Comparison Of 3-month Versus 12-month Dual Antiplatelet Therapy After Coronary Intervention Using The Contemporary Drug-eluting Stents With Ultrathin Struts And Advanced Polymer Technology:

The HOST-IDEA Randomized Clinical Trial

Hyo-Soo Kim, MD/PhD

Cardiovascular Center,

Seoul National University Hospital, Korea

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Objective

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- The **HOST-IDEA** trial,
  - **H**armonizing **O**ptimal **S**trategy for **T**reatment of coronary artery diseases –coronary **I**ntervention with next-generation **D**rug-**E**luting stent platforms and **A**bbreviated dual antiplatelet therapy
- To compare **SAPT after 3-month DAPT** with **12-month DAPT** in **all-comers** (excluding STEMI patients) undergoing PCI with **third-generation DES with the thinnest struts**.
- We designed this trial to be pragmatic, leaving the DAPT and SAPT regimens at the physician's discretion.

Working Hypothesis

A **3-month DAPT** will be non-inferior compared to the **12-month DAPT** at 1-year after PCI, in terms of the Net adverse clinical event (NACE).

Patient Population

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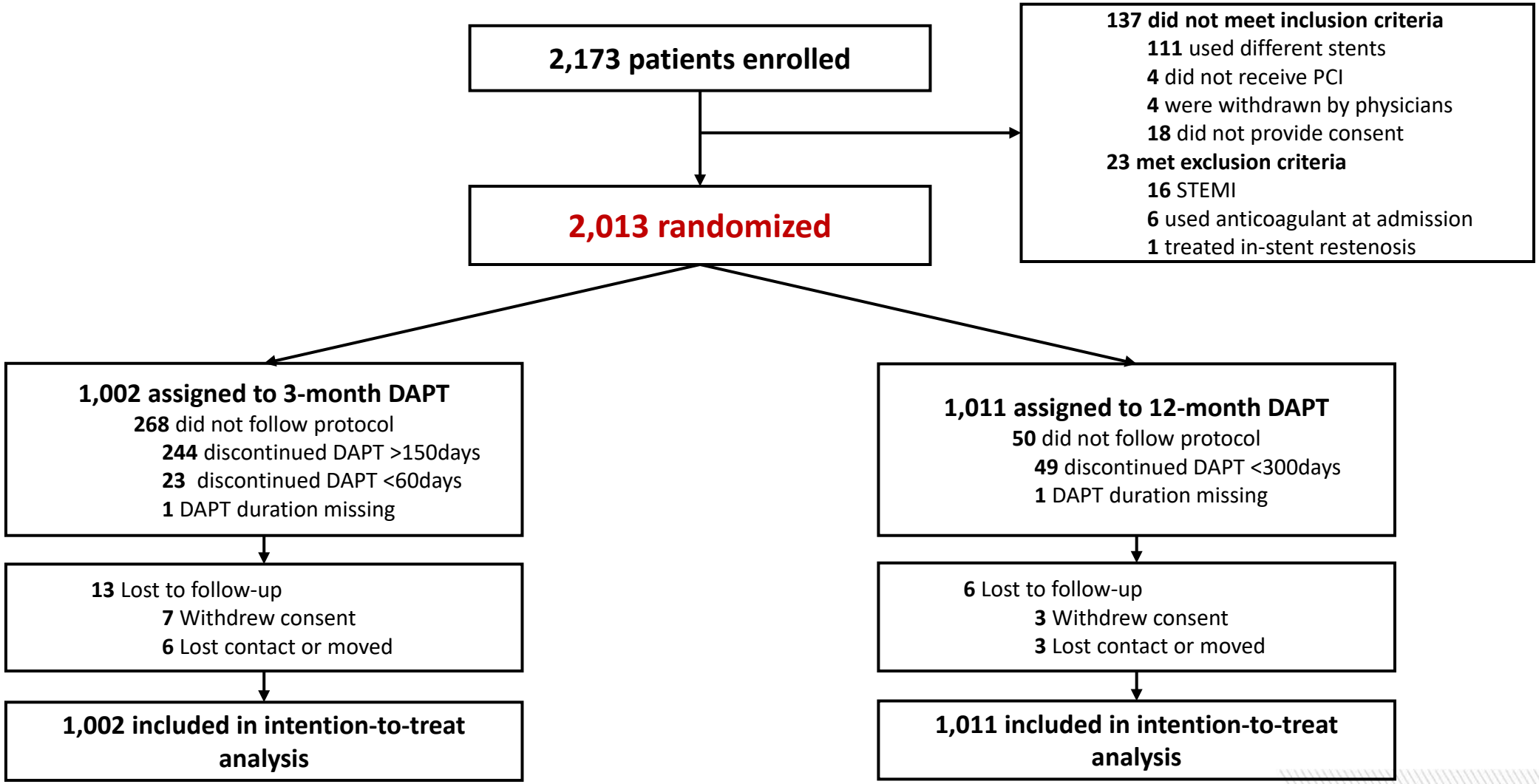
- From 37 centers in Korea
- Enrollment period: January 2016 to May 2021
- 2,173 eligible patients with de novo stenotic lesions suitable for DES implantation were enrolled.

Inclusion Criteria
Patients aged ≥19 years with **de novo stenotic lesions who will undergo PCI with Orsiro, or Coroflex ISAR stent** and agreed to give written informed consent
Exclusion Criteria
Patients with high-risk profiles for ischemic adverse events (**STEMI**, cardiogenic shock, concomitant severe decompensated heart failure, restenosis in stented segments, myocardial infarction or stent thrombosis in spite of the maintenance of antiplatelet therapy), Patients who cannot follow allocated DAPT schedule due to the planned surgery or elective procedure within 3 months after the stenting, Recent history of major surgery or evident events of gastrointestinal bleeding within 1 month from the procedure, Atrial fibrillation, valvular disease, or recent pulmonary embolism who requires warfarin or NOACs (new oral anticoagulants), Presence of non-cardiac comorbidity with life expectancy ≤ 1 year from randomization, Pregnancy, History of hypersensitivity or contraindication to aspirin, clopidogrel, prasugrel, ticagrelor, heparin, cobalt chromium, sirolimus

Study Flow


2,173 patients enrolled
137 did not meet inclusion criteria
111 used different stents
4 did not receive PCI
4 were withdrawn by physicians
18 did not provide consent
23 met exclusion criteria
16 STEMI
6 used anticoagulant at admission
1 treated in-stent restenosis
2,013 randomized
1,002 assigned to 3-month DAPT
268 did not follow protocol
244 discontinued DAPT >150days
23 discontinued DAPT <60days
1 DAPT duration missing
13 Lost to follow-up
7 Withdrew consent
6 Lost contact or moved
1,002 included in intention-to-treat analysis
1,011 assigned to 12-month DAPT
50 did not follow protocol
49 discontinued DAPT <300days
1 DAPT duration missing
6 Lost to follow-up
3 Withdrew consent
3 Lost contact or moved
1,011 included in intention-to-treat analysis

Primary Endpoint

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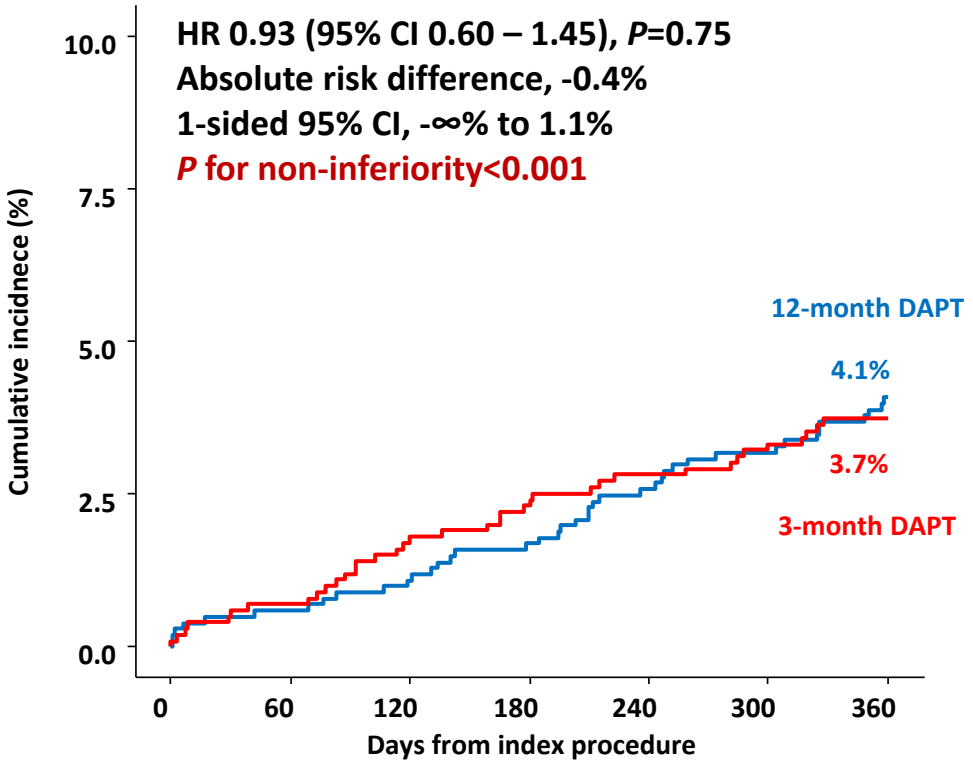
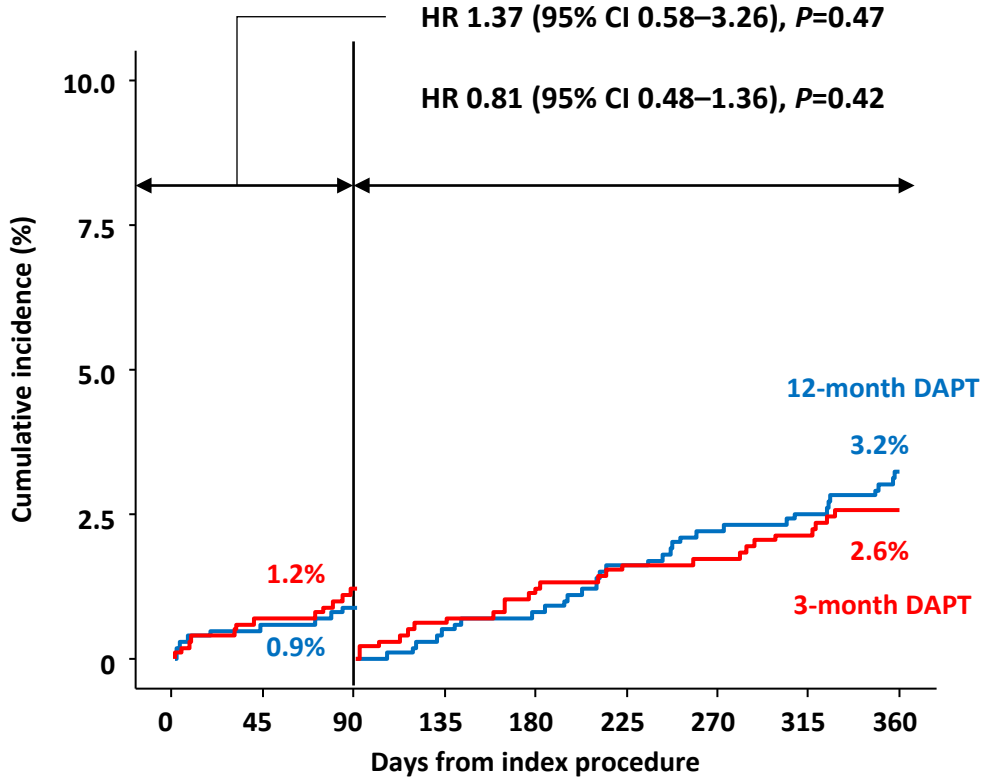
NACE (cardiac death, TVMI, CD-TLR, stent thrombosis, and major bleeding) at 12 months



Number at risk

12-month DAPT	1011	1004	995	988	978	967	938
3-month DAPT	1002	993	976	967	959	952	928



Number at risk

12-month DAPT	1011	1004	1000	992	988	979	973	963	938
3-month DAPT	1002	993	984	973	967	959	958	950	928

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Secondary Endpoints

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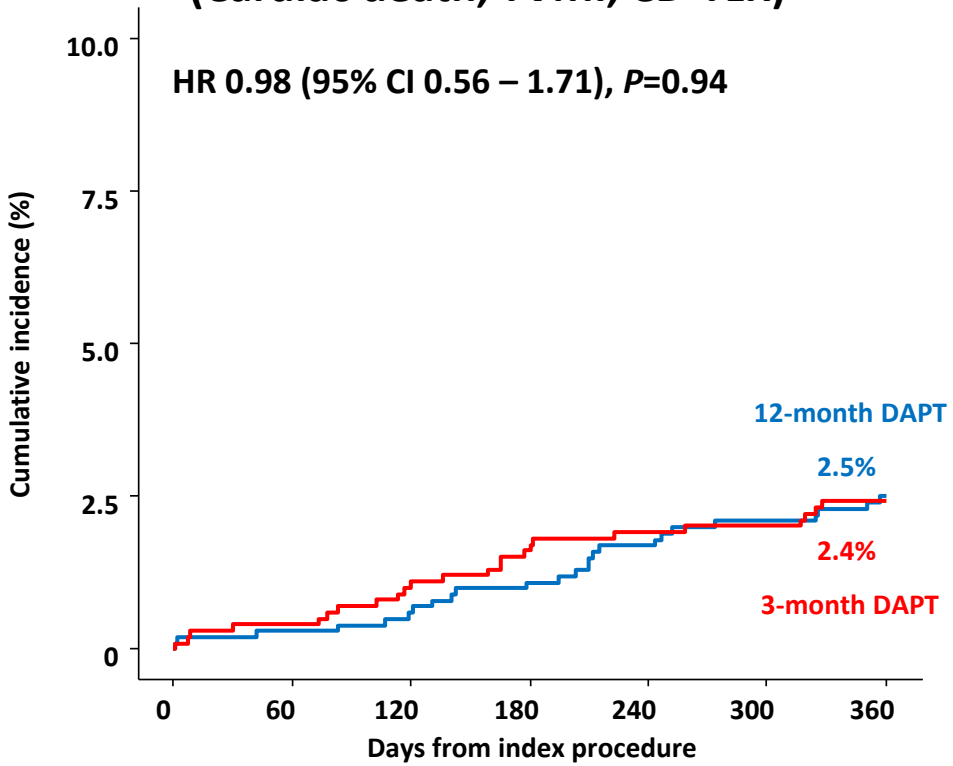
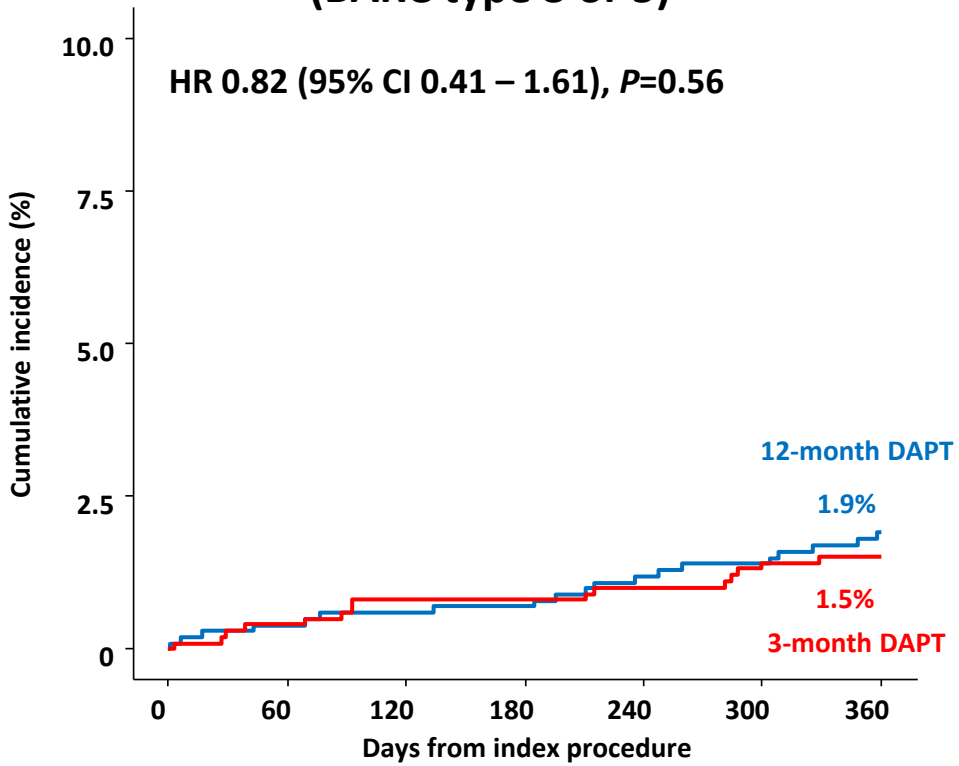
Target lesion failure
(Cardiac death, TVMI, CD-TLR)



Number at risk

12-month DAPT	1011	1007	999	993	986	976	951
3-month DAPT	1002	996	983	973	967	964	939

Major bleeding
(BARC type 3 or 5)



Number at risk

12-month DAPT	1011	1006	997	993	985	977	951
3-month DAPT	1002	993	980	976	971	964	942

All clinical outcomes at 12 months

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	3-month DAPT group (n=1,003)	12-month DAPT group (n=1,011)	Hazard ratio (95% CI)	*P* value
Net adverse clinical events	**37 (3.7)**	**41 (4.1)**	**0.93 (0.60 – 1.45)**	**0.75**
Target lesion failure	24 (2.4)	25 (2.5)	0.98 (0.56 – 1.71)	0.94
Cardiac death	7 (0.7)	10 (1.0)	0.71 (0.27 – 1.87)	0.49
Target-vessel myocardial infarction	10 (1.0)	7 (0.7)	1.47 (0.56 – 3.87)	0.43
Clinically driven target lesion revascularization	14 (1.4)	17 (1.7)	0.84 (0.41 – 1.70)	0.63
Definite or probable stent thrombosis	1 (0.1)	0 (0.0)	NA	0.32
Major bleeding (BARC type 3 or 5)	15 (1.5)	19 (1.9)	0.82 (0.41 – 1.61)	0.56
Patient-oriented composite outcome	60 (6.0)	69 (6.9)	0.88 (0.62 – 1.24)	0.47
All-cause death	17 (1.7)	20 (2.0)	0.86 (0.45 – 1.64)	0.65
Myocardial infarction	13 (1.3)	10 (1.0)	1.33 (0.58 – 3.03)	0.50
Any revascularization	36 (3.7)	43 (4.3)	0.85 (0.55 – 1.32)	0.47
Ischemic stroke	7 (0.7)	10 (1.0)	0.73 (0.28 – 1.91)	0.52
Any bleeding (BARC type 2, 3, or 5)	51 (5.2)	66 (6.6)	0.79 (0.54 – 1.14)	0.20
BARC type 2 bleeding	37 (3.7)	50 (5.0)	0.75 (0.49 – 1.15)	0.19

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Conclusions

Among **the general population** excluding patients with STEMI,

3-month DAPT was non-inferior to 12-month DAPT

for NACE at 12 months after PCI

using **third-generation DES**

with ultrathin struts and advanced polymer technology