Lo más relevante 2014:
Cardiólogo Intervencionista

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Madrid - Spain

ACC Annual Scientific Session
Washington, DC | March 29–31, 2014

ACC 2014

HEAT - ICP primaria

ACC Annual Scientific Session
Washington, DC | March 29–31, 2014

- **Único Centro: 1812 pacientes analizados**
- **Heparina 70 U/kg vs Bivalirudina 0,75 mg/kg bolus + Infusión 1,75 mg/kg/h durante procedimiento**
  - Abciximab solamente “bailout” (15,5% hepa y 13,5% biva)
  - Ticagrelor 62% pacientes, Prasugrel 27% y Clopidogrel 11%
  - Trombectomía: 59% y 57,6%
  - DES 79,8% y 79,9%
  - Radial: 80% y 80%
- **“Consentimiento tardío”**

MACE Outcome - All Events

	Bivalirudin			Heparin	
	n	%		%	n
Death	46	5.1 %	v	4.3 %	39
CVA	15	1.6%	v	1.2%	11
Reinfarction	24	2.7%	v	0.9%	8
TLR	24	2.7%	v	0.7%	6
Any MACE	79	8.7 %	v	5.7 %	52

Stent Thrombosis

ARC definite or probable stent thrombosis events

	Bivalirudin			Heparin	
	n	%		%	n
All Events	24	3.4 %	v	0.9 %	6

Relative risk = 3.91 (95% CI 1.6 - 9.5) P=0.001

Primary Safety Outcomes

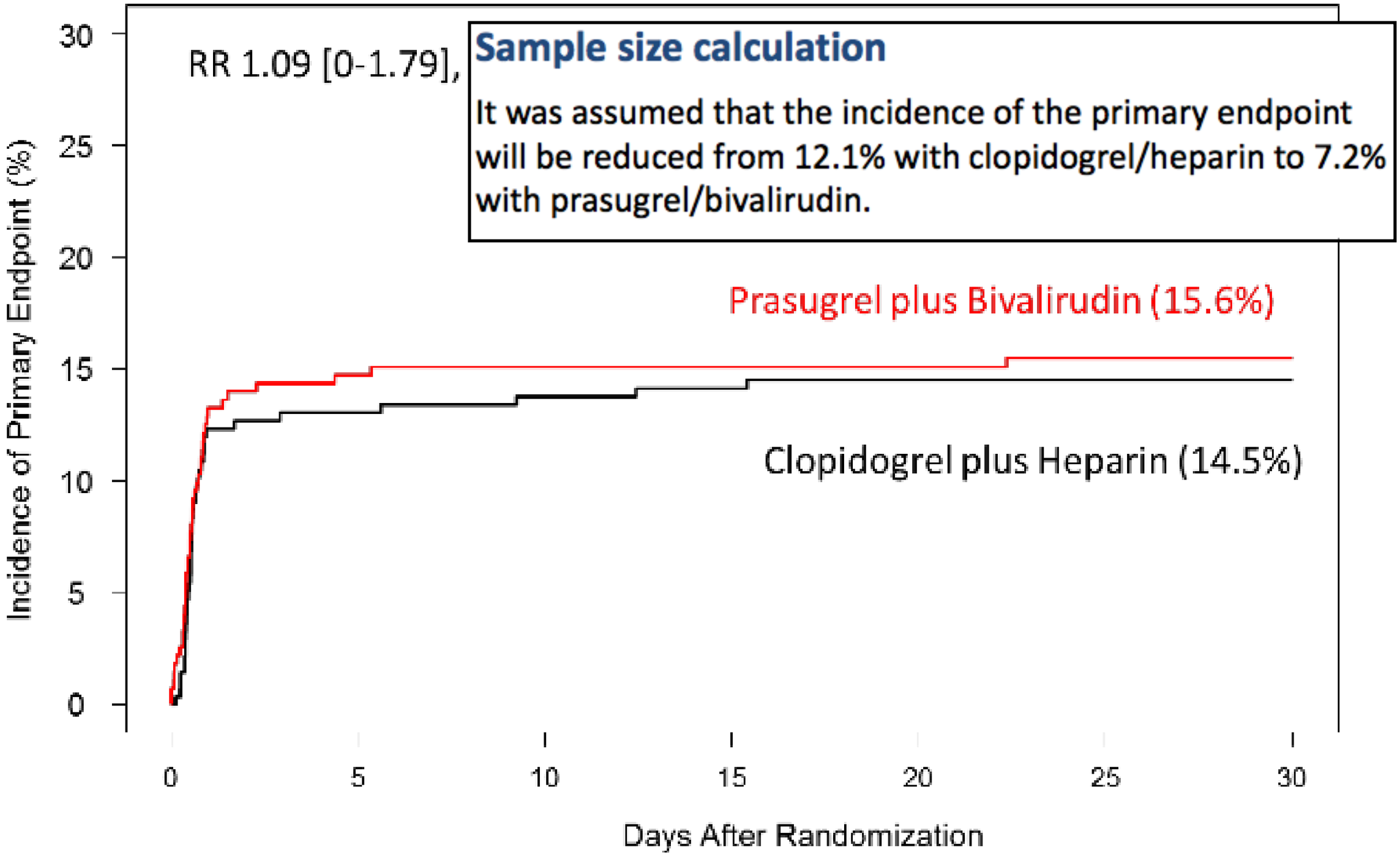
Major Bleed BARC grade 3-5

	Bivalirudin			Heparin	
	n	%		%	n
Major Bleed	32	3.5 %	v	3.1 %	28

Relative risk = 1.15 (95% CI 0.7 - 1.9) P=0.59

Primary Endpoint

Composite of death, myocardial infarction, unplanned revascularization of the infarct-related artery, stent thrombosis, stroke or major bleeding



Sample size calculation

It was assumed that the incidence of the primary endpoint will be reduced from 12.1% with clopidogrel/heparin to 7.2% with prasugrel/bivalirudin.

ESC 2014


ESC CONGRESS
BARCELONA 2014
30 Aug - 3 Sept
EUROPEAN SOCIETY OF CARDIOLOGY

ISRCTN 70913605

CvLPRIT

UK open-label randomised study
comparing

treatment of IRA only
with
complete revascularisation at index admission

randomisation was stratified for
- site of infarct (anterior/non-anterior)
- symptom onset to balloon time (< or >3 hours)

included CMR and nuclear sub-studies

: The primary endpoint was MACE :
composite of total mortality, recurrent MI, heart failure and ischaemia-driven revascularisation at 12 months

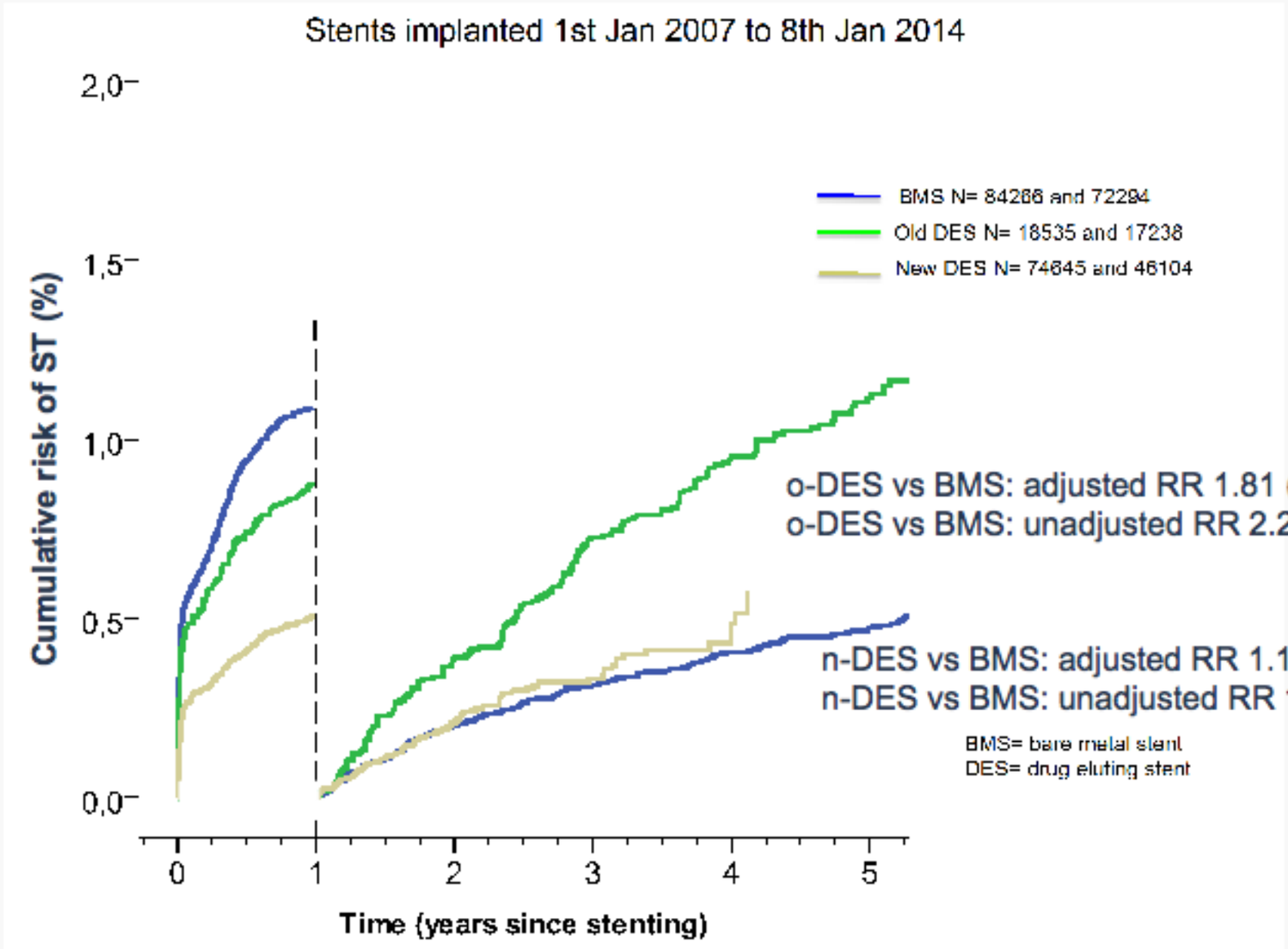
CvLPRIT

Variable	IRA only (N=146)	Complete Revascularisation (N=150)	HR (95% CI)	P value
Time to First Event				
MACE N= (%)	*31 (21.2)*	*15 (10.0)*	*0.45 (0.24, 0.84)*	*0.009*
Components N=(%)				
All-cause mortality	*6 (4.1)*	*2 (1.3)*	*0.32 (0.06, 1.60)*	*0.14*
Recurrent MI	*4 (2.7)*	*2 (1.3)*	*0.48 (0.09, 2.62)*	*0.39*
Heart failure	*9 (6.2)*	*4 (2.7)*	*0.43 (0.13, 1.39)*	*0.14*
Repeat Revascularisation	*12 (8.2)*	*7 (4.7)*	*0.55 (0.22, 1.39)*	*0.2*
Safety N= (%)				
CV mortality	*7 (4.8)*	*2 (1.3)*	*0.27 (0.06, 1.32)*	*0.11*
Stroke	*2 (1.4)*	*2 (1.3)*	*0.95 (0.13, 6.77)*	*0.96*
Major Bleed	*7 (4.8)*	*4 (2.7)*	*0.55 (0.16, 1.87)*	*0.34*
CIN	*2(1.4)*	*2 (1.4)*	*0.94 (013,6.75)*	*0.95*

SCAAR: Lower late and very late stent thrombosis rates with new generation drug eluting stents compared to bare metal stents

- We analyzed all implantations with BMS, o-DES (Cypher (Cordis), Taxus Liberté (Boston Scientific) and Endeavor (Medtronic)) and n-DES (Endeavor Resolute, Resolute Integrity (Medtronic Inc.), XienceV, Xience Prime/Xpedition (Abbott Laboratories), Promus, Promus Element/Plus (Boston Scientific Corporation), Nobori (Terumo), Biomatrix (Biosensors) and Orsiro (Biotronik)) between 1 January 2007 and 8 January 2014 (N= 177488)

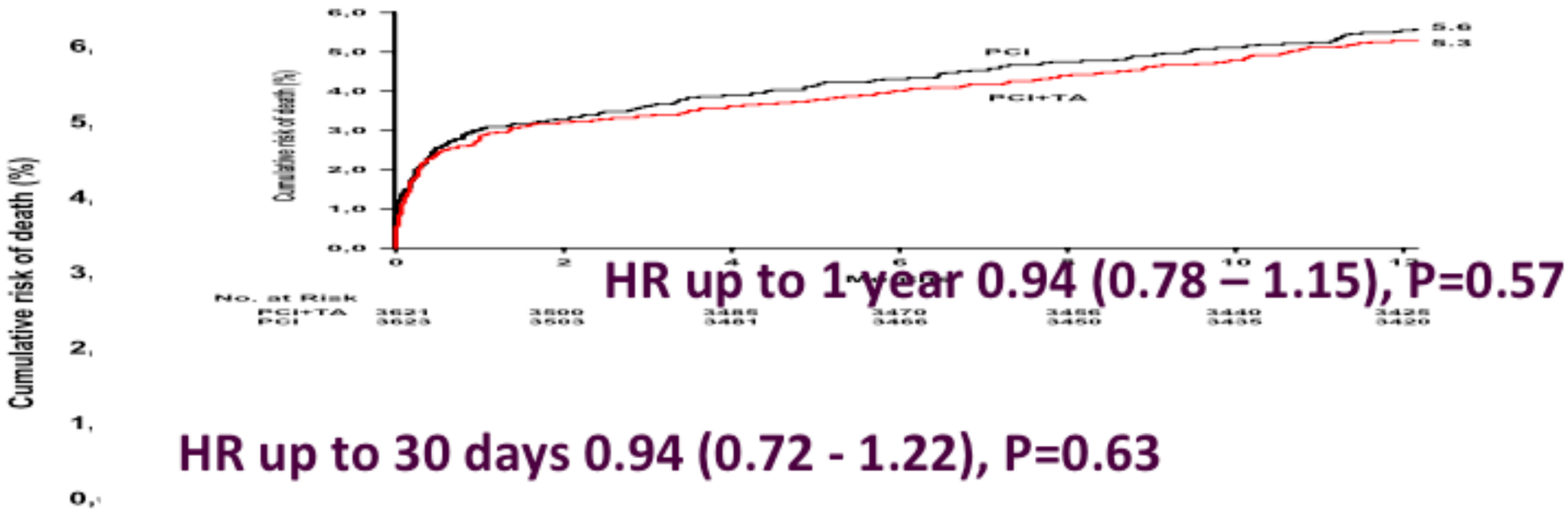
Cumulative risk of stent thrombosis in bare metal, new- and old generation stents: one year and onward



Similar low risk of ST in n-DES compared to BMS from one year and onward but higher risk in o-DES compared to BMS

o-DES=old generation drug eluting stents, n-DES=new generation drug eluting stents, BMS=bare metal stents, RR=risk ratio, ns=non significant

TASTE: 1-Year All-Cause Mortality



HR up to 1-year 0.94 (0.78 – 1.15), P=0.57

HR up to 30 days 0.94 (0.72 - 1.22), P=0.63

No benefit in any subgroups

No benefit in terms of MI or stent thrombosis

N=7244

B. Lagerqvist, SE, 5909

Primary PCI

2014 ESC/EACTS Guidelines on myocardial revascularization

Recommendations	Class[a]	Level[b]	Ref[c]
Strategy			
Primary PCI should be limited to the culprit vessel with the exception of cardiogenic shock and persistent ischaemia after PCI of the supposed culprit lesion.	IIa	B	234,264–266
Staged revascularization of non-culprit lesions should be considered in STEMI patients with multivessel disease in case of symptoms or ischaemia within days to weeks after primary PCI.	IIa	B	235
Immediate revascularization of significant non-culprit lesions during the same procedure as primary PCI of the culprit vessel may be considered in selected patients.	IIb	B	267
In patients with continuing ischaemia and in whom PCI of the infarct-related artery cannot be performed, CABG should be considered.	IIa	C	

Technique			
Stenting is recommended (over balloon angioplasty) for primary PCI.	I	A	241,242
New-generation DES are recommended over BMS in primary PCI.	I	A	128,247,248, 268,269
Radial access should be preferred over femoral access if performed by an experienced radial operator.	IIa	A	237,238,270
Thrombus aspiration may be considered in selected patients	IIb	A	250–256,259

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European Heart Journal
doi:10.1093/eurheartj/ehu278

Recommendations for antiplatelets in PCI-NSTEMI

ASA is recommended for all patients without contraindications at an initial oral loading dose of 150–300 mg (or 80–150 mg i.v.), and at a maintenance dose of 75–100 mg daily long-term regardless of treatment strategy.	I	A
A $P2Y_{12}$ inhibitor is recommended in addition to ASA, and maintained over 12 months unless there are contraindications such as excessive risk of bleeding. Options are:	I	A
• Prasugrel (60 mg loading dose, 10 mg daily dose) in patients in whom coronary anatomy is known and who are proceeding to PCI if no contraindication.	I	B
• Ticagrelor (180 mg loading dose, 90 mg twice daily) for patients at moderate-to-high risk of ischaemic events, regardless of initial treatment strategy including those pre-treated with clopidogrel if no contraindication.	I	B
• Clopidogrel (600 mg loading dose, 75 mg daily dose), only when prasugrel or ticagrelor are not available or are contraindicated.	I	B
GP IIb/IIIa antagonists should be considered for bail-out situation or thrombotic complications.	IIa	C
Pre-treatment with prasugrel in patients in whom coronary anatomy not known, is not recommended.	III	B
Pre-treatment with GP IIb/IIIa antagonists in patients in not known, is not recommended.	III	A

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A $P2Y_{12}$ inhibitor is recommended in addition to ASA and maintained over 12 months unless there are contraindications such as excessive risk of bleeding. Options are:	I	A
• Prasugrel (60 mg loading dose, 10 mg daily dose) if no contraindication	I	B
• Ticagrelor (180 mg loading dose, 90 mg twice daily) if no contraindication	I	B
• Clopidogrel (600 mg loading dose, 75 mg daily dose), only when prasugrel or ticagrelor are not available or are contraindicated.	I	B
It is recommended to give $P2Y_{12}$ inhibitors at the time of first medical contact.	I	B
GP IIb/IIIa inhibitors should be considered for bail-out or evidence of no-reflow or a thrombotic complication.	IIa	C
Upstream use of a GP IIb/IIIa inhibitor (vs. in-lab use) may be considered in high-risk patients undergoing transfer for primary PCI.	IIb	B

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European Heart Journal
doi:10.1093/eurheartj/ehu278

Recommendations PCI-oral anticoagulation

Recommendations	Class[a]	Level[b]
In patients with a firm indication for oral anticoagulation (e.g. atrial fibrillation with CHA_2DS_2-VASc score ≥2, venous thromboembolism, LV thrombus, or mechanical valve prosthesis), oral anticoagulation is recommended in addition to antiplatelet therapy.	I	C
New-generation DES are preferred over BMS among patients requiring oral anticoagulation if bleeding risk is low (HAS-BLED ≤2).	IIa	C
In patients with SCAD and atrial fibrillation with CHA_2DS_2-VASc score ≥2 at low bleeding risk (HAS-BLED ≤2), initial triple therapy of (N)OAC and ASA (75–100 mg/day) and clopidogrel 75 mg/day should be considered for a duration of at least one month after BMS or new-generation DES followed by dual therapy with (N)OAC and aspirin 75–100 mg/day or clopidogrel (75 mg/day) continued up to 12 months.	IIa	C
DAPT should be considered as alternative to initial triple therapy for patients with SCAD and atrial fibrillation with a CHA_2DS_2-VASc score ≤1.	IIa	C
In patients with ACS and atrial fibrillation at low bleeding risk (HAS-BLED≤2), initial triple therapy of (N)OAC and ASA (75–100 mg/day) and clopidogrel 75 mg/day should be considered for a duration of 6 months irrespective of stent type followed by (N)OAC and aspirin 75–100 mg/day or clopidogrel (75 mg/day) continued up to 12 months.	IIa	C
In patients requiring oral anticoagulation at high bleeding risk (HAS BLED ≥3), triple therapy of (N)OAC and ASA (75–100 mg/day) and clopidogrel 75 mg/day should be considered for a duration of one month followed by (N)OAC and aspirin 75–100 mg/day or clopidogrel (75 mg/day) irrespective of clinical setting (SCAD or ACS) and stent type (BMS or new-generation DES).	IIa	C
Dual therapy of (N)OAC and clopidogrel 75 mg/day may be considered as an alternative to initial triple therapy in selected patients.	IIb	B
The use of ticagrelor and prasugrel as part of initial triple therapy is not recommended	III	C
Anticoagulation therapy after PCI in ACS patient		
In selected patients who receive ASA and clopidogrel, low-dose rivaroxaban (2.5 mg twice daily) may be considered in the setting of PCI for ACS if the patient is at low bleeding risk.	IIb	B
Anticoagulation during PCI in patients on oral anticoagulation		
It is recommended to use additional parenteral anticoagulation, regardless of the timing of the last dose of (N)OAC.	I	C
Periprocedural parenteral anticoagulants (bivalirudin, enoxaparin or UFH) should be discontinued immediately after primary PCI.	IIa	C

Recommendation for the type of revascularization (CABG or PCI) in patients with SCAD with suitable coronary anatomy for both procedures and low predicted surgical mortality

Recommendations according to extent of CAD	CABG		PCI	
	Class[a]	Level[b]	Class[a]	Level[b]
One or two-vessel disease without proximal LAD stenosis.	IIb	C	I	C
One-vessel disease with proximal LAD stenosis.	I	A	I	A
Two-vessel disease with proximal LAD stenosis.	I	B	I	C
Left main disease with a SYNTAX score ≤ 22.	I	B	I	B
Left main disease with a SYNTAX score 23–32.	I	B	IIa	B
Left main disease with a SYNTAX score >32.	I	B	III	B
Three-vessel disease with a SYNTAX score ≤ 22.	I	A	I	B
Three-vessel disease with a SYNTAX score 23–32.	I	A	III	B
Three-vessel disease with a SYNTAX score >32.	I	A	III	B

European Heart Journal
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ATLANTIC

Conclusion

Pre-hospital ticagrelor administration a short time before PCI in patients with ongoing STEMI is **safe** but **does not improve pre-PCI coronary reperfusion**. It may, however, **reduce the risk of post-PCI stent thrombosis**.

TCT 2014

Bivalirudin versus Heparin and Heparin plus Tirofiban in Patients with AMI Undergoing PCI

Thirty-Day and One-Year Outcomes of the BRIGHT Trial

Yaling Han, MD, FACC

On behalf of the BRIGHT investigators

tct2014 In Partnership with the ACC

CARDIOVASCULAR RESEARCH FOUNDATION

Trial Design

(clinicaltrials.gov number: NCT01696110)

2194 patients with AMI eligible for emergent PCI

- STEMI:89%
- Transradial: 78%
- DES: 99%
- Clopidogrel: 100%

R

Bivalirudin alone
N=735

Biv 0.75mg/kg bolus + 1.75mg /kg/h infusion (0.3mg/kg bolus if ACT< 225s). Bailout GPI permitted.
Biv infusion (0.2mg/kg/h) continued for at least 30 min post PCI.

Heparin alone
N=729

Heparin 100U/kg bolus + additional dose if ACT <200 s.
Bailout GPI permitted
ACT goal = 250-300.

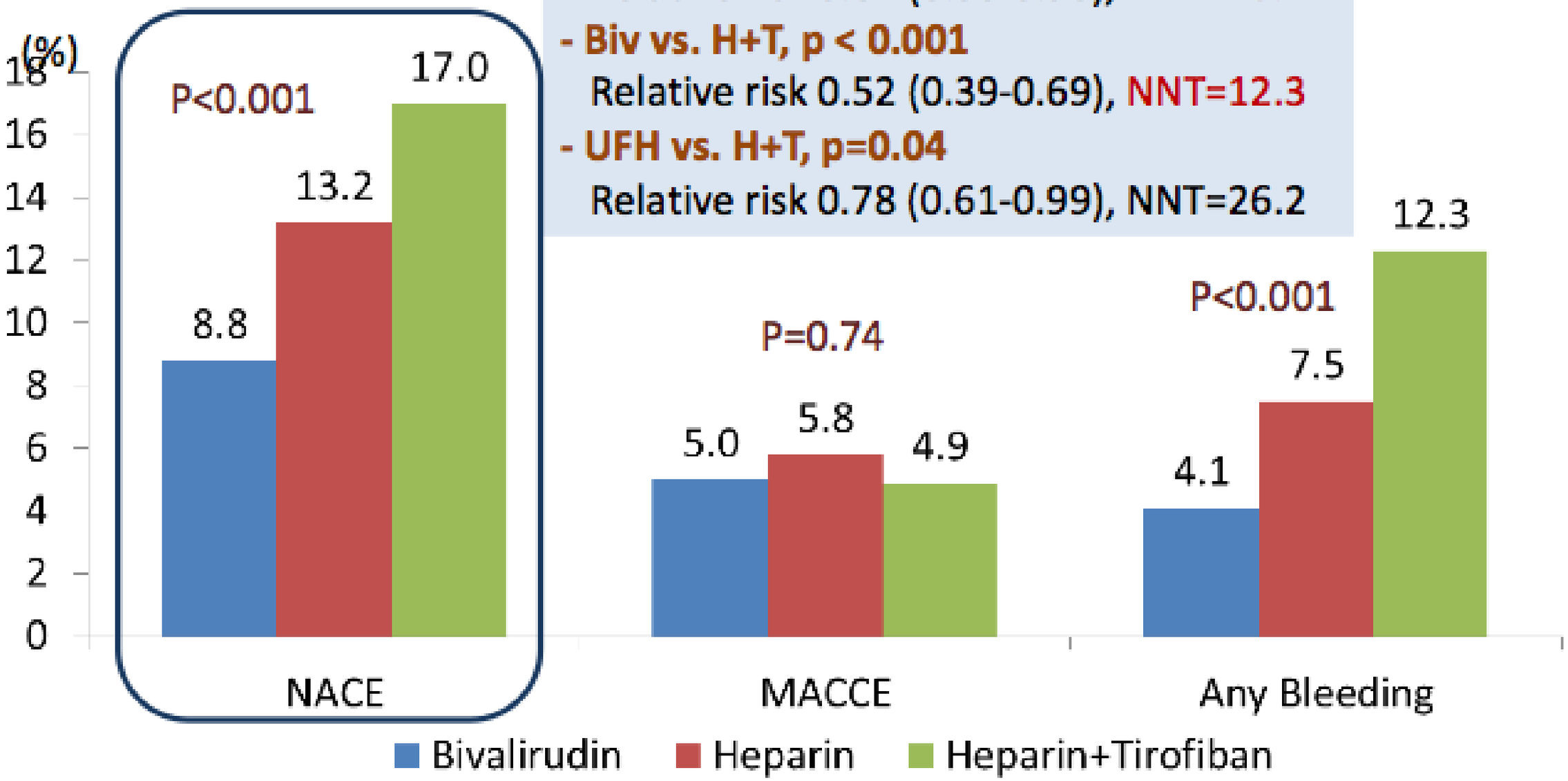
Heparin plus tirofiban
N=730

Heparin 60U/kg bolus .
Tirofiban 10µg/kg bolus + 0.15 µg/kg/min infusion for 18-36 h.
ACT goal = 200-250.

Clinical follow-up at 30 days and one year

Primary and Principal Secondary Endpoint Events at 30 Days

- **Biv vs. UFH, p=0.009**
  Relative risk 0.67 (0.50-0.90), NNT=23.1
- **Biv vs. H+T, p < 0.001**
  Relative risk 0.52 (0.39-0.69), NNT=12.3
- **UFH vs. H+T, p=0.04**
  Relative risk 0.78 (0.61-0.99), NNT=26.2



Biv=bivalirudin; UFH=Heparin; H+T=heparin + tirofiban

Methods

- The SECURITY trial [NCT00944333] was a prospective, randomized, non-inferiority, investigator-driven, multicenter, international study.

- 3 Countries, 38 centers (Italy: 31; Spain: 6; the Netherlands: 1)

- Second-generation DES used in the study were the Endeavor Resolute (Medtronic, MA), Xience (Abbott Park, Illinois), Promus (Boston Scientific, MN), Nobori™ (Terumo Corporation, Tokyo, Japan) and the Biomatrix™ (Biosensors Europe S.A.).

- No SCA

Outcome rates at 24 months according to treatment groups – Cox proportional hazards

	6-Month DAPT (N = 682)	12-Month DAPT (N = 717)	Hazard ratio 95% CI	P-value
Cardiac death	6 (0.9%)	6 (0.8%)	1.05 (0.34 to 3.26)	0.925
Myocardial Infarction	21 (3.1%)	19 (2.6%)	1.16 (0.62 to 2.16)	0.636
Stroke	6 (0.9%)	3 (0.4%)	2.10 (0.52 to 8.40)	0.636
Definite/probable ST	3 (0.4%)	3 (0.4%)	1.05 (0.21 to 5.20)	0.951
BARC 3 or 5	5 (0.7%)	8 (1.1%)	0.69 (0.25 to 1.96)	0.496

AHA 2014

American Heart Association.
SCIENTIFIC SESSIONS 2014

Subject Flow

DAPT STUDY

Index Stent Procedure	0-12 Months: All Subjects on Open-Label	At Month 12: 1:1 Randomization	12-30 Months: Blinded Treatment	Follow-Up	
				30 Months:	33
NSTEMI		15.5%	15.5%		0.93
STEMI		10.6%	10.3%		0.65

DES Treated Subjects 22,866 → **9,961**

- **5,020 Receive Thienopyridine + Aspirin** → **9,499 (95.4%)** → **9,390 (94.3%)**
- **4,941 Receive Placebo + Aspirin**

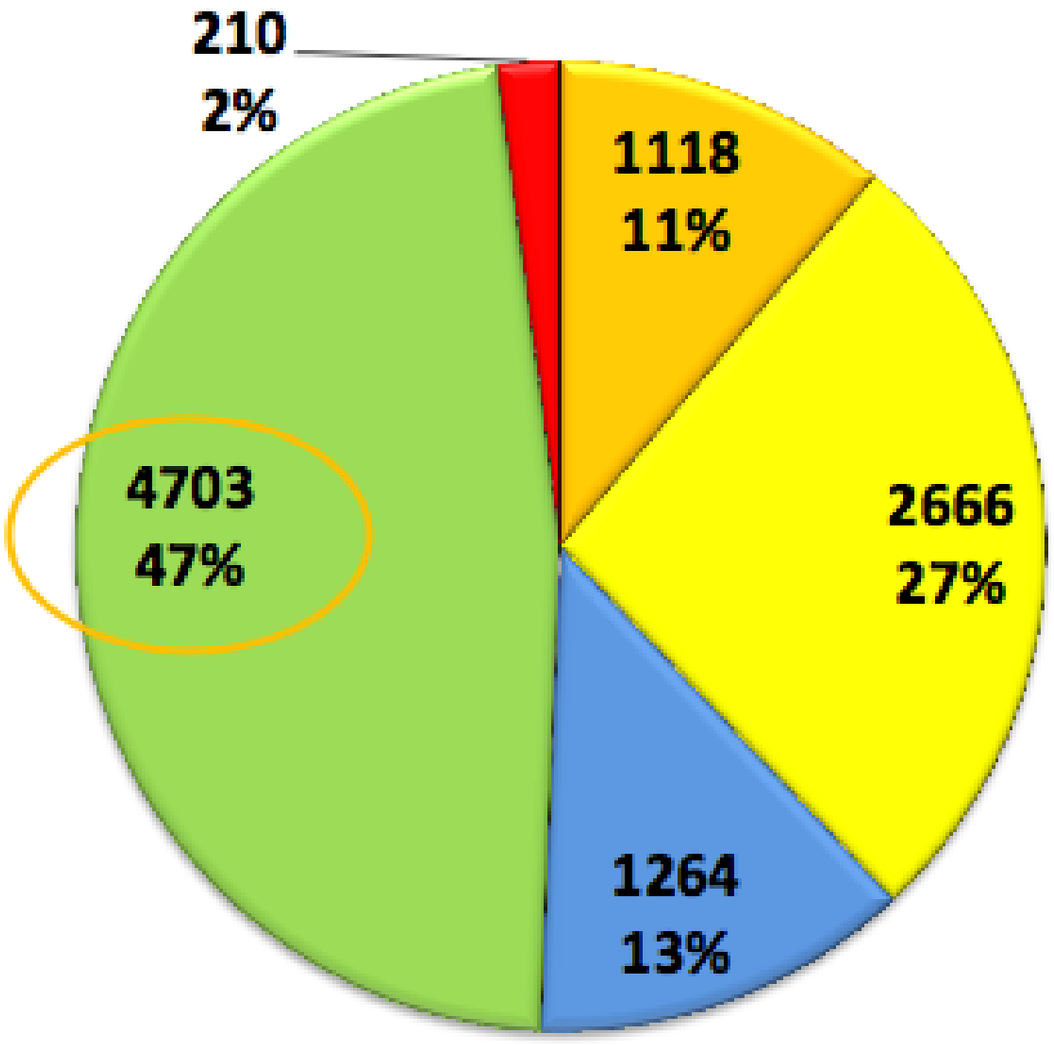
BMS Treated Subjects 2,816 → **1,687**

- **842 Receive Thienopyridine + Aspirin** → **1,580 (93.7%)** → **1,565 (92.8%)**
- **845 Receive Placebo + Aspirin**

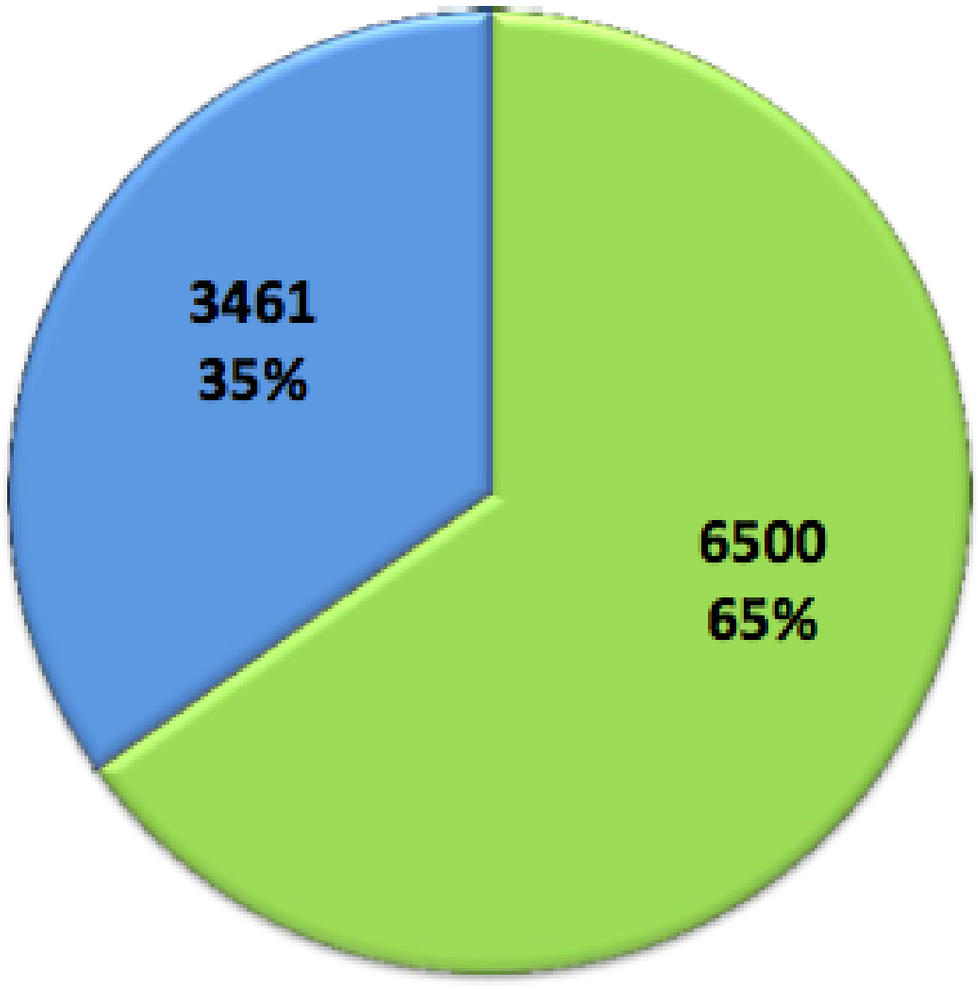
Stent & Drug Types

DAPT STUDY

Drug Eluting Stent Type

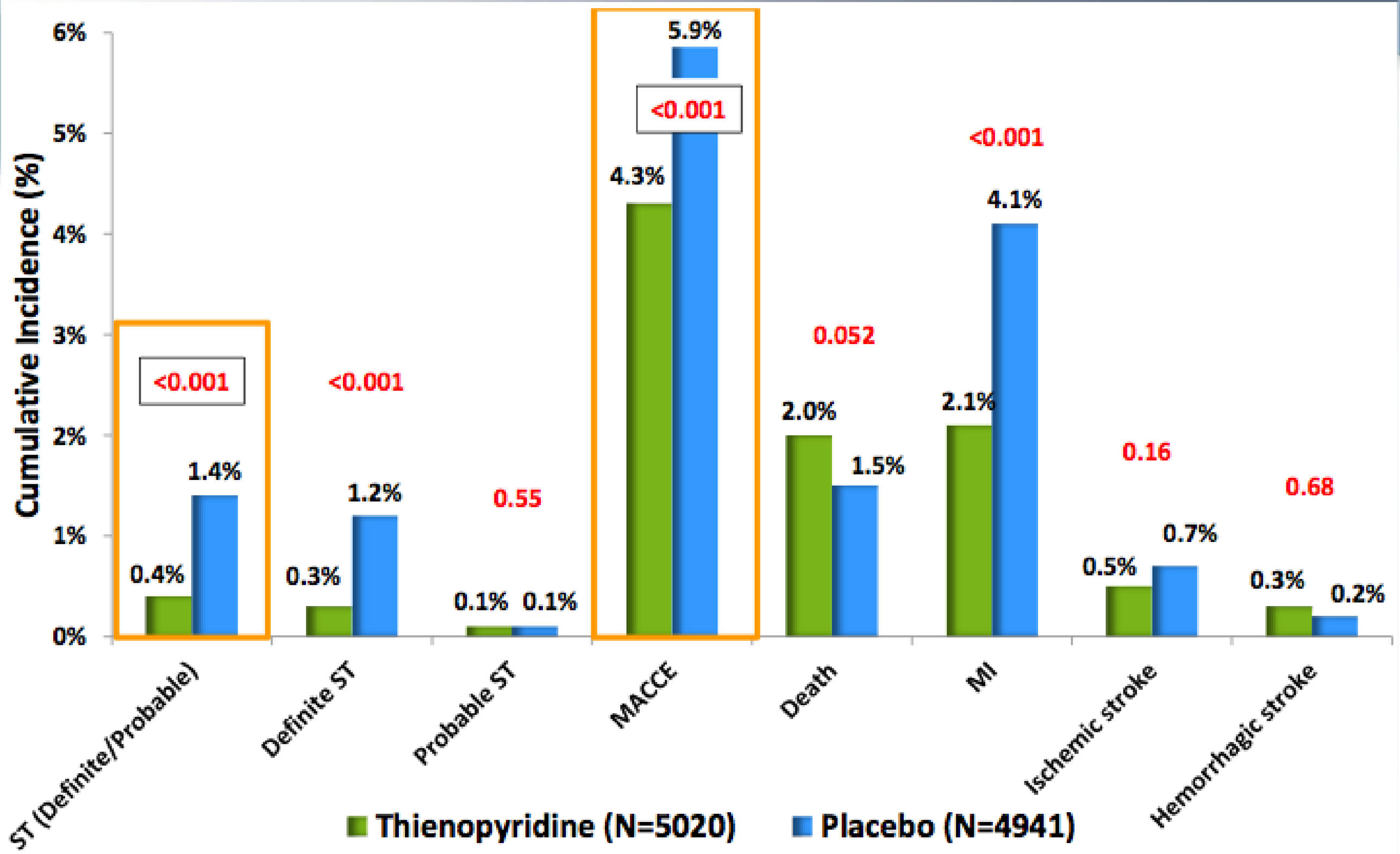


Thienopyridine Type



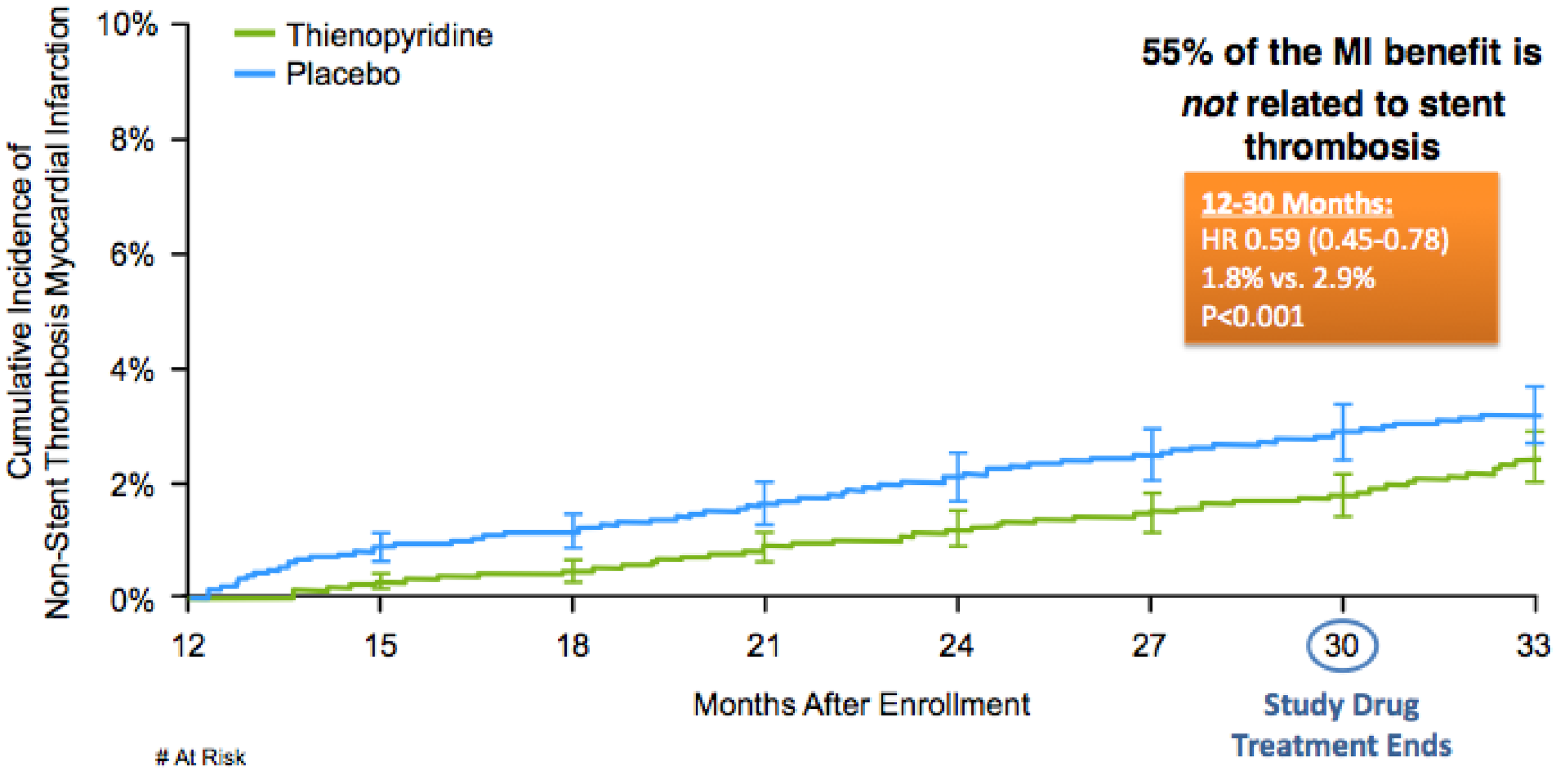
Co-Primary Effectiveness End Points & Components: 12-30 Months

DAPT STUDY



Non-Stent Thrombosis Myocardial Infarction

DAPT STUDY



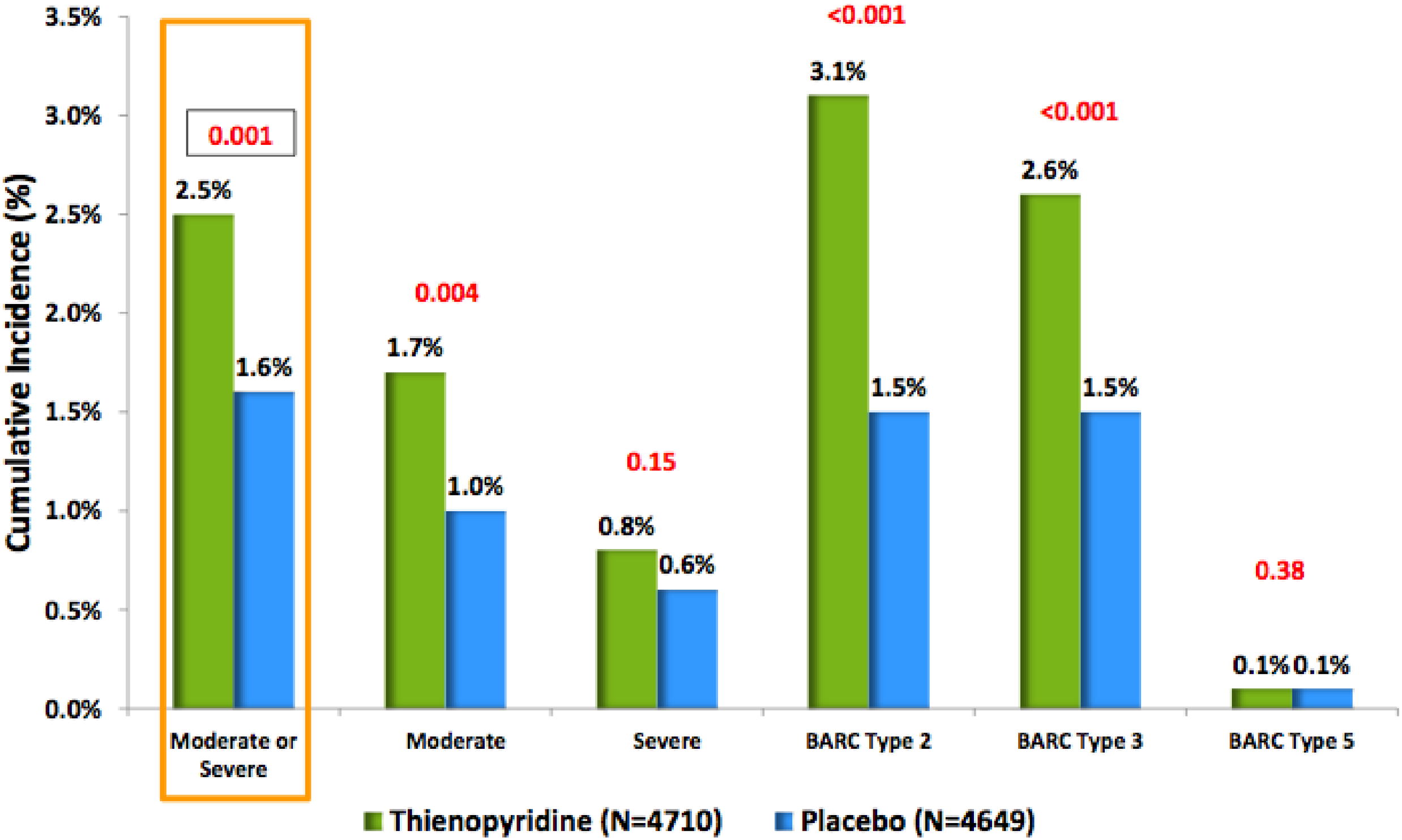
55% of the MI benefit is *not* related to stent thrombosis

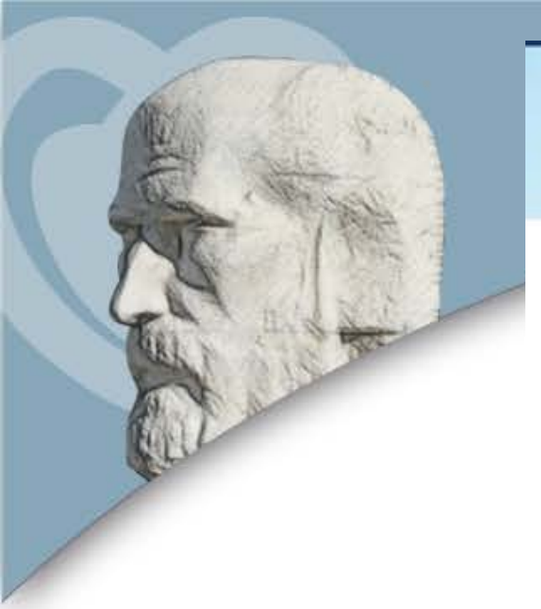
12-30 Months:
HR 0.59 (0.45-0.78)
1.8% vs. 2.9%
P<0.001

# 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

DAPT STUDY





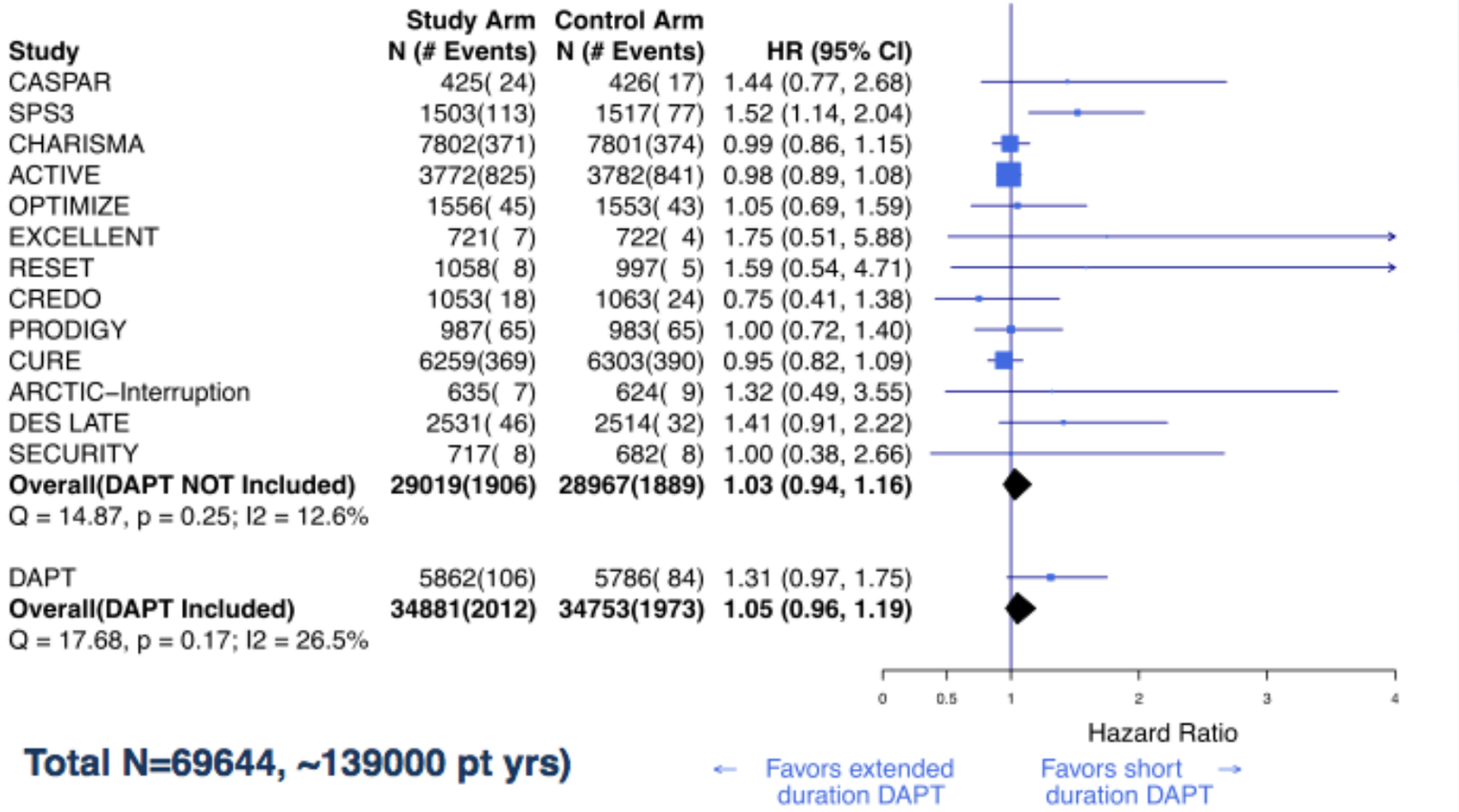
All-Cause Mortality

DAPT STUDY

	12-30 Months			
	Thienopyridine N=5020	Placebo N=4941	P-Value	Absolute Difference
All-Cause Mortality	**98 (2.0%)**	**74 (1.5%)**	**0.052**	**24 (0.5%)**
Cardiac	45 (0.9%)	47 (1.0%)	0.98	-2 (-0.1%)
Vascular	5 (0.1%)	5 (0.1%)	0.98	0 (-)
Non-Cardiovascular	48 (1.0%)	22 (0.5%)	0.002	26 (0.5%)

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

DAPT STUDY



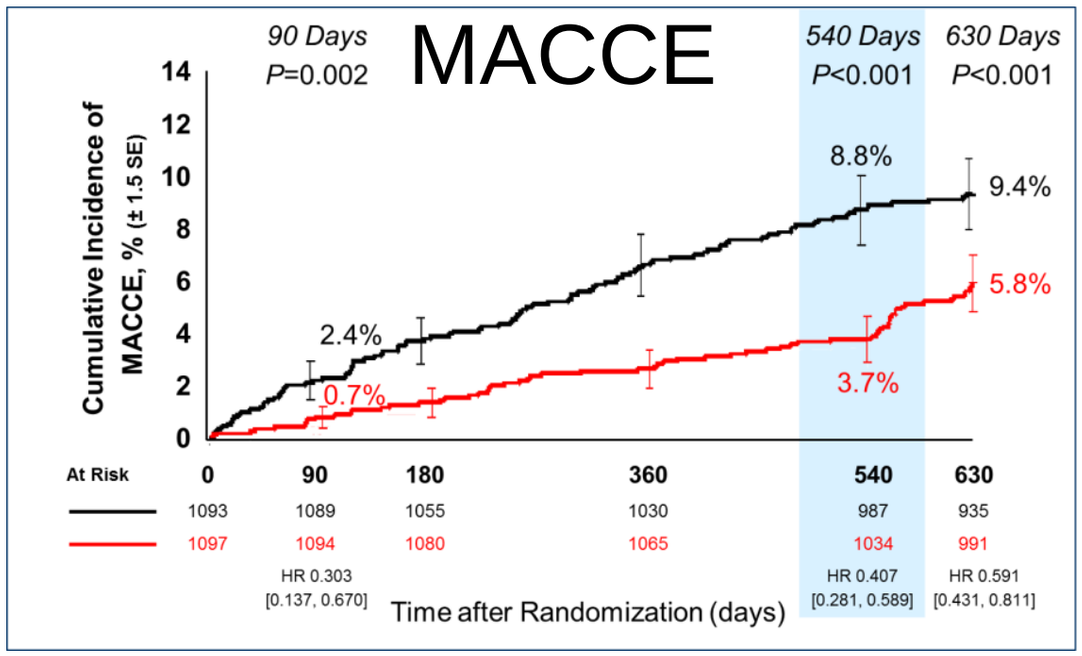
Total N=69644, ~139000 pt yrs)

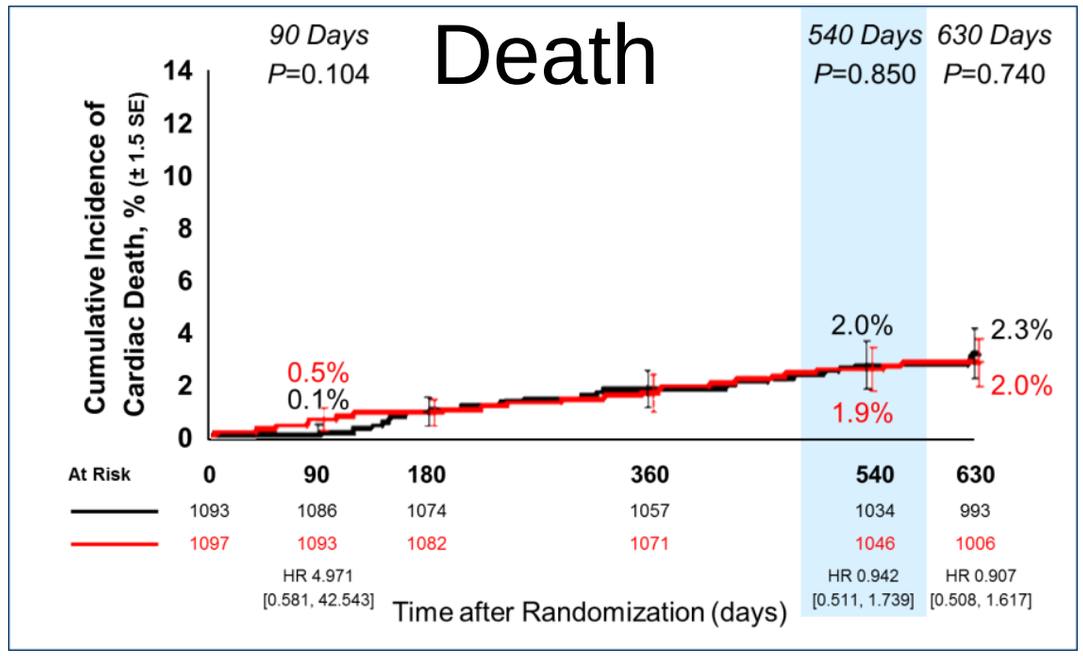
Elmariah S, Mauri L, Doros G, O'Neill KE, Steg PG, Kereiakes DJ, Yeh RW. Extended Duration Dual Antiplatelet Therapy and Mortality: A Systematic Review and Meta-analysis. *The Lancet*. Online ahead of print November 16, 2014.

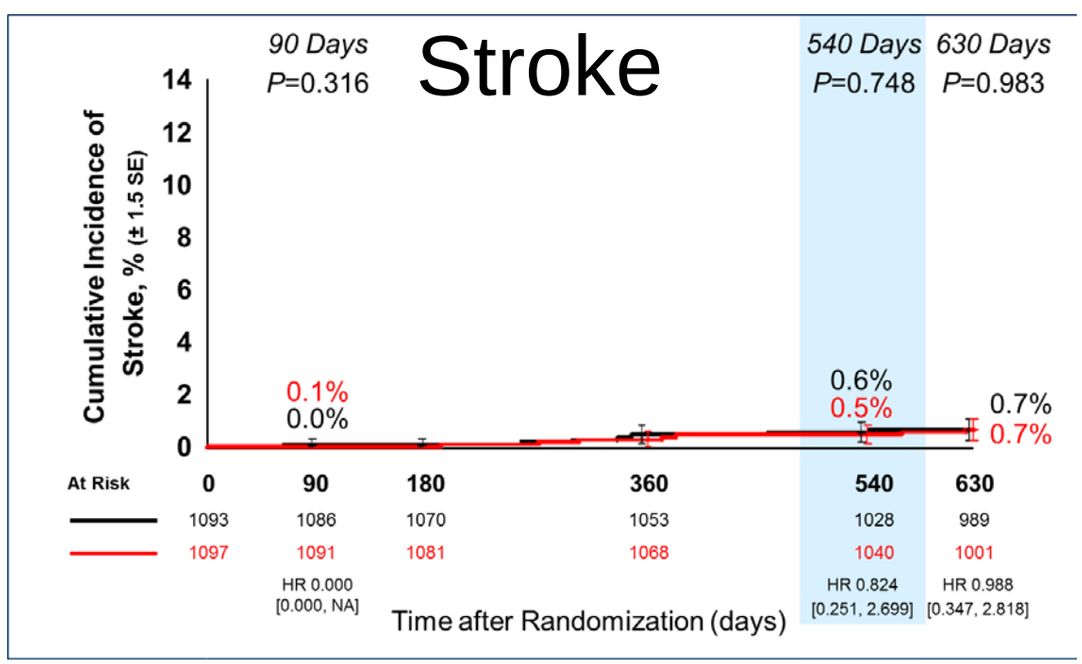
Results:
MACCE – All Death, Stroke, and MI

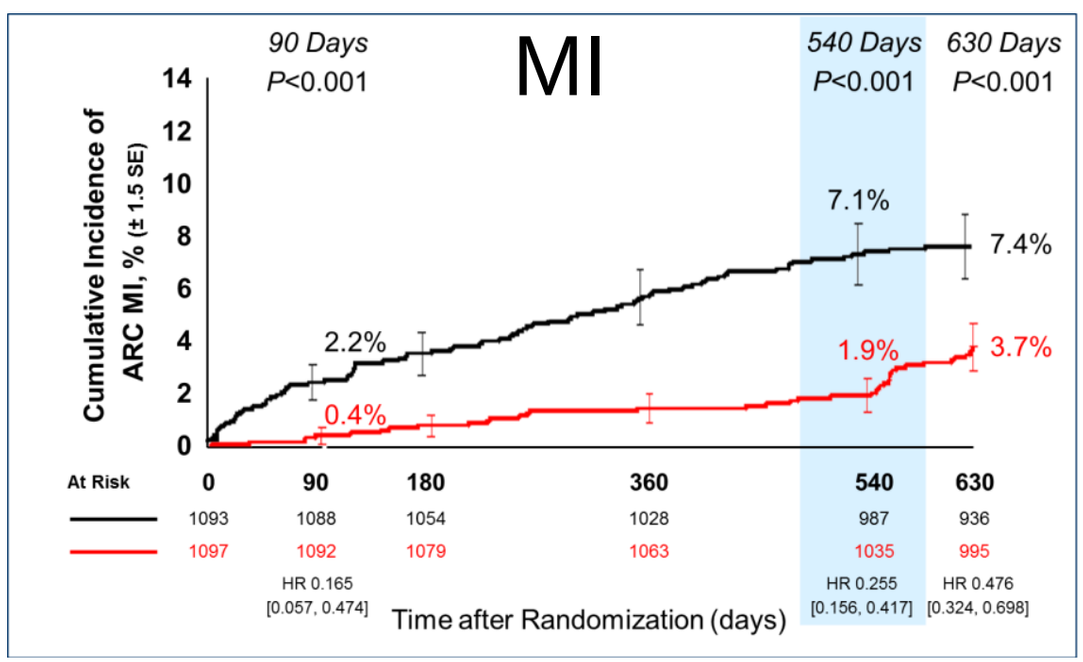
TAXUS Liberté

— 12-mo Prasugrel + ASA — 30-mo Prasugrel + ASA









Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value; HR=Hazard Ratio [95% confidence interval]

Methods

Patient with Xience V implantation

Aspirin resistant

With or without dose adjustment

Good aspirin responders

Randomization

Randomization applied

No events during first **6 months**

Resistant group

Clopidogrel (prasugrel or ticagrelor) + aspirin, duration decided by the team

Group 1:

DAPT for another **18 months** followed by aspirin alone

Group 2:

aspirin alone

Results

1-year clinical outcomes in the intention-to-treat study population

	Resistant Group n=131	24-month DAPT n=910	6-Month DAPT n=912	Hazard Ratio [95% CI]	p
Primary end point, n (%)					
Death from any cause, MI*, stroke, TVR†, major bleeding	**2 (1.5%)**	**14 (1.5%)**	**15 (1.6%)**	**1.072 (0.517 - 2.221)**	**0.85**
Secondary end point, n (%)					
Minor bleeding	**0**	**4 (0.4%)**	**5 (0.5%)**	**1.247 (0.335 - 4.643)**	**0.74**
Minimal bleeding	**1 (0.8%)**	**6 (0.7%)**	**6 (0.7%)**	**0.997 (0.321 - 3.090)**	**0.99**
Death, n (%)					
All deaths	**1 (0.8%)**	**7 (0.8%)**	**8 (0.9%)**	**1.143 (0.414 -3.152)**	**0.80**
Cardiac death	**0**	**3 (0.3%)**	**5 (0.5%)**	**1.667 (0.398 - 6.974]**	**0.48**
Myocardial infarction, n (%)	**0**	**4 (0.4%)**	**6 (0.7%)**	**1.500 (0.423 - 5.317)**	**0.53**
Stroke, n (%)	**0**	**4 (0.4%)**	**0**	**N/A**	
TVR, n (%)	**1 (0.8%)**	**2 (0.2%)**	**5 (0.5%)**	**2.499 (0.485 - 12.882]**	**0.27**
Stent thrombosis	**0**	**0**	**3 (0.3%)**	**N/A**	
Major bleeding, n (%)	**0**	**3 (0.3%)**	**0**	**N/A**	

*MI: myocardial infarction; †TVR: urgent target vessel revascularization

Clinical Outcomes

– the Randomized, Double-Blind, Placebo-Controlled ISAR-SAFE Trial

	Six months Clopidogrel (n=1997)	Twelve months Clopidogrel (n=2003)	HR (95% CI)	*P*
Secondary endpoints				
- Death	8 (0.4)	12 (0.6)	0.66 (0.27-1.63)	0.37
- Myocardial infarction	13 (0.7)	14 (0.7)	0.93 (0.44-1.97)	0.85
- Stent thrombosis	5 (0.3)	4 (0.2)	1.25 (0.33-4.65)	0.74
- Stroke	7 (0.4)	5 (0.3)	1.40 (0.44-4.41)	0.57
- TIMI major Bleeding	4 (0.2)	5 (0.3)	0.80 (0.21-2.98)	0.74
- Everolimus-eluting stent	47.5	49.3		
- Zotarolimus-eluting stent	15.6	14.7		
- Biolimus-eluting stent	8.3	8.5		
Clinical Presentation, %	**Six mos**	**Twelve mos**		
- Stable CAD	48.6	47.8		
- NSTE-ACS	**31.9**	**32.0**		
- STEMI	**7.9**	**8.3**		

Muchas gracias

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