ACC.25

Dual Antiplatelet Therapy After PCI According To Bleeding Risk

"HOST-BR RCT"

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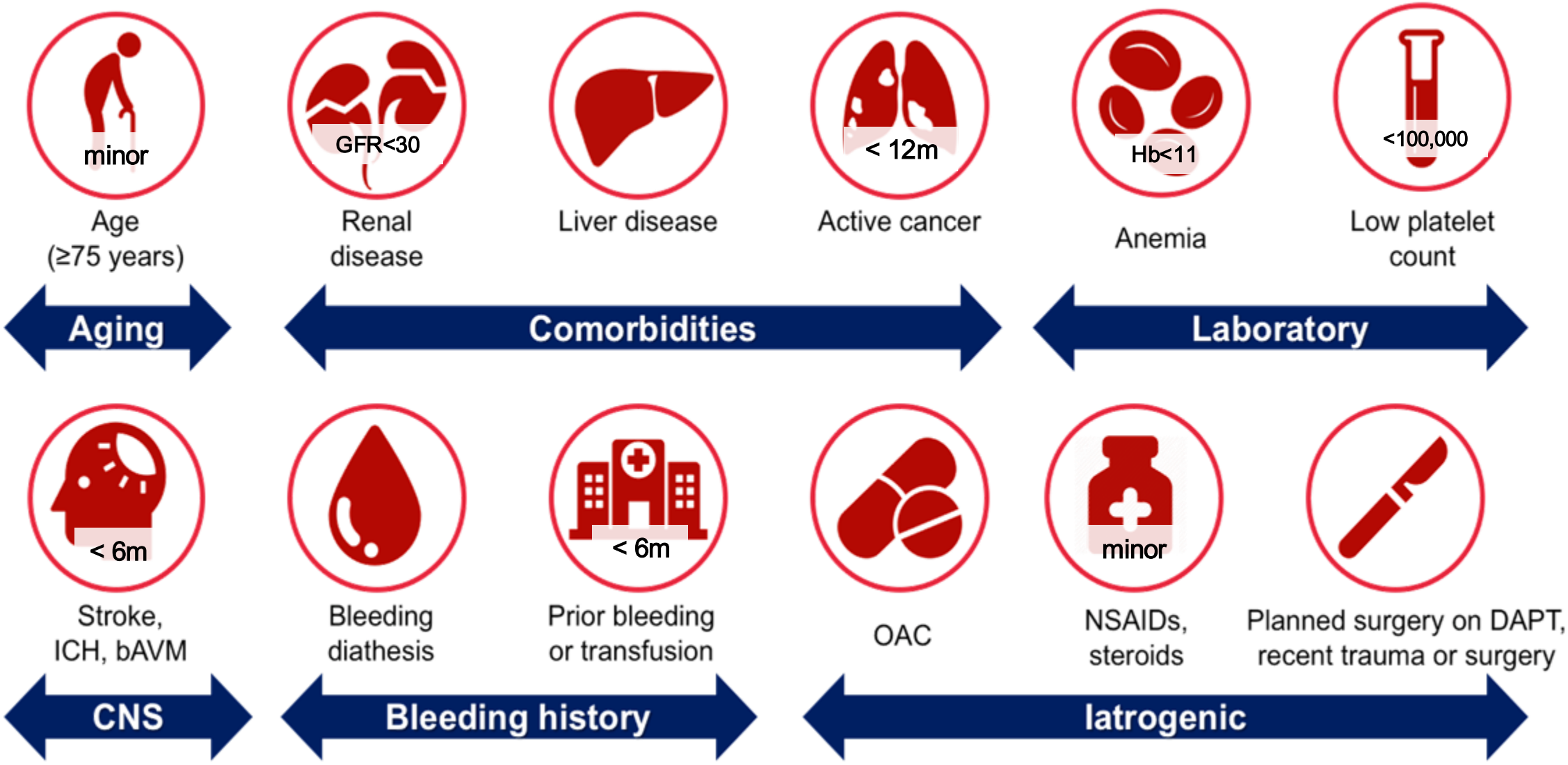
Disclosures

- The **HOST-BR** trial,
  - is an investigator-initiated, randomized, open-label, multicenter trial sponsored by Seoul National University Hospital
- The **HOST-BR** trial has received research funds from
  - A consortium of two Pharmaceutical Companies
    - Medtronic and Abbott
  - The Ministry of Health & Welfare, Republic of Korea

Background

ARC-HBR (High Bleeding Risk), annual major bleeding 4% or more



Background

- No previous study has evaluated specific durations of DAPT stratified according to bleeding risk (BR). The current guidelines recommend stratifying stented patients according to BR where low BR (LBR) patients can consider longer DAPT while high BR (HBR) patients should consider shorter DAPT.
- General recommendation is 1-3months DAPT for HBR & 3-12months DAPT for LBR.
- The consensus is that shorter DAPT maybe slightly better than longer one d/t less bleeding.

- However, we do not have evidence based on BR

  which duration would be optimal and where the thrombosis/bleeding risk will cross.

HOST-BR RCT

Harmonizing Optimal Strategy for Treatment (HOST) of coronary artery diseases – Bleeding Risk (BR)

- The first randomized study

  to stratify patients receiving PCI with DES according to BR based on the ARC HBR criteria and

  to test different durations of DAPT either in HBR or LBR population.

- Stratified & Randomized study :

  in the HBR stratum, randomized to 1-month vs. 3-month DAPT

  in the LBR stratum, randomized to 3-month vs. 12-month DAPT.

Hypothesis of HOST-BR RCT

HOST BR Bleeding Risk

- **Three co-primary end points assessed in hierarchical order**

  The 1st: net adverse clinical events (NACE)
  (all death, MI, stent thrombosis, stroke, major bleeding).

  The 2nd: major adverse cardiac or cerebral events (MACCE)
  (CVD, MI, stent thrombosis, ischemic stroke).

  The 3rd: BARC bleeding (2,3,5) at 12 months.

- **Hypothesis**

  within each stratum,
  the shorter DAPT be non-inferior to the longer DAPT for the first and second co-primary endpoints
  and be superior for the third co-primary endpoint.

Sample Size Calculation

- **HBR stratum (N=1600)**
  - **NACE**
    - Assumed at one year: Shorter DAPT group (7%) vs. Longer DAPT group (9%)
    - 2-sided alpha: 5%, Power: 90%
    - Type I error: 0.05, Estimated withdrawal rate: 2.0%
    - Non-inferiority margin: 2.7% (30% of expected events in control gr.)
  - **MACCE**
    - Assumed at one year: Shorter DAPT group (5.6%) vs. Longer DAPT group (7.2%)
    - 2-sided alpha: 5%, Power: 80%
    - Type I error: 0.05, Estimated withdrawal rate: 2.0%
  - **Any Actionable Bleeding**
    - Assumed at one year: Shorter DAPT group (8%) vs. Longer DAPT group (12%)
    - 2-sided alpha: 5%, Power: 80%

Sample Size Calculation

- **LBR stratum (N=3300)**
  - **NACE**
    - Assumed at one year: Shorter DAPT group (4%) vs. Longer DAPT group (5%)
    - 2-sided alpha: 5%, Power: 90%
    - Type I error: 0.05, Estimated withdrawal rate: 5.0%
    - Non-inferiority margin: 1.5% (30% of expected events in control gr.)
  - **MACCE**
    - Assumed at one year: Shorter DAPT group (3.2%) vs. Longer DAPT group (4.0%)
    - 2-sided alpha: 5%, Power: 90%
    - Type I error: 0.05, Estimated withdrawal rate: 5.0%
  - **Any Actionable Bleeding**
    - Assumed at one year: Shorter DAPT group (8%) vs. Longer DAPT group (12%)
    - 2-sided alpha: 5%, Power: 80%

Study Organization

Principle Investigator

Hyo-Soo Kim

Executive Committee

Hyo-Soo Kim
Young-Hyo Lim
Sang Rok Lee
Young Jin Choi
Kyung Woo Park
Jeehoon Kang

Clinical event adjudication committee

Kook-Jin Chun
Hyun Kuk Kim
Jun Hwan Cho

Publication Committee

Hyo-Soo Kim
Jeehoon Kang
Kyung Woo Park
Jung-Kyu Han
Doyeon Hwang
Han-Mo Yang
Sungjoon Park

Primary Statisticians

Jeehoon Kang
Sungjoon Park

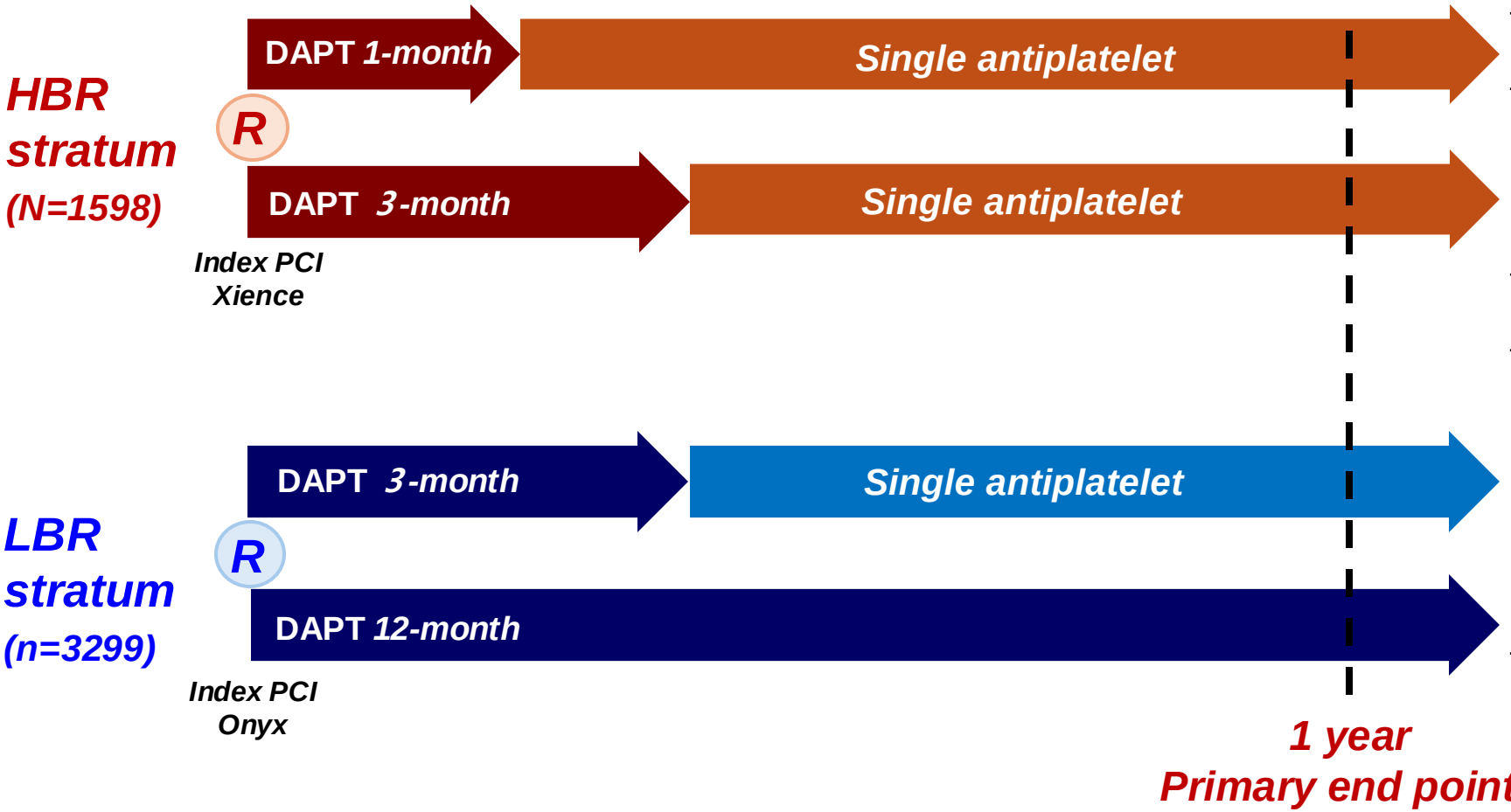
Data coordination and management

Medical Research Collaborating Center
of Seoul National University Hospital

Sponsor: Seoul National University Hospital, Korea

Study Design: stratified & randomized

- *4,897 eligible patients receiving PCI from 53 centers in Korea*



Inclusion Criteria

a) Subject must be ≥ 19 years

b) Undergone PCI with stents (Xience/Onyx)

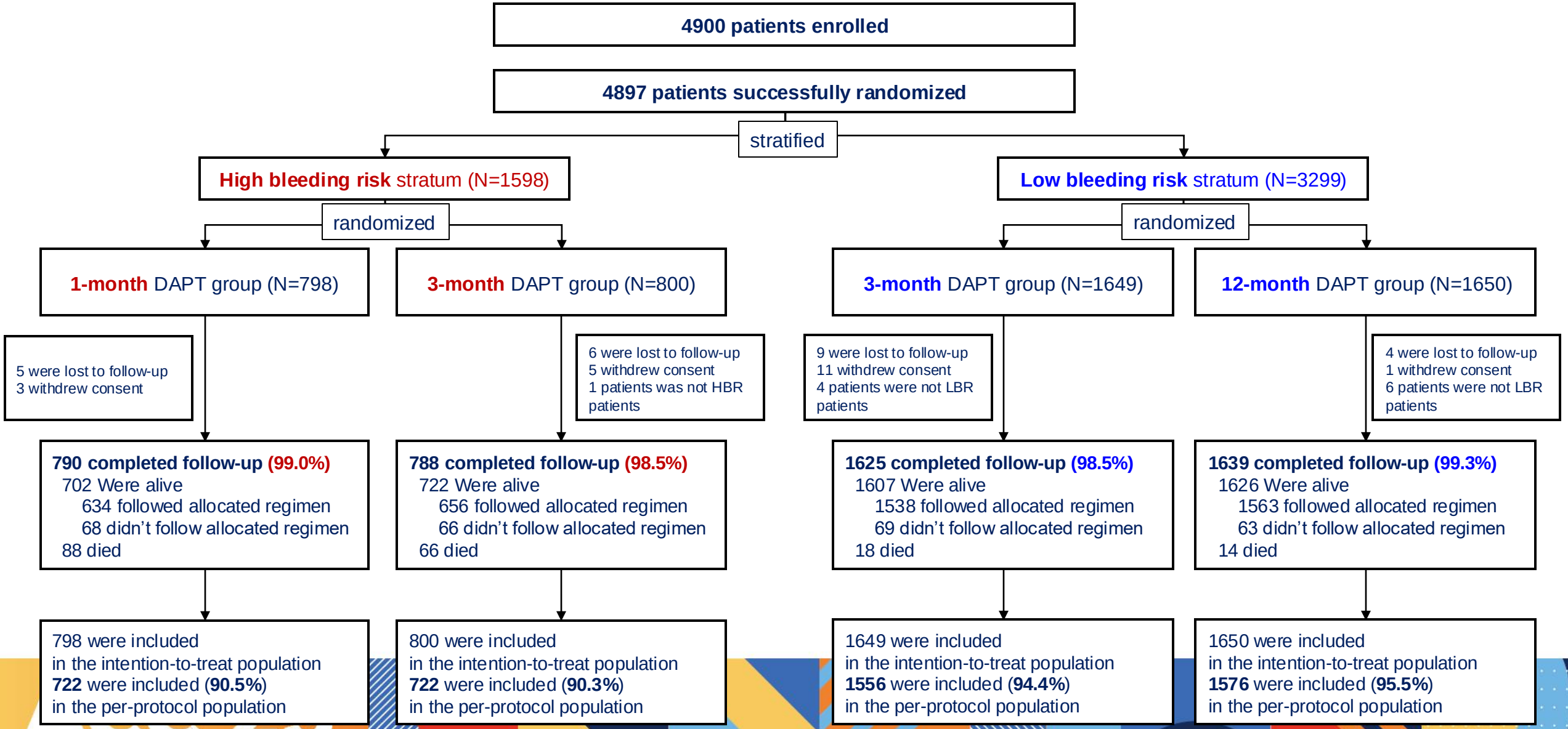
c) Agreement of written informed consent

Exclusion Criteria

a) Pregnant women

b) Patients with a history of allergic reactions or contraindications to the following medications: aspirin, clopidogrel, prasugrel, ticagrelor, heparin, cobalt chromium, sirolimus

Patient Population



Baseline Characteristics_ HBR

HOST BR Bleeding Risk

		Total (N=1598)	1M DAPT (N=798)	3M DAPT (N = 800)
Demographics	Age, years	73.8 ± 10.1	73.4 ± 10.3	74.1 ± 9.9
	Female, n (%)	535 (33.5)	265 (33.2)	270 (33.8)
Clinical diagnosis	Stable CAD, n (%)	649 (40.6)	328 (41.1)	321 (40.2)
	Unstable angina, n (%)	444 (27.8)	218 (27.3)	226 (28.2)
	NSTEMI, n (%)	396 (24.8)	200 (25.1)	196 (24.5)
	STEMI, n (%)	86 (5.4)	44 (5.5)	42 (5.3)
	Others, n (%)	23 (1.4)	8 (1.0)	15 (1.9)
Clinical risk factor	Hypertension, n (%)	1250 (78.3)	646 (81.0)	604 (75.6)
	DM, n (%)	849 (53.2)	440 (55.1)	409 (51.2)
	Insulin dependent DM, n (%)	149 (9.3)	86 (10.8)	63 (7.9)
	Dyslipidemia, n (%)	1138 (71.3)	583 (73.1)	555 (69.5)
	Congestive heart failure, n (%)	97 (6.1)	52 (6.5)	45 (5.6)
	Peripheral artery disease, n (%)	34 (2.1)	18 (2.3)	16 (2.0)
	Chronic kidney disease, n (%)	502 (31.4)	265 (33.2)	237 (29.7)
	Previous MI, n (%)	126 (7.9)	66 (8.3)	60 (7.5)
	Previous PCI, n (%)	327 (20.5)	160 (20.1)	167 (20.9)
	Previous CABG, n (%)	26 (1.6)	14 (1.8)	12 (1.5)
	Previous CVA, n (%)	248 (15.5)	134 (16.8)	114 (14.3)

Baseline Characteristics_ HBR

HOST BR Bleeding Risk

		Total (N=1598)	1M DAPT (N=798)	3M DAPT (N = 800)
Laboratory data	WBC (x 10^3/uL)	7.40 ± 2.96	7.34 ± 2.94	7.47 ± 2.98
	Hemoglobin (g/dL)	11.6 ± 2.0	11.4 ± 2.0	11.7 ± 2.0
	Platelet	212.5 ± 77.6	211.9 ± 77.1	213.1 ± 78.1
	Creatinine (mg/dL)	1.98 ± 2.44	2.08 ± 2.56	1.87 ± 2.31
	eGFR	60.6 ± 33.2	59.4 ± 33.6	61.9 ± 32.8
	Total Cholesterol (mg/dL)	140.2 ± 49.1	140.0 ± 57.9	140.4 ± 38.7
	Triglyceride (mg/dL)	112.2 ± 60.9	113.0 ± 63.6	111.4 ± 58.2
	HDL-cholesterol (mg/dL)	42.0 ± 13.5	41.7 ± 12.9	42.4 ± 14.2
	LDL- cholesterol (mg/dL)	76.4 ± 45.0	76.4 ± 54.9	76.3 ± 32.4
Discharge Medication	Aspirin, n (%)	1560 (97.7)	780 (97.6)	780 (97.7)
	P2Y12 inhibitor, n (%)	1577 (98.7)	789 (98.9)	788 (98.5)
	DAPT, n (%)	1553 (97.2)	777 (97.4)	776 (97.0)
	A+C	1434 (89.7)	718 (89.9)	716 (89.5)
	A+P	20 (1.3)	11 (1.4)	9 (1.1)
	A+T	99 (6.2)	48 (6.0)	51 (6.4)
	OAC, n(%)	275 (17.2)	123 (15.4)	152 (19.0)
	RAASi, n (%)	961 (60.1)	474 (59.4)	487 (60.9)
	Beta blocker, n (%)	836 (52.3)	430 (53.9)	406 (50.8)
	Statin, n (%)	1455 (91.1)	733 (91.9)	722 (91.9)
	Calcium channel blocker, n (%)	518 (32.4)	259 (32.5)	259 (32.4)

Baseline Characteristics_ LBR

HOST BR Bleeding Risk

		Total (N=3299)	3M DAPT (N=1649)	12M DAPT (N = 1650)
Demographics	Age, years	63.2 ± 9.9	63.5 ± 9.8	63.0 ± 10.0
	Female, n (%)	689 (20.9)	347 (21.0)	342 (20.7)
Clinical diagnosis	Stable CAD, n (%)	1227 (37.2)	625 (37.9)	602 (36.5)
	Unstable angina, n (%)	1016 (30.8)	508 (30.8)	508 (30.8)
	NSTEMI, n (%)	637 (19.3)	310 (18.8)	327 (19.8)
	STEMI, n (%)	363 (11.0)	177 (10.7)	186 (11.3)
	Others, n (%)	56 (1.7)	29 (1.8)	27 (1.6)
Clinical risk factor	Hypertension, n (%)	2035 (61.7)	1010 (61.4)	1025 (62.1)
	DM, n (%)	1066 (32.3)	531 (32.3)	535 (32.4)
	Insulin dependent DM, n (%)	86 (2.6)	43 (2.6)	43 (2.6)
	Dyslipidemia, n (%)	2342 (71.1)	1187 (72.2)	1153 (69.9)
	Congestive heart failure, n (%)	27 (0.8)	16 (1.0)	11 (0.7)
	Peripheral artery disease, n (%)	22 (0.7)	9 (0.5)	13 (0.8)
	Chronic kidney disease, n (%)	58 (1.8)	27 (1.6)	31 (1.9)
	Previous MI, n (%)	165 (5.0)	87 (5.3)	78 (4.7)
	Previous PCI, n (%)	425 (12.9)	221 (13.4)	204 (12.4)
	Previous CABG, n (%)	23 (0.7)	10 (0.6)	13 (0.8)
	Previous CVA, n (%)	87 (2.6)	41 (2.5)	46 (2.8)

Baseline Characteristics_ LBR

HOST BR Bleeding Risk

		Total (N=3299)	3M DAPT (N=1649)	12M DAPT (N = 1650)
Laboratory data	WBC (x 10^3/uL)	7.45 ± 2.64	7.42 ± 2.60	7.49 ± 2.67
	Hemoglobin (g/dL)	14.2 ± 2.5	14.2 ± 3.2	14.1 ± 1.4
	Platelet	229.2 ± 57.1	228.8 ± 56.2	229.7 ± 58.1
	Creatinine (mg/dL)	0.89 ± 0.46	0.88 ± 0.44	0.89 ± 0.48
	eGFR	87.8 ± 20.8	87.6 ± 20.5	87.9 ± 21.1
	Total Cholesterol (mg/dL)	160.9 ± 47.0	160.0 ± 46.1	161.9 ± 47.9
	Triglyceride (mg/dL)	144.5 ± 113.1	143.8 ± 106.7	145.2 ± 119.8
	HDL-cholesterol (mg/dL)	44.9 ± 13.2	45.1 ± 14.9	44.8 ± 11.4
	LDL- cholesterol (mg/dL)	88.1 ± 39.9	87.2 ± 39.8	89.1 ± 39.9
Discharge Medication	Aspirin, n (%)	3285 (99.7)	1641 (99.7)	1644 (99.6)
	P2Y12 inhibitor, n (%)	3290 (99.7)	1642 (99.6)	1648 (99.9)
	DAPT, n (%)	3284 (99.5)	1640 (99.5)	1644 (99.6)
	A+C	2504 (75.9)	1236 (75.0)	1268 (76.8)
	A+P	353 (10.7)	178 (10.8)	175 (10.6)
	A+T	427 (12.9)	226 (13.7)	201 (12.2)
	OAC, n(%)	0	0	0
	RAASi, n (%)	1823 (55.3)	905 (54.9)	919 (55.7)
	Beta blocker, n (%)	1529 (46.4)	753 (45.7)	776 (47.0)
	Statin, n (%)	3139 (95.2)	1567 (95.2)	1572 (95.3)
	Calcium channel blocker, n (%)	923 (28.0)	493 (30.0)	430 (26.1)

Primary End Points

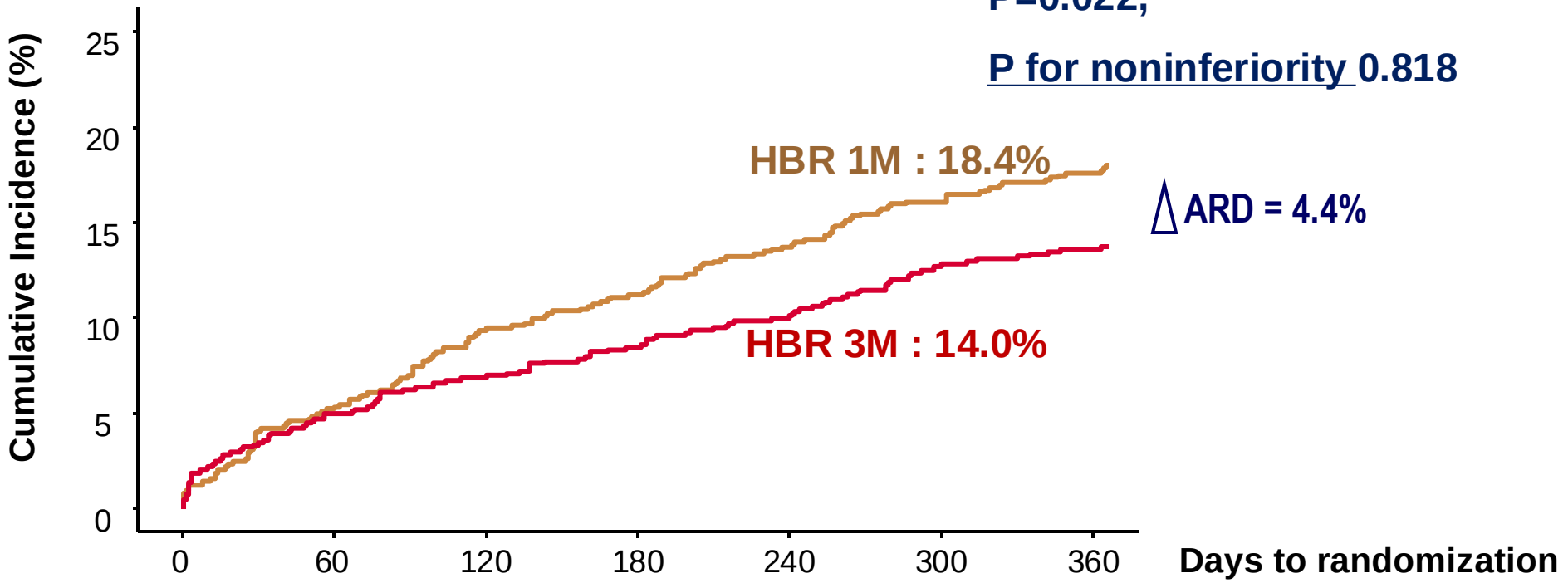
1Y NACE in the HBR Stratum

Hazard ratio 1.34

95%CI 1.04 to 1.71

P=0.022,

P for noninferiority 0.818



Numbers at risk

HBR 1M	798	754	708	693	673	638	566
HBR 3M	800	752	728	715	702	669	592

Primary End Points

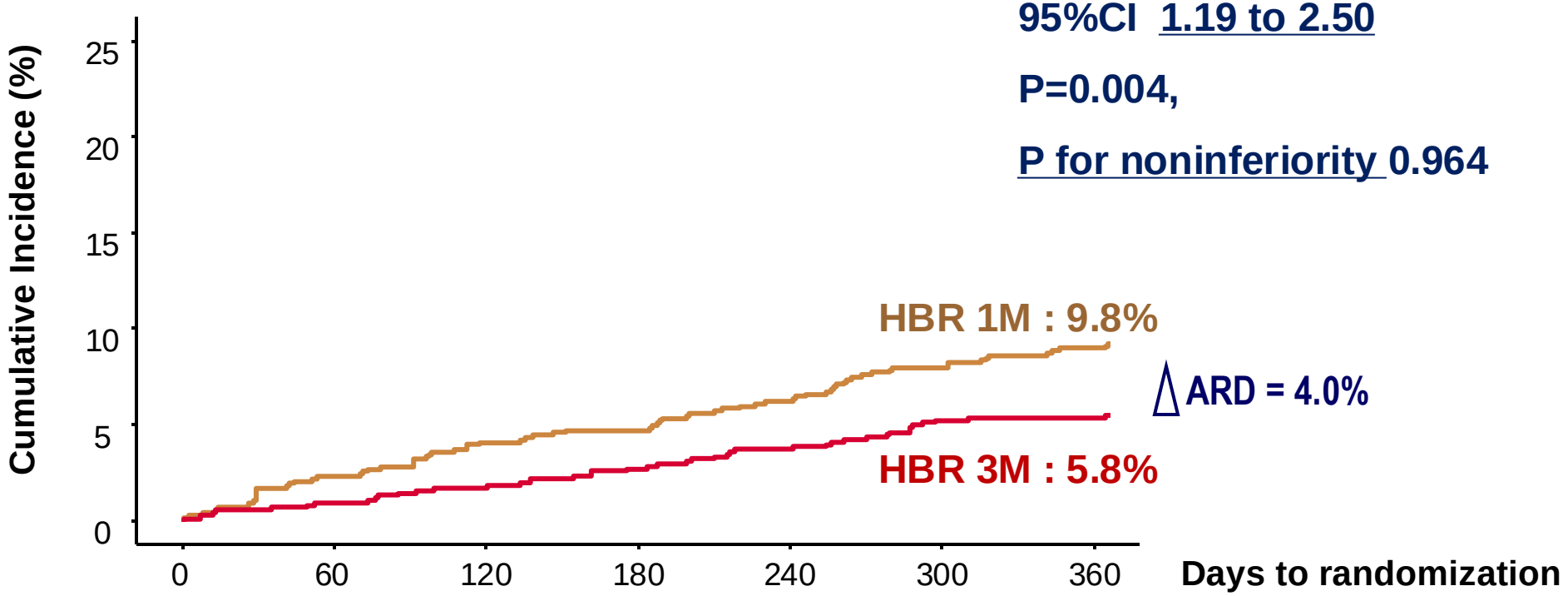
1Y MACCE in the HBR Stratum

Hazard ratio 1.72,

95%CI 1.19 to 2.50

P=0.004,

P for noninferiority 0.964



Numbers at risk

HBR 1M	798	771	733	718	702	670	596
HBR 3M	800	771	751	741	728	699	623

Primary End Points

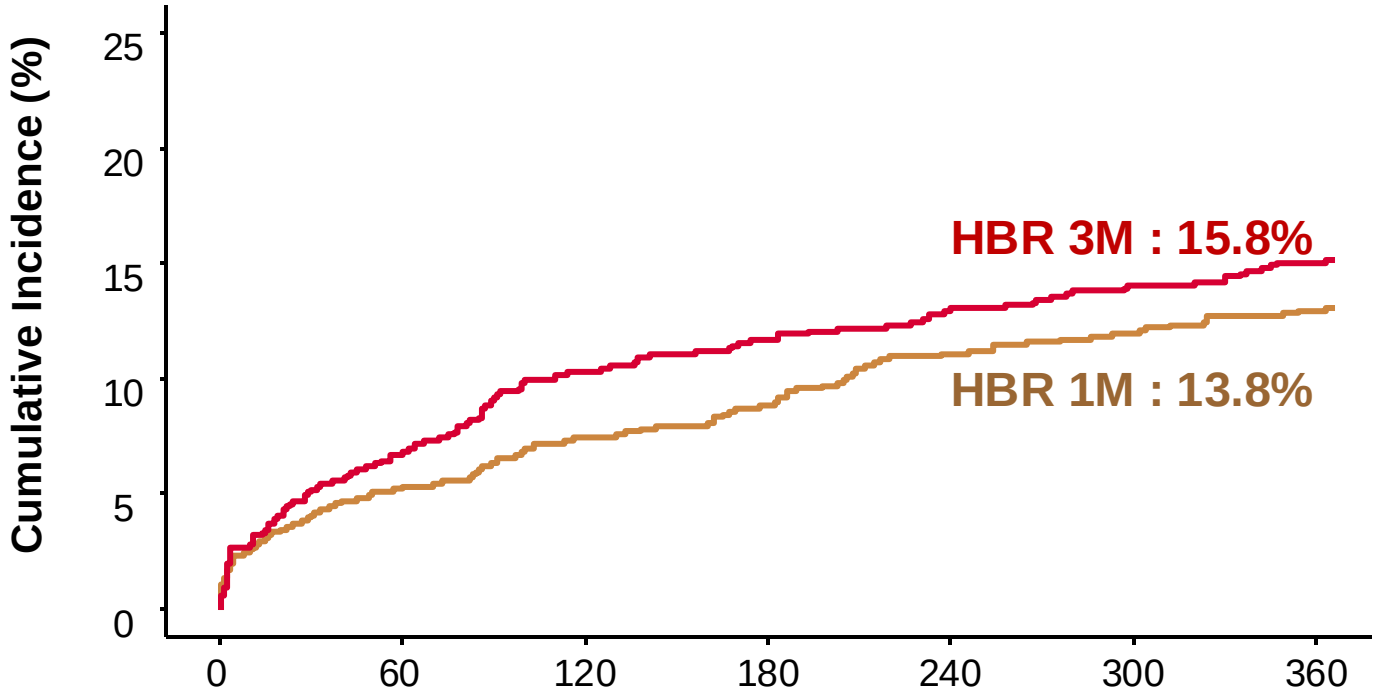
1Y BARC 2,3,5 Bleeding in the HBR Stratum

HOST BR Bleeding Risk

Hazard ratio 0.85,

95%CI 0.66 to 1.11

P=0.232



Numbers at risk

HBR 1M	798	741	699	681	656	622	547
HBR 3M	800	727	684	668	654	624	551

Primary End Points

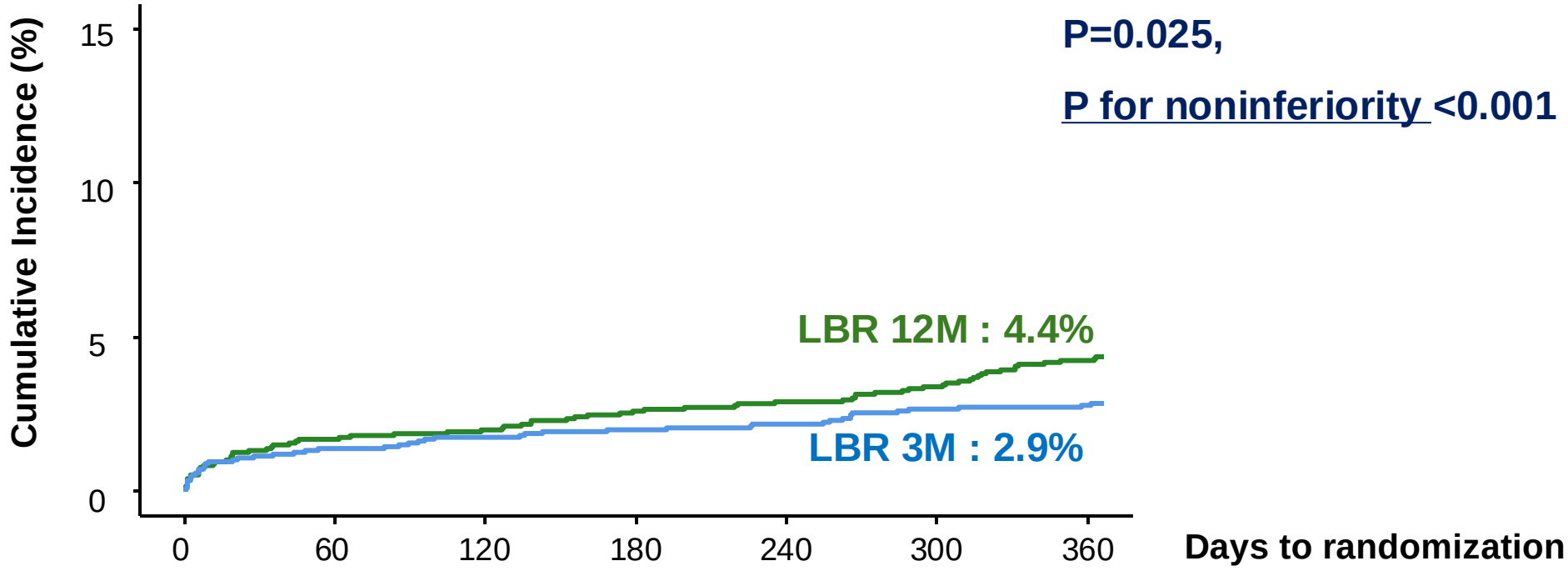
1Y NACE in the LBR Stratum

Hazard ratio 0.66,

95%CI 0.46 to 0.95

P=0.025,

P for noninferiority <0.001



Numbers at risk

LBR 3M	1649	1614	1591	1586	1581	1547	1361
LBR 12M	1650	1617	1606	1595	1589	1559	1397

Primary End Points

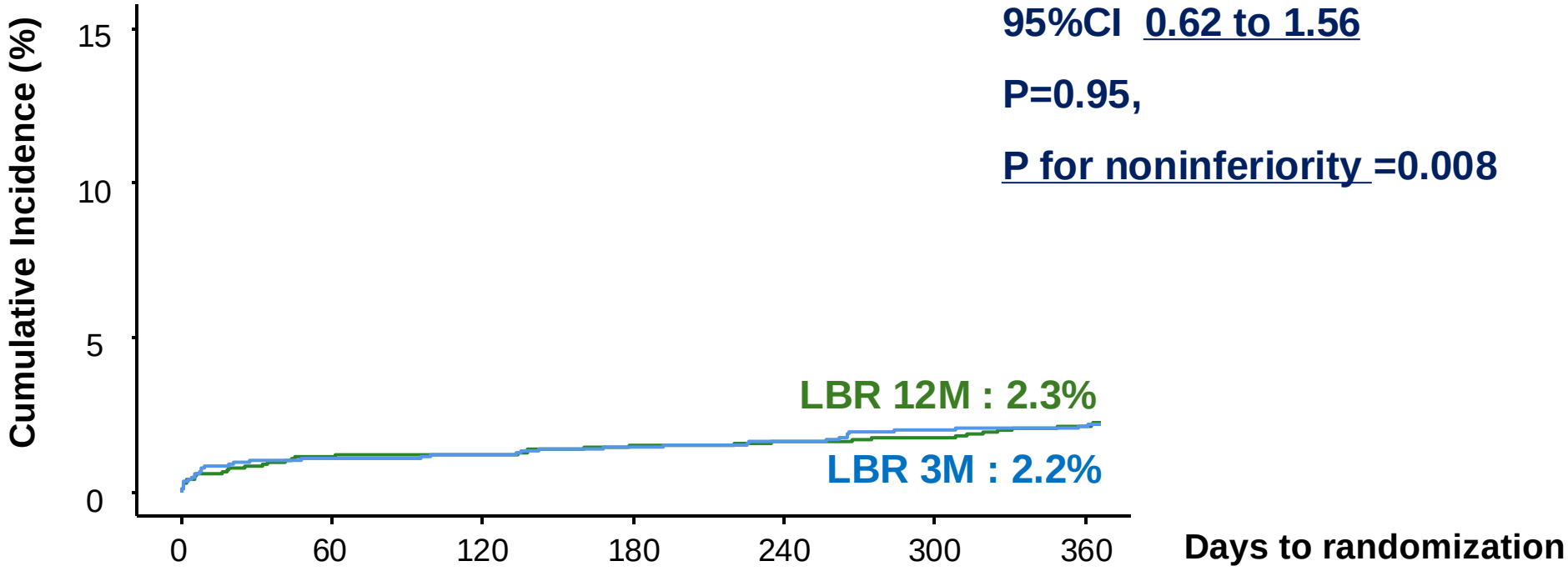
1Y MACCE in the LBR Stratum

Hazard ratio 0.98,

95%CI 0.62 to 1.56

P=0.95,

P for noninferiority =0.008



Numbers at risk

LBR 3M	1649	1617	1596	1591	1586	1553	1367
LBR 12M	1650	1626	1618	1612	1608	1581	1422

Primary End Points

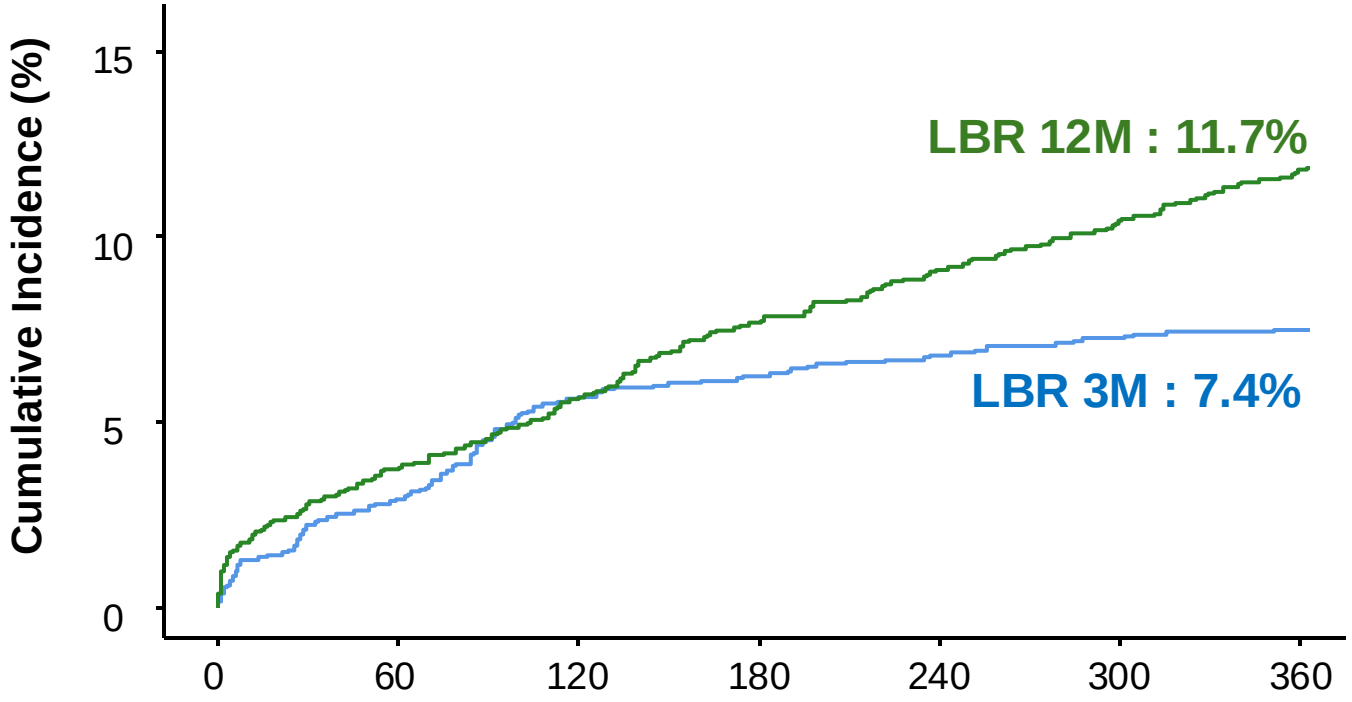
1Y BARC 2,3,5 Bleeding in the LBR Stratum

HOST BR Bleeding Risk

Hazard ratio 0.63,

95%CI 0.50 to 0.79

P<0.001



Numbers at risk

LBR 3M	1649	1583	1523	1512	1501	1467	1297
LBR 12M	1650	1581	1543	1507	1483	1441	1279

1Y Clinical Outcomes : HBR

HOST BR Bleeding Risk

H B R	Total (N=1598)	1M DAPT (N=798)	3M DAPT (N = 800)	Absolute difference (>0 / <0)	Hazard Ratio (>1 / <1)
NACE	*254 (16·2%)*	*144 (18·4%)*	*110 (14·0%)*	*4.39 (1.33, 7.46)*	*1·337 (1·043-1·713)*
MACCE	*118 (7·8%)*	74 (9·8%)	44 (5·8%)	3.98 (1.72, 6.23)	1·723 (1·186-2·502)
Any bleeding event	*227 (14·8%)*	105 (13·8%)	122 (15·8%)	-2.03 (-5.02, 0.96)	0·853 (0·657-1·107)
All cause death	*144 (9·2%)*	81 (10·4%)	63 (8·0%)	2.34 (-0.06, 4.75)	1·299 (0·9343-1·805)
Cardiovascular death	*70 (4·6%)*	42 (5·6%)	28 (3·7%)	1.91 (0.13, 3.69)	1·518 (0·941-2·449)
Myocardial infarction (MI)	*20 (1·3%)*	10 (1·3%)	10 (1·3%)	0.01 (-0.97, 0.99)	1·013 (0·422-2·433)
-Target vessel MI	*14 (0·9%)*	6 (0·8%)	8 (1·1%)	-0.27 (-1.08, 0.55)	0·757 (0·263-2·181)
-Non-target vessel MI	*6 (0·4%)*	4 (0·5%)	2 (0·3%)	0.28 (-0.27,0.83)	2·039 (0·373-11·130)
Stent thrombosis	*4 (0·3%)*	2 (0·3%)	2 (0·3%)	0.03 (-0.41, 0.47)	1·009 (0·142-7·163)
Coronary thrombotic event	*22 (1·5%)*	11 (1·5%)	11(1·5%)	-0.03 (-1.05,1.00)	0·987 (0·428-2·277)
Stroke	*44 (2·9%)*	30 (4·0%)	14 (1·9%)	2.11 (0.68, 3.55)	2·182 (1·157-4·115)
-Ischemic stroke	*34 (2·3%)*	25 (3·3%)	9 (1·2%)	2.12 (0.85, 3.38)	2·824 (1·318-6·050)
-Hemorrhagic stroke	*10 (0·7%)*	5 (0·7%)	5 (0·7%)	-0.01 (-0.70, 0.69)	1·009 (0·292-3·487)
Bleeding					
-BARC 2	*119 (8·0%)*	48 (6·5%)	71 (9·5%)	-3.00 (-5.33, -0.68)	0·670 (0·465-0·966)
-BARC 3	*102 (7·0%)*	53 (7·3%)	49 (6·7%)	0.53 (-1.67, 2.74)	1·072 (0·727-1·518)
-BARC 5	*6 (0·4%)*	4 (0·6%)	2 (0·3%)	0.31 (-0.25, 0.87)	1·983 (0·363-10·830)
Any revascularization	*69 (4·7%)*	*41 (5·7%)*	*28 (3·8%)*	*1.89 (0.05, 3.72)*	*1·499 (0·927-2·424)*
- Target lesion revascularization	*34 (2·3)*	24 (3·3%)	10 (1·4%)	1.91 (0.61, 3.22)	2·460 (1·177-5·145)
- Non-target lesion revascularization	*35 (2·4)*	17 (2·4%)	18 (2·4%)	-0.03 (-1.35, 1.30)	0·956 (0·493-1·855)

1Y Clinical Outcomes : LBR

L B R	Total (N=3299)	3M DAPT (N=1649)	12M DAPT (N = 1650)	Absolute difference (>0 / <0)	Hazard Ratio (>1 / <1)
NACE	*119 (3·7%)*	*47 (2·9%)*	*72 (4·4%)*	*-1.53 (-2.62, -0.45)*	*0·657 (0·455-0·949)*
MACCE	*73 (2·3%)*	36 (2·2%)	37 (2·3%)	-0.05 (-0.92,0.81)	0·984 (0·622-1·558)
Any bleeding event	*310 (9·6%)*	120 (7·4%)	190 (11·7%)	-4.32 (-6.02, -2.62)	0·631 (0·502-0·793)
All cause death	*31 (0·9%)*	17 (1·0%)	14 (0·9%)	0.18 (-0.37, 0.74)	1·229 (0·606-2·493)
Cardiovascular death	*19 (0·6%)*	11 (0·7%)	8 (0·5%)	0.19 (-0.25, 0.63)	1·389 (0·559-3·454)
Myocardial infarction (MI)	*24 (0·8%)*	11 (0·7%)	13 (0·8%)	-0.11 (-0.62, 0.39)	0·859 (0·385-1·918)
-Target vessel MI	*19 (0·6%)*	8 (0·5%)	11 (0·7%)	-0.18 (-0.63, 0.27)	0·738 (0·297-1·834)
-Non-target vessel MI	*5 (0·2%)*	3 (0·2%)	2 (0·1%)	0.07 (-0.17, 0.30)	1·526 (0·255-9·134)
Stent thrombosis	*5 (0·2%)*	2 (0·1%)	3 (0·2%)	-0.08 (-0.31, 0.16)	0·679 (0·114-4·069)
Coronary thrombotic event	*24 (0·8%)*	11(0·7%)	13 (0·8%)	-0.11 (-0.62, 0.39)	0·859 (0·385-1·918)
Stroke	*41 (1·3%)*	17 (1·0%)	24 (1·5%)	-0.44 (-1.09, 0.20)	0·716 (0·385-1·332)
-Ischemic stroke	*34 (1·1%)*	16 (1·0%)	18 (1·1%)	-0.13 (-0.72, 0.46)	0·899 (0·459-1·763)
-Hemorrhagic stroke	*7 (0·2%)*	1 (0·1%)	6 (0·4%)	-0.31 (-0.58, -0.04)	0·168 (0·02-1·402)
Bleeding					
-BARC 2	*269 (8·4%)*	110 (6·8%)	159 (9·9%)	-3.08 (-4.68, -1.48)	0·691 (0·542-0·882)
-BARC 3	*38 (1·2%)*	8 (0·5%)	30 (2·0%)	-1.46 (-2.11, -0.80)	0·266 (0·122-0·579)
-BARC 5	*3 (0·1%)*	2 (0·1%)	1 (0·1%)	0.06 (-0.13, 0.25)	1·997 (0·181-22·030)
Any revascularization	*100 (3·2%)*	*47 (3·0%)*	*53 (3·3%)*	*-0.32 (-1.34, 0.71)*	*0·905 (0·611-1·340)*
- Target lesion revascularization	*46 (1·5%)*	23 (1·5%)	23 (1·4%)	0.02 (-0.67,0.72)	1·021 (0·573-1·819)
- Non-target lesion revascularization	*54 (1·7%)*	24 (1·5%)	30 (1·9%)	-0.34 (-1.10, 0.42)	0·815 (0·476-1·394)

Limitation

- This was an open-label study.

  (Clinical events were adjudicated by an independent committee.)

- The use of specific P2Y12 inhibitor was left to the doctors' discretion

  during the DAPT period or as the monotherapy agent after DAPT.

- Clopidogrel was mainly used as the P2Y12 inhibitor at discharge.

  (Key RCTs of ACS or AMI enrolling East Asians have shown that clopidogrel is superior to ticagrelor leading to 'clopidogrel-DAPT' as the standard & most frequently-used regimen, although 'ticagrelor-DAPT' is recommended for ACS in Western world.)

- The findings may not be generalizable to all ethnic groups.

  (Optimal duration of 'Clopido-DAPT' for East Asians may be applicable to 'Tica-DAPT' for Westerners.)

Conclusion

<in HBR patients>

1-month DAPT did not meet non-inferiority to 3-month DAPT for NACE.

1-month DAPT was inferior to 3-month DAPT for NACE and MACCE at 1 year,

while there was no significant difference in any actionable bleeding.

<in LBR patients>

3-month DAPT reduced any actionable bleeding without increasing NACE or MACCE as compared with 12-month DAPT.

<over all>

3-month would be the optimal (de fault) duration of DAPT after PCI in general to meet the balance of thrombosis/bleeding.

Thank you for your kind attention

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