Randomized Trial of *COBRA* PzF Stenting to *REDUCE* Duration of Triple Therapy (*COBRA-REDUCE*)

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on behalf of the COBRA-REDUCE Investigators

Clinical Trial Registration: NCT02594501

Disclosures | Robert A. Byrne

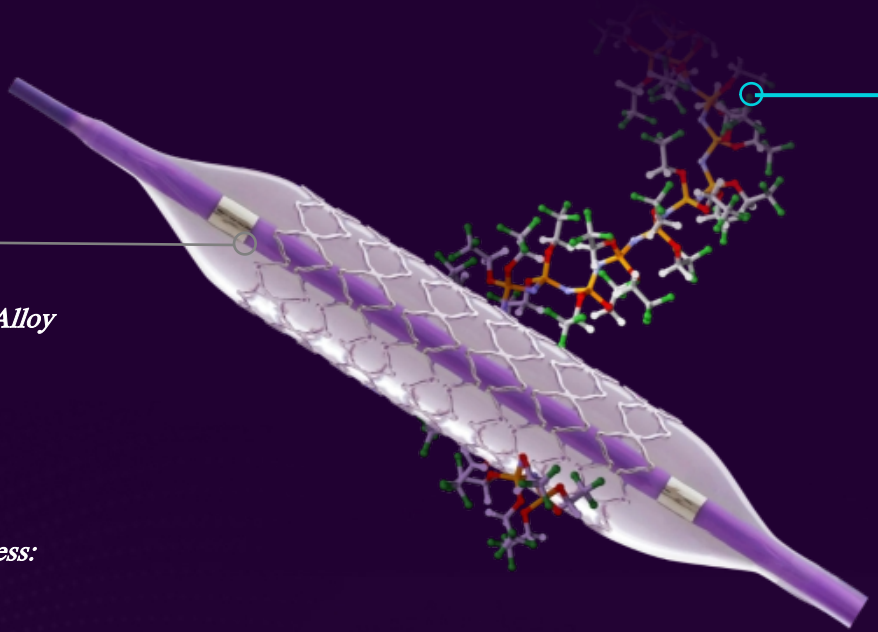
Personal fees

- None

Research funding

- Research contract with institution of prior employment: CeloNova Biosciences

COBRA PzF™ NanoCoated Coronary Stent (NCS)



Strut Material:
Cobalt Chromium Alloy

Strut Thickness:
71 µm

NanoCoating:
Polyzene -F

Polyzene-F Thickness:
≤0.05 µm

Polyzene-F

Poly [bis (trifluoroethoxy) phosphazene]

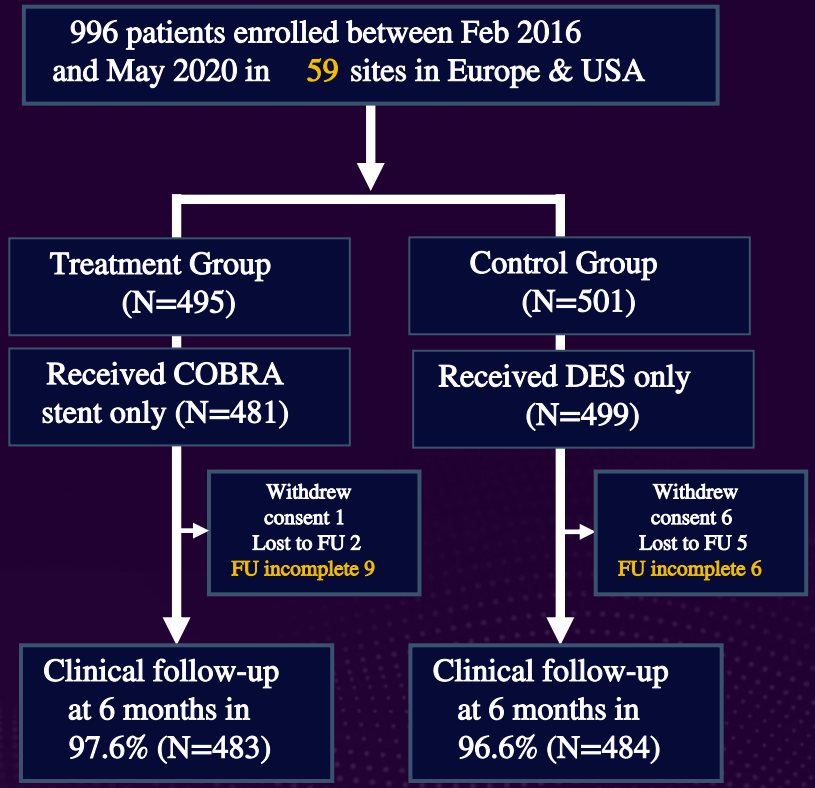
- *High molecular weight ultra pure polyphosphazene*
- *Stable fluorinated polymer, does not degrade under biological condition*
- *Thrombo-resistant, non inflammatory and pro-healing in pre-clinical studies*

COBRA-REDUCE | Trial Overview

Design

- Randomized, open-label, active-controlled, assessor-blinded, multi-center trial
- OBJECTIVE To determine whether COBRA PzF Stent with short duration DAPT (14d) results in a lower incidence of bleeding without increasing thrombotic events compared with DES * with std DAPT (3-6m) in patients taking OAC §
- PRINCIPAL INVESTIGATORS

Adnan Kastrati (PI), Deutsches Herzzentrum München , Technische Universität, Munich, Germany
Robert A. Byrne (Co-PI), Mater Private Hospital, RCSI University, Dublin, Ireland



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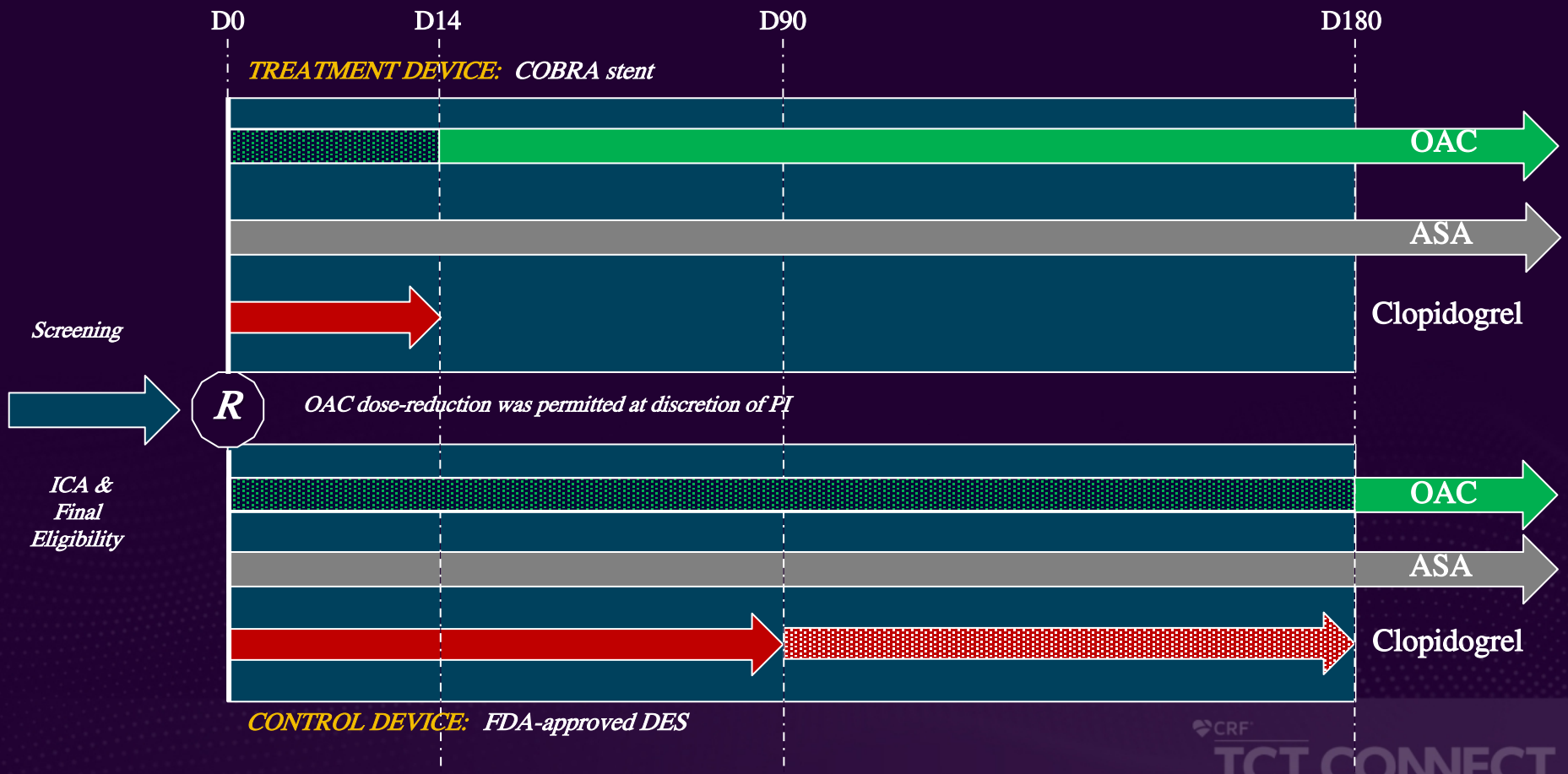
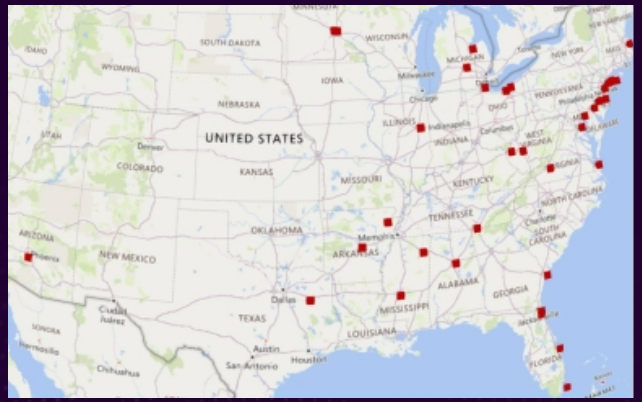
*FDA-approved second-generation DES
§OAC dose intensity reduction permitted at PI's discretion

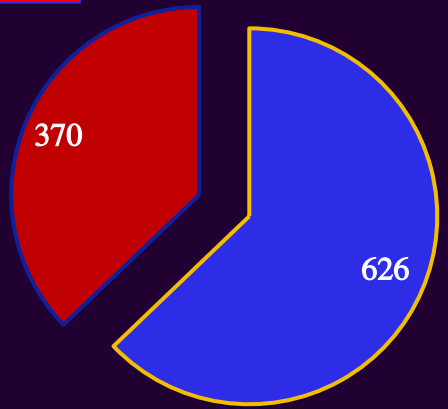
COBRA-REDUCE | Antithrombotic Treatment Regimen



COBRA-REDUCE : Trial Organization



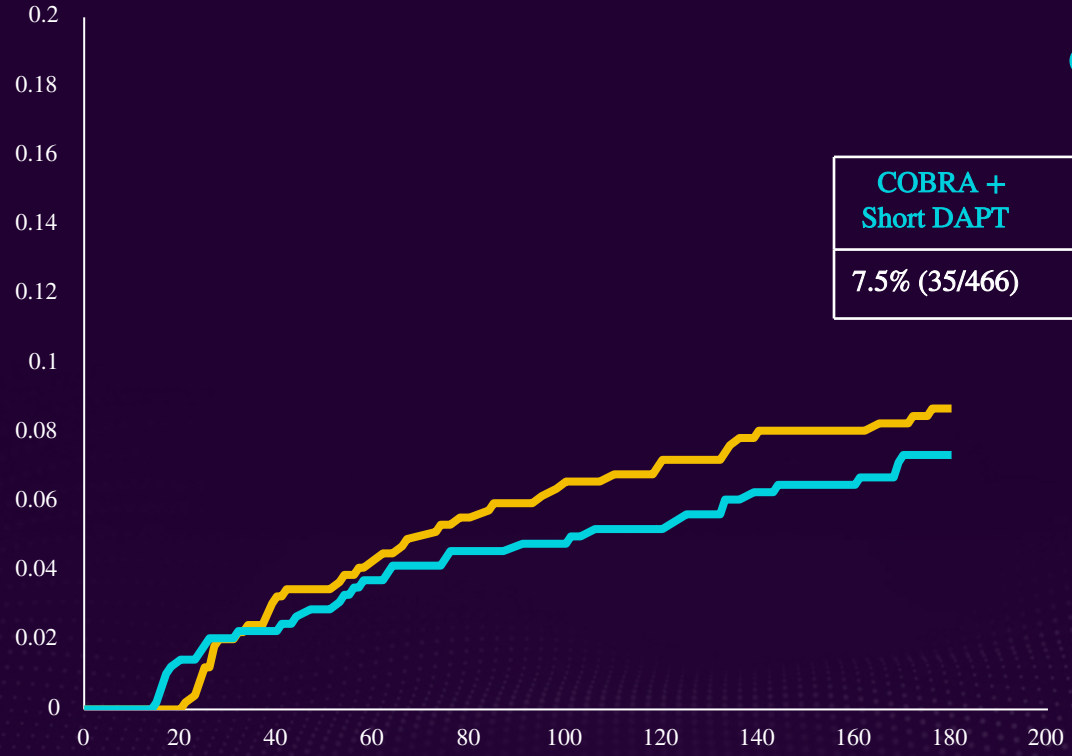
US



EU

COBRA-REDUCE | Primary Endpoint

BARC 2-5 Bleeding after 14 days*

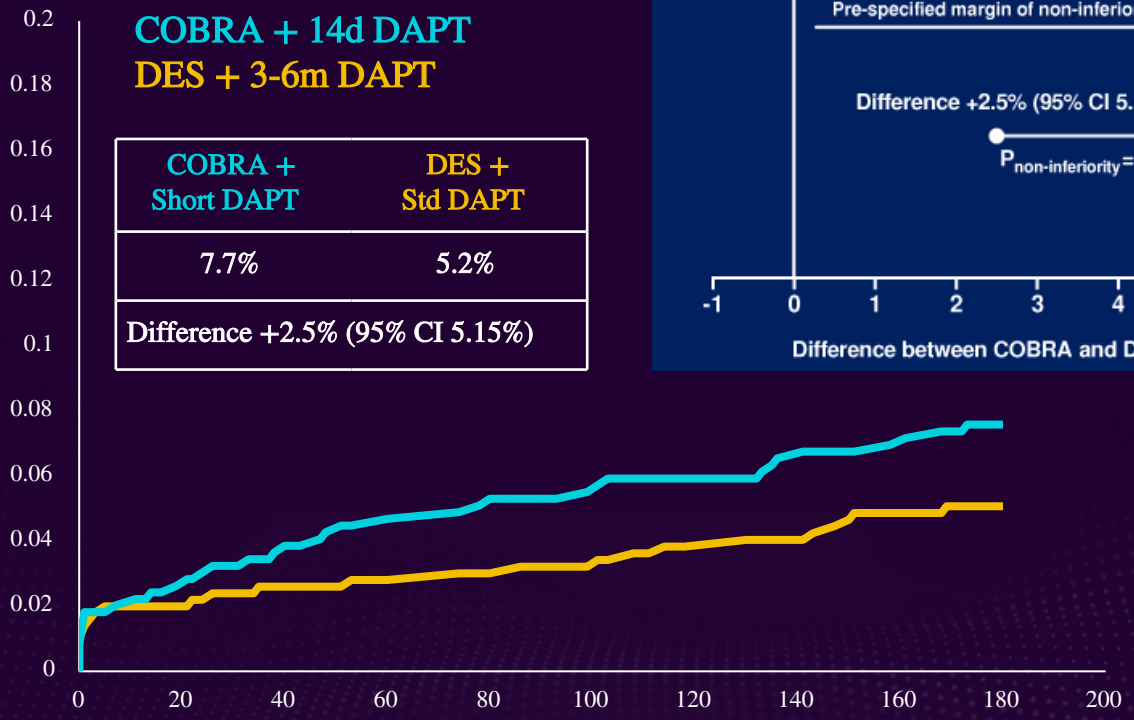


COBRA + 14d DAPT
DES + 3-6m DAPT

COBRA + Short DAPT	DES + Std DAPT	P-value
7.5% (35/466)	8.9% (42/474)	0.477

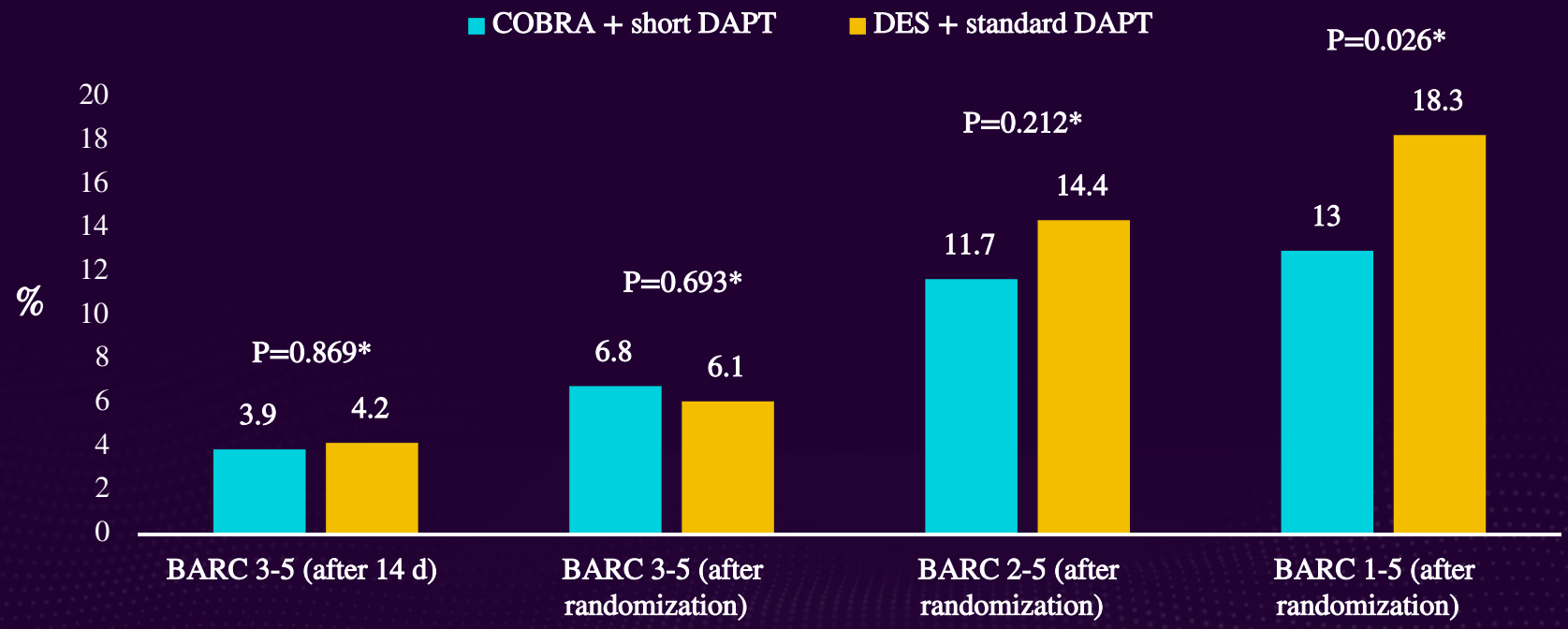
COBRA-REDUCE | Co-Primary Endpoint Thrombotic Composite

Composite of Death/MI/Stent Thrombosis/Ischemic Stroke



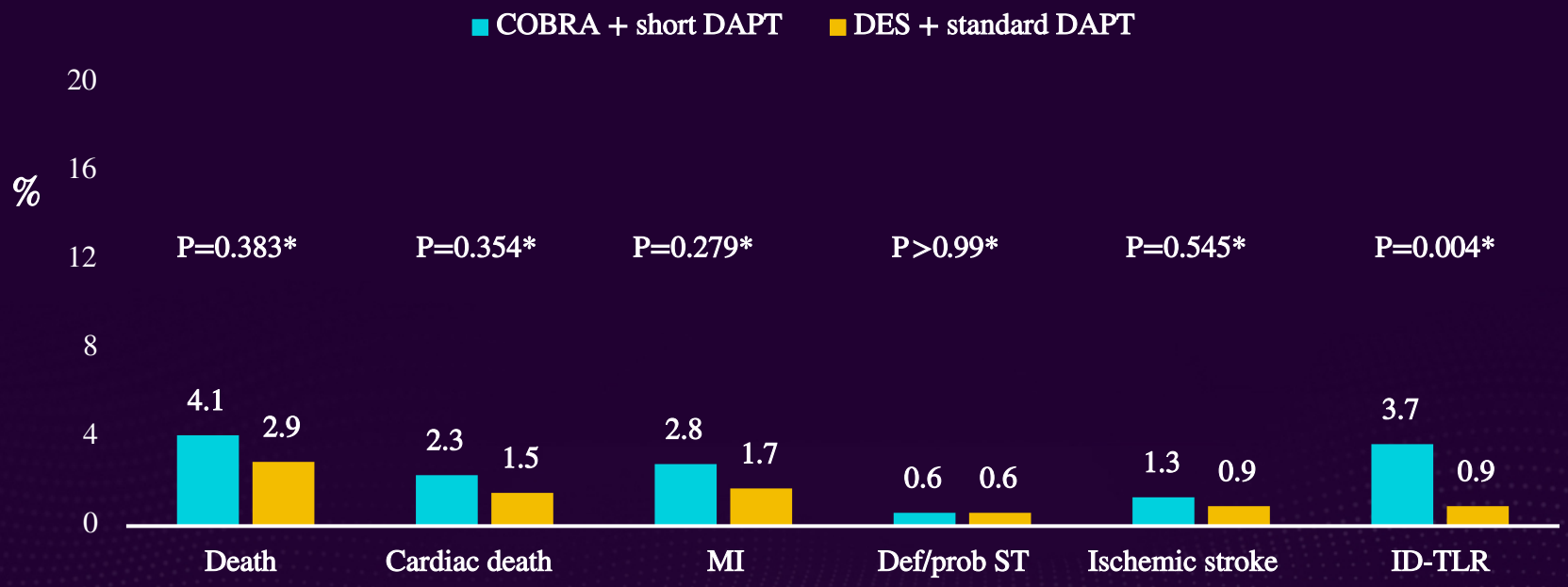
COBRA + Short DAPT	DES + Std DAPT
7.7%	5.2%
Difference +2.5% (95% CI 5.15%)	

Secondary bleeding endpoints



*superiority analysis

Secondary thrombo-embolic endpoints



*superiority analysis

COBRA-REDUCE | Conclusions

In patients undergoing PCI for acute or chronic coronary syndromes who are receiving oral anticoagulation, stenting with Cobra PzF stents with 14 days DAPT with or without reduced intensity OAC did not reduce bleeding and did not meet non-inferiority criteria with respect to thrombotic events compared with standard DES and 3-6 months of DAPT

COBRA-REDUCE | Conclusions

Treatment with Cobra PzF stent was safe with ST rates considerably lower than those seen in earlier trials with HBR patients despite DAPT duration of only 14 days

Ongoing follow-up and planned analysis of secondary outcomes at 12 months is awaited in order to assess comparative efficacy of the treatment arms in relation to the study devices

Analyses of bleeding events according to medication compliance, OAC dose and number of ARC-HBR criteria will permit examination of interaction between treatment effect, anticoagulation intensity and baseline bleeding risk