

Effect of Thrombus Aspiration in Patients With Myocardial Infarction Presenting Late After Symptom Onset

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

Company

- Medtronic
- None related to the study
- None related to the study
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Background

- Recent trials on **thrombus aspiration in STEMI** reported disappointing results with no reduction in mortality and possibly an increase in stroke.



Symptom onset:



Frobert et al. *N Engl J Med* 2013;369:1587-97.

Jolly et al. *N Engl J Med* 2015;372:1389-98.

Background

Hypothesis

- Routine **thrombus aspiration** reduces **microvascular obstruction (MVO)** assessed by cardiac magnetic resonance imaging (CMR) in patients with **subacute STEMI** presenting between 12 and 48 hours after symptom onset.

Design

- Prospective, randomized, controlled, single-blind
- Single-center

Methods

Main Inclusion Criteria

- STEMI ≥ 12 and ≤ 48 hours after symptom onset
- Age ≥ 18 and ≤ 90 years

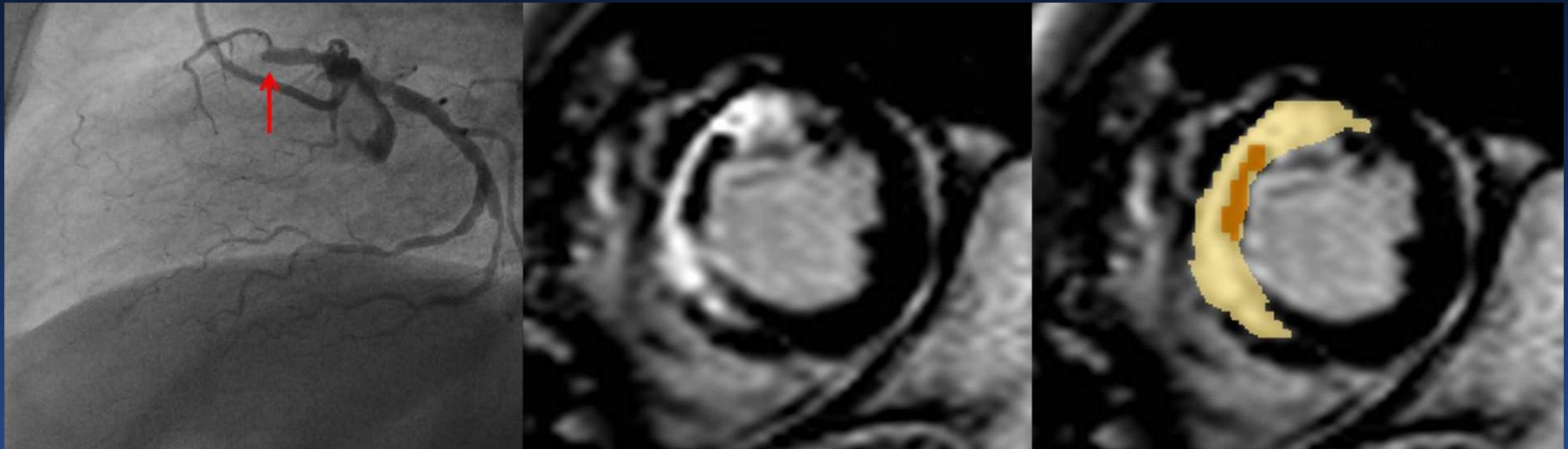
Main Exclusion Criteria

- Prior thrombolysis
- Contraindications for CMR
- Life expectancy < 6 months

Methods

Primary Endpoint

- Extent of MVO on late gadolinium enhancement CMR at day 1 - 4



Methods

Secondary Endpoints

- CMR
 - Infarct size
 - Myocardial salvage
 - LV volumes and ejection fraction
- Angiography
 - TIMI flow post-PCI
 - Myocardial blush grade post-PCI
- Enzymatic infarct size
 - High-sensitivity troponin T after 24 and 48 hours
- Clinical outcome
 - 30-day follow-up
 - All-cause and cardiovascular death, myocardial reinfarction, TLR, TVR, stent thrombosis, stroke

Methods

Percutaneous Coronary Intervention

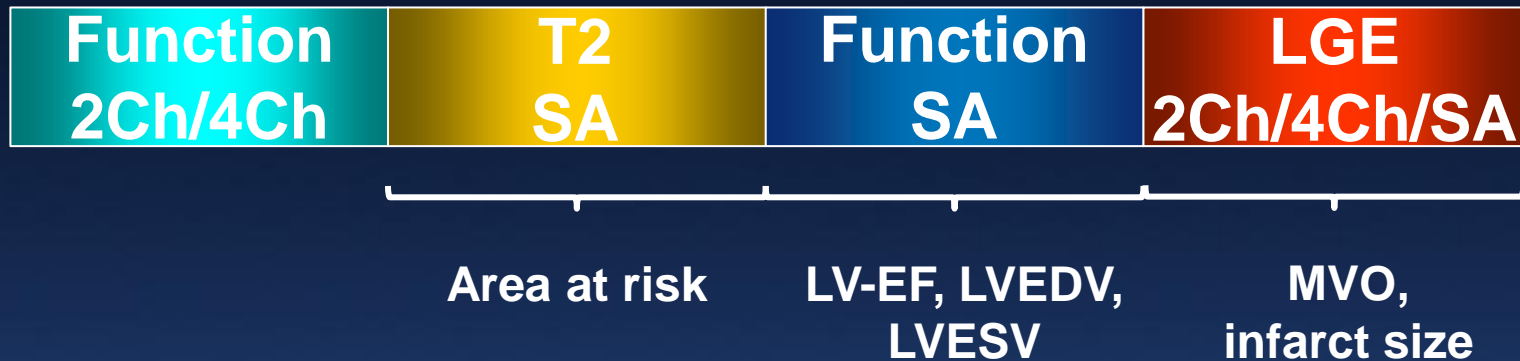
- **Thrombus aspiration:**
 - Before first balloon inflation
 - Manual aspiration catheter
(Export® AP, 6 French, Medtronic Inc.)
 - Minimum of 2 passages recommended

- **Additional procedural strategies:**
 - According to current best practice
(e.g. heparin/bivalirudin ± GP IIb/IIIa-inhibitor)

Methods

Cardiac Magnetic Resonance Imaging

- Standard protocol / day 1 - 4



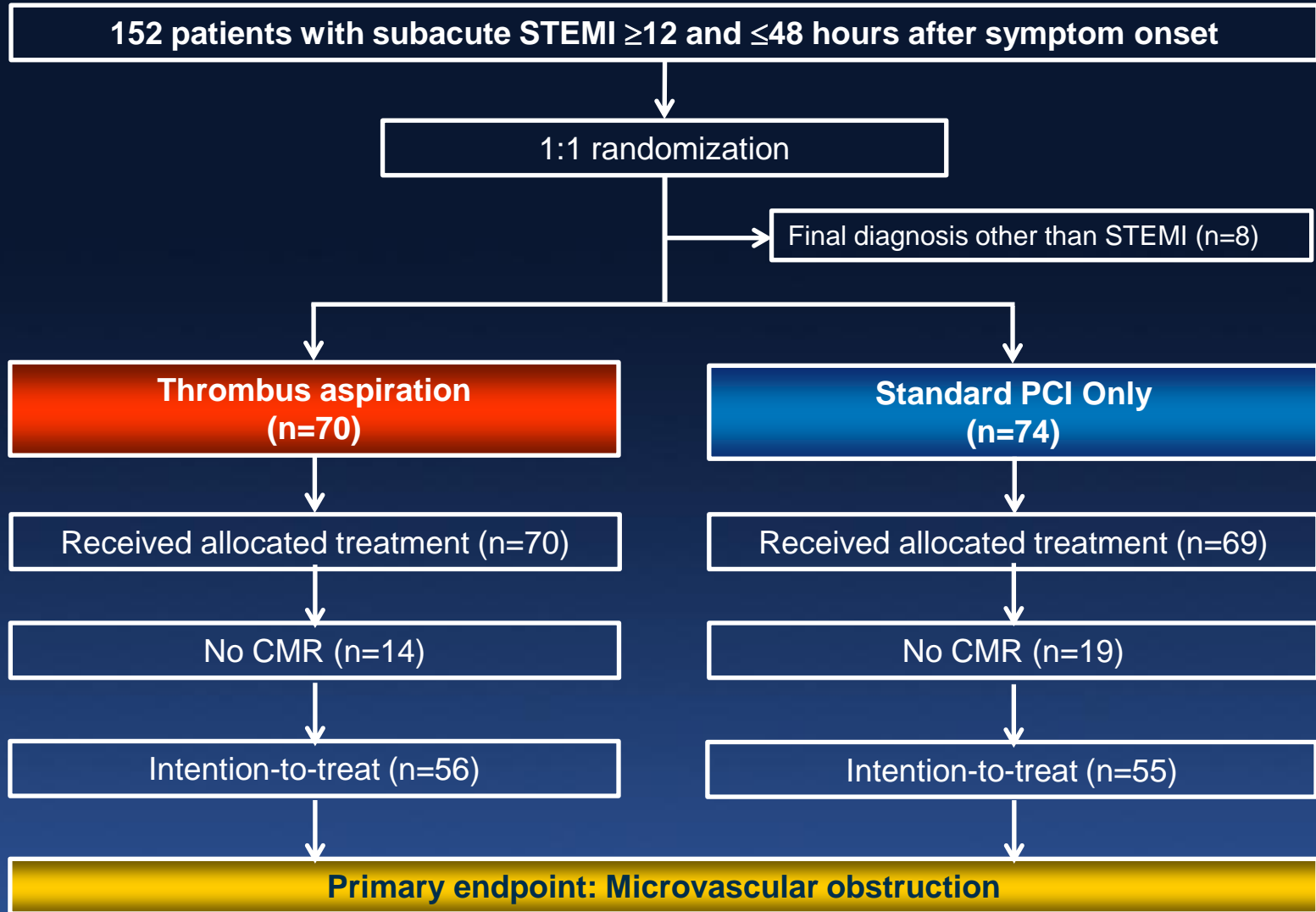
- CMR core laboratory
 - University Heart Center Lübeck, Germany
 - Assessment by fully blinded operators

Methods

Sample Size Calculation

Mean difference	2.0 %LV
Standard deviation	3.5 %LV
Power	90%
Alpha	0.05
Drop-out	15%
Sample size, n:	152 2 x 76

Study Flow



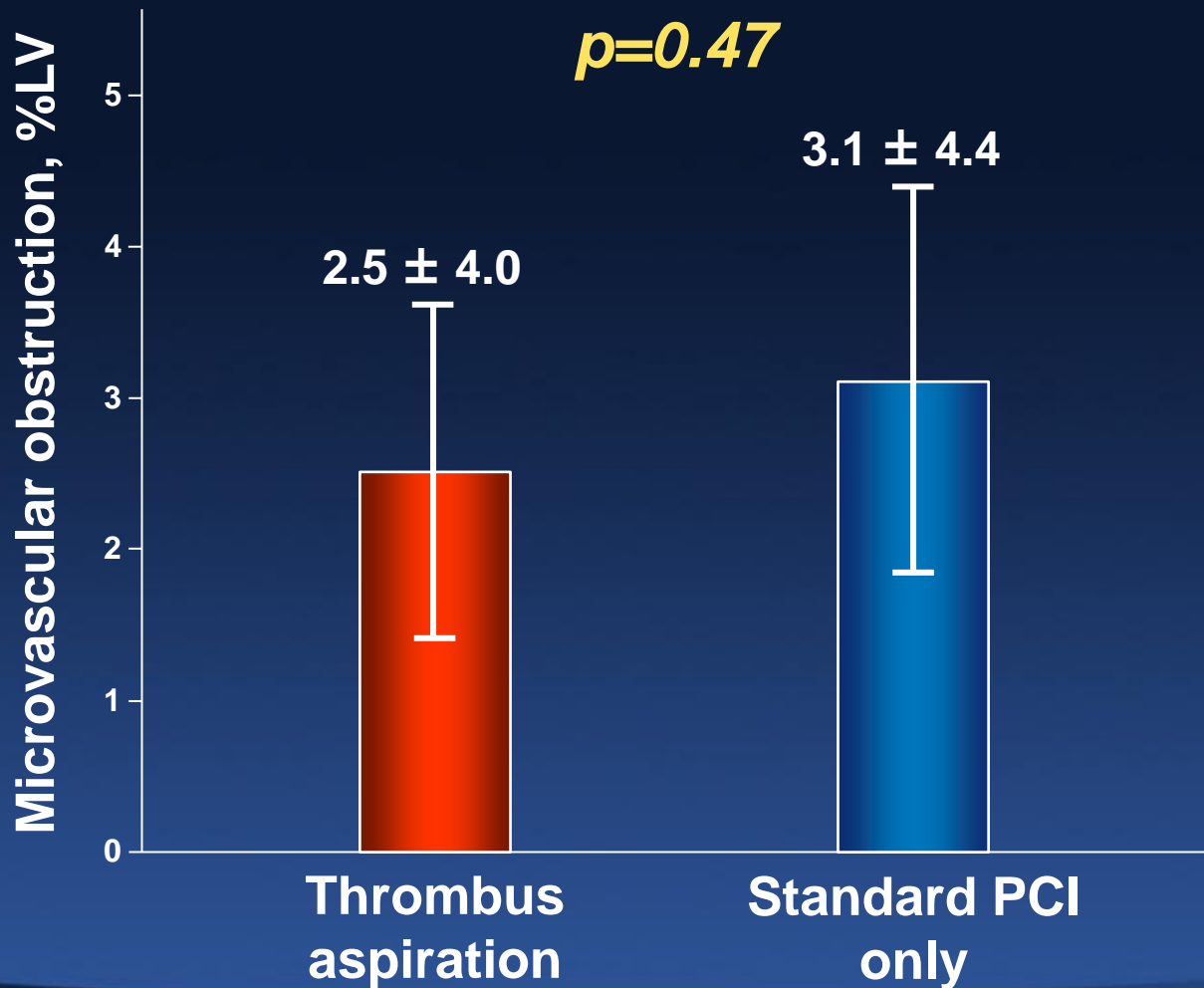
Results

Baseline Characteristics

	Thrombus aspiration n = 70	Standard PCI n = 74
Age, years	66 ± 12	66 ± 15
Hypertension, n (%)	55/70 (79)	48/74 (65)
Hyperlipoproteinemia, n (%)	11/70 (16)	17/74 (23)
Diabetes mellitus, n (%)	22/70 (31)	25/74 (34)
Ongoing signs of ischemia, n (%)	28/57 (49)	34/62 (55)
Symptom-onset-to-balloon, hours	26 ± 13	29 ± 12
TIMI flow pre-PCI 0, n (%)	44/70 (63)	46/74 (62)
GP IIb/IIIa-inhibitor, n (%)	18/70 (25)	21/74 (28)

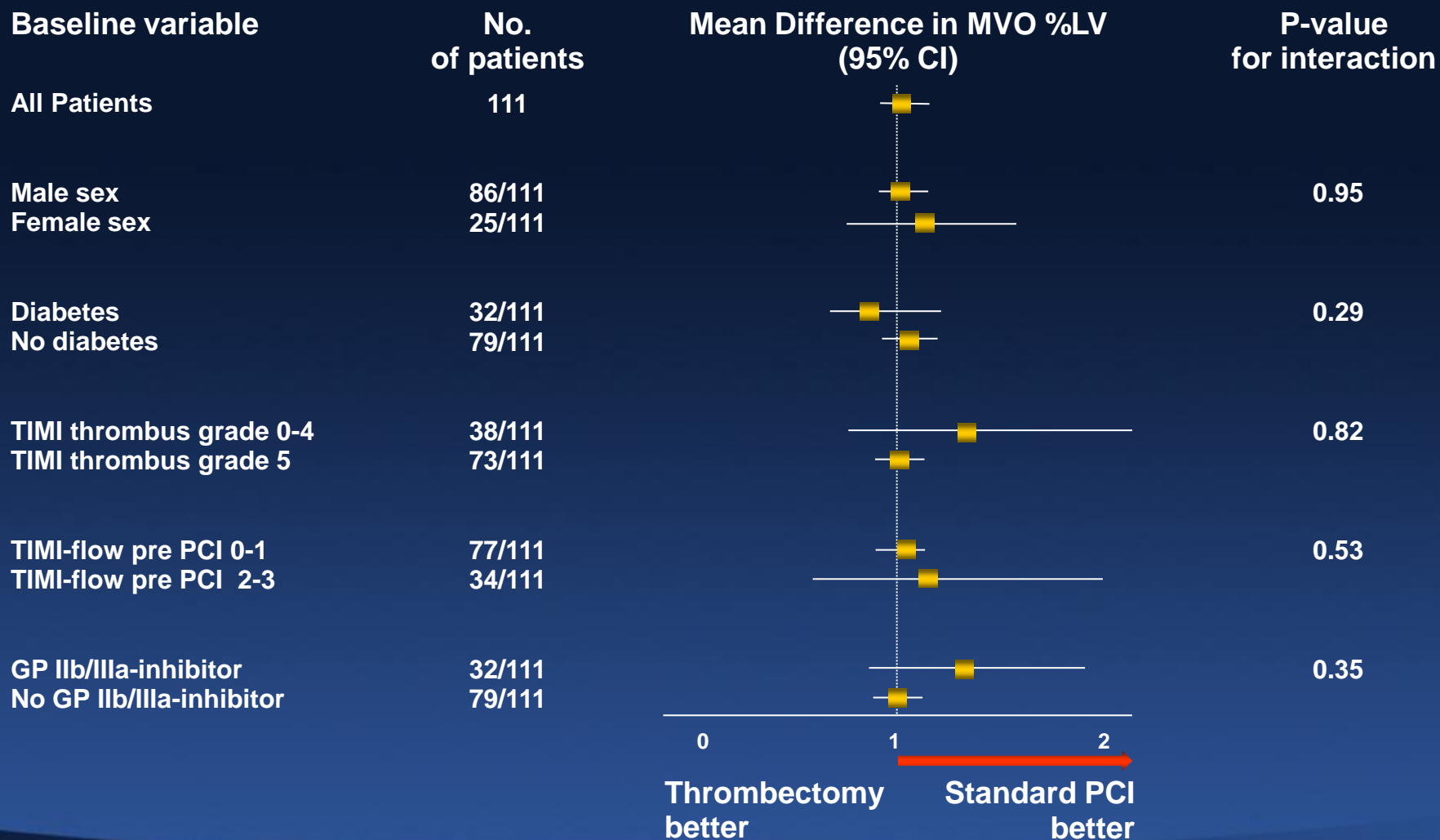
Results

Primary Endpoint: Microvascular Obstruction



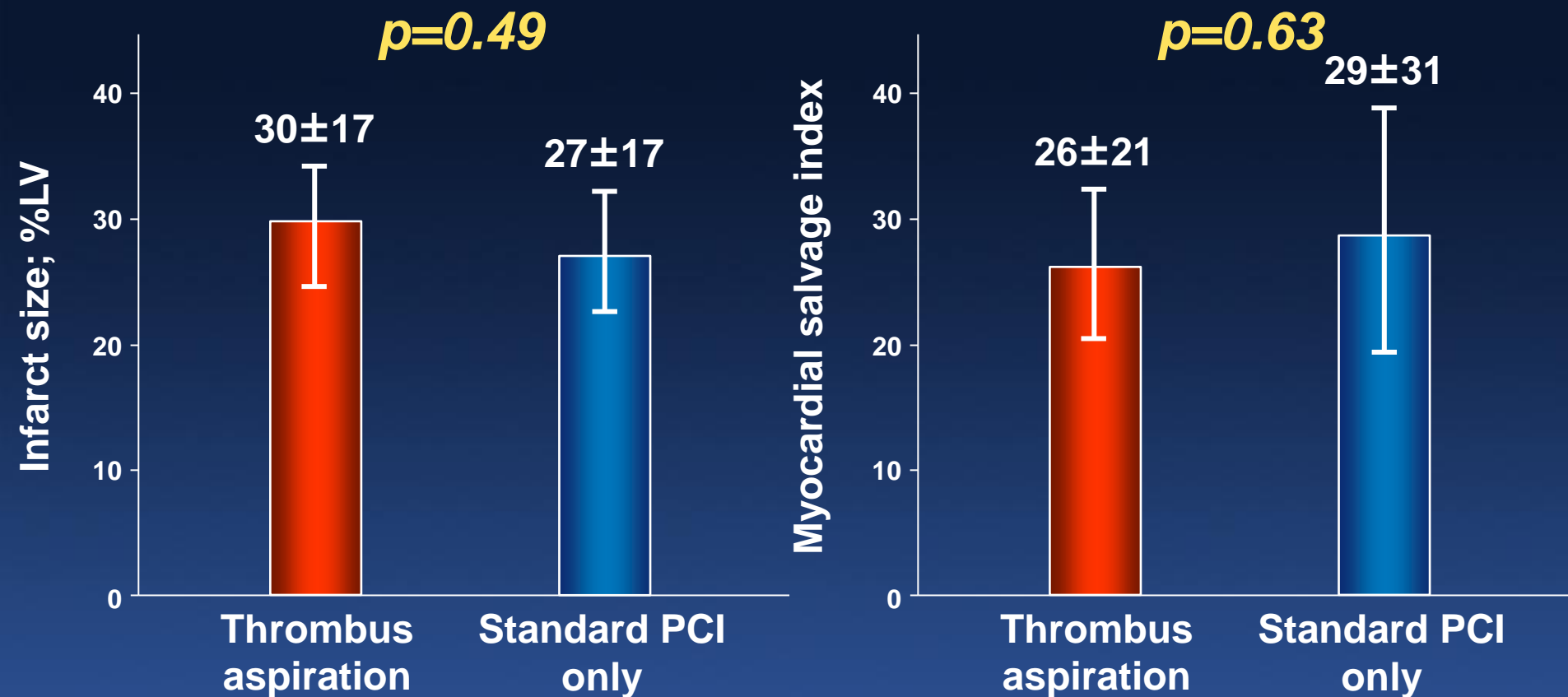
Results

MVO in Predefined Subgroups



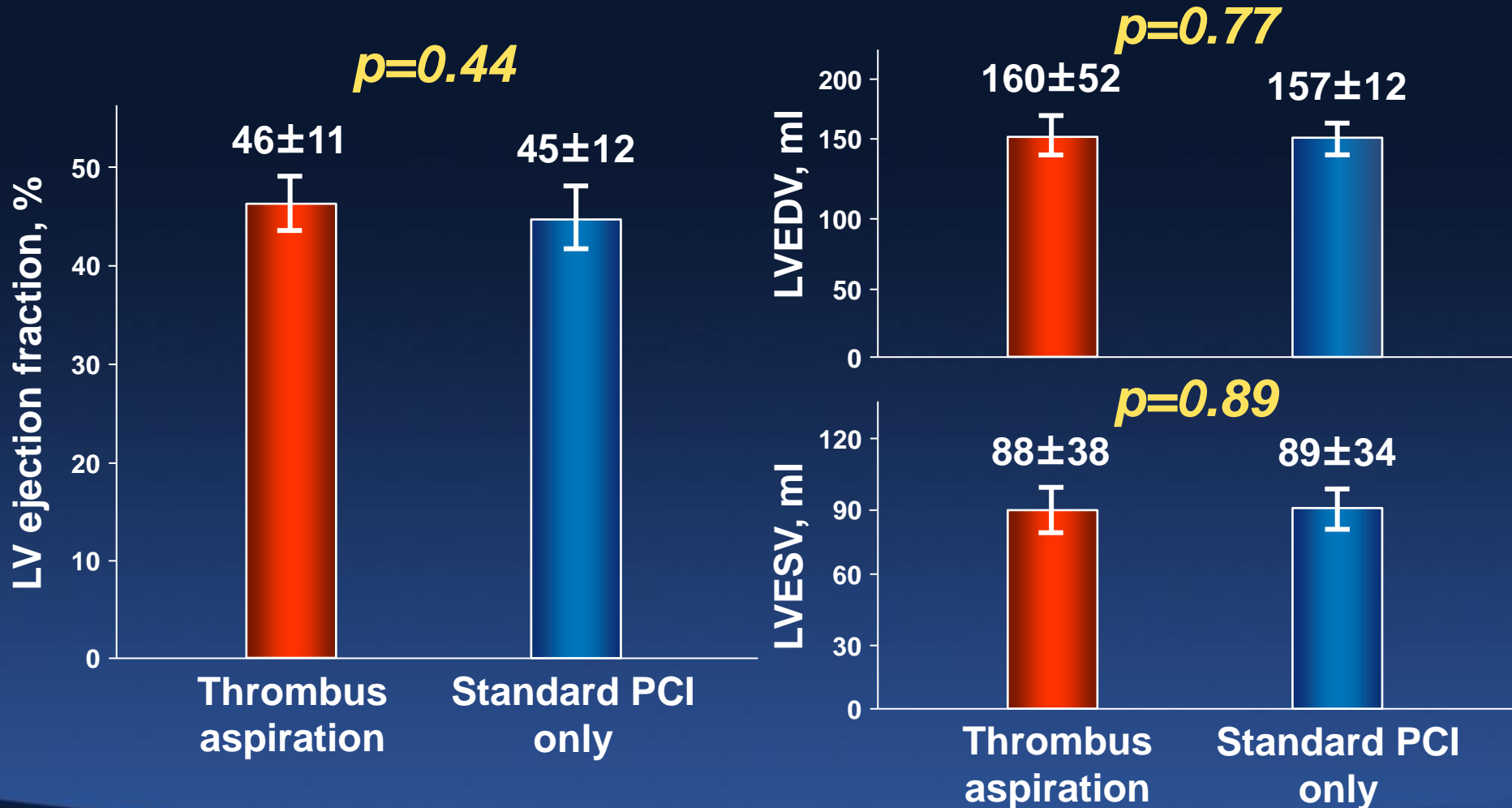
Results

Secondary Endpoints: Infarct Size and Salvage



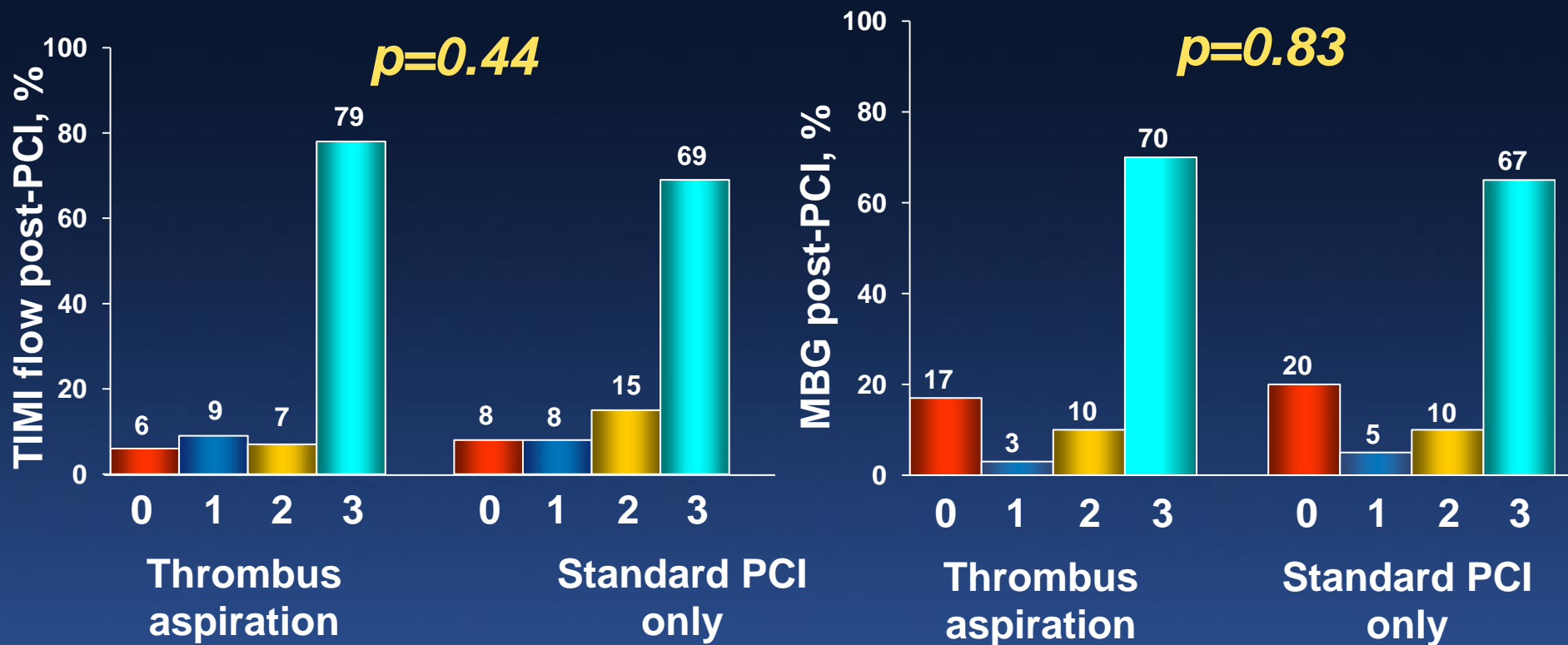
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Secondary Endpoints: LV Function and Volumes



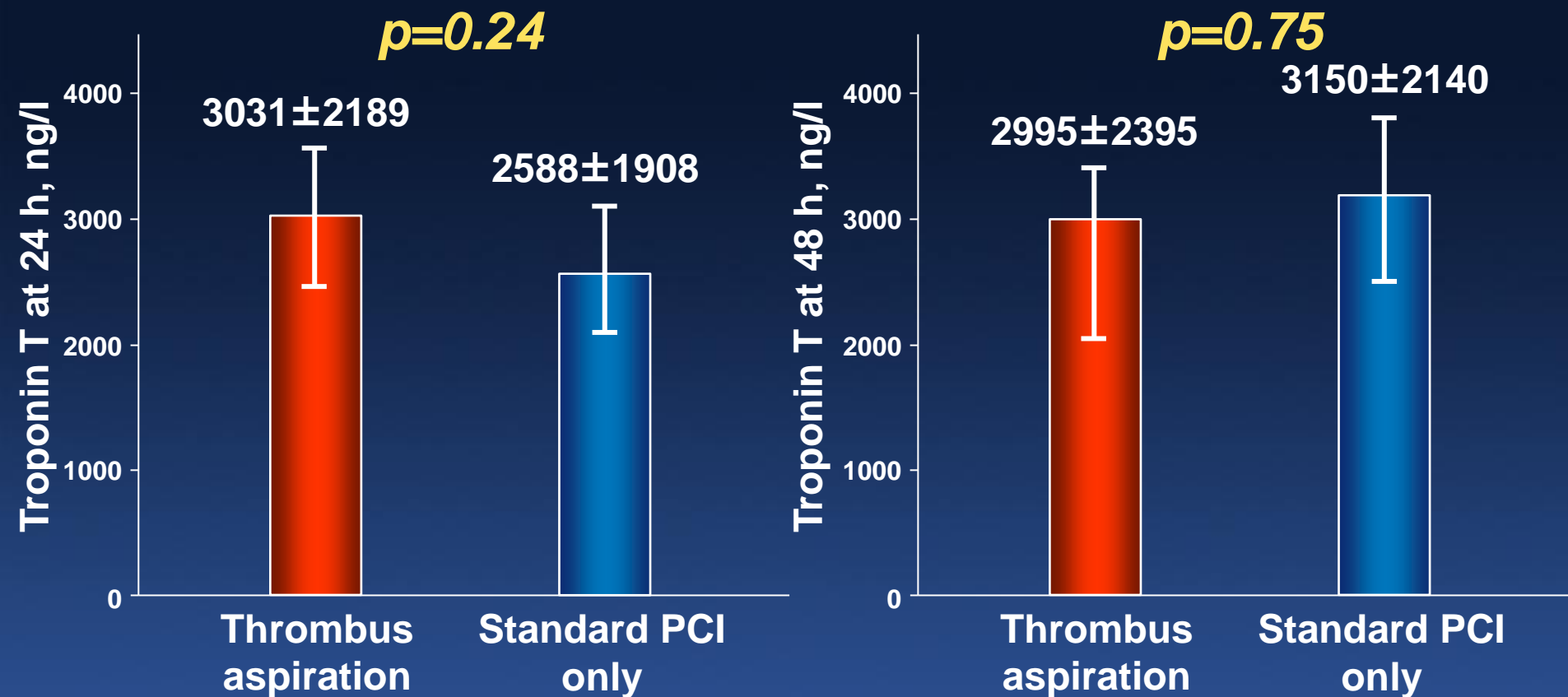
Results

Secondary Endpoints: Angiography



Results

Secondary Endpoints: Enzymatic Infarct Size



Results

Secondary Endpoints: Clinical Outcome

	Thrombus aspiration n = 70	Standard PCI n = 74	P Value
All-cause death, n (%)	2 (3)	4 (5)	0.68
Cardiovascular death, n (%)	2 (3)	3 (4)	1.0
Reinfarction, n (%)	0	0	-
TVR, n (%)	2 (3)	0	0.24
TLR, n (%)	2 (3)	0	0.24
Stent thrombosis, n (%)	0	0	-
Stroke, n (%)	0	1 (1)	0.24

Conclusion

- In patients with subacute STEMI routine manual thrombus aspiration before PCI failed to show a significant reduction in the primary endpoint of MVO assessed by CMR, as compared to conventional PCI alone.
- The finding is supported by a lack of benefit in angiographic, enzymatic, and clinical secondary endpoints.