ACC.25

Alternative Antithrombotic Pathways In Acute Myocardial Infarction With Large Thrombus Burden: A Randomized Trial

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UPO

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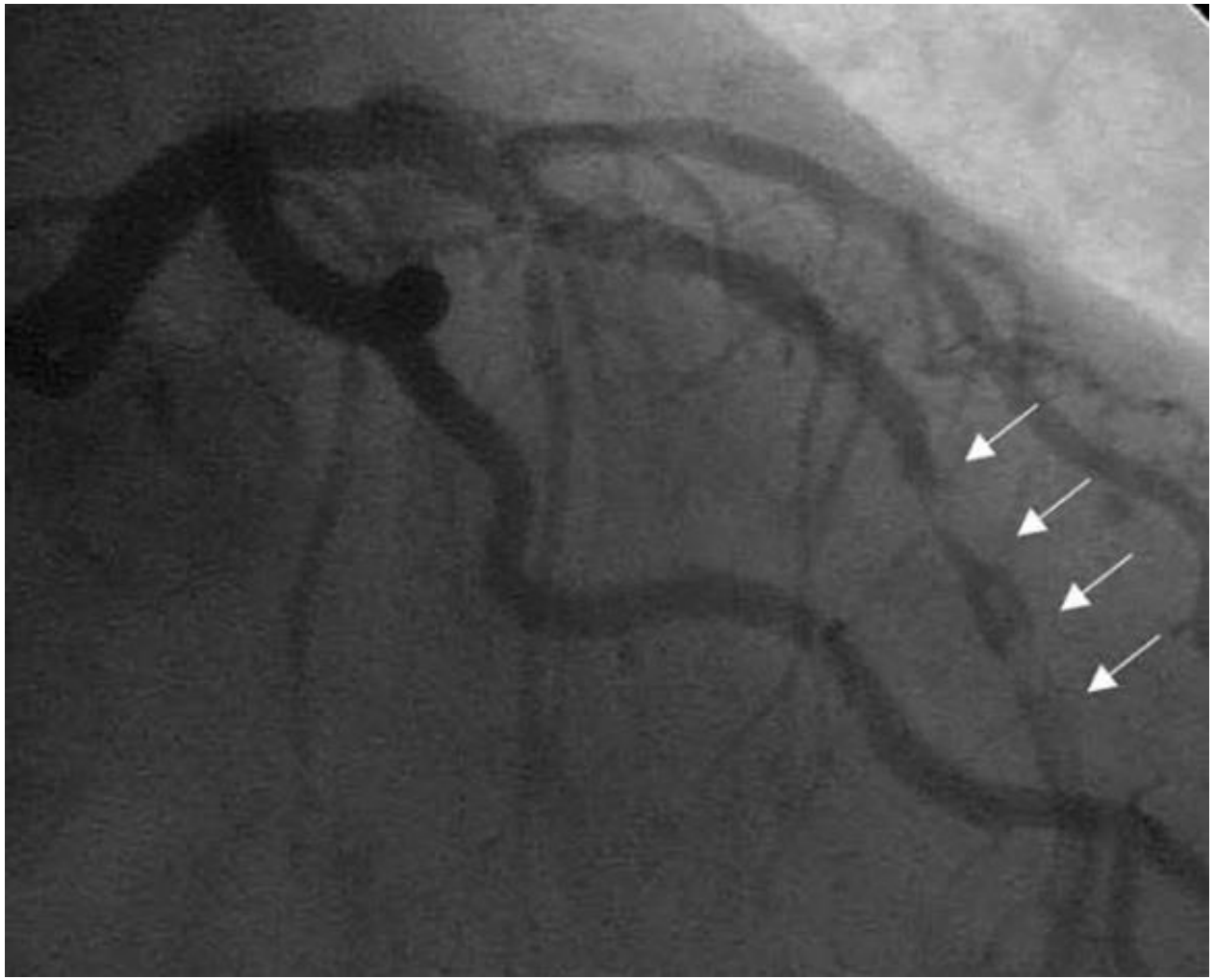
AMERICAN COLLEGE of CARDIOLOGY

BACKGROUND

- **A large coronary thrombus burden** in STEMI can impair PCI outcomes through distal embolization and microvascular obstruction [1]
- A **deferred stenting strategy** may reduce thrombus burden and improve revascularization outcomes [2]
- **Low dose rivaroxaban** (a Factor Xa inhibitor) added to DAPT reduced ischemic events post-ACS with acceptable safety [3]



1. Fokkema et al F. *Eur Heart J*. 2009
2. Qiao et al. *Journal of the American Heart Association.* 2017
3. Mega et al. ATLAS ACS 2–TIMI 51 Investigators. *N Engl J Med*. 2012

OBJECTIVES & DESIGN

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- To test feasibility and efficacy of **Rivaroxaban 2.5 BID + Aspirin and Ticagrelor (DAPT) vs. DAPT alone** in reducing thrombus burden.

- Prospective, randomized, open-label, mechanistic study.

ENPOINTS

Primary Endpoint:

Reduction of OCT-derived thrombus burden (Thrombus Score) after 6 days.

Secondary Endpoints:

Reduction of Thrombus Area, Thrombus Length, and Thrombus Volume, as assessed by OCT after 6 days

Distribution of Thrombus Types, i.e. red or white (baseline and at 6 days)

MACE at 30 days (composite of cardiovascular death, myocardial infarction, stroke, or unplanned new target vessel revascularization)

Bleeding complications by BARC scale at 30 days

STUDY CRITERIA

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Inclusion Criteria

- **STEMI** with symptom onset <24 hours
- **LCTB** at coronary angiography, assessed after wiring with 1.5 mm balloon
- Culprit **vessel diameter ≥3,0 mm**
- Successful pPCI by thrombus aspiration or balloon angioplasty (**TIMI flow ≥2**, residual **stenosis <50%,** >50% ST-segment resolution)
- Decision of **deferred stenting** by operator

Exclusion Criteria

- Any contraindication to anticoagulant therapy or unacceptable **risk of bleeding**
- **Femoral access**
- Significant **renal or liver impairment**
- **Cardiogenic shock** at presentation or life-threatening electrical instability
- High **risk of deep venous thrombosis**
- Use of **oral anticoagulants**

PRIMARY ENDPOINT ASSESSMENT: THE OCT-THROMBUS SCORE

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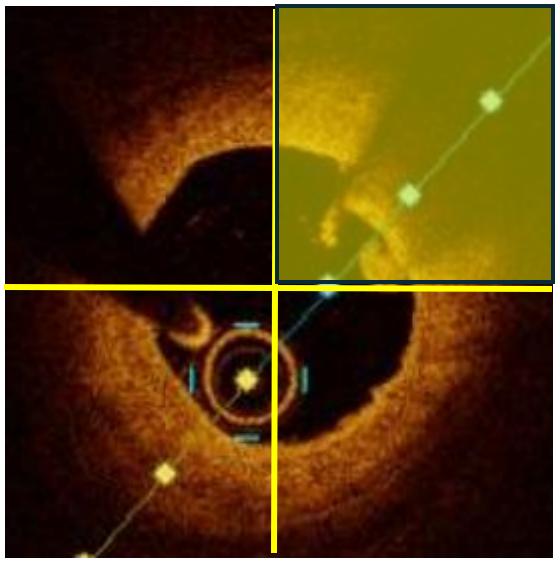
SCORE=1



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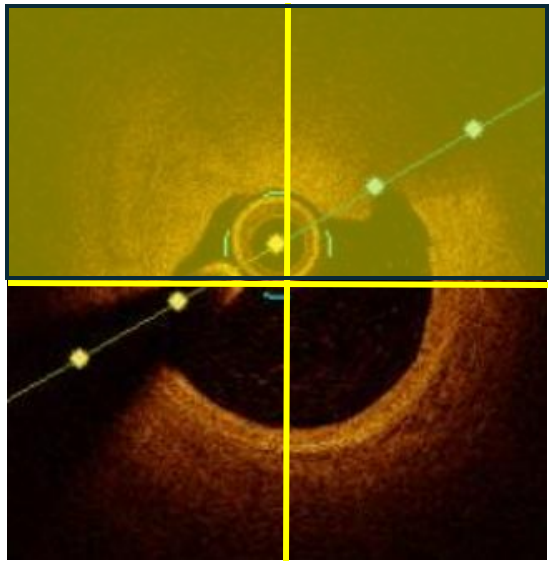

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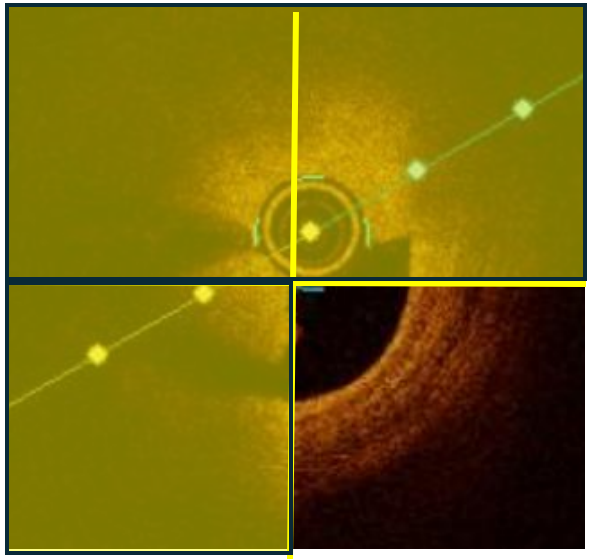

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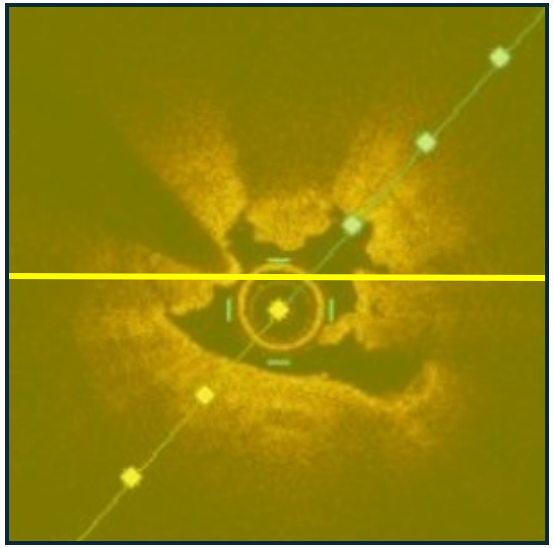
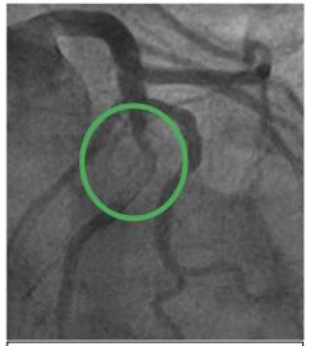


Optical Coherence Tomography (OCT) Thrombus Score is determined by dividing the coronary artery cross-section into four quadrants and counting how many of them contain thrombus along the length of the affected segment. The total Thrombus Score is calculated as the sum of quadrant involvement across all cross-sections.

Core Lab blinded to clinical and angiographic data (University of Genova).

STUDY FLOW



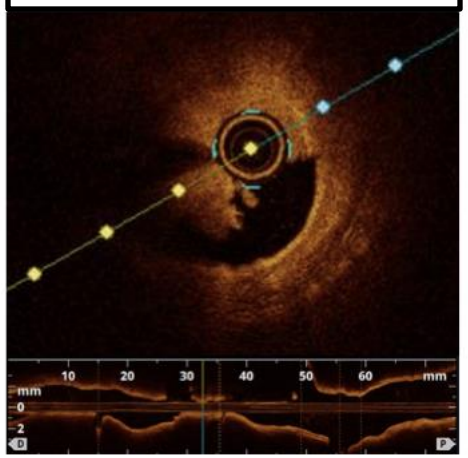
STEMI patients with **LCTB** undergoing deferred stenting strategy

Rivaroxaban 2.5 mg BID + DAPT

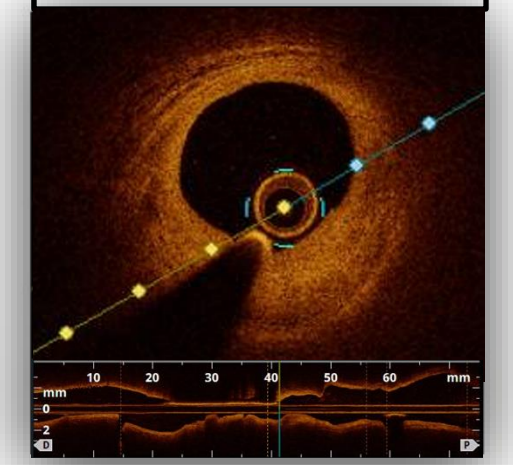
1:1 Randomization

DAPT

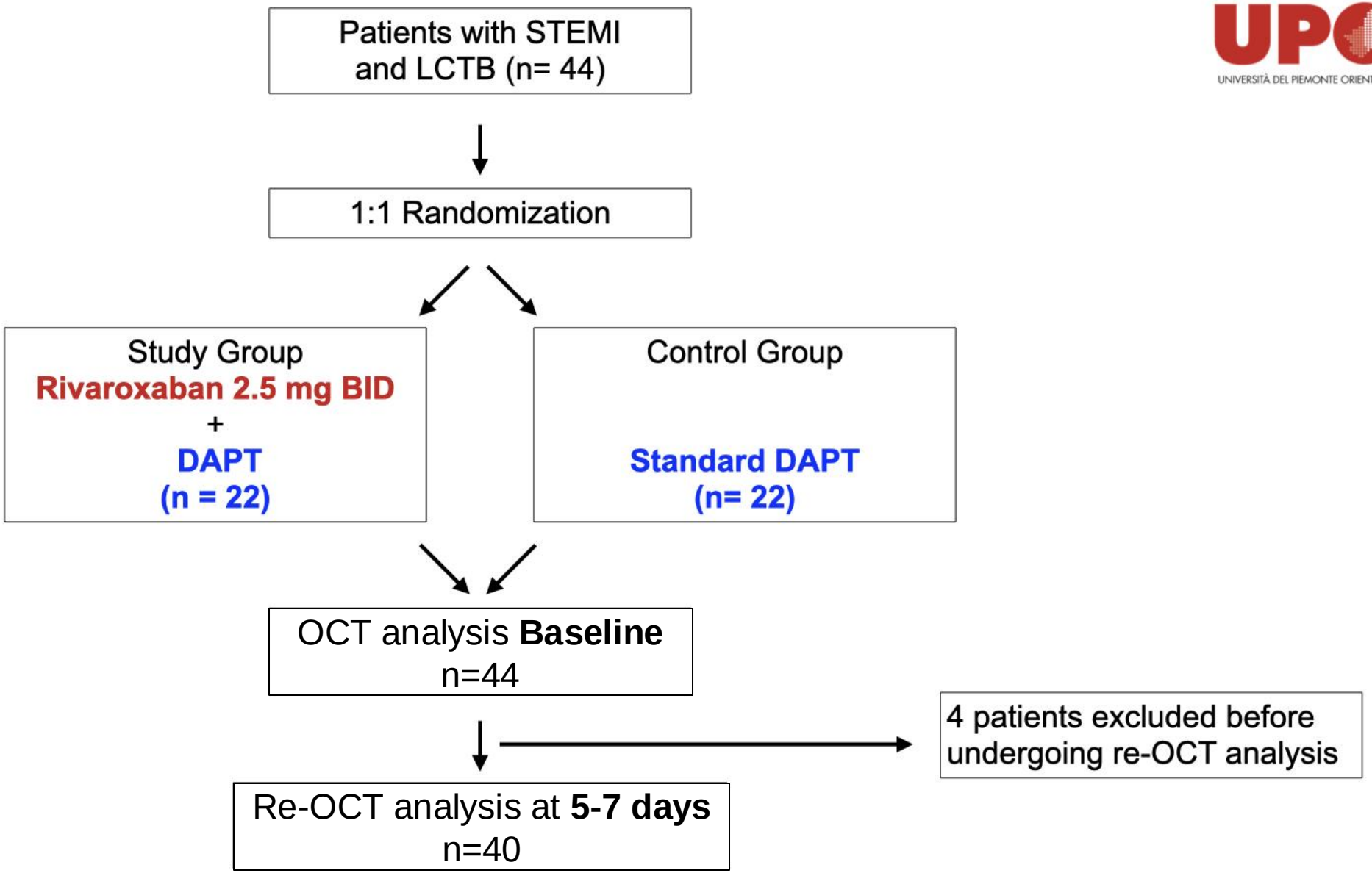
OCT **Baseline**



Re-OCT at **5-7 days**



STUDY POPULATION



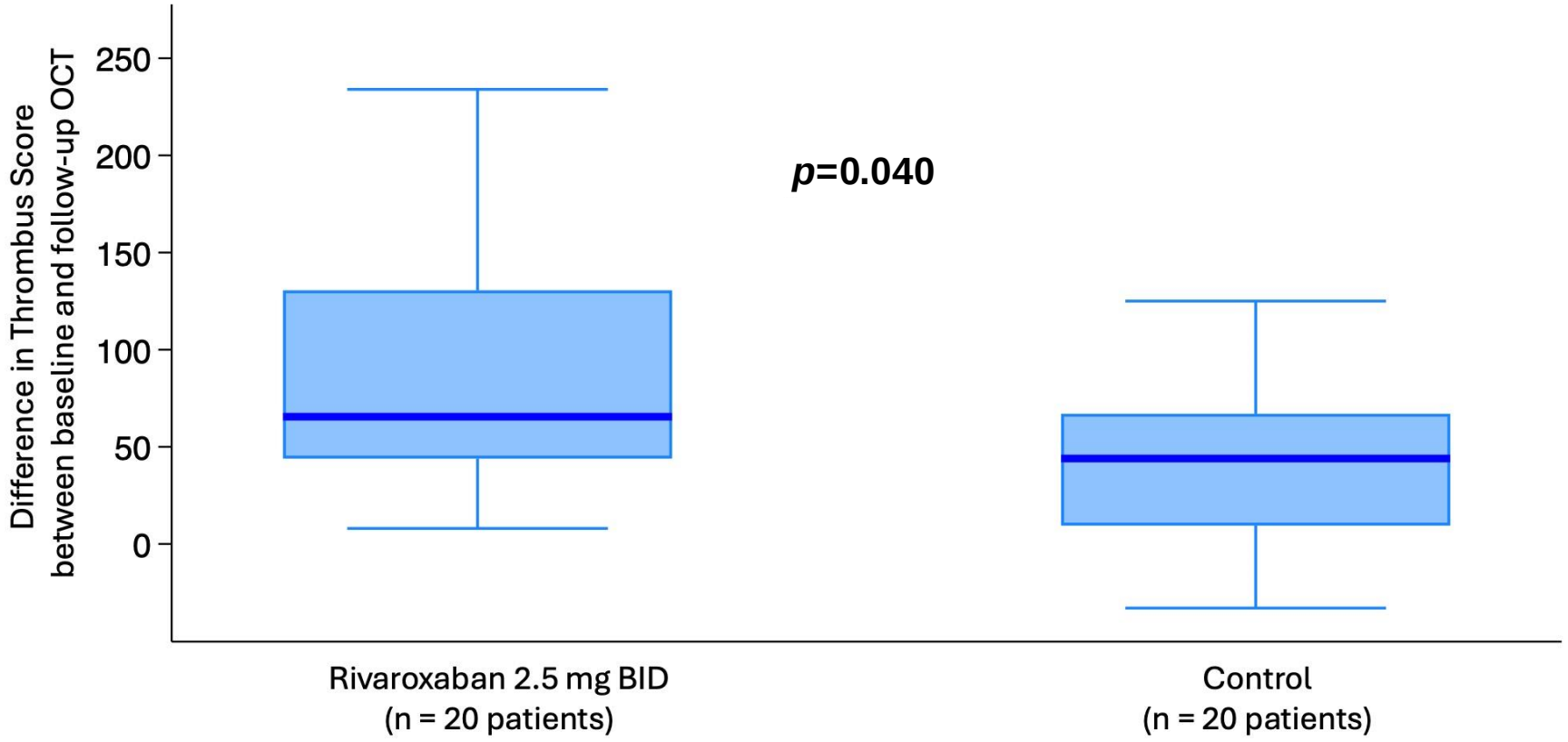
BASELINE CHARACTERISTICS — CLINICAL

	Rivaroxaban arm N = 20	Control arm N = 20
Age (years)	63.6 ± 12.3	61.0 ± 11.2
Female gender	2 (10)	3 (15)
BMI (Kg/m^2)	26.6 [22.5-28.4]	26.2 [24.5- 27.5]
Systemic hypertension	12 (60)	8 (40)
Diabetes	1 (5)	4 (20)
Previous MI	3 (15)	3 (15)
Peripheral arterial disease	3 (15)	1 (5)
Chronic kidney disease	2 (10)	1 (5)
Anterior MI	7 (35)	12 (60)
Killip class	1 [1-1]	1 [1-1]
Echocardiographic LVEF <40% at admission	2 (10)	3 (15)
Time from symptom onset to cath-lab (min)	180 [115-480]	180 [90-480]

BASELINE CHARACTERISTICS — ANGIOGRAPHIC

	Rivaroxaban arm N = 20	Control arm N = 20
Multivessel disease	12 (60)	11 (55)
Culprit vessel LAD	9 (45)	9 (45)
TIMI Flow Score	0 [0-1]	0 [0-0]
TIMI Thrombus Score	5 [4-5]	5 [5-5]
Thrombus aspiration	13 (65)	13 (65)
Balloon angioplasty	16 (80)	16 (80)
Distal embolization	1 (5)	1 (5)
No-reflow	2 (10)	0 (0)
Post-procedural TIMI flow	3 [3-3]	3 [3-3]
Post-procedural reference vessel diameter (mm)	3.40 ± 0.53	3.38± 0.78
Post-procedural diameter stenosis (%)	59.3± 9.5	54.5 ± 19.9
Post-procedural lesion length (mm)	16.09 [11.03-20.70]	21.76 [10.10- 42.68]
Use of IIb-IIIa inhibitors	13 (65)	17 (85)

PRIMARY ENDPOINT — CHANGES OF THROMBUS SCORE BETWEEN BASELINE AND RE-OCT



The rivaroxaban arm demonstrated a significantly greater reduction in thrombus burden compared to control arm, both in absolute terms (-66 [44–131] vs. -44 [10–67] quadrants; *p*=0.040) and relative percentage (-61% [50–81] vs. -36% [0–50]; *p*=0.002).

RELATIVE CHANGES OF THROMBUS VOLUME, THROMBUS LENGTH AND THROMBUS AREA BY OCT

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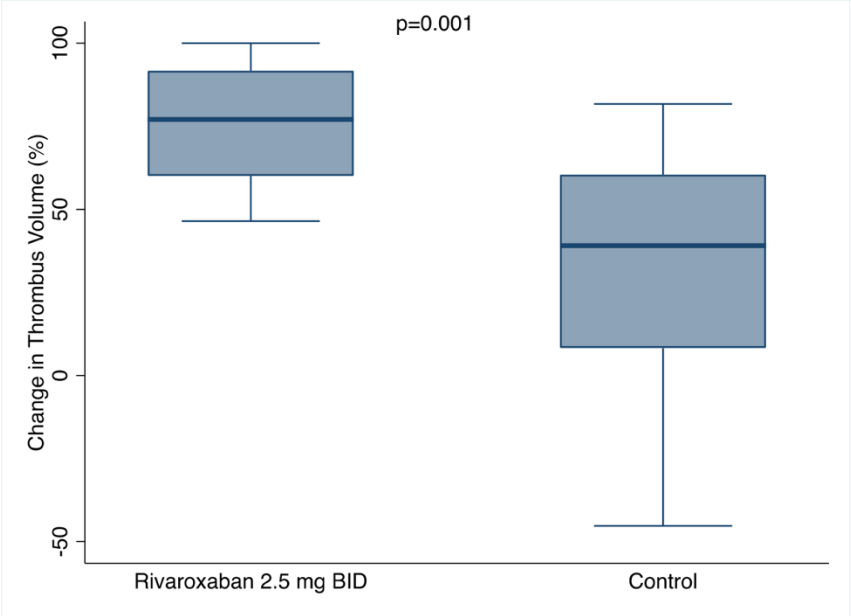
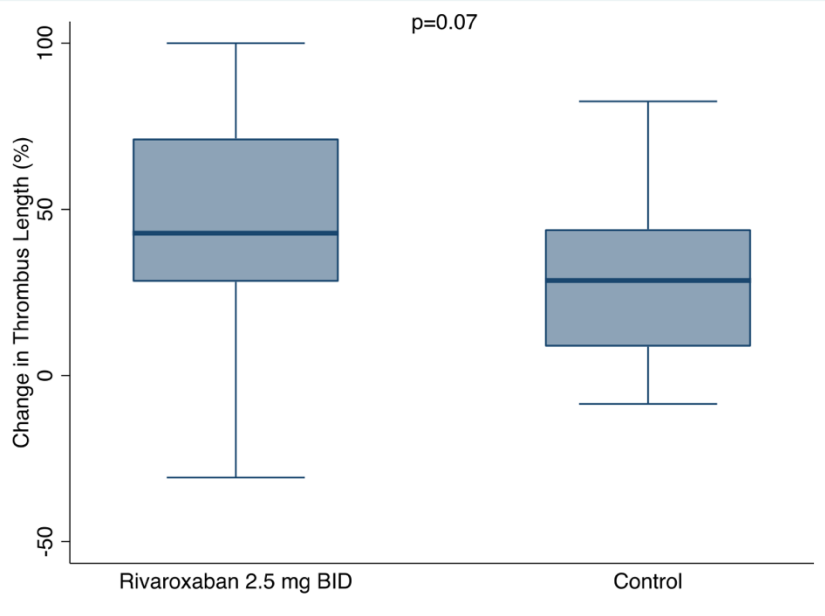
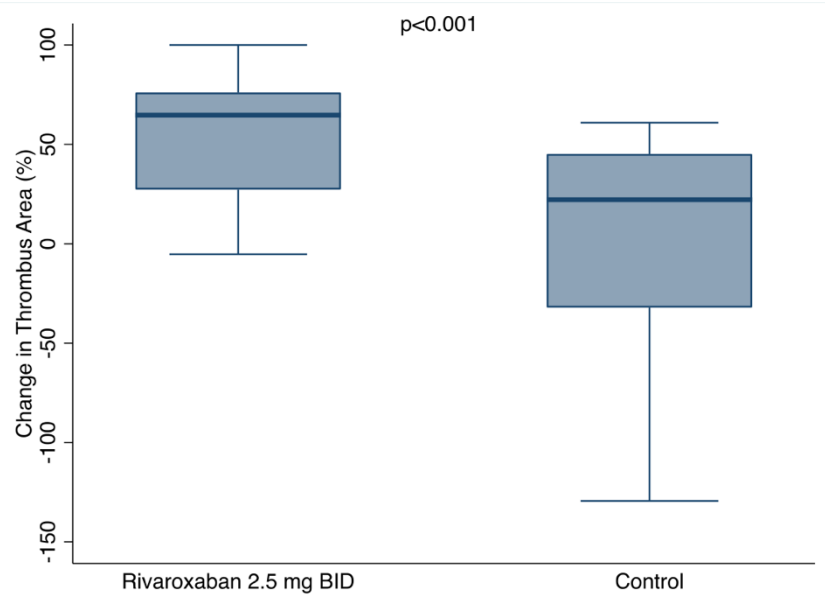
Thrombus Volume



Thrombus Length



Thrombus Area



EVOLUTION OF THROMBUS TYPE BEFORE AND AFTER TREATMENT

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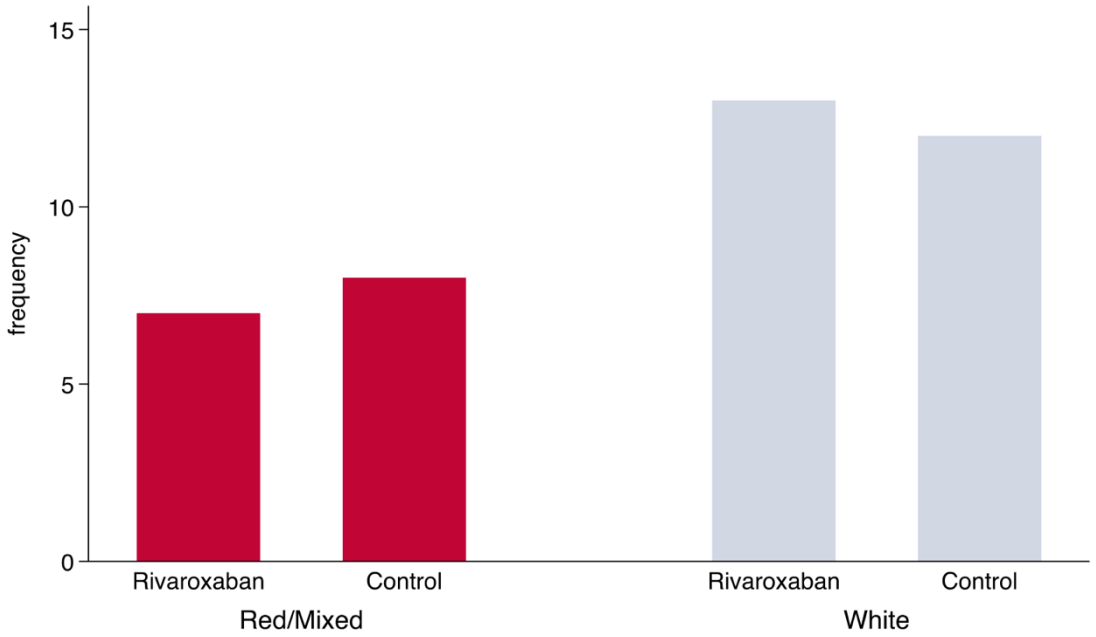
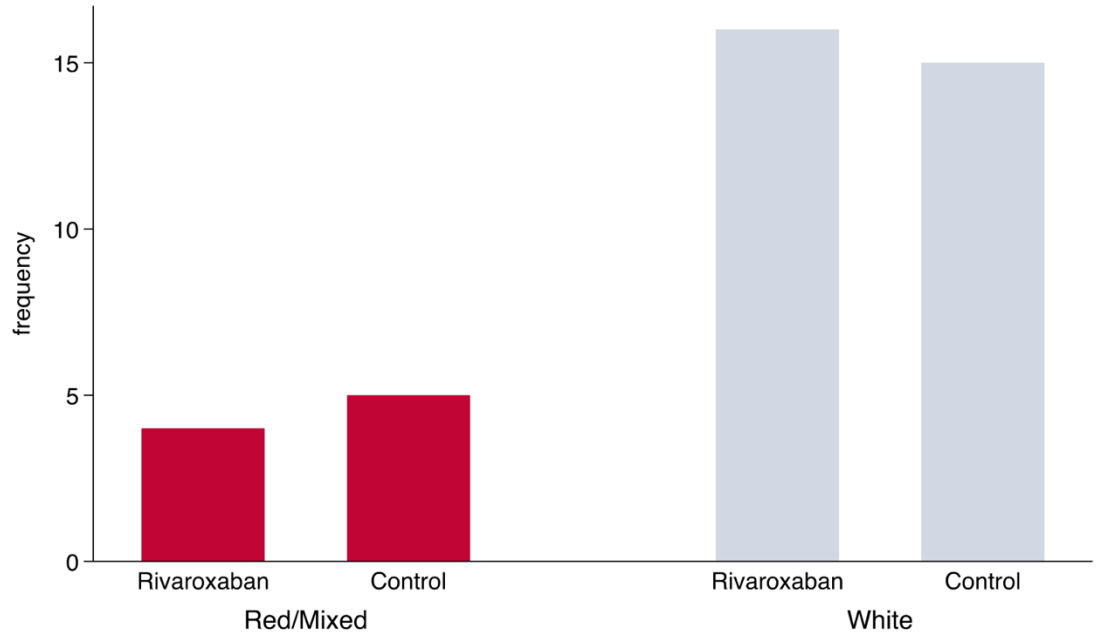
Baseline



After 6 days



CLINICAL OUTCOME AT 30 DAYS

	Rivaroxaban arm N=20	Control arm N=20	p value
MACE*	0 (0)	1 (5)	0.34
Death	0	0	-
MI	0	1 (5)	0.34
Stroke or TIA	0	0	-
TVR	0	0	-
Bleeding events **BARC 1** **BARC 2** **BARC >2**	 0 2 (10) 0	 0 0 0	0.15

*MACE defined as a composite of cardiovascular death, myocardial infarction, stroke, or unplanned new target vessel revascularization

LIMITATIONS

- **Small Sample Size**
  As a pilot study, ARISE-ARMYDA 7 was not powered for clinical outcomes and findings should be considered hypothesis-generating.
- **Open-Label Treatment**
  Although OCT endpoints were assessed by blinded core-lab, the lack of blinding of treatment may represent a performance bias.
- **Highly Selected Population**
  Patients with high bleeding risk were excluded, which may not reflect real-world practice.

CONCLUSIONS

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- **ARISE-ARMYDA 7** is the first randomized pilot trial demonstrating that a **very early, short-term use of low-dose rivaroxaban** on top of DAPT significantly reduces intracoronary thrombus burden in STEMI patients with large thrombus burden.
- This pharmacological strategy, integrated with **OCT-guided deferred stenting**, showed **no major bleeding increase** and a favorable safety profile.
- These findings support the **feasibility and biological plausibility** of dual-pathway inhibition in acute STEMI and justify further evaluations in larger outcome-driven trials.

Thanks…

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