Insight into real-world PCI practice and clinical outcomes of patients treated with a new generation DES

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On behalf of e-Ultimaster investigators

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☑ I have the following potential conflicts of interest to declare:

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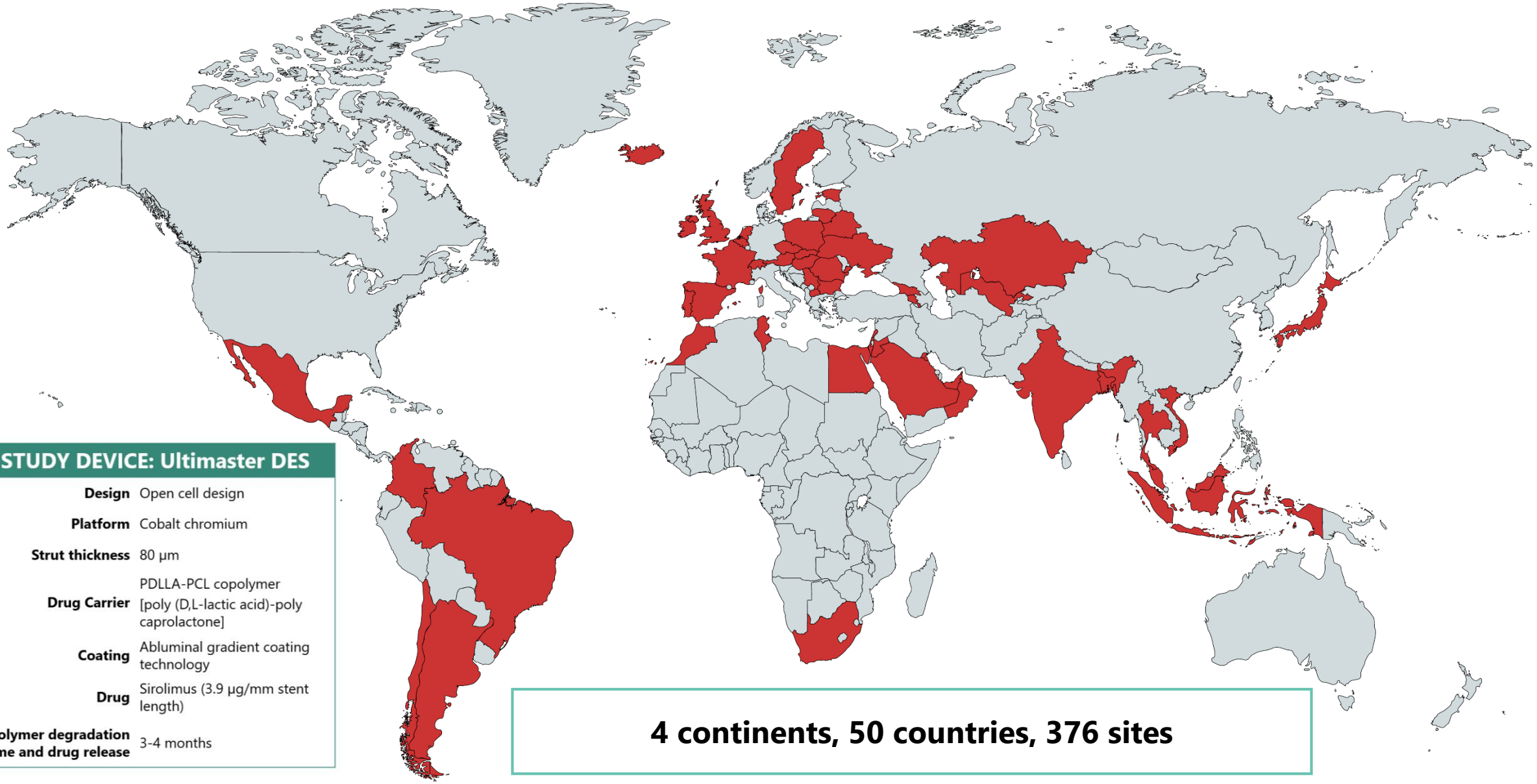
e-ULTIMASTER REGISTRY



STUDY DEVICE: Ultimaster DES	
Design	Open cell design
Platform	Cobalt chromium
Strut thickness	80 µm
Drug Carrier	PDLLA-PCL copolymer [poly (D,L-lactic acid)-poly caprolactone]
Coating	Abluminal gradient coating technology
Drug	Sirolimus (3.9 µg/mm stent length)
Polymer degradation time and drug release	3-4 months

4 continents, 50 countries, 376 sites

STUDY DESIGN AND ENDPOINTS

HOW WAS THIS STUDY EXECUTED?

e-Ultimaster registry
Study enrolment completed, follow-up ongoing
> 37,000 patients enrolled

Interim analysis
1-year follow-up
n=25,990 patients

Clinical follow-up

An independent Clinical Event Committee reviewed and adjudicated all endpoint-related serious adverse events

Dual antiplatelet therapy (DAPT) was at the discretion of the operator

Primary outcome

Target lesion failure at 1 year
(Cardiac death, target vessel MI or clinically driven TLR)

Secondary outcomes

Safety

- Cardiac death/MI
- Stent thrombosis (according to ARC)
- Major vascular and bleeding complications

Efficacy and patient-oriented (composite) endpoints

- Target lesion revascularization (TLR)
- Target vessel failure (TVF)
  (Cardiac death, target vessel MI or clinically driven target vessel revascularization)
- Patient-oriented composite endpoint (POCE)
  (All-cause death, any MI or any revascularization)

BASELINE CHARACTERISTICS

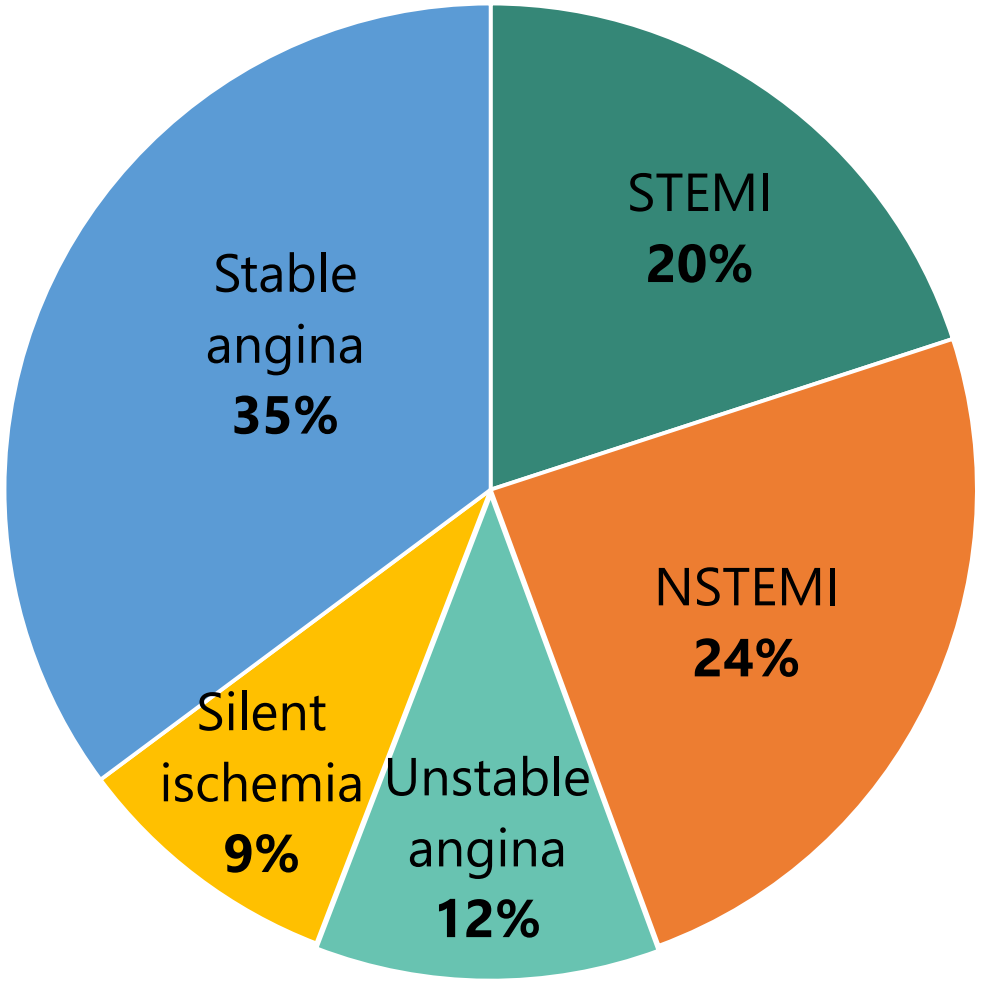
Patient characteristics	N patients = 25,990
Age, years	64.5±11.2
Gender, male %	76.6
Smoking, %	23.4
Diabetes, %	28.6
Hypertension, %	64.1
Hypercholesterolemia, %	56.2
Renal disease, %	7.3
Haemodialysis, %	0.9
Previous MI, %	22.3
Previous PCI, %	26.0
Multivessel disease, %	46.8
Vessel treated per patient, %	
RCA	34.2
Left main	3.2
LAD	51.6
CFX	34.2
Graft	1.3

Lesion/procedure characteristics	N patients = 25,990 N lesions = 32,670
N of lesions identified, n	1.87±1.1
N of lesions treated, n	1.45±0.8
Bifurcation, %	13.1
Chronic total occlusion, %	5.1
Calcified lesions, %	18.5
Small vessels (at least 1 stent ≤2.75 mm), %	44.3
Long lesions (at least 1 stent ≥25mm), %	43.4
Imaging used (IVUS or OFDI), %	8.4
N of stent implanted, N	1.47±0.8
Total stent length, mm	32.6±21.9
Radial access, %	82.3

CFX: circumflex; IVUS: intravascular ultrasound; LAD: left anterior descending; MI: myocardial infarction; OFDI: optical frequency domain imaging; PCI: percutaneous coronary intervention; RCA: right coronary artery

BASELINE CLINICAL PRESENTATION

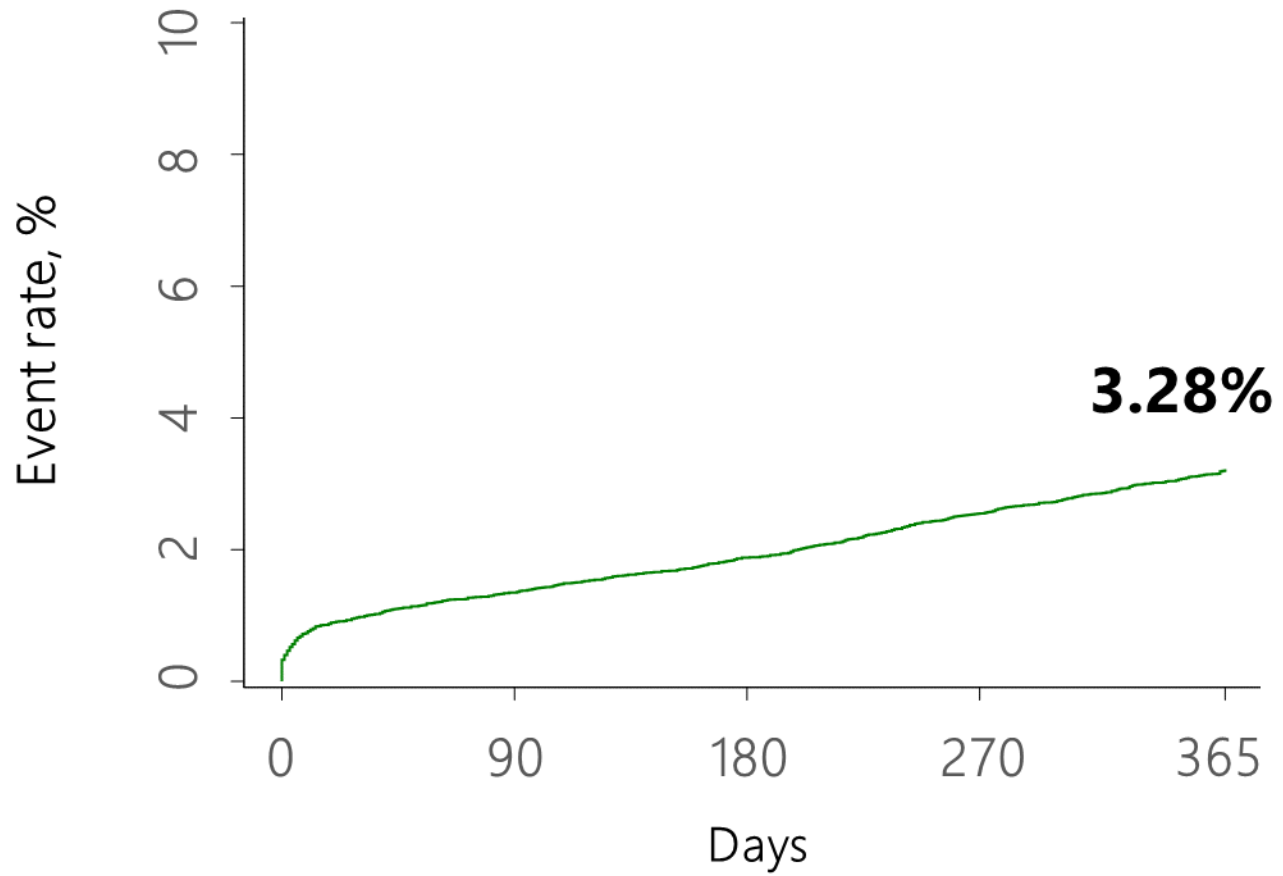
>50% ACS



(N)STEMI: (non) ST-elevated myocardial infarction

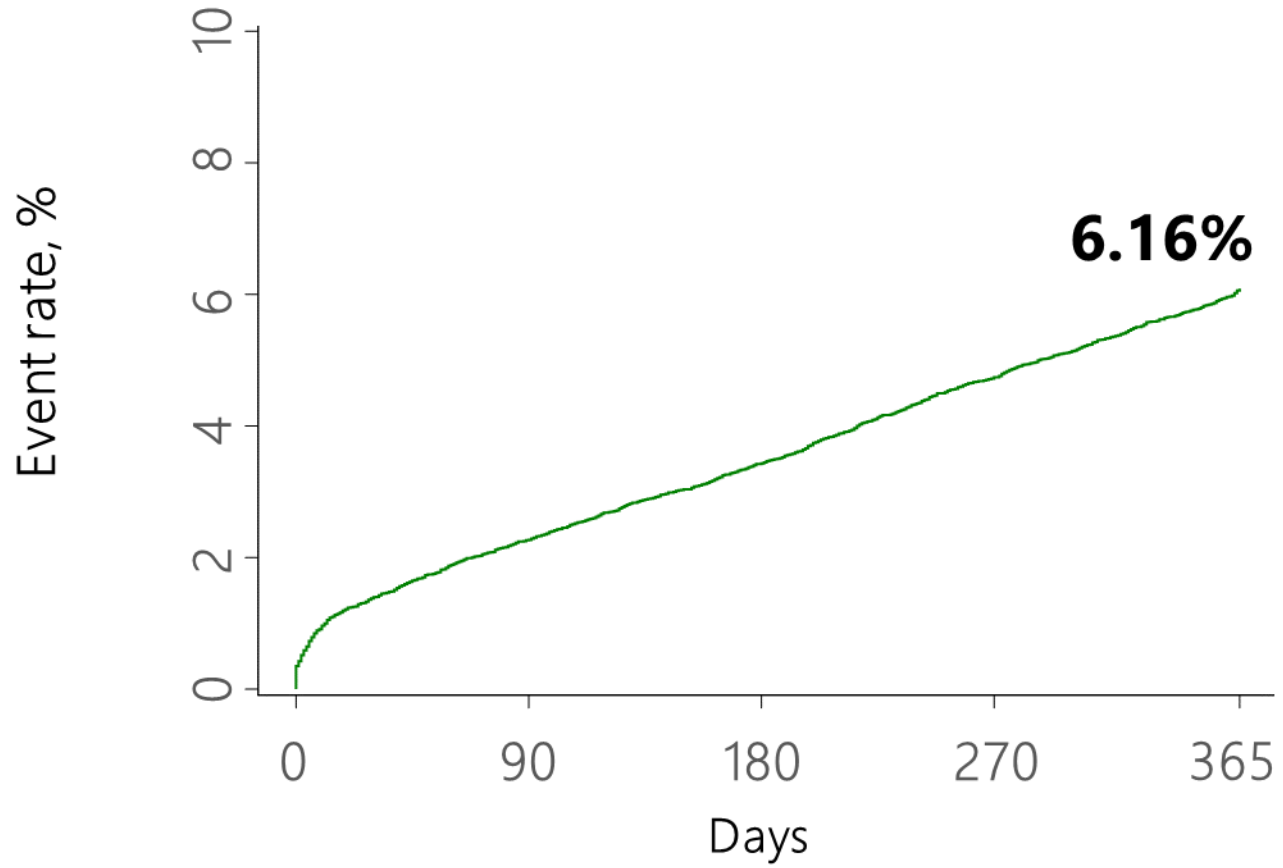
PRIMARY ENDPOINT

Target lesion failure at 1 year
Cardiac death, target-vessel MI or clinically-driven TLR

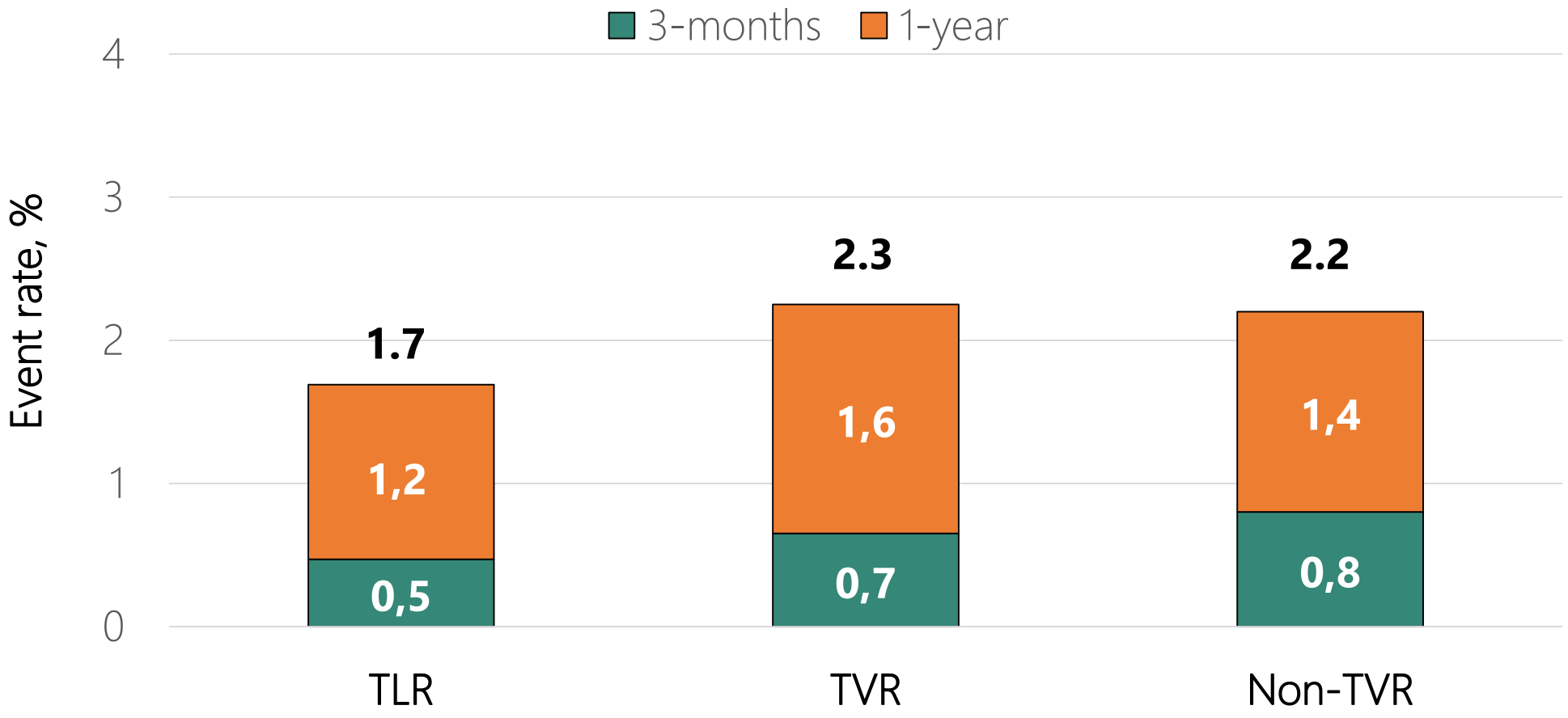


SECONDARY ENDPOINT

Patient-oriented composite endpoint (POCE)
All-cause mortality, any MI or any coronary revascularization

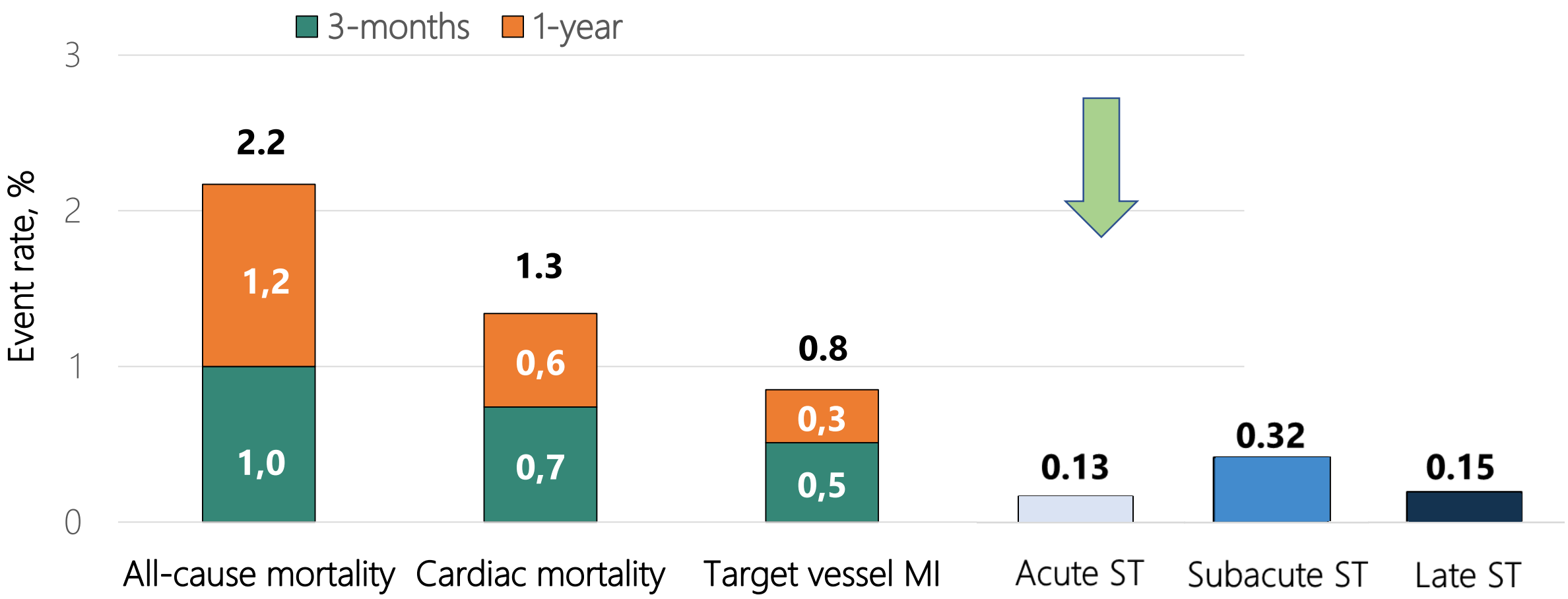


EFFICACY ENDPOINTS



TLR: target lesion revascularization; (non-)TVR: (non-) target vessel revascularization

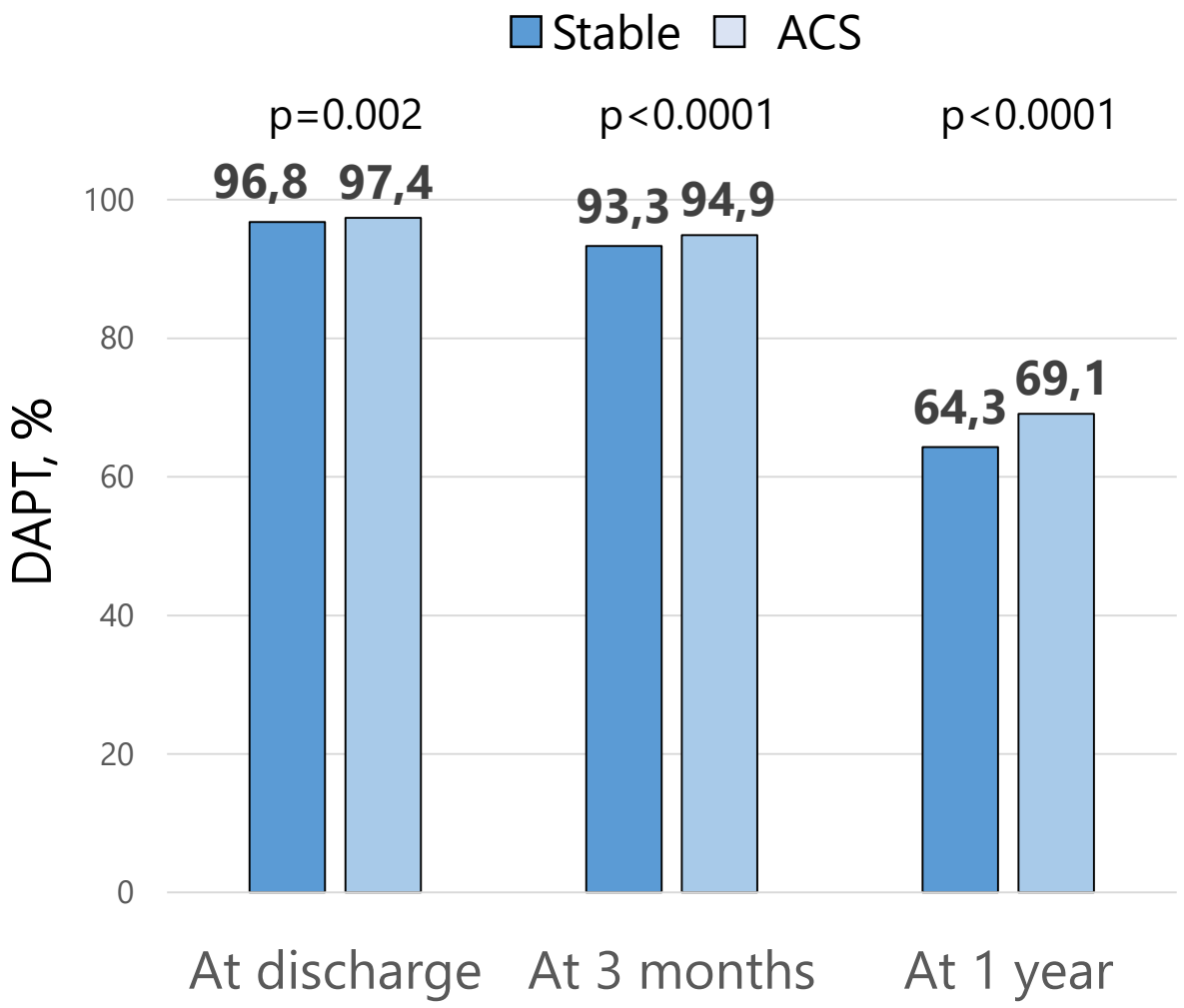
SAFETY ENDPOINTS



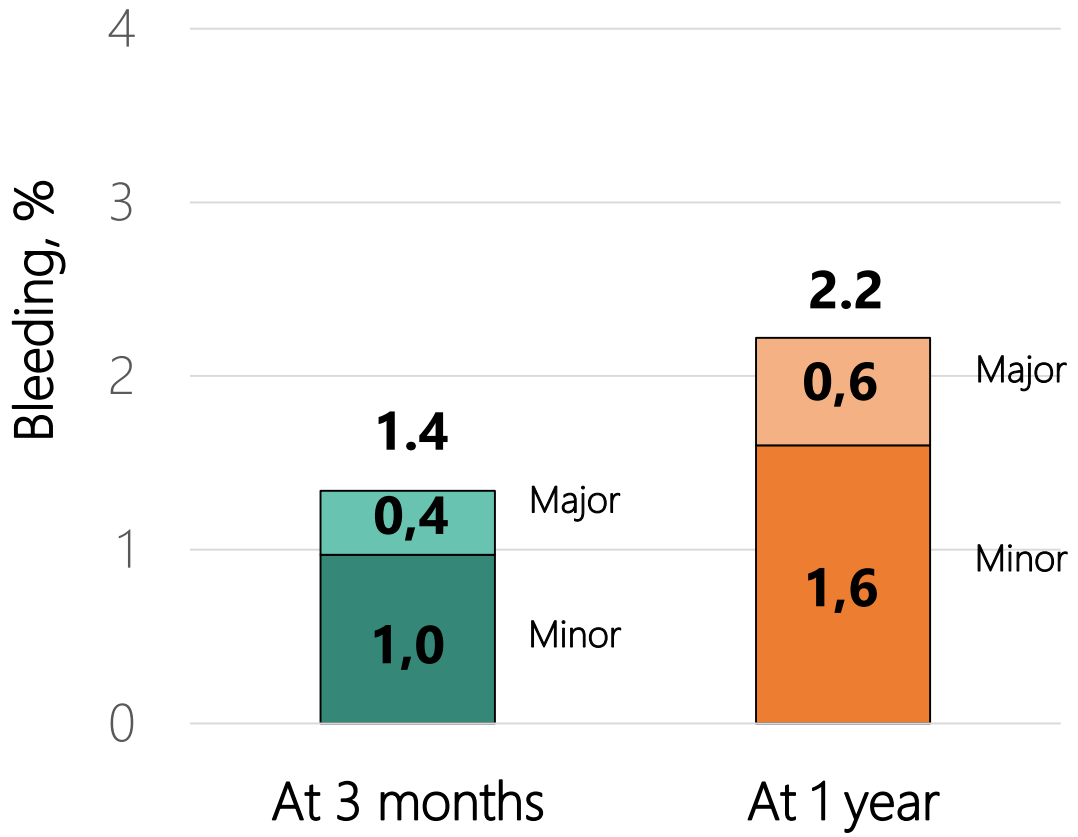
Acute ST: <24 hrs after index procedure
Subacute ST: 24 hrs - 1 month
Late ST: 1 month - 1 year

MI: myocardial infarction; Stent thrombosis (ST) = Definite + probable

DUAL ANTIPLATELET THERAPY AND BLEEDING RATE

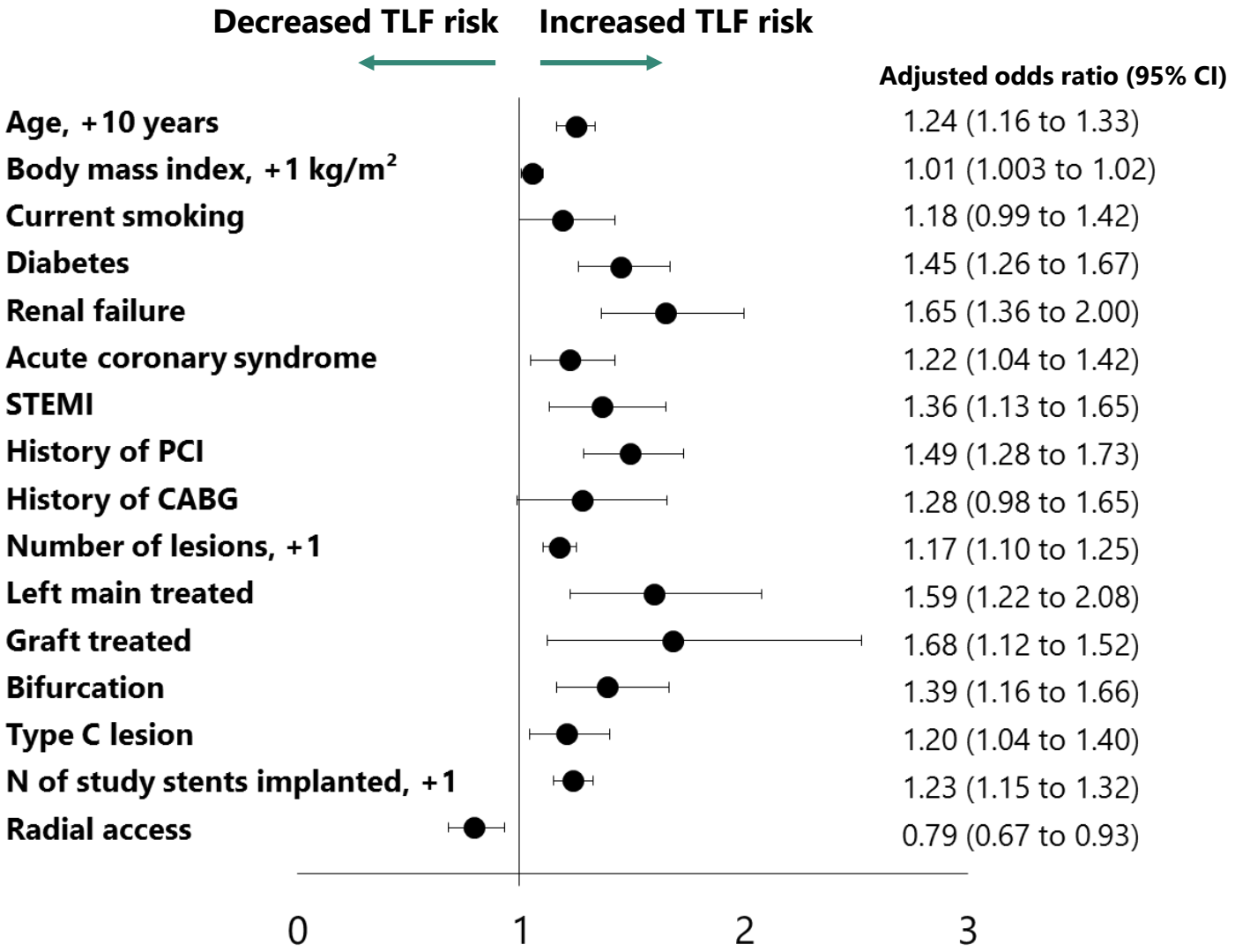


Stable: stable angina or silent ischemia
ACS: acute coronary syndrome: STEMI, NSTEMI or unstable angina



Bleeding was defined according to Bleeding Academic Research Consortium (BARC): minor bleeding BARC type 1-2
major bleeding BARC type 3-5

INDEPENDENT PREDICTORS OF 1-YEAR TFL

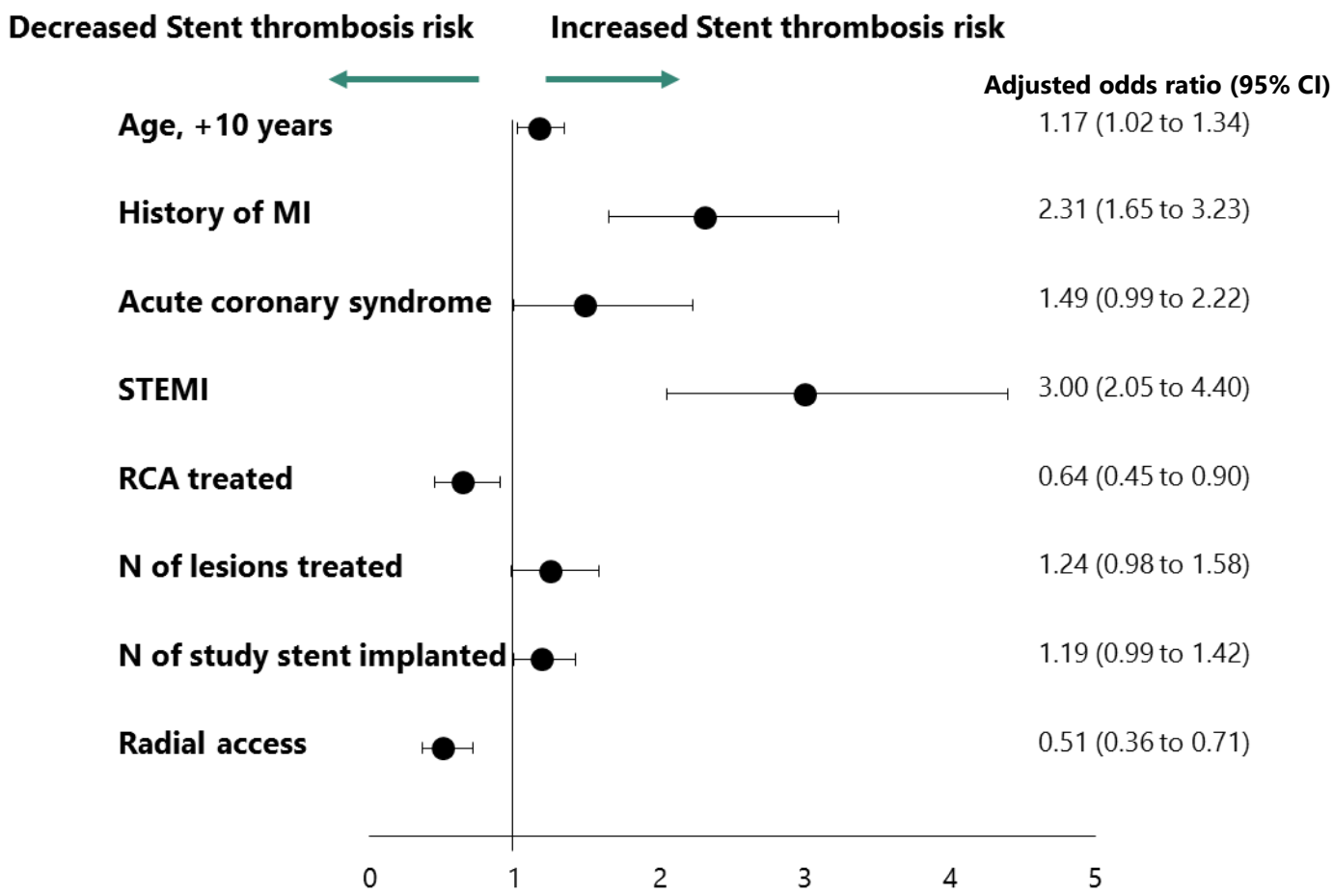


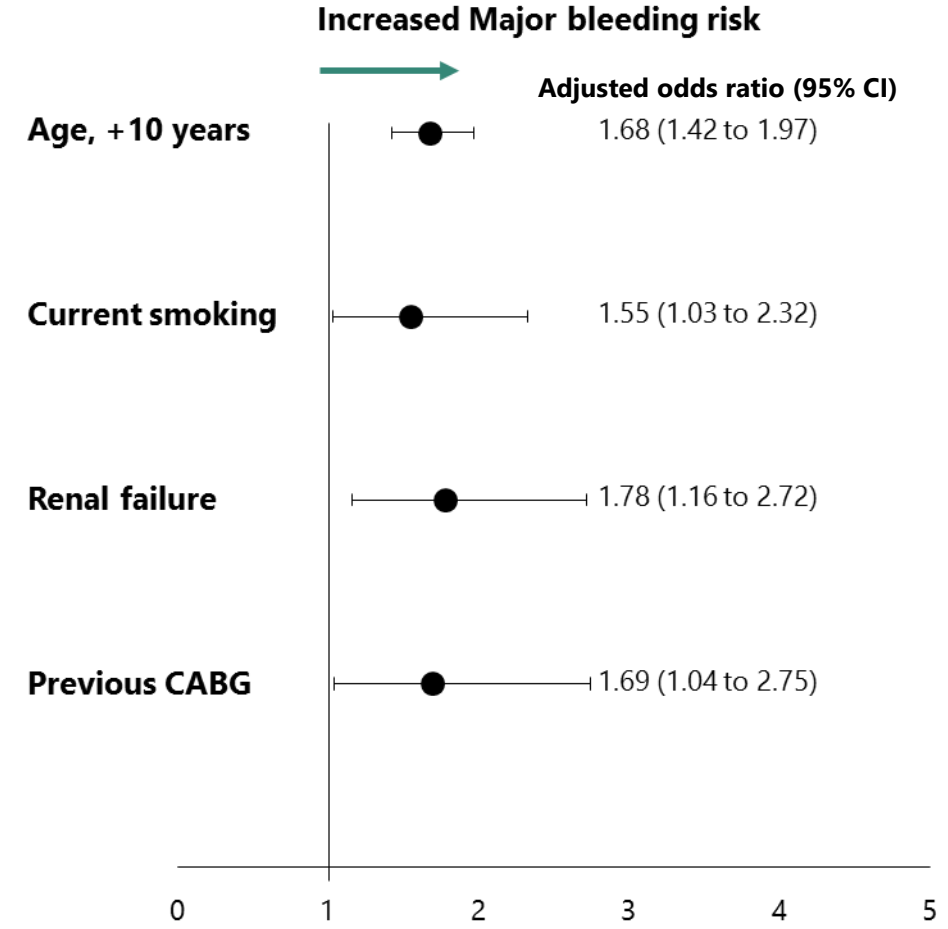
TLF: target lesion failure
Cardiac death, target-vessel MI or clinically-driven TLR

CABG: coronary artery bypass graft; PCI: percutaneous coronary intervention; STEMI: ST-elevated myocardial infarction; TLF: target lesion failure

Results based on stepwise logistic regression, with covariates considered for entering the model:
Age, gender, body mass index, diabetes, hypertension, hypercholesterolemia, smoking, previous MI, previous PCI, renal impairment, acute coronary syndrome, multi-vessel disease, N lesions identified, N lesions treated, vessel treated, N of stents implanted, length of stents implanted, in-stent restenosis, chronic total occlusion, bifurcation, long lesions, small vessels, calcification, AHA/ACC lesion classification, radial access

PREDICTORS OF DEFINITE/PROBABLE STENT THROMBOSIS AND MAJOR BLEEDING AT 1 YEAR





Diabetes was not an independent predictor of stent thrombosis
Adjusted OR: **1.16 (0.83 to 1.63; p=0.38)**

CABG: coronary artery bypass graft; RCA; right coronary artery; STEMI: ST-elevated myocardial infarction

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CONCLUSION

WHY IS THIS IMPORTANT?

Interim analysis of one of the largest, prospective, world-wide registries including >50% ACS patients and with independent event adjudication showed remarkable efficacy and safety of ULTIMASTER-based PCI, with in particular a target lesion failure and definite or probable stent thrombosis rates well below 5% and 1%, respectively.

THE ESSENTIALS TO REMEMBER

- **Why?** To assess efficacy and safety of the Ultimaster stent
- **What?** Ultimaster: thin strut, co-cr, sirolimus-eluting stent, abluminal bioresorbable polymer
- **How?** Over 25,000 all-comer PCI, followed up at 3 months and 1 year, independent event adjudication
- **What are the results?**

  Excellent efficacy and safety performance with in particular low rates of TLF and definite/probable ST

- **Why is this important?**

  Advances in stent design of newer-generation DES might contribute to improved PCI efficacy and safety

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e-Ultimaster top-enrollers

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