2019 euroPCR

Revascularization strategy of multivessel PCI – data from a worldwide registry

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On behalf of e-Ultimaster investigators

POTENTIAL CONFLICT OF INTEREST

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

Advisory/Consultancy to Terumo

BACKGROUND
WHY THIS STUDY?

- Patients with multivessel coronary artery disease (MVD) are at increased risk of adverse clinical outcomes following PCI
- More frequent use of PCI to treat MVD
- The value and timing of complete revascularization over incomplete revascularization is uncertain in patients with MVD
- (Current ESC guidelines do not give the highest class of recommendation regarding completeness of myocardial revascularization)

STUDY METHODS
WHAT DID WE STUDY?

Revascularization strategy in multivessel disease patients* treated with contemporary DES

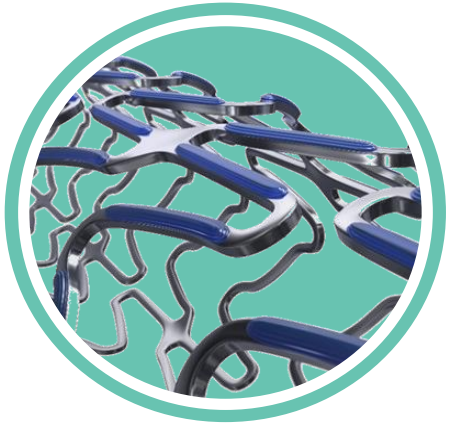
Revascularization strategy

Complete revascularization at index procedure**

Incomplete revascularization at index procedure

Clinical outcomes

Angina status
Safety endpoints
Efficacy endpoints



Ultimaster DES	
Platform	Strut thickness (**80 µm**) Co-Cr Open cell design
Drug Carrier	PDLLA-PCL copolymer resorbed within **3-4 months**
Coating	Abluminal **bioresorbable gradient coating** technology
Drug	**Sirolimus -** 3.9 µg/mm stent length

*Multivessel disease is defined as the presence of a >50% diameter stenosis in more than 1 coronary artery
**Also includes procedures which occurred after the initial (index) procedure within the period before discharge from hospital

STUDY DESIGN

HOW WAS THIS STUDY EXECUTED?

e-Ultimaster registry

4 continents, 50 countries, 376 sites

Study enrolment completed, follow-up ongoing

> 37,000 patients enrolled

Interim analysis
1-year follow-up
n=25,990 patients
n=9,164 MVD patients

COMPLETE
revascularization
n=3,777 patients

INCOMPLETE
revascularization
n=5,387 patients

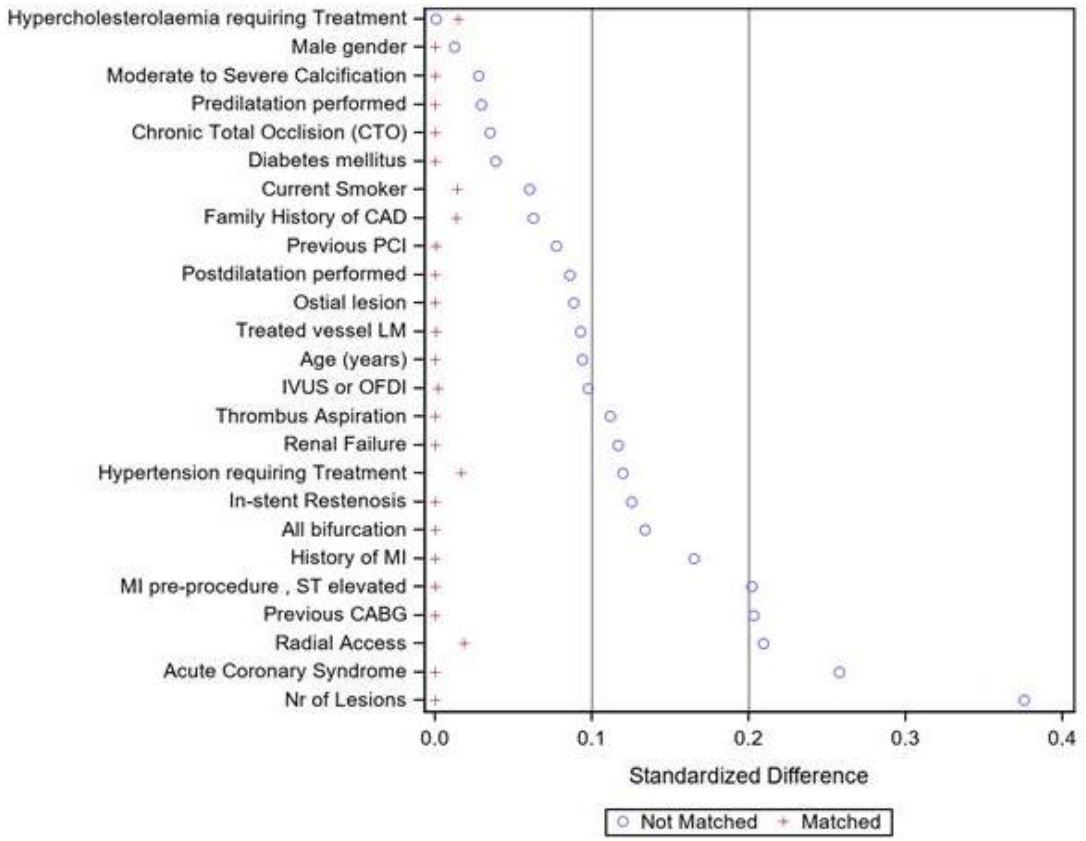
Clinical follow-up

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

STATISTICAL METHODOLOGY

Inverse probability of treatment weights (IPTW) methodology

- The Inverse Probability of Treatment Weights (IPTW) method creates balanced groups for comparison of subgroups that are not randomized and as a consequence, do not allow for direct statistical comparison due to the resulting imbalance in covariates (baseline characteristics).
- A **logistic regression model**, containing **all covariates that require balancing** as predictive factors and subgroup of interest as outcome, predicts the probability for each subject of belonging to the subgroup he is in ('**propensity scores**'), based on the array of covariates (see graph).
- The IPTW are then the **inverse of these propensity scores (1/PS)**, and can be used as **weight to balance the subgroups**, i.e. the covariates become similar between the subgroups.
- By performing **weighted statistical analyses on the outcomes**, using these inverse propensity weights, the results can be interpreted for the subgroup comparison, **balanced for the covariates included in the initial logistic regression** model that calculates the propensity scores.
- On of the advantages of this methodology is that all patients can be included in the weighted analysis (as opposed to 1 to 1 matched analyses, where only part of the population is included).



- Covariates to calculate the propensity score include
- The y-axis gives the covariates included in the propensity score; the x-axis gives the standardized difference between complete and incomplete revascularization group before and after weighted analyses

BASELINE PATIENT CHARACTERISTICS

	Complete revascularization n=3,777	Incomplete revascularization n=5,387	P-value
Age, years	**64.8±11.2**	**65.9±11.0**	<0.001
Gender, male	**78.0**	**77.5**	0.56
Current smoking	**23.8**	**21.3**	0.006
Diabetes	**30.9**	**32.8**	0.07
Hypertension	**65.5**	**71.1**	<0.001
Hypercholesterolemia	**59.0**	**59.1**	0.97
Renal disease	**7.4**	**10.7**	<0.001
Haemodialysis	**1.2**	**1.1**	0.76
Previous MI	**21.8**	**29.1**	<0.001
Previous PCI	**25.6**	**29.0**	<0.001

Unadjusted data; values are mean±SD or percentages

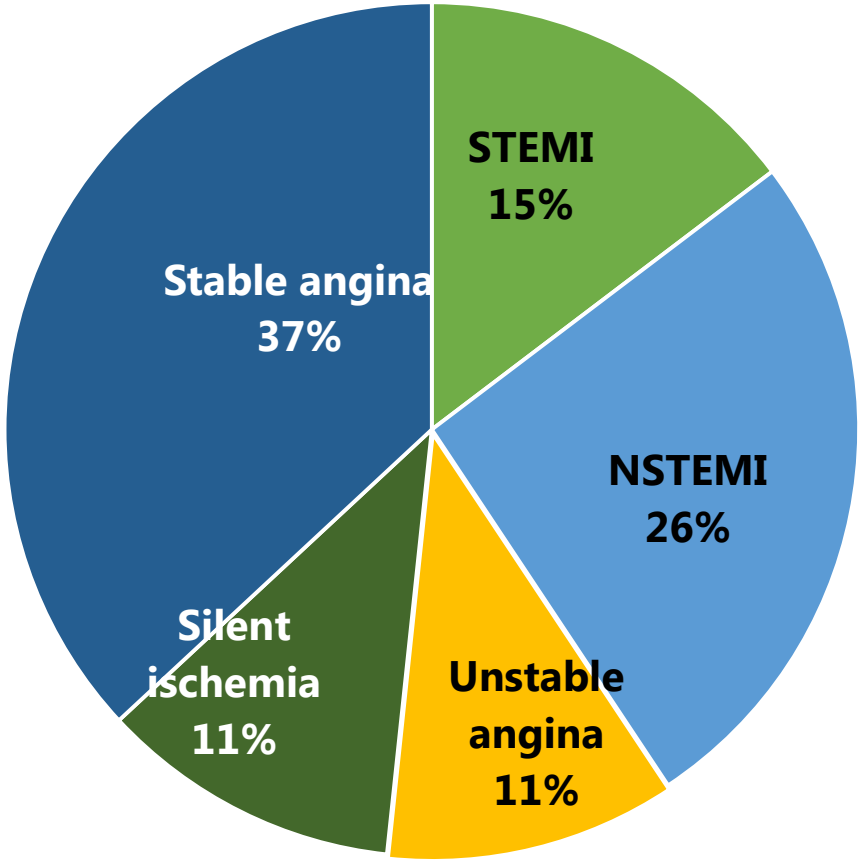
BASELINE LESION/PROCEDURE CHARACTERISTICS

	Complete revascularization n=3,777	Incomplete revascularization n=5,387	P-value
Bifurcation per patient	**18.4**	**13.4**	<0.001
Left main per patient	**6.5**	**4.4**	<0.001
N of lesions treated per patient, n	**2.4±0.7**	**1.4±0.7**	<0.001
N of stents implanted per patient, n	**2.7±1.1**	**1.7±0.9**	<0.001
Total stent length per patient, mm	**45.8±27**	**32.5±20.6**	<0.001
Type C lesions (AHA/ACC) per lesion	**25.1**	**28.3**	<0.001
Moderate/severe calcification per lesion	**18.0**	**21.7**	<0.001
Direct stenting per lesion	**39.5**	**32.1**	<0.001
Post-dilatation per lesion	**39.0**	**43.1**	<0.001
Imaging per patient	**5.1**	**3.4**	<0.001

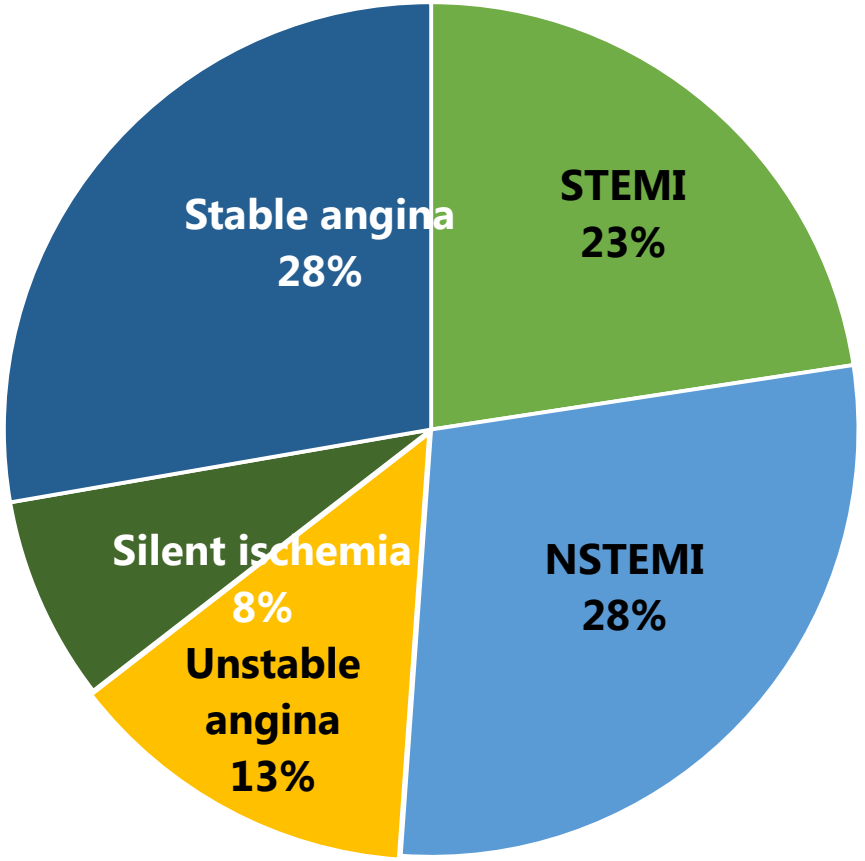
Unadjusted data; values are mean±SD or percentages

BASELINE CLINICAL PRESENTATION

Complete revascularization

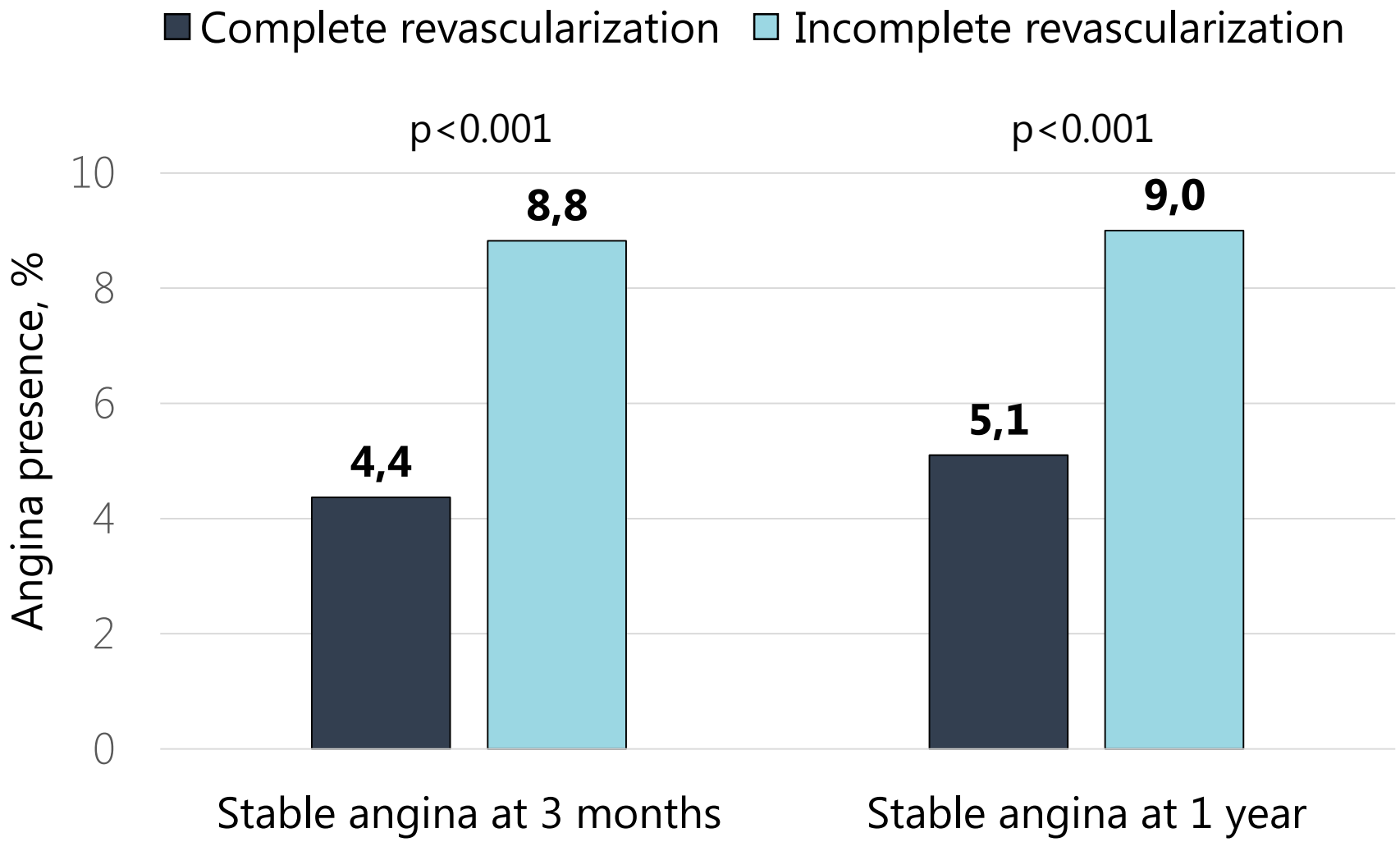


Incomplete revascularization



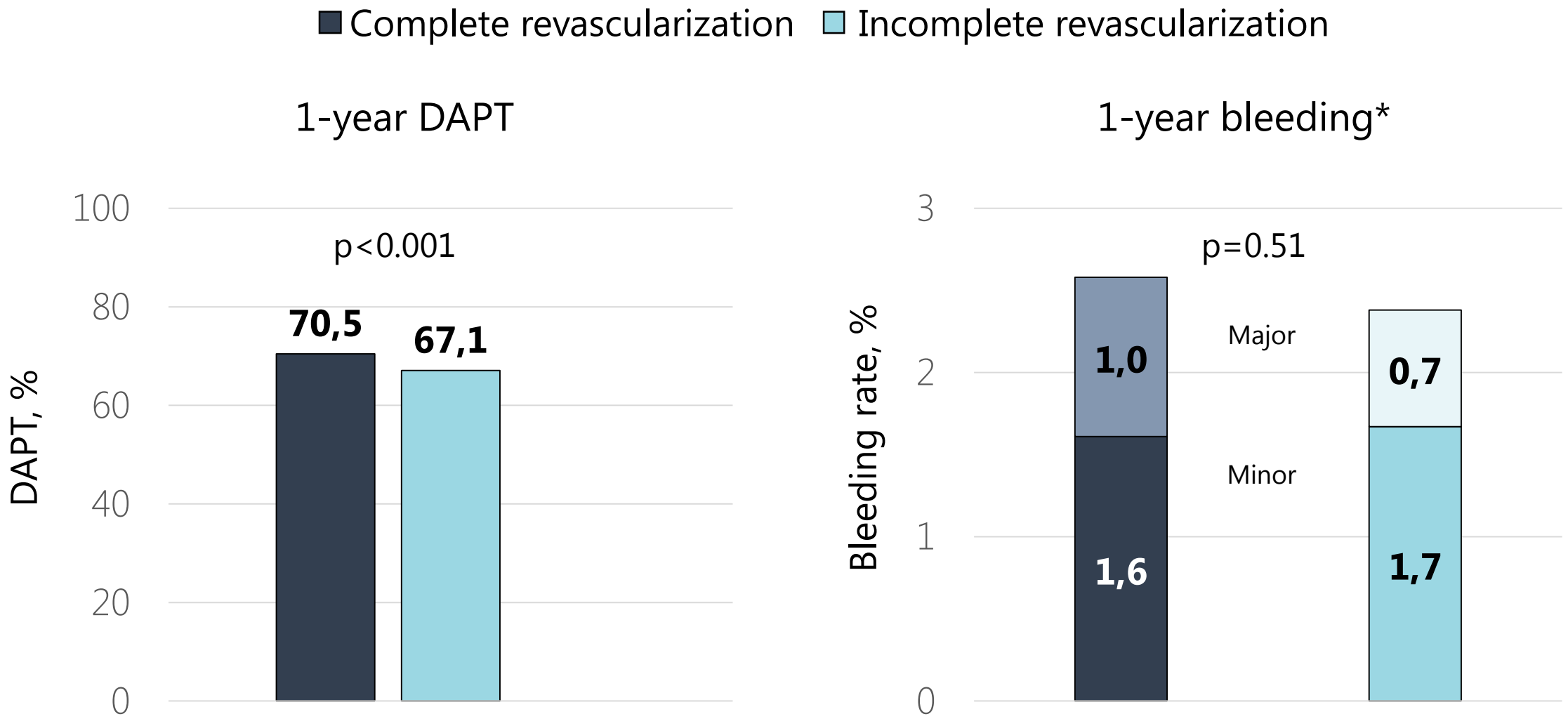
(N)STEMI: (non) ST-elevated myocardial infarction

STABLE ANGINA AT FOLLOW-UP



Results based on propensity weighted analysis

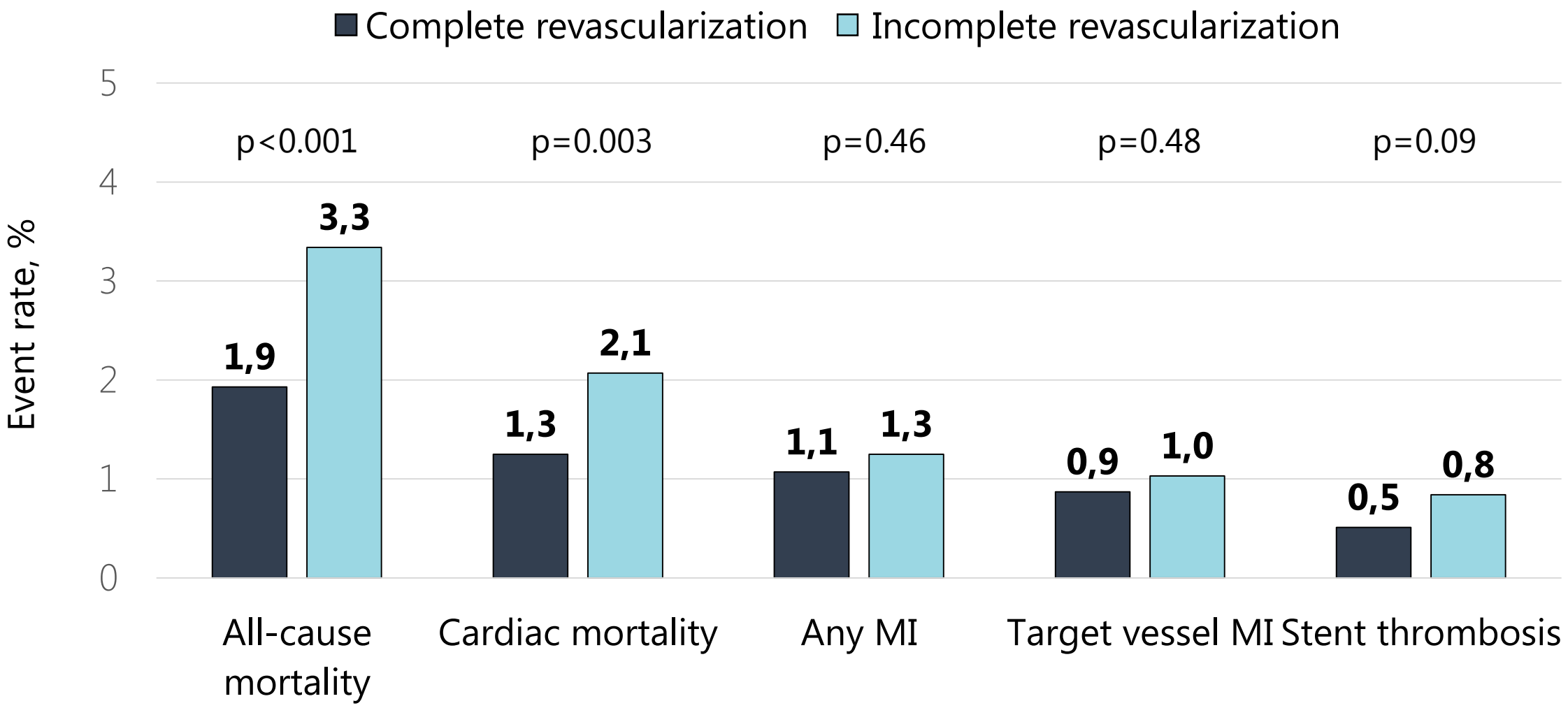
DUAL ANTIPLATELET THERAPY AND BLEEDING



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

Results based on propensity weighted analysis

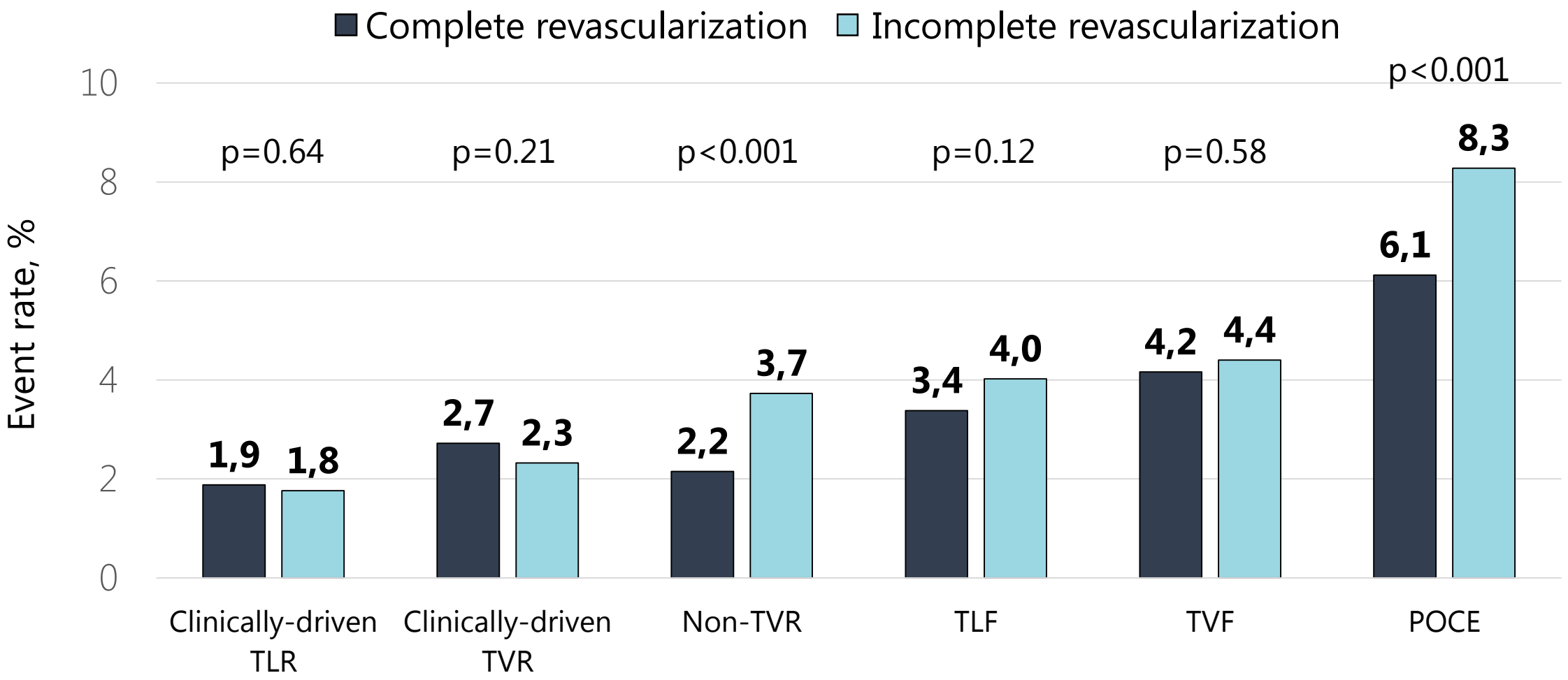
SAFETY ENDPOINTS AT 1 YEAR



Results based on propensity weighted analysis

MI: myocardial infarction; **Stent thrombosis:** Definite + probable stent thrombosis

EFFICACY AND COMPOSITE ENDPOINTS AT 1 YEAR



Results based on propensity weighted analysis

POCE: patient-oriented composite endpoint (all-cause mortality, any MI, any revascularization); **TLF**: target lesion failure (cardiac death, TV-MI and clinically driven target lesion revascularization); **TVF:** target vessel failure (cardiac death, TV-MI, clinically driven target vessel revascularization; **TLR**: target lesion revascularization; **TVR**: target vessel revascularization

CONCLUSION

WHY IS THIS IMPORTANT?

- Data reported from a subgroup of a large, prospective, world-wide registry on PCI treatment of multivessel CAD with a contemporary DES
- Less angina at 1 year with complete revascularisation
- Lower mortality at 1 year with complete revascularisation
- Physician-directed selective use of complete revascularization results in good clinical outcomes

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e-Ultimaster top-enrollers

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