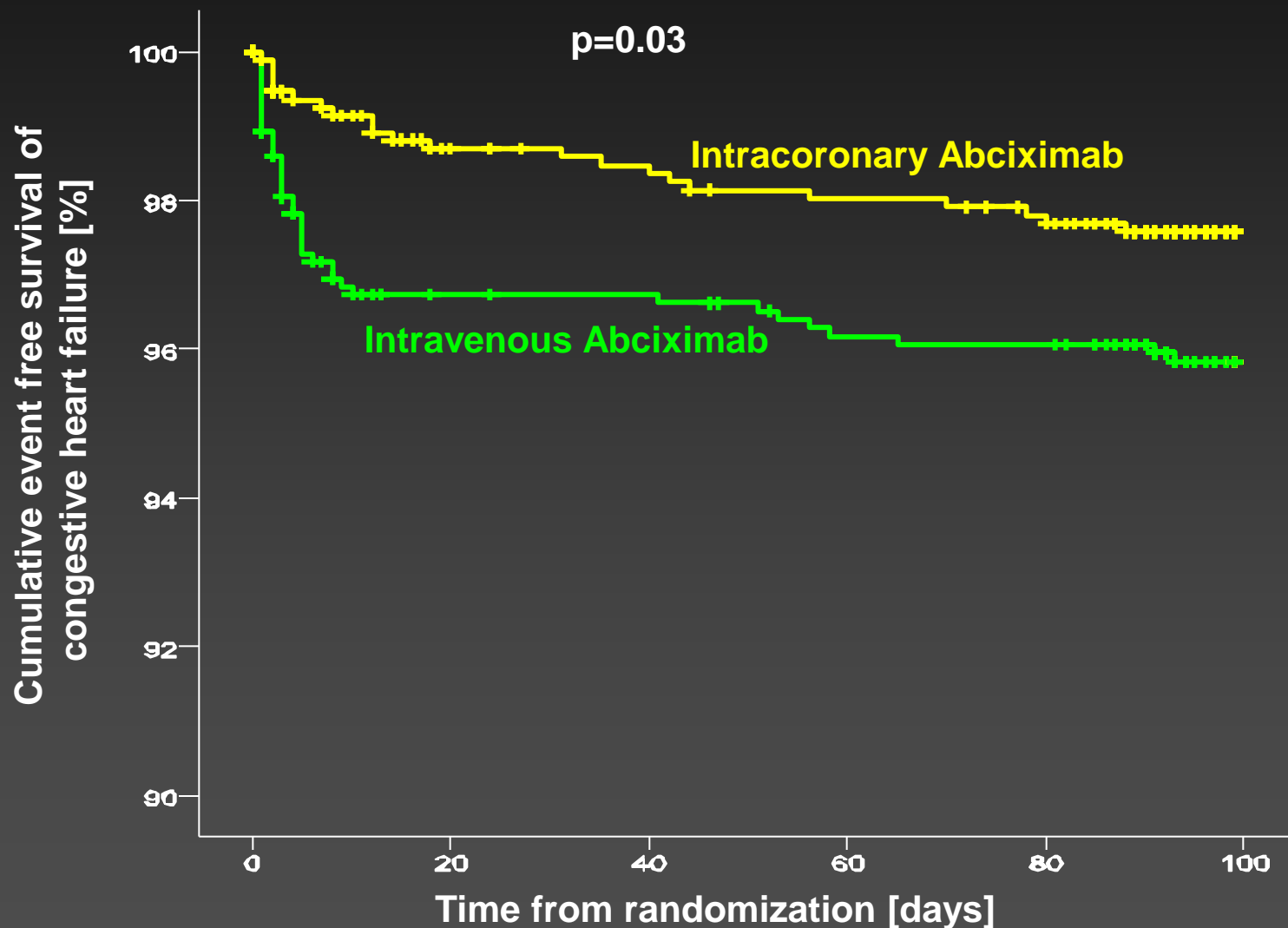
	IC Abciximab (n=1032)	IV Abciximab (n=1033)	p
Infarct-related artery; n/total n (%)			0.85
LAD	424/993 (42.7)	431/992 (43.4)	
LCX	130/993 (13.1)	122/992 (12.3)	
RCA	433/993 (43.6)	429/992 (43.2)	
Left main	4/993 (0.4)	7/992 (0.7)	
Bypass graft	2/993 (0.2)	3/992 (0.3)	
Thrombectomy; n/total n (%)	208/996 (20.9)	189/996 (19.0)	0.29
Drug-eluting stent; n/total n (%)	338/988 (34.2)	344/982 (35.0)	0.64
Bare metal stent; n/total n (%)	649/988 (65.7)	636/983 (64.7)	0.76
IABP; n/total n (%)	34/996 (3.4)	40/995 (4.0)	0.47
TIMI-flow III post PCI; n/total n (%)	877/990 (88.6)	870/978 (89.0)	0.74
Concomitant medications; n/total n (%)			
Beta-blocker	896/945 (94.8)	877/935 (93.8)	0.34
ACE-inhibitor/AT-1-antagonist	877/945 (92.8)	870/935 (93.0)	0.84
Aspirin	988/990 (99.8)	986/991 (99.5)	0.26
Clopidogrel	854/950 (89.9)	853/949 (89.9)	0.99
Prasugrel	187/713 (26.2)	197/720 (27.4)	0.63
Clopidogrel and/or Prasugrel	942/960 (98.1)	951/967 (98.3)	0.71
Statin	888/945 (94.0)	884/935 (94.5)	0.59
Aldosterone-antagonist	120/945 (12.7)	104/935 (11.1)	0.29
Completion of 12 h abciximab infusion	880/953 (92.3)	882/951 (92.7)	0.74

	IC	IV	OR	95% CI	P
Death/Reinfarction/new CHF					
n/total n (%)	65/935 (7.0)	71/932 (7.6)	0.91	0.91-1.28	0.58
Death					
Overall n/total n (%)	42/935 (4.5)	34/932 (3.6)	1.24	0.78-1.97	0.36
Cardiac	35	33			
Non-cardiac	7	1			
Reinfarction					
n/total n (%)	17/935 (1.8)	17/932 (1.8)	1.0	0.51-1.96	0.99
New CHF					
n/total n (%)	22/935 (2.4)	38/935 (4.1)	0.57	0.33-0.97	0.04

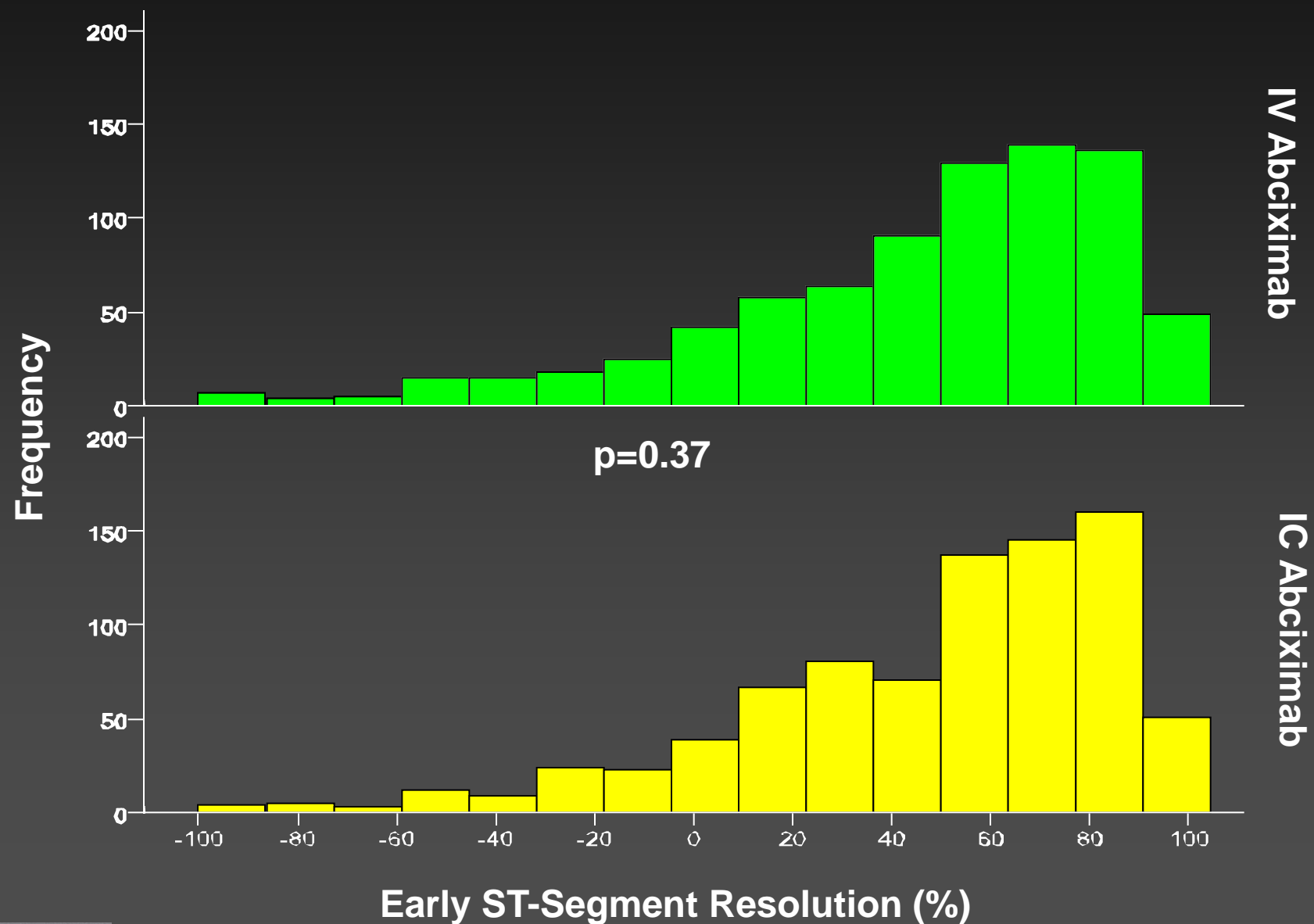
Combined Clinical Endpoint

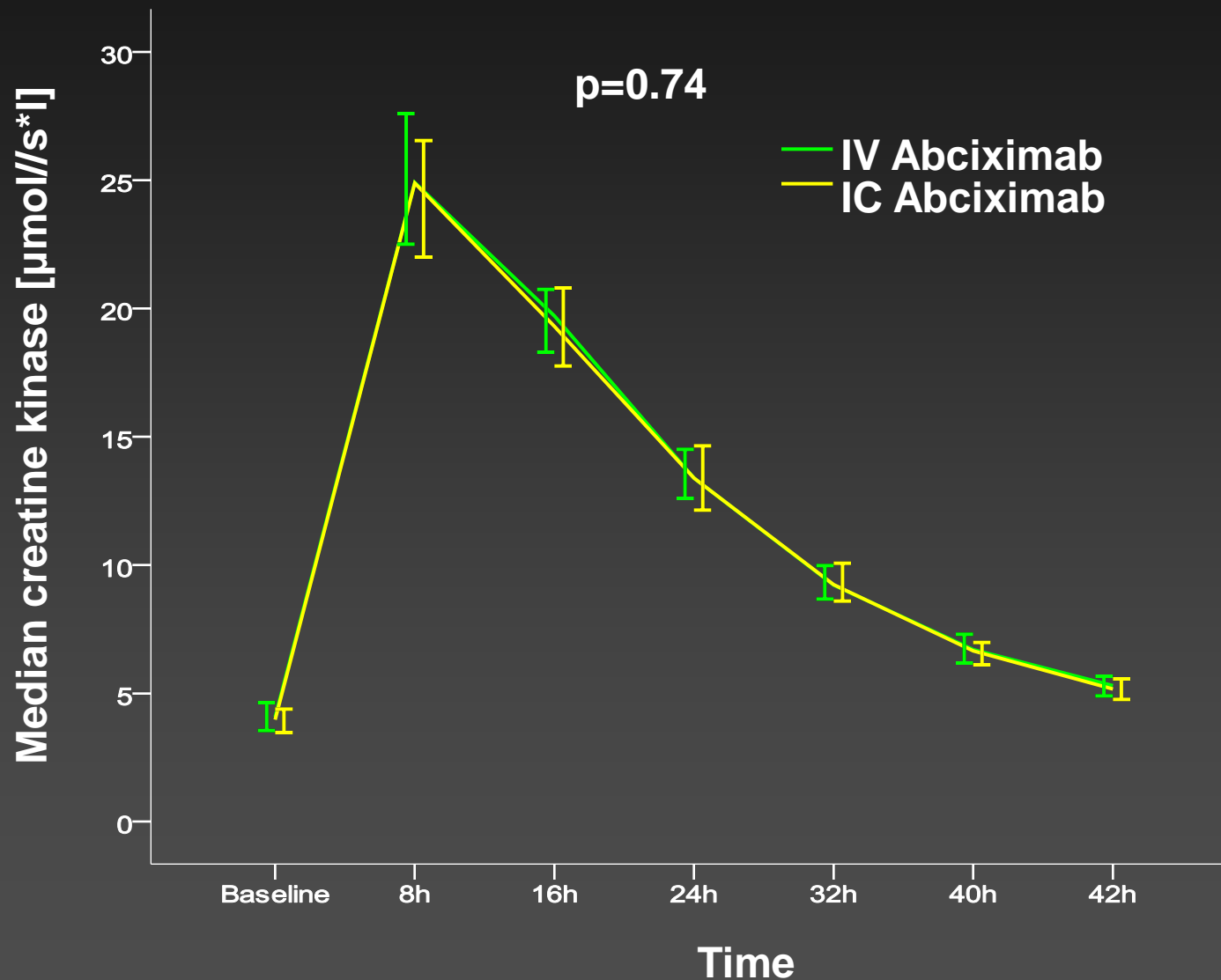


Congestive heart failure



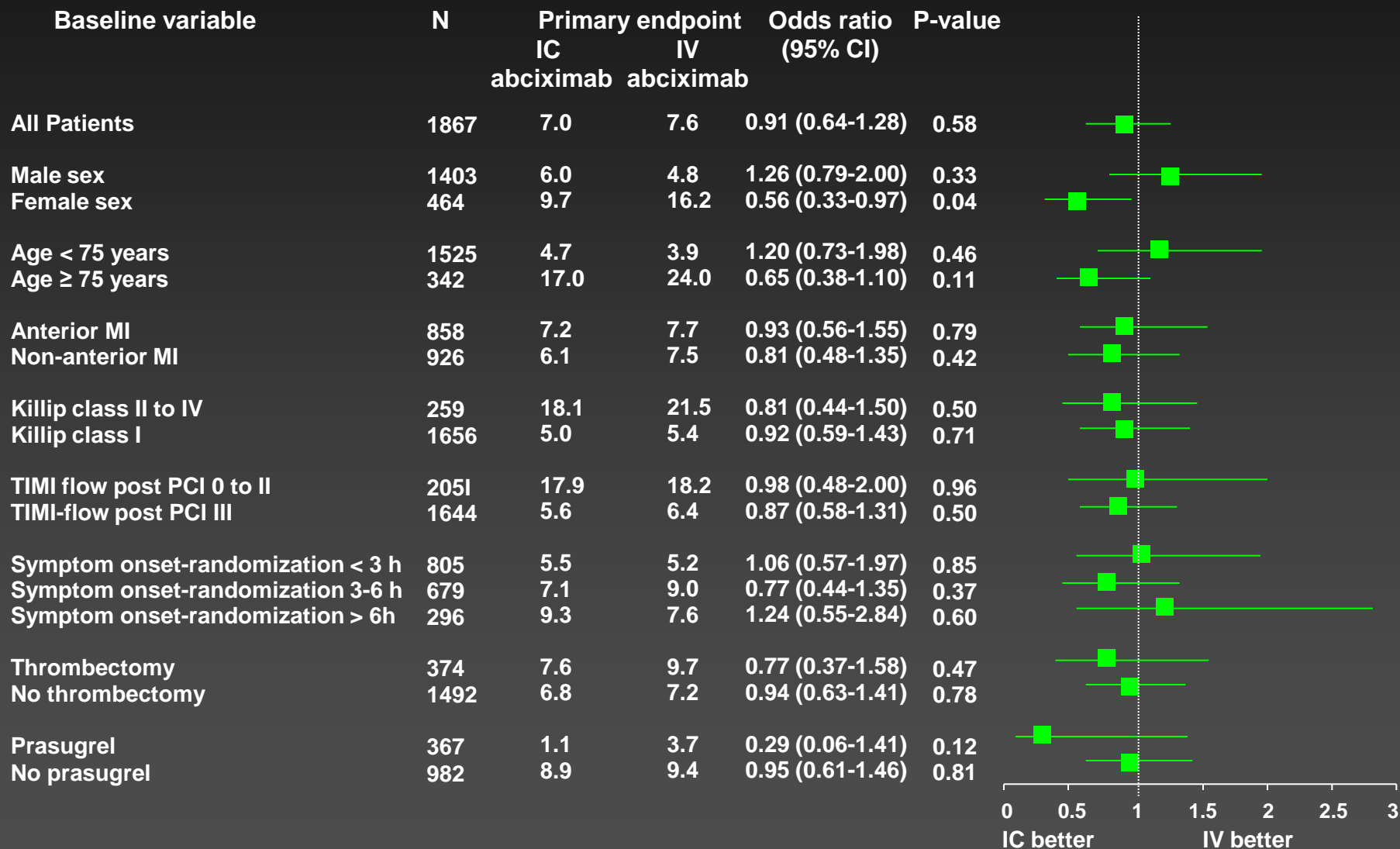
ST-Segment-Resolution





Subgroups

Results



	IC	IV	P
Stroke in-hospital			
n/total n (%)	5/985 (0.5)	7/999 (7.6)	0.7
Stent thrombosis (ARC)			
n/total n (%)	17/985 (1.7)	20/999 (2.0)	0.65
Definitive	5	12	
Probable	12	8	
GUSTO bleeding; n/total n (%)			0.63
Life-threatening/severe	26/985 (2.6)	18/999 (1.8)	
Moderate	26/985 (2.6)	26/999 (2.6)	
Mild	79/985 (8.0)	85/999 (8.5)	
Hemodynamic compromise during abciximab bolus; n/total n (%)	1/985 (0.1)	6/999 (0.6)	0.06
Life-threatening arrhythmia during PCI; n/total n (%)	17/985 (1.7)	21/999 (2.1)	0.22

Summary + Conclusions

- This randomized, multi-center, large-scale trial involving more than 2000 STEMI patients undergoing primary PCI showed that IC abciximab bolus administration is safe.
- The IC bolus administration of abciximab does not add a benefit in comparison to the standard IV bolus with respect to the combined primary study endpoint consisting of death, reinfarction, or new congestive heart failure within 90 days.
- The IC route might be related to reduced rates of new congestive heart failure.

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AIDA STEMI Investigators from 22 sites in Germany

Steering Committee

H. Thiele (Chair)
J. Wöhrle
O. Brosteanu
G. Schuler

ECG Core Lab

I. Eitel (Chair)
A. Baum
K.P. Rommel

Clinical Trial Center at University Leipzig

O. Brosteanu (Chair)
P. Neuhaus (Coordinator)
M. Doerschmann
K. Schosnig
S. Lehmann

Sponsors

Lilly Germany
BMBF

MRI Core Lab

H. Thiele (Chair)
I. Eitel (Coordinator)
H. Sünkel
J. Meissner

Study Sites

Leipzig; H. Thiele
Bremen: R. Hambrecht
Bad Berka: B. Lauer
Coburg: H. Rittger
Villingen-Schwenningen:
R. Birkemeyer
Ulm: J. Wöhrle
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Regensburg: P. Sick
Bad Oeynhausen: M. Wiemer
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Magdeburg: R. Braun-Dullaeus
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Halle: M. Buerke
Karlsruhe: C. Schmitt
Kempten: T. Nusser
Berlin: H. Schühlen
Suhl: W. Haberbosch

DSMB

U. Zeymer (Chair)
H.R. Arntz
C. Bode
K. Wegscheider

CEC

S. Desch (Chair)
H. Thiele
J. Wöhrle