P2Y12 Inhibitor or Aspirin for Long-term Antiplatelet Management

Kyung Woo Park, MD, PhD, MBA

May 6, 2023

- Within the past 12 months I have had a financial interest/arrangement or affiliation with the organization(s) listed below

Kyung Woo Park, MD, PhD, MBA

Speaker's fee

Daiichi Sankyo

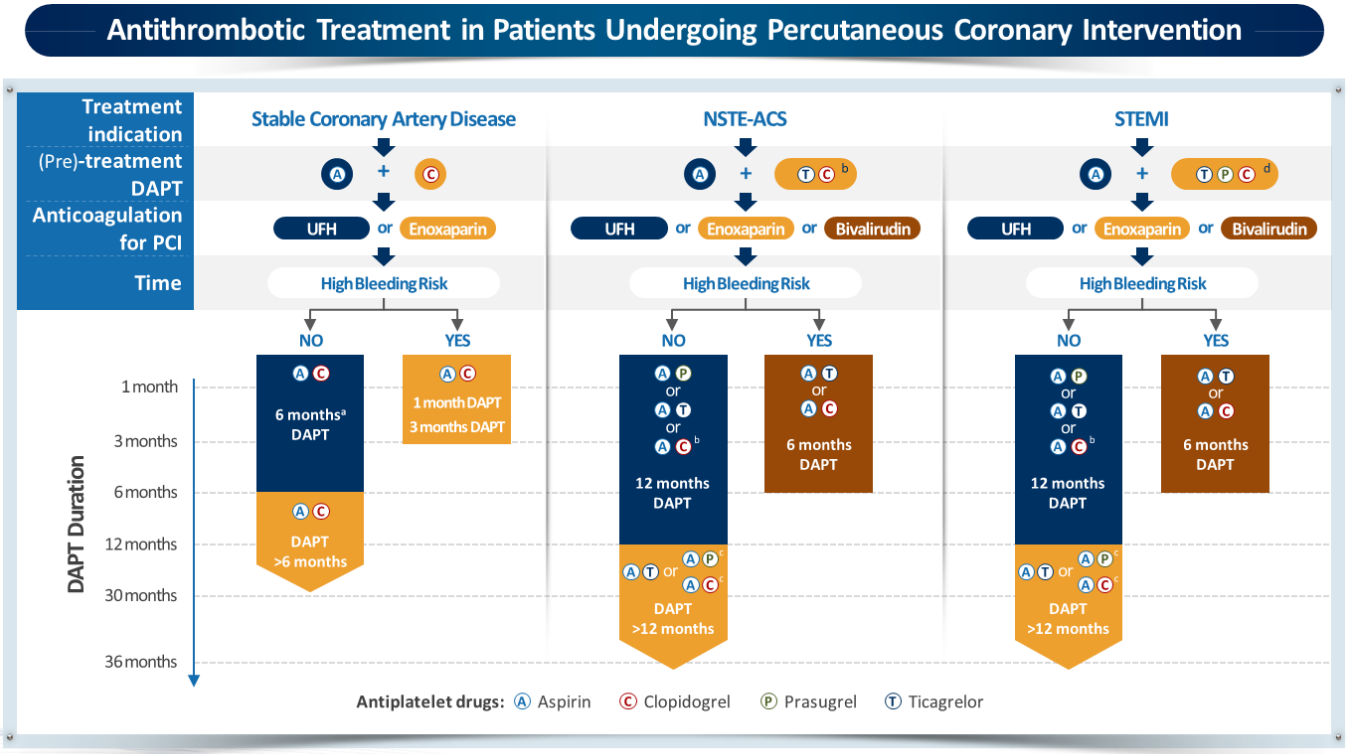
InnoN Pharmaceutical

Daewoong Pharmaceutical

JW Pharmaceutical

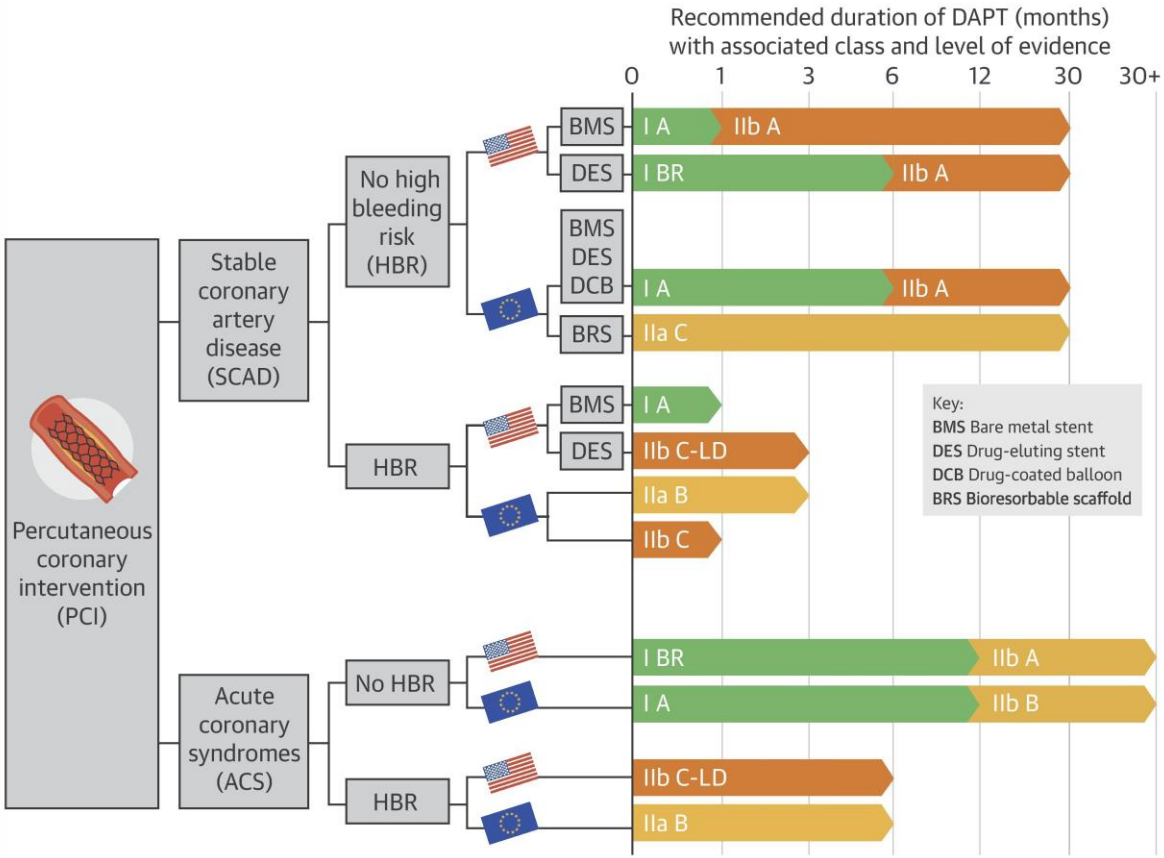
2018 ESC/EACTS Guideline:

Algorithm for the use of antithrombotic drugs in patients undergoing PCI



Neumann FJ, *et al.* Eur Heart J. 2018. doi: 10.1093/eurheartj/ehy394.

CENTRAL ILLUSTRATION: Recommendations for Dual Antiplatelet Therapy in Patients Undergoing Percutaneous Coronary Intervention



Capodanno, D. et al. J Am Coll Cardiol. 2018;72(23PA):2915-31.

Background

After due duration of DAPT, the comparative efficacy and safety of monotherapy with an oral P2Y 12 receptor inhibitor or aspirin remains incompletely understood in patients with established coronary artery disease and current guidelines recommend aspirin as first line treatment after DAPT cessation.

Post-interventional and maintenance treatment		
Life-long single antiplatelet therapy, usually aspirin, is recommended.[681,683]	I	A
Instruction of patients about the importance of complying with antiplatelet therapy is recommended.	I	C
In patients with SCAD treated with coronary stent implantation, DAPT consisting of clopidogrel in addition to aspirin is generally recommended for 6 months, irrespective of the stent type.[c 690–694]	I	A
In patients with SCAD treated with BRS, DAPT should be considered for at least 12 months and up to the presumed full absorption of the BRS, based on an individual assessment of bleeding and ischaemic risk.	IIa	C

Study Design and Patient Population

- ***5,530 eligible patients screened, from 37 centers in Korea***

✓ ***Key criterias***

Patients who recieved PCI with a drug-eluting stent (DES) and maintained DAPT without any clinical event during 12 ± 6 months after PCI.

No exclusion criteria of the clinical risk factors / clinical diagnosis / complexity of the PCI

Inclusion Criteria
a) Subject must be ≥ 20 years b) Maintenance of DAPT for at least 12 ± 6 months after PCI with DES c) No history of clinical event after PCI with DES before enrollment d) Agreement to give written informed consent
Exclusion Criteria
a) Known hypersensitivity or contraindication to key medications b) Patients with active pathologic bleeding c) Female of childbearing potential, unless a pregnancy test is negative d) History of bleeding diathesis, known coagulopathy e) Non-cardiac co-morbid conditions with life expectancy <1 year

Koo BK, Park KW, Kang J, Kim HS et al. Lancet 2021.

Trial Flow

Index PCI

Randomization

Primary outcome

All-cause death, nonfatal MI, stroke,
readmission due to ACS,
major bleeding (BARC type ≥3)

5530 patients enrolled

92 patients excluded from randomization

5438 patients successfully randomized

2,710 patients enrolled in the Clopidogrel monotherapy group

62 patients excluded for Per protocol analysis
8 withdrew consent
41 were lost to follow up
13 did not receive allocated antiplatelet agent

2,661 (98.2%) patients completed 24-month follow-up

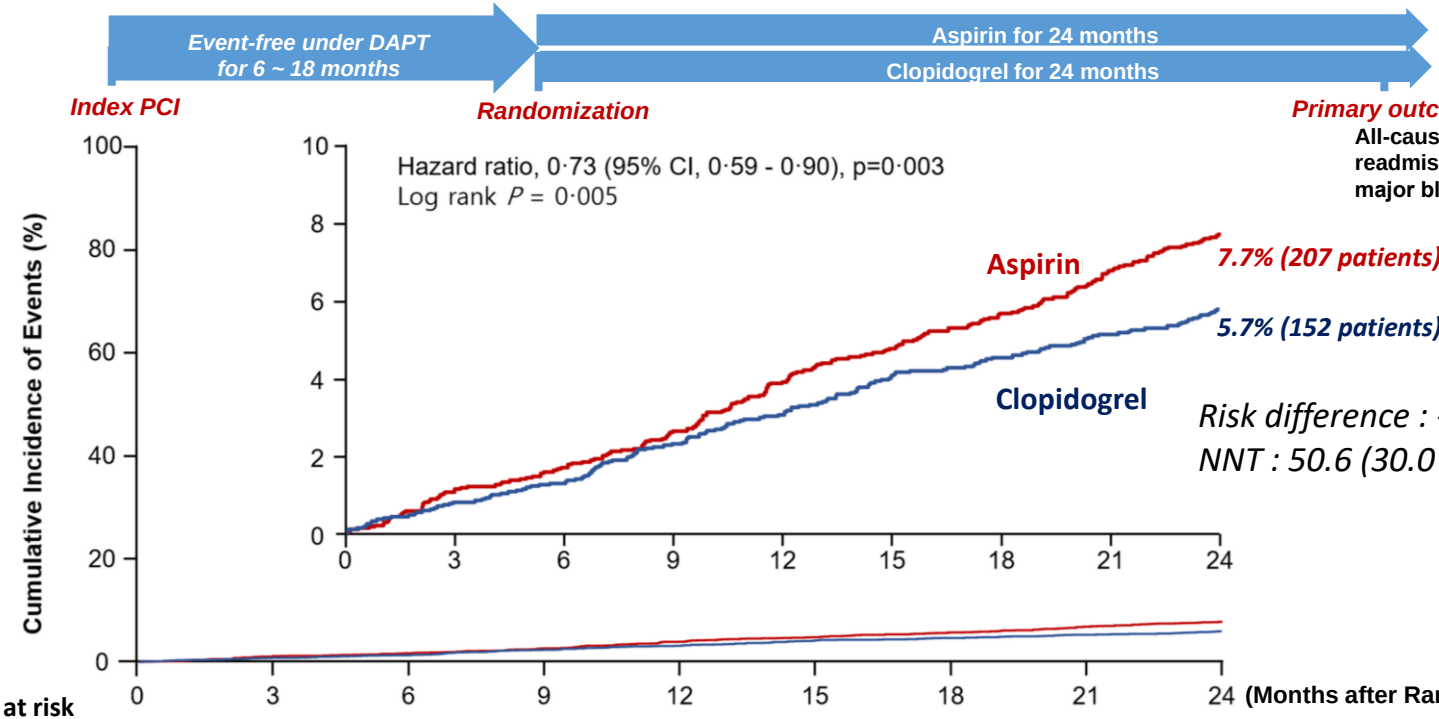
2,728 patients enrolled in the Aspirin monotherapy group

73 patients excluded for Per protocol analysis
1 withdrew consent
50 were lost to follow up
22 did not receive allocated antiplatelet agent

2,677 (98.1%) patients completed 24-month follow-up

Koo BK, Park KW, Kang J, Kim HS et al. Lancet 2021.

Primary Outcome

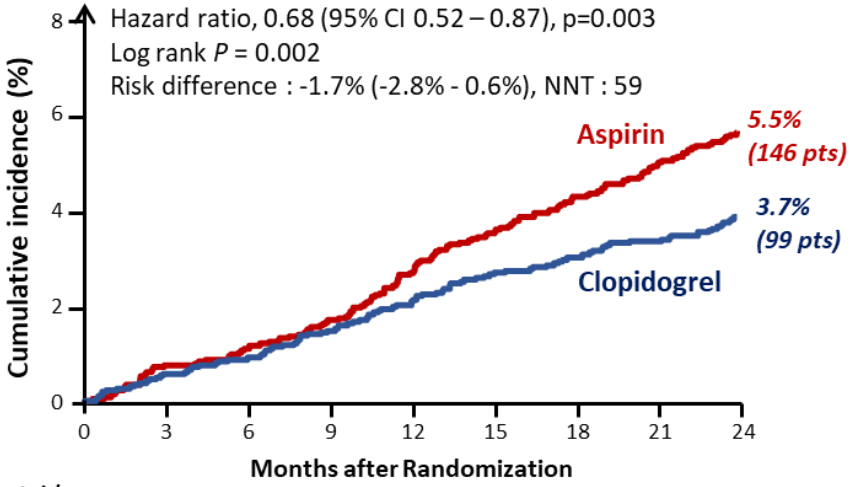


Koo BK, Park KW, Kang J, Kim HS et al. Lancet 2021.

Secondary Outcomes

Thrombotic composite outcome

(cardiac death, non-fatal MI, ischemic stroke, readmission due to ACS, and definite or probable stent thrombosis)

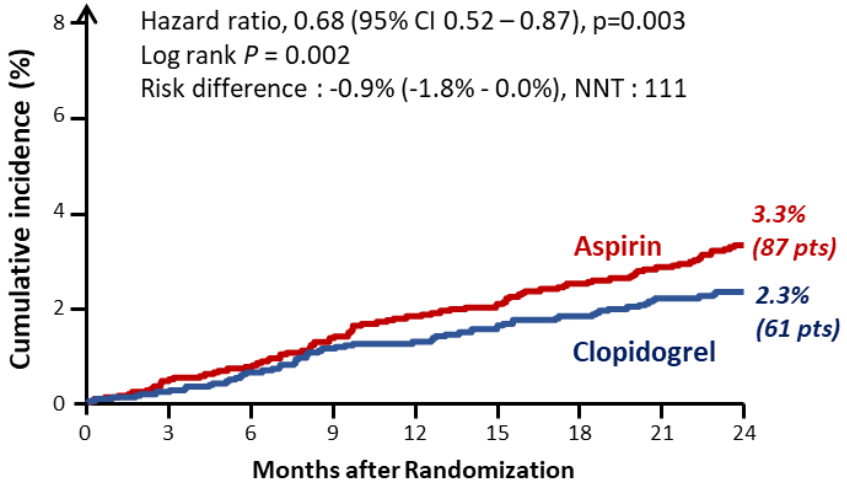


Number at risk

Clopidogrel	2710	2661	2612	2569	2524
Aspirin	2728	2670	2608	2557	2495

Any bleeding

(BARC type ≥2 bleeding)



	2710	2664	2621	2585	2542
	2728	2677	2626	2595	2547

Koo BK, Park KW, Kang J, Kim HS et al. Lancet 2021.

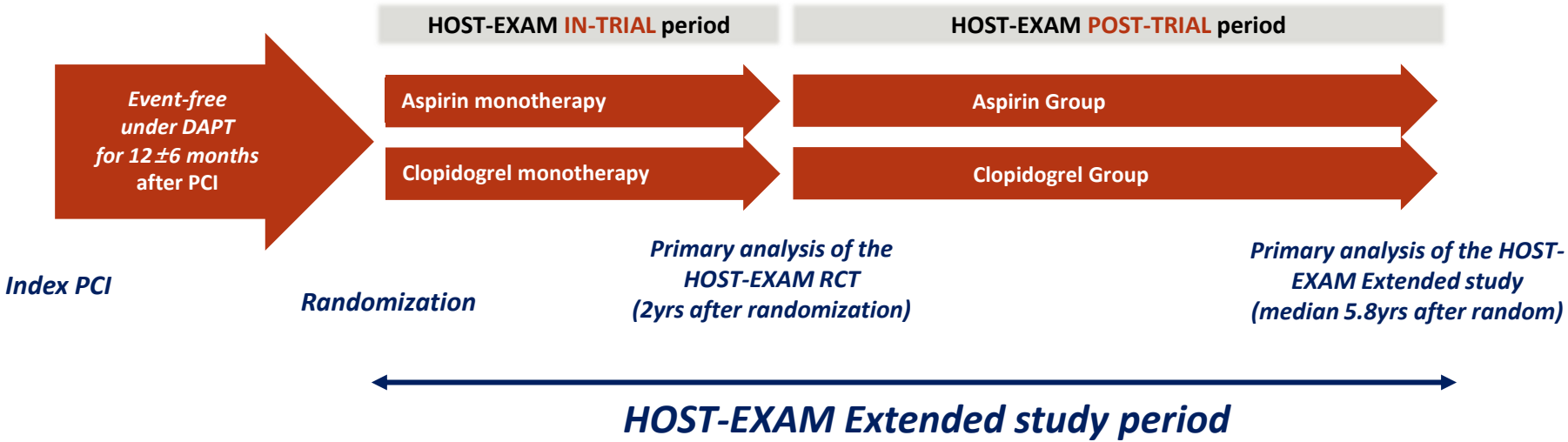
Component of Outcomes for 2 years

	Clopidogrel (n=2710)	Aspirin (n=2728)	Hazard Ratio (95% CI)	P value
	No. of patients (%)			
All-cause death	1.9% (51)	1.3% (36)	1.43 (0.93-2.19)	0.101
Cardiac death	0.7% (19)	0.5% (14)	1.37 (0.69-2.73)	0.374
Non-cardiac death	1.2% (32)	0.8% (22)	1.47 (0.85-2.52)	0.167
Non-fatal myocardial infarction	0.7% (18)	1.0% (28)	0.65 (0.36-1.17)	0.150
Stroke	0.7% (18)	1.6% (43)	0.42 (0.24-0.73)	0.002
Ischemic stroke	0.5% (14)	1.0% (26)	0.54 (0.28-1.04)	0.064
Hemorrhagic stroke	0.2% (4)	0.6% (17)	0.24 (0.08-0.70)	0.010
Readmission due to ACS	2.5% (66)	4.1% (109)	0.61 (0.45-0.82)	0.001
Major bleeding (BARC type ≥3)	1.2% (33)	2.0% (53)	0.63 (0.41-0.97)	0.035
Any revascularization	2.1% (56)	2.6% (69)	0.82 (0.57-1.16)	0.261
Target lesion revascularization	0.9% (24)	1.4% (36)	0.67 (0.40-1.12)	0.130
Target vessel revascularization	1.4% (37)	1.8% (48)	0.78 (0.50-1.19)	0.245
Definite or probable stent thrombosis	0.4% (10)	0.6% (16)	0.63 (0.29-1.39)	0.251
Any minor GI complications	10.2% (272)	11.9% (320)	0.85 (0.72-1.00)	0.048

Koo BK, Park KW, Kang J, Kim HS et al. Lancet 2021.

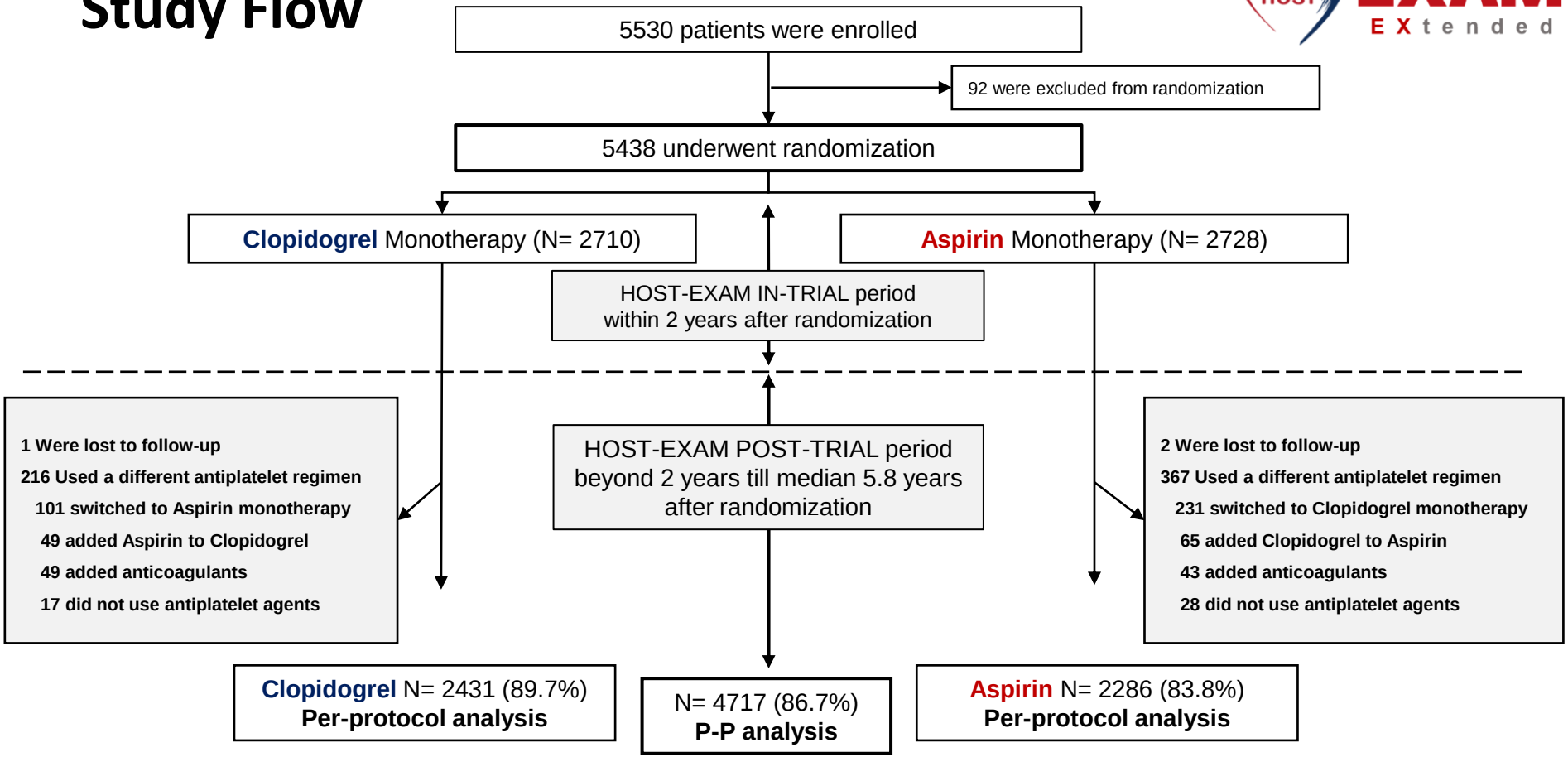
Study Design and Patient Population

- 5,530 eligible patients screened, from 37 centers in Korea



Clinical events and final clinical status ascertained at March, 2022.
The vital status of all patients coss-checked via the National Health Insurance Service system.

Study Flow

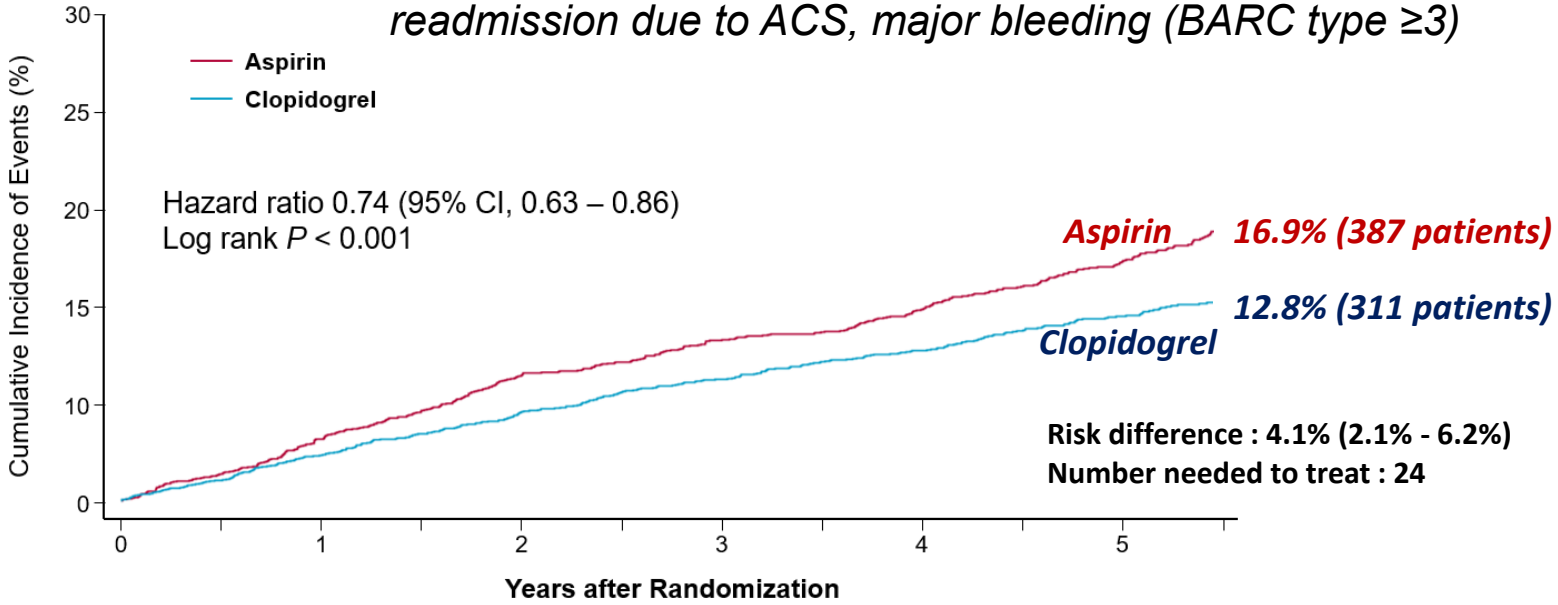


Kang J, Park KW, Koo BK, Kim HS et al. Circulation 2023

Clinical Outcomes

- ***Primary Endpoint***

Primary endpoint: *All-cause death, nonfatal MI, stroke, readmission due to ACS, major bleeding (BARC type ≥3)*



Number at Risk

Aspirin	2286	2189	2086	2014	1777	1287	1007
Clopidogrel	2431	2355	2280	2214	1964	1462	1181

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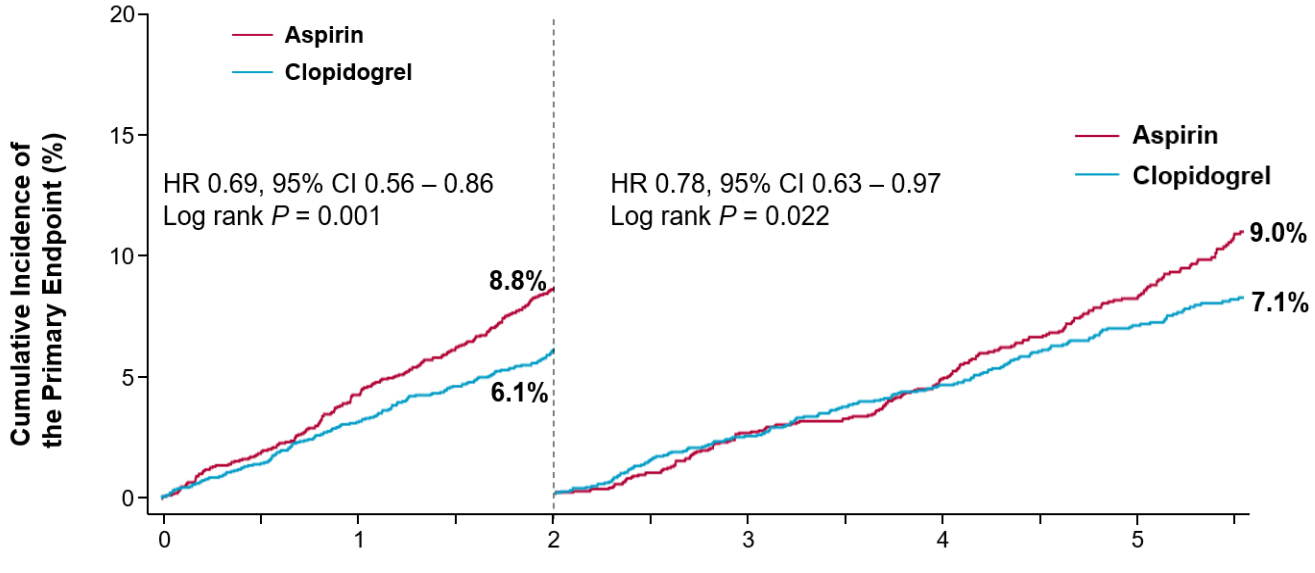
Clinical Outcomes

- ***Landmark analysis of the Primary Endpoint***

HOST EXAM Extended

Consistent beneficial effects
both
in the In-trial period
and post-trial period



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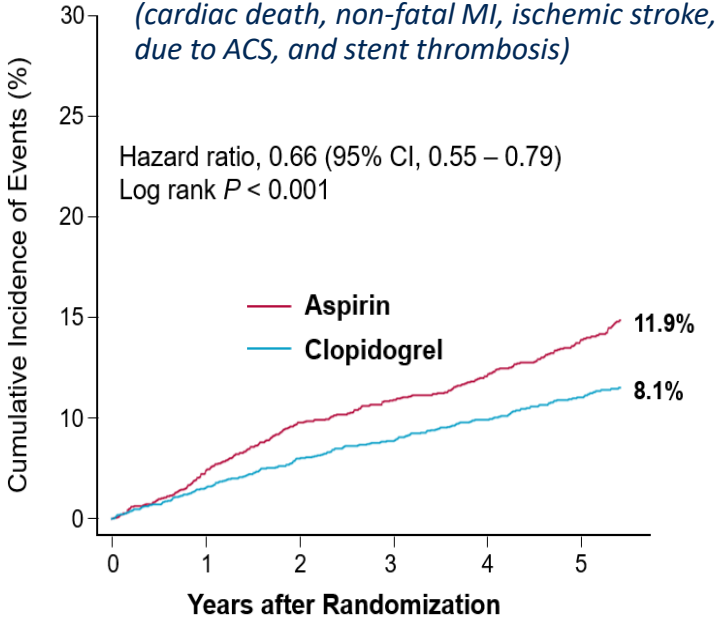
Clinical Outcomes

▪ *Secondary Endpoints*

HOST EXAM Extended

Thrombotic composite outcome

(cardiac death, non-fatal MI, ischemic stroke, readmission due to ACS, and stent thrombosis)

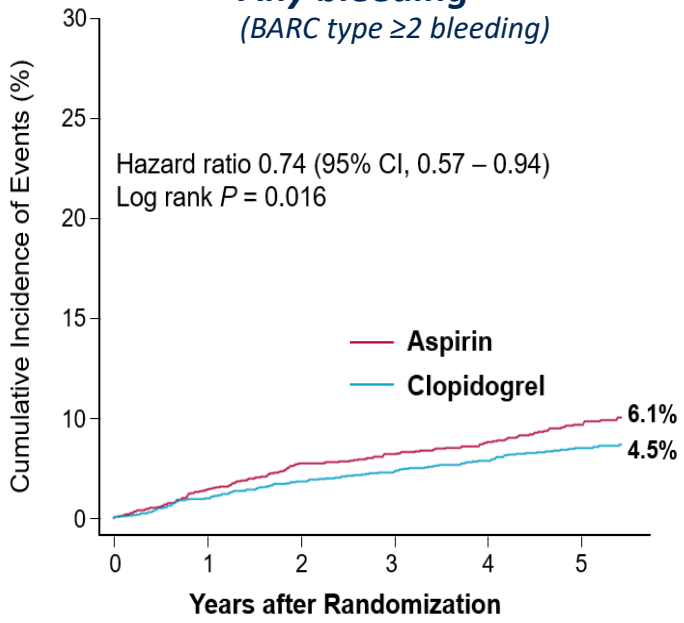


Number at Risk

Aspirin	2286	2120	1819	1040
Clopidogrel	2431	2304	1992	1202

Any bleeding

(BARC type ≥2 bleeding)



Number at Risk

Aspirin	2286	2175	1888	1104
Clopidogrel	2431	2323	2028	1238

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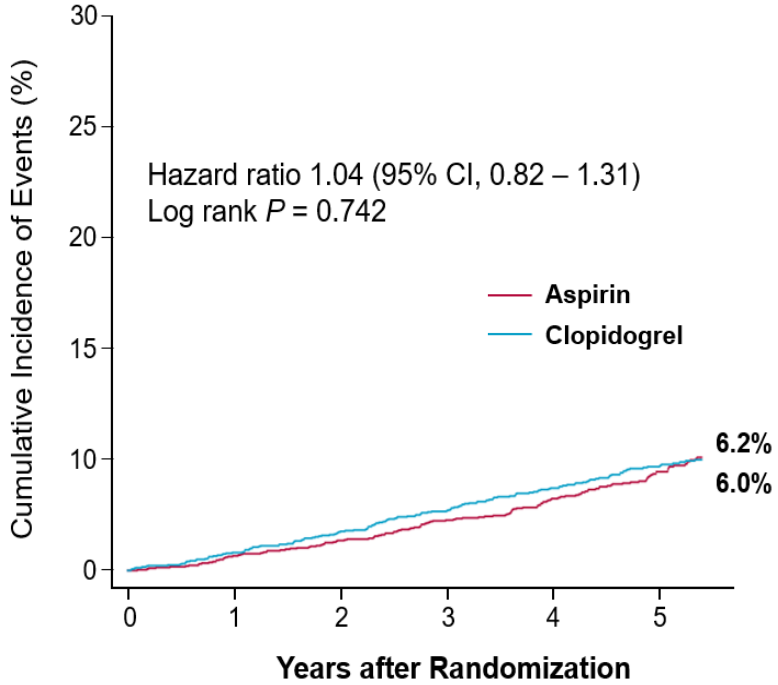
Clinical Outcomes

- ***Mortality***



Number at Risk

Aspirin	2286	2244	1971	1165
Clopidogrel	2431	2374	2088	1285

No. of patients	Clopidogrel (N=2431)	Aspirin (N=2286)	P value
Total mortality	150 (6.2%)	136 (6.0%)	0.753
Cardiovascular cause	69 (2.8%)	71 (3.1%)	0.587
Cardiac arrest	21	22	
Heart failure aggravation	5	3	
Cerebrovascular accident	7	3	
Unknown origin of death	36	43	
Non-cardiovascular cause	81 (3.3%)	65 (2.8%)	0.334
Malignancy	34	29	
- Gastrointestinal origin	15	12	
- Respiratory origin	8	11	
- Endocrinology origin	1	1	
- Genitourinary origin	4	3	
- Other	3	2	
- Unknown primary	3	0	
Infectious disease	4	5	
Suicide or Trauma	8	3	
Others	20	16	

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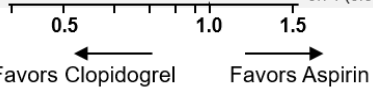
	Clopidogrel group (events/patients)	Aspirin group (events/patients)	Hazard Ratio (95% CI)	P value	Interaction P
Age (years)					
≥65	200/1040	232/992	0.80 (0.66-0.96)	0.019	0.176
<65	110/1390	155/1294	0.65 (0.51-0.83)	<0.001	
Sex					
Male	222/1807	287/1723	0.72 (0.60-0.85)	<0.001	0.563
Female	89/624	100/563	0.79 (0.59-1.05)	0.107	
Body Mass Index ≥ 25 kg/m²					
Yes	119/1103	140/976	0.74 (0.58-0.94)	0.014	0.936
No	179/1244	231/1233	0.75 (0.61-0.91)	0.003	
Diabetes Mellitus					
Yes	128/817	165/776	0.71 (0.57-0.90)	0.004	0.764
No	182/1613	222/1510	0.75 (0.62-0.91)	0.004	
Chronic Kidney Disease					
Yes	77/313	95/274	0.67 (0.50-0.90)	0.009	0.614
No	233/2117	292/2012	0.74 (0.62-0.88)	0.001	
Multivessel Disease					
Yes	170/1201	227/1145	0.69 (0.57-0.85)	0.002	0.356
No	140/1229	159/1140	0.80 (0.64-1.00)	0.054	
Acute Myocardial Infarction					
Yes	116/888	143/858	0.77 (0.60-0.98)	0.036	0.756
No	194/1542	244/1428	0.72 (0.59-0.86)	<0.001	
Acute Coronary Syndrome					
Yes	219/1758	274/1631	0.72 (0.61-0.86)	<0.001	0.556
No	91/672	113/655	0.76 (0.58-1.00)	0.053	
Complex PCI					
Yes	60/530	92/499	0.59 (0.43-0.82)	0.002	0.138
No	249/1882	294/1769	0.78 (0.66-0.92)	0.004	
High Bleeding Risk					
Yes	113/461	126/390	0.71 (0.55-0.92)	0.009	0.860
No	161/1616	204/1536	0.74 (0.60-0.90)	0.004	
Proton Pump Inhibitor usage					
Yes	39/251	56/266	0.72 (0.48-1.08)	0.113	0.888
No	272/2180	331/2020	0.74 (0.63-0.87)	<0.001	



HOST EXAM Extended

Subgroup Analysis

No significant interaction between the treatment effect and subgroups

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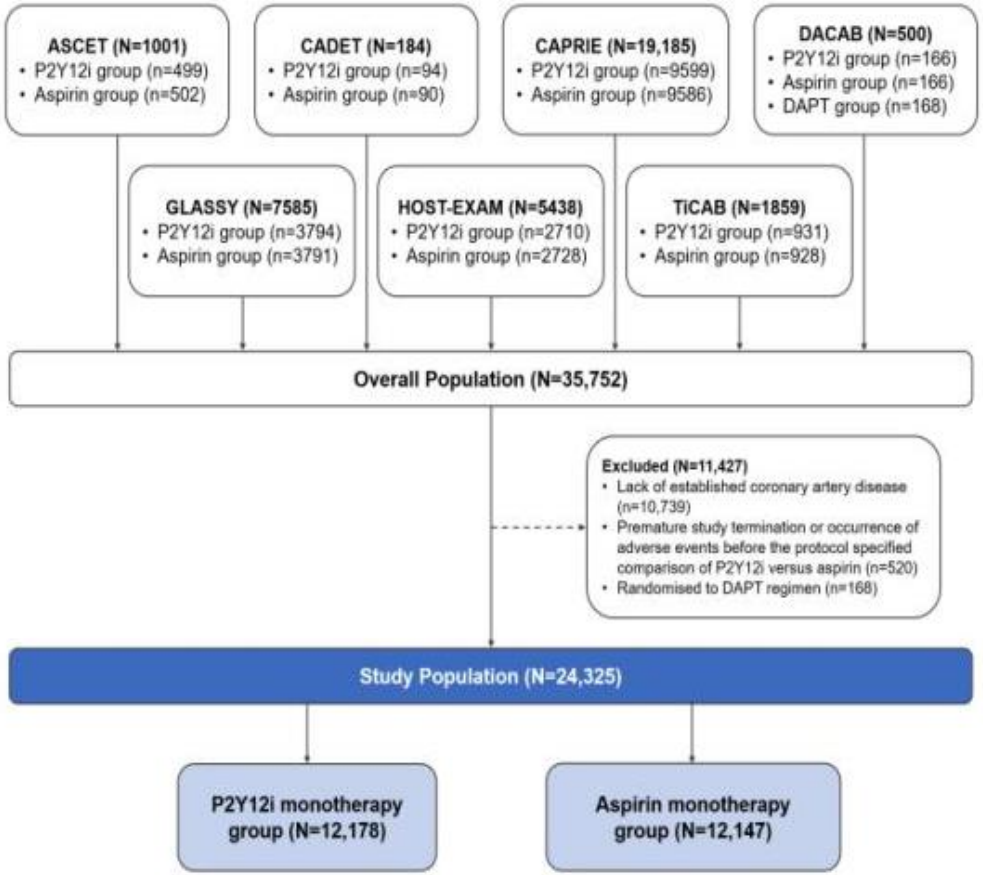
The PANTHER Collaboration

- RCTs comparing monotherapy with oral P2Y12 inhibitor (i.e., clopidogrel, prasugrel, or ticagrelor) or aspirin for secondary prevention of adjudicated events in patients with established CAD w/o indication for OAC.

- 7 studies identified

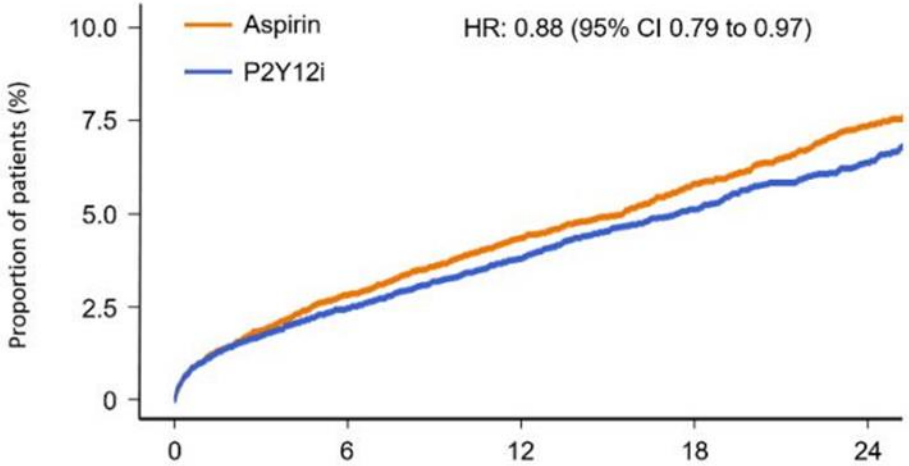
- **PROSPERO** registration (www.crd.york.ac.uk/prospero, CRD42021290774)



Gragnano F, Park KW, Kim HS, Valgimigli M et al. JACC in press 2023

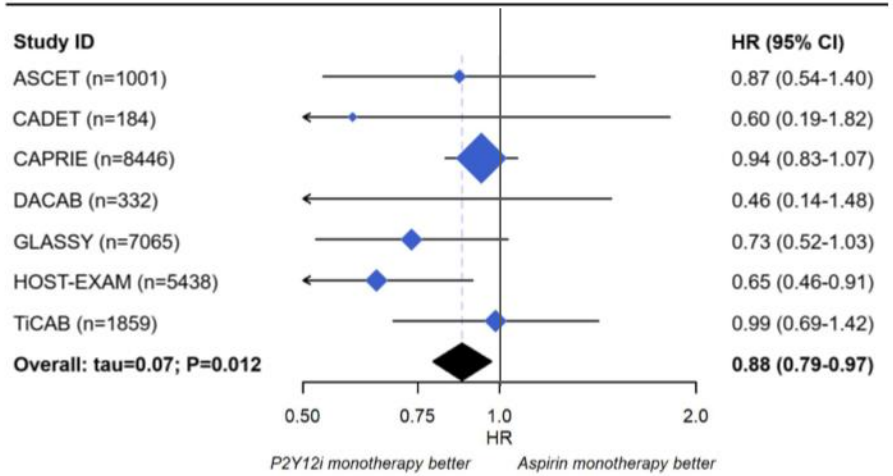
Primary Efficacy Outcome: CV death, MI, stroke

CV death, MI or stroke: 5.5% vs. 6.3%; HR 0.88, 95% CI 0.79 to 0.97, P=0.014; NNTB: 123



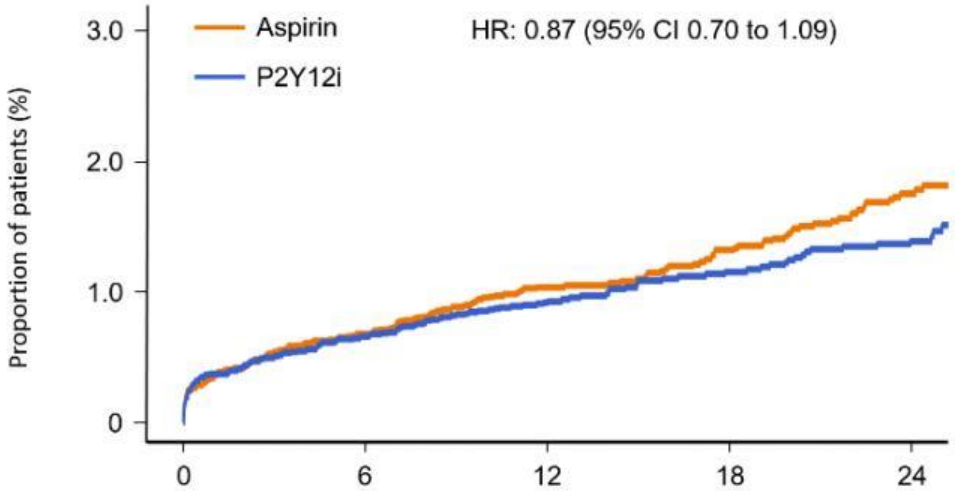
Number at risk

Aspirin	11645	11143	10141	5405	4288
P2Y12i	11679	11196	10142	5389	4357



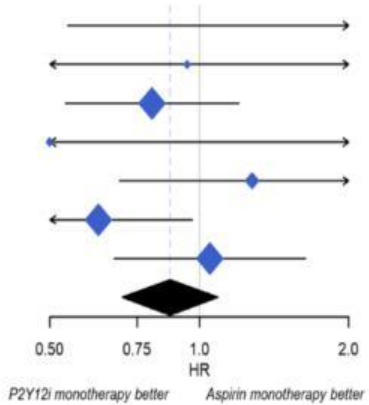
Primary Safety Outcome: Major Bleeding

Major bleeding: 1.2% vs. 1.4%; HR 0.87, 95% CI 0.70 to 1.09, P=0.23



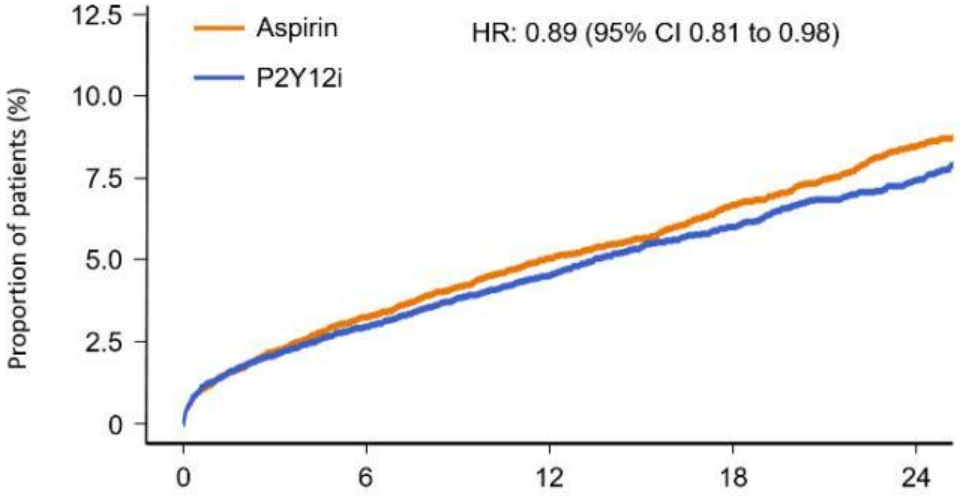
Number at risk

Aspirin	11479	11127	10220	5562	4430
P2Y12i	11513	11149	10179	5530	4459



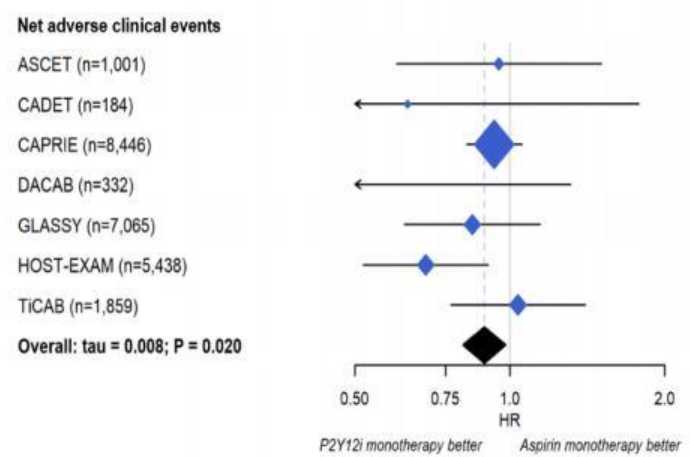
Key Secondary Outcome: Net Adverse Clinical Events

NACE: 6.4% vs. 7.2%; HR 0.89, 95% CI 0.81 to 0.98, P=0.02

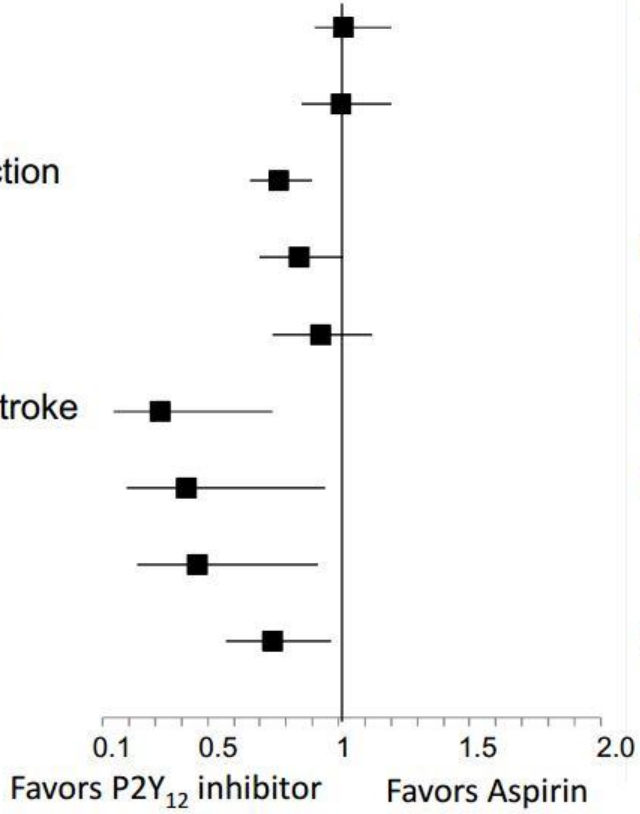


Number at risk

Aspirin	11479	10935	9949	5363	4244
P2Y12i	11513	10987	9959	5354	4323



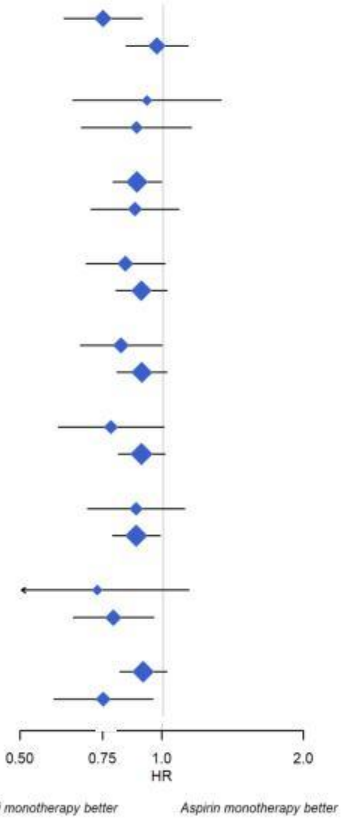
Secondary Outcomes



	Hazard Ratios (95% CI)	P-Values
Death	1.04 (0.91 to 1.20)	0.56
CV Death	1.02 (0.86 to 1.20)	0.82
Myocardial Infarction	**0.77 (0.66 to 0.90)**	**<0.001**
Stroke	0.85 (0.70 to 1.02)	0.088
Ischemic Stroke	0.93 (0.75 to 1.13)	0.45
Haemorrhagic Stroke	**0.32 (0.14 to 0.75)**	**0.009**
Definite ST	**0.42 (0.19 to 0.97)**	**0.041**
Def/prof ST	**0.46 (0.23 to 0.92)**	**0.028**
GI Bleeding	**0.75 (0.57 to 0.97)**	**0.027**

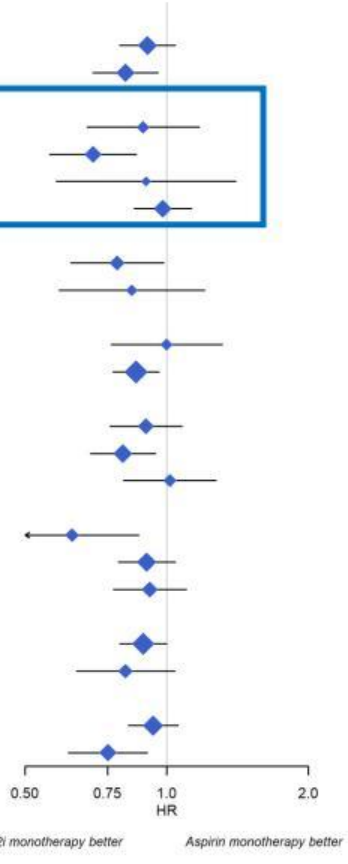
Primary Efficacy Outcome: subgroup analysis

Subgroup	N	P2Y12i monotherapy (%)	Aspirin monotherapy (%)	HR (95% CI)	P value for interaction
Age					
Male					
≤ 62 years	9,752	184 / 4,866 (3.8%)	245 / 4,886 (5.0%)	0.75 (0.62 to 0.90)	0.206
> 62 years	9,285	337 / 4,672 (7.2%)	337 / 4,613 (7.3%)	0.97 (0.83 to 1.13)	
Female					
≤ 67 years	2,562	56 / 1,292 (4.3%)	61 / 1,270 (4.8%)	0.93 (0.64 to 1.33)	
> 67 years	2,726	97 / 1,348 (7.2%)	119 / 1,378 (8.6%)	0.88 (0.67 to 1.15)	
Sex					
Male	19,037	521 / 9,538 (5.5%)	582 / 9,499 (6.1%)	0.88 (0.78 to 0.99)	0.921
Female	5,288	153 / 2,640 (5.8%)	180 / 2,648 (6.8%)	0.87 (0.70 to 1.08)	
Diabetes					
Yes	6,040	193 / 3,036 (6.4%)	229 / 3,004 (7.6%)	0.83 (0.69 to 1.01)	0.504
No	18,092	475 / 9,044 (5.3%)	525 / 9,048 (5.8%)	0.90 (0.80 to 1.02)	
Current smoker					
Yes	6,411	176 / 3,161 (5.6%)	217 / 3,250 (6.7%)	0.82 (0.67 to 0.99)	0.388
No	17,903	498 / 9,014 (5.5%)	545 / 8,889 (6.1%)	0.90 (0.80 to 1.02)	
Peripheral artery disease					
Yes	2,203	103 / 1,085 (9.5%)	129 / 1,118 (11.5%)	0.78 (0.60 to 1.01)	0.308
No	21,895	565 / 10,975 (5.1%)	625 / 10,920 (5.7%)	0.90 (0.80 to 1.01)	
Prior stroke					
Yes	1,598	131 / 807 (16.2%)	143 / 791 (18.1%)	0.88 (0.69 to 1.11)	0.999
No	22,535	538 / 11,271 (4.8%)	611 / 11,264 (5.4%)	0.88 (0.78 to 0.99)	
History of CKD					
Yes	1,719	33 / 870 (3.8%)	46 / 849 (5.4%)	0.73 (0.46 to 1.14)	0.694
No	13,959	176 / 6,964 (2.5%)	225 / 6,995 (3.2%)	0.78 (0.64 to 0.96)	
Previous MI					
Yes	13,637	558 / 6,839 (8.2%)	607 / 6,798 (8.9%)	0.91 (0.81 to 1.02)	0.158
No	10,648	115 / 5,320 (2.2%)	155 / 5,328 (2.9%)	0.75 (0.59 to 0.95)	



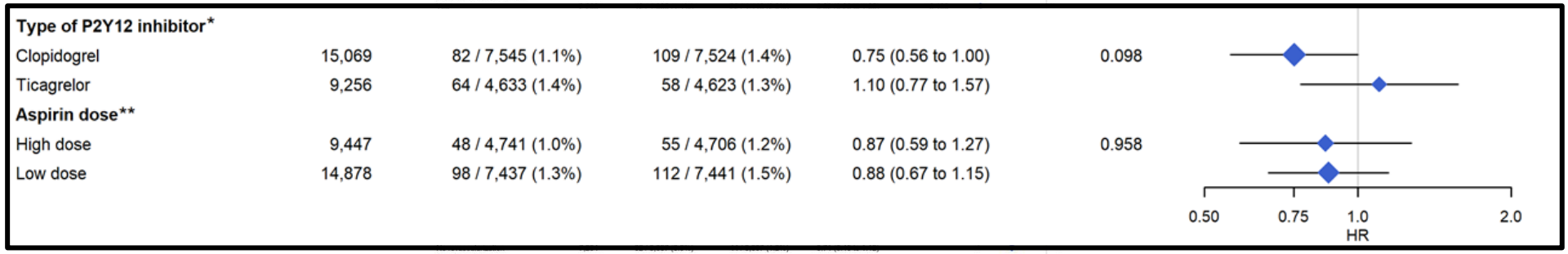
Primary Efficacy Outcome: subgroup analysis (ii)

Subgroup	N	P2Y12i monotherapy (%)	Aspirin monotherapy (%)	HR (95% CI)	P value for interaction
Clinical presentation					
ACS	14,746	394 / 7,394 (5.3%)	433 / 7,352 (5.9%)	0.91 (0.79 to 1.04)	0.360
Stable CAD	9,579	280 / 4,784 (5.9%)	329 / 4,795 (6.9%)	0.82 (0.70 to 0.96)	
Type of revascularisation					
Surgical	2,547	95 / 1,260 (7.5%)	110 / 1,287 (8.5%)	0.89 (0.68 to 1.17)	0.074
PCI	13,241	145 / 6,634 (2.2%)	206 / 6,607 (3.1%)	0.70 (0.56 to 0.86)	
Surgical & PCI	1,053	36 / 501 (7.2%)	46 / 552 (8.3%)	0.90 (0.58 to 1.40)	
No revascularisation	7,294	393 / 3,687 (10.7%)	392 / 3,607 (10.9%)	0.98 (0.85 to 1.13)	
Bleeding risk					
PRECISE DAPT < 25	11,581	133 / 5,803 (2.3%)	168 / 5,778 (2.9%)	0.79 (0.63 to 0.99)	0.723
PRECISE DAPT ≥ 25	2,500	55 / 1,240 (4.4%)	69 / 1,260 (5.5%)	0.84 (0.59 to 1.20)	
Use of proton pump inhibitors					
Yes	5,761	101 / 2,866 (3.5%)	108 / 2,895 (3.7%)	1.00 (0.76 to 1.31)	0.287
No	18,380	568 / 9,218 (6.2%)	646 / 9,162 (7.1%)	0.86 (0.77 to 0.96)	
BMI					
< 25 kg/m²	8,268	237 / 4,127 (5.7%)	260 / 4,141 (6.3%)	0.90 (0.76 to 1.08)	0.247
25 kg/m² ≤ BMI < 30 kg/m²	10,731	278 / 5,383 (5.2%)	338 / 5,348 (6.3%)	0.81 (0.69 to 0.95)	
≥ 30 kg/m²	4,769	150 / 2,391 (6.3%)	151 / 2,378 (6.3%)	1.02 (0.81 to 1.27)	
Region					
Asia	5,770	59 / 2,876 (2.1%)	94 / 2,894 (3.2%)	0.63 (0.46 to 0.87)	0.101
Europe	13,974	381 / 6,997 (5.4%)	418 / 6,977 (6.0%)	0.91 (0.79 to 1.04)	
North America	4,581	234 / 2,305 (10.2%)	250 / 2,276 (11.0%)	0.92 (0.77 to 1.10)	
Type of P2Y12 inhibitor*					
Clopidogrel	15,069	554 / 7,545 (7.3%)	615 / 7,524 (8.2%)	0.89 (0.80 to 1.00)	0.524
Ticagrelor	9,256	120 / 4,633 (2.6%)	147 / 4,623 (3.2%)	0.82 (0.64 to 1.04)	
Aspirin dose**					
High dose	9,447	494 / 4,741 (10.4%)	522 / 4,706 (11.1%)	0.94 (0.83 to 1.06)	0.058
Low dose	14,878	180 / 7,437 (2.4%)	240 / 7,441 (3.2%)	0.75 (0.62 to 0.91)	



Subgroup Analysis for Major Bleeding

Subgroup	N	P2Y12i monotherapy (%)	Aspirin monotherapy (%)	HR (95% CI)	P value for interaction
Age					
Male					
≤ 62 years	9,752	42 / 4,866 (0.9%)	38 / 4,886 (0.8%)	1.08 (0.70 to 1.68)	0.713
> 62 years	9,285	75 / 4,672 (1.6%)	93 / 4,613 (2.0%)	0.80 (0.59 to 1.09)	
Female					
≤ 67 years	2,562	9 / 1,292 (0.7%)	12 / 1,270 (0.9%)	0.78 (0.33 to 1.85)	
> 67 years	2,726	20 / 1,348 (1.5%)	24 / 1,378 (1.7%)	0.85 (0.47 to 1.54)	
Sex					
Male	19,037	117 / 9,538 (1.2%)	131 / 9,499 (1.4%)	0.89 (0.69 to 1.14)	0.781
Female	5,288	29 / 2,640 (1.1%)	36 / 2,648 (1.4%)	0.81 (0.50 to 1.33)	
Diabetes					
Yes	6,040	45 / 3,036 (1.5%)	60 / 3,004 (2.0%)	0.75 (0.51 to 1.10)	0.330
No	18,092	100 / 9,044 (1.1%)	106 / 9,048 (1.2%)	0.94 (0.72 to 1.24)	
Current smoker					
Yes	6,411	28 / 3,161 (0.9%)	43 / 3,250 (1.3%)	0.64 (0.40 to 1.03)	0.166
No	17,903	118 / 9,014 (1.3%)	124 / 8,889 (1.4%)	0.95 (0.74 to 1.22)	
Peripheral artery disease					
Bleeding risk					
PRECISE DAPT < 25	11,581	66 / 5,803 (1.1%)	60 / 5,778 (1.0%)	1.08 (0.76 to 1.54)	0.229
PRECISE DAPT ≥ 25	2,500	30 / 1,240 (2.4%)	42 / 1,260 (3.3%)	0.75 (0.47 to 1.19)	
Use of proton pump inhibitors					
Yes	5,761	49 / 2,866 (1.7%)	50 / 2,895 (1.7%)	1.00 (0.68 to 1.49)	0.478
No	18,380	96 / 9,218 (1.0%)	116 / 9,162 (1.3%)	0.83 (0.63 to 1.08)	
BMI					
< 25 kg/m²	8,268	47 / 4,127 (1.1%)	73 / 4,141 (1.8%)	0.65 (0.45 to 0.94)	0.120
25 kg/m² ≤ BMI < 30 kg/m²	10,731	66 / 5,383 (1.2%)	63 / 5,348 (1.2%)	1.05 (0.74 to 1.48)	
≥ 30 kg/m²	4,769	30 / 2,391 (1.3%)	27 / 2,378 (1.1%)	1.08 (0.64 to 1.82)	
Region					
Asia	5,770	34 / 2,876 (1.2%)	55 / 2,894 (1.9%)	0.62 (0.41 to 0.95)	0.089
Europe	13,974	92 / 6,997 (1.3%)	85 / 6,977 (1.2%)	1.08 (0.80 to 1.45)	
North America	4,581	20 / 2,305 (0.9%)	27 / 2,276 (1.2%)	0.73 (0.41 to 1.30)	
Type of P2Y12 inhibitor*					
Clopidogrel	15,069	82 / 7,545 (1.1%)	109 / 7,524 (1.4%)	0.75 (0.56 to 1.00)	0.098
Ticagrelor	9,256	64 / 4,633 (1.4%)	58 / 4,623 (1.3%)	1.10 (0.77 to 1.57)	
Aspirin dose**					
High dose	9,447	48 / 4,741 (1.0%)	55 / 4,706 (1.2%)	0.87 (0.59 to 1.27)	0.958
Low dose	14,878	98 / 7,437 (1.3%)	112 / 7,441 (1.5%)	0.88 (0.67 to 1.15)	



Summary and Conclusions (I)

1. HOST EXAM was the first study to compare clopidogrel vs aspirin for secondary prevention in a dedicated PCI population in the contemporary era of high intensity statin

2. Clopidogrel was superior to aspirin for the composite of all-cause death, nonfatal MI, stroke, readmission due to ACS, and BARC type ≥3 bleeding.

3. The benefit of clopidogrel was also observed for the thrombotic composite outcomes as well as any bleeding. Results were consistent in various subgroups

4. Extended follow up (median 5.8yrs) of the HOST EXAM showed continued benefit of clopidogrel over aspirin with no differences in all-cause or cardiovascular mortality.

Summary and Conclusions (II)

5. The PANTHER IPD meta-analysis studied whether P2Y12 inhibitor or aspirin monotherapy should be the standard in chronic mx of CAD patients.

6. P2Y12 inhibitor monotherapy was associated with significantly lower rates of the composite of CV death, MI, stroke, mainly due to lower rates of MI, which resulted in a reduced risk of net adverse clinical events.

7. Major bleeding was similar but GI bleeding and hemorrhagic stroke were lower with P2Y12 inhibitor monotherapy.

8. Based on the HOST EXAM RCT and the PANTHER analysis, it may be reasonable to use clopidogrel over aspirin as chronic antiplt monotherapy in pts with stabilized CAD