ACC.26

Each presenter will have **10 minutes** and each discussion period is **5 minutes.**

10-year Follow-up of Clopidogrel Vs Aspirin Monotherapy in Stable CAD after PCI With Drug-Eluting Stent : HOST-EXAM 10Y

(control number 27857)

Hyo-Soo Kim, MD/PhD. FAHA, FACC, FESC

Cardiovascular Center,

Seoul National University Hospital (SNUHospital, Korea)

AMERICAN COLLEGE of CARDIOLOGY

Disclosures

- *The **HOST-EXAM*** trial,

  (***H***armonizing ***O***ptimal ***S***trategy for ***T***reatment of coronary artery diseases – ***EX***tended ***A***ntiplatelet ***M***onotherapy)

  is an investigator-initiated, randomized, open-label, multicenter trial sponsored by Seoul National University Hospital

- *The **HOST-EXAM*** trial *has received research funds from,*
  - *The Ministry of Health & Welfare, Republic of Korea*
  - *A consortium of four Pharmaceutical Companies*
    - *ChongKunDang, SamJin, HanMi, and DaeWoong*

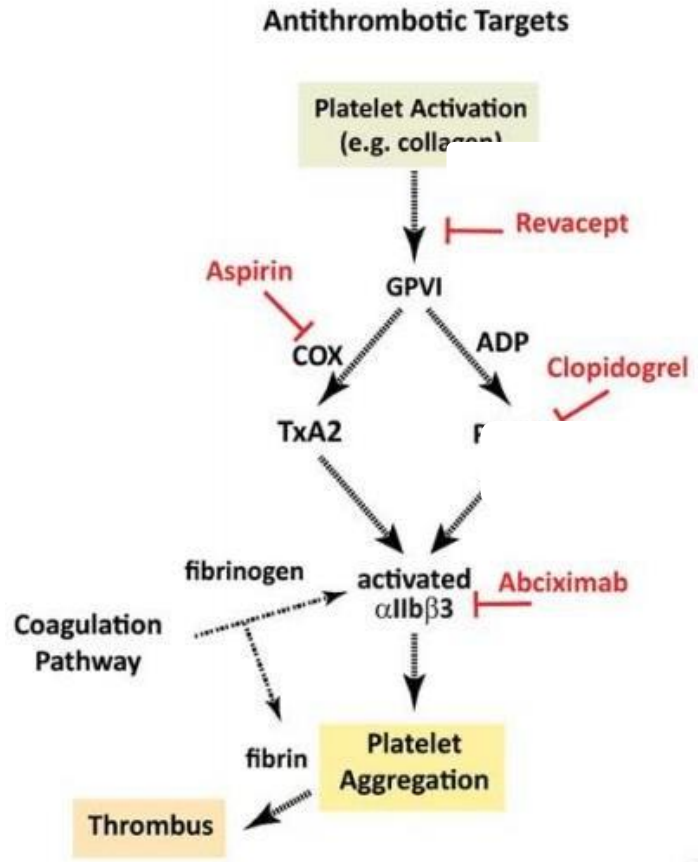
Background around 10 years ago

HOST EXAM
EXtended Antiplatelet Monotherapy

- After PCI (percutaneous coronary intervention), guidelines recommend indefinite maintenance of SAPT (single antiplatelet therapy) after the initial 6- to 12-months of DAPT (dual antiplatelet therapy).
- ***Aspirin*** is the most widely used, standard antiplatelet agent (**Class 1, LOE A**).

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

- ***Clopidogrel*** is recommended as an alternative strategy.
  - Previous trials have shown that clopidogrel may have potential benefits **in patients with atherosclerotic vascular disease**.



- However, no trial has addressed which antiplatelet agent may be the optimal choice during the chronic maintenance period after PCI with DES.

2018 ESC/EACTS Guidelines on myocardial revascularization
2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

Objective

- To compare the efficacy and safety between aspirin versus clopidogrel monotherapy as chronic maintenance therapy in patients who received PCI with a DES.
- **The HOST-EXAM trial**
  - ***H***armonizing ***O***ptimal ***S***trategy for ***T***reatment of coronary artery diseases
  - – ***EX***tended ***A***ntiplatelet ***M***onotherapy

Working Hypothesis

In the chronic maintenance period after PCI,
Clopidogrel will be superior to Aspirin,
In terms of patient oriented composite outcomes (POCO)

Lancet 2021;397(10293):2487–2496

Endpoints and Sample Size calculation

HOST EXAM
EXtended Antiplatelet Monotherapy

- ***Endpoints***
  - ***Primary Endpoint: POCO (Patient Oriented Composite outcome) at 24 months***
    - All-cause death, nonfatal myocardial infarction, stroke, readmission due to acute coronary syndrome, and major bleeding complications (defined as Bleeding Academic Research Consortium (BARC) type ≥3 bleeding)
  - ***Key Secondary Endpoints***
    - ***Thrombotic composite endpoint***: Cardiac death, nonfatal myocardial infarction, ischemic stroke, readmission due to acute coronary syndrome and stent thrombosis
    - ***Any Bleeding endpoint***: BARC type ≥2 bleeding
- ***Sample size calculation***
  - Assumed 24-month POCO in the aspirin monotherapy group: 12.0%
  - Assumed 24-month POCO in the clopidogrel monotherapy group: 9.6%
  - Type I error: 0.05, Power: 80%
  - Estimated withdrawal rate: 5%

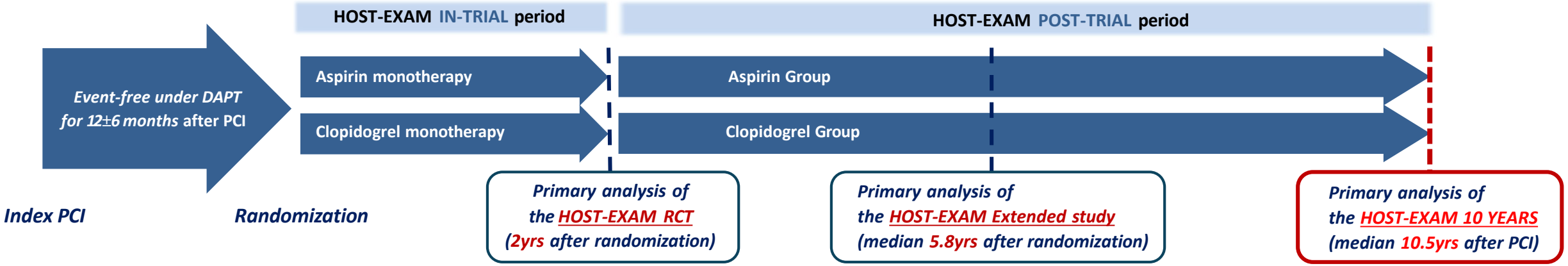
A total of 5,530 patients was needed to prove superiority of clopidogrel

Lancet 2021;397(10293):2487–2496

Study Design

HOST EXAM
EXtended Antiplatelet Monotherapy

- ***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

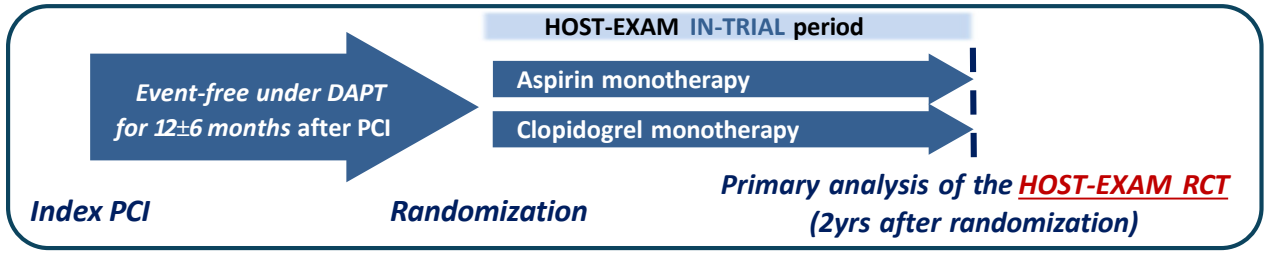
Exclusion Criteria

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

Lancet 2021;397(10293):2487–2496
Circulation 2023;147(2):108-117

Trial Flow 2yrs after randomization

HOST EXAM
EXtended Antiplatelet Monotherapy



5530 patients enrolled

92 patients excluded from randomization
50 did not meet the eligibility criteria
28 declined participation
14 randomization error

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

F/U 2,669 (98.5%) for 2 years & Per-protocol 2,648 (97.7%)

2,728 patients enrolled in the Aspirin monotherapy group

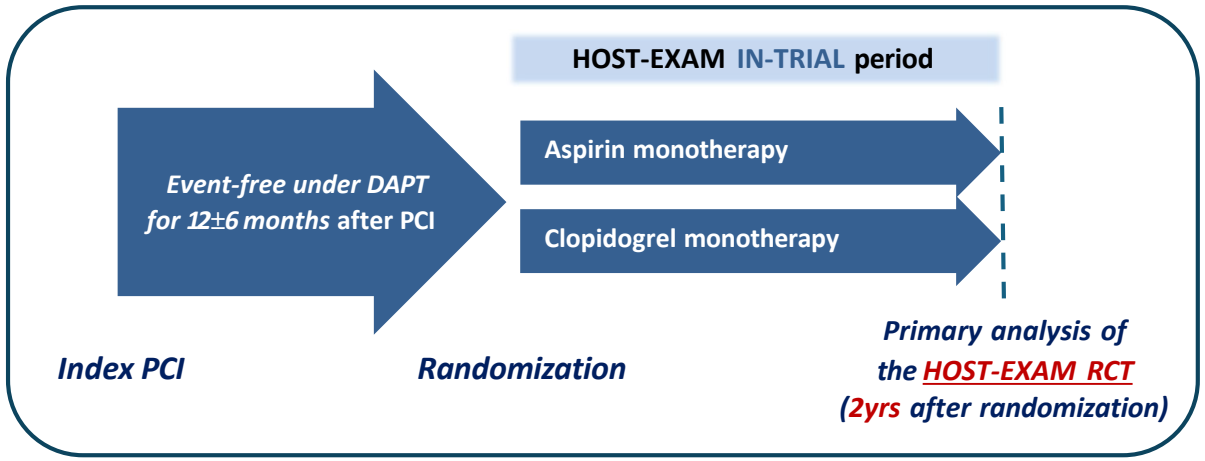
73 patients excluded for Per protocol analysis
1 withdrew consent
50 were lost to follow up
22 did not receive allocated antiplatelet agent

F/U 2,678 (98.2%) for 2 years & Per-protocol 2,655 (97.3%)

Lancet 2021;397(10293):2487–2496

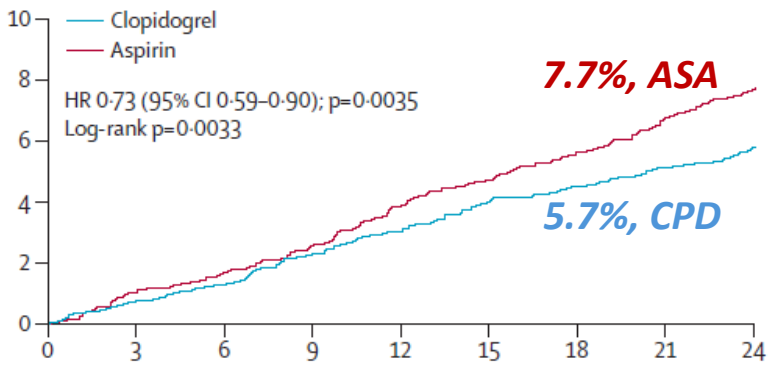
HOST-EXAM 2yrs after randomization; Intention-to-treat

HOST EXAM
EXtended Antiplatelet Monotherapy

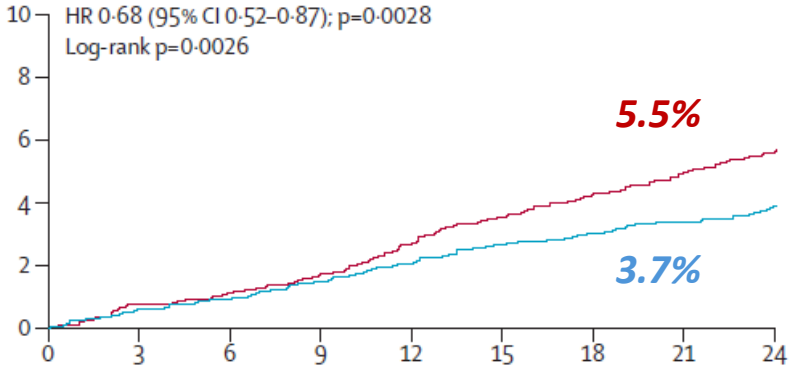


	Clopidogrel (n=2710)	Aspirin (n=2728)	Hazard ratio (95% CI)*	p value
Primary composite endpoint†	152 (5·7%)	207 (7·7%)	0·73 (0·59–0·90)	0·003
Thrombotic composite endpoint‡	99 (3·7%)	146 (5·5%)	0·68 (0·52–0·87)	0·003
Any bleeding (BARC type ≥2)§	61 (2·3%)	87 (3·3%)	0·70 (0·51–0·98)	0·036

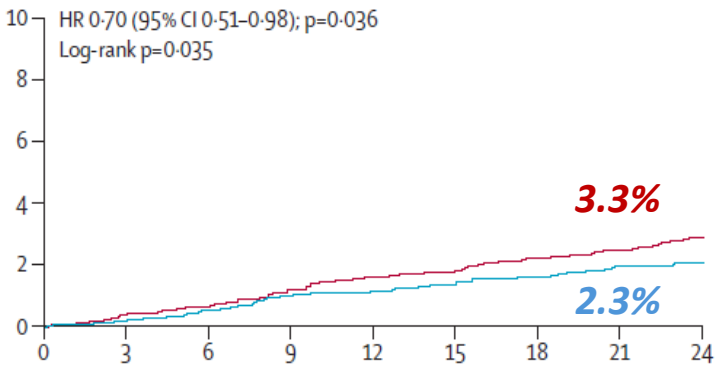
<Patient Oriented Composite outcome>



<Thrombotic outcome>



<Bleeding outcome>



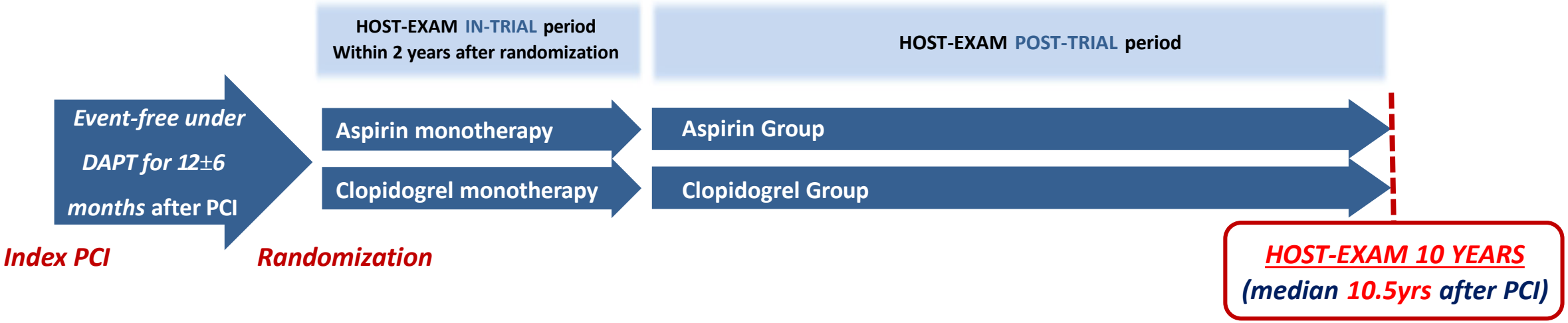
Lancet 2021;397(10293):2487–2496

HOST-EXAM 10 YEAR RESULT

10-year follow-up of the HOST-EXAM Study

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

- **5,530 eligible patients screened, from 37 centers in Korea during March 26, 2014 to May 29, 2018**



- **Median duration**
  10.5 yrs after PCI (interquartile range, 9.4 & 11.4 yrs)
  10.7 yrs after PCI (interquartile range, 9.8 & 11.·5 yrs) **in survivors**

10-year follow-up of the HOST-EXAM Study

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

5530 patients enrolled

92 patients excluded from randomization
50 did not meet the eligibility criteria
28 declined participation
14 randomization error

5438 patients successfully randomized

2,710 patients
Clopidogrel monotherapy group

2,728 patients
Aspirin monotherapy group

62 patients excluded for Per protocol analysis
8 withdrew consent
41 were lost to follow up
13 used a different antiplatelet regimen

HOST-EXAM IN-TRIAL period
Within 2 years

73 patients excluded for Per protocol analysis
1 withdrew consent
50 were lost to follow up
22 used a different antiplatelet regimen

510 patients excluded for Per protocol analysis
173 were lost to follow up
337 used a different antiplatelet regimen
113 aspirin
87 other antiplatelet agent
83 oral anticoagulants
54 no antithrombotic agent

HOST-EXAM POST-TRIAL period
Beyond 2 years till 10 years

614 patients excluded for Per protocol analysis
126 were lost to follow up
488 used a different antiplatelet regimen
276 clopidogrel
105 other antiplatelet agent
76 oral anticoagulants
31 no antithrombotic agent

F/U 2,496 (92.1%) for 10-years
Per-protocol 2,138 (78.9%)

F/U 2,552 (93.5%) for 10-years
Per-protocol 2,041 (74.8%)

Baseline Characteristics

	Clopidogrel (n=2710)	Aspirin (n=2728)
	No. of patients (%)	
Demographic & Comorbidity		
Age	64 (IQR 56, 72)	64 (IQR 56, 72)
Male	74·4% (2015)	74·7% (2039)
Diabetes mellitus	34·1% (925)	34·3% (935)
Insulin dependent DM	2·0% (55)	2·3% (62)
Hypertension	61·4% (1664)	61·4% (1674)
Dyslipidemia	69·5% (1884)	69·0% (1883)
Current smoker	20·1% (545)	21·3% (581)
Chronic kidney disease	13·1% (356)	12·4% (337)
Previous MI	16·1% (437)	15·9% (435)
Previous CVA	4·4% (120)	4·9% (133)
Clinical Indication of PCI		
Silent ischemia	2·1% (58)	2·6% (70)
Stable angina	25·4% (688)	25·7% (701)
Unstable angina	36·0% (975)	35·2% (959)
NSTEMI	19·4% (526)	19·4% (528)
STEMI	17·1% (463)	17·2% (470)

	Clopidogrel (n=2710)	Aspirin (n=2728)
	No. of patients (%)	
Laboratory results		
White blood cells – /uL	6·7 ± 1·9	6·8 ± 1·9
Hemoglobin, – g/dL	13·7 ± 1·7	13·8 ± 1·6
Creatinine – mg/dL	1·0 ± 0·7	1·0 ± 0·7
Total cholesterol – mg/dL	136·8 ± 29·8	138·2 ± 30·5
Triglyceride – mg/dL	126·8 ± 86·5	125·2 ± 70·8
HDL-cholesterol – mg/dL	46·3 ± 12·0	46·5 ± 12·2
LDL-cholesterol – mg/dL	70·7 ± 23·7	72·1 ± 23·2
HbA1c – %	6·5 ± 1·1	6·5 ± 1·2
Days (PCI to Randomization)	383 (357-424)	380 (358-421)
DAPT at Randomization Point		
Aspirin + Clopidogrel	81·8% (2218)	81·1% (2212)
Aspirin + Ticagrelor	9·8% (266)	9·8% (268)
Aspirin + Prasugrel	7·8% (212)	8·6% (235)
Aspirin + Clopidogrel + Cilostazol	0·5% (14)	0·5% (13)

Baseline Characteristics - continued

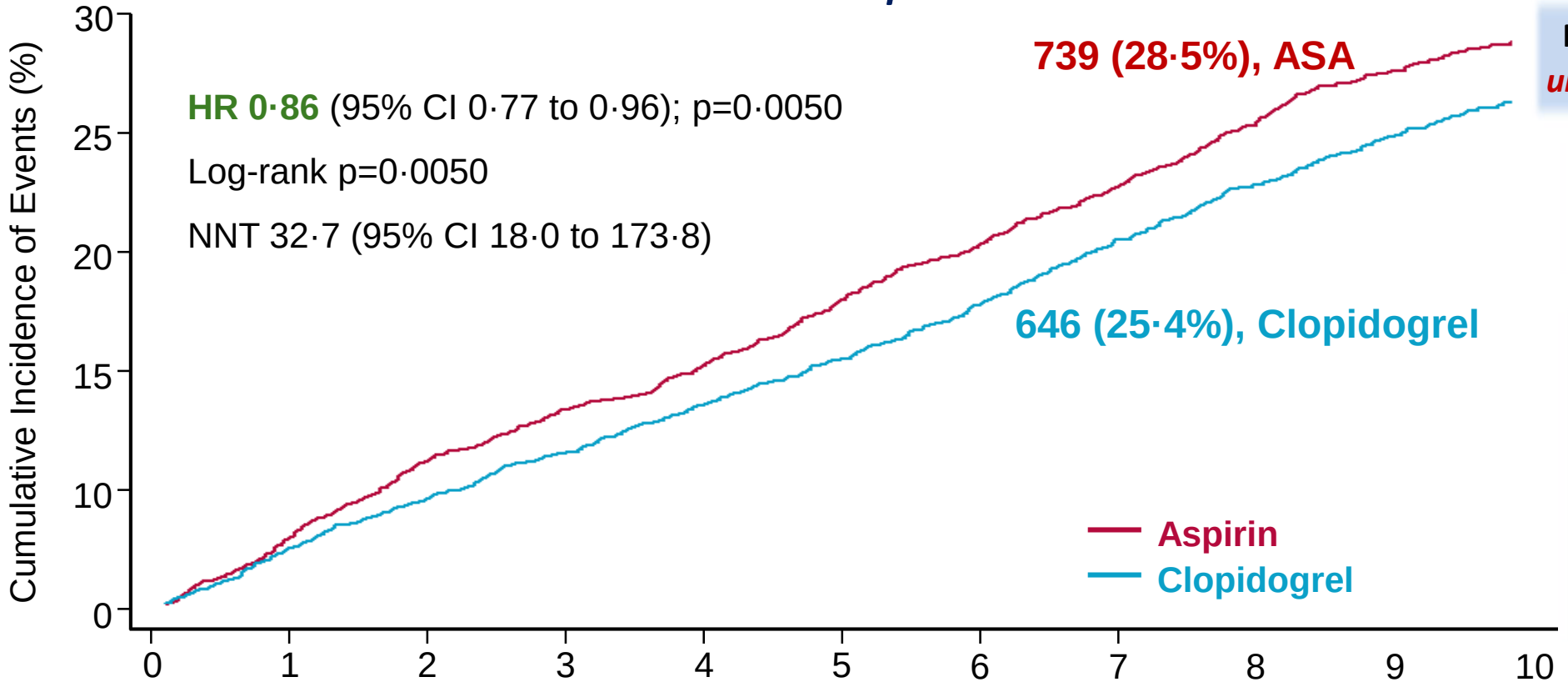
HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

	Clopidogrel (n=2710)	Aspirin (n=2728)
	No. of patients (%)	
Extent of CAD		
1-vessel disease	50·4% (1367)	50·4% (1376)
2-vessel disease	31·5% (855)	30·9% (844)
3-vessel disease	18·0% (488)	18·6% (507)
Left main disease	5·2% (142)	4·8% (130)
PCI for bifurcation lesion	10·5% (285)	10·8% (295)
2-stenting for bifurcation PCI	1·7% (46)	1·5% (42)
PCI for CTO lesion	9·5% (257)	9·3% (254)
Number of treated lesions	1·3 ± 0·6	1·3 ± 0·6
Mean diameter of implanted stents	3·1 ± 0·4	3·1 ± 0·4
Minimum diameter of implanted stents	3·0 ± 0·5	3·0 ± 0·5
Total length of implanted stents	36·1 ± 24·2	35·7 ± 23·6
Total number of implanted stents	1·5 ± 0·8	1·5 ± 0·8
Generation of DES		
1st generation DES	2·0% (54)	1·9% (52)
2nd generation DES	96·9% (2627)	97·2% (2651)
Unknown generation	1·1% (29)	0·9% (25)

10-year follow-up of the HOST-EXAM Study; Intention-to-treat

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

<Patient Oriented Composite outcome>



Number at Risk

Aspirin	2728	2621	2516	2442	2383	2290	2217	2138	1834	1352	779
Clopidogrel	2710	2625	2552	2481	2412	2345	2267	2187	1880	1410	820

Number needed to treat, NNT
under intention-to-treat analysis

Randomization

HOST-EXAM IN-TRIAL period

HOST-EXAM 2 years
NNT 51

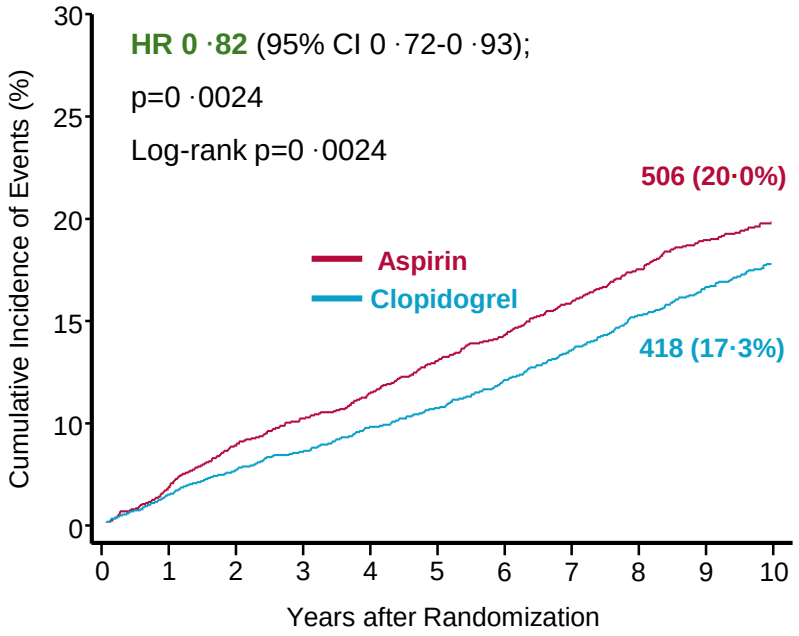
HOST-EXAM POST-TRIAL period

HOST-EXAM 10 years
NNT 33

10-year follow-up of the HOST-EXAM Study; Intention-to-treat

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

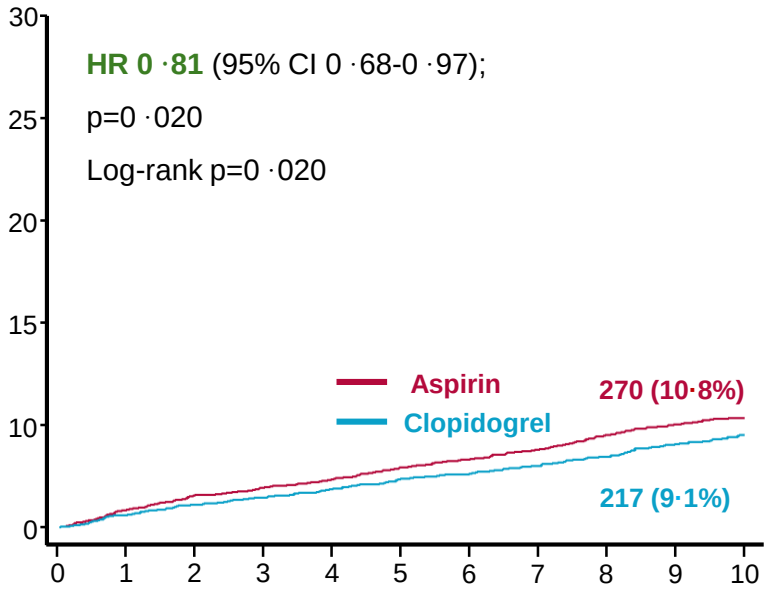
<Thrombotic outcome>



Number at Risk

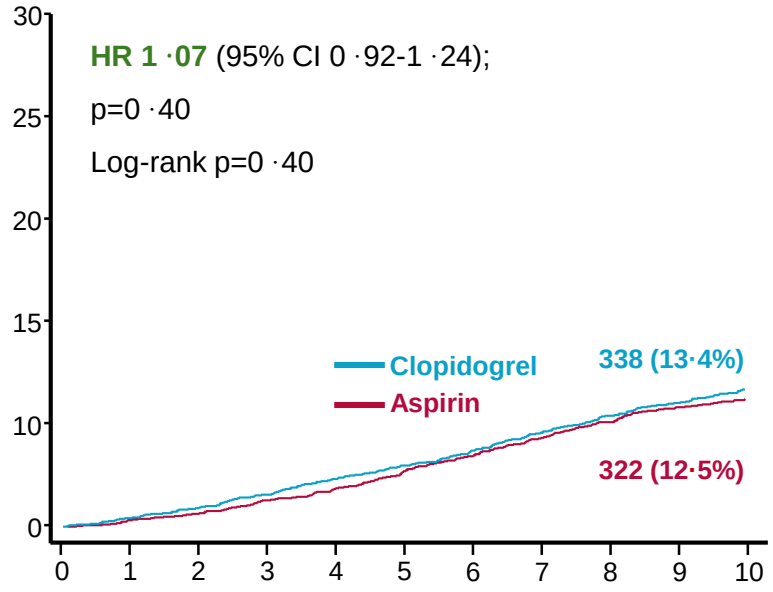
Aspirin	2728	2644	2554	2489	2431	2349	2286	2215	1920	1428	828
Clopidogrel	2710	2641	2575	2516	2452	2393	2324	2252	1939	1458	843

<Bleeding outcome>



	2728	2663	2609	2555	2510	2442	2392	2328	2022	1529	888
	2710	2649	2600	2543	2483	2422	2368	2307	2022	1533	902

<All-cause death>



	2728	2707	2687	2645	2614	2562	2521	2473	2185	1670	977
	2710	2681	2653	2609	2563	2517	2473	2427	2138	1642	976

10-year clinical outcomes of HOST-EXAM Study; Intention-to-treat

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

	Clopidogrel (n=2710)	Aspirin (n=2728)	Hazard Ratio (95% CI)	P value	Absolute risk reduction (95% CI)
	No. of patients (%)				
Primary composite endpoint	**646 (25·4%)**	**739 (28·5%)**	**0·86 (0·77-0·96)**	0·005	3·1 (0·6,5·6)
Thrombotic composite endpoint	**418 (17·3%)**	**506 (20·0%)**	**0·82 (0·72-0·93)**	0·002	2·8 (0·6, 5·0)
Any bleeding (BARC type ≥2	**217 (9·1%)**	**270 (10·8%)**	**0·81 (0·68-0·97)**	0·020	1·7 (0·0, 3·4)
All-cause death	338 (13·4%)	322 (12·5%)	1·07 (0·92-1·24)	0·399	-0·9 (-2·8, 0·9)
Cardiac death	167 (7·1%)	171 (6·9%)	0·99 (0·80-1·23)	0·953	-0·1 (-1·6, 1·4)
Non-cardiac death	171 (6·9%)	151 (6·0%)	1·15 (0·93-1·43)	0·205	-0·9 (-2·3, 0·5)
Non-fatal myocardial infarction	85 (3·6%)	105 (4·2%)	0·82 (0·62-1·09)	0·168	0·6 (-0·5, 1·7)
Stroke	**110 (4·6%)**	**154 (6·4%)**	**0·72 (0·56-0·92)**	0·008	1·8 (0·4, 3·1)
Ischemic stroke	85 (3·6%)	104 (4·%)	0·81 (0·61-1·08)	0·159	0·8 (-0·4, 1·9)
Hemorrhagic stroke	25 (1·0%)	50 (2·1%)	0·50 (0·31-0·81)	0·005	1·1 (0·4, 1·8)
Readmission due to ACS	208 (8·7%)	277 (11·0%)	0·75 (0·63-0·90)	0·002	2·3 (0·6, 4·0)
PCI	157 (6·8%)	207 (8·5%)	0·76 (0·62-0·93)	0·008	1·7 (0·1, 3·2)
CABG	5 (0·2%)	8 (0·3%)	0·62 (0·20-1·90)	0·405	0·1 (-0·2, 0·4)
Medical treatment	46 (1·8%)	62 (2·4%)	0·74 (0·51-1·09)	0·126	0·6 (-0·2, 1·4)
Major bleeding (BARC type ≥3)	**133 (5·6%)**	**190 (7·7%)**	**0·71 (0·57-0·88)**	0·002	2·1 (0·7, 3·5)

Subgroup analysis of *HOST-EXAM 10Y;* Intention-to-treat

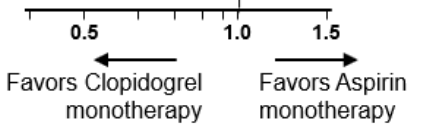
HOST EXAM
EXtended Antiplatelet Monotherapy

<Patient Oriented Composite outcome>

	Clopidogrel group (events/patients)	Aspirin group (events/patients)	Hazard Ratio (95% CI)	P value	Interaction P
Age (years)					
≥65	410/1177	459/1186	0·88 (0·77-1·00)	0·056	0·596
<65	236/1534	280/1541	0·83 (0·70-0·98)	0·034	
Sex					
Male	471/2015	523/2039	0·89 (0·79-1·01)	0·068	0·295
Female	175/695	216/689	0·78 (0·64-0·96)	0·017	
Body Mass Index ≥ 25 kg/m^2					
Yes	245/1221	288/1178	0·80 (0·68-0·95)	0·011	0·214
No	376/1390	415/1445	0·92 (0·80-1·06)	0·259	
Acute Myocardial Infarction					
Yes	236/989	260/998	0·90 (0·76-1·08)	0·258	0·494
No	410/1721	479/1730	0·84 (0·73-0·95)	0·008	
Acute Coronary Syndrome					
Yes	471/1964	511/1957	0·90 (0·80-1·02)	0·105	0·171
No	228/746	175/771	0·77 (0·63-0·93)	0·008	
Multivessel Disease					
Yes	369/1343	412/1352	0·88 (0·76-1·01)	0·068	0·676
No	277/1367	326/1376	0·84 (0·71-0·98)	0·031	
Diabetes Mellitus					
Yes	265/935	305/925	0·85 (0·72-1·00)	0·054	0·869
No	382/1785	434/1793	0·87 (0·75-0·99)	0·040	
Chronic Kidney Disease					
Yes	136/356	174/337	0·69 (0·55-0·87)	0·001	0·041
No	510/2354	565/2391	0·90 (0·80-1·01)	0·083	
Proton Pump Inhibitor					
Yes	80/290	110/331	0·80 (0·60-1·07)	0·126	0·568
No	566/2420	629/2397	0·87 (0·78-0·98)	0·019	
Complex PCI					
Yes	145/598	184/595	0·74 (0·60-0·92)	0·007	0·127
No	498/2091	551/2114	0·90 (0·80-1·02)	0·090	
High Bleeding Risk					
Yes	219/521	231/467	0·79 (0·66-0·95)	0·013	0·194
No	355/1800	385/1832	0·93 (0·80-1·07)	0·309	

< Thrombotic outcome >

	Clopidogrel group (events/patients)	Aspirin group (events/patients)	Hazard Ratio (95% CI)	P value	Interaction P
Age (years)					
≥65	241/1177	291/1186	0.82 (0.69-0.97)	0.022	0.97
<65	177/1534	215/1541	0.82 (0.67-0.99)	0.045	
Sex					
Male	298/2015	368/2039	0.81 (0.69-0.94)	0.0054	0.70
Female	120/695	138/689	0.85 (0.67-1.09)	0.20	
Body Mass Index ≥ 25 kg/m^2					
Yes	161/1221	211/1178	0.72 (0.58-0.88)	0.0015	0.091
No	239/1390	273/1445	0.90 (0.76-1.08)	0.26	
Acute Myocardial Infarction					
Yes	157/989	185/998	0.85 (0.69-1.05)	0.13	0.66
No	261/1721	321/1730	0.80 (0.68-0.94)	0.0076	
Acute Coronary Syndrome					
Yes	312/1964	360/1957	0.85 (0.73-0.99)	0.036	0.30
No	109/746	144/771	0.73 (0.57-0.94)	0.0014	
Multivessel Disease					
Yes	229/1343	287/1352	0.78 (0.66-0.93)	0.0064	0.49
No	189/1367	219/1376	0.86 (0.71-1.05)	0.13	
Diabetes Mellitus					
Yes	174/935	202/925	0.85 (0.69-1.04)	0.11	0.66
No	244/1785	304/1793	0.80 (0.67-0.94)	0.0088	
Chronic Kidney Disease					
Yes	83/356	102/337	0.72 (0.54-0.97)	0.029	0.39
No	335/2354	404/2391	0.83 (0.72-0.96)	0.013	
Proton Pump Inhibitor					
Yes	52/290	72/331	0.79 (0.55-1.12)	0.19	0.79
No	366/2420	432/2397	0.83 (0.72-0.95)	0.0074	
Complex PCI					
Yes	90/598	128/595	0.66 (0.50-0.86)	0.0025	0.087
No	325/2091	379/2114	0.87 (0.75-1.01)	0.058	
High Bleeding rRisk					
Yes	126/521	135/467	0.80 (0.62-1.01)	0.065	0.71
No	238/1800	285/1832	0.85 (0.71-1.00)	0.056	

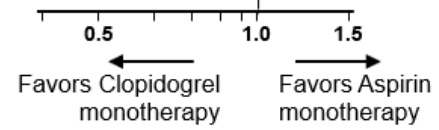


Subgroup analysis of *HOST-EXAM 10Y;* Intention-to-treat

HOST EXAM
EXtended Antiplatelet Monotherapy

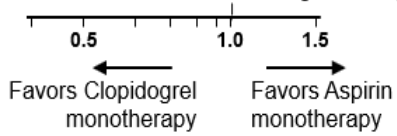
< Bleeding outcome >

	Clopidogrel group (events/patients)	Aspirin group (events/patients)	Hazard Ratio (95% CI)	P value	Interaction P
Age (years)					
≥65	128/1177	174/1186	0.75 (0.59-0.94)	0.012	0.26
<65	89/1534	97/1541	0.92 (0.69-1.23)	0.58	
Sex					
Male	161/2015	186/2039	0.87 (0.71-1.08)	0.22	0.17
Female	56/695	84/689	0.66 (0.47-0.93)	0.017	
Body Mass Index ≥ 25 kg/m^2					
Yes	98/1221	96/1178	0.99 (0.75-1.31)	0.93	0.086
No	112/1390	163/1445	0.71 (0.56-0.91)	0.0059	
Acute Myocardial Infarction					
Yes	81/989	92/998	0.90 (0.67-1.22)	0.50	0.36
No	136/1721	178/1730	0.76 (0.61-0.95)	0.016	
Acute Coronary Syndrome					
Yes	152/1964	186/1957	0.82 (0.66-1.02)	0.069	0.82
No	65/746	85/771	0.78 (0.57-1.08)	0.12	
Multivessel Disease					
Yes	116/1343	149/1352	0.78 (0.61-0.99)	0.049	0.67
No	101/1367	120/1376	0.85 (0.65-1.10)	0.22	
Diabetes Mellitus					
Yes	84/935	108/925	0.78 (0.59-1.04)	0.092	0.77
No	133/1785	164/1793	0.83 (0.66-1.04)	0.10	
Chronic Kidney Disease					
Yes	41/356	60/337	0.64 (0.43-0.95)	0.027	0.20
No	212/2354	176/2391	0.85 (0.70-1.04)	0.12	
Proton Pump Inhibitor					
Yes	30/290	48/331	0.72 (0.46-1.14)	0.16	0.58
No	187/2420	223/2397	0.83 (0.68-1.01)	0.063	
Complex PCI					
Yes	50/598	63/595	0.78 (0.54-1.13)	0.19	0.83
No	165/2091	207/2114	0.82 (0.67-1.00)	0.053	
High Bleeding rRisk					
Yes	76/521	85/467	0.78 (0.57-1.06)	0.11	0.99
No	110/1800	144/1832	0.78 (0.61-1.00)	0.051	



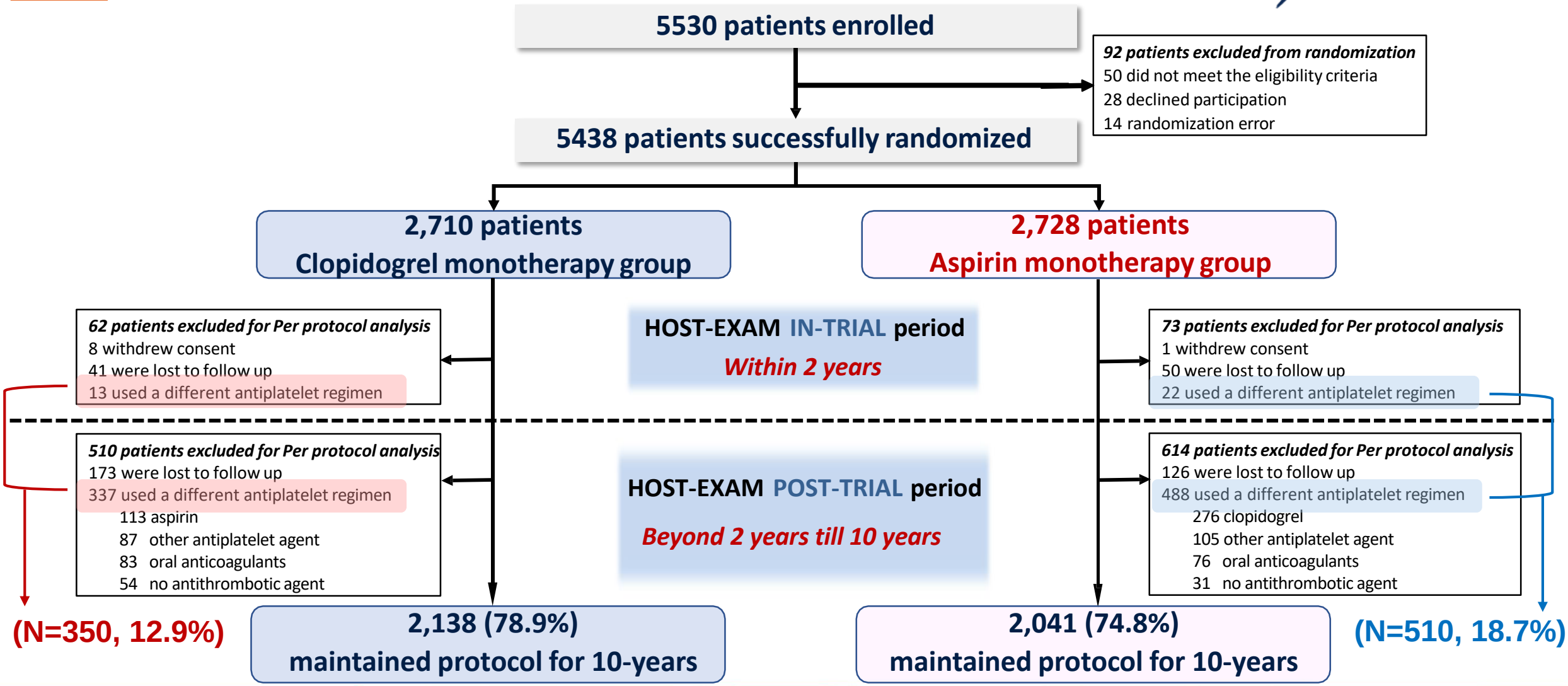
< All-cause death >

	Clopidogrel group (events/patients)	Aspirin group (events/patients)	Hazard Ratio (95% CI)	P value	Interaction P
Age (years)					
≥65	278/1177	258/1186	1.12 (0.94-1.33)	0.19	0.31
<65	66/1534	72/1541	0.92 (0.66-1.29)	0.64	
Sex					
Male	239/2015	228/2039	1.07 (0.89-1.28)	0.49	0.98
Female	102/695	95/689	1.07 (0.81-1.42)	0.63	
Body Mass Index ≥ 25 kg/m^2					
Yes	104/1221	102/1178	0.99 (0.75-1.30)	0.93	0.37
No	223/1390	206/1445	1.15 (0.95-1.40)	0.15	
Acute Myocardial Infarction					
Yes	131/989	115/998	1.17 (0.91-1.51)	0.21	0.36
No	212/1721	214/1730	1.01 (0.83-1.23)	0.92	
Acute Coronary Syndrome					
Yes	247/1964	210/1957	1.19 (0.99-1.43)	0.064	0.039
No	91/746	112/771	0.84 (0.64-1.11)	0.22	
Multivessel Disease					
Yes	207/1343	199/1352	1.08 (0.89-1.32)	0.42	0.82
No	138/1367	132/1376	1.05 (0.83-1.34)	0.67	
Diabetes Mellitus					
Yes	137/935	151/925	0.92 (0.73-1.16)	0.47	0.089
No	206/1785	178/1793	1.20 (0.98-1.47)	0.080	
Chronic Kidney Disease					
Yes	101/356	117/337	0.83 (0.63-1.09)	0.17	0.036
No	244/2354	214/2391	1.17 (0.97-1.41)	0.089	
Proton Pump Inhibitor					
Yes	38/290	53/331	0.86 (0.56-1.30)	0.48	0.27
No	307/2420	278/2397	1.11 (0.94-1.31)	0.22	
Complex PCI					
Yes	81/598	90/595	0.88 (0.65-1.19)	0.42	0.14
No	264/2091	237/2114	1.15 (0.96-1.37)	0.13	
High Bleeding Risk					
Yes	156/521	161/467	0.88 (0.70-1.09)	0.25	0.0031
No	155/1800	111/1832	1.45 (1.13-1.86)	0.0032	



10-year follow-up of the HOST-EXAM Study; Per-protocol

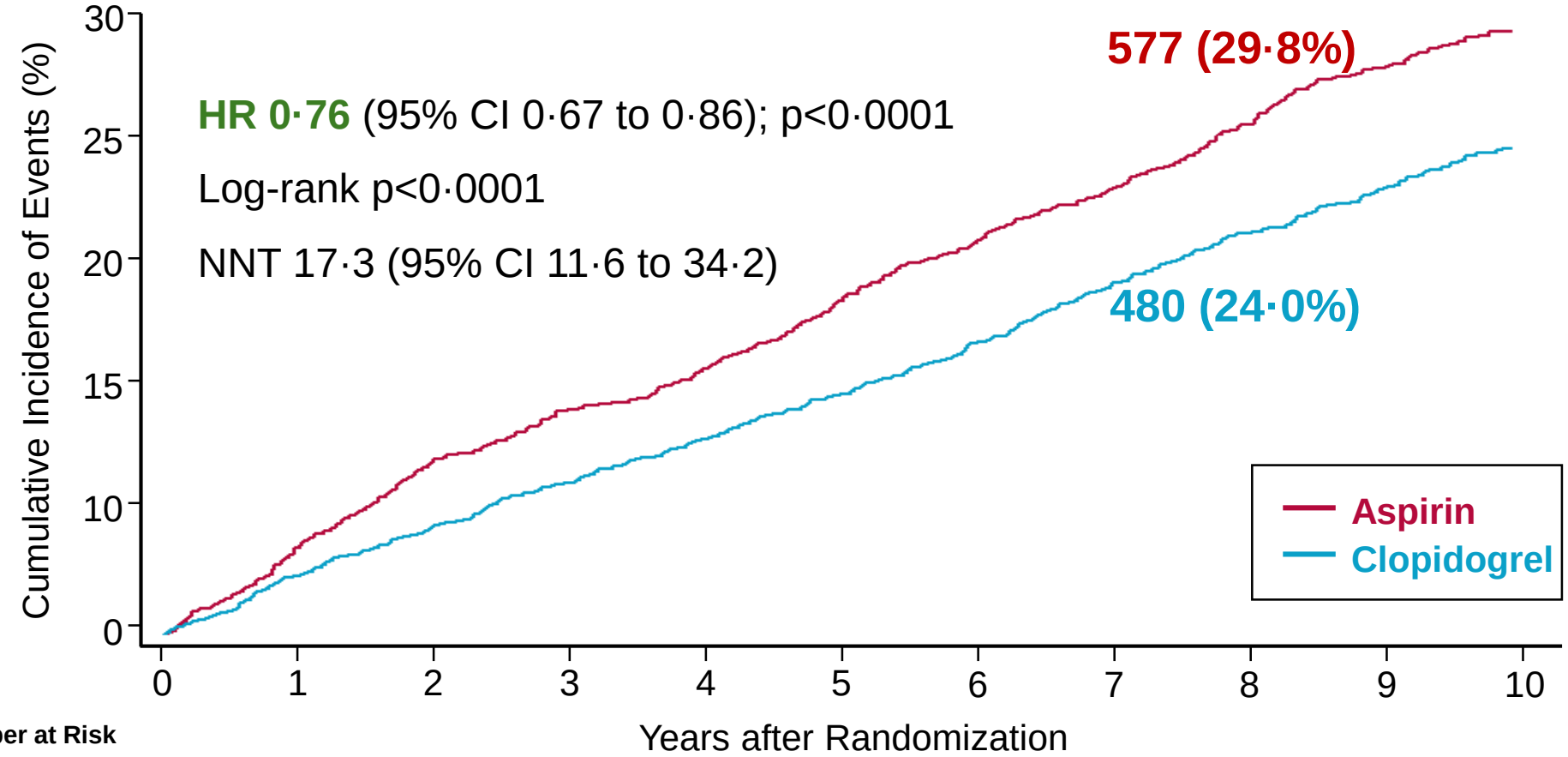
HOST EXAM 10Y
EXtended Antiplatelet Monotherapy



10-year follow-up of the HOST-EXAM Study; Per-protocol

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

<Patient Oriented Composite outcome>



Number at Risk

Aspirin	2041	1953	1865	1808	1768	1695	1638	1584	1353	971	551
Clopidogrel	2138	22075	2021	1963	1913	1864	1805	1749	1503	1137	660

NNT (Number needed to treat)

Per-protocol analysis

Randomization

HOST-EXAM IN-TRIAL period

HOST-EXAM 2y

NNT 45·0

HOST-EXAM POST-TRIAL period

HOST-EXAM Extended 5.8y

NNT 24·0

HOST-EXAM 10 YEARS

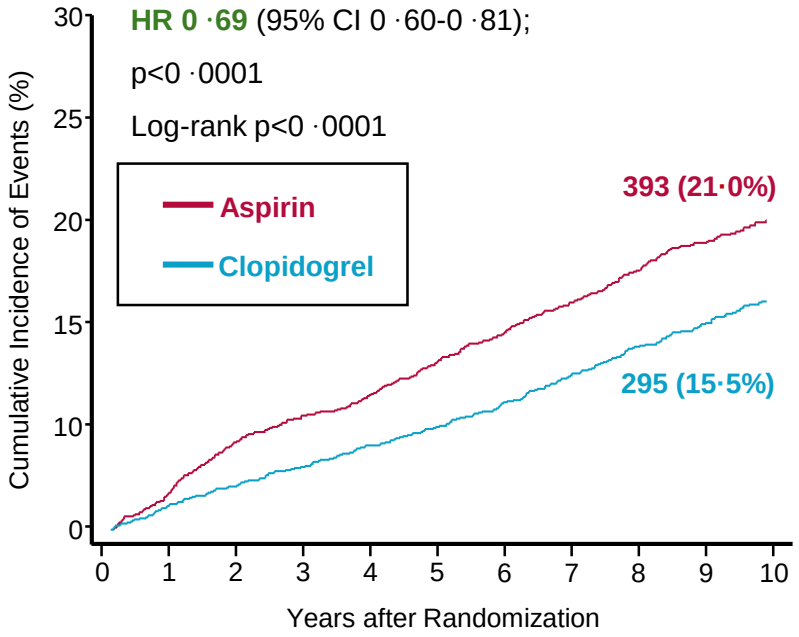
NNT 17·3

ACC.26

10-year follow-up of the HOST-EXAM Study; Per-protocol

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

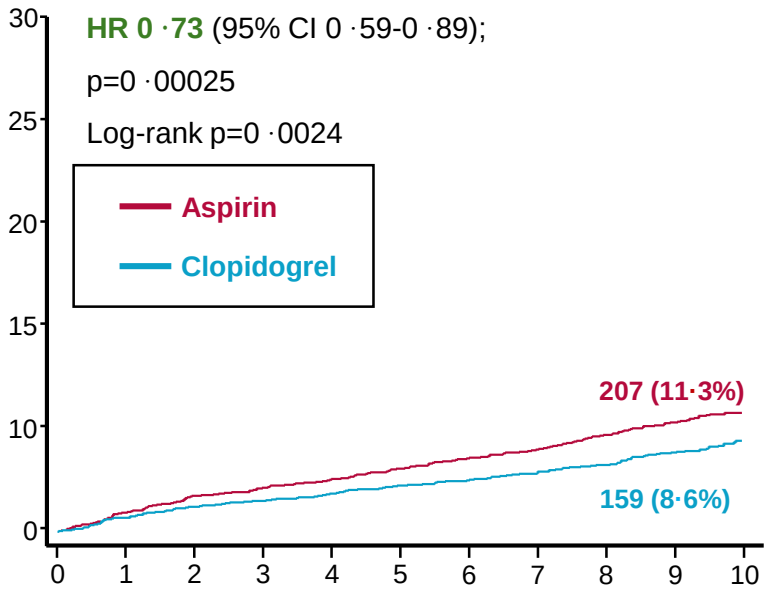
<Thrombotic outcome>



Number at Risk

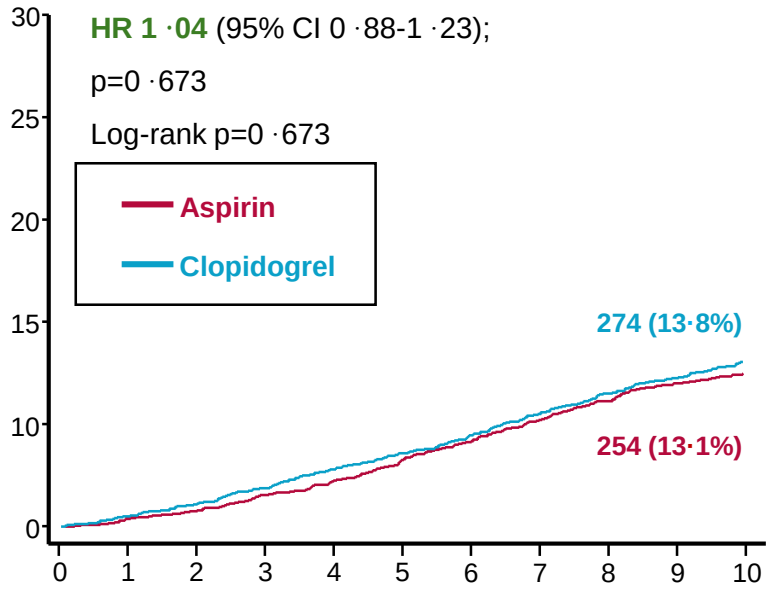
Aspirin	2041	1971	1893	1844	1805	1740	1692	1641	1420	1033	592
Clopidogrel	2138	2087	2038	1989	1944	1902	1848	1796	1544	1171	679

<Bleeding outcome>



	2041	1989	1944	1901	1866	1815	1778	1733	1497	1106	631
	2138	2088	2044	1997	1953	1911	1871	1826	1595	1216	705

<All-cause death>



	2041	2023	2006	1970	1945	1905	1877	1840	1622	1217	707
	2138	2114	2087	2048	2011	1978	1945	1910	1675	1292	761

10-year clinical outcomes of HOST-EXAM Study; Per-protocol

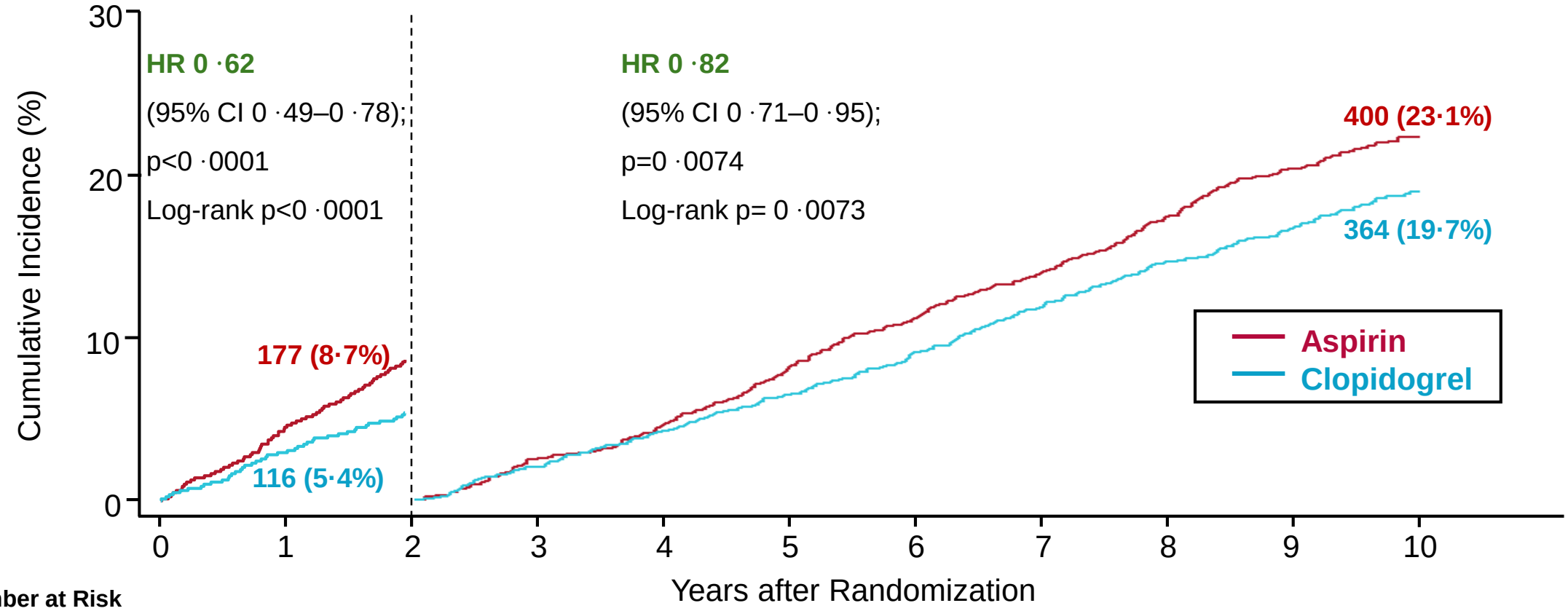
HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

	Clopidogrel (n=2138)	Aspirin (n=2041)	Hazard Ratio (95% CI)	P value	Absolute risk reduction (95% CI)
	No. of patients (%)				
Primary composite endpoint	**480 (24·0%)**	**577 (29·8%)**	**0·76 (0·67-0·86)**	< 0·001	5.8 (2.9, 8.6)
Thrombotic composite endpoint	**295 (15·5%)**	**393 (21·0%)**	**0·69 (0·60-0·81)**	< 0·001	5.5 (3.0, 8.0)
Any bleeding (BARC type ≥2	**159 (8·6%)**	**207 (11·3%)**	**0·73 (0·59-0·89)**	0·003	2.7 (0.7, 4.7)
All-cause death	274 (13·8%)	254 (13·1%)	1·04 (0·88-1·23)	0·673	0.7 (-2.9, 1.5)
Cardiac death	132 (7·1%)	136 (7·4%)	0·93 (0·73-1·19)	0·571	0.4 (-1.4, 2.1)
Non-cardiac death	142 (7·3%)	118 (6·2%)	1·16 (0·91-1·48)	0·240	-1.1 (-2.7, 0.5)
Non-fatal myocardial infarction	53 (3·0%)	87 (4·8%)	0·58 (0·41-0·81)	0·002	1.8 (0.5, 3.1)
Stroke	**66 (3.6%)**	**119 (6.7%)**	**0·52 (0·39-0·71)**	< 0·001	3.1 (1.7, 4.6)
Ischemic stroke	51 (2.8%)	80 (4.5%)	0·60 (0·42-0·86)	0·005	1.7 (0.5, 3.0)
Hemorrhagic stroke	15 (0.8%)	39 (2.3%)	0·36 (0·20-0·66)	< 0·001	1.5 (0.7, 2.3)
Readmission due to ACS	140 (7.5%)	214 (11.5%)	0·61 (0·50-0·76)	< 0·001	4.0 (2.1, 5.9)
PCI	100 (5.6%)	160 (8.9%)	0·58 (0·46-0·75)	<0·001	3.3 (1.5, 5.0)
CABG	4 (0.2%)	7 (0.4%)	0·53 (0·16-1·82)	0·317	0.2 (-0.2, 0.6)
Medical treatment	36 (1·8%)	47 (2.5%)	0·72 (0·47-1·12)	0·142	0.7 (-0.2, 1.6)
Major bleeding (BARC type ≥3)	**97 (5.3%)**	**148 (8.2%)**	**0·62 (0·48-0·80)**	< 0·001	2.9 (1.2, 4.6)

Landmark analysis at 2yrs till 10yrs; Per-protocol

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

<Patient Oriented Composite outcome>



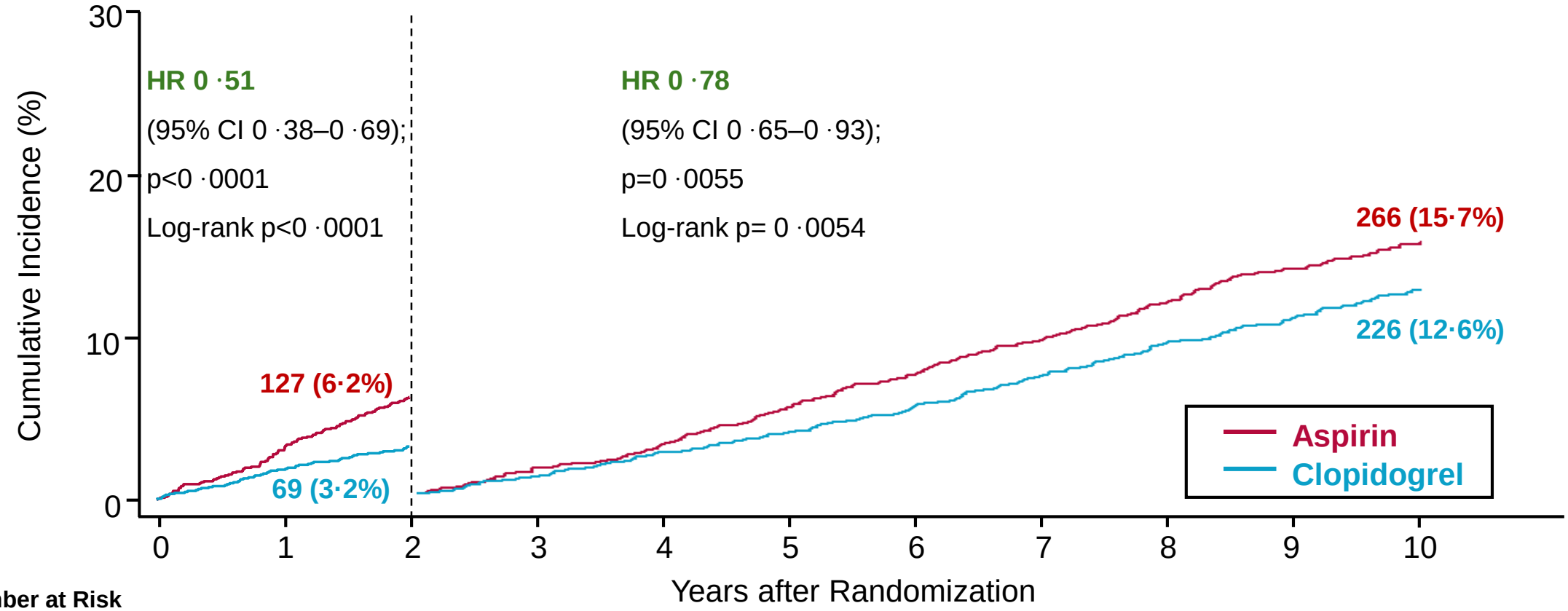
Number at Risk

Aspirin	2041	1953	1865	1808	1768	1695	1638	1584	1353	971	551
Clopidogrel	2138	2075	2021	1963	1913	1864	1805	1749	1503	1137	660

Landmark analysis at 2yrs till 10yrs; Per-protocol

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

<Thrombotic outcome>

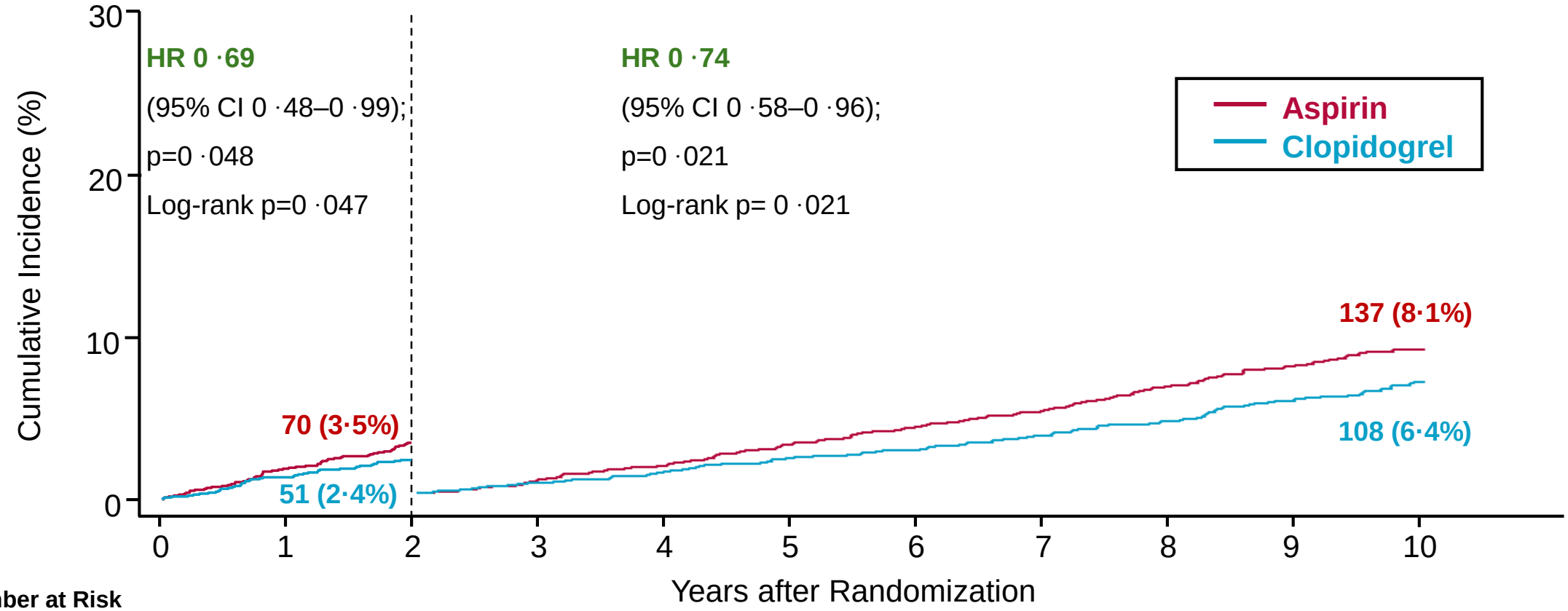


Number at Risk

Aspirin	2041	1971	1893	1844	1805	1740	1692	1641	1420	1033	592
Clopidogrel	2138	2087	2038	1989	1944	1902	1848	1796	1544	1171	679

Landmark analysis at 2yrs till 10yrs; Per-protocol

<Bleeding outcome>



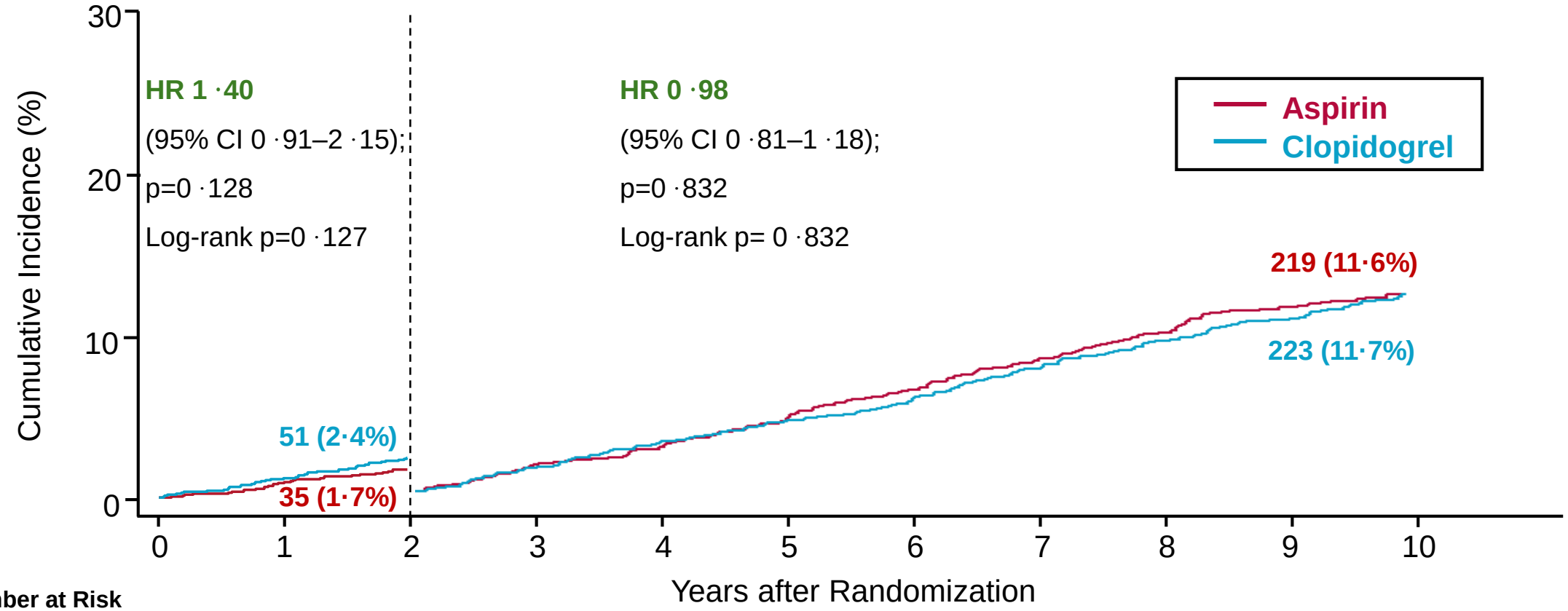
Number at Risk

Aspirin	2041	1989	1944	1901	1866	1815	1778	1733	1497	1106	631
Clopidogrel	2138	2088	2044	1997	1954	1911	1871	1826	1595	1216	705

Landmark analysis at 2yrs till 10yrs; Per-protocol

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

< All-cause death >



Number at Risk

Aspirin	2041	2023	2006	1970	1945	1905	1877	1840	1622	1217	707
Clopidogrel	2138	2114	2087	2048	2011	1978	1945	1910	1675	1292	761

Limitation: HOST-EXAM 10Y

HOST EXAM 10Y
EXtended Antiplatelet Monotherapy

- ✓ ***Extended follow-up of an original RCT***
  - There was no mandatory antiplatelet regimen after the 2-year period
  - The physicians' discretion on antiplatelet selection could have been influenced by multiple factors
- ✓ ***Phenotypic and genetic testing for clopidogrel*** was not performed
  - Despite the high prevalence of LOF mutations of the CYP2C19 gene, thrombotic event rates are lower in East Asians (East Asian paradox)
- ✓ ***Open-label design of the HOST-EXAM*** *introduce* ***bias*** *in the adjudication of certain clinical endpoint*
  - such as 'readmission due to ACS', which may be more susceptible to physician discretion than harder endpoints
- ✓ We did ***not systematically collect data on the temporary discontinuation*** due to urgent or elective invasive procedures which are not related with study
- ✓ ***Adjustment*** of multiple testing and the multiple outcomes ***were not performed***
- ✓ ***Under-representation of female participants (26%)*** may limit the generalizability of the findings to the broader population

Conclusion : HOST-EXAM 10Y

In patients who received ***PCI with a DES*** and

were ***event-free*** under DAPT for 6~18 months after PCI,

- ***Clopidogrel monotherapy*** as compared with ***Aspirin monotherapy*** significantly reduced the risk of the composite of “all-cause death, nonfatal myocardial infarction, stroke, readmission due to ACS, and majore bleeding (BARC type ≥3)” over **10-year follow-up period**
- The beneficial effect of clopidogrel was observed in ***thrombotic composite endpoints*** as well as ***any bleeding endpoint.***
- ***clopidogrel*** *may be considered as the preferred agent for long-term antiplatelet monotherapy* ***during the chronic maintenance phase after PCI.***

Aspirin versus clopidogrel for chronic maintenance monotherapy after percutaneous coronary intervention: 10-year follow-up of the HOST-EXAM trial

Jeehoon Kang, Sungjoon Park*, Han-Mo Yang*, Eun-Seok Shin, Seung-Woon Rha, Jang-Whan Bae, Nam Ho Lee, Hyuck-Jun Yoon, Yoon Haeng Cho, Ung Kim, Song-Yi Kim, Sang-Hyun Kim, Jung-Kyu Han, Kyung Woo Park, Hyo-Soo Kim, on behalf of the HOST-EXAM investigators†*

Summary

Background The long-term clinical outcomes of clopidogrel monother… percutaneous coronary intervention (PCI) remain uncerta… trial to assess the very long-term effects of …

Method… …without clinical events for … mg once daily or aspirin 100 mg once daily. … …ded follow-up of the HOST-EXAM trial. The primary composite e… …cause death, non-fatal myocardial infarction, stroke, readmission due to acute c… …ome, and Bleeding Academic Research Consortium type ≥3 bleeding. The primary analysis was done

Simultaneously published in the Lancet today on March 29th 2026 !