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STOPDAPT-2

(HOTLINES)

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XXVII. VÝROČNÍ SJEZD ČESKÉ KARDIOLOGICKÉ SPOLEČNOSTI
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MINISTERSTVO ŠKOLSTVÍ, MLÁDEŽE A TĚLOVÝCHOVY

EVROPSKÁ UNIE
EVROPSKÝ FOND PRO REGIONÁLNÍ ROZVOJ
INVESTICE DO VAŠÍ BUDOUCNOSTI

2007–13
OP Výzkum a vývoj pro inovace

STOPDAPT-2

DAPT PO PCI

Antiagregační léčba po implantaci stentu		
DAPT je indikována alespoň jeden měsíc po implantaci BMS.	I	A
DAPT je indikována šest měsíců po implantaci DES.	I	B
Kratší trvání DAPT (< šest měsíců) lze zvážit po implantaci DES u pacientů s vysokým rizikem krvácení.	IIb	A
Je doporučena celoživotní antiagregační léčba, obvykle ASA.	I	A
Je doporučeno pacienta podrobně poučit o nutnosti užívat antiagregační léčbu.	I	C
DAPT lze podávat déle než šest měsíců u nemocných s vysokým rizikem ischemie a nízkým rizikem krvácení.	IIb	C

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

Hirotoshi Watanabe

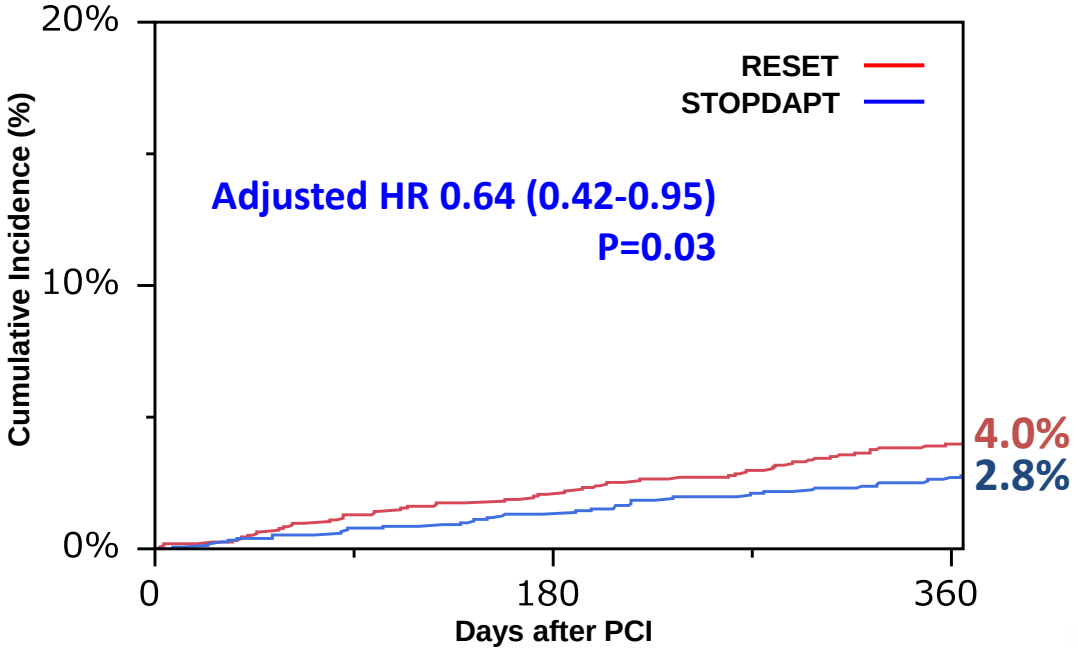
Takenori Domei, Takeshi Morimoto, Hiroki Shiomi, Masahiro Natsuaki, Toshiaki Toyota, Kensuke Takagi, Yoshiki Hata, Satoru Suwa, Mamoru Nanasato, Masanobu Ohya, Masahiro Yagi, Takafumi Yokomatsu, Mitsuru Abe, Kenji Ando, Kazushige Kadota, Ken Kozuma, Yoshihiro Morino, Yuji Ikari, Kengo Tanabe, Koichi Nakao, Kazuya Kawai, Yoshihisa Nakagawa, and Takeshi Kimura,
on behalf of STOPDAPT-2 investigators

STOPDAPT

Prospective multicenter open-label single arm trial evaluating 3-month DAPT after CoCr-EES implantation

Primary Endpoint

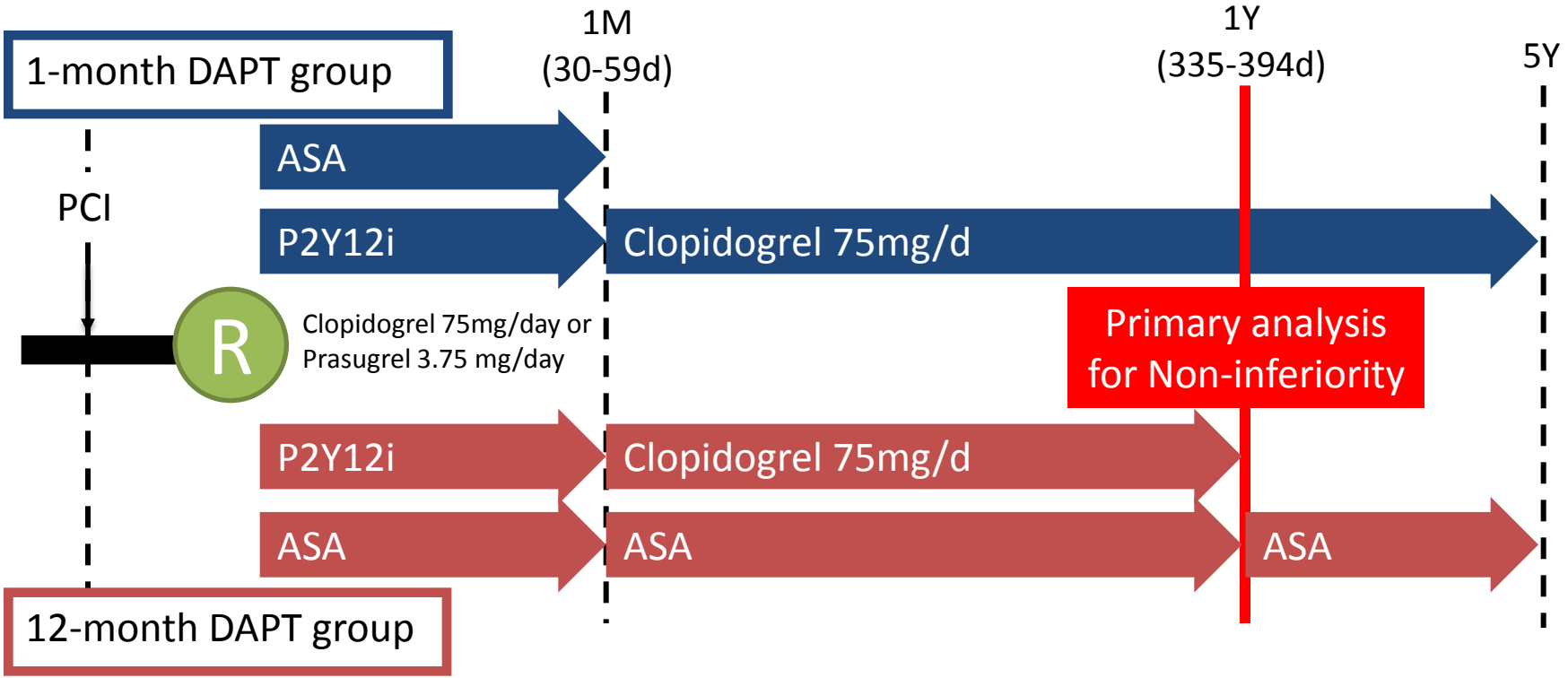
Cardiovascular death, MI, Stroke, Definite ST, and Bleeding



Cardiovasc Interv Ther 2016; 31: 196–209.

STOPDAPT-2:

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



Inclusion Criteria

- PCI with exclusive use of CoCr-EES (Xience™ 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:**

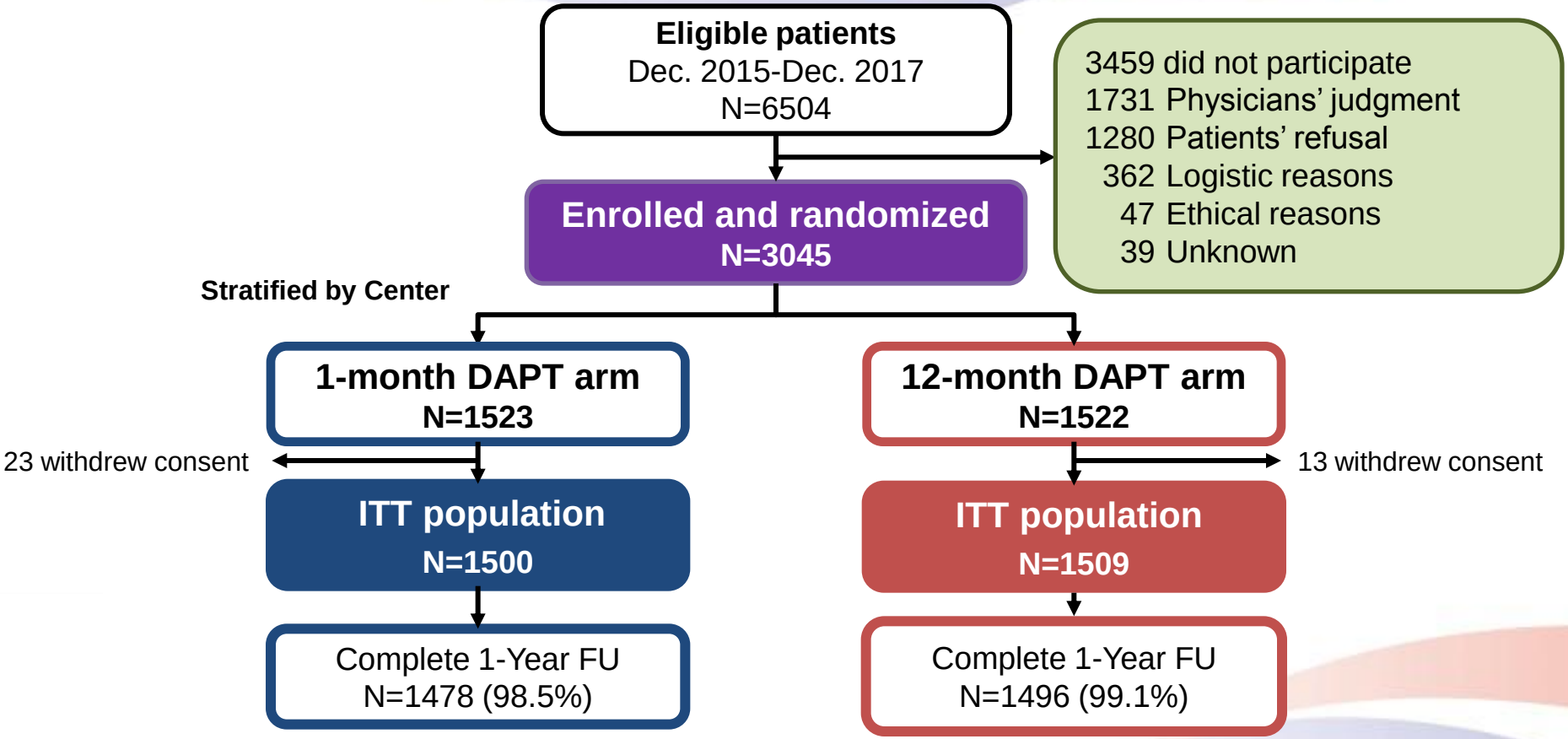
Ischemic composite endpoint

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

Bleeding endpoint

- TIMI major/minor bleeding

Study Flow


Eligible patients
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

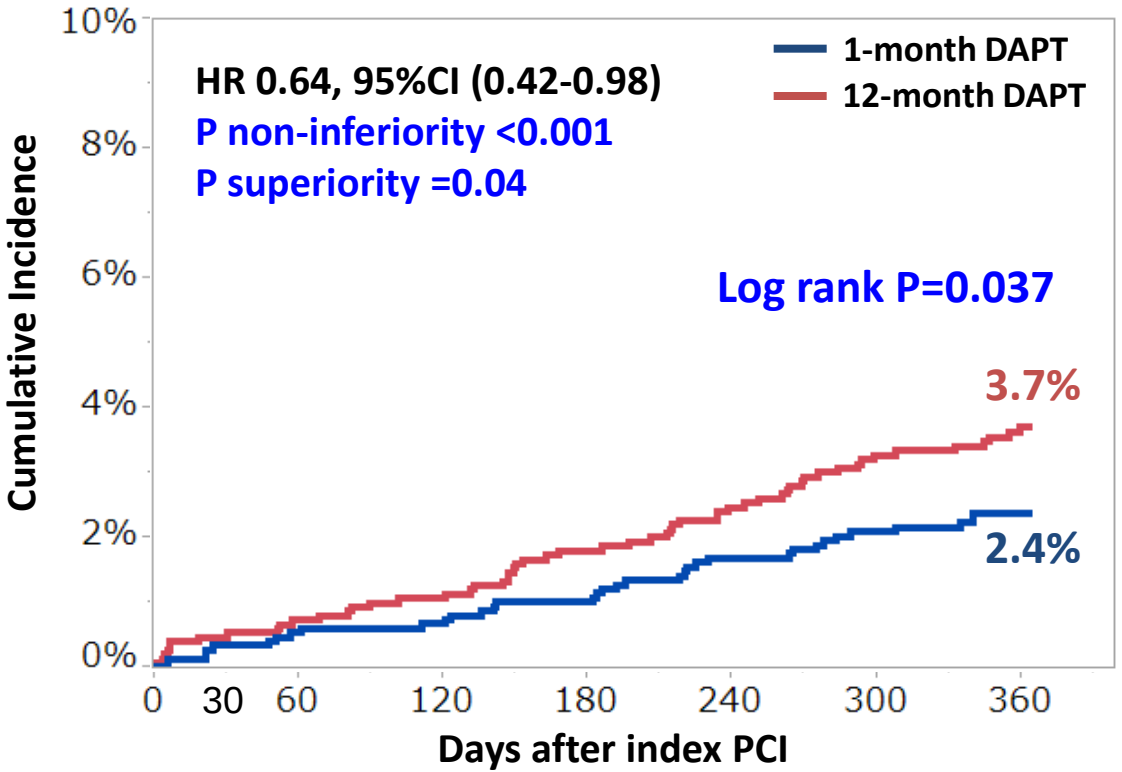
	1-month DAPT N=1500	12-month DAPT N=1509
Age, years	68.1±10.9	69.1±10.4
Men	79%	77%
ACS	38%	39%
STEMI	19%	18%
Stable CAD	62%	61%
Diabetes	39%	38%
Severe CKD (eGFR<30ml/min/m^2)	6%	6%
Prior MI	14%	13%
Prior PCI	34%	35%
CREDO-Kyoto thrombotic risk score		
High; Intermediate; Low	8%; 21%; 71%	8%; 24%; 68%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

Primary Endpoint: Net clinical benefit

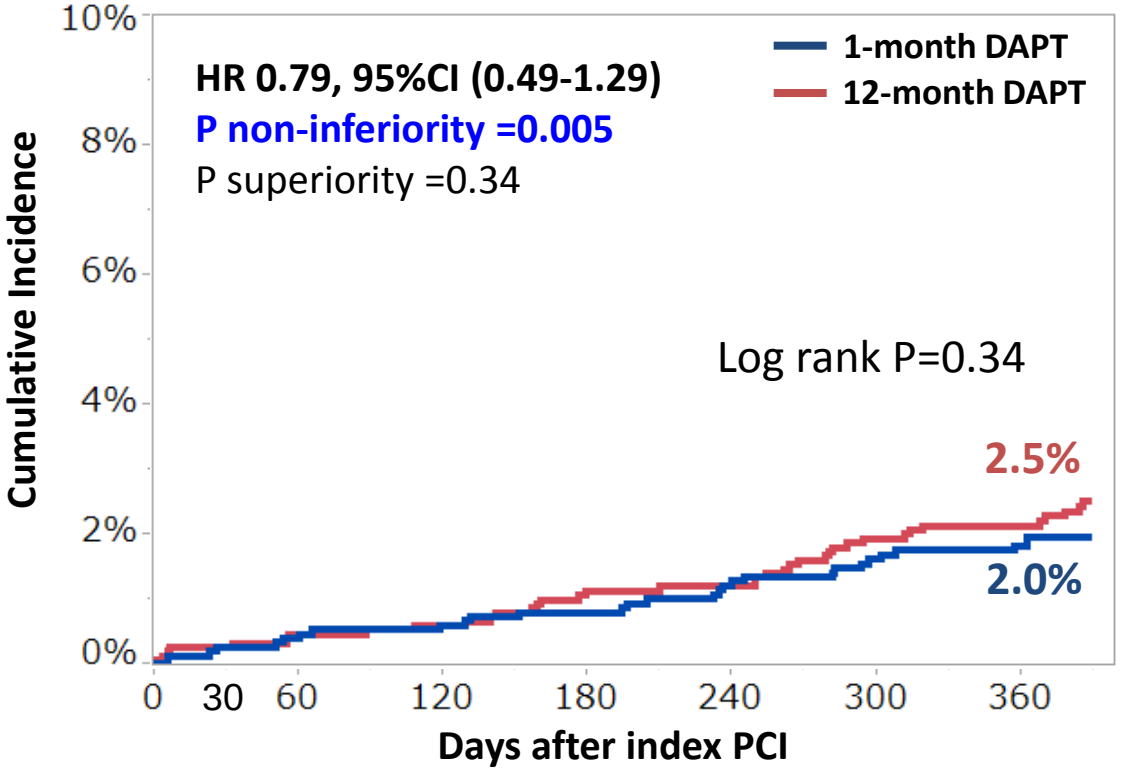
CV death/MI/ST/Stroke/TIMI major/minor bleeding



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

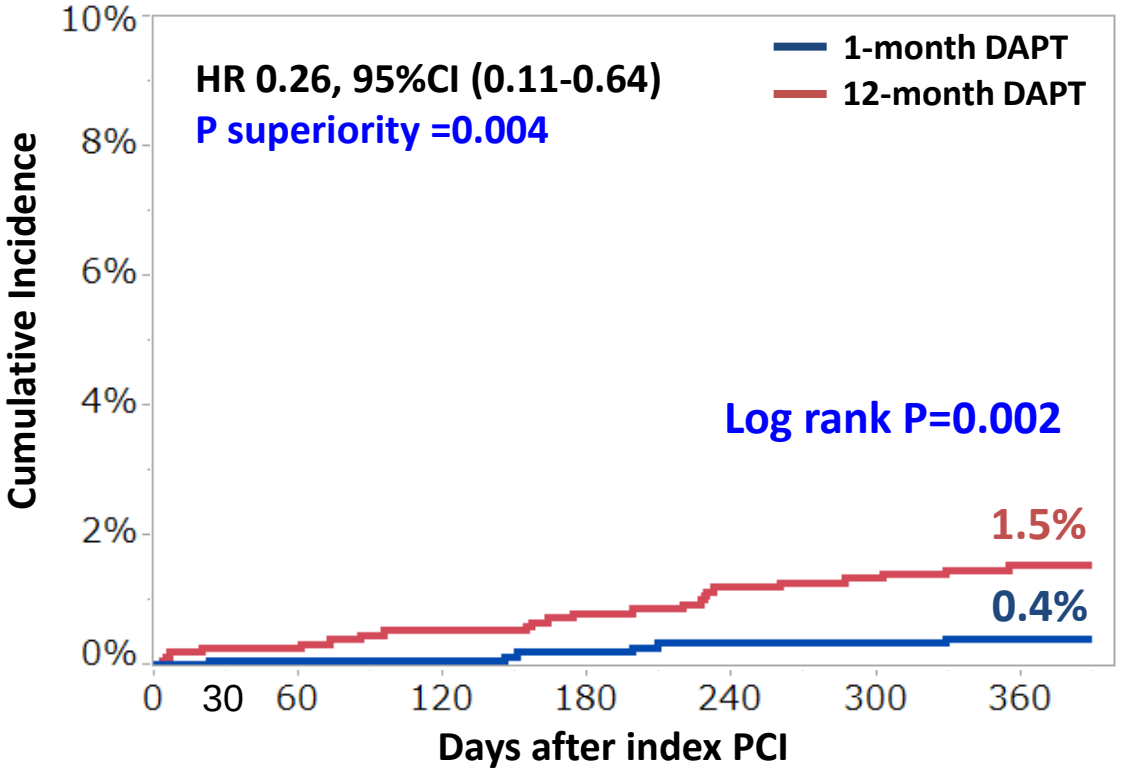
CV death/MI/ST/Stroke



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

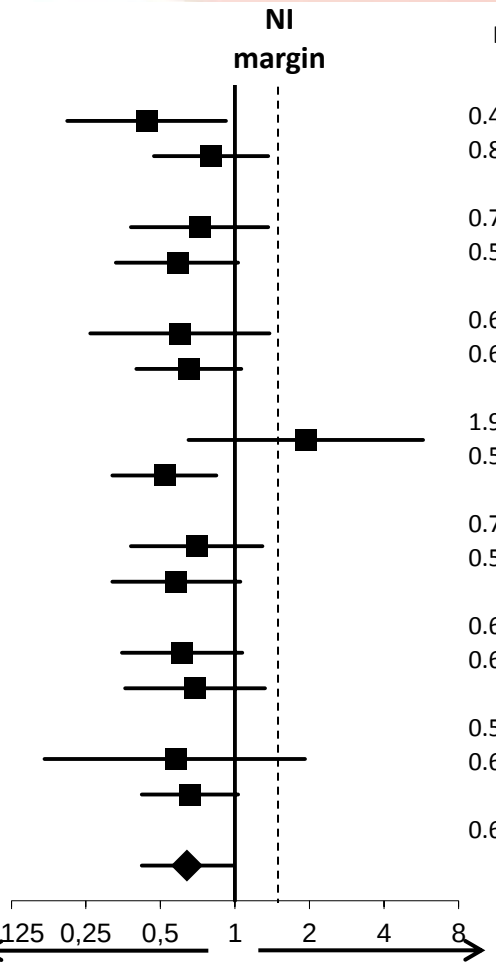
TIMI major/minor bleeding



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

Subgroup analysis for the primary endpoint (1)

	1-month DAPT (N=1500)	12-month DAPT (N=1509)	HR (95%CI)	P superiority	P interaction
Age					
>=75 years	10/448 (2.26%)	25/499 (5.08%)	0.44 (0.21-0.92)	0.03	0.20
<75 years	25/1052 (2.41%)	30/1010 (3.02%)	0.80 (0.47-1.36)	0.41	
ACS					
Yes	16/565 (2.88%)	23/583 (4.02%)	0.72 (0.38-1.36)	0.44	0.64
No	19/935 (2.05%)	32/926 (3.49%)	0.59 (0.33-1.03)	0.06	
STEMI					
Yes	9/291 (3.15%)	14/270 (5.26%)	0.60 (0.26-1.38)	0.23	0.87
No	26/1209 (2.18%)	41/1239 (3.36%)	0.65 (0.40-1.06)	0.08	
Severe CKD					
Yes	9/82 (11.22%)	5/84 (5.97%)	1.93 (0.65-5.75)	0.24	0.03
No	26/1418 (1.86%)	50/1425 (3.56%)	0.52 (0.32-0.84)	0.007	
Diabetes					
Yes	18/585 (3.12%)	25/574 (4.45%)	0.70 (0.38-1.29)	0.26	0.65
No	17/915 (1.88%)	30/935 (3.24%)	0.58 (0.32-1.05)	0.07	
Total stent length >=28mm					
Yes	19/742 (2.60%)	33/787 (4.23%)	0.61 (0.35-1.07)	0.08	0.76
No	16/758 (2.14%)	22/722 (3.12%)	0.69 (0.36-1.32)	0.26	
Two or more target vessels					
Yes	4/100 (4.14%)	8/116 (6.94%)	0.58 (0.17-1.92)	0.37	0.85
No	31/1400 (2.24%)	47/1393 (3.43%)	0.66 (0.42-1.03)	0.07	
Overall	35/1500 (2.36%)	55/1509 (3.70%)	0.64 (0.42-0.98)	0.038	



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.

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