Revascularization Strategies (SYNTAX, BARI 2D, and STICH)

Angioplasty Summit 2010
Seoul, Korea

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Presenter Disclosure Information

David R. Holmes, Jr., M.D.

"Revascularization Strategies (SYNTAX, BARI 2D, and STICH) "

The following relationships exist related to this presentation:

No relationships to disclose

Korean Alphabet

Consonants

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Vowels

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Pronunciations shown here are only rough approximations.

STICH Trial
Background

Surgical ventricular reconstruction has been developed for management of heart failure related to ventricular remodeling caused by coronary artery disease.

It has been suggested that surgical ventricular reconstruction may reduce rate of hospitalization and improve ventricular function better than CABG alone.

Jones RH et al: N Engl J Med 360:1705, 2009

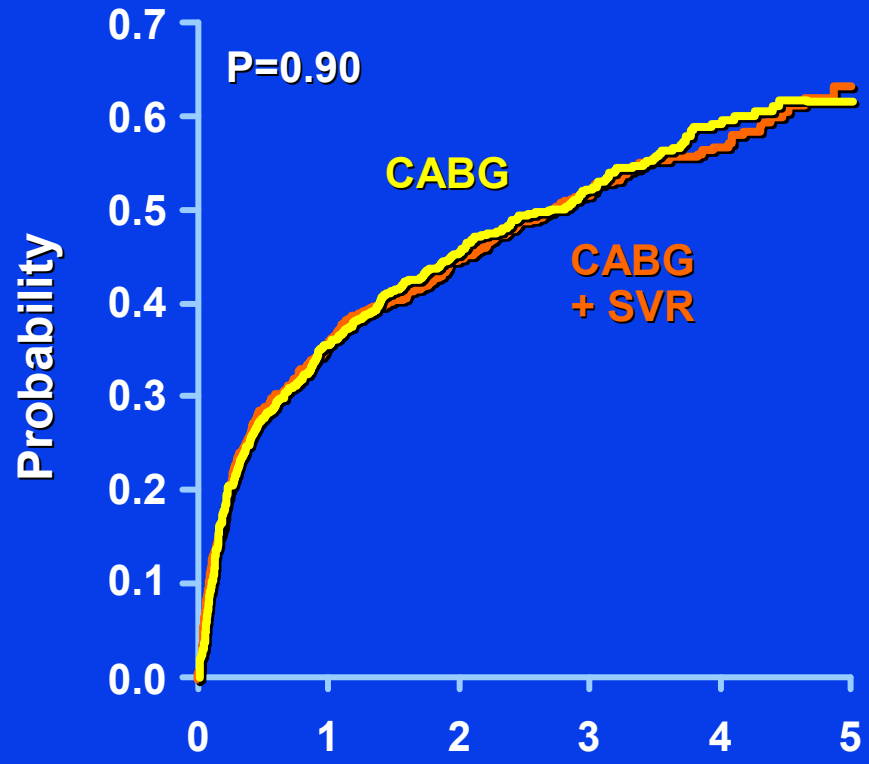
STICH Trial

- 1000 patients with EF ≤ 35%, amenable to CABG randomly assigned to either CABG plus surgical ventricular reconstruction vs CABG alone
- Primary end point:
  - Composite of death from any cause and hospitalization for cardiac causes

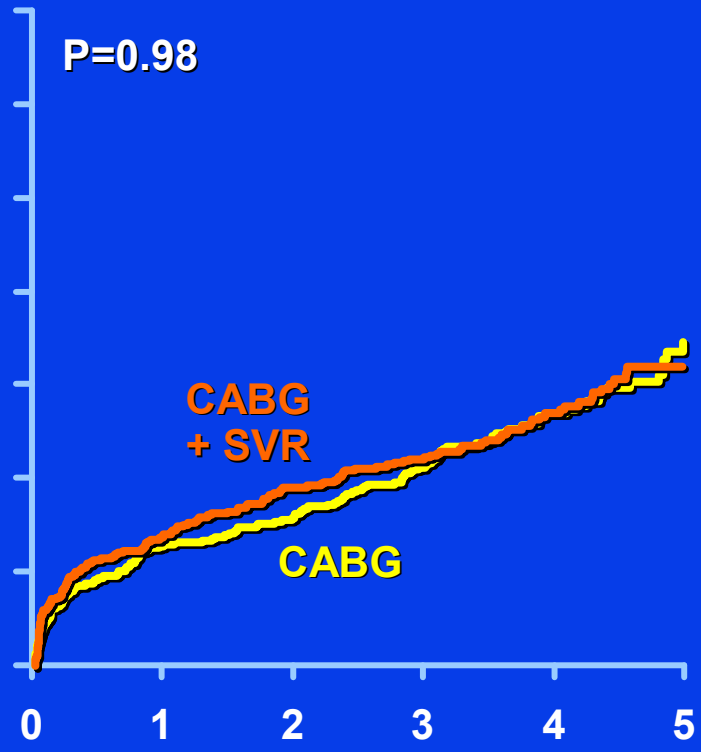
Jones RH et al: N Engl J Med 360:1705, 2009

STICH Trial

Death from Any Cause or Hospitalization for Cardiac Causes



Death from Any Cause



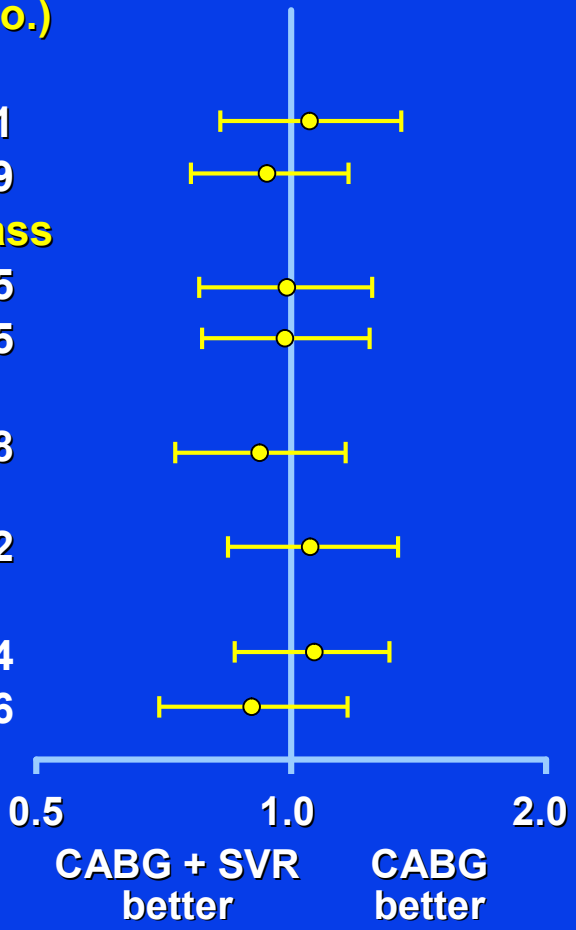
No. at risk						
CABG	499	319	270	220	99	23
CABG + SVR	501	319	275	216	111	23

499	434	417	363	201	59
501	429	404	352	193	53

Jones RH et al: N Engl J Med 360:1705, 2009

STICH Trial
Primary Outcome

Subgroup	Pt (no.)	HR for event (95% CI)	P for interaction
Age			0.48
≥65 yr	391	1.06 (0.83-1.35)	
<65 yr	609	0.94 (0.76-1.17)	
NYHA heart failure class			0.97
I or II	515	0.99 (0.78-1.25)	
III or IV	485	0.99 (0.79-1.24)	
CCS angina class			0.39
No angina or or ≤ class II	508	0.92 (0.73-1.16)	
Class III or IV	492	1.06 (0.85-1.34)	
LVEF			0.33
≤28%	534	1.07 (0.86-1.31)	
>28%	466	0.90 (0.70-1.17)	



Jones RH et al:
N Engl J Med 360:1705, 2009

Conclusions: Adding surgical ventricular reconstruction to CABG reduced the left ventricular volume, as compared with CABG alone. However, this anatomical change was not associated with a greater improvement in symptoms or exercise tolerance or with a reduction in the rate of death or hospitalization for cardiac causes. (ClinicalTrials.gov number, NCT00023595.)

Surgical ventricular reconstruction is a specific procedure designed to reduce left ventricular volume in patients with heart failure caused by coronary artery disease. We conducted a trial to address the question of whether surgical ventricular reconstruction added to coronary-artery bypass grafting (CABG) would decrease the rate of death or hospitalization for cardiac causes, as compared with CABG alone.

METHODS

Between September 2002 and January 2006, a total of 1000 patients with an ejection fraction of 35% or less, coronary artery disease that was amenable to CABG, and dominant anterior left ventricular dysfunction that was amenable to surgical ventricular reconstruction were randomly assigned to undergo either CABG alone (499 patients) or CABG with surgical ventricular reconstruction (501 patients). The primary outcome was a composite of death from any cause and hospitalization for cardiac causes. The median follow-up was 48 months.

RESULTS

Surgical ventricular reconstruction reduced the end-systolic volume index by 19%, as compared with a reduction of 6% with CABG alone. Cardiac symptoms and exercise tolerance improved from baseline to a similar degree in the two study groups. However, no significant difference was observed in the primary outcome, which occurred in 292 patients (59%) who were assigned to undergo CABG alone and in 289 patients (58%) who were assigned to undergo CABG with surgical ventricular reconstruction (hazard ratio for the combined approach, 0.99; 95% confidence interval, 0.84 to 1.17; P=0.90).

CONCLUSIONS

Adding surgical ventricular reconstruction to CABG reduced the left ventricular volume, as compared with CABG alone. However, this anatomical change was not associated with a greater improvement in symptoms or exercise tolerance or with a reduction in the rate of death or hospitalization for cardiac causes. (ClinicalTrials.gov number, NCT00023595.)

From the Duke Clinical Research Institute, Duke University Medical Center, Durham, NC (R.H.J., E.J.V., C.M.O., K.L.L.); the Montefiore Medical Center–Albert Einstein College of Medicine, Bronx, NY (R.E.M.); the National Heart, Lung, and Blood Institute, National Institutes of Health, Bethesda, MD (G.S., P.D.-N.); the Mayo Clinic, Rochester, MN (J.K.O.); the University of Florida College of Medicine, Gainesville (J.A.H.); San Donato Hospital, Milan (L.M.); National Institute of Cardiology, Warsaw, Poland (Z.S.); and Institut de Cardiologie de Montréal, University of Montreal, Montreal (J.-L.R.). Address reprint requests to Dr. Jones at P.O. Box 2986, Duke University Medical Center, Durham, NC 27710, or at jones060@mc.duke.edu.

*A complete list of investigators participating in the Hypothesis 2 component of the Surgical Treatment for Ischemic Heart Failure (STICH) trial is provided in the Supplementary Appendix, available with the full text of this article at NEJM.org.

This article (10.1056/NEJMoa0900559) was published at NEJM.org on March 29, 2009.

N Engl J Med 2009;360:1705-17.

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119 articles referenced by PubMed related To the COURAGE Trial


LIFE

True, True and Unrelated:

"The results of Hypothesis II of the STICH Trial will remain 'true, true and unrelated' and will go down as an expensive but clinically meaningless exercise in surgical research."

Conte J, Johns Hopkins University
J Heart Lung Transplant, 29:491-495, 2010

The STICH Trial:
Misguided Conclusions

"The STICH Trial conclusions show that statisticians can defy nature from a flawed database."

Buckberg GD, UCLA, J Thorac Cardiovasc Surg, 138:1060-65, 2009

To Reconstruct or Not

"The real message of the STICH Trial is this: if one is pondering treatment of patients with poor ventricular function and mild aneurysmal dilatation, do NOT perform SVR surgery because if you do not send the patient to heaven (i.e. kill them) you will only prolong his or her and your own suffering with no clinical benefit."

Kieser TM, Univ. of Calgary,
J Thorac Cardiovasc Surg, 138:1060-65, 2009

Korean Alphabet

Consonants

ㄱ	ㄴ	ㄷ	ㄹ	ㅁ	ㅂ	ㅅ	ㅇ	ㅈ	ㅊ	ㅋ	ㅌ	ㅍ	ㅎ
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Pronunciations shown here are only rough approximations.

BARI 2D Clinical Trial

Compare treatment strategies for patients with

- Type 2 diabetes mellitus
- Documented CAD suitable for elective revascularization (1 or more significant lesions)
- Documented ischemia
- No prior CABG or PCI within the last 12 months

Revascularization Decision
BARI 2D

Cardiologist a priori selected revascularization method based on clinical and angiographic factors

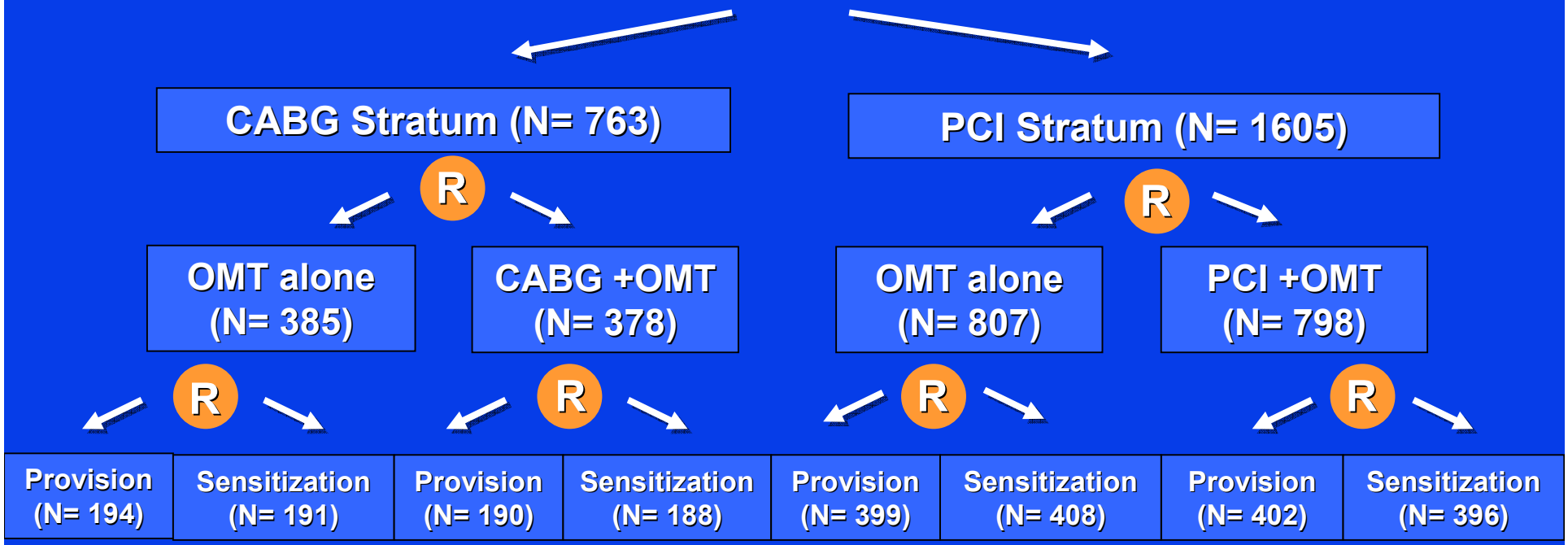
Percutaneous coronary intervention

or

Coronary artery bypass graft surgery

BARI 2D Trial: Study Design

2368 patients with mild to moderate CAD and Type 2 diabetes prior to randomization. Prospective. Randomized. Mean follow-up 5.3 years



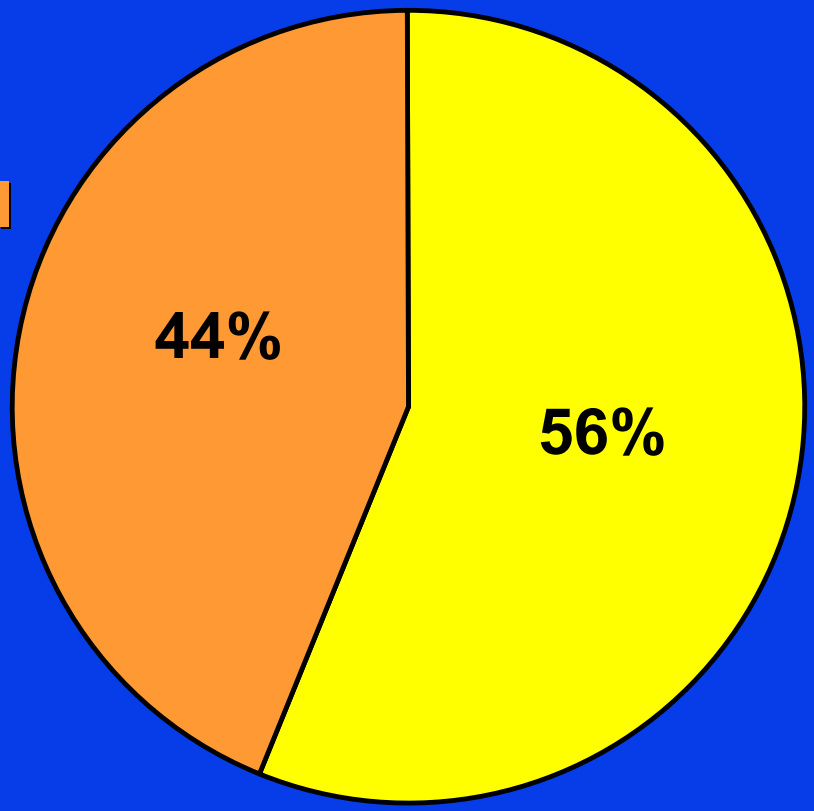
- Primary Endpoint: Death (from any cause)
- Secondary Endpoint: Composite of Death, MI, or Stroke

BARI 2D Study Group, NEJM 2009

BARI 2D

1593 patients with MVD

CABG: 11% suitable for PCI



PCI: 49% suitable for CABG

Kim LJ et al, JACC Intv 2:384-92, 2009

BARI 2D

- Selection of CABG rather than PCI
  - Based largely on greater extent, severity and complexity of CAD
  - More likely in patients >65 years
  - Less likely in patients with prior PCI
  - More likely in non U.S. centers
  - Less likely after introduction of DES

Kim LJ et al, JACC Intv 2:384-92, 2009

JACC: CARDIOVASCULAR INTERVENTIONS
© 2009 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER INC.
VOL. 2, NO. 5, 2009
ISSN 1936-8798/09/$36.00
DOI: 10.1016/j.jcin.2009.01.009

Conclusions: The majority of diabetic patients with multivessel disease were selected for PCI rather than CABG. Preference for CABG over PCI was largely based on angiographic features related to the extent, location, and nature of CAD, as well as geographic, demographic, and clinical factors. (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes [BARI 2D]; NCT00006035)

of coronary artery bypass graft (CABG) surgery versus percutaneous coronary intervention (PCI) in diabetic patients with multivessel coronary artery disease (CAD) in the BARI 2D (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes) trial.

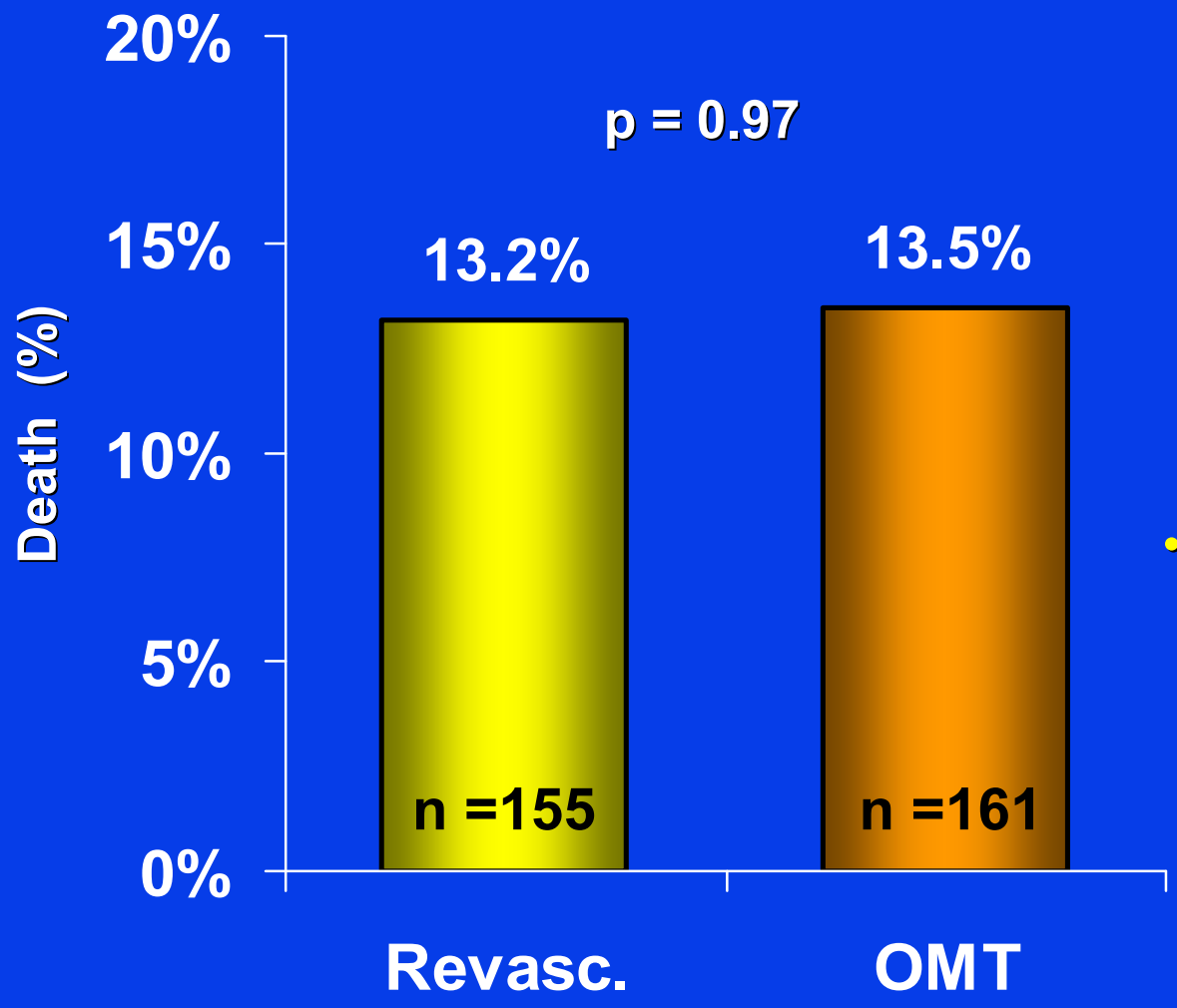
Background Factors guiding selection of mode of revascularization for patients with diabetes mellitus and multivessel CAD are not clearly defined.

Methods In the BARI 2D trial, the selected revascularization strategy, CABG or PCI, was based on physician discretion, declared independent of randomization to either immediate or deferred revascularization if clinically warranted. We analyzed factors favoring selection of CABG versus PCI in 1,593 diabetic patients with multivessel CAD enrolled between 2001 and 2005.

Results Selection of CABG over PCI was declared in 44% of patients and was driven by angiographic factors including triple vessel disease (odds ratio [OR]: 4.43), left anterior descending stenosis ≥70% (OR: 2.86), proximal left anterior descending stenosis ≥50% (OR: 1.78), total occlusion (OR: 2.35), and multiple class C lesions (OR: 2.06) (all $p < 0.005$). Nonangiographic predictors of CABG included age ≥65 years (OR: 1.43, $p = 0.011$) and non-U.S. region (OR: 2.89, $p = 0.017$). Absence of prior PCI (OR: 0.45, $p < 0.001$) and the availability of drug-eluting stents conferred a lower probability of choosing CABG (OR: 0.60, $p = 0.003$).

Conclusions The majority of diabetic patients with multivessel disease were selected for PCI rather than CABG. Preference for CABG over PCI was largely based on angiographic features related to the extent, location, and nature of CAD, as well as geographic, demographic, and clinical factors. (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes [BARI 2D]; NCT00006305) (J Am Coll Cardiol Intv 2009;2: 384–92) © 2009 by the American College of Cardiology Foundation

BARI 2D Trial: Primary Endpoint



- The 5-year death rate for the group receiving revascularization plus optimal medical therapy was 13.2% vs. 13.5% in the group receiving optimal medical therapy alone
- The difference between the two treatment groups did not reach statistical significance

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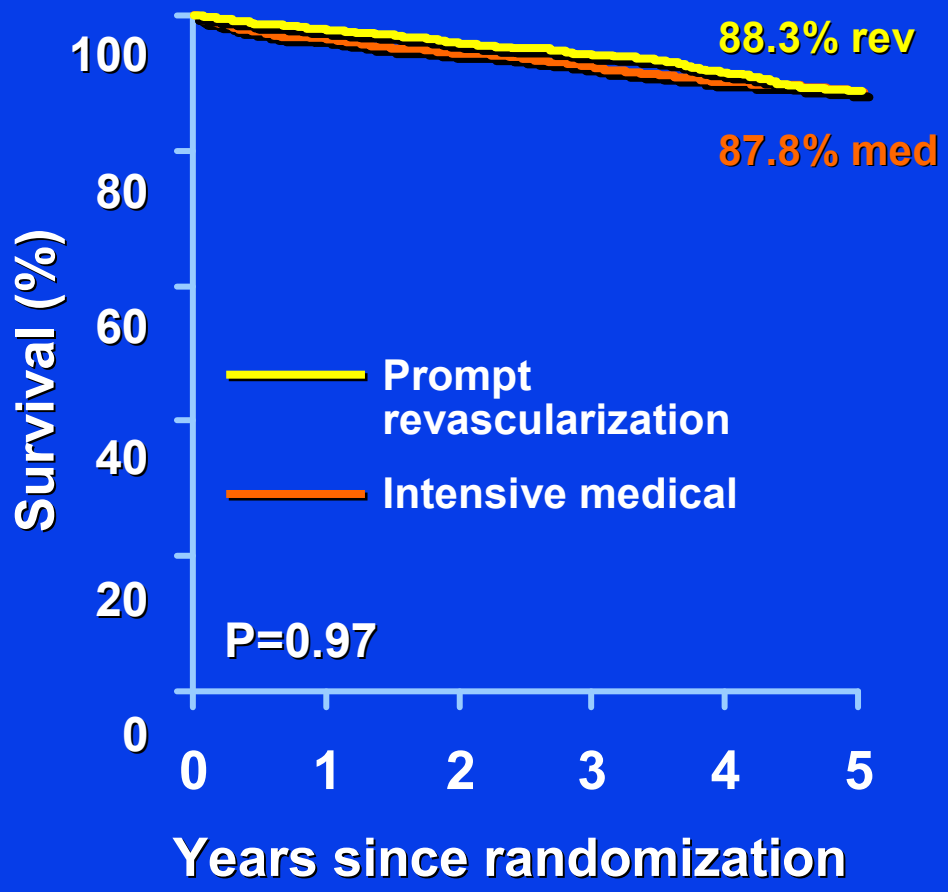
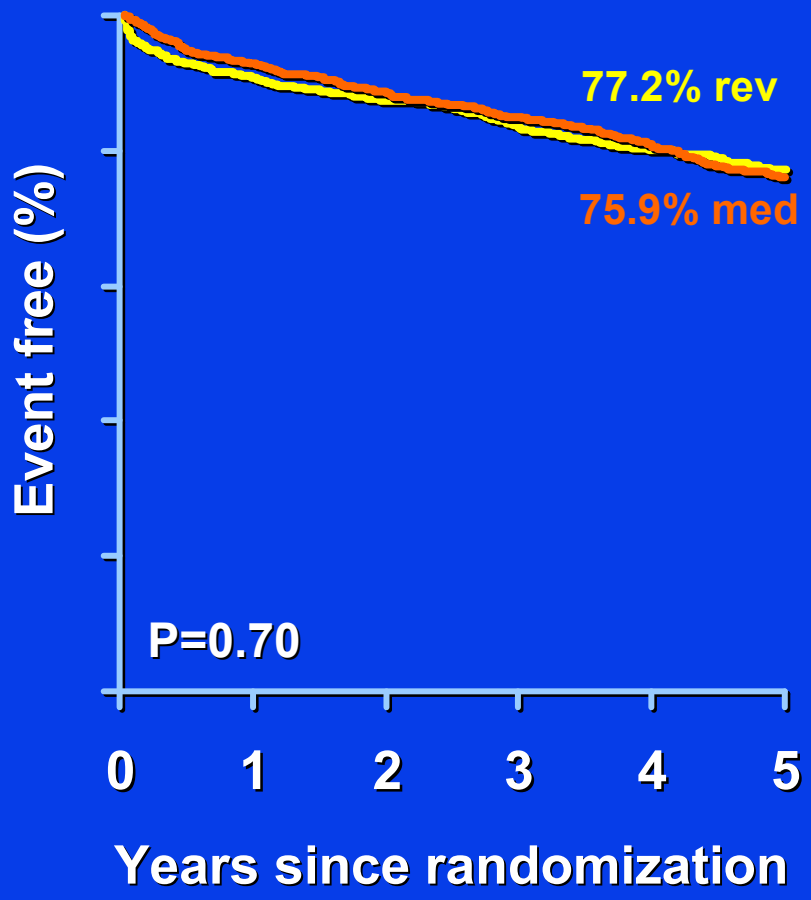
BARI 2D Study Group, NEJM 2009

Prompt Revascularization vs Medical Therapy

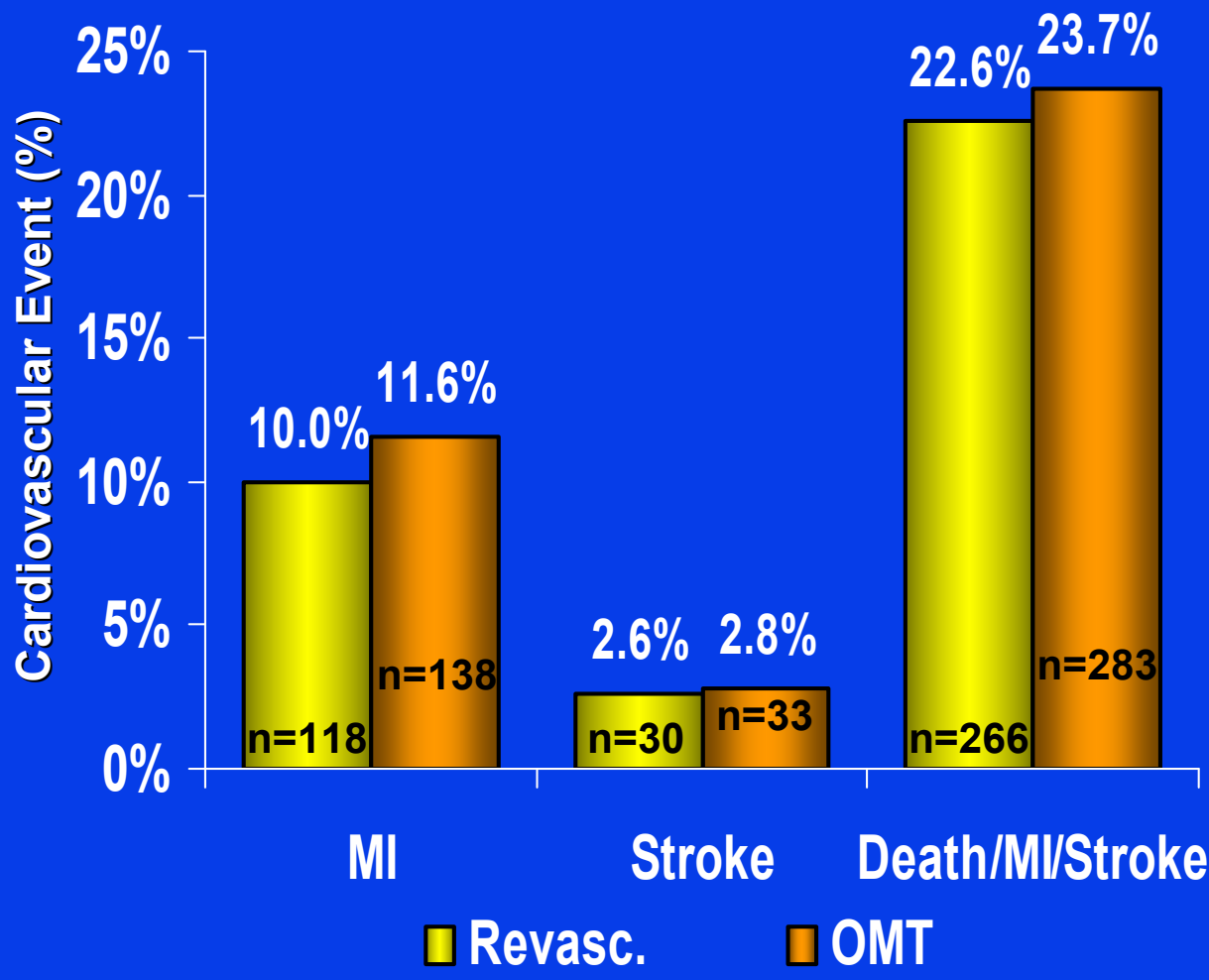
All-Cause Mortality



Death/MI/Stroke



BARI 2D Trial: Secondary Endpoint



- The rates of MI, stroke and the combined secondary endpoint of death, MI, and stroke were similar between the group receiving revascularization plus optimal medical therapy vs. the group receiving optimal medical therapy alone.
- The difference between the two treatment groups for the combined secondary endpoint of death, MI, and stroke did not reach statistical significance (p=0.70)

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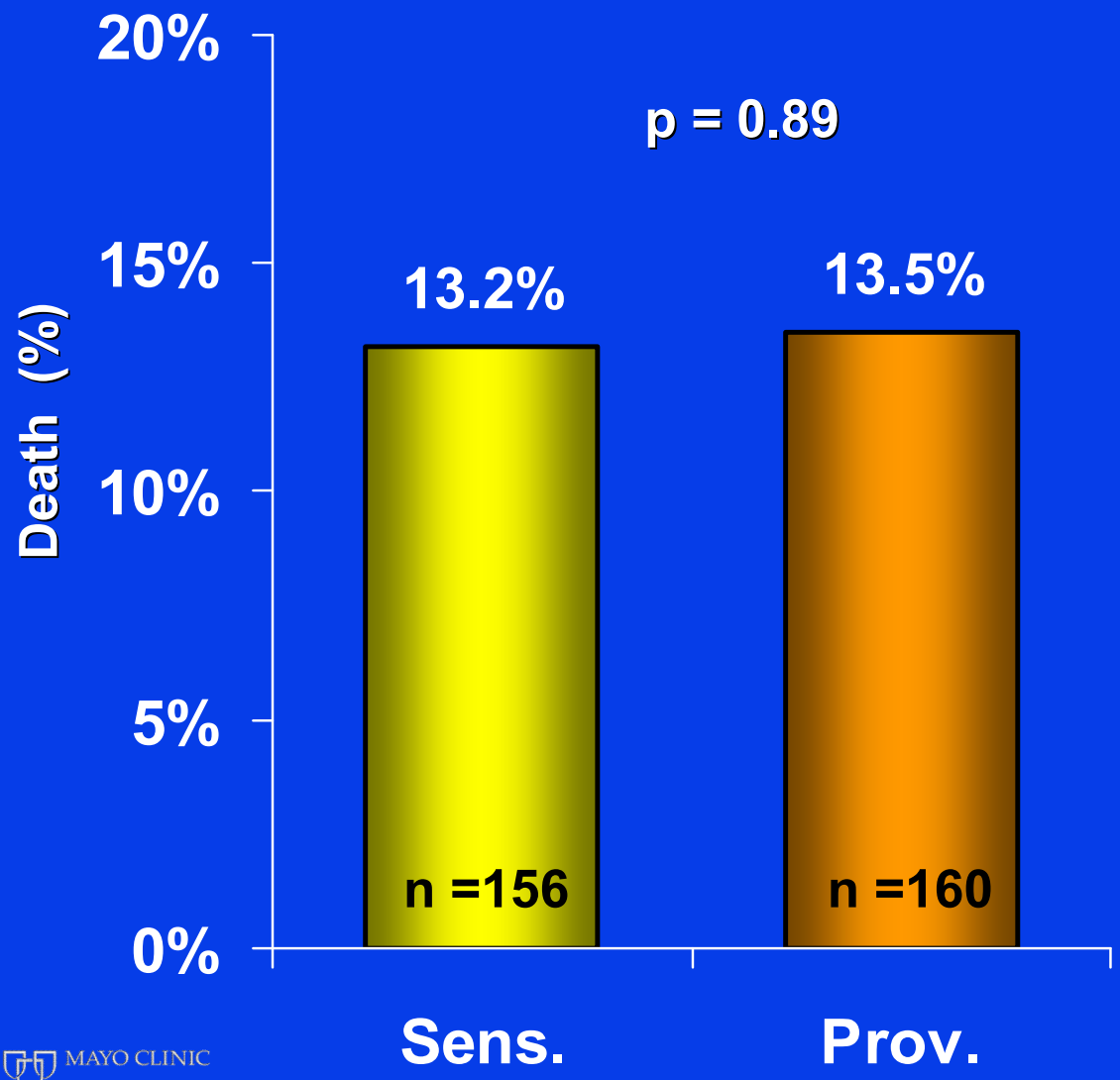
BARI 2D Study Group, NEJM 2009

BARI 2D Trial: Primary Endpoint



- The 5-year death rate for the group receiving insulin sensitization therapy was 13.2% vs. 13.5% in the group receiving insulin provision therapy.
- The difference between the two treatment groups did not reach statistical significance.

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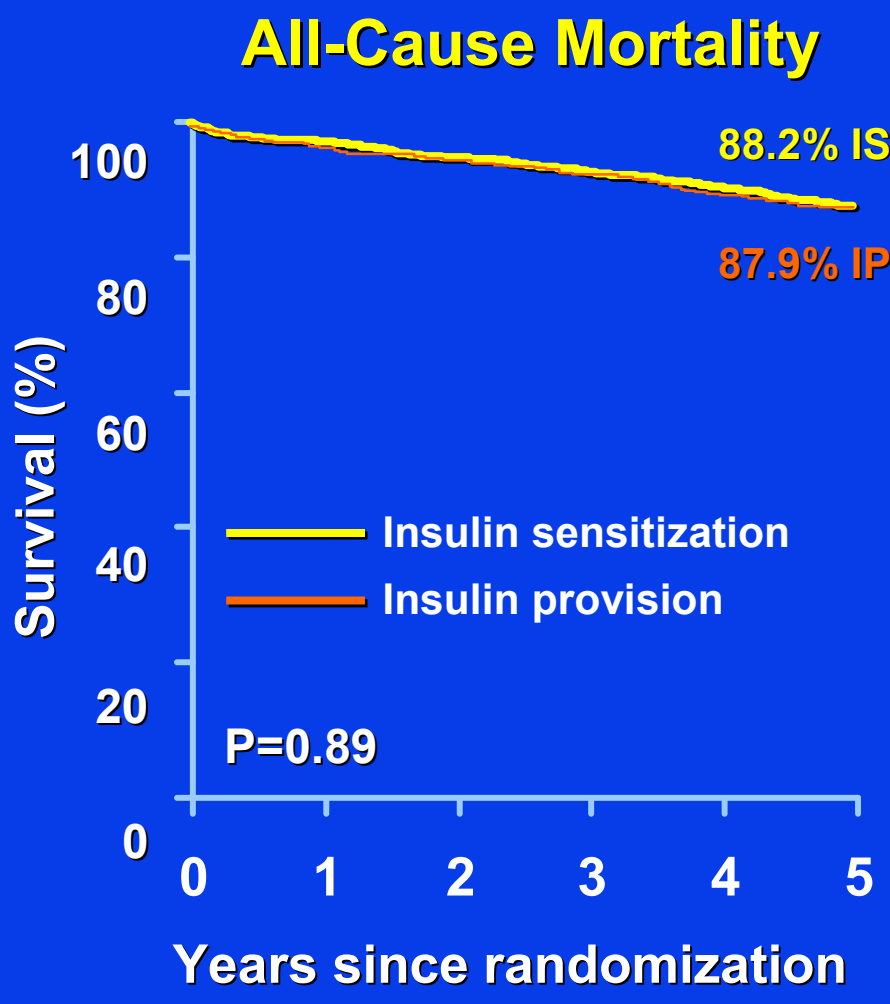
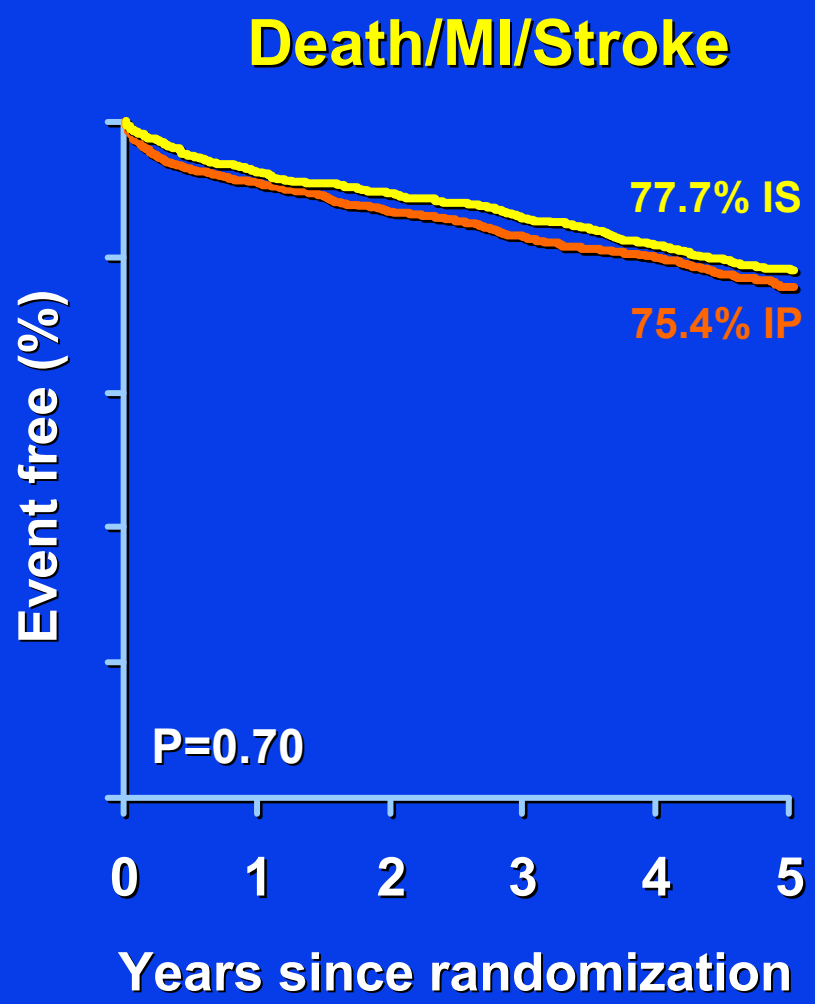
BARI 2D Study Group, NEJM 2009

Insulin Sensitization vs Insulin Provision





BARI 2D Primary Conclusion

Overall similar mortality and CV events

- Prompt revascularization vs delayed or no revascularization
- Insulin sensitization vs insulin provision

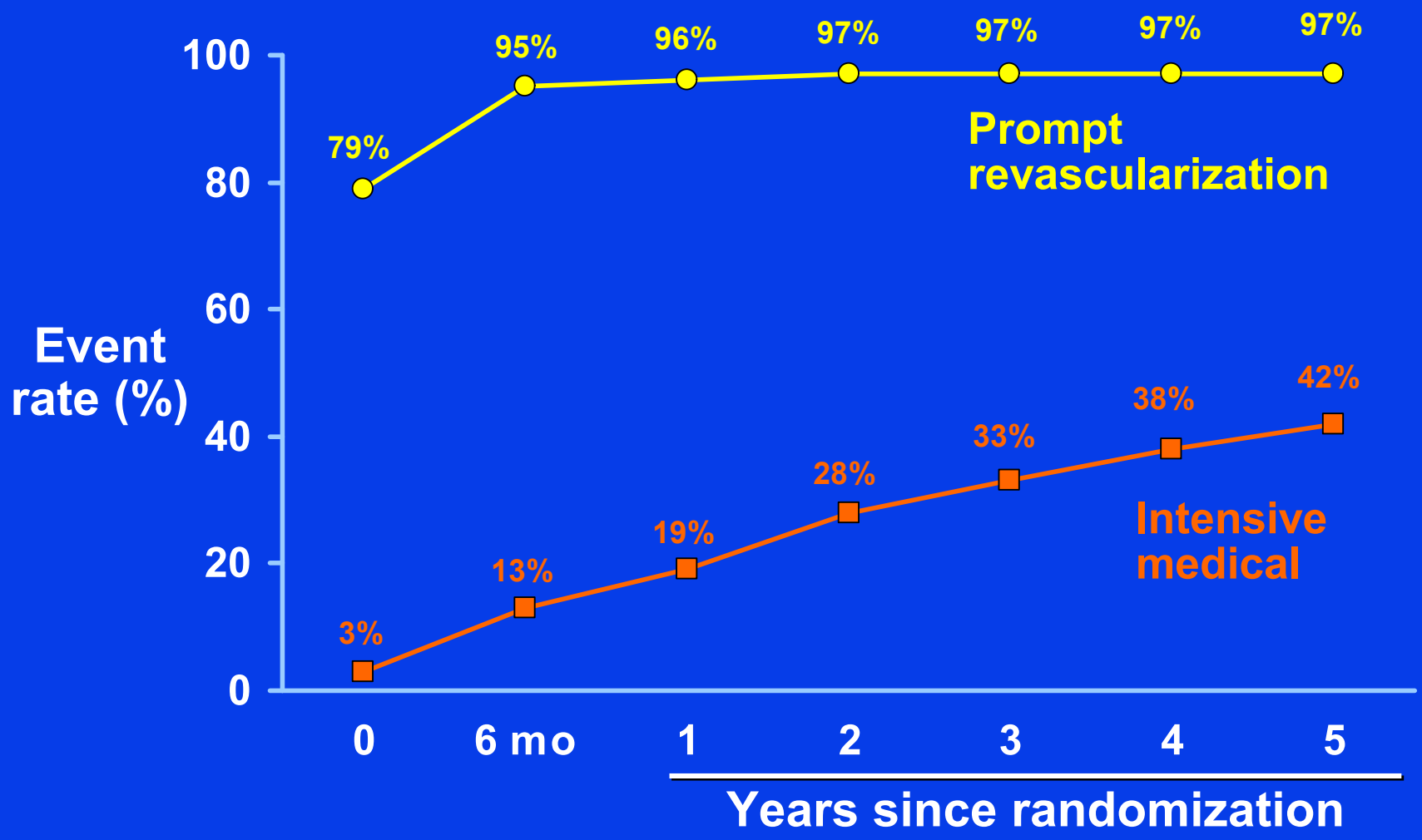
Among high-risk patients selected for CABG

- Prompt revascularization reduces major CV events compared with delayed or no revascularization (P=0.01)

Among lower-risk patients selected for PCI

- Prompt revascularization and delayed or no revascularization had similar rates for major CV events

Cumulative Rate of First Revascularization



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Conclusions

- Optimal medical therapy is required for diabetic patients with CAD
- Despite optimal medical therapy, 42% of diabetic patients will still undergo revascularization during 5 years FU
- Revascularization strategies chosen depend in large part on severity and extent of disease
- Clinical decision making still works

Korean Alphabet

Consonants

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g,k	n	d,t	r, l	m	b,p	s	ng	j	ch	k	t	p	h

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a	ya	eo	yeo	o	yo	u	yu	eu	i
father		saw		home		moon		put	meet

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ae	yae	e	ye	wa	wae	oe	wo	we	wi	ui
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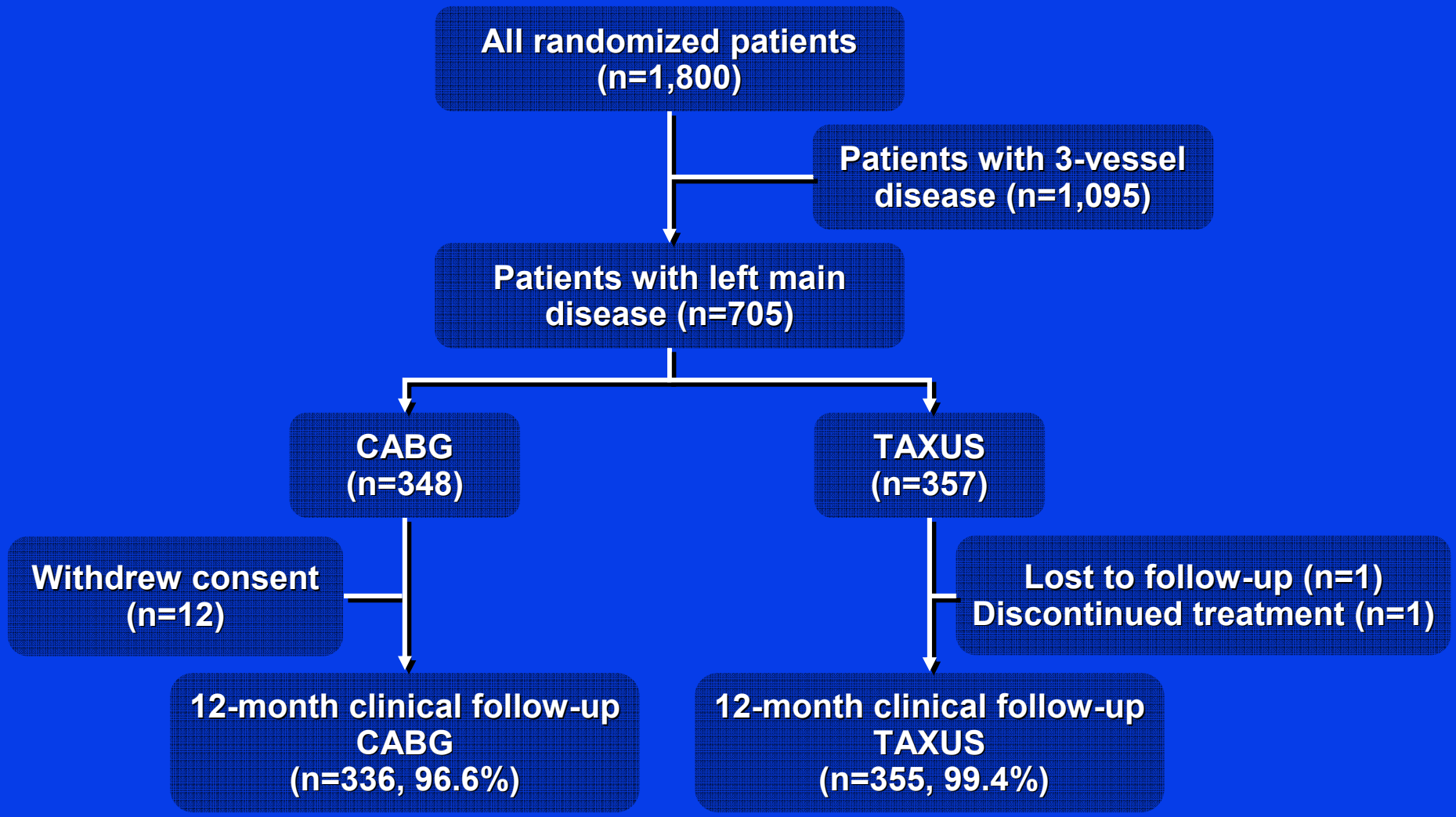
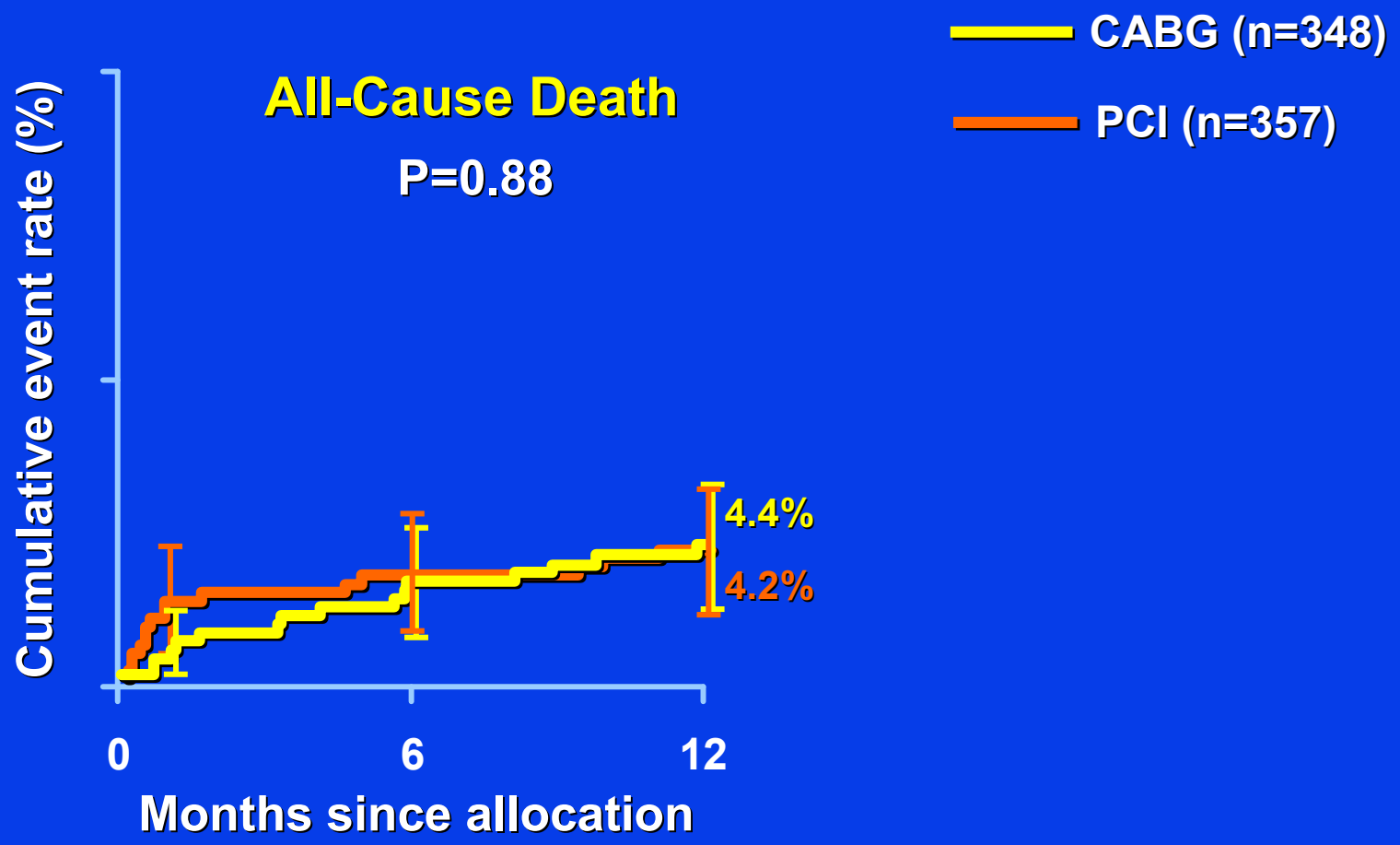
Pronunciations shown here are only rough approximations.

SYNTAX Left Main Trial
Patient Disposition



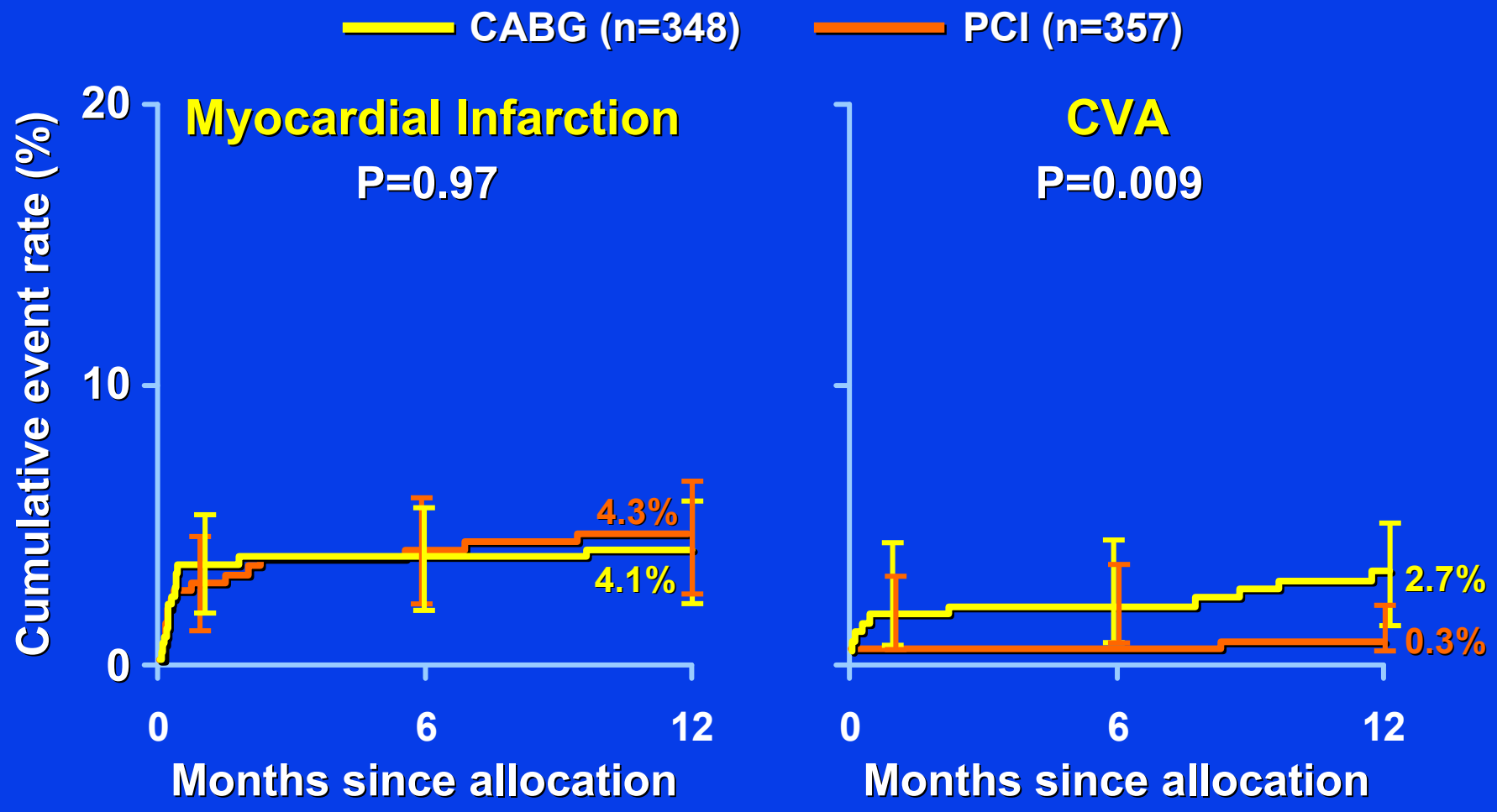
Morice MC et al: Circ, 2010 (in press)

SYNTAX Left Main Trial



Morice MC et al: Circ, 2010 (in press)

SYNTAX Left Main Trial



Morice MC et al: Circ, 2010 (in press)

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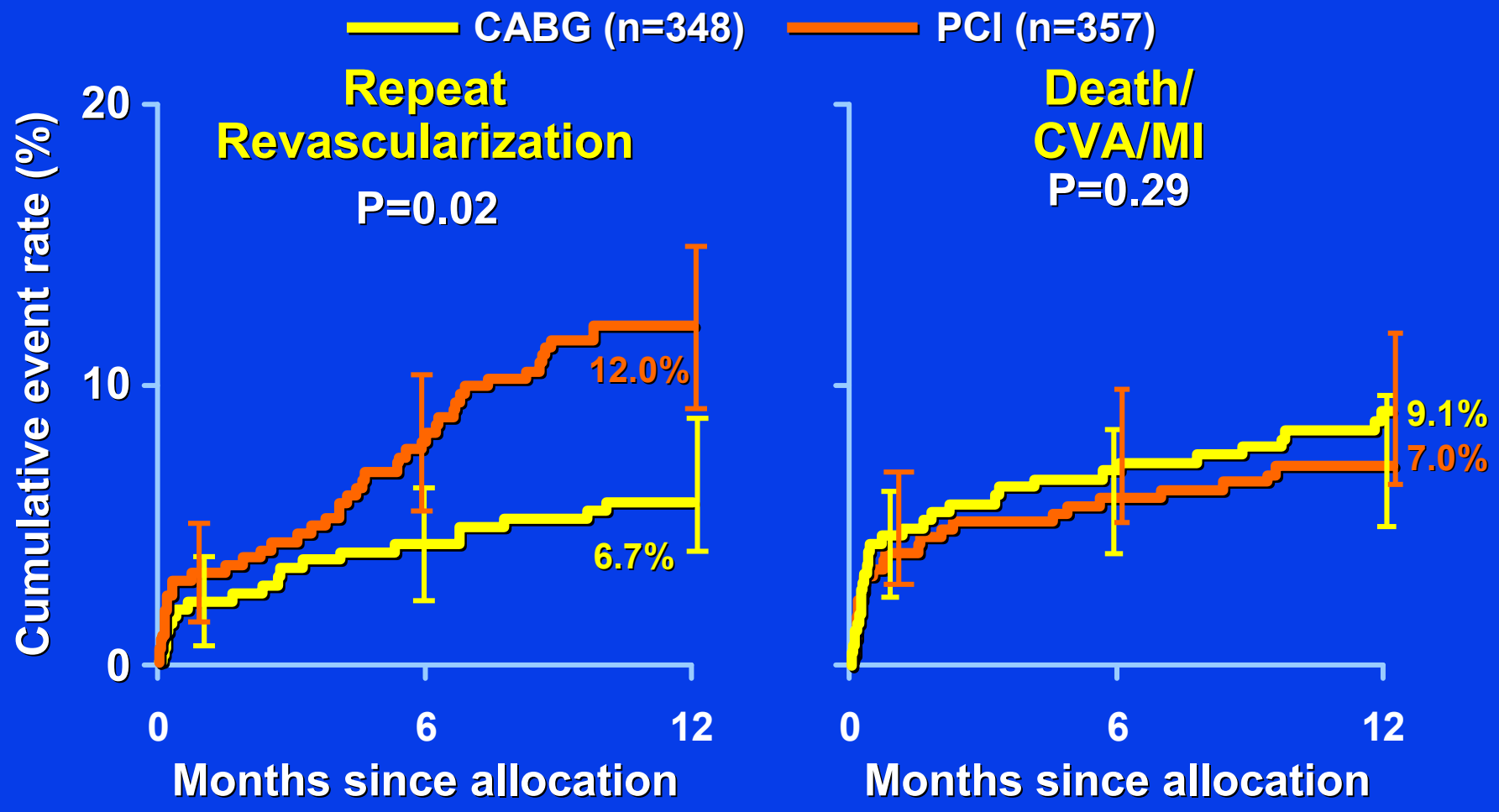
SYNTAX Left Main Trial



Morice MC et al: Circ, 2010 (in press)

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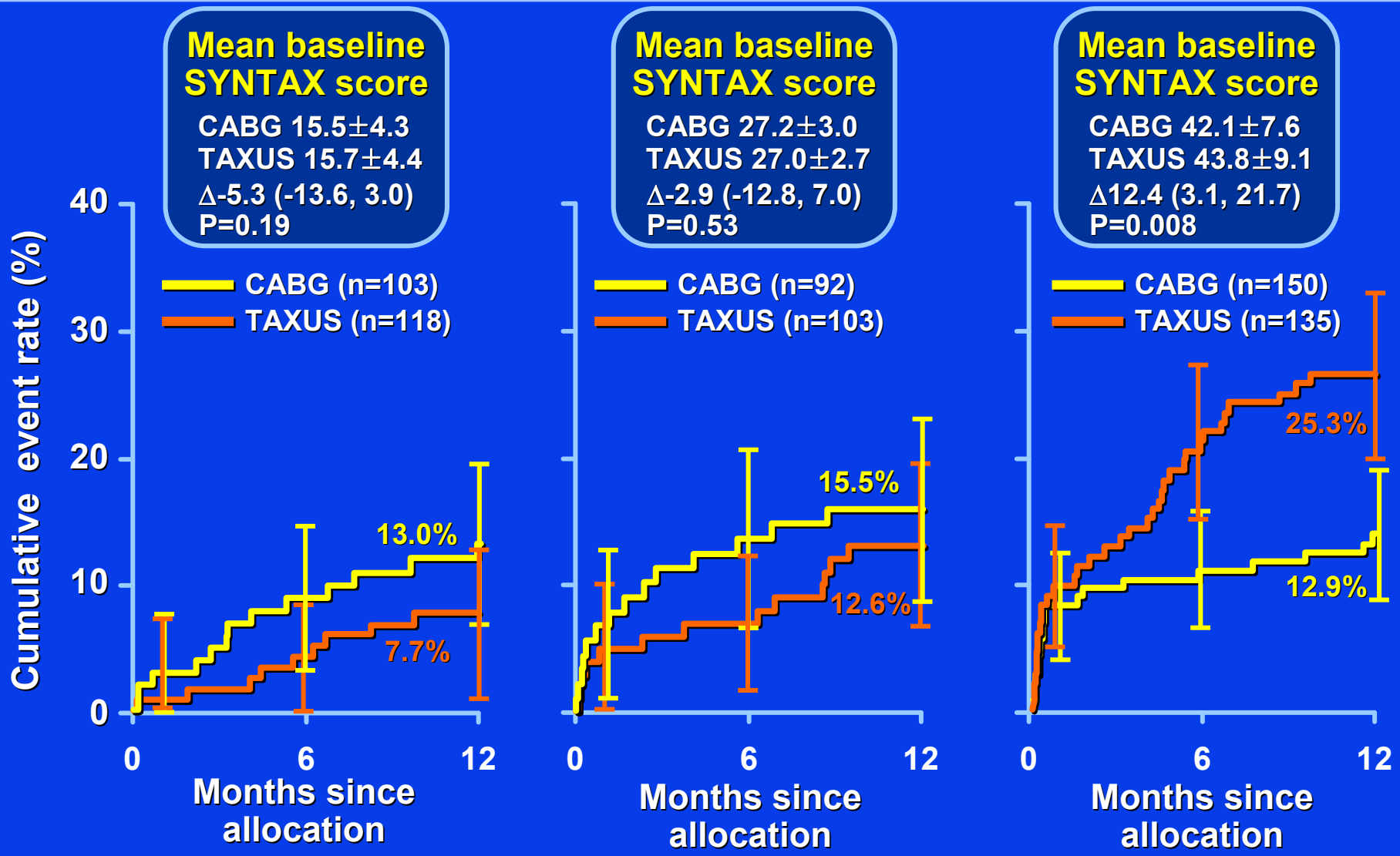
SYNTAX Left Main Trial
1-Year MACCE



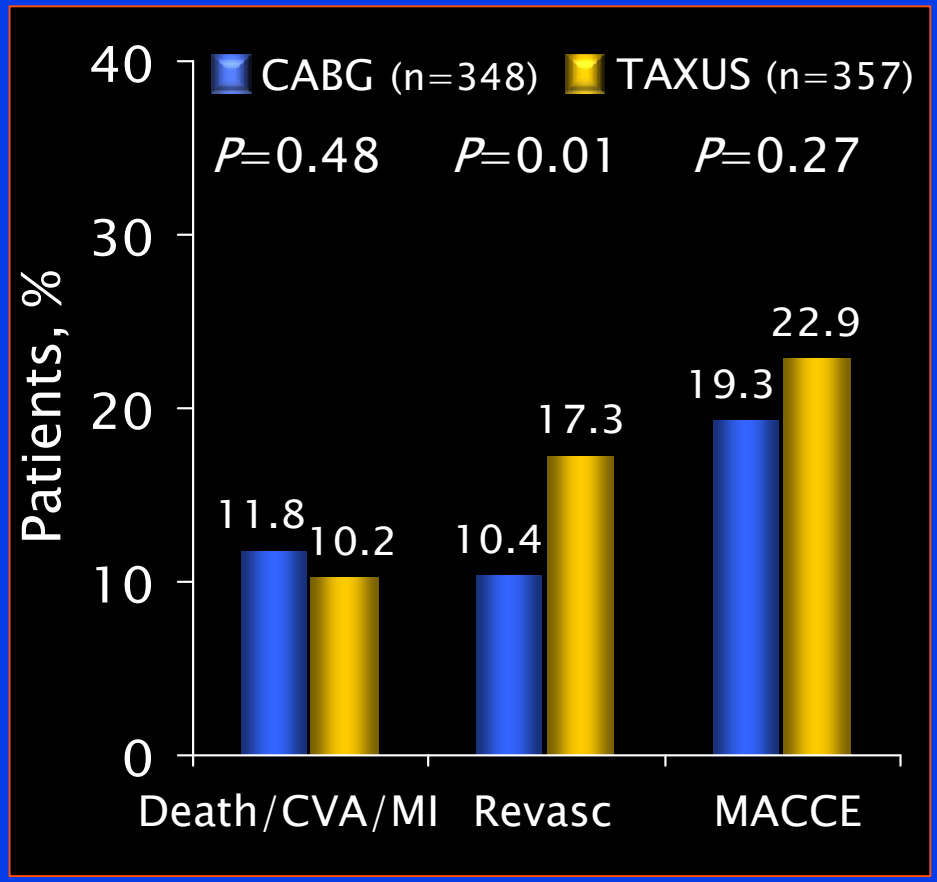
Morice MC et al: Circ, 2010 (in press)

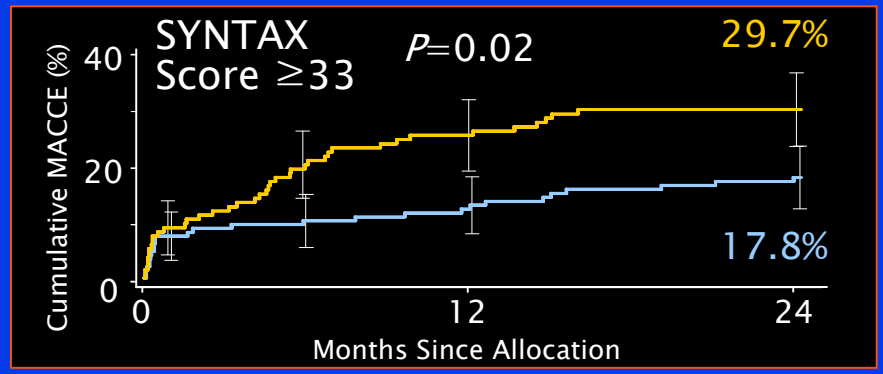
SYNTAX Trial
Conclusions

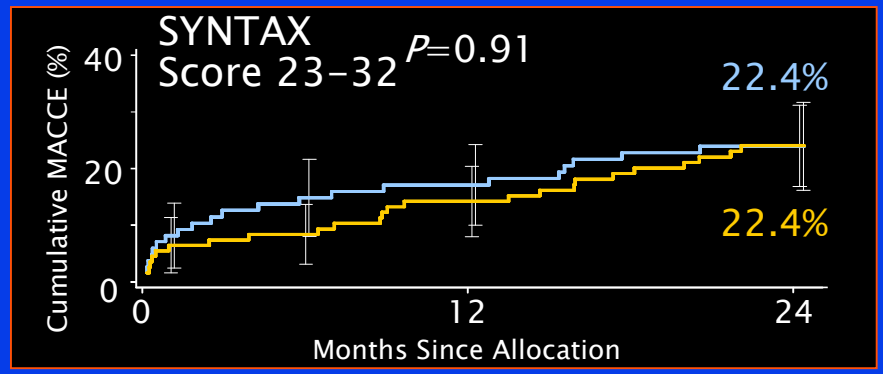
"Patients with LM disease who had revascularization with PCI had comparable safety and efficacy outcomes to CABG at 1 year."

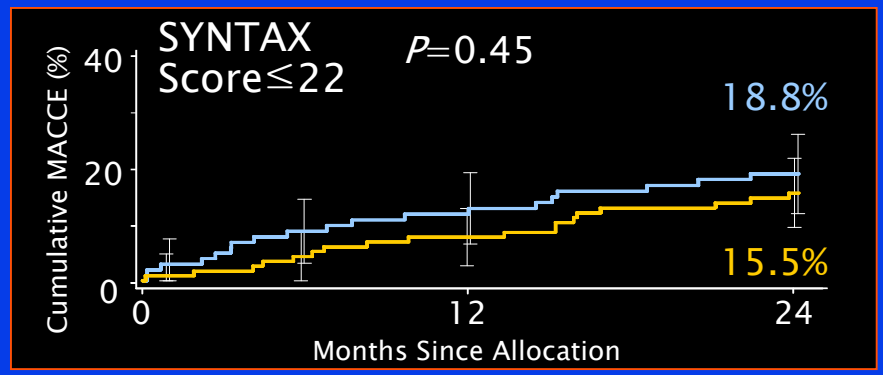
Morice MC et al: Circ, 2010 (in press)

MACCE to 2 Years
Left Main Population









- **Similar LM MACCE rates through 2 years between PCI and CABG**
- **PCI of LM is safe and feasible**

EuroSCORE and SYNTAX Trial
Background

- Whether SYNTAX score should be used as a stand-alone tool or whether its performance may be improved by the parallel use of clinical scores focusing on co-morbidities, such as EuroSCORE, is a matter of debate.

Capodanno D et al: Am Heart J 159:103, 2010

The Global Risk Score
EuroScore and SYNTAX Score
255 Patients with LMCA PCI

EuroSCORE	SYNTAX score <19	SYNTAX score 19-27	SYNTAX score >27
0-2	L	L	I
3-6	L	L	I
>6	I	I	H

Capodanno D et al: Am Heart J 159:103, 2010

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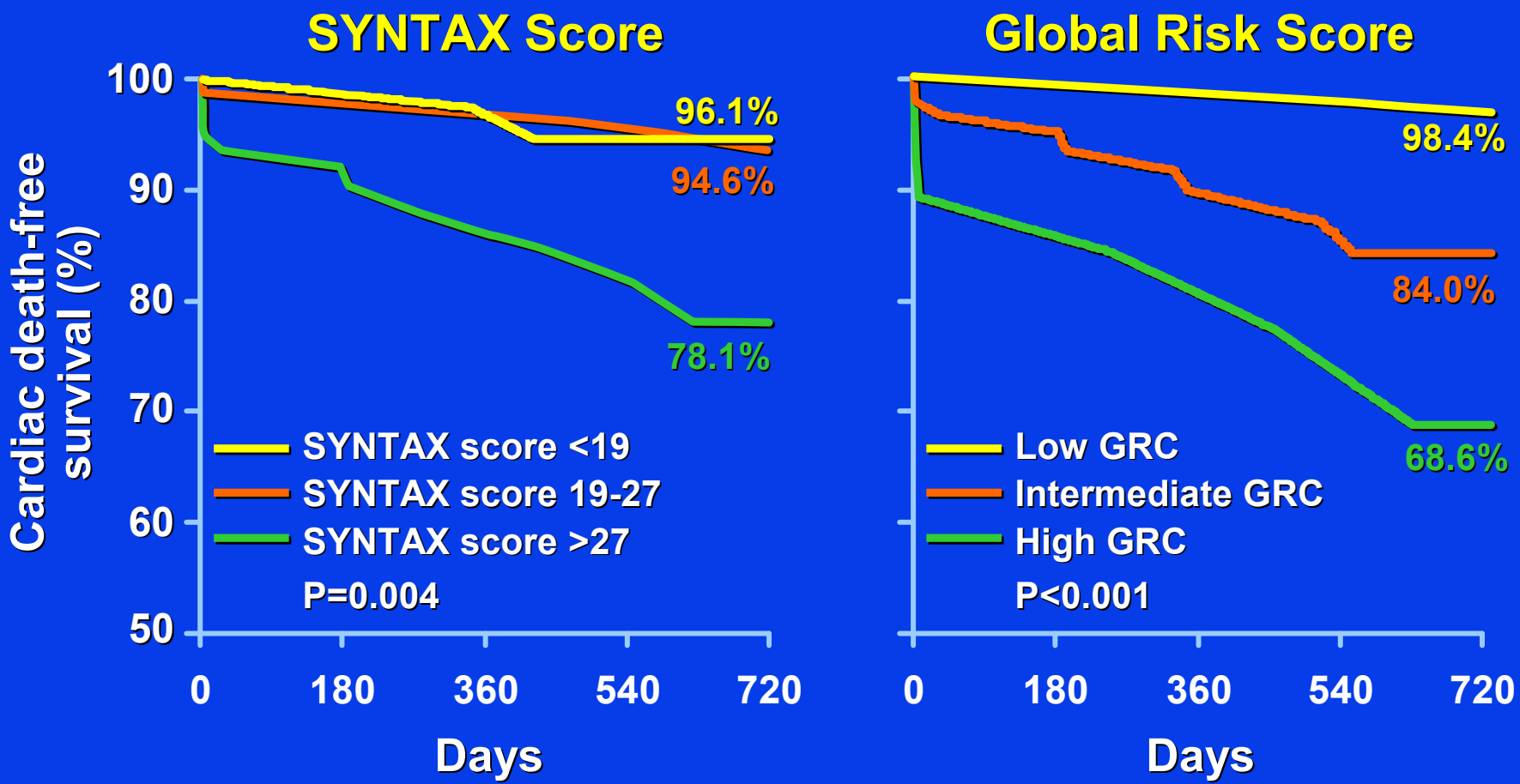
2-Year Survival



Capodanno D et al: Am Heart J 159:103, 2010

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Interventional Cardiology

EuroSCORE refines the predictive ability of SYNTAX score in patients undergoing left main percutaneous

Conclusions: We found a significant improvement in the prediction of cardiac mortality with the inclusion of EuroSCORE in a SYNTAX score-based model. The degree of reclassification between treatment threshold categories indicates that clinical and angiographic information are both important for assessing individual risk of patients undergoing left main PCI.

and angiographic information are both important for assessing individual risk of patients undergoing left main PCI. (Am Heart J 2010;159:103-9.)

In patients with unprotected left main coronary artery disease (CAD), prediction of individual outcomes can assist physicians, patients and their families to achieve a better comprehension of attendant risks and provide an objective basis to select the most appropriate treatment option.[1]

EuroSCORE is a prognostic scoring system developed for patients undergoing cardiac surgery,[2] including those with left main CAD, which has gained wide popularity over time as its performance has been validated in several local populations within and outside Europe.[3] Since most of its variables are derived from the clinical status of the patient, it is not surprising that EuroSCORE can also reasonably stratify into risk categories, although lacking in precision, a population undergoing percutaneous coronary intervention (PCI).[4] Other clinical risk scores have been specifically proposed over the last decade to predict adverse cardiovascular outcome following PCI.[5-9] However, one common concern of using clinical risk scores in the setting of PCI is that they do not incorporate any or a comprehensive information regarding the anatomy and extent of CAD.

SYNTAX score is an emerging tool developed to characterize the coronary vasculature in more detail with respect to the number of lesions and their complexity, functional impact, and location.[10] The performance of SYNTAX score in aiding treatment decision making of patients with complex CAD is encouraging,[11] and its potential for predicting long-term outcomes of PCI patients has also been suggested.[12,13] Whether SYNTAX score should be used as a stand-alone tool or whether its performance may be improved by the parallel use of clinical scores that determine the procedural risk, such as EuroSCORE, is currently unsolved.

To shed more light on the value of a so-called Global Risk Classification (GRC) resulting from merging the angiographic and clinical information contained in the

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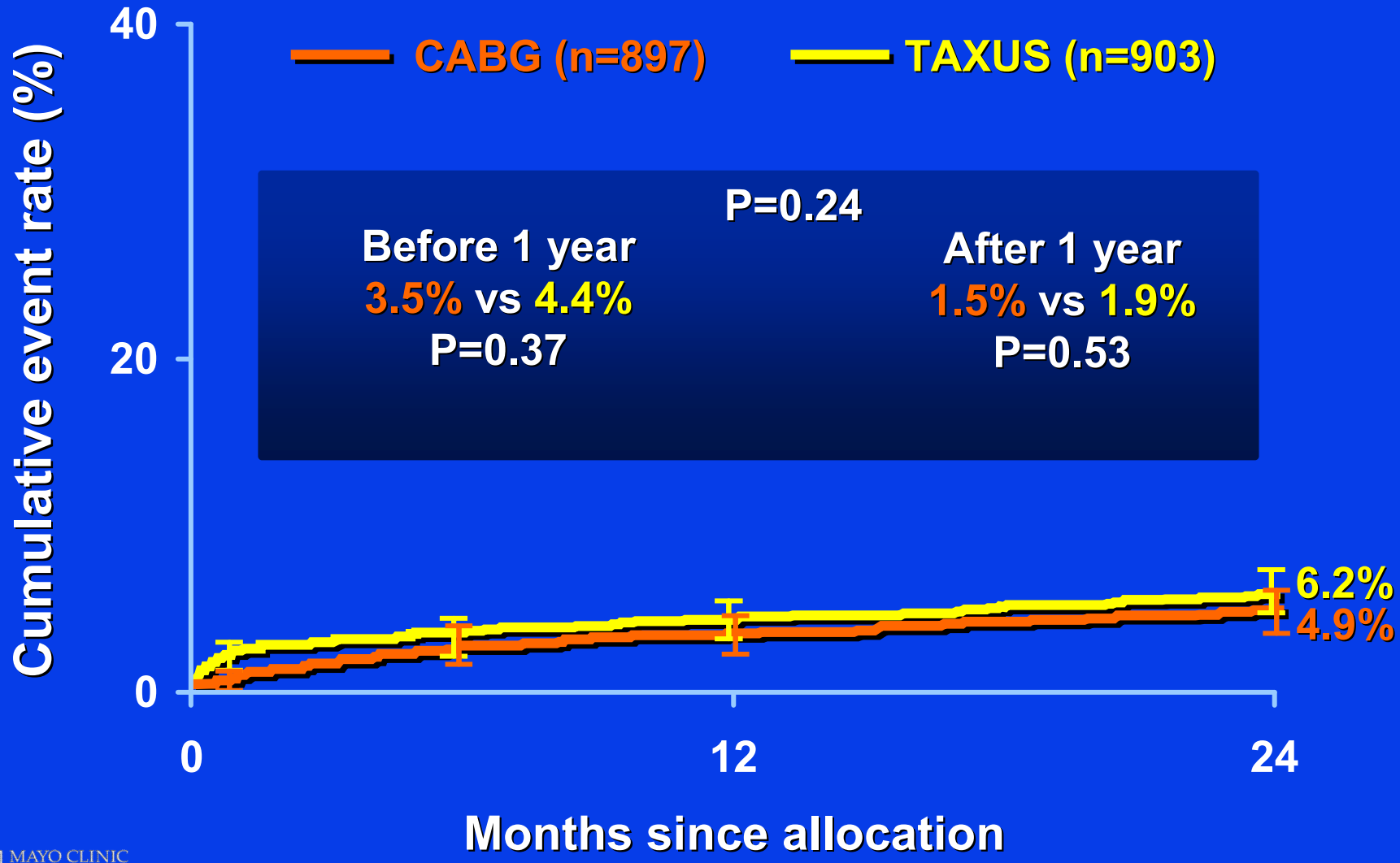
0002-8703/$ - see front matter

doi:10.1016/j.ahj.2009.10.021

MAYO CLINIC

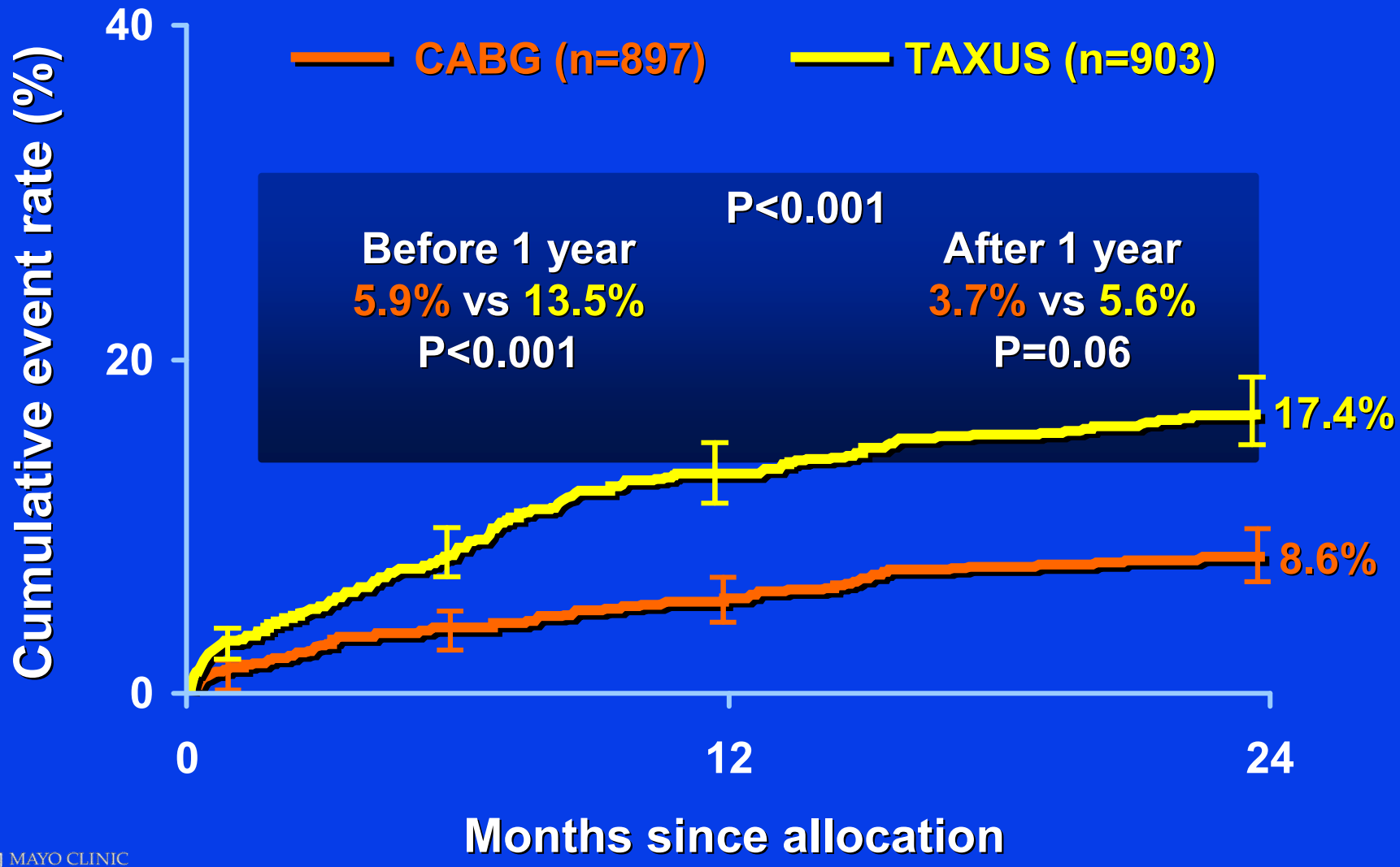
All-Cause Death to 2 Years



MAYO CLINIC

3016542-42

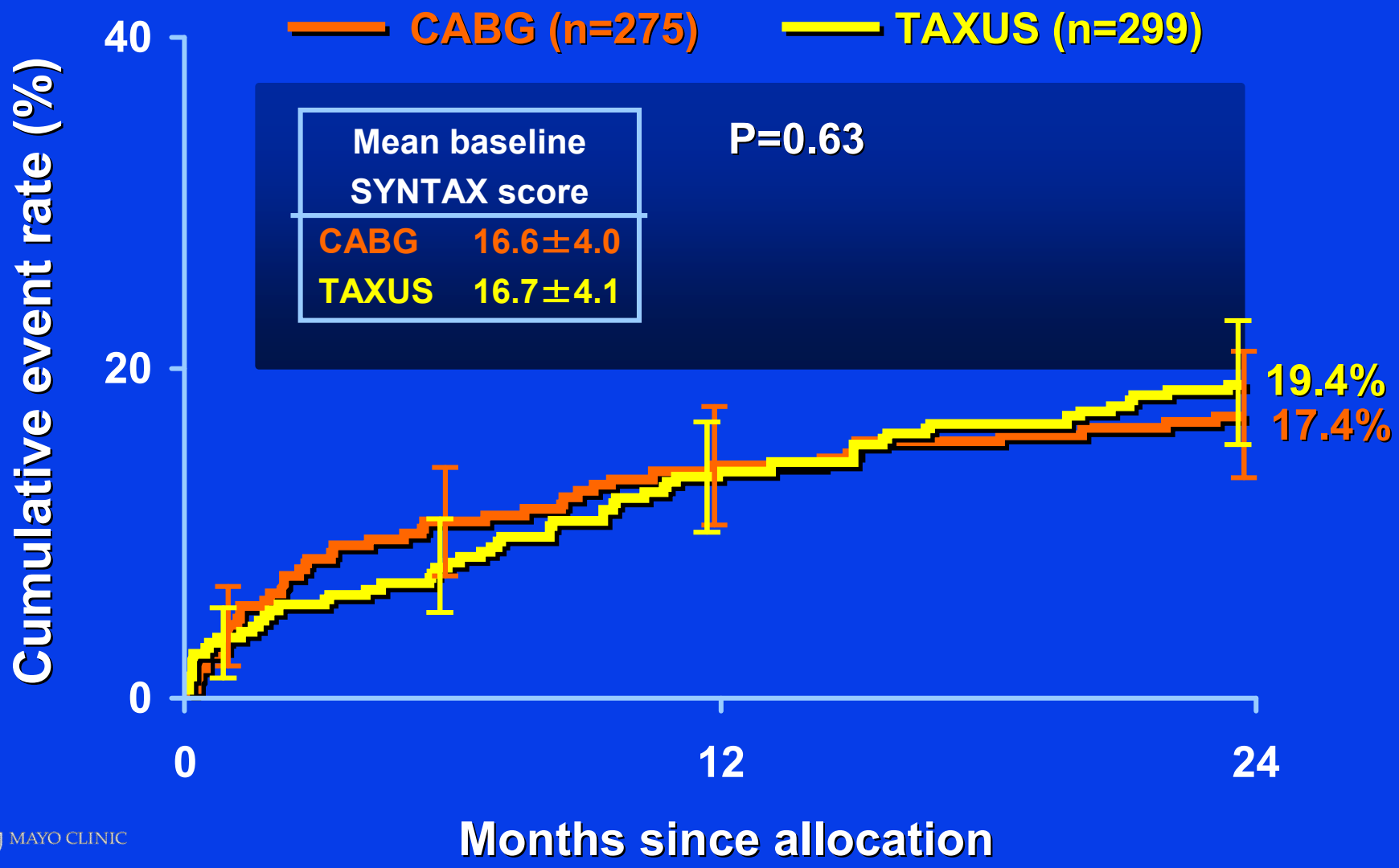
Repeat Revascularization to 2 Years



MAYO CLINIC

3016542-43

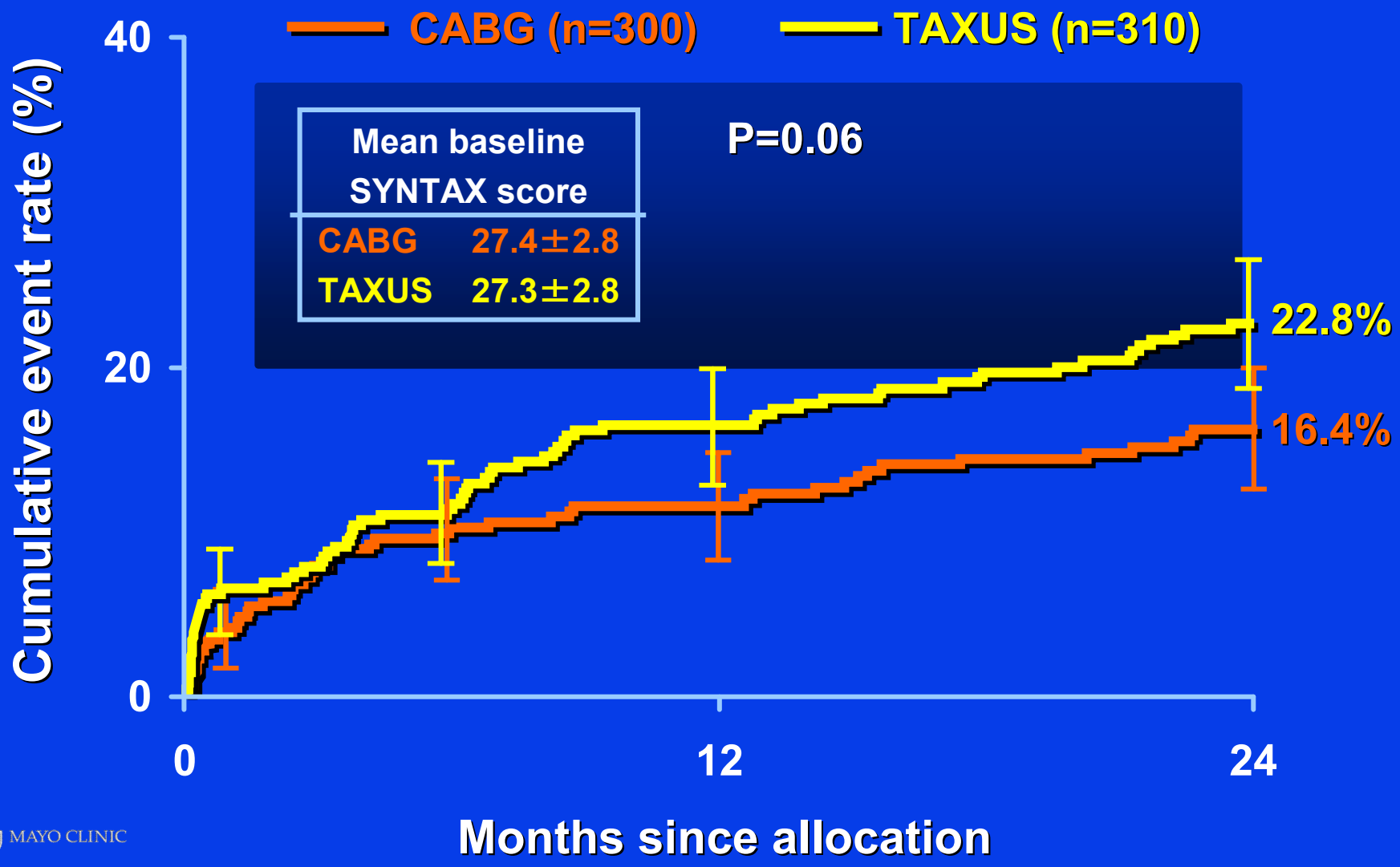
MACCE to 2 Years by SYNTAX Score Tercile
Low Scores (0-22)



MAYO CLINIC

3016542-44

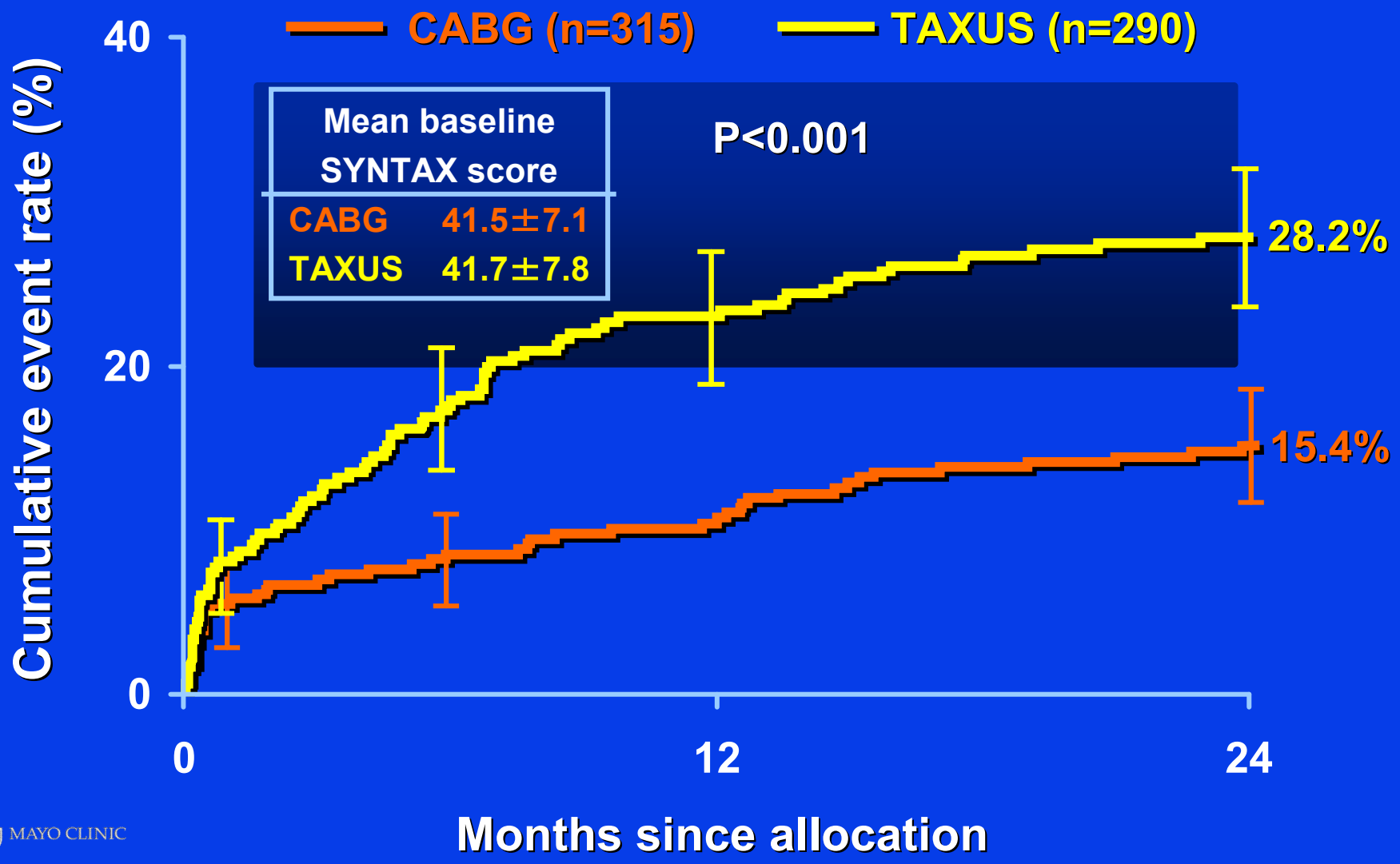
MACCE to 2 Years by SYNTAX Score Tercile
Intermediate Scores (23-32)



MAYO CLINIC

3016542-45

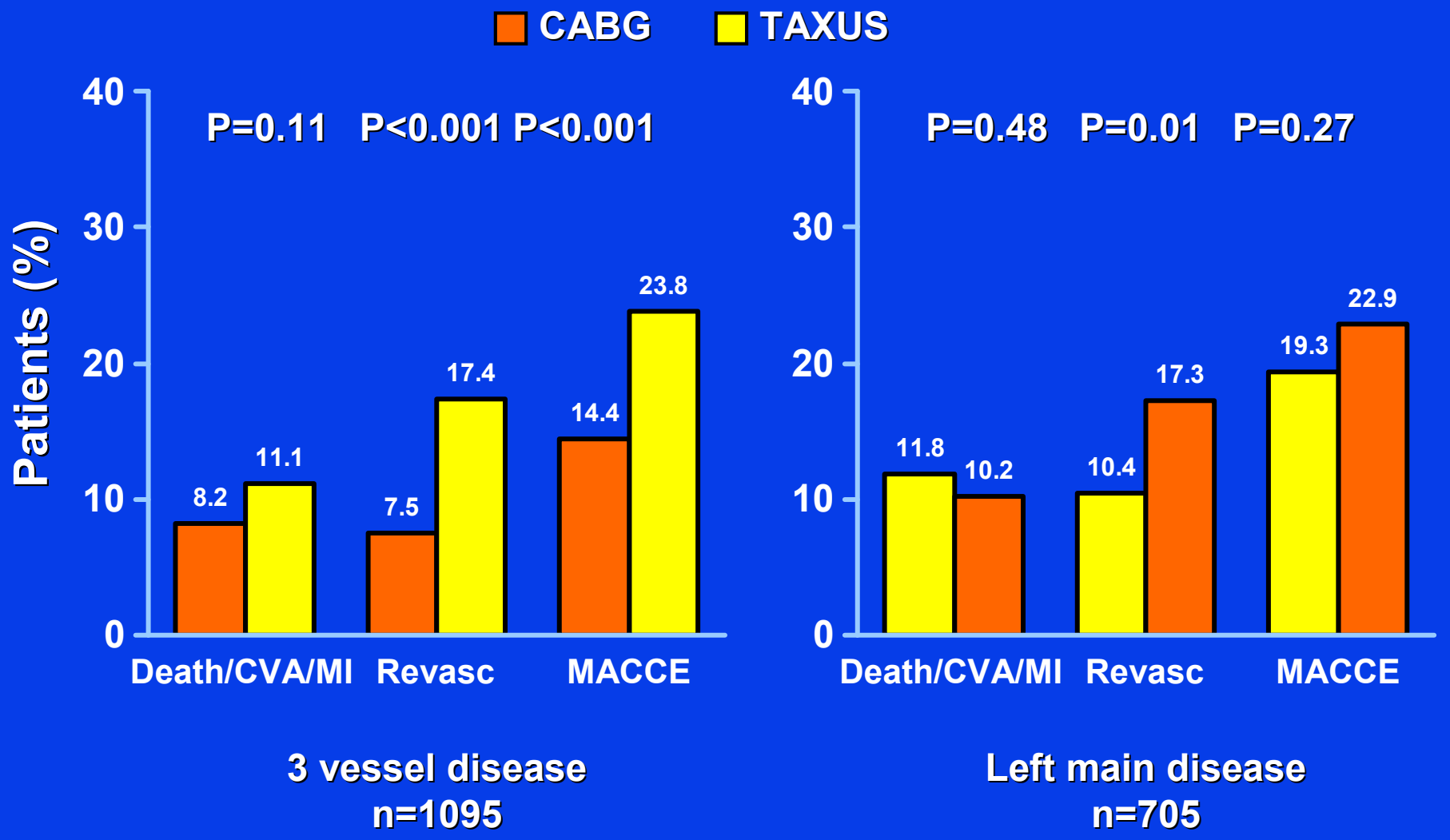
MACCE to 2 Years by SYNTAX Score Tercile
High Scores (≥33)



MAYO CLINIC

3016542-46

2-Year Outcomes in 3VD and LM Subgroups



MAYO CLINIC

3016542-47

Summary I

- In the SYNTAX randomized patients, 2-year MACCE rates were significantly higher for PCI than CABG, mainly driven by higher repeat revascularization in the PCI arm
  - Significant increase of MI compared to CABG at 2 years driven by higher PCI MI rate between years 1 and 2
  - Significantly higher CVA rate in CABG compared to PCI with the majority of CVAs occurring in the first year
  - Composite safety (death/CVA/MI) remains similar between arms at 2 years
- MACCE rates at 2 years not significantly different for patients with a low (0-22) or intermediate (23-32) baseline SYNTAX score; for patients with high SYNTAX scores (≥33), MACCE continued to be increased at 2 years in patients treated with PCI

Summary II

- In the predefined subgroups of patients with either 3VD or LM disease

  Safety outcomes (death/CVA/MI) in the 3VD group were similar for PCI and CABG, but the 2-year revascularization and MACCE rates favored CABG

  In the LM group, safety outcomes and MACCE rates were similar for PCI and CABG, but the 2-year revascularization rate was lower in the CABG group

- The 2-year SYNTAX results suggest that CABG remains the standard of care for patients with complex disease (high SYNTAX scores); however, PCI may be an acceptable alternative revascularization method to CABG when treating patients with less complex (low or intermediate SYNTAX score) disease

Korean Alphabet

Consonants

ㄱ	ㄴ	ㄷ	ㄹ	ㅁ	ㅂ	ㅅ	ㅇ	ㅈ	ㅊ	ㅋ	ㅌ	ㅍ	ㅎ
g,k	n	d,t	r, l	m	b,p	s	ng	j	ch	k	t	p	h

silent in initial position

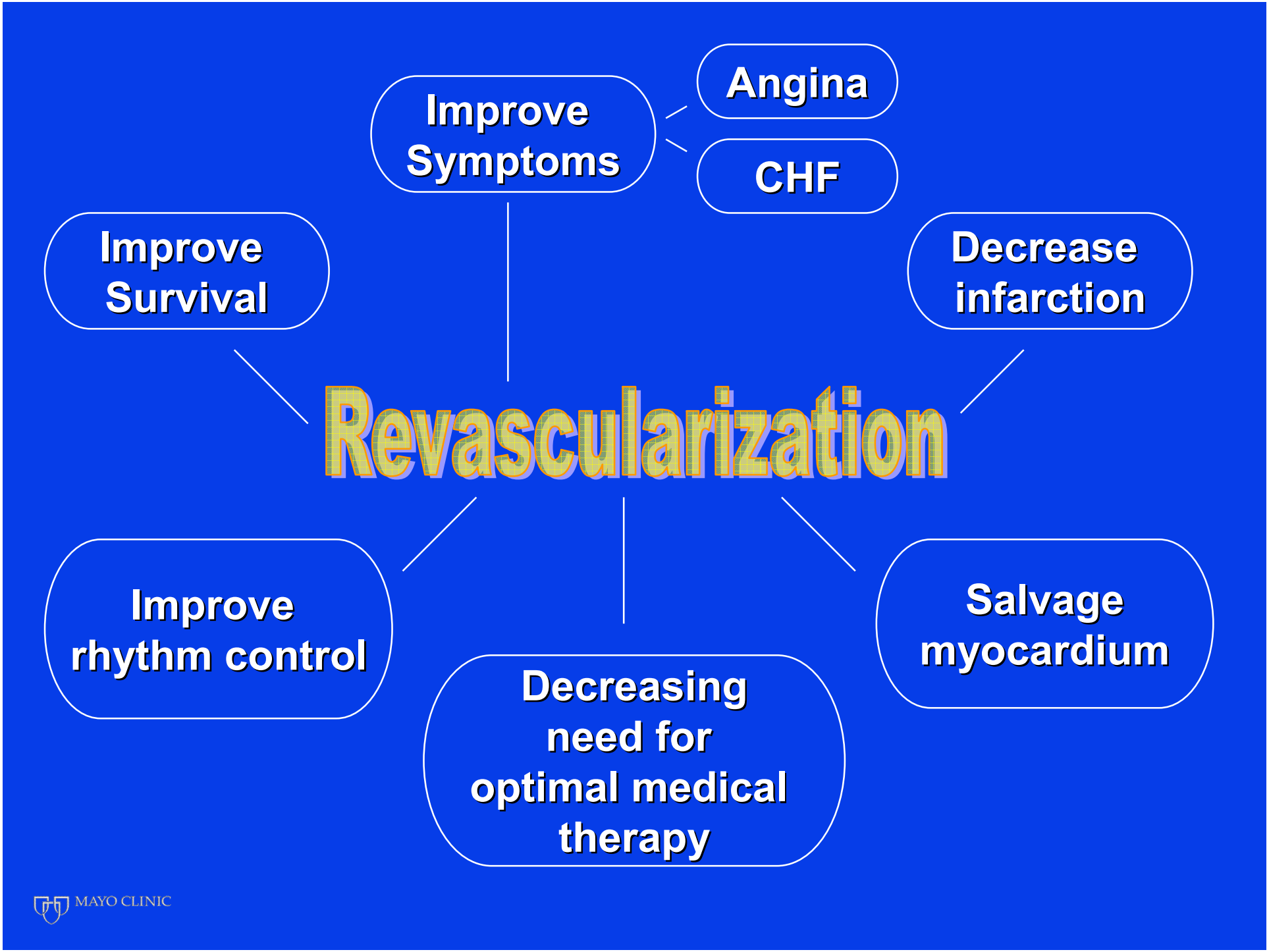
ㄲ	ㄸ	ㅃ	ㅆ	ㅉ
kk	tt	pp	ss	jj

Vowels

ㅏ	ㅑ	ㅓ	ㅕ	ㅗ	ㅛ	ㅜ	ㅠ	ㅡ	ㅣ
a	ya	eo	yeo	o	yo	u	yu	eu	i
father		saw		home		moon		put	meet

ㅐ	ㅒ	ㅔ	ㅖ	ㅘ	ㅙ	ㅚ	ㅝ	ㅞ	ㅟ	ㅢ
ae	yae	e	ye	wa	wae	oe	wo	we	wi	ui
hand		set				wet				

Pronunciations shown here are only rough approximations.


Improve Symptoms
Angina
CHF
Improve Survival
Decrease infarction
Revascularization
Improve rhythm control
Decreasing need for optimal medical therapy
Salvage myocardium
MAYO CLINIC

"In your case, Dave, there's a choice—elective surgery, outpatient medical therapy, or whatever's in the box that our lovely Carol is holding."

Blood is better than drugs for ischemic myocardium

Rahimtoola

The more disease present, the more blood helps

Surgeons can be vicious

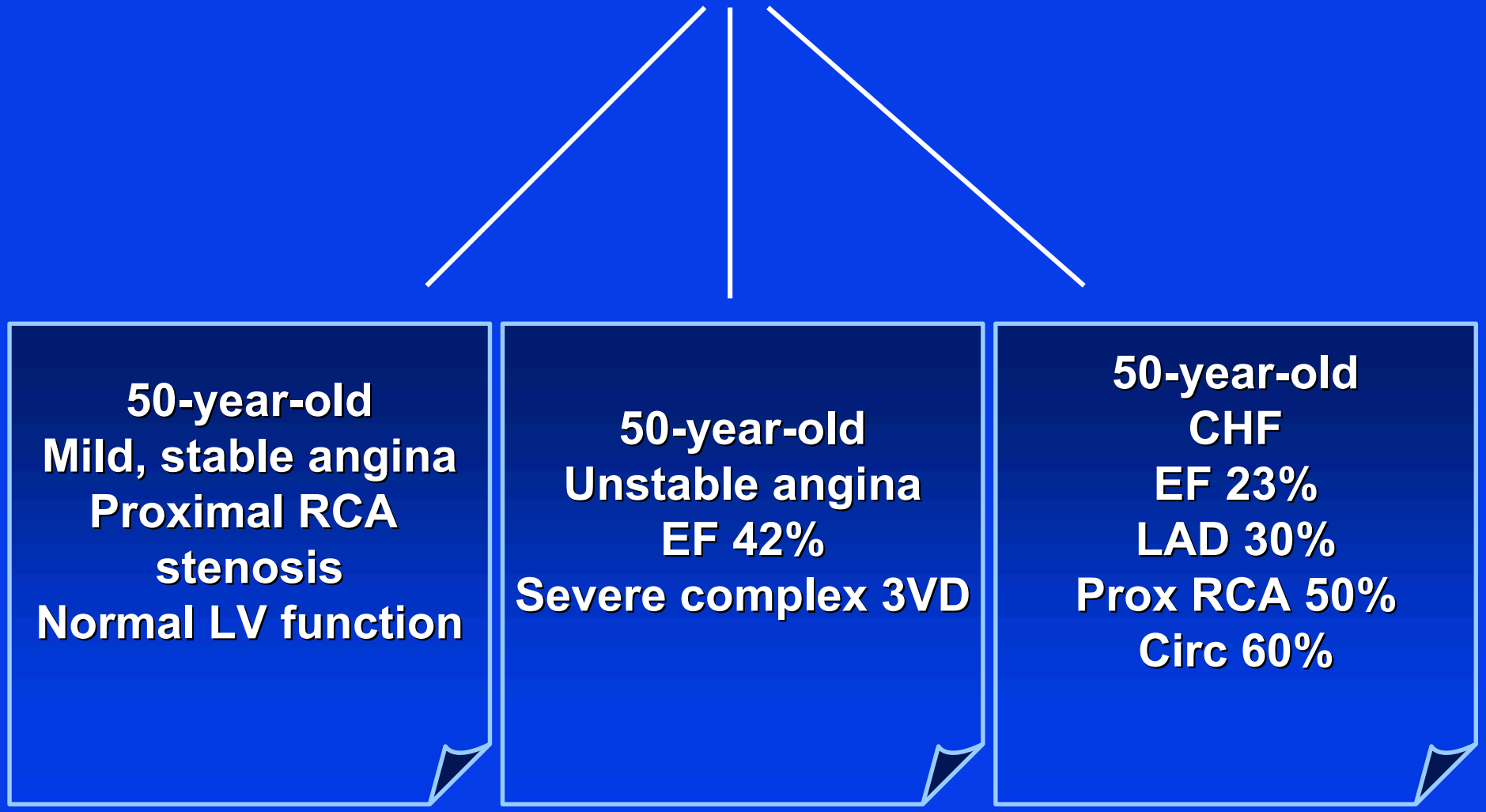
Modified


MAYO CLINIC

Revascularization Strategies Issues

- Patient demographics
- Lesion specifics
- Specific revascularization
- Timing of the specific revascularization
- What are the metrics for comparing these issues?
- At what time do we compare the metrics?

SCENARIOS

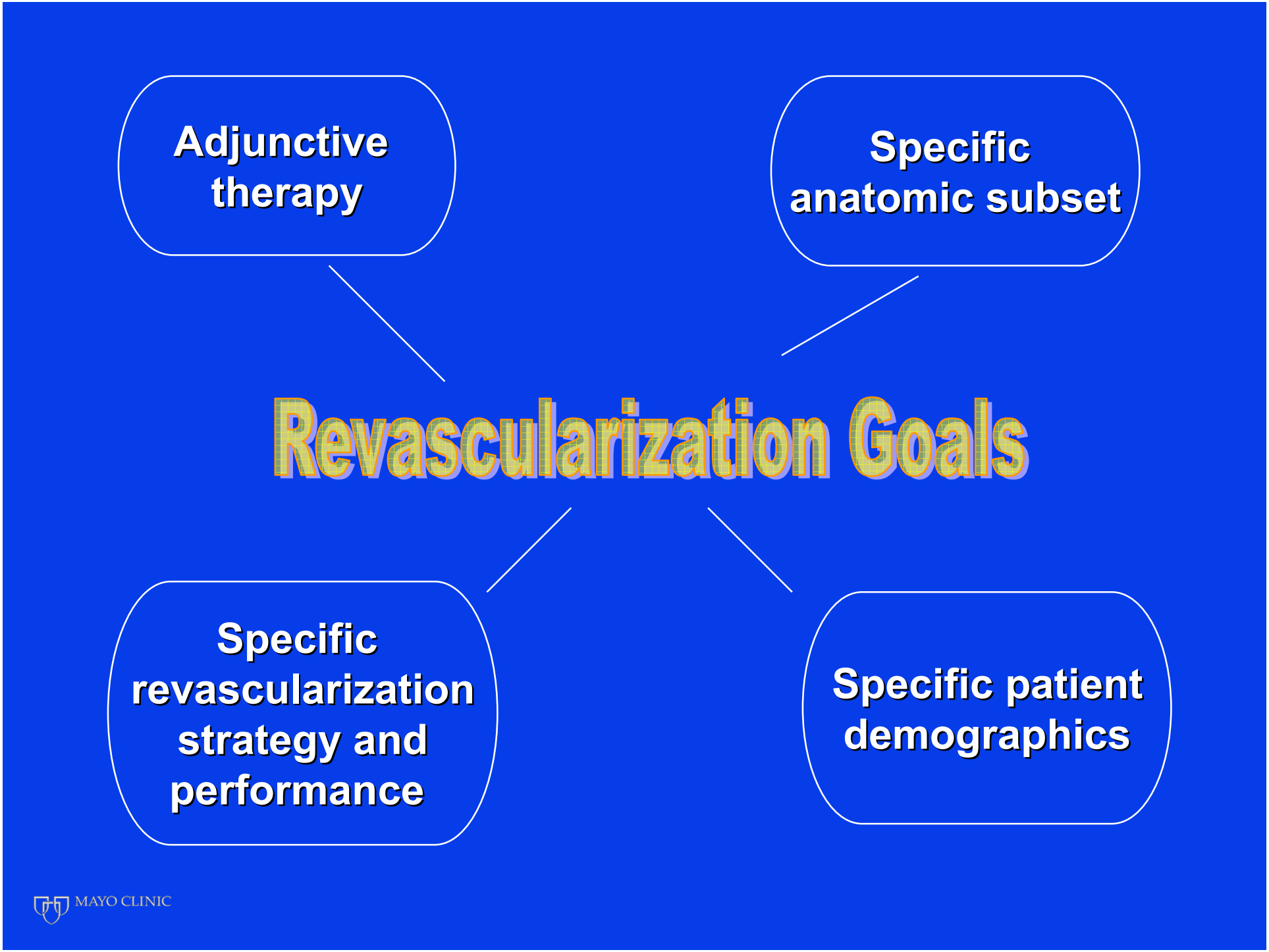

50-year-old
Mild, stable angina
Proximal RCA stenosis
Normal LV function
50-year-old
Unstable angina
EF 42%
Severe complex 3VD
50-year-old
CHF
EF 23%
LAD 30%
Prox RCA 50%
Circ 60%

Revascularization Goals

- Prolong survival
- Reduce infarction
- Reduce CHF
- Alleviate symptoms
- Reduce ischemia
- Reduce repeat hospitalization
- Reduce medical costs

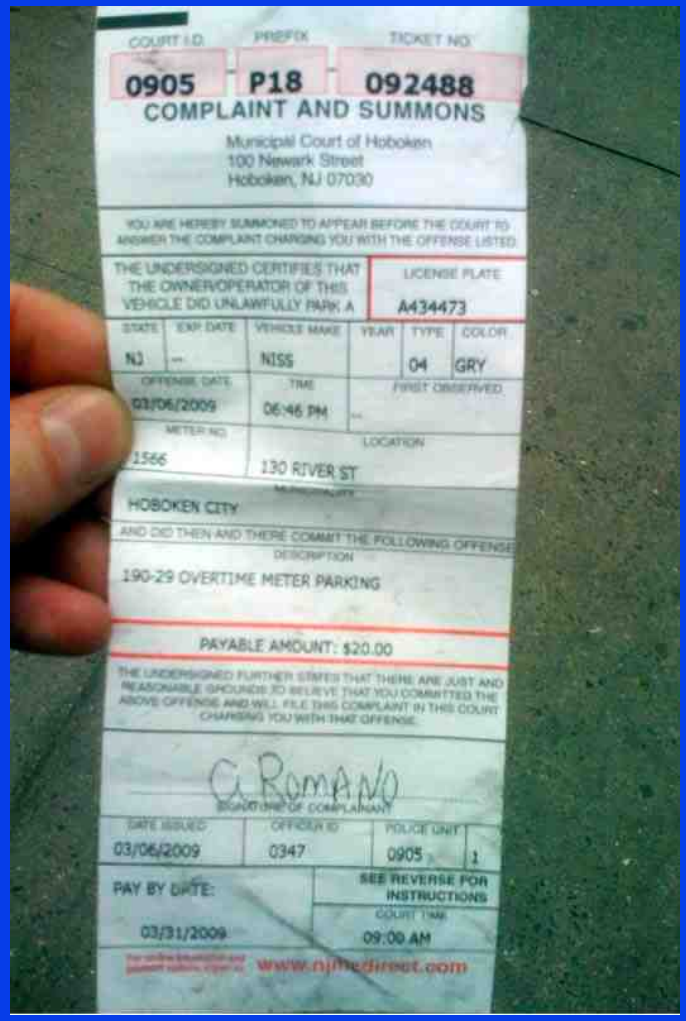
Revascularization Goals

- What is the comparator?
- How long do we compare against what we are comparing with?


Adjunctive therapy
Specific anatomic subset
Revascularization Goals
Specific revascularization strategy and performance
Specific patient demographics

Murder

Parking Ticket

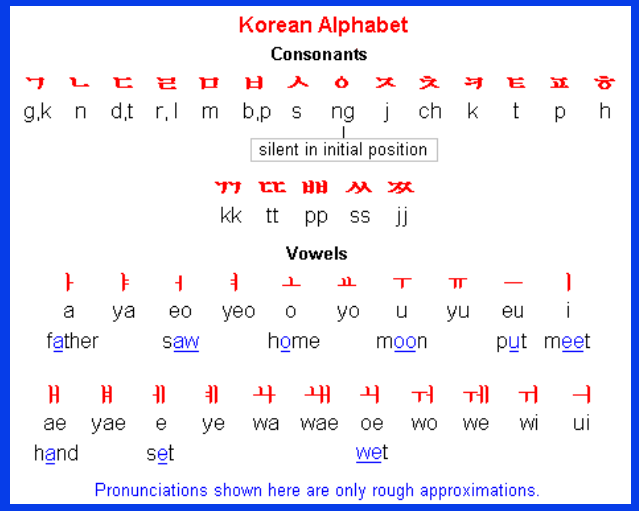


Murder

Parking Ticket

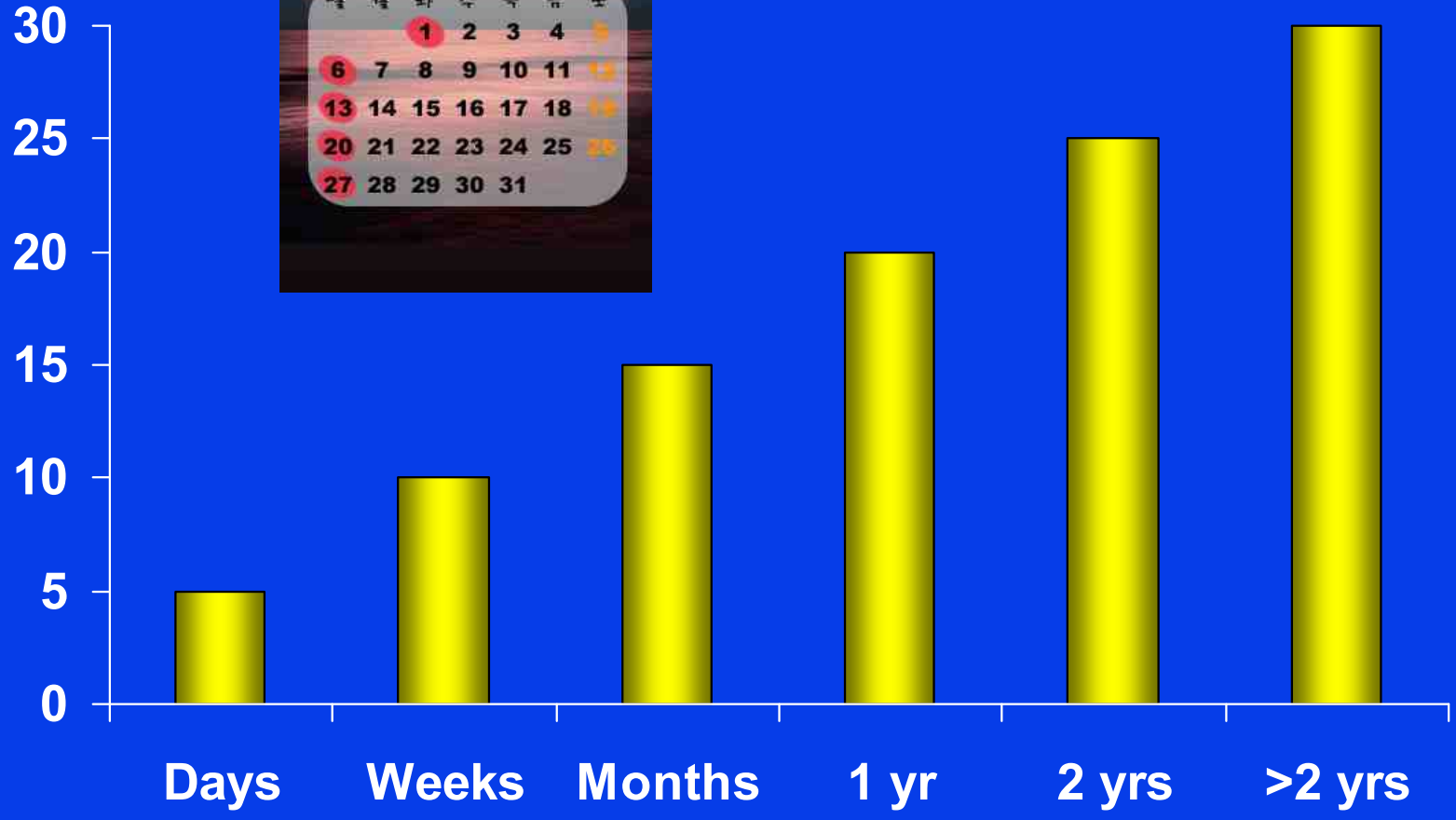
STICH

SYNTAX



BARI 2D


1
일 월 화 수 목 금 토
1 2 3 4
6 7 8 9 10 11
13 14 15 16 17 18
20 21 22 23 24 25
27 28 29 30 31


30
25
20
15
10
5
0
Days
Weeks
Months
1 yr
2 yrs
>2 yrs

MAYO CLINIC

Usefulness of the SYNTAX Score for Predicting Clinical Outcome After Percutaneous Coronary Intervention of

Conclusions: The SXscore is a useful tool to predict cardiac mortality and MACE in patients undergoing percutaneous revascularization of the left main coronary artery.

and the incidence of cardiac mortality, the primary end point of the study, and major adverse cardiac events (MACE). At 1 year, the SXscore significantly predicted the risk of cardiac death (hazard ratio, 1.12/unit increase; 95% CI, 1.06 to 1.18; $P<0.001$) and MACE (hazard ratio, 1.59/unit increase; 95% CI, 1.02 to 2.48; $P=0.043$). After adjustment for potential confounders, a higher SXscore remained significantly associated with cardiac mortality (adjusted hazard ratio, 1.15; 95% CI, 1.05 to 1.26; $P=0.003$) and MACE (adjusted hazard ratio, 1.06; 95% CI, 1.02 to 1.10; $P=0.005$). C-indexes for SXscores in terms of cardiac death and MACE were 0.83 and 0.64, respectively. Using classification tree analysis, discrimination levels of 34 and 37 were identified as the optimal cutoff to distinguish between patients at low and high risk of cardiac death and MACE, respectively.

Conclusions—The SXscore is a useful tool to predict cardiac mortality and MACE in patients undergoing percutaneous revascularization of the left main coronary artery. **(*Circ Cardiovasc Intervent*. 2009;2:302-308.)**

Key Words: SYNTAX score ■ left main coronary artery ■ percutaneous coronary intervention

The SYNTAX score (SXscore) has been recently developed as a combination of several previously validated angiographic classifications aiming to grade the coronary anatomy with respect to the number of lesions and their functional impact, location, and complexity.[1] Higher SXscores, indicative of a more complex condition, are likely to represent a bigger therapeutic challenge and to have a potentially worse prognosis in patients undergoing contemporary revascularization with percutaneous coronary intervention (PCI).

Clinical Perspective on p 308

The predictive value of the SXscore was recently validated on a series of patients undergoing PCI for 3-vessel coronary artery disease in the Arterial Revascularization Therapies Study Part II.[2] However, a validation of this angiographic tool on a restricted series of patients with unprotected left main coronary artery disease undergoing PCI is lacking.

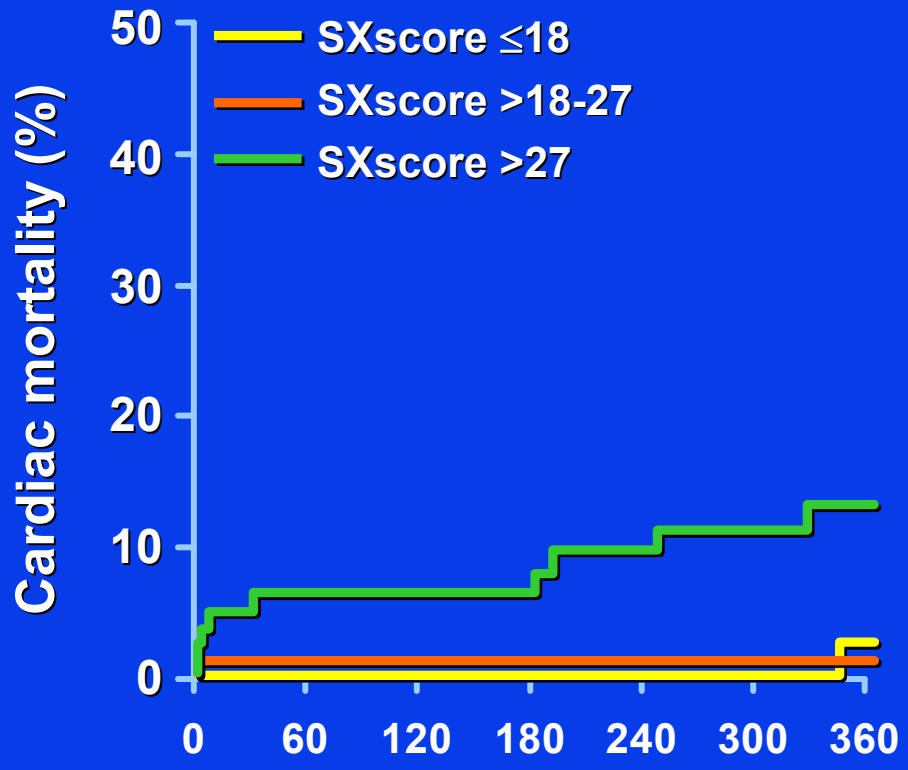
We sought to address this issue by applying the SXscore in patients who underwent percutaneous treatment for left main disease in our institution to examine its prognostic value in predicting in-hospital and long-term clinical outcomes. The performance of the SXscore was also explored in comparison with the modified lesion classification system of the American Heart Association/American College of Cardiology (AHA/ACC).

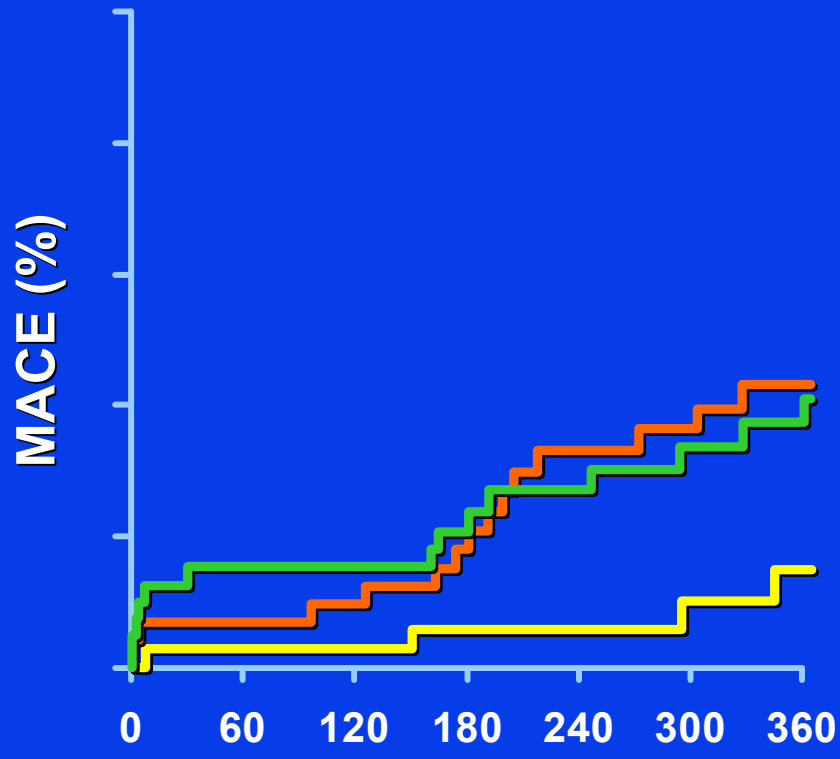
Methods

Patient Population

All consecutive patients undergoing PCI with either a sirolimus-eluting stent (Cypher, Cordis, a Johnson and Johnson Company, Miami Lakes, Fla) or a paclitaxel-eluting stent (Taxus, Boston Scientific, Natick, Mass) in left main coronary artery, from January 2003 to June 2008, at the Ferrarotto Hospital, Italy, were evaluated in this single-center study. The clinical outcome of a number of these patients was reported previously.[3] The left main coronary artery was defined as unprotected if there were no patent coronary artery bypass grafts to the left anterior descending artery or left circumflex artery. A percutaneous approach rather than a surgical one was performed in the presence of suitable anatomy and lesion characteristics for stenting and one of the following conditions: (1) high surgical risk defined as a European system for cardiac operative risk evaluation

SYNTAX and Unprotected LMCA



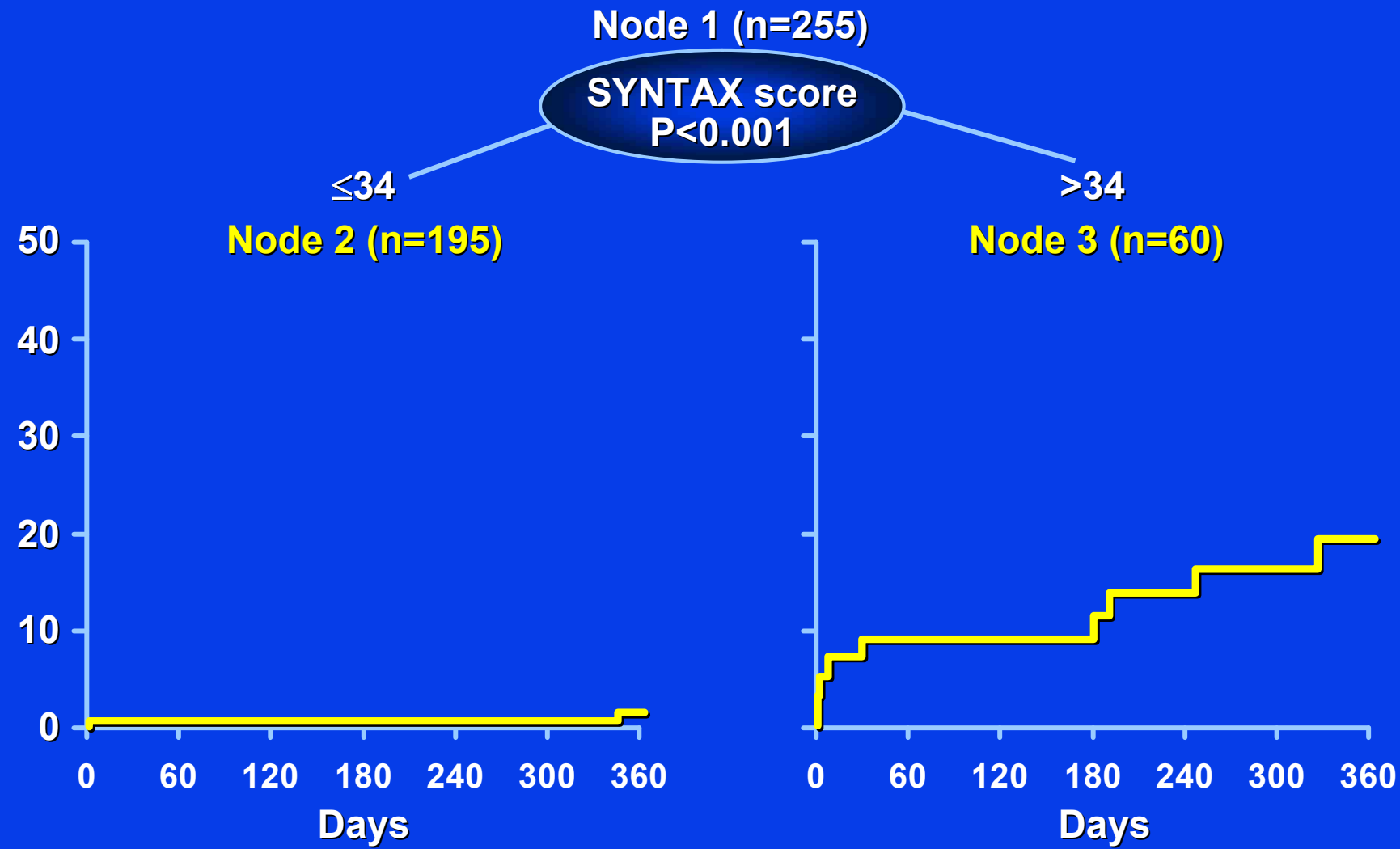


No. at risk			
I tertile	68	49	38
II tertile	71	52	46
III tertile	66	64	46

No. at risk			
I tertile	72	65	39
II tertile	72	54	46
III tertile	70	55	46

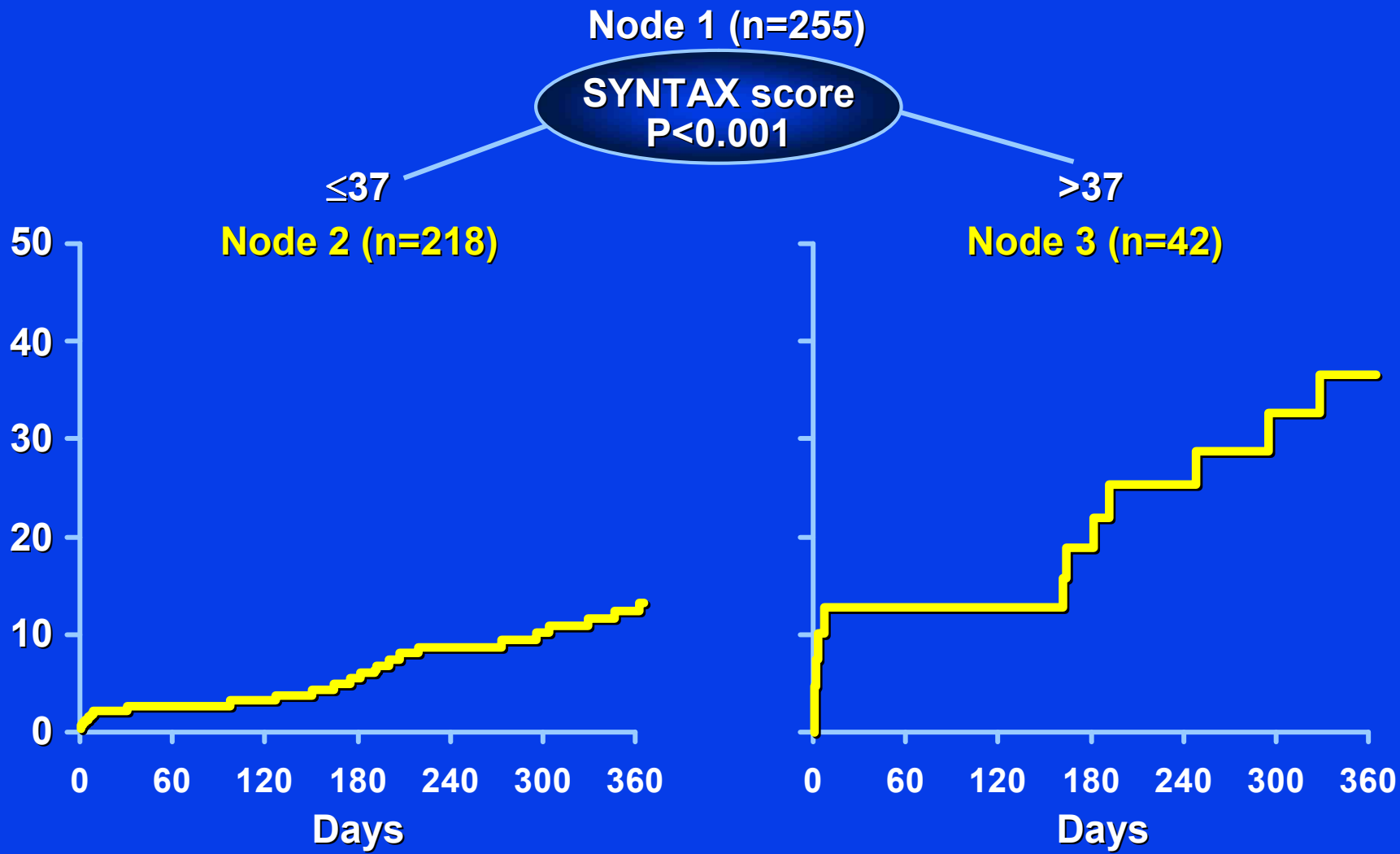
Capodanno D et al: Cardiovasc Intervent 2:302, 2009

SYNTAX and Unprotected LMCA
Cardiac Death



Capodanno D et al: Cardiovasc Intervent 2:302, 2009

SYNTAX and Unprotected LMCA MACE



Capodanno D et al: Cardiovasc Intervent 2:302, 2009

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Sub/drp–Job#: YW105/BK – 3038660

Subject: SYNTAX & Upprot. LMCA, Capodanno

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x, y only

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Subdue: BU31
Footnotes: BU41

PPT shooting instructions
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(4 images)

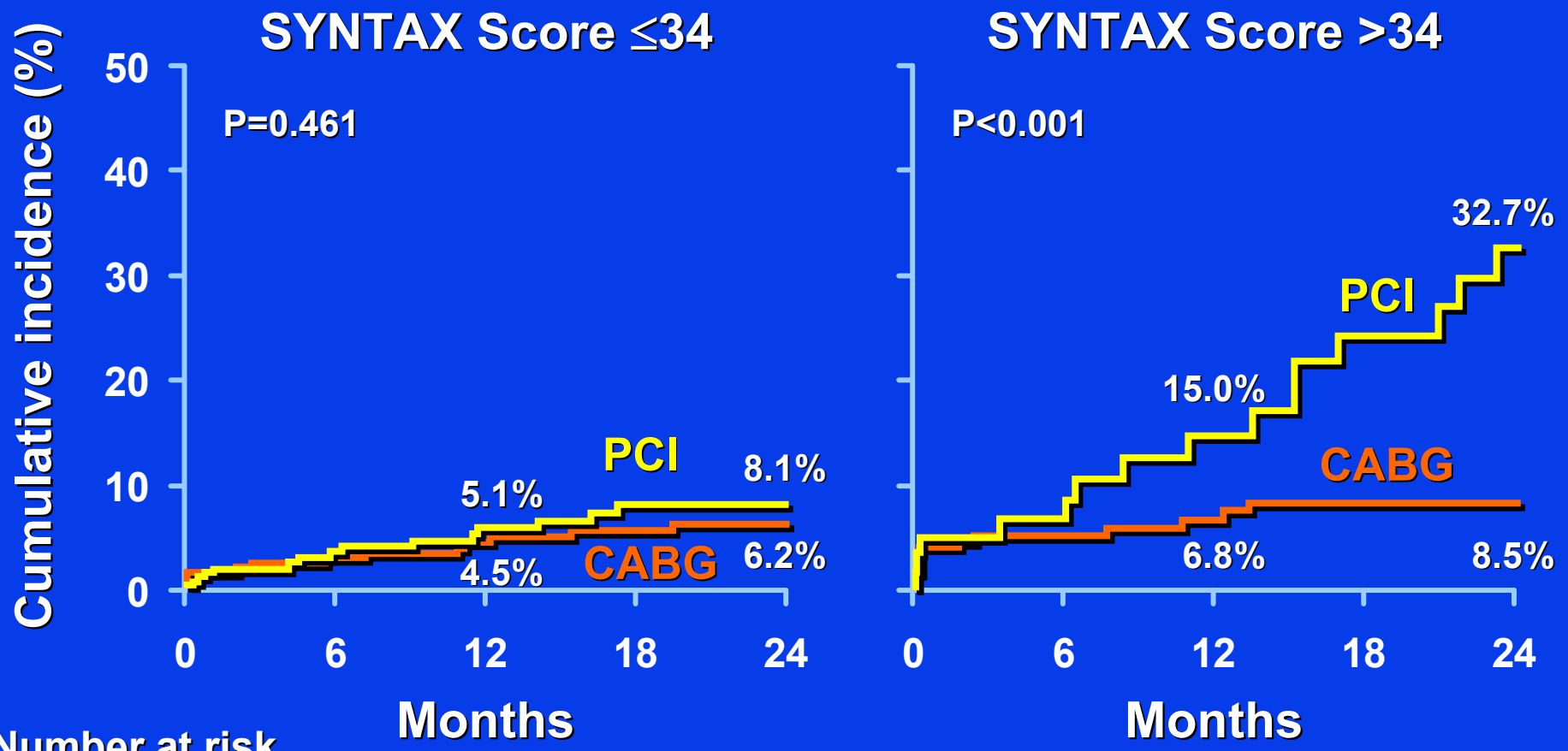
Artist: mls Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

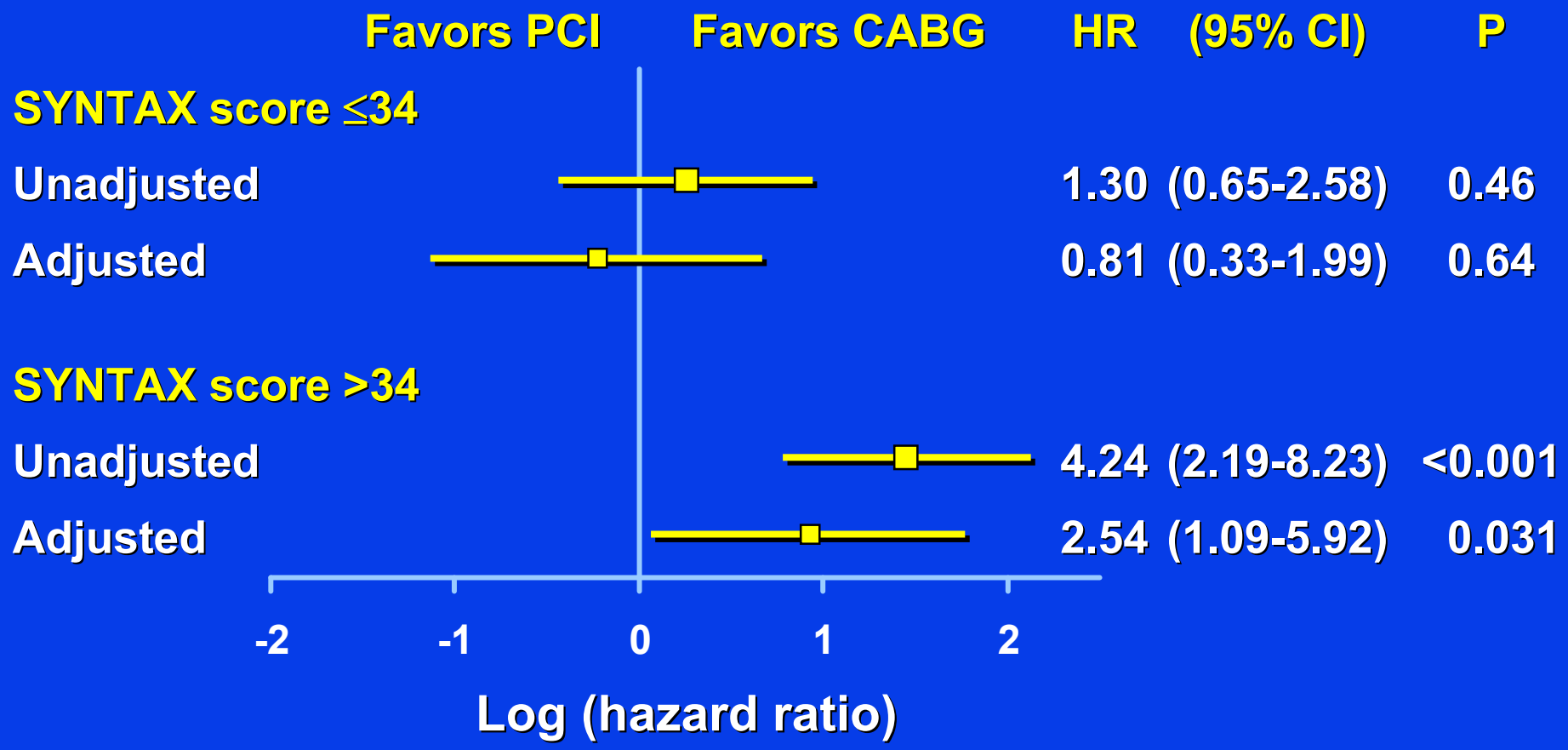
SYNTAX Score and UPLMCA
Unadjusted 2-Year Mortality



Number at risk								
PCI	186	148	124	87	49	39	31	22
CABG	204	186	153	129	145	123	104	96

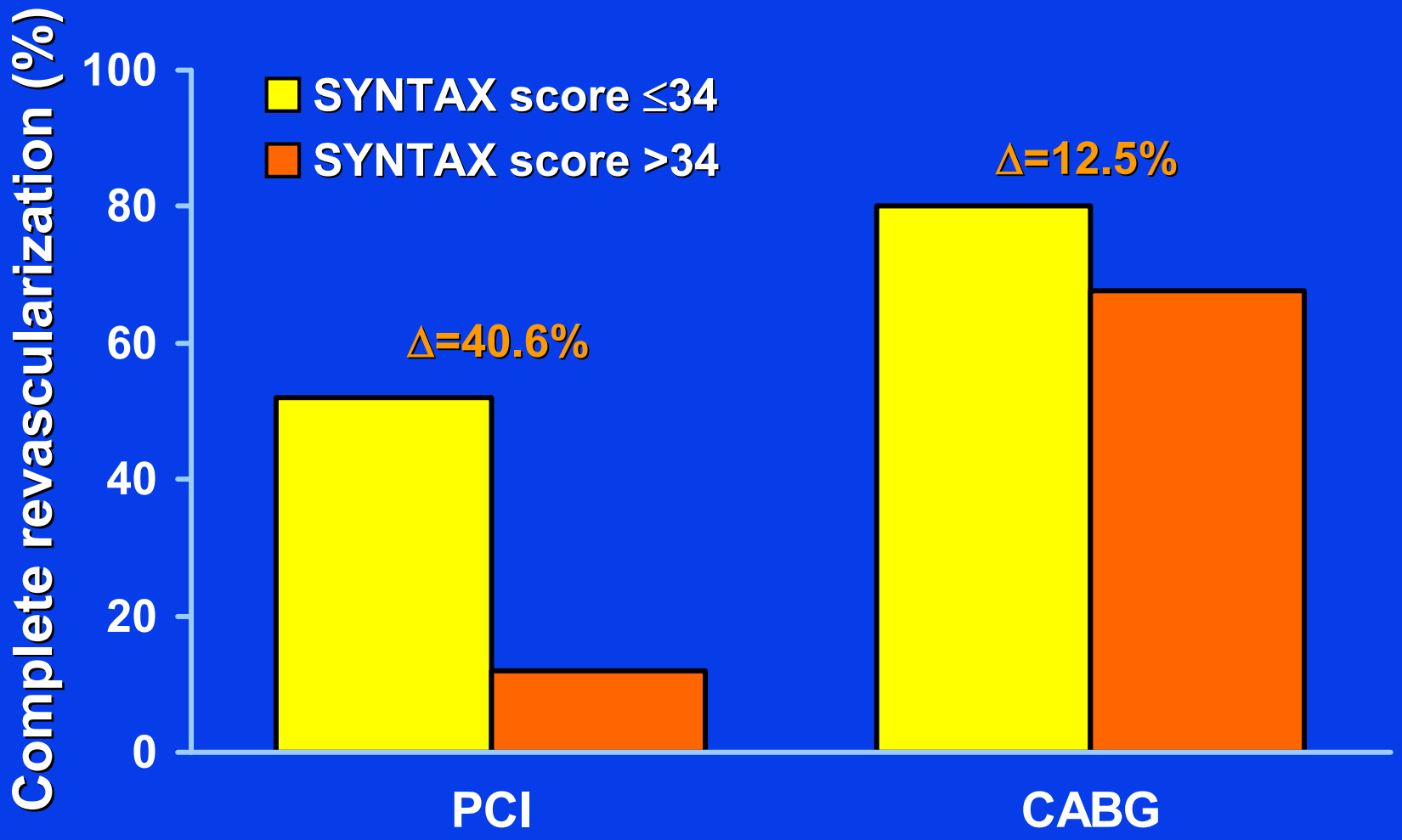
Capodanno D et al: J Am Coll Cardiol Intv 2:731, 2009

SYNTAX Score and UPLMCA
Unadjusted and Adjusted 2-Year RR of Death with PCI or CABG



Capodanno D et al: J Am Coll Cardiol Intv 2:731, 2009

SYNTAX Score and UPLMCA



Capodanno D et al: J Am Coll Cardiol Intv 2:731, 2009

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Subject: SYNTAX Score and UPLMCA, Capodanno

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x, y only

PPT shooting instructions
PPT File to Server
(3 images)

Artist: ma Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

Interventional Cardiology

EuroSCORE refines the predictive ability of SYNTAX score in patients undergoing left main percutaneous

Conclusions: We found a significant improvement in the prediction of cardiac mortality with the inclusion of EuroSCORE in a SYNTAX score-based model. The degree of reclassification between treatment threshold categories indicates that clinical and angiographic information are both important for assessing individual risk of patients undergoing left main PCI.

and angiographic information are both important for assessing individual risk of patients undergoing left main PCI. (Am Heart J 2010;159:103-9.)

In patients with unprotected left main coronary artery disease (CAD), prediction of individual outcomes can assist physicians, patients and their families to achieve a better comprehension of attendant risks and provide an objective basis to select the most appropriate treatment option.[1]

EuroSCORE is a prognostic scoring system developed for patients undergoing cardiac surgery,[2] including those with left main CAD, which has gained wide popularity over time as its performance has been validated in several local populations within and outside Europe.[3] Since most of its variables are derived from the clinical status of the patient, it is not surprising that EuroSCORE can also reasonably stratify into risk categories, although lacking in precision, a population undergoing percutaneous coronary intervention (PCI).[4] Other clinical risk scores have been specifically proposed over the last decade to predict adverse cardiovascular outcome following PCI.[5-9] However, one common concern of using clinical risk scores in the setting of PCI is that they do not incorporate any or a comprehensive information regarding the anatomy and extent of CAD.

SYNTAX score is an emerging tool developed to characterize the coronary vasculature in more detail with respect to the number of lesions and their complexity, functional impact, and location.[10] The performance of SYNTAX score in aiding treatment decision making of patients with complex CAD is encouraging,[11] and its potential for predicting long-term outcomes of PCI patients has also been suggested.[12,13] Whether SYNTAX score should be used as a stand-alone tool or whether its performance may be improved by the parallel use of clinical scores that determine the procedural risk, such as EuroSCORE, is currently unsolved.

To shed more light on the value of a so-called Global Risk Classification (GRC) resulting from merging the angiographic and clinical information contained in the

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E-mail: dcapodanno@gmail.com
0002-8703/$ - see front matter

doi:10.1016/j.ahj.2009.10.021

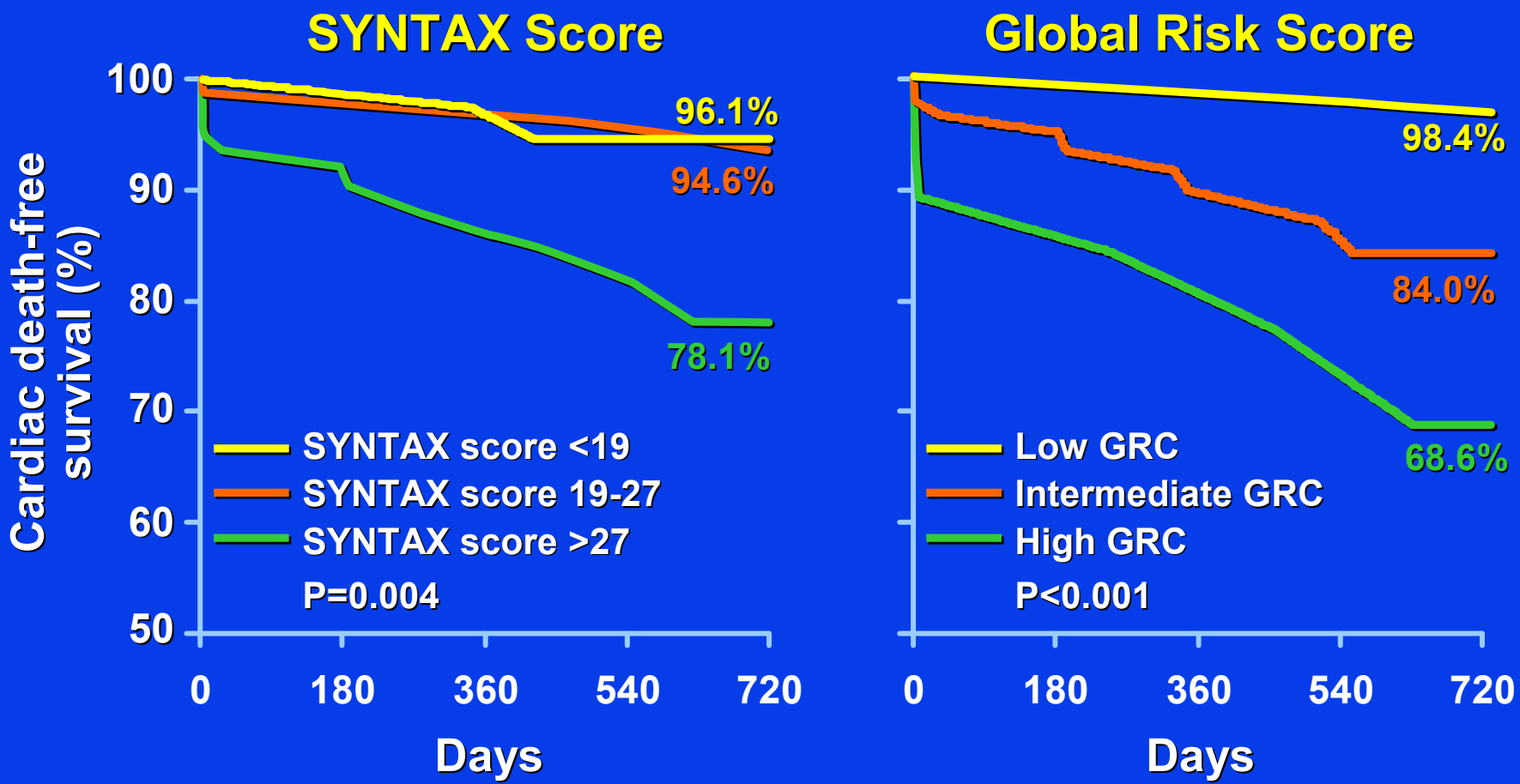
MAYO CLINIC

The Global Risk Score

EuroSCORE	SYNTAX score <19	SYNTAX score 19-27	SYNTAX score >27
0-2	L	L	I
3-6	L	L	I
>6	I	I	H

Capodanno D et al: Am Heart J 159:103, 2010

2-Year Survival



Capodanno D et al: Am Heart J 159:103, 2010

MAYO CLINIC

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3038649

Subject: Euro Score & SYNTAX, Capodanno

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Footnotes: BU41

PPT shooting instructions
PPT File to Server
(3 images)

Artist: mls Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

STICH Trial
Baseline Characteristics

Variable	CABG alone (n=499)	CABG with surgical ventricular reconstruction (n=501)
Demographic characteristics		
Age (yr)		
Median	62	62
Interquartile range	54-69	55-69
Female sex, no. (%)	78 (16)	69 (14)
Medical history		
MI, no. (%)	435 (87)	437 (87)
Diabetes, no. (%)	173 (35)	171 (34)
Chronic renal insufficiency	42 (8)	43 (9)
Stroke, no. (%)	28 (6)	28 (6)
Angina class		
III	203 (41)	205 (41)
IV	45 (9)	39 (8)
NY Heart Assoc HF class		
III	210 (42)	218 (44)
IV	31 (6)	26 (5)

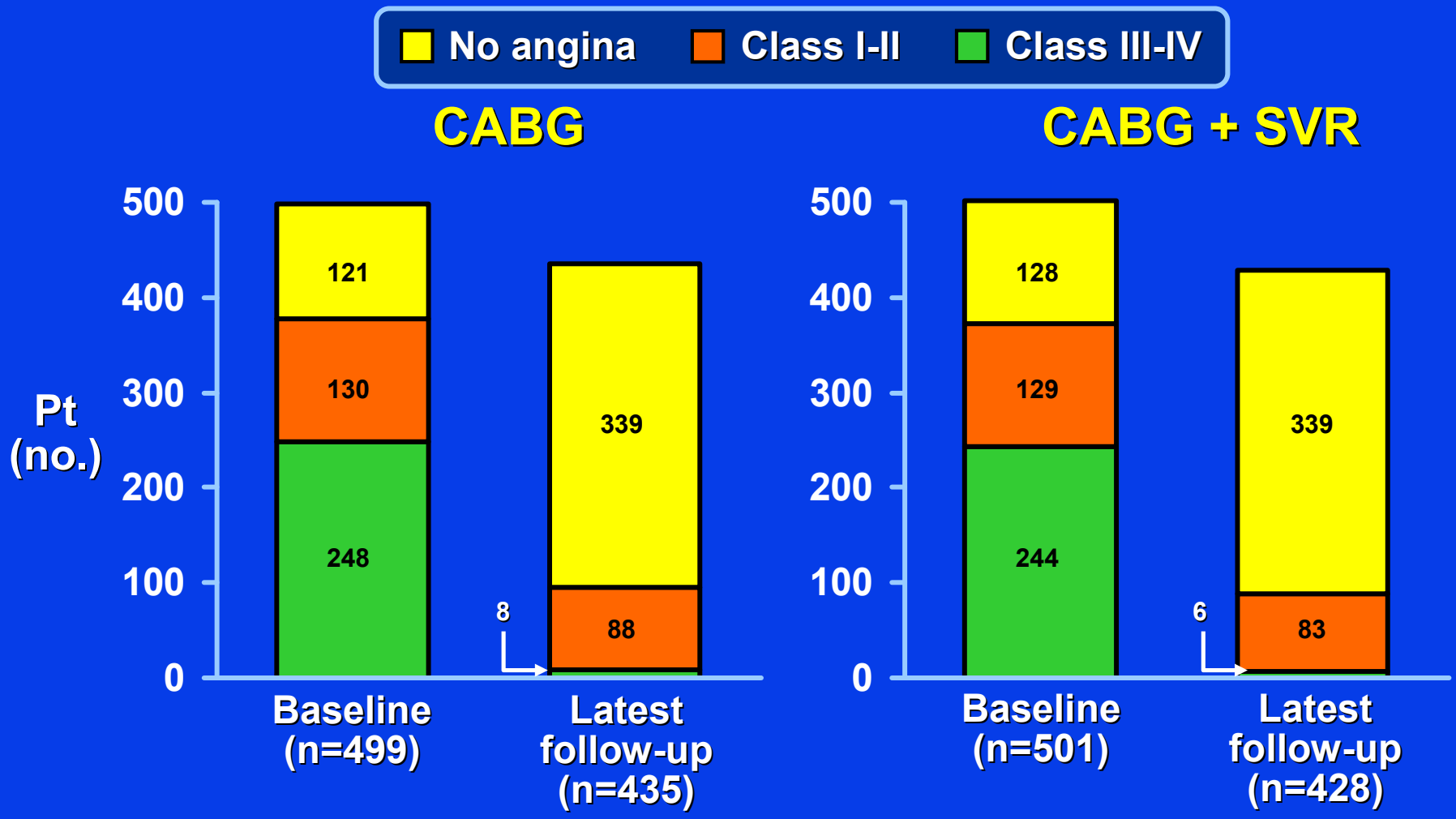
Jones RH et al: N Engl J Med 360:1705, 2009

STICH Trial
Baseline Characteristics

Variable	CABG alone (n=499)	CABG with surgical ventricular reconstruction (n=501)
Coronary anatomy		
No. of vessels with stenosis of ≥50%, no. (%)		
1	36 (7)	51 (10)
2	144 (29)	131 (26)
3	319 (64)	319 (64)
Stenosis of left main coronary artery, no. (%)		
50-74%	72 (14)	61 (12)
≥75%	31 (6)	33 (7)
≥75% stenosis of proximal LAD coronary artery, no. (%)	388 (78)	369 (74)

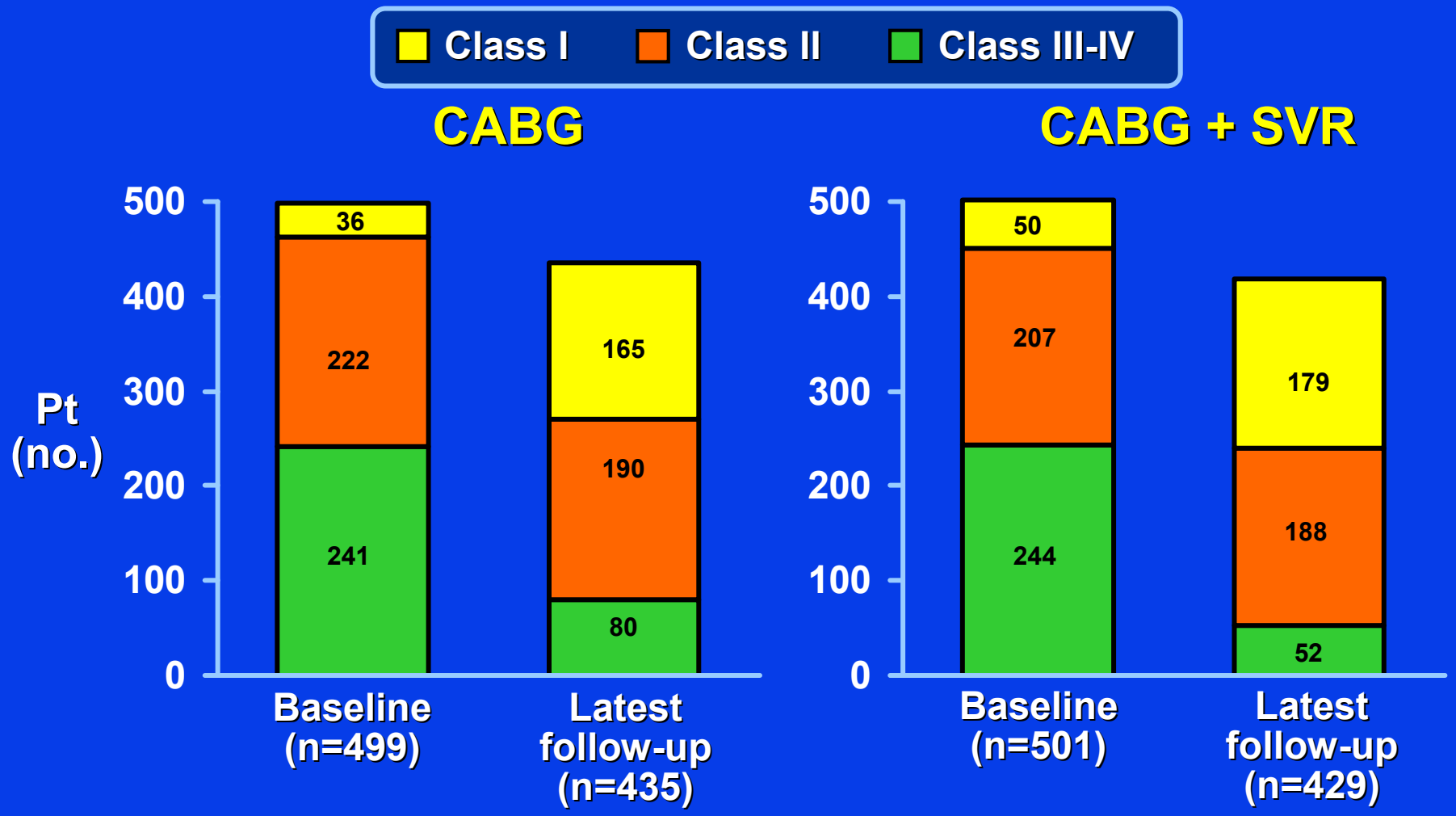
Jones RH et al: N Engl J Med 360:1705, 2009

STICH Trial
CCS Angina Class



Jones RH et al: N Engl J Med 360:1705, 2009

STICH Trial
NYHA Heart Failure Class



Jones RH et al: N Engl J Med 360:1705, 2009

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3039583

Subject: STICH Trial

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Footnotes: BU41

PPT shooting instructions
PPT File to Server
(7 images)

Artist: mls
Start Date: 4-15-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 2, NO. 5, 2009
© 2009 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
ISSN 1936-8798/09/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2009.01.009

Conclusions: The majority of diabetic patients with multivessel disease were selected for PCI rather than CABG. Preference for CABG over PCI was largely based on angiographic features related to the extent, location, and nature of CAD, as well as geographic, demographic, and clinical factors. (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes [BARI 2D]; NCT00006035)

of coronary artery bypass graft (CABG) surgery versus percutaneous coronary intervention (PCI) in diabetic patients with multivessel coronary artery disease (CAD) in the BARI 2D (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes) trial.

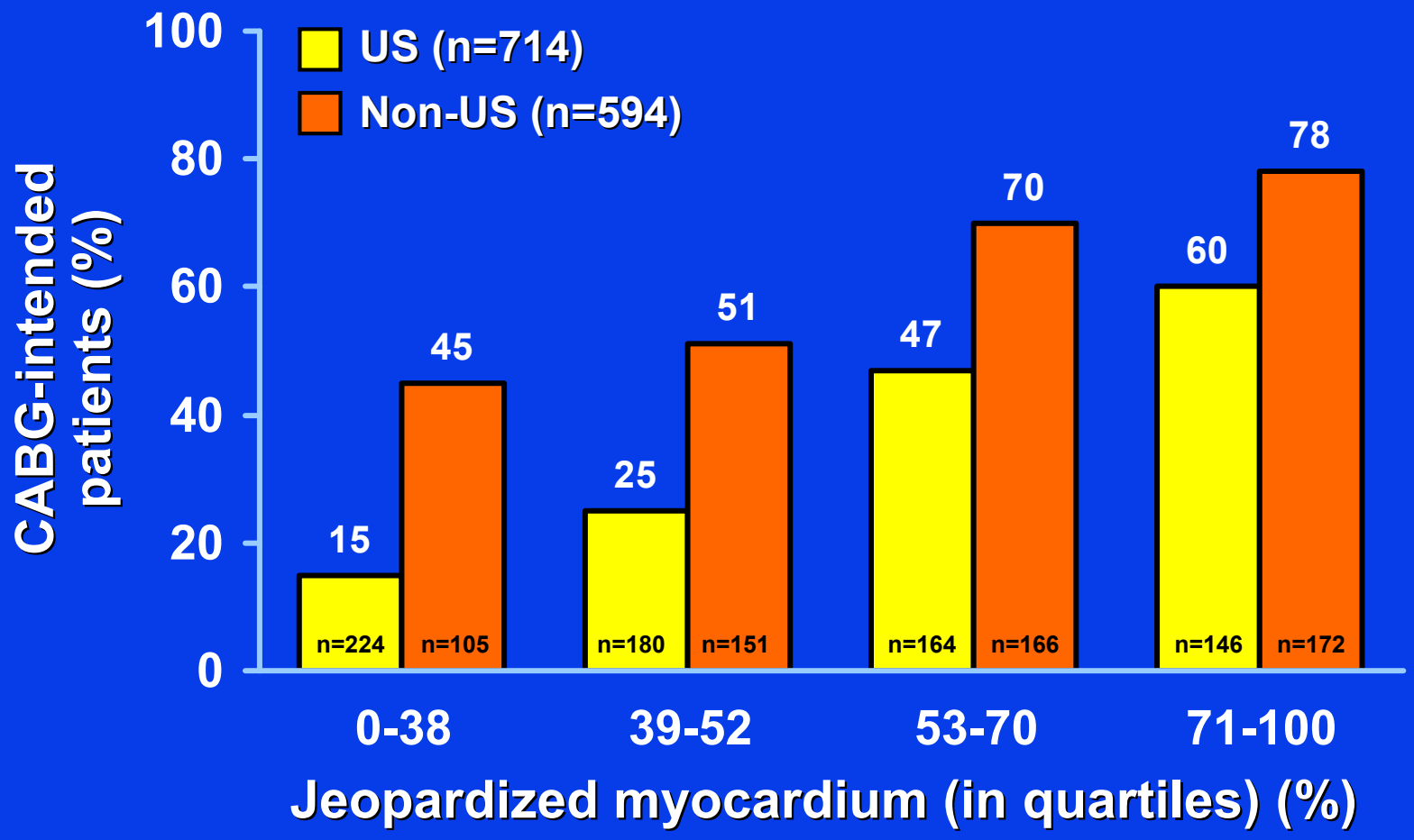
Background Factors guiding selection of mode of revascularization for patients with diabetes mellitus and multivessel CAD are not clearly defined.

Methods In the BARI 2D trial, the selected revascularization strategy, CABG or PCI, was based on physician discretion, declared independent of randomization to either immediate or deferred revascularization if clinically warranted. We analyzed factors favoring selection of CABG versus PCI in 1,593 diabetic patients with multivessel CAD enrolled between 2001 and 2005.

Results Selection of CABG over PCI was declared in 44% of patients and was driven by angiographic factors including triple vessel disease (odds ratio [OR]: 4.43), left anterior descending stenosis ≥70% (OR: 2.86), proximal left anterior descending stenosis ≥50% (OR: 1.78), total occlusion (OR: 2.35), and multiple class C lesions (OR: 2.06) (all $p < 0.005$). Nonangiographic predictors of CABG included age ≥65 years (OR: 1.43, $p = 0.011$) and non-U.S. region (OR: 2.89, $p = 0.017$). Absence of prior PCI (OR: 0.45, $p < 0.001$) and the availability of drug-eluting stents conferred a lower probability of choosing CABG (OR: 0.60, $p = 0.003$).

Conclusions The majority of diabetic patients with multivessel disease were selected for PCI rather than CABG. Preference for CABG over PCI was largely based on angiographic features related to the extent, location, and nature of CAD, as well as geographic, demographic, and clinical factors. (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes [BARI 2D]; NCT00006305) (J Am Coll Cardiol Intv 2009;2: 384–92) © 2009 by the American College of Cardiology Foundation

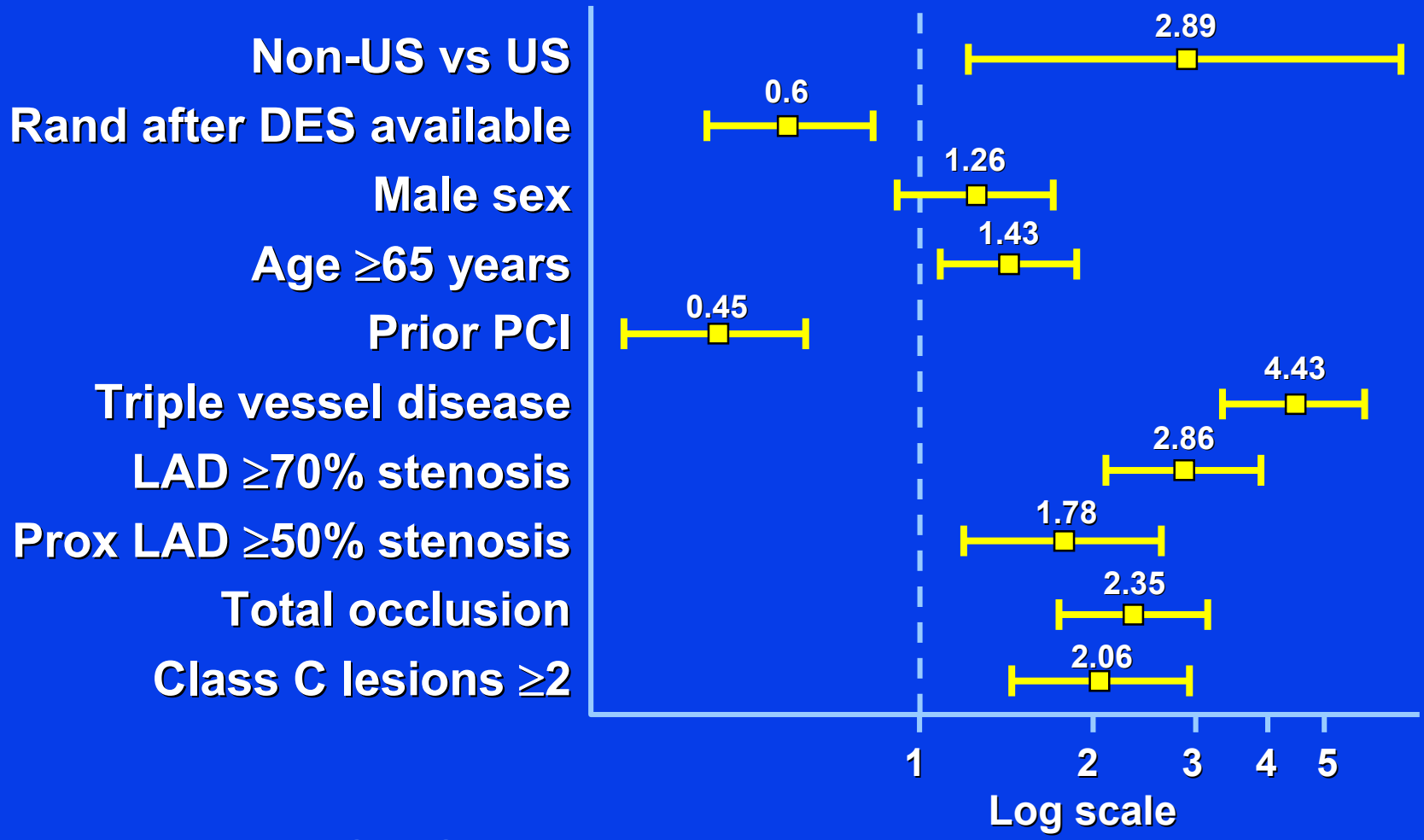
BARI 2D



Kim LJ et al: J Am Coll Cardiol Intv 2:384, 2009

MAYO CLINIC

Selection of CABG Rather than PCI



Kim LJ et al: J Am Coll Cardiol Intv 2:384, 2009

MAYO CLINIC

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3038666

Subject: BARI 2D Kim

Background: BU3
Banner/brdr: 0-40-159/BU41
Side title: YW105
• /colhdgs: YW105
Text: WT/BK
Highlight: YO114
Subdue: BU31
Footnotes: BU41

Plot/brdr: open/BU41
x, y only

PPT shooting instructions
PPT File to Server
(3 images)

Artist: mls Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

Stable Angina Should be Approached with PCI

14th Annual 2009 Cardiology at Cancun
February 2009

David R. Holmes, MD
Mayo Clinic
Rochester, MN

MAYO CLINIC

Presenter Disclosure Information

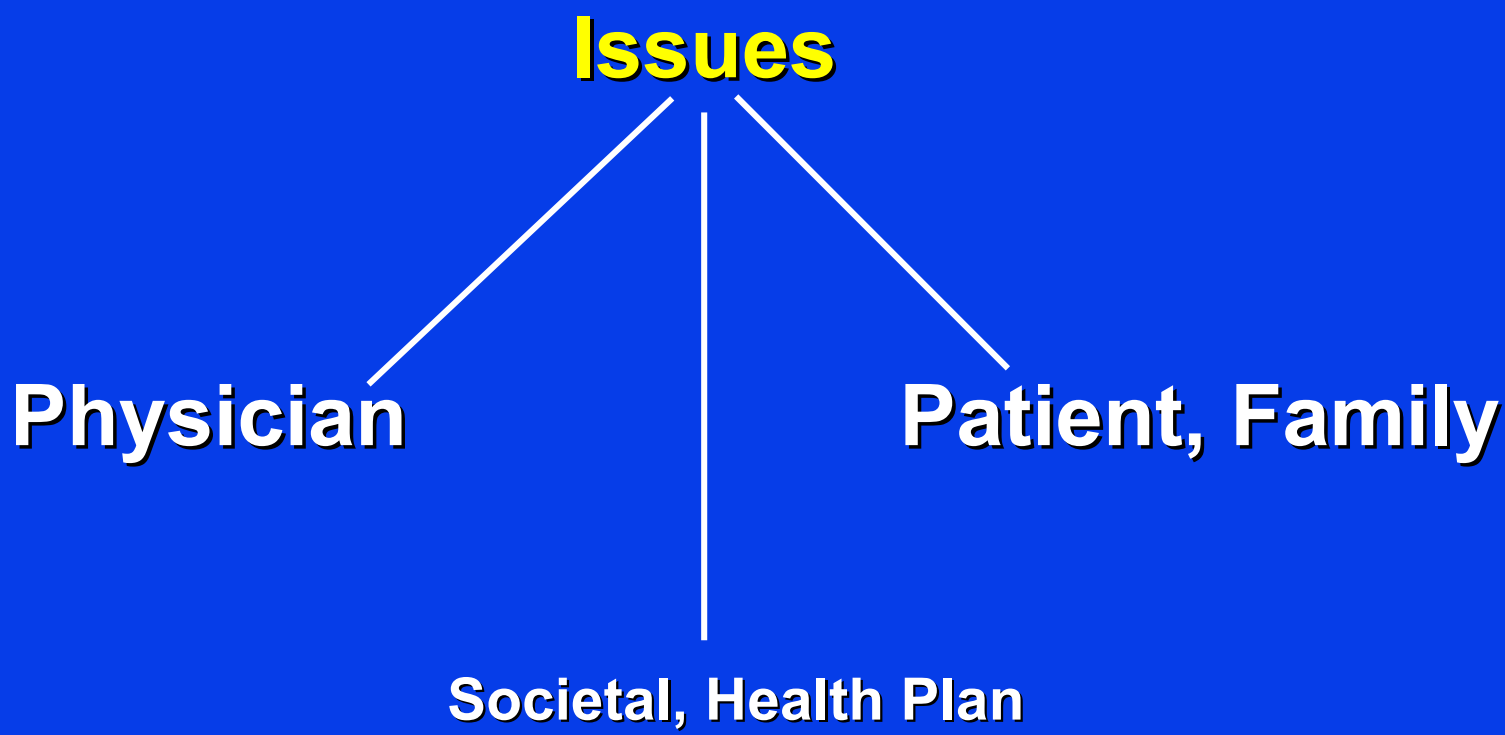
David R. Holmes, Jr., M.D.

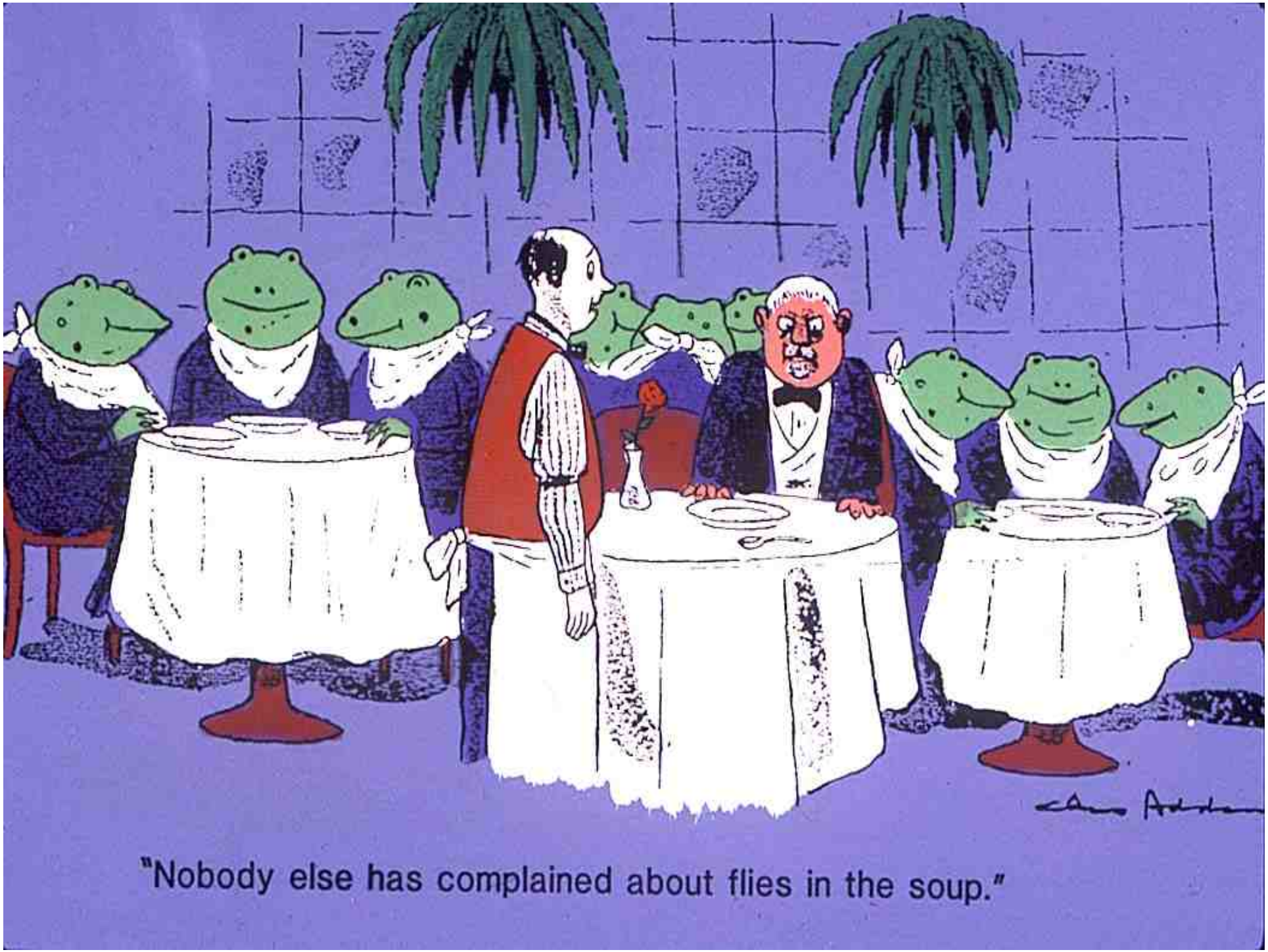
"Stable Angina Should be Approached with PCI"

The following relationships exist related to this presentation:

No relationships to disclose

How Do We Choose




"Nobody else has complained about flies in the soup."

Expectations

- Economic stimulus package will work
- The bathing suit will cover as well as it used to
- The sun will shine in Cancun while we are there
- I will not get a headache from the Tequila

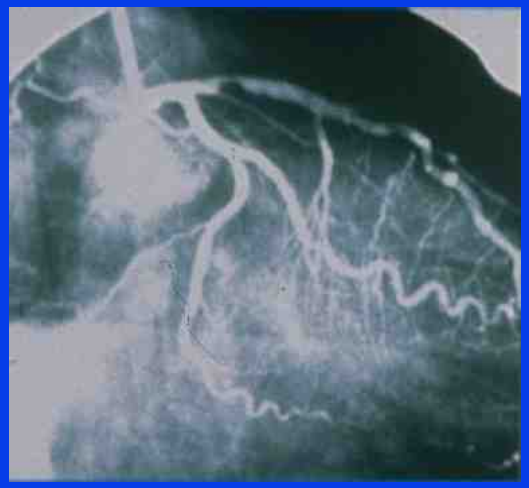
Mr. or Mrs. Mainstreet

- Want to live forever
- Want good health and thinness without sweat or carrot sticks
- Want to avoid a heart attack or death
- Most of all, want to avoid a stroke
- Want to go to heaven
- Certainly want to avoid surgery
- Would be nice if it improved their skills at shopping, bargain hunting, golf or fishing

Willpower lasts about 30 days and is soluble in alcohol

Which Would You Rather Have?

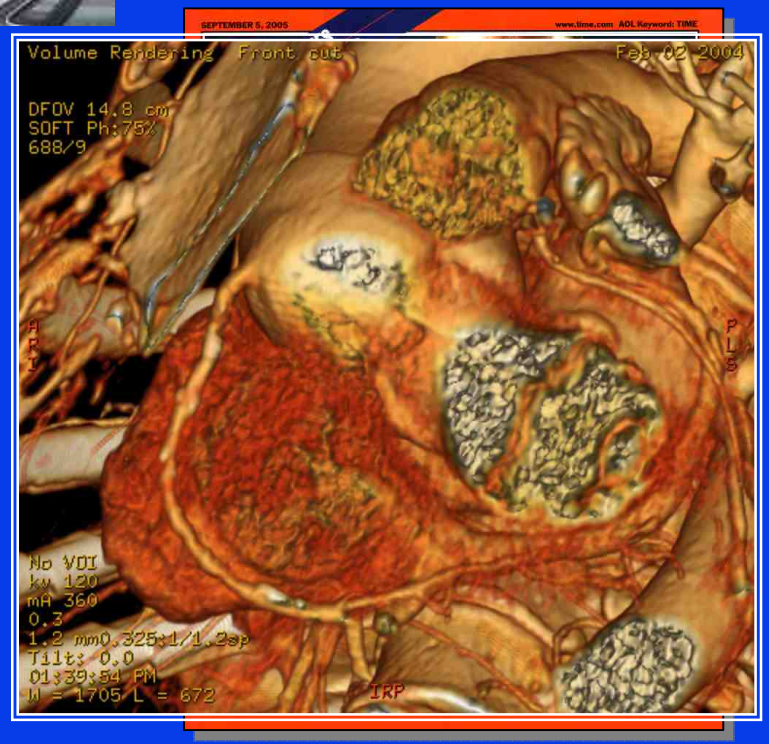
	Option A		Option B
LAD	70		0
RCA	20		20
Circ	10		10



Coated Stent

High dose statin

Increasingly Common

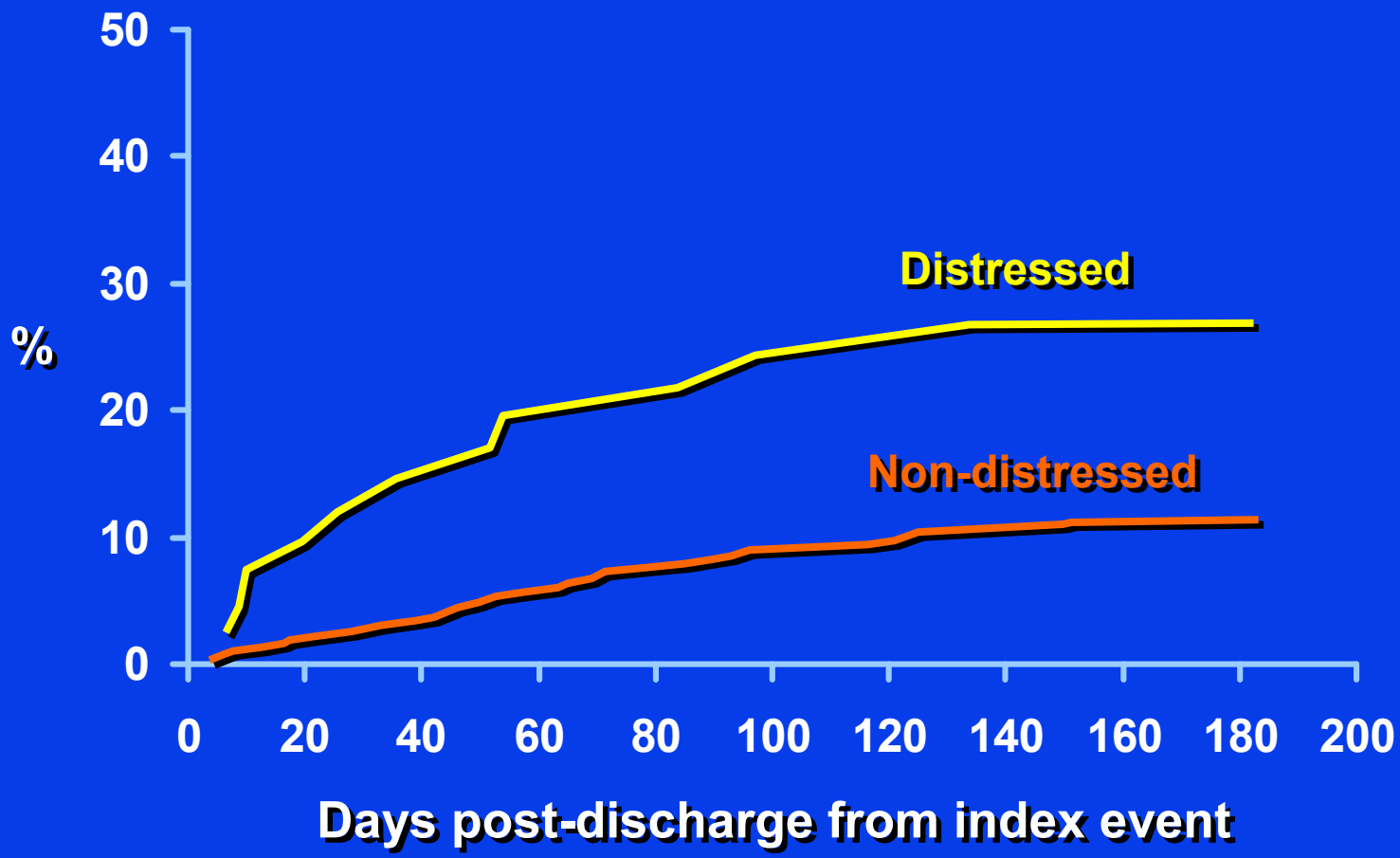


Psychologic Distress and CAD

- 381 patients (311 men, 70 women) referred for cardiac rehabilitation
- Assessment of psychologic distress using self report inventory (SCL – 90 – R)
- Distressed defined as SCL – 90 – R scores >90% for outpatient adults

Gau GT et al: Mayo Clin Proc 70:734-42, 2007

Cumulative Risk of Early Cardiovascular Rehospitalization



Gau GT et al: Mayo Clin Proc 70:734, 2007

MAYO CLINIC

CP1291758-1

Psychologic Distress and CAD

Psychologic distress adversely affects the prognosis of CAD patients

Gau GT et al: Mayo Clin Proc 70:734-42, 2007

We Can Help You...

Avoid a Stroke

In Just 10 Minutes

- Stroke is America's third leading killer.
- Stroke is the #1 cause of nursing home admissions.

Unfortunately, half of all stroke victims have no warning signs before a stroke occurs! Don't delay; sign up for a painless screening today!

Life Line Screening is America's Leading provider of quality health screenings. Since 1993, we have provided quick, painless and affordable vascular screenings to more than 2.5 million people.

Our mobile units are coming to neighborhoods across the country – SO CALL NOW!

We provide these non-invasive, completely painless screenings using Doppler ultrasound technology.

1 Stroke Screening/ Carotid Artery

Visualizes the buildup of fatty plaque in the carotid arteries which leads to stroke.

2 Abdominal Aortic Aneurysm (AAA) Screening

Visualizes the existence of an aneurysm (enlargement) in the abdominal aorta that could lead to a ruptured aortic artery.

3 Peripheral Arterial Disease Screening

Screens for peripheral arterial disease (plaque buildup) in the lower extremities which is linked to coronary artery disease.

4 Osteoporosis Screening

Screens for abnormal bone mass density in men and women. Osteoporosis is painless and silent in its early stages.

MAYO CLINIC

CP1190979-1

Patient Expectations

USA TODAY

The key to surviving a heart attack is promptly recognizing the warning signals and getting immediate medical attention.

Montana Heart Center

- Do Not Delay Seeking Treatment. It Could Save Your Life.
- The Quicker You Seek Treatment Following Symptoms, The Better The Outcome!

Treating A Heart Attack - Dealing With A Heart Attack: Heart Disease

If you have a heart attack and reach the hospital in time, chances are very good that you will walk out of the hospital within a week or even sooner. (provided by the Faculty of the Harvard Medical School)

Fast Action Saves Lives

Calling 9-1-1 is the fastest way to get lifesaving treatment. If you or someone you are with has any symptoms of a heart attack, call 9-1-1 immediately

MAYO CLINIC

Patient Expectations

If I or my spouse recognizes heart symptoms on time and gets me to the cardiologist and the cardiologist says it is my heart and that he/she can treat it, then that treatment will save my life.

PCI
What do we know?

- Treatment of choice for acute STEMI; documented to decrease death and recurrent MI
- Improves outcome in selected patients with ACS
- Reduces ischemia and symptoms in selected patient subsets

PCI
What do we know?

- It is not perfect
- It treats only the treated area
- It has the potential for ST or restenosis which while uncommon still occurs
- It does not do much to reduce weight, stop smoking, exercise, control BP, decrease BS or improve lipids

Aphorism

Blood is better than drugs for the ischemic myocardium

A burglar broke into a house one night. He shined his flashlight around, looking for valuables; and when he picked up a CD player to place in his sack, a strange, disembodied voice echoed from the dark saying,

Jesus is watching you

He nearly jumped out of his skin, clicked his flashlight off, and froze.

When he heard nothing more after a bit, he shook his head, promised himself a vacation after the next big score, then clicked the light on and began searching for more valuables.

Just as he pulled the stereo out so he could disconnect the wires, clear as a bell he heard,

Jesus is watching you

Freaked out, he shined his light around frantically, looking for the source of the voice.

Finally, in the corner of the room, his flashlight beam came to rest on a parrot.

“Did you say that?” he hissed at the parrot.

“Yep”, the parrot confessed, then squawked, “I’m just trying to warn you”.

The burglar relaxed, “Warn me, huh? Who in the world are you?”

“Moses”, replied the bird.

“Moses?’ the burglar laughed. What kind of people would name a bird Moses?”

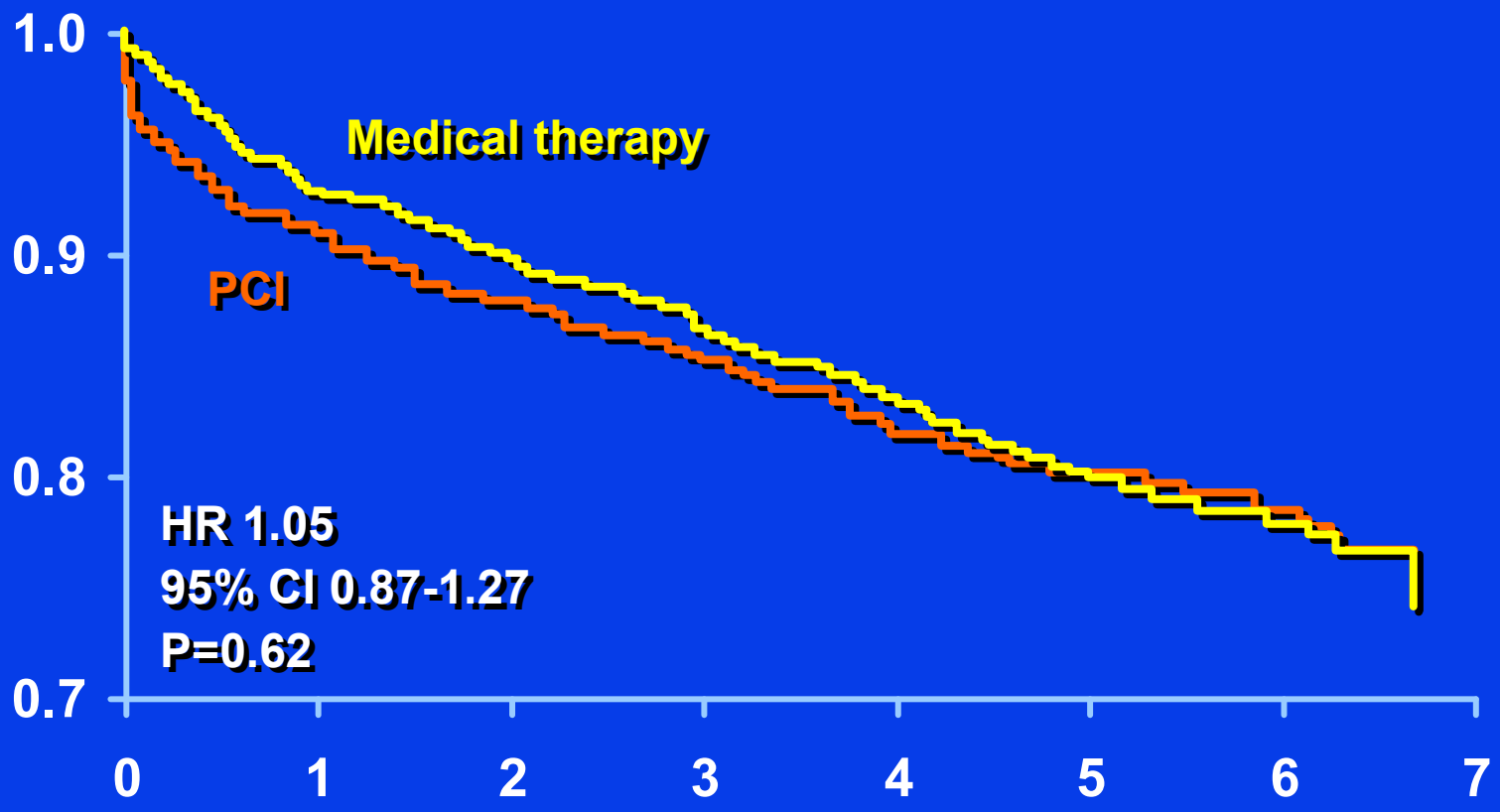
“The kind of people that would name a Rottweiler Jesus”.

COURAGE Trial

- Multicenter randomized clinical trial
- Screened 35,539 patients
- 2,287 patients randomized
  - Objective evidence of myocardial ischemia
  - Stable angina
- Randomization
  - PCI + optimal medical therapy vs
  - Optimal medical therapy

Boden WE, NEJM 2007; 356:1503-16

Survival Free of Death from Any Cause and MI



No. at risk							
1,138	1,017	959	834	638	408	192	30
1,149	1,013	952	833	637	417	200	35

NEJM 356(15):1512, 2007


COMMERCIALS

COURAGE Trial
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.

Boden WE, NEJM 2007; 356:1503-16

Paul Harvey
The Rest of the Story

Outcome	No. of Events		HR (95% CI)	P
	PCI Group	Med-Rx Group		
Revasc (PCI or CABG)	228	348	0.60 (0.51-0.71)	<0.001

Boden WE, NEJM 2007; 356:1503-16

Paul Harvey
The Rest of the Story
Outcomes - Details

Table 3. Primary and Secondary Outcomes.*

Outcome	Number of Events		Hazard Ratio (95% CI)†	P Value†	Cumulative Rate at 4.6 Years	
	PCI Group	Medical-Therapy Group			PCI Group	Medical-Therapy Group
					%	
Death and nonfatal myocardial infarction‡	211	202	1.05 (0.87–1.27)	0.62	19.0	18.5
Death§	68	74				
Periprocedural myocardial infarction	35	9				
Spontaneous myocardial infarction	108	119				
Death, myocardial infarction, and stroke	222	213				9.5

Large preponderence of procedural MIs – death and spontaneous MI actually less after PCI

30 % of OMT patients
"crossed over" because of failure of OMT alone

MAYO CLINIC

Chronic Stable Angina

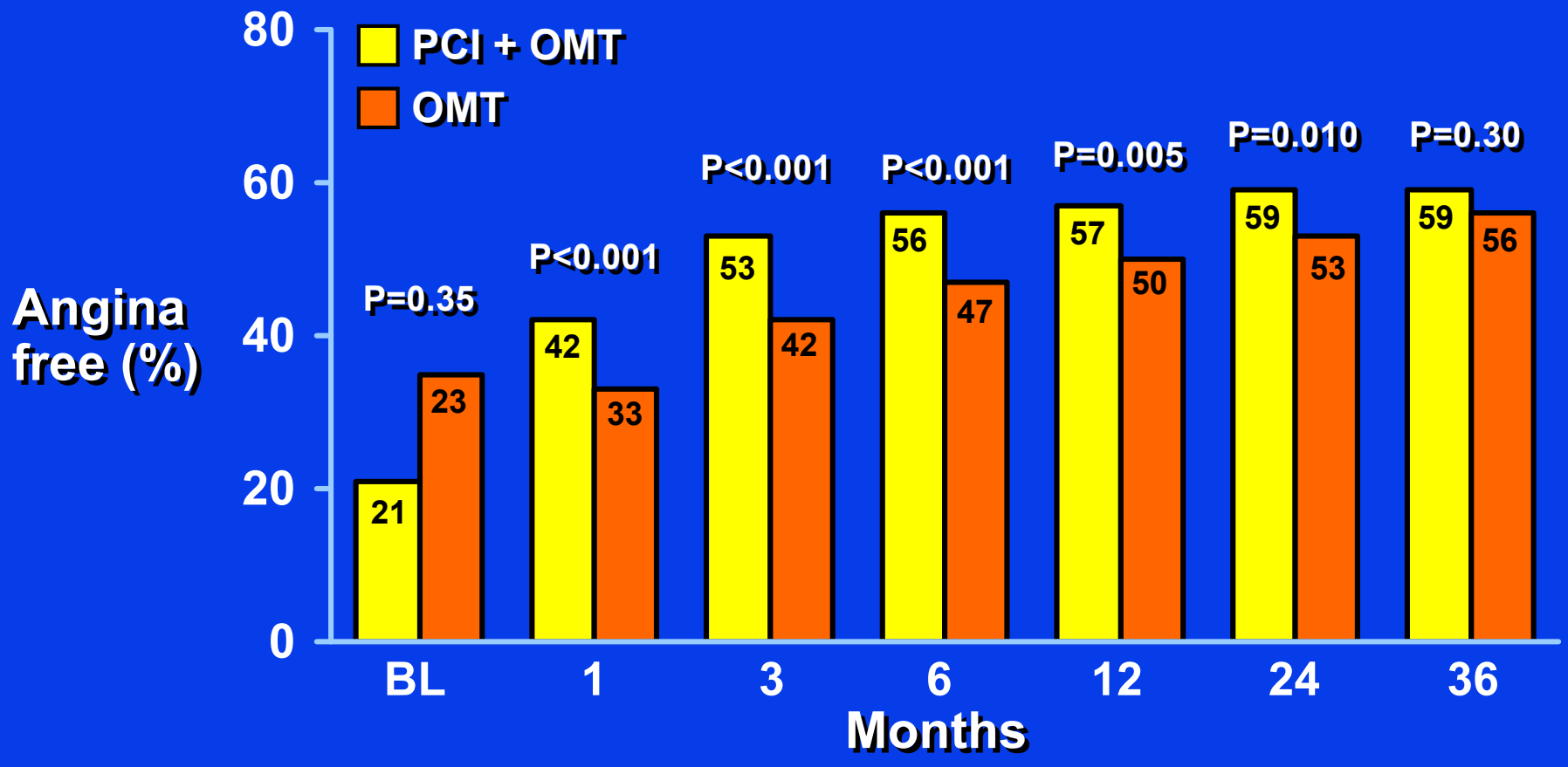
- PCI is very effective in reducing or abolishing angina and improving functional status
- In patients treated medically, crossover to PCI is frequent
- PCI is not more effective than aggressive medical therapy in reducing MI and death in stable mildly symptomatic patients
- Should we really have been surprised

Quality of Life
COURAGE Trial

- 2,287 patients with stable CAD to PCI + OMT or OMT alone
- QOL assessed using Seattle Angina Questionnaire and RAND – 36 item health survey

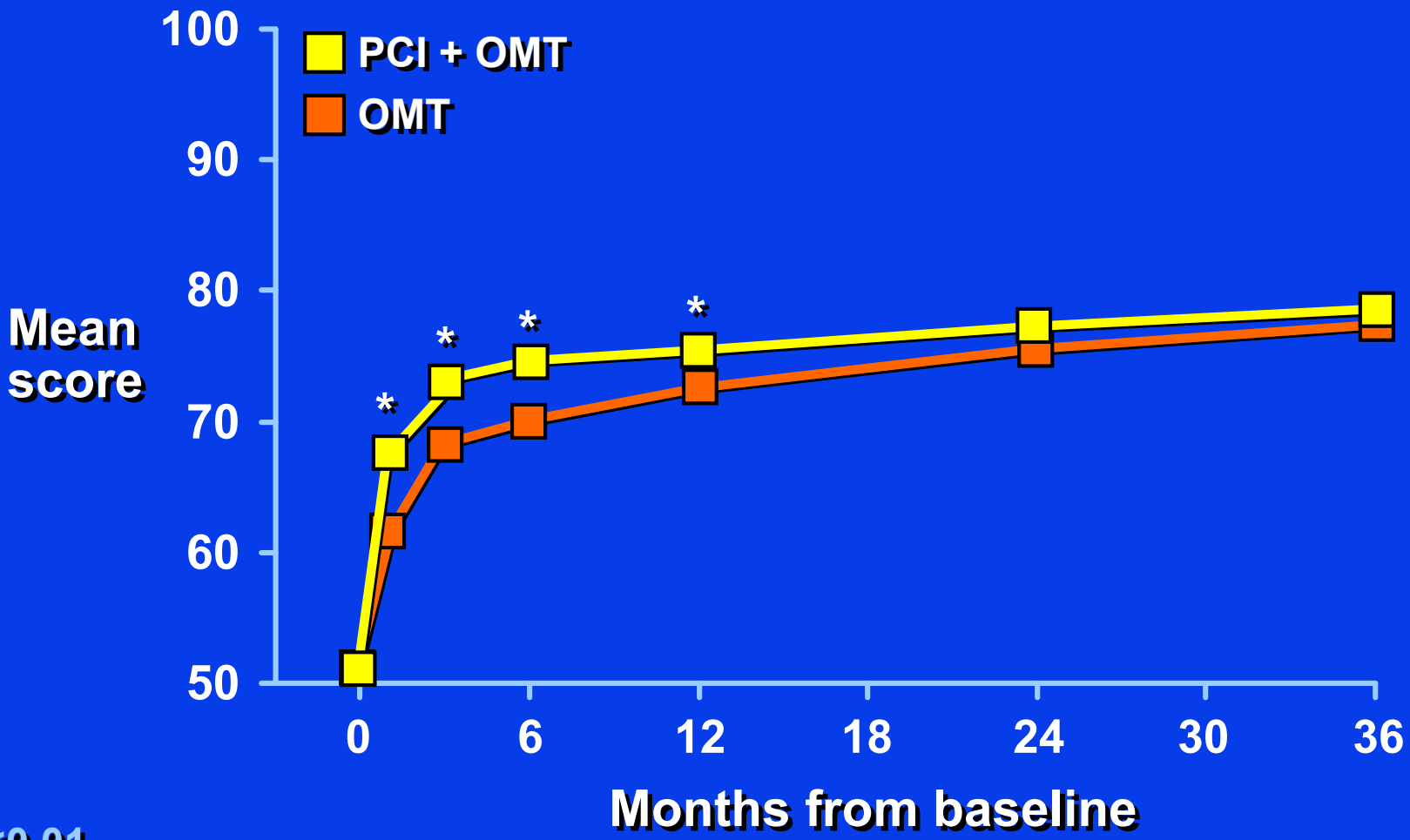
Weintraub WS et al: N Engl J Med 359:677-87, 2008

Quality of Life
Freedom from Angina



Weintraub WS et al: N Engl J Med 359:677, 2008

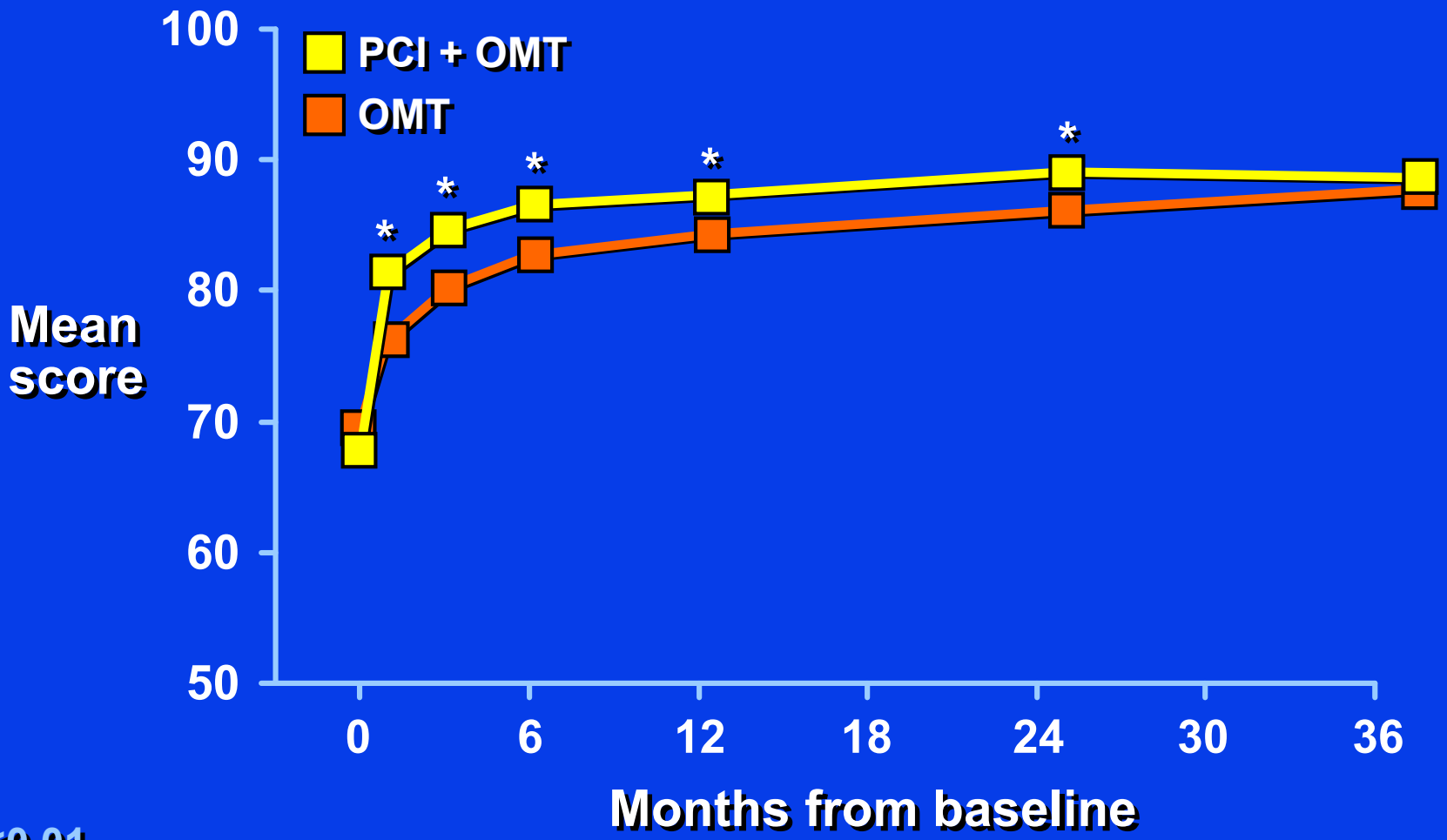
Quality of Life



*P<0.01

Weintraub WS et al: N Engl J Med 359:677, 2008

Angina Frequency



*P<0.01

Weintraub WS et al: N Engl J Med 359:677, 2008

Quality of Life
COURAGE Trial

- Improvement in angina frequency depended on severity at baseline
- Largest clinical improvement with PCI seen in patients with most severe angina at baseline. No improvement in patients with mildest angina.

Weintraub WS et al: N Engl J Med 359:677-87, 2008

ASK A HEART DISEASE SPECIALIST

Cardiac ischemia

What is cardiac ischemia? How serious is it?
From Ruth in Virginia

Mayo Clinic cardiologist Martha Grogan, M.D. and colleagues answer select questions from readers

Answer: Cardiac ischemia occurs when blood flow to the heart muscle (myocardium) is obstructed by a partial or complete blockage of a coronary artery. A sudden, severe blockage may lead to a heart attack (myocardial infarction). Cardiac ischemia may also cause a serious abnormal heart rhythm (arrhythmia), which can cause fainting or even sudden death.

In some people, especially those with diabetes, cardiac ischemia may cause no signs or symptoms. A doctor may make a diagnosis of cardiac ischemia based on: Medical History, Physical examination, Electrocardiogram, Stress Test, X-rays of coronary arteries (coronary angiogram)

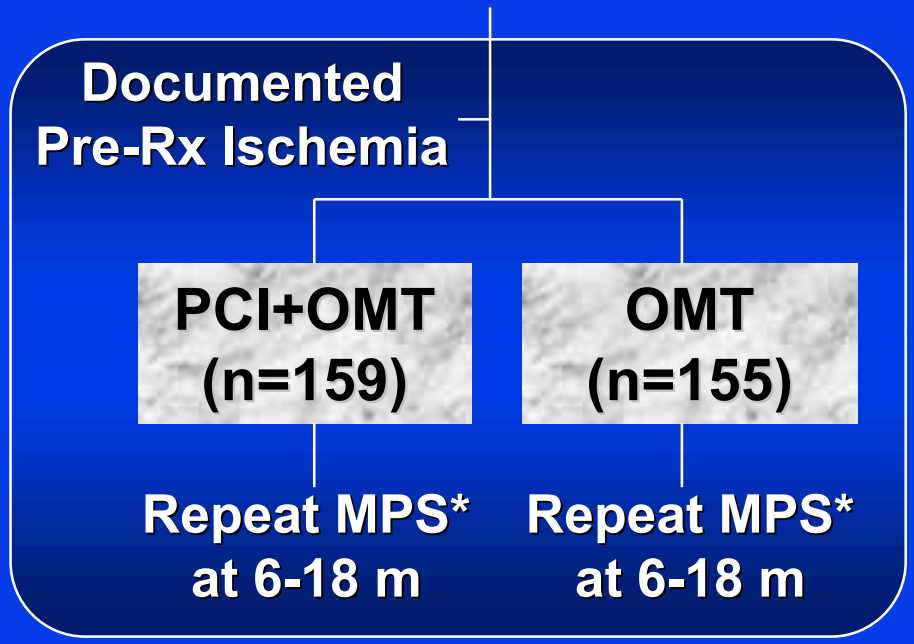
Treatment is directed at improving blood flow to the heart muscle.

Nuclear Substudy (n=314/2,287)

Hypothesis: Reduction in Ischemia will be greater for patients randomized to PCI+OMT than for those randomized to OMT

Serial Rest/Stress Myocardial Perfusion SPECT (MPS)
To compare patient management strategy for ischemia reduction

- Pre-Rx = Off Meds
- 6-18m = On Meds

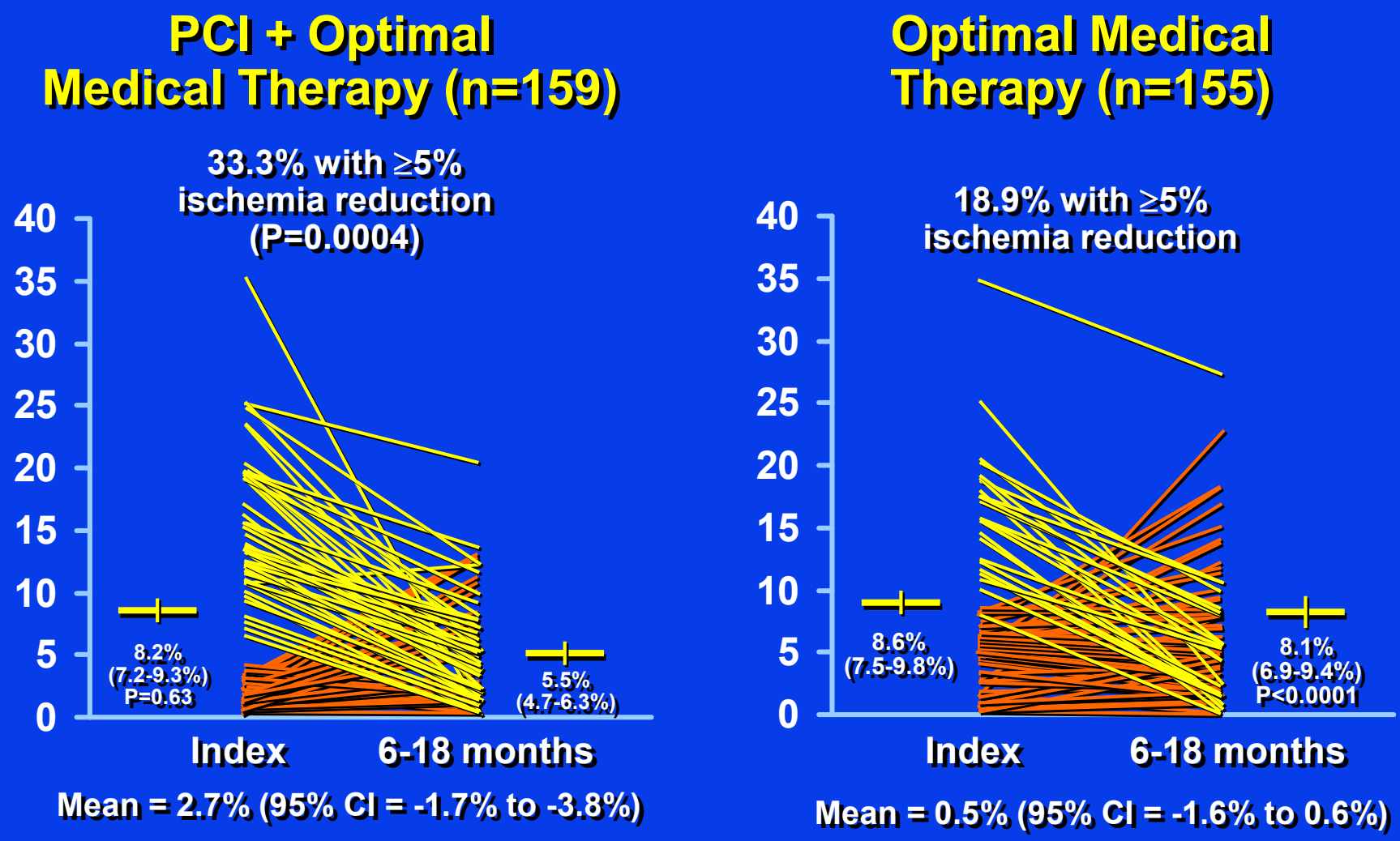


*Timing chosen to occur beyond window of in-stent restenosis & delayed to allow effects of medical Rx to be observed

Mean = 374±50 days

Shaw et al: J Nucl Cardiol 2006; 13:685-98

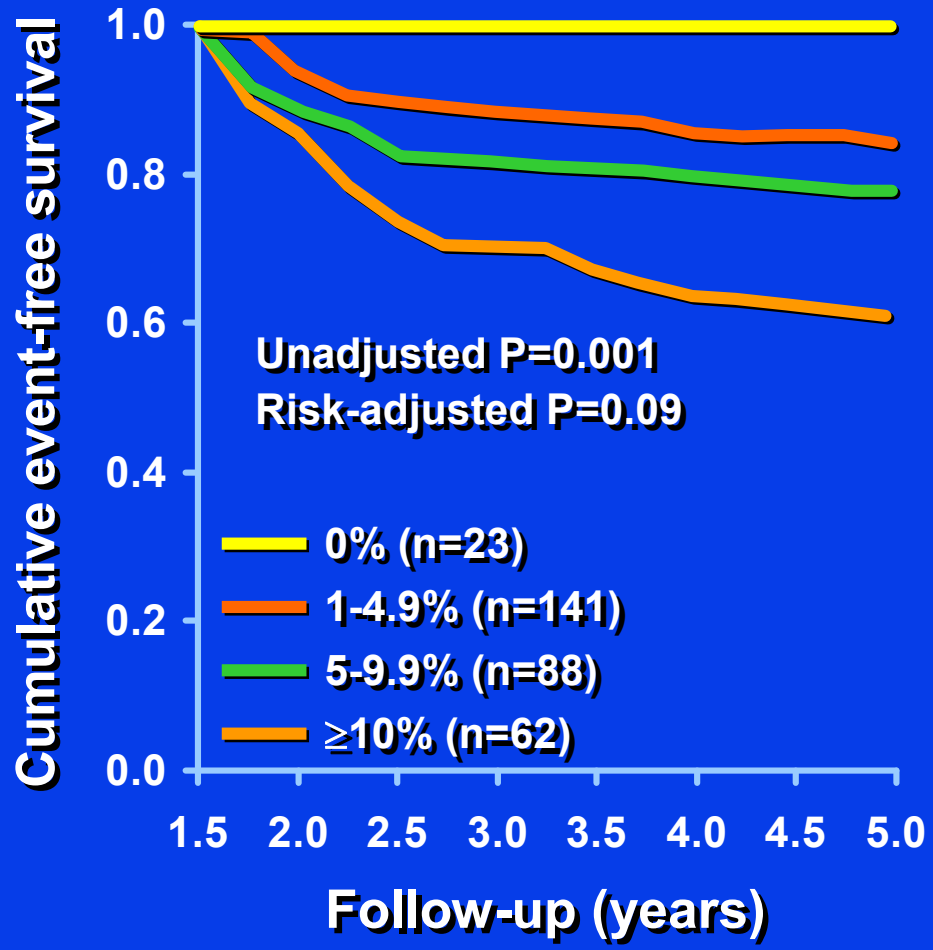
Inducible Ischemia

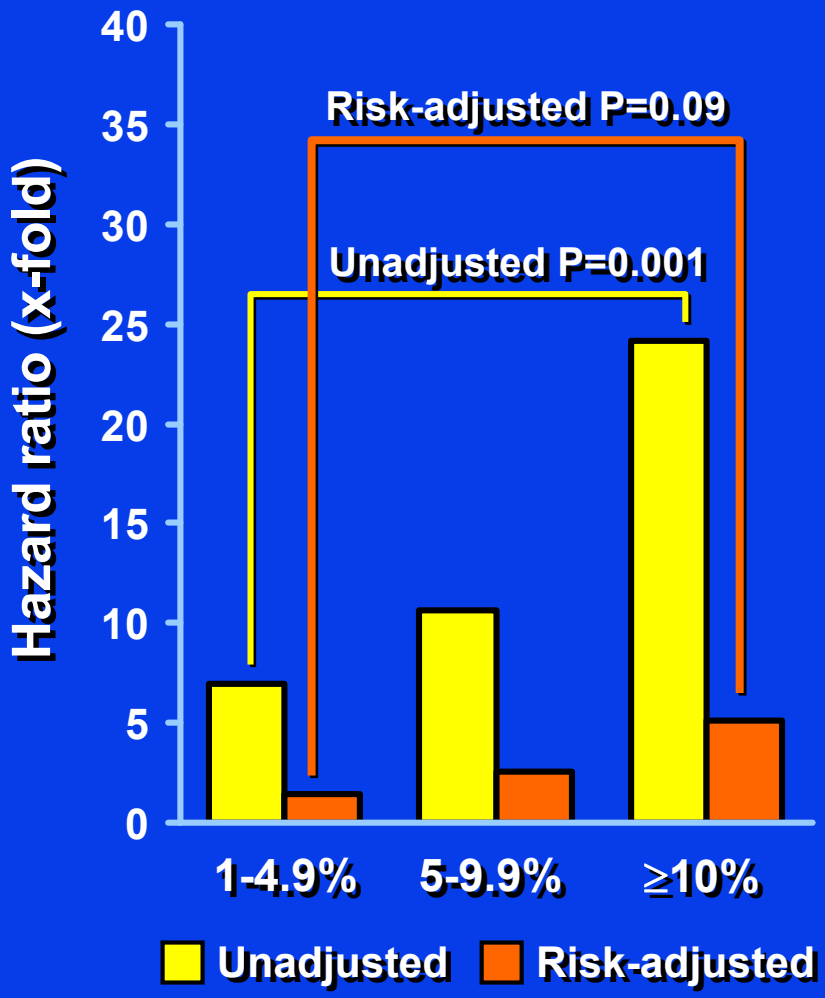


Shaw LJ et al: Circ 117: 283, 2008

CP1308112-1

Residual Ischemia and Outcome



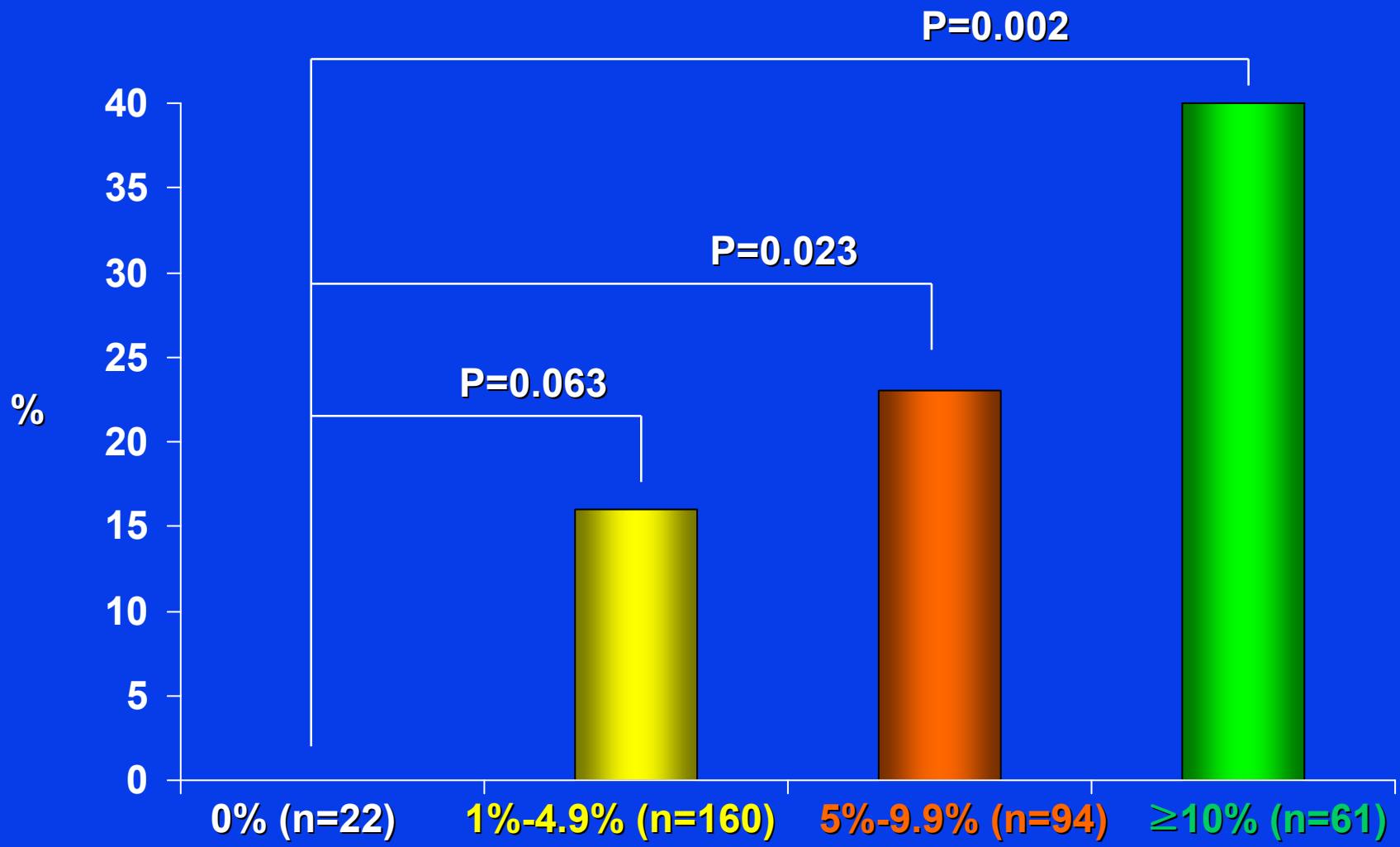


Shaw LJ et al: Circ 117: 283, 2008

MAYO CLINIC

CP1308112-4

Rates of Death or MI by Residual Ischemia



COURAGE
Nuclear Substudy

- Adding PCI to OMT results in greater reduction in ischemia compared with OMT alone
- Reduction of ischemia is associated with decreased death/MI
- Severity of residual ischemia is associated with outcome

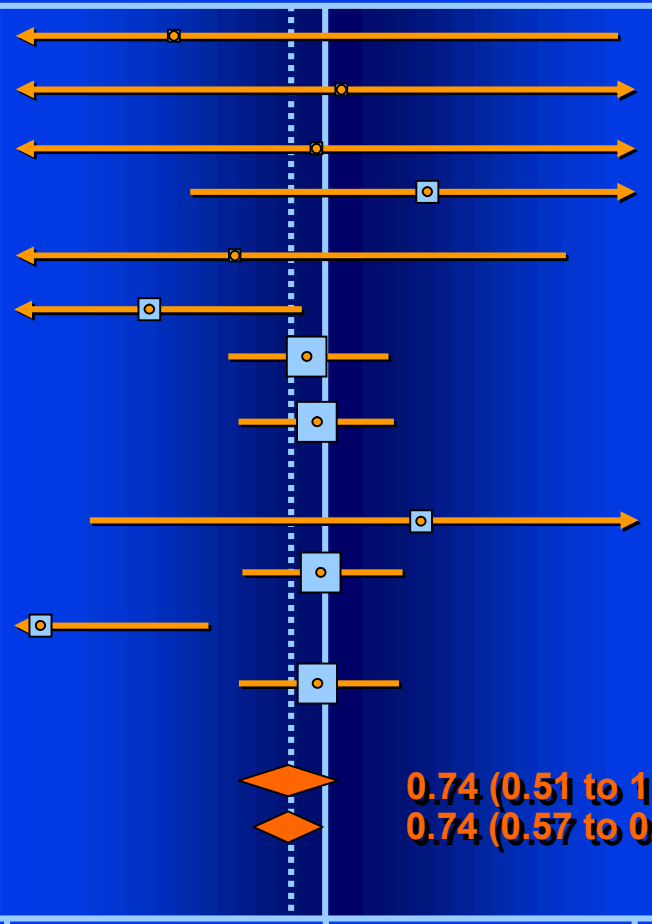
Shaw LJ et al: Circ 117: 283, 2008

Meta Analysis
PCI in Stable Angina

- 17 randomized trials
- 7,513 patients with symptoms/signs of ischemia but no ACS
- 3,675 assigned to PCI
- 3,838 assigned to medical therapy
- Primary endpoint: all cause death

Schomig A et al: J Am Coll Cardiol 52:894, 2008

Odds Ratios for Cardiac Death in Individual Trials Comparing the PCI-Based Strategy with Medical Treatment Strategy



Trial	Year of publication	Cardiac deaths/total PCI	Cardiac deaths/total Medical
Sievers et al	1993	0/44	1/44
Dakik et al	1998	1/21	1/23
AVERT	1999	1/177	1/164
MASS	1999	4/72	2/72
Bech et al	2001	1/90	2/91
ALKK	2003	4/149	14/151
RITA-2	2003	20/504	24/514
TIME	2004	32/153	33/148
Hambrecht et al	2004	0/50	0/51
INSPIRE	2006	2/104	1/101
MASS II	2006	24/205	25/203
SWISSI II	2007	3/96	22/105
COURAGE	2007	23/1149	25/1138
Overall		115/2814	151/2805
Random effects model		0.74 (0.51 to 1.06)	
Fixed effects model		0.74 (0.57 to 0.96)	

$P_{heterogeneity}$=0.161 ; I^2=29%

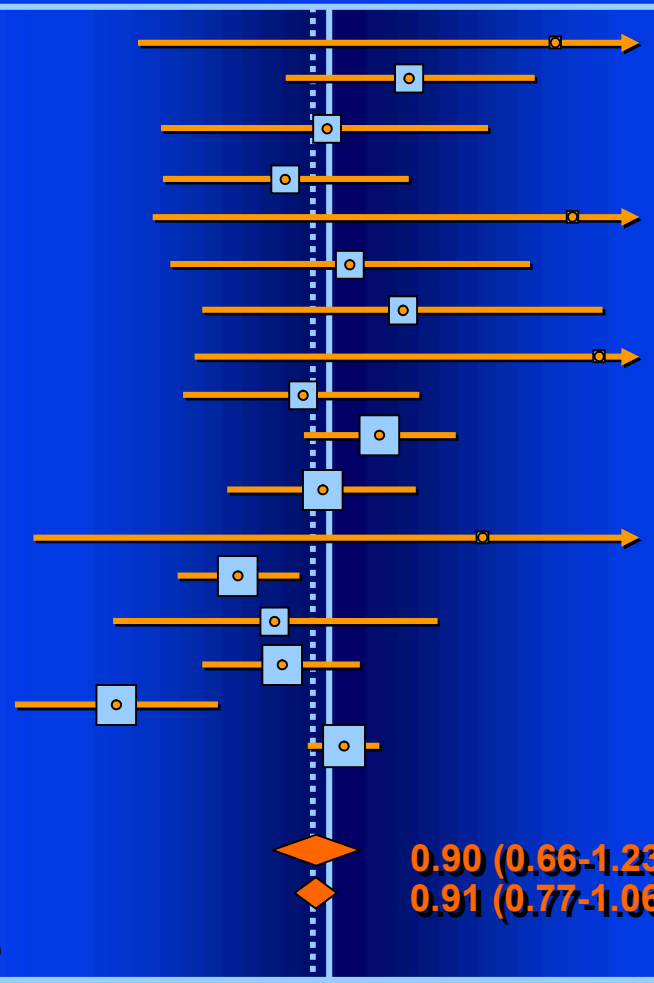
.1 1 10

Odds ratio (95% CI)

Schomig A et al:
J Am Coll Cardiol 52:894, 2008

CP1328101-2

Odds Ratios for Nonfatal Myocardial Infarction in Individual Trials Comparing the PCI-Based Strategy with medical Treatment Strategy



Trial	Year of publication	MI total PCI	MI total Medical
Sievers et al	1993	2/44	0/44
ACME-1	1997	14/115	8/112
ACME-2	1997	6/51	6/50
ACIP	1997	7/192	18/366
Dakik et al	1998	2/21	0/23
AVERT	1999	5/177	4/164
MASS	1999	5/72	3/72
Bech et al	2001	3/90	0/91
ALKK	2003	10/149	12/151
RITA-2	2003	32/504	23/514
TIME	2004	18/153	18/148
Hambrecht et al	2004	1/50	0/51
DANAMI	2006	32/503	59/505
INSPIRE	2006	5/104	7/101
MASS II	2006	23/205	31/203
SWISSI II	2007	11/96	40/105
COURAGE	2007	143/1,149	128/1,138
Overall		319/3,675	357/3,838

Random effects model 0.90 (0.66-1.23)

Fixed effects model 0.91 (0.77-1.06)

$P_{heterogeneity}$=0.263 ; I^2=17%

.1 1 10

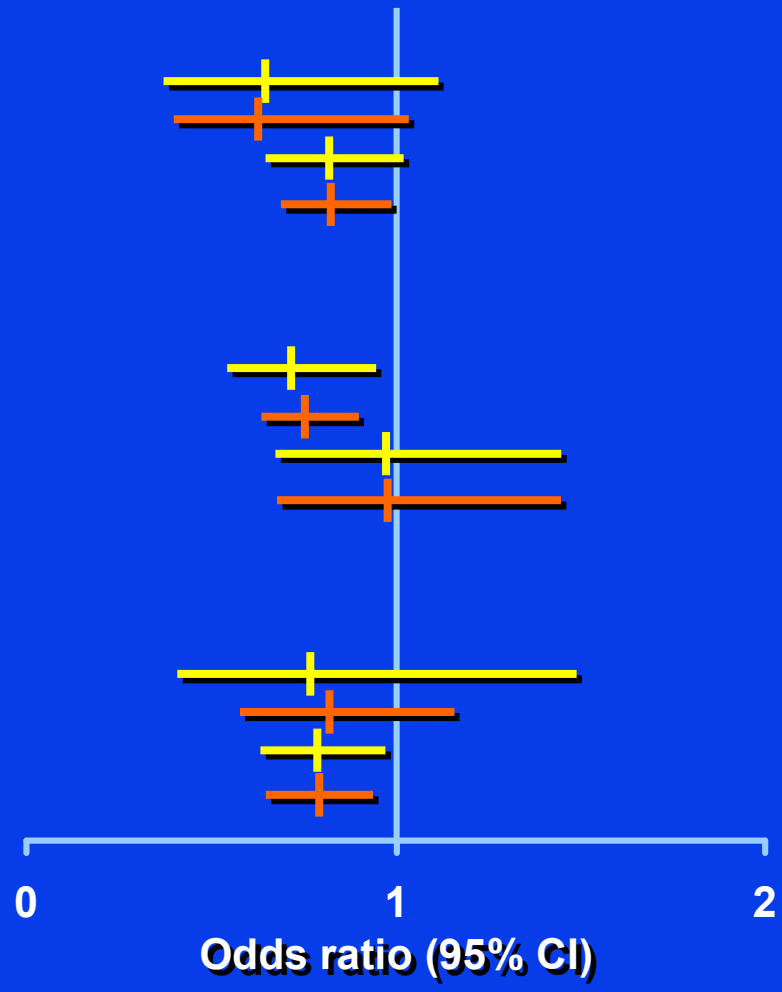
Odds ratio (95% CI)

Schomig A et al:
J Am Coll Cardiol 52:894, 2008

CP1328101-3

Odds Ratios for Mortality for PCI vs Medical Treatment

	Trials (no.)	Patients (no.)
Recent MI (<4 weeks)		
Yes	4	1,557
No	13	5,956
Angiography required before randomization		
Yes	14	5,999
No	3	1,514
CABG as a treatment option in PCI group		
Yes	4	2,072
No	13	5,441



Schomig A et al: J Am Coll Cardiol 52:894, 2008

Conclusions

These findings suggest that a PCI-based invasive strategy may improve long-term survival compared with a medical treatment-only strategy in patients with stable coronary artery disease.

Schomig A et al: J Am Coll Cardiol 52:894, 2008

PCI and Medical Therapy
Low Risk Coronary Artery Disease

- Multicenter randomized trial
- Stable low risk CAD:
  1 or 2 vessel CAD with stable angina
- Randomization to initial medical therapy alone or PCI plus medical therapy
- Medical therapy "recommended to the patient's physician"

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

Baseline Clinical and Angiographic Characteristics

Characteristic	Initial MT only group n=192	PCI + MT group n=192	P
Age (yr)	64.2±7.6	64.5±7.2	0.755
Male, no. (%)	144 (75.4)	141 (75.0)	0.930
Clinical			
Initial angina grade, no. (%)			0.396
0	24 (12.9)	21 (11.7)	
1	69 (37.1)	64 (35.8)	
2	74 (39.8)	68 (38.0)	
3	16 (8.6)	19 (10.6)	
4	3 (1.6)	6 (3.3)	
5	0 (0.0)	1 (0.6)	
Diabetes, no. (%)	76 (39.8)	76 (40.4)	0.900
MI, no. (%)	28 (15.1)	25 (14.0)	0.768
Previous PCI, no. (%)	54 (29.0)	44 (24.6)	0.337
CABG, no. (%)	3 (1.6)	5 (2.8)	0.441
Cerebrovasc disease, no. (%)	10 (5.4)	13 (7.3)	0.459

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

Baseline Clinical and Angiographic Characteristics

Characteristic	Initial MT only group n=192	PCI + MT group n=192	P
Stress test, no. (%)			
Total patients	149 (80.1)	146 (81.6)	0.724
Treadmill test	76 (40.9)	68 (38.0)	0.575
Duration of treadmill test, min, no. (%)	7.0±3.5	6.4±2.7	0.255
Nuclear medicine	55 (29.6)	63 (35.2)	0.251
Echocardiography	13 (7.0)	13 (7.3)	0.919
Angiographic			
Vessels with disease, no. (%)			0.998
1	129 (67.5)	127 (67.6)	
2	62 (32.5)	61 (32.5)	
Ejection fraction	65.8±9.6	64.0±9.7	0.171
Cardiac index	3.1±0.8	3.1±0.8	0.742

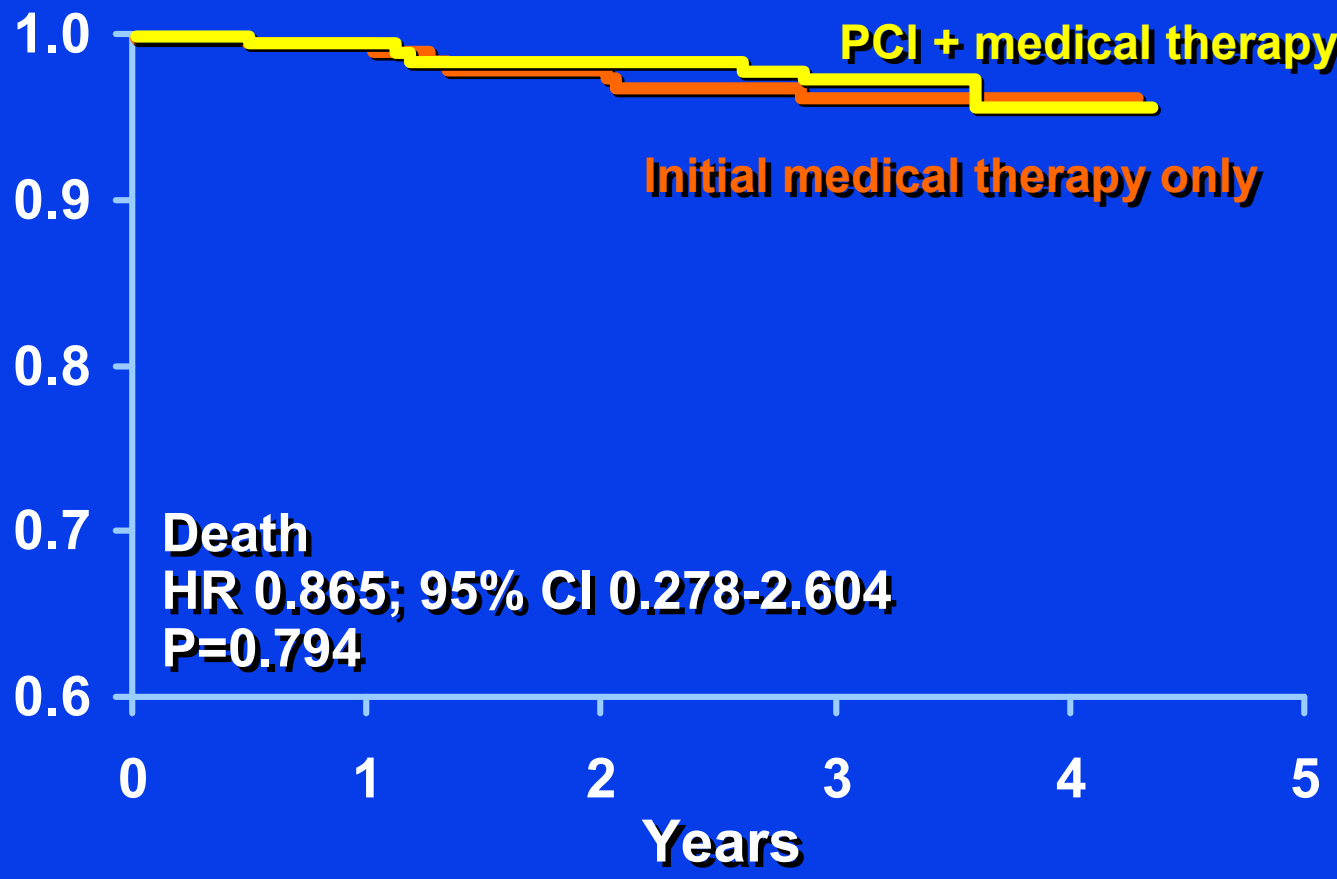
Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

Stable Coronary Artery Disease

- Mortality:
  - 271 deaths in PCI
  - 335 with medical therapy
  - 20% reduction (95% CI 0.64, 0.99)
- Non fatal infarction:
  - 319 in PCI group
  - 357 with medical therapy
  - 10% reduction (95% CI 0.66, 1.33)

Schomig A et al: J Am Coll Cardiol 52:894-904, 2008

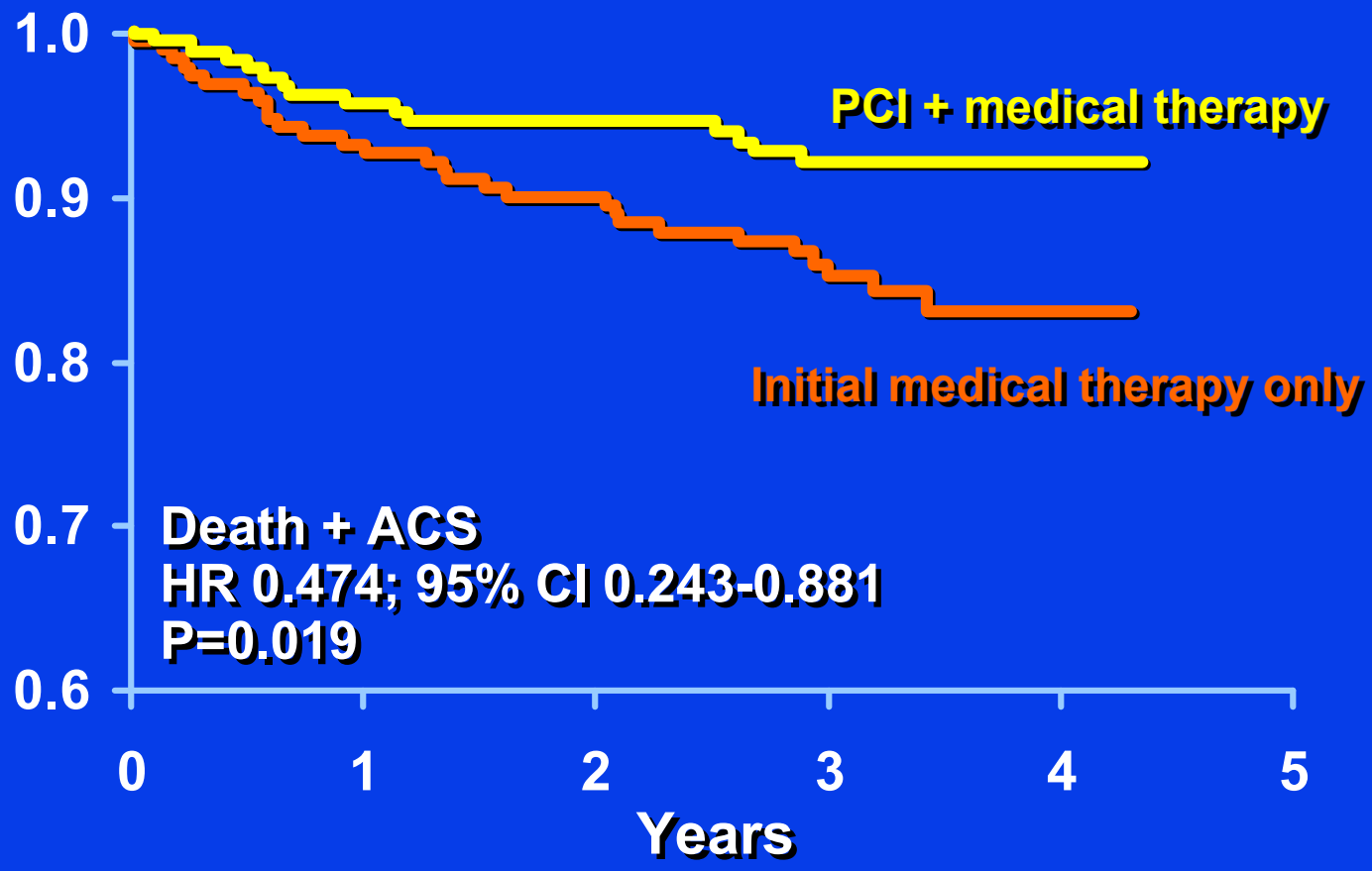
Death



Initial medical	188	188	180	133	19
PCI + medical	186	186	178	131	17

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

Death and ACS



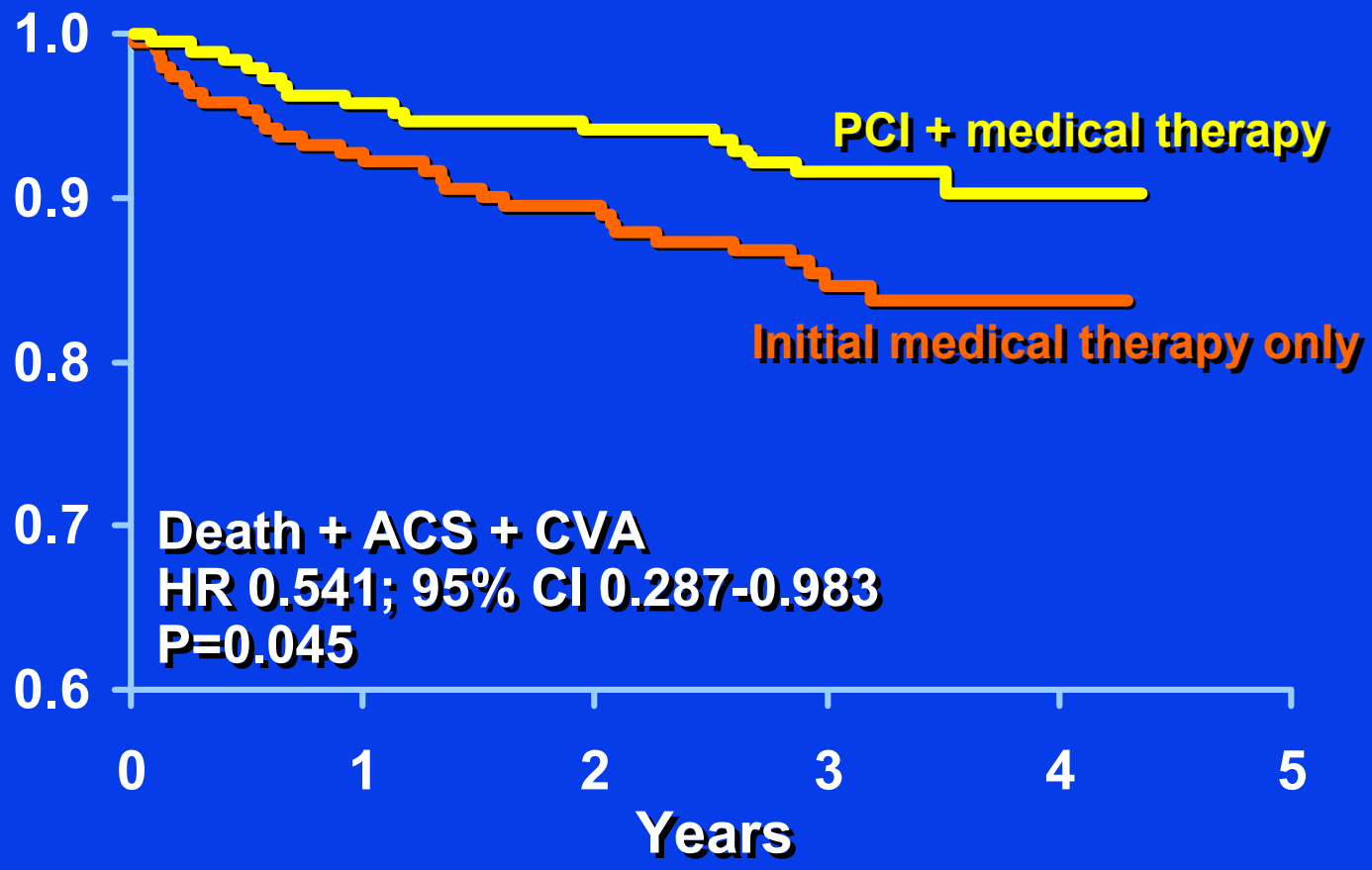
Initial medical	184	178	167	116	18
PCI + medical	183	179	171	124	16

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

MAYO CLINIC

CP1342734-4

Death, ACS, CVA



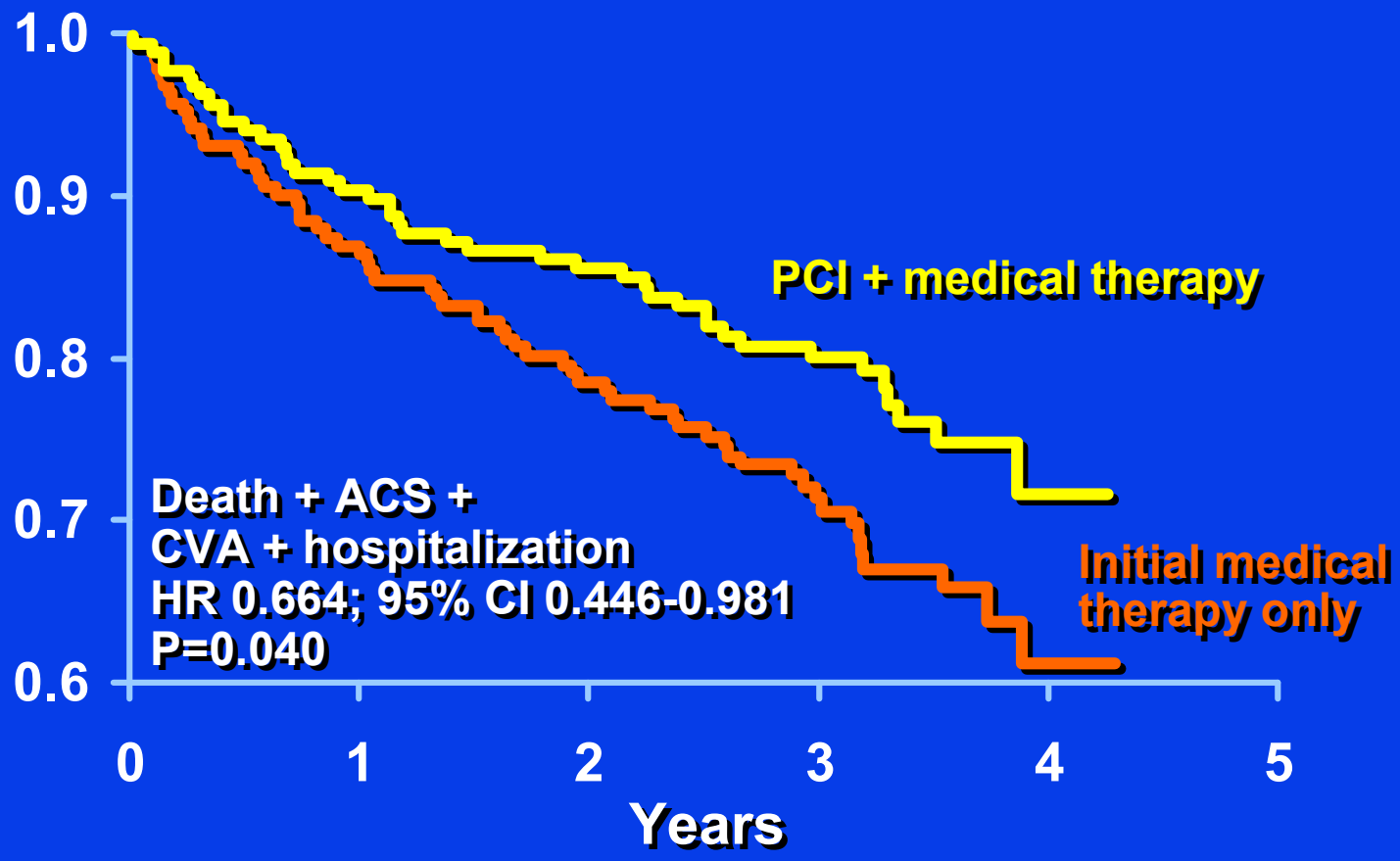
Initial medical	182	177	166	115	18
PCI + medical	183	179	170	123	15

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

MAYO CLINIC

CP1342734-5

Death, ACS, CVA, Hospitalization



Initial medical	176	166	146	97	14
PCI + medical	176	169	154	106	9

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

PCI and Medical Therapy
Conclusions

In stable low risk CAD, PCI and medical therapy may improve long-term prognosis more effectively than medical therapy alone

Nishigaki K et al: J Am Coll Cardiol Intv 1:469, 2008

The Bottom Line

- PCI is very good for the treatment of ischemia and for improving functional class and reducing angina
- In patients with significant ischemia, PCI improves the hard endpoints of cardiac death, nonfatal MI and need for symptom driven revascularization

It has long been recognized that the problems with alcohol relate not to the use of a bad thing but to the abuse of a good thing

Abraham Lincoln
1861

Who to Stent

- Significant stenosis
- Significant ischemia
- Informed consent
- Amenable to PCI

ACC PCI Guidelines
Asymptomatic Ischemia on CCS I/II AP

- PCI is reasonable for recurrent stenosis after PCI with large area of viable myocardium or high risk criteria on non-invasive testing
(IIA, level of evidence C)

Who to Not Stent

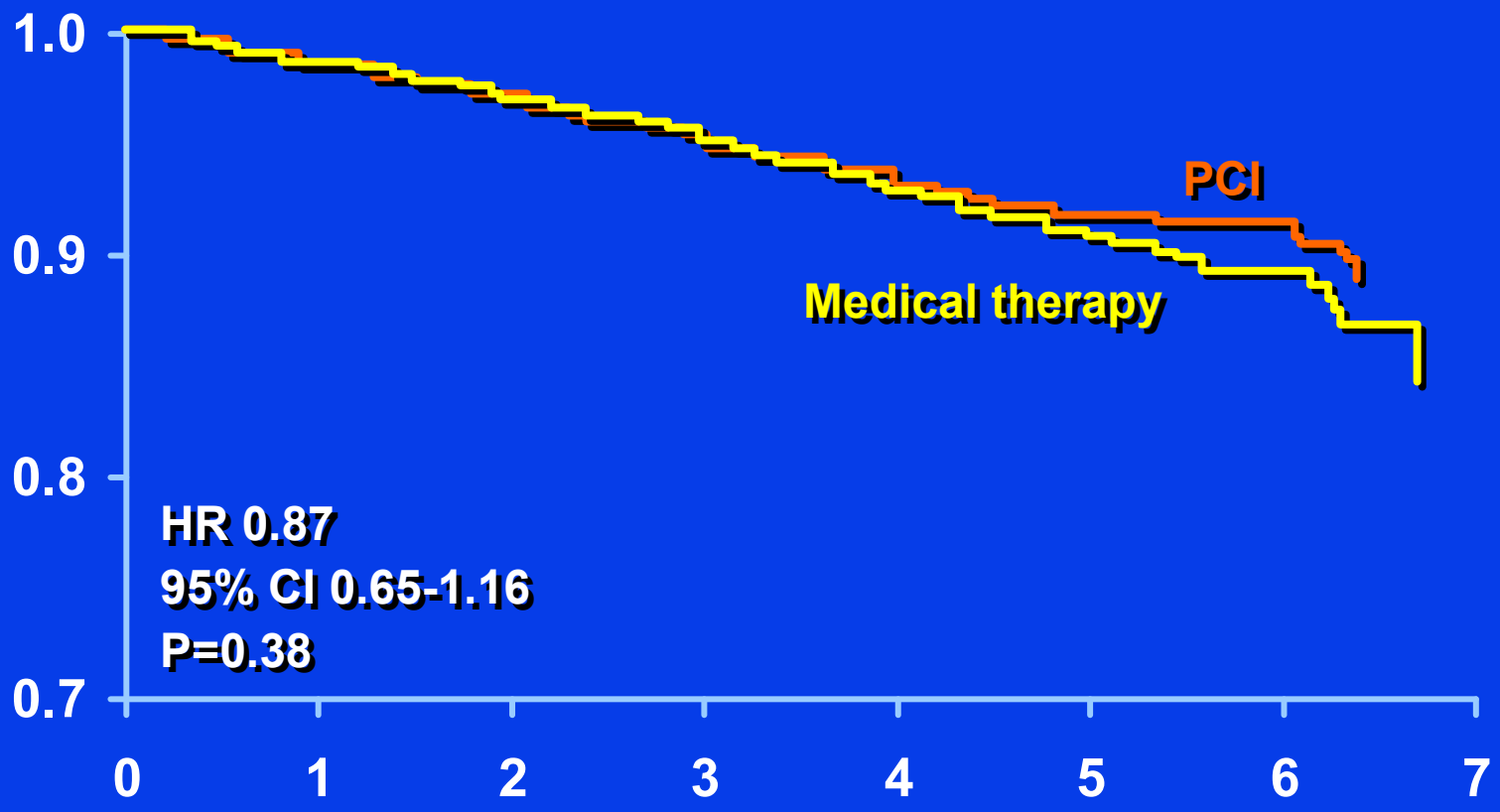
- Patients who do not need revascularization
- People who do not need revascularization
- Lesions which cannot be treated
- Lesions which should not be treated
- Patients in whom another approach is better

Courage Trial
Substudy

	PCI + OMT	OMT	P
Moderate-severe pre treatment	78%	52%	.007
Ischemia →			
Improved			

Shaw, AHA 2007

Overall Survival



No. at risk							
1,138	1,073	1,029	917	717	468	302	38
1,149	1,094	1,051	929	733	488	312	44

NEJM 356(15):1512, 2007

ACC PCI Guidelines
Asymptomatic Ischemia on CCS I/II AP

- Reasonable in patients with >50% stenosis of LMCA, who are candidates for revascularization but are not eligible for CABG (IIA, level of evidence B)

BARI 2D Primary and Principal Secondary Endpoints

- All-cause mortality

  Major cardiovascular events

- Composite of death/MI/stroke
- Average follow-up 5.3 years

Revascularization Decision
BARI 2D

Cardiologist a priori selected revascularization method based on clinical and angiographic factors

Percutaneous coronary intervention

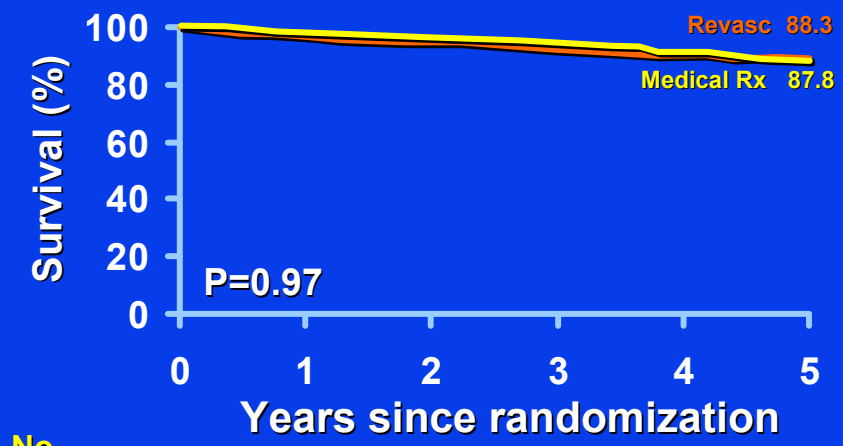
or

Coronary artery bypass graft surgery

The BARI 2D Study Group

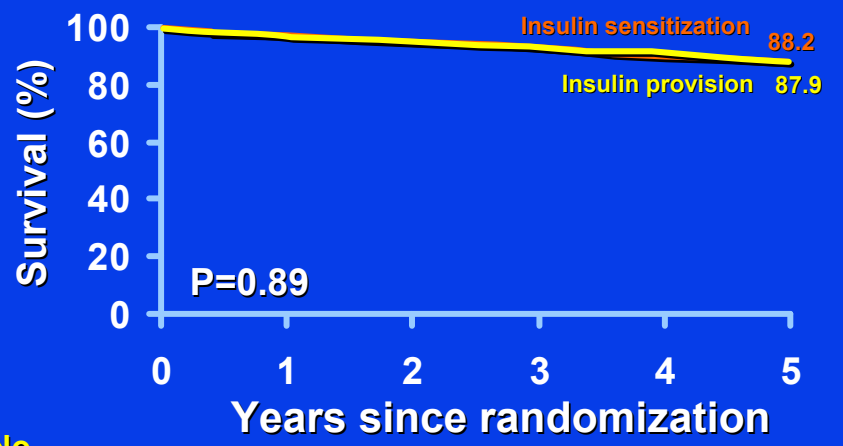
Rates of Survival and Freedom from Major CV Events

Survival, Revascularization vs Medical Therapy



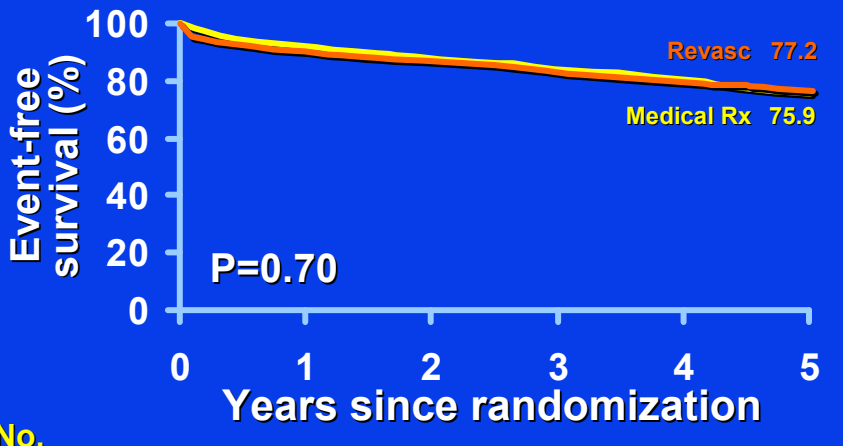
No. at risk						
	2,368	2,296	2,247	2,197	1,892	1,196

Survival, Insulin Sensitization vs Insulin Provision



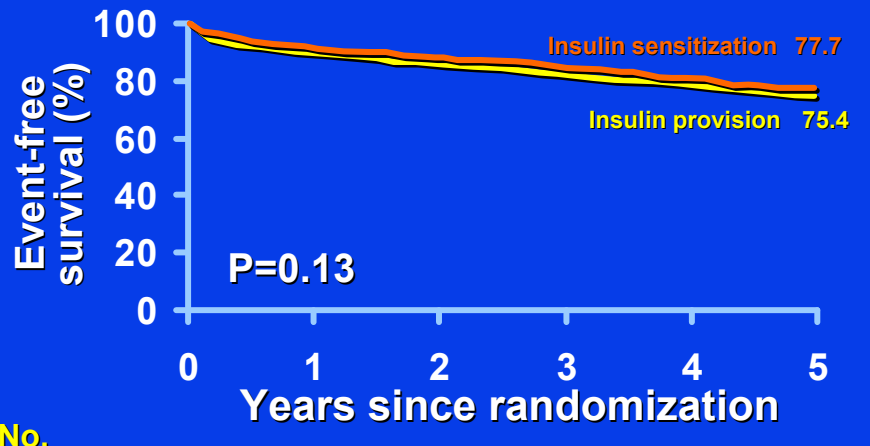
No. at risk						
	2,368	2,296	2,247	2,197	1,892	1,196

Freedom from Major CV Events, Revascularization vs Medical Therapy



No. at risk						
	2,368	2,094	1,984	1,807	1,459	823

Freedom from Major CV Events, Insulin Sensitization vs Insulin Provision



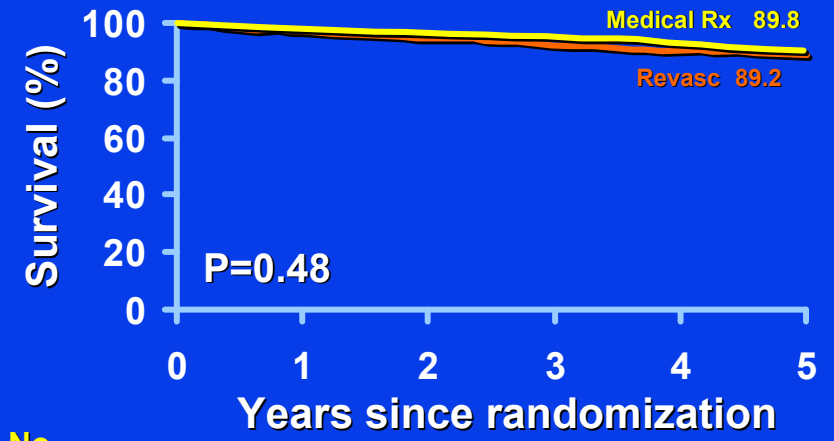
No. at risk						
	2,368	2,094	1,984	1,807	1,459	823

NEJM 360:2503, 2009

The BARI 2D Study Group

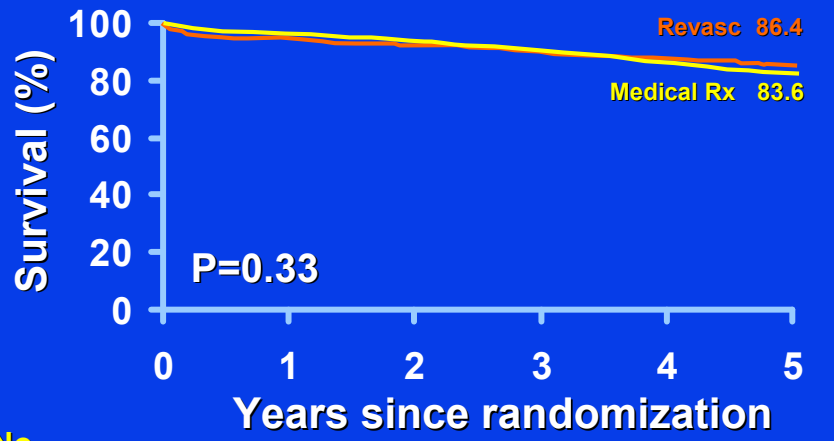
Rates of Survival and Freedom from Major CV Events According to PCI and CABG Strata

Survival in PCI Stratum



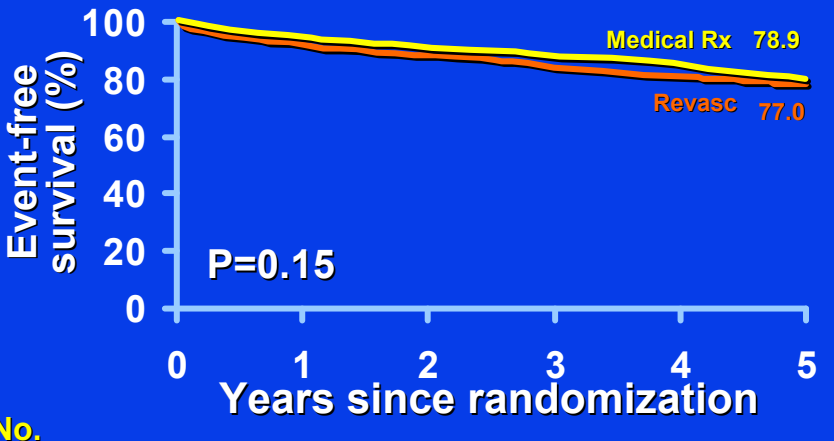
No. at risk						
	1,605	1,562	1,529	1,505	1,306	863

Survival in CABG Stratum



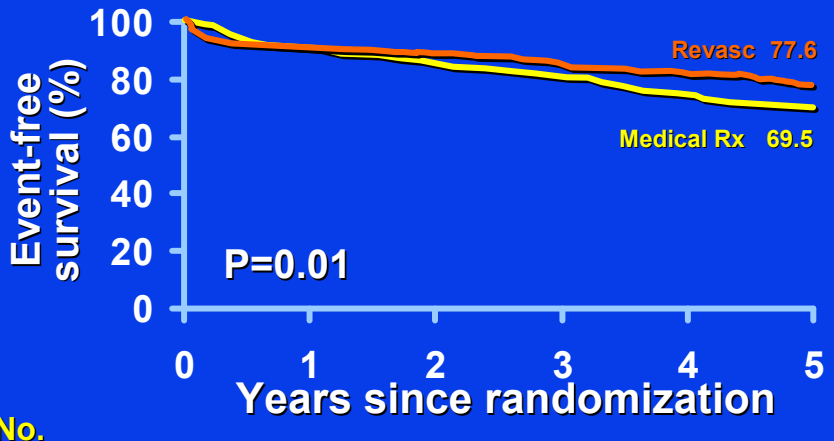
No. at risk						
	763	734	718	692	586	333

Freedom from Major CV Events in PCI Stratum



No. at risk						
	1,605	1,426	1,350	1,239	1,012	593

Freedom from Major CV Events in CABG Stratum



No. at risk						
	763	668	634	568	421	230

NEJM 360:2503, 2009

There are no facts, only interpretations.

-Friedrich Nietzsche