PCI vs Surgery in Left Main & Multivessel Disease: No More Routine Surgery

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Presenter Disclosure Information

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

"PCI vs Surgery in Left Main & Multivessel Disease: No More Routine Surgery "

The following relationships exist related to this presentation:

No relationships to disclose

Routine, the Noun
OED

- A sequence of actions regularly followed; a fixed unvarying program

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BALDMANS COMB

The History of Routineness

MEDICAL

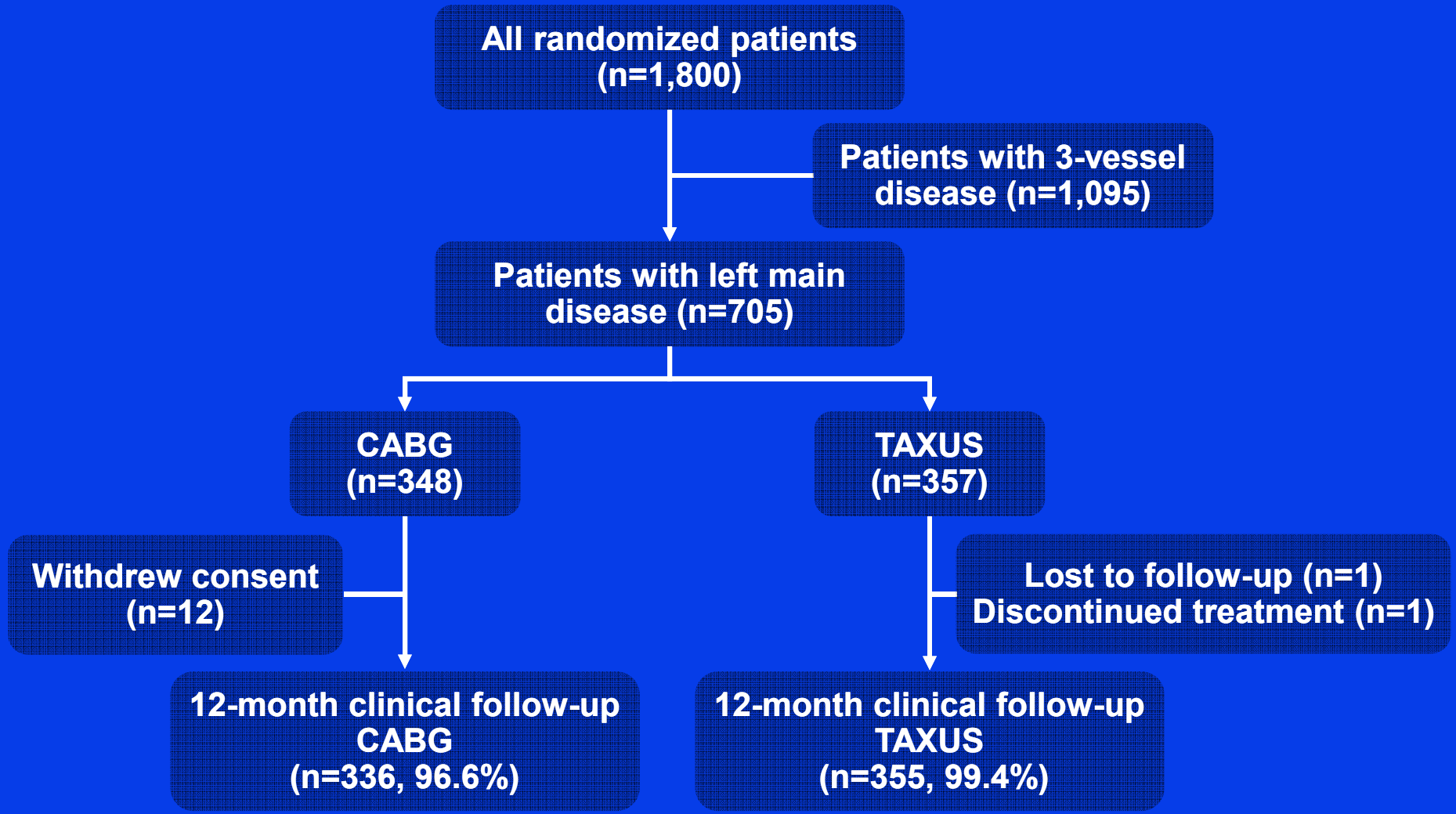
- Lidocaine for prevention of ventricular arrhythmias in acute infarction
- SBE prophylaxis for mid systolic clicks
- Hormone replacement therapy for prevention of cardiovascular disease in women

LIFE

- Meat and abstinence on Fridays until 1966
- Babies sleep safest on their back not on their stomach to avoid SIDS
- The hair of the dog that bit you is the cure for hangovers

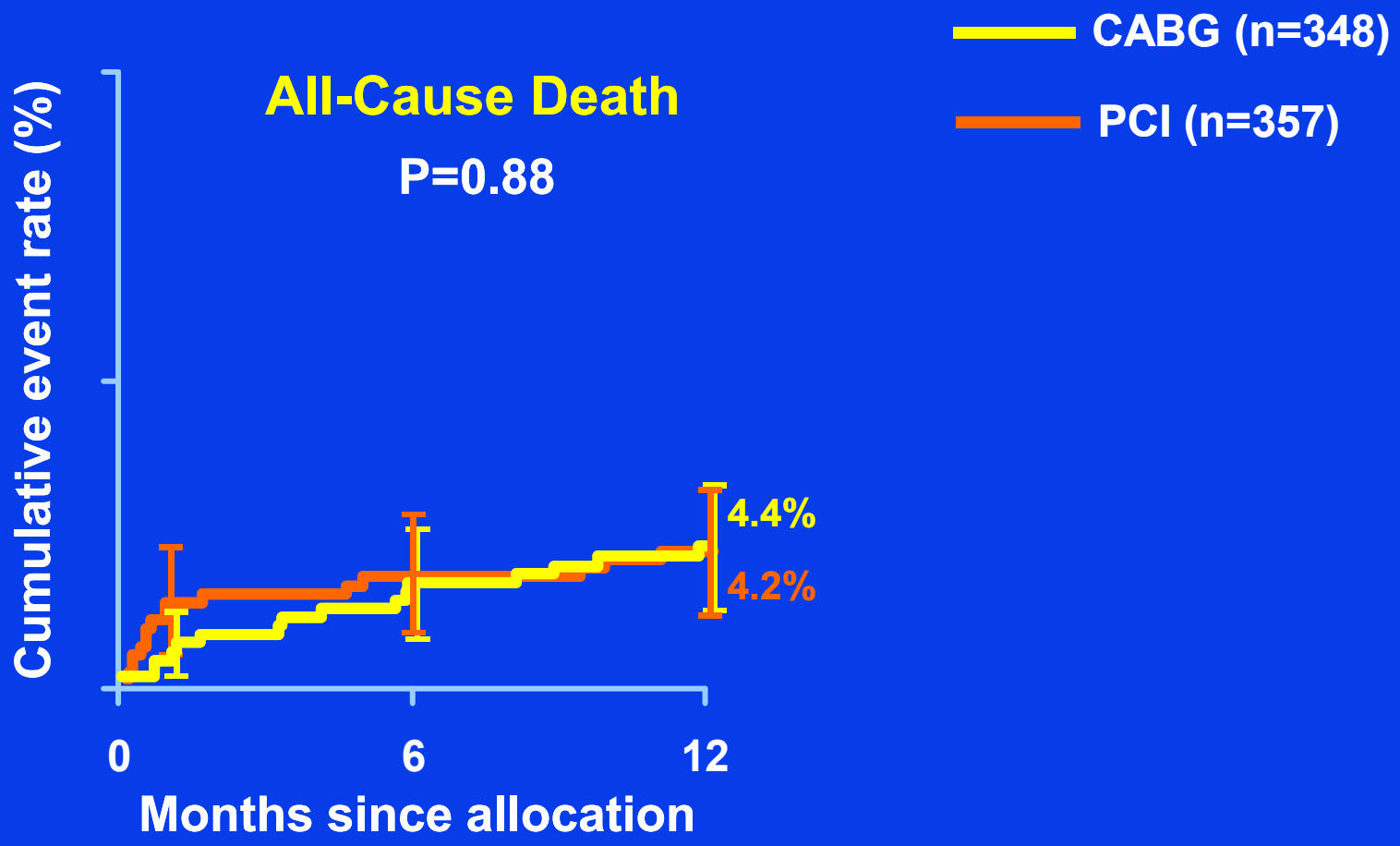

NEW!
HOT!
KIM CHEE

SYNTAX Left Main Trial
Patient Disposition



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

SYNTAX Left Main Trial



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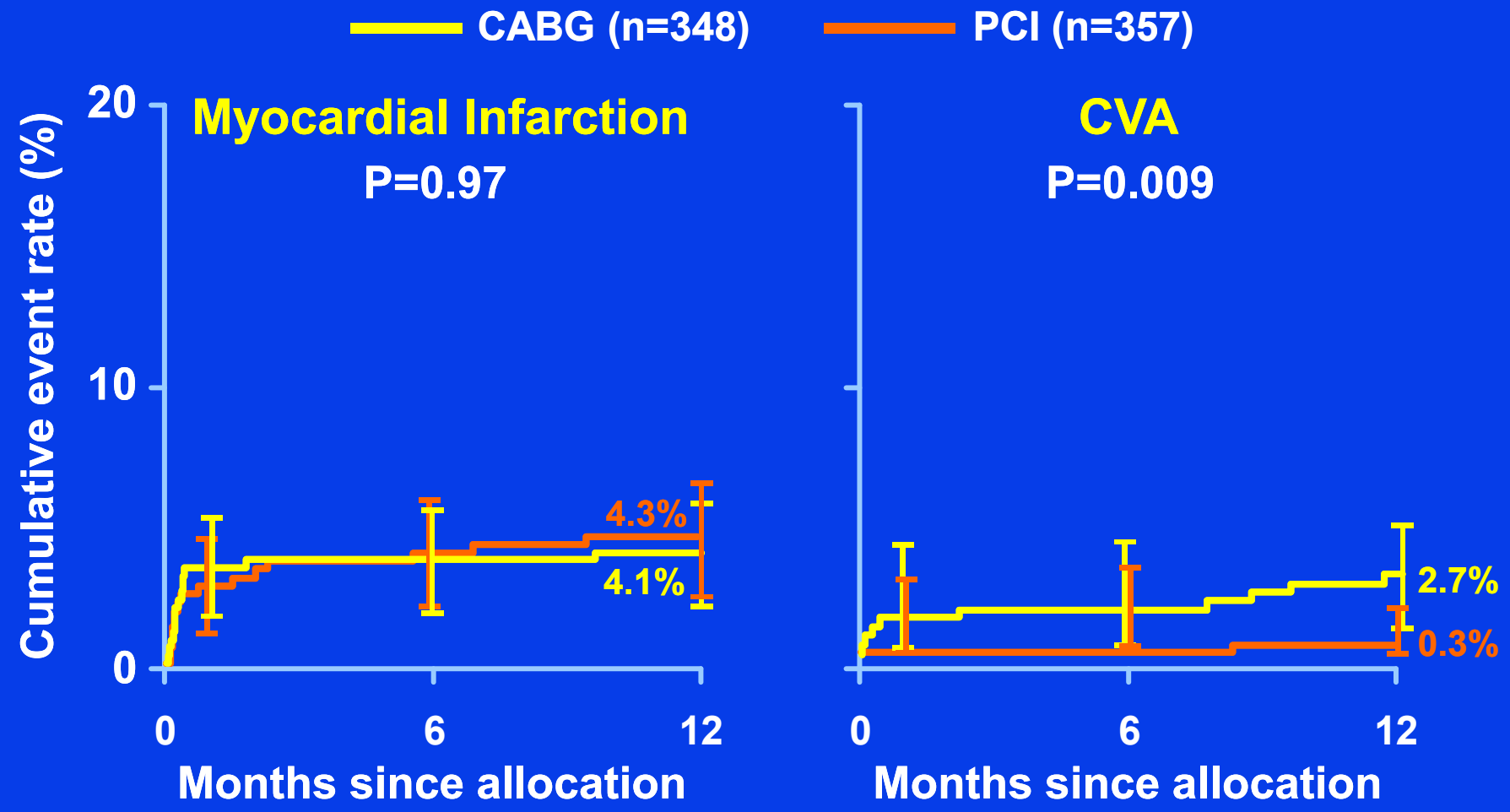
Morice MC et al: Circ, 2010 (in press)

SYNTAX Left Main Trial



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

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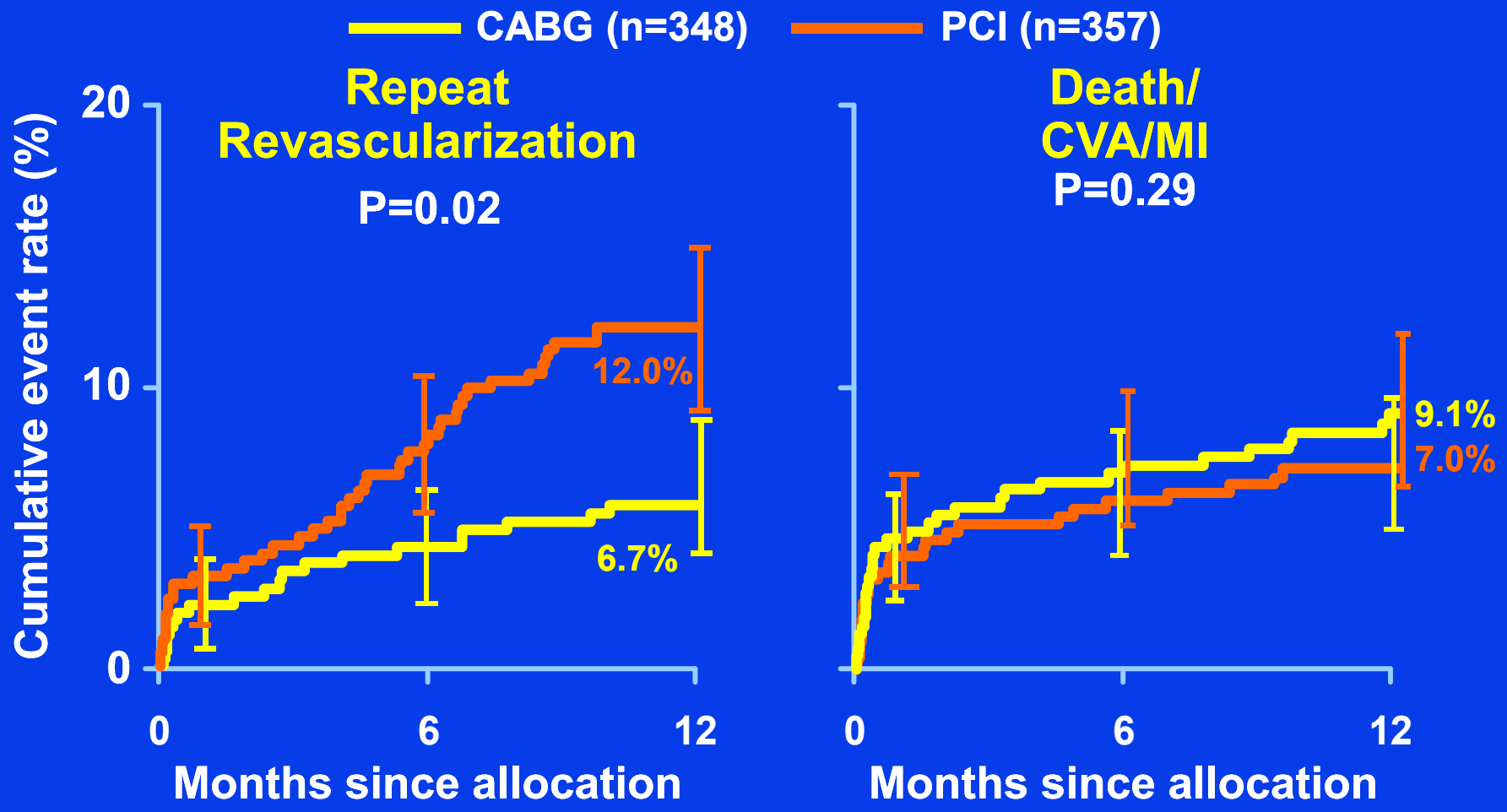
SYNTAX Left Main Trial



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

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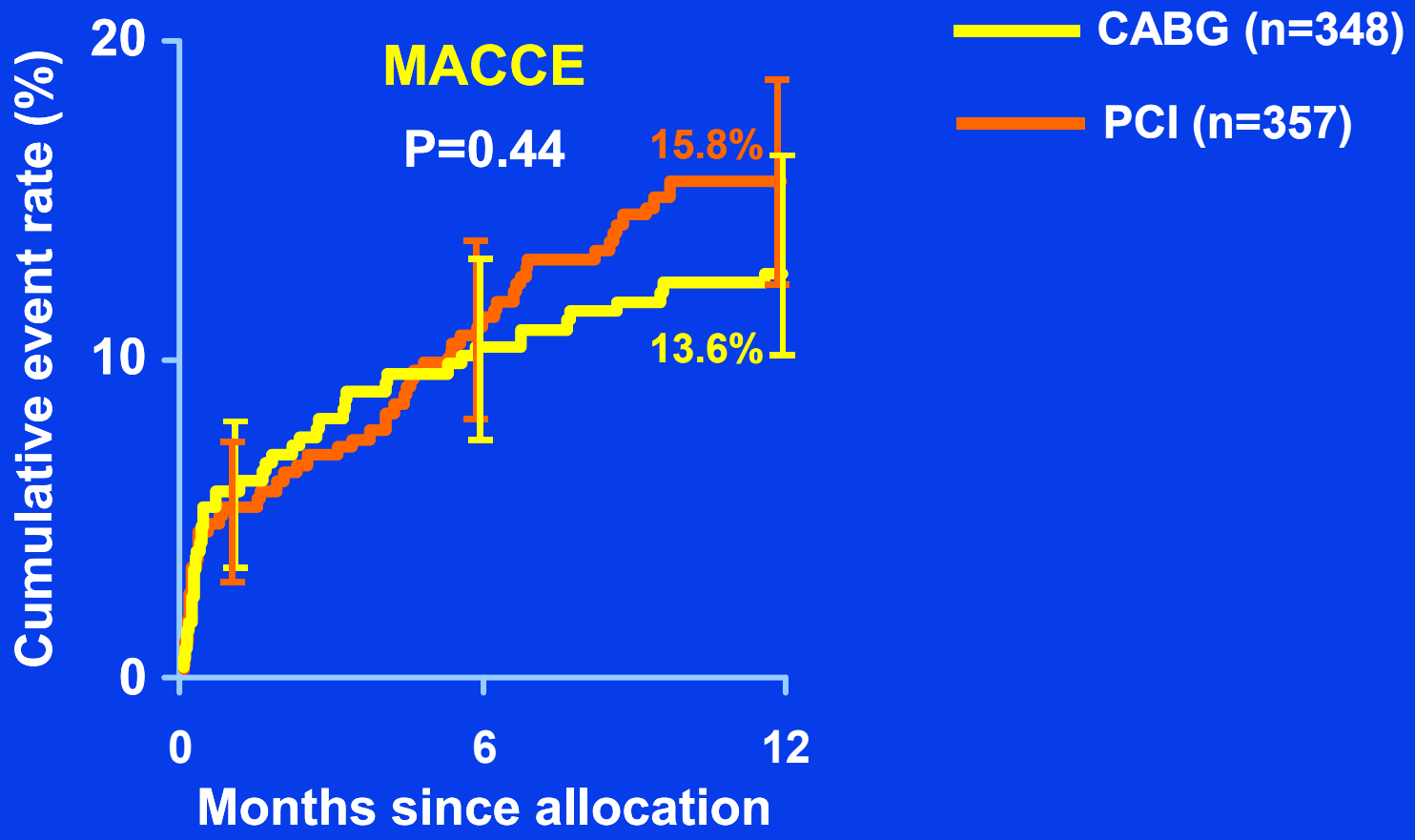
SYNTAX Left Main Trial



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

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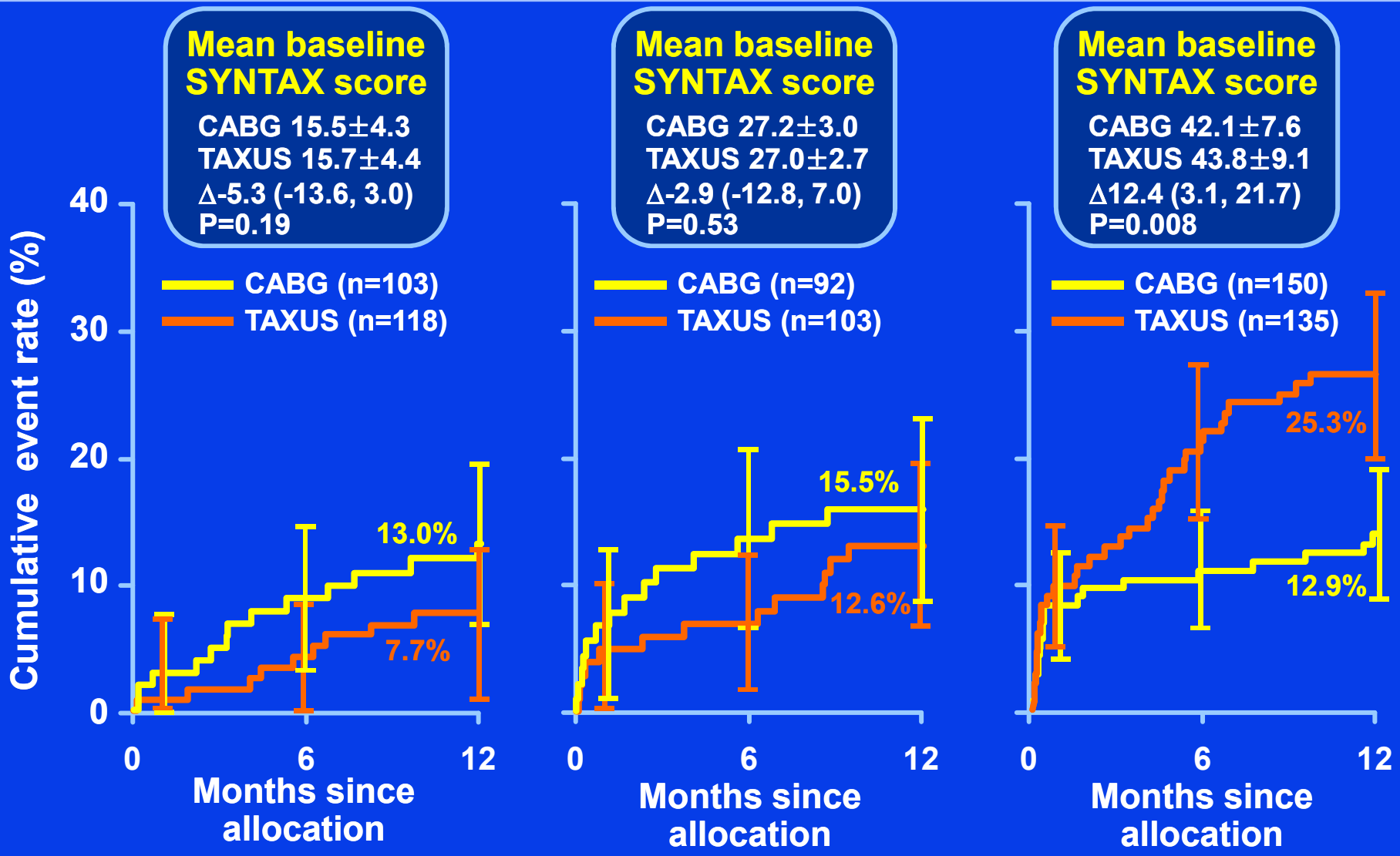
SYNTAX Left Main Trial
1-Year MACCE



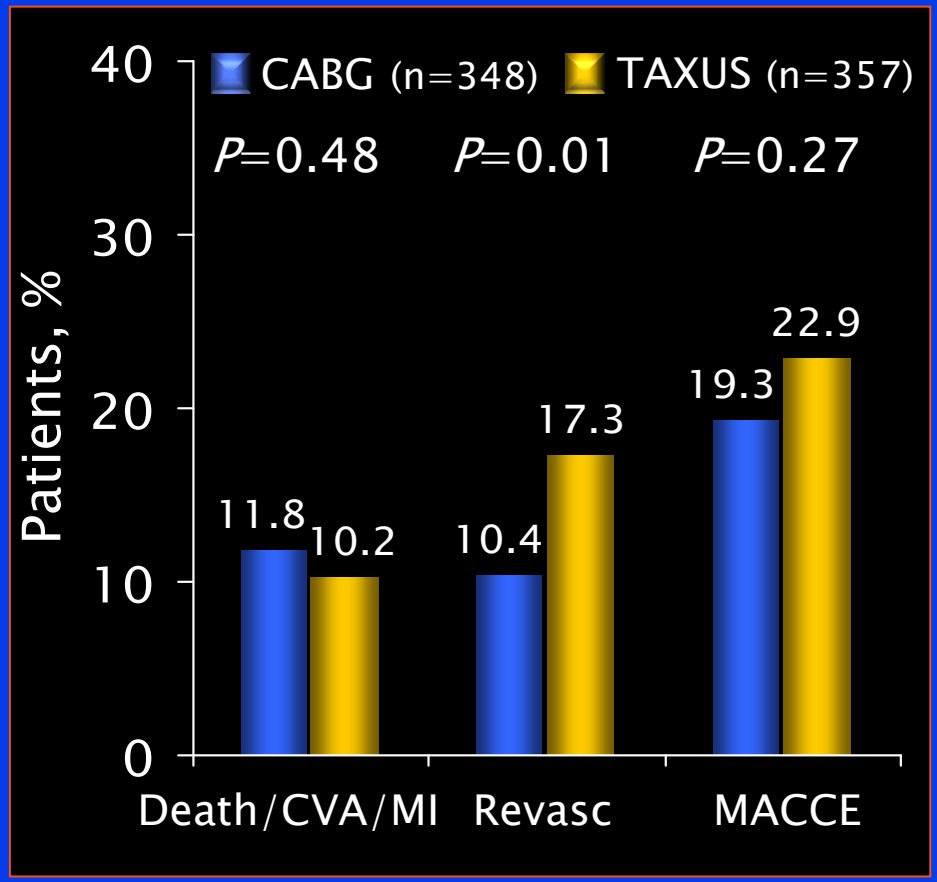
Morice MC et al: Circ, 2010 (in press)

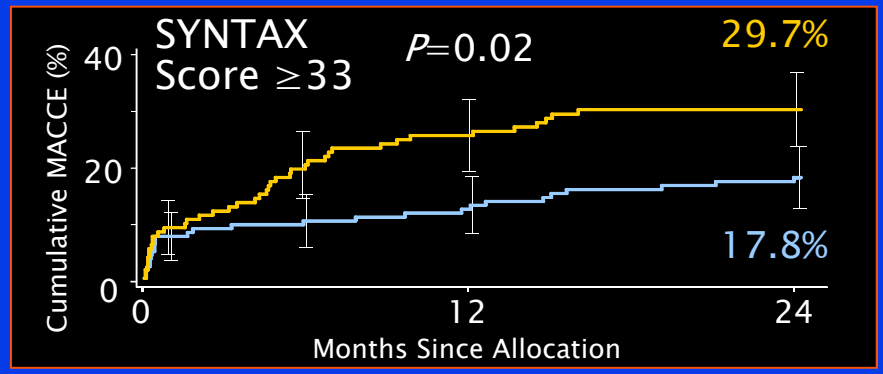
SYNTAX Trial
Conclusions

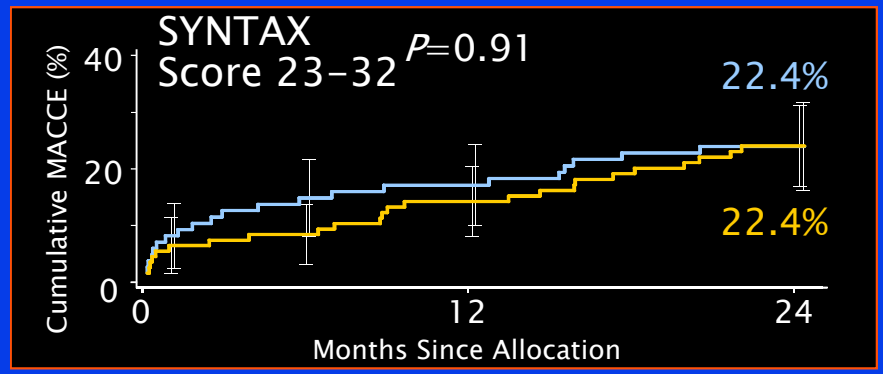
"Patients with LM disease who had revascularization with PCI had comparable safety and efficacy outcomes to CABG at 1 year."

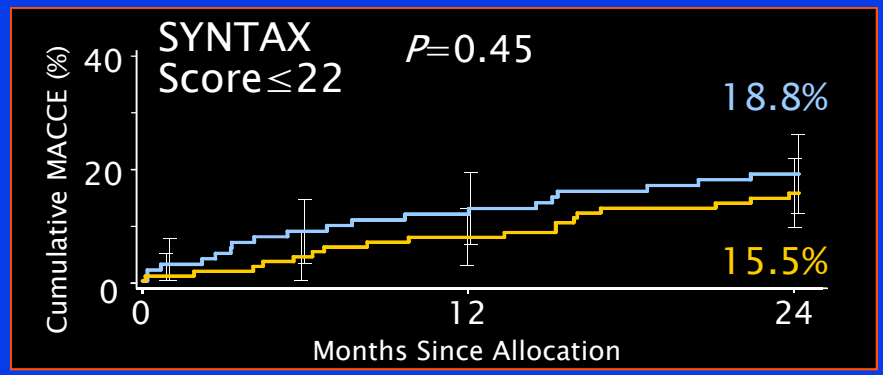
Morice MC et al: Circ, 2010 (in press)

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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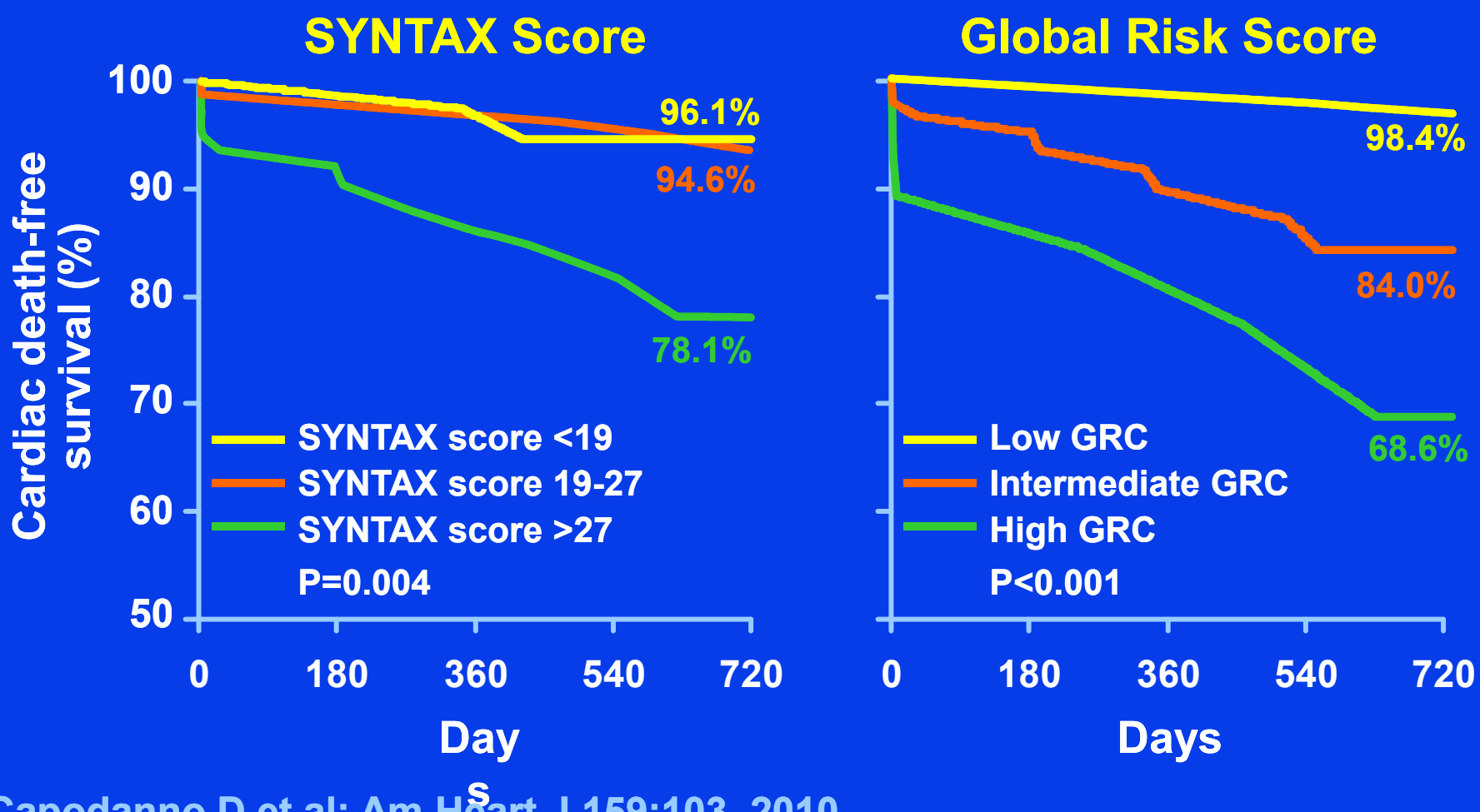
2-Year Survival



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

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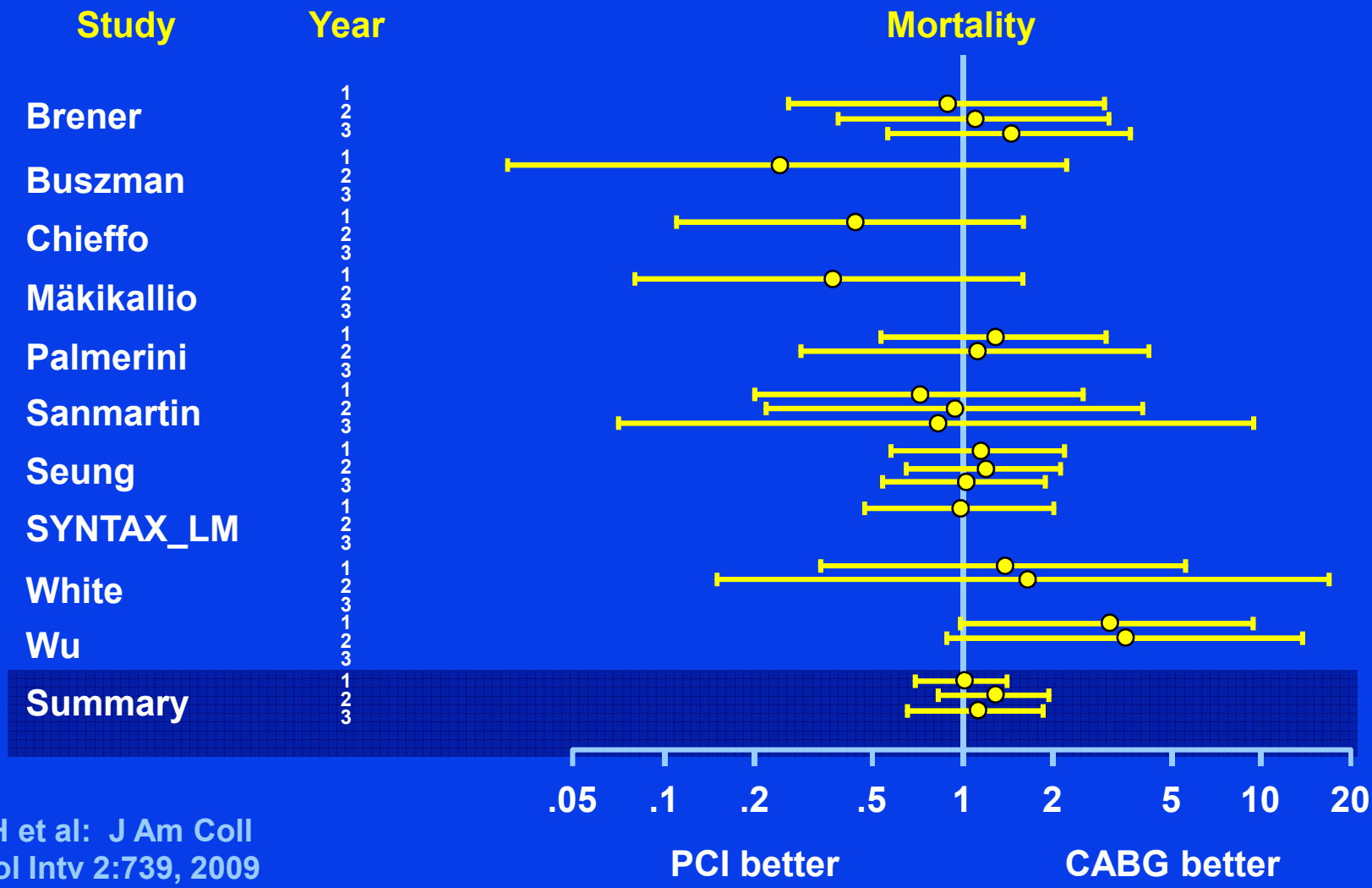
Unprotected LMCA
CABG vs PCI

- Meta-analysis of 3,773 patients in 10 studies
- CABG:
  - 2,114 patients,
  - Study range of patients 53-542
- PCI:
  - 1,659 patients
  - Study range of patients 35-542

Naik H et al: J Am Coll Cardiol Intv 2:739-47, 2009

Unprotected LMCA

Mortality Following Treatment for ULMCA Disease in PCI vs CABG Patients



Naik H et al: J Am Coll Cardiol Intv 2:739, 2009

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Unprotected LMCA
CABG vs PCI

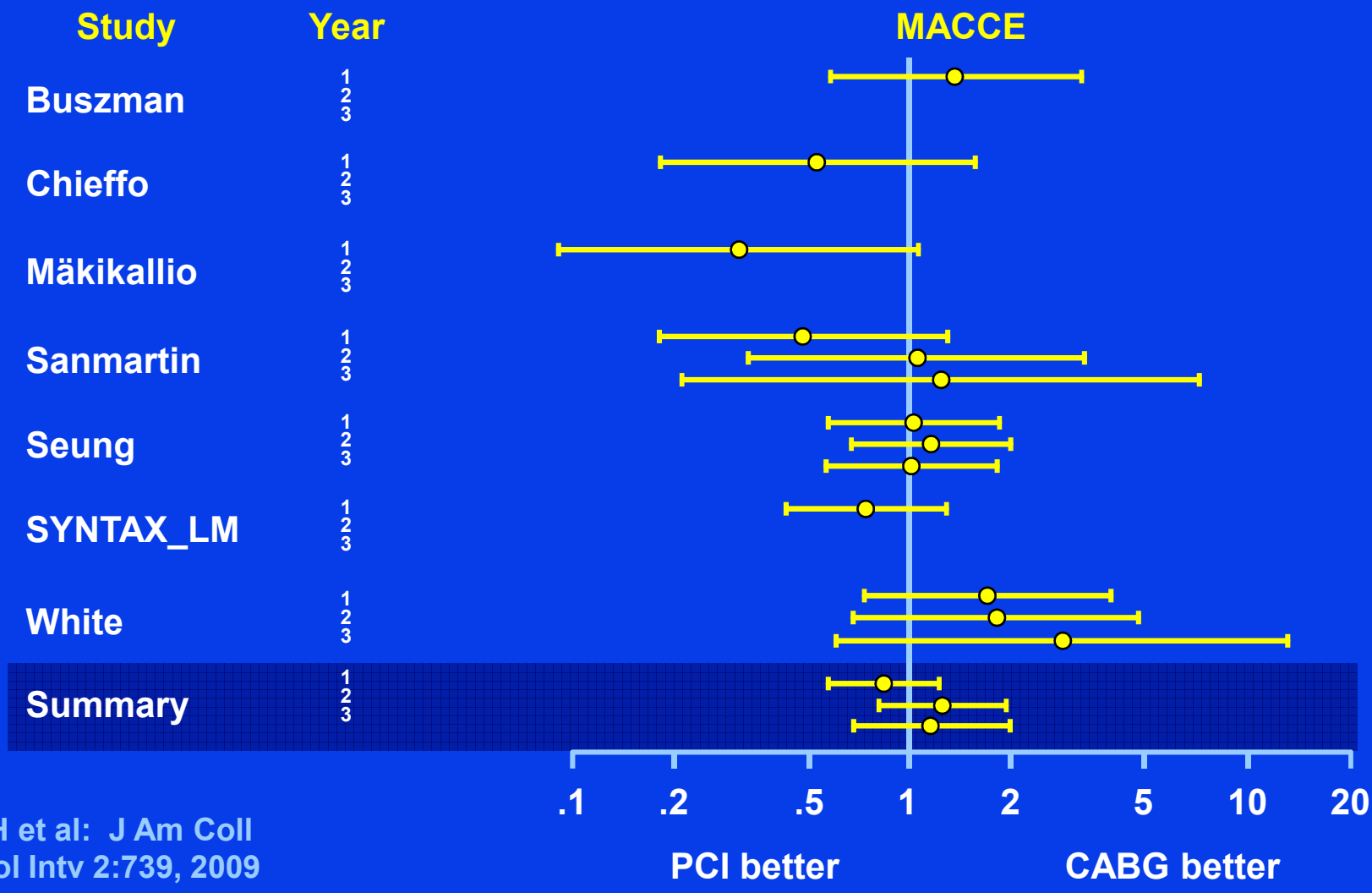
PCI Compared with CABG

Death	OR
1 year	1.00 (0.70, 1.41)
2 years	1.27 (0.83, 1.94)
3 years	1.11 (0.66, 1.86)
MACCE*	
1 year	0.84 (0.57, 1.22)
2 years	1.25 (0.81, 1.94)
3 years	1.16 (0.68, 1.98)

*Death, MI, stroke

Naik H et al: J Am Coll Cardiol Intv 2:739-47, 2009

Unprotected LMCA
MACCE in PCI vs CABG Patients



Naik H et al: J Am Coll Cardiol Intv 2:739, 2009

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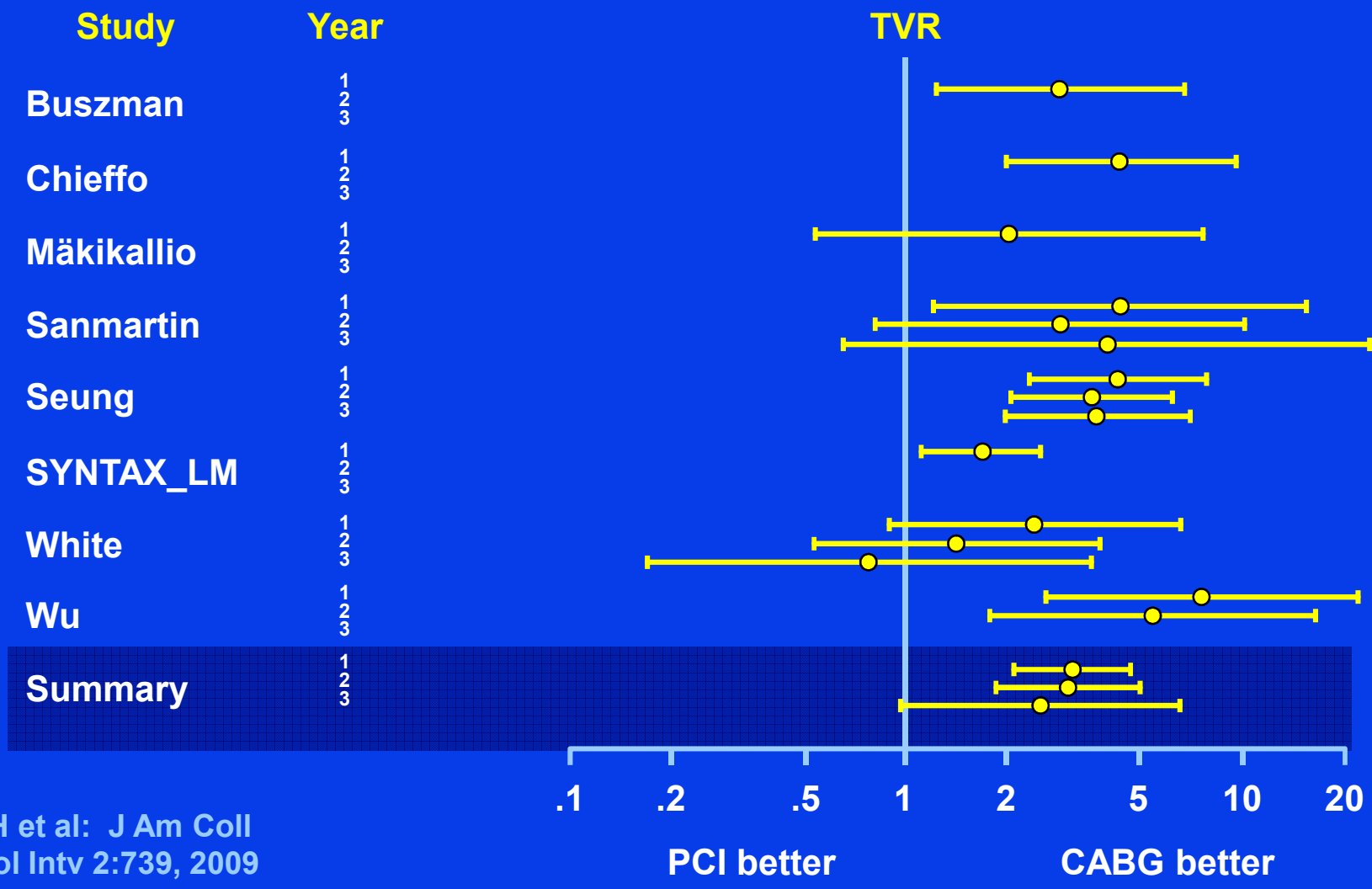
Unprotected LMCA
TVR in PCI vs CABG Patients



Naik H et al: J Am Coll Cardiol Intv 2:739, 2009

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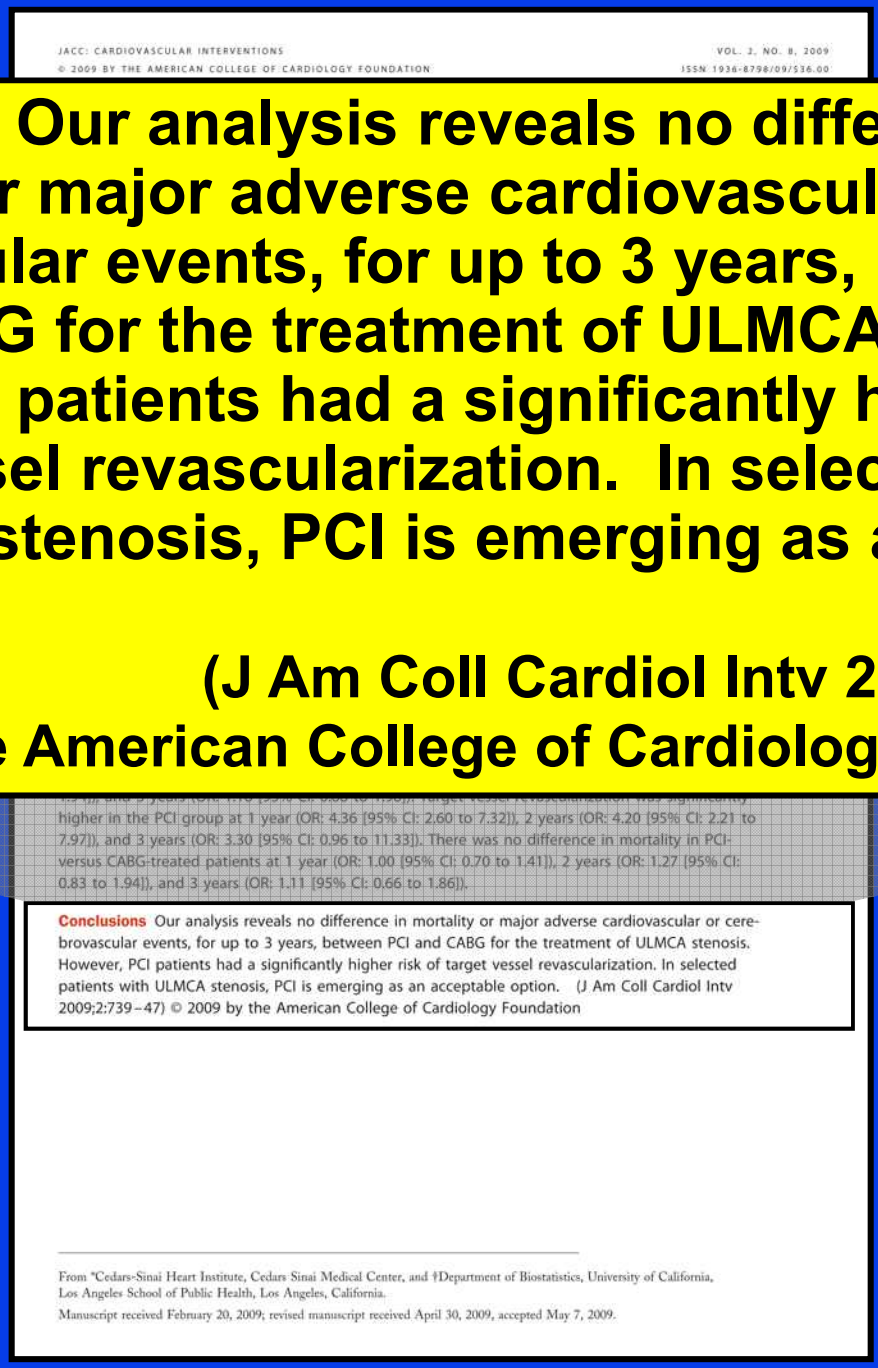
Conclusions: Our analysis reveals no difference in mortality or major adverse cardiovascular or cerebrovascular events, for up to 3 years, between PCI and CABG for the treatment of ULMCA stenosis. However, PCI patients had a significantly higher risk of target vessel revascularization. In selected patients with ULMCA stenosis, PCI is emerging as an acceptable option.

(J Am Coll Cardiol Intv 2009;2:739-47)



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higher in the PCI group at 1 year (OR: 4.36 [95% CI: 2.60 to 7.32]), 2 years (OR: 4.20 [95% CI: 2.21 to 7.97]), and 3 years (OR: 3.30 [95% CI: 0.96 to 11.33]). There was no difference in mortality in PCI- versus CABG-treated patients at 1 year (OR: 1.00 [95% CI: 0.70 to 1.41]), 2 years (OR: 1.27 [95% CI: 0.83 to 1.94]), and 3 years (OR: 1.11 [95% CI: 0.66 to 1.86]).

Conclusions Our analysis reveals no difference in mortality or major adverse cardiovascular or cerebrovascular events, for up to 3 years, between PCI and CABG for the treatment of ULMCA stenosis. However, PCI patients had a significantly higher risk of target vessel revascularization. In selected patients with ULMCA stenosis, PCI is emerging as an acceptable option. (J Am Coll Cardiol Intv 2009;2:739–47) © 2009 by the American College of Cardiology Foundation

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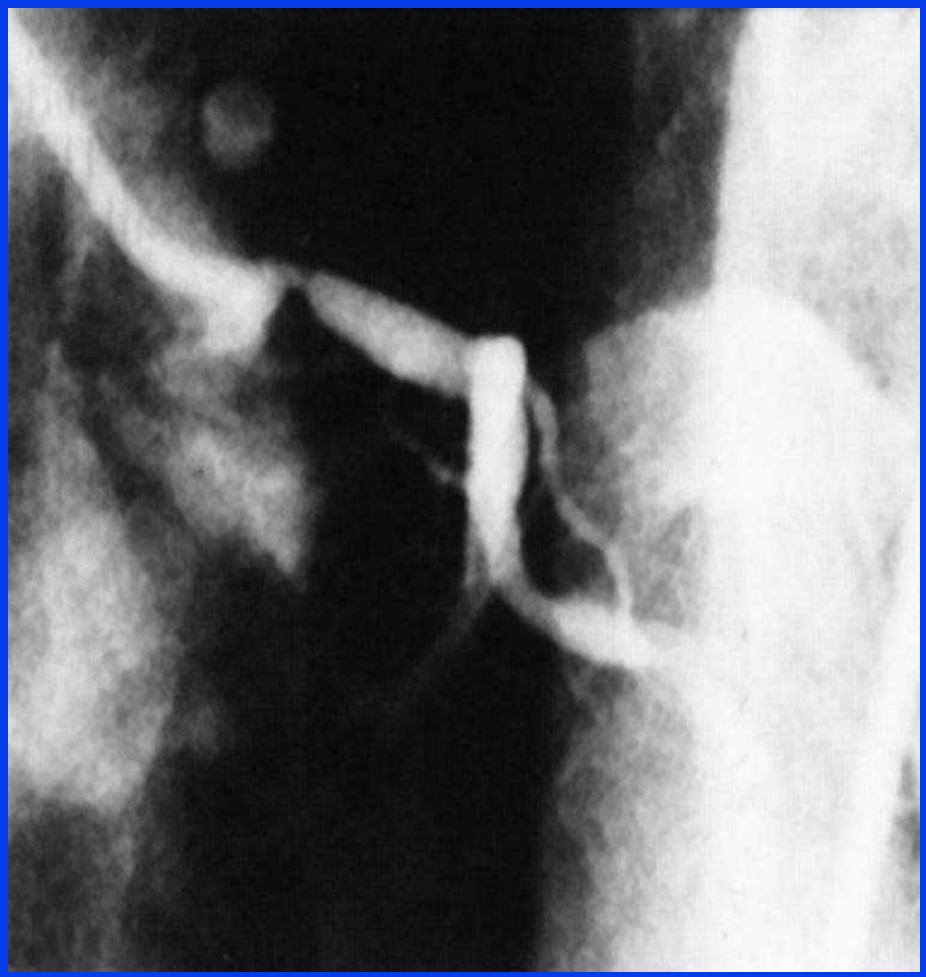
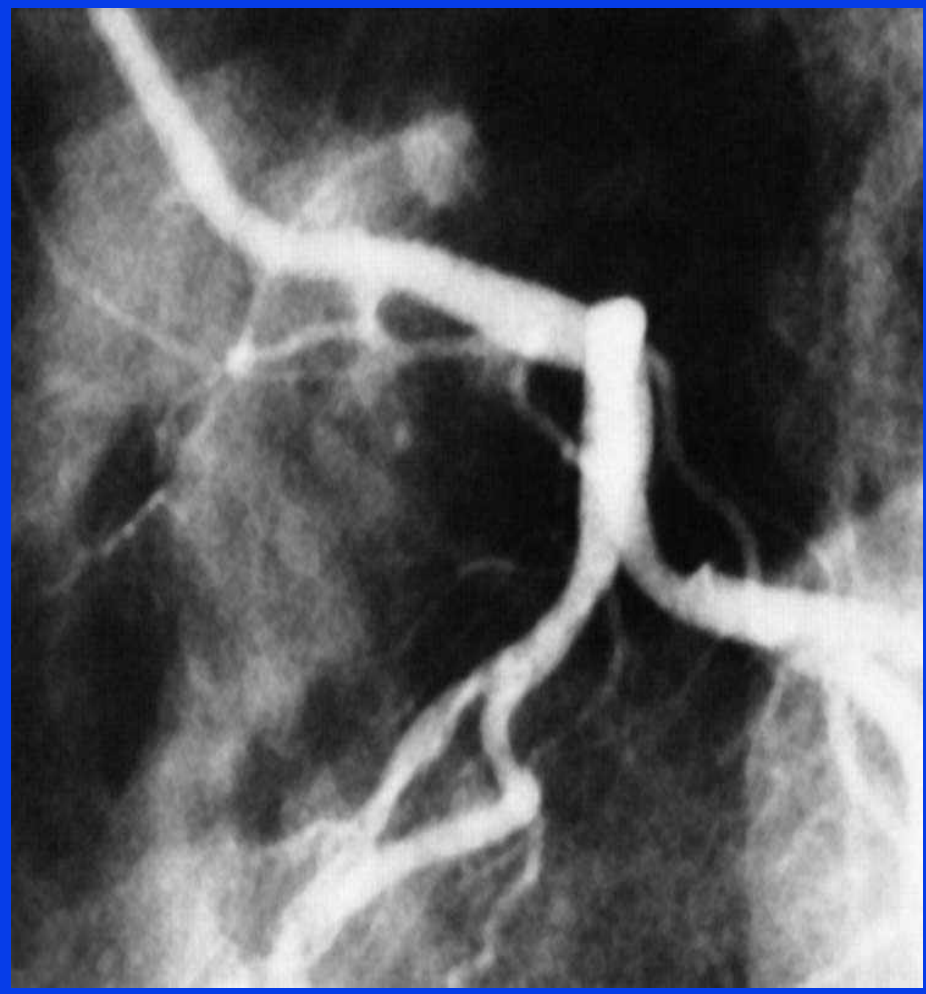
SYNTAX Trial
Conclusions

CABG remains the standard of care for patients with three-vessel or left main coronary artery disease, since the use of CABG, as compared with PCI, resulted in lower rates of the combined end point of major adverse cardiac or cerebrovascular events at 1 year.

Serruys PW et al, NEJM 360:961-72, 2009

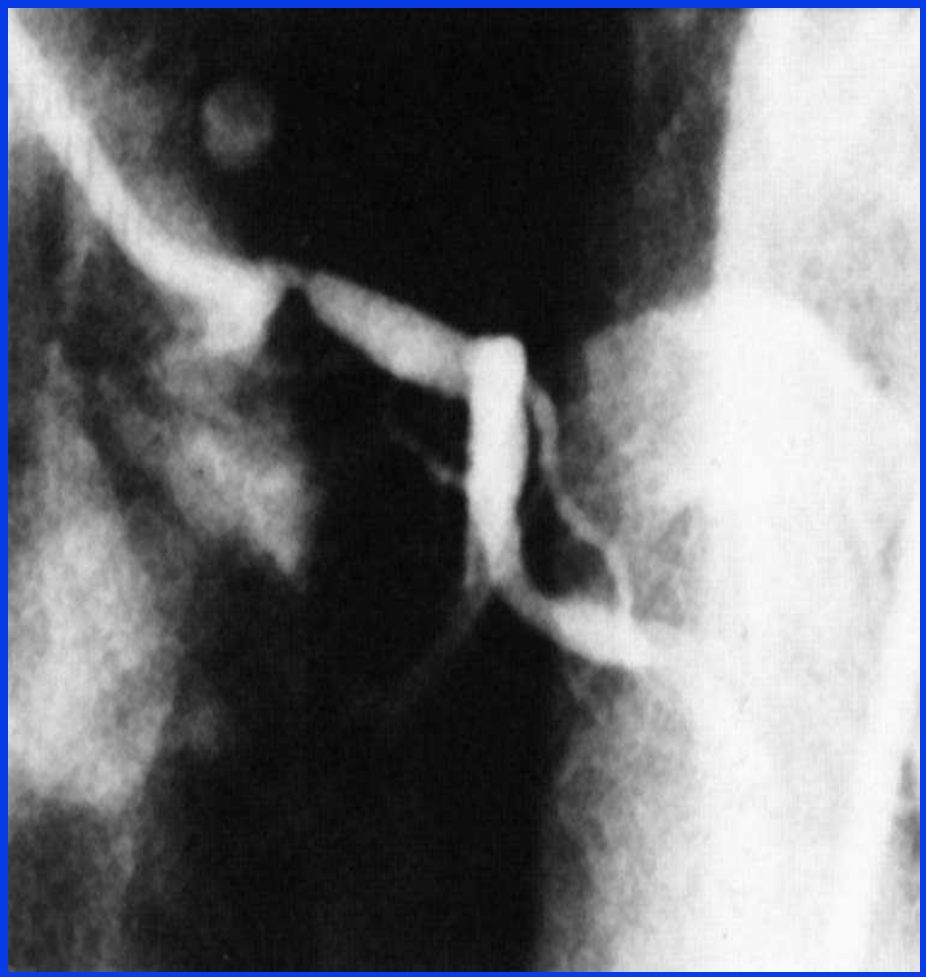
Plain old PTCA

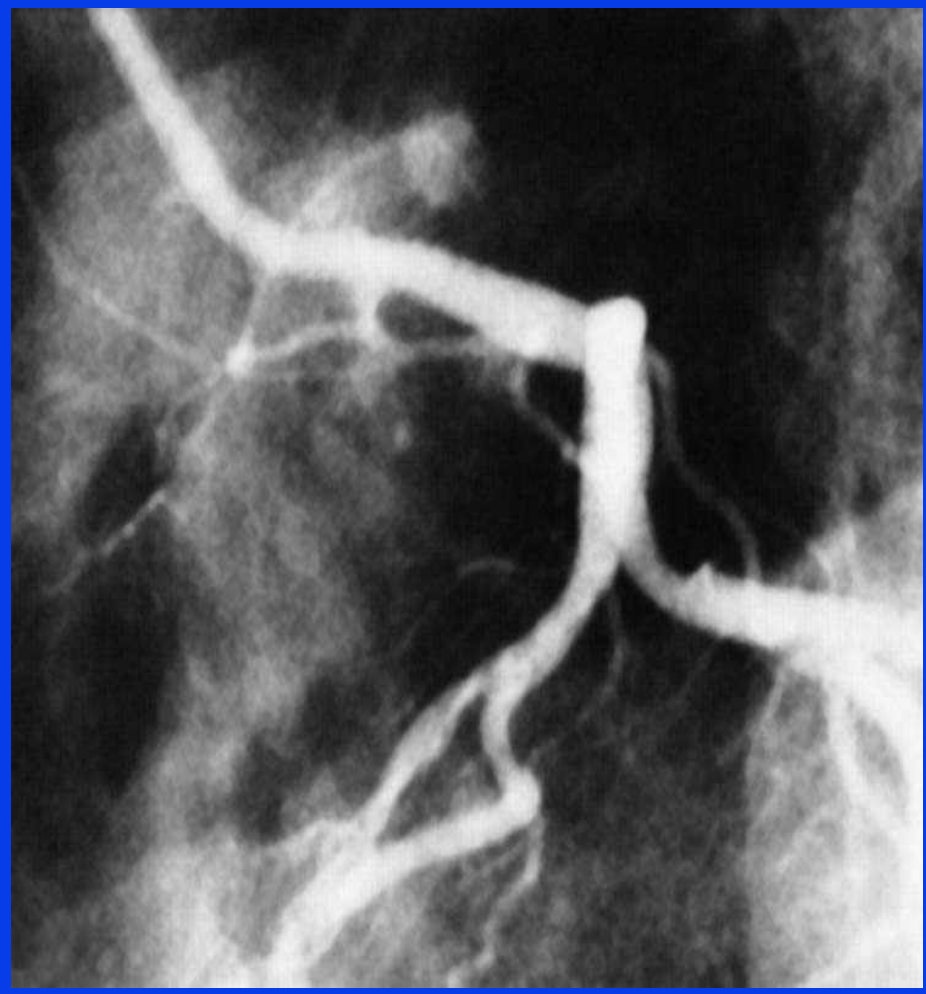


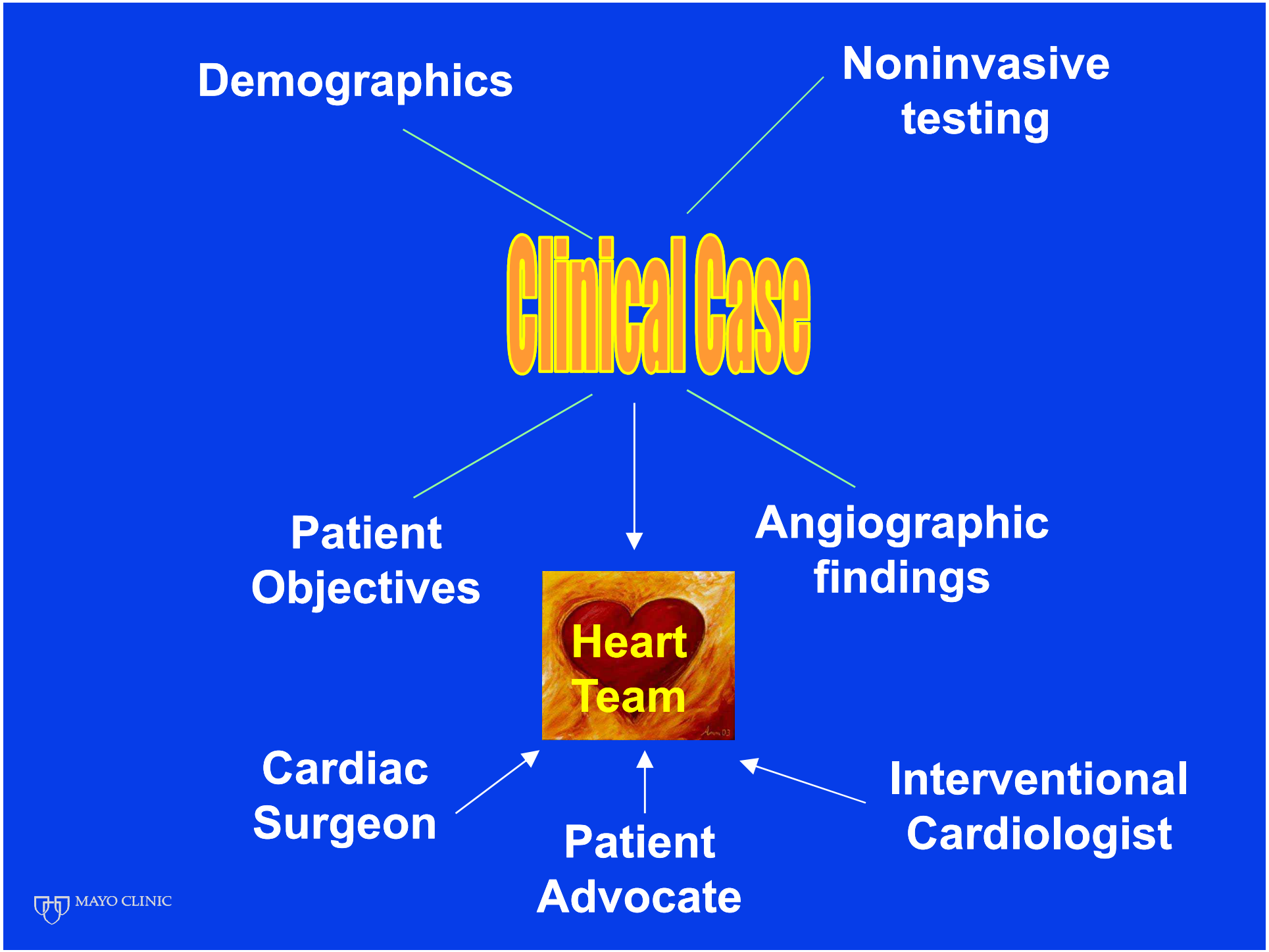


PTCA, eds Vlietstra and Holmes, 1987

Where we are now






Demographics
Noninvasive testing
Clinical Case
Patient Objectives
Angiographic findings
Heart Team
Cardiac Surgeon
Patient Advocate
Interventional Cardiologist
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ACC Guidelines
Unprotected Left Main Coronary Artery Disease

2004/2005/2007 recommendation	2009 PCI focused update recommendations	Comments
Class IIa		
1. It is reasonable that patients undergoing PCI to unprotected left main coronary obstructions be followed up with coronary angiography between 2 and 6 months after PCI (level of evidence C)		Deleted recommendation (no longer recommended)
Class IIb		
	1. PCI of the left main coronary artery with stents as an alternative to CABG may be considered in patients with anatomic conditions that are associated with a low risk of PCI procedural complications and clinical conditions that predict an increased risk of adverse surgical outcomes (level of evidence B)	New recommendation
Class III		
2005 PCI Guideline, Section 5.1 PCI is not recommended in patients with […] f. Left main disease and eligibility for CABG (*level of evidence C*)		Modified recommendation (bullet "f") from Section 5.1 and bullet "e" from Sections 5.2 and 5.3, are no longer current; see 2009 Class IIb recommendation #1)
2005 PCI guideline, Sections 5.2, 5.3 PCI is not recommended in patinets with […] e. Left main disease and eligibility for CABG (*level of evidence C*)		


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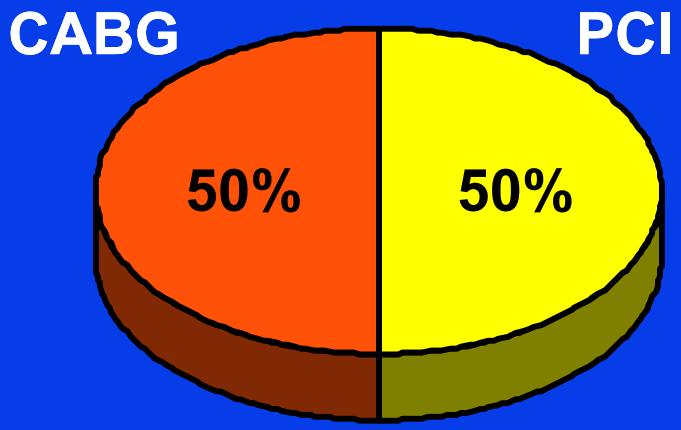
Stenting vs CABG
MVD

ARTS, ERACI-II, MASS II, SOS

Meta-analysis of 5-year patient level data

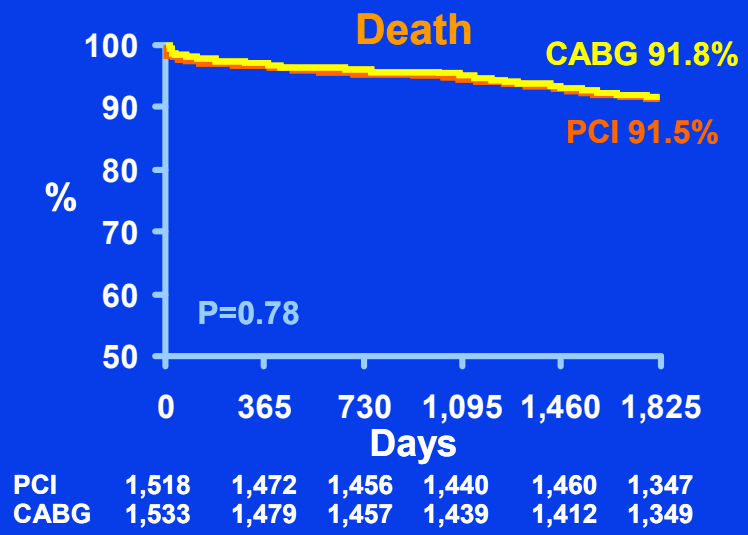
3,051 patients entered between June 1995 and June 2000



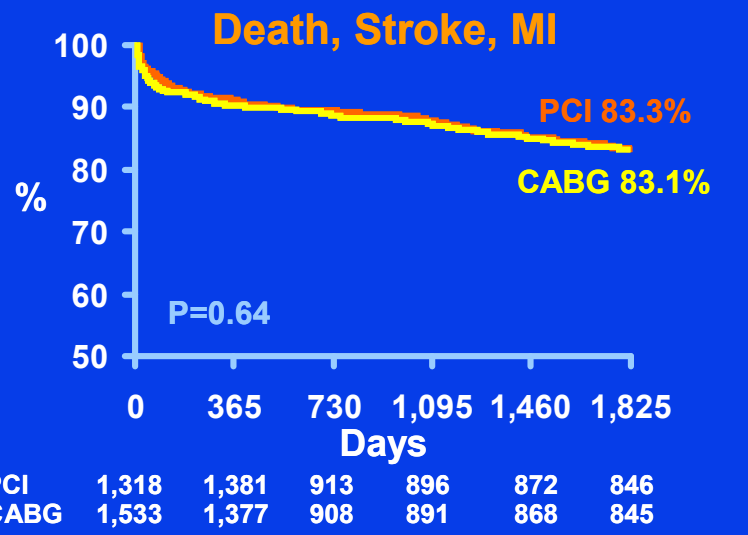
Purpose: evaluate safety and efficacy of PCI vs CABG for MVD

Daeman: Circ 118:1146, 2008

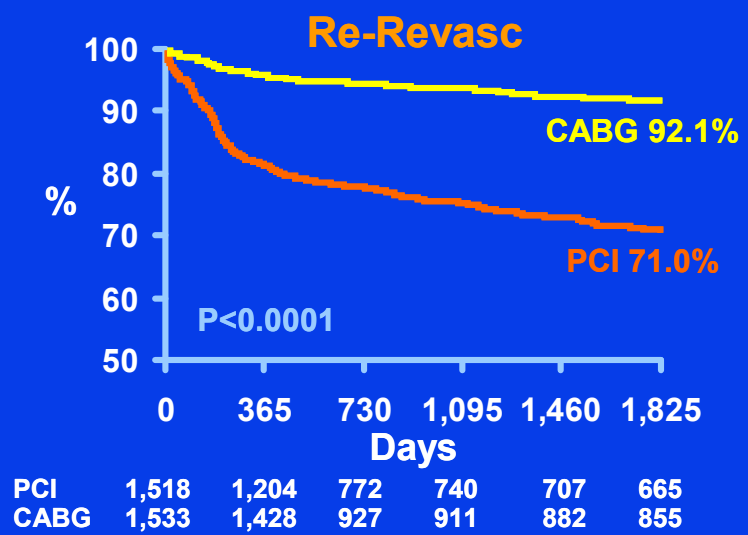
Stenting vs CABG



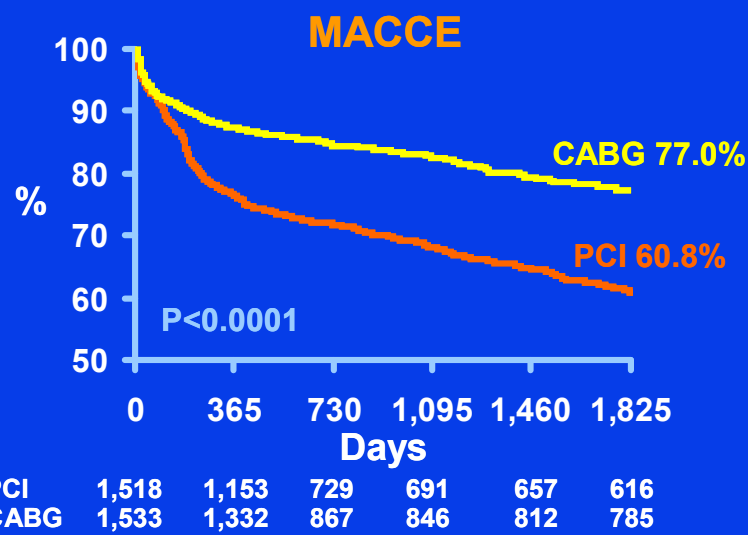
PCI	1,518	1,472	1,456	1,440	1,460	1,347
CABG	1,533	1,479	1,457	1,439	1,412	1,349



PCI	1,318	1,381	913	896	872	846
CABG	1,533	1,377	908	891	868	845



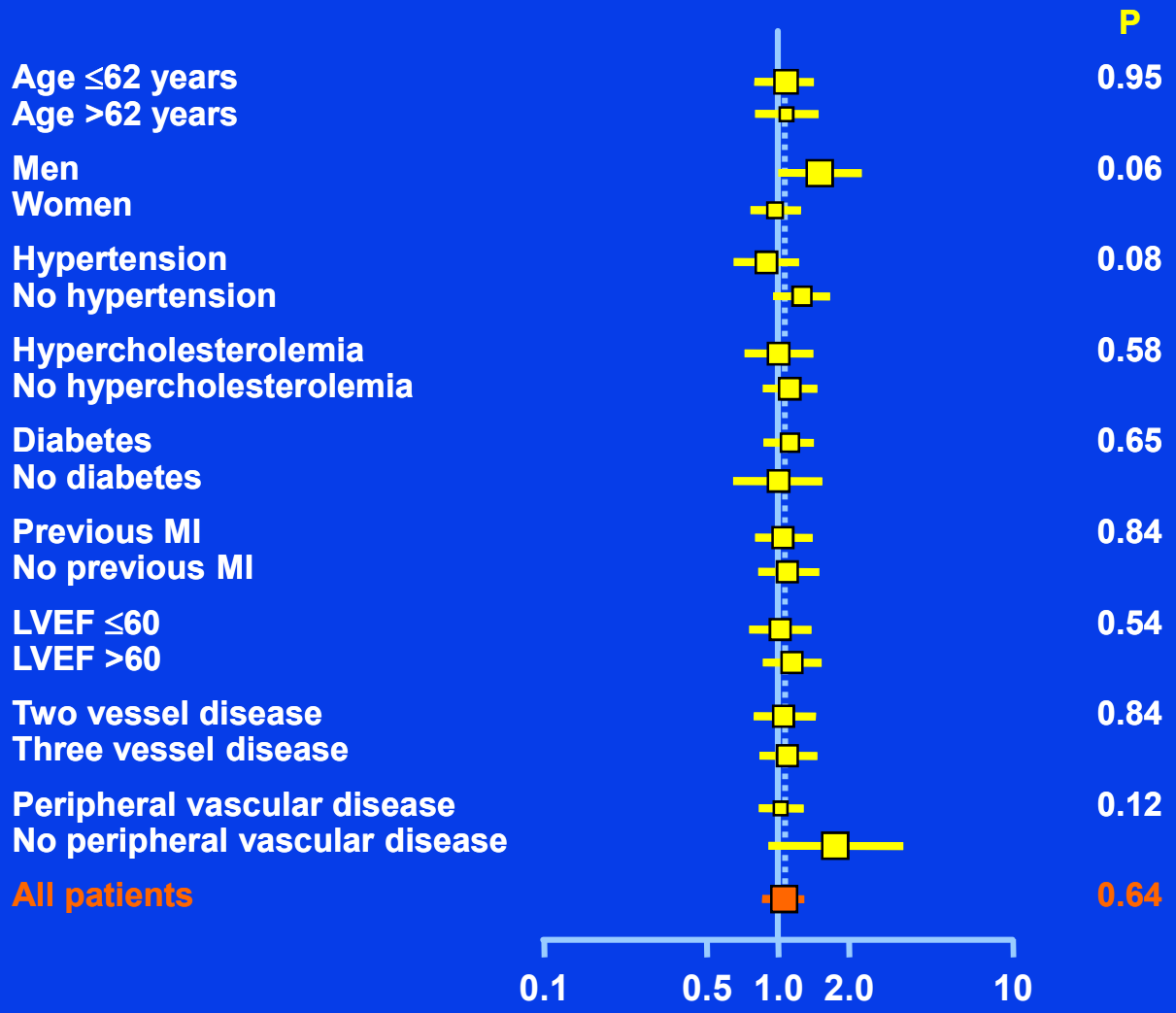
PCI	1,518	1,204	772	740	707	665
CABG	1,533	1,428	927	911	882	855



PCI	1,518	1,153	729	691	657	616
CABG	1,533	1,332	867	846	812	785

Daeman: Circ 118:1146, 2008

Stenting vs CABG



Daeman: Circ 118:1146, 2008

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Stenting vs CABG
Conclusion

In this pooled analysis of 4 RCT, PCI with stenting was associated with long-term safety profile similar to that of CABG

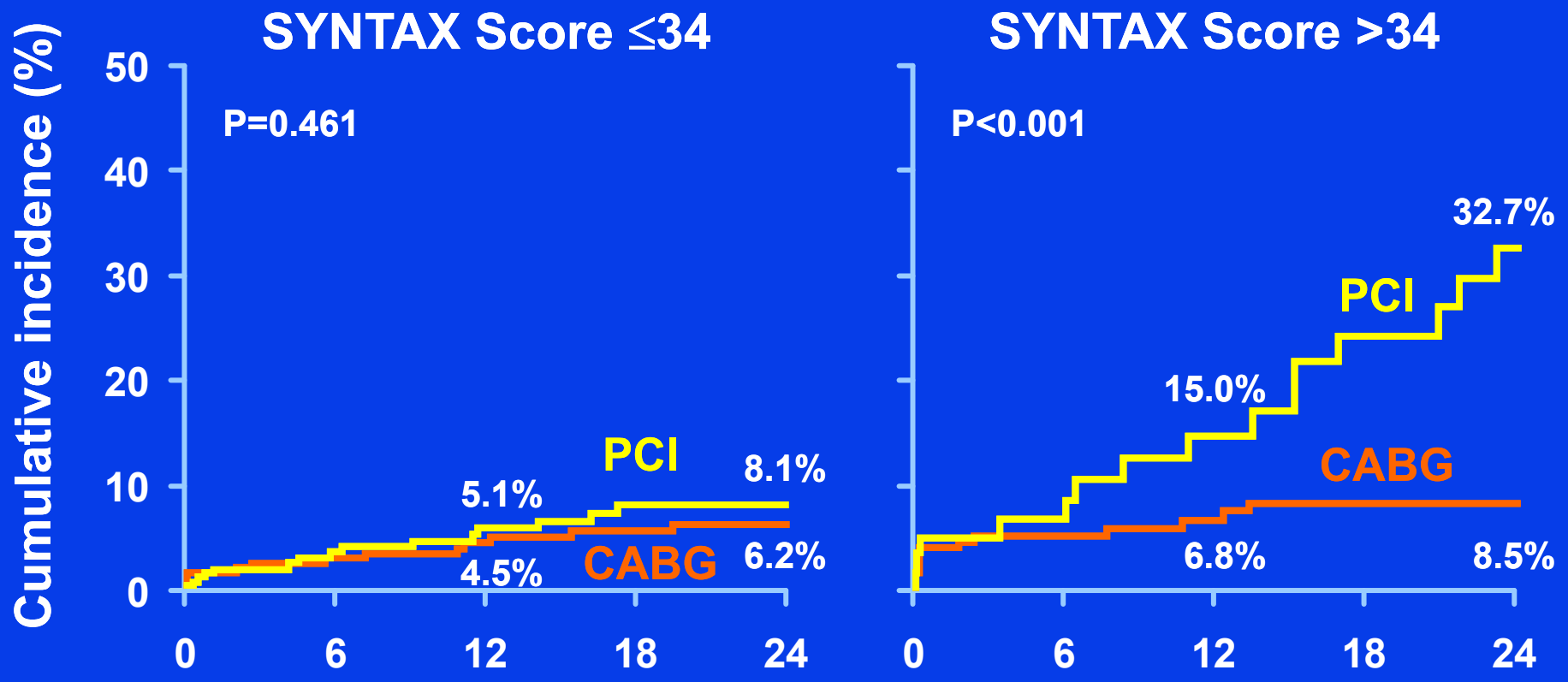
Daeman: Circ 118:1146, 2008

SYNTAX Score & Unprotected LMCA

- Registry study of clinical practice
- 819 patients with unprotected LMCA treated at 2 centers
- Comparison of clinical outcomes of PCI vs CABG depending on SYNTAX Score ≤34 vs >34

Capodanno D et al: J Am Coll Cardiol Intv 2:731-8, 2009

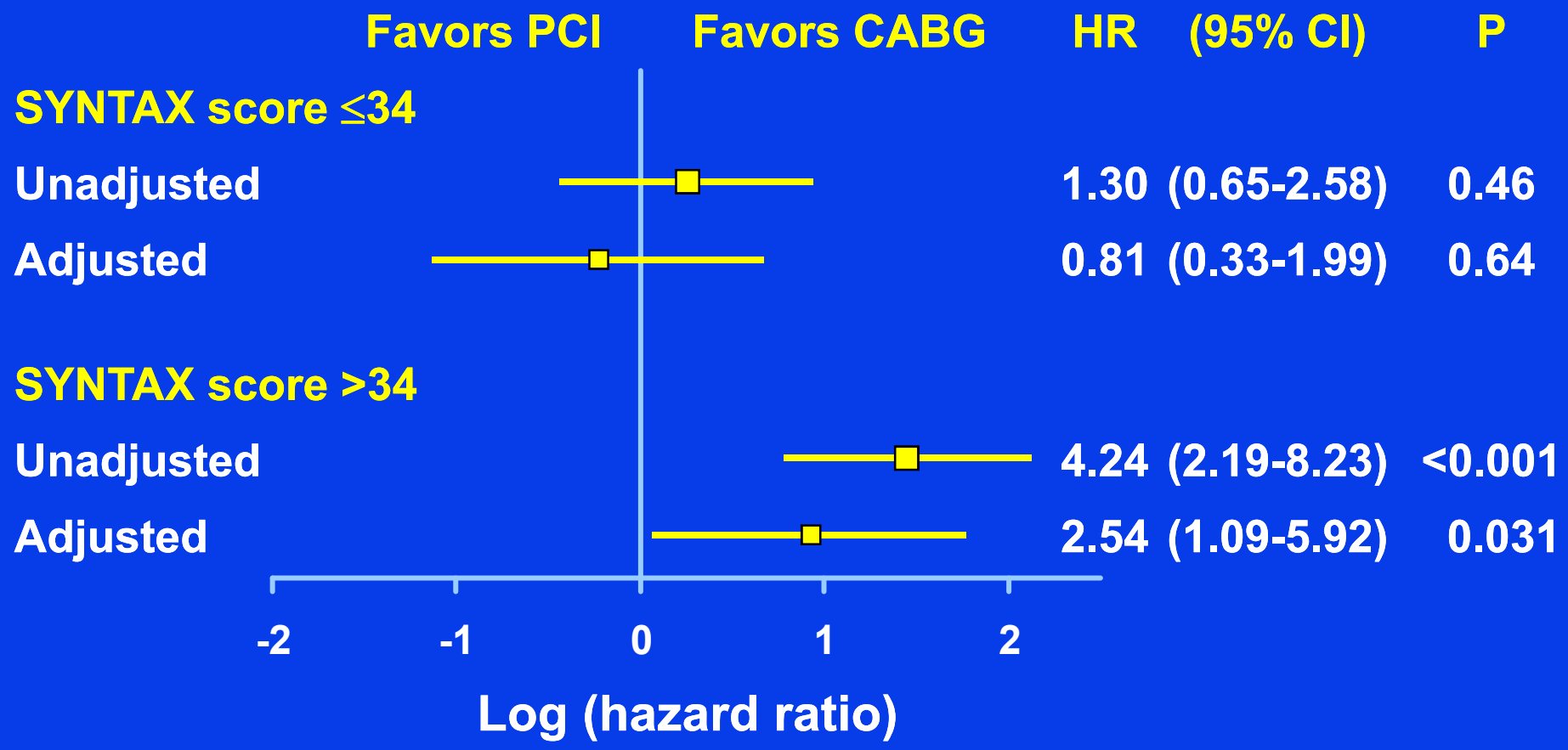
SYNTAX Score and UPLMCA
Unadjusted 2-Year Mortality



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 & Unprotected LMCA
Conclusions

"A SYNTAX score threshold of 34 may usefully identify a cohort of patients with left main disease who benefit most from surgical revascularization in terms of mortality."

Capodanno D et al: J Am Coll Cardiol Intv 2:731-8, 2009

Applying Classification of Recommendations and Level of Evidence

Class I	Class IIa	Class IIb	Class III
Benefit >>> Risk Procedure/ Treatment **SHOULD** be performed/ administered	*Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	*Benefit ≥ Risk* *Additional studies with broad objectives needed; Additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	*Risk ≥ Benefit* *No additional studies needed* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**
should is recommended is indicated is useful/effective/ beneficial	is reasonable can be useful/effective/ beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown /unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

Applying Classification of Recommendations and Level of Evidence

Class I	Class IIa	Class IIb	Class III
Benefit >>> Risk Procedure/ Treatment **SHOULD** be performed/ administered	*Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	*Benefit ≥ Risk* *Additional studies with broad objectives needed; Additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	*Risk ≥ Benefit* *No additional studies needed* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**

Level A:	Multiple populations evaluated; Data derived from multiple randomized clinical trials or meta-analyses
Level B:	Limited populations evaluated. Data derived from a single randomized trial or non-randomized studies
Level C:	Very limited populations evaluated. Only consensus opinion of experts, case studies, or standard-of-care.

ACC/AHA 2009 Joint STEMI/PCI Guidelines Focused Update

Routineness

- Routines are a useful aid
- Routines should not be cast in stone
- Routines should never take the place of good reasoned clinical judgment

Unprotected LMCA
CABG vs PCI

PCI Compared with CABG

TVR	OR
1 year	4.36 (2.60, 7.32)
2 years	4.20 (2.21, 7.97)
3 years	3.30 (0.96, 11.33)

Naik H et al: J Am Coll Cardiol Intv 2:739-47, 2009

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3038641

Subject: PCI for Unprot. LMCA, Naik

Background: BU3
Banner/brdr: 0-40-159/BU41
Plot/brdr: open/BU41
x, y only

Side title: YW105
• /colhdgs: YW105
Text: WT/BK
Highlight: YO114
Subdue: BU31
Footnotes: BU41

PPT shooting instructions
PPT File to Server
(4 images)

Artist: JS
Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

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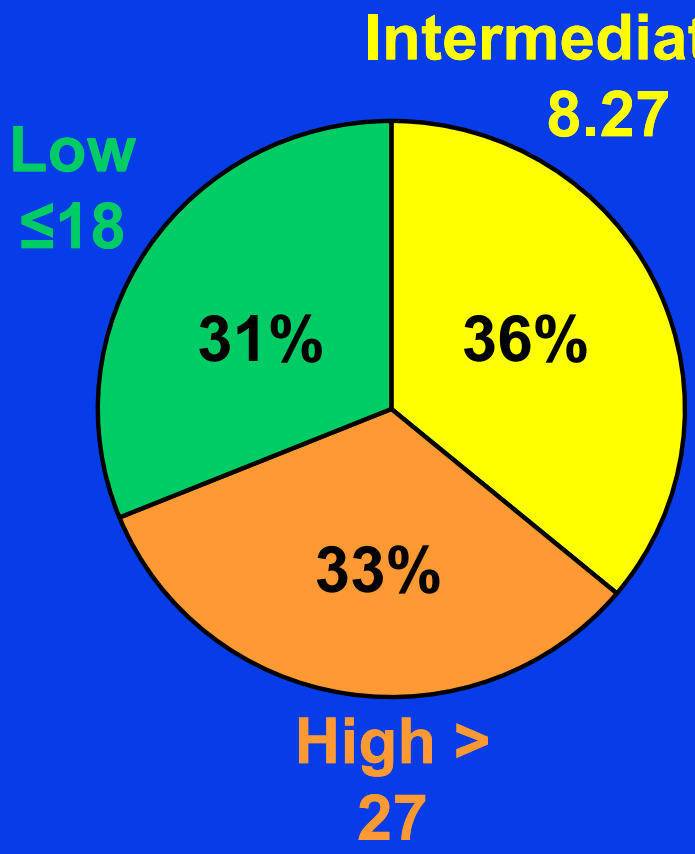
SYNTAX & Unprotected LMCA

- Single center observational study
- 255 consecutive patients undergoing PCI of unprotected LMCA stenosis
- Evaluate relationship between SYNTAX score and 1-year outcome
- Endpoints
  - Cardiac mortality
  - MACE

Capodanno D et al: Circ Cardiovasc Intervent 2:302-08, 2009

SYNTAX & Unprotected LMCA



	Low	Intermediate	High	P
% LAD	35	71	89	<0.001
# stents	1.8	2.9	3.3	<0.001
% CR	70	50	22	<0.001

Capodanno D et al: Circ Cardiovasc Intervent 2:302-08, 2009

SYNTAX & Unprotected LMCA
Outcome

	Low (%)	Intermediate (%)	High (%)
In hospital			
Cardiac death	0	1.1	3.5
MACE*	1.3	3.3	4.7
Long-term			
Cardiac death	2.5	1.1	13.1
MACE*	7.4	21.4	20.4

*Cardiac death, nonfatal MI, TLR

Capodanno D et al: Circ Cardiovasc Intervent 2:302-08, 2009

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).

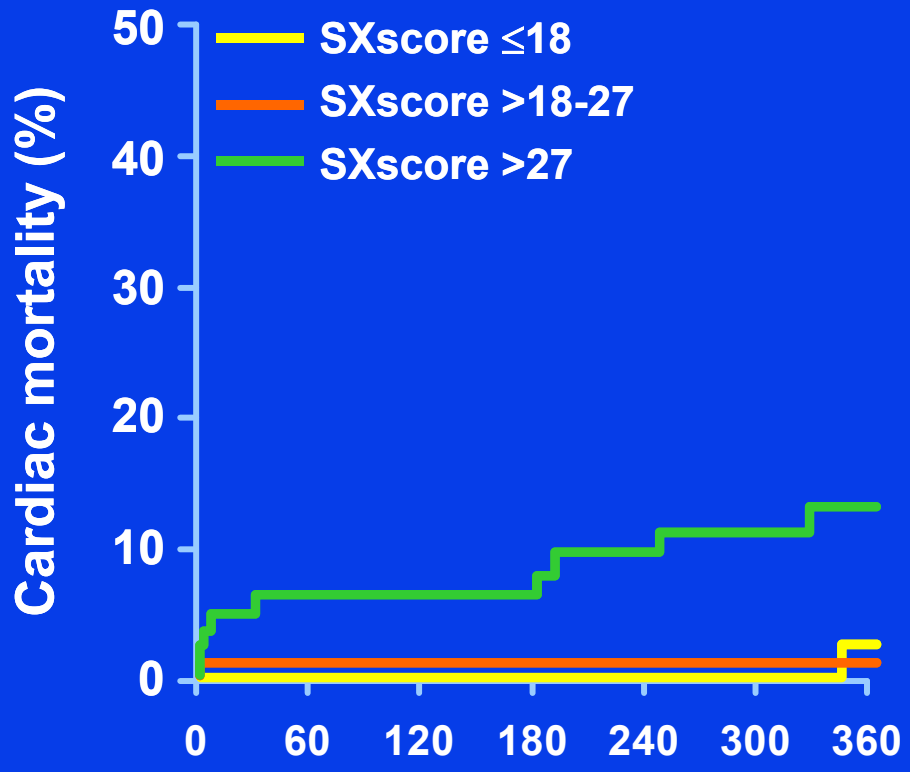
Methods

Patient Population

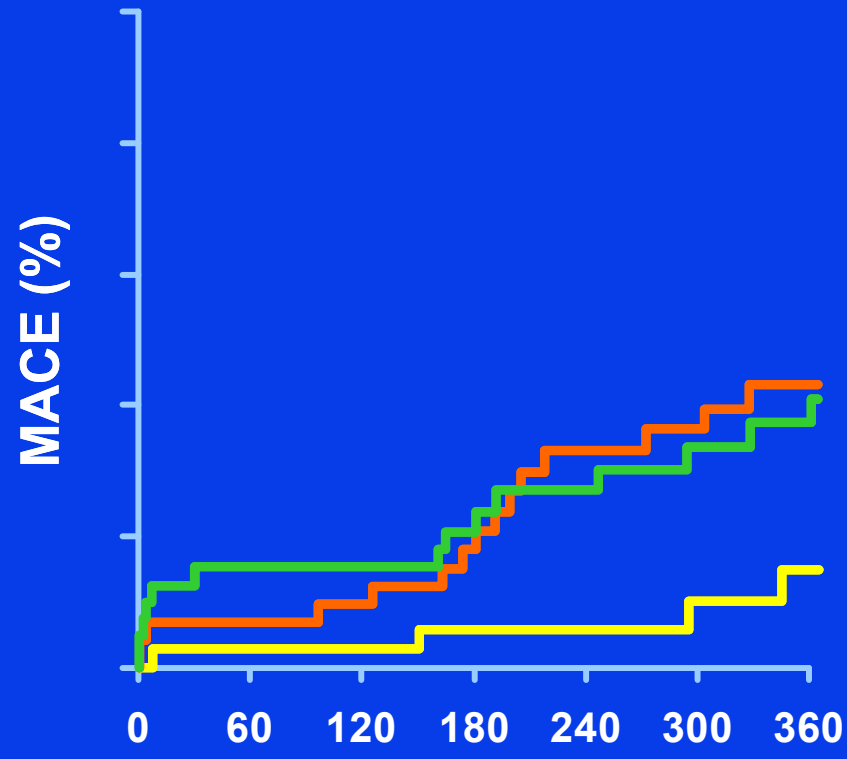
All consecutive patients undergoing PCI with either a sirolimus-eluting stent (Cypher, Cordis, a Johnson and Johnson Company, Miami Lakes, Fla) or a paclitaxel-eluting stent (Taxus, Boston Scientific, Natick, Mass) in left main coronary artery, from January 2003 to June 2008, at the Ferrarotto Hospital, 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

MAYO CLINIC

SYNTAX and Unprotected LMCA



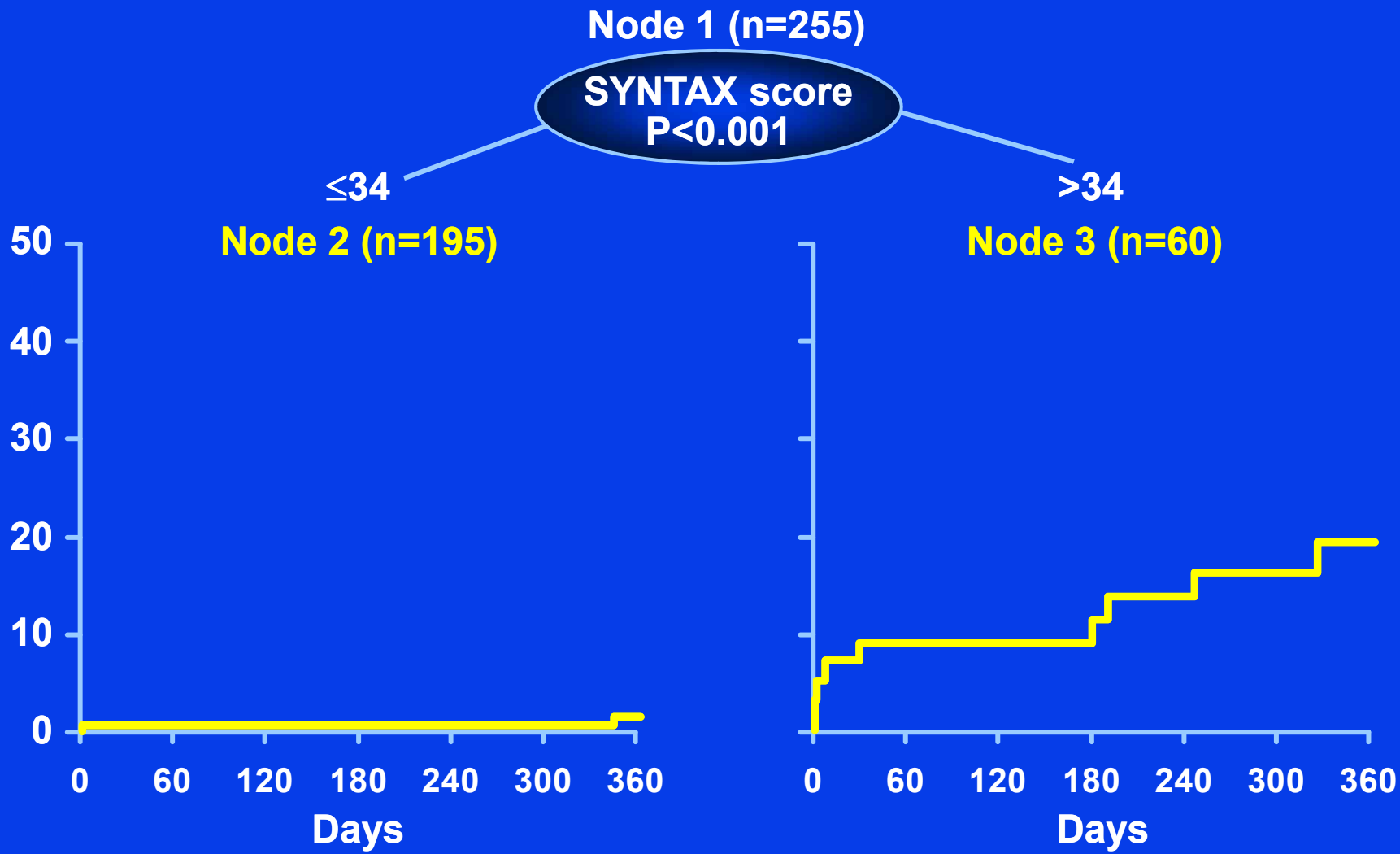
No. at risk			
I tertile	68	49	38
II tertile	71	52	46
III tertile	66	64	46



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

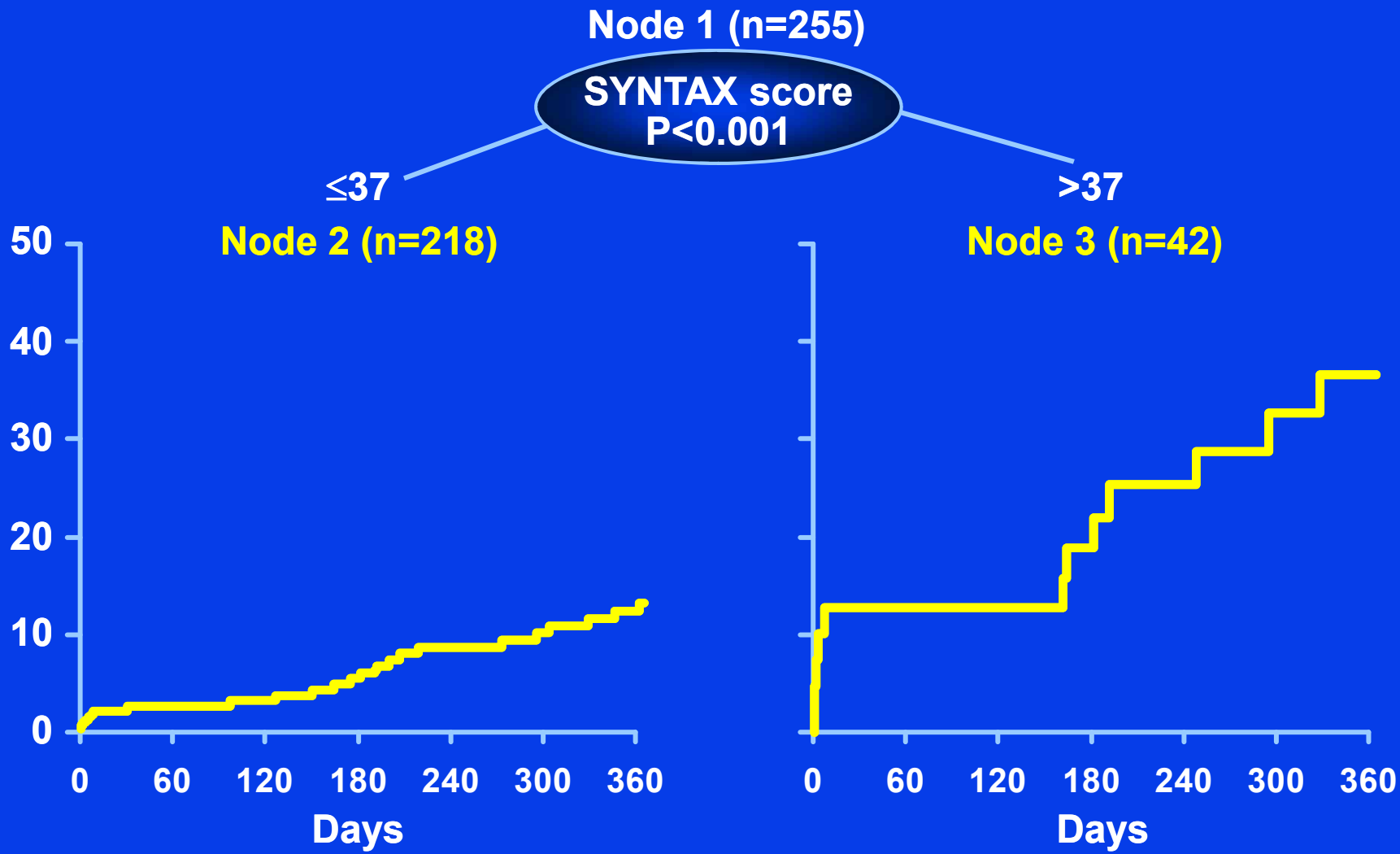
Capodanno D et al: Circ Cardiovasc Intervent 2:302, 2009

SYNTAX and Unprotected LMCA
Cardiac Death



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

SYNTAX and Unprotected LMCA MACE



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

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3038660

Subject: SYNTAX & Upprot. LMCA, Capodanno

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Footnotes: BU41

PPT shooting instructions
PPT File to Server
(4 images)

Artist: mls
Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

SYNTAX Score & Unprotected LMCA
Differences Between PCI & CABG

SYNTAX Score

≤34

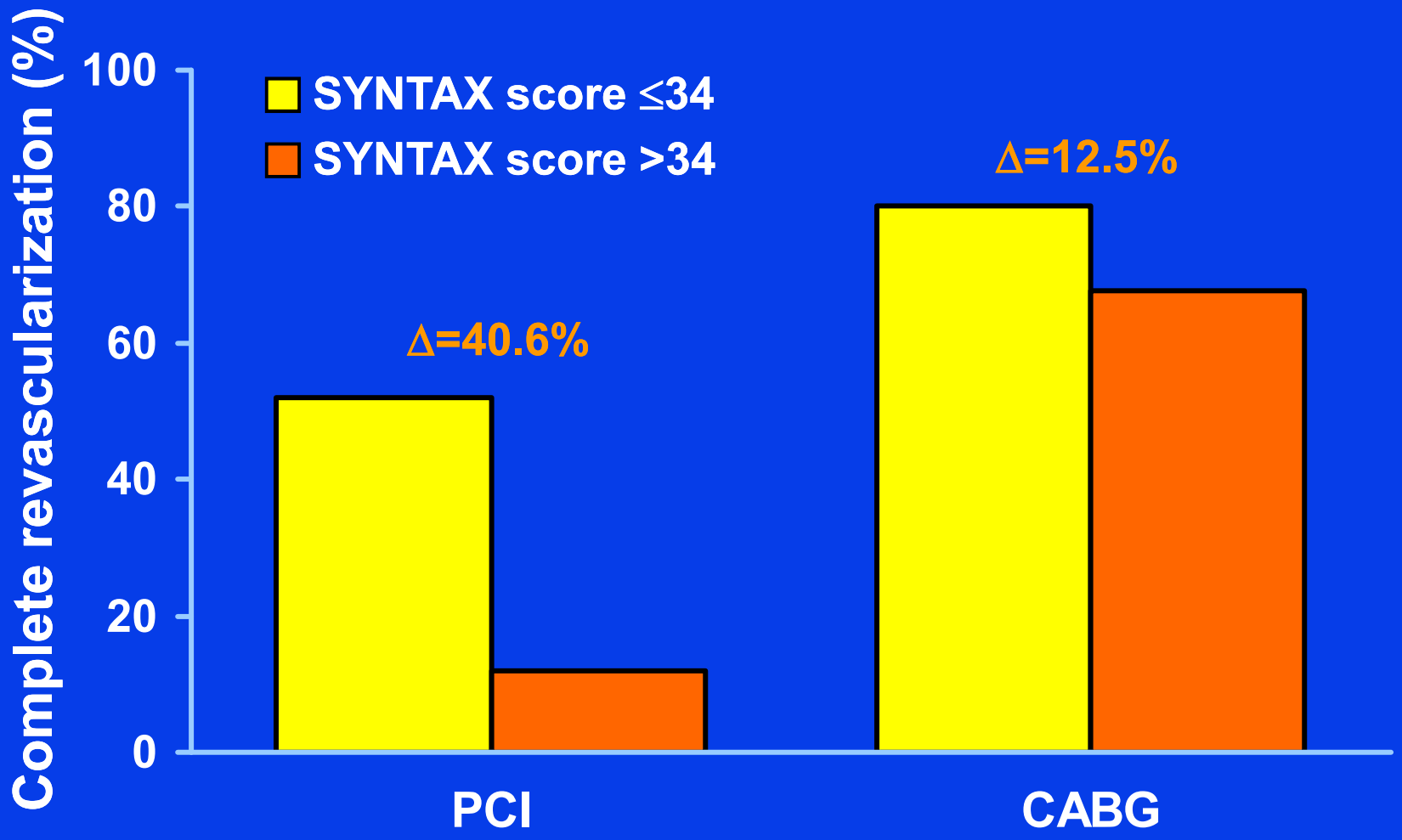
- More prior PCI
- More prior MI
- More acute MI
- More LMCA + IVD
- Less LMCA + 3VD
- Lower SYNTAX score
- Less distal LMCA
- Less CR

>34

- Lower EF
- Higher EuroSCORE
- Less distal LMCA
- Less SYNTAX score
- Less CR

Capodanno D et al: J Am Coll Cardiol Intv 2:731-8, 2009

SYNTAX Score and UPLMCA



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

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3038619

Subject: SYNTAX Score and UPLMCA, Capodanno

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PPT File to Server
(3 images)

Artist: ma
Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC

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

Subject: Euro Score & SYNTAX, Capodanno

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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

Austrian Multivessel TAXUS Registry
2-Year Results

- Multicenter registry of 441 consecutive patients with symptomatic MVD undergoing PCI in whom complete revascularization was feasible
- Patients with 2 or 3VD, with or without LMCA, stable or unstable angina (NSTEMI)
- Evaluation by a multidisciplinary team
- Primary endpoint:
  - MACCE (all cause death, nonfatal MI, TLR, cerebrovascular event at 2 years)

Gyongyosi M et al: J Am Coll Cardiol Intv 2:718-27, 2009

Austrian Multivessel TAXUS Registry
2-Year Results

- Complete revascularization achieved in 90.5%
  - Incomplete revascularization:
    - 3.6% side branch occlusion, dissection
    - 5.5% non treatment of a significant lesion for anatomic reasons
    - 0.4% unsatisfactory PCI

Gyongyosi M et al: J Am Coll Cardiol Intv 2:718-27, 2009

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CLINICAL RESEARCH

2-Year Results of the AUTAX (Austrian Multivessel TAXUS-Stent) Registry

Beyond the SYNTAX (Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery) Study

Mariann Gyöngyösi, MD, PhD,* Günter Christ, MD,* Irene Lang, MD,*
Gerhard Kreiner, MD,* Heinz Sochor, MD,* Peter Probst, MD,* Thomas Neunteufl, MD,*
Rosa Badr-Eslam, MD,* Susanne Winkler, MD,* Noemi Nyolczas, MD,* Aniko Posa, PhD,*

Conclusions: With the aim of complete revascularization, TAXUS stent implantations can be safe for patients with multivessel disease. The AUTAX registry including patients with post-PCI lesions provides additional information to the SYNTAX (Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery) study.

subacute, and late stent thrombosis were 0.7%, 0.5%, and 0.5%. Two-year follow-up identified AMI (1.4%), death (3.6%), stroke (0.2%), and TLR (13.1%), for a composite MACCE of 18.3%. The binary restenosis rate was 10.8%. The median of cumulative SYNTAX score was 23.0 (range 12.0 to 56.5). The SYNTAX score did not predict TLR or MACCE, due to lack of scoring of restenotic or bypass stenoses (29.8%). Age (hazard ratio [HR]: 1.03, p = 0.019) and acute coronary syndrome (HR: 2.1, p = 0.001) were significant predictors of 2-year MACCE. Incomplete revascularization predicted death or AMI (HR: 3.84, p = 0.002).

Conclusions With the aim of complete revascularization, TAXUS stent implantations can be safe for patients with multivessel disease. The AUTAX registry including patients with post-PCI lesions provides additional information to the SYNTAX (Synergy Between Percutaneous Coronary Intervention With TAXUS and Cardiac Surgery) study. (Austrian Multivessel TAXUS-Stent Registry; NCT00738686) (J Am Coll Cardiol Intv 2009;2:718–27) © 2009 by the American College of Cardiology Foundation

Austrian Multivessel TAXUS Registry
Patients with Multivessel CAD and Treatment Options

Screened patients	1,012
CABG	473
Complex anatomy	353 (74.6%)
CTO untreatable with PCI	78 (16.5%)
DAPT is not possible or patient incompliance	26 (5.5%)
Patient refused PCI	3 (0.7%)
Others	13 (2.7%)
PCI	542
Included in AUTAX registry	441
Comorbidities	208 (47.2%)
No. of graft vessel	24 (5.4%)
Poor distal vessel quality	48 (10.9%)
Patient refused CABG	131 (29.7%)
Others	30 (6.8%)
Not included in AUTAX registry (met exclusion criteria)	101

Gyöngyösi M et al: J Am Coll Cardiol Intv 2:718, 2009

Austrian Multivessel TAXUS Registry
Procedural Characteristics

	No.	%
Lesion in left main coronary artery	30	6.8
Left main with 1-vessel disease	5	1.1
Left main with 2-vessel disease	1	0.2
Left main with 3-vessel disease	24	5.4
2-vessel disease without left main lesion	274	62.1
3-vessel disease without left main lesion	161	36.5

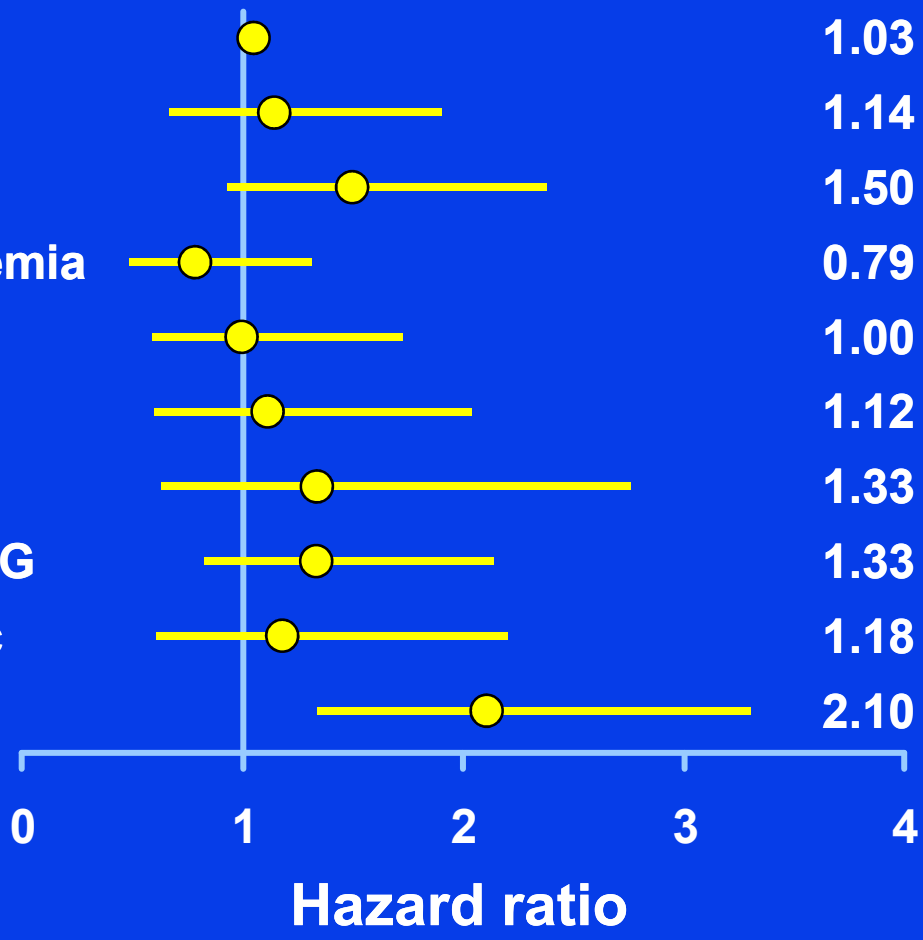
Gyöngyösi M et al: J Am Coll Cardiol Intv 2:718, 2009

Austrian Multivessel TAXUS Registry
Clinical 2-Year Follow-Up Events with MACCE

	No.	%
First 30 days, complications	15	3.4
Cumulative 6-mo MACCE	47	10.2
Cumulative 1-yr MACCE	66	15.7
Cumulative 2-yr MACCE	78	18.3
All-cause death and/or acute MI at 1 yr	20	4.8
All-cause death and/or acute MI at 2 yr	22	5.3

Gyöngyösi M et al: J Am Coll Cardiol Intv 2:718, 2009

Austrian Multivessel TAXUS Registry
Predictors of MACCE



	HR	95% CI	P
Age	1.03	1.00-1.05	0.019
Gender	1.14	0.66-1.89	0.637
Diabetes mellitus	1.50	0.94-2.36	0.081
Hypercholesterolemia	0.79	0.49-1.31	0.347
3-vessel disease	1.00	0.59-1.71	0.993
Total stent length	1.12	0.61-2.03	0.720
Syntax score	1.33	0.63-2.74	0.446
Previous PCI/CABG	1.33	0.83-2.12	0.227
Incomplete revasc	1.18	0.61-2.19	0.611
UA/NSTEMI	2.10	1.34-3.28	0.001

Gyöngyösi M et al: J Am Coll Cardiol Intv 2:718, 2009

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3038643

Subject: Austrian TAXUS Registry, Gyongyosi

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Subdue: BU31

Footnotes: BU41

PPT shooting instructions
PPT File to Server
(5 images)

Artist: ma

Start Date: 4-12-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

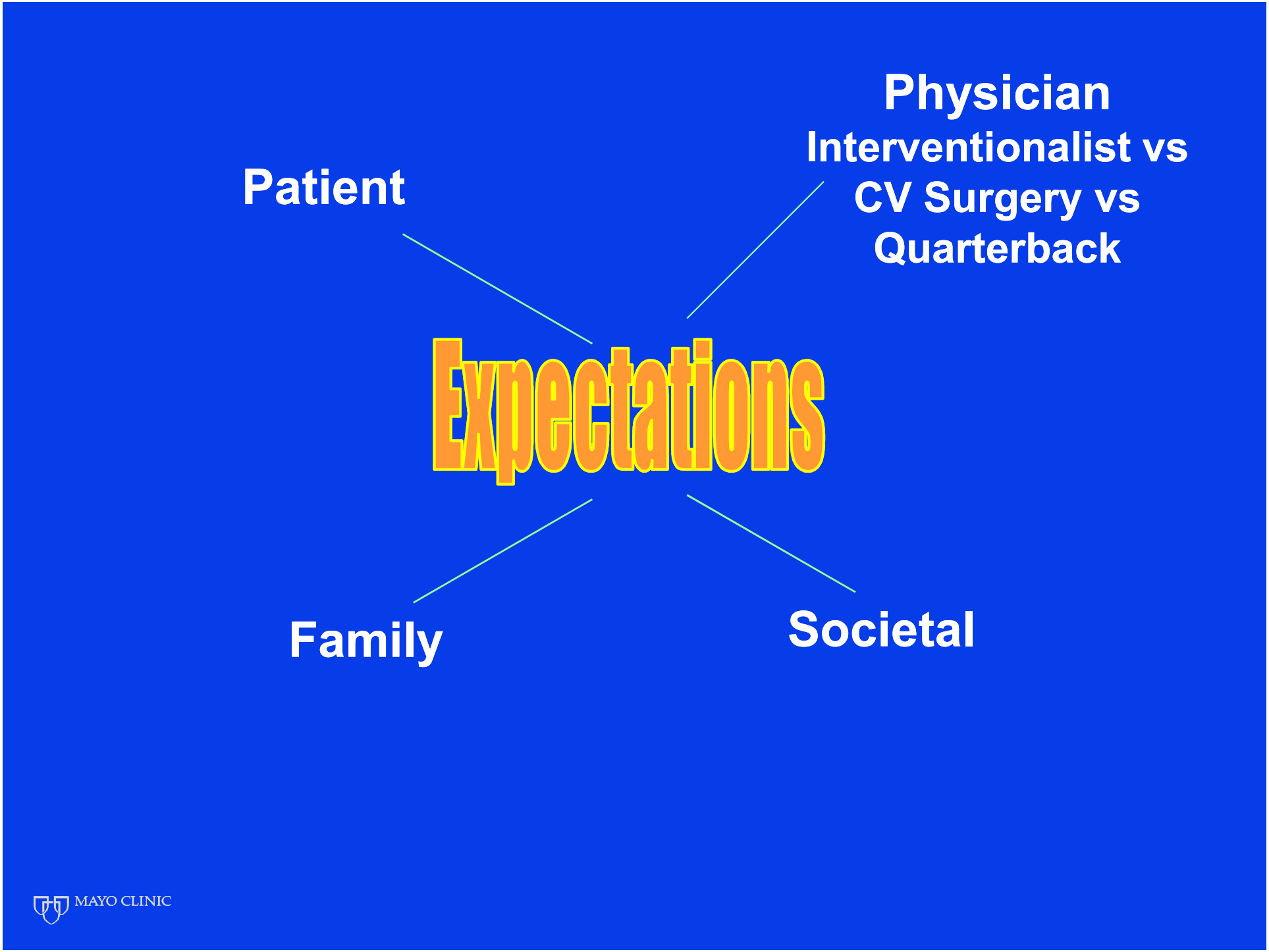
MAYO CLINIC

Evolution of Medical Care

- See one, do one, teach one
- Read about one, do one
- Evidence based medicine
  - 'Perpetuating other people's mistakes instead of your own'
- Guidelines
- Team care

Metrics

Hard Endpoints	Softer Endpoints	Other Endpoints
Death	Angina	Economics
Stroke	Exercise Tolerance	Return to work
MI	Repeat PCI	
Readmission		
Need for CABG	QOL	
CHF		


Physician
Interventionalist vs
CV Surgery vs
Quarterback
Patient
Expectations
Family
Societal

Title/drp–author: WT/BK– Holmes, D

Sub/drp–Job#: YW8/BK–3003873

Subject: Long Term Safety and Eff

Background: 6,61,232

Banner/brdr: BU4/BU41

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Subdue: BU31

Footnotes: BU41

Plot/brdr: open/BU31
x, y only

PPT shooting instructions
1 ppt file to server
(7 images)

COLOR REFERENCE ONLY

Match: CG-Mayo2bu (2002).pot

MAYO CLINIC

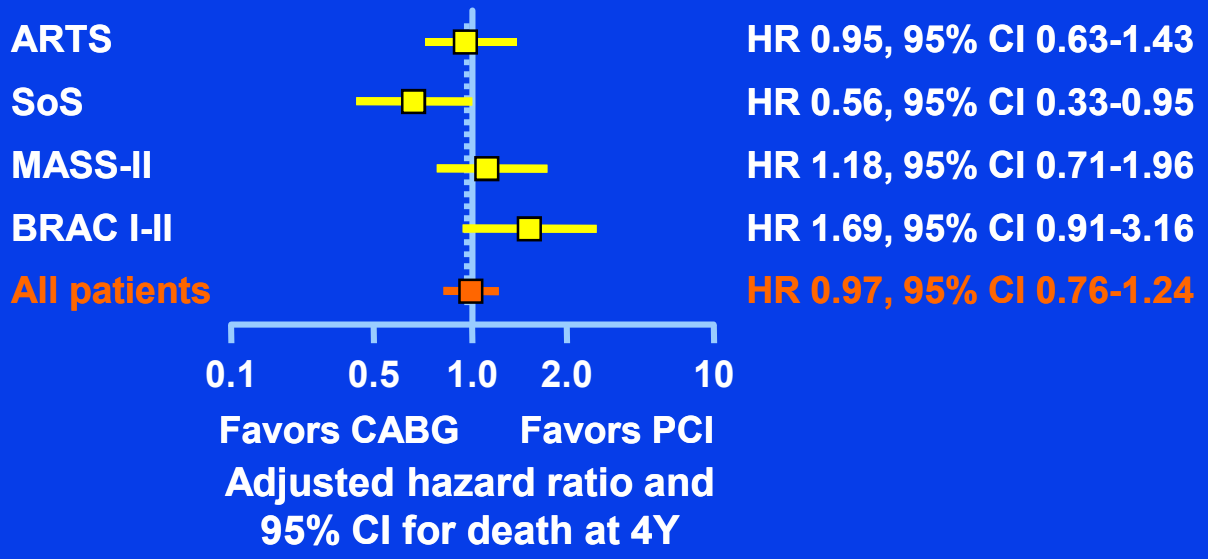
3003873-0

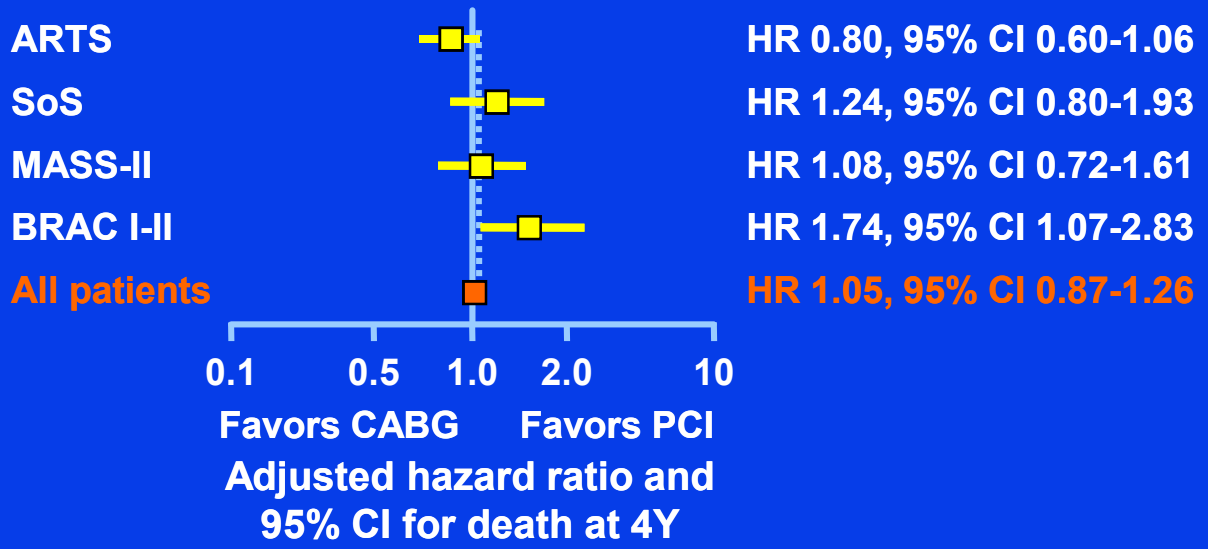
Stenting vs CABG

Variables	Crude event rates (%) PCI 1,518 patients	CABG 1,533 patients	P
Death	8.5 (129/1,518)	8.2 (125/1,533)	0.74
Stroke	2.5 (38/1,518)	2.9 (45/1,533)	0.51
MI	6.6 (100/1,518)	6.1 (94/1,533)	0.66
Repeat revascularization	25.0 (379/1,518)	6.3 (96/1,533)	<0.001
Repeat PCI	18.3 (278/1,518)	5.4 (83/1,533)	<0.001
Repeat CABG	9.1 (138/1,518)	1.2 (18/1,533)	<0.001
Death, stroke, or MI	14.2 (215/1,518)	14.6 (224/1,533)	0.76
Death, MI, or repeat revascularization	32.5 (494/1,518)	17.5 (268/1,533)	<0.001
Death, stroke, MI, or repeat revascularization	34.2 (519/1,518)	19.6 (301/1,533)	<0.001

Daeman: Circ 118:1146, 2008

Stenting vs CABG





Daeman: Circ 118:1146, 2008

Stenting vs CABG
MVD

	PCI	CABG	P
Age (yr)	61.6	61.6	0.37
DM (%)	18.1	17.5	0.67
Stable AP (%)	68.2	68.9	0.70
EF (%)	60	60	
2VD/3VD	59.3/36.1	57.0/40.0	
LAD (%)	89.9	91.8	0.017
CR	62.0	89.4	<0.001

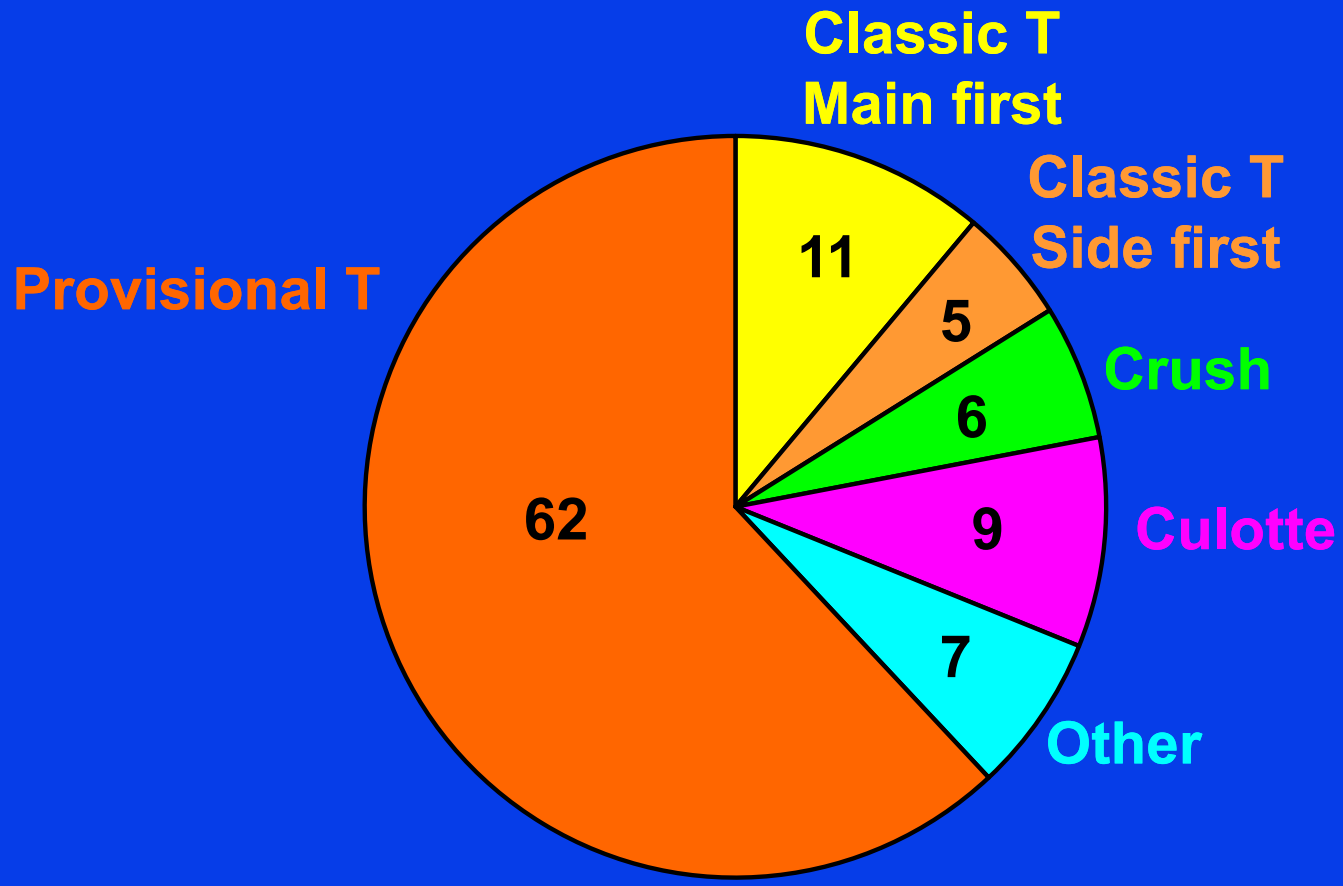
Daeman: Circ 118:1146, 2008

SYNTAX Trial

- LM pre-specified subset of 705 patients
- Recommended procedure
  - Complete lesion coverage
  - Stent overlapping (where required) by ~4 mm
  - Final kissing balloon following bifurcation stenting

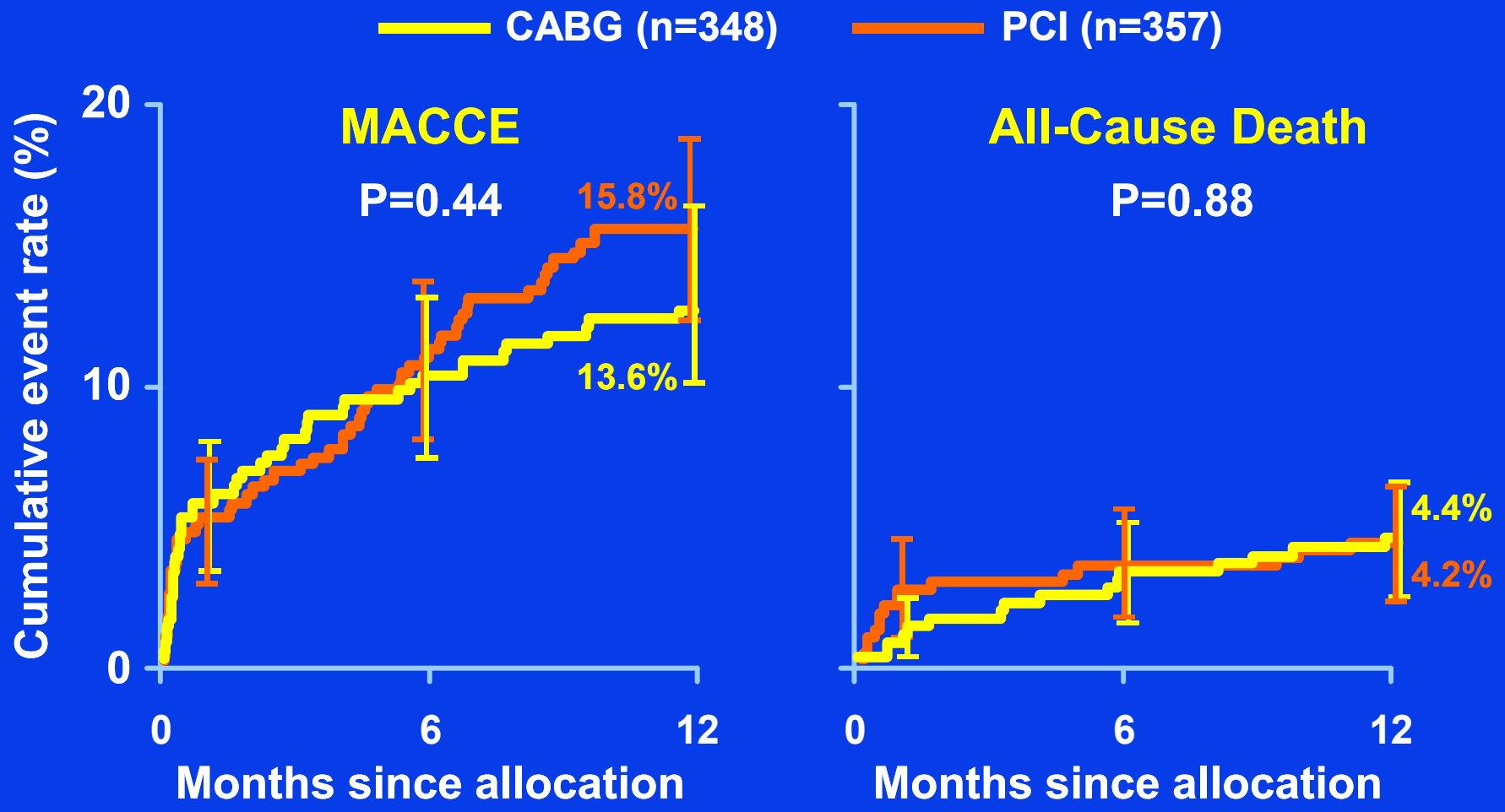
Morice MC et al: Circ, 2010 (in press)

SYNTAX Trial
LMCA Subset



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

SYNTAX Left Main Trial



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

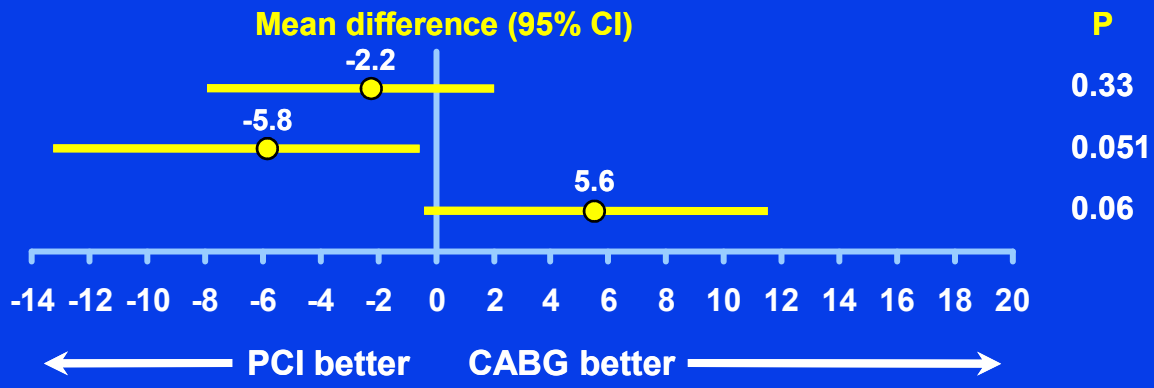
MAYO CLINIC

3041114-76

SYNTAX Left Main Trial
1-Year Incidence

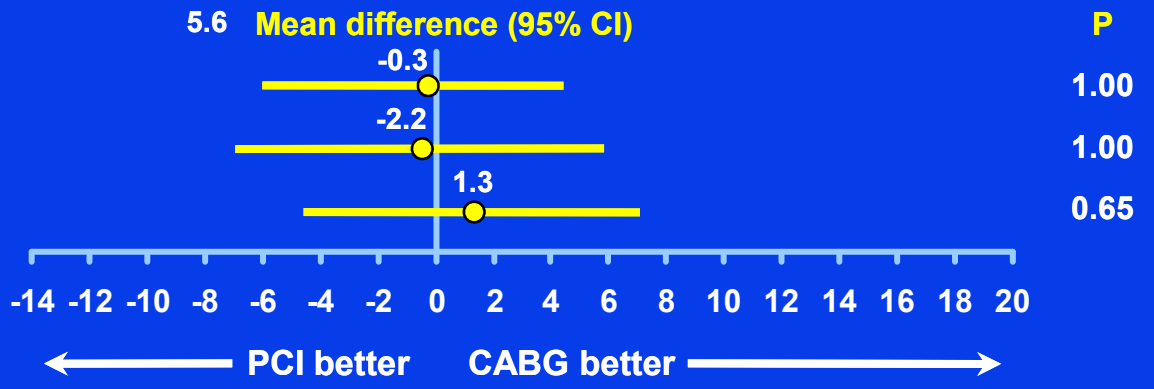
All-Cause Death

	CABG	PCI	P
0-22	3.0%	0.9%	0.33
23-32	6.7%	1.0%	0.051
≥33	4.1%	9.7%	0.06



MI

	CABG	PCI	P
0-22	2.0%	1.7%	1.00
23-32	3.4%	2.9%	1.00
≥33	6.1%	7.5%	0.65



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

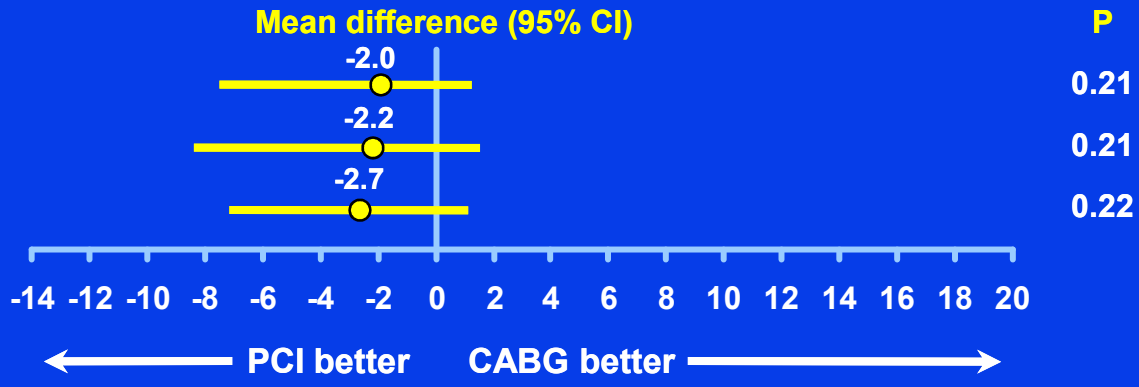
MAYO CLINIC

3041114-77

SYNTAX Left Main Trial
1-Year Incidence

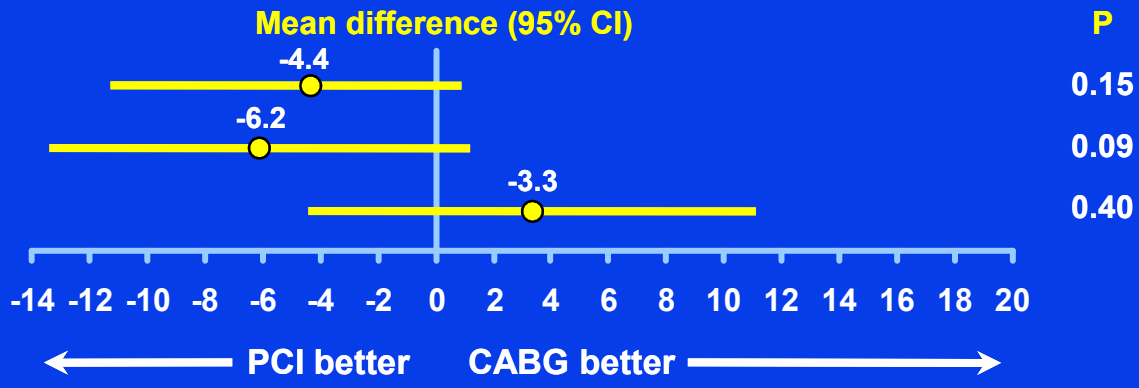
CVA

	CABG	PCI	P
0-22	2.0%	0%	0.21
23-32	2.2%	0%	0.21
≥33	3.4%	0.7%	0.22



Death/CVA/MI

	CABG	PCI	P
0-22	6.1%	1.7%	0.15
23-32	10.1%	3.9%	0.09
≥33	10.9%	14.2%	0.40



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

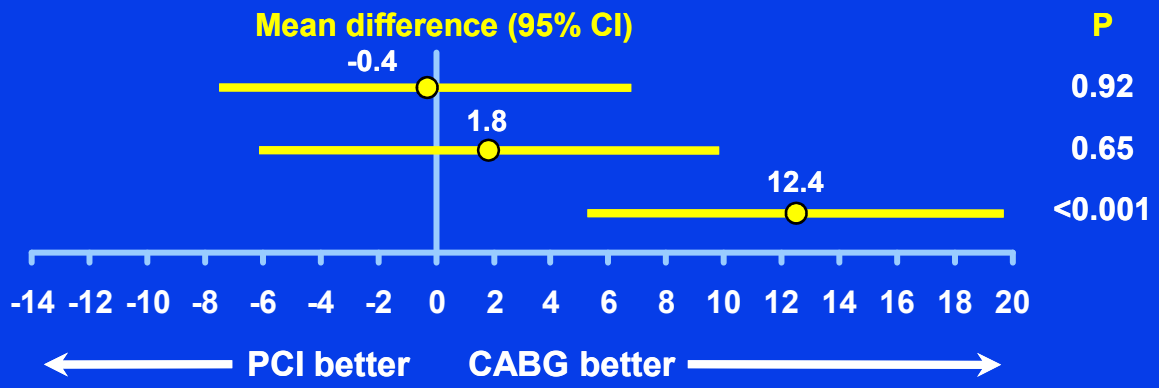
MAYO CLINIC

3041114-78

SYNTAX Left Main Trial
1-Year Incidence

Repeat Revascularization

	CABG	PCI
0-22	8.1%	7.7%
23-32	7.9%	9.7%
≥33	4.8%	17.2%



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

MAYO CLINIC

Title/drp–author: WT/BK – Holmes, David
Sub/drp–Job#: YW105/BK – 3041114

Subject: Syntax LM Trial, Morice

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Subdue: BU31
Footnotes: BU41

Plot/brdr: open/BU41
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PPT shooting instructions
1 PPT File to Server
(8 images)

Artist: mls/jmn/mn Start Date: 4-22-10

COLOR REFERENCE ONLY

Match: Mayo2bu-2002 (CP1111378)

MAYO CLINIC