

Critical Thinking When Reviewing a Randomized Clinical trial

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**You have 1 minute to evaluate
the results of a clinical trial**

1. Hard End Points

Total number of

Deaths,

Strokes

Significant myocardial infarctions



Dual Antiplatelet Therapy Beyond One Year After Drug-eluting Coronary Stent Procedures

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

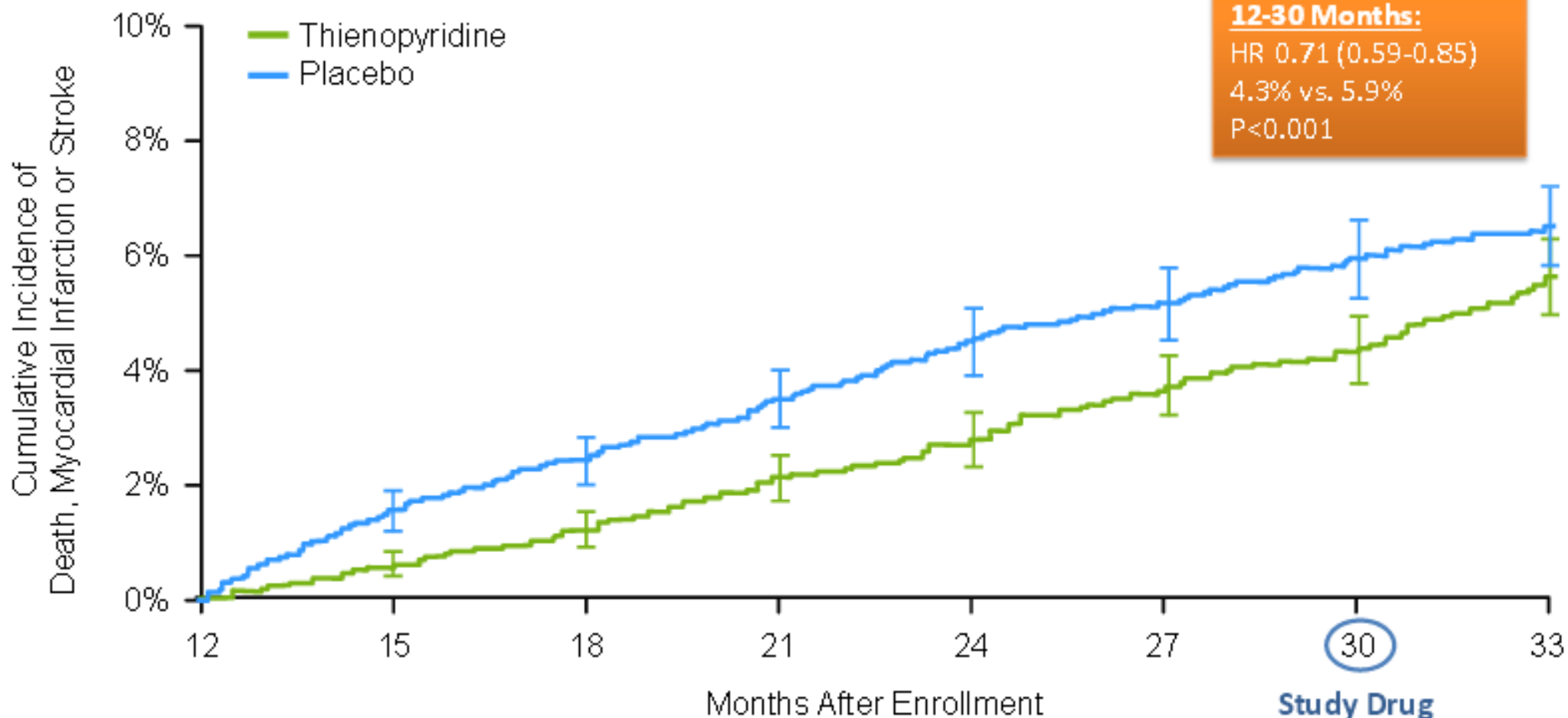
Primary Analysis Period

12-30 Months:

HR 0.71 (0.59-0.85)

4.3% vs. 5.9%

P<0.001



Study Drug Treatment Ends

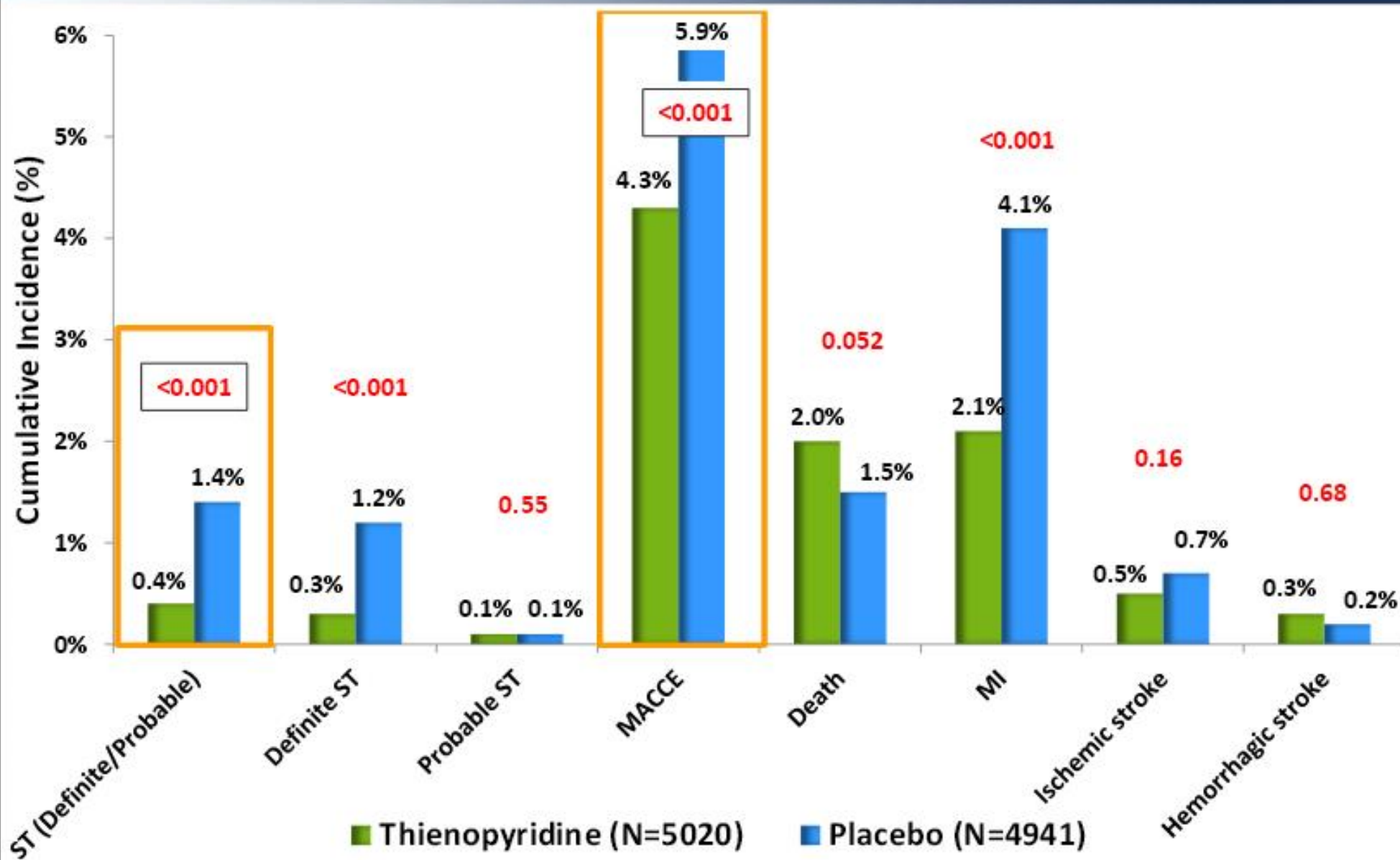
At Risk

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

2. Mechanism of Hard Endpoints

2. Which factor in the hard end points is the driver of the results?

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



3. Risk Profile of the Study Population

Does the risk profile of the patient population match the general patient population in real life?

Morphine's Worrisome Effects on Ticagrelor Affirmed in Pharmacokinetic Study

Table 1. Baseline characteristics of the study patients

Variable	Morphine	Placebo	p-value
	(n = 35)	(n = 35)	
Age (years)	60.7 ± 10.5	62.5 ± 10.5	0.47
Female	12 (34%)	7 (20%)	0.19
Body mass index [kg/m ²]	27.6 ± 4.3	27.4 ± 4.0	0.87
STEMI	24 (69%)	21 (60%)	0.45
NSTEMI	11 (31%)	14 (40%)	0.45
Metoclopramide use	1 (3%)	0 (0%)	n/a
Hypertension	15 (43%)	21 (60%)	0.15
Diabetes mellitus	8 (23%)	5 (14%)	0.36
Dyslipidemia	30 (86%)	31 (89%)	n/a
Current smoker	17 (55%)	14 (45%)	0.47
Prior AMI	5 (14%)	8 (23%)	0.20
Prior PCI	4 (11%)	9 (26%)	0.12
Prior CABG	0 (0%)	0 (0%)	n/a
Peripheral arterial disease	3 (9%)	1 (3%)	0.31
Chronic renal disease	1 (3%)	2 (6%)	0.31

AMI — acute myocardial infarction; CABG — coronary artery bypass grafting; n/a — not applicable; NSTEMI — non-ST-segment elevation myocardial infarction; PCI — percutaneous coronary intervention; STEMI — ST-segment elevation myocardial infarction

4. Number of Patients Who Withdraw

5. Impact on Subgroups

1. Diabetes mellitus
2. Coronary artery disease
3. Prior stroke
4. Elderly
5. Young age
6. Women
7. Asian
8. African Americans

Soft End Points

Conclusions

1. How was the mortality? *(if YES, then..)*
2. Was it mainly from the cardiovascular mortality?
(if YES, then..)
3. How was the risk profile of the studied patient population? *(if YES, then..)*
4. Which patients were excluded? *(if YES, then..)*
5. Could we translate the results to the general patient population and to other subgroups of patients?

Thank You

