

TATORT-NSTEMI: A prospective, randomized trial of Thrombus Aspiration in ThrOmbus containing culPriT lesions in Non-ST-Segment Elevation Myocardial Infarction

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on behalf of the TATORT-NSTEMI Investigators**

Disclosures

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Potential Conflict of Interest:

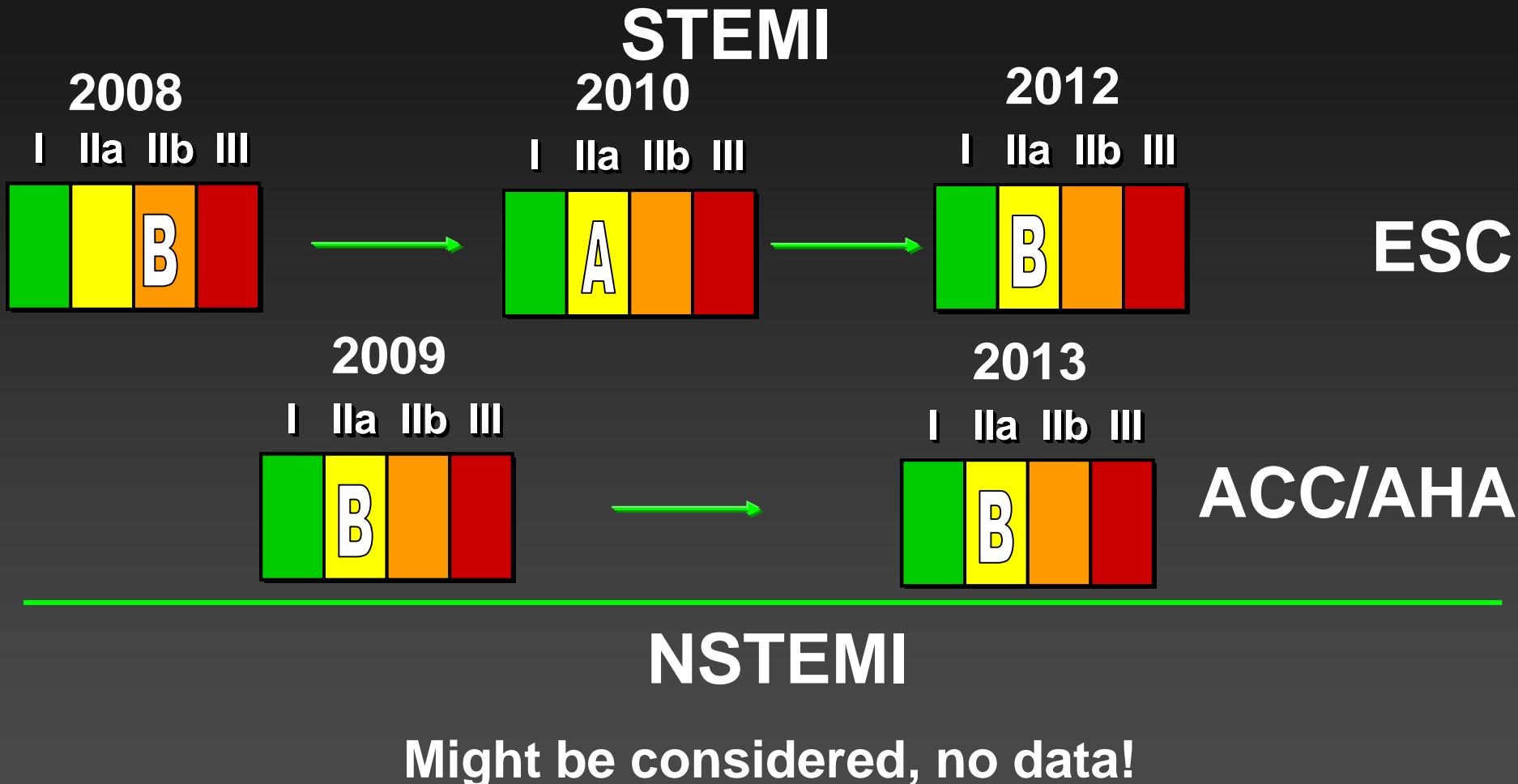
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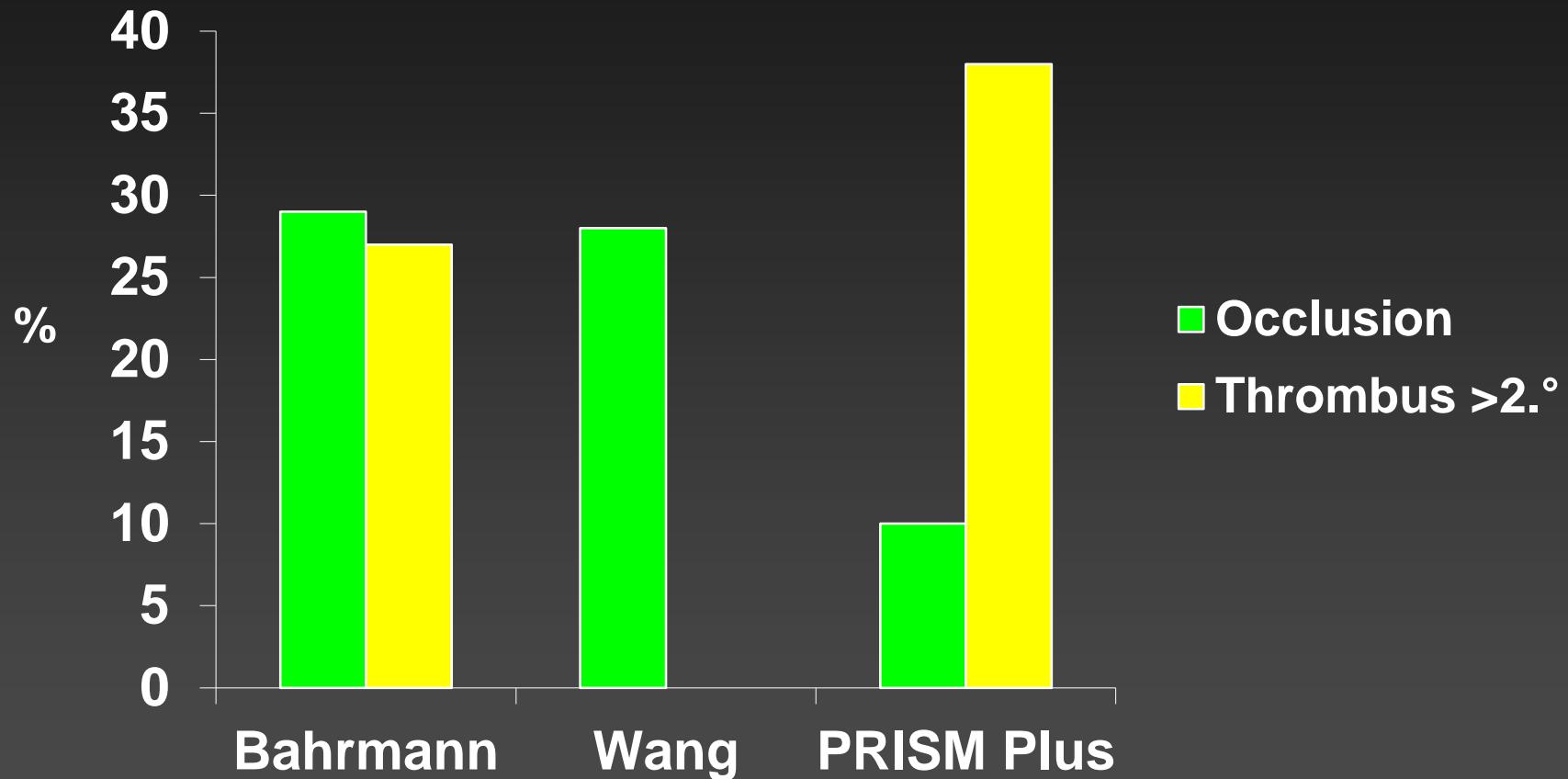
Thrombectomy Guidelines



O'Gara et al. Circulation 2013;127:e362-e425
 Kushner et al. JACC 2009;54:2205-2241

Hamm et al. Eur Heart J 2011; 32:2999-3054
 Steg et al. Eur Heart J 2012;33:2569–2619
 Wijns et al Eur Heart J 2010;31:2501-2555
 Van de Werf et al. Eur Heart J 2008; 29, 2909–2945

NSTEMI – Total Occlusion + Thrombus



Bahrmann et al. Clin Res Cardiol 2011;100:457-467

Wang et al. Am Heart J 2009;157:716-23

Zhao et al. Circulation 1999;100:1609-1615

Inclusion Criteria

NSTEMI with

1. Ischemic symptoms > 20 minutes
2. Last symptoms within 72 h pre randomization
3. Elevated cardiac troponin T or I above 99. percentile
4. Identifiable culprit lesion with relevant thrombus (TIMI thrombus-grade 2-5 in lesion) with intended PCI

Grade	Thrombus	Description
0	No Thrombus	No angiographic characteristics for thrombus
1	Possible thrombus	Angiography demonstrates thrombus characteristics such as reduced contrast density, haziness, irregular lesion contour or a smooth convex (meniscus) at the site of total occlusion suggestive but not diagnostic of thrombus
2	Thrombus present (small size)	Definitive thrombus with greatest dimension $\leq \frac{1}{2}$ vessel diameter
3	Thrombus present (medium size)	Definitive thrombus with greatest dimensions $> \frac{1}{2}$ vessel diameter but < 2 vessel diameter
4	Thrombus present (large size)	Definitive thrombus with greatest dimension > 2 vessel diameter
5	Total occlusion	

Exclusion Criteria

- **Cardiogenic shock**
- **ST-elevation myocardial infarction**
- **No identifiable culprit lesion**
- **Unsuitable coronary morphology for thrombectomy
(tortuous coronaries, calcification, etc.)**
- **Indication for immediate CABG**
- **Comorbidity with limited life expectancy < 6 months**
- **Age < 18 years**
- **Age > 90 years**
- **Contraindication for treatment with heparin, ASA or thienopyridines**
- **Pregnancy**
- **Participation in other trial**

Contraindication for CMR at randomization:

- a) **Severe claustrophobia**
- b) **Pacemaker**
- c) **Intracranial metallic clips**
- d) **Known gadolinium allergy**
- e) **Severe renal insufficiency with creatinine-clearance <30 ml/kg**

Study Endpoints

Primary Study Endpoint:

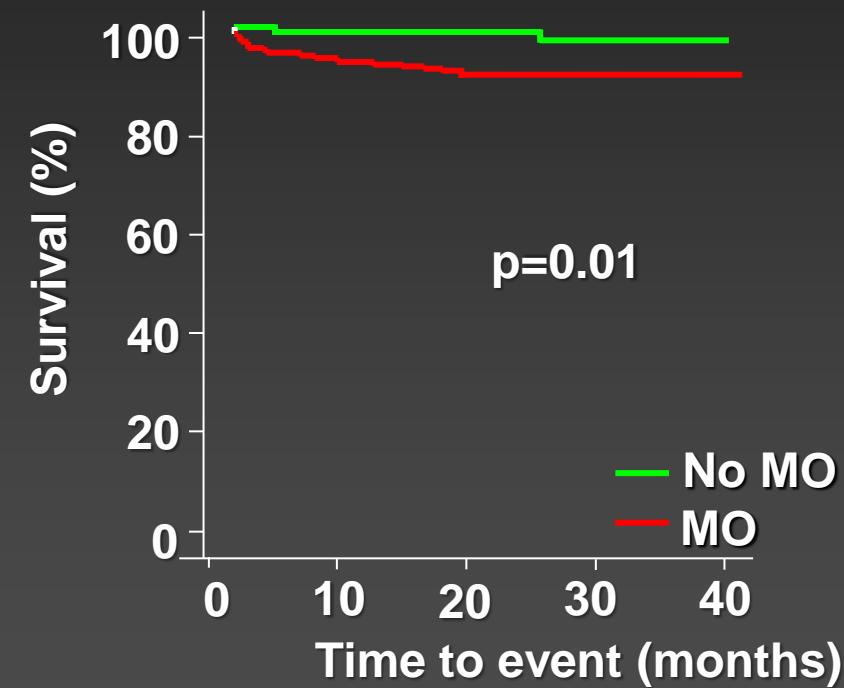
Microvascular obstruction day 1-4 in CMR

Secondary Study Endpoints:

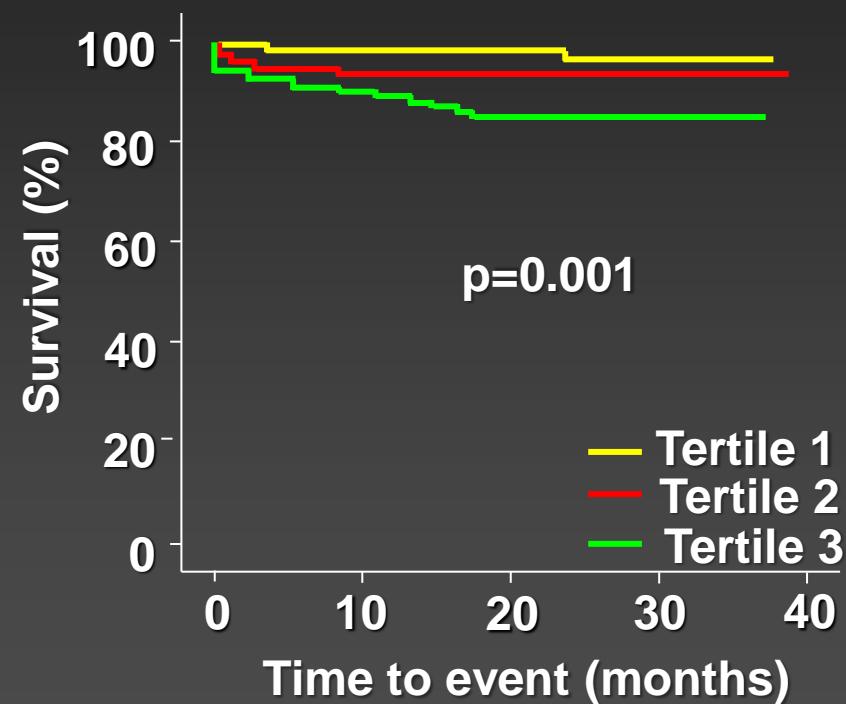
- Infarct size measured by delayed enhancement CMR day 1-4
- Myocardial salvage by CMR
- Combined clinical endpoint: Mortality, reinfarction, TVR, and congestive heart failure 6 months after randomization
- Individual clinical endpoints of combined endpoint
- TIMI-flow post PCI
- Myocardial blush grade post PCI
- Enzymatic infarct size measured by Troponin T at 24 and 48 h

Late Microvascular Obstruction + Mortality

Presence late MO



Extent late MO



Study Organization and Study Sites



Investigator Initiated Trial
7 study sites in Germany

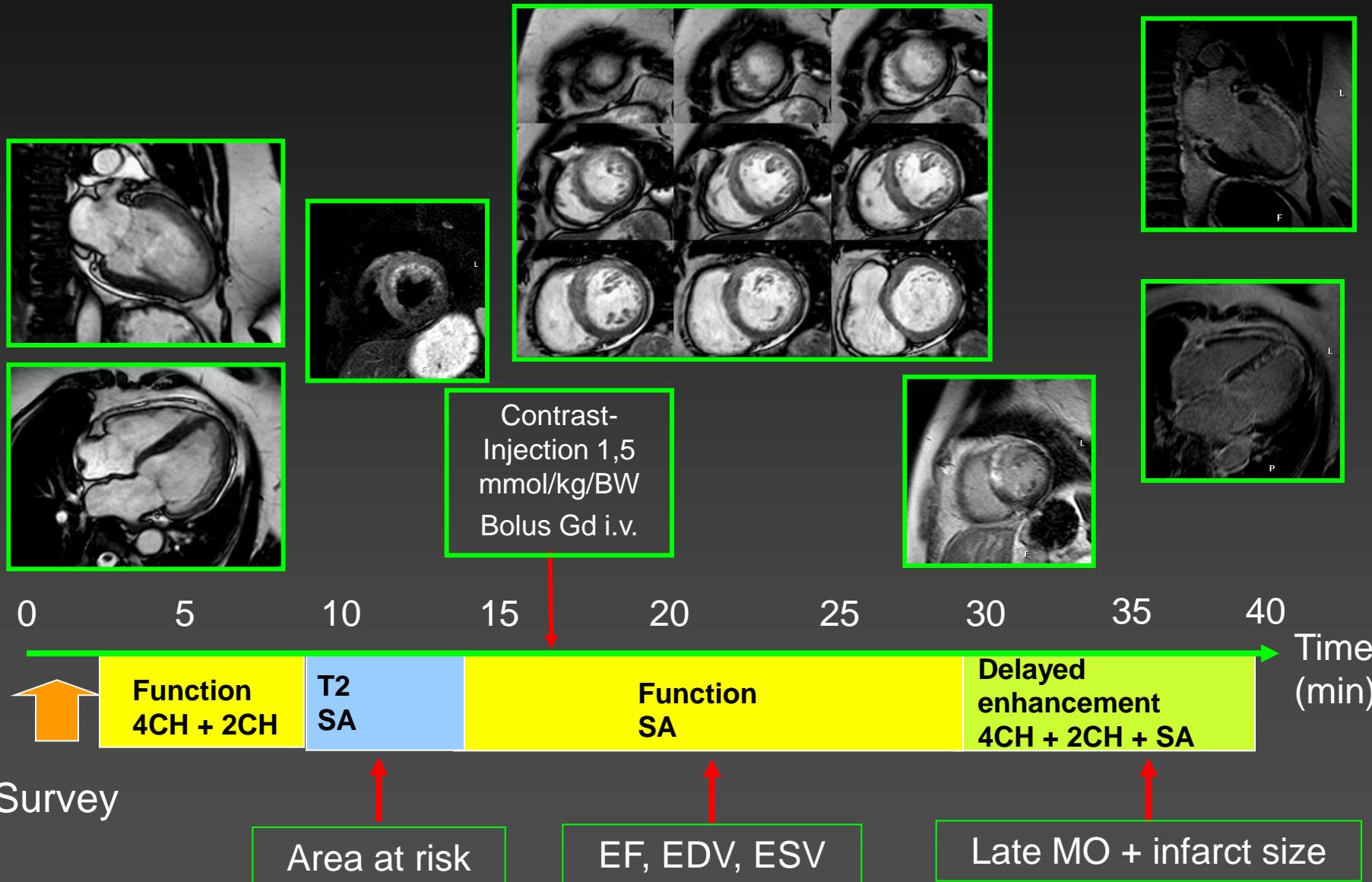
CMR core laboratory:
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Angiographic core laboratory:
Bruno Scheller, Homburg (Coordinator)

Steering Committee:
Holger Thiele
Bruno Scheller
Uwe Zeymer

CRO:
Institut für Herzinfarktforschung,
Ludwigshafen

CMR Protocol

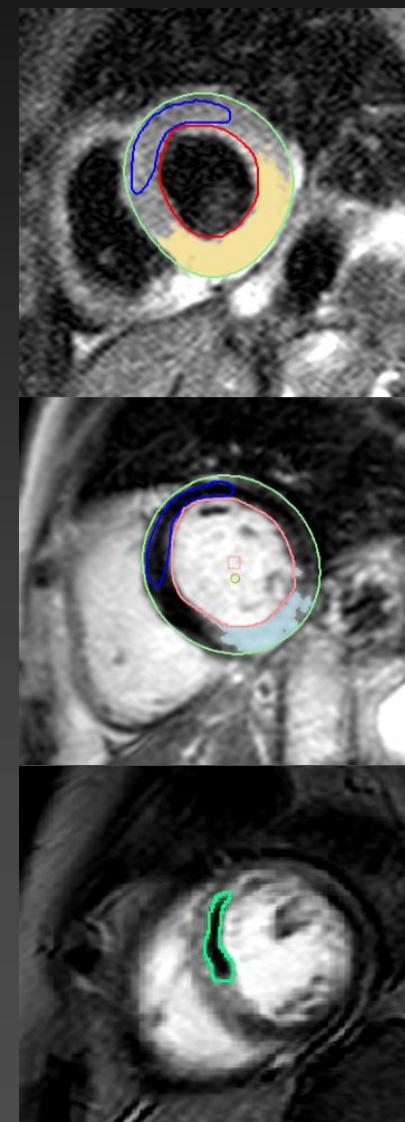


CMR Image Analysis

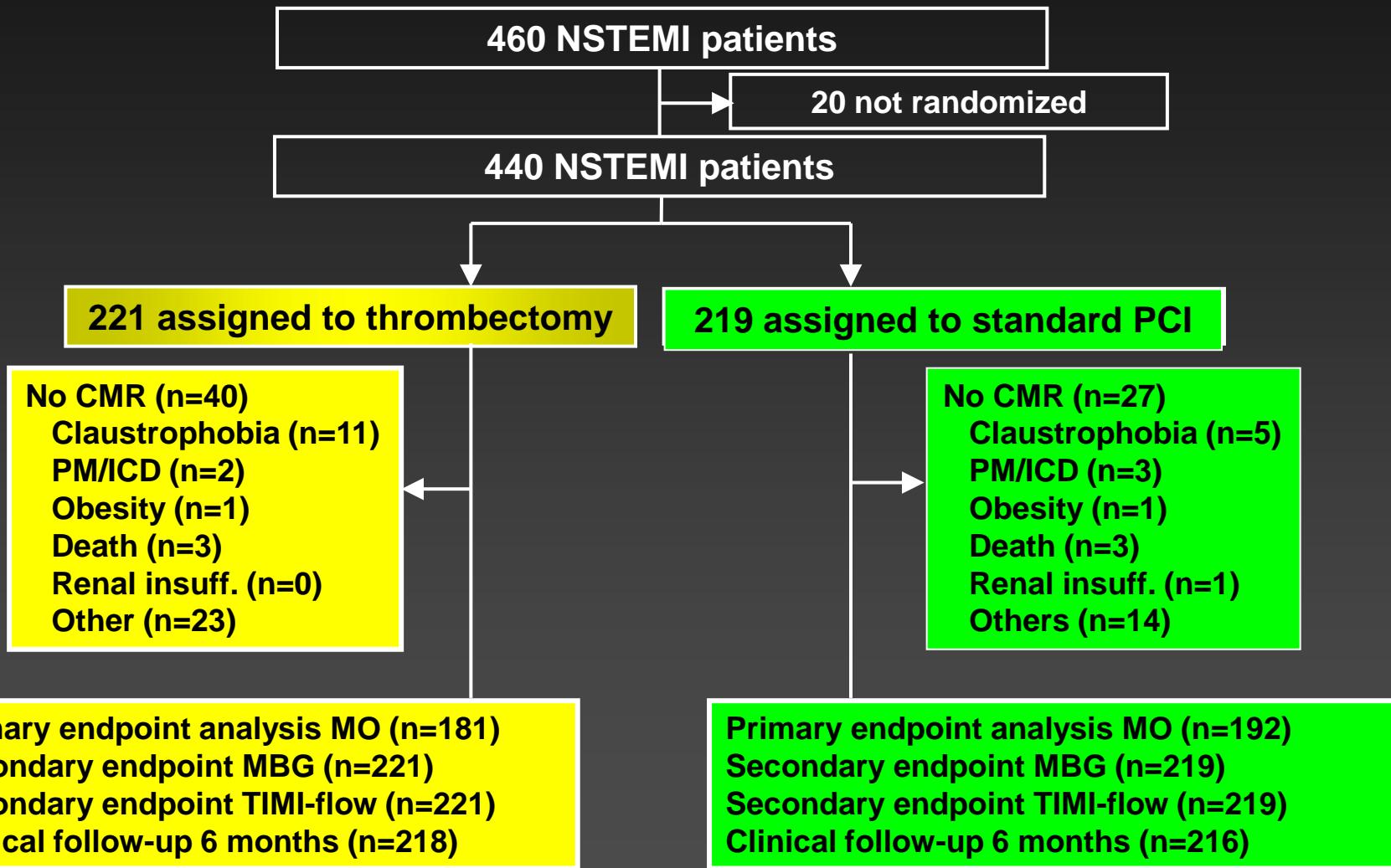
Core laboratory assessed by blinded observers:

- Edema
- Endocardial contours
- Epicardial contours
- Infarct
- Microvascular obstruction

Area at risk = Volume Edema/Volume LV mass
%Infarct Size = Volume Infarct/Volume LV mass
%MO = MO-Volume/Volume LV mass
Myocardial salvage = Edema-Infarct Size
Myocardial salvage index = Edema-Infarct Size/Edema



Study Design, Flow, and Compliance



Patient Characteristics

	Thrombectomy (n=221)	Standard PCI (n=219)
Age (years); median (IQR)	69 (58-75)	68 (58-74)
Male sex; n (%)	157 (72)	162 (75)
Current smoking; n (%)	92 (42)	80 (37)
Hypertension; n (%)	179 (82)	164 (76)
Hypercholesterolemia; n (%)	80 (37)	83 (38)
Diabetes mellitus; n (%)	63 (29)	63 (29)
Body mass index (kg/m ²); median (IQR)	27.7 (25.2-30.5)	28.1 (25.0-31.2)
Prior myocardial infarction; n (%)	16 (7)	26 (12)
Prior PCI; n/total n (%)	28 (13)	29 (13)
Prior CABG; n/total n (%)	7 (3)	10 (5)
Systolic blood pressure (mmHg); median (IQR)	144 (125-160)	140 (121-158)
TIMI thrombus grade; (%)		
2	29 (13)	20 (9)
3	59 (27)	66 (30)
4	56 (26)	60 (28)
5	75 (34)	71 (33)
GRACE-Score, median (IQR)	145 (116-168)	137 (115-162)

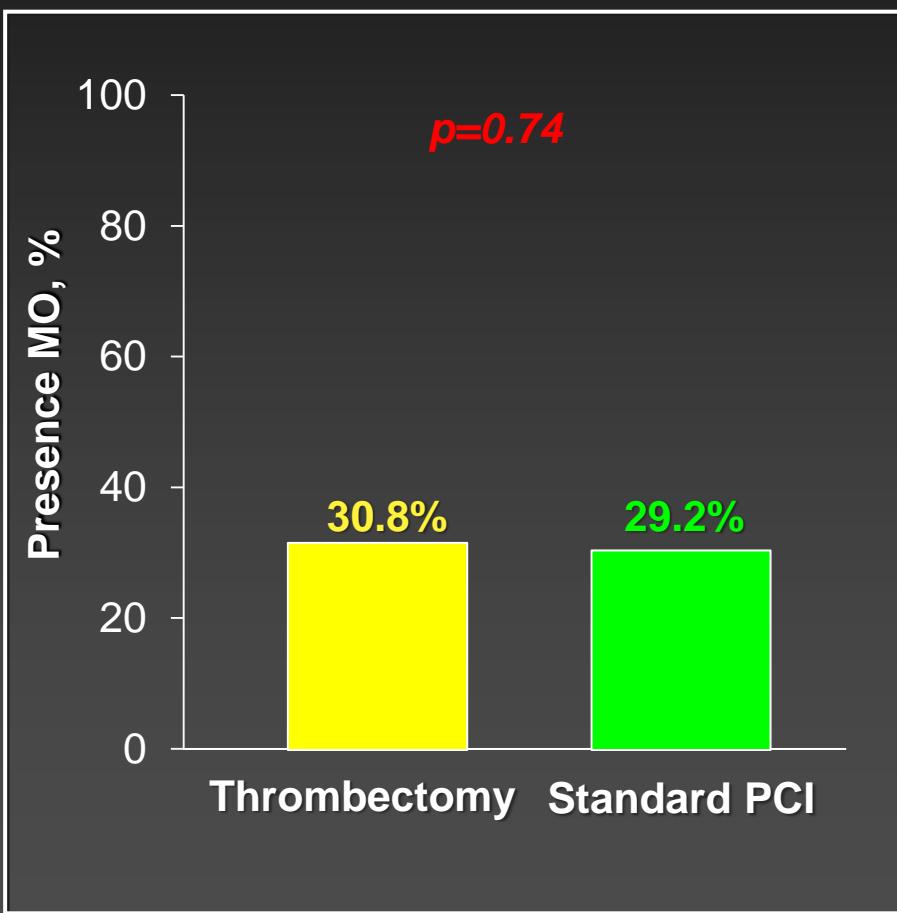
Results

Study Procedures and Medications

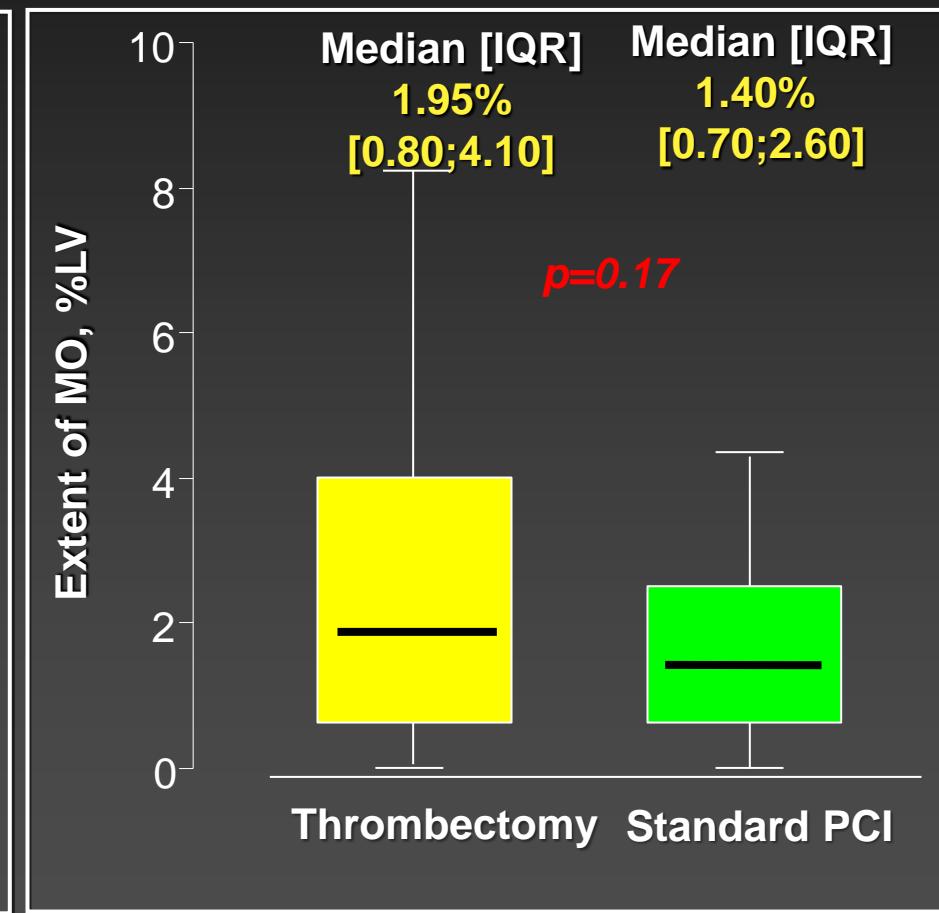
	Thrombectomy (n=221)	Standard PCI (n=219)	p
Infarct-related artery; n (%)			0.85
LAD	81 (37)	69 (32)	
LCX	83 (38)	89 (41)	
RCA	49 (22)	54 (25)	
Left main	1 (1)	0 (0)	
Bypass graft	5 (2)	5 (2)	
Single vessel disease; n (%)	87 (40)	105 (48)	0.18
Double vessel disease; n (%)	82 (37)	63 (29)	
Triple vessel disease; n (%)	50 (23)	49 (23)	
Radial access; n (%)	30 (14)	29 (13)	0.92
Thrombectomy; n (%)	217 (98)	0 (0)	
Aspiration of thrombus material; n (%)	162 (74)		
Primary Stenting; n (%)	131 (61)	95 (45)	<0.01
Drug-eluting stent; n (%)	153 (71)	146 (69)	0.62
Bare metal stent; n (%)	65 (30)	65 (30)	0.95
Concomitant medications; n (%)			
Beta-blocker	206 (95)	204 (96)	0.68
ACE-inhibitor/AT-1-antagonist	184 (85)	185 (87)	0.54
Statin	211(97)	208 (98)	0.78
Aspirin	221 (100)	219 (100)	0.99
Clopidogrel	57 (26)	55 (26)	0.92
Prasugrel	89 (41)	84 (39)	0.74
Ticagrelor	72 (61)	78 (63)	0.64

Primary Study Endpoint - MO

Presence of MO

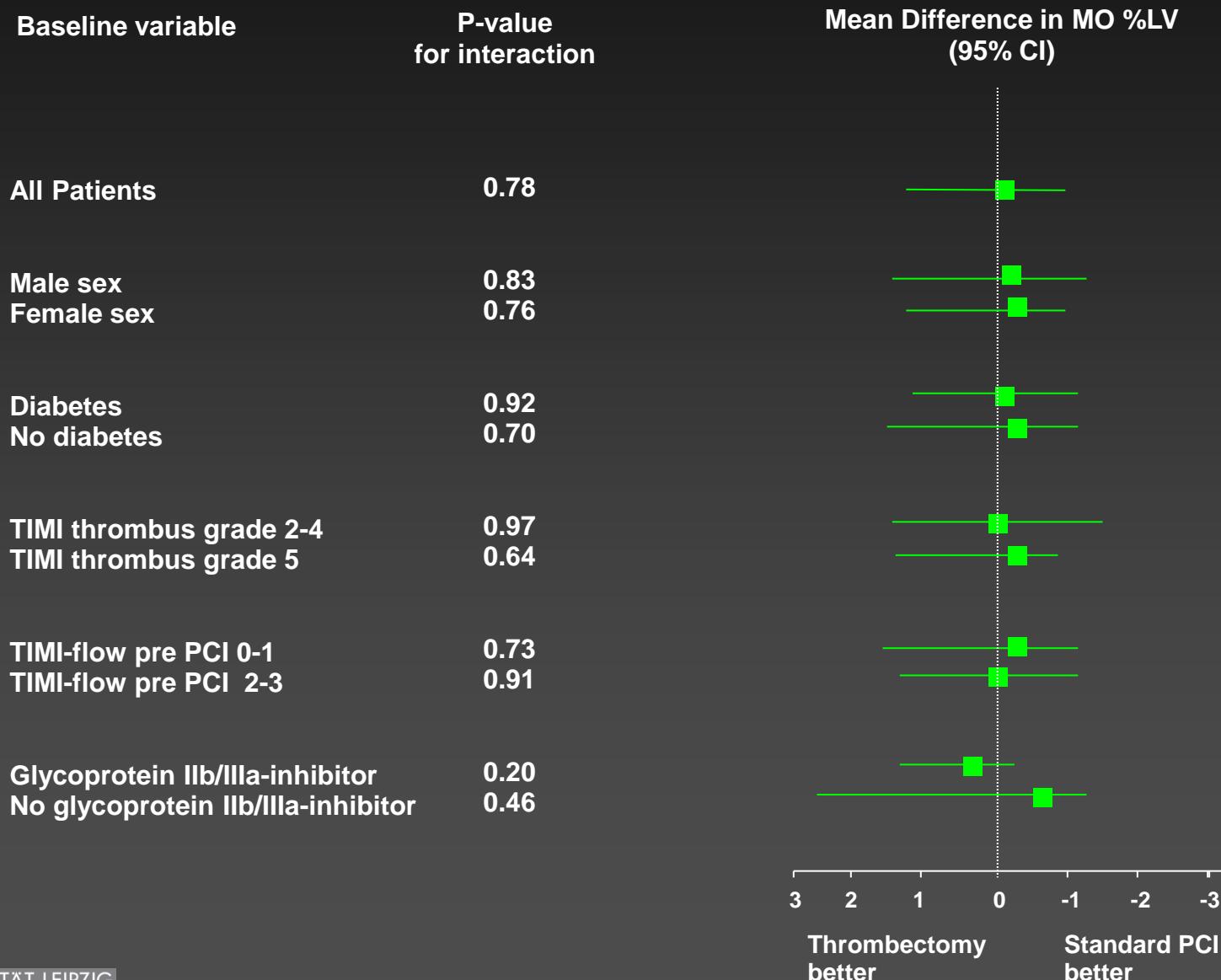


Extent of MO



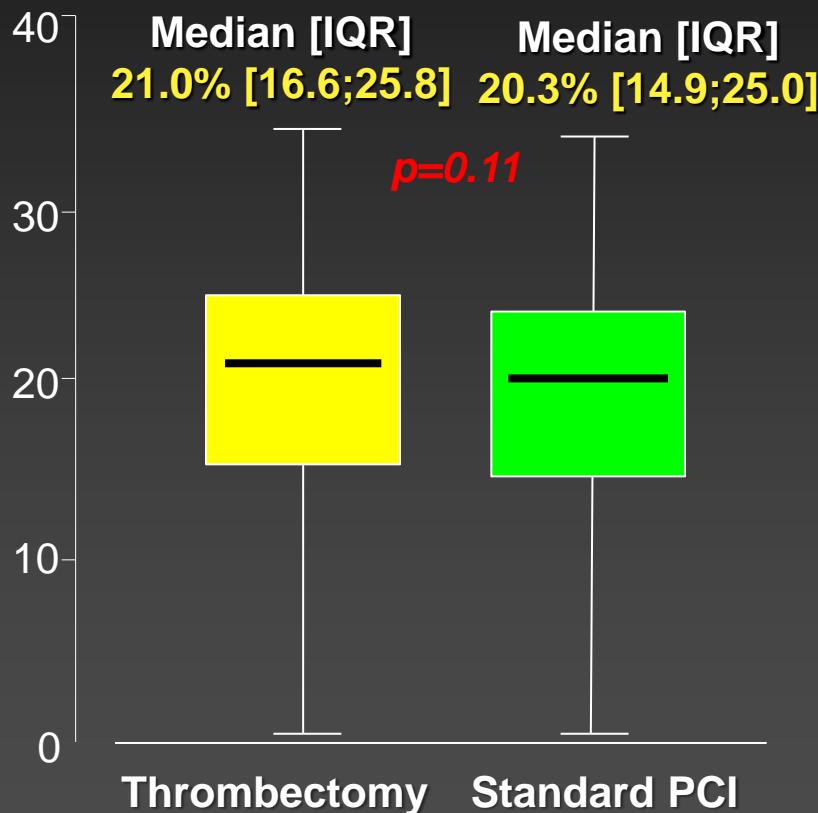
Core lab assessed

MO – Predefined Subgroups

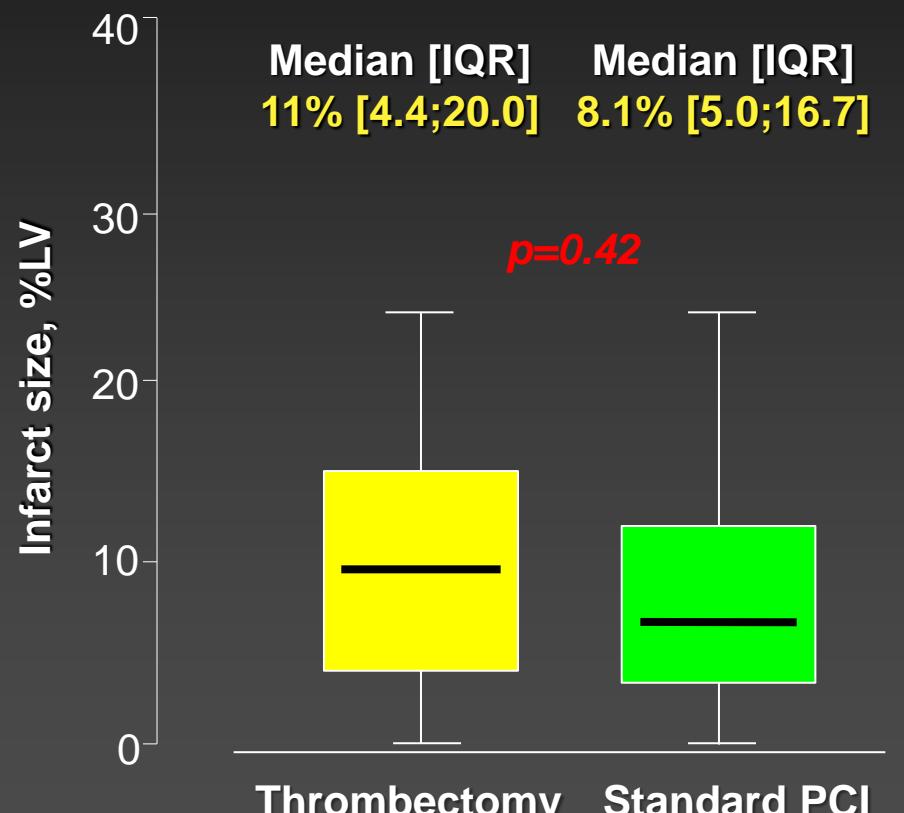


Area at Risk + Infarct Size

Area at risk

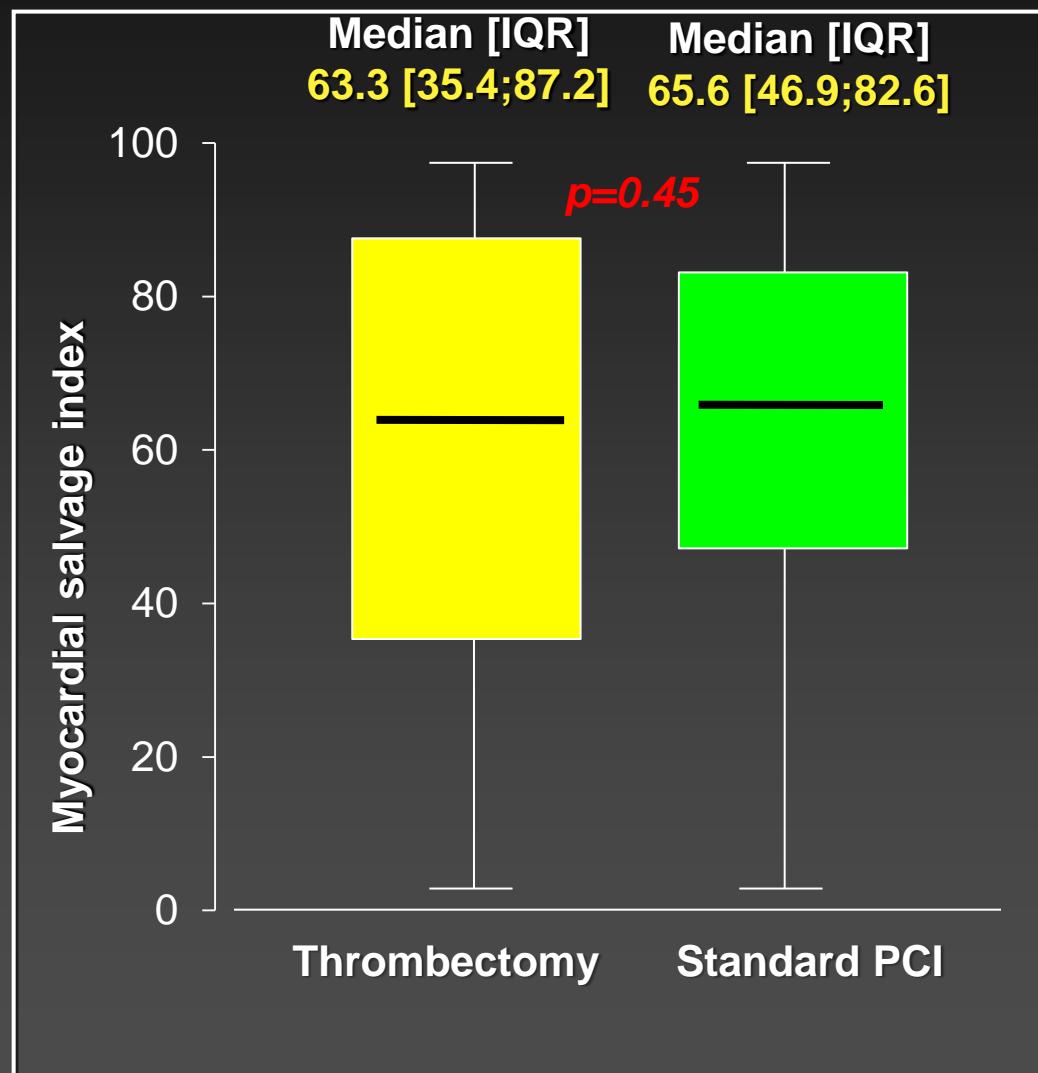


Infarct size



Core lab assessed

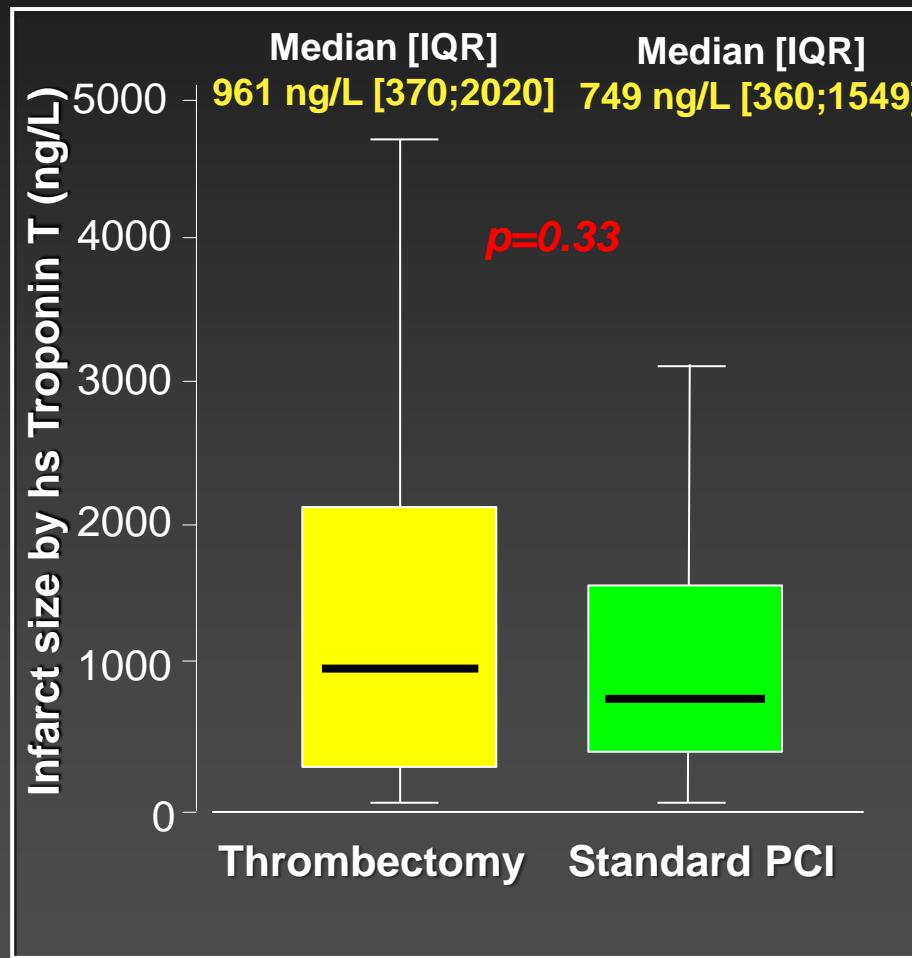
Myocardial Salvage Index



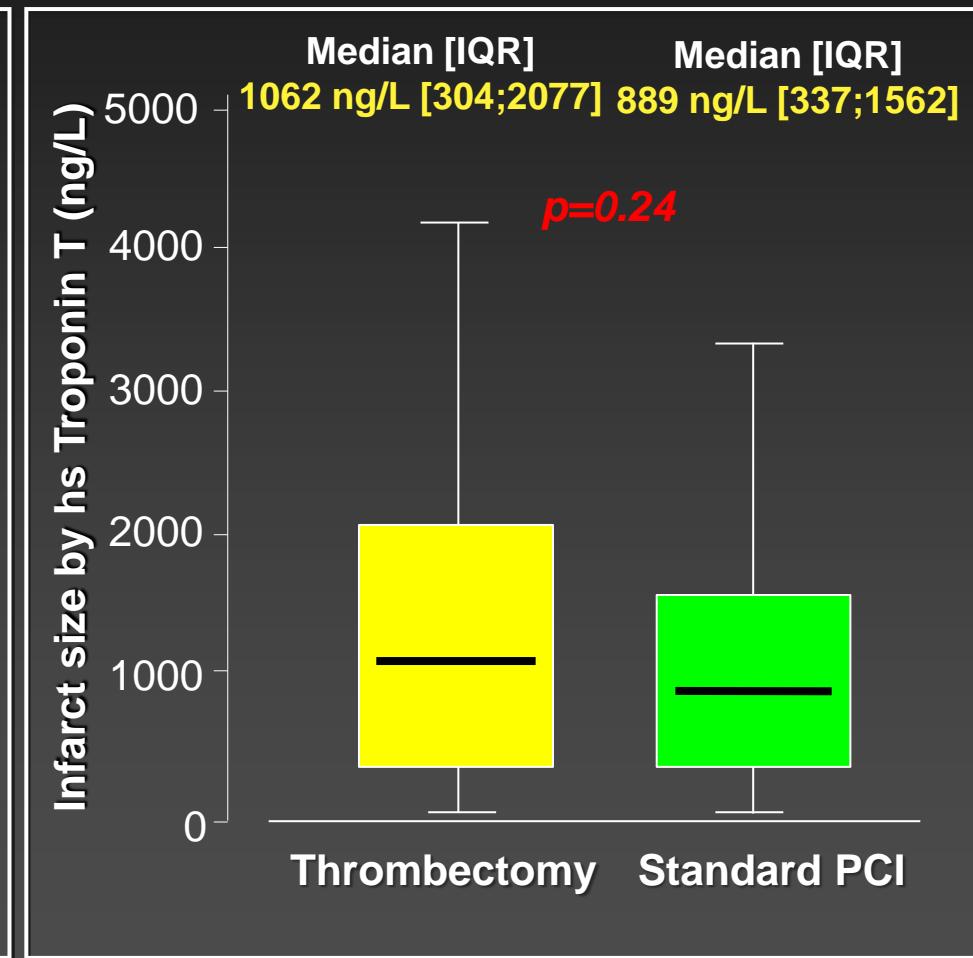
Core lab assessed

Enzymatic Infarct Size

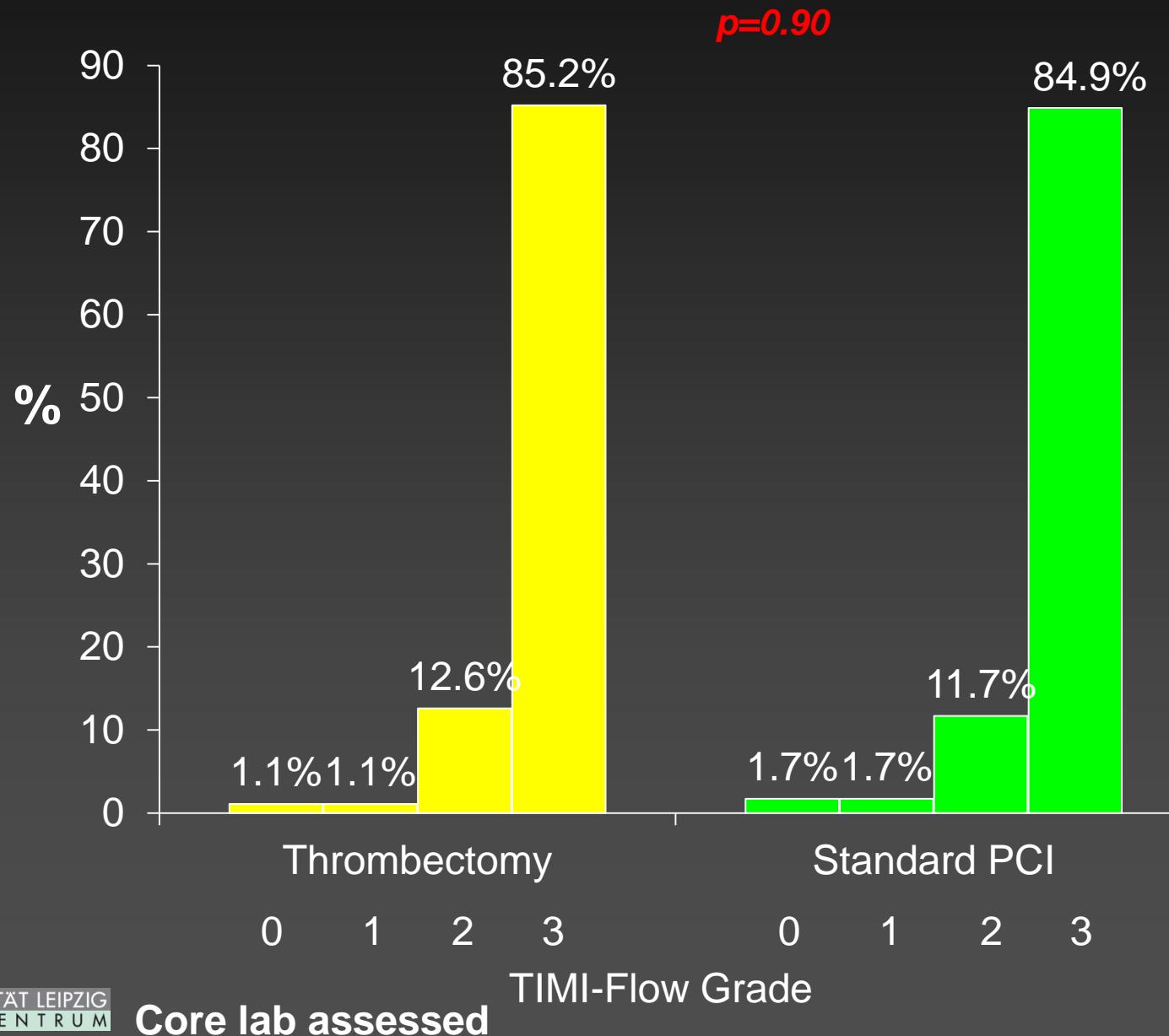
Infarct size 24 h



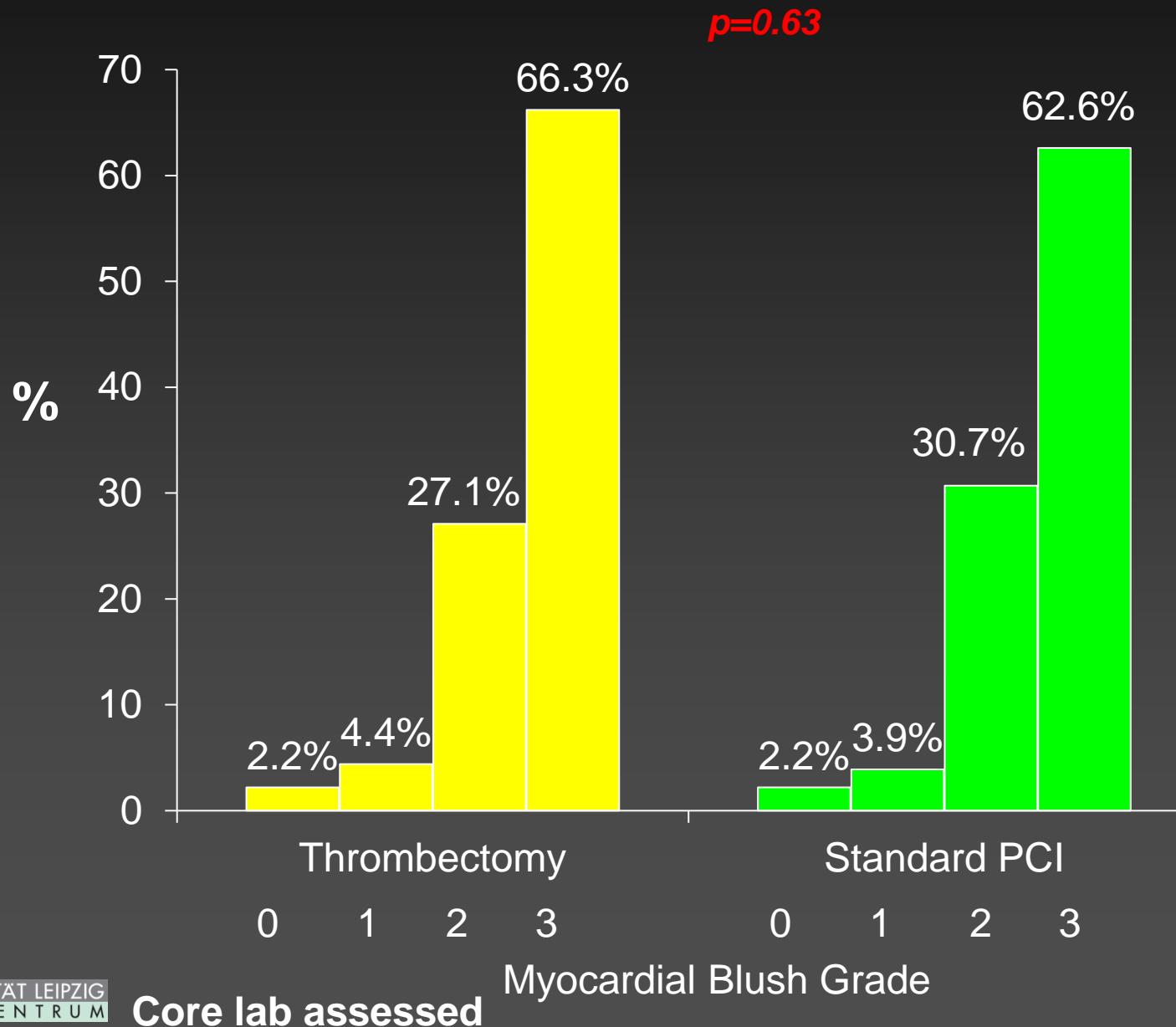
Infarct size 48 h



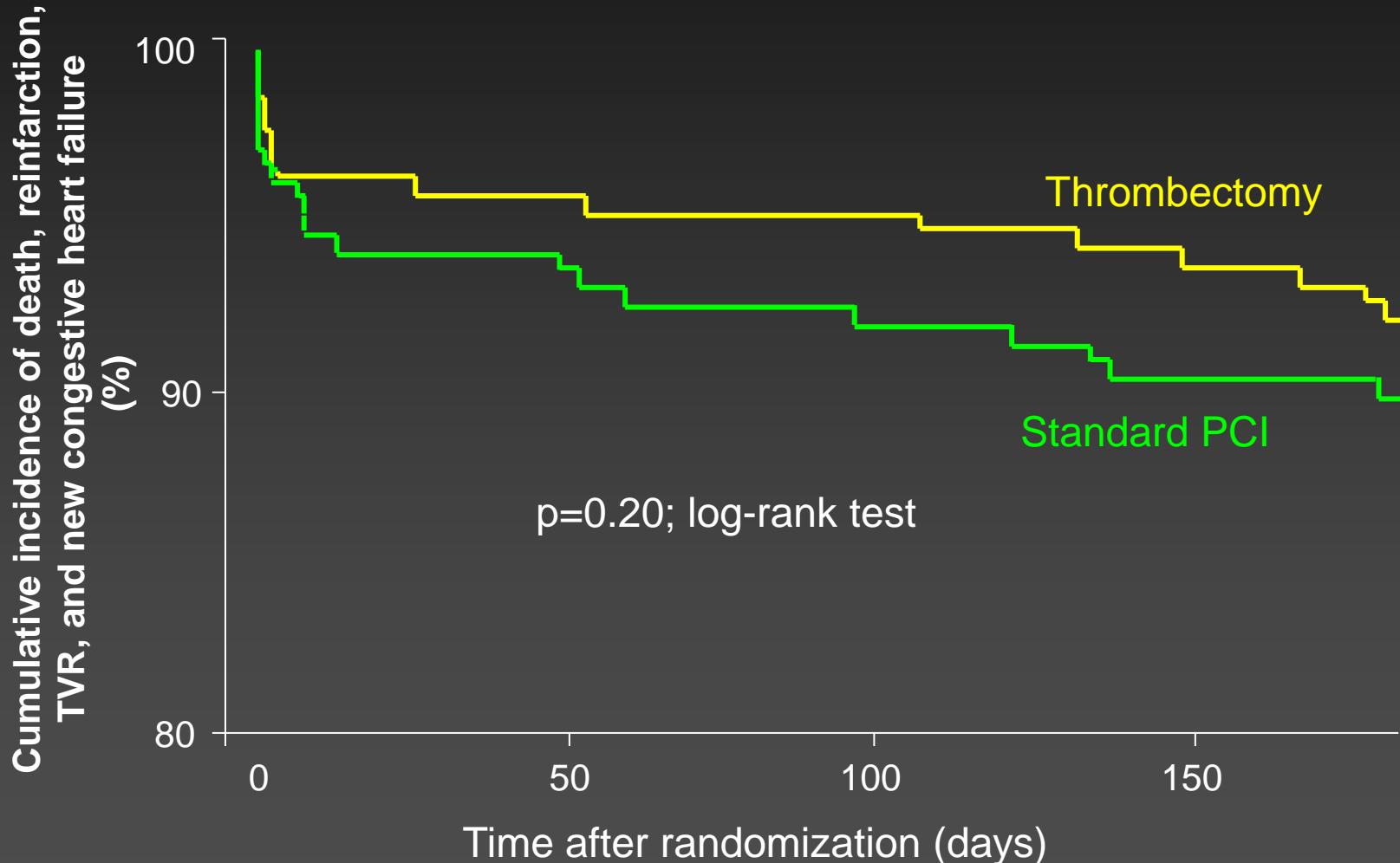
TIMI-Flow post PCI



Myocardial Blush Grade



Clinical Outcome 6 Months



Clinical Outcome 6 Months

	Thrombectomy	Standard PCI	HR	95% CI	P
Death/Reinfarction/TVR/ new CHF	7.3%	10.1%	0.72	0.37-1.41	0.34
Death	3.0%	3.3%	0.83	0.28-2.48	0.74
Reinfarction	2.1%	2.7%	0.78	0.21-2.89	0.70
TVR	2.1%	1.6%	1.30	0.29-5.80	0.73
New CHF	1.8%	4.4%	0.43	0.13-1.40	0.15

Summary + Conclusions

- In this first randomized, multicenter trial in patients with NSTEMI with thrombus containing lesions aspiration thrombectomy led to aspiration of thrombus material in 74%.
- This led to a higher rate of primary stent implantation in comparison to standard PCI.
- However, aspiration thrombectomy did not reduce the extent of microvascular obstruction in comparison to standard PCI without thrombectomy.
- The results are also supported by a lack of benefit in secondary endpoints.

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TATORT-NSTEMI Investigators from 7 sites in Germany

Steering Committee **Angio Core Lab Homburg**

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I. Eitel (Coordinator)

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Study Sites

Leipzig – Heart Center: H. Thiele

Leipzig – University: N. Klein, D. Pfeiffer

Berlin: L. Bruch

Frankfurt (Oder): O. Gunkel

Tübingen: T. Geisler, M. Gawaz

Ludwigshafen: U. Zeymer

Bad Berka: B. Lauer

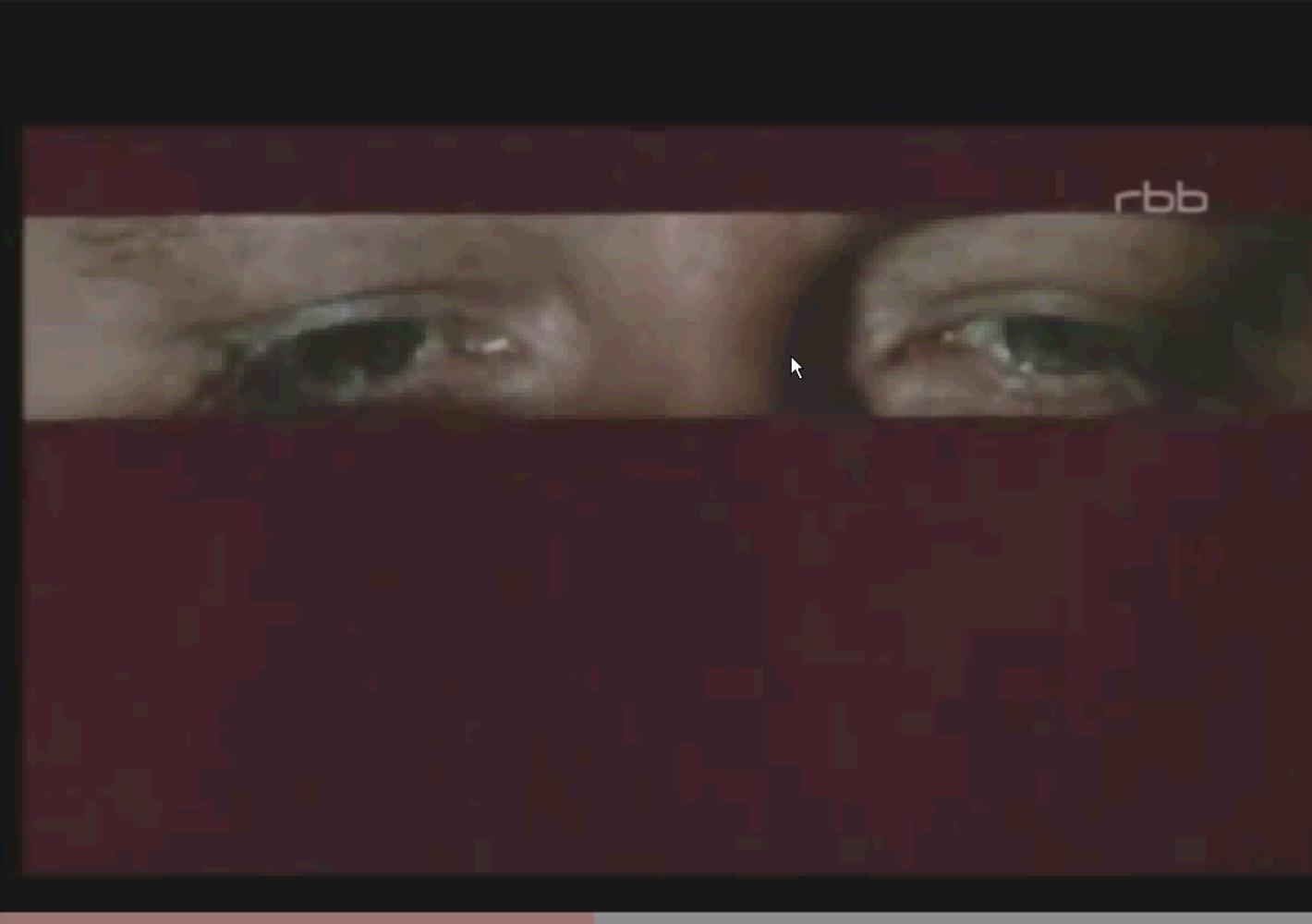
CEC

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Thank you for your attention

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