Best Stent and Best Antithrombotic Strategy in HBR patients: (MASTER DAPT, ONYX ONE, Leaders free and Others)

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Disclosures

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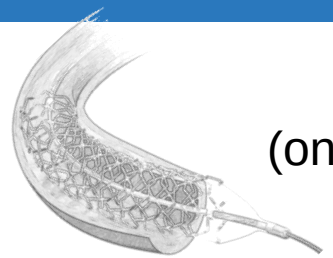
ISTITUTO CARDIOCENTROTICINO

Trials in patients at HBR

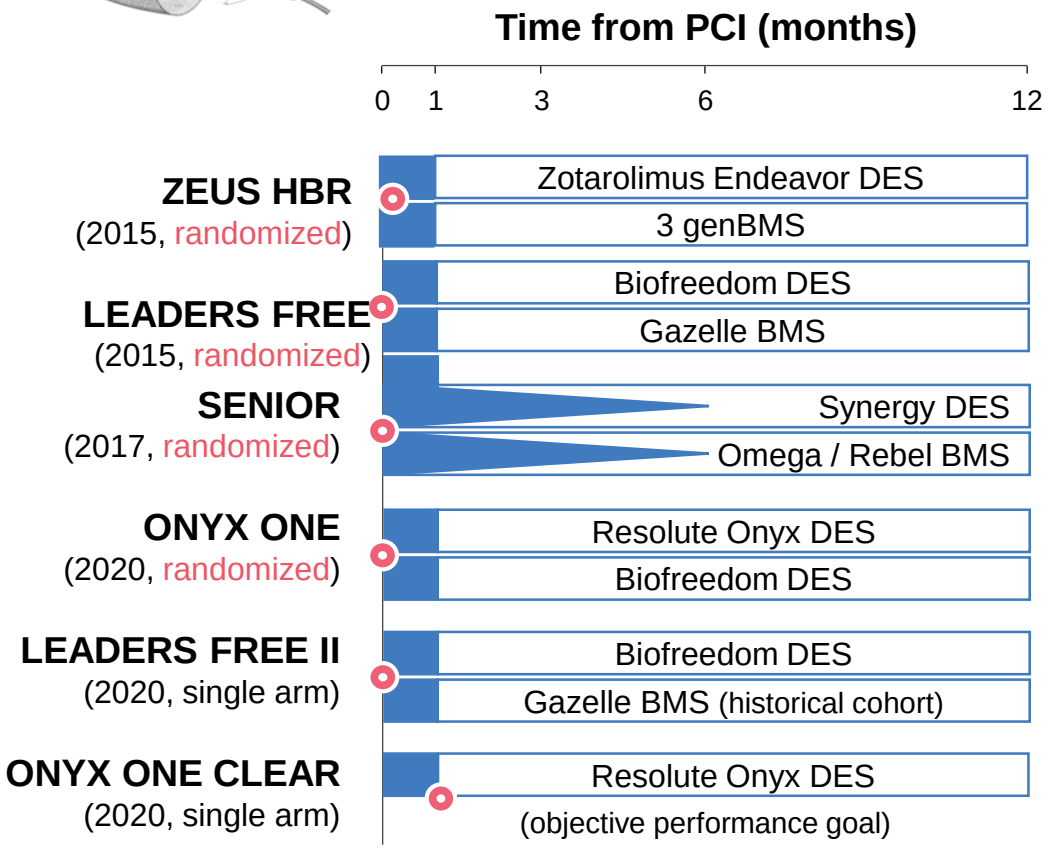


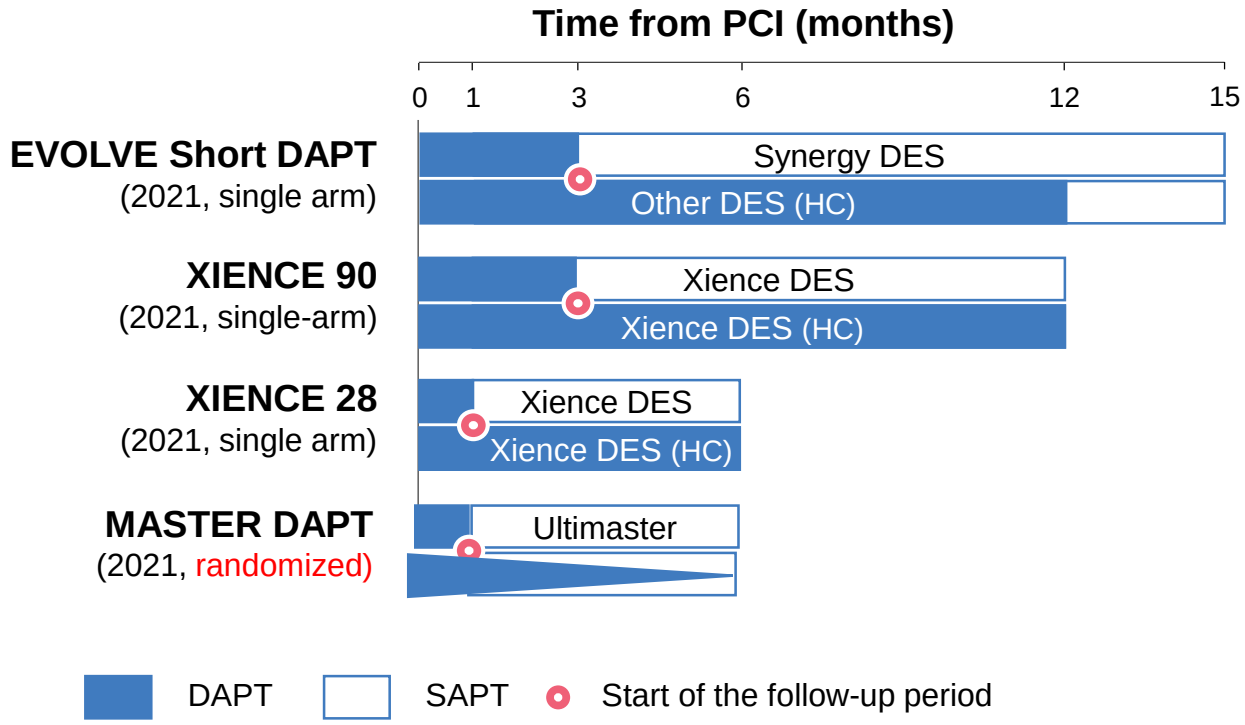
Stent A vs Stent B

(on a background of short DAPT)

Short vs Standard DAPT

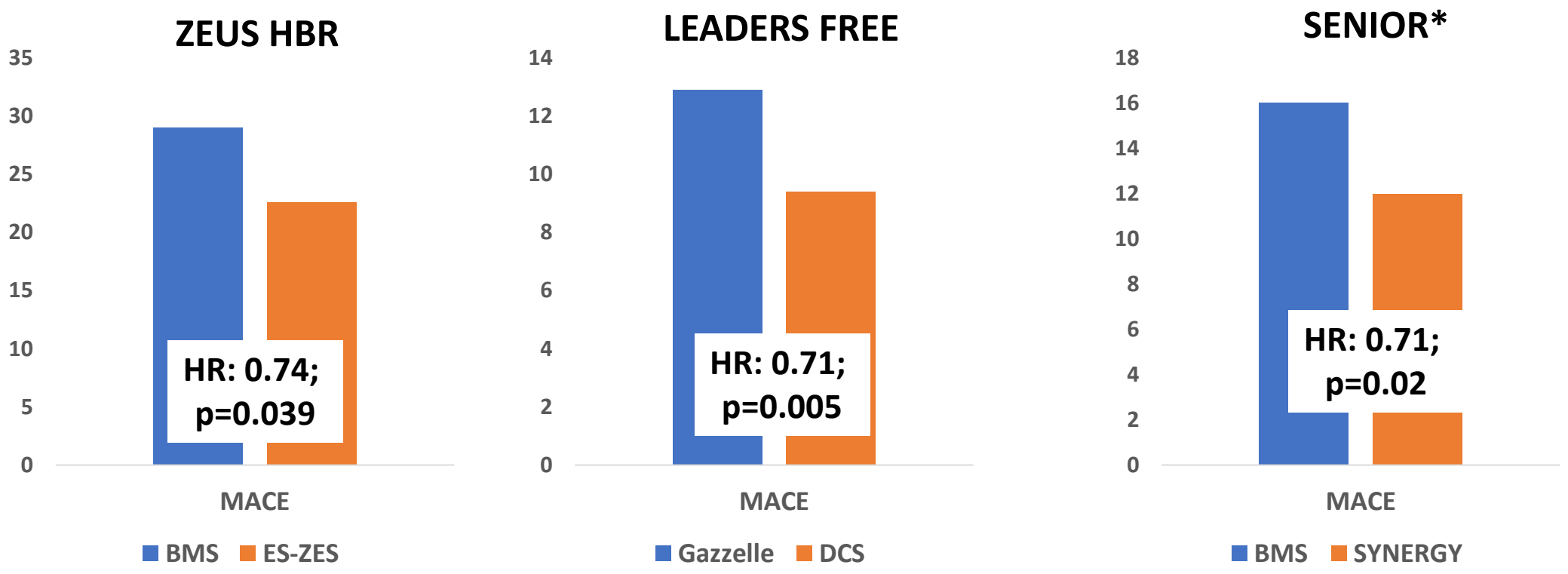
(using the same or different stents)





HC = historical cohort; DAPT trials in chronic OAC (e.g., WOEST, ISAR-TRIPLE, PIONEER AF PCI, RE-DUAL PCI, AUGUSTUS, ENTRUST-AF PCI) are not displayed

1 Month DAPT…which stent platform to choose ?



JACC C2015; 65(8); 808-815

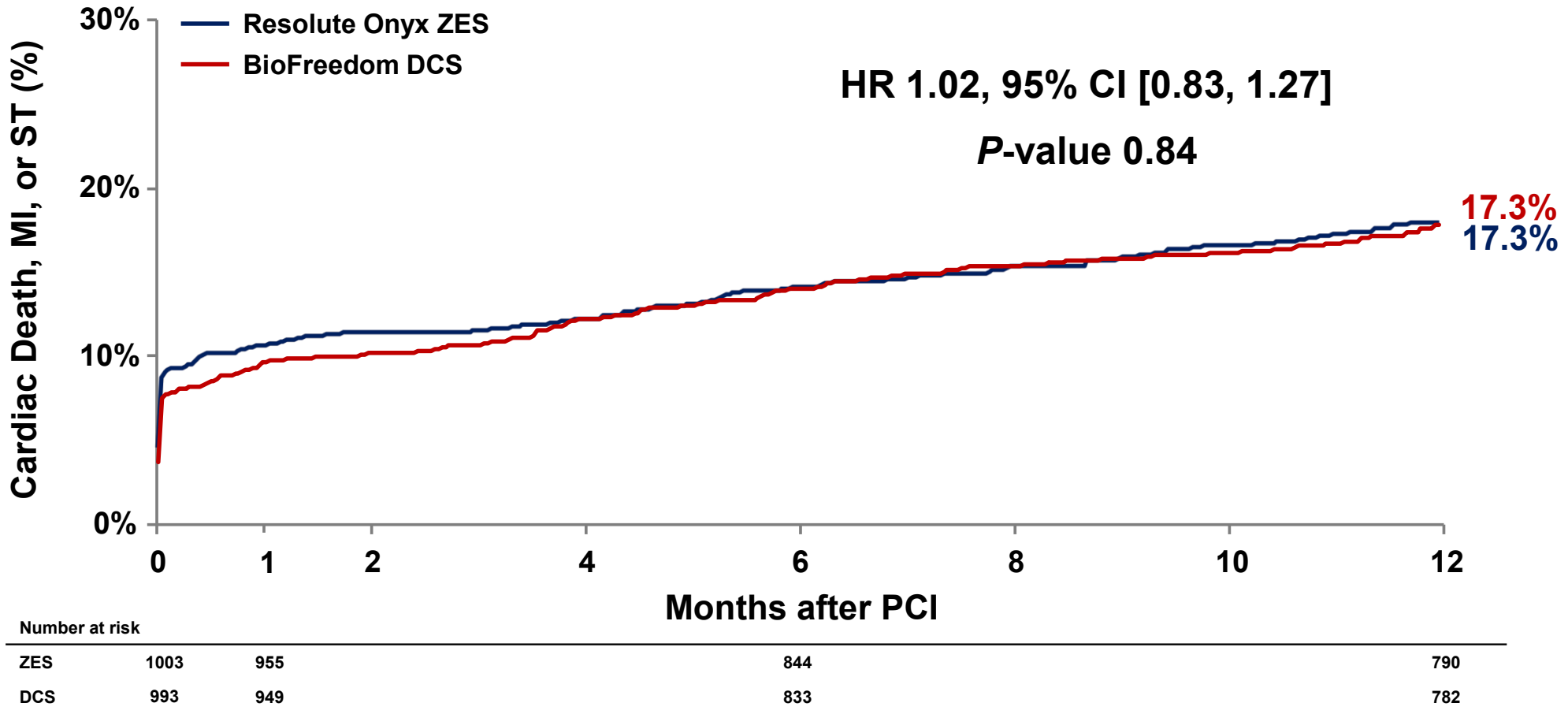
NEJM 2015; 573; 2038-47

Lancet 2018; 391; 41-50

*: 6 month DAPT for ACS; no difference for MI noted between stent platforms unlike the findings in ZEUS and LEADERS free

Onyx One

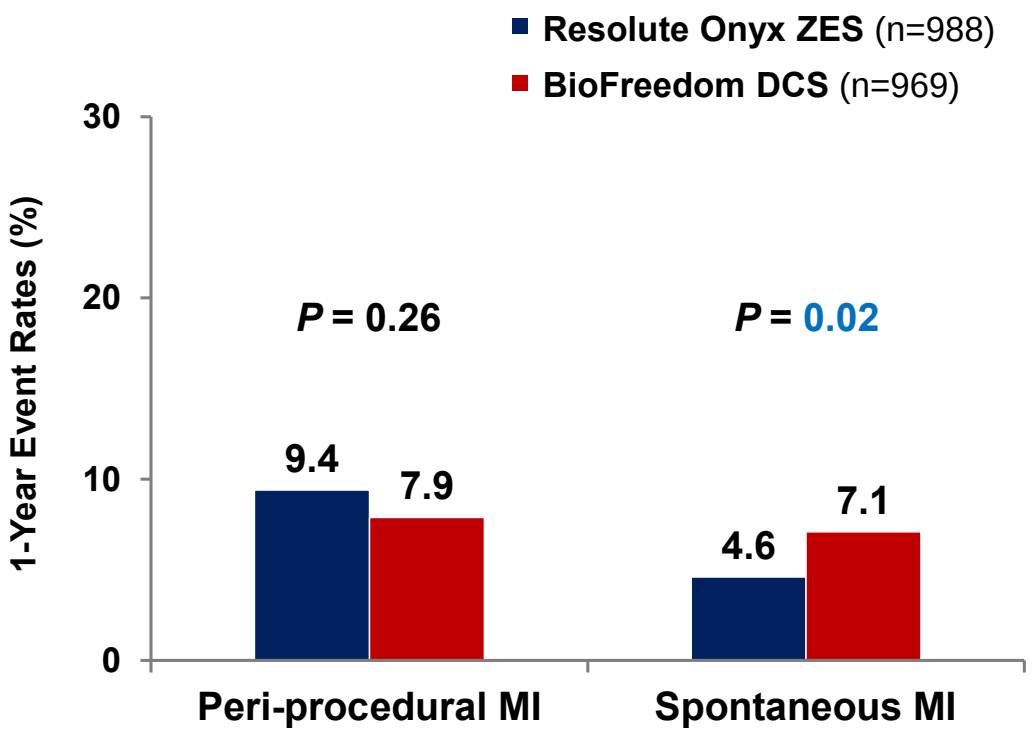
Primary Safety Endpoint: Cardiac Death, MI, or ST



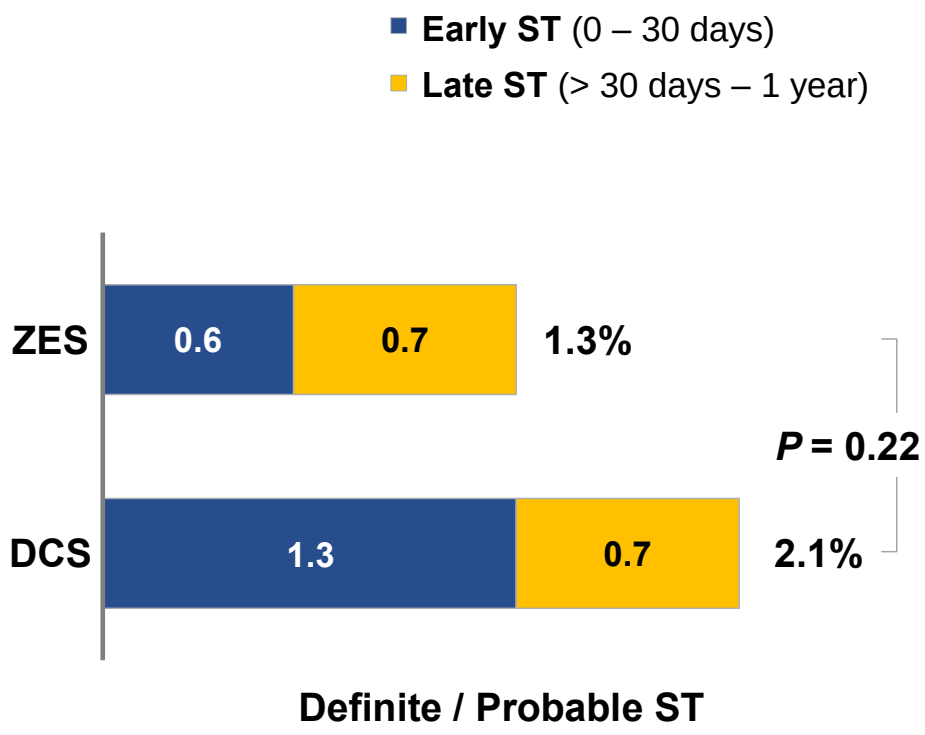
N Engl J Med 2020; 382:1208-1218

Onyx One

Myocardial Infarction



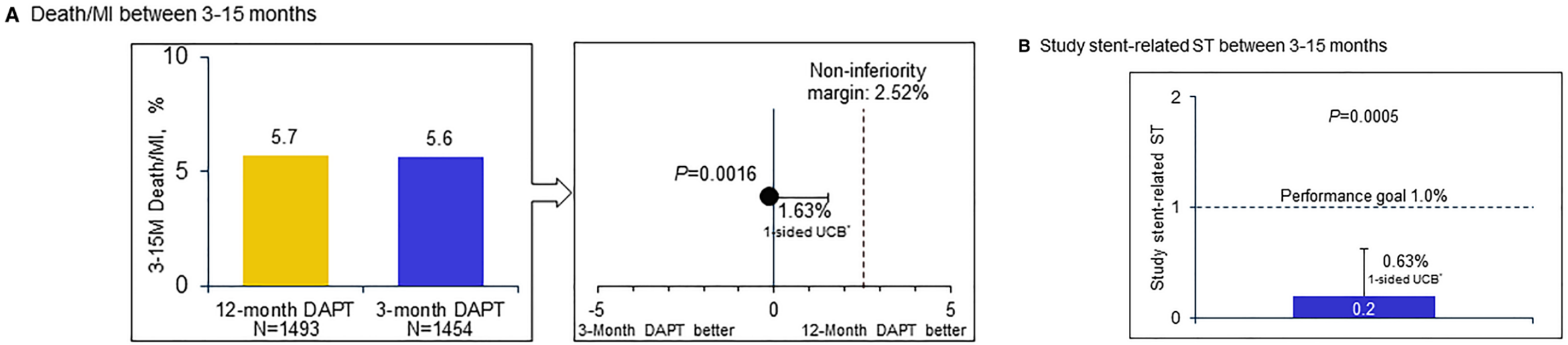
Stent Thrombosis



N Engl J Med 2020; 382:1208-1218

EVOLVE SHORT DAPT

1487 patients free from ischemic recurrences and eligible to discontinue the P2Y12 I at 3 months
Historical control group (DAPT study)
Patients with MI or complex PCI were excluded



BARC 2, 3 or 5 rates were 6.26% with 3 month DAPT and 4.17% with 12 month DAPT

Circ Cardiovasc Interv. 2021;14:e010144

XIENCE Short DAPT Program

Xience short DAPT

Xience short DAPT

XIENCE 90

3-month DAPT

101 sites in USA

2,047 patients

XIENCE 28

1-month DAPT

Global

52 sites

963 patients

USA

58 sites

642 patients

TOTAL OF ~3,600 PATIENTS WITH 1-MONTH OR 3-MONTH DAPT

JACC Cardiovasc Interv. 2021 Sep 13;14(17):1870-1883

Trial Objectives

Among HBR patients who have undergone successful PCI with the XIENCE stent:

Primary Objective:

- To evaluate the *safety (all death or MI)* of a short DAPT regimen (1 or 3 months) versus DAPT for up to 12 months

Secondary Objectives:

- To determine the impact of short DAPT (1 or 3 months) versus DAPT for up to 12 months on *clinically relevant bleeding (BARC 2-5)*
- To evaluate *stent thrombosis (definite/probable)* against a performance goal*

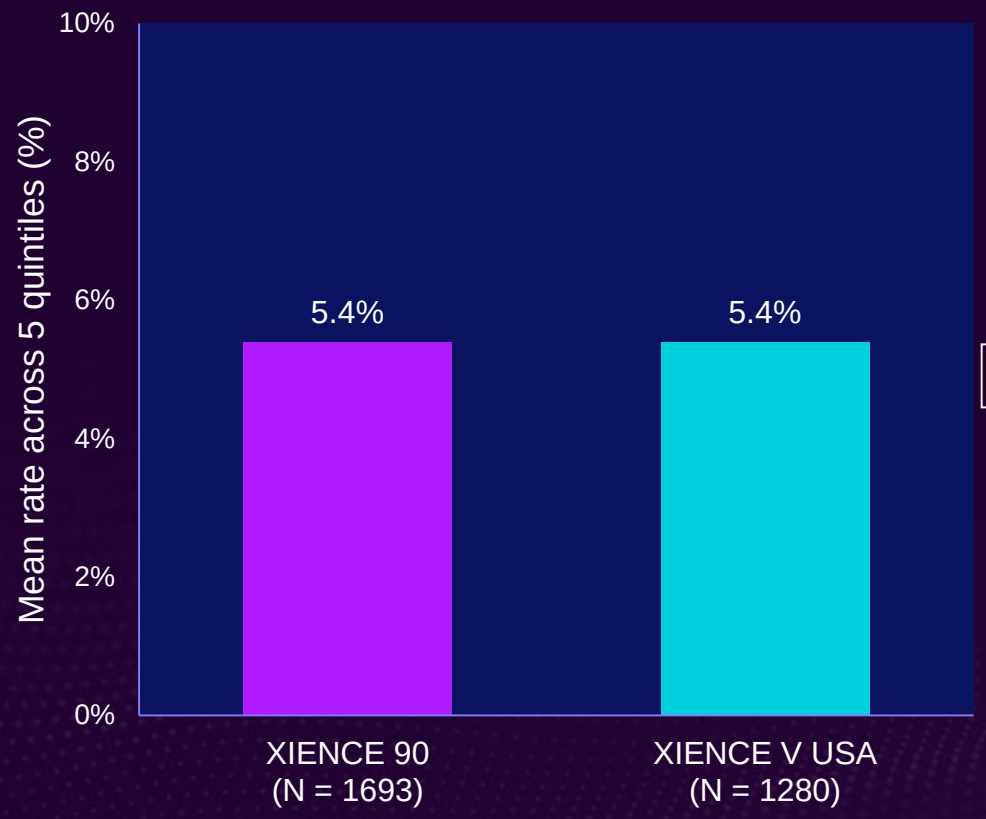
* Only for XIENCE 90

JACC Cardiovasc Interv. 2021 Sep 13;14(17):1870-1883

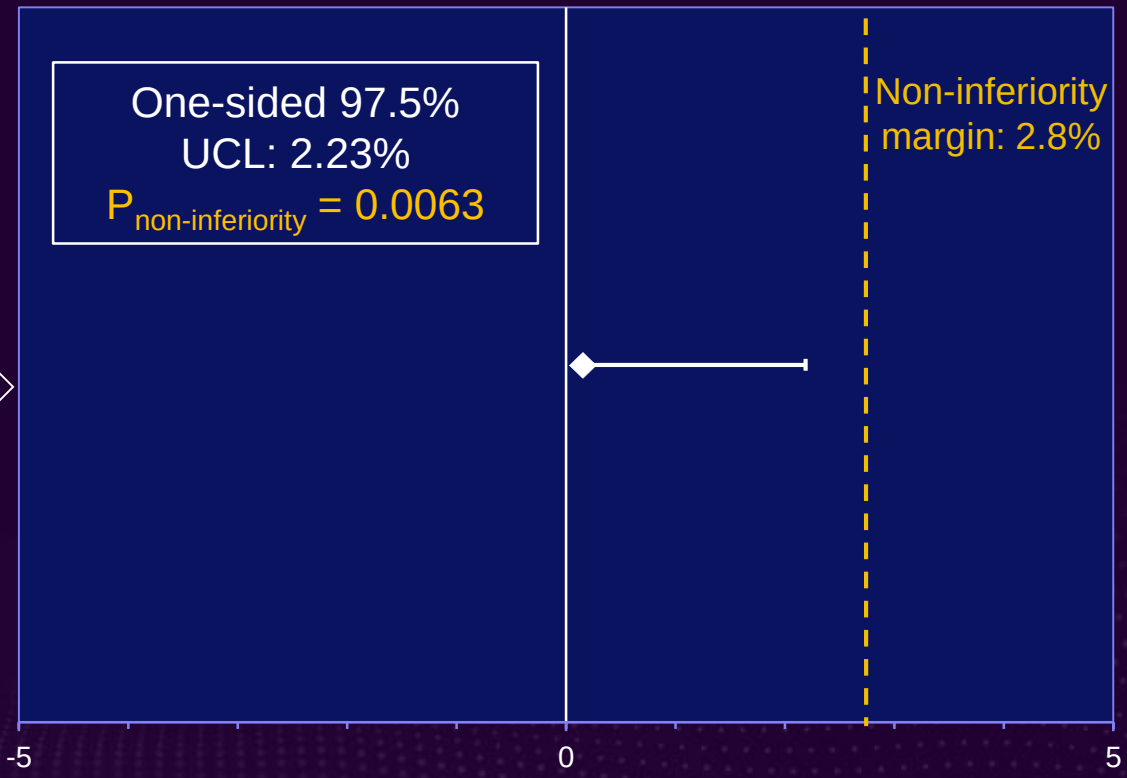
XIENCE 90: All Death or MI

Between 3 and 12 Months

PS Stratified Mean



Non-inferiority Analysis



Non-inferiority tested with the stratified Farrington-Manning method

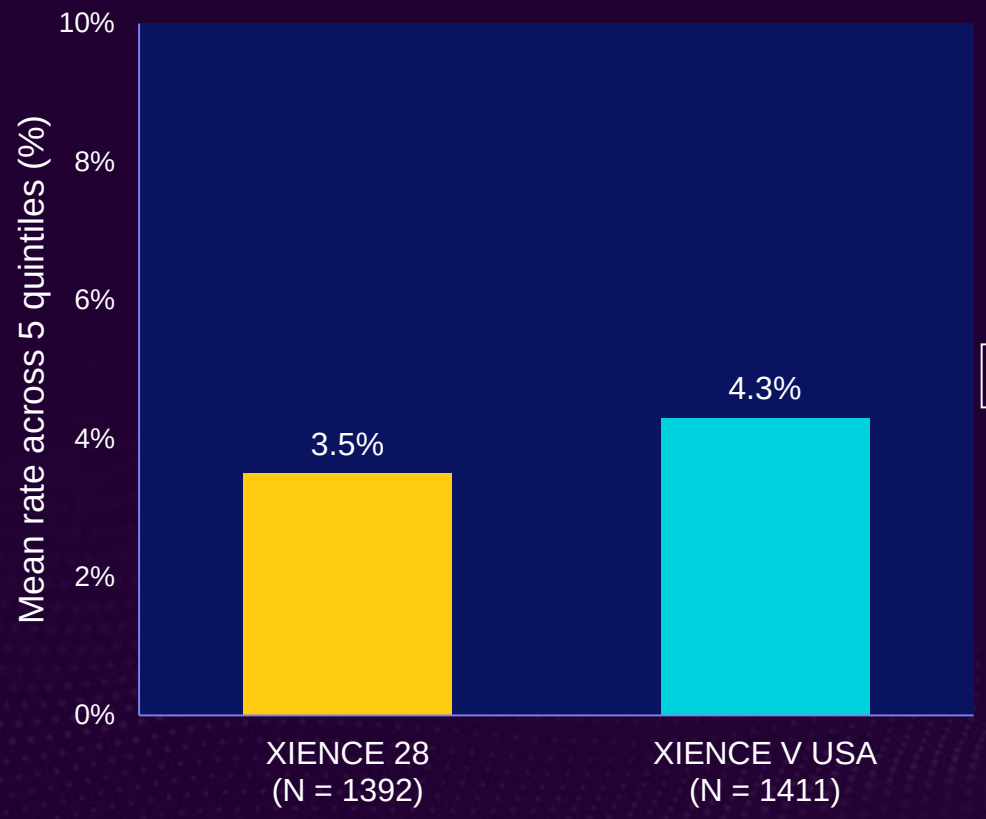
JACC Cardiovasc Interv. 2021 Sep 13;14(17):1870-1883

XIENCE 28: All Death or MI

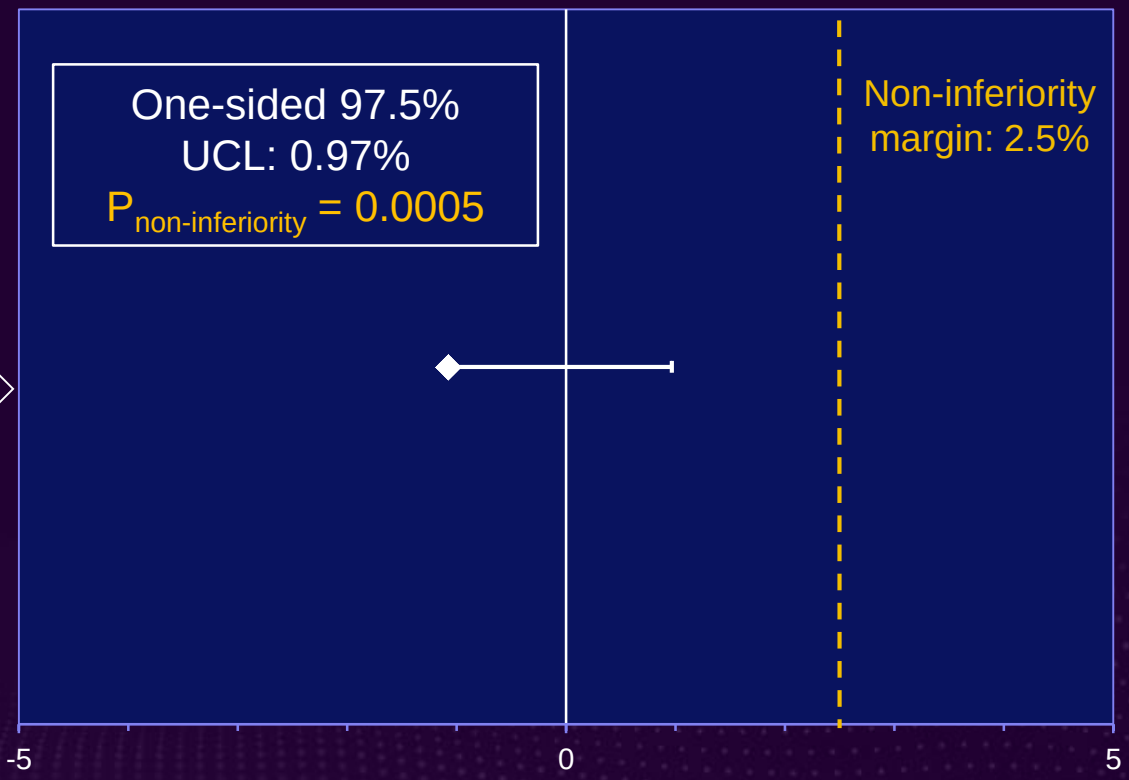
Between 1 and 6 Months

Xience short DAPT

PS Stratified Mean



Non-inferiority Analysis



Non-inferiority tested with the stratified Farrington-Manning method

JACC Cardiovasc Interv. 2021 Sep 13;14(17):1870-1883

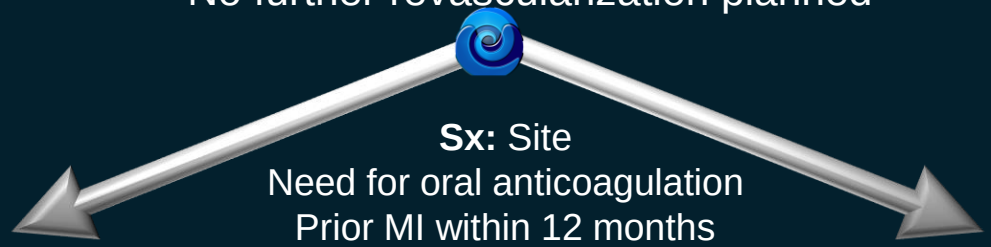
MASTER DAPT Trial

Screened Population: **HBR pts, treated exclusively with Ultimaster stent, with no restriction based on clinical presentation or PCI complexity**

Randomization and Regimens

30 (+14) Days after PCI

Free from cardiac and cerebral ischemic events
and active bleeding
No further revascularization planned



Sx: Site
Need for oral anticoagulation
Prior MI within 12 months

Abbreviated DAPT

Immediate DAPT discontinuation

followed by SAPT for 11 months
or 5 months if OAC is indicated

Standard DAPT

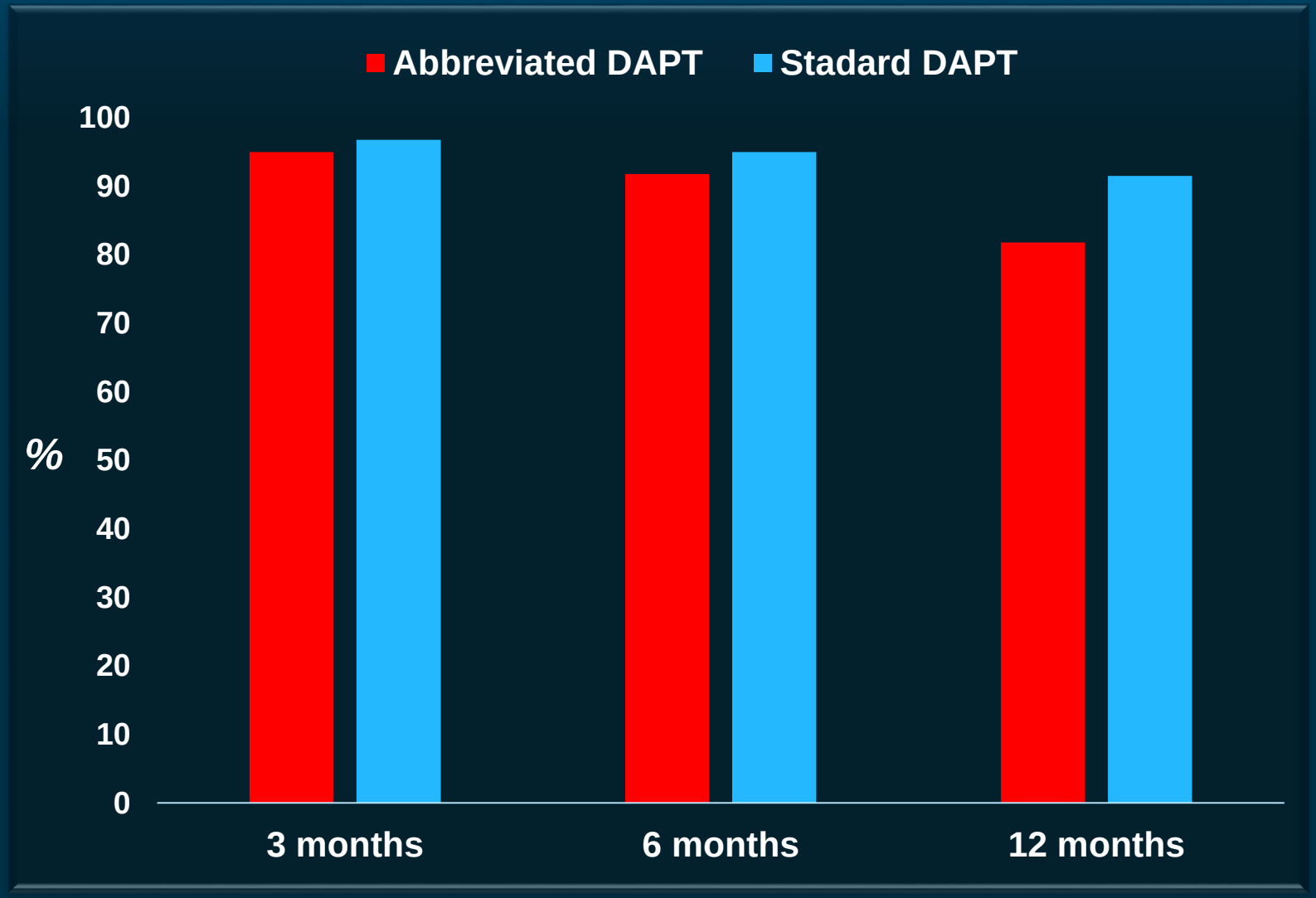
DAPT for ≥ 2 or 5 months in pts with or without OAC indication, respectively

followed by SAPT up to 11 months

HBR: high bleeding risk; DAPT: dual antiplatelet therapy; SAPT: single antiplatelet therapy; MI myocardial infarction: OAC: oral anticoagulation

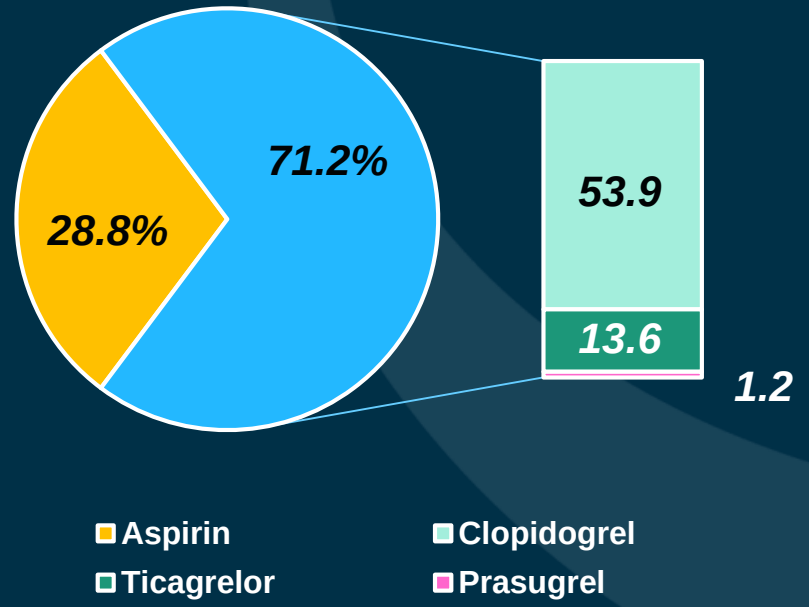
NARC 0 Adherence Rates* and Regimens

*: Perfect adherence rate, defined as 100% intake of protocol mandated regimen, counted on a daily basis



The median DAPT duration from the index coronary intervention was 34 days (IQR, 31-39) in the abbreviated- and 193 days (IQR, 102-366) in the standard-treatment groups.

Type of SAPT in the abbreviated DAPT

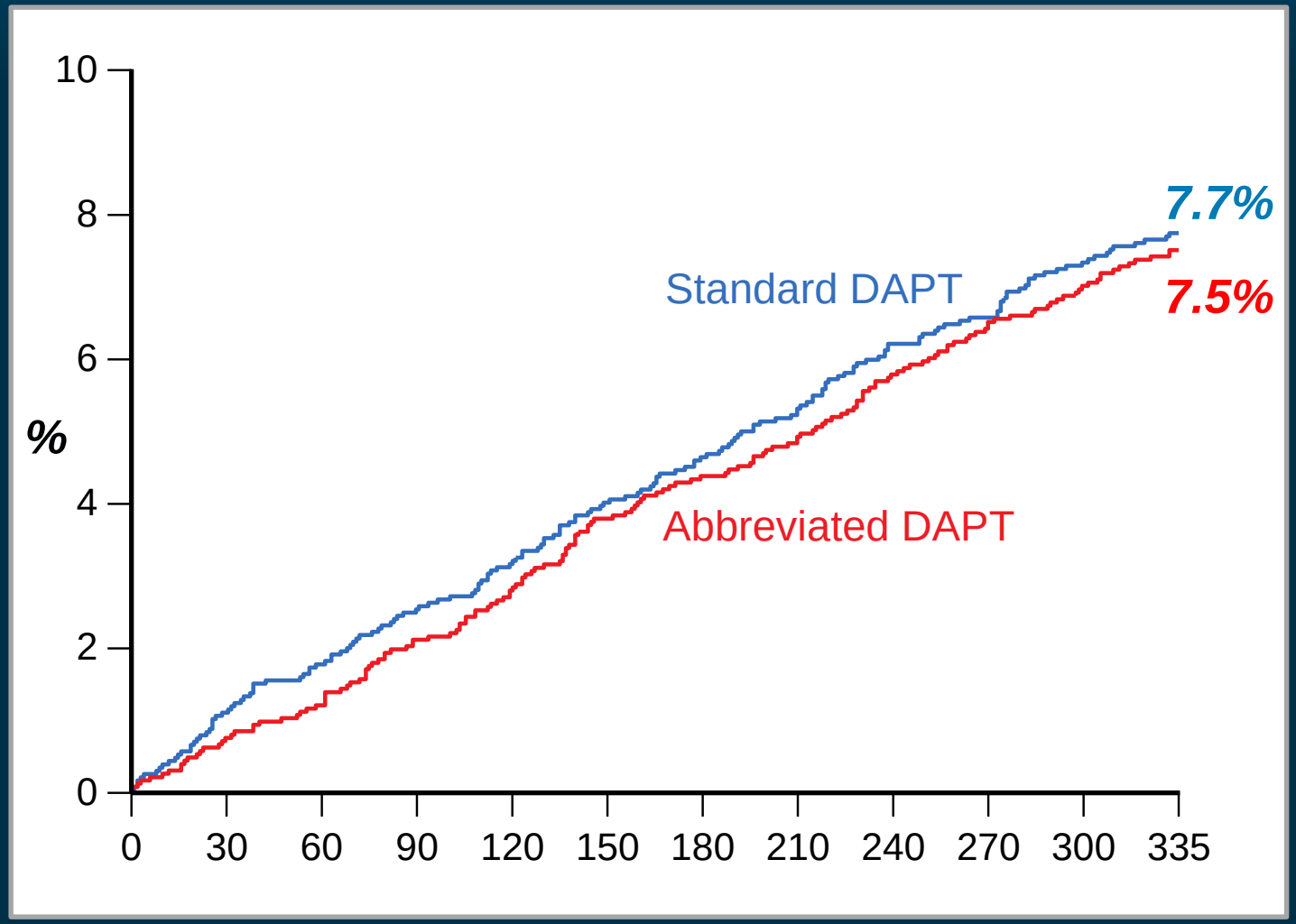


*:NARC definition and Framework, Eur Heart J. 2019 Jul 1; 40(25): 2070–2085.

Net adverse clinical events (NACE)

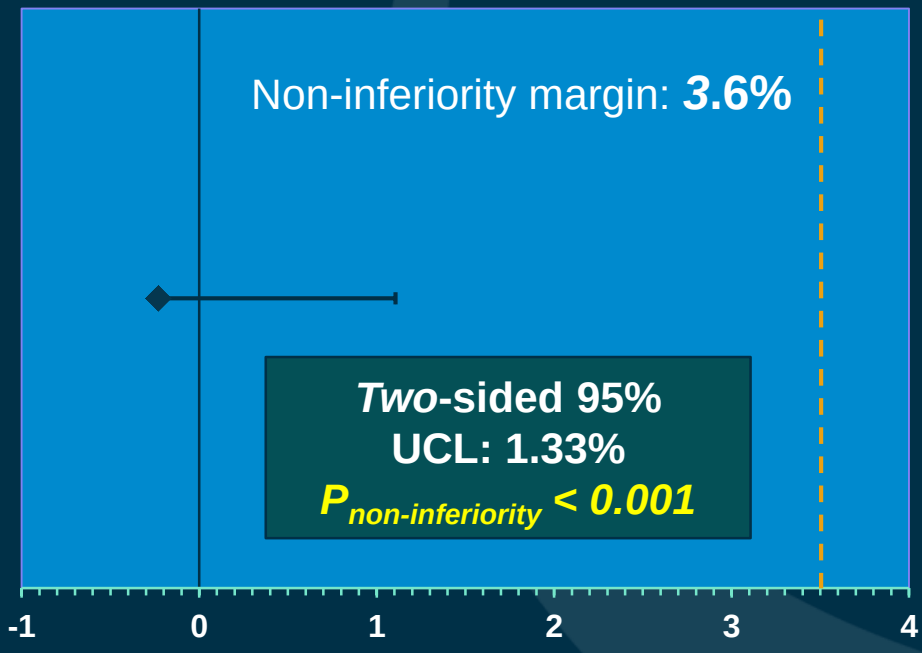
Per protocol population

N Engl J Med. 2021 Aug 28. doi: 10.1056/NEJMoa2108749



Non-inferiority Analysis

Difference in cumulative incidence, -0.23

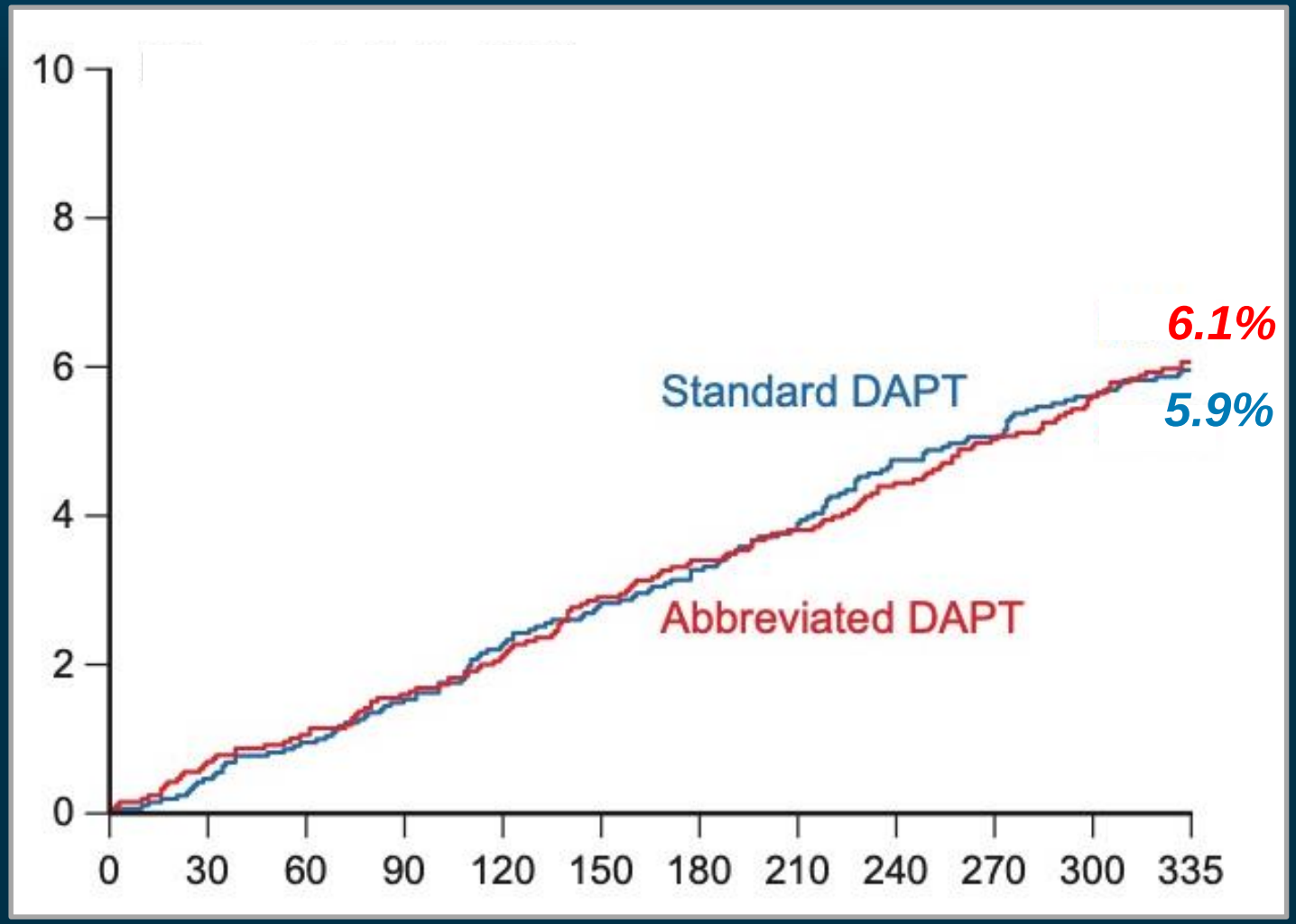


NACE: All-cause death, MI, stroke, and major bleeding events defined as BARC 3 or 5

Major adverse cardiac and cerebral events (MACCE)

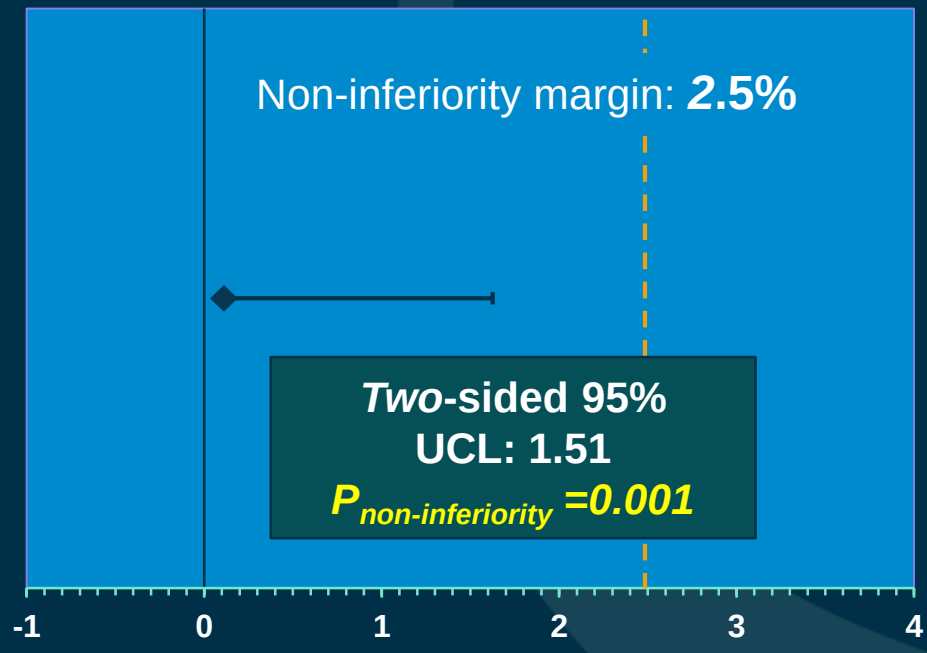
Per protocol population

N Engl J Med. 2021 Aug 28. doi: 10.1056/NEJMoa2108749



Non-inferiority Analysis

Difference in cumulative incidence, 0.11

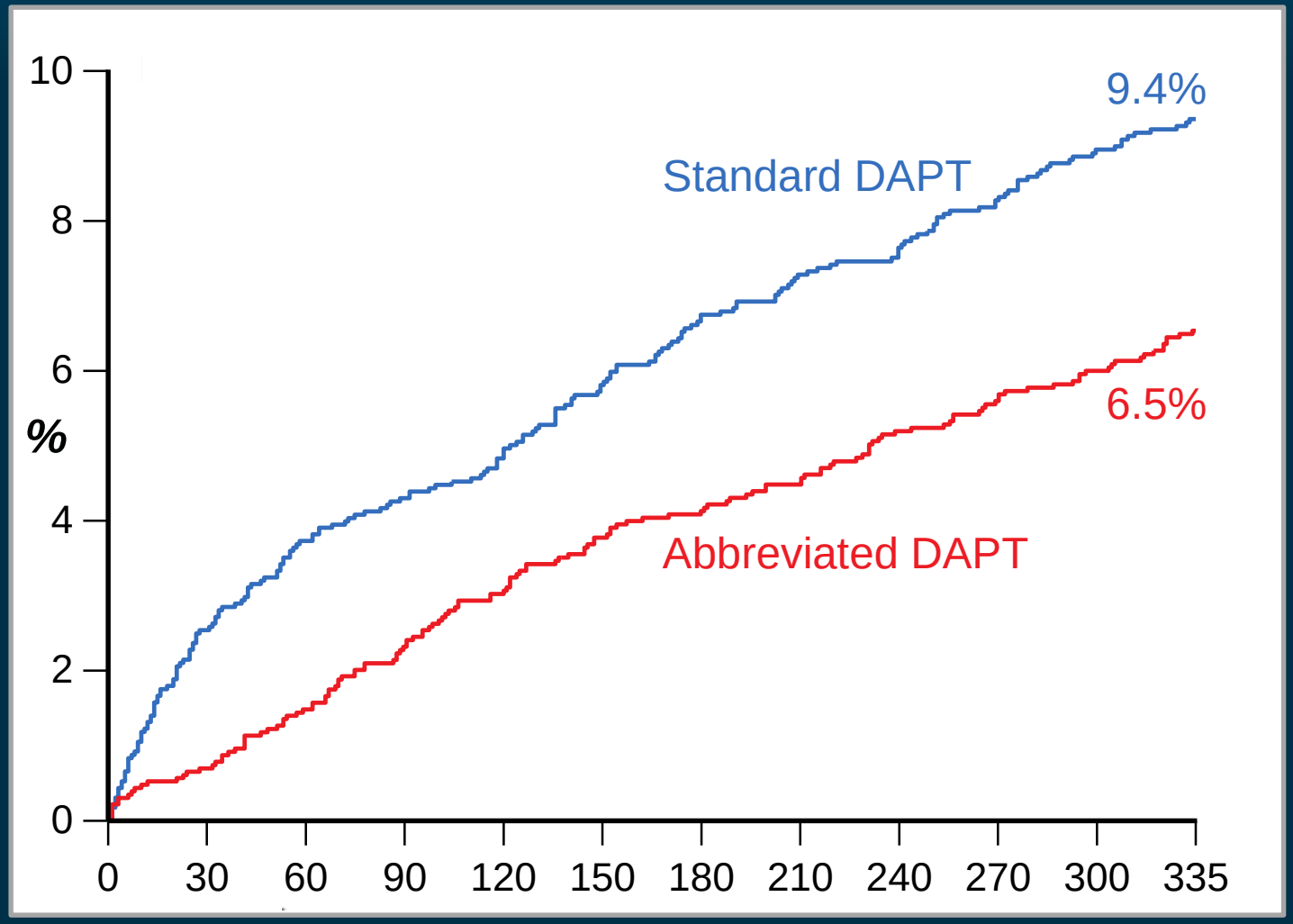


MACCE: All-cause death, MI, stroke

Major or clinically relevant nonmajor bleeding

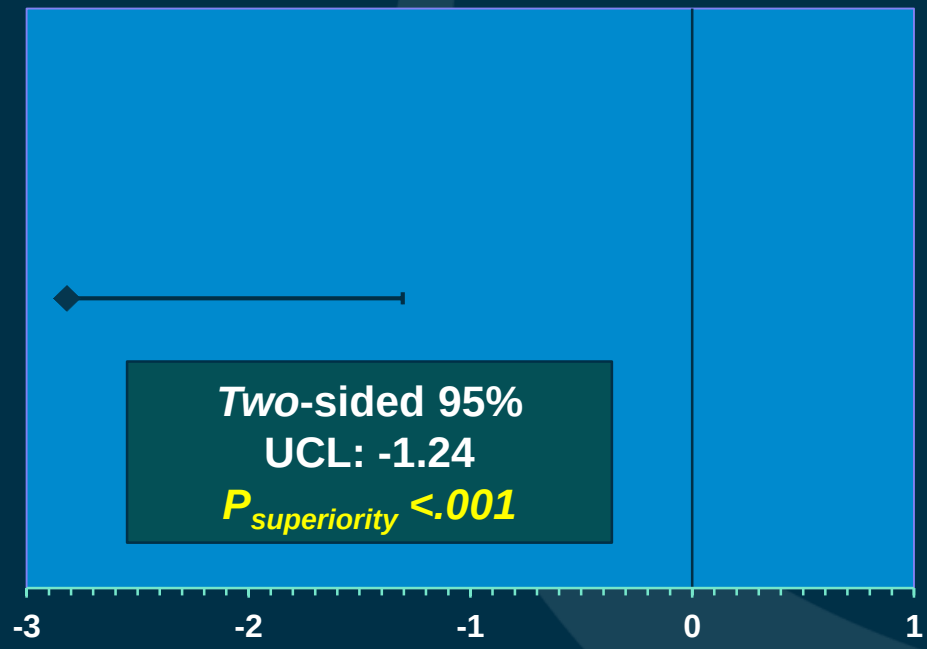
Intention to treat population

N Engl J Med. 2021 Aug 28. doi: 10.1056/NEJMoa2108749



Superiority Analysis

Difference in cumulative incidence, -2.82

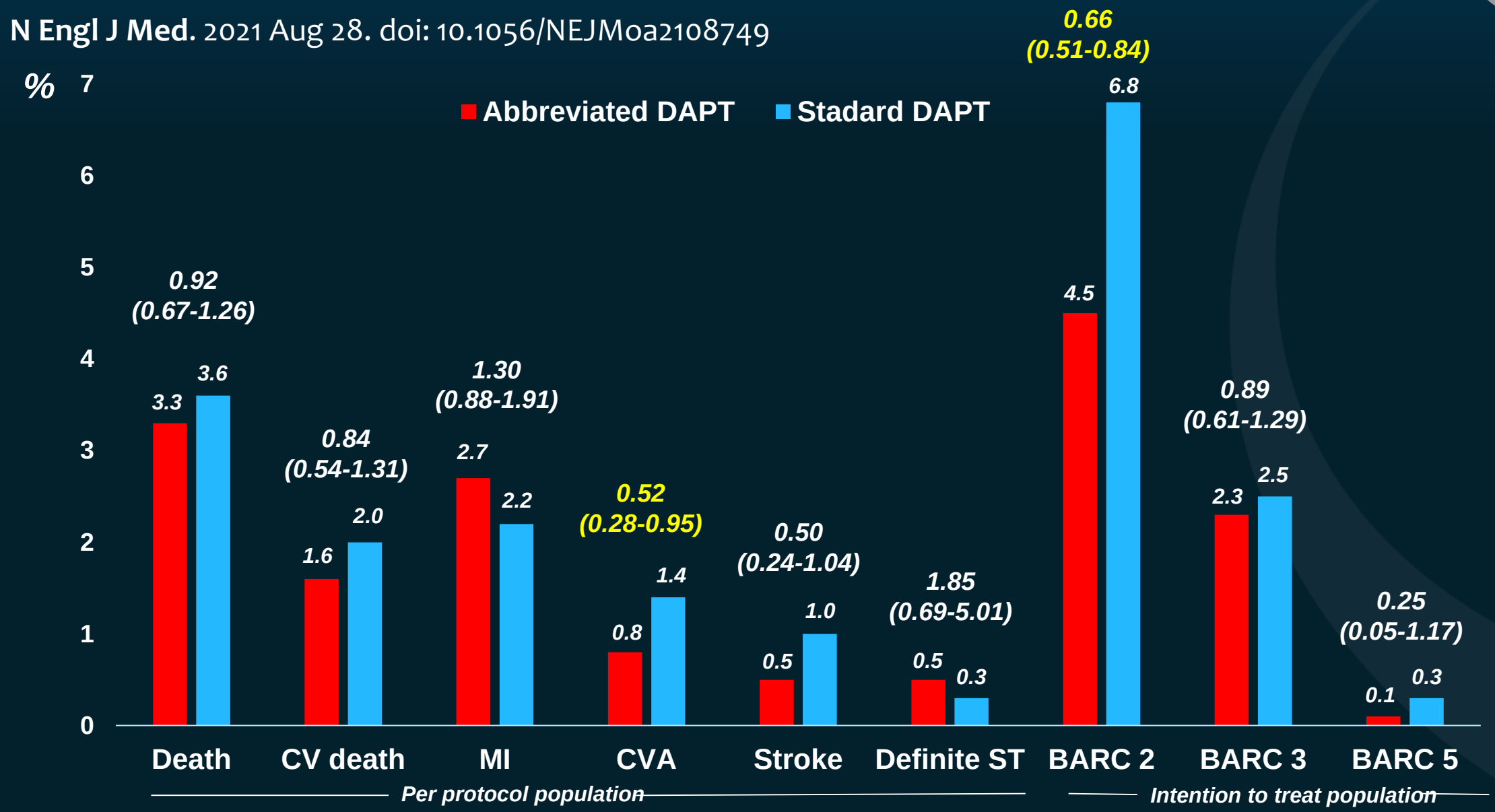


NNTB: 35

MCB: BARC 2, 3 or 5

Secondary Endpoints

N Engl J Med. 2021 Aug 28. doi: 10.1056/NEJMoa2108749



Conclusions:

BMS have no place in HBR patients as they are not safer even after 1 month DAPT and are associated to greater TVR and MI than DES

In selected HBR patients, single arm studies showed that shortening DAPT to 3 (SYNERGY and XIENCE) or 1 month(s) (XIENCE) is not associated to great Ischemic risk with potential for lower bleeding complications

The MASTER DAPT is the only all comer HBR trial showing that, after Ultimaster stent, 1 month DAPT followed by SAPT is associated with non-inferior NACE and MACE and lower bleeding events than a more prolonged, still relatively short, DAPT regimen.

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