Abbreviated dual antiplatelet therapy after percutaneous coronary intervention with ultrathin-strut drug-eluting stents in South Korea: 3-year outcomes of the multicentre, randomised HOST-IDEA trial

Jung-Kyu Han,[a,b,o] Doyeon Hwang,[a,o] Seokhun Yang,[a] Sang-Hyeon Park,[a] Jeehoon Kang,[a] Han-Mo Yang,[a,b] Kyung Woo Park,[a,b] Hyun-Jae Kang,[a,b] Bon-Kwon Koo,[a,b] Seung-Ho Hur,[c] Weon Kim,[d] Seok Yeon Kim,[e] Sang-Hyun Park,[f] Seung Hwan Han,[g] Sang-Hyun Kim,[h] Sanghoon Shin,[i] Kyungil Park,[j] Seung Jin Lee,[k] Jin Won Kim,[l] Namho Lee,[m,**] and Hyo-Soo Kim[n,*]

[a]Cardiovascular Center, Seoul National University Hospital, Seoul, Republic of Korea
[b]Department of Internal Medicine, College of Medicine, Seoul National University, Seoul, Republic of Korea
[c]Department of Internal Medicine, Keimyung University Dongsan Hospital, Daegu, Republic of Korea
[d]Division of Cardiology, Department of Internal Medicine, Kyung Hee University Hospital, Seoul, Republic of Korea
[e]Department of Cardiology, Cardiovascular Center, Seoul Medical Center, Seoul, Republic of Korea
[f]Department of Internal Medicine, Daejeon Eulji Medical Center, Eulji University School of Medicine, Daejeon, Republic of Korea
[g]Division of Cardiology, Department of Internal Medicine, Gachon University Gil Hospital, Incheon, Republic of Korea
[h]Division of Cardiology, Department of Internal Medicine, Boramae Medical Center, Seoul National University College of Medicine, Seoul, Republic of Korea
[i]Department of Cardiology, Seoul Hospital, Ewha Womans University College of Medicine, Seoul, Republic of Korea
[j]Department of Internal Medicine, Dong-A University College of Medicine, Busan, Republic of Korea
[k]Division of Cardiology, Department of Internal Medicine, Soonchunhyang University Cheonan Hospital, Cheonan, Republic of Korea
[l]Cardiovascular Center, Guro Hospital Korea University, Seoul, Republic of Korea
[m]Department of Internal Medicine, Hallym University Kangnam Sacred Heart Hospital, Seoul, Republic of Korea
[n]Seoul National University Hospital, Republic of Korea

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Summary

Background The HOST-IDEA trial demonstrated non-inferiority of 3-to-6-month dual antiplatelet therapy (DAPT) to 12-month DAPT for net adverse clinical event (NACE) at 1 year in patients undergoing percutaneous coronary intervention (PCI) with third-generation drug-eluting stents (DES). We evaluated the long-term outcomes of abbreviated antiplatelet therapy following PCI with third-generation DES.

Methods In the open-label, adjudicator-blinded, multicentre, randomised HOST-IDEA trial, 2013 patients from 37 hospitals in South Korea were randomly allocated to 3-to-6-month (n = 1002) or 12-month (n = 1011) DAPT between January 2016 and May 2021. The primary outcome was NACE at 3 years, comprising cardiac death, target vessel myocardial infarction (TVMI), clinically driven target lesion revascularisation (CD-TLR), stent thrombosis, and major bleeding (Bleeding Academic Research Consortium type 3 or 5). Major secondary outcomes were target lesion failure (TLF)—comprising cardiac death, TVMI, and CD-TLR—and major bleeding at 3 years. To evaluate the efficacy and safety of >1-year DAPT, patients event-free at 1 year were classified into >1-year and ≤1-year DAPT groups and matched using a propensity score. These 3-year clinical outcomes were prespecified in the published protocol as mandatory clinical follow-up. HOST-IDEA is registered with ClinicalTrials.gov, NCT02601157.

Findings At 3 years, clinical follow-up was completed in 955 patients (95.3%) and 966 patients (95.5%) in the 3-to-6-month and 12-month DAPT groups, respectively. The median follow-up duration was 1095 days (IQR 1095–1095). The primary outcome occurred in 7.7% and 8.2% of patients in the 3-to-6-month and 12-month DAPT groups, respectively (HR 0.94; 95% CI 0.69–1.29; $P = 0.71$). The risks of TLF (HR 0.92; 95% CI 0.62–1.36; $P = 0.66$) and major bleeding (HR 0.96; 95% CI 0.59–1.56; $P = 0.88$) were comparable between the two groups. Among patients who were event-free at 1 year, 583 remained on DAPT, while 1259 switched to single antiplatelet

*Corresponding author. Seoul National University Hospital, 101 Daehak-ro, Jongro-gu, Seoul, 110-744, Republic of Korea.
**Corresponding author. Department of Internal Medicine, Hallym University Kangnam Sacred Heart Hospital, 1 Singil-ro, Yeongdeungpo District, Seoul, Republic of Korea.
E-mail addresses: hyosoo@snu.ac.kr (H.-S. Kim), namholee@hanmail.net (N. Lee).
[o]Contributed equally.

therapy within the 1 year. In the matched cohort, there was some evidence of a higher risk of TLF in the >1-year DAPT group (HR 2.56; 95% CI 0.99–6.60; $P = 0.05$), whereas major bleeding risk was significantly higher with >1-year DAPT (HR 4.44; 95% CI 1.26–15.57; $P = 0.02$).

Interpretation 3-to-6-month and 12-month DAPT showed comparable 3-year clinical outcomes in patients undergoing PCI with third-generation DES. However, extending DAPT beyond 1 year was associated with increased major bleeding without additional ischemic benefits. Further studies are warranted to validate these findings and identify patient subsets who may benefit from extended DAPT.

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Keywords: Dual antiplatelet therapy; Long-term; Outcome; Percutaneous coronary intervention

Research in context

Evidence before this study

The development of third-generation drug-eluting stents (DES), characterised by ultrathin struts and improved polymer technology, has significantly reduced the incidence of stent-related adverse events. We systematically searched PubMed, EMBASE, and the Cochrane Library for English-language articles published up to May 1, 2023 (before publication of the HOST-IDEA trial), using the keywords "drug-eluting stent," "third generation," "dual antiplatelet," and "randomised controlled trial." This search identified 12 articles; however, no randomised controlled trials were found that specifically investigated dual antiplatelet therapy (DAPT) strategies with third-generation DES. The HOST-IDEA trial was the first large-scale randomised controlled trial evaluating the optimal duration of dual antiplatelet therapy (DAPT) in patients undergoing percutaneous coronary intervention (PCI) with third-generation DESs with ultrathin struts and advanced polymer technology.

Added value of this study

The HOST-IDEA trial demonstrated that 3-to-6-month DAPT was non-inferior to 12-month DAPT for net adverse clinical events (NACE) at 1 year in patients undergoing PCI with third-generation DES. This study extends the clinical follow-up of the HOST-IDEA trial to 3 years and shows comparable long-term outcomes between 3-to-6-month and 12-month DAPT after third-generation DES implantation. In addition, continuation of DAPT beyond 1 year was associated with an increased risk of major bleeding without a clear reduction in ischemic events. These findings support the long-term safety and efficacy of abbreviated DAPT in the contemporary DES era.

Implications of all the available evidence

These findings support the long-term safety and efficacy of abbreviated DAPT in the contemporary DES era. Further research is needed to determine how much shorter DAPT can be safely administered and to identify the optimal antiplatelet agents both during DAPT and for subsequent single antiplatelet therapy.

Introduction

Dual antiplatelet therapy (DAPT) is the cornerstone of thrombotic risk reduction after percutaneous coronary intervention (PCI). Current guidelines recommend a standard DAPT duration of 6 and 12 months for patients with stable ischemic heart disease (SIHD) and those with acute coronary syndrome (ACS), respectively.[1–4] However, prolonged DAPT after PCI increases the risk of bleeding events.[5,6] Given the impact of bleeding on overall mortality, bleeding risk must be carefully considered when selecting the optimal DAPT strategy.[5,7] Therefore, optimising DAPT duration remains a key consideration in contemporary PCI practice.

Advancements in stent technology, including third-generation drug-eluting stents (DES) with ultrathin struts and advanced polymer technology, have minimised the risk of stent-related adverse events.[8–11] These innovations have led to the hypothesis that a shorter DAPT duration may sufficiently balance efficacy and safety after PCI. The HOST-IDEA (Harmonizing Optimal Strategy for Treatment of Coronary Artery Stenosis–Coronary Intervention With Next Generation Drug-Eluting Stent Platforms and Abbreviated Dual Antiplatelet Therapy) trial was the first dedicated randomised clinical trial to compare the efficacy and safety of short-term DAPT following third-generation DES implantation, specifically the Orsiro biodegradable polymer sirolimus-eluting stent (SES) and the Coroflex ISAR polymer-free SES.[12,13] The trial demonstrated that a 3-to-6-month DAPT was non-inferior to a 12-month DAPT for net adverse clinical event (NACE) at 1 year in patients undergoing PCI with third-generation DES.

However, whether these findings persist over the long term remains unclear. There is limited data on the long-term outcomes of different DAPT durations, with conflicting evidence regarding the benefits and risks of extended DAPT beyond 1 year.[14–23] Moreover, this has not been studied in patients exclusively receiving third-generation DES. In this study, we report the pre-specified 3-year follow-up results of the HOST-IDEA trial to assess the long-term impact of abbreviated 3-to-6-month vs conventional 12-month DAPT. In addition, we explored the efficacy and safety of extended DAPT beyond 1 year in the third-generation DES era.

Methods

Study design

This study evaluated long-term follow-up data from the HOST-IDEA trial (ClinicalTrials.gov Number: NCT02601157) (Fig. 1). The study design and primary outcomes at 1 year have been published previously.[12,13,24,25] These 3-year clinical outcomes were prespecified in the published protocol as mandatory clinical follow-up. Briefly, the HOST-IDEA trial was an investigator-initiated, randomised, open-label, adjudicator-blinded, multicentre trial performed across 37 hospitals in South Korea. The trial initially exhibited a 2 × 2 factorial design to evaluate two independent hypotheses and consisted of two arms: an antiplatelet arm and a DES arm (Fig. 2). In the antiplatelet arm, patients undergoing PCI with third-generation DES were randomised to receive either 3-to-6-month or 12-month DAPT.[13] The DES arm originally randomised patients to receive one of two DES types with ultrathin struts and advanced polymer technology: the Orsiro biodegradable polymer SES or the Coroflex ISAR polymer-free SES.[12] However, during the trial, physicians showed a preference for the Orsiro SES in clinical practice, mainly due to its substantial clinical evidence compared with that for the Coroflex ISAR and the lack of a Coroflex ISAR stent longer than 28 mm. This preference slowed patient enrollment in the trial. In order to boost enrollment and ensure the feasibility of the trial, randomisation in this arm was discontinued, and the DES arm was converted into a registry that allowed the implantation of either DES type. Therefore, randomisation in this arm was discontinued during the trial, converting the DES arm into a registry that allowed the implantation of either DES type to facilitate patient enrollment. The original trial was designed to test the noninferiority of 3-to 6-month DAPT compared with 12-month DAPT at 1 year. For the extended 3-year follow-up, no noninferiority margin was prespecified, and no formal noninferiority analysis was planned.[12]

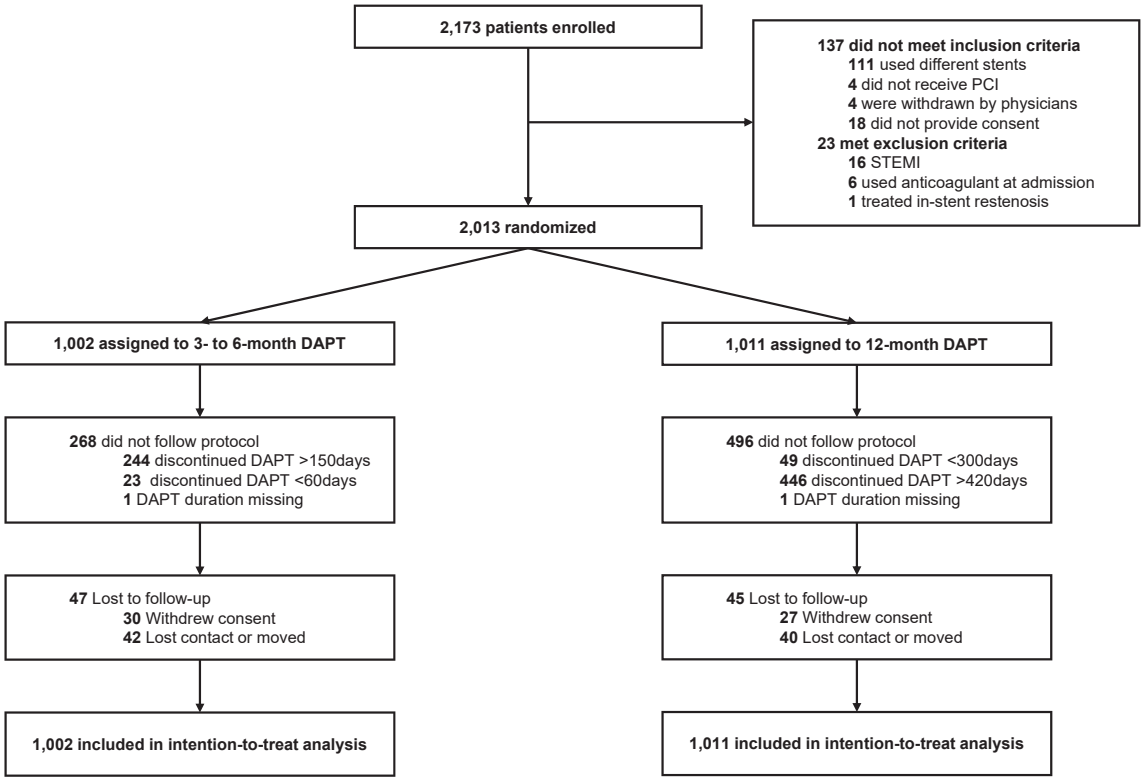

***Fig. 1:* Study flow**. Of the total 2173 eligible patients, 2013 are successfully randomized into the 3-to-6-month and 12-month DAPT groups. DAPT, dual antiplatelet therapy; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction.

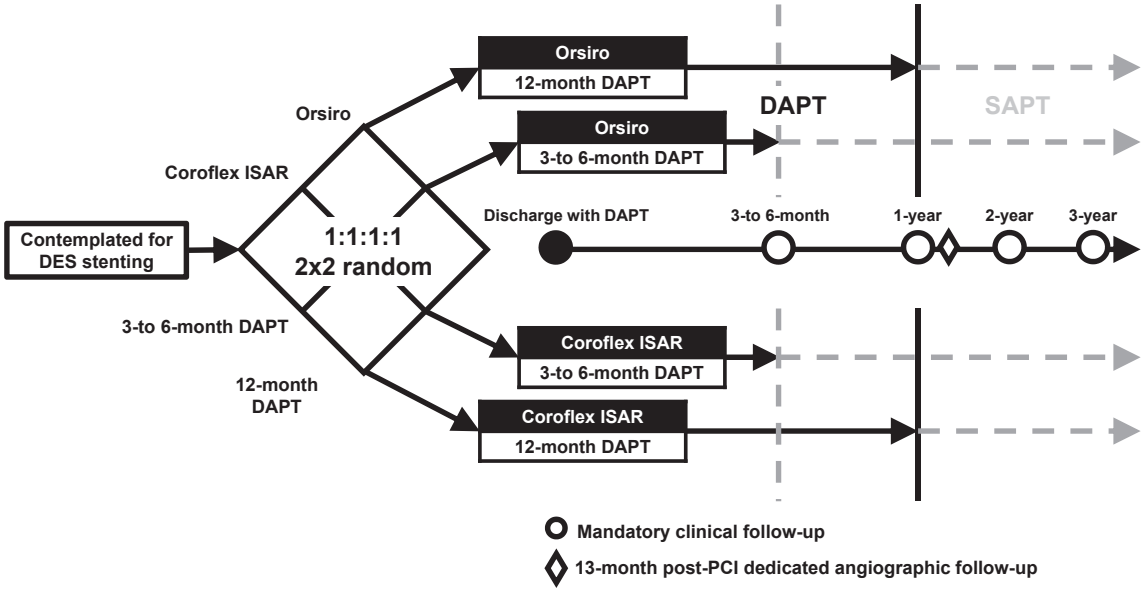

***Fig. 2:* Study outline and randomisation scheme**. The trial initially exhibited a 2 × 2 factorial design to evaluate two independent hypotheses and consisted of two arms: an antiplatelet arm and a DES arm. DES, drug-eluting stent; DAPT, dual antiplatelet therapy; PCI, percutaneous coronary intervention.

Ethics

The HOST-IDEA trial adhered to the principles of the Declaration of Helsinki and was approved by the institutional ethics committee of Seoul National University College of Medicine/Seoul National University Hospital (H-1508-118-697). All participants provided written informed consent prior to randomisation.

Study population, randomisation, and masking

Patients with de novo coronary artery lesions suitable for DES implantation were enrolled in the study. Major exclusion criteria were ST-segment elevation myocardial infarction, cardiogenic shock, severe decompensated heart failure, stent thrombosis, restenosis, and the need for oral anticoagulants. A detailed trial protocol, including the full inclusion and exclusion criteria, is available in Supplementary Materials. Following diagnostic coronary angiography, eligible patients were randomised into either the 3-to-6-month DAPT group or the 12-month DAPT group. Randomisation was conducted using a web-based system (http://www.ecrf.kr/hostidea/) and was performed in blocks of eight without stratification to ensure a balanced allocation between groups. The randomisation process was performed by independent nurse coordinators or research nurses not directly involved in the trial, thereby further reducing the risk of allocation bias. As the patients were not blinded to their assigned treatment groups in this open-label trial, efforts were made to minimise potential bias by emphasising protocol adherence through regular newsletters and telephone communications. The study participants and investigators were monitored regularly to ensure compliance with the study protocol.

Procedures and follow-up

All interventions were performed according to standard techniques using the allowed stent platforms (Orsiro SES or Coroflex ISAR SES), with no restrictions on stent length, diameter, or type. Intracoronary imaging and invasive physiological assessments were performed at the treating physician's discretion. After PCI, all patients in both randomised groups received DAPT with aspirin 100 mg once daily and a P2Y12 inhibitor (clopidogrel 75 mg once daily for CCS or ACS, ticagrelor 90 mg twice daily, or prasugrel 10 mg once daily for ACS) for at least 3 months. In the 3-to-6-month DAPT group, patients were transitioned to single antiplatelet therapy (SAPT) after 3 months, with the regimen chosen at the physician's discretion (aspirin or clopidogrel for SIHD; aspirin, clopidogrel, ticagrelor, or prasugrel for ACS). In the 12-month DAPT group, DAPT was recommended for at least 12 months, after which continuation or transition to SAPT was at the physician's discretion. Clinical follow-up was mandatory at 1, 3, and 12 months, with additional outpatient clinic visits recommended at 3-month intervals or less during the first year. After 1 year, clinical follow-up was mandatory at 2 and 3 years after randomisation. Telephone interviews were conducted for patients who missed scheduled visits to assess clinical status, adverse events, and medication adherence. Telephone interviews were performed in

11.3% of patients at 1 year and 24.1% at 3 years. The vital status of all patients was confirmed through the Korean National Health Insurance System, which provides complete ascertainment of mortality in Korea. All data were recorded in a centralised web-based database (http://www.ecrf.kr/hostidea/). If follow-up coronary angiography was planned by the treating physician, it was recommended to be performed 13 months after randomisation.

Outcomes

The primary aim of this study was to report the pre-specified 3-year follow-up results of the HOST-IDEA trial, assessing the long-term impact of abbreviated 3–6-month vs conventional 12-month DAPT. In addition, we explored the efficacy and safety of extended DAPT beyond 1 year in the third-generation DES era.

The primary outcome was the occurrence of NACE, a composite of cardiac death, target vessel myocardial infarction (TVMI), clinically driven target lesion revascularisation (CD-TLR), stent thrombosis, and major bleeding, defined as Bleeding Academic Research Consortium (BARC) type 3 or 5 at 3 years. The major secondary outcomes were target lesion failure (TLF) and major bleeding at 3 years. TLF was defined as a composite of cardiac death, TVMI, or CD-TLR, representing an ischemic outcome, whereas major bleeding was defined as BARC type 3 or 5 bleeding events at 3 years. Other secondary outcomes included all-cause death, myocardial infarction (MI), any revascularisation, ischemic stroke, any bleeding (BARC type 2, 3, or 5), minor bleeding (BARC type 2), and definite or probable stent thrombosis at 3 years. All deaths were classified as cardiac deaths unless a definitive non-cardiac cause was identified. Periprocedural myocardial infarction (MI) was not considered as a clinical outcome in this study. Clinically driven revascularisation was defined as repeat revascularisation in the presence of a diameter stenosis of ≥50%, along with at least one of the following criteria: 1) recurrence of anginal symptoms, 2) positive non-invasive test, 3) positive invasive physiologic test, or 4) presence of diameter stenosis ≥70%, even in the absence of other criteria. All clinical outcomes were determined according to the Academic Research Consortium-2 and BARC guidelines.[26,27] Clinical events were adjudicated by an independent clinical event adjudication committee blinded to the study group.

Statistical analysis

The sample size was calculated based on the working hypothesis of the 1-year results of the HOST-IDA trial, which has been described previously.[12,24] The current analysis is a pre-specified 3-year follow-up analysis, and the primary analyses were based on the intention-to-treat population. Continuous variables were reported as means with standard deviations, whereas categorical variables were presented as counts and percentages. Continuous and categorical variables were compared using the Student's t-test and chi-squared test, respectively. The cumulative incidence of clinical events was estimated using Kaplan–Meier censoring estimates, and group differences were assessed using the log-rank test. Landmark analyses at 1 year were performed to evaluate group differences. Cox proportional hazards regression models, stratified by study site, were used to estimate hazard ratios (HRs) with 95% confidence intervals (CIs). The validity of the proportional hazard assumption was tested using Schoenfeld residuals. Subgroup analyses were conducted to assess the consistency of treatment effects across various subgroups. As post-hoc exploratory analyses to evaluate the effect of extended DAPT use, we analysed clinical outcomes between patients receiving DAPT for ≤1 and > 1 year from 1 to 3 years of follow-up, including only those who were event-free until 1 year. Patients who received DAPT for >1 year were defined as those who received DAPT for more than 420 days from the index procedure, allowing a two-month window around the 1-year mark to reflect real-world variability in clinic visits and medication discontinuation. To adjust for baseline differences, multivariable Cox proportional hazard regression models and propensity score matching analyses were performed. For the propensity score matching analyses, the balance between the groups was assessed using absolute standardised differences. As a sensitivity analysis addressing potential bias from patients lost to follow-up, a tipping-point analysis was performed using model-free imputation with varying proportions (κ%) of patients lost to follow-up. Patients in the ≤1-year DAPT group were sequentially imputed as having events at their censoring time, whereas those in the >1-year DAPT group were assumed to remain event-free until the maximal follow-up period (675 days after the 1-year landmark). For each κ%, multiple imputed datasets (m = 20) were generated, and pooled hazard ratios were estimated from Cox proportional hazards models using Rubin's rule. Two-sided $P < 0.05$ was considered statistically significant. All statistical analyses were performed using the R software (version 4.1.0, R Foundation for Statistical Computing).

Role of the funding source

The funders of the study had no role in the design or conduction of this study, nor in the collection, analysis, and interpretation of data; writing and approval of the manuscript; or decision to submit the manuscript for publication.

Results

This study presents the pre-specified 3-year follow-up results of the HOST-IDEA trial. After PCI, a total of 2013 patients were randomly assigned to the 3-to-6-

month DAPT (1002 patients) or 12-month DAPT (1011 patients) groups between January 2016 and May 2021 (Fig. 1). Baseline characteristics of the participants are summarised in Supplementary Table S1. The mean age was 65.7 ± 10.5 years, and 73.9% of patients were male. Approximately half of the patients presented with ACS (55.1%) or multivessel disease (51.8%). The Orsiro SES was implanted in 72.0% of the patients, with a mean total stent length of 29.2 ± 16.5 mm and a mean stent number of 1.6 ± 1.0. Baseline clinical, angiographic, and procedural characteristics were well-balanced between the two groups. At 3 years, the clinical follow-up was completed in 955 patients (95.3%) and 966 patients (95.5%) in the 3-to-6-month and 12-month DAPT groups, respectively. The median follow-up duration was 1095 days (interquartile range: 1095–1095) (Fig. 1).

The median duration of DAPT was 99 days (interquartile range 91–148) and 403 days (interquartile range 363–750) in the 3-to-6-month and 12-month DAPT groups, respectively (Supplementary Table S1). Clopidogrel was used as a part of DAPT in 88.7% and 89.4% of patients in the 3-to-6-month and 12-month DAPT groups, respectively (Supplementary Table S1). The rates of DAPT at 3 months, 6 months, 1 year, 2 years, and 3 years were 97.4%, 25.2%, 18.9%, 11.9%, and 9.5% in the 3-to-6-month DAPT group, and 98.7%, 97.2%, 91.7%, 30.4%, and 23.5% in the 12-month DAPT group, respectively (Fig. 3). Among the patients who completed DAPT, 60.3% in the 3-to-6-month DAPT group continued with aspirin, 36.7% with clopidogrel, and 2.2% with a potent P2Y12 inhibitor (prasugrel or ticagrelor) upon completion. In the 12-month DAPT group, 44.5% of patients continued with aspirin, 53.6% with clopidogrel, and 0.4% with potent P2Y12 inhibitors.

Over 3 years of follow-up, the cumulative incidences of NACE were 7.7% and 8.2% in the 3-to-6-month and 12-month DAPT groups, respectively (HR 0.94, 95% CI 0.69–1.29, $P = 0.71$) (Fig. 4 and Table 1). In a 1-year landmark analysis of patients event-free at 1 year, the cumulative incidences of NACE were 4.1% and 4.3% in the 3-to-6-month and 12-month DAPT groups, respectively, between 1 and 3 years after randomisation (HR 0.95, 95% CI 0.61–1.49, $P = 0.84$) (Supplementary Figure S1 and Table 1). Subgroup analyses revealed consistent results (Supplementary Figure S2). As the key ischemic secondary outcome, the cumulative incidences of TLF were 4.9% and 5.4% in the 3-to-6-month and 12-month DAPT groups, respectively (Fig. 4 and Table 1). The risk of TLF did not differ between the groups (HR 0.92, 95% CI 0.62–1.36, $P = 0.66$). As the key bleeding secondary outcome, the cumulative incidences of major bleeding were 3.3% and 3.5% in the 3-to-6-month and 12-month DAPT groups, respectively, with comparable risk between the two groups (HR 0.96, 95% CI 0.59–1.56, $P = 0.88$) (Fig. 4 and Table 1). Per-procotol analyses showed consistent results (Supplementary Figure S3). Similarly, the risk of any bleeding was comparable between the groups (HR 0.88, 95% CI 0.67–1.16, $P = 0.36$) (Supplementary Figure S4 and Table S1). Landmark analyses at 1 year showed consistent results (Supplementary Figure S1 and Table 1).

Among the 1842 patients who did not experience an adverse clinical event for up to 1 year, 583 continued with DAPT, whereas 1259 switched to SAPT within the

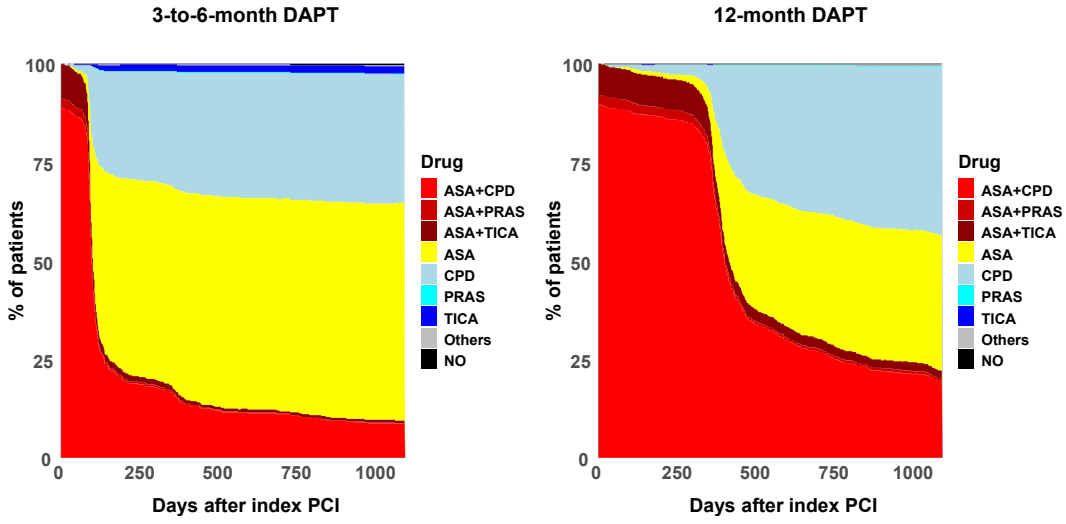

***Fig. 3:* Antiplatelet therapy during the follow-up**. The proportions of patients receiving each antiplatelet regimen throughout the follow-up period are presented according to the assigned DAPT groups. ASA, aspirin; CPD, clopidogrel; DAPT, dual antiplatelet therapy; PCI, percutaneous coronary intervention; PRAS, prasugrel; TICA, ticagrelor.

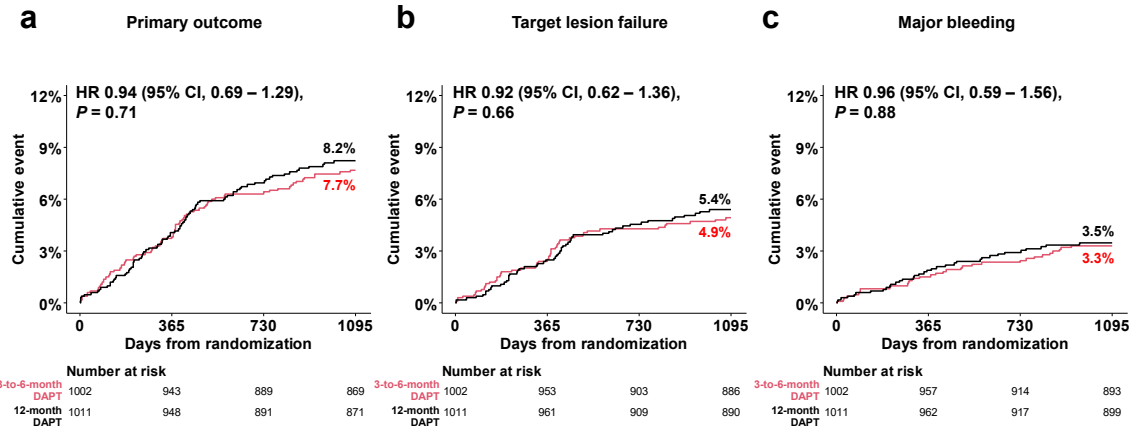

***Fig. 4:* Kaplan–Meier curves for primary and major secondary outcomes up to 3 years after randomisation**. The cumulative incidences of the primary outcome (a), target lesion failure (b), and major bleeding, defined as Bleeding Academic Research Consortium type 3 or 5 (c), in the assigned DAPT groups are compared. The risks of clinical outcomes in the 3-to-6-month DAPT group were compared with the 12-month DAPT group. CI, confidence interval; DAPT, dual antiplatelet therapy; HR, hazard ratio.

	3–6-month DAPT (n = 1002)	12-month DAPT (n = 1011)	Hazard ratio (95% CI)	*P* value
At 3-year				
Net adverse clinical events[a]	75 (7.7)	81 (8.2)	0.94 (0.69–1.29)	0.71
Target lesion failure[b]	48 (4.9)	53 (5.4)	0.92 (0.62–1.36)	0.66
Cardiac death	19 (2.0)	23 (2.4)	0.83 (0.45–1.53)	0.55
Target-vessel myocardial infarction	12 (1.2)	11 (1.1)	1.12 (0.49–2.53)	0.80
Clinically driven target lesion revascularisation	25 (2.6)	34 (3.5)	0.74 (0.44–1.24)	0.26
Definite or probable stent thrombosis	2 (0.2)	2 (0.2)	0.99 (0.14–7.00)	0.99
Major bleeding (BARC type 3 or 5)	32 (3.3)	34 (3.5)	0.96 (0.59–1.56)	0.88
All-cause death	48 (4.9)	52 (5.3)	0.93 (0.63–1.38)	0.73
Myocardial infarction	18 (1.8)	19 (1.9)	0.96 (0.50–1.83)	0.90
Any revascularisation	74 (7.7)	95 (9.8)	0.78 (0.58–1.06)	0.12
Ischemic stroke	16 (1.7)	20 (2.1)	0.81 (0.42–1.56)	0.52
Any bleeding (BARC type 2, 3, or 5)	95 (9.8)	108 (11.0)	0.88 (0.67–1.16)	0.36
Minor bleeding (BARC type 2)	63 (6.6)	74 (7.6)	0.85 (0.60–1.19)	0.33
Landmark at 1 year				
Net adverse clinical events[a]	38 (4.1)	40 (4.3)	0.95 (0.61–1.49)	0.84
Target lesion failure[b]	24 (2.6)	28 (3.0)	0.86 (0.50–1.49)	0.59
Cardiac death	12 (1.3)	13 (1.4)	0.92 (0.42–2.02)	0.84
Target-vessel myocardial infarction	2 (0.2)	4 (0.4)	0.50 (0.09–2.73)	0.42
Clinically driven target lesion revascularisation	11 (1.2)	17 (1.8)	0.65 (0.30–1.38)	0.26
Definite or probable stent thrombosis	1 (0.1)	2 (0.2)	0.49 (0.04–5.41)	0.56
Major bleeding (BARC type 3 or 5)	17 (1.8)	15 (1.6)	1.15 (0.57–2.30)	0.70
All-cause death	31 (3.3)	32 (3.3)	0.98 (0.60–1.61)	0.94
Myocardial infarction	5 (0.5)	9 (1.0)	0.55 (0.19–1.66)	0.29
Any revascularisation	38 (4.2)	52 (5.7)	0.73 (0.48–1.11)	0.14
Ischemic stroke	9 (1.0)	10 (1.1)	0.89 (0.36–2.18)	0.79
Any bleeding (BARC type 2, 3, or 5)	44 (4.9)	42 (4.7)	1.02 (0.66–1.56)	0.94
Minor bleeding (BARC type 2)	27 (3.1)	27 (3.1)	0.96 (0.56–1.65)	0.88

Data are presented as number (Kaplan–Meier estimates %). BARC, Bleeding Academic Research Consortium; CI, confidence interval; DAPT, dual antiplatelet therapy. [a]Net adverse clinical events is a composite of target lesion failure, stent thrombosis, and major bleeding. [b]Target lesion failure is a composite of cardiac death, target vessel myocardial infarction, and clinically driven target lesion revascularisation.

***Table 1:* Primary and secondary outcomes in the intention-to-treat population.**

1 year. Patients in the >1-year DAPT group exhibited a higher prevalence of multivessel disease and history of prior revascularisation (Supplementary Table S2). The median duration of DAPT was 115 days (interquartile range 92–361) in the ≤1-year DAPT group and 1025 days (interquartile range 543–1095) in the >1-year DAPT group (Supplementary Figure S5). At 1, 2, and 3 years, the rates of DAPT use were 34.3%, 0.0%, and 0.0% in the ≤1-year DAPT group, compared with 100.0%, 67.3%, and 53.4% in the >1-year DAPT, respectively (Supplementary Figure S5). After DAPT discontinuation in the ≤1-year DAPT group, 56.7%, 41.0%, and 1.7% of patients received aspirin, clopidogrel, and a potent P2Y12 inhibitor (prasugrel or ticagrelor), respectively. After propensity score matching, 581 patients in the >1-year DAPT group were compared with 581 patients in the ≤1-year DAPT group. The risk of NACE was significantly higher in the >1-year DAPT group than in the ≤1-year DAPT group between 1 and 3 years (HR 2.86, 95% CI 1.33–6.12, P = 0.007) (Fig. 5, Table 2, and Supplementary Table S3). There was some evidence of a higher risk of TLF in the >1-year DAPT group than the ≤1-year DAPT group (HR 2.56, 95% CI 0.99–6.60, P = 0.05), whereas the risk of major bleeding was significantly higher in the >1-year DAPT group than in the ≤1-year DAPT group (HR 4.44, 95% CI 1.26–15.57, P = 0.02) (Fig. 5 and Table 2). These findings were consistent in multivariable Cox proportional hazard regression analyses (Table 2). In the tipping-point sensitivity analysis, the higher risks of NACE and major bleeding in the >1-year DAPT group became statistically non-significant when approximately 40% and 10% of patients lost to follow-up were imputed as having events in the ≤1-year DAPT group and as remaining event-free until the maximal follow-up in the >1-year group, respectively (Supplementary Table S4).

Discussion

In this pre-specified 3-year follow-up of the HOST-IDEA trial, we investigated the long-term impact of abbreviated DAPT. The major findings of this study are as follows: (1) 3-to-6-months of DAPT did not affect the risk of NACE, TLF, or major bleeding over 3 years; (2) among patients who remained event-free during the first year, extending DAPT beyond 1 year was associated with an increased risk of major bleeding without reducing the TLF risk. These findings support the efficacy and safety of abbreviated 3-to-6-month DAPT following PCI using the third-generation DES.

Current guidelines recommend a standard DAPT duration of 6 and 12 months for patients with SIHD and those with ACS, respectively. The introduction of third-generation DES, incorporating ultrathin stent struts and advanced polymer technology, may minimise the risk of stent-related complications,[28] suggesting the possibility of a shorter DAPT duration as a reasonable option. The HOST-IDEA trial was the first dedicated randomised trial to evaluate the efficacy and safety of DAPT shorter than 6 months in patients receiving third-generation DES, specifically the Orsiro biodegradable polymer SES with 60–80 μm struts or the Coroflex ISAR polymer-free SES with 50–60 μm struts.[13] The 1-year results of the HOST-IDEA trial showed that 3-to-6-month DAPT was non-inferior to 12-month DAPT in terms of NACE, with comparable risks of TLF and major bleeding between the two groups. The present study, reporting the pre-specified 3-year results of the HOST-IDEA trial, revealed that these findings were sustained over 3 years.

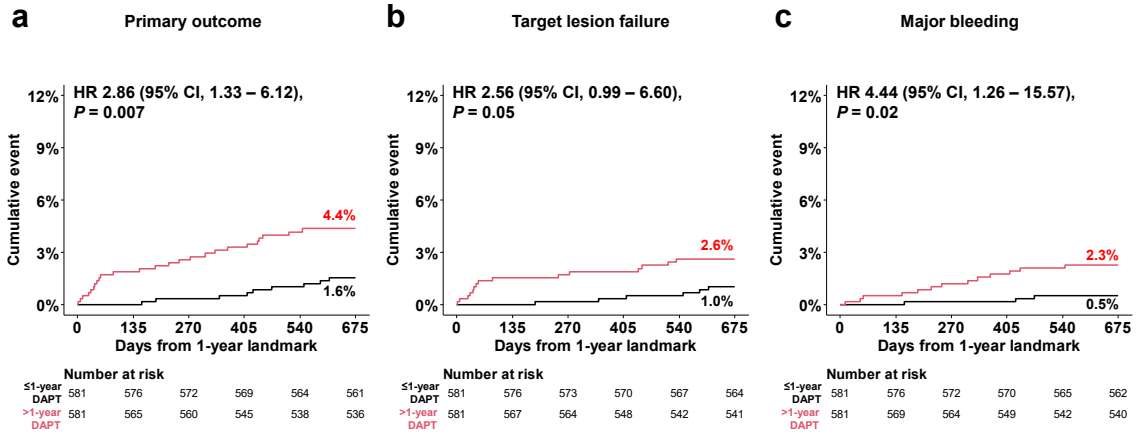

***Fig. 5*: Comparison of primary and major secondary outcomes 1 year after randomisation between ≤1-year and >1-year DAPT groups in propensity score matched cohort**. The cumulative incidences of the primary outcome (a), target lesion failure (b), and major bleeding (Bleeding Academic Research Consortium type 3 or 5) (c) are compared by DAPT duration (≤1 year vs. >1 year) among patients who remained event-free during the first year after randomisation. The risks of clinical outcomes in the >1-year DAPT group were compared with the ≤1-year DAPT group. HR, hazard ratio; CI, confidence interval; DAPT, dual antiplatelet therapy; HR, hazard ratio.

	≤1-year DAPT (n = 1259)	>1-year DAPT (n = 583)	Unadjusted HR (95% CI)	Adjusted HR (95% CI)	HR in PS matched population (95% CI)
Net adverse clinical events[a]	32 (2.6)	25 (4.4)	1.91 (1.11–3.29)	1.96 (1.13–3.42)	2.86 (1.33–6.12)
Target lesion failure[b]	19 (1.5)	15 (2.6)	2.08 (1.04–4.18)	1.99 (0.98–4.02)	2.56 (0.99–6.60)
Cardiac death	11 (0.9)	10 (1.7)	2.31 (0.95–5.65)	2.17 (0.88–5.34)	2.04 (0.70–5.98)
Target-vessel myocardial infarction	3 (0.2)	1 (0.2)	1.04 (0.11–10.00)	1.00 (0.10–9.85)	NA
Clinically driven target lesion revascularisation	7 (0.6)	7 (1.2)	2.64 (0.91–7.65)	2.79 (0.94–8.33)	7.12 (0.88–57.90)
Definite or probable stent thrombosis	1 (0.1)	0 (0.0)	NA	NA	NA
Major bleeding (BARC type 3 or 5)	14 (1.1)	13 (2.3)	2.06 (0.93–4.57)	2.35 (1.04–5.33)	4.44 (1.26–15.57)
All-cause death	27 (2.2)	23 (4.0)	1.94 (1.08–3.49)	1.86 (1.03–3.34)	1.96 (0.97–3.93)
Myocardial infarction	6 (0.5)	4 (0.7)	1.88 (0.53–6.75)	1.80 (0.50–6.52)	2.05 (0.38–11.19)
Any revascularisation	28 (2.3)	26 (4.8)	2.48 (1.42–4.32)	2.37 (1.34–4.16)	2.75 (1.33–5.70)
Ischemic stroke	10 (0.8)	3 (0.5)	0.66 (0.18–2.40)	0.50 (0.13–1.93)	0.62 (0.15–2.57)
Any bleeding (BARC type 2, 3, or 5)	42 (3.6)	29 (5.3)	1.42 (0.86–2.36)	1.48 (0.89–2.49)	2.28 (1.19–4.39)
Minor bleeding (BARC type 2)	28 (2.4)	16 (3.0)	1.12 (0.58–2.17)	1.10 (0.56–2.15)	1.64 (0.74–3.61)

Data are presented as number (Kaplan–Meier estimates %). The following covariates identified at randomisation were used for a multivariable Cox proportional hazard regression model for Net adverse clinical events: age, sex, diabetes, hypertension, dyslipidemia, chronic kidney disease, prior revascularisation, clinical diagnosis at index PCI, extent of disease, and stent type. The following covariates were used for a multivariable Cox proportional hazard regression model for ischemic events: age, diabetes, hypertension, dyslipidemia, clinical diagnosis at index PCI, extent of disease, and stent type. The following covariates identified at randomisation were used for a multivariable Cox proportional hazard regression model for bleeding events: age, sex, diabetes, hypertension, dyslipidemia, chronic kidney disease, prior revascularisation, and clinical diagnosis at index PCI. The following covariates identified at randomisation were used for a propensity score matching analysis: age, sex, diabetes, hypertension, dyslipidemia, chronic kidney disease, peripheral vascular disease, prior MI, prior revascularisation, prior cerebrovascular events, clinical diagnosis at index PCI, left main PCI, extent of disease, mean stent diameter, total stent length, and stent type. BARC, Bleeding Academic Research Consortium; CI, confidence interval; DAPT, dual antiplatelet therapy; HR, hazard ratio; PCI, percutaneous coronary intervention; PS, propensity score. [a]Net adverse clinical events is a composite of target lesion failure, stent thrombosis, and major bleeding. [b]Target vessel failure is a composite of cardiac death, target vessel myocardial infarction, and clinically driven target vessel revascularisation.

Table 2: **Primary and secondary outcomes in patients who were event-free until 1 year.**

Several studies have evaluated the efficacy and safety of prolonged DAPT beyond 1 year.[14–23] Earlier randomised trials such as the PRODIGY (Prolonging Dual Antiplatelet Treatment After Grading Stent-Induced Intimal Hyperplasia Study),[15] the ARCTIC (Assessment by a double Randomisation of a Conventional antiplatelet strategy vs a monitoring-guided strategy for drug-eluting stent implantation and, of Treatment Interruption vs Continuation 1 year after stenting)-Interruption,[16] and the REAL-LATE (Real-World Patients Treated with Drug-Eluting Stent Implantation and Late Coronary Arterial Thrombotic Events)/ZEST-LATE (Evaluation of the Long-Term Safety after Zotarolimus-Eluting Stent, Sirolimus-Eluting Stent, or Paclitaxel-Eluting Stent Implantation for Coronary Lesions — Late Coronary Arterial Thrombotic Events)[14] trials did not demonstrate clear ischemic benefit with extended therapy. In contrast, the larger-scale DAPT (Dual Antiplatelet Therapy study) trial reported that among patients who had not experienced adverse events during the first 12 months after DES implantation, extending DAPT to 30 months reduced the risk of stent thrombosis and major adverse cardiovascular and cerebrovascular events but increased the risk of moderate or severe bleeding compared to aspirin monotherapy.[18,19] Meta-analyses of randomised trials have reported an association between extended DAPT (beyond 1 year) and reduced risk of ischemic events, such as MI and stent thrombosis, but an increased risk of major bleeding compared with short-term DAPT.[20,21] More recently, studies have evaluated the impact of P2Y12 inhibitor monotherapy following short-term DAPT compared with prolonged DAPT. The long-term follow-up of the SMART-CHOICE (Smart Angioplasty Research Team: Comparison Between P2Y12 Antagonist Monotherapy vs Dual Antiplatelet Therapy in Patients Undergoing Implantation of Coronary Drug-Eluting Stents) trial demonstrated that P2Y12 inhibitor monotherapy after 3 months of DAPT was associated with a lower risk of major bleeding compared to prolonged DAPT for 3 years, without increasing the risk of ischemic events.[22] In this study, 64.9% of patients in the prolonged DAPT group continued DAPT up to the 3-year follow-up. The OPT-BIRISK (Optimal Antiplatelet Therapy for High Bleeding and Ischemic Risk Patients) trial demonstrated that clopidogrel monotherapy was superior to an additional 9 months of DAPT in reducing clinically relevant bleeding among patients at high risk for both bleeding and ischemic events following PCI, without increasing ischemic events, after completing 9–12 months of DAPT.[23] As clopidogrel is associated with a lower risk of both thrombotic and bleeding events compared with aspirin as a chronic maintenance therapy after PCI over a median follow-up of 5.8 years,[29,30] P2Y12 inhibitor monotherapy following short-term DAPT could be a reasonable alternative to extended DAPT for reducing bleeding risk without an increased risk of ischemic events.

The HOST-IDEA trial followed a pragmatic design, allowing physicians to determine DAPT and SAPT regimens to reflect real-world practice. Consequently, patients initially randomised to the 12-month DAPT group were more likely to continue DAPT beyond 1 year (23.5% vs 9.5% at 3 years), and aspirin was the most commonly prescribed SAPT agent in the 3-to-6-month DAPT group (60.3%), whereas clopidogrel was more frequently used in the 12-month DAPT group (53.6%). This notable difference appears to have been influenced more by randomisation assignment than by patients' underlying clinical risk profiles. We speculate that physicians tended to prefer extended DAPT regimen and potent antiplatelet agent—clopidogrel—over aspirin when stepping down from DAPT to SAPT in patients who had been assigned to a longer duration of DAPT. This behavior may suggest that randomisation itself can subtly influence clinical perceptions and therapeutic decisions. In addition, the HOST-EXAM (EXtended Antiplatelet Monotherapy) trial,[30] which demonstrated the superiority of clopidogrel over aspirin as long-term SAPT after PCI in reducing both ischemic and bleeding events, was published in May 2021, during the later phase of enrollment in the HOST-IDEA trial (January 2016–May 2021). In our study, patients who transitioned to SAPT after the publication of the HOST-EXAM trial more frequently received clopidogrel than aspirin. Furthermore, the proportion of such patients was relatively higher in the 12-month DAPT group compared to the 3-to-6-month group. These factors likely contributed to the greater use of clopidogrel as SAPT in the 12-month group. Taken together, the observed differences in SAPT selection between the two groups likely reflect a combination of the influence of initial randomisation and the impact of emerging clinical evidence during the course of the study. Notably, this trial demonstrated no association between 3-to-6-month DAPT and an increased risk of ischemic events over 3 years compared with 12-month DAPT, despite 23.5% of patients in the 12-month DAPT group continuing with DAPT up to the 3-year follow-up. The absence of an increased risk of ischemic events in the short-term DAPT group, despite the higher aspirin use, may be attributed to contemporary practice, characterised by advanced stent technology, high prevalence of statin prescriptions (93.9% in our study), and considerable utilisation of image-guided PCI (31.0% in our study). In addition, the current study demonstrated the lack of significant differences in the risk of major bleeding between the 3-to-6-month and 12-month DAPT groups, despite the fact that approximately 30% of the study population consisted of high bleeding risk patients who would be expected to benefit from an abbreviated DAPT regimen.[31] This may be explained by the antiplatelet agent selection during both the DAPT and SAPT periods. Aspirin, which is associated with a higher bleeding risk compared to clopidogrel also in high bleeding risk patients,[30,32] was more commonly used as SAPT in the 3-to-6-month DAPT group. In contrast, although many patients in the 12-month DAPT group remained on DAPT beyond 1 year, clopidogrel—not potent P2Y12 inhibitors—was the predominant agent prescribed during the DAPT period and was also preferred as SAPT after DAPT completion, potentially offsetting the bleeding risk associated with prolonged DAPT.

In our study, the risk of major bleeding gradually diverged between the >1-year DAPT and ≤1-year DAPT groups, highlighting the increased bleeding risk with extended DAPT. Notably, the TLF risk was numerically higher in the >1-year DAPT group compared with the ≤1-year DAPT group. Post-PCI bleeding is well recognised as a strong predictor of subsequent all-cause and cardiac death.[33] Given the complexity of determining the exact cause of death, distinguishing between cardiac and non-cardiac death is often challenging. The classification of unexplained deaths as cardiac deaths suggests that bleeding may elevate the risk of cardiac death, which is a component of TLF. Moreover, bleeding events may precipitate ischemic complications because of abrupt discontinuation or nonadherence to antiplatelet therapy, as well as through transfusion-related inflammation.[34] Consistent with our study, a meta-analysis of randomised trials demonstrated that extending DAPT beyond 1 year results in higher all-cause mortality compared with DAPT shorter than 6 months in patients receiving newer-generation DES.[20] The concentration of TLF events predominantly in the early phase after 1 year in the >1-year DAPT group suggests that potentially more patients in this group underwent TLR following pre-planned follow-up coronary angiography and subsequently continued extended DAPT. Although we compared the two groups using multivariable analysis and propensity score matching, the non-randomised design prevented complete elimination of selection bias.

The current study has some limitations. First, this study was initially designed pragmatically for antiplatelet regimens, resulting in approximately 90% of patients receiving clopidogrel for DAPT, although more than half of the patients were presented as ACS. Randomised clinical trials in East Asian patients with ACS have demonstrated that clopidogrel-based DAPT is superior to ticagrelor-based DAPT in terms of both bleeding and ischemic risks.[35,36] Consequently, clopidogrel-based DAPT became the standard and most widely used regimen in Asia. However, ethnic differences should be considered when applying these findings to Western populations. Second, the lack of centre-stratified randomisation may have introduced confounding in the study results. However, a Cox proportional hazards regression model with study site stratification was applied to overcome this limitation. Third, the lack of blinding for patients and physicians

to antiplatelet strategies may have introduced bias affecting the study results. However, the event adjudication was conducted in a blinded manner by an independent adjudication committee. Fourth, as we have analysed clinical outcomes between patients receiving >1-year and ≤1-year DAPT, including only those who were event-free until 1 year, there is an inherent limitation of the analyses from observational data of the survivor cohort. Even though we did multivariable analyses and propensity score matching analyses to overcome the group differences, these results should be considered hypothesis-generating. Fifth, a substantial proportion (46.6%) of patients in the >1-year DAPT group transitioned to SAPT during the extended follow-up period, which may have attenuated the differences in clinical outcomes between the >1-year and ≤1-year DAPT groups. However, our analysis still demonstrated a significantly higher risk of major bleeding in the >1-year DAPT group, suggesting that the bleeding risk was sufficiently elevated to remain detectable despite potential dilution. Sixth, this study permitted routine follow-up coronary angiography at the discretion of the treating physician, which could serve as a potential source of detection and treatment bias. Seventh, the event rates observed in this study were lower than expected at the time of study design. However, they were comparable with those reported in recently published studies.[22,37–39] These lower rates likely reflect improved outcomes after PCI with contemporary DES. Eighth, approximately 5% of patients were lost to follow-up over the 3-year period. Although all available clinical events up to the time of loss were collected and incorporated into the analysis, and vital status was completely verified through the Korean National Health Insurance System, the possibility of bias due to incomplete follow-up cannot be fully excluded. In addition, in the tipping-point analysis, the higher risks of NACE and major bleeding with >1-year DAPT became neutralised under an asymmetric imputation scenario, in which 40% and 10% of patients lost to follow-up in the ≤1-year DAPT group were imputed as having events, whereas those in the >1-year group were assumed to remain event-free until the maximal follow-up. Given the observed 3-year event rates of 2.6% for NACE and 1.1% for major bleeding (Table 2), this would require disproportionately high unobserved event rates among lost-to-follow-up patients in the ≤1-year group and none in the >1-year group, suggesting that a substantial deviation in unobserved outcomes would be needed to overturn the results and supporting the overall robustness of our findings. Finally, because several variables required for the Academic Research Consortium–High Bleeding Risk (ARC-HBR) classification were unavailable in our dataset, we could not apply the ARC-HBR criteria to define high bleeding risk. Instead, we used the PRECISE-DAPT score, for which all necessary variables were available.

The present study provides important long-term evidence regarding DAPT duration after PCI with contemporary third-generation DES. This 3-year follow-up analysis of the HOST-IDEA trial demonstrated the long-term safety of abbreviated 3-to-6-month DAPT compared with conventional 12-month DAPT, while exploratory analyses demonstrated that extending DAPT beyond 1 year was associated with a higher risk of major bleeding without additional ischemic benefit. These findings may be particularly relevant in the current clinical era, where improvements in stent platforms and PCI practice have substantially lowered event rates, and support the long-term efficacy and safety of abbreviated DAPT in PCI patients in the contemporary era.

Contributors

All authors contributed to the acquisition of the work. HS Kim and JK Han designed the analyses. D Hwang, S Yang, and SH Park assessed and verified the data. JK Han, D Hwang, and SH Park analysed the data and created figures and tables. JK Han and D Hwang wrote the first draft of the manuscript. All authors read and edited the drafted manuscript for important intellectual content and assisted in data interpretation. All authors approved the manuscript.

Data sharing statement

The data that support the findings of this study are available from the corresponding author on reasonable request.

Declaration of interests

JK Han reports the grants from ChongKunDang and HanMi, outside of the submitted work. KW Park reports the speaker's fees from Daiichi Sankyo, AstraZeneca, Sanofi, Bristol-Myers Squibb, Bayer, and Pfizer, outside of the submitted work. HS Kim reports the grants or speaker fees from Daiichi Sankyo, Boston Scientific, Terumo, Biotronik, Dio, Medtronic, Abbott Vascular, Edwards Life Science, Amgen, and Behringer Ingelheim, outside of the submitted work. All other authors declare no competing interests.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.eclinm.2025.103698.

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