Short DAPT following XIENCE implantation
Insights from the STOPDAPT Trials

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April 28, 2019
TCTAP 2019

COI Disclosure

Name of First Author :Kengo Tanabe

- **Remuneration for lecture: Terumo, Abbott vascular, Boston Scientific, Kaneka, Daiichi Sankyo, Bayer, Astellas Amgen**

＜Menu＞

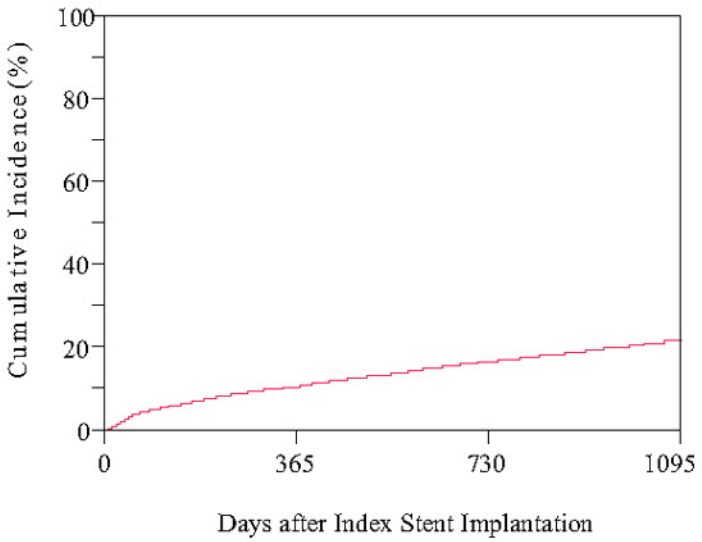
- Skytree Registry
  > Data at the time of non-cardiac surgery

- STOPDAPT Trial
  > 3 months DAPT prospective registry

- STOPDAPT2 Trial
  > RCT (1 month DAPT vs 12 months DAPT)

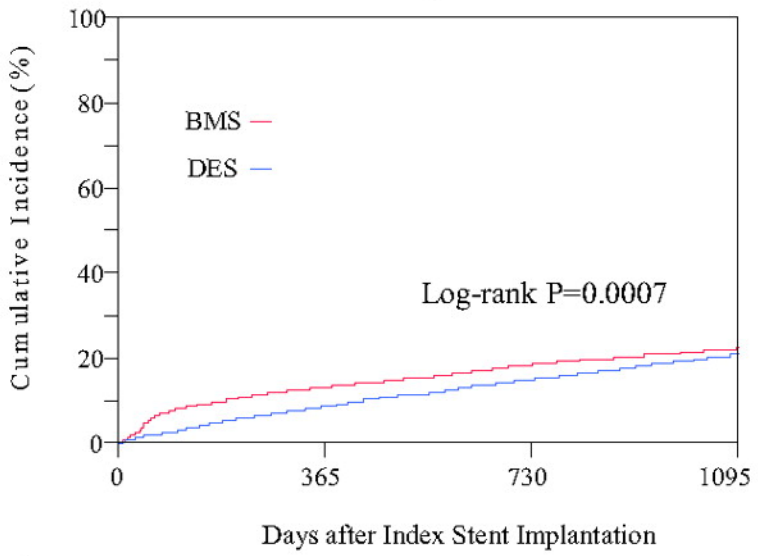
22% of Patients Require Non-Cardiac Surgery in 3 years following PCI in Japan !!

A



	Baseline	42 Days	1 Year	2 Years	3 Years
Incidence		3.0%	11%	17%	22%
Number of events		355	1253	1878	2218
Number of patients at risk	12207	11483	10050	7317	3673

B



	Baseline	42 Days	1 year	2 years	3 years
BMS					
Incidence		4.4%	13%	19%	23%
Number of events		227	682	914	1034
Number of patients at risk	5405	4933	4205	3105	1666
DES					
Incidence		1.9%	9%	15%	21%
Number of events		128	575	914	1034
Number of patients at risk	6802	6550	5845	4212	2007

American Heart Association.

Tokushige A et al. Circ Cardiovasc Interv 2012;5:237-246

22% of Patients Require Non-Cardiac Surgery in 2 years following PCI in USA !!

Research

Original Investigation

Risk of Major Adverse Cardiac Events Following Noncardiac Surgery in Patients With Coronary Stents

Mary T. Hawn, MD, MPH; Laura A. Graham, MPH; Joshua S. Richman, MD, PhD; Kamal M. F. Itani, MD; William G. Henderson, PhD; Thomas M. Maddox, MD, MSc

IMPORTANCE Guidelines recommend delaying noncardiac surgery in patients after coronary stent procedures for 1 year after drug-eluting stents (DES) and for 6 weeks after bare metal stents (BMS). The evidence underlying these recommendations is limited and conflicting.

OBJECTIVE To determine risk factors for adverse cardiac events in patients undergoing noncardiac surgery following coronary stent implantation.

DESIGN, SETTING, AND PARTICIPANTS A national, retrospective cohort study of 41 989 Veterans Affairs (VA) and non-VA operations occurring in the 24 months after a coronary stent implantation between 2000 and 2010. Nonlinear generalized additive models examined the association between timing of surgery and stent type with major adverse cardiac events (MACE) adjusting for patient, surgery, and cardiac risk factors. A nested case-control study assessed the association between perioperative antiplatelet cessation and MACE.

MAIN OUTCOMES AND MEASURES A composite 30-day MACE rate of all-cause mortality, myocardial infarction, and cardiac revascularization.

RESULTS Within 24 months of 124 844 coronary stent implantations (47.6% DES, 52.4% BMS), 28 029 patients (22.5%; 95% CI, 22.2%-22.7%) underwent noncardiac operations resulting in 1980 MACE (4.7%; 95% CI, 4.5%-4.9%). Time between stent and surgery was associated with MACE (<6 weeks, 11.6%; 6 weeks to <6 months, 6.4%; 6-12 months, 4.2%; >12-24 months, 3.5%; $P < .001$). MACE rate by stent type was 5.1% for BMS and 4.3% for DES ($P < .001$). After adjustment, the 3 factors most strongly associated with MACE were nonelective surgical admission (adjusted odds ratio [AOR], 4.77; 95% CI, 4.07-5.59), history of myocardial infarction in the 6 months preceding surgery (AOR, 2.63; 95% CI, 2.32-2.98), and revised cardiac risk index greater than 2 (AOR, 2.13; 95% CI, 1.85-2.44). Of the 12 variables in the model, timing of surgery ranked fifth in explanatory importance measured by partial effects analysis. Stent type ranked last, and DES was not significantly associated with MACE (AOR, 0.91; 95% CI, 0.83-1.01). After both BMS and DES placement, the risk of MACE was stable at 6 months. A case-control analysis of 284 matched pairs found no association between antiplatelet cessation and MACE (OR, 0.86; 95% CI, 0.57-1.29).

CONCLUSIONS AND RELEVANCE Among patients undergoing noncardiac surgery within 2 years of coronary stent placement, MACE were associated with emergency surgery and advanced cardiac disease but not stent type or timing of surgery beyond 6 months after stent implantation. Guideline emphasis on stent type and surgical timing for both DES and BMS should be reevaluated.

Editorial page 1451

Supplemental content at jama.com

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JAMA. 2013;310(14):1462-1472. doi:10.1001/jama.2013.278787
Published online October 7, 2013.

JAMA. 2013;310(14):1462-1472.

Therefore, PCI operators should pay careful attention to the patients at the time of non-cardiac surgery

However, there are some previous reports in the era of 1st generation DES .....

Problem of 1st generation DES
Late Stent Thrombosis at the time of Surgery

Late thrombosis in drug-eluting coronary stents after discontinuation of antiplatelet therapy

Eugène P McFadden, Eugenio Stabile, Evelyn Regar, Edouard Cheneau, Andrew T L Ong, Timothy Kinnaird, William O Suddath, Neil J Weissman, Rebecca Torguson, Kenneth M Kent, August D Pichard, Lowell F Satler, Ron Waksman, Patrick W Serruys

Lancet 2004; 364: 1519–21

See Comment page 1466

Drug-eluting stents: some bare facts

See Research Letters page 1519

In this issue of *The Lancet*, Eugène McFadden and colleagues report four cases of coronary thrombosis that occurred many months after implantation of drug-eluting stents.

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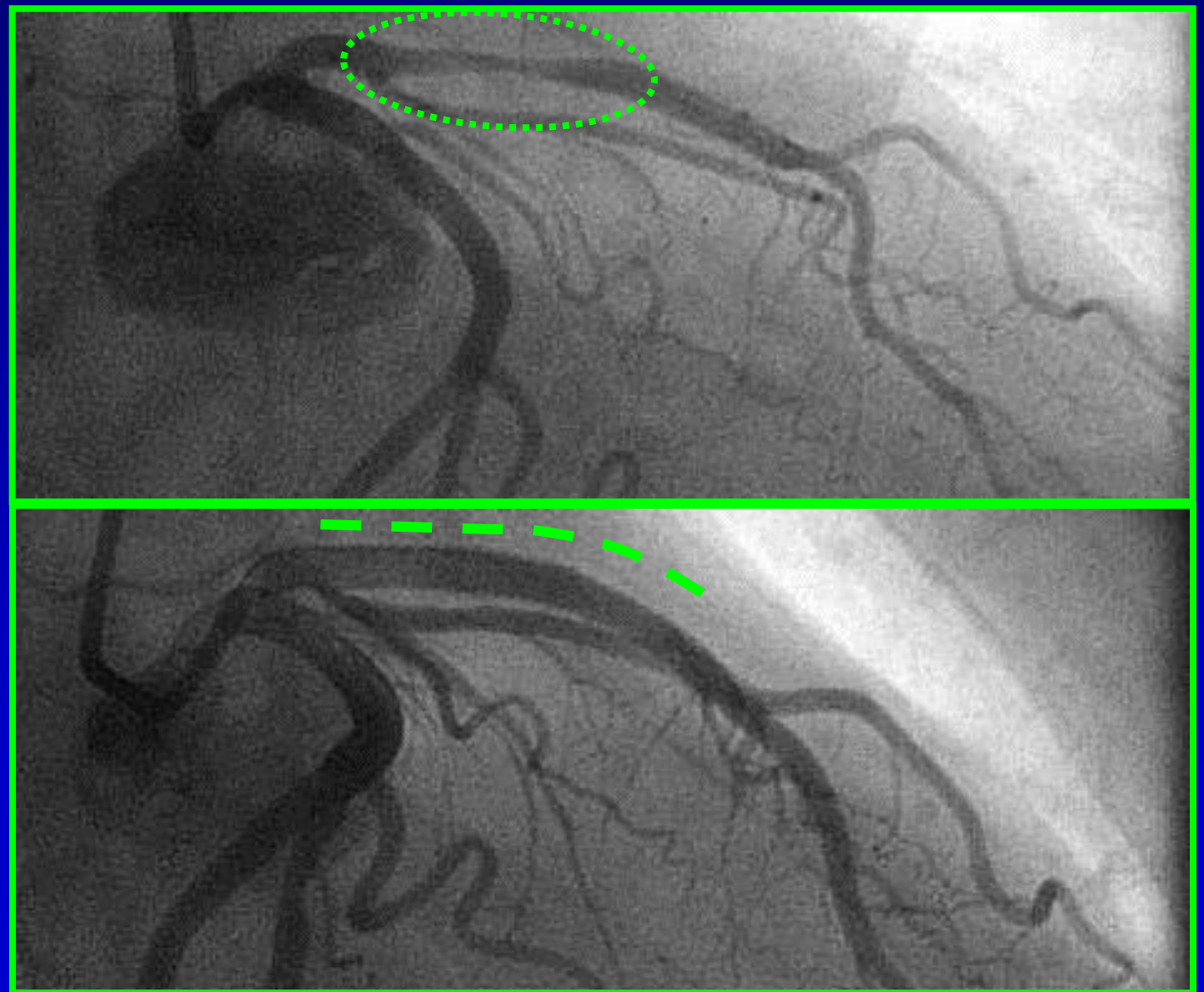
www.thelancet.com Vol 364 October 23, 2004

Summary of Patients

	1	2	3	4
Index Presentatn	UAP	VF arrest	VF arrest	SAP
Age	63	73	43	62
Vessel	RCA	LAD	LCx	LAD
Stent	PES	PES	SES *	SES *
Size	3.0x16	3.5x16	3.0x33	3.0x18
Reason	Elective bladder polyp resection	Elective hemicolectomy for Ca	Pt decision	Elective colonoscopy & polypectomy
Sx	AMI	AMI	AMI	AMI
Stopped ASA, days	5	7	14	4
Months after Stent Implantation	11.5	14.5	12	11

*** Also had BMS implanted in another vessel that was patent at repeat angiography**

Patient 2: Index

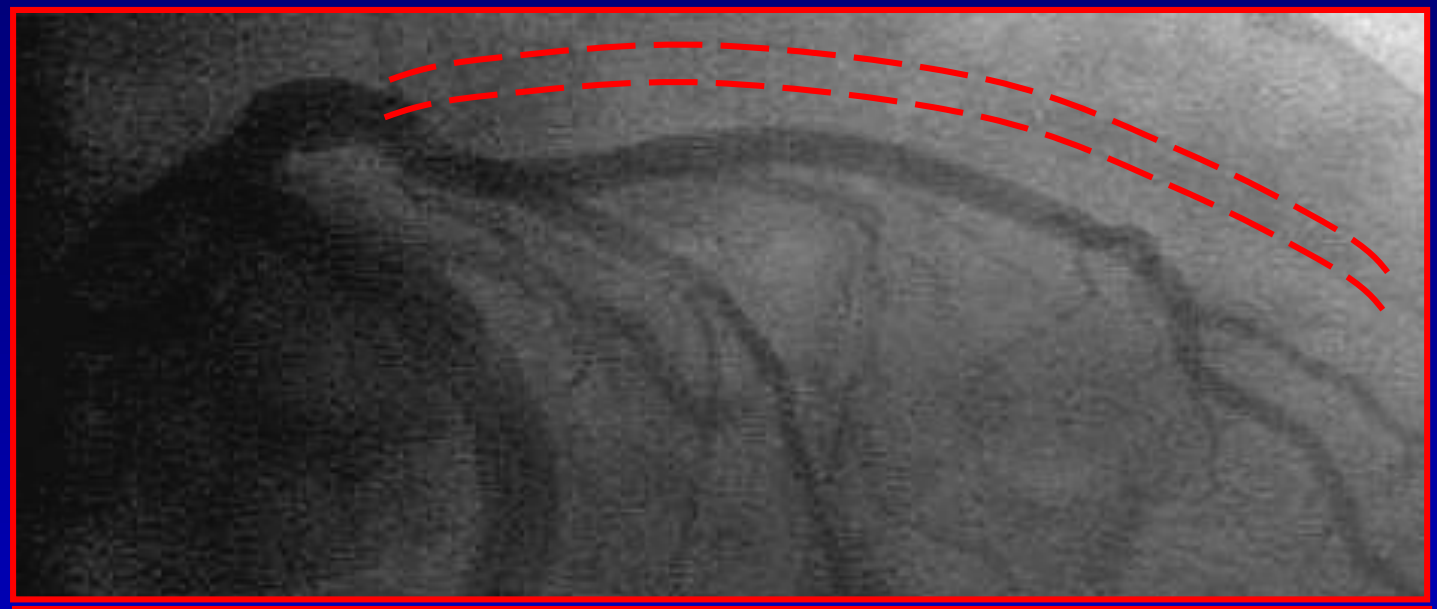


Baseline: Concentric lesion in proximal LAD

3.5x16mm PES

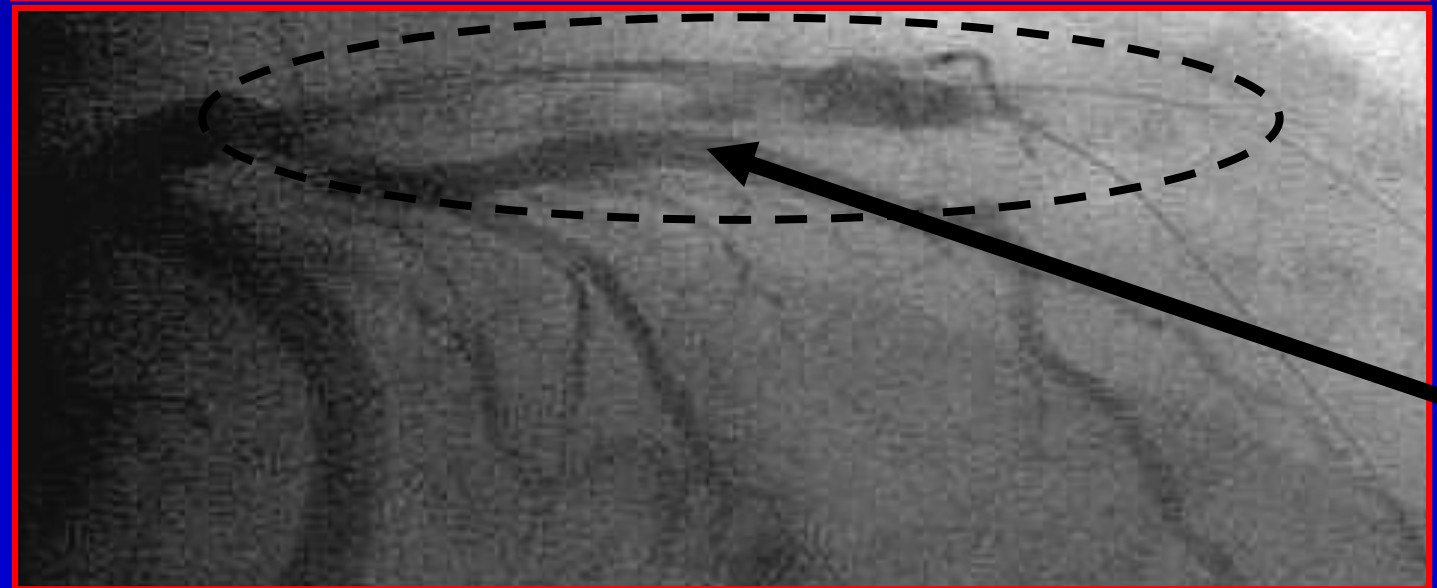
031204
041154

Patient 2: LAST 14.5 months later



Aspirin stopped for resection of colon cancer

1 week later: Acute MI



Thrombus +++ visible after wire passage

New generation DES such as Xience less stent thrombosis in network meta-analysis

Biodegradable-polymer drug-eluting stents vs. bare metal stents vs. durable-polymer drug-eluting stents: a systematic review and Bayesian approach network meta-analysis

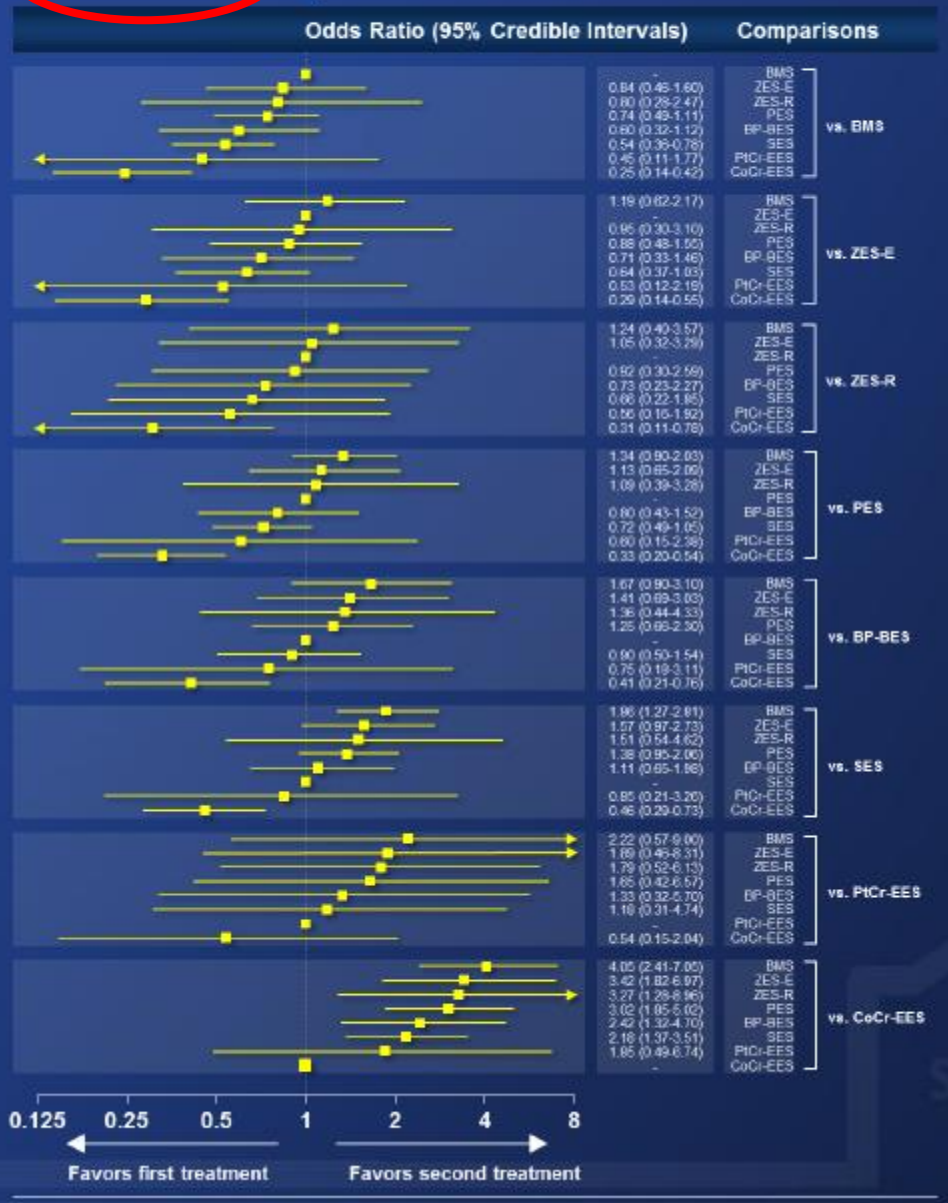
Si-Hyuck Kang[1†], Kyung Woo Park[1†], Do-Yoon Kang[1], Woo-Hyun Lim[1], Kyung Taek Park[1], Jung-Kyu Han[1], Hyun-Jae Kang[1], Bon-Kwon Koo[1], Byung-Hee Oh[1], Young-Bae Park[1], David E. Kandzari[2], David J. Cohen[3], Seung-Sik Hwang[4], and Hyo-Soo Kim[1*]

[1]Department of Internal Medicine and Cardiovascular Center, Seoul National University Hospital, 28 Yeongeon-Dong, Chongno-gu, Seoul 110-744, Korea; [2]Piedmont Heart Institute, Atlanta, GA, USA; [3]Saint Luke's Mid America Heart Institute, Kansas City, MO, USA; and [4]Department of Social and Preventive Medicine, Inha University School of Medicine, Incheon, Korea

Received 24 June 2013; revised 10 November 2013; accepted 18 December 2013

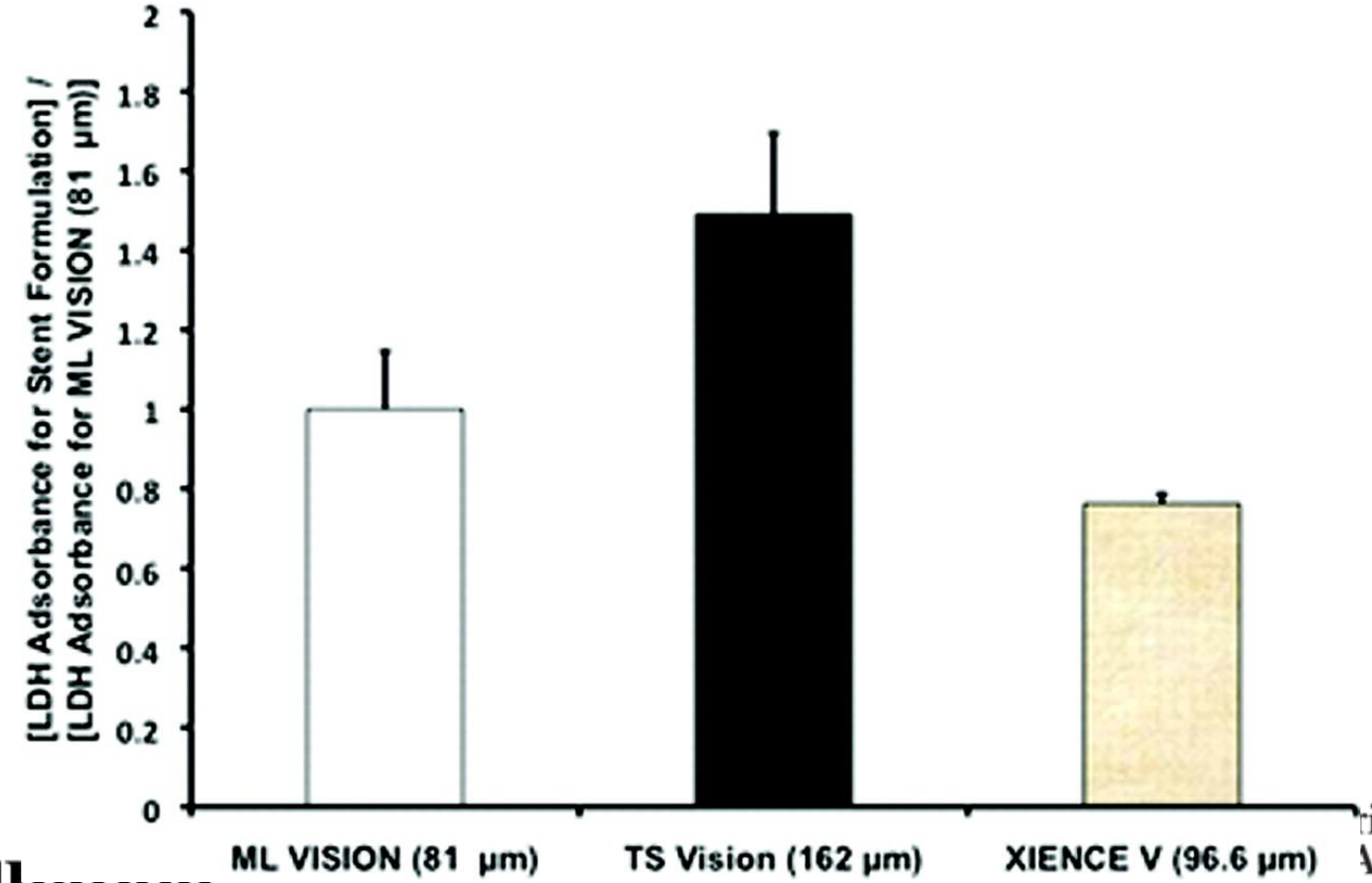
Definite ST Within 1 Year

CoCr-EES > (PtCr-EES ≥ SES ≥ BP-BES ≥ PES ≥ ZES-R ≥ ZES-E ≥ BMS)



- CoCr-EES superior to BMS, ZES-E, ZES-R, PES, BP-BES, and SES
- SES superior to BMS
- SES tended to be superior to ZES-E and PES

CoCr EES showed the least thrombogenicity among the 3 groups (thin BMS, thick BMS, Xience V) in ex vivo experiment Probably due to biocompatibility of fluoropolymer

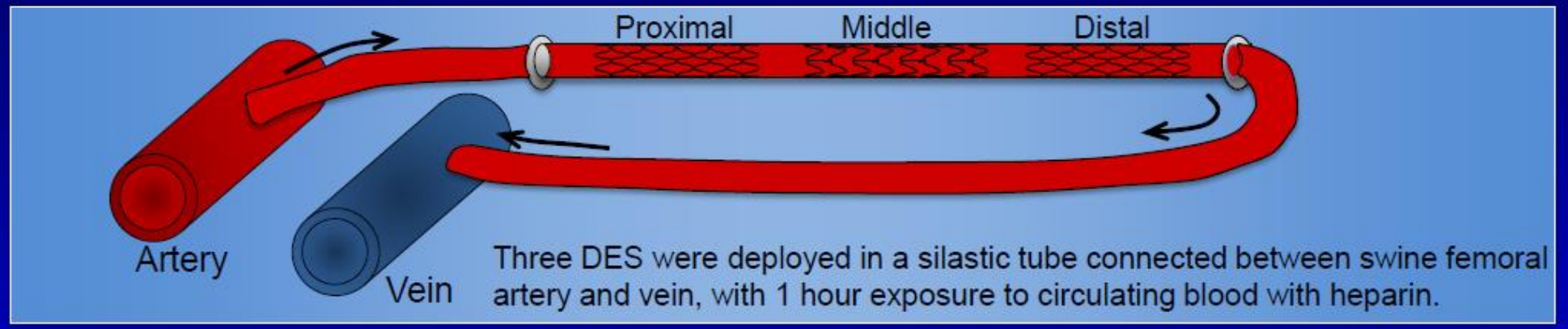


Circulation

Kolandaivelu, K. et al. Circulation 2011;123:1400-1409

American Heart Association
Learn and Live

Evaluation of Thrombus Formation on Biodegradable vs. Permanent Polymer DES in an Ex Vivo Porcine AV Shunt Model



Three DES were deployed in a silastic tube connected between swine femoral artery and vein, with 1 hour exposure to circulating blood with heparin.

Bisected longitudinally

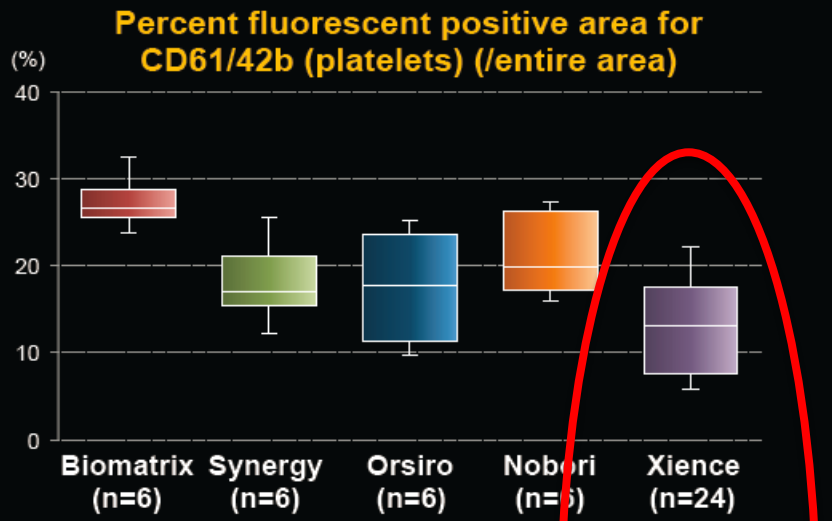
Immunostains for platelets (CD61/42b) followed by confocal microscopy

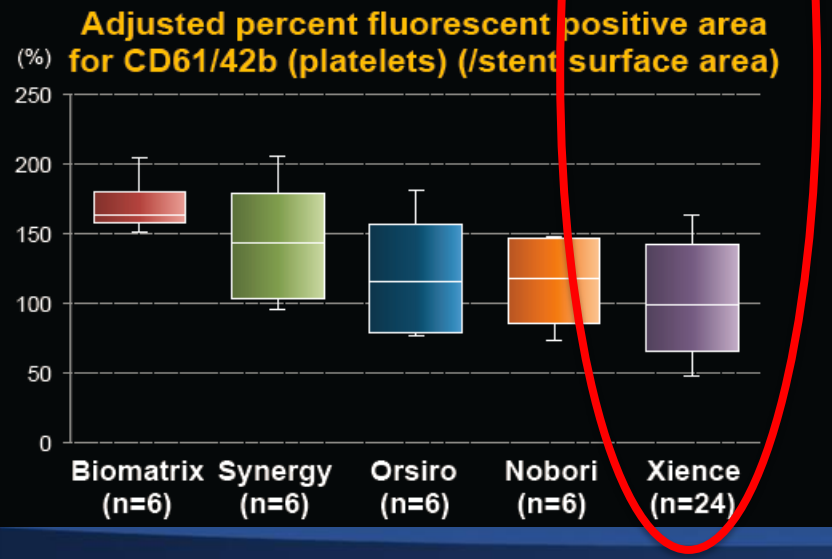
Scanning electron microscopy

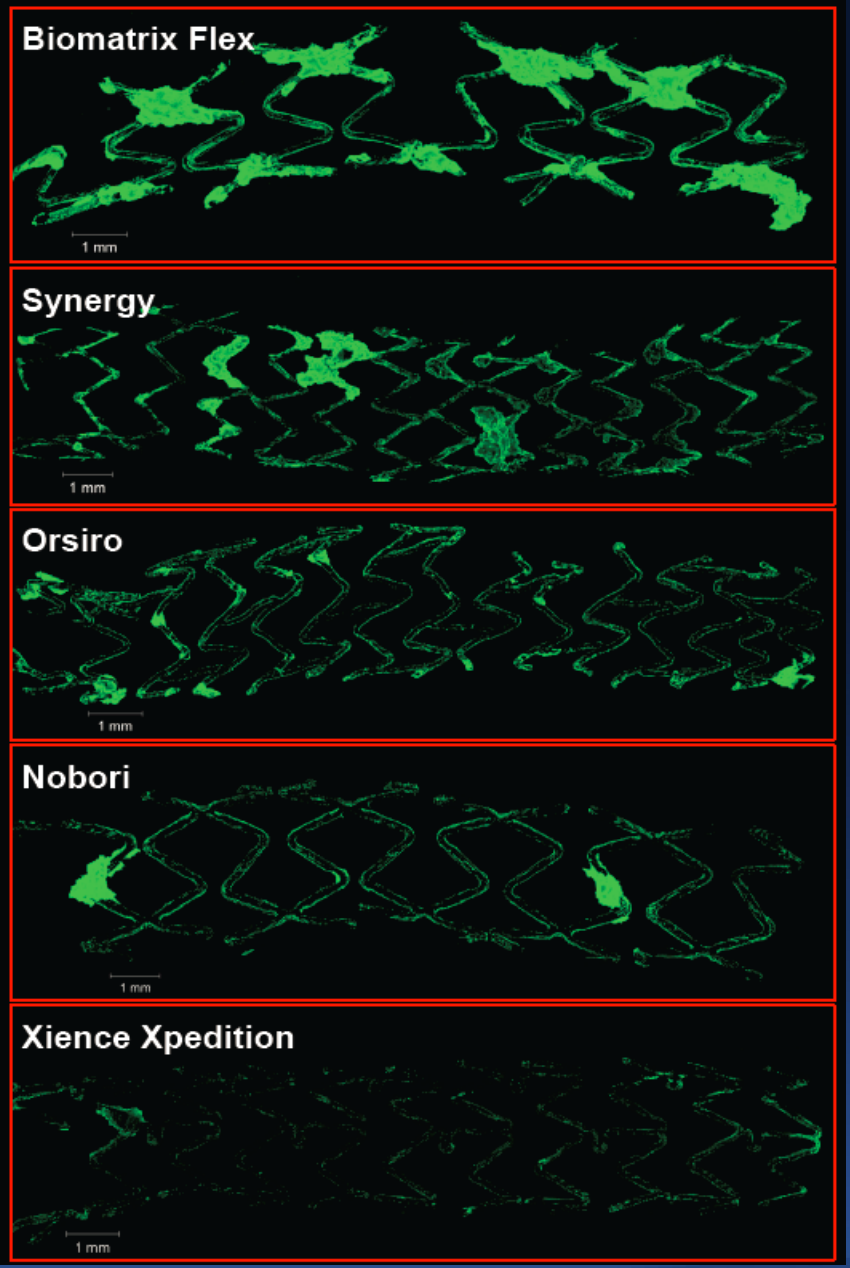
Evaluation of thrombogenicity in:

CoCr EES (XIENCE Xpedition™, n=24) vs 4 different types of biodegradable polymer coated DES (BioMatrix™ Flex, Nobori®, Orsiro, and Synergy™, n=6 each)

Thrombus Formation on Biodegradable vs. Permanent Polymer DES in a Porcine Shunt Model







＜Personal Thought＞

DES with thromboresistant durable polymer entire coating and thin struts, such as Xience, is considered to be beneficial at the time of non-cardiac surgery.

Clinical Impact of Discontinuation of Antiplatelet Therapy at the time of Noncardiac Surgery in Patients with Coronary Everolimus-Eluting Stents: Results of Prospective SKYTREE Registry

Kengo Tanabe [1*], Tetsuya Kitamura [2*], Junya Ako [3*], Ryu Iino [4*], Kazuhiko Aramaki [5*], Tetsuya Seko [6*], Takafumi Koji [7*], Taku Asano [8*], Takatoshi Wakeyama [9*], Masaaki Ito [10*], Mitsuru Abe [11*], Tomohiro Kawasaki [12*]
On Behalf of the SKYTREE investigators

1.Division of Cardiology Mitsui Memorial Hospital: 2. JA Mie Kouseiren Suzuka General Hospital: 3. Kitasato University Hospital: 4. Medical Corporation Kouseikai Iwatsuki Minami Hospital: 5. Social Medical Corporation Sekishinkai Saitamasekishinkai Hospital: 6. Japan Red Cross Society Isesekijyuji Hospital: 7. JA Mie Kouseiren Mstsusaka General Hospital: 8. ST. LUKE'S International Hospital: 9. JCHO Tokuyaya Central Hospital: 10. Mie University Graduate School of Medicine/Faculty of Medicine: 11. National Hospital Oranization Kyoto Medical Center: 12. Tenjikai Social Medical Corporation Shin Koga Hospital

PURPOSE

SKY TREE registry
Sequence of various Kinds of surgerY afTeR Everolimus-Eluting stent implantation

To investigate incidence of stent thrombosis and major adverse cardiovascular events at the time of non-cardiac surgery in patients with cobalt chrome EES (Xience™,Promus™, Xience Prime™, Xience Xpedition™) who require cessation of antiplatelet agents.

STUDY PATIENTS

SKY TREE registry
Sequence of various Kinds of surgerY aFTeR Everolimus-Eluting stent implantation

(1) Inclusion Criteria

✓ Patients with cobalt chrome EES (Xience™,Promus™, Xience Prime™, Xience Xpedition™) who require cessation of antiplatelet drug.

(2) Exclusion Criteria

✓ Patients with DES except for cobalt chrome EES

(Patients with prior BMS or POBA are allowed)

(3) Patient enrollment should be performed prior to non-cardiac surgery (prospective design)

The study was sponsored by Abbott Vascular Japan.
The data management was performed by Cardiocore Japan.

ENDPOINT

SKY TREE registry
Sequence of various Kinds of surgerY afTeR Everolimus-Eluting stent implantation

(1) Primary Endpoint

- ✓ MACE (cardiac death, MI, revascularization (PCI or CABG)) at 30 days after surgery

(2) Secondary Endpoints

- ✓ Following events after surgery or 30days after surgery
- ✓ Death (cardiac death, non-cardiac death)
- ✓ MI
- ✓ Stroke (cerebral infarct, hemorrhagic stroke)
- ✓ Cardiac arrest
- ✓ Stent Thrombosis (based on ARC definition)
- ✓ Revascularization (PCI, CABG)
- ✓ Hemorrhagic event
- ※ 30days follow up is to be clinical visits, but telephone interview is also allowed.

Patient Characteristics (1)

Patients	**135**
Age (years)	71.8 ± 8.6
Height (cm)	162.5± 8.5
Weight (kg)	61.9± 11.1
BMI	23.7± 3.3
Number of Prior PCI	1.7± 0.9
Number of CoCr EES implanted	**1.9± 1.2**

Patient Characteristics (2)

N = 135	N	%
Current Tobacco Use	69	56%
Diabetes	63	47%
Diet Therapy	13	10%
Oral Agent	44	33%
Insulin	6	4%
Dyslipidemia	111	82%
Hypertension	106	79%
Family History of CAD	23	17%
Prior MI	46	34%

Medications when surgery was planned (1)

N = 135	N	%
Aspirin	107	79.3%
Clopidogrel	82	60.7%
Cilostazol	6	4.4%
EPA	9	6.7%
Warfarin	7	5.2%
Dabigatran	1	0.7%
Rivaroxaban	2	1.5%
Apixaban	5	3.7%
Edoxaban	0	0%

Type of Surgical Procedures

N = 135	N	%
Abdominal Surgery	33	24.4%
Endoscopic Procedures	44	32.6%
Vascular Surgery	4	3.0%
Orthopedic Surgery	12	8.9%
Neurosurgery	1	0.7%
Respiratory Surgery	5	3.7%
Urologic Surgery	12	8.9%
Otolaryngology Surgery	5	3.7%
Dermatologic Surgery	2	1.5%

Summary of Antiplatelet Management

SKY TREE registry
Sequence of various Kinds of surgerY afTeR Everolimus-Eluting stent implantation

Of the135 patients analyzed, 111 patients (82%) were completely free of antiplatelet therapy at the time of non-cardiac surgery.

The average duration of free of antiplatelet was 8.6 ± 4.0 days (min 1, max 23).

Of the 111 patients free of antiplatelet agents, Bridge therapy was performed in 36 patients (32.4%): Heparin (27, 24.3%), Cilostazol (8, 7.2%), Sarpogrelate hydrochloride (1, 0.9%).

Time Interval

Time Interval (days) = Surgery Date – Last PCI Date

Average Time Interval (days)	**800±602**

Min Days 24 days, Max Days 2391 days

Clinical Events at 30days

N = 135	N	%
MACE	0	0%
Death	0	0%
Myocardial Infarction	0	0%
Revascularization	0	0%
Stent Thrombosis	0	0%
Stroke	0	0%
Heart Failure	1	0.7%
Bleeding Events	4	3.0%
BARC 2	2	1.5%
BARC 3	2	1.5%

Bleeding Events

SKY TREE registry
Sequence of various Kinds of surgerY afTeR Everolimus-Eluting stent implantation

Case No	BARC	Aspirin	Aspirin Stop	Clopidogrel	Clpidogrel Stop	Heparin Bridge
1	2	+	+	+	+	
2	2	+	+	+	+	+
3	3	+	-	+	+	
4	3	+	+	-		+

Of the 4 bleeding events, one case was performed with continued aspirin (stopped clopidogrel), two were performed with heparin bridge therapy.

Conclusions

SKY TREE registry
Sequence of various Kinds of surgerY aTTeR Everolimus-Eluting stent implantation

1, CoCr-EES seems to be safe at the time of non-cardiac surgery which requires cessation of antiplatelet agents without any stent thrombosis.

2, Bleeding events might be associated with continued antiplatelet therapy and heparin bridge therapy.

3, Further studies are warranted to confirm the findings.

＜Menu＞

- Skytree Registry
  > Data at the time of non-cardiac surgery

- STOPDAPT Trial
  > 3 months DAPT prospective registry

- STOPDAPT2 Trial
  > RCT (1 month DAPT vs 12 months DAPT)

STOPDAPT Trial

(ShorT and OPtimal duration of Dual AntiPlatelet Therapy after everolimus-eluting cobalt-chromium stent)

Multicenter, prospective, single-arm trial

1500 patients who agreed to follow the 3-month DAPT protocol after successful CoCr-EES implantation

Exclusion Criteria: Patients with previous DES implantation other than CoCr-EES

Thienopyridines were stopped at 3-month after CoCr-EES implantation

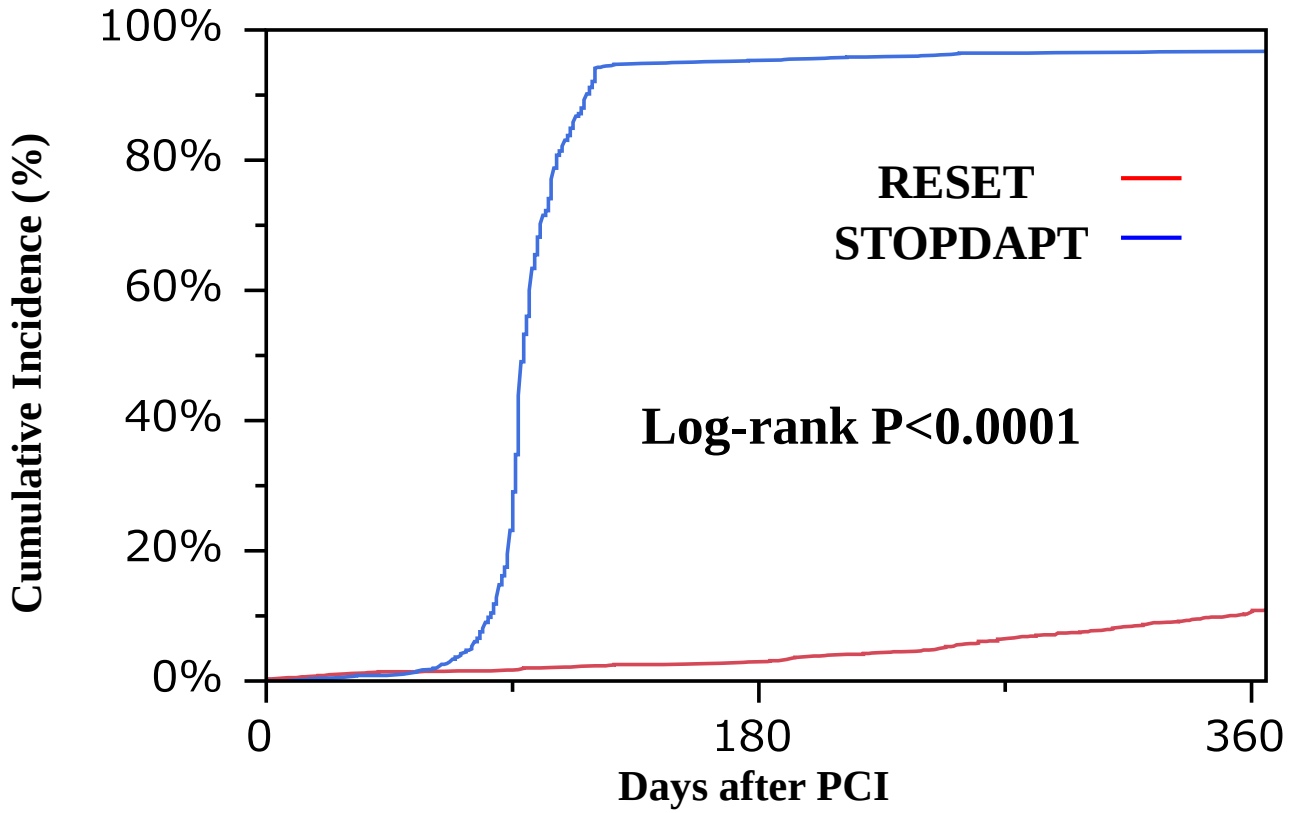
CoCr-EES Arm in the RESET trial

Primary Endpoint

A composite of cardiovascular death, myocardial Infarction (MI), stroke, definite stent thrombosis (ST) and TIMI major/minor bleeding at 1-year

Clinical Outcomes at 1-year

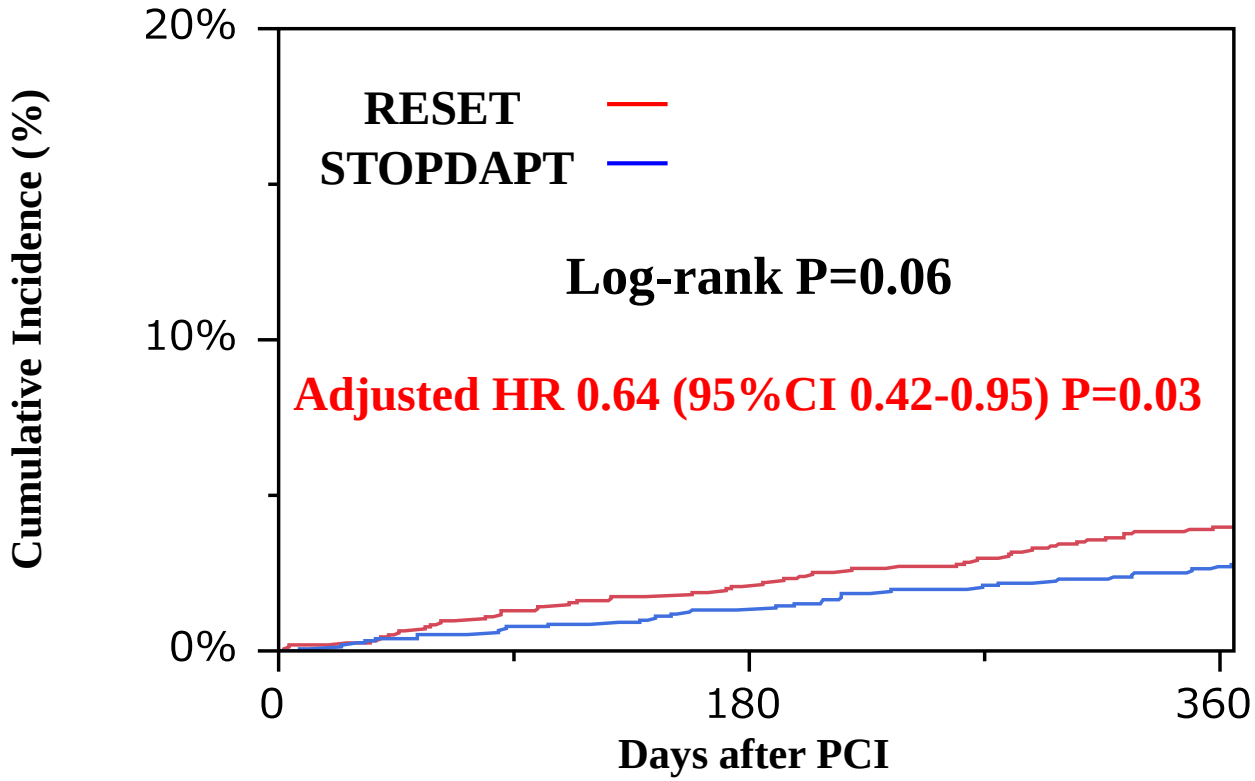
Persistent Discontinuation of Thienopyridine



Interval	0 day	30 days	90 days	120 days	180 days	240 days	365 days
RESET							
N of patients with discontinuation		18	27	36	46	73	163
N of patients at risk	1559	1525	1506	1494	1482	1442	1049
Cumulative Incidence		1.2%	1.8%	2.3%	3.0%	4.8%	11.1%
STOPDAPT							
N of patients with discontinuation		11	443	1432	1451	1462	1471
N of patients at risk	1525	1512	1078	88	69	58	47
Cumulative Incidence		0.7%	29.1%	94.2%	95.5%	96.2%	96.8%

Primary Endpoint

Cardiovascular death, MI, Stroke, Definite ST, and Bleeding



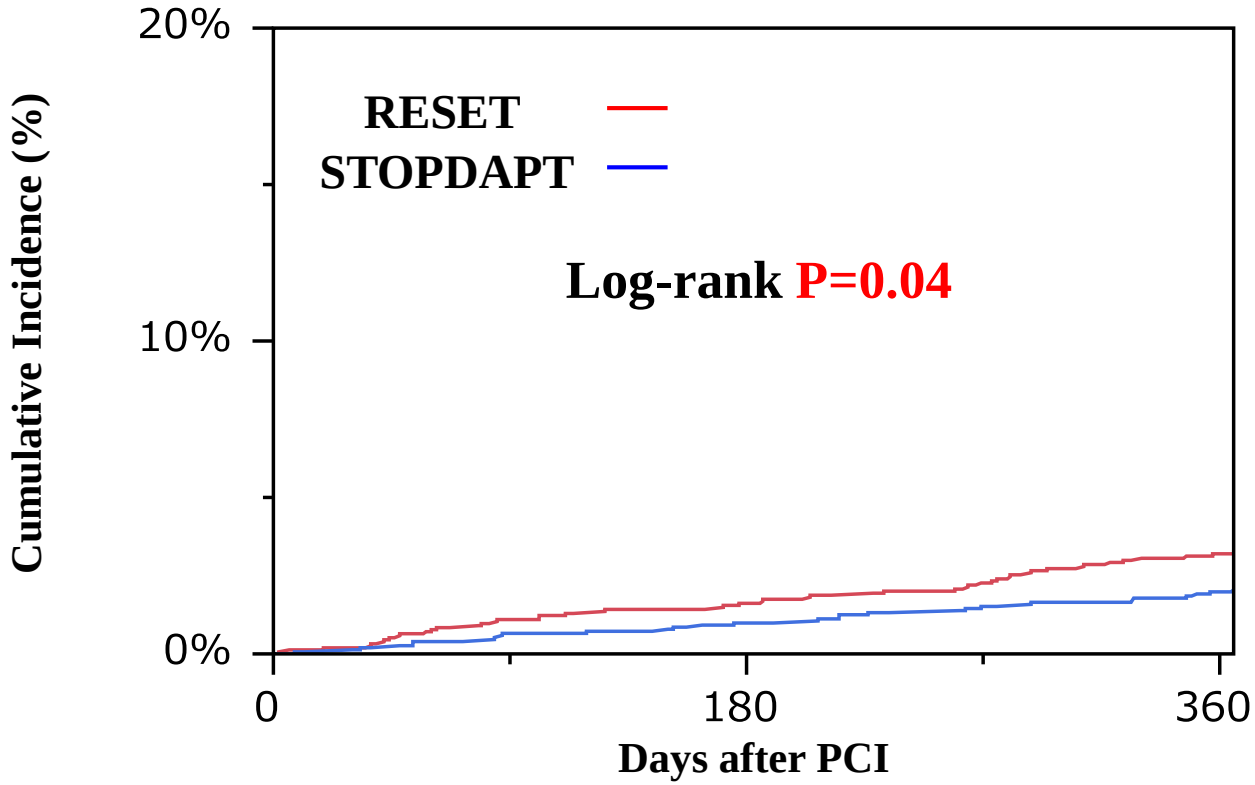
RESET: 4.0%

STOPDAPT: 2.8%

Interval	0 day	30 days	180 days	240 days	365 days
RESET					
N of patients with at least 1 event		4	33	42	61
N of patients at risk	1559	1545	1511	1495	1209
Cumulative Incidence		0.3%	2.1%	2.7%	4.0%
STOPDAPT					
N of patients with at least 1 event		4	21	30	42
N of patients at risk	1525	1520	1490	1480	1458
Cumulative Incidence		0.3%	1.4%	2.0%	2.8%

Major Secondary Endpoint

Cardiovascular death, MI, Stroke and Definite ST



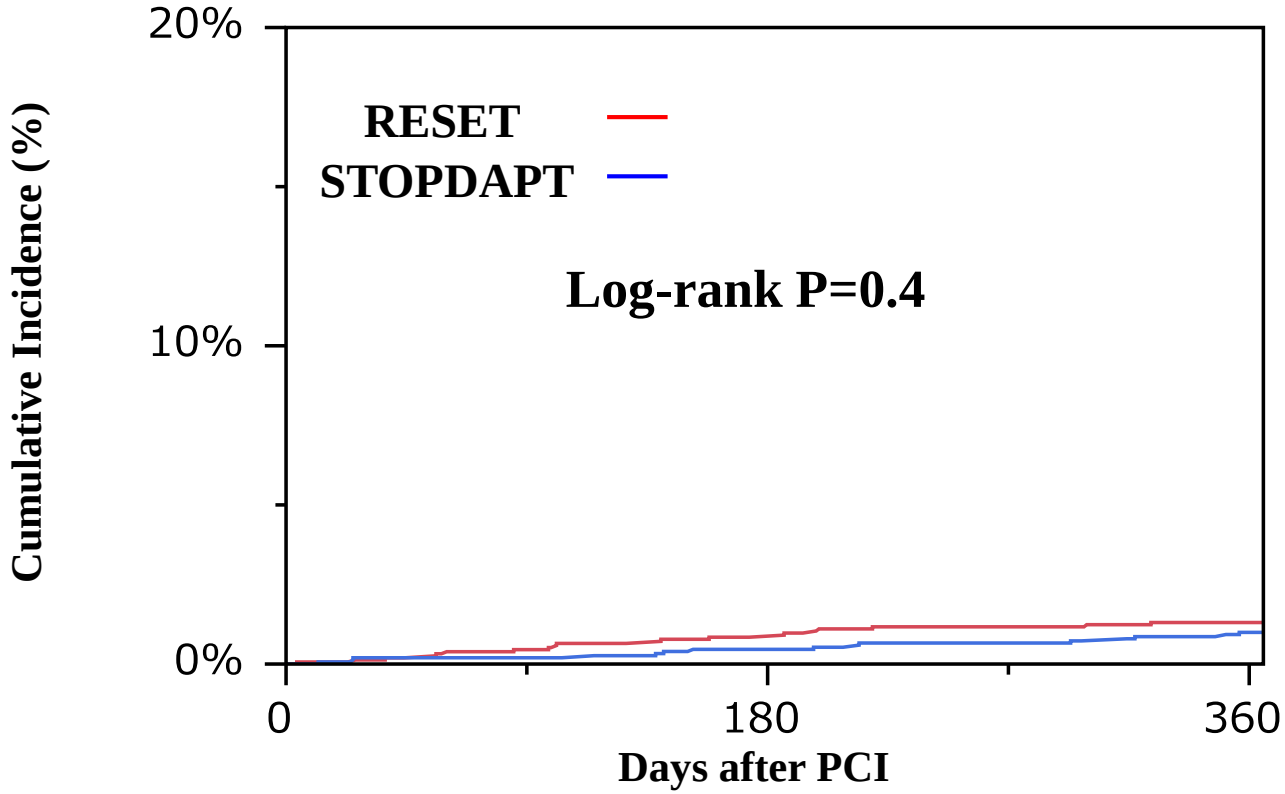
RESET: 3.2%

STOPDAPT: 2.1%

Interval	0 day	30 days	180 days	240 days	365 days
RESET					
N of patients with at least 1 event		3	25	31	49
N of patients at risk	1559	1546	1519	1506	1219
Cumulative Incidence		0.2%	1.6%	2.0%	3.2%
STOPDAPT					
N of patients with at least 1 event		2	15	21	31
N of patients at risk	1525	1522	1495	1488	1468
Cumulative Incidence		0.1%	1.0%	1.4%	2.1%

Major Secondary Endpoint

TIMI Major/Minor Bleeding

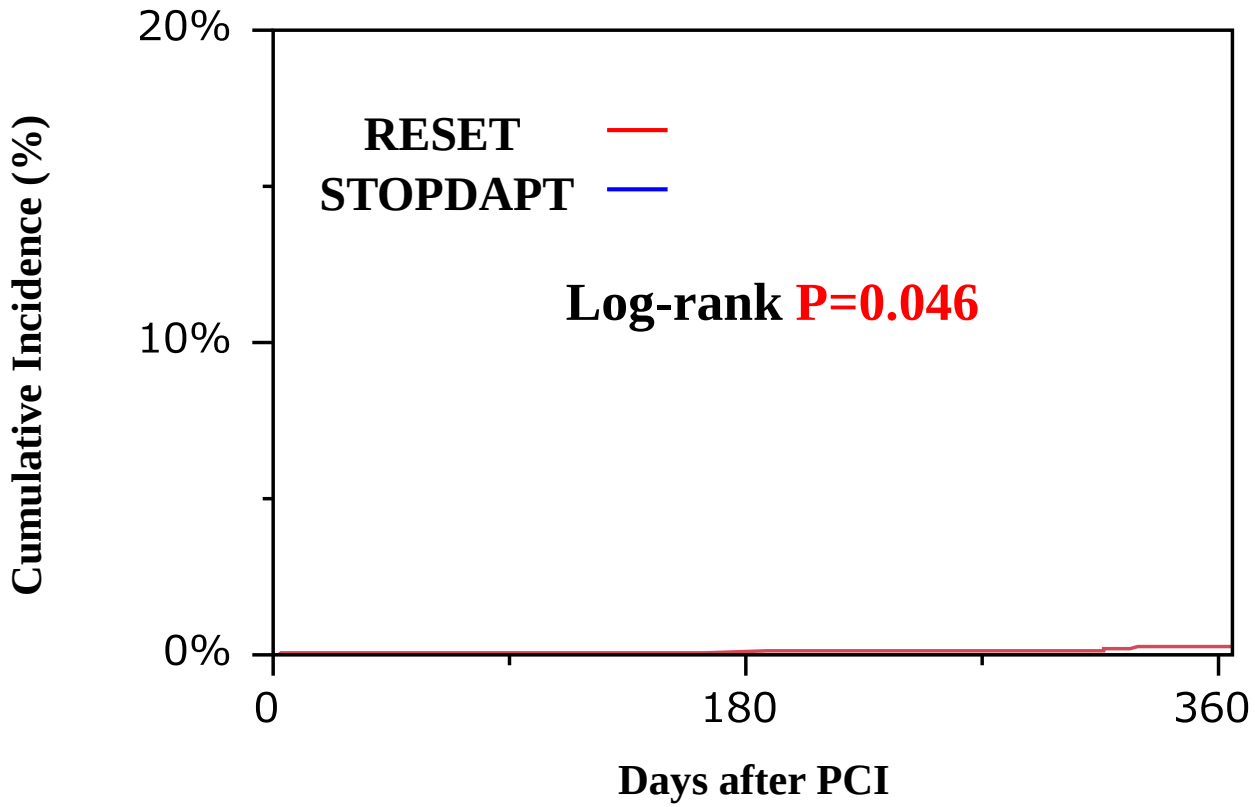


RESET: 1.3%

STOPDAPT: 1.0%

Interval	0 day	30 days	180 days	240 days	365 days
RESET					
N of patients with at least 1 event		2	14	18	20
N of patients at risk	1559	1547	1521	1504	1205
Cumulative Incidence		0.1%	0.9%	1.2%	1.3%
STOPDAPT					
N of patients with at least 1 event		3	7	10	15
N of patients at risk	1525	1520	1498	1493	1475
Cumulative Incidence		0.2%	0.5%	0.7%	1.0%

Definite ST



RESET: 0.3%

STOPDAPT: 0%

Interval	0 day	30 days	180 days	240 days	365 days
RESET					
N of patients with at least 1 event		1	2	2	4
N of patients at risk	1559	1548	1533	1520	1218
Cumulative Incidence		0.06%	0.1%	0.1%	0.3%
STOPDAPT					
N of patients with at least 1 event		0	0	0	0
N of patients at risk	1525	1523	1504	1502	1489
Cumulative Incidence		0%	0%	0%	0%

Conclusions

Stopping DAPT at 3-month after CoCr-EES implantation was at least as safe as the prolonged DAPT regimen adopted in the historical control group.

→

The time has come to organize short DAPT RCT following CoCr-EES implantation.

＜Menu＞

- Skytree Registry
  > Data at the time of non-cardiac surgery

- STOPDAPT Trial
  > 3 months DAPT prospective registry

- STOPDAPT2 Trial
  > RCT (1 month DAPT vs 12 months DAPT)

One-Month Dual Antiplatelet Therapy Followed by Clopidogrel Monotherapy versus Standard 12-Month Dual Antiplatelet Therapy with Clopidogrel After Drug-Eluting Stent Implantation:

TAKESHI KIMURA

Hirotoshi Watanabe, Takenori Domei, Takeshi Morimoto, Hiroki Shiomi, Masahiro Natsuaki, Toshiaki Toyota, Kensuke Takagi, Yoshiki Hata, Satoru Suwa, Mamoru Nanasato, Masanobu Ohya, Masahiro Yagi, Takafumi Yokomatsu, Mitsuru Abe, Kenji Ando, Kazushige Kadota, Ken Kozuma, Yoshihiro Morino,

Yuji Ikari, Kengo Tanabe, Koichi Nakao, Kazuya Kawai, and Yoshihisa Nakagawa,

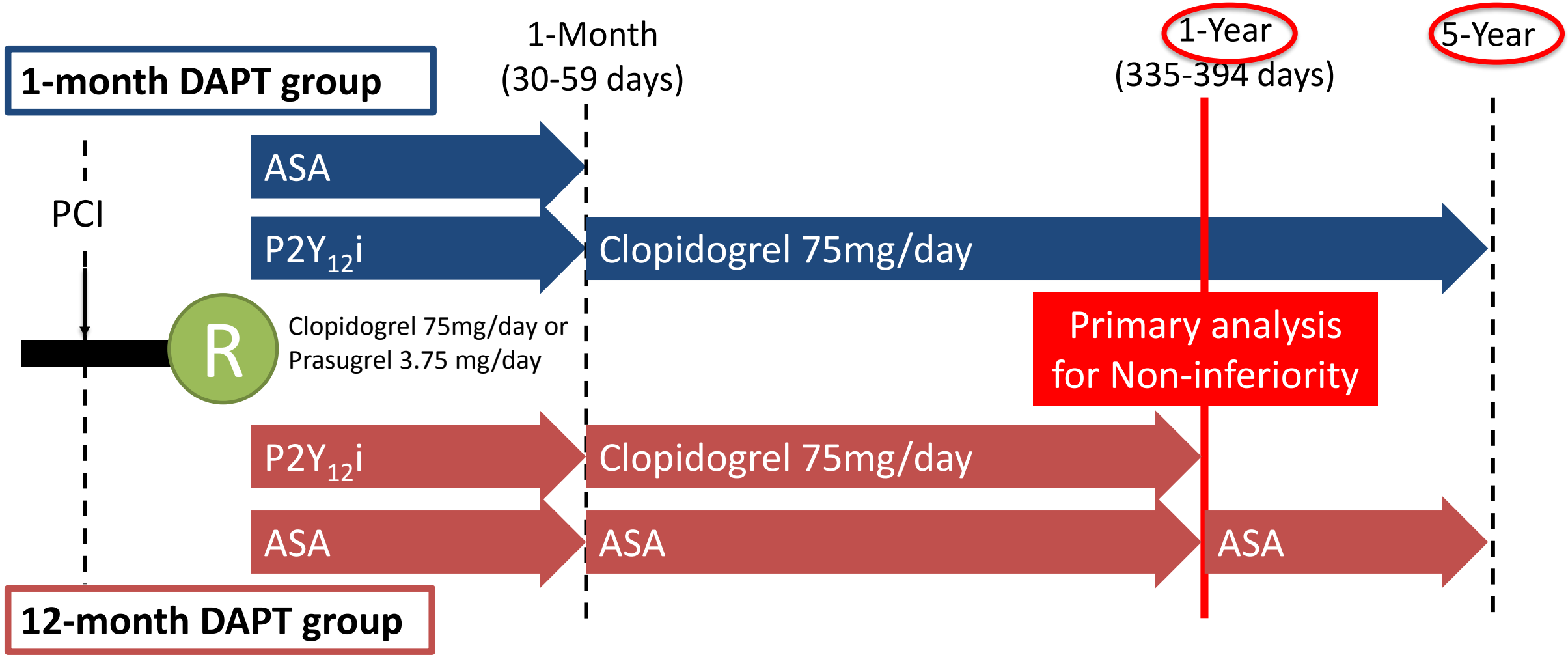
on behalf of STOPDAPT-2 investigators

Objective

The objective of the STOPDAPT-2 trial is to explore the safety and efficacy of the experimental regimen of 1-month DAPT followed by clopidogrel monotherapy as compared with the standard 12-month DAPT with aspirin and clopidogrel after implantation of cobalt-chromium everolimus-eluting stents (CoCr-EES).

STOPDAPT-2:

Prospective multicenter open-label randomized trial comparing 1-month versus 12-month DAPT after CoCr-EES implantation with limited exclusion criteria.



Inclusion/Exclusion Criteria

Inclusion Criteria

- PCI with exclusive use of CoCr-EES (Xience^{TM} series)
- No major complications during hospitalization for index PCI
- No plan for staged PCI
- Patients who could take DAPT with aspirin and $P2Y_{12}$ inhibitors

Key Exclusion Criteria

- **Needs for oral anticoagulants**
- **History of intracranial hemorrhage**

Endpoints

- **Primary endpoint:**

Net adverse cardiovascular events (NACE: Ischemia and Bleeding)

- A composite of cardiovascular death, MI, Definite ST, Stroke, or TIMI major/minor bleeding

- **Major secondary endpoints:**

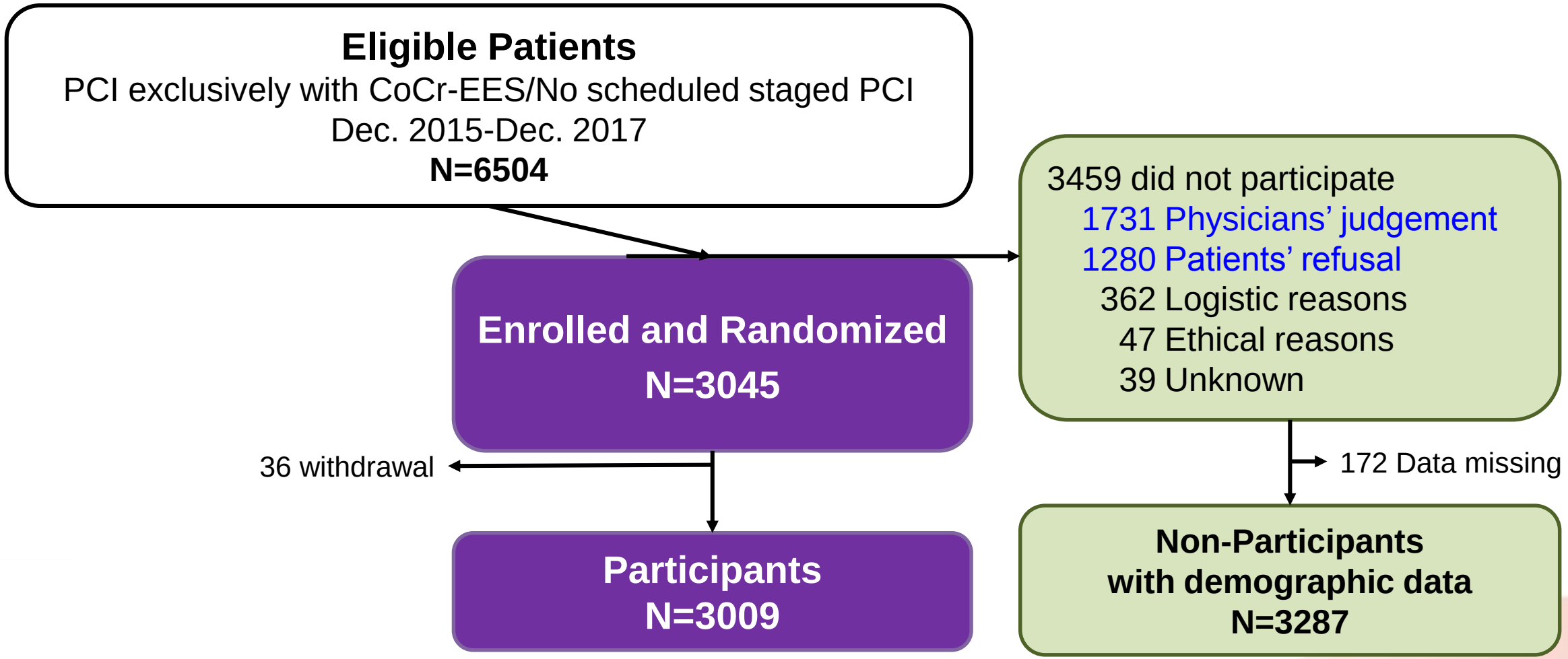
Ischemic composite endpoint

- A composite of cardiovascular death, MI, Definite ST, or Stroke

Bleeding endpoint

- TIMI major/minor bleeding

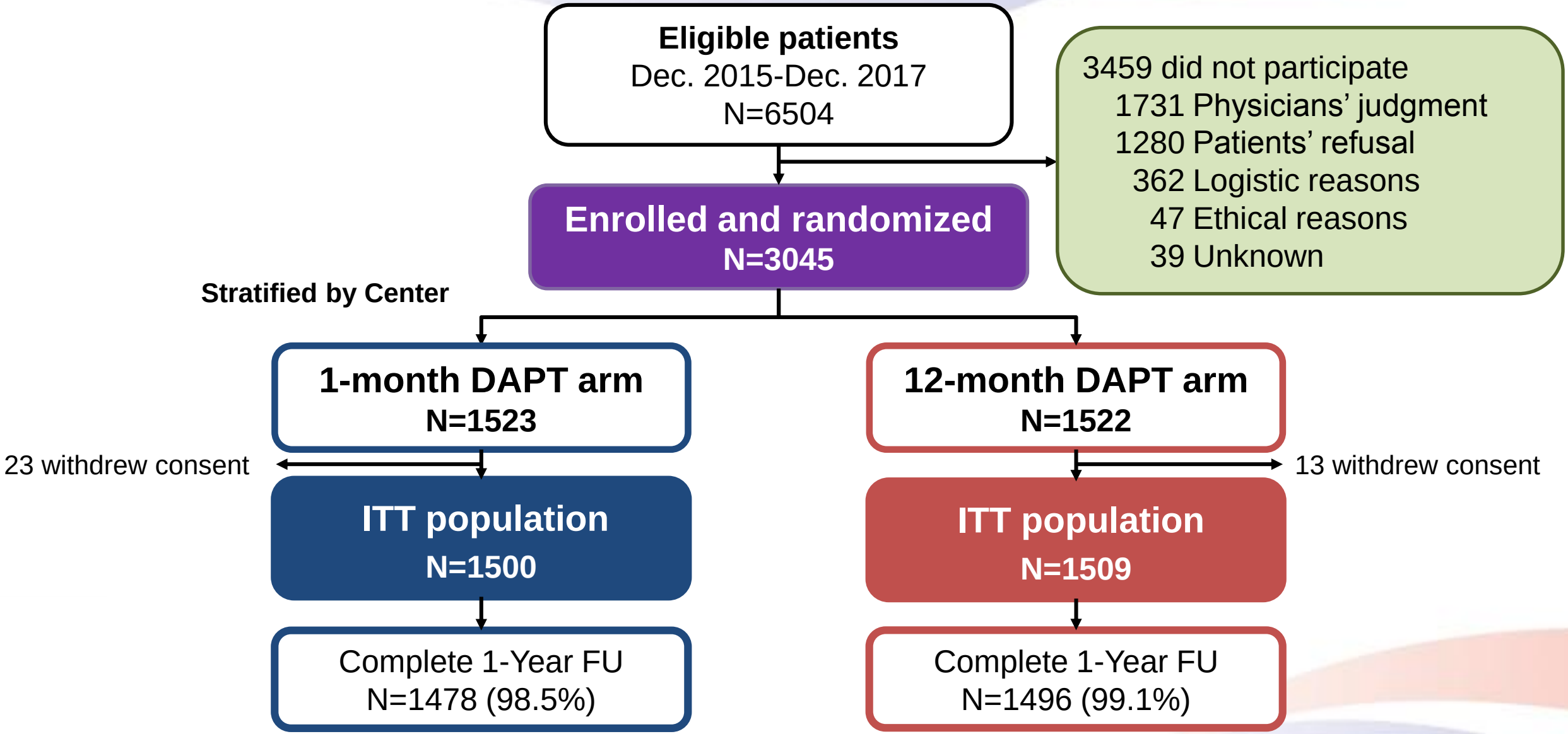
Study Flow


Eligible Patients
PCI exclusively with CoCr-EES/No scheduled staged PCI
Dec. 2015-Dec. 2017
N=6504
3459 did not participate
1731 Physicians' judgement
1280 Patients' refusal
362 Logistic reasons
47 Ethical reasons
39 Unknown
Enrolled and Randomized
N=3045
36 withdrawal
172 Data missing
Participants
N=3009
Non-Participants
with demographic data
N=3287

Baseline Characteristics: Participants vs Non-participants

	Participants N=3009	Non-participants N=3287	P value
Age, years	68.6±10.7	70.0±11.7	<0.001
ACS	38%	39%	0.61
STEMI	19%	22%	0.003
Prior MI	14%	23%	<0.001
Prior 1st-generation DES implantation	4%	6%	<0.001
Diabetes	39%	39%	0.47
Severe CKD	6%	9%	<0.001
Dialysis	3%	5%	<0.001
Target of LMCA	3%	5%	<0.001
Two or more target vessels	7%	9%	0.003

Study Flow


Eligible patients
Dec. 2015-Dec. 2017
N=6504
3459 did not participate
1731 Physicians' judgment
1280 Patients' refusal
362 Logistic reasons
47 Ethical reasons
39 Unknown
Enrolled and randomized
N=3045
Stratified by Center
1-month DAPT arm
N=1523
12-month DAPT arm
N=1522
23 withdrew consent
13 withdrew consent
ITT population
N=1500
ITT population
N=1509
Complete 1-Year FU
N=1478 (98.5%)
Complete 1-Year FU
N=1496 (99.1%)

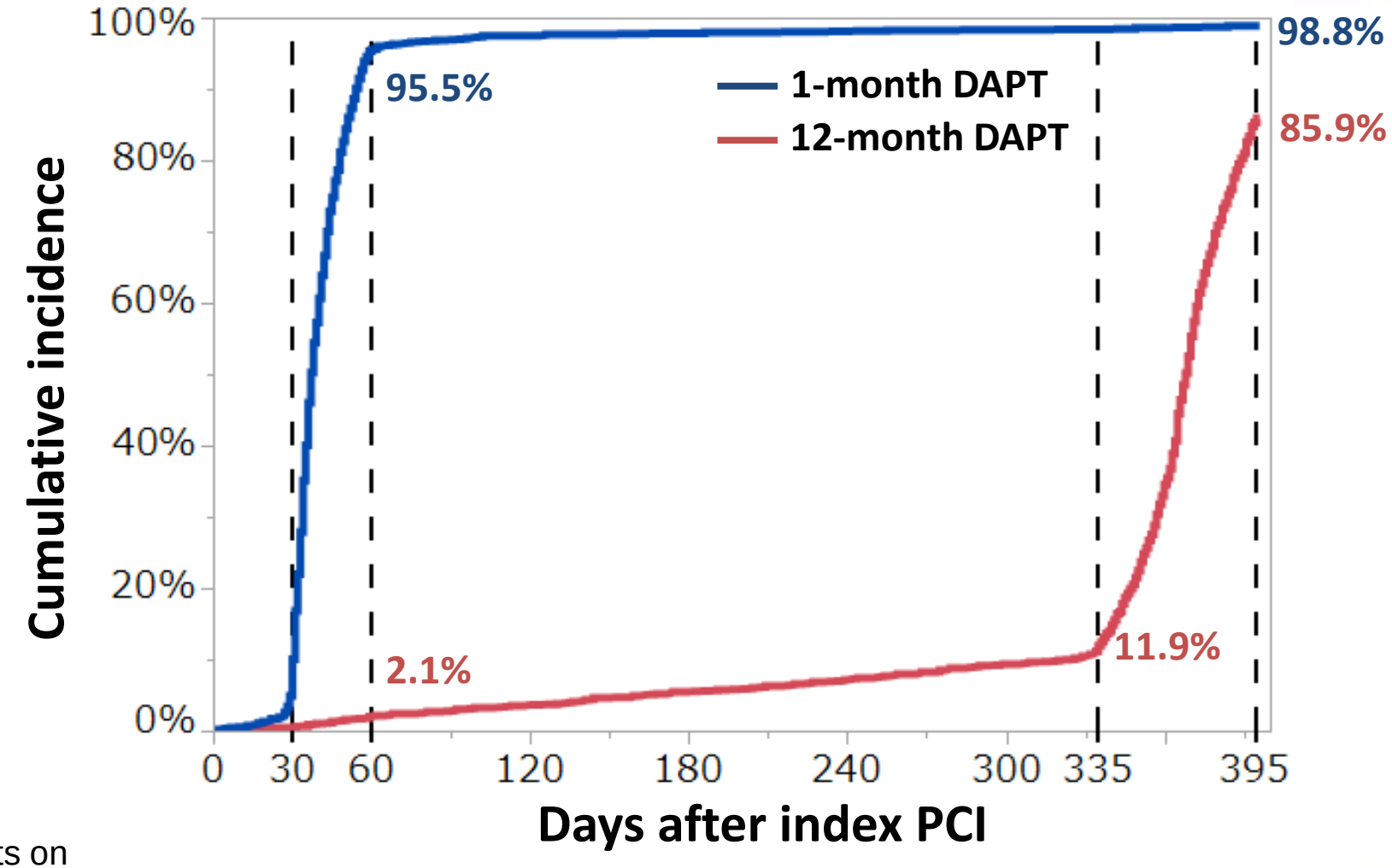
Baseline Clinical Characteristics

	1-month DAPT N=1500	12-month DAPT N=1509
Age, years	68.1±10.9	69.1±10.4
Men	79%	77%
ACS	38%	39%
STEMI	19%	18%
Stable CAD	62%	61%
Diabetes	39%	38%
Severe CKD (eGFR<30ml/min/m^2)	6%	6%
Prior MI	14%	13%
Prior PCI	34%	35%
CREDO-Kyoto thrombotic risk score		
High; Intermediate; Low	8%; 21%; 71%	8%; 24%; 68%
CREDO-Kyoto bleeding risk score		
High; Intermediate; Low	7%; 27%; 66%	7%; 27%; 66%

Procedural Characteristics and Medications

	1-month DAPT N=1500	12-month DAPT N=1509
Transradial approach	82%	84%
N of target lesions	1.12 ± 0.35	1.14 ± 0.39
Minimal stent diameter, mm	2.98 ± 0.49	2.96 ± 0.48
Total stent length, mm	30.3 ± 16.7	30.5 ± 16.8
SYNTAX Score	8 (5-14)	9 (6-15)
Target of LMCA	3%	3%
CTO	4%	4%
IVUS or OCT	97%	98%
ASA	99.8%	100%
Clopidogrel	60%	63%
Prasugrel (3.75mg/day)	40%	37%
Statin	88%	87%
PPI	79%	79%

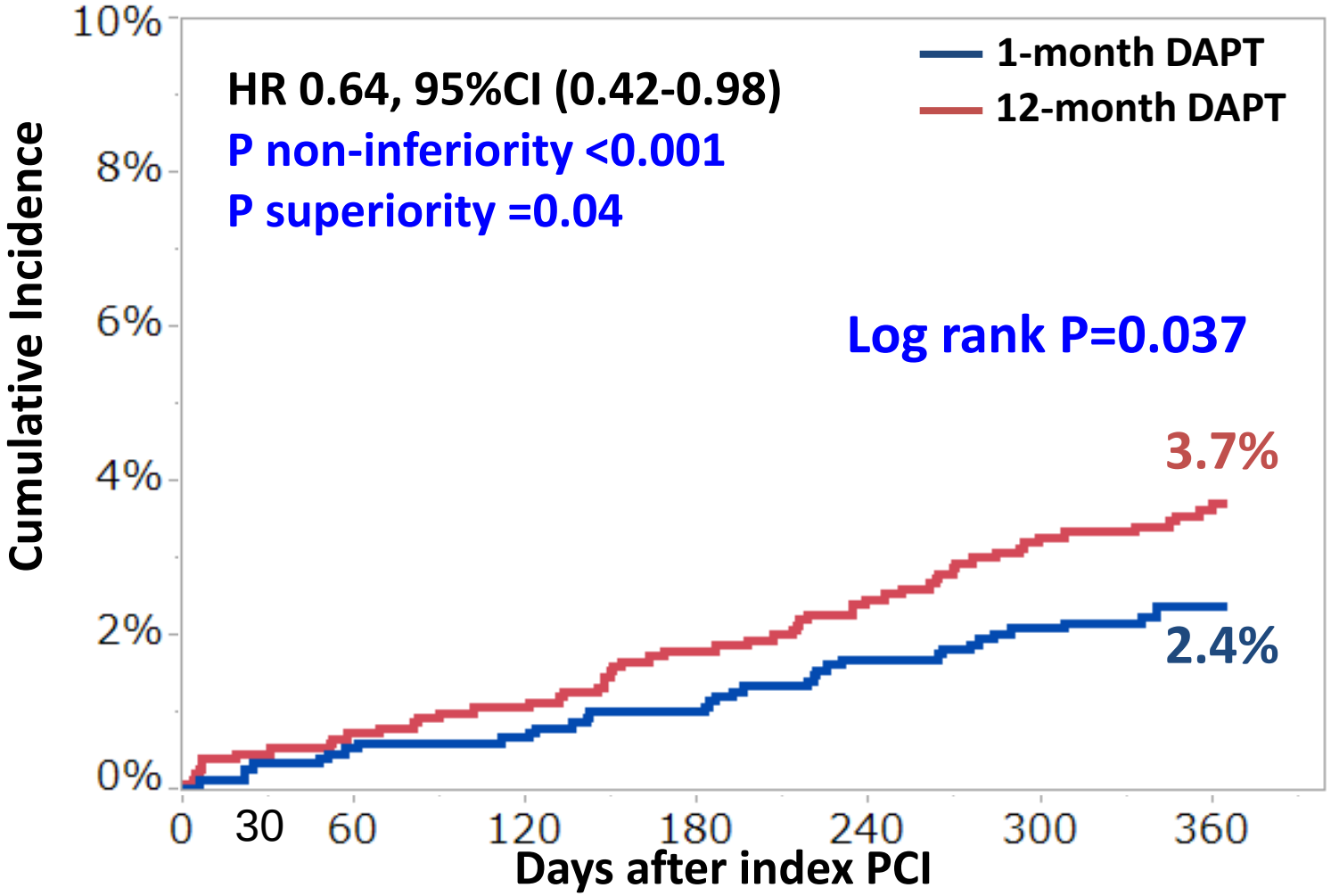
Persistent DAPT Discontinuation



Number of patients on DAPT									
1-month DAPT	1500	1346	67	38	32	28	25	23	9

Primary Endpoint: Net clinical benefit

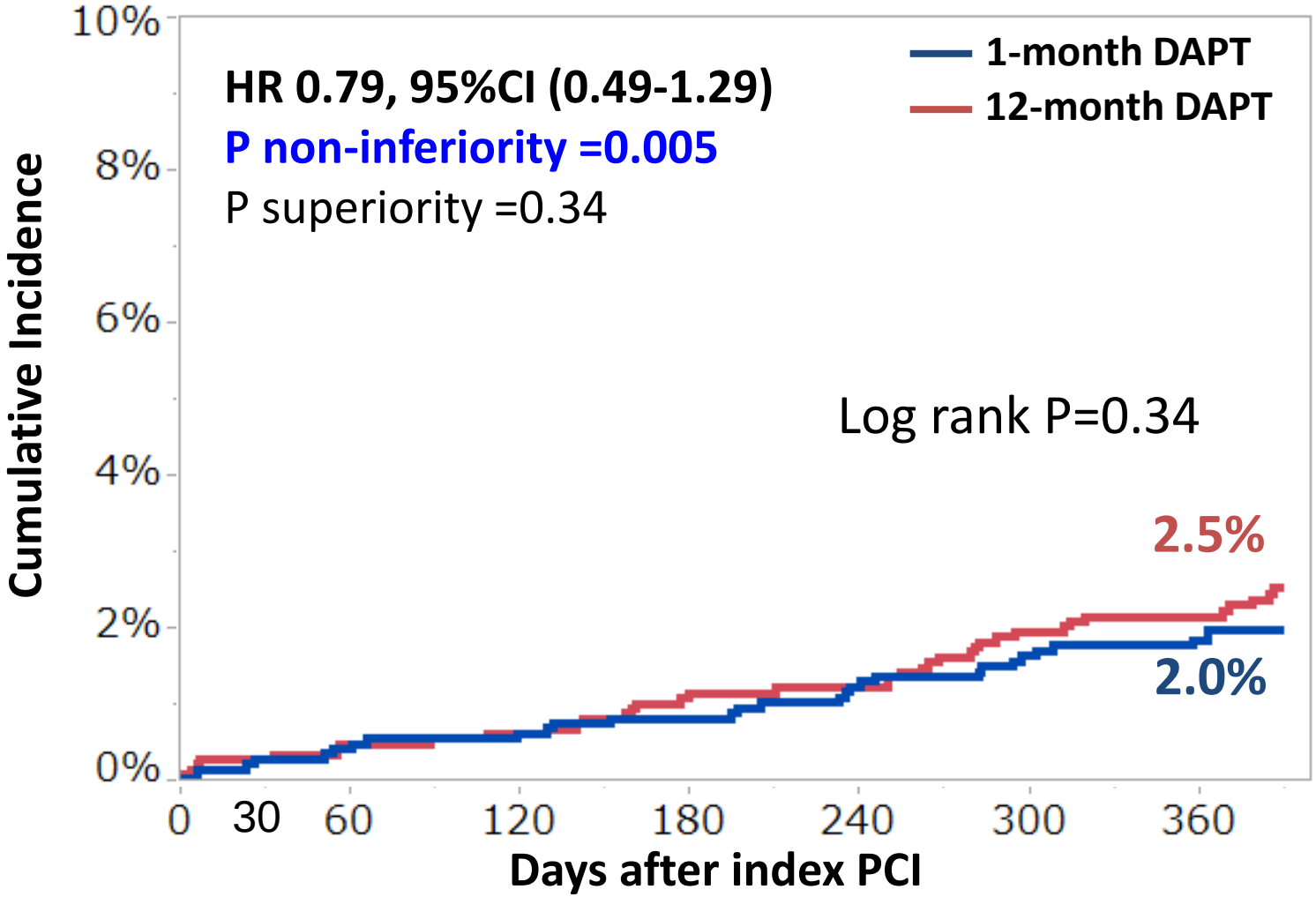
CV death/MI/ST/Stroke/TIMI major/minor bleeding



No. at risk								
12-month DAPT	1509	1501	1486	1481	1469	1458	1442	1159
1-month DAPT	1500	1494	1479	1475	1468	1453	1441	1151

Major secondary ischemic endpoint

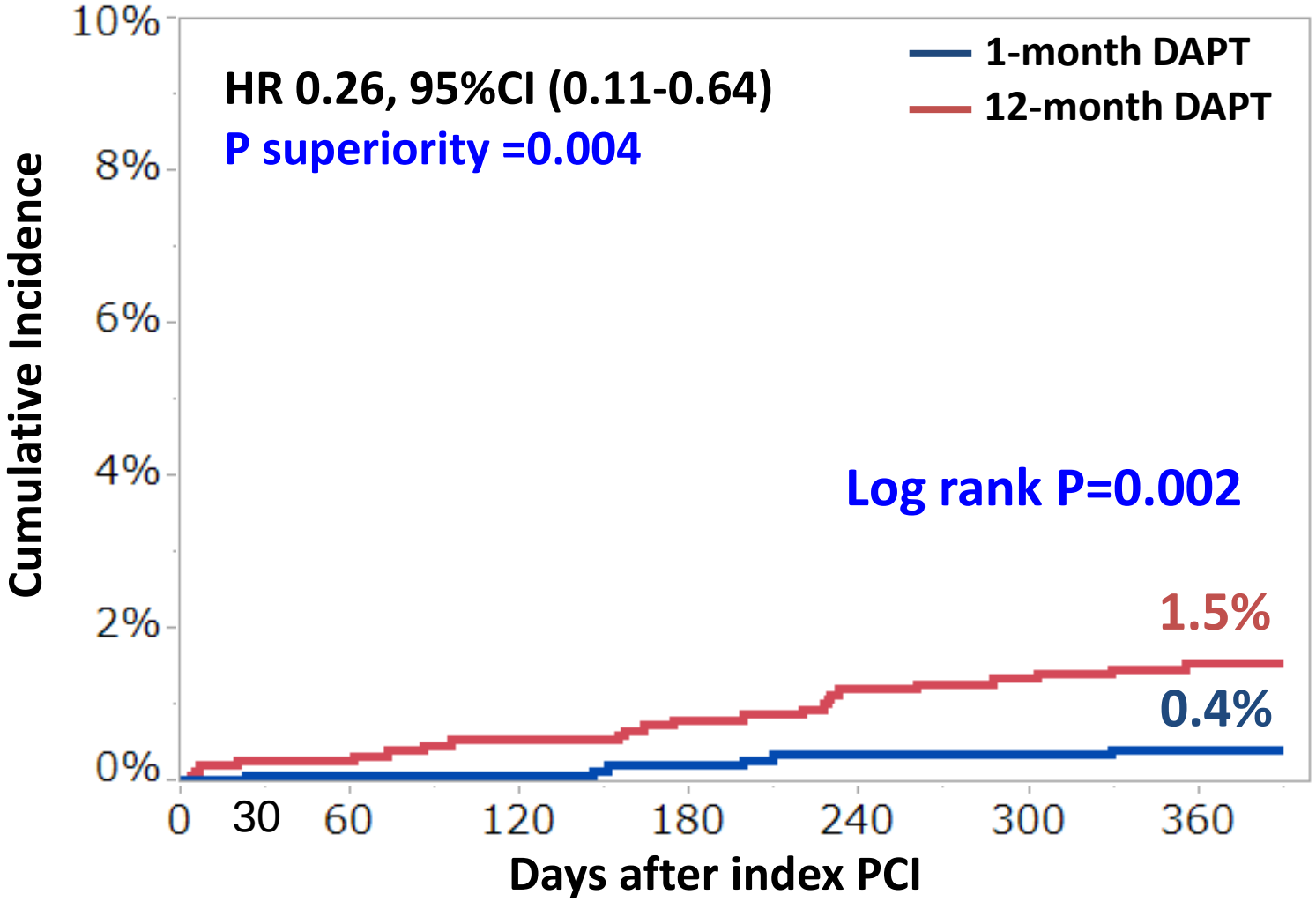
CV death/MI/ST/Stroke



No. at risk								
12-month DAPT	1509	1504	1490	1488	1479	1473	1458	1172
1-month DAPT	1500	1495	1480	1476	1471	1458	1446	1157

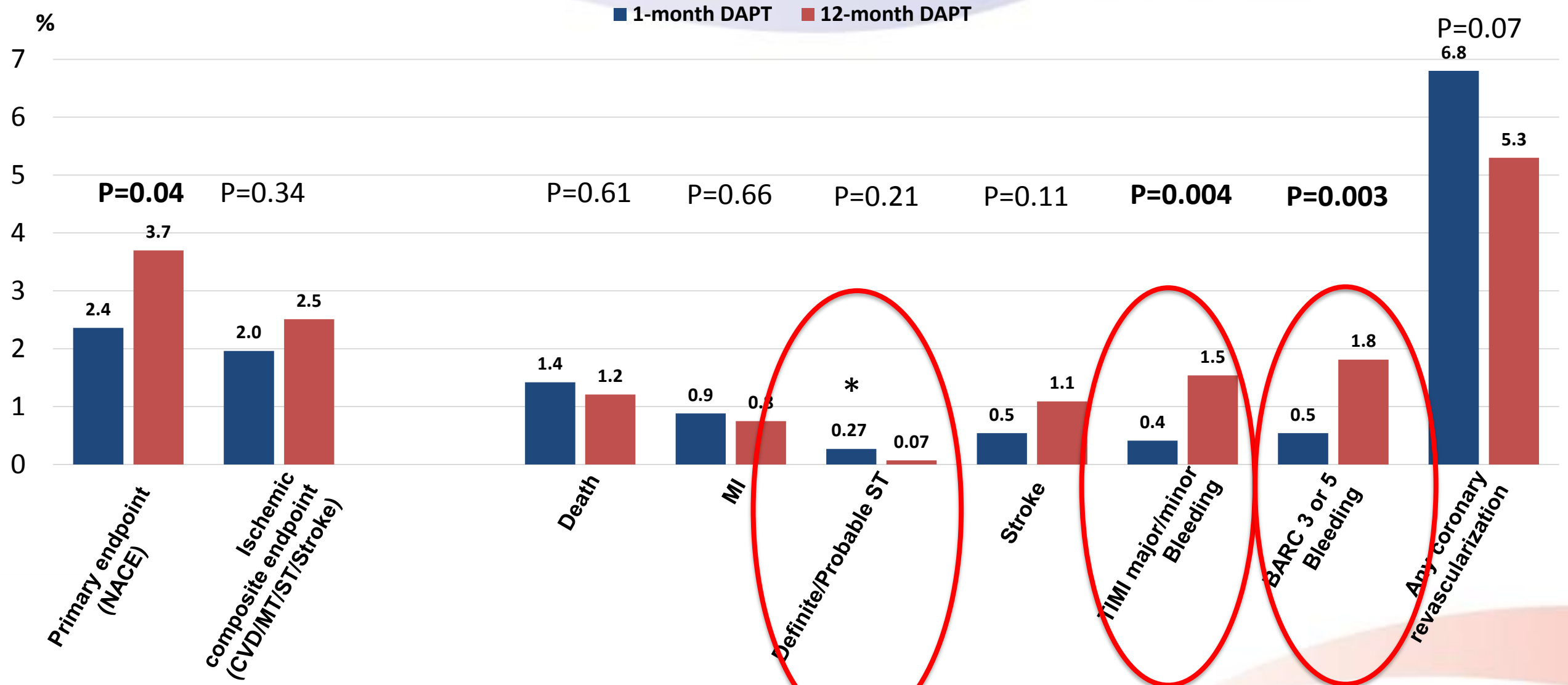
Major secondary bleeding endpoint

TIMI major/minor bleeding



No. at risk								
12-month DAPT	1509	1504	1491	1487	1480	1471	1462	1180
1-month DAPT	1500	1495	1483	1481	1477	1467	1457	1166

Clinical Outcomes at 1 year



* 2 cases of probable ST (undefined death) occurred before discontinuing DAPT at 1-month

Definite/Probable Stent Thrombosis

Case	Assigned Group	Age, Sex	Index presentation other risk factors	Index PCI	ARC definition	Days after index PCI	Medication at the event	Presentation, intervention	Prognosis
#1	1-month DAPT	64, Male	**STEMI** HL, Current Smoker	LCx CoCr-EES 3.5/23	Definite	51	Clopidogrel mono-therapy 22 days after ASA discontinued	STEMI Stent occluded, slight hard to pass wire. Small thrombus aspirated. Peak CK/CKMB 1297/106	alive
#2	1-month DAPT	51, Female	**UA** HTN, HL, past smoker Prior 1G-DES	LCx SES ISR lesion CoCr-EES 3.0/33	Definite	112	Clopidogrel mono-therapy 76 days after ASA discontinued	STEMI Coronary thrombus proved by IVUS and OCT. Aspiration failed POBA (DCB) Peak CK/CKMB 4263/367	alive
#3	12-month DAPT	69, Male	**UA** HTN, HL, DM Prior PCI LAD G2-DES	LAD CoCr-EES 2.5/15	Definite	148	ASA+ Clopidogrel	NSTEMI LAD#7 occluded, thrombus+ POBA Peak CK/CKMB 3787/488	alive
#4	1-month DAPT	70, Male	**UA** HTN, Current smoker	LAD CoCr-EES 3.5/12+3.0/18 KBT+ for Diagonal	Probable	6	ASA+ Prasugrel	SCD Found in a corpse, undefined death	dead
#5	1-month DAPT	78, Female	**Asymptomatic ischemia** Prior Stroke, Low EF Severe CKD, Dialysis, HTN, HL, DM with insulin	RCA ostium CoCr-EES 3.25/15	Probable	25	ASA+ Clopidogrel	SCD Cardiac arrest at home, undefined death	dead

2 probable ST were not associated with stopping DAPT

STOPDAPT-2

Conclusions

One-month DAPT followed by clopidogrel monotherapy provided a net clinical benefit for ischemic and bleeding events over 12-month DAPT with aspirin and clopidogrel after CoCr-EES implantation.

The benefit was driven by significant reduction in bleeding events without increase in ischemic events.

＜Summary＞

DES with thromboresistant durable polymer entire coating and thin struts, such as Xience, is considered to be beneficial at the time of non-cardiac surgery.

Ultra-short term DAPT such as 1 month DAPT seems to be safe and feasible approach following Xience implantation.

＜Thank you for your attention＞