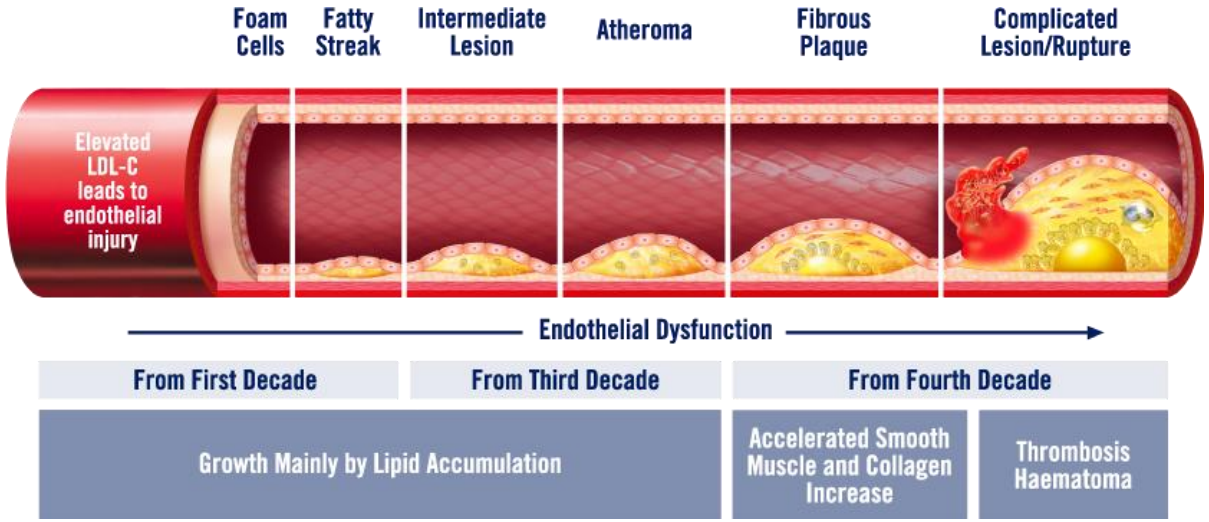
Modulation of DAPT Duration: What is the Best?

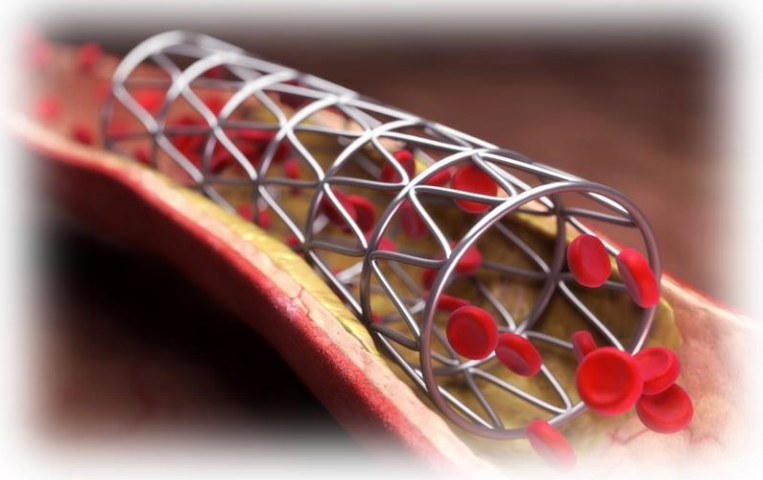
Kyung Woo Park, MD, PhD, MBA

Seoul National University Hospital

DAPT after PCI

- **PCI for coronary artery disease**
  - Treating **thrombotic lesions** with a potentially **thrombotic material**





  - Antiplatelets are used to inhibit post-procedural thrombosis formation
- Historical trials mainly focused on the thrombotic risk.
  - The **main purpose** of antiplatelets

Eur Heart J. 2019;40(2):87-165.
J Am Coll Cardiol. 2011;58(24):e44-122.

Ischemic and Bleeding Risks

- **Ischemic and bleeding risks after PCI**

Patient related factors

Intrinsic Ischemic risk
Intrinsic Bleeding risk

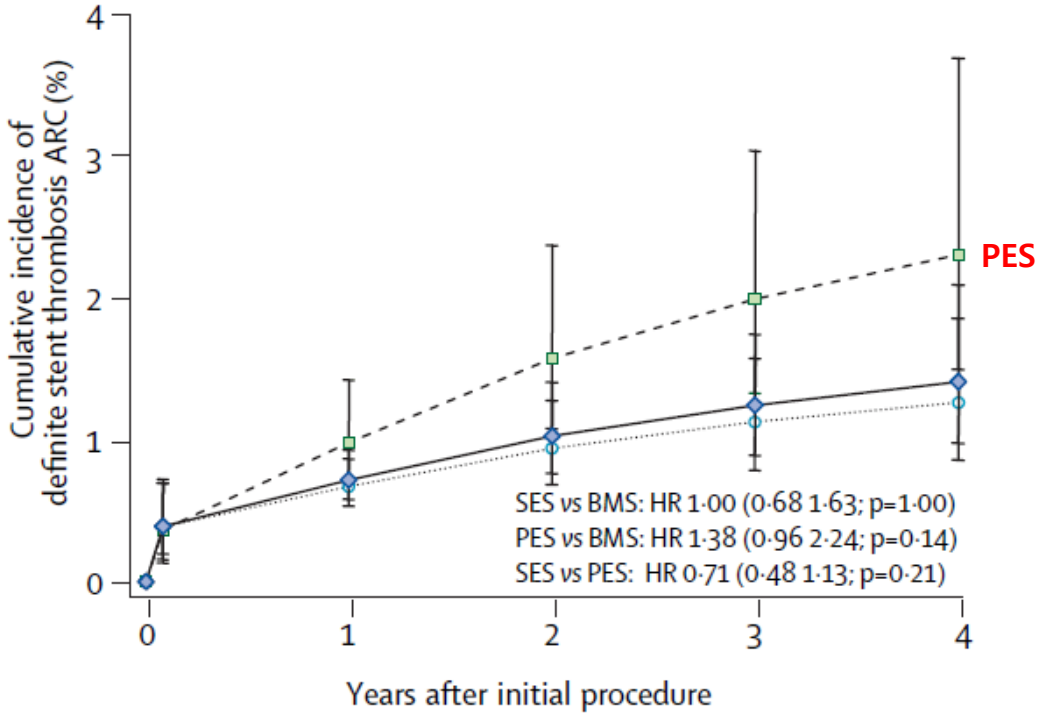
Age, HTN, DM, Dyslipidemia.
Chronic renal failure, Nutritional status, medications, etc.

Procedure related factors

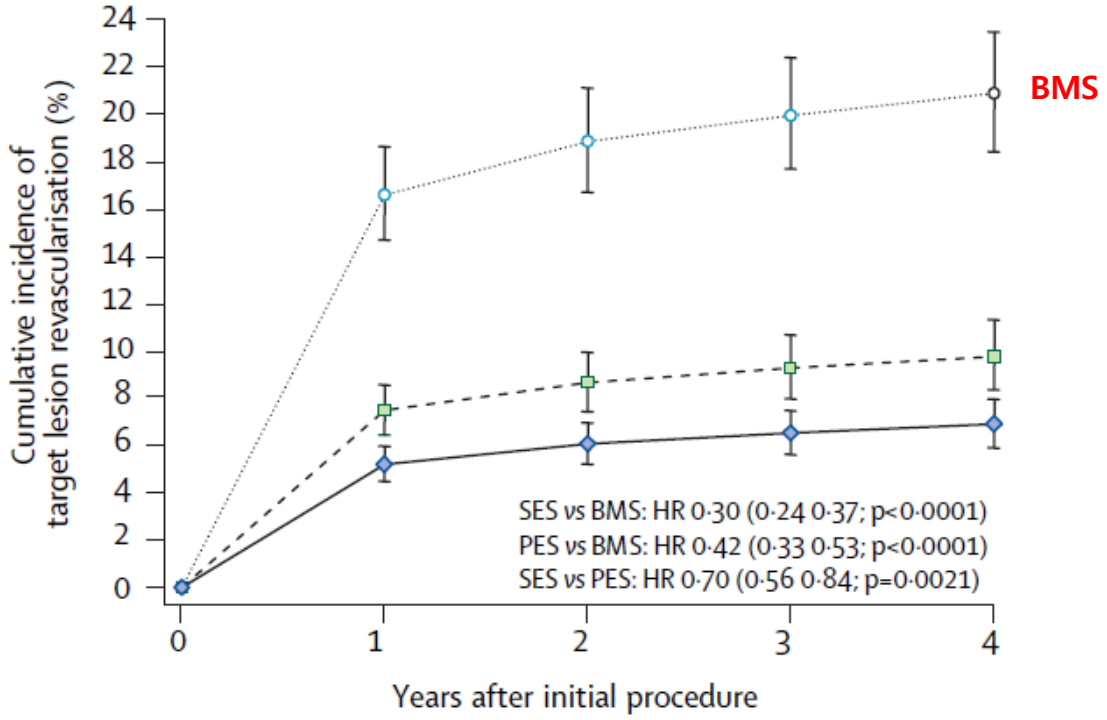
Device related risk
Procedure related risk

Stent type, GPIIb/IIa inh. usage, complications (coronary dissection, no-flow ph.), etc.

Early generation DES



BMS	4003	42/4000	4/3048	3/1928	1/1806
PES	4327	46/4321	20/3711	5/1853	1/762
SES	4643	52/4642	9/3804	3/2257	2/1070



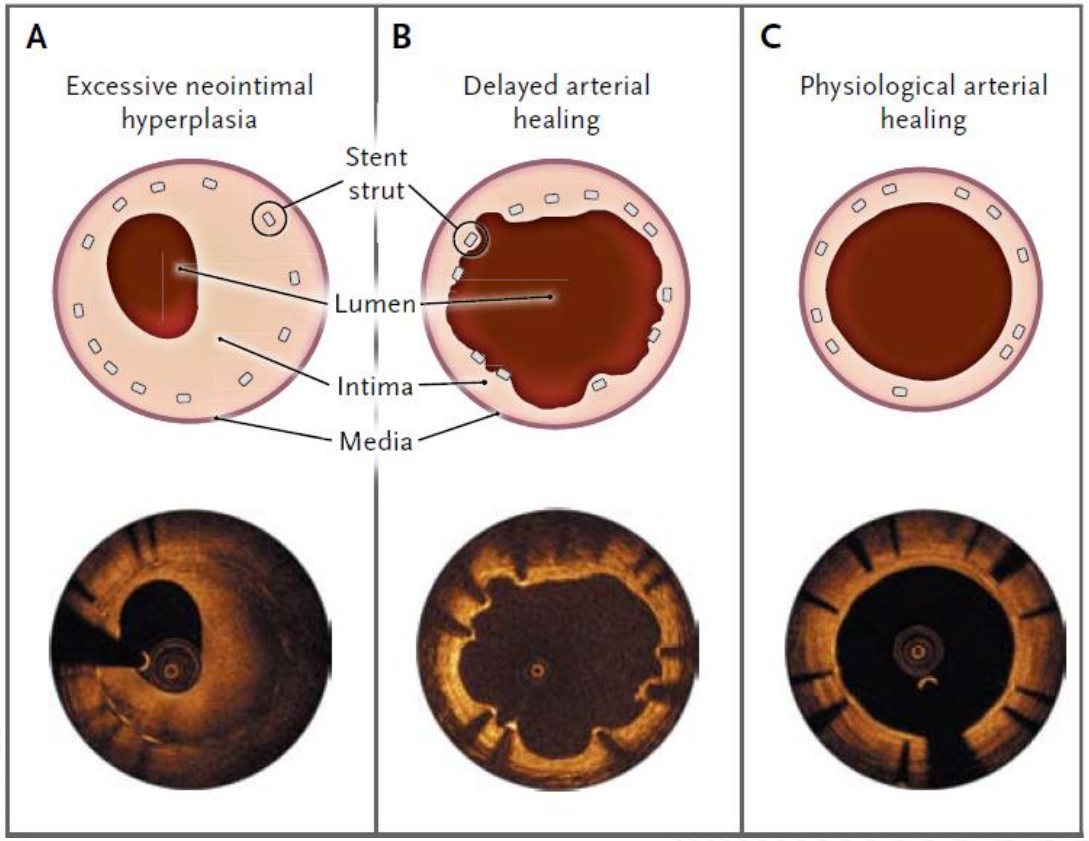
	4763	820/4746	53/2795	22/1871	10/1543
	6328	448/6280	98/3950	15/1999	6/832
	6621	356/6580	68/3801	16/2153	14/999

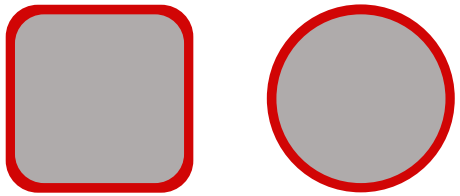
There was a marked reduction in the rate of repeat revascularization with early generation DES, as compared with bare-metal stents.
However, there was an increased risk of very late stent thrombosis, as compared with bare-metal stents.

Lancet 2007; 370: 937–48

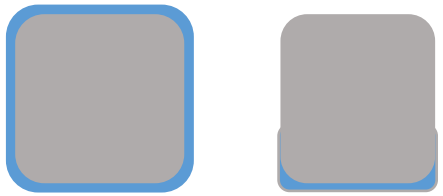
Evolution of polymer technologies

Although early generation DES overcame the major limitations of BMS in higher rates of stent thrombosis and restenosis, it still had substantial drawbacks.





Circumferentially-coated
more biocompatible durable polymer (DP)



Circumferentially or abluminally-coated
Biodegradable polymer (BP)

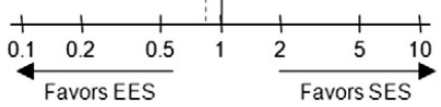
N Engl J Med 2013;368:254-65.
Lancet 2017; 390: 781–92

Better outcomes with new generation DESs

A systematic review and meta-analysis of 11 randomized trials

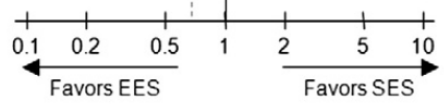
Study	EES Events	EES Total	SES Events	SES Total	Odds Ratio (95% CI) for Repeat Revascularization
BASKET-PROVE	29	774	33	775	0.88 (0.53, 1.46)
ESSENCE-DIABETES	1	149	4	151	0.25 (0.03, 2.25)
EXCELLENT	26	1,079	6	364	1.47 (0.60, 3.61)
ISAR-TEST 4	77	652	95	652	0.79 (0.57, 1.08)
SORT OUT IV	67	1,390	77	1,384	0.86 (0.61, 1.20)
SEA-SIDE	5	75	5	75	1.00 (0.28, 3.61)
LONG-DES-III	9	224	6	226	1.53 (0.54, 4.39)
Sakakibara et al	3	50	9	50	0.29 (0.07, 1.15)
RESET	65	1,597	76	1,600	0.85 (0.61, 1.19)
X-AMI	10	404	9	221	0.68 (0.26, 1.75)
APPENDIX-AMI	7	500	8	477	0.83 (0.30, 2.31)
Total	**299**	**6,894**	**328**	**5,975**	**0.85 (0.72, 1.00)**

Heterogeneity $P = .692$; $I^2 = 0\%$
Test for Overall Effect Z = 1.99 ($P = .047$)



Study	EES Events	EES Total	SES Events	SES Total	Odds Ratio (95% CI) for Definite or Probable Stent Thrombosis
BASKET-PROVE	5	774	6	775	0.83 (0.25, 2.74)
ESSENCE-DIABETES	1	149	1	151	1.01 (0.06, 16.35)
EXCELLENT	4	1,079	3	364	0.45 (0.10, 2.01)
ISAR-TEST 4	9	652	12	652	0.75 (0.31, 1.78)
SORT OUT IV	10	1,390	16	1,384	0.92 (0.42, 2.02)
SEA-SIDE	0	75	0	75	Not estimable
LONG-DES-III	1	224	0	226	3.04 (0.12, 75.03)
Sakakibara et al	0	50	0	50	Not estimable
RESET	6	1,597	6	1,600	1.00 (0.32, 3.11)
X-AMI	5	404	6	221	0.45 (0.14, 1.49)
APPENDIX-AMI	1	500	3	477	0.32 (0.03, 3.05)
Total	**42**	**6,894**	**53**	**5,975**	**0.68 (0.45, 1.02)**

Heterogeneity $P = .948$; $I^2 = 0\%$
Test for Overall Effect Z = 1.85 ($P = .065$)

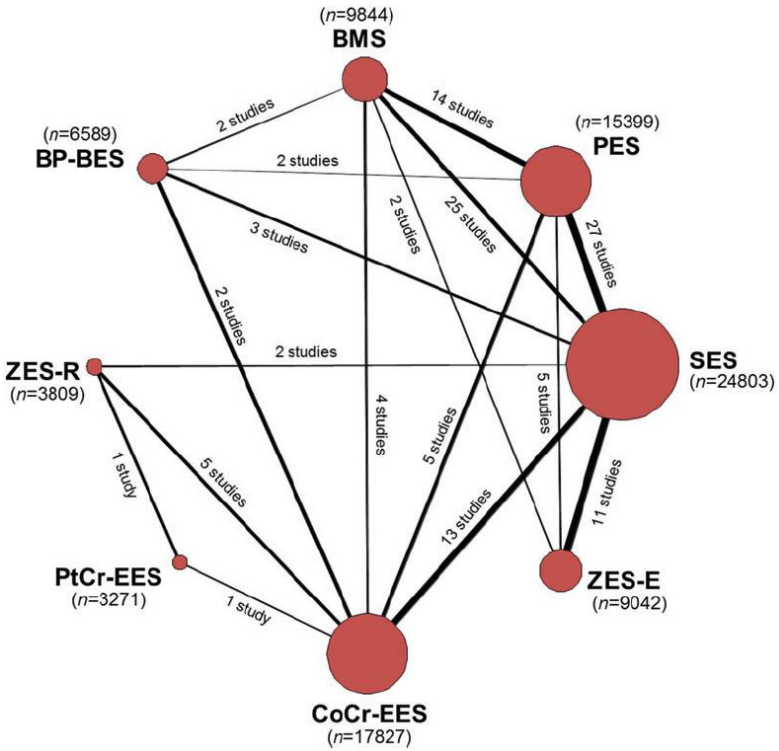


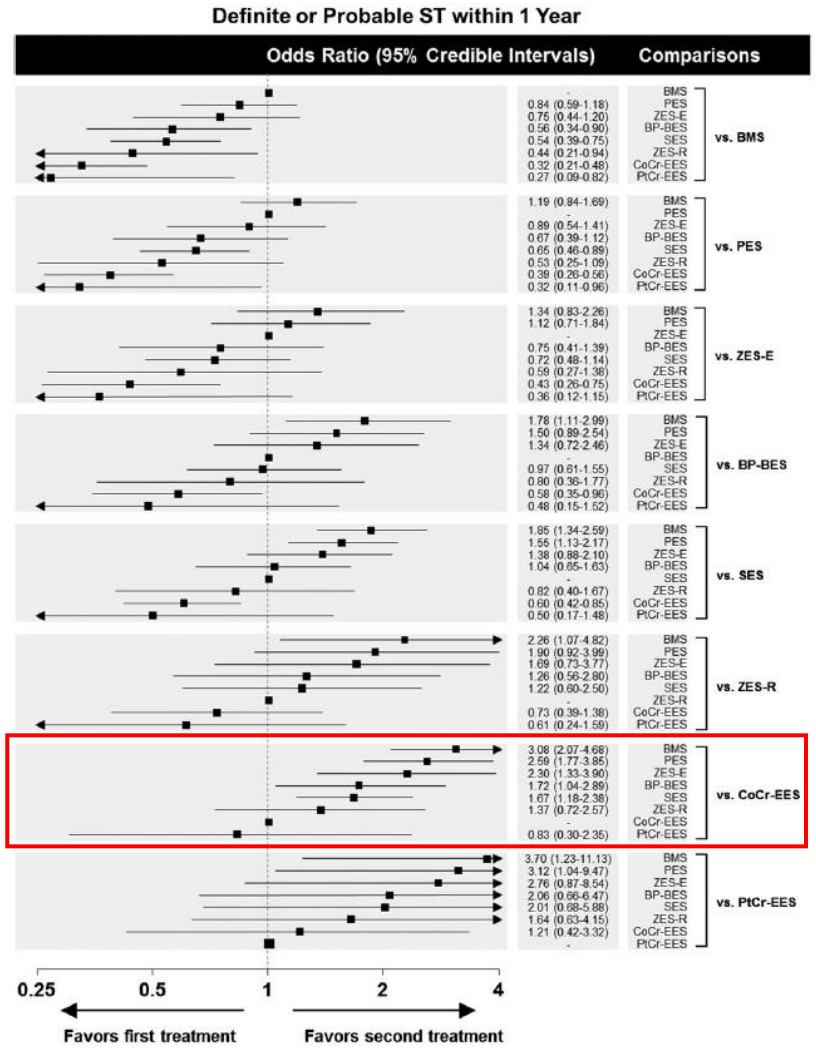
Treatment with EES significantly reduced the risk of repeat revascularization and definite ST compared to SES.

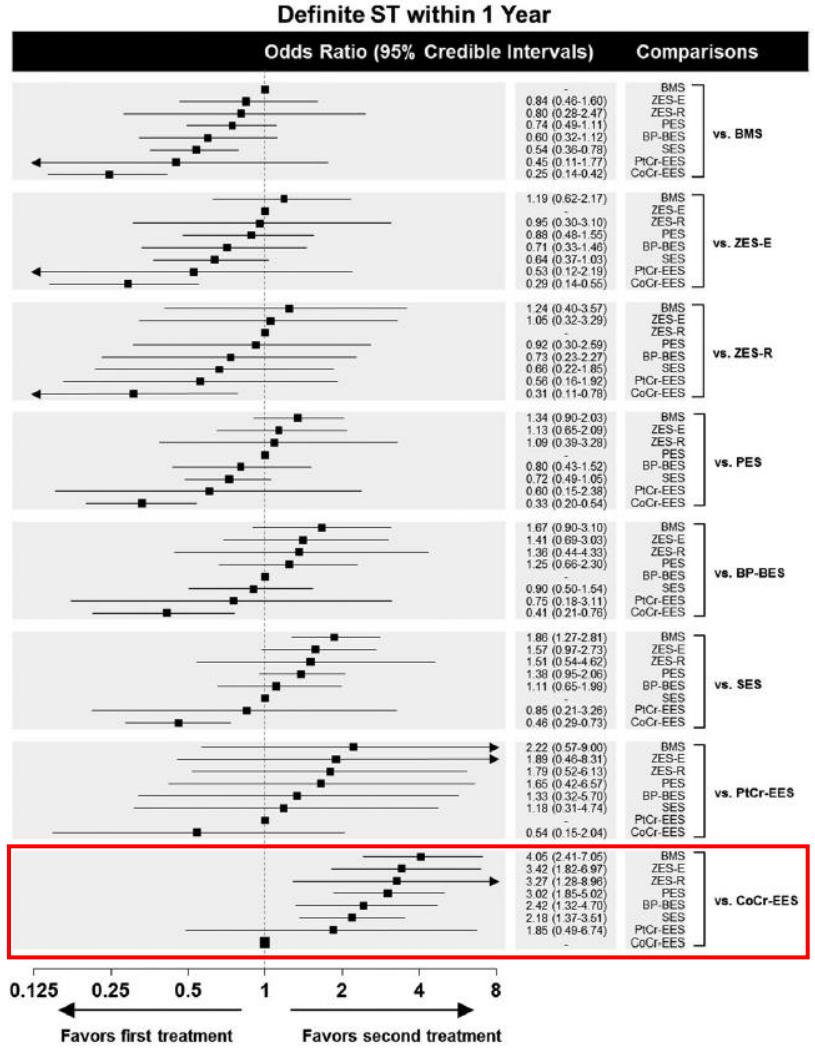
Park KW, Kim HS et al. Am Heart J 2013

Better outcomes with new generation DESs

A systematic review and meta-analysis of 113 trials with 90,584 patients







Cobalt–chromium everolimus-eluting stents was safer than any DES even including BP-BES.

Kang SH, Park KW, Kim HS et al. Eur Heart J. 2014

Trials of DAPT duration after PCI

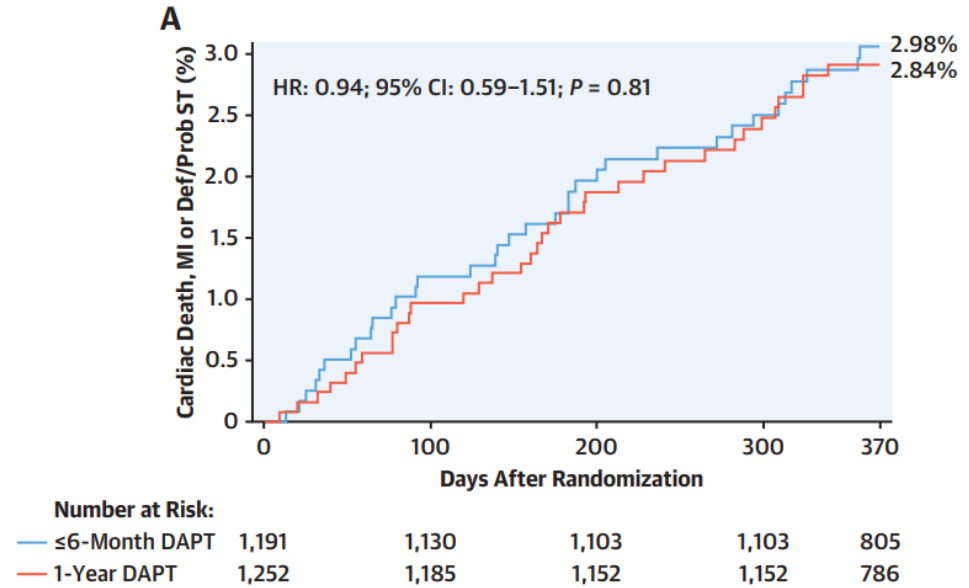
14 studies, ~40,000 patients randomised

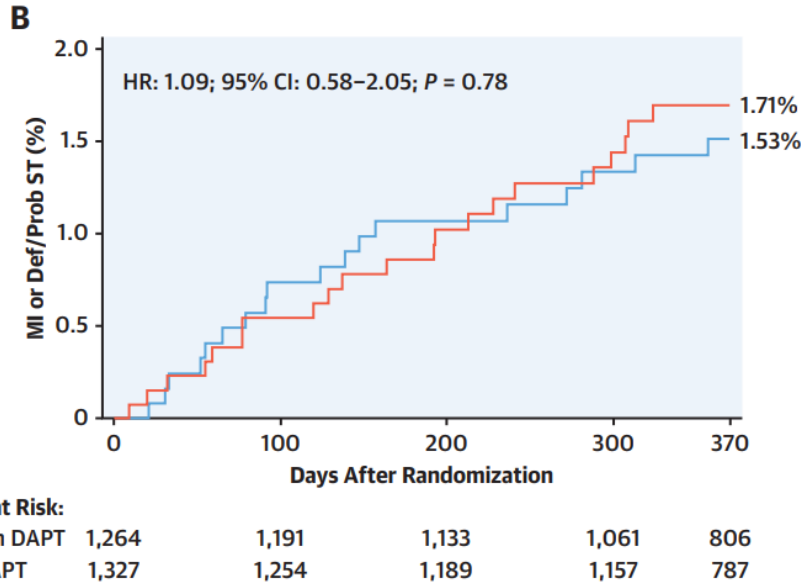
	Study	Patients	Hypothesis	Result
Trials of short-term DAPT	RESET	N=2,117	3 months non-inferior to 12 months	✔
	OPTIMIZE	N=3,199	3 months non-inferior to 12 months	✔
	EXCELLENT	N=1,443	6 months non-inferior to 12 months	✔
	SECURITY	N=1,399	6 months non-inferior to 12 months (stopped)	✔
	ISAR-SAFE	N=4,000	6 months non-inferior to 12 months (stopped)	✔
	I-LOVE-IT 2	N=1,829	6 months non-inferior to 12 months	✔
	IVUS-XPL	N=1,400	6 months non-inferior to 12 months	✔
Trials of long-term DAPT	PRODIGY	N=1,970 (DES=1,501)	24 months superior to 6 months	✖
	ARCTIC-I	N=1,259	>12 months (median 17) superior to 12 months	✖
	DAPT	N=9,961	30 months superior to 12 months	✔
	DES-LATE	N=5,045	36 months superior to 12 months	✖
	OPTIDUAL	N=1,385	48 months superior to 12 months (stopped)	✖
	ITALIC	N=1,850	6 months non-inferior to 12 and 24 months (stopped)	✔
	NIPPON	N=3,307	6 months non-inferior to 18 months (stopped)	✔

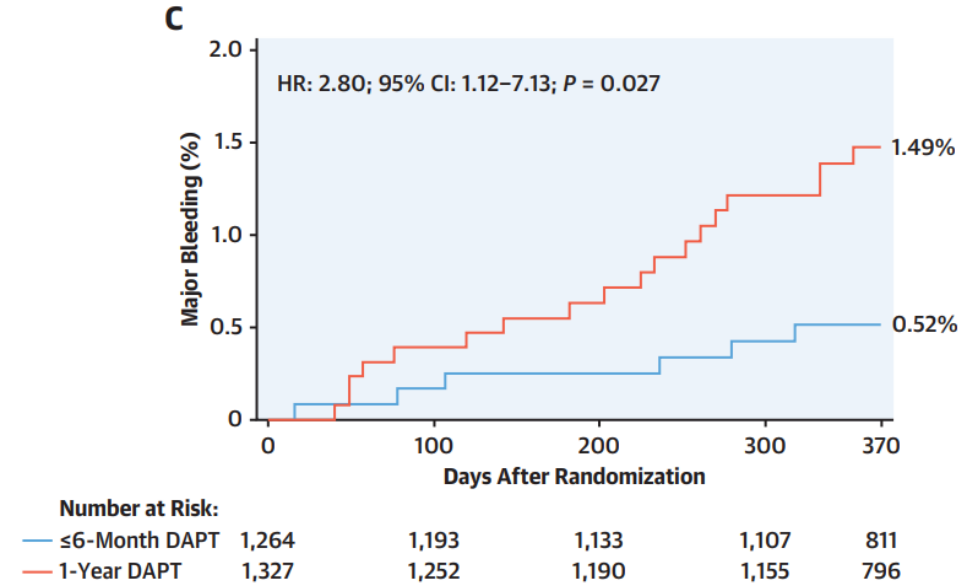
Gargiulo G et al. Eurointervention 2017

1YR vs. <6mo DAPT : IPD Meta-Analysis

→ **No benefit in Ischemic Events with increased risk of major bleeding**



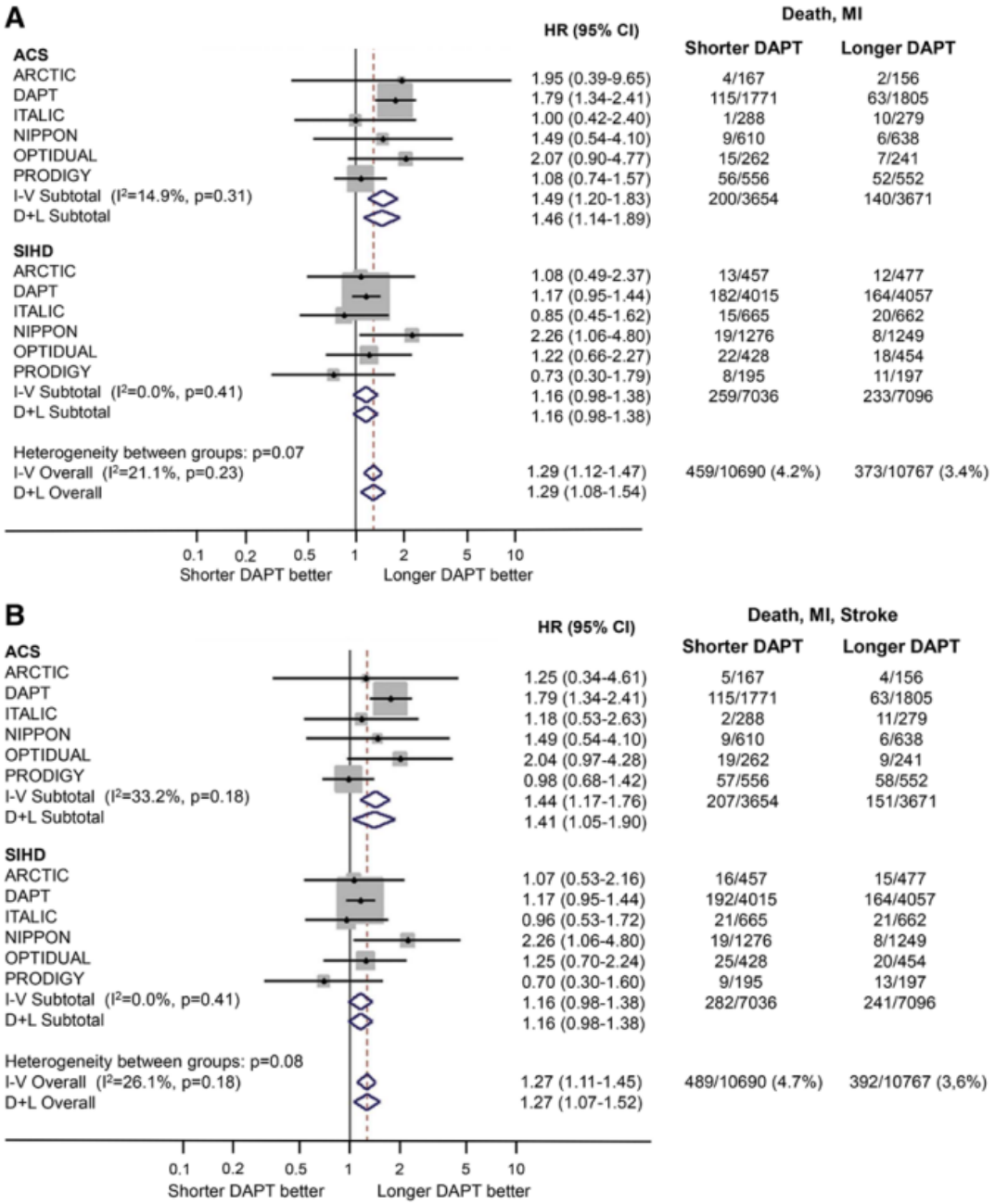


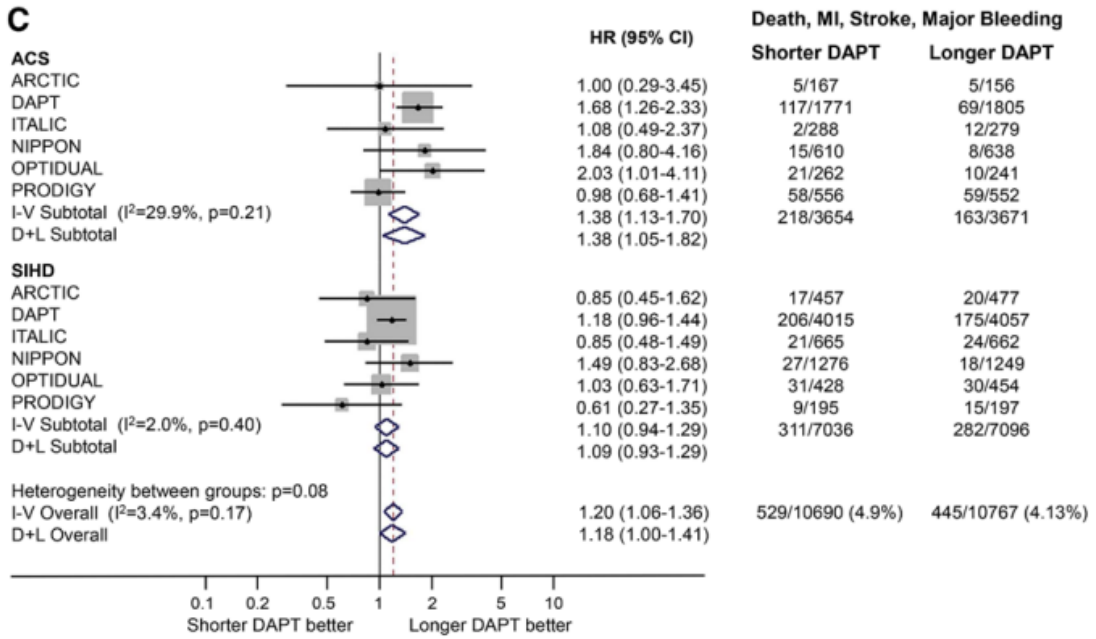


Palmerini T, Stone GW et al. J Am Coll Cardiol 2021

> 1 Year DAPT After DES

: Benefit > Risk for ACS (>21,000 Patients)

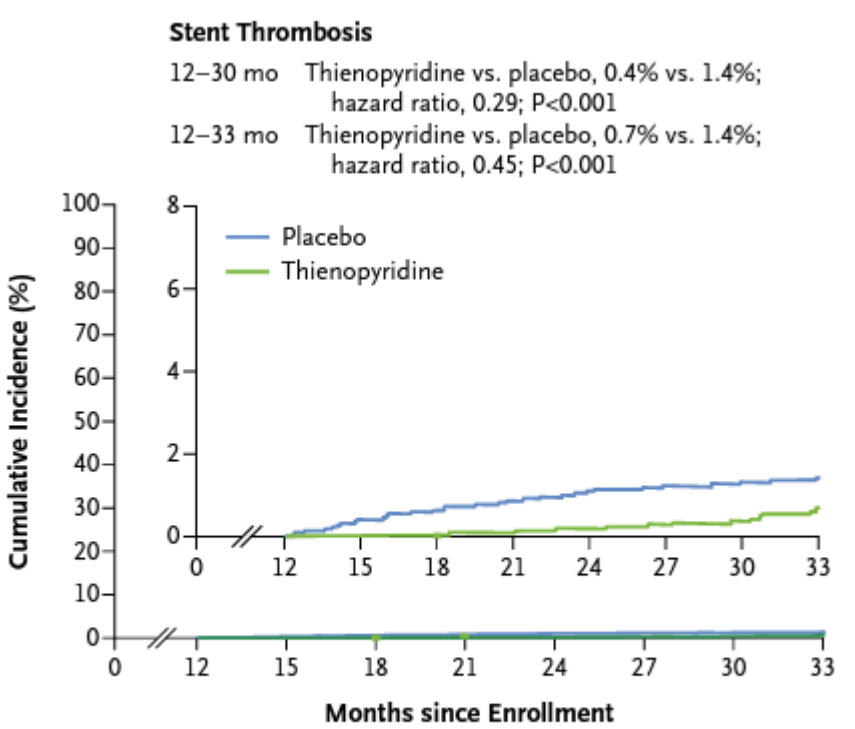




Palmerini T, Stone GW et al. Circ CV Int 2019

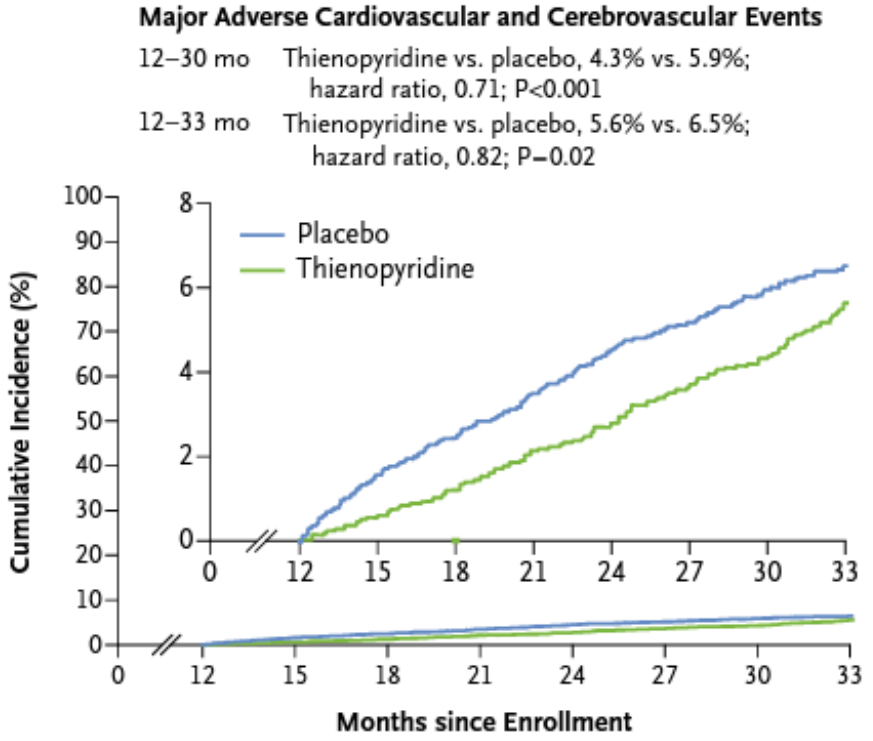
Results of DAPT trial

Extended use of DAPT beyond 1 year after PCI significantly reduced the risks of stent thrombosis and major adverse cardiovascular and cerebrovascular events but was associated with an increased risk of bleeding.



No. at Risk

Thienopyridine	5020	4934	4870	4828	4765	4686	4642	3110
Placebo	4941	4845	4775	4721	4651	4603	4556	3105



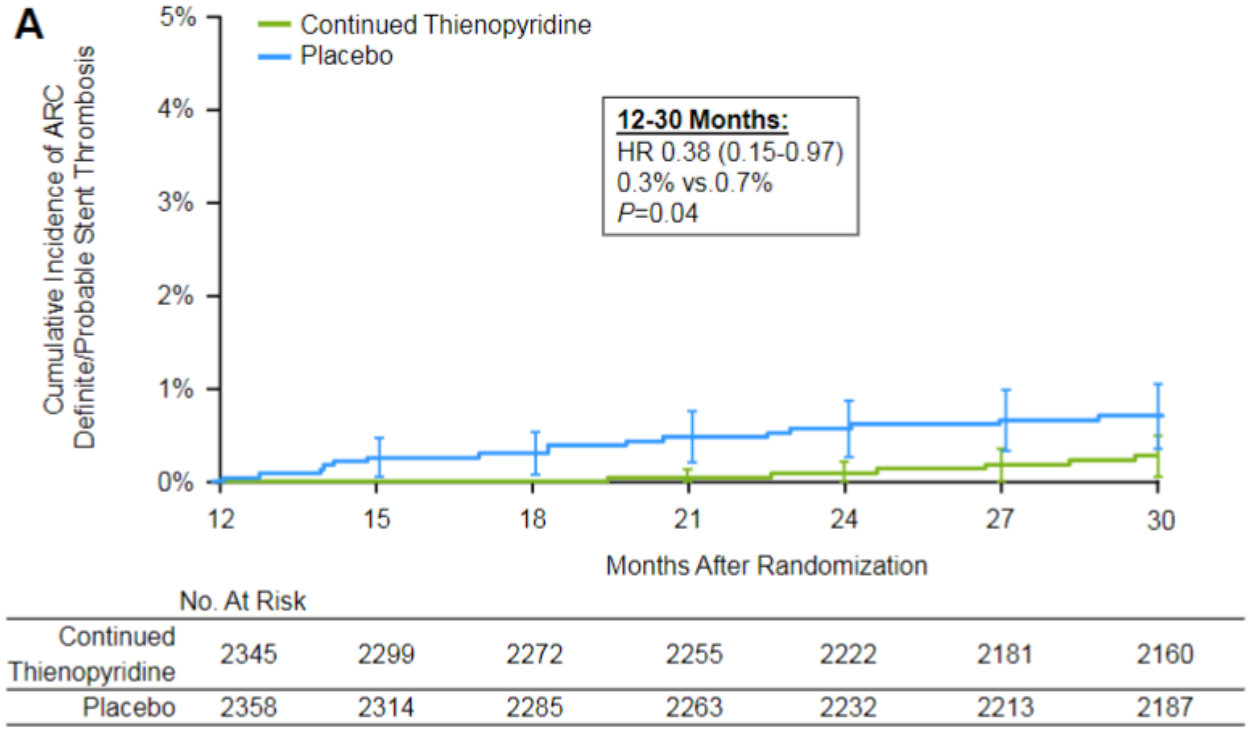
No. at Risk

Thienopyridine	5020	4917	4840	4778	4702	4611	4554	3029
Placebo	4941	4799	4715	4635	4542	4476	4412	2997

N Engl J Med. 2014 Dec 4;371(23):2155-66.

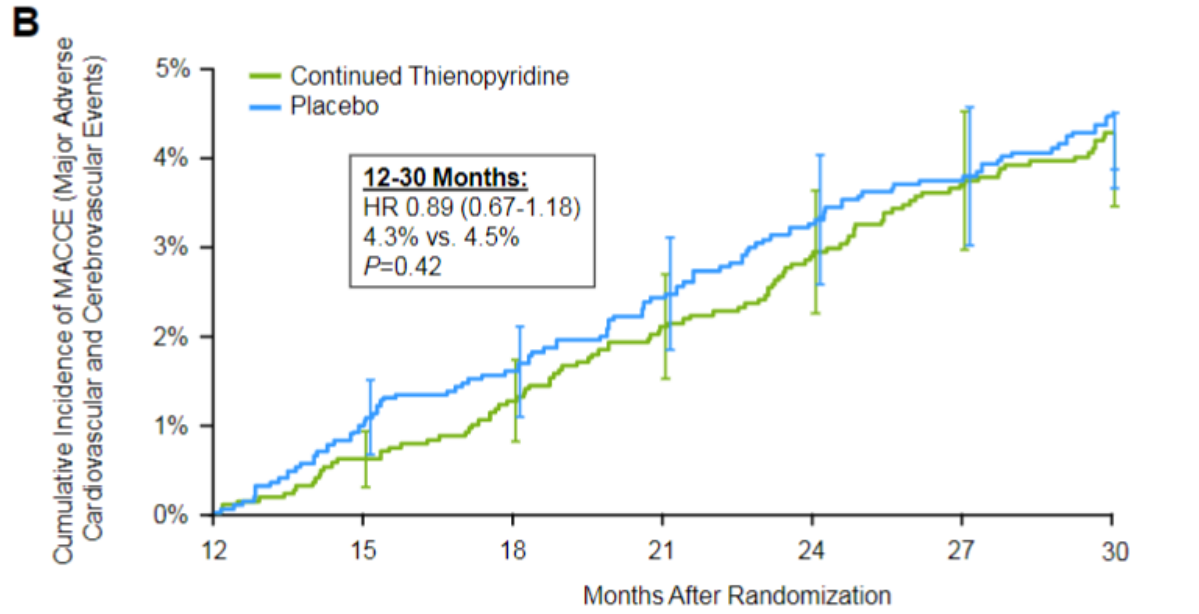
Results of DAPT trial in new generation DES

In EES-treated subjects, significant reductions in stent thrombosis and MI and an increase in bleeding were observed with continued thienopyridine beyond 1 year compared with aspirin alone



No. At Risk

Continued Thienopyridine	2345	2299	2272	2255	2222	2181	2160
Placebo	2358	2314	2285	2263	2232	2213	2187



No. At Risk

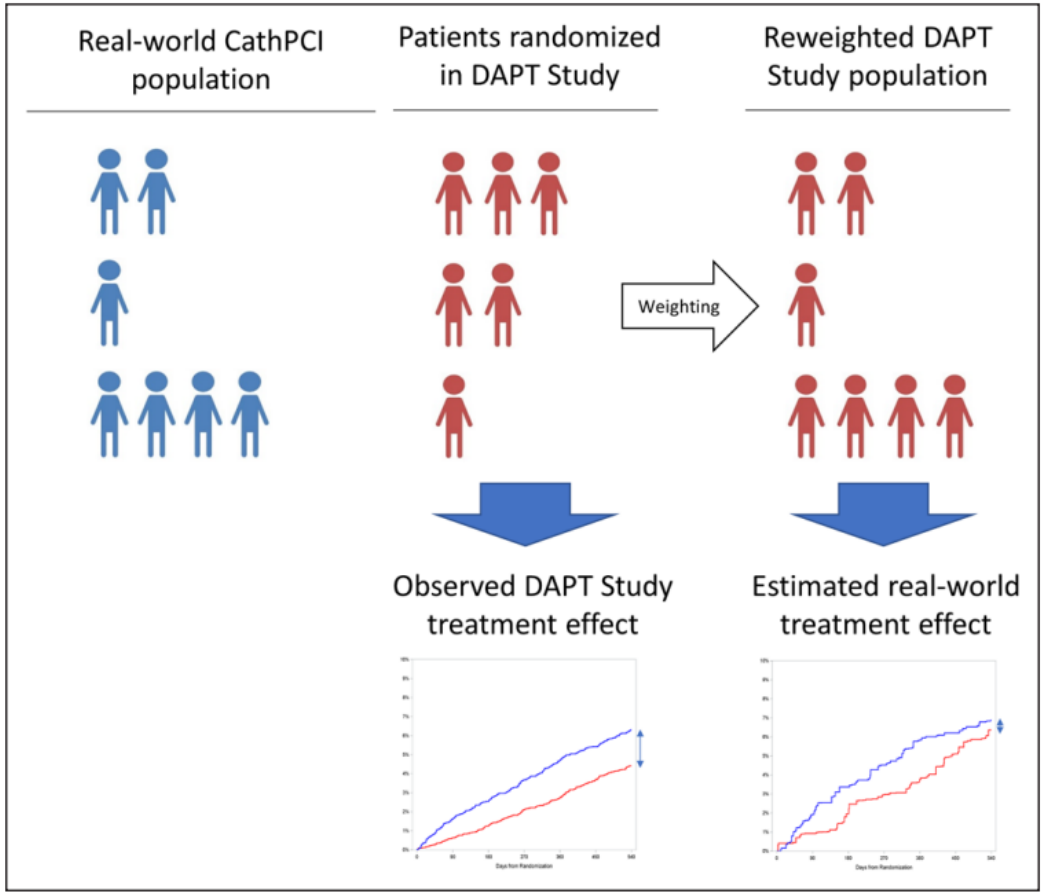
Continued Thienopyridine	2345	2289	2256	2233	2193	2148	2122
Placebo	2358	2298	2264	2230	2188	2161	2126

J Am Coll Cardiol Intv 2016;9:138–47

ORIGINAL RESEARCH ARTICLE

Estimation of DAPT Study Treatment Effects in Contemporary Clinical Practice: Findings From the EXTEND-DAPT Study

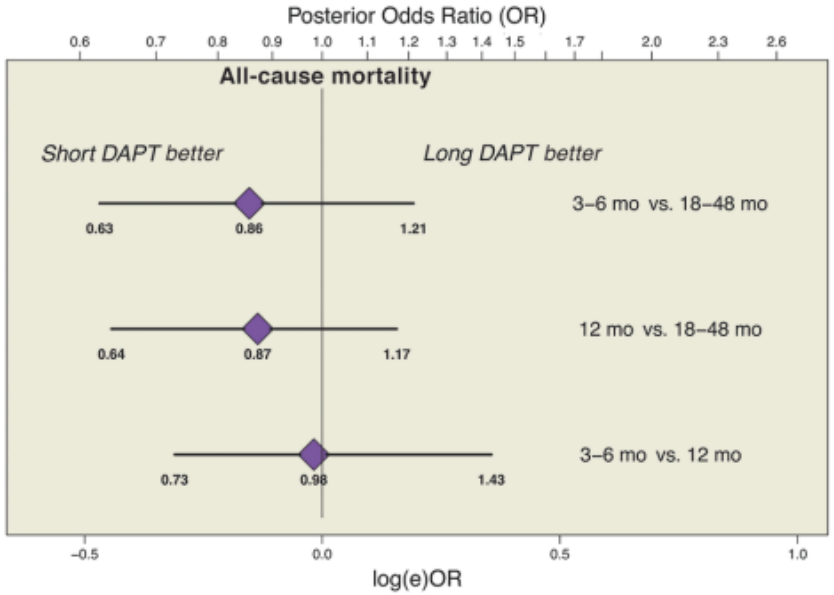
Neel M. Butala, MD, MBA; Kamil F. Faridi, MD, MSc; Hector Tamez, MD, MPH; Jordan B. Strom, MD, MSc; Yang Song, MSc; Changyu Shen, PhD; Eric A. Secemsky, MD, MSc; Laura Mauri, MD, MSc; Dean J. Kereiakes, MD; Jeptha P. Curtis, MD; C. Michael Gibson, MD, MS; Robert W. Yeh, MD, MSc

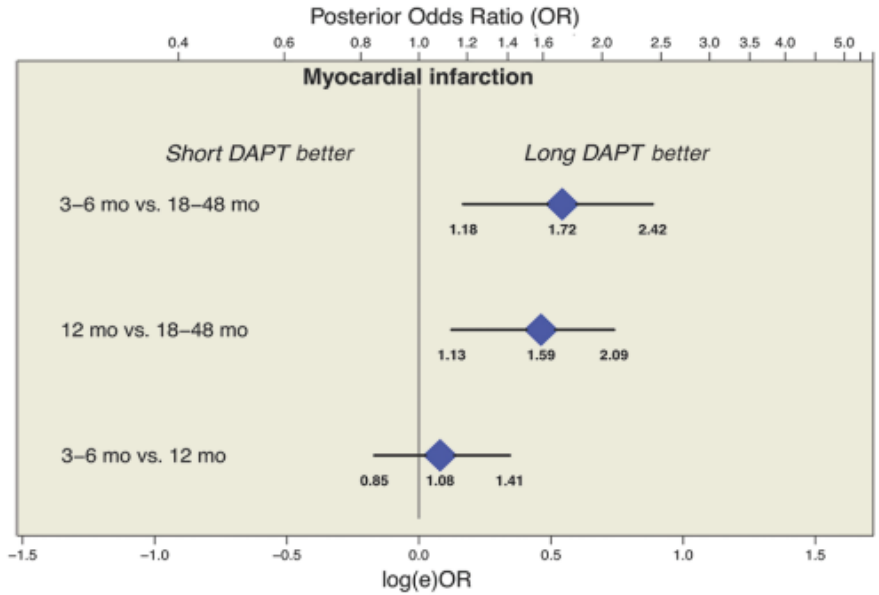


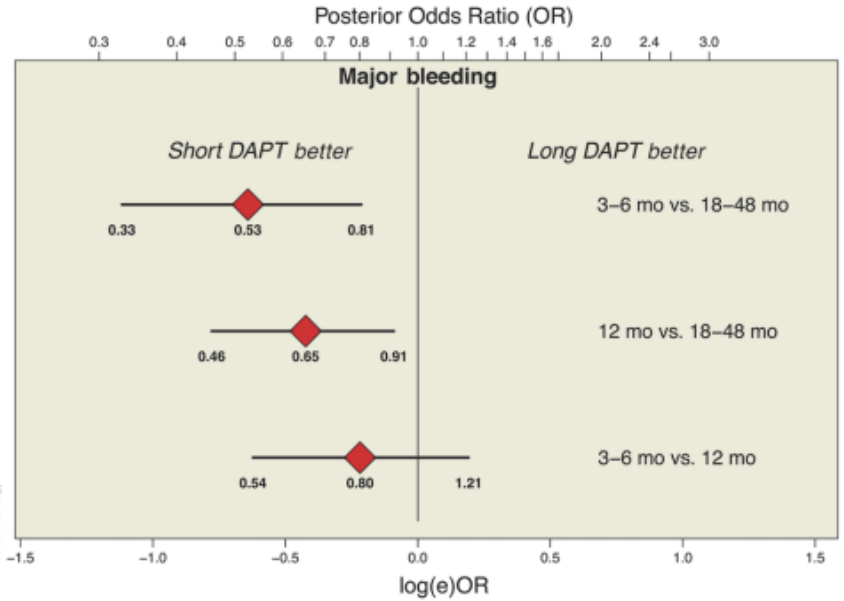
CONCLUSIONS: The differences between the patients and devices used in contemporary clinical practice compared with the DAPT Study were associated with the attenuation of benefits and greater harms attributable to prolonged DAPT duration. These findings limit the applicability of the average treatment effects from the DAPT Study in modern clinical practice.

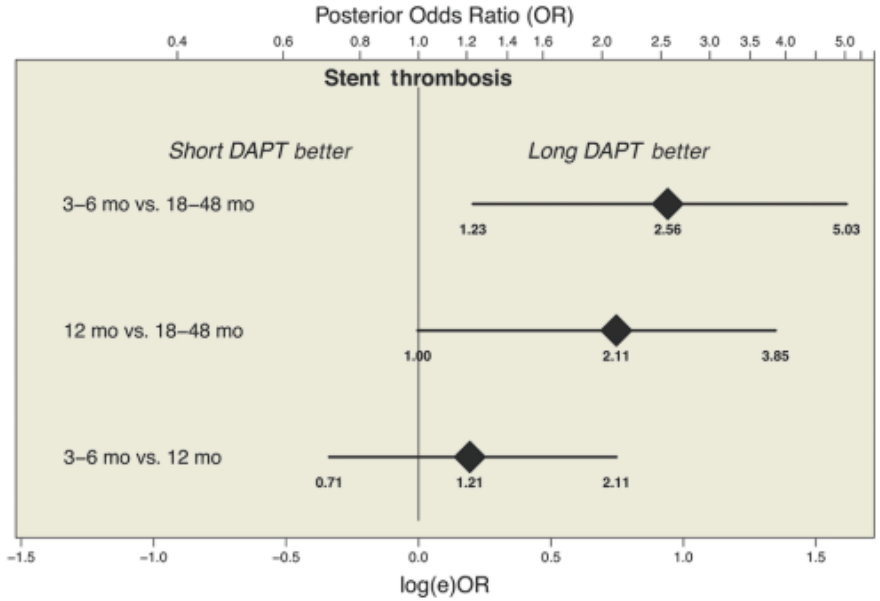
Butala NM, Yeh RW et al. Circulation 2022

Baysian Meta-Analysis of Different Duration of DAPT







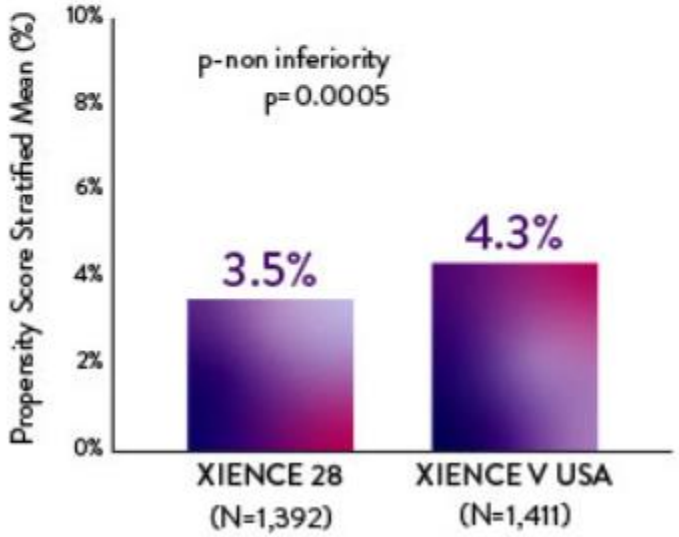


Bittl JA, He Y. Circ Cardiovasc Qual Outcomes. 2017

The XIENCE Short DAPT Program: XIENCE 90/28

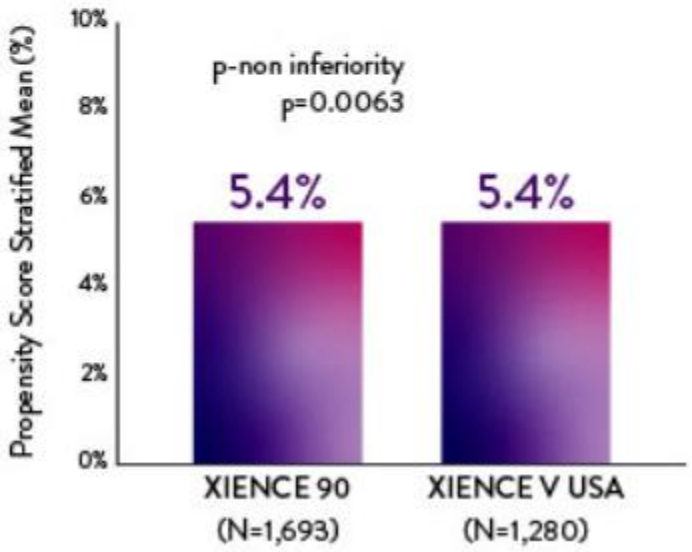
XIENCE 28: 1-month DAPT in HBR Patients
XIENCE 28: All Death or MI

Between 1 and 6 months



XIENCE 90: 3-month DAPT in HBR Patients
XIENCE 90: All Death or MI

Between 3 and 12 months

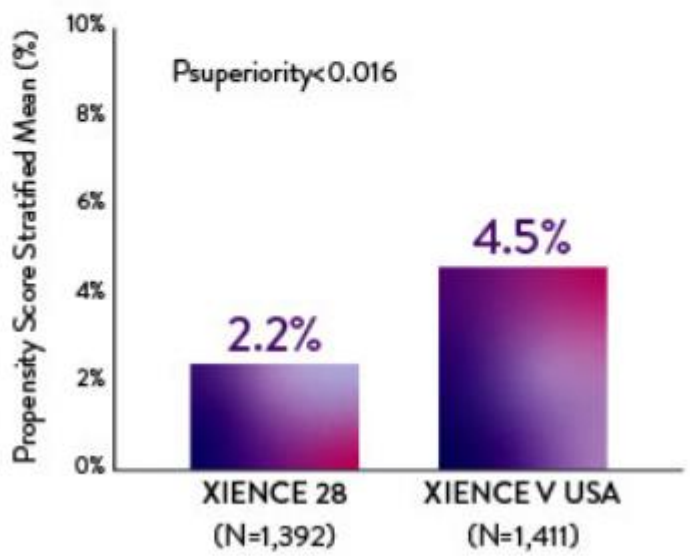


https://www.cardiovascular.abbott/int/en/hcp/products/percutaneous-coronary-intervention/xience-family/clinical-outcomes/short-dapt.html#shortdapt

The XIENCE Short DAPT Program: XIENCE 90/28

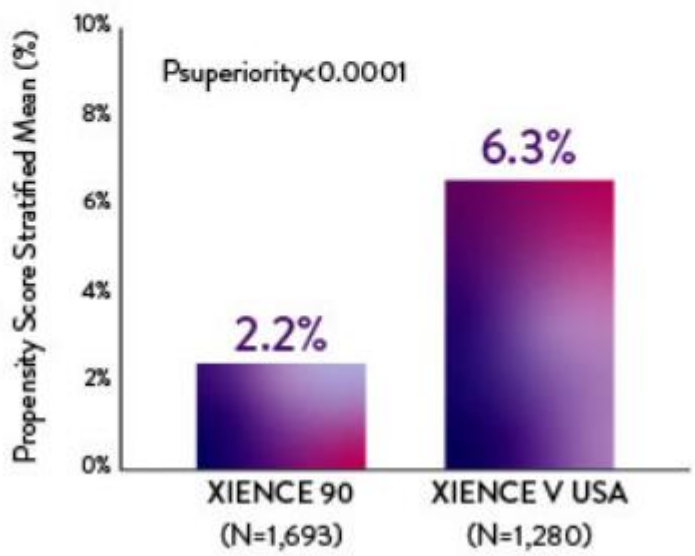
XIENCE 28: BARC 3-5 Bleeding

Between 1 and 6 months



XIENCE 90: BARC 3-5 Bleeding

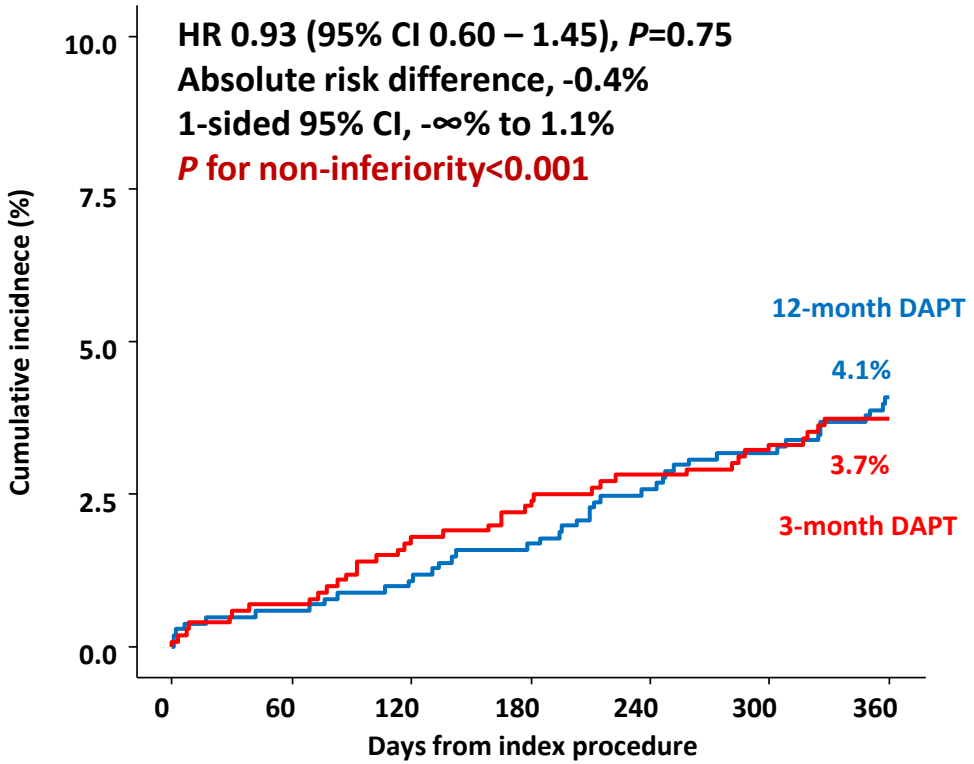
Between 3 and 12 months



https://www.cardiovascular.abbott/int/en/hcp/products/percutaneous-coronary-intervention/xience-family/clinical-outcomes/short-dapt.html#shortdapt

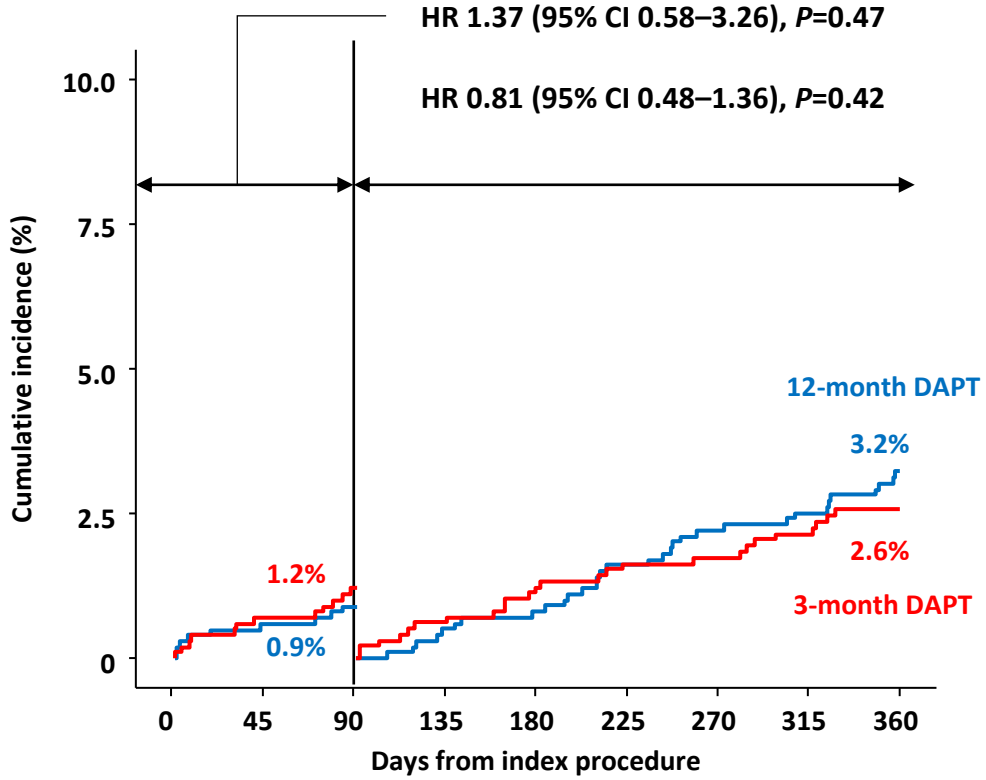
Comparison Of 3-month Versus 12-month Dual Antiplatelet Therapy With Ultrathin Struts And Advanced Polymer Technology HOST-IDEA trial

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



Number at risk

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



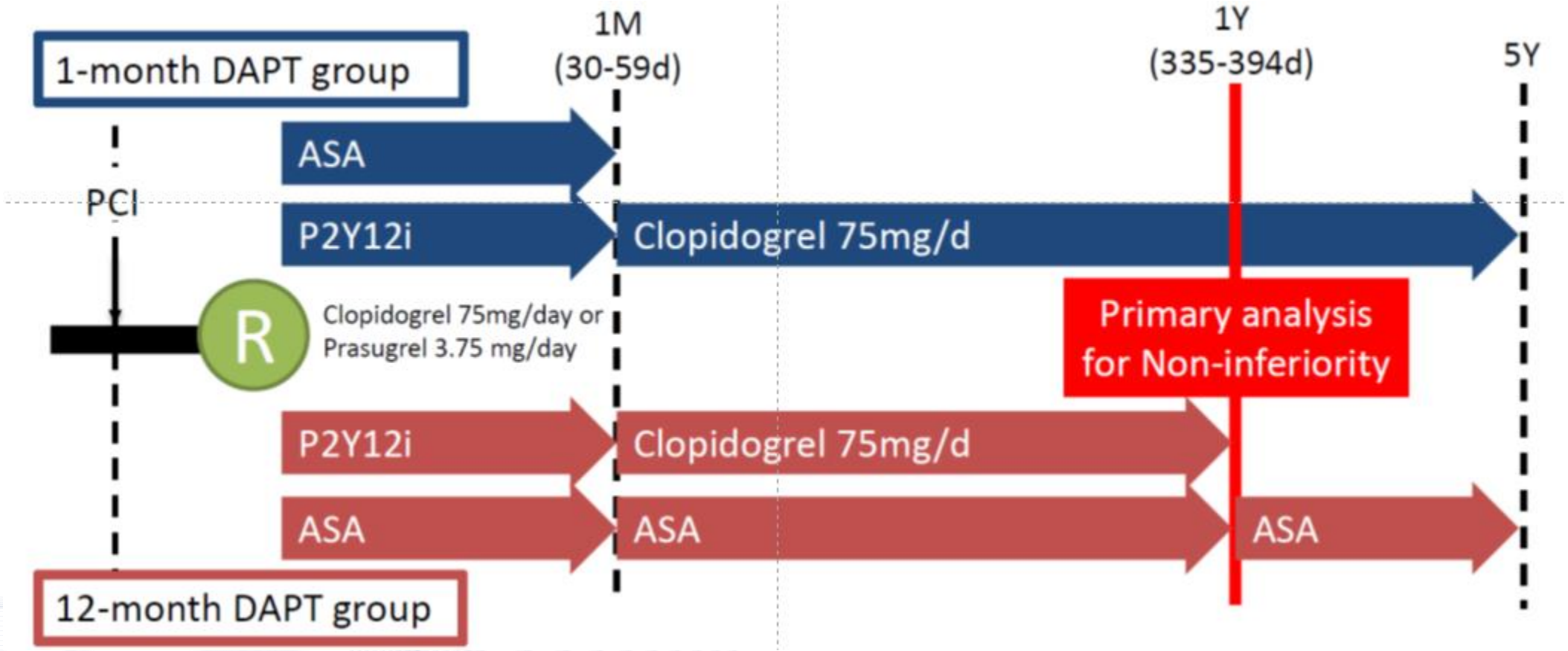
Number at risk

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

Circulation. 2023 May 2;147(18):1358-1368.

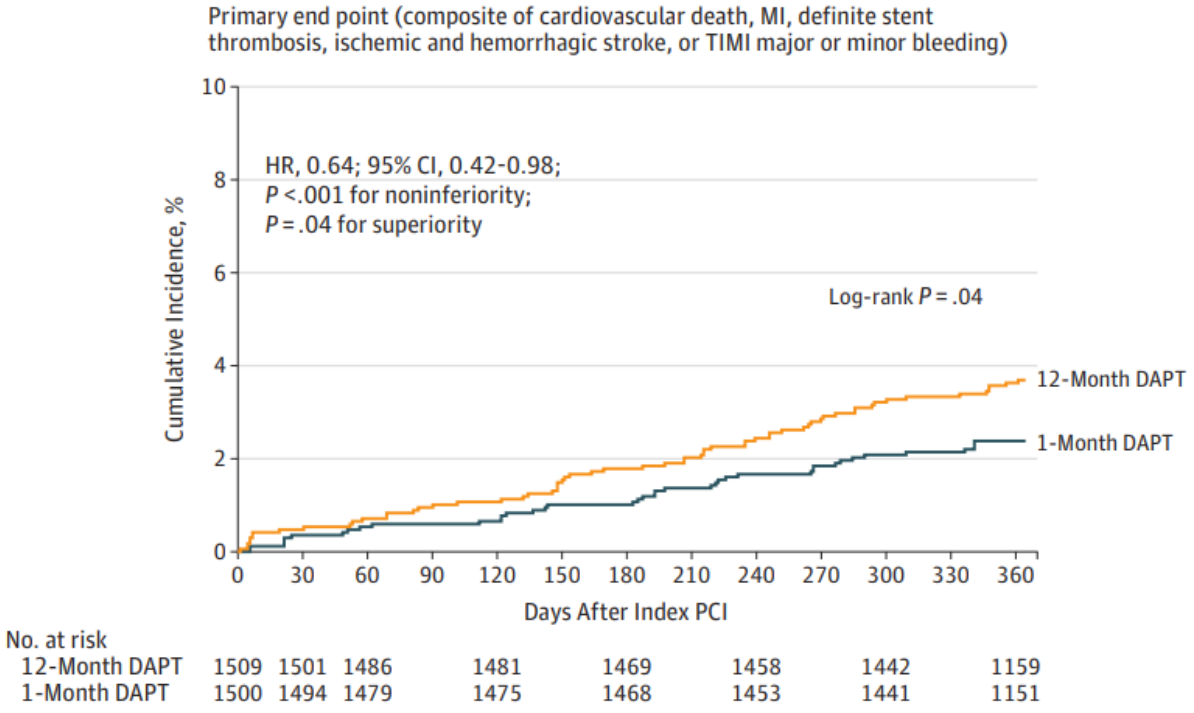
STOPDAPT-2 trial

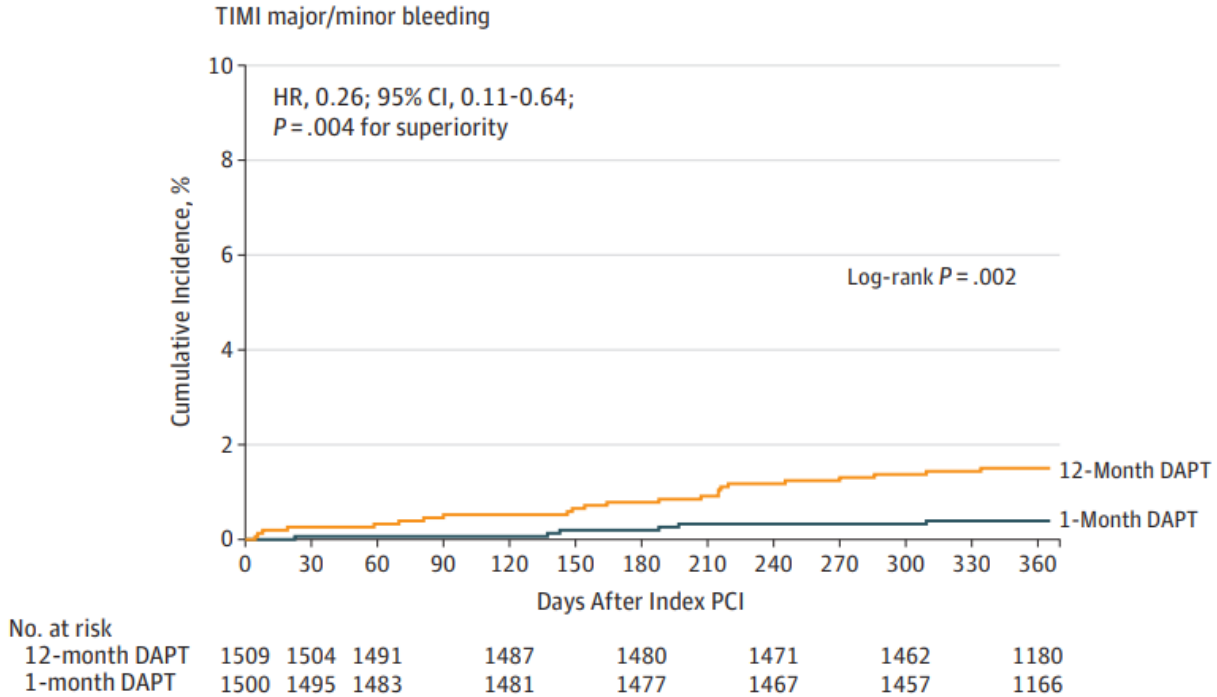
To test the hypothesis of noninferiority of 1 month of DAPT compared with standard 12 months of DAPT for a composite end point of cardiovascular and bleeding events



JAMA. 2019;321(24):2414-2427.

STOPDAPT-2 trial



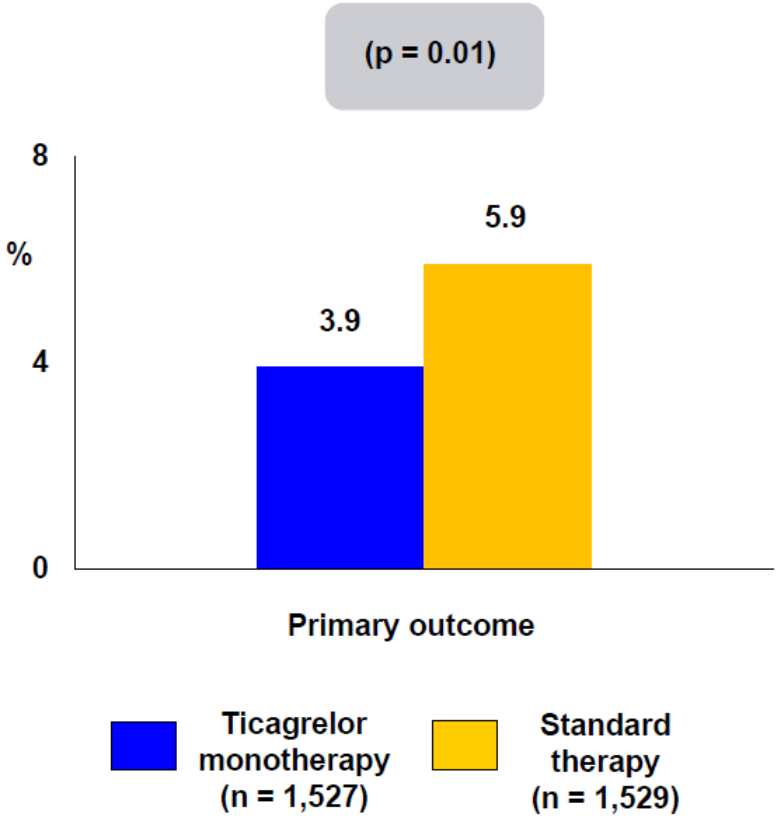


1 month of DAPT followed by clopidogrel monotherapy, compared with 12 months of DAPT with aspirin and clopidogrel, resulted in a significantly lower rate of a composite of cardiovascular and bleeding events, meeting criteria for both noninferiority and superiority.

JAMA. 2019;321(24):2414-2427.

TICO

Trial Description: Patients undergoing PCI with an ultrathin biodegradable-polymer sirolimus-eluting stent for acute coronary syndrome were randomized to ticagrelor monotherapy after 3 months of DAPT vs. standard therapy.



RESULTS

- Primary outcome, death, myocardial infarction, stent thrombosis, stroke, target vessel revascularization, or TIMI major bleeding at 12 months: 3.9% of the ticagrelor monotherapy after 3 months of DAPT group vs. 5.9% of the standard therapy group (p = 0.01)
- Major bleeding: 1.7% of the ticagrelor monotherapy after 3 months group vs. 3.0% of the standard therapy group (p = 0.02)

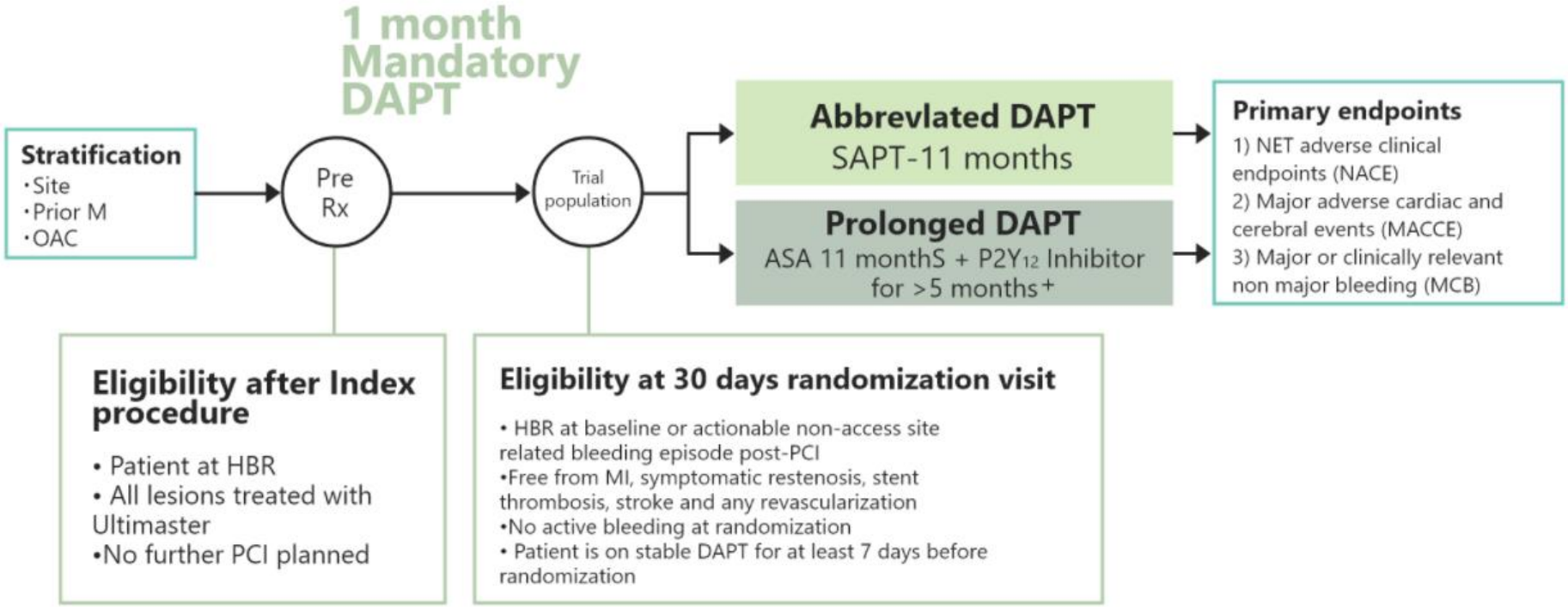
CONCLUSIONS

- Among acute coronary syndrome patients who underwent PCI with an ultrathin biodegradable-polymer sirolimus-eluting stent, ticagrelor monotherapy after 3 months of DAPT was superior to standard therapy of DAPT for 12 months
- Ticagrelor monotherapy was effective at preventing net composite ischemic and bleeding events

Presented by Dr. Byeong-Keuk Kim at ACC.20/WCC

JAMA. 2020;323(23):2407-2416.

MASTER DAPT



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dual Antiplatelet Therapy after PCI in Patients at High Bleeding Risk

M. Valgimigli, E. Frigoli, D. Heg, J. Tijssen, P. Jüni, P. Vranckx, Y. Ozaki, M.-C. Morice, B. Chevalier, Y. Onuma, S. Windecker, P.A.L. Tonino, M. Roffi, M. Lesiak, F. Mahfoud, J. Bartunek, D. Hildick-Smith, A. Colombo, G. Stanković, A. Iñiguez, C. Schultz, R. Kornowski, P.J.L. Ong, M. Alasnag, A.E. Rodriguez, A. Moschovitis, P. Laanmets, M. Donahue, S. Leonardi, and P.C. Smits, for the MASTER DAPT Investigators*

ABSTRACT

BACKGROUND
The appropriate duration of dual antiplatelet therapy in patients at high risk for bleeding after the implantation of a drug-eluting coronary stent remains unclear.

METHODS
One month after they had undergone implantation of a biodegradable-polymer sirolimus-eluting coronary stent, we randomly assigned patients at high bleeding risk to discontinue dual antiplatelet therapy immediately (abbreviated therapy) or to continue it for at least 2 additional months (standard therapy). The three ranked primary outcomes were net adverse clinical events (a composite of death from any cause, myocardial infarction, stroke, or major bleeding), major adverse cardiac or cerebral events (a composite of death from any cause, myocardial infarction, or stroke), and major or clinically relevant nonmajor bleeding; cumulative incidences were assessed at 335 days. The first two outcomes were assessed for noninferiority in the per-protocol population, and the third outcome for superiority in the intention-to-treat population.

RESULTS
Among the 4434 patients in the per-protocol population, net adverse clinical events occurred in 165 patients (7.5%) in the abbreviated-therapy group and in 172 (7.7%) in the standard-therapy group (difference, −0.23 percentage points; 95% confidence interval [CI], −1.80 to 1.33; P<0.001 for noninferiority). A total of 133 patients (6.1%) in the abbreviated-therapy group and 132 patients (5.9%) in the standard-therapy group had a major adverse cardiac or cerebral event (difference, 0.11 percentage points; 95% CI, −1.29 to 1.51; P=0.001 for noninferiority). Among the 4579 patients in the intention-to-treat population, major or clinically relevant nonmajor bleeding occurred in 148 patients (6.5%) in the abbreviated-therapy group and in 211 (9.4%) in the standard-therapy group (difference, −2.82 percentage points; 95% CI, −4.40 to −1.24; P<0.001 for superiority).

CONCLUSIONS
One month of dual antiplatelet therapy was noninferior to the continuation of therapy for at least 2 additional months with regard to the occurrence of net adverse clinical events and major adverse cardiac or cerebral events; abbreviated therapy also resulted in a lower incidence of major or clinically relevant nonmajor bleeding. (Funded by Terumo; MASTER DAPT ClinicalTrials.gov number, NCT03023020.)

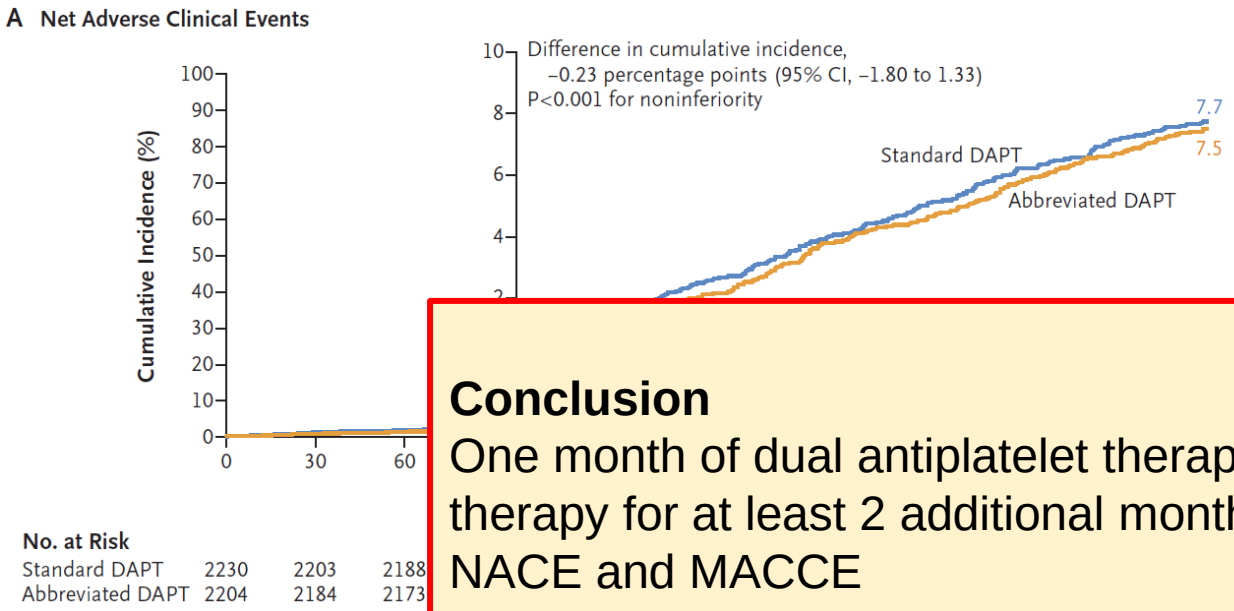
- **Hypotheses (hierarchical order)**

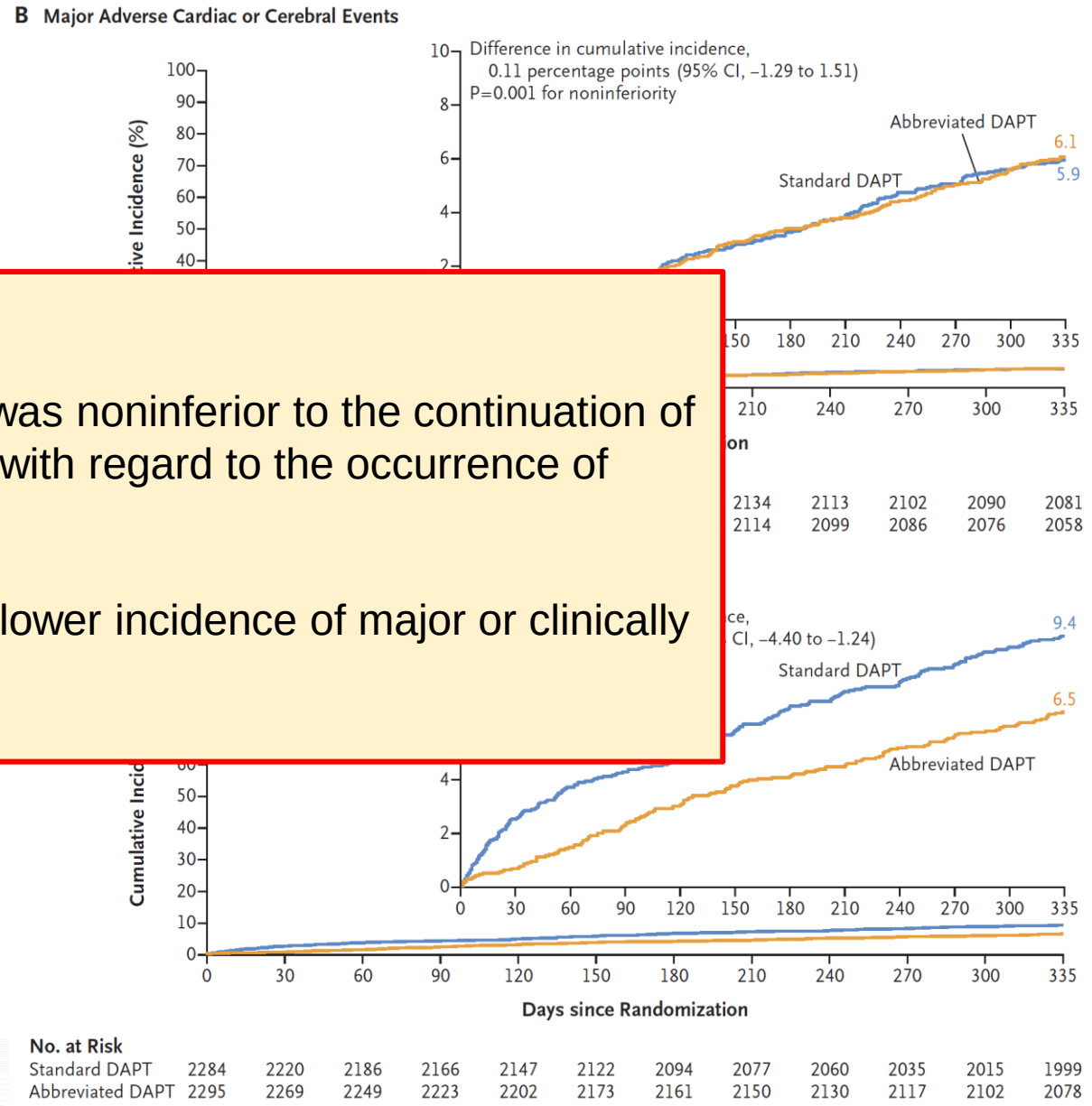
(1) An abbreviated antiplatelet regimen is **noninferior** to standard antiplatelet in terms of **NACE**,
(2) An abbreviated antiplatelet regimen is **noninferior** to standard antiplatelet in terms of **MACCE**,
(3) An abbreviated antiplatelet regimen is **superior** to standard antiplatelet in terms of **Major+Minor Bleeding**.

[The 5% type I error preserved by the sequential hierarchical testing]

N Engl J Med. 2021;385(18):1643-1655.

MASTER DAPT





NACE: death from an
MACCE: death from a
Major or clinically rel

Conclusion

One month of dual antiplatelet therapy was noninferior to the continuation of therapy for at least 2 additional months with regard to the occurrence of NACE and MACCE

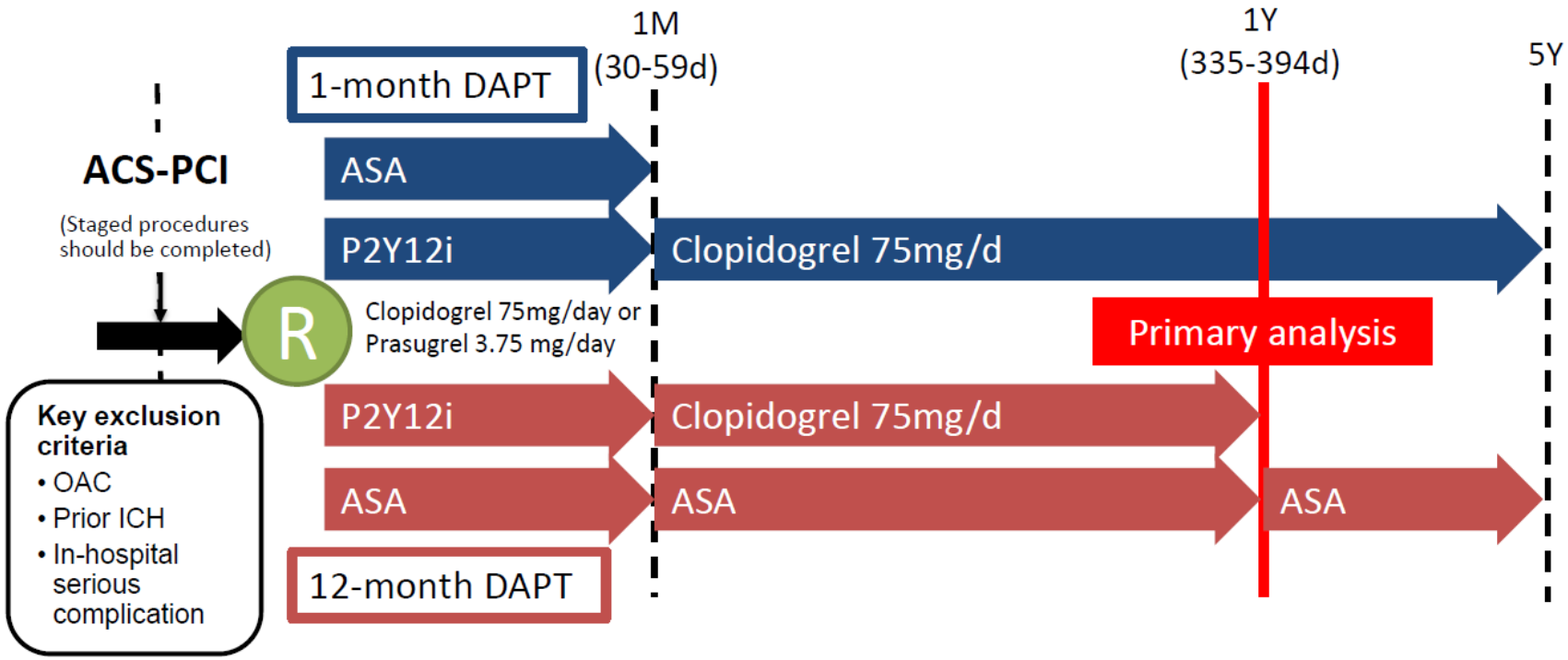
; abbreviated therapy also resulted in a lower incidence of major or clinically relevant nonmajor bleeding.

- Hypotheses (hierarchical order)

(1) NACE: Abbreviated antiplatelet is noninferior to standard antiplatelet
(2) MACCE: Abbreviated antiplatelet is noninferior to standard antiplatelet
(3) Any Bleeding: Abbreviated antiplatelet is superior to standard antiplatelet

STOPDAPT-2 ACS

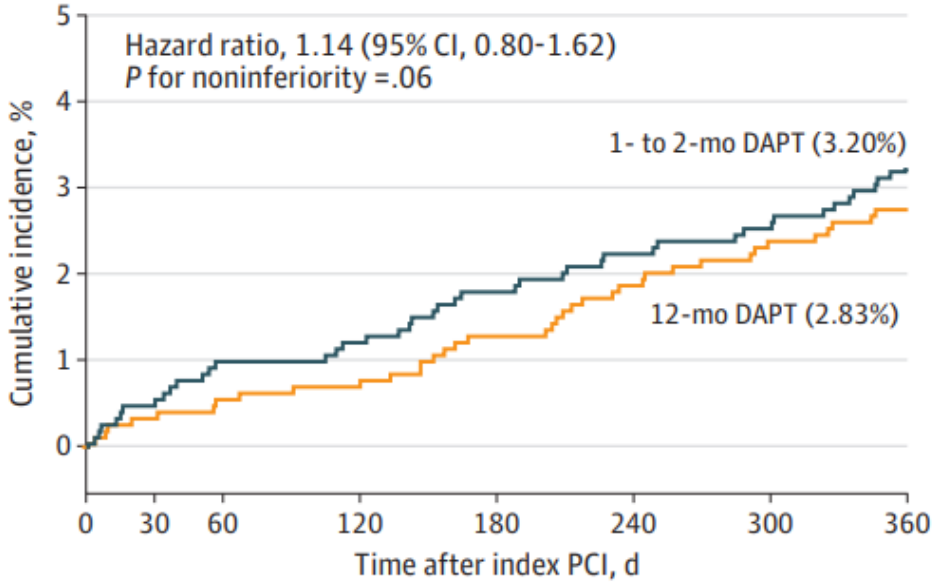
✓ The STOPDAPT-2 ACS trial sought to evaluate the safety and efficacy of **1 month DAPT followed by clopidogrel monotherapy** as compared with the **standard 12 month DAPT with aspirin and clopidogrel** after implantation of cobalt chromium everolimus eluting stents (CoCr EES) in ACS patients.



JAMA Cardiol. 2022;7(4):407-417.

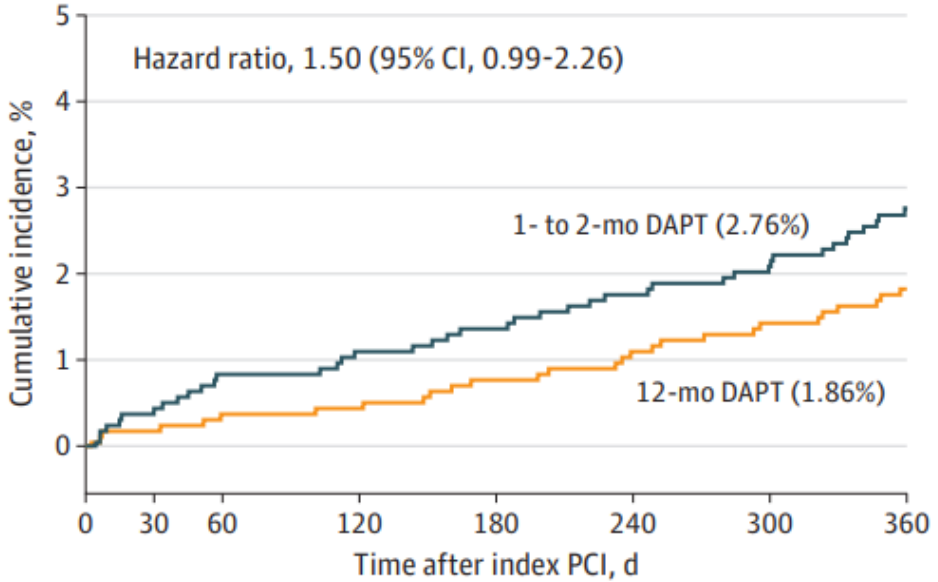
STOPDAPT-2 ACS

Cardiovascular death, myocardial infarction, definite stent thrombosis, any stroke, or Thrombolysis in Myocardial Infarction major/minor bleeding



1- to 2-mo DAPT							
No. with event	11	20	25	36	45	53	65
No. at risk	2058	2047	2028	2021	2007	1993	1982	1606
12-mo DAPT							
No. with event	7	11	15	26	39	49	58
No. at risk	2078	2070	2055	2048	2036	2021	2010	1581

Cardiovascular death, myocardial infarction, definite stent thrombosis, or any stroke)

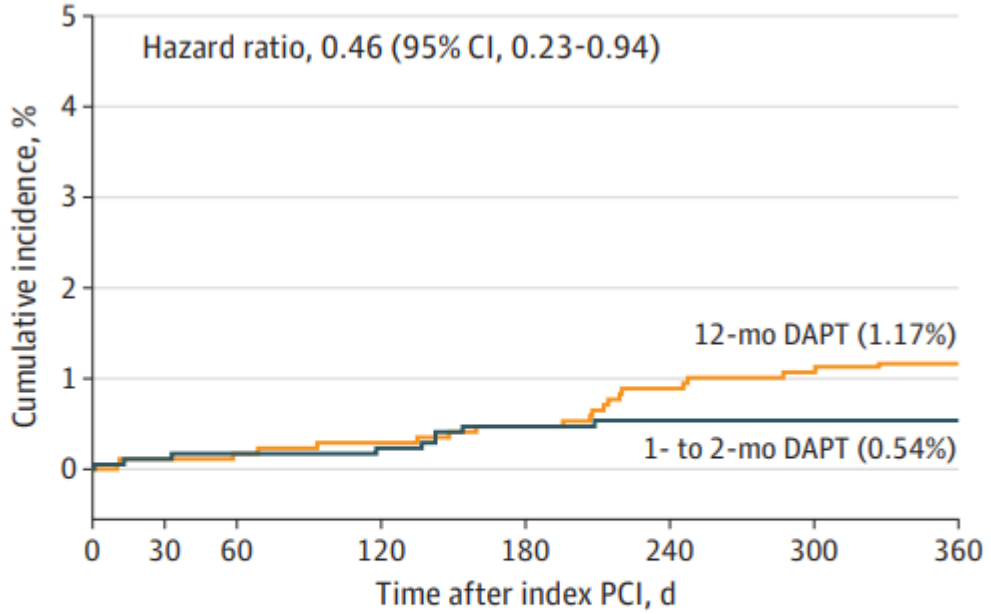


1- to 2-mo DAPT							
No. with event	9	17	22	28	36	44	56
No. at risk	2058	2049	2031	2024	2015	2002	1991	1614
12-mo DAPT							
No. with event	4	7	9	16	22	30	38
No. at risk	2078	2073	2059	2054	2046	2038	2028	1597

JAMA Cardiol. 2022;7(4):407-417.

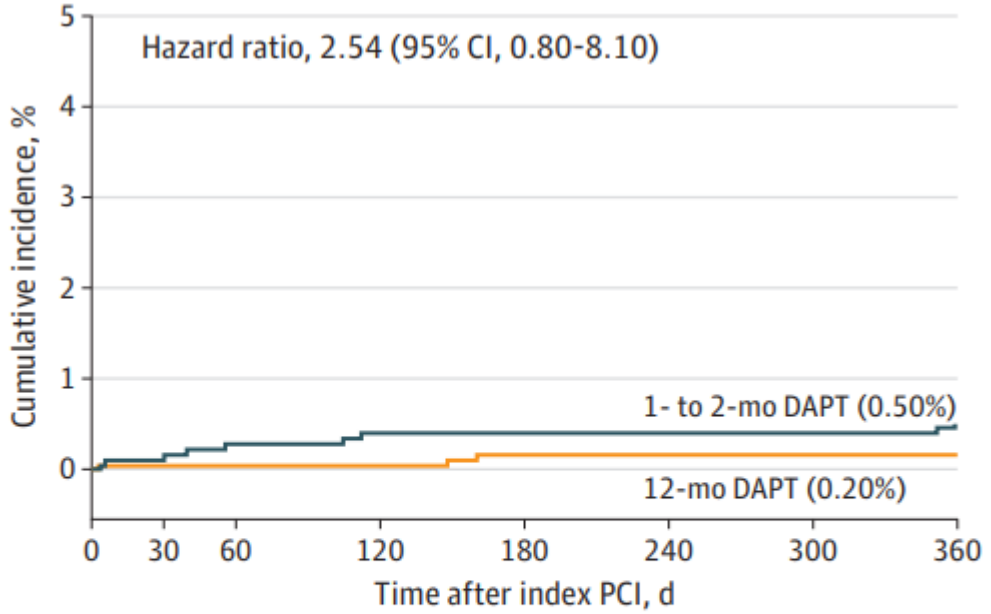
STOPDAPT-2 ACS

Thrombolysis in Myocardial Infarction major or minor bleeding



1- to 2-mo DAPT							
No. with event	2	4	5	10	11	11	11
No. at risk	2058	2052	2041	2038	2030	2023	2015	1642
12-mo DAPT							
No. with event	3	4	6	10	19	23	24
No. at risk	2078	2073	2060	2054	2045	2033	2027	1603

Definite or probable stent thrombosis

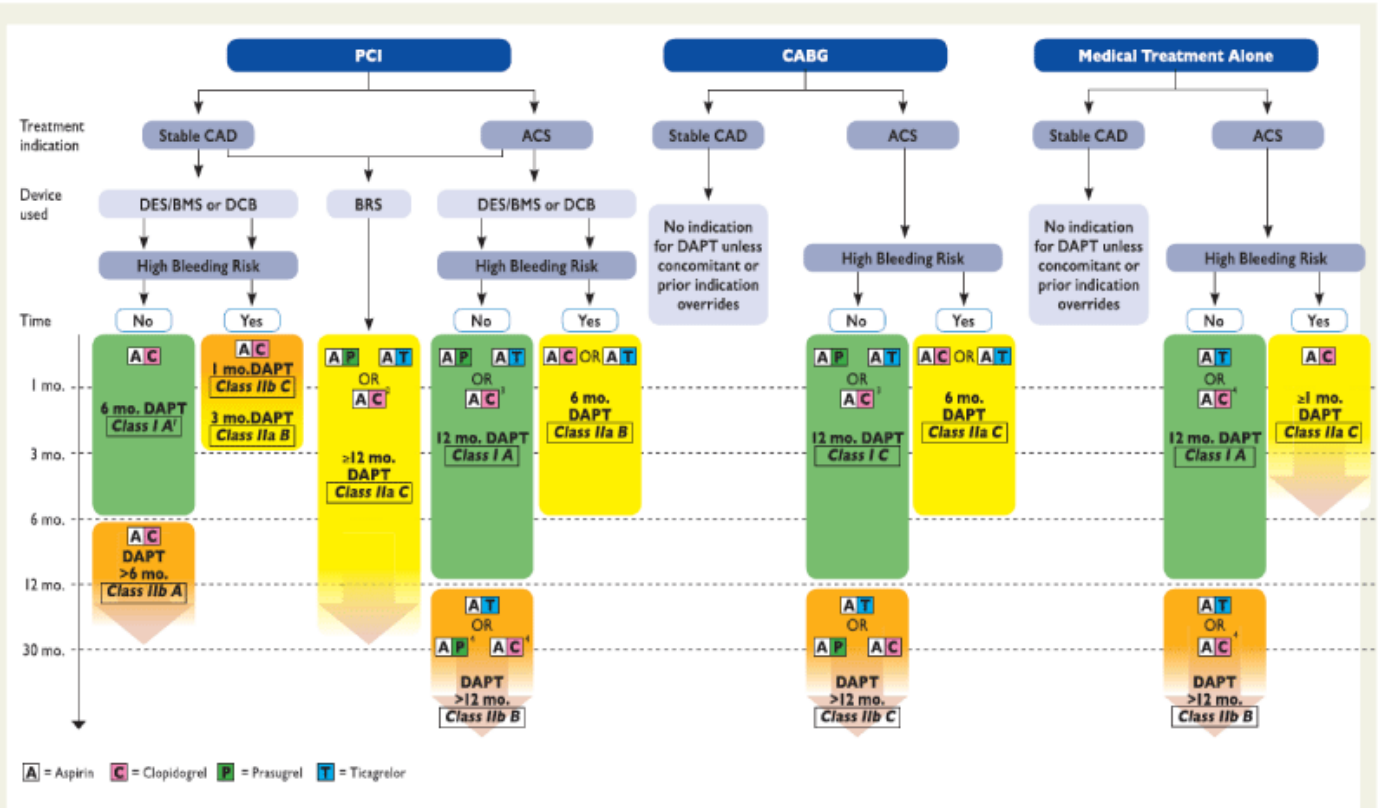


1- to 2-mo DAPT							
No. with event	3	6	8	8	8	8	10
No. at risk	2058	2053	2040	2035	2032	2026	2018	1643
12-mo DAPT							
No. with event	1	1	1	3	3	3	4
No. at risk	2078	2075	2063	2059	2052	2049	2046	1620

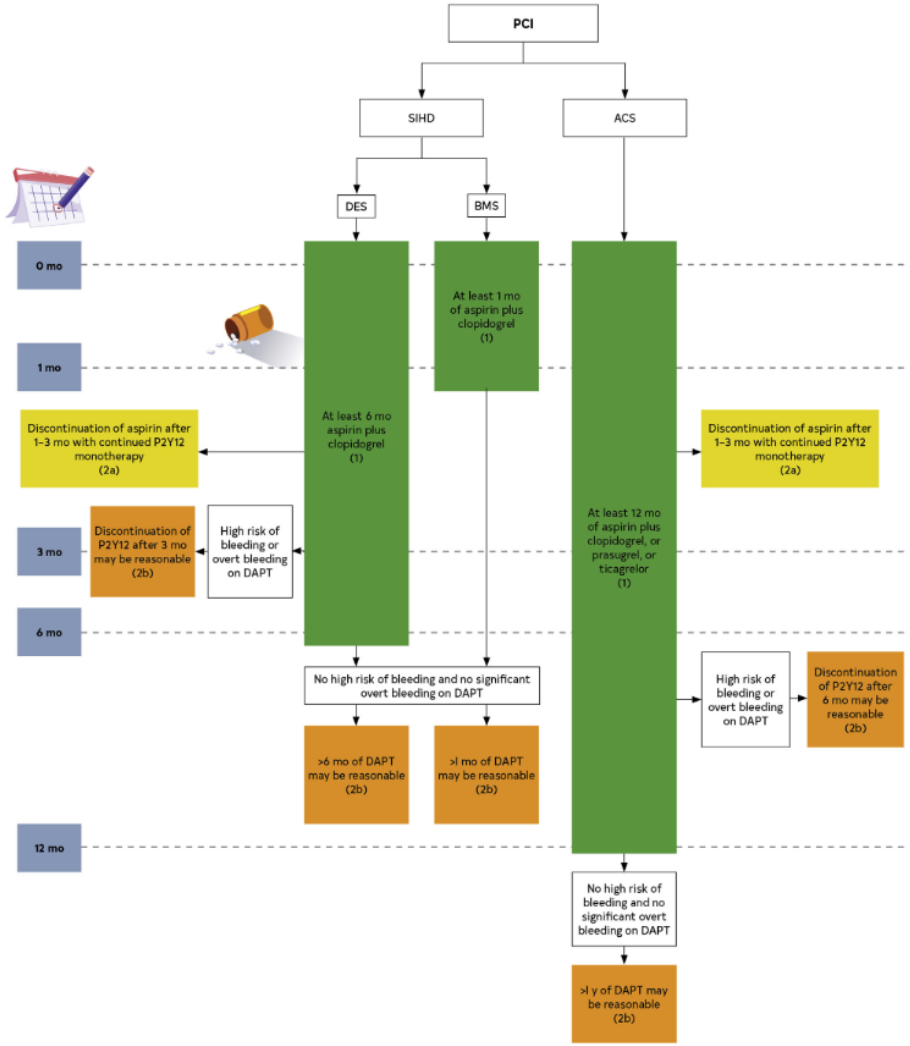
JAMA Cardiol. 2022;7(4):407-417.

Current guidelines recommend,

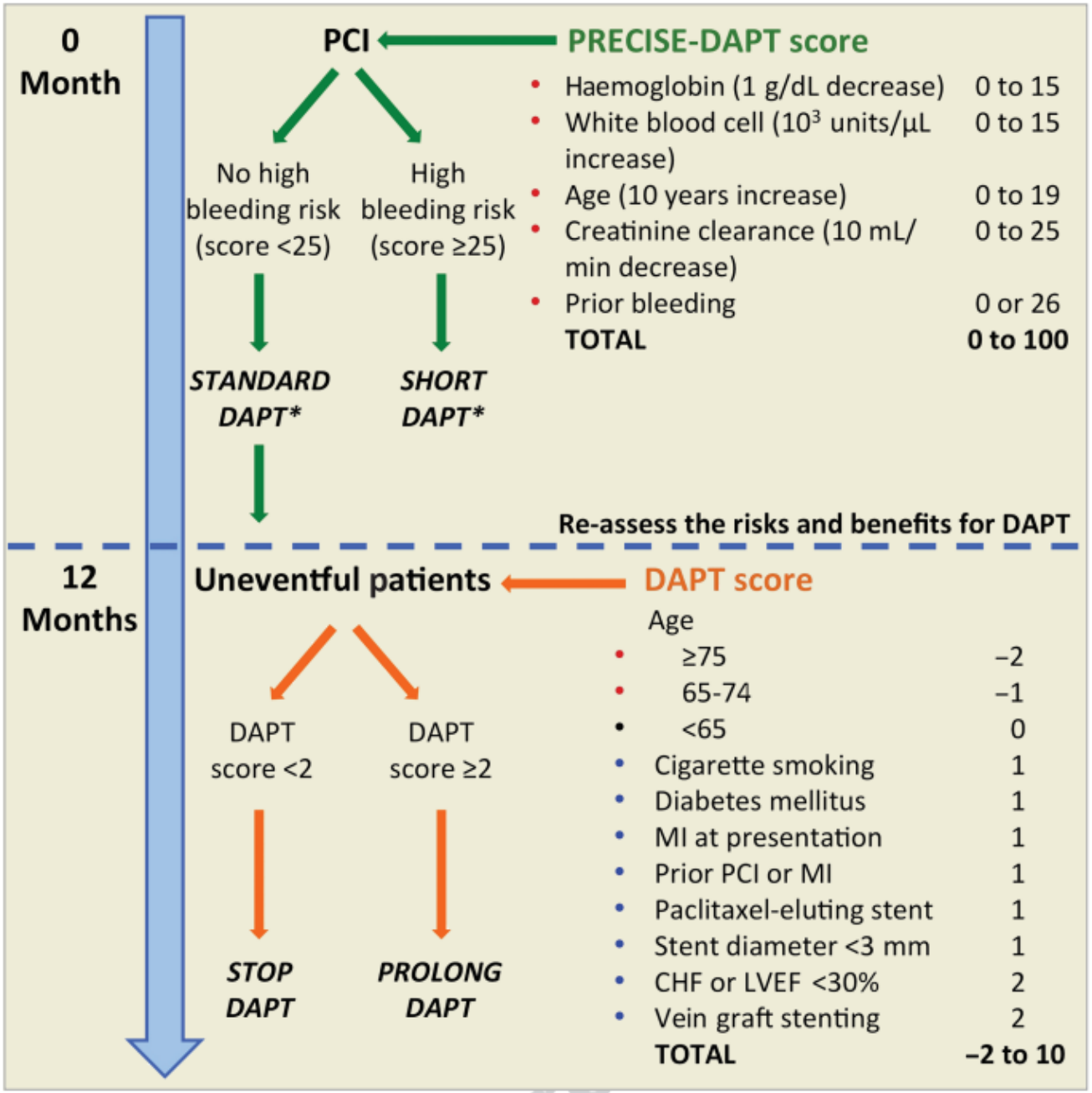
European guideline



US guideline



Eur Heart J. 2019 Jan 7;40(2):87-165. / Circulation. 2022 Jan 18;145(3):e4-e17.



Gargiulo G et al. Eurointervention 2017

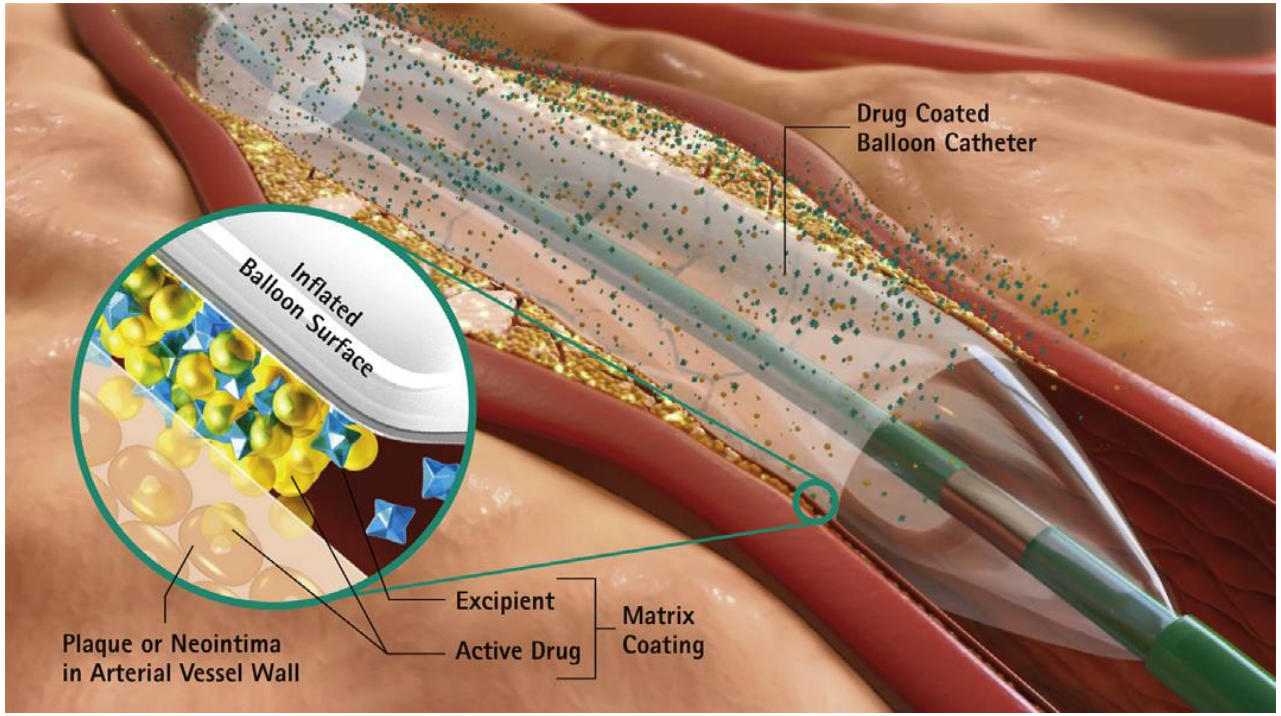
Drug-Coated Balloon

Neointimal hyperplasia and negative vessel remodeling and both contribute to restenosis after angioplasty.

These are slow processes that can be prevented by a sustained release of antiproliferative drugs for restenosis prevention.

The combination of a highly lipophilic drug and a specific coating matrix showed a dose-dependent reduction of neointimal formation.

Local paclitaxel therapy showed the positive remodeling phenomenon.



“Leaving nothing behind”

JACC Cardiovasc Interv. 2020;13(12):1391-1402.

Current Recommendations

2018 ESC/EACTS Guidelines on myocardial revascularization

Restenosis		
DES are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
Drug-coated balloons are recommended for the treatment of in-stent restenosis of BMS or DES.[373,375,378,379]	I	A
In patients with recurrent episodes of diffuse in-stent restenosis, CABG should be considered by the Heart Team over a new PCI attempt.	IIa	C
IVUS and/or OCT should be considered to detect stent-related mechanical problems leading to restenosis.	IIa	C

At present, there are no convincing data to support the use of DCB angioplasty for this indication.

Eur Heart J. 2019;40(2):87-165.

De Novo Lesions in Small Vessels
- BELLO -

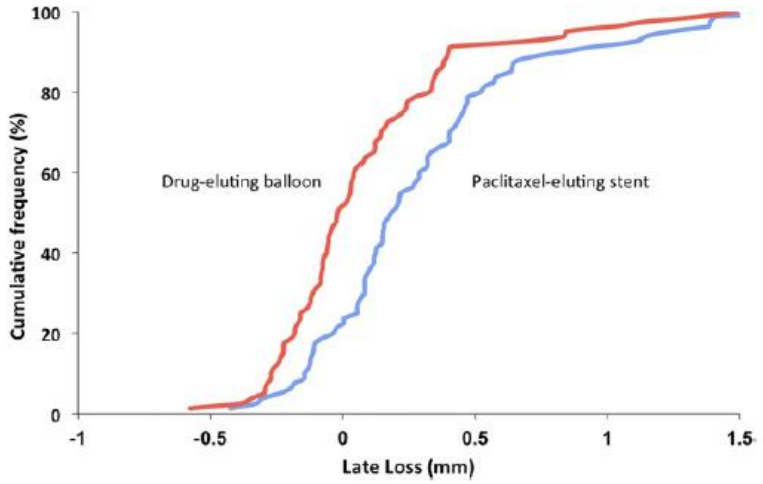


Figure 2 Late Loss Distribution

Cumulative frequency distribution curves of in-stent (in-balloon) late loss at follow-up angiography.

Table 4 Angiographic Outcomes at Follow-up

	DEB	PES	p Value
No. with angiographic follow-up	81	82	
Minimal lumen diameter, mm			
In-stent/in-balloon	1.48 ± 0.41	1.68 ± 0.51	0.006
In-segment	1.42 ± 0.40	1.52 ± 0.50	0.16
Diameter stenosis, %			
In-stent/in-balloon	32.31 ± 16.66	26.69 ± 20.38	0.06
In-segment	34.99 ± 15.97	33.33 ± 19.99	0.56
Late lumen loss, mm			
In-stent/in-balloon	0.08 ± 0.38	0.29 ± 0.44	0.001
In-segment	0.05 ± 0.37	0.17 ± 0.45	0.06
Net gain, mm			
In-stent/in-balloon	0.87 ± 0.41	1.06 ± 0.52	0.009
In-segment	0.81 ± 0.39	0.90 ± 0.49	0.20
Binary restenosis, %			
In-stent/in-balloon	8 (10)	10 (12.4)	0.64
In-segment	8 (10)	12 (14.6)	0.35

Table 5 Clinical Outcomes

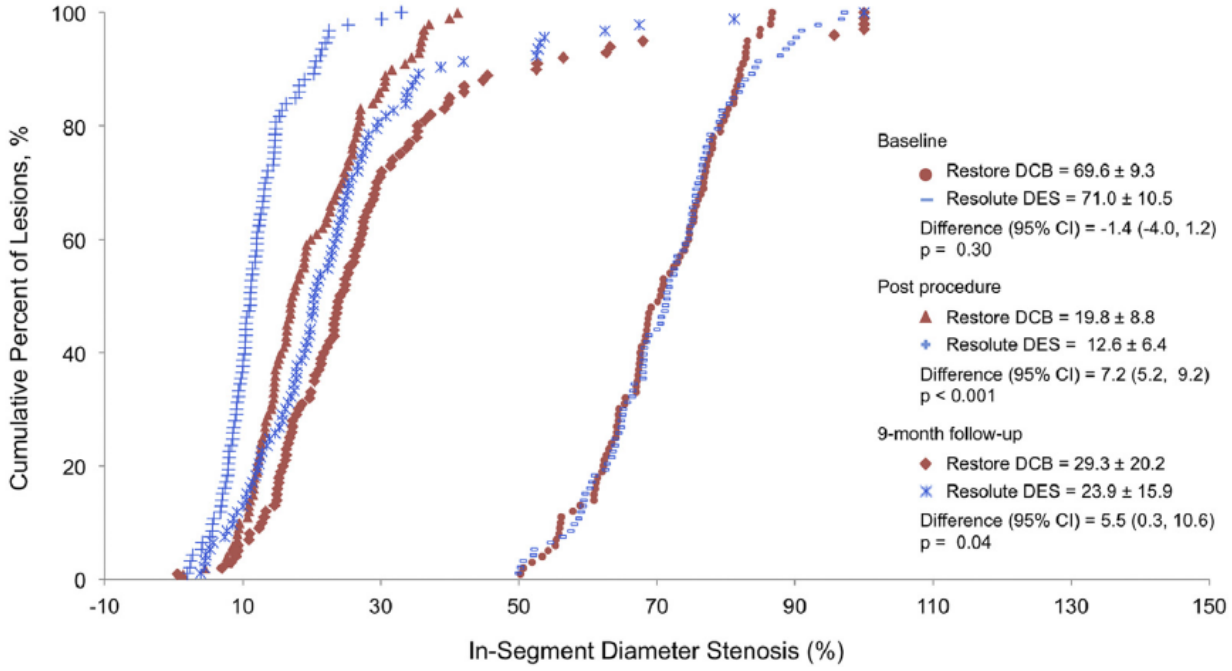
	DEB (n = 90)	PES (n = 92)	p Value
In-hospital MACE			
Periprocedural MI	1 (1.1)	3 (3.3)	0.33
Recurrent PCI	0	0	
Death	0	0	
30-day MACE (days 0–30)			
MACE	2 (2.2)	4 (4.3)	0.42
MI	1 (1.1)	4 (4.4)	0.18
TLR	1 (1.1)	0	0.31
TVR (including TLR)	2 (2.2)	0	0.15
Death	0	0	
Cumulative MACE (days 0–180)			
MACE	9 (10)	15 (16.3)	0.21
MI	1 (1.1)	5 (5.5)	0.10
TLR	4 (4.4)	7 (7.6)	0.37
TVR (including TLR)	7 (7.8)	10 (11.0)	0.46
Death	1 (1.1)	1 (1.1)	0.99

IN.PACT Falcon paclitaxel-coated DEB was noninferior to PES in suppressing neointimal proliferation, as measured by angiographic late loss at 6 months.

DAPT duration was 1 month in DCB only treatment vs. 3 months in DCB + BMS treatment vs. 12 months in PES.

J Am Coll Cardiol 2012;60:2473–80

De Novo Lesions in Small Vessels
- RESTORE SVD -



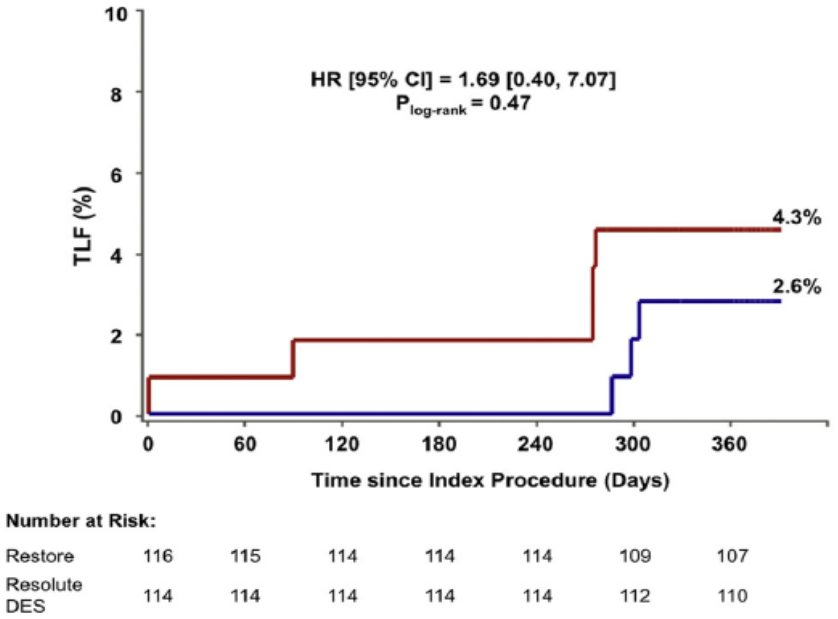
Primary endpoint: In-segment percentage diameter stenosis at 9 months

Restore DCB was noninferior to the RESOLUTE DES.

DAPT duration was at least 6 months in both groups.

TABLE 4 Nine-Month In-Segment Percentage Diameter Stenosis in the Intention-to-Treat and As-Treated Populations

	Restore DCB Group	Resolute DES Group	Difference (95% CI)	Noninferiority p Value
Intention-to-treat population	(n = 100, 100 lesions)	(n = 93, 93 lesions)		
In-segment diameter stenosis, % (per subject)	29.6 ± 2.0	24.1 ± 2.0	5.5 (0.2-10.9)	<0.001
In-segment diameter stenosis, % (per lesion)	29.6 ± 2.0	24.1 ± 2.0	5.5 (0.2-10.9)	<0.001
As-treated set	(n = 96, 96 lesions)	(n = 93, 93 lesions)		
In-segment diameter stenosis, % (per subject)	30.1 ± 2.1	24.1 ± 2.0	6.0 (0.5-11.4)	0.04
In-segment diameter stenosis, % (per lesion)	30.1 ± 2.1	24.1 ± 2.0	6.0 (0.5-11.4)	0.04

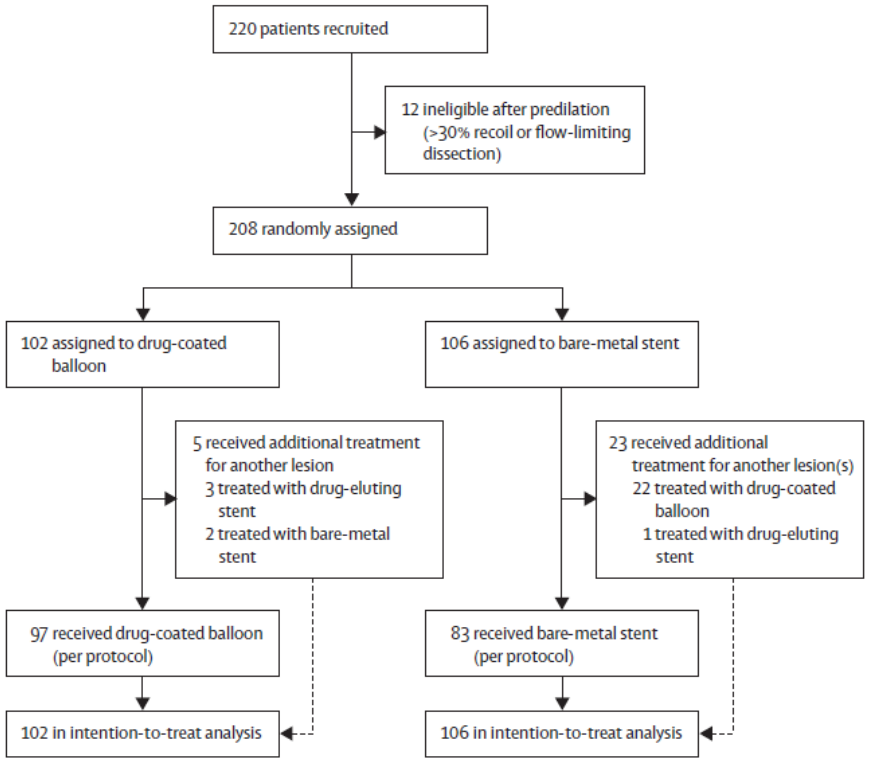


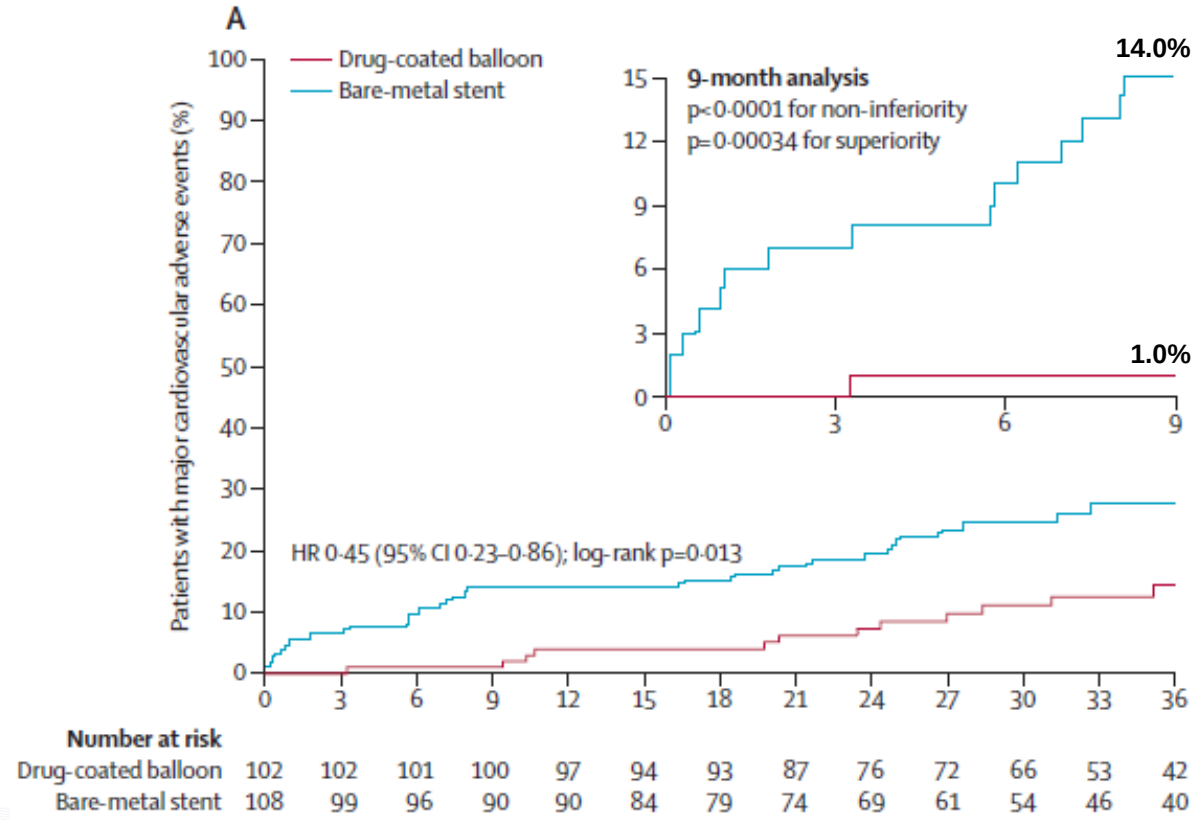
J Am Coll Cardiol Intv 2018;11:2381–92

De Novo Lesions in Large Vessels
- DEBUT -

Primary objective was to show non-inferiority of DCB versus BMS regarding major adverse cardiac events at 9 months in high bleeding risk patients.
: DCB was superior to BMS in patients at bleeding risk.
DAPT duration was 1 month in both groups.

Reference vessel diameter of 2·5–4·0 mm

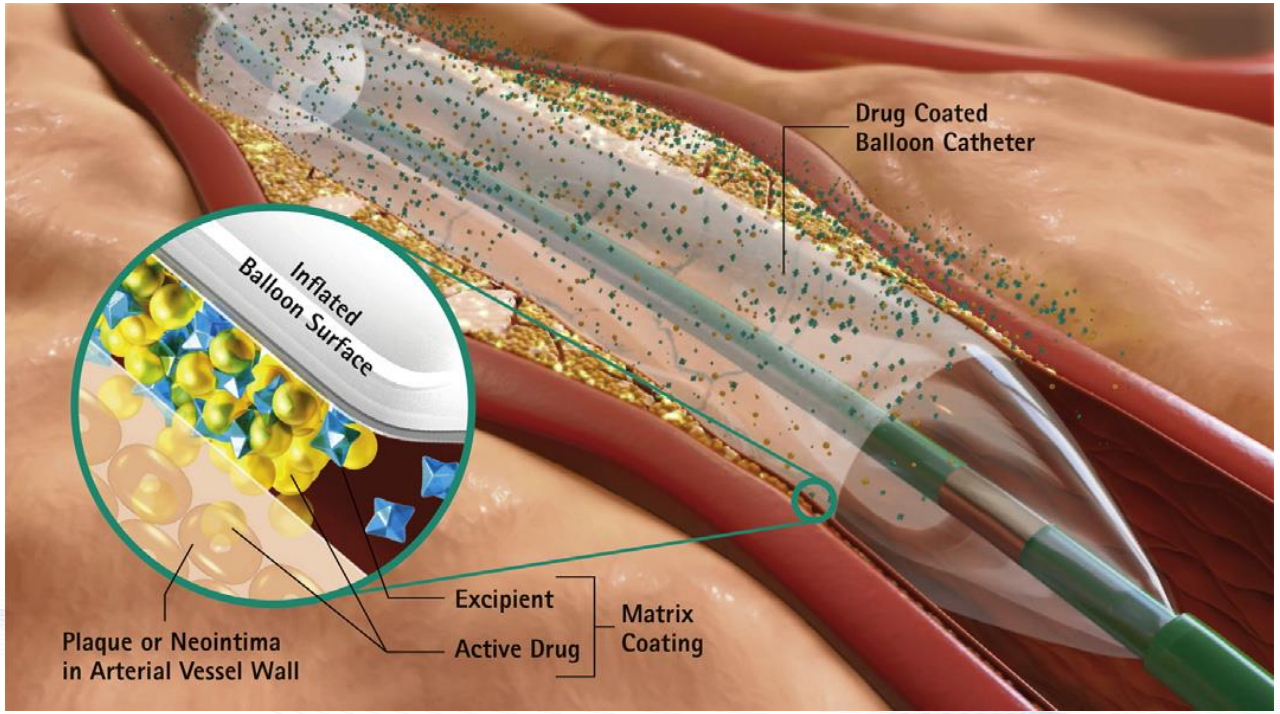




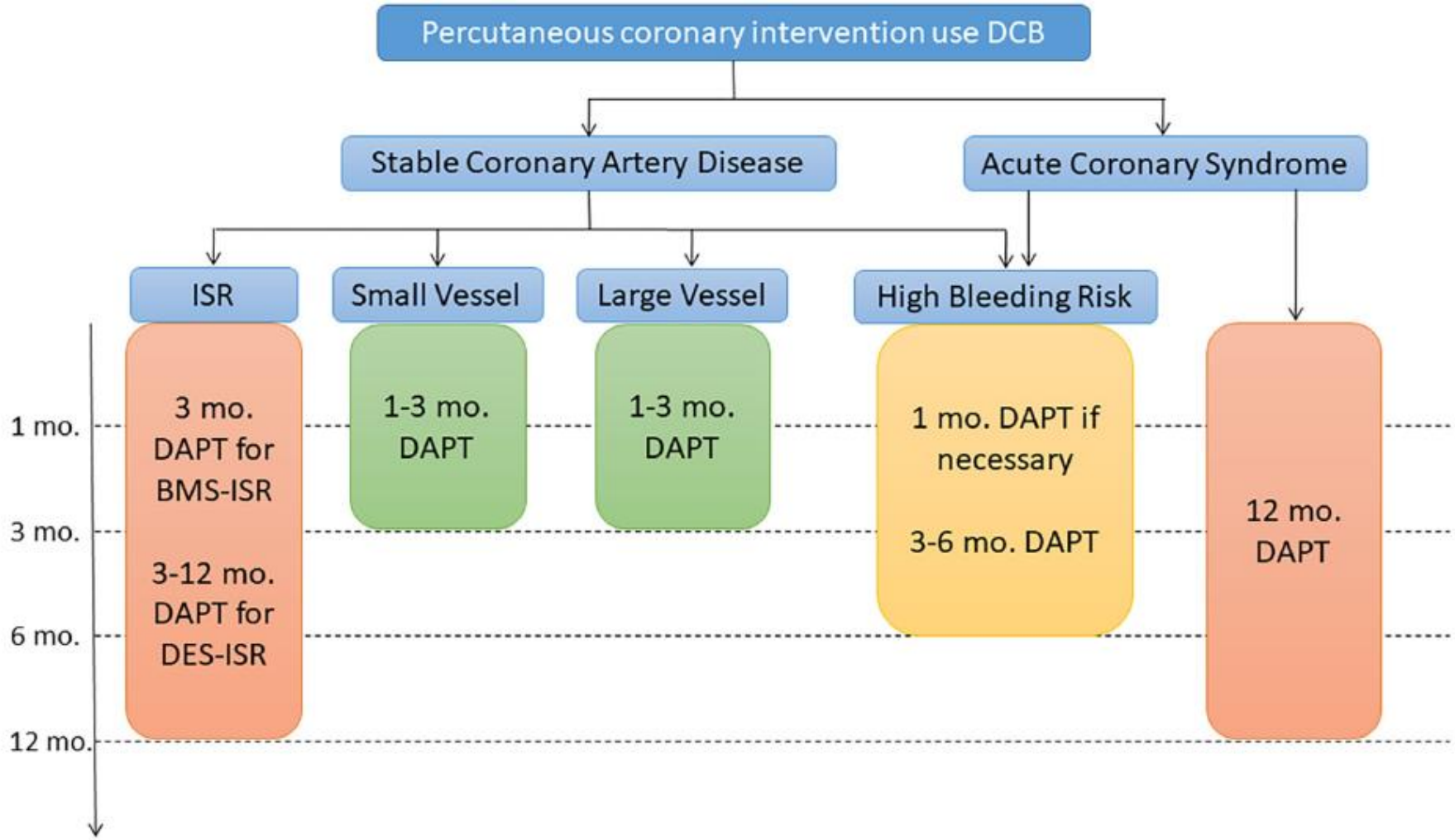
Lancet. 2019;394(10194):230-239.

DCB in De Novo Lesions

- Leaving nothing behind
- **Shortening the duration of DAPT**
- Favorable vascular remodeling
- Theoretical lack of any stent thrombosis



DAPT duration in DCB treatment



Front Cardiovasc Med. 2021 Dec 1;8:762391