Risk Awareness Of Secondary Events in post MI Patients and Secondary Prevention

Will Long Term DAPT Improve Late Outcome?

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New York, NY

Mount Sinai Heart

Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below. These relationships may lead to bias in my presentation.

Affiliation/Financial Relationship	Company
• Grant/Research Support (Institutional)	• The Medicines Co., AZ, BMS, Lilly/Daiichi Sankyo
• Advisory Board	• Janssen (J+J),
• Consulting Fees/Honoraria	• AstraZeneca, Boston Scientific, Covidien, CSL Behring, Janssen (J+J), Maya Medical, Merck, Sanofi-Aventis

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Journal of the American College of Cardiology
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Published by Elsevier Inc.

Vol. 58, No. 24, 2011
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2011.08.007

PRACTICE GUIDELINE

2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention

A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions

$P2Y_{12}$ inhibitors		
In patients receiving a stent (BMS or DES) during PCI for ACS, $P2Y_{12}$ inhibitor therapy should be given for at least 12 mo. Options include clopidogrel 75 mg/d, prasugrel 10 mg/d, and ticagrelor 90 mg twice daily.	I	B
In patients receiving DES for a non-ACS indication, clopidogrel 75 mg/d should be given for at least 12 mo if patients are not at high risk of bleeding.	I	B
In patients receiving BMS for a non-ACS indication, clopidogrel should be given for a minimum of 1 mo and ideally up to 12 mo (unless the patient is at increased risk of bleeding; then it should be given for a minimum of 2 wk).	I	B
If the risk of morbidity from bleeding outweighs the anticipated benefit afforded by a recommended duration of $P2Y_{12}$ inhibitor therapy after stent implantation, earlier discontinuation (e.g., <12 mo) of $P2Y_{12}$ inhibitor therapy is reasonable.	IIa	C
Continuation of clopidogrel, prasugrel, or ticagrelor beyond 12 mo may be considered in patients undergoing placement of DES.	IIb	C

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2014 ESC Revasc Guidelines

DAPT After Stenting

Bleeding risk- An important driver!

Stable CAD

DAPT for at least 1 month after BMS — **IA** — ISAR, SARS, PRODIGY

DAPT for 6 Months after DES — **IB** — PRODIGY, EXCELLENT, Meta-analysis

Shorter DAPT duration (< 6 mos) may be considered after DES in patients at high bleeding risk — **IIb A** — RESET, OPTIMIZE

NSTEACS

DAPT to 12 mos **unless excessive bleeding risk** — **IA/B** — PLATO, TRITON, PCI CURE

STEMI

DAPT to 12 mos **unless excessive bleeding risk** — **IA/B** — PLATO, TRITON

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Windecker et al. EHJ 2014

Challenging the guidelines

One-year dual antiplatelet therapy is:

- Too long!
- Not long enough!

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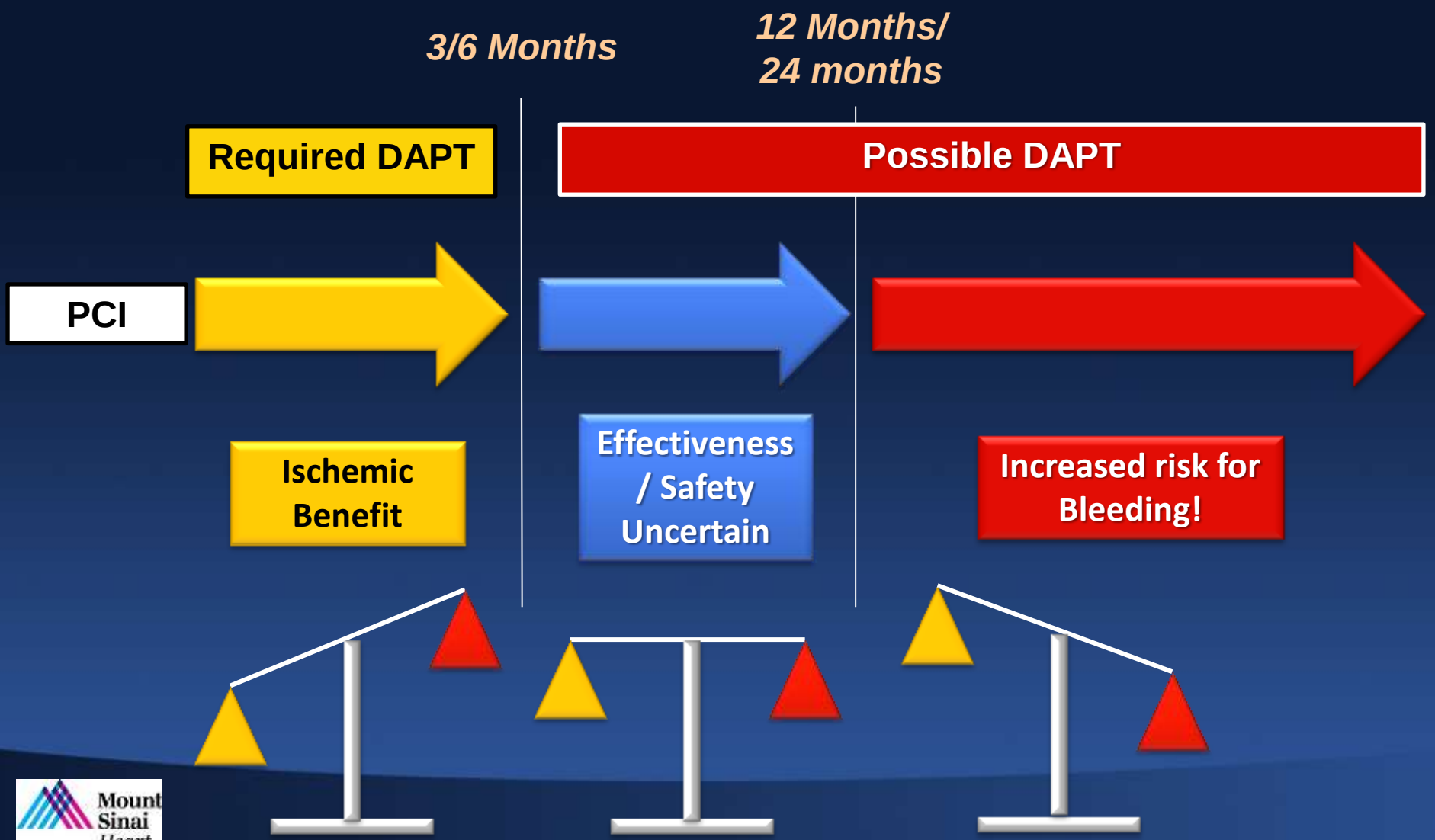
Optimal DAPT duration after DES Implantation: What does it really mean?



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Historical Overview

STARS 1998

Cypher/TAXUS Stent® Launch 2003-2004

ESC Firestorm ARC paper – 2006/2007

BARC 2011

ESC Revasc. Updated Guidelines 2014

6-mo post DES, 3- mo in high bleeding risk

Era of Thrombosis | **Bleeding Awareness** | **Equipoise**

- Defined the optimal approach to lower early post-PCI thrombosis
- Recognized late ST
- Identified risk factors for ST, particularly DAPT cessation

- Recognized importance of Bleeding
- Variability in Risk/Impact of bleeding

- Safer Stent Platforms
- More nuanced understanding of DAPT cessation
- Experimental approaches (shorter durations; withdrawal)

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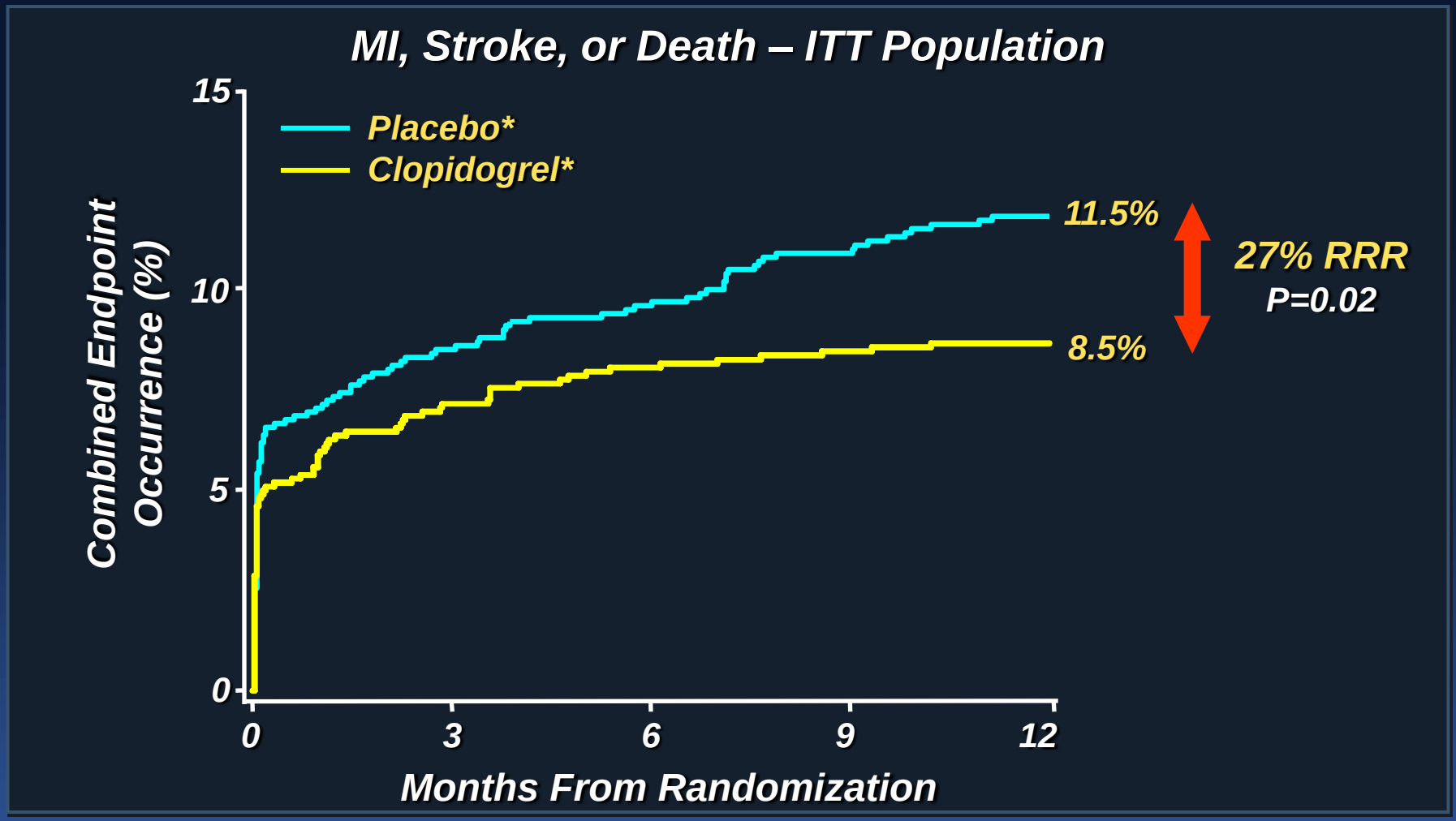
CREDO: Long-Term Benefits of Clopidogrel in PCI Patients



- Plus ASA and other standard therapies

Steinhubl S, et al. JAMA. 2002; 288(19):2411-2420.

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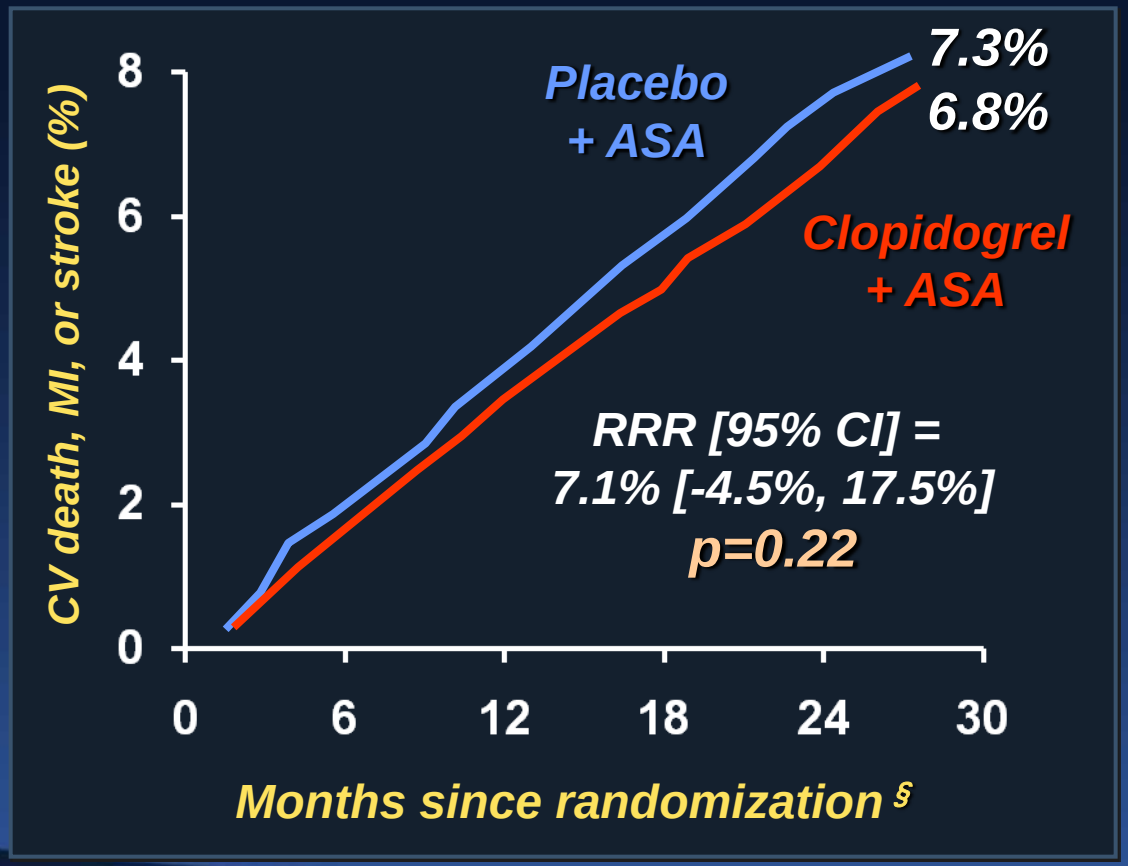
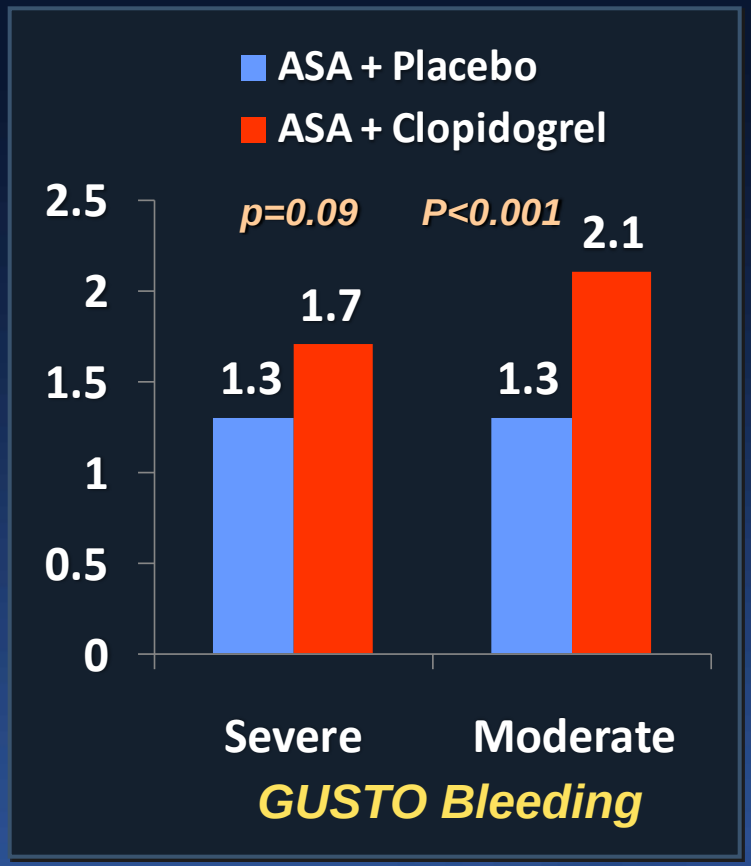
Impact of Long-term Clopidogrel: CHARISMA

15,603 pts age >45 yrs with either clinically evident CV ds. or multiple risk factors were treated with aspirin (75–162 mg/d) and randomized to clopidogrel 75 mg/d vs. placebo and followed for a median of 28 months

Primary Efficacy Outcome = CV Death, MI, or Stroke





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Bhatt DK et al. NEJM 2006;354:1706–17

Predictors of Stent Thrombosis with First-Generation DES

Prospective observational cohort study conducted including 2229 consecutive patients who underwent DES implantation between April 2002 and January 2004

Variables	Hazard Ratio (95% Confidence Interval)	*P* Value
Subacute stent thrombosis		
Premature antiplatelet therapy discontinuation	161.17 (26.03-997.94)	<.001
Renal failure	10.06 (3.13-32.35)	<.001
Bifurcation lesion	5.96 (1.90-18.68)	.002
Diabetes	5.84 (1.74-19.55)	.004
Left ventricular ejection fraction per 10% decrease	1.12 (1.06-1.19)	<.001
Stent length, per 1-mm increase	1.03 (1.00-1.05)	.01
Late stent thrombosis		
Premature antiplatelet therapy discontinuation	57.13 (14.84-219.96)	<.001
Bifurcation lesion	8.11 (2.50-26.26)	.001
Left ventricular ejection fraction per 10% decrease	1.06 (1.01-1.12)	.03
Cumulative stent thrombosis		
Premature antiplatelet therapy discontinuation	89.78 (29.90-269.60)	<.001
Renal failure	6.49 (2.60-16.15)	<.001
Bifurcation lesion	6.42 (2.93-14.07)	<.001
Diabetes	3.71 (1.74-7.89)	.001
Left ventricular ejection fraction per 10% decrease	1.09 (1.05-1.13)	<.001

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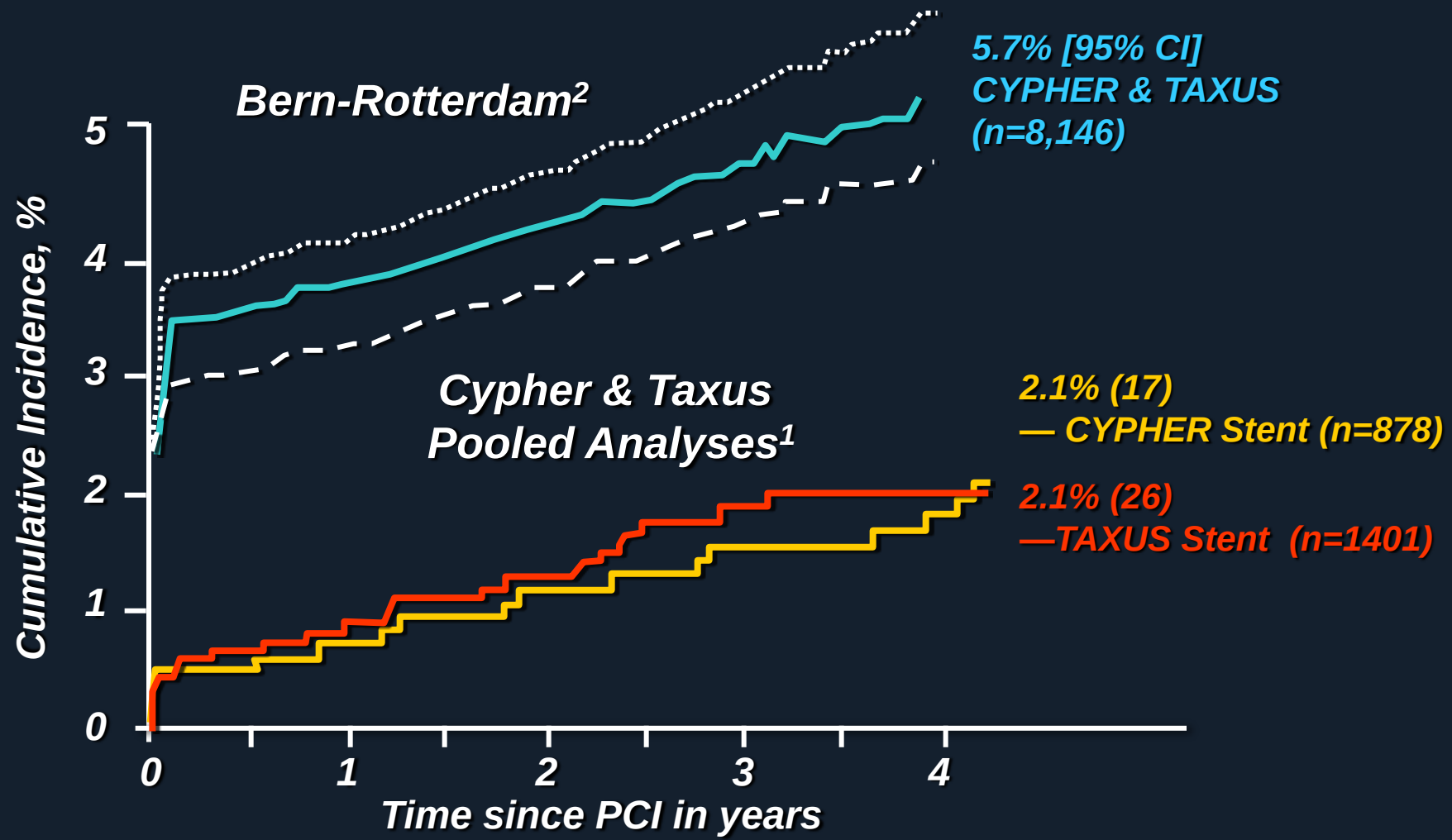
Iakovou et al - JAMA, May 4, 2005—Vol 293, No. 17

Cumulative Incidence of ARC Def/Prob ST over 4 yrs after DES (CYPHER & TAXUS)

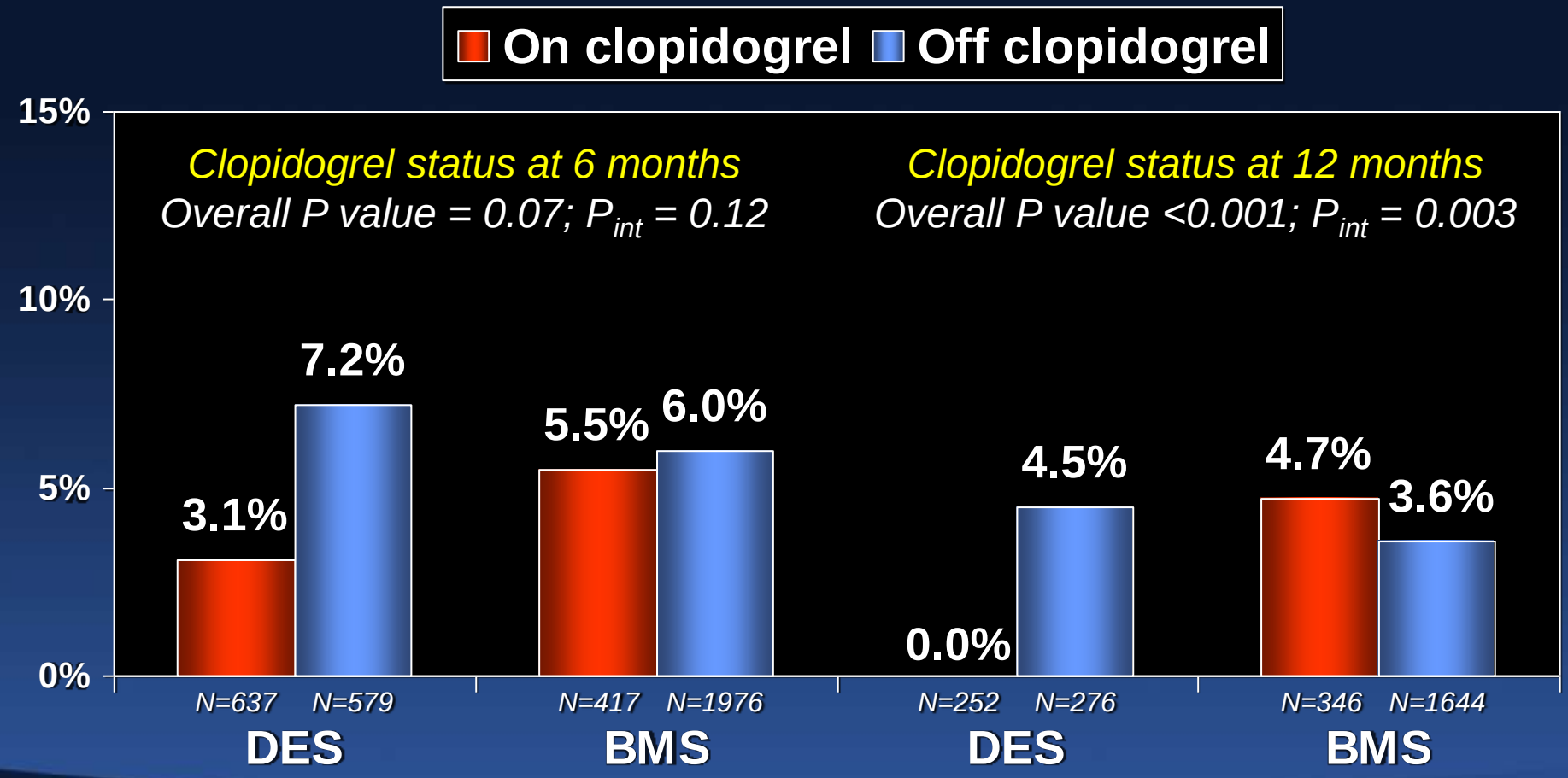


[1] Mauri et al; N Engl J Med 2007;356:1020-9

[2] Wenaweser et al; J Am Coll Cardiol 2008;52:1134-40

Duke Database Death/MI Analysis

Adjusted death/MI rates at 24 months in patients without events at 6 months



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Eisenstein EL et al. JAMA 2007

Bleeding Awareness

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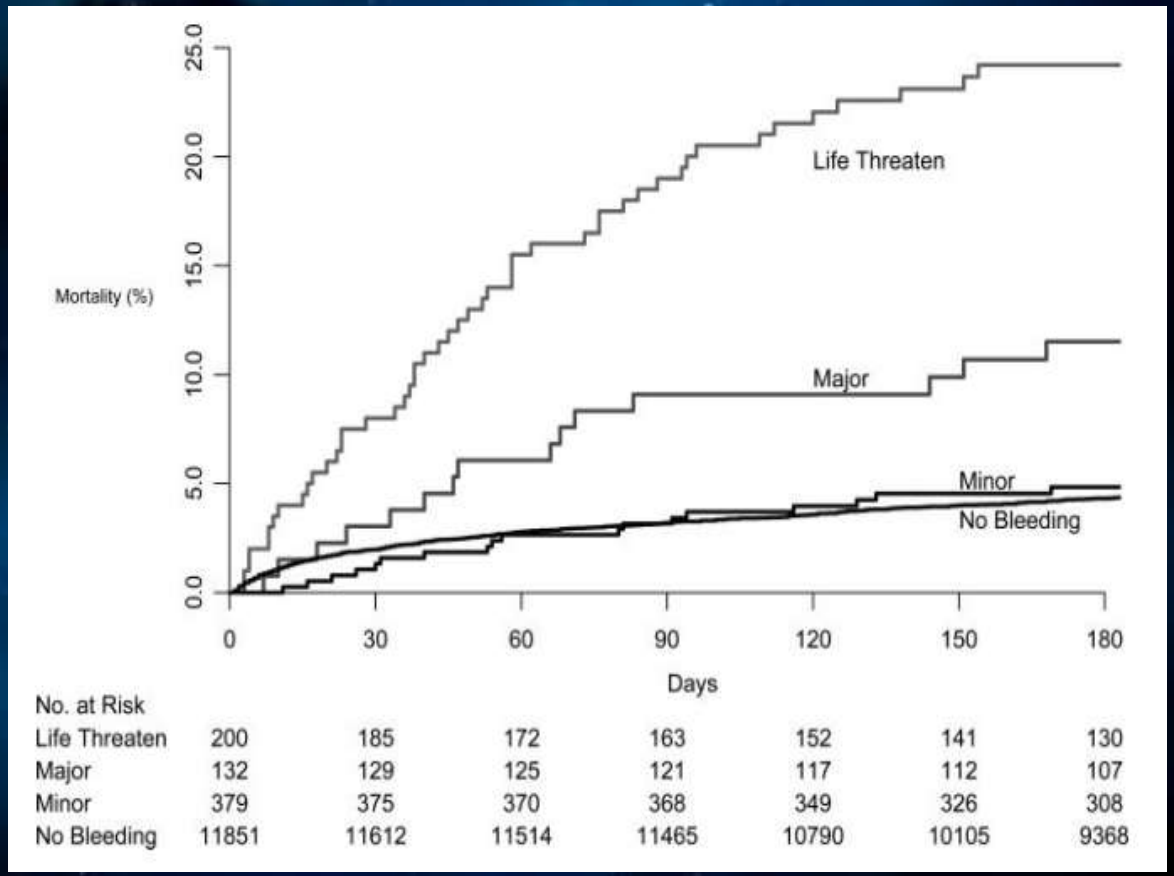
Adverse Impact of Bleeding on Prognosis in Patients With Acute Coronary Syndromes

John W. Eikelboom, MBBS, MSc; Shamir R. Mehta, MD, MSc; Sonia S. Anand, MD, PhD; Changchun Xie, PhD; Keith A.A. Fox, MBChB; Salim Yusuf, MBBS, DPhil

First Alarm (2006): Bleeding is Bad!



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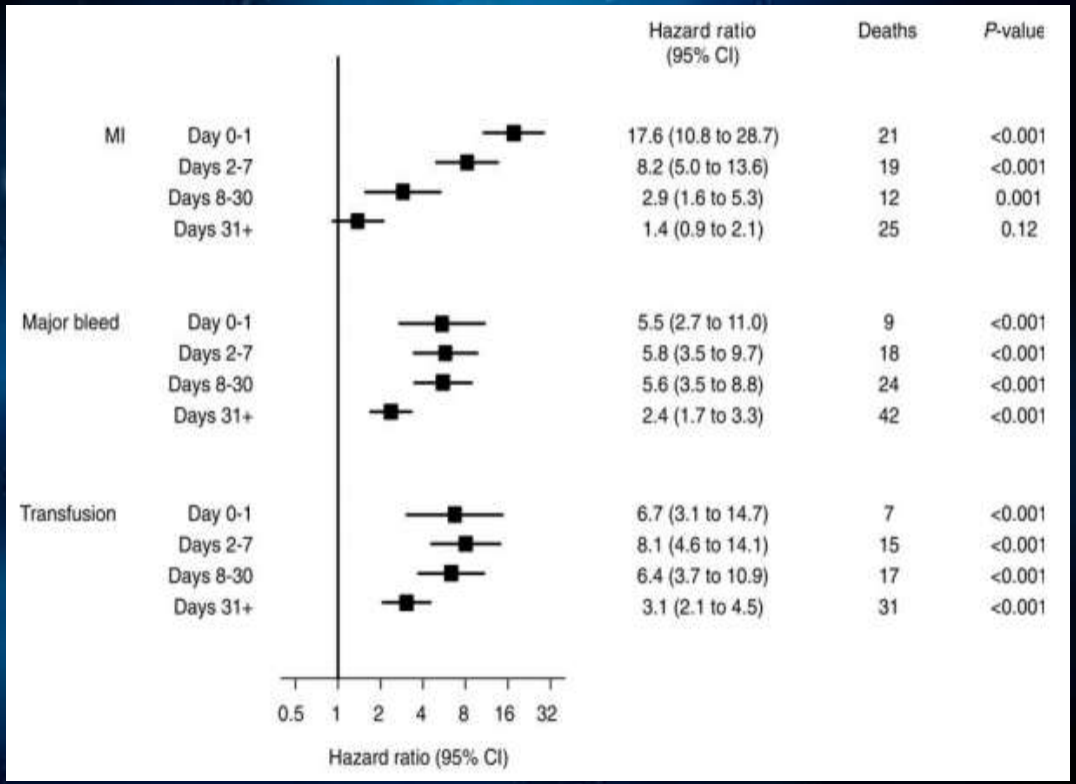
Circulation. 2006;114:774-782.

European Heart Journal (2009) 30, 1457–1466
doi:10.1093/eurheartj/ehp110

CLINICAL RESEARCH
Coronary heart disease

Associations of major bleeding and myocardial infarction with the incidence and timing of mortality in patients presenting with non-ST-elevation acute coronary syndromes: a risk model from the ACUITY trial

Major bleeds and MI have similar overall strength of association with mortality in the first year after ACS. MI is correlated with a dramatic increase in short-term risk, whereas major bleeding correlates with a more prolonged mortality risk.



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Mehran et al - European Heart Journal (2009) 30, 1457–1466

Equipoise

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First- Versus Second-Generation DES and risk for Stent Thrombosis.. Where is the difference?

1st-generation DES

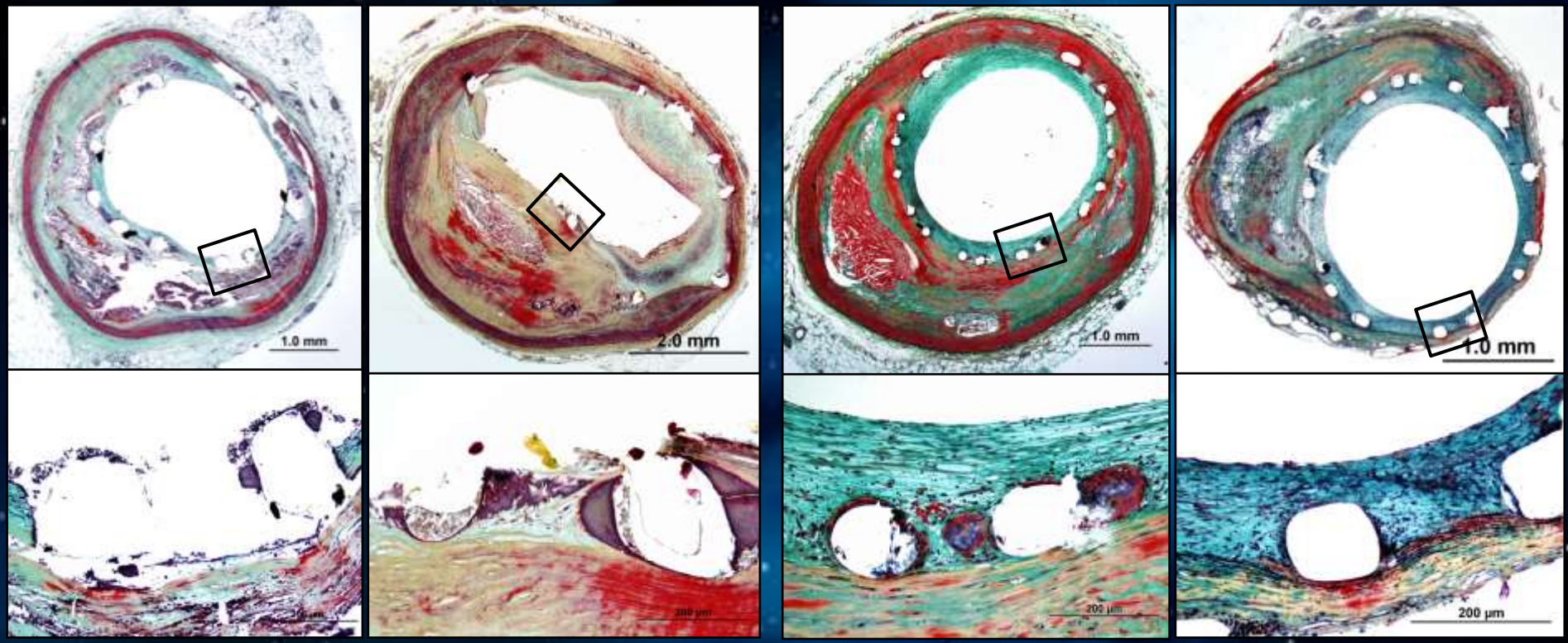
2nd-generation DES

SES 13 months

PES 11 months

ZES 3 months

EES 6 months



Representative Images of 2nd- vs. 1st-generation DES in Human Coronary Arteries

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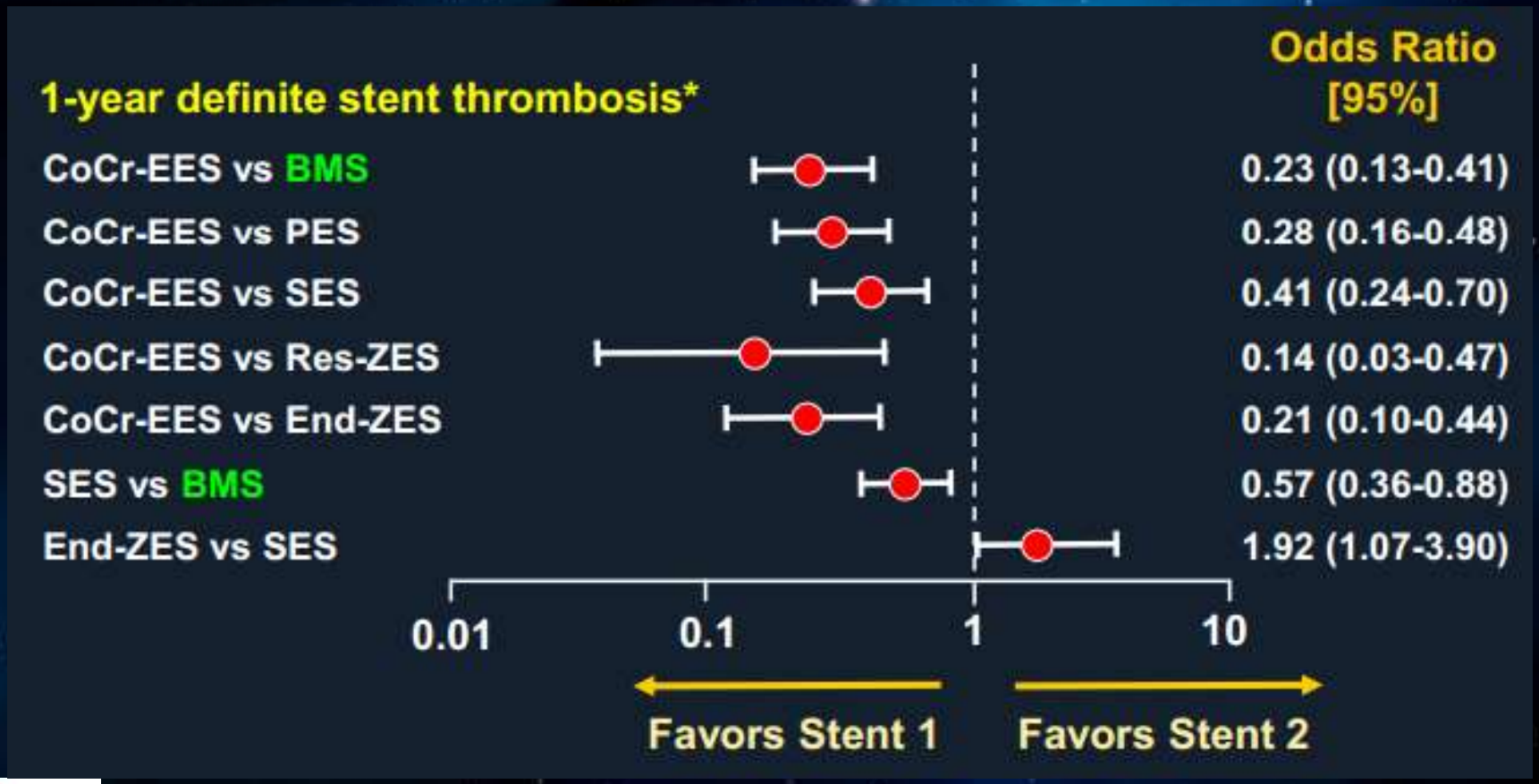
Stent thrombosis: has the firestorm been extinguished?

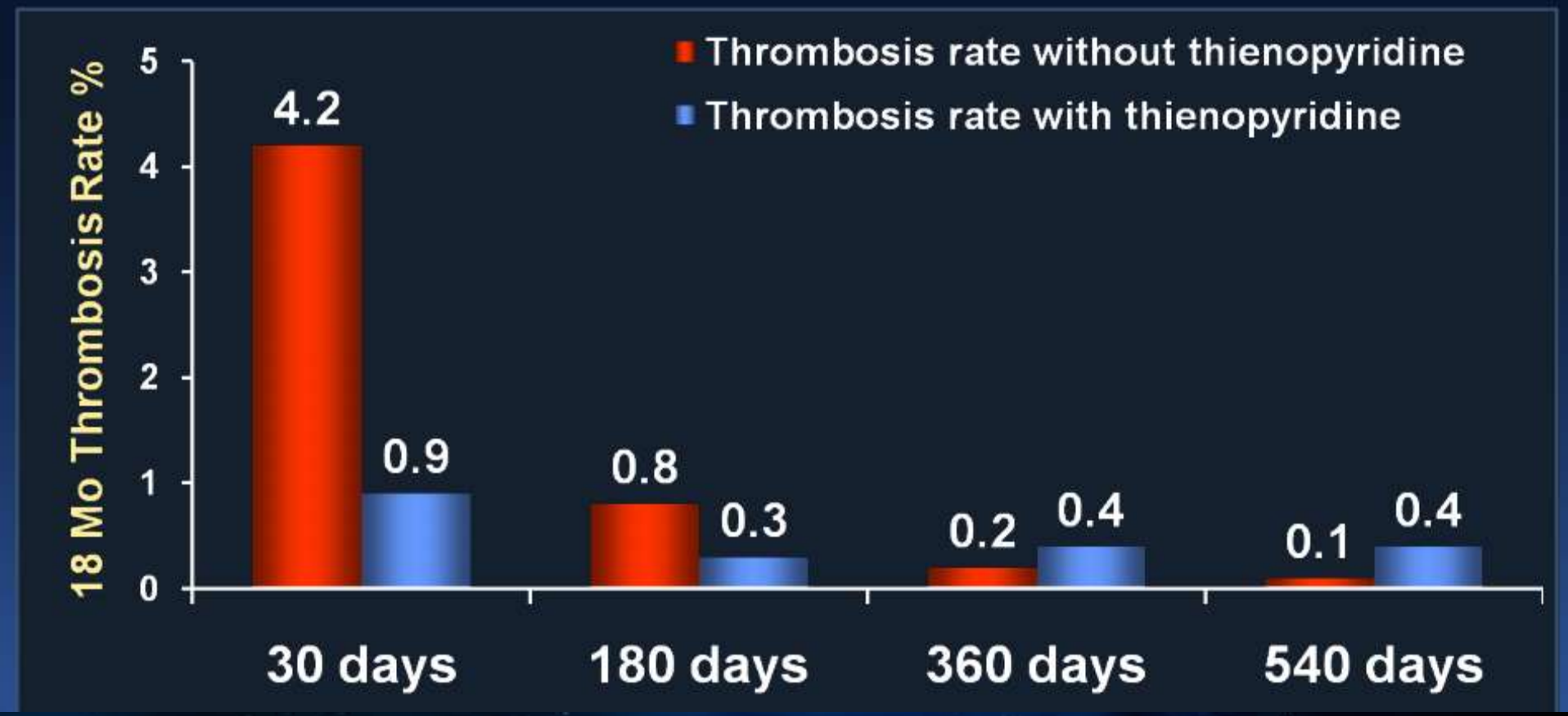
THE LANCET
Volume 379, Issue 9824, 14–20 April 2012, Pages 1368–1369

Second-Generation DES are safer!



Palmerini T et al. *Lancet* 2012

Initial observations regarding the interaction between DAPT, DES and Thrombotic Risk



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Airoldi F et al. Circulation 207;16:745-54

DAPT STUDY

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 4, 2014 VOL. 371 NO. 23

Twelve or 30 Months of Dual Antiplatelet Therapy after Drug-Eluting Stents

Laura Mauri, M.D., Dean J. Kereiakes, M.D., Robert W. Yeh, M.D., Priscilla Driscoll-Shempp, M.B.A., Donald E. Cutlip, M.D., P. Gabriel Steg, M.D., Sharon-Lise T. Normand, Ph.D., Eugene Braunwald, M.D., Stephen D. Wiviott, M.D., David J. Cohen, M.D., David R. Holmes, Jr., M.D., Mitchell W. Krucoff, M.D., James Hermiller, M.D., Harold L. Dauerman, M.D., Daniel I. Simon, M.D., David E. Kandzari, M.D., Kirk N. Garratt, M.D., David P. Lee, M.D., Thomas K. Pow, M.D., Peter Ver Lee, M.D., Michael J. Rinaldi, M.D., and Joseph M. Massaro, Ph.D., for the DAPT Study Investigators*

Is there a benefit in extending DAPT beyond one year?

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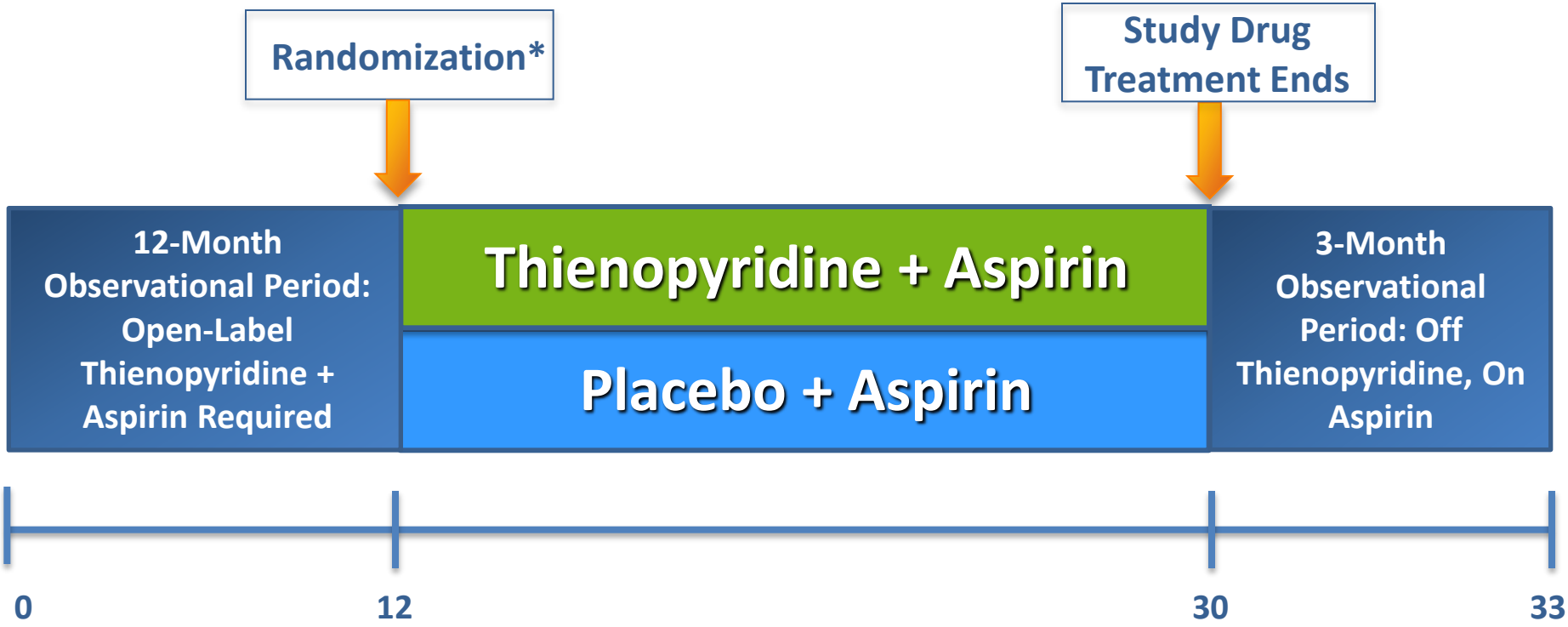
Mauri et al. NEJM 2014
DOI: 10.1056/NEJMoa1409312

Design



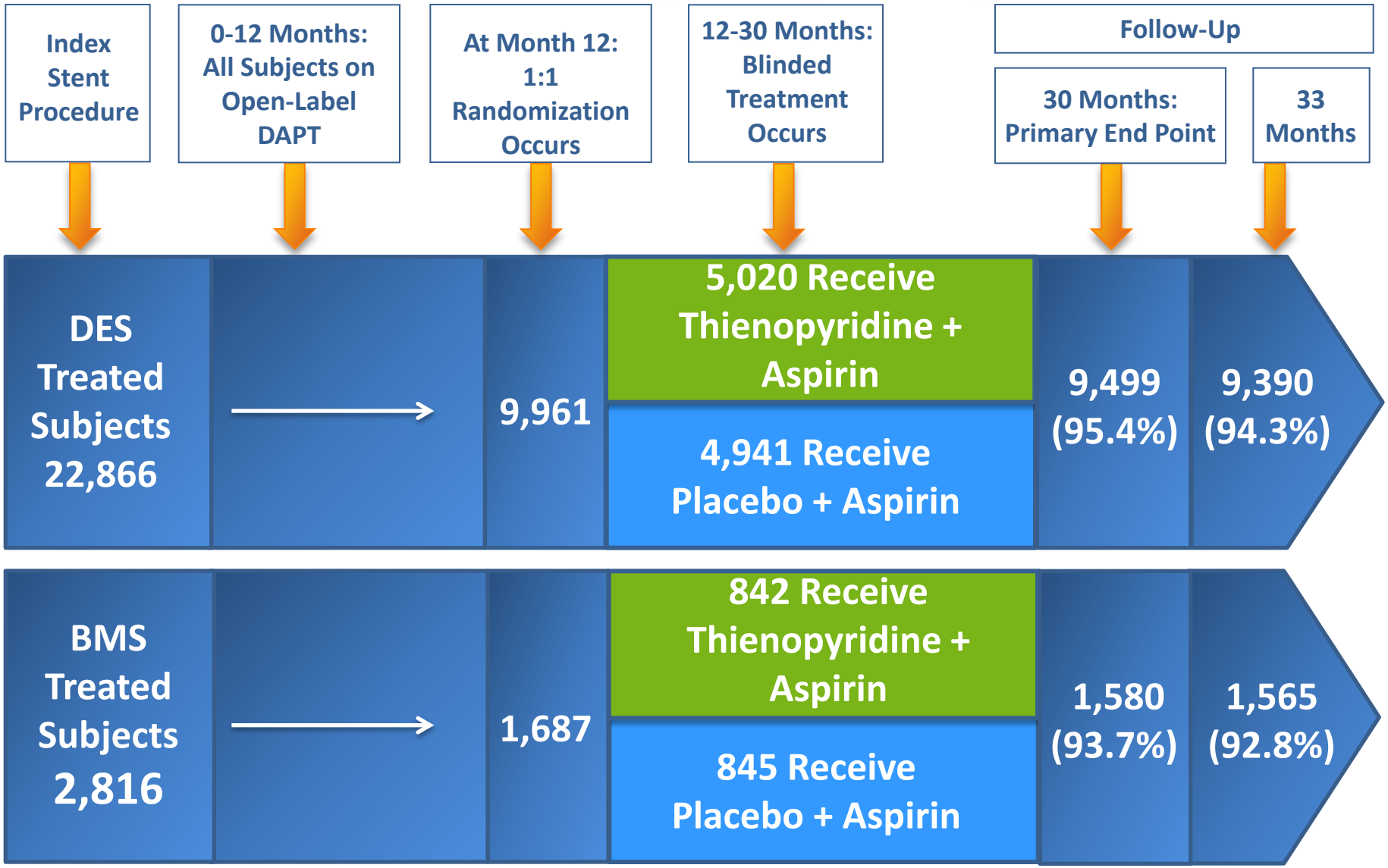
Enrolled: Subjects treated with FDA-approved DES or BMS. Subjects on oral anticoagulant therapy or with life expectancy < 3 years excluded.

Randomized: Free from MI, stroke, repeat revascularization, and moderate or severe bleeding, and adherent with thienopyridine (80% to 120% of doses taken and no interruption > 14 days).

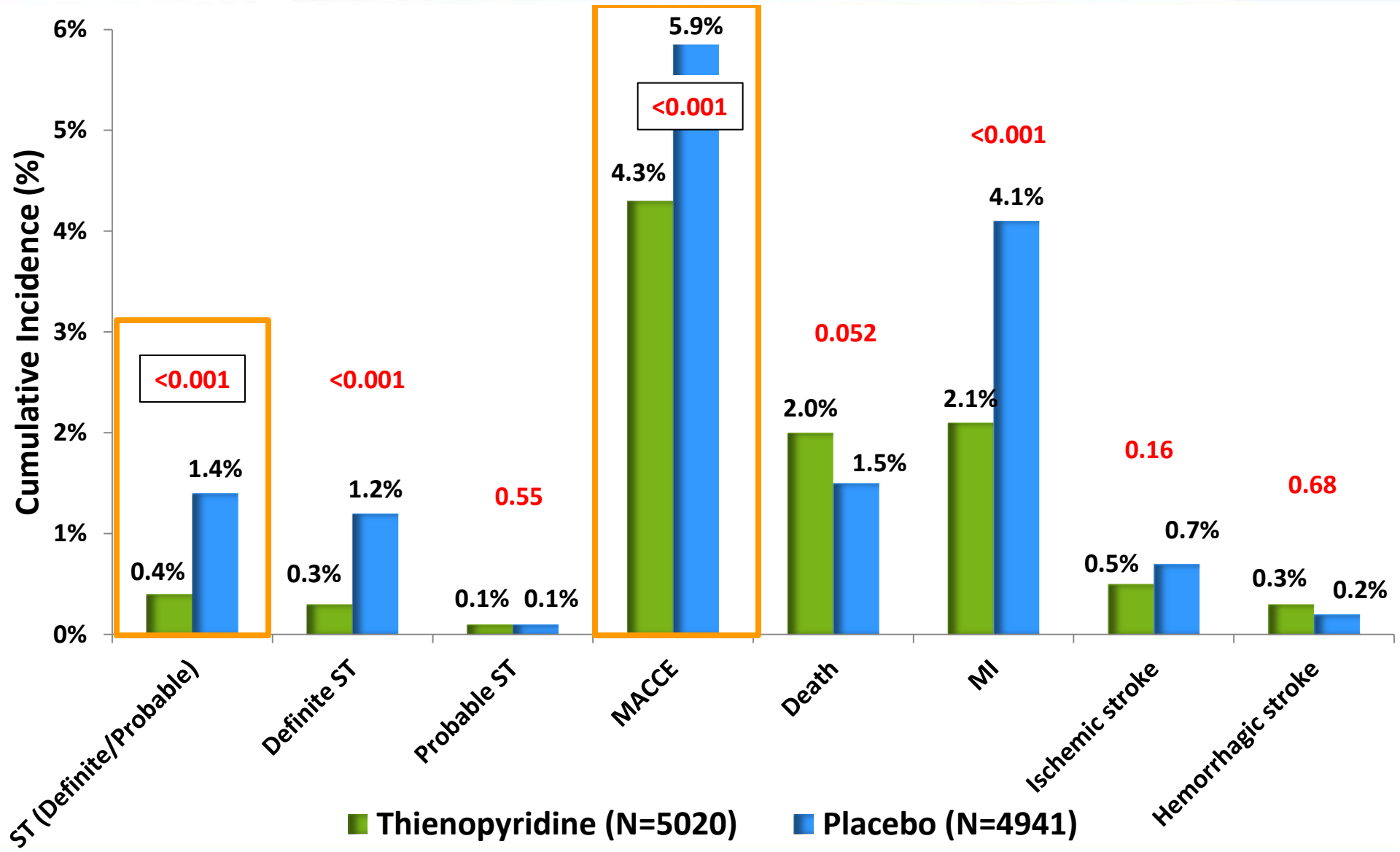
Mauri, Kereiakes et al AHJ 2010; 160(6): 1035-1041

ClinicalTrials.gov number NCT00977938

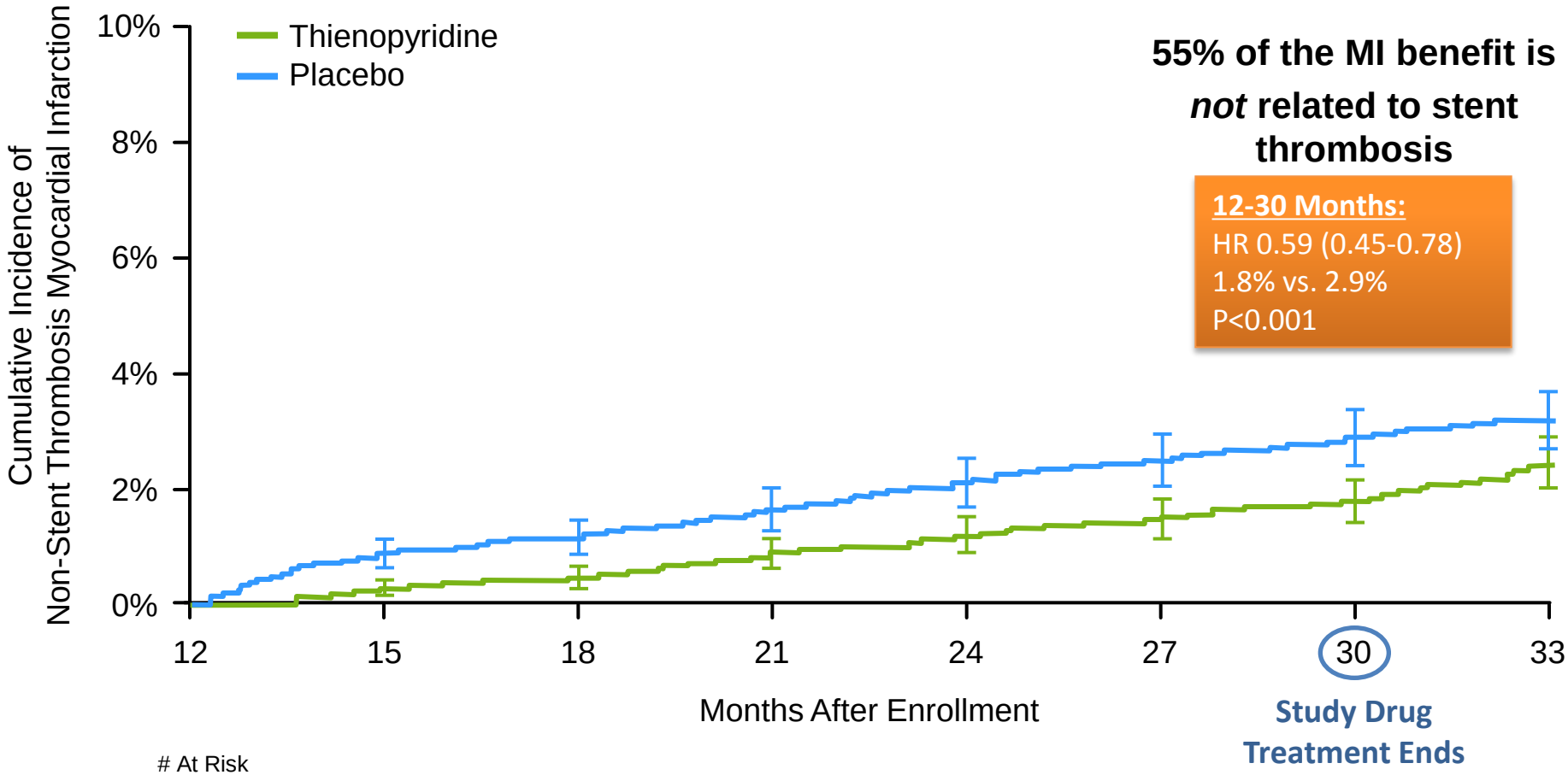
Subject Flow



Co-Primary Effectiveness End Points & Components: 12-30 Months



Non-Stent Thrombosis Myocardial Infarction

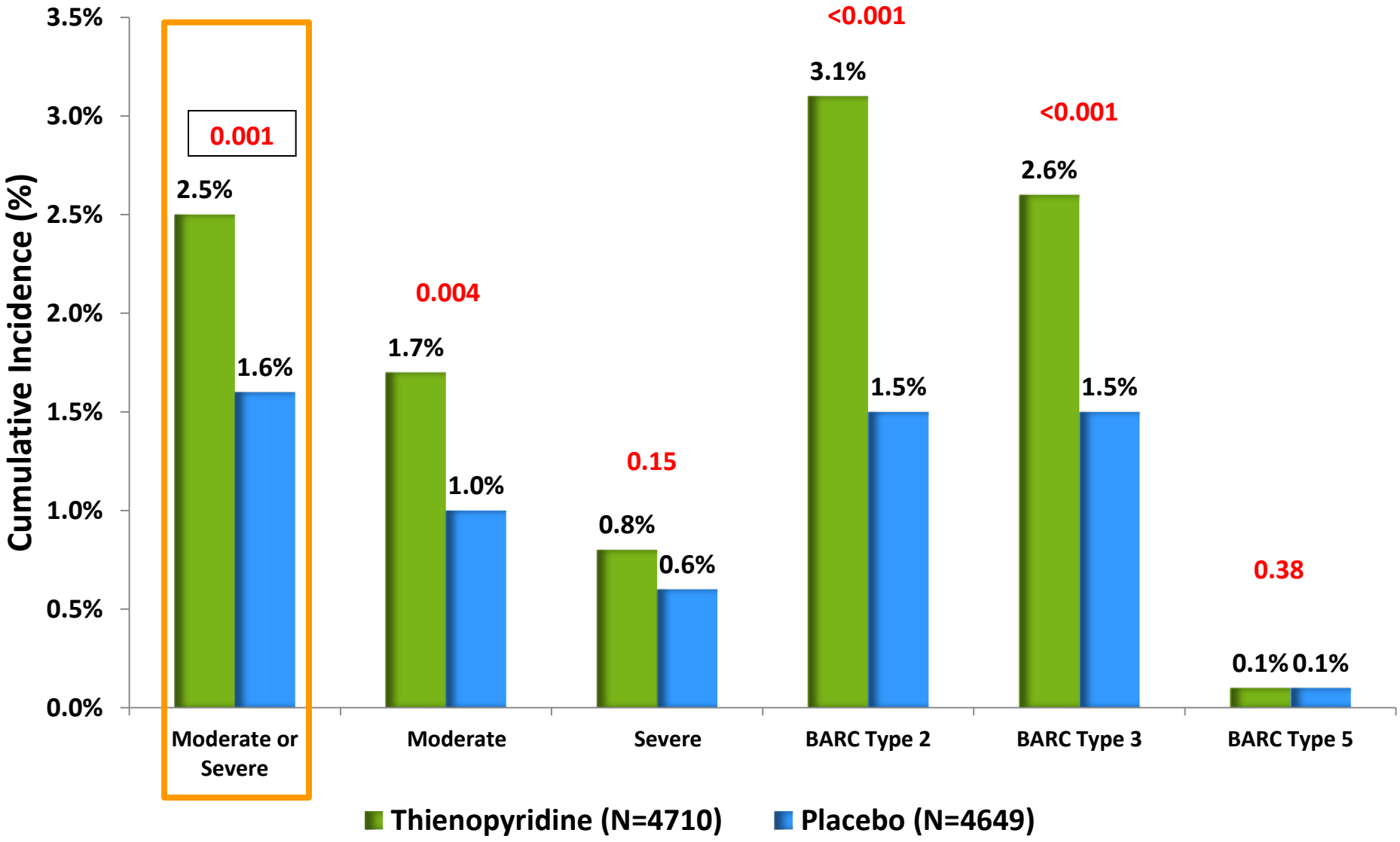


55% of the MI benefit is *not* related to stent thrombosis

12-30 Months:
HR 0.59 (0.45-0.78)
1.8% vs. 2.9%
P<0.001

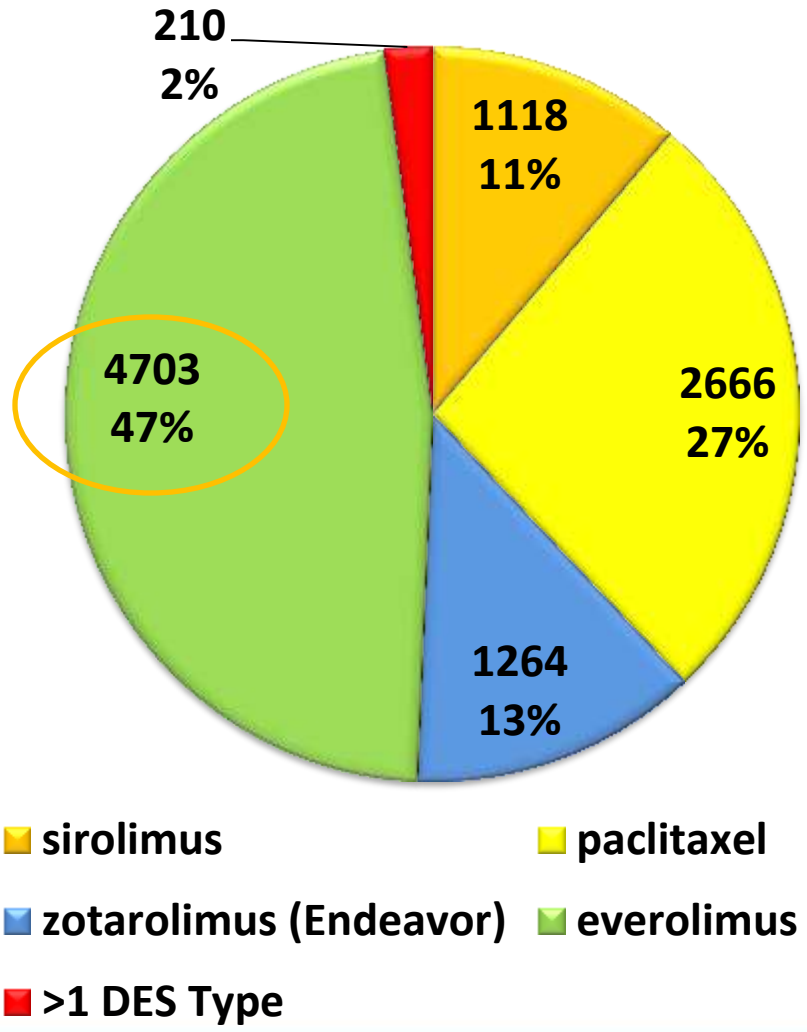
# At Risk								
Thienopyridine	5020	4920	4851	4792	4721	4641	4588	3066
Placebo	4941	4820	4751	4686	4607	4547	4491	3052

Primary Safety End Point (Moderate or Severe Bleeding): 12-30 Months

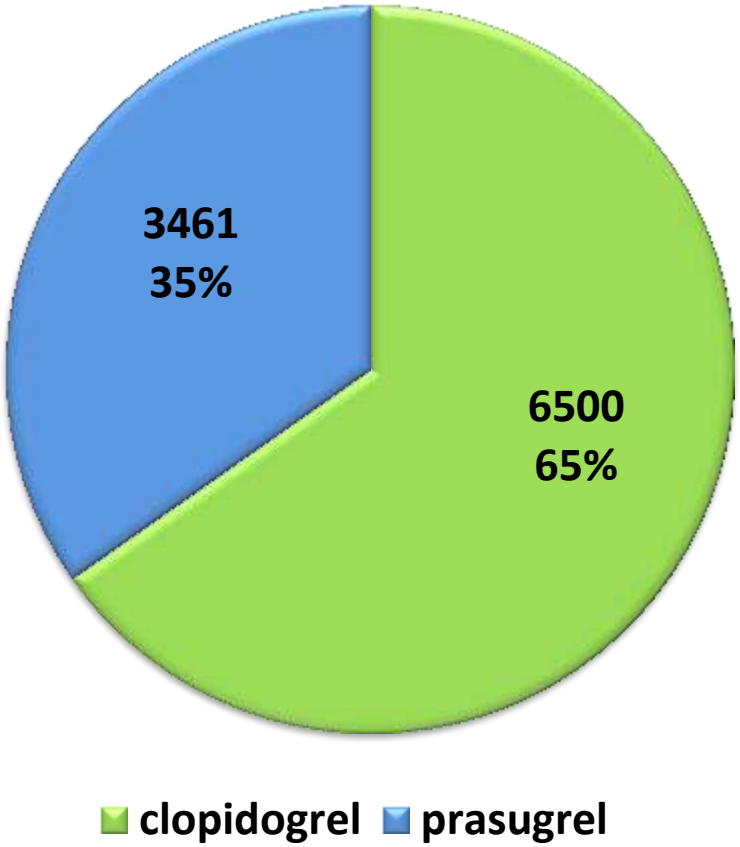


Stent & Drug Types

Drug Eluting Stent Type



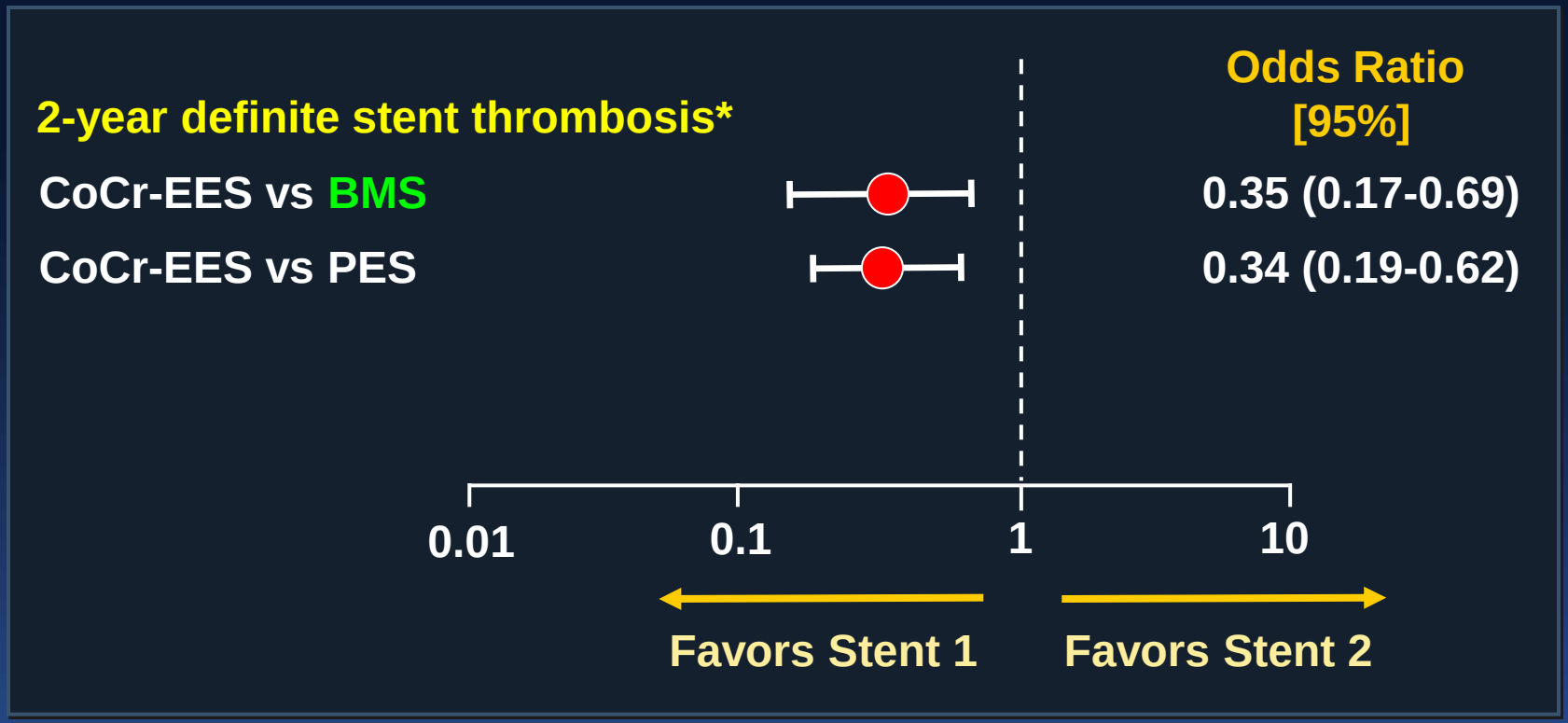
Thienopyridine Type



Stent Thrombosis Network Meta-analysis

Primary EP: ARC Definite ST (FU through 2 years)

49 RCTs, 50,844 pts



*Only statistically significant results are shown

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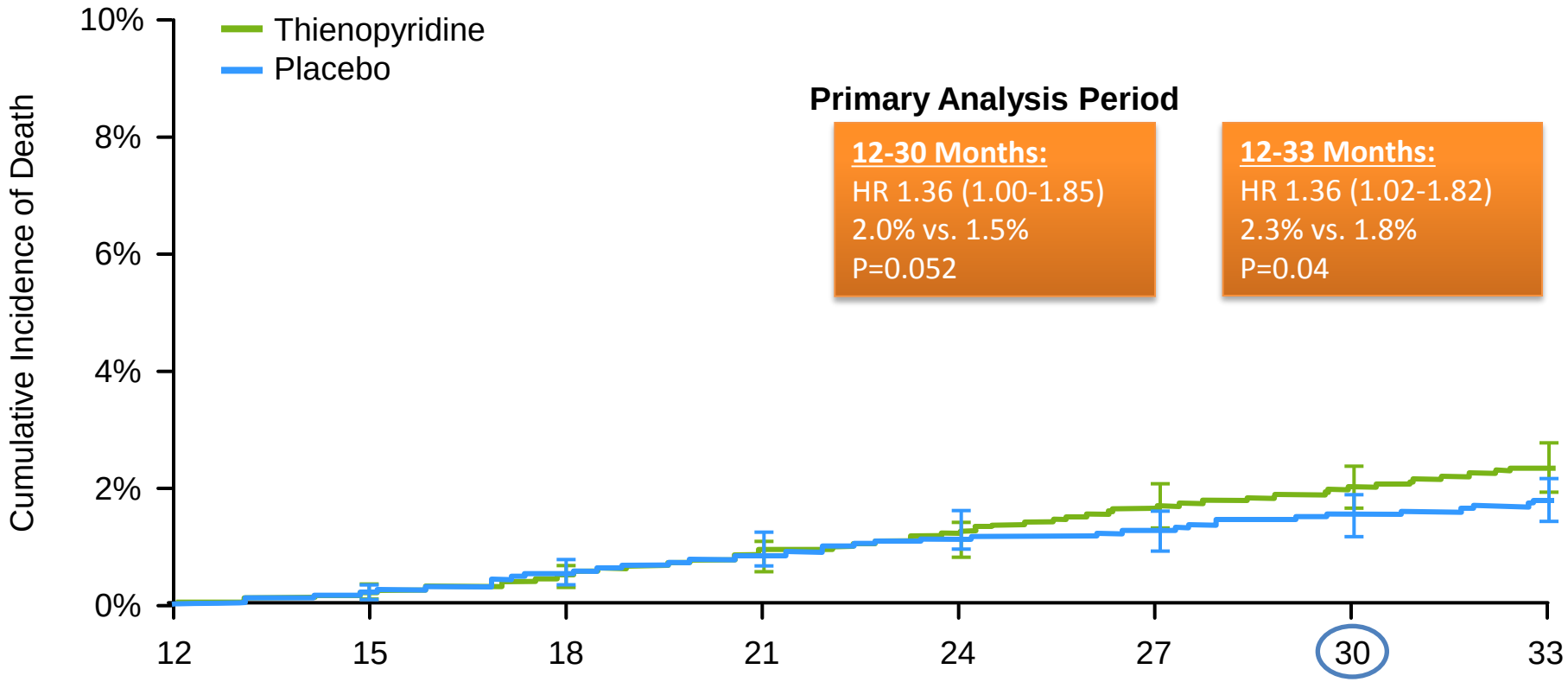
Palmerini T et al. *Lancet* 2012

All-Cause Mortality



Primary Analysis Period

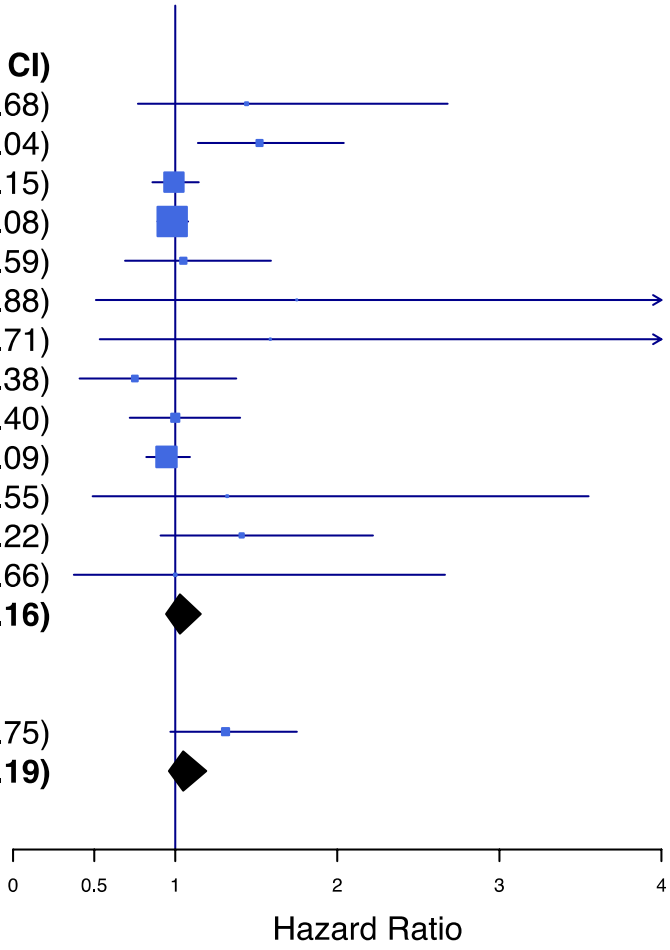
12-30 Months:
HR 1.36 (1.00-1.85)
2.0% vs. 1.5%
P=0.052

12-33 Months:
HR 1.36 (1.02-1.82)
2.3% vs. 1.8%
P=0.04

# At Risk								
Thienopyridine	5020	4936	4875	4835	4777	4703	4663	3139
Placebo	4941	4866	4805	4761	4700	4659	4618	3159

Randomized Trials of Thienopyridine+Aspirin vs. Aspirin Alone; All-Cause Mortality

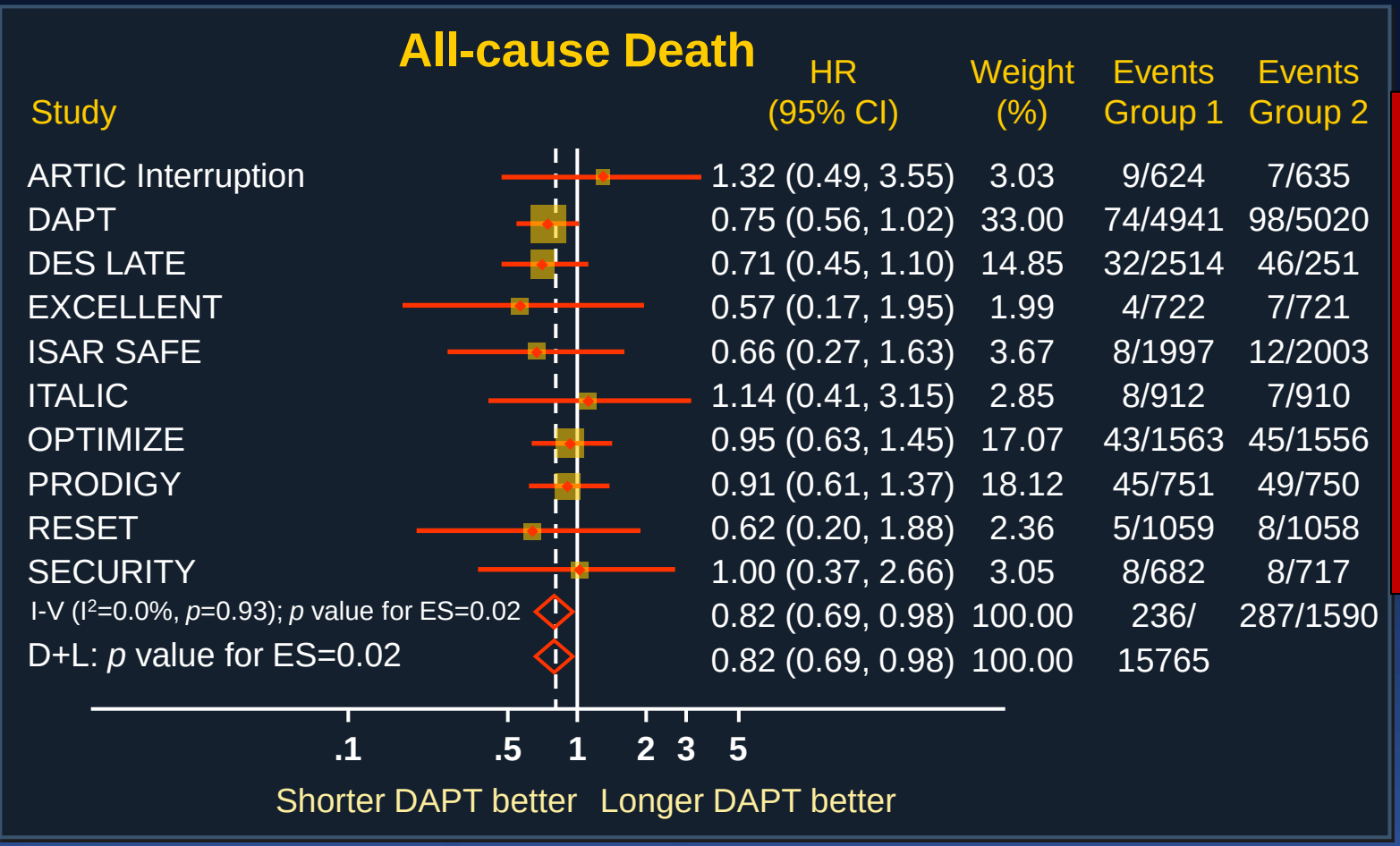
Study	Study Arm N (# Events)	Control Arm N (# Events)	HR (95% CI)
CASPAR	425(24)	426(17)	1.44 (0.77, 2.68)
SPS3	1503(113)	1517(77)	1.52 (1.14, 2.04)
CHARISMA	7802(371)	7801(374)	0.99 (0.86, 1.15)
ACTIVE	3772(825)	3782(841)	0.98 (0.89, 1.08)
OPTIMIZE	1556(45)	1553(43)	1.05 (0.69, 1.59)
EXCELLENT	721(7)	722(4)	1.75 (0.51, 5.88)
RESET	1058(8)	997(5)	1.59 (0.54, 4.71)
CREDO	1053(18)	1063(24)	0.75 (0.41, 1.38)
PRODIGY	987(65)	983(65)	1.00 (0.72, 1.40)
CURE	6259(369)	6303(390)	0.95 (0.82, 1.09)
ARCTIC–Interruption	635(7)	624(9)	1.32 (0.49, 3.55)
DES LATE	2531(46)	2514(32)	1.41 (0.91, 2.22)
SECURITY	717(8)	682(8)	1.00 (0.38, 2.66)
Overall(DAPT NOT Included)	**29019(1906)**	**28967(1889)**	**1.03 (0.94, 1.16)**
Q = 14.87, p = 0.25; I2 = 12.6%			
DAPT	5862(106)	5786(84)	1.31 (0.97, 1.75)
Overall(DAPT Included)	**34881(2012)**	**34753(1973)**	**1.05 (0.96, 1.19)**
Q = 17.68, p = 0.17; I2 = 26.5%			



Total N=69644, ~139000 pt yrs)

Elmariah S, Mauri L, Doros G, O'Neill KE, Steg PG, Kereiakes DJ, Yeh RW. Extended Duration Dual Antiplatelet Therapy and Mortality: A Systematic Review and Meta-analysis. *The Lancet*. Online ahead of print November 16, 2014.

Mortality with Extended Duration DAPT After DES: A Pairwise and Bayesian Network Meta-Analysis of 10 RCTs and 31,666 Pts



22% ↑ mortality with prolonged DAPT (p=0.02)

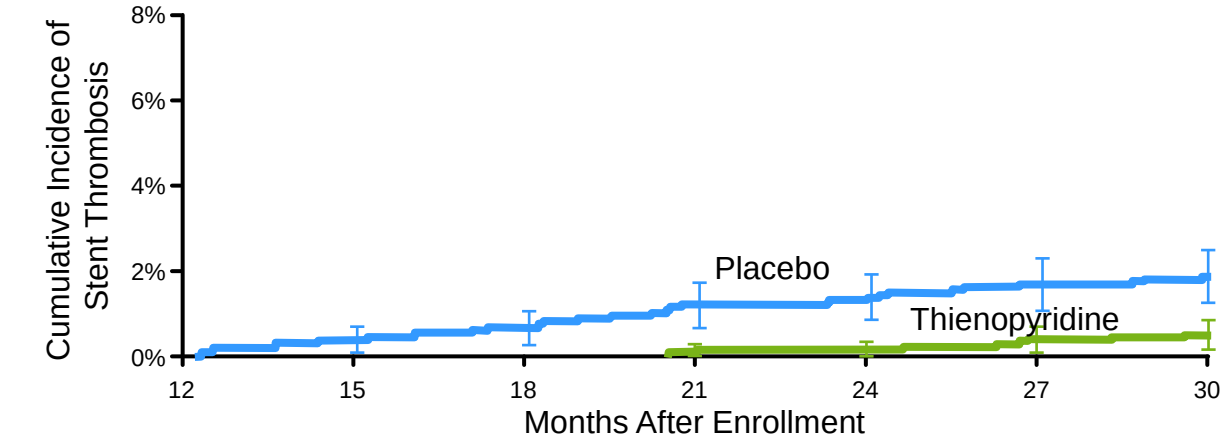
ES=effect size

Palmerini T and Stone GW. Lancet 2015: In press

Continued Thienopyridine vs. Placebo in Patients With and Without ACS: Stent Thrombosis

DAPT STUDY

ACS Patients

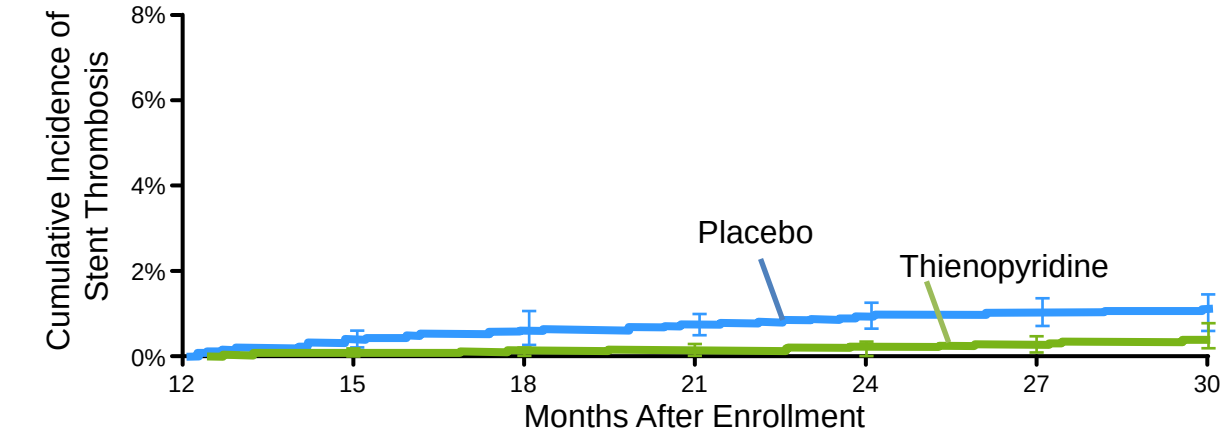


Thienopyridine	1802	1790	1769	1750	1729	1705	1680
Placebo	1766	1748	1719	1693	1659	1629	1602

1.9%
0.5%

HR 0.27 (0.13-0.57)
p<0.001

Non-ACS Patients



Thienopyridine	4050	4015	3959	3918	3881	3822	3771
Placebo	4008	3979	3918	3873	3833	3785	3747

1.1%
0.4%

HR 0.33 (0.18-0.60)
p<0.001

All DES and BMS randomized patients

Interaction
P = 0.69

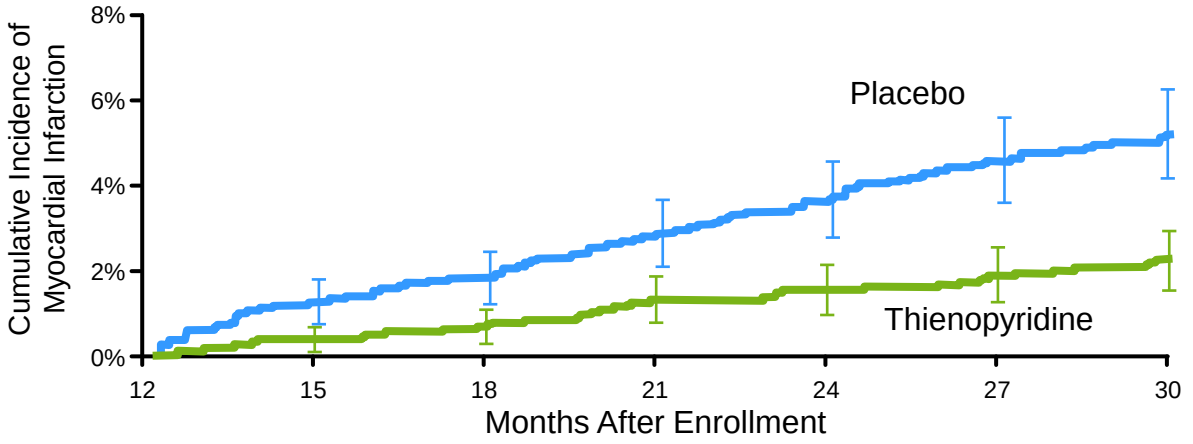
R. Yeh ACC 2015

Continued Thienopyridine vs. Placebo in Patients With and Without ACS: Myocardial Infarction

DAPT STUDY

ACS Patients

All DES and BMS randomized patients

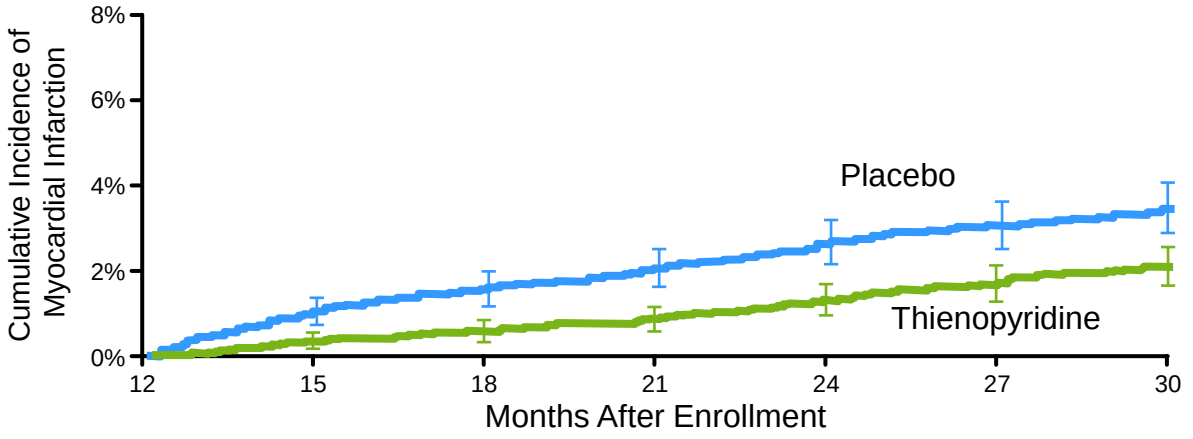


Thienopyridine	1802	1790	1762	1738	1709	1683	1656
Placebo	1766	1748	1704	1675	1633	1594	1558

HR 0.42 (0.29-0.62)
p<0.001

Interaction
P = 0.15

Non-ACS Patients



Thienopyridine	4050	4016	3974	3914	3876	3818	3746
Placebo	4008	3979	3893	3839	3786	3724	3677

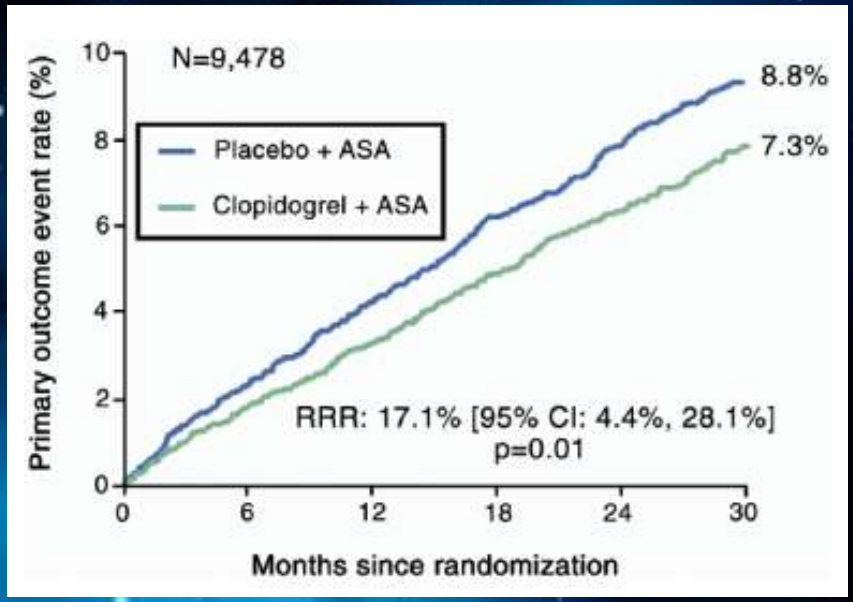
HR 0.60 (0.45-0.79)
p<0.001

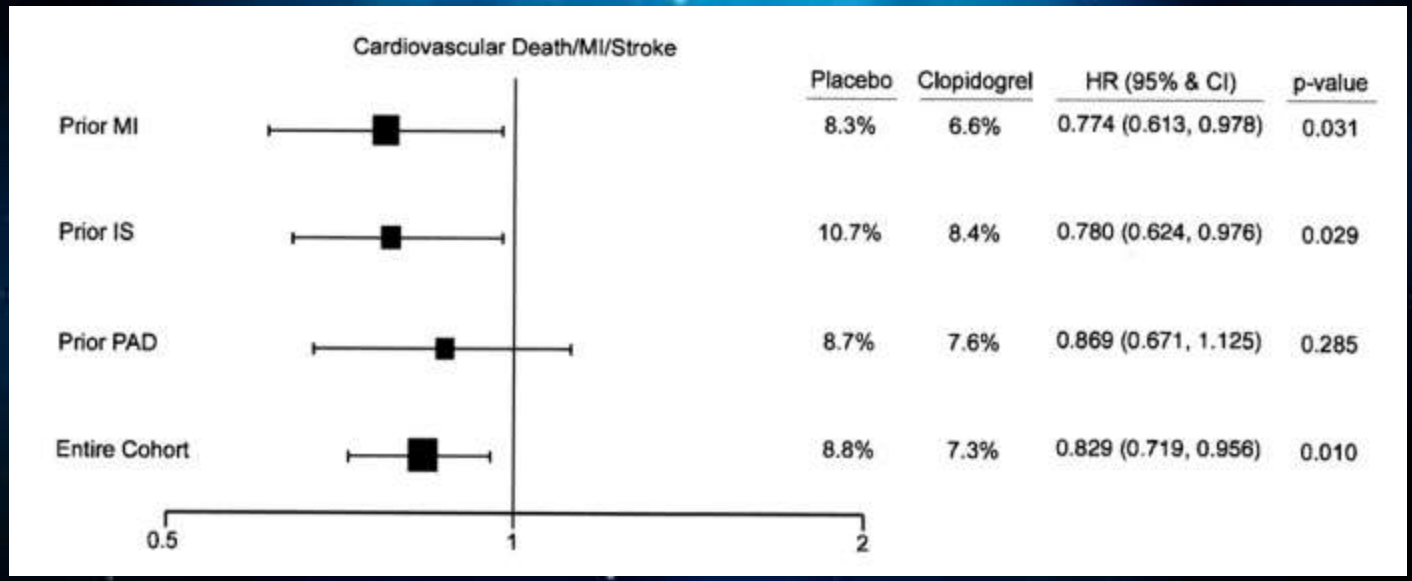
R. Yeh ACC 2015

Who may benefit of prolonged DAPT?

Subgroup analysis in patients at high atherothrombotic risk (prior MI, stroke or peripheral arterial disease) from the CHARISMA trial (DAPT versus aspirin for 28 months in 15,603 patients with CAD or multiple risk factors)

Lower risk of cardiac death / MI / stroke in patients on DAPT!

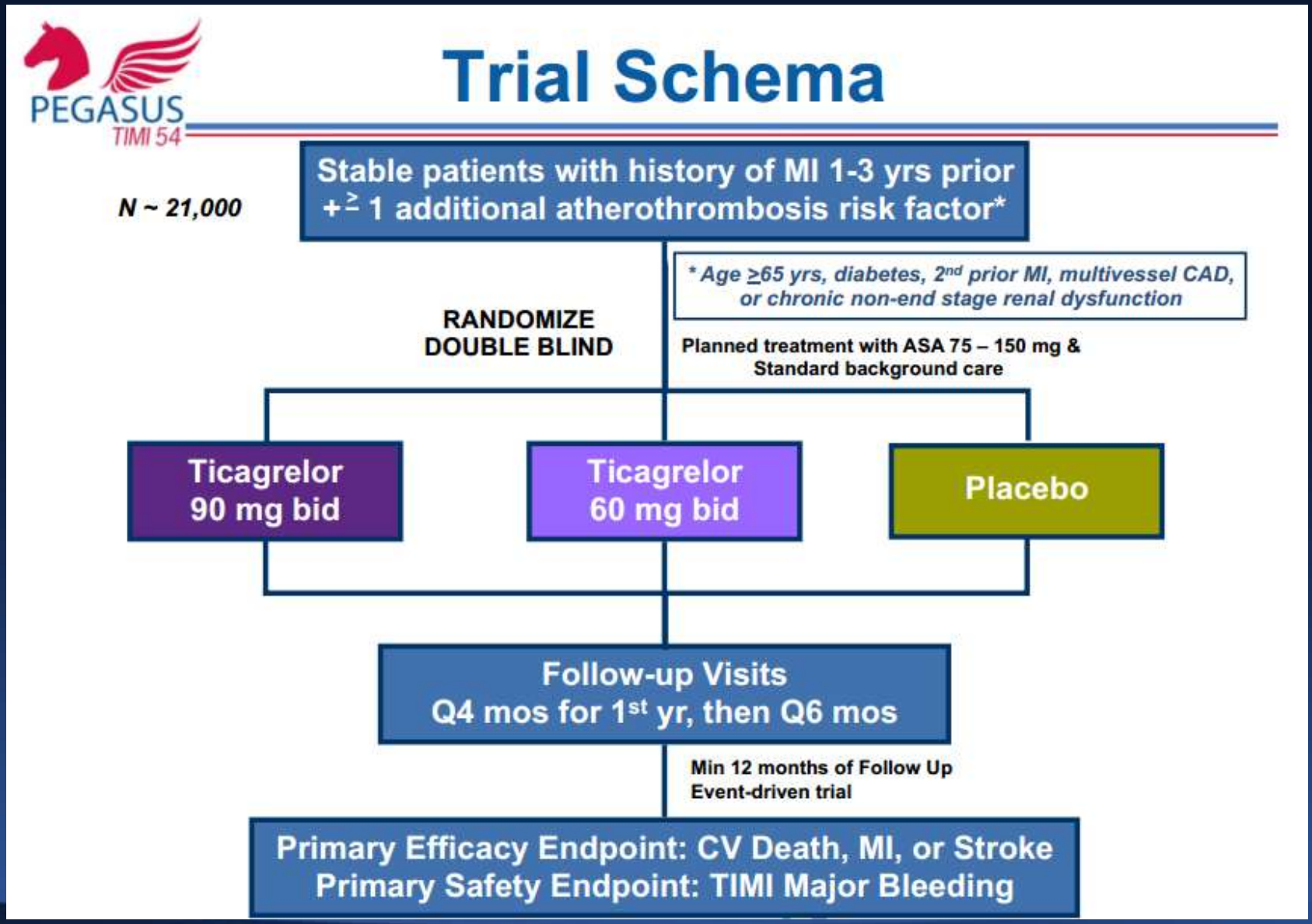




Mount Sinai Heart

Bhatt et al - JACC Vol. 49, No. 19, 2007

PEGASUS-TIMI 54 Trial



Mount Sinai Heart

Key Inclusion & Exclusion Criteria

KEY INCLUSION

- Age ≥50 years
- At least 1 of the following:
  - Age ≥65 years
  - Diabetes requiring medication
  - 2nd prior MI (>1 year ago)
  - Multivessel CAD
  - CrCl <60 mL/min
- Tolerating ASA and able to be dosed at 75-150 mg/d

KEY EXCLUSION

- Planned use of $P2Y_{12}$ antagonist, dipyridamole, cilostazol, or anticoag
- Bleeding disorder
- History of ischemic stroke, ICH, CNS tumor or vascular abnormality
- Recent GI bleed or major surgery
- At risk for bradycardia
- Dialysis or severe liver disease

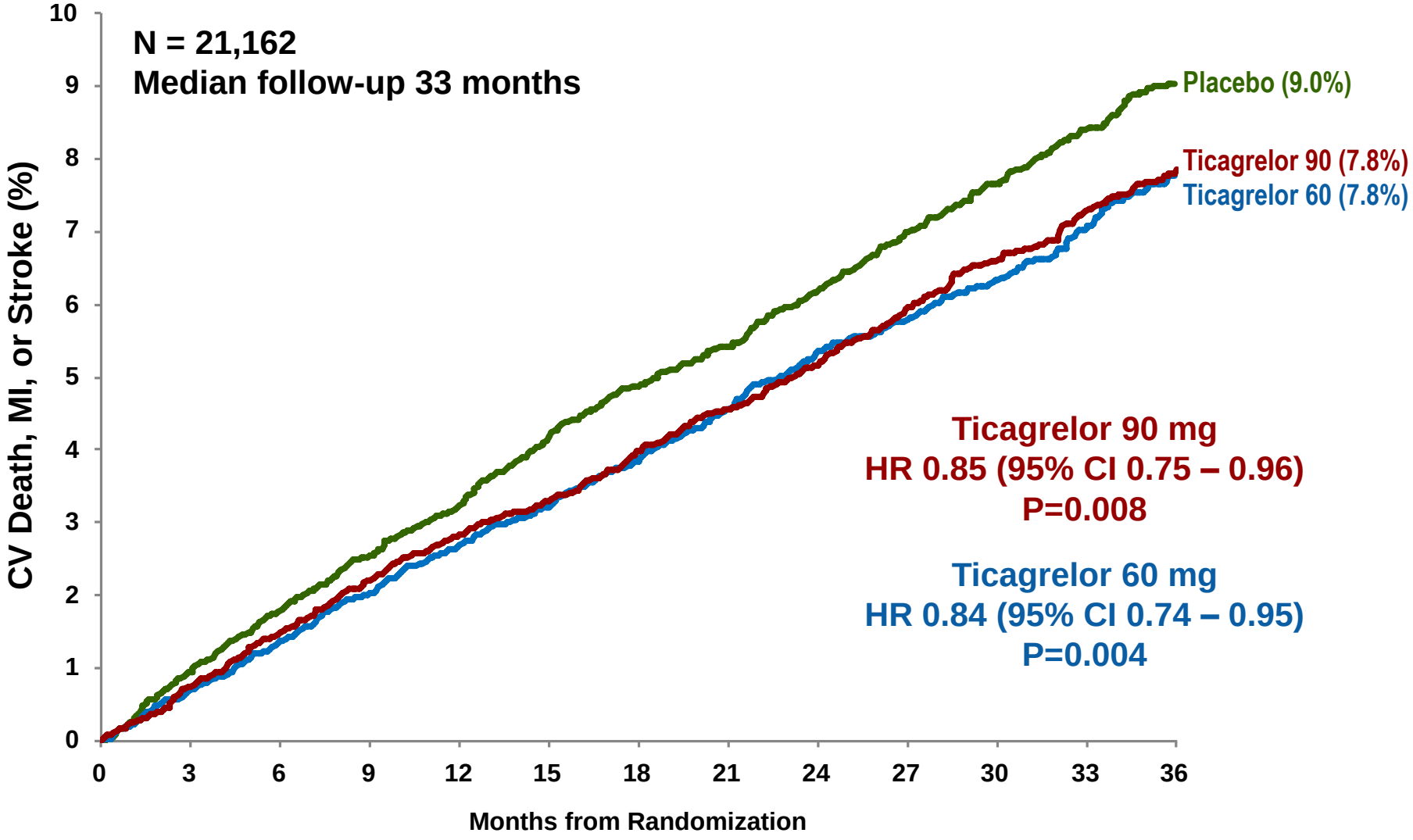
Bonaca MP et al. *Am Heart J* 2014;167:437-44

Baseline Characteristics

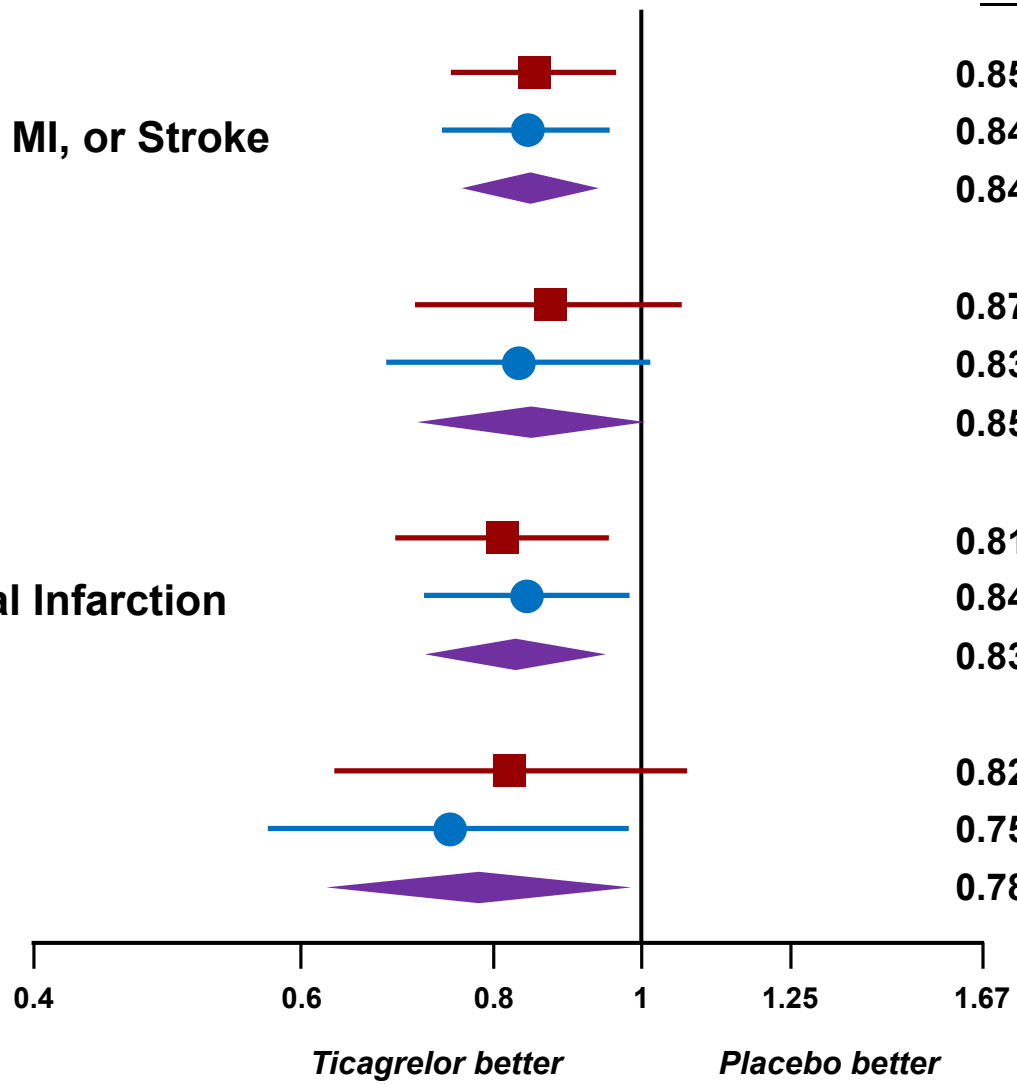
Characteristic	Value
Age – yr, mean (SD)	65 (8)
Female	24
Hypertension	78
Hypercholesterolemia	77
Current smoker	17
Diabetes mellitus	32
Estimated GFR <60 mL/min/1.73m^2	23
History of PCI	83
Multivessel coronary disease	59
History of more than 1 prior MI	17

No difference between treatment arms.
Values for categorical variables are %.

Primary Endpoint



Components of Primary Endpoint



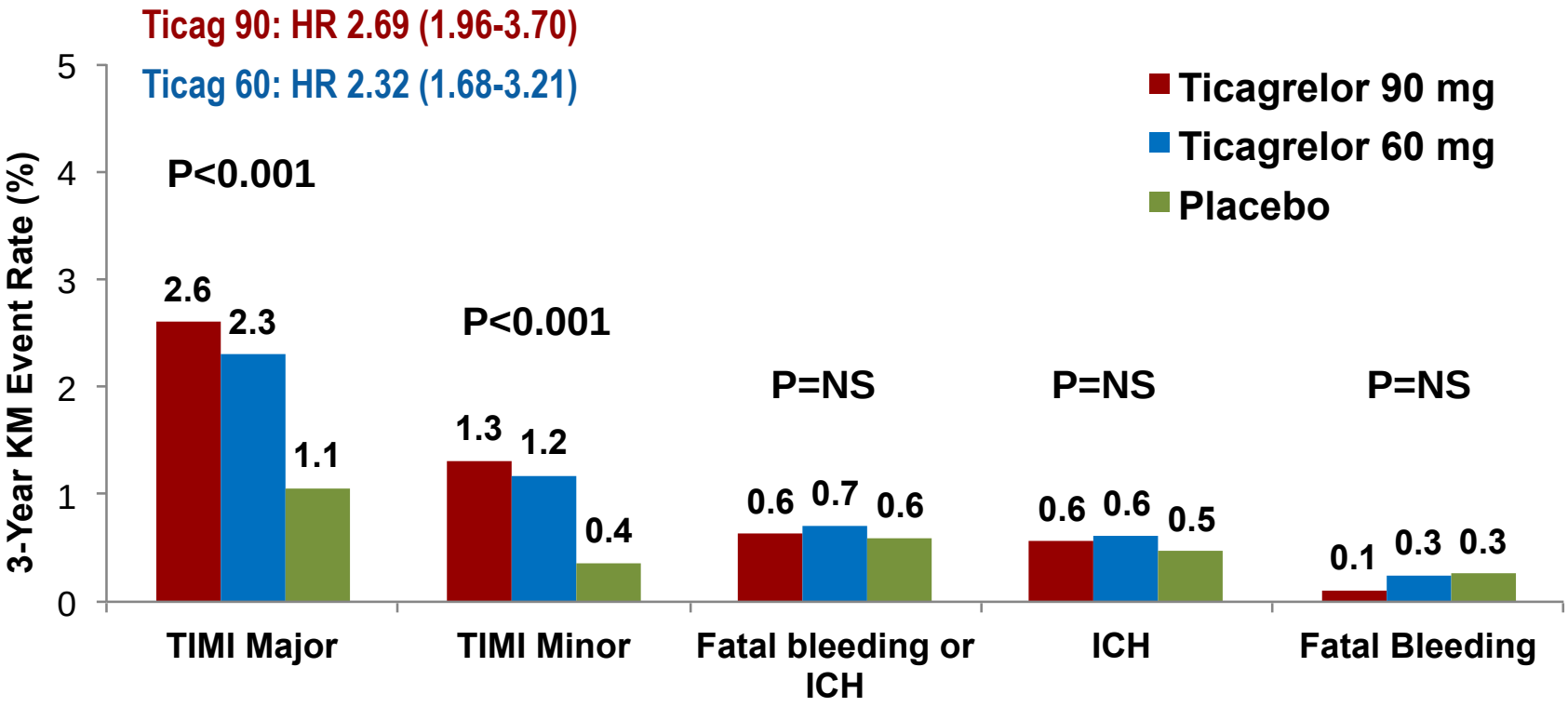
Endpoint	HR (95% CI)	P value
CV Death, MI, or Stroke (1558 events)	0.85 (0.75-0.96)	0.008
	0.84 (0.74-0.95)	0.004
	0.84 (0.76-0.94)	0.001
CV Death (566 events)	0.87 (0.71-1.06)	0.15
	0.83 (0.68-1.01)	0.07
	0.85 (0.71-1.00)	0.06
Myocardial Infarction (898 events)	0.81 (0.69-0.95)	0.01
	0.84 (0.72-0.98)	0.03
	0.83 (0.72-0.95)	0.005
Stroke (313 events)	0.82 (0.63-1.07)	0.14
	0.75 (0.57-0.98)	0.03
	0.78 (0.62-0.98)	0.03

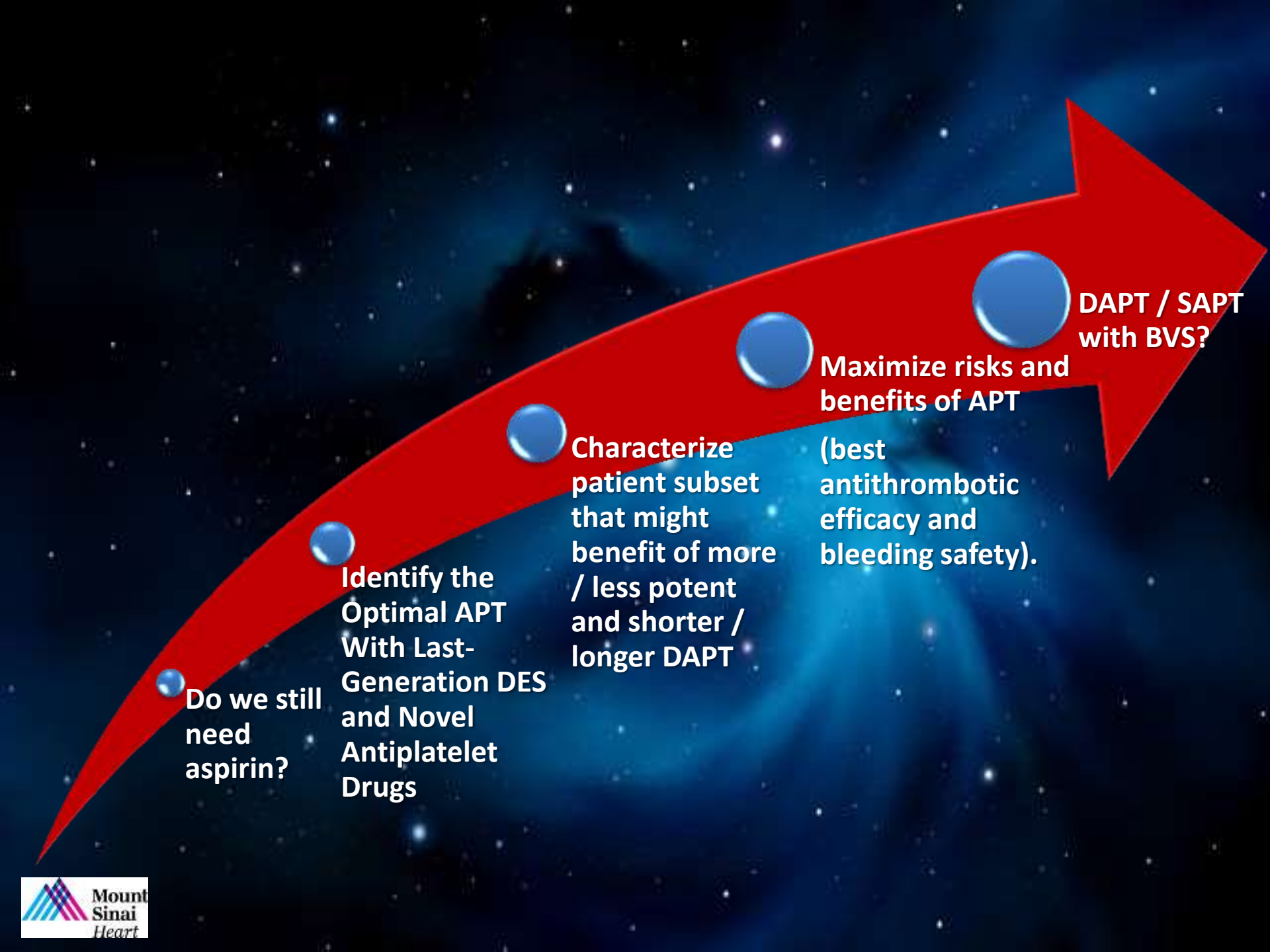
Ticagrelor 90 mg
Ticagrelor 60 mg
Pooled

Other Efficacy Outcomes

Outcome	Ticagrelor 90 mg bid (N=7050)	Ticagrelor 60 mg bid (N=7045)	Placebo (N=7067)	Ticagrelor 90 vs Placebo p-value	Ticagrelor 60 vs Placebo p-value
	3-yr KM rate (%)				
Coronary Death, MI, or Stroke	7.0	7.1	8.3	HR 0.82 P=0.002	HR 0.83 P=0.003
Coronary Death or MI	5.6	5.8	6.7	HR 0.81 P=0.004	HR 0.84 P=0.01
Coronary Death	1.5	1.7	2.1	HR 0.73 P=0.02	HR 0.80 P=0.09
Death from any cause	5.2	4.7	5.2	HR 1.00 P=0.99	HR 0.89 P=0.14

Bleeding

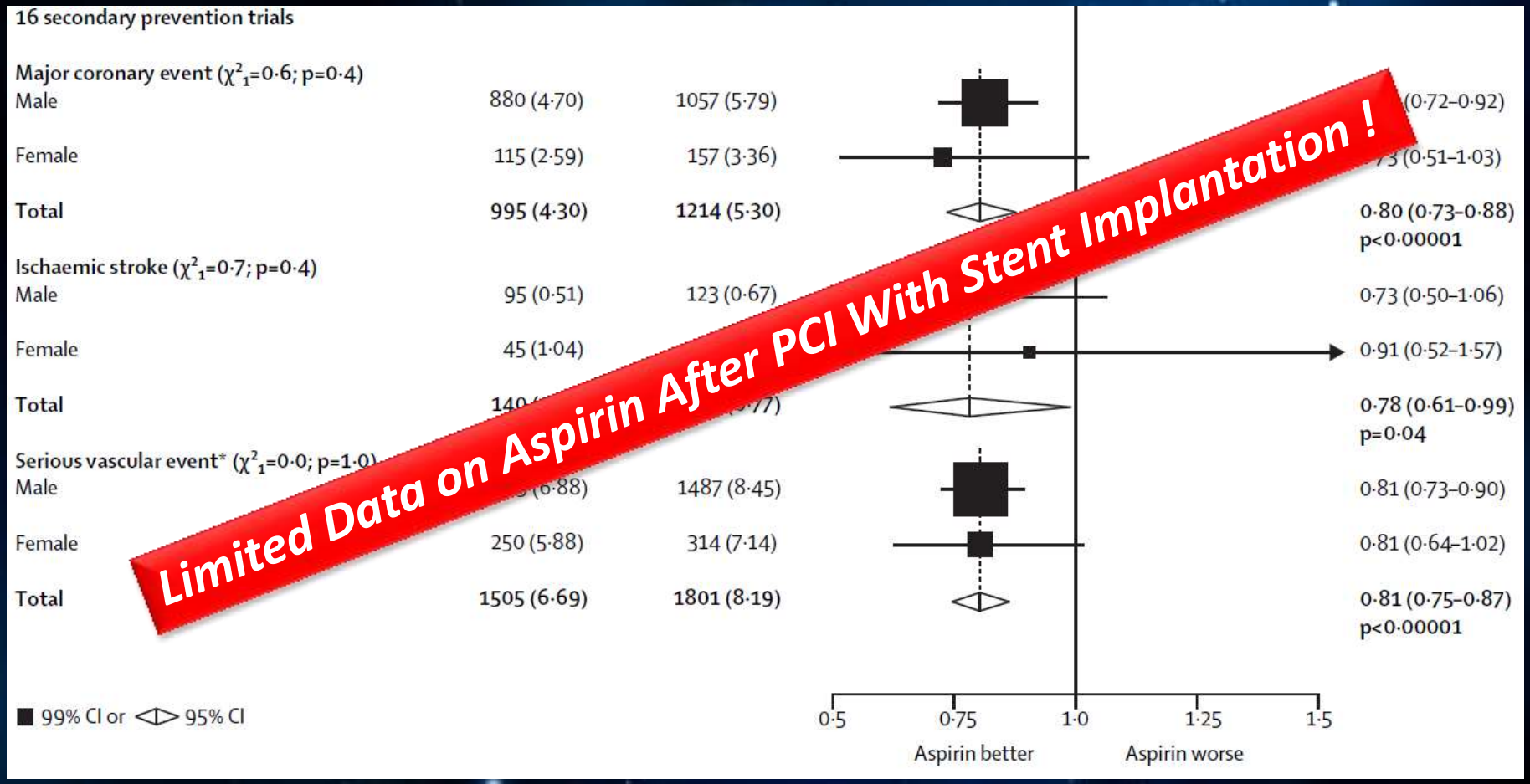

Ticag 90: HR 2.69 (1.96-3.70)
Ticag 60: HR 2.32 (1.68-3.21)
Ticagrelor 90 mg
Ticagrelor 60 mg
Placebo
3-Year KM Event Rate (%)
0
1
2
3
4
5
P<0.001
2.6
2.3
1.1
P<0.001
1.3
1.2
0.4
P=NS
0.6
0.7
0.6
P=NS
0.6
0.6
0.5
P=NS
0.1
0.3
0.3
TIMI Major
TIMI Minor
Fatal bleeding or ICH
ICH
Fatal Bleeding



Mount Sinai Heart

Aspirin in Secondary Prevention

Antithrombotic Trialists Collaboration. Lancet 2009; 373:1849–60



Limited Data on Aspirin After PCI With Stent Implantation !

16 Secondary Prevention Trials – 43,000 Patient-Years

Mount Sinai Heart

Bleeding Risk With ASA

Study	Study Type	Comparators	Relative Bleeding Increase
Baigent et al., Lancet 2009	Pooled Data from Randomized trials	ASA vs. placebo/control	50% (1° prev) 170% (2° prev)
WOEST, Lancet 2013	RCT	ASA vs. placebo	~ 60%
CAPRIE, Lancet 1996	RCT	ASA vs. Clopidogrel	~35% (GI hemorrhage)
Physician Health Study, NEJM 1989	RCT	ASA vs. Placebo	~35%
De Berardis et al., JAMA 2012	Cohort study	ASA vs. No ASA	55%
Seshasai et al., Archives Int Med 2012	Meta-analysis of 9 RCTs	ASA vs. Placebo	~31%
HOT Trial, Lancet 1998	RCT	ASA vs. Placebo	~ 80%

Is Withdrawal of ASA Safe?

Therapy	N	Time to Cessation (days)	% patients that d/c therapy < 1 year	Number of patients with ST or AMI	Proportion of patients with ST or AMI during study (p = 0.27)	ST or AMI annual rate
Permanent d/c Aspirin + Clopidogrel	118	459 ± 408	40.9%	1	0.85%	0.25%
Permanent d/c Aspirin	187	338 ± 411	69.9%	0	0.00%	0.00%
Permanent d/c Clopidogrel	713	614 ± 375	17.5%	4	0.56%	0.15%
Uninterrupted DAPT	4070	-	-	47	1.16%	0.43%

Groups are mutually exclusive (patients were only assigned to a single group).

Kovacic et al., JIC 2012

Mount Sinai Heart

Use of clopidogrel with or without aspirin in patients taking oral anticoagulant therapy and undergoing percutaneous coronary intervention: an open-label, randomised, controlled trial

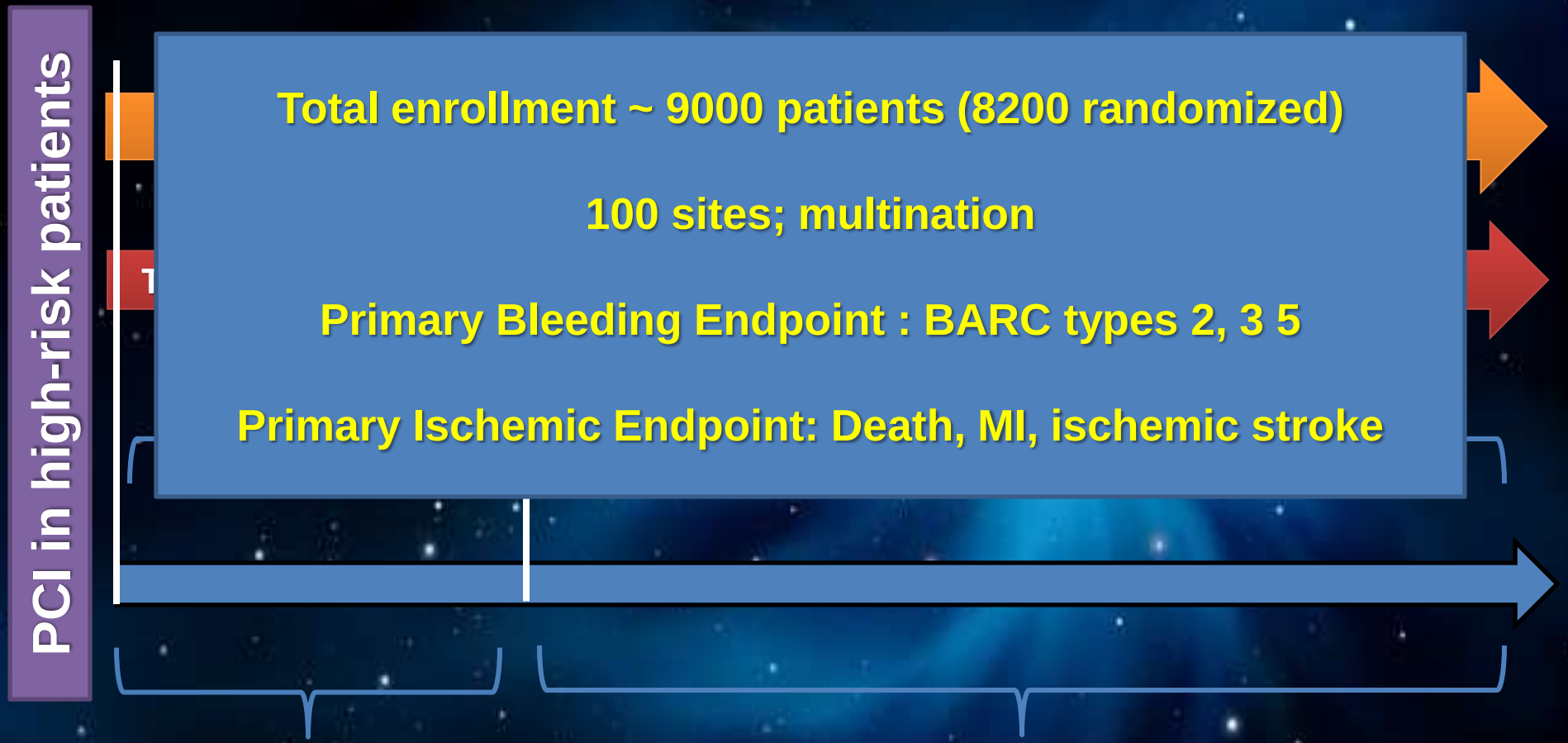
Willem J M Dewilde, Tom Oirbans, Freek W A Verheugt, Johannes C Kelder, Bart J G L De Smet, Jean-Paul Herrman, Tom Adriaenssens, Mathias Vrolix, Antonius A C M Heestermans, Marije M Vis, Jan G P Tijsen, Arnoud W van 't Hof, Jurriën M ten Berg, for the WOEST study investigators

	Double therapy (n-279)	Triple therapy (n=284)	Hazard ratio (95% CI)	p value
Any bleeding event	54 (19·4%)	126 (44·4%)	0·36 (0·26–0·50)	<0·0001
TIMI bleeding				
Major	9 (3·2%)	16 (5·6%)	0·56 (0·25–1·27)	0·159
Major and minor	39 (14·0%)	89 (31·3%)	0·40 (0·27–0·58)	<0·0001
GUSTO bleeding				
Severe	4 (1·4)	10 (3·5%)	0·40 (0·12–1·27)	0·119
Severe and moderate	15 (5·4%)	35 (12·3%)	0·42 (0·23–0·76)	0·003
BARC bleeding				
3	18 (6·5%)	36 (12·7%)	0·49 (0·28–0·86)	0·011
3c	3 (1·1%)	3 (1·1%)	1·00 (0·20–4·90)	0·996
3b	6 (2·2%)	14 (5·0%)	0·43 (0·17–1·10)	0·074
3a	9 (3·2%)	19 (6·7%)	0·47 (0·21–1·00)	0·054·
2	23 (8·2%)	59 (20·8%)	0·36 (0·23–0·59)	<0·0001
2+3	40 (14·3%)	90 (31·7%)	0·40 (0·28–0·58)	<0·0001
1	18 (6·5%)	45 (15·8%)	0·38 (0·22–0·66)	0·0004
Any blood transfusion	11 (3·9%)	27 (9·5%)	0·39* (0·17–0·84)	0·011

Higher risk for bleeding in patients with atrial fibrillation treated with Warfarin + Clopidogrel + Aspirin versus Warfarin + Clopidogrel alones

Mount Sinai Heart

Dual Antiplatelet Therapy After PCI: The TWILIGHT Study

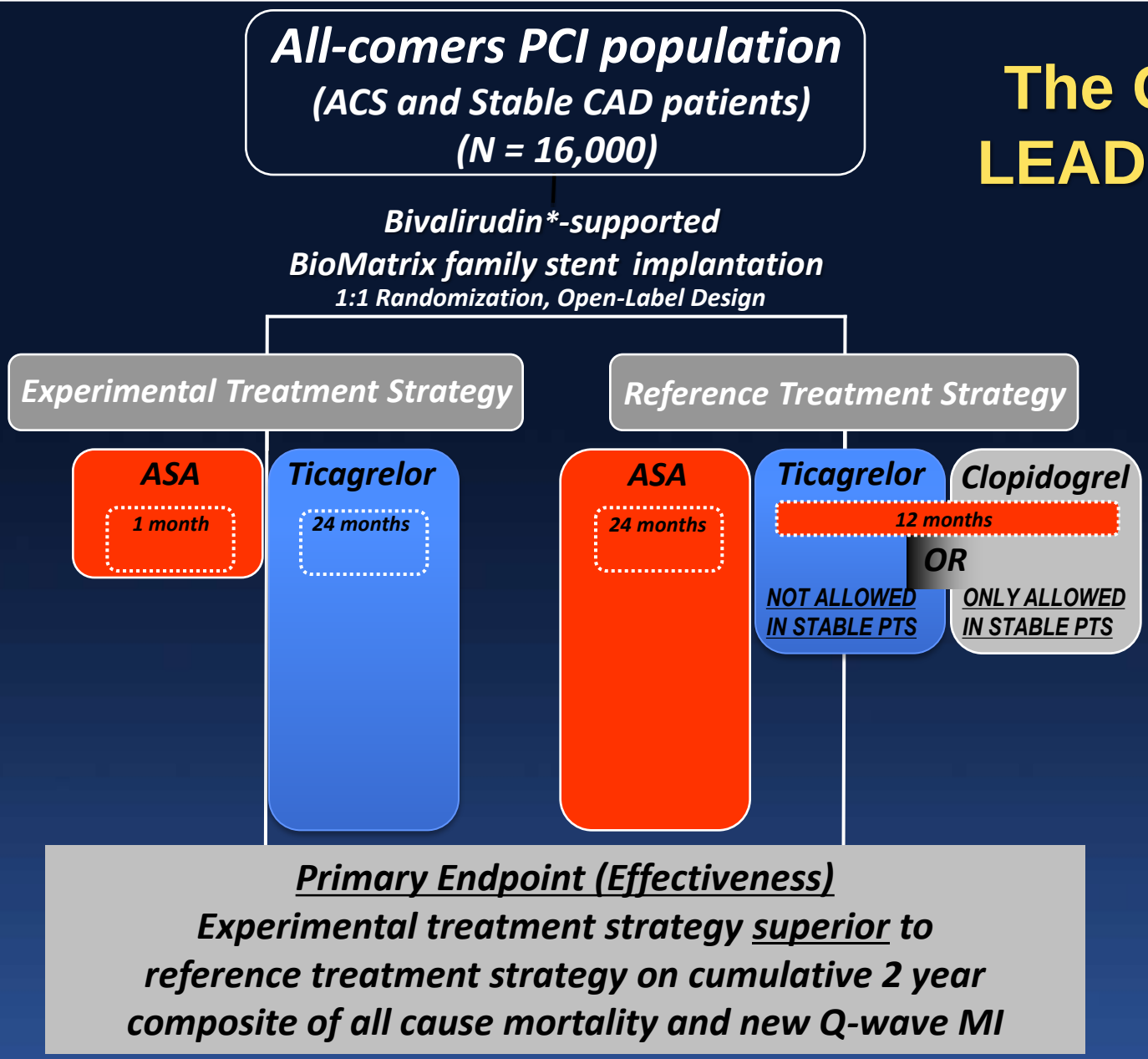


Short course of DAPT to minimize stent-related thrombotic events

Monotherapy with a potent platelet inhibitor protects against systemic thrombosis while reducing ASA-related bleeding

Mount Sinai Heart

The GLOBAL LEADERS Trial

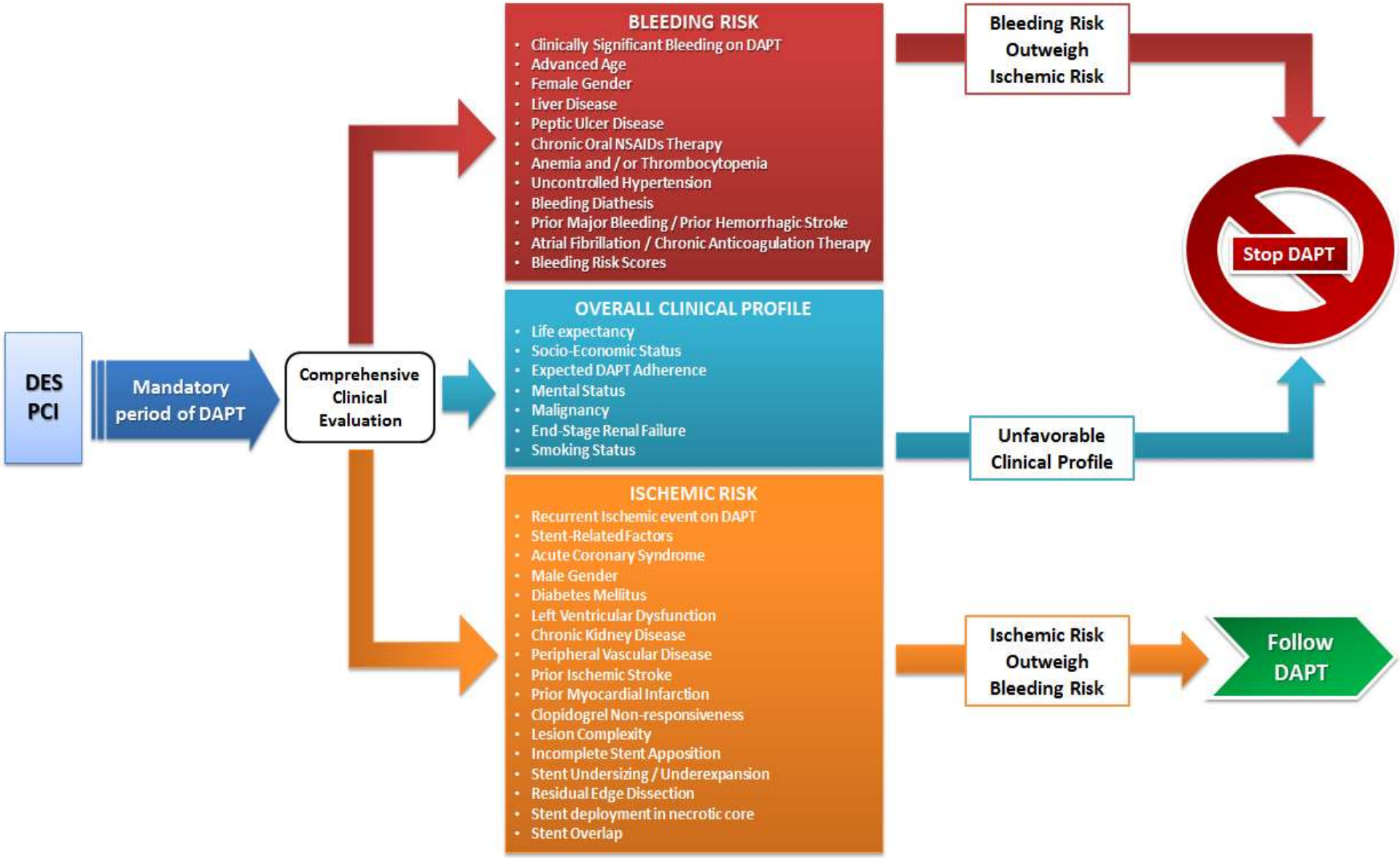


IMPORTANT: In the Reference Treatment Strategy arm, ticagrelor is not allowed in stable patients, and clopidogrel must be given in combination with ASA. However, patients already on stable maintenance treatment with ticagrelor (or prasugrel) can continue with ticagrelor treatment (for 12 months post index-PCI).

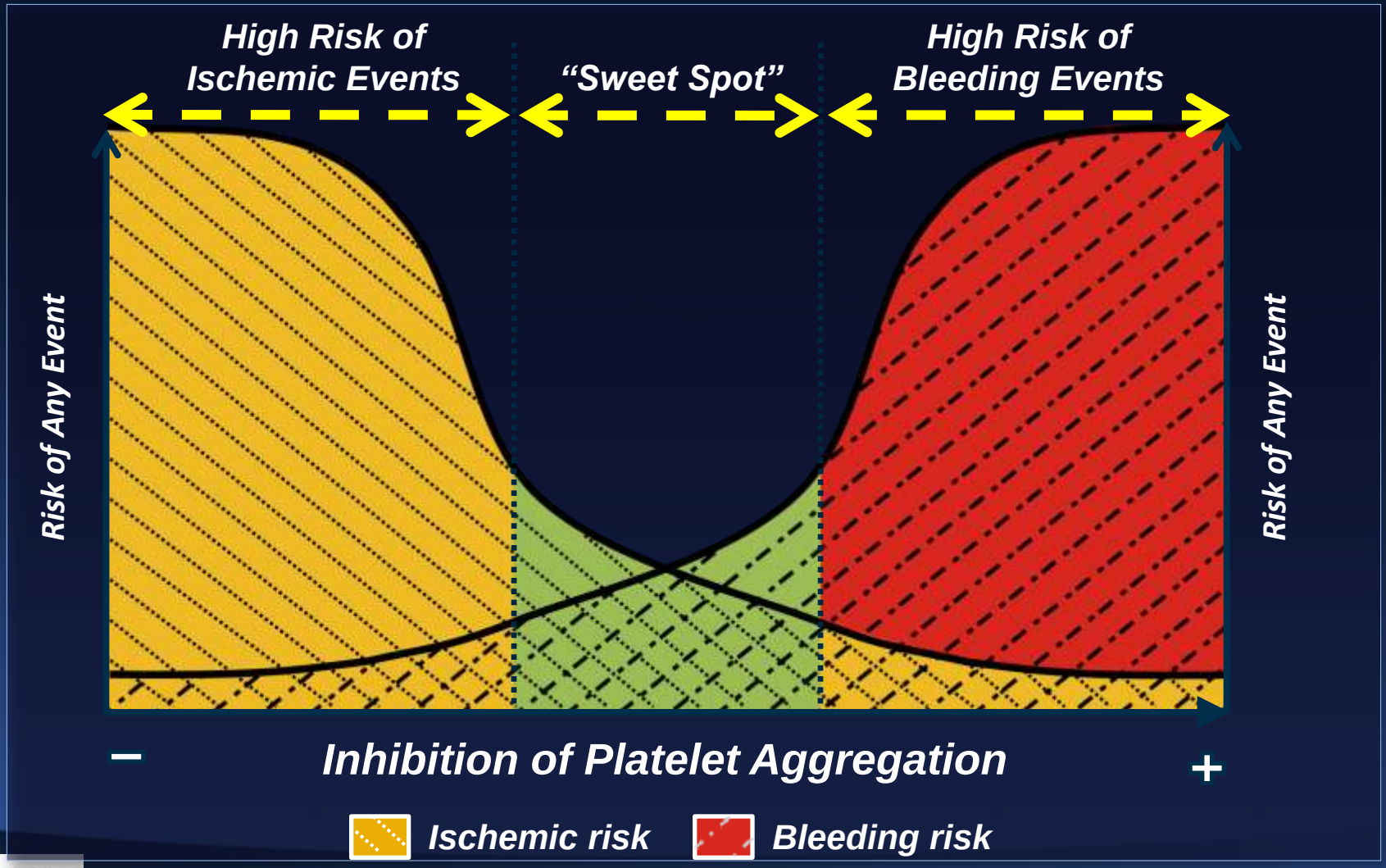
* In countries where available.

Mount Sinai Heart

The Clinician Choice: Implication for Dual Antiplatelet Therapy



Balancing Safety and Efficacy



Mount Sinai Heart

Ferreiro JL, Sibbing D, et al. Thromb Haemost. 2010;103(6):1128-1135.