

## Supplementary Online Content

Watanabe H, Domei T, Morimoto T, et al; for the STOPDAPT-2 Investigators. Effect of 1-month dual antiplatelet therapy followed by clopidogrel vs 12-month dual antiplatelet therapy on cardiovascular and bleeding events in patients receiving PCI: the STOPDAPT-2 randomized clinical trial [published June 25, 2019]. *JAMA*. doi:10.1001/jama.2019.8145

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This supplementary material has been provided by the authors to give readers additional information about their work.

## 1 **eAppendix 1. Study Organization and Participating Centers**

### 2 **Steering Committee:**

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13

14 Following 90 institutes in Japan screened or enrolled one or more eligible patients.

15

16 Teine Keijinkai Hospital, Sapporo, (Mitsugu Hirokami)

17 Hokko Memorial Hospital, Sapporo, (Yoichi Nozaki)

18 Hirosaki University Hospital, Hirosaki, (Hirofumi Tomita)

19 Iwate Medical University Hospital, Morioka, (Yoshihiro Morino)

20 Sendai Kousei Hospital, Sendai, (Tatsushi Ootomo)

21 Sendai Cardiovascular Center, Sendai, (Masahiro Yagi)

22 Tohoku Medical and Pharmaceutical University Hospital, Sendai, (Tatsuya Komaru)

23 Nakadori General Hospital, Akita, (Ryohei Sakamoto)

24 Nihonkai General Hospital, Sakata, (Shigeo Sugawara)

25 Hoshi General Hospital, Koriyama, (Yoshitane Seino)

26 Jichi Medical University Hospital, Shimotsuke, (Kazuomi Kario)

27 Mashiko Hospital, Kawaguchi, (Shogo Shimizu)

28 Mitsui Memorial Hospital, Tokyo, (Kengo Tanabe)

29 Juntendo University Hospital, Tokyo, (Hiroyuki Daida)

30 The Fraternity Memorial Hospital, Tokyo, (Yasuhiro Takahashi)

31 Edogawa Hospital, Tokyo, (Hiroshi Ohira)

32 Showa University Koto Toyosu Hospital, Tokyo, (Kohei Wakabayashi)

33 Tokyo Women's Medical University Hospital, Tokyo, (Nobuhisa Hagiwara)

34 Tokyo General Hospital, Tokyo, (Toshiya Muramatsu)

35 Juntendo University Nerima Hospital, Tokyo, (Hiroshi Tamura)

- 1 Kawakita General Hospital, Tokyo, (Atsushi Tosaka)
- 2 Sakakibara Heart Institute, Fuchu, (Itaru Takamisawa)
- 3 Tokyo Metropolitan Tama Medical Center, Fuchu, (Hiroyuki Tanaka)
- 4 Minamino Cardiovascular Hospital, Hachioji, (Yoshiki Hata)
- 5 Higashiyamato Hospital, Higashiyamato, (Ryuichi Kato)
- 6 St. Marianna University School of Medicine Hospital, Kawasaki, (Yoshihiro Akashi)
- 7 Yokohama Rosai Hospital, Yokohama, (Kazuhiko Yumoto)
- 8 Showa University Fujigaoka Hospital, Yokohama, (Hiroshi Suzuki)
- 9 Saiseikai Yokohamashi Tobu Hospital, Yokohama, (Yoshiaki Ito)
- 10 Yokohama City University Medical Center, Yokohama, (Kiyoshi Hibi)
- 11 Kitasato University Hospital, Sagamihara, (Junya Ako)
- 12 Hiratsuka Kyosai Hospital, Hiratsuka, (Yuko Onishi)
- 13 Tokai University Hospital, Isehara, (Yuji Ikari)
- 14 Kimitsu Chuo Hospital, Kisarazu, (Masashi Yamamoto)
- 15 Kanazawa Cardiovascular Hospital, Kanazawa, (Masanobu Namura)
- 16 University of Fukui Hospital, Fukui, (Hiroyasu Uzui)
- 17 Municipal Tsuruga Hospital, Tsuruga, (Kanichi Otowa)
- 18 University of Yamanashi Hospital, Chuo, (Jun-ei Obata)
- 19 Gifu Prefectural General Medical Center, Gifu, (Toshiyuki Noda)
- 20 Ogaki Municipal Hospital, Ogaki, (Kensuke Takagi)
- 21 Juntendo University Shizuoka Hospital, Izunokuni, (Satoru Suwa)
- 22 Shizuoka General Hospital, Shizuoka, (Hiroki Sakamoto)
- 23 Japanese Red Cross Nagoya Daini Hospital, Nagoya, (Mamoru Nanasato)
- 24 Handa City Hospital, Handa, (Susumu Suzuki)
- 25 Tosei General Hospital, Seto, (Hiroshi Asano)
- 26 Ichinomiyanishi Hospital, Ichinomiya, (Tomohiko Teramoto)
- 27 Yokkaichi Hazu Medical Center, Yokkaichi, (Masaki Kawamura)
- 28 Matsusaka Central General Hospital, Matsusaka, (Takashi Tanigawa)
- 29 Nabari City Hospital, Nabari, (Kazuaki Kataoka)
- 30 Otsu Red Cross Hospital, Otsu, (Kazuaki Kaitani)
- 31 Hikone Municipal Hospital, Hikone, (Akira Nakano)
- 32 Kyoto University Hospital, Kyoto, (Takeshi Kimura)
- 33 Kyoto Medical Center, Kyoto, (Masaharu Akao)
- 34 Mitsubishi Kyoto Hospital, Kyoto, (Takafumi Yokomatsu)
- 35 Kitano Hospital, Osaka, (Moriaki Inoko)

- 1 Osaka Red Cross Hospital, Osaka, (Tsukasa Inada)
- 2 National Cerebral and Cardiovascular Center, Osaka, (Satoshi Yasuda)
- 3 Kindai University Hospital, Sayama, (Shunichi Miyazaki)
- 4 Mimihara General Hospital, Sakai, (Shozo Ishihara)
- 5 Bell Land General Hospital, Sakai, (Toru Kataoka)
- 6 Kobe City Medical Center General Hospital, Kobe, (Makoto Kinoshita)
- 7 Kindai University Nara Hospital, Ikoma, (Kiyonori Togi)
- 8 Tenri Hospital, Tenri, (Toshihiro Tamura)
- 9 Japanese Red Cross Wakayama Medical Center, Wakayama, (Takashi Tamura)
- 10 Wakayama Medical University Hospital, Wakayama, (Takashi Akasaka)
- 11 Shimane University Hospital, Izumo, (Kazuaki Tanabe)
- 12 Japanese Red Cross Okayama Hospital, Okayama, (Tetsuya Sato)
- 13 Kurashiki Central Hospital, Kurashiki, (Kazushige Kadota)
- 14 Hiroshima University Hospital, Hiroshima, (Yasuki Kihara)
- 15 Iwakuni Medical Center, Iwakuni, (Satoru Sakuragi)
- 16 Tokuyama Central Hospital, Shunan, (Takatoshi Wakeyama)
- 17 Shimonoseki City Hospital, Shimonoseki, (Takeo Kaneko)
- 18 Tokushima University Hospital, Tokushima, (Tetsuzo Wakatsuki)
- 19 Tokushima Red Cross Hospital, Komatsushima, (Koichi Kishi)
- 20 Kagawa Prefectural Central Hospital, Takamatsu, (Masayuki Doi)
- 21 Ehime Prefectural Central Hospital, Matsuyama, (Hideki Okayama)
- 22 Matsuyama Red Cross Hospital, Matsuyama, (Kunio Morishige)
- 23 Chikamori Hospital, Kochi, (Kazuya Kawai)
- 24 Kokura Memorial Hospital, Kitakyusyu, (Kenji Ando)
- 25 Hospital of University of Occupational and Environmental Health Japan, Kitakyusyu, (Shinjo Sonoda)
- 26 Saiseikai Fukuoka General Hospital, Fukuoka, (Nobuhiro Suematsu)
- 27 Fukuoka Tokushukai Hospital, Kasuga, (Hideki Shimomura)
- 28 Kumamoto University Hospital, Kumamoto, (Kenichi Tsujita)
- 29 Saiseikai Kumamoto Hospital, Kumamoto, (Tomohiro Sakamoto)
- 30 Japanese Red Cross Kumamoto Hospital, Kumamoto, (Tomokazu Ikemoto)
- 31 Miyazaki Prefectural Nobeoka Hospital, Nobeoka, (Nobuyasu Yamamoto)
- 32 Ibusuki Medical Center, Ibusuki, (Katsuro Kashima)
- 33 Izumi Regional Medical Center, Akune, (Kazuhiro Anzaki)
- 34 Urasoe General Hospital, Urazoe, (Hiroki Uehara)
- 35 Nakagami Hospital, Okinawa, (Hiroshi Ishimori)
- 36

1 **eAppendix 2. Primary and Secondary Endpoints and the Time Point to**  
2 **Assessment**

3 **Primary endpoint (assessed at 12-month [between 335- to 394-day]):**

4 A composite cardiovascular and bleeding events, defined as composite of cardiovascular death, myocardial  
5 infarction (MI), stroke (ischemic and hemorrhagic), definite stent thrombosis, and Thrombolysis in  
6 Myocardial Infarction (TIMI) major/minor bleeding.

7 **Major secondary endpoints (assessed at 12-month [between 335- to 394-day])**

8 **Major secondary cardiovascular endpoint:** A composite of cardiovascular death, MI, stroke  
9 (ischemic and hemorrhagic), and definite stent thrombosis.

10 **Major secondary bleeding endpoint:** TIMI major/minor bleeding

11  
12 **Other secondary endpoints (assessed at 12-month [between 335- to 394-day])**

- 13 • Death
- 14 • Death from cardiac cause (cardiac death)
- 15 • Death from cardiovascular cause (cardiovascular death)
- 16 • Death from non-cardiovascular cause (non-cardiovascular death)
- 17 • MI
- 18 • MI (classified with infarct size of MI by peak values of myocardial enzyme); large MI (Creatine kinase  
19 MB [CKMB]≥10 times of upper limit of normal [ULN]), small MI (CKMB<10 times ULN), MI without  
20 CKMB elevation, and MI without measurement of CKMB
- 21 • Definite stent thrombosis
- 22 • Definite/probable stent thrombosis
- 23 • Stroke (ischemic and hemorrhagic)
- 24 • Ischemic stroke
- 25 • Hemorrhagic stroke
- 26 • TIMI major bleeding
- 27 • TIMI minor bleeding,
- 28 • Bleeding Academic Research Consortium (BARC) 3 or 5 bleeding
- 29 • BARC 5 bleeding
- 30 • BARC 3 bleeding
- 31 • Global Use of Strategies to Open Occluded Arteries (GUSTO) moderate/severe bleeding
- 32 • GUSTO severe bleeding
- 33 • GUSTO moderate bleeding
- 34 • Intracranial bleeding
- 35 • Gastrointestinal bleeding

- 1 • Any coronary revascularization
- 2 • Target lesion revascularization (TLR)
- 3 • Clinically-driven TLR
- 4 • Non-TLR coronary revascularization
- 5 • Coronary artery bypass grafting
- 6 • A Composite of death or MI
- 7 • A Composite of cardiovascular death or MI
- 8 • Major adverse cardiac events, defined as a composite of cardiac death, MI, and clinically-driven TLR
- 9
- 10

## 1 **eAppendix 3. Definition of Endpoints**

### 2 **1. Death**

3 As classified by Academic Research Consortium (ARC)

- 4 • **Cardiac Death**

5 Any death due to proximate cardiac cause (e.g. myocardial infarction [MI], low-output failure, fatal  
6 arrhythmia), unwitnessed death and death of unknown cause, all procedure related deaths including  
7 those related to concomitant treatment. All deaths are considered cardiac unless an unequivocal  
8 non-cardiac cause can be established. Specifically, any unexpected death even in subjects with  
9 coexisting potentially fatal non-cardiac disease (e.g. cancer, infection) should be classified as  
10 cardiac.

- 11 • **Vascular Death**

12 Death due to non-coronary vascular causes such as cerebrovascular disease, pulmonary embolism,  
13 ruptured aortic aneurysm, dissecting aneurysm, or other vascular cause.

- 14 • **Non-cardiovascular Death**

15 Any death not covered by the above definitions such as death caused by infection, malignancy,  
16 sepsis, pulmonary causes, accident, suicide or trauma.

### 17 **2. Myocardial Infarction: MI**

18 As classified by Academic Research Consortium (ARC): However, the sensitivity is too high for the evaluation  
19 with Troponin of the peri-procedural MI, thus CKMB will be used.

- 20 • **Preprocedural Adjudication of MI**

21 Myocardial Infarction (MI) is defined by the ARC criteria. However, periprocedural MI will be  
22 evaluated by CKMB, because the evaluation by troponin is too sensitive.

- 23 • **Baseline MI evaluation**

24 ECG showing ST elevation, development of new abnormal Q-wave, clinical symptoms specific to  
25 MI, troponin or CKMB values exceeding the standard values

- 26 • **Periprocedural MI**

- 27 ○ Occurrence of any of the following events within 48 hours after PCI procedure will be  
28 judged as MI.

- 29 ■ **CKMB  $\geq 3$  times Upper Reference Limit (URL)** (CKMB value exceeding URL  
30 before procedure is not considered as a new MI, but as MI at enrollment.)

- 31 ■ **Abnormal ECG** (new Q-wave, left bundle branch block)

- 32 ○ Occurrence of troponin  $\geq 5$  times URL or CKMB  $\geq 5$  times URL within 72 hours after  
33 coronary artery bypass grafting (CABG) procedure accompanied by any of the following  
34 criteria will be judged as MI. (CKMB value exceeding URL before procedure is not  
35 considered as a new MI, but as MI at enrollment.)

- 1                   ▪ Abnormal ECG (new Q-wave, left bundle branch block)
- 2                   ▪ New occlusion of coronary autografts or grafts
- 3                   ▪ Reduction in living myocardium confirmed by diagnostic imaging
- 4       • **Spontaneous MI**
- 5           ○ Occurrence of any of the following events at > 48 hours after PCI or > 72 hours after
- 6           CABG will be judged as MI. MI caused by revascularization procedures, such as TLR
- 7           and TVR, is defined as periprocedural MI.
- 8           ▪ Abnormal ECG (new Q-wave, left bundle branch block)
- 9           ▪ Troponin or CKMB value > **URL** (CKMB value exceeding URL before procedure is
- 10           not considered as a new MI, but as MI at enrollment.)
- 11       • **Sudden Death**
- 12           ○ When death occurred before blood sampling for biomarker measurements or while
- 13           biomarkers appeared to be increasing, MI will be judged according to the following
- 14           criteria:
- 15           ▪ Clinical symptoms suggesting ischemia that are accompanied by one of the
- 16           following:
- 17           - New ST elevation or left bundle branch block
- 18           - Thrombus determined by angiography or at autopsy
- 19       • **Reinfarction**
- 20           ○ When after onset of MI stable or decreasing values are confirmed in 2 biomarker
- 21           measurements, but 20% increase 3 to 6 hours is observed after the second measurement.
- 22           ▪ If biomarkers are increasing or have not yet reached the peak, data are insufficient to
- 23           diagnose reinfarction.

#### 24 **Electrocardiographic Classification:**

- 25       • **Classification based on Q-wave**
- 26           ○ **Q-wave MI (QMI)**
- 27           ▪ Development of abnormal Q-waves confirmed in 2 or more contiguous leads with or
- 28           without elevation in cardiac enzymes.
- 29           ○ **Non-Q-wave MI (NQMI)**
- 30           ▪ All MIs not classified as Q-wave.
- 31       • **Classification based on ST segment.**
- 32           ○ **ST-elevation myocardial infarction (MI) (STEMI)**
- 33           ▪ New or presumably new elevation of ST segment at J point in 2 or more contiguous
- 34           leads. Cut-off point is  $\geq 0.2$  mV in V1, V2 and V3 leads and  $\geq 0.1$  mV in other leads.



1 ○ **Non-ST elevation myocardial infarction (MI) (NSTEMI)**

- 2 ■ MI that is not STEMI

3 **Determination by Infarction Size:**

4 • **Major Infarction**

- 5 ○ CKMB level is  $\geq 10$  times the upper limit of normal (ULN) (or CK level is  $\geq 10$  times ULN  
6 in case CKMB level is not measurable).

- 7 ■ Even if the above conditions are not met, fatal MI is determined as large infarction.

8 • **Minor Infarction**

- 9 ○ All types of MI other than the major infarction

10 • **Classification of MI Size Based on the ARC Classification**

- 11 ○ Increase in the cardiac enzyme (CKMB, Tn, and total CK) levels  $\geq 10$  times ULN

- 12 ○ Increase in the cardiac enzyme (CKMB, Tn, and total CK) levels  $\geq 5$  times,  $< 10$  times  
13 ULN

- 14 ○ Increase in the cardiac enzyme (CKMB, Tn, and total CK) levels  $\geq 3$  times,  $< 5$  times  
15 ULN

- 16 ○ Increase in the cardiac enzyme (CKMB, Tn, and total CK) levels  $< 3$  times ULN

- 17 ○ Increase in the troponin level; no increase in the CKMB and total CK levels

- 18 ○ Increase in the troponin level; no measurements of the CKMB and total CK levels

19 **The cardiac enzymes should be prioritized in the order of CKMB, Tn, and total CK.**

20 • **Classification of MI Size Based on the CKMB Level**

- 21 ○ Increase in the cardiac enzyme (CKMB) level  $\geq 10$  times ULN

- 22 ○ Increase in the cardiac enzyme (CKMB) level  $\geq 5$  times,  $< 10$  times ULN

- 23 ○ Increase in the cardiac enzyme (CKMB) level  $\geq 3$  times,  $< 5$  times ULN

- 24 ○ Increase in the cardiac enzyme (CKMB) level  $< 3$  times ULN

- 25 ○ Increase in the troponin level; no increase in the CKMB level

- 26 ○ Increase in the troponin level; no measurement of the CKMB level

27 • **Classification of MI Size Based on the Troponin Level**

- 28 ○ Increase in the cardiac enzyme (Tn) level  $\geq 10$  times ULN

- 29 ○ Increase in the cardiac enzyme (Tn) level  $\geq 5$  times,  $< 10$  times ULN

- 30 ○ Increase in the cardiac enzyme (Tn) level  $\geq 3$  times,  $< 5$  times ULN

- 31 ○ Increase in the cardiac enzyme (Tn) level  $< 3$  times ULN

- 32 ○ Increase in the troponin level; no increase in the CKMB level

- 33 ○ Increase in the troponin level; no measurement of the CKMB level

34 **3. Revascularization**

35 **Classification:**

- 1 • **Target Lesion Revascularization (TLR)**  
2 PCI performed in the target lesion (within 5 mm of the stent edges), or CABG performed for  
3 restenosis of the target lesion or for treatment of other complications
- 4 • **Target Vessel Revascularization (TVR)**  
5 PCI performed in the target vessel or revascularization by CABG, including TLR
- 6 • **Target Vessel Revascularization-Remote (TVR-Remote)**  
7 Revascularization of a non-target lesion in the target vessel
- 8 • **Non Target Vessel Revascularization (Non-TVR)**  
9 Any revascularization in a vessel other than the target vessel
- 10 • **Non Target Lesion Revascularization (Non-TLR)**  
11 Any revascularization in a lesion other than the target lesion  
12 Non-TLR = TVR-Remote + Non-TVR

#### 13 **Clinically indicated revascularization:**

- 14 • The revascularization that meets the following criteria is considered as clinically indicated  
15 revascularization. Presence/absence of clinical findings is judged by the operator of the procedure  
16 before the revascularization.
  - 17 ○ Recurrence of angina pectoris, presumably related to the target vessel;
  - 18 ○ Objective signs of ischemia at rest or during exercise test (or equivalent), presumably  
19 related to the target vessel;
  - 20 ○ Signs of functional ischemia revealed by any invasive diagnostic test (e.g., Doppler flow  
21 velocity reserve [FVR], fractional flow reserve [FFR]);
  - 22 ○ Revascularization for  $\geq 70\%$  diameter stenosis even in the absence of the above-  
23 mentioned ischemic signs or symptoms.

#### 24 **4. Stent Thrombosis**

25 Based on the ARC definition, Stent thrombosis is classified into definite, probable and possible  
26 according to the “probability”, and into acute, subacute late and very late according to timing of the  
27 onset.

- 28 • **Definite Stent Thrombosis**
  - 29 ○ Angiographic confirmation of stent thrombosis\*:
    - 30 ■ The presence of a thrombus† that originates in the stent segment (including 5 mm of  
31 the stent edges) is revealed by angiography, and presence of at least one of the  
32 following criteria within a 48-hour time window is observed:
      - 33 - Acute onset of ischemic symptoms at rest
      - 34 - New ECG changes that suggest acute ischemia

- 1                    - Typical rise and fall in cardiac biomarkers (refer to definition of spontaneous
- 2                    MI)
- 3                    - Nonocclusive thrombus
- 4                        ▪ Intracoronary thrombus is defined as a noncalcified filling defect (spherical,
- 5                                       ovoid, or irregular) or lucency surrounded by contrast material (on 3 sides or
- 6                                       within a coronary stenosis) seen in multiple projections, or persistence of
- 7                                       contrast material within the lumen, or a visible embolization
- 8                    - Occlusive thrombus
- 9                        ▪ TIMI 0 or TIMI 1 intrastent or proximal to a stent up to the most adjacent
- 10                                       downstream side branch or main branch
- 11                    ○ Pathological confirmation of stent thrombosis:
- 12                        ▪ Evidence of recent thrombus within the stent determined at autopsy or via
- 13                                       examination of tissue retrieved following thrombectomy
- 14                    • **Probable Stent Thrombosis**
- 15                        ○ When the following cases occurred after intracoronary stenting:
- 16                        ▪ Any unexplained death within the first 30 days after procedure<sup>‡</sup>
- 17                        ▪ Irrespective of the time after the index procedure, any MI in the territory of the
- 18                                       implanted stent in the absence of any other obvious cause such as angiography or
- 19                                       other lesions
- 20                    • **Possible Stent Thrombosis**
- 21                        ○ Any unexplained death from 30 days after intracoronary stenting
- 22                    \*                    The incidental angiographic documentation of stent occlusion in the absence of clinical
- 23                    signs is not considered to be a confirmed stent thrombosis (silent occlusion)
- 24                    †                    Intracoronary thrombus
- 25                    • **Acute Stent Thrombosis**
- 26                    0-24 hours post stent implantation (Time 0 is defined as the time of removal of the guiding
- 27                    catheter).
- 28                    • **Subacute Stent Thrombosis**
- 29                    > 24 hours-30 days post stent implantation
- 30                    • **Late Stent Thrombosis \***
- 31                    > 30 days-1 year post stent implantation
- 32                    • **Very Late Stent Thrombosis \***
- 33                    > 1 year post stent implantation
- 34                    \*                    Including “primary” as well as “secondary” stent thrombosis after stented segment
- 35                    revascularization.

1 **5. Surgery**

- 2 • Including endoscopic surgeries and therapies
- 3 • Including CABG
- 4 • Excluding percutaneous intravascular treatments
- 5 • Including aortic aneurysm stent graft procedure
- 6 • Excluding tooth extraction

7 **6. Bleeding/Hemorrhagic Complications**

8 Bleeding/Hemorrhagic Complications will be evaluated using the TIMI, GUSTO and BARC definitions

9 **TIMI bleeding classification:**

10 Bleeding is classified by the Thrombosis in Myocardial Infarction (TIMI). Measurement of hemoglobin  
11 and hematocrit values at baseline is required for the severity rating.

12 • **Major Bleeding**

- 13 ○ When any of the following criteria is met.
  - 14 ▪ Intracranial hemorrhage
  - 15 ▪ Decrease in hemoglobin to  $\geq 5$  g/dL decrease in the hemoglobin concentration
  - 16 ▪ Absolute drop in hematocrit to  $\geq 15\%$  (Baseline – Onset of the event)

17 • **Minor Bleeding**

- 18 ○ When blood loss is observed, and any of the following criteria is met:
  - 19 ▪ Decrease in hemoglobin to  $\geq 3$  g/dL
  - 20 ▪ Decrease in hematocrit to  $\geq 10\%$  (Baseline – Onset of the event)
- 21 ○ When no blood loss is observed, but any of the following criteria is met:
  - 22 ▪ Decrease in hemoglobin to  $\geq 4$  g/dL
  - 23 ▪ Decrease in hematocrit to  $\geq 12\%$  (Baseline – Onset of the event)

24 • **Minimal Bleeding**

- 25 ○ Any clinically overt sign of hemorrhage that is associated with a fall in hemoglobin to <  
26 3 g/dL.  
27 (Microscopical urine occult blood and fecal occult blood are not defined as Minimal  
28 bleeding.)

29 **GUSTO bleeding classification:**

30 **Severe Bleeding**

- 31 • Life-threatening bleeding
- 32 • Intracranial hemorrhage
- 33 • Hemorrhage or bleeding that causes drop in blood pressure and requires interventions, such as  
34 infusion, blood transfusion, administration of a hypertensor, surgical interception.

35 **Moderate Bleeding**

- Bleeding that requires blood transfusion but does not meet criteria for severe bleeding

## BARC bleeding classification:

Bleeding is classified based on definitions by the Bleeding Academic Research Consortium (BARC).

Measurement of hemoglobin concentration is required for severity rating.

- **Type 0:** No bleeding
- **Type 1:** Bleeding that is not medically significant and does not cause the patient to seek unscheduled performance of studies, hospitalization, or treatment by a health care professional.
- **Type 2:** Any overt sign of hemorrhage that should be treated and does not fit the criteria for Types 3, 4, or 5, but does meet at least one of the following criteria:

(1) requiring non-surgical, medical intervention by a health care professional, (2) leading to hospitalization or increased level of care, (3) prompting evaluation.

- **Type 3:**

- Type 3a

- Overt bleeding plus hemoglobin drop of 3-5 g/dL
- Transfusion with overt bleeding

- Type 3b

- Overt bleeding plus hemoglobin drop of  $\geq 5$  g/dL
- Cardiac tamponade
- Bleeding requiring surgical intervention (excluding dental/nasal/skin/hemorrhoid)
- Bleeding requiring intravenous vasoactive drugs

- Type 3c

- Intracranial hemorrhage
- Intraocular bleeding compromising vision

- **Type4:** CABG-related bleeding

- Perioperative intracranial hemorrhage within 48 hours
- Reoperation following closure of sternotomy for the purpose of controlling bleeding
- Transfusion of  $\geq 5$  units of whole blood or concentrated red blood cell within 48 hours
- Chest tube output  $\geq 2$  L within 24 hours

- **Type5:** Fatal bleeding

- Type 5a

Probable Fatal bleeding: no autopsy or imaging confirmation, but clinically suspicious

- Type 5b

Definite fatal bleeding: overt bleeding or autopsy or imaging confirmation

## 7. Composite Endpoint

Composite endpoint of secondary endpoints will be defined as follows:

1           • **TLF: Target Lesion Failure**

2           Cardiac death, myocardial infarction (MI) of target vessels, Clinically-indicated TLR

3           • **TVF: Target Vessel Failure**

4           Cardiac death, MI or Clinically-indicated TVR.

5           • **MACE: Major Adverse Cardiac Events**

6           Cardiac death, MI or Clinically-indicated TVR

7 **8. Stroke or Cerebrovascular Accident**

8 Acute onset of a neurological deficit that persists for at least 24 hours and is the result of a disturbance of the  
9 cerebral circulation due to ischemia or hemorrhage. Deficits that last  $\leq$  24 hours are due to transient ischemic  
10 neurological attack and are not classified in this category.

11 **9. Classification of Angina**

12           • **Braunwald Classification of Unstable Angina**

- 13           ○ **Class I** : New onset of severe or accelerated angina: Patients with new onset (< 2 months  
14           in duration) exertional angina pectoris that is severe or frequent (> 3 episodes/day) or  
15           patients with chronic stable angina who develop accelerated angina (angina distinctly  
16           more frequent, severe, longer in duration, or precipitated by distinctly less exertion than  
17           previously) but who have not experienced pain at rest during the preceding 2 months.  
18           ○ **Class II** : Angina at rest, subacute: Patients with 1 or more episodes of angina at rest  
19           during the preceding month but not within the preceding 48 hours  
20           ○ **Class III** : Angina at rest, acute: Patients with 1 or more episodes of angina at rest within  
21           the preceding 48 hours

22           • **Canadian Cardiovascular Society (CCS) Classification of Stable Angina**

- 23           ○ **Class I** : Ordinary physical activity does not cause angina, such as walking or climbing  
24           stairs. Angina occurs with strenuous, rapid or prolonged exertion at work or recreation.  
25           ○ **Class II** : Slight limitation of ordinary activity. Angina occurs on walking or climbing  
26           stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, in wind,  
27           under emotional stress or only during the few hours after awakening. Angina occurs on  
28           walking more than two blocks on the level and climbing more than one flight of ordinary  
29           stairs at a normal pace and in normal condition.  
30           ○ **Class III** : Marked limitation of ordinary physical activity. Angina occurs on walking  
31           one to two blocks on the level and climbing one flight of stairs in normal conditions and  
32           at a normal pace.  
33           ○ **Class IV** : Inability to carry on any physical activity without discomfort – angina  
34           symptoms may be present at rest.

1 **eTable 1. Clinical and Procedural Characteristics Compared Between the**  
 2 **Enrolled Patients and the Eligible But Non-enrolled Patients**

	<b>Enrolled</b>	<b>Non-enrolled</b>	<b>P value</b>
	<b>N=3009</b>	<b>N=3287</b>	
Acute coronary syndrome, no (%)	1148 (38.2)	1257 (38.8)	0.61
STEMI, no. (%)	561 (18.6)	702 (21.7)	0.003
NSTEMI, no. (%)	180 (6.0)	192 (5.9)	0.92
Unstable angina, no. (%)	407 (13.5)	363 (11.2)	0.005
Stable coronary artery disease, no. (%)	1861 (61.9)	1984 (61.2)	0.61
Age, yr	68.6±10.7	70.0±11.7	<0.001
Men, no (%)	2337 (77.7)	2497 (76.0)	0.11
Body-mass index, kg/m <sup>2</sup>	24.3±3.5	24.0±3.7	0.002
Hypertension, no (%)	2221 (73.8)	2447 (74.4)	0.57
Diabetes, no (%)	1159 (38.5)	1295 (39.4)	0.47
Treated with insulin, no (%)	202 (6.7)	228 (6.9)	0.73
Smoking, no (%)	1844 (61.3)	1875 (57.0)	<0.001
Current smoking, no (%)	710 (23.6)	704 (21.4)	0.039
Prior myocardial infarction, no (%)	406 (13.5)	746 (22.7)	<0.001
Prior ischemic/hemorrhagic stroke, no (%)	186 (6.2)	253 (7.7)	0.018
Prior PCI, no (%)	1032 (34.3)	1253 (38.1)	0.002
Prior 1st generation DES implantation, no (%)	112 (3.7)	183 (5.6)	<0.001
Heart failure, no (%)	222 (7.4)	247 (7.5)	0.84
Peripheral artery disease, no (%)	196 (6.5)	206 (6.3)	0.69
Serum creatinine, mg/dl	1.12±1.36	1.27±1.69	<0.001
Dialysis, no (%)	102 (3.4)	170 (5.2)	<0.001
Atrial fibrillation, no (%)	57 (1.9)	82 (2.5)	0.1
Number of treated vessels	1.1±0.4	1.2±0.5	<0.001
Number of stents	1.3±0.5	1.3±0.6	0.004
Minimal stent diameter, mm	2.97±0.48	2.94±0.49	0.007
Total stent length, mm	30.4±16.7	30.7±18.2	0.48

3

4

1 **(eTable 1. continued)**

	<b>Enrolled</b>	<b>Non-enrolled</b>	<b>P value</b>
	<b>N=3009</b>	<b>N=3287</b>	
Target lesion location			
Left main coronary artery, no. (%)	80 (2.7)	154 (4.7)	<0.001
Left anterior descending artery, no. (%)	1682 (55.9)	1804 (54.9)	0.42
Left circumflex coronary artery, no. (%)	573 (19.0)	659 (20.1)	0.31
Right coronary artery, no. (%)	846 (28.1)	905 (27.5)	0.61
Bypassed graft, no. (%)	6 (0.2)	11 (0.3)	0.3
Treatment of 2 vessels or more, no. (%)	216 (7.2)	303 (9.2)	0.003
Treatment of 3 vessels or more, no. (%)	11 (0.4)	7 (0.2)	0.26

2

3 Among 4525 screened patients not enrolled in the trial, complete screening data was available in 4331 patients. The baseline  
 4 characteristics were compared between 3009 enrolled patients and 3287 eligible but non-enrolled patients.

5 STEMI denotes ST-segment elevation myocardial infarction, NSTEMI non- ST-segment elevation myocardial infarction, PCI  
 6 percutaneous coronary intervention, and DES drug-eluting stents.

7

8



1 **eTable 2. Complete Baseline Characteristics**

	All	1-month DAPT	12-month DAPT
	N=3009	N=1500	N=1509
<b>Patient demographics</b>			
Age, -yr	68.6±10.7	68.1±10.9	69.1±10.4
≥75, no. (%)	947 (31.5)	448 (29.9)	499 (33.1)
Men, no. (%)	2337 (77.7)	1183 (78.9)	1154 (76.5)
Women, no. (%)	672 (22.3)	317 (21.1)	355 (23.5)
Body mass index, kg/m <sup>2</sup> <sup>1)</sup>	24.3±3.5	24.4±3.5	24.2±3.5
Body mass index <25, no. (%) <sup>1)</sup>	1815 (60.3)	879 (58.6)	936 (62.0)
<b>Presentation</b>			
Acute coronary syndrome, no. (%)	1148 (38.2)	565 (37.7)	583 (38.6)
ST segment elevation MI, no. (%)	561 (18.6)	291 (19.4)	270 (17.9)
Non-ST segment elevation MI, no. (%)	180 (6.0)	81 (5.4)	99 (6.6)
Unstable angina, no. (%)	407 (13.5)	193 (12.9)	214 (14.2)
Stable coronary artery disease, no. (%)	1861 (61.8)	935 (62.3)	926 (61.4)
<b>Past Cardiovascular Treatment</b>			
Prior PCI, no. (%)	1032 (34.3)	503 (33.5)	529 (35.1)
Prior 1 <sup>st</sup> -generation DES, no. (%)	112 (3.7)	65 (4.3)	47 (3.1)
Prior CABG, no. (%)	59 (2.0)	17 (1.1)	42 (2.8)
Prior MI, no. (%)	406 (13.5)	207 (13.8)	199 (13.2)
Prior ischemic/hemorrhagic stroke, no. (%)	186 (6.2)	81 (5.4)	105 (7.0)
<b>Comorbidities</b>			
Hypertension, no. (%)	2221 (73.8)	1105 (73.7)	1116 (74.0)
Hyperlipidemia, no. (%)	2244 (74.6)	1116 (74.4)	1128 (74.8)
Smoker, no. (%)	1844 (61.3)	941 (62.7)	903 (59.8)
Current Smoker, no. (%)	710 (23.6)	399 (26.6)	311 (20.6)
Diabetes, no. (%)	1159 (38.5)	585 (39.0)	574 (38.0)
Diabetes with insulin, no. (%)	202 (6.7)	104 (6.9)	98 (6.5)
Anemia, no. (%) <sup>2)</sup>	263 (8.7)	121 (8.1)	142 (9.4)
Cancer, no. (%)	256 (8.5)	114 (7.6)	142 (9.4)
Heart failure, no. (%)	222 (7.4)	115 (7.7)	107 (7.1)

## 1 (eTable 2. continued)

	All	1-month DAPT	12-month DAPT
	N=3009	N=1500	N=1509
Left ventricular ejection fraction, % <sup>3)</sup>	59.8±10.4	59.8±10.2	59.7±10.6
<40%, no. (%) <sup>3)</sup>	115/2763 (4.2)	59/1368 (4.3)	56/1395 (4.0)
Peripheral artery disease, no. (%)	196 (6.5)	96 (6.4)	100 (6.6)
Severe chronic kidney disease, no. (%) <sup>4)</sup>	166 (5.5)	82 (5.5)	84 (5.6)
Estimated glomerular filtration rate <30 mL/min/1.73m <sup>2</sup> not on dialysis, no. (%) <sup>4)</sup>	64 (2.1)	30 (2.0)	34 (2.3)
Dialysis, no. (%)	102 (3.4)	52 (3.5)	50 (3.3)
Chronic obstructive pulmonary disease, no. (%)	84 (2.8)	40 (2.7)	44 (2.9)
Mitral regurgitation grade 3/4, no. (%)	75 (2.5)	30 (2.0)	45 (3.0)
Atrial fibrillation, no. (%)	57 (1.9)	35 (2.3)	22 (1.5)
Prior bleeding disease, no. (%)	47 (1.6)	19 (1.3)	28 (1.9)
Thrombocytopenia, no. (%) <sup>5)</sup>	31 (1.0)	15 (1.0)	16 (1.1)
Cirrhosis, no. (%)	10 (0.3)	6 (0.4)	4 (0.3)
<b>Procedural Characteristics</b>			
Emergent procedure, no. (%)	750 (24.9)	387 (25.8)	363 (24.1)
Radial approach, no. (%)	2496 (83.0)	1232 (82.1)	1264 (83.8)
Brachial approach, no. (%)	160 (5.3)	85 (5.7)	75 (5.0)
Femoral approach, no. (%)	382 (12.7)	202 (13.5)	180 (11.9)
Invasive fractional flow reserve, no. (%)	415 (13.8)	213 (14.2)	202 (13.4)
Number of target lesions	1.13±0.37	1.12±0.35	1.14±0.39
Number of implanted stents	1.26±0.54	1.26±0.54	1.26±0.55
Minimal stent diameter	2.97±0.48	2.98±0.49	2.96±0.48
<3.0 mm, no. (%)	1237 (41.1)	610 (40.7)	627 (41.6)
Total stent length	30.4±16.7	30.3±16.7	30.5±16.8
>=28mm, no. (%)	1529 (50.8)	742 (49.5)	787 (52.2)

2

3

## 1 (eTable 2. continued)

	All	1-month DAPT	12-month DAPT
	N=3009	N=1500	N=1509
Target lesion location			
Left main coronary artery, no. (%)	80 (2.7)	43 (2.9)	37 (2.5)
Left anterior descending artery, no. (%)	1682 (55.9)	828 (55.2)	854 (56.6)
Left circumflex coronary artery, no. (%)	573 (19.0)	268 (17.9)	305 (20.2)
Right coronary artery, no. (%)	846 (28.1)	436 (29.1)	410 (27.2)
Bypassed graft, no. (%)	6 (0.2)	3 (0.2)	3 (0.2)
Chronic total occlusion, no. (%)	122 (4.1)	55 (3.7)	67 (4.4)
Bifurcation lesions, no. (%)	769 (25.6)	376 (25.1)	393 (26.0)
Final 2 stents implantation, no. (%)	16 (0.5)	9 (0.6)	7 (0.5)
Treatment of 2 vessels or more, no. (%)	216 (7.2)	100 (6.7)	116 (7.7)
Treatment of 3 vessels or more, no. (%)	11 (0.4)	5 (0.3)	6 (0.4)
Use of intravascular ultrasound, no. (%)	2556 (85.0)	1276 (85.1)	1280 (84.8)
Use of optical coherence tomography, no. (%)	443 (14.7)	210 (14.0)	233 (15.4)
<b>Medication at discharge</b>			
Aspirin, no. (%)	3006 (99.9)	1497 (99.8)	1509 (100)
P2Y <sub>12</sub> receptor blockers, no. (%)	3007 (99.9)	1499 (99.9)	1508 (99.9)
Ticlopidine, no. (%)	4 (0.1)	2 (0.1)	2 (0.1)
Clopidogrel, no. (%)	1852 (61.6)	903 (60.2)	949 (62.9)
Prasugrel, no. (%)	1151 (38.3)	594 (39.6)	557 (37.0)
Anticoagulation, no. (%) <sup>6</sup>	13 (0.4)	7 (0.5)	6 (0.4)
Noble oral anticoagulants, no. (%)	7 (0.2)	4 (0.3)	3 (0.2)
Warfarin, no. (%)	6 (0.2)	3 (0.2)	3 (0.2)
Beta-blockers, no. (%)	1315 (43.7)	672 (44.8)	643 (42.6)
Angiotensin converting enzyme inhibitors, no. (%)	851 (28.3)	436 (29.1)	415 (27.5)
Angiotensin-2 receptor blockers, no. (%)	1041 (34.6)	504 (33.6)	537 (35.6)
Calcium channel blockers, no. (%)	1158 (38.5)	568 (37.9)	590 (39.1)
Nitrates, no. (%)	367 (12.2)	178 (11.9)	189 (12.5)
Statin, no. (%)	2635 (87.6)	1318 (87.9)	1318 (87.3)

2

1 **(eTable 2. continued)**

	<b>All</b>	<b>1-month DAPT</b>	<b>12-month DAPT</b>
	<b>N=3009</b>	<b>N=1500</b>	<b>N=1509</b>
Histamine type-2 blockers, no. (%)	135 (4.5)	62 (4.1)	73 (4.8)
Proton pump inhibitors, no. (%)	2383 (79.2)	1190 (79.3)	1193 (79.1)

2 DAPT denotes dual antiplatelet therapy, DES drug eluting stents, MI myocardial infarction, PCI percutaneous coronary  
 3 intervention, and CABG coronary artery bypass grafting.

- 4 1) Body mass index were missing in 36 patients, who were included into the BMI <25 group.  
 5 2) Anemia was defined as hemoglobin less than 11 g/dl. Hemoglobin values were missing in 6 patients, who were assigned  
 6 into the no anemia group.  
 7 3) Left ventricular ejection fraction was missing in 246 patients, who were excluded when the proportion of patients with left  
 8 ventricular ejection fraction <40% was calculated.  
 9 4) Severe chronic kidney disease was defined as estimated glomerular filtration rate <30ml/min/1.73m<sup>2</sup> or maintenance  
 10 dialysis therapy. Preprocedural creatinine values were missing in 10 patients. Two of these patients who were on dialysis  
 11 were included in severe chronic kidney disease, while other 8 patients were regarded as not having severe chronic kidney  
 12 disease.  
 13 5) Thrombocytopenia was defined as platelet counts less than 100\*10<sup>9</sup>/L. Platelet counts were missing in 11 patients, who  
 14 were assigned into the no thrombocytopenia group.  
 15 6) Requirement of oral anticoagulants is one of the exclusion criteria, but some patients required anticoagulation after  
 16 enrollment (e.g. new onset of atrial fibrillation or venous thrombosis).

17

1 **eTable 3. Baseline Angiographic Data Analyzed in the Angiographic Core**  
 2 **Laboratory**

	All	1-month DAPT	12-month DAPT	P value
No. of patients analyzed	N=589	N=293	N=296	
No. of lesions analyzed	N=638	N=314	N=324	
<b>Before index procedure</b>				
Lesion length, mm	18.6±11.0	18.9±10.8	18.4±11.2	0.57
Reference vessel diameter, mm	2.66±0.56	2.64±0.53	2.68±0.58	0.42
Minimum lumen diameter, mm	0.73±0.45	0.73±0.44	0.72±0.46	0.72
Diameter stenosis, %	72.5±16.1	72.1±15.7	72.9±16.4	0.58
Long lesions (>18mm)	218 (40.8)	117 (44.0)	101 (37.7)	0.14
Small vessel (RVD=<2.75mm)	378 (59.2)	188 (59.9)	190 (58.6)	0.75
TIMI flow, no. (%)				0.9
3	475 (74.5)	234 (74.5)	241 (74.4)	
2	52 (8.2)	27 (8.6)	25 (7.7)	
1	17 (2.7)	7 (2.2)	10 (3.1)	
0	94 (14.7)	46 (14.7)	48 (14.8)	
SYNTAX score	9 (6-14)	8 (5-14)	9 (6-15)	0.24
AHA lesion type, no. (%)				0.17
C	243 (38.1)	132 (42.0)	111 (34.3)	
B2	247 (38.7)	110 (35.0)	137 (42.3)	
B1	114 (17.9)	57 (18.2)	57 (17.6)	
A	34 (5.3)	15 (4.8)	19 (5.9)	
In-stent restenosis, no. (%)	35 (5.5)	14 (4.5)	21 (6.5)	0.26
Thrombus, no. (%)	94 (14.7)	48 (15.3)	46 (14.2)	0.7
Dissection, no. (%)	6 (0.9)	4 (1.3)	2 (0.6)	0.39
Haziness, no. (%)	26 (4.1)	11 (3.5)	15 (4.6)	0.47
Eccentric lesion, no. (%)	155 (24.3)	77 (24.5)	78 (24.1)	0.9
Bend lesion (>45°), no. (%)	51 (8.0)	25 (8.0)	26 (8.0)	0.98
Moderate or Severe calcification, no. (%)	100 (15.7)	48 (15.3)	52 (16.1)	0.79
Ulceration, no. (%)	14 (2.2)	9 (2.9)	5 (1.5)	0.25

3

1

2 (eTable 3. continued)

	All	1-month DAPT	12-month DAPT	P value
No. of patients analyzed	N=589	N=293	N=296	
No. of lesions analyzed	N=638	N=314	N=324	
Tortuosity, no. (%)				0.04
None	574 (9.0)	275 (87.6)	299 (92.3)	
Moderate	53 (8.3)	30 (9.6)	23 (7.1)	
Severe	11 (1.7)	9 (2.9)	2 (0.6)	
Ostial lesion, no. (%)	18 (2.8)	8 (2.6)	10 (3.1)	0.68
Bifurcation, no. (%)	234 (36.7)	106 (33.8)	128 (39.5)	0.13
True bifurcation (Medina 1,1,1; 1,0,1; 0,1,1), no. (%)	73 (11.4)	41 (13.1)	32 (9.9)	0.21
Final two stent, no. (%)	4 (0.2)	2 (2.0)	2 (1.8)	0.91
Chronic total occlusion, no. (%)	101 (15.8)	49 (15.6)	52 (16.1)	0.88
Peri-stent contrast staining, no. (%)	4 (0.6)	3 (1.0)	1 (0.3)	0.29
<b>Post procedure</b>				
Minimum lumen diameter, mm				
In-stent	2.45±0.46	2.45±0.46	2.45±0.46	0.97
In-segment	2.11±0.52	2.10±0.53	2.12±0.52	0.57
Diameter stenosis, %				
In-stent	10.2±6.8	10.0±6.4	10.4±7.1	0.44
In-segment	19.5±10.7	20.4±10.9	18.7±10.4	0.048
Acute gain, mm				
In-stent	2.02±0.60	2.00±0.58	2.03±0.62	0.51
In-segment	1.89±0.60	1.89±0.59	1.88±0.61	0.87
TIMI flow scale				
3	632 (99.1)	311 (99.0)	321 (99.1)	0.97
2	6 (0.9)	3 (1.0)	3 (0.9)	

3 Among the participants receiving randomization, the angiographic data of randomly selected 589 patients were to be analyzed

4 by central core laboratory (Cardio Core Japan, Tokyo)

5 DAPT denoted dual antiplatelet therapy, RVD reference vessel diameter, SYNTAX SYnergy between percutaneous coronary

6 intervention with TAXus and cardiac surgery, AHA American Heart Association, and TIMI Thrombolysis in Myocardial Infarction.

7

1 **eTable 4. Post Hoc Analysis of the Mixed Effect Model With Site as a Random**  
 2 **Effect for the Primary Endpoint**

<b>Model</b>	<b>Parameter</b>	<b>Parameter estimate</b>	<b>Hazard ratio</b>	<b>95% CI</b>	<b>P value</b>
Fixed model (original)	Assigned group (1-month vs 12-month)	-0.448 <u>10</u>	0.639	0.418-0.976	.0382
Mixed effect model with site as a random effect (ad-hoc)	Assigned group (1-month vs 12-month)	-0.448 <u>26</u>	0.639	0.418-0.976	.0382

3

4

1 **eTable 5. Per-Protocol and As-Treated Population According to the Mode of**  
 2 **Antithrombotic Therapy at 60 Days**

	1-month DAPT	12-month DAPT	
	<b>N=1500</b>	<b>N=1509</b>	
1. Follow-up at 60-day	1484 (98.9)	1496 (99.1)	
2. Aspirin on treatment at 60-day	73 (4.9)	1485 (99.1)	
3. Aspirin off treatment at 60-day	1411 (94.0)	11 (0.7)	
4. P2Y <sub>12</sub> inhibitors on treatment at 60-day	1471 (99.1)	1476 (98.5)	
5. Clopidogrel on treatment at 60-day	1435 (97.6)	1416 (95.9)	
6. no OAC at 60-day	1470 (99.1)	1484 (99.2)	
7. No other exclusion criteria (prior BVS/Hemorrhagic stroke/Other APT)	1486 (99.1)	1494 (99.0)	
<b>Per protocol population</b>			
3, 5, 6, and 7 (1-month DAPT)	1359 (90.6)	-	
2, 5, 6, and 7 (12-month DAPT)	-	1386 (91.8)	
<b>As-treated population</b>			<b>Subtotal</b>
1, 3, 5, and 6 (Clopidogrel mono-therapy)	1371 (91.4)	6 (0.4)	1377
1, 2, 5, and 6 (Aspirin + Clopidogrel dual therapy)	53 (3.5)	1399 (92.7)	1452

3 DAPT denoted dual antiplatelet therapy, OAC oral anticoagulation, BVS bioresorbable vascular scaffold, and APT antiplatelet  
 4 therapy.



1 **eTable 6. Details of Cases With Definite or Probable Stent Thrombosis**

Age, gender	Assigned Group	Index presentation, other risk factors	Index PCI	Days after index PCI	ARC definition	Medication at the event	Presentation, intervention	Prognosis
69 yr Male	12-month DAPT	UA, Braunwald 1 HTN, HL, DM Prior PCI (-5M); LAD G2-DES implanted (different site from the index PCI). PARIS-T/B: 4/4, CREDO-Kyoto-T/B: 1/0	LAD proximal CoCr-EES 2.5/15	148	Definite	Aspirin +Clopidogrel	NSTEMI 100% occluded, thrombus+ POBA Peak CK/CKMB 3787/488	alive
70 yr Male	1-month DAPT	UA, Braunwald III HTN, Current smoker PARIS-T/B 2/7, CREDO-Kyoto T/B 0/0	LAD proximal CoCr-EES 3.5/12+3.0/18 KBT for #9	6	Probable	Aspirin +Prasugrel	SCD Found in a collapse, Undefined death	dead
51 yr Female	1-month DAPT	UA, Braunwald II HTN, HL, past smoker Prior PCI (-5y): G1-DES implanted in Cx PARIS-T/B; 4/1, CREDO-Kyoto-T/B; 1/0	Cx SES ISR lesion CoCr-EES 3.0/33	112	Definite	Clopidogrel, Aspirin discontinued at day 36	STEMI Coronary thrombus suggested by IVUS and OCT. POBA by drug-coating balloon. Peak CK/CKMB 4263/367	alive
78 yr Female	1-month DAPT	Asymptomatic ischemia Prior Stroke, Severe CKD/Dialysis, HTN, HL, DM with insulin Reduced EF 40% PARIS-T/B; 3/10, CREDO-Kyoto T/B: 6/2	RCA ostium CoCr-EES 3.25/15	25	Probable	Aspirin +Clopidogrel	SCD  Cardiac arrest at home, Undefined death.	dead
64 yr Male	1-month DAPT	STEMI Peak CK/CKMB 3055/259 HL, Current Smoker PARIS-T/B; 3/4, CREDO-Kyoto-T/B: 0/0	Cx CoCr-EES 3.5/23	51	Definite	Clopidogrel, Aspirin discontinued at day 29	STEMI Stent occluded The small amount of thrombus aspirated. Peak CK/CKMB 1297/106	alive

2

3 PARIS-T/B, and CREDO-Kyoto T/B indicate PARIS thrombotic/bleeding risk score and CREDO-Kyoto thrombotic/bleeding risk scores. ARC denoted academic research consortium, CK creatine  
4 kinase, CKD chronic kidney disease, CoCr-EES, cobalt-chromium everolimus-eluting stents, Cx left circumflex coronary artery, DAPT dual antiplatelet therapy, DES drug-eluting stents, DM diabetes  
5 mellitus, EF ejection fraction, G1 first generation, G2 second generation, HTN hypertension, HL hyperlipidemia, ISR in-stent restenosis, IVUS intravascular ultrasound, KBT kissing balloon  
6 technique, LAD left anterior ascending coronary artery, OCT optical coherence tomography, PCI percutaneous coronary intervention, POBA plain old balloon angioplasty, RCA right coronary artery,  
7 SCD sudden cardiac death, SES sirolimus-eluting stents, ST stent thrombosis, STEMI ST-segment elevation myocardial infarction, and UA unstable angina.

8

1 **eTable 7. Clinical Outcomes With Landmark Analysis at 30 Days and up to 1 Year**

2

Outcomes	1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup>	12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup>	Hazard ratio (95% CI)	P <sub>non-inferiority</sub> <sup>b</sup>	P <sub>superiority</sub> <sup>b</sup>
<b>Primary endpoint</b>					
A composite of cardiovascular death, MI, definite stent thrombosis, ischemic/hemorrhagic stroke, or TIMI major/minor bleeding	30 (2.04%)	48 (3.25%)	0.63 (0.40-0.99)	<.001	.045
<b>Major secondary endpoints</b>					
<b>Cardiovascular endpoint:</b> A composite of cardiovascular death, MI, definite stent thrombosis, or ischemic/hemorrhagic stroke	25 (1.70%)	33 (2.25%)	0.76 (0.45-1.29)	.006	.31
<b>Bleeding endpoint:</b> TIMI major/minor bleeding	5 (0.34%)	19 (1.28%)	0.26 (0.10-0.71)		.008

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1 (eTable 7. continued)

Outcomes	1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup>	12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup>	Hazard ratio (95% CI)	P <sub>non-inferiority</sub> <sup>b</sup>	P <sub>superiority</sub> <sup>b</sup>
<b>Other secondary endpoints</b>					
Death	18 (1.23%)	17 (1.14%)	1.07 (0.55-2.08)		.84
Death from cardiac cause	5 (0.34%)	8 (0.54%)	0.63 (0.21-1.93)		.42
Death from cardiovascular cause	6 (0.41%)	10 (0.67%)	0.61 (0.22-1.67)		.33
Death from non-cardiovascular cause	12 (0.82%)	7 (0.47%)	1.73 (0.68-4.40)		.25
MI	13 (0.88%)	10 (0.68%)	1.31 (0.58-3.00)		.52
Large MI (CKMB≥10*ULN)	5 (0.34%)	2 (0.13%)	2.52 (0.49-13.01)		.27
Small MI (CKMB<10*ULN)	7 (0.48%)	4 (0.28%)	1.77 (0.52-6.05)		.36
MI without CKMB elevation	1 (0.07%)	2 (0.14%)	0.51 (0.05-5.59)		.58
MI without measurement of CKMB	0 (0.00%)	2 (0.13%)	-		-
Definite ST	2 (0.13%)	1 (0.07%)	2.02 (0.18-22.26)		.57
Definite/Probable ST	2 (0.13%)	1 (0.07%)	2.02 (0.18-22.26)		.57
Stroke (ischemic/hemorrhagic)	7 (0.48%)	13 (0.90%)	0.54 (0.22-1.36)		.19
Ischemic	7 (0.48%)	13 (0.90%)	0.54 (0.22-1.36)		.19
Hemorrhagic	0 (0.00%)	0 (0.00%)	-		-

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1 (eTable 7. continued)

Outcomes	1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup>	12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup>	Hazard ratio (95% CI)	P <sub>non-inferiority</sub> <sup>b</sup>	P <sub>superiority</sub> <sup>b</sup>
Bleeding					
TIMI major	3 (0.20%)	13 (0.87%)	0.23 (0.07-0.81)		.02
TIMI minor	2 (0.14%)	6 (0.40%)	0.34 (0.07-1.66)		.18
BARC 3 or 5	7 (0.47%)	22 (1.48%)	0.32 (0.14-0.75)		.01
BARC 5	1 (0.07%)	2 (0.13%)	0.50 (0.05-5.56)		.58
BARC 3	6 (0.41%)	20 (1.35%)	0.30 (0.12-0.75)		.01
GUSTO moderate/severe	5 (0.34%)	19 (1.28%)	0.26 (0.10-0.71)		.008
GUSTO severe	3 (0.20%)	10 (0.67%)	0.30 (0.08-1.10)		.07
GUSTO moderate	2 (0.14%)	9 (0.60%)	0.22 (0.05-1.03)		.06
Intracranial bleeding	2 (0.14%)	4 (0.27%)	0.51 (0.09-2.76)		.43
Gastrointestinal bleeding	3 (0.20%)	16 (1.08%)	0.19 (0.05-0.65)		.008
Any coronary revascularization	97 (6.70%)	73 (5.07%)	1.35 (0.998-1.83)		.051
TLR	35 (2.38%)	23 (1.60%)	1.55 (0.91-2.62)		.10
Clinically-driven TLR	26 (1.77%)	19 (1.32%)	1.39 (0.77-2.51)		.28
Non-TLR	70 (4.87%)	57 (3.94%)	1.24 (0.88-1.76)		.22
CABG	6 (0.42%)	5 (0.34%)	1.21 (0.37-3.98)		.75

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1 (eTable 7. continued)

Outcomes	1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup>	12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup>	Hazard ratio (95% CI)	P <sub>non-inferiority</sub> <sup>b</sup>	P <sub>superiority</sub> <sup>b</sup>
Death or MI	29 (1.97%)	27 (1.82%)	1.09 (0.64-1.83)		.76
Cardiovascular death or MI	18 (1.22%)	20 (1.35%)	0.91 (0.48-1.72)		.77
Major adverse cardiac events <sup>c</sup>	35 (2.38%)	31 (2.13%)	1.15 (0.71-1.86)		.58

2 Abbreviation: BARC, bleeding academic research consortium; CABG, coronary artery bypass grafting; CKMB, creatine kinase MB; GUSTO, Global Use of Strategies to Open Occluded Arteries; MI,  
3 myocardial infarction; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction; TLR, target-lesion revascularization.

4 <sup>a</sup> Percentages were Kaplan-Meier estimates of event from 60-day to 365-day by landmark analysis.

5 <sup>b</sup> P values were derived from Cox's hazard model.

6 <sup>c</sup> Major adverse cardiac events were defined as composite of cardiac death, MI, and clinically driven target-lesion revascularization.

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1 **eTable 8. Clinical Outcomes With Landmark Analysis at 60 Days and up to 1 Year**

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<b>Outcomes</b>	<b>1-month DAPT (N=1500) N of patients with event (cumulative incidence)<sup>a</sup></b>	<b>12-month DAPT (N=1509) N of patients with event (cumulative incidence)<sup>a</sup></b>	<b>Hazard ratio (95% CI)</b>	<b>P<sub>non-inferiority</sub><sup>b</sup></b>	<b>P<sub>superiority</sub><sup>b</sup></b>
<b>Primary endpoint</b>					
A composite of cardiovascular death, MI, definite stent thrombosis, ischemic/hemorrhagic stroke, or TIMI major/minor bleeding	27 (1.84%)	44 (2.99%)	0.62 (0.38-0.99)	<.001	.047
<b>Major secondary endpoints</b>					
<b>Cardiovascular endpoint:</b> A composite of cardiovascular death, MI, definite stent thrombosis, or ischemic/hemorrhagic stroke	22 (1.50%)	30 (2.05%)	0.74 (0.43-1.28)	.006	.28
<b>Bleeding endpoint:</b> TIMI major/minor bleeding	5 (0.34%)	18 (1.21%)	0.28 (0.10-0.75)		.012

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1 (eTable 8. continued)

Outcomes	1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup>	12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup>	Hazard ratio (95% CI)	P <sub>non-inferiority</sub> <sup>b</sup>	P <sub>superiority</sub> <sup>b</sup>
<b>Other secondary endpoints</b>					
Death	18 (1.23%)	16 (1.07%)	1.14 (0.58-2.23)		.71
Death from cardiac cause	5 (0.34%)	7 (0.47%)	0.72 (0.23-2.27)		.58
Death from cardiovascular cause	6 (0.41%)	9 (0.61%)	0.67 (0.24-1.89)		.45
Death from non-cardiovascular cause	12 (0.82%)	7 (0.47%)	1.73 (0.68-4.40)		.25
MI	12 (0.82%)	9 (0.62%)	1.35 (0.57-3.20)		.50
Large MI (CKMB≥10*ULN)	5 (0.34%)	2 (0.13%)	2.52 (0.49-13.01)		.27
Small MI (CKMB<10*ULN)	6 (0.41%)	3 (0.21%)	2.02 (0.51-8.09)		.32
MI without CKMB elevation	1 (0.07%)	2 (0.14%)	0.51 (0.05-5.59)		.58
MI without measurement of CKMB	0 (0.00%)	2 (0.13%)	-		
Definite ST	1 (0.07%)	1 (0.07%)	1.01 (0.06-16.13)		.99
Definite/Probable ST	1 (0.07%)	1 (0.07%)	1.01 (0.06-16.13)		.99
Stroke (ischemic/hemorrhagic)	5 (0.34%)	12 (0.83%)	0.42 (0.15-1.19)		.10
Ischemic	5 (0.34%)	12 (0.83%)	0.42 (0.15-1.19)		.10
Hemorrhagic	0 (0.00%)	0 (0.00%)	-		

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1 (eTable 8. continued)

Outcomes	1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup>	12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup>	Hazard ratio (95% CI)	P <sub>non-inferiority</sub> <sup>b</sup>	P <sub>superiority</sub> <sup>b</sup>
Bleeding					
TIMI major	3 (0.20%)	12 (0.81%)	0.25 (0.07-0.89)		.03
TIMI minor	2 (0.14%)	6 (0.40%)	0.34 (0.07-1.66)		.18
BARC 3 or 5	7 (0.47%)	21 (1.41%)	0.33 (0.14-0.79)		.01
BARC 5	1 (0.07%)	2 (0.13%)	0.50 (0.05-5.56)		.58
BARC 3	6 (0.41%)	19 (1.28%)	0.32 (0.13-0.79)		.01
GUSTO moderate/severe	5 (0.34%)	17 (1.15%)	0.30 (0.11-0.80)		.02
GUSTO severe	3 (0.20%)	9 (0.61%)	0.34 (0.09-1.24)		.10
GUSTO moderate	2 (0.14%)	8 (0.54%)	0.25 (0.05-1.18)		.08
Intracranial bleeding	2 (0.14%)	4 (0.27%)	0.51 (0.09-2.76)		.43
Gastrointestinal bleeding	3 (0.20%)	14 (0.94%)	0.22 (0.06-0.75)		.02
Any coronary revascularization	94 (6.51%)	73 (5.07%)	1.31 (0.97-1.78)		.08
TLR	34 (2.31%)	23 (1.60%)	1.50 (0.89-2.55)		.13
Clinically-driven TLR	25 (1.70%)	19 (1.32%)	1.34 (0.74-2.43)		.34
Non-TLR	68 (4.74%)	57 (3.94%)	1.21 (0.85-1.72)		.29
CABG	6 (0.42%)	5 (0.34%)	1.21 (0.37-3.98)		.75

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1 **(eTable 8. continued)**

<b>Outcomes</b>	<b>1-month DAPT (N=1500) N of patients with event (cumulative incidence) <sup>a</sup></b>	<b>12-month DAPT (N=1509) N of patients with event (cumulative incidence) <sup>a</sup></b>	<b>Hazard ratio (95% CI)</b>	<b>P<sub>non-inferiority</sub> <sup>b</sup></b>	<b>P<sub>superiority</sub> <sup>b</sup></b>
Death or MI	28 (1.90%)	25 (1.69%)	1.13 (0.66-1.94)		.65
Cardiovascular death or MI	17 (1.16%)	18 (1.22%)	0.95 (0.49-1.85)		.89
Major adverse cardiac events <sup>c</sup>	34 (2.31%)	29 (2.00%)	1.19 (0.72-1.95)		.49

2 Abbreviation: BARC, bleeding academic research consortium; CABG, coronary artery bypass grafting; CKMB, creatine kinase MB; GUSTO, Global Use of Strategies to Open Occluded Arteries; MI,  
3 myocardial infarction; PCI, percutaneous coronary intervention; TIMI, Thrombolysis in Myocardial Infarction; TLR, target-lesion revascularization.

4 <sup>a</sup> Percentages were Kaplan-Meier estimates of event from 60-day to 365-day by landmark analysis.

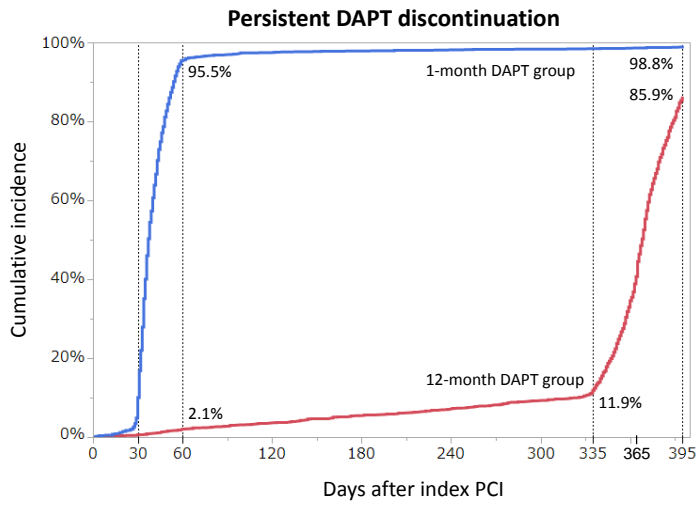
5 <sup>b</sup> P values were derived from Cox's hazard model.

6 <sup>c</sup> Major adverse cardiac events were defined as composite of cardiac death, MI, and clinically driven target-lesion revascularization.

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1 **Figure 1. DAPT Discontinuation Rate**

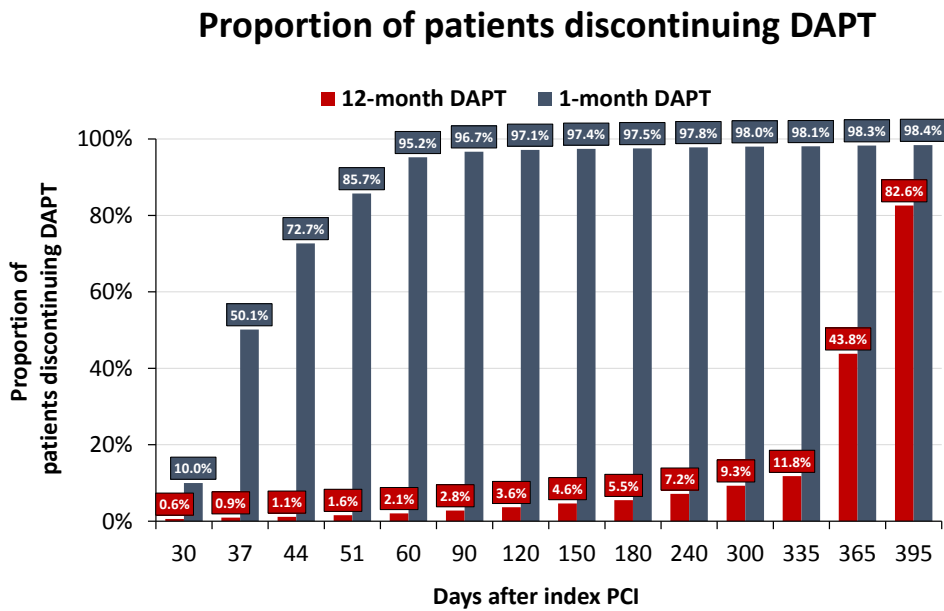
2 **(A) Cumulative incidence rate of persistent DAPT discontinuation**



No. at risk	1500	1346	67	38	32	28	25	23	17	9
1-month DAPT	1500	1346	67	38	32	28	25	23	17	9
12-month DAPT	1509	1499	1467	1442	1412	1387	1352	1314	811	178

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4 **(B) Proportions of patients discontinuing DAPT by the assigned groups**

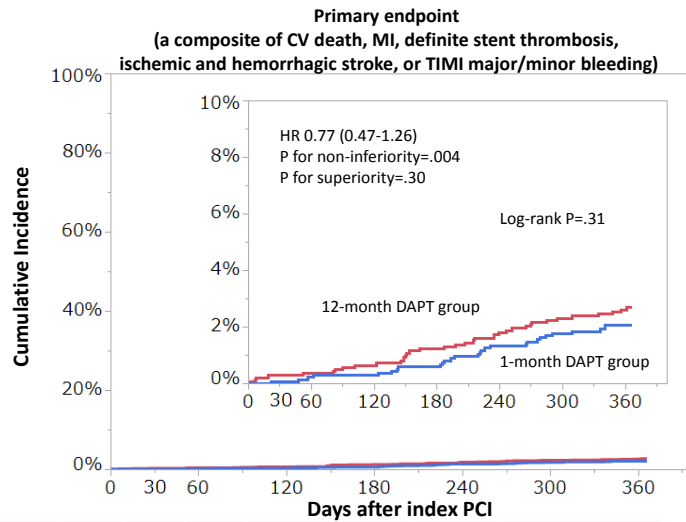


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6 These figures showed the data of DAPT discontinuation. Persistent DAPT discontinuation was defined as discontinuation of  
 7 either aspirin or P2Y12 inhibitors according to the study protocol or discontinuation lasting for >60 days. (A) The cumulative  
 8 incidence rate of persistent DAPT discontinuation from Kaplan-meier analysis. (B) The proportion of persistent DAPT  
 9 discontinuation in each group at the various timing after index PCI. The percentages were different from (A), because these  
 10 proportions were calculated as the number of patients with DAPT discontinuation simply divided by total number of each group  
 11 (1500 in 1-month DAPT group and 1509 in 12-month DAPT group) and the patients with death or drop-out without  
 12 discontinuation were not considered. DAPT denoted dual antiplatelet therapy, PCI percutaneous coronary intervention.

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1 **eFigure 2. Per-Protocol Analysis for the Primary Endpoint**

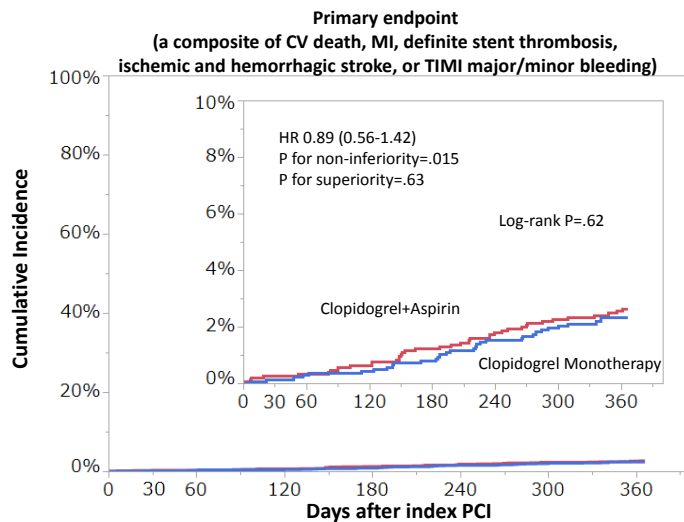


	0	30	60	120	180	240	300	365
<b>12-month DAPT</b>								
Number of patients with event		4	5	9	17	25	32	37
Number of patients at risk	1386	1382	1380	1376	1367	1358	1348	1091
Cumulative incidence (%)		0.3	0.4	0.7	1.2	1.8	2.3	2.7
<b>1-month DAPT</b>								
Number of patients with event		1	3	4	8	18	24	28
Number of patients at risk	1359	1358	1356	1353	1347	1332	1320	1052
Cumulative incidence (%)		0.1	0.2	0.3	0.6	1.3	1.8	2.1

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Primary outcome in the per-protocol population. This analysis included the patients in 1-month DAPT group receiving clopidogrel monotherapy without aspirin, and the patients in 12-month DAPT group receiving both aspirin and clopidogrel at 60-day after index PCI. Patients with oral anticoagulants use, use of other antiplatelet therapy, history of hemorrhagic stroke, and history of implantation of bioabsorbable vascular scaffolds were excluded according to the protocol defined exclusion criteria. DAPT denoted dual antiplatelet therapy, PCI percutaneous coronary intervention, CV cardiovascular, MI myocardial infarction, and TIMI Thrombolysis in Myocardial Infarction.

1 **eFigure 3. As-Treated Analysis for the Primary Endpoint**

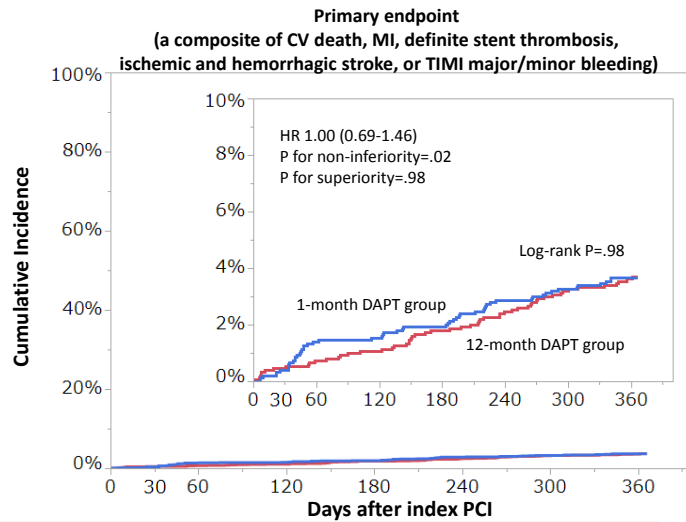


<b>Clopidogrel+Aspirin</b>	<b>0</b>	<b>30</b>	<b>60</b>	<b>120</b>	<b>180</b>	<b>240</b>	<b>300</b>	<b>365</b>
Number of patients with event		4	5	9	18	26	33	38
Number of patients at risk	1452	1448	1446	1442	1432	1423	1413	1144
Cumulative incidence (%)		0.3	0.3	0.6	1.2	1.8	2.3	2.6
<b>Clopidogrel Monotherapy</b>	<b>0</b>	<b>30</b>	<b>60</b>	<b>120</b>	<b>180</b>	<b>240</b>	<b>300</b>	<b>365</b>
Number of patients with event		2	4	6	11	21	28	32
Number of patients at risk	1377	1375	1373	1369	1362	1347	1334	1063
Cumulative incidence (%)		0.2	0.3	0.4	0.8	1.5	2.0	2.3

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Primary outcome in the as-treated population. In this analysis, regardless of randomly assigned group, 1) the patients receiving clopidogrel monotherapy without oral anticoagulants at 60-day were set as clopidogrel monotherapy group, and 2) the patients receiving both aspirin and clopidogrel without anticoagulants at 60-day were set as aspirin plus clopidogrel group. We did not consider other exclusion criteria (history of hemorrhagic stroke, oral anticoagulants use, use of other antiplatelet therapy, history of implantation of bioabsorbable vascular scaffolds). PCI denoted percutaneous coronary intervention, CV cardiovascular, MI myocardial infarction, and TIMI Thrombolysis in Myocardial Infarction.

1 **eFigure 4. Sensitivity Analysis**



12-month DAPT	0	30	60	120	180	240	300	365
Number of patients with event		7	11	16	27	37	49	55
Number of patients at risk	1509	1501	1486	1481	1469	1458	1442	1159
Cumulative incidence (%)		0.5	0.7	1.1	1.8	2.5	3.3	3.7
1-month DAPT	0	30	60	120	180	240	300	365
Number of patients with event		6	21	23	29	43	49	55
Number of patients at risk	1500	1494	1479	1475	1468	1453	1441	1151
Cumulative incidence (%)		0.4	1.4	1.5	1.9	2.9	3.3	3.7

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- 3 A sensitivity analysis assuming that patients lost to follow-up in the experimental arm had the primary endpoint event, while
- 4 those in the control arm did not have the event.
- 5 DAPT denoted dual antiplatelet therapy, PCI percutaneous coronary intervention, CV cardiovascular, MI myocardial infarction,
- 6 and TIMI Thrombolysis in Myocardial Infarction.