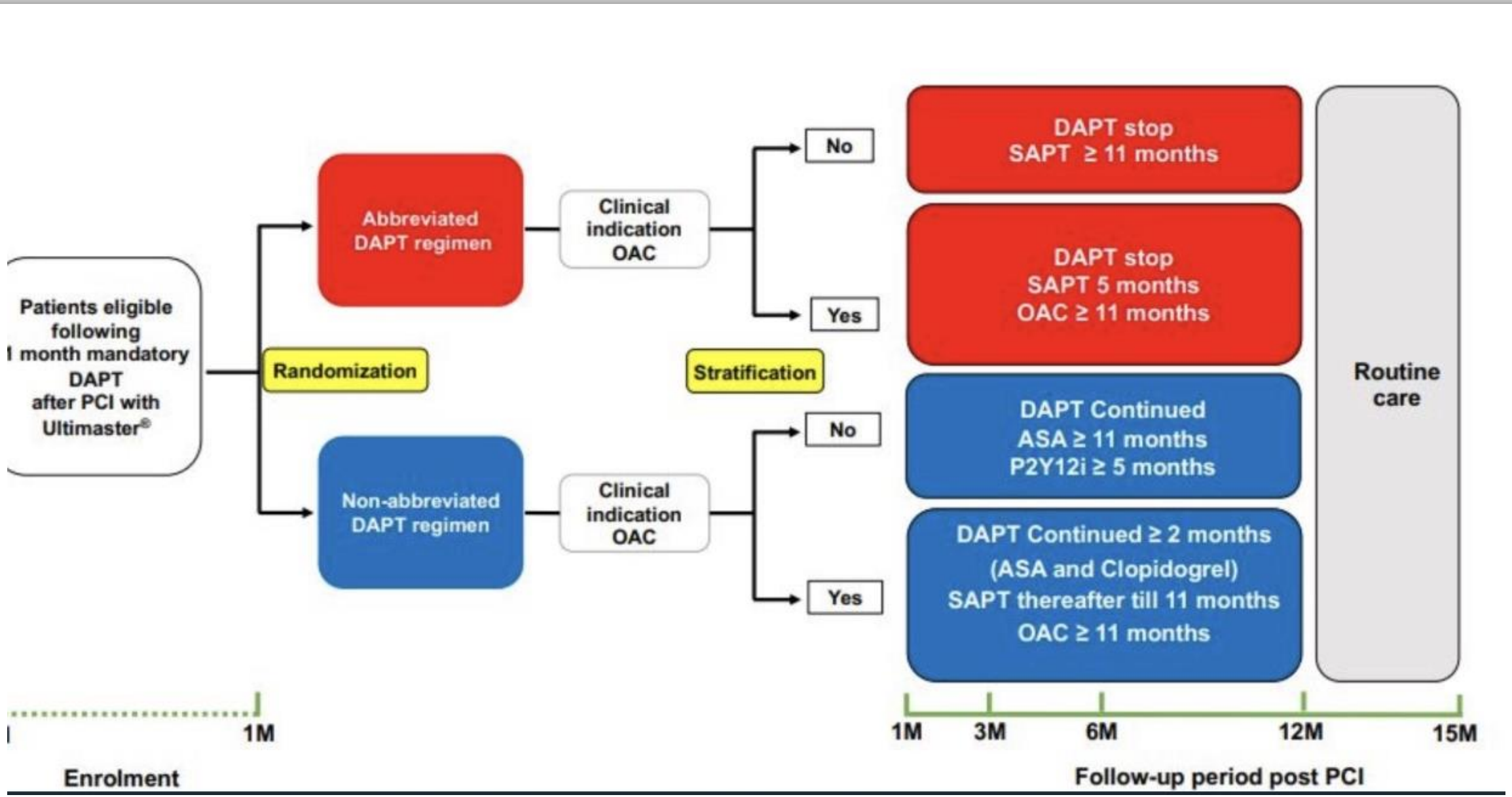

Patients eligible following
month mandatory DAPT
after PCI with Ultimaster®
Randomization
Abbreviated DAPT regimen
Non-abbreviated DAPT regimen
Clinical indication OAC
Clinical indication OAC
Stratification
No
Yes
No
Yes
DAPT stop
SAPT ≥ 11 months
DAPT stop
SAPT 5 months
OAC ≥ 11 months
DAPT Continued
ASA ≥ 11 months
P2Y12i ≥ 5 months
DAPT Continued ≥ 2 months
(ASA and Clopidogrel)
SAPT thereafter till 11 months
OAC ≥ 11 months
Routine care
1M
1M
3M
6M
12M
15M
Enrolment
Follow-up period post PCI

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

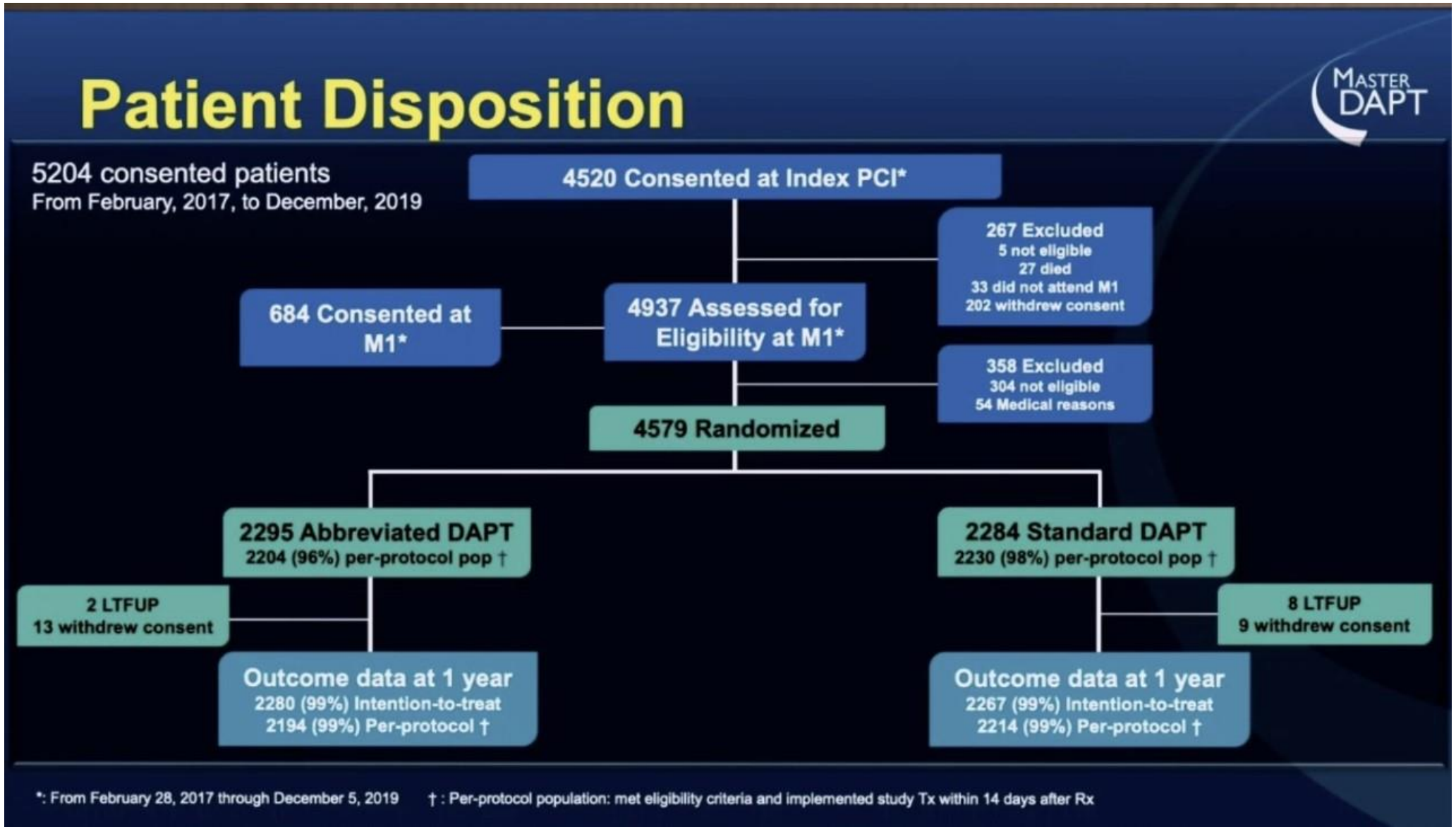
High Bleeding Risk Definition

MASTER DAPT

Patients are at high bleeding risk if at least one of the following criteria applies:

1. Clinical indication to oral anticoagulants (OAC) for at least 12 months
2. Recent (<12 months) non-access site bleeding episode(s), which required medical attention
3. Previous bleeding episode(s) which required hospitalization if the underlying cause has not been definitively treated (i.e. surgical removal of the bleeding source)
4. Age ≥75 years
5. Systemic conditions associated with an increased bleeding risk
6. Documented anemia (Hb<11 g/dL) or transfusion within 4 weeks before randomization
7. Need for chronic treatment with steroids or non-steroidal anti-inflammatory drugs
8. Diagnosed malignancy (other than skin) considered at high bleeding risk
9. Stroke at any time or transient ischemic attack (TIA) in the previous 6 months
10. PRECISE DAPT score ≥25

Patient Disposition



Study Endpoints

MASTER DAPT

The study has 3 primary endpoints to be tested in an hierarchical order:

Net adverse clinical events (NACE): the composite of all-cause death, MI, stroke, and major bleeding defined as BARC type 3 or 5

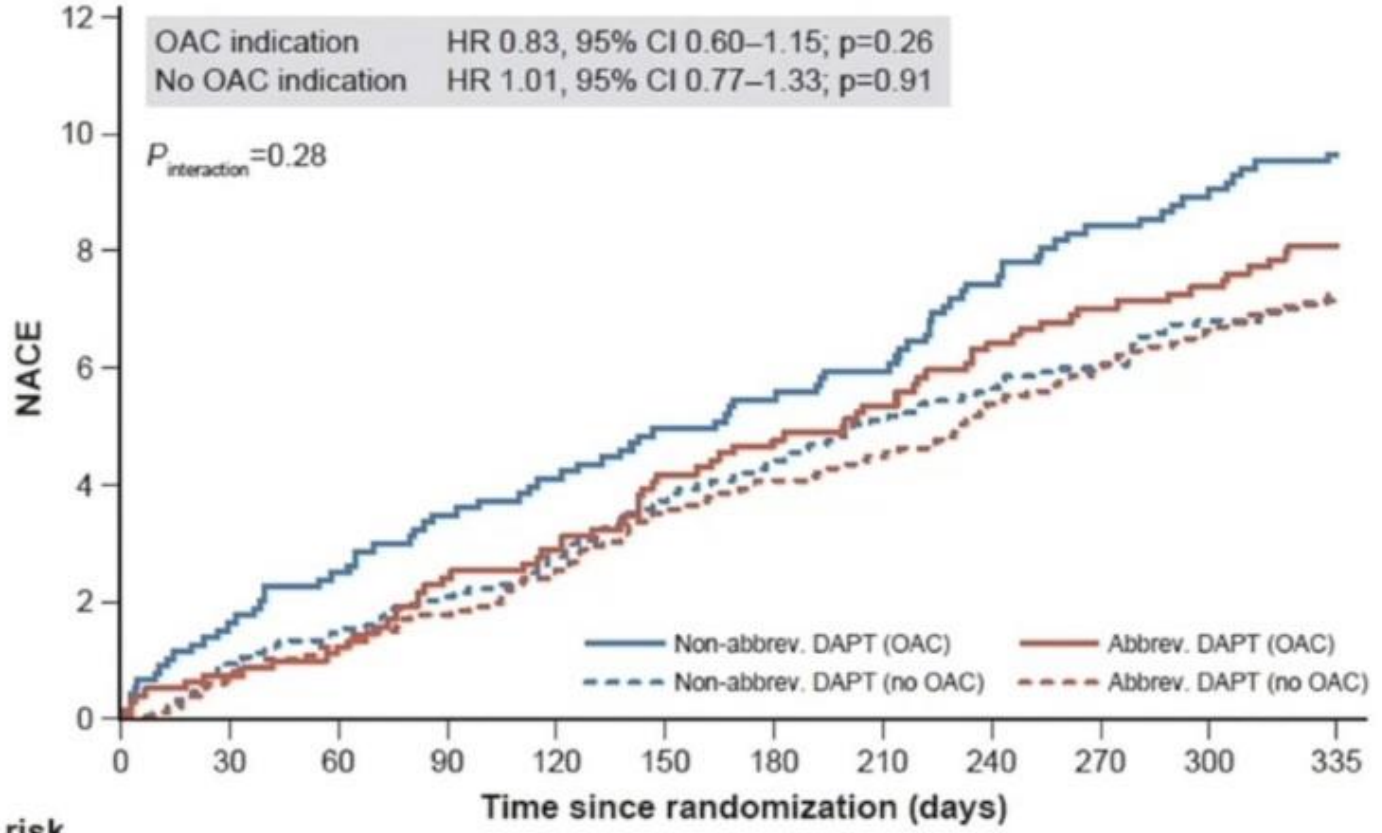
Major adverse cardiac and cerebral events (MACCE): the composite of all-cause death, MI, and stroke

Major or clinically relevant non-major bleeding (MCB): the composite of BARC type 2, 3 and 5 bleeding

The first two primary endpoints were to be tested on a non-inferiority basis in the per protocol population. If non-inferiority was met for both, the third primary endpoint was to be tested on superiority basis in the Intention to treat population. The main analyses evaluate the occurrence of the primary endpoints between randomization and 335 after index PCI

NACE

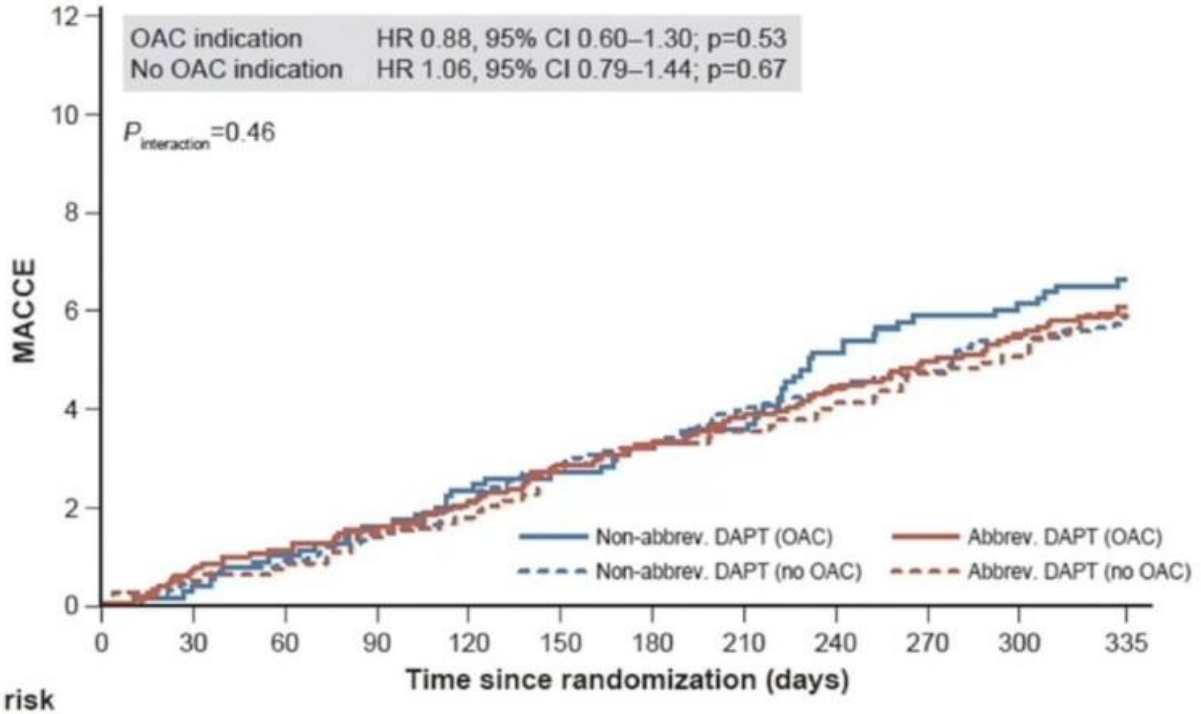
All cause death, MI, Stroke and BARC 3 or 5 Bleeding



No. at risk												
Non-abbrev. DAPT (OAC)	818	802	794	784	779	772	765	761	749	740	735	730
Abbrev. DAPT (OAC)	848	841	837	826	822	811	805	800	790	785	782	775
Non-abbrev. DAPT (no OAC)	1466	1453	1444	1435	1425	1411	1399	1387	1377	1371	1360	1354
Abbrev. DAPT (no OAC)	1447	1432	1425	1415	1404	1388	1381	1375	1362	1353	1344	1333

MACCE

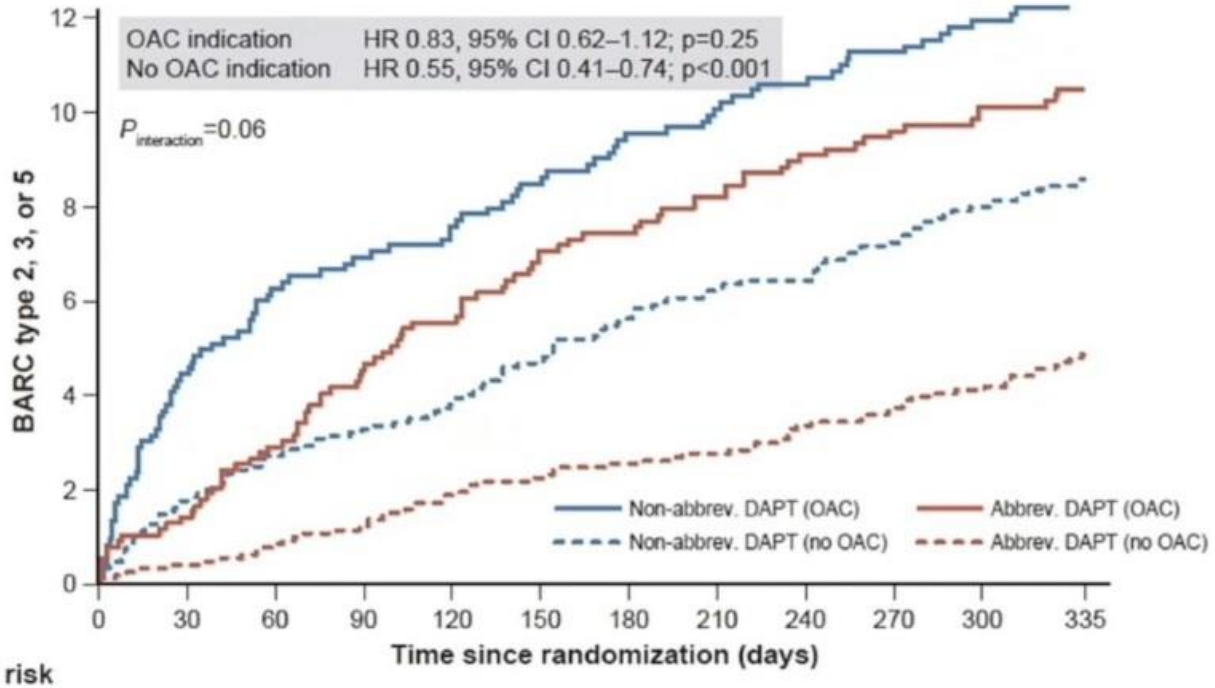
All cause death, MI, Stroke



No. at risk												
Non-abbrev. DAPT (OAC)	818	812	806	799	793	790	783	780	767	760	758	754
Abbrev. DAPT (OAC)	848	843	840	834	831	823	817	815	809	804	801	792
Non-abbrev. DAPT (no OAC)	1466	1459	1453	1445	1434	1424	1415	1403	1394	1389	1379	1374
Abbrev. DAPT (no OAC)	1447	1432	1426	1418	1410	1398	1392	1384	1375	1367	1359	1349

Clinically relevant nonMajor or Major Bleeding

BARC 2, 3 or 5



No. at risk												
Non-abbrev. DAPT (OAC)	818	780	764	755	748	740	729	724	715	704	698	693
Abbrev. DAPT (OAC)	848	834	821	804	796	780	774	768	759	754	748	740
Non-abbrev. DAPT (no OAC)	1466	1440	1422	1411	1399	1382	1365	1353	1345	1331	1317	1306
Abbrev. DAPT (no OAC)	1447	1435	1428	1419	1406	1393	1387	1382	1371	1363	1354	1338