

SYNTAX Left Main Classification & Outcomes

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Conflicts of Interest

- Employee
 - Boston Scientific Corporation
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STENTING OR SURGERY?

PLUS Your views on MTAS
Tests in postmenopausal bleeding
Organophosphorus poisoning
The Change Page

March 24th, 2007

Current controversies

Surgery is the best intervention for severe coronary artery disease

David P Taggart

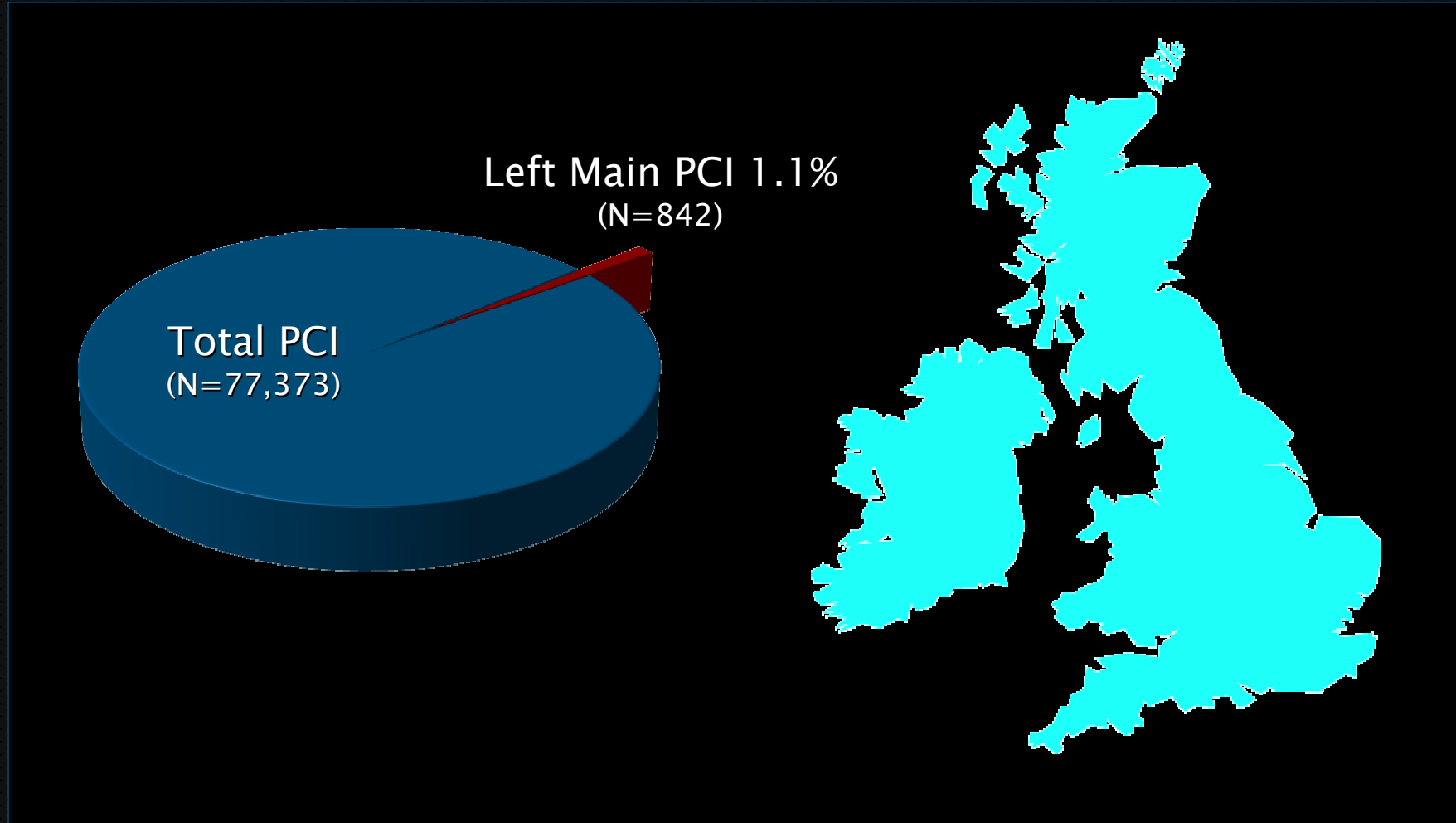
A multidisciplinary approach is essential, but best evidence favours surgery over percutaneous intervention

artery bypass grafting. The current tendency of some cardiologists to exclusively investigate and treat patients with severe multivessel disease without a surgical opinion not only belittles the traditional multidisciplinary approach but ensures that the best and most balanced advice is unlikely to be consistently offered. Most importantly, by effectively denying patients the opportunity of making a fully informed choice, it falls far short of best practice.

Why is Left Main Stem PCI Different?

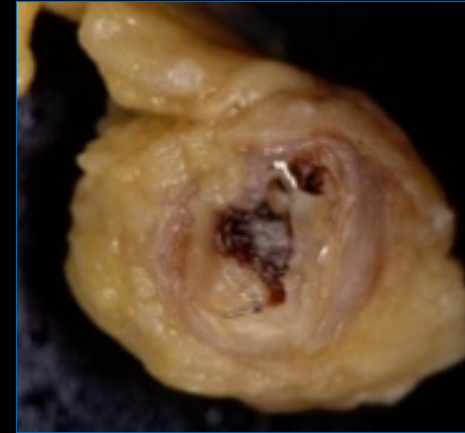
- **Anatomic Variations**
 - Short vs. Long LMS
 - Ostial, Shaft, Distal lesions
 - Protected vs. Unprotected
- **Alternative Strategies to PCI**
 - Medical Treatment
 - Surgical Revascularisation
- **Co-Morbidity**
 - LV Function
 - Emergency presentation
 - Diabetes Mellitus
- **PCI: Additional Technology**
 - Intravascular Ultrasound
 - Debulking (Directional & Rotational Atherectomy)
 - Bifurcation Techniques
- **Concern relating to late outcomes**
- **Difficulties assessing the literature**

Unprotected Left Main PCI (UK 2007)





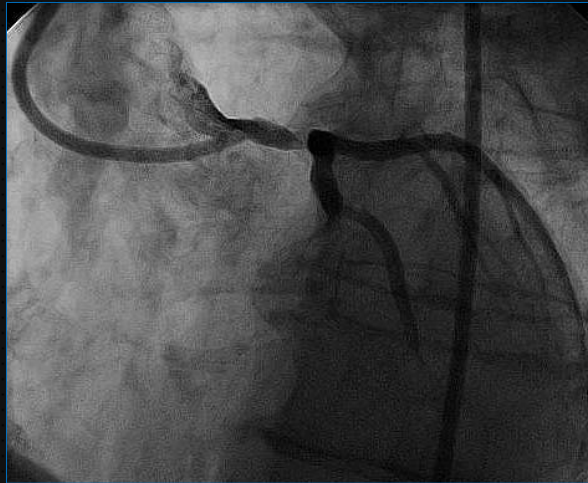
LMS PCI



Stent Thrombosis



LMS: Medical Treatment



Left Main Stem



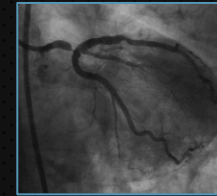
Medical Treatment

Mortality (5 years) = 36.5%
Odds Ratio (*vs.* CABG) = 0.32 [0.15–0.70], $p=0.04$

Lancet 1994;344:563–570

Contemporary Trials of LM CABG *vs.* PCI

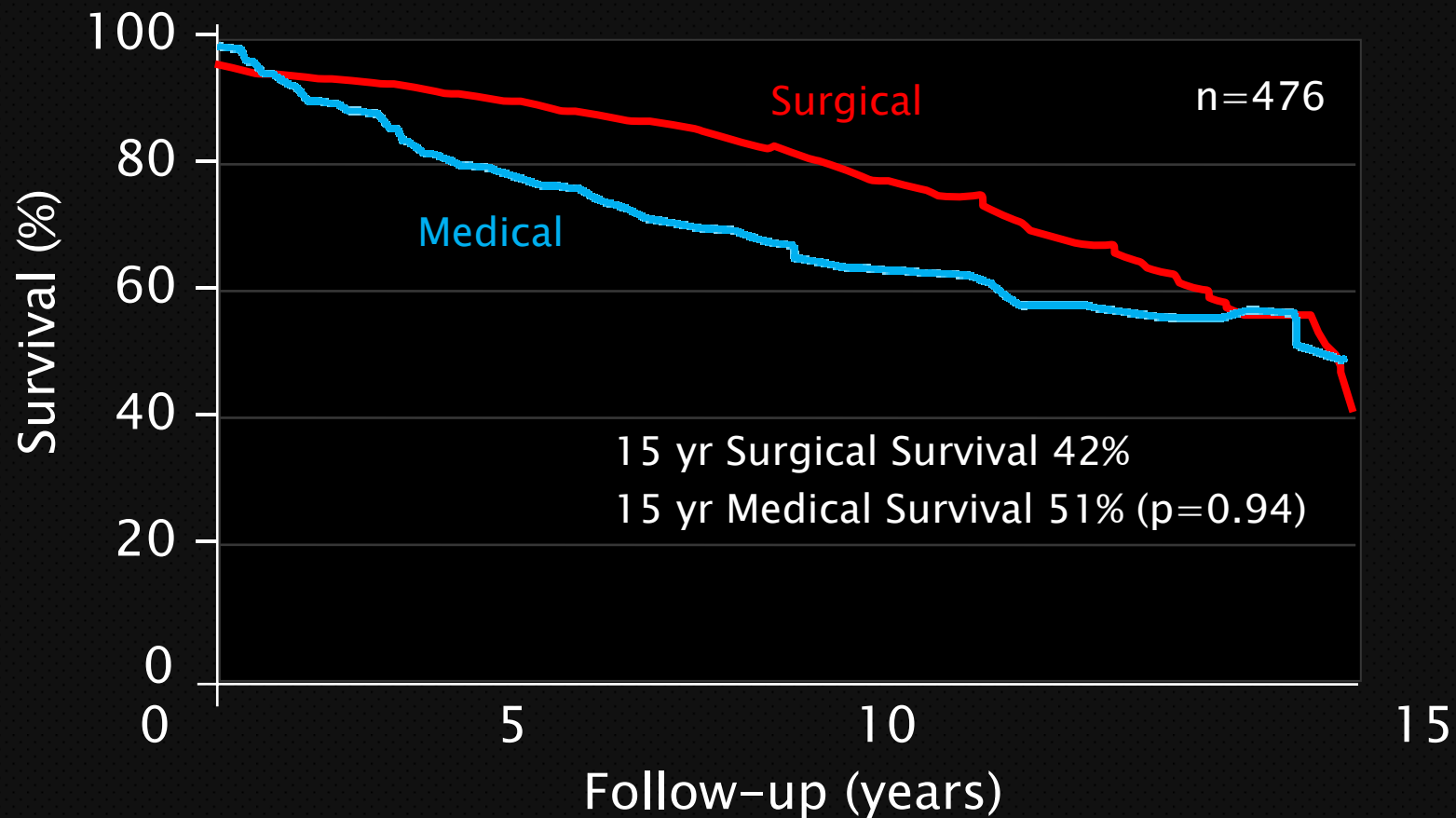
Superior Treatment Modality for Outcomes



Trial*	N	Death [†]	MI	Stroke	Revasc	
Wu 2008 (DES)	112	ND	n/a	n/a	CABG Better	
MAIN-COMPARE 2008	1102		ND			ND
LEMANS 2008	105					
Palmerini 2006	311					
Sanmartin 2007	341			ND		
Chieffo 2006	249			PCI Better		
Lee 2006	173		ND	ND	ND	
Makikallio 2008	287					
Rodés-Cabau 2008 [†]	249					
Brener 2008	287		n/a	n/a	n/a	
White 2008	343					

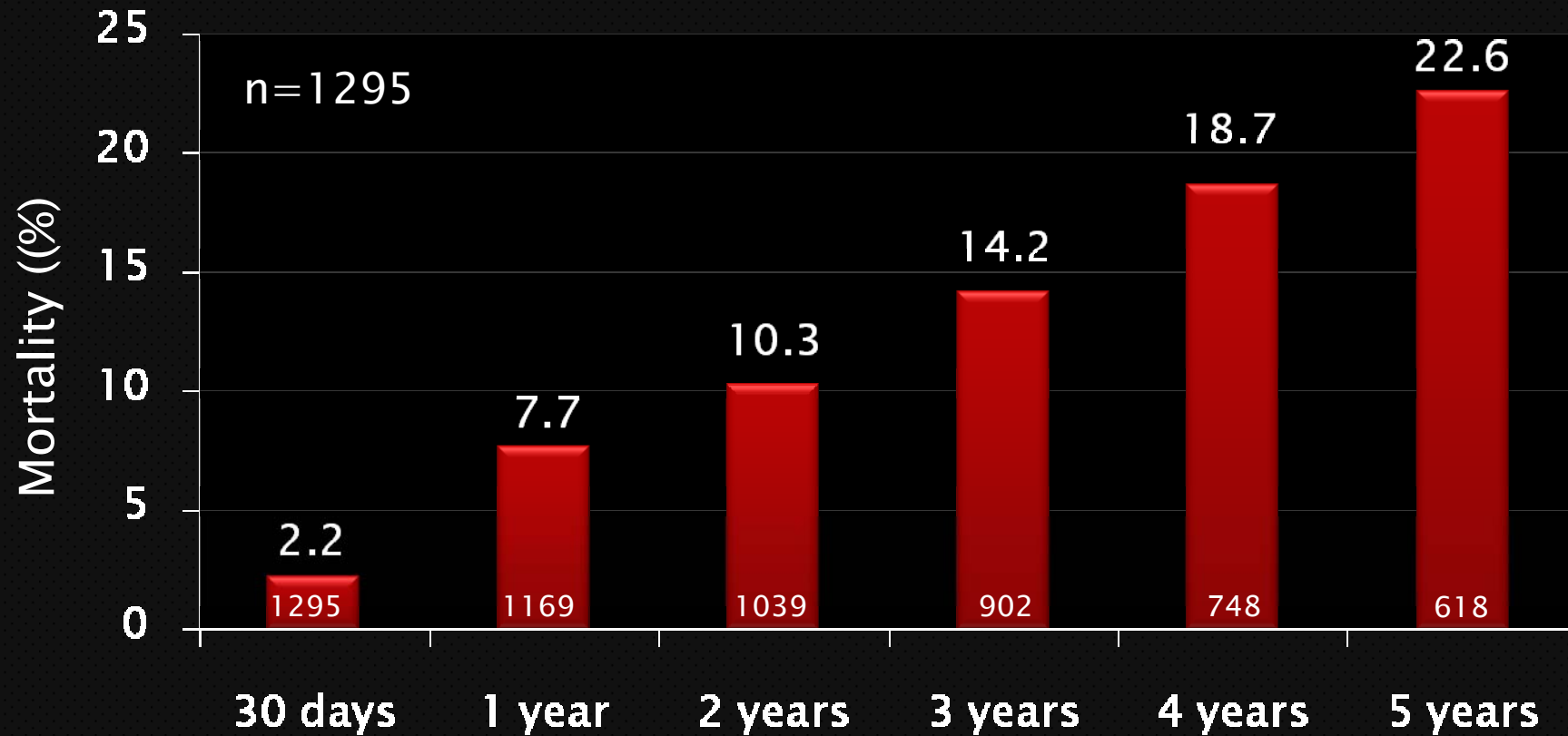
*Studies with >100 patients per arm reported; [†]Cardiac death
 ND=no difference; n/a=not available/not reported

Comparison of Surgical & Medical Survival in Patients with Left Main Disease (Normal LV)



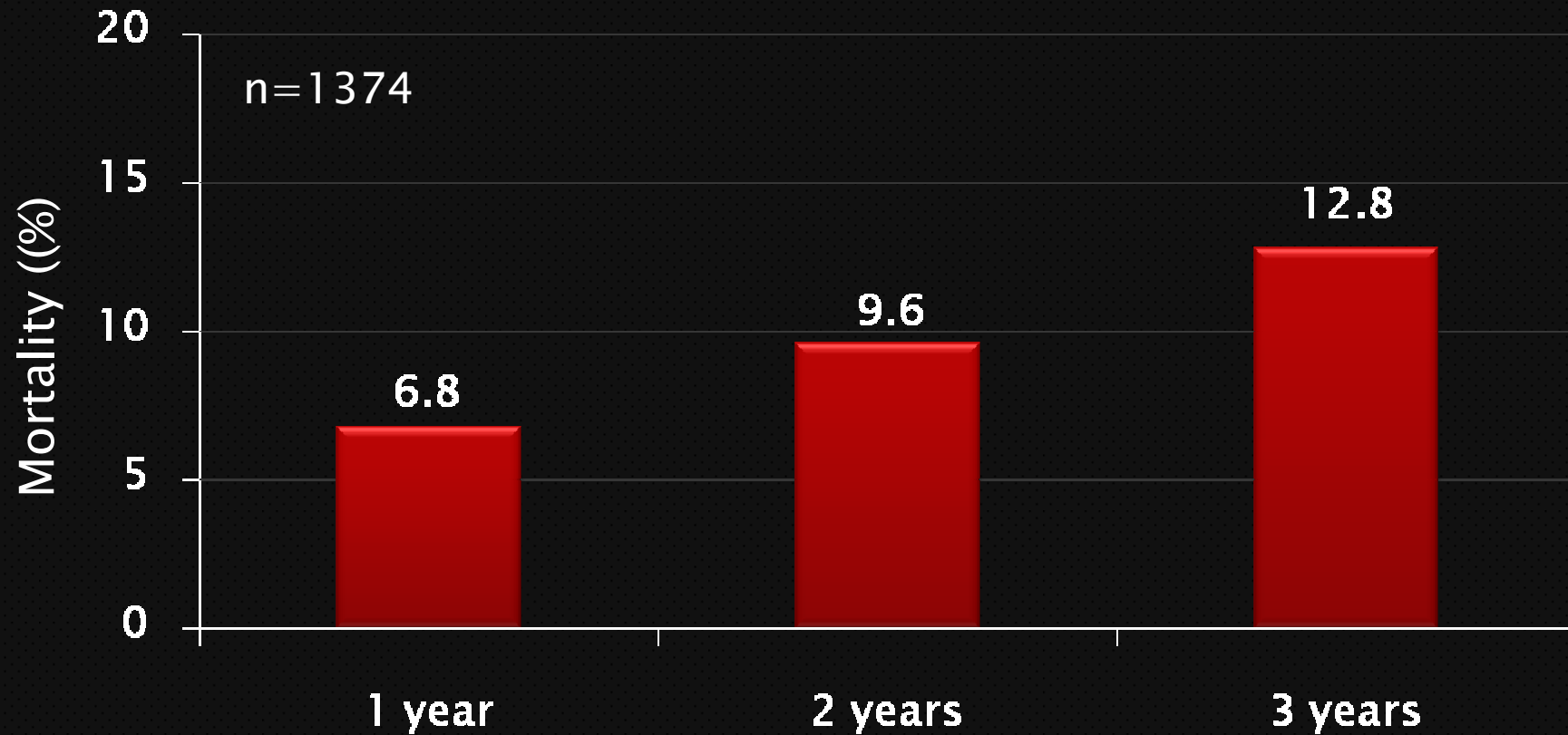
CABG for Left Main Disease

Duke Database



CABG for Left Main Disease

NYS Database



Left Main PCI?



...CABG using IMA grafting is the 'gold standard' for treatment of unprotected left main disease and has proven benefit on long-term outcomes. The use of DES has shown encouraging short-term outcomes, but long-term follow-up is needed...

It is likely that during the progress of their disease, many patients will benefit from a combined application of percutaneous and surgical techniques, taking advantage of the low morbidity of percutaneous methods and the established long-term benefit of surgical revascularization with arterial conduits.

Appropriate Revascularization?

ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization

A Report of the American College of Cardiology Foundation Appropriateness Criteria Task Force, Society for Cardiovascular Angiography and Interventions, Society of Thoracic Surgeons, American Association for Thoracic Surgery, American Heart Association, and the American Society of Nuclear Cardiology

Endorsed by the American Society of Echocardiography, the Heart Failure Society of America, and the Society of Cardiovascular Computed Tomography

Coronary revascularization is appropriate when the expected benefits, in terms of survival or health outcomes (symptoms, functional status, and/or quality of life) exceed the expected negative consequences of the procedure.

Increasing Numbers of Studies Exploring PCI as a Treatment Option in LM Disease...

Longest Available Clinical Outcomes After Drug-Eluting Stent Implantation for Unprotected Left Main Coronary Artery

The DELFT (Drug Eluting stent for LeFT main) R

Emanuele Meliga MD*†, Hector Manuel Garcia-Garcia MD, MS
Alaide Chieffo, M
Stephen Cook, M
Igor F. Palacios,
Ron van Dombu

One-year clinical outcomes of protected and unprotected left main coronary artery stenting

Michael P. Kelley^a, Bruce D. Klugherz^a, Seyed M. Hashemi^a,
Nicolas F. Meneveau^b, Janet M. Johnston^c, William H. Matthai Jr^a,
Vidya S. Banka^a, Howard C. Herrmann^a, John W. Hirshfeld Jr^a,
Stephen E. Kimmel^a, Daniel M. Kolansky^a, Phillip A. Horwitz^a,
Francois Schiele^b, Jean-Pierre I. Bassand^b, Robert L. Wilensky^{a*}

Comparison of Drug-Eluting Stents Versus Surgery for Unprotected Left Main Coronary Artery Disease

Marcelo Sanmartín, PhD^{a,*}, José Antonio Baz, MD^a, Ramon Claro, MD^a, Vanesa Asorey, MD^b,
Darío Durán, PhD^b, Gonzalo Pradas, MD^b, and Andrés Iñiguez, PhD^a

Orig

Long-term outcomes following drug-eluting stent implantation in unprotected left main bifurcation lesions

Comparison of Coronary Percutaneous Coronary Intervention Stents for Unprotected Le

Michael S. Lee, MD, Nikhil Kapoor, MI
James Forrester, MD, Saibal Kar, MD, S
Alfredo Trento, MD, Prediman K. Shah,

Stents versus Coronary-Artery Bypass Grafting for Left Main Coronary Artery Disease

Ki Bae Seung, M.D., Duk-Woo Park, M.D., Young-Hak Kim, M.D., Seung-Whan Lee, M.D., Cheol Whan Lee, M.D.,
Myeong-Ki Hong, M.D., Seong-Wook Park, M.D., Sung-Cheol Yun, Ph.D., Hyeon-Cheol Gwon, M.D.,
Myung-Ho Jeong, M.D., Yangsoo Jang, M.D., Hyo-Soo Kim, M.D., Pum Joon Kim, M.D., In-Whan Seong, M.D.,
Hun Sik Park, M.D., Taehoon Ahn, M.D., In-Ho Chae, M.D., Seung-Jea Tahk, M.D., Wook-Sung Chung, M.D.,
and Seung-Jung Park, M.D.

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Percutaneous Coronary Intervention versus Coronary-Artery
Bypass Grafting for Severe Coronary Artery Disease

Patrick W. Serruys, M.D., Ph.D., Marie-Claude Morice, M.D., A. Pieter Kappetein, M.D., Ph.D.,
Antonio Colombo, M.D., David R. Holmes, M.D., Michael J. Mack, M.D., Elisabeth Stähle, M.D.,
Ted E. Feldman, M.D., Marcel van den Brand, M.D., Eric J. Bass, B.A., Nic Van Dyck, R.N., Katrin Leadley, M.D.,
Keith D. Dawkins, M.D., and Friedrich W. Mohr, M.D., Ph.D., for the SYNTAX Investigators*

SYNTAX Background



SYNTAX was designed to answer the following three questions in patients with left main and/or 3VD:

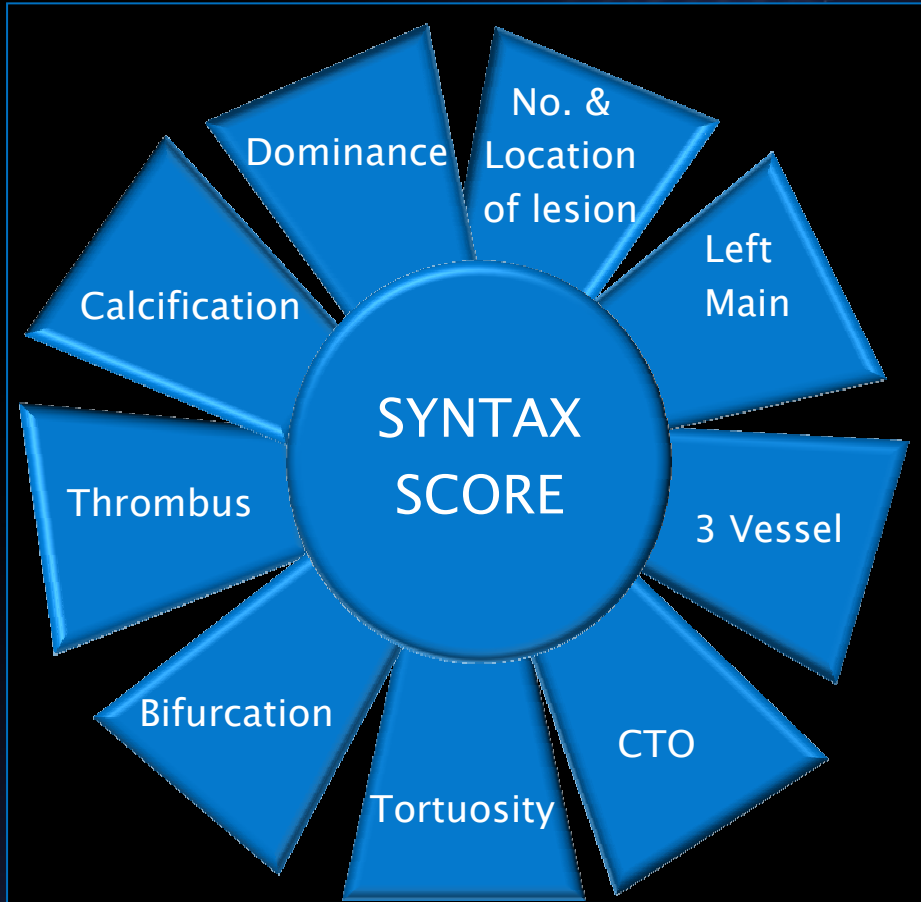
- How does modern CABG compare to PCI in high-risk patients eligible for both techniques?
- Which patient group continues to be solely eligible for CABG?
- What characterizes complex patients not eligible for CABG?

Patient Profiling



Local Heart team (surgeon & interventional cardiologist) assessed each patient in regards to :

- Patient's operative risk (EuroSCORE & Parsonnet score)
- Coronary lesion complexity (Newly developed SYNTAX score)
- Goal: SYNTAX score to provide guidance on optimal revascularization strategies for patients with high risk lesions



Sianos et al, EuroIntervention 2005;1:219-227
Valgimigli et al, Am J Cardiol 2007;99:1072-1081
Serruys et al, EuroIntervention 2007;3:450-459

BARI classification of coronary segments
Leaman score, Circ 1981;63:285-299
Lesions classification ACC/AHA, Circ 2001;103:3019-3041
Bifurcation classification, CCI 2000;49:274-283
CTO classification, J Am Coll Cardiol 1997;30:649-656

SYNTAX Statistical Analysis



Non-inferiority was not met for the primary endpoint (MACCE at 12 months), further comparisons for the LM and 3VD subgroups are observational only and hypothesis generating

SYNTAX Eligible Patients



De novo disease

Limited Exclusion Criteria



- Previous interventions
- Acute MI with CPK > 2x
- Concomitant cardiac surgery

Left Main Disease
(isolated, +1, +2 or +3 vessels)

3 Vessel Disease
(revasc all 3 vascular territories)

SYNTAX Trial Design



 62 EU Sites +  23 US Sites

Heart Team (surgeon & interventionalist)

Amenable for both treatment options

Amenable for only one treatment approach

Stratification:
LM and Diabetes

Randomized Arms
N=1800

Two Registry Arms
N=1275

CABG
n=897

vs

TAXUS*
n=903

CABG
n=1077

PCI
n=198

3VD
66.3%

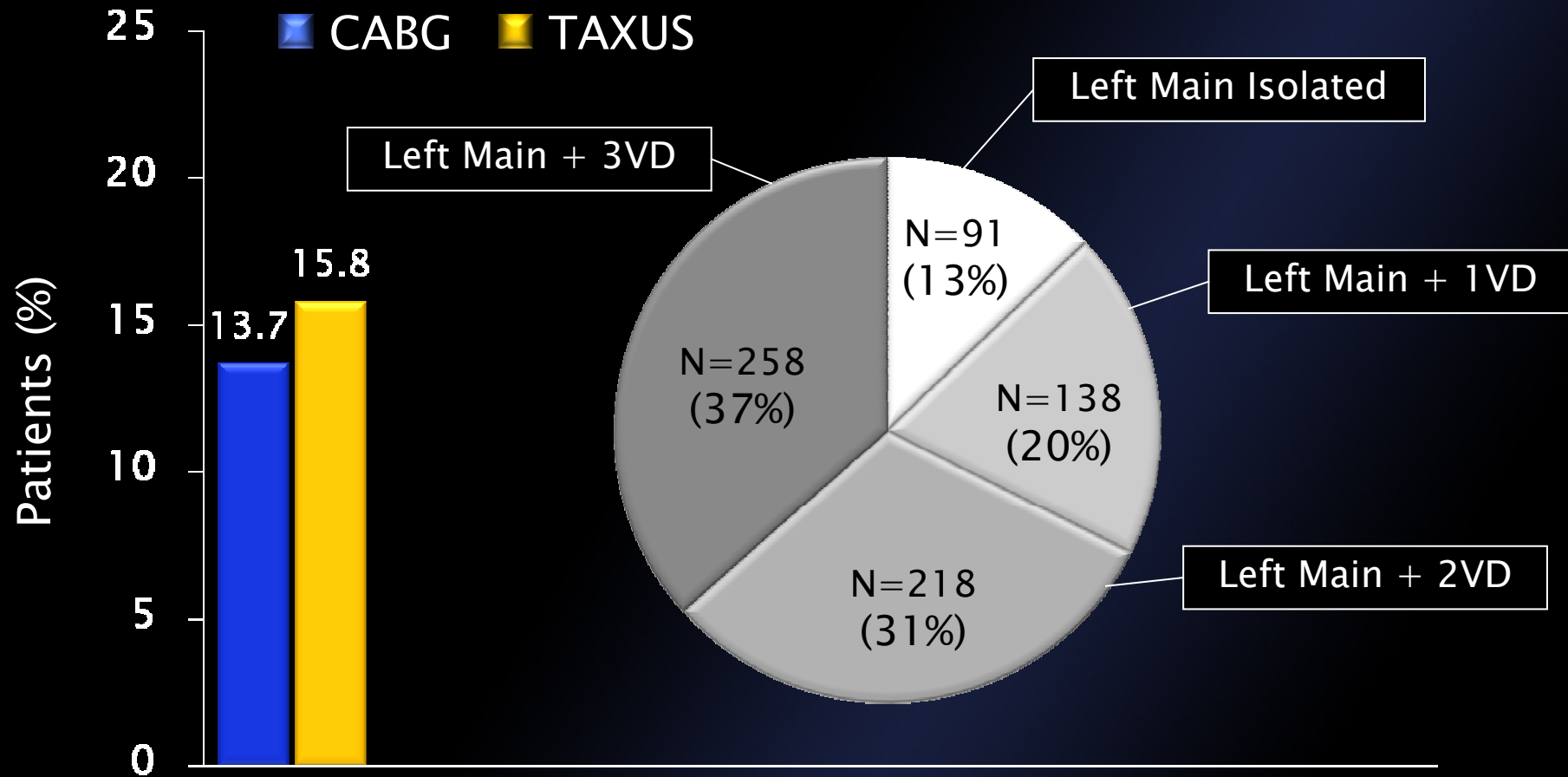
LM
33.7%

3VD
65.4%

LM
34.6%

*TAXUS Express

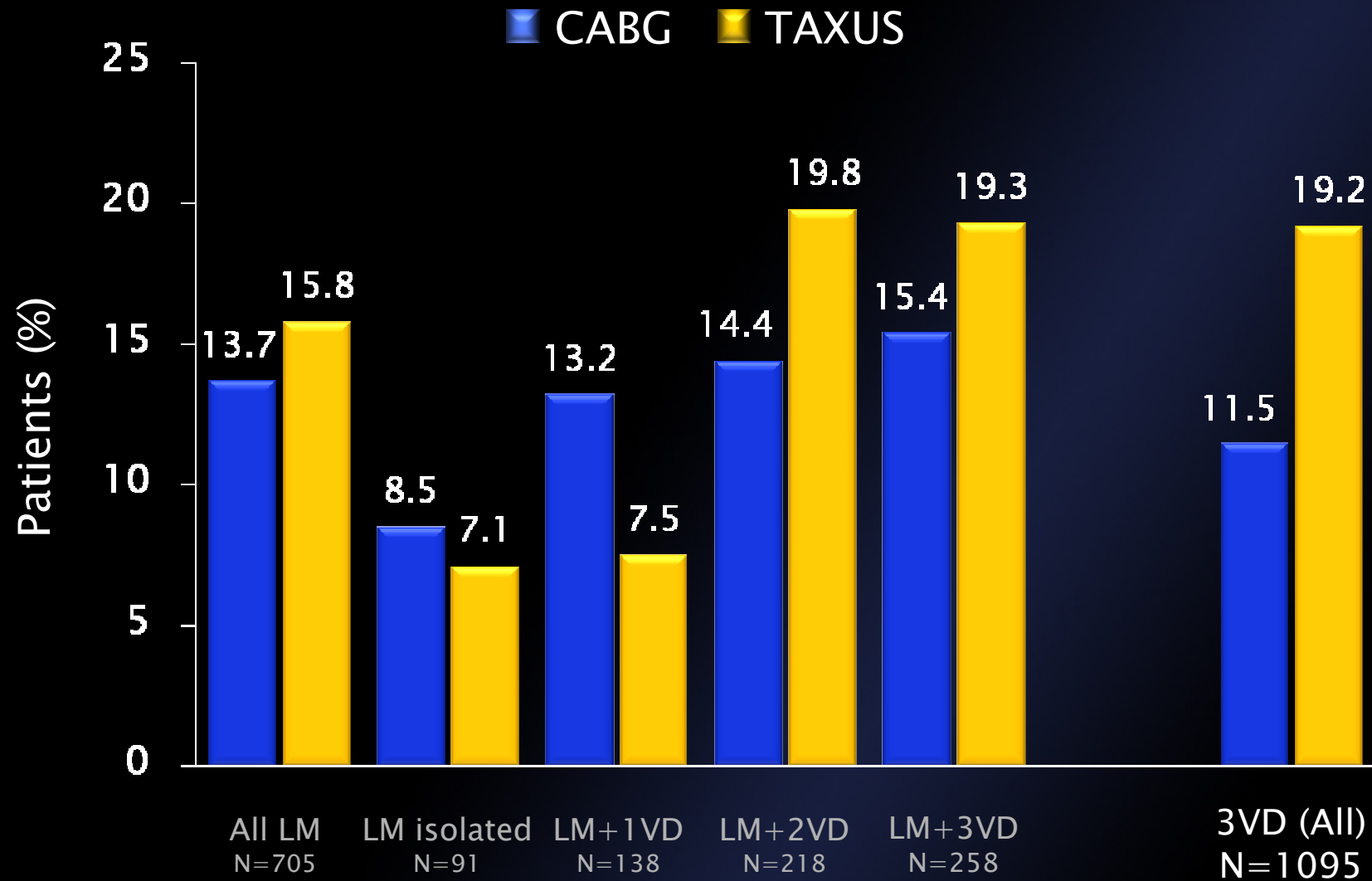
Left Main Subgroup MACCE Rates



All LM
N=705

12-months

Left Main Subgroup MACCE Rates



12-months

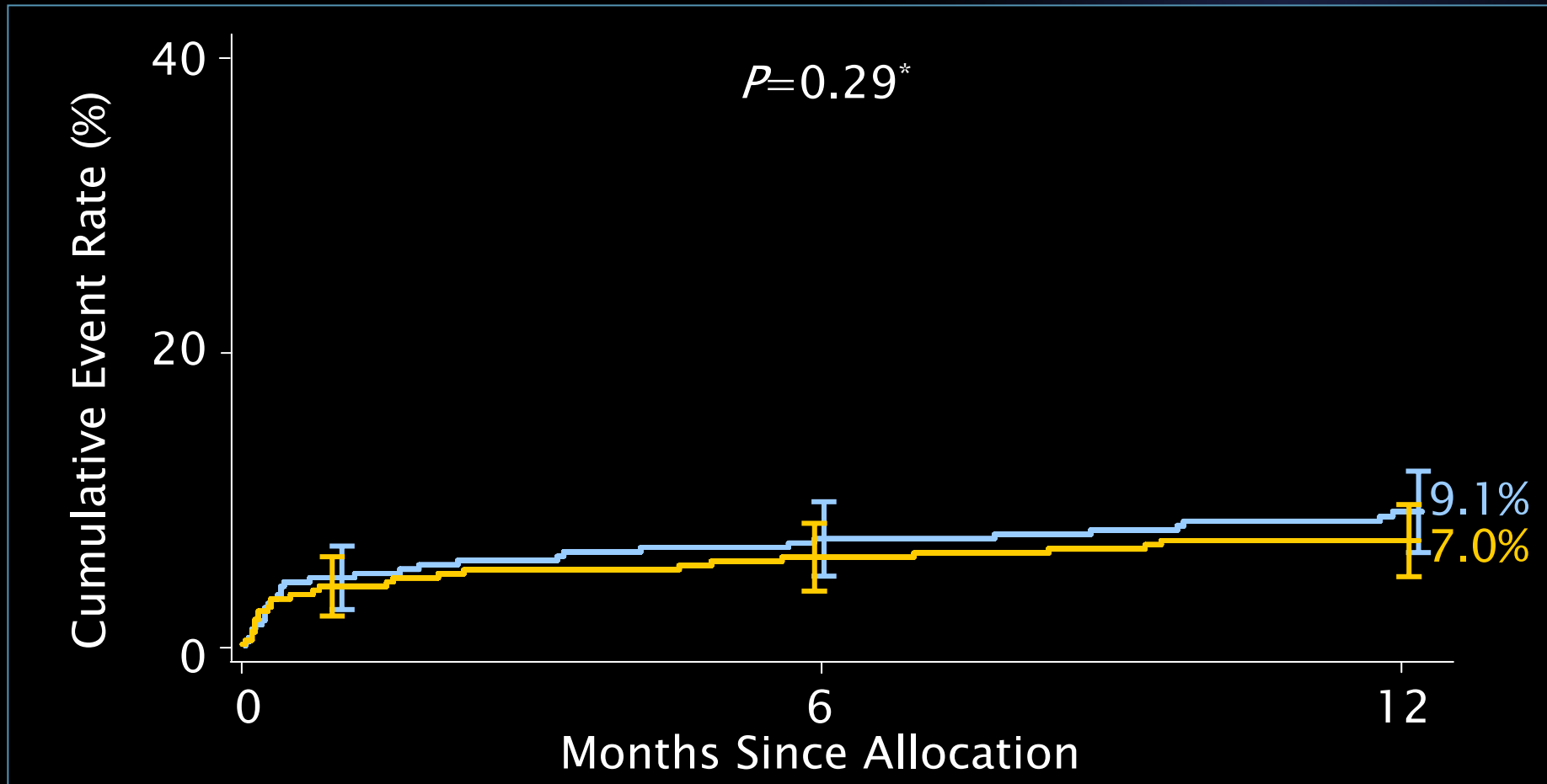
Death/CVA/MI to 12 Months

Left Main Subset



■ CABG (N=348)

■ TAXUS (N=357)



Event rate \pm 1.5 SE, *Fisher exact test

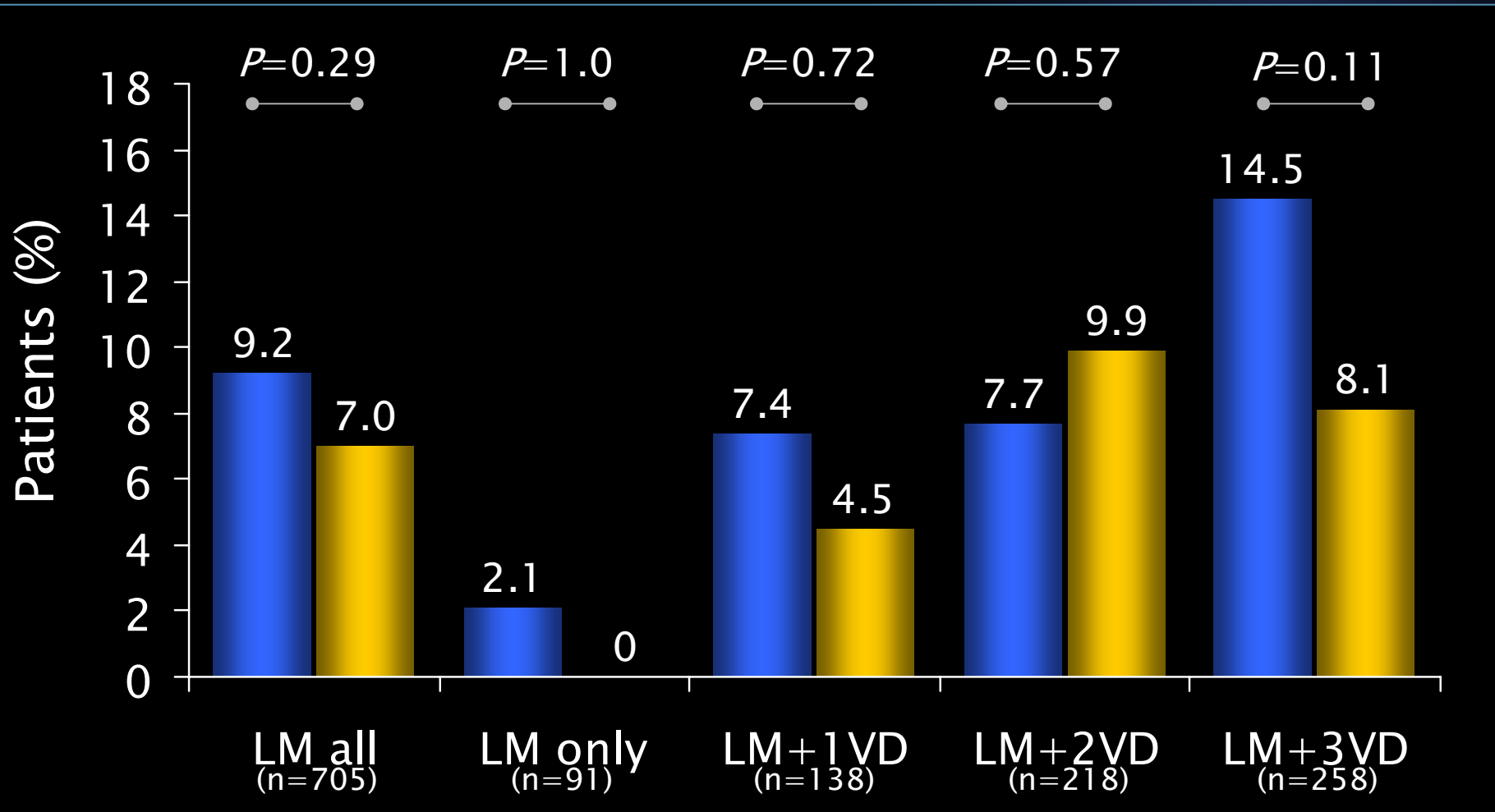
ITT population

Safety at 12 Months

Death/CVA/MI in the Left Main Subset



■ CABG ■ TAXUS



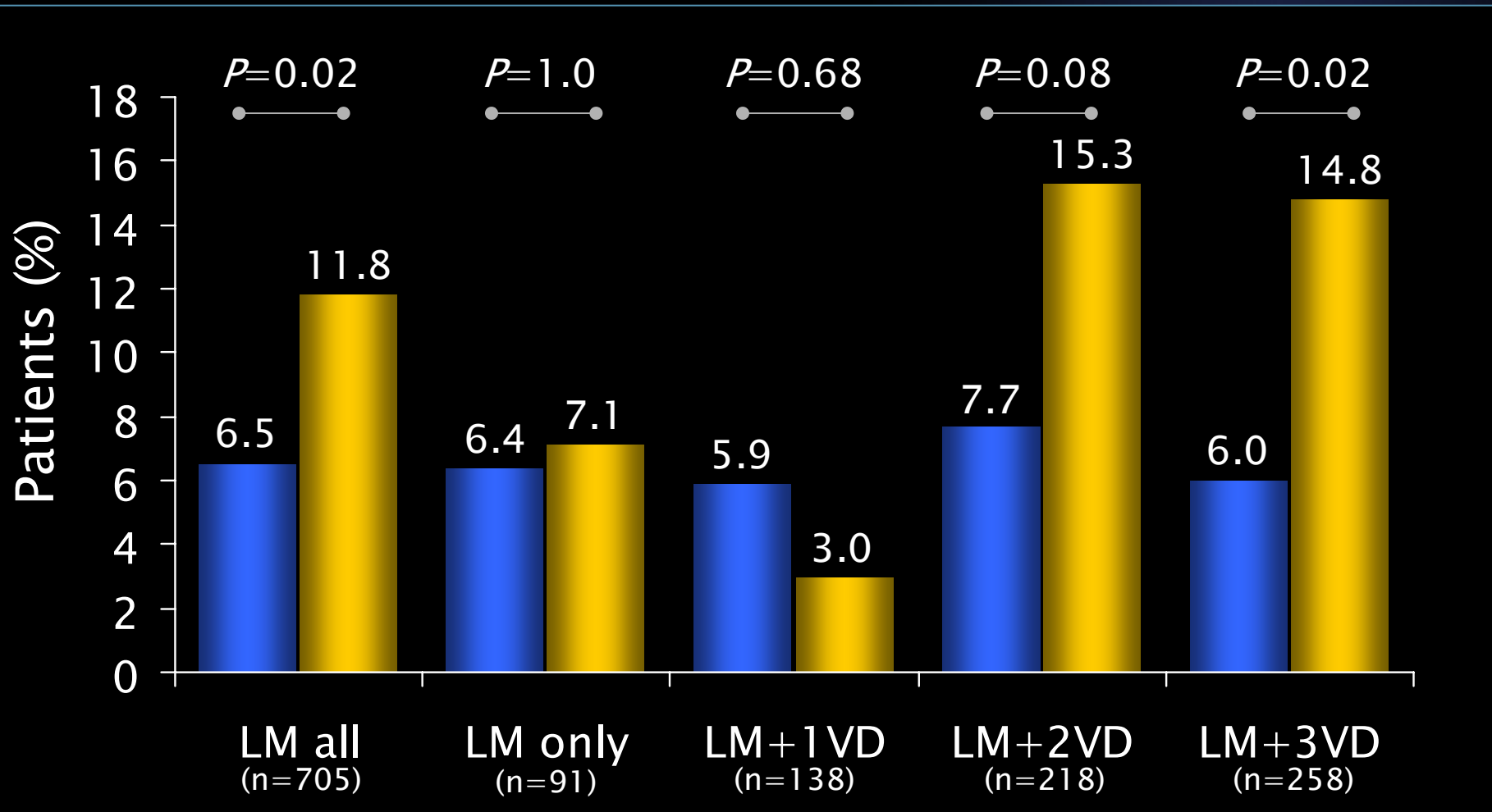
ITT population

Revascularization* at 12 Months

Left Main Subset



CABG TAXUS



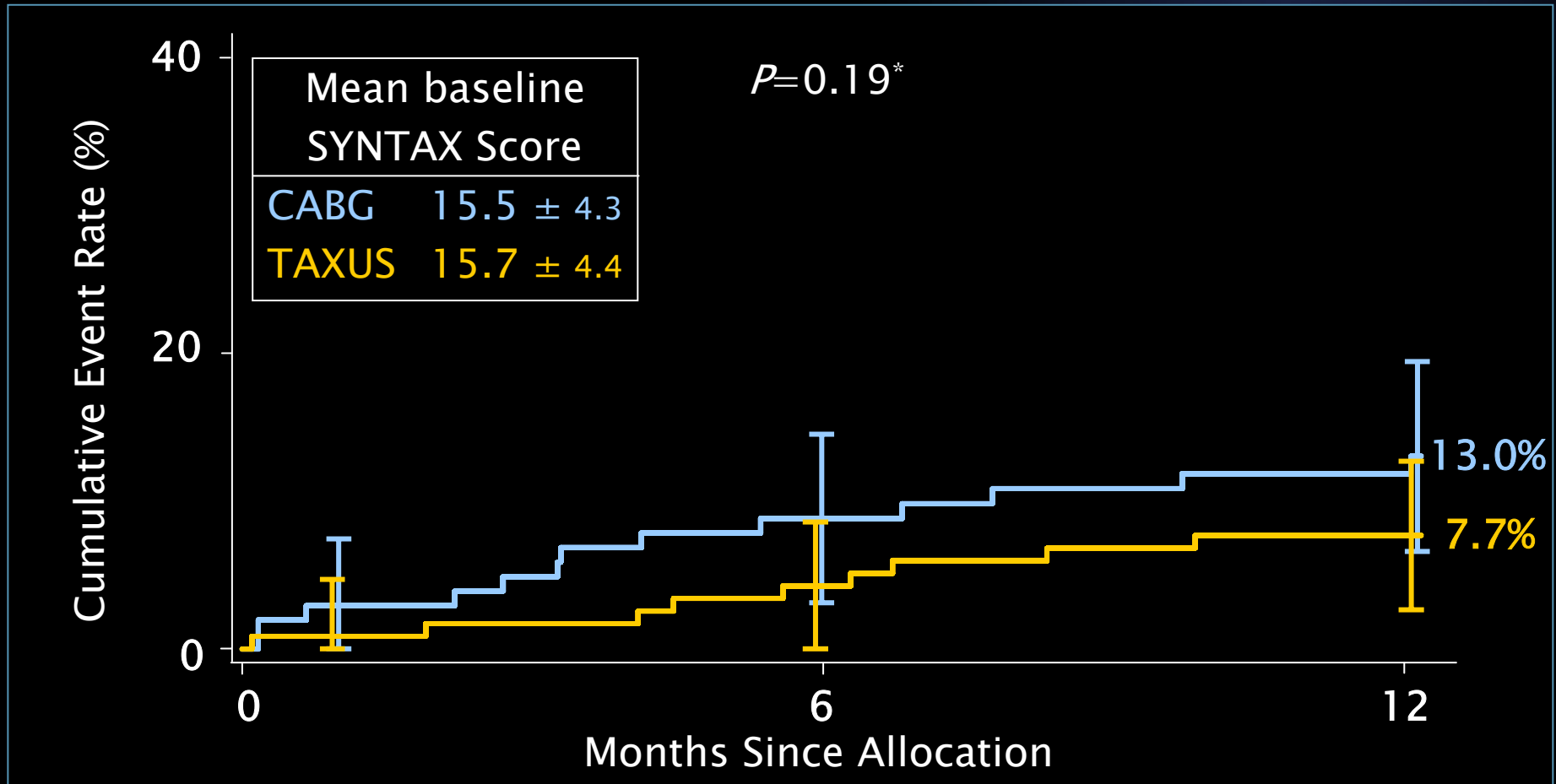
*Any revascularization (PCI or CABG)
ITT population

MACCE to 12 Months by SYNTAX Score Tertile: *Low Scores (0-22) LM Subset*



■ CABG (N=103)

■ TAXUS (N=118)



Event rate ± 1.5 SE, *Fisher exact test

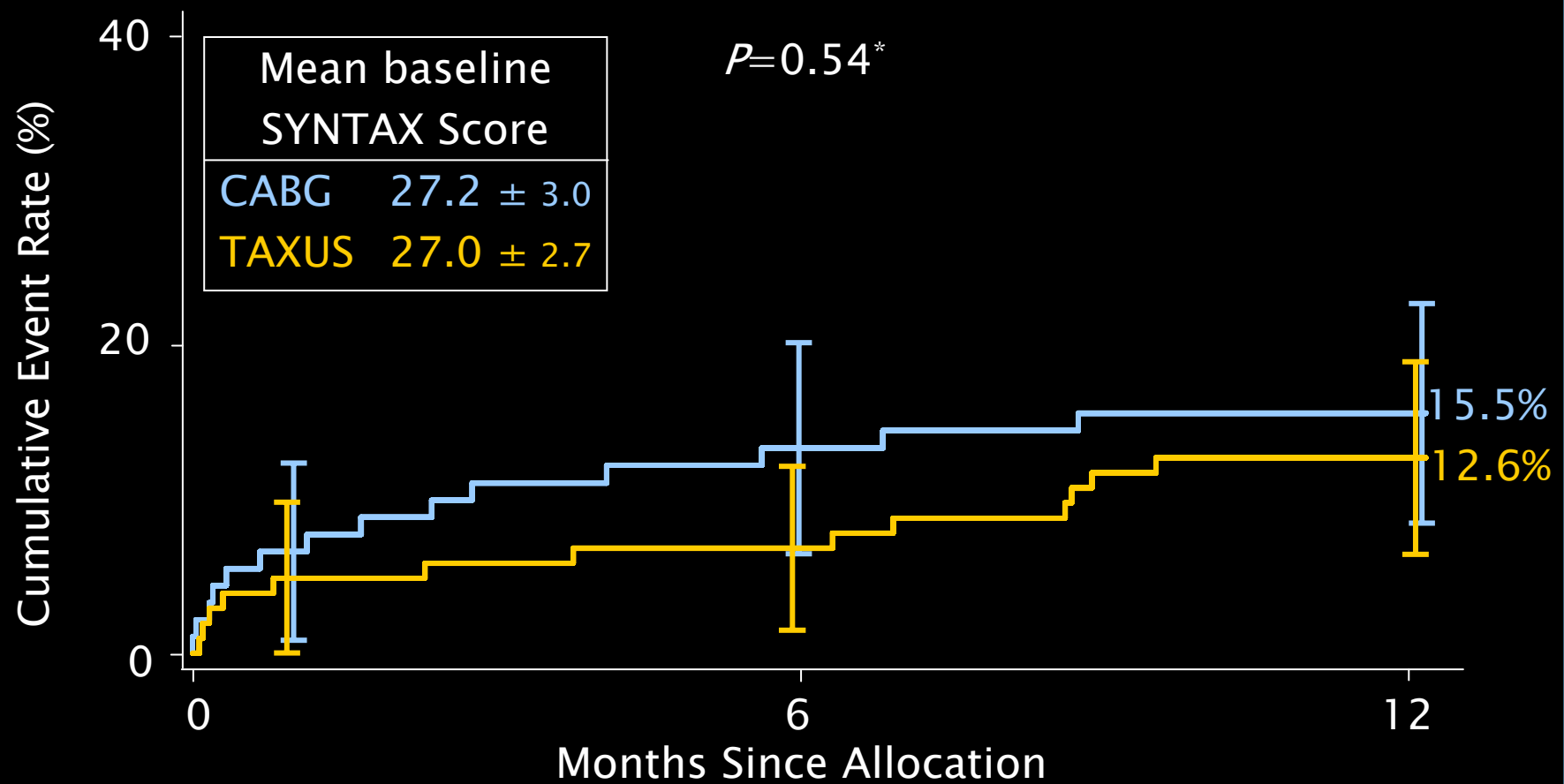
Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile: Intermediate Scores (23-32) LM Subset



■ CABG (N=92)

■ TAXUS (N=195)



Event rate ± 1.5 SE, *Fisher exact test

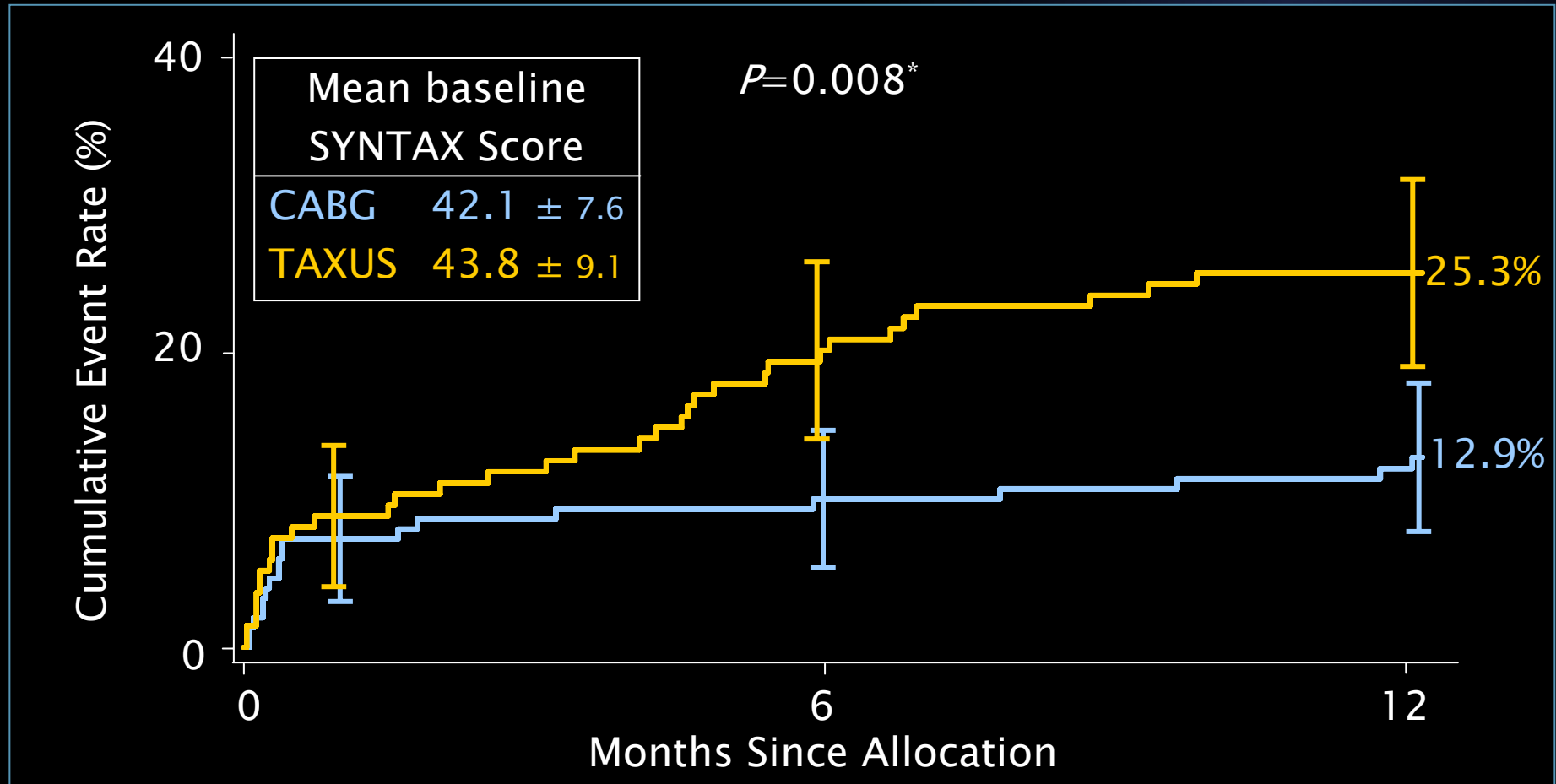
Calculated by core laboratory; ITT population

MACCE to 12 Months by SYNTAX Score Tertile: High Scores (≥ 33) Left Main Subset



■ CABG (N=150)

■ TAXUS (N=135)

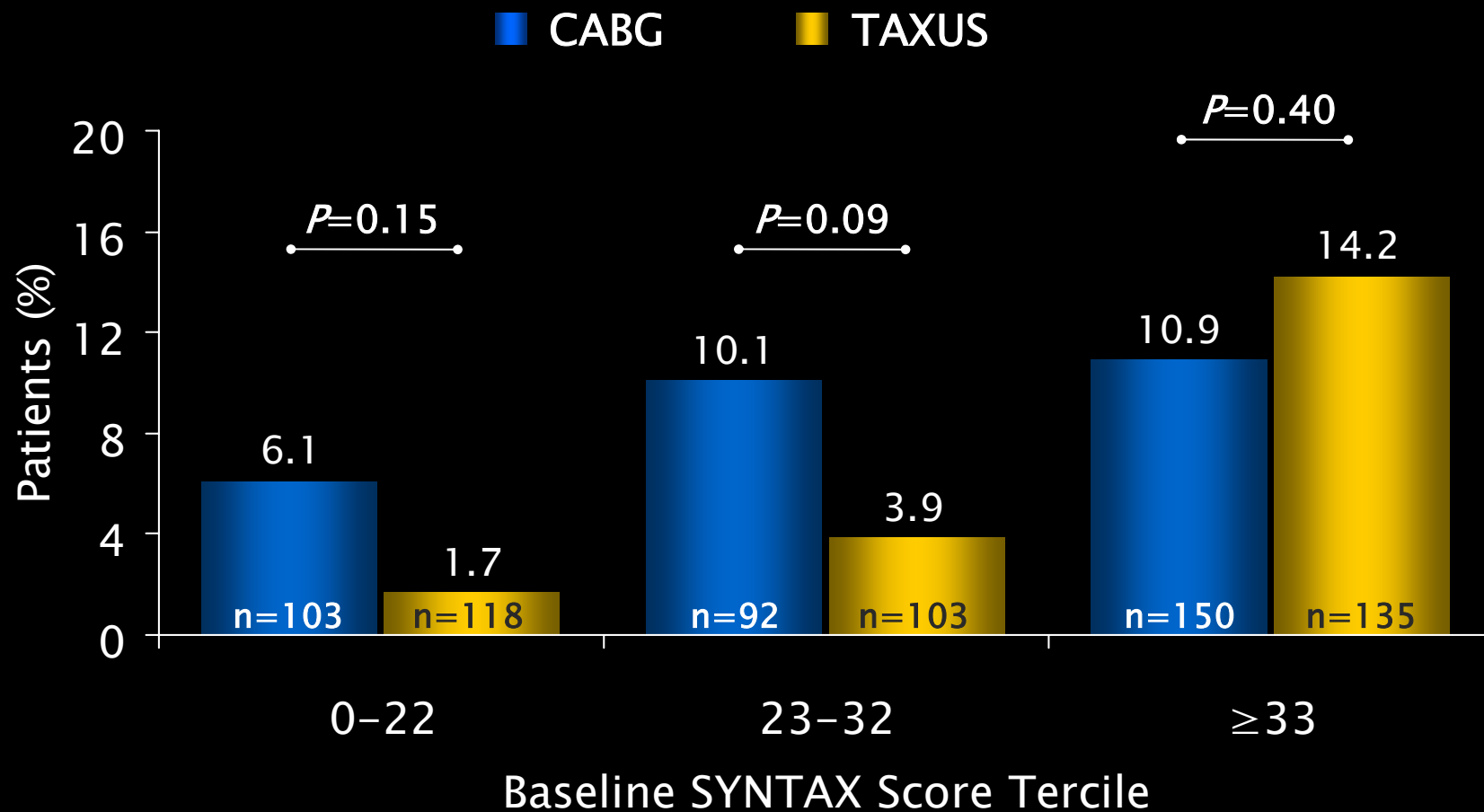


Event rate \pm 1.5 SE, *Fisher exact test

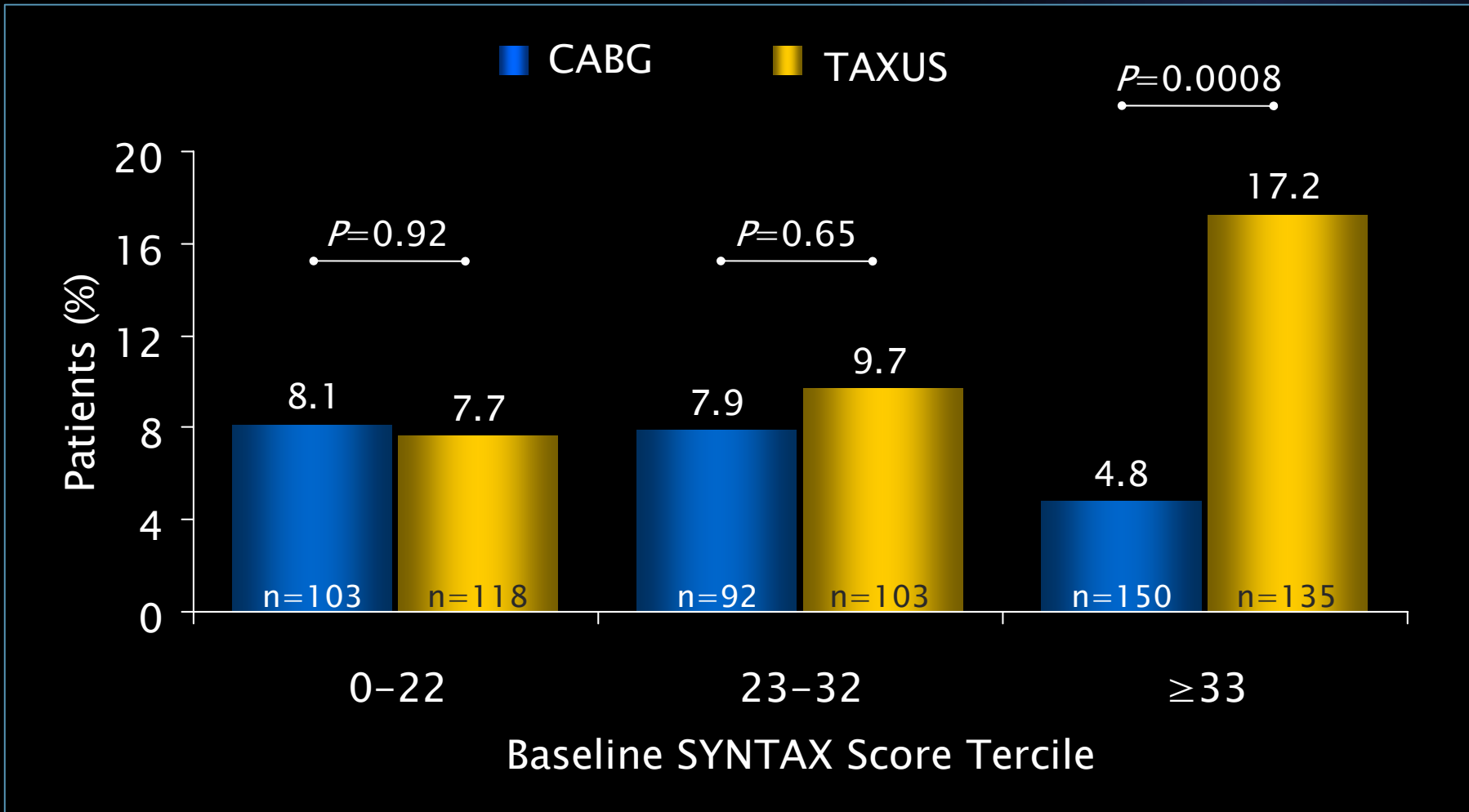
Calculated by core laboratory; ITT population

Safety (Death/CVA/MI) at 12 Months

Stratified by Baseline SYNTAX Score *LM Subset*



Revascularization at 12 Months Stratified by Baseline SYNTAX Score *LM Subset*



SYNTAX Facts (One Year)



- Overall, number of CABG needed to avoid one re-PCI = 13, at the cost of almost 4x as many strokes
- In the Left Main subset, number of CABG needed to avoid one re-PCI = 19, at the cost of 9x as many strokes
- In the Left Main + 3VD subset, number of CABG needed to avoid one re-PCI = 11

You Decide!

Percutaneous Coronary Intervention With Stent Implantation Versus Coronary Artery Bypass Surgery for Treatment of Left Main Coronary Artery Disease Is It Time to Change Guidelines?

Seung-Jung Park, MD, PhD; Duk-Woo Park, MD, PhD

Abstract—On the basis of clinical trials comparing coronary-artery bypass grafting (CABG) with medical therapy, current guideline recommend CABG as the treatment of choice for patients with asymptomatic ischemia, stable angina, or unstable angina/non-ST elevation myocardial infarction who have left main coronary artery disease. Percutaneous coronary intervention can be selectively performed in patients who are candidates for revascularization but who are ineligible for CABG. However, because of advances in periprocedural and postprocedural medical care in patients undergoing either CABG or percutaneous coronary intervention with stenting, new evaluation, and a review of current indications, may be required to determine the standard of care for patients with left main coronary artery disease. Current evidences indicate that stenting results in mortality and morbidity rates that compared favorably with those seen after CABG, suggesting that a current guideline (the Class III recommendation of percutaneous coronary intervention for unprotected left main coronary artery disease) may no longer be justified. Data from several extensive registries and a large clinical trial may have prompted many interventional cardiologists to select percutaneous coronary intervention with stenting as an alternative revascularization strategy for such patients. In addition, these data may inform future guidelines and support the need for well-designed, adequately powered, prospective, randomized trials comparing the 2 revascularization strategies. The cumulative evidence from ongoing and future clinical trials will change the current clinical practice of revascularization for unprotected left main coronary artery disease, which was introduced several decades ago and which has continued to date without major revision. (*Circ Cardiovasc Intervent.* 2009;2:59-68.)

Conclusions:

- The SYNTAX trial provides a unique pre-specified Left Main dataset (n=705)
- There are no significant safety differences (Death, CVA, AMI) between PCI (TAXUS Express) and CABG at one year
- In lower complexity Left Main disease, PCI treatment is favorable
- The positive Left Main PCI results are both hypothesis generating and thought provoking, but fit with the available literature and clinical experience