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	Company
Grant/Research Support	Medtronic
Consulting Fees/Honoraria	None related to the study
Major Stock Shareholder/Equity	None related to the study
Royalty Income	None related to the study
Ownership/Founder	None related to the study
Intellectual Property Rights	None related to the study
Other Financial Benefit	None related to the study

Background

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

↓

Symptom onset:

| 0 | 12 h | 24 h | 36 h | 48 h |

TASTE
TOTAL

?

Frobert et al. *N Engl J Med* 2013;369:1587-97.
Jolly et al. *N Engl J Med* 2015;372:1389-98.

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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**

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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**

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Methods

Primary Endpoint

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

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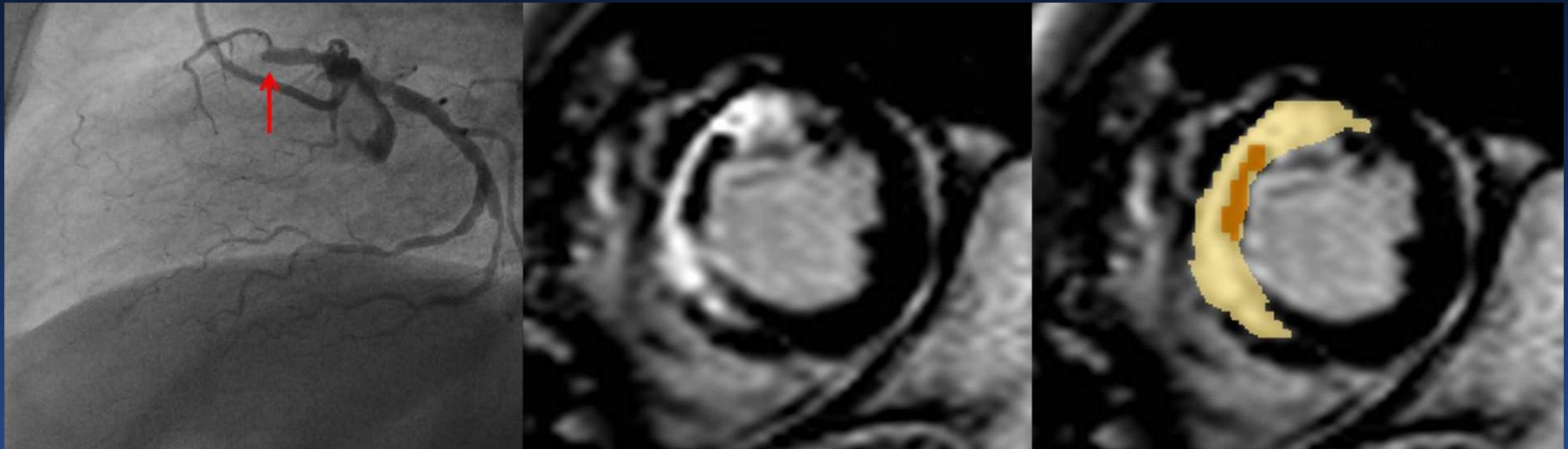
Methods

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**
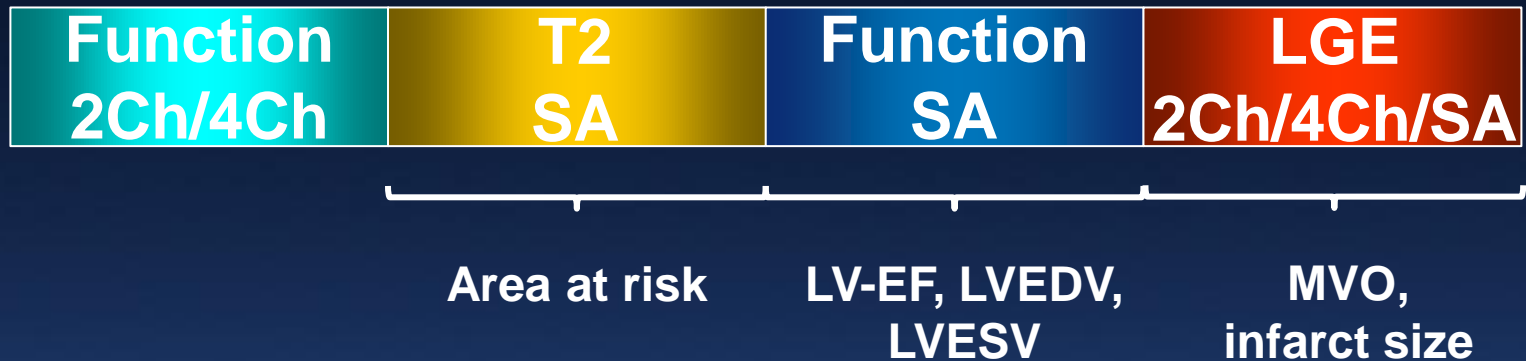
Methods

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)

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Methods

Cardiac Magnetic Resonance Imaging

- **Standard protocol / day 1 - 4**

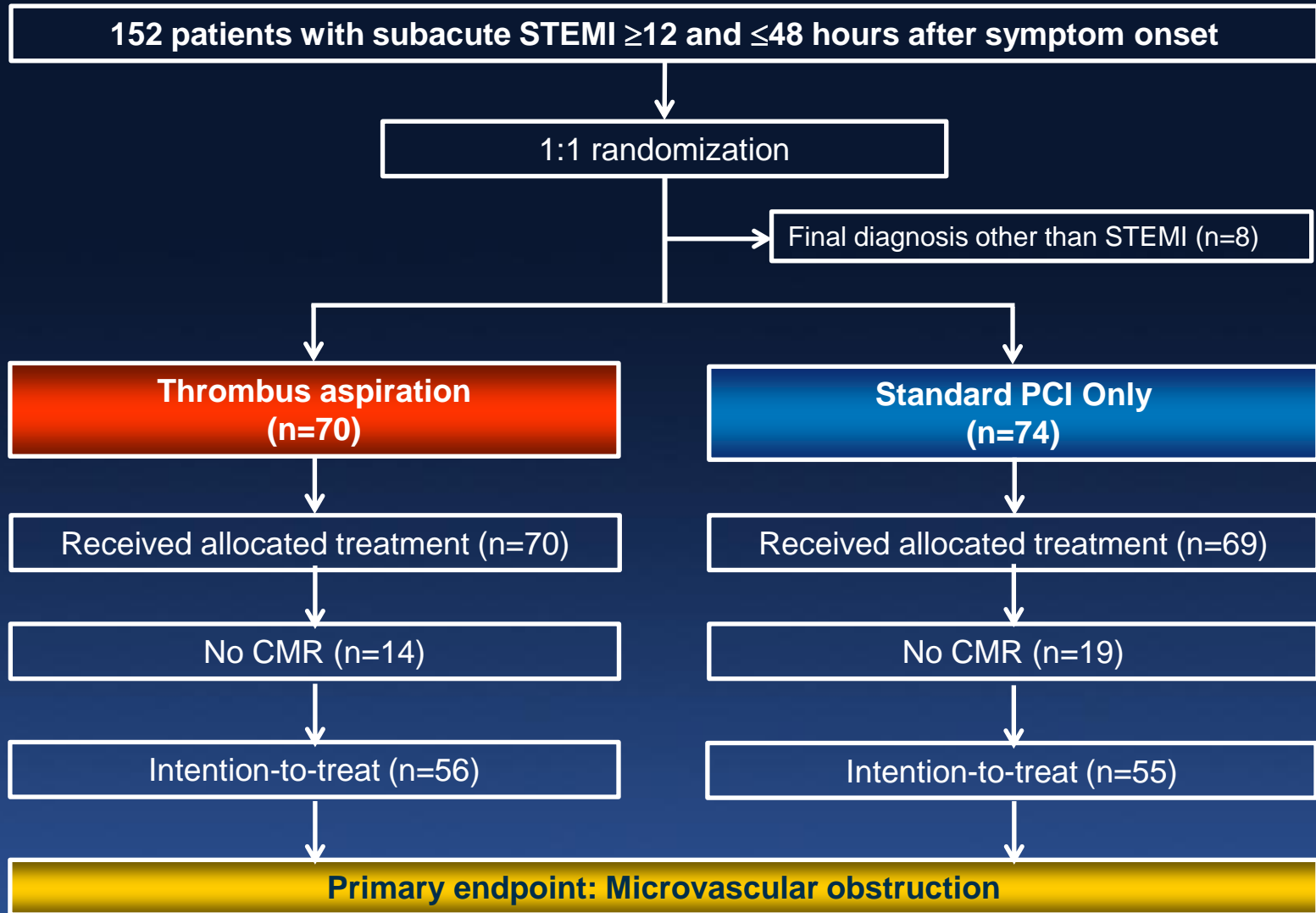| Function 2Ch/4Ch	T2 SA	Function SA	LGE 2Ch/4Ch/SA
	Area at risk	LV-EF, LVEDV, LVESV	MVO, infarct size

- **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**

Results

Baseline Characteristics

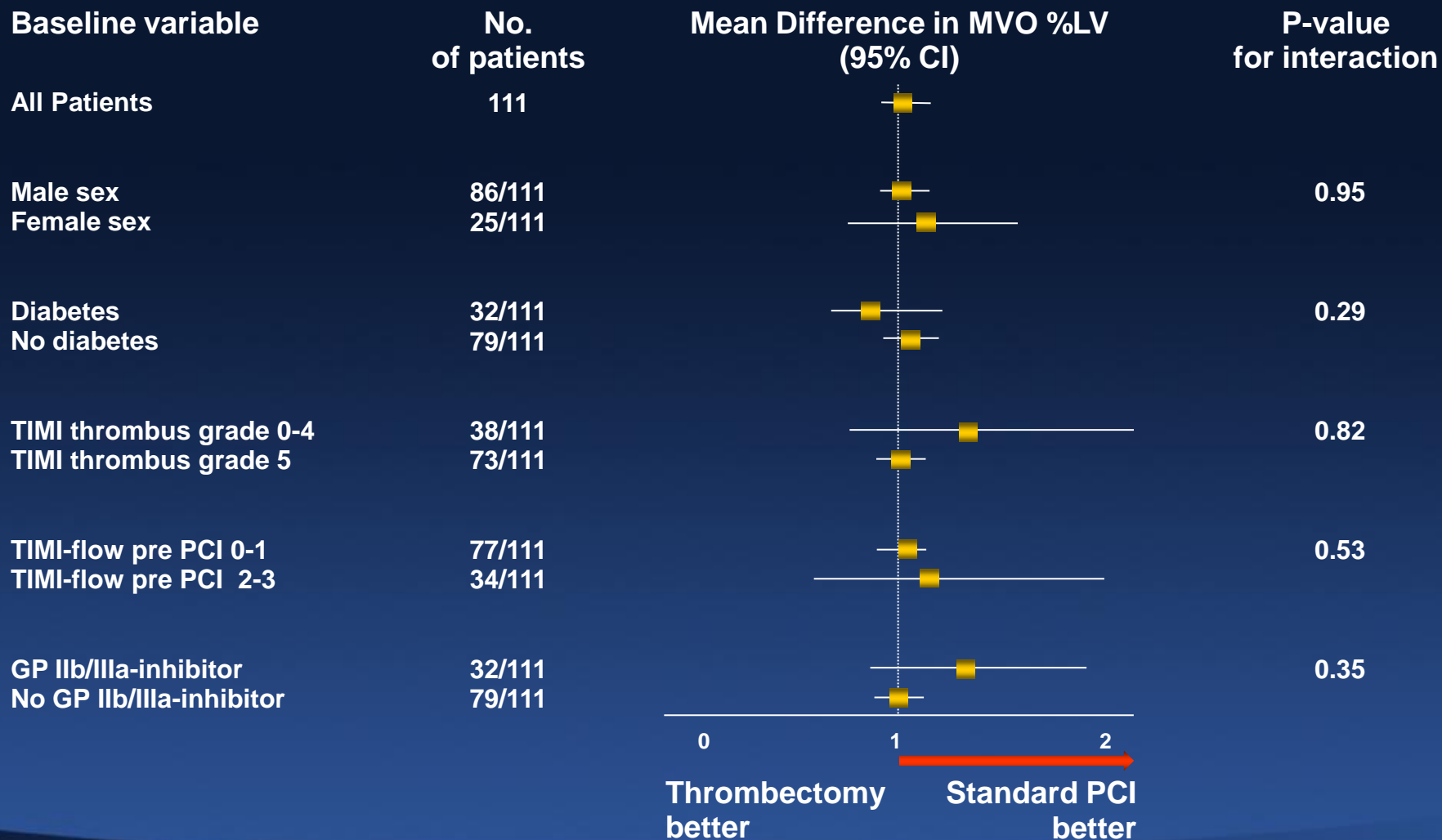|	Thrombus aspiration n = 70	Standard PCI n = 74
Age, years	66 ±12	66 ± 15
Hypertension, n (%)	55/70 (79)	48/74 (65)
Hyperlipoproteinemia, n (%)	11/70 (16)	17/74 (23)
Diabetes mellitus, n (%)	22/70 (31)	25/74 (34)
Ongoing signs of ischemia, n (%)	28/57 (49)	34/62 (55)
Symptom-onset-to-balloon, hours	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)
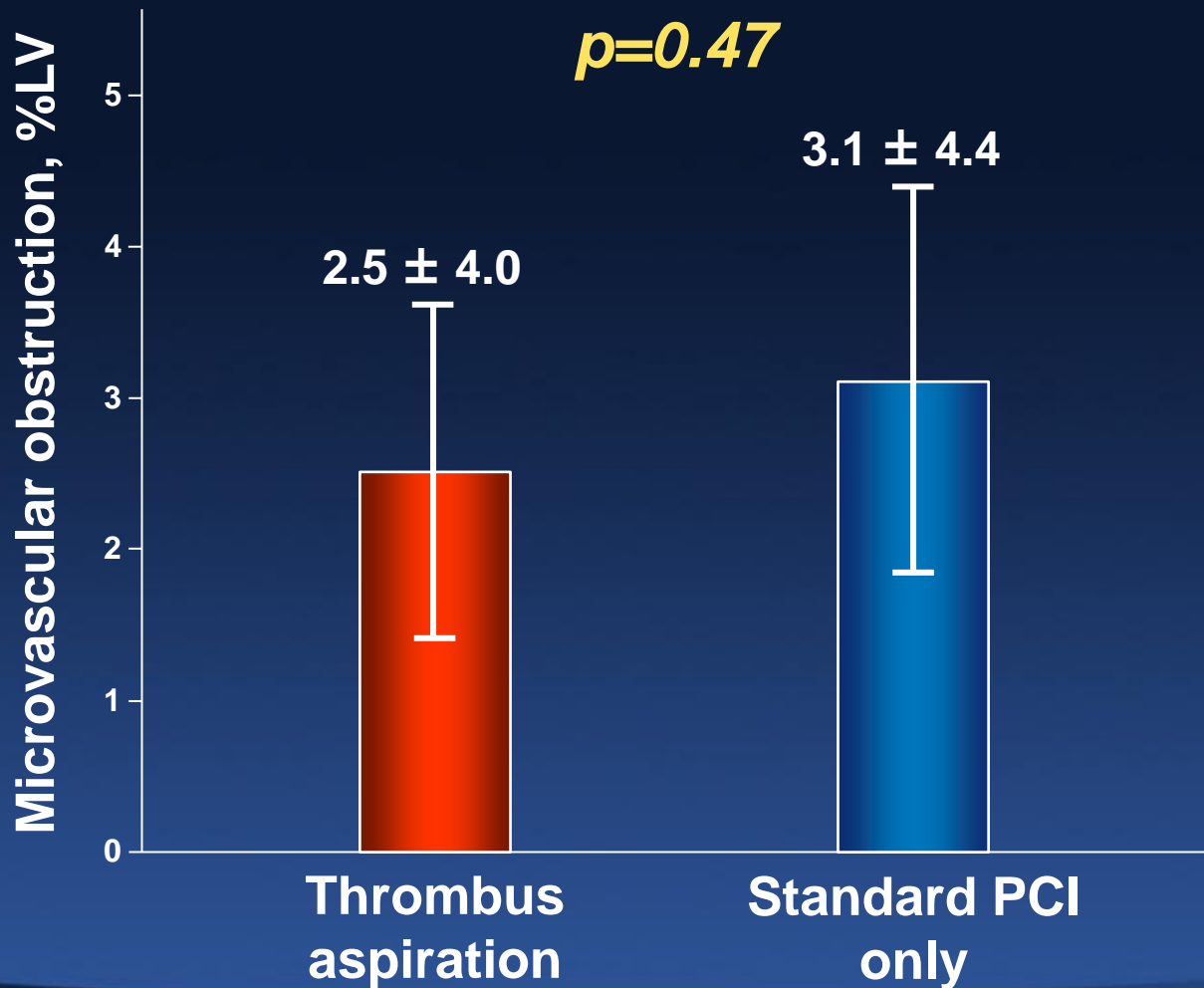
Results

MVO in Predefined Subgroups

Baseline variable	No. of patients	Mean Difference in MVO %LV (95% CI)	P-value for interaction
All Patients	111		
Male sex	86/111		0.95
Female sex	25/111		
Diabetes	32/111		0.29
No diabetes	79/111		
TIMI thrombus grade 0-4	38/111		0.82
TIMI thrombus grade 5	73/111		
TIMI-flow pre PCI 0-1	77/111		0.53
TIMI-flow pre PCI 2-3	34/111		
GP IIb/IIIa-inhibitor	32/111		0.35
No GP IIb/IIIa-inhibitor	79/111		

0   1   2

Thrombectomy better   **Standard PCI better**

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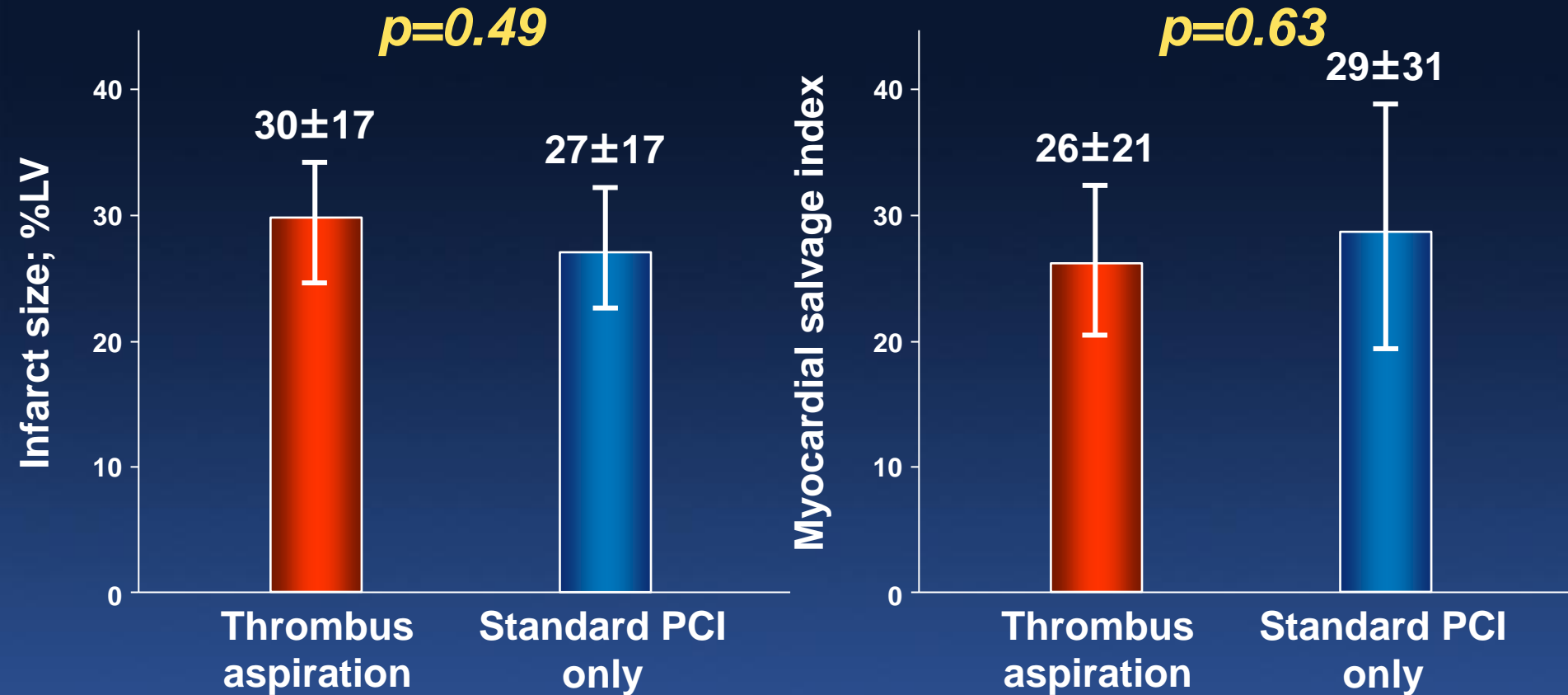
Results

Secondary Endpoints: Infarct Size and Salvage

Results

Secondary Endpoints: LV Function and Volumes

p=0.44

46±11 — Thrombus aspiration
45±12 — Standard PCI only

LV ejection fraction, %

p=0.77

160±52 — Thrombus aspiration
157±12 — Standard PCI only

LVEDV, ml

p=0.89

88±38 — Thrombus aspiration
89±34 — Standard PCI only

LVESV, ml
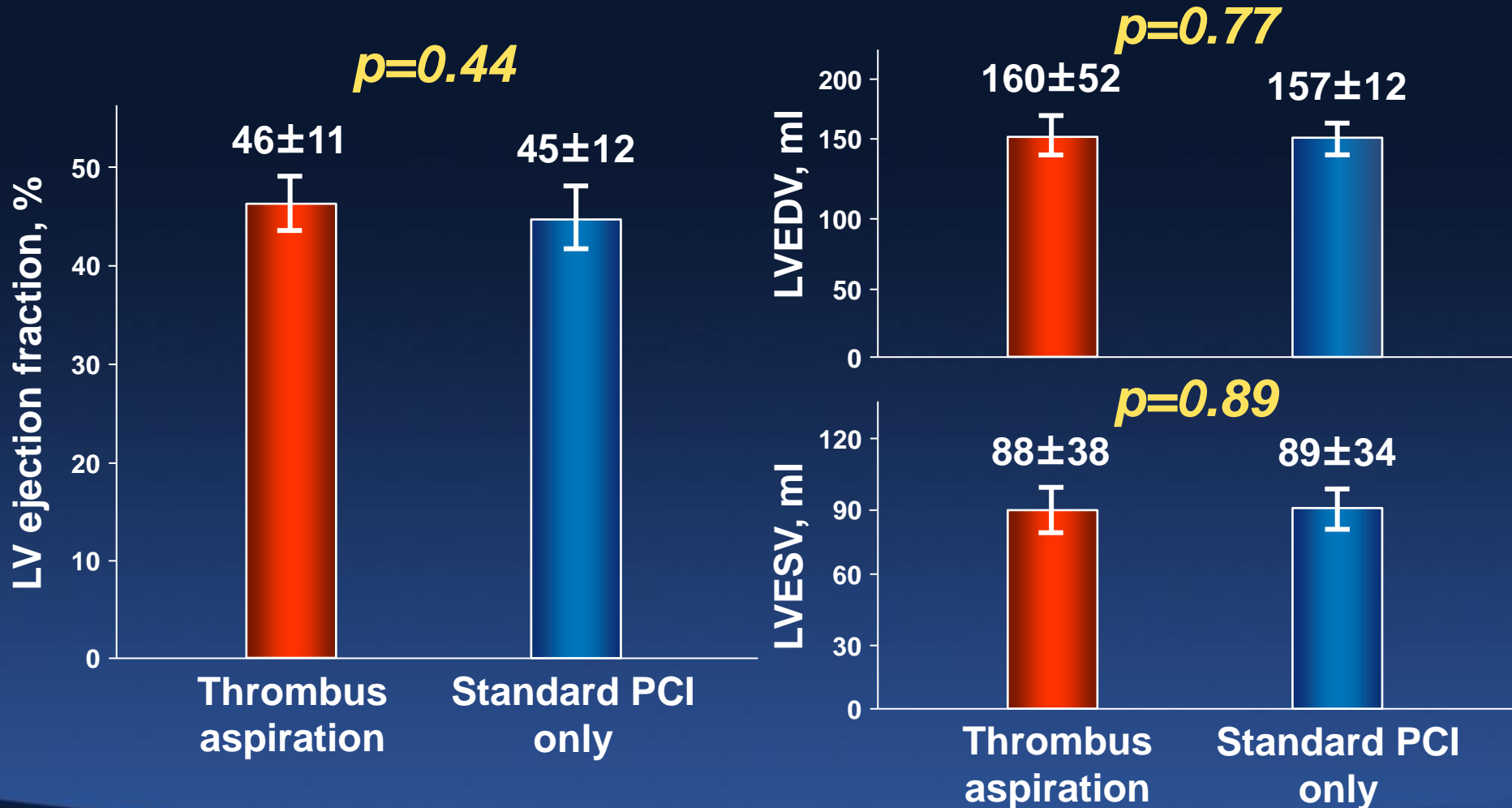
Results

Secondary Endpoints: Angiography
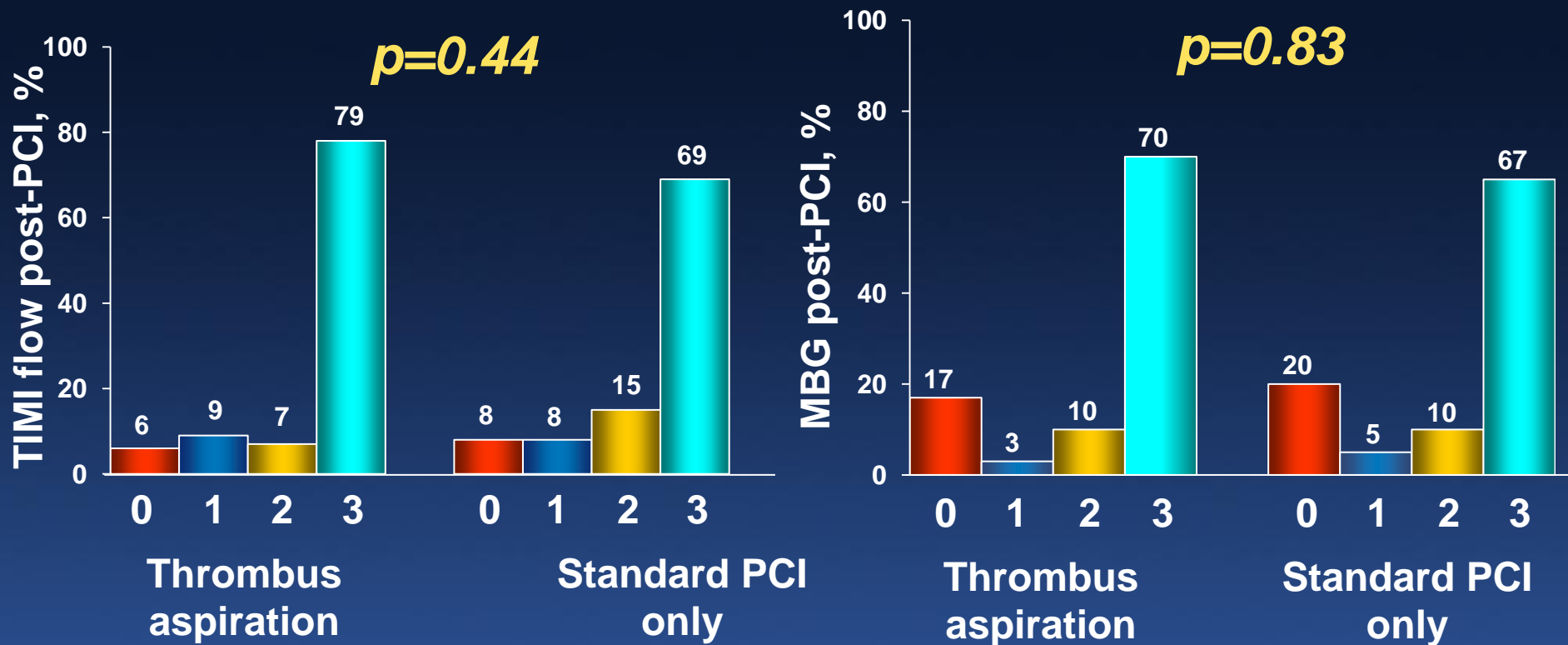
Results
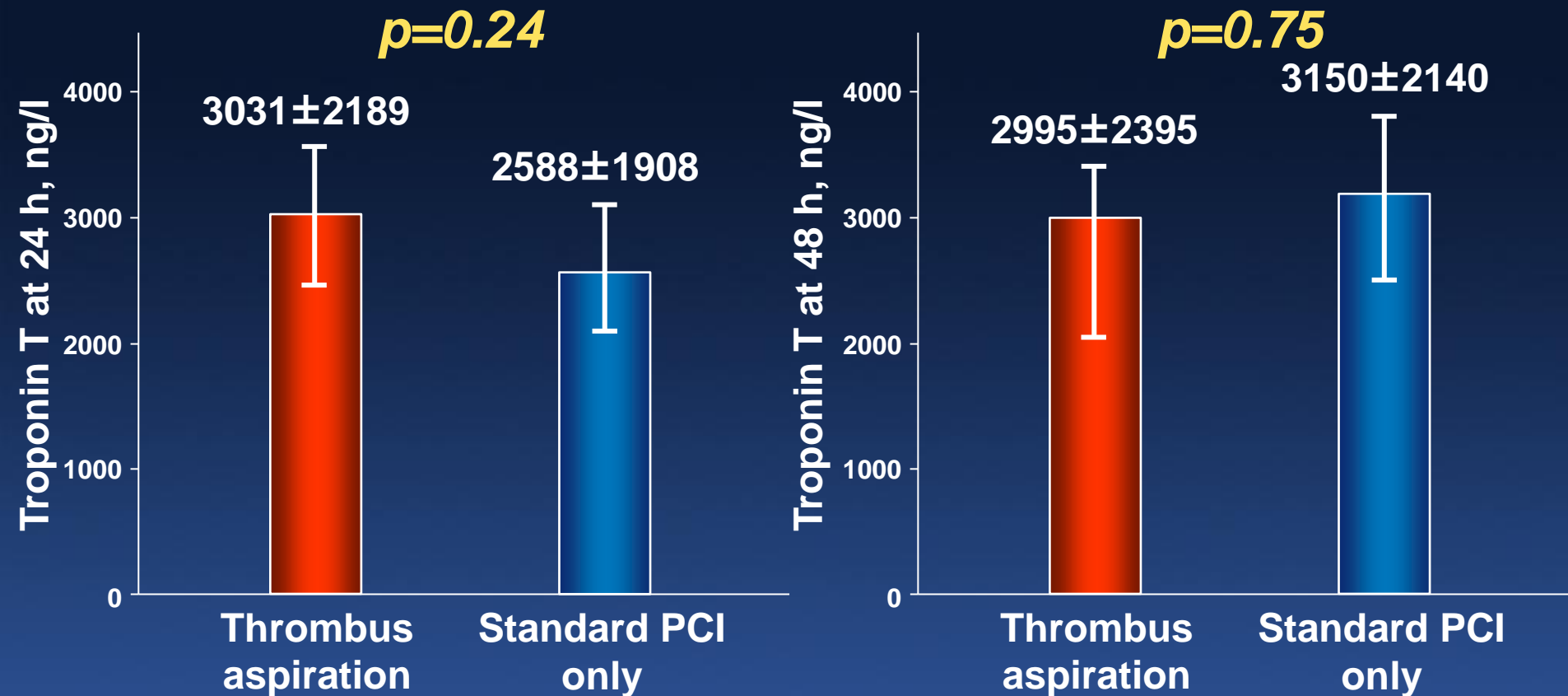
Secondary Endpoints: Clinical Outcome

	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.**

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