Prof. Dr. med. Sigmund Silber
Cardiology Practice and Hospital
Munich, Germany

Outpatient
Cardiology Practice

Heart Center
Munich at the Isar

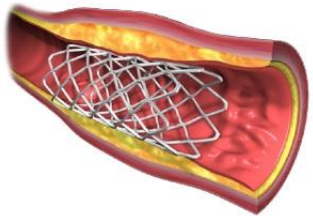
Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?

1. **What Coronary Revascularization ?**
2. **Which Trials ?**

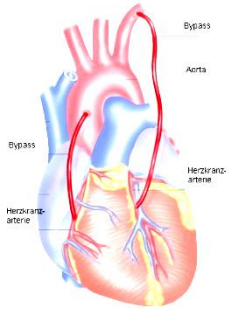
Approaches to Coronary Revascularization

Conservative

PCI



Bypass Surgery

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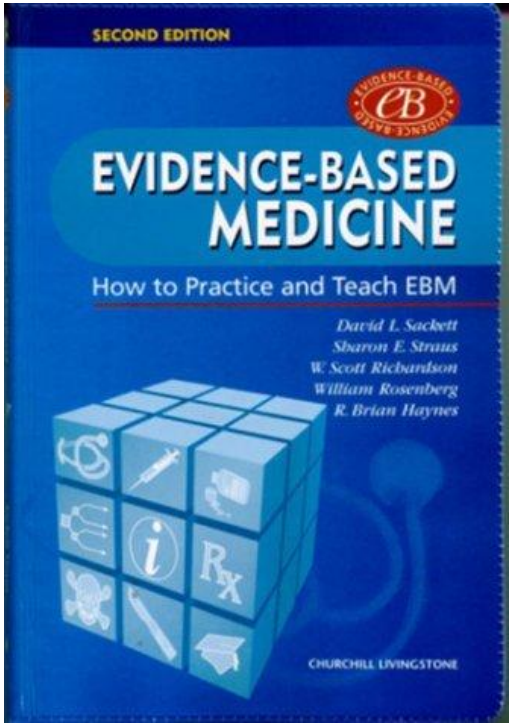
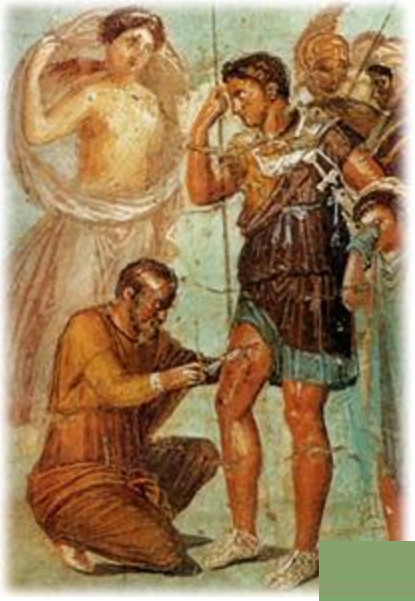
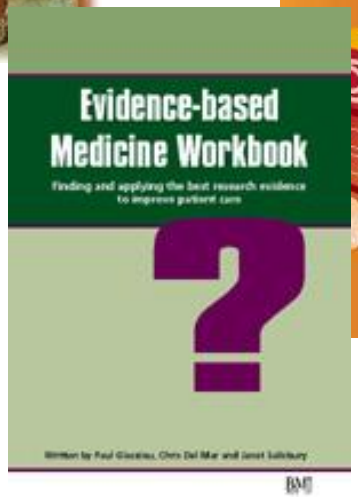
902 656 186

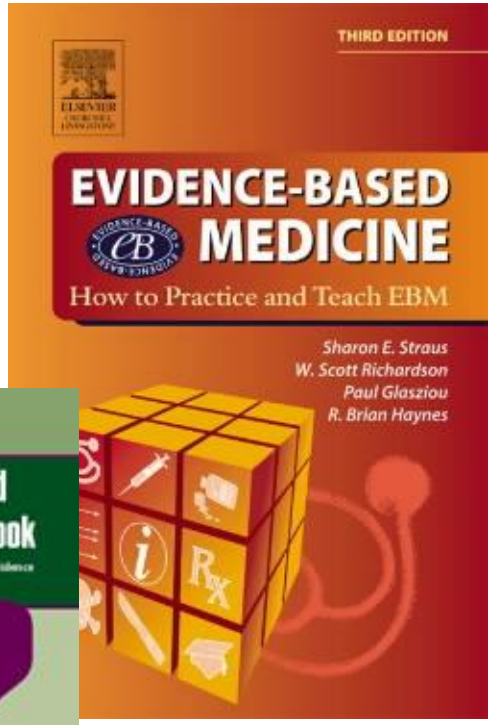
Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?

Guidelines are based on Evidence: What is Evidence ?









1920


Demand
BAYER
ASPIRIN
SAY "BAYER ASPIRIN"— Genuine
Unless you see the "Bayer Cross" on tablets, you are not getting the genuine Bayer Aspirin prescribed by physicians and proved safe by millions over 25 years for
Colds Headache Neuritis Lumbago
Pain Neuralgia Toothache Rheumatism
DOES NOT AFFECT THE HEART
Safe
Accept only "Bayer" package which contains proven directions.
Handy "Bayer" boxes of 12 tablets.
Also bottles of 24 and 100—Druggists.
Aspirin is the trade mark of Bayer Manufacture of Monoaceticacidester of Salicylicacid

Only Randomized Trials

(no „adjustments“ necessary)

The Power for the Clinical Outcome must also be considered !

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

Authors/Task Force Members: Sigmund Silber, Chairperson* (Germany), Per Albertsson (Sweden), Francisco F. Avilés (Spain), Paolo G. Camici (UK), Antonio Colombo (Italy), Christian Hamm (Germany), Erik Jørgensen (Denmark), Jean Marco (France), Jan-Erik Nordrehaug (Norway), Witold Ruzyllo (Poland), Philip Urban (Switzerland), Gregg W. Stone (USA), William Wijns (Belgium)

the basis of evidence (*Table* on Levels of evidence). To verify the applicability of the recommendations to a specific area, the expert panel emphasized the importance of the primary endpoint for the randomized trials, giving high priority to the importance of significantly improving patients' outcome as the primary endpoint investigated in an adequately powered sample size.

European Heart Journal (2005) **26**, 804–847

ESC GUIDEL

To improve the qual re in Europe

How did major randomized trials presented after March 2005 affect the ESC guidelines ?

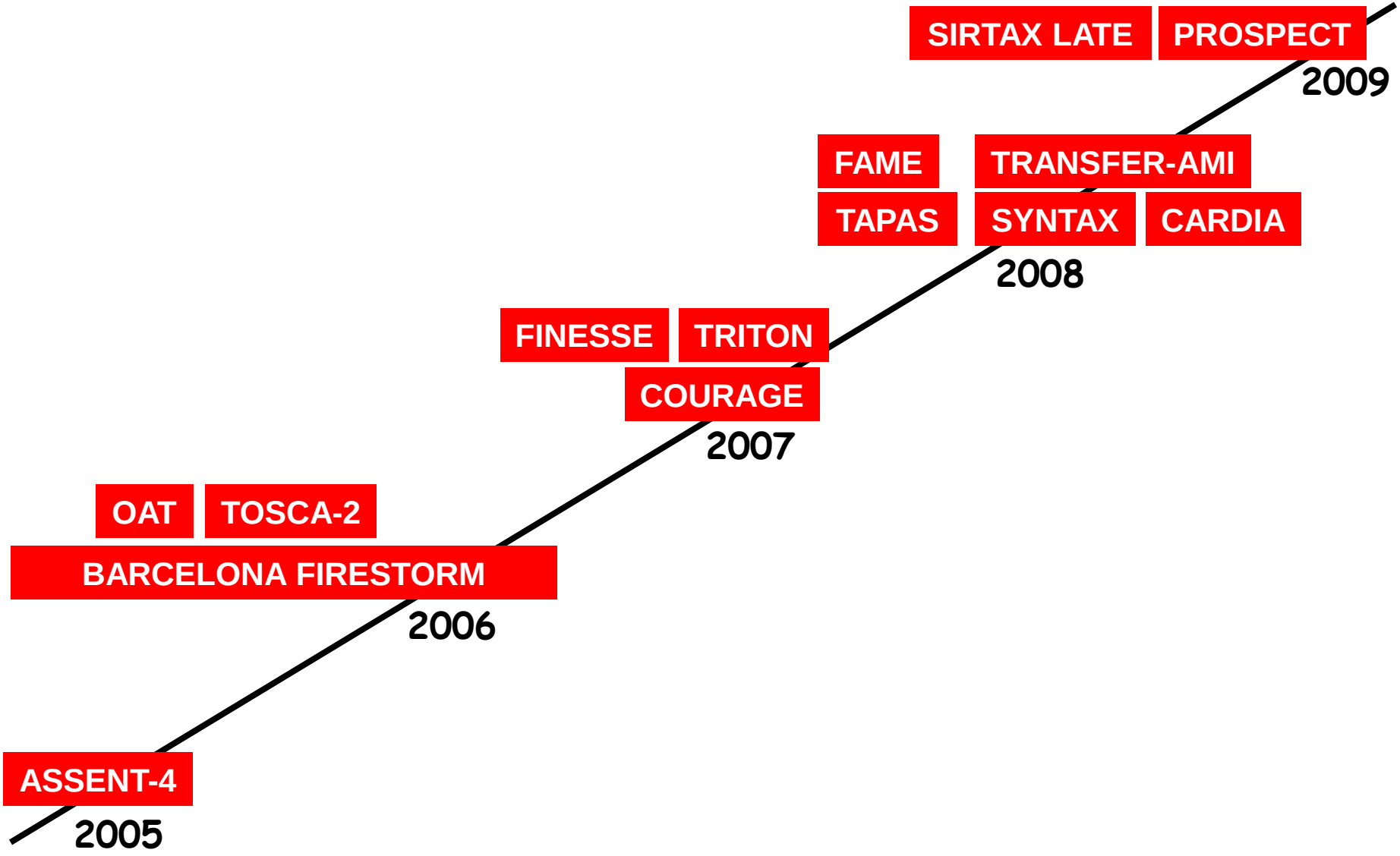
Guidelines for P oronary Interventions

The Task F eous Coronary Interventions of th y of Cardiology

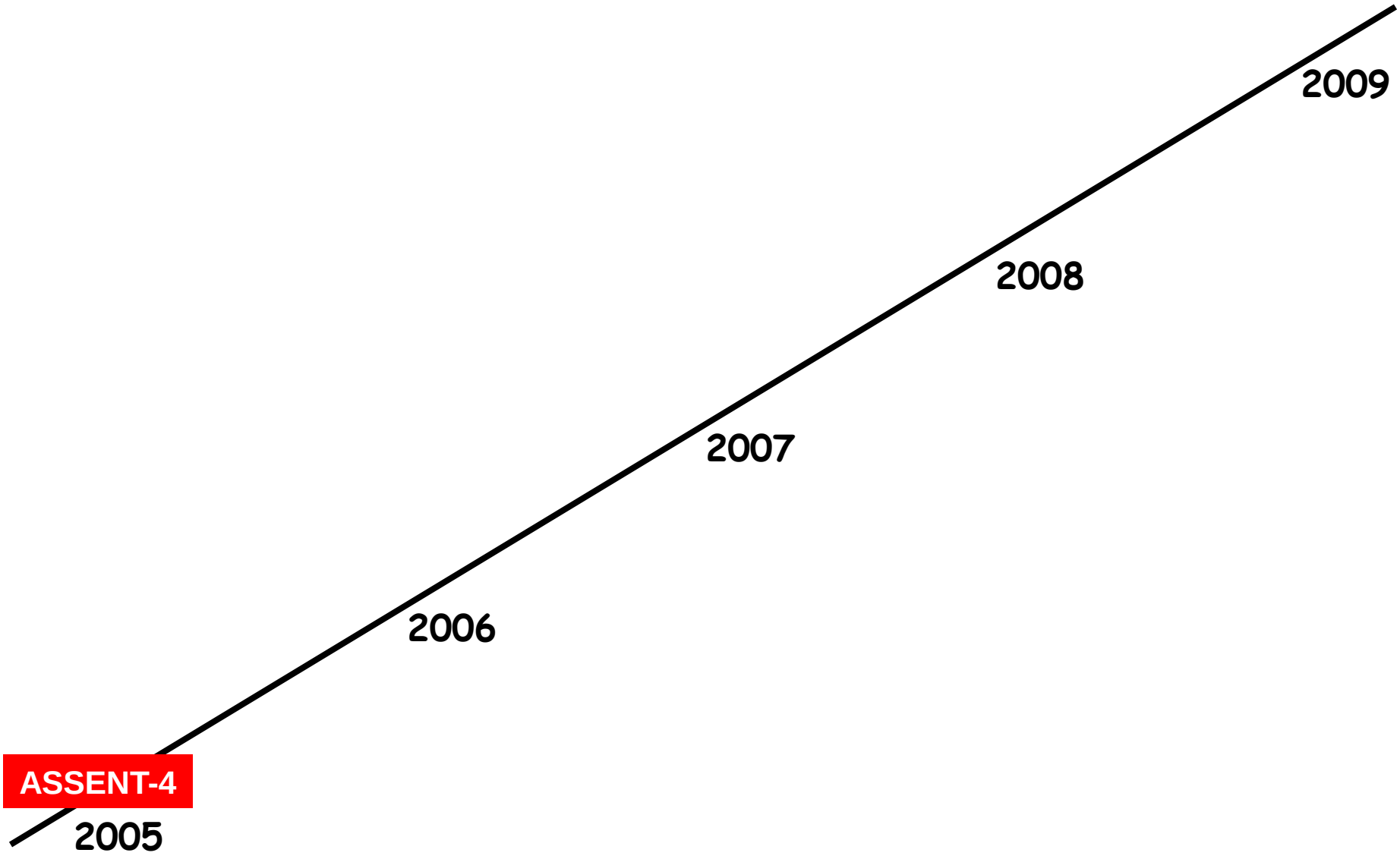
e Members: Sigmund Silber, Chairperson* (Germany), P on (Sweden), Francisco F. Avilés (Spain), Paolo G. Camici (UK), An Colombo (Italy), Christian Hamm (Germany), Erik Jørgensen (Denmark), Jean Marco (France), Jan-Erik Nordrehaug (Norway), Witold Ruzyllo (Poland), Philip Urban (Switzerland), Gregg W. Stone (USA), William Wijns (Belgium)

European Heart Journal (2005) 26, 804–847

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



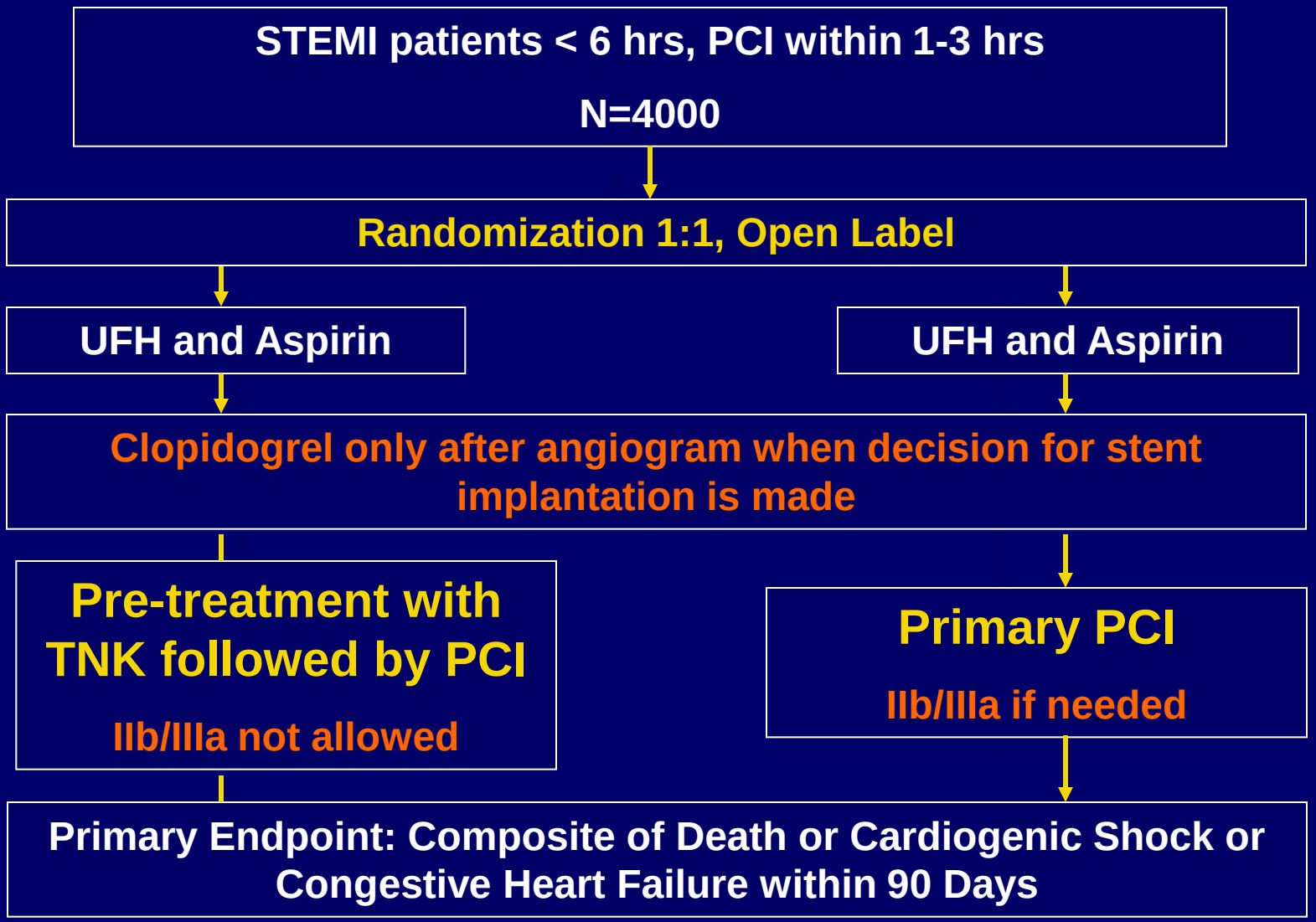
ASSENT-4 PCI:

The ASsessment of the Safety and Efficacy of a New Treatment Strategy for Acute Myocardial Infarction

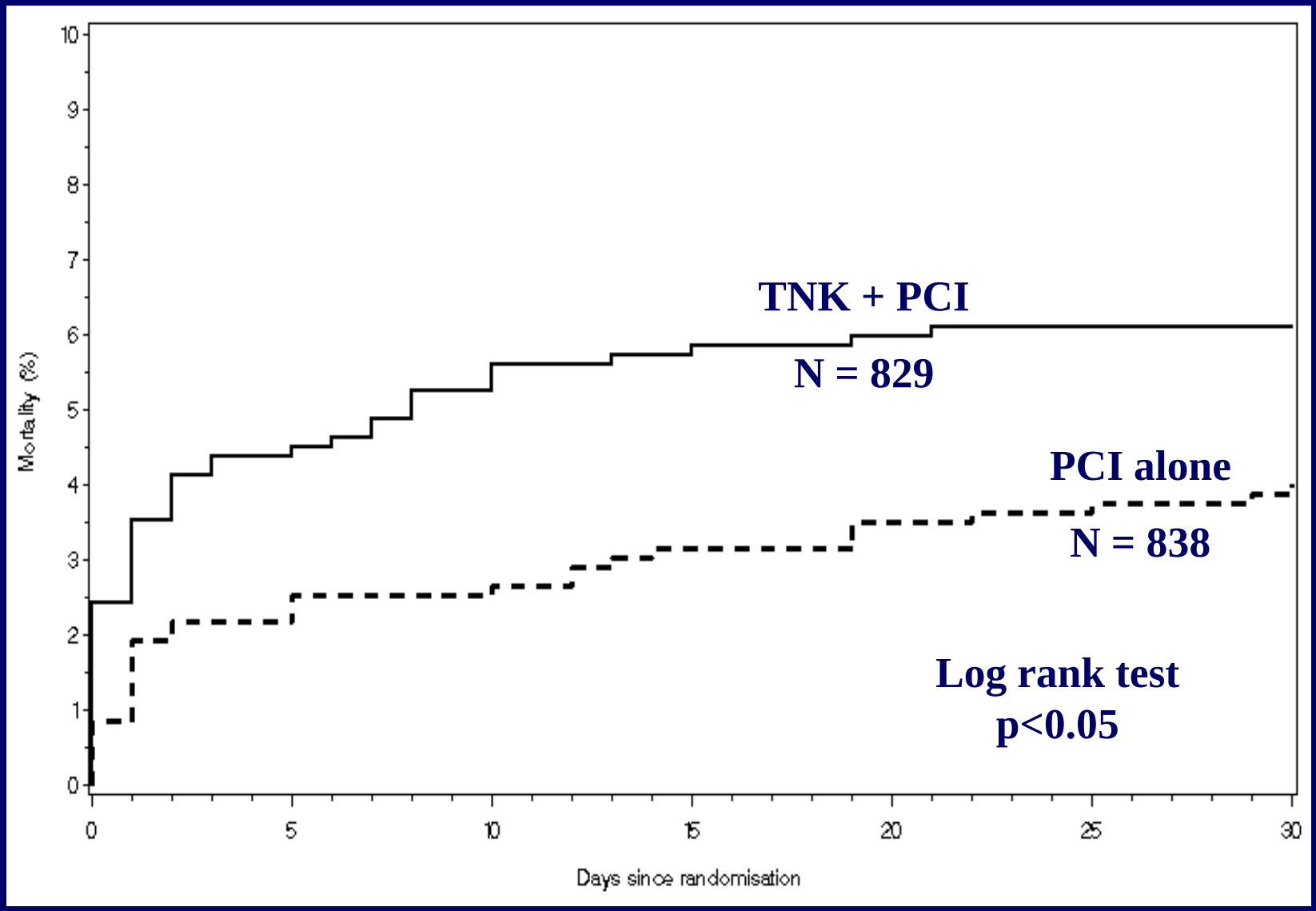
Frans Van de Werf, MD, PhD, FESC
University of Leuven
Leuven, Belgium

on behalf of the ASSENT-4 PCI investigators

ASSENT IV - Trial Design



Kaplan-Meier Curves for 30 DAY MORTALITY



Primary versus tenecteplase-facilitated percutaneous coronary intervention in patients with ST-segment elevation acute myocardial infarction (ASSENT-4 PCI): randomised trial

*Assessment of the Safety and Efficacy of a New Treatment Strategy with Percutaneous Coronary Intervention (ASSENT-4 PCI) investigators**

Interpretation A strategy of full-dose tenecteplase with antithrombotic co-therapy, as used in this study and preceding PCI by 1–3 h, was associated with more major adverse events than PCI alone in STEMI and cannot be recommended.

Lancet 2006; 367: 569–78

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

ESC Guidelines

term 'facilitated PCI' is not uniformly used for identical settings: it should be used as initially planned PCI, following shortly after initiating thrombolysis and/or GP IIb/IIIa inhibitors. Therefore, in randomized studies testing the concept of facilitated PCI, all patients (with or without pre-treatment) should undergo planned primary PCI.

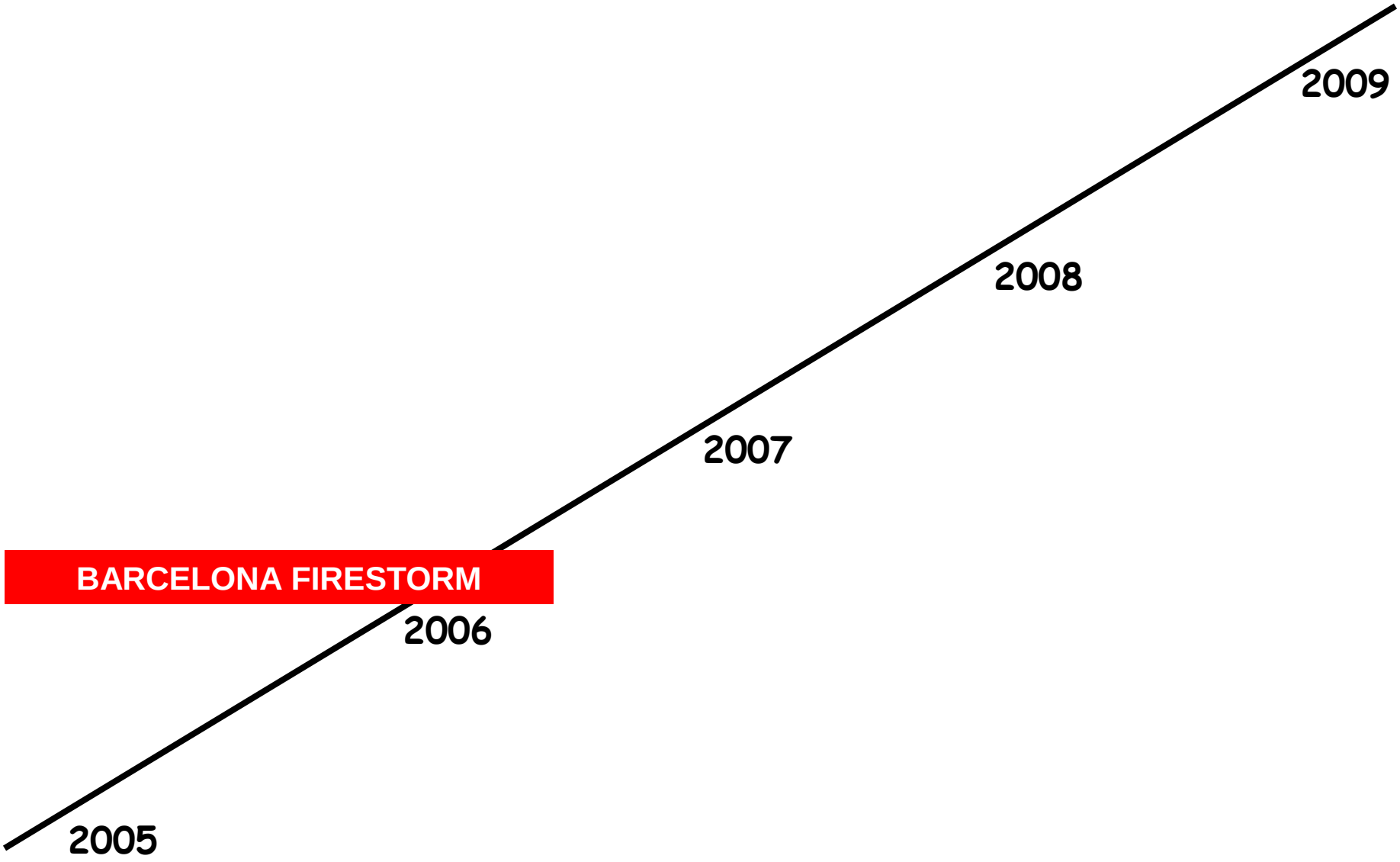
we prefer primary PCI over thrombolysis in the first 3 h of chest pain to prevent stroke and, in patients presenting 3–12 h after the onset of chest pain, to salvage myocardium and also prevent stroke. At the moment, there is no evidence to recommend facilitated PCI.

European Heart Journal (2005) **26**, 804–847

Take Home Messages from ASSENT-4:

- **If thrombolysis is performed, do not start PCI within 3 hours.**
- **This is a prothrombotic period, potentially dangerous for stenting.**
- **ASSENT-4 did not change the ESC PCI guidelines (no recommendation of facilitated PCI) and was implemented in the recent ESC STEMI guidelines.**

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



TUESDAY

ESC Congress News

EUROPEAN SOCIETY OF CARDIOLOGY®

WORLD HEART FEDERATION®

World Congress of Cardiology 2006

The unique meeting of the European Society of Cardiology Congress 2006 and the World Heart Federation's XVth World Congress of Cardiology

Do drug-eluting stents increase deaths?

TWO SEPARATE, independent meta-analyses, presented in Hot Line session I, suggest drug-eluting stents (DES) may increase death, Q-wave myocardial infarction (clinical surrogates of in-stent thrombosis) and cancer deaths, bringing the long-term safety of DES firmly into the spotlight. Discussant Salim Yusuf (McMaster University, Canada) hailed the data as one of the most important presentations to come out of this year's meeting.

"Six million people in the world have been implanted with DES, yet their long-term safety and efficacy is unknown," said Yusuf. "I've a feeling the data we're seeing today is only the tip of the iceberg. We need to encourage more

obtain this data from the manufacturer," said Nordmann. He speculated that the increase in cancer might be due to a rapid impairment of the immune system.

Yusuf widened the debate to include percutaneous coronary intervention (PCI). "The overuse of PCI is an insidious change in the culture of cardiology that needs to be reversed," he said. The use of PCI was established in MI, high-risk unstable angina and cardiogenic shock. However, its use in stable disease was a totally different question.

"There's no beneficial influence on mortality – PCI does nothing to prevent heart attack. All we are doing is providing short-term relief of chest

ANGIOGRAPHIC FOLLOW-UP AFTER PLACEMENT OF A SELF-EXPANDING CORONARY-ARTERY STENT

PATRICK W. SERRUYS, M.D., BRADLEY H. STRAUSS, M.D., KEVIN J. BEATT, M.B., B.S., MICHEL E. BERTRAND, M.D., JACQUES PUEL, M.D., ANTHONY F. RICKARDS, M.B., B.S., BERNHARD MEIER, M.D., JEAN-JACQUES GOY, M.D., PIERRE VOGT, M.D., LUKAS KAPPENBERGER, M.D., AND ULRICH SIGWART, M.D.

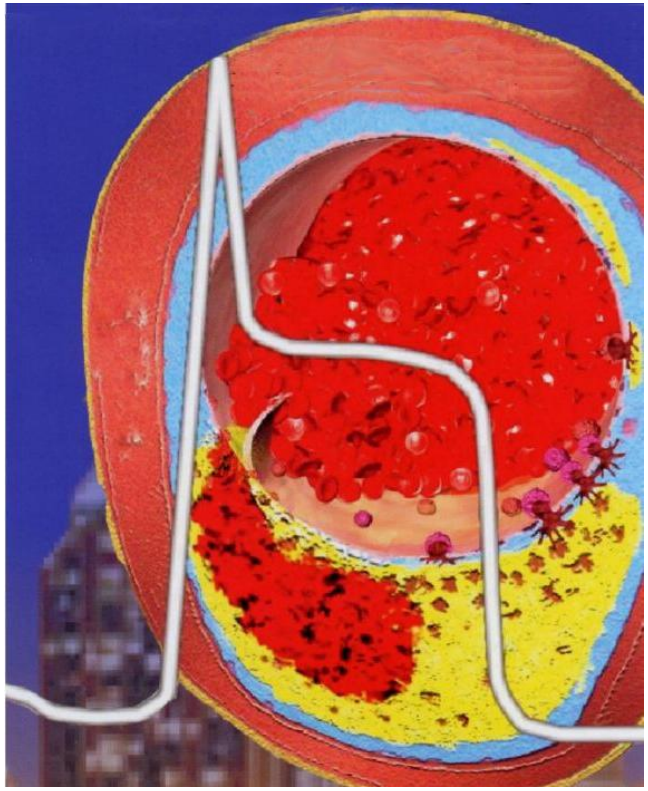
Table 2. Deaths after Stent Implantation.

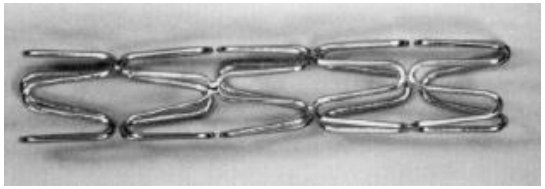
PATIENT NO.	TIME AFTER IMPLANTATION	CAUSE OF DEATH
1	<24 hr	Stent occlusion after vessel closure during PTCA
2	48 hr	Sudden death
3	2 days	Stent occlusion after [illegible] followed by emergency bypass procedure
4	8 days	Stent occlusion during implantation, myocardial infarction, shock
5	11 days	Sudden death
6	1½ mo	Sudden death
7	2½ mo	Surgery for new lesion of left main artery, after bypass procedure
8	6 mo	Chronic congestive heart failure

25% Stent Thrombosis !

(N Engl J Med 1991; 324:13-7.)

Stent Thrombosis presents usually as an Acute Myocardial Infarction





Incidence, Predictors, and Outcome of Thrombosis After Successful Implantation of Drug-Eluting Stents

Ioannis Iakovou, MD
Thomas Schmidt, MD
Erminio Bonizzoni, PhD
Lei Ge, MD
Giuseppe M. Sangiorgi, MD
Goran Stankovic, MD
Flavio Airoldi, MD
Alaide Chieffo, MD
Matteo Montorfano, MD
Mauro Carlino, MD
Iassen Michev, MD
Nicola Corvaja, MD
Carlo Briguori, MD
Ulrich Gerckens, MD
Eberhard Grube, MD
Antonio Colombo, MD

The clinical consequences were death in 45% of patients and nonfatal MI in the m ity of the others.

Mortality of Stent thrombosis: 30% - 45%

JAMA. 2005;293:2126-2130

TCT2007
TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

CARDIOVASCULAR RESEARCH FOUNDATION

TCT DAILY

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Wednesday • October 24, 2007

WASHINGTON, DC

INSIDE

Do Drug-eluting Stents Decrease Mortality?

Registry data from real-world practice with DES are showing consistently positive safety, efficacy data.

According to reports presented at TCT 2007, DES have improved outcomes and done so safely, in some cases reducing mortality.

"It is encouraging that these data so consistently show safety and efficacy. The challenge will be synthesizing the data from so many different areas into information for clinical practice," **Gregg Stone, MD,**

Gregg Stone, MD

dine treatment beyond one year in patients who were event-free after either treatment with DES or bare-metal stents in single, de novo lesions in native

Vagaonescu concluded that the use of a single DES in the setting of AMI was associated with a significant reduction of two-year all-cause mortality and cardiovascular mortality when compared with the use of a single bare-metal stent.

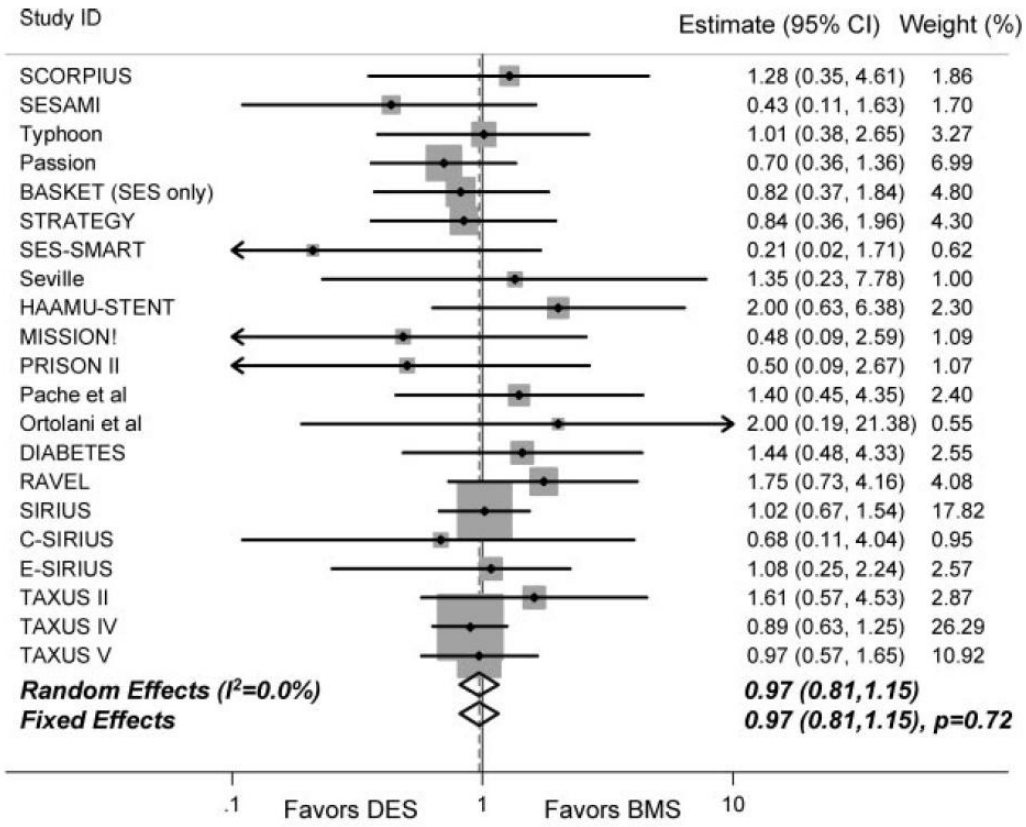
For complete coverage see Emerging DES Data articles inside.

Cardiologist

Safety and Efficacy of Drug-Eluting and Bare Metal Stents

Comprehensive Meta-Analysis of Randomized Trials and Observational Studies

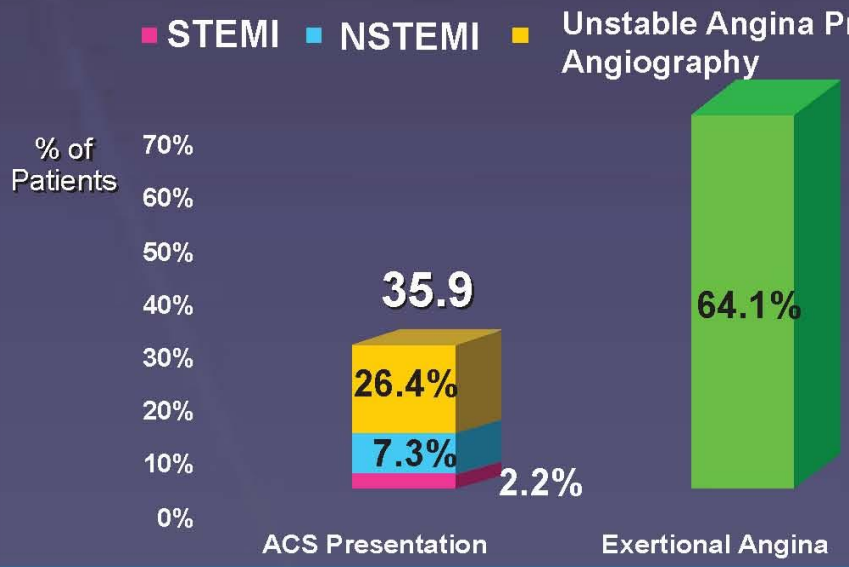
Ajay J. Kirtane, MD, SM; Anuj Gupta, MD; Srinivas Iyengar, MD; Jeffrey W. Moses, MD; Martin B. Leon, MD; Robert Applegate, MD; Bruce Brodie, MD; Edward Hannan, PhD; Kishore Harjai, MD; Lisette Okkels Jensen, MD; Seung-Jung Park, MD, PhD; Raphael Perry, MD; Michael Racz, PhD; Francesco Saia, MD, PhD; Jack V. Tu, MD, PhD; Ron Waksman, MD; Alexandra J. Lansky, MD; Roxana Mehran, MD; Gregg W. Stone, MD



Mortality

(*Circulation*. 2009;119:3198-3206.)

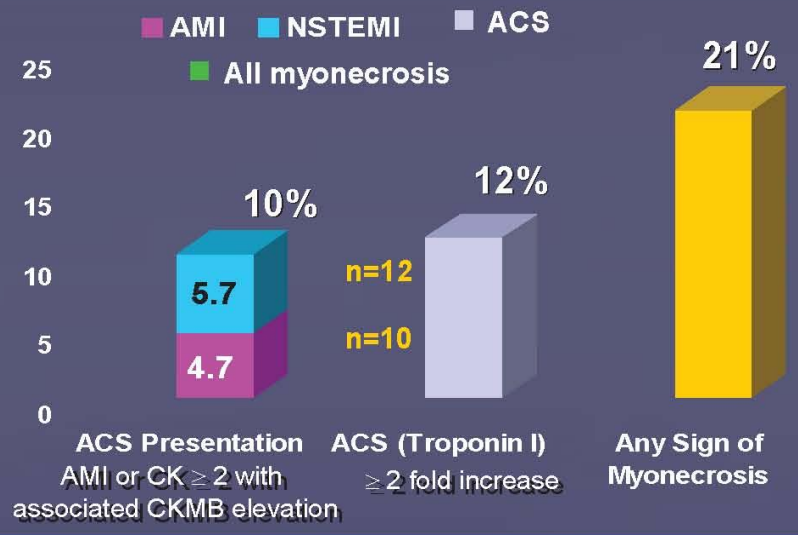
In-Stent Restenosis is NOT a benign Disease !



~36% Present as ACS
9.5% as AMI

Chen M., et al., *Am Heart J* 2006;151:1260-64.

10% of BMS
In-Stent Restenosis Cases
Presented as an MI



Nayak AK., et al., *Circ* 2006;70:1026-9.

Offsetting Impact of Thrombosis and Restenosis on the Occurrence of Death and Myocardial Infarction After Paclitaxel-Eluting and Bare Metal Stent Implantation

Gregg W. Stone, MD; Stephen G. Ellis, MD; Antonio Colombo, MD; Keith D. Dawkins, MD; Eberhard Grube, MD; Donald E. Cutlip, MD; Mark Friedman, MD; Donald S. Baim, MD; Joerg Koglin, MD

Conclusions—ST, although infrequent, results in a high incident rate of death and MI, whereas the more frequent occurrence of target lesion revascularization is associated with a finite but lower rate of death and MI. The marked reduction in restenosis with drug-eluting stents compared with BMS may counterbalance the potential excess risk from late ST with drug-eluting stents. (***Circulation*****. 2007;115:&NA;-.)**

Barcelona 2009 looks back to Barcelona 2006 for its update on drug-eluting stent safety

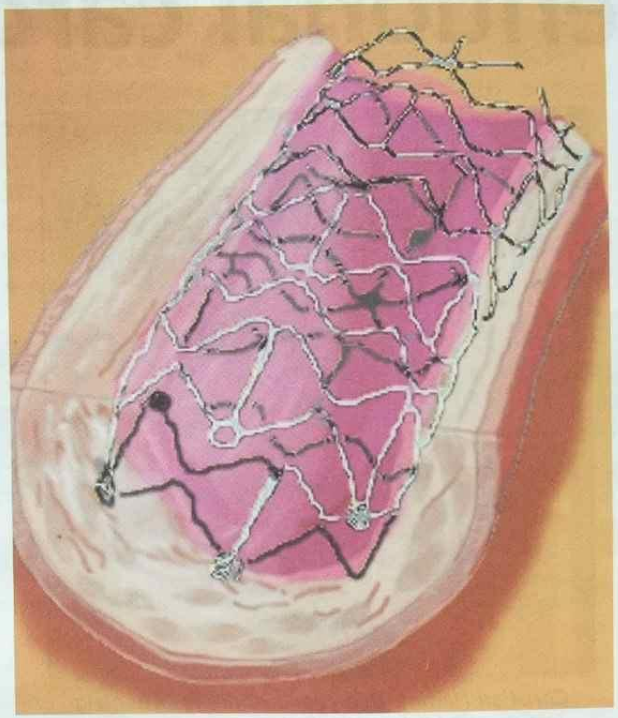
By Janet Fricker
ESC Congress News

THE ESC'S LAST CONGRESS in Barcelona in 2006 will largely be remembered for what's gone down in cardiology folklore as the "ESC firestorm" or "Barcelona brawl"; it was all about the safety of drug-eluting stents (DES). Returning to Barcelona for ESC Congress 2009, the programme committee has taken the brave decision to revisit the controversy, with a main session titled "Is it time to turn the page on Barcelona 2006?".

At ESC Congress 2006 two independent meta-analyses, presented during a Hot Line session, raised the possibility that first generation DES might increase the risk of death. In one presentation Alain Nordmann from Basel, Switzerland, suggested the sirolimus (but not the paclitaxel) eluting stent was associated with small but significant increases in non-cardiac mortality; while in a second presentation Edoardo Camezind from Geneva, Switzerland, pooled published data from four randomised trials to show rates of overall death and Q wave MI to be higher (6.3%) for the Cypher stent than the BMS stent (3.9%, p=0.03).

The fall-out was immediate. According to data from Morgan Stanley, DES stent penetration in Europe fell from 56.2% in the third quarter of 2006 to 49.4% in the fourth quarter of that year, and to a low of 45.7% in the third quarter of 2007. The decline in DES use was even more dramatic in the USA.

In tomorrow's session Stefan James from Uppsala Clinical Research Centre, Sweden, will review data from registries, focussing on the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) which analysed outcomes of all the 47,967 patients receiving stents in Sweden between 2003 and 2006.



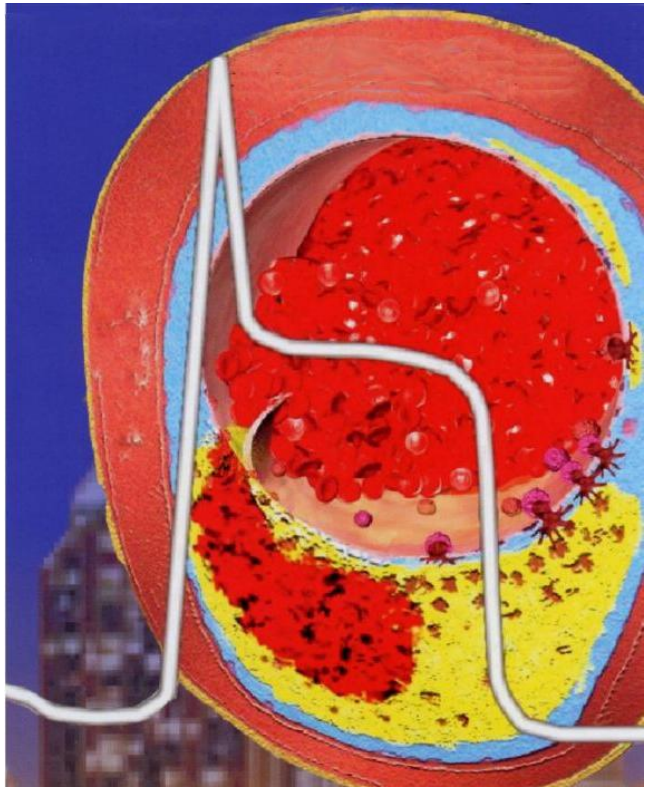
The latest SCAAR data "add to a growing number of randomised trials, registry studies and updated analyses demonstrating no higher mortality associated with DES than with BMS".

The updated SCAAR registry, says Adnan Kastrati from the German Heart Centre in Mun Germany, adds to a growing number randomised trials, registry studies and upda analyses demonstrating no higher morta associated with DES than with BMS. "Now, th years after Barcelona 2006, there's abun evidence to show that the benefit of DES in te of restenosis is not achieved at the expens compromised safety," says Kastrati.

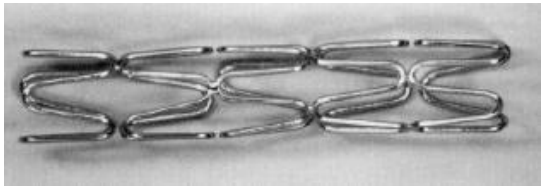
Trials are now under way in more com cases, such as acute MI, in-stent restenosis, complex and long lesions. Recent changes in design, says Kastrati, include those enrolling comers" to better reflect real life situations, follow-up lasting at least two years. Moreover, technology continues to evolve with biodegradable polymers for drug release, poly free release of drugs, drug-eluting ba technology and completely biodegradable ste

Most opinion leaders are agreed that scientific debate sparked by ESC Congress at least prompted research into stent safety. then, an unprecedented wave of published safety data in more than 200,000 patient reassured both physicians and patients tha proven efficacy of first generation DES was the cost of safety. Moreover, trial desig changed, placing greater emphasis on aspects in the evaluation and approval of generation DES. And at tomorrow's se participants at ESC Congress 2009 undoubtedly listen with particular attenti Camezind's own presentation simply titled, repent?".

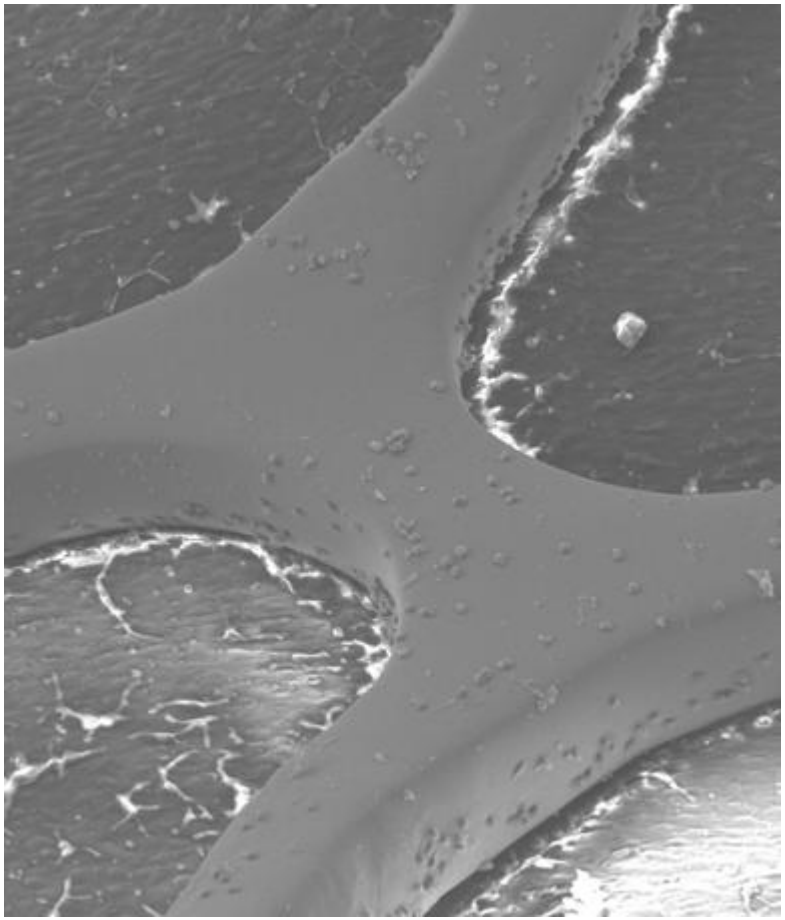
Stent Thrombosis solved ?



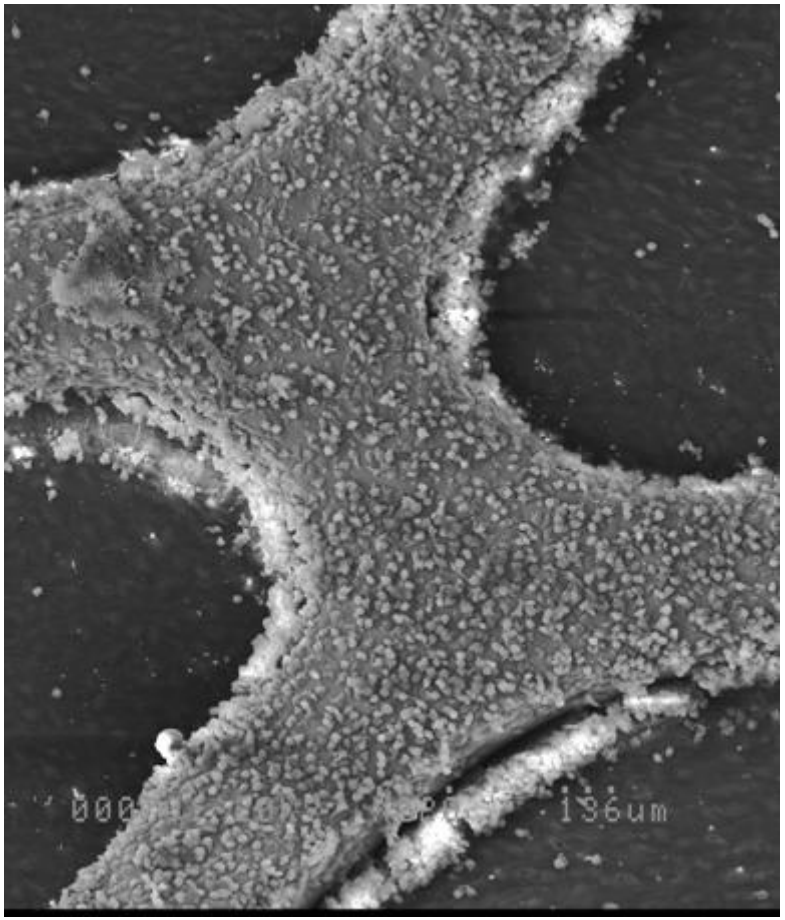
no !



Endothelialisization after Stent Implantation:



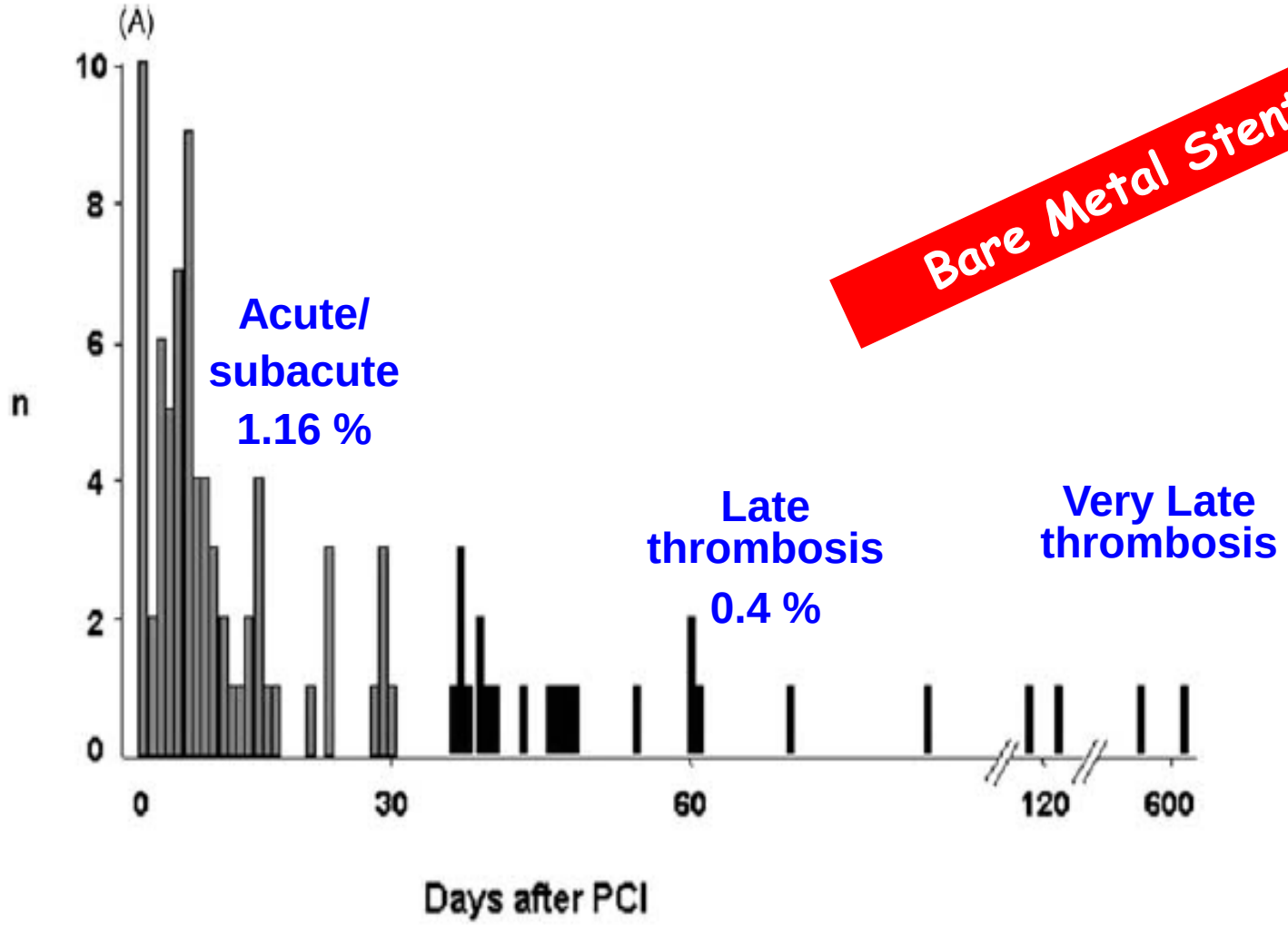
immediately
after stent Implantation



Endothelialization:
- bare metal stents: 4 weeks
- DES: at least 6-12 months

Angiographically confirmed Bare Metal Stent Thrombosis

(1.56%, 95/6058)

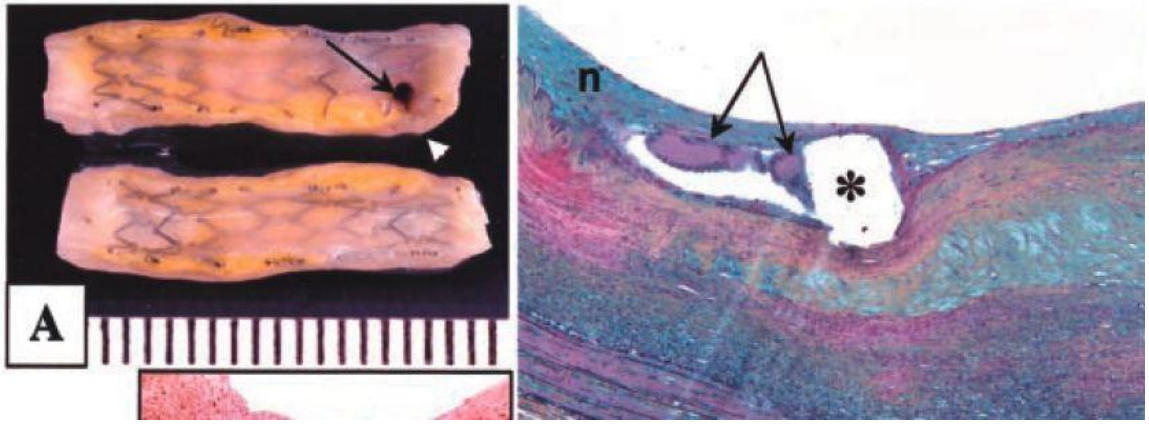


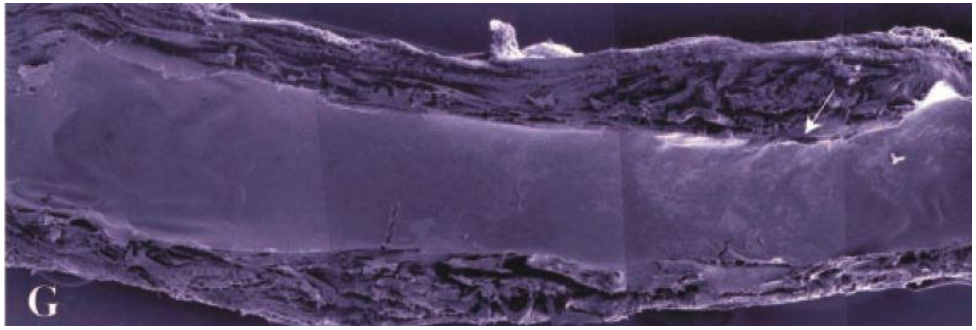
P. Wenaweser, European Heart J, 2005, 26,1180-87

Sirolimus-Eluting Stent Implanted in Human Coronary Artery for 16 Months

Pathological Findings

Giulio Guagliumi, MD; Andrew Farb, MD; Giuseppe Musumeci, MD; Orazio Valsecchi, MD; Maurizio Tespili, MD; Teresio Motta, MD; Renu Virmani, MD

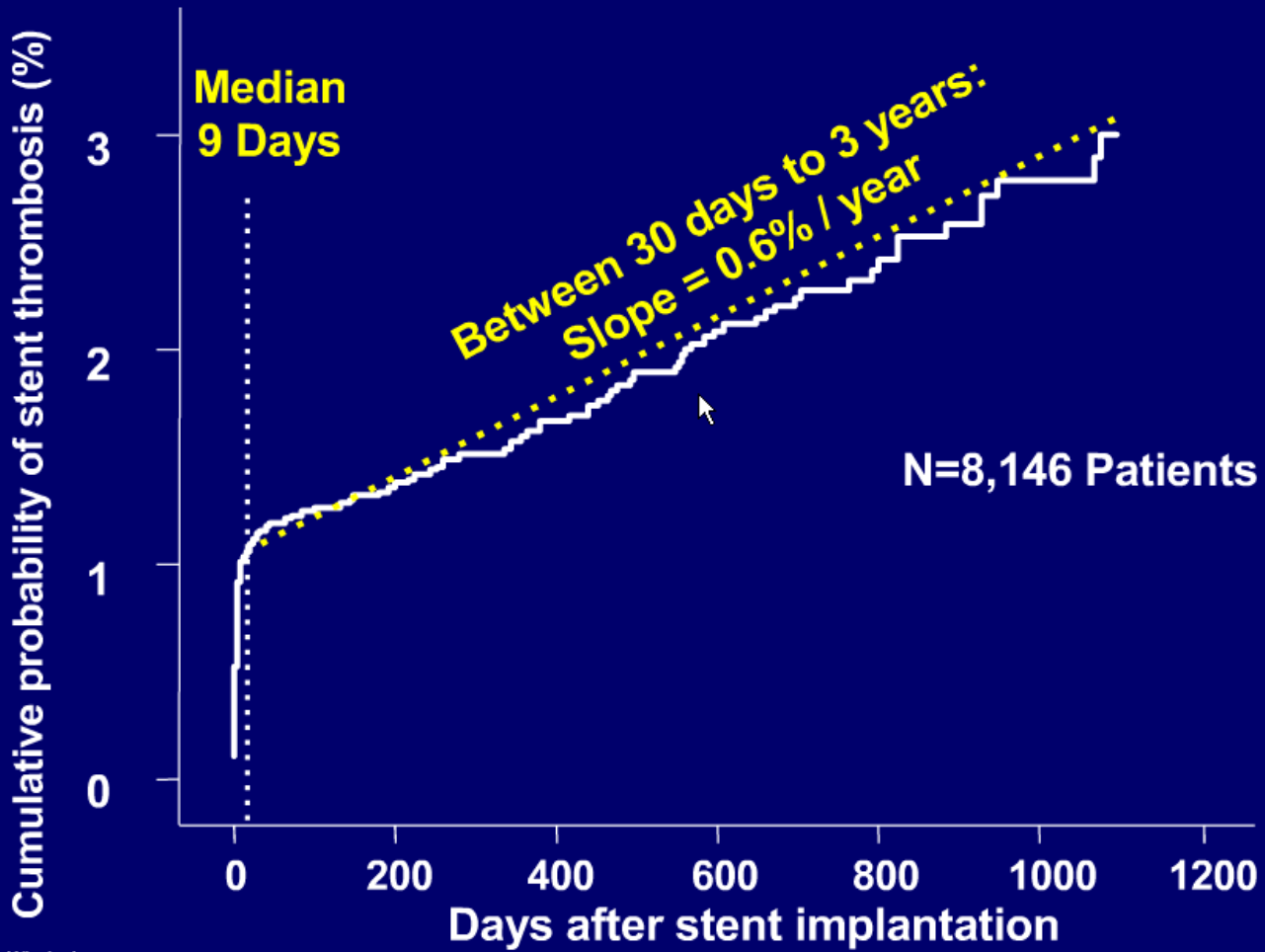




- small thrombi
- thin Neointima
- Foci without endothelialization

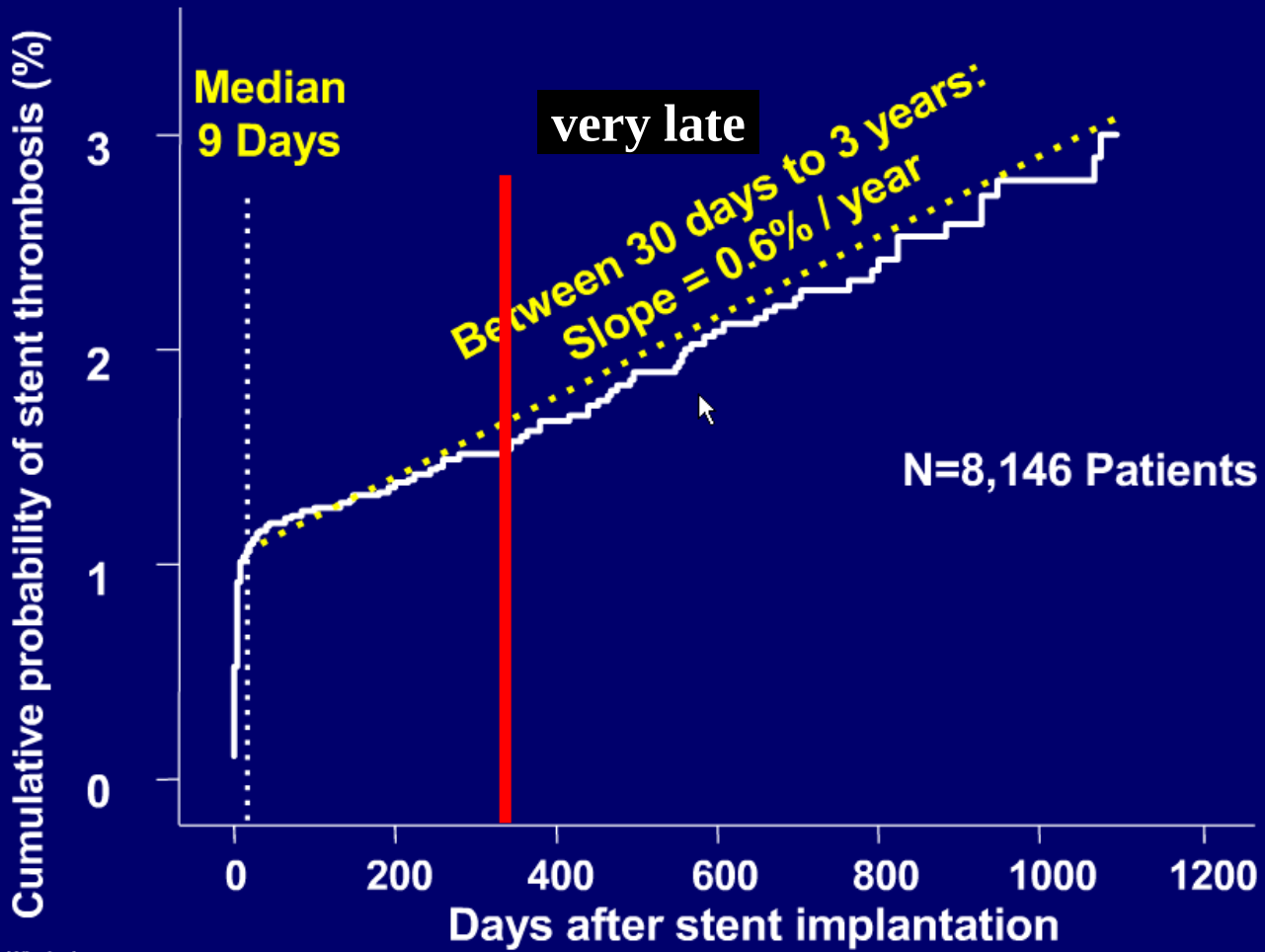
(*Circulation.* 2003;107:1340-1341.)

Angiographic DES Stent Thrombosis
Bern - Rotterdam Cohort Study



Courtesy dr S. Windecker

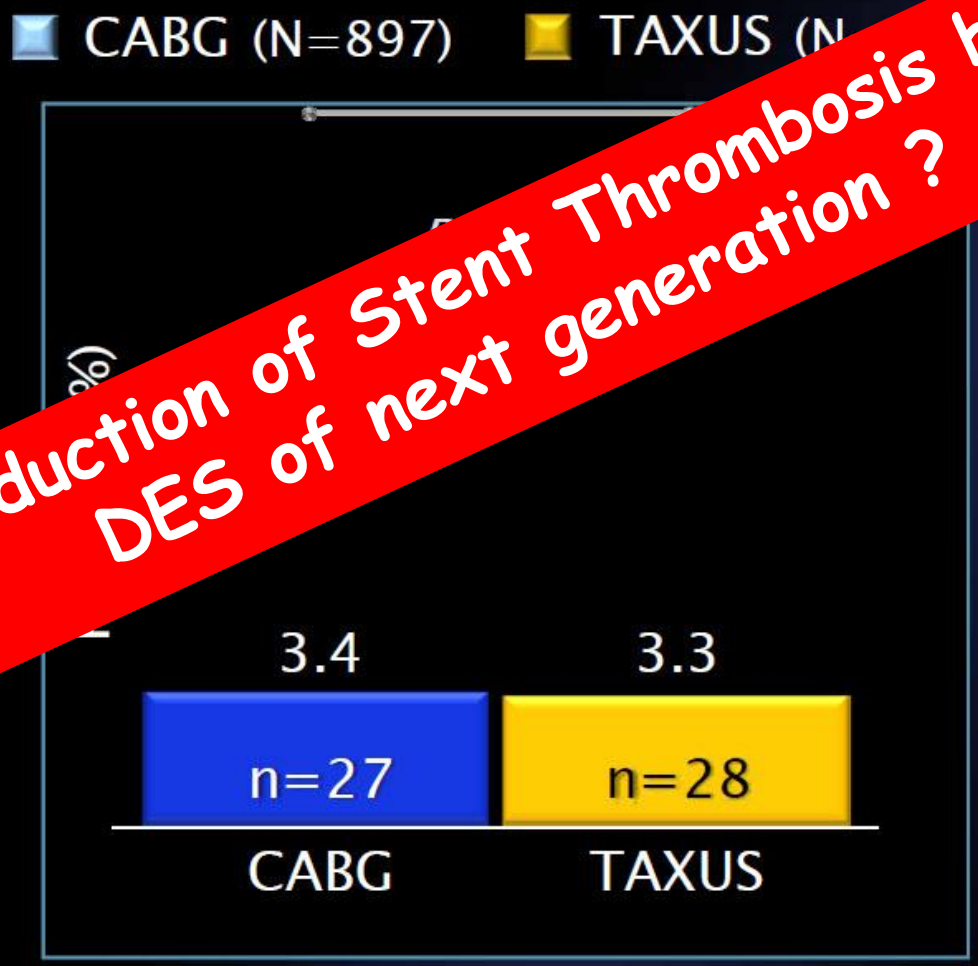
Angiographic DES Stent Thrombosis
Bern - Rotterdam Cohort Study



Courtesy dr S. Windecker

Symptomatic Graft Occlusion & Stent Thrombosis to 12 Months

SYNTAX



Reduction of Stent Thrombosis by DES of next generation ?

ITT population

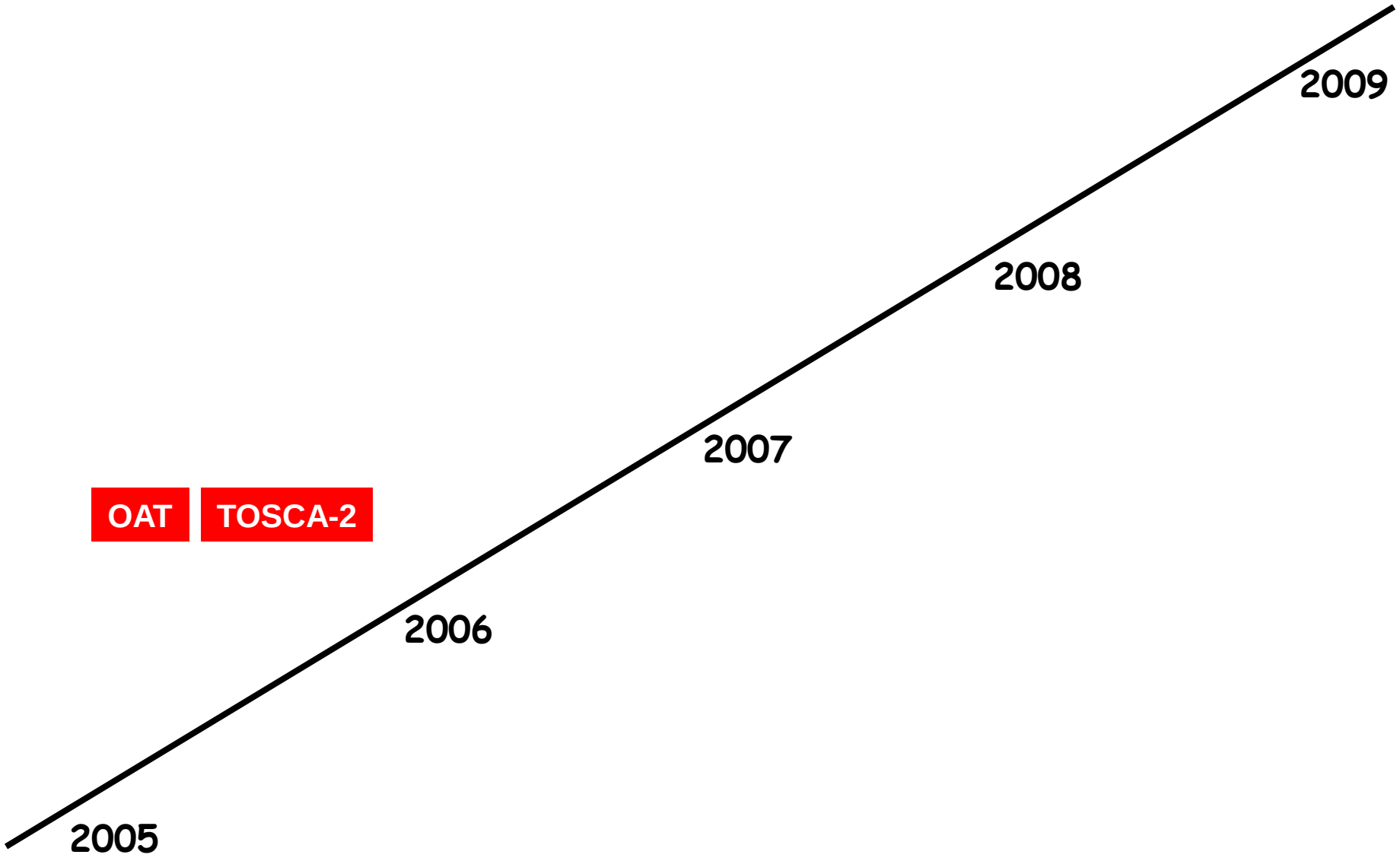
Take Home Messages from DES FIRESTORM:

- **The wild beast „increased mortality after DES“ was born in Barcelona at the ESC 2006.**

Take Home Messages from DES FIRESTORM:

- **The wild beast „increased mortality after DES“ was born in Barcelona at the ESC 2006.**
- **It was finally buried in Barcelona at the ESC 2009.**
- **The „Barcelona Firestorm“ did not change the ESC guidelines.**
- **Late and very late stent thrombosis occurs also with bare metal stents - but more often with DES, so - although rare - this concern still remains.**
- **The highly effective reduction of restenosis after DES also reduces ACS with subsequent reduction of mortality.**
- **For optimal treatment, new DES must be developed for faster healing to enable shorter need of dual antiplatelet medication, thus hopefully decreasing mortality following DES implantation.**

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



Occluded Artery Trial (OAT)

Presented at
The American Heart Association
Scientific Session 2006

Presented by Dr. Judith S. Hochman

OAT Trial: Background

Objective:

To evaluate outcomes of percutaneous coronary intervention (PCI) versus medical therapy among high-risk but stable patients with persistent total occlusion of the infarct-related artery post-myocardial infarction (MI).

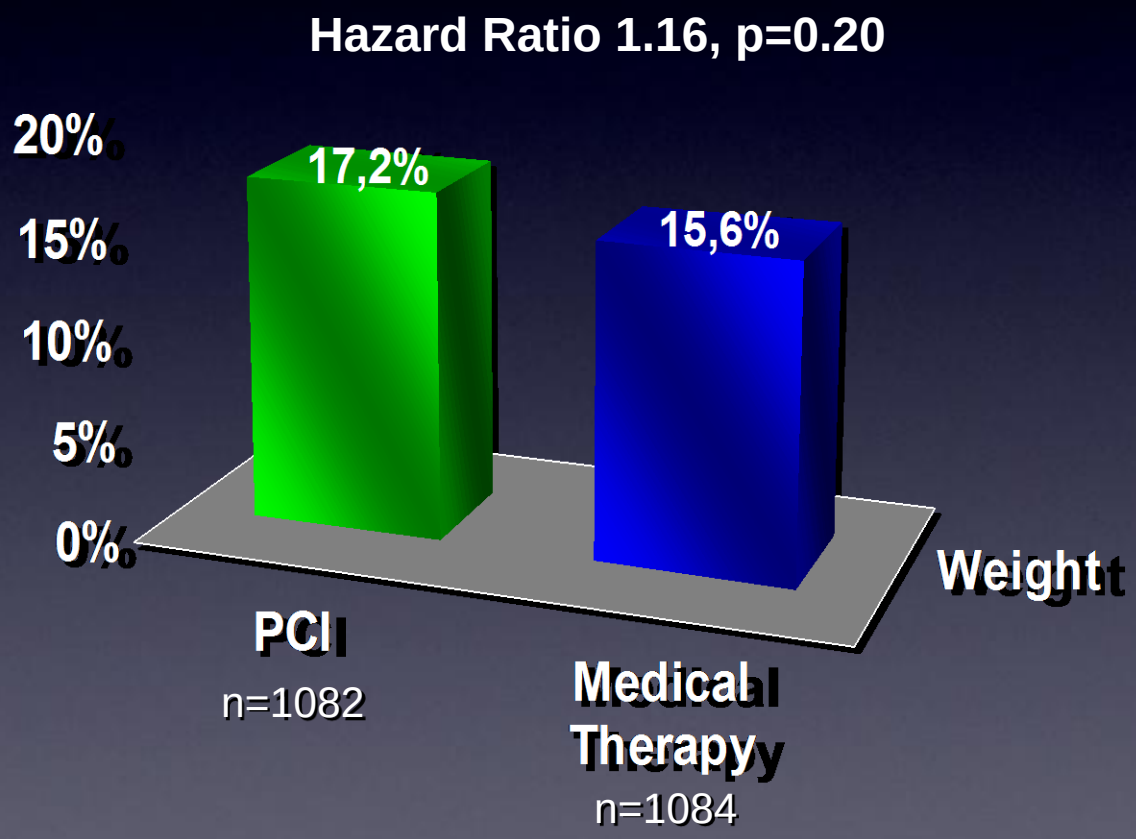
Hypothesis:

Routine PCI for total occlusion of the infarct-related artery 3-28 days after acute MI would reduce the composite end point of death, reinfarction, or New York Heart Association (NYHA) class IV heart failure.

Presented at AHA 2006

Result:

Primary Endpoint of death, reinfarction, NYHA class IV heart failure (% patients)

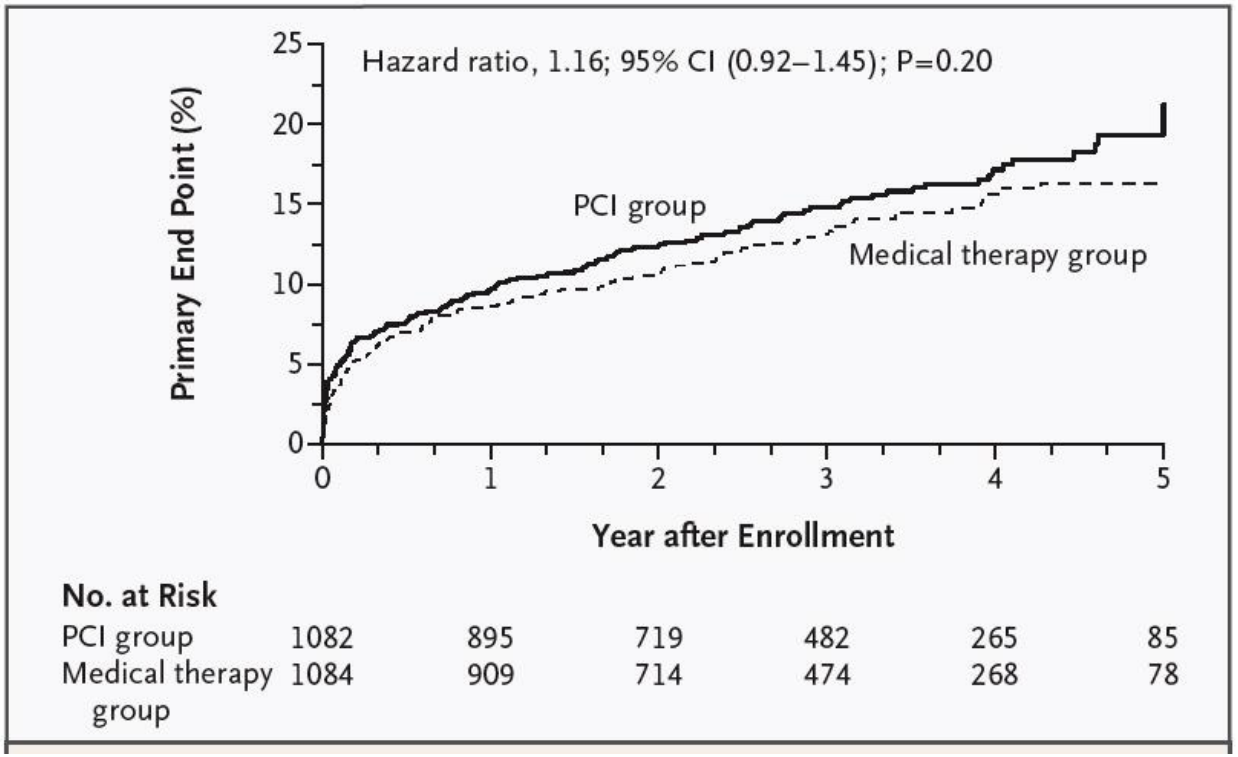


- The primary endpoint: death, reinfarction, or NYHA class IV heart failure occurred in 17.2% of the PCI group and 15.6% of the medical therapy group ([HR] 1.16, p=0.20).

Presented at AHA 2006

Coronary Intervention for Persistent Occlusion after Myocardial Infarction

Judith S. Hochman, M.D., Gervasio A. Lamas, M.D., Christopher E. Buller, M.D., Vladimir Dzavik, M.D., Harmony R. Reynolds, M.D., Staci J. Abramsky, M.P.H., Sandra Forman, M.A., Witold Ruzyllo, M.D., Aldo P. Maggioni, M.D., Harvey White, M.D., Zygmunt Sadowski, M.D., Antonio C. Carvalho, M.D., Jamie M. Rankin, M.D., Jean P. Renkin, M.D., P. Gabriel Steg, M.D., Alice M. Mascette, M.D., George Sopko, M.D., Matthias E. Pfisterer, M.D., Jonathan Leor, M.D., Viliam Fridrich, M.D., Daniel B. Mark, M.D., M.P.H., and Genell L. Knatterud, Ph.D., for the Occluded Artery Trial Investigators*



N Engl J Med 2006;355.

Coronary Intervention for Persistent Occlusion after Myocardial Infarction

Judith S. Hochman, M.D., Gervasio A. Lamas, M.D., Christopher E. Buller, M.D., Vladimir Dzavik, M.D., Harmony R. Reynolds, M.D., Staci J. Abramsky, M.P.H., Sandra Forman, M.A., Witold Ruzyllo, M.D., Aldo P. Maggioni, M.D., Harvey White, M.D., Zygmunt Sadowski, M.D., Antonio C. Carvalho, M.D., Jamie M. Rankin, M.D., Jean P. Renkin, M.D., P. Gabriel Steg, M.D., Alice M. Mascette, M.D., George Sopko, M.D., Matthias E. Pfisterer, M.D., Jonathan Leor, M.D., Viliam Fridrich, M.D., Daniel B. Mark, M.D., M.P.H., and Genell L. Knatterud, Ph.D., for the Occluded Artery Trial Investigators*

Table 1. Baseline Clinical and Angiographic Core Laboratory Characteristics.*

Characteristic	PCI Group (N = 1082)	Medical Therapy Group (N = 1084)	P Value
Ischemia in infarct-related artery territory — no./total no. (%)			0.22
Severe (ineligible)	0/290 (0)	1/299 (0.3)	
Moderate	27/290 (9)	32/299 (11)	
Mild	98/290 (34)	80/299 (27)	
None	165/290 (57)	186/299 (62)	

N Engl J Med 2006;355.

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

Table 1 Recommendations of PCI indications in stable CAD

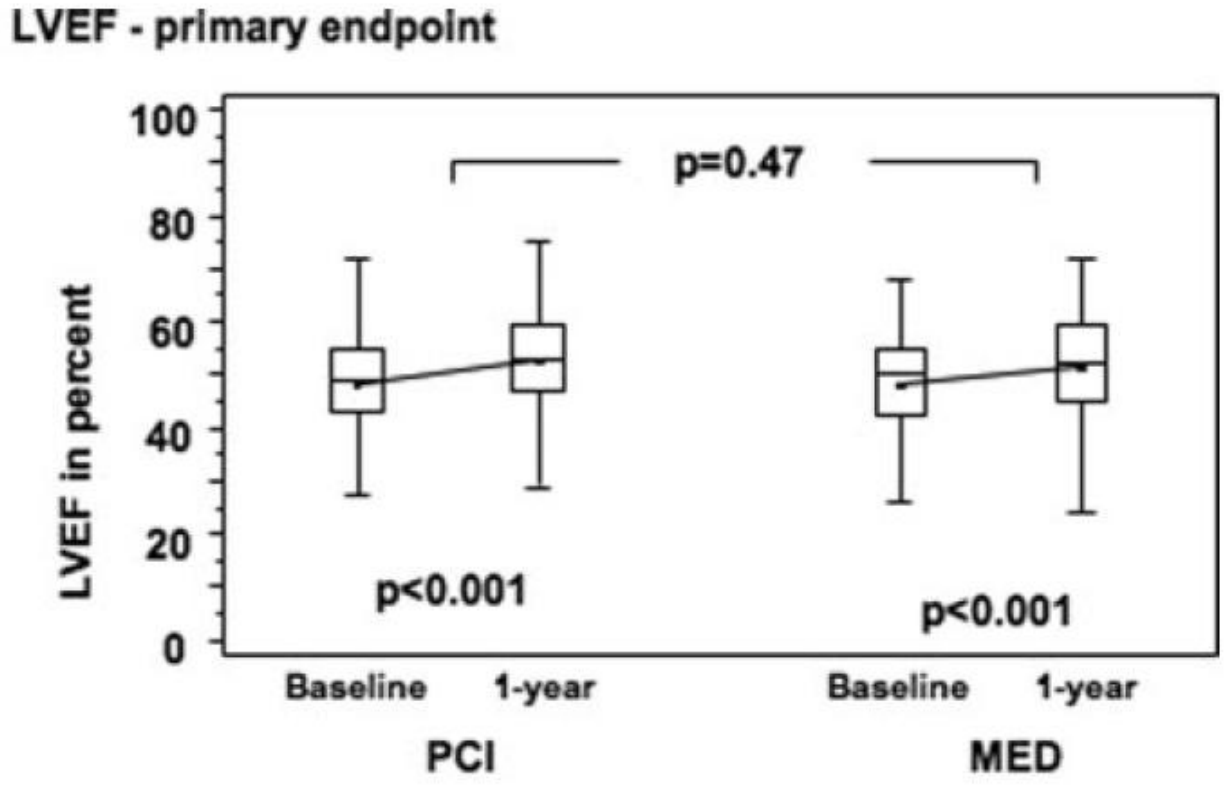
Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Objective large ischaemia	I A	ACME[a] ACIP[b]

European Heart Journal (2005) **26**, 804–847

Randomized Trial of Percutaneous Coronary Intervention for Subacute Infarct-Related Coronary Artery Occlusion to Achieve Long-Term Patency and Improve Ventricular Function

The Total Occlusion Study of Canada (TOSCA)–2 Trial

Vladimír Džavík, MD; Christopher E. Buller, MD; Gervasio A. Lamas, MD; James M. Rankin, MD; G.B. John Mancini, MD; Warren J. Cantor, MD; Ronald J. Carere, MD; John R. Ross, MD; Deborah Atchison, PhD; Sandra Forman, MA; Boban Thomas, MD; Pawel Buszman, MD; Carlos Vozzi, MD; Anthony Glanz, MD; Eric A. Cohen, MD; Peter Mečiar, MD; Gerald Devlin, MD; Alice Mascette, MD; George Sopko, MD; Genell L. Knatterud, PhD; Judith S. Hochman, MD; for the TOSCA-2 Investigators

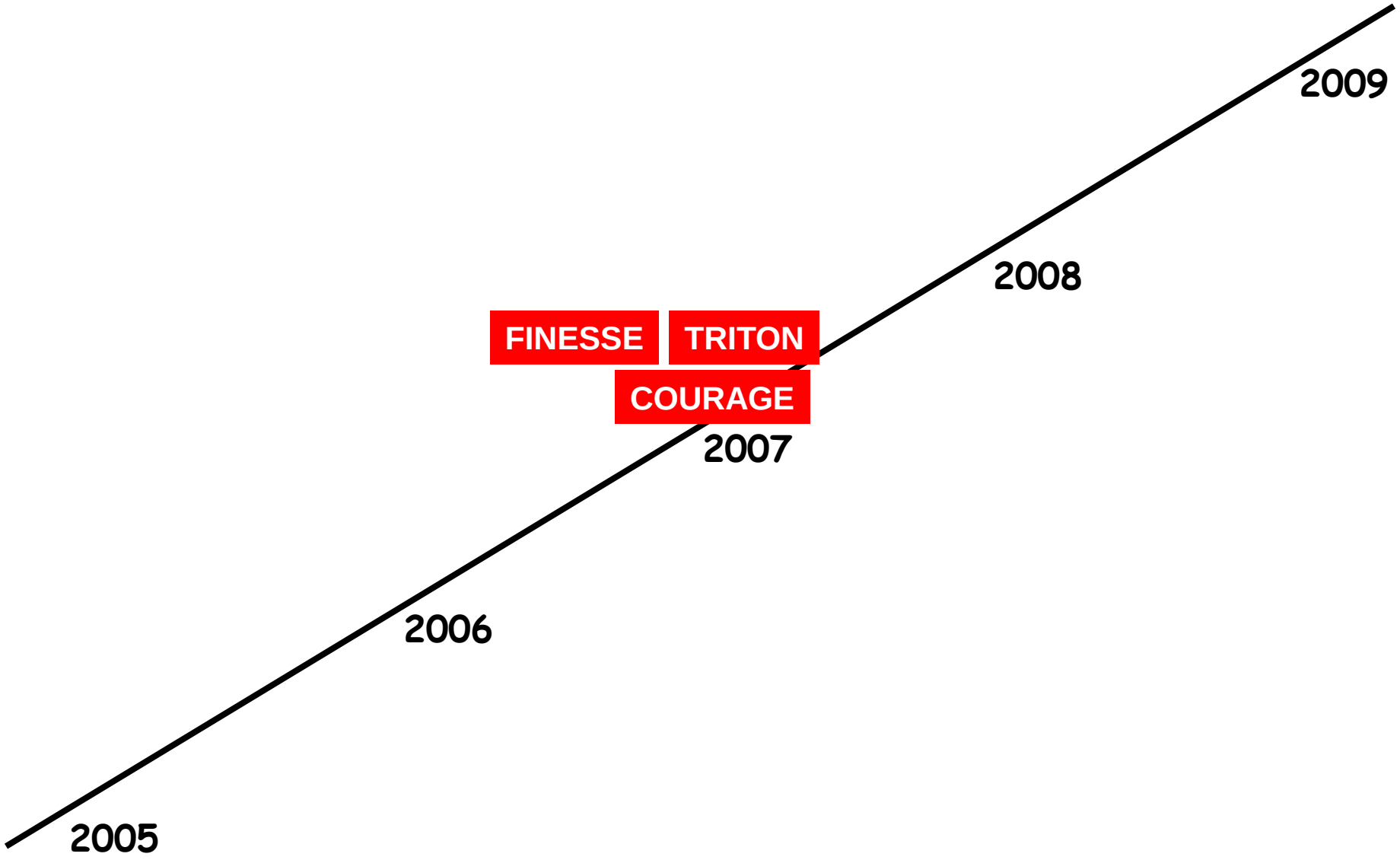


(*Circulation*. 2006;114:2449-2457.)

Take Home Messages from OAT (TOSCA-2):

- **No reperfusion is the worst „treatment“ of myocardial infarction.**
- **Reopening an occluded infarct artery one week later is not helpful, especially if there is no proof of residual ischemia.**
- **OAT (and TOSCA-2) were no CTO studies (no chronic occlusion).**
- **OAT (and TOSCA-2) did not change the ESC guidelines.**

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



ACC.07

56th Annual Scientific Session
March 24 - 27, 2007 New Orleans

THE NATION'S NEWSPAPER

USA TODAY

NO. 1 IN THE USA

Medicine enough for pain in chest?

Study sees way to avoid angioplasty

By Steve Sternberg
USA TODAY

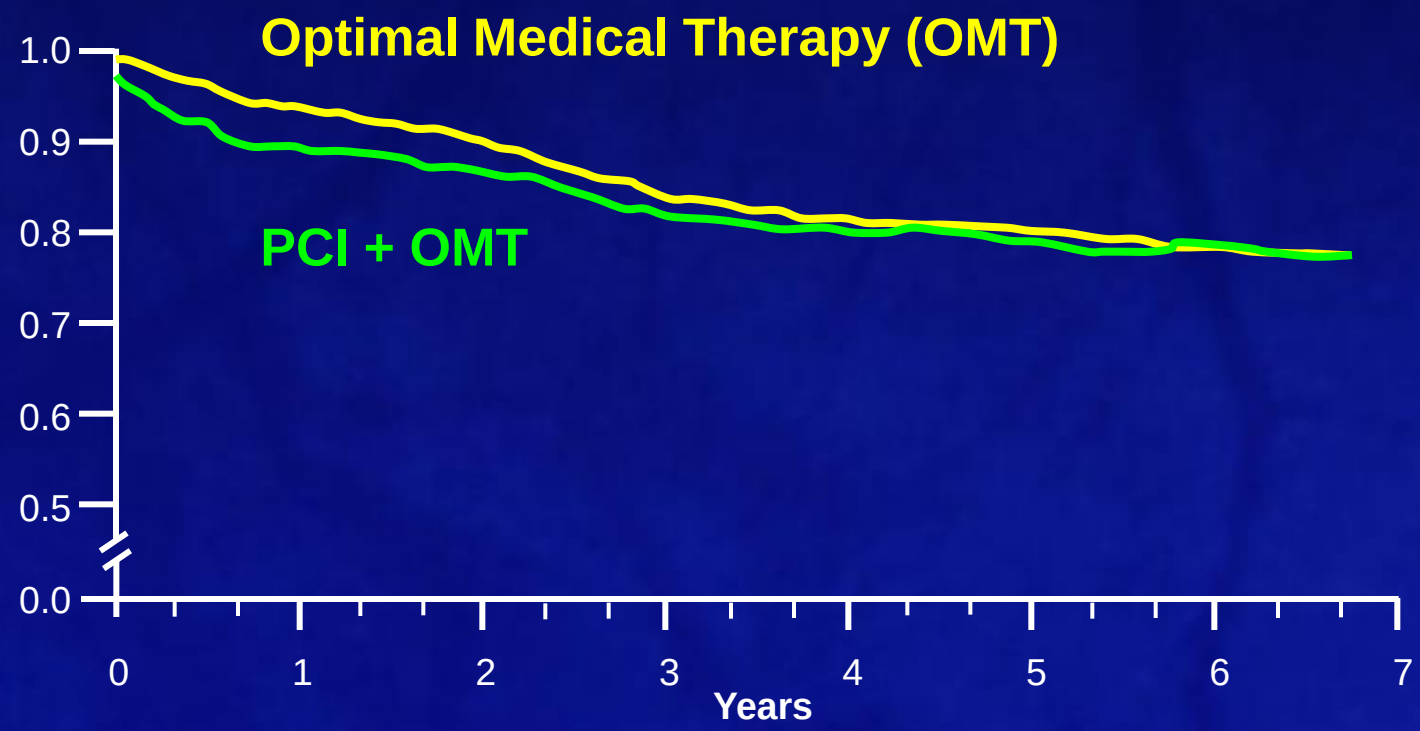
Hypothesis

PCI + Optimal Medical Therapy

will be Superior to

Optimal Medical Therapy Alone

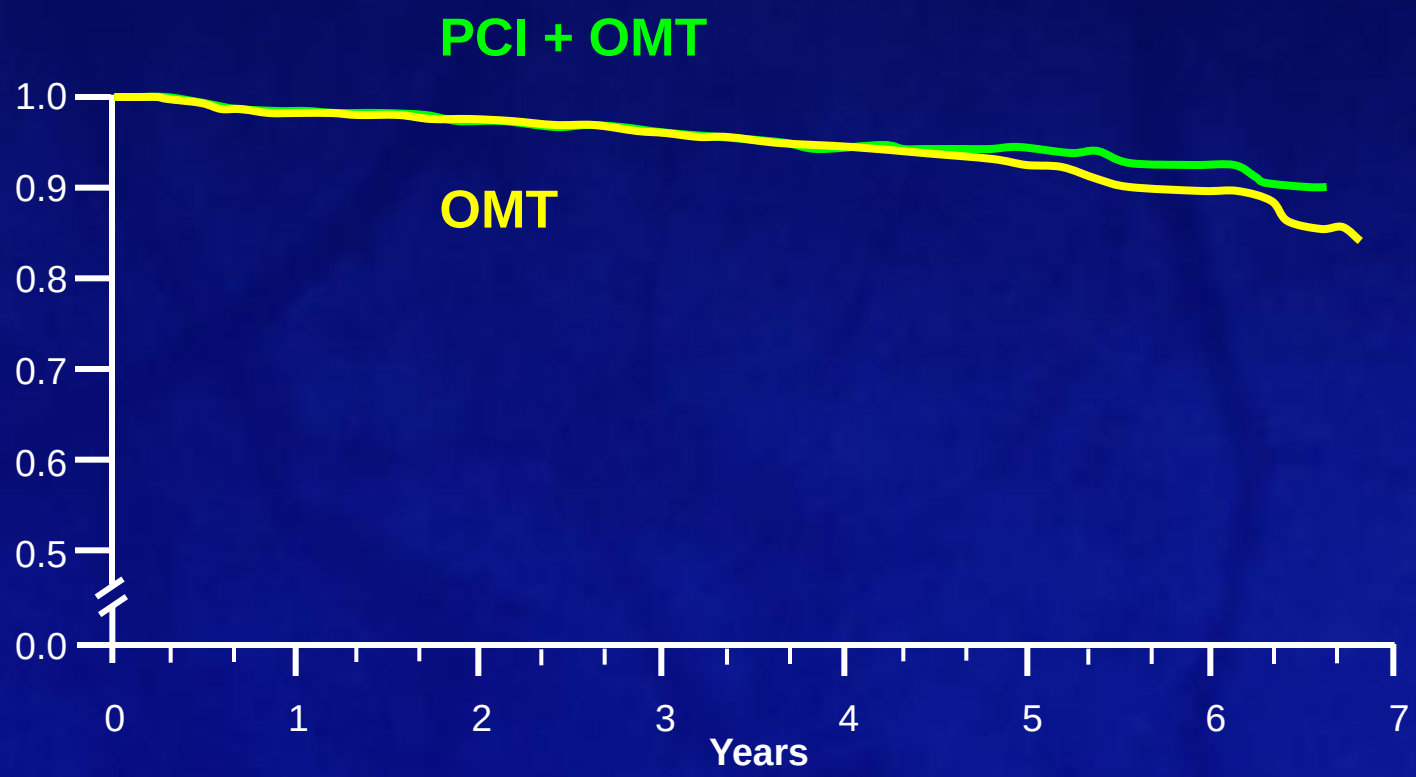
Survival Free of Death from Any Cause and Myocardial Infarction



Number at Risk

Medical Therapy	1138	1017	959	834	638	408	192	3
PCI	1149	1013	952	833	637	417	200	3

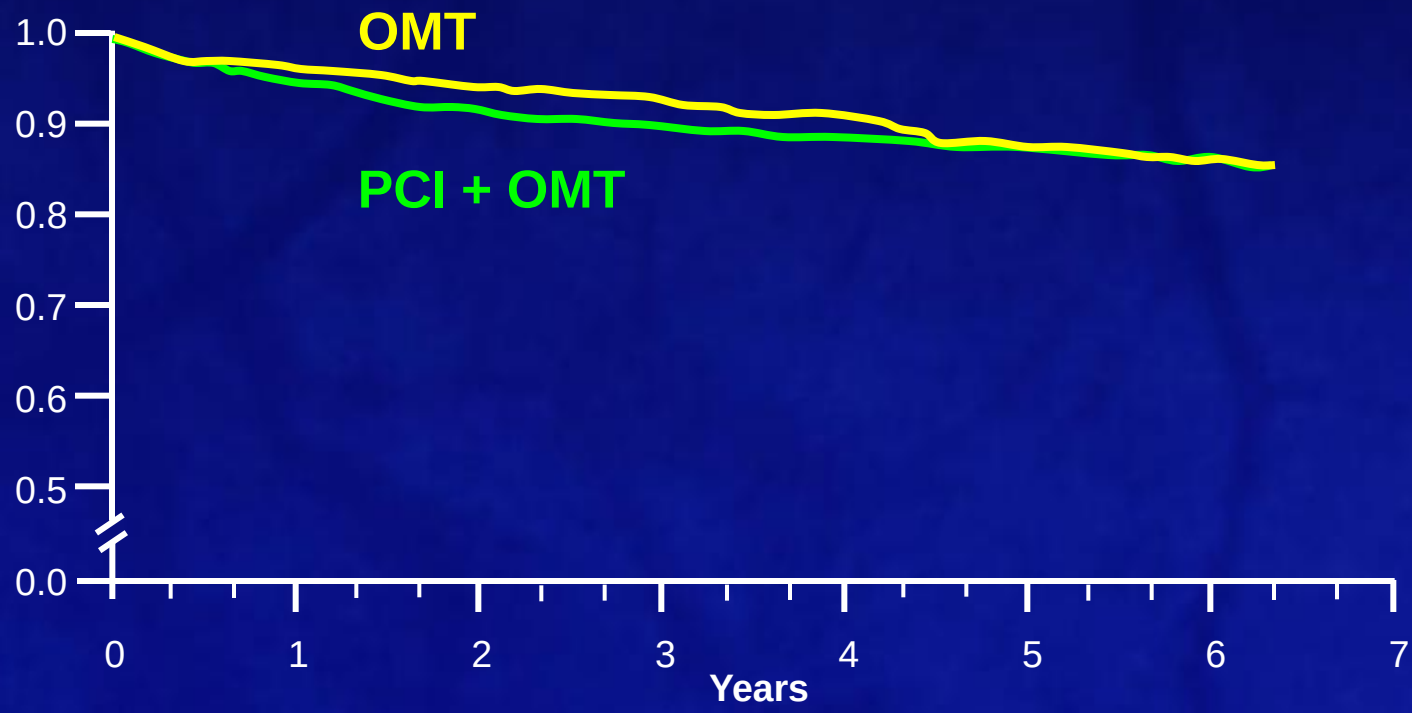
Overall Survival



Number at Risk

Medical Therapy	1138	1073	1029	917	717	468	302	3
PCI	1149	1094	1051	929	733	488	312	4

Survival Free of Hospitalization for ACS



Number at Risk

Medical Therapy	1138	1025	956	833	662	418	236	12
PCI	1149	1027	957	835	667	431	246	13

The NEW ENGLAND JOURNAL of MEDICINE

Optimal Medical Therapy with or without PCI for Stable Coronary Disease

William E. Boden, M.D., Robert A. O'Rourke, M.D., Koon K. Teo, M.B., B.Ch., Ph.D., Pamela M. Hartigan, Ph.D., David J. Maron, M.D., William J. Kostuk, M.D., Merril Knudtson, M.D., Marcin Dada, M.D., Paul Casperson, Ph.D., Crystal L. Harris, Pharm.D., Bernard R. Chaitman, M.D., Leslee Shaw, Ph.D., Gilbert Gosselin, M.D., Shah Nawaz, M.D., Lawrence M. Title, M.D., Gerald Gau, M.D., Alvin S. Blaustein, M.D., David C. Booth, M.D., Eric R. Bates, M.D., John A. Spertus, M.D., M.P.H., Daniel S. Berman, M.D., G.B. John Mancini, M.D., and William S. Weintraub, M.D., for the COURAGE Trial Research Group*

CONCLUSIONS

As an initial management strategy in patients with stable coronary artery disease, PCI did not reduce the risk of death, myocardial infarction, or other major cardiovascular events when added to optimal medical therapy.

N Engl J Med 2007;356:1503-16

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

Authors/Task Force Members: Sigmund Silber, Chairperson* (Germany), Per Albertsson (Sweden), Francisco F. Avilés (Spain), Paolo G. Camici (UK), Antonio Colombo (Italy), Christian Hamm (Germany), Erik Jørgensen (Denmark), Jean Marco (France), Jan-Erik Nordrehaug (Norway), Witold Ruzyllo (Poland), Philip Urban (Switzerland), Gregg W. Stone (USA), William Wijns (Belgium)

2. Indications for PCI

2.1. Indications for PCI in stable coronary artery disease

In patients with no or mild symptoms, however, the scenario is different and unlikely to be improved by PCI

European Heart Journal (2005) **26**, 804–847

Guidelines for Percutaneous Coronary Interventions

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2. Indications for PCI

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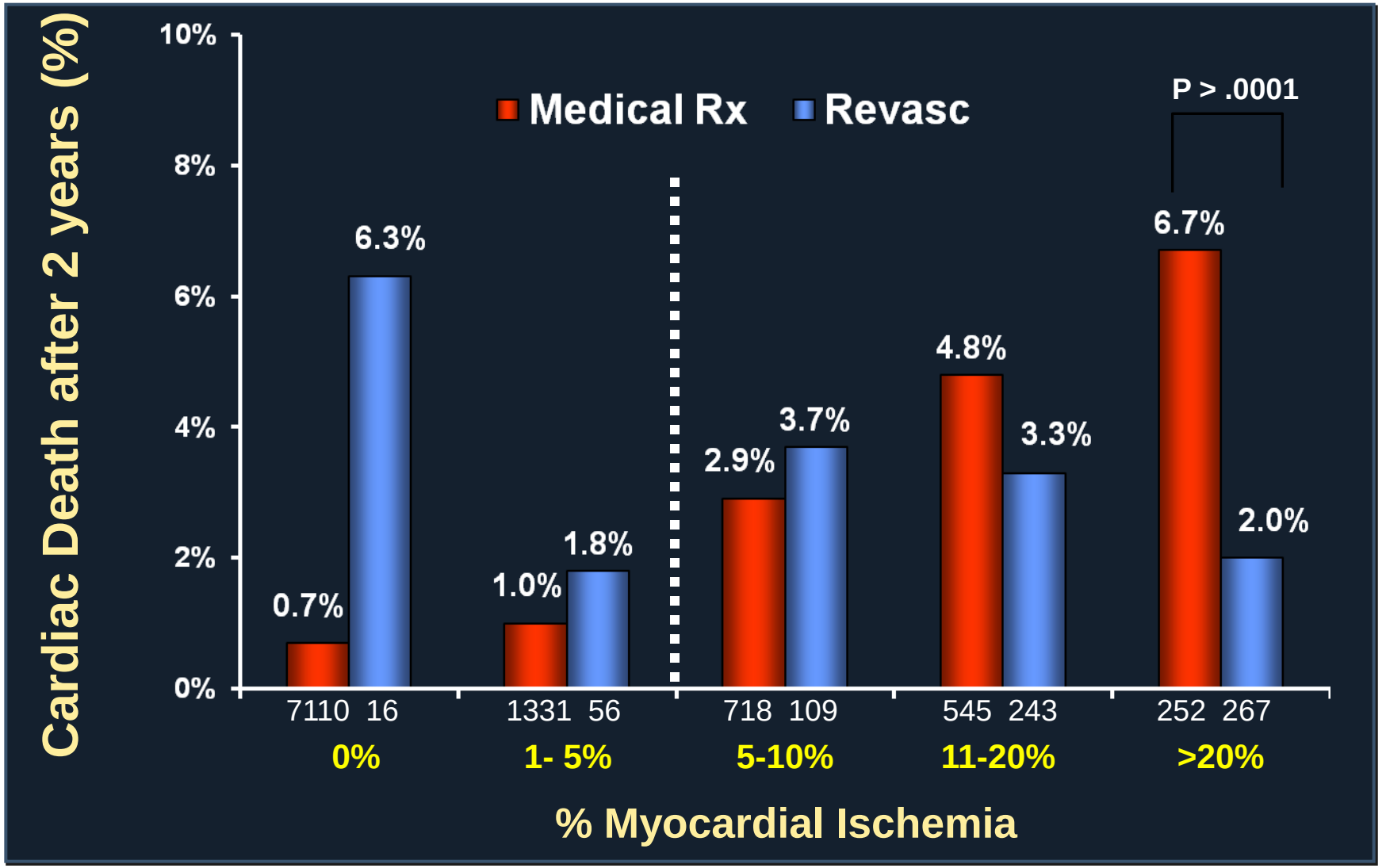
Table 1 Recommendations of PCI indications in stable CAD

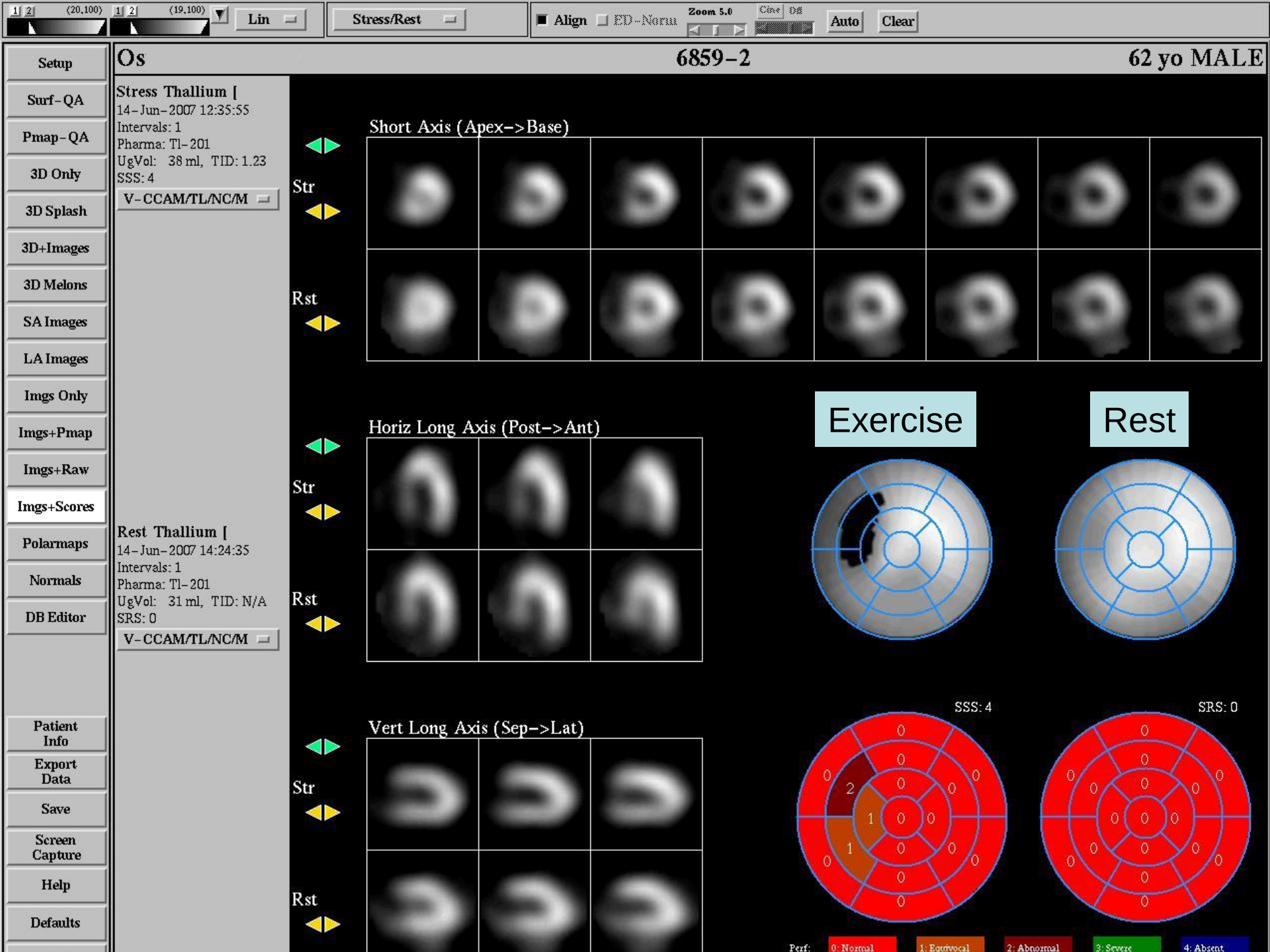
Indication	Classes of recommendations and levels of evidence	Randomized studies for levels A or B
Objective large ischaemia	I A	ACME[a] ACIP[b]

European Heart Journal (2005) 26, 804–847

Improvement of Prognosis depends on the Extent of Myocardial Ischemia



Hachamovitch et al Circulation. **2003;107:2900-07.**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3D Splash
3D+Images
3D Melons
SA Images
LA Images
Imgs Only
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Rst
Horiz Long Axis (Post->Ant)
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Rst
Vert Long Axis (Sep->Lat)
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Exercise
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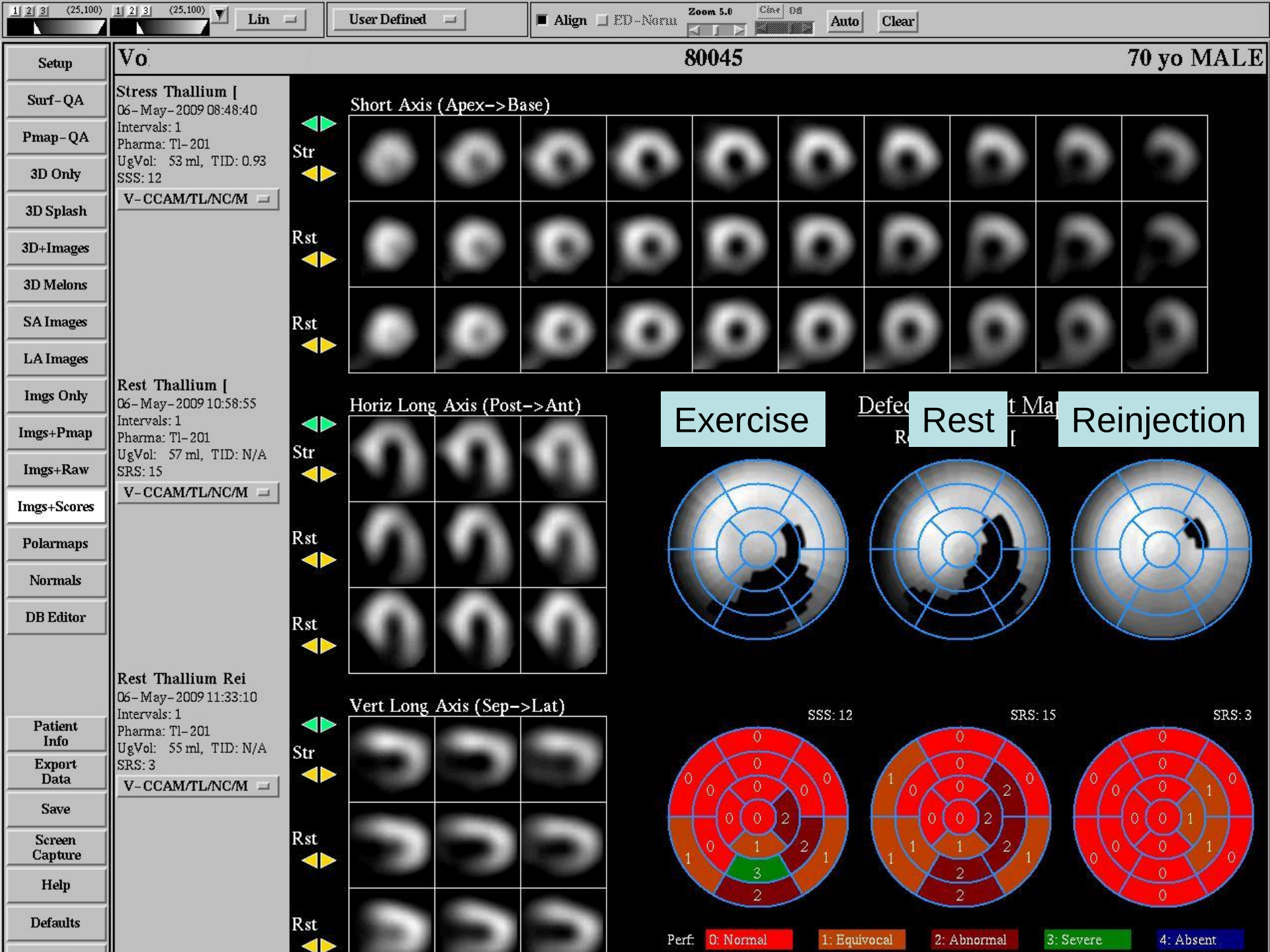
SSS: 4
SRS: 0
Perf:
0: Normal
1: Equivocal
2: Abnormal
3: Severe
4: Absent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Pmap-QA
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3D Melons
SA Images
LA Images
Imgs Only
Imgs+Pmap
Imgs+Raw
Imgs+Scores
Polarmaps
Normals
DB Editor
Patient Info
Export Data
Save
Screen Capture
Help
Defaults
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70 yo MALE
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Intervals: 1
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UgVol: 53 ml, TID: 0.93
SSS: 12
V-CCAM/TL/NC/M
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V-CCAM/TL/NC/M
Rest Thallium Rei
06-May-2009 11:33:10
Intervals: 1
Pharma: Tl-201
UgVol: 55 ml, TID: N/A
SRS: 3
V-CCAM/TL/NC/M
Short Axis (Apex->Base)
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Vert Long Axis (Sep->Lat)
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Rst
Exercise
Rest
Reinjection
SSS: 12
SRS: 15
SRS: 3
Perf:
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3: Severe
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Stable Angina
2006

Guidelines on the management of stable angina pectoris: full text‡

The Task Force on the Management of Stable Angina Pectoris of the European Society of Cardiology

Authors/Task Force Members, Kim Fox, Chairperson, London (UK)*, Maria Angeles Alonso Garcia, Madrid (Spain), Diego Ardissino, Parma (Italy), Pawel Buszman, Katowice (Poland), Paolo G. Camici, London (UK), Filippo Crea, Roma (Italy), Caroline Daly, London (UK), Guy De Backer, Ghent (Belgium), Paul Hjemdahl, Stockholm (Sweden), José Lopez-Sendon, Madrid (Spain), Jean Marco, Toulouse (France), João Morais, Leiria (Portugal), John Pepper, London (UK), Udo Sechtem, Stuttgart (Germany), Maarten Simoons, Rotterdam (The Netherlands), Kristian Thygesen, Aarhus (Denmark)

European Heart Journal (2006) **27**, 1341–1381

PCI for stable CAD

ESC GUIDELINES

To improve the quality of clinical practice and patient care in Europe

Table 6 Summary of recommendations for revascularization in stable angina

Indication	For prognosis[a]		For symptoms[b]	
	Class of recommendation	Level of evidence	Class of recommendation	Level of evidence
PCI (assuming suitable anatomy for PCI, appropriate risk stratification,and discussion with the patient)				
Angina CCS Classes I to IV despite medical therapy with single vessel disease			I	A
Angina CCS Classes I to IV despite medical therapy with multi-vessel disease (non-diabetic)			I	A
Stable angina with minimal (CCS Class I) symptoms on medication and one-, two-, or three-vessel disease but objective evidence of large ischaemia	IIb	C		

PCI for stable CAD

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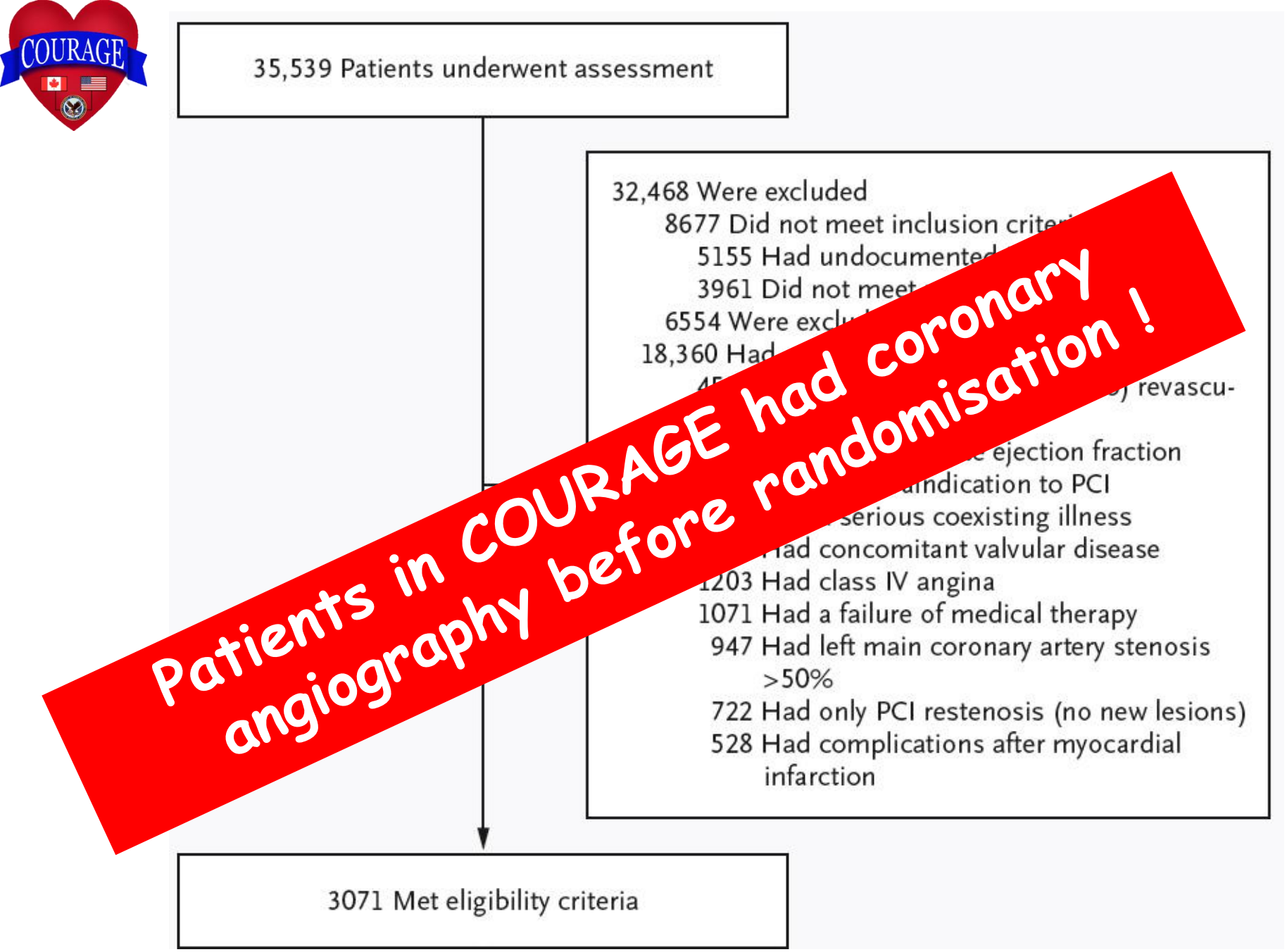
European Heart Journal (2006) **27**, 1341–1381



Patients in COURAGE had coronary angiography before randomisation !

N Engl J Med 2007;356:1503-16

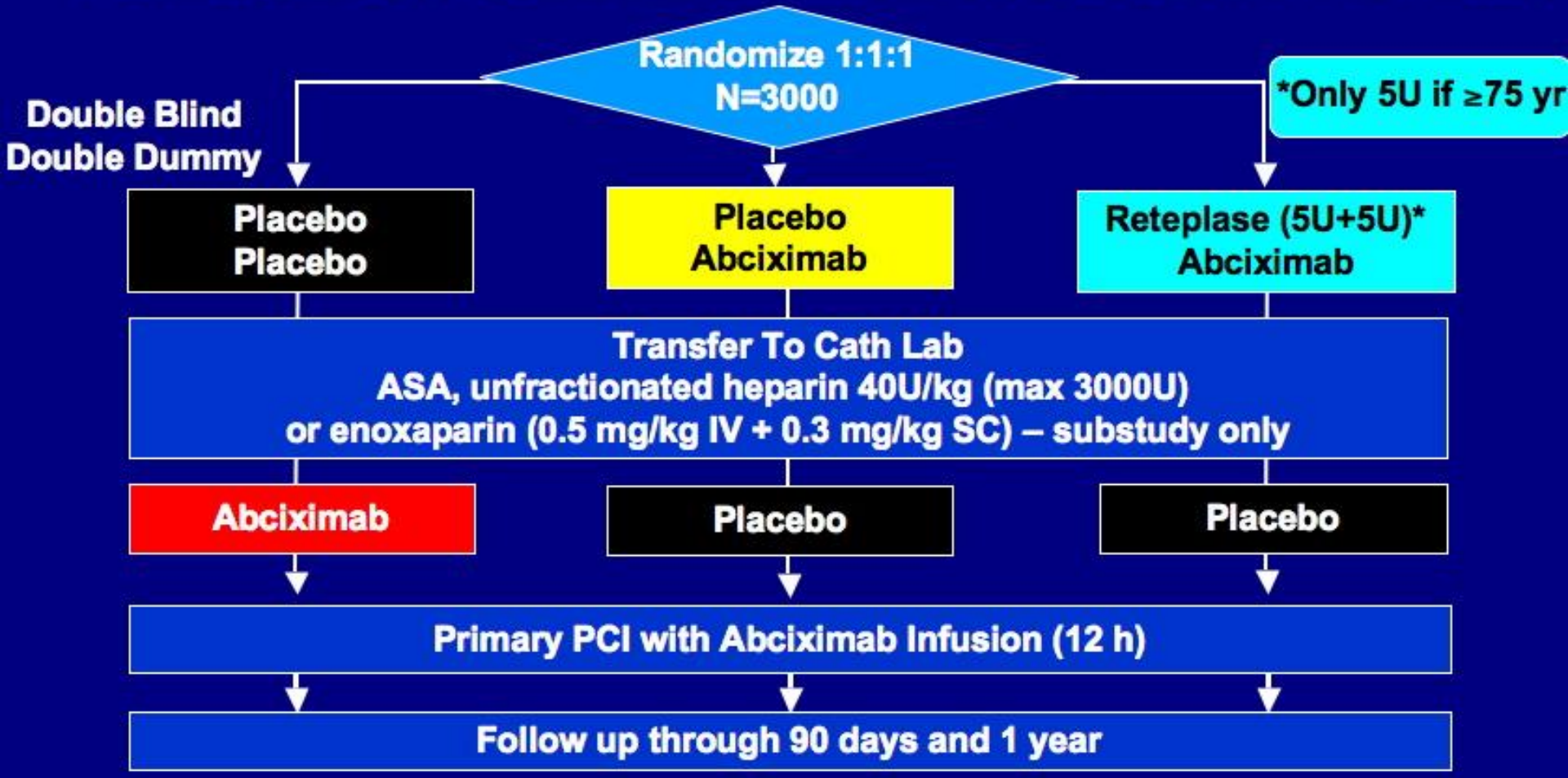
Take Home Messages from COURAGE:

- **Conservative treatment in patients with stable CAD is an option, if**
  - **Coronary anatomy is known**
  - **Patients with left main stenosis, depressed LV-EF etc. are excluded**
  - **No major signs of myocardial ischemia**
- **COURAGE did not change the ESC guidelines.**

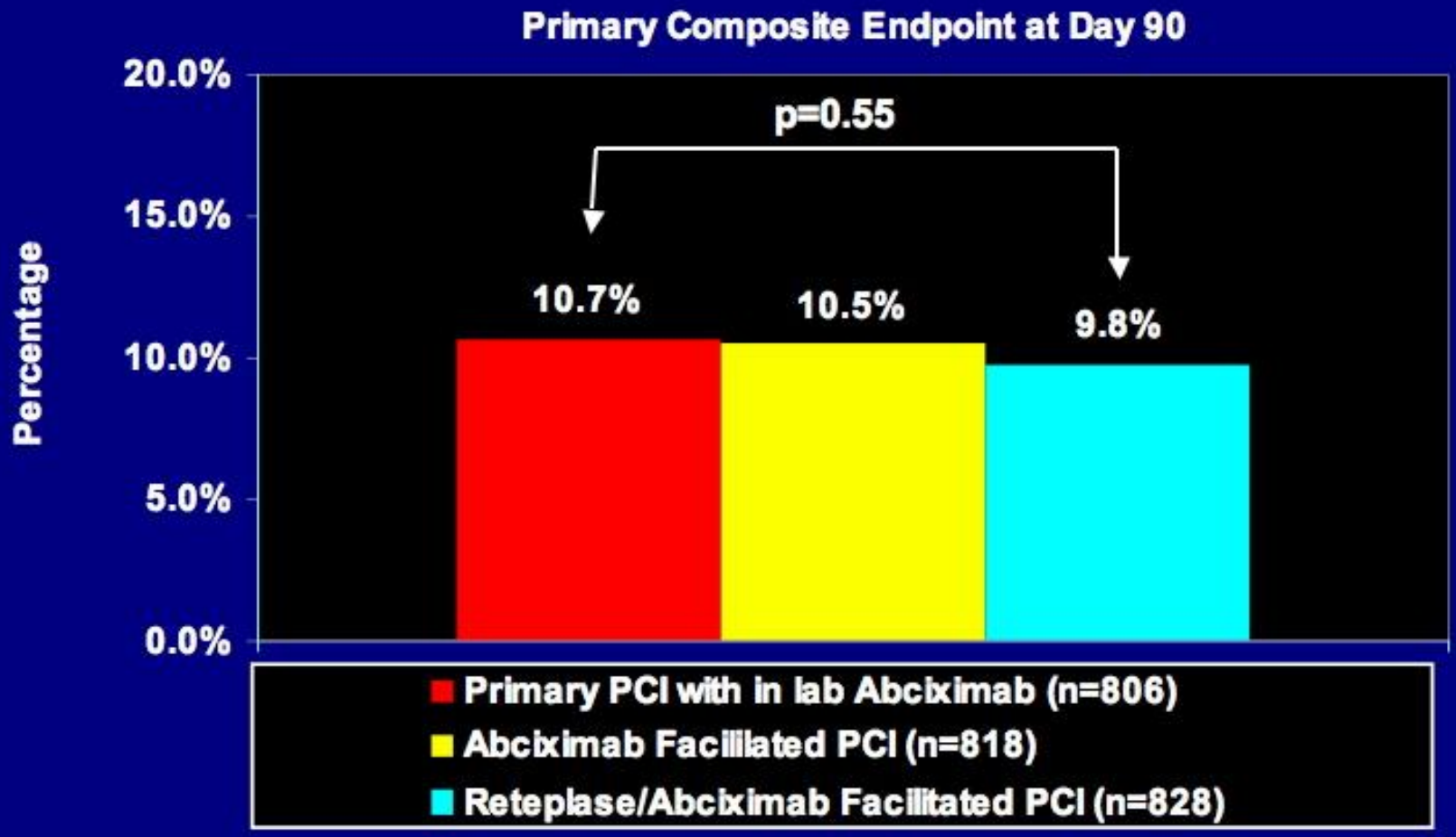
FINESSE: Study Design

Acute ST Elevation MI (or New LBBB) within 6h pain onset

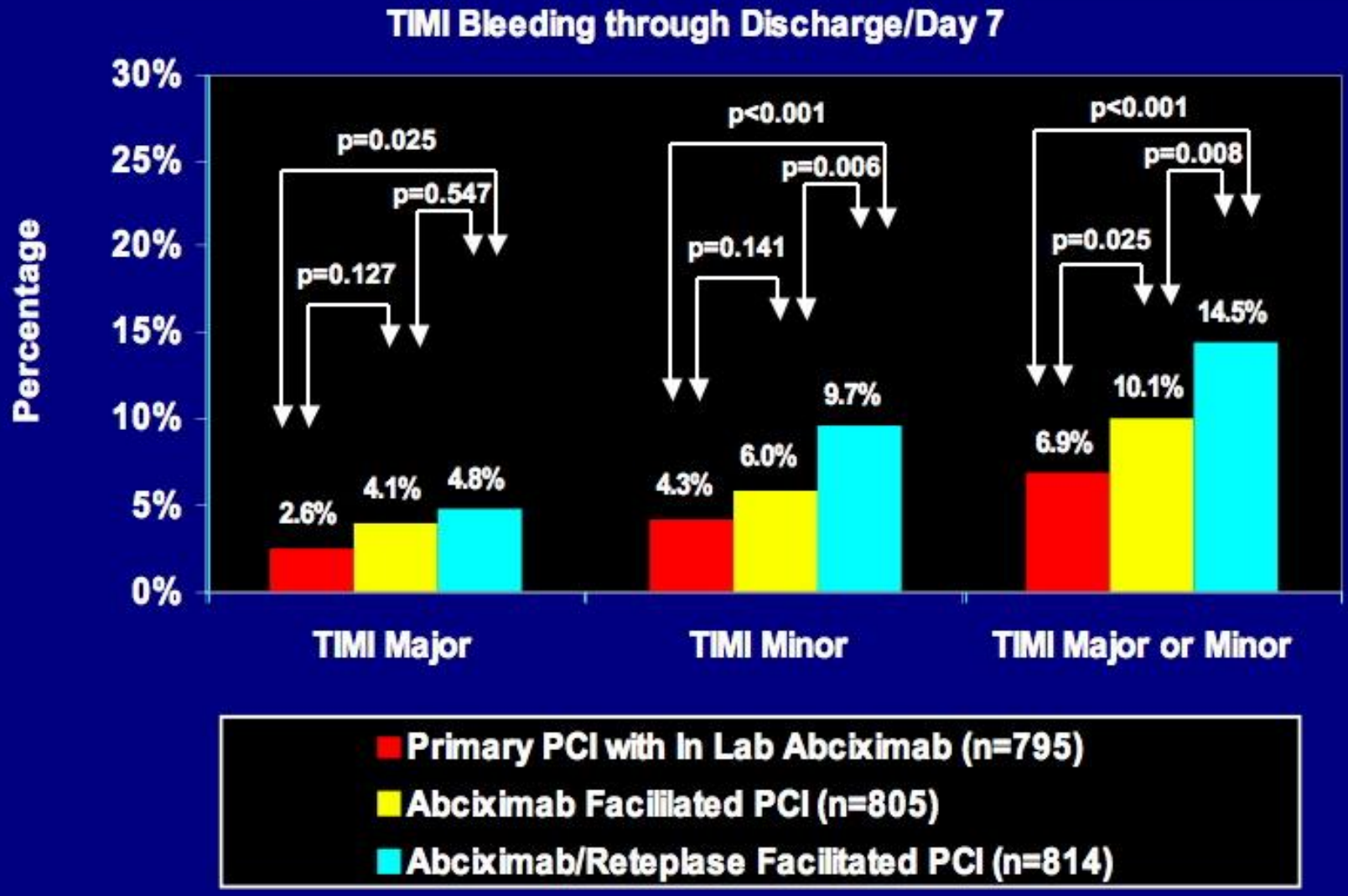
Presenting at Hub or Spoke with estimated time to Cath between 1 and 4 hours



Primary Endpoint



TIMI Major or Minor Bleeding (nonintracranial) through Discharge/Day7



TUESDAY

ESC Congress News

EUROPEAN SOCIETY OF CARDIOLOGY®

VIENNA ESC CONGRESS 2007 4 SEPTEMBER

Facilitation may be finished by FINESSE

FINESSE and CARESS studies report results

In your ESC Congress News today

Large trials needed to ensure women get optimal treatment Page 3

How to take COURAGE? We ask two US cardiologists for their reactions to the controversial COURAGE trial Pages 4 and 5

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

ESC Guidelines

term 'facilitated PCI' is not uniformly used for identical settings: it should be used as initially planned PCI, following shortly after initiating thrombolysis and/or GP IIb/IIIa inhibitors. Therefore, in randomized studies testing the concept of facilitated PCI, all patients (with or without pre-treatment) should undergo planned primary PCI.

we prefer primary PCI over thrombolysis in the first 3 h of chest pain to prevent stroke and, in patients presenting 3–12 h after the onset of chest pain, to salvage myocardium and also prevent stroke. At the moment, there is no evidence to recommend facilitated PCI.

European Heart Journal (2005) **26**, 804–847

Take Home Messages from FINESSE:

- **FINESSE corroborated the concept of avoiding routine upstream administration of abciximab before primary PCI in STEMI.**
- **FINESSE further confirmed previous ESC guidelines.**

TRÎTON TIMI·38

TRial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet InhibitioN with Prasugrel

TRITON-TIMI 38
AHA 2007
Orlando, Florida

Disclosure Statement:
The TRITON-TIMI 38 trial was supported by a research grant to the Brigham and Women's Hospital from Daiichi Sankyo Co. Ltd and Eli Lilly & Co.

TRITON TIMI-38

Study Design

ACS (STEMI or UA/NSTEMI) & Planned PCI

ASA ↓ N= 13,600

Double-blind

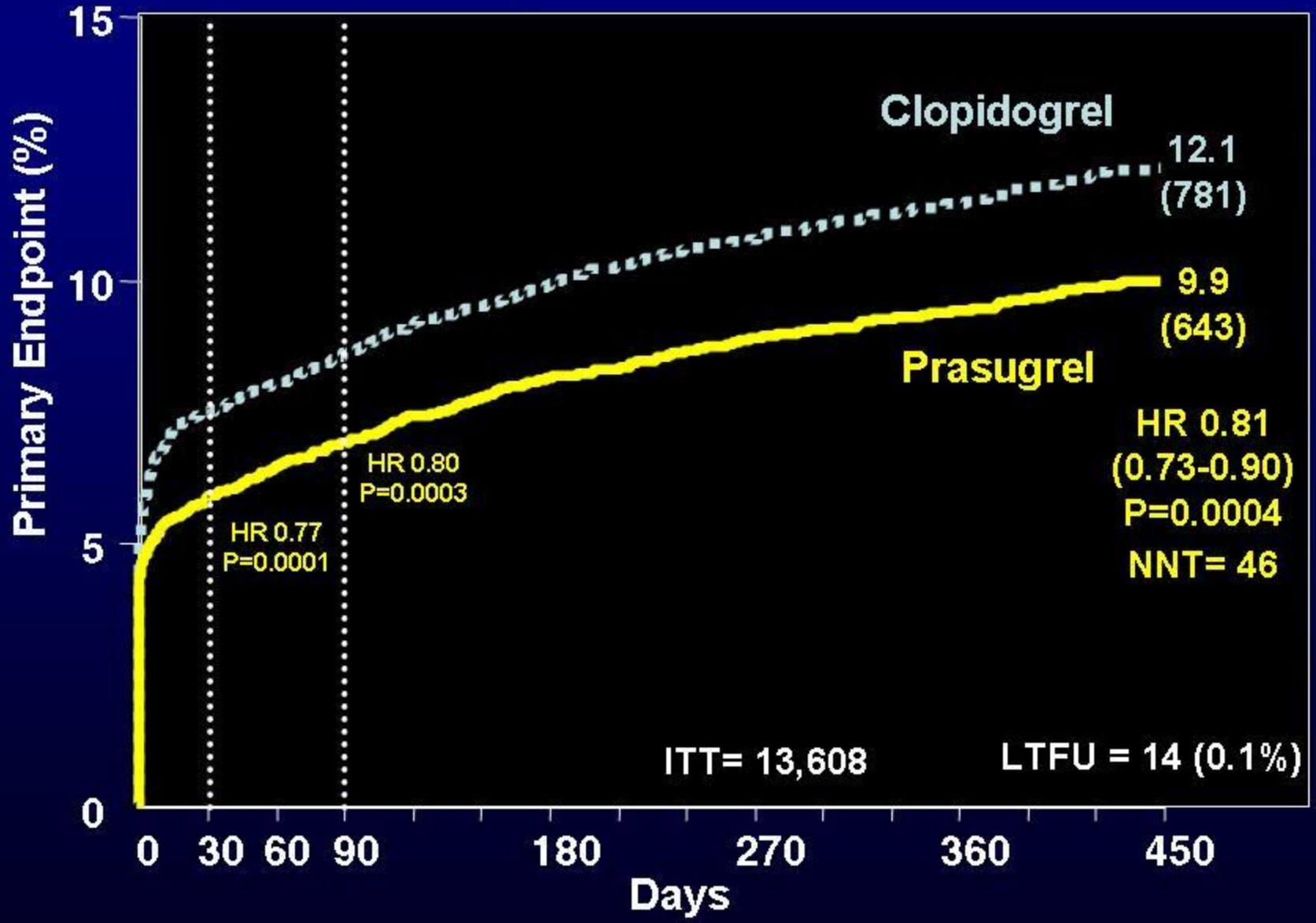
CLOPIDOGREL	PRASUGREL
300 mg LD/ 75 mg MD	60 mg LD/ 10 mg MD

Median duration of therapy - 12 months

1º endpoint:	CV death, MI, Stroke
2º endpoints:	CV death, MI, Stroke, Rehosp-Rec Isch
	CV death, MI, UTVR
	Stent Thrombosis (ARC definite/prob.)
Safety endpoints:	TIMI major bleeds, Life-threatening bleeds
Key Substudies:	Pharmacokinetic, Genomic

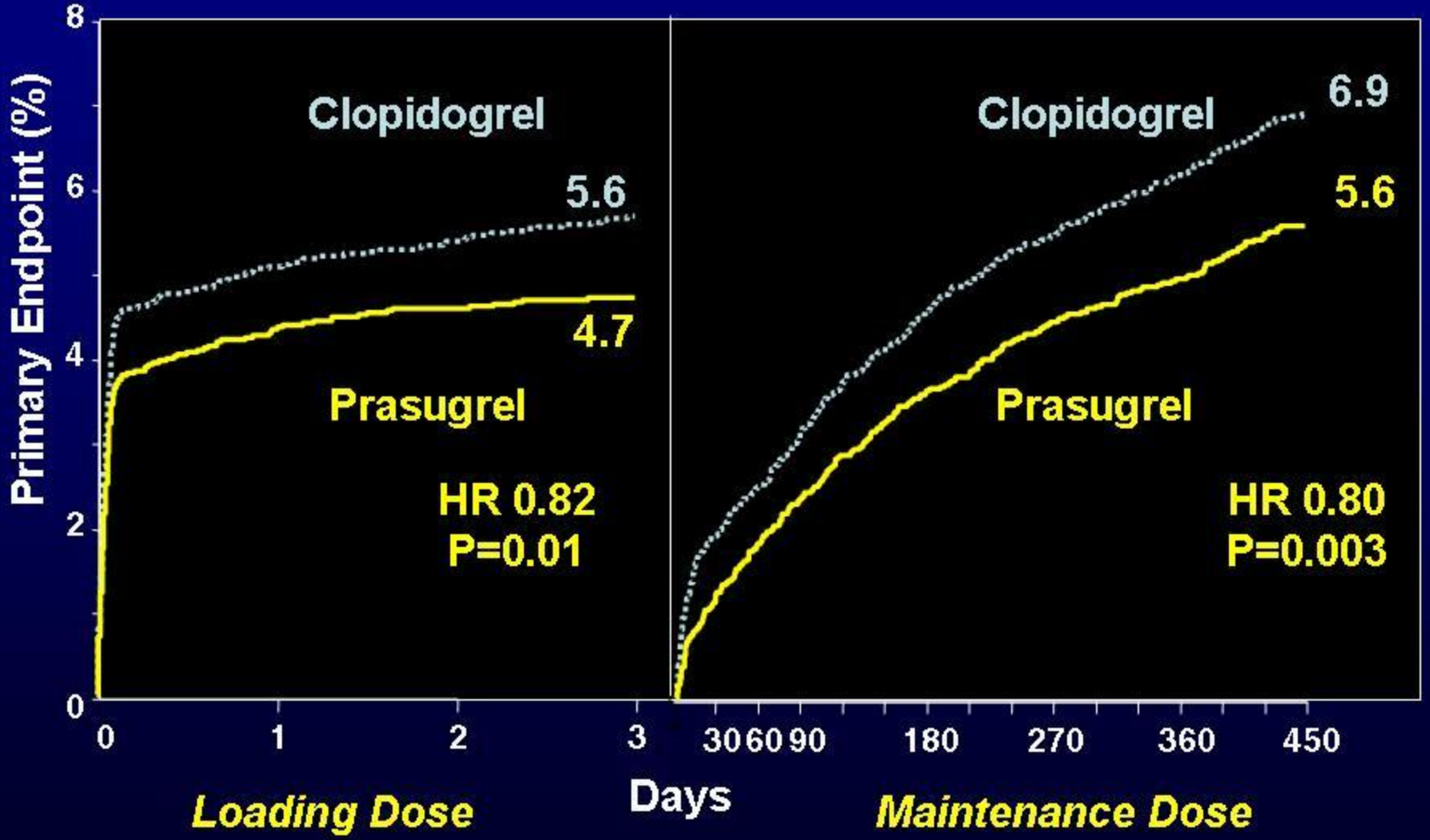
TRITON TIMI-38

Primary Endpoint
CV Death,MI,Stroke



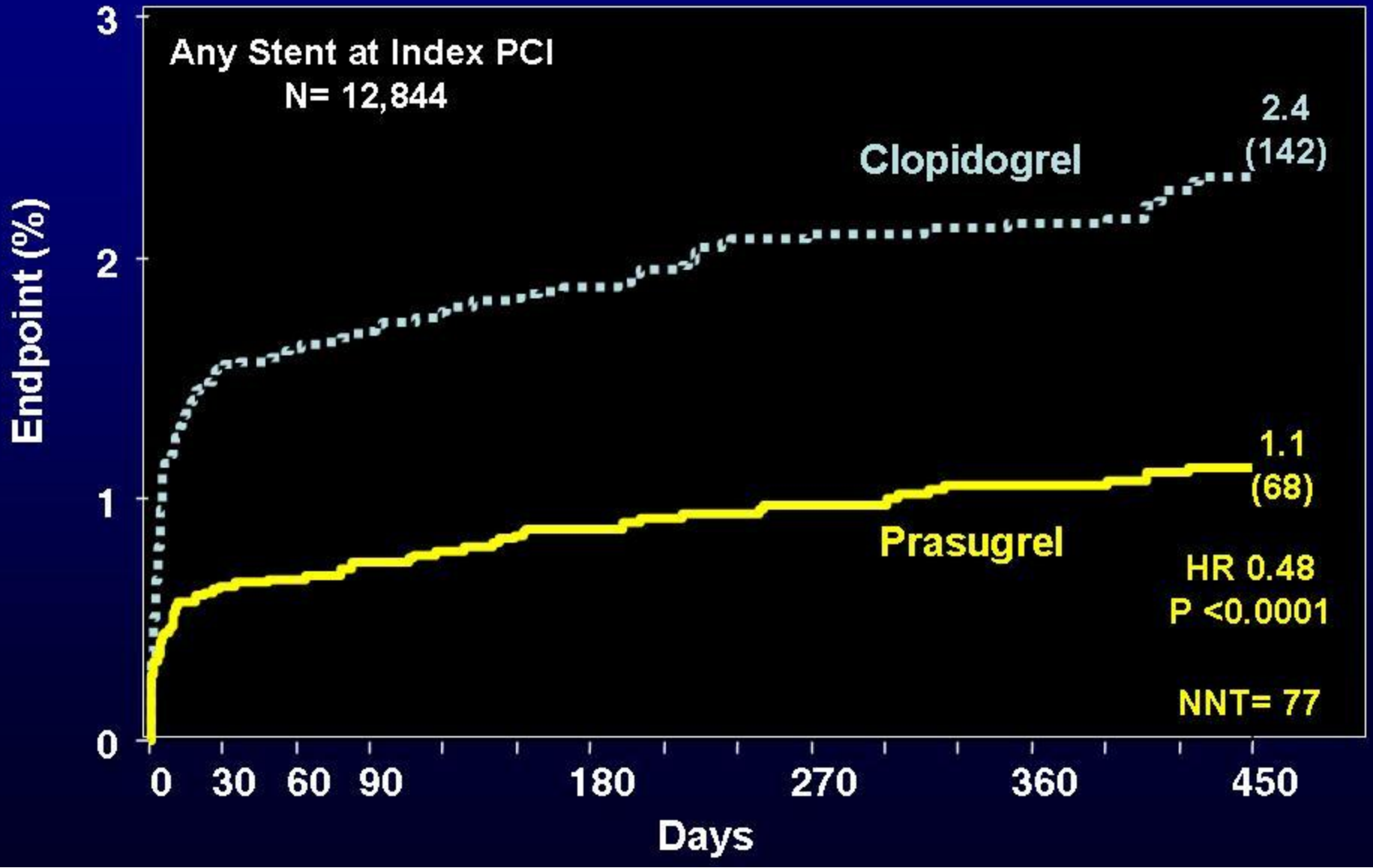
TRITON TIMI-38

Timing of Benefit (Landmark Analysis)



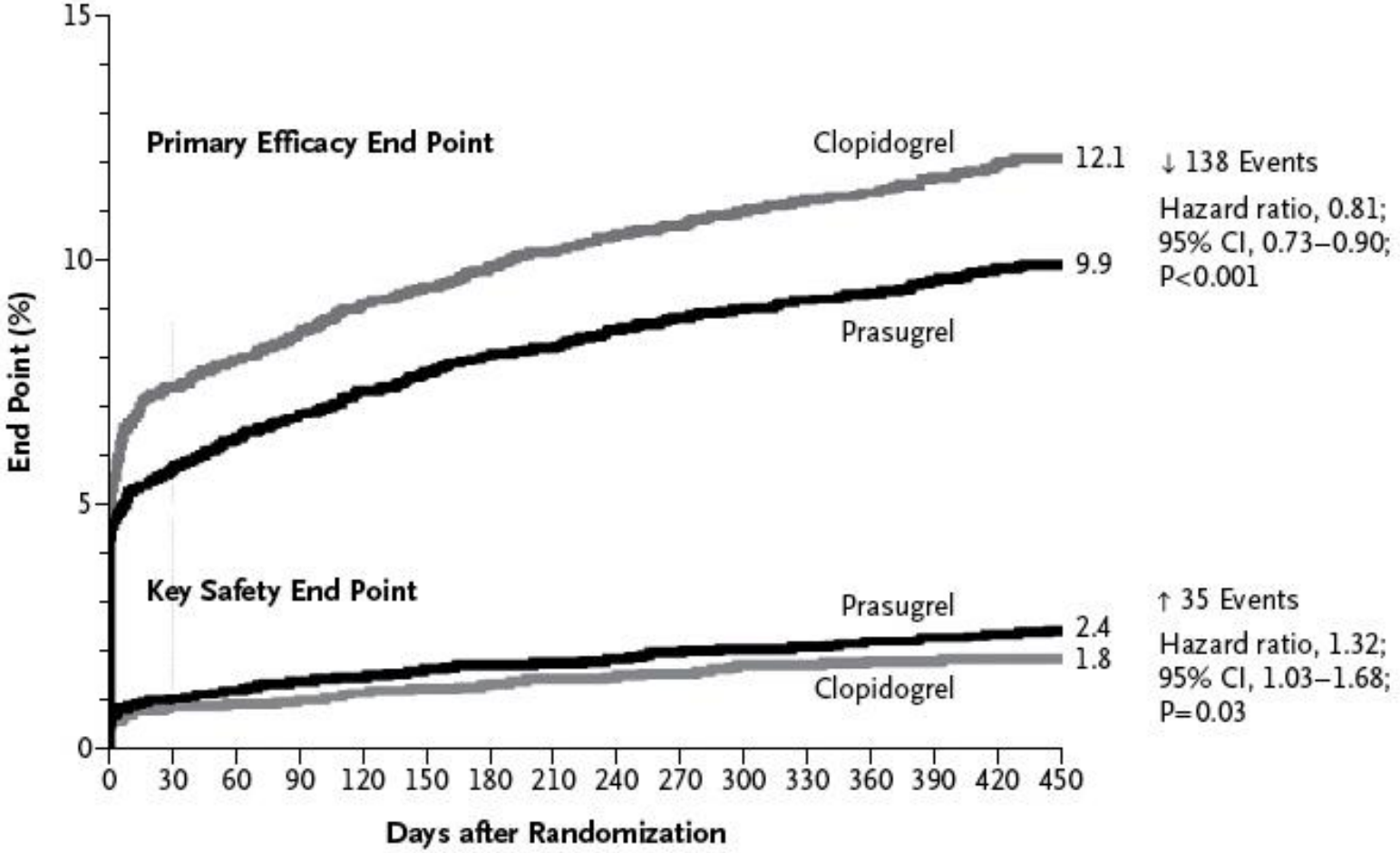
TRÎTON TIMI·38

Stent Thrombosis
(ARC Definite + Probable)



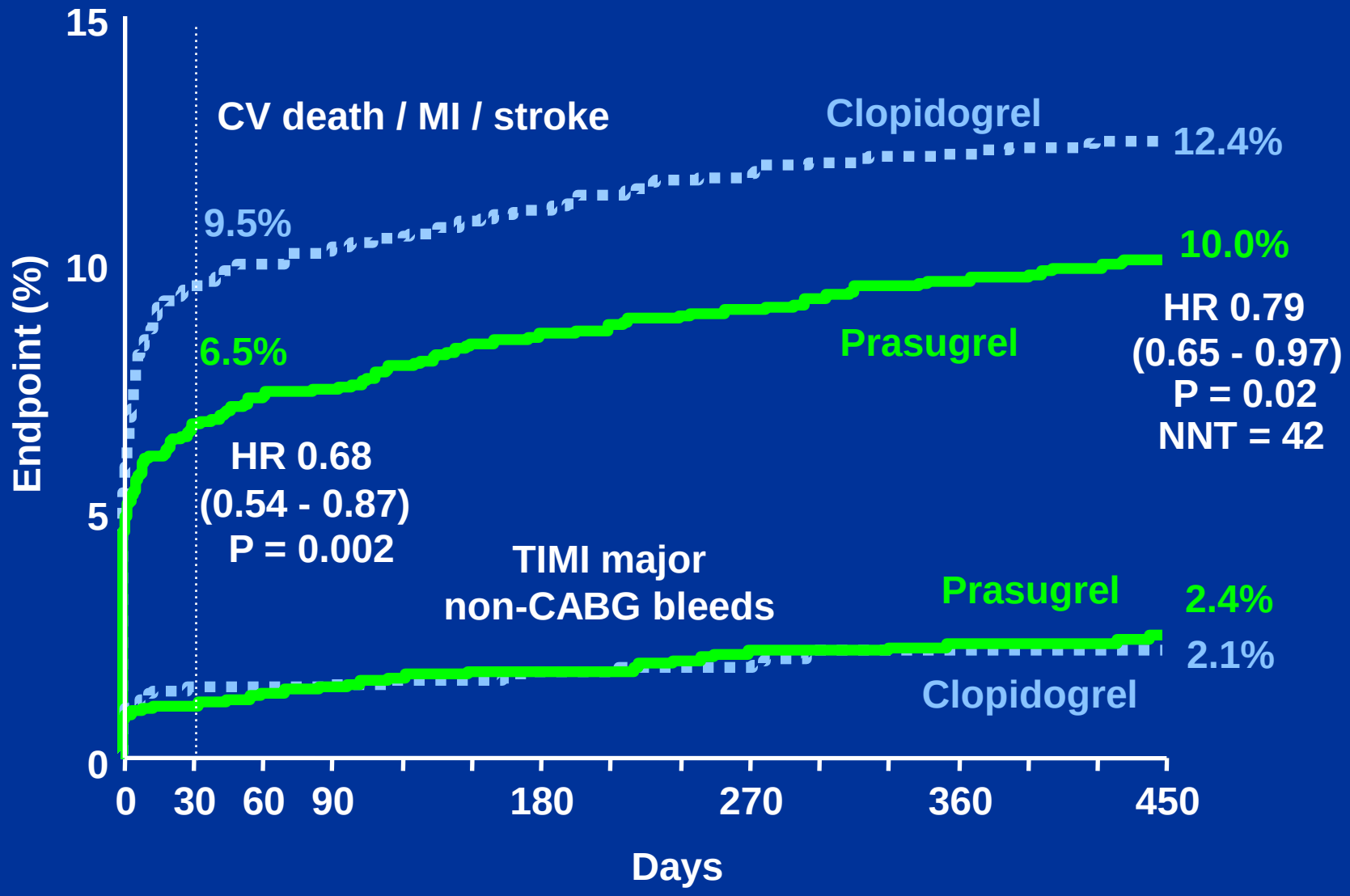
Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes

Stephen D. Wiviott, M.D., Eugene Braunwald, M.D., Carolyn H. McCabe, B.S., Gilles Montalescot, M.D., Ph.D., Witold Ruzyllo, M.D., Shmuel Gottlieb, M.D., Franz-Joseph Neumann, M.D., Diego Ardissino, M.D., Stefano De Servi, M.D., Sabina A. Murphy, M.P.H., Jeffrey Riesmeyer, M.D., Govinda Weerakkody, Ph.D., C. Michael Gibson, M.D., and Elliott M. Antman, M.D., for the TRITON–TIMI 38 Investigators*



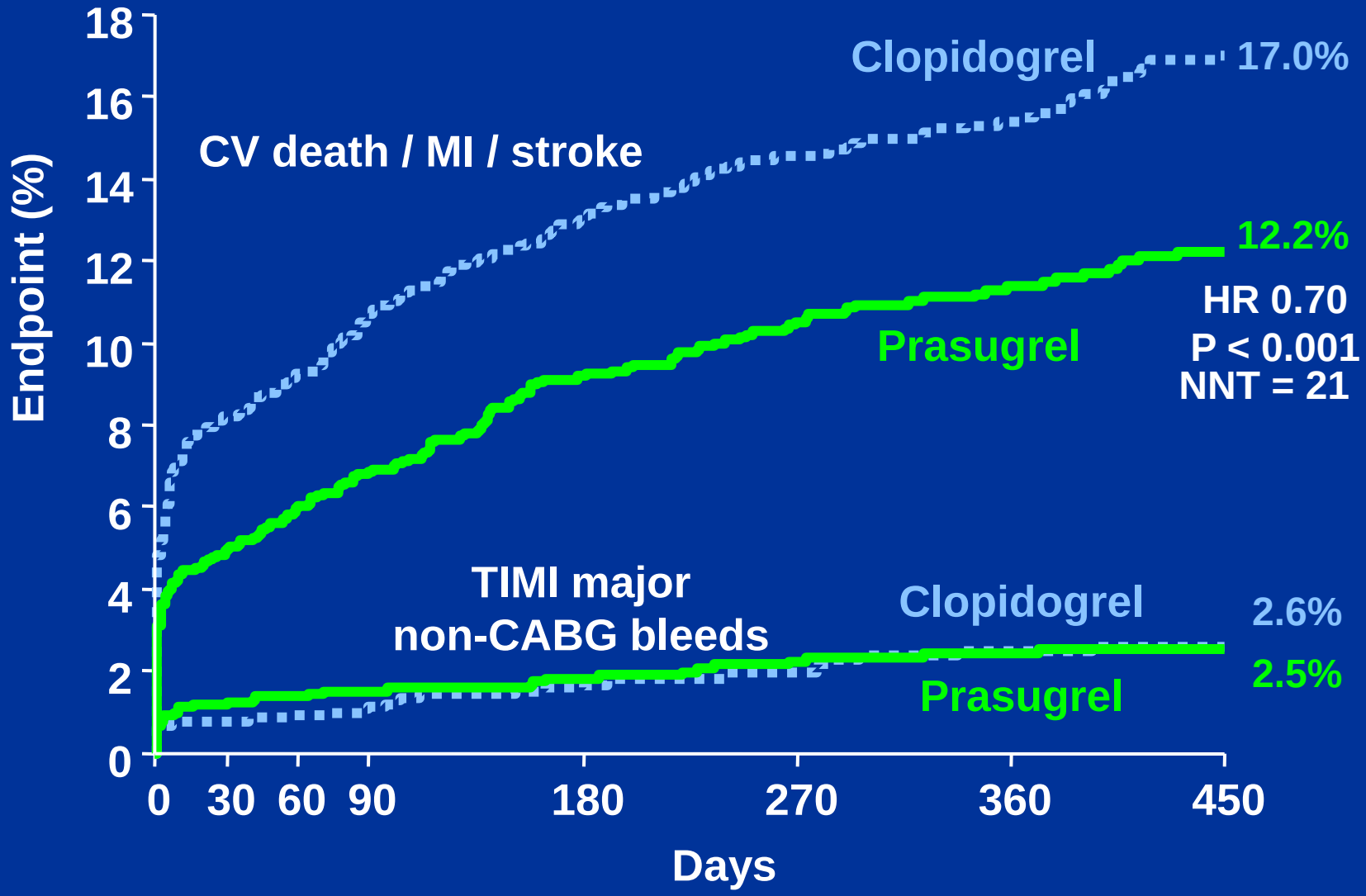
NOVEMBER 15, 2007 N Engl J Med 2007;357:2001-15.

STEMI Subgroup (n = 3534)



Montalescot G et al *Lancet* 2009

Diabetic Subgroup (n =3146)

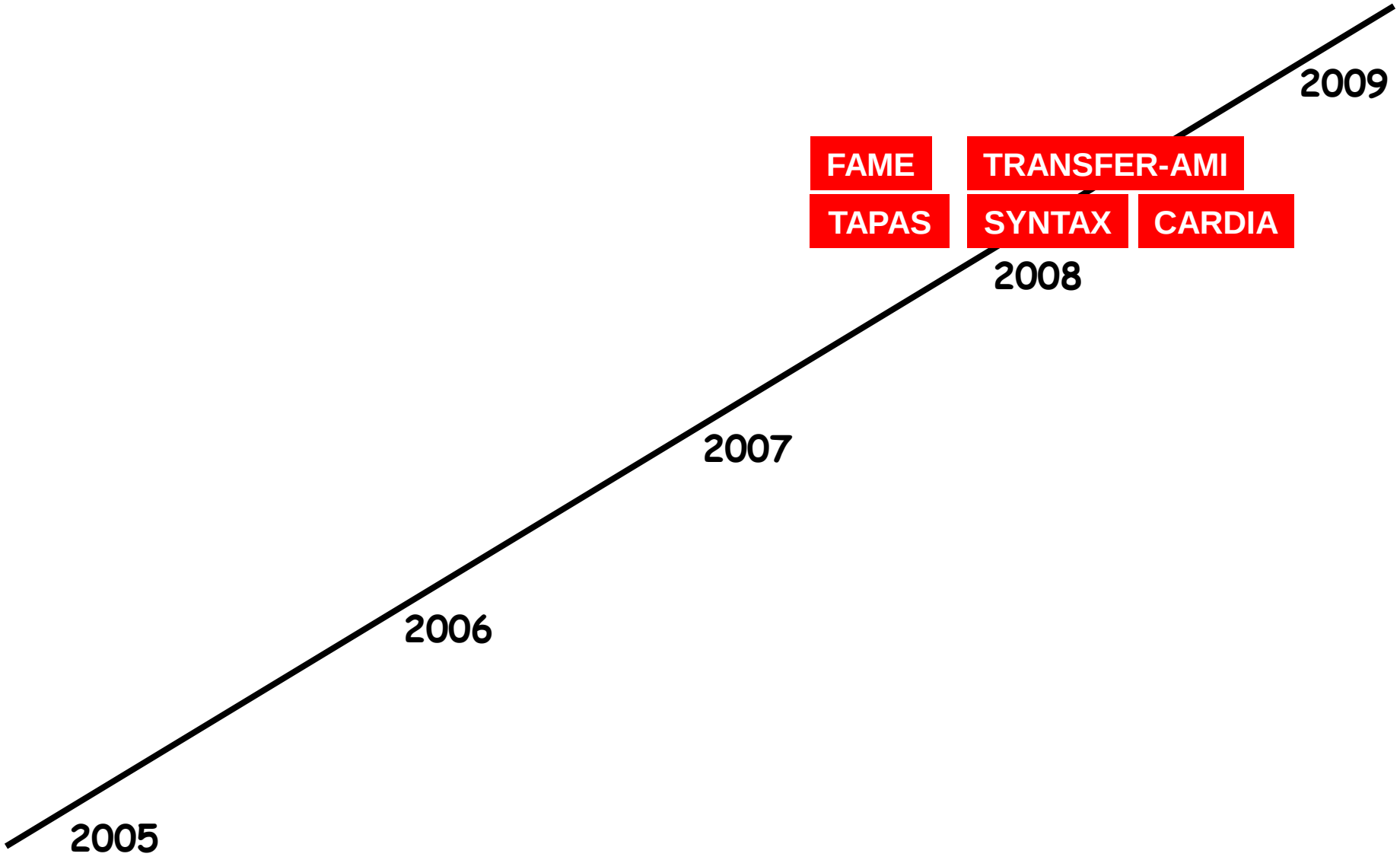


Wiviott SD et al. *Circulation* 2008; 118: 1626-1636

Take Home Messages from TRITON:

- **Prasugrel is a serious alternative to Clopidogrel in PCI for ACS.**
- **The most benefit is achieved in patients with STEMI and/or Diabetes with a reduction of ischemic events without increased bleeding complications.**
- **In patients with stent thrombosis during Clopidogrel, a switch to Prasugrel may be strongly considered.**
- **Prasugrel will change future guidelines.**

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS)

Mortality and reinfarction at 1 year

F. Zijlstra, MD PhD
Thoraxcenter
University Medical Center Groningen,
The Netherlands

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 FEBRUARY 7, 2008 VOL. 358 NO. 6

Thrombus Aspiration during Primary Percutaneous Coronary Intervention

Tone Svilaas, M.D., Pieter J. Vlaar, M.Sc., Iwan C. van der Horst, M.D., Ph.D., Gilles F.H. Diercks, M.D., Ph.D., Bart J.G.L. de Smet, M.D., Ph.D., Ad F.M. van den Heuvel, M.D., Ph.D., Rutger L. Anthonio, M.D., Ph.D., Gillian A. Jessurun, M.D., Ph.D., Eng-Shiong Tan, M.D., Albert J.H. Suurmeijer, M.D., Ph.D., and Felix Zijlstra, M.D., Ph.D.

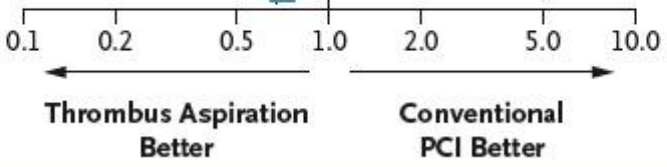
CONCLUSIONS

Thrombus aspiration is applicable in a large majority of patients with myocardial infarction with ST-segment elevation, and it results in better reperfusion and clinical outcomes than conventional PCI, irrespective of clinical and angiographic characteristics at baseline.

N Engl J Med 2008;358:557-67.

TAPAS

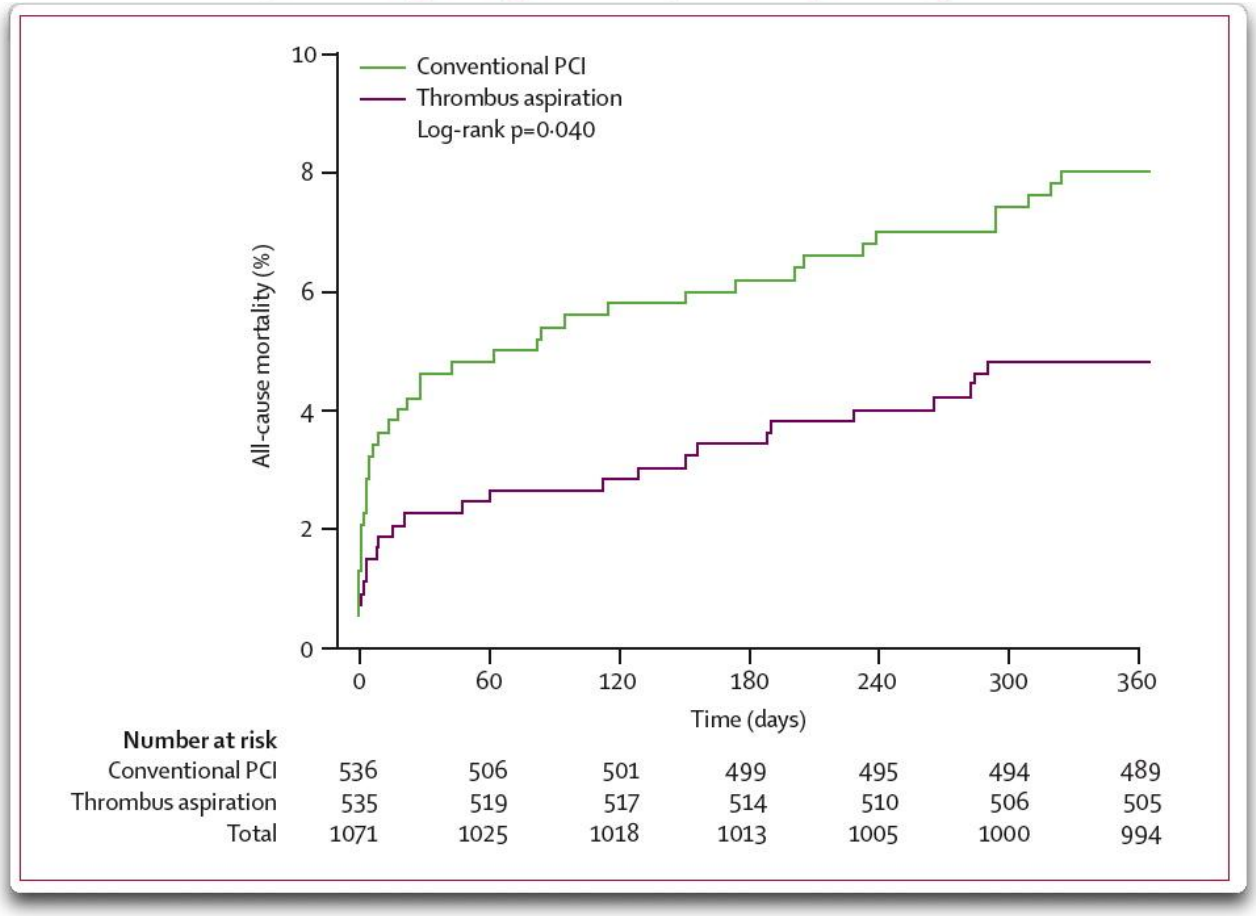
Baseline Characteristic	Thrombus Aspiration (no./total no.)	Conventional PCI (no./total no.)	Risk Ratio for Aspiration (95% Confidence Interval)	P Value
All patients	84/490	129/490	0.65 (0.51–0.83)	
Sex				0.43
Male	52/337	91/356	0.60 (0.44–0.82)	
Female	32/153	38/134	0.74 (0.49–1.11)	
Age				0.34
>65 yr	52/202	78/223	0.74 (0.55–0.99)	
≤65 yr	32/288	51/267	0.58 (0.39–0.88)	
Total ischemic time				0.09
≥180 min	58/256	75/243	0.73 (0.55–0.99)	
<180 min	20/222	46/231	0.45 (0.28–0.74)	
Infarct-related vessel				0.19
RCA	18/177	42/199	0.48 (0.29–0.81)	
Other	66/313	87/291	0.71 (0.53–0.93)	
Infarct-related segment				0.57
Proximal lesion	41/290	72/307	0.60 (0.43–0.85)	
No proximal lesion	43/200	57/183	0.69 (0.49–0.97)	
TIMI flow grade before PCI				0.54
0 or 1	62/275	96/306	0.72 (0.55–0.95)	
2 or 3	22/210	31/179	0.60 (0.36–1.01)	
Thrombus seen on angiography				0.58
Yes	39/236	60/221	0.61 (0.43–0.87)	
No	44/241	68/262	0.70 (0.50–0.98)	



N Engl J Med 2008;358:557-67.

Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study

Pieter J Vlaar, Tone Svilaas*, Iwan C van der Horst, Gilles F H Diercks, Marieke L Fokkema, Bart J G L de Smet, Ad F M van den Heuvel, Rutger L Anthonio, Gillian A Jessurun, Eng-Shiong Tan, Albert J H Suurmeijer, Felix Zijlstra*



Number at risk							
Conventional PCI	536	506	501	499	495	494	489
Thrombus aspiration	535	519	517	514	510	506	505
Total	1071	1025	1018	1013	1005	1000	994

Lancet 2008; 371: 1915–20

Limitations and open Questions for TAPAS:

1. Primary endpoint was a surrogate (myocardial blush), therefore not powered to show a mortality reduction.
2. Aspiration was performed only in 84% of the patients.
3. PCI was performed only in 94%.

The huge and statistically significant reduction in mortality after 1y from 7.6% to 4.0% (almost 50%) is surprising in the light of:

- ✓ Only a modest benefit in improvement of the surrogate parameters, like myocardial blush and ST-segment resolution.
- ✓ No improvement of peak CK and peak CK-MB.

Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study

Pieter J Vlaar, Tone Svilaas*, Iwan C van der Horst, Gilles F H Diercks, Marieke L Fokkema, Bart J G L de Smet, Ad F M van den Heuvel, Rutger L Anthonio, Gillian A Jessurun, Eng-Shiong Tan, Albert J H Suurmeijer, Felix Zijlstra*

	Thrombus aspiration (N=535)	Conventional PCI (N=536)	p
Final TIMI flow 3	431/501 (86·0%)	409/496 (82·5%)	0·12
Distal epicardial vessel obstruction after PCI	25/446 (5·6%)	25/434 (5·8%)	0·92
Peak creatine kinase (total)	N=421	N=418	
Median (IQR)	565 (247–1506)	637 (291–1420)	0·24
Time to peak creatine kinase (total), h			
Median (IQR)	8 (5–12)	7 (5–12)	0·84
Peak creatine kinase-MB	N=406	N=405	
Median (IQR)	58 (24–118)	63 (30–114)	0·46
Time to peak creatine kinase-MB, h			
Median (IQR)	7 (5–10)	7 (5–10)	0·80

Lancet 2008; 371: 1915–20

Role of adjunctive thrombectomy and embolic protection devices in acute myocardial infarction: a comprehensive meta-analysis of randomized trials

Anthony A. Bavry[1], Dharam J. Kumbhani[2], and Deepak L. Bhatt[3]*

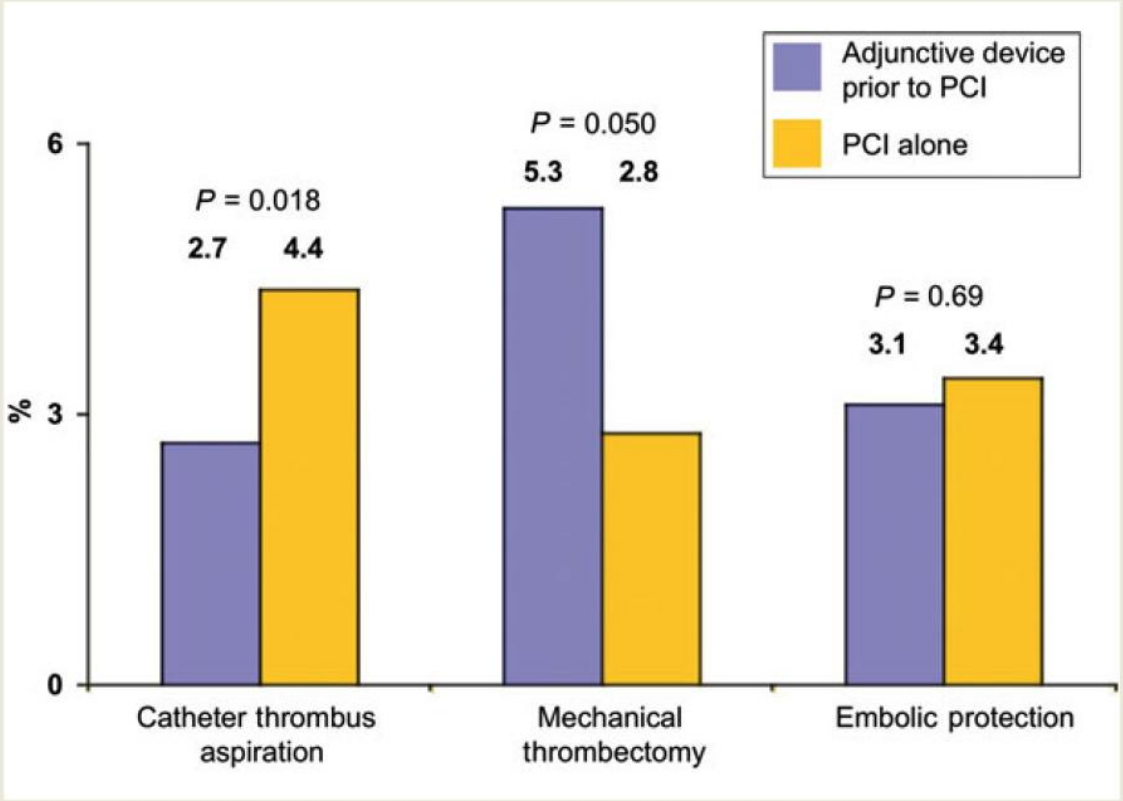
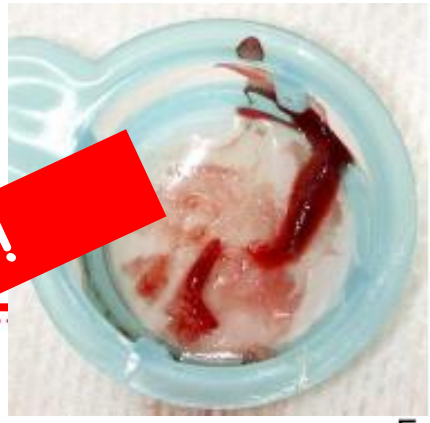


Figure 3 Incidence of mortality with similar type adjunctive thrombectomy devices grouped together.

Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation

Table 5 Reperfusion therapy

Recommendations	Class[a]	Level[b]
Reperfusion therapy is indicated in all patients with history of chest pain/discomfort of <12 h and with persistent ST-segment elevation or (presumed) new left bundle-branch block	I	A
GPIIb/IIIa antagonist		
Abciximab	IIa	A
Tirofiban	IIb	B
Eptifibatide	IIb	C
Antithrombin therapy[c]		
Heparin	I	C
Bivalirudin	IIa	B
Fondaparinux	III	B
Adjunctive devices		
Thrombus aspiration	IIb	B



manual !

European Heart Journal (2008) **29**, 2909–2945

Take Home Messages from TAPAS:

- **Before stenting patients with STEMI, manual thrombus extraction should be strongly considered.**
- **TAPAS was a single center study and should be confirmed by a large multicenter trial.**
- **TAPAS has already changed the ESC guidelines.**


MUNICH
ESC Congress 2008
30 August
3 September
IMPORTANT DATES
www.escardio.org
www.escardio.org
SYNTAX Randomized Trial
SYNTAX
De novo disease acceptable for revascularization
N=3300
Left main disease
and /or
3-vessel disease
Randomize 1500
CABG registry N=2750
TAXUS PCI
CABG
PCI registry N=50
Primary NI endpoint – 1 year MACCE
All cause death, MI, cerebrovascular events, repeat revascularization
Led by Patrick Serruys and Frederick Mohr

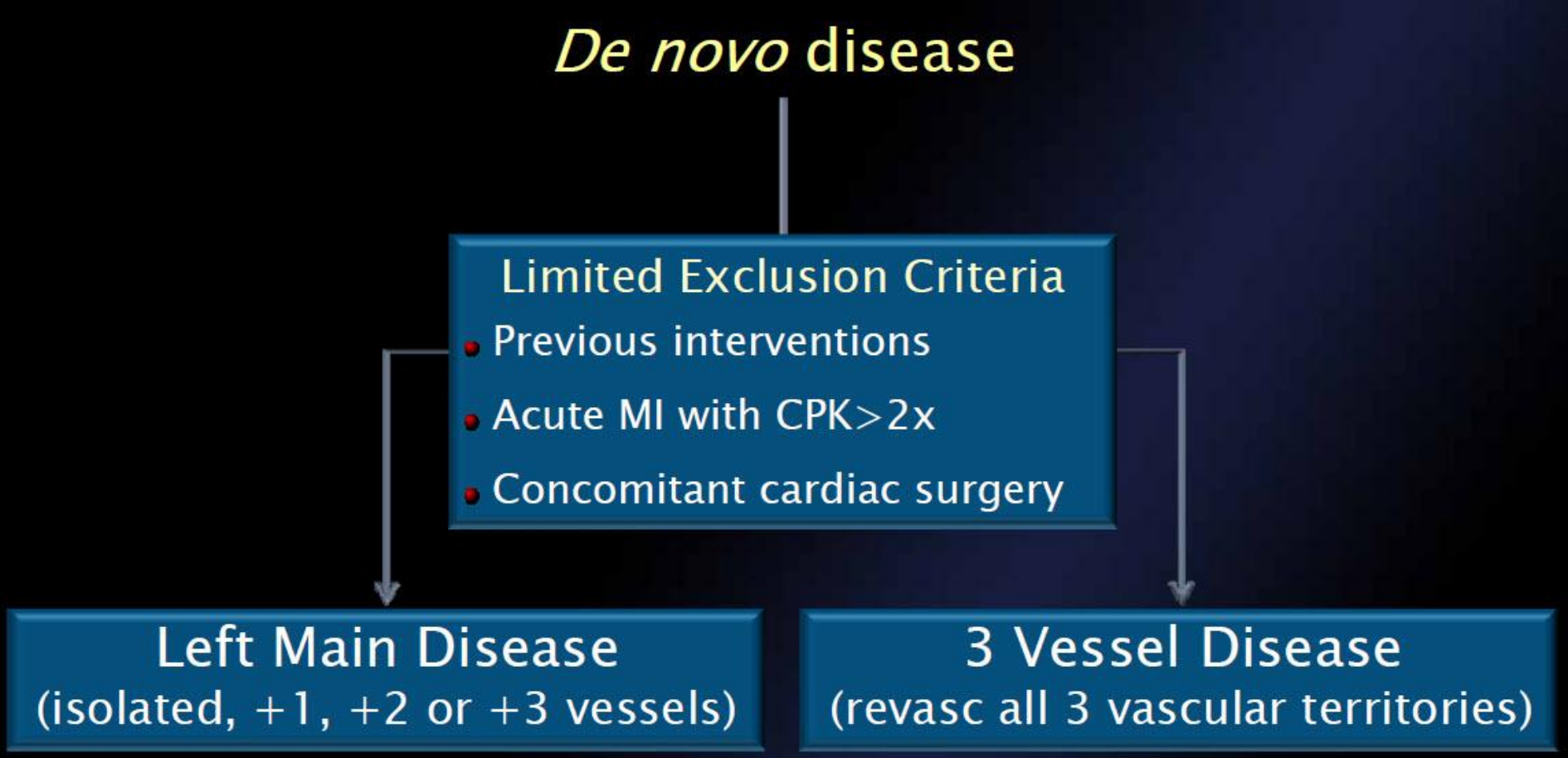
The Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery: The SYNTAX Study

Primary Endpoint Results at One Year in the Randomized Cohort

Patrick W. Serruys MD PhD
Friedrich W. Mohr MD PhD
On behalf of the SYNTAX investigators

Conflicts of Interest: None

SYNTAX Eligible Patients



SYNTAX Primary Endpoint
Randomized trial

SYNTAX

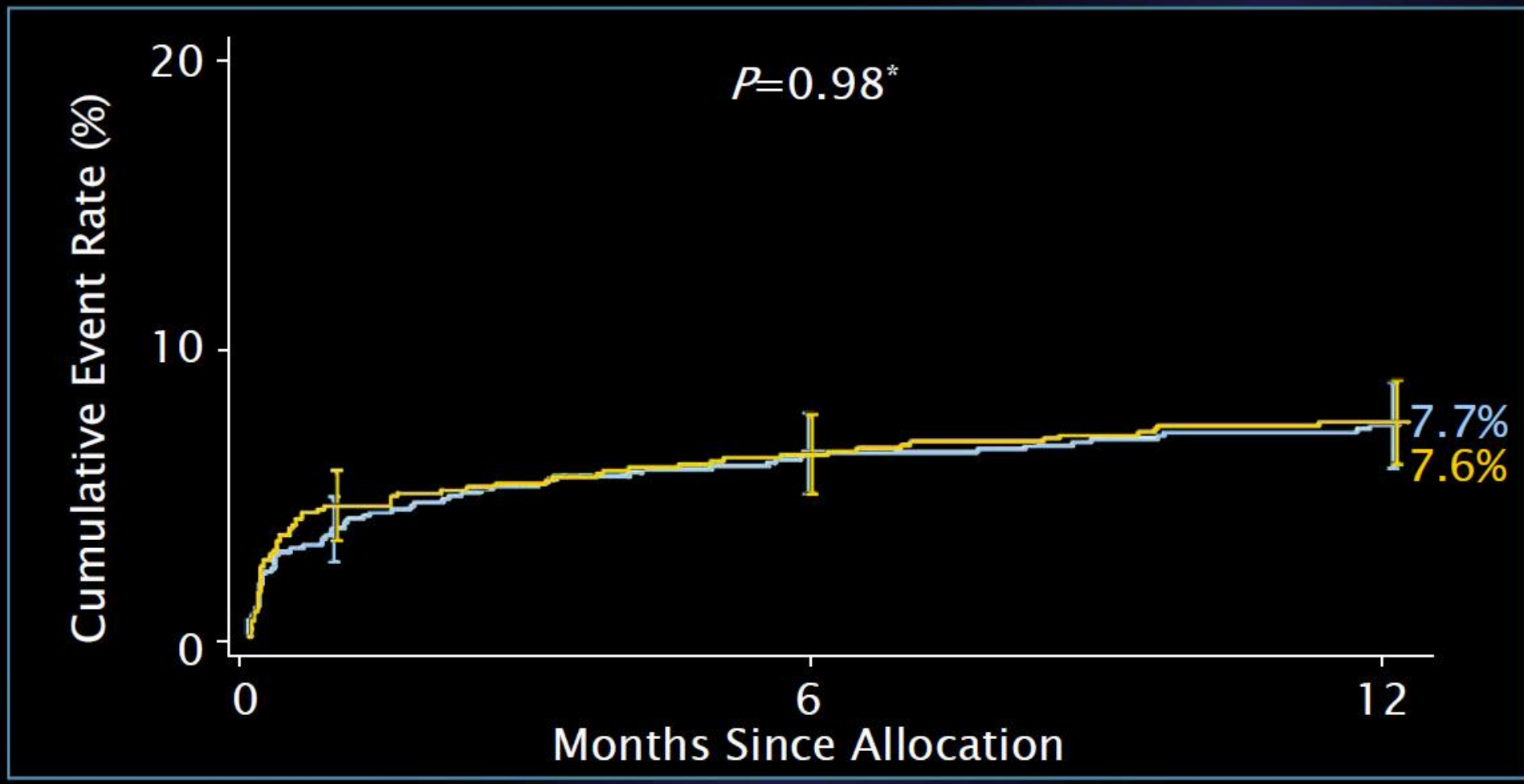
*The primary clinical endpoint is the 12 Month major Cardiovascular or Cerebrovascular event rate (MACCE *)*

- MACCE is defined as:
  - All cause Death
  - Cerebrovascular Accident (CVA/Stroke)
  - Documented Myocardial Infarction (ARC definition)
  - Any Repeat Revascularization (PCI and/or CABG)
- All events CEC Adjudicated

*ARC MACCE definition Circ 2007; 115:2344-2351

All-Cause Death/CVA/MI to 12 Months

SYNTAX

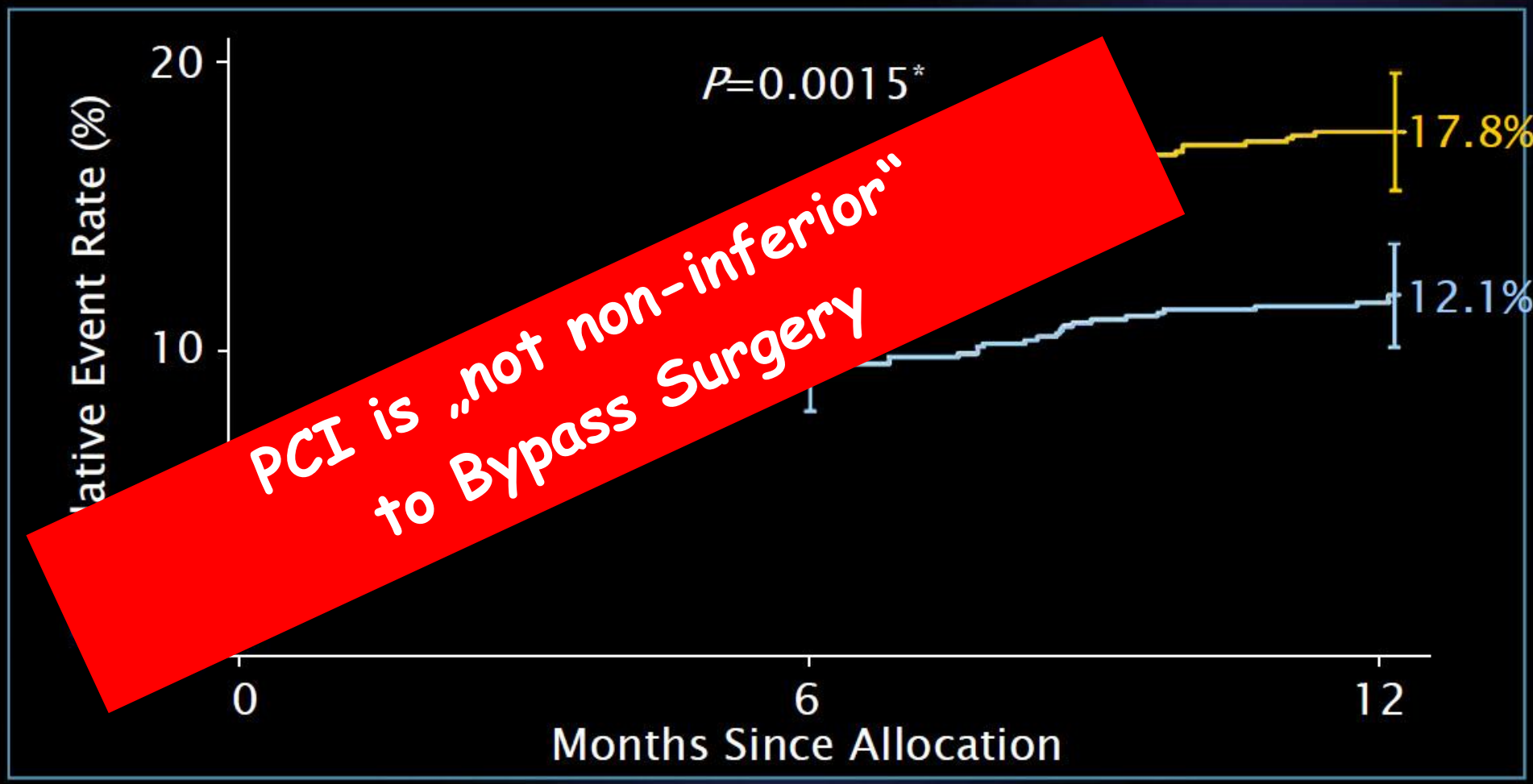


Event Rate ± 1.5 SE. *Fisher's Exact Test

ITT population

MACCE to 12 Months

SYNTAX

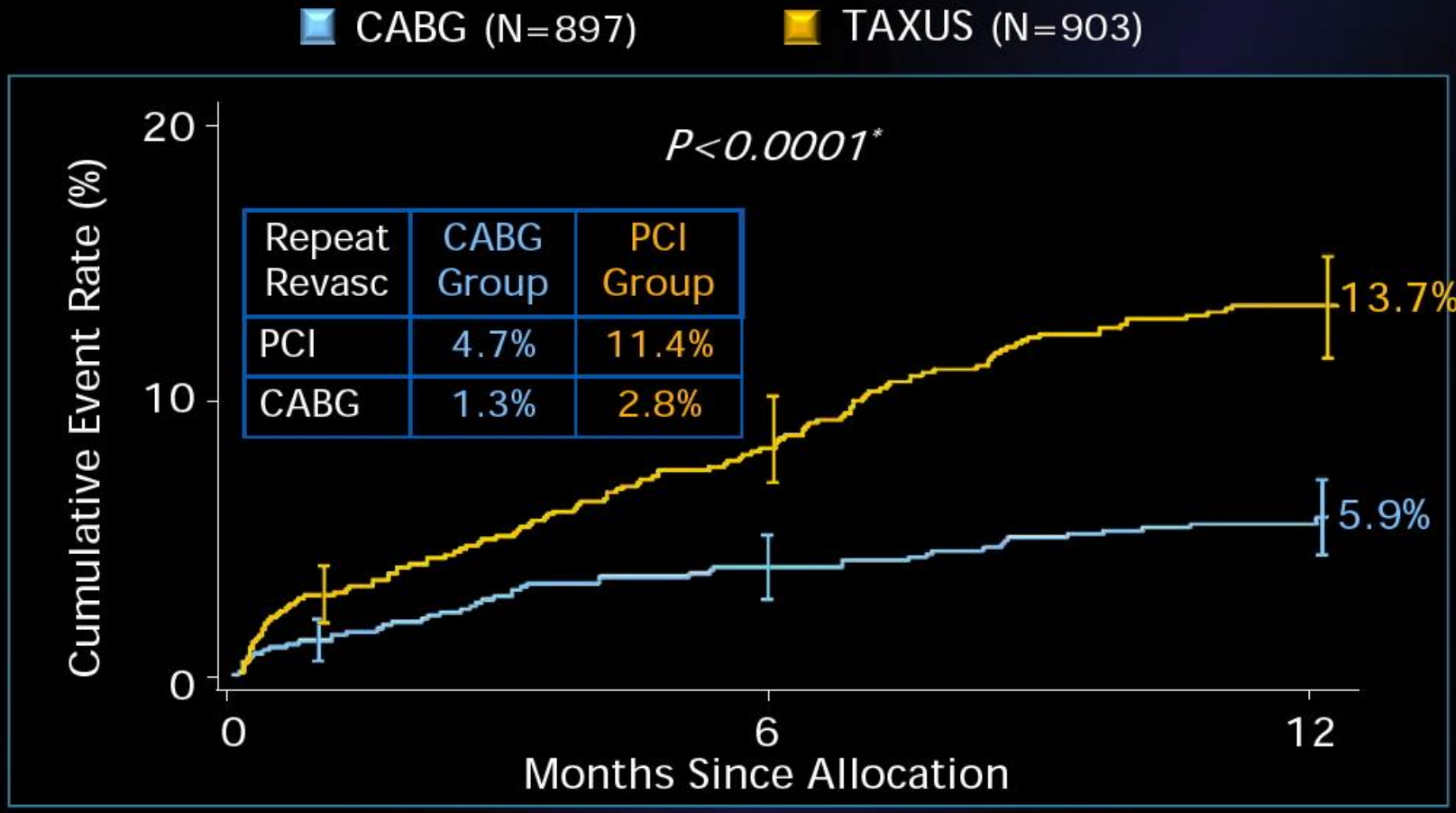


PCI is „not non-inferior" to Bypass Surgery

Event Rate ± 1.5 SE. *Fisher's Exact Test

ITT population

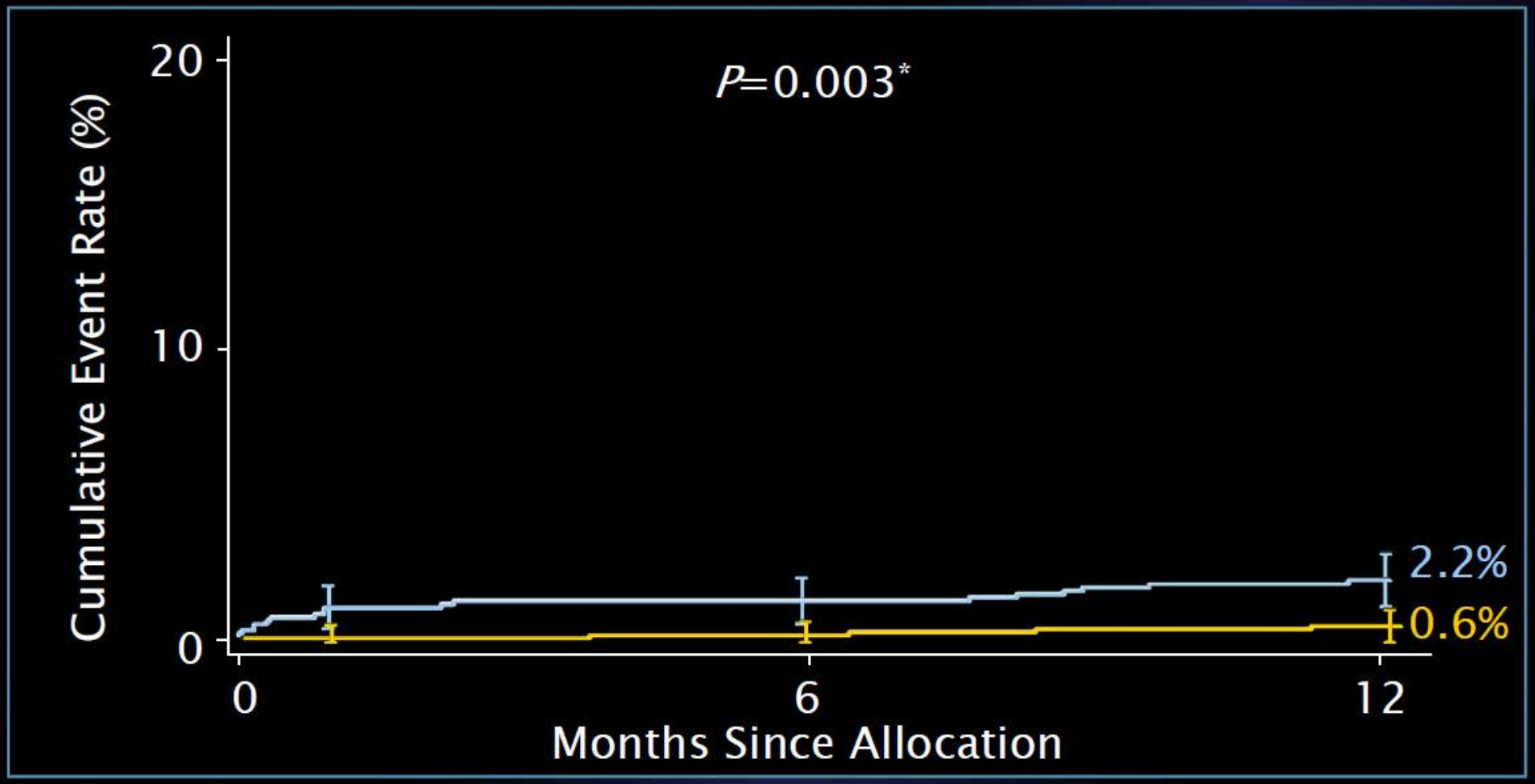
Repeat Revascularization to 12 Months SYNTAX



Event Rate ± 1.5 SE. *Fisher's Exact Test

ITT population

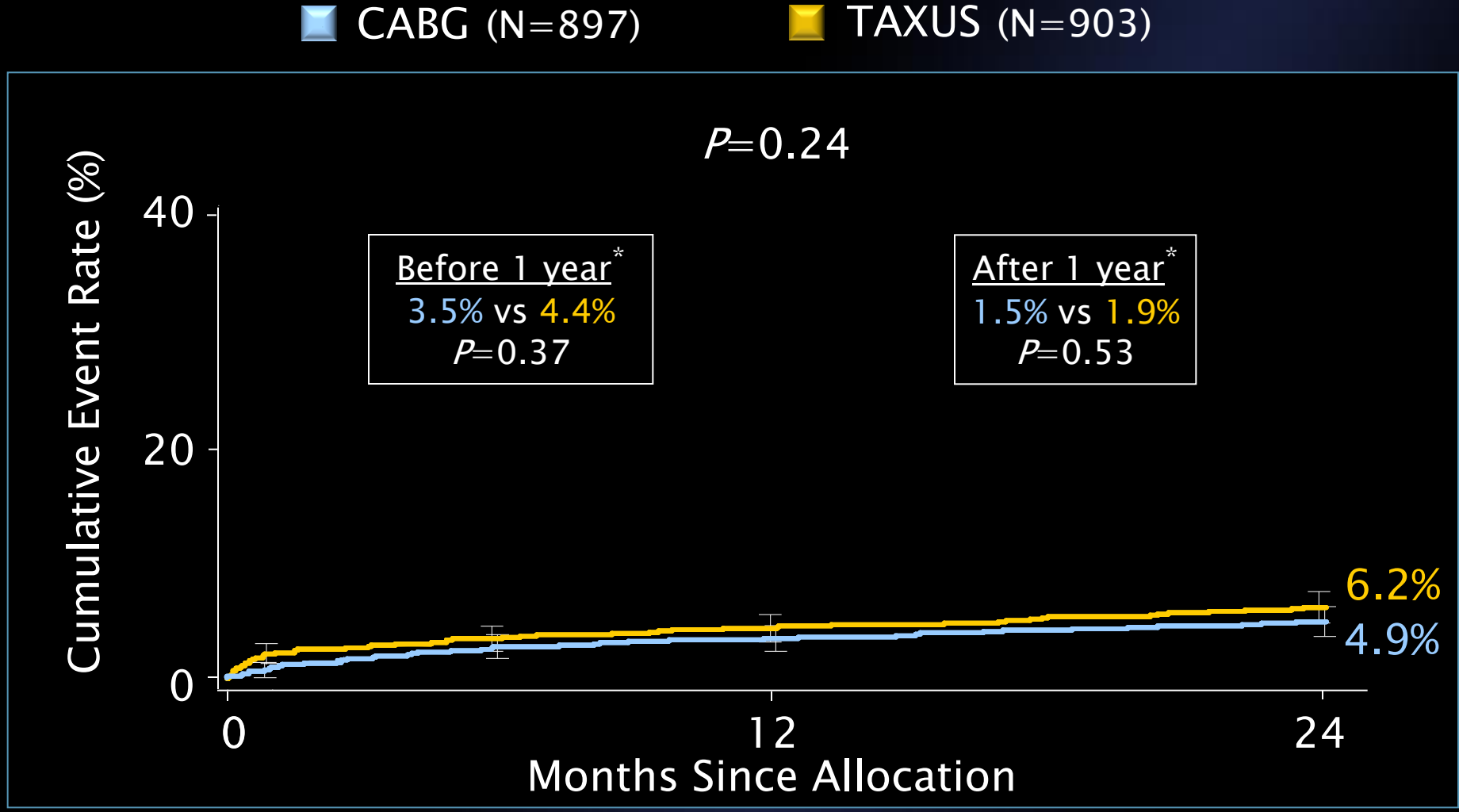
CVA to 12 Months



Event Rate ± 1.5 SE. *Fisher's Exact Test

ITT population

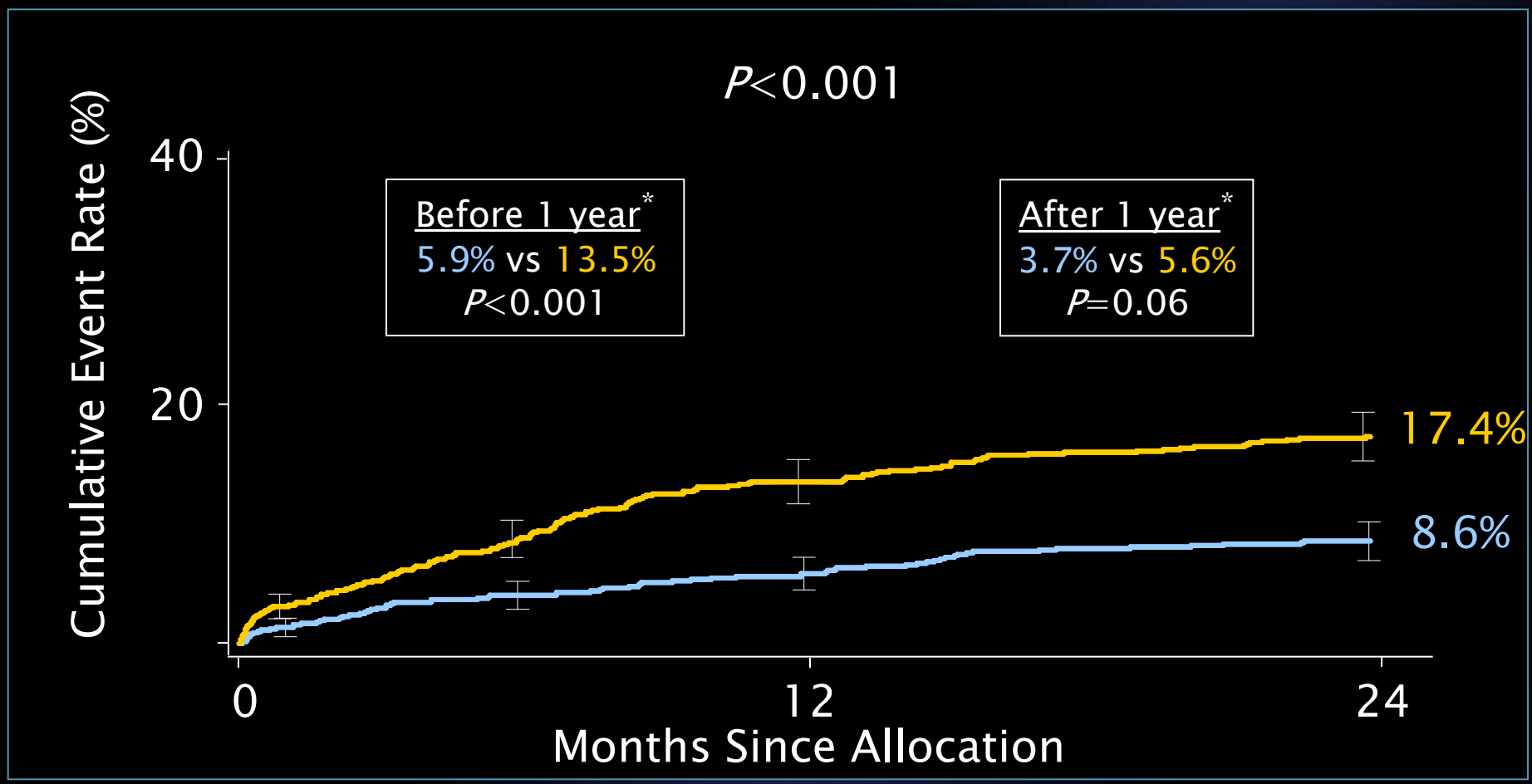
All-Cause Death to 2 Years



Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value;*Binary rates

ITT population

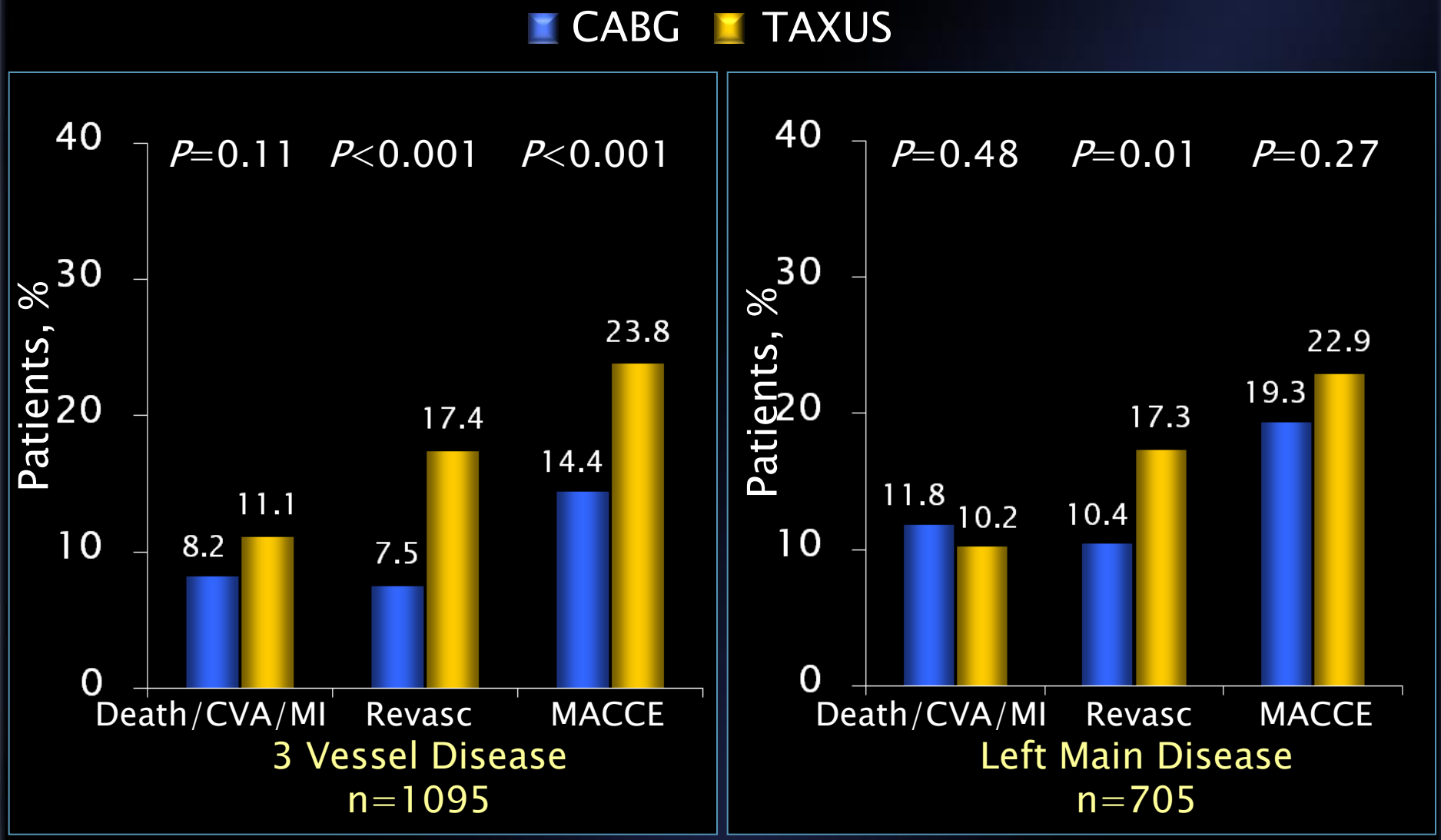
Repeat Revascularization to 2 Years



Cumulative KM Event Rate ± 1.5 SE; log-rank *P* value;*Binary rates

ITT population

2 Year Outcomes in 3VD and LM Subgroups

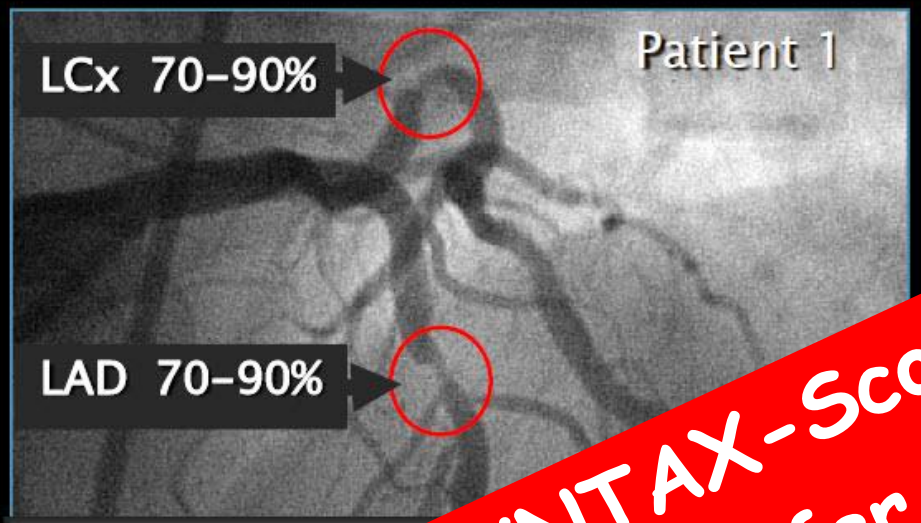


Time-to Event; Log-rank *P* value

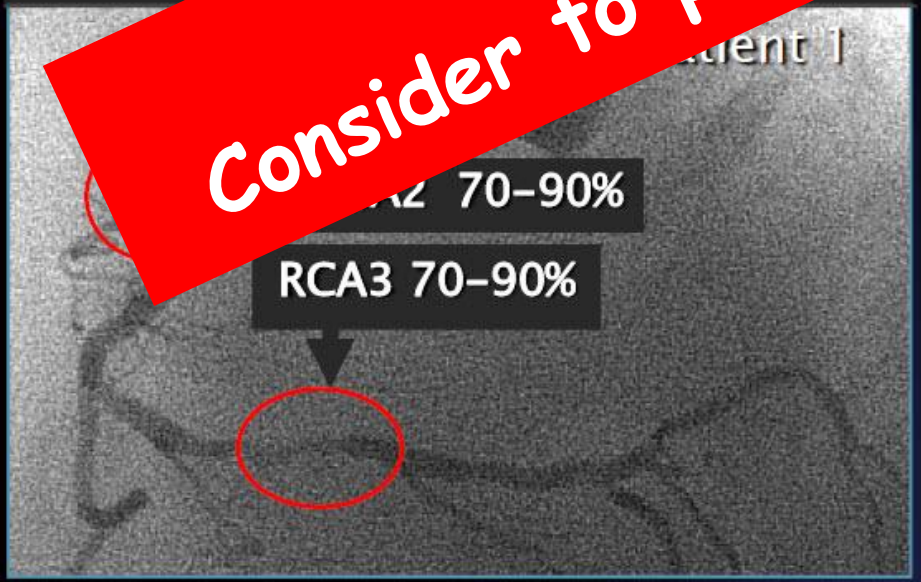
ITT population

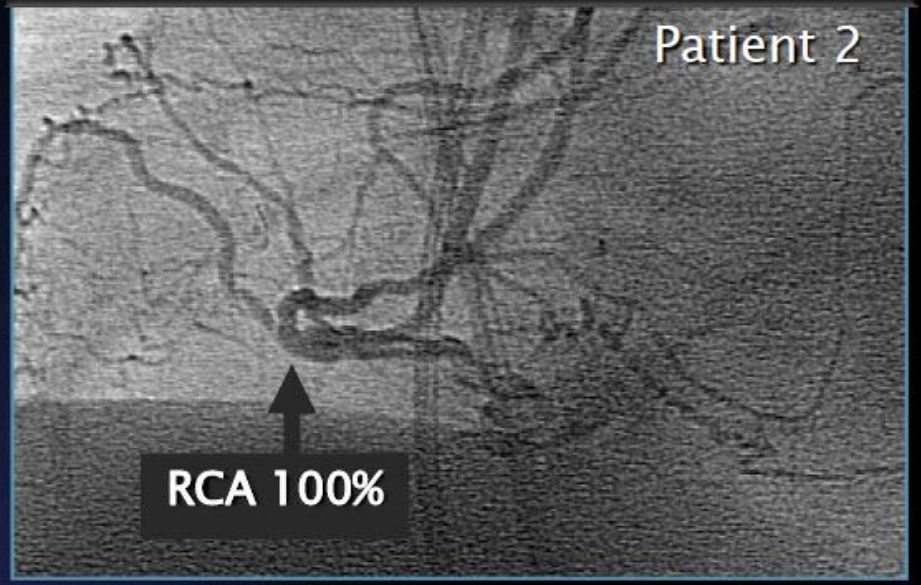
There is '3-vessel disease' and '3-vessel disease'

SYNTAX



SYNTAX SCORE 52





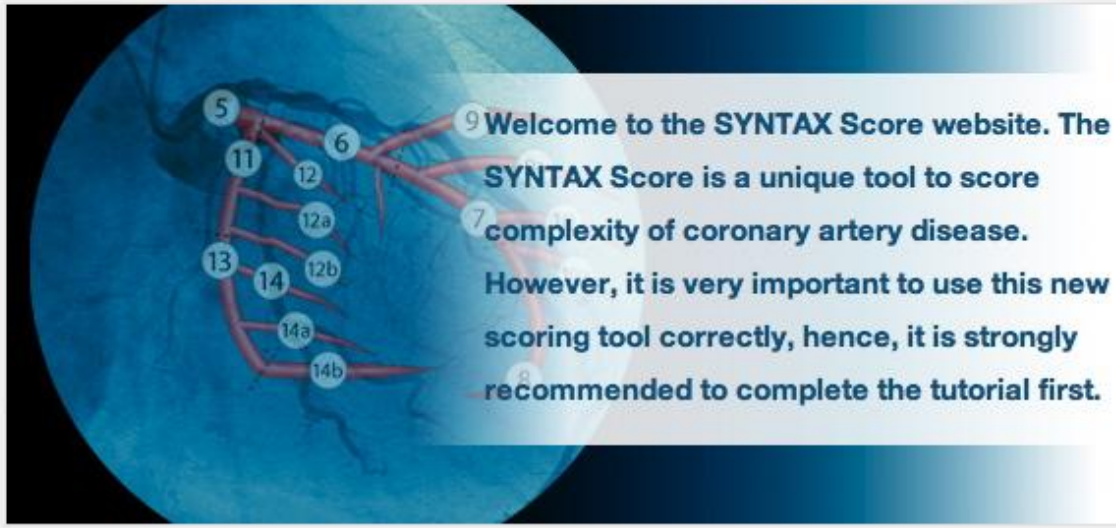
SYNTAX-Score > 33:
Consider to prefer Bypass Surgery !

www.syntaxscore.com

Home Tutorial Calculator References Contact

SYNTAX SCORE

Search...



Welcome to the SYNTAX Score website. The SYNTAX Score is a unique tool to score complexity of coronary artery disease. However, it is very important to use this new scoring tool correctly, hence, it is strongly recommended to complete the tutorial first.

TUTORIAL

Knowledge of definitions is vital. Please use the tutorial prior to first calculator use.

Start tutorial...

CALCULATOR

Start using the calculator when you have successfully completed the tutorial.

Start calculator...

Introducing the SYNTAX Score at EuroPCR 2009

ESC Congress News
EUROPEAN SOCIETY OF CARDIOLOGY®
BARCELONA ESC CONGRESS 2009 30 AUGUST

key Even more important is the choice of bypass conduit,
the which is a dominant factor in the long-term follow-up
The of CABG.
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SYNTAX score, an excellent by-product

One interesting product of the study is the SYNTAX score. The more complex the coronary anatomy - ie, the higher the SYNTAX score - the better the outcomes of CABG as opposed to PCI. If the SYNTAX score is low, the two therapies seemed comparable in terms of outcomes. This Score taken together with the clinical profile will help in patient selection for the most appropriate technique.

diac
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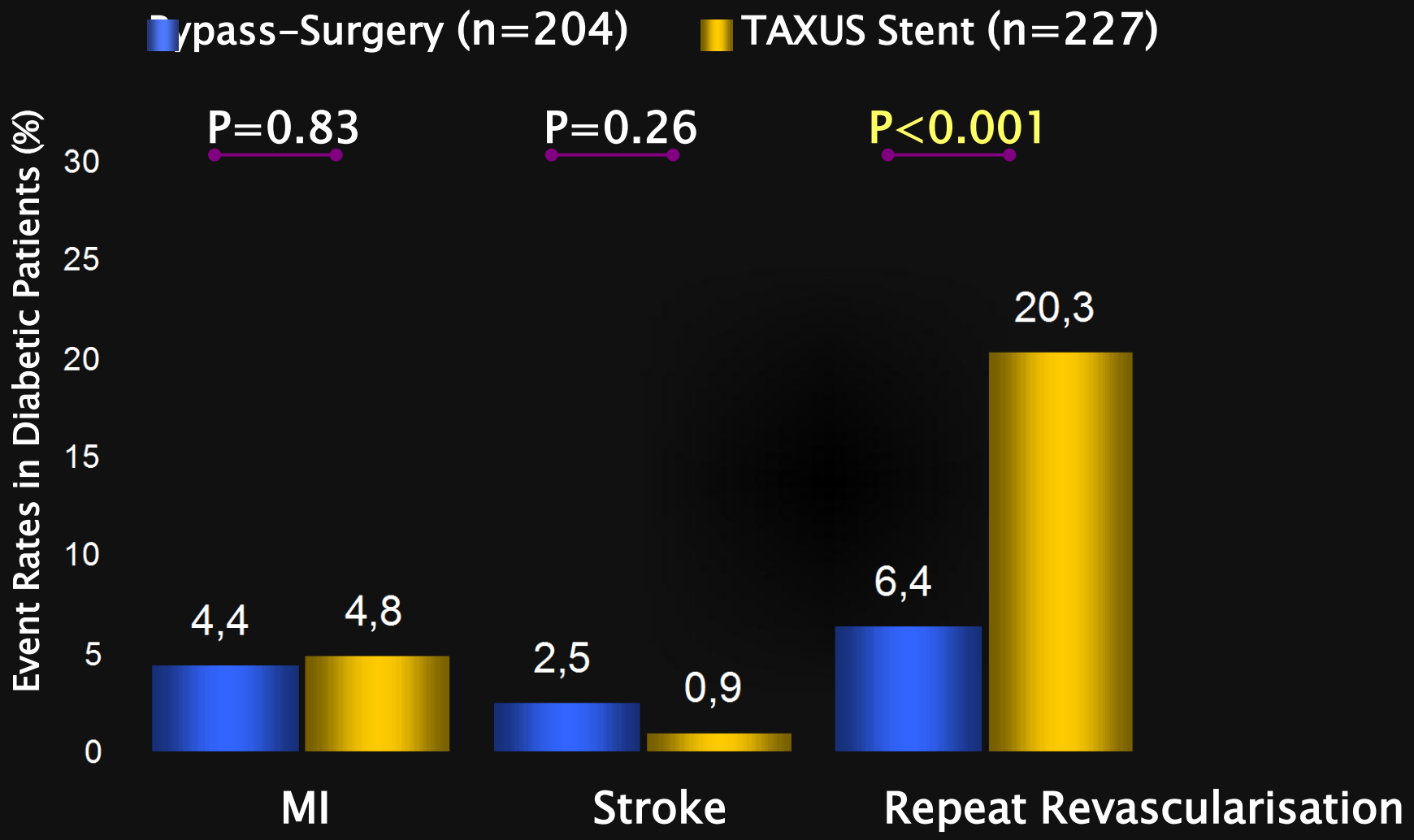
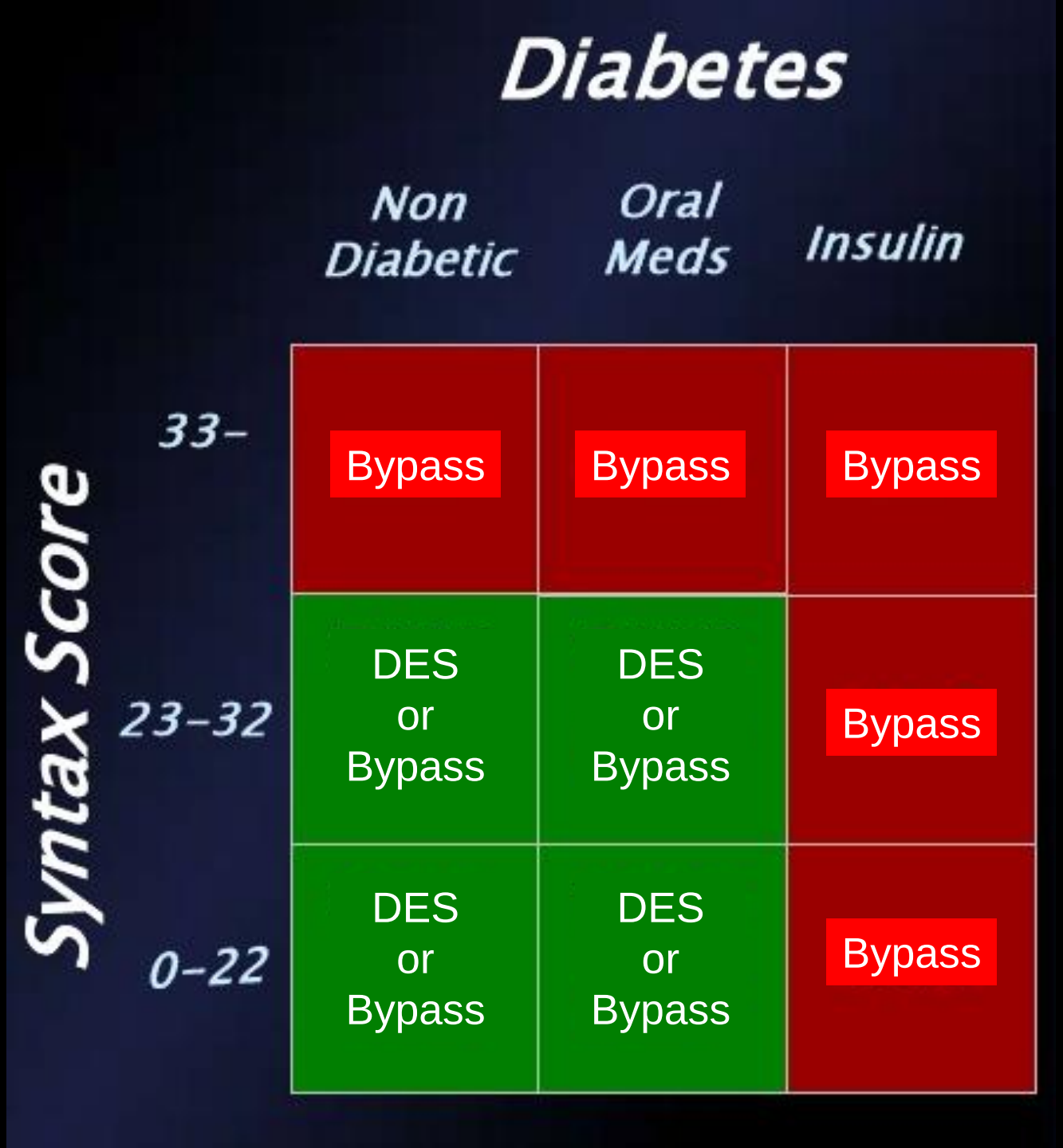
Why does SYNTAX not represent the best surgical management of CABG? "The internal thoracic artery: The drug eluting graft!"

Only 18.9% of patients in the SYNTAX trial had pure

Barcelona

SYNTAX: Diabetic Patients

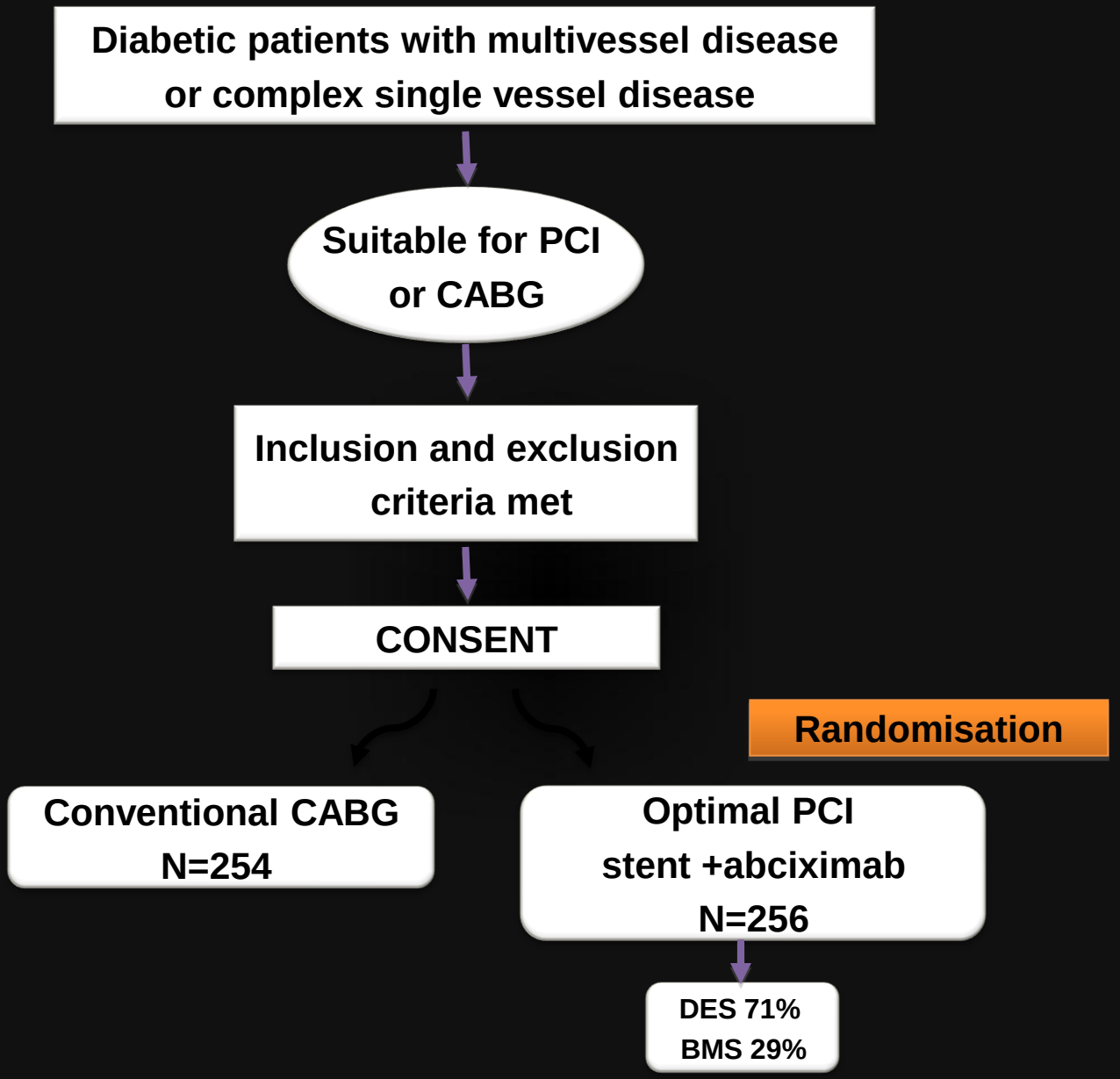



Diabetes
Non Diabetic
Oral Meds
Insulin
Syntax Score
33–
23–32
0–22
Bypass
Bypass
Bypass
DES or Bypass
DES or Bypass
Bypass
DES or Bypass
DES or Bypass
Bypass

Take Home Messages from SYNTAX:

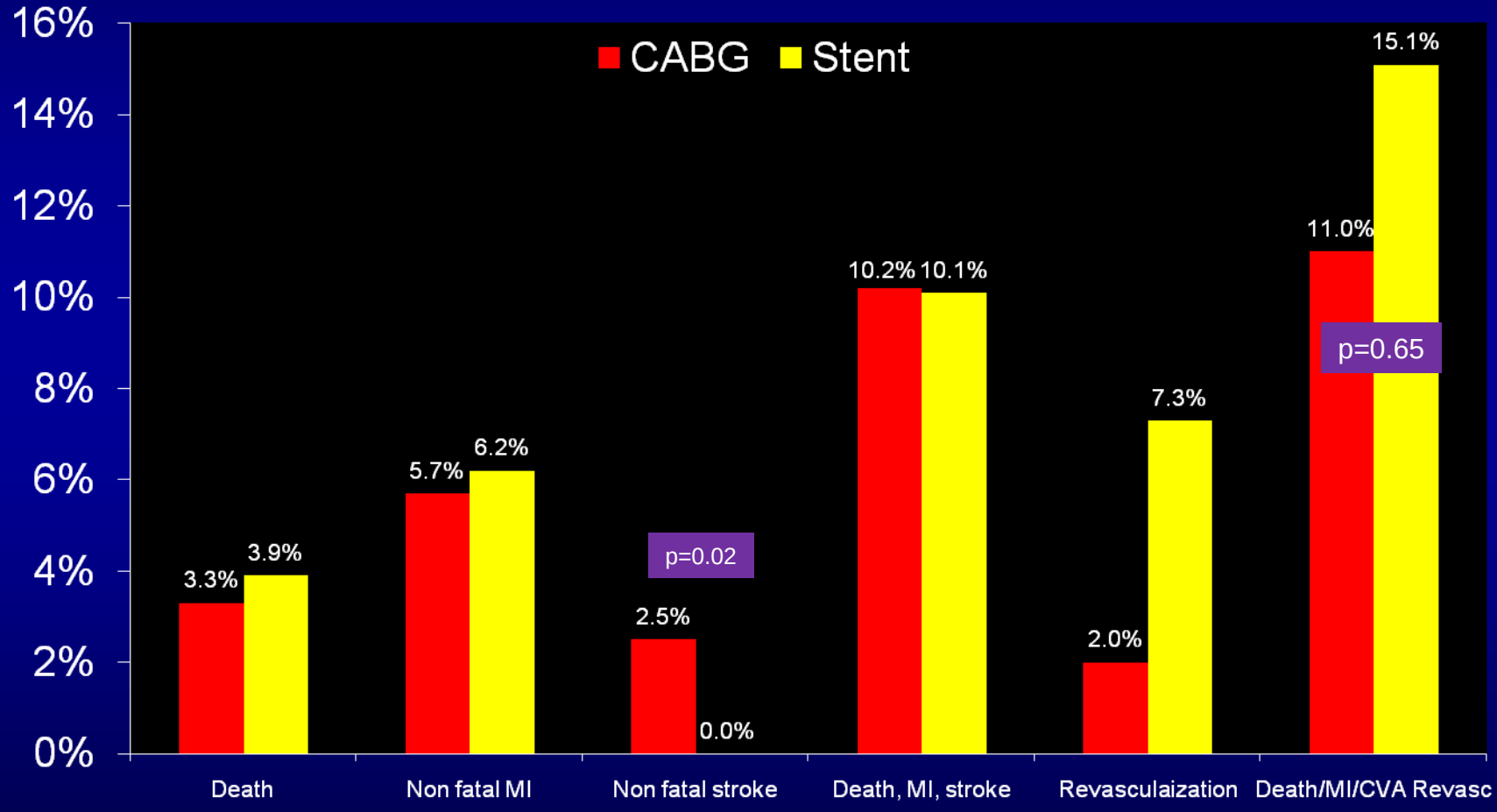
- **SYNTAX did not reach its primary endpoint, because repeat revascularization was a part of it.**
- **After 2 years, repeat revascularization was 17.4% in the TAXUS-DES group and still significantly higher than the 8.6% in the CABG group.**
- **The advantage of bypass surgery over PCI was especially prominent in patients with diabetes.**
- **However, stroke was significantly higher after bypass surgery.**
- **With the data from SYNTAX, PCI of unprotected left main stenosis is a true option for some patients with stable CAD.**
- **The SYNTAX-Score is purely anatomic and is helpful for decision making of DES vs. surgery, esp. after correction for functional parameters.**
- **SYNTAX will change future ESC guidelines.**

CARDia Trial Design



CARDIA
(Coronary Artery Revascularization Diabetes Trial)

- 510 diabetic pts randomized to CABG vs PCI (71% DES)



ESC, 2008

FRACTIONAL FLOW RESERVE *versus* ANGIOGRAPHY FOR GUIDING PCI IN PATIENTS WITH MULTIVESSEL CORONARY ARTERY DISEASE

Late Breaking Trial at
TCT, October 14 th , 2008

Nico H.J.Pijls, MD, PhD
Catharina Hospital, Eindhoven
The Netherlands,
on behalf of the ***FAME investigators***

FLOW CHART

Patient with stenoses ≥ 50% in at least 2 of the 3 major epicardial vessels

Indicate all stenoses ≥ 50% considered for stenting

Randomization

Angiography-guided PCI

Stent all indicated stenoses

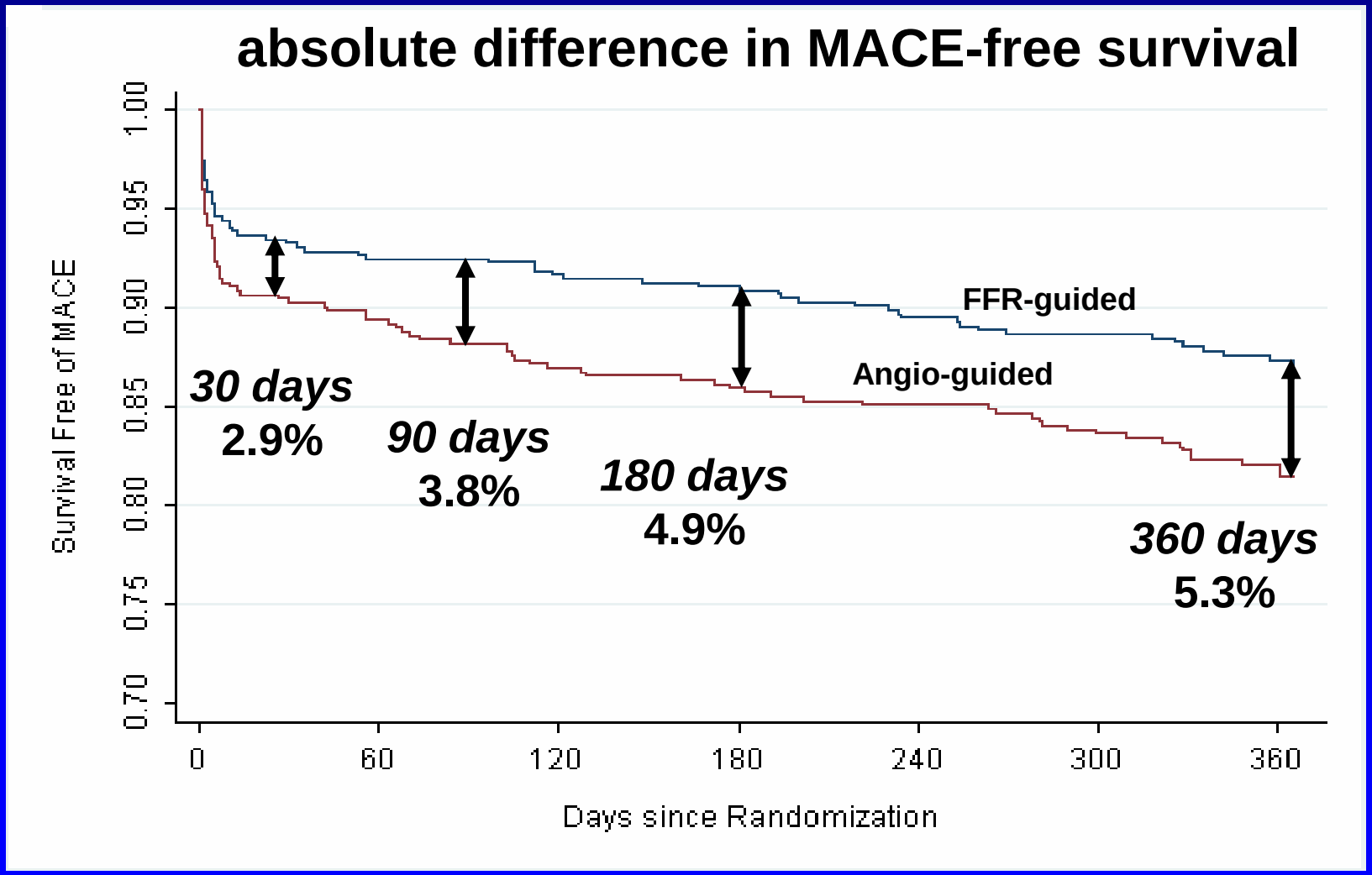
FFR-guided PCI

Measure FFR in all indicated stenoses

Stent only those stenoses with FFR ≤ 0.80

1-year follow-up

FAME study: Event-free Survival



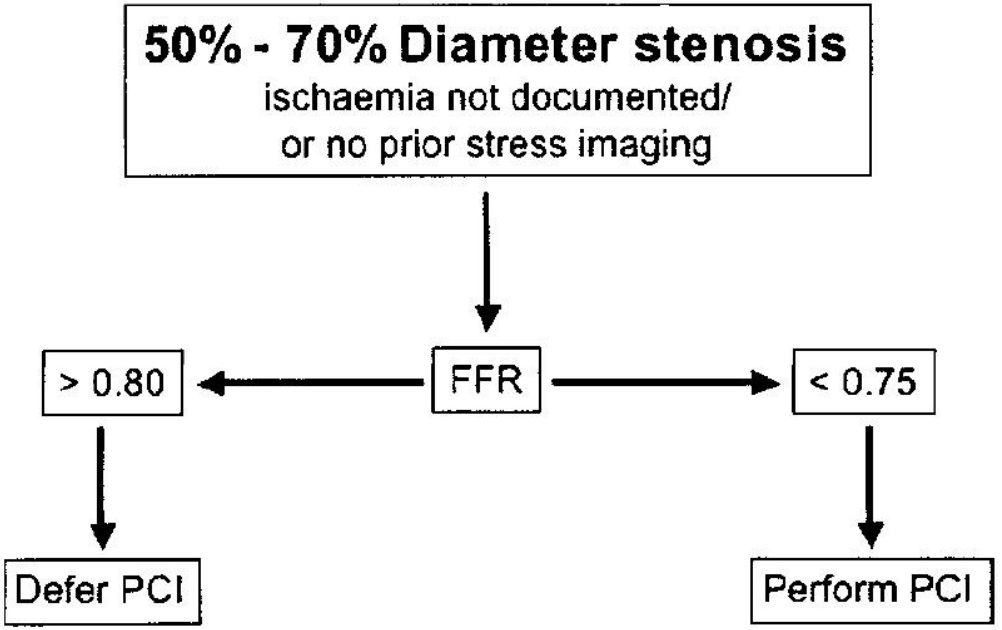
FAME study: CONCLUSIONS (2)

Routine measurement of FFR during PCI with DES in patients with multivessel disease, when compared to current angiography guided strategy, *furthermore:*

- ***is cost-saving and does not prolong the procedure***
- ***reduces the number of stents used***
- ***decreases the amount of contrast agent used***
- ***results in a similar, if not better, functional status***

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions
of the European Society of Cardiology



European Heart Journal (2005) **26**, 804–847

FFR vs. Angiography for Multivessel Evaluation

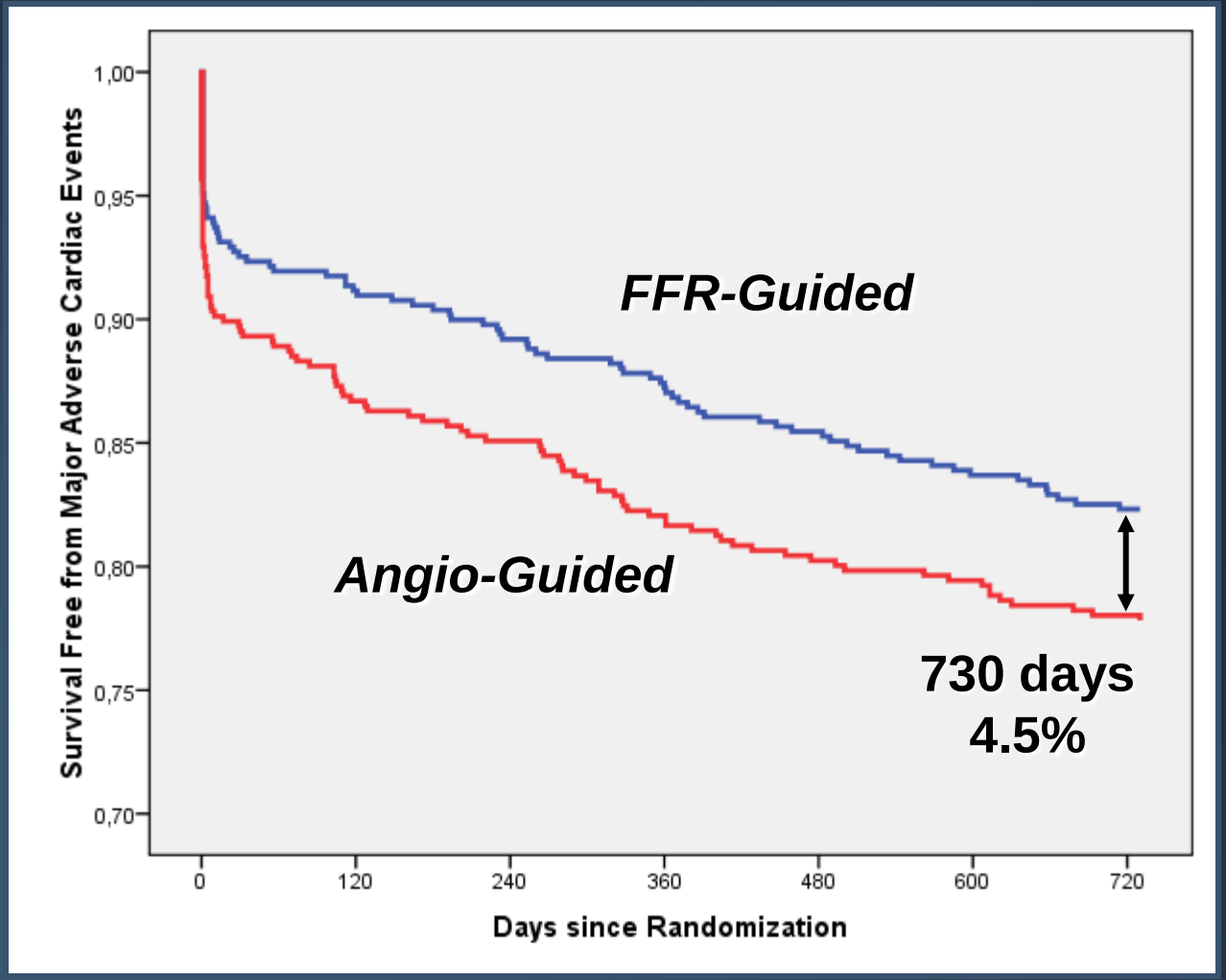
FAME
2 Year Follow-Up

William F. Fearon, Pim A.L. Tonino, Bernard De Bruyne,

Uwe Siebert and Nico H.J. Pijls,

on behalf of the FAME Study Investigators

2 Year Survival Free of MACE



Take Home Messages from FAME:

- **FAME corrobrated the findings of DEFER for multivessel disease suggesting to obstain from stenting, if FFR is > 0.8.**
- **Thus, FFR may be cost saving, avoiding unnecessary stenting**
- **FAME further confirmed previous ESC guidelines.**

20 YEARS OF INNOVATION
TCT2008

TRANSFER-AMI: Should urgent transfer after fibrinolysis now be standard of care?

Warren J. Cantor, MD

Medical Director, Interventional / Invasive Program,

Southlake Regional Health Centre

Newmarket, Ontario, Canada

Assistant Professor, University of Toronto

CARDIOVASCULAR RESEARCH FOUNDATION

Transfer AMI

Community Hospital Emergency Department

High Risk ST Elevation MI within 12 hours of symptom onset

TNK + ASA + Heparin or Enoxaparin + Clopidogrel

Randomization

Pharmacoinvasive Strategy
Urgent Transfer to PCI Centre

Standard Treatment

Assess chest pain, ST↑ resolution at 60-90 minutes after randomization

Failed Reperfusion**

Successful Reperfusion

PCI Centre Cath Lab

Cath / PCI within 6 hrs regardless of reperfusion status

Cath and Rescue PCI ± GP IIb/IIIa Inhibitor

Elective Cath ± PCI > 24 hrs later

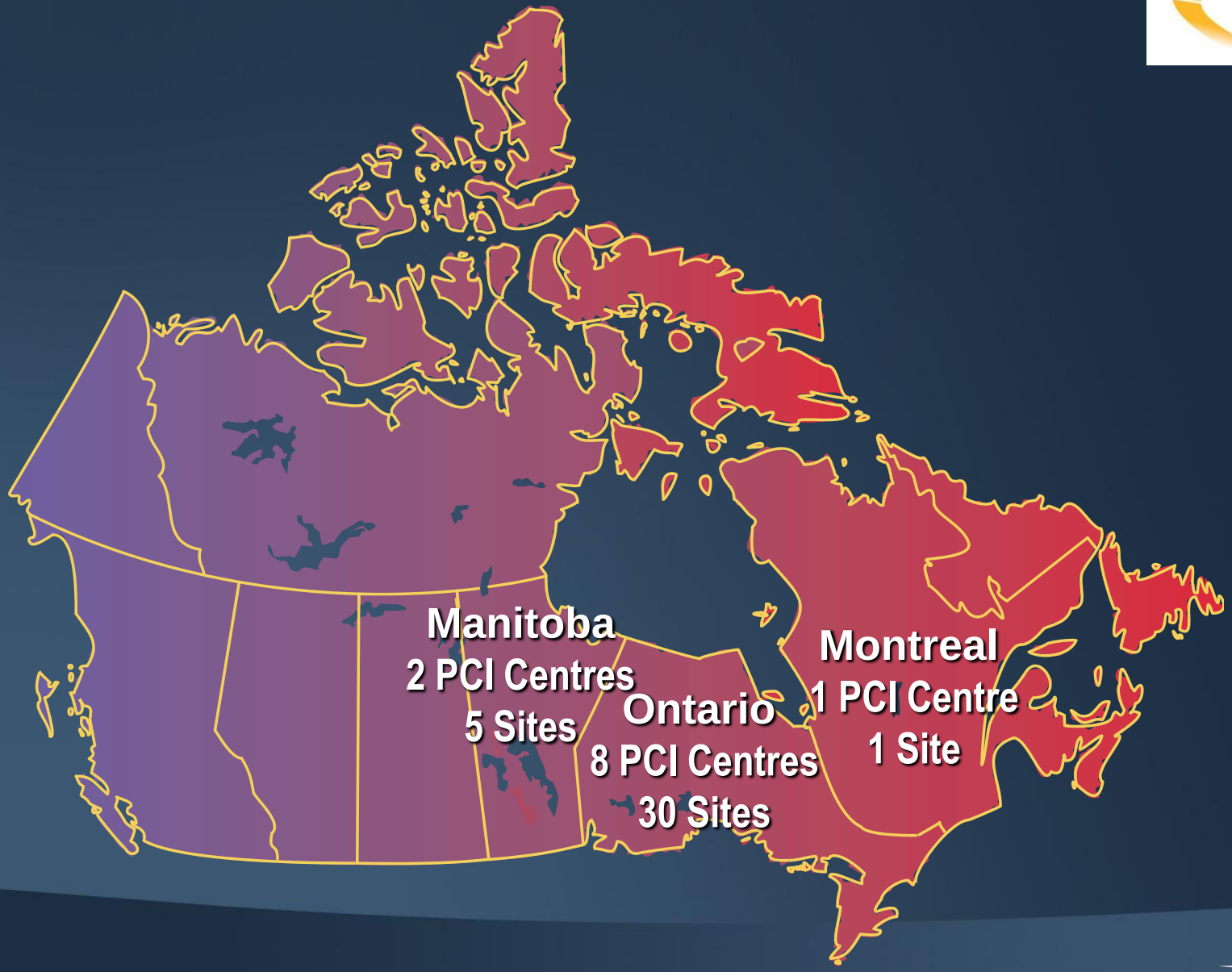
Repatriation of stable patients within 24 hrs of PCI

** ST segment resolution < 50% & persistent chest pain, or hemodynamic instability

CARDIOVASCULAR RESEARCH FOUNDATION

20 YEARS OF INNOVATION
TCT2008

TRANSFER-AMI Sites

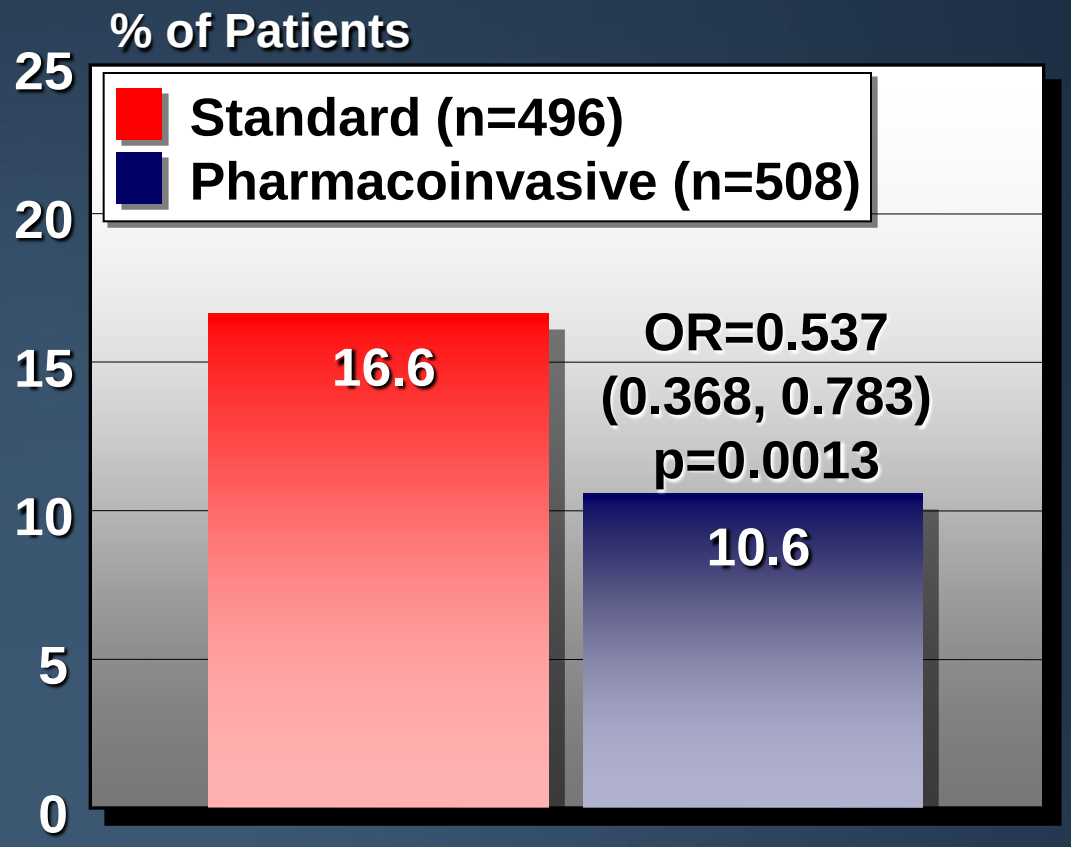


CARDIOVASCULAR RESEARCH FOUNDATION

Primary Endpoint:

30-Day Death, re-MI, Heart Failure, Severe Recurrent Ischemia, Cardiogenic Shock

PRELIMINARY



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JUNE 25, 2009 VOL. 360 NO. 26

Routine Early Angioplasty after Fibrinolysis for Acute Myocardial Infarction

Warren J. Cantor, M.D., David Fitchett, M... g, M.D., John Ducas, M.D., Michael Heffernan, M.D., Eric A. Co... rison, M.D., Anatoly Langer, M.D., Vladimir Dzavik, M.D., Shami... es Lazzam, M.D., Brian Schwartz, M.D., Amparo Casanova, M.D., Ph.D... an, M.D., for the TRANSFER-AMI Trial Investigators*

Was this new ?

CONCLUSIONS

Among high-risk patients who had a myocardial infarction with ST-segment elevation and who were treated with fibrinolysis, transfer for PCI within 6 hours after fibrinolysis was associated with significantly fewer ischemic complications than was standard treatment.

N Engl J Med 2009;360:2705-18.

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

Routine post-thrombolysis coronary angiography and PCI, if applicable	Up to 24 h after thrombolysis, independent of angina and/or ischaemia	I A	SIAM III GRACIA-1 CAPITAL-AMI

European Heart Journal (2005) **26**, 804–847

The GRACIA – 1 trial

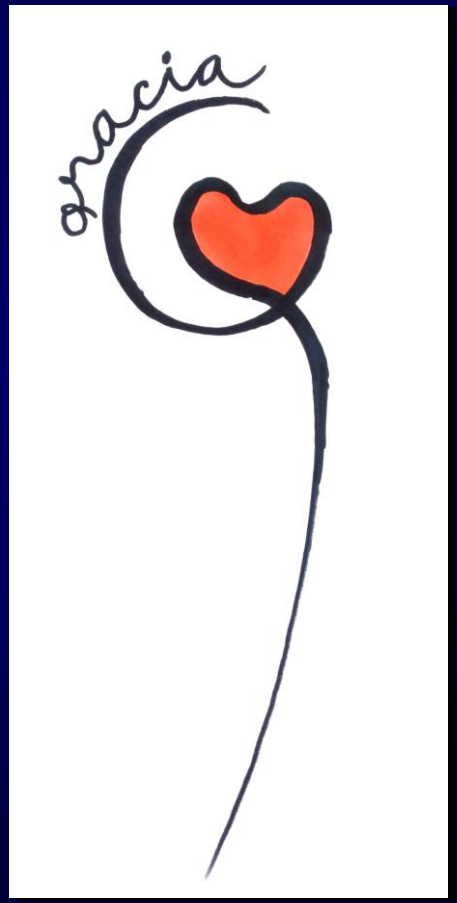
(GRupo de Análisis de la Cardiopatía Isquémica Aguda)

ESC 2003

Randomised trial comparing stenting within 24 hours of thrombolysis versus conservative ischaemia-guided approach to STEMI

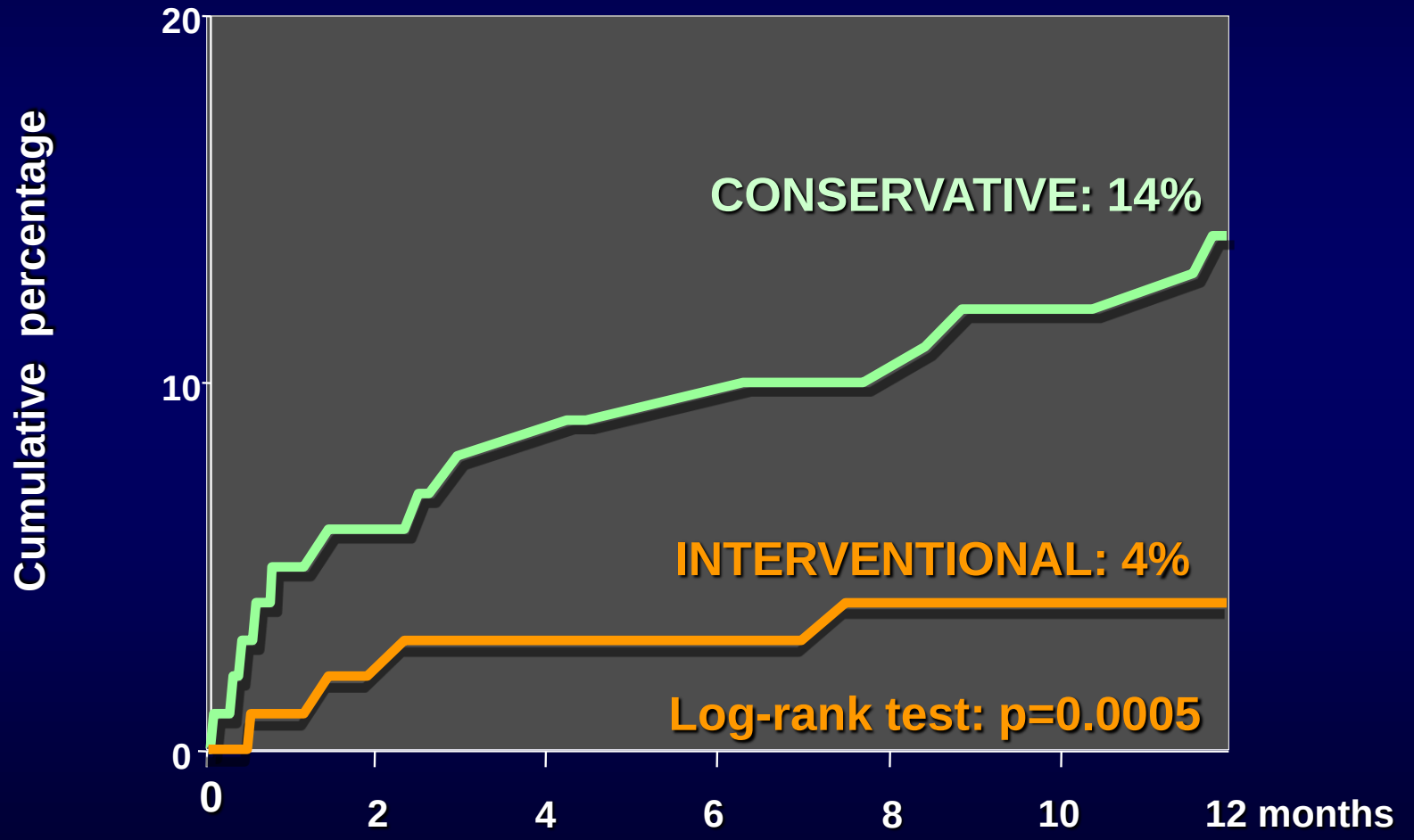
One-year Results

Francisco F. Avilés
(on behalf on the GRACIA group)



GRACIA – 1

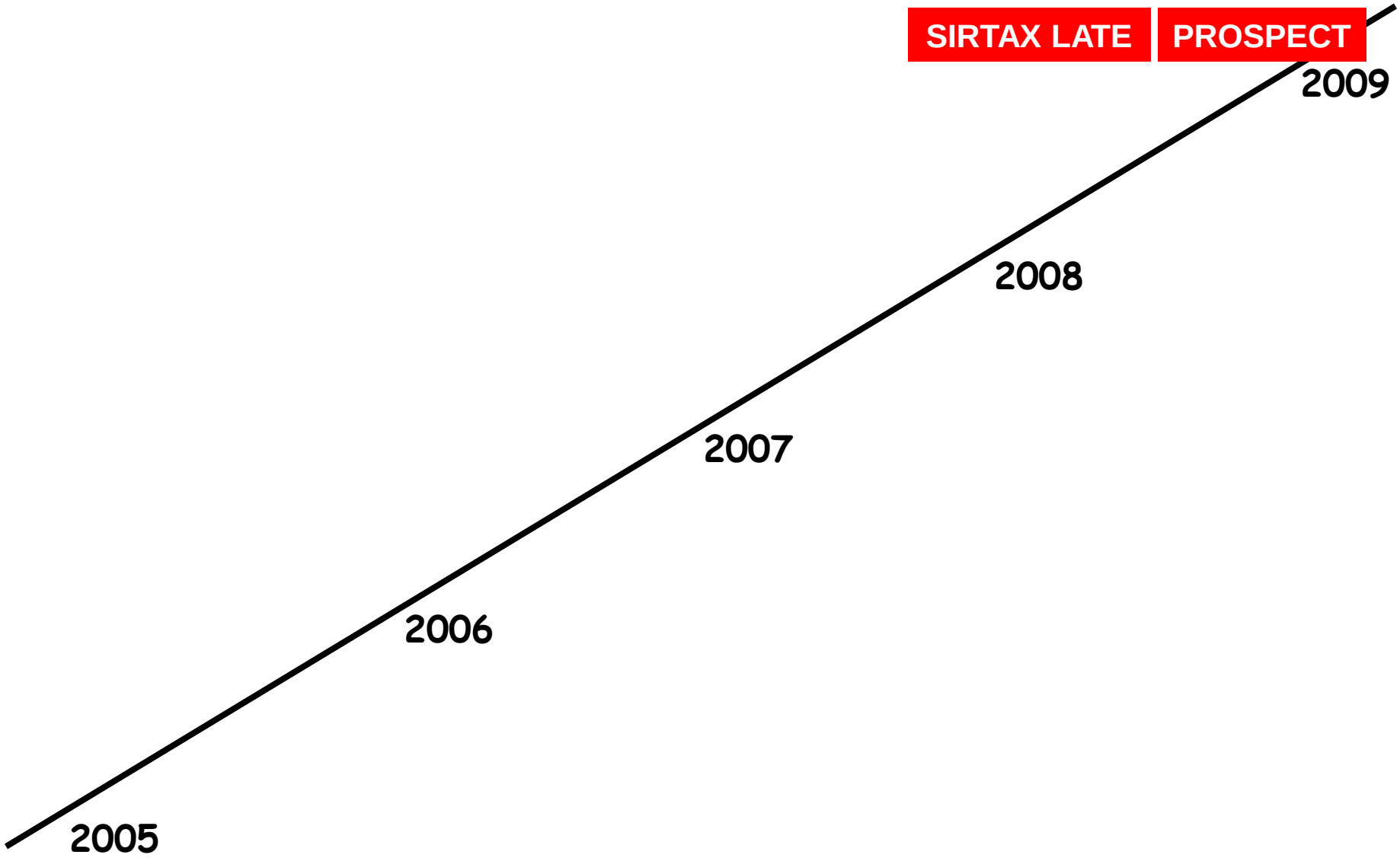
One – year outcome REVASCULARIZATION



Take Home Messages from TRANSFER-AMI:

- **TRANSFER-AMI corroborated the concept of routine coronary angiography with PCI, if applicable, after thrombolysis.**
- **TRANSFER-AMI further confirmed previous ESC guidelines.**

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?



Cypher Versus Taxus: Are There Differences?

SIGMUND SILBER, M.D., F.E.S.C., F.A.C.C.

From the Cardiology Practice and Hospital, Munich, Germany

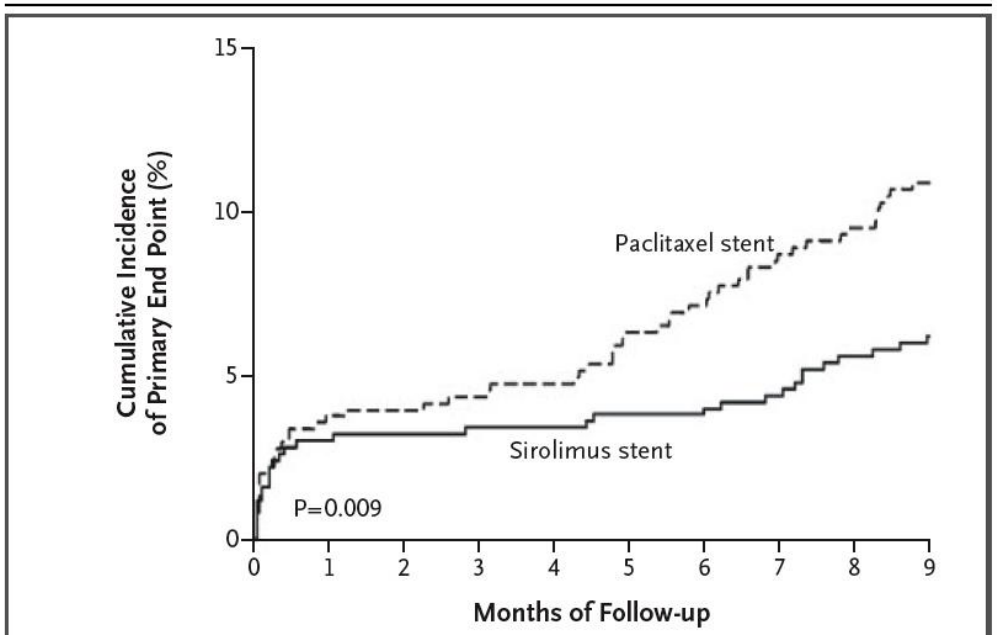
Of the four studies comparing Cypher stents to Taxus stents, one did not define the primary endpoint (TAXi[19]), two assumed superiority of the Cypher stent (REALITY[20] and SIRTAX[21]), and one was designed as a non-inferiority trial (ISAR-Diabetes[22]) (Table 5). The multicenter REALITY trial did not reach the primary endpoint, whereas the single-center SIRTAX trial did (Table 5). No randomized, controlled multicenter trial with a primary clinical endpoint and adequate power calculation exists, showing that one DES is superior to another.

(J Interven Cardiol 2005;18:441–446)

Sirolimus-Eluting and Paclitaxel-Eluting Stents for Coronary Revascularization

SIRTAX

Stephan Windecker, M.D., Andrea Remondino, M.D., Franz R. Eberli, M.D., Peter Jüni, M.D., Lorenz Räber, M.D., Peter Wenaweser, M.D., Mario Togni, M.D., Michael Billinger, M.D., David Tüller, M.D., Christian Seiler, M.D., Marco Roffi, M.D., Roberto Corti, M.D., Gabor Sütsch, M.D., Willibald Maier, M.D., Thomas Lüscher, M.D., Otto M. Hess, M.D., Matthias Egger, M.D., and Bernhard Meier, M.D.*



CONCLUSIONS

As compared with paclitaxel-eluting stents, the use of sirolimus-eluting stents results in fewer major adverse cardiac events, primarily by decreasing the rates of clinical and angiographic restenosis.

N Engl J Med 2005;353:653-62.

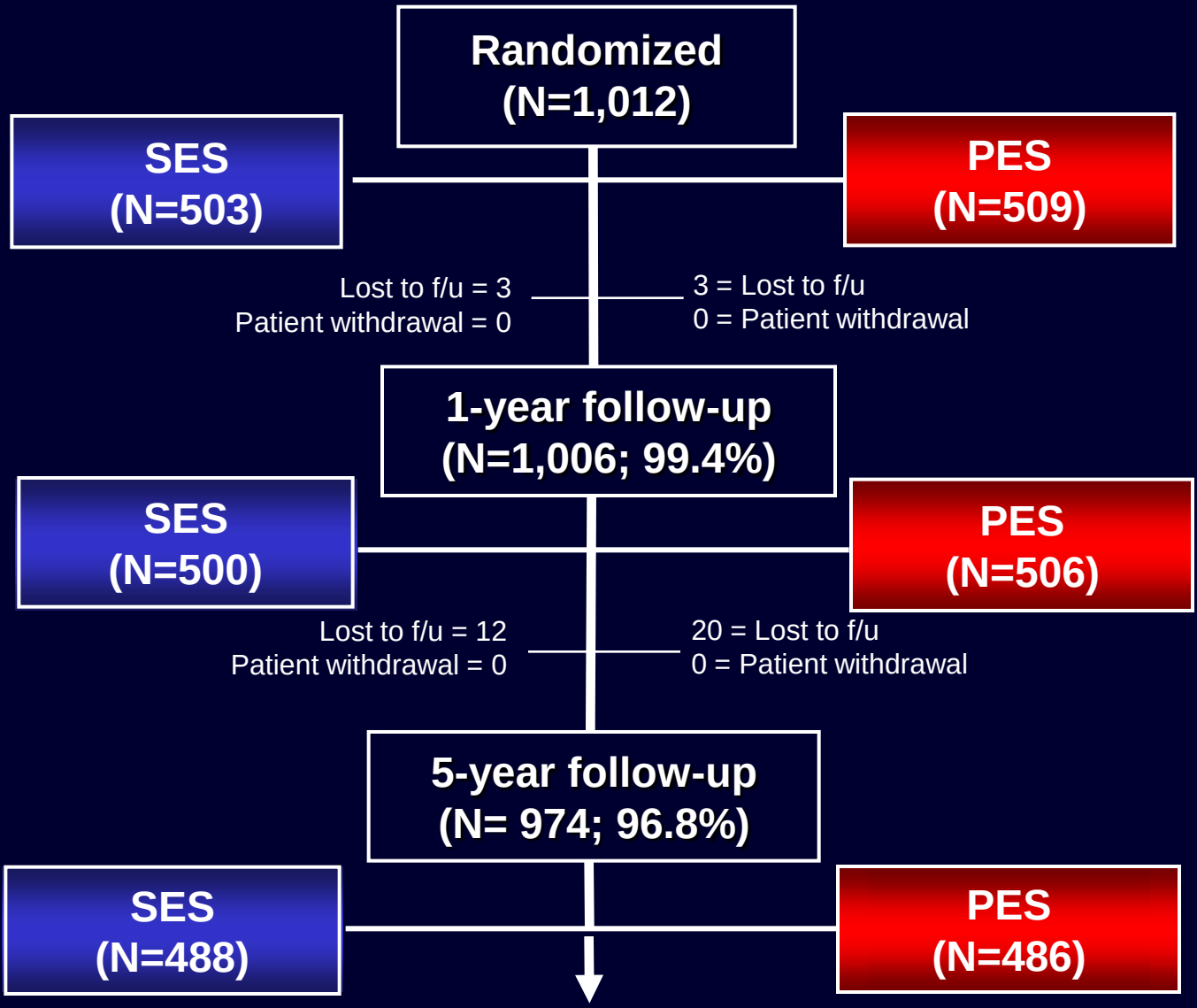
SIRTAX-LATE

5-Year Clinical and Angiographic Follow-up From a Prospective, Randomized Trial Comparing Sirolimus-Eluting With Paclitaxel-Eluting Stents

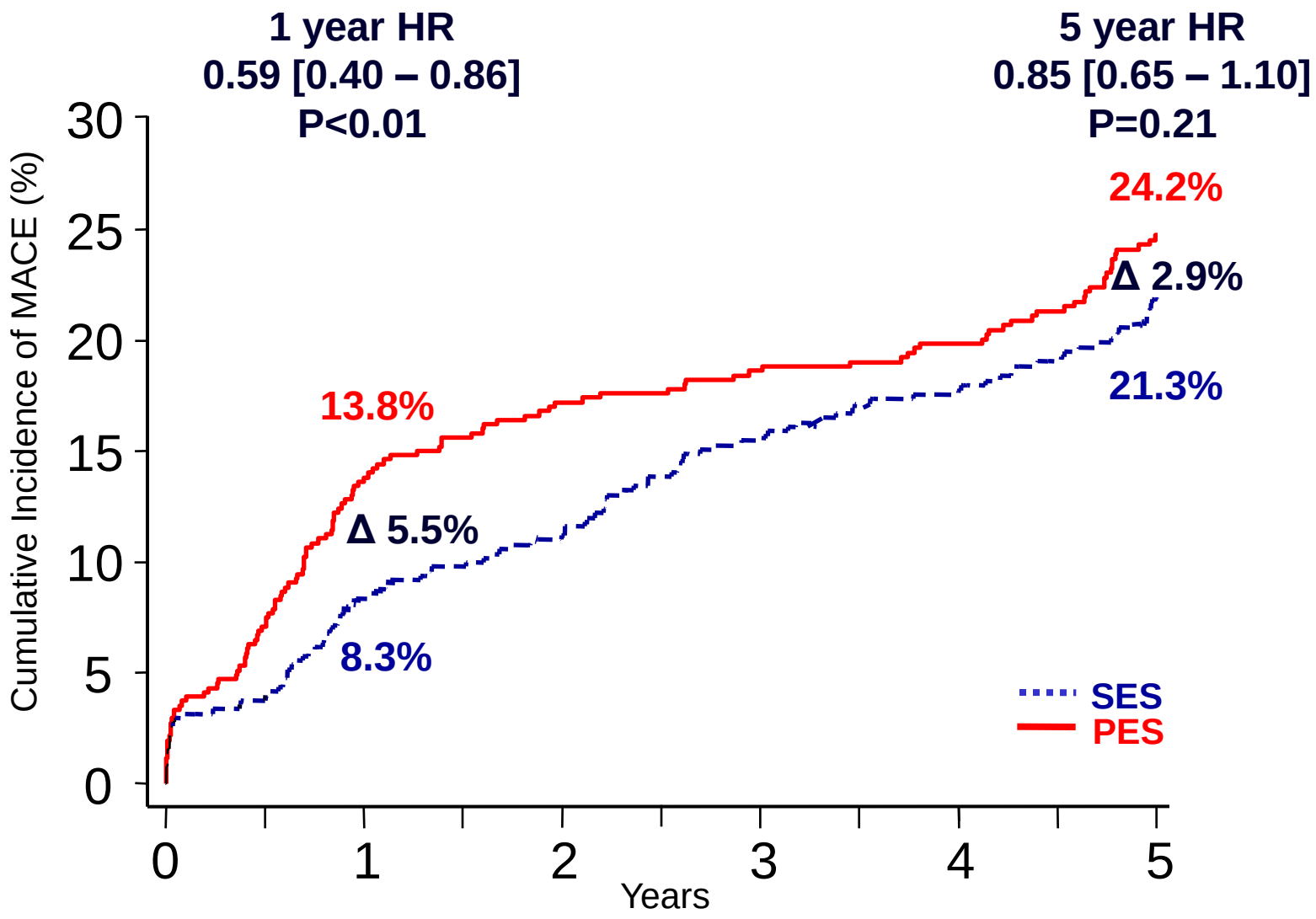
Lorenz Räber, Mario Togni, Simon Wandel
Mathias Wigger, Lea Wohlwend, Stéphane Cook,
Peter Wenaweser, Christian Seiler, Franz Eberli,
Thomas Lüscher, Bernhard Meier, Peter Jüni
and Stephan Windecker

Funded by Bern University Hospital, Switzerland

Flow of Patients – Clinical F/U Through 5 Years

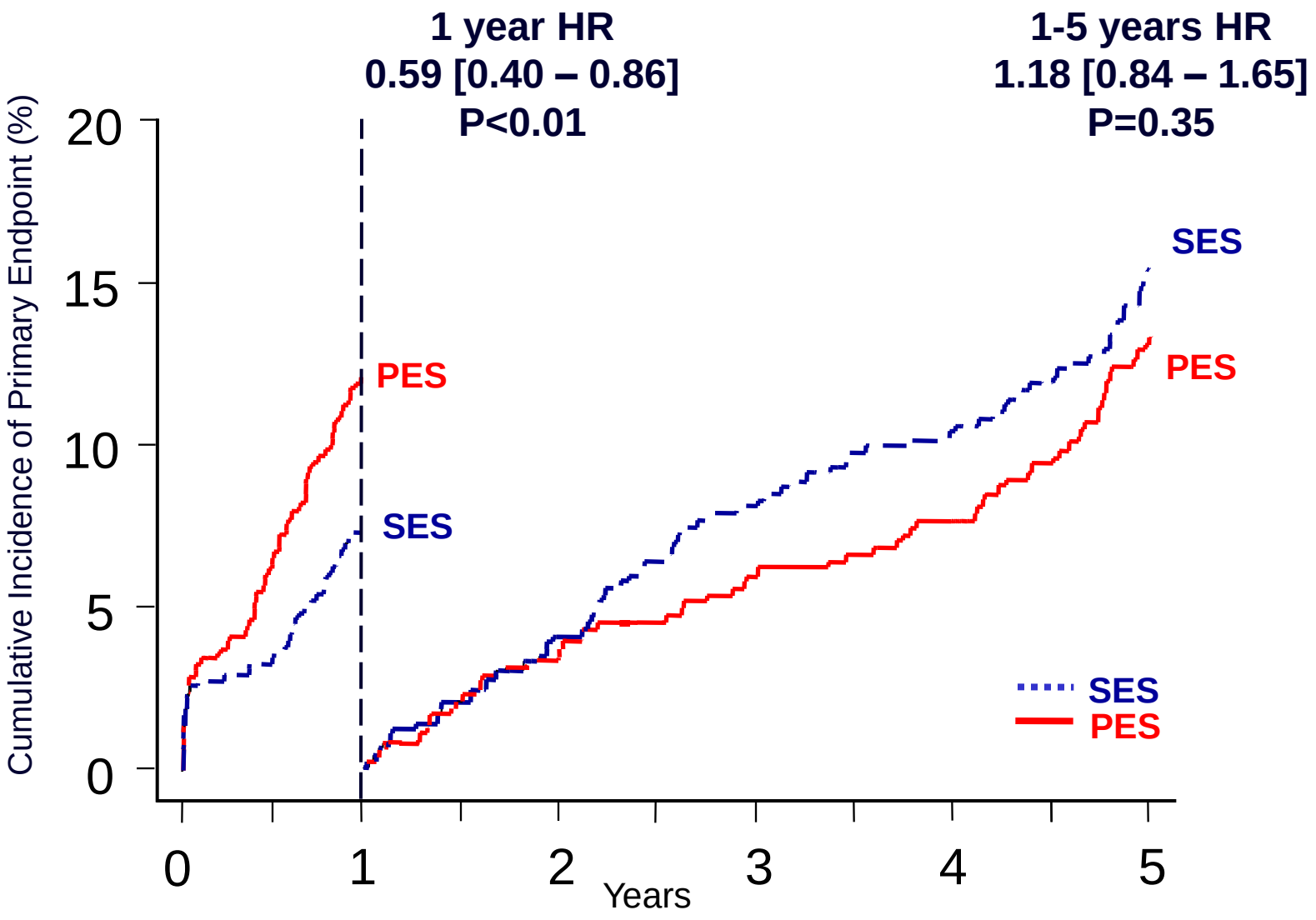


Major Adverse Cardiac Events @ 5 Years



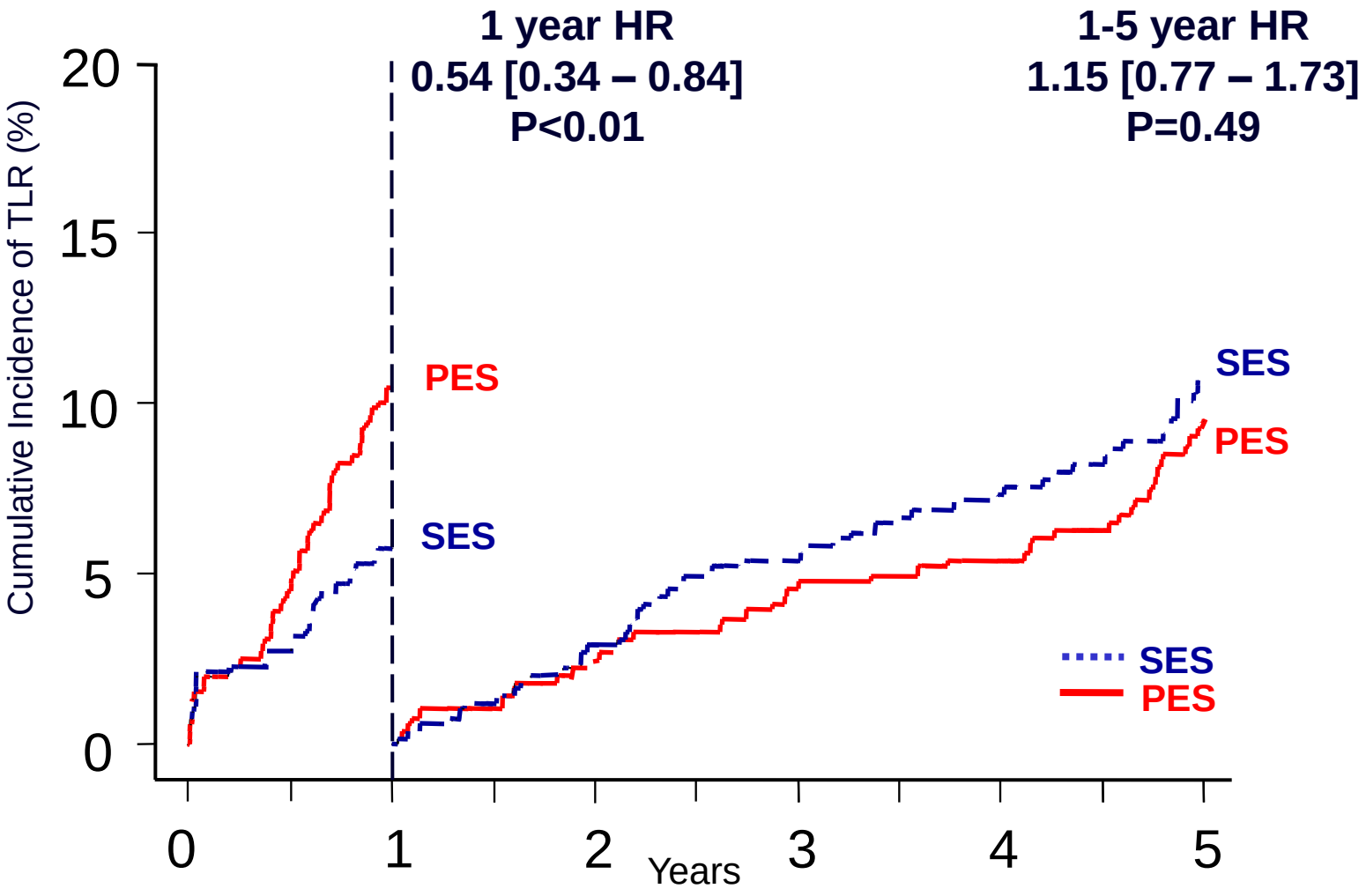
Major Adverse Cardiac Events

Landmark-Analysis



Target lesion Revascularization

Landmark-Analysis



Take Home Messages from SIRTAX-LATE:

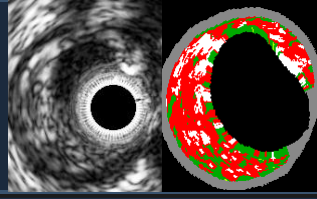
- **There is no clinical difference between Cypher and Taxus.**
- **SIRTAX-LATE further confirmed previous ESC guidelines.**
- **The problem of long-term follow-up with DES:**

  when the results are available, the DES will be replaced:

  - Cypher will be replaced by the Nevo Sirolimus-eluting stent

  - Taxus Liberté will be replaced by the Taxus Element Paclitaxel-eluting stent

The PROSPECT Trial



***P**roviding **R**egional **O**bservations to **S**tudy **P**redictors of **E**vents in the **C**oronary **T**ree*

A Natural History Study of Atherosclerosis Using Multimodality Intracoronary Imaging to Prospectively Identify Vulnerable Plaque

Gregg W. Stone, MD

PROSPECT Investigators

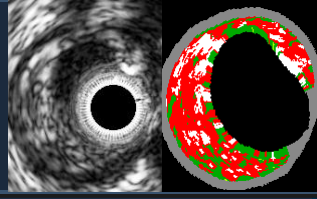
CARDIOVASCULAR RESEARCH FOUNDATION

COLUMBIA UNIVERSITY MEDICAL CENTER

NewYork-Presbyterian

The University Hospital of Columbia and Cornell

The PROSPECT Trial



3-vessel imaging post PCI

Culprit artery, followed by non-culprit arteries

Angiography (QCA of entire coronary tree)

IVUS

Virtual histology

Palpography (n=~350)

Proximal 6-8 cm of each coronary artery

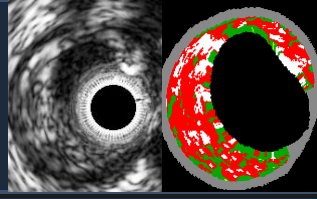
Meds rec
Aspirin
Plavix 1yr
Statin
Repeat biomarkers
@ 30 days, 6 months

F/U: 1 mo, 6 mo, 1 yr, 2 yr, ±3-5 yrs

MSCT Substudy
N=50-100

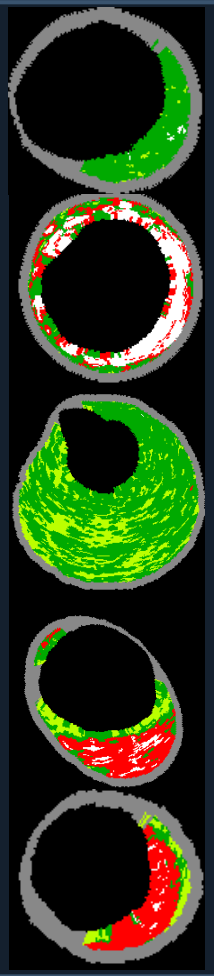
Repeat imaging in pts with events

PROSPECT: Methodology



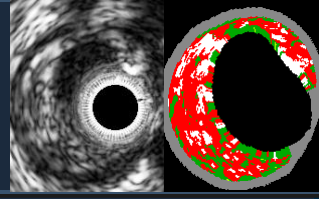
Virtual histology lesion classification

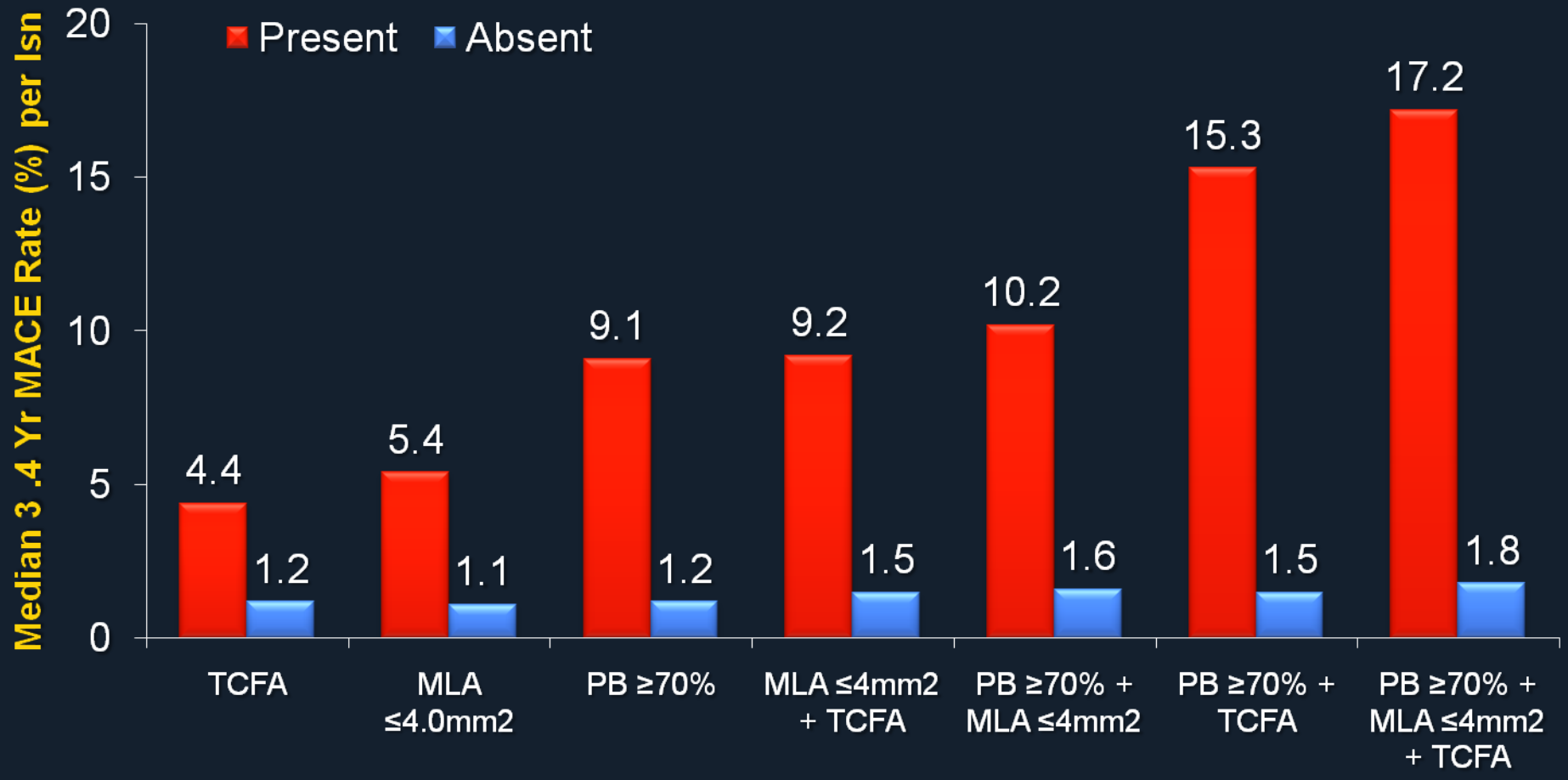
Lesions are classified into 5 main types



1. Fibrotic
2. Fibrocalcific
3. Pathological intimal thickening (PIT)
4. Thick cap fibroatheroma (ThCFA)
5. VH-thin cap fibroatheroma (VH-TCFA)
   (presumed high risk)

PROSPECT: Correlates of Non Culprit Lesion Related Events





	TCFA	MLA ≤4.0mm2	PB ≥70%	MLA ≤4mm2 + TCFA	PB ≥70% + MLA ≤4mm2	PB ≥70% + TCFA	PB ≥70% + MLA ≤4mm2 + TCFA
Lesion HR	3.8 (2.2, 6.6)	5.0 (2.9, 8.7)	7.9 (4.6, 13.8)	6.4 (3.4, 12.2)	6.7 (3.4, 13.0)	10.8 (5.5, 21.0)	10.8 (4.3, 27.2)
P value	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Prevalence*	51.2%	49.1%	30.7%	17.4%	15.4%	11.0%	4.6%

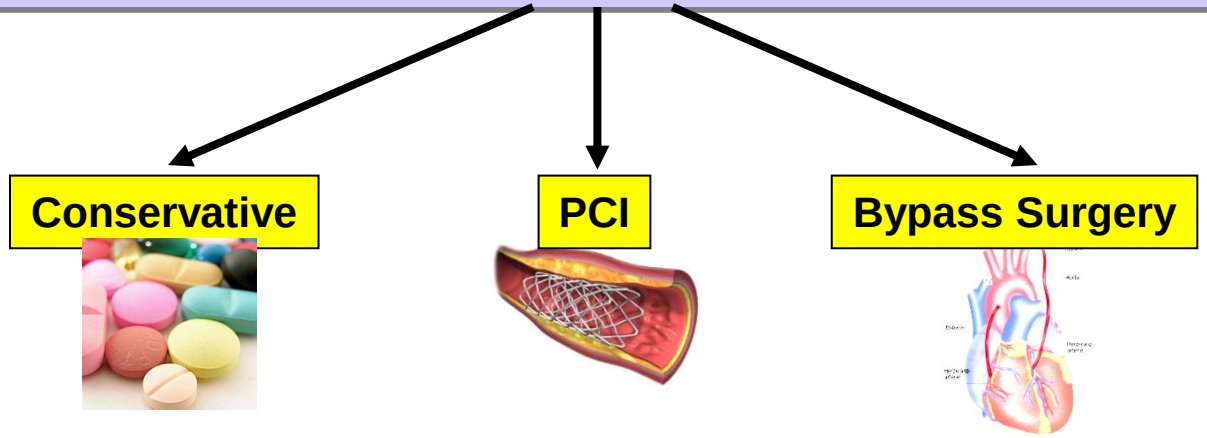
*Likelihood of one or more such lesions being present per patient. PB = plaque burden at the MLA

Take Home Messages from PROSPECT:

- **The combination of IVUS and Virtual Histology is a useful diagnostic tool to assess the non-culprit lesions after having stented the culprit lesion in patients with ACS.**
- **PROSPECT may possibly change future ESC guidelines.**

Has the Approach to Coronary Revascularization Changed after Recent Clinical Trials ?

Summary:



- ✓ **Most of the recent randomized trials have further underlined the existing concepts of coronary revascularization and confirmed the ESC guidelines.**
- ✓ **SYNTAX has probably the greatest impact on changing the approaches to coronary revascularization:**
  - ➢ **identifying patients predominantly benefiting from bypass surgery**
  - ➢ **stenting of unprotected left main as an option**
- ✓ **Based on DEFER, FAME and PROSPECT, the combination of FFR (fractional flow reserve), IVUS and VH (virtual histology) may better identify „insignificant“ lesions to be stented or to be treated conservatively in order to improve patients‘ prognosis.**

ESC GUIDELINES

To improve the quality of clinical practice and patient care in Europe

Guidelines for Percutaneous Coronary Interventions

The Task Force for Percutaneous Coronary Interventions of the European Society of Cardiology

Authors/Task Force Members: Sigmund Silber, Chairperson* (Germany), Per Albertsson (Sweden), Francisco F. Avilés (Spain), Paolo G. Camici (UK), Antonio Colombo (Italy), Christian Hamm (Germany), Erik Jørg
(Denmark), Jean Marco (France), Jan-Erik Nord
Witold Ruzyllo (Poland), Phili
William Wijns (Bel

When will they be updated ?

European Heart Journal (2005) 26, 804–847

ESC GUIDELINES

To improve the quality of clinical practice and patient care in Europe

EUROPEAN SOCIETY OF CARDIOLOGY

ESC Stockholm 2010